ICS 2020 LAS VEGAS SCIENTIFIC PROGRAMME

WEDNESDAY 18TH NOVEMBER

08:00 - 10:00 **ICS SCIENTIFIC COMMITTEE**

Meeting Room 1
Chair: Mr Laurence Stewart (United Kingdom)
Members: Prof Carlos Levi D'Ancona (Brazil), Prof Adrian Stuart Wagg (Canada), Dr Melanie Morin (Canada), Dr Kathleen Frances Hunter (Canada), Mr Ammar Alhasso (United Kingdom), Dr Jennifer Kruger (New Zealand), Prof Vincent Tse (Australia), Prof Gamal M Ghoniem (United States), Dr Elise Jaques Billings De (United States), Dr Alex Digesu (United Kingdom), Dr Howard B Goldman (United States), Dr Vani Dandolu (United States)

08:00 - 10:00 **ICS PHYSIOTHERAPY COMMITTEE**

Meeting Room 2
Chair: Dr Heather Lynn Moky (United States)
Members: Prof Cristiane Carboni (Brazil), Dr Rhonda Kay Kotarinos (United States), Nelly Faghani (Canada), Miss Jenniffer Voelkl (Colombia), Prof Gustavo Latorre (Brazil), Mrs Paula Igualada-Martinez (United Kingdom), Miss Adelia Lucio (Brazil), Dr Cristina Naranjo Ortiz (United States)

08:00 - 10:00 **ICS STANDARDISATION STEERING COMMITTEE**

Meeting Room 3
Chair: Prof Bernard T Haylen (Australia)
Members: Mr Rizwan Hamid (United Kingdom), Prof Marcio Augusto Averbeck (Brazil), Dr Roger Roman Dmochowski (United States), Prof Philip Edward Van Kerrebroeck (Belgium), Prof Matthias Oelke (Germany), Ms Jacqueline Cahill (Canada), Mr Alexis M P Schizas (United Kingdom), Dr Sarah Haag (United States), Mr Joan Melendez-Munoz (Spain), Prof Donna Zimmaro Bliss (United States), Giovanni Mosiello (Italy)

09:00 - 10:30 **WORKSHOP 1 - ICS INSTITUTE OF MODERN TECHNOLOGY - ADVANCES IN NEUROSTIMULATION: TECHNOLOGY-BASED APPROACH**

Pavilion 9
Chair: Emre Huri (Turkey),
Speakers: Stefan de Wachter (Belgium), John Heesakkers (Netherlands), David Castro-Diaz (Spain), Emmanuel Chartier-Kastler (France)

09:00 - 12:00 **WORKSHOP 2 - INTEGRATED TOTAL PELVIC FLOOR ULTRASOUND IN PELVIC FLOOR DYSFUNCTION**

Brasilia 2
Chair: Alison Hainsworth (United Kingdom),
Speakers: Alexis Schizas (United Kingdom), Linda Ferrari (United Kingdom), Karina Cuinas (United Kingdom)

09:00 - 10:30 **WORKSHOP 3 - SURGICAL TREATMENT OF POSTPROSTATECTOMY INCONTINENCE – WORKUP, OPTIONS AND DECISION MAKING**

Brasilia 1
Chair: Ralf Anding (Germany),
Speakers: Wilhelm Hübner (Austria), Flavio Trigo Rocha (Brazil)

09:00 - 10:30 **WORKSHOP 4 - NEURODEGENERATIVE DISORDERS, LUTS AND THE ANTICHOLINERGIC BURDEN**

Brasilia 4
Chair: Jalesh Panicker (United Kingdom),
Speakers: Ryuji Sakakibara (Japan), Joanne Robinson (United States), Enrico Finazzi Agrò (Italy)

09:00 - 10:30 **WORKSHOP 5 - THE CHALLENGE OF MANAGING CHRONIC PELVIC PAIN**

Brasilia 5
Chair: Sohier Elneil (United Kingdom),
Speakers: Ulrich Mehnert (Switzerland), Jure Tornic (Switzerland), Guldzhan Vorona (United Kingdom), Bary Berghmans (Netherlands)

10:30 - 12:30 **ICS NEUROUROLOGY PROMOTION COMMITTEE**

Meeting Room 2
Chair: Prof Emmanuel Jean Chartier-Kastler (France)
Members: Dr Sanjay Sinha (India), Giulio Del Popolo (Italy), Dr Ryuji Sakakibara (Japan), Prof Magdy M Hassouna (Canada), Dr Juan Carlos Castaño (Colombia), Dr Charalampos Konstantinidis (Greece), Dr Emmanuel Braschi (Argentina), Daniele Minardi (Italy), Prof Pierre Manuel Denys (France), Dr Pawan Vasudeva (India), Ms Desiree Vrijens (Netherlands), Mrs Collette Haslam (United Kingdom), Mr Marcus John Drake (United Kingdom), Mr Rizwan Hamid (United Kingdom)

10:30 - 11:30 **ICS CHILDRENS AND YOUNG ADULTS COMMITTEE**
Meeting Room 3
Chair: Ms Ashani Couchman (Australia)
Members: Mr Marcus John Drake (United Kingdom), Giovanni Mosiello (Italy), Dr Stuart B Bauer (United States), Prof Rien Johan Marien Nijman (Netherlands), Giuseppe Masnata (Italy), Mrs Dragana Dragan Zivkovic (Serbia), Israel Franco (United States), Dr Jennifer Dart Yin Sihoe (Hong Kong), Dr Beulah Jebakani (India)

10:30 - 11:00 **COFFEE BREAK**

11:00 - 12:30 **WORKSHOP 6 - ICS CORE CURRICULUM (FREE): USERS' GUIDES TO PRACTICAL INTERPRETATION OF RESEARCH EVIDENCE FOR SHARED DECISION MAKING**
Pavilion 9
Chair: Marco Blanker (Netherlands),
Speakers: Kari Tikkinen (Finland), Philippe Violette (Canada), Rufus Cartwright (United Kingdom)

11:00 - 12:30 **WORKSHOP 7 - MANAGEMENT OF COMPLICATIONS OF MESH PROLAPSE AND SLING SURGERY - DEMONSTRATION THROUGH SURGICAL VIDEO CASES**
Brasilia 1
Chair: Howard Goldman (United States),
Speakers: Sandip Vasavada (United States), Mauro Cervigni (Italy), Karen Guerrero (United Kingdom), Paraskeve Granitsiotis (United Kingdom)

11:00 - 12:30 **WORKSHOP 8 - BLADDER AND BOWEL DYSFUNCTION IN NEUROGENIC PATIENTS**
Brasilia 4
Chair: Michele Spinelli (Italy),
Speakers: Julien Renard (Switzerland), Gianluca Sampogna (Italy)

11:00 - 12:30 **WORKSHOP 9 - CONTEMPORARY MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE**
Brasilia 5
Chair: Rizwan Hamid (United Kingdom),
Speakers: Roger Dmochowski (United States), Christopher Chapple (United Kingdom), Tomi Mikkola (Finland)

11:30 - 12:30 **ICS URODYNAMICS COMMITTEE**
Meeting Room 3
Chair: Prof Enrico Finazzi Agrò (Italy)
Members: Dr John PFA Heesakkers (Netherlands), Dr Alexandre Fornari (Brazil), Dr Michael Louis Guralnick (United States), Mr Christopher Harding (United Kingdom), Prof Tufan Tarcan (Turkey), Dr Luis Miguel Abranches-Monteiro (Portugal), Maurizio Serati (Italy), Mr Eskinder Solomon (United Kingdom)

12:30 - 15:30 **ICS EDUCATION COMMITTEE**
Meeting Room 2
Chair: Dr Elise Jaques Billings De (United States)
Members: Prof David Castro-Diaz (Spain), Mrs Paula Igualada-Martinez (United Kingdom), Dr Alex Digesu (United Kingdom), Mrs Frankie Bates (Canada), Prof Enrico Finazzi Agrò (Italy), Dr Matthew Oliver Fraser (United States), Dr Mikolaj Przydacz (Poland), Dr Nikolaus Veit-Rubin (Austria), Dr Amy D. Dobberfuhl (United States)

12:30 - 13:30 **ICS DEVELOPING WORLD COMMITTEE**
Meeting Room 3
Chair: Prof Sherif Mourad (Egypt)
Members: Dr Alex Tong-Long Lin (Taiwan), Dr Ajay Singla (United States), Dr Margaret McDougald (United Kingdom), Laleh Amini Ricard (France), Ms Kate Sloane (Australia)

12:30 - 13:30 **BREAK**

13:30 - 15:00 **WORKSHOP 10 - ICS INSTITUTE OF ANORECTAL DYSFUNCTION: OBSTRUCTIVE DEFECATION SYNDROME: CONSERVATIVE AND SURGICAL TREATMENT**
Pavilion 9
Chair: Linda Ferrari (United Kingdom),
Speakers: Alison Hainsworth (United Kingdom), Liliana Bordeianou (United States), Paula Igualada-Martinez (United Kingdom)

13:30 - 16:30 **WORKSHOP 11 - ICS INSTITUTE OF UROGYNAECOLOGY AND FEMALE & FUNCTIONAL UROLOGY: LAPAROSCOPIC SACROPEXY HANDS-ON**
Brasilia 2
Chair: Elisabetta Costantini (Italy),
Speakers: Nikolaus Veit-Rubin (Austria), Joan Melendez-Munoz (Spain), Rufus Cartwright (United Kingdom), Bruno Deval (France), Mija Blaganje (Slovenia)

13:30 - 15:00 **WORKSHOP 12 - PELVIC FLOOR ULTRASOUND IN ASSESSMENT OF COMPLEX VOIDING DYSFUNCTION AND MESH COMPLICATIONS**
Brasilia 1
Chair: Lewis Chan (Australia),
Speakers: Vincent Tse (Australia), Stephanie The (Australia), Sean Mungovan (Australia)

13:30 - 15:00 **WORKSHOP 13 - MANAGEMENT OF FEMALE LOWER URINARY TRACT DYSFUNCTION SECONDARY TO LONG TERM RADIATION EFFECTS: A CASE BASED APPROACH**
Brasilia 4
Chair: Ayman Mahdy (United States),
Speakers: David Ginsberg (United States), Angelo Gousse (United States)

13:30 - 15:30 **ICS NURSING COMMITTEE**
Meeting Room 3
Chair: Prof Donna Zimmaro Bliss (United States)
Members: Dr Cristina Naranjo Ortiz (United States), Ms Tamara Dickinson (United States), Dr Joan Ostaszkiewicz (Australia), Dr Joanne Patterson Robinson (United States), Dr Sandra J Engberg (United States), Miss Angie Rantell (United Kingdom), Prof Jo Booth (United Kingdom), Ms Joanne Margaret Dean (Australia), Lisa Krabbenhoft (United States), Mrs Juliana Neves da Costa (Brazil), Dr Amy Elizabeth Hunter (United Kingdom)

15:00 - 15:30 **COFFEE BREAK**

15:30 - 17:00 **WORKSHOP 14 - BLADDER MANAGEMENT: MERGING PATIENT-CENTRED CARE WITH EVIDENCE-BASED RESEARCH**
Pavilion 9
Chair: Diane Newman (United States),
Speakers: Tomas Griebling (United States), Angie Rantell (United Kingdom), Sharon Eustice (United Kingdom)

15:30 - 17:00 **WORKSHOP 15 - THE ROLE OF ULTRASOUND IMAGING IN WORK-UP AND MANAGEMENT OF MESH COMPLICATIONS**
Brasilia 1
Chair: SEYED Shobeiri (United States),
Speakers: Jonia Alshiek (Israel), Talia Friedman (Israel)

15:30 - 17:00 **WORKSHOP 16 - CLINICAL APPLICATION OF THE AUA/SUFU GUIDELINE FOR INCONTINENCE AFTER PROSTATE TREATMENT**
Brasilia 4
Chair: Daniel Kirages (United States),
Speakers: Jaspreet Sandhu (United States), Kurt McCammon (United States), Ouida Westney (United States)

15:30 - 17:00 **EARLY CAREER SESSION**
Brasilia 5
Chairs: Dr Amy D. Dobberfuhl (United States), Dr Mikolaj Przydacz (Poland)

15:30 - 17:00 **ICS ETHICS COMMITTEE**
Meeting Room 3
Chair: Dr Nina Sarah Davis (United States)
Members: Prof Mauro Cervigni (Italy), Dr Ruwan Janaka Fernando (United Kingdom), Antonella Giannantoni (Italy), Dr Alvaro Bedoya-Ronga (United Kingdom), Mrs Heidi FA Moossdorff-Steinhauser (Netherlands), Dr Martha Spencer (Canada), Dr Anne M Suskind (United States), Dr Elise Jaques Billings De (United States), Ms Tamara Dickinson (United States)

17:00 - 19:00 **WELCOME RECEPTION IN EXHIBITION HALL**

19:00 - 23:00 **EARLY CAREER PROFESSIONALS NIGHT OUT**

THURSDAY 19TH NOVEMBER

08:15 - 08:30 **WELCOME AND OPENING WORDS**
Pavilion 9
Chairs: Prof David Castro-Diaz (Spain), Prof Gamal M Ghoniem (United States)

08:30 - 09:00 **STATE OF THE ART LECTURE 1 - PLACEBO EFFECT ON LUTS**
Pavilion 9
Chairs: Prof David Castro-Diaz (Spain), Prof Gamal M Ghoniem (United States)
Speaker: Dr Alan J Wein (United States)

09:00 - 10:30 **SESSION 1 (PODIUM) - BEST UROLOGY**
Abstracts 1-6
Pavilion 9
Chairs: Prof David Castro-Diaz (Spain), Prof Gamal M Ghoniem (United States)

09:00 - 10:30 **SESSION 2 (PODIUM SHORT ORAL) - STRESS URINARY INCONTINENCE**
Abstracts 7-18
Brasilia 2
Chairs: Mr Dudley Timothy Robinson (United Kingdom), Dr Michael E Albo (United States)

09:00 - 10:30 **SESSION 3 (PODIUM SHORT ORAL) - CONSERVATIVE MANAGEMENT**
Abstracts 19-30
Brasilia 1
Chairs: Dr Melanie Morin (Canada), Ms Tamara Dickinson (United States)

09:00 - 10:30 **WORKSHOP 17 - ICS CORE CURRICULUM (FREE):UPDATES IN DIAGNOSIS AND TREATMENT OF NEUROGENIC BLADDER IN CHILDREN AND ADOLESCENT**
Brasilia 4
Chair: Jian Guo Wen (China),
Speakers: Israel Franco (United States), Soren Rittig (Denmark)

09:00 - 10:30 **WORKSHOP 18 - ICS CORE CURRICULUM (FREE): NEUROUROLOGY IN 2020**
Brasilia 5
Chair: Sanjay Sinha (India),
Speakers: Charalampos Konstantinidis (Greece), Desiree Vrijens (Netherlands), Carlos D'Ancona (Brazil)

09:00 - 10:30 **ICS MEETINGS COMMITTEE**
Meeting Room 2
Chair: Prof David Castro-Diaz (Spain)
Members: Prof Mauro Cervigni (Italy), Dr Lori A Birder (United States), Mr Marcus John Drake (United Kingdom), Prof Philip Edward Van Kerrebroeck (Belgium), Prof Carlos Levi D'Ancona (Brazil), Dr John PFA Heesakkers (Netherlands), Dr Alex Tong-Long Lin (Taiwan), Dr Cristina Naranjo Ortiz (United States)

10:30 - 11:00 **SESSION 4 (OPEN DISCUSSION EPOSTER) - EPOSTER 1**
Abstracts 31-45
Exhibition Hall

10:30 - 11:00 **BREAK, EXHIBITION + S4 OPEN DISCUSSION EPOSTERS**

11:00 - 12:30 **SESSION 5 (PODIUM SHORT ORAL) - OAB: NEUROMODULATION AND UNUSUAL ASSOCIATIONS**
Abstracts 46-57
Pavilion 9
Chairs: Prof Philip Edward Van Kerrebroeck (Belgium), Dr Michael Joseph Kennelly (United States)

11:00 - 12:30 **SESSION 6 (PODIUM SHORT ORAL) - PROLAPSE**
Abstracts 58-69
Brasilia 2
Chairs: Prof Mauro Cervigni (Italy), Dr Charles W Nager (United States)

11:00 - 12:30 **SESSION 7 (PODIUM SHORT ORAL) - BEST BOWEL DYSFUNCTION**
Abstracts 70-75
Brasilia 1
Chair: Dr Liliana Bordeianou (United States)

11:00 - 12:30 **WORKSHOP 19 - ICS CORE CURRICULUM (FREE): INSTITUTE OF PHYSIOTHERAPY: NEW FRONTIERS IN CONSERVATIVE MANAGEMENT FOR PELVIC FLOOR DYSFUNCTION IN CONJUNCTION WITH THE ICS PHYSIOTHERAPY COMMITTEE**
Brasilia 4
Chair: Cristiane Carboni (Brazil),
Speakers: Melanie Morin (Canada), Heather Moky (United States), Serge Marchand (Canada)

11:00 - 12:30 **WORKSHOP 20 - ICS INSTITUTE OF MALE LUTS AND LUTD: NON INVASIVE EVALUATION OF BLADDER OUTLET OBSTRUCTION**
Brasilia 5
Chair: Carlos D'Ancona (Brazil),
Speakers: Andrew Gammie (United Kingdom), Matthias Oelke (Germany), Gommert van Koeveringe (Netherlands)

12:30 - 13:30 **SESSION 8 (OPEN DISCUSSION EPOSTER) - EPOSTER 2**
Abstracts 76-130
Exhibition Hall

12:30 - 14:30 **ICS BOARD OF TRUSTEES & COMMITTEE CHAIRS**

Meeting Room 2
Chair: Prof David Castro-Diaz (Spain)
Committee Members: Prof Ervin Kocjancic (United States), Prof Jian Guo Wen (China), Dr Peter F.W.M. Rosier (Netherlands), Prof Karl-Erik Andersson (United States), Prof Emre Huri (Turkey), Prof Mauro Cervigni (Italy), Dr Lori A Birder (United States), Prof Donna Zimmaro Bliss (United States), Prof Emmanuel Jean Chartier-Kastler (France), Mr Marcus John Drake (United Kingdom), Prof Philip Edward Van Kerrebroeck (Belgium), Prof Carlos Levi D'Ancona (Brazil), Dr John PFA Heesakkers (Netherlands), Dr Elise Jaques Billings De (United States), Dr Kristene E Whitmore (United States), Dr Melanie Morin (Canada), Dr Sandra J Engberg (United States), Prof Enrico Finazzi Agrò (Italy), Mr Laurence Stewart (United Kingdom), Prof Sherif Mourad (Egypt), Dr Alex Tong-Long Lin (Taiwan), Prof Bernard T Haylen (Australia), Dr Nina Sarah Davis (United States), Dr Cristina Naranjo Ortiz (United States), Ms Ashani Couchman (Australia), Mr Alexis M P Schizas (United Kingdom), Mr Rizwan Hamid (United Kingdom), Dr Heather Lynn Moky (United States), Dr Ran Pang (China), Prof Cristiane Carboni (Brazil), Dr Nikolaus Veit-Rubin (Austria)

12:30 - 13:30 **BREAK, EXHIBITION + S8 OPEN DISCUSSION EPOSTERS**

13:30 - 14:30 **ROUND TABLE DISCUSSION 1 - IF YOU CAN'T STAND THE HEAT…. APPRAISING THE EVIDENCE FOR THERMAL THERAPY IN LOWER URINARY TRACT DYSFUNCTION**

Pavilion 9
Chair: Mr Dudley Timothy Robinson (United Kingdom)
Speakers: Prof Linda Cardozo (United Kingdom), Prof Stefano Salvatore (Italy), Dr Cheryl Bernadette Iglesia (United States), Prof Seyed Shobeiri (United States)

13:30 - 14:30 **ROUND TABLE DISCUSSION 2 - POTPOURRI OF INDWELLING CATHETERS: WASHOUTS, COLLABORATIVE RESEARCH AND MORE**

Brasilia 2
Chair: Dr Diane K Newman (United States)

13:30 - 14:30 **ROUND TABLE DISCUSSION 3 - NEW UDS TECHNOLOGY**

Brasilia 1
Chair: Prof Marcio Augusto Averbeck (Brazil)
Speakers: Dr Margot Damaser (United States), Prof Enrico Finazzi Agrò (Italy), Dr Adam Philip Klausner (United States)

13:30 - 14:30 **ROUND TABLE DISCUSSION 4 - MALE INCONTINENCE AND ERECTILE DYSFUNCTION FOLLOWING PROSTATECTOMY**

Brasilia 4
Chair: Dr Heather Lynn Moky (United States)
Speakers: Miss Adelia Lucio (Brazil), Prof Paul Hodges (Australia), Dr Cristina Naranjo Ortiz (United States)

13:30 - 14:00 **SPOTLIGHT ON 1 - SPOTLIGHT ON IUGA: CHILDBIRTH! WILL MY PELVIC FLOOR EVER BE THE SAME AGAIN?**

Brasilia 5
Chair: Dr Howard B Goldman (United States)
Speaker: Dr Ranee Thakar (United Kingdom)

14:00 - 14:30 **SPOTLIGHT ON 2 - SPOTLIGHT ON SUFU: FRAILTY AND OTHER IMPORTANT CONSIDERATIONS IN OLDER ADULTS WITH PELVIC FLOOR DISORDERS**

Brasilia 5
Speaker: Dr Anne M Suskind (United States)

14:30 - 16:00 **SESSION 9 (PODIUM SHORT ORAL) - INCONTINENCE FROM PROSTATE CANCER TREATMENT**

Abstracts 131-142
Pavilion 9
Chairs: Prof Carlos Levi D'Ancona (Brazil), Dr Ajay Singla (United States)

14:30 - 16:00 **WORKSHOP 21 - ICS CORE CURRICULUM (FREE): PROMOTING BLADDER AND PELVIC HEALTH IN POPULATIONS WITH CONTINENCE VULNERABILITY**

Brasilia 2
Chair: Angie Rantell (United Kingdom),
Speakers: Lori Saiki (United States), Lisa Krabbenhoft (United States), Amy Hull (United States)

14:30 - 16:00 **SESSION 10 (PODIUM SHORT ORAL) - FEMALE LOWER URINARY TRACT SYMPTOMS**

Abstracts 143-154
Brasilia 1
Chair: Prof Jerry G Blaivas (United States)

14:30 - 16:00 **SESSION 11 (PODIUM SHORT ORAL) - THERAPEUTIC MECHANISMS**

Abstracts 155-166

Brasilia 4
Chairs: Prof Karl-Erik Andersson (United States), Dr David R Staskin (United States)

14:30 - 16:00 **WORKSHOP 22 - ICS INSTITUTE OF TRANSGENDER HEALTH: VAGINOPLASTY: THE GOOD, THE BAD AND THE UGLY IN TRANS FEMALE AFFIRMING SURGERY**
Brasilia 5
Chair: Ervin Kocjancic (United States),
Speakers: Cecille Ferrando (United States), Ömer Acar (Turkey)

14:30 - 16:00 **WORKSHOP 23 - ICS CORE CURRICULUM (FREE): AUTONOMY AND CONSENT IN MODERN MEDICAL PRACTICE: A CASE-BASED DIALOGUE**
Meeting Room 2
Chair: Nina Davis (United States),
Speakers: Antonella Giannantoni (Italy), Kristene Whitmore (United States)

16:00 - 16:30 **COFFEE BREAK WITH THE NURSING COMMITTEE**
Brasilia 2

16:00 - 16:30 **SESSION 12 (OPEN DISCUSSION EPOSTER) - EPOSTER 3**
Abstracts 167-189
Exhibition Hall

16:00 - 16:30 **BREAK, EXHIBITION + S12 OPEN DISCUSSION EPOSTERS**

16:30 - 18:07 **SESSION 13 (PODIUM SHORT ORAL) - URODYNAMICS 1**
Abstracts 190-201
Pavilion 9
Chairs: Mr Marcus John Drake (United Kingdom), Stephen R Kraus (United States)

16:30 - 18:00 **NURSES FORUM**
Brasilia 2
Chair: Prof Donna Zimmaro Bliss (United States)
Speakers: Dr Mikel Gray (United States), Ms Tamara Dickinson (United States)

16:30 - 18:00 **SESSION 14 (PODIUM SHORT ORAL) - FUNCTIONAL AND MORPHOLOGICAL INVESTIGATIONS**
Abstracts 202-213
Brasilia 1
Chairs: Prof Dirk de Ridder (Belgium), Dr Anthony John Kanai (United States)

16:30 - 18:00 **SESSION 15 (PODIUM VIDEO) - VIDEO 1: PROLAPSE SURGERY**
Abstracts 214-222
Brasilia 4
Chairs: Mr Ammar Alhasso (United Kingdom), Dr Ayman Mahdy (United States)

16:30 - 18:00 **WORKSHOP 24 - NEUROMODULATION IN THE MANAGEMENT OF LOWER URINARY TRACT DYSFUNCTION: CURRENT BEST PRACTICE, INNOVATION AND THE FUTURE**
Brasilia 5
Chair: Arun Sahai (United Kingdom),
Speakers: Tom Marcelissen (Netherlands), Marcio Averbeck (Brazil), Roger Dmochowski (United States)

16:30 - 17:30 **ICS INSTITUTE DIRECTORS MEETING**
Meeting Room 2
Committee Members: Dr Nikolaus Veit-Rubin (United Kingdom), Dr Elise Jaques Billings De (United States), Prof David Castro-Diaz (Spain), Prof Carlos Levi D'Ancona (Brazil), Dr Kristene E Whitmore (United States), Prof Karl-Erik Andersson (United States), Prof Emre Huri (Turkey), Mr Alexis M P Schizas (United Kingdom), Mr Rizwan Hamid (United Kingdom), Prof Jian Guo Wen (China), Dr Sandra J Engberg (United States), Prof Cristiane Carboni (Brazil), Prof Ervin Kocjancic (United States), Dr Peter F.W.M. Rosier (Netherlands)

18:00 - 18:30 **SPOTLIGHT ON 3 - SPOTLIGHT ON SUNA: DEFINING THE ROLE OF THE UROLOGY CONTINENCE NURSE SPECIALIST**
Brasilia 2
Speaker: Donna L Thompson (United States)

FRIDAY 20TH NOVEMBER

07:30 - 08:30 **UROVANT SCIENCES SATELLITE SYMPOSIUM - NON-CME**
Pavilion 9

08:00 - 15:00 **19TH PHYSIOTHERAPY FORUM**
Brasilia 5
Chair: Nelly Faghani (Canada)
Speakers: Dr Sinéad Patricia Dufour (Canada), Dr Linda McLean (Canada), Dr Carina Marie Siracusa (United States), Julie Wiebe (United States), Susan Clinton (United States), Sandy Hilton (United States), Serge Marchand (Canada), Dr Rhonda Kay Kotarinos (United States), Dr Heather Lynn Moky (United States), Prof Paul Hodges (Australia)
Members: Mrs Paula Igualada-Martinez (United Kingdom), Miss Adelia Lucio (Brazil), Dr Cristina Naranjo Ortiz (United States), Prof Cristiane Carboni (Brazil), Miss Jenniffer Voelkl (Colombia), Prof Gustavo Latorre (Brazil)

08:00 - 09:00 **NAU EDITORIAL BOARD MEETING**
Meeting Room 1
Chair: Dr Roger Roman Dmochowski (United States)

09:00 - 09:30 **STATE OF THE ART LECTURE 2 - EVIDENCE BASED REVIEW OF TRANSVAGINAL HYSTEROPEXY FOR UTEROVAGINAL PROLAPSE**
Pavilion 9
Chair: Dr Vani Dandolu (United States)
Speaker: Prof Holly E Richter (United States)

09:30 - 11:00 **SESSION 16 (PODIUM) - BEST UROGYNAECOLOGY**
Abstracts 223-228
Pavilion 9
Chairs: Dr Alex Digesu (United Kingdom), Dr Elise Jaques Billings De (United States)

09:30 - 11:00 **SESSION 17 (PODIUM SHORT ORAL) - OAB: NEUROTOXIN AND IMAGING**
Abstracts 229-240
Brasilia 2
Chairs: Dr John PFA Heesakkers (Netherlands), Dr Victor William Nitti (United States)

09:30 - 11:00 **SESSION 18 (PODIUM SHORT ORAL) - MALE VOIDING DYSFUNCTION AND LUTS 1**
Abstracts 241-252
Brasilia 1
Chair: Prof Sherif Mourad (Egypt)

09:30 - 11:00 **SESSION 19 (PODIUM) - BEST BASIC SCIENCE**
Abstracts 253-258
Brasilia 4
Chairs: Prof Christopher Henry Fry (United Kingdom), Dr Toby C. Chai (United States)

11:00 - 11:30 **SESSION 20 (OPEN DISCUSSION EPOSTER) - EPOSTER 4**
Abstracts 259-281
Exhibition Hall

11:00 - 11:30 **BREAK, EXHIBITION + S20 OPEN DISCUSSION EPOSTERS**

11:30 - 12:30 **ROUND TABLE DISCUSSION 5 - ROBOTIC FUNCTIONAL UROLOGY: FACT OR FICTION?**
Pavilion 9
Chair: Elisabetta Costantini (Italy)
Speakers: Prof Emmanuel Jean Chartier-Kastler (France), Prof Ervin Kocjancic (United States), Dr Roger Roman Dmochowski (United States)

11:30 - 12:30 **ROUND TABLE DISCUSSION 6 - YOUR STRESS INCONTINENCE SURGERY FAILED - NOW WHAT?**
Brasilia 2
Chair: Prof Helen Elizabeth O'Connell (Australia)
Speakers: Dr Vivian Sung, MD, MPH (United States), Dr Sanjay Sinha (India), Dr Rufus Cartwright (United Kingdom)

11:30 - 12:00 **SPOTLIGHT ON 4 - SPOTLIGHT ON: UPDATE ON ICS TERMINOLOGY**
Brasilia 1
Chair: Prof Bernard T Haylen (Australia)

12:00 - 12:30 **SPOTLIGHT ON 5 - SPOTLIGHT ON INUS: BLADDER MANAGEMENT AFTER SCI: SUCCESSES & CHALLENGES**
Brasilia 1
Speakers: Dr Blayne Welk (Canada), Dr Michael Joseph Kennelly (United States), Prof Marcio Augusto Averbeck (Brazil)

12:00 - 12:30 **AGM ENTRANCE SCANNING**
Brasilia 4

12:30 - 13:30 **ICS AGM**
Brasilia 4
Chair: Prof David Castro-Diaz (Spain)
Members: Prof Mauro Cervigni (Italy), Dr Lori A Birder (United States), Mr Marcus John Drake (United Kingdom), Prof Philip Edward Van Kerrebroeck (Belgium), Prof Carlos Levi D'Ancona (Brazil), Dr John PFA Heesakkers (Netherlands), Dr Alex Tong-Long Lin (Taiwan), Dr Cristina Naranjo Ortiz (United States)

12:30 - 13:30 **SESSION 21 (OPEN DISCUSSION EPOSTER) - EPOSTER 5**
Abstracts 282-341
Exhibition Hall

12:30 - 13:30 **BREAK, EXHIBITION + S21 OPEN DISCUSSION EPOSTERS**

13:30 - 15:00 **SESSION 22 (PODIUM SHORT ORAL) - URETHRA / PROSTATE**
Abstracts 342-353
Pavilion 9
Chairs: Dr Alex Tong-Long Lin (Taiwan), Craig Comiter (United States)

13:30 - 15:00 **SESSION 23 (PODIUM SHORT ORAL) - PELVIC FLOOR DYSFUNCTION 1**
Abstracts 354-365
Brasilia 2
Chairs: Dr Anna Rosamilia (Australia), Lauri Romanzi (United States)

13:30 - 15:00 **SESSION 24 (PODIUM SHORT ORAL) - SENSORY FUNCTION AND FIBROSIS**
Abstracts 366-377
Brasilia 1
Chairs: Dr Lori A Birder (United States), Prof Georgi Petkov (United States)

13:30 - 17:30 **JOINT SOCIETY MEETING OF SINUG, CAU AND ALAPP**
Brasilia 4
Chairs: Dr Salvador Arlandis Guzmán (Spain), Dr Alejandro Tarazona Reyes (Colombia), Dr Cleveland Antonio Beckford (Panama)
Speakers: Dr Montserrat Espuña Pons (Spain), Prof Nucelio L B M Lemos (Canada), Luis López-Fando Lavalle (Spain), Dr Bárbara Padilla-Fernández (Spain), Prof Paulo CR Palma (Brazil), Dr Christian Hector Cobreros (Argentina), Dr Humberto Chiang (Chile), Dr Sergio Duran (Mexico), Dr Mauricio Plata (Colombia), Prof Rogerio de Fraga (Brazil), Merycarla Pichardo (Dominican Republic), Dr Arturo Garcia-Mora (Mexico), Prof Cassio Zanettini Riccetto (Brazil), Juan Fernando Cerezuela Requena (Spain), Dr virginia roncatti (Brazil), Prof Marcio Augusto Averbeck (Brazil), Dr Cristina Naranjo Ortiz (United States)

15:00 - 15:30 **SESSION 25 (OPEN DISCUSSION EPOSTER) - EPOSTER 6**
Abstracts 378-404
Exhibition Hall

15:00 - 15:30 **BREAK, EXHIBITION + S25 OPEN DISCUSSION EPOSTERS**

15:30 - 17:00 **SESSION 26 (PODIUM SHORT ORAL) - MALE VOIDING DYSFUNCTION AND LUTS 2**
Abstracts 405-416
Pavilion 9
Chairs: Prof Vincent Tse (Australia), Dr Roger Roman Dmochowski (United States)

15:30 - 17:00 **SESSION 27 (PODIUM SHORT ORAL) - GERIATRICS AND SPECIAL POPULATION**
Abstracts 417-428
Brasilia 2
Chairs: Prof Adrian Stuart Wagg (Canada), Anne P Cameron (United States)

15:30 - 17:10 **SESSION 28 (PODIUM VIDEO) - VIDEO 2: URETHRA AND GENDER RECONSTRUCTION**
Abstracts 429-438
Brasilia 1
Chairs: Prof Ervin Kocjancic (United States), Dr Ann Gormley (United States)

15:30 - 17:30 **WORKSHOP 25 - ICS CORE CURRICULUM WORKSHOP (FREE): THE CLINICAL URODYNAMIC ROUND. HOW TO SYSTEMATICALLY EVALUATE AND REPORT AN INVASIVE URODYNAMIC STUDY?**
Brasilia 5
Chair: Enrico Finazzi Agrò (Italy),
Speakers: Peter Rosier (Netherlands), Michael Guralnick (United States), Alexandre Fornari (Brazil), Eskinder Solomon (United Kingdom), Luis Abranches-Monteiro (Portugal), Tufan Tarcan (Turkey), Maurizio Serati (Italy), Christopher Harding (United Kingdom)

SATURDAY 21ST NOVEMBER

08:30 - 11:30 **WORKSHOP 26 - BASIC URODYNAMICS - AN INTERACTIVE WORKSHOP**
Brasilia 4
Chair: Andrew Gammie (United Kingdom),
Speakers: Marcus Drake (United Kingdom), Arturo Garcia-Mora (Mexico), Hwee Lee Connie Chew (United Kingdom), Laura Thomas (United Kingdom)

09:00 - 10:30 **SESSION 29 (PODIUM SHORT ORAL) - OAB: MEDICATION AND SENSATION**
Abstracts 439-450
Pavilion 9
Chair: Prof Christopher R Chapple (United Kingdom)

09:00 - 10:30 **SESSION 30 (PODIUM SHORT ORAL) - NEW FRONTIERS**
Abstracts 451-462
Brasilia 2
Chair: Dr Margot Damaser (United States)

09:00 - 10:30 **SESSION 31 (PODIUM) - BEST CONSERVATIVE MANAGEMENT**
Abstracts 463-468
Brasilia 1
Chairs: Dr Kathleen Frances Hunter (Canada), Dr Diane K Newman (United States)

10:30 - 11:00 **SESSION 32 (OPEN DISCUSSION EPOSTER) - EPOSTER 7**
Abstracts 469-494
Exhibition Hall

10:30 - 11:00 **BREAK, EXHIBITION + S32 OPEN DISCUSSION EPOSTERS**

11:00 - 11:30 **STATE OF THE ART LECTURE 3 - BUGS, BRAIN AND THE GUT – TOWARDS A BETTER UNDERSTANDING OF PATHOPHYSIOLOGY AND MANAGEMENT OF NEUROGENIC BOWEL DYSFUNCTION**
Pavilion 9
Speaker: Dr Anton Emmanuel (United Kingdom)

11:30 - 13:00 **SESSION 33 (PODIUM SHORT ORAL) - PEDIATRIC UROLOGY / NOCTURIA**
Abstracts 495-506
Pavilion 9
Chair: Prof Jian Guo Wen (China)

11:30 - 13:00 **SESSION 34 (PODIUM SHORT ORAL) - PELVIC FLOOR DYSFUNCTION 2**
Abstracts 507-518
Brasilia 2
Chair: Dr Kathleen C Kobashi (United States)

11:30 - 13:00 **SESSION 35 (PODIUM SHORT ORAL) - ASSESSMENT AND PATHOPHYSIOLOGY**
Abstracts 519-530
Brasilia 1
Chairs: Dr Chantale L Dumoulin (Canada), Dr Elizabeth R Shelly (United States)

13:00 - 14:00 **SESSION 36 (OPEN DISCUSSION EPOSTER) - EPOSTER 8**
Abstracts 531-576
Exhibition Hall

13:00 - 14:00 **BREAK, EXHIBITION + S36 OPEN DISCUSSION EPOSTERS**

14:00 - 15:00 **ROUND TABLE DISCUSSION 7 - ENTREPRENEURSHIP LESSONS: FROM DISCOVERY TO COMPANY**
Pavilion 9
Chair: Prof Michael Chancellor (United States)
Speakers: Dr Samantha Pulliam (United States), Mary Gardner (United States)

14:00 - 15:00 **ROUND TABLE DISCUSSION 8 - MESH: UTILISATION, REGULATION, AND LITIGATION - LESSONS LEARNED**
Brasilia 2
Chair: Dr Saad Juma (United States)
Speakers: Dr Wael I Agur (United Kingdom), Prof Mauro Cervigni (Italy), Dr Gopal Badlani (United States), Dr Charles W Nager (United States)

14:00 - 15:00 **ROUND TABLE DISCUSSION 9 - FIBROSIS AND THE LOWER URINARY TRACT: CAUSES, CONSEQUENCES AND CORRECTION**
Brasilia 1
Chair: Prof Christopher Henry Fry (United Kingdom)
Speakers: Dr Anthony John Kanai (United States), Dr Margot Damaser (United States), Prof Adrian Stuart Wagg (Canada), Dr Lori A Birder (United States)

14:00 - 14:30 **SPOTLIGHT ON 6 - A SIZEABLE PROBLEM: SHOULD WE OPERATE ON THE MORBIDLY OBESE? AN ETHICS DEBATE**
Brasilia 4
Chair: Prof Linda Cardozo (United Kingdom)
Speakers: Ms Tamsin Greenwell (United Kingdom), Dr Kristene E Whitmore (United States)

14:30 - 15:00 **SPOTLIGHT ON 7 - SPOTLIGHT ON: ASCRS**
Brasilia 4

15:00 - 16:30 **SESSION 37 (PODIUM SHORT ORAL) - URODYNAMICS AND BEST OF THE REST**
Abstracts 577-588
Pavilion 9
Chairs: Dr Sender Herschorn (Canada), Dr Ouida Lenaine Westney (United States)

15:00 - 16:30 **SESSION 38 (PODIUM SHORT ORAL) - INFECTION AND POT POURRI**
Abstracts 589-600
Brasilia 2
Chairs: Prof Nucelio L B M Lemos (Canada), Dr Vani Dandolu (United States)

15:00 - 16:30 **SESSION 39 (PODIUM SHORT ORAL) - QUALITY OF LIFE AND HEALTH DELIVERY**
Abstracts 601-612
Brasilia 1
Chair: Dr Cristina Naranjo Ortiz (United States)

15:00 - 16:30 **SESSION 40 (PODIUM VIDEO) - VIDEO 3: CREATIVE IDEAS**
Abstracts 613-621
Brasilia 4
Chairs: Prof Helen Elizabeth O'Connell (Australia), Dr Joanna Togami (United States)

16:30 - 17:00 **CLOSING CEREMONY**
Brasilia 2
Member: Dr Lori A Birder (United States)

ICS 2020 LAS VEGAS ABSTRACTS

THURSDAY 19TH NOVEMBER

SESSION 1 (PODIUM) - BEST UROLOGY
Abstracts 1-6
09:00 - 10:30, Pavilion 9
Chairs: Prof David Castro-Diaz (Spain), Prof Gamal M Ghoniem (United States)

1 | www.ics.org/2020/abstract/1

BEST CLINICAL ABSTRACT

TREATMENT OF URETHRAL STRICTURE DISEASE IN WOMEN: A MULTI-INSTITUTIONAL COLLABORATIVE PROJECT

Lane G[1], Anger J[2], Brandes E[3], Carmel M[4], Chung D[5], Cox L[6], DeLong J[7], Elliott C[8], Eltahawy E[9], França W[10], Gousse A[11], Hagedorn J[12], High R[13], Khan A[14], Padmanabhan P[15], Lee R[16], Lucioni A[17], MacDonald S[18], Powell C[19], Sajadi K[20], Smith A[21], Vollstedt A[22], Welk B[23], Cameron A[1]
1. University of Michigan, 2. Cedars-Sinai, 3. Dartmouth Hitchcock Medical Center, 4. University of Texas Southwestern Medical Center, 5. Columbia University, 6. Medical University of South Carolina, 7. Eastern Virgina Medical Center, 8. Santa Clara Valley Medical Center, 9. University of Arkansas for Medical Sciences, 10. Hospital do Servidor Público Estadual de São Paulo, 11. Memorial Hospital Miramar, 12. University of Washington, 13. Baylor Scott & White, 14. Mayo Clinic Arizona, 15. Kansas University Medical Center and Beaumont Hospital, 16. Weill Cornell Medicine, 17. Virginia Mason Medical Center, 18. Penn State Hershey Medical Center, 19. Indiana University, 20. Oregan Health & Science University, 21. University of Pennsylvania, 22. Beaumonth Hospital, 23. Western University

HYPOTHESIS / AIMS OF STUDY

Female urethral stricture disease is rare and little guidance exists on its surgical treatment. Several surgical approaches exist to treat female urethral stricture, including endoscopic dilations (ENDO), urethroplasty with local tissue (vaginal) flap (ULT) and urethroplasty with free graft (UFG). However, outcome data comparing these approaches is limited and large, multicenter studies comparing different techniques directly are non-existent. [1] This study aims to evaluate the outcomes of surgical treatment for female urethral stricture.

STUDY DESIGN, MATERIALS AND METHODS

This is a multi-institutional retrospective cohort study of surgery for female urethral stricture disease. Women who underwent surgery for urethral stricture disease from 2010-18 were included. Women with malignancy, congenital disease, undergoing gender affirming and office based surgery were excluded. Authors from each institution directly submitted de-identified data into a central database (REDCap).

The REDCap database included comprehensive information on patient demographics, medical history, urethral stricture history, presenting symptoms and patient reported outcome measures, preoperative diagnostic assessment, urethral stricture surgery, and post-operative follow-up at three visit times: initial postoperative visit (2-6 weeks), second postoperative visit (>6 weeks postoperatively), third postoperative visit (most recent visit).

Surgeries were grouped into three categories endoscopic (ENDO), urethroplasty with local tissue flap (ULT) and urethroplasty with free graft (UFG). For the primary outcome of interest, time from surgery to stricture recurrence by surgery type, a Kaplan-Meier time to event analysis was performed. To adjust for confounders, a Cox-proportional hazard model was fit for time to stricture recurrence. The Cox-proportional hazard model was adjusted for the covariates listed in the Table.

RESULTS

Twenty-three surgical centers contributed data, the majority of which were from academic centers within the United States (90%). A total of 1051 patient charts were reviewed and after exclusions 248 patients charts were abstracted. Of these, 215 patients met inclusion criteria. Patients were mostly caucasian (73%) with a mean age of 56 years (SD 13). The majority of patients were post menopausal (70%). The etiology of stricture formation was unknown or missing for 25% (N=55), idiopathic for 17% (n=37), prior instrumentation (cystoscopy or non-stricture urethral dilation) for 16% (n=34), and catheter related for n=20 (9%).

Types of surgery performed were evenly distributed (ENDO: 35% (n=75), ULT: 33% (n=72), UFG: 32% (n=68)). The majority of ENDO surgeries were cystoscopy with dilation (90%). ULT surgeries primarily consisted of vaginal advancement flap (46%) or tubularized vaginal flap (40%). UFG were primarily dorsal onlay (94%) using buccal grafts (97%). There were no differences in demographics nor etiology of stricture between groups.

Overall, 65% of women remained recurrence free (n=120/185, [recurrence data missing in n=30]) at median follow-up of 14 months (IQR 3-36). Median follow-up time was not significantly different between groups (ENDO: 17, ULT 12, UFT 14 months, p=0.66). In unadjusted analysis, recurrence rates were significantly different between surgery categories with

68% ENDO, 77% UFG and 84% ULT of patients being recurrence free at 12 months. Figure

In the adjusted model, recurrence rates were significantly different between surgery categories, with women undergoing ULT having 65% less risk of recurrence compared to those undergoing endoscopic treatment. (ENDO: Ref ULT: HR 0.35 [95% CI 0.18-0.69], p=0.003) (UFG: HR 0.5 [95% CI 0.28-0.91], p=0.02) Table We also found that abnormal tissue quality was significantly associated with risk of recurrence (HR 1.99 [95% CI 1.05-3.79], p=0.04).

INTERPRETATION OF RESULTS

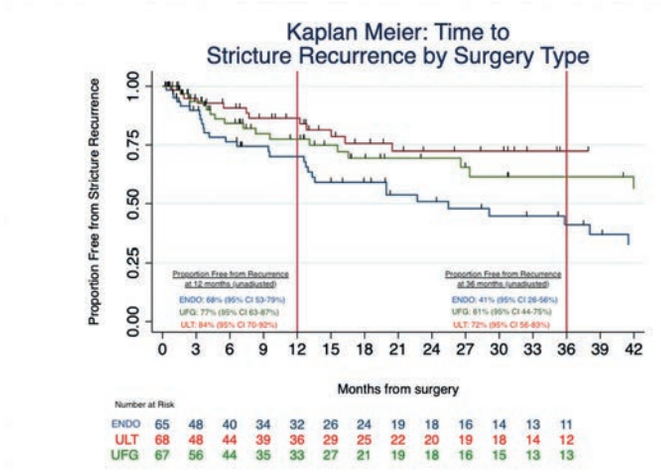
In this retrospective, multi-institutional study of 215 women who underwent surgical treatment for female urethral stricture we find that 65% of women remained stricture free at median follow-up of 14 months. On adjusted and unadjusted analysis, we find that time to recurrence was significantly different between surgical categories, with endoscopic management having the poorest outcomes with an unadjusted 12 month stricture recurrence free of 68%.

Our data parallels prior data on outcomes of urethral stricture, showing the poorest outcomes among women treated with endoscopic management (27-58%). [1-2] Our UFG outcomes are also consistent with a 2019 retrospective, multi-institutional study of 39 women undergoing UFG (dorsal onlay, buccal mucosal graft) for urethral stricture, which found that 77% (n=23) of women remained stricture free, median time to recurrence was 14 months. [3] Our study reinforces these previous studies and together, this data supports the conclusion that endoscopic approaches to treatment of urethral stricture are less durable than urethroplasty.

CONCLUDING MESSAGE

This data provides the first, large, multicenter comparison of surgical outcomes for different approaches to female urethral stricture. We find that patients undergoing endoscopic management have significantly higher risk of recurrence compared to those undergoing either urethroplasty with local flap or free graft.

FIGURE 1



Kaplan-Meier Survival Curve: Unadjusted Time to Recurrence By Surgery Type

FIGURE 2

Table 1: Cox Proportional Hazard Model for Time to Female Stricture Recurrence

n=177	Haz. Ratio	Std. Err.	p	[95% Conf.	Interval]
Surgery Type (ref: endoscopic)					
Urethroplasty local tissue flap (ULT)	0.35	0.12	0.003	0.18	0.69
Urethroplasty free graft (UFG)	0.51	0.15	0.02	0.28	0.91
Age at Surgery	1.00	0.01	0.77	0.98	1.02
Time from Diagnosis to Surgery	1.02	0.01	0.14	0.99	1.05
Diabetes (ref: no)	0.81	0.35	0.62	0.35	1.87
Lung Disease (ref: No)	1.17	0.44	0.67	0.56	2.43
History of Prior Stricture Surgery (Ref: No)	1.61	0.47	0.10	0.91	2.84
Tissue Quality (Ref: normal)*	1.99	0.65	0.04	1.05	3.79
Intra or Postop Complication (Ref: none)	0.86	0.30	0.68	0.44	1.71

* binary composite assigning 'abnormal' to those with lichen, straddle injury, pelvic fracture, intermittent catheterization, radiation

Table: Cox Proportional Hazard Model for Time to Female Stricture Recurrence

REFERENCES

1. Faiena I, Koprowski C, Tunuguntla H. Female Urethral Reconstruction. J. Urol. [Internet]. 2016;195:557–567. Available from: http://dx.doi.org/10.1016/j.juro.2015.07.124.
2. Popat S, Zimmern PE. Long-term management of luminal urethral stricture in women. Int. Urogynecol. J. [Internet]. 2016;27:1735–1741. Available from: http://dx.doi.org/10.1007/s00192-016-3006-8.
3. Hampson LA, Myers JB, Vanni AJ, et al. Dorsal buccal graft urethroplasty in female urethral stricture disease: a multi-center experience. Transl. Androl. Urol. [Internet]. 2019;8:S6–S12. Available from: http://dx.doi.org/10.21037/tau.2019.03.02.

Funding SUFU Research Network **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Review Board at University of Michigan (and at each participating site) **Helsinki** Yes **Informed Consent** No

2 www.ics.org/2020/abstract/2

BEST IN CATEGORY PRIZE "URODYNAMICS"

CLINICIAN FACTORS AFFECTING EXPOSURE TO RADIATION DURING VIDEO URODYNAMICS.

Yasmin H[1], Toia B[1], Axell R[1], Aleksejeva K[1], Pakzad M[1], Hamid R[1], Ockrim J[1], Greenwell T[1]

1. University College London Hospital

HYPOTHESIS / AIMS OF STUDY

Video urodynamics allow for correlation of lower urinary tract anatomy with physiology during the filling and voiding phases – and enable more precise delineation of site and cause of bladder outlet obstruction and/or incontinence as well as additional findings such as vesico-ureteric reflux at the expense of radiation exposure. We have assessed whether clinician related factors affect the total radiation exposure time (RET, an operator controlled component that affects total radiation dose) and the actual radiation dose (RD) during video urodynamics.

STUDY DESIGN, MATERIALS AND METHODS

The radiation exposure time and radiation dose of all 986 consecutive patients having video urodynamics to investigate refractory lower urinary tract symptoms between 13/01/2018 and 31/01/2019 were retrospectively reviewed from our Radiology Information System database. 208 (31.2%) patients were excluded owing to: missing information fields, failure to complete video urodynamics due to patient or equipment factors and owing to additional simultaneous tests that further exposed patients to radiation such as the retrograde leak point pressure test.

Clinical Scientists and training Urologists used a standardised Female, Functional and Restorative (FFR) Urology protocol when performing the video urodynamics whilst the other groups did not.

Total radiation exposure time and total radiation dose were determined and correlated with speciality and grade of clinician performing the test. Statistical analysis was by Kruskal-Wallis with pairwise multiple comparisons by Dunn's test. Statistical significance was determined at $P < 0.001$.

RESULTS

678 patients (413 female, 60.6%) fulfilled the above criteria and their results are listed in Figure 1.

The rate of non diagnostic video urodynamics (reported as normal or with diagnosis at variance with patient symptoms) was similar in all groups and was 20% overall.

There was no significant difference in patient's age, presenting lower urinary tract symptoms and sex amongst the groups (with the exception of the gynaecologists).

INTERPRETATION OF RESULTS

There is wide variation in total radiation exposure time (median=38s, range=247s) and hence radiation dose (median=151cGy.cm^2, range=345cGy.cm^2) during video urodynamics. Clinical Scientists and Urologists in training have significantly lower radiation exposure times and radiation doses whilst Consultants, in particular Radiology Consultants, have significantly longer exposure times for the same diagnostic yields. A further sub analysis of patients that underwent video urodynamics on the same fluoroscopy unit that were either on the radiology or gynaecology pathway (i.e. non-FFR) revealed similar findings - with Consultant Radiologists and Gynaecologists delivering near double the radiation exposure times and over double the radiation dose compared to the Clinical Scientists.

CONCLUDING MESSAGE

Patients may benefit from adoption of the Female, Functional and Restorative Urology video urodynamics protocol to reduce total radiation exposure time and hence radiation dose.

FIGURE 1

Clinician Group	NRET (NRD)	Median RET (s)	Median RD (cGy.cm^2)
Radiologists	323 (320)	57.0*	170*
Gynaecologists	25 (25)	53.0*	236
Urologists	53 (52)	25.0*	155
Clinical Scientists	281 (275)	26.0*	116*
Radiographers	6 (6)	54	204
Consultants	101 (99)	66.0*	258*
Training Doctors	300 (298)	49.0*	160
Training Urologists	53 (52)	25.0*	155
Training	247 (246)	54.0*	160
Clinical Scientists (non-FFR patients)	68 (95)	35.0*	84.6*

- *P < 0.001

Funding NA **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Service audit **Helsinki** Yes **Informed Consent** Yes

3 www.ics.org/2020/abstract/3

BEST IN CATEGORY PRIZE "OVERACTIVE BLADDER"

PIVOTAL STUDY OF SUBCUTANEOUS TIBIAL NERVE STIMULATION WITH COIN-SIZED IMPLANTABLE TIBIAL NEUROSTIMULATOR (ECOIN DEVICE) FOR URGENCY URINARY INCONTINENCE

Rogers A[1], McCrery R[2], MacDiarmid S[3], Lukban J[4], Kaaki B[5], Shapiro A[6], Giudice T[7], Nguyen J[8], Gauta J[9], Serels S[10], Threatt C[11], Kaminetsky J[12], Lucente V[13], Dutta S[14], Sand P[14], Ferrante K[15]

1. Sansum Clinic, 2. Adult/Pediatric Urology & Urogynecology, 3. Alliance Urology, 4. Colorado Pelvic Floor Consultants, 5. Allen Memorial Hospital, 6. Chesapeake Urology, 7. South Carolina Ob/Gyn, 8. SCPMG, 9. Florida Bladder Institute, 10. Urology Associates of Norwalk, 11. Sequoia Urology Center, 12. Manhattan Medical Research, 13. The Institute for Female Pelvic Medicine, 14. Evanston Continence Center, NorthShore University Health System, 15. Kaiser Permanante San Diego

HYPOTHESIS / AIMS OF STUDY

The pivotal study of a coin-sized implantable tibial neurostimulator (eCoin device) aims to show safety and effectiveness of the study device for treatment of urgency urinary incontinence.

STUDY DESIGN, MATERIALS AND METHODS

This is a prospective, single-arm study enrolling up to 135 human subjects across 15 sites in the United States with overactive bladder syndrome primarily focusing on the symptom of urgency urinary incontinence (UUI). Subjects enrolled had at least 1 UUI episode daily on a 3-day voiding diary, and were intolerant or showed an inadequate response to at least 1 second or third-line therapy prior to enrollment with the exception of prior sacral neuromodulation therapy. Subjects were washed off any overactive bladder medication (2 weeks), onabotulinumtoxinA (9 months), or percutaneous tibial nerve stimulation therapy (1 month). Subjects with lower leg conditions posing a higher risk of poor wound healing, neurogenic bladder, bladder pain syndrome, >1/3 stress urinary incontinence (SUI) episodes, or retention (PVR >150cc) were excluded.

The eCoin device is a flat and leadless neurostimulator containing a primary cell battery with an average operating life of 3 years. A conically shaped field of stimulation radiates from a center cathode to an anode outer rim of the 23.3 mm diameter and 2.4mm thick coin-sized and shaped device. The eCoin device was implanted subcutaneously above the fascia utilizing only local anesthetic. Following the procedure, the incision was covered for several days, a shower bag was worn during bathing for 2 weeks, flat footwear was worn for 4 weeks, and vigorous ankle movement (i.e. running, cycling) was restricted for 8 weeks to mitigate device migration prior to encapsulation. The eCoin device was activated after an approximate 4-week healing period. Automated low-duty stimulation of 30 minutes duration was thereafter provided every 3 days for the first 18 weeks then every 4 days without subject involvement. The subjects were followed for 48 weeks post-activation. Follow up visits occurred at 4, 8, 12, 24, and 48 weeks post-activation and included the collection of a 3-day voiding diary; completion of an Overactive Bladder Questionnaire (OABq), Patient Global Impression of Improvement in Incontinence (PGI-I), and satisfaction questionnaires; and assessment of adverse events.

This study was conducted in compliance with FDA and International Conference on Harmonization regulations for Good Clinical Practice. The Western Institutional Review Board approved the protocol and informed consent forms, and regulatory bodies in the United States approved conduct of study. All participants provided informed consent.

RESULTS

The study includes 133 subjects who were enrolled and implanted with the eCoin device during a 7-month period (9 urogynecologists and 6 urologists). Utilizing a Mayo tray with provided materials for implant and without reliance on imaging or interrogation of the device, implantation took an average of 21 minutes. The subject population had a mean age of 63.9 (11) and BMI of 30.4 (9.1). Most subjects were female (98.5%) and Caucasian (84.21%). Baseline mean UUI episodes were 4.28 (3.08), and baseline mean OABq symptom bother and quality of life scores were 65.7 (30.0) and 45.7 (22.6), respectively.

After 36 weeks, outcome data are available on 122 subjects. The mean change in daily UUI episodes compared to baseline was -2.73 (-3.24, -2.22) (P<0.001), and the proportion of subjects in whom UUI episodes decreased by at least 50% (the "responder rate") was 72.95% (95% CI, 64.16, 80.59). Additionally, 49.18% (95% CI, 40.02, 58.38) of subjects UUI episodes decreased by at least 75% and 30.33% (95% CI, 22.33, 39.30) were dry (100% decrease of UUI episodes). On the PGI-I scale, 77% of subjects reported feeling at least "better" and 36.89% of subjects reported feeling "very much better." OABq symptom bother scores improved significantly by -36.2 (95% CI, -41.2, -31.3) (P<0.001), and quality of life scores improved significantly by 35.9 (95% CI, 31.3, 40.7) (P<0.001). Subjects' urinary incontinence episodes decreased significantly by 2.73 (95% CI, 1.04, 2.06) (P<0.001). Figures 1 and 2 graphically depict subject responder rate and average UUI episodes at baseline, 12- 24- and 36-weeks post activation. Error bars in figure 2 indicate the 95% confidence interval for displayed UUI episode means.

Mild to moderate wound healing issues were seen in 12.8% of subjects. The majority resolved within 4 weeks with no effect on the subsequent therapy. Typically, minimal (i.e. ~5 mm) migrations of the device occurred prior to encapsulation with no significant correlation to efficacy. One related serious adverse event occurred with incision site infection

prior to activation, which was managed with explant at a hospital with no long-term sequela.

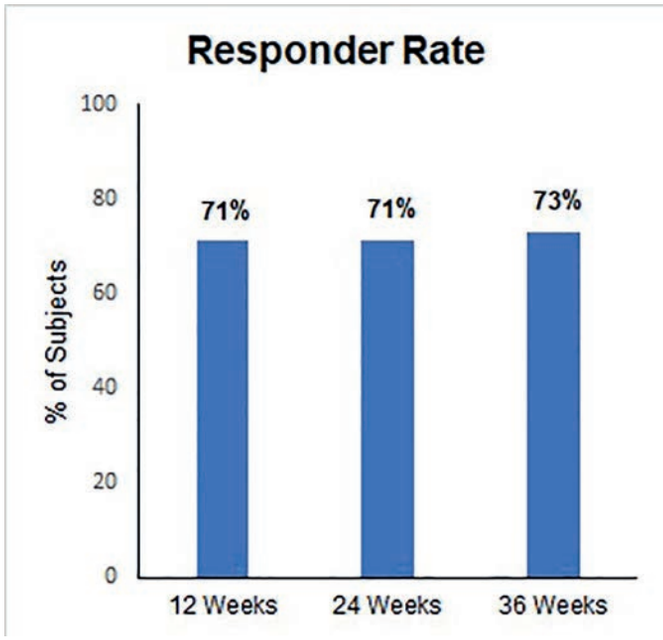
INTERPRETATION OF RESULTS

133 of 137 (97%) enrolled patients were implanted with no exclusion based on a trial procedure or screening test. Patient reported outcomes align with objective voiding diary data, showing at the 36 week point 77% of subjects feeling at least better and a 72.95% responder rate pertaining to UUI. Similarly, the OABq shows subjects are experiencing clinically significant improvements in their quality of life and in their symptom bother score. Compared to baseline, patients experienced a dramatic and sustained reduction in UUI, as indicated by the significant decrease at 12-weeks post activation, with similar results maintained at 24- and 36-weeks post activation. The dry rate is high at 30.33%, particularly given the limited operator experience with the eCoin device. Additionally, the low incidence of temporary mild to moderate wound healing issues, presence of just one related serious adverse event, and an average implantation time of 21 minutes, suggest the procedure to implant the eCoin device is both safe and brief.

CONCLUDING MESSAGE

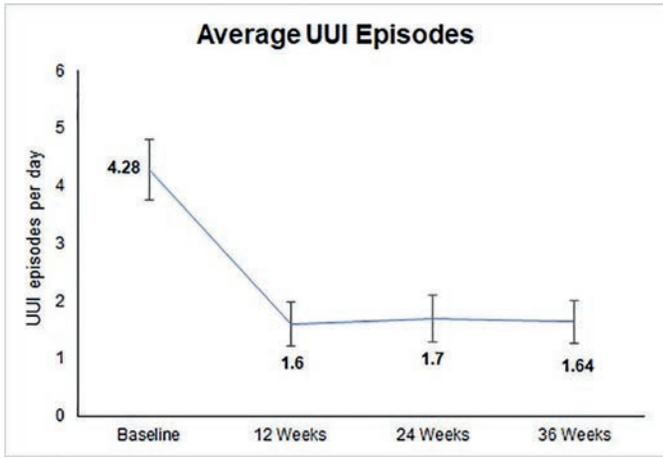
The study proved subcutaneous implantation of the eCoin device is easy to perform with minimal resources. Compliance with aftercare instructions provided to the patient was achieved without difficulty. Management of the device post-implant was seamless with no direct patient involvement, such as the use of a patient controlled remote for recharging or device powering. Once commercially available, eCoin implant and management is expected to be efficient from a workflow perspective. Clinically significant improvements in UUI, including an impressive dry rate and patient reported outcomes were shown. Such results obtained without a trial or screen test before implantation, and from urologist and urogynecologist investigators previously unfamiliar with the anatomy are very compelling. The results suggest that placement of the eCoin is less specific than placement of a sacral lead, though intuitively more specific than placement of a pulse generator. The eCoin device is a promising new therapy offering years of automated, sustained, desirable therapy for patients with overactive bladder syndrome.

FIGURE 1



Responder Rate

FIGURE 2



Average UUI Episodes

Funding Valencia Technologies Corporation **Clinical Trial** Yes **Registration Number** NCT03556891 **RCT** No **Subjects** Human **Ethics Committee** Western Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

4 www.ics.org/2020/abstract/4

BEST IN CATEGORY PRIZE "MALE STRESS URINARY INCONTINENCE (POST PROSTATECTOMY INCONTINENCE)"

POST-ARTIFICIAL URINARY SPHINCTER PROSTATE RADIATION IS A PREDICTOR OF URETHRAL ATROPHY WITH RECURRENT INCONTINENCE

Berger A[1], Szymaniak J[1], Kathrins M[1]

1. Brigham and Women's Hospital/Harvard University

HYPOTHESIS / AIMS OF STUDY

Prior data suggests radiation is associated with shorter artificial urinary sphincter (AUS) device survival. However, there is a paucity of data on outcomes of patients who undergo radiation after AUS. Thus, we aimed to compare AUS outcomes between patients receiving prostate radiation before or after AUS placement.

STUDY DESIGN, MATERIALS AND METHODS

After IRB approval, we utilized our institutional Partners Research Patient Data Registry to identify all men who underwent AUS, radical prostatectomy and prostate radiation from 1989-2019 with any surgeon. After these patients were identified, we undertook a retrospective chart review to collect demographic and clinical information. Patients were grouped by radiation before or after AUS and clustered by surgeon. Our primary outcomes were diagnosis of urethral atrophy – recurrent incontinence with functional device – and revision surgery for atrophy as well as time to these outcomes. Time to outcome was calculated from the date by which patients had received both AUS and radiation. We performed univariate, multivariable logistic and Cox proportional hazard survival analyses.

RESULTS

We identified 154 patients meeting our study criteria. Of these men, 137 (88.96%) underwent radiation a median 48 mo (3-267) prior to AUS. 17 patients (11.04%) underwent radiation after AUS at a median 16.5 mo (2-77). There was no difference in age, race, Charlson Comorbidity Index, smoking, diabetes, prior male urethral sling, prior endoscopic bulking agent injection, pre-existing bladder neck contracture, androgen deprivation, or AUS cuff size between groups. Median follow-up post-exposure was 25 (0-216) mo.

Atrophy occurred in significantly more men in the radiation after AUS group (47.0% v 10.2%, p=<0.001) at a median 12.0 vs. 35.5 mo (p=0.04). Our multivariable regression including all collected variables revealed that receipt of radiation after AUS (OR 6.73, p<0.001) was associated with recurrent incontinence due to atrophy. Previous or current smoking (OR 1.40, p=0.02), previous urethral sling (OR 2.32, p<0.001) and increased size of AUS cuff (OR 4.08, p=0.02) were also associated with atrophy on multivariable analysis.

Multivariable survival analysis demonstrated that those with radiation after AUS developed atrophy earlier (12.0 mo vs 35.5 mo, HR 4.02, p=0.04) and had a shorter time to device revision for atrophy (57.0 mo vs 45.5 mo, HR 9.2, p=0.003). There was no difference in urologic complications, erosion, explant or revision between those undergoing AUS before or after radiation on either univariate or multivariable analysis.

INTERPRETATION OF RESULTS

While there was no difference of overall post-operative urologic complications between pre-AUS radiation and post-AUS radiation patients in this small cohort study, we found that post-AUS radiation is associated with higher rates of atrophy and revision for atrophy as well as shorter time to device revision for atrophy.

CONCLUDING MESSAGE

Our study suggests that if radiation is anticipated, urologists should consider waiting until radiation is complete prior to AUS insertion.

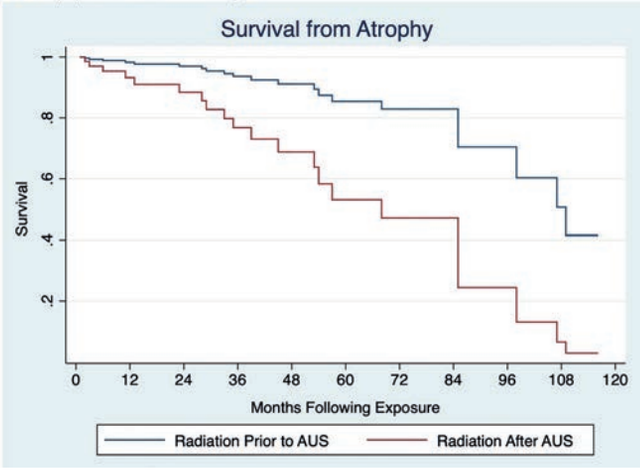
FIGURE 1

Table 1. Univariate and multivariable analysis of time between exposure and diagnosis of urethral atrophy with recurrent incontinence

		Univariate Analysis			Multivariable Analysis		
Model Cohort (n=154)	n	HR	95% CI	p-value	HR	95% CI	p-value
Radiation after AUS placement	**154**	**4.22**	**1.96-9.10**	**<0.001**	**4.02**	**1.07-15.12**	**0.04**
Age at time of AUS	154	0.97	0.96-0.99	<0.001	0.99	0.95-1.03	0.65
Non-White Race	152	4.26	1.73-10.45	<0.001	0.75	0.17-3.27	0.70
Current or Former Smoker	150	1.18	0.62-2.21	0.62	**1.40**	**1.06-1.85**	**0.02**
Charlson Comorbidity Index Score	154	0.87	0.67-1.13	0.30	0.87	0.63-1.19	0.38
Diabetes	153	0.99	0.45-2.18	0.98	1.78	0.86-3.70	0.12
Androgen deprivation therapy	153	2.50	0.69-9.40	0.16	4.21	0.94-18.91	0.06
Prior urethral sling	154	1.33	0.87-2.02	0.19	**2.32**	**1.54-3.51**	**<0.001**
Prior urethral bulking	153	1.26	0.42-3.80	0.68	4.28	0.83-21.99	0.08
Prior treatment for bladder neck contracture	154	0.59	0.11-3.10	0.54	0.47	0.58-3.87	0.49
AUS cuff size	**151**	**3.40**	**1.62-7.14**	**0.001**	**4.08**	**1.29-12.87**	**0.02**
Concurrent placement of penile prosthesis	154	0.71	0.21-2.44	0.59	1.55	0.20-12.34	0.68

FIGURE 2

Figure 1. Cox proportional hazard survival analysis.



Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Brigham and Women's IRB **Helsinki** Yes **Informed Consent** No

5 www.ics.org/2020/abstract/5

5-YEAR DATA ON EFFICACY, SAFETY AND DURABILITY OF ADJUSTABLE TRANSOBTURATOR MALE SYSTEM (ATOMS) IN A MULTICENTRE STUDY

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HYPOTHESIS / AIMS OF STUDY

There is accumulated evidence to consider adjustable transobturator male system (ATOMS) is an effective treatment for male stress urinary incontinence (SUI), especially in mild to moderate cases (1). Also, high patient satisfaction and limited complication rate can be anticipated according to several studies (2,3).

Significantly better results have been described in the short-term in non-severe and non-radiated cases (1). However, long-term data with this device is lacking. The system is not prone to mechanical failure but durability of the device in the long-term is unknown. Our objective is to evaluate long-term efficacy and safety of ATOMS for male SUI, and also to evaluate durability of the system and factors influencing endurance.

STUDY DESIGN, MATERIALS AND METHODS

Retrospective multicentre IRB aproved study conducted in nine Iberian institutions using a board-approved database of 215 consecutive patients updated using an eCRF to periodically evaluate long-term continence status, complications, explants and secondary treatments. Initial outcomes were reported in 2017 (1). SUI severity was defined as mild if baseline pad-count was 1-2 PPD, moderate 3-5 PPD and severe >5 PPD. All patients were updated to March 2020, except for eleven cases deceased of unrelated cause.

Primary objective was evaluation of long-term efficacy by the proportion of patients achieving continence with the implant at last follow-up. Continence at the time of adjustment was defined as SUI with use of none or one security pad/day (PPD) with <10cc urine loss. The same definition was used during follow-up. Kaplan-Meier curve was also performed to investigate evolution of dryness in patients achieving continence after adjustment.

Secondary objective was evaluation of long-term safety and device durability. Complications were registered during follow-up and device explant rate and reasons were evaluated in the total series. Factors affecting explant and consequent recurrence of SUI were evaluated using univariate and multivariate analysis. Kaplan-Meier study and log-rank test were performed to investigate long-term device durability in a real practice setting. Secondary treatments after ATOMS explant were also evaluated, based on investigator decision.

RESULTS

A total of 215 cases were included in the Iberian ATOMS study (1). SUI baseline severity was mild in 50 patients (23.3%), moderate in 106 (49.3%) and severe in 59 (27.4%). Device generation was inguinal port in 34 patients (15.8%), simple scrotal port in 31 (14.4%) and silicone-covered scrotal port in 150 (69,8%). Mean follow-up from surgery to March 2020 was 60.6±18.4 months (range 39-91). Totally 72.1% of the patients remained dry (n=155; 99 (46%) used no pads and 56 (26%) a security PPD). Kaplan Meier analysis revealed that among the population achieving dryness after adjustment (n=173), 96% remained free of SUI 1-year after implant, 93.6% 2-years, 91.1% 3-years, 89.2% 5-years and 86.7% 8-years.

Complications occurred in 43 patients (20%). In order of frequency they included: perineal pain (15 cases), port erosion and infection (10 cases), de novo urge incontinence (4 cases) scrotal hematoma (4 cases), incipient port erosion without infection (2 cases), wound dehiscence (2 cases); and acute urinary retention, wound infection, urinary infection, haematuria, delirium and ictus (1 case each). Three cases (1.4%) received radiation after ATOMS implant without significant complication or malfunction. Perineal pain did not present newly after the initial report; however, all cases with de novo urge incontinence developed later.

Device explant occurred in 25 patients (11.6%). Reasons for explant were device inefficacy (11 cases, 44%), inefficacy and pain (3 cases, 12%), port erosion and infection (10 cases, 40%) and wound infection (1 case, 4%). Secondary implant was performed in 11 (5.1%) cases, artificial urinary sphincter (AUS) in 6 (2.8%) and repeated ATOMS in 5 (2.3%). Device explant was associated to complications (p<.0001), baseline SUI severity (p=.01) and former irradiation (p=.03); but was not related to patient age (p=.39) or device generation (p=.17). Multivariate analysis revealed presence of complications (HR 8.71; 3.83-19.82), irradiation before ATOMS placement (HR 2.26; 0.99-5.18) and baseline severity, moderate compared

to mild (HR 8.77, 1.15-66.67) and severe compared to mild (HR 14.92, 1,87-125) were independent factors to determine ATOMS explant. Kaplan-Meier analysis revealed durability of ATOMS was 99.5% 1-yr after implant, 97.2% 2-yrs, 92.6% 3-yrs, 86.3% 5-yrs and 80.4% 8-yrs.

INTERPRETATION OF RESULTS

The Iberian study gave excellent data to evaluate long-term efficacy, safety and durability of ATOMS device to treat male SUI. This real practice study was performed by the collaboration of eight institutions in Spain and Portugal. Results initially reported at 24-months mean follow-up confirmed ATOMS device was safe and achieved high treatment efficacy and patient satisfaction (1,2). Updated data to 60-month mean follow-up allow a better understanding of long-term device explant and secondary treatments and give a better idea of real-life data regarding long-term safety and efficacy of the device.

Less than 10% decrease in continence rate is proved in the long-term (72.1% compared to 80.5% previously reported) and less than 5% increase in complications rate (20% compared to 15.3%). These data are again reassuring. Patients achieving continence after adjustment may become incontinent again if complications lead to device explant, most often due to port erosion and device infection (3). Perineal pain is the most frequent complication, characteristically present in the first months after surgery, but not later. On the other hand, de novo urge incontinence is typically a late complication, but an infrequent one (1.9%). Further studies with urodynamics data should better define the reason and significance of de novo overactive bladder after ATOMS placement.

Interestingly, this is the first report to address ATOMS durability in the long-term, that appears excellent. ATOMS was explanted in 11.6% and main reasons were infective complications or device clinical inefficacy. In no case device was explanted due to pain exclusively. Infective complications occurred in 5.1% of the cases. Prospective comparison between ATOMS and AUS durability should be performed. In the meantime, the figures given in the Iberian study suggest durability of ATOMS may exceed that of AUS as surgical revisions are rarely needed and explant rate is low in the long-term. Severe baseline incontinence (6 or more PPD) and complications, not only after surgery but also during follow-up, are the most important risk factors for ATOMS explant. Although not so strong, radiation is also an independent factor for explant, probably because of diminished clinical efficacy (1). Two options appear feasible to re-treat SUI after ATOMS explant: AUS and second ATOMS. Possibly, repeated ATOMS is the best choice for patients with good operative results who lost their device for infection and AUS is the best choice for cases with failed ATOMS and severe SUI still motivated to receive a second implant. These data are pioneer to give an idea on clinical management options after ATOMS failure. However, further studies with bigger numbers appear necessary to define optimum secondary treatment options.

CONCLUDING MESSAGE

ATOMS device is efficacious and safe in the log-term to treat male SUI. 5-year after surgery 71% of the patients intervened were continent, and 89% of those that achieved continence after device adjustment. Complications occurred in 20% of the cases and the device was explanted in 11.6% of the cases during follow-up. Determinants for device explant included baseline severity of incontinence, complications during follow-up and previous irradiation. Also, durability of the device is re-assuring with 86.3% of the devices in place at 5 years.

REFERENCES

1. Neurourol Urodyn. 2018;37(4):1458-1466
2. World J Urol. 2019 Oct;37(10):2189-2197
3. World J Urol. 2019 Sep 21. doi: 10.1007/s00345-019-02962-w.

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6 www.ics.org/2020/abstract/6

INTRADETRUSOR INJECTION OF ADULT MUSCLE-DERIVED CELLS FOR THE TREATMENT OF UNDERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Underactive bladder (UAB) is a disease of unmet medical need that affects over 15% of the population, yet no consensus treatment exists beside clean intermittent catheterization (CIC). We hereby report on the first regulatory approved clinical trial of a one-year prospective open label physician-initiated study assessing the safety and efficacy of intradetrusor injected autologous muscle-derived cells (AMDC) treatment for UAB.

STUDY DESIGN, MATERIALS AND METHODS

20 non-neurogenic UAB patients were treated and all patients had at least a 1 month visit post-injection. Baseline evaluation included medical history, physical examination, 3-day voiding diary, multi-channel urodynamic testing, and endoscopy to confirm no obstruction. Approximately 150 mg of quadriceps femoris muscle was collected using a spirotome 8-gauge needle. The muscles biopsy was sent to Cook MyoSite (Pittsburgh, PA) for processing. Upon reaching a final concentration of 62.5 million AMDC/mL, patients received 30 intradetrusor injections of 0.5 mL delivered to the bladder, for a total of 15 mL, performed utilizing a flexible

cystoscope under direct vision using topical local anesthesia. Follow-up assessments included adverse events and efficacy via voiding diary and urodynamics testing at 1, 3, 6 & 12-month post-injection. An optional second injection was offered at the end of the 6 months visit.

RESULTS

20 patients received the first injection and 19 of 20 patients requested and received a second injection. Age of patients ranged from 41-82 years old with a median age of 65 years. There were 16 male (80%) and 4 female (20%) patients. Etiology included seven men (35%) with persistent urinary retention after transurethral resection of the prostate for benign prostatic hyperplasia and 13 patients (65%) with idiopathic chronic urinary retention. At baseline, 10/20 (50%) patients were CIC dependent, 9/20 patients reported mixed voiding, and 1/20 (5%) patients reported no CIC, but had persistent high post-void residual (PVR) urine volume. 1 patient dropped from this study before the 12-month follow-up assessment.

Table 1 is the patient-reported global response assessment (GRA). At the primary outcome time point of 12 months, 11/19 patients (58%) reported a GRA > 5, showing slight to marked improvement in their UAB symptoms, compared to 6/20 (30%) patients at 3-months post-injection. One patient reported temporary worsening at month 6 but reported no change in symptoms from baseline at month 12.

Figure 1 illustrate the improvements in voiding efficiency from baseline to 6- and 12-months post injection in patients who were able to void during the urodynamics test at the 6- and 12-mont follow-up visits.

No serious procedure or treatment-related adverse events occurred. No adverse events related to the AMDC injection were reported. All biopsy and injection-related adverse events were expected complications and were either self-resolved or easily treated.

INTERPRETATION OF RESULTS

Analysis up to 12 months revealed encouraging improvement in bladder function and safety for UAB patients with catheter dependent chronic urinary retention who received intradetrusor AMDC injections. Improvements are noted in decreased patient PVR, increased voiding efficiency, and decreased catheter use. Limitations of study include small size and lack of randomization, but this is in line with a first in human physician-initiated feasibility study of safety and efficacy.

CONCLUDING MESSAGE

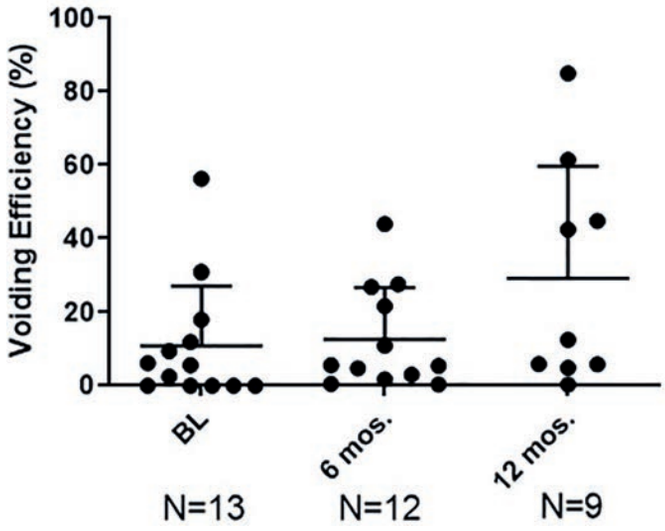
Intradetrusor injected autologous muscle-derived cells as treatment for UAB was successfully completed in a physician sponsored 20-patient trial without serious adverse event and with signal of efficacy. Cellular therapy may be a promising novel treatment for catheter dependent chronic urinary retention. A multicenter controlled trial is needed to further assess the promise of regenerative medicine in the treatment of lower urinary tract dysfunction.

FIGURE 1

Follow-up	3 Mo.	6 Mo.	12 Mo.
Improved (GRA≥5)	30% (6/20)	50% (10/20)	58% (11/19)
No Change (GRA=4)	70% (14/20)	45% (9/20)	21% (4/19)
Worse (GRA≤3)	0	5% (1/20)	0
Undetermined	0	0	21% (4/19)

Global Response Assessment at 3, 6, and 12-months post-injection

FIGURE 2



Voiding Efficiency improvements at 6-months and 12-months post injection in patients able to void during urodynamics

REFERENCES

1. Jankowski RJ, Tu LM, Carlson C, Robert M, Carlson K, Quinlan D, Eisenhardt A, Chen M, Snyder S, Pruchnic R, Chancellor M, Dmochowski R, Kaufman MR, Carr L. A double-blind, randomized, placebo-controlled clinical trial evaluating the safety and efficacy of autologous muscle derived cells in female subjects with stress urinary incontinence. Int Urol Nephrol. 2018 Dec;50(12):2153-2165. PMID: 30324580

Funding The Aikens Research Center at Beaumont Health System (Royal Oak, MI, USA). The authors would like to acknowledge the NIA, NIDDK, the Underactive Bladder Foundation (www.underactivebladder.org). **Clinical Trial** Yes **Registration Number** ClinicalTrial.gov NCT02463448 **RCT** No **Subjects** Human **Ethics Committee** William Beaumont Hospital Institutiional Review Board (IRB #2015-134) **Helsinki** Yes **Informed Consent** Yes

7 www.ics.org/2020/abstract/7

FEMALE URODYNAMIC STRESS INCONTINENCE IN OVERWEIGHT AND OBESE WOMEN AFTER MID-URETHRAL SLINGS: SURGICAL OUTCOMES AND PRE-OPERATIVE PREDICTORS OF FAILURE

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HYPOTHESIS / AIMS OF STUDY

The link between obesity and female stress urinary incontinence (SUI) is well established. Obesity results in elevated intra-abdominal pressure, leading to pelvic floor denervation and weakened musculature. Mid-urethral sling (MUS) procedures are commonly performed surgeries for SUI. Studies have shown varying MUS success in population groups with high-risk factors, like obesity and intrinsic sphincter deficiency (ISD). Literature on surgical outcomes of all three generations of MUS on overweight and obese patients remains lacking, limiting clinicians' ability to individualize pre-operative counseling and decision making. Our primary objective was to evaluate surgical outcomes in overweight and obese patients with USI (urodynamic stress incontinence) treated with various MUS compared to normal weight patients. Our secondary objective was to identify risk factors predicting MUS failure in this population.

STUDY DESIGN, MATERIALS AND METHODS

Records of 688 women between January 2004 and July 2017 were retrospectively reviewed. Women who underwent MUS surgery for USI were included. Women were excluded if they had SUI symptoms without demonstrable USI on urodynamic studies (UDS), ≥ stage II genital prolapse in all compartments according to POP-Q, detrusor overactivity, mixed incontinence, neurogenic bladder dysfunction, post-void residual urine >100ml, or received concurrent prolapse surgery. All 3 generations of MUS (single incision slings, trans-obturator and retropubic tapes) were utilized. Paired-samples t-test and either ANOVA, chi-squared, McNemar's, and Fisher exact tests were used to analyze continuous and categorical data, respectively. Patients received UDS, one-hour pad test, Urogenital Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7), and were divided into normal weight, overweight, and obese. Objective cure at 1-year was defined as no involuntary urine leakage during filling cystometry and pad test <2grams. Subjective cure was established by negative response to question 3 on UDI-6.

RESULTS

729 women underwent MUS surgeries during the study period. 41 were excluded due to incomplete data. 688 patients were included in our final analysis. Slightly over half our cohort was overweight or obese (n= 264 and 75 respectively). 57% (199/349), 41% (109/264) and 45% (34/75) of normal weight, overweight and obese patients respectively received SIS surgery. TOT surgery was performed in 32% (113/349), 42% (112/264) and 43% (32/75) of normal weight, overweight and obese patients respectively. The remaining 11% (37/349), 16% (43/264) and 12% (9/75) of normal weight, overweight and obese patients respectively received MUS-r surgery. There were no significant differences in age, parity, menopausal status, previous history of prolapse or anti-incontinence surgery, pre-operative ISD, urethral function, operating time, blood loss, hemoglobin change, duration of hospitalization, and surgical complications between the 3 groups. Overweight and obese patients had a significantly higher prevalence of diabetes mellitus (DM) compared to normal weight patients (18.9% and 26.7% versus 8.9% respectively, p <0.001). UDI-6 and IIQ-7 scores reflected significant QOL improvement pre- and post-operatively in all patients (Table 2). The obese group had significantly worse UDI-6 and IIQ-7 scores pre- and post-operatively compared to normal weight and overweight groups, although score improvement was similar in magnitude across all 3 groups. There were no significant differences in pre- and post-operative DO, BOO and urodynamic parameters. At 1-year follow-up, the overall objective and subjective cure rates were 88.2% and 85.9% respectively. There was a significantly higher rate of persistent USI in the overweight and obese groups compared to the normal weight group (12.1% and 21.4% versus 7.7% respectively). 6 patients developed post-operative detrusor overactivity incontinence with pad test ≥ 2grams – 3 in the normal weight group, 1 in overweight group and 2 in obese group. Table 3 shows the significantly lower overall objective and subjective cure rates (76% and 70.1% respectively) in the obese group compared to normal weight (91.4% and 89.1% respectively) and overweight (87.5% and 86% respectively) groups. With regards to the sling used, obese patients had significantly lower objective cure rates with all slings except TOT, and significantly lower subjective cure rate with all slings except MUS-r. The clinical features of patients in the overweight and obese groups stratified into MUS success and failure groups. Factors that were more common in obese patients with failed MUS surgery were analyzed via univariate logistic regression and included age ≥ 66 years (OR 1.72), menopause (OR 4.77), previous prolapse surgery (OR 4.19), and presence of DM (OR 2.34). A common factor present in both overweight and

obese patients was a pre-operative diagnosis of ISD (OR 4.67, p<0.001 and OR 4.86, p= 0.001 respectively).

INTERPRETATION OF RESULTS

Our results showed an adverse impact of obesity on the overall objective and subjective MUS success rates, with no effect on operative complications. It is worthwhile noting that majority of existing literature has focused on TVT and/or TOT. Our study has thus shed light on aspects lacking in previous publications. Interestingly, while we found consistently lower objective and subjective cure rates in obese patients across all SIS types, there was no difference in objective and subjective success rates for TOT and MUS-r respectively across all 3 BMI groups. Our study also showed that obese patients experienced greater severity of bother of USI with impact on their QOL at baseline and 1-year post-operatively compared to their normal weight and overweight counterparts, although the magnitude of UDI-6 and IIQ-7 score improvements were similar across all 3 groups. We found that MUS failures were more likely to occur in obese women who were elderly (age ≥ 66 years), diabetic, menopausal, with previous prolapse surgeries and pre-operative ISD, of which the latter 3 factors each accounted for a greater than 4-fold increased risk of failure at 1-year. Age and menopausal status are closely intertwined factors implicated in the pathophysiology of SUI. DM was identified in our cohort, it may have been a confounder given its higher baseline prevalence in the overweight and obese groups. We found previous prolapse surgery and ISD to be significant risk factors, with the latter found to have over 4-fold increased risk for MUS failure in both overweight and obese groups.

CONCLUDING MESSAGE

Obese women with MUS had lower objective and subjective cure rates at 1-year, and worse quality-of-life scores compared to normal weight and overweight women. Risk factors for failure include old age, diabetes, menopause, previous prolapse surgery and ISD. Surgeons should incorporate this information for individualized patient counseling as part of informed consent process.

Funding Nil **Clinical Trial** No **Subjects** Human **Ethics Committee** Chang Gung institutional review board (IRB: No, 201700320B0C601) **Helsinki** Yes **Informed Consent** Yes

8 www.ics.org/2020/abstract/8

VOIDING TRIAL AFTER COLPOCLEISIS WITH AND WITHOUT CONCOMITANT MIDURETHRAL SLING

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HYPOTHESIS / AIMS OF STUDY

Colpocleisis is a highly effective obliterative procedure offered to women with significant prolapse and no desire for vaginal function. However, much remains to be learned regarding concomitant treatment of stress urinary incontinence (SUI) and postoperative voiding function after colpocleisis. It is unclear whether concomitant placement of a midurethral sling (MUS) during colpocleisis significantly affects voiding trial failure rates. The primary aim of this study was to compare failure rates of first voiding trial (VT) within 7 days after colpocleisis with and without MUS placement. The secondary aim was to compare failure rates of VT on postoperative day (POD) 1 after colpocleisis with and without MUS placement. Our hypothesis is that there will be no difference in VT failure rates after colpocleisis in women undergoing concomitant MUS compared to colpocleisis alone.

STUDY DESIGN, MATERIALS AND METHODS

After Institutional Review Board approval, data were collected via electronic chart review of women who underwent colpocleisis at a single academic institution between January 2012 and October 2019 as identified by Current Procedural Terminology (CPT) billing codes. Individuals with a history of a neurological disorder that could affect voiding function or history of urinary diversion were excluded. All patients underwent a standardized VT within 7 days postoperatively; 300mL (or maximum tolerated volume if less than 300mL) of sterile water was instilled by Foley catheter into the bladder by gravity. VT failure was defined as inability to void ≥2/3 of an instilled volume after catheter removal. The timing of VT, inpatient (performed prior to hospital discharge on POD1) versus (vs) outpatient first VT, was made based on surgeon preference.

Clinical and demographic characteristics between those who did and did not have a MUS placed at the time of colpocleisis were compared. Student's t test or Mann-Whitney U test for continuous variables and chi-squared test or Fisher's exact test for categorical variables were used as appropriate. Logistic regression was used to examine the relationship between MUS placement and subsequent VT failure controlling for potential confounders (p<0.2). In the regression model for the risk of VT failure in the first 7 postoperative days, age, American Society of Anesthesiologists (ASA) class, prolapse stage, preoperative PVR, postoperative day of first VT, preoperative subjective urgency urinary incontinence (UUI), estimated blood loss (EBL), vaginal estrogen use at the time of surgery, and prior prolapse surgery were included.

Similarly, the risk of POD1 VT failure was assessed controlling for ASA class, preoperative PVR, subjective UUI, and EBL. Level of statistical significance was set at 0.05.

RESULTS

119 women met inclusion criteria. All patients had a VT performed within 7 days postoperatively. The majority were Caucasian (82%) with a mean age of 77.3±7.1 years. There was no significant association between VT failure within 7 days and patient characteristics. 54/119 women (45.4%) had a concomitant MUS at the time of colpocleisis. First VT was performed a mean±SD of 3.1±2.2 days in the MUS group vs 1.8±1.8 days in no MUS group (p<0.001). Baseline clinical and demographic characteristics were similar between those with and without concomitant MUS except those who underwent concomitant MUS placement had more subjective and objective stress urinary incontinence (SUI) preoperatively (p<0.001), higher rates of reported urgency UI (UUI) preoperatively (81.5% vs 51.6%, p<0.001) and lower estimated blood loss (95.1 vs 126.9mL, p=0.02). Bivariate analysis revealed that VT failure rate within 7 days did not differ between those who did and did not undergo concomitant MUS placement (22.2% [77.8% success] vs 32.8% [67.2% success], p=0.20, respectively). Logistic regression demonstrated that the risk of VT failure in the first 7 postoperative days did not differ between women undergoing colpocleisis alone vs colpocleisis with MUS (aOR 0.56, 95% confidence interval [CI] 0.16,1.93). Of 119 women, 81 (68%) underwent a VT on POD1. Significant association was noted between overall VT failure on POD1 and diabetes (OR 3.21, 95%CI 1.13, 9.1). Concomitant MUS procedures were performed in 27/81 (33%). Clinical and demographic characteristics were similar between MUS vs. no MUS groups, except those undergoing MUS placement had higher subjective and objective preoperative SUI (p<0.001) and subjective preoperative UUI (85.2% vs. 43.4%, p<0.001). ASA class also differed between groups (p=0.049). Bivariate analysis revealed that VT failure rate on POD1 did not differ between those who did and did not undergo concomitant MUS placement (33.3% [66.7% success] vs 39.6% [60.4% success], p=0.58, respectively). Logistic regression demonstrated that risk of POD1 VT failure (aOR 0.8, 95% CI 0.22, 2.91) did not differ significantly between MUS vs. no MUS groups. Of note, 5/119 (4.2%) women continued to fail VT on POD7 (MUS group: 3(5.6%) vs No MUS group 2(3.1%), p=0.66).

INTERPRETATION OF RESULTS

Relatively high success rates of VT, both within 7 days and on POD1, were observed in a large cohort of women undergoing colpocleisis regardless of undergoing a concomitant MUS or not. At 1 week post-surgery, less than 5% of subjects continued to have incomplete bladder emptying, which did not differ between groups.

CONCLUDING MESSAGE

In conclusion, concomitant surgical management of SUI with a midurethral sling at the time of colpocleisis for advanced pelvic organ prolapse did not affect voiding trial failure rates in the first week after surgery. Therefore, the placement of concomitant MUS should not influence the timing of VT in women undergoing colpocleisis. This information may be used in preoperative counseling and help inform to patients' expectations post surgery.

FIGURE 1

	MUS	No MUS	aOR	95% CI	p
1st VT FAILURE within 7 days	n=54 21 (32.8%)	n=64 12 (22.2%)	0.56*1	0.16, 1.93	0.53
POD1 VT FAILURE	n=27 21 (39.6%)	n=53 9 (33.3%)	0.80*2	0.22, 2.86	0.73

*1 controlled for age, ASA class, prolapse stage, preoperative PVR, postoperative day of first VT, preoperative subjective UUI, EBL, vaginal estrogen use at the time of surgery, and prior prolapse surgery

*2 controlled for ASA class, preoperative PVR, subjective UUI, and EBL

Table 1. Risk of Voiding Trial Failure with and without Concomitant Midurethral Sling

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9 www.ics.org/2020/abstract/9

ROLE OF DYNAMIC ENDOVAGINAL ULTRASOUND IN ASSESSMENT OF URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

Understanding the urethral closure mechanism and dysfunction in female stress urinary incontinence (SUI) has been debated by many investigators for decades. There are numerous hypotheses attempting to accurately explain the function of the urethral structures. The severity of SUI depends upon the ability of the urethra to maintain a robust urethral closure pressure during fluctuations in intra-abdominal pressure. Pelvic floor ultrasound is a useful tool to visualize urethral shape and motion during Valsalva. This study aimed to establish whether the closure mechanism of the urethra can be quantified by studying changes in the urethra's shape and position during strain across varying

degrees of SUI. Our hypothesis was that excessive urethral motion and urethral shape would differ between continent, mild SUI, and severe SUI groups.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective cohort study. Women who presented to our tertiary urogynecology center for urodynamic testing for urinary incontinence evaluation or pre-operative assessment for occult urinary incontinence were recruited to the study. Women with urinary retention, history of significant central nervous system disease, floor reconstructive surgery, anti-incontinence surgery, or third line treatment for overactive bladder were excluded. Additionally, patients were excluded after the urodynamic test if they had newly diagnosed urinary retention, low bladder capacity, or high-pressure detrusor instability.

This urodynamic study was performed according to the International Continence Society criteria, using a 7-Fr transurethral double-lumen catheter and an 8-Fr rectal/vaginal pressure sensor with a bladder filling rate of 70 mL/min. Serial Valsalva maneuvers were performed during the filling phase to replicate stress urinary leakage. Urethral pressure profiles and urethral closure pressures were obtained and then permission to void was given.

Pelvic floor ultrasound imaging was obtained at the time of the study visit using the BK Medical BK5000 X14L4 12 MHz transducer. All ultrasound studies were performed with the patient in the dorsal lithotomy position with hips flexed and abducted. Patients were instructed to arrive with a partially full bladder. The probe was inserted into the vagina in a neutral position and dynamic ultrasound videos were saved.

Dynamic anterior compartment ultrasound took 5 second videos of the midsagittal plane. The view included the bladder and urethra, with the urethral meatus, pubic symphysis, and bladder neck serving as landmarks. Patients were asked to perform a squeeze and then a Valsalva maneuver. Total urethral length and retropubic and infrapubic urethral length, urethral thickness at three levels, bladder neck retropubic angle, and the bladder neck and distal urethra's swing angle relative to the pubic bone were measured during Valsalva.

Statistical shape modeling was carried out by calculating corresponding points using Deformetrica and then using the Procrustes method and performing a principal component analysis (PCA) in Mathematica. This output modes of variation describing shape variance. PC scores were calculated for the significant modes for subsequent statistical analyses.

For statistics, only patients with a maximum urethral closure pressure of 40 cm H20 were included and categorized into "No SUI", "Mild SUI", or "Severe SUI" groups based on the symptoms present on a daily basis. Using SAS 9.4, patients' demographics, symptoms, POP-Q, urodynamic, and changes in dynamic ultrasound measurements were compared between these groups using Fisher's exact or chi-squared test for categorical variables and ANOVA (parametric) or Kruskal-Wallis test (nonparametric) for continuous variables. Changes in dynamic ultrasound were quantified by subtracting values at rest from those at Valsalva. Position and shape variables were evaluated together using a multinomial logistic regression. Using IBM SPSS Statistics v26, PC scores were analyzed with a Two-Way Mixed MANOVA with univariate ANOVAs and Benjamini-Hochberg corrections (with a false discovery rate of 10%) post hoc performed to evaluate the influence of the between-subjects variable, SUI severity, and the within-subjects variable, maneuver (Rest vs Valsalva).

RESULTS

76 women met the inclusion criteria for the final analysis (23 with no SUI, 31 with mild SUI, and 22 with severe SUI). There were no statistically significant differences in age, parity or BMI among groups. 12 modes of variation explained significant shape variance and maneuver significantly influenced the overall urethra shape ($p<0.001$). The difference between rest and Valsalva was significant for modes 1 and 2 specifically ($p<0.001$). Qualitatively, mode 1 described variation in "c" shape concavity and mode 2 variation in "s" shape concavity that exists in all SUI severity groups. During Valsalva, the urethra became more "s" shaped with distal urethral wall thickening (Figure 1).

Changes in bladder neck retropubic angle, infrapubic urethral length, and the distal urethra's swing angle relative to the pubic bone from rest to Valsalva were significantly different between groups ($p=0.0157$, 0.0154, and 0.0098, respectively) (Figure 2). SUI severity influenced the overall urethral shape significantly ($p<0.001$) and was significant for modes 5 ($p=0.001$), 7 ($p=0.001$), and 11 ($p=0.009$) specifically. For these modes, the continent and severe SUI groups differed significantly ($p=0.001$, 0.002, and 0.007, respectively) and the continent and mild SUI groups differed for mode 7 ($p=0.007$). Modes 5, 7, and 11 describe variation in the proportional wall thickness of specific regions of the urethra, indicative of more or less "pinching" or "squeezing" across SUI severity, regardless of maneuver. Together, these modes describe increased "s" shape concavity, distal urethral wall thickening, and proximal urethral pinching in mild and severe SUI urethras compared those in the no SUI group.

The multiple logistic regression comparing mild and severe SUI patients to those with no SUI demonstrated that increased "s" shape concavity and distal urethral wall thickening (described by modes 2, 5, 7, and 11) and urethral swing angle were significant predictors of severe SUI as indicated by their respective odds ratios (OR=1.728, 0.228, 0.309, 9.357, and 1.005) and p-values ($p=0.0321$, 0.0015, 0.0030, 0.0014, and 0.0012).

INTERPRETATION OF RESULTS

These results suggest that dynamic endovaginal anterior compartment ultrasound can visualize and allow for quantification of passive closure of the urethra during Valsalva due to shape changes and motion caused by increased intra-abdominal pressure.

The instability and excessive swinging motion of the bladder neck and distal urethra relative to the pubic bone, increasing "s" shape concavity and urethral wall thickness (mode 2), and increasing distal urethral thickening (mode 11) were associated with a higher likelihood of having severe SUI. Meanwhile, increased distal urethral pinching (mode 5) and more exaggerated bending of the ends of the urethra towards the pubic symphysis to make a more pronounced "c" shape (mode 7) were associated with an increased likelihood of being continent.

CONCLUDING MESSAGE

Endovaginal dynamic anterior compartment ultrasound can visualize and allow for quantification of the mechanisms involved in urinary continence. This imaging modality and subsequent analyses could provide improved understanding of female SUI and guide future treatment planning.

FIGURE 1

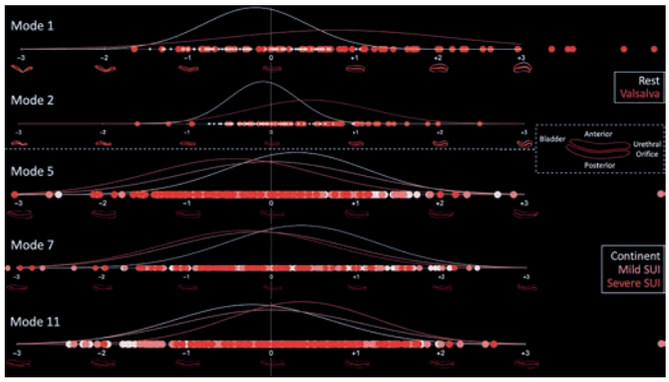

Figure 1: Urethral shape variation visualized within ±3 standard deviations of the mean shape (at 0) for modes 1, 2, 5, 7, and 11. Points represent where individual shapes lie along each mode and normal curves portray subgroup distributions.

FIGURE 2

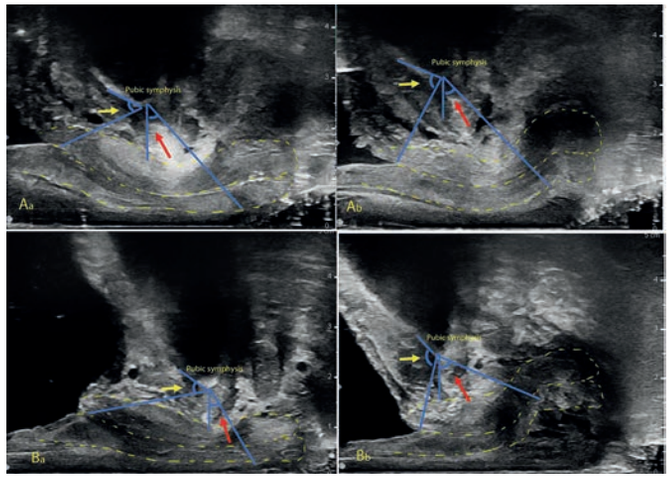

Figure 2: The anterior compartment Aa) at rest and Ab) Valsalva in urinary continent and Ba) at rest and Bb) Valsalva in incontinent subjects. Urethras (outlined) and bladder neck retropubic (yellow) and distal urethra swing (red) angles are indicated.

Funding NSF GRFP Grant #1747452 **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Review Board committee at NorthShore University HealthSystem **Helsinki** Yes **Informed Consent** Yes

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HOW DO LOCAL MULTI-DISCIPLINARY TEAM MEETINGS IMPACT OUTCOMES FOR PATIENTS CONSIDERING INVASIVE TREATMENTS FOR STRESS URINARY INCONTINENCE?

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HYPOTHESIS / AIMS OF STUDY

Traditional single-speciality approaches may no longer be adequate in addressing surgical intervention for women suffering from stress urinary incontinence (SUI). There is paucity of data discussing the effectiveness of multi-disciplinary teams (MDT) in the surgical management of SUI in women since NICE introduced the concept in the 2013 National Guideline in.(1)(2) The aim of this study is to explore the impact of a purpose-designed MDT in the management of SUI in women over the last three years (2017 – 2019).

STUDY DESIGN, MATERIALS AND METHODS

Monthly MDT meetings to discuss women who were considering invasive treatment for stress urinary incontinence, overactive bladder or primary prolapse, have been held a university hospital and a local District General Hospital during the study period. These meetings were attended by

gynaecologists, urologists, continence nurses, physiotherapists, urodynamicists and administrative staff.

At the meetings, each patient's condition was discussed in details, looking at presenting symptoms, medical history, concerns, personal choice of treatment, urodynamics diagnosis and proposed treatment plan amongst the multidisciplinary team. This provides a focus of patient-centred care, ensuring each patient receives the highest standard of management for complex conditions that lack evidence of gold standard approaches.

All patient data was collected and anonymised. Age, parity, BMI, primary diagnosis, urodynamics, symptom questionnaires, patient preference and referring consultant preference was analysed alongside the final recommendations from the MDT. The purpose of the study is to assess the impact of the local MDT on patient management including any changes to proposed treatment plans or further involvement with other allied health professionals. SPSS Statistics (version 23) was used to analyse the data.

RESULTS

123 women had their conditions discussed by the MDT. The average age was 54.5 (range 35 – 85 years), the median parity was 2 (range:0 -7) and the mean BMI was 30.8 (range: 21 – 49). No underweight women presented with symptoms during the study period.

The highest incidence of incontinence appears to be within the age range of 49 – 53 years, reflecting the time of menopause and consistent with other studies. The parity also reflects that childbirth was common in our population.Only 2 patients never had children.

Table 1 shows the frequency of patient and MDT choice of the 4 main SUI procedures for 102 out of 123 responses. The most favoured procedure was colposuspension (60.8%) followed by Bulking Agent Injection (28.4%) followed by Autologous Fascial Sling (10.8%). No patient has chosen the mesh tape surgery.

The MDT choice was available for 96 out of 123 patients (78%). MDT choices followed a similar pattern with colposuspension being the favoured procedure (46.9%) closely followed by Bulking Agent Injection (37.5%) and lastly the Autologous Fascial Sling procedure (8.3%). MDT has recommended no surgical intervention in 7 women (7.3%) and, instead, advised further investigation or further conservative treatment. Despite the availability of mesh tape procedures in a nearby hospital, the MDT did not recommend such surgery in any patient.

In 19 instances (15.4%) the MDT has recommended a course of action that was different from the woman's choice. The MDT has recommended Bulking Agent Injection in 12 instances (63.3%) or continuous conservative treatment or further investigation in 6 instances (31.6%) and,in one occasion, an Autologous Fascial Sling Procedure instead of a Colposuspension procedure because of low urethral pressures.

86 women documented what matters to them in making the choice of SUI procedure. "Cure from leakage" was selected as one of the top 3 values by 83 out of 86 women. While the second most important value was "avoid repeat surgery in the future" with 41 (47.7%) women choosing this value and avoiding mesh complications by 30 women (11.2%). See table 2.

INTERPRETATION OF RESULTS

The MDT significantly changed the management of patients in 19 (15.4%) cases, mostly to a less invasive intervention. This figure is also in keeping with other regional MDT outcomes and suggests that discussion by a group of cross-specialty experts influences the professional choice of treatment.

This is one of the first studies to analyse the impact of a local MDT which is a real strength of this work. It is in keeping with other studies analysing regional MDTs that suggest it is a beneficial exercise for the patients and specialists involved(3).

This study focused on patient choices and the outcomes of MDT discussions prior to surgical treatment. We are currently analysing the clinical outcomes using patient-reported outcome measures following the proposed MDT recommendation of surgical treatment.

MDTs have been in place since 2014, but due to the lack of data recorded, only evidence from 2017-2019 are included. There is a specific proforma for the local MDT and increasingly the data is being recorded to a higher standard without missing information on patient choices and MDT outcomes. This will help strengthen follow up studies in the future.

The age of the patients in this study are in keeping with other reports suggesting that incontinence and prolapse affect women of all ages, but most commonly around or after the menopause.(3)

CONCLUDING MESSAGE

Local Multidisciplinary Team discussions have changed the proposed management for women considering surgery for stress urinary incontinence. Most changes were to a less-invasive intervention. A further study is underway to relate the recommended MDT procedure to the clinical outcome in terms of safety and efficacy.

FIGURE 1

	Patient Choice *frequency*	Patient Choice *Percent*	MDT Choice *frequency*	MDT Choice *Percent*
Colposuspension	62	**60.8**	45	**46.9**
Bulking agent injection	29	**28.4**	36	**37.5**
Autologous Fascial Sling	11	**10.8**	8	**8.3**
No surgery	0	**0**	7	**7.3**
Mesh tape surgery	0	**0**	0	**0**

Table 1- Patient and MDT choices

FIGURE 2

	Frequency	Percentage (%)
Cure from leakage	83	96.5
Avoid repeat surgery in the future	41	47.7
Avoiding mesh complications	30	34.9

Table 2- Most concerning values documented by patients

REFERENCES

1. Anon. Urinary incontinence and pelvic organ prolapse in women: management. NICE guideline NG123. April 2019. https://www.nice.org.uk/guidance/ng123/chapter/Context
2. Pandeva I, Biers S, Pradhan A, Verma V, Slack M, Thiruchelvam N. The impact of pelvic floor multidisciplinary team on patient management: the experience of a tertiary unit. Journal of Multidisciplinary Healthcare 2019; 12(): https://www.dovepress.com/the-impact-of-pelvic-floor-multidisciplinary-team-on-patient-managemen-peer-reviewed-article-JMDH (accessed 08/03/2020).
3. Dieter AA, Wilkins MF, Wu JM. Epidemiological trends and future care needs for pelvic floor disorders.Curr Opin Obstet Gynecol. 2015; 27(5) 380-384

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** No research ethics were required for this project as it is a retrospective study of prospectively collected data. **Helsinki** Yes **Informed Consent** Yes

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ASSESSING THE PREVALENCE OF SPORT-INDUCED URINARY INCONTINENCE AND ITS EMOTIONAL IMPACT ON FEMALE GYMNASTS

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HYPOTHESIS / AIMS OF STUDY

Stress urinary incontinence (SUI) is the involuntary loss of urine due to an increase in intraabdominal pressure or weakening of the pelvic floor muscles. High performing female gymnasts, were thought to experience less SUI because of their athleticism and well-developed pelvic floor and abdominal musculature. Current literature suggests female athletes have higher rates of SUI compared to age and gender matched counterparts [1-3]. SUI in these females negatively affects their quality of life and can be associated with higher rates of depression, anxiety, and low self-esteem [2]. This project seeks to quantify the prevalence of SUI in female gymnasts and its impact on quality of life. We hypothesize there to be a high prevalence of SUI in young female gymnasts compared to nonathletic females.

STUDY DESIGN, MATERIALS AND METHODS

A quantitative approach was used to explore the prevalence of urinary incontinence within the female gymnastics population in the United States through survey methods implemented from October 2018-March 2019. An electronic survey created on Qualtrics was distributed to past and present competitive gymnasts. The survey contained an optional free text section where the athletes could provide anonymous comments (table 1). A similar survey was sent to female medical students to serve as an age and gender-matched control group. Sports practices, SUI frequency and emotional distress associated with SUI were addressed in the survey. The study group received a small incentive for their participation. The medical students were unable to be compensated due to university policy. Data was analyzed in SAS 9.4 (SAS Institute Inc., Cary, NC, USA). Chi-Square analysis was used with a P-value <0.05 indicating statistical significance.

RESULTS

96.50% (n=200) of female gymnasts experienced a urine leak during gymnastics training, 42.86% (n=98) of the control experienced a urine leak in their lifetime ($P < 0.0001$). The median age of SUI onset in the sample group was 13 (Interquartile Range: 10,17). 31.61% (n=193) of the sample group reported SUI nearly every time they practice gymnastics with 90.67% (n=193) reporting to have never leaked outside of gymnastics. 63.21% reported leaking most on spring floor, 50.78% reported balance beam, 51.30% reported tumble track (a 25-meter trampoline track designed for acrobatic practice), 37.82% reported vault and 17.62% reported uneven bars. 46.11% (n=193) reported experiencing the most SUI when they land on the ground after tumbling, and 47.67% (n=193) reported leaking most when front tumbling (rotating their center of gravity forwards over a horizontal axis). 24.87% of gymnasts and 10.00% of the control group were definitely embarrassed/isolated about urine leaks ($P = 0.0003$). 22.80% of gymnasts and no control group members reported their urine leaks as an extreme problem ($P < 0.0001$) (figure 1). 63.21% of gymnasts and 20.00% of the control reported that finding a solution for their incontinence was important to them ($P = < 0.0001$). Unfortunately, response rate from the sample group could not be determined because of how the survey was distributed. Response rate from the control group was roughly 42%.

INTERPRETATION OF RESULTS

A significantly greater proportion of female gymnasts experience more leaks during gymnastics training than the control population experienced in their lifetime. Most gymnasts reported that they leak only during gymnastics training and have never experienced a leak outside of gymnastics. This finding is in support of our hypothesis, that there is a high prevalence of SUI in female gymnastics compared to their age and gender matched counterparts. Female gymnasts reported to have the highest probability of leaking on spring floor, trampoline, vault and balance beam when landing after completing a high-impact tumbling pass. This is thought to be secondary to increased intraabdominal pressure, displacing abdominal and pelvic organs inferiorly putting strain on the pelvic floor architecture.

Female gymnasts are overall more embarrassed and feel greater isolation related to their SUI than the control group. Our data suggests that female gymnasts are less likely to seek care from their physicians regarding their SUI due to embarrassment and associated stigma with SUI. There was a significant difference between gymnasts and control when comparing the emotional impact of SUI, providing testament to the level of concern these young athletes have regarding their condition (table 1). There was a significant difference between gymnasts and the control group about the importance of a solution, where finding a solution for their SUI was more important to the gymnasts compared to the control population. Most gymnasts reported SUI to be a problem (figure 1). This suggests that SUI can impact the quality of life of young female gymnasts.

CONCLUDING MESSAGE

There is an overwhelming prevalence of SUI in young female gymnasts. SUI appears to be more prevalent in the female gymnastics community compared to their age and gender matched counterparts. Most gymnasts reported SUI to be a problem in their lives and a solution is of importance to them. Our survey elicited conversations amongst teammates and has helped raise awareness of the prevalence of SUI in the gymnastics community (table 1).

FIGURE 1

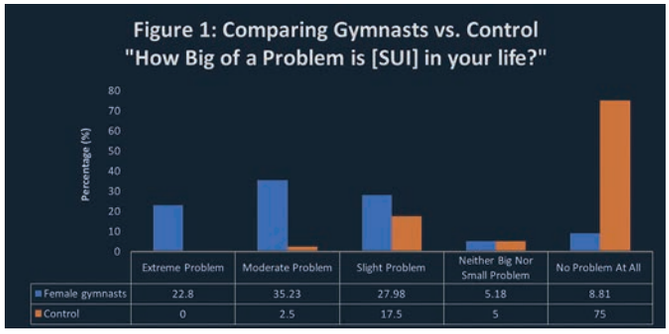

Figure 1: Comparing Impact of SUI on Gymnasts vs. Control

FIGURE 2

Table 1: Free Text Comments

Comments from Female Gymnasts	Comments from Control
"I started playing a video game with my vagina from France. In 2 weeks, the leaking quit. I wish talking about incontinence and leaks and how to actually control your muscles and strengthen your pelvic floor was common knowledge, rather than hidden"	"I had leaking issues when I was younger (17-18) but it only happened during that time frame and doesn't affect me now. During this time, I did change from mild activity to high activity; not sure if the two changes are related though."
"I still leak even after stopping gymnastics."	"Not really an issue for me"
"Please let me know if there is any way [we] could solve this problem! Thank you."	"Some association with menstrual cycle"
"If there is anything [that] would reduce leaking, that would be great. I could never forget the first time I had it. So embarrassed."	
"It bothered me a lot when I was a teenager. If there is anything I could do to stop it, please let me know. I really appreciate it!"	
"I drank a lot of water, so I would have to pee often, resulting in leakage on circumstance where there's an action of pounding."	
"It happened specifically on front tumbling if I landed at a certain angle (usually after front handspring layouts)"	
"Feel not happy with it"	
"Peeing before tumbling helped stop it or sometimes lessen it for me"	

Table 1: Free Text Comments From Gymnasts and Control

REFERENCES

1. Almeida MBA, Barra AA, Saltiel F, Silva-Filho AL, Fonseca AMRM, Figueiredo EM. Urinary incontinence and other pelvic floor dysfunctions in female athletes in Brazil: A cross-sectional study. Scand J Med Sci Sports. 2016;26(9):1109-1116. doi:10.1111/sms.12546
2. Casey EK, Temme K. Pelvic floor muscle function and urinary incontinence in the female athlete. Phys Sportsmed. 2017;45(4):399-407. doi:10.1080/00913847.2017.1372677
3. Bø K. Urinary incontinence, pelvic floor dysfunction, exercise and sport. Sports Med. 2004;34(7):451-464. http://www.ncbi.nlm.nih.gov/pubmed/15233598. Accessed February 5, 2018.

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12 www.ics.org/2020/abstract/12

THE EVOLUTION OF INCONTINENCE INTO RESOLVED, REFRACTORY AND DE-NOVO URGENCY URINARY INCONTINENCE FOLLOWING SLING PLACEMENT AT TIME OF PELVIC ORGAN PROLAPSE REPAIR IN A LARGE URODYNAMIC COHORT (N=139)

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HYPOTHESIS / AIMS OF STUDY

To improve counseling in women at risk of refractory and/or de-novo urgency urinary incontinence (UUI) following sling placement at time of prolapse repair, we created a UUI outcome model to characterize changes in storage dysfunction following surgery.

STUDY DESIGN, MATERIALS AND METHODS

We identified 139 women who underwent urodynamics followed by prolapse repair with or without sling placement at our institution from 2009 to 2015 using Current Procedural Terminology (CPT) codes. Inclusion criteria included the presence of a Pelvic Organ Prolapse Quantification System (POP-Q) stage 2 or greater cystocele and at least 7 days of follow-up. Our primary outcome was the presence of UUI following sling placement at the time of prolapse repair. Patients were classified into either no, de-novo, resolved or refractory urgency urinary incontinence after prolapse surgery, when compared to their preoperative state prior to surgery. Data were analyzed in Statistical Analysis System software (SAS, Cary, NC) using chi-square and Fisher's exact tests (categorical variables), Student t-test (continuous variables), and Kaplan-Meier methods. Tabulated data are presented as mean +/- standard deviation (SD). A p-value less than 0.05 was defined as significant. Kaplan-Meier analysis with the Cox proportional hazard was performed to look at the association between time and the proportion of women free of UUI and stress incontinence at longest follow up after surgery, stratified by sling placement.

RESULTS

139 women (mean age, 62.6 +/- 11.4 years) met inclusion criteria, underwent urodynamics and were included for analysis. Baseline characteristics for sling and no sling group included age (years, 60.4 +/-11.9 vs. 65.6 +/- 10.1, p=0.006), and BMI (27.2 +/- 5.5 vs. 26.8 +/- 5.2, p=0.786). The most common POP-Q prolapse stage was stage 3 (77/139, 55.4%). Baseline POP-Q stage was well matched between the two groups (stage 2, p=0.989; stage 3, p=0.794; stage 4, p=0.408). Preoperative incontinence included (i) subjective, objective and occult stress urinary incontinence (SUI), and (ii) subjective and objective UUI. Subjective SUI was defined as patient report of symptoms such as leaking when coughing or lifting heavy objects. Objective SUI was defined as leakage of urine with valsalva observed during pelvic exam. Occult SUI was defined as absence of subjective incontinence but presence of urine leakage with prolapse reduced on pelvic exam. Subjective UUI was defined as patient report of symptoms such as urinary frequency as a result of strong urge to void or inability to hold before reaching the restroom. Objective UUI was defined as the presence of detrusor overactivity on urodynamics. Subcategories of SUI or UUI were not mutually exclusive. The sling group had a significantly higher subjective SUI [62/81 (76.5%) vs 18/58 (31.0%), p<0.001], objective SUI [62/81 (76.5%) vs. 6/58 (10.3%), p<0.001], and occult SUI [41/81 (56.8%) vs. 29/58 (50.0%), p<0.001) compared to the no sling group. There was no significant different in rates of baseline subjective UUI [46/81 (56.8%) vs. 29/58 (50.0%), p=0.428] and objective UUI [15/81 (18.5%) vs. 9/58 (15.5%), p=0.644]. Preoperative urodynamics (sling vs. no sling) demonstrated statistically significant differences in Pdet@Qmax (cmH2O, 17.6 vs. 24.6, p=0.005), Qmax (mL/s, 19.4 vs. 15.3, p=0.014), PVR (mL, 86.8 vs. 159.4, p=0.025), and bladder outlet obstruction index (BOOI=Pdet@Qmax-2*Qmax, 2.1 vs. 7.9, p=0.002). Otherwise, urodynamic capacity and BCI were similar between sling groups.

Following surgery women were followed for a mean follow-up of 859 days. Post-operatively, rates of subjective SUI, objective SUI, and further surgical treatments for SUI (bulking agent, repeat sling) were not statistically different between the sling groups. In the sling group following surgery, a significantly greater proportion of women had subjective UUI compared to the no sling group [44/81 (54.3%) vs. 19/58 (32.8%), p≤0.001]. Subsequently a highly proportion of women underwent further pharmacologic UUI treatments in the sling group (anticholinergics, beta-3 agonist), although not statistically significant. Additional treatments required for post-operative incomplete bladder emptying were characterized (alpha blocker, any requirement for intermittent catheterization, any requirement for indwelling catheterization, sling incision, and sling excision). There was a similar proportion of these treatments utilized after surgery, with the exception of greater requirement for indwelling catheterization following surgery in the sling group [13/81 (15.0%) vs. 3/58 (5.2%), p=0.048].

Women were stratified by type of UUI after surgery (never UUI, de-novo UUI, resolved UUI, and refractory UUI) with respect to the presence of UUI prior to surgery (Table 1). There was a similar proportion of women who never experienced UUI before or after surgery who underwent sling placement (20/81, 24.7%) when compared to those who did not undergo sling placement (19/58, 33.8%, p=0.341). In those women who underwent sling placement, following surgery they demonstrated de-novo (13/81, 16.0%) and resolved (17/81, 21.0%) UUI at a similar rate compared to those women who did not undergo sling placement [de-novo (6/58, 10.3%, p=0.454), and resolved (19/58, 32.8%, p=0.169) UUI]. Refrac-

tory UUI was demonstrated in a higher proportion of women following sling placement (31/81, 38.3%) compared to those who did not undergo sling placement (14/58, 24.1%, p=0.048).

On Kaplan-Meier analysis, there was no difference in the proportion of women not reporting SUI at the time of longest follow between the sling and no sling groups [HR 0.98 (95% CI 0.43-2.23), p=0.969]. For UUI, there was a trend towards a greater proportion of women not reporting UUI in the no sling group (Figure 1) compared to the sling group however this difference did not achieve statistical significance [HR 0.63 (95% CI 0.37-1.06), p=0.081].

INTERPRETATION OF RESULTS

Rates of de-novo and resolved UUI following prolapse repair did not differ regardless of concurrent sling placement at time of prolapse surgery. Refractory UUI was demonstrated in a higher proportion of women following sling placement compared to those who did not undergo sling placement.

CONCLUDING MESSAGE

Patients should be counseled on the risk of refractory UUI following sling placement.

FIGURE 1

Table 1. UUI classification following pelvic organ prolapse surgery				
		Sling placement		
	Overall (n=139)	Yes (n=81)	No (n=58)	p-value
Never UUI	39 (28.1%)	20 (24.7%)	19 (33.8%)	0.341
De-novo UUI	19 (13.7%)	13 (16.0%)	6 (10.3%)	0.454
Resolved UUI	36 (25.9%)	17 (21.0%)	19 (32.8%)	0.169
Refractory UUI	45 (32.3%)	31 (38.3%)	14 (24.1%)	**0.048**

Table 1. UUI classification following pelvic organ prolapse surgery

FIGURE 2

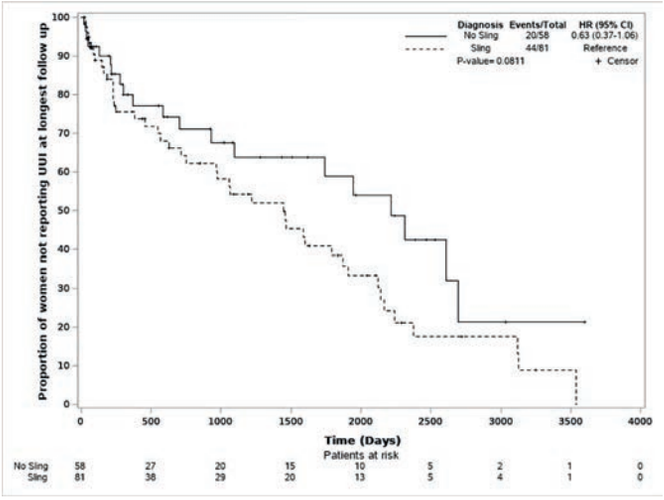

Figure 1. Kaplan-Meier curve for sling (dotted line) versus no sling (solid line) groups showing the proportion of women not reporting UUI at longest follow up

Funding NIH 1L30DK115056-01 **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional IRB Protocol # 35034 **Helsinki** Yes **Informed Consent** No

13 www.ics.org/2020/abstract/13

PROSPECTIVE RANDOMISED CONTROLLED STUDY COMPARING THE EFFECTS OF TVT AND TOT IN WOMEN OVER 75 YEARS WITH STRESS OR STRESS PREDOMINANT URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

The primary objective of this study was to evaluate the subjective and objective SUI cure rates. Secondary outcomes included effect on QoL and other urinary symptoms and late adverse events.

STUDY DESIGN, MATERIALS AND METHODS

This is a single-centre prospective randomised study on women over 75 years who underwent mid-urethral sling [TVT (1) or 'out-in' TOT (2)] for stress urinary incontinence (SUI) or stress predominant mixed urinary incontinence (MUI). All patients had undergone pelvic floor muscle training without success.

Exclusion criteria were: previous POP or SUI surgery; previous radical pelvic surgery; comorbidities such as diabetes or neurological disease; pelvic organ prolapse (POP) stage 2 or greater.

All patients underwent a standardised pre-op work-up comprising: urogynecological history; pelvic examination using the POP-Q classification; standardised cough stress test (CST); a conventional urodynamic study (UDS) according to ICS criteria.

SUI was defined according to ICS standardisation and classified according to the Ingelmann-Sundberg scale. Urinary symptoms were evaluated using the standardised questionnaire UDI-6. The King's Health Questionnaire (KHQ) was used to evaluate QoL. Surgery was performed by the same expert surgeon.

Follow-up visits were scheduled for one month, six months, one year, then annually using the preoperative protocol, with the exception of urodynamic testing. Patients also completed the Patient Global Impression of Improvement (PGI-I) scale. We report results at 24 months.

The follow-up examinations and interviews were performed by urologists who were not involved in the surgical phase of the study.

The severity of complications was classified using both the ICS/IUGA classification of mesh complications and the modified Clavien–Dindo classification.

Objective cure for SUI was defined as the absence of urine leakage during CST. Subjective cure was defined by a 'no-answer' to question 3 of the UDI-6 questionnaire.

We considered PGI-I scores to indicate satisfaction when patients reported either 'very much better' or 'much better' (score of ≤ 2).

Institutional Review Board Committees approved this study. All participants gave informed consent.

A preliminary power analysis indicated that a sample size of 20 patients per group at P <.05 would have 80% power to reject the null hypothesis that TVT and TOT are not equivalent. Power calculation was performed using PS: Power and Sample Size ver.3.0, 2009 (http://pspower-and-sample-size-calculation.

software.informer.com/). The Mann-Whitney and Wilcoxon tests for unpaired and paired data, respectively, were used to compare ordinal and nonnormally distributed continuous variables. Categorical data were analyzed by the McNemar, chi-square, or Fisher exact test. Two-tailed P <.05 was considered

significant. All calculations were performed with IBM SPSS, version 22.0.

RESULTS

From September 2017 to December 2019, 47 consecutive women aged over 75 with SUI or prevalent stress MUI were enrolled. Four out of the 47 patients were not included: 3 did not meet all inclusion criteria and 1 refused to give consent. Forty-three patients were included in the analysis (Figure 1). Among these, 21 patients underwent TVT and the other 22 underwent 'out-in' TOT. The mean age of our sample was 77.67+2.82; median parity was 2; mean BMI was 27.54+3.10.

No intra-operative complications occurred.

Pre and post-operative symptoms are reported in Table 1.

At 24 months follow-up, the objective cure rate was 76.7% (85.7% in TVT group and 68,2% in TOT group).

The subjective cure rate was 83.7% (90.5% in TVT group and 81.8% in TOT group).

We had de novo UUI in 1 patient of TOT group and de novo dry OAB in 8 patients (18.6%) of which 5 in TVT group and 3 in TOT group. No case of de novo voiding symptoms was observed. Mesh extrusion was observed only in 1 patient (TVT group), who was treated with local therapy for three weeks with a complete resolution. QoL was significantly improved in all domains in both groups.

PGI-I scores showed patient satisfaction in 90.5% in TVT group (19 patients) and 90.9% in TOT group (20 patients). The other 2 patients in each group reported an improvement of 'a little better'. No patients reported 'no change' or worse

INTERPRETATION OF RESULTS

SUI cure rates were satisfactory and were superior in the TVT group. Correction of UUI in both groups was good.

We had a high number of de novo dry OAB: 2 of these had no pre-op OAB symptoms and the other 6 had pre-op wet OAB. As OAB symptoms are more common at advanced age, we hypothesise that their continuation in these 6 patients is attributable to their age. This indicates that MUS is a good solution for treating incontinence in women over 75 but is less effective in resolving their OAB symptoms.

CONCLUDING MESSAGE

This study demonstrates that both MUS procedures are safe and efficient choices for stress-incontinent women over 75. Even if objective results are less good than those in literature for younger women, patient satisfaction is comparable, perhaps because older women have less active lifestyles or lower expectations from their surgery.

FIGURE 1

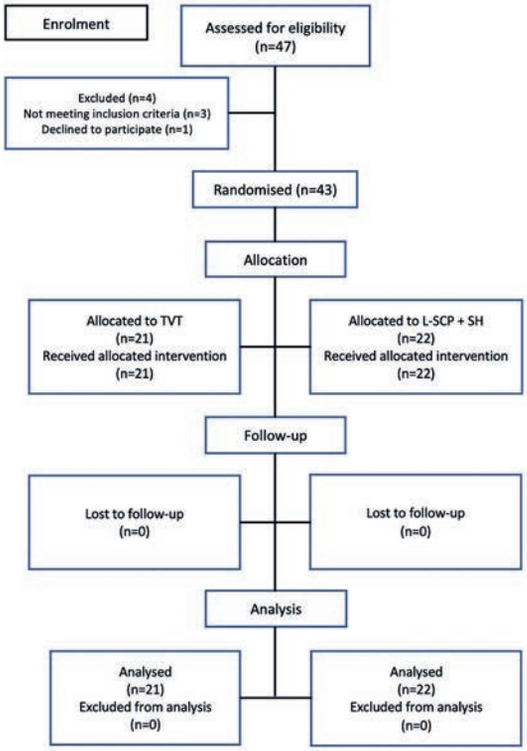

Figure 1 – CONSORT statement

FIGURE 2

	Group 1 (TVT) N° 21			Group 2 (TOT) N° 22		
N° (%)	Pre-op	Post-op	p*	Pre-op	Post-op	p*
Objective SUI	21 (100)	3 (14.3)	0.000	22 (100)	7 (31.8)	0.001
UUI	14 (66.6)	3 (14.3)	0.013	14 (63.6)	5 (22.7)	0.003
Dry OAB	2 (9.5)	8 (38.1)	0.073	4 (18.2)	5 (22.7)	0.386
Voiding symptoms	2 (9.5)	2 (9.5)	0.479	1 (5.5)	2 (9.1)	0.503

Table 1- Pre and post-operative symptoms in both groups

REFERENCES

1. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 1996;7(2):81-5; discussion 85-6. PubMed PMID: 8798092.
2. Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol. 2001 Dec;11(6):1306-13. French. PubMed PMID: 11859672.

Funding No source of funding or grant **Clinical Trial** Yes **Public Registry** No **RCT** Yes **Subjects** Human **Ethics Committee** Local Committee 2489 **Helsinki** Yes **Informed Consent** Yes

14 www.ics.org/2020/abstract/14

CONTASURE-NEEDLELESS SINGLE INCISION SLINGS VERSUS TRANSOBTURATOR SLINGS (TOT/TVT-O) FOR FEMALE PATIENTS WITH STRESS URINARY INCONTINENCE: A SYSTEMATIC REVIEW AND META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

To assess the current evidence on the effectiveness and safety of Contasure-Needleless (C-NDL) versus transobturator (TOT/TVT-O) slings in the management of female stress urinary incontinence (SUI).

STUDY DESIGN, MATERIALS AND METHODS

A comprehensive literature review of articles that investigated the efficacy and safety of C-NDL and TOT/TVT-O was performed based on studies published before June 2019 and retrieved from PubMed, Embase, CNKI and the Cochrane Library. Two reviewers searched the literature, independently extracted the data and evaluated the quality of the data according to the inclusion and exclusion criteria. A meta-analysis was performed by using Review Manager 5.3 software.

RESULTS

Nine studies with 1349 SUI female patients were included. Our meta-analysis showed that C-NDL has a noninferior clinical efficacy compared with TOT/TVT-O with respect to the subjective cure rate [OR = 0.81, 95% confidence interval (CI) (0.58 to 1.14), p =0.23] and objective cure rate [OR = 0.82, 95% CI (0.57 to 1.17), p = 0.27]. In addition, C-NDL is associated with an obviously shorter operative time [mean difference (MD) = -6.94, 95% CI (-10.66 to -3.22), p = 0.0003]. In terms of the postoperative visual analogue scale (VAS) and the incidence of postoperative pain, C-NDL has a greater advantage [MD = -1.71, 95% CI (-2.91 to -0.50), p = 0.005]; [OR = 0.21, 95% CI (0.05 to 0.96), p = 0.04]. There was no statistically significant difference in the rate of complications found between the two groups except for that of groin pain.

INTERPRETATION OF RESULTS

The most important indicators for evaluating efficacy are the subjective and objective cure rates. The tension provided by the tape support plays a significant role in the efficacy and is associated with the cure rate and necessity of re-surgery. Some SIMS procedures have been performed in clinical practice to evaluate the efficacy. The meta-analysis compared the TVT-Secure, Mini-Arc and Ophira together with standard midurethral slings, and the result showed an inferior cure rate for these SIMSs. An animal trial reported that with the highest surface area to counteract extraction, the anchor of C-NDL has the highest mean immediate extraction forces compared with those of other SIMSs. Relative to other SIMSs,

the C-NDL has a greater contact area and is more similar to the standard sling, which ensures sufficient firmness. Based on our meta-analysis, no significant differences were found in the comparison of subjective and objective cure rates. In addition, the incidence of repeated SUI surgery was not obviously different between the C-NDL and TOT/TVT-O groups. Apart from the investigation of Bakay et al., the follow-up time of the other included studies is longer than 12 months. Therefore, the results also confirmed that the tension of C-NDL is not inferior to that of TOT/TVT-O and that the mid-term efficacy of C-NDL is reliable. Until now, due to the short period of C-NDL use, the long-term efficacy still needs more high quality RCTs to verify.

Our meta-analysis showed that the patients who underwent C-NDL had a shorter operation time, which confirmed the previously published outcome. In addition, the pooled results showed that patients receiving C-NDL presented improved postoperative pain and postoperative VAS scores. In particular, groin pain greatly improved. These results are consistent with those of Kim's study, which reports that SIMSs are superior with respect to immediate postoperative pain. The difference may be explained by the surgical procedure. Similar to other SIMSs, the C-NDL is inserted through a single vaginal incision and blindly avoids the retropubic space and obturator foramen. The pain occurrence is related to the fact that there is no incision in the groin area, the sling does not reach the groin, and there is no foreign body sensation. The surgical routine also decreased the risk of blood vessel and nerve injury, which was in line with our present analysis. In Baya's study with a three-year follow-up, there were no cases of groin pain, and only one patient had a mild haematoma. In addition to the cure rate, postoperative pain also plays an important role in patient satisfaction. In a study by Schellart et al., patients with SUI were willing to accept a relatively lower cure rate with a less invasive procedure in order to avoid postoperative pain. Therefore, with a high efficacy and less pain, it seems that C-NDL is a better choice to manage SUI in patients.

With respect to the hospital stay, a previous meta-analysis showed that SIMSs involve a shorter hospitalization time than that for transobturator slings. However, our results showed no significant differences in hospital stay between the two groups. According to our clinical experiences, the hospital stay might be associated with the patients' baseline basic characteristics and with hospital conditions, which are affected by human factors. In addition, the inpatient stay was arranged for 1 to 2 days, which also indicates that C-NDL yields a faster recovery rate, which indicates enhanced recovery after surgery.

CONCLUDING MESSAGE

Our data suggest that C-NDL is an effective method for treating female SUI. Compared to TOT/TVT-O, C-NDL is associated with a shorter operative time, and the incidence of postoperative pain is obviously decreased. In addition, both methods have proven to be safe. Nevertheless, these findings should be further confirmed through large-volume, well-designed prospective randomized controlled trials (RCTs) with extensive follow-up.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It is a meta-analysis, Not Available. **Helsinki** Yes **Informed Consent** Yes

15 www.ics.org/2020/abstract/15

TRANSOBTURATOR FASCIAL SLING(TOFS) VERSUS TRANSOBTURATOR TAPE(TOT) IN RECURRENT FEMALE STRESS URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

Recurrent incontinence is one of the most disastrous complications of continence surgery. Midurethral slings are commonely used nowadays for female stress urinary incontinence .Recurrenct incontinence ,Tape erosion and sometimes infection l still a big problem with these techniques . Fascial Sling is another good option in such like cases especially in sever incontinence.However fixation of fascial sling is more invasive and needes more dissection ,so we replaced the mid part of the tape (around the urethra)by rectus fascia or fascia lata and connect it on both sides by polpropyline tape to pass through obturator foramen like TOT.we compared this technique with the standard TOT. In this study we evaluated efficacy, safety and long term results of transobturator fascial sling and Trans obturator tape in recurrent female stress urinary incontinence.

STUDY DESIGN, MATERIALS AND METHODS

From jan. 2010 till April 2015, 71 female patients with recurrent SUI were evaluated. After counselling all patients about surgery and signing written consent, They were randomly divided into 2 groups :Group 1(G1) 34 patients underwent (TOFS)using either rectus fascia or fascia lata patch one by two centimeters connected on both sides by polypropylene tape . and Group 2 (G2) 37 patients underwent Transobturator Tape (TOT) .

Operative time, intra and postoperative complications using (Clavien grading system), duration of catheterization and Hospital stay as well as success rate of surgery were recorded.

All patients were evaluated by history, physical examination, urine culture, pelviabdominal ultrasound, and urodynam-

ics. International Consultation of Incontinence Questionnaire-Short Form (ICIQ-SF), and female sexual function index (FSFI) questionnaire (Arabic versions were applied for all patients . patients were followed for 3years.3 patients did not complete the follow up period ,2 from G1 and 1 From G2.

RESULTS

Both groups were matched at baseline for mean age (33.41±12.36 and 34.95±11.63 years group 1 and 2 respectively), comorbidity profile, (ICIQ-SF) , and (FSFI) questionnaire . Operative time, intra-operative bleeding were significantly lower in) G2 (24.08 ± 4.06 versus 43.94 ± 7.7 minutes , (p <0.001) as regard time and 0.3±0.4 versus 1.1±0.2 as regard HB drop, (p <0.001). No significant difference could be detected as regard catheterization period and hospital stay with range 1-2 and 1-3 days for both (P >0.05). Significant improvement in ICIQ-SF occurred in both groups (from15.1±3.6 to1.6 ±5.5), in G1 and (15.9±1.2 to 8.5±5.7)in G2 (p <0.001). Success rate defined as cure and improvement was 93% (30 patients) in GA, 64% (23 patients) in GB. In Patients with valsalva leak point pressure less than 60cm H2O (9 cases in GA and &6 in GB) only one in GA failed while no improvement recorded in G2(p <0.001). .Vaginal erosion occurred in 2 cases and urethral erosion in 1 case in G2 within the 1st year follow up. (p <0.001). 91% of sexually active women in G1 achieved significant improvement in their sexual FSFI ,while only 50% in G2. Four cases of recurrence occurred in G2 after 1 year while no recurrence occurred in G1all over three years follow up.

INTERPRETATION OF RESULTS

Vaginal and urethral erosion occured with TOT technique while not in TOFS ,at the same time there is significant difference in success rate in favor of TOFS.

CONCLUDING MESSAGE

Transobturator Fascial Sling is more effective and safe than TOT in recurrent female stress incontinence with good long term data especially in severe cases.

Funding NONE **Clinical Trial** No **Subjects** Human **Ethics Committee** BENHA FACULTY OF MEDICINE **Informed Consent** Yes

16 www.ics.org/2020/abstract/16

HOW THE PAUSE ON SYNTHETIC TAPE INSERTION FOR THE TREATMENT OF STRESS URINARY INCONTINENCE HAS AFFECTED SURGICAL PRACTICE IN ONE UK CENTRE

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HYPOTHESIS / AIMS OF STUDY

In July 2018 a pause was placed on synthetic mesh tape insertion in the UK as a treatment option for patients with stress incontinence. The aim of this study was to assess how stress urinary incontinence (SUI) procedures had changed since the ban and how satisfied patients were with the outcomes.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective case note review was conducted. All cases undergoing surgery 18 months before July 2018 and 18 months after were recorded. Information on baseline demographics, surgery undertaken, post-operative complications and requirement for further surgery were collected using Excel. All surgical procedures during the time periods were included. Patients whom this was not their primary surgery for SUI were also included.

RESULTS

Thirty operations were conducted in each 18-month period. Patient demographics including age, type of incontinence and conservative treatments were matched (table 1).

In the pre-ban group 29 patients underwent urodynamics, this failed to demonstrate SUI in six cases. In the post-ban group 27 patients had urodynamics, SUI was not demonstrated in eight cases. Seven patients in the pre-ban group had already undergone a surgical procedure for SUI and eight in the post ban group, these ranged from intra-urethral bulking agent, tension-free vaginal tape (TVT) and colposuspension.

In the pre-ban group 12 patients underwent TVT, 16 had intra-urethral bulking agent, one patient had an autologous sling and one colposuspension. Post ban 29 patients underwent intra-urethral bulking agent and one patient had an artificial urinary sphincter (AUS).

Minimal surgical complications occurred. Pre-ban, two TVT patients had an intra-operative bladder perforation of which re-positioning was performed and they had no further complications. There were no other intra-operative complications with other procedures. 30 day complications included two TVT patients who were treated for UTI and one intra-urethral bulking patient had urinary retention in the pre-ban group. In the post ban group, the patient with

whom the AUS placed had an intra-operative urethral perforation, she had no other post-operative complications. 30 day complications in the post-ban group receiving intra-urethral bulking agent identified four patients who went into retention and one patient had a myocardial infarction, which was not found to be related to the surgery. One patient in the pre-ban group was lost to follow up and one did not attend follow up compared to two patients lost to follow up in the post-ban group.

Success in achieving dryness was higher in the pre-ban group; 47% (14/30) patients were dry and happy with the outcome compared to only 27% (8/30) patients in the post ban group. Of the patients that remained incontinent in the pre-ban group five were still happy with the outcome, two of these patients had undergone a TVT and three intra-urethral injections. In the post-ban group 57% (17/30) patients were unsatisfied with the outcome and requested further treatment. A number of patients who were not satisfied with the response after initial surgery in both groups are awaiting or have undergone further procedures (table 2).

INTERPRETATION OF RESULTS

Since the pause on synthetic tape insertion in July 2018 we have performed the same number of SUI surgeries. Immediate and 30 day complications were minimal in both groups. During the follow up of patients who had a TVT none had a mesh erosion. Post ban more patients opted for the minimally invasive option of intra-urethral injections however a higher number of patients were unsatisfied with the results, and are awaiting decision on more invasive surgical options. 30 day complications in the intra-urethral bulking agent patients was higher when compared to TVTs.

CONCLUDING MESSAGE

The pause on synthetic mesh insertion has caused more patients to have a sub-optimal procedure, and a higher number of patients unsatisfied with the outcome. More patients are considering major intervention to treat their incontinence, which have additional risks.

FIGURE 1

	Pre-ban (n=30)	Post-ban (n=30)
Mean age years (range)	54 (28-88)	55 (19-83)
Incontinence type (n):		
• Stress	12	11
• mixed	18	19
Number patients with daily incontinent episodes	26	27
Conservative treatments (n)		
• Pelvic floor	27	19
• Duloxetine	3	2
• OAB treatment	17	21

Table 1: Patient demographics

FIGURE 2

	Management of patients unsatisfied with outcome	
Initial operation	Pre-ban (n=7)	Post-ban (n=17)
TVT	AUS: 1 awaited	n/a
Intra-urethral bulking	Repeat injections: 1 Sling: 1 AUS: 1 Decision awaited: 2 Catheter: 1	Repeat injections: 6 Sling: 2 Decision awaited: 4 Catheter: 2 OAB treatment: 3

Table 2: Further management of patients who were unhappy with initial surgery

Funding No funding required **Clinical Trial** No **Subjects** None **Ethics not Req'd** Not required

17 www.ics.org/2020/abstract/17

VOIDING DYSFUNCTION AND SURGICAL OUTCOME AFTER REVISION OF TENSION FREE VAGINAL TAPE-TRANSOBTURATOR SURGERY OVER 10-YEAR OF EXPERIENCE

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HYPOTHESIS / AIMS OF STUDY

Tension free vaginal tape-transobturator route (TVT-O) is one of the most common and effective treatment of stress urinary incontinence worldwide. Voiding dysfunction is one of the recognized complications from all types of mid-urethral sling surgery. There were different methods described on management of voiding dysfunction. There was lack of standardized treatment and limited evidence showing which methods being the most appropriate.1 We have adopted the method of early mobilization and revision of tape tension. Yet, there were concerns of reducing the effectiveness of TVT-O. This study investigated the outcome of women receiving early tape revision due to voiding dysfunction after TVT-O surgery.

STUDY DESIGN, MATERIALS AND METHODS

This is a retrospective analysis of a prospectively collected database of all the women undergoing TVT-O for urinary stress incontinence in a territory urogynaecology university hospital from 2010-2019. Their demographics data and pre-operative urinary symptoms results were collected in a standard consultation form. All women received an urodynamic study including uroflowmetry and pressure-flow cystometrogram before proceeding to TVT-O. TVT-O could be performed concomitantly with pelvic floor repair surgery. Operative records and post-operative symptoms were all collected. Voiding dysfunction such as incomplete bladder emptying, intermittent stream or straining to void, on the post-operative 1-3 days, if any, were reviewed and their oper-

ative records of revision of tape were reviewed. Subsequent urinary symptoms were documented. Outpatient follow-up were arranged firstly at 8 weeks, then one and two years after the surgery, to review their surgical outcome including the subjective outcome classified as "same, improved, or worse" were documented. Ethics approval was obtained. Statistical analysis was done by SPSS version 22.

RESULTS

A total of 680 women underwent TVT-O surgery. Twenty-four (3.5%) of them were found to have voiding dysfunction shortly after surgery and were managed by early tape mobilization. Their mean age was 63.0 ± 11.1 years, with median parity of 3.0 (1.3, 4.0) and mean body mass index 23.9±3.0 kg/m2. They underwent revision of tape tension at a median post-operative day 2.5 (2.0, 6.8), ranging from post-operative day 1 to 21 days. All the revisions were performed under local anaesthesia at bedside. The mean operative time or revision was 14.6 ± 5.5 minutes with mean estimated blood loss of 7.3±4.0 ml. Among them, 22 (91.7%) of them resumed normal voiding without significant retention of urine on the day or within 1-3 days after the revision. Two women required suprapubic catherization (SPC) for further bladder training. One SPC was performed on the day of tape tension revision and one was performed at 10 days after tape tension revision. Both of them can achieve normal voiding at 3 weeks after SPC insertion.

All of them attended the follow-up with a mean follow-up duration of 124.1 ± 108.7 weeks. Two (8.3%) complained of occasional minimal stress urinary incontinence. Due to mild symptoms, no medical or surgical treatment were required. There was no recurrence of stress urinary incontinence in others (91.7%). All of them were satisfied with the surgical outcome and graded outcome as "improved" after operation. Five (20.8%) women had urge urinary incontinence, with only one (4.2%) of them being de novo in nature after TVT-O. No medical nor surgical treatment were needed. There was no voiding difficulty or pain upon follow-up.

INTERPRETATION OF RESULTS

The chance of success of resuming normal voiding after early mobilization and revision of tape tension was similar to other studies1. This study showed that early mobilization and revision of tape tension can help to resume normal voiding for women suffering from voiding dysfunction after TVT-O while minimal recurrence of symptoms of stress urinary incontinence and presence of de novo urge urinary incontinence were found at intermediate term of follow-up. Longer follow-up would be helpful to review if any recurrence of urinary symptoms.

CONCLUDING MESSAGE

Early mobilization and revision of tape tension is an effective treatment option for women suffering from voiding dysfunction and early detection of voiding dysfunction post-operatively is required for early intervention.

REFERENCES

1. Management of post-midurethral sling voiding dysfunction. International Urogynecological Assocation research and development committee opinion. Int Urogynecol J. 2018 Jan;29(1):23-28.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** e The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research **Ethics Committee Helsinki** Yes **Informed Consent** Yes

18 www.ics.org/2020/abstract/18

THE IMPACT OF MID-URETHRAL SLING SURGERY ON FEMALE SEXUAL FUNCTION IN STRESS URINARY INCONTINENCE PATIENTS: A SYSTEMATIC REVIEW AND META-ANALYSIS OF PROSPECTIVE RANDOMIZED AND NON-RANDOMIZED STUDIES

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HYPOTHESIS / AIMS OF STUDY

Though mid-urethral sling (MUS) surgeries are recommend as the gold standard therapy of stress urinary incontinence (SUI), the impact of MUS operations on female sexual function remains controversial. Consequently, we sought to provide high-quality evidence around the impact of MUS treatments on sexual function for female patients with SUI.

STUDY DESIGN, MATERIALS AND METHODS

A systematic search of PubMed, EMBASE, and the Cochrane Library was conducted to identify studies which assessed the impact of MUS treatments on sexual function in sexually active women with SUI. The MUS techniques including retropubic tension-free vaginal tape (TVT), transobturator tension-free vaginal tape (outside-in, TOT; inside-out, TVT-O) and single-incision mini-sling (SIMS). All studies included were prospective randomized or non-randomized trials which assessed patients with two validated questionnaires i.e., the Female Sexual Function Index (FSFI) and the Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ-12)[1, 2]. Pre- and postoperative data pertaining to sexual functions were extracted. Comparable data were meta-analyzed using Review Manager 5.3 software.

RESULTS

Of the 24 studies identified, 17 utilized FSFI and seven adopted PISQ-12 to assess sexual functions. Of the 2188 patients involved, 50.55% (n = 1106) underwent transobturator approach MUS (i.e., TOT, TVT-O and Monarc), 28.06% (n = 614) retropubic route MUS (i.e., TVT), and 9.87% (n = 216) SIMS (i.e., Ajust®, MiniArc® and TVT Secur System®), while the remaining 11.52% (n = 252) were reported without clearly defined techniques and were therefore broadly categorized as 'other MUS'.

Pooled analysis indicates that 6-month postoperative PISQ-12 total scores were significantly higher than preoperative scores (Weighted mean difference (WMD) -3.31 points, 95% confidence interval (CI) -5.32 to -1.30, p=0.001; Fig.1A). Additionally, similar results were found at the 12-month juncture (WMD -3.30 points, 95% CI -6.01 to -0.58, p=0.02; Fig.1B) and 24-month follow-up point (WMD -4.44 points, 95% CI -5.45 to -3.44, p<0.00001; Fig.1C). Unfortunately, follow-up data from 4 to 15 years were insufficient for meta-analysis of the longer term effects. Although, findings do suggest that women's postoperative sexual functioning is at least not inferior to preoperative sexual functions.

Consistently, pooled postoperative FSFI total scores were significantly higher than preoperative scores at 6-months (WMD -2.22 points, 95% CI -3.36 to -1.08, p=0.00001; Fig.2A) and 12-months (WMD -3.49 points, 95% CI -5.96 to -1.02, p=0.006; Fig.2B). Postoperative FSFI sub-scores at 6-months and 12-months suggest that desire, arousal, orgasm, lubrication, satisfaction and pain during sexual intercourse were also significantly higher than baseline scores (all p<0.05).

INTERPRETATION OF RESULTS

To the best of our knowledge, both the PISQ-12 and FSFI are internationally validated questionnaires and are recommended by the International Continence Society to assess sexual functions. Findings from this meta-analysis add to the evidence base demonstrating that sexually active women with SUI can experience an improved sex life after MUS treatment. The primary reason for this improvement may be the absence of incontinence and decreased negative emotional responses during intercourse[3]. Critically speaking, even though the PISQ-12 or FSFI are validated and can provide insight into sexual functioning, these questionnaires are subjective measures which may not have the capacity to explore the nuances of personal experience or concept of self. Therefore, these findings also suggest there may be a need for more unstructured qualitative research to explore the complexity of personal perceptions involved sexual desirability and comfort during, and after intercourse.

CONCLUDING MESSAGE

MUS treatments appear to improve sexual function for women with SUI. However, these findings should be further confirmed through well-designed prospective randomized controlled trial with larger samples and it may prove worthwhile intercalating more qualitative research into personal perceptions of stigma related to SUI and sexual performance.

FIGURE 1

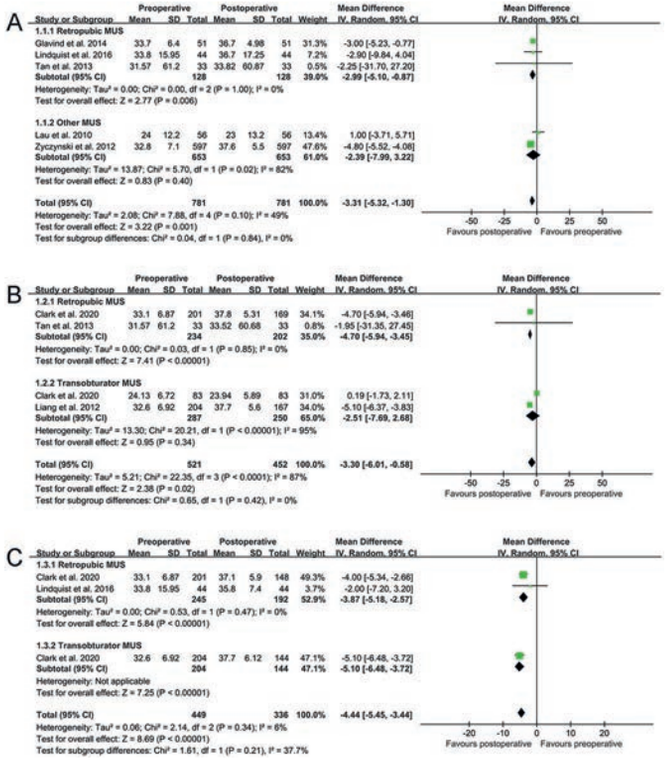

Figure 1. Impact of MUS surgeries on sexual function assessed using PISQ-12: (A) meta-analysis of pre- and postoperative scores at 6 months, (B) 12 months, and (C) 24 months.

FIGURE 2

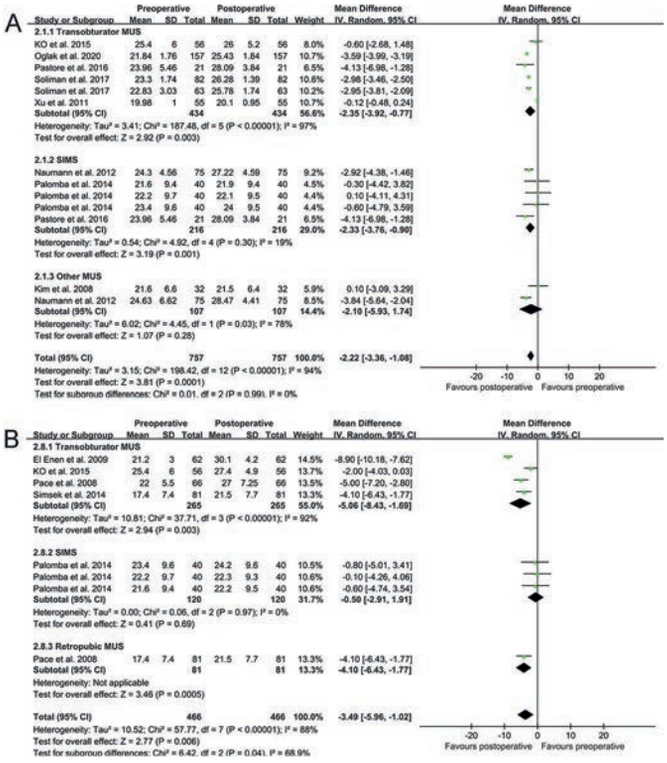

Figure 2. Impact of MUS surgeries on sexual function assessed using FSFI: (A) meta-analysis of the pre- and postoperative scores at 6 months, and (B) 12 months.

REFERENCES

1. Rosen R, Brown C, Heiman J, et al. The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. J Sex Marital Ther. 2000. 26(2): 191-208.
2. Rogers RG, Coates KW, Kammerer-Doak D, Khalsa S, Qualls C. A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Int Urogynecol J Pelvic Floor Dysfunct. 2003. 14(3): 164-8; discussion 168.
3. Glavind K, Larsen T, Lindquist AS. Sexual function in women before and after tension-free vaginal tape operation for stress urinary incontinence. Acta Obstet Gynecol Scand. 2014. 93(10): 986-90.

Funding National Key R&D Program of China **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This study was a systematic review and meta-analysis.All data were carefully extracted from existing literature, and this article did not involve handling of individual patient data. In addition, all of the included studies mentioned the Approval of Institutional Review Board. **Helsinki** Yes **Informed Consent** No

SESSION 3 (PODIUM SHORT ORAL) - CONSERVATIVE MANAGEMENT
Abstracts 19-30

09:00 - 10:30, Brasilia 1

Chairs: Dr Melanie Morin (Canada), Ms Tamara Dickinson (United States)

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EXAMINING THE ROLE OF THE PHYSIOTHERAPIST IN TREATMENT RESPONSE OF WOMEN WITH PROVOKED VESTIBULODYNIA

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HYPOTHESIS / AIMS OF STUDY

Vulvodynia or chronic vulvar pain is a highly prevalent and debilitating condition affecting up to 16% of women and provoked vestibulodynia (PVD) is the most common subtype. Physiotherapy (PT) is recognized as a first-line treatment for PVD and is effective for reducing pain and improving sexual function. It has been shown in different fields of medicine that the therapist himself, beyond the treatment provided, plays a significant role in treatment efficacy [1-2]. For instance, in psychology, the relationship with the patient, including support given by the therapist, is a predominant factor in treatment response [1]. In surgical treatments, it was shown that the surgeon's experience influences treatment success [2]. However, no studies thus far have investigated the role of the physiotherapist in PT treatment response in women with PVD. Given that PT requires both interpersonal and technical skills, it could be hypothesized that both the physiotherapist's support and experience will affect treatment response. This is the first study to evaluate the moderating role of the physiotherapist by investigating the associations between (1) the physiotherapist's support, as perceived by the patient during treatment and (2) the physiotherapist's experience, and the improvement in pain and sexual function in women with PVD.

STUDY DESIGN, MATERIALS AND METHODS

This study is embedded in a randomized clinical trial treating women with PVD with either pelvic floor physical therapy or topical lidocaine. Data of the 105 women allocated to the physical therapy group were considered in the analyses.

Women were included in the study after having their diagnosis of PVD confirmed by one of our collaborating gynecologists following a standardized protocol. They had to report a mean pain intensity of ≥5 (at the numerical scale from 0 to 10), for at least 90% of sexual intercourse attempts and for a ≥6 month duration.

PT treatment response was assessed at baseline, post-treatment and at 6-months follow-up by an assessor blinded to group assignation using the following validated and recommended outcomes [3]: pain intensity during intercourse (numerical rating scale 0-10), pain quality (McGill Pain Questionnaire) and sexual function (Female Sexual Function Index).

The physiotherapist's support as perceived by the patient during treatment was assessed with the Interpersonal Behavior Scale-short form (IBS-SF). The questionnaire total score, ranging from 10 to 70, was calculated to assess behaviors pertaining to relatedness (or sense of care), competence and autonomy support with higher score being associated with higher support.

The physiotherapist's clinical experience was assessed for each professional at the time they were conducting the treatment of each participant. It was calculated as the total number of days worked per week was converted into years of experience as a general physiotherapist, pelvic floor physiotherapist, and pelvic pain physiotherapist, by considering the number of working days after deducting weekends, holidays and work leave.

Multilevel modeling analyses were used to assess the moderating effect of physiotherapist's experience and support on changes from baseline to post-treatment and from baseline to 6-months follow-up. Data was analyzed using the software SPSS® 25.0 (Statistical Package for the Social Sciences, IBM) and significance level considered $p<0.05$.

RESULTS

Of 105 patients enrolled in the study, 99 completed post treatment and 94 returned for the 6-months follow-up. A total of 15 female physiotherapists were involved in treatments. As for the physiotherapist's support as perceived by the patients, the average score was 6.2 (±0.8 SD; range 3.3 to 7.0). The physiotherapist's support perceived by the patient was associated with greater improvements in pain quality (B -4.924; SE 1.890; 95%CI -8.675; -1.175) and sexual function (B 1.749; SE 0.838; 95%CI 0.081; 3.416) from baseline to post-treatment. The moderating role of the physiotherapist's support was not significant for changes in pain intensity and for all three outcomes at 6-month follow-up ($p>0.05$). Physiotherapists had an averaged total experience of 5.2 years (±3.9 SD) of which 2.6 years (2.4 SD) of experience was specifically on treating pelvic floor muscles and 0.9 years (±1.2 SD) on treating pelvic pain. Results showed that the physiotherapist's experience (general or specific to pelvic floor/pelvic pain) was not associated with treatment response outcomes ($p>0.05$).

INTERPRETATION OF RESULTS

This study presents original data regarding the role of the physiotherapist in PT treatment response in women with pain. Our results showed that higher physiotherapist' support was associated with greater improvement of pain quality and sexual function from baseline to post-treatment. Our findings emphasize the importance of the supportive behaviors from the physiotherapist to enhance patient's response to PT during the active phase of treatment. These significant outcomes were however not sustained at 6-month follow-up which could be anticipated given that the interrupted contact with the physiotherapist during this period.

In regards to clinical experience, our results showed a non-significant moderating effect on treatment response. However, it is important to highlight that the present study was carried out in a clinical research trial setting where the physiotherapists received an intensive training in order to provide standardized treatment.

CONCLUDING MESSAGE

Findings of this study reveal that the physiotherapist's support as perceived by the patient was identified as an important factor related to improvement in pain quality and sexual function immediately after treatment in women with PVD. In the context of our randomized controlled trial where the physiotherapists are following a standardized protocol and are highly trained in pelvic floor rehabilitation, the physiotherapist's clinical experience was not related to treatment response. Future clinical research and practitioners should focus on the quality of the support given to patients with PVD in order to improve the effectiveness of their intervention.

REFERENCES

1. Anderson, T., et al., A prospective study of therapist facilitative interpersonal skills as a predictor of treatment outcome. J Consult Clin Psychol, 2016. 84(1): p. 57-66.
2. Cahill, P.J., et al., The effect of surgeon experience on outcomes of surgery for adolescent idiopathic scoliosis. J Bone Joint Surg Am, 2014. 96(16): p. 1333-9.
3. Pukall, C.F., et al., Recommendations for Self-Report Outcome Measures in Vulvodynia Clinical Trials. Clin J Pain, 2017. 33(8): p. 756-765.

Funding Canadian Institutes of Heath Research **Clinical Trial** Yes **Registration Number** NCT01455350 **RCT** Yes **Subjects** Human **Ethics Committee** RESEARCH ETHICS OF CENTRE HOSPITALIER UNIVERSITAIRE DE SHERBROOKE AND INSTITUT UNIVERSITAIRE DE MONTRÉAL **Helsinki** Yes **Informed Consent** Yes

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IMPACT OF THE INNOVATIVE PELVIC FLOOR MUSCLE TRAINING ON THE QUALITY ADJUSTED LIFE YEARS (QALYS) IN WOMEN WITH STRESS URINARY INCONTINENCE TREATED BY DULOXETINE

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HYPOTHESIS / AIMS OF STUDY

The stress urinary incontinence (SUI) is one of the most common dysfunctions of the lower urinary tract, which affects a women's quality of life. Measuring a women's quality of life is very important to assess women's perception of health. This is based on the interaction of physical, psychological, social, functional, emotional factors, mental well-being, as well as the status of work, environmental quality, vitality, pain, fear, and depression. The aim of this study was to measure the impact of the innovative pelvic floor muscle training (iPFMT) on the Quality Adjusted Life Years (QALYs) in women with stress urinary incontinence (SUI) treated by duloxetine.

STUDY DESIGN, MATERIALS AND METHODS

This analysis is a part of the study conducted between February 2019 and 2020. The clinical trial was a randomized intervention, parallel, multicentre study at urological outpatient clinics at the national level for 12 weeks. Women were assigned in a 1:1 ratio to the experimental and control groups, using simple randomization according to odd and even numbers assigned sequentially to the patients at each clinic. An estimated 63 women were required for each group.

Inclusion criteria: woman over 18 years old who provided written informed consent; experienced uncomplicated SUI; experienced symptoms of urinary incontinence for at least three consecutive months immediately prior to the study; scored 14 points or more on ICIQ-UI-SF; experienced at least seven urinary incontinence episodes per week; exhibited a degree of pelvic organ prolapse equal to stage 2 or less; expressed willingness to accept the randomization process and fully participate in tests.

Exclusion criteria: a woman who is pregnant, lactating or actively trying to become pregnant; use of any pharmacologic agent to treat symptoms of urinary incontinence in the past 6 months; the history of anti-incontinence surgery in the past 12 months; use of onabotulinumtoxinA for the treatment of urinary incontinence in the past 12 months; the history of pelvic prolapse repair or urethral surgery in the past 12 months; the history of PFMT in the past 12 months; the history of interstitial cystitis or bladder-related pain; the history of chronic severe constipation; the history of clinically significant renal or hepatic impairment; the history of clinically significant heart impairment; non-compliance with limitation of duloxetine treatment for mixed urinary incontinence; current positive urinary tract infection; use of rehabilitation aids; use of antidepressant(s); insufficient understanding of iPFMT and/or omitting iPFMT; participation in any clinical study in the past 6 months.

The control group received oral duloxetine treatment (40 mg BID), the experimental group received oral duloxetine treatment (40 mg BID) and iPFMT with lumbopelvic stabilization. The iPFMT was performed 5 times a week for 20–30 minutes a day, in cooperation with a physiotherapist.

The SUI was analyzed during a baseline and a final period according to the International Consultation on Incontinence Questionnaire - Urinary Incontinence - Short Form (ICIQ-UI-SF) with the range from 0 (without SUI) to 21 (the most severe SUI) (1). The calculation of the weighting factor (WF) was done by a linear transformation of the ICIQ-UI-SF (WF = 1 – ICIQ-UI-SF score/21). The QALYs gained were calculated by multiplying life expectancy (LE) by a weighting factor (QALYs = LE * WF). Statistical non-parametric tests were used for statistical analyses at a significance level of 0.05 using the IBM SPSS Statistics for Mac, version 25.0 (IBM Corp., Armonk, N.Y., USA).

RESULTS

The study included 158 women, of whom 129 women (81.6%) were fully analyzed in the control group (n = 64) and experimental group (n = 65). All women were Caucasians with a mean age of 55.2±13.0 years (range 29-80 years), body mass index of 27.6±4.9 kg/m2. The mean life expectancy for the control group was 26.3±11.8 years and for the experimental group 29.0±11.7 years. The mean baseline ICIQ-UI-SF score was in control vs an experimental group of 15.2±1.7 vs 15.1±1.5 and final ICIQ-UI-SF score of 9.8±4.2 vs 8.3±3.8 ($p<0.05$). The mean baseline weighting factor was in control vs an experimental group of 0.27±0.08 vs 0.28±0.07 and a final weighting factor of 0.53±0.20 vs 0.60±0.18 ($p<0.05$). Following 12 weeks of treatment, incremental QALYs in the control vs experimental group had increased as follows: 0.12±0.04 vs 0.14±0.04 ($p<0.05$). The mean baseline QALYs gained per year in control vs experimental group was 0.27±0.08 vs 0.28±0.07 and final QALYs 0.53±0.20 vs 0.60±0.18 ($p<0.05$). Before the treatment, the number of QALYs gained per life expectancy in control vs experimental group was 7.53±4.24 vs 8.30±4.01. The number of QALYs gained per life expectancy in control vs experimental group had increased following treatment: 15.03±9.63 vs 17.90±9.86 ($p<0.05$). The number of QALYs gained per life expectancy was increased in con-

trol vs experimental group by 99.7±71.1% vs 127.0±95.2% (p<0.05). The stress urinary incontinence evaluated with the ICIQ-UI-SF was decreased in control vs experimental group by 37.0±22.3% vs 45.0±23.3% (p<0.05).

INTERPRETATION OF RESULTS
The ICIQ-UI-SF confirmed statistically significant differences between women receiving duloxetine and women receiving combination treatment with duloxetine and iPFMT. The number of QALYs gained was approximately 100% higher following duloxetine treatment, but combined duloxetine with iPFMT achieved 30% more.

CONCLUDING MESSAGE
The combination treatment of duloxetine with iPFMT statistically significantly increased the number of QALYs and reduced the degree of urinary incontinence in women with stress urinary incontinence.

REFERENCES
1. Neurourol Urodyn. 2004;23:322–30

Funding NONE **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov as NCT04140253 **RCT** Yes **Subjects** Human **Ethics Committee** The **Ethics Committee** at University Hospital, Martin, Slovak Republic **Helsinki** Yes **Informed Consent** Yes

21 www.ics.org/2020/abstract/21

IS THE EXTENT OF IMPROVEMENT IN PELVIC FLOOR MUSCLE FUNCTION ACHIEVED THROUGH PELVIC FLOOR MUSCLE TRAINING ASSOCIATED WITH IMPROVEMENTS IN STRESS URINARY INCONTINENCE SYMPTOMS?

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HYPOTHESIS / AIMS OF STUDY
While there is strong evidence for pelvic floor muscle (PFM) training (PFMT) as an intervention for women with stress urinary incontinence (SUI) (1) the mechanisms through which PFM exercise is effective at reducing the signs and symptoms of SUI in women are not known (2). The aims of this study were to determine (i) if any, aspects of PFM function, measured through manual assessment, are associated with the severity of SUI in women and (ii) whether improvements in certain aspects of PFM function are associated with improvements in SUI signs or symptoms. We hypothesized that PFM strength, power and endurance would be negatively associated with SUI severity and that improvements in these parameters would be correlated with reductions in symptoms.

STUDY DESIGN, MATERIALS AND METHODS
This secondary analysis of data was planned apriori within a prospective interventional cohort study that included females with SUI who underwent a 12-week PFMT program. Females with symptoms of SUI were recruited from surgical wait lists for mid-urethral sling insertion and from new referrals to participating, local pelvic floor physiotherapists. Before the intervention period, SUI symptom severity was determined subjectively through the International Consultation on Incontinence Questionnaire -Female Lower Urinary Tract Symptoms Urinary Incontinence subscale score (ICIQ-FLUTS-UI) which participants completed at home. Both SUI severity, measured objectively using a standardized 30-minute pad test (30MPT), and PFM function were measured at a laboratory session conducted by an experienced (>5 years) pelvic floor physiotherapist.

The 30MPT was conducted once bladder volume was between 300 and 500mL as confirmed through transabdominal ultrasound imaging. Participants donned a pre-weighed incontinence pad and performed a standardized circuit of activities over 30 minutes, after which the pad was removed and reweighed.

PFM function was evaluated through vaginal palpation using the PERFECT scheme, which is a clinical assessment approach used to guide intervention around specific impairments identified during assessment (3). The overall PERFECT scheme score was computed, and the first four items of the PERFECT scheme were also considered separately: Performance(P) was quantified using the Modified Oxford Scale (MOS; range 0-5) as a measure of PFM force generated through maximal voluntary contraction (MVC); Endurance(E) was the time in seconds (up to 10) that the MVC force could be held before it was deemed (through palpation) to have reduced by half or more; repetitions(R) was the number of times (up to 10) that the MVC force could be achieved and held for the duration of the endurance time (determined under E); and Fast contractions(F) was the number of times the MVC force (determined under P) could be repeatedly achieved at one-second intervals. These four items can be interpreted in light of PFM function as described by the International Continence Society (ICS) (2): P=MVC force, E=local static muscle endurance at MVC, R=capacity for dynamic repetition of local static muscle endurance at MVC, and F=a combination of power and motor control.

After the baseline assessment, women underwent a 12-week physiotherapist-supervised PFMT intervention. They attended six sessions through which they learned to perform a proper PFM contraction (manual and biofeedback) and learned PFM exercises and functional PFM contractions ("The Knack"). Women were instructed to complete a series

of prescribed PFM exercises daily. The ICIQ-FLUTS questionnaire, the 30MPT and the PERFECT scheme assessments were repeated after the intervention period.

To detect a significant moderate correlation (r=0.6) between changes in aspects of PFM function and signs and symptoms of SUI, a required sample size of n=20 was estimated using G*Power software. Changes in the individual aspects of PFM function and in SUI severity were determined through separate paired t-tests, while associations among aspects of PFM function and SUI severity at baseline, and associations among changes in aspects of PFM function and SUI severity were evaluated using Spearman's rho (α=0.05).

RESULTS

Baseline data from 98 females with SUI were available from the main study, from which follow-up data were available from 75 females who completed the PFM intervention program and returned for follow-up assessment; all data were retained to maximize study power. The mean age was 50 (±10) years, mean body mass index was 28.36 (±7.32) kg/m2) and the vast majority (96.5%) of participants were parous. Because aspects of PFM function measured using the PERFECT scheme may be constrained by minimum and maximum scores, the frequency distributions of all PERFECT scheme outcomes were inspected to ensure that floor or ceiling effects were not evident; all data were normally distributed.

At baseline, there was a significant positive correlation (ρs=0.203, p=0.045, n=98) between urine leakage on the 30MPT and the number of repetitions of the local PFM static endurance contraction (R) women could perform, while there were no significant associations between ICIQ-FLUTS UI and any measured aspect of PFM function (Table 1). All aspects of PFM function improved significantly over the intervention period, as did subjective and objective measures of SUI severity, as shown in Table 2. There were no associations between Improvements in subjective (ICIQ-FLUTS UI) nor objective (30MPT) measures of SUI severity and improvements in the overall PERFECT score nor the individual aspects of PFM function (P,E,R or F). Indeed, while correlation coefficients were low, in some instances the Spearman's correlation coefficients were counter to what was expected. For example, greater improvements in PFM MVC measured by the Modified Oxford Scale (ρs=0.234, p=0.045, n=75) and greater capacity to repeat PFM MVCs (ρs=0.229, p=0.049, n=75) were associated with smaller improvements on the 30MPT after the intervention. Similarly, greater gains in capacity to repeat PFM static endurance contractions were associated with less improvement on the FLUTS-UI subscale score (ρs=0.289, p=0.012, n=75).

INTERPRETATION OF RESULTS

Consistent with the literature (1), all measured aspects of PFM function assessed through the PERFECT scheme were improved after a 12-week PFMT intervention, and women's symptoms (ICIQ-FLUTS-UI) and signs (30MPT) of SUI concurrently improved. Yet the severity of women's signs and symptoms of SUI were not associated with impairments in any aspect of their PFM function measured by the PERFECT scheme. Further the extent of improvements in PFM function (PERFECT overall or P,E,R,F0 were not associated with improvements in women's signs and symptoms of SUI.

These results suggest that improvements in SUI derived from PFMT may be largely through mechanisms other than improvements in PFM strength or endurance, such as changes to levator ani muscle morphology or tissue mechanics, co-ordinated recruitment of the PFMs with the urethral sphincters, or improved urethral sphincter function. Because manual palpation of PFM strength is discrete and subjective, it is possible that associations between PFM function and SUI severity do exist, but that the PERFECT scheme is not sensitive enough to detect them.

CONCLUDING MESSAGE

The importance of the PFMT in the treatment and prevention of female SUI is already well established in the literature. Yet the results of this study suggest that there is a need for greater understanding of the role of the PFMs in SUI and the mechanisms through which PFMT is an effective intervention. Further study with more sensitive measures of PFM mechanics and function, such as those obtained through intravaginal dynamometry, and measures of PFM motor control, such as those obtained through electromyography, are required to more fully evaluate these relationships.

FIGURE 1

Table 1: Spearman's correlation coefficients (ρ_s) between aspects of pelvic floor muscle function measured by the PERFECT Scheme and the severity of signs and symptoms of Stress Urinary Incontinence evaluated at baseline (n=98).

Baseline	30MPT		ICIQ-FLUTS-UI	
	ρ_s	p	ρ_s	p
PERFECT score (overall)	0.196	0.053	-0.003	0.973
PERFECT scheme subscales				
Performance (MVC - MOS) (score; 0-5)	-0.027	0.790	-0.079	0.449
Endurance (Static local muscle endurance) (time; 0-30s)	0.125	0.219	-0.013	0.898
Repetitions (Static/dynamic local muscle endurance) (n; 0-10)	**0.203***	**0.045**	0.074	0.478
Fast contractions (Power/motor control) (n; 0-10)	0.193	0.057	0.116	0.264

*Spearman correlation is significant at α= 0.05; 30MPT: 30-minute pad test; ICIQ FLUTS-UI: International Consultation on Incontinence Questionnaire - Female Lower Urinary Tract Symptoms Urinary incontinence subscale; MVC: maximal voluntary contraction; MOS: Modified Oxford Scale.

FIGURE 2

Table 2: Measures of pelvic floor muscle function measured by the PERFECT scheme and signs and symptoms of stress urinary incontinence measured before and after the pelvic floor muscle training intervention

Variables	Baseline (n=98) mean±sd	Follow up (n=75) mean±sd	Paired differences	Effect size (Cohen's d)	P- value
PERFECT Scheme score (units. range 0 to 35)	14.83 (31)	22.52 ±6.44	7.69	1.31	0.00
PERFECT Scheme subscales					
Performance (MOS units, range 0 to 5)	3.37 (4)	4.28 ± 0.83	0.91	1.04	0.00
Endurance (time, range 0 to 10s)	4.10 (9)	6.63 ±2.44	2.53	1.05	0.00
Repetitions (units, range 0 to 10)	3.54 (9)	5.44 ±2.18	1.90	0.96	0.00
Fast contractions (units, range 0 to 10)	3.79 (9)	6.25 ±2.36	2.46	1.14	0.00
ICIQ FLUTS (UI subscale) (units 0 to 20)	9.86 (17)	6.77 ±3.93	-3.09	0.82	0.00
30MPT (g)	20.17 (74.32)	11.12 ±19.03	-9.05	0.46	0.00

Caption: sd: standard deviation; ICIQ FLUTS UI: International Consultation on Incontinence Questionnaire - Female Lower Urinary Tract Symptoms urinary incontinence subscale score; 30MPT: 30- minute pad test; MOS: Modified Oxford Scale.

REFERENCES

1. Dumoulin, C., Cacciari, L. P., & Hay-Smith, E. J. C. (2018). Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database of Systematic Reviews.
2. Bo, K., Frawley, H. C., Haylen, B. T., et al. (2016). An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. Neurourology and Urodynamics, 36(2), 221–244. doi:10.1002/nau.23107
3. Laycock, J., & Jerwood, D. (2001). Pelvic Floor Muscle Assessment: The PERFECT Scheme. Physiotherapy, 87(12), 631–642. doi:10.1016/s0031-9406(05)61108-x

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22 www.ics.org/2020/abstract/22

FACTORS INFLUENCING NONCOMPLIANCE WITH PELVIC FLOOR MUSCLE EXERCISES IN THE MANAGEMENT OF URINARY INCONTINENCE FOLLOWING ROBOTIC-ASSISTED LAPAROSCOPIC PROSTATECTOMY

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence is common after robotic-assisted laparoscopic prostatectomy (RALP). Post-prostatectomy incontinence (PPI) rates vary considerably in the literature and can be as high as 80% depending on the definition of continence and timing of evaluation [1]. Pelvic floor muscle exercises (PFMEs) represent the most commonly employed non-invasive management strategy for PPI [2]. However, studies provide inconsistent findings regarding its efficacy. Noncompliance has been postulated to be one of the possible reasons that can decrease the success rate of PFMEs in enhancing recovery of continence following RALP. Our objective was to identify barriers to PFME compliance in patients with PPI.

STUDY DESIGN, MATERIALS AND METHODS

The sample included 28 men diagnosed with localized prostate cancer and elected to undergo RALP between August 2019 and December 2019. The setting for this quality improvement study was a University Hospital-based clinic in the US. Patients with end-stage renal disease, urinary diversion, or those who were visually or cognitively impaired were excluded from the study.

At the one-week post-RALP visit, the nurse practitioner (NP), who had more than 10 years of experience in the field of Urology, removed the indwelling Foley catheter and provided patients with verbal instruction and illustration of three PFMEs. Patients were then asked to do 10 repetitions each exercise 3 times daily at home. Those who exercised exactly as advised were considered as being compliant and those who did not as noncompliant.

During the one-month visit following catheter removal, the barriers influencing PFME compliance were evaluated by the same NP via administration of the 10-item PFME Barrier Questionnaire, which was created based on the data gathered out of the relevant literature and the input accumulated throughout the years from the patients who were advised to do PFMEs after RALP.

Content validity of the questionnaire was obtained by review of experts in the field of lower urinary tract dysfunction including urologists, physical therapists, and urology nurses. The questionnaire was solely composed of yes-no questions and did not take longer than 5 minutes to complete. None of the patients had asked for supervision or help from a healthcare provider while answering the questions.

RESULTS

The barriers to PFME compliance, which were identified based on the responses given to the questionnaire items, have been summarized in Figure 1. A total of 10 patients (35.7%) responded that "body soreness" was the reason for noncompliance in performing PFMEs. Seven patients (25%) indicated that the fear of "damaging the site of surgery" was the reason as to why they did not do the exercises as instructed. In contrast, no patients responded "yes" to the possible barriers of "being too busy" or "urinary leakage".

Regarding the distribution of barriers with respect to the frequency of PFMEs (Figure 2); only 4 patients (14.3%) exercised 3 times a day exactly as instructed. These patients were not devoid of postoperative problems, with "body soreness" being the most commonly reported one. However, they were able to overcome these potential barriers and comply with the recommendations.

Four other patients (14.3%) reported performing PFMEs 4 or 5 times a day. Among these patients; "body soreness" and the fear of "damaging the site of surgery" seemed to be equally contributing to PFME noncompliance.

One fourth of the patients reported less than 2 PFME sessions per day. "Body soreness" and loss of the educative brochure were the leading reasons for PFME noncompliance within this subgroup.

The largest group of noncompliant patients (n= 13, 46.5%) repeated PFMEs twice daily and they specified "body soreness" (n= 4, 14.3%) and the fear of "damaging the site of surgery" (n= 3, 10.7%) as the main barriers to PFME compliance.

INTERPRETATION OF RESULTS

Pain and perceived possible damage to the surgical site were the main barriers to PFME compliance in 35.7% and 25% of the patients with PPI, respectively. Only 14% of the patients repeated the PFMEs exactly as instructed. Pain was the most prevalent barrier across all PFME daily frequency subgroups. Thus, identification and better management of the factors contributing to postoperative pain is crucial in promoting compliance with PFME.

Nurses play an essential role in this respect, as they are actively involved in the postoperative counselling of these patients regarding pain prevention and treatment strategies [3]. Moreover, the input they provide to the patients regarding relevant anatomical landmarks and what to expect in the surgical site while doing PFMEs would possibly further motivate the patient towards compliant behavior.

CONCLUDING MESSAGE

Pain and perceived possible damage to the surgical site are the main reasons underlying PFME noncompliance in patients with urinary incontinence following RALP. Optimizing postoperative pain management and relaying information regarding possible surgical site changes that can be encountered while training the pelvic floor (in addition to routine exercise descriptions) might potentially improve compliance with PFMEs.

FIGURE 1

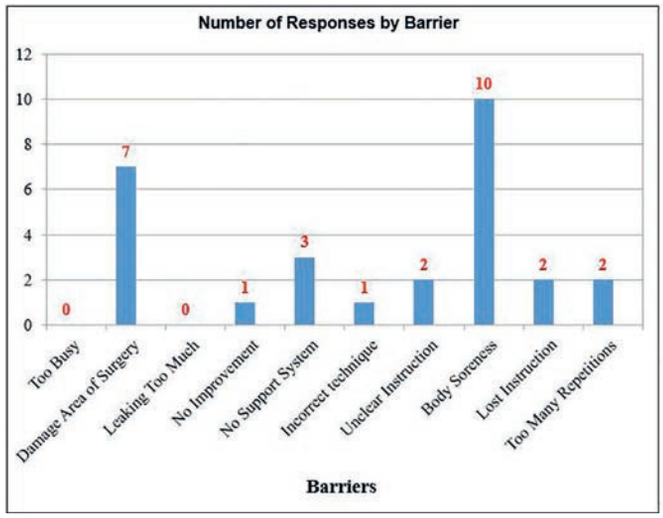

Figure 1. Barriers to compliance with PFME

FIGURE 2

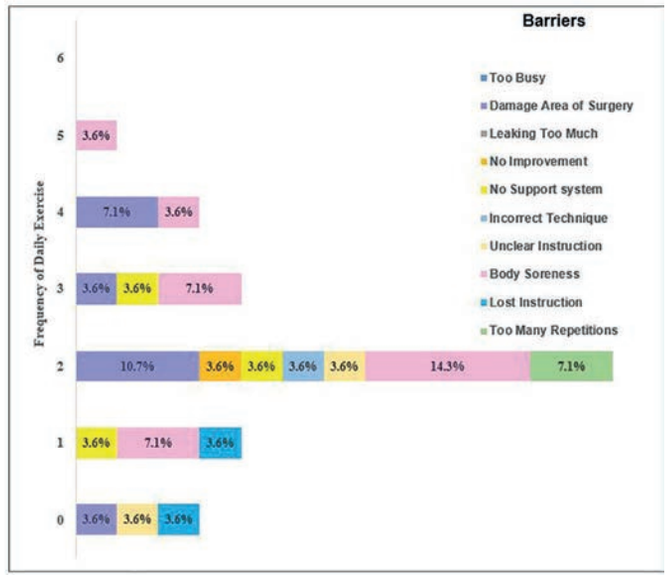

Figure 2. Distribution of barriers with respect to the daily frequency of PFME. The number in each colored bar represents the percentage of patients (out of the whole group) reporting that barrier.

REFERENCES

1. Borello-France, D., Burgio, K., Goode, P., Markland, A., Kenton, K., Balasubramanyam, A., & Stoddard, A. (2010). Urinary incontinence treatment network, adherence to behavioral interventions for urge incontinence when combined with drug therapy: adherence rates, barriers, and predictors. Physical Therapy, 90 (10), 1493–1505. https://doi-org.proxy.cc.uic.edu/10.2522/ptj.20080387
2. Campbell, S.E., Glazener C., Hunter, K.F., Cody, J.D., & Moore, N. (2012). Conservative management for postprostatectomy urinary incontinence. Cochrane

Database Systemic Review, 1: CD001843. doi: 10.1002/14651858.CD001843.pub4.
3. Ene, K. W., Nordberg, G., Sjöström, B., & Bergh, I. (2008). Prediction of postoperative pain after radical prostatectomy. BMC Nursing, 7 (14), 7-14. Retrieved from https://doi.org/10.1186/1472-6955-7-14.

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23 www.ics.org/2020/abstract/23

THE EFFECT OF SUPERVISED PELVIC FLOOR MUSCLE TRAINING ON PELVIC FLOOR MUSCLE FUNCTION FOR THE PATIENTS WITH URINARY INCONTINENCE AFTER ROBOT-ASSISTED LAPAROSCOPIC RADICAL PROSTATECTEMY - A RANDOMISED CONTROLLED TRIAL-

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HYPOTHESIS / AIMS OF STUDY

Cancer is considered as the leading cause of death and the single most important factor in threatening life expectancy in the twenty-first century. The estimated incidence of prostate cancer 1,276,106 (7.1%) in 2018 in the world [1]. Also, prostate cancer is the second most commonly diagnosed cancer and the leading cause of cancer death in males. Robot-assisted laparoscopic radical prostatectomy (RARP) may result in better early continence outcomes when compared to other approaches, including open and laparoscopic radical prostatectomy. The incontinence rates at 3, 12, 24-36 months after RARP were approximately 78, 84 and 88% with continence defined as 0 pads use daily, respectively. Pelvic floor muscle training (PFMT) for urinary incontinence (UI) occurred after prostatectomy was recommended as Grade B. The previous studies conducting PFMT for patients with radical prostatectomy assessed 24-hour pad weight or UI-specific quality of life (QOL) questionnaires as main outcome. However, there are no randomized controlled studies (RCT) that assessed pelvic floor muscle (PFM) function quantitatively. The purpose of this study was to investigate the effect of supervised PFMT on PFM function for male patients with UI after RARP.

STUDY DESIGN, MATERIALS AND METHODS

The current study was designed as assessor-blinded two-armed RCT. The supervised PFMT group was compared with control group. The participants who were scheduled RARP in our hospital were recruited in the current study from February 2017 to May 2019. Inclusion criteria was more than 1 month before RARP to perform preoperative PFMT. Exclusion criteria were serious psychiatric, neurological diseases or lower urinary tract infection. The study was approved by the Ethics Committee in our institution. All participants were given written informed consent before entering the current study. Power calculation was based on the former study conducted 24-hour pad weight at 3 months after radical prostatectomy as primary endpoint [2]. The sample size was set at 27 participants per group to provide a power of 80% and a significance level of 5% for detecting the difference between groups. A final sample size was set at 30, which considered 3 participants as dropouts in each group. We randomly assigned men to receive either supervised PFMT or control group. The participants were evaluated by the following outcomes. The primary endpoint was conducted 24-hour pad weight (g) at 3 months after RARP. Other outcomes were PFM function including resting anorectal pressure, maximum anorectical squeeze pressure, duration, and Expanded Prostate Cancer Index Composite as QOL questionnaire. With regard to PFM function, a manometer with anal sensor (PeritronTM cat 9300A; Laborie, Canada) was used for quantitative PFM assessment. All participants were lying on the bed in a lateral position with knees drawn up at 45° and a pillow placed under the head. An assessor gave standardized instructions to "squeeze and lift or tighten and pull up the PFM as hard as you can" for maximum contraction of the PFM. We defined the PFM function as the percentage changes in resting anorectal pressure, maximum anorectal squeeze pressure equal that the value at each time point divided by the preoperative value, multiplied by 100. These outcomes were assessed before RARP, 7days, 1, 3, 6, 12 months after RARP. In supervised PFMT group, the participants were delivered one-to-one PFMT guidance, which performed three times preoperatively, and at 7 days, 1, 3, 6, 12 months after RARP. They received verbal information about pelvic floor anatomy and function using an anatomical male pelvic model. They were taught isolated contraction of PFM without contracting the other muscles, including the outer abdominal muscles, muscles of the hip joint with verbal instruction and palpation of PFM. Home-based PFMT was performed throughout the current study. In control group, the participants were instructed and given booklets about PFMT and lifestyle advice verbally, as daily care in our hospital. Statistical analysis was performed using SPSS version 23.0. Data distribution was assessed with the Shapiro-Wilk test for continuous variables. For between group comparisons, we used the two-sample t test with normally distributed data, and the Mann–Whitney U test with not normally distributed data. The significance level was set at $p<0.05$.

RESULTS

A total of 50 participants scheduled RARP were completed in the current study (supervised PFMT group: 24 men, control group: 26 men). The characteristics of included participants, such as age, body mass index, serum prostate specific anti-

gen, console time, nerve preservation, estimated blood loss, prostate size, pathologic T stage, smoking history, grison score were not significant differences between supervised PFMT and control group. Forty-eight of the 50 participants (96.0%) who underwent RARP had UI at 7 days after surgery. 24-hour pad weight in supervised PFMT group was significantly lower than that in the group control group at 3 and 12 months after surgery ($p<0.05$). The percentage changes of maximum anorectal squeeze pressure in supervised PFMT and control group were median: 94.7 (16.6-441.3) and median: 67.2 (21.9-196.5) at 7 days, median:126.0 (47.0-352.6) and median: 94.6 (37.7-267.7) at 3 months, respectively. The percent changes in maximum anorectal squeeze pressure in supervised PFMT group was significantly higher compared to control group ($p<0.05$). Other parameters of PFM function did not change significantly between groups. There was no significant difference in QOL questionnaire score between two groups.

INTERPRETATION OF RESULTS

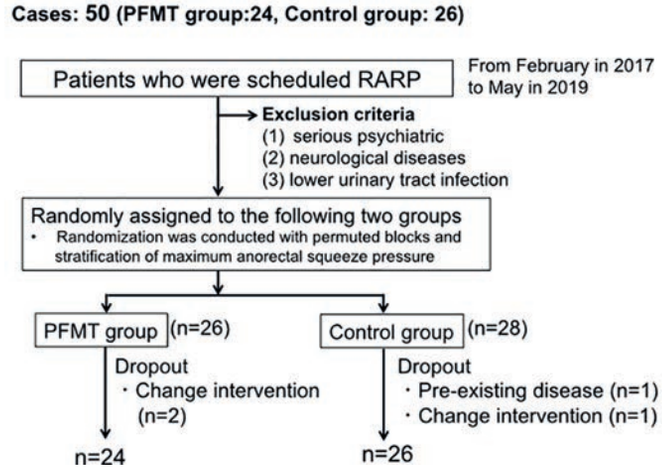
To our knowledge, this is the first study to investigate the effect of supervised PFMT on PFM function for male patients with UI after RARP. We found that higher maximum anorectal squeeze pressure in supervised PFMT group compared to control group. A manometer with an anorectal sensor was used to assess the levator ani muscle as PFM function in men since anorectal measurement is only a practical option. In our preliminary study, the reliability assessment of the resting anorectal pressure and the maximum anorectal squeeze pressure were evaluated, and found the intra- and inter-rater reliability of resting pressure, anorectal squeeze pressure were substantial to almost perfect for two examiners (unpublished data). The previous single-arm study performed PFMT for the patients after radical prostatectomy demonstrated that PFM strength improved continuously until 6 months after surgery [3]. The limitation of the previous study was that natural recovery could not be excluded. The current study showed supervised PFMT maintained PFM function (anorectal squeeze pressure) after RARP by conducting RCT.

There was a significant improvement of UI in supervised PFMT group than control, which suggests that PFMT prevented the deterioration of postoperative UI. This is because supervised PFMT, which provided guidance on PFM contraction by visual inspection and palpation, improved the PFM function, rather than using booklets and verbal explanations of PFMT.

CONCLUDING MESSAGE

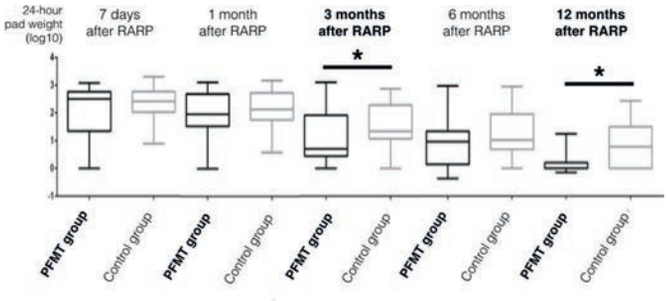
The results of the current study showed that PFM function played an essential role in maintaining continence after RARP. Pre- and post-operative supervised PFMT was beneficial for patients with UI after RARP to progress PFM function, leading to the improvement incontinence.

FIGURE 1



Flowchart of participants in the current study

FIGURE 2



Comparison of 24-hour pad weight between PFMT and control group after RARP

REFERENCES

1. Bray F, et al. GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2018;68(6):394-424
2. Mariotti G et al. Early recovery of urinary continence after radical prostatectomy using early pelvic floor electrical stimulation and biofeedback associated treatment. J Urol. 2009;181(4):1788-93.
3. Zachovajeviene B et al. Dynamics of pelvic floor muscle functional parameters and their correlations with urinary incontinence in men after radical prostatectomy. Neurourol Urodyn. 2017;36(1):126-131.

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BLADDER ELEVATION IN PELVIC FLOOR MUSCLE TRAINING EVALUATED BY CINE MRI (MAGNETIC RESONANCE IMAGING) IS ASSOCIATED WITH EARLY RECOVERY OF CONTINENCE AFTER RADICAL PROSTATECTOMY.

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HYPOTHESIS / AIMS OF STUDY

Postprostatectomy incontinence (PPI) is a major complication of prostatectomy. Although pelvic floor muscle training (PFMT) is a good treatment of PPI, there is no evidence of how the muscle movement affects recovery of continence. MRI (magnetic resonance imaging) is a good tool to evaluate the risk factors of PPI such as membranous urethral length (MUL). In the present study, we evaluated some dynamic factors of prostatectomy patients using cine MRI to identify the risk factors of PPI and reveal the contribution of pelvic floor muscle to recovery of continence.

STUDY DESIGN, MATERIALS AND METHODS

A total of 128 male prostate cancer patients were enrolled in the present study. The all prostatectomy was robot assisted laparoscopic surgery. Cine MRI was performed preoperatively and at 6 months after surgery. Continence was defined as pad free or safety pad. We defined bladder neck elevation length during PFMT as "bladder elevation length (BEL)". Other static or dynamic parameters were also measured. Patients who got recovery of continence within a month were divided into Continence-group (n=48), and others were into Incontinence-group (n=80). We analyzed the parameters between two groups using Mann-Whitney U test or chi-square test, and between pre-post operations using Wilcoxon signed rank test. Preoperative parameters were also analyzed using multivariable analysis. Kaplan-Meier analysis with log-rank testing was also applied for preoperative BEL.

RESULTS

In the two groups, there was no significant difference in any parameters of patient characteristics, perioperative data, pathological results and with or without nerve-sparing technique. In Continence-group, preoperative BEL was significantly longer than Incontinence-group (10.4 vs 8.2 mm; P<0.001). Postoperative BEL of Continence-group also tended to be longer (9.9 vs 8.9 mm; P=0.057). Only in postoperative state, posterior urethrovesical angle (PUVA) of Continence-group was significantly smaller than Incontinence-group at both resting and voiding phase (130 vs 135 °; P=0.005, 138 vs 143 °; P=0.026). Postoperative membranous urethral length (MUL) of Continence-group was significantly longer (14.5 vs 12.4 mm; P<0.001). Multivariate analysis showed that preoperative BEL significantly contributed to getting recovery of continence (HR=0.96, P=0.016). Patients with longer preoperative BEL (>8.8mm) got recovery of continence significantly faster than patients with shorter (<8.8mm) (log-rank test; P=0.038).

INTERPRETATION OF RESULTS

Preoperative BEL could be a great predictor for early recovery of continence after radical prostatectomy. This parameter is acquired from dynamic and highly accurate data of cine MRI. Moreover, cine MRI could detect not only anatomical features, but also actual function of pelvic floor muscle. We and the patient can consider his own risk of PPI using cine MRI. Moreover, long BEL might indicate better PFMT, and PFMT biofeedback using cine MRI has a potential to achieve early recovery of continence.

Some reports demonstrated that smaller PUVA made recovery of continence earlier, and the results of the present study supported the theory. Surgical effort to preserve MUL would also result in preventing PUVA opened.

CONCLUDING MESSAGE

A novel dynamic parameter of BEL was strongly related to recovery of early continence after radical prostatectomy. This is the first study to show that cine MRI is useful for digitizing the level of PMFT skill and predicting the risk of PPI.

Funding NONE **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** the ethical board for epidemiological studies at Nagakubo hospital **Helsinki** Yes **Informed Consent** Yes

25 www.ics.org/2020/abstract/25

INTRAVAGINAL ELECTRICAL STIMULATION AS AN INTERVENTION IN WOMEN WHO ARE UNABLE TO PERFORM A VOLUNTARY PELVIC FLOOR MUSCLES CONTRACTION: AN ASSESSOR BLINDED RANDOMIZED CONTROLLED TRIAL.

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HYPOTHESIS / AIMS OF STUDY

It is estimated that 30% of women are unable to perform a voluntary pelvic floor muscle (PFM) contraction [1]. Many women, even after careful instruction about the anatomy

and function of the PFM will not be able to distinguish the contraction of the PFM from the contractions of other muscles, such as the rectus abdominis, gluteus maximus and hip adductors. Deficiencies in PFM function has been associated with pelvic organ prolapse (POP), urinary incontinence (UI) fecal incontinence (FI), and sexual dysfunctions. PFM training is considered first-line treatment for UI in women. However, for those not able to contract, this treatment is unavailable. The primary aim of this study was to assess the efficacy of intravaginal electrical stimulation (iES), to provide a voluntary PFM contraction in women unable to contract. The secondary aim was to assess the effect of this intervention on UI reports.

STUDY DESIGN, MATERIALS AND METHODS

This is an assessor blinded randomized controlled trial. Women over 18 years of age, routinely referred to a tertiary care, with PFM dysfunctions were recruited. Exclusion criteria were neurological diseases; symptoms of vaginal or urinary tract infection; pelvic organ prolapses > stage 2; suspected or confirmed pregnancy and cognitive impairments. In the first session, demographic data were collected, and a standardized PFMs assessment using vaginal palpation was performed by a women´s health physiotherapist. Only participants with PFM function grade 0 or 1 assessed by bi-digital palpation on the Modified Oxford Scale (MOS) were included. Eligible participants were randomized to either the intervention group (IG) to receive iES or to the control group (CG) with no intervention. The randomization procedure was conducted using computer-generated random numbers. The primary outcome measure was PFM strength, evaluated through vaginal palpation using the Modified Oxford Scale (MOS) and the secondary outcome, was UI assessed by the International Consultation on Incontinence Questionnaire on Urinary Incontinence – Short Form (ICIQ-UI-SF). All participants were assessed at baseline and after 8 weeks. The intervention was performed once a week using the device Dualpex Quark®. A biphasic current was used and the stimulation parameters were: 50 Hz frequency, pulse width of 200 microseconds, contraction time (Time on) of 5 seconds, relaxation time (Time off) of 10 seconds, current intensity set according to the participants sensitivity (tolerance), and total stimulation time of 20 minutes [2]. In the last 10 minutes of the intervention, voluntary PFM contractions were requested along with the involuntary contractions caused by the stimulator. The same examiner performed all the assessments and was blind to the allocation of the groups, not being involved with the intervention. The intervention sessions were conducted by a single physical therapist who had 20 years of experience in women's health physical therapy and who had no contact with the assessor. The adherence to the intervention was recorded at the time of the physiotherapy session and was registered by the researcher who applied the intervention. Data analysis was also done without knowing which group the participant was allocated to. Data were first tested for normality. For comparison between groups, continuous variables were tested using t-test, for variables with normal distribution Anderson-Darling test was used, and for the remaining variables non-parametric test (Mann-Whitney e Brunner-Munzel) were used. For categorical variables Fisher test was used. Primary outcome was analyzed using logistic regression and for the secondary outcome mixed regression model. The level of significance adopted was 0.05 using the software R 3.6.0. Sample size calculation was based on a pilot sample considering the capacity for voluntary contraction of the PFM assessed using the MOS. It was considered that the participants who had a score greater than or equal to 2 according to the MOS acquired the ability to contract their PFM. Then, the proportions between each group were compared. The sample size was based on the test of differences between proportions and Fisher's exact test. Adopting a significance level of 5% and a test power of 90%, the need to obtain 14 participants per group was estimated. Considering possible sample losses, a minimum of 20 women in each should be included in the study.

RESULTS

A total of 172 women were recruited, of those, 40 did not agree to participate and 29 did not attend the first assessment. One hundred and three women were screened for eligibility, of whom 39 did not meet the inclusion criteria (34 scored 2 or more in the MOS and 6 had some neurological impairment). Sixty-four women were randomized, 31 to the IG and 33 to the CG. Demographic data are presented in Table 1. Sixty-one women provided data that could be included in the regression analysis (IG n=28 and CG n=33). There were 3 losses to follow up. After the intervention, the ability to contract the PFM was acquired by 35.7% of the participants in the IG vs 12.1% of the participants in the CG. Table 2 shows that the IG had 4.03 higher odds of being able to voluntarily contract PFM in comparison with the CG. At baseline the mean ICIQ score on the IG was 16.29 (SD±3.17; 95%CI 15.23 – 17.52) and on the CG 14.24 (SD±3.69; 95%CI 12.93 – 15.55) (p=0.029) and after the intervention on IG was 13.54 (SD±5.32; 95%CI 11.54 – 15.64) and on CG was 13.45 (SD±4.69; 95%CI 11.97 – 15.00) (p=0.73). The ICIQ-UI-SF total scores showed statistically significant difference between groups (p=0.036), but no difference between the time (p=0.25) and its interaction group:time (p=0.051) (Table 2). At baseline 100% of participants reported UI on both groups and after the intervention 92.86% on the IG and 96.97% on the CG (p=0.47) Adherence to the intervention was high, 20 participants completed 8/8 sessions, 3 completed 7/8, 3 completed 6/8,1 did 3/8 sessions and 1 did 1/8 session.

INTERPRETATION OF RESULTS

The results of the present study suggest that the use of intravaginal electrical stimulation, together with attempts of simultaneous voluntary PFM contractions with the stimulation can facilitate ability to voluntarily contract the PFM. To our knowledge this is the first RCT showing that women can learn to contract the PFM via attempts to contract during

electrical stimulation. However, the protocol with only one training session per week did not reduce the ICIQ-UI-SF sum score [3]. This approach can be considered for women who are unable to contract their PFM prior to engage in a PFM training program.

CONCLUDING MESSAGE

Intravaginal electrical stimulation can be considered to be used to teach women unable to contract the PFM. However, it was not effective in reducing the severity of UI.

FIGURE 1

Table 1. Demographic data from both groups at baseline.

Variables	IG (n=31)			CG (n=33)		
Age (years) – Mean ±SD	52.9 ±12.3			53.8 ±13.3		
BMI (kg/cm²) – Mean ±SD	29.3 ±4.3			29.8 ±4.7		
Obstetrical History–n (%)	Parity	Vaginal delivery	C-section	Parity	Vaginal delivery	C-section
0	1(3.2%)	9(29.0%)	17(54.8%)	2(6.1%)	10(30.3%)	21(63.6%)
1	8(25.8%)	2(6.5%)	5(16.1%)	12(36.4%)	5(15.2%)	6(18.2%)
2	6(19.4%)	8(25.8%)	4(12.9%)	7(21.2%)	5(15.2%)	3(9.1%)
3	10(32.3%)	7(22.6%)	4(12.9%)	5(15.2%)	6(18.2%)	1(3.0%)
>3	6(19.3%)	5(16.1%)	1(3.2%)	7(21.1%)	7(21.1%)	2(6.1%)
Use of HT – n (%)						
Yes		3(9.7%)			3(9.1%)	
No		28(90.3%)			30(90.9%)	
UI – n (%)		31(100%)			33(100%)	
AI – n (%)		3(9.7%)			4(12.1%)	

Absolute values with percentages are presented as: n (%); Means with standard deviation are presented as: Mean ±SD; IG: Intervention Group; CG: Control Group; SD: Standard Deviation; HT: Hormonal therapy; UI: Urinary Incontinence; AI: Anal Incontinence

FIGURE 2

Table 2. Main outcome measures after the 8 weeks intervention (comparison electrical stimulation and untreated control group).

Variables	p-value [a]	Coefficient	SD Coefficient	Odds Ratio (OR)	OR IC 95%
MOS	**0.036**	1.39	0.66	**4.03**	1.10 – 14.77
ICIQ-UI-SF total scores	p-value [b]	Coefficient	Standard error coefficient		Coefficient IC 95%
Group	**0.027**	4.08	1.81		0.54 – 7.61
Time	0.252	-0.79	0.68		-2.13 – 0.55
Group:Time	0.051	-2.0	1.01		-3.97 – -0.02

[a] Analysis using logistic regression; [b] Analysis using mixed regression model; SD: Standard Deviation; OR: Odds Ratio; MOS: Modified Oxford Scale; ICIQ-UI-SF: International Consultation on Incontinence Questionnaire on Urinary Incontinence – Short Form.

REFERENCES

1. Talasz H, Himmer-Perschak G, Marth E, Fischer-Colbrie J,Hoefner E, Lechleitner M. Evaluation of pelvic floor musclefunction in a random group of adult women in Austria. IntUrogynecol J Pelvic Floor Dysfunct. 2008;19(1):131---135.
2. Mateus-Vasconcelos ECL, Brito LGO, Driusso P, Silva TD, Antonio FI, Ferreira CHJ. Effects of three interventions in facilitating voluntary pelvic floor muscle contraction in women: a randomized controlled trial. Braz J Phys Ther. 2018 Sep - Oct;22(5):391–399.
3. Dumoulin C, Cacciari LP, Hay-Smith JC. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane database Syst Rev, 10 (10), CD005654, 2018 Oct 4.

Funding Auxilio Regular FAPESP **Clinical Trial** Yes **Registration Number** NCT03319095 **RCT** Yes **Subjects** Human **Ethics Committee** Comitê de Ética em Pesquisa em Seres Humanos do Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto da USP - CEP HCFMRP/USP , Approval number: 2.310.370 **Helsinki** Yes **Informed Consent** Yes

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NOVEL PELVIC FLOOR TREATMENT WITH MECHANOTHERAPY: FINAL CLINICAL TRIAL RESULTS IN WOMEN WITH STRESS URINARY INCONTINENCE (SUI)

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HYPOTHESIS / AIMS OF STUDY

Hypothesis / Aims of Study

Urinary incontinence is common in women with an estimated prevalence of 500 Million world-wide, half of whom have stress urinary incontinence (SUI). Pelvic Floor Muscle Training (PFMT) is the standard of care for nonsurgical treatment of SUI with improvements reported in clinical measures including urine leak volume via pad weight (PW), voiding frequency and Quality of Life (QoL). Enhancements to improve the efficacy of PFMT are needed, especially in women who are not interested in or are not candidates for surgery. The aim of this study was to evaluate whether mechanotherapy (MT) applied to the pelvic floor muscles (PFM) in conjunction with standard PFMT improves continence in women with SUI.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective, randomized, controlled, double-blinded, cross-over trial. The novel device used for this study (Flyte™, Pelvital, Inc., Minneapolis, MN, USA) is a vaginal device that provides 2-part MT: Part 1 MT - a carefully engineered probe that creates a preload on the pelvic floor muscles prior to muscle contraction. This pre-stress is expected to augment the effect of PFMT; and Part 2 MT - mechanical transduction with biofeedback which has been shown to provide incremental benefit in a previous study using the Flyte™ device. Subjects with SUI were randomized to an Intervention Arm (Part 1 and Part 2 MT + PFMT) versus a Control Arm (Part 1 MT only + PFMT). Subjects were asked to perform therapy daily for 5 minutes for 12 weeks. Endpoints were assessed at 6 and 12 weeks. The primary endpoint was 24-Hr PW determined at 6 weeks, at which time Control subjects were crossed over to the Intervention arm. There were multiple secondary endpoints, including PW at 12 weeks and Quality of life (QOL) assessed with the validated ICIQ-UI-SF. QOL was assessed every 6 months thereafter for 24 months.

RESULTS

Data on 119 subjects were analyzed on an intent-to-treat basis. Overall, compared to Baseline PW there was a median 59% relative improvement at 6 weeks (IQR, 18% to 79%) and median 68% relative improvement at 12 weeks (IQR, 43.5% to 87%; P<0.001). The absolute change was from a median pad weight of 27 g/24hr to 11.6 g/24hr at 6 weeks, and 6.4 g/24hr at 12 weeks (p<0.001) (Figure 1). There was no a sig-

nificant difference in PW between study arms at either 6 or 12 weeks (at which time all subjects received MT Part 1 plus MT Part 2), although trends favored the Part 2 group that received mechanical transduction for the entire 12 weeks. This was particularly evident in the final 34 subjects who received a study device with enhanced user biofeedback for stronger muscle contraction. Furthermore, QOL measured by the Total ICIQ-UI-SF score improved significantly at both 6 and 12 weeks compared to Baseline (both p<0.001). PW data was further stratified by Baseline PW severity level. Statistically significant improvements were noted in the full study cohort in all severity levels at 6 and 12-weeks compared to Baseline, (Figure 2). Mild and Moderate severity groups saw incremental improvement between Week 6 and Week 12, whereas Severe subjects saw a relative plateau. There were no significant differences between study arms, although a favorable trend was again noted in those receiving mechanical transduction.

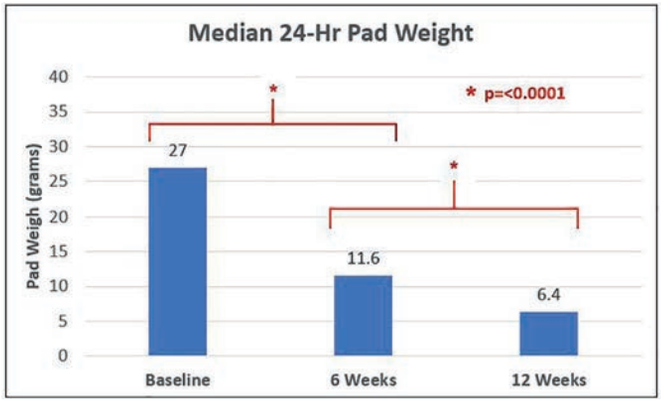
INTERPRETATION OF RESULTS

Study subjects demonstrated significant reductions in 24-Hr pad weight and improved QOL using Flyte™ therapy. Of participants, 71% (81/114) achieved a clinically meaningful reduction (>50%) in pad weight by 12 weeks of therapy; with a 57% (68/119) having a >50% reduction in the first 6 weeks. Long term follow-up initially indicates that QOL benefits were generally sustained after the study ended. It was noted that some subjects responded exceptionally well with almost complete eradication of urine leakage while approximately 20% of women were non-responders. These observations occurred irrespective of incontinence severity level at baseline. The lack of response in some subjects suggests a possible condition requiring further clinical evaluation and potentially more aggressive treatment. While a trend in incremental benefit of mechanical transduction was noted, the lack of significant difference in therapy response between study arms is presumed to be due to: 1) the greater than expected benefit from Part 1 MT muscle pre-stretch alone as an adjunct to PFMT; 2) the reduced amount of data from those subjects that received the updated patient interface. As a result, the study was under powered to detect a significant difference between study arms at 6 weeks.

CONCLUDING MESSAGE

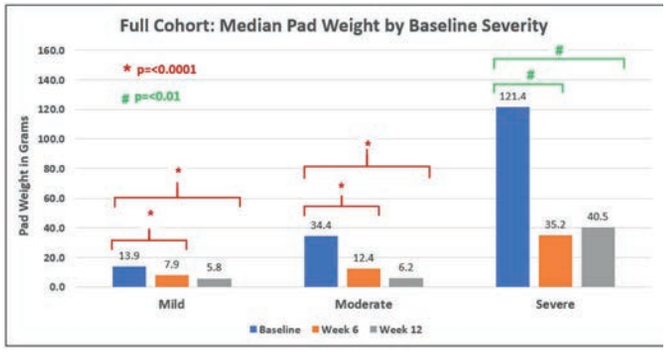
Flyte™ therapy with 2-part MT used as an adjunct to PFMT provided an effective, non-invasive therapeutic option in women with SUI as reflected by successful objective (PW) and subjective (QOL) outcomes. While trends towards incremental benefit of mechanical transduction (Part 2 MT) were observed at 6 weeks, the study was underpowered to evaluate for statistical significance. Nevertheless, subjective QOL improvements appear to be sustained during long-term follow-up. Possible variables contributing to the differentiation of Flyte therapy responders versus non- responders warrants further investigation.

FIGURE 1



Median 24-Hr Pad Weight - Full Cohort

FIGURE 2



Median 245-Hr Pad Weight - By Baseline Severity

Funding Pelvital USA, Inc. **Clinical Trial** Yes **Registration Number** ClincTrials.gov, NCT02954042 **RCT** Yes **Subjects** Human **Ethics Committee** University of Minnesota, Western IRB **Helsinki** Yes **Informed Consent** Yes

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URINE LUCK! DESIGN AND DEVELOPMENT OF A MOBILE APPLICATION FOR AN INTRA-VAGINAL DEVICE INTENDED FOR PELVIC FLOOR MUSCLE TRAINING.

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HYPOTHESIS / AIMS OF STUDY

It is well-recognised that pelvic floor muscle (PFM) training can resolve symptoms of stress urinary incontinence for women. Barriers to effective PFM training are incorrect PFM contraction, and low adherence. The World Health Organisation states that digital technology has the potential to enhance health with self-management of care, and there is

scope for this to be applied in the area of PFM health. Biofeedback can help women undertake correct PFM contraction, although more research is still required for home use. It is proposed that a mobile application (app), with visual biofeedback, could guide women through a clinically developed exercise programme for home PFM training.

The aim of this project was to use co-operative design with an iterative framework to attain user feedback and develop a fun and motivating app for women to self-guide PFM training. The project also aimed to ensure the app meets user requirements, conforms to medical device standards (ISO 62366-1 and ISO13485), and follows the Mobile Application Rating Scale (MARS) to create a high-quality health app. Design and development checklists [1], were incorporated into the framework and approach.

STUDY DESIGN, MATERIALS AND METHODS

This study used human-centered design and qualitative, iterative framework methodologies. This approach focused on engaging a wide range of potential users to create a product that would be relevant within the context of their lives, experiences, and attitudes. The design emphasized both problem-finding and problem-solving, resulting in effective solutions. Focus groups and one-to-one sessions were used to gather information about perceptions and attitudes towards an intra-vaginal biofeedback device (femfit) and to develop its associated mobile app. A flowchart showing the multi-disciplinary iterative design approach for this project is shown in Figure 1.

The femfit is an intra-vaginal pressure sensor array that transmits pressure via Bluetooth to display real time biofeedback on a mobile app [2]. It comprises eight pressure sensors encapsulated in biocompatible silicon. It is flexible and comfortable, so does not obstruct natural anatomical movement during a PFM contraction. The femfit has been manufactured adhering to the ISO13485 quality standard. Women can use the femfit to effectively locate and exercise their PFM, and via an app can self-guide through an evidence-based clinically relevant training programme.

Four focus groups (2 hours each) and two sets of one-to-one interviews (1 hour each) were held over 18 months. Focus groups were used to gather information about potential users' perceptions and attitudes towards the app's development. Recurring statements were identified and summarised to document key themes. Where possible, the same women were used for successive focus groups, to build on their PFM knowledge and app exposure, allowing for iterative design. Topic areas and themes were pre-defined and adapted to each iteration of the app. The focus groups facilitated interaction and discussion about the various aspects of the app, and discussion highlighted potential users' questions, concerns, and experiences. Participants were selected as they had some experience of urinary incontinence (UI) – from mild to severe – and the researchers were conscious of creating a permissive and safe space to encourage participants to share their experiences. Farquhar notes that group methods can make an important contribution to sensitive research [3]. This is of particular relevance to women who experience UI and whose voice is 'silenced' by personal vulnerability or societal stigma.

RESULTS

A total of 26 women (22 to 62 years) participated in the focus groups and one-on-one interviews. Qualitative results are shown in Table 1.

INTERPRETATION OF RESULTS

All participants were open to the idea of using the femfit and app for home PFM training. The focus groups provided valuable insight into the complexity and nuance of app development, how group members may interact and their relationship with it – along with insight into the diversity of individual's views. One-to-one interviews enabled participants to engage directly with the femfit and app, followed up with detailed in-depth discussion. Recurring themes throughout the usability study aligned with sections of the MARS document: clear, concise information (Information); progress tracking (Engagement); intuitive aesthetic interface (Aesthetics/Functionality); reliable biofeedback (Engagement/Information). The MARS framework will continue to be central to the assessment of ongoing app iterations.

CONCLUDING MESSAGE

Human-centered design to develop a mobile app is necessary to effectively communicate health information for self-care management. The utility of this app will be tested in a feasibility study with and without the femfit device.

FIGURE 1

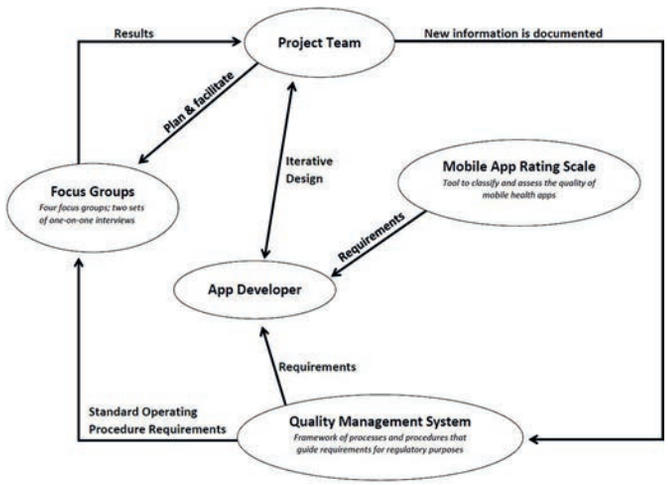

Figure 1. Flowchart of multi-disciplinary iterative design process for mobile app development.

FIGURE 2

Co-operative design approach with aim (introduced by the researcher) and summary	
Focus Group 1	Aim: Introduce prototype device, app and PFM exercises. Participant Summary: Positive response to the concept of real-time PFM biofeedback. Key themes discussed: • Information: PFM health and exercises; display progress of PFM strength change. • Data security and sharing: FDA (or equivalent) approval would assist app reputability; opt-in to share data with others e.g. clinician. • Additional features: aesthetic interface; motivational; reminder notifications.
Focus Group 2	Aim: Introduce an initial app wireframe and gather feedback for app features Participant Summary: Discussed criteria: intuitive, reliable, useable, motivational, look/feel. User requirements: • Information needs to be clear, concise, and accurate. • Exercises to be novel, personalised, with clinical evidence. • Ability to view progress towards goals set by a user. • Games to make the app approachable, fun and non-medical. • An online femfit community (opt-in) was welcomed. No interest for in person meet-ups.
Focus Group 3	Aim: Gather feedback on app development to date; identify areas to improve/modify Participant Summary: Overall, impressed with app progress to date. Improvements areas identified: • Bluetooth connection must be reliable. • Instructional information and real-time biofeedback requires refinement. • More information on PFM anatomy and how the app gamification works. • Timing and motivational feedback while undertaking PFM exercises.
Focus Group 4	Aim: Gather feedback about the exercise protocol and evaluate the onboarding process Participant Summary: Participants continued to raise minor queries (e.g. large print settings) but overall, the app was well received. • Positives: the interface is visual and clear; fun and feminine (compared to other exercise apps); app navigation is intuitive. • Risk identified: potential to develop a familiar, but incorrect pattern for exercising PFM was questioned. • Onboarding: content is as users would expect, with minor amendments.
One-on-one interview	Aim: Assess women's reaction to biofeedback and the exercise protocol effectiveness Participant Summary: Participants excited by real-time biofeedback and found the data motivating and empowering. • Understood how the app could be used to work towards goals. • Valued visual feedback and muscle differentiation. • Background information to be simplified. Audio could help. • Biofeedback game was hard! Emphasis required that this is exercises are only a guide. • Some concern that if the femfit was positioned incorrectly, biofeedback is meaningless. • Further information is required before the exercises e.g. how to play the game/do a PFM contraction?

Table 1. Qualitative findings from the usability study.

REFERENCES

1. Stoyanov, S.R., et al., Mobile App Rating Scale: A New Tool for Assessing the Quality of Health Mobile Apps. JMIR mHealth uHealth, 2015. 3(1): p. e27.
2. Schell, A., et al., Design and Development Of A Novel Intra-Vaginal Pressure Sensor Array, in 46th Annual Meeting of the International Continence Society. 2016: Tokyo, Japan.
3. Farquhar, C. and R. Das, Are focus groups suitable for 'sensitive' topics?, in Developing focus group research: Politics, theory and practice. 1999, Sage Publications Ltd: Thousand Oaks, CA. p. 47-63.

Funding Ministry of Business, Innovation and Employment – Smart Sensors for the Medical Industry. **Clinical Trial** No **Subjects** Human **Ethics Committee** University of Auckland Human Participants **Ethics Committee**; Protocol Number 022043. **Helsinki** Yes **Informed Consent** Yes

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COST EFFECTIVENESS OF EMG BIOFEEDBACK ASSISTED PELVIC FLOOR MUSCLE THERAPY FOR WOMEN WITH OVERACT

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HYPOTHESIS / AIMS OF STUDY

The overactive bladder syndrome (OAB) is defined as urinary urgency (the primary symptom of OAB), usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UUI) by the International Continence Society (ICS). Within conservative management, behavioural treatment in combination with biofeedback-assisted pelvic floor muscle training (BAPFMT) is a first-line treatment option for OAB.

Literature on comparative effectiveness indicates that behavioural treatments are either equivalent to or more effective than medications for reducing incontinence and overactive bladder (OAB) symptoms, without exposing patients to the typical side effects of medications. However, cost-effectiveness of pelvic floor physiotherapy and BAPFMT have a lack of evidence regarding long-term outcomes compared to other treatments.

The aim of these analyses was to determine the Incremental Cost Effectiveness Ratio (ICER) of EMG Biofeedback Assisted Pelvic Floor Muscle Therapy (BAPFMT) with the Novuqare MAPLe in women with OAB (1,2).

STUDY DESIGN, MATERIALS AND METHODS

Patients were randomly divided into an intervention group that received lifestyle instructions & toilet behaviour (L&T) and BAPFMT (8 sessions) or into a control group which received L&T (1 session) first and BAPFMT (7 sessions) after 9 weeks (2). The outcomes of the King's Health Questionnaire (KHQ), the number of therapy-sessions and pad-use at baseline, after 9 weeks, 6 months and 1 year were taken as inputs.

From the KHQ, Quality-Adjusted Life Years (QALYs) could be determined (3). As costs, €42,25 per therapy-session, €75 for MAPLe EMG probe and €0,24 per pad used per day were taken.

A complete case analysis was done for two scenario's; cost-effectiveness of adding BAPFMT to L&T and cost-effectiveness of L&T + BAPFMT and L&T + postponed BAPFMT compared to their baseline. For the first evaluation the outcomes at 9 weeks were extrapolated to 1 year. For the second evaluation all outcomes at baseline, 9 weeks, ½ year and 1 year were compared to the extrapolated baseline to 1 year. Within group t-test were perform to detect differences over time.

RESULTS

The Flow diagram and number of complete cases used in both scenarios can be found in Figure 1. The utilities and pads/day as input for evaluating adding BAPFMT to L&T can be found in Figure 2a. For the L&T + BAPFMT group within group t-tests show that utility significantly increases and number of pads per day significantly decrease after 9 weeks. Figure 2b gives the resulting costs and QALYs used to calculate the ICERs. For the L&T group t-tests show that utility significantly increases after 9 weeks but the number of pads per day is slightly lower, but not significant. The ICER of adding BAPFMT to L&T is €29.207.

The utilities and pads/day as input for evaluating L&T + BAPFMT and L&T + postponed BAPFMT compared to their baseline can be found in Figure 2c. For the L&T + BAPFMT within group t-tests show that utility significantly increases and number of pads per day is lower, but not significant, in 1 year. For the L&T + postponed BAPFMT group t-tests show that utility significantly increases and the number of pads significantly decrease in 1 year. Figure 2d shows the resulting costs and QALYs used to calculate the ICERs Compared to baseline, L&T + BAPFMT has an ICER of €22.204. Postponing BAPFMT for 9 weeks increases ICER to €37.089.

INTERPRETATION OF RESULTS

With a willingness to pay between €20.000-€30.000, L&T with BAPFMT with MAPLe is a cost-effective strategy for first-line therapy for women with OAB. And over a longer period it would even become cost-saving Since the costs are a function of time (pads/day), the benefit of (adding) BAPFMT increases over time. For the combined groups, L&T + (postponed) BAPFMT is cost-saving after less than 5 years. Larger RCTs are necessary to gain more insight in the cost-effectiveness, but these analyses look promising.

CONCLUDING MESSAGE

Lifestyle advice and Toilet behaviour in combination with Biofeedback Assisted Pelvic Floor Muscle Therapy (with MAPLe) is a cost-effective strategy which becomes cost-saving over time and should be considered as a first-line therapy for women with OAB.

FIGURE 1

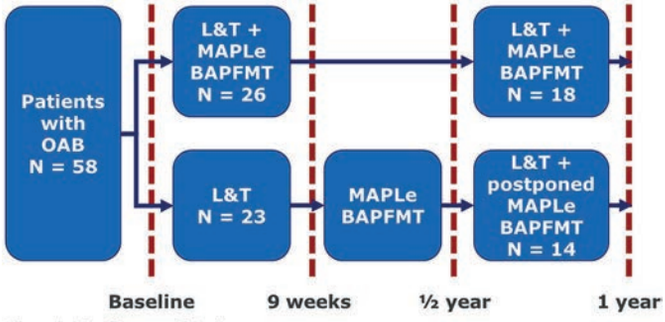

Figure 1: Flow Diagram of study

Figure 1: Flow diagram

FIGURE 2

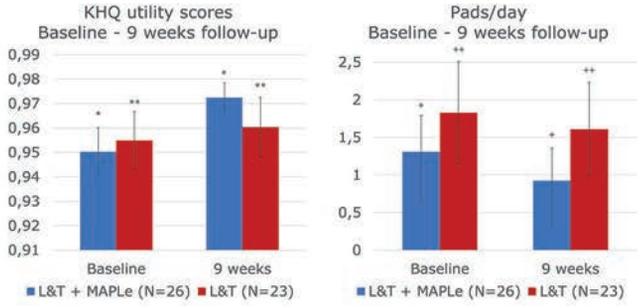

Figure 2a) KHQ Utility scores and Pads/day at baseline and 9 weeks and confidence intervals. Within groups t-tests: * p < 0.001, ** p = 0.047; + p = 0.030, ++ p = 0.171

	L&T+BAPFMT	L&T
Costs (€)	497	185
QALYs	0,9705	0,9599
ICER (€)	29.207	

Figure 2b) Costs, QALYs and ICER for adding MAPLe BAPFMT to L&T

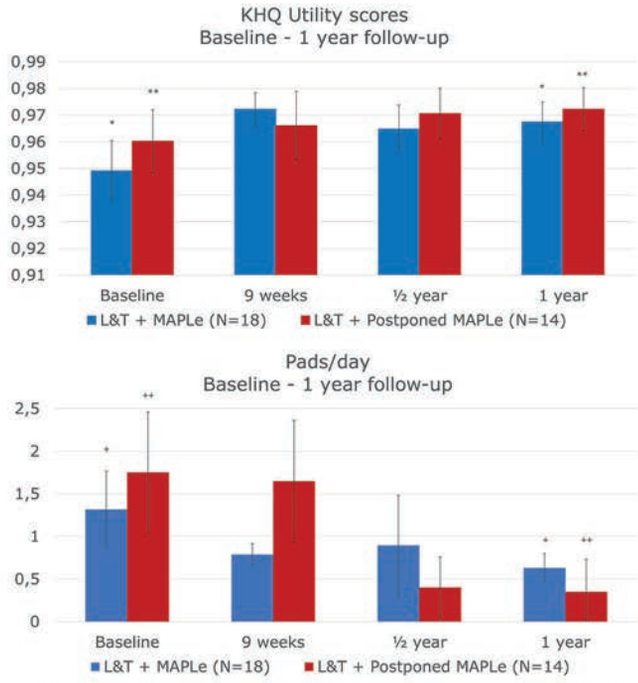

Figure 2c) KHQ Utility scores and Pads/day at baseline, 9 week, ½ & 1 year and confidence intervals. Within groups t-tests: * p = 0.003, ** p = 0.008; + p = 0.055, ++ p = 0.001

		L&T+BAPFMT	L&T+postponed BAPFMT
Cost(€)	**Baseline**	115	153
	Therapy	486	484
QALY	**Baseline**	0,9491	0,9602
	Therapy	0,9660	0,9691
ICER(€)		22.024	37.089

Figure 2d) Costs, QALYs and ICERs for L&T + (postponed) MAPLe BAPFMT compared to baseline

Figure 2: Utility scores, pad use and calculated costs, QALYs and ICERs

REFERENCES

1. Voorham-van der Zalm PJ, Voorham JC, van den Bos TW, Ouwerkerk TJ, Putter H, Wasser MN. Reliability and differentiation of pelvic floor muscle electromyography measurements in healthy volunteers using a new device: the Multiple Array Probe Leiden (MAPLe). Neurourol Urodyn. 2013;32:341–348. https://doi.org/10.1002/nau.22311
2. Voorham JC, De Wachter S, Van den Bos TW, Putter H, Lycklama à Nijeholt GA, Voorham - van der Zalm PJ. The

effect of EMG biofeedback assisted pelvic floor muscle therapy on symptoms of the overactive bladder syndrome in women: A randomized controlled trial. Neurourology and Urodynamics. 2017;36:1796–1803. https://doi.org/10.1002/nau.23180
3. Brazier J, Czoski-Murray C, Roberts J, Brown M, Symonds T, Kelleher C. Estimation of a preference-based index from a condition-specific measure: the King's Health Questionnaire. Med Decis Making. 2008 Jan-Feb;28(1):113-26. https://doi.org/10.1177/0272989X07301820

Funding Study was partially funded with and unrestricted grant from Novuqare Pelvic Health BV **Clinical Trial** Yes **Registration Number** Dutch CCMO register NL17997.058.08 **RCT** Yes **Subjects** Human **Ethics Committee** Leiden University Medical Center EC **Helsinki** Yes **Informed Consent** Yes

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DIFFERENT MODELS OF DELIVERING PELVIC FLOOR MUSCLE TRAINING FOR PROLAPSE: A COMPARISON OF WOMEN'S OUTCOMES

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HYPOTHESIS / AIMS OF STUDY

Evidence exists that pelvic floor muscle training (PFMT) is effective for the treatment of prolapse symptoms (1). In the UK, the recently-updated NICE guidelines (https://www.nice.org.uk/guidance/ng123/chapter/Recommendations#non-surgical-management-of-pelvic-organ-prolapse) recommend considering a programme of supervised PFMT for at least 16 weeks as a first option for women with symptomatic prolapse (stage I or stage II). In most trials to date evaluating the effects of PFMT for prolapse, the PFMT has been delivered by specialist physiotherapists. However, in the UK the number of specialist physiotherapists is limited and insufficient to deliver the necessary treatment for the 5-10% of women likely to experience symptomatic prolapse (1). We undertook an implementation study to investigate what service models the UK NHS might use to ensure wide availability of PFMT, and how different models would impact on women's treatment outcomes.

STUDY DESIGN, MATERIALS AND METHODS

Informed by the realist evaluation framework, the study used a longitudinal multiple case study design, in four diverse NHS centres. With support from the study team, the centres developed and implemented a model of PFMT delivery suited to their local context, workforce and resources. These were compared with a fifth NHS centre where a specialist pelvic floor physiotherapy service was already available. Women were recruited in all five centres to an observational prospective cohort study to assess their prolapse symptoms at baseline, 6 and 12 months. Participants were aged ≥ 18 years, presenting with symptomatic stage I, II or III prolapse of any type, and were suitable to be referred for PFMT. Women were excluded if they were pregnant or <1 year postnatal, had pelvic cancer, cognitive impairment or neurological disease. The primary outcome was the Pelvic Organ Prolapse Symptom Score (POP-SS) (7 items scoring frequency of different prolapse symptoms, range 0 to 28, higher scores indicating greater symptom severity) (2). Assuming a minimum clinically important difference in the POP-SS of 2 points and standard deviation (SD) of the difference between baseline and follow-up of 5.5 points (3), a sample size of 120 would provide 80% power to detect important differences. Analyses: 1) paired t-tests were conducted to compare POP-SS at baseline with those at follow-up, and 2) independent-samples t-tests were used to compare the mean change in POP-SS from baseline to follow-up for women treated by a specialist physiotherapist with those treated by other healthcare professionals (HCPs). Analyses 1) and 2) were then built upon by fitting linear mixed models to adjust for covariates (including ethnicity, parity, age and BMI). A 5% significance level was used throughout.

RESULTS

Service models: The models for delivering PFMT adopted by the different centres consisted of a mix of different staff types (specialist and non-specialist physiotherapists and nurses) and grades (Band 5, 6 and 7). All centres, except one, had a model whereby women were initially triaged into the service by a specialist or consultant.

Staff training: A one-day prolapse training course developed for the study was attended by all staff delivering treatment to participants in the study centres. It was delivered by an experienced pelvic health physiotherapist and workshop tutors from the Pelvic, Obstetric and Gynaecological Physiotherapy Professional Network of the Chartered Society of Physiotherapy, and covered assessment and treatment, with pre-attendance learning material and additional resources provided.

Recruitment: 102 women were recruited. Baseline questionnaires were available from 91 women, and 71 women completed the 6-month follow-up questionnaire, for whom 68 questionnaires were matched to baseline questionnaires. There were 31 completed questionnaires at 12 months, of which 30 were matched to baseline. The mean age of participants was 57.5 years (SD 11.5), and mean BMI was 27.1 (SD 4.6). One woman was nulliparous, and the majority of parous women (n=38, 16.5%) had had two births.

Women's outcomes at 6 and 12 months: These was a significant improvement in POP-SS score between baseline and 6 months in the whole cohort (mean difference -3.20 [95% CI

-4.40 to -2.00]) (Table 1) which was confirmed in the linear mixed model adjusting for covariates (effect estimate –3.48 [95% CI –4.93 to –2.04]). Comparing the improvement in POP-SS from baseline to 6 months between those treated by a specialist physiotherapist and those treated by another HCP showed no significant difference (mean difference 0.39 [-1.41 to 3.69]) (Table 2) and this was confirmed after adjusting for covariates (effect estimate 0.05 [95% CI -2.59 to 2.69]). There was also a significant improvement in POP-SS score for the whole cohort from baseline to 12 months (mean difference -2.73 [95% CI -4.48 to -0.99]). Limited further analysis was carried out on the 12-month data however, due to the reduced sample size.

INTERPRETATION OF RESULTS

We found that women having PFMT for prolapse had improved symptoms after 6 months, and the magnitude of improvement was similar to the effect observed in a trial context (effect estimate for change in POP-SS: -2·84 [2·05–3·63], p<0·0001)(3). In addition, there was no difference in the improvement in symptoms obtained from PFMT delivery by specialist physiotherapists compared with PFMT delivery by other HCPs, suggesting implementation via different models in the "real world" is feasible. It seems there is scope for other members of the healthcare team, with appropriate training and support, to deliver PFMT safely and effectively. Although the number of women recruited was lower than anticipated, with additional attrition by 12 months, and varying recruitment rates across centres, the sample size was sufficient to enable the key research questions to be answered.

CONCLUDING MESSAGE

Findings of this implementation study suggest it is possible to develop service models that involve training of different staff to effectively deliver PFMT to women with prolapse. Women's self-reported outcomes significantly improved across all service models delivering PFMT.

FIGURE 1

Table 1. Summary of POP-SS at baseline and 6 months and the change

Variable	N*	mean	SD	95% CI
Baseline POP-SS	65	10.18	5.63	8.79 to 11.58
6 month POP-SS	65	6.98	5.23	5.69 to 8.28
Difference 0–6 months	65	-3.20	4.85	-4.40 to -2.00

* 3 missing responses

FIGURE 2

Table 2. Change in POP-SS between baseline and 6-month follow-up comparing those seen by specialist physiotherapists with those seen by other HCPs

Treated by:	N*	Mean change in POP-SS 0-6 months	SD	95% CI
Specialist physio	22	-3.95	4.86	-6.11 to -1.79
Other health professional	43	-2.81	4.86	-4.31 to -1.32
Difference		0.39		-1.41 to 3.69

* 3 missing responses

REFERENCES

1. Abrams,P, Cardozo, L, Wagg, A, Wein, A. (Eds) Incontinence 6th Edition (2017). ICI-ICS. International Continence Society, Bristol UK, ISBN: 978-0956960733.
2. Hagen S, Glazener C, Sinclair L, Stark D, Bugge C. Psychometric properties of the Pelvic Organ Prolapse Symptom Score (POP-SS). BJOG: an International Journal of Obstetrics and Gynaecology. 2009; 116: 25-31
3. Hagen, S., Stark, D., Glazener, C., Dickson, S., Barry, S., Elders, A., Frawley, H., Galea, M.P., Logan, J., McDonald, A. and McPherson, G., 2014. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. The Lancet, 383(9919), pp.796-806

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30 www.ics.org/2020/abstract/30

INTERACTIVE EVIDENCE MAPS OF RANDOMIZED TRIALS ON PELVIC FLOOR MUSCLE TRAINING (PFMT) FOR URINARY INCONTINENCE IN ADULT WOMEN

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HYPOTHESIS / AIMS OF STUDY

Pelvic floor muscle training (PFMT) is a first-line treatment for urinary incontinence (UI) in adult women. Clinicians have proposed a large array of variations and add-ons to support PFMT, but their underlying evidence is sometimes unclear. Furthermore, the sheer amount of research, as well as the complexity of its clinical questions, make it difficult to appreciate where the evidence is solid versus where it is shaky. To address these issues, our interdisciplinary team performed a comprehensive systematic review and constructed interactive online evidence maps.

STUDY DESIGN, MATERIALS AND METHODS

Our 6 data sources comprised 3 completed systematic reviews, the PCORI website, ClinicalTrials.gov, and an updated literature search. For the literature search, an experienced information specialist searched PubMed, EMBASE/Medline, and PsycINFO from December 4, 2017 to July 5, 2019. We only included English-language randomized trials on one of 4 comparison types: the effect of PFMT, the effect of variations on PFMT, the effect of add-ons, and alternatives to PFMT. At least 90% of those enrolled had to be adult women with UI. Included studies had to report either cure rates, data on the frequency of UI events, or quality of life data using one of four specific QOL instruments. The minimum follow-up was 4 weeks, and we required that the study report data on at least 10 patients per group at follow-up who represented at least 50% of those enrolled. We excluded studies of women who were pregnant, or had neurogenic lower urinary tract dysfunction, cognitive impairment, surgically-treated UI, were seen in acute care settings, or at least 10% had received ancillary UI treatments. We also excluded studies in which the researchers' method of administering PFMT varied by type of UI.

A team of 3 systematic reviewers screened abstracts and full articles (at least two screeners per article, with disagreements resolved by consensus). Within each of the four types of treatment comparisons, we created sub-comparisons comprised of studies making similar comparisons (for example, within the variations category, one subcategory was group PFMT vs individual PFMT). For each outcome, we computed the effect size and its standard error (odds ratio for cure, and Hedges' g for the other two outcomes). We performed random-effects meta-analyses using the method of DerSimonian and Laird. We rated the strength of evidence using a modification of the system developed by the AHRQ Evidence-based Practice Centers. For statistically non-significant differences, we evaluated the confidence interval against the minimal important difference in order to determine whether a conclusion of equivalence was appropriate.

RESULTS

Seventy-three RCTs met our inclusion criteria (62 from previous reviews, and 11 from the search update), and we also included 13 unpublished trials from ClinicalTrials.gov.

We created two maps using Tableau: a Research Volume (RV) map, and a Treatment Effects (TE) map. The RV map (Figure 1) uses a bar chart to display the number of women with outcome data (vertical axis) for each of the 4 overall categories (horizontal axis). The top of the chart shows the total number of treatment comparisons as well as the number of RCTs. Five interactive filters along the left side of the map (type of UI, age, number of weeks since the start of treatment, publication year, and region of the world) allow the user to redraw the chart according to their specific interests (filters can be used in any combination). Hovering over a bar provides additional details such as the top 2 comparisons in that category (by number of women), and clicking on a bar yields counts for each subcategory, per-study Ns, and hyperlinks to trial abstracts.

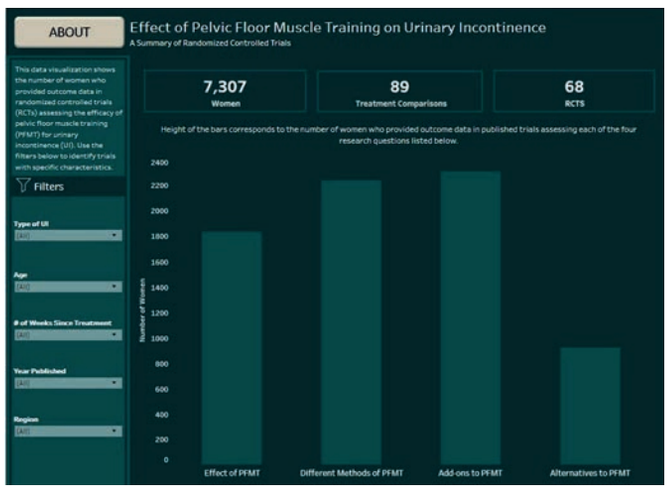
INTERPRETATION OF RESULTS

The TE map (Figure 2) is a bubble chart displaying meta-analytic results in each of the four comparison categories (one tab per category). For each tab, the bubbles are arranged in a grid in which each column is an outcome and each row is a specific treatment comparison. Bubble color indicates the direction of effect (with gray indicating insufficient data), and for non-gray bubbles, the bubble size is linearly related to the meta-analytic point estimate. An asterisk in a cell indicates that there is no evidence on that outcome for that comparison. Hovering over a bubble provides the overall conclusion for that bubble, and clicking on a bubble gives more details including the meta-analytic summary estimate and confidence interval, a forest plot, and hyperlinks to trial abstracts. The first tab has 2 interactive filters down the left side (type of UI and age), whereas the other 3 tabs only have a type-of-UI filter. Using the filters redraws the bubbles accordingly. Note that the TE map only includes comparisons investigated by at least 2 studies; data for single-study comparisons are accessible by clicking a box below the filters.

CONCLUDING MESSAGE

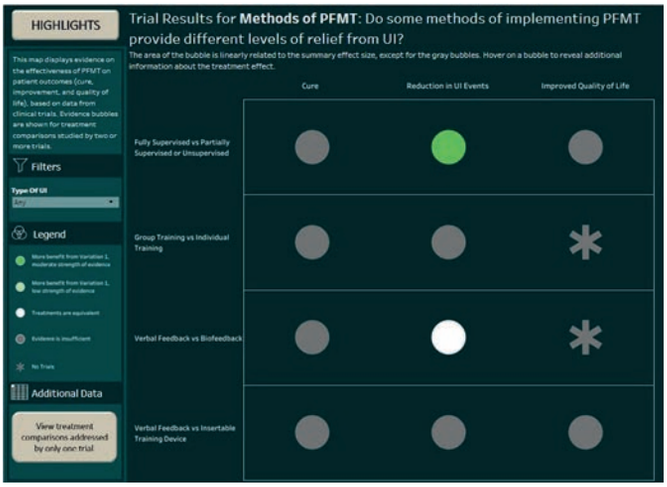
Evidence is often voluminous and confusing. Carefully constructed evidence maps can efficiently use bars, bubbles, and colors to accelerate users' understanding of the evidence. Interactive features, such as filters, hovers and clicks, allow users to tailor the display to their clinical interests and desired detail.

FIGURE 1



Research Volume Map

FIGURE 2



Funding Patient-Centered Outcomes Research Institute (PCORI) **Clinical Trial** No **Subjects** None

SESSION 5 (PODIUM SHORT ORAL) - OAB: NEUROMODULATION AND UNUSUAL ASSOCIATIONS
Abstracts 46-57
11:00 - 12:30, Pavilion 9
Chairs: Prof Philip Edward Van Kerrebroeck (Belgium), Dr Michael Joseph Kennelly (United States)

46 www.ics.org/2020/abstract/46

PREVALENCE OF SHORT TERM FALSE POSITIVES AFTER SACRAL NEUROMODULATION: A DESCRIPTIVE SINGLE CENTRE STUDY.

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HYPOTHESIS / AIMS OF STUDY

Sacral neuromodulation (SNM) is a two-stage surgical procedure for refractory bladder dysfunctions and faecal incontinence. Appropriate screening for success during the test period (Stage I) to determine a good candidate for a full implant (Stage II) is crucial since the high financial burden for the social security. Ideally screening of subjective and objective success is performed by the evaluation of standardized patient reported outcome measures (PROMS) and an accurate analysis of bladder and/or bowel diaries, so as standard of care prescribes. We aimed to carry out a quality control on our own tertiary centre screening and decision strategy by answering the following research questions: 1) Is the current decision strategy on our SNM patient population applied conform the standard of care? 2) What is the current prevalence of false positive cases at short term follow-up, i.e. 1 month after Stage II? and 3) Can we reduce the number of false positive cases by applying the standard of care?

STUDY DESIGN, MATERIALS AND METHODS

A single tertiary centre prospective study was held between February 2018 and October 2019. Fifty-three patients planned for a two-stage tined lead procedure, from both the Urology (UD) (n= 36) and Colorectal surgery department (CRD) (n=17) were enrolled. According to the current practice, the decision to proceed from Stage I to Stage II (i.e. positive advice) was made at the control visit during the test period. The evaluation was accomplished based on a quick, rather intuitive screening for changes in bladder and bowel diary parameters and on the anamnesis of patient satisfaction. As a quality control on the physician's advice for implant, a mathematical re-analysis of bladder and bowel diaries was performed after the control visit. An improvement of at least 50% in one or more of the bothersome voiding and/or bowel diary parameters was considered as objective success (ObS). Subjective success (SS) was defined as a score of ≥ 5/7 on the validated Patient Global Impression of Change (PGIC) questionnaire, administered at the end of the test period (PGIC1) and at 1 month after Stage II (PGIC2). Correct advice according to standard of care was fulfilled if both ObS and SS were present. False positive cases were defined as patients reporting a PGIC2 score < 5/7 (no change to somewhat better, but hardly any difference), in spite of having SS during the test phase and being implanted. Patients with missing PCIG1 scores and missing diaries were excluded from analyses (n=12). Descriptive statistics using SPSS version 25.0 were performed.

RESULTS

Forty-two patients were included for analysis, median age (IQR) 52 years (46-64), 76% female. Indications were OAB wet (n=10), OAB dry (n=2) & bladder pain syndrome (BPS) (n=2), non-obstructive urinary retention (n=6), Fowler syndrome (n=5), faecal incontinence (n=7) and combined incontinence (n=10). The total conversion rate was 81% (34/42), with a 81% (26/32) and 80% (8/10) implantation rate for UD and CRD respectively. 1) A positive advice for implantation had a positive predictive value (PPV) of 94% (32/34) to predict the presence of both ObS and SS and a negative predictive value (NPV) of 75% (6/8). This implicates that 9% of the cases (4/42) got incorrect advice for implantation conform the criteria of standard of care. 2) Twenty-eight patients from the 34 implanted cases completed the PGIC2 questionnaire. Continued SS (PGIC2 ≥ 5/7) was reported in 89% (24/27), implicating a prevalence of false positive cases of 11% (3/27). In one case subjective success at 6 months follow-up was restored after reprogramming. 3) Two on 4 implanted cases with absence of SS at 1 month follow-up, did not show concomitant ObS and SS during the test phase, the other 2 on 4 did.

INTERPRETATION OF RESULTS

1) Ninety-one percent (38/42) of the advices under the current decision practice were given conform the criteria of standard of care. However, 2 patients being good candidates for a full implant were incorrectly refused from Stage II, whereas 2 patients who did not show both ObS and SS during the test phase got incorrectly a positive advice for implant. 2 + 3) The prevalence of false positives is rather low. However, this number could have been reduced if both the objective and subjective changes would have been assessed by thorough mathematical diary analysis and the use of a standardized questionnaire. Nevertheless, a small percentage (2/4) of cases with loss of SS at 1 month follow-up couldn't have been avoided if standard of care would have been applied. The sample size of false positive cases was too small to conduct a multivariate analysis in search of predictive factors for this loss of SS, but a possible placebo effect should be kept in mind.

CONCLUDING MESSAGE

Ninety-one percent of the advices for implantation in our tertiary centre met the criteria of standard of care. Moreover, the prevalence of false positives at one month follow-up showed to be low. Thorough analysis of both objective and subjective success and the requisite of meeting both criteria can reduce the number of false positive cases at 1 month, but cannot completely avoid them. In the future more research is needed to define factors, others than inaccurate screening, that can predict loss of subjective success.

FIGURE 1

Table 1: ObS + SS according to the advice for implantation.

		ObS + SS1		
		No	Yes	Total
Advice for implantation	Negative	6	2	8
	Positive	2	32	34
	Total	8	34	42
PVW: 94 % (32/34), NVW 75 % (6/8)				

Objective + subjective success according to the advice for implantation

FIGURE 2

Table 2: Subjective success at 1 month according to ObS + SS during the test phase.

		SS2		
		No	Yes	Total
ObS + SS1	No	2	0	2
	Yes	2	24	26
	Total	4	24	28
PVW: 94 % (32/34), NVW 75 % (6/8)				

Subjective success at 1 month according to ObS + SS during the test phase

Funding This study is part of the OptiLUTS trial, funded by the Optiluts chair handed out by Medtronic. **Clinical Trial** Yes **Registration Number** EC/2018/0244 **RCT** No **Subjects** Human **Ethics Committee** Ethics Comitee of the Ghent University Hospital. **Helsinki** Yes **Informed Consent** Yes

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STIMULATION OUTPUT AND TISSUE IMPEDANCE OVER 6-MONTHS OF SACRAL NEUROMODULATION THERAPY WITH A CONSTANT CURRENT SYSTEM

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HYPOTHESIS / AIMS OF STUDY

Neuromodulation systems can deliver electrical stimulation either as constant voltage (CV) or constant current (CC). CC systems adjust their output to deliver consistent stimulation current to the body when tissue impedance changes, while a

CV system allows the current output to vary with impedance, which may impact stimulation efficacy. Sacral neuromodulation (SNM) is a guideline-recommended neuromodulation treatment for urinary dysfunctions and fecal incontinence [1]. The ARTISAN-SNM study was designed to evaluate the safety and effectiveness of the Axonics System, a constant current SNM system, for the treatment of urinary urgency incontinence (UUI). This abstract provides a summary of the stimulation output and impedance over the first 6 months of therapy.

STUDY DESIGN, MATERIALS AND METHODS

129 participants with UUI across 19 centers were treated with the Axonics System. Participants were implanted with a tined lead and neurostimulator in a non-staged procedure and programmed post-operatively or within 2 weeks of implant. At 6-months, 125 participants are included in this analysis, which utilizes their stimulation parameter and impedance data recorded at their study visits. Impedance values reported here is the impedance at the active stimulation electrodes, and voltage was calculated using Ohm's law (Voltage =Impedance * Current).

RESULTS

Across the 125 participants, active electrode impedance increased from 1,004 Ω (±310) at activation to 1,460 Ω (±355) at 6 months, an average increase of 42%. Stimulation current increased from 1.1 mA (±0.5) at activation to 1.6 (±0.8) at 6 months, and the stimulation output voltage increased from 1.1 V (±0.8) to 2.3 V (±1.2). Stimulation output voltage increased by 109%, while stimulation current increased by 45%.

Sub-analysis was conducted in 78 participants that remained on the same active electrode configuration from 1 month to 6 months (Figure 1). The average stimulation amplitude across the 78 participants increased from 1.41 mA to 1.55 mA, an increase of 10%. During this period, the voltage output increased from 1.48 V to 2.26 V, an increase of 53%. Across these participants, 68% of the participants experienced a <25% increase in current output at 6 months, including 35% experiencing a <5% increase. In contrast, 75% of participants experienced a >50% increase in output voltage, including 24% experiencing a >75% increase compared to activation.

INTERPRETATION OF RESULTS

Electrode impedance increases significantly in the first 6 months of SNM therapy. Stimulation with a constant current SNM system results in a modest increase in stimulation current while stimulation output voltage increases by a significantly greater degree.

CONCLUDING MESSAGE

Constant current SNM systems may reduce patient or clinician adjustment of therapy by providing consistent stimulation current to the sacral nerve despite changing tissue impedance at the stimulating electrodes.

FIGURE 1

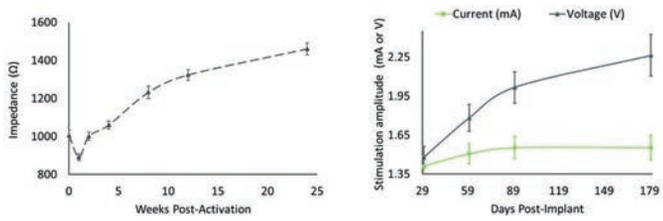

Figure 1. Left: Change in impedance of the active electrode configuration from 0 to 6 months post-implant. Right: Current and voltage output from 1 month to 6 months post-activation.

REFERENCES

1. Gormley EA, Lightner DJ, Faraday M, Vasavada SP. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. J Urol. 2015 May;193(5):1572-80.

Funding Axonics Modulation Technologies, Inc. **Clinical Trial** Yes **Registration Number** NCT03327948 **RCT** No **Subjects** Human **Ethics Committee** IRB **Helsinki** Yes **Informed Consent** Yes

48 www.ics.org/2020/abstract/48

COMPARING THE EFFICACY OF ONABOTULINUMTOXINA, SACRAL NEUROMODULATION, AND PERIPHERAL TIBIAL NERVE STIMULATION AS THIRD LINE TREATMENT FOR THE MANAGEMENT OF OVERACTIVE BLADDER SYMPTOMS IN ADULTS: SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

Hypothesis /Aims: The American Urological Association (AUA) guidelines for the management of non-neurogenic overactive bladder (OAB) recommend the use of OnabotulinumtoxinA , sacral neuromodulation (SNM), and peripheral tibial nerve stimulation (PTNS) as third line treatment options with no treatment hierarchy.

There has not been a direct comparison of the three available treatments, and there has also been a lack of efficiency and safety comparisons between the three treatment options. The current study used network meta-analysis to compare the efficacy of these three modalities for managing adult overactive bladder (OAB) syndrome.

STUDY DESIGN, MATERIALS AND METHODS
Materials and Methods: We performed systematic literature searches of several databases from January 1995 to September 2019 with language restricted to English.

All randomized control trials that compared any dose of OnabotulinumtoxinA, sacral neuromodulation (SNM), and peripheral tibial nerve stimulation (PTNS) with each other or a placebo for the management of adult overactive bladder (OAB) were included in the study.

RESULTS
Results: The initial search identified 1940 and 5722 potential studies from PubMed and EMBASE, respectively. After the removal of duplicates the total number of articles was 7662. After screening, a total of 5738 articles were excluded based on their title and/or abstract, while another 185 articles were removed after a full-text assessment. A total of 20 articles met the qualitative inclusion criteria, while 17 trials, including 3038 participants, met the criteria for systematic review and network meta-analysis. These 17 randomized control trials, with a follow up of 3–6 months in the predominance of trials (range 1.5–24 months), were included for analysis. For each trial outcome, the results were reported as an average number of episodes of the outcome at baseline.

INTERPRETATION OF RESULTS
Pairwise meta-analysis revealed that all three modalities were more efficacious than a placebo with regard to the outcomes of interests, including urinary frequency, incontinence, and achieving ≥50% of symptoms improvement. SNM achieved the greatest reduction in urinary incontinence episodes and voiding frequency/day. OnabotulinumtoxinA was associated with the highest risk of urine retention and UTI episodes in the follow-up period. As none of the included studies used a unified or standard questionnaire to evaluate the QoL, the results regarding QoL were not pooled for the meta-analysis. We suggested that International Continence Society or International Urogynecology Association should unify the QoL questionnaire based on evidence and experts' opinion for a better evaluation of post treatment result. Compared with OnabotulinumtoxinA and PTNS, SNM resulted in the greatest reduction in urinary incontinence episodes and voiding frequency.

CONCLUDING MESSAGE
Conclusion: The results revealed that all three modalities were efficacious in managing adult OAB syndrome, and all were better than a placebo on the specific symptoms reported to be the outcome of the study. This review shows that at 12 weeks follow-up, SNM yielded the greatest reduction in urinary incontinence episodes and urinary frequency/day. OnabotulinumtoxinA resulted in a higher incidence of complications, including urinary tract infection and urinary retention. However, comparison of their long-term efficacy was lacking. Further studies on the long-term effectiveness of the three treatment options, with standardized questionnaires and parameters are warranted.

Funding Division of Urology, Department of Surgery, Taipei Tzu Chi Hospital, The Buddhist Tzu Chi Medical Foundation, New Taipei, Taiwan **Clinical Trial** No **Subjects** Human **Helsinki** Yes **Informed Consent** Yes

49 www.ics.org/2020/abstract/49

EFFICACY OF SACRAL NEUROMODULATION THERAPY ON PATIENT REPORTED URINARY SYMPTOMS AND BOWEL SYMPTOMS ACCORDING TO THE MEDICAL DEPARTMENT: A PROSPECTIVE SINGLE CENTRE STUDY.

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HYPOTHESIS / AIMS OF STUDY
Sacral neuromodulation (SNM) is a widespread therapy for refractory lower urinary tract symptoms (LUTS) and faecal incontinence. Patients are separately managed by the Urology department (UD) or the Colorectal surgery department (CRD). Additionally, history taking is usually directed to discipline specific symptoms, with urologists focusing on LUTS and colorectal surgeons focusing on bowel dysfunctions. The aim of this interim-analysis was to report the prevalence of baseline concomitant bowel symptoms and urinary symptoms in patients consulting the UD and CRD respectively. Secondly, we aimed to explore the efficacy of SNM on non-discipline specific patient reported outcome measures (PROMs) in the patient groups of each medical department.

STUDY DESIGN, MATERIALS AND METHODS
A single centre prospective study was held between February 2018 and March 2020. Patients planned for a 2 staged tined lead procedure using the InterStim II® system, consulting the UD or the CRD for LUTS and/or bowel dysfunctions were enrolled. Approvement from the Ethics Committee of the University Hospital of Ghent was obtained (EC/2018/0244). The decision to proceed from first stage to definitive implant was based on the assessment of bladder or bowel diaries and patient reported satisfaction. Independently from the treating physician's advice for implant, all patients were asked to complete a battery of Dutch PROMs on an online

survey platform. The survey was completed at different time points: at baseline, at the end of the test phase, 1 month, 6 months and 12 months after the definitive implant. The survey consisted of the following questionnaires: the male and female International Consultation on Incontinence Questionnaire (ICIQ-MLUTS and ICIQ-FLUTS), the ICIQ on urinary Incontinence short form (ICIQ-UI-SF), the ICIQ-Bowel (ICIQ-B), the Wexner Score for faecal incontinence and the Cleveland Constipation Score (CCS). For each scoring system, a higher score marked a higher grade of symptoms. Additionally, patients were asked if they had urinary symptoms or bowel symptoms ('yes or no'). Concomitant bother from urinary symptoms (US) and bowel symptoms (BS) had to be rated on a numeric rating scale from 0 (no bother at all) to 10 (extremely bothered). For this interim-analysis, only absolute changes between the test phase and baseline PROMs scores were analysed. Patients with missing PROMs were excluded. Descriptive and analytical statistics were performed using SPSS Statistics 25. A paired samples t-test was used for a paired comparison between questionnaires with normally distributed outcome data, using means and standard deviations. A Wilcoxon Signed Rank Test was used for questionnaires with non-normal distributed outcome data, using medians and interquartile ranges. P-values below 0,05 were considered as statistically significant. The analyses were performed for each medical department separately.

RESULTS

Fifty patients were included for analysis, mean (SD) age 52 (15) years, 78% female. The indications for which patients underwent the first stage procedure are listed in table 1. In the UD consulting group, 20/33 (61%) patients reported to have concomitant bowel symptoms, 5 among them with combined incontinence. In the CRD group, 9/17 (53%) reported to have concomitant urinary problems, 4 among them having combined incontinence. The implantation rates for the UD and CRD were 88% (29/33) and 88% (15/17) respectively. After the first stage, UD patients showed a significant reduction in all Urinary PROMS (U-PROMs), as well in all Bowel PROMS (B-PROMs) except from a reduction in the Wexner score. CRD patients showed a significant reduction in all B-PROMs, except from a change in CCS scores. A significant reduction of ICIQ-UI scores and a trend towards significant reduction of US bother scores and ICIQ-FLUTS scores were seen in CRD patients. Outcomes for baseline and test phase PROMs are listed in table 2.

INTERPRETATION OF RESULTS

The prevalence of patient reported bowel symptoms in UD patients, undergoing SNM for urinary indications is high. This study demonstrates that apart from a significant decrease in urinary symptoms, also bowel symptoms can significantly improve after the first stage in this UD group. More than half of the patients consulting the CRD undergoing SNM for bowel indications also report to have urinary symptoms. In the CRD patients, the results suggest an improvement in concomitant urinary symptoms as well, after the first stage. However, the sample size of CRD patients might have been too small to discover significant changes in all urinary symptom scores. No comparisons between the two medical departments can be made since the sample sizes of patients were not equal between both groups. These findings however do suggest that in the future, all UD and CRD patients should be counselled on the positive effect of SNM on both urinary and bowel symptoms, regardless of which symptoms are the most prominent. Therefore, in both medical departments a more holistic approach in the assessment of pelvic floor symptoms is needed. Both for baseline screening and evaluating the therapeutic efficacy of SNM, both bladder and bowel diaries and non-discipline specific PROMs should be used.

CONCLUDING MESSAGE

In both the Urology and Colorectal surgery department the prevalence of concomitant non-discipline specific symptoms is high. UD patients undergoing SNM for urological indications are likely to show an improvement on bowel symptoms as well. Analogously, CRD patients receiving SNM for bowel indications might also show improvement in urinary symptoms. However, in the future, bigger sample sizes are needed to draw more robust conclusions. Nevertheless, a multidisciplinary assessment of pelvic floor symptoms in every SNM candidate is appropriate to deliver optimal holistic care.

FIGURE 1

Table 1: Indications for SNM according to the medical department.

		Medical department		
		Urology (n)	Colorectal surgery (n)	Total (n)
Indications	OAB wet	14	0	14
	OAB dry	3	0	3
	Non-obstructive urinary retention	6	0	6
	Fowler syndrome	5	0	5
	Faecal incontinence	0	13	13
	Combined incontinence	5	4	9
Total				50

Table 1: Indications for SNM according to the medical department.

FIGURE 2

Table 2. PROMs scores at baseline and during the test phase according to the medical department.

	Patients consulting the Urology department (n= 33)					Patients consulting the Colorectal surgery department (n=17)				
PROMs (Score range)	**N**	**Baseline score** Mean (SD)* or Median (IQR)**	**Test phase score** Mean (SD)* or Median (IQR)**	***	**p-value**	**N**	**Baseline score** Mean (SD)* or Median (IQR)**	**Test phase score** Mean (SD) or Median (IQR)	***	**p-value**
U-PROMs										
ICIQ-MLUTS (0-44)	7	20,43 (8,48)	13,14 (8,48)	-7,28 (6,08)	0,019*	3	18,33 (12)	14 (4,36)	-4,33 (8,51)	0,471
ICIQ-FLUTS (0-48)	26	22,12 (8,34)	12,5 (6,61)	-9,61 (10,18)	< 0,001*	14	10, 07 (5,80)	7,64 (3,82)	-2,43 (4,51)	0,066
ICIQ-UI (0-21)	33	13 (0-17)	6 (0-8,5)	- 3,28	0,001*	17	3 (0 – 5,5)	0 (0-4)	-2,37	0,018*
US bother scale (0-10)	33	8 (7-10)	3 (1-5)	-4,32	<0,001*	17	1 (0-5,5)	0 (0-2)	-1,91	0,056
B-PROMs										
ICIQ-Bowel (1-75)	33	20 (9,75 -34)	12 (7,5-18,5)	-3,76	<0,001*	17	48,97 (6,72)	29,68 (14,05)	-19,29 (11,18)	< 0,001*
Wexner (0-20)	33	4 (0,5-9,5)	4 (1,5-6)	- 1,94	0,052	17	15,88 (3,16)	9 (5,37)	-6,88 (3,87)	< 0,001*
CCS (0-30)	33	11 (4-14)	5 (3-9,5)	-3,008	0,003*	17	7,47 (3,50)	5,47 (3,64)	-2 (1,21)	0,119
BS Bother scale (0-10)	33	3 (0-7)	1 (0-3)	-3,12	0,002*	17	8 (7 – 8,5)	3 (1,5-5)	-3,42	0,001*

* If means (SD) are reported, a paired samples t-test was used.
** If medians (IQR) are presented a Wilcoxon Signed Rank test was used.
*** Mean (SD) difference between test phase and baseline score * or z-score if the Wilcoxon Signed Rank Test was used**.
\+ Significant p-values: p < 0,05.

Table 2. PROMs scores at baseline and during the test phase according to the medical department.

Funding This research was funded by the Medtronic OptiLUTS chair. **Clinical Trial** Yes **Registration Number** EC/2018/0244 **RCT** No **Subjects** Human **Ethics Committee Ethics Committee** University Hospital Ghent **Helsinki** Yes **Informed Consent** Yes

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REINVIGORATING MODULATION OF SPINAL REFLEX PATHWAY FOR TREATMENT OF BLADDER OVERACTIVITY IN PATIENTS WITH SPINAL CORD INJURY BY SURFACE STIMULATION OF SOLE OF FOOT.

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HYPOTHESIS / AIMS OF STUDY

To reduce detrusor overactivity by modulating spinal reflex pathways using surface electrical stimulation at sole of foot in patients with spinal cord injury.

STUDY DESIGN, MATERIALS AND METHODS

Patient having urinary incontinence and symptoms of detrusor overactivity, were invited to try electrical stimulation of sole of the foot. Patients were asked to withdraw drugs pertaining to treatment of detrusor overactivity (if any) and were also asked to maintain voiding chart one week prior to the treatment. Twenty patients, meeting key inclusion/exclusion criteria, consented for the study.

Following inclusion/exclusion criteria were used for the study:-

Inclusion criteria:

1. Patient with spinal cord injury having at least one leak per day as reported in the voiding chart.
2. CMG proven detrusor overactivity
3. On Clean Intermittent Catheterization
4. Presence of Ankle jerk
5. Age-18 years and above.

Exclusion criteria:

1. Peripheral neuropathy
2. Urinary tract infection
3. Pregnant women
4. Any psychiatric ailment
5. Symptoms of stress urinary incontinence
6. Presence of any implantable devices such as pacemaker, cochlear implant or any metallic implantable plate were contraindication for this study.

All the patients maintained voiding chart for two weeks during the treatment. Cystometrogram was done on day 1 and 15. Electrical stimulation was given half-an-hour daily for fourteen consecutive days. The Parameters for stimulation were 200 µs pulse width, rectangular pulses with current strength ranging between 10–80 mA and frequency 20 Hz (1). Cathode was placed at the level of medial arch of foot while anode was placed approximately 2cm apart at the level of metatarsophalangeal (MTP) joint. The electrodes were customized to fit the site of stimulation for each patient. In-house developed stimulator costing less than Rs 2000, was used. Satisfaction questionnaire were taken on day 15. Voiding chart data was analyzed using novel Cumulative Voiding Chart Index(CvCi). In CvCi , each voiding chart parameter was graded either -1 (worsen), 0 (no change) or +1 (improved) as a representation of state of the bladder (pre and post-intervention). Wilcoxon signed-ranked test was used for CMG data while Binomial distribution for voiding chart data as test of significance. The p-value<0.05 was considered as significant. Study was approved by Institutional review board and ethics committee.

RESULTS

Twenty subjects were stimulated at the sole of foot for two weeks.

There was improvement in reflex volume, cystometric capacity and maximum detrusor pressure. Following treatment, 12 subjects showed increase, 6 showed decrease and 2 had no significant change in reflex volume. There was significant improvement in cystometric capacity of 14 subjects, 3 did not show much improvement and remaining persons showed reduced bladder capacity. Thirteen patients had reduction, 3 had increase and 4 had no significant change in maximum detrusor pressure.

Eighteen patients showed improvement in bladder function and two subjects did not show any signs of improvement as reported by CvCi score derived from voiding chart.

INTERPRETATION OF RESULTS

The p-value for improvement in cystometric capacity (p-value-0.04) and maximum detrusor pressure (p-value-0.03) was statistically significant while p-value of reflex volume (p-value-0.13) was not significant.

The CvCi scoring shows that 18 patients had improvement in bladder capacity / number of leaks /maximum urine output after two weeks of electrical stimulation therapy while 2 patients did not shown any improvement.

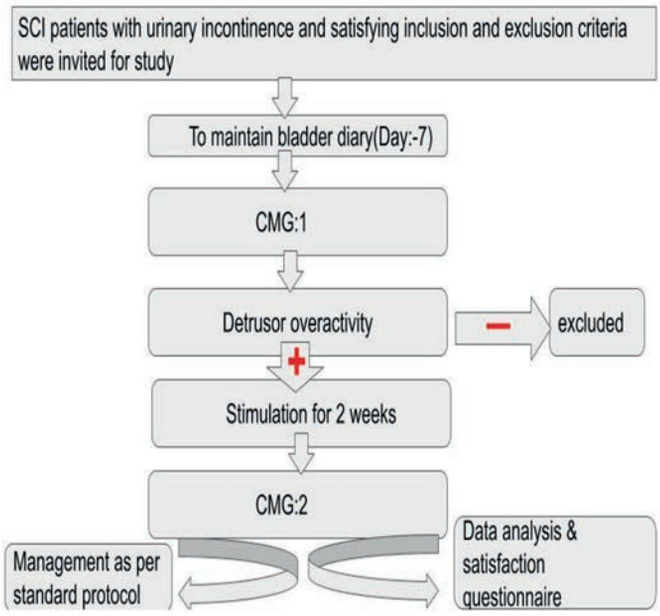
The Binomial distribution test conducted on improved population against not improved population was found to have significant p value(p-value 0.001).

In regards to satisfaction with feedback questionnaire, all patient were satisfied with treatment methodology and easy to use procedure.

CONCLUDING MESSAGE

Neuromodulation by surface electrical stimulation at sole of foot is simple, non-pharmacological, non-invasive, inexpensive, promising alternative treatment modality for reducing bladder overactivity.

FIGURE 1



Flowchart of study

REFERENCES

1. Ojha R, George J, Chandy BR, Tharion G, Devasahayam SR. Neuromodulation by surface electrical stimulation of peripheral nerves for reduction of detrusor overactivity in patients with spinal cord injury: A pilot study. The Journal of Spinal Cord Medicine. 2015 Mar 1;38(2):207–13.

Funding Institution review board, Christian medical college, Vellore, India **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Institutional review board, Christian medical College, Vellore, India **Helsinki** Yes **Informed Consent** Yes

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PREDICTIVE FACTORS OF PNE SUCCESS IN A CONTEMPORARY SERIES: A SINGLE INSTITUTION EXPERIENCE

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HYPOTHESIS / AIMS OF STUDY

Peripheral nerve evaluation (PNE) permits a trial of sacral neuromodulation to determine candidates for permanent system implant in a single operation. Pre-fluoroscopy PNE success rates with unipolar leads are typically quoted at 40-50%, whereas staged procedures with tined quadripolar leads have an estimated 77% success rate [1,2]. With the availability of in-office fluoroscopy and improved technique over time, more contemporary data on PNE success rates appear limited. This study evaluated a recent series of PNE pa-

tients to determine predictive factors toward PNE screening success and persistent functional response following permanent system implant.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective review of all patients who underwent PNE at a large academic center from 2015-2019 was performed. All unipolar leads were placed percutaneously in-office under local anesthesia utilizing fluoroscopy by one of four FPMRS fellowship-trained providers. Patients with refractory urgency-frequency and/or urge urinary incontinence were included, while those with chronic urinary retention were excluded. Rates of full system implant after successful PNE trial and continued improvement at ≥1-month following permanent implant were reviewed. Multivariable logistic regression determined predictors of PNE success and continued functional success at follow-up.

RESULTS

102 PNE patients (87 females and 15 males) were included. Mean age was 65.9 years and BMI was 29.4. Median ASA score was 3. Bilateral leads were placed in 95 patients (93.1%). 78 patients (76.5%) were PNE responders (≥50% symptom improvement). Median postoperative follow-up time was four months following permanent implant. On multivariate analysis, patient predictors of PNE success included younger age (p=0.014), urge incontinence (p=0.021), fecal incontinence (p=0.017), and absence of a neurologic diagnosis (p=0.04). PNE factors associated with satisfactory screening included presence of bellows and plantar toe flexion (p=0.038), and perineal sensation (p=0.027) (Table). 68 patients (87.2% of PNE responders [68/78] and 66.7% of all patients [68/102]) had a successful working implant at ≥1-month follow-up. Absence of a neurologic diagnosis was predictive of persistent implant success on long-term follow-up (p=0.013).

INTERPRETATION OF RESULTS

This contemporary series of unselected patients undergoing PNE with fluoroscopy revealed screening success rates (76.5%) equivalent to available reports on staged implant (approximately 77%). Patient predictors of PNE success included younger age, urge incontinence, fecal incontinence, and absence of a neurologic diagnosis. PNE testing factors associated with satisfactory screening included presence of bellows and plantar toe flexion, and perineal sensation. In this broad group of PNE patients, 67% of all patients demonstrated an optimal response following permanent implant at ≥1-month follow-up. Conversion from successful screening test to permanent implant may not be the ideal outcome and evaluation for persistent improvement should be considered as an indicator of successful screening.

CONCLUDING MESSAGE

This contemporary series of unselected patients undergoing PNE with fluoroscopy revealed screening rates equivalent to available reports on staged implant. Patient predictors of PNE success included younger age, urge incontinence, fecal incontinence, and absence of a neurologic diagnosis. 67% of all patients demonstrated an optimal response following permanent implant at ≥1-month follow-up. We suggest success of the permanent implant be considered when defining PNE "success" rates.

FIGURE 1

	PNE Responders (n=78)	PNE Non-Responders (n=24)	p*
Patient Factors			
Age, mean (SD)	64.2 (SD 16.3)	71.4 (SD 12.6)	**0.014**
Gender, n (% Female)	66 (84.6)	21 (87.5)	0.14
BMI, kg/m^2 (SD)	29.7 (5.4)	28.6 (5.6)	0.12
Coronary Artery Disease, n (%)	13 (16.7)	3 (12.5)	0.36
Congestive Heart Failure, n (%)	2 (2.6)	1 (4.2)	0.44
Hypertension, n (%)	47 (60.3)	13 (54.2)	0.25
Hyperlipidemia, n (%)	34 (43.6)	10 (41.7)	0.81
Chronic Obstructive Pulmonary Disease, n (%)	7 (9.0)	0 (0)	0.30
Diabetes Mellitus, n (%)	21 (26.7)	2 (8.3)	0.21
Cerebrovascular Accident, n (%)	8 (10.3)	3 (12.5)	0.42
Obstructive Sleep Apnea, n (%)	22 (28.2)	3 (12.5)	0.71
Neurologic Diagnosis, n (%)	5 (6.4)	8 (33.3)	**0.04**
Urge Urinary Incontinence, n (%)	69 (88.5)	19 (79.9)	**0.021**
Fecal Incontinence, n (%)	11 (14.1)	0 (0)	**0.017**
PNE Test Factors			
Bilateral Leads, n (%)	72 (92.3)	23 (95.8)	0.37
At Least Bellows, n (%)	67 (85.9)	21 (87.5)	0.41
At Least Toe Plantar Flexion, n (%)	63 (80.8)	20 (83.3)	0.056
Bellows and Toes, n (%)	63 (80.8)	19 (79.2)	**0.038**
Sensation, n (%) Rectal Perineal None	 20 (25.6) 55 (70.5) 3 (3.8)	 9 (37.5) 11 (45.5) 4 (16.7)	**0.027**

Comparison of Patient and PNE Test Factors in PNE Responders and Non-Responders

REFERENCES

1. Janknegt RA, Weil EH, Eerdmans PH. Improving neuromodulation technique for refractory voiding dysfunctions: two-stage implant. Urology. 1997 Mar;49(3):358-62.
2. Spinelli M, Weil E, Ostardo E, et al. New tined lead electrode in sacral neuromodulation: experience from a multicenter European study. World J Urol. 2005 Jul;23(3):225-9.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This is a retrospective chart review **Helsinki** not Req'd This is a retrospective chart review **Informed Consent** No

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LONG-TERM RECHARGING EXPERIENCE IN PATIENTS USING THE AXONICS SNM SYSTEM

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HYPOTHESIS / AIMS OF STUDY

Sacral neuromodulation (SNM) is a guideline-recommended treatment for urinary dysfunctions and fecal incontinence [1]. The Axonics® System is the first rechargeable SNM System approved in United States, Europe, Canada and Australia to provide therapy for at least 15 years. Use of rechargeable SNM systems could potentially eliminate or significantly reduce the number of replacement surgeries required due to battery depletion of non-rechargeable neurostimulators. Further, the use of long-lived rechargeable systems could result in significant cost savings for healthcare systems [2]. The ARTISAN-SNM study treated urinary urgency incontinence (UUI) patients with the rechargeable Axonics System. Study participants' long-term recharging experience is presented.

STUDY DESIGN, MATERIALS AND METHODS

129 participants with UUI across 19 centers in the US and Europe were implanted with the Axonics System in a single, non-staged procedure. Participants were provided detailed instructions on how to recharge their implanted neurostimulator (INS), including the audiovisual feedback designed to indicate a fully recharged INS. Participants were instructed to recharge every 7 days but were not discouraged from forming recharging habits that suited their lifestyle. For example, participants may choose a longer recharging session every 14 days instead of a shorter recharging duration every 7 days. Patients reported their typical charge frequency and duration at each scheduled follow-up visit. Recharge duration per week was calculated as (Recharge duration / Number of days between recharge) * 7. Average and standard error (SE) are reported as appropriate. Recharging outcomes at 18 months are compared with recharging outcomes at 3 months to evaluate how the charging experience changed over time. The completers analysis is presented.

RESULTS

Across the 129 study participants, average age was 59.3 years old (range: 21 - 86 years) and the average body mass index (BMI) was 32 (range: 18-58).

The average (± SE) participant reported recharge duration per week was 46 ± 2 minutes at 3 months (Figure 1). At 18 months, the average study participant reported recharge duration per week was 44 ± 2 minutes, which was slightly shorter but not significantly different as compared to the recharge duration per week at 3 months ($p = 0.1$). A vast majority of the study participants (84%) reported recharging for less time or within 10 minutes more than their charging duration at 3 months (Figure 1). Ninety-six percent (114 of 119) of the study participants reported recharging their Axonics SNM System every 7 days or less frequently, and 89% of the study participants reported recharging for an hour or less. Ninety three percent of the study participants reported that recharging was easy and acceptable, and 94% of the study participants were satisfied with the SNM therapy. Participant satisfaction with therapy and perception that recharging was easy and acceptable was consistently high across study visits (Figure 2).

Study participant age was not correlated with recharging duration per week ($R2 = 0.03$). Study participant BMI was not correlated with recharging duration per week ($R2 = 0.01$).

INTERPRETATION OF RESULTS

A vast majority of study participants find recharging to be easy & acceptable through 18 months post-implant. Recharging duration per week at 18 months was consistent with that at 3 months, indicating no decline in battery efficiency. Age and BMI were not correlated to recharging duration per week, indicating the applicability of results to a wide population. Participant recharging experience and satisfaction with the Axonics System is consistent with similarly high satisfaction rates with rechargeable spinal cord and deep brain neurostimulators [3].

CONCLUDING MESSAGE

A vast majority of the study participants, with diverse demographics, reported that the recharging experience with the Axonics System is easy and acceptable. These results provide compelling rationale for widespread adoption of the rechargeable Axonics SNM system.

FIGURE 1

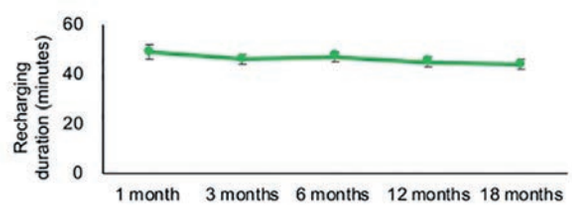

Figure 1: Average recharging duration per week

FIGURE 2

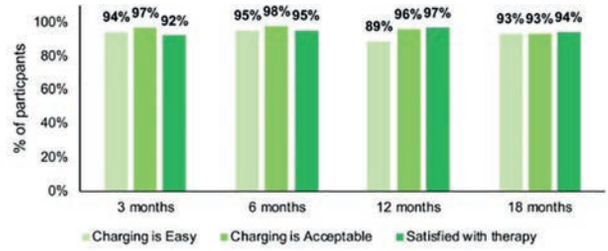

Figure 2: Participant satisfaction with therapy and recharging

REFERENCES

1. Gormley EA, Lightner DJ, Faraday M, Vasavada SP. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. J Urol. 2015 May;193(5):1572-80.
2. Noblett KL, Dmochowski RR, Vasavada SP, Garner AM, Liu S, Pietzsch JB. Cost profiles and budget impact of rechargeable versus non-rechargeable sacral neuromodulation devices in the treatment of overactive bladder syndrome. Neurourol Urodyn. 2017 Mar;36(3):727-733.
3. McCrery R, Lane F, Benson K, Taylor C, Padron O, Blok B, De Wachter S, Pezzella A, Gruenenfelder J, Pakzad M, Perrouin-Verbe MA, Le Normand L, Van Kerrebroeck P, Mangel J, Peters K, Kennelly M, Shapiro A, Lee U, Comiter C, Mueller M, Goldman HB. Treatment of Urinary Urgency Incontinence Using a Rechargeable SNM System: 6-Month Results of the ARTISAN-SNM Study. J Urol. 2020 Jan;203(1):185-192.

Funding Axonics Modulation Technologies, Inc. **Clinical Trial** Yes **Registration Number** NCT03327948 **RCT** No **Subjects** Human **Ethics Committee** IRB **Helsinki** Yes **Informed Consent** Yes

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ASSOCIATION BETWEEN TOOTH LOSS DUE TO CHRONIC PERIODONTITIS AND OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Metabolic syndrome/lifestyle diseases such as hypertension, diabetes mellitus and obesity are associated with overactive bladder (OAB) and other lower urinary tract symptoms (LUTS). Chronic periodontitis, the leading cause of tooth loss in the elderly, is also associated with metabolic syndrome/lifestyle diseases. However, few studies have examined the relationship between tooth loss/chronic periodontitis and LUTS/OAB. This study aimed to determine the relationship between LUTS/OAB and tooth loss.

STUDY DESIGN, MATERIALS AND METHODS

Individuals aged >40 years who had not been treated for LUTS, and who had lost teeth due to chronic periodontitis were enrolled in the study.

Participants were divided into two groups: the OAB group and non-OAB group according to the Overactive Bladder Symptom Score (OABSS). Individuals with tooth loss from dental caries or external trauma, LUTS due to neurological disease, and males with a prostate size >30g were excluded. OAB was defined as a score ≥2 on OABSS item Q3 (urgency) and a total score ≥3. Multivariate analysis was conducted to assess the relationship between the number of lost teeth and symptoms of LUTS/OAB. All participants provided written informed consent.

RESULTS

A total of 232 participants (OAB group: n=103, non-OAB group: n=129) were enrolled. Their mean age was 70.1±10.5 years and 65.7±10.9 years in the OAB group and non-OAB group, respectively (P=0.001). The number of remaining teeth was 12.8±8.8 and 21.5±8.5 in the OAB group and non-OAB group, respectively (P<0.001). There was a statistically significant inverse association between the number of remaining teeth and each of the OABSS items and the total OABSS (daytime frequency: r=-0.416, P<0.001; nighttime frequency: r=-0.525, P<0.001; urinary urgency: r=-0.474, P<0.001; urgency incontinence: r=-0.290, P<0.001; total OABSS: r=-0.572, P<0.001). The number of remaining teeth was also significantly associated with the voided volume (r=0.303, P<0.001), and maximum flow rate (r=0.219, P<0.001), but was not significantly associated with residual urine volume (r=-0.125, P=0.06). There was a significant inverse association between the number of remaining teeth and serum C-reactive protein (CRP) level (r=-0.264, P<0.001). With the exception of urgency incontinence, serum CRP

level was significantly associated with each OABSS item and the total OABSS (daytime frequency: r=0.152, P=0.02; nighttime frequency: r=0.247, P<0.001; urinary urgency: r=0.262, P<0.001; urgency incontinence: r=0.115, P=0.08; total OABSS: r=0.270, P<0.001). Multivariate analysis revealed that the number of lost teeth was an independent risk factor for OAB (odds ratio: 1.08, 95% confidence interval:1.04-1.14, P<0.001).

INTERPRETATION OF RESULTS
OAB was correlated with the tooth loss and systemic, chronic inflammation. In addition, the severity of OAB was correlated with the tooth loss; thus future studies should focus on the utility of oral care as a means to prevent OAB.

CONCLUDING MESSAGE
In this study, it was suggested that there is a relationship between the number of remaining teeth and LUTS including OAB.

Funding None. **Clinical Trial** No **Subjects** Human **Ethics Committee Ethics Committee** of Nagasaki University Hospital **Helsinki** Yes **Informed Consent** Yes

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FEASIBILITY AND EFFECTIVENESS OF AN INTERPROFESSIONAL MINDFULNESS-INFORMED GROUP-BASED INTERVENTION FOR TREATMENT OF OVERACTIVE BLADDER: A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY
Behavioral interventions are the first-line approach for addressing symptoms of overactive bladder (OAB). Distraction for managing urinary urgency is a common component of behavioral interventions; recently, a focus on mindfulness has been proposed as an alternative to distraction. The primary purpose of this pilot study was to examine the feasibility of implementing a novel mindfulness-informed group-based intervention for OAB, using a modified mindfulness-based stress reduction (MBSR) approach tailored to include behavioral interventions specific to OAB. The secondary purpose was to examine the potential clinical utility of the program by evaluating the results of several outcome measures for indications of effectiveness of the intervention on improving OAB symptoms.

STUDY DESIGN, MATERIALS AND METHODS
This was a single-arm pre-intervention post-intervention pilot study using a convenience sample. No randomization or blinding occurred. Participants were recruited by flyer placement at community venues, a local university, and a local hospital, and via email from area medical providers specializing in the treatment of women with OAB. Inclusion criteria were women > 18 years of age with self-identified OAB symptoms, English language fluency, willingness to undergo screening, and a diagnosis of OAB based on their score on the Overactive Bladder Symptom Score (OAB-SS). Exclusion criteria included current pregnancy, recent urinary tract infection (< 4 weeks), pelvic organ prolapse, any surgery for incontinence, initiation of OAB medication within the last month, previous nonpharmacologic treatment for urinary symptoms (behavioral interventions, physical therapy), past diagnosis of interstitial cystitis or painful bladder syndrome, or any neurological condition affecting bladder sensation. The program was developed by two physical therapists with extensive training and clinical experience in physical therapy management of overactive bladder and one psychologist with specific training in MBSR, and was administered by one of the physical therapists and the psychologist. Participants underwent six weekly group-based 2-hour sessions addressing mindfulness techniques related to bladder sensation and management of urinary urgency as well as healthy bladder habits, pelvic floor muscle exercise, and information on diet and fluid intake. Program feasibility was assessed by measuring the number of potential participants screened, the number enrolled, retention rates, and personnel time spent preparing for and conducting of the sessions. The desired sample size was ten, with plans to proceed with the program as long as at least three participants were available. Potential clinical utility was measured with pre-intervention – post-intervention comparisons of individual scores on the OAB-SS, the University of South Australia Urinary Sensation Assessment (USA2), the 15-item Five-Facet Mindfulness Questionnaire (FFMQ-15), a one-day bladder diary, and a post-intervention 7-point global rating of change (GROC) scale.

RESULTS
Recruitment was limited to four weeks due to unforeseen schedule constraints. Seven women expressed interest in study participation, five of whom completed the initial screening, fit the inclusion criteria and agreed to enroll in the study. One attended the first session and then was unable to continue due to illness and scheduling issues (no USA2, FFMQ-15, or bladder diary data gathered); the other four completed all six sessions (retention rate 80%, 100% session participation rate by retained participants). Total personnel hours (clinicians and assistants combined) for program set-up (including organizing the venue and contacting participants) and delivery were 15 hours/week for the six-week intervention (5 hours for the investigators and 10 hours for the assistants), and 30 hours were spent on recruitment pro-

cedures and screening potential participants. While the desired n was not achieved, the minimum n to administer the program was met. Additionally, the retention goal was met, and the time required to run the study was deemed feasible.

All four participants perceived a benefit from the program, based on improvements on some or all of the outcomes measured. (Table 1) No adverse events were reported. Of note, during the second half of the study all four participants requested referrals to mental health professionals. Contact information for a local counseling center was provided but no data were available regarding how many participants followed up on the referrals.

INTERPRETATION OF RESULTS

The primary purpose of this study was to investigate program feasibility. The original intent was for the program to be eight weeks long, but various delays necessitated shortening it to six weeks and reducing the recruitment period to four weeks. Despite the shortened timeframe, the investigators were able to recruit enough participants to run the program and were able to cover all topics deemed relevant. Regarding the feasibility outcomes, a longer timeline for recruitment would likely allow for larger recruitment numbers. However, given that all topics were adequately covered in six weeks, we believe this to be an appropriate timeframe for this program. Time estimated for clinicians to organize and deliver this program once recruitment was completed was 15 hours per week, making it a potentially effective way to treat OAB in the community.

The secondary purpose was to evaluate the potential clinical usefulness of the program. While the small n negates generalizability of the results, the results support the potential clinical usefulness of the program. The most impactful results were from the OAB-SS and the GROC (Table 1). Three out of four participants met the minimum clinically important difference (MCID) of 3 points on the OAB-SS, indicating a clinically important improvement in their OAB symptoms. Global Rating of Change results indicated all participants perceived a benefit from the program, rating themselves either "somewhat better" (n=2) or "moderately better" (n=2).

This may be the first study to combine mindfulness-informed approaches with traditional behavioral interventions for OAB. The key strength of this study is that it demonstrates feasibility of a novel group-based, mindfulness-informed intervention for OAB, including recruitment, retention, and program time burden. Additionally, the program may be clinically useful in reducing the symptoms of OAB in women. In combination, these results present an opportunity for researchers to further evaluate the program's utility in larger, more diverse samples. If positive results are found in future studies, clinicians may consider re-evaluating their approach to behavioral therapies for OAB to include a component of mindfulness. Weaknesses include the small sample size which was not representative of the population of women with OAB, as well as no long-term follow-up. Future studies should include a longer recruitment period to allow for a larger sample size, as well as a plan for long-term follow-up.

CONCLUDING MESSAGE

Findings from this study provide preliminary evidence in support of the feasibility and potential clinical utility of a group-based mindfulness-informed intervention for women with OAB. Future studies should include a longer recruitment period and more extensive recruiting efforts in order to achieve a larger sample size, and should compare this intervention to other established interventions for OAB as well as the longer-term results of the intervention.

FIGURE 1

Table 1. Participant demographics and outcome measures

	Age	BMI	OAB-SS start/finish, met MCID (yes/no)	USA2 start/finish	FFMQ-15 start/finish	GROC score
Participant 1	73	22.9	9/6 (yes)	32/19	51/48	Somewhat better
Participant 2	65	26.6	14/11 (yes)	49/49	45/45	Somewhat better
Participant 3	23	23.8	6/6 (no)	23/35	43/37	Moderately better
Participant 4	22	20.1	13/6 (yes)	40/48	50/39	Moderately better

Table 1

Funding Pacific University Faculty Development Grant **Clinical Trial** No **Subjects** Human **Ethics Committee** Pacific University Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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A SURVEY OF OAB IN CHINESE JUNIOR UNIVERSITY STUDENTS OF FEMALE AND ITS INFLUENCE ON PSYCHOLOGY

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HYPOTHESIS / AIMS OF STUDY

To investigate the prevalence and related risk factors of overactive bladder disease (OAB) in Chinese junior university students of female, and to evaluate the effect of OAB on their psychology.

STUDY DESIGN, MATERIALS AND METHODS

From September 2019 to January 2020, 14160 22-year-old female junior university students from 2 universities in China were selected and investigated on the epidemiology of OAB by anonymous questionnaire. The questionnaire included basic information, history of urinary tract infection (UTI), lower urinary tract symptoms (LUTS), intestinal symptoms, OAB symptom score (OABSS), Depression scale and Pittsburgh sleep scale. OAB is defined as urinary urgency with or without urgent urinary incontinence, usually with increased

frequency of urine and nocturnal urine, but without urinary tract infections or other exact lesions. The diagnostic criteria of OAB were that the urination urgency score of OABSS was ≥ 2, and the total score was ≥ 3, Dry OAB referred to OAB without urgency incontinence (urgency incontinence score of OABSS=0); wet OAB referred to OAB with urgency incontinence (the urgency incontinence score of OABSS≥1. In addition, the relationships between OAB and sex, age, residence, body mass index (BMI), intestinal symptoms, UTI, menstrual regularity and nocturnal enuresis (NE) were evaluated.

RESULTS

A total of 12701 subjects (age 19 ± 1.0 years) were qualified for statistical analysis. The overall prevalence of OAB was 6.1% (770/12701) in junior university students, the prevalence of dry OAB was 3.8% (478/12701) and wet OAB was 2.3% (292/12701). The prevalence of OAB was related to BMI, NE, constipation, history of UTI and irregular menstruation ($P < 0.05$), but not with residence and age ($P > 0.05$). The depression score of OAB group was higher than that of normal group, and OAB seriously affected the sleep quality of patients.

INTERPRETATION OF RESULTS

The prevalence of OAB in this study is lower than that in other countries, which might be due to differences in OAB definitions, study populations and survey methods. The prevalence of wet OAB is lower than that of female aged 20-29 years old in another study (3.9%), [1]which may be related to the age difference of the investigated population, and the subjects in the current study have a high level of knowledge and a high rate of correct response to the questionnaire. OAB patients frequently use toilets and are afraid to participate in social activities because of urgent and frequent urination, which leads to a series of psychological changes such as inferiority, shame and so on, which seriously affects the mental health of patients.

CONCLUDING MESSAGE

OAB in junior university students of female is common and significant affects the mental health of patients. Obesity, NE, constipation, UTI and irregular menstruation are the risk factors of OAB.

REFERENCES

1. Zhang W, Song Y, He X, et al. Prevalence and risk factors of overactive bladder syndrome in Fuzhou Chinese women[J]. Neurourol Urodyn, 2006, 25(7): 717-721.

Funding Henan Province Medical Science Provincial-ministerial Co-construction Project (No: SBGJ2018059), Natural Science Foundation of China (NSFC) (No. 81670689) and Natural Science Foundation of China (NSFC) (No. U1904208). **Clinical Trial** No **Subjects** Human **Ethics Committee** Xinxiang Medical University **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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FREQUENCY OF URINARY INCONTINENCE IN PEOPLE WITH PORTAL HYPERTENSION

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HYPOTHESIS / AIMS OF STUDY

Portal hypertension is an increase of the pressure within the portal vein and its most common cause is cirrhosis of the liver. However, some other conditions increasing vascular resistance could be also implemented in the development of this situation. The major symptoms for patients with portal hypertension are gastrointestinal bleeding, ascites, encephalopathy and coagulation disorders. Several drugs can be used to reduce portal hypertension complications, with non-selective beta-blockers to be the one of the most common therapeutic choices. Non-selective beta-blockers apart from decreasing cardiac output via β-1 receptors, cause splanchnic vasoconstriction by blocking β-2 receptors, resulting in unopposed α-1 activity. This non-selective action over β-2 and α-1 receptors, could have an indirect impact on bladder function, implying symptoms like frequency or urinary incontinence (UI). The aim of this study is to explore any association of non-selective β-blockers with incontinence and their possible influence in quality of life of patients with portal hypertension.

STUDY DESIGN, MATERIALS AND METHODS

This is a descriptive study, including outpatients receiving non-selective β-blockers, pooled up from the Internal Medicine Department and the Neuro-urology and Urodynamics Unit of our Hospital. Patients have been allocated into two Groups; Group A included patients receiving any non-selective β-blocker for high blood pressure, while Group B included those taking such therapy for clinically non-significant portal hypertension and a hepatic venous pressure gradient less than 5 mmHg. All of them were receiving treatment for at least 6 months before the survey begins. Exclusion criteria were any treatment for lower urinary tract symptoms at last six months, medical history of urological or gynecological surgeries, history of recent urinary tract infections, men with a known benign prostate enlargement regardless of receiving treatment, diabetes, already diagnosed nocturnal polyuria, receiving diuretics, neurological diseases and any grade of kidney damage. The evaluation of symptoms and their impact on quality of life have been based on Overactive Bladder Symptoms Score (OABSS) and ICIQ-SF questionnaire. All patients were fully informed about the study, signing an informed consent form. Data were analyzed with SPSS v.23, so as to examine relationships between β-blockers, presence of urinary incontinence and impact on quality of life, as well as the role of portal hypertension as an independent factor.

RESULTS

Finally, 44 patients have been enrolled and all of them completed the survey, including 24 women and 20 men with a mean age of 69.5 years old. Throughout subjects, 21 patients have been allocated in Group A and 23 in Group B, with a self-report of urinary incontinence of 23.8% and 34.8% respectively. There was no statistical difference in the prevalence of incontinence between two Groups (p= 0.104). The mean OABS score, among patients with UI in Group A was 8.5, while in Group B it was 9. Additionally, the mean ICIQ-SF in the same subgroup of patients has been calculated at 14.5 and 16.5 for each Group. No statistical difference has been detected for these variables (p= 0,963 and p= 0.207 respectively). More specifically, looking at the interference of urinary incontinence in patients' quality of life, Group A has been scored at a mean of 4.5, while Group B at mean score of 6.5, proving also a quite marginal statistical difference between the two Groups (p= 0.03).

INTERPRETATION OF RESULTS

Patients receiving non-selective β-blockers could have symptoms of incontinence, affecting their quality of life. Focusing on those who need this medication for portal hypertension, it seems that their quality of life is more affected comparing to those without this underlying disease. However, the limitations of our study are that we have no data for lower urinary tract symptoms before treatment begins and there can be no cease of therapy, as it is considered as unethical.

CONCLUDING MESSAGE

Urinary incontinence seems to be considerable among patients receiving β-blockers, but portal hypertension tends to appear as an independent factor only in the area of patients' quality of life. Prospective studies could disclose more clinically applicable results.

REFERENCES

1. Mauseth SA, Skurtveit S, Skovlund E, Langhammer A, Spigset O. Medication use and association with urinary incontinence in women: Data from the Norwegian Prescription Database and the HUNT study. Neurourol Urodyn. 2018 Apr;37(4):1448-1457. doi: 10.1002/nau.23473.
2. Tannenbaum C, Johnell K. Managing therapeutic competition in patients with heart failure, lower urinary tract symptoms and incontinence. Drugs Aging. 2014 Feb;31(2):93-101. doi: 10.1007/s40266-013-0145-1.
3. Hwang R, Chuan F, Peters R, Kuys S. Frequency of urinary incontinence in people with chronic heart failure. Heart Lung. 2013 Jan-Feb;42(1):26-31. doi: 10.1016/j.hrtlng.2012.08.003.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Scientific Council of General Hospital of Larissa, Greece **Helsinki** Yes **Informed Consent** Yes

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WHAT IS KNOWN ABOUT LOWER URINARY TRACT SYMPTOMS (LUTS) IN HEART FAILURE? A SCOPING REVIEW.

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HYPOTHESIS / AIMS OF STUDY

The prevalence of congestive cardiac failure (CCF) is increasing as a result of improved survival of myocardial infarction, and increases in prevalence with increasing age . Lower urinary tract symptoms, including urgency, frequency, and nocturia, are also highly prevalent in older adults . National and international guidelines, as well as custom and practice, suggest assessment and treatment of CCF in older adults with LUTS , but the evidence that treating CCF can impact LUTS is sparse.

This scoping review aimed to review and summarise existing knowledge regarding LUTS in patients with heart failure and to identify research gaps. To our knowledge this is the first formal review of this topic.

STUDY DESIGN, MATERIALS AND METHODS

We performed a scoping review, based on the methods of Arksey and O'Malley, to search Ovid, Medline, and Scopus using a combination of key words ("urine OR urinary frequency, urine OR urinary urgency, urine OR urinary incontinence, overactive bladder (OAB), nocturia, dysuria or lower urinary tract symptoms (LUTS) AND heart failure (HF) or congestive cardiac failure (CCF) or cardiac failure"). We included studies which broadly related to lower urinary tract symptoms in patients with heart failure and excluded any non-human studies, commentaries, editorials, studies not published in English and any studies published before 1986. Articles titles were reviewed by a single author, and the abstracts of those meeting the criteria were reviewed by two authors. Those which either reviewer felt met criteria were read in full by both authors and included in the analysis. A scoping review, rather than systematic review or meta-analysis was preformed due to the lack of rigorous clinical trials and allowed us to map the current research with the aim of identifying evidence gaps and research opportunities.

RESULTS

The initial search identified 2780 citations of which 34 articles which met our inclusion criteria: 24 were original articles and 10 review articles, as shown in Figure 1. Key themes were identified within the selected studies with existing knowledge focused in seven key areas (Table 1); 1. Epidemiology of LUTS in heart failure, 2. Causes of LUTS in heart failure, 3. Impact of sex, 4. Impact of medications, 5. Link between severity of heart failure and LUTS, 6. Impact of nocturia on sleep, 7. Management options.

INTERPRETATION OF RESULTS

The published evidence regarding the link between LUTS and heart failure is limited, largely comprising small scale studies which are observational in nature. The overarching conclusion from this scoping review is that the evidence is patchy making it difficult to draw robust clinical conclusions. Estimates of prevalence, the pathophysiology, cause and treatment options of LUTS in patients with heart failure remain unclear. The paucity of data, and the potential role of LUTS in discouraging concordance of patients with their heart failure treatments, makes this an important area for future research, particularly as the studies give the impression that these symptoms are relatively common, which may lead to an underestimation by those treating CCF of the impact on LUTS and patients' quality of life. To ensure patients with heart failure and co-existing LUTS receive adequate symptomatic and life-extending treatments, without increased co-morbidity and side effects, there is a need for long-term studies tracking the prevalence, causes of, and changes in LUTS following a diagnosis and treatment of heart failure, as well as possible management strategies.

CONCLUDING MESSAGE

Clinical experience and practice suggests that CCF and LUTS interact. However, there is no good evidence to explain this interaction, its extent or the optimal management strategies of these urinary symptoms in patients with heart failure and vice versa. Despite this lack of data, health professionals interacting with patients with heart failure should be aware of the potential implications of the diagnosis and treatment options on urinary symptoms as this may impact quality of life and medication compliance.

FIGURE 1

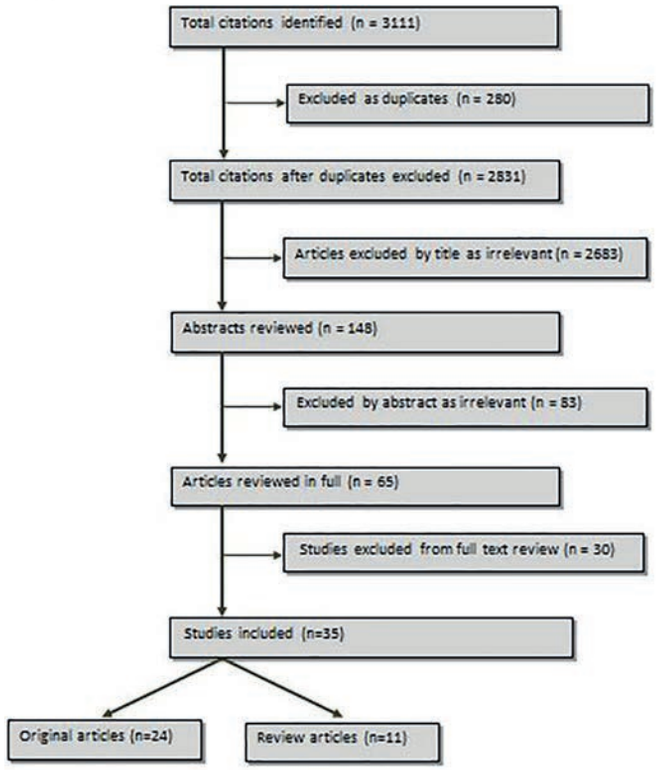

Figure 1: Flow diagram of the search process

Figure 1: Flow diagram of the search process

FIGURE 2

Key theme	Summary of evidence
Epidemiology of LUTS in heart failure	Only two epidemiological studies estimated the prevalence of all LUTS in patients with heart failure; one reported 86% of patients with heart failure LUTS, the other found 43.5% had moderate to severe LUTS. A further 16 reported the prevalence of specific LUTS, predominantly incontinence and nocturia.
Causes of LUTS in heart failure	No studies identified the mechanisms of LUTS in heart failure. All the studies aiming to establish a link were correlative and so do not provide convincing evidence as to mechanism or causality.
Impact of sex	Six studies compared the rates of various LUTS between males and females with heart failure; three studies found no significant difference.
Impact of medications	Studies were identified addressing the potential link between medications used for heart failure and LUTS, particularly focusing on diuretics. Three found no link between diuretics and LUTS, 4 reported correlation between certain LUTS and taking diuretics. Generally, the studies included were too small scale to advise altering clinical practice.
Link between severity of heart failure and LUTS	There is some evidence that worsening New York Heart Association (NYHA) class of heart failure is associated with more severe LUTS.
Impact of nocturia on sleep	Three studies reported nocturia as one of the commonest reasons for poor sleep in patients with heart failure. However, in a study, unrelated to heart failure, sleep study participants who woke up for various reasons and then needed to urinate often attributed the need to urinate as their reason for waking. This could mean that patients are falsely attributing nocturia as their reason for poor sleep.
Management options.	The majority of the studies identified were epidemiological in nature with very few investigating particular management strategies for patients with heart failure to manage or reduce LUTS. Antimuscarinic medications, commonly used for OAB, are thought to be safe for patients with heart failure but side effects include an increase in heart rate and QT prolongation so additional monitoring may be required. The only licenced alternative, the selective beta-3 agonist Mirabegron, has no specific published data for patients with heart failure.

Table 1: Summary of the existing knowledge in the seven key areas identified

Table 1: Summary of the existing knowledge in the seven key areas identified

REFERENCES

1. Anh LB et al., Epidemiology and risk profile of heart failure. Nat Rev Cardiol. 2011 Jan; 8(1): 30–41.
2. Coyne, K.S., et al., The impact of overactive bladder, incontinence and other lower urinary tract symptoms on quality of life, work productivity, sexuality and emotional well-being in men and women: results from the EPIC study. BJU Int, 2008. 101(11): p. 1388-95
3. Wagg, A., et al., Urinary incontinence in frail elderly persons: Report from the 5th International Consultation on Incontinence. Neurourol Urodyn, 2015. 34(5): p. 398-406.

Funding None **Clinical Trial** No **Subjects** None

SESSION 6 (PODIUM SHORT ORAL) - PROLAPSE
Abstracts 58-69

11:00 - 12:30, Brasilia 2

Chairs: Prof Mauro Cervigni (Italy), Dr Charles W Nager (United States)

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INSTAGRAM'S PELVIC ORGAN PROLAPSE CONTENT DISCUSSES LIMITED TREATMENT OPTIONS LEAVING USERS SUSCEPTIBLE TO BIASED INFORMATION

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HYPOTHESIS / AIMS OF STUDY

Instagram is a highly used interface on social media with 110 million users in the United States and over 1 billion users worldwide [1]. As social media platforms have evolved, consumers are increasingly utilizing Instagram to learn about their medical condition using hashtags. Hashtags are short phases preceded by '#' on social media websites. The aim of this study was to examine the quality of pelvic organ prolapse (POP) posts on Instagram and to evaluate the understandability and actionability for its consumers.

STUDY DESIGN, MATERIALS AND METHODS

Using the hashtag, '#PelvicOrganProlapse' the first 105 Instagram posts that met inclusion criteria were analyzed. Posts were limited to the English-language and POP content. We used validated questionnaires, the DISCERN criteria and Patient Education Materials Assessment Tool for audiovisual (PEMAT), to assess the post [2]. DISCERN questionnaire consisted of 16 items that were answered as 1=no, 2, 3=partially, 4, or 5=yes, respectively. PEMAT evaluates the understandability and actionability of patient education resources using a questionnaire containing 17 items (13 on understandability and 4 on actionability) that receive a score of agree= 1, disagree= 0, or not applicable= N/A. Misinformation was examined, using a Likert scale ranging from no misinformation=1, some misinformation=3, to high misinformation= 5, comparing posts content to accepted POP management recommendations from educational literature and an Inter-

national Urogynecological Association (IUGA) /International Continence Society (ICS) joint report guidelines, as the reference standard. Data was analyzed using STATA software to produce the descriptive statistics.

RESULTS

In total, 105 Instagram posts with a total of 8,859 likes were evaluated. Characteristics of Instagram pelvic organ prolapse posts are shown in Table 1. The most commonly published posts were by health and wellness groups (44%). Pelvic floor muscle training (PFMT) was the most frequently reported treatment option (59%), while surgical repair was reported in 11% of posts. Surgical repair was mentioned in 13% of posts by health and wellness groups. Twenty-two percent of posts discussed causes of POP and 36% of posts mentioned associated symptoms of POP.

Posts with content that includes low quality or insufficient scientific validation are shown in Table 2. Seventy-six percent of posts were comprised of moderate to poor quality information, or an overall DISCERN score less than or equal to 3. Poor quality posts often failed to address risk of treatment, other available treatment options, and/or shared decision making with medical professionals. One-fourth of posts had commercial bias. Thirty-six percent of posts were given low PEMAT scores (a score below 75%) for understandability, while 69% of these posts had a low PEMAT score for actionability. One-fourth of PFMT posts had moderate to poor quality information, while over one-third of PFMT posts had commercial bias. Forty percent of PFMT posts contained low PEMAT scores (a score below 75%) for understandability, while 56% of these posts had a low PEMAT score for actionability.

INTERPRETATION OF RESULTS

Instagram contains POP posts lacking complete information which is crucial for users' medical decisions. Forty-four percent of the posts were published by health and wellness groups, with most of these posts mentioning PFMT (64%) as a treatment option. Previously reported studies found 20.0% of women will have a lifetime risk of undergoing POP surgery by the age of 80; however, the readily available content on Instagram does not reflect these trends [3]. Only 13% of Instagram posts by health and wellness groups mentioned surgical repair. Despite the high prevalence and the increased risk of developing POP, many women continue to lack fundamental knowledge and awareness of this common gynecologic condition and the paucity of accurate information being disseminated on social media is not of much benefit to lay persons. Many users are encountering POP posts which encourages PFMT as a treatment modality without being aware that 33% of these posts contain biased content.

Our study reported over three-fourths of posts lacked high quality information and a quarter of posts contained commercial bias, or promoted the use of certain products to rapidly alleviate aggravating POP symptoms. This is worrisome because information on social media is easily accessible, yet content is not validated and can negatively influence a patients' decision-making. Furthermore, over 50% of both POP and PFMT posts were comprised of content with moderate to poor actionability, perturbing users as they attempt to navigate the often-mystifying medical field. These posts can accelerate confusion among patients and inhibit their ability to seek proper medical care, affecting their well-being.

CONCLUDING MESSAGE

Overall, Instagram posts contain limited content with poor quality information, which increasingly focuses on pelvic organ prolapse with pelvic floor muscle training . The absence of complete information on treatment modalities can limit unknowing users from alternative options, thus precluding their judgement.

FIGURE 1

Publisher Type	Number of posts (%), N=105
Commercial media/industry	4 (3)
Consumer/patient	11 (10)
Doctor	8 (8)
Foundation/advocacy group	3 (3)
Health/wellness group	46 (44)
Physical therapy group	24 (23)
Unknown/unclear	5 (5)
Treatment Options	Number of posts (%), N=105
No treatment	3 (3)
Pelvic floor muscle training (PFMT)	62 (59)
Pessary	7 (7)
Surgical Repair	12 (11)
Pelvic Organ Prolapse Content	Number of posts (%), N=105
Anatomy of prolapse	
Complete	3 (3)
Incomplete	21 (20)
None	81 (77)
Causes of pelvic organ prolapse	
Yes	23 (22)
Symptoms of pelvic organ prolapse	
Yes	38 (36)
PFMT Pelvic Organ Prolapse Content	Number of posts (%), N=62
Anatomy of prolapse	
Complete	3 (5)
Incomplete	18 (29)
None	41 (66)
Causes of pelvic organ prolapse	
Yes	11 (18)
Symptoms of pelvic organ prolapse	
Yes	28 (45)

Table 1. Characteristics of Instagram pelvic organ prolapse posts.

FIGURE 2

Pelvic Organ Prolapse Content	Percent of posts
Poor quality (DISCERN score <=3)	76%
Misinformation* (score >=3)	8%
Commercial Bias	24%
Low PEMAT Understandability (<75%)	36%
Low PEMAT Actionability (<75%)	69%
PFMT Pelvic Organ Prolapse Content	Percent of posts
Poor quality (DISCERN score <3)	24%
Misinformation* (score >=3)	8%
Commercial Bias	35%
Low PEMAT Understandability (<75%)	40%
Low PEMAT Actionability (<75%)	56%

*Score of some misinformation to high misinformation (i.e. inaccurate treatment options) on a likert scale.

Table 2. Posts with content that includes low quality, biased data, or insufficient scientific validation.

REFERENCES
1. Smith K. 49 Incredible Instagram Statistics you Need to Know. Brandwatch. https://www.brandwatch.com/blog/instagram-stats/. Published May 7, 2019. Accessed December 8, 2019.
2. Loeb S, Sengupta S, Butaney M, et al. Dissemination of Misinformative and Biased Information about Prostate Cancer on YouTube. European Urology. 2019;75(4):564-567. doi:10.1016/j.eururo.2018.10.056.
3. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. Obstetrics & Gynecology. 2014;123(6):1201-1206. doi:10.1097/AOG.0000000000000286.

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OUTCOMES AND LEARNING CURVE OF LAPAROSCOPIC LATERAL SUSPENSION VERSUS LAPAROSCOPIC SACROCERVICOPEXY FOR PELVIC ORGAN PROLAPSE: A RANDOMIZED CLINICAL TRIAL.

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HYPOTHESIS / AIMS OF STUDY
Laparoscopic approach for pelvic organ prolapse offer many advantages including better anatomical structures identification, shorter hospitalization, decreased postoperative pain and reduced complication rates. Sacro-colpopexy is considered the gold standard in the treatment of apical prolapse, although dissection of the promontory may be challenging. The purpose of the study was to compare two laparoscopic operative techniques, lateral- versus sacro-cervicopexy, in terms of anatomical and functional effectiveness, complications rates, and learning curve.

STUDY DESIGN, MATERIALS AND METHODS
From January 2016 to October 2019, we enrolled patients with uterine Pelvic Organ Prolapse Quantification (POP-Q) > stage 2, randomly located for lateral- or sacro-cervicopexy. Inclusion criteria were: uterine prolapse POP-Q > stage 2. Exclusion criteria were: cervical pathologies, previous urogynecological operations, neurological diseases, associated posterior vaginal wall defect, stress urinary incontinence. Data were prospectively collected in a dedicated database. Data collected consisted of: (i) Demographic details; (ii) pre- and post-operative clinical evaluation measurement by POP-Q assessed by maximum Valsalva effort in the seated semi-lithotomy position; (iii) Subjective pre- and post-operative evaluation by PFDI-20 and POPIQ-7 Quality of Life validated questionnaires; (iiii) surgical data (operating time, blood loss); (iiiii) complications, ranked by Clavien-Dindo scale. Follow-up included an outpatient evaluation and the compilation of questionnaires for subjective evaluation at 12 months. The evaluation was carried out in our center by experienced clinician (E.M). Statistical analysis was performed using the Student t-test. P value less than 0.001 was considered statistically significant. To compare data we used linear regression analysis.

RESULTS
89 patients were treated, 51.7% (46/89) underwent sacro-cervicopexy while 48.3% (43/89) had lateral- cervicopexy. The median follow-up was 12 months (SD). Laparoscopic sacro-cervicopexy anatomic success rates were 90.7% for the apical compartment and 88.37% for the anterior compartment. Laparoscopic lateral suspension anatomic success rates for the apical compartment and for the anterior compartment were 89.1% and 91.3% respectively. We did not observe any increased prevalence of the posterior compartment prolapse in both groups. Quality of life questionnaires showed highly satisfaction with the outcome in both the procedures. Differences in mean operative time were not statistically significant. However, learning curve after 43 procedures was shorter for laparoscopic lateral suspension than for laparoscopic sacrocervicopexy (figure 1-2). None of patients had mesh exposure. In the lateral suspension group there were two bladder injuries rated grade 1 on the Clavien-Dindo. In the sacro-cervicopexy group there was one complication rated grade 3b on the Clavien-Dindo classification: 1 patient required a second-look laparoscopy due to severe lower back pain in the sacral area due to promontory fixation. All these data are resumed in table 1.

INTERPRETATION OF RESULTS
Lateral- as well as sacro-colpopexy has proven effective and safe in cervical suspension. However, lateral-cervicopexy required shorter learning curve. Lateral suspension does not need promontory preparation which is at high risk of vascular damage and mesh pathway is far from ureter. Furtheromore, this technique has fewer risks than sacro-colpopexy. Thus, lateral-cervicopexy may be easier to learn than sacro-colpopexy for a novel surgeon.

CONCLUDING MESSAGE
The laparoscopic lateral suspension is a good alternative to the laparoscopic sacrocervicopexy.

Lateral-cervicopexy has a shorter learning curve which make it a good surgical choice for a novel surgeon.

FIGURE 1

Table 1. Outcomes of lateral- and sacro-cervicopexy.

	Lateral-cervicopexy	Sacro-cervicopexy
Patients	43/89 (48.3%)	46/89 (51.7%)
Apical compartment success rate	90.7%	89.1%
Anterior compartment success rate	88.37%	91.3%
Complications	2 bladder injuries	1 severe back pain
Mean blood loss	100 ml	90 ml

FIGURE 2

Figure 1. Learning curve for laparoscopic sacro-cervicopexy by using regression analysis.

Figure 2. Learning curve for laparoscopic lateral-cervicopexy by using regression analysis.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Department Committee for Ethics **Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE "PELVIC ORGAN PROLAPSE"

PREVALENCE OF PELVIC ORGAN PROLAPSE IN US RACIAL POPULATIONS: A SYSTEMATIC REVIEW AND META-ANALYSIS OF POPULATION-BASED SCREENING STUDIES

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HYPOTHESIS / AIMS OF STUDY

By year 2050, 40% of Americans aged 65 years and older will be from one of the following 5 racial/ethnic groups: Hispanic/Latino, non-Hispanic Black, Asian, American Indian, and Pacific Islander. The prevalence of pelvic organ prolapse (POP) is not well understood in women from underrepresented racial/ethnic populations. This is the first study with the aim to determine if there were differences in the pooled prevalence estimates of POP among underrepresented US racial populations from population-based epidemiologic studies.

STUDY DESIGN, MATERIALS AND METHODS

A systematic search of MEDLINE, EMBASE, Cochrane, and Scopus was conducted to retrieve eligible studies. Studies were included if POP was identified by either physical exams or questionnaires, in population-based and non-care seeking settings, and with a representative sample of US community-dwelling women from more than one racial/ethnic groups with prevalence rates reported individually. Quality of the included articles were appraised with STROBE checklist. Meta-analysis was performed with the pooled estimates calculated, and chi-squared tests performed to examined association between race and POP prevalence.

RESULTS

Of the 2,604 studies reviewed, 5 were included. All 5 studies were deemed as high quality. Of the studies included, one used physical exam to determine the presence of POP (with WHI Prolapse Classification System grades 2 and 3 defined as prolapse to introitus or outside the vagina, respectively) while others used questionnaires to identify symptomatic POP or prior POP diagnoses (Table 1). Except Brazell et al (2013), all other studies demonstrated statistically significant differences in POP prevalence rates based on race/ethnicity (Figure 1). The overall pooled prevalence of POP for White, Hispanic, Black, and Asian American were 10.76% (95% CI 10.30-11.22%), 6.55% (95% CI 5.83-7.28%), 3.80% (95% CI 3.22-4.38%), and 3.40% (95% CI 2.09-4.71%), respectively.

A significant difference in the pooled prevalence between these 4 racial/ethnic groups was found (p<0.01).

INTERPRETATION OF RESULTS

Our findings reflect the wide variation in POP prevalence among studies ranging from 1.1% to 14.6%. Our study found that White women had a higher POP pooled prevalence rate than Hispanic women; furthermore, these two populations each had greater pooled prevalence rates than Black women and Asian American women. Lastly, we also found women of American Indian and Pacific Island descents were absent from the current POP epidemiologic literature.

CONCLUDING MESSAGE

White women had the highest POP prevalence overall while Hispanic women experienced the highest POP burden compare to other minority groups. However, it is unclear from the current population-based literature to know if POP-related impacts on women's quality of life also differed between racial and ethnic groups. Studies included in our meta-analysis have several inherent limitations due to the complexity and heterogeneity of racial/ethnic health disparities. Finally, there was no data on other underrepresented minority groups, specifically for Native Americans and Pacific Islanders. While awaiting for a better understanding and more effective treatments of POP, more studies are needed in order to accurately reflect the diversity of communities throughout the US and to identify women in underrepresented populations who may be at higher risk for POP. This information will guide clinicians and policy makers to tailor culturally appropriate services and deliver pelvic floor care to women from all backgrounds more efficiently and strategically.

FIGURE 1

Table 1. Prevalence of pelvic organ prolapse (POP) with racial minority populations in the United States

Study Years / Location	Population	Ages	Mean Age±SD	Method of Identification	POP	White POP	Source, Year
Non-Hispanic Black							
WHI[1] 1993-1998, National	800 Black 1,1185 White	<50-59 (n=37,44) 60-69 (n=5,507) 70-79+ (n=2,747)	N/A	WHI prolapse grades 2-3[2] on physical exam in the supine lithotomy position with/without Valsalva	7.6%	14.6%	Kudish et al, 2011
NHANES[3] 2005-2006, 2007-2008, 2009-2010, National	1,445 Black 3,475 White	20-29 30-39 40-49 50-59 60-69 70-79 ≥80	N/A	"Do you see or feel a bulge in the vaginal area?"	2.2%	2.7%	Wu et al, 2014
RRISK[4] Oct 1999 - Feb 2003, Northern California	372 Black 938 White	40-69	N/A	"During the past 12 months, have your pelvic organs (uterus, bladder, rectum) been dropping out of your vagina causing a feeling of bulging, pressure, or protrusion?" or "During the past 12 months, has there been a visible bulging or protrusion from your vagina?"	3.2%	6.2%	Rortveit et al, 2007
RRISK 2 June 2003 - Jan 2008, Northern California	443 Black 1,006 White	40-69	N/A	"During the past 3 months, have your pelvic organs (uterus, bladder, rectum) been dropping out of your vagina, causing a feeling of bulging, pressure, or protrusion or a sensation like your "insides are coming out"?" or "During the past 3 months, have you had a bulge from your vagina or something falling out of your vagina that you can see or touch?"	1.1%	4.3%	Whitcomb et al, 2009
BACH[5] April 2002 – June 2005, Boston	1,070 Black 1,024 White	30-79	Black 50.8±12.8 White 53.2±12.8	"Have you ever been told by a health care provider that you have or had a prolapsed uterus?" or "Have you ever been told by a health care provider that you have or had a prolapsed bladder or rectum?"	4.4%	6.7%	Brazell et al, 2013
Hispanic							
WHI 1993-1998, National	665 Hispanic 11185 White	<50-59 (n=3,732) 60-69 (n=5,427) 70-79+ (n=2,704)	N/A	WHI prolapse grades 2-3 on physical exam in the supine lithotomy position with/without Valsalva	12.1%	14.6%	Kudish et al, 2011
NHANES 2005-2006, 2007-2008, 2009-2010 – Mex. Am. & other Latinos, National	1,267 Mex. Am. 662 Other Hispanic 3,475 White	20-29 30-39 40-49 50-59 60-69 70-79 ≥80	N/A	"Do you see or feel a bulge in the vaginal area?"	Mex. Am. 5.3% Other 4.5%	2.7%	Wu et al, 2014
RRISK Oct 1999 - Feb 2003, Northern California	331 Hispanic 938 White	40-69	N/A	"During the past 12 months, have your pelvic organs (uterus, bladder, rectum) been dropping out of your vagina causing a feeling of bulging, pressure, or protrusion?" or "During the past 12 months, has there been a visible bulging or protrusion from your vagina?"	8.8%	6.2%	Rortveit et al, 2007
RRISK 2 June 2003 - Jan 2008, Northern California	419 Hispanic 1006 White	40-69	N/A	"During the past 3 months, have your pelvic organs (uterus, bladder, rectum) been dropping out of your vagina, causing a feeling of bulging, pressure, or protrusion or a sensation like your "insides are coming out"?" or "During the past 3 months, have you had a bulge from your vagina or something falling out of your vagina that you can see or touch?"	4.5%	4.3%	Whitcomb et al, 2009
BACH April 2002 – June 2005, Boston	1,111 Hispanic 1,024 White	30-79	Hispanic 48.2±11.9 White 53.2±12.8	"Have you ever been told by a health care provider that you have or had a prolapsed uterus?" or "Have you ever been told by a health care provider that you have or had a prolapsed bladder or rectum?"	6.0%	6.7%	Brazell et al, 2013
Asian American							
RRISK Oct 1999 - Feb 2003, Northern California	335 As. Am. 938 White	40-69	N/A	"During the past 12 months, have your pelvic organs (uterus, bladder, rectum) been dropping out of your vagina causing a feeling of bulging, pressure, or protrusion?" or "During the past 12 months, has there been a visible bulging or protrusion from your vagina?"	5.4%	6.2%	Rortveit et al, 2007
RRISK 2 June 2003 - Jan 2008, Northern California	401 As. Am. 1,006 White	40-69	N/A	"During the past 3 months, have your pelvic organs (uterus, bladder, rectum) been dropping out of your vagina, causing a feeling of bulging, pressure, or protrusion or a sensation like your "insides are coming out"?" or "During the past 3 months, have you had a bulge from your vagina or something falling out of your vagina that you can see or touch?"	1.7%	4.3%	Whitcomb et al, 2009

Note:
1. WHI: Women's Health Initiatives Estrogen plus Progestin (E+P) Clinical Trial
2. WHI prolapse grades: 2 – prolapse to introitus; 3 – prolapse outside vagina.
3. NHANES: National Health and Nutritional Examination Survey
4. RRISK: Reproductive Risks for Incontinence Study at Kaiser
5. BACH: Boston Area Community Health survey

Table 1. Prevalence of pelvic organ prolapse (POP) with racial minority populations in the United States

FIGURE 2

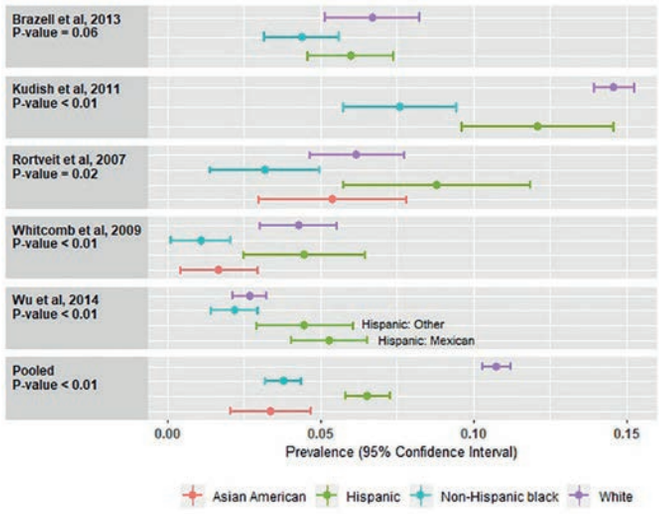

Figure 1. Forest plot of racial POP prevalence rates

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PELVIC ORGAN PROLAPSE CONTENT ON PINTEREST SHOWS EVIDENCE OF COMMERCIAL BIAS AND INCONSISTENCY WITH TREATMENT GUIDELINES

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HYPOTHESIS / AIMS OF STUDY

Pinterest is a social media platform designed as a "visual discovery engine" to help users discover websites and information on topics of interest. There are 322 million monthly active users, 70% female, and a growing international presence since its advent in 2010 [1]. A 2018 study showed that 36% of all adults 18 and older in the UK are using Pinterest; 49% of adults aged 35-44, 32% aged 45-54, and 21% of 55-64 year-olds [2]. In the U.S., it is the fourth most commonly used social media site among American women age 45-64, and the fifth most commonly used among those 65 and older.

Pelvic organ prolapse (POP) is a common problem with significant functional and quality of life implications. Risk factors include parity, vaginal delivery, age, connective tissue disorders, menopausal status, and disorders causing increased intra-abdominal or pelvic pressure. There are multiple modalities of treatment, including conservative management, pelvic floor muscle training (PFMT), pessary, and numerous surgical options.

Given that Pinterest content is entirely user-driven, and much of the demographic affected by POP uses Pinterest, we became interested in evaluating content available on this subject. We hypothesized that available information may not align with medical guidelines and best practices. We therefore aimed to assess the type, quality, understandability, and actionability of available POP-related content.

STUDY DESIGN, MATERIALS AND METHODS

Results were analyzed by searching the term "pelvic organ prolapse," looking closely at the first 100 pin results, which reached over five million followers. We examined the publisher of each pin and the content linked (Table 1). Using validated tools including the DISCERN criteria for quality of consumer health information and the Patient Education Materials Assessment Tool (PEMAT), we reviewed understandability and actionability of content. DISCERN criteria includes 16 questions regarding publication quality, each scored 1-5 (1=no, 3=partially, 5=yes). PEMAT contains 26 questions of which we used the 17 most relevant (13 on understandability and 4 on actionability), selecting "agree" or "disagree." Scores for actionability and understandability were obtained by assigning one point to each "agree", dividing by the total number of applicable questions, and multiplying by 100 (in the respective category). We further compared content to textbook standards of care and professional guidelines for discussing and treating POP. The presence of misinformation was evaluated using a Likert scale. We also evaluated for commercial bias and subjectively analyzed the overall quality of pins.

RESULTS

Five million followers were reached with 100 pins. Surgical options for prolapse treatment was discussed in 43/100 pins (Table 1). Of posts that discuss surgery, 27.9% specifically discussed placement of either transvaginal or abdominal surgical mesh, 14.0% discussed use of native tissue, and 9.3% discussed use of biologic materials. Only 23.3% of posts that mention surgery went on to discuss the postoperative course (Table 2). Pessary was discussed in 29/100 pins as a treatment option.

Pinterest posts on PFMT as a treatment option were extremely common, discussed in 79/100 pins (Table 1). Furthermore, pins discussing PFMT often provided incomplete information – 34.2% of pins relating to PFMT failed to discuss POP symptoms, and 43% failed to discuss causes and risk factors for the condition. Complete discussion of the anatomy of prolapse was present in only 10.1% of PFMT pins. Quality was also an issue: 13.9% received a PEMAT understandability score <75%, and 26.6% had a PEMAT actionability score <75% (Table 2). Commercial bias was seen commonly, in 36/100 total pins, 31 of which were related to PFMT. 39.2% of all PFMT pins were commercially biased.

It was found that only 38/100 reviewed pins emphasized shared decision making with a physician, scoring >3 on this DISCERN criteria. Quality of life was emphasized more commonly, with 54/100 pins scoring >3 for this category. Also, 27/100 pins provided some level of misinformation.

In a subjective rating of source quality, only 36.7% of PFMT pins were rated >3, implying moderate to low quality of information in most pins.

INTERPRETATION OF RESULTS

Despite frequent use of surgical treatment for POP, the high rates of POP surgeries and various modalities were not reflected in Pinterest results. When surgery was discussed in pinned content, it was often an incomplete discussion that did not provide significant conversation about options for surgery or risks and benefits of various surgical and non-surgical options.

PFMT, on the other hand, was discussed in pinned content far more commonly. While this modality has been proven to be effective in treating mild to moderate prolapse [3], this caveat was not always reflected in the content we observed. Discussions of PFMT frequently failed to provide complete information about the problem of prolapse. PFMT was also commonly promoted with commercial bias with content be-

ing posted by trainers or therapists selling their own PFMT routines and programs.

While guidelines indicate that pessary is an appropriate first-line treatment, it was mentioned in only 29 pins. The under-representation of a valid and common treatment of POP is further evidence of the disproportionate representation of treatment options available on Pinterest.

The multiple treatment modalities available necessitate shared medical decision making between physician and patient, balancing quality of life with risk and benefit of each treatment. However, an overwhelming minority of pins – 38/100 – emphasized the importance of shared medical decision making with a physician, as evidenced by a DISCERN score of 4 or 5 in this category. Also, of concern is the level of misinformation available, as 27/100 pins provided information inconsistent with known guidelines and treatment standards.

Overall, subjective quality ratings were fairly low, with 63.3% rated low to moderate. Ratings were based on whether the pin provided complete and balanced information, utilized scientific evidence/data, provided sources, and gave a clear description of the treatment and alternatives. For instance, one low quality pin (score = 2) was from a strength coach discussing benefits of kettlebell training as a mode of PFMT. In addition to lack of evidence for this approach, there was no mention of options such as pessary or surgery. The alternative of traditional PFMT was misrepresented, described as consisting merely of kegels.

CONCLUDING MESSAGE

As social media has become ubiquitous in modern society, its implications in medicine have not gone unnoticed. Multiple studies have found high levels of medical misinformation posted on social media and have warned patients about the dubious credibility of online sources. Our study has reached similar conclusions about the body of information on Pinterest regarding POP. It highlights the need for vigilance and awareness in the medical community, as patients may be receiving information from non-medical and biased sources on the internet.

FIGURE 1

Publisher Type	**Number of pins (N=100)**
Commercial media/industry	10
Consumer/patient	22
Health/wellness group	33
Hospital/clinic	3
Medical education	1
News source/media outlet	4
Physical therapy group	21
Professional society	1
Unknown/unclear	5
Treatment Options Discussed	**Number of pins (N=100)**
No treatment	23
Pelvic Floor Muscle Training (PFMT)	79
Pessary	29
Surgical Repair	43
Analyzed Metric	**Number of pins (N=100)**
Emphasize shared medical decision making with a physician	38
Overall quality rating moderate-high or high	31
Evidence of commercial bias	36
Significant discussion of quality of life issues	54
Provide some level of misinformation	27
PEMAT understandability <75%	16
PEMAT actionability <75%	30

Table 1: Nature of Pinterest Content Discussing Pelvic Organ Prolapse

FIGURE 2

Posts Discussing Surgery	**Number of pins (%, N=43)**
Discuss use of native tissue	6 (14.0%)
Discuss use of biologic materials	4 (9.3%)
Discuss use of mesh	12 (27.9%)
Discuss postoperative course	10 (23.3%)
Posts Discussing PFMT	**Number of pins (%, N=79)**
Discuss symptoms of POP	52 (65.8%)
Discuss causes of POP	45 (57.0%)
Describe POP exam	6 (7.6%)
Complete discussion of POP anatomy	8 (10.1%)
Lack commercial bias	41 (51.9%)
Overall rating moderate-high or high	29 (36.7%)
PEMAT understandability ≥75%	68 (86.1%)
PEMAT actionability ≥75%	58 (73.4%)

Table 2: Nature of Posts Pertaining to Surgery or Pelvic Floor Muscle Training

REFERENCES

1. Lin, Ying. "10 Pinterest Statistics Every Marketer Should Know in 2020 [Infographic]." Oberlo, 15 Jan. 2020, www.oberlo.com/blog/pinterest-statistics.
2. "Main Findings - Social Media Demographics 2018." Cast From Clay, castfromclay.co.uk/main-findings-social-media-demographics-uk-usa-2018.

3. Hagen, Suzanne, et al. "Individualised Pelvic Floor Muscle Training in Women with Pelvic Organ Prolapse (POPPY): a Multicentre Randomised Controlled Trial." The Lancet, vol. 383, no. 9919, 2014, pp. 796–806., doi:10.1016/s0140-6736(13)61977-

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ANTERIOR COLPOTOMY CLOSURE: DO SUTURE AND STITCHING TECHNIQUE MATTER?

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HYPOTHESIS / AIMS OF STUDY

In urogynecology there are no data on the preferred sutures used to close colpotomy in the anterior compartment. Moreover, we don't know if the different timing of resorption of the sutures may have a rule in the incidence of complications.

First aim of this study was to assess if the type of suture used to close anterior colpotomy may impact on wound healing in women with native tissues surgeries, and in those with prosthetic material implantation. Second aim was to assess if the stitching technique may be related with better wound healing. Others outcomes were to evaluate how vaginal colpotomy was closed by different surgeons, and to assess surgical in relation to the type of used suture.

STUDY DESIGN, MATERIALS AND METHODS

This is a multicenter, prospective study involving nine different urological/gynecological departments and 13 surgeons skilled in urogynecology. Study design. Recruitment: women naïve for urogynecological surgery affected by anterior vaginal wall defect, stress urinary incontinence. Surgical procedures: anterior vaginal wall repair (AVWR) with native tissue (N-AVWR) or polypropylene mesh (M-AVWR), middle urethral sling (MUS). Used sutures: Vycril 2-0, Vycril Rapide 2-0, Monocryl 3-0. Stitching technique: running interlocking, interrupted. Surgeons performed the type of suture, and the kind of stitching technique usually used. Data collected were: the type of suture; the stitching technique; surgical technique data (kind and length of incision, procedure); wound, length and treatment dehiscence; dyspareunia; leucorrhea; vaginal discharge; the duration of vaginal blood spots. Complications were ranked by Clavien-Dindo scale. Follow-up was done in outpatient clinic at the discharge, after 30 days, and 3 months later. Suture failure was considered in case of wound dehiscence and when the tape/mesh extrusion was at the level of the area of suture within 30 days of surgery.

RESULTS

An amount of 1139 patients were enrolled. In all the cases there was a vertical midline vaginal incision, with a length ranging from 1 cm (MUS) to 4 cm (AVWR). AVWR were 790, 89.1% N-AVWR and 10.9% M-AVWR, while polypropylene MUS were 349. Therefore, a total amount of 435 women (38.2%) had synthetic material implantation, and 704 (61.8%) had native tissue repair.

Sutures used (Table 1):

The sutures used to close the anterior colpotomy of N-AVWR were Vicryl 53.97%, Vicryl Rapide 33.6%, and Monocryl 12,3%. In M-AVWR Vicryl was used in 58.1%, Vicryl Rapide in 41.9%.

MUS procedures were 349, Vicryl was used in 184 (52.7%), Vicryl Rapide in 153 (43.8%), Monocryl in 12 (3.4%).

Stitching technique (Table 1):

In N-AVWR the stitching technique was running interlocking in 674 patients (83.5%), while interrupted were 30 (16.5%). In M-AVWR, 35 (40.7%) running interlocking and 51 (59.3%) interrupted.

In MUS running interlocking in 49 (14%), while interrupted in 300 (86%).

Wound dehiscences (Table 2):

Wound dehiscences were 5 in AVWR (2 N-AVWR, 3 M-AVWR), and 5 in MUS. Therefore, 80% (8/10) of dehiscences were in women with implanted prosthetic material (Chi-Square test p 0.0062, with Yates correction p 0.016).

Comparing data:

Analysing the stitching technique in wound dehiscences we found: 3 running interlocking sutures (1 Vycril, 1 Monocryl, 1 Rapide), 7 interrupted sutures (4 Vycril, 1 Monocryl, 2 Rapide). Using Chi-Square with test Yates correction we did not found significative correlation between wound dehiscences and the kind of stitching technique (p 0.058). Analysing the

three different materials used for suturing and the rate of wound dehiscence for each material we did not find a statistical difference (p 0.66).

Overall, all wound dehiscences with underlying prosthetic material (80%) were surgically closed and the other conservatively managed. Ranking complication with the Clavien-Dindo scale we had 3 case of Grade III complications, two IIIa and 1 IIIb. At 3 months none of the patient had wound complication.

Outcomes of surgery at 3 months follow-up did not differ comparing the kind of suture used and/or the kind of suturing technique.

INTERPRETATION OF RESULTS

We collected interesting data on the type of suture and the suture technique used by gynaecologists and urologists in vaginal surgery. For the first time in the literature our study highlights how the presence of prosthetic material is a risk factor for wound dehiscence regardless of the type of suture used to close the wound. Moreover, we have documented how stitching techniques are not related to the incidence of wound dehiscences. Wound dehiscences were conservatively treated only in native tissues surgeries. The kind of suture and stitching technique used did not impact remarkably on the outcomes.

CONCLUDING MESSAGE

This study showed that outcomes of patients did not relevantly change according to the suture and stitching technique used. However, prosthetic material implantation has a statistically significant risk of dehiscence in the colpotomy site. Thus, our data documented how the surgeons can choose sutures and stitching technique according to their personal preferences.

FIGURE 1

Table 1: Sutures and stitching techniques in different anterior vaginal wall surgical procedures.

	Vicryl		Vicryl Rapide		Monocryl	
	Interrupted	Interlocking running	Interrupted	Interlocking running	Interrupted	Interlocking running
N-AVWR	30	350	-	237	-	87
M-AVWR	50	-	1	35	-	-
MUS	184	-	116	37	-	12

N-AVWR, *native tissue anterior vaginal wall repair*

FIGURE 2

Table 2: Incidence of wound dehiscence in the three group of sutures, and type of related surgical procedure.

	Vicryl	Vicryl Rapide	Monocryl
Interrupted, n	264	117	-
Dehiscence, % (n)	1,13% (3/264)	2,56% (3/117)	-
	• 1 mesh	• 1 mesh	
	• 2 tape	• 2 tape	
Interlocking running, n	350	309	99
Dehiscence, % (n)	0,28% (1/350)	0,64% (2/309)	1,01 (1/99)
• Surgical procedure	• 1 AVWR	• 1 mesh	• 1 AVWR
		• 1 tape	

N-AVWR, *native tissue anterior vaginal wall repair*

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Surgical Department Internal Committee **Helsinki** Yes **Informed Consent** Yes

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COMPLICATION, REVISION AND PERCEIVED HEALTH AFTER PELVIC ORGAN PROLAPSE SURGERY. PROSPECTIVE MEDIUM-TERM RESULTS FOR 2,340 WOMEN PARTICIPATING IN THE VIGI-MESH REGISTER

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HYPOTHESIS / AIMS OF STUDY

Pelvic organ prolapse is a frequent situation which leads in 19% of cases to surgical treatment [1]. Information about the risk of complications and recurrence is essential to help women and surgeons in choosing the best surgical procedure. This information comes from the surgeon's experience and clinical studies. However, clinical studies (or the surgeon's experience) may be limited in the number of patients observed, which does not allow rare events to be collected.

The VIGI-MESH registry aims are to collect the surgical activity for the treatment of pelvic organ prolapse (POP) in several surgical centers and to monitor complications, surgical revisions and women perceived health [2].

Here we report the first medium-term results of our registry.

STUDY DESIGN, MATERIALS AND METHODS

Eligible POP surgical procedures included were vaginal repair (with native tissue), transvaginal mesh placement, and abdominal or laparoscopic repair. All surgeons described each operation performed on a specific case report form. We checked the data collection by reviewing deliveries from the hospital pharmacies and surgical procedure codes recorded by each hospital's medical data department.

We defined serious complications using Clavien-Dindo classification: mesh use canceled due to peroperative injury (Grade III), subsequent surgical intervention related to a complication (Grade III), life-threatening complication (Grade IV), woman's death (Grade V). We collected also surgical revisions for POP relapse. We used several sources to identify complications and revisions: the monitoring of surgical procedures by the data departments, surgeons' spontaneous reports, and a questionnaire sent to the women a year later. These annual follow-up questionnaires collected also information about perceived health and improvement (WHO, EQ5D, and PGI-I).

RESULTS

Between February 2017 and November 2019, 2,375 women underwent a POP surgical repair in 19 centers and agree to participate. In two cases the laparoscopic surgery was abandoned due to surgical difficulties, in eleven cases the sacropexy was planned by laparotomy, in seven cases the procedure planned was a laparoscopy without mesh insertion, and in fifteen cases it was a lateral fixation with mesh by laparoscopy; these 35 women were not included in the analysis.

The analysis include 2340 women whose planned surgery was a sacropexy by laparoscopy with mesh (hysteropexy, colpopexy or rectopexy, N = 1142), a transvaginal mesh procedure (N = 694) or a vaginal repair without mesh (N = 504). Sacropexy by laparoscopy was converted ten times (0.9%) to another surgical procedure: five in sacropexy by laparotomy, two in lateral fixation by laparoscopy, two in transvaginal mesh, and one in vaginal repair.

The women characteristics differs according to the type of intervention with younger and healthier patients in the sacropexy group, and more frequent surgical history in patients operated by the vaginal route. Surgeons preferred mesh surgery more often in case of anterior or apical prolapse.

Median follow-up was 15 months. We observed complications grade III or higher in 48 women (2.05%).

Complications grade III or IV occurred during surgery or in the first 48 hours in 12 women: one had a cardiac infarct, seven an intraoperative injury, and four a postoperative haemorrhage or haematoma. Placement of the mesh were cancelled six times; three women returned to OR for haemostasis; three women needed intensive care.

Grade III complications required a surgical treatment from two days to two months after the index surgical procedure in 15 women: one peritonitis related to ileal injury after sacropexy, one appendicitis after sacropexy, one bladder retentions related to transvaginal mesh, five hemorrhages or hematomas, four ureteral obstructions, four pelvic abscess, one severe pain related to vaginal repair with sacrospinofixation, and two vaginal mesh exposure related to sacropexy. Two laparoscopy were performed to treat appendicitis and peritonitis; ureteral obstructions were treated by double J stents, by hematoma drainage, or by nephrostomy; pelvic abscess or/and mesh exposures were treated by mesh removal in four cases and drainage in one case; a bladder retention was treated by removal of the stitches between the mesh and the uteri cervix; a severe pain after sacrospinousfixation was treated by fixation removal; and the two last returned to OR for haemostasis or hematoma drainage.

Between 2 and 12 postoperative months, 19 women required surgical treatment for grade III complications: ten vaginal mesh exposure, one bladder exposure after sacropexy, 6 severe or chronic pain, 2 ureteral obstructions after transvaginal mesh, one scar hernia after sacropexy, three vaginal granuloma. Eleven women need a surgery for mesh removal because of mesh exposure, ureteral obstruction, or pain; six for vaginal scar revision without mesh removal because of vaginal mesh exposure or granuloma; one for scar hernia treatment; and one for pudendal infiltration.

Two women returned to OR more than a year after sacropexy, one for scar hernia, and one for bladder toxin injection.

The complication-free survival curve showed a significant difference between the types of surgery (Figure 1 in months, logrank test p=0.005). The incidence of serious complications at 12 months was estimated at 1.28 in case of vaginal repair [95 % CI 0.25-2.30], 1.44 in case of sacropexy [0.71-2.17], and 3.72% in case of transvaginal mesh [2.29-5.15]. An history of hysterectomy (RR 2.11 [1.11-4.10]), and transvaginal mesh versus vaginal repair (RR 2.98 [1.22-7.26], Figure 1) were associated with an higher risk of complications.

Twenty-nine women (1.24%) benefited from surgical revision due to failure or recurrence of the prolapse: 11 after sacropexy (0.96%), 6 after transvaginal mesh (0.86%), and 12 after vaginal repair (2.38%). Compared to native vaginal repair, the risk of surgical revision for recurrent prolapse is three times lower in case of sacropexy with mesh (RR 0.34 [0.15-0.77]) or in case of transvaginal mesh (RR = 0.29 [0.11 -0.76]; Figure 2). We did not identify any other risk factor for prolapse recurrence.

Among the 1,598 women operated between February 2017 and December 2018 contacted by mail, we received 931 responses to the health questionnaire sent a year or more after their surgery (58.3%). To the question "What do you think of

your current state of health compared to what it was before your surgery for incontinence or prolapse?", they were 90.3% (787/872) who consider themselves better (much better, better, or a little better; PGI-I). 96.4% (823/854) rated their general health as good (very good, good, or fairly good). We did not find any difference depending on the surgical group. Compared to the French population of the same age, women operated for POP declared a better perceived health .

INTERPRETATION OF RESULTS

Sacropexy by laparoscopy was the most performed intervention in the registry, but was not always possible with a risk of conversion of approximately 1%. At mid-term, serious complications were uncommon (2%) especially after sacropexy by laparoscopy. Recurrences requiring surgical revision were infrequent (1%), especially after sacropexy by laparoscopy.

Women were more than 90% improved after surgery and their perceived health was better than in the general population.

CONCLUDING MESSAGE

In our registry, compared to vaginal repair and transvaginal mesh, laparoscopic sacropexy with mesh presented the best benefit-risk profile. Native vaginal repair exposed to a low risk of complications, but the risk of recurrence was 3 times greater than transvaginal mesh. Transvaginal mesh exposed to a low risk of recurrence but the risk of serious complication was 3 times greater than vaginal repair.

FIGURE 1

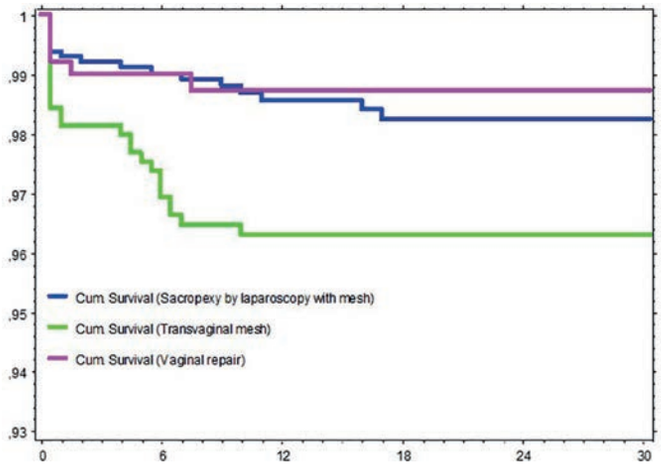

Figure 1. Survival without grade III or more complication depending on the time (months) and the surgical group (2340 women)

FIGURE 2

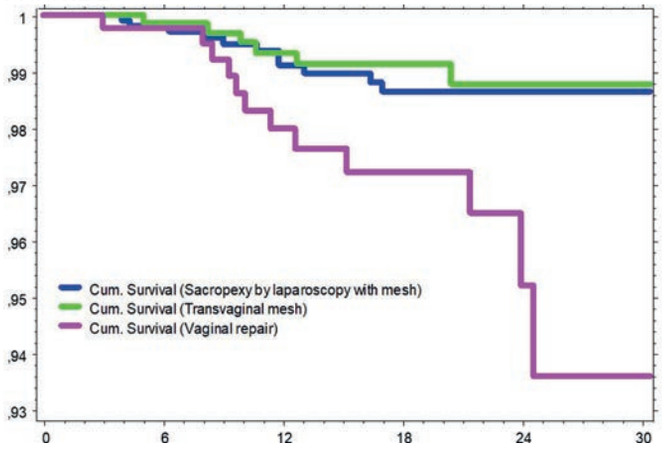

Figure 2. Survival without surgical revision for POP relapse depending on time (months) and surgical group (2340 women)

REFERENCES

1. Smith et al. Lifetime Risk of Undergoing Surgery for Pelvic Organ Prolapse. Obstet Gynecol 2010.
2. Fritel et al. Complications after pelvic floor repair surgery (with and without mesh): short-term incidence after 1873 inclusions in the French VIGI-MESH registry. BJOG 2020.

Funding National medicines agency (Agence Nationale de Sécurité du Médicament et des produits de santé, ANSM) **Clinical Trial** No **Subjects** Human **Ethics Committee** The Comité de Protection des Personnes Ouest III approved the protocol 9 February 2017 (IDRBC 2017-A000308-45) **Helsinki** Yes **Informed Consent** Yes

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A COMPARISON OF AUTOLOGOUS FASCIA LATA VS MESH DURING ROBOTIC SACRAL COLPOPEXY

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HYPOTHESIS / AIMS OF STUDY

Robotic sacral colpopexy (RSC) is rapidly emerging as a safe and effective approach for the treatment of advanced stage pelvic organ prolapse. The operation can be performed with either mesh or autologous fascia lata. The use of autologous fascia lata during RSC has previously been described as a safe option with rare apical prolapse recurrences and complications mainly related to fascia harvest including seroma, DVT [1,2]. Mesh is considered to be the gold standard option with low prolapse recurrence rates and complications mainly related to mesh erosion[3]. The hypothesis is that fascia lata will provide non-inferior prolapse outcomes with no risk of mesh erosion.

STUDY DESIGN, MATERIALS AND METHODS

We performed a single-institution, institutional review board approved analysis of patients enrolled in a prospective non-randomized trial to undergo RSC from November 2017-December 2019. Patients were offered mesh or autologous fascia lata. No patients were excluded from the study. Patient data were extracted from medical records and patient surveys. Data analyzed included preoperative factors, operative timing, postoperative hospital stay, and complications, Pelvic Organ Prolapse Quantification (POP-Q) exam, and patient reported outcomes including Urogenital Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7). Failure was defined as POP-Q stage 2 or greater in any compartment.

RESULTS

A total of 64 patients underwent RSC during this timeframe; 19 (29.7%) elected to undergo fascia lata RSC and 45 (70.3%) elected to undergo mesh RSC. At the time of surgery, all patients had ≥2cm apical descent with median POP-Q stage of 3. Nine of 19 (31.6%) underwent hysterectomy in the fascia lata group while 19/45 (42.2%) underwent hysterectomy in the mesh group. Patient-reported and anatomic outcomes appear in Figure 1. The average operative time was 289 ±39 minutes for fascia lata with harvest time average of 25 ±7.4 minutes. The average operative time for mesh was 237 ±39 minutes. The average hospital stay for both groups was 1.5 ±0.5 days. There were two failures in the fascia lata group (10%) with one apical and one anterior compared to two failures (4%) in the mesh group both occurring in the posterior compartment at an average follow-up of 10.7 ±9.1 months. The difference was not significant (p=0.36). In the fascia lata group, the most significant complications included one hematoma at harvest site requiring transfusion and one ipsilateral DVT. In the mesh group, one mesh erosion was noted.

INTERPRETATION OF RESULTS

There were significant improvements in patient-reported outcomes and POP-Q exams for both groups with a failure rate in the fascia lata group that was not significant as seen in Figure 1. The average operative time including harvest was longer for fascia lata. The complication rates associated with both methods were low, but differed in nature.

CONCLUDING MESSAGE

This is the first prospective comparison of fascia lata to mesh during RSC. Overall fascia lata RSC appears to have comparable short term failure rates to mesh RSC and low numbers of complications related to fascia harvest, without the risk of mesh erosion. A longer-term randomized controlled trial is necessary to further compare these two options. Instructive video describing the technique has been published [1].

FIGURE 1

Combined Outcomes for Fascia Lata

	PREOP	POSTOP	
UDI-6	10.3 ± 5.0	5.4 ± 3.0	p< 0.001
QoL	6.5 ± 1.9	3.4 ± 2.5	p< 0.001
IIQ-7	10.5 ± 8.6	4.9 ± 4.6	p< 0.05
Pads/24 h	1.2 ± 1.3	1.2 ± 1.3	p< NS
POP-Q EXAM			
Aa	0.7 ± 1.1	-2.7 ± 0.5	p< 0.001
Ba	1.8 ± 1.9	-2.5 ± 0.7	p< 0.001
C	-5.4 ± 1.4	-8.3 ± 1.0	p< 0.001
TVL	8.2 ± 1.1	8.6 ± 0.9	p= NS
Ap	-1.3 ± 1.4	-2.4 ± 0.7	p< 0.01
Bp	-0.8 ± 1.5	-1.7 ± 1.1	p< 0.05
Preop POP Q stage 1	0	0%	
Preop POP Q stage 2	4	21%	
Preop POP Q stage 3	9	47%	
Preop POP Q stage 4	6	32%	
FAILURE			
at Apex	1 / 19		5%
Anterior compartment	1 / 19		5%
Posterior compartment	0 / 19		0%

Combined Outcomes for MESH

	PREOP	POSTOP	
UDI-6	9.9 ± 4.5	4.4 ± 3.8	p< 0.05
QoL	7.0 ± 2.2	2.5 ± 2.4	p< 0.001
IIQ-7	12.6 ± 7.4	2.1 ± 5.1	p< 0.001
Pads/24 h	1.3 ± 1.8	0.7 ± 1.7	p< NS
POP-Q EXAM			
Aa	0.6 ± 1.8	-2.3 ± 0.9	p< 0.001
Ba	1.9 ± 2.5	-1.8 ± 1.3	p< 0.001
C	-4.6 ± 2.6	-7.7 ± 1.3	p< 0.001
TVL	8.1 ± 1.2	8.1 ± 1.2	p= NS
Ap	-1.2 ± 1.6	-1.8 ± 1.1	p< 0.05
Bp	-0.6 ± 1.8	-1.2 ± 1.4	p< NS
Preop POP Q stage 1	4	9%	
Preop POP Q stage 2	11	24%	
Preop POP Q stage 3	14	31%	
Preop POP Q stage 4	16	36%	
FAILURE			
at Apex	0 / 45		0%
Anterior compartment	0 / 45		0%
Posterior compartment	2 / 45		4%

Comparison of pre-operative and post-operative anatomical and patient reported outcomes using autologous fascia lata vs. polypropylene mesh. Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), Quality of Life (QoL).

REFERENCES

1. Isamu Tachibana, Mark Pickhardt, C.R. Powell. Robotic Sacral Colpopexy with Fascia Lata for Pelvic Organ Prolapse. Videourology VOL. 33, NO. 3. Published Online: 4 Jun 2019 https://doi.org/10.1089/vid.2019.0007
2. Scott V, Oliver J, Raz S, Kim JH. Robot-assisted sacral colpopexy with autologous fascia lata: Technique and initial outcomes. International Urogynecology. 2019: 30 (11): 1965-1971. Doi:10.1007/s00192-019-03884-2.
3. CR Powell, I Tachibana, B Eckrich, J Rothenberg, J Hathaway. Robotic Sacral Colpopexy. Journal of endourology. 32 (S1), S-111-S-116. 2018.

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FACTORS ASSOCIATED WITH EARLY POSTOPERATIVE COMPLICATIONS OF EARLY AND LATE DISCHARGE OF PATIENTS UNDERGOING SURGERY FOR PELVIC ORGAN PROLAPSE. A NATIONAL DATABASE STUDY

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HYPOTHESIS / AIMS OF STUDY

Compared to inpatient surgery, outpatient surgery has the advantages of an easier in-home recovery time, reduced stress, predictable scheduling, and lower healthcare costs.

[1] Additionally, outpatient surgery is associated high patient satisfaction in several reports.[2] Contemporary reports on perioperative morbidity of outpatient versus inpatient pelvic organ prolapse surgeries are scarce. This study compare 30-day postoperative complications between early (≤1 day) versus late (>1 day) discharge following colporrhaphy, and also determine the factors that are associated with early postoperative complications following colporrhaphy.

STUDY DESIGN, MATERIALS AND METHODS

The National Surgical Quality Improvement Program (NSQIP) database of the American College of Surgeons was utilized to extract the study cohort from 2005-2016. Female patients with at least 18 years of age who underwent colporrhaphy as the primary procedure were identified. The colporrhaphy procedure (either anterior, posterior, or combined) was identified using the following current procedural terminology (CPT) codes: 57240, 57250, 57260 and 57265. We excluded patients who had concurrent colpopexy, colpocleisis, hysterectomy, perineoplasty, oophorectomy, urethral plication, vulvectomy, cervicectomy, sphincteroplasty, vaginectomy, cystostomy, or vesicourethropexy. Patients were categorized according to length of hospital stay into same day hospital discharge/outpatient group (OPG) and >1 day/inpatient group (IPG). Patient characteristics, pre-operative labs, American Society of Anesthesiologists (ASA) Classification, whether colporrhaphy was received with concomitant sling procedure, operating time, 30-day readmission, reoperation and complications were recorded. Descriptive statistics were used to compare patient characteristics and complications between the two groups. Multivariable logistic regressions determined factors associated with increased risk of postoperative complications following colporrhaphy. Adjusted odds ratios (aOR) and 95% CIs were reported. All analyses were conducted using SAS v9.4 (SAS Institute Inc., Cary, NC). All statistical inference were made based on p=0.05 significance level.

RESULTS

Of 11,652 females receiving colporrhaphy, 32% (n=3,728) were OPG and 68% (n=7,924) were IPG. Patients in IPG were older than those in OPG (16.8% of patients aged ≥ 75 years in IPG vs. 10.9% in OPG, p<0.001). Generally, patients in IPG were sicker (higher ASA class), had higher body mass index, more likely to be current smokers, and required longer operating time than those in OPG. 74% of patients in OPG received their surgery in or after 2013 compared to 53.8% of the patients in IPG (p<0.001). Compared to OPG, more proportion of patients in IPG were white, had abnormal hematocrit (<45%), had abnormal while blood cell count (WBC) (<4,000 or >11,000) and received combined colporrhaphy and concomitant sling. Mean length of stay in IPG was 2.4±1.6 days. Mean operating time (minutes) was shorter in OPG vs. IPG (55±34 vs. 78±47, p<0.001). The overall 30-day morbidity (3.7% vs. 6.2%, aOR=0.67 [0.55–0.82]), reoperation (0.8% vs. 1.4%, OR=0.59 [0.39–0.90]), and readmission (0.9% vs. 2.4%, OR=0.40 [0.26–0.90]) were significantly lower in OPG versus IPG. Factors that independently associated with higher risk of early postoperative complications in both groups were white race (aOR [95%CI] =1.89 [1.17-4.82]), ASA class IV/V (vs. I/II) (1.23 [1.01-1.5]), preoperative abnormal WBC count (1.48 [1.14-1.91]), longer operating time (10-minute increment) (1.05 [1.04-1.07]) and receiving anterior colporrhaphy (vs. combined) (1.22 [1.00-1.49]). Unexpectedly, older age groups (45-54) and (55-64) were associated with lower risk of early postoperative complications (0.69 [0.51-0.92] and 0.69 [0.52-0.90], respectively).

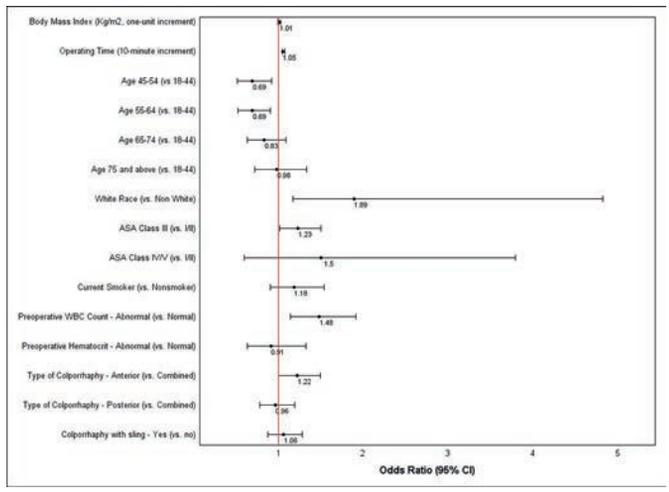
INTERPRETATION OF RESULTS

Based on a national database, our results showed that electing to perform outpatient colporrhaphy would not increase the rate of early postoperative complications, readmission and reoperation. Following colporrhaphy, factors associated with increased risk of postoperative complications were white race, higher ASA class, abnormal WBC count, longer operating time and undergoing anterior rather than combined colporrhaphy procedure. These factors should be considered during patient counseling prior to colporrhaphy procedure.

CONCLUDING MESSAGE

Outpatient colporrhaphy was associated with lower 30-day morbidity compared to inpatient. Generally, white race, higher ASA class, abnormal WBC count, longer operating time and undergoing anterior colporrhaphy rather than combined were associated with higher risk of early postoperative complications following colporrhaphy. Cooperative prospective studies to confirm these observations are warranted.

FIGURE 1



Predictors of complications in patients undergoing colporrhaphy.

REFERENCES
1. Jain S, Saltzman B, Miller A, Ortiz J, Nofziger J. Same-day discharge for laparoscopic donor nephrectomy. JSLS 2017;21(2):e2017.00019.
2. Litwin MS, Shpall AI, Dorey F. Patient satisfaction with short stays for radical prostatectomy. Urology 1997;49(6):898–905:discussion 905-6.

Funding None **Clinical Trial** No **Subjects** None

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A COMPARISON OF OUTCOMES FOR PELVIC ORGAN PROLAPSE SURGERY BETWEEN NURSING HOME RESIDENTS AND COMMUNITY-DWELLING OLDER ADULTS

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HYPOTHESIS / AIMS OF STUDY
Surgery for pelvic organ prolapse (POP) among older women is common and a growing number of older women are frail, meaning that they experience a decrease in physiological capacity that predisposes them to stressors such as surgery. The effects of frailty on surgical outcomes in older women undergoing surgery for pelvic organ prolapse (POP), however, are unknown. The purpose of this study is to compare short- and long-term surgical outcomes between nursing home residents (who are by definition frail) and matched community-dwelling older adults undergoing surgery for POP.

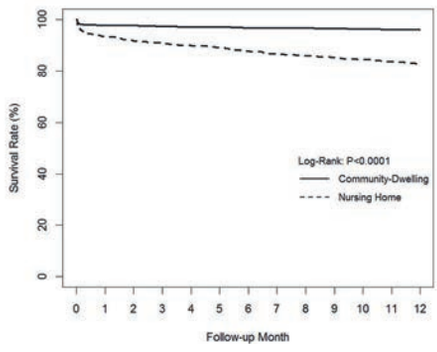
STUDY DESIGN, MATERIALS AND METHODS
This is a retrospective cohort study of women >/=65 years of age undergoing different types of POP repairs (anterior/posterior repairs, apical repairs and colpocleisis procedures) between 2007 and 2012 using Medicare Inpatient claims (MedPAR file) and the Minimum Data Set (MDS file) for Nursing Home Residents. Long-stay nursing home residents undergoing POP surgery were identified in the MDS and propensity score matched (1:2) to community dwelling older individuals based on procedure type, age, race, and Charlson Score. Linear regression models were created to determine the relative risk of hospital length of stay >/=3 days and 30-day complications between the two groups. Kaplan Meier curves were created comparing 1-year mortality between groups.

RESULTS
There were 804 nursing home residents and 1606 matched community-dwelling older adults who underwent POP surgery and were included in our analyses. Among the study cohort, 62.3% had anterior/posterior repairs, 14.8% had apical repairs, and 22.9% had colpocleisis procedures. Mean age of the study cohort was 79.7 years, 88.7% of the cohort was white, and 9.1% had a Charlson Score >/=3. Mean hospital length of stay was 3.4 days for nursing home residents, compared to 2.1 days for community-dwelling older adults (p<.0.0001). Thirty-day complications were 16.2% among nursing home residents compared to 3.9% among community dwelling older adults (p<0.0001). In the year following surgery, nursing home residents experienced a mean of 1.6 hospital readmissions compared to 0.3 hospital readmissions among community-dwelling older adults (p<0.0001). Nursing home residents demonstrated statistically significant increased relative risks for hospital length of stay ≥3 days [40.5% vs 19.8%, adjusted RR 2.20 (95% CI 1.78-2.30)] and 30-day complications [16.2% vs 3.9%, aRR 4.11 (95% CI 3.08-5.48)] compared to community-dwelling older adults. Kaplan Meier curves illustrating significantly higher 1-year mortality for nursing home residents are shown in the Figure (p<0.0001).

INTERPRETATION OF RESULTS
Despite matching on several demographic characteristics, nursing home residents demonstrated worse outcomes in terms of hospital length of stay, 30-day complications, and 1-year mortality, compared to community-dwelling older adults.

CONCLUDING MESSAGE
These findings illustrate that frailty adds additional surgical risk, beyond age, race and comorbidity, among older adults and should be considered during surgical decision-making.

FIGURE 1
Figure. Kaplan Meier curve comparing 1-year mortality between nursing home residents and matched community-dwelling older adults undergoing surgery for POP.



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DOES CYSTOCELE TYPE VARY BETWEEN VAGINALLY PAROUS AND NULLIPAROUS WOMEN?

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HYPOTHESIS / AIMS OF STUDY

The aim of our observational study was to determine whether cystocele type varies between vaginally parous and vaginally nulliparous women in order to gain insights into the etiology of cystocele.

STUDY DESIGN, MATERIALS AND METHODS

This is a retrospective analysis of 464 vaginally nulliparous women seen routinely at two tertiary urogynecology centers between November 2006 and November 2019. Our control group consisted of 872 vaginally parous women who had visited our unit between July 2017 and November 2019. All patients underwent a standardized interview, clinical examination, uroflowmetry, multichannel urodynamic testing and 3D/4D translabial ultrasound. On imaging, a significant cystocele was defined as a bladder descent to 10mm or more below the symphysis pubis. Volume datasets were retrieved and analyzed offline by the first author, blinded against all clinical data. Statistical analysis was carried out with SAS version 9.4 (Cary, USA).

RESULTS

Of 5266 women seen during the inclusion period, 464 were vaginally nulliparous. Three datasets were excluded because of missing volumes. Out of 872 vaginally parous women, one patient was excluded due to missing volumes. Compared to vaginally parous women, vaginally nulliparous women presented at a younger age, 58 compared to 49 years respectively ($p < 0.0001$). 104 vaginally nulliparous (22.4%) and 489 vaginally parous women (56.1%) presented with symptoms of prolapse ($p < 0.0001$). 306 vaginally nulliparous (66.1%) and 648 parous women (74.3%) presented with symptoms of urinary stress incontinence (SUI) ($p < 0.002$). Mean bladder descent on ultrasound was significantly different between vaginally nulliparous and parous women with 11mm above and 8mm below symphysis pubis, respectively ($p < 0.0001$). Of 461 vaginally nulliparous women, 43 (9.3%) had a significant cystocele on ultrasound, with 23 (53.5%) being of Green type II and 20 (46.5%) Green type III. Out of 871 vaginally parous women, 418 (48.0%) had a significant cystocele on ultrasound, of whom 145 (34.7%) were Green type II and 273 (65.3%) Green type III cystocele ($p < 0.0001$). This significant difference was confirmed after excluding women with previous anterior repair and/or incontinence surgery.

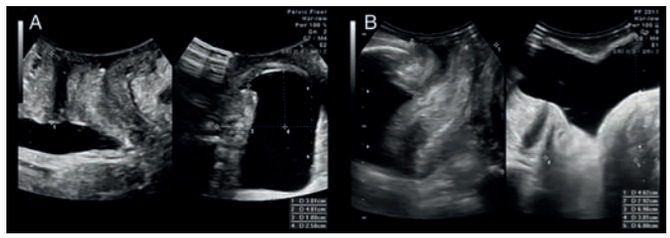
INTERPRETATION OF RESULTS

Cystoceles were much more prevalent in vaginally parous women, but they do also occur in nulliparae. There are two distinct types of cystocele, classified on the basis of retrovesical angle (RVA) and the degree of urethral rotation (1). Cystourethrocele or Green type II cystocele has in the past been considered to be due to a lateral fascial defect, while Green type III cystocele was thought to be due to a central fascial defect. However, sonographic studies have not provided any support for this thesis. On the contrary, it has been demonstrated that Green type III cystocele is associated with avulsion injury of the levator ani muscle and hence more likely to be caused by birth-related trauma (2, 3). In vaginally nulliparous women, a Green type II cystocele was more prevalent while Green type III cystocele was more common in women who had given birth vaginally ($p < 0.015$). On testing for multiple confounders (age, BMI, asthma, smoking, heavy lifting and familial history of prolapse) on multivariate analysis, the difference in proportions of cystocele Green type II and III in vaginally nulliparous versus parous women remained significant ($p < 0.0001$).

CONCLUDING MESSAGE

Nulliparity was associated with a higher proportion of Green type II cystoceles. Green type III cystocele was more common in vaginally parous women. This suggest that Green type III cystocele may be more likely to be due to birth-related trauma to pelvic floor structures.

FIGURE 1



The distinction between Type II (A) and Type III (B) cystocele as seen on translabial ultrasound in the midsagittal plane. The left image in both panels is at rest, the right image is at maximal Valsalva.

REFERENCES

1. Green, T.H., Jr., Urinary stress incontinence: differential diagnosis, pathophysiology, and management. Am J Obstet Gynecol, 1975. 122(3): p. 368-400.
2. Eisenberg, V.H., et al., Does levator ani injury affect cystocele type? Ultrasound Obstet Gynecol, 2010. 36(5): p. 618-23.
3. Chantarasorn, V. and H.P. Dietz, Diagnosis of cystocele type by clinical examination and pelvic floor ultrasound. Ultrasound Obstet Gynecol, 2012. 39(6): p. 710-4.

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Trial No **Subjects** Human **Ethics Committee** Nepean Blue Mountains Local Health District Human Research Ethics **Helsinki** Yes **Informed Consent** No

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CAN WE PREDICT OVERACTIVE BLADDER RESOLUTION AFTER PROLAPSE SURGERY?

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder (OAB) is common among women with pelvic organ prolapse (POP) but the pathophysiology of this association is still unknown. There is an improvement of OAB after prolapse surgery, however symptoms do not disappear in all cases. It is unclear whether the OAB symptoms will remain or not after surgery (1). The aim of this study was to evaluate the influence of prolapse stage in the presence of OAB, and its resolution after anterior prolapse repair. Our study hypothesis was that the increased structural damage present in severe anterior prolapse could be associated with more initial symptoms and less chance of resolution after surgery.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective multicentre study including all women with symptomatic anterior compartment prolapse that were scheduled for surgery in the pelvic floor units of two different hospitals between May 2015 and September 2017. Those women who finally did not have surgery were excluded. Other exclusion criteria were prior POP surgery, use of meshes in POP surgery, concomitant surgery for SUI, and patients unable to complete questionnaires.

Pelvic organ prolapse was described according to the Pelvic Organ Prolapse Quantification (POPQ) system. Two gynecologists blinded to symptoms reports performed the prolapse examination. At inclusion and one year after surgery, urgency and urgency urinary incontinence (UUI) were identified using the specific questions of the validated Spanish versions of the Bladder Control Self-Assessment Questionnaire (B-SAQ) and Pelvic Floor Distress Inventory short form (PFDI-20) respectively.

Correlation of preoperative prolapse POPQ stage with urinary urgency at baseline visit, and one year after surgery, were examined by multiple logistic regression models including age as potential confounder. Statistical significance was set as p=0.05.

RESULTS

We recruit 377 patients with symptomatic anterior compartment prolapse that underwent primary vaginal surgery during the inclusion period. One year after surgery 367 (97.3%) attended the follow up visit and formed the study group.

Mean age was 63.2 years (SD:9.7; range:37-84) and mean body mass index (BMI) was 29.5 kg/m2 (SD:5.4; range:16.8-49.5). Age was categorized as <60 years: 128 (34.9%); 60-69 years: 141 (38.4%) and ≥ 70 years: 98 (26.9%). At inclusion 197 (53.6%) women referred urgency, and 145 (39.5%) UUI. The distribution of urgency related to prolapse stage in the anterior compartment, and categorized age is shown in table 1. Patients with POPQ stage 3 or 4 were more at risk of having OAB as compared with stage 2 in the baseline visit. Increased risk adjusted with age were OR:4.33 for stage 3 and OR:12.90 for stage 4. Age was also an independent risk factor for baseline urgency.

One year after surgery 121 (33.0%) women referred urgency and 63 (17.2%) UUI. Of those 18 (10.6%) and 12 (7.1%) were new cases of urgency and UUI respectively. The remaining 103 (52.3%) and 51 (25.9%) persisted with urgency and UUI from baseline visit. The distribution of persistent urgency according to preoperative POP stage in shown in table 1. Patients with stage 3 or 4 in the anterior compartment were more at risk of persisting with urgency as compared with stage 2. Increased risk adjusted with age were OR:3.85 for stage 3, and OR:5.59 for stage 4. Age ≥ 70 was also an independent factor for the persistence of OAB.

INTERPRETATION OF RESULTS

The pathophysiology of OAB in women with pelvic organ prolapse is still unclear and different theories have been hypothesized. Prolapse can cause bladder outlet obstruction, being the most accepted mechanism for developing OAB. The stretching of receptors in the urothelium due to bladder distension and the opening urethra secondary to traction from a prominent cystocele are also mechanisms that have been proposed (1). Women with severe anterior compartment prolapse were more at risk not only for baseline OAB, but also for persisting with urgency one year after surgery. The risk of persisting with urgency was as high as 4.0 for stage 3, and 5.7 for

stage 4. Greater structural damage in the pelvic floor tissues of these patients could justify both results. Which of the three mechanisms described above participate in OAB related to POP, and its resolution after surgery is yet to be established.

As expected, our results also indicate that older women with POP are more at risk for OAB at baseline and after prolapse surgery. Age-related changes in the bladder and pelvic floor tissues and/or in the nervous system contribute to the high prevalence of OAB in elderly women (2). These permanent changes could justify the high prevalence of OAB among the

elderly (70.4%) and its high persistence after POP surgery (OR:5.59).

CONCLUDING MESSAGE

POPQ stage ≥ 3 and age ≥ 60 years increased the risk of urgency in women with symptomatic anterior compartment prolapse. This increase is higher in POPQ stage 4 and age ≥ 70 years. Close to half of patients with OAB experience improvement of urgency one year after surgery, although those who had a preoperative POPQ stage ≥ 3 or age ≥ 70 may be at higher risk of persist with urinary urgency. This information may be useful to advise women with OAB undergoing POP surgery regarding postoperative expectations.

FIGURE 1

	Urgency at baseline visit			Persistent urgency after surgery		
	n	OR	95% CI	n	OR	95% CI
Anterior prolapse						
POPQ 2 (%)	16 (22.4)	1 (ref)		3 (18.8)	1 (ref)	
POPQ 3 (%)	151 (57.9)	4.33	2.33 -8.07	79 (52.3)	3.85	1.01-14.68
POPQ 4 (%)	30 (83.3)	12.90	4.48-37.18	21 (70.0)	5.59	1.19-26.18
Age (years)						
< 60 (%)	50 (39.1)	1 (ref)		15 (30.0)	1 (ref)	
60 – 69 (%)	78 (55.3)	1.87	1.12-3.13	37 (47.4)	1.96	0.91-4.23
≥ 70 (%)	69 (70.4)	2.90	1.61-5.22	51 (73.9)	5.59	2.43-12.90

OR: odds ratio; CI: confidence interval

Results of the analysis performed to associate preoperative POPQ stage and age, with urgency at baseline and persistent symptoms one year after vaginal POP surgery.

REFERENCES

1. De Boer et al. Pelvic organ prolapse and overactive bladder. Neurourol Urodyn 2010; 29(1):30-39.
2. Zhu J, Hu X, Dong X, Li L. Associations Between Risk Factors and Overactive Bladder: A Meta-analysis Female Pelvic Med Reconstr Surg 2019;25: 238–246.

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COSMETIC ANALYSIS OF SINGLE INCISION VERSUS MULTIPLE PORT INCISIONS IN WOMEN UNDERGOING LOWER URINARY TRACT SURGERY

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HYPOTHESIS / AIMS OF STUDY

To compare the cosmetic appeal of incisions used for open (Pfannenstiel or Vertical midline) versus robotic-assisted laparoscopic lower urinary tract reconstructive surgery in women. It is often assumed that the minimally invasive "keyhole" robotic-assisted approach leads to favourable cosmetic outcomes for patients. However, robotic-assisted laparoscopic surgery requires multiple small abdominal incisions in highly visible areas of the abdomen.

STUDY DESIGN, MATERIALS AND METHODS

Our study involved administering a brief survey (descriptive) to women in our outpatient urology clinic . Patients were provided illustrations of A) Pfannenstiel incision (incision at "bikini line"); B) Vertical midline laparotomy incision (incision from midline symphysis to umbilicus); C) Robotic-assisted laparoscopic incisions – variation 1 [9] and D) Robotic-assisted laparoscopic incisions – variation 2 [10]. Patients were asked to rate each incision based on its cosmetic appeal in order of preference. Demographic data was collected regarding patient age, BMI, occupation and surgical history (existing abdominal scars). Chi square distribution was used to compare mean previous surgeries and no previous surgeries between different preferred incisional groups and ages of the patients.

RESULTS

Open incisions are preferred over robotic incisions.Descriptive statistics including ranks, means and medians were used to summarise results. We have compared proportions of different demographic groups regarding their preferred incision using a chi-square test. P values < 0.05 will be considered significant.

INTERPRETATION OF RESULTS

One hundred patients with mean age were 53.11±15.05 years with minimum 19 years and maximum 84 years and mean BMI was 28.18±7.05 kg/m2 with minimum 15.6 and maximum 55 kg/m2 calculated. Out of 100 patients (1st preference of incision), 78% preferred incision A Pfannenstiel incision (incision at "bikini line"); 3% preferred B incision Vertical midline laparotomy incision (incision from midline symphysis to umbilicus); and 16% & 3% patients preferred incision C Robotic-assisted laparoscopic incisions-variation I and D Robotic-assisted laparoscopic incisions-variation II respectively. Similarly (2nd preference of incision) 3% patients

preferred incision A, 19% preferred B incision and 56% & 22% patients preferred incision C and D respectively. The mean comparison between first preferred incision with second preferred incision with respect of surgeries (previous surgeries and no previous surgeries) showed significant difference p≤0.05 (chi value=167.692, p=0.000). Relation of preferred incisions with respect to ages of the patients showed no significant difference (Pearson relation value -0.182 and p=0.069).

CONCLUDING MESSAGE

Overall, open incisions were preferred over robotic incisions. Patient perception of the "visibility" of abdominal incisions and previous experience in term of surgical scars may be the distinguishing issue to explain the difference in the preferences between open versus robotic-assisted laparoscopic incisions in women.

REFERENCES

1. Yaxley JW, Coughlin GD, Chambers SK et al. Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study. Lancet 2016; 388 (10049): 1057-1066.
2. Babbar P, Yerram N, Sun A et al. Robotic-assisted ureteral reconstruction – current status and future directions. Urol Ann 2018; 10(1): 7-14.
3. Mehta S, Dasgupta P & Challacombe BJ. Robotic reconstructive urology: possibilities for the urological surgeon beyond the prostate. BJU Int 2010; 106:1247-8.

Funding No **Clinical Trial** No **Subjects** Human **Helsinki** Yes **Informed Consent** Yes

SESSION 7 (PODIUM SHORT ORAL) - BEST BOWEL DYSFUNCTION
Abstracts 70-75
11:00 - 12:30, Brasilia 1
Chair: Dr Liliana Bordeianou (United States)

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MEN AND WOMEN EXPERIENCE DIFFERENT BARRIERS TO CARE SEEKING FOR ANAL INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

1) To compare barriers to care seeking for anal incontinence between men and women

2) To characterize rates of and delays in care seeking for anal incontinence among men and women

3) To characterize experiences seeking care for anal incontinence among men and women

STUDY DESIGN, MATERIALS AND METHODS

This study is a secondary analysis of electronic survey data collected from adult men and women with anal incontinence about their condition and care seeking experiences. The invitation to participate in the electronic survey was distributed via an electronic mailing list of a company that markets a containment device specifically for anal incontinence; details of survey distribution have been previously described (1). The primary goal of initial data collection was to validate an instrument to quantify barriers to care seeking for anal incontinence among women specifically. The goal of this analysis is to characterize and compare care seeking experiences of adult men and women with anal incontinence, since responses from men were excluded from the instrument validation.

Descriptive analyses characterized respondents' demographics, anal incontinence severity, and rates of and delays in care seeking, using Chi-squared testing to compare categorical variables and t-testing to compare continuous variables between women and men. Similar analyses compared prevalence of specific barriers to care seeking and experiences with care seeking between women and men in the subset of respondents who had previously sought care. A P-value of .05 was considered statistically significant.

RESULTS

Among 1,677 click-throughs, 736 (44%) entered and 548 (75%) completed the survey (458 women, 90 men). The sample was predominantly non-Hispanic white (424/548, 90%) and well-educated, with 376/473 (80%) having attended at least some college; 219/548 (46%) were retired. The majority (329/472, 70%) perceived themselves to be in good, very good, or excellent health; mean Vaizey score was consistent with moderate to severe symptoms: 13.4 (SD 5.3) overall, 13.5 (SD 5.3) in women and 12.7 (SD 5.2) in men, p=.22. The duration of anal incontinence symptoms was similar in women and men, with 36 (7%) having symptoms for less than 1 month; 106 (20%) 1 month to 1 year; 251 (46%) 1 – 5 years; and 151 (28%) more than 5 years (p=.71).

Table 1 reports rates of reported barriers to care seeking for anal incontinence faced by respondents, stratified by sex.

Men were statistically significantly more likely to endorse the following barriers: belief that a healthcare provider cannot help with symptoms; belief that symptoms are a normal part of aging; not wanting to pay a co-pay for something that I can manage myself; having symptoms under control; and lack of interference with life. Women were significantly more likely to endorse barriers including: worry about having an accident away from home; fear of surgical treatment; hoping symptoms will go away on their own; and perception that discussion with a healthcare provider would be discouraging. Healthcare provider sex did not represent a barrier to care seeking for anal incontinence for most respondents. Overall, 53% (246/463) respondents did not have a gender preference for their provider. Among those who did, 41% (16/39) of male respondents preferred a male provider and 8% (3/39) preferred a female provider; 45% (190/424) of female respondents preferred a female provider and 2% (8/424) preferred a male provider (p<.001).

Overall, 277/548 (53%) percent of respondents had previously sought care for their anal incontinence: 230/458 (53%) women and 47/90 (54%) men, p=.81. Only 101/524 (19% overall, 15% of men and 20% of women) had ever been asked about anal incontinence by a healthcare provider, and only 43/524 (8%) had ever seen information about anal incontinence in a healthcare provider's office. The length of time respondents waited prior to discussing their anal incontinence symptoms with a healthcare provider did not differ between men and women (Table 2). Men were more likely than women to report that a healthcare provider did not provide any information about treatment options, and significantly less likely to be told that effective treatments exist.

INTERPRETATION OF RESULTS

In this sample of over 500 adults with anal incontinence, condition severity and rates of care seeking were similar between men and women. While many barriers were similar in men and women, there were specific barriers to care seeking that differed by sex. While men endorsed more barriers related to normative thinking and limited life impact, women endorsed more barriers related to fear, avoidance, and discouragement. Men were more likely than women to report belief that a healthcare provider could not help as a barrier to care seeking, which is not surprising, given that they were more likely than women to be given no information when discussing their symptoms with a healthcare provider, and less likely to be told that effective treatments exist.

The high rate of care seeking in this sample (>50%) may be a result of their condition severity, since symptom severity correlates with care seeking, coupled with our recruitment strategy using a convenience sample from a voluntary email list of individuals who have purchased containment products for anal incontinence.

While the small number of male compared to female respondents is a limitation, we still had 90 men participate, and thus were able to make meaningful comparisons.

CONCLUDING MESSAGE

Overall, men and women with anal incontinence seek care at similar rates and after experiencing symptoms for a similar duration of time. While many barriers are common to both men and women, barriers related to normative thinking and limited life impact are more common in men, while barriers related to fear, avoidance, and discouragement are more common in women. These findings suggest that interventions to help facilitate care seeking for anal incontinence should target men and women differently. Further, men are less likely to be given information about treatments for anal incontinence by their healthcare provider, and are significantly less likely to be told that effective treatments exist, suggesting that interventions targeting providers of male patients with incontinence may be indicated to improve outcomes of care seeking attempts.

FIGURE 1

	Total	Men	Women	P-Value
I worry about having an accident if I leave home. (N=465)	**387 (83.2)**	**25 (62.5)**	**362 (85.2)**	**0.001**
I think of my accidental bowel leakage as a medical condition. (N=466)	344 (73.8)	26 (65.0)	318 (74.6)	0.184
I am afraid to have surgery for this condition. (N=481)	**363 (75.5)**	**54 (66.7)**	**309 (77.3)**	**0.044**
I don't want to deal with a therapy that might be unpleasant. (N=481)	362 (75.3)	64 (79.0)	298 (74.5)	0.391
I am embarrassed to seek care. (N=458)	320 (69.9)	26 (66.7)	294 (70.2)	0.649
I don't want to seek care because I hope it will just go away on its own. (N=463)	**293 (63.3)**	**16 (41.0)**	**277 (65.3)**	**0.003**
There are no good treatments for this problem. (N=528)	324 (61.4)	48 (55.2)	276 (62.6)	0.194
It has not occurred to me to seek care for this problem. (N=419)	296 (70.6)	24 (60.0)	272 (71.8)	0.12
I don't want to talk to seek care because this is a sensitive matter. (N=458)	288 (62.9)	22 (56.4)	266 (63.5)	0.382
I am worried about the side effects of treatments. (N=481)	316 (65.7)	54 (66.7)	262 (65.5)	0.84
The cost of seeing a health care provider is a concern. (N=465)	263 (56.6)	22 (55.0)	241 (56.7)	0.835
My condition is because of something that happened to me in the past. (N=530)	286 (54.0)	48 (54.5)	238 (53.8)	0.904
There really isn't anything a healthcare provider can do to help me. (N=466)	**263 (56.4)**	**29 (72.5)**	**234 (54.9)**	**0.032**
I have other concerns to discuss with a healthcare provider. (N=465)	255 (54.8)	25 (62.5)	230 (54.1)	0.308
This problem will go away if I get my other health issues under control. (N=530)	280 (52.8)	52 (59.1)	228 (51.6)	0.198
I don't want to seek care because it only happens once in awhile. (N=463)	233 (50.3)	22 (56.4)	211 (49.8)	0.427
Talking about this with a healthcare provider would be discouraging. (N=452)	**214 (47.3)**	**12 (30.8)**	**202 (48.9)**	**0.03**
I don't want this to be part of the way a healthcare provider thinks of me. (N=452)	211 (46.7)	15 (38.5)	196 (47.5)	0.282
I don't want to seek care because I feel ashamed. (N=458)	203 (44.3)	14 (35.9)	189 (45.1)	0.268
Accidental bowel leakage cannot be treated. (N=527)	214 (40.6)	33 (37.9)	181 (41.1)	0.578
Accidental bowel leakage is just another part of aging. (N=536)	**220 (41.0)**	**46 (52.3)**	**174 (38.8)**	**0.019**
I don't want to pay a co-pay to talk about something I can manage myself. (N=465)	**192 (41.3)**	**23 (57.5)**	**169 (39.8)**	**0.029**
Talking about this with a health care provider would make me feel bad about myself. (N=452)	173 (38.3)	10 (25.6)	163 (39.5)	0.089
I feel like I am the only person who has this problem. (N=466)	169 (36.3)	11 (27.5)	158 (37.1)	0.228
I don't want to seek care because I have my symptoms under control. (N=463)	**177 (38.2)**	**22 (56.4)**	**155 (36.6)**	**0.015**
I don't want this diagnosis in my medical record. (N=465)	147 (31.6)	13 (32.5)	134 (31.5)	0.9
I don't want to seek care because this is a taboo topic. (N=452)	140 (31.0)	9 (23.1)	131 (31.7)	0.265
Accidental bowel leakage is a typical bodily change for women/men. (N=536)	159 (29.7)	29 (33.0)	130 (29.0)	0.46
Transportation to see a health care provider is a concern. (N=465)	137 (29.5)	11 (27.5)	126 (29.6)	0.776
I don't want to seek care because it does not interfere with my life. (N=463)	**137 (29.6)**	**18 (46.2)**	**119 (28.1)**	**0.018**
My accidental bowel leakage is my fault. (N=528)	133 (25.2)	28 (32.2)	105 (23.8)	0.1
I do not want to seek care because of my healthcare provider's gender. (N=463)	86 (18.6)	6 (15.4)	80 (18.9)	0.592

Table 1. Barriers to Care Seeking for Anal Incontinence, Stratified by Sex

FIGURE 2

	All	Men	Women	P value
Delay before seeking care – n (%)	N=266	N=44	N=222	.229
None (sought care immediately)	58 (21.7)	11 (24.4)	47 (21.2)	
1 month - 1 year	86 (32.2)	15 (33.3)	71 (32.0)	
1 to 5 years	92 (34.5)	13 (28.9)	79 (35.6)	
Longer than 5 years	30 (11.2)	5 (11.1)	25 (11.3)	
Experience with healthcare provider – n (%)	N=268	N=45	N=223	
Felt comfortable (vs. uncomfortable)	133 (49.6)	27 (60.0)	106 (47.5)	.127
Provider was attentive (vs. dismissive)	167 (62.3)	27 (60.0)	140 (62.8)	.726
Provider was encouraging (vs. discouraging)	167 (62.3)	25 (55.6)	142 (63.7)	.305
Provider was helpful (vs. unhelpful)	148 (55.2)	22 (48.9)	126 (56.5)	.349
Provider seemed comfortable	200 (74.6)	32 (71.1)	168 (75.3)	.552
Information provided by provider – n (%)	N=275	N=47	N=228	.004
No information provided about treatments	129 (46.9)	27 (57.4)	102 (44.7)	
No treatments available for ABL	25 (9.1)	9 (19.1)	16 (7.0)	
Treatments exist but they do not work well	52 (18.9)	6 (12.8)	46 (20.2)	
Treatments exist and they work well	69 (25.1)	5 (10.6)	64 (28.1)	
Outcome of provider encounter – n (%)	N=121	N=11	N=110	.624
Provider offered recommendations	95 (78.5)	8 (72.7)	87 (79.1)	
Patient followed recommendations	82 (86.3)	6 (75.0)	76 (87.4)	.330
Provider did not offer recommendations	26 (21.5)	3 (27.3)	23 (20.9)	
Patient sought care elsewhere	5 (19.2)	1 (33.3)	4 (17.4)	.510
Would seek care with a specialist – n (%)	N=274	N=46	N=228	.100
Likely	245 (89.4)	38 (82.6)	207 (90.8)	

Table 2. Care Seeking Experiences, Stratified by Sex

REFERENCES

1. Int Urogynecol J. 2017 Sep;28(9):1319-1328. doi: 10.1007/s00192-016-3261-8. Epub 2017 Feb 24.

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CAN WE PREDICT SYMPTOMS' IMPROVEMENT IN PATIENTS WITH OBSTRUCTIVE DEFAECATION SYNDROME FROM INITIAL ASSESSMENT?

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HYPOTHESIS / AIMS OF STUDY

Obstructive defaecation syndrome (ODS) includes a spectrum of abnormal evacuation symptoms such as straining, incomplete emptying, repetitive toilets visit. ODS primarily develop via maladaptive pelvic floor coordination during defaecation. Anatomical abnormalities (such as pelvic floor descent and rectocoeles) can coexist and being primary or secondary to this.

In terms of patients' management, conservative approach should be the first line management while surgery might indicated only when anatomical defects are present and patients haven't achieved satisfactory improvements. The aim of the study was to review our cohort of patients presenting with ODS and establish predictors of success for ODS treatment, based on initial assessment using demographic, validated questionnaires and tests.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective review of prospectively collected data was performed for patients presenting to a tertiary referral pelvic floor unit for the assessment of ODS over a period of 4 years (2013-2017). All patients underwent a dedicated telephone triage assessment clinic (TTAC), where symptoms severity scores were assessed and completed using Obstructive defaecation score (ODS), ICIQ-BS (International Consultation on Incontinence Modular Questionnaire-Bowel Symptoms), St Mark's faecal incontinence grading system and Bristol stool chart. Obstructive defaecation syndrome (ODS) has been assessed using the main symptom reported from patients and evaluating scores from different questionnaires used.

The following tests have been done:

1. Station pull-through anal manometry with a water-perfused catheter system. This provided measurements of anal resting tone (lower limit of normal 50 cmH2O) an anal squeeze increment pressures (lower limit of normal 50 cmH2O).

2. Assessment of rectal sensation. Three sensory thresholds were determined via ramp distension of a latex balloon positioned 10 cm from the anal verge: threshold volume (upper limit of normal, 150 mL); defaecatory desire volume (upper limit of normal, 190 mL); and maximum tolerable volume (MTV; lower limit of normal 80 mL, upper limit of normal 320 mL). Subjects were stratified as having rectal hyposensitivity (RH) when 1 or more sensory thresholds were greater than normal, or for rectal hypersensitivity when MTV was lower 80 mL. All subjects in between were defined as having normal rectal sensation.

3. Endoanal ultrasound two transducer, one sagittal and one axial). The internal and external anal sphincters were categorized as intact or abnormal by two independent reviewers.

4. Evacuation proctography. A standard mixture of porridge oats, water, and barium, with similar consistency to soft stool, was instilled using a calibrated large syringe into the unprepared rectum to a maximum of 180 mls. Patient was then transferred to a commode and defaecation assessed under fluoroscopy. Complete defaecation was defined as ≥ 90% of instilled past expelled, subjects repeated the evacuation attempts three times if unable to empty at first attempt with additional manoeuvres, like vaginal splinting

for women. Grading of intussusception has been reported according to Oxford internal rectal prolapse grading system. Low grade are grade I (descent to proximal limit of rectocoele) and grade II, descends into the level of rectocoele (but not onto the anal canal). High grade of intussusception are grade III (descents onto anal canal), grade IV (descents into anal canal). External rectal prolapse is grade V, with prolapse protrudes from the anus. Rectocoele has been defined as an outpouching of the rectal wall on defaecation and measurements have been calculated as the distance between the maximal anterior out bulge and the extrapolated line of the anterior rectal wall.

RESULTS

During the study period, 545 patients were referred to our third referral centre with the main symptoms of ODS, 471 females (86.4%) and 74 males (13.6%). Based on results from last appointment, patients have been classified into two groups "improvement" and "no improvement". Several predicting factors have been analysed to understand if we can stratify patients during their initial assessment.

Among demographic data, only age have reach statistical significance to predict improvement (median age is 51.6 in improvement group and 48.5 in the non-improvement, p=0.019). On the contrary, sex, previous proctological or pelvic floor surgery, hysterectomy, vaginal deliveries haven't been reach statistical significance as predictors.

Regards questionnaires, we have divided ICIQ-B in Bowel pattern symptoms (BPS), Bowel continence symptoms (BCS) and Quality of life (QoL) and we have found that patients with baseline worse QoL has worse outcomes (13.41 improvement vs 15.07 no improvement, p=0.012). Initial ODS score hasn't results significant (9.7 improvement vs 9.8 no improvement, p=0.75) as well as Bristol stool chart (2.7 improvement vs 2.5 no improvement, p=0.2).

In terms of pelvic floor tests, 403 (74.9%) had endoanal ultrasound and anorectal manometry, while 385 (70.6%) had defaecating proctography. None of the results from tests have resulted to be significant in predicting patients' outcomes (results reported in table 1 and 2).

Regards interventions, 485 (89%) patient had conservative treatment, with a median number of sessions of 4.28 (range between 0-16) and a length of follow-up of 14.4 months (range 0-67.7), while 51 (9.4%) had surgery when conservative measures failed to achieve patients' satisfactory improvements. Conservative measures include counselling and correct toilet position training, information leaflets, pelvic floor exercises, prokinetics (19.8%), laxatives (37.1%), medications to increase the stools consistency (6.2%), use of suppositories (71.7%) and selective us of low and high volume irrigation (41.8%). None of them has been result a predictors of success for conservative treatment. Surgical interventions were offered to 51 (9.4%) in total, (11.5% in the improvement group and 5.3% in the no improvement group, p=0.02). Length of follow-up has been 14.8 months (16.6 in the improvement and 14.5 in the no improvement group, p=0.002).

INTERPRETATION OF RESULTS

Initial assessment for patients with ODS is important to direct them to conservative treatment only or a combination of conservative and surgical repair for those having associated anatomical abnormalities. Predictors of success are important to avoid unnecessary interventions to patients and to use the available resources patients with specific symptoms.

Despite our extensive statistical analysis, we have found that only advanced age (51.6 vs 48.5, p=0.019) and less compromised QoL in the ICIQ-B (13.41 vs 15.07, p=0.012) are predictors of success for improvement. Results obtained from tests as well as the presence or the absence of anatomical abnormalities or abnormal physiology haven't been found to get any prognostic value in our cohort. Based on these findings and the fact that pelvic floor tests are invasive and expensive procedures, we should reserve them for patients not improving first line treatment.

CONCLUDING MESSAGE

Pelvic floor tests are not predictive of success for treatment of obstructive defaecation syndrome, which should be treated with a combination of conservative measures as first line. Tests should be reserved to patients who has failed first line treatment in the view to offer surgery, if anatomical abnormalities are present. Predictors of success should be identify to predict outcomes for patients with difficult defaecation.

FIGURE 1

Table 1. Anorectal physiology results

Anorectal physiology		Total (n= 403)	Improvement (n=273)	No improvement (n= 130)	p-value
Resting pressure					
	Low	179 (44.4%)	129 (47.3%)	50 (38.5%)	0.139
	Normal	214 (53.1%)	136 (49.8%)	78 (60%)	
	High	10 (2.5%)	8 (2.9%)	2 (1.5%)	
Squeeze pressure					
	Low	194 (48.1%)	129 (47.3%)	65 (50%)	0.569
	Normal	162 (40.2%)	109 (39.9%)	53 (40.8%)	
	High	47 (11.7%)	35 (12.8%)	12 (9.2%)	
Anal canal length					
	Normal	361 (89.6%)	245 (89.7%)	116 (89.2%)	0.875
	Short	42 (10.4%)	28 (10.3%)	14 (10.8%)	
Rectal sensation					
	Hyposensitive	48 (11.9%)	27 (9.9%)	21 (16.2%)	0.114
	Normal	276 (68.5%)	195 (71.4%)	81 (62.3%)	
	Hypersensitive	79 (19.6%)	51 (18.7%)	28 (21.5%)	

FIGURE 2

Table 2. Endoanal ultrasound results

Endoanal Ultrasound		Total (n= 403)	Improvement (n= 273)	No improvement (n= 130)	p-value
Internal anal sphincter (IAS)					
	Normal	357 (88.6%)	238 (87.2%)	119 (91.5%)	0.198
	Abnormal	46 (11.4%)	35 (12.8%)	11 (8.5%)	
External anal sphincter (EAS)					
	Normal	320 (79.4%)	212 (77.7%)	108 (83.1%)	0.208
	Abnormal	83 (20.6%)	61 (22.3%)	22 (16.9%)	
Either IAS/EAS					
	Normal	296 (73.4%)	195 (71.4%)	101 (77.7%)	0.183
	Abnormal	107 (26.6%)	78 (28.6%)	29 (22.3%)	

REFERENCES
1. Palit S, Lunniss PJ, Scott SM (2012) The physiology of human defecation. Dig Dis Sci. 2012 Jun;57(6):1445-64.
2. Bharucha AE, Lacy BE (2020) Mechanisms, Evaluation, and Management of Chronic Constipation. Gastroenterology. 2020 Jan 13. pii: S0016-5085(20)30080-9.
3. Palit S, Thin N1, Knowles CH, Lunniss PJ, Bharucha AE, Scott SM (2016) Diagnostic disagreement between tests of evacuatory function: a prospective study of 100 constipated patients. Neurogastroenterol Motil. 2016 Oct;28(10):1589-98.

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BEST IN CATEGORY PRIZE "ANORECTAL / BOWEL DYSFUNCTION"

ARE LARS AND COREFO QUESTIONNAIRE GOOD EVALUATION TOOLS TO COVER DIFFERENT ASPECTS OF BOWEL SYMPTOMS IN RECTAL CANCER PATIENTS AFTER LOW ANTERIOR RESECTION SURGERY?

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HYPOTHESIS / AIMS OF STUDY
Many patients experience bowel complaints after a total mesorectal excision for rectal cancer, such as: anal incontinence for feces, frequency and clustering of bowel movements, urgency and soiling. These symptoms are often referred to as low anterior resection syndrome (LARS) symptoms. The symptoms may be evaluated by the LARS questionnaire, the ColoRectal Functional Outcome (COREFO) questionnaire and the golden standard, a real-life stool diary.

The aim of the study is to investigate whether the different LARS symptoms can be sufficiently well evaluated by the LARS or the COREFO questionnaire and this compared to the stool diary, in rectal cancer patients after low anterior resection surgery. We hypothesize that LARS symptoms can be sufficiently well evaluated by the LARS questionnaire and by the COREFO questionnaire as well.

STUDY DESIGN, MATERIALS AND METHODS
Data from 77 patients treated for rectal cancer were included in this study. All of them underwent a total mesorectal excision and were recruited in 3 different hospitals. Data were collected at one month following surgery or, in case of a temporary ileostomy, one month after stoma closure. After consent, patients filled out the LARS-questionnaire (short questionnaire, including 5 items, 4-week recall period), COREFO-questionnaire (longer questionnaire, including 27 items, 2-week recall period) and a seven-day stool diary (more demanding for the patient to fill out and from the clinician to process). In the stool diary, patients were asked to keep track of frequency of 'anal incontinence, bowel movements, urgency, clustering and soiling' during 24 hours for 7 consecutive days.

Canonical correlation analysis (multivariate analysis of correlation between sets of variables) was used to identify the amount of shared information between the different domains of the questionnaires and the stool diary. For each bowel complaint (anal incontinence for feces, frequency and clustering of bowel movements, urgency and soiling) all corresponding items were selected in the different evaluation tools. An overview of the number of items used for every evaluation tool is listed in Table 1. Canonical correlation analysis allows to compare multiple variables on both sides of the equation. In the case that two pairs of canonical variates were significantly correlated, a range was displayed concerning the correlation coefficient. In this study, the comparison was made between the LARS and COREFO questionnaire-items on the one hand and the stool diary-items on the other, to determine the magnitude of the possible relationship.

RESULTS
Results (overview in Table 2) demonstrated that items on anal incontinence for feces correlated ($r = .470$) significantly ($p < .05$) between the COREFO-questionnaire and the stool dairy. The fraction of information found in the COREFO-questionnaire that could be explained by the stool diary items was 13.5%.

The items on frequency of bowel movements were significantly ($p < .05$) correlated ($r = .456$) between the LARS-questionnaire and the stool diary. The fraction of information found in the LARS-questionnaire that could be explained by the stool diary items was 20.8%. Moreover, COREFO-items on frequency of bowel movements were also significantly ($p < .05$) correlated ($r = .573$-$.587$) with the stool diary items. The fraction of information found in the COREFO-questionnaire that could be explained by the stool diary items was 23.5%.

Lastly, items on soiling were significantly ($p < .05$) correlated ($r = .515$) between the COREFO-questionnaire and the stool diary and 20.3% of information found in the COREFO-questionnaire could be explained by the stool diary items.

The remaining items from the LARS-questionnaire (anal incontinence, clustering and urgency) and the COREFO-questionnaire (clustering and urgency) did not significantly correlate with the corresponding stool diary items, which means no overlap in information between sets could be found.

For the LARS-questionnaire, no item on soiling is represented. The COREFO-questionnaire consists of more items (such as social impact and medication use) than were used in the analyses, but these did not correspond with items from either the LARS-questionnaire or the stool diary.

INTERPRETATION OF RESULTS

Both questionnaires (LARS and COREFO) are valuable tools in assessing LARS symptoms developed after rectal cancer surgery. However, only one item of the LARS questionnaire, (frequency of bowel movements) showed sufficient agreement compared to the stool diary. In particular, the LARS questionnaire contained only 20.8% of the information regarding frequency of bowel movements, available in the stool diary.

For the COREFO questionnaire, three items showed sufficient agreement compared to the stool diary. Of information that the COREFO-questionnaire contained, 13.5%, 23.5% and 20.3% was available in the stool diary, regarding anal incontinence for feces, frequency of bowel movements and soiling, respectively.

Overall, moderate to high correlations were found, although the overlapping amount of information between the questionnaires and the stool dairy was rather small.

CONCLUDING MESSAGE

Both the LARS and the COREFO questionnaire are efficient tools to evaluate specific LARS symptoms after low anterior resection for rectal cancer. However, neither of the questionnaires has the potential to replace the stool diary entirely. In order to evaluate all aspects of the LARS, it seems essential to at least combine both questionnaires or ideally use a stool diary to optimize postoperative therapy for bowel complaints.

FIGURE 1

Bowel symptom	Number of items in LARS	Number of items in COREFO	Number of items in stool diary
Anal incontinence for feces	1	4	2
Frequency of bowel movements	1	2	6
Clustering of bowel movements	1	1	3
Urgency	1	1	3
Soiling	0	2	3

Table 1: overview of number of items used per evaluation tool.

FIGURE 2

	LARS vs. stool diary			COREFO vs. stool diary		
	p-value	correlation coefficient	proportion of variance explained by stool diary	p-value	correlation coefficient	proportion of variance explained by stool diary
Anal incontinence for feces	> 0.05	-	-	**.002**	.470	13.5%
Frequency of bowel movements	**.010**	.456	20.8%	**< .001**	.573 - .587	23.5%
Clustering of bowel movements	> 0.05	-	-	> 0.05	-	-
Urgency	> 0.05	-	-	> 0.05	-	-
Soiling	not applicable			**< .001**	.515	20.3%

Table 2: overview of results.

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FECAL URGENCY INCONTINENCE VERSUS PASSIVE FECAL LEAKAGE: 3D AND DYNAMIC PELVIC FLOOR ULTRASOUND FINDINGS

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HYPOTHESIS / AIMS OF STUDY

Fecal incontinence (FI), defined as the complaint of involuntary loss of feces, has two subtypes: fecal urgency incontinence (FUI), the complaint of the loss of feces associated with urgency, and passive fecal leakage (PFL), involuntary soiling of liquid or solid stool without sensation or warning or difficulty wiping clean [1]. Fecal continence is multifactorial, depending on an adequate rectal reservoir, adequate fecal sensation, stool consistency, and a functioning integral sphincter mechanism. Incontinence occurs when one or more of these mechanisms are compromised beyond compensation by any of the other factors. 3D endovaginal and endoanal ultrasound have an established role in evaluation of FI [2]. The current study aimed to compare the shape and function of the pelvic floor, the rectum and the anal sphincter complex detected by pelvic exam and 3D endoluminal and 2D posterior compartment dynamic ultrasound in women with FUI versus PFL.

STUDY DESIGN, MATERIALS AND METHODS

This was a retrospective observational study and received approval of the Institutional Review Board. Women who presented for evaluation of FI to our tertiary center, between January 2018 and February 2020, were recruited to the study. The presence of FI symptoms was documented if they answered “yes” to questions 9, 10, or 13 on PFDI-20 questionnaire. During the visit, patients underwent a complete interview including: a detailed review of FI pattern and Bristol stool chart for stool type; pelvic exam including POP-Q and rectal exam; and 3D endovaginal pelvic floor ultrasound, 3D endoanal ultrasound and 2D posterior compartment dynamic ultrasound. The imaging was performed in the office with patient in lithotomy position.

Patients were categorized to three groups: FUI-dominant FI, PFL-dominant FI, and both.

A dominant pattern was established if the patient reported at least twice the frequency of one pattern over the other. The patient was categorized as "both" if neither pattern was dominant.

3D Endovaginal ultrasound measurements: The levator muscle was divided in to three subgroups (3): the puboperinealis/puboanalis (PA), puborectalis (PR), and iliococcygeus (IC). Subgroups were evaluated and were scored (0=no defect, 1=minimal defect with < 50% muscle loss, 2=major defect with >50% muscle loss, 3=total absence of the muscle) on each side based on thickness and detachment from the pubic bone. Each muscle score ranged from 0, indicating no defects, to a maximum score of 3, indicating total muscle absence. Minimal levator hiatus, anorectal angle and rectal area at the level of anorectal junction were measured.

3D endoanal ultrasound measurements: The external anal sphincter (EAS) was visualized and, if present, defects were detected. The appearance of an EAS defect is a break in the circumferential integrity of the mixed hyperechoic band. A defect can have either a hypoechoic or hyperechoic pattern. This corresponds to replacement of the normal striated muscle with granulation tissue and fibrosis.

Defects of the internal anal sphincter (IAS) are easily recognized given the prominent appearance of the IAS in the mid-anal canal. They appear as hyperechoic breaks in the normally hypoechoic ring.

2D dynamic posterior compartment ultrasound: The distance between the posterior cul-de-sac and anorectal junction ("rectovaginal septum length") was measured both at rest and during Valsalva in the mid-sagittal plane, Figure1. "Compression ratio" was calculated as a means to quantify the relative change in length of the rectovaginal septum (RVS), in other words the degree of hypermobility / sliding rectum, and was expressed as a percentage.

Statistics: Baseline symptoms, physical examination and 3D-pelvic ultrasound were performed and compared using chi-squared, Fisher's exact test and ANOVA. A sample size of 121 women were needed to detect a 30% difference in pelvic floor defects between the groups with 90% power and $p<0.05$.

RESULTS

145 patients were included in the analysis; 57 categorized as FUI-dominant FI, 69 PFL-dominant FI, and 19 categorized as "both". There were not statically significant differences in the demographic values except for age. The urge-predominant patients were significantly younger than the rest predominant (65.58 ± 12.85 vs 70.32 ± 12.71, p 0.040). While comparing bowel habit and symptoms of obstructed defecation, patient with FUI-dominant FI had more frequent bowel movements (15.5 +/- 13.0/week vs. 10.9 +/- 7.6 /week, p=0.039) and were more likely to have loose stools (12.5% vs. 4.3%, p=0.01). The physical exam findings including POP-Q, levator ani muscle tone and anal sphincter rest and squeeze tone were similar among the groups. Table 1 has summarized the comparison of ultrasound parameters and demonstrated the only statistically significant difference being in rectal compression ratio between urge FI and PFL (28.1 +/- 26.6 vs. 16.6 +/- 21.19, p=0.01).

INTERPRETATION OF RESULTS

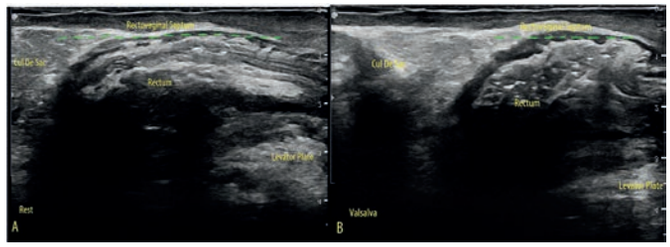
Patients with FUI-dominant FI had more frequent bowel movement and a higher prevalence of loose stool compared with patients with PFL-dominant FI. These findings are consistent with existing studies.

Amongst the ultrasound parameters, patients with FUI had higher rectal compression ratio during Valsalva. The higher rectal compression ratio is associated with presence of rectal intussusception, rectal prolapse and enterocele. This suggests that there may be a dynamic anatomic component to the symptom of FUI.

CONCLUDING MESSAGE

Patients with FUI-dominant FI had more frequent bowel movement and a higher prevalence of loose stool compared with patients with PFL-dominant FI. Patients with FUI-dominant FI had more mobility of their rectum on Valsalva as compared to PFL-dominant FI.

FIGURE 1



Demonstration of "rectovaginal septum length" on rest and on Valsalva

FIGURE 2

Table 1 – Ultrasound Measurements

	Total (N=145)		Urge (N=57)		Rest (N=69)		Both (N=19)		P-value	P-value
	n	%	n	%	n	%	n	%	All 3	Urge vs. Rest
RVS at Rest (cm), mean ± SD	4.65 ± 1.08		4.39 ± 1.13		4.83 ± 0.95		4.68 ± 1.29		0.0964	**0.0264**
RVS at Strain (cm), mean ± SD	3.81 ± 1.60		3.30 ± 1.57		4.12 ± 1.42		3.94 ± 2.03		**0.0212**	**0.0041**
Rectal Compression Ratio (%), mean ± SD	21.22 ± 24.69		28.11 ± 26.65		16.56 ± 21.19		19.97 ± 28.12		**0.0431**	**0.0109**
Dyssynergia										
Yes	6	4.55	1	2.00	4	6.15	1	5.88	0.4978	0.3857
No	126	95.45	49	98.00	61	93.85	16	94.12		
Right Puboanalis, median (range)	2 (0-3)		2 (1-3)		2 (0-3)		2 (1-2)		0.9865	0.9469
Left Puboanalis, median (range)	2 (0-3)		1.5 (1-3)		2 (0-3)		2 (1-2)		0.9669	0.8628
Right Puborectalis, median (range)	1 (0-3)		1 (0-3)		1 (0-3)		2 (1-3)		0.6720	0.9291
Left Puborectalis, median (range)	1 (0-3)		1 (0-3)		1 (0-3)		1 (1-3)		0.7932	0.5495
Right Iliococcygeous, median (range)	2 (0-3)		2 (0-3)		2 (0-3)		3 (1-3)		0.0914	0.9567
Left Iliococcygeous, median (range)	2 (0-3)		2 (0-3)		2 (0-3)		2 (1-3)		0.9362	0.9749
MLH (cm^2), mean ± SD	15.39 ± 3.92		15.74 ± 4.22		15.03 ± 3.39		16.01 ± 4.49		0.4882	0.3116
LPDA (degrees), mean ± SD	7.14 ± 11.45		5.67 ± 13.44		7.85 ± 10.23		8.04 ± 8.87		0.5387	0.3297
Rectal Area (cm^2), mean ± SD	1.96 ± 0.73		1.96 ± 0.73		2.00 ± 0.72		1.88 ± 0.78		0.8114	0.7537
Anorectal Angle (degrees), mean ± SD	168.20 ± 8.85		168.12 ± 9.89		168.29 ± 8.16		169.43 ± 7.13		0.8826	0.9157
EAS Defect										
Yes	18	14.17	6	11.32	10	17.24	2	12.50	0.6570	0.3750
No	109	85.83	47	88.68	48	82.76	14	87.50		
IAS Defect										
Yes	20	15.75	6	11.32	11	18.97	3	18.75	0.5106	0.2640
No	107	84.25	47	88.68	47	81.03	13	81.25		

[1]RVS, Rectovaginal Septum; MLH, Minimal Levator Hiatus; LPDA, Levator Plate Descent Angle; EAS, External Anal Sphincter; IAS, Internal Anal Sphincter

Table 1 - Ultrasound Measurements

REFERENCES

1. Sultan AH, Monga A, Lee J, Emmanuel A, Norton C, Santoro G, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female anorectal dysfunction. Neurourol Urodyn. 2017;36(1):10-34
2. Rostaminia G, White D, Quiroz LH, Shobeiri SA. 3D pelvic floor ultrasound findings and severity of anal incontinence. Int Urogynecol J. 2013.
3. Shobeiri SA, Chesson RR, Gasser RF. The internal innervation and morphology of the human female levator ani muscle. Am J Obstet Gynecol. 2008;199(6):686.e1-6.

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EVALUATION OF SACRAL NEUROMODULATION ON BOWEL DYSFUNCTION IN NEUROGENIC BLADDER PATIENTS BY NEUROGENIC BOWEL DYSFUNCTION SCORE

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HYPOTHESIS / AIMS OF STUDY

This original retrospective study was to evaluate the clinical effect of SNM on neurogenic bowel function in neurogenic bladder patients using the neurogenic bowel dysfunction (NBD) score.

STUDY DESIGN, MATERIALS AND METHODS

We reviewed the medical records of patients who underwent SNM permanent implantation from 2012.7 to 2019.7. Forty-one patients with both neurogenic bladder and bowel dysfunction were evaluated using the NBD score before the testing phase and at follow up. The NBD score is a symptom-based score developed by Krogh et al[1]. which is used to assess the severity of clinical colorectal dysfunction in patients with neurogenic decease or injury. The NBD score is a questionnaire consisting of 10 items related to impaired quality of life caused by bowel symptoms, including frequency of defecation (0–6 points), duration of time for each defecation (0–7 points), uneasiness, headache or perspiration during defecation (0–2 points), regular use of tablets to combat constipation (0–2 points), regular use of drops to combat constipation (0–2 points), digital stimulation or evacuation of the anorectum (0–6 points), frequency of fecal incontinence (0–13 points), medication to combat fecal incontinence (0–4 points), flatus incontinence (0–2 points) and perianal skin problems (0–3 points). The overall NBD score ranges between 0 and 47 points. A higher score indicates more severe bowel symptoms. The severity of NBD is classified into four grades: very minor (0–6); minor (7–9); moderate (10–13) and severe (14 and more).

RESULTS

Overall, 41 patients who underwent permanent SNM implantation were included in the study. The mean age was 38±14.7 years (range 13–73 years), and the mean duration from the beginning of the test phase to discharge after permanent implantation was between 24 and 38 days. The Clinical and demographic characteristics of patients were in table 1.

The mean NBD score decreased from 11.0±5.83 before the testing phase to 5.2±5.32(n=41,$P<0.05$) after permanent implantation before discharge.

Before the testing phase, there were 9 patients of very minor grade, 10 of minor grade, 13 of moderate grade and 9 of severe grade. However, the overall severity of NBD tended to decrease after permanent implantation, with 26 patients of very minor grade, 7 of minor grade, 4 of moderate grade and 4 of severe grade.

From a longitudinal perspective, the NBD grade decreased in 21 (51.2%) patients and did not change in 20 (48.8%) patients (Table 2). However, in the 20 patients whose grade did not change, the mean NBD scores decreased from 8.6±5.00 to 7.2±6.07 ($P < 0.05$).

INTERPRETATION OF RESULTS

Patients with neurologic disease commonly suffer from bladder and bowel dysfunction (constipation and/or fecal incontinence), because the bladder and rectum have closely related somatic and autonomic innervation, and their voluntary control depends on a complete neural network. Sacral neuromodulation (SNM) can improve not only neurogenic lower urinary tract dysfunction but also bowel dysfunction in patients.

In our previous study[2], 23 patients with multiple bladder and/or bowel problems secondary to spinal cord disease or injury were treated with a preliminary test SNM. In the test phase, the rate of improvement in constipation (75.0%) was significantly higher than the rates of improvement in urgency frequency (64.7%), urinary incontinence (69.2%) and dysuria (29.4%). However, we focused on constipation rather than fecal incontinence in that study.

Therefore, in this retrospective study, we aimed to evaluate the effect of SNM in patients with NBD according to NBD scores which can evaluate constipation and fecal incontinence. This finding illustrates the success of SNM in reducing NBD symptoms.

CONCLUDING MESSAGE

SNM facilitates a significant reduction in NBD scores in patients with NBD. The improvement in NBD symptoms can also be used as a future indicator to judge the clinical efficacy of SNM permanent implantation in the treatment of NB.

FIGURE 1

Table 1 Clinical and demographic characteristics of patients (N = 41)

Variables	Number
Demographic data	N=41
Age (years), mean ±SD	38±14.7
Male gender	23
Female gender	18
Etiology	N=41
Incomplete spinal cord injury	10
Spina bifida	18
Postoperative spinal and spinal Cord surgery	8
Encephalomyelitis	4
Multiple system atrophy	1
Symptoms of bowel function	N=41
Constipation	23
Fecal incontinence	8
Constipation combined with fecal incontinence	10

FIGURE 2

Table 2 Longitudinal changes in NBD score grade after permanent implantation in 41 patients

NBD score grade before the testing phase (no. of patients)		Longitudinal changes in NBD score grade after permanent implantation (no. of patients)			
		severe	moderate	minor	very minor
severe	9	4	1	1	3
moderate	13	0	3	2	8
minor	10	0	0	4	6
very minor	9	0	0	0	9

REFERENCES
1. Krogh K, Christensen P, Sabroe S, Laurberg S. Neurogenic bowel dysfunction score. Spinal Cord. 2006;44:625-31.
2. Chen G, Liao L. Sacral neuromodulation for neurogenic bladder and bowel dysfunction with multiple symptoms secondary to spinal cord disease. Spinal Cord. 2014;53:204-08.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** the **Ethics Committee** of our center (Project identification code: 2018-053-1) **Helsinki** Yes **Informed Consent** Yes

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LONG TERM FOLLOW-UP OF TRANS-ANAL IRRIGATION: RESULTS OF ADHERENCE, NBD SCORE AND UTIS IN A SINGLE CENTRE

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1. ASST Ovest Milanese

HYPOTHESIS / AIMS OF STUDY
Neurogenic bowel dysfunction (NBD) affects quality of life: lots of aspects, such as job, hobbies, daily activities, can be conditioned by symptoms related to NBD. Through the establishment of specific bowel program it is possible to mitigate these problems.

Retrograde Trans-Anal Irrigation (TAI) has become an established treatment for neurogenic bowel dysfunction (NBD) which does not respond to conservative management (1). The impact of TAI in NBD is considerable and it improves quality of life by reducing constipation and faecal incontinence.

Moreover through complete emptying of the descending colon, sigmoid colon and rectal ampulla, obtained by TAI, it is possible to carry out more control on the incidence of urinary tract infections (UTIs) (1, 2), because TAI can remove residual stool, the main source of infection

However, some long-term studies have shown a reasonable rate of non-adherence to treatment due to compromised effectiveness and difficulty to use. The percentage of drop out varies from 54% in a series of 19 months follow-up (1), to 14% in a series of children (3). Nevertheless there are only a few studies that investigate adherence to TAI in long term period: long term follow-up of TAI use is not clearly known and the percentage of infections reduction is not clearly demonstrated.

STUDY DESIGN, MATERIALS AND METHODS
From July 2008 to February 2020, 88 patients have been trained in our centre to perform TAI using a system called Peristeen (Coloplast A/S). It is an integrated system consisting of a coated rectal balloon catheter, a control unit including a manual pump, and a water container. The catheter was inserted into the rectum and the balloon inflated to hold the catheter in the rectum while a tap water enema was slowly administered with the manual pump, keeping a stable pressure in the bowel. Subsequently, the balloon was deflated and the catheter removed, followed by bowel emptying of the enema and other bowel contents.

In 2013 we established a "TAI unit" made up of a dedicated team (1 doctor and 3 nurses): before 2013 38 patients were trained, from 2013 50 patients were trained.

We performed a prospective study with the last 50 patients trained to TAI in our centre: we administrated a questionnaire about bowel function (NBD score before and after TAI) ; we asked them the frequency (episodes per year) of urinary tract infections before and after TAI. With the term "infection" we mean symptomatic infection that lead to prescription of antibiotic therapy. Moreover, we asked patients if they follow an antimicrobial prophylaxis, with antibiotics or supplements. We followed the patients by visit or phone interview or e-mail, asking them if they still use TAI; if they do not use TAI yet, we asked them the reason that had determinate the abandonment of the treatment.

RESULTS
From September 2013 to February 2020 we teached TAI technique to 50 patients.

From the 50 patients trained in TAI in our centre, none of the patients is lost at follow up.

Mean follow-up is 40 months (min 2 months, max 77 months).

21 patients are male, 29 patients are female. 20 patients had a spinal cord injury, 6 patients spina bifida, 9 multiple sclerosis, 15 suffered from other pathologies. All of them were adults patients (more than 18 years old).

Currently 40 patients still use Peristeen (80%, group A) and 10 patients (20%, group B) interrupted the treatment. Among group B, the reasons for discontinuing TAI were: unsatisfactory effect in 4 patients (40%), troublesome in using Peristeen in 2 patients (20%), difficulty to source the TAI system (contract health business) in 2 patients (20 %), other reasons in 2 patients (20% - bowel ischemia in 1 patient, worsing of the multiple sclerosis in the other patient).

We evalued NBD score and UTI's frequency in group A before TAI training and after TAI training.

We recorded that mean NBD in group A before TAI is 18 (min 2 – max 32) which corresponds to severe level of bowel dysfunction, after TAI mean NBD score is 6 (minimum score 2 – maximum score 10), which corresponds to very low level of

bowel dysfunction. Best benefits are related to decrease of digital stimulation or evacuation, decrease of faecal incontinence and decrease of discomfort during defecation.

As far as UTIs frequency is concerned, in group A patients meanly reported 7 episodes of UTI per year (min 2 – max 15 episodes per year) before TAI use; after TAI training, patients report meanly 2 episodes of UTI per year (min 0 – max 6 episodes per year). Moreover, 1 patient had a urinary sepsis that required hospitalization before starting TAI; this never happened after the beginning of TAI. As far as antimicrobial prophylaxis is concerned, 16 patients took prophylaxis before starting Peristeen system: among them, 12 patients used supplements, while 4 patients used antibiotics (nitrofurantoin); at the present day, 8 patients take prophylaxis: among them, 7 use supplements and only 1 patient still uses nitrofurantoin.

INTERPRETATION OF RESULTS

First of all, our follow-up is among the longest ones reported in literature.

In our centre the percentage of drop out (20%) is lower than in other series of adult patients.

The reasons for discontinuing TAI were: unsatisfactory effect in 4 patients (40%), troublesome in using Peristeen in 2 patients (20%), difficulty to source the TAI system (contract health business) in 2 patients (20 %), other reasons in 2 patients (20% - bowel ischemia in 1 patient, worsing of the multiple sclerosis in the other patient). The reason of a high retention rate is the creation of a "TAI unit" with a dedicated team, which can adequately study, train and follow the patients.

The level of bowel dysfunction recorded in patients still using TAI is highly decreased (NBD score from 18 before TAI to 6 after TAI), showing that TAI improves QOL.

As reported in literature, TAI reduces UTIs: in our records UTI's episodes per year have been significantly decreased and even the use of prophylaxis had also decreased. However, UTIs meanly did not zero: this is probably related to patient's features and intermittent cateterization; moreover the antibiotics prescription is usually made by physicians that wrongly treat asymptomatic batteriuria.

CONCLUDING MESSAGE

As reported in literature, patients that perform colonic irrigation feel improvements on NBD, that is demonstrated by the decreasing of NBD score. Best results are obtained for digital stimulation, faecal incontinence and discomfort during defecation. TAI has a good impact on urinary tract infection on long term: this study demonstrates that TAI can reduce (and sometimes can zero) the incidence of urinary tract infection straight related to neurogenic bowel dysfunction; TAI can also decrease the use of antimicrobial prophylaxis. Reduction of urinary tract infections produces less hospitalization, decrease of health costs and prevention of bacterial resistance to antibiotics.

The better result is adherence to TAI: in our centre only 20% of patients have stopped TAI treatment, which is one of the best retention rate reported in literature. The recurrent reasons for discontinuing TAI were unsatisfactory effect, troublesome in using the system and difficulty to source the irrigation system. The drop out rate can be reduced by establishing a "TAI unit" to better follow the patients. However, the problem of sourcing the irrigation system remains.

REFERENCES

1. Review of the efficacy and safety of trans-anal irrigation for neurogenic Bowel disfunction - Emmanuel A. – Spinal Cord 48, 664-673 – 2010
2. Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients - P Christensen, J Andreasen and L Ehlers - Spinal Cord (2009) 47, 138–143
3. Spinal Cord (2013), 1–7 2013 - Consensus review of best practice of transanal irrigation in adults - AV Emmanuel, K Krogh, G Bazzocchi, A-M Leroi, A Bremers, D Leder, D van Kuppevelt, G Mosiello, M Vogel, B Perrouin-Verb, M Coggrave, P Christensen and Members of the working group on Trans Anal Irrigation from UK, Denmark, Italy, Germany, France and the Netherlands

Funding Coloplast gave me the TAI system for training **Clinical Trial** No **Subjects** Human **Ethics not Req'd** TAI is a normal clinical practice **Helsinki** Yes **Informed Consent** Yes

SESSION 9 (PODIUM SHORT ORAL) - INCONTINENCE FROM PROSTATE CANCER TREATMENT
Abstracts 131-142
14:30 - 16:00, Pavilion 9
Chairs: Prof Carlos Levi D'Ancona (Brazil), Dr Ajay Singla (United States)

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CHANGES IN LOWER URINARY TRACT SYMPTOMS AFTER PROSTATE BRACHYTHERAPY WITH THE USE OF SPACEOAR® SYSTEM

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HYPOTHESIS / AIMS OF STUDY

Permanent iodine-125 low-dose-rate brachytherapy (LDR-BT) with or without external beam radiotherapy (EBRT) has been one of the standard definitive radiotherapies for localized prostate cancer. As the LDR-BT has been refined, delivered radiation doses have increased, thus maximizing the therapeutic potential of LDR-BT. However, the escalation of local radiation doses may result in acute or chronic toxicities, including genitourinary (GU) or gastrointestinal (GI) toxicities. The SpaceOAR® System (SpaceOAR) (Augmenix Inc., Waltham, MA, USA) is a synthetic polyethylene glycol hydrogel injected between the prostate and rectum that moves the rectum away from the prostate to reduce irradiation of the anterior rectal wall. It has been reported that SpaceOAR led to a reduction in GI events by reducing rectal exposure, furthermore it reduced the GU toxicity and urethral dose of prostate cancer patients treated with EBRT. However, there were few studies which evaluate changes in lower urinary tract symptoms (LUTS) of prostate cancer patients who underwent radiation therapy in combination use of SpaceOAR. We therefore investigated changes of LUTS in patients who were treated with LDR-BT with the use of SpaceOAR.

STUDY DESIGN, MATERIALS AND METHODS

This study was approved by the institutional review board. From August 2004 to February 2020, 483 patients underwent LDR-BT for localized prostate cancer at our hospital. Of those, 30 patients were treated with LDR-BT in combination use of SpaceOAR (SpaceOAR group), and 453 patients were treated with LDR-BT alone (non-SpaceOAR group).

All LDR-BT with iodine-125 seeds were performed using the ultrasonography-guided intraoperative transperineal technique. The prescribed minimum peripheral doses of iodine-125 seeds were 145Gy for LDR-BT alone and 104Gy for LDR-BT + EBRT. To minimize the artifact in ultrasound imaging and avoidance of potential pubic arch interference SpaceOAR placement was carried out just after seed implantation. Neoadjuvant androgen deprivation therapy (ADT) was used for reducing prostate volume and/or for anticancer effects as required. Alpha-1 blocker was routinely initiated on all patients after LDR-BT to reduce risk of urinary retention, and it was discontinued after recovery of LUTS.

LDR-BT post plan CT and MRI were taken 30 day after seed implantation, and dosimetric parameters (minimum dose received by 90% of the target volume [D90], percentage of target volume receiving minimum of 100% of prescribed dose [V100], minimum dose received 30% of urethral volume [UD30], rectal volume receiving minimum of 100% of prescribed dose [RV100], rectal volume receiving minimum of 150% of prescribed dose [RV150]) were evaluated. To evaluate LUTS, the changes from pretreatment in International Prostate Symptoms Score (IPSS), Overactive Bladder Symptoms Score (OABSS) and quality of life due to urinary symptoms (IPSS-QOL) were assessed at 1, 3, 6, 9, 12 months after LDR-BT. Uroflowmetry and post-voided residual urine (PVR) were also assessed at pretreatment, 1, 3, 6, 9 and12 months.

Linear mixed-effect models were used to analyze the longitudinal data and to assess the least square means differences between two groups at the period of each measurement. The interaction term between SpaceOAR group and period were incorporated into the model to evaluate the effect mofdification. In addition, age, body mass index (BMI), ADT, number of seeds, prostate volume, D'Amico risk classification and baseline value of outcome were treated as adjusted variables in each model. All analyses used 5% two-sided significant level and performed using R software version 3.6.3 (www.r-project.org) with "lme4" package.

RESULTS

The patient characteristics are shown in Table. The median age at baseline, median prostate-specific-antigen (PSA) at diagnosis of prostate cancer, and median prostate volume at LDR-BT were 66 years (interquartile range [IQR]; 62-71 years), 6.4 ng/mL (IQR; 5.1-9.0 ng/ mL) and 22.5 mL (range; 17.7-29.1 mL), respectively in non-SpaceOAR group and 72 years (IQR; 61.3-71 years), 7.3 ng/ mL (IQR; 5.8-10.6 ng/ mL) and 27.3 mL (range; 21.4-31.8 mL), respectively in SpaceOAR group. The LDR-BT + EBRT consisted of 192 patients (42.4%) in non-SpaceOAR group and 16 patients (53.3%) in SpaceOAR group. The median IPSS, OABSS, IPSS-QOL, maximum flow rate (Qmax), voided volume (VV), and PVR before LDR-BT were 5 (IQR; 3-9), 3 (IQR; 2-4), 2 (IQR; 1-3), 17.6 mL/s (IQR;

14.5-21.7 mL/s), 250 mL (IQR; 183-349 mL) and 15.0 mL (IQR; 3.9-30 mL), respectively in non-SpaceOAR group and 7 (IQR; 3-10), 3 (IQR; 2-5), 3 (IQR; 1-4), 15.1 mL/s (IQR; 11.7-19.1 mL/s), 177.8 mL (IQR; 125.8-292.5 mL) and 30 mL (IQR; 2.0-52.5 mL), respectively in SpaceOAR group. There were no significant differences of D90, V100, and UD30 between two groups, while RV100 ($p<0.001$) and RV150 ($p=0.033$) were significantly lower in SpaceOAR group.

Both in non-SpaceOAR group and SpaceOAR group, IPSS, OABSS, and IPSS-QOL increased at 3 months after LDR-BT, and the scores decreased at 12 months. Analysis of variance revealed that follow-up time was significantly related change of IPSS, OABSS, and IPSS-QOL ($p<0.001$, $p<0.001$ and $p<0.001$, respectively). SpaceOAR did not show significant differences in relationship between follow-up time and following factors, IPSS, OABSS and IPSS-QOL. Although transient deterioration of Qmax and VV were observed, all factors recovered in 6 to 9 months after LDR-BT in both group. Analysis of variance revealed that follow-up time was significantly related changes of PVR ($p<0.001$). Interestingly, the use of SpaceOAR significantly affected chronological change in PVR ($p=0.001$). The least square mean of PVR in SpaceOAR group was significantly increased compared with non-SpaceOAR group at 3 months after LDR-BT (49.8mL vs 30.5mL, $p=0.002$).

INTERPRETATION OF RESULTS

SpaceOAR significantly reduce irradiation of the rectum, which is same as previous reports. Although post-voided volume increased significantly in SpaceOAR group at 3 months after LDR-BT, changes in following factors IPSS, OABSS, IPSS-QOL and uroflowmetry were not significant. Less than 50 mL of PVR that could not affect symptoms may explain this discrepancy.

CONCLUDING MESSAGE

This is the first study demonstrating changes in LUTS in prostate cancer patients who were treated with LDR-BT in combination use of SpaceOAR. The use of SpaceOAR may increase PVR temporally along with no significant change in LUTS after treatment of LDR-BT. Overall, changes in LUTS after LDR-BT in combination use of SpaceOAR were seemed to be tolerable.

FIGURE 1

Table. Characteristics of patients

	Overall (n=483)	Non-SpaceOAR group (n=453)	SpaceOAR group (n=30)
Age (year, median, IQR)	66 (62 - 71)	66 (62 - 71)	72 (61.3 - 71)
Initial PSA (ng/mL, median, IQR)	6.5 (5.1 - 9.1)	6.4 (5.1 - 9.0)	7.3 (5.8 - 10.6)
Gleason score (median, IQR)	7 (6 - 7)	7 (6 - 7)	7 (7- 7)
Clinical T stage (number, %)			
T1c	250 (51.7%)	244 (53.9%)	6 (20.0%)
T2a	139 (28.8)	126 (27.8%)	13 (43.3%)
T2b	31 (6.4%)	26 (5.7%)	5 (16.7%)
T2c	50 (10.4%)	46 (10.2%)	4 (13.3%)
T3a	13 (2.7%)	11 (2.4%)	2 (6.7%)
Risk classification (number, %)			
Low	183 (37.9%)	180 (39.7%)	3 (10.0%)
Intermediate	219 (45.3%)	202 (44.6%)	17 (56.7%)
High	81 (16.8%)	71 (15.7%)	10 (33.3%)
BMI (kg/m^2, median, IQR)	23.5 (21.9 - 25.4)	23.5 (21.9 - 25.3)	24.1 (22.8 - 25.6)
Prostate volume (mL, median, IQR)	22.9 (18 - 29.3)	22.5 (17.7 - 29.1)	27.3 (21.4 - 31.8)
Inserted seed (number, median, IQR)	64 (52 - 78)	64 (51.5 - 78)	65 (56.3 - 76.5)
Neoadjuvant ADT (number, %)	369 (76.4%)	353 (77.9%)	16 (53.3%)
Treatment modality (number, %)			
LDR-BT	274 (56.7%)	261 (57.6%)	13 (43.3%)
LDR-BT + EBRT	209 (43.3%)	192 (42.4%)	17 (56.7%)
Preoperative IPSS (median, IQR)	5 (3 - 9)	5 (3 - 9)	7 (3 - 10)
Preoperative OABSS (median, IQR)	3 (2 - 4)	3 (2 - 4)	3 (2 - 5)
Preoperative IPSS-QOL (median, IQR)	2 (1- 3)	2 (1 - 3)	3 (1 - 4)
Preoperative Qmax (mL/s, median, IQR)	17.5 (14.2 - 21.5)	17.6 (14.5 - 21.7)	15.1 (11.7 - 19.1)
Preoperative VV (mL, median, IQR)	248 (180.5 - 347.2)	250 (183 - 349)	177.8 (125.8 - 292.5)
Preoperative PVR (mL, median, IQR)	15 (4.1 - 30)	15 (3.9 - 30)	30 (2.0 - 52.5)

Table

Funding None. **Clinical Trial** No **Subjects** Human **Ethics Committee** Gifu university **Helsinki** Yes **Informed Consent** Yes

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DAILY AMOUNT OF URINARY INCONTINENCE IMMEDIATELY AFTER CATHETER REMOVAL CAN BE A GOOD PREDICTOR OF LONG-TERM URINARY INCONTINENCE FOLLOWING ROBOT-ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY

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HYPOTHESIS / AIMS OF STUDY

Robot-assisted laparoscopic radical prostatectomy (RARP) is becoming a standard treatment for localized prostate cancer, and it is being performed worldwide. Stress urinary incontinence (SUI), one of the most important complications after prostatectomy, has been reported to affect the quality of life (QOL) negatively. De novo SUI after RARP improved

within a year after surgery in majority of the patients; however, some patients continued to suffer from SUI for over a year after RARP. A decrease in urethral functions after RARP, such as maximum urethral closing pressure (MUCP) and functional profile length (FPL), has been reportedly associated with the occurrence of SUI. In patients with a greater decrease in urethral function, the postoperative urinary incontinence (UI) tends to be prolonged. Hence, the evaluation of urethral function is useful in predicting the UI recovery period; however, this evaluation is invasive because catheterization is required to measure the urethral pressure. Therefore, there is a need for easily obtainable parameters to evaluate the long-term UI after RARP, in order to provide an appropriate course of treatment for patients undergoing RARP in a timely fashion. Recently, some studies have reported that the amount of urine loss on day 1 after catheter withdrawal was the most important predictor of urinary continence recovery after prostatectomy. Thus, the present study aimed to investigate easily obtainable parameters in clinical practice, including the amount of urine loss on day 1 after catheter withdrawal, to predict the long-term SUI after RARP.

STUDY DESIGN, MATERIALS AND METHODS

We prospectively examined 350 patients who underwent RARP for localized prostate cancer. We divided the patients into two groups (continence group and incontinence group) 12 months after surgery, according to the presence or absence of SUI evaluated using a 24-hour pad test. The following parameters were compared between the groups to identify clinical signs associated with long-term SUI: pre-operative parameters including age, body mass index (BMI), initial serum prostate-specific antigen (PSA) level, total-international prostate symptom score (IPSS), IPSS-voiding sub-score, IPSS-storage sub-score, total overactive bladder symptom score (OABSS), MUCP, and FPL; operative parameters including blood loss, resected prostate volume, nerve-sparing, and amount of UI using the 24-hour pad test after catheter removal (on postoperative day 6 [6POD]); and postoperative parameters including MUCP and FPL (3 months postoperatively). In the present study, UI was defined as less than 2 g of UI using the 24-hour pad test.

RESULTS

A total of 315 patients with a mean age of 66.7 years were included in this analysis. At 12 month after RARP, Urinary continence was obtained in 250 patients (79.4%), and 65 patients (20.6%) had SUI. The comparison between the continence and incontinence groups for pre-operative parameters showed that age (66.2 years vs. 68.7 $p = 0.004$), total-IPSS (9.7 vs. 11.7, $p = 0.004$), and IPSS-storage score (4.3 vs. 5.3, $p = 0.006$) were significantly lower in the continence group. For the operative parameters, the nerve-sparing rate was significantly higher in the continence group (58% vs. 25%, $p < 0.001$). Furthermore, the 24-hour amount of UI at the time of catheter removal (6POD) was significantly lower in the continence group (166 g vs. 706 g, $p< 0.001$). As for the postoperative parameters, the MUCP (60.1 cmH2O vs. 40.9 cmH2O, $p < 0.001$) and FPL (25.2 mm vs. 21.3 mm, $p < 0.001$) at postoperative 3 months were significantly higher in the continence group. A multivariate logistic regression analysis using the parameters that showed significant differences in the univariate analysis revealed that the 24-hour UI immediately after catheter removal and postoperative MUCP were significant predictors of long-term SUI after RARP. Receiver operating characteristic (ROC) curve analysis identified 325 g/day and 50 cmH2O as the optimal cut-off values for 24-hour amount of UI at 6POD and postoperative MUCP, respectively, as the predictors of long-term UI. The values of 24-hour UI at 6POD and postoperative MUCP yielded sensitivities of 91% and 78%, respectively, and specificities of 84% and 80%, respectively (Figure). The area under the curve value in the ROC curve analysis of the 24-hour amount of UI at 6POD and postoperative MUCP were 0.928 and 0.840, respectively. Additionally, 24-hour UI at 6POD showed a positive correlation with the urinary continence recovery period ($r = 0.74$, $p < 0.001$).

INTERPRETATION OF RESULTS

The detailed mechanism explaining how the 24-hour UI at 6POD efficiently predicts the long-term UI after RARP remains unclear, but we can offer a plausible hypothesis. The 24-hour UI after catheter removal negatively correlated with postoperative MUCP ($r = –0.55$, $p < 0.001$) and postoperative FPL ($r = –0.34$, $p < 0.001$). Thus, the 24-hour UI after catheter removal probably reflected the postoperative urethral functions.

CONCLUDING MESSAGE

The 24-hour amount of UI at the time of catheter removal after RARP can be an efficient predictor of the recovery time of urinary continence following RARP.

Funding This study has been not funded or supported by any company. All authors declare that they have no conflict of interest. **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** The ethics committee of the Nagoya University Graduate School of Medicin **Helsinki** Yes **Informed Consent** Yes

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ADVERSE EVENTS ASSOCIATED WITH MALE URETHRAL SLING PLACEMENTS: A REVIEW OF THE MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE DATABASE (MAUDE)

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HYPOTHESIS / AIMS OF STUDY

Several therapies involving medical devices exist to treat male stress urinary incontinence (SUI), most commonly a result of sphincteric incompetence following radical prostatectomy. An earlier development in surgical correction for male SUI, the artificial urinary sphincter (AUS) has been dubbed the gold standard implant, particularly in moderate to severe cases. Alternatively, the male urethral sling was designed to buttress the bulbar urethra via ventral compression and elevation, often reserved for patients with milder cases and diminished dexterity. In the United States, three perineal male sling systems have been popularized: the AMS AdVance™ (trans-obturator), the AMS InVance™ (bone-anchored), and the Coloplast Virtue™ (quadratic) slings. Few studies have investigated long-term outcomes of such devices, with a recent review reporting median follow-up ranging from 12 to 58 months [1]. In light of recent heightened scrutiny and regulatory changes in mesh therapy for female pelvic floor surgery, we decided to analyze adverse events reported for male urethral slings to the United States Food and Drug Administration (FDA) [2]. We aimed to review this publicly available federal database for unfavorable outcomes associated with these devices as well as evaluate trends in salvage therapy after sling failure.

STUDY DESIGN, MATERIALS AND METHODS

We queried the Manufacturer and User Facility Device Experience Database (MAUDE) for event types classified as "injury", "malfunction" or "death" with relation to male urethral sling systems from July 1, 2009 to June 30, 2019. We also searched the commercially available devices by brand name—AMS AdVance, AMS InVance and Coloplast Virtue—to ensure we captured all associated reports. Our search generated a raw tally of 776 reports. After filtering duplicated entries and applying our exclusion criteria for insufficient information, we identified 429 total remaining reports. A minority of the reports required reclassification of the event types based on the event description provided.

RESULTS

The AMS products accounted for 420/429 (98%) reports, including 326/429 (76%) AdVance and 68/429 (16%) InVance slings; an additional 26/429 (6%) AMS slings were unspecified. There were otherwise only 9/429 (2%) total reports for the Coloplast Virtue sling. Notably, 51/68 (75%) of the InVance reports were submitted prior to 2014, while 25/26 (96%) of the unspecified AMS slings were reported in 2018-2019 (Figure 1).

Overall, no deaths were recorded. Of the event types, there were 406/429 (94.6%) injuries and 23/429 (5.4%) malfunctions observed (Table 1). Time to presentation was not consistently noted, however, 38/429 (9%) were described as intra-operative events, of which 20/38 (53%) were classified as malfunctions. Persistent SUI was by far the most common primary complication reported at 209/406 (51%), followed by erosion at 37/406 (9%) and infection at 32/406 (8%). The most common intra-operative injury described was a urethral or bladder perforation and accounted for 19/406 (4.7%) reports, all of which involved the trans-obturator AdVance sling. The most common device malfunction, 10/23 (43%), involved either the sheath or plastic connector of the AdVance sling being inadvertently left in situ. A break in the mesh product was the second most common malfunction, reported 7/23 (30%) times. The only malfunctions seen for InVance slings were 3/23 (13%) cases in which the anchoring bone screws were displaced.

Of the 409 injury reports, 335 (82%) described a necessary surgical intervention for the unfavorable outcome. The remaining 74 (18%) reports either managed the complication conservatively or did not note an operative treatment in the event description. Overall, new continence devices were implanted in 275/429 (64%) cases. An AUS was implanted in 118/275 (43%), and an additional 137/275 (50%) noted placing an "alternative continence device" but did not identify the specific product. Only 20/275 (7%) cases noted a new sling was implanted, 6/20 (30%) of which were replaced at the time the original sling malfunctioned. A majority of the malfunctions, 16/23 (70%), otherwise did not require a new device. At least 91/429 (21%) slings required removal, 41/91 (45%) of which had a new device implanted concurrently. All 53/406 (13%) reports that detailed a salvage procedure but could not specify an injury described an AUS placed in managing the adverse event.

INTERPRETATION OF RESULTS

The general distribution of adverse events per sling device is consistent with prior literature noting AdVance slings to be most popularly implanted followed by InVance and Virtue [3]. The observation that InVance reports were predominately submitted earlier in the cohort may be reflective of the device no longer being available on the market by the latter half of the decade. Persistent SUI, which can be considered a marker of sling failure, was the most common reason why additional surgery was required. Device malfunctions accounted for a minor fraction of all reports in this current study, the bulk of which can be attributed to user error. Though the incidence of complications and success rates for male slings in the literature may vary, it is important to acknowledge this report's surgical outcomes information as it is publicly available to our patients.

CONCLUDING MESSAGE

As male urethral slings are implantable synthetic products, medical device safety should be considered in their use. An array of adverse events has been reported in the publicly available MAUDE database for the three popular fixed male slings. The majority of these events necessitated surgical intervention and a considerable amount involved implanting secondary continence devices.

FIGURE 1

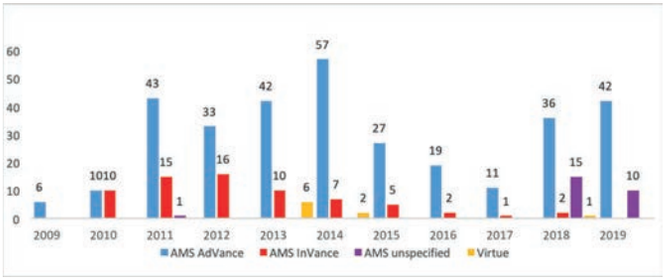

Figure 1. Distribution of adverse events by sling type and year of submission

FIGURE 2

	AMS AdVance	AMS InVance	AMS unspecified	Virtue	Grand Total
Injury					
Persistent SUI	172	31	6		209
Unspecified	31	2	19	1	53
Erosion	35	1		1	37
Infection	12	19	1		32
Urethral/Bladder perforation	19				19
Pain	7	6		3	16
Retention	10	1		1	12
Urge incontinence	6			1	7
Dysuria/Urinary tract infection	6				6
Bleeding/Hematoma	4				4
Numbness	3			1	4
Erectile dysfunction	1	1			2
Fistula		2			2
Urethral stricture	1	1			2
Hernia		1			1
Total injury	**307**	**65**	**26**	**8**	**406**
Malfunction					
Sheath/Plastic connector left in situ	10				10
Mesh broke	7				7
Bone screw displaced		3			3
Poor trocar attachment	2				2
Poor suture delivery				1	1
Total malfunction	**19**	**3**	**0**	**1**	**23**
Grand Total	**326**	**68**	**26**	**9**	**429**

Table 1. Adverse events and associated sling types

REFERENCES

1. Meisterhofer K, Herzog S, Strini KA, et al. Male slings for postprostatectomy incontinence: a systematic review and meta-analysis. Eur Urol. 2019;01:008.
2. Sandberg JM, Gray I, Pearlman A, Terlecki RP. An evaluation of the Manufacturer and User Facility Device Experience database that inspired the United States Food and Drug administration's reclassification of transvaginal mesh. Investig Clin Urol. 2018 Mar;59(2):126-132.
3. Doudt AD and Zuckerman JM. Male slings for post-prostatectomy Incontinence. Rev Urol 2018; 20(4): 158-169

Funding None **Clinical Trial** No **Subjects** None

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PROSPECTIVE REGISTRY FOR PATIENTS UNDERGOING SURGERY FOR MALE STRESS URINARY INCONTINENCE IN MULTIPLE EUROPEAN CENTRES. A NOVEL UPDATE OF THE EUROPEAN REGISTRY 'SATURN'

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HYPOTHESIS / AIMS OF STUDY

Artificial urinary sphincter (AUS) or AMS800 implantation has been the standard of care for refractory male stress urinary incontinence (SUI). New procedures with other devices are increasingly used. Prospective multicentre outcome data are lacking. There are no clear recommendations which patient factors determine the best treatment option for SUI. The prospective registry for patients undergoing surgery for male stress urinary incontinence SATURN: Surgery for mAle incontinence with arTificial Urinary sphincters and slings, a EAU Reference Network, was started to overcome these issues. Objectives of this registry are to prospectively evaluate the effects (efficacy, complications/revisions and PROMs) of surgical treatment of SUI with current available devices and to determine prognostic factors that correlate with outcomes.

STUDY DESIGN, MATERIALS AND METHODS

The aim of the Saturn registry is to prospectively recruit 1000 male patients undergoing implant surgery to treat SUI. All existing devices are registered. The patients will be followed up for 10 years with regard to safety and efficacy. Cure rate is defined as no pad use or the use of 1 security pad. PROMS (quality of life; incontinence, technical failures, infection and or erosion, pain, handling of device, etcetera) and clinical data are collected from study visits at baseline; date of surgery; 6 weeks for activation in case of AUS or devices that need to be activated, 12 weeks post-surgery and yearly post-surgery up to year 10.

RESULTS

After obtaining ethical committee approval in 2016, so far 587 patients have been recruited over 38 months in the Netherlands (2 centres, n=132), Belgium (4 centres, n=189), Czech Republic (1 centre, n=39), Spain (8 centres, n=99),

Germany (3 centres, n=7), United Kingdom (2 centres, n=32), Norway (1 centre, n=82) and Italy (1 centre, n=16). 27 % of participating centres included more than 25 patients/year, while 45% of centres included less than 10 patients/year. Recruitment speed is currently 40 patients/month. Devices used were AMS 800TM (66.1 %), Victo Plus TM (4.2 %), ZSI 375 TM (0.5%), Argus TM Sling (2.4%), Advance XP TM (18.1%), ATOMS TM (4.4 %), ProACT TM (3.3%), Virtue Sling TM (0.5%), Reemex TM (0.2 %) and TiLOOP (0.2 %). 56% of centres use 2 or more techniques to treat SUI.

The main cause of SUI was radical prostatectomy (RP) (81.6 %), radiotherapy (RT) (5.2 %), minimally invasive treatments for voiding LUTS (9.1 %), or other (4.1 %). In case of RP as main cause of SUI, the type of procedure was Open Prostatectomy (OP) (28.5 %), Laparoscopic Prostatectomy (17.3 %) (LAP), Robot Assisted Radical Prostatectomy (RARP) (50.2 %) or other (4.0 %). From these patients, 28.5% have undergone adjuvant RT. 40.1 % of AUS patients and 15.4 % of Sling patients had a history of RT. 36 (6.1 %) patients underwent device explant with a median time from surgery to explantation of 15 weeks (AUS) vs. 66 weeks (Sling).

INTERPRETATION OF RESULTS

Baseline data show a 2:1 distribution of AUS compared to other devices. The major cause of SUI was prostatectomy which in most cases was performed by RARP. Prospective collection of predefined data from patients undergoing surgical SUI treatment in multiple European centres will enable evaluation of long term efficacy, safety and impact on QoL. Due to the real life setting we will be able to analyze the value of different techniques but also the significance of centre and patient characteristics. With the current inclusion rate planned recruitment numbers are achievable and the registry will yield clinically useful and long term results.

CONCLUDING MESSAGE

Prospective multicentered data are, also for surgical treatments for stress urinary incontinence in males, of utmost importance to select the best treatment option for patients. Based on non-biased data patients can select that treatment option that fits them best, based on solid expectations about efficacy and complications that they might encounter.

The Saturn prospective registry helps in fulfilling these needs and provides honest data about treatments which enables patients to select the optimal treatment, based on the possibilities and experience per participating center.

Funding Unrestricted grant from Boston Scientific **Clinical Trial** Yes **Registration Number** The EAU Research Foundation # EAU-RF 2016-01 **RCT** No **Subjects** Human **Ethics Committee** CMO Radboudumc Nijmegen, the Netherlands **Helsinki** Yes **Informed Consent** Yes

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ARTIFICIAL URINARY SPHINCTER OUTCOMES IN MEN WITH A HISTORY OF RADIATION THERAPY

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HYPOTHESIS / AIMS OF STUDY

Stress urinary incontinence (SUI) is an unfortunate and common comorbidity associated with the treatment of prostate cancer. With the use of primary or adjuvant radiation therapy, men can develop debilitating SUI that significantly impacts their quality of life. The Artificial urinary sphincter (AUS) is the gold standard surgical intervention for severe SUI in men with a history of radiation therapy. In this study, we aimed to evaluate our institution's experience with AUS placement after radiation therapy.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective chart review was completed of patients with a history of radiation therapy who underwent AUS placement from 2003-2019. Baseline characteristics included demographics, type of radiation, history of radical prostatectomy, number of pads used, history of stricture disease, and history of prior incontinence procedure. Post-surgical outcomes included continence status measured by pads per day, post-operative complications, and activation of AUS per protocol. Additionally, need for future procedures such as urethral dilation and redo/removal of AUS was evaluated.

RESULTS

130 men with a history of radiation therapy underwent AUS placement at our institution from 2003-2019 for urinary incontinence. The mean follow up was 10.7 months (IQR 0.25-63.4). Patient demographic characteristics included a mean age of 71.8 years, median American Society of Anesthesiologists class of 2, and a median BMI of 30.13 kg/m2. In regards to radiation therapy, 108 (83.1%) had external beam radiation therapy, 1 (0.8%) had proton beam therapy, 6 (4.6%) had both brachytherapy and external beam therapy. 111 (85.4%) had previously undergone radical prostatectomy and 59 (45.4%) had a history of urethral stricture disease, with the majority of these patients requiring dilation. 38 (29.2%) had a previous incontinence procedure. Of these patients, 20 (52.6%) had previous sling, 17 (44.7%) had previous AUS, and 1 (2.6%) had prior sling and AUS placed. Mean pads per day pre-operatively was 6.2 (IQR 1-20). Post-operatively, mean pads per day was 1.7 (IRQ 0-20). Post-operative complications included hematoma formation (n=4, 3.1%), infection (n=6, 4.6%), and urinary retention (n=11, 8.5%). Additional procedures were required in 51 patients and included further dilation (n=20, 15%) and AUS removal or revision (n=28, 22%).

INTERPRETATION OF RESULTS
Based upon the study results, it is evident that AUS placement after radiation therapy can significantly improve SUI as demonstrated by a mean 4.5 pads per day improvement in pad usage. AUS placement can be completed with minimal post-operative complications, as 21 patients experienced a complication within 30 days of surgery which resolved without further surgical intervention. However, patients should be counseled regarding the potential for reoperation, as 22% of patients required revision or removal of the AUS during our follow up period.

CONCLUDING MESSAGE
We present the largest prospective series to date of men undergoing AUS placement after radiation therapy, which remains the gold standard surgical intervention for management of SUI in this patient population. Our study demonstrates that men can have significant improvement with SUI with AUS placement. However, patients need to be counseled on the potential for reoperation.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective study **Helsinki** Yes **Informed Consent** No

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PREDICTIVE FACTORS FOR URINARY RETENTION AFTER ROBOT-ASSISTED RADICAL PROSTATECTOMY

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HYPOTHESIS / AIMS OF STUDY
Urinary retention is a problematic complication of robot-assisted radical prostatectomy (RARP). This adverse effect can occasionally develop and lead to a reduction in quality of life, increased medical costs, and so on. However, the pathophysiology remains unclear, and there are no predictive factors for postoperative urinary retention. Moreover, it is unknown whether postoperative urinary retention is related to postoperative lower urinary tract symptoms (LUTS) in the long term. The aim of this study was to investigate the factors contributing to urinary retention after RARP as well as the impact of urinary retention on postoperative LUTS.

STUDY DESIGN, MATERIALS AND METHODS
This was a retrospective, single-center study. We assessed 963 patients who had undergone RARP for prostate cancer between May 2010 and January 2020 at our institution. RARP was carried out via the transperitoneal approach with six ports. Postoperative urinary retention was defined as urinary retention developing within 3 days after removal of the urethral catheter. We evaluated the relationships between postoperative urinary retention and the following factors: age, body mass index, prostate volume, preoperative international prostate symptom score (IPSS), intraoperative hemorrhage, nerve-sparing surgery, lymph node dissection, vesicourethral anastomosis methods (barbed suture or no-barbed suture), and the time of urethral catheter removal. Furthermore, we evaluated the difference in postoperative IPSS 12 months after surgery between patients with and without urinary retention.

RESULTS
The urethral catheter was removed, on average, 5.4±1.5 days after RARP. Of the 963 patients, 33 (3.4%) developed urinary retention after RARP. All 33 patients were treated with a temporal indwelling urethral catheter or intermittent self-catheterization. Only 3 patients developed anastomotic strictures subsequently. Univariate analysis showed that preoperative IPSS question 1 (incomplete emptying) and nerve-sparing surgery were significantly associated with urinary retention after RARP (p=0.02 and 0.04, respectively). Multivariate analysis also showed that these factors were significantly associated with urinary retention after RARP (incomplete emptying: odds ratio [OR], 1.34; p=0.03; 95% confidence interval [CI], 1.03–1.75; nerve-sparing surgery: OR 0.24; p=0.02; 95%CI, 0.07–0.81) (Table 1). Furthermore, multivariate analysis showed that preoperative IPSS question 5 (weak stream; OR, 1.63; p<0.001; 95% CI, 1.35–1.96) and postoperative urinary retention (OR, 3.24; p=0.03; 95% CI, 1.10–9.52) were significantly associated with postoperative IPSS question 5 (Table 2). In contrast, postoperative urinary retention was not significantly associated with other postoperative IPSS domains.

INTERPRETATION OF RESULTS
Our study indicates that (1) post RARP surgery, urinary retention is associated with the preoperative sensation of incomplete emptying and nerve-sparing surgery and (2) postoperative urinary retention leads to the postoperative sensation of weak stream 12 months after the RARP surgery. Since postoperative urinary retention was not associated with prostate volume in this study, preoperative detrusor underactivity may be one of the underlying mechanisms of postoperative urinary retention. In addition, moderate anastomotic stricture may occur after urinary retention as these patients in this study experience postoperative sensation of a weak stream. It is possible that nerve-sparing surgery could prevent postoperative urinary retention and the following anastomotic stricture via preservation of urethral blood supply. Further studies are required to confirm this.

CONCLUDING MESSAGE
Postoperative urinary retention is associated with preoperative sensation of incomplete emptying and nerve-sparing surgery. Since patients with postoperative urinary retention could have LUTS in the long term, they require careful follow-up.

FIGURE 1

Univariate analysis

	Age	Prostate volume	Body mass index	Intraoperative haemorrhage	the time of urethral catheter removal	Nerve-sparing	Lymph node dissection	Vesicourethral anastomosis methods
P-value	0.91	0.56	0.56	0.09	0.92	0.04	0.12	0.05
	IPSS Q1	IPSS Q2	IPSS Q3	IPSS Q4	IPSS Q5	IPSS Q6	IPSS Q7	IPSS total
P-value	0.02	0.80	0.10	0.50	0.05	0.12	0.95	0.07

Multivariate analysis

	IPSS Q1	IPSS Q5	Nerve-sparing	Vesicourethral anastomosis methods
P-value	0.03	0.74	0.02	0.14
Odds ratio	1.34	1.05	0.24	1.81
95% confidential intervals	1.03-1.75	0.77-1.42	0.07-0.81	0.82-4.00

Table 1 Univariate and multivariate analyses of the predictive factors for postoperative urinary retention.

FIGURE 2

Univariate analysis								
	Urinary retention	Age	Body mass index	Preoperative IPSS Q5	Prostate volume	Nerve-sparing	Lymph node dissection	Vesico-urethral anastomosis
P-value	<0.001	0.16	0.18	0.005	0.83	0.005	0.001	0.14
Multivariate analysis								
P-value	0.03			<0.001		0.78	0.93	
Odds ratio	3.24			1.63		0.91	1.02	
95% confidential intervals	1.10-9.52			1.35-1.96		0.47-1.76	0.70-1.47	

Table 2 Univariate and multivariate analyses of predictive factors for postoperative IPSS question 5 (weak stream).

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** the ethics committee of Nagoya University Graduate School of Medicine **Helsinki** Yes **Informed Consent** No

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POST RADICAL PROSTATECTOMY INCONTINENCE: DIAGNOSIS OF DYSFUNCTION, OUTCOME AND REVISION RATE IN A PROSPECTIVE SET OF 293 SUCCESSIVE PATIENTS WITH A UNIFORM DIAGNOSTIC WORKUP.

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HYPOTHESIS / AIMS OF STUDY

Incontinence after radical prostatectomy (PRPi) affects the patient's quality of life. Adequate selection of treatment depends on correct diagnosis. The prevalence of sphincter deficiency in this group of patients is high. Pelvic floor training (PFT) is effective in many patients and is usually first line management. In a proportion of patients however, bothersome incontinence remains after 6 months of conservative measures and PFT. Many of these patients request further treatment. In one (US-cancer) outcomes surveillance 1,057 out of 16,348 men (6%) had undergone at least 1 incontinence procedure. In 34% of these, artificial urinary sphincter placement was the only procedure performed. PMID: 230175282013. In a more recent study, based on insurance data, 1,068 out of 29,287 men (3.6%) were treated with incontinence surgery. PMID: 31642741. Predicting success of surgical treatment for male incontinence , based on severity of incontinence (symptoms or volume loss) or urodynamic parameters (leak point pressure, detrusor overactivity or compliance), has not been very succesful.1,2 In an analysis of PRPi in combination with frequent voiding and or small bladder capacity, detrusor overactivity was not found to have an impact on the overall outcome although small capacity predicted frequent voiding after implantation. PMID: 21497853 Various methods have been published for PRPi urodynamic assessment, but standardization is lacking.3 We are a tertiary referral center for artificial sphincter implantations and designed a standardized urodynamic workup to evaluate PRPi. From our pool of patients with uniform diagnostic data and management follow-up, we aimed to analyze the value of individualized specific and objective diagnosis of dysfunction and its role in treatment outcome.

STUDY DESIGN, MATERIALS AND METHODS

237 Patients referred between Jan 2006 and July 2019 with PRPi or post prostatectomy were mean age 68.7 (43-86) years at the time of urodynamic investigation; 49.7 months after the index-surgery (4-218 months). Of all patients 12% had treatment for (neo-bladder-neck) strictures, 8% had failed sling(s) or failed cuff(s) (4%) or bulking (2%). Pelvic floor exercise programs according to local protocols were completed by 58% of patients with moderate or positive effects in 29% of the patients. 61% had no urine loss while asleep. 58% of the patients voided on the toilet more than

once a day and 74% used condom catheter or diapers. The other patients 'only' used pads. When referred to our hospital for further investigation 50% was on (or had tried) anticholinergic treatment. Two patients died during the recruitment period. Subtraction urodynamic studies were done in sitting position with 9F transurethral catheter with room temperature saline with medium fill-rate. All studies were performed according to (ICS) standard urodynamic practice and have concentrated on the demonstration of incontinence. We used a treatment simulating urodynamic investigation technique (TSUIT) allowing focus on the storage and emptying capacity of the bladder while preventing leakage, to simulate the situation after incontinence surgery. We have done so by simply (self-) squeezing of the penis during cystometry up to a tolerable volume. We report cystoscopy, PAD-test results and urodynamic results.

RESULTS

The urodynamic technique was well accepted and apprehended by the patients. Table 1 shows; that the mean bladder capacity using the TSUIT was 355 ml (range 150-1000 ml) in these patients (who usually continuously leak while physically active). 62% had a normal bladder storage phase, without detrusor-overactivity and with a normal sensation of bladder filling. In 31%, the storage phase was abnormal because of detrusor overactivity and in 27% patients because of reduced compliance. Four patients (7%) had obstructed voiding on pressure flow analysis. Purely based on TSUIT, we advised a sphincter prosthesis to 148 patientsand 90 patients were advised against; Two patients ultimately did not undergo the surgery. The table shows significantly different urodynamic results in the patients with a negative advise, specifically a severely reduced bladder capacity, detrusor overactivity or other filling phase abnormalities. Bladder outlet obstruction was a voiding phase marker leading to advize against an artificial sphincter. In 28 patients (19%) the prosthesis was revised. Their pretreatment results did not differ from the implanted group in total.

INTERPRETATION OF RESULTS

This analysis shows that rational selection of patients for a sphincter prosthesis has ensured optimal outcome. Only 6% of patients were incontinent after prosthesis placement and only 4% needed auxiliary medical management. Only 19% of these had device failure, unrelated to their lower urinary tract dysfunction. 37% of patients had clinically significant LUT dysfunction when filling was allowed above the incontinence volume up to 400mL or earlier when limited by strong desire to void or pain. Only a small proportion had urethral of neo-bladder neck stenosis. The feedback of the urodynamic results has been helpful in counselling these patients. Patients who were advised against an artificial sphincter were managed conservatively or (strictures) surgically. A proportion of patients received a prosthesis after secondary successful individualized conservative management.

CONCLUDING MESSAGE

The treatment-simulating urodynamic investigation technique for patients with incontinence after radical prostatectomy, mimicking the situation after sphincter prosthesis surgery, is feasible with no (extra) patient discomfort over standard urodynamic technique. The test results are relevant for selection of treatment and anticipation of lower urinary tract function after restored sphincter function. In our hands, continence rate after implantation is 73% without auxiliary management and the (medium term 5-10y) revision rate is low,

FIGURE 1

Table 1

AFTER RRP N237	All (sd)	AMS Implant N=148	No AMS N=89	T-test Y/N implant	With failing AMS N=28	T-test Y/N failure
Age (y)	69 (7)	67	70	.002	68	.985
Months After RRP	49 (46)	43	59	.010	61	.087
PadTest (mL)	115 (132)	132	77	.053	138	.416
UDI-FSF (mL)	220 (99)	239	189	.000	251	.437
UDI-ND (mL)	283 (107)	313	233	.000	343	.001
UDI-SD (mL)	340 (120)	360	303	.000	372	.127
UDI-MCC (mL)	355 (130)	385	306	.000	401	.019
UDI-VV (mL)	345 (147)	385	276	.000	415	.002
UDI-Pdet Qmax (cmH2O)	30 (22)	25	37	.000	25	.231
UDI-Qmax (ml/s)	14.4 (9)	16	12	.014	15.4	.492
BCI	103 (46)	104	102	.708	104	.992
BOOI	0.3 (31)	-6	11	.000	-5	.165
PVR (mL)	55 (86)	50	62	.423	44	.579
				Chi^2		Chi^2
RTX %	37	34	46	.056	34	.838
Sphincter defic. (UCS) %	39	31	50	.026	50	.252
Stenosis (UDS) %	17	11	35	.000	8	.096
Sens filling abnormal %	43	35	56	.000	18	.023
DO UDI-yes %	39	30	48	.000	32	.038
Compliance reduced %	54	52	58	.065	64	.021
Strain-void UDI	47	46	50	.588	47	.413

Table 2

All Patients N =237	AMS	No AMS
Continence	30% 71/91 implants 73%	
Incontinence	6% 14/91 implants 15%	
Device handling	1%	
Auxiliary Management	4% 10/91 implants 11%	
No Follow-up (abandoned invasive treatment)		25%
Medic		7%
Urethral proc		3%
Radio -cystitis		1%
PCa progressive		1%
Abandoned treatment		6%
1st Medic start > AMS	4%	
1st Incont with AMS >revision	2%	

REFERENCES

1. Rocha et al: Urology, 71, 85-89 (2008)
2. Thiel et al: Urology, 69; 315-319 (2007)
3. Porena et al: Eur Urol, 52; 38-45 (2007)

Funding Institutional **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Anonymous analysis of routine assessment according to contemporary clinical standards **Helsinki** Yes **Informed Consent** No

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HEALTH RELATED QUALITY OF LIFE WITH HIGH RISK LOCALIZED PROSTATE CANCER: RETROSPECTIVE STUDY OF ROBOT-ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY VERSUS RADIATION THERAPY

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HYPOTHESIS / AIMS OF STUDY

Radical prostatectomy and radiotherapy are standard treatments for localized prostate cancer. When making decisions about treatment, it is important to not only consider medical information and complications, but also the impact on quality of life (QOL) after treatment. Our purpose was to compare QOL after robot-assisted laparoscopic radical prostatectomy (RARP) versus radiation therapy with high risk localized prostate cancer retrospectively.

STUDY DESIGN, MATERIALS AND METHODS

Patients with high risk localized prostate cancer receiving RARP (Group A), intensity-modulated radiation therapy (IMRT) (Group B) and brachytherapy combined with external beam radiation therapy (EBRT) (Group C) at our department between October 2010 and March 2017 were enrolled in this study. QOL was assessed using the Expanded Prostate Cancer Index Composite (EPIC) before treatment and 1, 3, 6, 12, 18, 24, and 36 months post-treatment in each group. Urinary, bowel, sexual domains and satisfaction were evaluated.

RESULTS

Complete responses to the questionnaire were obtained from 131/152 patients receiving RARP, 87/121 patients receiving IMRT, 50/93 patients receiving brachytherapy with EBRT. Table 1 showed patients characteristics. Patients in Group C had higher clinical stage and higher Grison score compared to other groups.

For urinary summary score, Group A was lower than the other groups within 12 months after treatment, but there was no significant difference after 18 months.

For urinary function and bother, Group A was lower than the other groups until the 12 months, but improved after 18 months. This may affect improving urinary incontinence.

For the Bowel summary score, all groups declined in after one month, but then improved. Then it was significantly higher in Group A compared to the other groups. Group A improved to the same extent as before the treatment, but the other groups were lower than before the treatment. For Bowel function and bother were lower after one month in all Groups. Group A was improved over the time thereafter, but the other two Groups remained lower than before treatment.

For satisfaction, there was no significant difference in all Groups.

INTERPRETATION OF RESULTS

This study demonstrated that the QOL after RARP was inferior at 1 month compared with radiotherapy, however, the QOL subsequently improved, and was better than in radiotherapy patients' after 6 months. These findings could help to select treatment for localized prostate cancer and provide information to support decision-making by patients and healthcare professionals.

CONCLUDING MESSAGE

Our study suggested that QOL was inferior at 1 month after RARP, however, recovered at 12 months after RARP and was better than IMRT and brachytherapy combined with EBRT. These difference in urinary and bowel QOL should be considered in selecting the treatment.

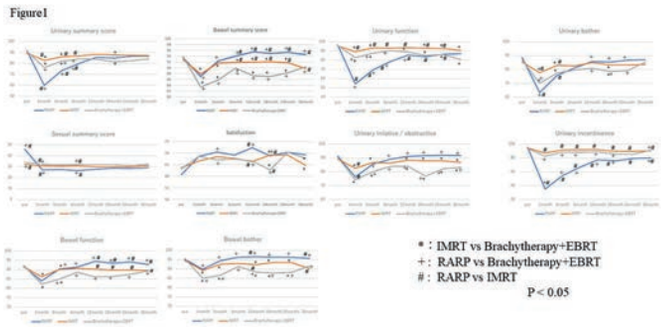
FIGURE 1

Table 1

Patients characteristics

	RARP	IMRT	Brachytherapy with EBRT
patient no	131	87	50
age (years)	65 (49-75)	72 (62-80)	64 (57-76)
PSA (ng/ml)	11.9 (4.1 - 30.2)	28.3 (4.7-78.4)	25.3 (7.9-87.5)
T stage			
T1c	15	2	0
T2a	52	15	6
T2b	6	7	0
T2c	26	13	0
T3a	28	35	28
T3 b	2	12	13
T4	2	3	3
Gleason score			
3+3	4	0	0
3+4	10	0	0
3+5	3	0	0
4+3	7	12	1
4+4	77	37	11
4+5	23	27	16
5+4	5	8	13
5+5	2	3	9

FIGURE 2



Funding I have no COI. **Clinical Trial** No **Subjects** Human **Ethics Committee** Tottori University ethics committee. (no. 2545) **Helsinki** Yes **Informed Consent** Yes

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CUMULATIVE SUMMATION (CUSUM) ANALYSIS OF LEARNING CURVES FOR MULTIPLE OUTCOMES OF MALE SLING PLACEMENT FOR POST-PROSTATECTOMY URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

Male sling placement has been proved to be an effective treatment for postprostatectomy urinary incontinence (PPI). The existence of a learning curve (LC) has been established for sling surgery in females [1]. Male sling implantation has several critical steps and may potentially involve a LC. Scant and conflicting data are available on this topic that may have implications concerning training and evaluation of surgeons. We aimed to perform a LC analysis of a single surgeon's experience of sling placement evaluating multiple outcomes.

STUDY DESIGN, MATERIALS AND METHODS

From Jan. 2013 to Dec. 2018, consecutive patients with PPI undergoing sling placement at our institution were included. Only patients that underwent implantation of the same sling (TiLOOP Male) were included. Exclusion criteria included previous sling, incontinence due to causes different from radical prostatectomy, and follow-up lower than 12 months.

TiLOOP Male, a 2-arm titanium-coated fixed retrourethral sling, was implanted using an inside-out, single-incision standard technique, leaving the bulbourethral muscle in place and attaining the cranial relocation of the proximal bulbar urethra [2].

LCs were derived by the cumulative sum (CUSUM) control chart analysis using the cumulative observed minus expected failure method [3]. Expected values were obtained from published literature.

The primary outcome was the 12-months failure of objective cure (no pad use or 1 dry "security" pad). Secondary outcomes included 12-months failure of overall objective success defined as cure plus improvement (reduction of at least 50% of the pad count), 12-months failure of subjective success evaluated with PGI-I, operative time>60 minutes, need for further incontinence surgery (performed or scheduled) and overall complications occurrence. To adjust for case-mix, multivariate logistic regressions were performed using surgical order, adjusted for age, BMI, incontinence severity, pelvic irradiation, and previous urethrotomy, to predict outcomes.

RESULTS

Sixty-five patients (mean age 68 ±5.8 years) with a mean follow-up of 46.2 ±20.5 months were included. CUSUM analyses revealed clear LC effects for continence outcomes, operative time and need for further incontinence surgery, but not for complications occurrence. LC effect was graphically more evident for objective cure than for overall objective success, with a plateau achieved after 59 cases (Figure 1).

At multivariate analyses, surgical order (OR=0.96; CI:0.93-0.99;p=0.031) and irradiation (OR=10.7; 95%CI:1.18-97.1; p=0.035) were statistically significant for predicting 12-months failure of objective cure, while irradiation was the sole variable independently predicting 12-months failure of overall objective success (OR=27.4; 95%CI: 4.8-156.3;p=0.000). Surgical order and irradiation were also independent predictors of 12-months failure of subjective success and of need for further incontinence surgery.

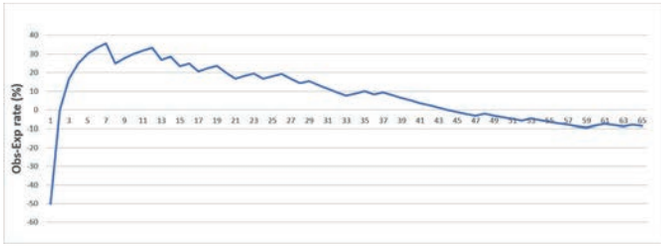
INTERPRETATION OF RESULTS

A rather long learning curve was observed in our series of sling placement to achieve stable proficiency, especially when objective cure was considered as continence outcome, independently from main factors involved in patient selection.

CONCLUDING MESSAGE

Individualized structured training with expert mentorship for urologists naïve in male sling surgery should likely benefit patients treated in the initial surgeon's experience. This study supports the CUSUM analysis as an effective method for surgeons' self-appraisal to prompt continuous quality improvement.

FIGURE 1



Cumulative summation (CUSUM) observed minus expected plots of sequential monitoring of failure of objective cure. Expected rate was set at 50%. The curve moves upward if there are more failure than expected and downward if there are fewer.

REFERENCES
1. Hilton P, Rose K. The "learning curve" for retropubic mid-urethral sling procedures: a retrospective cohort study. Int Urogynecol J. 2016 Apr;27(4):565-70
2. Sacco E, Gandi C, Vaccarella L, et al. Titanized Transobturator Sling Placement for Male Stress Urinary Incontinence Using an Inside-out Single-incision Technique: Minimum 12-Months Follow-up Study. Urology. 2018;115:144-150
3. Biau DJ, Resche-Rigon M, Godiris-Petit G, Nizard RS, Porcher R. Quality control of surgical and interventional procedures: a review of the CUSUM. Qual Saf Health Care. 2007 Jun;16(3):203-7

Funding No source of funding to declare. **Clinical Trial** No **Subjects** Human **Ethics Committee** Ethical committee of Catholic University of Rome **Helsinki** Yes **Informed Consent** Yes

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URINARY INCONTINENCE SYMPTOMS, SEVERITY, AND ASSOCIATED CHARACTERISTICS IN GAY AND BISEXUAL PROSTATE CANCER SURVIVORS ENROLLED IN A RANDOMIZED CLINICAL TRIAL OF AN ONLINE REHABILITATION PROGRAM FOR URINARY AND SEXUAL DYSFUNCTION

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence is a common persistent symptom after prostate cancer treatment, yet little is known about how its occurrence may differ for sexual and gender minorities. The aims of this study are to 1) describe urinary incontinence symptoms and severity experienced by gay and bisexual men (GBM) treated for prostate cancer, 2) identify if urinary incontinence symptoms and severity differ by the type of prostate cancer treatment, and 3) identify characteristics associated with severity of urinary incontinence.

STUDY DESIGN, MATERIALS AND METHODS

Design: Baseline characteristics of 400 GBM enrolled in Restore 2, a randomized controlled trial testing the efficacy of an online rehabilitation program for urinary and sexual dysfunction after prostate cancer treatment.

Methods: Participants were self-identified gay and bisexual prostate cancer patients in the United States recruited mainly from online dating sites, prostate cancer survivor support groups, and social networking sites. Eligible participants had to have been diagnosed with prostate cancer with curative treatment (e.g., prostatectomy or radiation) completed, ongoing, or scheduled within 2 months of baseline. Participants were excluded if they did not speak English fluently or lived outside the United States. Baseline data was collected online using Qualtrics software© prior to participants' being randomly assigned to a treatment or control group. Urinary incontinence symptoms and severity were measured with the International Consultation on Incontinence Questionnaire – short form (ICIQ). Participants self-reported their cancer treatment as surgery, radiation, surgery and radiation, or treatment other than surgery and radiation (e.g., cryotherapy, hormone therapy or chemotherapy). The following self-reported demographic, health, and cancer status characteristics were used to determine their association with urinary incontinence severity: age, race, obesity, number of alcoholic drinks consumed in a typical day, self-reported health, number of comorbidities, time since diagnosis and treatment, prostate cancer stage and Gleason score at time of diagnosis and type of cancer treatment. Descriptive statistics were used to describe sample characteristics, urinary incontinence symptoms and severity. Analysis of variance (for continuous variables) and chi-square tests (for categorical variables) were used to determine if urinary incontinence symptoms or severity differed by the type of prostate cancer treatment. Linear regression and Pearson correlation coefficients were used to determine what characteristics were associated with urinary incontinence severity.

RESULTS

Participants had a mean age of 63.5 years, were 5.3 years on average past treatment, and were treated with surgery (59%), radiation (28%), surgery and radiation (11%) or treatment other than surgery and radiation (2%). Over 80% of participants reported any urinary incontinence and 43% experienced at least daily incontinence. The most common urinary incontinence symptoms were stress, post-void dribbling, urge and incontinence without awareness. Less common symptoms were nocturnal enuresis, mixed stress and urge, and continuous incontinence (see Table). Incontinence severity reported as the mean(SD) ICIQ score was 6.56(4.86) for the entire sample. Incontinence severity differed by cancer treatment ($p<0.01$). Patients treated with surgery & radiation had the highest ICIQ scores followed by surgery patients, radiation patients, and other treatment patients (see Table). Patients treated with surgery and radiation or surgery only were more likely to experience stress urinary incontinence ($p<0.1$) and insensible urinary incontinence incontinence ($p<.01$), while those treated with radiation only were more likely to experience urgency urinary incontinence ($p<0.01$). Urinary incontinence severity was associated with obesity ($r=0.14$, beta [95% CI] = 1.76 [0.51, 3.00]), poorer self-reported health ($r=-0.25$, beta [95% CI] = -0.08 [-0.11, -0.05]), and an increased number of co-morbidities ($r=0.18$, beta [95% CI] = 0.62 [0.28, 0.96]). Urinary incontinence severity was not associated with age ($r=-0.03$, beta [95% CI] = -0.02 [-0.09, 0.05]), race ($r=-0.0001$, beta [95% CI] = 0.001 [-1.41, 1.41]), Gleason score at diagnosis ($r=0.02$), prostate cancer stage at diagno-

sis (r=0.07), time since diagnosis (r=0.06, beta [95% CI] = 0.06 [-0.03, 0.16]) or time since treatment (r=0.03, beta [95% CI] = -0.33 [-1.28, 0.63]).

INTERPRETATION OF RESULTS

These findings represent the first reports of urinary incontinence symptoms, severity, and associated characteristics for gay and bisexual prostate cancer survivors - providing new knowledge on potential health disparities and treatment targets for sexual minorities in this area. Urinary incontinence symptoms were associated with the type of prostate cancer treatment. Patients treated with surgery and radiation or surgery alone experienced greater severity of urinary incontinence and more symptoms of stress urinary incontinence and insensible urinary incontinence. Patients treated with radiation only experienced more symptoms of urgency urinary incontinence. Urinary incontinence severity was associated with obesity, poor self-reported health, and an increased number of co-morbidities, but not with prostate cancer status at the time of diagnosis or time since diagnosis. Study limitations include the use of a cross sectional design that prohibits causal inference, and results that may not generalize beyond GBM interested in enrolling in an online rehabilitation program for urinary and sexual dysfunction. The prevalence of urinary incontinence and its severity may be higher than that for GBM not interested in rehabilitation.

CONCLUDING MESSAGE

The type of prostate cancer treatment, obesity, co-morbidity, and poor self-rated health were associated with urinary incontinence symptoms and severity in GBM prostate cancer survivors. Treatments for GBM treated surgically should focus on treatments for stress urinary incontinence and insensible urinary incontinence, while those for GBM treated with radiation should focus on treatments for urgency urinary incontinence. Understanding these symptoms will help tailor treatments for this underserved population of sexual and gender minorities.

FIGURE 1

ICIQ Item (Urinary Incontinence Symptom)		Type of Prostate Cancer Treatment				
	Entire Sample N=400	Surgery N=236	Radiation N=111	Surgery + Radiation N=44	Other N=9	*p*-value
	Mean (SD) or N (%)					
ICIQ total score	6.6 (4.9)	7.1 (4.8)	4.8 (4.7)	8.5 (4.7)	3.8 (3.1)	<0.01
1. Never—urine does not leak	78 (20)	36 (15.2)	37 (33.3)	2 (4.6)	3 (33.3)	<0.01
2. Leaks before you get to the toilet (Urgency urinary incontinence)	108 (27)	49 (20.7)	45 (40.5)	10 (22.7)	4 (44.4)	<0.01
3. Leaks when you cough or sneeze (Stress urinary incontinence)	150 (38)	112 (47.3)	12 (10.8)	26 (59.1)	0 (0)	<0.01
4. Leaks when you are asleep (Nocturnal enuresis)	61 (15)	46 (19.4)	5 (4.5)	10 (22.7)	0 (0)	<0.01
5. Leaks when you are physically active/exercising (Stress urinary incontinence)	164 (41)	123 (51.9)	11 (9.9)	30 (68.2)	0 (0)	<0.01
6. Leaks when you have finished urinating and are dressed (Post-voiding incontinence)	147 (37)	85 (35.9)	46 (41.4)	13 (29.6)	3 (33.3)	0.54
7. Leaks for no obvious reason (Insensible urinary incontinence)	97 (24)	72 (30.4)	6 (5.4)	19 (43.2)	0 (0)	<0.01
8. Leaks all the time (Continuous urinary incontinence)	8 (2)	5 (2.1)	2 (1.8)	1 (2.3)	0 (0)	0.97
Item 2 plus item 3 and/or 5 (Mixed urinary incontinence)	49 (12)	26 (11.0)	14 (12.6)	9 (20.5)	0 (0)	0.22

Table 1. Difference in Urinary Incontinence Symptoms and Severity by Type of Prostate Cancer Treatment Among Gay and Bisexual Men

Funding National Cancer Institute 1R01 CA218657-01 **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov NCT03343093 **RCT** Yes **Subjects** Human **Ethics Committee** University of Minnesota Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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DOES PENILE REHABILITATION WITH PDE-5 INHIBITORS AFTER ROBOT-ASSISTED RADICAL PROSTATECTOMY AFFECT URINARY INCONTINENCE, ERECTILE DYSFUNCTION, AND QUALITY OF LIFE? A PROPENSITY SCORE-MATCHED ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

Recent reports suggest that phosphodiesterase-5 (PDE-5) inhibitors are effective against lower urinary tract dysfunction, including storage dysfunction [1]. There have also been reports that penile rehabilitation using PDE-5 inhibitors influence erectile dysfunction after robot-assisted radical prostatectomy (RARP) [2]. However, the effect of penile rehabilitation on urinary incontinence after RARP and health-related quality of life (QOL) is unclear. In this study, we examined the effects of penile rehabilitation after RARP on incontinence

and QOL with adjustment by propensity score matching (PSM).

STUDY DESIGN, MATERIALS AND METHODS

The study included patients who underwent RARP in our department from October, 2010 to August, 2019. The patients who 1. had an observation period of less than two years, 2. did not answer the International Index of Erectile Function (IIEF) questionnaire preoperatively, or 3. received pre- or post-operative hormone and radiation therapy were excluded. For penile rehabilitation, a PDE-5 inhibitor (tadalafil 20 mg) was administered twice a week for 1–6 months after surgery. We used the Short Form Health Survey (SF)-8 questionnaire, the IIEF questionnaire (question 1 and EF-domain), and the Expanded Prostate cancer Index Composite (EPIC) questionnaire (sexual function subscale (SFS); urinary domain summary score (USS): urinary irritative subscale (UIR); urinary bother subscale (UBS); urinary incontinence subscale (UIN); and urinary function subscale (UFS)). The relevant evaluation items in SF-8 were physical function (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), mental health (MH), physical component summary (PCS), and mental component summary (MCS). The questionnaires were collected preoperatively and postoperatively at 1, 3, 6, 9, 12, 18 and 24 months. Postoperative urinary incontinence was assessed at scheduled visits 1, 3, 6, 9, 12, 18, and 24 months after the RARP. Patients who used no security liner pads were considered to have urinary continence and those who used one or more security liner pads per day were considered to have urinary incontinence. We investigated the relationship between the presence or absence of penile rehabilitation and pre- and post-operative urinary incontinence, health-related QOL, and erectile function, with adjustment by PSM.

RESULTS

Of the 257 patients who met the enrolment criteria, 95 patients were in the penile rehabilitation group (PR group) and 162 patients were in the nonpenile-rehabilitation group (non-PR group). Patients in the PR group were significantly younger and had a higher preoperative IIEF Q1 score, a higher preoperative IIEF EF-domain score, and a longer total surgical time than the non-PR group. After PSM, there were 156 effective analyses, of which 78 were in the PR group (mean age 64.9 ± 6.0 years) and 78 were in the non-PR group (mean age 64.6 ± 5.2 years). There was no significant difference in demographic factors between the two groups after PSM. In the IIEF Q1 and EF-domain scores, there were no significant differences between the two groups one month postoperatively, but there were significantly higher differences in the PR group 3–18 months and 3–24 months postoperatively as compared to the non-PR group ($p < 0.001$). The recovery rates for urinary incontinence (the pad free rate) after the RARP were 16.7%, 33.3%, 47.4%, 55.1%, 62.8%, 66.7%, and 72.4% in the non-PR group and 29.5%, 46.2%, 59.0%, 62.8%, 67.5%, 71.1%, and 71.1% in the PR group at 1, 3, 6, 9, 12, 18, and 24 months, respectively. There was no significant difference in the recovery rate of urinary incontinence between the two groups. In EPIC, the SFS score was significantly higher differences in the PR group 3–24 months as compared to the non-PR group ($p < 0.001$). The USS, UIR, UBS scores were significantly higher in the PR group 3-6 months postoperatively ($p < 0.05$), and the UBS scores were significantly higher in the PR group 9 months postoperatively ($p < 0.05$). In SF-8, the GH, VT, SF, RE, MH, and MCS scores were significantly higher in the PR group three months postoperatively ($p < 0.05$), and the SF, RE, MH, and MCS scores were significantly higher in the PR group six months postoperatively ($p < 0.05$).

INTERPRETATION OF RESULTS

In all patients before PSM, the preoperative IIEF Q1 and EF-domain scores were significantly higher in the PR group than those in the non-PR group. This study was not a randomized trial and patients who requested PR might have had a high level of sexual activity, hence it was likely that the scores would have been high even before surgery and one month postoperatively. After PSM, these groups were no longer significantly different preoperatively and one month postoperatively and the baseline seemed to be consistent. Three months postoperatively, with adjustment by PSM, the values were significantly higher in the PR group and the effect of PR was evident. In addition, this effect was long-lasting, persisting beyond 9 months postoperatively. The rate of improvement in the urinary incontinence of the PR group tended to be slightly better in the early postoperative period, but there was no significant difference between the two groups. However, there were significant improvement in EPIC scores (USS, UIR and UBS) from 3 months postoperatively, indicating that PR may improve urinary-related quality of life. Concerning health-related QOL, some scores were significantly higher in the PR group, and it was considered that PR also improved the health-related QOL.

CONCLUDING MESSAGE

Our results suggest that PR with PDE-5 inhibitor after RARP improves erectile function, health-related and urinary-related QOL.

FIGURE 1

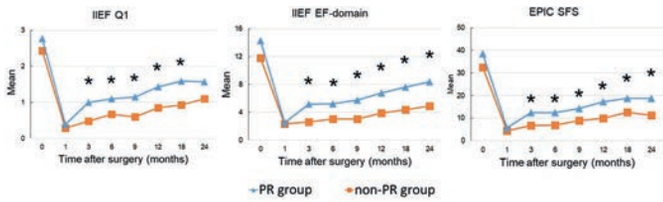

Figure 1. Comparison of the sexual function in the International Index of Erectile Function (IIEF) Question1, IIEF-Erectile Function (EF) and the Expanded Prostate cancer Index Composite (EPIC)-sexual function scale (SFS) between penile rehabilitation (PR) group (n=78) and non-PR group (n=78) after the robot-assisted radical prostatectomy with adjustment by propensity score matching. *, significant difference, p<0.05

FIGURE 2

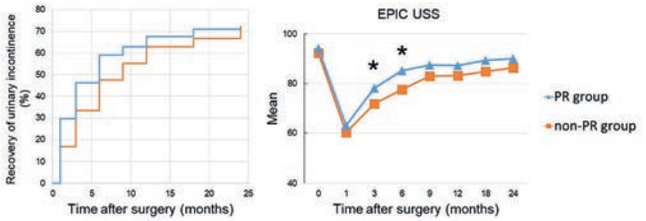

Figure 2. Changes of recovery rate of urinary incontinence and comparison of the Expanded Prostate cancer Index Composite (EPIC)-urinary domain summary score (USS) between penile rehabilitation (PR) group (n=78) and non-PR group (n=78) after the robot-assisted radical prostatectomy with adjustment by propensity score matching. *, significant difference, p<0.05

REFERENCES

1. Matthias Oelke, et al: European Urology. 2012, 61, 917-925.
2. Kim S, et al: Sexual Medicine. 2018, 6, 108-114.

Funding Non **Clinical Trial** No **Subjects** Human **Ethics Committee** Tottori University Faculty of Medicine **Helsinki** Yes **Informed Consent** Yes

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IMPACT OF URETHROVESICAL ANASTOMOTIC LEAKAGE POST RARP ON EARLY AND LATE CONTINENCE RECOVERY : A SINGLE CENTRE STUDY

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HYPOTHESIS / AIMS OF STUDY

Vesicourethral anastomosis leaks are not uncommon following RARP. In this study we are trying to find out if anastomotic leakage has an effect on continence recovery post RARP on both short and long terms. Our objective was to retrospectively review all patients operated at our centre by 2 different surgeons to assess the impact of the presence of a leak on early and late urinary continence using patient report outcome measures.

STUDY DESIGN, MATERIALS AND METHODS

We retrospectively evaluated post-operative cystograms for leakage from urethrovesical anastomosis in 184 patients who had RARP in our department. The degree of continence was determined by number of pads, ICIQ-UI-SF, EPIC26. These findings were compared with other parameters; patients age, body mass index (BMI), salvage radiotherapy, previous pelvic surgery, post operative complications, tumour T-stage, Gleason score and surgical technique used. Data was collected from our electronic patient record and tabulated in microsoft excel. Data was assessed for distribution and chi squared testing performed, p value for significance <0.05.

RESULTS

Among 184 patients who had RARP at our institute we identified 27 patients (14.8%) who had a leak on their routine post-operative cystograms done at 10-14 days post operatively. There was no statistically significant difference between late urinary incontinence and the presence of anastomotic leakage at cystogram. This was also true when adjusted for other parameters such as patient T stage, PSA or BMI.

INTERPRETATION OF RESULTS

Patient characteristics:

Men's age ranged from 44 to 78, mean age was 67.3. Their body mass indices ranged from 20 to 38.6, with mean BMI 28.09. At 6 weeks post operative 52 patients (28.4%) were completely continent, using no pads. On the otherside 32 patients (17.4%) used more than 3 pads per day. Inbetween there were 94 patients (51%) that used from 1 to 3 pads per day. Fourty four patients (24%) used 1 pad, 28 patients (15.3%) used 2 pads, 22 patients (12%) used 3 pads. At 12 months post operative 114 patients (62.3%) were completely continent, using no pads. On the otherside 17 patients (9.3%) used more than 3 pads per day. Inbetween there were 46 patients (25.1%) that used from 1 to 3 pads per day. Thirt two patients (17.5%) used 1 pad, 5 patients (2.7%) used 2 pads, 9 patients (4.9%) used 3 pads.

Only 11 patients (6%) have received salvage radiotherapy. Eight patients had previous pelvic surgery in the form of hernia repair, TURP, or colorectal surgery.

Surgery characteristics:

Prostatectomies were done by 3 expert surgeons at our institute. One hundred thirty one prostatectomies (71.6%) were done by nerve sparing technique, while 50 prostatectomies (27.3%) were done by non nerve sparing technique. Apart from urinary incontinence, erectile dysfunction, leakage from urethrovesical anastomosis, 15 patients had postoperative complications.

Cystograms:

All patients had a cystogram at 2 weeks post-operative before twoc. Twenty seven patients (14.8%) had leakage on cystogram. Leakage from both sides, right side alone, left side alone, right posterolateral, left posterolateral, anterior, posterior was shown in 7, 3, 5, 5, 4, 1, 2 cases respectively.

Tumour characteristics:

According to histopathological examination of radical prostatectomy specimen, 92 specimens (51%) showed T2 disease, while 68 specimens (38%) showed T3a disease, 20 specimens showed (11%) T3b disease, and only 1 specimen

(0%) showed T4 disease. Regarding gleason score, 140 patients (76.5%)were gleason 7, then 24 patients(13.1%) were gleason 6, 14 patients (7.7%) were gleason 8, 5 patients (2.7%) were gleason 9.

Correlation between urinary incontinence and leakage through urethrovesical anatomsis, and other parameters:

When comparing between group of no leakage and group who had leakage on cystogram, with respect to age and BMI, no statistical significance was found.

When comparing between group of no leakage and group who had leakage on cystogram, with respect to number of pads used at 6 weeks and 12 months, no statistical significance was found.

When comparing between group of no leakage and group who had leakage on cystogram, with respect to surgical technique (whether nerve sparing or non nerve sparing), previous pelvic surgery, post operative complications (other than incontinence, leakage, and impotence), salvage radiotherapy, no statistical significance was found.

When comparing between group of no leakage and group who had leakage on cystogram, with respect to Gleason score and T stage of prostate cancers, no statistical significance was found.

When comparing between group of no leakage and group who had leakage on cystogram, with respect to ICIQ-UI-SF and EPIC26 at early(<3months) and late (>6months) follow up, no statistical significance was found.

No statistically significant correlation was found between ICIQ-UI-SF and EPIC26 at early(<3months) and late (>6months) follow up from one side and the other parameters (Age, BMI, Tstage, Radiotherapy, Surgical technique, previous pelvic surgery, post-operative complications) from the other side.

CONCLUDING MESSAGE

We found no clear link between vesicourethral anastomotic leak and urinary incontinence post RARP. Age, BMI, Salvage radiotherapy, previous pelvic surgery, Tstage, gleason score did not lead to a statistically significant difference.

Funding Didn't need funding. **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This study was given approval by the head of quality improvement at NHS Lothian. **Helsinki** not Req'd This study was given approval by the head of quality improvement at NHS Lothian. **Informed Consent** No

SESSION 10 (PODIUM SHORT ORAL) - FEMALE LOWER URINARY TRACT SYMPTOMS
Abstracts 143-154
14:30 - 16:00, Brasilia 1
Chair: Prof Jerry G Blaivas (United States)

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MILITARY SEXUAL TRAUMA AND VOIDING DYSFUNCTION IN FEMALE VETERANS

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HYPOTHESIS / AIMS OF STUDY

Women currently make up 17% of active military personnel and make up the fastest growing segment of new Veterans Health users [1]. Post deployment health and readjustment issues among women veterans have been identified as a priority toward building a quality improvement research agenda for women. Military Sexual Trauma (MST), as defined by Federal Law (Title 38 U.S. Code 1720D), is "the psychological trauma, which in the judgement of a VA mental health professional, resulted from a physical assault of a sexual nature, battery of a sexual nature, or sexual harassment which occurred while in the Veteran was serving on active duty, active duty for training, or inactive duty training." Cohort analyses of the civilian population have shown that there is an association between sexual abuse history and pelvic pain, interstitial cystitis, gastrointestinal complaints, vulvodynia, and vasomotor symptoms[2]. The purpose of our study is to investigate the relationship between MST and Lower Urinary Tract Symptoms (LUTS) in the female VA population.

STUDY DESIGN, MATERIALS AND METHODS

This is a retrospective chart review utilizing VA electronic health records. We included all women who answered either yes or no to the standard screening question for MST as of 12/31/2014 and who had complete covariate data. We used logistic regression with LUTS diagnosis between 1/1/2010 and 12/31/2014 coded as the yes response and MST as the predictor along with possible confounding variables for adjustment (age, BMI, blood pressure, race, ethnicity, diagnosis of PTSD, HTN, diabetes, and history of mental health treatment visits). In each cohort we assessed for the following diagnostic codes commonly found with LUTS: interstitial cystitis/bladder pain syndrome, incontinence, over-active

bladder, urinary urgency, urinary frequency, urge urinary incontinence, stress urinary incontinence, recurrent UTI, chronic UTI, fecal incontinence, dyspareunia, voiding dysfunction, urinary retention, dysuria. We will also queried for interventions related to LUTS: cystoscopy, prescription of OAB medications (oxybutynin, trospium, tolterodine, Flomax, elmiron), referral to pelvic floor physical therapy, or visits to a urologist.

RESULTS

In total we had 311,298 patients, with 31,952 of these screening positive for MST. After further analysis 10,360 of the 31,952 patients screening positive for MST were also determined to have LUTS. Based on this analysis patients reporting military sexual trauma have a 13.3% greater odds of having LUTS (95% CI for OR: (1.10, 1.17). PTSD increases odds of LUTS by 21.8% (CI: 1.18, 1.26).

INTERPRETATION OF RESULTS

Female veterans with a history of MST have an increased likelihood of being diagnosed with LUTS compared to those without MST. This association could potentially guide proper treatment of LUTS in this population, leading providers to consider both medical treatment and psychological treatment.

CONCLUDING MESSAGE

This is the first study of its kind to investigate the association of military sexual trauma and voiding dysfunction in the female veteran population. A greater understanding of MST and its physical manifestations could have a tremendous impact on our understanding of the female veterans' health care needs, both at a systems and an individual level.

REFERENCES

1. Yano, E.M., et al., Using research to transform care for women veterans: advancing the research agenda and enhancing research-clinical partnerships. Womens Health Issues, 2011. 21(4 Suppl): p. S73-83. 2. Seth, A. and J.M. Teichman, What's new in the diagnosis and management of painful bladder syndrome/interstitial cystitis? Curr Urol Rep, 2008. 9(5): p. 349-57.
2. Seth, A. and J.M. Teichman, What's new in the diagnosis and management of painful bladder syndrome/interstitial cystitis? Curr Urol Rep, 2008. 9(5): p. 349-57.

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BRAIN CHANGES ASSOCIATED WITH TREATMENT OF UUI WITH ONABOTULINUMTOXINA

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HYPOTHESIS / AIMS OF STUDY

The complex mechanism of brain control of the bladder is not yet well understood. We used a therapeutic probe to investigate brain changes associated with therapy-induced changes in urgency urinary incontinence (UUI) frequency. We performed functional magnetic resonance imaging (MRI) during an urgency simulation task both before and 6-8 weeks after onabotulinumtoxinA treatment for UUI. We selected onabotulinumtoxinA on the premise that it is a peripheral treatment without central effects and therefore the brain changes associated with successful treatment should be relatively simple to interpret, reflecting response to changes in bladder function and not because of a direct effect on the brain.

STUDY DESIGN, MATERIALS AND METHODS

We recruited 22 women over 60 years of age with non-neurogenic UUI and >5 leaks per week, who were scheduled to have onabotulinumtoxinA treatment. Each participant underwent clinical and physical examination, urinary incontinence evaluation, and a 3-day bladder diary. Prior to treatment, participants underwent MRI investigation, including structural brain imaging and concurrent functional MRI evaluation with an urgency-simulating protocol. This MRI protocol was repeated 6-8 weeks after onabotulinumtoxinA injection when therapeutic bladder responses had been achieved. The functional urgency simulating protocol was performed with a full bladder (strong urge to void signaled by the participant): 20 ml fluid was infused per 8Fr catheter over 12 seconds and withdrawn 20 seconds later over a 12 second period. This was repeated 4 times. 'Activity' was defined as blood oxygenation level dependent (BOLD) signal during the fluid withdrawal phases subtracted from that during the fluid infusion phases.

Activity was evaluated individually at the first level (production of voxel-wise t-statistic maps for each individual) at baseline and post-therapy and compared at the second level (paired t-test of pre- vs post- in each individual combined to form a group average t-map) (SPM12, Wellcome trust, UK), and then evaluated by response rate; responders were classed as those with reduction in number of UUI episodes >50%). After voxel-wise calculations, we used the SPM12 small volume correction tool to assess our a priori selected regions of interest (ROI): medial prefrontal cortex; dorsal anterior cingulate cortex/supplementary motor area; and right insula). Finally, we used a pattern recognition leave-one-out

classification (PRoNTo[1]) with the baseline functional images to initially assess the ability to sort the participants into responders and non-responders for identifying predictive patterns for treatment response.

RESULTS

We analyzed 20 women; 2 were excluded for technical reasons. Ages were 60-84 years (mean (SD)=70.2(6.2)). Comparing all participants pre- and post- treatment, we found decreased activity following treatment in the right insula, posterior cingulate, right superior and right inferior parietal lobules, left inferior frontal gyrus, precentral gyrus, precuneus, caudate and right and left middle frontal gyri ($p<0.05$, uncorrected; 16 voxel threshold). We found increased activity following treatment in the left inferior parietal lobule, hippocampus, left posterior cingulate and culmen ($p<0.05$ uncorrected; 16 voxel threshold).

When sub-analysis was performed by response rate, we found decreased activation following treatment in responders (n=13) in the right inferior frontal and supramarginal gyri, right inferior and superior parietal lobules (Figure 1) as well as in our a priori ROI, the right insula (MNI [38 16 6]; r=10mm; cluster-level $p<0.026$, FWE corrected). We found no changes in non-responders from pre- to post-treatment.

Using a leave-one-out cross-validation, we developed a support vector machine (SVM) classifier model to differentiate by response using the baseline functional images. We found an accuracy of 95%: 17/18 images were classified correctly.

INTERPRETATION OF RESULTS

There were significant preliminary changes in brain activity in response to urgency simulation after onabotulinumtoxinA therapy. The initial analysis of all participants showed many areas often found in continence investigation of the brain, including the insula which is found in the working model of continence control.

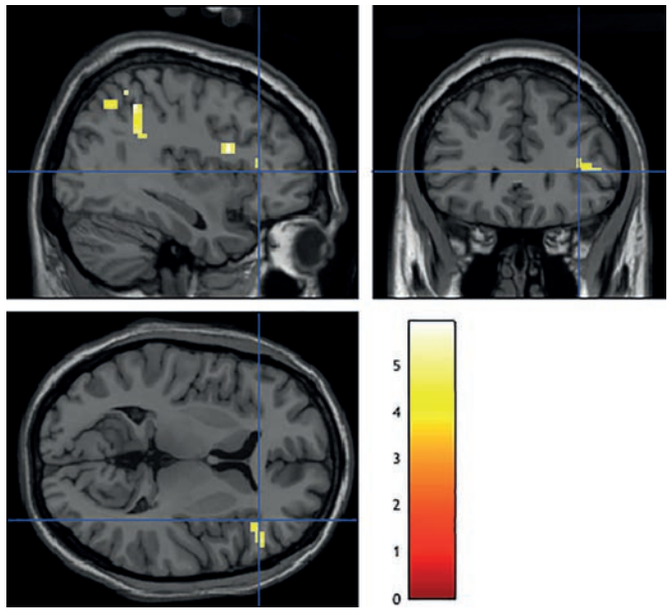
We did further sub-analysis by response to assess if these changes were a function of reduction in UUI. fMRI imaging showed that activity significantly decreased in the insula, specifically within our a priori selected volume of interest ($p<0.05$ FWE corrected), after onabotulinumtoxinA therapy. This reduction appears to be driven by responders to therapy as it is more significant (whole brain analysis: $P<0.001$, uncorrected) once non-responders are grouped separately. This could signify that in those who respond, there is less afferent sensation from the bladder reaching the insula. No other ROI reached this level of significance in either the responders or non-responders.

The use of PRoNTo as a pattern recognition tool is the first step towards a new way of using and understanding imaging data. Our aim was to find patterns within the imaging data that correspond to treatment response. The high accuracy rate of the SVM classifier to differentiate responders from non-responders is particularly encouraging. This is the first step in identifying patterns of brain activity which might predict therapeutic response, which, when probed further, might highlight important brain areas suggestive of different phenotypes of UUI. When applied to changes in response to therapy, this could also provide insight into more complex changes in brain function in response to urgency.

CONCLUDING MESSAGE

There are changes in brain activity in response to onabotulinumtoxinA therapy for UUI. One a priori selected ROI, the right insula, showed a significant reduction in activity after successful therapy which may reflect the reduction of bladder afferent sensation. Exploratory work using pattern recognition software suggests the potential for future analysis to identify functional brain activity patterns important in both predicting the success of therapy and changes associated with therapy, potentially highlighting further pathways involved in the continence mechanism.

FIGURE 1



REFERENCES

1. Neuroinformatics. 2013 Jul;11(3):319-37

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A PROSPECTIVE, RANDOMIZED TRIAL COMPARING INTRAVESICAL DIMETHYL SULFOXIDE (DMSO) TO BUPIVACAINE, TRIAMCINOLONE, AND HEPARIN (BTH), FOR NEWLY DIAGNOSED INTERSTITIAL CYSTITIS/ BLADDER PAIN SYNDROME (IC/BPS) IN A FEMALE POPULATION.

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HYPOTHESIS / AIMS OF STUDY

Several intravesical instillation regimens for the treatment of IC/BPS have been described in the literature, and they have been utilized for decades based on individual physician preference and anecdotal experience. To date, there has been a lack of evidence to inform best practices and to delineate the impact of the most commonly used intravesical IC/BPS therapies on both objective and subjective outcomes. The aim of this prospective RCT was to compare the overall impact of DMSO versus BTH intravesical installation therapy in female subjects newly diagnosed with IC/BPS.

The primary study outcome was defined as greater than 29.5% change in O'Leary-Sant Interstitial Cystitis Symptoms Index (ICSI) total score. Secondary outcomes included changes in urinary frequency and nocturia, and objective change in bladder capacity after treatment. We utilized change in bladder capacity as an objective outcome because reduced bladder capacity tends to be observed among patients with IC/BPS, and therefore may be expected to increase with successful treatment. Our hypothesis was that intravesical therapy with DMSO would be associated with a greater decrease in ICSI score, as well as a greater increase in bladder capacity as compared to intravesical BTH therapy for the treatment of IC/BPS.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective, randomized, non-blinded study; a blinded study was not feasible due to the characteristic strong odor of DMSO. After obtaining IRB approval, patients with newly diagnosed IC/BPS were randomized 1:1, with treatment allocations stored in sealed opaque envelopes, to receive treatment with six weekly bladder instillations using either 50 mL DMSO and 1mL triamcinolone (10mg/mL) or 30 mL 0.5% bupivacaine (5mg/mL), 2 mL triamcinolone (10mg/mL), and 2 mL Heparin (10,000 units/mL). At each visit, subjects completed the O'Leary-Sant Interstitial Cystitis Symptom Index (ICSI) and Problem Index (ICPI) and questionnaires detailing number of voids during day and night. Bladder capacity was measured at each visit by retrograde filling of the bladder with sterile water through a catheter, until the patient reported their maximum capacity sensation.

The ICSI is a valid and reliable method for measuring successful IC/BPS treatment, with a reduction of at least 29.5% in ICSI score corresponding with moderate to marked improvement in symptoms on the Patient Overall Rating of Improvement of Symptoms Index [1]. One study utilizing global assessments of response determined that 40% of patients receiving DMSO had a moderate improvement after treatment [2]. Another study determined that 15% of patients had a moderate response to lidocaine and heparin instillations [3]. Our power and sample size calculations were performed using these previously published response rates and using the validated outcome of a percent reduction in ICSI of at least 29.5%. It was determined that 49 subjects per group would be required to detect the expected difference in response (25%) with 80% power at a 0.05 significance level. Data were analyzed using Student's t-test or Chi-squared tests.

RESULTS

Eighty-three patients were randomized and 70 participants completed the six once-weekly instillations (42 DMSO, 28 BTH). The groups were similar in baseline demographics and clinical characteristics with the exception of baseline CMG maximum capacity (DMSO 338.62 +/- 139.44mL, BTH 447.43+/- 180.38mL, p= 0.01). A greater than 29.5% reduction in total ICSI score was seen at the conclusion of treatment in 63% of DMSO patients and 43% of BTH patients (p=0.15). Overall, there was a significant difference in the change of total ICSI score favoring DMSO at visit 5 and 6 (p=0.02 each). At treatment visits 5 and 6, there were significantly greater improvements in the individual ICSI pain question for DMSO compared to BTH (p=0.03 and p=0.01, respectively). Significant improvements were observed in individual ICSI question scores between visits 1, 5 and 6 in regard to urgency, frequency, nocturia, and pain (p<0.0001 each) in the DMSO group, while questions addressing urgency and daytime frequency were significantly improved in the BTH treatment group (p=0.009 and p=0.003) but not for pain.

Bladder capacity increased significantly from baseline for both DMSO and BTH (p<0.01 each). There was a nonsignificant difference in percent change in bladder capacity at the conclusion of treatment (DMSO 74% vs BHT 42%, p=0.16). There was no significant difference between treatment groups with respect to daytime voiding frequency or nocturia; however, there was a significant reduction in nocturia in the DMSO treatment arm (mean -1, p=0.01).

INTERPRETATION OF RESULTS

These data revealed several interesting and clinically relevant differences in outcomes between DMSO and BTH treatment groups, which became apparent only towards the end of the 6-week treatment cycle. Patients receiving their last two bladder instillations (weeks #5 and #6) of DMSO reported statistically significant improved pain as compared to those receiving BTH, according to individual ICSI question scores. Responses to ICSI questions pertaining to urgency, frequency, nocturia and bladder pain all improved significantly in the DMSO group, while questions addressing urgency and daytime frequency were significantly improved in the BTH treatment group.

Bladder capacity increased from baseline in both groups, indicating that bladder instillations with DMSO and BTH are effective in improving capacity. The maximum capacity was significantly lower in the DMSO group, at baseline. While a statistically significant difference between percent change in bladder capacity was not observed between the two groups, a trend suggested the possibility of a greater increase in bladder capacity from baseline in the DMSO versus the BTH group; further exploring this finding may require a larger sample size.

Whereas the percentage of patients reporting greater than 29.5% reduction in total ICSI score was not statistically significant between the two treatment groups (63% of DMSO and 43% of BTH, p=0.15), this finding may have been impacted by our recruitment not achieving the target of 49 per group as defined by the power calculation. Despite this limitation, the individual ICSI question analyses, as well as bladder capacity analysis, all revealed positive findings pointing towards consistent conclusions relating to our fundamental study questions: both therapies demonstrate the ability to provide effective symptom relief and improved bladder capacity, and when systematically compared in newly diagnosed IC/BPS patients, DMSO appears to outperform BTH in several respects. As always, these findings need to be considered through additional perspectives including cost, which were not addressed by the current study.

CONCLUDING MESSAGE

Bladder instillations with DMSO or BTH provide overall symptomatic improvement, larger bladder capacity, and improved frequency and nocturia in patients with newly diagnosed IC/BPS. DMSO appears to provide greater improvement in symptoms, particularly bladder pain. The impact of these therapies, and the differences between groups, tend to be fully revealed only after 5 sessions of once-weekly therapy.

REFERENCES

1. Lubeck DP, Whitmore K, Sant GR, Alvarez-Horine S, Lai C. Psychometric validation of the O'Leary-Sant Interstitial Cystitis Symptom Index in a clinical trial of pentosan polysulfate sodium. Urology 2001 57(Suppl 6):62-66.
2. Perez-Marrero R, Emerson LE, and Feltis JT. A controlled study of dimethyl sulfoxide in interstitial cystisis. J Urol 1988;140(1):36-39.
3. Nomiya A, Naruse T, Niimi A, Nishimatsu H, Kume H, Igawa Y, Homma Y. On- and post-treatment symptoms relief by repeated instiallations of heparin and alkalized lidocaine in intersititial cystitis. International Journal of Urology 2013 20:1118-112.

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BEST IN CATEGORY PRIZE "FEMALE LOWER URINARY TRACT SYMPTOMS (LUTS) / VOIDING DYSFUNCTION"

EFFECT OF ALPHA BLOCKER ON LOWER URINARY TRACT SYMPTOMS IN WOMEN: SYSTEMATIC REVIEW AND META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

Alpha-blockers have been used in women with voiding problem. However, the use of alpha-blockers in clinical practice to treat bothersome lower urinary tract symptom (LUTS) in women is based on these limited studies, some anecdotal case reports as well as local experience. This study aimed to evaluate the effects of the alpha-blocker on the symptoms in female patients.

STUDY DESIGN, MATERIALS AND METHODS

We conducted a systematic review and meta-analysis on published a-priori protocols. We searched multiple data sources for published and unpublished randomized controlled trials in any language. Review outcomes included urologic symptom scores, quality of life and overall adverse

events. We performed meta-analysis using RevMan 5.3 and rated the certainty of evidence (CoE) using GRADE.

RESULTS

A total of 1406 studies identified through our search, we included 12 studies (alpha-blockers vs. placebo: 5 studies, combination with alpha-blockers and other treatments vs. other treatments: 7 studies). Based on 4 studies comparing alpha-blockers and placebo, comprising 456 randomized participants, we are uncertain about the effects of alpha-blockers on urologic symptom scores based on IPSS (mean difference (MD): -1.13, 95% confidence interval (CI): -3.10 to 0.85; very low CoE), quality of life (MD: -0.48, 95% CI: -1.20 to 0.24; ; very low CoE), and overall adverse events (risk ratio (RR): 1.09, 95% CI: 0.55 to 2.15; ; very low CoE). Based on one studies comparing combination therapy with an alpha-blocker and anticholinergic and anticholinergic alone, comprising 144 randomized participants, we are uncertain about the effects of alpha-blocker on urologic symptom scores based on IPSS (MD: 0.30, 95% CI: -2.80 to 3.40; very low CoE) and quality of life (MD: 0.00, 95% CI: -0.56 to 0.56; very low CoE). There were no overall adverse events reported in the study. Based on 1 study comparing combination therapy with an alpha-blocker and cholinergic and cholinergic alone, comprising 81 randomized participants, we are uncertain about the effects of alpha-blocker on urologic symptom scores based on IPSS (MD: -3.06, 95% CI: -7.20 to 1.08; very low CoE). There were no quality of life and overall adverse events reported in the study.

INTERPRETATION OF RESULTS

From the present meta-analysis, alpha-blockers have been used to reduce storage LUTS as well as voiding LUTS in women. The inclusion criteria of most of the studies in this meta-analysis were based on symptoms using questionnaires regardless of the cause of LUTS. Therefore, this meta-analysis showed that symptom-based alpha-blockers treatment appeared to have little to no effects on urologic symptom scores, quality of life, and overall adverse events compared to placebo and other treatments in women.

CONCLUDING MESSAGE

Alpha-blockers treatment depending on subjective LUTS might have little effects on urologic symptom scores, quality of life, and overall adverse events compared to placebo and other treatments in women.

REFERENCES

1. Ann Pharmacother 2014;48:711-22

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Meta-analysis **Helsinki** not Req'd Meta-analysis **Informed Consent** No

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THE COLPOPEXY AND URINARY REDUCTION EFFORTS (CARE) TRIAL—HAS IT CHANGED PRACTICE PATTERNS IN THE STATE OF NEW YORK?

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HYPOTHESIS / AIMS OF STUDY

Pelvic organ prolapse (POP) is an incredibly prevalent issue estimated to affect anywhere between 40-75% of adult women [1]. According to the AUA, POP is defined as the descent of either the anterior or posterior vaginal wall beyond the vaginal introitus secondary to weakness in the pelvic floor muscles involving the vagina, bladder, rectum, or small bowel. Repair of POP is performed in an estimated 10-20% of women with the abdominal sacrocolpopexy (SCP) as the gold standard operative intervention [2]. In 2006, the landmark Colpopexy and Urinary Reduction Efforts (CARE) trial demonstrated that in women without stress urinary incontinence, abdominal SCP with Burch colposuspension significantly reduced postoperative stress urinary incontinence [3]. The impact of a high quality evidence based studies such as the CARE trial on practice patterns is not well elucidated. We sought to investigate the effect of these findings on the use of abdominal SCP with or without an anti-incontinence procedure using a statewide database.

STUDY DESIGN, MATERIALS AND METHODS

Institutional review board approval was obtained for a retrospective review of the NY Statewide Planning and Research Cooperative System (SPARCS) database. The SPARCS database was queried for inpatient procedures that describe SCP (ICD-9-CM 70.77 and 70.78), retropubic urethral suspension (ICD-9 CM 59.5), suprapubic sling procedures (ICD-9 CM 59.4), and other repair of stress urinary incontinence (ICD-9 CM 59.79). Data extracted from 5 years before the CARE trial (2001-2006) and 5 years after the CARE trial (2006-2011) were analyzed. Statistical analysis was performed using SPSS v26 and linear regression was performed to assess trends. Statistical significance was defined as p-value <0.05.

RESULTS

Over the 10-year study period, a total of 248,876 procedures for POP and stress urinary incontinence were identified. Of these, 71,340 SCP procedures and 140,888 anti-incontinence procedures including retropubic urethral suspension, suprapubic sling, and other repair of stress urinary incontinence were performed. There was a significant increase in the number of SCP with concomitant SUI procedures ($r2=0.848$, $p<0.001$) and SCP alone ($r2=0.575$, $p=0.007$) performed after publication of the CARE trial.

INTERPRETATION OF RESULTS

In New York State, there was a significantly positive correlation in the number of SCP performed with or without anti-incontinence procedures after the publication of the CARE trial when compared to prior to the CARE trial.

CONCLUDING MESSAGE

Of the numerous studies that become abstracts and manuscripts, an overwhelming amount of these studies do not affect change in the way physicians and providers practice. The CARE trial is an example of how evidence-based medicine translates into measurable changes in practice patterns. Future studies are needed to investigate the impact of the CARE trial on surgical outcomes.

FIGURE 1

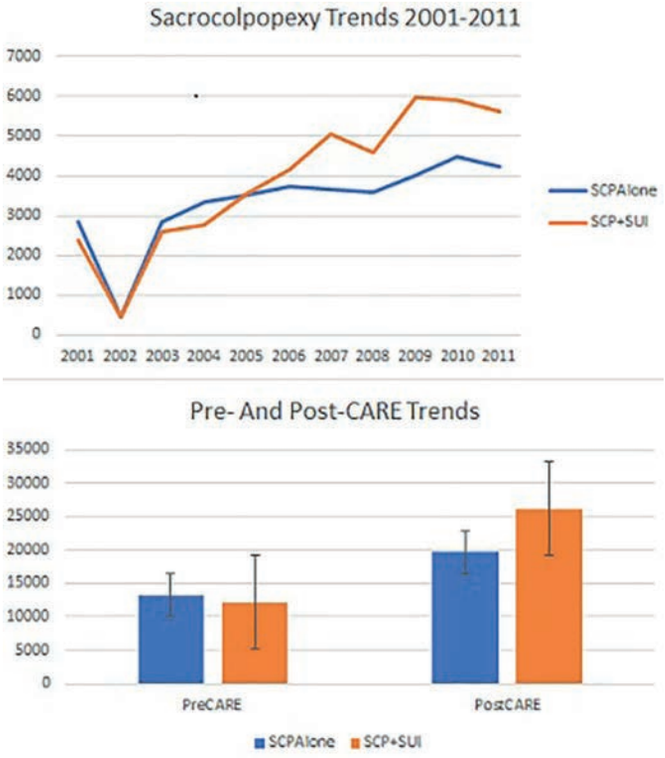

Figure 1: Sacrocolpopexy (SCP) trends (top) by year. Pre- and post-CARE trial trends stratified by SCP alone or SCP plus stress urinary incontinence (SUI) procedure.

REFERENCES

1. Hendrix S. L., Clark A., Nygaard I., et al. (2002). Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. Am J Obstet Gynecol, 186(6), 1160-1166. doi:10.1067/mob.2002.123819
2. Nygaard I., Brubaker L., Zyczynski H. M., et al. (2013). Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse. Jama, 309(19), 2016-2024. doi:10.1001/jama.2013.4919
3. Brubaker L., Cundiff G. W., Fine P., et al. (2006). Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence. N Engl J Med, 354(15), 1557-1566. doi:10.1056/NEJMoa054208

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Review Board **Helsinki** Yes **Informed Consent** No

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IMPACT OF LOWER URINARY TRACT SYMPTOMS ON DIURETIC ADHERENCE

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HYPOTHESIS / AIMS OF STUDY

Diuretics are associated with worsening of lower urinary tract symptoms (LUTS). LUTS have a tremendous impact on quality of life and are hypothesized to decrease medication adherence among diuretic users. The aim of the present study is to assess the relationship of urinary symptom severity with non-adherence to diuretic regimen.

STUDY DESIGN, MATERIALS AND METHODS

Participants taking a diuretic were contacted via Researchmatch.org, a resource to help investigators find research volunteers. Participants were given a link to an anonymous REDCap survey. LUTS severity was measured with the Overactive Bladder Questionnaire-Short Form (OAB-q SF) [1]. Adherence was assessed via three approaches. We used two validated adherence measures which produced continuous variable adherence scores (Adherence to Refills and Medications Scale and Self-Efficacy for Managing Medications and Treatments – Short Form) [2,3]. We then asked participants if they skip diuretic doses due to increased urinary frequency or worsening stress urinary incontinence (SUI), with categorical yes/no response options. Linear regression was used to assess the relationship of OAB-q SF score with continuous adherence variables and logistic regression was used calculate odds ratio (OR) and confidence intervals (CI) for categorical variables. Significant relationships were further evaluated with multivariate regression. Potential confounding variables included in the multivariate model were identified by using $\chi 2$ and t test to assess demographic differences between adherent and non-adherent groups.

RESULTS

4,029 participants were contacted, and 280 surveys were completed (6.9% response rate). Mean age was 61 years old, 70.4% were female, mean BMI was 32.5 kg/m2, and mean OAB-q SF score was 22.2%. The majority of participants were taking the diuretic for hypertension (57%). Twenty-four percent were taking a loop diuretic and 55.4% reported expe-

riencing SUI (table 1). Of the entire cohort, 54 participants (19.3%) admitted skipping diuretic doses due to increased LUTS (33 due to increased urinary frequency, 3 due to worsening SUI, 18 due to both).

Linear regression of OAB-q SF versus the two validated adherence measures produced best fit lines with positive slopes, indicating direct relationship between LUTS severity and diuretic non-adherence. However, R-coefficients were low (0.012 and 0.002). Logistic regression showed increasing OAB-q SF score was significantly associated with skipping diuretic doses due to increased urinary frequency (OR 1.029; 95% CI, 1.014-1.044, P<0.001) and worsening SUI (OR, 1.069; 95% CI, 1.046-1.096; P<0.001; table 2). After controlling for BMI, smoking status, and education, OAB-q SF score remained significantly associated with skipping doses due to increased urinary frequency (OR, 1.028; 95% CI, 1.012-1.044; P<0.001) and worsening SUI in multivariate analysis (OR 1.069; 95% CI 1.045-1.099; P<0.001; table 2).

INTERPRETATION OF RESULTS

For every additional point in OAB-q SF score, we found a 2.8% increase in odds of participants skipping diuretic doses due to increased urinary frequency and a 6.9% increase in odds of skipping diuretic doses due to worsening stress urinary incontinence.

CONCLUDING MESSAGE

Increasing OAB-q SF score was significantly associated with skipping diuretic doses, supporting the hypothesis that worsening LUTS lead to decreased diuretic adherence. This is the first study to examine the relationship of LUTS with diuretic adherence in participants with a variety of chronic diseases.

FIGURE 1

Table 1: Characteristics of the Cohort

	Entire cohort (N=280)	Non-Adherent (N=54)	Adherent (N=226)	*P* Value
OAB-q SF, mean (SD)	22.2 (±19.8)	32.6 (±17.6)	19.7 (±23.3)	<0.01
Loop diuretic, no. (%)	67 (23.9%)	25 (46.3%)	42 (18.6%)	<0.01
BMI, mean (SD)	32.48 (±8.42)	35.6 (±9.66)	31.7 (±3.41)	<0.01
Smoking status, no. (%)	17 (6.1%)	7 (13.0%)	10 (4.4%)	0.02
Experience SUI, no. (%)	155 (55.4%)	37 (68.5%)	118 (52.2%)	0.03
Education, no. (%)				
Further education beyond college	121 (43.2%)	17 (31.5%)	104 (46.0%)	
Completed college	108 (38.6%)	24 (44.4%)	84 (37.2%)	0.13
Completed high school	47 (16.8%)	11 (20.4%)	36 (15.9%)	
Do not wish to provide	4 (1.43%)	2 (3.7%)	2 (0.88%)	
Sex, female, no. (%)	197 (70.4%)	42 (77.8%)	155 (68.6%)	0.18
Age, y, (SD)	61.0 (±14.7)	62.7 (±12.9)	60.6 (±8.61)	0.26
Indication for diuretic				
Hypertension	159 (57.0%)	28 (52.8%)	131 (58.0%)	
Other	64 (22.9%)	10 (18.9%)	54 (23.9%)	
Congestive heart failure	20 (7.17%)	8 (15.1%)	12 (5.31%)	
"I'm not sure"	14 (5.02%)	2 (3.77%)	12 (5.31%)	0.33
Swelling/edema from steroids or estrogen	12 (4.30%)	3 (5.66%)	9 (3.98%)	
Chronic kidney disease	4 (1.43%)	1 (1.89%)	3 (1.33%)	
Diabetes insipidus	3 (1.08%)	1 (1.89%)	2 (0.88%)	
Kidney stones	3 (1.08%)	0 (0.0%)	3 (1.33%)	
Ethnicity, no. (%)				
Not Hispanic or Latino	265 (94.6%)	50 (92.6%)	215 (95.1%)	0.66
Do not wish to provide	9 (3.21%)	2 (3.70%)	7 (3.10%)	
Hispanic or Latino	6 (2.14%)	2 (3.70%)	4 (1.77%)	
Race, no. (%)				
White	248 (88.6%)	46 (85.2%)	202 (89.4%)	
Black or African American	21 (7.50%)	6 (11.1%)	15 (6.64%)	
American Indian or Alaskan Native	3 (1.07%)	1 (1.85%)	2 (0.88%)	0.71
Do not wish to provide	6 (2.14%)	1 (1.85%)	5 (2.21%)	
Asian	2 (0.72%)	0 (0%)	2 (0.88%)	

Note. OAB-q SF, Overactive Bladder Questionnaire Short Form. BMI, body mass index. SUI, stress urinary incontinence.

FIGURE 2

Table 2: Association of OAB-q SF score with diuretic non-adherence

	Outcome: Non-adherent due to increased urinary frequency (*n*=51)		Outcome: Non-adherent due to worsening stress urinary incontinence (*n*=21)	
Variable	Odds Ratio (95% CI)	*P* value	Odds Ratio (95% CI)	*P* value
Unadjusted				
OAB-Q SF score	1.029 (1.014-1.044)	<0.001	1.069 (1.046-1.096)	<0.001
Adjusted*				
OAB-Q SF score	1.028 (1.012-1.044)	<0.001	1.069 (1.045-1.099)	<0.001

Note. OAB-q SF, Overactive Bladder Questionnaire Short Form. CI, confidence interval.
*Body mass index, smoking status, and education included in the multivariate model

REFERENCES

1. Pfizer PCOA. https://www.pfizerpcoa.com/. Accessed April 1, 2020.
2. Kripalani S, Risser J, Gatti ME, Jacobson TA. Development and Evaluation of the Adherence to Refills and Medications Scale (ARMS) among Low-Literacy Patients with Chronic Disease. Value in Health. 2009;12(1):118-123. doi:10.1111/j.1524-4733.2008.00400.x.
3. Gruber-Baldini A, Velozo C, Romero S, Shulman L, Gruber-Baldini AL, Shulman LM. Validation of the PROMIS® measures of self-efficacy for managing chronic conditions. Quality of Life Research. 2017;26(7):1915-1924. doi:10.1007/s11136-017-1527-3.

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IS TRANSURETHRAL BLADDER OUTLET SURGERY USEFUL FOR WOMEN WITH DETRUSOR UNDERACTIVITY?

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HYPOTHESIS / AIMS OF STUDY

Detrusor underactivity (DU) is a common condition with a prevalence of 13.3% - 24% in female population1. Management of DU remains challenge since no standard treatment is available. This study aims to assess the effect of transurethral bladder outlet surgery (TBOS) in women with DU refractory to pharmacotherapy.

STUDY DESIGN, MATERIALS AND METHODS

A total of 53 women with DU refractory to alpha-blockers underwent TBOS between March 2013 and December 2018. The DU was diagnosed based on the urodynamic criteria of Qmax ≤12 mL/s and PdetQmax ≤10 cmH2O2. In terms of TBOS procedure, the patients' urethral length was measured and subsequently the distal position of incision which was 2.5 cm apart from external urethral orifice was marked with a Wolf 24F resectoscope. The incisions were made at the 5-, and 7-o'clock position of bladder neck extending proximally to the ureteral orifice and distally to the marked position.

Thereafter, the tissue of bladder neck and proximal urethra was excised between two incisions to make proximal urethra was even with vesical triangle. After the surgery, a 20F Foley catheter was indwelled for one week. The voiding efficiency (VE), post-void residual urine volume (PVR), and uroflowmetry were used to assess the effectiveness of TBOS. Patients with a VE of >90% were considered as the complete responders and those with a VE of 50% - 90% were considered as the partial responders.

RESULTS

The mean age of the patients was 53 ± 16 years (range 28-84) and the median follow-up period was 43 months (ranged 12 to 72 months). Of the 53 patients, 36 (68%) were diagnosed as neurogenic DU, while 17(32%) as idiopathic DU. At baseline, 28 patients required catheterization including clean intermittent catheterization (CIC) and indwelling catheter, and 25 patients presented a significant PVR (>300ml). Besides pharmacotherapy, seven patients also failed to sacral neuromodulation. After the surgery, 49 patients (92.5%) could void spontaneously by abdominal straining and without catheterization. During the follow-up period, eight patients (15.1%) achieved complete response and 33 patients (62. 3%) got partial response. Moreover, the patients' Qmax and PVR were also significantly improved (Table 1). Interestingly, of the seven patients failed to sacral neuromodulation, six showed a good response to TBOS. In addition, six patients had mild urinary incontinence and no one developed vesicovaginal fistula during the follow-up.

INTERPRETATION OF RESULTS

It has been reported that transurethral surgery is effective in improving DU female patients' lower urinary tract symptoms and recovering spontaneous voiding. The most of reported procedures were transurethral incision of bladder neck. However, we found that the length of urethra varied from 3 to 5.5 cm in women after measuring female urethra. The procedure of classic incision of bladder neck might not achieve the optimal effect for some patients. Based on the results, our procedure could help 77.4% women with DU to get significant improvement, which seems to be higher than 52% reported in the procedure of transurethral incision of bladder neck3. The important limitation of our study is lack of control, which will be solved in our future study.

CONCLUDING MESSAGE

TBOS is a safe and effective procedure for female patients with DU.

FIGURE 1

Table 1. The patients' urodynamic parameters before and after TBOS

	Baseline	Follow-up	P-value
Voiding efficiency (%)[a]	0 (0, 12.5)	72.5 (40, 82.5)	<0.001
PVR (mL)[b]	463 ± 257	115 ± 86	<0.001
Qmax (mL/s)[b]	2.8 ± 3.4	9.7 ± 4.8	<0.001

a. Measurements are given as median (interquartile range); b. Measurements are given as mean ± standard deviation.

Table 1. The patients' urodynamic parameters before and after TBOS

REFERENCES

1. Yu YD, Jeong SJ. Epidemiology of underactive bladder: Common but underresearched. Investig Clin Urol. 2017;58(Suppl 2):S68-S74.
2. Jeong SJ, Kim HJ, Lee YJ, Lee JK, Lee BK, Choo YM, et al. Prevalence and clinical features of detrusor underactivity among elderly with lower urinary tract symptoms: a comparison between men and women. Korean J Urol 2012;53:342-348.
3. Jhang JF, Jiang YH, Lee CL, Kuo HC. Long-term follow up and predictive factors for successful outcome of transurethral incision of the bladder neck in women with detrusor underactivity. J Formos Med Assoc. 2016;115(9):807-13.

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IS THE 50% IMPROVEMENT THRESHOLD ADEQUATE FOR PROGRESSION TO IMPLANTATION IN SACRAL NEUROMODULATION?

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HYPOTHESIS / AIMS OF STUDY

When using sacral neuromodulation (SNM) for overactive bladder (OAB), an at least 50% improvement in urinary symptoms is needed to justify progressing from the 1st stage/test phase (St1) to implantation of the device in the 2nd stage (St2). We sought to determine if this 50% improvement threshold is adequate for longer term efficacy of the device by comparing patients with a 50-75% symptom improvement after St1 who had a subsequent St2 implant to those with a >75% improvement after St1.

STUDY DESIGN, MATERIALS AND METHODS

We conducted a retrospective review of 213 patients who underwent SNM for OAB by two surgeons from 2005 – 2018. Patients were divided into cohorts (50-75% and >75% improvement) based on symptom improvement using a combination of patient-reported degree of improvement (0-100%), symptom questionnaires, bladder diary and pad usage. Patient demographic and clinical variables were compared between the cohorts using chi-squared and t-test analyses. Cox proportional hazard regression was performed to assess for associations between these variables, reported improvement after St1, and long-term success after St2

RESULTS

Of 213 OAB patients who underwent St1i, 84 (39.4%) reported 50-75% improvement and 75 (90.4%) of those progressed to St2i (group 1) whereas 69 patients (32.3%) reported >75% and 60 (86.9%) of those progressed to St2i (group 2). Baseline characteristics (comorbidities, symptom scores, bladder diaries, pad usage and urodynamic parameters) were not significantly different between groups except that neuropathy was more prevalent in group 1 (29% vs 13%, p=0.01). After SNSt, improvements in symptom scores and diary/pad usage were not significantly different between groups apart from a greater improvement in AUASS bother score in group 2 (3.43 vs. 1.6, p=0.04). After St2, group 2 patients were more likely to report a >75% improvement (71.2% vs 34.2%, p<0.01). With a mean follow-up of 46 months, 24/75 group 1 patients and 31/60 group 2 patients still had a functioning device providing symptomatic benefit (p=0.06) with no significant difference found between groups on regression (OR=0.481,95% CI: 0.217 – 1.063, p=0.07).

INTERPRETATION OF RESULTS

We found no significant differences in the majority of baseline characteristics and clinical data between patients who had a 50-75% improvement and those with >75% improvement after SNM. As well, there was no statistically significant difference between groups with respect to patients with longer term device efficacy. This suggests the current threshold of an at least 50% improvement during SNM testing is adequate to progress to implantation of the device. However, the lack of a statistically significant difference between groups might be a reflection of the patient numbers and therefore these results should be interpreted with caution. It is noteworthy that the degree of bother was lower after SNM testing and the subjective degree of improvement significantly greater after stage 2 implant in the group who had >75% improvement after SNM testing. Additional study and followup is warranted to more reliably determine if we need to modify the threshold for a successful SNM test.

CONCLUDING MESSAGE

Based on the lack of a statistically significant difference between groups, a >50% symptom improvement threshold during SNM testing for progression to stage 2 implant seems reasonable. However, better long-term results might be achievable with a higher threshold.

FIGURE 1

Baseline St1 Subjective Improvement Groups			
	St1 50-75%	St1 >75%	p-value
Patients (n)	84	69	
Age (mean, yrs.)	51.0	50.7	0.96
Sex (n= #female,%)	76 (91.6%)	61 (88.4%)	0.67
OAB category (n = wet, %)	67 (79.7%)	56 (81.1%)	0.95
Neuropathy present	25 (29.8%)	9 (13.4%)	0.01
SUI (i.e. MUI; n= #pts, %)	34 (40.5%)	44 (63.8%)	0.04
AUASS Total Baseline (mean ± SD)	22.8 ±8.2	19.9 ±8.0	0.23
Urinary Freq (#/24h, mean ± SD)	12.7 ±6.1	12.4±5.6	0.73
Pad Test (#pads/24h, mean ± SD)	3.7±3.0	3.7±1.6	0.61
Cystometric capacity (mL, mean ± SD)	336.7±263	336.2±244	0.82
Detrusor Overactivity (n= #pts, %)	35 (43.2%)	34 (53.1%)	0.24
PNE only (n= #pts, %)	32 (38.1%)	30 (43.5%)	0.79
Staged Implant (n= #pts, %)	46 (58.9%)	36 (54.5%)	
Patients (n= #pts, %) Advance to St2	75 (90.4%)	60 (86.9%)	0.54

Baseline Characteristics of St1 Improvement Groups

FIGURE 2

Long-Term Follow-up, Subjective Improvement Groups			
	St1 50-75%	St1 >75%	p-value
Mean follow-up time (months)	45.8	46.2	0.96
Continued symptom improvement (n= #pts, %)	24 (45%)	31 (63.2%)	0.06
Initiated Alternative Therapy (n= #pts,%)*	8 (16.7%)	18 (25.4%)	0.002
Implant Explanted (n=#pts, %) **	23 (31%)	14 (23.3%)	0.34

Long Term Follow-up

Funding No funding **Clinical Trial** No **Subjects** Human **Ethics Committee** Medical College of Wisconsin Institutional Review Board **Helsinki** Yes **Informed Consent** No

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INCREASED RISK OF INCIDENT DEMENTIA FOLLOWING USE OF ANTICHOLINERGIC AGENTS: A META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

Anticholinergic medications—which exert their effects by blocking the action of the neurotransmitter acetylcholine—are prescribed to treat a wide range of medical conditions. An accumulating base of literature suggests that chronic treatment with these agents could lead to an increased risk of cognitive impairment or dementia, prompting some groups, such as the American Geriatrics Society, to recommend restricting their use. Further studies have shown that the risk posed by use of these agents is dependent on cumulative exposure over time, with longer durations of treatment presenting a greater risk of negative effects on cognition. Antimuscarinic drugs, used to treat overactive bladder specifically, have very high anticholinergic activity, and many have precautions included in their prescribing information regarding central nervous system anticholinergic effects. Given the potential for symptom exacerbation, the oxybutynin label additionally recommends caution for use in patients with preexisting dementia treated with cholinesterase inhibitors.

Results of a recent meta-analysis of short-term anticholinergic use (average follow-up duration of 12 weeks across studies) by Salahia and colleagues [1] suggest that perhaps the link between anticholinergics and cognitive impairment/dementia has not been fully established, although their review was limited by only one study available to assess the outcome of dementia. The current systematic literature review and meta-analysis assessed the impact of ≥3 months of anticholinergic use on the risk of incident dementia (all subtypes), incident mild cognitive impairment, and change in cognitive function across all patients, as well as specifically in patients treated with anticholinergic medications for overactive bladder.

STUDY DESIGN, MATERIALS AND METHODS

This systematic literature review and meta-analysis utilized the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for systematic reviews and meta-analyses, and the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) reporting guidance. The protocol was registered in the PROSPERO database. PubMed, Embase, and Cochrane Library databases were used to identify studies published prior to August 8, 2019. All articles were independently screened and assessed for quality by two reviewers. Data abstraction was conducted by one reviewer using a standardized data abstraction form, and data were verified by the second reviewer against the original publications.

Titles and abstracts were reviewed and moved to the full-text review if they met the following inclusion criteria: (1) examined the impact of ≥3 months of anticholinergic drug use on dementia or cognitive function in adult patients (18+ years of age), (2) was a randomized-controlled trial, case-control study, or cohort study, (3) contained an adequate description of the methods used, and (4) was a primary publication. Quality was assessed using the Cochrane Risk-of-Bias Tool for Randomized Trials (RoB 2) and the Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) for observational studies.

All studies included in the qualitative review were considered for the meta-analysis if they met all other criteria and contained a comparison group with no anticholinergic use. Meta-analyses were conducted using random effects models. The 95% confidence intervals (CIs) and 95% prediction intervals (PIs) were reported. The CI reflects random error in estimating the mean but does not reflect the spread of the random-effects distribution. The PI reflects heterogeneity and random estimation error and may be informally interpreted as the interval within which we expect the true value estimated from a future study to lie. Influence analysis was performed to assess if any individual study had a particular impact on the results. The impact of study characteristics was explored using stratified and meta-regression analyses. Funnel plot asymmetry was also assessed. Analyses were conducted with STATA v.16 statistical software (Stata Corporation LP, College Station, TX).

RESULTS

A total of 2092 articles were retrieved based on the electronic search, with another 30 identified from a supplemental manual search. After deleting 132 duplicates, 1990 records were screened based on their titles and abstracts, and 316 were included in the full-text review. Finally, 21 studies were included for qualitative synthesis, with the majority reporting an increased risk with anticholinergic use overall or for ≥1 dosing exposure level (incident dementia: 8 of 9 studies; incident Alzheimer's disease: 4 of 4 studies; incident mild

cognitive impairment: 2 of 2 studies; cognitive impairment/ decreased performance: 7 of 11 studies).

Six of 9 studies assessing incident dementia were considered relevant for inclusion in a meta-analysis. The study characteristics are summarized in Figure 1. Individual dementia subtypes, incident mild cognitive impairment and change in cognitive function could not be examined via meta-analysis given the limited number of articles.

Across the 6 studies, the rate ratios (RR) for incident dementia ranged from 1.05 to 2.63, with an estimated average RR of 1.46 (95% CI, 1.17 to 1.81; 95% PI, 0.70 to 3.04; Figure 2). No single study was exceedingly influential on the results. When data from studies that assessed daily dosing information were examined, all dosing exposure levels were associated with increased rates of incident dementia, with higher dosing categories presenting greater risk (90-365 total standardized daily doses [TSDD]/defined daily doses [DDD] vs 0: 1.14 [1.07 to 1.21; n=3]; 365-1095 vs 0 TSDD/DDD: 1.35 [1.24 to 1.48; n=2]; >1095 vs 0 TSDD/DDD: 1.49 [1.38 to 1.61; n=2]).

Subgroup analysis and meta-regression of study characteristics showed that the RRs were generally consistent with the main analysis. On average, positive associations were reported in case-control studies, studies with no lag, studies with a minimum age at enrollment of at least 65 years, studies with enrollment starting after 2000, studies with <70% female patients, and studies with ≥70% female patients. Begg and Egger tests yielded p values greater than 0.8 for asymmetry, and using the trim and fill method, the random-effects summary RR also was not dramatically affected (RR=1.63). Overactive bladder medications could not be examined in a separate meta-analysis given limited studies (n=2), but these nested case-control studies both reported an increased risk of dementia with ≥3-month use of bladder antimuscarinics (adjusted odds ratio range: 1.35 to 1.65 in Coupland [2] and 1.21 to 1.35 in Richardson [3]). Higher exposure categories appeared to present a greater risk (i.e., comparisons including >365 TSDD/DDD).

INTERPRETATION OF RESULTS

Use of anticholinergic agents for 3 months or longer was found to increase the risk of dementia an average of 46% relative to non-use. This increased risk also was reported in the two studies from the meta-analysis that evaluated anticholinergic medications used to treat overactive bladder. Based on subgroup analyses of study characteristics, the cognitive impact of anticholinergics appears to span age and sex groups, but additional studies are needed. Cumulative exposure modified the increased risk presented by anticholinergics in the current analysis, with greater increases at higher exposure categories.

CONCLUDING MESSAGE

Given the substantially increased risk of developing dementia associated with use of anticholinergic agents for ≥3 months, physicians should carefully weigh the risk versus the potential benefits prior to prescribing.

FIGURE 1

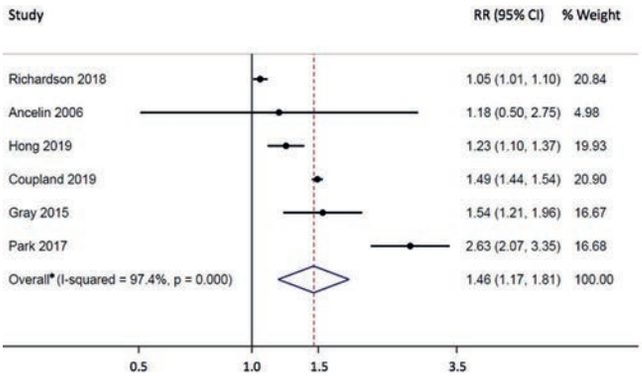
Study	Design	Study Setting/ Participants	Patient Characteristics	Drug Exposure Assessment	Follow-up/ Study Duration	Risk of Bias	Reported Association
Ancelin 2006	Prospective cohort	General practitioner patients (France) N=327	>60 years 77% women among exposed	Prevalent use at baseline and 1 year after	7 years	Moderate	No
Coupland 2019	Nested case-control	QResearch database (UK) N=284,343	≥55 years 63% women	10 years: 1 to 11 years before index date	N/A	Moderate	Yes
Gray 2015	Prospective Cohort	Sampled patients (GroupHealth, USA) N=3,434	≥65 years 60% women	≥10 years of GroupHealth care plan enrollment	Mean (SD) follow-up: 7.3 (4.8) years	Moderate	Yes/No depending on level of TSDD
Hong 2019	Retrospective cohort	National Health Insurance Research Database (Taiwan) N=21,934	≥45 years 52% women	1 year after index date	Mean (SD) follow-up: 5.9 (3.4) years among unexposed 5.7 (3.4) years among exposed	Moderate	Yes
Park 2017	Nested case-control	National Health Insurance Service (South Korea) N=11,124	≥65 years 72% women	2 years before index date	N/A	Moderate	Yes
Richardson 2018	Nested case-control	Clinical Practice Research Datalink (UK) N=324,703	65-99 years 63% women	Median (IQR, range) = 7.1 (4.0-11.3, 1-16) years before index date	N/A	Low	Yes

Studies: Ancelin ML et al. BMJ (Clinical research ed). 2006;332(7539):455-459. Coupland CA et al. JAMA Intern Med. 2019;179(8):1084-1093. Gray SL et al. *JAMA Intern Med*. 2015;175(3):401-407. Hong CT et al. *Parkinsonism Relat Dis*. 2019;65:224-229. Park HY et al. *PLoS One*. 2017;12(1):e0169463. Richardson K et al. *BMJ* (Clinical research ed). 2018;361:k1315.

IQR, interquartile range; N/A, not applicable; SD, standard deviation; TSDD, total standardized daily doses; UK, United Kingdom; USA, United States of America.

Figure 1. Qualitative Summary of Studies Included in the Meta-Analysis Assessing the Impact of Anticholinergic Agent Use on Incident Dementia.

FIGURE 2



*95% Prediction Interval = 0.70 to 3.04
The CI reflects random error in estimating the mean, but does not reflect the spread of the random-effects distribution. The PI reflects heterogeneity and random estimation error, and may be informally interpreted as the interval within which we expect the true value estimated from a future study to lie.

Studies: Ancelin ML et al. BMJ (Clinical research ed). 2006;332(7539):455-459. Coupland CA et al. JAMA Intern Med. 2019;179(8):1084-1093. Gray SL et al. *JAMA Intern Med*. 2015;175(3):401-407. Hong CT et al. *Parkinsonism Relat Dis*. 2019;65:224-229. Park HY et al. *PLoS One*. 2017;12(1):e0169463. Richardson K et al. *BMJ* (Clinical research ed). 2018;361:k1315.

CI, confidence interval; PI, prediction interval; RR, rate ratio.

Figure 2. Forest plot of estimated rate ratios for the association between ≥3 months anticholinergic use and incident dementia

REFERENCES

1. Salahia S et al. Anticholinergic drugs and risk of cognitive impairment or dementia in patients with overactive bladder syndrome: a systematic review and meta-analysis. Poster presentation at the International Continence Society 2019 Meeting; September 3-9, 2019; Gothenburg, Sweden.
2. Coupland CA et al. JAMA Intern Med. 2019;179(8):1084-1093.
3. Richardson K et al. BMJ (Clinical research ed). 2018;361:k1315.

Funding Urovant Sciences **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Not needed for a meta-analysis. **Helsinki** not Req'd Not needed for a meta-analysis. **Informed Consent** No

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POLYURIA AND OLIGURIA PHENOTYPES IN WOMEN WITH LUTS

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HYPOTHESIS / AIMS OF STUDY

Behavioral modification is recommended as an initial management strategy in women with a clinical diagnosis of overactive bladder (OAB). This study was done to determine the magnitude and clinical characteristics of the subpopulation of women with LUTS for whom fluid restriction would be a useful strategy.

STUDY DESIGN, MATERIALS AND METHODS

In this IRB approved study, an online database was searched for patients with persistent LUTS who completed a 24 hour bladder diary (24HBD) and the Lower Urinary Tract Symptom Score (LUTSS) from 2015 through 2019 using a mobile app*[1]. Data from patients who completed a LUTSS and a 24HBD within a two-week period were contemporaneously matched, excluding patients with any changes in symptoms or treatment, incomplete or inaccurate data entries, or a primary clinical diagnosis of stress incontinence. The earliest recorded set was analyzed when multiple 24HBD and/or LUTSS entries were present. 504 patients completed the LUTSS questionnaire and contemporaneous 24HBD. Of these, 134 women with an OAB score greater than or equal to 8 had proper data entry. Of these 134 women, 46 had urodynamic data available. Polyuria was defined as (>2.5 L/24 H), oliguria (<1 L/24 H) and normal (1 to 2.5 L/24 H) [2]. Table 1 lists the LUTSS, 24HBD, and urodynamic data variables of interest.

RESULTS

Table 1 displays the results of a one-way ANOVA test comparing the three urinary groups across the LUTS questionnaire, 24HBD, and urodynamic parameters. Results of the two-tailed independent sample t-tests directly comparing oliguria and polyuria groups are also presented in Table 1. Of this cohort, 44 had primary clinical diagnosis data available: 16 had a diagnosis of OAB, 1 with Nocturia, 3 with UTI, and 24 that were classified as "Other."

INTERPRETATION OF RESULTS

Our data demonstrates that when categorized by 24 hour voided volume, women with LUTS fall into distinct phenotypes based on clinical characteristics.

There were several significant factors of clinical importance between the polyuria and oliguria groups. Data from the LUTSS questionnaire shows that the scores for LUTS, Storage, OAB, and Incontinence were greater in the oliguria group. Diary data showed that the parameters for 24H VV, MVV, total urgency voids, total difficulty voids, number of nighttime voids, and total voids were significantly lower in the oliguria group. Lastly, urodynamic data showed that the Qmax and Voided Volume parameters were significantly lower in the oliguria group, demonstrating greater severity of underlying conditions.

As expected, the LUTSS questionnaire scores were greater in the oliguria group while the 24HBD and urodynamic data had parameters that were lower for this group. Next, we expect those with oliguria to have more severe symptoms when compared to those in the polyuria group. For most categories of the LUTSS questionnaire, greater scores were

associated with the oliguria group. This data suggests that the LUTSS may potentially correlate with the severity of underlying pathology in this sample of women.

Similarly, we expect to see more incontinent voids and difficulty voiding episodes in the oliguria group when compared to the polyuria group. The data shows otherwise. There are a couple of plausible explanations for these differences. Polyuria patients have more opportunities to void than oliguria patients, in turn, allowing for a greater opportunity for difficulty voiding episodes. On the other hand, oliguria patients may void as soon as they sense the urge, which is in itself a form of self-behavior modification. Thus, polyuria patients are more likely to benefit from behavior modification therapy. Also, patients with oliguria may restrict fluid intake to reduce the impact that their underlying pathology has on their symptoms.

CONCLUDING MESSAGE

Voiding diaries reveal that a large fraction of women presenting with LUTS exhibit polyuria (25%). These women are symptomatically distinguishable from those with oliguria (13%) and are the group in which fluid restriction is more likely to be efficacious. This highlights the essential role of a 24HBD and LUTS questionnaire in the behavioral management of OAB for patients.

FIGURE 1

Table 1. Polyuria vs oliguria data based on LUTSS, 24HBD and urodynamic data for women (Abbreviations VV = Voided Volumes, MVV = Maximum Voided Volumes)

	Normal Mean (SD) (59%)	Oliguria Mean (SD) (13%)	Polyuria Mean (SD) (28%)	ANOVA P-Value	Oliguria vs polyuria P-value
Age	53.9 (17.2)	59.9 (18.2)	58.0 (12.9)	.24	.70
LUTSS Data					
LUTS Score*	28.4 (8.7)	31.7 (8.3)	26.1 (9.4)	.093	.033
Voiding Score	9.3 (5.0)	8.8 (5.0)	8.2 (5.1)	.54	.66
Storage Score**	16.7 (6.0)	20.0 (6.2)	15.3 (5.3)	.025	.011
OAB Score**	14.3 (4.1)	17.0 (3.9)	13.9 (4.2)	.028	.012
Incontinence Score*	4.1 (4.2)	5.7 (4.1)	3.4 (3.1)	.13	.049
Nocturia Score	1.4 (1.3)	1.7 (1.5)	1.1 (1.1)	.26	.163
Bother Score	2.4 (1.1)	2.8 (0.7)	2.6 (1.0)	.38	.32
Bladder Diary Data					
24H VV**	1651 (361)	622 (238)	3326 (989)	<.001	<.001
MVV**	333.7 (106.9)	178.9 (88.0)	543.5 (343.8)	<.001	<.001
Diary Score*	9.2 (5.9)	9.5 (6.0)	12.8 (7.0)	.015	.082
Total Incontinent Void	0.1 (0.5)	0.4 (1.0)	0.4 (1.2)	.25	.89
Total Urgency Void*	3.2 (3.5)	1.5 (2.3)	4.2 (4.8)	.059	.008
Total Difficulty Void*	4.3 (5.3)	1.9 (3.1)	5.0 (6.2)	.13	.015
Number of Nighttime Voids*	1.7 (2.0)	0.8 (1.1)	1.7 (1.9)	.15	.030
Total Voids**	10.1 (4.6)	6.5 (3.0)	12.7 (5.6)	<.001	<.001
Urodynamic Data					
Qmax** (n =46)	20.6 (8.8) (n =24)	10.4 (6.4) (n =10)	20.0 (11.8) (n=12)	.016	.026
Voided Volume** (n =46)	288.7 (136.2) (n=24)	137.3 (98.6) (n =10)	324.8 (215.5) (n=12)	.015	.016
PVR* (n =46)	22.7 (49.6) (n=24)	49.5 (45.8) (n=10)	82.9 (131.4) (n=12)	.10	.424

*Denotes Statistical Significance across either ANOVA or T-test.
**Denotes Statistical Significance across both ANOVA and T-test.
***Listed Urodynamic Voided volume associated with the specific Qmax flow.

Table 1

REFERENCES

1. Blaivas JG, Tsui JF, Mekel G, et al. Validation of the lower urinary tract symptom score. The Canadian Journal of Urology. 2015 Oct;22(5):7952-7958.
2. Hashim, H., Blanker, M. H., Drake, M. J., Djurhuus, J. C., Meijlink, J., Morris, V., Petros, P., Wen, J. G., & Wein, A. (2019). International Continence Society (ICS) report on the terminology for nocturia and nocturnal lower urinary tract function. Neurourology and urodynamics, 38(2), 499–508.

Funding Institute for Bladder and Prostate Research **Clinical Trial** No **Subjects** None

153 www.ics.org/2020/abstract/153

IMPACT OF REGIONAL MULTI-DISCIPLINARY TEAM ON MANAGEMENT OF WOMEN WITH COMPLEX UROGYNAECOLOGY CONDITIONS

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HYPOTHESIS / AIMS OF STUDY

Following the publication of the NICE guidelines in the management pelvic floor dysfunction, articles speculating the benefits and costs of local and regional multi-disciplinary teams have been circulating. The main rationale behind establishing regional MDTs is to provide an equal expert assessment to all patients and a broader range of management plans while removing dangers of traditional, focused and organ-specific approaches to managing complex cases. However, arguments have been made that MDTs are costly, time-consuming and may delay management and affect the efficacy of treatment. Despite these concerns, there has been no formal assessment of the impact of a regional MDT on patient management in urogynaecology. This study aims to evaluate the structure and impact of the Regional MDT on the management of women with pelvic floor dysfunction.

STUDY DESIGN, MATERIALS AND METHODS

Throughout the existence of our Regional Continence MDT, between May 2010 and December 2015, 60 patients were discussed. Data on all 60 patients were collected and anonymised. Information gathered included time between referral, discussion, investigation and implementation of the management plan, patients' presenting condition, reason for referral to MDT, pre and post-MDT management plans and treatment outcomes. The efficacy of the MDT was analysed by comparing the original recommendation by referring clinicians to the MDT recommendation and whether there was a clinical improvement.

RESULTS

The average age of patients discussed was 52.6 years (range 21-91). All meetings had at least a urogynaecologist, a gynecologist, a reconstructive urologist, a urodynamicist and on average 3 continence nurses, 4 physiotherapists, a clinical librarian, and the secretary. It took an average of 101.45 days between date of referral to MDT discussion, 263.55 days between MDT discussion to surgical treatment, 203.47 days between MDT discussion and results of recommended further investigations. The majority of the referrals dealt with Urinary Incontinence (n=34) and there were 8 patients who presented with mesh complications alongside other pelvic floor disorders. The MDT made changes to the original management plans in at least 25 (41.7%). 22 (36.7%) of all patients discussed were reported as cured or improved in their condition following MDT-recommended management.

INTERPRETATION OF RESULTS

The composition of our team largely matches NICE recommendations despite being established before the NICE publications in April 2019. It included all the team members recommended by NICE except the care of the elderly physician. This study demonstrates that Regional MDTs are both feasible and useful to patient care. The challenges ahead include resources, particularly administrative support and including time for MDT meetings in individual professional job plans. The presence of a clinical librarian provided access to the evidence-based support to address any scientific uncertainty, formulating research questions and conducting and circulating the literature search to the MDT members. The 'clinical librarian initiative' provided the principles upon which MDT participation of our librarian was established.

Our regional MDT was robust and has made a significant impact on the healthcare provided to women with complex urogynaecology and female urology conditions. The MDT recommended a change in the original management plan by the referring professional in 25 cases (41.7%). The conditions discussed by our group largely match the referral criteria recommended by NICE. The majority of women presented with either recurrent stress incontinence and/or mesh complications following continence surgery. Among 28 patients who required surgery, the MDT recommended alternative surgical treatment in 12 patients (42.9%). MDT meetings were also a gateway against more invasive testing including video urodynamics and UPPs.

Our experience with regional Urogynaecology MDT suggests that adequate administrative support is key in its success, as well as the appropriate allocation of time in job plans for healthcare professionals to be able to prepare, attend and act upon the actions of the MDT meetings. Regional MDTs offer excellent opportunities to train junior doctors to run MDT.

Following the NICE recommendation for regional MDT, our model could be used to draft a care pathway for a referral to regional MDTs. The size of MDT reflects the size of the catchment area it serves.

CONCLUDING MESSAGE

Our Regional Continence Multidisciplinary Team had an impact on patient management. Cross-sharing of resources between hospitals within the region provided a wider range of management plans, better tailored to each individual patient.

FIGURE 1

Figure 1: Impact of MDT discussion on original decision:

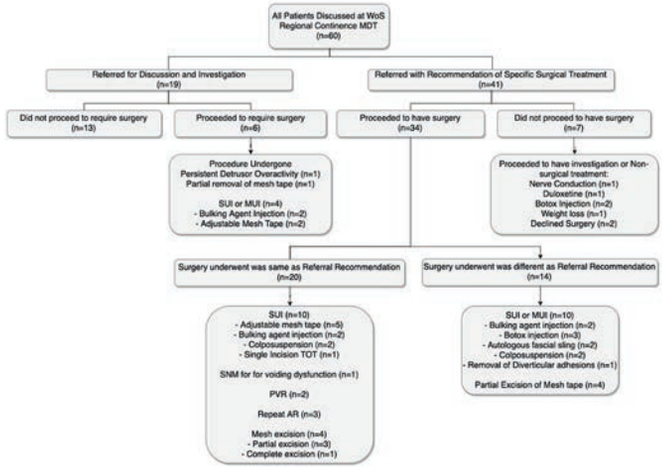

FIGURE 2

Table 1: Categories of complex cases referred for discussion at the Regional Continence MDT

Categories of Cases Referred to Regional Continence MDT	No of cases (%)	Change in Management(%)
Women with mesh complications	8 (13.3)	4 (50.0)
and voiding dysfunction	2 (3.3)	0 (0.0)
and recurrent SUI	1 (1.7)	1 (100.0)
and recurrent prolapse	4 (6.6)	3 (75.0)
Women with Complex Urinary Incontinence	42 (70)	18 (43.9)
Women with Complex Pelvic Organ Prolapse	7 (11.7)	2 (28.6)
Women with Complex Bowel Dysfunction	1 (1.7)	1 (100.0)
Persistent Voiding Dysfunction	8 (13.3)	3 (37.5)

REFERENCES

1. National Institute for Health and Care Excellence (NICE). Urinary Incontinence and Pelvic Organ Prolapse in Women: Management. Nice guideline 123. April 2019.
2. Pandeva I, Biers S, Pradhan A, Verma V, Slack M, Thiruchelvam N. The impact of pelvic floor multidisciplinary team on patient management: the experience of a tertiary unit. J Multidiscip Healthc. 2019;12:205-210.

Funding N/A **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective analysis of routinely collected data. **Helsinki** not Req'd Retrospective analysis of routinely collected data. **Informed Consent** No

154 www.ics.org/2020/abstract/154

A COMPARISON OF LONG-TERM PATIENT REPORTED CONTINENCE AND SEXUAL OUTCOMES AFTER SUCCESSFUL TRANSABDOMINAL AND TRANSVAGINAL VESICOVAGINAL REPAIR

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HYPOTHESIS / AIMS OF STUDY

Vesicovaginal fistula (VVF) is a devastating condition posing a negative impact on the quality of life in both the patient and partner. Although various approaches have been described in the literature, transabdominal (TA) and transvaginal (TV) approaches were commonly done surgical procedures. While the anatomical success rate following both the procedures is comparable, there is a dearth in the literature on long-term continence and sexual outcomes following successful repair. With this background, we tried to analyse the continence of the patient and sexual functions of the couple long after successful VVF repair between the two approaches.

STUDY DESIGN, MATERIALS AND METHODS

We retrospectively analysed women who underwent VVF repair at our institute from 2011 to 2019. Isolated ureterovaginal fistula, vesicouterine fistula, urethrovaginal fistula and fistula after radiation were excluded. Medical records of preoperative, intraoperative and postoperative details were reviewed from the electronic data software. We assessed urinary and sexual function outcomes using International Consultation of Incontinence Questionnaire–Short Form (ICIQ-SF) and Female Sexual Function Index (FSFI) questionnaires, respectively at the time of the last follow-up. Successful repair (continence) was defined as the cessation of urine leakage following catheter removal. Stress urinary incontinence (SUI) was defined as an involuntary loss of urine on effort or physical exertion or on sneezing or coughing. Urge urinary incontinence (UUI) was defined as an involuntary loss of urine associated with urgency. The individual couple were called in person to the follow-up clinic for evaluation of functional outcomes. Patients not able to turn to the follow-up clinic were reached by a structured telephone interview with the same questionnaires. All statistical analyses were performed using STATA version 14.0.

RESULTS

A total of 94 patients underwent VVF repair, including 34 with transabdominal (TA) and 60 with transvaginal (TV) repairs. The mean age was 36.7 years (range 19 to 58 years), mean fistula diameter was 12.9 mm (range 3 to 30 mm) and mean follow-up was 31.7 months (range 6 to 80 months). The most common cause of VVF was hysterectomy 64.9% (61 patients) followed by obstetric cause in 28.7% (27 patients). Thirty-nine patients (41.5%) had previous failed repairs. Ten patients (10.6%) had three or more fistulae. The fistulae were found at supra-trigonal and trigonal regions in 80.9% (76 patients) and 19.1% (18 patients), respectively. Women with TA repair had significantly higher fistula size (14.5 vs 11.9 mm, p value=0.008), operative time (141.6 vs 102.8 minutes, p value=0.001) and estimated blood loss (147.6 vs 102.8 ml, p value=0.001) than women with TV repair. Overall, 81 patients (86.2%) had successful VVF repair (82.4% vs 88.3% in TA and TV, respectively; p value=0.42). Length of stay, catheterisation time and postoperative complications were comparable between the two groups. In the postoperative period, de novo SUI were reported by 3 patients with TA and 5 patients with TV repair (p value=1.00). Five women reported de novo UUI following TA as compared to 2 women following TV repair (p value=0.09). All the patients had conservative treatment as symptoms were tolerable. Eighty-three patients (88.3%) reported being sexually active before developing VVF, and 20 patients (21.3%) had intercourse even with VVF. Of the 81 women with successful repair, 74 patients (91.4%) reported being sexually active, however, 11 patients denied completing the questionnaires. Seven women (8.6%) reported sexual inactivity despite successful repair. 63 patients (77.8%) completed the FSFI and ICIQ-SF questionnaires at the time of the last follow-up. Both the groups were comparable in all the domains (desire, arousal, lubrication, orgasm, satisfaction and pain) of FSFI questionnaire. The mean overall FSFI score (17.1±14.7 vs 21.5±14.8, p value=0.16) was comparable. Similarly, the mean ICIQ-SF score (the sum of 3 domains- frequency, amount and bother) between the two groups were comparable (0.5±1.4 vs 0.3±1.0, p value=0.35). When asked specifically, women reported urine leak during coitus (2 patients), fear of urine leak (3 patients) and fear of VVF recurrence (1 patient) as the reasons for sexual inactivity despite successful VVF repair (1 patient did not reveal).

INTERPRETATION OF RESULTS

Our data suggested comparable long-term sexual and continence outcomes following successful TA and TV repairs for VVF. Although 15 women (18.5%) had de novo incontinence (including SUI and UUI) after the successful repair, none of them had bothersome symptoms requiring invasive treatment. Also, the mean ICIQ-SF score at the time of the last follow-up was comparable. Because VVF repairs inherently involve mobilisation of vaginal and/or paravaginal tissues, it is appreciable that it may anatomically or physiologically affect the detrusor, sphincter and perineal tissues resulting in issues of continence and sexual health of the individual.

Though 7 patients (8.6%) reported sexual inactivity because of psychological or situational issues, in the present study, both the groups had comparable sexual function outcomes.

CONCLUDING MESSAGE
Although a subset of patients developed de novo urinary incontinence and sexual dysfunction, our data on vesicovaginal fistula repair suggests comparable long-term continence and sexual function outcomes between TA and TV repairs.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Institute Ethical Committee **Helsinki** Yes **Informed Consent** Yes

SESSION 11 (PODIUM SHORT ORAL) - THERAPEUTIC MECHANISMS
Abstracts 155-166
14:30 - 16:00, Brasilia 4
Chairs: Prof Karl-Erik Andersson (United States), Dr David R Staskin (United States)

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LONG-TERM INCREASE IN ICAM-1 IS AN INDICATION OF ENDOTHELIAL DISTRESS IN RADIATION CYSTITIS.

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HYPOTHESIS / AIMS OF STUDY
Radiation cystitis (RC), a long-term side effect from radiation therapy for pelvic cancers, is characterized by inflammation, fibrosis and vascular damage. In addition to lower urinary tract symptoms, patients with RC suffer from hematuria, which can range from microscopic hematuria to gross hematuria with blood clots. In patients with hemorrhagic (radiation) cystitis, arresting bleeding is the primary focus. Choice of treatment is dependent on the severity of hematuria and includes bladder irrigation, instillation of astringent agents, hyperbaric oxygen therapy, and as a last resort formalin instillation and cystectomy [1]. However, existing treatments have high recurrence rates or can have severe side effects. The lack of mechanistic insight in the vascular defect of RC has limited the development of effective therapies. We hypothesize that radiation-induced damage to the vasculature drives the chronic inflammation, fibrosis and hemorrhaging in radiation cystitis patients. In this study we evaluated the effect of radiation damage on endothelial cell function and assessed the expression of ICAM-1. ICAM-1 is a ligand involved in the recruitment of leukocytes from the bloodstream, hereby supporting a pro-inflammatory phenotype.

STUDY DESIGN, MATERIALS AND METHODS
For in vitro studies, primary human umbilical vein endothelial cells (HUVEC) were exposed to low (1 Gy) or high (6 Gy) dose irradiation. Cell proliferation, migration and cellular senescence were assessed 1, 3 and 7 days post-irradiation. At those same time points, the expression of ICAM-1 and VCAM-1 were determined using quantitative PCR. The bladder vasculature was subsequently studied in our radiation cystitis mouse model. The bladders of C57BL/6 mice received a single dose of 40 Gy irradiation using SARRP. Mice were monitored for urinary frequency and hematuria. Bladders were harvested at various time points after radiation exposure (from 2 days up to 1 year after radiation), processed for histology and analyzed for vascular health, fibrosis and inflammation. The expression of ICAM-1 in bladder vasculature was determined using RNAscope.

RESULTS
Exposure to radiation caused decreased proliferation of HUVEC in a dose dependent manner without increasing cell death. Likewise, irradiation reduced the ability of HUVEC to migrate in a wound healing assay. Beta-galactosidase staining indicated increased cellular senescence in irradiated HUVEC. qPCR analysis revealed increased expression of ICAM-1 and VCAM-1 that lasted at least 1 week after radiation in culture. In vivo, radiation resulted in decreased bladder vascularization that was visible starting at 12 weeks post-irradiation. In addition, irradiated blood vessels had higher expression of ICAM-1 than blood vessels of littermate controls after irradiation.

INTERPRETATION OF RESULTS
Our results indicate that radiation of primary endothelial cells disrupts normal endothelial function as measured by reduced proliferation and migration of HUVEC. A plausible mechanism is that radiation accelerates endothelial cell senescence, as we observed a higher number of senescent cells after irradiation without observing a change in the number of dead cells after radiation exposure. We detected increased ICAM-1 expression up to 7 days after irradiation. A previous study demonstrated that increased ICAM-1 expression is associated with senescence in endothelial cells [2], which supports our findings. In vivo, radiation results in visible damage to bladder vasculature, which include loss of vascularization, telangiectasia and hemorrhaging. These damaged blood vessels have higher levels of ICAM-1 expression 48 hours after radiation exposure, possibly due to irradiation-induced endothelial cell senescence. Ongoing studies

are assessing ICAM-1 expression at later time points after irradiation in vivo and are determining if radiation-induced ICAM-1 expression results in increased leukocyte recruitment and adhesion.

CONCLUDING MESSAGE

These studies indicate that bladder irradiation induces early endothelial cell senescence resulting in increased ICAM-1 expression, hereby setting the scene for a pro-inflammatory state.

FIGURE 1

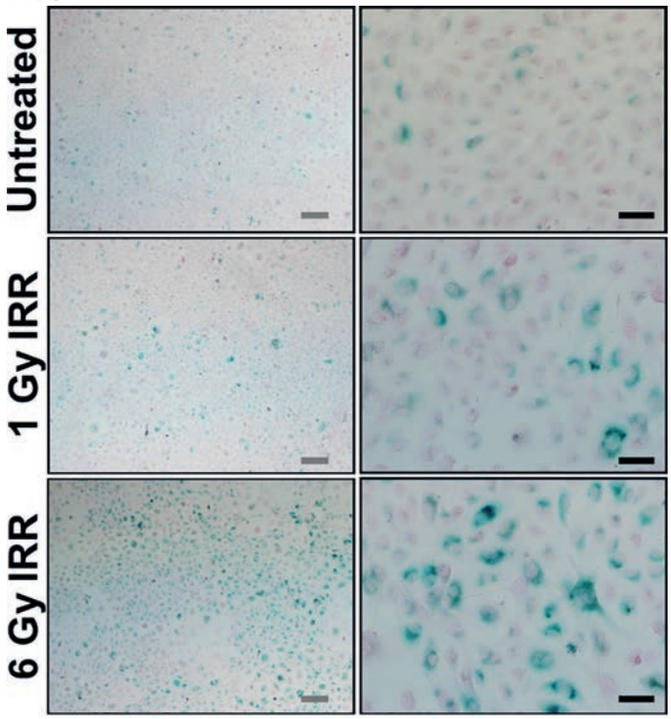

Figure 1: Increased cellular senescence in HUVEC 7 days after radiation exposure. Black bar = 50µm; Grey bar = 200 µm.

Increased cellular senescence in HUVEC 7 days after radiation exposure

FIGURE 2

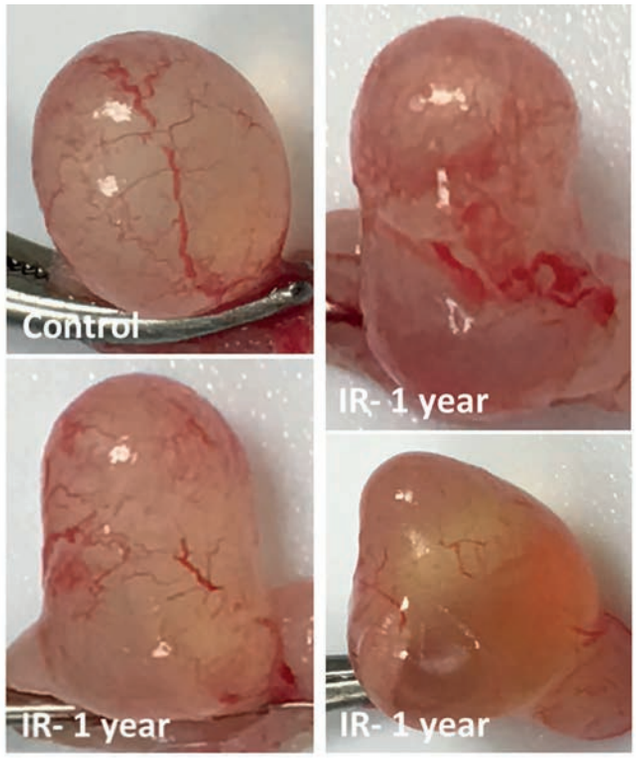

Figure 2: macroscopic images of normal and irradiated (IR) bladder indicating vascular defects including telangiectasia, loss of blood vessels and hemorrhaging.

Macroscopic images of normal and irradiated bladder

REFERENCES

1. Zwaans BMM, Nicolai HE, Chancellor MB, Lamb LE (2016). Challenges and Opportunities in Radiation-Induced Hemorrhagic Cystitis. Reviews in Urology, 18(2):57-65.
2. Minamino T, Miyauchi H, Yoshida T, Ishida Y, Yoshida H, Komuro I (2002). Endothelial cell senescence in human aterosclerosis: role of telomere in endotelial dysfunction. Circulation, 105(13): 1541-4

Funding Aikens Center for Neurology Research, U Can-Cer Vive Foundation, NIDDK K01 Career development award DK114334 **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** Beaumont Health IACUC #AL-17-12

156 www.ics.org/2020/abstract/156

STRETCH- AND CARBACHOL-INDUCED ATP RELEASE FROM THE BLADDER WALL OF YOUNG AND AGED MICE.

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HYPOTHESIS / AIMS OF STUDY

Stretch of the bladder mucosa, direct imposition of physical stresses on urothelial cells or local addition of muscarinic receptor agonists such as carbachol releases several modulators, including ATP. This phenomenon has been proposed as a sensory transduction system to monitor bladder filling, as released ATP may then activate nearby afferent nerves [1]. In addition, ATP release is greater from tissues associated with pathologies such as overactive bladder (OAB) or bladder pain syndrome (BPS) where it may underlie symptoms of increased urgency. Several features of urothelial ATP release that remain unclear would be useful to evaluate the pathophysiological basis of abnormal sensory responses arising from the bladder wall. These include: i) is ATP release dependent on the extent of bladder wall stretch or the change of wall tension as a result of stretch? Bladders with increased fibrosis are stiffer (i.e. a given stretch will generate greater wall tension) and often associated with increased urgency. Thus, does a given stretch of a fibrotic bladder wall during filling lead to greater ATP release. ii) what is the relative quantity of ATP released by physical stretch or carbachol? This is relevant as antimuscarinic agents could significantly modulate stretch-induced ATP release. We tested two hypotheses: i) wall tension rather than the extent of stretch determines ATP release; ii) carbachol- and stretch-induced ATP release are comparable. These were tested in bladder wall preparations from young and aged mice; the latter used because fibrosis is greater in aged mice.

STUDY DESIGN, MATERIALS AND METHODS

Experiments were performed on detrusor strips from young (9-12 weeks) or aged (24 months) C57/BL6 mice. Animals were killed by a Schedule 1 procedure, the bladder immediately removed, and a strip of detrusor (≤1 mm diameter, 5 mm length), with an intact mucosa, was tied to a fixed hook and an isometric force transducer. The force transducer was mounted on a micromanipulator to allow variation of length according to pre-determined protocols. With some preparations the mucosa was removed. Preparations were superfused with Tyrode's solution (24 mM HCO_3^-/ 5% CO_2, pH 7.4, 36°C) and allowed to equilibrate for 30 min with a resting tension of 2 mN. The stiffness, E, of the tissue was estimated from the increase of steady-state tension after a stretch of 1 mm (20% of resting length): values of E are expressed as mN.mm-2 tissue cross-section area. ATP was measured in 100 µl superfusate samples taken 1 mm lateral to the preparation before and at 0.1, 2, 4, 6, 8, 10 and 30 mins after commencement of the 60-s stretch. After the 30-min sample, 10 µM carbachol was introduced and a further sample taken after 2 min.

ATP was measured with a luciferin-luciferase assay (FLAAM, Sigma-Aldrich, Dorset, UK) and a luminometer (Glomax 20/20, Promega). The system was calibrated between 10 fM and 1 µM ATP before each experiment. Data are median values (25,75% interquartiles), n=number of preparations, as several data sets were significantly skewed). Differences between pairs of data sets were tested by Wilcoxon tests. The null hypothesis was rejected at *$p<0.05$. For comparison of non-parametric ATP release data from young and aged mice, a median absolute deviation (MAD) for data from young mice was calculated [2], where 1.483*MAD (MAD(E)) is comparable to a standard deviation. Aged mice data more than 3 MAD(E) values from those of young mice were classified as significantly ($p<0.01$) different.

RESULTS

Experiments with young mice. ATP release measured over a 30 min time-course showed a peak at two minutes followed by a return to control after 30 minutes, followed by release two minutes after addition of carbachol (figure 1A). Paired comparison of carbachol and stretch-induced ATP release values, each after two minutes, showed that ATP release was greater with carbachol than rapid stretch (97 [59, 172] vs 44 [14, 68] fmol.ml-1.mg-1, $p<0.01$, n=10, figure 1B). The relationship between ATP release and passive tension, after a constant extent of stretch, was constructed. For this evaluation, the integral of ATP release over 10 minutes (∫ATP10; shaded area in figure 1A) was plotted as a function of passive tension where a significant positive association was obtained ($r=0.78$, $p<0.005$, n=12; figure 1C). Control experiments showed that stretch-induced ATP release was very much less if the preparation was denuded of mucosa compared to intact samples (∫ATP10 values: 10 [8, 13] vs 128 [81,173] fmol.ml-1.mg-1, n=4, 12, $p<0.05$); no release was measured with 10 µM carbachol.

Experiments with aged mice. A similar time course of ATP release after a rapid stretch was recorded (figure 2A). Carbachol-induced ATP release in aged mice was significantly less than in young mice (35 [20, 82] vs 97 [59, 172] fmol.ml-1.mg-1, $p<0.01$, n=19,10), but ATP release 2-min after stretch was similar to that in young mice. Most noticeable was the wide range of stretch-induced ATP release that made analysis of such data on the basis of a homogenous set difficult. Values of ∫ATP10 in aged mice preparations were divided into three groups (figure 2B): values comparable to those from young mice; much greater values (defined as more than three MAD(E) - see Methods - above those of young mice); much smaller values (more than three MAD(E) below those of young mice). In view of the wide range of ∫ATP10 there were no significant relationships between stretch-induced ∫ATP10 values and either stretch-induced passive

tension or carbachol-induced ATP release, as in tissue from young animals.

INTERPRETATION OF RESULTS

For young mice, data from these experiments are consistent with the original hypotheses. Firstly, stretch-induced ATP release is a function of tension-generated in the preparation (i.e. tissue stiffness) and not the extent of stretch per se. Secondly, carbachol induced ATP release is comparable, in fact greater, than stretch-induced release. Stretch of the bladder wall, or shear stress applied to urothelial cells, releases more ACh than ATP and at lower stimulus intensities [3]. Thus, ACh release represents a positive autocrine pathway to augment stretch-activated ATP release. Identification of ACh release channels from urothelial cells, and the cell pathways that regulate ATP release are important targets to downregulate excessive ATP release and the sensory pathways that ATP controls. With bladder wall tissue from aged animals the relationship between tissue stiffness and ATP release is absent, due to the large variability of the amount of ATP released with stretch. Enhanced ATP release is a feature of tissues from bladder pathologies and to this may be added a subset of aged bladders. Thus, data from aged animals does not represent a homogeneous group and that co-morbid conditions may overwhelm any effect of age per se, and if translated to elderly humans would underlie the variable incidence of urinary urgency.

CONCLUDING MESSAGE

An increase of bladder wall passive tension, as well as muscarinic receptor activation are equally potent stimuli for ATP release from the mucosa. Stretch-activated release is augmented by increased bladder wall tension, say due to fibrosis and could contribute to increased urgency. This suggests that antimuscarinic agents or that reduce fibrosis as targets to reduce this symptom. However, with aged animals other as yet unidentified factors greatly increase stretch-induced ATP release that is relatively independent of a muscarinic-dependent pathway.

FIGURE 1

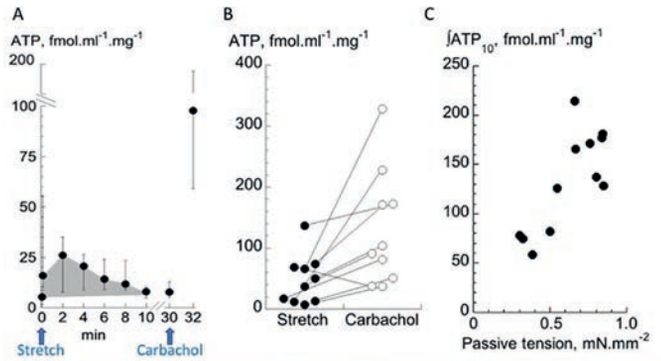

Figure 1. Stretch and carbachol-induced ATP release – young mice. A: Time-course of ATP release after a 60-s rapid stretch and 60-s exposure to 10 μM carbachol (at arrows), B: Comparison of ATP release at two minutes after a rapid stretch and exposure to carbachol. C: Relationship between stretch-induced ATP release over 10 minutes ($\int ATP_{10}$), shaded area in part A) and passive tension induced by a similar length change in different preparations.

Figure 1

FIGURE 2

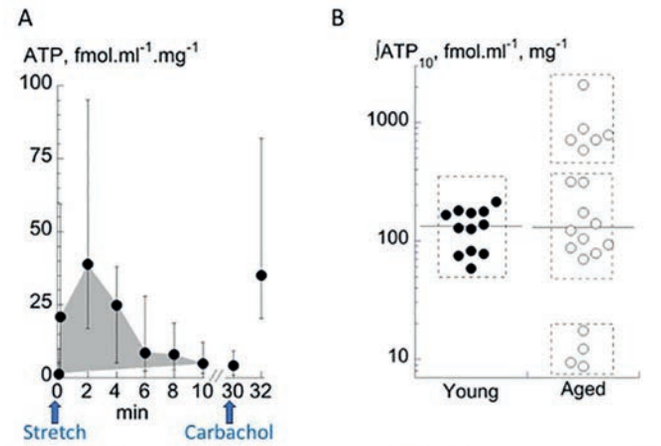

Figure 2. Stretch and carbachol-induced ATP release – aged mice. A: Time-course of ATP release after a 60-s rapid stretch and 60-s exposure to 10 μM carbachol (at arrows), B: Values of $\int ATP_{10}$ in young and aged mice. The box around data from young mice represents three SD limits above and below the median. Data from aged mice are divided into three cohorts – see text for details. Note the logarithmic ordinate in part B.

Figure 2

REFERENCES

1. Birder LA, Andersson KE. Physiol Rev 2013; 93: 653-680.
2. Rousseeuw PJ, Croux C. J Am Stat Assoc 1993; 88: 1273–1283.
3. McLatchie LM, Young JS, Fry CH. Br J Pharmacol 2014; 171: 3394-3403

Funding The Braithwaite Foundation **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** Bristol University AWERB

157 www.ics.org/2020/abstract/157

DESMOPRESSIN STIMULATES UROTHELIAL VASOPRESSIN RECEPTORS AND INHIBITS ADENOSINE METABOLISM IN THE AGED URINARY BLADDER: NOVEL MECHANISM FOR REDUCING NOCTURIA/NOCTURNAL POLYURIA

Wolf-Johnston A[1], Menchikova E[1], Apodaca G[1], Wein A[2], Dmochowski R[3], Weiss J[4], Jackson E[1], Birder L[1]

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HYPOTHESIS / AIMS OF STUDY

Maintaining and regulating water balance is fundamental to survival. The "perceived view" is that: 1) fine-tuning of water homeostasis along the collecting duct of the kidney where arginine vasopressin (AVP) type 2 receptors (V2Rs) are found in high density; and 2) the urinary bladder urothelium (UT), due to its low permeability to water and urea and high electrical resistance, only serves as an impermeable blood-urine barrier.

Several reports now challenge the traditional view that the UT is an impermeable barrier and suggest that the UT exhibits a transport function that participates in adjusting the composition of urine by affecting net transport of solutes. Thus, the UT may be an active participant in normal physiological fluid and solute reabsorption. In support of this concept, we recently obtained novel preliminary findings that the urinary bladder mucosa expresses AVP type 2 receptors (V2Rs). Further, our findings also show that UT cells strongly express V2Rs; this suggests that UT cells are the major cell type in the bladder mucosa that expresses V2Rs.

A number of factors and conditions can modulate V2R signaling including aging as well as autocoids such as adenosine. For example, in the kidney adenosine can inhibit AVP-induced effects via adenosine type 1 receptors (A1Rs), effectively acting as a 'brake' on V2R-mediated signaling and fluid reabsorption. The main purpose of this study was to test the hypothesis that V2Rs are expressed within the apical UT and that the adenosine/A1R system in the UT might potentially regulate V2R signaling in the urinary bladder. An additional goal was to determine whether the expression and regulation of the apical UT V2R system is altered with aging.

STUDY DESIGN, MATERIALS AND METHODS

Urinary bladders (excised from anesthetized young versus aged Fischer 344 rats) were used to examine expression of V2Rs using fluorescent immunocytochemistry (measures total V2R expression) and surface biotinylation/western blot methodology (measures specifically apical surface V2R expression). In addition, we also utilized a recently validated methodology that utilizes N6-etheno-bridge chemistry to examine adenosine formation (i.e., metabolism of etheno-adenine nucleotides by ecto-nucleotidases) in aged versus young bladders. In brief, bladders from young versus aged rats were filled with either vehicle (Krebs buffer) or 100 nM desmopressin for one hour, followed by instillation of 10 uM N6-etheno-ATP which is a substrate for ecto-nucleotidases (Axxora, USA). The solution was removed and the metabolism of etheno-bridged adenine nucleotides by ecto-nucleotidases was monitored by high pressure liquid chromatography with fluorescence detection. We used western immunoblotting using the bladders from these animals to assess the expression of ectonucleotidases (nucleotide metabolizing enzymes) in young versus aged bladder.

RESULTS

We observed V2Rs localized to the UT including basolateral surfaces of umbrella cells and surfaces of intermediate and basal UT cells. V2Rs were also found in small vesicles scattered throughout the apical cytoplasm of umbrella cells. In addition, surface biotinylation/western blots in rat bladder showed evidence for a large apical surface fraction of uroplakin 3A (apical surface protein used as positive control) and V2Rs. Western immunoblots revealed an age-related increase in CD39, which is a major ecto-nucleotidase that regulates extracellular purine levels by mediating the metabolism of ATP to ADP and ADP to AMP (adenosine precursor). In addition, in the aged bladder we observed a significant increase in the metabolism of N6-etheno-ATP to N6-etheno-adenosine, a finding consistent with the increased expression of CD39. These age-associated increases in ecto-nucleotidase expression and corresponding increases in purine metabolism to adenosine are normalized to levels in that of a younger state by treatment with desmopressin.

INTERPRETATION OF RESULTS

The metabolism of ATP to adenosine is regulated in large part by activities of two enzymes, ENTPD1 (aka, CD39) and CD73. Our findings that aging upregulates CD39 (2-fold increase) in the urinary bladder suggests that adenosine (via A1R stimulation) may act as a "brake" on V2R function; thus, similar to the kidney, adenosine may inhibit water absorption by the UT. Indeed, we find significantly more rapid metabolism of ATP to adenosine in the aging bladder UT that is normalized to younger levels with desmopressin (there was no change in young bladder mucosa). These findings point to an augmented braking mechanism on bladder V2R signaling via an interaction between bladder V2Rs and A1Rs at adenylate cyclase.

CONCLUDING MESSAGE

Dysregulation of the kidney V2R system results in abnormalities of water homeostasis, which may lead to urinary disturbances in patients, for example nocturia, hyponatremia or lower urinary tract symptoms (LUTS). Whether and how bladder V2Rs affect bladder function and whether and how this might impact LUTS and hyponatremia remain open

questions. Nonetheless, our initial findings demonstrate that adenosine production by the bladder mucosa is increased with age due to upregulation of one of the enzymes in the adenosine biosynthesis pathway. This would likely brake V2R signaling and tend to cause nocturia in the elderly because there would be more "adenosine brake" and impairment of urinary concentrating ability. Notably, agents such as desmopressin could reduce nocturia/nocturnal polyuria in the older patient both by stimulating V2Rs and by inhibiting the putative "adenosine brake". Further studies are warranted to determine the role and significance of V2R/A1R interactions in the UT.

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A NOVEL BLADDER FIBROSIS PATHWAY THROUGH PDGFRA+ CELLS IN RELATION WITH ESTROGEN DEFICIENCY AND REPLACEMENT

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HYPOTHESIS / AIMS OF STUDY

Decline in estrogen (E2) after menopause possibly causes overactive bladder. There is a report indicating systemic E2 application rather worsens bladder function [1]. E2 deficiency may also induce fibrosis that leads to bladder dysfunction [2], however, little has been known about relationship between fibrosis and platelete derived growth factor receptor (PDGFR) α+ cells in the bladder. PDGF is essential to generate the extracellular matrix (ECM) [3]. This original work was aimed at investigating the effects of E2 on bladder function and assessing changes of bladder PDGFRα+ cells associated with inflammation and fibrosis.

STUDY DESIGN, MATERIALS AND METHODS

C57BL/6 female mice (Charles River Laboratories) were used. Bilateral ovariectomy (OVX) or sham surgery was performed at 7 weeks old and then E2 (3 μ/kg/day, administered every other day) was applied subcutaneously in OVX mice for two weeks before experiment. Each protocol was done 1 (11 weeks old), 3 (19 weeks old) and 7 (35 weeks old) months after OVX (These were named 1, 3 and 7 month groups). To perform in vivo cystometrogram (CMG), PE10 catheter was inserted one week before CMG. Mice were restrained with specific holder under awake condition. Saline was infused at 15 μl/hr after two hours acclimation of mice and voiding cycles were recorded for at least one hour after three reproducible micturition was confirmed. Storage parameters were analyzed and data were expressed as mean ± SEM. qPCR, western blotting (WB) was carried out to investigate the relationship between E2 deficiency/replacement and fibrosis marker, while immunohistochemistry (IHC) was done to check relationship between PDGFRα+ and estrogen receptor (ER) positive cells. To further explore this, bladder was divided into urothelium/suburothelial layer (UT) and detrusor smooth muscle layer (SM) and then cultured with control media, E2 (10 ng/ml) or TNFα (100 ng/ml) for 7 days. Cultured tissues were collected and frozen at -80°C to investigate fibrosis marker.

RESULTS

Bladder compliance was decreased in 1, 3 and 7 month OVX groups (20.3 ± 6.5, 10.2 ± 1.5 and 14.2 ± 2.7 μl/mmHg) compared to age-matched sham groups (35.1 ± 6.1, 24.6 ± 3.2 and 24.2 ± 4.5 μl/mmHg), while E2 recovered bladder compliance in 1 and 3 month (35.9 ± 4.9 and 22.2 ± 3.4 μl/mmHg) but not in 7 month group (13.3 ± 2.2 μl/mmHg). Bladder capacity was reduced in 3 and 7 month OVX groups (155.7 ± 27.9 and 161.9 ± 23.7 μl) compared to sham (255.0 ± 16.7 and 256.3 ± 45.7 μl), but was not fully recovered by E2 (150.7 ± 16.8 μl and 197.7 ± 29.7 μl), whilst intercontraction interval (ICI) was also reduced in 3 and 7 month OVX groups (10.3 ± 1.8 and 10.7 ± 1.5 min) compared to age-matched sham groups (17.0 ± 1.1 and 17.0 ± 3.0 min) but was not rescued by E2 treatment (10.0 ± 1.1 and 13.1 ± 1.9 min). Unexpectedly, E2 markedly increased the number of non-voiding contractions (NVCs) in 1, 3 and 7 month OVX+E2 groups in comparison with age-matched sham or OVX groups (Fig. 1). E2 even induced an increase of NVCs in 1 month sham, demonstrating E2 failed to rescue OVX-induced bladder dysfunction and rather exacerbated the detrusor contraction. Estrogen receptor (ERα) was dominantly immunoreactive against detrusor, however bladder interstitial cells were immunopositive upon ERβ. Colocalizations of PDGFRα+ and ERβ positive interstitial cells were observed both in UT (Fig. 2) and SM. Expression of PDGFRα and collagen 1a1 was upregulated in 3 month OVX group compared to sham, while E2 replacement further increased the expression of PDGFRα and fibrosis markers (collagen 1a1, interleukin (IL) 6, cadherin and TNFα) compared to age-matched sham or OVX groups. In qPCR of cultured bladder tissue, TNFα dramatically upregulated the expression of Acta2, TIMP2, Tgfβ, Col1a1, Col1a2, cadherin and IL6 in UT but had marginal effects on SM. Conversely, E2 increased the expression of fibrosis markers in SM but had little impact in UT. In WB, signal intensity of ERβ was higher in 3 month OVX than age-matched sham group, while that was further upregulated in OVX+E2 group.

INTERPRETATION OF RESULTS

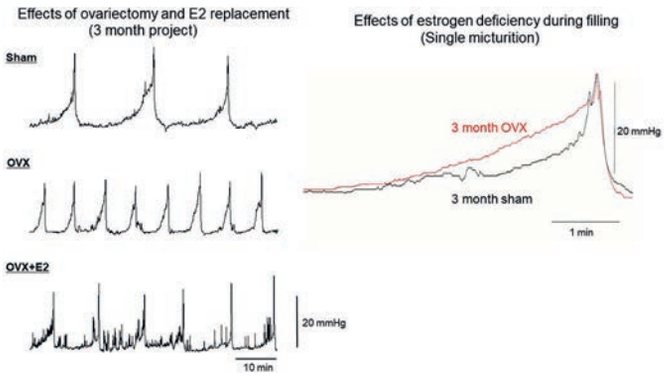
Combined effects of the upregulation of fibrosis markers in UT and SM may decrease bladder compliance and induce an increase in NVCs in in vivo CMG in systemic application

of E2. Coexpression of PDGFRα+ and ERβ immunoreactive interstitial cells demonstrates E2 might promote an increase in PDGFRα+ cells through ERβ which may play an important role in generating ECM.

CONCLUDING MESSAGE

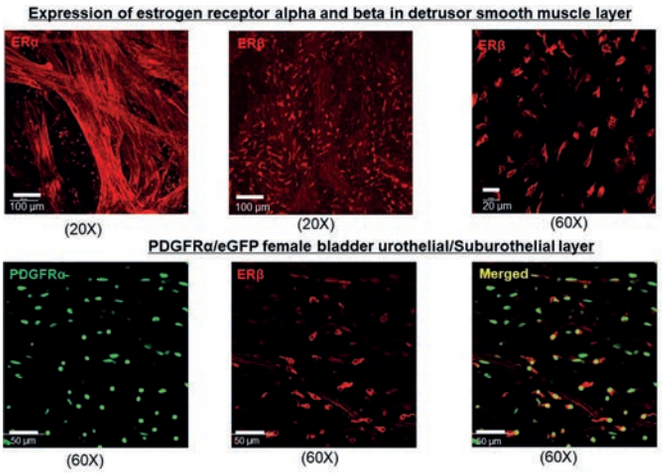
Urothelium/suburothelial layer may be common site for the initiation of fibrosis. Inflammation or E2 deficiency/replacement may cause fibrosis through the activation of PDGFRα+ cells. These novel findings might point to a novel approach toward the treatment of bladder fibrosis. We will further investigate the specific increase of these fibrosis markers as well as morphological changes after inducing inflammation using PDGFRα+/eGFP mice.

FIGURE 1



Effects of ovariectomy and E2 replacement

FIGURE 2



Immunodetection of ERα and ERβ in relation with bladder PDGFRα+ cells

REFERENCES

1. Cody JD, Jacobs ML, Richardson K, Moehrer B, Hextall A. Oestrogen therapy for urinary incontinence in post-menopausal women. Cochrane Database Syst Rev. 2012;10:CD001405.
2. Lee YL, Lin KL, Wu BN, et al. Epigallocatechin-3-gallate alleviates bladder overactivity in a rat model with metabolic syndrome and ovarian hormone deficiency through mitochondria apoptosis pathways. Sci Rep. 2018;8(1):5358.
3. Ying HZ, Chen Q, Zhang WY, et al. PDGF signaling pathway in hepatic fibrosis pathogenesis and therapeutics (Review). Mol Med Rep. 2017;16(6):7879–7889.

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IN VIVO EXAMINATION OF PROSTATE-TO-BLADDER CROSS-SENSITIZATION IN A RAT MODEL: HOW DOES CHRONIC PELVIC PAIN SYNDROME AFFECT BLADDER FUNCTION?

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HYPOTHESIS / AIMS OF STUDY

Male patients who suffer from painful inflammatory disease of the lower urinary tract, often chronic prostatitis/chronic pelvic pain syndrome (CPPS), often lack satisfactory treatment options. The situation is worsened by the negative effects that CPPS has on urinary bladder function [1]. Considering the relatively large number of male patients suffering from CPPS who do not respond positively to treatment, new and more effective pharmacological options are needed. For this, potential common pathophysiological changes in urinary bladder and prostate need to be investigated. In particular, more effort is required to investigate the potential association between inflammatory pathways in pelvic organs.

The aim of the present study was to investigate which effects CPPS has on bladder function and pathophysiology. For this purpose, a broad methodological approach was used.

STUDY DESIGN, MATERIALS AND METHODS

A total of 24 adult male Sprague-Dawley rats (300-450 g) were used in the study, which followed national guidelines for the care and use of laboratory animals and was approved by the local ethics committee (permit number:1794/2018).

The animals were randomly divided into four groups. In the first three groups, zymosan (Sigma-Aldrich, St Louis, MO, USA; 0.1 mg in 10 µl saline) was injected into the dorsal lobe of the prostate to create a functional model for CPPS. In the fourth group, rats were injected with vehicle (10 µl saline, serving as control). Metabolic cage experiments were performed 7, 14 and 21 days after zymosan injection (termed as group Z7, Z14 and Z21, respectively) and after 14 days in the control group. The obtained parameters included the total

number of micturitions, total urine volume produced and total water intake. From these parameters it was possible to calculate micturition frequency and volume per micturition.

Immediately following the metabolic cage experiment, cystometry was performed. Briefly, the femoral artery and vein were catheterized to allow for blood pressure monitoring and drug administration, respectively. Via a careful incision in the bladder dome a pressure sensing catheter and cannula were placed in the urinary bladder and subsequently fixed with a ligature. Bladder pressure, residual urine volume, bladder capacity, compliance, voiding time and non-voiding contractions (NVCs) were measured during cystometry. Bladder compliance was calculated by dividing the volume change (ΔV) by the change in intravesical pressure (ΔP) that occurred during bladder filling (ΔV/ΔP). Saline was infused via the cannula to induce simulated micturition cycles. This was repeated five times both before and after concentration-response series of the cholinergic agonist methacholine (1, 2 and 5 µg*kg-1, i.v.) and the purinergic agonist ATP (5, 10 and 100 µg*kg-1, i.v.).

Following cystometry, the prostate and urinary bladder were excised and weighed, then fixed in paraformaldehyde and subsequently examined histopathologically for possible inflammatory changes. For this blinded assessment, the tissues were stained with haematoxylin-eosin and given an inflammatory score (0-3) by an independent pathologist. Two-way ANOVA followed by Tukey's correction for multiple comparisons was used to compare data between groups. Statistical analysis was performed using GraphPad Prism version 8.3 (GraphPad Software Inc., San Diego, USA). The level of statistical significance was set at $p < 0.05$.

RESULTS

Compared to controls, the volume/micturition was lower in all zymosan-treated CPPS groups (Figure 1a; 0.91±0.23, 0.92±0.09, 0.78±0.11 and 1.62±0.28 ml in Z7, Z14, Z21 and control groups, respectively; control vs Z7, p=0.065; control vs Z14, p=0.066; control vs Z21, p=0.014). The number of micturitions per hour were significantly higher in all CPPS groups, as compared to controls (Figure 1b; 0.95±0.09, 1.08±0.13, 1.18±0.10 and 0.40±0.03 in Z7, Z14, Z21 and control groups, respectively; control vs Z7, p=0.0029; control vs Z14, p=0.0005; control vs Z21, p<0.0001). Similarly, the total number of micturitions during the entire metabolic cage time period were higher in all CPPS groups, as compared to controls (Figure 1c; 15.25±1.44, 17.25±2.06, 18.83±1.62 and 6.40± 0.51 in Z7, Z14, Z21 and control groups, respectively; control vs Z7, p=0.0029; control vs Z14, p=0.0005; control vs Z21, p<0.0001).

Cystometry revealed a significant increase in the number of NVCs in all CPPS groups, as compared to controls (Figure 2a; control vs Z7, p=0.046; control vs Z14, p=0.033; control vs Z21, p=0.014). Similarly, lower bladder compliance was seen in the CPPS groups, as compared to controls. This decrease tended to worsen as the time after zymosan injection proceeded.

Rats with chemically induced CPPS displayed significantly longer voiding times compared to controls. There was also a trend towards longer voiding time as a result of increased time after zymosan injection (Z21 & Z14 > Z7).

There was a tendency towards decreased methacholine-induced contractions in all CPPS groups, as compared to controls (Figure 2b; at 5 µg*kg-1; Z14 vs control, p=0.0023; Z21 vs control, p<0.0001). ATP-induced bladder contractions tended to be lower in the CPPS groups, as compared to controls (Figure 2c; at 100 µg*kg-1; Z7 vs control, p=0.0007; Z14 vs control, p=0.0016; Z21 vs control, p=0.0003).

There were no significant differences between the groups regarding total bladder or prostate weight. However, all zymosan-treated prostate tissues displayed signs of inflammation (avg score 2.2 as compared to 1.0 in controls). Interestingly, while excised bladders from control animals did not show signs of inflammation (avg score 0.5), bladders from zymosan-treated animals did (avg score 1.5).

INTERPRETATION OF RESULTS

In the present study, we created an animal model for CPPS without benign prostate hyperplasia (BPH) to investigate potential effects of chronic prostate inflammation on bladder function. To the best of our knowledge, the current study represents the first study in an animal model for CPPS to demonstrate the effects of chronic prostate inflammation on bladder function over time. Further, this is the first study that simultaneously studies basic bladder function (micturition parameters), afferent (cystometry) and efferent (drug) effects. Induction of prostatitis by zymosan injection did not cause any increase in total prostate weight, confirming it to be a good model for CPPS without BPH. Metabolic cage data showed that zymosan-induced prostatic inflammation could provoke urinary frequency. Likewise, cystometry showed a significant increase of NVCs and a trend towards worsened bladder compliance over time in the animals with CPPS. In addition, we observed that CPPS caused significantly increased voiding times. Taken together, these findings indicate cross-sensitization between prostate and bladder.

Our findings revealed incidences of reduced cholinergic contractile bladder responses in animals with CPPS. Similar findings were seen regarding ATP-induced contractions. These findings are in accordance with previous studies that investigated the possible effects of non-bacterial urinary bladder inflammation on ATP and acetylcholine evoked contractile responses [2]. Based on our findings, and how they correlate with previous findings, we hypothesize that CPPS causes functional changes in the urothelium in a similar way as what is observed during cystitis. It is possible that the neg-

ative effects of CPPS on bladder function are conveyed via common dorsal root pathways, which has been suggested in a previous study [3].

CONCLUDING MESSAGE

The current findings demonstrate a potential prostate-to-bladder cross-sensitization which causes bladder dysfunction and evident signs of inflammation. The underlying mechanisms of this cross-talk remain to be unravelled. Future clinical studies are required to verify the outcomes of the current study and enable advancement of patient care.

FIGURE 1

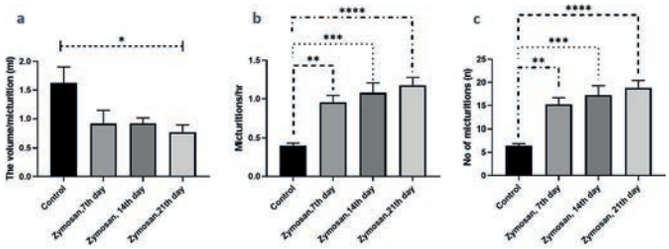

Figure 1

FIGURE 2

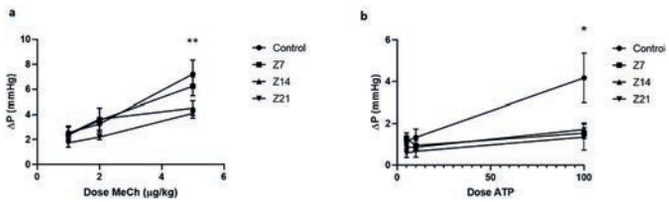

Figure 2

REFERENCES

1. Schwartz ES, La JH, Young EE, Feng B, Joyce S & Gebhart GF. Chronic prostatitis induces urinary bladder hypersensitivity and sensitizes bladder afferents in the mouse. J Urol. 2016; 196(3): 892–901
2. Stenqvist J, Winder M, Carlsson T, Aronsson P & Tobin G. Urothelial acetylcholine involvement in ATP-induced contractile responses of the rat urinary bladder. Eur J Pharmacol. 2017; 15; 809:253-260
3. Funahashi Y, Takahashi R et al. Bladder overactivity and afferent hyperexcitability induced by prostate-to-bladder cross-sensitization in rats with prostatic inflammation. J Physiol. 2019; doi: 10.1113/JP277452

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GROWTH MECHANISM OF BENIGN PROSTATIC HYPERPLASIA BY NLRP3 INFLAMMASOME THOROUGH COMPLEMENT PATHWAY.

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HYPOTHESIS / AIMS OF STUDY

We have reported that the complement system activation, a major component of the innate immune system, including classical complement pathway was involved in the growth of benign prostatic hyperplasia (BPH) by using model rats and human BPH tissues. However, the mechanism from complement system activation to the growth process of BPH remained unclear. On the other hand, it has recently been noted that inflammasome, the protein complex which works as an inflammation amplification system, was associated with complement activation thorough C5a activation. Furthermore, resveratrol, a natural polyphenolic agent, was reported to exert a protective effect in acute lung injury by suppressing the NLR family pyrin domain containing 3 (NLRP3) inflammasome signaling. Therefore, we analyzed the expression and function of NLRP3 inflammasome including related molecules for inflammasome using BPH model rats and the antiproliferative effect by resveratrol to elucidate the mechanism of BPH growth.

STUDY DESIGN, MATERIALS AND METHODS

BPH model rats, which resembles human BPH tissues pathologically, were used in this study. The urogenital sinus (UGS) isolated from the 20-day-old male rat embryos was implanted under the right ventral prostate of 7-week-old male rats. After the host rats had been sacrificed at 2, 3, or 8 weeks after UGS implantation, the right ventral prostate was used as BPH tissue, and the left ventral prostate tissue was used as a control. Expression and function analysis of C5a, NLRP3, Caspase-1, IL-1β, IL-18 by qRT-PCR, western blotting analysis, and immunohistochemical (IHC) analysis using pathological BPH model rat tissues at 2, 3, and 8 weeks (n=6, respectively) after fetal UGS implantation was performed. Serum IL-1β levels were also measured by ELISA to evaluate inflammasome activation. Furthermore, the NLRP3 pathway inhibitor, resveratrol (50 mg/kg), was administered to BPH model rats to evaluate the antiproliferative effect. The expression and function analysis of C5a, NLRP3, Caspase-1, IL-1β, IL-18 was performed by using BPH model rat with or without resveratrol. Proliferative effect of BPH tissues was evaluated by the expression of Ki-67 proteins.

RESULTS

Gene and protein expression levels of C5a, NLRP3, Caspase-1, IL-1β, and IL-18 was significantly up-regulated in BPH tissues compared to normal prostate tissues respectively, and showed an increase time-dependently ($p<0.05$). BPH model rats had significantly increased serum IL-1β levels compared to intact rats (987.6 pg/mL vs. 1501.1 pg/mL; $p<0.05$), and showed an increase time-dependently. In IHC analysis, significant deposition of NLRP3 was observed abundantly in stromal area. Resveratrol administration significantly decreased the prostate weight of BPH tissues and the expression of NLRP3, Caspase-1, IL-1β, and IL-18 ($p <0.05$). The expression of Ki-67 in BPH tissues with resveratrol showed a significant decrease compared to the BPH tissues without resveratrol ($p <0.05$).

INTERPRETATION OF RESULTS

In this study, the association between NLRP3 inflammasome system and the growth process of BPH was analyzed by using stromal-dominant BPH model rat. The expression and function analysis of C5a, NLRP3, Caspase-1, IL-1β, and IL-18 indicated that the pathway of NLRP3 inflammasome by C5a was activated in the growth process of BPH. In addition, this activation of inflammasome was located in the stromal area of BPH, describing that NLRP3 inflammasome system had an important role for the proliferation of BPH stromal area. The expression and function analysis by resveratrol administration showed that the expression of the molecules at downstream from NLRP3 inflammasome was significantly decreased in BPH tissues with resveratrol compared to without resveratrol. These results suggested that resveratrol effectively suppressed the NLRP3 inflammasome activation during the BPH growth process in model rats. Furthermore, resveratrol significantly suppressed the BPH proliferation and reduced prostate weight.

CONCLUDING MESSAGE

The activation of NLRP3 inflammasome by complement component C5a promotes IL-1β and IL-18 production via Caspase-1 and amplifies inflammation during the growth process of BPH. In addition, the inhibition of NLRP3 inflammasome decreased inflammasome activation, and induced reduction of prostate volume. Our results suggested that inflammasome might be a therapeutic target during the growth process of BPH.

REFERENCES

1. Hata J, Matsuoka K, Kojima Y, et al. Complement activation by autoantigen recognition in the growth process of benign prostatic hyperplasia. Sci Rep. 2019; 9: 20357.

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161 www.ics.org/2020/abstract/161

EFFECTS OF ORAL ADMINISTRATION OF HISTAMINE-H1 RECEPTOR ANTAGONIST ON BLADDER OVERACTIVITY AND PROSTATIC INFLAMMATION IN A RAT MODEL OF NON-BACTERIAL PROSTATITIS

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HYPOTHESIS / AIMS OF STUDY

Patients with chronic prostatitis often exhibit irritative bladder symptoms despite no evidence of bladder inflammation. Previous studies in animal models demonstrated that prostatic inflammation (PI) can induce bladder overactivity via prostate-to-bladder cross-organ afferent sensitization through activation of the pelvic nerve [1]. However, the underlying mechanisms for PI-induced afferent sensitization are not fully elucidated. Histamine released from mast cells activated by tissue inflammation has been implicated as an important mediator causing pain and itch sensation, and inhibition of histamine H1 receptors is reportedly effective for the treatment of pain and other bladder symptoms in patients with interstitial cystitis/bladder pain syndrome (IC/BPS). Thus, the present study examined the effect of a second-generation, anti-histamine H1 receptor antagonist, which has a lesser degree of anticholinergic effects [2] [3], on bladder overactivity, molecular expressions of histamine H1 receptors (HT1R), TRPV1 and cytokines in the bladder, the prostate and pelvic afferent pathways in a rat model of non-bacterial PI.

STUDY DESIGN, MATERIALS AND METHODS

Male Sprague-Dawley rats were divided into three groups: (1) Sham group; control rats without intraprostatic instillation and with oral administration of an HT1R antagonist (desloratadine), (2) Placebo group; PI rats with oral administration of vehicle (methyl cellulose), (3) Treatment group; PI rats with oral administration of desloratadine. On day 0, formalin (5%, 50 µl) was injected into each ventral lobe of the prostate to induce PI in Placebo and Treatment groups, for which vehicle and desloratadine at a dose of 3 mg/kg dissolved in methyl cellulose (0.5w/v % , 0.1 ml) was respectively administrated daily by oral gavage for 14 days from day 14. On day 28, we performed conscious cystometry (CMG) and harvested tissues to evaluate mRNA expressions of HT1R in the bladder, TRPV1, HT1R and inflammation markers (IL-β and IL-18) in the prostate and TRPV1 in L6-S1 dorsal root ganglia (DRG) by RT-PCR.

RESULTS

In CMG, Treatment group had significant longer intercontraction intervals (ICIs) than Placebo group, in which ICIs were significantly reduced compared to Sham group (Fig. 1A, 1B). In other CMG parameters, Placebo group had significantly higher post voided volume (PVR) than Sham group while there were no significant differences in PVR between Treatment and Sham groups (Fig. 1C). In Placebo group, mRNA levels of TRPV1 in the prostate and L6-S1 DRG were significantly increased, and mRNA expression of HT1R in the prostate and the bladder were also significantly increased compared to Sham group (Fig. 2A and 2B). However, these changes were normalized in Treatment group (Fig. 2A and 2B). In addition, mRNA expressions of IL-1β and IL-18 in the prostate of Placebo group were significantly higher compared to Sham group while there were no significant differences between Treatment and Sham groups (Fig. 2C).

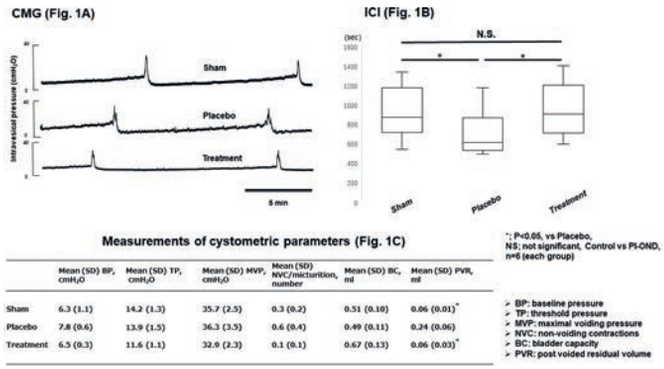
INTERPRETATION OF RESULTS

These results indicate that PI induces bladder overactivity shown by decreased ICI in association with HT1R upregulation in the bladder and the prostate, and that inhibition of HT1R improved PI-induced cytokine production, bladder overactivity and C-fiber afferent marker (TRPV1) overexpression in L6-S1 DRG that contain bladder and prostate afferent neurons. Thus, it is assumed that HT1R plays a significant role in prostate-to-bladder cross-organ sensitization, which induces bladder overactivity due to enhanced bladder afferent activity, after PI.

CONCLUDING MESSAGE

Blockade of histamine H1 receptors improved not only prostatic inflammation, but also bladder overactivity in a rat model of PI. Thus, the histamine-H1 receptor mechanism would be a potential target for the treatment of irritative bladder symptoms in patients with chronic prostatitis. Also, it is possible that second-generation, anti-histamine H1 receptor antagonists such as desloratadine, which have a lesser anticholinergic effect [2] [3], can induce therapeutic effects without affecting PI-associated voiding problems because desloratadine did not increase, but rather improved PVR in PI rats.

FIGURE 1



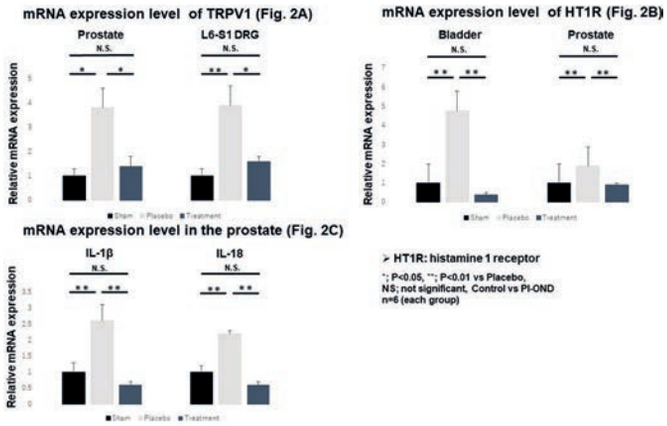
Measurements of cystometric parameters (Fig. 1C)

	Mean (SD) BP, cmH_2O	Mean (SD) TP, cmH_2O	Mean (SD) MVP, cmH_2O	Mean (SD) NVC/micturition, number	Mean (SD) BC, ml	Mean (SD) PVR, ml
Sham	6.3 (1.1)	14.2 (1.3)	35.7 (2.5)	0.3 (0.2)	0.51 (0.10)	0.06 (0.01)*
Placebo	7.8 (0.6)	13.9 (1.5)	36.3 (3.5)	0.6 (0.4)	0.49 (0.11)	0.24 (0.06)
Treatment	6.5 (0.3)	11.6 (1.1)	32.9 (2.3)	0.1 (0.1)	0.67 (0.13)	0.06 (0.03)*

*; P<0.05, vs Placebo, NS; not significant, Control vs PI-OND, n=6 (each group)

- BP: baseline pressure
- TP: threshold pressure
- MVP: maximal voiding pressure
- NVC: non-voiding contractions
- BC: bladder capacity
- PVR: post voided residual volume

FIGURE 2



- HT1R: histamine 1 receptor

*; P<0.05, **; P<0.01 vs Placebo, NS; not significant, Control vs PI-OND n=6 (each group)

REFERENCES

1. Funahashi et al.
2. Theoharides TC et al: Hydroxyzine therapy for interstitial cystitis. Urology 49: 108-110. 1997
3. Grundy L et al: Histamine induces peripheral and central hypersensitivity to bladder distension via the histamine H1 receptor and TRPV1. American journal of physiology-renal physiology, 318, F298–F314, 2020

Funding NIH U54 DK112079 **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** University of Pittsburgh Institutional Animal Care and Use Committee

162 www.ics.org/2020/abstract/162

PELVIC RADIATION DECREASES NERVE MEDIATED BLADDER CONTRACTIONS AND INCREASES URETHRAL SPHINCTER CONTRACTIONS IN FEMALE RATS

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HYPOTHESIS / AIMS OF STUDY

Radiation therapy (RT) is necessary for stage IIB and greater cervical cancers. Within 6 months of diagnosis, 53% of women will receive pelvic RT. Although external beam and brachytherapy radiation techniques can deliver adequate radiation to the targeted neoplasm, healthy neighboring tissues in the pelvis may become ionized leading to urinary incontinence. Tissue injury from RT is both an acute and chronic process. In male rats, prostatic radiation induced an early decrease and late increase in bladder contractility. RT is shown to induce cystitis in several pre-clinical models, yet the pathological mechanisms leading to urinary incontinence are largely unknown. The aim of this study is to determine how a single dose of pelvic radiation administered to a rat model impacts bladder and urethra contractions at 4 and 9 weeks post RT. We hypothesize RT will decrease bladder and urethra contractions by 9 weeks post RT.

STUDY DESIGN, MATERIALS AND METHODS

Adult female Sprague Dawley rats were anesthetized, given a single dose of 20 Gy radiation selectively targeted to the pelvis and allowed to recover for 4 or 9 wks (4RT n=8; 9RT n=8). Age matched controls (4CON n=3; 9CON n=4) underwent the same procedure without receiving any radiation. Bladders, internal urethral sphincters (IUS), and external urethral sphincters (EUS) were excised. The bladder was cut into strips and the urethral sphincters were cut into 2 mm rings, and mounted in tissue baths. Contractility was measured using a high potassium solution (KCl, 120 mM), carbachol (10-9 to 10-4 M; bladder only), caffeine (40 mM), and electric field stimulation (EFS, 1-48 Hz at fixed parameters) in the absence or presence of a ryanodine receptor antagonist, dantrolene (10-5 M) to determine striated muscle contribution, or sodium channel inhibitor, tetrodotoxin (TTX, 10-6 M) to determine if contractions are of neuronal origin and not a result of direct smooth muscle stimulation.

RESULTS

Overall, there were no differences between the bladder and sphincter data for 4CON and 9CON groups; therefore, both groups were combined and referred to collectively as CON. Within the bladder, RT decreased EFS contractions at both 4 and 9 weeks (Figure 1, CON: 58.8±7.84, 4RT: 41.5±4.13, 9RT: 38.0±2.58mN; $p<0.05$). In contrast, RT did not change KCl or carbachol-induced bladder contractions. Conversely in the IUS, RT increased EFS contractions after 4 weeks, but contractions returned to CON values by 9 weeks (CON: 2.0±0.34, 4RT: 3.1±0.55, 9RT: 2.1±0.27mN; $p<0.05$). EFS IUS contractions were unaffected by dantrolene incubation, confirming the absence of striated muscle contribution. IUS contractions to KCl, and caffeine did not change following RT. Multiple RT induced changes were noted in the EUS. At 4 weeks post RT, no changes were noted in EUS KCl contractions; however, by 9 weeks KCl contractions doubled (CON: 3.9±1.04, 4RT: 4.1±0.71, 9RT: 8.9±0.50mN; $p<0.05$). Caffeine induced contractions increased only 9 weeks after RT (CON: 5.3±1.08, 4RT: 9.0±0.69, 9RT: 11.4±1.82mN; $p<0.05$). RT caused a three-fold increase in 4RT and 9RT EFS contractions (Figure 2, CON: 3.2±1.06, 4RT: 7.6±1.67, 9RT: 10.34±2.22mN; $p<0.05$). When incubated with dantrolene to eliminate striated muscle EFS contribution, no change in EFS contractions were noted at 4 or 9 weeks post RT (CON: 1.6±0.35, 4RT: 3.0±0.75, 9RT: 3.9± 0.99mN). To confirm neuronal origin, all EFS contractions within the bladder, IUS, and EUS were inhibited following incubation with TTX.

INTERPRETATION OF RESULTS

Pelvic RT decreases nerve mediated bladder contractions yet increases nerve mediated urethral sphincter contractions. Interestingly, most changes occur within the EUS – the urethral sphincter under voluntary striated muscle control.

CONCLUDING MESSAGE

The adaptive physiological changes in smooth muscle signaling of the bladder and urethral sphincters following radiation has been poorly described in previous literature but is crucial to understand the development of urinary incontinence. Further studies may provide mechanistic detail necessary to prevent or treat RT induced incontinence and improve the quality of life for cervical cancer survivors

FIGURE 1

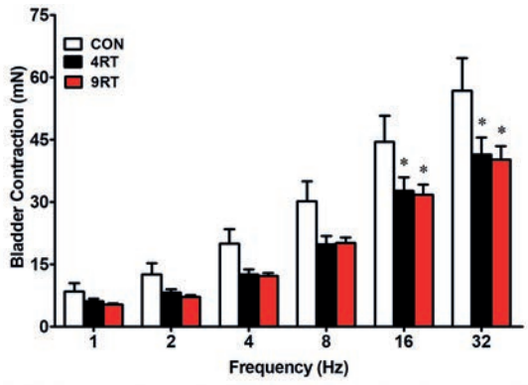

Figure 1: Bladder contractions mediated by EFS decrease at 4 and 9 weeks post RT. (*p<0.05)

FIGURE 2

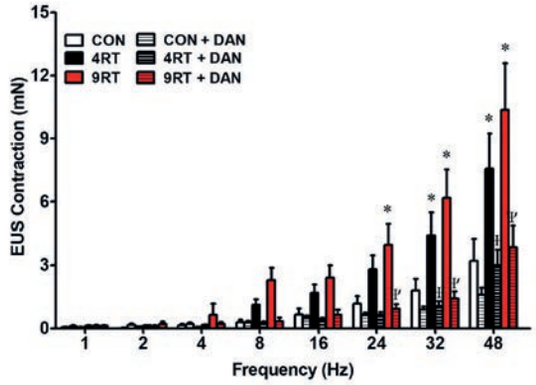

Figure 2: EUS contractions mediated by EFS decrease at 4 and 9 weeks post RT. Dantrolene incubation inhibits the contractility increase to indicate contractions are mediated by striated muscle. (*p<0.05 vs CON, Ψp<0.05 vs CON + DAN)

Funding ISSWSH research grant awarded to Shelby Powers **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** East Carolina University Institutional Animal Care and Use Committee

163 www.ics.org/2020/abstract/163

THE EFFECT OF TESTOSTERONE ON URINARY BLADDER SMOOTH MUSCLE CONTRACTILE RESPONSE IN CASTRATED RATS

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HYPOTHESIS / AIMS OF STUDY

Decreased testosterone in elderly men is known to result in a variety of physical symptoms. According to the clinical practice guidelines for male lower urinary tract symptoms, 41.9% of elderly men who do not have lower urinary tract obstruction but have lower urinary tract symptoms have been reported to have detrusor contractile dysfunction. However, the effect of testosterone deficiency on bladder and urinary function has not yet been elucidated. Therefore, we aimed to elucidate the effect of testosterone on bladder function in castrated rats using pharmacological and molecular biological techniques.

STUDY DESIGN, MATERIALS AND METHODS

We divided sexually mature 12-week-old male Wistar-ST rats into into the following groups: castrated (Cast), castrated with testosterone (Cast+T), and sham (Sham). Testosterone was administered with silastic tubing at 3 months after the castration. After 4 months, voiding function and detrusor muscle contraction were evaluated. Cystometrography (CMG) was performed to assess the voiding interval and intravesical pressure. Detrusor muscle contraction was measured by isometric tension using bladder tissue. Contraction was induced by carbachol and electrical field stimulation (EFS). Moreover, a muscarinic receptor antagonist was used. Real-time PCR was used to examine variations in the expression of mRNA in the excised bladder tissue.

RESULTS

Based on the CMG (80 μL/min) results, castration did not significantly affect the voiding interval (Cast group: 653.3 ± 145.7 seconds, Sham group: 767.7 ± 233.2 seconds Cast+T group: 955.0 ± 109.6 seconds). Intravesical pressure was also not significantly different between groups. On the other hand, castrated rats showed significantly weaker contractile force of the detrusor muscle in response to carbachol (Cast group: 61.9 ± 15.4 N/g, Sham group: 220.6 ± 62.4 N/g). Testosterone administration significantly increased the response (Cast+T group: 104.8 ± 7.5 N/g). Similarly, castrated rats showed weaker contractile force against EFS (Cast group: 73.0 ± 19.0 N/g, Sham group: 183.6 ± 26.4 N/g, Figure A) and testosterone administration significantly increased the force (Cast+T group: 150.8 ± 3.7 N/g). The addition of atropine decreased the contractile response. The addition of the atropine eliminated the differences between the groups (Figure B). After a muscarinic receptor antagonist was added, the contractile force against EFS was not significantly different between the Sham and Cast groups. Muscarinic receptor (M2 and M3) mRNA expression was significantly lower in the Cast group than in the Sham group (Figure C-D). Testosterone administration significantly increased the mRNA expressions.

INTERPRETATION OF RESULTS

CMG did not reveal a difference in the urinary function of sham-operated and castrated rats 4 months after castration. On the other hand, weaker detrusor muscle contraction force by carbachol and EFS was observed in castrated rats. The inhibited muscarinic receptor and real-time PCR results showed that testosterone deficiency decreased urinary bladder smooth muscle contractile response through muscarinic receptors. However, testosterone administration improved the detrusor muscle contraction force by carbachol and EFS and the urinary bladder smooth muscle contractile response.

CONCLUDING MESSAGE

Testosterone deficiency might cause an under active bladder by decreasing the response of the muscarinic receptors and urinary bladder smooth muscle contractility. Testosterone administration might improve the under active bladder induced by testosterone deficiency.

FIGURE 1

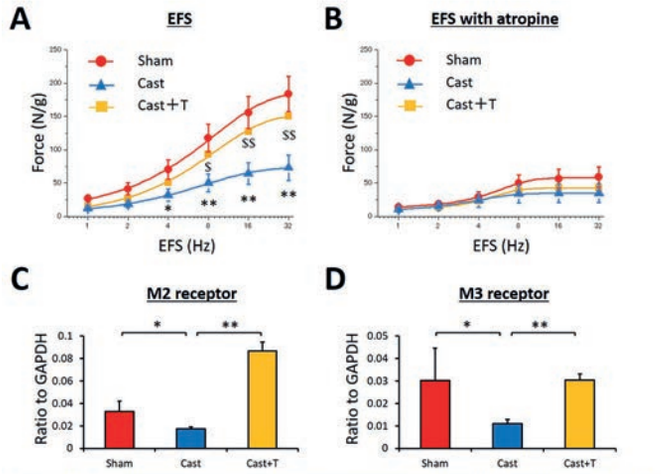

Figure (A-B) Detrusor muscle contraction was measured by isometric tension using bladder tissue. (A) Electrical field stimulation (EFS)-induced contraction curve for rat bladder strips, showing the contractile effect of increasing hertz of EFS (1–64 Hz) on bladder strips. (B) EFS-induced contraction curve with addition of atropine. (C-D) Real time PCR analysis of muscarinic receptor (M2 and M3) mRNA expression. Each bar indicates mean ± standard error. $^{*}P < 0.05$, $^{**}P < 0.01$ vs. Sham, $^{\$}P < 0.05$, $^{\$\$}P < 0.01$ vs. cast by Tukey–Kramer's *t*-test.

Funding N/A **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** The ethics review board of Nagoya City University

164 www.ics.org/2020/abstract/164

THE MODULATION OF CAMP BY ADENOSINE INHIBITS NEURONAL ATP RELEASE FROM EFFERENT NERVE TERMINALS TO THE DETRUSOR OF MOUSE BLADDER

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HYPOTHESIS / AIMS OF STUDY

The purinergic system regulates bladder function at several sites by the action of ATP or its metabolites. ATP is a co-transmitter with acetylcholine (ACh) at parasympathetic nerve terminals, and with detrusor from most animal bladders it has an excitatory role in generating nerve-mediated contractions. ATP is released over lower stimulation frequencies (<~12 Hz), whilst ACh release predominates at higher frequencies. However, with human bladder, ATP only has such a role in bladder pathologies, such as overactive bladder; but with normal human detrusor ACh is the sole functional transmitter, explained by variable rates of extracellular ATP hydrolysis by endonucleotidases [1]. It would therefore be highly desirable to selectively reduce ATP release from nerve terminals, leaving ACh release intact. Adenosine, an ATP metabolite, reduces nerve-mediated contractions, with a large effect at low stimulation frequencies, but very much less at higher frequencies. The action is mediated by A1 receptors on nerve terminals and will reduce intracellular cyclic AMP (cAMP) levels and similarly reduce activity of its major target, protein kinase A (PKA) [2]. Thus, it may be inferred that adenosine selectively reduces nerve-mediated ATP release but there has been no direct demonstration. We hypothesised that A1 receptor agonists do reduce nerve-mediated ATP, but not ACh, release, an action mediated by an A1 receptor-cAMP-PKA pathway.

STUDY DESIGN, MATERIALS AND METHODS

Bladders were dissected from 12-week male C57BL/6 mice, and tissue strips with mucosa intact, were mounted to record contractions generated by electrical field stimulation (EFS; 0.1-ms pulses, 1-40 Hz, 3-s train every 90 s) and inhibited by 1 μM tetrodotoxin. Drug interventions were delivered by the superfusate, Tyrode's solution (24 mM NaHCO3:5%CO2, pH 7.4, 36°C). Peak tension (mN) was normalised to preparation weight (mN.mg-1). Tension was plotted as a function of stimulation frequency and analysed to estimate the maximum tension at high frequencies (Tmax, mN.mg-1) and the frequency to generate Tmax/2, f1/2 (Hz). A reduction of Tmax implies an action on force mainly via ACh-dependent pathways; an increase of f1/2 implies a force reduction mainly via ATP-dependent pathways. Nerve-mediated ATP and ACh release was measured in superfusate 100 μl samples taken immediately before and during EFS. ATP was measured using a luciferin-luciferase assay [3] at 8 Hz stimulation, and ACh release was measured at 20 Hz stimulation using a choline/ACh assay kit (Sigma); the frequencies were chosen to reflect when ATP and ACh release was near optimal [3]. Data are presented are mean±SEM; differences between data sets were tested with repeated measures two-way ANOVA followed by parametric post-hoc tests or Student's paired t-tests where appropriate; the null hypothesis was rejected at $p<0.05$.

RESULTS

Adenosine (1 mM) reduced nerve-mediated contractions at low frequencies (f1/2 increased) and reduced ATP release (Fig 1A, B). However, there was no effect on higher frequency contractions (Tmax) and there was no effect on ACh release (Fig 1C, D). Further experiments were undertaken to find the cellular pathway underlying these effects of adenosine on contractile function and ATP release (Fig 2). Similar results to adenosine on f1/2 and ATP release were recorded with the A1 receptor selective agonist CPA (N6-cyclopentyladenosine, 10 μM, Fig 2A) and the non-selective A1/A2 receptor agonist NECA (5'-(N-ethylcarboxamido) adenosine, 10 μM, Fig 2B). The effect of adenosine was blocked by the A1 receptor antagonist, DCPCX (dipropyl-cyclopentylxanthine, 1 μM, Fig 2C). Direct inhibition of PKA by CAMPs-Rp (10 μM) also increased f1/2 and decreased ATP release (Fig 2D). Two agents that increase cAMP, the adenylate cyclase activator forskolin (1 μM) to activate and the cell permeable cAMP analogue 6-MB-cAMP (100 μM) had no effect on f1/2 values and ATP release (data not shown). An additional target for intracellular cAMP, over PKA, is EPAC (exchange protein di-

rectly activated by cAMP) that may regulate ATP release. An EPAC activator (007-AM, 10 μM) and EPAC inhibitor (ESI-09, 20 μM) both had no effect on f1/2 values and ATP release (data not shown). None of the interventions listed above had a significant effect on Tmax values.

INTERPRETATION OF RESULTS

Adenosine and A1 receptor agonists generated a frequency-dependent attenuation of nerve-mediated contractions. The significant increase on f1/2 values, with no effect on Tmax demonstrate that greater effects were at lower stimulation frequencies where ATP release is more predominant. This was corroborated by direct measurement of reduced nerve-mediated ATP release. DPCPX abolished the effects of adenosine, consistent with the hypothesis that adenosine acts via A1 receptor activation. The main target for cAMP in mediating nerve-mediated ATP release is via PKA and not by the EPAC route. An increase of cAMP by forskolin or 6-MB-cAMP had no effect which implies that normal levels of intracellular cAMP are sufficient to maintain nerve-mediated ATP release. By contrast adenosine had no effect on ACh release or Tmax. This the first direct demonstration that differential regulation of transmitter release is possible at the detrusor nerve-muscle junction. Because ATP is associated with pathological contractile function in the human bladder, the ability to specifically attenuate its release offers a novel therapeutic drug target.

CONCLUDING MESSAGE

This study has shown for the first time that adenosine selectively reduces ATP release from motor nerves supplying detrusor smooth muscle. The pathway of this action has also been characterised: initially by activation of an A1 receptor, with downstream inhibition of adenylate cyclase, cAMP generation and PKA. Modulation of cyclic nucleotide levels, such as cAMP, provides a novel target of pathological purinergic motor pathways.

FIGURE 1

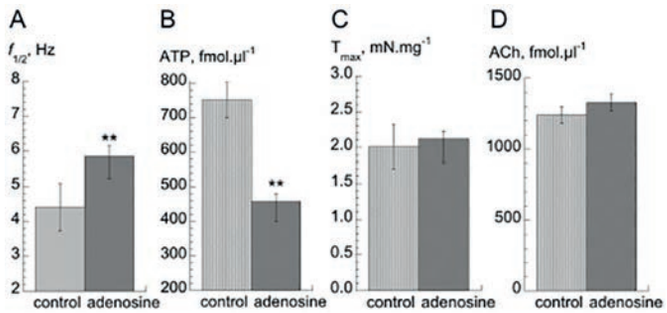

Figure 1. Effect of adenosine on detrusor contractile properties and ATP and acetylcholine (ACh) transmitter release. Effect on A) f1/2, B) nerve-mediated (8 Hz) ATP release, C) Tmax, and D) nerve-mediated (20 Hz) ACh release. Means±SEM, n=6; **p<0.01.

FIGURE 2

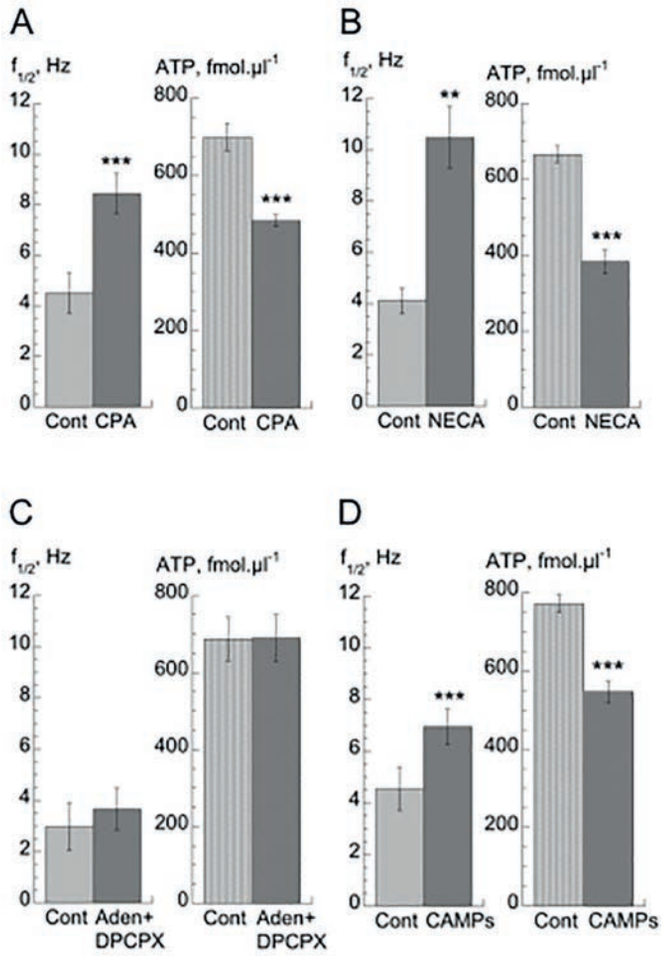

Figure 2. Effect of adenosine receptor mediators, A) CPA, B) NECA, C) DPCPX, with adenosine (aden), and D) CAMPs-Rp, on detrusor contractile properties and ATP transmitter release. Cont = control. Means±SEM, n=6; **p<0.01, ***p<0.001.

REFERENCES

1. Fry CH, Bayliss M, Young JS, Hussain M (2011). Influence of age and bladder dysfunction on the contractile properties of isolated detrusor smooth muscle. BJU Int 108:E91-E96.
2. Pakzad M, Ikeda Y, McCarthy C, Kitney DG, Jabr RI, Fry CH (2016). Contractile effects and receptor analysis of adenosine-receptors in human detrusor muscle from stable and neuropathic bladders. Naunyn Schmiedebergs Arch Pharmacol 389(8):921-9.
3. Chakrabarty B, Ito H, Ximenes M, Nishikawa N, Vahabi B, Kanai AJ, Pickering AE, Drake MJ, Fry CH (2019). Influence of sildenafil on the purinergic components of nerve-mediated and urothelial ATP release from the bladder of normal and spinal cord injured mice. Br J Pharmacol 176:2227-2237.

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CONTROL OF RAT BLADDER NECK RELAXATION USING "NORD-1", A LIGHT-REACTIVE NITRIC OXIDE RELEASER

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HYPOTHESIS / AIMS OF STUDY

The internal urethral sphincter, which is the smooth muscle of the bladder neck, controls the complex micturition system by relaxing during the voiding phase and contracting during the storage phase. Relaxation impairment of this muscle causes a voiding dysfunction. In severe cases, patients need an intermittent urethral catheterization for voiding, which reduces their quality of life and poses a risk of infection.

Nitric oxide (NO) plays an important role in the relaxation of the internal urethral sphincter; however, NO has not been used for voiding dysfunction for two reasons. First, it is difficult to avoid systemic side effects, such as headache or hypotension. Second, the internal urethral sphincter must be relaxed only during the voiding phase. Therefore, we developed a novel light-reactive NO donor, "NORD-1". It is possible to regulate the NO release temporally and spatially by irradiating NORD-1 with red light. In this study, we examined whether it was possible to control the relaxation of the bladder neck of intact rats by using NORD-1 and red light.

STUDY DESIGN, MATERIALS AND METHODS

We used 10-11-week-old male and female Wistar/ST rats. In the NORD-1 group, 10^-4 M NORD-1 (500 µL) was instilled into the bladder via a PE-50 tube inserted into the bladder dome under anesthesia. In the vehicle group, we administered the vehicle. The rats were kept in the supine position for 20 min, following which, the bladder was harvested. Next, the bladder was separated into a circular bladder neck specimen and a longitudinal bladder body strip for isometric tension study. Carbachol (10^-5 M) was added to the organ bath to induce precontraction. After equilibration, the specimens were irradiated with red light (8 mW/cm2, 30 mW/cm2, 58 mW/cm2, and 121 mW/cm2) and their relaxation responses were measured. We also evaluated their response in the presence of 10^-5 M [1,2,4] oxadiazolo [4,3-a] quinoxalin-1-one (ODQ), an inhibitor of the soluble guanylyl cyclase (sGC). All measurements were performed with 10^-5 M NG-nitroarginine methyl (L-NAME), an inhibitor of the endogenous NO synthase. Moreover, bladder necks were harvested from rats treated with vehicle or NORD-1 and frozen sections were prepared to analyze the permeability of NORD-1. Paired samples t-test with the Bonferroni correction was used for the statistical analysis of the difference in response to each light intensity, and ANOVA and the Bonferroni-type multiple t-tests were used for the analysis of the response with or without NORD-1 and ODQ.

RESULTS

Fig. 1A shows representative charts of the female rat's bladder neck response to irradiation with red light under each condition. In the vehicle group, the bladder neck specimens did not respond to irradiation and were relaxed due to the application of sodium nitroprusside, an NO donor (Fig. 1A). In contrast, in the NORD-1 group, the bladder neck specimens were relaxed when irradiated, and the response was significantly increased in proportion to the light intensity (Fig. 1A, 1B). In addition, the tension returned as soon as the light was turned off. These responses were significantly inhibited in the presence of ODQ (Fig. 1A, 1C). Contrarily, the bladder body specimens of both groups did not relax when irradiated. There were no differences based on sex in the relaxation responses. According to the histological evaluation, NORD-1 was localized in the urothelium, but not in the smooth muscle of the bladder neck specimens (Fig. 2).

INTERPRETATION OF RESULTS

We succeeded in controlling the start and end of the relaxation of bladder neck specimens obtained from intact rats by using NORD-1 and light irradiation. In contrast, the bladder body specimens did not react to them. These differences may originate from a cellular expression of the sGC. The sGC is an intracellular receptor of NO, which induces the relaxation of smooth muscles. It was reported that sGC was not detected in the smooth muscle cells of the bladder body, but was present in those of the bladder neck [1]. Thus, the bladder neck relaxed via the NO/sGC signal when NORD-1 was applied and irradiated, while the bladder bodies did not respond. However, NORD-1 is localized in the urothelium rather than the smooth muscle of the bladder neck. It is known that NO migrates from the producer cells to the target cells freely and quickly. In this study, NO was produced in the urothelial cells of the bladder neck specimens and transferred to the smooth muscle cells immediately.

CONCLUDING MESSAGE

This study is the first to apply a light-reactive NO releaser to a bladder neck specimen. This method may resolve the problems that the usual NO donors face by controlling an NO release spatially and temporally. Light-reactive NO releaser and light irradiation may be a novel therapy for voiding dysfunction that affects the patient physically and mentally.

FIGURE 1

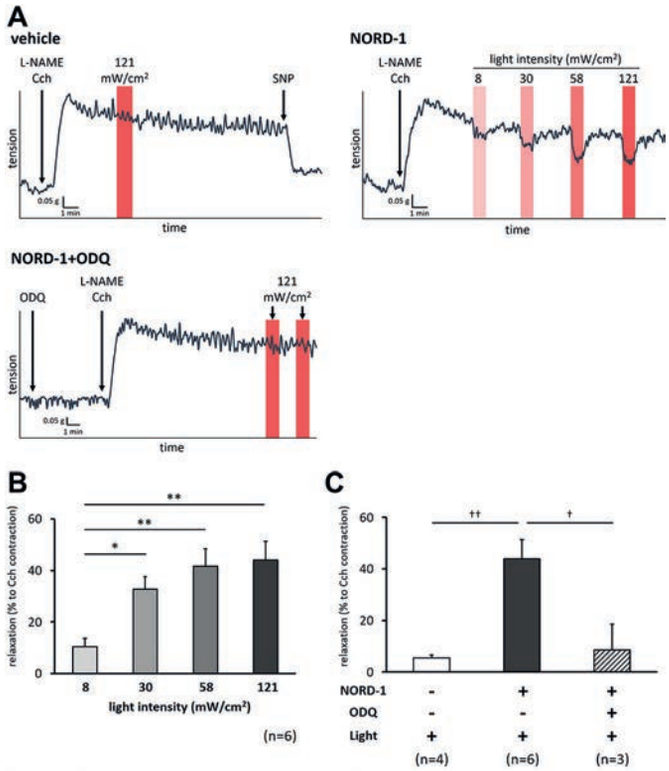

Figure 1. The results of an isometric tension study
Representative charts of the female rat's bladder neck response to irradiation under each condition (A), the results of relaxation rate corresponding to the light intensity (B), and the results of relaxation rate responding to 121 mW/cm² red light with or without NORD-1 and ODQ (C). SNP, sodium nitroprusside; L-NAME, NG-nitroarginine methyl; Cch, carbachol; ODQ, [1,2,4] oxadiazolo [4,3-a]quinoxalin-1-one. Mean ± S.E. *<0.05, **<0.01, paired samples *t*-test with the Bonferroni correction; †<0.05, ††<0.01, ANOVA and the Bonferroni-type multiple *t*-tests.

FIGURE 2

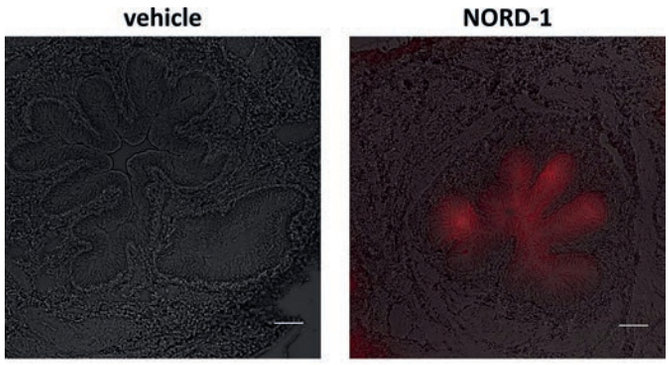

Figure 2. The permeability of NORD-1 in the bladder necks of each group.
Red staining indicates NORD-1. Scale bar = 100 μm.

REFERENCES

1. Lies B, Groneberg D, Friebe A. Correlation of cellular expression with function of NO-sensitive guanylyl cyclase in the murine lower urinary tract. J Physiol. 2013 Nov 1;591(21):5365-75.

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166 www.ics.org/2020/abstract/166

EFFECTS OF FILTERED ADIPOSE-DERIVED STEM CELL LYSATES ON BLADDER FUNCTION IN RATS WITH HYDROCHLORIC ACID-INDUCED CYSTITIS

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HYPOTHESIS / AIMS OF STUDY

Many reports have shown that stem cell therapy is useful for stress urinary incontinence or interstitial cystitis.[1] However, cell therapy has many hurdles, including immunoreactivity, unexpected mal-differentiation, embolization, complications of maintenance and culture cells, and high cost. In addition, many reports have shown that paracrine effects are important for improvement.[1] Here, we focused on the contents of stem cells that have the potential to solve these problems and made filtered adipose-derived stem cell lysate (FADSCL). In this study, we investigated whether FADSCL was useful using a hydrochloric acid (HCl)-induced rat model of cystitis.

STUDY DESIGN, MATERIALS AND METHODS

Rat adipose-derived stem cells (ADSCs) were collected from the subcutaneous fat of a rats. Cultured ADSCs (passage 3 or 4) were collected and fixed in PBS (1x10^7 cells/1 mL PBS). Then, the cells were crushed by freeze-thaw, and the filtrate (FADSCL) was collected. Eight-week-old female Fisher 344 rats were divided into (1) sham+vehicle (n=10), (2) HCl+vehicle (n=11), and (3) HCl+FADSCL (n=9) groups. On the first day (day one), saline or 1 M HCl (250 μL/body) were intravesically administered from a transurethral catheter. The next day (day two), PBS as vehicle or FADSCL (250 μL/body) were intravesically administered from a transurethral catheter. Cystometrograms were performed on day eight to evaluate intercontraction intervals (ICIs) and maximum voiding pressure (MP) in each group. Bladder weight and bladder morphology were evaluated by hematoxylin and eosin staining.

Analysis of variance and Bonferroni multiple t-tests were performed for statistical analysis.

RESULTS

Representative cystometrogram charts are shown in Figure 1A. ICIs in the HCl+PBS group were significantly shorter than those in the sham+PBS group ($P < 0.01$), while the ICIs of the HCl+FADSCL group were significantly longer than those of the HCL+PBS group ($P < 0.01$) (Figure 1B). The maximum voiding pressure did not change among the three groups (Figure 1C). The bladder weight/body ratio did not change among the three groups. Bladder structure was not changed significantly among the three groups on day eight.

INTERPRETATION OF RESULTS

These data suggested that FADSCL might be useful for treating cystitis. This HCl-induced model is used as a hemorrhagic cystitis or interstitial cystitis model, suggesting that FADSCL may be useful in these conditions. It is very important that improvement was obtained by local administration (intravesical infusion) only once. However, this study has two limitations. First, this model is a chemical model and does not purely reflect clinical conditions. Second, the mechanisms responsible for this improvement are unknown. Further research is needed on these points.

CONCLUDING MESSAGE

FADSCL improved frequent urinary symptoms in rats with HCl-induced cystitis, suggesting that intravesical injection of FADSCL may be a useful treatment for hemorrhagic cystitis or interstitial cystitis.

FIGURE 1

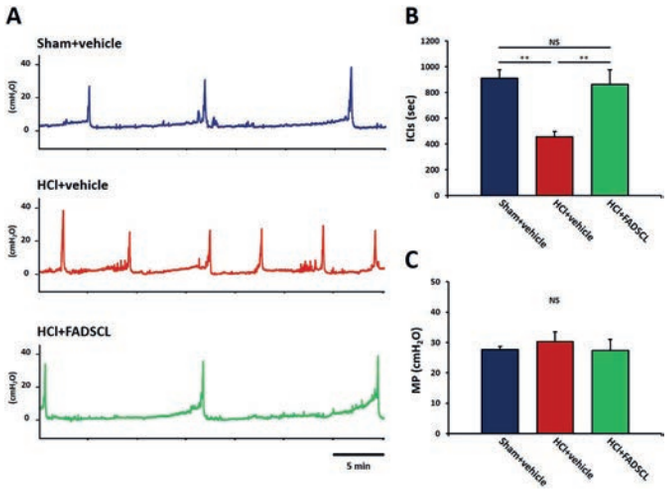

Figure 1. Cystometrogram results for each group. A, Representative charts. B, Intercontraction intervals (ICIs). C, Maximum voiding pressure (MP). Sham+vehicle (n=10), HCl+vehicle (n=11), HCl+FADSCL (n=9). **P < 0.01.

REFERENCES

1. Nat Rev Urol. 2019;16(6):363-375.

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SESSION 13 (PODIUM SHORT ORAL) - URODYNAMICS 1
Abstracts 190-201
16:30 - 18:07, Pavilion 9
Chairs: Mr Marcus John Drake (United Kingdom), Stephen R Kraus (United States)

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CAN RESTING STATE REFLECT URODYNAMIC TESTING IN DELINEATING VOIDING NETWORKS USING FMRI?

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HYPOTHESIS / AIMS OF STUDY

Several studies have reported brain activation and functional connectivity (FC) during micturition using fMRI and concurrent urodynamics (UDS) testing [1,2]. However due to the invasive nature of UDS procedure, non-invasive resting state fMRI is being explored as a potential alternative. To evaluate the feasibility of this approach, we compared FC in brain regions belonging to the voiding network [1] during the following states: 'full urge', 'initiation of voiding/or attempt of voiding', and 'voiding or attempt of voiding' with FC during rest in female multiple sclerosis (MS) patients.

STUDY DESIGN, MATERIALS AND METHODS

Subjects: Six female patients diagnosed with stable MS and voiding dysfunction (age 53.5±15.5). Voiding dysfunction was defined as having post-void residual volume ≥20% of their maximum cystometric capacity, or belonging in the lower 10 percentile of the Liverpool nomogram for women.

Urodynamics testing: Prior to scanning, an MRI compatible lumen catheter was inserted into the patients' bladder. During fMRI scanning, the patients' bladder was filled and permission to void was given 30 sec after cessation of filling. Residual of urine was manually aspirated. Patients communicated their progress using a response grid indicating: "full urge", "initiation of voiding", or "voiding". This urodynamic testing was repeated 3-4 times for each patient.

Data acquisition: MR images were acquired on an FDA-approved human 7T scanner (Siemens MAGNETOM Terra). Each session included the following scans: 3D T1-weighed anatomical scan (isotropic 0.7mm spatial resolution) and T2*-weighted blood oxygen level-dependent (BOLD) fMRI scans in a resting state (8 min) and during urodynamics testing (TR=2500ms, isotropic spatial resolution 1.4mm).

Data analysis: MRI data was preprocessed in standard steps (slice time correction, motion correction, spatial normalization, and spatial smoothing). 13 regions-of-interest (ROIs) previously associated with voiding located in the inferior/medial/superior frontal gyrus, superomedial primary motor cortex, supplementary motor area (SMA), and dorsolateral prefrontal cortex. Average fMRI time series were computed across each region and functional connectivity (Pearson's correlation coefficient) between region pairs was computed for each state and compared to the resting state. The similarity between connectivity matrices was quantified with the 2D correlation coefficient.

RESULTS

The SMA exhibited highest connectivity strength while the bilateral motor regions for pelvic floor construction showed lowest (Fig. 1, Table 1). The highest correlations were observed between resting state and the 'voiding' state (Fig. 1). Additionally, figure 2 shows high correlations within the 13 ROIs across all subjects during voiding and in a resting state (Fig. 2).

INTERPRETATION OF RESULTS

Results from figure 1 suggest that the FC between the ROIs closely resembles resting state only during voiding, thereby indicating the resting state FC's potential for assessing the voiding process. The high correlations within the 13 ROIs across all subjects during voiding as shown in figure 2 strongly suggests that voiding is consistently achieved through similar network activations independent from the activations required for 'full urge', 'initiation of voiding', and 'voiding'. An observed high inter-subject correlation in the resting state (Fig. 2) supports consistency within the individual intrinsic voiding networks.

CONCLUDING MESSAGE

Brain regions within the voiding network are highly correlated only during voiding and not during full urge or initiation. Additionally, the task-related voiding network closely resembles the resting state intrinsic network only during voiding. These results were found to be consistent across all six subjects and suggests that resting state fMRI can be potentially utilized to reflect voiding-related brain networks during the voiding process but not the other states. Concurrent urodynamic testing is still necessary for studying the effects of full urge and initiation of micturition.

FIGURE 1

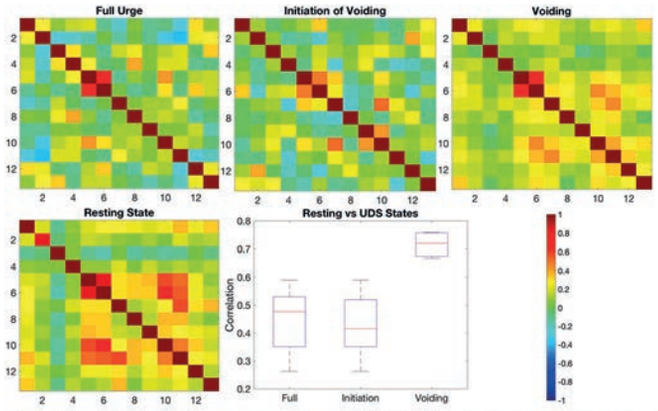

Figure 1 Averaged functional connectivity matrices of all 13 ROIs for six subjects in a resting state and during the three urodynamic stages. The row and column represent each ROI number. The color bar represents correlation values. The boxplot shows a group analysis of correlations within the voiding network between resting state and the three urodynamic states, respectively.

FIGURE 2

Table 1 Thirteen ROIs associated with the voiding network

ROI #	MNI	Brodmann Area	Hemisphere	Area
1	52,24,12	44/45	Right	Inferior Frontal Gyrus
2	63,18,18	44/45	Right	Inferior Frontal Gyrus
3	40,35,6	46	Right	Inferior Frontal Gyrus
4	48,4,10	6	Right	Inferior Frontal Gyrus
5	6,-18,57	6	Right	Medial Frontal Gyrus
6	3,-18,57	6	Right	Superior Frontal Gyrus
7	2,2,62	6	Right	Superior Frontal Gyrus
8	-12,-26,66	4	Left	Superomedial M1
9	12,-24,66	4	Right	Superomedial M1
10	-2,-16,68	6	Left	SMA
11	4,-6,64	6	Right	SMA
12	40,38,38	9	Right	dlPFC
13	52,38,12	46	Right	dlPFC

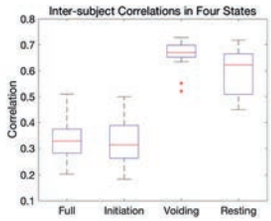

Figure 2 Group analysis of inter-subject correlations in connectivity within 13 ROIs across 6 subjects during four states, respectively.

REFERENCES

1. Shy, M., Fung, S., Boone, T.B., Karmonik, C., Fletcher, S.G. and Khavari, R. (2014), 'Functional magnetic resonance imaging during urodynamic testing identifies brain structures initiating micturition', The Journal of urology, vol. 192, no. 4, pp. 1149-1154.
2. Schrum, A., Wolff, S., Van der Horst, C. and Kuhtz-Buschbeck, J.P. (2011), 'Motor cortical representation of the pelvic floor muscles', The Journal of urology, vol. 186, no. 1, pp. 185-190.

Funding K23DK118209 by National Institute of Heath, NIDDK (RK); Houston Methodist Clinician Scientist Award (RK) **Clinical Trial** No **Subjects** Human **Ethics Committee** Methodist Hospital institutional review board committee **Helsinki** Yes **Informed Consent** Yes

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URODYNAMIC CRITERIA OF DETRUSOR UNDERACTIVITY: CLINICAL IMPACT ON THE OUTCOMES OF WOMEN UNDERWENT MIDDLE URETHRAL SLING FOR STRESS URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

There are very limited data on the impact of detrusor underactivity (DUA) on stress urinary incontinence (SUI) surgery outcomes. Indeed, no definitive standardized urodynamics (UDS) criteria of DUA have been defined in women. Aim of this study was to assess the influence of DUA, according to the main UDS parameters, on the outcomes of women underwent middle urethral sling (MUS).

STUDY DESIGN, MATERIALS AND METHODS

Women with SUI, naïve for SUI surgery, and treated with MUS were enrolled in this prospective study from January 2014 to January 2019. Informed consent was obtained. Exclusion criteria were: previous SUI surgery, associated pelvic organ prolapse, previous pelvic surgery and/or radiotherapy, neurologic diseases. All patients underwent pre-operative UDS. Patients were stratified according to the 4 main available UDS criteria of DUA: i) Pdet@Qmax ≤10 cm H2O and Qmax ≤12 mL/s (Jeong et al.); ii) Pdet@Qmax<30 cm H2O and Qmax<10 mL/s (Abarbanel and Marcus); iii) Pdet@Qmax<20 cm H2O and Qmax<15 mL/s and BE<90% (BVE criteria); iiii) Pdet@Qmax<20 cm H2O + Qmax (PIP1 Griffiths). The control group (CG) was represented by women with no-DUA. Preoperative evaluation included also free uroflowmetry (UF), post void residual urine (PVR), PVR-ratio (PVR-R) defined as the ratio between bladder volume and PVR, and the International Continence Index Questionnaire Urinary Female LUTS (ICIQ-FLUTS). The occurrence of postoperative urinary retention (POUR), defined as the presence of PVR ≥200 ml in > 2 evaluations, was assessed. In case of POUR, a transient drainage of the bladder by clear intermittent catheterization (CIC) or indwelling catheter (IC) was share decided with the women, and counselling on the POUR management was done. The follow-up, scheduled at 1, 6 moths and then each year, included: physical examination and vaginal inspection, UF, PVR and PVR-R, ICIQ-FLUTS. Statistical tests were: T student, Mann Whitney, Q-square, ANOVA.

RESULTS

The 102 patients who fulfilled the 2-years follow-up were considered for the analysis. DUA rate ranged from 16.7% (BVE) to 53.9% (PIP1-Griffith). Table 1 resumes mean age of the patients, prevalence of DUA according to the UDS criteria, and the main voiding complications. POUR rate varied from 20% (PIP1-Griffith) to 35.3% (BVE) and was higher than in CG (10%). The lowest duration of postoperative catheterisation before the resolution of POUR was found in PIP1-Griffith group. An early surgical treatment for POUR (7-30 days – tape incision) was performed in 2 women with DUA and in 2 women without DUA, and the rate was higher in the BVE group (11.8%), while no patients had to be treated surgically in the Arbanel group. At 2-yrs follow-up, no patient was in CIC or in IC. Functional outcomes are reported in Table 2. No significant differences were found between preoperative and at follow-up Qmax, VV, PVR, while PVR-R decreased significantly only in BVE group. Preoperative mean PVR was low in all DUA groups, and in the BVE group was the highest (55mL). ICIQ-FLUTS scores decreased in all DUA groups, but remained still higher than in CG. Mean Valsalva Leak Point Pressure (VLPP) was similar in all groups (55-59 cmH20). Only patients of Jeong group had a SUI recurrence rate lower than CG (3.3% vs 4.5%), while in the other DUA groups was very higher (21-23.6%). Women of Jeong group had OAB de novo rate similar to CG group (13.3% vs 11.3%), while the other DUA groups patients had very higher rates (21%-29.4%). At the multivariate analysis, without control group, we found that preoperatively there were significant differences in PVR, and at follow-up in ICIQ-FLUTS scores. At the multivariate analysis with also control group, the items without significant difference were preoperative VV and ICIQ-FLUTS, and at follow-up PVR and PVR-R (Table 2).

INTERPRETATION OF RESULTS

According to DUA definitions, POUR had a twice or three times higher prevalence than the control group, and the surgery treatment rate for POUR had a high variability (3.6% to 11.8%). This finding may have a very relevant impact on the counselling and on the post-operative management. DUA did not negatively impact on voiding outcomes at 2-years follow-up, regardless the type of DUA diagnosed. However, according to the DUA type, we found very different OAB de novo and SUI rates at follow-up. Only patients of Jeong group had OAB de novo and SUI recurrence rates similar to the control group, while in the other DUA groups the prevalence of these outcomes almost doubled. The mean VLPP was similar in all groups, and so the SUI severity may not have been significant different in the patients. Thus, a possible explanation of the higher SUI recurrence could be a softer tape placement in some patients of these DUA groups to avoid POUR.

CONCLUDING MESSAGE

According to the UDS criteria used, DUA diagnosis had a high variability and relevantly changed. The clinical consequences have been remarkable because the women in the diverse DUA groups had also differences in terms of POUR/surgery for POUR rate, duration of postoperative catheterisation, SUI recurrence and OAB de novo rate. Thus, the choice of UDS criteria for DUA diagnosis may have a very relevant impact

on the patients counselling, post-operative management, and both MUS functional and success outcomes.

FIGURE 1

Table 1. POUR analysis in DUA groups and in control group. POUR: post-operative urinary retention. CIC: clean intermittent catheterisation. IC: indwelling catheterisation. Student's test and Anova test.

	Jeong		Abarbanel		BVE		PIP1		Control Group	
Overall 102 Pts mean age	n= 30 (29.4%) 66.8 (+8.1)		n= 23 (22.5%) 68.5 (±10.7)		n= 17 (16.7%) 66.5 (±8.2)		n= 55 (53.9%) 66.1 (±9.6)		n= 44 (43.1%) 61.9 (±10.9)	
	Rate	Days range/mean (ds)	Rate	Days range/mean (ds)	Rate	Days range/mean (ds)	Rate	Days range/mean (ds)	Rate	Days range/mean (ds)
POUR	33.3%	8-30	30.4%	4-30	35.3%	6-36	20%	3-11	10%	7-35
CIC	13.3%	18.6(11.4)	13%	30(0)	23.5%	23.6(12.1)	9.1%	7.1(4.1)	2.2%	7(0)
IC	20%	6.6(10.2)	17.4	6.2(2.2)	11.8%	7.3(1.2)	10.9%	7(1.3)	6.8%	13.7(21.3)
POUR surgery	6.6%		0		11.8%		3.6%		5%	

Table 1. POUR analysis in DUA groups and in control group. POUR: post-operative urinary retention. CIC: clean intermittent catheterisation. IC: indwelling catheterisation. Student's test and Anova test.

FIGURE 2

Table 2. Comparison between preoperative data and outcomes at 2-years follow-up in each group, and evaluation of stress urinary incontinence recurrence rate and new onset of overactive bladder syndrome and comparison among groups on both pre-operative data and outcomes at follow-up

	Jeong		Abarbanel		BVE		PIP1		Control Group	
Overall patients n.102	n= 30 (29.4%)		n= 23 (22.5%)		n= 17 (16.7%)		= 55 (53.9%)		= 44 (43.1%)	
	Mean (±sd)	p	Mean (±sd)	p	Mean (±sd)	p	Mean (±sd)	p	Mean (±sd)	p
Qmax ml/s										
Pre-MUS	13.4 (6.3)	<0.8	13.7 (6.9)	<0.3	12.2 (5.1)	<0.1	17.4 (19.8)	<0.6	21.9 (9.4)	<0.3
Follow-up	13.1 (5.1)		15.5 (5.8)		14.9 (5.1)		16 (5.5)		22.5 (6.1)	
VV ml										
Pre-MUS	242.4 (137)	<0.6	264.8 (127.5)	<0.8	253.1 (113.1)	<0.9	250.6 (127)	<0.9	268.2 (99)	<0.8
Follow-up	231.1 (85)		271.9 (100.7)		250.9 (67.3)		247.8 (97)		330.1 (116)	
PVR ml										
Pre-MUS	27.1 (43.6)	<0.6	16.7 (29.8)	<0.6	55.3 (59.4)		20.1 (40.5)	<0.5	11.1 (27.3)	<0.6
Follow-up	33.7 (57.3)		29 (27.3)		40.7 (83.7)	<0.5	26.2 (50.1)		28.1 (41.8)	
PVR-R %										
Pre-MUS	16 (40)	<0.5	7 (10)	<0.7	30 (50)	<0.09*	11 (30)	<0.5	5 (10)	<0.7
Follow-up	11 (10)		6 (10)		9 (10)		8 (10)		9 (10)	
ICIQ-FLUTS										
Pre-MUS	87.8 (25.3)	<0.00*	47.8%	<0.7	91.5 (18.7)	<0.00*	83.4 (24.8)	<0.00*	78.6 (24)	<0.00*
Follow-up	34.6 (5.6)		17.4%		39.3 (28)		24.8 (22.9)		14.2 (25)	
SUI recurrence	3.3%		21%		23.5%			23.6%	4.5%	
OAB de novo	13.3%		21%		29.4%			27.7%	11.3%	

Student's test and Q-square test

Overall pts n= 102		Jeong n= 30 (29.4%)	Abarbanel n= 23 (22.5%)	BVE n= 17 (16.7%)	PIP1 n= 55 (53.9%)	Control Group n= 44 (43.1%)	p**	p***
		Mean (±sd)	Mean (±sd)	Mean (±sd)	Mean (±sd)	Mean (±sd)		
Qmax	Pre-MUS	13.4 (6.3)	13.7 (6.9)	12.2 (5.1)	17.4 (19.8)	21.9 (9.4)	<0.01*	<0.4
	F-up	13.1 (5.1)	15.5 (5.8)	14.9 (5.1)	16.5 (5.5)	22.5 (6.1)	<0.00*	<0.1
VV	Pre-MUS	242.4 (137.8)	264.8 (127.5)	253.1 (113.1)	250.6 (127)	268.2 (99.3)	<0.8	<0.9
	F-up	231.1 (85.2)	271.9 (100.7)	250.9 (67.3)	247.8 (97.1)	330.1 (116.8)	<0.00*	<0.4
PVR	Pre-MUS	27.1 (43.6)	16.7 (29.8)	55.3 (59.4)	20.1 (40.5)	11.1 (27.3)	<0.003*	<0.01*
	F-up	33.7 (57.3)	20 (27.3)	40.7 (83.7)	26.2 (50.1)	28.1 (41.8)	<0.7	<0.5
PVR-R	Pre-MUS	16 (40)	7 (10)	30 (50)	11 (30)	5 (10)	<0.04*	<0.1
	F-up	11 (10)	6 (10)	9 (10)	8 (10)	6 (10)	<0.4	<0.4
ICIQ-FLUTS	Pre-MUS	87.8 (25.3)	77.6 (25.9)	91.5 (18.7)	83.4 (24.8)	78.6 (24)	<0.2	<0.2
	F-up	34.6 (25,6)	20.1 (25.9)	39.3 (28)	24.8 (22.9)	14,2 (25)	<0.001*	<0.03*

** statistical significance. **Anova multivariate analysis considering all DU groups and control group. ***Anova multivariate analysis considering only DU groups without control group. Student's test. Mann Whitney test. Qmax: maximum peak flow; VV: voided volume; PVR: post-void residual urine; PVR-R%: post-void residual urine-ratio; MUS: middle urethral sling; SUI: stress urinary incontinence; OAB: overactive bladder; ICIQ-FLUTS: International Continence Index Questionnaire Urinary Female LUTS*

Table 2. Comparison between pre-op data and outcomes at 2-yrs f-up in each group; evaluation of SUI recurrence rate, new onset of OAB and comparison among groups on both pre-op data and outcomes at f-up

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Internal **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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DOES OVERNIGHT AUDS CHANGE MANAGEMENT STRATEGIES AND IMPROVE LONG-TERM OUTCOMES IN PATIENT'S PRESENTING WITH ISOLATED SYMPTOMS OF NOCTURIA AND/OR NOCTURNAL ENURESIS?

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HYPOTHESIS / AIMS OF STUDY

Overnight ambulatory urodynamics (aUDS) is performed as a second-stage test in patients with isolated nocturnal symptoms in whom conventional or video urodynamics have been non-diagnostic. The aims of this study were to determine if a urodynamic diagnosis of detrusor overactivity (DO) or urge urinary incontinence (UUI) on overnight aUDS resulted in a change in patient management and an improvement in their urinary symptoms.

STUDY DESIGN, MATERIALS AND METHODS

Twenty-five consecutive patients (28% male) having overnight aUDS whose most bothersome urinary symptoms were nocturia and/or nocturnal enuresis seen at our tertiary referral centre between November 1998 and August 2018 were identified from our prospectively acquired database and retrospectively reviewed. Their median age was 38 years (range 18-86). All patients had previously had conventional pressure-flow studies or video UDS (vUDS). aUDS were performed when conventional UDS were non-diagnostic or when the conventional UDS diagnosis was contradictory to the patient's major presenting symptom of nocturia and/or nocturnal enuresis. Six patients were excluded because follow-up data was not available. All conventional UDS, vUDS and overnight aUDS studies were analysed by an experienced urodynamicist and reviewed at a multidisciplinary team (MDT) meeting to ensure accuracy of diagnosis and to determine treatment options.

Data are expressed as mean ± standard deviation and P-values were calculated using a two-tailed unpaired student t-test for pairwise comparisons of parametric data, unless otherwise stated. Categorical data are expressed as number (percentage) and compared with the Fisher Exact test. A $P < 0.05$ was considered statistically significant. Analysis was performed using SigmaPlot 12.5 (Systat Software Inc, San Jose CA) statistical analysis package.

RESULTS

Following overnight aUDS all studies were evaluable and a definitive UDS diagnosis of DO was made in 79% (n=19) of 24 patients presenting with nocturia (mean DO pressure 69.1 ± 53.3 cmH2O) and in 90% (n=18) of the 20 patients

presenting with nocturnal enuresis. UUI was demonstrated in 80% (n=16) of the 20 patients presenting with nocturnal enuresis. Of the remaining patients, five had a diagnosis of sensory urgency confirmed and one patient was diagnosed with reduced functional capacity due to high PVRs. A change in the primary UDS diagnosis occurred in 80% (n=20) of patients following aUDS.

INTERPRETATION OF RESULTS

Nineteen patients had post aUDS follow-up data available for review. DO was demonstrated in 14 of the 15 patients who presented with nocturnal enuresis, and the final patient was found to have reduced functional capacity due to high PVRs. Of the remaining four patients who presented with isolated nocturia symptoms, one patient was found to have DO and the remaining three patients had a diagnosis of sensory urgency confirmed.

Therefore, 84% (n=16) of this patient sub-group had their clinical diagnosis and management changed following aUDS. In the 15 patients who had DO demonstrated 3 were treated with a clam, 5 were treated with Botox, and the remaining patients were treated with combination medical therapy after refusing Botox/ surgery. Of the three patients with confirmed sensory urgency, one patient was treated with reduced fluid intake, one was treated with desmopressin and the final patient was sent for cognitive behavioural therapy. The patient diagnosed with reduced functional capacity due to high PVRs had their catheterisation technique reviewed by the urology clinical nurses specialist and was advised to catheterise more often.

These treatment changes led to a statistically significant improvement in the reported urinary symptoms of daytime frequency, nocturia and nocturnal enuresis in 79% of patients (Table 1). 61% (11 out of 18) of patients had resolution of their noctuira and 73% (11 out of 15) of patients had resolution of their nocturnal enuresis.

CONCLUDING MESSAGE

This is the first study to show that overnight aUDS studies demonstrated DO in 79% of patients presenting with nocturia and 90% of patients presenting with nocturnal enuresis. 80% of patients presenting with nocturnal enuresis were also demonstrated to have a diagnosis of UUI. Therefore, the clinical diagnosis and subsequent management pathway were changed in 84% of patients. This resulted in a significant improvement in symptomatic outcomes. 61% of patients had resolution of their noctuira and 73% of patients had resolution of their nocturnal enuresis.

FIGURE 1

Parameter	Pre Overnight Ambulatory Urodynamics	Post Overnight Ambulatory Urodynamics	P-Value
Nocturia, N(%)	18(95)	7(37)	0.004
Nocturnal Enuresis, N(%)	15(79)	4(21)	0.0009
Day Time Frequency, N(%)	12(63)	5(26)	0.0489
SUI, N(%)	4(21)	4(21)	1

Table 1

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective review of historical data and registered as an audit **Helsinki** not Req'd Retrospective review of historical data **Informed Consent** No

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CHANGES IN URODYNAMIC PARAMETERS IN NEUROGENIC BLADDER PATIENTS WITH OR WITHOUT VESICOURETERAL REFLUX UNDERGOING SACRAL NEUROMODULATION

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HYPOTHESIS / AIMS OF STUDY

This original retrospective study was to assess the changes in urodynamic parameters in NB patients with or without vesicoureteral reflux (VUR) who underwent sacral neuromodulation (SNM).

STUDY DESIGN, MATERIALS AND METHODS

We retrospectively reviewed the records of 19 patients with neurogenic lower urinary tract dysfunction (NLUTD) who underwent SNM at our center from July 2018 to July 2019. Clinical data and video-urodynamic parameters were collected. The inclusion criteria: a clear history of neurogenic disease; video urodynamic examination showed DO or low bladder compliance with or without VUR; ineffective or intolerable for anticholinergic drugs; not willing to accept botox injection or augmentation cystoplasty. The patients with complete spinal cord injury or wheelchair use were excluded. The test results were evaluated through a urodynamic evaluation. The criteria used to implant the sacral neuromodulator was that the safe bladder volume was enough for intermittent catheterization. If the test was positive at the end of test phase, an implant (InterStim Model 3058; Medtronic, Inc., Minneapolis, MN, USA) was implanted.

RESULTS

Between 7/2018 and 7/2019, 19 patients (11 women and 8 men), mean age 32±14.1 years, received test stimulation for treating NLUTD. Neurological diseases included spina bifida(9 patients), incomplete spinal cord injury(4 patients), en-

cephalomyelitis(3 patients), pelvic surgery(2 patients), spinal cord surgery(1 patient). The mean time between the onset of the underlying neurological disease and the test was 8.8±8.10 years. All the patients had low bladder compliance and/or DO with or without VUR in storage period and no voluntary detrusor contraction in voiding period. Preoperative urodynamic evaluation data was in table 1. These patents all needed the Credé maneuver, Valsalva maneuver, or triggered reflex voiding during the voiding phase or indwelling catheter before the testing phase. All patients were operated on by the same experienced urologist.

The mean test duration was 24±8.2 days. The urodynamic evaluation at the end of the testing phase showed a significant increase in the mean maximum cystometric capacity (136.3±118.2 vs. 216.5±137.8 ml, P=0.0071) and compliance (8.7±8.5 vs. 18.3+16.5 ml/H2O, P=0.016), as well as a decrease in the maximum intravesical pressure (57.0±39.2 vs. 36.6±31.2 H2O, P=0.0064).

Eight of 19 patients had DO revealed by urodynamic evaluations at baseline. At the end of the testing phase, the DO in 4 patients disappeared according to urodynamic re-evaluations. In the remaining 4 patients, the volume of first uninhibited detrusor contraction and maximum detrusor pressure during uninhibited detrusor contraction all improved (92.5±33.8 vs. 153.0±64.5ml; 100.8±32.7 vs. 77.3±36.1 H2O), although there was no significant difference (P>0.05). In the voiding phase, none of the patients had detrusor contraction.

Before the testing phase, 12 of 38 ureter units (10 patients) had VUR. According to urodynamic re-evaluations at the end of the testing phase, the VUR in 3 of 12 ureter units disappeared. The grade of VUR or the volume before VUR improved in 8 ureter units, and the remaining 1 did not change significantly (table 2).

Implantation was performed in 16 cases. Three patients (patients 6, 7, and 8 in table 2) did not undergo implantation of the stimulator. After permanent implantation, all patients needed intermittent catheterization to empty the bladder in order to avoid damage to the upper urinary tract because VUR or detrusor underactivity still existed. In addition to SNM, 10 of the 16 patients also took anticholinergic drugs in the follow-up treatment. The remaining three patients, who did not have permanent implants, underwent augmentation cystoplasty with or without nonrefluxing ureteral reimplantation, as well as intermittent catheterization

INTERPRETATION OF RESULTS

In some neurogenic bladder (NB) patients, detrusor overactivity (DO) and poor compliance may lead to a high intravesical pressure during urine storage. This high pressure will result in vesicoureteral reflux (VUR), hydronephrosis and even renal failure.

In the treatment of NB with SNM, clinicians pay more attention to the improvement of clinical symptoms[1]. However, as a very important parameter in the management of patients with NLUTD, the pressure of the detrusor during the filling period is rarely used to evaluate the success of SNM treatment.

In this study, SNM not only improved the mean maximum cystometric capacity , compliance and the maximum intravesical pressure but also cured or reduced VUR. Because SNM can play a positive role in the filling period and improve the function of urine storage, it can protect the UUT or improve the damaged UUT.

An implant was performed in 16 cases after the testing phase. According to the results of urodynamic examination, SNM improves the storage function but does not significantly improve the voiding function of the bladder. The patient is still unable to urinate autonomously. Therefore, there is still a risk imposed on the UUT[2]. To protect the UUT, these patients still rely on intermittent catheterization to empty the bladder after permanent implantation.

CONCLUDING MESSAGE

This retrospective study indicates that SNM can improve the urinary storage function of the bladder in appropriate patients with NLUTD. For patients with VUR, SNM can cure or reduce VUR by improving DO and bladder compliance.

FIGURE 1

Table 1. Preoperative Urodynamic Evaluation Data

Urodynamic evaluation	N=19
Bladder contractility	
Detrusor overactivity with impaired contractility	8
Acontractile detrusor	11
Compliance	
>20 ml/cm H2O	3
<20 ml/cm H2O	16
Vesicoureteral reflux	38 units (19 patients)
0	27
I	2
II	3
III	3
IV	1
V	3

FIGURE 2

Table 2. VUR at the baseline and testing phases

	Baseline		Testing phase	
	Grade of VUR	The volume before VUR (ml)	Grade of VUR	The volume before VUR (ml)
1	Left II	71		
2	Left III	46	I	48
3	Left I	57		
4	Left II	42	I	120
5	Left III	45	I	149
6	Left IV	70	II	75
	Right I	227		
7	Left III	104	II	64
8	Left V	117	V	106
	Right V	60	V	66
9	Right II	64	I	68
10	Left V	98	III	250

REFERENCES

1. Chen G and Liao L: Sacral neuromodulation for neurogenic bladder and bowel dysfunction with multiple symptoms secondary to spinal cord disease. Spinal Cord 2014;53:204.
2. Amarenco G , Samer Sheikh Ismaël, Chesnel C et al: Diagnosis and clinical evaluation of neurogenic bladder. European journal of physical and rehabilitation medicine 2017;53:975.

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QUANTIFICATION OF SPONTANEOUS RHYTHMIC CONTRACTIONS IN INDIVIDUALS WITH AND WITHOUT OVERACTIVE BLADDER: IS ALL DETRUSOR OVERACTIVITY CLINICALLY RELEVANT?

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HYPOTHESIS / AIMS OF STUDY

Spontaneous Rhythmic bladder Contractions (SRC) are thought to allow the bladder to maintain tone throughout filling and prepare for a productive active voiding contraction to occur at any volume. SRC have been shown to be elevated in muscle strips taken from patients with overactive bladder (OAB) [1] and are identified clinically in bladders with detrusor overactivity (DO) [2]. The aim of this study was to compare objectively identified SRC during the first and second halves of filling in individuals with and without OAB symptoms.

STUDY DESIGN, MATERIALS AND METHODS

Individuals with and without urgency based on ICIq-OAB survey question 5a were prospectively enrolled in a urodynamics (UD) study. Participants were grouped as no/low OAB (5a=0-2) or high OAB (5a=3-4). Vesical and abdominal pressure tracings from these studies were analyzed iteratively throughout the entire filling phase to determine which volume regions contained significant rhythmic amplitude (≥1cm-H2O) in vesical pressure in the frequency range of 1.75 to 8.0 cycles/minute that was independent of rhythmic activity in abdominal pressure (S&I) using an established algorithm [3]. The maximum SRC amplitude and the corresponding frequency were recorded, along with the volumes at which S&I SRC was detected. Individuals were grouped based on whether S&I SRC occurred 1) only during the first half of filling (<50% cystometric capacity, "First Half Only") or 2) during only the second half of filling or throughout filling ("Second Half or Throughout").

RESULTS

Data from 143 consecutive participants with sufficient data were analyzed and 49 (34%) were found to have S&I SRC, and these were grouped based on OAB (no/low OAB: n=31/98, 32% or high OAB: n=18/45, 40%). The maximum S&I SRC amplitude was elevated in the high OAB group compared to the no/low OAB group (12.6 cm-H20 and 5.7 cm-H20, respectively, t-test, $p<0.05$), but the corresponding frequencies were not different (3.85 cycles/minutes and 4.72 cycles/minute, respectively, $p>0.05$). Of those found to have S&I SRC in the First Half Only of filling, only 1/14 had high OAB (Fig 1). The presence of S&I SRC during the First Half Only

was significantly associated with no/low OAB (Fisher's exact test, $p<0.05$, Fig 1, *).

INTERPRETATION OF RESULTS

In this study, S&I SRC was identified in several participants with and without high OAB based on the symptom of urgency, suggesting 1) that not all quantifiable contractile activity, or DO, during UD filling necessarily leads to OAB symptoms or 2) that SRC may be an artifact of UD in some participants. Specifically, individuals with S&I SRC in the First Half Only did not have high OAB (13/14, 93%), suggesting that SRC during the First Half Only of filling may not be clinically relevant. In contrast, individuals with high OAB had S&I SRC either in the Second Half or Throughout filling.

CONCLUDING MESSAGE

This study suggests that DO identified only during early filling may not be as clinically relevant as DO identified either throughout filling or in later stage filling. Additional studies are needed to determine whether the portion of the filling phase where SRC occurs correlates with the presence of OAB or its severity.

FIGURE 1

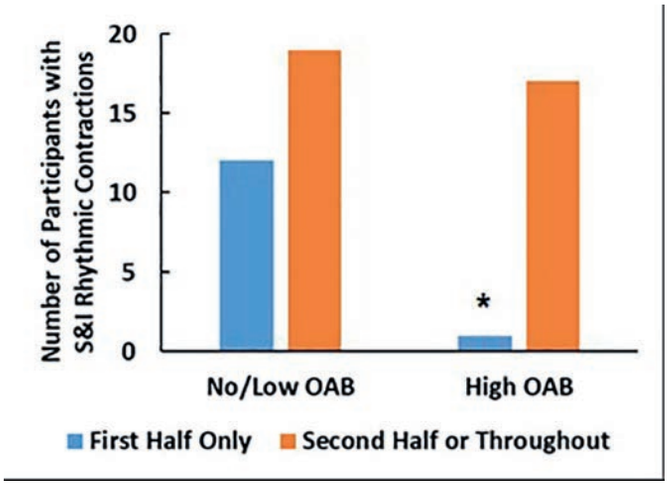

Fig. 1: Number of participants with no/low OAB vs. high OAB with S&I SRC in the First Half Only or in the Second Half or Throughout Filling

REFERENCES

1. Kinder RB, Mundy AR. Pathophysiology of idiopathic detrusor instability and detrusor hyper-reflexia. An in vitro study of human detrusor muscle. Br J Urol. 1987;60(6):509-515.
2. Colhoun AF, Speich JE, Cooley LF, Bell ED, 3rd, Barbee RW, Guruli G, Ratz PH, Klausner AP. Low amplitude rhythmic contraction frequency in human detrusor strips correlates with phasic intravesical pressure waves. World J Urol. 2017;35(8):1255-1260.
3. Cullingsworth ZE, Kelly BB, Deebel NA, Colhoun AF, Nagle AS, Klausner AP, Speich JE. Automated quantification of low amplitude rhythmic contractions (LARC) during real-world urodynamics identifies a potential detrusor overactivity subgroup. PLoS One. 2018;13(8):e0201594.

Funding NIH grant R01DK101719 **Clinical Trial** No **Subjects** Human **Ethics Committee** Virginia Commonwealth University Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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HOW DO WE DIAGNOSE DETRUSOR UNDERACTIVITY? THE POTENTIAL OF PARAMETERS CALCULATED WITH WATTS FACTOR

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HYPOTHESIS / AIMS OF STUDY

Detrusor underactivity (DU) increases with age. The International Continence Society definition of DU contains two different pathophysiological causes, namely weak detrusor contraction force and abnormally short detrusor contractions. Each of the incidence and prevalence of the condition is highly dependent on both the definition and diagnostic methods used. Urodynamic studies have attempted to define DU, but no precise definition is widely accepted. Widely used measurements of bladder contractility are bladder contractility index (BCI) and the Watts factor (WF). Impaired bladder contraction represent not only decreased the peak of WF, but also poorly sustained contractions. From this point of view, the maximum height of the resulting curve (Wmax) and its pattern should be discussed separately. In the present study, we compare several contemporary urodynamic criteria and parameters calculated with WF.

STUDY DESIGN, MATERIALS AND METHODS

Thirty five patients with pre and post radical prostatectomy were evaluated. The urodynamic parameters included the maximum flow rate (Qmax), postvoid residual volume (PVR), detrusor pressure at maximum flow (Pdet at Qmax), Wmax, W (Qmax), BCI (bladder contractility index; Pdet Qmax + 5Qmax), rV (Wmax), Line (W), W80-W20 were examined. (Each definition was shown in figure)

(BCI; Pdet Qmax + 5Qmax, and parameters calculated with WF (rV: volume of fluid during emptying and was expressed in a relative volume (rV = 1; completely full bladder and rV = 0: volume of residual urine), Line (W); slope of a straight line fitted to the W function between, rV = 0.20 and rV = 0.80; rV (Wmax), relative bladder volume at which this maximum occurred; W80-W20, value of W at a relative volume rV = 0.80 minus its value at a relative volume rV = 0.20) (Figure).

RESULTS

After radical prostatectomy, Qmax increased significantly (pre: 13.6 ± 6.7, post: 18.0 ± 7.0 ml/min; P < 0.01), whereas PdetQmax and PVR decreased significantly (50.6 ± 21.0 and 29.9 ± 16.9 cmH2O, 51.3 ± 61.9 and 15.1 ± 28.6 ml; P < 0.05). BCI, Wmax and W (Qmax) did not change significantly after radical prostatectomy (123.7 ± 36.0 and 114.0 ± 19.9, 11.5 ± 2.8 and 11.1 ± 3.0 W/m2, 8.8 ± 2.6 and 9.7 ± 2.9 W/m2), but rV(Wmax), Line(W), W80 – W20 decreased significantly (0.47 ± 0.3 and 0.20 ± 0.20, –0.0016 ± 0.01 and –0.010 ± 0.01 W/m2/mL, –0.4 ± 2.0 and –2.1 ± 2.6 W/m2; P < 0.05).

INTERPRETATION OF RESULTS

Wmax and W (Qmax) represents the maximum power of bladder contraction at a particular point in time, whereas rV(Wmax) Line(W), W80 – W20 can be used to detect whole detrusor contraction pattern. The commonly used threshold values for the definition of DU are BCI < 100 or W max < 7 W/m2. In our current study, we couldn't detect DU using these criteria. However, parameters calculated with WF detect subtle change or pattern of micturition.

CONCLUDING MESSAGE

The parameters calculated with Watts factor provides some insight into the diagnosis of DU.

FIGURE 1

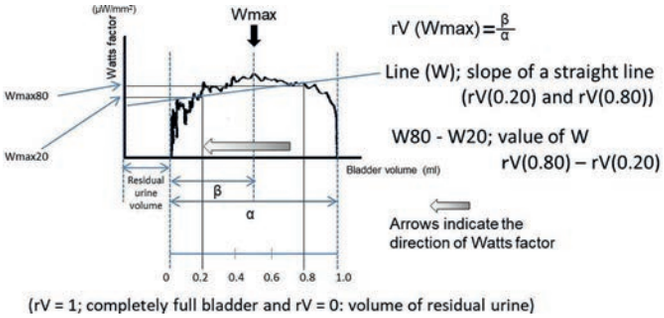

Figure definition of parameters

FIGURE 2

	Pre	Post	P
Bladder capacity (mL)	376 ± 128	354 ± 108	NS
Q_{max} (mL/s)	13.6 ± 6.7	18.0 ± 7.0**	<0.01
$P_{det}Q_{max}$ (cmH_2O)	50.6 ± 21.0	29.9 ± 16.9**	<0.01
Residual urine volume (mL)	51.3 ± 61.9	15.1 ± 28.6**	<0.01
BCI	123.7 ± 36.0	114.0 ± 19.9	NS
W_{max} (W/m^2)	11.5 ± 2.8	11.1 ± 3.0	NS
W (Q_{max}) (W/m^2)	8.8 ± 2.6	9.7 ± 2.9	NS
rV (W_{max})	0.47 ± 0.3	0.20 ± 0.20**	<0.01
Line(W) ($W/m^2/mL$)	−0.0016 ± 0.01	−0.010 ± 0.01 *	<0.05
W80 – W20 (W/m^2)	−0.4 ± 2.0	−2.1 ± 2.6*	<0.05

Table Results of the pressure flow studies

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** 017-0472 **Helsinki** Yes **Informed Consent** Yes

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ABDOMINAL LEAK POINT PRESSURE - A SIMPLE WAY TO PREDICT URINARY INCONTINENCE FOLLOWING SURGICAL TREATMENT OF UNILATERAL ECTOPIC URETER IN GIRLS

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HYPOTHESIS / AIMS OF STUDY

Conventional treatment of ectopic ureter is reimplantation. However, in some case of ectopic ureter - unilateral ectopic ureter (UEU), subsequent malformation of the bladder neck may result in postoperative persistent incontinence and ureteric reimplantation alone may not solve the urological symptoms. This unusual scenario has been described in literature in association of bilateral single system ectopic ureters, but persistent incontinence following surgical management

of UEU with ureteral opening at or distal to bladder neck in girls have not been clearly addressed in literature.

STUDY DESIGN, MATERIALS AND METHODS

Twenty three female children operated for UEU between January 2009 to May 2018 were evaluated after getting Institutional approval. History including presenting complaints and other relevant symptoms were noted. The age and other basic demographic profile were recorded. Blood investigations including hemogram and renal function tests were done with other workup for pre anesthetic clearance. An ultrasonography was performed in all patients to rule out other anomalies. Further imaging in the form of Intravenous urography (IVU), Contrast enhanced CT (CECT) scan or Magnetic Resonance (MR) urography were done as required to establish a diagnosis on a case to case basis. An MCU (micturating cystourethrogram) was obtained in all patients to assess the bladder capacity and status of the bladder neck. A dynamic renal scan with L-ethyl cysteine was done in all patients to assess the drainage and split function of the ectopic system.

All patients underwent a urodynamic assessment preoperatively after obtaining ethical clearance. Patients were positioned in sitting position and 7 Fr pressure transducer catheter was inserted into the bladder to measure the intravesical pressure. Intraabdominal pressure was monitored via a rectal probe. The bladder was filled with saline at a rate of 5 to 10 ml/min depending on the weight of the patient to a volume of 150 ml or approximately half of the estimated functional capacity. The patient was then instructed to perform a Valsalva manoeuvre (expulsive effort against a closed glottis). The lowest increase in vesical pressure which results in sudden urinary leakage during this manoeuvre was considered as her ALPP.

Patients with a non functioning kidney/moiety or poorly functioning kidney/ moiety (<10% contribution of the global renal function) with ectopic ureteric insertion underwent nephroureterectomy and those patients with functioning system underwent reimplantation or ureterourterostomy.

All patients underwent cystoscopic examination prior to the definitive procedure. The cystoscopic findings were noted such as the bladder capacity, position of the ectopic ureteral orifice and the status of the bladder neck and trigone. Reimplantation was done in funcitoning moieties either by an open Cohen cross trigonal approach or by a laparoscopic extravesical approach over a double J stent.

The patients who had leak in the first 3 months of their postoperative period were managed conservatively with anticholinergics. The patients were then assessed again for persistent urinary incontinence after three months. The patients were divided into two groups depending on the status of incontinence. Group A included the patients who had persistent incontinence at 3 months and Group B included those patients who were completely dry at 3 months. Patients with very low ALPP (less than 30 cm H2O) were taken for bladder neck reconstruction procedure. Patients with more than 30 cm H2O ALPP were managed with conservative management with Kegels exercise and/or anticholinergics for a period of 6 weeks. Those who did not respond with conservative management during this time period were managed with bulking agents (Macroplastique®/Deflux®) at the bladder neck.

Statistical analysis was done using IBM® SPSS® v23.0. Mean and standard deviation were used for descriptive statistics. Chi-square test for categorical variables and Mann-Whitney U test for continous variables were used to test significance and p value < 0.05 was considered signficant.

RESULTS

Twenty three girls were operated for UEU with their ureteric orifice at or distal to bladder neck with mean age of 10.9 ± 3.15 yrs. Six underwent nephroureterectomy and 17 had reimplantation/ureteroureterostomy. Nine (39.1 %, Group A) girls had varying degree of incontinence postoperatively and 14 (60.9%, Group B) were dry. In group A, cystometrogram had demonstrated abdominal leak point pressure (ALPP) < 60 cm of water in 7 patients with mean ALPP of 43.9 ±16.15 while only one patient in Group B demonstrated leak. Preoperative ALPP predicted leak with 90% PPV. In Group A, 3 patients were managed with bladder neck reconstruction and two with bulking agents (Macroplastique® or Deflux®) and became completely dry. One improved with conservative management and three patients were lost to follow up.

INTERPRETATION OF RESULTS

Twenty three girls were operated for UEU with their ureteric orifice at or distal to bladder neck with mean age of 10.9 ± 3.15 yrs. Six underwent nephroureterectomy and 17 had reimplantation/ureteroureterostomy. Nine (39.1 %, Group A) girls had varying degree of incontinence postoperatively and 14 (60.9%, Group B) were dry. In group A, cystometrogram had demonstrated abdominal leak point pressure (ALPP) < 60 cm of water in 7 patients with mean ALPP of 43.9 ±16.15 while only one patient in Group B demonstrated leak. Preoperative ALPP predicted leak with 90% PPV. In Group A, 3 patients were managed with bladder neck reconstruction and two with bulking agents (Macroplastique® or Deflux®) and became completely dry. One improved with conservative management and three patients were lost to follow up.

CONCLUDING MESSAGE

More than one third girls with unilateral ectopic ureter suffered from varying degrees of persistent postoperative incontinence. A low ALPP (<60 cm H2O) could reliably predict the possibility of postoperative incontinence specially in single system ectopics. This may further help in counselling the

parents for the probable need of secondary procedures for complete resolution of urological symptoms.

FIGURE 1

Table1

	Number of patients	
	Group A (n = 9)	**Group B (n = 14)**
Leak on CMG	9/9	1/14
D O (detrusor overactivity)	2	-
ALPP	43.89 ± 16.15 cm H_2O	90 cm H_2O

Cystometrogram findings

FIGURE 2

Table 2: Absolute ALPP in Group A patients

Sl No	Group A
1	20 cm H2O
2	30 cm H2O
3	30 cm H2O
4	40 cm H2O
5	40 cm H2O
6	50 cm H2O
7	55 cm H2O
8	60 cm H2O
9	70 cm H2O

Absolute ALPP in Group A patients

REFERENCES

1. Stavrinides V, Charlesworth P, Wood D, et al. Isolated bilateral simplex ureteric ectopia: Bladder capacity as an indicator of continence outcome. J Pediatr Urol. 2017;13(5):493.e1-493.e9.
2. Roy choudhury S, Chadha R, Bagga D, Puri A, Debnath PR. Spectrum of ectopic ureters in children. Pediatr Surg Int. 2008;24(7):819-23.

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PREOPERATIVE FUNCTIONAL ASSESSMENT OF MEN UNDERGOING RADICAL PROSTATECTOMY; CORRELATION OF CLINICAL AND URODYNAMIC PARAMETERS.

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence (UI) following radical prostatectomy (RP) requiring one or more pads a day is experienced by nearly half of all men at 6 months after RP compared to 1% at baseline(1). Post RP UI has a detrimental effect on quality of life (QoL) for up to 2 years after RP when compared to active monitoring. Aside from membranous urethral length measured on MRI, no strong predictive factors for post-RP UI have been identified (2).

The Robotic and Open Surgery for Prostate Cancer: A Prospective, Multi-centre, Comparative Study of Functional and Oncological Outcomes (ROSE) study was set up in 2017 to assess oncological and functional outcomes of men undergoing robot assisted RP compared to open RP. The primary outcomes are oncological (positive surgical margins, extracapsular extension etc), urinary and sexual functional outcomes using EPIC and IIEF questionnaires and QoL outcomes using the physical and mental functioning domains of the SF-36 V2 questionnaire. Secondary outcomes of the ROSE study include the identification of urodynamic , dynamic 3D pelvic floor US and anatomical features such as prostate volume and urethral length measured on MRI and 3D pelvic floor US, that may impact urinary function after RP. Previous studies have shown moderate to severe LUTS to be present in 37% - 50% of men undergoing RP(3). The urodynamics of men undergoing RP has not been prospectively evaluated to date.

This study aims to analyse the baseline lower urinary tract symptoms, urodynamic parameters and establish any correlations in this contemporary cohort of men with localised prostate cancer undergoing open and robot assisted RP.

STUDY DESIGN, MATERIALS AND METHODS

Men over 18, clinically suitable for radical prostatectomy and cognitively able to give consent were prospectively recruited into this trial.

Baseline oncological demographics together with IPSS, EPIC, IIEF questionnaires were collected at baseline and 2 weeks, 6 weeks, 3 months, 6 months, 9 months and 12 months.

At baseline, men underwent urodynamic studies following ICS guidelines and functional 2D and 3D pelvic floor Ultrasound. Men did not undergo urodynamics if their surgery was planned in less than 4 weeks from the date of initial assessment.

Demographic and clinical characteristics of patients were compared using chi-square tests and Fisher's test. Mean differences in scores between patient groups was compared using t tests or Wilcoxon rank sum tests depending on the distribution of the data.

RESULTS
88 men were prospectively recruited, with mean age 63.6 (44.5-77.8) years to undergo clinical assessment, urodynamic testing and functional pelvic floor ultrasound prior to RP.

Of 74 patients with complete baseline data, 39(53%), 28(38%) & 7(9%) had mild (IPSS <8), moderate (IPSS 8-19) & severe (IPSS>20) LUTS. Urodynamic abnormalities were noted in 41/88(46%). Of 62 patients who completed the voiding phase, 18(29%) were obstructed (BOOI>40) and 9(15%) showed poor contractility (BCI<100).

Of 38(52.1%) patients who reported overactive bladder (OAB), 19(50%) had urodynamic filling abnormalities.

Of 15(19%) patients with DO on UDS, 12(80%) reported OAB. Of 17(18%) who were obstructed, 6(35%), 10(59%) and 1(14%) reported mild, moderate and severe LUTS. Patients with filling abnormalities had higher IPSS-storage scores ($p = 0.01$) and lower filling capacity ($p = 0.02$).

INTERPRETATION OF RESULTS
OAB, moderate & severe LUTS are all more common in patients undergoing radical prostatectomy. Approximately 50% of all men undergoing radical prostatectomy were found to have moderate or severe LUTS

29.5% of men undergoing radical prostatectomy were obstructed on baseline UDS. Less than 50% of all men reporting OAB have urodynamic filling abnormalities. In those with DO on UDS, 80% reported OAB symptoms at baseline

The 20% with asymptomatic detrusor overactivity may represent a group whose symptoms significantly deteriorate after radical prostatectomy.

CONCLUDING MESSAGE
Identification of significant voiding and storage dysfunction preoperatively may allow better counselling and management of urinary function recovery post RP.

REFERENCES
1. Donovan J et al, N Engl J Med 2016; 375: 1425-1437
2. Mungovan S et al, Eur Urol 2017; 71: 368-378
3. Prabhu V et al, J Urol 2014; 191: 412-417

Funding N/A **Clinical Trial** Yes **Registration Number** Australia New Zealand clinical trials registry (ANZCTR), ACTRN12617000296336 **RCT** No **Subjects** Human **Ethics Committee** Royal Prince Alfred Hospital Ethics Review Committee, Royal Prince Alfred Hospital, Missenden Road Camperdown NSW 2050, Australia **Helsinki** Yes **Informed Consent** Yes

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UTILITY OF VIDEOURODYNAMICS, IMAGING, AND CYSTOSCOPY IN VOIDING DYSFUNCTION AND RECURRENT URINARY TRACT INFECTIONS: SHOULD WE THROW IN THE KITCHEN SINK?

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HYPOTHESIS / AIMS OF STUDY
Recurrent urinary tract infection (rUTI) is a very common outpatient problem. However, there is a variety of practices and paucity of quality evidence as to how best these patients should be managed. This is the largest study that evaluates the utility of videourodynamics (VUD), the role of additional imaging, and cystoscopy in the complete workup of these patients with rUTI. The specific questions we wanted to address were: 1. In patients with rUTI, what is the utility of VUD? and 2. What is the role of additional imaging or cystoscopy?

STUDY DESIGN, MATERIALS AND METHODS
This is a retrospective cohort study that was performed on 1031 consecutive patients referred for physician performed VUD from 2013-2019. All patients with rUTI were then selected for further data collection. We defined rUTI as 3 or more episodes in the past year or at least 2 in the past 6 months. Patients were excluded if they were pregnant, had indwelling catheters, performed intermittent self-catheterization or had incomplete data. Subsequent repeat VUD encounters were also excluded. Institutional ethics board approval was obtained, and data were collected and analyzed on demographics, symptoms, cystoscopy results, imaging, and VUD parameters.

RESULTS
After 1031 VUD were reviewed, 132 patients were included after applying exclusion criteria. The median age was 62 years (range: 18-87). There were 115 females and there were 17 (13%) men. A cause for rUTI was identified on VUD in 88 (67%) patients. Causes found included obstruction, Fowler's syndrome, detrusor sphincter dyssynergia, and detrusor underactivity. About half of all patients were referred for VUD with rUTI as the primary indication; n=73 (55%).

Interestingly, 88/132 (67%) patients presented with voiding symptoms. Importantly, in those with a history of voiding symptoms, 68/88 (77%) had an identifiable cause for rUTI found in VUD, compared with those without a history of voiding symptoms 20/44 (45%) p=0.00056. Gender was not predictive for finding an identifiable cause for rUTI; p=0.861.

There were 42 patients (32%) with an obvious neurogenic history. Cystoscopic abnormalities was seen in 27 patients, majority of which were of low clinical significance (inflammation, cystitis cystica). Fluoroscopy was abnormal in 19 patients (vaginal prolapse, vesico-ureteric reflux, trabeculation, diverticuli, and high residual volume). In patients investigated primarily for rUTI, there were 59 patients with additional imaging available (ultrasound or CT) with none being diagnostic for rUTI cause. No patients had malignancy found on imaging or cystoscopy.

INTERPRETATION OF RESULTS

In patients with rUTI and a history of voiding symptoms, VUD is an important investigative step to find a possible underlying cause. This step helps direct specific treatment and offers management options. We have shown that in these selected patients, a very high proportion (77%) will have some treatable VUD diagnosis. Even those without a specific history of voiding symptoms may benefit from additional VUD, as overall, 67% had a cause found.

The addition of other imaging or cystoscopy to VUD was not helpful in diagnosing any more causes of rUTI. Importantly, no important diagnosis were found that were not explained by VUD. Nor were there any alarming diagnoses found that would be missed if these modalities were omitted, or considered subsequent to VUD.

CONCLUDING MESSAGE

This study confirms that VUD is useful in selected patients with rUTI, as many of these patients have identifiable and treatable causes. Use of VUD is warranted in those with a history of voiding symptoms, as a high percentage of these patients have a diagnosis identified with VUD. Additional imaging, adjunct fluoroscopy, and cystoscopy are unlikely to be of individual benefit.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Austin Health Office for Research **Helsinki** Yes **Informed Consent** No

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IMPORTANCE OF VOIDING DYSFUNCTION AS RISK FACTOR FOR URINARY TRACT INFECTION IN MEN

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HYPOTHESIS / AIMS OF STUDY

Risk factors for urinary tract infection (UTI) has been extensively studied in patients with neurogenic lower urinary tract dysfunction (NLUTD), children and women. Although the prevalence of UTI in adult men is less frequent than in these populations, it has been noted that adult male patients with UTI show high occurrences of predisposing factors (1). Urodynamic dysfunctions are an important risk factor for UTI in NLUTD, children and women. In women, abdominal straining during voiding has been demonstrated to be a risk factor for recurrent urinary tract infections (2). However, studies on urodynamic risk factors for UTI in adult men are scarce. Our hypothesis is that urodynamic dysfunctions are also an important risk factor in men. Consequently, the objective of the present study is to assess if there is any relationship between UTI and urodynamic findings in men.

STUDY DESIGN, MATERIALS AND METHODS

Study design

case-control study

Materials and methods

We carried out a case-control study. Cases were men with UTI. UTI was defined as the presence of lower urinary tract symptoms (LUTS) associated to positive urine culture (>105 colony forming units per millilitre). Controls were men with LUTS and negative urine culture. Inclusion criteria were male 18 years old or over. Exclusion criteria were neurogenic lower urinary tract dysfunction, urinary catheterization, antibiotic treatment, anatomical abnormalities of the urinary tract, urolithiasis and genitourinary neoplasms. We reviewed the most recent urodynamic studies of these patients. The mean interval between the last urodynamic study and urine culture was 12 months. Urodynamic studies were performed according ICS specifications and guidelines of Good Urodynamic practices. Detrusor contractility was calculated using the Bladder Contractility Index (BCI) (PdetQmax + 5. Qmax), and urethral resistance using the Bladder Outlet Obstruction Index (BOOI) (PdetQmax – 2. Qmax). Because of no definition of abdominal activity during voiding has been made by ICS, we measured this parameter by multiplying de abdominal pressure increment (defined as the difference between max-

imum abdominal pressure during voiding minus baseline abdominal pressure in cm H2O) by the time of abdominal contraction (in seconds).

The study integrated a sample of 32 cases and 95 controls. Sample size was calculated based on data published by Yang and Huang (3). Assuming that the prevalence of abdominal straining in patients with UTI is 50 % and the prevalence in the control group is 20%, an alpha level of 5%, a statistical power of 80%, and a case/ control ratio of 1 to 3, thus, the minimum sample size should be 30 patients in the case group, and 90 patients in the control group.

Qualitative variables were analysed by the Fisher exact, parametric variables by Student's t test, and non-parametric quantitative data by Mann-Whitney's U. Quantitative data were tested for normal distribution using the Kolmogorov-Smirnov test. A stepwise logistic regression analysis was performed to identify variables that were independently associated with UTI. Statistical significance was set at $p < 0.05$ bilaterally.

RESULTS

Distribution of urodynamic data for both groups is shown in Table 1. The variables that showed significant differences were age (greater in the case group), BOOI (greater in the case group) and abdominal activity (greater in the case group). The multivariate analysis found that age was a dependent variable. Therefore, the variables that independently influenced on urinary tract infection were BOOI and abdominal activity (Table 2).

INTERPRETATION OF RESULTS

It is widely accepted that some urodynamic dysfunctions like post void residual urine and detrusor overactivity are related to bacteriuria, (defined as positive culture urine without considering the presence of LUTS). It has been demonstrated that residual urine increases the bladder microorganism concentration. Detrusor overactivity can alter the shape of bladder and consequently it can retain bacteria. However, the influence of these factors on UTI remain controversial. Bacteriuria does not always lead to UTI because for ITU, bacteria must enter the urinary tract. This depends on virulence of germ and on host factors. It is well known that an intact urinary tract is important for resistance against infection. One of the protective mechanisms is the glycosaminoglycan layer. This layer can be disrupted by increasing intravesical pressure. Intravesical pressure can be increased during voiding phase because of bladder outlet obstruction or abdominal strength. Our study validates this hypothesis because both conditions were related to UTI.

On the other hand, our results also confirm that other urodynamic dysfunctions like post void residual urine, detrusor overactivity or detrusor underactivity did not have influence on UTI presence. Studies that state the influence of these factors on UTI should take into consideration the presence of an increased BOOI or abdominal straining, because of the possible relationship between those factors and BOOI or abdominal straining.

CONCLUDING MESSAGE

There is a relationship in adult males between bladder outlet obstruction index and abdominal straining during voiding and UTI. Adult men with demonstrated UTI should be submitted to a urodynamic study in order to rule out these voiding dysfunctions.

FIGURE 1

Table 1.- Comparing the distribution of urodynamic data between groups

	Case group (UTI) (n= 32)	Control group (no UTI) (n=95)	Significance
Age (years)	69 ± 14.7	62 ± 15.0	0.018‡
Post void residual in free Uroflowmetry (ml)*	78 ± 118.6	60 ± 110.2	0.455
Maximum flow rate in free uroflowmetry (ml/s) *	12 ± 6.4	12 ± 7.6	0.824
Cystometric bladder capacity (ml)*	254 ± 131.9	251 ± 109.1	
Bladder compliance (cm H2O/ ml) *	43 ± 66.0	42 ± 32.8	0.903
Detrusor overactivity †	14 (52%)	42 (46%)	0.381
Urodynamic stress urinary incontinence †	1 (3%)	8 (8%)	0.286
BOOI*	46 ± 27.7	33 ± 31.2	0.037‡
BCI*	116 ± 30.7	107 ± 31.4	0.099
Voiding abdominal activity (cm H2O. s) *	249 ± 213.6	154 ± 263.2	0.008‡

* Mean ± standard deviation. †Number of patients (percentage). ‡ Significant

BOOI. Bladder outlet obstruction index. BCI. Bladder contractility index

Table 1

FIGURE 2

Table 2.- Analysis of multivariate logistic regression.

Variable	Multivariate coefficient	Standard deviation	Significance
BOOI	0.016	0.008	0.036
Abdominal activity	0.002	0.001	0.025
Constant	-2.385	0.480	0.000

Table 2

REFERENCES

1. Childs SJ, Egan RJ. Bacteriuria and urinary infections in the elderly. Urol Clin North Am. 1996;23(1):43-54
2. Salinas J, Virseda M, Méndez S, Menéndez P, Esteban M, Moreno J. Abdominal strength in voiding cystometry: a risk factor for recurrent urinary. Int Urogynecol J. 2015;26(12):1861-5.
3. Yang JM, Huang WC. Implications of abdominal straining in women with lower urinary tract symptoms. Urology 2002; 60(3):428–433

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** San Carlos Hospital Ethics Commitee **Helsinki** Yes **Informed Consent** Yes

200 www.ics.org/2020/abstract/200

CAN UROFLOWMETRY PATTERN PREDICT DETRUSOR UNDERACTIVITY OR OUTLET OBSTRUCTION IN MALE PATIENTS WITH LOWER URINARY TRACT SYMPTOMS?

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HYPOTHESIS / AIMS OF STUDY

Clinical practice for overactive bladder (OAB) has been expanding since the introduction of OAB definition based on "urgency" symptom. On the other hand, there are not yet universally accepted definition of underactive bladder (UAB) reflecting the urodynamic observation of detrusor underactivity (DUA). Many studies have attempted to determine the definition of UAB or to evaluate DUA without invasive urodynamics. Uroflowmetry (UFM) is a non-invasive urodynamic examination to evaluate voiding condition. A wide variety of curve pattern on UFM is traced depending on a condition of detrusor contractility and outlet obstruction. However, there is no internationally accepted definition of how to interpret UFM curve pattern in adults. The ICS terminology only mentions continuous and intermittent pattern on UFM [1]. A recent literature showed that the sawtooth and interrupted pattern on UFM was strongly correlated with DUA diagnosed by invasive urodynamics [2]. They reported that 80% of patients with DUA without bladder outlet obstruction (BOO) represented the sawtooth and interrupted patterns while only 12.8% of patients with BOO without DUA did. If this pattern is reproducible, the UFM curve patterns could help to determine DUA. In this study, we investigated if the UFM curve patterns represented DUA or BOO.

STUDY DESIGN, MATERIALS AND METHODS

According to the statistical calculation based on the previous report, we estimated that the data of 15 patients in each group (i.e., Group 1: BOO without DUA and Group 2: DUA without BOO) would be needed to confirm the occurrence rate of sawtooth and interrupted pattern. Thus, we retrospectively collected 100 consecutive data of male patients who were evaluated using UFM and invasive urodynamics (pressure-flow study). DUA and BOO were diagnosed according to bladder contractility index (BCI) and BOO index (BOOI). DUA and BOO were defined as BCI ≤100 and BOOI >40, respectively. The UFM curve with 2 or more notches was defined as sawtooth pattern and the interrupted pattern was defined if several curves with interruptions reducing to zero were noted (Figure). The occurrence rate of these patterns was compared between the 2 groups. We also compared other UFM parameters including maximum and average flow rate (Qmax and Qave), postvoid residual (PVR), voiding time (VT), time to Qmax, Qmax and Qave corrected by voided volume (cQmax and cQave), the slope to 1st peak flow, the number of notches on the curve (sawtooth pattern), the number of curves (interrupted pattern) and the maximum drop on the sawtooth pattern (Figure).

RESULTS

Among the 100 consecutive male patients, 25 patients in Group 1 and 49 in Group 2 were collected. The sawtooth pattern was observed in 8 patients (32%) in Group 1 and 28 (57%) in group 2 with a significant difference between the 2 groups. The interrupted pattern was observed in 9 (36%) and 24 (49%), and the both patterns was observed in 5 (20%) and 14 (29%), respectively, without significant difference. Among the other parameters, there were significant differences in age, prostatic volume (PV), the slope to 1st peak flow, the number of notches on the curve and the maximum drop between the 2 groups (Table). The area under the curve (AUC) of each significant parameter on ROC curve was 0.75 (age), 0.67 (PV), 0.58 (the slope to 1st peak flow), 0.61 (the number of notches), and 0.76 (the maximum drop), respectively (Table).

INTERPRETATION OF RESULTS

The sawtooth pattern was more frequently observed in patients with DUA than in those with BOO. This is consistent with the previous study [2]. However, in the present study, the sawtooth pattern was observed in as much as 32% of the patients with BOO. The occurrence rate of the interrupted pattern was similar in the 2 groups. Thus, compared with the previous study, the differences detected in these UFM patterns between the 2 groups were subtle in the present study.

Qmax, Qave or VT that are automatically analyzed parameters on UFM were not significantly different between the 2 groups. The new UFM parameters such as the slope to 1st peak flow, the number of notches and the maximum drop might help to distinguish DUA from BOO.

CONCLUDING MESSAGE

The sawtooth UFM pattern is more common in patients with DUA than in those with BOO. New parameters on UFM curve patterns could be helpful to evaluate DUA and BOO without invasive urodynamics.

FIGURE 1

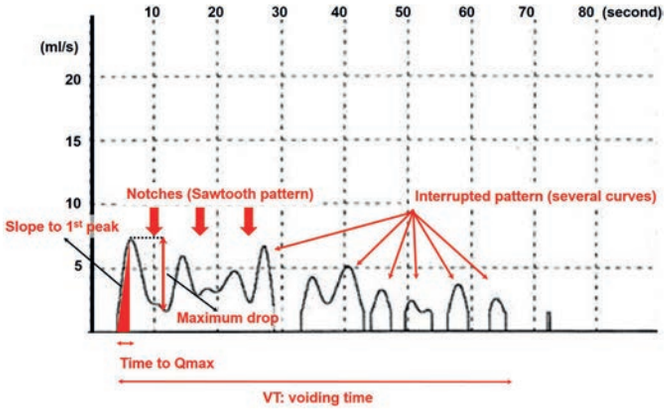

Figure: Representative UFM curve and measured parameters

FIGURE 2

Table: Differences in parameters between groups

	N	Age (yrs)	PV (ml)	PVR (ml)	Qmax (ml/s)	Qave (ml/s)	VT (sec.)	Time to Qmax (sec.)	cQmax (/s*100)	cQave (/s*100)	Slope to 1st peak	No. notches	No. curves	Maximum drop (ml/s)
Group 1 BOO without DUA	25	64.8	43.7	94	11.9	7.8	29.7	8.3	7.3	5.0	2.9	1.6	3.0	4.1
Group2 DUA without BOO	49	71.5	25.6	71	13.2	7.6	39.7	9.2	6.9	4.1	4.1	3.2	3.8	7.2
P value		*0.006*	*0.038*	*0.27*	*0.38*	*0.82*	*0.13*	*0.76*	*0.65*	*0.09*	*0.033*	*0.04*	*0.31*	*0.001*
AUC on ROC		0.75	0.67								0.58	0.61		0.76
Cut-off value		69.0	29.0								3.9	2.0		4.7

BOO: bladder outlet obstruction, DUA: detrusor underactivity, PV: prostatic volume, PVR: postvoid residual, VT: voiding time, cQmax and cQave: corrected Qmax and Qave by voided volume

Table: Differences in parameters between groups

REFERENCES

1. D'Ancona C, et al. Neurourol Urodyn. 38; 433-77, 2019
2. Matsukawa Y, et al. Int J Urol. 27; 47-52, 2020

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Asahikawa Medical University **Ethics Committee Helsinki** Yes **Informed Consent** Yes

201 www.ics.org/2020/abstract/201

UROMONITOR CATHETER-FREE WIRELESS AMBULATORY CYSTOMETRY IS FEASIBLE, SAFE, AND WELL-TOLERATED

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HYPOTHESIS / AIMS OF STUDY

Urodynamics (UDS) is the gold-standard method of quantitatively evaluating the ability of the lower urinary tract to efficiently store and empty urine. However, performing UDS poses numerous challenges including requiring specialized equipment and staff as well as causing patient discomfort. We have developed a wireless catheter-free intravesical pressure sensor, the UroMonitor (Figure 1), to enable bladder monitoring for patients whose symptoms are not confirmed through UDS and to enhance our diagnostic capabilities. In this first ever human subject trial, we aim to evaluate the accuracy of UroMonitor generated pressure data and the feasibility of using the device in humans. We hypothesized that the device would obtain pressure data to describe detrusor activity and be safely placed, well tolerated, and easily extracted in all study participants.

STUDY DESIGN, MATERIALS AND METHODS

This is a proof-of-concept pilot study with an intended sample of 11 subjects from a single institution. Ambulatory adult female patients undergoing evaluation for refractory overactive bladder (OAB) with multi-channel UDS were recruited, excluding those with an active urinary tract infection (UTI), > stage 2b pelvic organ prolapse (POP), neurogenic bladder, interstitial cystitis/bladder pain syndrome (IC/BPS), or history of radical pelvic or anti-incontinence surgery.

The UroMonitor uses low-power flexible electronics housed in a medical silicone housing which curles into a pigtail shape after insertion to remain in the bladder (Figure 1). It wirelessly transmits vesical pressure data at 10 Hz to a small pager-like radio receiver taped to the subject's abdomen. The radio receiver stores the data on a micro secure digital (microSD) memory card and simultaneously transmits it wirelessly to a nearby laptop using Bluetooth. A silk suture was attached to one end of the UroMonitor to aid in transurethral retrieval from the bladder.

A pre-procedure urine culture confirmed the absence of infection. After a baseline standard multi-channel UDS was performed, the UroMonitor was transurethrally inserted into the bladder. The attached suture was taped to the subject's thigh. Flexible cystoscopy confirmed appropriate UroMonitor positioning. The radio was placed on the subject's abdomen and taped at the location of best reception using Tegaderm. An experimental second multi-channel UDS was performed with the device in place while UroMonitor data were received by the radio. Then, the UDS catheters were removed, and the patient was allowed to ambulate and void with only the UroMonitor in place while data were collected wirelessly and catheter-free. A repeat voided urine sample was obtained for culture and heavy metal assay. Then, the UroMonitor was manually extracted from the bladder by pulling on the attached suture. Visual-analog pain scales (VAS) assessed patient discomfort at baseline and after baseline UDS, cystoscopy, UroMonitor insertion, repeat UDS + UroMonitor, the UroMonitor monitoring period, and UroMonitor removal. Overall comfort during testing was also assessed. A follow-up phone call 48-hours post-procedure re-evaluated pain, lower-urinary tract symptoms, or changes in voiding habits.

RESULTS

Our interim results include 3 of 11 patients. It took a median 46 (range: 19 – 81) seconds to insert the UroMonitor. Cystoscopy demonstrated that the UroMonitor was easily inserted into the bladder with no insertion tool or guidewire needed (Figure 1). After UroMonitor insertion, we noted a 22% average reduction in bladder capacity during the testing period (baseline UDS: 335 cc vs. UDS + UM: 262 cc). If phasic DO was appreciated during the baseline study, a 50% increase was noted after UroMonitor insertion (baseline average DO episodes: 3.0 vs. UDS + UM: 4.5). No new UDS findings were elicited after UroMonitor placement during the filling phase. UroMonitor presence did not impede urinary flow (baseline average flow: 8.5 cc/s vs. UDS + UM: 9.3 cc/s, p=0.93).

The UroMonitor reliably reproduced vesical pressure data patterns during both filling cystometry and ambulatory measurements, including rise in pressure with non-voiding contractions and larger rise in pressure with voiding contractions (Figure 2).

Patient reported VAS scores ranged from 0-2 throughout the study. The most uncomfortable study segment was UroMonitor Insertion (Avg. Score: 1.33). One patient voided out the device immediately after cystoscopy without discomfort; it was replaced for study completion. No changes to OAB or voiding symptoms were noted during the ambulatory phase. All patients voided freely with the device in place and reported no discomfort. It took a median 2.5 (range: 2.2 – 3.5) seconds to remove the UroMonitor.

No post-procedure reportable complications (including UTIs) or heavy metal detection were reported. There were no other unexpected or adverse events. No changes to baseline voiding symptoms were noted 48 hours after the procedure.

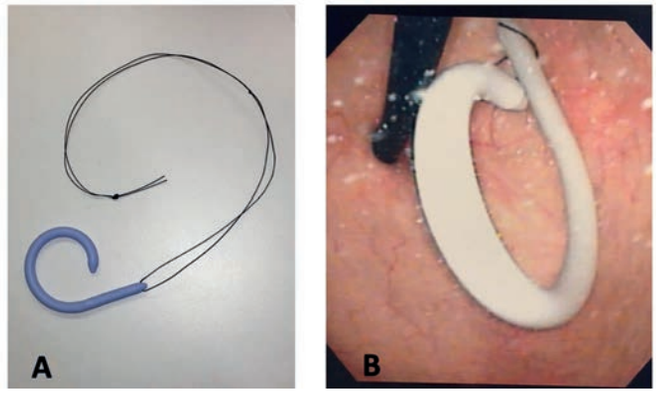
INTERPRETATION OF RESULTS

The UroMonitor can be inserted and extracted safely without difficulty in women. The device may initially exacerbate OAB symptoms but subjectively causes minimal patient discomfort during testing and after removal. The changes to urodynamic findings after initial UroMonitor placement are confounded by potential irritation caused by cystoscopy and the necessity to repeat the UDS procedure for study purposes. UroMonitor data showed strong correlation to measured catheter pressures and voiding behaviors. Detrusor force interaction with the UroMonitor device potentially limits static pressure accuracy and accentuates voiding pressures, but more subjects are needed for definitive conclusions.

CONCLUDING MESSAGE

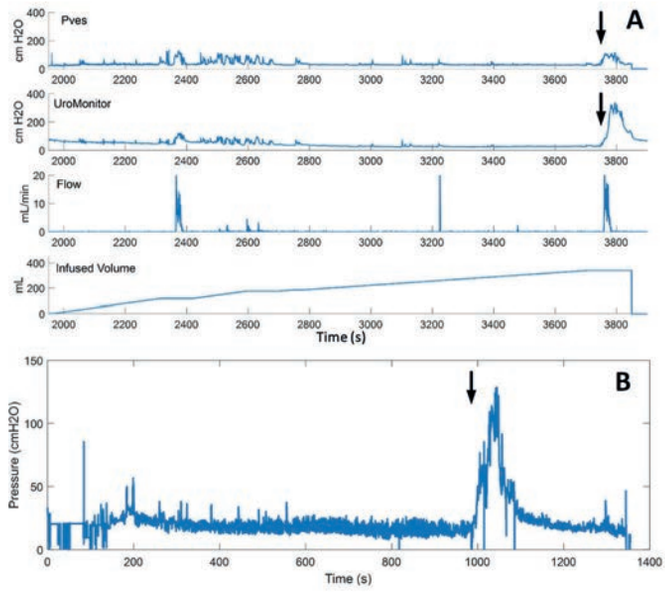
To our knowledge, this is the first example of wireless catheter-free bladder pressure data collection in humans. The UroMonitor enables ambulatory bladder pressure data collection without catheters or wires impeding normal activity. Preliminary results indicate the UroMonitor is able to identify urodynamically relevant bladder events. The device is easily inserted and removed in ambulatory female patients. While in place, it does not cause voiding obstruction nor does it cause any subjective discomfort.

FIGURE 1



A) UroMonitor device, B) UroMonitor in situ imaged during flexible cystoscopy

FIGURE 2



A) Urodynamics testing with UroMonitor measuring vesical pressure (Pves). B) UroMonitor measured vesical pressure in natural filling and during voiding without catheter in freely-moving patient. Arrows indicate onset of voiding contractions.

Funding Urology Care Foundation Research Scholar Award 2019, Cleveland Clinic Research Program Committee (RPC) Award **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Cleveland Clinic IRB **Helsinki** Yes **Informed Consent** Yes

SESSION 14 (PODIUM SHORT ORAL) - FUNCTIONAL AND MORPHOLOGICAL INVESTIGATIONS
Abstracts 202-213
16:30 - 18:00, Brasilia 1
Chairs: Prof Dirk de Ridder (Belgium), Dr Anthony John Kanai (United States)

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A POSSIBLE MECHANISM UNDERLYING MOOD DISORDERS ASSOCIATED WITH LUTS: CHRONIC BLADDER OUTLET OBSTRUCTION CAUSES NLRP3-DEPENDENT INFLAMMATION IN THE HIPPOCAMPUS AND DEPRESSIVE BEHAVIOR IN RATS

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HYPOTHESIS / AIMS OF STUDY

Numerous reports, including the Epidemiology of LUTS (Epi-LUTS) study, support an association between urinary dysfunction and mood disorders such as depression and anxiety. Regarding benign prostatic hyperplasia, patients with a concurrent diagnosis of clinical depression have a higher rate of reported LUTS while patients with significant BPH symptoms are more likely to develop depression. This suggests a bidirectional relationship between urinary dysfunction and mood disorders, but a causative mechanism has never been postulated.

Critically, inflammation in areas of the brain are well-established to cause mood disorders such as depression. Recent breakthroughs demonstrate that a local inflammatory response in a peripheral organ can trigger an inflammatory response in the brain, particularly the hippocampus, and this is mediated through the NLRP3 inflammasome. The NLRP3 inflammasome is a multimeric complex that senses Damaged Associated Molecular Patterns (DAMPS) and send out an inflammatory response by activating caspase-1 to cleave pro-IL-1β into its active form and promote its release, where it acts as a strong pro-inflammatory cytokine.

A previous study from our laboratory demonstrated that chemical cystitis (cyclophosphamide-induce hemorrhagic cystitis) elicits NLRP3-dependent inflammation in the hippocampus in rats and was associated with depressive behavior. Since BOO, a much clearer and pathologically relevant bladder-centric insult, also evokes a local inflammatory response in the bladder, we hypothesize that it will also induce inflammation in the hippocampus and mood disorders and will do so in an NLRP3-dependent manner. Here, we investigate this hypothesis and define an immunologically driven bladder-brain axis.

STUDY DESIGN, MATERIALS AND METHODS

Female rats were divided into 4 groups: control, sham, BOO or BOO + gly (glyburide; an NLRP3 inhibitor). BOO was created by urethral ligation over a 1 mm transurethral catheter. Glyburide was provided by subcutaneous pellet (50 mg, 21 day release, replaced as needed). Rats were analyzed 12 weeks post-op. Hippocampal inflammation was quantitated by Evan's blue extravasation. Microglia and neurogenesis by IbA-1 and Ki-67 staining, respectively. Depression was assessed by open field and sucrose preference tests. As an additional control for the mood disorder assays a separate group of BOO rats were provided with fluoxetine (an anti-depressant) in the drinking water (0.50 mg/ml) for the last 4 weeks of the experiment. Fluoxetine concentration was adjusted twice weekly to insure ≈20 mg/kg/day.

RESULTS

As shown in Figure 1, there was an increase in inflammation (Evans blue) in the hippocampus in BOO rats which was blocked by glyburide. To confirm this result we quantitated the density of microglia (activated immune cells) in the fascia dentate, which is the critical brain location first identified in our cyclophosphamide mood disorder studies. BOO was accompanied by an increase in activated microglia and this change was reduced back to control levels by glyburide.

In the hippocampus BOO also caused a significant decrease in neurogenesis (Ki-67+ cells). Decreases in neurogenesis, and more generally plasticity, in the hippocampus have been directly linked with neuroinflammation and depression and it is thought that these changes may lead to permanent, or at least long lasting, changes in cognitive function or mood. This decrease was also blocked by glyburide.

To assess mood disorders we performed the open field (a measure of anxiety) and sucrose preference (a measure of anhedonia) assays. As shown in Figure 2, there was a decrease in exploratory behavior in the open field behavioral assay and a decrease in sucrose preference in the BOO rats, both of which are signs of mood disorders such as depression. Like inflammation, these symptoms were diminished to control values by glyburide. These behaviors were also blocked by the anti-depressant fluoxetine.

INTERPRETATION OF RESULTS

BOO, a bladder-localized event, stimulates NLRP3-dependent inflammation in the hippocampus of rats after 12 weeks and depressive behavior indicative of mood disorders in behavioral studies.

CONCLUDING MESSAGE

This study provides the first-ever causative explanation of the previously anecdotal link between BOO and mood disorders.

FIGURE 1

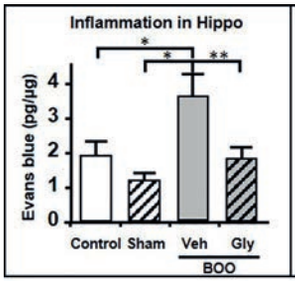

Figure 1. After 12 weeks of BOO, inflammation is present in the hippocampus of rats. This inflammation is blocked by concomitant treatment with glyburide. Following the treatments indicated, inflammation was assessed by the Evans blue assay as described in the Materials and Methods section. Veh = vehicle-treated, Gly = glyburide-treated. Results are the mean ± SEM; *p<0.05, **p<0.01, ***p<0.005 by ANOVA and Student-Newman-Keuls test. (n= 6,6,5,7)

FIGURE 2

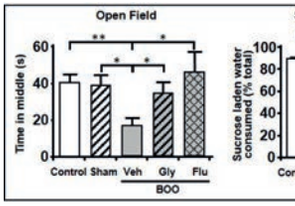

Figure 2. At 12 weeks of BOO, rats show signs of mood disorders. These behavior changes were not present when rats were given glyburide or fluoxetine (Flu), an anti-depressant. All assays were performed as described and scored by a blinded investigator. Veh = vehicle-treated, Gly = glyburide-treated. Results are the mean ± SEM; *p<0.05, **p<0.01, ***p<0.001 by ANOVA and Student-Newman-Keuls test. (n= 26,22,14,12,6).

REFERENCES

1. Coyne, K. S., Wein, A. J., Tubaro, A. et al.: The burden of lower urinary tract symptoms: evaluating the effect of LUTS on health-related quality of life, anxiety and depression: EpiLUTS. BJU Int, 103 Suppl 3: 4, 2009

Funding NIDDK: R01DK103534 **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Institutional Animal Care and Use Committee

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SUBTHALAMIC NUCLEUS DEEP BRAIN STIMULATION MODULATE URINARY AFFERENT SIGNALS BY CHANGING THE ACTIVITY OF MEDIAL PREFRONTAL CORTEX IN PARKINSON'S DISEASE MODEL RAT

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HYPOTHESIS / AIMS OF STUDY

Parkinson's disease (PD) is characterized clinically by combination of bradykinesia, rigidity, and resting tremor. In addition, it is also well known that PD patients are usually suffering from overactive bladder (OAB) symptoms. Several studies suggested that subthalamic nucleus deep brain stimulation (STN-DBS) ameliorate OAB in PD patients. Although, detailed mechanisms regarding how STN-DBS improve OAB in PD patients are not well understood, functional brain imaging study reported that STN-DBS might normalize the afferent urinary information and thereby leading to the improvement of OAB [1]. It is also well known that medial prefrontal cortex (mPFC) play an important role in regulating micturition reflex based on urinary afferent information conveyed by periaqueductal grey (PAG) [2]. However, we do not know how STN-DBS affect the relationships between mPFC and PAG network which is important in regulating micturition reflex. We aimed to clarify how STN-DBS modulate the neuronal activity of mPFC induced by PAG stimulation (increased urinary afferent projections) and its effects on bladder contraction in PD model rat.

STUDY DESIGN, MATERIALS AND METHODS

All experiments were performed on adult female Sprague–Dawley (SD) rats (14–16 weeks old, weighing 200–300 g), in accordance with the Guideline for the Care and Use of Laboratory Animals. PD model rat was constructed by a unilateral injection of 2 μg/ml 6-hydroxydopamine (6-OHDA) dissolved in 5 μl of 0.9% sterile saline containing 0.1% ascorbic acid into the left medial forebrain bundle at a rate of 1 μl / min.

Experiments were performed under urethane anesthesia in 6-hydroxydopamine hemi-lesioned PD rats (n=6). A single-lumen catheter was trans-urethrally inserted into the bladder to measure bladder pressure. Stimulation electrodes were inserted into left subthalamic nucleus and ventrolateral PAG. Recording electrode was inserted into mPFC. Extracellular local field potential (LFP) recordings of mPFC were performed before stimulation, during PAG stimulation, during PAG+STN stimulation, and after cessation of stimulation. The power spectrum of mPFC was analyzed off-line using the Lab Chart software . Fast Fourier transforms (FFTs) were performed to analyze mPFC LFP in a frequency domain range of 0.3 to 50 Hz. Power spectral densities (PSDs) were estimated with 131072 FFT size, Hann window, and a 50% overlap, and normalized by log10 (PSD).

RESULTS

PAG stimulation significantly decreased bladder inter-contraction intervals from 568.07 ± 46.67 s (pre stimulation) to 342.15 ± 39.87 s (during PAG stimulation) (p =0.0004). Adding STN-DBS to PAG stimulation tended to increase bladder inter-contraction intervals from 342.15 ± 39.87 s to 412.06± 40.10 s (p =0.07) and cessation of stimulation changed bladder inter-contraction interval from 412.06± 40.10 s to 493.55± 50.04 s (p=0.08).

Power spectrum analysis revealed that PAG stimulation significantly decreased the mean logarithmic power in mPFC alpha frequency (8-15Hz) from 7.80 ± 0.03 (a.u.) to 7.56± 0.03

(a.u.) (p<0.01) and adding STN-DBS to PAG stimulation significantly increased the mean logarithmic power in mPFC alpha frequency from 7.56± 0.03 (a.u.) to (a.u.) (p < 0.01) (Figure) and cessation of stimulation slightly increased the mean logarithmic power in mPFC alpha frequency from 7.56± 0.03 (a.u.) to 7.86 ± 0.03(a.u.) (p =0.12) during bladder relaxation phase.

In addition, PAG stimulation significantly decreased the mean logarithmic power in mPFC alpha frequency (8-15Hz) from 8.23± 0.02 (a.u.) to 7.97± 0.03 (a.u.) (p<0.01) and adding STN-DBS to PAG stimulation significantly decreased the mean logarithmic power in mPFC alpha frequency from 7.97± 0.03 (a.u.) to 8.28 ± 0.03 (a.u.) (p < 0.01)(Figure) and cessation of stimulation decreased the mean logarithmic power in mPFC alpha frequency from 8.28 ± 0.03 (a.u.) to 7.75 ± 0.03(a.u.) (p < 0.01) during bladder contraction phase.

INTERPRETATION OF RESULTS

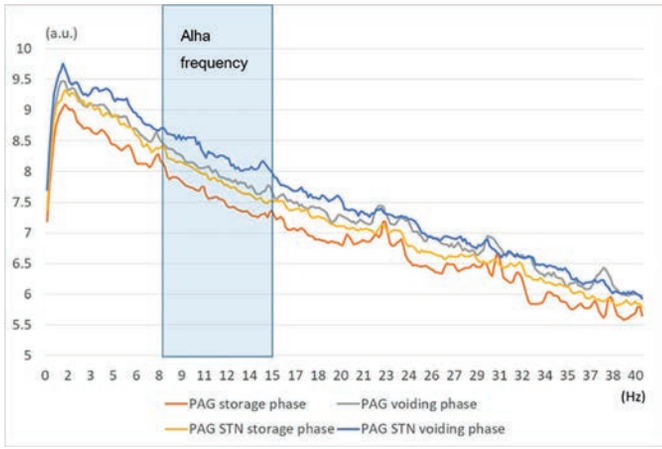
The present study revealed that PAG stimulation significantly decreased bladder inter-contraction interval with concomitant decrease in mPFC alpha power during storage and voiding phase, whereas adding STN stimulation tended to increase bladder inter-contraction interval with concomitant increase in mPFC alpha power during storage and voiding phase.

The PAG stimulation is more likely to induce bladder contraction probably via activation of potine micturition centre (PMC)-sacral parasympathetic nucleus pathway and also induce urinary afferent projection from PAG to higher micturition centre located in cerebral cortex. The present study suggested that decreased mPFC alpha power might be related to urinary frequency observed during PAG stimulation, and adding STN stimulation tended to improve urinary frequency by increasing mPFC alpha power. This result also indicated that the activity of mPFC was influenced by afferent urinary information (stimulating PAG in this study) and STN-DBS might tend to increase bladder inter-contraction interval via increasing mPFC alpha power.

CONCLUDING MESSAGE

PAG stimulation decreased bladder inter-contraction interval and decreased the alpha power in mPFC in PD model rat. STN-DBS might increase bladder inter-contraction in interval by increasing the alpha power in mPFC in PD model rat.

FIGURE 1



Adding STN stimulation to PAG stimulation significantly increased the mean logarithmic power in mPFC alpha frequency

REFERENCES

1. Herzog J, Weiss PH, Assmus A, Wefer B, Seif C, Braun PM, Pinsker MO, Herzog H, Volkmann J, Deuschl G, Fink GR. Improved sensory gating of urinary bladder afferents in Parkinson's disease following subthalamic stimulation. Brain. 2008 ;131(Pt 1):132-45.
2. Fowler CJ, Griffiths D, de Groat WC. The neural control of micturition. Nat Rev Neurosci. 2008 :453-66. doi: 10.1038/nrn2401.

Funding This work was supported by Collaborative Research **Funding** from Chiba Prefectural University of Health Sciences (2019-01) **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Chiba University guidelines for care and use of laboratory animals

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PARCELLATION OF FUNCTIONAL CLUSTERS WITHIN THE HUMAN PERIAQUEDUCTAL GRAY AT 7T FMRI IN FULL AND EMPTY BLADDER STATE

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HYPOTHESIS / AIMS OF STUDY

The periaqueductal gray (PAG) is a brainstem area that is assumed to serve as a relay station in the central nervous system pathways involved in control of micturition. The PAG is proposed to be responsible for projecting afferent information from the bladder to cortical and subcortical brain areas and acts as a gatekeeper projecting efferent information

from cortical and subcortical areas to the pons and spinal cord [1]. The role of the PAG in lower urinary tract symptoms (LUTS) is not well understood, but a better understanding could provide a framework for new therapies or diagnostic procedures. Studies using animal models have shown that the PAG is organized in a columnar fashion. Technological advances during recent years have made ultra high-field magnetic resonance imaging (MRI) scanners more readily available, and the use of these scanners will allow for the investigation of PAG activity in sub-millimeter detail in human participants. Additionally, the advancement of MRI analysis methods allows for more data-driven analyses and systematical approaches.

The current study aims to use 7 Tesla functional magnetic resonance imaging (fMRI) to parcellate the PAG into clusters of voxels with a higher within-cluster connectivity than between-cluster connectivity in, both, an empty and a full bladder state. We will assess the similarity between parcellation results of both bladder states and expect a significant spatial overlap between the cluster constellations found in both states. A significantly higher agreement between parcellations based on fMRI data obtained during empty and full bladder states indicates that parcellation of the PAG is independent of the level of bladder fullness and experienced bladder sensations. This is necessary to qualify this novel methodological approach to be utilized for studying PAG activity related to bladder functioning.

STUDY DESIGN, MATERIALS AND METHODS

This study was approved by the local ethical committee, and informed consent was obtained from of our participants. We evaluated 7 Tesla fMRI parcellations for 6 female participants (mean age: 50). We acquired fMRI data during an empty bladder state. We then filled our participants' bladder at a rate of 30ml/min until they indicated they experienced a strong desire to void using a joystick they could control from the scanner. Once the participant indicated a strong desire to void we started a second fMRI scan.

Functional data were preprocessed using BrainVoyager 21. Using a mask drawn on the anatomical images for each individual subject we selected all voxels within the PAG, on which we computed a voxel-by-voxel correlation matrix based on the functional time course of each voxel during the full bladder scan. We parcellated this matrix using an implementation of the Louvain module detection algorithm in MATLAB (Fig. 1.A), which outputs clusters with stronger within-cluster connectivity than between-cluster connectivity [2]. Using the empty bladder parcellation we computed random parcellations using a script that randomly places an anchor point in the 3D space of the PAG mask and grows modules, similar in size to the original modules, from this anchor point. We iterated this script to obtain 1000 different random parcellations. These random parcellations were subsequently used to assess the agreement between our parcellations based on fMRI data acquired during an empty and full bladder state compared to what could be expected based on chance.

RESULTS

The Sørensen–Dice coefficient is a useful measure of spatial overlap which can be applied to studies of reproducibility and accuracy in image segmentation, it is based on the percentage of spatial overlap between two images [3]. For each participant, we computed the Sørensen–Dice coefficient between each cluster in the empty bladder parcellation and each cluster in the full bladder parcellation. Next, we computed the Sørensen–Dice coefficient between each cluster from the empty and full bladder parcellations and each cluster from the 1000 iterations of the random parcellation. This allowed us to statistically test the extent to which the similarity between empty and full bladder parcellations was higher than could be expected based on chance on a single subject level. For each of our participants we found that the agreement between at least one of the clusters in both states resulting from the parcellation procedure was higher than could be expected based on chance ($p = <0.05$, corrected for multiple comparisons using a false discovery rate ($q=0.05$)) (table 1). For two of our participants we managed to find a counterpart for each module in both parcellations that had a significantly higher agreement than could be expected on chance.

INTERPRETATION OF RESULTS

Our results indicate that PAG activity in an empty and full bladder state can reliably be subdivided in clusters that are largely independent on bladder state, and show a higher similarity between each other than could be expected based on chance (figure 1). Thereby supporting the idea that fMRI based parcellation of the PAG allows for replication of neuro-anatomical findings based on animal work. These results imply that PAG parcellations can be used to study changes in dynamic connectivity between PAG clusters related to bladder fullness and paticipants' experienced bladder sensations. These connectivity changes can serve to create dynamic response profiles which, when established in healthy controls, could serve as a benchmark to which LUTS patients' response profiles can be compared. This opens new possibilities to investigate the effects of treatments of LUTS on signal processing in the PAG. It will also provide a new and necessary framework for translational research into new therapeutic targets, treatment effectivity predictors, and diagnostic measurements.

CONCLUDING MESSAGE

The human PAG can reliably be parcellated into functional modules that are largely independent of bladder state using ultra high-field fMRI. This method of functionally subdividing the PAG can be used to assess connectivity changes between PAG clusters in relation to bladder sensations. This will enable us to take an interdisciplinary and translational ap-

proach to find new and more optimally targeted treatment and diagnostic options for LUTS patients.

FIGURE 1

Table 1: Number of modules for each parcellation, and specification of pairs of modules with significantly higher similarity across parcellations than could be expected based on chance. Numbers are assigned to modules at random during the parcellation procedure.

Participant	Number of modules empty	Number of modules full	Significant similarity ratio
1	3	3	2/3
2	3	4	2/3
3	3	3	3/3
4	3	3	1/3
5	3	3	3/3
6	3	2	1/2

FIGURE 2

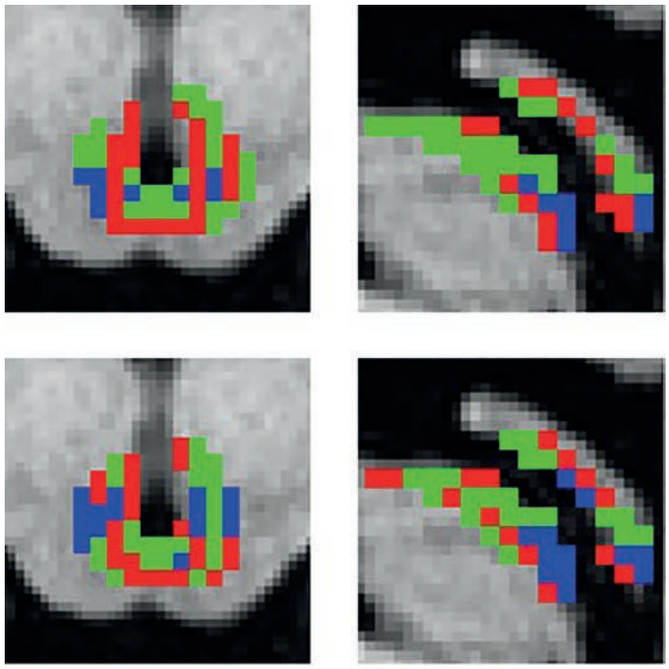

Figure 1: Visualization of the spatial correspondence between modules that show a significantly larger spatial overlap than could be expected on chance. Top row: transversal and sagittal view of parcellations based on data acquired during an empty bladder state. Bottom row: transversal and sagittal view of parcellations based on data acquired during a full bladder state. Colors indicate corresponding modules.

REFERENCES

1. Fowler, C.J., D. Griffiths, and W.C. de Groat, The neural control of micturition. Nat Rev Neurosci, 2008. 9(6): p. 453-66.
2. Fortunato, S. (2010). Community detection in graphs. Physics reports, 486(3), 75-174.
3. Zou, K. H., Warfield, S. K., Bharatha, A., Tempany, C. M., Kaus, M. R., Haker, S. J., ... & Kikinis, R. (2004). Statistical validation of image segmentation quality based on a spatial overlap index 1: Scientific reports. Academic radiology, 11(2), 178-189.

Funding Funding for this study was provided by the Astellas Europe Fund 2015 and the Faculty of Health, Medicine and Life Sciences of Maastricht University in the Netherlands. **Clinical Trial** No **Subjects** Human **Ethics Committee** Medisch-ethische toetsingscommissie academisch ziekenhuis Maastricht and Maastricht University (METC azM/UM) **Helsinki** Yes **Informed Consent** Yes

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18F-FDG PET/CT PET MAPPING OF BRAIN ACTIVITY FOLLOWING TRANSCUTANEOUS POSTER TIBIAL NERVE STIMULATION FOR LOWER URINARY TRACT SYMPTOMS IN PEDIATRIC PATIENTS

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HYPOTHESIS / AIMS OF STUDY

Peripheral nerve stimulation via lumbosacral route has shown to modulate cortical and subcortical brain areas which seem to control the complex process of micturion, i.e. sensation of bladder filling and the timing of micturition. The present study was conducted to investigate the changes in brain activity during modulation of various brain areas after transcutaneous posterior tibial nerve stimulation (TcPTNS) for lower urinary tract symptoms (LUTS) in pediatric patients.

STUDY DESIGN, MATERIALS AND METHODS

We used 18 FDG PET CT to investigate the effects of PTNS on brain activity in pediatric patients with urodynamically proven detrusor overactivity (DO) or underactive detrusor (UD). Exclusion criteria were neurogenic bladder, lower urinary tract surgery, urinary tract infection and lower urinary symptoms secondary to anatomical anomalies such as posterior urethral valves, ureterocele or ectopic ureter. A voiding diary was maintained for 3 days as an assessment tool for all patients. The number of voids daily (NV), average voided volume (AVV) and maximum voided volume (MVV) before and after treatment were evaluated using voiding diary. Transcutaneous posterior tibial nerve stimulation (TcPTNS) was performed using TENS III stimulator. Two Self-adhesive surface electrodes were used (13). All the patient underwent weekly session for 30 minutes for 12 weeks followed by 3 weekly maintenance therapy. PET CT brain was done before the start of TcPTNS and at the end of induction therapy i.e. 3 months.

The clinical outcome was assessed on the basis international children continence society (ICCS) definition along with im-

provement in the parameters in bladder diary, uroflowmetry and post void residual urine.

RESULTS

The study included 21 pediatric patients with a mean age of 5.6Yrs (range 4-16 yrs.). Of the 21 patients, 12 (57.15%) had overactive bladder with urodynamically proven DO and 9 (42.85%) had under active detrusor. In cases overactive bladder TcPTNS decreased the activity in the mid-cingulate gyrus, Hypothalamus, premotor cortex [more on right side] and Lateral pons (Figures 1a, b, c and d).

These findings were explored further as to correlate them with the neuroanatomical and physiological regions of the brain involved in the process of micturition. It is interesting to note that these are the areas which actually modulate in integrated manner during the process of bladder filling (8, 9, 11, 20, and 21).

On the contrary avid uptake was noted in lateral cingulate gyrus, mid pons and periaqueductal grey [PAG] in cases of underactive detrusor (Figures 2 a, b, c and d). Again these findings were correlated with the neuroanatomical and physiological regions of the brain it was noted that hyper metabolism in these areas has been recorded during strong urge or the act of micturition (7, 10, 11, and 14).

On assessment of clinical outcome, over all 12 (57.14%) patients reported improvement in their symptoms. In cases of overactive bladder 7 (58.3%) patients were improved, of these 3 (42.85%) were completely cured, while 3 (42.85%) improved and 1(14.3%) had partial improvement. Four (33.3%) patient failed to show any clinical benefit. Interesting to note that in spite showing desired changes in the brain physiology 33.3 % of the patient failed to show any clinical improvement.

In cases of underactive bladder 5 (55.6%) patients reported improvement, of these 2 (40%) were completely cure, while 2 (40%) improved and 1(20%) had partial improvement. Four (44.4%) of the patients were not benefited clinically.

Here again in spite showing desired changes in the brain physiology 44.4% of the patient failed to show any clinical improvement. This shows that brain activation may not always translate in to successful clinical outcome.

INTERPRETATION OF RESULTS

The study included 21 pediatric patients with a mean age of 5.6Yrs (range 4-16 yrs).

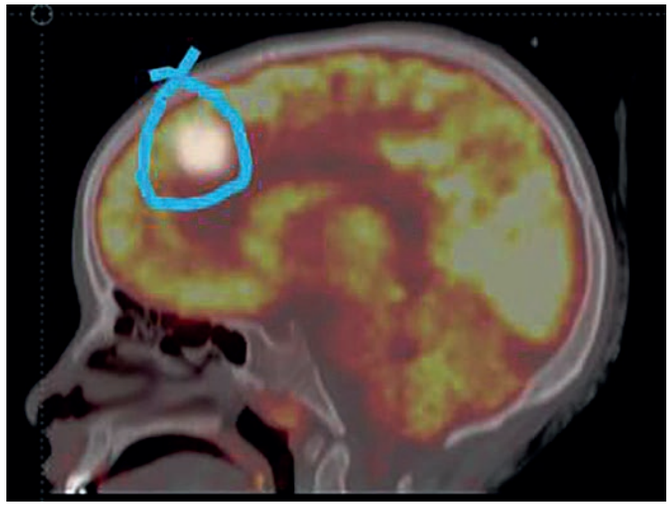
Of the 21 patients, 12 had overactive bladder with urodynamically proven DO and 9 had under active detrusor.

In cases overactive bladder TcPTNS decreased the activity in the cerebellum, midbrain and adjacent midline thalamus and limbic cortical areas, i.e. the cingulate gyrus, ventromedial orbitofrontal gyrus and prefrontal cortex. These are the areas involved in the sense of bladder filling. While, FDG uptake was more avid in these areas before the start of TcPTNS. On contrary the avid uptake was noted in hypothalamus and prefrontal area in cases of underactive detrusor. These are the areas involved sensorimotor learning and the initiation of voiding.

CONCLUDING MESSAGE

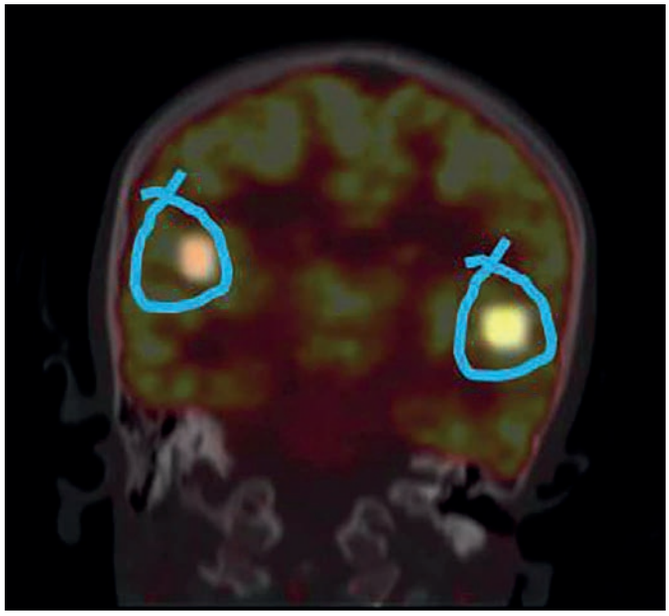
These findings suggest that after therapy by TcPTNS the focus of brain activation changes according to the sense of bladder filling or voiding i.e. to overcome urge in cases of overactive bladder and to initiate voiding in cases of underactive detrusor.

FIGURE 1



Decreased uptake at mid-cingulate gyrus in detrusor overactivity

FIGURE 2



Avid uptake at lateral cingulate gyrus in underactive detrusor

REFERENCES

1. Patidar N, Mittal V, Kumar M, Sureka SK, Arora S, Ansari MS. Transcutaneous posterior tibial nerve stimulation in pediatric overactive bladder: A preliminary report. J Pediatr Urol. 2015 Dec;11(6):351
2. Das Gupta R1, Kavia RB, Fowler CJ. Cerebral mechanisms and voiding function. BJU Int. 2007;99(4):731-4.
3. Michael Shy, Steve Fung, Timothy B. Boone, Christof Karmonik, Sophie G. Fletcher, and Rose Khavari Functional Magnetic Resonance Imaging during Urodynamic Testing Identifies Brain Structures Initiating Micturition. Urol. 2014 October ; 192(4): 1149–1154

Funding None **Clinical Trial** Yes **Registration Number** IEC/151/2017 **Subjects** Human **Ethics Committee** IEC/151/2017 **Helsinki** Yes **Informed Consent** Yes

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PATHOPHYSIOLOGY AND PRINCIPLES OF THERAPY OF A NEUROGENIC HYPERACTIVE URINARY BLADDER IN PATIENTS AFTER CEREBROVASCULAR ACCIDENT

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder (OAB) is a frequent complication of stroke and vascular dementia. It is a complex syndrome manifesting in the impaired analysis of afferent impulses and the impaired efferent signals generation in the cortex and subcortical brain zones involved in urination regulation. Disruption between urination brain centers and spinal structures leads to impaired cholinergic (urge incontinence), indirect sympathetic (pollakiuria) and non-cholinergic impulse transmission. Nocturia and polyuria are caused by melatoninergic and vasopressinergic transmission impairment respectively. Urge incontinence (UI) is the most common symptom of brain disease. OAB early diagnosis and treatment are still to be improved. A great part of experimental research of the last decades disregarded the psychological aspect of AOB and thus could not describe psychologically-mediated reflexes. Still such symptoms as compelling urge to urinate and loss of urethral sensitivity can not be well described by experimental research. In order to reveal them patient history and complaints should be assessed in their combination with the neurological symptoms, process localization (Barrington's nucleus, etc.) as well as its clinical characteristics (progression speed and cyclic character, rehabilitation prognosis). We think that the assessment of reflexes involved in lower urinary tract (LUT) complex function plays a key role in AOB patient assessment. The main 12 urination LUT reflexes have been described by F. J. F. Barrington, M. Kuru and D. T. Mahony. Studying the changes of these reflexes in various neurologic conditions is an important task of neurourology.

STUDY DESIGN, MATERIALS AND METHODS

The article presents a new concept of formation of the syndrome of hyperactive bladder on the basis of violations of the implementation of the 4 reflexes of urination, which provides the normal retention of urine and are responsible for the accumulation function of the bladder. First we analyzed the main point of application of drugs of anticholinergic and sympathomimetic actions in the reflexes of urination and mechanisms of restoration of function of the lower urinary tract in patients with acute and chronic vascular diseases of the brain.

Study was provided in Scientific center of Neurology (Moscow). 140 patients were included in study, 50 patients after ischemic stroke and 70 patients with discirculatory encephalopathy. In comparison group were 20 patients with DE and Benign hyperplasia prostate. There were 3 stages of trial: 1.research of clinical aspects of overactive bladder in all patients groups. Also comparative diagnostic evaluation was performed. 2. Clinical examination of all patients. 3. Pharmacological analysis of cholinergic and adrenergic regulation lower urinary tracts.

Methods of research: Neurological examination, assessment of mental condition urological evaluation: anamnesis of life, assessment of complaints, voiding dairy, IPSS, rectal evaluation, bacteriological evaluation of urine samples, ultrasound diagnostic, urodynamic study. Also ultrasound of vessels of the head and neck was provided. Method of neurovisualisation: MRI, CT.

RESULTS

Cerebral representations of the bladder and its sphincters include dominant center (right insular cortex - правый островок Рейля?) and paired zones. Paired zones lesion leads to reversible urination disorders. Ischemic lesion of functionally unpaired lower frontal cortex results in irreversible diurnal pollakiuria.

Changes in the central nervous system zones involved in urination regulation can be caused by acute and chronic ischemia as well as other pathological process. Reflex assessment is recommended to analyze such changes.

Clinical manifestations of UI include 4 symptoms: compelling urge to urinate, urge incontinence per se and less often (in the lack of frontal control due to ischemia) pollakiuria and inability to stop urination once it began. In post-stroke UI patients we identified 4 reflexes that if impaired result in a full range of UI clinical symptoms: detrusor inhibiting reflex, perineodetrusorinhibitory reflex, urethrosphincteric guarding reflex, detrusourethral inhibitory reflex.

Thus the following three mechanisms underlie UI in post-stroke patients.

INTERPRETATION OF RESULTS

first UI mechanism takes place at urine accumulation phase. Dysfunction of urethral sphincter охраняющего (protective?) reflex results in reduction of mean effective bladder volume. Much lower urine volume in the bladder is perceived by the brain as normal due to the decrease of lower frontal cortex perception threshold.

Second UI mechanism takes place during an urge to urinate. Impairment of detrusor inhibiting sympathetic reflex causes limbic system overreaction and manifests in compelling urge to urinate. In the first case patients complain of frequent urination with a small amount of urine at each micturition. This can be easily traced by using a bladder diary. In the second case patients complain of compelling urge to urinate that can arise suddenly at any time. Spinal part of the sympathetic nervous system also plays an indirect role in this condition by regulating bladder filling with urine.

Third UI mechanism takes place at the urination start. Impairment of perineal detrusor inhibiting reflex and detrusor reflex that inhibits urethral contraction leads to inability to prevent urination start (first reflex) and to stop urination once it began (second reflex). Detrusor inhibiting perineal reflex is provided by pyramidal system and indirectly involves n-cholinergic system in urine continence. Thus the voluntary control of pelvic floor muscles contraction is lost. Detrusor reflex that inhibits urethral contraction is an involuntary parasympathetic reflex that causes initial detrusor contraction at urination start.

CONCLUDING MESSAGE

Urination impairment is a clinical symptom of stroke. Its clinical presentation depends on the localization of brain ischemic lesion. Single symptom manifestation results from a local brain lesion, polysymptomatic condition is accounted for by multiple brain lesions. Consequence of urologic signs and symptoms in patients with brain vascular disease reflects the dynamics of pathological process in the brain. Sudden appearance of symptoms is characteristic of lacunar and hemisphere infarction, a gradual symptom development is typical for leucoaraiosis. Functional reorganization of brain neuronal networks following a stroke account for symptoms regression whereas the increasing neuronal degeneration in chronic brain ischemia leads to symptoms progression. Bladder diary and urodynamic testing help to differentiate sensory, motor and sphincter neurogenic urination disorders in post-stroke patients.

FIGURE 1

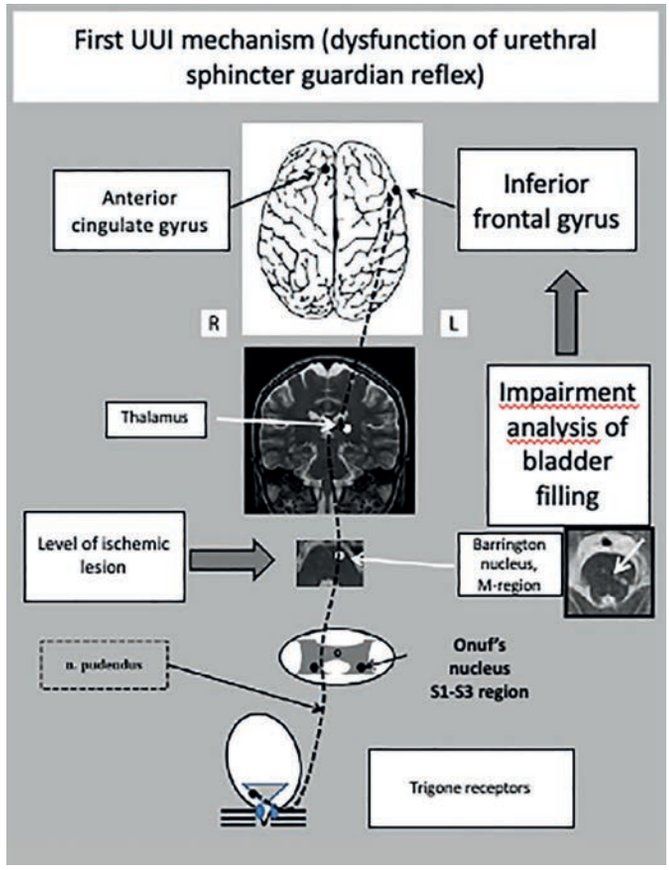
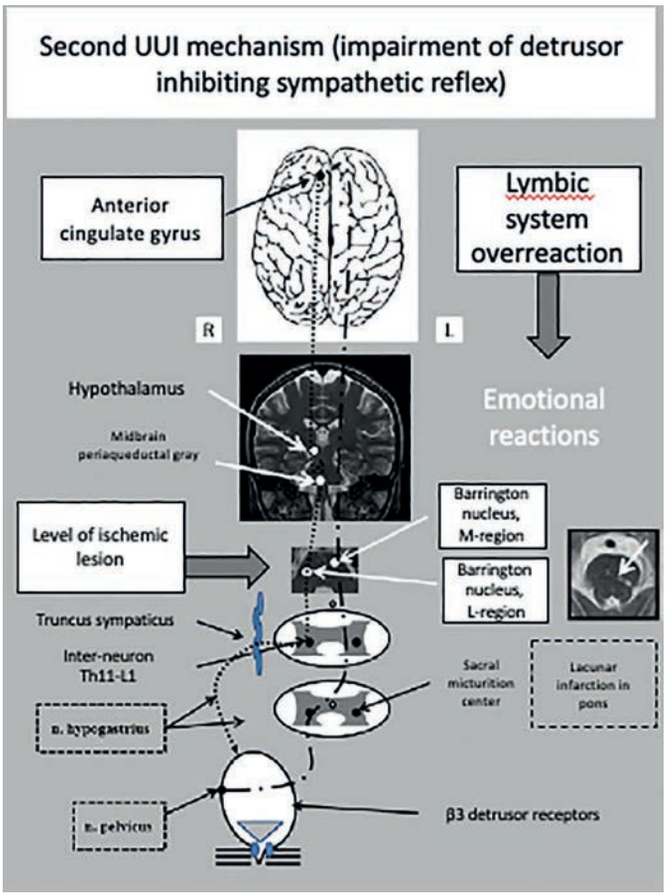


FIGURE 2



REFERENCES

1. Barrington F. J. F. The effect of lesions of the hind- and mid-brain on micturition in the cat. Q. J. Exp. Physiol. 1925; 15: 81–102.
2. Mahony DT, Laferte RO, Blais DJ. Intergral storage and voiding reflexes. Neuro- physiologic concept of continence and micturition. Urology. 1977; 9 (1): 95–107.
3. Goldfarb RA, Pisansky A, Fleck J, Hoversten P, Cotter KJ, Katorski J, et al. Neuro- genic Lower Urinary Tract Dysfunction in Adults with Cerebral Palsy: Outcomes fol- lowing a Conservative Management Approach. J Urol. 2016 Apr;195 (4 Pt 1):1009–13. DOI: 10.1016/j.juro.2015.10.085

Funding I dont have any source of funding or grant **Clinical Trial** No **Subjects** Human **Ethics Committee** LEC in Federal Government Budget Scientific Institution "Scientific center of Neurology" (Moscow city) **Helsinki** Yes **Informed Consent** Yes

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PROXIMAL URETHRAL ELECTRICAL STIMULATION DRAMATICALLY IMPROVES UNDERACTIVE BLADDER FUNCTION IN RATS AFTER UNILATERAL PELVIC NERVE TRANSECTION

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HYPOTHESIS / AIMS OF STUDY

We previously demonstrated reliable bladder contractions in neurologically-intact rats in response to proximal urethra electrical stimulation (PUES). We sought to investigate whether stimulating with a novel flexible electrode support, placed in an anatomically-similar position to that of a urethral sling, could improve bladder function in the setting of underactive bladder (UAB) caused by unilateral pelvic nerve transection (PNx).

STUDY DESIGN, MATERIALS AND METHODS

The current study was approved by our Institutional Animal Care and Use Committee. Twenty-five urethane-anesthetized female Sprague-Dawley rats received ureteral diversion and transvesical catheters via laparotomy. The ventral pubis was removed to expose the urethra. A 3mm lattice with integrated bipolar electrodes (flexible electrode support) was placed between the urethra and vagina. Following 3 hours of continuous cystometry, 3 single-fill cystometrograms were performed prior to right PNx (eight of twenty-five rats served as sham PNx controls). After 1 hour of continuous cystometry, 3 single-fill cystometrograms were performed again. In PNx rats, the bladder was filled to the largest pre-PNx total bladder capacity (TBC) or 75% of lowest post-PNx TBC (the lower of the two volumes was tested first) and PUES was performed at 20, 30, 40, and 50 Hz (varied randomly) at 50 V for 60 sec stimulation/120 sec recovery periods. PUES was then repeated at the higher of the two test volumes. When voiding occurred, the bladders were emptied to calculate voiding efficiency (VE) and refilled to the test volumes. Measurements included TBC and VE before and after PNx, as well as, the presence or absence of bladder contraction or voiding during PUES. Data were analyzed using non-parametric repeated measures 2-Way ANOVA for sham PNx vs PNx comparisons of TBC and VE, and contingency analysis (CA) for comparisons of different test fill volumes and sequence/frequency effects of PUES.

RESULTS

After unilateral PNx, mean TBC increased by 80% and mean VE decreased by 71% ($P < 0.0001$ for both); no changes were observed in sham PNx rats. PUES elicited voids (in absence of somatomotor response) at both test volumes; CA revealed significant stimulus frequency effect ($P=0.0009$) with lower frequencies more effectively evoking voiding contractions

(percentage voiding 52, 23, 10, 10% at 20, 30, 40, 50 Hz, respectively, P=0.0013). Mean VE of voiding contractions was 115% of pre-PNx.

INTERPRETATION OF RESULTS

Pelvic surgery is a known etiology for UAB presumed to involve unilateral pelvic nerve plexus injury. We noted a significant increase in TBC and a decrease in VE after unilateral PNx that was not demonstrated in sham-PNx rats, thereby eliminating the possibility that our results were due to the cystometric fill-rate acclamation. Our flexible electrode support reversed sensory (TBC) and motor (VE) deficits that were caused by PNx.

CONCLUDING MESSAGE

Our validated unilateral PNx model induces conditions of dramatically increased TBC and decreased VE which effectively proxy for UAB. Following PNx, PUES with flexible electrode support at 20-30Hz elicited voiding contractions at decreased fill volumes with a reversal of VE changes, thereby normalizing functional voiding in this UAB model.

Funding Discretionary Research Funds **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Durham VA Medical Center IACUC

208 www.ics.org/2020/abstract/208

COMPARISON OF PRE- AND POST-GANGLIONIC NERVE STIMULATION OF THE PIG AND RAT BLADDER.

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HYPOTHESIS / AIMS OF STUDY

Excitatory bladder efferent innervation consists of pre- and post-ganglionic parasympathetic nerves, and an intermediate ganglion. Frequency-dependent properties of post-ganglionic fibres have been characterised; raising the firing rate between 1-40 Hz increases detrusor contraction force. At low frequencies (1-10 Hz) ATP release at the nerve-muscle junction is important, but at high frequencies acetylcholine (ACh) increasingly dominates. In the normal human bladder, ACh is the only functional transmitter, but with benign pathologies (and also in most non-human animals) ATP also has a role. Strategies to selectively minimise nerve-related ATP release may therefore have the potential to reduce overactive bladder contractions. The frequency domain of pre-ganglionic nerves is less well-characterised, although it may be up to 15 Hz [1]. However, it is unclear if the intermediate ganglia act as frequency-dependent filters, i.e. do they manipulate selectively low or high-frequency stimulation of post-ganglionic nerves. This is important in the field of neuromodulation for conditions such as pelvic pain where pre-ganglionic nerve activity can be regulated by external sources [2], and selective low frequency block of post-ganglionic nerves should be useful. The null hypothesis under test, using rat and pig models, was that intermediate ganglia do not offer frequency-dependent modulation of parasympathetic detrusor muscle activation. This was tested in two animal models, pigs and rats, by comparing the frequency-dependence of detrusor contraction when stimulating pre- or post-ganglionic nerves.

STUDY DESIGN, MATERIALS AND METHODS

Data were from adult pigs (Sus scrofa domestica, 6-months) obtained from a local abattoir, immediately after slaughter, and rats (Wistar, female, 200-240 g). Pig bladders were perfused with Tyrode's solution (24mM HCO3-/5% CO2, pH 7.4) via the abdominal aorta with free venous outflow and housed in a water-jacketted chamber with a drainage siphon sufficient to maintain the bladder in a humidified environment [1]. The bladder was filled with 150 ml Tyrode's solution. Intravesical pressure was measured by a 6-Ch catheter introduced through the left ureter and the right ureter tied off. Interventions were introduced into the arterial perfusate. Pre-ganglionic stimulation was by Pt-Ir cuff-electrodes around the pelvic nerve. Mixed pre-and post-ganglionic stimulation was by titanium mesh electrodes, with a Pt coating, sutured to the lateral wall of the dome, and changes to intravesical pressure recorded. After these experiments a bladder wall section from the mid-dome was dissected, the mucosa removed and a detrusor strip (<1 mm diam.) tied to an isometric force transducer to record post-ganglionic nerve-mediated isometric contractions. The same stimulation protocol was used in all preparations: a 3-s train of 0.1-ms square waves, frequency 1-40 Hz, every 90 s.

Rats were anaesthetised with urethane (1.4 g.kg-1, i.p.); the right femoral artery cannulated to record blood pressure and heart rate; the right femoral vein used for fluid infusion; the trachea cannulated to ensure airway patency; core temperature was maintained at 37°C. Through a midline laparotomy, the pelvic nerve was gently separated from the uterine wall and a cuff electrode placed round the distal part. Intravesical pressure was monitored via a suprapubic penetration with a 25G needle tip. The same stimulation protocol was used as with pig experiments. At the end of the experiment the animal was killed (Na pentobarbital (200 mg.kg-1, i.p.), the bladder immediately removed and a detrusor strip, after removal of mucosa, mounted as above to record post-ganglionic responses.

Data sets are mean±SD; n=number of animals. Tension (T)- or pressure (P)-frequency relations were parameterised using the formulation: T(P) = (T(P)max.f^n)/(f1/2^n+f^n), where Tmax (Pmax) is the maximum value at high frequencies (f) and f1/2 the frequency required to attain Tmax/2 (Pmax/2); n is a constant that raises f and f1/2 to this power. Differences between data sets were tested with ANOVA and

post-hoc parametric t-tests. The null hypothesis was rejected at *p<0.05.

RESULTS

Pig experiments. The frequency-dependence of responses to pelvic nerve, bladder wall and isolated detrusor strip stimulation were not significantly different (figure 1A), with f1/2 values (frequency to attain half maximal responses) of 6.4±0.3 (n=7), 7.1±0.5 (n=7) and 6.5±0.7 (n=10), respectively. Lidocaine-HCl (7.4 mM) abolished responses in all three preparations indicating they were all nerve-mediated. The nicotinic receptor antagonist hexamethonium (300 µM) completely abolished responses to pre-ganglionic pelvic nerve stimulation (n=6). In contrast, there was no significant effect on post-ganglionic detrusor strip stimulation (102.8±6.1% control, n=6). However, there was an intermediate effect on responses to bladder wall stimulation (pre- and post-ganglionic stimulation; 32.6±11.2% control, n=6). The action of the PDE5 inhibitor sildenafil was also tested. With all preparations, responses were reduced (figure 1B); with this effect on pelvic nerve-stimulation > bladder wall stimulation > detrusor strip stimulation.

Rat experiments. Similar experiments with pelvic nerve and isolated detrusor strip stimulation also revealed similar frequency-response curves (figure 2A); the inset shows paired f1/2 values with the two methods of stimulation and no significant difference of mean values. Hexamethonium (300 µM) had no effect on post-ganglionic detrusor-evoked responses and partially reduced pre-ganglionic pelvic nerve-evoked responses (30 mg.kg-1; figure 2B).

INTERPRETATION OF RESULTS

The similarity of frequency-response curves with pre-and post-ganglionic stimulation was shown in two animal models - pigs and rats, the former physiologically similar to the human bladder. An interpretation is that, under these experimental conditions, the frequency-dependence of contractions is not modulated by the intermediate ganglion under these experimental conditions, unlike similar experiments in rabbits and cats [1]. The significance is that at postganglionic nerve-muscle junctions two transmitters (ATP and ACh) are released, both of which initiate contraction, but whose release may be separately modulated with agents such as the PDE5 inhibitor, sildenafil [3]. Selective blockade of low-frequency responses would reduce disproportionate dependence on ATP, a transmitter associated with human overactive bladder syndromes. Thus, neuromodulation of pre-ganglionic efferent firing would be reflected in post-ganglionic rates. Moreover, the greater suppression by sildenafil of pre-ganglionic, compared to post-ganglionic, responses is consistent with the hypothesis that there is also dual transmitter release at the nerve-ganglion junction which offers a potential selective targeted drug model.

CONCLUDING MESSAGE

Data from a rat and a pig animal model show that the parasympathetic ganglion to the bladder does not offer a frequency-dependent filter of excitatory efferent firing. However, sildenafil experiments show that the PDE5 inhibitor may modulate both pre-and post-ganglionic neurotransmitter release.

FIGURE 1

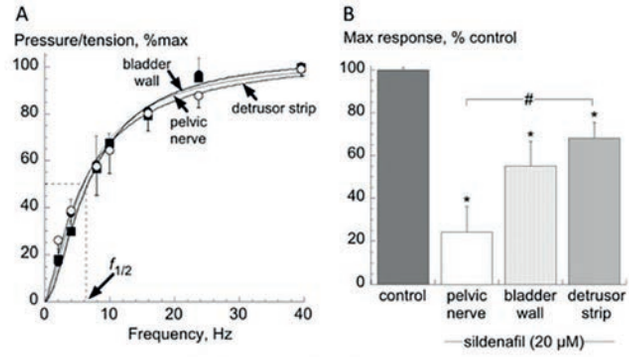

Figure 1. A: Pig bladder frequency-dependent nerve-mediated contractions to pelvic nerve (closed circles), the bladder wall (closed squares), or detrusor strip (open circles) stimulation. The $f_{1/2}$ frequency to attain half-maximum pressure or tension is shown. B: Effect of sildenafil on maximum responses to the three modes of stimulation. *p<0.05 *vs* control; #p<0.05 pelvic nerve *vs* detrusor stimulation.

Figure 1

FIGURE 2

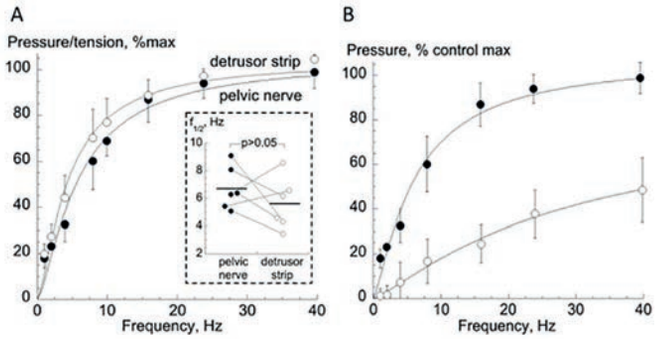

Figure 2. A: Rat bladder frequency-dependent nerve-mediated contractions to pelvic nerve (closed circles) or detrusor strip (open circles) stimulation. Paired $f_{1/2}$ values from the same animal are shown in the inset. B: Effect of hexamethonium (open circles) on responses to pelvic nerve stimulation.

Figure 2

REFERENCES

1. de Groat WC, Saum WR. J Physiol 1976; 256: 137-158.
2. Roy H, Offiah O, Dua A. Brain Sci 2018; 8: 180.
3. Chakrabarty B, Ito H, Ximenes M, Nishikawa N, Vahabi B, Kanai AJ, Pickering AE, Drake MJ, Fry CH. Br J Pharmacol. 2019; 176: 2227-2237

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IMPACT OF LUMBOSACRAL EPIDURAL STIMULATION ON LOWER URINARY TRACT FUNCTION IN ANESTHETIZED FEMALE WISTAR RATS.

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HYPOTHESIS / AIMS OF STUDY

Urological dysfunctions are ranked as a top priority by the spinal cord injury (SCI) population. Traditional methods that include pharmacotherapy, non-electrical devices such as catheters and surgical procedures when deemed necessary target management but do not replace or restore control of the lower urinary tract. It is hypothesized that spinal cord epidural stimulation (scES) has clinical effectiveness for restoration of voluntary and reflex control of the lower urinary tract. The objective of the current functional mapping pre-clinical animal study is to identify scES configurations (location, amplitude and frequency) that can promote optimal neural control of urine storage (adequate bladder capacity at safe pressures without incontinence) and/or sufficient controlled emptying (high voiding efficiency at safe leak point pressures).

STUDY DESIGN, MATERIALS AND METHODS

Mapping at L5-S1 with scES was performed in 20 female Wistar rats to identify parameters for bladder storage and/or emptying. The L5-S1 spinal cord was targeted first as this level has inputs/outputs of pelvic (parasympathetic) and pudendal (somatic) nerves supplying the pelvic visceral organs (equivalent to S2-4 in humans). Using spinally intact (n=10) and chronic complete transected rats (T9 spinal level; n=10) in an acute urethane-anesthetized terminal preparation, scES was systematically applied over a wide surface area with a modified Medtronic 5-6-5 electrode during bladder filling/emptying cycles while recording bladder pressures along with external urethral sphincter EMG activity. Note that a power analysis was performed on the expected group means based on literature from similar studies showing that a sample size of 8 per group would achieve a significant difference between the groups with a power of 99% (2 rats added for a total of 10/group to account for possible attrition rates based on complications). In addition, a specially designed rodent-sized miniature 15-electrode array was then used in five more spinally intact female rats to assess the optimal responsive location within the L5-S1 region.

RESULTS

With scES on, all spinally intact rat cystometrograms show a steep rise in bladder pressure when capacity is reached and a subsequent overflow incontinence, with a contraction and void only upon offset of scES. In contrast, animals with a chronic spinal transection void immediately at the onset of scES. Intensity parameters in the 300-500 µA range and frequencies in the 30-60 Hz range at L5-S1 were necessary for holding in the intact rats and for an immediate void in the transected group. Although 100% of the intact rats had consistent fill/void cycles, 40% of the transected group had overflow incontinence without any contractions, although scES was still effective in inducing a void. Note that the EMG pattern during the scES-induced hold was reflective of guarding-like activity and had the typical consistent phasic bursting pattern during emptying. In contrast, the transected group of rats had intermittent patterns of high activity consistent with detrusor sphincter dyssynergia. Furthermore, the optimal urinary system effects were found with the miniature 15-electrode array to be located at L6. The scES parameters were at the same frequencies but intensities were at significantly lower levels (50-80 µA) with minimal concomitant motor responses.

INTERPRETATION OF RESULTS

The results indicate frequency and intensity dependent effects on bladder capacity, micturition, and sphincter EMG activity that differed depending upon neurological intactness. These findings are consistent with known plasticity of the lower urinary tract segmental circuitry in the intact versus the chronic transection model.

CONCLUDING MESSAGE

Epidural stimulation for activating spinal circuits involved with urinary function is a promising neuromodulation approach for expedient translation to individuals with SCI.

Funding The studies were funded by the NIH SPARC Grant OT2OD024898. **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Local University Institutional Animal Care and Use committee

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REGIONAL DISTRIBUTION OF URINARY BLADDER SENSORY RECEPTORS RECRUITING TONIC OR PHASIC BURSTING ACTIVITY OF THE EXTERNAL URETHRAL SPHINCTER IN FEMALE RATS

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract (LUT) functions are storage and urine expulsion. In rats, the external urethral sphincter (EUS) has basal tonic contraction during urine storage and phasic bursting discharge (EUS-PBD) during voiding [1]. EUS-PBD concurs with bladder contraction and facilitates voiding efficiency [2]. The coordinated activity of the bladder and urethra is under neural control. Since EUS-PBD is recruited during voiding we hypothesize that mechanorreceptors localized at the base of the bladder recruits EUS-PBD. The aim of the present study is to investigate in spinally intact rats whether sensory mechanoreceptors recruiting EUS-PBD are regionally distributed in the bladder, as well as to determine the afferent pathways of this viscero-motor reflex.

STUDY DESIGN, MATERIALS AND METHODS

The experimental protocol was approved by the University Committee on Laboratory Animals, according to the guidelines of the Mexican Council on Laboratory Animals Care (NOM-062-ZOO-1999) and NIH Guide for the Care and Use of Laboratory Animals. We employed 18 (urethane 1.2g/kg) anesthetized adult Wistar female rats (250–300 g) to assess the EUS electromyography (EMG) pattern. In the Experiment 1 (n=6), a suprapubic catheter was implanted. Simultaneous EUS-EMG-cystometrograms (CMG) were recorded, before and during 5-20 min after an injection of 0.05 mL topical anesthetic (Lidocaine-epinephrine 2%) in four points of the bladder dome, body or bladder neck (randomly order). Bladder contraction amplitude and EUS-PBD were evaluated. In Experiment 2 (n=6), the bladder was emptied and the ureters were bilaterally cut to avoid bladder filling. EUS EMG was recorded before and during sequential mechanical distension of the urinary bladder wall. Mechanical distension was externally applied in the bladder dome, with forceps, then this region was transversally cut off. The bladder wall of the cut site was brushed with a cotton bud (~10 g) and slightly distended with forceps, and then was sectioned. This procedure was repeated at one mm long steps, from the dome to the bladder neck. Intersection interval was 5 min interval. In Experiment 3 (n=6), the rostral half of the bladder was sectioned. EUS EMG was recorded before, during and after mechanical stimulation of the bladder neck with a cotton bud; in intact condition and after unilateral and bilateral transection of the hypogastric (HG) and/or viscerocutaneous branch of the pelvic nerve (VCBPN). Mechanical stimulation of the clitoris was performed to corroborate integrity of the motor pathway of the reflex. Statistical analysis was performed using Sigma Plot Software (version 12, Systat Software, Inc.). Paired Student´s t-test was used to analyze the data. P values of <0.05 indicated a statistically significant difference for statistical comparisons.

RESULTS

Experiment 1. EUS tonic activity was observed during bladder filling and EUS-PBD during voiding. Amplitude of bladder contraction significantly decreased ($p<0.01$) after 3-5min of application of lidocaine in bladder dome or bladder body, EUS-PBD was not abolished. Normal CMG returned after 25-30 min of lidocaine. Lidocaine injection in the bladder neck not only eliminated EUS-PBD, but also bladder contraction. In 100% of the rats of the Experiment 2, mechanical distension of the bladder dome and bladder body evoked EUS tonic activity. However, distension of the bladder neck evoked EUS-PBD in 83.33% (5/6) of the animals. Experiment 3. Unilateral and bilateral transection of the HG nerve did not significantly ($p>0.05$) modify the amplitude or frequency of the EUS EMG tonic response, neither abolished EUS-PBD. In contrast, unilateral transection of the VCBPN significantly decreased EUS EMG amplitude (tonic and phasic). Bilateral VCBPN transection abolished both, tonic and EUS-PBD EMG response. However, clitoris stimulation was still discharging EUS EMG activity.

INTERPRETATION OF RESULTS

In rats, EUS-PBD discharge during voiding has been considered as an indicator or bladder-sphincter synergy. Our findings show that mechanical distension of the rostral region of the bladder recruits only EUS tonic activity, furthermore, distension on the bladder neck discharges EUS-PBD, which suggest there are two types of EUS motor units. Tonic and bursting motor units have been localized at L6-S1 (tonic) and in L3-L5 (bursting) spinal cord segments [3]. Our data suggest that during micturition, L3-L5 motor units are recruited by mecanoreceptors localized in the bladder neck.

CONCLUDING MESSAGE

Bladder mechanoreceptors recruiting tonic and bursting EUS motor units are regionally segregated. This segregation may convey to a functional segmented bladder, with the distal region being important to induce bladder-urethral synergy during voiding. Further studies are necessary to determine whether alteration of this segregation system may result in urinary disorders.

REFERENCES

1. D'Amico, S. C., Collins, W. F., 3rd: External urethral sphincter motor unit recruitment patterns during micturition in the spinally intact and transected adult rat. J Neurophysiol, 108: 2554, 2012
2. Cruz, Y., Pastelin, C. F., Balog, B. M. et al.: Somatomotor and sensory urethral control of micturition in female rats. American journal of physiology. Renal physiology: ajprenal 00255 2014, 2014
3. Chang, H. Y., Cheng, C. L., Chen, J. J. et al.: Serotonergic drugs and spinal cord transections indicate that different spinal circuits are involved in external urethral sphincter activity in rats. Am J Physiol Renal Physiol, 292: F1044, 2007

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BEST IN CATEGORY PRIZE "ANATOMY / BIOMECHANICS"

THE FRESH FROZEN CADAVERIC STUDY OF DIRECT POUCH OF DOUGLAS TROCAR INSERTION FOR VAGINAL NATURAL ORIFICE TRANSLUMINAL ENDOSCOPIC SURGERY

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HYPOTHESIS / AIMS OF STUDY

In order to overcome the risks of bowel or vascular injury during blind entrance to the Pouch of Douglas (POD), ultrasound and other imaging modalities have been investigated and the ultrasound technique can be easily learned by surgeons. In this study we hypothesized that in patients without suspected history of POD obliteration, blind POD entry for the purposes of creating a surgical port using a transvaginal trocar can be feasible. This concept has previously been tested in an Ovine Model. As such we chose to test our hypothesis on female frozen cadavers to demonstrate safe angles for entry of the trocar into POD.

STUDY DESIGN, MATERIALS AND METHODS

Four fresh frozen cadaveric specimens with an intact uterus were identified. Laparotomy incisions were made and the abdominal content was packed cephalad in the upper abdomen. Posterior fornix was grasped 3 cm posterior to the cervix with an Alice clamp. The distance between S2 and POD was measured. The Alice clamp effectively provided traction and kept the rectum posterior to the entry point. A 2 cm incision was made between the posterior cervix and the Alice clamp. An 11 mm trocar (Ethicon ENDOPATH Excel) was placed at the incision site and maximum pressure was exerted, horizontal to the axis of the bed, to the extent that the tip of the trocar tented the peritoneum. The distance between the S2 and the trocar tip under the peritoneum was measured. The S2 was designated at zero centimeters. The trocar tip movement of POD with pressure was: Difference = (sacrum to POD with pressure) - (Sacrum to POD). At this point, the trocar was advanced to puncture the peritoneum and pointed anteriorly to clear the sacrum and the bifurcation of the major vessels. The angle required to safely clear the sacral blood vessels was measured.

The trocar insert was removed and passing the measuring tape through the trocar, the distance between S2 and the hymen was measured as a direct line. The POD distensibility was calculated as % Change = Difference / Sacrum to the hymen. The mean of these measurements was calculated. The above procedure was repeated with robotic trocars (Memic Innovative Surgery, Israel) and measurements were obtained. The Memic trocar is a specialized trocar that has a needle tip that engages to prevent movement of the peritoneum.

RESULTS

The average age of cadavers was 60. With the full deployment of the trocar in the POD, the tip of neither trocar was less than 2 cm away from the sacrum before it had to be curved anteriorly to clear the sacrum. With removal of the trocar insert at full deployment and pressure, this distance increased to 4 cm. The average distance for sacrum to the hymen, sacrum to cul de sac, and sacrum to POD with pressure were respectively, 18.75, 9.75, and 7.25 cm respectively. After the deployment of the trocar, the tip was 2 cm below the cervix at the POD (Table 1). The distance between the sacrum and the POD with the application of trocar pressure was reduced on 35% on average. The mean trocar angle to clear the sacral promontory and neurovascular structures without injury to the uterus was 25-40 degrees from the horizontal plane, and 15-30 degrees from the mid-sagittal plane (Fig 1).

INTERPRETATION OF RESULTS

In this fresh-frozen cadaveric study, the technique for direct laparoscopic trocar entry into the POD is validated. It is shown that with appropriate technique and angulation of the trocar, the rectum and sacral vascular structures can be avoided. This technique needs to be authenticated in the clinical setting for patients undergoing laparoscopic or robotic vNOTES surgeries.

CONCLUDING MESSAGE

The aim of the current study was to investigate if transvaginal direct pouch of Douglas entry using a laparoscopic trocar. This concept is important as the use of the POD as surgical port access has gained popularity for both vNOTES surgeries [10-13] and vaginal robotic surgery. This is particu-

larly important as POD port of entry affords enlargement of the port for primary surgeries such as hysterectomy, bladder repair, ureteroneocystostomy or adnexectomy, or large tissue extraction without the need for additional abdominal incisions.

FIGURE 1

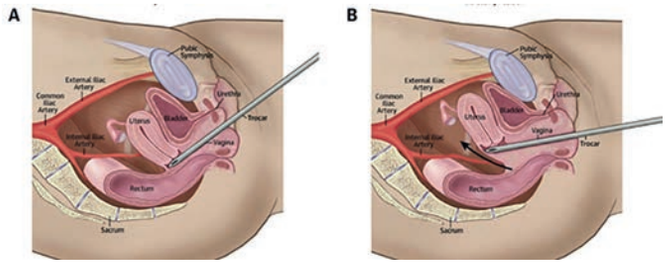

Fig 1. The angle of trocar POD entry A. Insertion and pressure is applied, 2) the POD is lifted anteriorly to allow for the trocar to advance above the sacrum area if necessary.

FIGURE 2

Table 1.

Sacrum to POD	Sacrum to POD with pressure	Difference in cm	Sacrum to hymen	% Reduction Sacrum to POD	% change (Dispensability)	Degrees from Horizontal
12	8	4	19	50	21	25
10	8	2	20	25	10	40
8	6	2	18	33	11	35
9	7	2	18	29	11	33
Mean	Mean	Mean	Mean	Mean	Mean	Mean
9.75	7.25	2.5	18.75	35	13.3	33

Table 1. shows the individual measurements in each cadaver.

REFERENCES

1. Alshiek, J., L. Bar-El, and S.A. Shobeiri, Vaginal Robotic Supracervical Hysterectomy in an Ovine Animal Model: The Proof of Concept. Open Journal of Obstetrics and Gynecology, 2019. 09(08): p. 1114-1129.
2. Sheth, S.S., K.P. Paghdiwalla, and A.R. Hajari, Vaginal route: a gynaecological route for much more than hysterectomy. Best Pract Res Clin Obstet Gynaecol, 2011. 25(2): p. 115-32.
3. Bernhardt, J., et al., Update in natural orifice translumenal endoscopic surgery. Current opinion in gastroenterology, 2017. 33(5): p. 346-351.

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HISTOLOGIC AND IMMUNOLOGIC CHARACTERIZATION OF PELVIC FLOOR IN WOMEN, 1: INFLAMMATORY CYTOKINE EXPRESSION IN PELVIC FLOOR MUSCLE OF A MOUSE MODEL

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HYPOTHESIS / AIMS OF STUDY

Vaginal birth increases the risk for developing pelvic organ prolapse (POP) among parous women and is the single most important modifiable risk factor for this condition (1). The first vaginal birth has been shown to pose the greatest risk for POP. This hidden epidemic indicates the urgent need to prioritize research focused on understanding mechanisms involved in pelvic floor injury and repair and to develop prevention strategies. Although we are now capable of identifying the presence and location of injury, factors involved in the repair of birth-related injury that will impact healing and eventual development of a pelvic floor disorder remain unknown.

Pro-inflammatory cytokines such as interleukin 6 (IL-6) are known to be induced in response to skeletal muscle injury and are essential for modulating inflammation and healing following injury (2). Altered expression of specific inflammatory cytokines could lead to altered inflammation and poor healing of pelvic floor muscle injury following vaginal delivery and to later development of pelvic floor dysfunction. The current lack of research using a human model to determine the specific markers to evaluate when investigating pelvic floor injury indicates the need for the development of an animal model. The present study aimed to develop a mouse model to investigate the expression of inflammatory markers in mice with levator ani (LA) injury similar to that seen in vaginal delivery, and what role the pleiotropic cytokine IL-6 plays in this process.

STUDY DESIGN, MATERIALS AND METHODS

IL-6 knockout (KO) and C57 wild type mice were used to develop a model for simulating birth injury to the LA. To simulate injury, a Word catheter was inserted into the rectum of the study mice and inflated with 0.3ml saline and affixed to a 100-gram weight hung to gravity. Injured LA muscles from these mice were harvested and evaluated histologically for injury and inflammatory response relative to mouse strain. Expression of IL-1β, TNFα, IL-10, CCL2, CCL3, CCL4, CXCL1, CXCL2, and CXCL10 protein and mRNA was measured by multiplex protein assay and RT-PCR respectively.

Non-parametric Mann-Whitney U exact tests were used to determine differences in cytokine expression. The dependent variable in the model was the cytokine expression and the independent variable was mouse strain. An a priori significance level was set at an alpha 0.05 and cytokine expression between strains considered statistically significantly different when the calculated p-value was less than 0.05.

RESULTS

IL-6 KO mice had a greater inflammatory response following LA injury seen with histologic estimation of the number of inflammatory cells on post-injury day 5 than C57 mice (p=0.0351). Additionally, the IL-6 KO strain displayed increased protein expression of IL-1β, CCL3, and CCL4 compared to C57 mice five days post-injury (p=0.0106, p=0.0182, and p=0.0364, respectively).

INTERPRETATION OF RESULTS

This study is the first attempt to characterize which, if any, inflammatory mediators may be important in the immune response to pelvic floor muscle injury (specifically, the levator ani muscle). Using our model, we successfully demonstrated that, in a murine model simulating injury to the LA muscle that would be expected with childbirth, mice deficient IL-6 respond differently as compared to wild-type mice. Specifically, the concentration of IL-1β, CCL3, and CCL4 in injured muscle tissue was significantly greater in IL-6 deficient mice than in the C57 strain as late as post-injury day 5 (Fig 1). This would indicate a possible prolonged pro-inflammatory response in the IL-6 KO mice. Furthermore, although not statistically significant, the IL-6 KO mice had a lower concentration of only one protein: CCL2. This protein is known to be pro-healing (3), and thus its lower concentration raises the question of delayed anti-inflammatory/pro-healing actions in these mice (Graph 1).

CONCLUDING MESSAGE

IL-6 KO mice have decreased healing and increased inflammatory cell infiltration and pro-inflammatory cytokine expression following simulated birth injury to the LA muscle compared to C57 wild-type mice.

FIGURE 1

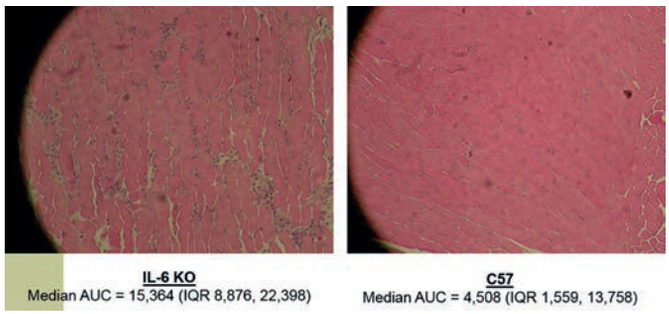
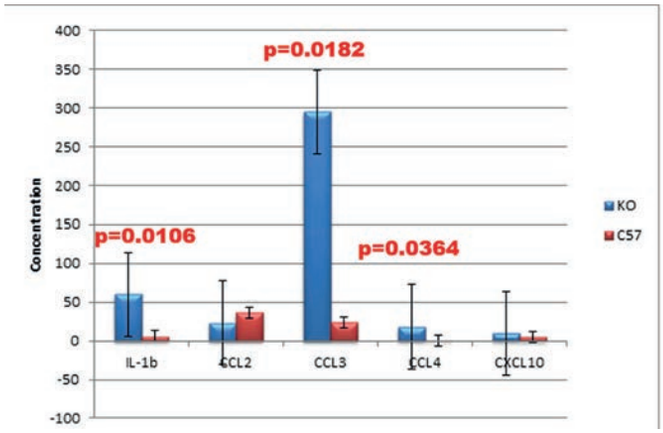


Fig 1.

FIGURE 2



Graph 1.

REFERENCES

1. Patel DA, Xu X, Thomason AD, Ransom SB, Ivy JS, DeLancey JOCINAJOGM, et al. Childbirth and pelvic floor dysfunction: an epidemiologic approach to the assessment of prevention opportunities at delivery. American journal of obstetrics and gynecology.
2. Philippou A, Bogdanis G, Maridaki M, Halapas A, Sourla A, Koutsilieris M. Systemic cytokine response following exercise-induced muscle damage in humans. Clinical chemistry and laboratory medicine : CCLM / FESCC. 2009;47(6):777-82.
3. Warren GL, Hulderman T, Mishra D, Gao X, Millecchia L, O'Farrell L, et al. Chemokine receptor CCR2 involvement in skeletal muscle regeneration. FASEB journal : official publication of the Federation of American Societies for Experimental Biology. 2005;19(3):413-5.

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213 www.ics.org/2020/abstract/213

CHARACTERIZATION OF FUNCTIONAL AND HISTOLOGICAL CHANGES OF THE URETHRA IN RAT MODELS OF STRESS URINARY INCONTINENCE (SUI) INDUCED BY SIMULATED BIRTH TRAUMA OR ESTROGEN DEFICIENCY

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HYPOTHESIS / AIMS OF STUDY

Stress urinary incontinence (SUI) is the common type of urinary incontinence with a significantly negative impact on quality of life in women. Although the etiology of SUI in women seems to be multifactorial, multiple vaginal parities and estrogen deficiency are considered to be important risk factors of SUI in elderly women. Thus, animal models of simulated birth trauma induced by multiple vaginal distention (VD) and estrogen deficiency induced by bilateral ovariectomy (OVX) have been used to study the SUI pathophysiology in rats. It is well known that simulated birth trauma injury induced by single VD elicits a SUI condition in rats, which is, however, usually restored within 2 weeks. In previous studies, multiple birth trauma injuries in rats significantly impairs urethral function, resulting in longer-lasting SUI [Ref.1]. It has also been reported in rats that OVX significantly impairs urethral function from the early stage (3 weeks), but does not induce SUI until the late phase (6 weeks).

In rats, bilateral OVX reportedly induces morphological changes in the urethral epithelium [Ref.2]. It has also been reported that serotonergic (5HT) paraneurons uniquely located in the urethra can modulate urethral sensory function and that their numbers decrease in aged or diabetes rats [Ref.3]. However, the difference of changes in the urethra in these two models has not been well characterized, especially regarding epithelial morphology and the expression of 5HT+ paraneurons in the urethra. We therefore evaluated the urethral histological changes of the epithelium and 5HT+ cell expression, and urethral continence function in rats with OVX-induced estrogen deficiency or VD-induced simulated birth trauma.

STUDY DESIGN, MATERIALS AND METHODS

A total of 60 adult virgin Sprague-Dawley rats (8-12 weeks old) were used. Rats were divided into; (1) sham operation group (laparotomy and wound closure) (N=12); (2) OVX 3-weeks group (N=12); (3) OVX 6-weeks group (N=12); (4) one-time VD group (N=12) [VD-1] ;(5) three-times VDs group (N=12) [VD-3]. VD was induced by balloon catheter inflation in the vagina (4ml, 4 hour) as previously described [Ref.1]. In the VD-1 group, VD was performed once 2 weeks before the evaluation. In the VD-3 group, VD was repeated every 2 weeks for 3 times, and the urethral evaluation was performed at 2 weeks after the final VD. In the OVX group, the urethral evaluation was performed after 3 or 6 weeks of bilateral OVX.

The surgical techniques for urethral function testing were same as previously described [Ref.1]. The bladder was exposed through an abdominal incision, ureters were cut bilaterally, and their distal ends were ligated. The visceral branches of the pelvic nerves were transected bilaterally near the internal iliac vessels to prevent reflex bladder contractions. Urethral function was evaluated by a 3.5-Fr nylon catheter with a side-mounted microtransducer located 1 mm from the catheter tip in 6 rats of each group. The catheter was inserted into the middle urethra (10 to 15 mm from the urethral orifice), at which the highest urethral baseline pressure (UBP) was obtained. The microtransducer-tipped catheter was connected to a pressure transducer, and urethral responses were recorded with data-acquisition software on a computer system equipped with an analog-to-digital converter. The catheter position was monitored throughout the experiments to confirm that the location of the transducer had not been changed. After UBP became stable, approximately 20 min after the catheter insertion, sneezes were induced by an insertion of a rat's whisker into the nostril; and the changes of urethral responses during sneezing were examined by measuring amplitudes of the urethral responses during sneezing (A-URS), which were determined as the maximal pressure change from the baseline in centimeters per H2O during sneezing.

Following the urethral function analysis, the mid urethra was harvested, and the tissue sections (10 μm) were stained with Hematoxylin-eosin (H&E) and anti-5HT antibodies (rabbit anti-5-HT, 1:100, No. 20080, Immunostar, Houston, TX, and Alexa Fluor 488 Donkey Anti-Rabbit IgG, 1:400, ab150073, abcam, Cambridge, MA) for immunofluorescent detection of 5HT+ paraneurons. Quantitative morphometric analysis was done by the image J software.

In addition, in separate groups of rats (n=6, each group), changes in urethral mRNA levels of tryptophan hydroxylase-1 (TPH1), a key enzyme of 5HT synthesis, were quantified and normalized by a housekeeping gene (glyceraldehyde-3-phosphate dehydrogenase ; GAPDH) using RT-PCR.

All data are represented as means ± SE. Statistical significance was evaluated in each group vs. sham group using one-way ANOVA followed by Dunnett's multiple comparison test. Thereafter, repeated ANOVA measures followed by Tukey's multiple comparison test for the comparison between two groups. All data were analyzed using the JMP software (ver. 11; SAS Institute, Cary, NC). $P < 0.05$ was considered significant.

RESULTS

In the 3-weeks or 6-weeks OVX groups, UBP was significantly decreased only in 6-weeks rats compared to sham rats (45.3% reduction, P < 0.05, Fig.1A). Also, A-URS were significantly reduced in OVX 3-weeks (19.0% reduction) and 6-weeks (49.7% reduction) compared to sham rats (P < 0.05, Fig.1A). In the single or multiple VD groups, UBP was significantly decreased only in VD-3 rats compared to sham rats (51.2% reduction, P < 0.001). Also, A-URS was significantly decreased only in VD-3 rats compared to sham rats (51.1% reduction, P < 0.001, Fig.1A). In histological analyses, the mean thickness of the epithelium of the mid-urethra was significantly decreased in OVX 3-weeks (30.2±2.18 μm), OVX 6-weeks (29.3±1.98 μm), VD-1 (54.1±2.21 μm) and VD-3 (29.9±2.07 μm) rats compared to sham rats (72.3±2.19 μm, P < 0.0001, Fig1.B,C). The reduction of epithelial thickness in VD-1 rats were significantly milder compared to OVX 3, 6-weeks and VD- 3 groups (Fig.1C). The number of 5HT+ paraneurons in the urethra wall was significantly decreased in OVX 3-weeks (10.1±0.64/mm2), OVX 6-weeks (9.48±0.60/mm2), VD-1 (13.6±0.93/mm2) and VD-3 (9.10±0.72/mm2) rats compared to sham rats (17.7±0.59/mm2, P < 0.001, Fig2.A,B). The reduction of 5HT+ paraneurons in VD-1 rats was significantly milder compared to OVX 3, 6-weeks and VD-3 groups (Fig.2B). In RT-PCR, relative mRNA levels of TPH-1 were significantly decreased in OVX 3-weeks (0.497±0.06), OVX 6-weeks (0.456±0.05) and VD-3 rats (0.469±0.06) compared to sham rats (1.000 ±0.15, Fig2.C, P < 0.01). VD-1 rats exhibited a tendency in a decrease of TPH-1 expression (0.824±0.06), without statistical significance compared to sham rats (P = 0.598).

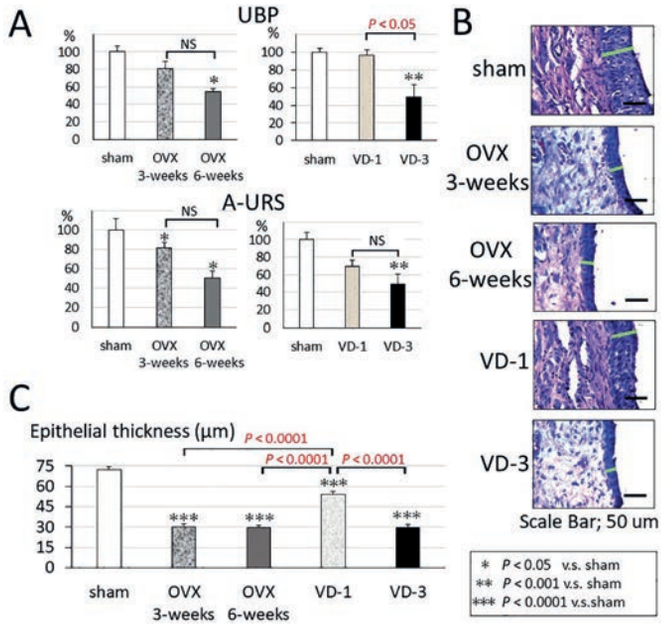
INTERPRETATION OF RESULTS

The two SUI models exhibited similar urethral dysfunction evident as reductions in UBP and urethral responses during sneezing. The assessment of urethral structural changes in these two models also revealed that urethral epithelial atrophy and loss of 5HT+ paraneurons occur prior to urethral dysfunction inducing SUI in both models and that these changes occur rapidly at a greater degree from the early phase (3 weeks) of OVX, compared to VD groups, which showed the slower onset of these histological changes. Thus, the tissue-damaging process in the urethra, which contributes to the establishment of SUI, could be different between VD-induced simulated birth trauma and OVX-induced estrogen deficiency.

CONCLUDING MESSAGE

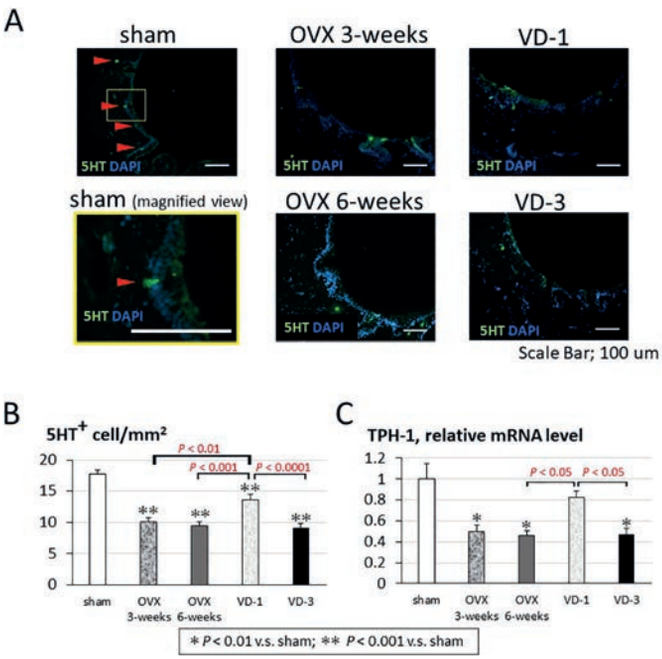
Both multiple birth trauma and estrogen deficiency play significant roles in inducing SUI; however, the pathohistological process of these two conditions might be different. Therefore, the combination of these two risk factors could accelerate the disease process of SUI in women. In addition, the two SUI models used in this study would be suitable for the study of different aspects of the pathophysiological mechanisms of SUI.

FIGURE 1



Urethral function and histology. (A) Urethral Function (B) Representative histological image (C) Epithelial thickness of urethra

FIGURE 2



(A) Immunofluorescence staining from urethral sections double-stained with 5-HT+ paraneurons (green) and DAPI (blue) (B) Density of 5-HT+ cells in urethra (C) Relative mRNA levels of TPH1 in urethra

REFERENCES

1. Yoshikawa S, et al. Effects of multiple simulated birth traumas on urethral continence function in rats. Am J Physiol Renal Physiol (2017) 313:1089-1096.

2. dos Santos AR, et al. Morphometric analysis of the urethra of castrated female rats treated with tamoxifen. Maturitas (2008) 59:275-80
3. Cao N, et al. Streptozotocin-induced diabetes causes upregulation of serotonin (5-HT)2A/C receptors in lumbosacral cord motoneurons and down regulation of serotonergic paraneurons in the urethra. Brain Res (2019) 1715:21-26.

Funding NIH R01DK107450, Uehara Memorial Foundation, Mochida Memorial Foundation for Medical and Pharmaceutical Research **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** University of Pittsburgh institutional animal care and use committee

SESSION 15 (PODIUM VIDEO) - VIDEO 1: PROLAPSE SURGERY
Abstracts 214-222
16:30 - 18:00, Brasilia 4
Chairs: Mr Ammar Alhasso (United Kingdom), Dr Ayman Mahdy (United States)

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RECTAL PROLAPSE REPAIR IN MALES: IS ROBOTIC VENTRAL MESH RETROPEXY THE RIGHT CHOICE?

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INTRODUCTION
Rectal prolapse is uncommon in men, representing 10% of rectal prolapse cases. Surgical options for repair include abdominal and perineal approaches. Abdominal approaches have gained favor for appropriate patients as they may provide more durable results. Minimally invasive abdominal approaches, such as robotic ventral mesh rectopexy, have gained acceptance as safe and effective procedures to treat pelvic organ prolapse.

Rectal prolapse repair in male patients requires additional consideration of pelvic nerve anatomy to reduce the risk of injury to hypogastric or parasympathetic nerves during rectal mobilization. Existing data suggests that minimally invasive ventral mesh rectopexy can be completed safely in male patients with minimal risk of postoperative sexual dysfunction [1-3]. We review the relevant anatomy and techniques necessary to complete robotic ventral mesh rectopexy safely in male patients.

DESIGN
In this video, we discuss the technique for robotic ventral mesh rectopexy using a sample case in a male patient. We demonstrate potential nerve injuries that can occur during male abdominal rectal prolapse procedures and how to avoid them.

RESULTS
We present the case of a healthy 77-year-old man with full thickness rectal prolapse, whose progressive symptoms led to obstructed defecation. Preoperative workup included anorectal manometry and MRI defecography. Robotic ventral rectopexy was planned. Following standard port placement and docking, the peritoneum overlying the sacrum was opened and cleared until the anterior longitudinal ligament was visualized. Anterior dissection was performed by dividing the anterior peritoneum overlying Denonvilliers' fascia, mobilizing the peritoneum off of the rectum. Dissection proceeded inferiorly towards the rectovesical pouch, staying close to the rectum. Wide lateral dissection was avoided to prevent disruption of the pelvic neural plexus. A Biodesign (Cook) rectopexy graft was cut to a hockey-stick configuration and sutured to the anterior rectum at the prolapse lead point using 2-0 PDS sutures. The graft was attached to the sacral promontory using 2-0 Prolene sutures. The entrance and exit point of the needle was visualized to confirm that the hypogastric nerve was not been inadvertently involved. Repeat rectal examination elicited no further prolapse, confirming the integrity of the repair. Peritoneal flaps were closed using 2-0 Monocryl to cover the graft. The patient recovered uneventfully and was discharged to home on POD1 with improved quality of life reported at one month postoperatively.

CONCLUSION
We support the use of minimally invasive ventral mesh rectopexy for males with rectal prolapse. Critical technical points include maintaining a plane close to the rectum and avoiding wide lateral dissection to minimize pelvic nerve plexus disruption. Mesh placement should fixate the prolapse lead point distally and avoid involving the hypogastric nerve proximally during fixation on the sacral promontory. Unnecessary mesh tension should be avoided and peritoneum overlying the mesh should be closed.

REFERENCES
1. Owais AE, Sumrien H, Mabey K, McCarthy K, Greenslade GL, Dixon AR. Laparoscopic ventral mesh rectopexy in male patients with internal or external rectal prolapse. Colorectal Dis. 2014;16(12):995-1000.
2. Siddika A, Saha S, Siddiqi S. Evolution of male rectal prolapse surgery and initial experience of robotic rectopexy in men. J Robot Surg. 2017;11(3):311-316.

3. Rautio T, Makela-Kaikkonen J, Vaarala M, et al. Laparoscopic ventral rectopexy in male patients with external rectal prolapse is associated with a high reoperation rate. Tech Coloproctol. 2016;20(10):715-720.

Funding None **Clinical Trial** No **Subjects** None

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BEST VIDEO ABSTRACT

ROBOTIC-ASSISTED SACROCOLPOPEXY UTILIZING A POSTERIOR RECTUS FASCIA GRAFT

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INTRODUCTION
Recurrent prolapse and mesh erosion are known complications that can arise in the setting of pelvic organ prolapse repair utilizing synthetic mesh. Management of such outcomes can be technically demanding and require surgical innovation. The objective of this presentation is to outline a novel surgical technique for a robotic-assisted sacrocolpopexy utilizing a posterior rectus fascia graft.

DESIGN
A 68-year-old G3P3 female with three previous vaginal deliveries presented with pelvic organ prolapse and symptomatic vaginal mesh erosion. The patient had a previous vaginal hysterectomy and right salpingo-oophorectomy followed by a robotic-assisted sacrocolpopexy for symptomatic pelvic organ prolapse. This was complicated by vaginal mesh erosion and she underwent a transvaginal mesh excision. As a result, the patient presented for management of ongoing mesh erosion as well as symptomatic pelvic organ prolapse recurrence. Given her previous surgical history as well as current state of mesh erosion, the patient was counseled on surgical management and elected to proceed with a robotic-assisted sacrocolpopexy utilizing a posterior rectus fascia graft.

RESULTS
Preoperative physical exam demonstrated pelvic organ prolapse recurrence and vaginal mesh erosion. Intraoperatively, she was placed in the dorsal lithotomy position and was prepped and draped in the normal sterile fashion with administration of preprocedural antibiotics. Four robotic ports were inserted in the standard robotic-assisted sacrocolpopexy fashion as well as a right-sided assistant port. The sacral limb of the previous mesh was identified and the overlying peritoneum was incised and dissected inferiorly towards the vagina utilizing a vaginal probe to guide the dissection. A vaginotomy was created to excise the eroded mesh in its entirety. The previous mesh was then dissected off of the vagina both anteriorly and posteriorly and the vaginotomy was closed. The robot was redocked after rotating the boom with the utilization of two additional left sided ports to create the posterior rectus fascial graft harvest. Borders of the facial harvest included the linea alba medially, semilunar line laterally, and the inferior border was just immediately superior to the arcuate line. The dissection was carried superiorly for a distance of approximately 20 cm to construct a "Y" autologous suspension graft. The robot was then docked in the original position and the fascial harvest was secured to the vagina anteriorly and posteriorly with the superior limb secured to the sacral limb of the previous mesh. Two months postoperatively, the patient had a well-supported vaginal apex with no evidence of foreign body extrusion and a well-healed vaginal cuff.

CONCLUSION
Robotic-assisted sacrocolpopexy using a posterior rectus fascia graft is feasible, particularly in the setting of previous surgical repair of pelvic organ prolapse.

Funding None **Clinical Trial** No **Subjects** None

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ROBOTIC COLPOSACROPEXY WITH AUTOLOGOUS FASCIA LATA

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INTRODUCTION
The treatment of vaginal vault prolapse is still challenging. Abdominal colposacropexy with syntethic mesh is considered the gold standard. Despite the good anatomical outcome, this tecnique is perfectible because of the risk of mesh complications, first of all exposure.

Some American authors have started using autologous graft obtained by fascia lata during colposacropexy, a strong and easily accessible tissue. No european experience is reported as far as we know.

Our objective was to evaluate the feasibility and safety of a technique for robotic sacrocolpopexy using autologous fascia lata mesh for the treatment of pelvic organ prolapse.

DESIGN
The video shows our technique for robotic sacrocolpopexy with autologous fascia lata.

The harvest of two pieces of fascia lata from dominant leg was obtained by orthopedist (8x4 cm and 15x3 cm), then robotic operating time was started by gynaecologists.

First piece was used to cover vaginal vault and reinforce anterior and posterior vaginal wall after extended dissection. Absorbable suture were used. The second piece was secured to the sacral promontory with two non absorbable sutures and attached to vaginal cuff.

RESULTS
The procedure was performed on 3 patients with vaginal vault prolapse after hysterectomy.

Mean age was 73 years. One patient underwent concomitant posterior repair for rectocele.

Colposuspension was very satisfying at a mean follow up of 6 months and all the patients improved their symptoms. Neither operative complications nor hernia at the harvest site occurred.

CONCLUSION
Robotic sacrocolpopexy with total autologous fascia lata is a feasible alternative to traditional surgery with synthetic mesh. Vaginal suspension is very satisfying at short- term follow up. Further studies are needed to verify the effectiveness over time.

REFERENCES
1. Scott VCS et al. Robot-assisted laparoscopic sacrocolpopexy with autologous fascia lata: technique and initial outcomes. Int Urogynecol J. 2019 Nov;30(11):1965-1971.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comitato etico ASST Lecco **Helsinki** Yes **Informed Consent** Yes

217 www.ics.org/2020/abstract/217

ROBOTIC-ASSISTED LAPAROSCOPIC VESICOUTERINE FISTULA REPAIR

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INTRODUCTION
Vesicouterine fistulas are uncommon in comparison to other urogenital tract fistulas in women, accounting for 1-4% of cases. Risk factors include cesarean delivery, dehiscence of uterine closure after repair, placenta percreta, and intrauterine device-associated injury. Presenting symptoms include leakage of urine per vagina, cyclic hematuria (Youssef's syndrome), or, amenorrhea. Diagnosis of a vesicouterine fistula includes a high degree of suspicion based on history, physical examination, cystoscopy at the time of menses and MRI imaging. Other modalities such as cystogram or hysteroscopy can be utilized as well. In this video, we demonstrate a robotic-assisted laparoscopic approach to repair of a vesicouterine fistula.

DESIGN
The patient presented is a 33-year-old woman, G4P4 (4 cesarean sections), who noticed blood in her urine after her last cesarean section 4 years prior to presentation to our clinic. She was told that she may be having urinary tract infections and was treated with antibiotics. After several years, she realized that the hematuria was cyclic and associated with her period. She additionally noted occasional urine leakage per vagina. Given this history, she underwent MRI urogram and cystoscopy at the time of menses in our clinic. MRI demonstrated tethering of the urinary bladder to the c-section scar and endometrium abutting the urinary bladder lumen, concerning for a vesicouterine fistula. Cystoscopy at the time of menses demonstrated a fistulous opening at the dome/posterior bladder wall with blood emanating from the opening. She was counseled on proceeding with robotic-assisted laparoscopic repair of vesicouterine fistula and an informed consent for the procedure and video recording was obtained.

RESULTS
The patient was given pre-operative broad-spectrum antibiotics and placed in the dorsal lithotomy position, after induction of general anesthesia. Pneumoperitoneum was created via Veress needle and 5 ports were placed in a straight line (RIGHT: 12mm Air seal port, 5mm assistant port, 8mm robotic port; LEFT: 8mm camera port, 8mm robotic ports x 2). Da Vinci Xi robot was docked after patient was placed in steep Trendelenburg position. Monopolar scissors were placed in the right arm, bipolar forceps in the left arm, and prograsp for the assistant "fourth arm". The procedure is detailed in the video with the following steps: (1) Dissection of vesicouterine space and identification of fistula (2) Closure of uterus (3) Pre-placement of omental tacking sutures (4) Closure of bladder and peritoneum (5) Omental flap interposition.

CONCLUSION
The patient was discharged on POD1 with a large bore urethral catheter for 2 weeks and oral contraception for 3 months to prevent menstruation and allow our repair to heal appropriately. Patient did well at short term follow-up with no complications. She additionally denied leakage of urine per vagina. Once removed from oral contraception, she will be evaluated for persistent bleeding with history and cystoscopy. This video details a step-by-step, minimally invasive approach to repair of a vesicouterine fistula and elucidates important anatomic considerations.

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Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Video abstract, consent obtained **Helsinki** Yes **Informed Consent** Yes

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ANATOMY OF THE RETROPUBIC SPACE

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INTRODUCTION

The retropubic Space which is also called the Space of Retzius was first described by Anders Adolf Retzius in 18491. The modern era of retropubic surgery for stress incontinence began in 1949, with Marshall et al2. A variety of modifications of this operation were then performed to expose the space of Retzius and attach the periurethral or perivesical endopelvic fascia to another supporting structure in the anterior pelvis.

Rates of injury of the external iliac vein and the aberrant obturator vessels have been quoted to be as much as 25% during colposuspension3. It is important to be aware of the retropubic anatomy, especially with increased numbers of colposuspension being performed due to increasing concerns regarding vaginal meshes. This video looks at this anatomy in a woman who has a laparoscopic colposuspension so that greater familiarity of this space is obtained.

DESIGN

This is a video demonstrating the anatomy of the retropubic space in a patient who has had a laparoscopic colposuspension.

The retropubic space is also called the pre-vesical space or the space of Retzius. It can be visualised after opening the fold of peritoneum between the bladder and the anterior abdominal wall. It is bounded anteriorly by the pubic symphysis and the superior pubic ramus laterally. The ileo-pectineal ligament runs on the pectineal line of the pubic bone. As we go laterally, inferior to the superior pubic ramus is the obturator foramen. Further lateral dissection would reveal the neuro-vascular bundle that runs into this foramen.

Superior to the superior pubic ramus, we can see the pulsation of the external iliac artery. Superior to this, we can also see the origin of the inferior epigastric artery from the external iliac artery which then enters the anterior abdominal wall. In the majority of the cases, we can see the aberrant obturator artery arising from the external iliac artery, crossing the superior pubic ramus and entering the obturator foramen.

The area of the iliopectineal ligament that is safe to places sutures on during a laparoscopic colposuspension is defined.

CONCLUSION

Awareness of the landmarks in the retropubic space reduces rates of complications during this procedure. This includes avoiding the aberrant obturator vessels which is a relatively common anatomic variation4 and therefore important in clinical practice.

REFERENCES

1. Breimer L. Anders Adolf Retzius (1796- 1860). Investigative Urology. 1978;16(253).
2. Marshall V, Marchetti A, Krantz K. The correction of stress incontinence by simple vesicourethral suspension. Surgery, Gynecology & Obstetrics. 1949;88:509–518.
3. Negura A, Andreescu G, Marderos G, Marderos G, Margarit L. Hemorrhagic risks in the Burch procedure. International Urogynecology Journal. 1993;4:310–313.

Funding None **Clinical Trial** No **Subjects** None

219 www.ics.org/2020/abstract/219

ROBOTIC COLPOSUSPENSION FOR FEMALE STRESS URINARY INCONTINENCE (SUI): A PROSPECTIVE SERIES

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INTRODUCTION

The suspension of use of sub-urethral mesh in the United Kingdom in 2018 has seen the resurgence of colposuspension in female stress urinary incontinence (SUI) surgery. Open and Laparoscopic Colposuspension techniques are well recognised. Robotic assisted laparoscopic surgery is known to confer advantages of reduced length of stay, blood loss and complications compared to open surgery. We present data from 17 Robotic Colposuspension procedures from a Tertiary Hospital in London, reporting on technique, safety and efficacy.

DESIGN

Approval was obtained from the hospital New and Novel Procedures Committee. The surgical team consisted of 2 functional urologists and 2 robotic uro-oncology surgeons. Since May 2019, 17 cases were performed through a transperitoneal four port technique using the daVinci Si system. Port placement included a supra-umbilical camera port, 2 robotic arms and a 12 mm assistant port, 5cm away from the

Left Anterior Superior Iliac Spine, for passage of sutures. The bladder was dropped, the urethrovesical angle was identified along with Cooper's ligament and the vagina. Placement of three tensioned sutures bilaterally suspending paravaginal tissue, towards Cooper's ligament, incorporating the obturator shelf. A cystoscopy was performed at the end of the procedure to ensure no visible suture in the bladder. Extraperitonealisation of the bladder was performed at the end of the procedure to restore anatomy. (A video of the technique is included). All patients had urodynamic assessment prior to surgery. Data was prospectively gathered including demographic details, pre and post-op pad usage, and urinary incontinence short form questionnaire (ICIQ-UI-SF) scores to assess symptom severity and quality of life. Paired T test analysis for pad usage and ICIQ-UI-SF was conducted.

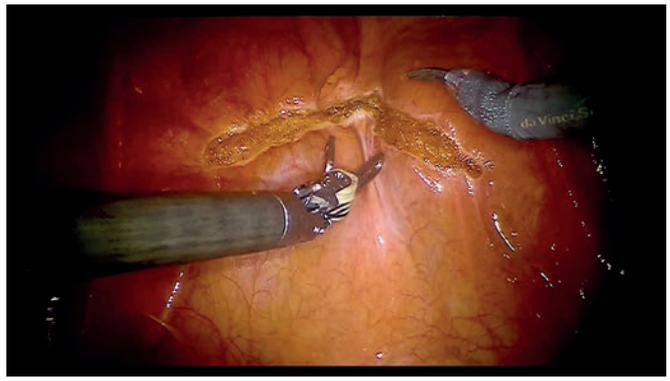
RESULTS

Since May 2019, 17 cases were performed, with a mean age and BMI of 47(years) and 29(kg/m2) respectively, with a mean follow-up period of 6 months (range 1-10 months). 11 (65%) of patients had pure urodynamic SUI, and 2 (11%) patients had a neuropathic history. 7 (41%) of patients had a previous anti-SUI procedure, where 6 patients had urethral bulking and one Transvaginal Synthetic Tape. Average operating time was 121 mins, blood loss 14mls and length of stay 2 (1-3) days. There were no post-operative complications. One patient had to start temporary de-novo intermittent self-catheterisation three times a week for 4 weeks. There was an 83% improvement in mean pad usage (from 4.8 to 0.8) and a 50% improvement in mean ICIQ-UI-SF scores (from 17 to 8.5). These translated to significant improvements using paired t-testing for pad usage (p=0.001) and ICIQ-UI-SF scores (p=0.0001). On day one post-operatively the mean pain score post operatively on day one was 5/10. One patient had to temporarily perform intermittent self-catheterisation, three times a week for one month, and one patient reported a post operative urinary tract infection.

CONCLUSION

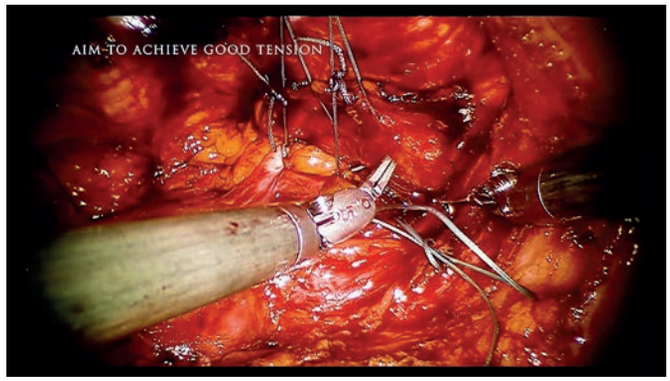
This report is the largest UK series to date of its kind. Two thirds of this cohort had pure urodynamic SUI, the remainder had mixed urinary incontinence. 41% had previous treatment for SUI. Significant improvements were seen in quality of life scores and number of pads used per day. Robotic Colposuspension is safe and feasible with satisfactory early functional outcomes. It presents a minimally invasive treatment option in female SUI, however needs larger volume evaluation and longer follow-up for further evaluation.

FIGURE 1



Bladder Drop

FIGURE 2



Tensioning Sutures

REFERENCES

1. Ward, K.L., P. Hilton, and U.a.I.T.T. Group, Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG, 2008. 115(2): p. 226-33.
2. Khan, M.S., et al., Robotic colposuspension: two case reports. J Endourol, 2007. 21(9): p. 1077-9.
3. Liu, C.Y., Laparoscopic retropubic colposuspension (Burch procedure). A review of 58 cases. J Reprod Med, 1993. 38(7): p. 526-30.

Funding No conflicts of interest **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This was a prospective clinic series **Helsinki** Yes **Informed Consent** Yes

220 www.ics.org/2020/abstract/220

SACROSPINOUS HYSTEROPEXY WITH AN AUTOLOGOUS RECTUS FASCIA SLINF FOR TREATMENT OF ADVANCED APICAL PELVIC ORGAN PROLAPSE.

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INTRODUCTION

Pelvic Organ Prolapse (POP) is a common health condition in women, especially in the elderly. Although it is not a life-threatening condition, it impacts on quality of life. The surgical approaches using synthetic meshes grew in popularity once they show good long term results and more accessible applications. However, mesh-related events increased with its widespread usage, including mesh exposure, pain, and dyspareunia. Looking for an alternative technique to avoid mesh usage, we proposed to use the autologous rectus fascia (ARF) in a similar way that it has been successfully used in urinary stress incontinence surgeries. With the ARF, it is possible to support the vaginal apex successfully. This video aims to demonstrate the technique of sacrospinous hysteropexy using autologous rectus fascia for apical POP treatment.

DESIGN

A 63-year-old woman with POP stage IV had obstructive lower urinary tract symptoms without urinary incontinence. She described the necessity to reduce the prolapse as the only way to void. No topic estrogen was prescribed before the surgery, neither oral hormone replacement therapy. Through a Pfannenstiel incision, it was possible to harvest a rectus fascia sling with approximately 90 x 10 millimeters. Our goal was to harvest an aponeurosis size quite similar to a synthetic apical sling available in the market. The anterior vaginal wall was hydrodissected and incised longitudinally from the level of the bladder neck to the cervix. It is essential to maintain the vaginal wall thickness during the dissection, and carefully sort out the connective tissue between the bladder and the vagina. The bladder base is then released from the anterior aspect of the cervix in order to create a site to pericervical ring repair and to fix the ARF. Blunt dissection was extended downwards through the lateral aspect of the levator ani fascia until the identification of the ischial spine and sacrospinous ligaments bilaterally. The pubocervical fascia rupture was identified and sutured to the anterior aspect of the cervix using 2.0 polypropylene interrupted stitches. Therefore, the anterior prolapse was corrected, and the next step aimed at the apical correction. A 2.0 polypropylene thread mounted on a specially designed tissue anchor system (TAS) was fixed into the sacrospinous ligament about 2 cm away from the ischial spine for further rectus fascia anchoring. The same step was repeated on the opposite side. We sutured the middle section of the rectus fascia to the anterior aspect of uterine cervix fascia with interrupted polypropylene 2.0 stitches. Later, both sides of rectus fascia were fixed to the two polypropylene threads previously attached to sacrospinous ligaments. After the sutures were tied, the autologous fascia took the cervix upwards and corrected the apical prolapse. Finally, the vaginal wall was closed with absorbable interrupted sutures. A vaginal pack was kept overnight as well as the Foley catheter. Both were removed at the first postoperative day when the patient was discharged from the hospital.

RESULTS

The patient resumed her usual activities after one week. She was advised not to do hard physical activities, neither sexual intercourse for two months. This patient underwent a monthly follow-up with appointments to evaluate complaints of urinary incontinence, dysfunctional voiding, pelvic pain, and dyspareunia. After six months of follow-up, she was still satisfied without recurrence, neither local complications.

CONCLUSION

This video demonstrates stepwise the feasibility of transvaginal correction of high stage apical pelvic organ prolapse without using synthetic mesh. This technique can be used for advanced stage POP patients, especially for those who want to keep her uterus and vaginal length. It is also an alternative to avoid even laparoscopic or robotic mesh implants techniques.

REFERENCES

1. Slieker-ten Hove MC, Pool-Goudzwaard AL, Eijkemans MJ, Steegers-Theunissen RP, Burger CW, Vierhout ME. The prevalence of pelvic organ prolapse symptoms and signs and their relation with bladder and bowel disorders in a general female population. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Sep;20(9):1037-45.
2. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997; 89: 501–06.
3. Clark AL, Gregory T, Smith VJ, Edwards R. Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2003; 189: 1261–67.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comitê de Ética em Pesquisa da UNICAMP **Helsinki** Yes **Informed Consent** Yes

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CYSTOCELE REPAIR BY BILATERAL PUBOCOCCYGEUS PLICATION: LONG-TERM SURGICAL AND FUNCTIONAL RESULTS OF A NOVEL TECHNIQUE.

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INTRODUCTION

In cystocele repair the use of transvaginal mesh has been strongly criticized and suspended in many countries. To date, the search for native tissues surgeries that guarantee duration and efficacy is a priority.

The aim of this study is to describe and illustrate in the accompanying video the bilateral pubococcygeus plication (BPCP) as novel technique for anterior vaginal wall repair and to report the long-term outcomes.

DESIGN

Data were prospectively collected from women undergoing BPCP for the treatment of anterior vaginal wall defect in the period from January 2012 to December 2017. Inclusion criteria was naïve women with symptomatic cystocele > POP-Q 2nd stage.

Data collected: (i) Demographic details; (ii) Objective anterior vaginal wall defect measurement by POP-Q system assessed by maximum Valsalva effort in the seated semi-lithotomy position; (iii) Subjective evaluation by validated questionnaires: the Global Impression of Improvement (PGI-I) and Patient Perception of Bladder Condition (PPBC); (iiii) Female sexual function by FSFI questionnaire; (iiiii) pre-operative urodynamic evaluation.

To better evaluate the results we decided to exclude women with concomitant stress urinary incontinence, or other associated prolapses.

Surgery was performed using a standardized technique shown in the video. Clavien-Dindo classification was used to rank complications. For this study women were routinely followed by an examiner not directly involved into the surgical procedure on annual scheduled visit to evaluate objective and subjective results, and female sexual function.

Objective cure was defined if the anterior vaginal wall was inferior to the POP-Q 2nd stage, while any anterior vaginal wall defects > 2nd stage were considered failures.

Subjective cure rates were considered patients with PGI-I < 3, and PPBC < 2.

De novo storage symptoms were assessed by direct questioning and voiding diaries for 3 days.

To investigate patient's personal satisfaction, we asked the following questions by a Likert-type scale: (i) "Are you satisfied with the surgical procedure?" (ii) "Would you confirm the same surgical choice during the counseling before surgery?"

RESULTS

153 naïve women for surgery underwent BPCP between the years 2012 and 2017. The mean age was 67.1 yr. POP-Q stage and mean Aa/Ba are reported in table 1.

Mean follow-up was 63.3 months. Mean operative time was 64 minutes. Median length of hospital stay was 2 days.

Objective success rate was 88.2%. 18 women had an anterior vaginal wall recurrence (11.8%). In table 2 objective success and recurrences are compared between the preoperative and follow-up POP-Q stages. Most of recurrences were POP-Q stage 2 (16/18, 88.9%). Subjective satisfaction rate was 92.2%, mean PGI-I was 1.9, mean PPBC was 1.2. At the VAS scales, 90% of women reported personal satisfaction, and 92% would confirm the same surgical choice.

Preoperative OAB rate was 36.6%, while after surgery this rate significantly decreased by 60.7%. Postoperative storage symptoms were observed in 7.2%, but in only 4.1% these symptoms occurred de novo. OAB-screener score significantly improved at the follow-up (table 3). None of the patients had post void residual, and recurrent urinary tract infections occurred in 3.3%. FSFI domains significantly improved after the surgical treatment in sexually active women. Re-operation rate was 1.3%, in one case a mesh was placed while in the other the same technique was successfully performed. A total amount of 4.6% of patients had complications (table 4).

CONCLUSION

The BPCP technique is as a novel surgical procedure to repair cystocele. This procedure guarantees a high objective and subjective cure rate in a long-term follow-up avoiding the use of synthetic material or autologous tissues. Main recurrences were low grade, of these only a few required a re-intervention. The BPCP is a fast and safe surgical option that no alter functional outcomes and sexual function.

FIGURE 1

Table 3: Functional outcomes.

Patients affected by OAB symptoms	PRE	POST	P value, T-Student test
OAB	36.6% (56/153)	14.4% (22/153)	<0.05
OAB-screener	23.1 (8.8)	13.1 (5.9)	<0.05
De Novo OAB	-	4.1% (4/97)	

Table 4: complications.

Complications		*Clavien-Dindo Classification*
Detrusor intraoperative injurie	2 (1.3%)	
Hematoma	3 (1.9%)	One IIIa (percutaneous drainage); one IIIb (surgical drainage)
Pain	2 (1.3%)	

FIGURE 2

Table 1: Patients characteristics.

N° Pts.	152
POP-Q stage, % (n)	
2	46.7% (71/152)
3	49.3% (75/152)
4	3.9% (6/152)
Aa mean (SD)	1.4 (1.2)
Ba mean (SD)	1.2 (1.0)

Table 2: Patients outcomes.

Follow-up, months mean	63.3 (range 95-24)	
Objective success		
POP-Q <2 stage, % (n)	88.2% (135/152)	
Aa mean (SD)	- 2.4 (0.9)	
Ba mean (SD)	- 2.1 (1.1)	
Recurrences, % (n)	***Pre-operative POP-Q stage***	***Follow-up POP-Q stage***
11.3% (8/71)	2	2
9.3% (7/75)	3	2
1.3% (1/75)	3	3
16.7% (1/6)	4	2
16.7% (1/6)	4	3
0% (0/6)	4	4

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Department Internal **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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ROBOTIC-ASSISTED LAPAROSCOPIC HIGH UTEROSACRAL LIGAMENT SUSPENSION AND BURCH URETHROPEXY

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INTRODUCTION

Pelvic organ prolapse can include the anterior, posterior, or apical compartments, individually or in combination. When apical suspension is planned for pelvic organ prolapse repair, the surgeon and patient must decide if hysterectomy should be performed simultaneously. Recent literature suggests that 36-60% of women would choose uterine preservation with prolapse repair, if the option was of equivalent efficacy. Interestingly, 21% of women would still choose uterine preservation even if the prolapse repair had lower success rates. There are a variety of techniques for apical suspension with uterine preservation, one of which includes uterosacral ligament suspension, either transvaginal or transabdominal. The risk of ureteral injury during high uterosacral ligament suspension is 1-11%. The main advantage of the laparoscopic approach is appropriate visualization of the ureters in a minimally invasive fashion. In this video, we demonstrate a robotic-assisted laparoscopic approach to high uterosacral ligament suspension with uterine preservation, and Burch urethropexy.

DESIGN

The patient presented is a 51-year-old woman, G2P2, who presented to the clinic for evaluation of a vaginal bulge and stress urinary incontinence. She reported frequent urination, nocturia, and stress urinary incontinence for the past 20 years. She reported use of 10 pads per day which were soaked at time of change. More recently she noticed a progressive vaginal heaviness. Pelvic examination demonstrated a 7cm total vaginal length, 3cm apical descent with Valsalva, stage 1 anterior wall prolapse and urethral hypermobility. Urodynamic testing showed a no detrusor overactivity, a VLPP 106cmH20 and CLPP of 128cmH20 at a volume of 250mL. After discussion of various treatment options, she stated the importance of uterine preservation. Therefore, she was counseled on proceeding with robotic-assisted laparoscopic high uterosacral ligament suspension and Burch urethropexy. An informed consent for the procedure and video recording was obtained.

RESULTS

The patient was given pre-operative broad-spectrum antibiotics and placed in the dorsal lithotomy position, after induction of general anesthesia. Pneumoperitoneum was created via Veress needle and 5 ports were placed in a straight line (RIGHT: 12mm Air seal port, 5mm assistant port, 8mm robotic port; LEFT: 8mm camera port, 8mm robotic ports x 2). Da Vinci Xi robot was docked after patient was placed in steep Trendelenburg position. Monopolar scissors were placed in the right arm, bipolar forceps in the left arm, and prograsp for the assistant "fourth arm". The procedure is detailed in the video in two parts, (1) Uterosacral ligament suspension (2) Burch urethropexy. Relevant anatomy is elucidated throughout.

CONCLUSION

The patient was kept overnight for observation, and she was discharged on post-operative day 1 after a successful voiding trial. She was seen at 2 week and 3 month follow-up visit during which she was completely dry with an undetectable PVR, and had no descent of her uterus on examination. Robotic-assisted laparoscopic uterosacral ligament suspension offers a minimally invasive approach to uterine preserving

prolapse surgery, and allows for clear visibility of the ureters as well as ease of performing concomitant procedures such as the Burch urethropexy.

Music: Motivate Me by Mixaund | https://mixaund.bandcamp.com Music promoted by https://www.free-stock-music.com

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Informed consent was obtained with the patient regarding video capture **Helsinki** Yes **Informed Consent** Yes

FRIDAY 20TH NOVEMBER

SESSION 16 (PODIUM) - BEST UROGYNAECOLOGY
Abstracts 223-228
09:30 - 11:00, Pavilion 9
Chairs: Dr Alex Digesu (United Kingdom), Dr Elise Jaques Billings De (United States)

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BEST IN CATEGORY PRIZE "FEMALE STRESS URINARY INCONTINENCE (SUI)"

COMPLICATION, REVISION AND PERCEIVED HEALTH AFTER STRESS URINARY INCONTINENCE SURGERY BY MID URETHRA SLING IN THE VIGI-MESH REGISTER. DESCRIPTION AND MEDIUM-TERM INCIDENCE FOR 1814 WOMEN.

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HYPOTHESIS / AIMS OF STUDY

Surgery for stress urinary incontinence by mid urethra sling (MUS) has become a standard widely used in routine clinical practice. The retropubic procedure is the one for which there is the most long-term data. Technical variants (transobturator and single incision sling) have been developed with the intention of simplifying the surgical procedure and reducing the risk of complications.

Clinical trials are limited in size and are not designed to specify the incidence of rare complications. The registers offer the possibility of specifying the occurrence of rare events in routine clinical practice [1].

Our objective is to specify the incidence, and to describe the serious complications relating to surgery by MUS in routine clinical practice according to the type of sling (retropubic, transobturator, or single incision) using the medium-term data from the VIGI-MESH register MESH [2].

STUDY DESIGN, MATERIALS AND METHODS

All surgeons described each surgical procedure performed on a specific case report form. We checked the data collection by reviewing sling deliveries from the hospital pharmacies and surgical procedure codes recorded by each hospital's medical data department.

We defined serious complications using Clavien-Dindo classification: sling placement cancelled due to peroperative injury (Grade III), subsequent surgical intervention related to a complication (Grade III), life-threatening complication (Grade IV), woman's death (Grade V). We collected also surgical revisions for SUI relapse. We used several sources to identify complications and revisions: the monitoring of surgical procedures by the data departments, surgeons' spontaneous reports, and a questionnaire sent to the women a year later. These annual follow-up questionnaires collected also information about perceived health and improvement (WHO, EQ5D, and PGI-I questionnaires).

RESULTS

Between February 2017 and November 2019, 1814 women underwent a surgical procedure with MUS in 18 centers and agree to participate. The sling procedures were performed through a retropubic route in 923 cases, a transobturator in 521 cases, and a single incision in 370 cases.

An history of hysterectomy or previous incontinence surgery was more common (15.5%) in women who underwent a retropubic sling (Table).

The median follow-up time was 15 months. We observed serious complications in 82 women, 5.7% after retropubic sling (53/923), 4.0% after transobturative sling (21/521) and 2.2% after single incision sling (8/370).

Ten complications occurred during surgery and six in the first 48 hours: nine intraoperative injuries (six bladder inju-

ries, two urethral injuries, one vaginal injury), two intraoperative haemorrhage, six obstructed micturition (related to five retropubic and one single-incision sling). Placement of the MUS was cancelled ten times and in six cases the sling was loosened vaginally.

There were 33 complications treated from two days to two months after the initial intervention: 27 cases of obstructed micturition (related to 20 retropubic, 6 transobturator, and 1 single-incision sling) resulted in loosening the sling in 22 women, dividing it in 3, and removing it in 2; one woman with severe groin pain after transobturator sling placement needed to return to OR on day two to remove the sling and replace it by a retropubic one; a woman needed a laparotomy on D9 due to infected haematoma of Retzius space after transobtur sling; one woman needed to return to the operative room (OR) on day 13 to evacuate a suburethral thrombus that had resulted in obstructed micturition after transobturator sling; an early suprapubic abscess on retropubic BSU with purulent vaginal discharge led to the removal of the sling 13 days after placement; in the second month a part of the MUS had to be removed in 2 women because of vaginal exposure (associated with pain in one case).

Between 2 and 12 postoperative months, 26 complications were managed: 8 related to late urinary retention, 5 to overactive bladder, 6 to chronic pain, 15 to vaginal exposure, 2 to urethral exposure. These complications required MUS division (3 cases), partial removal of the MUS (19 cases), removal of a non-absorbable thread (1 case), and vaginal trimming without MUS resection (2 cases).

Seven women returned to OR more than a year after applying the procedure (including 4 single incision slings) to remove part of the sling (6 cases) or the vaginal scar (one case). The reasons were pain (4 cases), vaginal exposure (1 case), overactive bladder (1 case), and obstructed micturition (2 cases).

The survival curve without serious complication showed a significant difference between MUS types (Figure in months, logrank test p = 0.011). The estimated incidence at 18 months of serious complications was 6.3% [95% CI 4.6-8.0] in case of retropubic sling, 4.2% [2.4-6.0] in the case of a transobturator, and 1.6% [0.2- 3.1] in case of single incision. The risk of complication was 3 times lower with a single incision compared to a retropubic sling (RR 0.36 [0.17-0.75]), the risk was not significantly different for the transobturator approach compared to the retropubic (RR 0.67 [0.40-1.11]).

Twenty-seven women (1.5%) benefited from a surgical revision due to a failure or a recurrence of stress urinary incontinence, 15 after retropubic MUS (1.6%), 7 after transobtur (1.4%) and 5 after single incision (1.4%; p=0.95). The revision procedure was the re-tensioning of the BSU (9 cases including 2 adjustable sling, 4 retropubic, 2 transobturator, and 1 single-incision sling), an injection of Bulkamid (2 cases), and the new placement of MUS (16 cases).

Among the 1,167 women operated on between February 2017 and December 2018 contacted by mail, we received 692 responses to the health questionnaire sent a year or more after their surgery (59.3%). To the question "What do you think of your current state of health compared to what it was before your surgery for incontinence or prolapse?" 91.4% (608/665) felt better (much better, better, or a little better) (PGI-I). The perceived improvement was better in the absence of serious complications (p=0.008). 96.2% (630/655) rated their general health as good (very good, good, or fairly good) (Figure 3). The perceived health status was similar with or without complication. Compared to the French population of the same age, the operated women reported a better perceived state of health.

INTERPRETATION OF RESULTS

The retropubic approach was more often chosen in the event of failure of previous surgery. The main complications needing surgical revision were in order of frequency: voiding obstruction (2.4%), MUS exposure (1.1%), and chronic pain (0.8%). The retropubic route was associated with a higher risk of complication compared to the single incision. However, after 18 months the curves seem to get closer (Figure). In the medium term, the risk of surgical revision for failure on SUI is low (1.5%) and similar regardless of the type of sling applied.

Most women (over 90%) were improved by surgery and their health was better than in the general population.

CONCLUDING MESSAGE

Analysis of the first medium-term results in our registry shows that the single incision is a valid option for the first-line surgical treatment of stress urinary incontinence. However, we believe it is necessary to continue follow-up in the longer term.

FIGURE 1

Characteristics	MUS	Retropubic N=923	Transobturator N=521	Single incision N=370
	Age, mean (sd)	57.8 (13.5)	58.5 (12.4)	58.5 (13.3)
	BMI, mean (sd)	26.3 (5.4)	26.6 (5.3)	26.2 (4.7)
	Menopausal, % (n)	60.3 (557)	62.8 (327)	58.6 (217)
	Smoking, % (n)	10.8 (100)	12.9 (67)	11.6 (43)
	Diabetes, % (n)	5.9 (54)	5.4 (28)	6.2 (23)
	Physical status (ASA), % (n)	1.7 (0.6)	1.7 (0.6)	1.7 (0.7)
	*Hysterectomy, % (n)	15.7 (145)	14.8 (77)	9.7 (36)
Surgical history	*SUI surgery, % (n)	15.5 (143)	3.5 (18)	5.1 (19)
	POP surgery, % (n)	12.5 (115)	10.6 (55)	8.4 (31)
	*Hysterectomy, % (n)	2.3 (21)	11.7 (61)	3.8 (14)
Operative	*POP surgery, % (n)	12.8 (118)	29.6 (154)	15.7 (58)
procedure	*length (min), mean (sd) #	32 (13)	23 (10)	15 (12)
	*blood loss (ml), mean (sd) #	37 (64)	35 (48)	19 (29)

*Significant difference related to MUS type. # Surgeries combining several procedures excluded.

Table. Women and operative characteristics (N=1814)

FIGURE 2

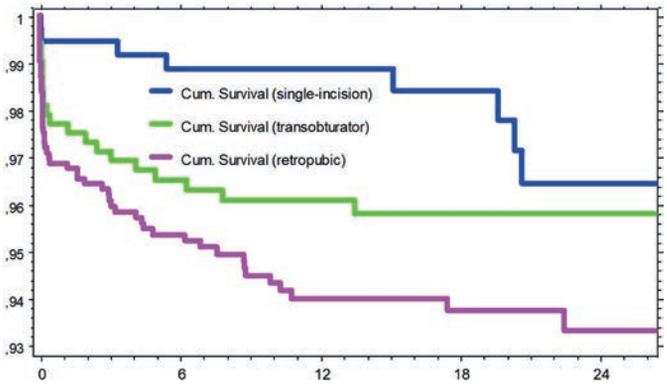

Figure. Survival curve without serious complication after MUS (time in months; N=1814)

REFERENCES

1. Fritel X. Evidence About Surgical Revision for MUS Complications Will Come from Large Retrospective Cohorts and Prospective Registers. BJOG 2010.
2. Fritel et al. Complications after pelvic floor repair surgery (with and without mesh): short-term incidence after 1873 inclusions in the French VIGI-MESH registry. BJOG 2020.

Funding The national medicines agency (Agence Nationale de Sécurité du Médicament et des produits de santé, ANSM) provided funding for the study **Clinical Trial** No **Subjects** Human **Ethics Committee** The Comité de Protection des Personnes Ouest III approved the study 9 February 2017 (IDRBC 2017-A000308-45) **Helsinki** Yes **Informed Consent** No

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LOWER URINARY TRACT DYSFUNCTION AFTER NERVE-SPARING RADICAL HYSTERECTOMY: URODYNAMIC EVALUATION AND PROTEOMICS STUDY

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HYPOTHESIS / AIMS OF STUDY

Despite increasing interest in detrusor underactivity (DU), its pathophysiology remains unclear. In addition, since invasive tests are usually performed for the diagnosis of DU, the development of less invasive techniques is required, such as the use of urinary biomarkers. DU usually develops after radical hysterectomy. The aim of this study was to evaluate lower urinary tract dysfunction after radical hysterectomy via a urodynamic study and identify urinary biomarkers for DU based on proteomics analysis.

STUDY DESIGN, MATERIALS AND METHODS

This was a single-center, prospective study. Female patients undergoing nerve-sparing radical hysterectomy for cervical carcinoma were enrolled in the study. The International Prostate Symptom Score (IPSS), Overactive Bladder Symptom Score (OABSS), and International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form were evaluated at the time of the urodynamic study. Urethral pressure profiling (UPP) and a pressure flow study (PFS) were performed before surgery and at 1 and 6 months post-surgery. Detrusor contractility was assessed using the projected isovolumetric pressure (PIP1). Moreover, using urine samples obtained at the time of the urodynamic study, a proteomics study was performed. Correlation analysis was performed to investigate the relationship between the changing ratio of pre- to postoperative (6 months) PIP1 and urinary protein levels to identify urinary biomarkers for DU.

RESULTS

Twenty-five patients were included in the study. Their mean age was 46±12 years. The total IPSS significantly increased 1 month after surgery and thereafter decreased 6 months after surgery. The changes in the OABSS also showed a similar tendency. The UPP showed that the maximum urethral closure pressure significantly decreased 1 month after surgery but remained at the same over the next 5 months. The PFS indicated that the first urge to void and maximum cystometric capacity were increased both 1 and 6 months after surgery. PIP1 and voiding efficiency were decreased 1 month after surgery but improved 6 months post-surgery (Table 1). The proteomics study indicated that the changing ratio of pre- to post-operative urinary moesin, ezrin, and transthyretin were significantly correlated with the changing ratio of pre- to post-operative PIP1 (r=-0.85, -0.70, and -0.68; p=0.01, 0.03, and 0.02, respectively) (Table 2). The optimum cutoff values of these proteins to diagnose DU (PIP1 <30) based on receiver-operating characteristic curves were 8.8×105 (area under the curve [AUC], 0.84; 95% confidence interval [CI], 0.68–1.00) for moesin, 1.2×106 (AUC, 0.87; 95% CI, 0.72–1.00) for ezrin, and 1.2×106 (AUC, 0.70; 95% CI, 0.50.0.90) for transthyretin.

INTERPRETATION OF RESULTS

These results indicate that (1) bladder contractility is impaired 1 month after radical hysterectomy but improves 6 months after the surgery; (2) bladder sensation, as well as urethral function, are impaired 1 month after radical hysterectomy and remain impaired 6 months after surgery; (3) urinary moesin, ezrin, and transthyretin increase in association with the impairment of bladder contractility; and (4) optimum cutoff values of these proteins for the diagnosis of DU can be determined.

CONCLUDING MESSAGE

Our study demonstrates that nerve-sparing radical hysterectomy tends to cause impaired detrusor contractility and urethral function. Urinary moesin, ezrin, and transthyretin may be related to the pathophysiology of DU and could be useful urinary biomarkers for the diagnosis of DU.

FIGURE 1

	Baseline	1 month	6 months	P-value		
				Baseline v.s. 1 month	Baseline v.s. 6 months	1 month v.s. 6 months
FDV	117 ± 41	174 ± 111	166 ± 82	< 0.001	0.03	0.71
MCC	368 ± 88	419 ± 108	373± 105	0.01	0.64	0.11
Compliance	50 ± 33	32 ± 18	26 ± 12	0.16	0.17	0.87
Q max	20 ± 7	15 ± 8	21 ± 10	0.008	0.47	0.004
Pdet Qmax	32 ± 14	22 ± 14	26 ± 16	0.005	0.11	0.19
PIP1	51 ± 14	37 ± 14	47 ± 21	< 0.001	0.35	0.02
VE	96 ± 10	81 ± 24	97 ± 4	0.008	0.14	0.01
PVR	13 ± 33	77 ± 109	16± 38	0.006	0.19	0.006
MUCP	70 ± 21	56 ± 17	56 ± 14	< 0.001	< 0.001	0.63

Table 1. The results of pressure flow study and urethral pressure profile.

FIGURE 2

	p-value	r
Transthyretin	0.02	-0.68
Ezrin	0.03	-0.70
Moesin	0.01	-0.85

Table 2. The results of proteomics study

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** the ethics committee of Nagoya University Graduate School of Medicine **Helsinki** Yes **Informed Consent** Yes

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PREGNANCY AND DELIVERY AFTER MID-URETHRAL SLING OPERATION

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HYPOTHESIS / AIMS OF STUDY

There is no guideline or consensus concerning pregnancy and delivery after mid-urethral sling (MUS) operation even though this operation is performed also to women at fertile age. Important clinical questions are whether future pregnancy carries a risk for stress urinary incontinence (SUI) relapse or sling exposure problems during pregnancy and how to choose the mode of delivery.

We assessed as the primary outcome the effect of pregnancy after MUS on risk for new SUI re-procedure, and as secondary outcomes, risk for an incontinence-related re-visit and MUS-related complications during post-operative pregnancy and postpartum.

STUDY DESIGN, MATERIALS AND METHODS

We conducted a retrospective case-control study that included retropubic and trans-obturator MUS operations in Finland in 1996-2016: 97 cases with a subsequent pregnancy and 340 controls without subsequent pregnancies matched by age, operation type and year. We followed them up until 31 December 2017 and the mean follow-up time was 10.4 years (IQR 7.1-13.8). Data were collected from national health care registers.

The main outcome was new SUI procedures. Secondary outcomes were re-visits for SUI or mixed urinary incontinence after the index operation and complications during pregnancies and post-partum after MUS operation. We were able to identify the time-points of SUI re-procedures and re-visits, and the deliveries. For the case women, we included re-procedures and re-visits if they occurred after the delivery subsequent to the index operation.

RESULTS

The number of re-procedures for SUI did not differ significantly between the case and control groups (3.1% and 5.1%, respectively; OR 0.6, 95% CI 0.2-2.1). Additionally, three cases (3.1%) had a SUI re-procedure before the delivery subsequent to the index MUS operation, but the difference in re-procedure rate remained insignificant even when these re-procedures were included (OR 1.1, 95% CI 0.6-1.8). Of the three cases who had a SUI re-procedure, two delivered vaginally and one had an elective caesarian section after MUS.

There was significantly fewer re-visits for SUI and MUI in the case group (16%) than in the control group (26%; OR 0.5, 95% CI 0.3-1.0, p=0.04). This difference did not remain significant when re-visits between the index operation and the

subsequent delivery were included in the case group (OR 1.1, 95% CI 0.6-1.8, p=0.8).

Of the 97 first deliveries after the MUS operation, 56 (57.7%) were vaginal deliveries, 25 (25.8%) were elective caesarian sections and 16 (16.5%) were urgent or emergency caesarian sections. The number of elective and all caesarean section was significantly higher after the MUS operation compared with the last delivery before the MUS operation (p<0.001).

During the pregnancy and postpartum after MUS, 18 cases (18.6%) had a visit for urinary tract infection, urinary incontinence, or pelvic or perineal or lower abdominal pain. There were no visits for urinary retention or other lower urinary tract symptoms.

INTERPRETATION OF RESULTS

We did not find pregnancy and delivery as a risk factor for a SUI re-procedure or an incontinence related re-visit. It seemed that previous MUS operation did not increase the rate of MUS related complications during pregnancy, delivery and post-partum. Therefore, the results show no reason to regard future pregnancy plans as a contraindication for MUS operation.

Previous MUS operation was likely sometimes viewed as an indication for caesarean section as 42% of the case women delivered with caesarean section after the index MUS operation even though 82% of case women with earlier deliveries had no previous caesarean sections.

CONCLUDING MESSAGE

Pregnancy and delivery after mid-urethral sling operation did not increase the risk for a re-procedure for stress urinary incontinence in our retrospective case-control study of 437 women.

Funding ST has received research grants from Finnish Society of Gynecological Surgery, the Finnish Cultural Foundation (FCF) and **Helsinki** University Hospital. PRS has received funding for congress attendance from Olympus and Astellas Pharma outside the submitted work. MG has no funding or grant to declare. TM has received personal lecture fees from Astellas and Mylan and unrestricted grant from Contura outside the submitted work. MM has received research grant from FCF outside the submitted work. **Clinical Trial** No **Subjects** Human **Ethics not Req'd** The register authorities assessed the ethics of the study and as no contact with the subjects was included and the subjects were not identified, the study was exempted from evaluation by an **Ethics Committee**. **Helsinki** Yes **Informed Consent** No

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A COST-EFFECTIVENESS ANALYSIS OF VAGINAL HYSTEROPEXY COMPARED TO VAGINAL HYSTERECTOMY WITH APICAL SUSPENSION FOR THE TREATMENT OF PELVIC ORGAN PROLAPSE

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HYPOTHESIS / AIMS OF STUDY

Uterine preserving hysteropexy (HP) for the treatment of uterine prolapse has become more popular in recent years. Studies suggest that hysteropexy has equivalent medium-term efficacy compared to traditional vaginal hysterectomy (VS) with apical suspension (sacrospinous ligament fixation (SS) or uterosacral ligament suspension (US)). Each surgical approach confers different risks and costs. Costs between uterine-sparing and traditional prolapse repair have not been compared. Our objective was to perform a cost-effectiveness analysis of hysteropexy versus vaginal hysterectomy with apical suspension for the treatment of uterine prolapse.

STUDY DESIGN, MATERIALS AND METHODS

In order to determine the most cost-effective surgical strategy, we used TreeAge Pro® software to construct a decision model tree comparing the cost-effectiveness of four surgical options: HP with SS (HP-SS), HP with US (HP-US), VH with SS (VH-SS) and VH with US (VH-US). We modeled a population of healthy women undergoing surgery with a model time horizon of 1 year. Recurrence rates, repeat surgery for surgical failures and complication rates associated with each surgery were modeled. Parameter values were modeled using published Health Utility Indices included baseline uterine prolapse (0.83), repeat surgery for recurrent prolapse (0.75), GU injury (0.75), dyspareunia (0.90), neuropathy (0.66), and transfusion (0.76). Cost data reflects Stanford Hospital costs billed to insurance providers, including HP-SS $41,637.33, HP-US $41,466.00, VH-SS $50,258.00, and VH-US $50,258.00. Cost-effectiveness was defined as an incremental cost-effectiveness ratio (ICER) of < $50,000 per quality-adjusted life year (QALY). Strategies were considered "dominated" if they were both less effective and more expensive than another strategy. Base-case, threshold and 2-way sensitivity analyses were performed.

RESULTS

HP-SS was the most cost-effective strategy, where incremental cost of HP-US was $1,096.21, VH-SS was $7,681.34 and VH-US was $8,775.98 (Table 1). With similar QALY measures between surgical options, the VH-SS and VH-US were dominated strategies (Figure 1A). VH strategies are cost-effective

when cost of HP-SS is > $52,500 and HP-US is > $49,500. VH strategies also become cost-effective when recurrence rates of hysteropexy is > 30% with a repeat surgery rate >60%, or with recurrence >40% and repeat surgery rate >40% (Figure 1B).

INTERPRETATION OF RESULTS

In our model, sacrospinous hysteropexy was the most cost-effective strategy followed by uterosacral hysteropexy, vaginal hysterectomy with sacrospinous ligament fixation and then vaginal hysterectomy with uterosacral ligament suspension. With similar QALY measures between surgical options, both vaginal hysterectomy with apical suspension surgeries were dominated strategies. When we varied the costs of the different strategies, vaginal hysterectomy strategies became the most cost-effective option when the cost of sacrospinous hysteropexy is > $52,500 and uterosacral hysteropexy is > $49,500. Of note vaginal hysterectomy with sacrospinous ligament suspension was more cost-effective than vaginal hysterectomy with uterosacral ligament suspension. The likely driver for a more expensive uterosacral ligament procedure is the 1-3% risk of GU injury which can lead to a repeat surgery costing ~$50,000. Our results also suggest that even if the probability of recurrent uterine prolapse is 15% and all these patients undergo a second surgery, sacrospinous hysteropexy will remain the optimal cost-effective strategy. However, as the probability of recurrent uterine prolapse and the probability of repeat surgery increases, vaginal hysteropexy no longer remains cost-effective.

CONCLUDING MESSAGE

In conclusion, our study suggests that even if we assume higher rates of recurrence and repeat POP surgery, sacrospinous hysteropexy is the most cost-effective transvaginal surgical approach for management of uterine prolapse. These results should only be used as a guide as clinical decision-making should be comprehensive.

FIGURE 1

Sensitivity Analysis

FIGURE 2

Table 1: Base Case Scenario

Strategy	Cost	Incremental cost	Effectiveness (QALY)	Incremental effectiveness (QALY)	ICER
Sacrospinous hysteropexy (HP-SS)	$42,097.56	-	0.83	-	-
Uterosacral hysteropexy (HP-US)	$43,193.77	$1,096.21	0.84	0.01	$93,059.38
Vaginal hysterectomy + sacrospinous (VH-SS)	$50,875.10	$7,681.34	0.83	-0.01	$605,101.44 Dominated
Vaginal hysterectomy + uterosacral (VH-US)	$51,969.74	$8,775.98	0.83	-0.00	$1,962,608.51 Dominated

Base case one-year cost, effectiveness, and incremental cost-effectiveness ratio for apical POP surgical strategies ranked by cost

Funding Female Foundation for Health Awareness **Clinical Trial** No **Subjects** None

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FACTORS INVOLVED IN PROLAPSE RECURRENCE ONE YEAR AFTER ANTERIOR VAGINAL REPAIR

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HYPOTHESIS / AIMS OF STUDY

Anterior colporrhaphy is the surgery with the highest recurrence rates among traditional pelvic floor reconstructive surgeries, but the specific factors involved in this recurrence are not well established yet. A recent systematic review, including a large number of different pelvic organ prolapse (POP)

surgeries affecting one, two or the three compartments, has point out that levator avulsion, prolapse stage, and family history of POP are significant risk factors for prolapse recurrence (1). Nevertheless, studies focused in the prolapse recurrence after anterior vaginal repair are scarce.

The aim of this study was to identify which demographic or clinical factors were associated with prolapse recurrence in the anterior compartment one year after anterior vaginal repair. Our study hypothesis was that mayor defects in the pelvic floor structures could be associated with higher recurrence rates.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective multicentre study including all women with symptomatic anterior compartment prolapse that were scheduled for surgery in the pelvic floor units of two different hospitals between May 2015 and September 2017. Those women who finally did not have surgery were excluded. Other exclusion criteria were prior POP surgery, use of meshes in POP surgery, or patients unable to complete questionnaires.

Pelvic organ prolapse was described according to the Pelvic Organ Prolapse Quantification (POPQ) system. Prolapse symptoms were identified using the specific questions of the validated Spanish version of the Pelvic Floor Distress Inventory short form (PFDI-20). Levator ani avulsion and hiatal area were identified by translabial three-dimensional ultrasonography performed in supine position with an empty bladder. A complete avulsion was diagnosed on tomographic ultrasound imaging if all three central slices showed an abnormal insertion of the puborectalis muscle on the inferior pubic ramus (2). Levator hiatal area during Valsalva was measured at the plane of minimal hiatal dimensions, and categorized with a cut-off point of 25 cm2 (3). All women underwent a traditional anterior colporrhaphy with fascial plication. Anterior anatomical recurrence was defined as a point Ba equal or greater than 0, and symptomatic anterior recurrence was defined as feeling and/or seeing a vaginal bulge in the vaginal area (women that answered "yes" to the question 3 of the PFDI-20) among women who had been identified as having an anterior anatomical recurrence.

The potential associations of clinical and demographic characteristics with recurrent anterior prolapse were explored by comparison of percentages (Chi-square and Fisher's test). Multiple logistic regression was used to investigate independent associations. Statistical significance was set at p=0.05.

RESULTS

We recruit 455 patients with symptomatic anterior compartment prolapse that underwent primary vaginal surgery during the inclusion period. One year after surgery 442 (97.1%) attended the follow up visit. In three cases ultrasound data were not available, the remaining 439 women formed the study group.

Mean age was 63.0 years (SD:9.7; range:37-86) and mean body mass index (BMI) was 29.7 kg/m2 (SD:5.4; range:16.8-49.5). The surgery was performed only in the anterior compartment in 185 (32,1%) women, in two compartments in 103 (56.3%), and in the three compartments in 51 (11.6%). Vaginal hysterectomy was performed in 216 (49.2%), posterior colporrahpy in 89 (20.3), and urinary incontinence surgery in 75 (17.1%) women. Avulsion was present in 185 (42.1%) women and hiatal area >25 cm2 in 150 (34.2%).

One year after surgery anatomical recurrence was identified in 126 (28.3%) women and symptomatic recurrence in 21 (4.8%). Risk factors in the univariable analysis for anatomical and symptomatic recurrence were POPQ stage >2, levator avulsion and hiatus area >25 cm2. Age>60 was only a risk factor for anatomical recurrence. We did not find any statistical association between anatomical or symptomatic recurrence and BMI, family history of POP, constipation, abdominal hernia or bronchopulmonary diseases. The results of the multivariable model built with the variables that reached statistical significance is shown in table 1. Women with preoperative more advanced prolapse (POPQ>2), levator avulsion and hiatal area >25 cm2, were independently associated with an increased risk of both anatomical and symptomatic recurrence in the anterior compartment one year after native tissue anterior vaginal repair. Age >60 was associated with a greater risk of anatomical recurrence, but not symptomatic.

INTERPRETATION OF RESULTS

Anatomical recurrence of anterior compartment prolapse after anterior vaginal repair is high, while symptomatic recurrence occurs less frequently. In this study we have identified three independent risk factors for both anatomical and symptomatic anterior prolapse recurrence, reflecting all of them an important pelvic floor damage. Levator avulsion and abnormal distensibility of the levator hiatus area are considered muscular injuries that could favor connective tissue damage. Advanced prolapse also represents significant structural damage of the patient's pelvic floor. Therefore, recurrence risk after anterior colporrhaphy is mainly determined by the mayor defects of the pelvic floor structures prior to surgery. The preoperative identification of this greater damage could have as a result a mayor probability of recurrence.

CONCLUDING MESSAGE

Mayor defects on the pelvic floor structures such as advanced stage of prolapse, levator avulsion or abnormal distensibility of the levator hiatus area, increase the risk of anatomical and symptomatic recurrence in the anterior compartment, one year after native tissue vaginal repair. This should be consid-

ered in the treatment counseling of women assessed for this condition.

FIGURE 1

		Anatomical recurrence			Symptomatic recurrence		
	n	n, %	OR	95% CI	n, %	OR	95% CI
Age (years)							
⩽ 60	169	34 (20.1)	1				
>60	270	92 (34.1)	1.64	1.02-2.66			
POPQ stage							
2	91	11 (12.1)	1		0 (0)	1	
3	309	95 (30.7)	2.76	1.38-5.51	19 (6.1)	1.06	1.03-1.09
4	39	20 (51.3)	5.36	2.12-13.58	2 (5.1)	1.05	0.98-1.13
Levator Avulsion							
no	254	53 (20.9)	1		5 (2.0)	1	
yes	185	73 (39.5)	1.70	1.08-2.69	16 (8.6)	3.00	1.02-8.82
Hiatal area >25 cm^2							
no	289	64 (22.1)	1		7 (2.4)	1	
yes	150	62 (41.3)	2.11	1.34-3.33	14 (9.3)	3.13	1.19-8.23

OR: odds ratio; CI: confidence interval

Table 1. Multivariate regression analysis of the risk factors for anterior prolapse recurrence

REFERENCES

1. Friedman T, Eslick GD, Dietz HP. Risk factors for prolapse recurrence: systematic review and meta-analysis. Int Urogynecol J. 2018; 29(1):13-21.
2. Dietz HP, Bernardo MJ, Kirby A, Shek KL. Minimal criteria for the diagnosis of avulsion of the puborectalis muscle by tomographic ultrasound. Int Uroginecol J 2011; 22:699-704.
3. Dietz HP, Shek C, De Leon J; Steensma AB. Balloning of the levator hiatus. Ultrasound Obstet Gynecol 2008; 31:676-680.

Funding No **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité Ético de Investigación Clínica de Euskadi **Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE "IMAGING"

USE OF MAGNETIC RESONANCE IMAGING IN WOMEN WITH SUSPECTED COMPLICATIONS FROM PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE MESH IMPLANTS.

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HYPOTHESIS / AIMS OF STUDY

Mesh implants for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) have been under scrutiny due to their potential complications. Women are referred to our tertiary centre with complaints that may be related to their implants. We use Magnetic Resonance Imaging (MRI) as an assessment tool in this patient population. However, there is limited published data in the use of MRI to evaluate mesh implant complications [1,2].

The aim of this study is to present our experience as a tertiary centre of using MRI selectively in assessing women presenting with potential implant complications, to evaluate the concordance of MRI reports to clinical and surgical findings and to evaluate the role of MRI in this patient group.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective cohort study of a sub-set of women who presented to our unit with suspected complications, from either vaginally and / or abdominally placed mesh implants for POP and/or SUI and were investigated with MRI , between January 2018 – December 2019 was carried out.

We looked at the primary complaint of the woman, clinical symptoms and signs leading to an MRI request, MRI results and intra-operative findings, if the woman had surgery for this reason, over this time period.

MRI was carried out in these women to potentially identify the extent of any infection and to confirm location and placement of the implants. Additionally, an MRI was done in women presenting with symptoms that were not clinically attributable to implants to see if mesh-related pathology was apparent on imaging. In some cases, it was also used to investigate other causes for patient symptoms (e.g. pain due to musculoskeletal causes).

All of these MRIs were reviewed by our mesh centre radiology team, as part of our Multidisciplinary team (MDT) mesh service, even if the MRI was performed in a different unit.

On MRI:

A. An implant was deemed to be 'partially' seen if the radiologist reported that only part of the implant was visible. If the report did not mention the implant, this data has been recorded as such.

B. mesh-related complications were identified, which included:

1. Infection- defined as evidence of abscess, sinus tract or collections directly associated with the mesh implant,

2. Mesh rupture- defined as the detachment of an abdominal mesh from point of attachment

3. Mesh exposure.

RESULTS

65 women with either vaginal implants, abdominal mesh or both presented with suspected complications and were investigated with an MRI during this time period. 47 patients had only 1 mesh implant in situ, 12 patients had 2 separate mesh implants and 6 had 3 separate mesh implants in place.

26 women had transobturator tapes (TOT) implants in situ, 8 had a Retropubic-tape (RP-Tape) mesh implants in situ, 20 had trans-vaginal mesh (TVM) implants for POP and 23 had abdominal mesh for POP (sacrocolpopexy / rectopexy).

Women had more than one presenting complaint. 45 women presented with pain, 11 with vaginal mesh exposure, 5 with urinary symptoms, 1 with bowel symptoms, 6 with vaginal discharge, 7 with dyspareunia. 3 women also had concurrent POP However, 3 women presented with a recurrent POP following a sacrocolpopexy as their only symptom.

Looking at the separate implant types, MRI was able to detect:

oAbdominal meshes in 91.3% (21/23) of women,

oRetropubic tape in 75% (6/8) of women,

oTOT mesh in 42.3% (11/26) of women,

oTVM in 50 % (10/20) of women.

Overall, MRI picked up pathology, both mesh-related and not, in 23.1% (15/65) of women. MRI detected no positive radiological findings in 50 women.

4/15 patients in whom the initial complaint was of pelvic pain had an MRI which showed no mesh related complications, but which revealed other pathology which could explain their pain. 2 of them were subsequently referred to Orthopaedics for further investigation of degenerative hip changes, 1 to Neurology for investigation of spinal abnormalities and 1 to General Surgery for investigation of proctitis.

In the 11/15 women in whom a mesh-associated complication was detected, the mesh itself was identified on MRI in 7 of them, was partially seen in 3 and was not identified in 1 of them. The positive findings are described below:

oIn the 5 women with mesh-associated infection (Table 1), MRI showed more extensive pelvic infection than the initial clinical findings suggested (example Picture 1) and helped inform surgical management and patient counselling. All 5 women underwent surgery and MRI were confirmed at time of surgery. Of these 5 women, MRI also identified the concurrent vaginal mesh exposure in 1 patient,

o1 woman had mesh exposure in the bladder with concomitant vaginal exposure and 1 woman had urethral exposure on MRI. Cystoscopy and subsequent surgery confirmed the findings.

oWith abdominal meshes, 2 women had mesh rupture on MRI. MRI findings were confirmed on surgery in one woman and the other 1 is awaiting surgery.

o1 woman, who presented with groin pain, was found to have inflammation linked to the right arm of her TOT implant on MRI. She is awaiting surgery for tape removal.

oOverall, MRI identified vaginal mesh exposure in 18.8% (3/16) of patient with clinically confirmed vaginal mesh exposure. 1 woman had vaginal mesh exposure alone on MRI and 2 had concomitant MRI findings, (1 with pelvic infection, other with bladder mesh exposure, as described above).

INTERPRETATION OF RESULTS

Looking at the separate implant types, MRI was able to detect abdominal meshes in 91.3% (21/23) of women, retropubic tape in 75% (6/8) of women, TOT mesh in 42.3% (11/26) of women and TVM in 50 % (10/20) of women. Overall, MRI picked up pathology, both mesh-related and not, in 23.1% (15/65) of women.

Non-mesh related pathology that could be a cause for pain as a symptom was found in 7.4% (4/54) of women. MRI confirmed infection in 100% of cases with clinically suspected implant-related infection and helped identify its extent.

MRI picked up abdominal mesh rupture in 2 cases- 1 case was confirmed at surgery and the other is awaiting surgery.

Diagnosis of vaginal exposure is poor. This, however, is something that is clinically apparent. MRI was however good at identifying more extensive infection accompanying exposure, when clinically suspected.

CONCLUDING MESSAGE

MRIs have a high likelihood of identifying abdominal meshes and RP-tapes but poorer at visualising vaginal meshes and TOTs.

MRIs are able to detect mesh related infection, in every case in this series, and often shows more extensive disease than is first clinically apparent. This can be useful in patient counselling and planning surgery.

MRI may be helpful in identifying other causes for pelvic pain, but the pick up in our selected population is low.

MRI can be a useful tool in the assessment of this complex symptomatic patient group, to aid decision-making in their

clinical and surgical management. However, this has its limitations.

FIGURE 1

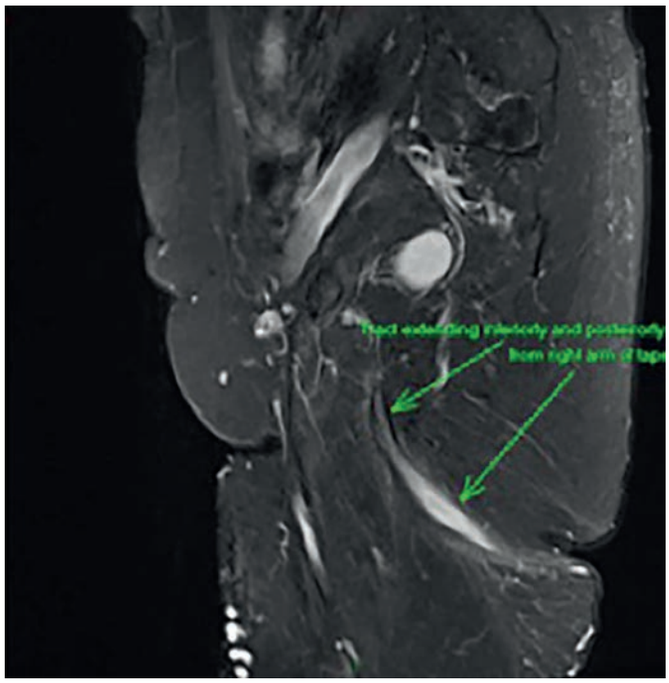

Figure 1: Sinus tract arising from the right arm of transobturator mesh implant

FIGURE 2

Type of tapes in situ	Presenting complaint	Clinical Findings	MRI findings	Surgical management	Surgical findings
TOT and posterior mesh	Right medial thigh abscess and vaginal discharge	Right medial thigh sinus tract only. Provoked tenderness on palpation of vaginal portion of TOT. No left groin symptoms. Post Mesh not involved	Sinus tract of 15cm in length extending from right anterolateral aspect of vagina into the right thigh via obturator foramen. Possible continuing inflammation of urethral portion of the tape and tape as it enters left obturator foramen. Post mesh not involved	Entire TOT tape removal and left groin dissection	Infected TOT (vaginal and both extravaginal portions) with a sinus tract extending from right groin through the obturator foramen termination in the left vaginal fornix.
TOT	Vaginal discharge and bilateral groin pain	Sub urethral polyp. No exposure.	Band of chronic inflammation/ ? infection affecting all vaginal tape but not the extravaginal portions.	Vaginal excision of TOT and sinus tract	Fibrotic band comprising of infected, un-incorporated mesh in thick fibrosed capsule : extending from obturator internus on one side to the obt internus on the other side, but not beyond into groin Pus in left sinus tract.
TOT	Vaginal discharge	Vaginal mesh exposure of 3cm of sub-urethral tape exposure with further exposure in left sulci; foul-smelling vaginal discharge	Inflammation/ infection related to the TOT involving the anterior left vaginal wall with lateral extension to the obturator internus muscle. No extension into groins.	Total excision of TOT tape-vaginal and bilateral groin dissection	Completely exposed vaginal tape. Presence of sinus tract extending to obturator internus but into not groins.
Posterior POP mesh	RIF tenderness, mesh exposure	RIF tenderness on palpation, midline vaginal mesh exposure of 2cm area.	Midline vaginal defect with, blind-ending chronic sinus tract into an area of pelvic sepsis on left side.	Complete Excision of vaginal mesh	Pus PV. Midline vaginal mesh exposure of 2cm. Indurated and contracted mesh. All vaginal mesh appeared infected; sinus tract along left arm of mesh to sacrospinous ligament attachment
Posterior POP mesh	PV bleeding; Recurrent UTIs	Vaginal mesh exposure of 2cm area posteriorly; pus PV	area of infection confined to the rectovaginal septum.	Total excision of posterior vaginal wall mesh.	Infected, exposed and contracted posterior mesh with infection affecting most of implant.

Table 1: Clinical, MRI and surgical findings in women with mesh-associated infection

REFERENCES

1. NICE. (2019). Urinary incontinence and pelvic organ prolapse in women: management (p. 40).

2. Mahoney, C., Hindle, A., & Rajashenkar, B. (2019). MR scan evaluation of pelvic organ prolapse mesh complications and agreement with intra-operative findings. International Urogynaecology Journal.

Funding None **Clinical Trial** No **Subjects** None **Ethics not Req'd** It was a service evaluation project. **Helsinki** not Req'd This was a service evaluation project

SESSION 17 (PODIUM SHORT ORAL) - OAB: NEUROTOXIN AND IMAGING
Abstracts 229-240
09:30 - 11:00, Brasilia 2
Chairs: Dr John PFA Heesakkers (Netherlands), Dr Victor William Nitti (United States)

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ONABOTULINUMTOXINA VERSUS INCOBOTULINUMTOXINA IN THE TREATMENT OF IDIOPATHIC AND NEUROGENIC DETRUSOR OVERACTIVITY

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HYPOTHESIS / AIMS OF STUDY
Recent published studies on the long-term efficacy and safety of Onabotulinumtoxin A (Onabot/A) in both idiopathic and neurogenic detrusor overactivity (IDO, NDO), reported a large intra-individual variability or a loss of response along repeat treatments, with high rates of urinary tract infections (UTIs) and bacteriuria after the intravesical administration of the neurotoxin. IncobotulinumtoxinA (Incobot/A) is a purified botulinum neurotoxin type A formulation free from complexing proteins, with proven efficacy and good tolerability for the treatment of several neurological conditions, but with a very limited evidence in the treatment of refractory DO as not yet licensed for the use in the urologic field. The aim of the present study was to compare the efficacy and safety of the two neurotoxins in patients affected by urinary incontinence (UI) due to refractory IDO and NDO.

STUDY DESIGN, MATERIALS AND METHODS
Fifty-four naïve patients were enrolled in a multicentric, prospective, randomized, study. Patients were randomized 1:1 to receive intradetrusor injections of equal doses of Onabot/A or Incobot/A. Prior to and 8 weeks after injection, patients underwent the recording of the 3-day voiding diary, urodynamics, the Visual Analog Scale (VAS) to score the impact of urinary symptoms on Quality of Life (QoL; 10=worse, 0=best) and the Incontinence-QoL (I-QoL) Questionnaire. Side effects were accurately recorded. Primary end points were change from baseline in daily UI episodes and in VAS scores, and the assessment of reported adverse effects.

RESULTS
Twenty-six pts (10 with NDO and 16 with IDO) received Incobot/A intradetrusor injections, and 28 (12 with NDO and 16 with IDO) underwent Onabot/A intradetrusor treatment. Patients with IDO and those affected by NDO received 100 U or 200 U of Onabot/A or Incobot/A respectively, and intradetrusor injections were performed as usually, under cystoscopic guidance. At 8 wks follow up, urinary symptoms, VAS and I-QoL scores significantly improved in both the 2 groups of patients (Table). Nocturia significantly decreased particularly in IDO patients treated with Incobot/A. UTIs and bacteriuria were detected in 1 and 3 cases treated with Incobot/A and in 5 and 7 cases treated with Onabot/A (p=0.12 and p=0.22, respectively) Overall, post-void residual volume increased, but not significantly in IDO patients.

INTERPRETATION OF RESULTS
These preliminary results show the noninferiority of Incobot/A, as compared to Onabot/A intradetrusor injections, in improving urinary symptoms and QoL in patients affected by both IDO and NDO in a short term follow up. Importantly, although in a limited number of patients in our study, our results also show that Incobot/A intradetrusor injections are followed by less episodes of UTIs and bacteriuria as compared to Onabot/A, an effect that can be explained by the different properties of the two neurotoxins. Onabot/A formulation contains the neurotoxin as part of a larger protein complex with accessory proteins that are not required for the pharmacological activity of the neurotoxin. The presence of complexing proteins may facilitate an immunogenic reaction and the development of neutralizing antibodies against the active neurotoxin, leading to partial or complete clinical unresponsiveness. In the Incobot/A formulation, the neurotoxin has been purified so that it is free from complexing proteins and thus exhibits a high specific biological activity. That complexing proteins can induce an inflammatory response has recently been demonstrated in a human neuroblastoma cell line; in addition, the complexing proteins are also responsible for an increased release of multiple inflam-

matory cytokines in the injected tissues. These effects have not been described with Incobot/A.

CONCLUDING MESSAGE

Incobot/A and Onabot/A intradetrusor injections are both effective and safe in improving urinary symptoms and QoL in patients with IDO and NDO, in a short term follow up. The more significantly reduction in frequency of nocturia and the lower frequency of UTIs and bacteriuria in patients treated with Incobot/A could be linked to the different pharmacological properties of this neurotoxin, and to a limited ability to induce an inflammatory response in the injected tissues. These effects need to be confirmed in a larger number of patients and with additional prospective, randomized studies.

FIGURE 1

Table

	Baseline	2 mos F-up	p
Daytime urinary frequency			
Incobot/A	11.5±2.9	7.8±2.2	<0.01
Onabot/A	11.03±2.7	7.3±1.8	<0.01
Night-time urinary frequency			
Incobot/A	3.2±1.2	1.5±0.9	<0.01
Onabot/A	3.9±1.2	2.4± 0.8	<0.05
UUI (daily frequency)			
Incobot/A	4.3±1.7	1.7±1.8	<0.01
Onabot/A	4.5±1.7	1.4±1.2	<0.01
VAS			
Incobot/A	8.07±1.2	4.7±1.6	<0.01
Onabot/A	7.8 ±1.3	4.9±1.1	<0.01
I-QoL scores			
Incobot/A	41.3±28.4	77.8±13.9	<0.01
Onabot/A	39.5±31.6	75.3±11.8	<0.01

Funding None **Clinical Trial** Yes **Registration Number** EudraCT: 2016-003949-28 **RCT** Yes **Subjects** Human **Ethics Committee** CEAS Umbria (Italy), CEAS N. 3210/18 **Helsinki** Yes **Informed Consent** Yes

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THE RELATIONSHIP BETWEEN LOWER URINARY TRACTFUNCTION AND 123I-IOFLUPANE SCINTIGRAPHYIN PARKINSON'S DISEASE IN EARLY STAGE.SCINTIGRAPHY IN PARKINSON'S DISEASE.

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HYPOTHESIS / AIMS OF STUDY

To investigate the relationship between lower urinary tract function and 123I-ioflupane dopamine transporter scintigraphy in Parkinson's disease(PD).

STUDY DESIGN, MATERIALS AND METHODS

We had 30 patients with PD who underwent a systematized lower urinary tract symptom (LUTS) questionnaire and a urodynamics, which were performed irrespective of the presence of LUTS. The diagnosis of PD was made according to the published criteria. We evaluated all patients with PD using single-photon emission computerized tomography (SPECT) imaging of the dopamine transporter with 123I-ioflupane. The patients included 18 men and 12 women; mean age 70 (53-83) years; mean disease duration 1.3 (0.4-5) years. All patients had gait difficulty with the mean Hoehn Yahr stage 2.2. Cognitive function was assessed in all patients; and the mean Mini Mental Sate Examination (MMSE) score was 26.5 (less than 24 indicates cognitive decline). Urodynamics/ sphincter electromyography (EMG) was performed according to the International Continence Society methods. Before participating in the study, informed consent was obtained from all subjects and their families. This study was approved in local Ethics Committee.

RESULTS

A questionnaire revealed that all patients had LUTS; comprising night-time urinary frequency in 70%, urinary incontinence in 40%, daytime urinary frequency in 80% and urinary retention (post-void residual > 100 ml) in 2%. A urodynamic study revealed a mean volume at the first sensation 92.3 ml (29-231 ml; 100< normal <300 ml): bladder capacity 200.9 ml (41-351 ml, 200< normal <600 ml); and detrusor overactivity in 50%. Sphincter electromyography (EMG) revealed neurogenic change in 13% on whom the test was performed. By 123I-ioflupane scintigraphy, the average specific binding ratio (SBR) had significant correlation with bladder capacity and Watts factor (Spearman's correlation coefficients $p<0.05$. Figure 1,2).

INTERPRETATION OF RESULTS

In the present study, EMG-cystometry revealed DO in 50% of the patients studied. The result in the present report was less than those in the previous report (Stocchi et al 1997,Palleschi et al 2006 and Uchiyama et al 2006). The reason why our incidence of DO was not common, presumably reflects the short disease duration of our patients with PD. 123I-ioflupane scintigraphy SBR average had significant correlation with bladder capacity. Abnormal 123I-ioflupane scintigraphy is thought to reflect loss of nigral dopaminergic cells. In addition, it is known that prefrontal-nigrostriatal D1 dopaminergic pathway might regulate bladder function. Therefore, our study result strongly suggests that loss of brain dopaminergic cells directly relates with lower urinary tract dysfunction in PD.

CONCLUDING MESSAGE

PD has common lower urinary tract dysfunction as indicated by urinary incontinence and detrusor overactivity. our study result suggests that loss of brain dopaminergic cells directly relates with lower urinary tract dysfunction in PD.

FIGURE 1

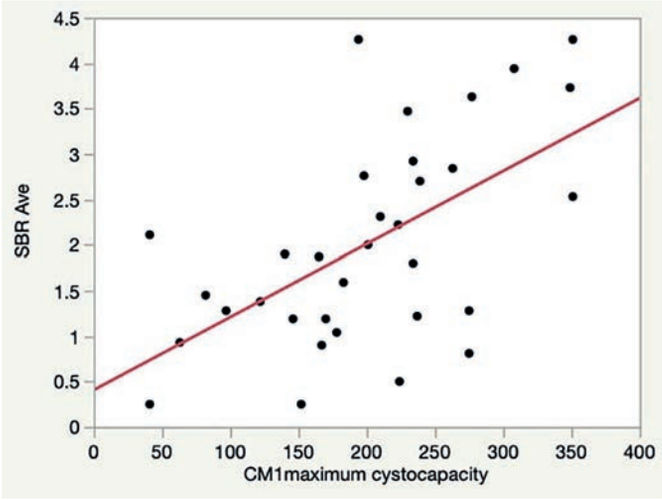
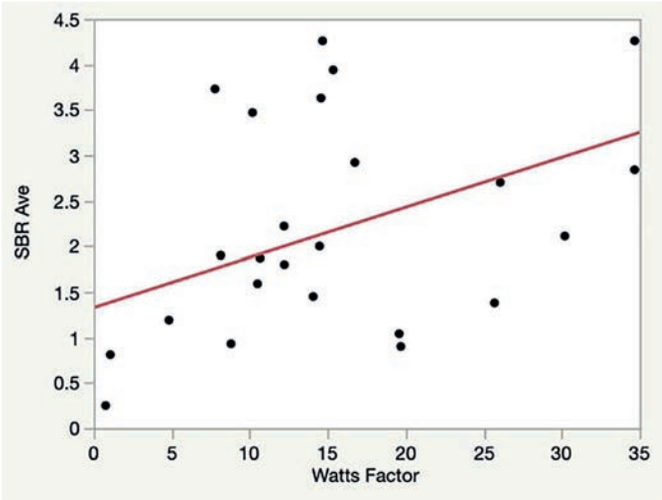


FIGURE 2



REFERENCES

1. Stocchi F, Carbone A, Inghilleri M, Monge A, Ruggieri S, Be- rardelli A, et al. Urodynamic and neurophysiological evaluation in Parkinson's disease and multiple system atrophy. J Neurol, Neuro- surg Psychiatry 1997; 62:507–11.
2. Palleschi, G., Pastore, A.L., Stocchi, F., Bova, G., Inghilleri, M., Sigala, S., Carbone, A., Correlation between the Overactive Bladder questionnaire (OAB-q) and urodynamic data of Parkinson disease patients affected by neurogenic detrusor overactivity during antimuscarinic treatment. Clin. Neuropharmacol. 2006; 29, 220–229.
3. Winge, K., Friberg, L., Werdelin, L., Nielsen, K.K., Stimpel, H. Relationship be- tween nigrostriatal dopaminergic degeneration, urinary symptoms, and bladder control in Parkinson's disease. Eur. J. Neurol. 2005; 12, 842–850.

Funding No **Clinical Trial** No **Subjects** Human **Ethics Committee** Toho-Sakura Ethics committee **Helsinki** Yes **Informed Consent** Yes

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CONCOMITANT RETROPUBIC MIDURETHRAL SLING AND ONABOTULINUMTOXINA INJECTIONS ARE A SAFE TREATMENT OPTION FOR MIXED URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

The objective of this study was to determine whether retropubic midurethral sling (MUS) combined with onabotulinumtoxinA (ONA) is more effective than MUS alone in improving mixed urinary incontinence (MUI) symptoms. We hypothesize that a combined treatment approach for women with MUI is superior to treating with MUS alone. Specifically, women with MUI undergoing MUS with concomitant intradetrusor ONA will have greater improvement in incontinence symptoms at 3-months postoperatively than women undergoing MUS alone.

STUDY DESIGN, MATERIALS AND METHODS

We conducted a prospective, double-blind, randomized, controlled trial of women with MUI planning to undergo MUS from March 2016 to November 2019. Participants all had positive cough stress tests. Women who responded "somewhat," "moderately," or "quite a bit" bothered to both questions 2 and 3 on the Urinary Distress Inventory-6 (UDI) were recruited. These questions assess urinary urgency and stress symptoms respectively. Patients were excluded if they (1) had previous incontinence surgery or intradetrusor ONA, (2) taken overactive bladder medications within 2-months, or (3) found to have a post void residual (PVR) greater than 150ml. Participants were randomly assigned on the day of MUS surgery to receive 100U of intradetrusor ONA or placebo (10ml of normal saline). Participants completed the Patient Global Impression of Severity (PGI-S) for overall incontinence symptoms and subscales for SUI and UUI symptoms, UDI, and Pelvic Floor Impact Questionnaire-7 (PFIQ) before and 3-months after MUS surgery. They also completed the Patient Global Impression of Improvement (PGI-I) for overall incontinence symptoms and subscales for SUI and UUI symptoms at 3-months postoperatively. Adverse events were recorded. Our primary outcome was improvement in PGI-I scores. Secondary outcomes included incontinence symptom severity and quality of life measures. Assuming a PGI-I of "very much better" or "much better" in 66% of women in MUS and 93% in MUS with ONA, 68 women were needed to show a significant difference with 80% power at 0.05 significance level.

RESULTS

103 women were enrolled and 78 were randomized (ONA: 41; placebo: 37). The mean age was 51±10 years, and median BMI was 29.1 (IQR 25.7, 34.9) kg/m2. The majority was Caucasian (76.9%) and 20.5% had urodynamically proven DO. Neither demographics nor baseline incontinence survey data differed between the groups (TABLE 1). At 3-months, UDI, PFIQ, and PGI-S scores improved significantly from baseline in both groups. Those who responded "very much better" or "much better" on PGI-I did not differ between groups 3-months after treatment (82.9% vs. 83.8%, p=1.0). Similarly, UDI and PFIQ scores did not differ (TABLE 2). Median PGI-S scores were significantly lower for UUI, indicating less severe symptoms, at 3-months for the ONA group than the placebo group (1.0 IQR 1.0, 2.0 vs. 2.0 IQR 1.0, 3.0, p=0.03). Similarly, median PGI-I scores for UUI were significantly lower for the ONA group, indicating greater symptom improvement (1.0 IQR 1.0, 3.0 vs. 2.0 IQR 0, 3.0, p=0.03). Rates of immediate postoperative voiding dysfunction did not differ between groups (5.4% placebo; 7.3% ONA, p=1.0) nor did the proportion of women requiring ISC within the 2-weeks after surgery (5.6% placebo; 12.5% ONA, p=0.5). Between 2-weeks and 3-months, more women in the ONA arm initiated ISC (2.7% placebo; 20.0% ONA, p=0.05). UTI was experienced more frequently in the ONA group at 3-months, but this did not reach statistical significance (5.4% placebo; 22.5% ONA, p=0.07).

INTERPRETATION OF RESULTS

While our primary outcome of a difference in overall PGI-I scores between groups at 3-months did not meet statistical significance, there were secondary outcomes that did show differences between the ONA and placebo groups. The median PGI-S and PGI-I scores specifically for the UUI subscale were significantly better for the ONA group indicating that adding ONA at the time of MUS may decrease the severity of urgency symptoms. Notably, all survey scores improved significantly from baseline for both groups implying that significant improvement can be expected in all MUI symptoms with MUS alone.

As expected, there were no differences in immediate postoperative voiding dysfunction, given that ONA does not take effect immediately. Between 2-weeks and 3-months, the ONA group had more patients initiate ISC and a higher rate of UTI, though this did not reach statistical significance. These findings are in line with previous data on intradetrusor ONA.[1]

CONCLUDING MESSAGE

Women with MUI undergoing MUS report significant improvement in overall incontinence symptoms, regardless of addition of ONA. However, women who received concurrent ONA reported less UUI symptom severity and more improvement in urgency symptoms, without a significant increase in adverse outcomes. Some patients with MUI may benefit from concomitant ONA with MUS, but most will improve with MUS alone.

FIGURE 1

Table 1. Baseline comparison of demographic data between groups

Variable	OnabotulinumtoxinA	Placebo	P-value
	n (%)	*n (%)*	
N (% total cohort)	41 (52.6)	37 (47.4)	
Demographic Variables			
Age (years); *mean (SD)*	51.1 (10.1)	50.5 (9.5)	0.84
Race/Ethnicity			0.51
Caucasian	32 (78.0)	28 (75.7)	
African American/Black	4 (9.8)	5 (13.5)	
Asian/Asian American/Southeast Asian	2 (4.9)	0 (0.0)	
Other/Unknown Race	3 (7.3)	4 (10.8)	
Hispanic/Latina Ethnicity	11 (26.8)	8 (21.6)	0.79
BMI (kg/m^2); *median (IQR)*	29.8 (26.6, 33.9)	29.1 (25.7, 34.9)	0.79
Current Smoker or Former Smoker	16 (39.0)	8 (21.6)	0.10
Multiparous	31 (75.6)	31 (83.8)	0.78
Diabetes	1 (2.4)	1 (2.7)	1.0
Systemic Connective Tissue Disease	1 (2.4)	1 (2.7)	1.0
History of Prior Hysterectomy	3 (7.3)	4 (10.8)	0.70
Postmenopausal	18 (43.9)	15 (40.5)	0.94
Currently on Systemic HRT	4 (9.8)	2 (5.4)	0.77
Currently on Local Vaginal Estrogen Therapy	1 (2.4)	1 (2.7)	1.0
Urodynamic and POP-Q Variables			
POP-Q Stage greater than 2	1 (2.4)	0 (0.0)	1.0
Baseline PVR (mL) *median (IQR)*	12.0 (4.0, 19.0)	18.0 (8.0, 22.0)	0.07
Detrusor Overactivity Detected on UDS	7 (17.1)	9 (24.3)	0.61
Leak with Cough	38 (92.7)	36 (97.3)	0.68
Leak with Valsalva	30 (73.2)	30 (81.1)	0.58
MUCP (cm H_2O) *mean (SD)*	70.6 (29.7)	72.9 (21.7)	0.69
Previous Incontinence Treatments			
Previous PFPT	15 (36.6)	12 (32.4)	0.88
Previous overactive bladder medication	9 (22.0)	7 (18.9)	0.96
Survey Scores at Baseline			
UDI-6 (range 0-100); *median (IQR)*	66.7 (54.2, 70.8)	58.3 (54.2, 75.0)	0.88
PFIQ-7 (range 0-300); *median (IQR)*	52.4 (33.3, 85.7)	47.6 (33.3, 71.4)	0.71
IIQ-7 (range 0-100); *median (IQR)*	47.6 (33.3, 71.4)	47.6 (28.6, 66.7)	0.80
PGI-S for overall incontinence symptoms (range 1-4), *median (IQR)**	3.0 (3.0, 4.0)	3.0 (3.0, 4.0)	0.70
PGI-S for overall stress incontinence symptoms only (range 1-4), *median (IQR)**	4.0 (3.0, 4.0)	4.0 (3.0, 4.0)	0.94
PGI-S for overall urgency incontinence symptoms only (range 1-4), *median (IQR)**	3.0 (3.0, 4.0)	3.0 (3.0, 4.0)	0.32

*PGI-S Scale: 1. Normal; 2. Mild; 3. Moderate; 4. Severe

Table 1

FIGURE 2

Table 2. 3-month Survey and PGI-I Scores

Variable	OnabotulinumtoxinA	Placebo	P-value
	41 (52.6%)	37 (47.4%)	
3-month Survey Scores			
UDI-6 (range 0-100); *median (IQR)*	4.2 (0.0, 8.3)	8.3 (0.0, 12.5)	0.20
PFIQ-7 (range 0-300); *median (IQR)*	0.0 (0.0, 14.3)	4.8 (0.0, 23.8)	0.65
IIQ-7 (range 0-100); *median (IQR)*	0.0 (0.0, 9.5)	4.8 (0.0, 23.8)	0.24
PGI-S for overall incontinence symptoms (range 1-4), *median (IQR)**	1.0 (1.0, 2.0)	2.0 (1.0, 2.0)	0.14
PGI-S for overall stress incontinence symptoms only (range 1-4), *median (IQR)**	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	0.58
PGI-S for overall urgency incontinence symptoms only (range 1-4), *median (IQR)**	1.0 (1.0, 2.0)	2.0 (1.0, 3.0)	**0.03**
3-month PGI-I Scores			
PGI-I for overall incontinence symptoms (range 1-7), *median (IQR)***	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0
PGI-I for overall stress incontinence symptoms only (range 1-7), *median (IQR)***	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	0.46
PGI-I for overall urgency incontinence symptoms only (range 1-7), *median (IQR)***	1.0 (1.0, 3.0)	2.0 (2.0, 4.0)	**0.03**

*PGI-S Scale: 1. Normal; 2. Mild; 3. Moderate; 4. Severe

** PGI-I Scale: 1. Very much better; 2. Much better; 3. A little better; 4. No change; 5. A little worse; 6. Much worse; 7. Very much worse

Table 2

REFERENCES

1. Visco AG, Brubaker L, Richter HE, et al. Anticholinergic therapy vs. onabotulinumtoxina for urgency urinary incontinence. The New England journal of medicine 2012;367:1803-13.

Funding Friends of Prentice **Clinical Trial** Yes **Registration Number** clinicaltrials.gov, NCT02678377 **RCT** Yes **Subjects** Human **Ethics Committee** Northwestern University IRB **Helsinki** Yes **Informed Consent** Yes

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ATTRITION RATES AND PREDICTORS OF LONG-TERM (> 5 YEAR) CONTINUATION TREATMENT WITH ONABOTULINUMTOXINA INTRADETRUSOR INJECTIONS

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HYPOTHESIS / AIMS OF STUDY

Predictors of long-term continuation of therapy with intradetrusor injections of onabotulinumtoxinA (BTX) for refractory overactive bladder (OAB) are not well defined. The objective of this study was to examine the attrition rates of BTX therapy and potential demographic and urodynamic factors predictive of long-term continuation of therapy in patients with at least 5 years of follow-up.

STUDY DESIGN, MATERIALS AND METHODS

We conducted an IRB-approved retrospective review of patients who underwent at least one BTX injection between December 2007 to October 2019 and had at least 5 years of follow up. Patients were instructed to continue therapy only if they perceived significant benefit. We excluded patients with history genitourinary malignancy, genitourinary fistula/malformation or previous bladder augmentation. We examined pre-injection demographic, co-morbidities, medications, ambulatory status, bladder management, and urodynamic parameters. Multivariate logistic regression was used to identify independent predictors of long-term continuation of BTX and a Kaplan Meier survival analysis was conducted to determine attrition rates.

RESULTS

186 patients met our criteria, with 72 (38.7%) continuing therapy for at least 5 years. The mean follow-up was 6.6 ±1.9 years. Patients who continued therapy received an average of 8.3 ±4.1 injections during the 5 years of treatment. The average age of our cohort was 54.7±17.1 years, with 133 (71.5%) being female. At the time of first injection, 73 (39%) were on an OAB medication. At baseline, 87 (47%) were voiding, with 85 (46%) requiring clean intermittent catheterization or 14 (7%) using an indwelling catheter. There were 51 patients (27%) with idiopathic overactivity (iOAB). On univariate analysis, age (OR 1.022, 95% CI 1.002-1.042; p= 0.03), female gender (OR 2.930, 95% CI 1.418-6.053, p<0.01) and diagnosis of nOAB (OR 3.062, 95% CI 1.427-6.574, p<0.01) were predictive of continuing therapy. On multivariate analysis, female gender (OR 3.321, 95% CI 1.179 to 9.352, p=0.02) and diagnosis of nOAB (OR4.934; 95%CI 1.324 to 18.382, p=0.02) were predictors of continuing BTX. There were no urodynamic or baseline questionnaire factors predictive of continuing therapy. A Kaplan Meier survival analysis is shown (Figure 1) noting significantly varying attrition rates between subgroups.

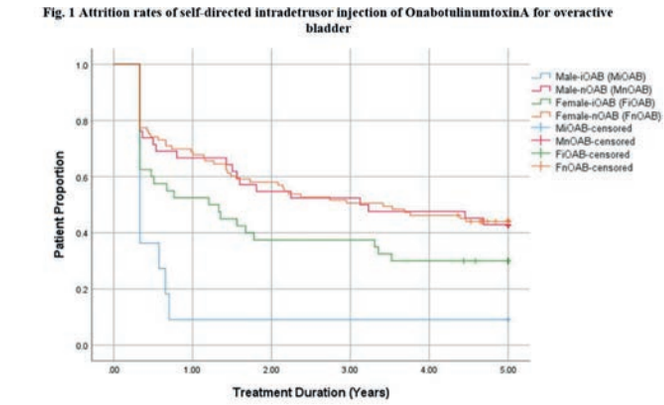
INTERPRETATION OF RESULTS

This study shows that females and patients diagnosed with neurogenic overactive bladder had an increased likelihood of continuing therapy with BTX for at least 5 years. Within the nOAB population, both genders behaved similarly with attrition rates of 57.1% in males and 55.9% in females. The most notable demonstration of the gender differences appears in the iOAB where females had an attrition rate of 70% compared to the over 90.9% attrition rate in men. Remarkably, only one male patient with iOAB continued for five years with the remainder of patients discontinuing therapy before the one-year mark. Interestingly, there was no correlation between continuation of BTX therapy with urodynamic findings or bladder management strategy.

CONCLUDING MESSAGE

This a real-world experience of BTX adherence and continuation of therapy, with over 40% of patients continue BTX therapy beyond 5 years. Female gender and a diagnosis of nOAB are predictive of a patient preference for continued

FIGURE 1



Years	0	1	2	3	4	5
MiOAB, N	11	1	1	1	1	1 (9.1%)
MnOAB, N	42	28	23	22	20	18 (42.9%)
FiOAB, N	40	21	15	15	12	12 (30%)
FnOAB, N	93	64	54	48	44	41 (44.1%)
Overall, N(%)	186 (100%)	114 (61.3%)	93 (50%)	86 (46.2%)	77 (41.4%)	72 (38.8%)

Figure 1: Attrition rates of self-directed intradetrusor injection of OnabotulinumtoxinA for overactive bladder

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** University of Texas Southwestern medical center- institutional review board **Helsinki** Yes **Informed Consent** No

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EFFICACY AND SAFETY OF ALTERNATIVE ONABOTULINUMTOXINA INJECTION PARADIGM FOR OVERACTIVE BLADDER: FINAL DOUBLE BLIND AND OPEN LABEL RESULTS

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HYPOTHESIS / AIMS OF STUDY

In phase 3 trials, onabotulinumtoxinA (onabotA) 100U, administered as 20 evenly spaced intradetrusor injections avoiding the trigone (standard injection paradigm), significantly reduced urinary incontinence (UI) and improved quality of life (QoL) in patients with overactive bladder (OAB). The reported rate of clean intermittent catheterization (CIC) use was 6.5%. This phase 4 study tested the hypothesis that an alternative injection pattern for onabotulinumtoxinA of 10 injections into the trigone and peri-trigonal region could be effective and have a lower incidence of CIC use compared with the standard injection paradigm. Here we report final double blind and open label results.

STUDY DESIGN, MATERIALS AND METHODS

This was a multicenter, randomized, double-blind trial (Clinicaltrials.gov identifier, NCT03052764) which included adults with OAB and UI that was inadequately managed with an anticholinergic. Eligibility criteria were identical to prior phase 3 and 4 studies. The study was performed in compliance with Good Clinical Practice regulations and was approved by an instituitional review board prior to study initiation. All patients provided written informed consent prior to enrollment. Patients were randomized 2:1 to onabotA 100U or placebo, administered as 2 trigonal and 8 peri-trigonal injections (Figure 1). Patients eligible for retreatment received onabotA 100U in the open label extension.

RESULTS

120 patients (115 female; 5 male) were randomized to onabotA (n=80) or placebo (n=40). At week 12 following treatment 1, the least squares mean (LSM) reduction in UI (episodes/day) from baseline was significantly greater for onabotA versus placebo (-2.90 versus -0.16; p<.0001). The proportion of patients achieving ≥75% reduction in UI episodes from baseline was 37.5% versus 8.1%. There was a significant improvement from baseline in LSM incontinence (I)-QoL total score for onabotA versus placebo (20.7 versus -3.5; p=.0012). In the first 12 weeks after treatment 1, CIC was used by 2/78 (2.6%) patients in the onabotA group and 0 in the placebo group. Both were male with a history of risk factors for CIC. Incidence of urinary tract infection (UTI) was higher for onabotA versus placebo (overall: 30.8% versus 17.9%; symptomatic: 17.9% vs 7.7%). 91 patients (90 female; 1 male) received onabotA open label retreatment (onabotA/onabotA, n=58; placebo/onabotA, n=33). At week 12 following treatment cycle 2, the mean change from the open label baseline in UI was -1.76 in the onabotA/onabotA group and -3.44 in placebo/onabotA group. 43.4% and 29.0% patients in the onabotA/onabotA and placebo/onabotA groups, respectively achieved ≥75% reduction in UI episodes from baseline, and the mean change from baseline in I-QoL was 9.1 and 23.4. In the first 12 weeks after treatment 2, CIC was used by 3/91 patients (3.3%, all female). Incidences of overall and symptomatic UTIs were 30.8% and 14.3%, respectively.

INTERPRETATION OF RESULTS

Although not a direct comparison, the results of this study suggests that the alternative onabotA injection paradigm reduces the need for CIC versus the standard paradigm (2.6% versus 6.5%).There was no CIC use in the female population following the first study treatment. Efficacy with the alternative onabotA paradigm was similar to that of the standard paradigm, but the UTI rate appears to be higher (30.8% versus 19.4%). Outcomes for patients who received a second alternative onabotA injection in the open label period of the trial were similar to those observed after the first treatment in the double blind period of the trial.

CONCLUDING MESSAGE

The efficacy of the alternative onabotA injection paradigm utilizing fewer, more targeted injections was similar to the standard injection paradigm; CIC use was lower, but UTI rates were higher. The efficacy and safety of the alternative injection paradigm in patients receiving onabotA after treatment 2 was similar to that observed after treatment 1, and the QoL improvement was also maintained through the entirety of this study.

FIGURE 1

Figure 1. Alternative onabotulinumtoxinA injection pattern

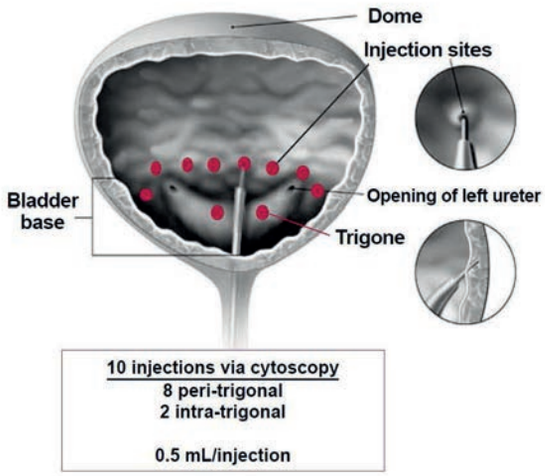

Figure: Alternative onabotulinumtoxinA injection pattern

Funding Allergan plc **Clinical Trial** Yes **Registration Number** U. S. Library of Medicine ClinicalTrials.gov, NCT03052764 **RCT** Yes **Subjects** Human **Ethics Committee** Quorum; IRB00003226 **Helsinki** Yes **Informed Consent** Yes

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REDUCTION IN INCONTINENCE PRODUCT USE AND ASSOCIATED COST SAVINGS AFTER ONABOTULINUMTOXINA TREATMENT IN PATIENTS WITH OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

In patients with overactive bladder (OAB), onabotulinumtoxinA 100U has been demonstrated to reduce urinary incontinence (UI) and significantly improve quality of life. However, little information is available regarding cost savings seen after onabotulinumtoxinA treatment as a result of a reduced reliance on incontinence products. The aim of this analysis of the phase 4 GRACE study was to estimate those potential cost savings in a real-world clinical setting.

STUDY DESIGN, MATERIALS AND METHODS

This 12-month prospective, observational, non-randomized multinational phase 4 study (ClinicalTrials.gov: NCT02161159) was performed in 4 European countries (Germany, Sweden, Spain, and the United Kingdom). Efficacy outcomes reported here include percent reduction from baseline in UI episodes/day, proportion of patients achieving ≥50% and 100% reduction in UI episodes/day, treatment benefit score (TBS), and the number of incontinence products (liner/pads/diapers) used in the previous month. Costs of incontinence products (pads/liners and diaper pants) were estimated using available pricing data from reliable sources (Medical Supply Depot and Healthy Kin.com) filtered by medium female waist size for diaper pants and largest package size for best value. The mean overall costs of incontinence product use were determined at each time point (12, 20, 28, 36, and 52 weeks). Patients could request retreatment ≥12 weeks after the first treatment. This study was performed in compliance with Good Clinical Practice regulations and was approved by the independent ethics committee at each site prior to study initiation as required by each country. All patients provided written informed consent prior to initiation of any study treatment.

RESULTS

Overall, 504 patients received onabotulinumtoxinA treatment in this study. The mean number of pads/liners and diaper pants used in the previous month dropped from baseline (67.7 and 13.9) to week 12 (29.9 and 4.4) and was sustained until week 52 (23.6 and 4.3). The mean cost for pads/liners was determined to be $0.51/unit (range of cost $0.08/unit to $2.06/unit) and for diaper pants was $0.82/unit (range of cost $0.25/unit to $3.33/unit). Overall monthly costs of pads/liners and diaper pants decreased substantially from baseline ($34.43 and $11.37, respectively) to week 12 ($15.21 and $3.60, Figure 1). The reduction in cost was sustained through to week 52 ($12.00 and $3.52). Daily episodes of urinary incontinence were (mean ± standard deviation [SD]) 4.9 ± 4.2 episodes/day at baseline. UI episodes were significantly reduced by 46.9% ± 64.8% ($P < .001$) at week 1 and 61.3% ± 58.6% at week 12 ($P < .001$, Figure 2). The proportion of patients achieving a ≥50% and 100% reduction in UI episodes/day was 60.7% and 25.5% at week 1 and 73.9% and 41.8% at week 12. TBS data were available for 347 patients at week 12 and a positive treatment response was seen in 87.6% of these patients.

INTERPRETATION OF RESULTS

This preliminary analysis is the first of its kind based on a prospective, real-world clinical study detailing potential cost savings in patients with OAB treated with onabotulinumtoxinA that resulted in a reduced need for incontinence products. After treatment with onabotulinumtoxinA there was a greater than 50% reduction in monthly costs of pads/liners and a nearly 70% reduction in diaper pant costs. The reductions in monthly cost of incontinence products were in line with the proportion of patients becoming completely continent over the same time period. The cost savings were sustained out to 52 weeks.

CONCLUDING MESSAGE

Following treatment with onabotulinumtoxinA, patients saw considerable reductions in monthly costs associated with incontinence product use. This information could assist physicians in counseling patients refractory to second-line treatments for OAB.

FIGURE 1

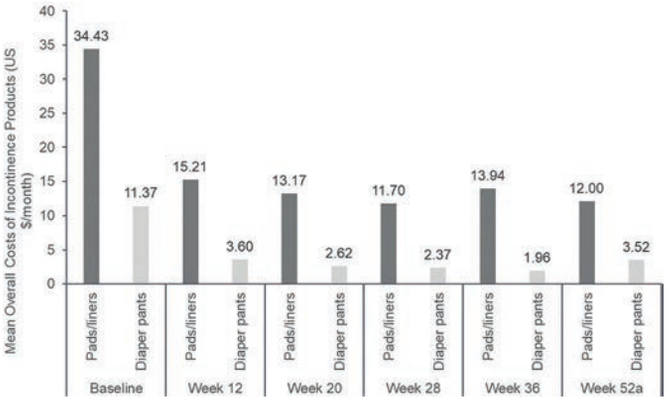

Figure 1: Estimated monthly cost of incontinence products. aWeek 52; only patients without reinjection of onabotulinumtoxinA

FIGURE 2

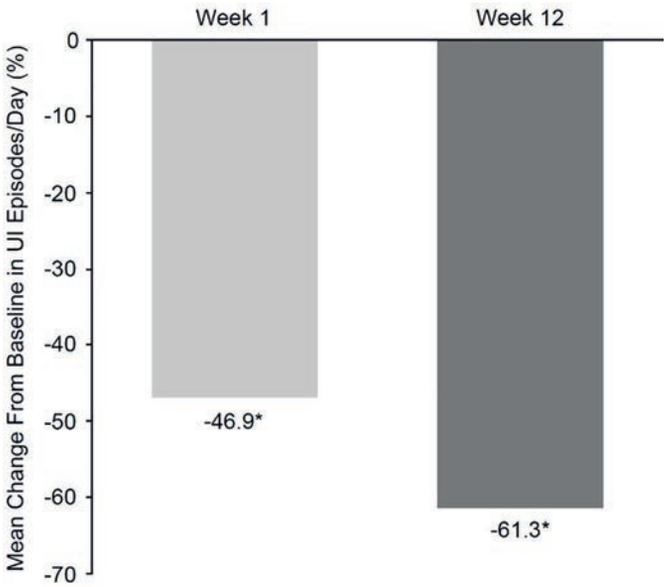

Figure 2: Reduction in UI episodes after onabotulinumtoxinA treatment. * P < .001 vs baseline (4.9 ± 4.2 episodes/day). UI, urinary incontinence

Funding Allergan plc **Clinical Trial** Yes **Registration Number** U.S. National Library of Medicine ClinicalTrials.gov, NCT02161159 **RCT** Yes **Subjects** Human **Ethics Committee** Institutional Review Board of the Karolinska Institute; Stockholm, Sweden; University College London Hospital, London, UK; **Ethics Committee** at the Landesärztekammer Baden-Württemberg; Stuttgart, Germany; Institutional Review Board of University Hospital of Avila (Spain) **Helsinki** Yes **Informed Consent** Yes

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REAL WORLD OUTCOMES OF INTRAVESICAL ONABOTULINUM TOXIN A IN PATIENTS WITH SYMPTOMATIC OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Prospective randomised trial data shows significant benefit from intravesical Onabotulinum Toxin A (Botox A) in 60% of index patients with symptomatic overactive bladder (OAB). The evidence also suggests that efficacy following the first injection persists throughout subsequent cycles of treatment. However, the available data may not reflect outcomes in all-comers. We aimed to assess the outcomes of treatment with Botox A in real world patients.

STUDY DESIGN, MATERIALS AND METHODS

The notes of 418 consecutive patients (median age 61 years, range 22-90 years) with symptomatic OAB refractory to behavioural and medical treatment, and urodynamically-proven idiopathic detrusor overactivity, having their first intravesical Botox A treatment between 1st January 2006 and 31st December 2018, were reviewed. Any patient who had not been seen within the last six months was contacted by telephone. Five patients had inadequate notes and were excluded from assessment. Data was collected on patient demographics, improvement after treatment, continuance of Botox A treatment, number and dosage of repeat treatments and the need for intermittent self-catheterisation (ISC). Improvement was assessed using the Patient Global Impression of Improvement (PGI-I) score following the first Botox injection. This is a validated tool for symptoms of OAB in the form of a single question asking patients to rate their condition after treatment as compared to baseline on a scale of 1 (very much better) to 7 (very much worse). Patients were then stratified based on PGI-I scores into three groups; Good Response (PGI-I scores 1 and 2), Partial Response (PGI-I score 3) and No Response (PGI-I scores of greater than or equal to 4).

RESULTS

A total of 413 patients (285 female, 69%) fulfilled the inclusion criteria, 202 of whom (48.9%) had had previous pelvic surgery. Their outcomes are listed in Table 1.

INTERPRETATION OF RESULTS

A total of 235 (56.9%) patients had a good response to treatment with Botox A. A partial response was observed in 48 (11.6%) patients. The remaining 130 (31.4%) had no response. Of those in the Good Response group, 174 (74%) were female and in the Partial Response group 32 (66.7%) were female. Although 69% of the total patients were female

this was statistically significant. There were no significant differences between age ranges or rates of previous pelvic surgery across the treatment response groups, as shown in Table 1.

A total of 269 patients (65.1%) had more than one Botox A injection; the number of repeat treatments ranged from 1-19. Treatment with Botox A resulted in the need for ISC in 146 (35.4%) patients.

CONCLUDING MESSAGE

In real world patients (almost half of whom had undergone previous pelvic surgery), Botox A improves symptoms in 68.5%, at the expense of new-onset ISC in 35%. A good response is significantly more likely in women, but does not appear to be dose-dependent.

FIGURE 1

	Good Response (PGI-I 1 and 2)	Partial Response (PGI-I 3)	No Response (PGI-I ≥4)
Total	235 (56.9%)	48 (11.6%)	130 (31.4%)
Female	174 (74%)	32 (66.7%)	80 (61.5%)*
Male	61 (26%)	16 (33.3%)	50 (38.5%)
Median age years (range)	61 (22-98)	63 (26-91)	59 (20-89)
Previous pelvic surgery	117 (49.8%)	25 (52%)	60 (46.1%)
300IU	14 (5.9%)	2 (4.1%)	13 (10%)
200IU	121 (51.5%)	25 (51.1%)	71 (54.6%)
100IU	97 (41.3%)	21 (43.8%)	46 (35.4%)
Other	3 (1.3%)	0	0
New ISC (includes suprapubic catheters)	75 (31.9%)	19 (39.6%)	52 (40%)
Repeat Botox A	192 (81.7%)	36 (75%)	41 (32%)
Median [mean] number repeats (range)	3 [4.069] (1-19)	2 [2.25] (1-7)	2 [2.36] (1-4)

* P < 0.05

Table 1

FIGURE 2

	Good Response (PGI-I 1 and 2)	Partial Response (PGI-I 3)	No Response (PGI-I ≥4)
Total	235 (56.9%)	48 (11.6%)	130 (31.4%)
Female	174 (74%)	32 (66.7%)	80 (61.5%)*
Male	61 (26%)	16 (33.3%)	50 (38.5%)
Median age years (range)	61 (22-98)	63 (26-91)	59 (20-89)
Previous pelvic surgery	117 (49.8%)	25 (52%)	60 (46.1%)
300IU	14 (5.9%)	2 (4.1%)	13 (10%)
200IU	121 (51.5%)	25 (51.1%)	71 (54.6%)
100IU	97 (41.3%)	21 (43.8%)	46 (35.4%)
Other	3 (1.3%)	0	0
New ISC (includes suprapubic catheters)	75 (31.9%)	19 (39.6%)	52 (40%)
Repeat Botox A	192 (81.7%)	36 (75%)	41 (32%)
Median [mean] number repeats (range)	3 [4.069] (1-19)	2 [2.25] (1-7)	2 [2.36] (1-4)

* P < 0.05

Table 1

Funding Nil **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This was a retrospective records review, therefore not requiring ethical approval **Helsinki** Yes **Informed Consent** No

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THE EFFICACY OF ONABOTULINUM TOXIN A IN PATIENTS WITH PREVIOUS FAILED AUGMENTATION CYSTOPLASTY

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1. UCLH

HYPOTHESIS / AIMS OF STUDY

To investigate the role of onabotulinum toxin A (BTX-A) injections in patients with failed augmentation cystoplasty for neuropathic or idiopathic detrusor overactivity (NDO or IDO).

STUDY DESIGN, MATERIALS AND METHODS

A retrospective review of all cystoplasty patients who underwent BTX-A injection at a tertiary centre between 2008-2019. Details including indications and time from cystoplasty, video-urodynamic, BTX-A dose and clinical outcomes were analysed. Telephone interview were performed for patients that requested repeat BTX-A injections. The interview included PGIC7 and UDI6 questionnaires. A positive clinical response was considered improvement of overactive symptoms sufficient to merit repeat BTX injection and a PGIC7 of 4 or above.

RESULTS

30 patients were identified (11 men and 19 women). The indications for augmentation were IDO (n=18) or NDO (n=12). Mean age at the time of cystoplasty was 42 years (range 10-61)

Interval between cystoplasty and initial BTX-A was 98 months (range 3-271). Video-urodynamics before BTX-A revealed loss of compliance (LOC) in 13 patients, DO in 22 patients, and combined LOC/DO in 10. The median bladder capacity was 338mls (range 77-570ml).

13 patients responded to BTX-A injections. Higher peak DO pressure was associated with a significantly higher chance that the patient would experience benefit from the injections (p=0.026).

The patients that responded to BTX-A underwent a total of 115 procedures (mean 8.8 injections) over a mean 88 months (range 20-157 months).

INTERPRETATION OF RESULTS

The only predictor of response in our series was peak detrusor pressure. This may reflect residual overactivity primarily in the bladder segment, as overactivity related to bowel peristalsis would be expected to be more consistent pressure, and compliance loss a steady state pressure related to volume. More work is required to assess whether this hypothesis can guide therapy and predict outcome.

This study is a reflection of our clinical experience with an uncommon and challenging patient cohort. As such, the study has limitations. The retrospective analyses did not allow assessment by the commonly used criteria for BTX-A studies, and indeed frequency-volume and incontinence charts would be difficult to achieve in many of these complex patients. We tried to compensate for this using phone administration of questionnaires. In future theses questionnaires will be used in a prospective fashion. The study is also limited by the heterogeneous population and small sample size, inherent to the rarity of the circumstances

CONCLUDING MESSAGE

Forty-three percent of patients responded well to intra-detrusor BTX-A injections. This avoided the need for more invasive surgery and had a positive impact on their quality of life.

FIGURE 1

Figure 1. Response to BTX-A and to indication for augmentation cystoplasty

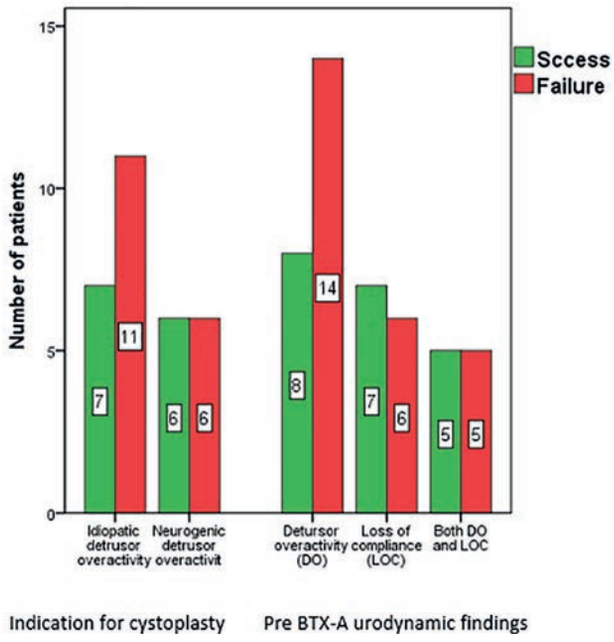

FIGURE 2

Table 1. Population characteristics

	Treatment Success (n=13)	Treatment Failure (n=17)	p value
Sex	7F, 6M	12F, 5M	0.34
Age at cystoplasty	40.5 years	42.6 years	0.64
Age at first BTX-A	49.3 years	50.7 years	0.75
Indication for cystoplasty	7 IDO, 6 NDO	11 IDO, 6 NDO	0.54
Interval between cystoplasty and BTX-A	7.9 years	7.4 years	0.87
PreBXT-A Urodynamics			
- Mean capacity	331 ml	345 ml	0.78
- LOC	7 cases	6 cases	0.31
- Mean End-fill pressure	16.1 cmH_2O	14.5 cmH_2O	0.79
- DO	8 cases	14 cases	0.2
- Mean DO peak pressure	56.3cmH_2O	34 cmH_2O	**0.02***
- Presence of voluntary detrusor contraction	4 cases	8 cases	0.40

REFERENCES

1. Overactive Bladder (OAB) Guideline - American Urological Association [Internet]. [cited 2020 Mar 21]. Available from: https://www.auanet.org/guidelines/overactive-bladder-(oab)-guideline
2. Biers SM, Venn SN, Greenwell TJ. The past, present and future of augmentation cystoplasty [Internet]. Vol.

109, BJU International. 2012 [cited 2020 Mar 21]. p. 1280–93. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22117733
3. Mehmood S, Alhazmi H, Al-Shayie M, Althobity A, Al-shammari A, Altaweel WM, et al. Long-term outcomes of augmentation cystoplasty in a pediatric population with refractory bladder dysfunction: A 12-year follow-up experience at single center. Int Neurourol J. 2018 Dec 1;22(4):287–94

Funding No funding was required **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Ethical committee approval was not required because the study utilised non sensitive questionnaires also used in standard care and a retrospective review of case notes **Helsinki** Yes **Informed Consent** No

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POST VOID RESIDUAL VOLUME AND RATES OF CLEAN INTERMITTENT CATHETERIZATION WITH SPONTANEOUS AND NON-SPONTANTEOUS VOIDING AFTER ONABOTULINUMTOXINA TREATMENT: POOLED ANALYSIS OF TWO PHASE 3 STUDIES

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HYPOTHESIS / AIMS OF STUDY

OnabotulinumtoxinA is a well-tolerated and effective treatment for overactive bladder (OAB). Transient increases in post void residual volume (PVR) have been reported following onabotulinumtoxinA treatment with some cases requiring clean intermittent catheterization (CIC). Increases in PVR after onabotulinumtoxinA treatment may be a driver for follow-up and initiation of CIC in real-world practice. The rate of the complete inability to void has not previously been reported. This pooled analysis in patients with OAB sought to evaluate the maximum PVR (maxPVR) after onabotulinumtoxinA 100U treatment, subsequent CIC use, and the rates of spontaneous versus non-spontaneous voiding.

STUDY DESIGN, MATERIALS AND METHODS

This was a pooled post hoc analysis of two phase 3 studies (ClinicalTrials.gov: NCT00910845 and NCT00910520). Patients (males and females) were stratified based on maxPVR measured within 12 weeks after initial onabotulinumtoxinA 100U treatment into groups of 100 mL increments (0-100 mL, 101-200 mL, 201-300 mL, 301-400 mL, 401-500 mL, 501-600 mL, and ≥601 mL). Rates of clean intermittent catheterization (CIC) were assessed at each maxPVR category and rates of spontaneous and non-spontaneous voiding were calculated. Per phase 3 protocols, CIC was initiated if PVR was ≥200 to <350 mL with relevant associated symptoms assessed by the investigator, or if PVR was ≥350 mL regardless of symptoms. Both studies were performed in compliance with Good Clinical Practice regulations and were approved by the institutional review board or Independent Ethics Committee at each site prior to study initiation. All patients provided written informed consent prior to initiation of any study treatment.

RESULTS

This analysis included 551 patients treated with onabotulinumtoxinA. Most patients had a maxPVR ≤200 mL (494/551, 89.7%) and few patients had a maxPVR ≥201 mL (57/551, 10.3%). Most episodes of significantly raised PVR occurred within the first 2 weeks. Those patients in the highest maxPVR category (≥601 mL, n=5) appeared to be older. In total, 36/551(6.5%) patients receiving onabotulinumtoxinA required CIC throughout the study and was highest in patients with maxPVR >300 mL (25/30, 83.3%) versus ≤300 mL (11/521, 2.1%). No consistent trend in mean CIC duration was observed across the PVR subgroups (39-106 days). Of the 551 patients treated with onabotulinumtoxinA, one patient (0.2%) was unable to spontaneously void, this patient had a PVR ≥601 mL (Figure).

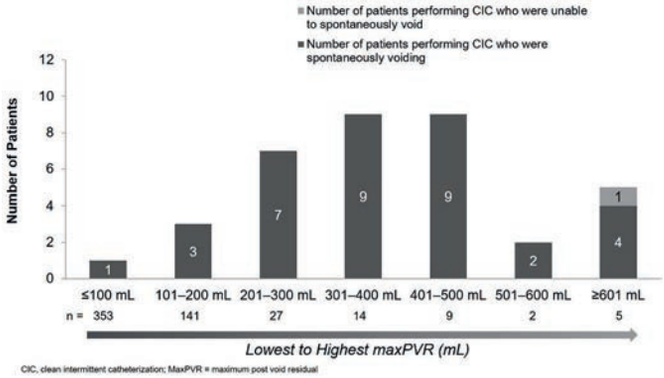
INTERPRETATION OF RESULTS

In this pooled analysis few patients had a maxPVR ≥200 mL after treatment with onabotulinumtoxinA for OAB. Overall, the rates of CIC were low, and CIC was used primarily in patients in the higher maxPVR categories, as required based on the study protocols. The duration of CIC did not appear to correlate with maxPVR.

CONCLUDING MESSAGE

This analysis suggests that the vast majority of patients (99.8%) receiving onabotulinumtoxinA do not develop a complete inability to void; seen here in only one patient. All other patients that initiated CIC were still able to spontaneously void and so did not meet the International Continence Society's definition of urinary retention (inability to pass urine despite persistent effort).

FIGURE 1



Spontaneous and Non-Spontaneous Voiding by MaxPVR in Patients Receiving CIC After Treatment With OnabotulinumtoxinA

Funding Allergan plc **Clinical Trial** Yes **Registration Number** U.S. National Library of Medicine ClinicalTrials.gov, NCT00910845 and NCT00910520 **RCT** Yes **Subjects** Human **Ethics Committee** Quorum Review Inc, Seattle, Washington; 47 sites involved also completed IRB's individually **Helsinki** Yes **Informed Consent** Yes

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RESULTS AFTER ONABOTULINUMTOXIN A INJECTION IN PATIENTS WITH DETRUSOR OVERACTIVITY AFTER STRESS URINARY INCONTINENCE SURGERY

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1. Fundacio Puigvert

HYPOTHESIS / AIMS OF STUDY

Detrusor overactivity (DO) may be present in men after SUI surgery, representing a challenging scenario. To our knowledge, few studies have addressed the results of intradetrusor onabotulinumtoxin A injection (BoNT-A) in male patients and, more specifically, in patients with DO after SUI surgery. Our aim was to assess treatment response, complications, and rate of continuation on treatment after intradetrusor onabotulinumtoxin A injection (BoNT-A) in these patients.

STUDY DESIGN, MATERIALS AND METHODS

Retrospective analysis of men with prior SUI surgery treated with 100 UI of BoNT-A because of DO since 2010 in our department. Injection was performed with a 5-Fr 4-mm depth needle via a rigid cystoscope in those patients with no history of artificial urinary sphincter (AUS) placement. In patients with AUS, the same needle was inserted via a flexible cystoscope after AUS cuff deflation and deactivation, reactivating the device 12 h after the procedure.

Follow-up included a urodynamic test after 3 months. Treatment response was assessed with a treatment benefit scale (TBS): 1, greatly improved; 2, improved; 3, not changed; 4, worsened after treatment (1-2: response to treatment; 3-4: non-response to treatment). Complications were classified according to the Clavien-Dindo (CD) classification. Treatment continuation was considered present if, at the last visit, patients had received BoNT-A within the preceding 12 months. Reasons for discontinuation were also collected. The pre- and postoperative urodynamic variables were compared using the Student's t test for paired samples, the paired-sample Wilcoxon test, or the McNemar when appropriate. Ethical approval and written patient consent were obtained in accordance with our institution's policy.

RESULTS

18 men were included, median age 71.1 (59.1–83.5) years. 15 (83.3%) patients had history of prior prostatectomy and 3 (16.7%) patients of prior TURP. 9 (50%) patients had undergone an AUS (AMS 800®) placement, 7 (38.9%) a Remeex® sling, and 2 (11.1%) an AdVanceXP® sling. 12 (66.7%) patients reported response to treatment. While all patients presented with DO before BoNT-A injection, DO was present in 8 (53.3%) patients after treatment (p0.016).

Two (11.1%) postoperative complications occurred (urinary retention requiring CIC, CD2). No complications related to the previous SUI surgery were detected. 15 (83.3%) patients had a follow-up >12 months [median follow-up 57 (15–89) months] and all of them had discontinued treatment at the end of follow-up. Reasons for discontinuation were lack of therapeutic benefit in 4 (26.7%), complications in 1 (6.7%), lack of severe symptoms in 3 (20%), and unwillingness to repeat treatment despite treatment response in 7(46.7%) patients.

INTERPRETATION OF RESULTS

According to our results, most male patients with DO and prior history of SUI surgery respond to BoNT-A injection treatment. Moreover, it seems a safe treatment as complications were infrequent and mild.

Recurrent SUI due to a loss of fluid from the pressure-regulating balloon has been reported in a small series of pediatric patients with neurogenic DO with a previously implanted AUS who underwent an intradetrusor BoNT-A injection [1]. Although no complications related to the previous SUI surgery, such as urethral erosion or AUS mechanical failure, occurred in our series, we strongly believe that transurethral instrumentation through an AUS cuff must be conducted with extreme caution and with the minimum gauge possible in order to avoid urethral damage and further cuff erosion, as well as avoiding injection of BoNT-A into the bladder wall against which the AUS balloon leans.

Despite BoNT-A injection can be a treatment choice in male patients with prior SUI surgery, all patients included in our study discontinued treatment during follow-up. However, it has to be mentioned that efficacy issues were a minor reason for treatment discontinuation.

CONCLUDING MESSAGE

BoNT-A injection is an effective and safe treatment for male patients with DO after SUI surgery. However, patients discontinue treatment due to several reasons.

REFERENCES

1. Mazzone L, Weber D, van der Hoeff M, Gobet R, González R. Hazard of botulinum toxin type A injection into the detrusor in patients with an artificial urinarysphincter. J Pediatr Urol. 2006;2(5):399-401.

Funding NONE **Clinical Trial** No **Subjects** Human **Ethics Committee** CEIm Fundació Puigvert IUNA **Helsinki** Yes **Informed Consent** Yes

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ALTERED WHITE MATTER INTEGRITY IN PATIENTS WITH OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Overactive Bladder (OAB) is associated with elevated urgency and urinary incontinence. These lower urinary tract symptoms (LUTS) seems to be paralleled by structural white matter (WM) hypointensities in the brain [1].

We aimed to investigate the role of global and local WM tract function in women with OAB using traditional and novel structural imaging markers.

STUDY DESIGN, MATERIALS AND METHODS

13 female OAB patients (37.3±8.6 years) and eighteen healthy female controls (HC, 32.6±9.5 years) were included in this study. All participants were assed using the female LUTS (FLUTS) questionnaire. Diffusion Tensor Imaging (DTI) was recorded on a 3-Tesla Philips Ingenia scanner. To analyze DTI data in a voxel-wise fashion, Tract-Based Spatial Statistics (TBSS) was used to minimize multi-subject registration errors (FSL, http://www.fmrib.ox.ac.uk/fsl). The four primary quantitative DTI measures, fractional anisotropy (FA), mean (MD), axial (AD), and radial diffusivity (RD) as well as fiber density (FD, a novel non-tensor-derived diffusion marker) are then derived voxel-wise. Correlations with urological scores within the OAB group were only explored in regions with significant differences from HC. Statistical analysis, comparing OAB to HC, was performed using FSL randomise tool and results were corrected for multiple comparisons ($p<0.05$) [2].

RESULTS

Using a whole brain (voxel-to-voxel) approach, FA (Fig. 1) and FD (Fig. 2) was reduced in patients with OAB compared to HC in the corpus callosum (genu and splenium), corona radiata (anterior and posterior), and superior longitudinal fasciculus (SLF). Using a tract-based approach, we found lower FD in the left thalamic radiation, corpus callosum forceps minor, inferior fronto-occipital fasciculus, inferior longitudinal fasciculus (ILF), SLF, and arcuate fasciculus.

OAB patients showed a positive correlation between "Female LUTS" scores and FD (all $p < 0.019$, $r = 0.64$-0.67) of the left ILF, SLF and arcuate fasciculus as well as between the "LUTS Quality of life" scores and FA in corpus callosum forceps major and FD of the left arcuate fasciculus, ILF, and SLF (all $p < 0.044$, $r = 0.61$-0.81).

INTERPRETATION OF RESULTS

Our results demonstrate regional and global WM alterations in patients with OAB, as seen by lacking commissure pathways connecting bilateral frontal and thalamic regions as well as parietal and premotor cortex..

Using FD, we claim that OAB patients showed an altered fiber weighting in certain intra-axonal compartments such as SLF and ILF, i.e. in important associations fibers regulating attention, motor behavior and memory processing.

The positive correlation of FA and LUTS scores could index an overuse of particular WM regions, which do normally show higher values in HC (as sign of intact neuronal integrity).

CONCLUDING MESSAGE

We conclude that the described white matter alterations in OAB patients contribute to their deminished capability of LUT control. These neuroimaging findings help to improve our understanding of OAB aetiology and the involved supraspinal attribute.

FIGURE 1

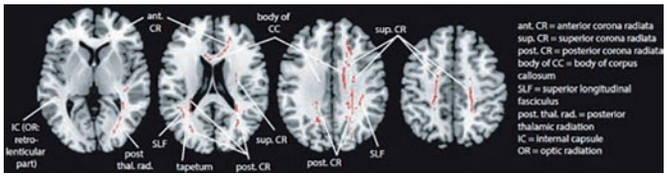

Fig. 1: Significant (p < 0.05, corrected) differences in FA comparing HC to NNOAB. HC showed higher FA values e.g. in the corpus callosum, corona radiata (anterior and posterior), and SLF.

FIGURE 2

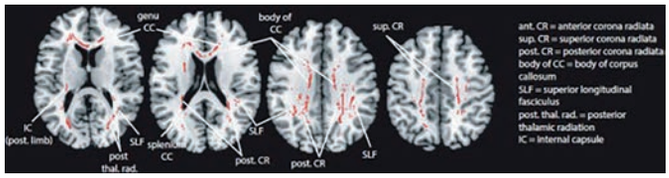

Fig. 2: Significant (p < 0.05, corrected) differences in FD comparing HC to NNOAB. HC showed higher FD values in corpus callosum (genu and splenium), corona radiata (anterior and posterior), and SLF.

REFERENCES

1. Tadic SD, Griffiths D, Murrin A, Schaefer W, Aizenstein HJ, Resnick NM. Brain activity during bladder filling is related to white matter structural changes in older women with urinary incontinence. Neuroimage. 2010 Jul 15;51(4):1294-302.
2. Smith SM, Nichols TE. Threshold-free cluster enhancement: addressing problems of smoothing, threshold dependence and localisation in cluster inference. Neuroimage. 2009 Jan 1;44(1):83-98.

Funding Swiss National Science Foundation **Clinical Trial** No **Subjects** Human **Ethics Committee** Kantonale Ethikkommission Zürich **Helsinki** Yes **Informed Consent** Yes

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A NOVEL METHOD TO EVALUATE NEUROEXCITATION CHANGES IN RESPONSE TO AUDIO-VISUAL URGENCY TRIGGERS USING FUNCTIONAL NEAR-INFRARED SPECTROSCOPY (FNIRS)

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HYPOTHESIS / AIMS OF STUDY

Audio-visual triggers may lead to or exacerbate sensations of urgency in certain individuals with overactive bladder (OAB) [1]. Functional near-infrared spectroscopy (fNIRS) of the brain can be used to quantify neuroexcitation in response to bladder filling [2]. The aim of this preliminary study was to determine whether fNIRS is a feasible tool for non-invasively identifying objective changes in neuroexcitation in response to audio-visual triggers of urinary urgency.

STUDY DESIGN, MATERIALS AND METHODS

Individuals with OAB and healthy participants with minimal urgency were recruited based on ICIq-OAB survey scores (question 5a ≥2 or ≤1, respectively). Participants completed an accelerated oral hydration study while brain fNIRS data were collected using an Artinis Brite24 headcap and while real-time participant-reported bladder sensation was recorded on a 0% to 100% scale using a tablet-based sensation meter [3]. A 1.5-minute control period at 50% sensation was compared to a subsequent 3-minute period during which participants watched and listened to a video containing scenes and sounds of expected triggers of urinary urgency (restrooms, running water, fountains, rain, waterfalls and swimming). fNIRS oxygenated hemoglobin (O2Hb) data were obtained with a receiver located just above the right ear, corresponding to known cortical areas of bladder neuroexcitation [2]. Data were filtered by a 0.1Hz low-pass filter, analyzed to quantify relative changes in neuroexcitation and correlated with changes in participant-reported sensation.

RESULTS

Data from individuals with relatively flat O2Hb signals during the control period were available for two healthy participants and three participants with OAB. Overall, 4/5 participants (80%) demonstrated an increase in O2Hb during the trigger video. This includes 2/3 participants with OAB and 2/2 healthy participants. An example is presented in Figure 1 for an OAB participant with a relatively flat O2Hb control period (Figure 1A) and an increase in O2Hb during the fountain portion of the trigger video (Figure 1B) that also corre-

sponded with an increase in reported sensation (Figure 1B, red line). Figure 2 shows a cortical mesh plot of O2Hb from another participant with OAB. In the region of interest (black rectangle), the color change from blue (Figure 2A) to green (Figure 2B) illustrates an increase in neuroexcitation from the start of the control period to the first peak during the trigger video.

INTERPRETATION OF RESULTS

The results from this pilot fNIRS study revealed that some individuals with OAB may experience an increase in both neuroexcitation and perceived bladder sensation when they are exposed to audio-visual urgency triggers.

CONCLUDING MESSAGE

This preliminary study suggests that fNIRS may be feasible for the objective quantification of neuroexcitation changes evoked by audio-visual triggers of urgency. Additional studies are necessary to determine whether non-invasive fNIRS can be used to identify patients with brain-associated OAB.

FIGURE 1

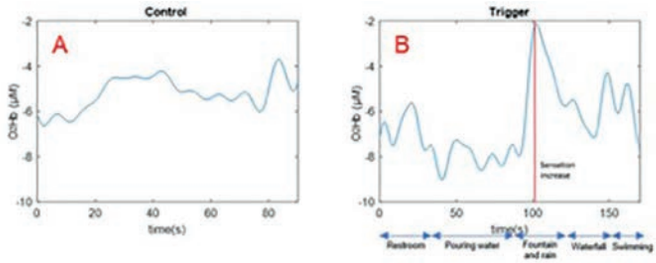

Fig 1. Example O_2Hb data for a participant with OAB demonstrating relatively flat O_2Hb in the control period (left) and an increase in O_2Hb during the fountain and rain portion of the trigger video (right) that also corresponded with an increase in sensation reported by the participant (right, red line).

Figure 1

FIGURE 2

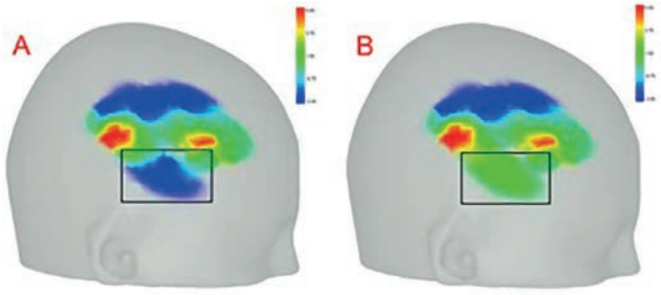

Fig 2. Example cortical mesh plot of O_2Hb for a participant with OAB. Neuroexcitation in the region of interest (black rectangle) increased from the start of the control period (A, blue) to the first peak in neuroexcitation during the trigger video (B, green).

Figure 2

REFERENCES

1. O'Connell KA, Singer J, Rajan S. Stimulus-associated urinary urges in overactive bladder syndrome. Neurourol Urodyn. 2018;37(1):284-290, DOI:10.1002/nau.23290.
2. Macnab AJ, Stothers L, Speich JE, Klausner AP. Evaluation of cortical neuroexcitation in urinary urgency using simultaneous near infrared spectroscopy of the brain and bladder with quantification of sensation. Paper presented at: SPIE Optics and Optoelectronics 2019; Prague, Czech Republic.
3. Nagle AS, Speich JE, De Wachter SG, Ghamarian PP, Le DM, Colhoun AF, Ratz PH, Barbee RW, Klausner AP. Non-invasive characterization of real-time bladder sensation using accelerated hydration and a novel sensation meter: An initial experience. Neurourology and Urodynamics. 2017;36(5):1417-1426.

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SESSION 18 (PODIUM SHORT ORAL) - MALE VOIDING DYSFUNCTION AND LUTS 1
Abstracts 241-252
09:30 - 11:00, Brasilia 1
Chair: Prof Sherif Mourad (Egypt)

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EFFECT ON SEXUAL FUNCTION AS WELL AS VOIDING FUNCTION AFTER VISUAL INTERNAL URETHROTOMY FOR PATIENTS OF URETHRAL STRICTURE WITH FAILED URETHRAL STENT (MEMOKATHTM)

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HYPOTHESIS / AIMS OF STUDY
A thermo-expandable stent (MemokathTM, Pnn Medical, Denmark) have currently used for recurrent bulbar urethral stricture. However, many complications which needed removal of stent, such as recurrent stricture, migration of stent, encrustation, and infection, have been reported in some studies and re-surgical treatment as urethroplasty or visual internal urethrotomy have been needed in many cases. Thus, we investigated the outcomes of voiding parameters and sexual function of visual internal urethrotomy after removal of urethral stent (MemokathTM).

STUDY DESIGN, MATERIALS AND METHODS
From January 2011 and December 2015, thirty-five patients who underwent visual internal urethrotomy immediately after removal of urethral stent (MemokathTM) because of re-stricture within 1 year were included in this study. Successful outcome was defined as normal voiding pattern, without need of any postoperative procedure until 3 years after surgery. We analyzed voiding parameters, including International Prostate Symptom Score (IPSS), Qmax, and residual urine, and sexual function parameter, using Male Sexual Health Questionnaire (MSHQ) at preoperative, postoperative 1 year, 2 years, and 3 years.

RESULTS
The mean age was 47.5±11.6 years and the mean interval between implantation and removal of urethral stent (MemokathTM) was 7.4±2.6 months. After removal of stent, all of patients newly had urethral stricture and stricture portions were reported in follows: 14 anterior stricture; 21 bulbo-membranous stricture and the mean stricture lengths were 8.4±6.5 mm. The recurrence free survival (RFS) rate was 98.71%, 94.48%, and 87.19% at 1, 2, and 3 years, respectively. No difference in RFS was observed regarding the site of stricture (log-rank, p=0.497). With voiding parameters, total IPSS, QoL, Qmax, and PVR significantly improved after postoperative 1 year (p=0.009, <0.001, <0.001, and 0.01, respectively). In terms of sexual function, erection and satisfaction domain score were significantly improved after postoperative 1 year, compared with urethral stent (p<0.001 and p=0.032, respectively).

INTERPRETATION OF RESULTS
All patients who underwent removal of the thermo-expandable urethral stent had newly urethral stricture, with not previous urethral stricture. Location of stricture was proximal and distal end part of urethral stent and we hypothesized that it is because each end part of urethral stent were wider than the body of urethral stent. After VIU, the recurrence free survival (RFS) rate of urethral stricture was 98.71%, 94.48%, and 87.19% at 1, 2, and 3 years, respectively.

CONCLUDING MESSAGE
Although there are many cases that thermo-expandable urethral stent (MemokathTM) is removed by re-stricture, visual internal urethrotomy immediately after removal of urethral stent is an effective surgical treatment of reconstruction with a high recovery rate of sexual function as well as high success rate and few complications.

Funding No **Clinical Trial** No **Subjects** Human **Ethics Committee** 2019-08-035 **Helsinki** Yes **Informed Consent** Yes

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A RETROSPECTIVE STUDY ANALYZING THE EFFECT OF TRANSCUTANEOUS TIBIAL NERVE STIMULATION FOR ADULTS WITH IDIOPATHIC UNDERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY
The aim of this study is to explore the effect of transcutaneous tibial nerve stimulation (TTNS) in the treatment of idiopathic underactive bladder (iUAB) with regards to symptom and quality of life (QoL) improvement, as well as to compare its effectiveness with peripheral nerve evaluation (PNE) in order to better select patients for sacral neuromodulation (SNM).

STUDY DESIGN, MATERIALS AND METHODS

This is a retrospective, single-center study of patients with a clinical and urodynamic diagnosis of iUAB without bladder outlet obstruction (BOO) who are on the waiting list for SNM. The patients followed a 3-week TTNS treatment. A one-hour long session per day was completed for the first week, followed by 3-4 hour-long sessions daily for weeks 2 and 3. Voiding diaries (daily urinary frequency, voided volume per micturition, number of daily self-catheterizations and post-void residual volume (PVR)) were collected at baseline, week 1 and week 3. Changes in UAB symptoms were measured with validated scoring instruments [Patient Global Impression of Improvement (PGII)]. Baseline demographic variables, urodynamic parameters such as bladder contractility index (BCI), previous treatments and adverse effects were also studied.

Descriptive data were reported as median values and percentiles when they were quantitative or with counts and percentages when they were qualitative. Statistical analysis was carried out with the SPSS 2.4 software.

RESULTS

A total of 24 patients were included in the study. The median age was 67 years old(Q153, Q370) and 20(83%) were male. The median BCI at diagnosis was 56.

19 patients completed their bladder diaries. Overall, 9(47.4%) patients had an increase in voided volume per micturition (Q1 12.7 mL; Q3 53.9 mL); 14(73.7%) patients saw an increase in their daily voiding frequency (Q1 1.6 voids/day; Q3 3.1 voids/day); 11(68.8%) patients had a decrease in the PVR (Q1 -112.1 mL; Q3 -31.9 mL), and 4(21.1%) saw a decrease in the number of daily self- catheterizations (Q1 -1.7 catheterizations/day; Q3 -0.9 catheterizations/day).

The changes from baseline to week 1, and from week 1 to week 3, respectively, were as follows: 5(26.3%) and 9(50.0%) had an increase in voided volume per micturition; 14(73.7%) and 9(50.0%) saw an increase in their daily voiding frequency; 7(43.8%) and 11(68.8%) had a decrease in the PVR, and 9(47.4%) and 3(16.7%) saw a decrease in the number of daily self-catheterizations. (See table 1)

19 patients had PNE after the TTNS trial. 3(12.5%) had a failure, 11(45.8%) had a success, and 5(20.8%) are still undergoing the PNE trial.

17 patients completed the PGII questionnaire and 9(37.5%) patients had no improvement, 5(20.8%) patients reported a moderate improvement and 3(12.5%) patients reported a significant improvement.

INTERPRETATION OF RESULTS

Despite the fact that it can have damaging health impacts such as Lower Urinary Tract Symptoms (LUTS), urinary tract infections, urinary retention and renal failure, and that it generates negative effects on quality of life, UAB remains relatively underresearched [1]. Treatment options for UAB are sparse and often unsatisfactory. SNM is the only FDA approved treatment for non-obstructive urinary retention [2]. Studies have demonstrated the effectiveness and safety of TTNS in overactive bladder (OAB), but no clinical trials have been reported for iUAB.

This study demonstrates that TTNS could be a potential treatment for some iUAB patients without BOO. Indeed, a good proportion of patients saw improvements in all bladder diary parameters. There is also a considerable range and variability of responses among patients. Further studies looking at baseline demographic and/or urodynamic characteristics of patients in order to better understand this variability would be interesting.

The reason why sessions were increased from 1 hour to 3 hours between week 1 and week 2 was to better reproduce the continuous stimulations of PNE and SNM. The increase in duration of treatment also aimed to increase the effectiveness of TTNS. Our results show that the voided volume and the PVR were improved with increased duration of TTNS sessions. On the other hand, voiding frequency and number of daily catheterizations had greater improvements between baseline and week 1 of treatment.

The proportion of patients who had improvements in bladder diary parameters (47%, 74%, 21% and 69% for voided volume per micturition, voiding frequency, number of daily catheterizations and PVR, respectively) is comparable to the success rate of PNE in this study (46%). Although larger studies would be needed to confirm it, our study demonstrates that TTNS could also be used as a tool to better select patients for SNM. In addition, TTNS is much less invasive, time-consuming and costly than PNE [3].

Our study is not without its limitations, such as the small sample size, the absence of a control group and the possibility for selection bias. Indeed, a larger sample size would allow us to establish statistical significance levels in order to compare the bladder diary parameter changes over the course of the treatment, as well as to decrease inter-patient variability.

Despite this, our study demonstrates the potential of TTNS as a treatment for iUAB without BOO. Further studies with greater power and/or conducted prospectively should be pursued to better assess its clinical efficacy.

CONCLUDING MESSAGE

To our knowledge, this is the first study that evaluates the effectiveness of TTNS as a treatment for iUAB. Some patients have shown encouraging results, and further studies should be conducted in this direction to establish its clinical efficacy.

FIGURE 1

Table 1. Number of patients who saw increases, decreases or no change in bladder diary parameters between baseline, week 1 and week 3

Parameter	Increase(%)	Decrease(%)	No change(%)
Voided volume per micturition			
Baseline – week 1	5(26.3)	12(63.2)	2(10.5)
Week 1 – week 3	9(50.0)	6(33.3)	3(16.7)
Baseline – week 3	9(47.4)	8(42.1)	2(10.5)
Voiding frequency			
Baseline – week 1	14(73.7)	5(27.8)	4(22.2)
Week 1 – week 3	9(50.0)	5(27.8)	4(22.2)
Baseline – week 3	14(73.7)	3(15.8)	2(10.5)
Number of daily catheterizations			
Baseline – week 1	5(26.3)	9(47.4)	5(26.3)
Week 1 – week 3	6(33.3)	3(16.7)	9(50.0
Baseline – week 3	6(31.6)	4(21)	9(47.4)
PVR			
Baseline – week 1	9(56.3)	7(43.8)	0(0)
Week 1 – week 3	5(31.1)	11(68.8)	0(0)
Baseline – week 3	5(31.3)	11(68.8)	0(0)

REFERENCES

1. Uren, Alan D., and Marcus J. Drake. "Definition and Symptoms of Underactive Bladder." Investigative And Clinical Urology, vol. 58, no. Suppl 2, Dec. 2017, pp. S61–67. 29279877, EBSCOhost, doi:10.4111/icu.2017.58.S2.S61.
2. Kim, Dae Kyung. "Current Pharmacological and Surgical Treatment of Underactive Bladder." Investigative And Clinical Urology, vol. 58, no. Suppl 2, Dec. 2017, pp. S90–98. 29279881, EBSCOhost, doi:10.4111/icu.2017.58.S2.S90.
3. Booth, Joanne, Connelly, Lesley, Dickson, Sylvia, Duncan, Fiona, and Lawrence, Maggie. "The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: A systematic review." Neurourology and Urodynamics, vol. 37, no. Suppl 2, Feb. 2018, pp.S528-541, doi: https://doi.org/10.1002/nau.23351

Funding None Applicable **Clinical Trial** No **Subjects** Human **Ethics Committee** Clinical **Ethics Committee** of the CIUSSS de l'Estrie-CHUS **Helsinki** Yes **Informed Consent** Yes

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THE MECHANISM OF ACTION OF THE UNIQUELY DESIGNED PROSTATIC URETHRAL LIFT IMPLANT

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HYPOTHESIS / AIMS OF STUDY

The prostatic urethral lift (PUL) using UroLift® implants has been shown to provide rapid, significant, durable improvement of symptoms from benign prostatic hyperplasia (BPH). Since little has been published about the short-term and long-term mechanism of action of the implants, animal and clinical studies and post-market data were analyzed to elucidate these points.

STUDY DESIGN, MATERIALS AND METHODS

4 PUL patients underwent cystoscopy at 6-27 months post-procedure. Prostatic tissue was then resected from these patients at 13-43 months for symptom return, and histopathology was performed on the tissue surrounding the excised implants. In animal studies, 24 dogs underwent PUL and histopathology was used to examine the tissue surrounding the implants excised at 1, 3, 6 and 12 months. Worldwide post-market data from April 2018 to September 2019 were reviewed for implant migration, encrustation, and breakage

RESULTS

Clinical cystoscopy shows a widened urethra and retracted lobes when the implant capsular tab (CT) is anchored on the capsule and the urethral endpiece (UE) compresses the urothelium. Canine histopathology shows that this localized tissue compression decreases blood flow, inciting benign lobular atrophy (Figure 1) that continues until compression is relieved. Human data showed similar results. Healing begins immediately post-implantation with 1) tissue compression that results in decreased blood flow, followed by 2) minimal-mild chronic inflammation at 1 month which decreased to minimal chronic inflammation by 12 months, 3) moderate lobular atrophy beginning at 1 month post-implantation and increasing at 12 months, and 4) minimal-mild fibrosis first seen at 6 months post-implantation which is stable through 12 months. Canine and human tissue histopathology also shows no encrustation or necrosis and a stable healing process marked by minimal-mild chronic inflammation, fibrosis, lobular atrophy, and implant epithelialization. The UE invaginates into the tissue and typically becomes epithelialized. Post-market data from over 400,000 implants demonstrate no cases of migration after a successful deployment, a 0.005% rate of stone formation from encrustation and a 0.004% breakage rate.

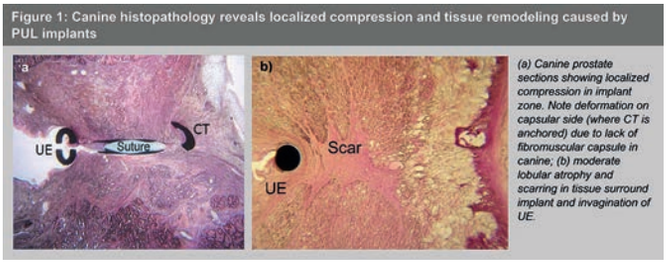
INTERPRETATION OF RESULTS

The PUL implants utilize a mechanical mode of action by attaching onto the fibromuscular capsule and peri-urethral tissue, thus widening the urethra. Human and animal histopathology data and post-market analysis indicate that the implants are benign and safe with no cases of implant migration, and minimal risk for stone formation or breakage. The healing process is stable and begins with minimal-mild chronic inflammation which decreases by 12 months; tissue remodeling occurs beginning with moderate lobular atrophy at 1 month and continues until the tissue acclimates to compression.

CONCLUDING MESSAGE

Results from human and animal tissue analysis and post-market worldwide data indicates the benign, non-irritative nature of this non-thermal approach. The implants cause localized compression that induces remodeling, scarring and fibrosis, and when placed properly, safely affects these changes with minimal risk of migration, encrustation, or breakage.

FIGURE 1



Canine hispathology reveals localized compression and tissue remodeling caused by PUL implants

Funding NeoTract/Teleflex **Clinical Trial** No **Subjects** Human **Ethics Committee** Sterling IRB **Helsinki** Yes **Informed Consent** Yes

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IS REZUMTM WATER VAPOUR ABLATION THERAPY SUITABLE OPTION FOR MEN WITH LARGER PROSTATE GLANDS?

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HYPOTHESIS / AIMS OF STUDY

With increasing life expectancy for men and improved health care systems, there has been a growing demand for managing age related diseases; one of the most common being Benign Prostatic Hyperplasia (BPH). In a large proportion of BPH patients, prostate enlargement causes bladder outflow obstruction (BOO), resulting in troublesome lower urinary tract symptoms (LUTS). This can have a significant impact on a patient's' quality of life (QoL).

Rezum is an ablative water vapour minimally invasive treatment for symptomatic benign prostatic enlargement (BPE). There is little in the literature to describe or support the efficacy of steam vapour for treating larger prostate volumes. We report on our UK experience following Rezum tissue ablation on a cohort of patents with large glands.

STUDY DESIGN, MATERIALS AND METHODS

Data collected prospectively for 475 patients, those have been categorized according to prostate volume into 2 groups (group 1: glands <80mls - and Group 2: glands >80mls). Median age for group 1 and 2 was (67&68 years) respectively, with average prostate volume of 48 cc for group 1 and 95 cc for group 2.

Both Objective parameters (flowmetry/ post voiding/ bladder scan/ reduction in prostate volume) and subjective parameters (IPSS/ QOL) has been recorded and compared between both groups. Patients were followed for up to 24 months with a minimum follow up of 6 months and data interpretation for comparison was used at point of 12 month.

Independent t-test used to compare both groups using SPSS-17 software.

RESULTS

389 were in group 1 whilst 86 were in group 2. Average increase in flow rate was 73% (from 10.8 pre-operatively to 18.7 at 12 months) in group 1 and there was 81 % increase in group to (from 8.7 to 15.8) with no statistical difference between both groups (p=0.321) (Fig 1). Residual urine showed reduction of 29% (from 165 cc pre-operatively to 116 cc post operatively) in group 1 and 46% (from 151 to 81 cc) in group 2. IPSS showed improvement of 17 point on the scale in both groups (from 21 preoperatively to 4 post operatively) in group 1 and (from 20 to 3) in group 2(Fig 2).Patients in both groups had significant improvement in their QOL (from 4.5 to 1.3) and (from 4.7 to 0.8) in group 1 and 2 respectively. Prostate volume reduction was 29% in group 1 (from 48 cc to 34 cc) and 32% (from 95 cc to 64 cc) in group 2

INTERPRETATION OF RESULTS

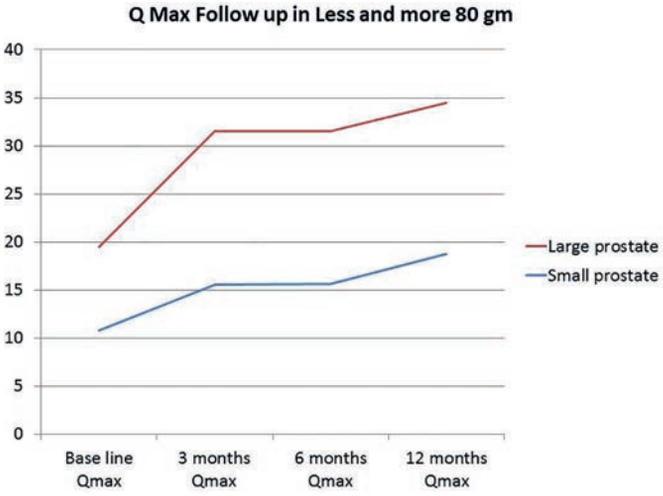
The outcomes of our study are confirming similar early results for this technique when treating larger prostate volumes > 80 cc in both objective and subjective parameters. This is more favourable when compared to outcomes from a previous study reporting on large gland volumes. (Darson et al)

CONCLUDING MESSAGE

Rezūm system has gained popularity and acceptance among many urologists. It is quick to perform and with a short learning curve. This treatment modality that can be adopted as an office or ambulatory outpatient procedure with minimal transient perioperative side effects, and an effective and durable alleviation of urinary symptom with favourable safety profile including preservation of erectile and ejaculatory function.

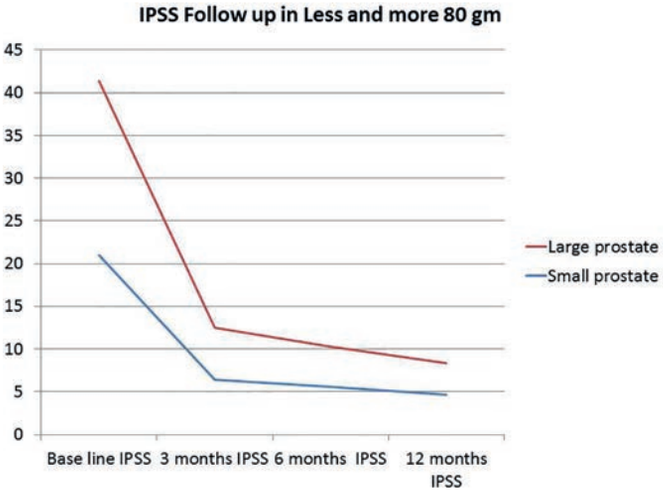
In this series of Rezum water vapor thermal therapy for BPH tissue ablation our analysis has demonstrated non inferiority in treating > 80 cc glands. The symptomatic improvement and favorable side effects profile previously reported for gland volumes of 30-80mls appears to extend to larger gland sizes.

FIGURE 1



Qmax follow up in small and large glands

FIGURE 2



IPSS follow up in small and large glands

REFERENCES

1. Darson MF, Alexander EE, Schiffman ZJ, Lewitton M, Light RA, Sutton MA, Delgado-Rodriguez C, Gonzalez RR. Procedural techniques and multicenter postmarket experience using minimally invasive convective radiofrequency thermal therapy with Rezum system for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Research and reports in urology. 2017;9:159.

Funding None **Clinical Trial** No **Subjects** None **Ethics Committee** Basingstoke and North Hampshire NHS Foundation trust, UK

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PREOPERATIVE POST-VOID RESIDUAL URINE IN THE ASSESSMENT OF THE MALES CANDIDATES FOR TRANSURETHRAL RESECTION OF THE PROSTATE: CLINICAL INFLUENCE AND ASSOCIATION WITH OUTCOMES AFTER 2 YEARS FOLLOW-UP

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HYPOTHESIS / AIMS OF STUDY

Post-void residual (PVR) urine is a common part of the routine clinical assessment in males with lower urinary tract symptoms (LUTS). Aim of this study was to assess the clinical role, the values, and the correlation with other main pre-operative examinations of the pre-operative PVR in males underwent transurethral resection of the prostate (TURP) and the related outcomes after the procedure.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective study involving males with LUTS candidates for TURP. Patients underwent medical and urological history. Both pre-operative evaluation and the 2-year follow-up consisted in: peak flow (Qmax), PVR, PVR-ratio as the ratio of PVR to bladder volume (BV: voided volume (VV) + PVR), and the International Prostate Symptoms Score (IPSS) Questionnaire. Patients were also distributed in 5 groups, according to pre-operative PVR thresholds: i) PVR 0-50ml; ii) PVR 51-100ml; iii) PVR 101-150ml; iiii) PVR 151-200ml; iiiii) PVR>200ml. Statistical analysis was performed using T-test, Wilcoxon test, one-way ANOVA test, Kruskal-Wallis Test.

RESULTS

Patients enrolled in the study were 100 (mean±SD age: 68.8±8.7 yrs). At baseline, 38/100 patients (38%) showed a PVR <50 ml, in 62/100 patients (62%) the PVR was <100 ml, while 37/100 patients (37%) had a PVR between 51-150 ml and 25/100 patients (25%) a PVR >150 ml. A significant improvement in VV, Qmax, PVR and IPSS score (p<0,001) was

documented in all patients (Table 1). No significant difference was found in Qmax and IPSS score among the groups, in both pre-operative and post-operative assessment. In each group we found a significant improvement in Qmax and IPSS score after prostate resection, particularly in PVR <150 ml or >200 ml (p<0,001; Table 2). Table 2 shows how PVR decreased significantly after TURP in all the groups except in the Group i (PVR 0-50ml). This finding may be related to the low pre-operative PVR.

INTERPRETATION OF RESULTS

This study demonstrated the controversial clinical role of pre-operative PVR. Indeed, the majority of the candidates for TURP showed a low pre-operative PVR (<100 ml), despite both pre-operative uroflowmetry and IPSS score were pathological. Thus, pre-operative PVR was poorly correlated to micturition patterns and to urinary symptoms. Males underwent prostate resection notwithstanding the low values of pre-operative PVR, and therefore uroflowmetry outcomes and urinary symptoms had the main influence on the clinical decision-making. Furthermore, the patient's outcomes at 2-years follow-up were not affected by the pre-operative values of PVR, and Qmax and IPSS score improved after TURP regardless of pre-operative PVR. This finding suggests that PVR may be not always correlated to voiding dysfunctions and should be considered only as one part of the examinations of the pre-operative assessment of the males with LUTS. On the other hand, it is remarkable that the PVR volumes, when pre-operatively higher than 50 ml, always decreased after TURP and that the mean post-operative PVR lowered to less the 50 ml. Thus, in patients with no more bladder outlet obstruction, mean PVR was less than 50 ml, regardless of the amount of the pre-operative PVR. This data may indicate that patients with pre-operative PVR higher than 50 ml may be at risk of voiding dysfunctions, but that the severity of voiding dysfunctions is not correlated to the higher PVR volumes. Further data are needed to confirm this finding.

CONCLUDING MESSAGE

Pre-operative PVR is a controversial clinical parameter in the assessment of men with LUTS. Only a minor part of the candidates for TURP showed a high pre-operative PVR. Pre-operative PVR did not significantly influenced prostate resection outcomes and was poorly correlated to pre-operative micturition patterns and urinary symptoms. Thus, this parameter should be considered only as one part of the pre-operative investigations in the assessment of the males with LUTS. Mean PVR decreased after prostate resection, and our data suggest that a PVR higher than 50 ml could be a sign of pathological bladder emptying, but that higher volumes of pre-operative PVR are not correlated to the severity of the disease. Further data are needed to confirm this finding.

FIGURE 1

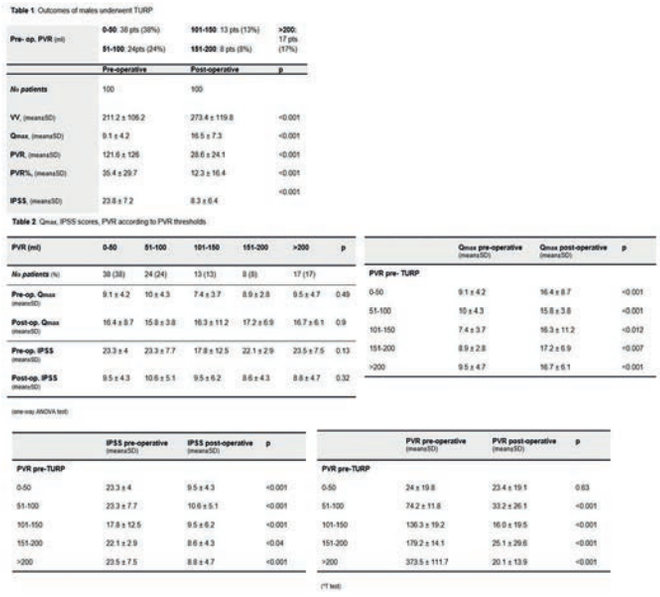

Table 1. Outcomes of males underwent TURP

Pre- op. PVR (ml)	0-50: 38 pts (38%)	101-150: 13 pts (13%)	>200: 17 pts (17%)
	51-100: 24pts (24%)	151-200: 8 pts (8%)	

	Pre-operative	Post-operative	p
No patients	100	100	
VV, (means±SD)	211.2 ± 106.2	273.4 ± 119.8	<0.001
Qmax, (means±SD)	9.1 ± 4.2	16.5 ± 7.3	<0.001
PVR, (means±SD)	121.6 ± 126	28.6 ± 24.1	<0.001
PVR%, (means±SD)	35.4 ± 29.7	12.3 ± 16.4	<0.001
IPSS, (means±SD)	23.8 ± 7.2	8.3 ± 6.4	<0.001

Table 2. Qmax, IPSS scores, PVR according to PVR thresholds

PVR (ml)	0-50	51-100	101-150	151-200	>200	p
No. patients (%)	38 (38)	24 (24)	13 (13)	8 (8)	17 (17)	
Pre-op. Qmax (means±SD)	9.1 ± 4.2	10 ± 4.3	7.4 ± 3.7	8.9 ± 2.8	9.5 ± 4.7	0.49
Post-op. Qmax (means±SD)	16.4 ± 8.7	15.8 ± 3.8	16.3 ± 11.2	17.2 ± 6.9	16.7 ± 6.1	0.9
Pre-op. IPSS (means±SD)	23.3 ± 4	23.3 ± 7.7	17.8 ± 12.5	22.1 ± 2.9	23.5 ± 7.5	0.13
Post-op. IPSS (means±SD)	8.5 ± 4.3	10.6 ± 5.1	9.5 ± 6.2	8.6 ± 4.3	8.8 ± 4.7	0.32

(one-way ANOVA test)

	Qmax pre-operative (means±SD)	Qmax post-operative (means±SD)	p
PVR pre- TURP			
0-50	9.1 ± 4.2	16.4 ± 8.7	<0.001
51-100	10 ± 4.3	15.8 ± 3.8	<0.001
101-150	7.4 ± 3.7	16.3 ± 11.2	<0.012
151-200	8.9 ± 2.8	17.2 ± 6.9	<0.007
>200	9.5 ± 4.7	16.7 ± 6.1	<0.001

	IPSS pre-operative (means±SD)	IPSS post-operative (means±SD)	p
PVR pre-TURP			
0-50	23.3 ± 4	9.5 ± 4.3	<0.001
51-100	23.3 ± 7.7	10.6 ± 5.1	<0.001
101-150	17.8 ± 12.5	9.5 ± 6.2	<0.001
151-200	22.1 ± 2.9	8.6 ± 4.3	<0.04
>200	23.5 ± 7.5	8.8 ± 4.7	<0.001

	PVR pre-operative (means±SD)	PVR post-operative (means±SD)	p
PVR pre-TURP			
0-50	24 ± 19.8	23.4 ± 19.1	0.83
51-100	74.2 ± 11.6	33.2 ± 26.1	<0.001
101-150	136.3 ± 19.2	16.0 ± 19.5	<0.001
151-200	179.2 ± 14.1	25.1 ± 29.6	<0.001
>200	373.5 ± 111.7	20.1 ± 13.9	<0.001

(*t test)

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Internal **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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SYMPTOMS AND NONINVASIVE TEST PARAMETERS THAT DIFFERENTIATE DETRUSOR UNDERACTIVITY FROM BLADDER OUTLET OBSTRUCTION IN MEN WITH LOWER URINARY TRACT SYMPTOMS

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HYPOTHESIS / AIMS OF STUDY

Detrusor underactivity (DU) and bladder outlet obstruction (BOO) are the two major cause of voiding symptoms in elderly men. Because the treatment strategies of these two conditions are quite different, differential diagnosis is very important. Although pressure flow study (PFS) is a useful tool for the diagnosis of DU and the differentiation of these two conditions, it is not so popular among general urologists due to it's invasiveness and complexity. Therefore, noninvasive approaches to differentiate DU from BOO have been demanded. In the present study, we focused on how to differentiate DU from BOO without PFS and tried to find the symptoms and noninvasive test parameters that are useful for the differentiation of DU from BOO using a large database of male patients undergoing PFS.

STUDY DESIGN, MATERIALS AND METHODS

The clinical data of male lower urinary tract symptoms (LUTS) patients who underwent PFS between January 2010 and January 2017 were reviewed. We included 909 men who underwent PFS and had their international prostate symptom score (IPSS) and their free-uroflowmetry (UFM), post-void residual urine volume (PVR) and prostate volume (PV) results. Using these data, the significant symptoms and noninvasive test parameters associated with DU or BOO were examined. DU was defined as bladder contractility index (BCI = detrusor pressure at maximum flow (PdetQmax)+5Qmax) < 100. BOO was defined as BOO index (BOOI = PdetQmax-2Qmax) > 40. Pure DU was defined as BCI < 100 and BOOI ≤ 40, whereas pure BOO was defined as BCI ≥ 100 and BOOI > 40. Patients with urodynamic diagnosis of detrusor overactivity (DO) were excluded in pure DU and pure BOO analysis following the previous studies1,2).

RESULTS

Multivariate logistic regression analysis showed that DU patients were older, had a smaller PV, lower urgency symptom score (IPSS Q4), higher weak stream symptom score (IPSS Q5) and lower Qmax compared to non-DU patients. Conversely, BOO patients had a larger PV, higher IPSS Q4, higher IPSS Q5, lower Qmax, and higher PVR compared to non-BOO patients. These results suggest that three factors including older age, smaller PV and lower IPSS Q4 would be the useful predictive factors to differentiate DU from BOO. We also classified patients into pure DU and pure BOO and compared their parameters. As shown in Table 1, univariate and multivariate comparison of the parameters between pure DU and pure BOO patients showed that older age, lower PV and lower IPSS Q4 were the independent predictors. Optimal cut-off values for age (74 years), PV (34.8 ml) and IPSS Q4 score (1) were determined by ROC curves and patients were categorized according to the number of significant predictors (score 0-3). As shown in Figure 1, the probability of having DU increased and the probability of having BOO decreased as the score increased.

INTERPRETATION OF RESULTS

First, we examined the significant factors between DU and non-DU patients, and also examined the significant factors between BOO and non-BOO patients. These results showed that urgency symptom score (IPSS Q4) and PV were significantly lower in DU patients and were significantly higher in BOO patients, showing the opposite responses between DU patients and BOO patients. In addition, older age was the significant factor only in DU patients. On the other hand, higher weak stream symptom (IPSS Q5) and lower Qmax were observed in both DU and BOO patients. Therefore, we considered that three factors, namely older age, smaller PV and lower urgency symptom score (IPSS Q4) would be the significant factors to differentiate DU from BOO. Second, we evaluated that the significant factors between pure DU and pure BOO patients. As shown in Table 1, older age, lower PV and lower urgency symptom score (IPSS Q4) were the significant factors, which were the same results as those obtained in our first analysis. Taken together, we considered that three factors, namely, older age, smaller PV, and less urgency symptom (IPSS Q4) would be the predictive factors to differentiate DU from BOO.

CONCLUDING MESSAGE

Three factors, namely, older age (≥ 74 years old), smaller PV (≤ 34.8 ml), and lower urgency symptom (IPSS Q4) (≤ 1) would be the useful predictive factors to differentiate DU from BOO. A combined evaluation of these factors might be useful for the differentiation of DU from BOO.

FIGURE 1

Table 1

A

	Pure DU (N=136)	Pure BOO (N=125)	P value
Age (years)	69.4 ± 9.0	68.0 ± 7.2	0.19
Prostate volume (mL)	28.57 ± 12.67	54.5 ± 23.9	< 0.001
IPSS - total	16.74 ± 7.83	19.2 ± 8.4	0.02
IPSS - incomplete emptying	2.1 ± 1.8	2.5 ± 1.8	0.08
IPSS - frequency	2.7 ± 1.8	3.0 ± 1.7	0.14
IPSS - intermittent stream	2.3 ± 1.9	2.7 ± 1.9	0.10
IPSS - urgency	1.45 ± 1.71	2.5 ± 1.8	< 0.001
IPSS - slow stream	3.7 ± 1.7	3.5 ± 1.7	0.47
IPSS - straining	2.0 ± 1.9	2.3 ± 1.8	0.21
IPSS - nocturia	2.4 ± 1.4	2.6 ± 1.3	0.30
IPSS - QOL	4.6 ± 1.5	5.3 ± 4.2	0.07
Qmax on UFM (mL/s)	9.3 ± 4.8	8.5 ± 4.8	0.20
PVR on UFM (mL)	54.8 ± 81.3	85.6 ± 97.5	0.006
VV on UFM (mL)	201.0 ± 125.4	170.6 ± 90.4	0.03

B

	OR (95% CI)	P value
Age	1.050 (1.000-1.090)	0.046
Prostate volume	0.916 (0.894-0.938)	< 0.001
IPSS - incomplete emptying	0.944 (0.747-1.190)	0.63
IPSS - frequency	1.120 (0.867-1.440)	0.39
IPSS - intermittent stream	1.090 (0.854-1.390)	0.49
IPSS - urgency	0.673 (0.536-0.845)	< 0.001
IPSS - slow stream	1.070 (0.813-1.410)	0.62
IPSS - straining	1.030 (0.820-1.300)	0.78
IPSS - nocturia	0.890 (0.673-1.180)	0.42
IPSS - QOL	0.881 (0.668-1.160)	0.37
Qmax on UFM	1.030 (0.931-1.140)	0.57
PVR on UFM	0.997 (0.992-1.000)	0.15
VV on UFM	0.999(0.995-1.000)	0.69

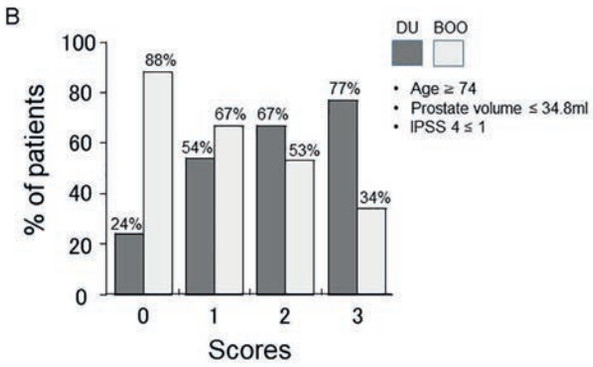
FIGURE 2

Fig 1

A

	AUC	95% CI	sensitivity	specificity	Cut-off values
Age	0.583	0.546-0.620	0.719	0.427	74.0
Prostate volume	0.711	0.677-0.744	0.708	0.623	34.8
IPSS - urgency	0.580	0.544-0.617	0.635	0.511	1.00

B



REFERENCES

1. Osman NI, Chapple CR, Abrams P et al: Detrusor underactivity and the underactive bladder: a new clinical entity? A review of current terminology, definitions, epidemiology, aetiology, and diagnosis. Eur Urol 2014; 65: 389.
2. Gammie A, Kaper M, Dorrepaal C et al: Signs and symptoms of detrusor underactivity: an analysis of clinical presentation and urodynamic tests from a large group of patients undergoing pressure flow studies. Eur Urol 2016; 69: 361.

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DO CHRONIC DISEASE AFFECT LOWER URINARY TRACT SYMPTOMS? RESULTS FROM THE KOREAN COMMUNITY HEALTH SURVEY

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract symptoms (LUTS) occur in 20-50% of people and decrease quality of life. Clinical observations indicate that manychronic diseases seem to be associated with LUTS. To evaluate the relationships between LUTS and Chronic disease [Hypertension (HTN), Diadetes mellitus (DM), Dyslipidemia (DL), Stroke, Myocardial Infarction (MI), Arthritis, Osteoporosis, Glaucoma, Depression] in Korean men.

STUDY DESIGN, MATERIALS AND METHODS

In this study, we analyzed raw data from the Korean Community Health Survey (KCHS) performed by the KCDC from August to November 2011. This survey targets South Koreans older than 19 years of age and was performed based on 1:1 direct interviews using Computer Assisted Personal Interviewing (CAPI). KCHS has performed this survey to generate regional health statistics since 2008. Aged over 40 years of south Korean men was 73,643, excluding 1,002 whose question items were not completed, 8,006 were incomplete and complete of doctor-diagnosed BPH and current-treatment status, and 196 were incomplete status of BPH treatment leaving a final sample of 64,439 respondents whom interviews were conducted using questionnaires. Trained interviewers performed face-to-face surveys using computer-assisted personal interviewing, the International Prostate Symptom Score (IPSS), and standard questions. We assessed the relationships of Chronic disease with LUTS.

RESULTS

We observed higher IPSS scores in participants who engaged in HTN (n=17,111 [24.1%], IPSS=4.17±6.02) than in those who was negative to HTN (n=47,314 [75.9%, IPSS=2.58±4.70). Other chronic diseases showed higher IPSS scores compare to none holders. DM patients showed higher storage and voiding symptom scores compare no none DM patients. In DL patients, none DL patients showed higher storage symptom scores who have storage symptoms compare to DL holders. Other chronic diseases showed higher storage and voiding symptom scores in group of presenting storage and voiding symptoms. In multivariable logistic regression analysis, we detected no relationship between LUTS and Chronic disease. Most of chronic disease were related with LUTs and severity. Depression showed highest odds ratio (moderate: 2.13; 95% confidence interval [CI], 2.13–2.13; P<0.001, severe: 1.58; 95% CI, 1.58–1.58; P<0.001). However, Osteoporosis showed irrelevant figure (moderate:

0.98; 95% confidence interval [CI], 0.98–0.98; P<0.001). Most of Chronic diseases have related with storage symptoms and voiding symptoms. Arthritis and glaucoma showed relationship with storage symptoms (1.71; 95% confidence interval [CI], 1.52–1.93; P<0.001, 1.65 ; 95% CI, 1.28–2.13; P<0.001, respectively). Participants with depression presented strong relationship with voiding symptoms (2.11; 95% confidence interval [CI], 1.65–2.7; P<0.001).

INTERPRETATION OF RESULTS

Most of chronic diseases had relationship with LUTS. Arthritis, stroke, and depression were associated with a greater severity of LUTS. Arthritis and glaucoma were also related to storage symptoms. Also, depression presented strong relationship with voiding symptoms.

CONCLUDING MESSAGE

Chronic diseases need to be considered in clinics with LUTS and further studies should be necessary.

FIGURE 1

Table 1. **Selected characteristics of study subjects according to lower urinary tract symptoms (LUTS)**

	IPSS scores		LUTS severity						Rao-Scott Chi-Square p-value
			Mild(≤IPSS)		Moderate (8≤IPSS≤19)		Severe (20≤IPSS)		
	Score	N(%)	Score	N(%)	Score	N(%)	Score	N(%)	
Hypertension									
No	2.58± 4.70	47,314 (75.9)	1.26±1.81	42,414(91.7)	11.63±3.16	4,050(7.0)	25.38±4.48	850(1.2)	<0.0001
Yes	4.17± 6.02	17,111 (24.1)	1.75±2.04	13,871(83.9)	11.90±3.24	2,623(13.2)	25.63±4.62	617(2.9)	
Diabetes mellitus									
No	2.81± 4.94	57,091 (89.8)	1.32±1.85	50,453(90.8)	11.72±3.16	5,466(7.8)	25.38±4.56	1,172(1.4)	<0.0001
Yes	4.50± 6.24	7,317 (10.2)	1.89±2.10	5,817(81.8)	11.86±3.30	1,205(14.8)	25.90±4.44	295(3.4)	
Dyslipidemia									
No	2.96± 5.13	57,322 (87.7)	1.35±1.87	50,182(90.2)	11.76±3.20	5,829(8.3)	25.52±4.5	61,311(1.6)	<0.0001
Yes	3.29± 5.07	6,989 (12.3)	1.96±11.65	6,019(87.8)	3.13±25.21	821(10.3)	25.21±4.33	149(1.9)	
Stroke									
No	2.88± 4.97	62,775 (98.1)	1.36±1.87	55,247(90.3)	11.71±3.17	6,237(8.2)	25.36±4.49	1,291(1.5)	<0.0001
Yes	7.50± 8.35	1,657 (1.9)	2.28±2.16	1,043(65.3)	12.35±3.35	438(25.4)	26.40±4.81	176(9.2)	
MI									
No	2.94± 5.06	63,106 (98.3)	1.37±1.88	55,345(90.2)	11.72±3.18	6,372(8.3)	25.45±4.51	1,389(1.6)	<0.0001
Yes	5.74± 7.13	1,298 (1.7)	1.98±2.12	927(73.6)	12.44±3.27	298(21.6)	26.14±4.95	73(4.8)	
Arthritis									
No	2.78± 4.86	60,192 (95.3)	1.34±1.86	53,342(90.7)	11.65±3.17	5,672(7.9)	25.36±4.52	1,178(1.4)	<0.0001
Yes	6.16± 7.36	4,227 (4.7)	2.14±2.15	2,943(72.3)	12.30±3.27	996(21.8)	25.99±4.60	288(5.9)	
Osteoporosis									
No	2.95± 5.06	63,584 (99.1)	1.37±1.87	55,738(90.0)	11.73±3.19	6,454(8.4)	25.42±4.53	1,392(1.6)	<0.0001
Yes	7.08± 8.03	824 (0.9)	2.31±2.27	536(69.9)	12.32±3.29	215(21.8)	26.77±4.66	73(8.2)	
Glaucoma									
No	2.97± 5.10	63,793 (99.1)	1.37±1.88	55,844(90.0)	11.74±3.19	6,526(8.4)	25.49 ±4.55	1,423(1.6)	<0.0001
Yes	6.01± 7.22	623 (0.9)	2.06±2.11	434(71.2)	12.13±3.29	147(22.2)	25.40±4.42	42(6.5)	
Depression									
No	2.97± 5.10	63,724 (99.0)	1.37±1.88	55,792(90.0)	11.74±3.19	6,509(8.4)	25.46±4.53	1,423(1.6)	<0.0001
Yes	5.87± 7.25	712 (1.0)	1.98±2.17	501(73.5)	12.16±3.01	167(22.3)	26.27±4.84	44(4.2)	

MI : Myocardial Infarction, SD, standard deviation, Value are expressed as mean ± SD or N (%).

Table 2. **Relationships between Chronic disease and LUTS severity**

	Multivariable Model					
	Moderate (8≤IPSS≤19)			Severe (20≤IPSS)		
	OR	95%CI	p-value	OR	95%CI	p-value*
Hypertension						
No	1.00	ref.	-	1.00	ref.	-
Yes	1.12	(1.12,1.12)	<.0001	1.18	(1.18,1.18)	<.0001
Diabetes mellitus						
No	1.00	ref.	-	1.00	ref.	-
Yes	1.2	(1.2,1.12)	<.0001	1.3	(1.3,1.3)	<.0001
Dyslipidemia						
No	1.00	ref.	-	1.00	ref.	-
Yes	1.17	(1.17,1.17)	<.0001	1.12	(1.12,1.12)	<.0001
Stroke						
No	1.00	ref.	-	1.00	ref.	-
Yes	1.08	(1.08,1.09)	<.0001	1.6	(1.6,1.6)	<.0001
MI						
No	1.00	ref.	-	1.00	ref.	-
Yes	1.32	(1.32,1.32)	<.0001	1.07	(1.07,1.07)	<.0001
Arthritis						
No	1.00	ref.	-	1.00	ref.	-
Yes	1.52	(1.52,1.52)	<.0001	1.74	(1.74,1.74)	<.0001
Osteoporosis						
No	1.00	ref.	-	1.00	ref.	-
Yes	0.98	(0.98,0.98)	<.0001	1.15	(1.15,1.15)	<.0001
Glaucoma						
No	1.00	ref.	-	1.00	ref.	-
Yes	1.13	(1.13,1.13)	<.0001	1.34	(1.34,1.34)	<.0001
Depression						
No	1.00	ref.	-	1.00	ref.	-
Yes	2.13	(2.13,2.13)	<.0001	1.58	(1.58,1.58)	<.0001

LUTS: lower urinary tract symptom score, OR : odds ratio, CI : confidence interval. Multivariable model: Adjusted for age, smoking status, drinking status, BMI, stress, physical activity, and chronic diseases (hypertension, diabetes, dyslipidemia, stroke, angina pectoris, MI : myocardial infarction, osteoarthritis, osteoporosis, cataract, glaucoma, depression). *P-value and P-value for trend were determined by multivariable survey logistic regression analyses.

REFERENCES

1. Markland AD, Vaughan CP, Okosun IS, Goode PS, Burgio KL, Johnson TM. Cluster analysis of multiple chronic conditions associated with urinary incontinence among women in the USA. BJU Int. 2018 Dec;122(6):1041-1048.
2. Reigota RB, Pedro AO, de Souza Santos Machado V, Costa-Paiva L, Pinto-Neto AM. Prevalence of urinary incontinence and its association with multimorbidity in women aged 50 years or older: A population-based study. Neurourol Urodyn. 2016 Jan;35(1):62-8.
3. Koskimäki J, Hakama M, Huhtala H, Tammela TL. Association of non-urological diseases with lower urinary tract symptoms. Scand J Urol Nephrol. 2001 Oct;35(5):377-81.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Analyzing previous data **Helsinki** Yes **Informed Consent** No

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EFFECT OF VITAMIN D SUPPLEMENTATION ON URINARY INCONTINENCE AND OVERACTIVE BLADDER SYMPTOMS IN OLDER MEN: ANCILLARY FINDINGS FROM A RANDOMIZED TRIAL

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HYPOTHESIS / AIMS OF STUDY

A small number of observational epidemiologic studies indicate that vitamin D insufficiency is associated with increased prevalence and incidence of urinary incontinence (UI) and overactive bladder (OAB) in men but limited clinical trial data are available regarding supplementation with vitamin D and UI or OAB [1-2]. We leveraged a unique opportunity to test vitamin D supplementation as a possible preventive treatment to reduce UI and OAB among older men, in an ancillary study of men enrolled in a nationwide vitamin D and omega-3 prevention trial for cancer and cardiovascular disease, the VITamin D and omegA-3 TriaL (VITAL) [3]. Our objectives were to evaluate the effects of vitamin D supplementation on UI and OAB prevalence after 2 and 5 years of supplementation, including secondary analysis of men with low serum vitamin D levels prior to randomization. We hypothesized that older men assigned to vitamin D would have lower prevalence of UI and OAB than men assigned to placebo after 2 and 5 years.

STUDY DESIGN, MATERIALS AND METHODS

We performed a pre-specified ancillary study to VITAL, a 2 x 2 factorial randomized trial conducted among 25,871 men and women recruited between November 2011 and March 2014 from all 50 US states. Follow-up was completed in January 2018. Randomized vitamin D treatments included: 1) vitamin D3 (cholecalciferol) at a dose of 2000 IU/day, and 2) placebo. Validated UI questions (frequency and type) and OAB questions (urgency, frequency, and nocturia) were assessed in year 2 and year 5 at the trial close. The pre-specified outcomes were the prevalence of UI at year 2 and year 5, along with OAB assessed only at year 5, with subgroup

analysis for men with low pre-randomization serum levels of vitamin D (25OHD<30 ng/mL). Among the 12,786 men randomized, UI data were available from 11,486 at year 2, 10,474 men at year 5; with OAB data on 5,732 at year 5 (OAB items were added late in the questionnaire follow-up). For the primary analyses, men were analyzed according to their randomization to vitamin D supplementation or placebo using the intention-to-treat principle, along with similar analyses among men with 25OHD biosamples at baseline.

RESULTS

As expected, no sociodemographic differences were seen between men randomized to vitamin D versus placebo (mean age = 68 years, 24% racial/ethnic minority), including the subset with low plasma 25OHD. At year 5, 41% reported UI and 35% reported OAB. Supplementation with vitamin D compared to placebo was not associated with lower odds of prevalent UI at year 2 and year 5 or prevalent OAB at year 5 (Table). In men with low 25OHD, no differences were found in prevalent UI, although there was a borderline significant decrease in OAB prevalence (OR 0.83, 95% CI 0.69-1.01, p=0.06, Table). For all men and men with low 25OHD, UI type (urge, stress, mixed, or other) did not differ between randomization groups, and prevalence of OAB combined with UI did not differ either (data not shown).

INTERPRETATION OF RESULTS

Vitamin D supplementation of 2,000 IU daily in men was not associated with decreased prevalence of any UI, weekly UI or OAB symptoms. Among men with low 25OHD levels, there was no decrease in prevalence of any UI and weekly UI. However, among men with low 25OHD, we found a non-significant trend toward decreased odds of OAB symptoms at 5 years, which deserves further evaluation.

CONCLUDING MESSAGE

This study provides novel clinical trial data that vitamin D supplementation compared to placebo does not substantially affect UI or OAB in older men after 2 and 5 years of treatment.

FIGURE 1

	N	Vitamin D N (%)	Placebo N (%)	Odd Ratio	95% Confidence Interval	P value
Any UI at Year 2						
All Men	11,486	1776 (31%)	1808 (32%)	0.97	0.90-1.05	0.49
Low 25(OH)D	3,588	588 (33%)	595 (33%)	0.98	0.73-1.09	0.27
Weekly UI at Year 2						
All men	11,438	614 (10.7%)	654 (11.4%)	0.93	0.83-1.05	0.24
Low 25(OH)D	3576	209 (11.7%)	231 (12.9%)	0.89	0.73-1.09	0.27
Any UI at Year 5						
All men	10,474	2161 (41%)	2145 (41%)	1.00	0.93-1.08	1.00
Low 25(OH)D	3,298	720 (44%)	694 (42%)	1.08	0.94-1.24	0.29
Weekly UI at Year 5						
All men	5,732	580 (20%)	631 (22%)	0.91	0.80-1.03	0.15
Low 25(OH)D	1,848	169 (18%)	210 (23%)	0.75	0.60-0.94	0.01
OAB at Year 5						
All men	5,732	1000 (35%)	1030 (36%)	0.97	0.87-1.08	0.59
Low 25(OH)D	1,848	314 (34%)	349 (38%)	0.83	0.69-1.01	0.06

REFERENCES

1. Vaughan CP, Johnson TM, II, Goode PS, Redden DT, Burgio KL, Markland AD. Vitamin D, Urinary Incontinence, and Lower Urinary Tract Symptoms among US Men: Results from the National Health and Nutrition Examination Survey. Urology. 2011 Dec;78(6):1292-7.
2. Vaughan CP, Tangpricha V, Motahar-Ford N, Goode PS, Burgio KL, Allman RM, Daigle SG, Redden DT, Markland AD. Vitamin D and incident urinary incontinence in older adults. Eur J Clin Nutr 2016.
3. Manson JE, Cook NR, Lee IM, et al. Vitamin D Supplements and Prevention of Cancer and Cardiovascular Disease. N Engl J Med. 2019;380(1):33–44

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RELATIONSHIP BETWEEN CHRONIC PERIODONTITIS AND LOWER URINARY TRACT SYMPTOMS/BENIGN PROSTATIC HYPERPLASIA

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HYPOTHESIS / AIMS OF STUDY

Chronic periodontitis (CP) is an infectious disease resulting in inflammation within the supporting tissue of the teeth, progressive attachment, and bone loss. Recent data showed that CP was related to systemic diseases, such as cardiovascular disease, metabolic syndrome, and endothelial dysfunction. However, there have been scanty data about the relationship between lower urinary tract symptoms (LUTS)/benign prostatic hyperplasia (BPH) and CP. This study was conducted to investigate the relationship between CP and LUTS/BPH.

STUDY DESIGN, MATERIALS AND METHODS

A total of 208 men in their 40s and 50s who had received a health checkup were included. All of the data from the participants were collected prospectively. CP was defined as a 30 % increase in clinical attachment level (CAL)≥4mm of the total probed site. And, CAL was defined as the distance between the cementoenamel junction of the tooth and the

deepest aspect of the pocket. All periodontal measurements were taken on 6 surfaces per tooth (mesiobuccal, mid-buccal, distobuccal, mesiolingual, mid-lingual, and distolingual) in all teeth except the third molars, using a Willams probe. All periodontal examinations were performed by a single periodontist who was blind urological data. LUTS/BPH was assessed using IPSS, transrectal ultrasonography, uroflowmetry, and postvoiding residual urine volume. Additionally, a full metabolic workup including testosterone was carried out. The Mann-Whitney U test and the multiple linear regression test were used for the evaluation of the relationships.

RESULTS

Median age, total prostate volume, IPSS total score, average flow rate, and maximal flow rate were 55.0 years old, 29.0 mL, 9.0, 9.0 mL/sec, and 20.5 mL/sec, respectively. In addition, the prevalence of CP was 26.7%. IPSS total, IPSS voiding, IPSS storage, and QoL score were significantly higher in patients with CP (median [interquartile range], P; IPSS total, 8.0 [5.0-13.5] vs. 12.0 [7.5-20.5], P=.004; IPSS voiding, 5.0 [2.0-9.0] vs. 8.5 [4.0-15.0], P=.002; IPSS storage, 3.0 [2.0-5.0] vs. 4.0 [3.0-6.0], P=.021; QoL, 2.0 [1.0-3.0] vs. 3.0 [2.0-4.0], P=.015). And, average flow rate was significantly lower in patients with CP (median [interquartile range] (mL/sec), P; 9.0 [8.0-13.0] vs. 8.0 [6.0-11.0], P=.042). After adjusting for age, testosterone, prostate volume, glucose, total cholesterol, and waist circumference, IPSS total and IPSS voiding score were significantly and positively related to CP (Estimated, Std. Error, P; IPSS total, 4.9498, 1.8573, .0093; IPSS voiding, 4.0077, 1.2835, .0025).

INTERPRETATION OF RESULTS

Our data suggest that LUTS/BPH is significantly related to CP. Metabolic syndrome, systemic inflammation, and direct dissemination of oral pathogen to prostate would be possible explanations for their relationships. For a better understanding of the pathophysiology of LUTS/BPH, further clinical and experimental studies would be needed.

CONCLUDING MESSAGE

LUTS/BPH is significantly related to CP.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** NPH **Helsinki** Yes **Informed Consent** Yes

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PELVIC FLOOR MUSCLE ACTIVITY IN MEN WITH AND WITHOUT PELVIC FLOOR SYMPTOMS: AN OBSERVATIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY

The possible role of pelvic floor muscle activity in male pelvic floor symptoms has not been studied thoroughly (1), due to difficulties in assessing pelvic floor muscle function in detail. These difficulties may be overcome with the Multiple Array Probe Leiden (MAPLe), a probe used to detect electromyography (EMG) signals from the different pelvic floor muscles (2). We explored pelvic floor muscle activity in men with and without lower urinary tract symptoms (LUTS), and with and without sexual dysfunction.

STUDY DESIGN, MATERIALS AND METHODS

We conducted an observational cohort study in men with and without pelvic floor symptoms. For this, we invited all men aged >16 years, without a terminal disease, limited cognition or psychiatric or psychological problems, who lived in a Dutch municipality, to complete a questionnaire.

The International Consultation on Incontinence Questionnaire male LUTS Module (ICIQ-mLUTS) was used to assess LUTS, and categorize men into a group without symptoms (first quartile) and a group with severe symptoms (fourth quartile). Sexual functioning was assessed using the 'Sexual Health in the Netherlands' questionnaire and the ICIQ-Male Sexual Matters Associated with LUTS Module (ICIQ-MLUTS-sex). Having erectile and/or ejaculation problems and/or pain during intercourse or ejaculation was defined as having sexual dysfunction. For this we selected sexually active men.

We selected men (aged >21 years), for additional measurements, based on their symptom scores, to allow comparison between men with and without symptoms. Measurements included a MAPLe assessment, according to the manufacturers' protocol, including one-minute rest, ten maximum voluntary contractions (MVC) held for 1-2 seconds, and three sub-maximal endurance contractions held for 30 seconds. Raw output data of the MAPLe-measurements were retrieved for each of the 24 electrodes. Data were structured to assess muscle activity for the puborectal (PR) muscle, external anal sphincter (EAS), pubo- and iliococcygeal muscles (PIC) and the urogenital diaphragm (UDF).

Differences in pelvic floor muscle activity, for the three tasks and four muscle groups, between men with and without symptoms were analyzed using Mann-Whitney U Tests.

RESULTS

Data from 198 men (mean age 63.0±12.6 years) were available. Men without LUTS had 3 points or less on the ICIQ-mLUTS (n=61), men with severe symptoms had scores of 10 and higher (n=56). In total 158 men were sexually active (with or without partner); 75 men were classified as having sexual dysfunction.

In men with and without LUTS, no differences in pelvic floor muscle activity were recorded during rest-test, but MVC-outcomes were significantly lower in men with LUTS for PR, UDF and PIC (Table 1). During the endurance task, only PIC-activity was lower in men with LUTS, whereas other muscle groups showed no significant differences.

In men with and without sexual dysfunction no significant differences were found in any of the measurements (Table 1, Figure 1).

INTERPRETATION OF RESULTS

This is the first observational study in the general population comparing pelvic floor muscle activity in men with and without symptoms. Using the MAPLe device, we were able to collect detailed information on pelvic floor muscle activity for the relevant muscle groups and urogenital diaphragm. We used purposive sampling to compare men with and without symptoms. As such, this study does not reflect a random sample of the population.

No differences were found in men with and without sexual dysfunction. This could be explained by the combination of different sexual dysfunctions (erectile dysfunction, ejaculation disorders, pain) in the group with symptoms, which may have a different origin. We are unaware of other studies on this topic to allow comparisons.

Pelvic floor muscle activity during maximum voluntary contractions was notably different between men with and without LUTS. We have sought for a maximum difference, by categorizing men based on the lower and upper quartile of the ICIQ-mLUTS questionnaire. Outcomes of the maximum voluntary contraction assessment illustrate lower muscle activity in puborectal, and pubo- and iliococcygeal muscles, and the urogenital diaphragm. Due to the cross-sectional nature of this study, no causal associations can be shown. The clinical relevance of the differences is difficult to interpret, as no normal values or minimal clinically relevant differences (MCID) for muscle activities are available. Still, data illustrate that differences in pelvic floor muscle activities may indeed play a role in male LUTS. Ageing is associated with a decrease in proportion of fast-twitch type 2 fibers. This may explain the lower muscle activity measured in men with severe LUTS during maximum voluntary contraction, as this group is generally older than men without LUTS.

CONCLUDING MESSAGE

This observational study showed no differences in pelvic floor muscle activity in men with and without sexual dysfunction. Men with severe LUTS showed significantly lower muscle activity during maximum voluntary contraction than men without LUTS. Longitudinal studies are needed to further clarify this possible role of pelvic floor muscle activity in male LUTS.

FIGURE 1

Table 1. Pelvic floor muscle activity (µV) in men with and without pelvic floor symptoms, assessed with the MAPLe device

	Lower urinary tract symptoms*			Sexual dysfunction #		
	No (n=61)	Severe (n=56)	p	No (n=78)	Yes (n=75)	p
			Rest			
EAS	6.6 (4.2 – 10.0)	7.2 (4.3 – 9.9)	.67	6.6 (4.5 – 9.3)	7.4 (4.5 – 10.5)	.35
PR	6.2 (4.1 – 8.6)	5.6 (4.0 – 8.6)	.62	5.9 (4.1 – 8.8)	6.2 (3.9 – 8.6)	.96
UDF	5.4 (4.1 – 6.7)	4.8 (3.5 – 7.4)	.79	5.1 (3.9 – 7.2)	5.2 (3.5 – 7.7)	.88
PIC	5.3 (3.4 – 6.8)	4.5 (3.5 – 6.8)	.61	5.2 (3.4 – 7.1)	4.9 (3.1 – 7.6)	.89
			Maximum voluntary contraction			
EAS	15.0 (11.6 – 20.5)	13.2 (10.1 – 17.1)	.20	14.7 (11.0 – 20.9)	13.8 (11.1 – 19.1)	.57
PR	**20.0 (15.3 – 28.8)**	**17.4 (13.4 – 21.6)**	**.02**	19.7 (15.7 – 27.8)	17.8 (13.2 – 24.6)	.06
UDF	**14.8 (11.9 – 20.1)**	**12.6 (10.0 – 16.3)**	**.02**	15.3 (11.7 – 19.4)	13.1 (10.5 – 18.2)	.11
PIC	**16.5 (11.6 – 23.7)**	**12.4 (9.2 – 17.6)**	**<.01**	15.3 (11.3 – 22.3)	13.4 (10.0 – 22.2)	.19
			Endurance			
EAS	10.8 (6.9 – 16.3)	10.2 (6.6 – 14.0)	.46	10.7 (6.8 – 16.3)	10.9 (8.5 – 14.5)	.71
PR	14.4 (9.6 – 22.4)	12.9 (7.3 – 16.8)	.11	12.9 (9.7 – 19.1)	13.9 (9.3 – 20.5)	.67
UDF	10.1 (8.0 – 17.1)	9.7 (6.8 – 12.4)	.10	10.1 (8.0 – 14.5)	10.8 (7.7 – 14.9)	.80
PIC	**10.8 (8.0 – 17.4)**	**9.0 (6.2 – 13.4)**	**.03**	10.5 (7.6 – 14.8)	11.8 (7.3 – 16.1)	.59

EAS = external anal sphincter; PR = puborectalis; UDF = urogenital diaphragm; PIC = pubo- and iliococcygeus;
* based on ICIQ-mLUTS quartiles; # assessed in sexually active men.
Data are displayed as median (interquartile range) values (µV). p-values reflect Mann-Whitney U Tests.

Table 1. Pelvic floor muscle activity (µV) in men with and without pelvic floor symptoms, assessed with the MAPLe device

FIGURE 2

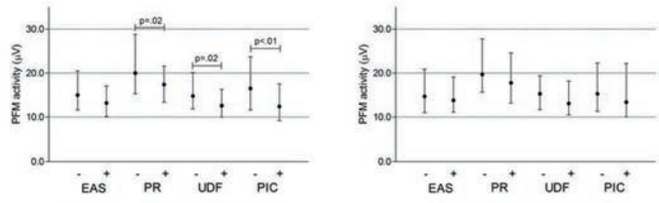

Figure 1. Pelvic floor muscle activity during maximum voluntary contraction test in men without (-) and with (+) lower urinary tract symptoms (A) and sexual dysfunction (B)

Figure 1. Pelvic floor muscle activity during maximum voluntary contraction test in men without (-) and with (+) lower urinary tract symptoms (A) and sexual dysfunction (B)

REFERENCES

1. Cohen et al. The Role of Pelvic Floor Muscles in Male Sexual Dysfunction and Pelvic Pain. Sex Med Rev 2016; 4(1): 53-62
2. Voorham-van der Zalm et al. Reliability and Differentiation of Pelvic Floor Muscle Electromyography Measurements in Healthy Volunteers Using a New Device: The Multiple Array Probe Leiden (MAPLe). Neurourol Urodyn 2013; 32(4): 341-348

Funding The Netherlands Organisation for Health Research and Development (ZonMw). Call Gender and Health. Project number 849200004 **Clinical Trial** No **Subjects** Human **Ethics Committee** Medical ethical committee (METc) University Medical Center Groningen (UMCG). NL67503.042.18 **Helsinki** Yes **Informed Consent** Yes

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CONCOMITANT PELVIC FLOOR SYMPTOMS IN MEN – A DUTCH POPULATION-BASED SURVEY

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HYPOTHESIS / AIMS OF STUDY

Pelvic floor symptoms (PFS) are prevalent and often bothersome in both females and males (1,2). PFS include micturition problems (e.g. urinary incontinence, urgency, voiding dysfunction), defaecation problems (e.g. fecal incontinence, constipation, obstructed defaecation), sexual problems (e.g. erectile dysfunction, ejaculation problems, dyspareunia), and genito-pelvic pain.

Although the pelvic floor is an anatomical and functional unit, and therefore different PFS may co-occur, the literature on prevalence of concomitant PFS is scarce. Furthermore, PFS is understudied in the male population. We aimed to study the prevalence of concomitant PFS in a general population of men.

STUDY DESIGN, MATERIALS AND METHODS

A prospective observational population-based cohort study started in May 2019. Eligible participants were invited through general practices in a Dutch municipality. This included all men aged 16 years and older, except those with terminal disease, dementia, cognitive impairment or current psychological condition precluding informed consent, and those not suitable or too ill to participate based on the judgement of the general practitioner. Participants signed informed consent before completion of the study questionnaire. The questionnaire included the International Consultation on Incontinence Questionnaire male Lower Urinary Tract Symptoms (ICIQ-mLUTS); the Groningen Defaecation and Fecal Continence (DeFeC) questionnaire, which includes all items for the Wexner score (incontinence and constipation); item M1 of the 'Sexual Health in the Netherlands' questionnaire; the ICIQ-Male Sexual Matters Associated with LUTS Module (ICIQ-MLUTSsex); and items on genito-pelvic pain in the pelvic region (location, duration and severity).

For most of these questionnaires, clear cut-off values are lacking. Therefore, we defined the presence of LUTS based on the upper quartile of ICIQ-mLUTS scores (scores ≥9), and defaecation problems on the upper quartile of the combined Wexner scores (scores ≥6). Having erectile and/or ejaculation problems and/or pain during intercourse or ejaculation was defined as having sexual dysfunction. Presence of pain in the pelvic region was defined as having pelvic pain.

As a result, no prevalence rates of individual PFS could be calculated for the study population. For men with PFS, the prevalence of concomitant symptoms was calculated. Data were presented as a Sankey diagram for each main symptom. So, each diagram starts with the subgroup of men with the specific PFS. Data were ranked according to the largest overlap between symptoms.

RESULTS

In total 11,723 citizens received a postal invitation including information about the study. 694 males responded by returning informed consent. In total 566 males (mean age 62.1±13.7 years) completed all PFS parts of the questionnaire. Of these, 212 (37.5%) reported no PFS; the other men had one or more PFS. Median ICIQ-mLUTS score was 6.0 (Interquartile range 3.0-10.0); median Wexner score was 3.0 (IQR 2.0-6.0).

202 of the 436 sexually active men reported sexual dysfunction. The Sankey diagram illustrated that 37.1% of men with sexual dysfunction reported no concomitant PFS, and 33.1% reported defaecation problems with or without LUTS, and 41.1% reported concomitant LUTS with or without pain or defaecation problems (Figure 1A).

The most frequent concomitant PFS in men with LUTS was defaecation problems (Figure 1B): approximately half of all men with LUTS also reported defaecation problems. Likewise, for men who reported defaecation problems, the main concomitant PFS was LUTS (52.2%, Figure 1C).

Pelvic pain was reported by 88 men and showed considerable overlap with both LUTS and sexual dysfunction (Figure 1D), only 15.9% of men with pain reported no other PFS.

INTERPRETATION OF RESULTS

This is the first study in the general population aimed at finding concomitant PFS in men, who not necessarily have requested care for their symptoms. The low response rate limits generalization of the outcomes. Since clear cut-off values are lacking, we were unable to assess the prevalence of separate PFS. This was the case especially for LUTS and defaecation problems. As the main goal of this study was to

find clusters of symptoms, we feel that this approach is feasible, and the study outcome reflects clinically relevant issues.

We have found a large overlap between the presence of LUTS and defaecation problems. In addition, the presence of sexual dysfunction coincided with the presence of LUTS in 41% and defaecation problems in 33% of cases. These estimates were higher than expected and deserve special attention in clinical practice, i.e. when men present with either LUTS, defaecation problems or sexual dysfunction, health care providers should ask about the other two pelvic floor symptoms.

We found that the vast majority of men with pelvic pain also has another PFS, especially LUTS and sexual dysfunction.

The co-occurrence of different PFS could reflect a common cause, but the cross-sectional nature of this survey limits to draw conclusions on the causal associations. Longitudinal studies are needed to clarify this further.

CONCLUDING MESSAGE

This study in the general population showed a considerable overlap between PFS in adult men, especially between LUTS and defaecation symptoms, whether or not in combination with sexual dysfunction.

FIGURE 1

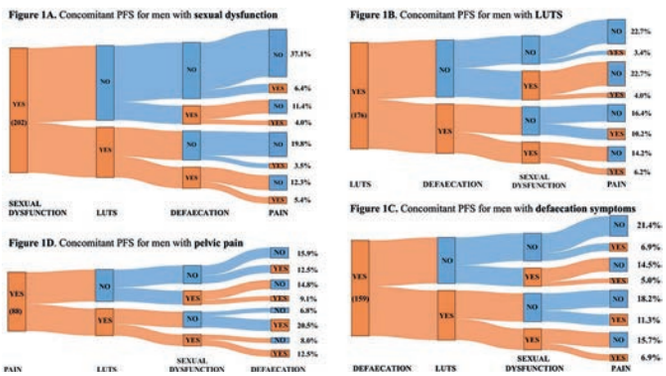

Figure 1. Sankey diagrams showing concomitant pelvic floor symptoms: sexual dysfunction (A), lower urinary tract symptoms (LUTS) (B), defaecation problems (C) and pelvic pain (D).

REFERENCES

1. Davis K, and Kumar D. Pelvic floor dysfunction: A conceptual framework for collaborative patient-centred care. J Adv Nurs. 2003;43:555-68.
2. Pierce H, et al. A systematic review of prevalence and impact of symptoms of pelvic floor dysfunction in identified workforce groups. J Adv Nurs. 2016;72:1718-34.

Funding The Netherlands Organisation for Health Research and Development (ZonMw). Call Gender and Health. Project number 849200004 **Clinical Trial** No **Subjects** Human **Ethics Committee** Medical ethical committee (METc) University Medical Center Groningen (UMCG). NL67503.042.18 **Helsinki** Yes **Informed Consent** Yes

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BACTERIAL MICROBIOME OF MEN WITH LOWER URINARY TRACT SYMPTOMS – A PILOT STUDY

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HYPOTHESIS / AIMS OF STUDY

The urinary microbiome has only recently been described, and its potential relations with health and disease are still under investigation. It is reasonable to assume that functional abnormalities of the lower urinary tract, such as detrusor overactivity or bladder outlet obstruction, could lead to significant changes in the urinary microbiome. Our aim was to conduct a pilot study of a selected group of men with lower urinary tract symptoms and correlate their clinical and urodynamic findings with the ability to detect and characterize the bladder microbiome.

STUDY DESIGN, MATERIALS AND METHODS

We prospectively selected male patients over 50 years of age with lower urinary tract symptoms who would be submitted to urodynamic study due to investigation of LUTS (Lower Urinary Tract Symptoms). We collected prostatic specific antigen (PSA) value, post void residual volume (PVR) and prostate volume measured by ultrasound. They also self-completed the IPSS (International Prostate Symptom score) and Overactive Bladder V-8 questionnaires (OAB V8) as a way of quantify their symptoms. They were submitted to a conventional urodynamic study as recommended by the ICS (International Continence society) and then classified as having or not detrusor overactivity and bladder outlet obstruction. Before the urodynamic study, a urine sample of 50 ml was collected by aseptic bladder catheterization and subjected to DNA extraction and quantification. To perform the sequencing, we amplified the V4 hypervariable region of the 16s rRNA gene through Polymerase Chain Reaction (PCR) and subsequent sequencing in the Illumina® MiSeq system. The sequences were clustered into operational taxonomic units (OTUs) based on 97% similarity and were identified against the SILVA v132 reference database. Then, we evaluated for correlation between OTUs richness and number of reads with patients' symptom scores, age, PVR, prostate volume, and urodynamic diagnosis.

Exclusion criteria for this study are the presence of any other abnormality in the urodynamic study than bladder outlet obstruction or detrusor overactivity, presence of urethral stenosis, diabetes, obesity (IMC > 30), smoking, alcoholism,

previous pelvic surgery, any known neurological disease, use of diuretics, use of any medications that may have an impact on the lower urinary tract function, urinary tract infections in the last 12 months, use of antibiotics for any reason in the last 6 months, acute or chronic prostatitis and chronic pelvic pain.

Based on the sample size of published male urinary bacterial microbiome studies (n = 10 per group in Nelson et al, 2010) [1], a total of 12 samples was felt to be practical for fast recruitment considering an initial study.

RESULTS

We collected urine samples from 49 patients. Due to amount and/or quality of DNA, 16S rRNA amplification was possible to be done in 13 samples (26.5%), but only 12 (24.5%) yielded results after sequencing. These are described in Table 1 and Figure 1. We did not find any correlation of successful sequencing with the parameters of interest like age (63.17±10.63 for positive sequencing vs 64.87±8.50 for negative sequencing, p=0.574), PVR (49 (5-350) for positive sequencing vs 45 (6-925) for negative sequencing, p=0.723), IPSS (18.58±6.68 for positive sequencing vs 17.19±7.26 for negative sequencing, p=0.560), OAB V-8 (17.67±7.43 for positive sequencing vs 15.32±7.54 for negative sequencing, p=0,351) , prostate volume (42.5±21.5 for positive sequencing vs 38.5 ±16.9 for negative sequencing p=0.868), PSA (2.02±1.97 for positive sequencing vs 2.11±1.49 for negative sequencing, p=0.508), presence of detrusor overactivity (7/12 for positive sequencing vs 14/37 for negative sequencing. P=0.362) or bladder outlet obstruction (8/12 for positive sequencing vs 23/37 for negative sequencing. P=0.950). All of our patients had an IPSS score of 9 or more, denoting at least moderate LUTS.

About the caractherization of the bladder urinary micobiome, the predominant phyla were Proteobacteria (10/12 samples), Firmicutes (9/12 samples) and Actinobacteria (8/12 samples). The prevalent families were Enterobacteriaceae (10/12 samples), Burkholderiaceae (7/12 samples), Sphingomonadaceae (7/12 samples). The Staphylococcus genus was present in 58.3% samples. We found 7/12 samples (58,3%) with a dominant genus (>50% of the reads belonging to the same genus), thus these samples were considered as having a low diversity[2]. The Shannon index is H'=0,918 (0,003 - 2,436) confirming the low diversity for this group of samples. Again, we did not find any correlation of bacterial microbiome composition or diversity with detrusor overactivity, bladder outlet obstruction or any other evaluated parameter (p>0.05).

INTERPRETATION OF RESULTS

We had a low rate of bacterial identification in urine samples (24.5%), although it was comparable to that of a previous study[3] with a similar samples collection method (aseptic bladder catheterization). Bladder asseptic catheterization is described as the best method to evaluate the bladder urinary microbiome[3].

The bladder is a low biomass environment and is difficult to identify the microbiome, eventhough we believe that we have a microbiome in all patients. Strategies to improve this detection rate should be apply in the main study.

This is the first study that correlates urodynamic findings and bladder microbiome. Although we have no correlation in this pilot study, this issue should be better evaluated with a more robust study that we are carry on nowadays.

The main finding is the low diversity in this group of patients with LUTS. Low diversity, with a dominant genus, could increase the chance to develop a symptomatic urinary tract infection or chronic inflammation as described in patients with moderate and severe LUTS. Notably, the range of the Shannon index (measure of the microbial diversity and expressed as H') is high, with two samples with H'>2, that is associated with good diversity. It could be a reason why some patients with LUTS have recurrent urinary tract infections and others don´t have it. But we need a more robust study with different design to confirm this association.

As weak points, we have a small sample (this is a pilot study) and we did not have patients with mild symptoms.

CONCLUDING MESSAGE

We were able to detect and characterize the bladder urinary microbiome in only 24.5% of the patients through 16S rRNA sequencing in this inital study. The detection rate has no association with age, PSA, symptoms severity, prostate volume, detrusor overactivity or bladder outlet obstruction. We found that the bladder microbiome of most patients with moderate and severe LUTS is characterized by low bacterial diversity and this finding could be linked to some clinical caractheristics of this group of patients, like recurrent urinary tract infections or chronic inflammation (prostatitis, benign prostatic hyperplasia). Further robust studies with a larger number of patients and additional urodynamic parameters are needed to obtain definitive evidence of this pattern. Additionally, this pilot study reveals the need to seek strategies to increase the detection rates of the bladder microbiome in order to be more representative of the entire population, and should ideally include patients with mild symptoms.

FIGURE 1

Table 1. Age, symptoms, patient characteristics, reads, and OTUs per sample in men with LUTS and successful 16S rRNA sequencing

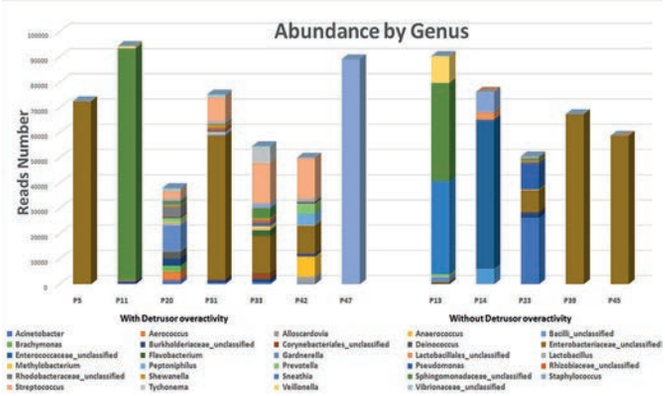
Patient number	Age	IPSS	OAB v8	Detrusor overactivity	Bladder outlet obstruction	PVR (ml)	PSA (ng/dl)	Prostate volume (cm^3)	Reads	OTUs
47	63	26	29	Present	Present	95	2.10	32	89116	17
42	58	31	8	Present	Present	65	0.77	40	56492	205
33	50	18	22	Present	Absent	32	0.28	30	63394	529
31	60	13	12	Present	Present	10	7.20	67	77789	208
20	82	13	23	Present	Present	60	2.70	45	46792	483
11	85	20	24	Present	Present	125	4.20	50	94949	215
5	63	26	28	Present	Present	38	2.30	35	72487	28
45	59	21	13	Absent	Present	350	1.20	60	58803	24
39	67	11	11	Absent	Absent	72	1.28	90	67336	41
23	51	9	12	Absent	Absent	14	0.60	15	51984	234
14	59	19	12	Absent	Present	5	1.00	26	76201	37
13	61	16	12	Absent	Absent	10	0.67	20	91712	185

There was no correlation between age, presence of detrusor overactivity or bladder outlet obstruction, PSA, PVR and symptoms with reads and OTUs numbers (p<0.05).

Legend:
OTUs - Operational taxonomic units. A group of closely related organisms (In this study bacteria with at least 97% of DNA similarity)
Reads – Genetic sequence of DNA that can represent the presence of a bacteria. The group of reads with 97% of DNA similarity represent an OTU.

Table 1

FIGURE 2



REFERENCES

1. Nelson DE, Van Der Pol B, Dong Q, Revanna KV, Fan B, et al. (2010) Characteristic Male Urine Microbiomes Associate with Asymptomatic Sexually Transmitted Infection. PLoS ONE 5(11): e14116. doi:10.1371/journal.pone.0014116.
2. Thomas-White KJ, Hilt EE, Fok C, Pearce MM, Mueller ER, Kliethermes S, et al. Incontinence medication response relates to the female urinary microbiota. Int Urogynecol J. 2016 May 1;27(5):723–33.
3. Bajic P, Van Kuiken ME, Burge BK, Kirshenbaum EJ, Joyce CJ, Wolfe AJ, et al. Male Bladder Microbiome Relates to Lower Urinary Tract Symptoms. Eur Urol Focus. 2020 Mar 15;6(2):376-382. doi: 10.1016/j.euf.2018.08.001

Funding Own resources **Clinical Trial** No **Subjects** Human **Ethics Committee** Santa Casa de Porto Alegre **Ethics Committee Helsinki** Yes **Informed Consent** Yes

SESSION 19 (PODIUM) - BEST BASIC SCIENCE
Abstracts 253-258
09:30 - 11:00, Brasilia 4
Chairs: Prof Christopher Henry Fry (United Kingdom), Dr Toby C. Chai (United States)

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BEST NON-CLINICAL ABSTRACT

DIMINUTION OF THE SPINAL CORD COLLAGEN SCAR WITH CONCOMITANT IMPROVEMENT IN GAIT, DETRUSOR-SPHINCTER-DYSSYNERGIA AND BLADDER OVERACTIVITY IN SPINAL CORD CONTUSED MICE USING LM22B-10

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HYPOTHESIS / AIMS OF STUDY

Spinal cord injury (SCI), besides resulting in paralysis, can induce lower urinary tract (LUT) dysfunctions that are also highly debilitating and increase morbidity in afflicted individuals. Neurogenic LUT dysfunction includes bladder overactivity, detrusor-sphincter dyssynergia (DSD), urinary retention, frequent urinary tract infections and potential damage to the upper urinary tract. Alterations in neurotrophin signalling has been shown to play a major role in the development of LUT dysfunction. Previous studies have indicated a time dependent downregulation in brain derived neurotrophic factor (BDNF) dependent signalling that results in further deterioration of LUT function [1]. Compensating for the decrease in BDNF may represent a treatment for preventing degeneration of LUT function. Thus, our aim was to elucidate whether LM22B-10, a selective small molecule agonist of TrkB/C receptors [2], affects the development of bladder overactivity and DSD in a spinal cord contused mouse model.

STUDY DESIGN, MATERIALS AND METHODS

Spinal cord contusion (SCC) surgery and functional assessments: Adult female C57Bl/6 mice (8-12 weeks old) were anesthetized using 2% isoflurane, a laminectomy performed, and the spinal cord exposed between T9-T10 vertebrae. The exposed cord was subjected to severe contusion injury (75 kDy force; Infinite Horizon Impactor, Precision Instrument). Sham controls underwent laminectomy surgeries without contusion (N=4). The area partially devoid of column segments was packed with haemostatic sponge and the muscle and skin sutured. After surgery, the animals had their bladders expressed twice daily by gentle abdominal compression and were given daily prophylactic antibiotics and analgesics for up to one week. Mice were evaluated for hindlimb locomotion recovery using the Basso mouse scale [3] at one, three, seven, 14, 28 and 42-days following injury. LM22B-10 was administered by subcutaneous implanted osmotic pumps that delivered 5 mg/kg/day of drug (N=8) or vehicle (N=9) over a four-week period (Alzet model 1004, vehicle consisted of 50% DMSO with sterile saline). Osmotic pumps were implanted at the time of SCC surgeries without priming which delays drug release by 24-48 hours. At 42 days post SCC, mice were subjected to decerebrate cystometrogram and external urethral sphincter electromyogram (CMG-EUS-EMG) recordings to examine bladder and EUS activities, respectively.

Histology: Following cystometric measurements, the urinary bladder was dissected out and the mouse transcardially perfused with 1 x tris-buffered saline (1xTBS) followed by 4% paraformaldehyde for perfusion fixation of the spinal cord and bladder. Bladders were weighed then further fixed flat in a dissection dish with 4% PFA. Spinal cord and bladder tissues were stored overnight in 30% sucrose solution then embedded in optimal cutting temperature compound for cryosectioning. Spinal cord and bladder tissue sections were processed for immunofluorescence to image glial fibrillary acidic protein (GFAP) and TrkB receptors and/or to Trichome staining for visualization of tissue collagen content. Slides were imaged using brightfield montage microscopy (Olympus Fluoview3000) and analyzed using HCImage software (Hamamatsu Photonics). Quantitative data were expressed as mean ± SEM. Unpaired Student's t-test determined differences between contused vs. sham controls and parameters with and without treatment. One-way ANOVA multiple comparison was performed to determine between group differences followed by Tukey's multiple comparisons test.

RESULTS

Histological evaluation of spinal cord injury sites showed reduced scarring and decreased collagen deposition (Fig. 1A, white circles indicate necrotic core) and by void area bound by GFAP and TrkB expressing cells in the spinal cords (Fig. 1B) of LM22B-10 treated mice compared to vehicle controls. Furthermore, LM22B-10 treated mice showed improvement in hindlimb locomotion recovery at 28- and 42-days post injury compared to vehicle treated group (Fig. 1C). Bladders of LM22B-10 treated SCC mice also showed decreased collagen deposition and bladder hypertrophy (Fig. 1E and 1F) compared to controls. Continuous filling CMG recordings in chronic SCC mice demonstrated bladder overactivity and non-voiding contractions that were not present in sham controls (Fig. 2B vs. 2A). EUS-EMG recordings from sham mice show a guarding reflex as bladder pressure increased, and decreased EUS tonic activity accompanied by bursting as the bladder emptied; characteristic of normal rodent voiding (Fig. 2A inset, tonic EUS activity denoted by red arrows). Conversely, vehicle treated SCC mice showed high

baseline pressures, consistent non-voiding contractions with increased EUS tonic activity during bladder contraction which is the hallmark of DSD. (Fig 2B inset). SCC mice that received LM22B-10 treatment exhibited reduced numbers of non-voiding contractions that correlated decreased tonic activity (Fig. 2C) when compared to vehicle controls.

INTERPRETATION OF RESULTS

These data demonstrate that activation of TrkB/C signalling by LM22B-10 reduced bladder overactivity and DSD in the contused mouse model. Our data showed that contusion injury resulted in the formation of large scar regions and secondary cysts within the spinal cord that can prevent neural regeneration. This scar region was smaller in LM22B-10 treated mice which suggests that the drug may be eliciting its positive effects by reducing deposition of inhibitory extracellular proteins around the glial scar and/or promoting neural growth.

CONCLUDING MESSAGE

LM22B-10 treatment improved hindlimb function and reduced the development of bladder overactivity and DSD in chronic SCC mice that correlated with decreased spinal cord scar volume and secondary injuries. Targeting neurotrophin signalling pathways could hold significant potential as a treatment for neurogenic LUT dysfunction.

FIGURE 1

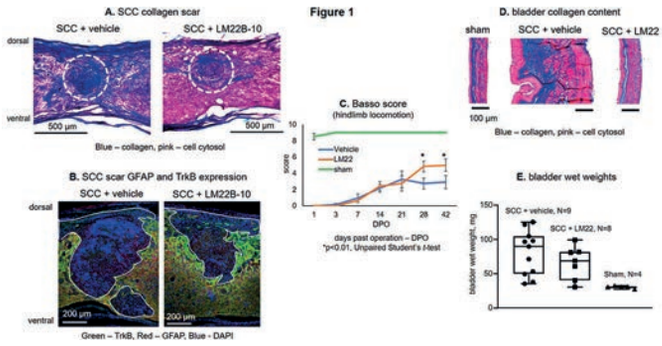
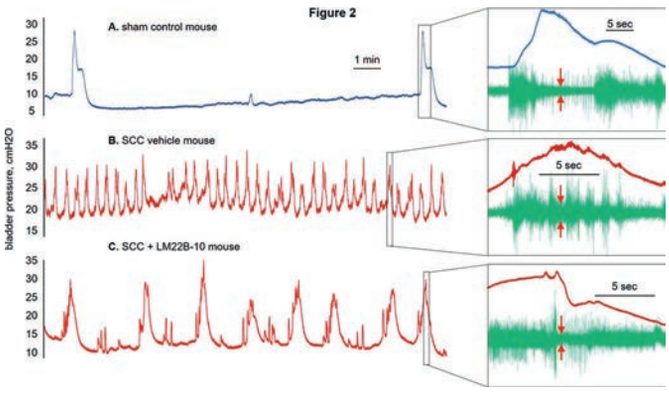


FIGURE 2



REFERENCES

1. Frias B et al., J Neurosci.;35(5):2146-60, 2015
2. Matyas J et al., J Neursci., 37(14):3956-3971, 2017
3. Basso et al., J Neurotrauma, 23(5):635-59, 2006

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BEST IN CATEGORY PRIZE "CONTINENCE CARE PRODUCTS / DEVICES / TECHNOLOGIES"

MEASUREMENT OF FELINE BLADDER PRESSURE AND VOLUME USING CATHETER-FREE WIRELESS INTRAVESICAL SENSOR

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract neurophysiology research relies on animal models (e.g. feline) with implanted nerve recording and stimulating electrodes. These systems enable conscious recording of peripheral nerve data, e.g. from the dorsal root ganglia [1], but there are few options for simultaneous measurements of bladder function. In research animal models, catheterization for cystometry requires anesthesia which affects neuro-urological pathways, or animal restraint, limiting measurement time and social behaviors surrounding natural bladder filling and micturition. To overcome this limitation, we developed a catheter-free, wireless, intravesical sensor that is implanted into the bladder lumen of felines and is designed to transmit untethered bladder pressure and volume data in the absence of a wire crossing the detrusor tethering the bladder [2]. This research tool is expected to enable studies in physiologically-relevant settings, and would allow long-term monitoring of lower urinary tract changes in reaction to neuromodulation or pharmacologic interventions. This study validated sensor function and physiologic outcomes over 4-week implantations, including untethered catheter-free wireless recordings of bladder pressure during natural bladder filling and voiding in felines.

STUDY DESIGN, MATERIALS AND METHODS

A wireless sensor incorporating low-power pressure-sensing electronics, platinum electrodes for measuring urine concentration and conductance for volume estimation, and antennas for wireless battery recharge and data transmission was developed [3]. The sensor transmitted data 10 times per second to an external antenna up to 20 cm away. The external antenna was connected to a pager-like wearable radio for ambulatory data recording. Conscious wireless recharge

used a 10-cm inductive coil attached to a rubberized pad which could be placed above or below the animal during rest. Benchtop and in vitro experiments validated sensor performance, wireless transmission and recharge range, and anticipated lifespan. Sensors were encapsulated in layers of medical epoxy and medical silicone rubber, and sterilized by ethylene oxide gas prior to implantation.

Implantations were performed on 8 male felines: 3 were sham implants (no device), 1 implant used an inactive device, and 3 used active devices measuring 18 mm x 12 mm x 5.6 mm. Under isoflurane anesthesia, the bladder was exposed following a midline incision. A 1-cm incision through the bladder dome was made and a sensor device was inserted into the lumen. Following implant, the detrusor was sutured to allow water-tightness and the abdominal wall and skin were closed in layers.

Anesthetized cystometry for all felines (device and sham) was performed immediately before and after implant surgery, as well as 2 weeks and 4 weeks post-implant to assess bladder response to the surgery and device. Cystometry used a 3-Fr angioaccess catheter and an external syringe pump to infuse room-temperature saline at a rate of 2 mL/min. An external data acquisition system and pressure transducer were used to measure reference bladder pressures while filling. Pressure, volume, and saline concentration data were transmitted by the implanted sensor throughout cystometry. Animals were transitioned to propofol anesthesia 15 minutes before the start of cystometry; felines produced reflex bladder contractions under this anesthetic. Urine samples were also collected at these times and sent for laboratory bacteremia and heavy metal assays.

Animals were monitored during acute recovery for 5 days. Conscious data collection was performed 3 days per week in the 2 animals with active implanted devices, along with video recording and photography of movement and voiding behaviors. Data collection used a small radio receiver, which was attached to a harness worn by the animal for up to 2 hours. The implanted bladder sensor transmitted data to the radio receiver, which was continuously logged to an internal memory card. Devices were explanted after 4 weeks.

RESULTS

All animals showed rapid recovery from surgery, returning to normal movement within 24 hours. All animals showed a similar decrease in bladder capacity (up to 50%) following surgery, which resulted in increased bladder spasticity for 2 weeks after implantation surgery. Evidence for spasticity included frequent voiding attempts inside the litter box with low voided volumes, or spontaneous squatting behavior during otherwise normal ambulation. After 2 weeks all animals resumed normal voiding frequency.

All devices remained patent without obstructing the bladder outlet for 4 weeks. One device stopped transmitting 12 days after implant; the others functioned through 4 weeks. In 2 animals that received large detrusor incisions (1 sham surgery, 1 device), visual inspection during terminal dissection showed tissue adhesion which constricted the bladder. Surgical technique was altered after this to use a smaller incision and no further tissue adhesions were observed.

Wireless pressure data was linearly correlated with spontaneous reflex contractions during anesthetized urodynamics ($R2 = 0.96$). Bench testing of the volume sensor showed accuracy within 10 mL and 98% accuracy measuring conductivity references, but conscious in vivo data showed more variability. Conscious data recording was performed on 11 occasions, producing over 200 minutes of catheter-free pressure and volume recordings.

INTERPRETATION OF RESULTS

Our initial results suggest that small wireless sensors can be surgically implanted in the feline detrusor for ambulatory monitoring of bladder function. Bladder function was temporarily affected by the surgical implantation but probably not any further by device implantation. Animals tolerated the wearable radio harness well, and moved and used litter boxes freely while wearing the backpack recording system. Animals also spontaneously rested on the wireless recharging pad, enabling battery recharge for long periods. This suggests that long-term studies would be feasible with animals sleeping on the recharger system as needed.

Recorded vesical pressures during video-recorded voiding showed the characteristic voiding shape during animal squatting behaviors. Pressure data were also validated against anesthetized catheter measures of vesical pressure during anesthetized cystometry. Even without an abdominal pressure sensor, vesical pressure data were accurate enough to detect frequency and magnitude of voiding and non-voiding bladder contractions.

The volume sensor in vivo accuracy was significantly impaired compared to bench calibration. We believe the inaccuracy was partly due to in vivo effects of current conduction through tissue; volume data were thus only accurate enough to roughly categorize bladder fullness (e.g. empty vs. full). Volume sensor performance will be improved through sensor hardware, software, and form factor changes.

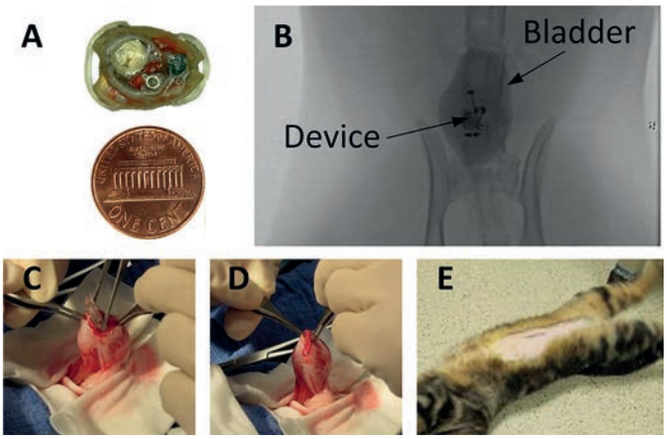
While anesthetized catheterization affects bladder function, so does this device implantation due to the need for surgical implantation. The device volume of 1.2 cm3 displaced a negligible volume of urine in the feline bladder with typical capacity of roughly 20-50 mL. Therefore, we conclude that reduced bladder capacity after implantation is due to a healing response and bladder capacity seems to recover after 2 weeks. Healing response is likely dependent on surgical

technique, as we found that tissue adhesion which halved bladder capacity occurred in those animals in which large detrusor incisions were made.

CONCLUDING MESSAGE

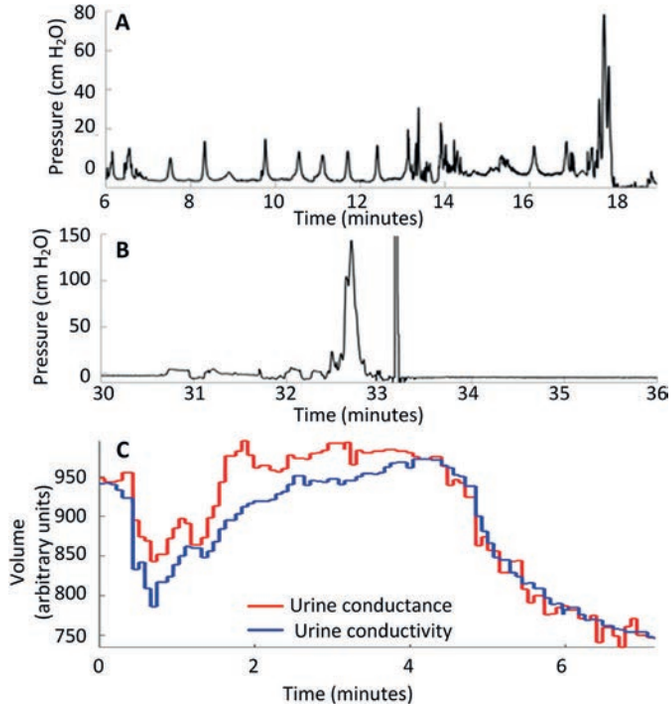
Small wireless, intravesical sensors permitted conscious catheter-free untethered recordings of bladder pressure in felines over 30 days. While in vivo volume data were not reliable, changes to the sensor design is expected to enable volume measurement in future devices. As a research tool, these sensors can be combined with existing neurorecording systems to improve neurophysiological research of the lower urinary tract. Clinical translation of this technology could enable urethrally-inserted sensors for wireless ambulatory urodynamics in humans without catheters.

FIGURE 1



The wireless pressure and volume sensor (A) was implanted surgically in the feline bladder (B). After implanting the device in the detrusor (C,D), animals returned to normal behavior within 24 hours (E).

FIGURE 2



Wireless data from freely-moving felines showed voiding and non-voiding contractions (A,B). Volume data were inaccurate when animals were conscious, but showed correlation to a 10 mL infusion/extraction during anesthetized procedures (C).

REFERENCES

1. Ouyang Z, Sperry ZJ, Barrera ND, Bruns TM. Real-Time Bladder Pressure Estimation for Closed-Loop Control in a Detrusor Overactivity Model. IEEE Trans Neural Syst Rehabil Eng. 2019;27(6):1209-1216
2. McAdams I, Kenyon H, Bourbeau D, Damaser MS, Zorman C, Majerus SJA. Low-cost, Implantable Wireless Sensor Platform for Neuromodulation Research. Proc. IEEE Intl. Bio Circ. Sys. Conf., BioCAS, 2018
3. McAdams IS, Majerus SJA, Hanzlicek B, Zorman C, Bourbeau D, Damaser MS. A Conductance-Based Sensor to Estimate Bladder Volume in Felines. Proc.Ann. Intl. Conf. IEEE Eng. Med. Biol. Soc., EMBS, 2018

Funding This work was funded by the NIH Stimulating Peripheral Activity to Relieve Conditions (SPARC) program, NIH grant number OT2OD023873 **Clinical Trial** No **Subjects** Animal **Species** Cat **Ethics Committee** Cleveland Clinic IACUC

255 www.ics.org/2020/abstract/255

REAL-TIME CONDITIONAL SACRAL NEUROMODULATION USING WIRELESS BLADDER PRESSURE SENSOR

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HYPOTHESIS / AIMS OF STUDY

Sacral neuromodulation is clinically used for refractory urinary incontinence and generally uses continuous stimulation. Recent studies have indicated conditional SNM, which applies stimulation intermittently, can produce equivalent functional outcome to continuous SNM [1]. Conditional SNM could reduce energy use and is a potential research tool for optimizing SNM use. However, conditional SNM requires feedback on bladder state (pressure or volume) to enable stimulation decisions.

This proof-of-concept study was to demonstrate feasibility of automatically triggering SNM using real-time wireless bladder pressure data in urologically normal sheep. Sheep were implanted with Summit™ RC+S, an implantable research stimulator allowing for sub-second control of stimulation through wireless communication. A minimally invasive bladder pressure (MIBP) sensor and a computer algorithm detected the onset of bladder contractions and automatically controlled the Summit device (Figure 1). Continuous and four conditional SNM paradigms were tested over 5 days in four conscious sheep.

STUDY DESIGN, MATERIALS AND METHODS

The MIBP device used low-power flexible electronics housed in a medical silicone housing which curled into a pigtail shape after insertion to remain in the bladder. The MIBP transmitted vesical pressure data at 10 Hz wirelessly. MIBP data were processed by a Context-Aware Thresholding (CAT) algorithm in a custom Labview (National Instruments) program to detect bladder contractions in real time. The Labview program communicated with the Summit system software to remotely control an implanted neurostimulator (INS) (Figure 1).

SNM studies were performed on four Polypay sheep (age: 15.9 ± 1.1 months; weight: 57.3 ± 2.4 kg). Surgical and urological monitoring methods were detailed previously [2]. Briefly, animals were anesthetized for bilateral implantation of two Model 3889 InterStim® quadripolar leads in S3 (n=2) or S4 (n=2) based on intraoperative perianal response to stimulation. Leads were connected to the INS (Summit RC+S, B35300R). All animals were recovered for at least 30 days prior to the study.

Sheep stood in a sling frame during repeat, single fill cystometry to assess bladder capacity at baseline (no stimulation) or in response to SNM protocols. Bladder pressure was recorded (Mikro-CathTM, Millar, Houston, TX) in 3 sheep through a 12 Fr filling catheter (Lubri-Sil®, Bard Medical, Covington, GA) and 1 sheep with an 8 Fr catheter due to urethral sensitivity. Warmed saline was infused at 30 ml per minute (Flo-Gard R pump, Baxter, Deerfield, IL) until voiding or a pressure of 30-mmHg was reached. Capacity was defined as the saline amount infused.

Sheep remained in the sling frame during insertion of the MIBP without analgesia or antibiotics. MIBPs were inserted through the urethra similarly to catheterization. After insertion, a wireless antenna was placed near the animal's hip to receive MIBP pressure data. The MIBP was removed using conscious cystoscopy.

Animals received three baseline cystometric fills followed by a random progression of conditional or continuous SNM trials. Baseline capacity per experiment day was calculated as the average of 3-6 fills without stimulation. Testing consisted of two conditional physiologic paradigms, two pressure-triggered paradigms, and continuous SNM (Figure 2). For continuous SNM, stimulation was activated prior to filling start. For physiologically-timed paradigms, SNM was either delivered during the first half of the fill cycle or the second half of the fill cycle. Fill cycle duration was determined per sheep, per day, by averaging initial baseline fills. Physiologic conditional SNM was triggered manually based on infused bladder volume.

The two pressure-triggered stimulation paradigms were oscillating and latched-stimulation. In the oscillating paradigm, the pressure signal was used to trigger stimulation on and off based on the CAT algorithm. The latched paradigm used CAT to detect the start of bladder contractions after an initial 30-s lockout period, then started and maintained SNM until the void. The lockout period was used to prevent CAT false positives due to pressurization artifacts when bladder capacity was below 15 mL.

RESULTS

The MIBP was easy to insert and extract and did not cause any noticeable discomfort or urinary tract complications. Throughout cystometry, the MIBP showed repeatable artifacts on initial pressurization (below 15 mL) and after voiding. We conclude that the MIBP was measuring contact force from the detrusor in addition to bladder pressure which limited the ultimate pressure accuracy compared to catheter values. MIBP data was time-correlated with catheter-measured contractions.

132 cystometric trials were performed with the MIBP in place (55 baseline, 19 continuous SNM, 20 oscillating SNM, 17 latched SNM, 4 first-half SNM, 4 second-half SNM). 13 trials were discarded from analysis due to early voids below 50% baseline capacity, likely caused by catheter-related

spasticity. Pooled analysis showed capacity changes relative to baseline of: 157% (continuous SNM), 147% (oscillating SNM), 112% (latched SNM), 84% (first-half SNM), and 268% (second-half SNM).

In general, the CAT algorithm was sufficiently accurate to detect detrusor contractions, triggering SNM 2.8 times (median, excluding discarded trials) per bladder fill cycle. SNM was occasionally falsely triggered due to MIBP data reception loss or pressurization artifacts. Including all stimulation paradigms, a total of 1,224 commands were sent to the Summit system. A median latency of 72 ms occurred between data received into the Labview system and the implanted RC+S pulse generator changing SNM state.

INTERPRETATION OF RESULTS

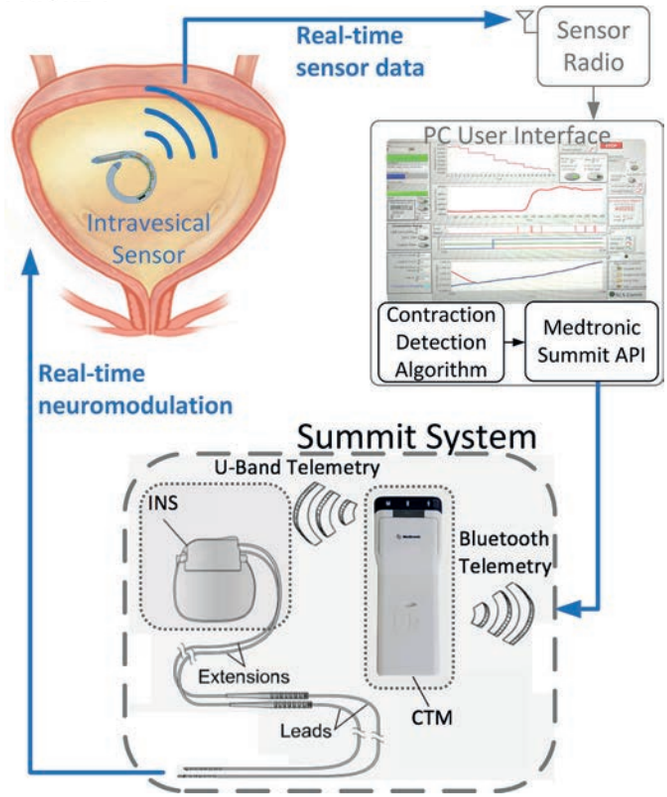
To our knowledge, this study is the first to demonstrate a wireless system using real-time bladder pressure data to automatically trigger SNM. While our approach was limited to conscious animals with short-range communication to PC software, an integrated system could conceivably be developed in future work. The median time to send bladder data, process it by CAT, and communicate to the Summit system was within the range of human reaction time, indicating that rapid decisions and activation of SNM is feasible. Occasionally SNM was errantly triggered due to data interruptions from the MIBP radio link. Our results indicate basic feasibility of automatic, conditional SNM; reliable reception of the feedback signal was a critical link of this approach.

This study's limitations prevent statistical conclusions on the efficacy or mechanisms of conditional SNM paradigms. It was limited to five days of observation, tested on only four animals, and stimulation paradigms were tested 1-6 times per animal. This study also used a urologically normal animal model which has been shown to increase bladder capacity during continuous SNM [2]. Conditional, physiologically-timed SNM has also been demonstrated to affect bladder capacity in this continent model [3]. However, conditional neuromodulation could perform differently in the case of an incontinent model, and is an area of future research

CONCLUDING MESSAGE

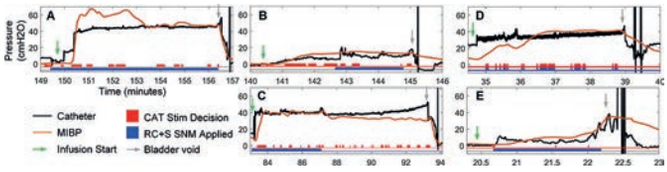
This study showed that both algorithm-controlled and physiologically-timed conditional SNM paradigms were technically feasible with this system, as conditional SNM was reliably triggered in the sheep. Outcomes from oscillating and latched paradigms suggested that some animals responded more strongly than others. This could have been due to a number of variable but is also representative of clinical use as the effectiveness of SNM varies between individuals. Future research with greater statistical power could quantify the efficacy of conditional SNM for improving bladder capacity.

FIGURE 1



Closed-loop bladder stimulation used a wireless intravesical sensor and a bladder contraction detection algorithm to control an implanted INS configured for sacral neuromodulation.

FIGURE 2



Stimulation paradigms tested included (A) continuous SNM, and (B) second-half SNM, (C) first-half SNM, (D) rapid oscillating SNM, and (E) conditional latched SNM.

REFERENCES

1. S. Siegel, K. Kreder, E. Takacs, R. McNamara, and F. Kan, "Prospective randomized feasibility study assessing the effect of cyclic snm on UUI in women," Female Pelvic Med. Reconstr. Surg., 2018
2. T. S. Brink, P. L. Zimmerman, M. A. Mattson, X. Su, and D. E. Nelson, "A chronic, conscious large animal platform to quantify therapeutic effects of sacral neuromodulation on bladder function," J. Urol., vol. 194, no. 1, pp. 252–258, 2015
3. B. A. Potts et al., "Timing of sacral neurostimulation is important for increasing bladder capacity in the anesthetized rat," Am. J. Physiol. Renal Physiol., vol. 317, no. 5, pp. F1183–F1188, 2019

Funding Medtronic **Clinical Trial** No **Subjects** Animal **Species** Sheep **Ethics Committee** Medtronic

256 www.ics.org/2020/abstract/256

BEST IN CATEGORY PRIZE "PHARMACOLOGY"

MODULATING CGMP AND PROTEIN KINASE G (PKG) ATTENUATES NERVE-MEDIATED ATP RELEASE, AND NOT ACH RELEASE, IN THE MOUSE DETRUSOR

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1. University of Bristol, 2. University of Surrey, 3. University of Pittsburgh

HYPOTHESIS / AIMS OF STUDY

Parasympathetic nerve terminals to detrusor muscle release two excitatory neurotransmitters, acetylcholine (ACh) and ATP. In the normal human bladder, ACh fully supports contraction due to rapid extracellular breakdown of ATP, whereas in bladder pathologies such as overactive bladder ATP also contributes to contractile activation [1]. However, in most animals, including mice, detrusor from normal bladders also has a dual nerve-mediated ATP/ACh component to contraction. Thus, in this context, mouse detrusor offers a good model for overactive human tissue. Phosphodiesterase type 5 (PDE5) inhibitors like sildenafil inhibit cGMP breakdown and reduce the purinergic component of nerve-mediated contractions [2]. We hypothesise that increasing intracellular cGMP levels by different pathways decreases nerve-mediated ATP release. However, the effect on ACh release is not known, and this will also be tested. cGMP levels were raised by: i) increasing soluble guanylate cyclase activity with the activator cinaciguat; ii) reducing its breakdown with sildenafil; iii) by addition of a cell permeable cGMP analogue. The involvement in any effect on the enzyme target for cGMP, protein kinase G (PKG), was also investigated.

STUDY DESIGN, MATERIALS AND METHODS

Bladders were dissected from 12-week male C57BL/6 mice, and tissue strips, with an intact mucosa, were attached to an isometric force transducer and superfused with Tyrode's solution (pH 7.4, with 24 mM NaHCO3/5% CO2 buffer, 36°C). Contractions were generated by electrical field stimulation (EFS; 0.1-ms pulses, 1-40 Hz, 3-s train every 90 s) that were inhibited by tetrodotoxin (1 μM). Drug interventions were delivered by the superfusate and the effects on nerve-mediated contractions measured. Tension amplitude (mN) was normalised to preparation weight (mN.mg-1). Nerve-mediated amplitude, plotted as a function of stimulation frequency, was analysed to generate Tmax, the maximum tension at high frequencies and f1/2, the frequency to attain Tmax/2. A reduction of Tmax implies an action on force mainly via ACh-dependent pathways; an increase of f1/2 implies a force reduction mainly via ATP-dependent pathways. Superfusate samples were taken from a fixed point near the preparation with minimal mechanical disturbance [2]. ATP release was measured across the frequency range using a luciferin-luciferase assay, and ACh release was measured at 20 Hz stimulation using a choline/ACh assay kit (both Sigma). Data are mean±SEM and differences between data sets were tested with repeated measures two-way ANOVA followed by parametric post-hoc tests or Student's paired t-tests where appropriate; the null hypothesis was rejected at $P<0.05$.

RESULTS

Cinaciguat (10 μM, Fig. 1A) and sildenafil (20 μM, Fig. 1B) both reduced nerve-mediated ATP release, but had no significant effects on ACh release. Nerve-mediated contraction data were consistent with this result, with no effect of either compound on Tmax, but each an increase of the f1/2 value (Fig 1A, B). The cGMP analogue 8-bromo-cGMP (1 μM) had a similar effect on ATP dynamics: nerve-mediated ATP release was reduced, f1/2 increased (Fig. 2A) and no effect on Tmax. The PKG inhibitor, Rp-8-CPT-cGMPS (10μM), had no effect itself on nerve-mediated contractions and ATP release. It also inhibited the effects of sildenafil so that there was now no decrease of nerve-mediated ATP release and no increase of f1/2 values (Fig 2B).

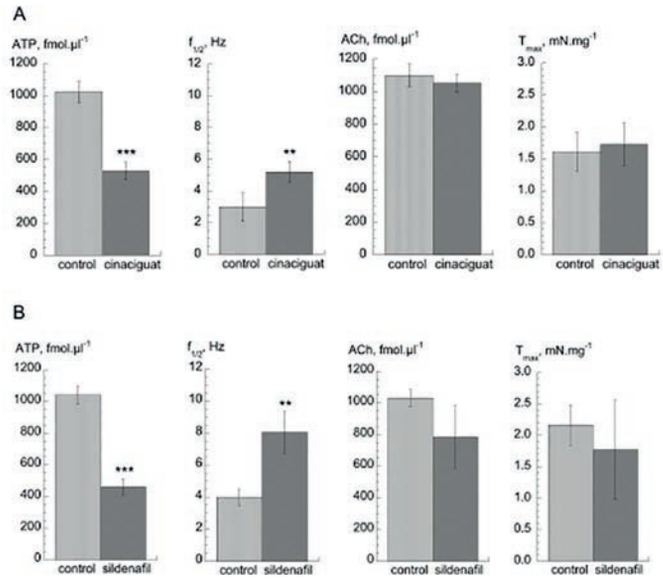
INTERPRETATION OF RESULTS

Three interventions were designed to increased intracellular cGMP levels: to increase its production by enhancing guanylate cyclase activity, reduce its breakdown by PDE5 inhibition, or add directly to the intracellular pool. All were similarly efficacious to reduce nerve-mediated ATP release and selectively reduced low frequency contraction (increase f1/2 values). Two of these compounds, cinaciguat and sildenafil were tested on nerve-mediated ACh release where there was no significant effect, or on the contractile equivalent, Tmax values. The intracellular target for cGMP in regulating transmitter release is PKG, as its separate inhibition, abolished contractile changes associated with sildenafil and its attenuation of ATP release. This is the first demonstration of selective inhibition of neurotransmitter, namely ATP, release from nerves supplying detrusor smooth muscle. Because ATP is associated with pathological contractions in the human bladder it offers a therapeutic target to selectively attenuate these contractions whilst leaving physiological contractile regulation intact.

CONCLUDING MESSAGE

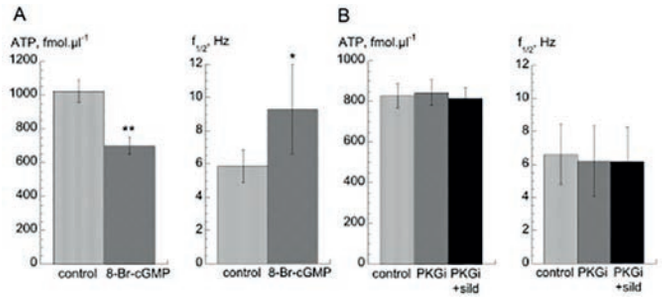
Elevation of intracellular cGMP by a number of different routes selectivity reduces transmitter release to detrusor smooth muscle; attenuating ATP release whilst leaving ACh release intact. This offers a specific target for pathological mechanisms associated with abnormal functional bladder activity but leaving normal physiological pathways intact.

FIGURE 1



Increased cGMP by A: cinaciguat (10 µM) or B: sildenafil (20 µM), on nerve-mediated ATP release, contractile f1/2 values, nerve-mediated ACh release and contractile Tmax values. Data are mean±SEM, n=6, **p<0.01; ***p<0.001.

FIGURE 2



The effect of A: 8-Br-cGMP (1 µM) or B: PKG inhibition (PKGi) with Rp-8-CPT-cGMPS (10 µM) in the absence and presence of sildenafil (20 µM), on nerve-mediated ATP release and contractile f1/2 values. Data are mean±SEM, n=6, *p<0.05, **p<0.01; ***p<0.001.

REFERENCES

1. McCarthy CJ, Ikeda Y, Skennerton D, Chakrabarty B, Kanai AJ, Jabr RI, Fry CH (2019). Characterisation of nerve-mediated ATP release from bladder detrusor muscle and its pathological implications. Br J Pharmacol 2019; 176: 4720-4730.
2. Chakrabarty B, Ito H, Ximenes M, Nishikawa N, Vahabi B, Kanai AJ, Pickering AE, Drake MJ, Fry CH (2019). Influence of sildenafil on the purinergic components of nerve-mediated and urothelial ATP release from the bladder of normal and spinal cord injured mice. Br J Pharmacol 176:2227-2237.

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THERAPEUTIC EFFECTS OF INTRAVESICAL INSTILLATION OF LIPOSOME-CONJUGATED NGF ANTISENSE ON NGF OVEREXPRESSION IN THE BLADDER AND BLADDER OVERACTIVITY IN A RAT MODEL OF PROSTATIC INFLAMMATION

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HYPOTHESIS / AIMS OF STUDY

There is increasing evidence indicating the positive correlation between prostatic inflammation and lower urinary tract symptoms (LUTS) in male with benign prostatic hyperplasia (BPH). Also, in animal models, prostatic inflammation (PI) reportedly induces bladder overactivity via prostate-to-bladder cross-organ afferent sensitization through activation of the pelvic nerve [1]. Previous reports further demonstrated that nerve growth factor (NGF) is an important mediator to induce bladder afferent hyperexcitability, which contributes to lower urinary tract dysfunction (LUTD) [2] and that local suppression of NGF in the bladder improves bladder overactivity in rat models of cystitis or colitis [3]. The present study therefore examined the effect of liposomes conjugated with antisense oligonucleotide (OND) targeting NGF on local overexpression of NGF and bladder overactivity in rats with PI.

STUDY DESIGN, MATERIALS AND METHODS

Male Sprague-Dawley rats were divided into three groups: (1) Control group; intact rats, (2) PI-NS group; rats with PI and intravesical instillation of Normal Saline (NS), (3) PI-OND group; rats with PI and intravesical instillation of liposome-conjugated NGF antisense. PI was induced by intraprostatic 5% formalin injection (50 µl per each ventral lobe). On day 0, PI was induced, and on day 14, 0.5ml of 12µM of phosphorothioated NGF antisense OND complexed with liposomes (PI-OND group) or NS (PI-NS group) was instilled into the bladder directly using a 30G needle punctured through the bladder dome after draining urine, and kept for 60 minutes under isoflurane anesthesia. Then, on day 28, we evaluated awake cystometry (CMG) and harvested tissues for the histological analysis as well as measurements of protein levels of NGF by ELISA methods and mRNA expressions of NGF and TRPV1 in the bladder, inflammation markers (IL-β and IL-18) in the prostate, and mRNA expressions of C-fiber

afferent markers (TRPV1 and TRPA1) and the A-type K+ channel α-subunit (Kv 1.4) in L6-S1 dorsal root ganglia (DRG) by RT-PCR.

RESULTS

In CMG, PI-OND group had significant longer Intercontraction intervals (ICI) than PI-NS group while there were no significant differences between PI-OND and Control groups (Fig. 1A, 1B). Other CMG parameters were not significantly different among groups. mRNA expression levels of TRPV1 and TRPA1 in L6-S1 DRG of PI-OND group were significantly lower than those of PI-NS group, while there were no significant differences in their expressions between PI-OND and Control groups (Fig. 1C). mRNA expression levels of Kv 1.4 subunit in L6-S1 DRG in PI-OND group were significantly lower than those in PI-NS group while there were no significant differences between PI-OND and Control groups (Fig. 1C). Both mRNA and protein expressions of NGF in the bladder mucosa in PI-OND group were significantly lower than those in PI-NS group, while there were no significant differences in their expressions between PI-OND and Control groups (Fig. 2A). In addition, in the prostate tissue, mRNA expression levels of NGF as well as IL1β & IL-18 in PI-OND group were significantly lower than those in PI-NS group (Fig. 2B).

INTERPRETATION OF RESULTS

Intravesical instillation of liposome-conjugated NGF antisense OND reduced local NGF suppression in both bladder and prostate, which was increased after prostatic inflammation. Also, the intravesical NGF antisense treatment reduced PI-induced bladder overactivity evident as longer ICI in association with the reduction of TRPV1 and TRPA1 mRNA expressions in L6-S1 DRG, which contain bladder and prostate afferent neurons. Moreover, mRNA expressions of Kv1.4 in L6-S1 DRG, which is an α-subunit of A-type K+ channels and reportedly decreased in hyperexcitable bladder afferent neurons from LUTD animal models [1], was reduced after prostatic inflammation, but improved after local NGF suppression in PI-OND group.

CONCLUDING MESSAGE

These results indicate that NGF locally expressed in the bladder is an important mediator to induce bladder overactivity with upregulation of C-fiber afferent markers and downregulation of an A-type K+ channel subunit in L6-S1 DRG following prostatic inflammation and that liposome-based, local NGF-targeting therapy could be effective for not only bladder overactivity and afferent sensitization, but also prostatic inflammation. Thus, local blockade of NGF in the bladder could be a therapeutic modality for male LUTS due to BPH with prostatic inflammation.

FIGURE 1

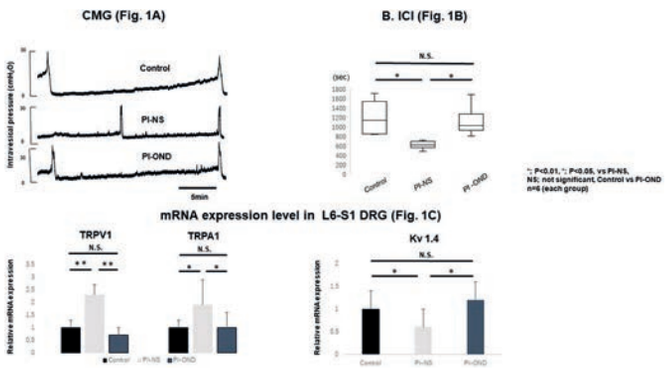
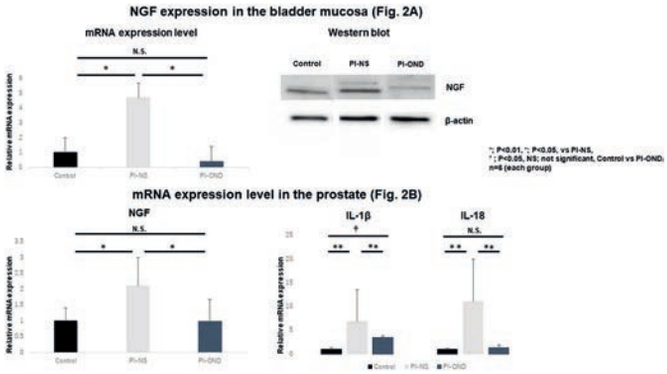


FIGURE 2



REFERENCES

1. Funahashi, Y., Takahashi, R., Mizoguchi, S., Suzuki T., Takaoka, E., Ni, J., Wang, Z., DeFranco, D.B., de Groat, W.C., Tyagi, P., Yoshimura, N.: Bladder overactivity and afferent hyperexcitability induced by prostate-to-bladder cross-sensitization in rats with prostatic inflammation. Journal of Physiology (London), 597: 2063-2078, 2019
2. Ochodnický, P., Cruz, C.D., Yoshimura, N., Cruz, F.: Neurotrophins as regulators of urinary bladder function. Nature Reviews Urology, 9, 628–637, 2012.
3. Kawamorita, N., Yoshikawa, S., Kashyap, M., Tyagi, P., Arai, Y., Chancellor, M.B., Yoshimura, N.: Liposome-based intravesical therapy targeting nerve growth factor (NGF) ameliorates bladder hypersensitivity in rats with experimental colitis. Journal of Urology, 195: 1920-1926, 2016.

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BEST IN CATEGORY PRIZE "PELVIC PAIN SYNDROMES / SEXUAL DYSFUNCTION"

AUTOIMMUNITY TO UROTHELIAL ANTIGEN CAUSES BLADDER INFLAMMATION, PELVIC PAIN AND VOIDING DYSFUNCTION: A NOVEL ANIMAL MODEL FOR HUNNER TYPE INTERSTITIAL CYSTITIS

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HYPOTHESIS / AIMS OF STUDY

Hunner type interstitial cystitis (HIC) is a chronic inflammatory disorder of the urinary bladder characterized by persistent pelvic/bladder pain, urinary frequency and/or urgency. Histologically, HIC bladder manifests subepithelial chronic inflammatory changes such as lymphoplasmacytic infiltration, epithelial denudation, and stromal oedema, neovascularization and hyperemia. To date, few animal models which reproduce the histological and clinical correlates of HIC have been yet established. Although the aetiology of HIC remains elude, recent evidence suggests that enhanced immune responses may underlie the pathophysiology of HIC (1). The higher prevalence of comorbid systemic autoimmune disorders is a well-known fact in patients with HIC. Based on this evidence, we aimed to develop a novel animal model for HIC via autoimmunity to the bladder urothelium in this study.

STUDY DESIGN, MATERIALS AND METHODS

A transgenic model (URO-OVA) mouse, that expresses the membrane form of the model antigen ovalbumin (OVA) on the bladder urothelium as a self-antigen, was used in this study (2). Antigen OVA-specific lymphocytes were generated by immunization of C57BL/6 mice with complete Freund's adjuvant-emulsified OVA protein (100μg) subcutaneously. Splenocytes (a mixture of T and B cells) of the OVA-immunized C57BL/6 mice were prepared 14 days after immunization and immediately injected to the URO-OVA mice intravenously, or cultured at 1 x 105 cells/well in a 48-well plate for 3 days in the absence or presence of OVA, OVA257-264 peptide (a MHC class I-restricted peptide epitope), OVA323-339 peptide (a MHC class II-restricted peptide epitope), or ras control peptide for subsequent ELISA analysis of IFN-γ levels in the culture supernatants. Bladder histology (Hematoxylin-Eosin staining and immunohistochemistry for CD3-positive T lymphocytes and CD19-positive B lymphocytes), gene expression levels of IFN-γ, TNF-α, and pre-substance P in the bladder tissues, pain behaviour (von Frey filament test), and voiding function were evaluated at 7, 14, 21, 28 days after adoptive transfer of OVA-primed splenocytes. Age-matched normal URO-OVA mice that were not underwent adoptive transfer served as controls. Each timepoint contained 3 to 5 mice for both groups.

RESULTS

The URO-OVA mice transferred with OVA-primed splenocytes developed cystitis from day 7 exhibiting histological chronic inflammatory changes such as remarkable mononuclear cell infiltration, increased vascularity, and mucosal hyperemia in the bladder with a peak at day 21, which perpetuated until day 28. Immunohistochemical detection revealed that infiltrating mononuclear cells were predominantly composed of T and B lymphocytes in the cystitis bladder. Meanwhile, the control mice did not show any histological changes (Fig. 1). In parallel, the cystitis URO-OVA mice demonstrated significantly increased pelvic pain and urinary frequency, and reduced micturition volume compared to the controls from day 7 to 28 (Fig. 2). The gene expression levels of IFN-γ, TNF-α, and substance P precursor in the bladder were significantly up-regulated in the cystitis URO-OVA mice compared to the controls (Fig. 3a and 3b). In vitro stimulation of the cultured OVA-primed splenocytes by OVA, OVA257-264, and OVA323-339 proteins resulted in increased IFN-γ production by these cells (Fig. 3c).

INTERPRETATION OF RESULTS

The results indicate that autoimmunity to the urothelium antigen induced bladder chronic inflammation with increased nociceptive responses and voiding dysfunction perpetuating more than 4 weeks, which mimics the characteristic features of human HIC.

CONCLUDING MESSAGE

To the best of our knowledge, this is the first study to demonstrate that adoptive immunity to the bladder urothelial antigen reproduces histological and clinical correlates of HIC. This model has potential to be a novel animal model which could contribute to the future research on HIC.

FIGURE 1

Figure 1

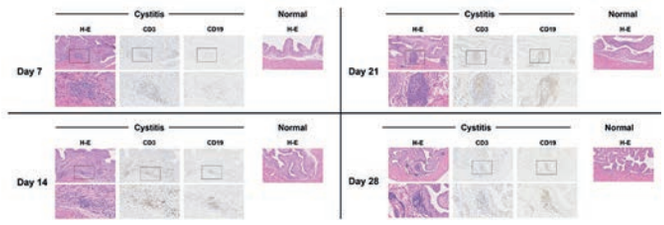
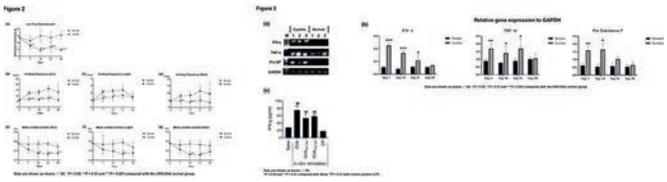


FIGURE 2



2. Urinary bladder epithelium antigen induces CD8+ T cell tolerance, activation, and autoimmune response. J Immunol. 2007; 178: 539-46

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REFERENCES

1. Molecular Taxonomy of Interstitial Cystitis/Bladder Pain Syndrome Based on Whole Transcriptome Profiling by Next-Generation RNA Sequencing of Bladder Mucosal Biopsies. J Urol. 2019; 202: 290-300

SESSION 22 (PODIUM SHORT ORAL) - URETHRA / PROSTATE
Abstracts 342-353
13:30 - 15:00, Pavilion 9
Chairs: Dr Alex Tong-Long Lin (Taiwan), Craig Comiter (United States)

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SAFETY AND EFFICACY OF HOLMIUM LASER VERSUS COLD KNIFE DIRECT VISION INTERNAL URETHROTOMY IN MANAGEMENT OF BULBAR URETHRAL STRICTURE

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HYPOTHESIS / AIMS OF STUDY

Male urethral stricture is a common condition in urological practice. The traditional therapeutic methods, including urethral dilatation and cold knife urethrotomy. The one that is most appealing to urologists and patients is direct VIU, as it is a minimally invasive endoscopic procedure. The aim of this study is to compare the safety and efficacy of using Holmium:YAG laser and the cold knife in treatment of short segment bulbar urethral stricture .

STUDY DESIGN, MATERIALS AND METHODS

A total of 60 patients were included in this rondom prospective contolled study from April 2017 to September 2019 using retrograde endoscopic Ho:YAG laser and cold knife. They were divided into two groups,group 1 included 30 patients(18cases with stricture length <1cm and 12 more than 1cm), each patient was submitted to conventional or cold knife urethrotomy and group 2 included 30 patients(23cases with stricture length <1cm and 7 more than 1cm), each patient was submitted to HO:YAG laser urethrotomy. Inclusion criteria included Fresh, short and single stricture. Exclusion criteria were, Long stricture segments more than 1.5 cm, Urethral stricture following pelvic fracture and rupture urethra, Recurrent cases after open urethroplasty or endoscopic dilatation or visual internal urethrotomy and complicated cases as those associated with diverticulum or multiple level strictures.The diagnosis of urethral stricture was based on clinical history (obstructive symptoms), uroflowmetry, and combined Antegrade and retrograde urethrography.

RESULTS

Mean patients' age was 42.90±16.01 years (range 18 - 70 years) for direct VIU cases and 41.89±12.51 years (range23-66 years) for the Laser VIU cases. Urethral strictures ranged from 0.5-1.5 cm long;. Mean operative time of the studied cases was 24.07±5.53 min for direct VIU and 31.25±6.18 min for Laser VIU, The mean peak urinary flow rate (Q(max)) preoperatively was 8.09± 2.00m l/s(for direct VIU cases while it was 8.78±1.70 m l/s for Laser VIU with insignificant difference ($p<0.177$)

INTERPRETATION OF RESULTS

After 6 months, no recurrence occurred in 14 cases from 18 (77.8%) with less than 1 cm stricture length of direct VIU cases versus 18 cases from 23 (78.3%) with less than 1 cm stricture length of Laser VIU cases and this difference was not statistically significant ($p=0.970$). On the other side, no recurrence occurred in 5 cases from 12 (41.7%) with stricture more than 1 cm of direct VIU cases versus 3 cases from 7 (42.9%) with more than 1 cm stricture length of Laser VIU cases which either was not statistically significant ($p=0.960$).

CONCLUDING MESSAGE

YAG laser urethrotomy (laser VIU) is a safe and effective minimally invasive therapeutic modality for short segment bulbar urethral stricture with the same results comparable to those of conventional cold knife urethrotomy(direct VIU). However, randomized comparitive studies with longer fol-

low-up are necessary to determine the clinical value of the holmium laser in the treatment of urethral strictures.

Funding No funding **Clinical Trial** No **Subjects** Human **Ethics Committee** Menoufia university Hospital Ethical committee **Helsinki** Yes **Informed Consent** Yes

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PREDICTORS OF SHORT-TERM POSTOPERATIVE MORBIDITY ASSOCIATED WITH EARLY VERSUS LATE DISCHARGE FOLLOWING URETHROPLASTY UTILIZING A NATIONAL DATABASE

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HYPOTHESIS / AIMS OF STUDY

Urethroplasties have experienced a significant increase in the ratio of outpatient to inpatient procedures, with a marginal increase in the rate of postoperative complications. The rate of urethroplasty procedures being performed as outpatient procedures has been increased in a national report.[1] Advocating outpatient approach provides multiple advantages including conservation of resources, reduced healthcare costs, and increased patient convenience.[2] We sought to compare short-term (30-day) postoperative morbidity between patients who were discharged early (same-day) versus late (>1 day) following urethroplasty and to determine factors associated with postoperative complications in each group.

STUDY DESIGN, MATERIALS AND METHODS

Utilizing the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database from 2005-2016, patients who underwent urethroplasty procedure were identified. Study cohort included adult (≥ 18 years) male patients who received primary anterior urethroplasty (current procedural terminology (CPT) codes: 53400, 53405, 53410) and posterior urethroplasty (CPT codes: 53415, 53431, 53425, 53420). Secondary CPT codes (14040, 14041, 15240, 15740, 20926, 40818, 41870) were used to identify whether patients received any tissue transfer (i.e. flaps or grafts) during urethroplasty procedure. We categorized the study cohort into two groups based on their length of stay (LOS, days): "early discharge" (LOS = 1) and "late discharge" (LOS > 1). Extracted data included patient characteristics, preexisting chronic medical conditions, the American Society of Anesthesiologists (ASA) patient classification, preoperative labs and short-term (30-day) postoperative complications and mortality. Multivariable logistic regressions were performed to determine factors associated with increased risk of postoperative complications in each group. Adjusted odds ratios and 95% CIs were reported.

RESULTS

Overall n=1,435 male urethroplasty patients were identified, of which 396 (27.6%) were discharged early and 1,039 (72.4%) were discharged late. Approximately, 43% of the patients in the study cohort were aged 18–44 years and 58.8% were of white race. The majority of patients had ASA class I/II (72.3%), normal WBC count (61.7%), low hematocrit (48.5%) before receiving urethroplasty and received urethroplasty in 2011 onward (88.5%). Regards etiology of urethral stricture, about 89% of all patients had idiopathic stricture, with small proportion who had a post-traumatic (9.7%) and post-infective (1.4%) urethral stricture. About 69% of the patients received an anterior urethroplasty, and only 27.9% received tissue transfer during their surgery. Among those who had tissue transfer whether flaps and grafts, 70.5% received anterior urethroplasty and 29.5% received posterior urethroplasty. The average operating time (minutes) in patients who were discharged early was shorter compared to those who were discharged late (124.2 ± 74.9 vs. 179.9 ± 89.9, p<0.001). The average LOS of patients in late-discharge group was 2.9±2.8 days. The proportion of patients with postoperative complications was relatively lower among early-discharge group compared to those in the late discharge (5.6% vs. 7.4%, p=0.215). Rates of early mortality (0.2% vs. 0%, p=0.275, respectively) and reoperation (0.8% vs. 1.2%, p=0.578, respectively) were similar between early- and late-discharge groups. After adjusting for confounders, patients discharged early had a lower likelihood of being readmitted (OR [95%CI]: 0.35 [0.14, 0.88]) compared to those discharged late. The multivariable analysis suggested that patient's age of 45-54 years (vs. 18-44) was associated with increased risk of postoperative complications in early-discharge group (OR [95%CI]: 3.60 [1.05, 12.35]). In late-discharge group, white race (OR [95%CI]: 0.53 [0.28, 0.99]) was associated with decreased risk of postoperative complications, while every 10-minute increment in operating time (OR [95%CI]: 1.04 [1.02, 1.07]) increased the odds of early postoperative complications.

INTERPRETATION OF RESULTS

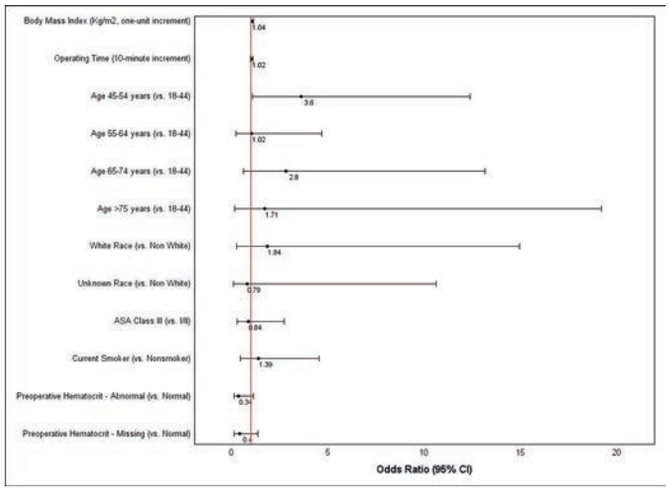
Our results showed that there was no significant difference in the rates of early postoperative complications, readmissions and reoperations between early- and late-discharge groups following urethroplasy. This would encourage reconstructive urologists to adopt the outpatient approach of urethroplasty procedure for selected patients. Older age (45-54 years) among early-discharge group and longer op-

erating time among late-discharge group were associated with higher risk of early postoperative complications. These factors would help urologists selecting the best approach in terms of LOS when dealing with urethral stricture patients.

CONCLUDING MESSAGE

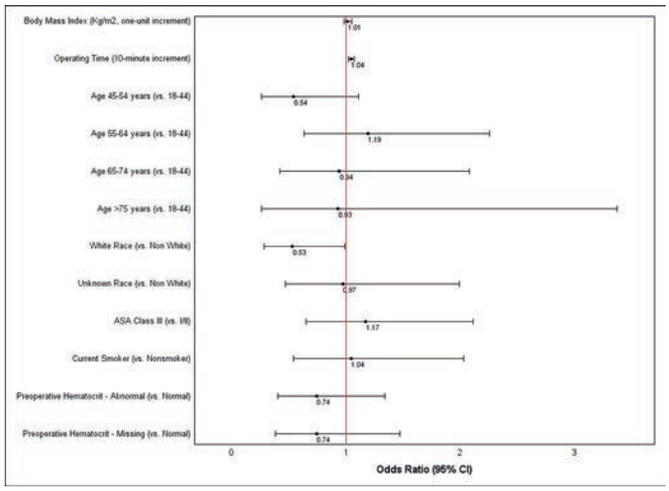
Rates of 30-day morbidity, mortality and reoperation were similar between early- and late-discharge groups following urethroplasty. Predictors of early complications following urethroplasty was age group of 45-54 (vs. 18-44) in early-discharge group and longer operating time (10-minute increment) in late-discharge.

FIGURE 1



Factors associated with 30-day postoperative complications in early discharge group following urethroplasty

FIGURE 2



Factors associated with 30-day postoperative complications in late discharge group following urethroplasty

REFERENCES

1. MacDonald S, Haddad D, Choi A, Colaco M, Terlecki R (2017) Anterior urethroplasty has transitioned to an outpatient procedure without serious rise in complications: data from the national surgical quality improvement program. Urology 102:225–228. https ://doi.org/10.1016/j.urolo gy.2016.09.043
2. Mandal A, Imran D, McKinnell T, Rao GS (2005) Unplanned admissions following ambulatory plastic surgery—a retrospective study. Ann R Coll Surg Engl 87(6):466–468. https ://doi.org/10.1308/00358 8405X 60560

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RELATIONSHIP BETWEEN CHANGE OF PROSTATE VOLUME AND LOWER URINARY TRACT SYMPTOMS AFTER LOW-DOSE-RATE BRACHYTHERAPY FOR PROSTATE CANCER

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HYPOTHESIS / AIMS OF STUDY

As shown in the many previous studies, low-dose-rate brachytherapy (LDRB) is one of the effective treatment options, and is currently a standard treatment for localized prostate cancer. Although LDRB is generally reported to be well tolerated, lower urinary tract symptoms (LUTS) often occur following implantation of LDRB. The presumed causes of LUTS after LDRB are the traumatic effect of needle insertion, direct irritation of peripheral nerves by irradiation, edematous change following seed implantation, and inflammatory changes in urethra and prostate following radiation exposure (1, 2). Even though the cause of LUTS after LDRB is multi-factorial, investigation about the pathogenesis is important to establish adequate treatment for LUTS after LDRB. However, the mechanisms and process of LUTS after LDRB have not been proved yet.

Moreover, the previous report indicated the severity of LUTS after LDRB synchronized to decrease of prostate volume (PV) (3). These results indicate that atrophic change of prostate tissue might mainly cause LUTS after LDRB. However, the changes of PV have different degree and many variations including enlargement in size due to intraprostatic bleeding or edema after implantation. Therefore, relationship between PV and LUTS should be investigated in detail to clarify the pathogenesis of LUTS after LDRB. Herein, we evaluated the impact of PV change on severity of LUTS after LDRB focusing on the two cohorts; increase and decrease of prostate volume. The aim of this study is to clarify the pathogenesis

of LUTS after LDRB for establishment of adequate management for LUTS after LDRB.

STUDY DESIGN, MATERIALS AND METHODS

Prostate cancer patients who received LDRB from 2014 to 2018 were retrospectively enrolled in this study. Very low risk, low risk, and intermediate risk localized cancer were eligible for LDRB in accordance with National Comprehensive Cancer Network risk classification. Patients with T2c, prostate specific antigen (PSA) > 10.0 ng/mL, and Gleason score 4+3 were received external beam radiation therapy (EBRT) before LDRB. Patients who have large prostate (40 cm3<), severe LUTS due to neurogenic bladder, and more than 50 mL of residual urine volume (RUV) were excluded for LDRB. International Prostate Symptom Score (IPSS), IPSS-QOL, Overactive Bladder Symptom Score (OABSS), uroflowmetry including voided volume (VV), maximum flow rate (Qmax), RUV, and PV were evaluated at the preimplantation stage and 1, 3, 6, 9 and 12 months after implantation of LDRB. RUV and PV was measured by transabdominal ultrasound by a single ultrasonographer.

First, clinical parameters were compared with the baseline data. Correlation of PV and IPSS was also evaluated in all of the patients. Second, for the sub-analysis to assess the role of PV change after LDRB, the patients were separated into two groups; PV increase group or PV decrease group. PV 3 months after LDRB were used to separate the patients.

Paired t-test was used for comparison of all of the basic and clinical data at 1, 3, 6, 9, and 12 months after LDRB. Spearman's correlation was used to evaluate the correlation between PV and IPSS. Clinical background and parameters were compared among the groups including age, initial PSA, Gleason score, T stage, IPSS, IPSS-QOL, OABSS, VV, Qmax, RUV, and PV. For the statistical analysis, unpaired t-test and chi square test ware used to comparison among the groups.

RESULTS

Eighty-four patients of prostate cancer were enrolled in this study. The basic clinical characteristics of the patients are shown in Table 1. Comparisons between PV increase group and PV decrease group were also included in Table 1.

Change of PV and IPSS were presented in Figure 1. PV decreased and IPSS increased at 3 months after LDRB, and both recovered in a process of a year. IPSS-QOL, OABSS, Qmax, VV, and RUV were changed similarly to IPSS after the implantation of LDRB. Figure 2 demonstrate the correlation between change of PV and IPSS 3 months after LDRB (at the peak of decrease of PV and increase of IPSS). However, there was no significant correlation, and coefficient of correlation was 0.103. The comparisons of PV increase group and PV decrease group were presented in Figure 3a-c. IPSS and Qmax were similarly changed in the 2 groups. There are no statistical changes among the groups in all of the process. Other parameters also changed similarly in the 2 groups.

INTERPRETATION OF RESULTS

LUTS reached the peak 3 months after LDRB synchronizing to decrease of PV. From 3 months to 1 year after LDRB, LUTS improved as PV recovery. However, PV and LUTS after LDRB showed no significant correlation, and there is much individual difference of PV change after LDRB. Moreover, there are no statistical differences of IPSS between PV increase group and PV decrease group. These results indicate that change of PV after LDRB does not associate with LUTS after LDRB. If so, LUTS after LDRB is not due to the pathogenesis related to PV change, such as edema, hematoma, inflammation, and atrophic change of prostate induced by radiation. Therefore, the pathogenesis of LUTS after LDRB might be independent factors from those leading PV change, such as direct neural irradiation. In fact, high radiation activities theoretically remain almost 3 months after LDRB implantation.

CONCLUDING MESSAGE

PV change synchronized severity of LUTS after LDRB. However, PV change might not associate with LUTS after LDRB. Other pathogenesis such as direct neural irritation by irradiation was indicated as the main cause of LUTS after LDRB.

FIGURE 1

Table 1. The basic clinical characteristics of the enrolled 84 patients

		All	PV increase group	PV decrease group	p
Number of patients		84	34	50	0.081
Age, years (range)		67 (50-80)	68 (53-80)	67 (50-79)	0.341
Initial PSA, ng/mL (range)		6.66 (3.32-11.6)	6.59 (3.86-11.6)	6.72 (3.32-9.50)	0.739
Gleason Score, n (%)	3+3	49 (58)	17 (50)	32 (64)	0.318
	3+4	30 (36)	13 (38)	17 (34)	
	4+3	5 (6)	4 (12)	1 (2)	
T stage, n (%)	T1c	51 (61)	27 (79)	24 (48)	0.036
	T2a	29 (34)	7 (21)	22 (44)	
	T2b or T2c	4 (5)	0 (0)	4 (8)	
PV, cm^3 (range)		22.7 (7.1-43.4)	19.4 (10.6-34.3)	25.0 (7.1-43.4)	<0.01
Supplementary EBRT, n(%)		9 (11)	6 (18)	3 (6)	0.092
Combined Hormonal therapy, n(%)		14 (17)	4 (12)	10 (20)	0.487
Pre-use of alpha-1 adrenoceptor antagonist, n(%)		13 (15)	4 (12)	9 (18)	0.639
Baseline parameter, mean (SD)	IPSS	8.7 (5.7)	7.5 (6.0)	9.6 (5.3)	0.116
	IPSS-QOL	2.7 (1.4)	2.4 (1.1)	2.8 (1.4)	0.158
	OABSS	2.9 (2.1)	2.8 (2.0)	2.9 (2.2)	0.827
	VV, mL	366 (149)	345 (129)	376 (159)	0.362
	Qmax, mL/s	19 (9.1)	20 (11)	19.1 (7.7)	0.721
	RUV, mL	19 (26)	14 (14)	22 (31)	0.151

FIGURE 2

Figure 1. Change of PV and IPSS for all patients

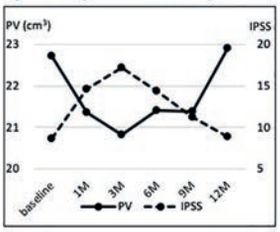


Figure 2. Correlation between change of PV and IPSS 3 months after LDRB

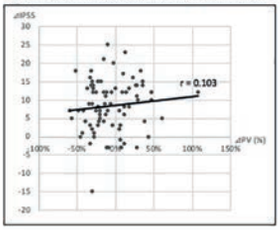
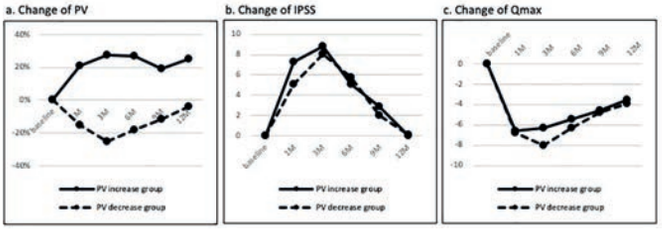


Figure 3. Comparison between PV increase group and PV decrease group



REFERENCES

1. Mallick S, Azzouzi R, et al. Urinary morbidity after 125I brachytherapy of the prostate. BJU Int. 2003; 92(6): 555-8.
2. Keyes M, Miller S, et al. Predictive factors for acute and urinary toxicity after permanent prostate brachytherapy: long-term outcome in 712 consecutive patients. Int J Radiat Oncol Biol Phys. 2009; 73: 1023-32.
3. Daimon H, Minagawa T, et al. Assessment for correlation between prostatic volume change and lower urinary tract symptoms after low-dose-rate brachytherapy for prostate cancer. ICS Annual Meeting 2017.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Ethical committee of Shinshu University **Helsinki** Yes **Informed Consent** No

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BEST IN CATEGORY PRIZE "PROSTATE CLINICAL / SURGICAL"

CERNITIN POLLEN EXTRACT VERSUS TADALAFIL THERAPY FOR REFRACTORY CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME: A RANDOMIZED, PROSPECTIVE STUDY

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HYPOTHESIS / AIMS OF STUDY

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is characterized by pelvic or perineal pain or painful voiding, in addition to LUTS including urgency, frequency, hesitancy, and poor interrupted flow. Since CP/CPPS has a significant negative impact on the patient's quality of life (QOL), the desire for treatment is high and effective treatment is required in clinical practice. Phytotherapy using cernitin pollen extract (cernitin), which is one of the traditional treatment options for CP/CPPS, is considered to be safe and effective for the relief from pelvic pain. PDE5 inhibitor such as tadalafil, which has multiple actions, including suppression of inflammation by the downregulation of Rho-kinase activity, is reported to be effective for CP/CPPS.

It is of clinical interest to determine whether these old and new drugs, cernitin and tadalafil, respectively, can improve chronic pain or discomfort of the pelvic or perineal in patients with CP/CPPS. To the best of our knowledge, no randomized controlled studies have compared the improvement in chronic prostatitis symptoms in patients treated with one of these medications. Therefore, the aim of the present study was to compare the efficacy of treatment with cernitin or tadalafil on not only LUTS, but also pelvic pain or discomfort, in patients with persistent CP/CPPS.

STUDY DESIGN, MATERIALS AND METHODS

This was a single-center, open label, and randomized controlled trial. The study included men who had persistent chronic prostatitis symptoms such as perineal and/or pelvic discomfort and/or pain after α1-blocker monotherapy for 12 weeks or more. The inclusion criteria were as follows: age ≥ 45 years; National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) pain sub-score ≥ 4; total International Prostate Symptom Score (IPSS) ≥ 8; and prostate volume ≥ 20 mL. .

A total of 100 patients with refractory CP/CPPS despite α1-blocker monotherapy were randomized to receive add-on therapy with cernitin (4 capsules/day) or tadalafil (5 mg/day) for 12 weeks. At week 12, changes from baseline in the patients' CP/CPPS, LUTS, and voiding function, as assessed

using NIH-CPSI, IPSS, and uroflowmetry, respectively, were compared between the groups. The primary endpoint was defined as the change from baseline to week 12 in the NIH-CPSI total score and NIH-CPSI pain sub-score. Additionally, we evaluated the change in NIH-CPSI urinary sub-score, NIH-CPSI QOL sub-score, IPSS, and voiding parameters on UFM as secondary endpoints.

RESULTS

The final analysis included 42 and 45 patients in the cernitin and tadalafil groups, respectively. Although the NIH-CPSI total, NIH-CPSI pain sub-score, and NIH-CPSI quality of life (QOL) sub-score significantly improved in both groups, the cernitin (vs. tadalafil) group showed significantly greater improvements in the NIH-CPSI total score (-6.8 vs. -4.6, $p = 0.02$) and NIH-CPSI pain sub-score (-4.1 vs. -1.5, $p < 0.001$) (Figure. 1). Half (50%) of the patients in the cernitin group showed a reduction greater than 50% in their NIH-CPSI pain sub-score; in the tadalafil group, only four patients (8.9%) showed ≥ 50% improvement ($p < 0.001$). In contrast, the improvement in LUTS, including the NIH-CPSI urinary sub-score and IPSS storage sub-score, was significantly superior in the tadalafil group.

INTERPRETATION OF RESULTS

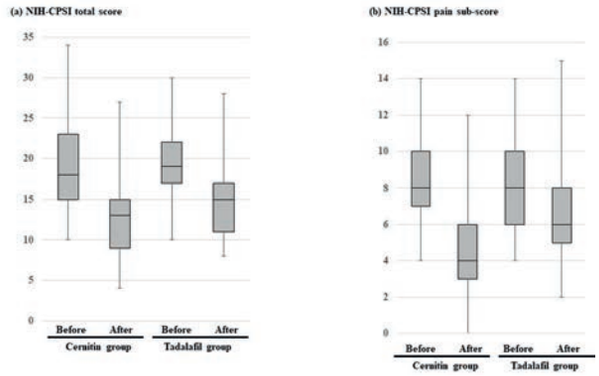
These findings may provide clinicians with an evidence-based strategy in selecting a medical treatment for the subgroup of patients with persistent chronic prostatitis despite α1-blocker monotherapy, who are frequently encountered in clinical practice. The detailed mechanisms underlying the significantly greater efficacy of cernitin than that of tadalafil in the improvement in chronic pelvic pain remains incompletely understood, but we can offer a plausible hypothesis. Although few studies have focused on the association between the inflammatory suppression of prostate tissue and the alleviation of pelvic pain, the suppression of chronic prostatic inflammation may contribute to the improvement of chronic pelvic pain and discomfort. When comparing the beneficial effects of the two drugs on prostate inflammation, cernitin might suppress inflammation more effectively in prostate tissue than tadalafil.

CONCLUDING MESSAGE

This comparative study showed that both cernitin and tadalafil significantly improved chronic pelvic pain and QOL in patients with refractory CP/CPPS (NIH category IIIA) despite α1-blocker monotherapy. The add-on of cernitin was more effective than tadalafil for pelvic pain and discomfort, which are pathognomonic symptoms in CP/CPPS, although the improvement of LUTS such as storage symptoms was significantly superior for the add-on treatment with tadalafil.

FIGURE 1

Fig. 1



Funding This study has been not funded or supported by any company. All authors declare that they have no conflict of interest. **Clinical Trial** Yes **Public Registry** No **RCT** Yes **Subjects** Human **Ethics Committee** the protocol was approved by the ethics committee of Nagoya University Graduate School of Medicine (IRB approval number: 2017-0136). **Helsinki** Yes **Informed Consent** Yes

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DOES SYMPTOMATIC IMPROVEMENT IN IPSS & IIEF SCORES CORRELATES WITH OBJECTIVE CHANGES IN URODYNAMIC PARAMETERS AMONGST PATIENTS WITH SYMPTOMATIC BPH FOLLOWING TAMSULOSIN/TADALAFIL MONOTHERAPY OR COMBINATION OF BOTH? : A PROSPECTIVE STUDY.

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1. PGIMER, Chandigarh

HYPOTHESIS / AIMS OF STUDY

Erectile dysfunction(ED) and LUTS are highly prevalent and often coexist in the elderly with BPH. Recent studies have shown the efficacy of phosphodiesterase5 (PDE5) inhibitors alone and in combination with alpha-adrenergic blockers in managing lower urinary tract symptoms. Although clinical benefit of PDE5 inhibitors has been shown, urodynamic data regarding the effect of PDE5 inhibitors is sparse. This study was designed to assess the efficacy of tamsulosin, tadalafil or a combination of the two in terms of improving LUTS, urodynamic parameters and sexual function in patients with BPH.

STUDY DESIGN, MATERIALS AND METHODS

45 symptomatic BPH patients were prospectively randomized to receive tamsulosin (Group A), tadalafil (Group B) or a combination (Group C). Patients were assessed at the start of the study and at the end of 3 months. Outcome was

measured in terms of change in IPSS, QOL, IIEF-5 and urodynamic parameters including change in Qmax, Pdet Qmax, BCCI,BCI and PVR.

RESULTS

The three groups were comparable . The mean age was 61.82±8.794 years with mean duration of LUTS were 2.51±1.576 years. A statistically significant change in IPSS score[7.93±6.90 (p = .001) in Group A, 7.00±5.59 (p = .000) in Group B and 5.80±5.51 (p = .001)in Group C] was observed. However, there was no significant difference on intergroup comparison (p=0.628). Significant improvement in the QOL Index in Group A (p= .000) and B (p= .003) was noted.

Statistically significant improvement of ED was noted only in patients who received Tadalafil (Group B and C). The mean change in Qmax, Pdet Qmax and PVR were insignificant and similar in all the three groups. The bladder outlet obstruction index (BOOI) and bladder contractility index (BCI) failed to show any significant change following therapy (Table2). Adverse events (headache and body aches) were noted more frequently in Group C although none discontinued treatment.

INTERPRETATION OF RESULTS

Our study shows that LUTS and QOL do improve with PDE5 inhibitors and the improvement is comparable to that seen with alpha-adrenergic blockers. Combination therapy however, failed to show any additive improvement in LUTS. Erectile function, expectedly, improved in patients who received PDE5 inhibitors, alone or along with tamsulosin. Tamsulosin alone did not improve erectile function. Surprisingly, improvement in LUTS was not reflected in urodynamic studies. Urodynamic parameters did not show any significant change after therapy in any of the three groups. Our study suggests that factors other than changes in bladder function and prostatic resistance are involved in improving symptoms in patients with BPH.

CONCLUDING MESSAGE

Tamsulosin and tadalafil significantly improved LUTS secondary to BPH. However, combination therapy did not give added benefit. The improvement in erectile function with tamsulosin was insignificant. Therefore, for patients with symptomatic BPH with bothersome ED, monotherapy with tadalafil may be considered rather than as a combination with tamsulosin. Interesting to note that the subjective improvement in LUTS was not reflected objectively in urodynamic parameters.

FIGURE 1

Table 2. Change in clinical and urodynamic parameters with treatment in the study groups.

	Group	Baseline [X]	3 months [Y]	Mean Change [X-Y]	p
IPSS	A	15.27±6.8	7.33±3.71	7.93±6.90	0.001
	B	14.40±6.506	7.40±4.53	7.00±5.59	<0.001
	C	13.13±6.12	7.33±3.87	5.80±5.51	0.001
QOL	A	3.87±1.30	1.67±0.90	2.20±1.61	<0.001
	B	3.07±1.16	2.00±0.66	1.07±1.16	0.003
	C	2.67±1.29	2.20±1.08	0.47±1.25	0.169
IIEF-5	A	10.87±10.41	11.07±10.55	-0.20±0.77	0.334
	B	17.40±6.62	20.20±7.27	-2.80±4.75	0.039
	C	19.52±6.27	22.53±3.69	-3.00±3.33	0.004
Qmax (mL/sec)	A	7.93±4.06	7.00±2.95	0.93±3.32	0.296
	B	6.93±2.94	7.67±4.03	-0.73±-2.25	0.228
	C	9.27±4.37	8.12±3.44	1.13±3.29	0.204
PdetQmax (cmH20)	A	62.20±19.57	58.20±16.0	4.00±12.63	0.240
	B	75.13±43.71	72.93±43.42	2.20±12.64	0.511
	C	56.33±21.2	54.27±21.01	1.07±10.95	0.712
PVR (mL)	A	73.00±72.11	82.20±97.76	-9.20±99.8	0.726
	B	96.93±100.91	86.67±54.17	10.24±112.43	0.729
	C	71.47±71.98	36.53±46.93	34.93±57.88	0.035
BOOI	A	46.63±22.474	44.20±17.473	- 2.1333±11.59351	0.488
	B	61.27±45.998	57.60±46.355	- 3.6667±15.64182	0.379
	C	36.80±26.047	38.00±22.216	1.2000±11.99524	0.704
BCI	A	101.87±25.450	93.20±20.912	8.6667±24.69432	0.196
	B	109.80±41.211	111.27±42.361	- 1.4667±11.19226	0.627
	C	101.67±23.314	94.93±24.138	6.7333±20.96073	0.234

Funding Nil **Clinical Trial** No **Subjects** Human **Ethics Committee** Institute ethics committee, PGIMER, Chandigarh **Helsinki** Yes **Informed Consent** Yes

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INCIDENCE AND PREDICTORS OF EARLY AND LATE HOSPITAL READMISSION FOLLOWING TRANSURETHRAL RESECTION OF THE PROSTATE: A POPULATION-BASED COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY

To evaluate the the incidence and predictors of hospital readmission and emergency visits in patients with benign prostatic hyperplasia treated by transurethral resection of the prostate (TURP).

STUDY DESIGN, MATERIALS AND METHODS

We conducted a retrospective cohort study using linked administrative dataset from Calgary, Canada. Participants were men who underwent their first TURP procedure between 2015 and 2017. We examined patient demographics, and status of surgery (elective, urgent). Comorbidities were scored using the Charlson comorbidity index (CCI). The pri-

mary outcomes were unplanned hospital readmissions and emergency department visits at 30-, 60-, and 90-days after TURP surgery. The secondary outcome was to identify potential predictors across these groups.

RESULTS

We identified 3059 men, most of whom underwent elective TURP (83%). Mean patient age (SD) was 71.0 (10.0) years. A total of 224 (7.4%) patients were readmitted to the hospital within 30 days, 290 (9.5%) within 60 days, and 339 (11.1%) within 90 days of discharge (Table 1). The frequency of return visits within 30-, 60-, and 90-days after TURP were 21.4%, 26%, and 28.6% respectively (Table 2). The most responsible diagnosis for ED visit within 90 days were hematuria (15.4%), and retention of urine (12.8%). Multi-variable analysis revealed age (OR 1.61, p<0.001), surgery status (OR 2.20, p<0.001), and CCI (OR 2.03, p<0.001) were independently associated with odds of readmission and ED visits at all time points.

INTERPRETATION OF RESULTS

This is the first large-scale population-based cohort study in North America to compare hospital readmission and ED visits after TURP at 30-, 60-, and 90-days post-discharge. Of the 90-day ED visits, approximately one- quarter required re-hospitalization. Individuals who experienced a readmission and/or ED visit were more likely to be older, to have poorer health (higher CCI) and to have undergone urgent surgical transurethral resection of the prostate. We thus inferred that men aged 75 and older with BPH/LUTS and significant comorbidities have a higher risk of complications after urgent TURP and therefore are at higher risk of readmission and ER visits. We report that 17% of patients returning to ED had undergone an expedited ("urgent") TURP - within 7 days of catheterization. This finding highlights the importance of ensuring that patients are fully optimized medically before their surgery.

The present study therefore strongly supports a need to implement strategies to reduce the risk of return visits to the ED and hospital readmission following TURP, both to improve health outcomes and to lessen the economic burden of care. These strategies must involve efforts upstream, midstream and downstream of the surgical intervention. The other factor to consider is the changes in surgical management of BPH that are occurring with the use of minimally invasive technologies.

CONCLUDING MESSAGE

Older age, poorer health and urgent surgery predicted return to emergency department or readmission after TURP; efforts should be made to improve selection, counsel and preoperative optimization based on these risks.

FIGURE 1

Table 1. Patients being readmitted at least once within **30, 60, or 90 days**, by Age Group, CCI, and Surgery Status

Age Group	Surgery Status	CCI Status	N-All	30d Readmission N	30d Readmission %	60d Readmission N	60d Readmission %	90d Readmission N	90d Readmission %
<75	Elective	CCI 0	1438	63	4.4%	76	5.3%	92	6.4%
		CCI 1+	233	20	8.6%	28	12.0%	31	13.3%
		All Elective	**1671**	**83**	**5.0%**	**104**	**6.2%**	**123**	**7.4%**
	Urgent	CCI 0	187	15	8.0%	19	10.2%	23	12.3%
		CCI 1+	71	13	18.3%	16	22.5%	18	25.4%
		All Urgent	**258**	**28**	**10.9%**	**35**	**13.6%**	**41**	**15.9%**
	All <75		**1929**	**111**	**5.8%**	**139**	**7.2%**	**164**	**8.5%**
≥75	Elective	CCI 0	631	51	8.1%	61	9.7%	67	10.6%
		CCI 1+	237	29	12.2%	38	16.0%	40	16.9%
		All Elective	**868**	**80**	**9.2%**	**99**	**11.4%**	**107**	**12.3%**
	Urgent	CCI 0	147	14	9.5%	22	15.0%	29	19.7%
		CCI 1+	115	19	16.5%	30	26.1%	39	33.9%
		All Urgent	**262**	**33**	**12.6%**	**52**	**19.9%**	**68**	**26.0%**
	All 75+		**1130**	**113**	**10.0%**	**151**	**13.4%**	**175**	**15.5%**
	All Patients		**3059**	**224**	**7.4%**	**290**	**9.5%**	**339**	**11.1%**

FIGURE 2

Table 2. Patients visiting an ED at least once within 30, 60, and 90 days after discharge, stratified by age group, surgery category, and CCI^

Age Group	Surgery Status	CCI Status	N-All	30d ED Visit N	30d ED Visit %	60d ED Visit N	60d ED Visit %	90d ED Visit N	90d ED Visit %
<75	Elective	CCI 0	1438	248	17.3%	291	20.2%	328	22.8%
		CCI 1+	233	58	24.9%	74	31.8%	79	33.9%
		All Elective	**1671**	**306**	**18.3%**	**365**	**21.8%**	**407**	**24.4%**
	Urgent	CCI 0	187	39	20.9%	48	25.7%	52	27.8%
		CCI 1+	71	24	33.8%	30	42.3%	33	46.5%
		All Urgent	**258**	**63**	**24.4%**	**78**	**30.2%**	**85**	**33.0%**
	All <75		**1929**	**369**	**19.1%**	**443**	**23.0%**	**492**	**25.5%**
≥75	Elective	CCI 0	631	142	22.5%	168	26.6%	182	28.8%
		CCI 1+	237	64	27.0%	71	30.0%	76	32.1%
		All Elective	**868**	**206**	**23.7%**	**239**	**27.5%**	**258**	**29.7%**
	Urgent	CCI 0	147	43	29.3%	62	42.2%	67	45.6%
		CCI 1+	115	36	31.3%	50	43.5%	58	50.4%
		All Urgent	**262**	**79**	**30.2%**	**112**	**42.8%**	**125**	**47.7%**
	All 75+		**1130**	**285**	**25.2%**	**351**	**31.1%**	**383**	**33.9%**
	All Patients		**3059**	**654**	**21.4%**	**794**	**26.0%**	**875**	**28.6%**

Funding No **Funding Clinical Trial** No **Subjects** Human **Ethics Committee** Conjoint Health Research Ethics Board (CHREB) at the University of Calgary **Helsinki** Yes **Informed Consent** No

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ANALYSIS OF PRESENT STATUS FOR SURGERY OF BENIGN PROSTATIC HYPERPLASIA IN KOREA USING NATIONWIDE HEALTHCARE SYSTEM DATA

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HYPOTHESIS / AIMS OF STUDY

There are no established statistical data available for the comparison of different surgical methods adopted for the resection of benign prostatic hyperplasia (BPH) in Korea. This study investigates the present status related to BPH surgery in Korea for the past 8 years.

STUDY DESIGN, MATERIALS AND METHODS

National-level data from the National Health Insurance Service and National Statistical Office were analyzed in this study. From 2010 to 2017, The trends of surgeries for BPH were reviewed according to the procedure code including transurethral resection of the prostate (TURP), holmium laser enucleation prostate surgery (HoLEP), or high-power potassium titanyl phosphate (KTP), and this trend also analyzed by age, geographic distribution, and hospital type.

RESULTS

Over the past 8 years, there was no significant difference in the total number of operations between 2010 (10,393) and 2017 (11,072). TURP remained the most commonly performed operation for transurethral prostate surgery. Total number of conventional TURP remained stable (from 6,801 in 2010 to 6,645 in 2017). KTP was the second common operation in 2010 and 2011, but the number of KTP showed a gradual decrease from 3,314 to 2,751, and eventually dropped to 622 in 2017. On the other hand, the number of HoLEP dramatically increased. In 2010, the number of HoLEP was only 278, but the number steadily increased, and finally exceeded the number of KTP in 2012, with a continuing steady increase in the difference (Fig. 1). The number of surgeries by age group was most common in the 70s and the total number of surgeries is decreasing in all age groups; for HoLEP, the trend is steadily increasing over the age of 60 years(Fig. 2). Most of the BPH surgeries were performed in metropolitan areas, such as Seoul, Gyeonggi, and Busan, and in larger hospitals compared to smaller hospital settings.

INTERPRETATION OF RESULTS

Currently available surgeries for BPH in Korea are TURP, KTP, HoLEP, open prostatectomy, and Prostate ligation (UroLift System, NeoTract, Inc., Pleasanton, CA, USA). All of the procedures mentioned are available in Korea. HoLEP is rapidly replacing other open BPH operations since its introduction, and open prostatectomy is no longer performed. Currently, the most commonly performed surgeries in Korea are TURP, KTP, and HoLEP. The health insurance claim data provided by HIRA is a representative data of the medical contents of the all citizens and has representative and inclusiveness. In our present study, the traditional TURP was found to be the most common among the prostate surgeries, and the number of surgeries remained stable for 8 years. The number of HoLEP has surged rapidly, surpassing the number of KTPs since 2012. These results were comparable to other studies conducted in US, Canada, and Japan [1-3]. Previous studies have reported TURP to be the most common procedure without a significant difference in the number of operations. Further, laser treatments including HoLEP and KTP showed an increase forming the second most common treatment for BPH. However, the rates of total number of operations with TURP and laser therapies vary between countries due to the differences in the study period, the time of introduction of BPH procedures, acquisition costs, different reimbursement incentives, and insurance policies. In this study, the number of operations per 100,000 BPH patients tended to decrease in all age groups. This decrease might be attributed to the large number of new drugs that have been recently developed for the lower urinary tract symptoms due to BPH. It has been reported that the most common age group to receive the BPH surgeries is the 70s. This might indicate that the overall health status and morbidity of the BPH surgeries have improved in the older age groups. In addition, BPH surgeries are mainly conducted in the big cities or metropolitan areas where large hospitals are located rather than based on the absolute number or regional distribution of urology patients. This in turn implies that most of the HoLEP surgeries are mainly performed in large hospitals.

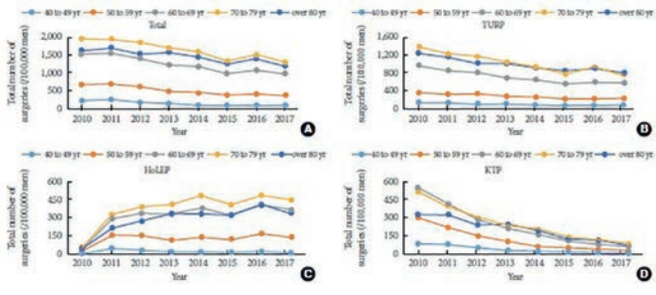
CONCLUDING MESSAGE

Through the data of the National Health Insurance Service, we could apprehend the present status of BPH-related surgery in Korea. Then, we could know about the trend according to several factors and we think these results will be valuable as academic references as well.

FIGURE 1

Total number of operations for benign prostatic hyperplasia during the 8 years in Korea. TURP, transurethral resection of prostate; HoLEP, holmium enucleation of the prostate; KTP, high-power potassium titanyl phosphate.

FIGURE 2



The trend of age-related surgery for benign prostatic hyperplasia (/100,000 persons). All surgeries (A), TURP (B), HoLEP (C), and KTP (D).

REFERENCES

1. Masumori N, Kamoto T, Seki N, Homma Y; Committee for Clinical Guideline for Benign Prostatic Hyperplasia. Surgical procedures for benign prostatic hyperplasia: a nationwide survey in Japan. Int J Urol 2011;18:166-70.

2. Hueber PA, Zorn KC. Canadian trend in surgical management of benign prostatic hyperplasia and laser therapy from 2007-2008 to 2011-2012. Can Urol Assoc J 2013;7:E582-6.
3. Schroeck FR, Hollingsworth JM, Kaufman SR, Hollenbeck BK, Wei JT. Population based trends in the surgical treatment of benign prostatic hyperplasia. J Urol 2012;188:1837-41.

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OVERCUTTING AS THE MAIN RISK FACTOR OF DEVELOPING BLADDER NECK CONTRACTURE AFTER ENDOSCOPIC SURGICAL TREATMENT OF BPH

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HYPOTHESIS / AIMS OF STUDY
Currently, transurethral resection (TURP) and endoscopic enucleation of the prostate (EEP) are the "gold" standards of endoscopic surgery for benign prostatic obstruction (BPO). Nonetheless, many complications such as bladder neck contracture (BNC) steel occurs after endoscopic surgery for benign prostatic obstruction (BPO). There are many theories and risk factors concerning development of bladder neck contracture. This study aims to determine the main risk factor of postoperative BNC by providing a retrospective analysis the groups of patients who have underwent endoscopic prostate resection and enucleation.

STUDY DESIGN, MATERIALS AND METHODS
We retrospectively analyzed the complication reports of 458 patients, who underwent TURP and EEP for symptomatic BPH during the period 2016-2019. Patients are divided in two groups: TURP group (n-213) and EEP group (n-245). The patients in all two groups had comparable characteristics (IPSS, Qmax, PVR, prostate volume, urine tract infection) before surgery. All interventions are performed by single expertise surgeon, using two- and tree lobe enucleation techniques and bipolar energy for TURP. During endoscopic enucleations of the prostate were clear seen and separated bladder neck structures, avoiding their damage. Following perioperative and follow-up clinical data being collected.

RESULTS
After TURP and EEP were observed the following intraoperative and early postoperative complications: severe hemorrhage in 4 (1.9%), 0 (0%), bladder neck injury in 7 (3,9%), 0 (0%), fever due to UTI in 3 (1.4%), 2 (0,8%), the bladder tamponade in 2 (0.9%), 1 (0.4%) and acute urinary retention in 8 (3.7%), 5 (2%) patients, respectively. At 6 months' follow-up, patients in all groups had a significant improvement from baseline in IPSS, Qmax, and PVR. In both TURP and EEP groups were included the late complications: urethral stricture n-2 (0,94%) and n-1 (0,4%), stress incontinence n-1 (0,47%) and n-4 (1,6%), continuing urine tract infection n-16 (7,5%) and n-22 (8,9%), respectively. Bladder neck contracture in the postoperative period were diagnosed in 3 (1,4%) patients after TURP and no such complication recorded in EEP group.

INTERPRETATION OF RESULTS
Correctly performed endoscopic enucleation of the prostate preserves the bladder neck by clear identification of plane between adenomas and surgical capsule. In contrast, transurethral resection of BPH may overcut and damage bladder neck due to difficulties in differentiation of underlying structures. In our opinion, other risk factors, such as prostate volume, UTI are minor and worsening ones. But these statements are required further well-designed research in a large cohort of patients.

CONCLUDING MESSAGE
Preserving the bladder neck during endoscopic surgical treatment is key point in avoiding of its contracture.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** None

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THE USEFULNESS OF CYSTOGRAPHY MEASURED BLADDER NECK ELEVATION ON PREDICT RECOVERY OF CONTINENCE AFTER ROBOT-ASSISTED RADICAL PROSTATECTOMY

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HYPOTHESIS / AIMS OF STUDY
Many researched revealed that the mechanism of post-prostatectomy incontinence. There is impairment of various muscles and nerves surrounding the urethral sphincter, rectum and bladder neck. These injuries make a delayed recovery from postoperative incontinence. Therefore, it could be hypothesized that contractile urethral length was a good tool to identify the saving of the muscle and nerve structure surround the urethra. We evaluated the correlation between

calculated contractile urethral length using cystography and the duration of postoperative incontinence in patients undergoing radical prostatectomy.

STUDY DESIGN, MATERIALS AND METHODS

The subjects of this study were 98 men who underwent radical prostatectomy. We measured the urethral movement between relaxing and contracting the pelvic muscle at the time of removing the urethral catheter using cystography (CG). Protocol for radiologic procedures. 10% Diluted contrast media was instilled into the bladder under gravity until a sensation of fullness was reported. Sequencing films were taken every 10 seconds during the procedure to identify Urethro-vesical anastomosis (UVA) leakage. After patients reported a full bladder, an anterior-posterior view and both oblique views of the bladder were obtained. Next, patients were instructed to contract the pelvic muscle, such as when performing a Kegel exercise, to identify the movement of the bladder neck, which was recorded by radiography. After the drainage of contrast media containing fluid from the bladder, a post-drainage view of the bladder was obtained. During the CG, cystography measured bladder neck ascendable vertical length (BNAL) was defined as the vertical length of contrast filled bladder apex between relaxing pelvic muscles and contracting them. If the patient did not effectively contract pelvic muscles in the first trial, after teaching the exercise of contracting pelvic muscle, and then tried to do the second time. The urinary leakage was asked in visiting the office every week until postoperative day 14 and was asked every month until postoperative months 3. And then was asked every 3 months afterward. Recovering urinary incontinence was defined as a pad-free condition for daily living without anxiety.

RESULTS

The median length of the urethral movement during CG was 0.5 cm (range 0–1.5 cm). MEG group revealed parameters such as Number of patients (n=42), Median age (62 ± 5.3 yrs), Median prostate volume (46 ± 17.9cc), Median initial total IPSS (9 ± 2.1), median initial QoL (3 ± 1.2), Median initial Qmax (15.3 ± 6.7 ml/s), BN opening(%) -Narrow (12.5), Moderate (62.5) and wide (25), NBV saving (54 %), Median length of urethral movement (0.9 ± 0.6 cm) and Mean time to recovery (0.5 ± 0.1 months).

LEG group revealed parameters such as Number of patients (n=56), Median age (69 ± 4.4 yrs), Median prostate volume (44 ± 14.9cc), Median initial total IPSS (14 ± 7.9), median initial QoL (4 ± 1.7), Median initial Qmax (14.7 ± 5.6 ml/s), BN opening(%) - Moderate (88.2) and wide (11.8), NBV saving (62.5 %), Median length of urethral movement (0.2 ± 0.1 cm) and Mean time to recovery (2.4 ± 1.2 months)

INTERPRETATION OF RESULTS

The median length of the urethral movement during CG was 0.5 cm (range 0–1.5 cm). There was no significant correlation between preoperative patient characteristics and duration of urinary incontinence. We used ROC analysis to decide the optimal cut-off value of the urethral movement for predicting postoperative recovery of urinary continence. The cut-off value of 0.6 cm gave the best accuracy in ROC analysis. The area under the ROC curve, sensitivity and specificity were 0.703, 0.583 and 0.863, respectively.

Patients were classified into two groups according to the length of the urethral movement. There were 29 patients with the urethral movement of 0.6 cm or more in a more elevating group (MEG), and 38 patients with a movement of less than 0.6 cm in a less elevating group (LEG). The median lengths of the urethral movement were 0.2 cm in MEG and 0.9 cm in LEG. Four of the 24 patients in the LEG showed no urethral movement. When we compared the time to recovery of urinary incontinence in both groups, the meantime to the recovery of urinary incontinence in MEG was 0.5 month and in LEG were 2.4 months, respectively. MEG was significantly shorter than LEG. Spearman's correlation analysis revealed an inverse correlation between the length of the urethral movement and the urinary incontinence volume rate on day 7 after urethral catheter removal ($r = -0.488$, $p < 0.001$). There was also a significant difference in recovering the incontinence between two groups until post-operative 10 months.

CONCLUDING MESSAGE

In this study, we objectively measured the length of the urethral movement. Based on the optimal cut-off value of 0.6cm, the more elevated group showed a fast recovery from postoperative incontinence than the others. In clinical practice, these results can help to estimate the period of restoring the urinary incontinence and describe the prognosis of postoperative incontinence to applicable patients. In conclusion, this study suggests that bladder neck ascending movement on cystogram is significantly associated with early recovery from post-prostatectomy incontinence. This may be easy to proceed and also useful for predicting the course of incontinence. There were a few limitations to this study. We calculated the duration of incontinence using the patient's memory about sustained urinary incontinence at visiting the clinic.

Funding The author claims no conflicts of interest. **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Jeju National University Hospital (IRB No. 2018-08-006-001) **Helsinki** Yes **Informed Consent** No

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IMPACT OF MEDIAN LOBES ON URINARY FUNCTION AFTER ROBOTIC RADICAL PROSTATECTOMY

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HYPOTHESIS / AIMS OF STUDY

An enlarged median lobe (ML) presents a technical challenge during robotic prostatectomy (RP) and its potential effects on outcomes are not well known. If known, the impact of a potentially larger bladder neck on continence as well as the impact of preoperative chronic outlet obstruction on postoperative urinary symptoms might aid in patient counseling. We assessed the impact of intraoperatively identified median lobes (ML) on urinary function.

STUDY DESIGN, MATERIALS AND METHODS

We reviewed our prospective database of 1899 RPs performed between July 2013- July 2019. International Prostate Symptoms Scores (I-PSS) were assessed preoperatively and at one, three, and six months postoperatively. In addition, a functional urinary survey was obtained regarding postoperative frequency, nocturia, urgency and continence at the same time points. Continence was defined as the use of 0-1 pads daily. We compared patients with ML and without ML (NoML). Bladder-neck sparing was routinely performed to avoid reconstructions regardless of ML whenever possible.

RESULTS

Of 663 patients who completed I-PSS at all time points, 202 (30%) had ML. There were no significant differences in demographics, PSA or clinical stage between ML and NoML patients. Only two ML and one NoML patients required bladder neck reconstruction. There was no immediate or long-term difference in continence rates between groups (Figure 1). Baseline mean I-PSS was higher in ML patients and showed more improvement 6 months postoperatively (-5.5 versus -3.6, $p<0.05$) (Figure 2). Voiding symptoms significantly decreased in both groups at all time points. However, mean sub-score for storage symptoms (items 2, 4 and 7 of I-PSS) was higher in NoML patients with mild symptoms (I-PSS 1-7) at each postoperative time point. Mean pre-operative frequency was higher in the ML group (6.9 episodes/24hs versus 7.6 episodes/24hs, p= 0.02) rising to 8.2 episodes/24hs in ML and 8.8 episodes/24hs in No ML group at one month postoperatively (p=0.07). The rate of patients with urgency decreased 5% in ML and 6% in NoML at 6 months following RP. Differences in I-PSS between groups resolved by 6 months postoperatively (6 vs 6.5, p=0.638). Overall, there were no correlations between prostate volume and I-PSS at any postoperative time point.

INTERPRETATION OF RESULTS

Patients with ML appear to benefit more in terms of postoperative urinary function initially. RP has higher impact on voiding rather than storage symptoms in both groups. Prostate volume was not related to symptom severity.

CONCLUDING MESSAGE

ML enlargement does not have an increased risk of incontinence and has only a short-term effect on urinary function after RP.

FIGURE 1

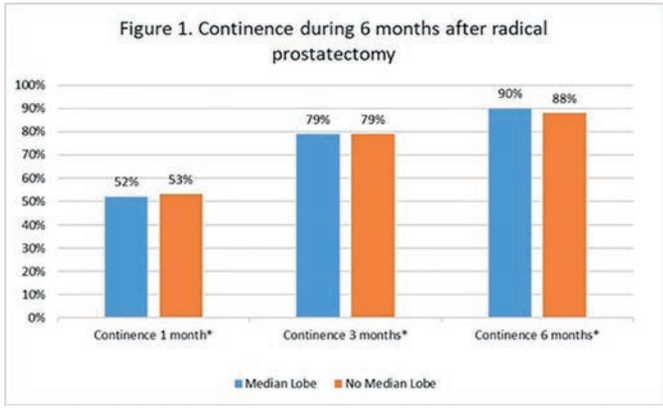

Figure1. Continence during 6 months after radical prostatectomy

FIGURE 2

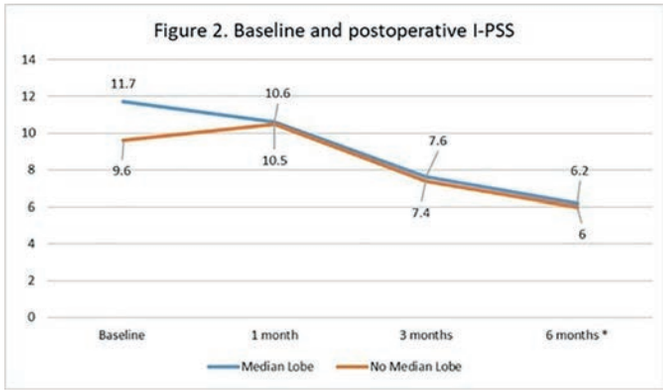

Figure 2. Baseline and postoperative I-PSS

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** OhioHealth Corporation Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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URINARY INCONTINENCE AFTER SALVAGE RADICAL PROSTATECTOMY. RISK FACTORS AND DIFFERENCES BETWEEN OPEN AND ROBOTIC APPROACH IN A HIGH VOLUME SINGLE CENTER.

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HYPOTHESIS / AIMS OF STUDY

Prostate cancer (PC) represents the most commonly diagnosed non-cutaneous cancer in men. Approximately, 30% of the patients who receive external beam radiation therapy or brachytherapy (BT) for localized prostate cancer, will undergo biochemical recurrence within the first five years after treatment. Approximately 20 to 30% of patients who recurrence after radiation therapy still have a localized disease with a potential benefit from salvage therapy with curative intent. Salvage radical prostatectomy (SRP) represents a challenge due to the technical difficulties involved, and postoperative complications that affects the quality of life of patients. Urinary incontinence rates were identified, at one and two years of follow-up, and risk factors for urinary incontinence (UI) were identified in open and robotic approaches in a high volume single center.

STUDY DESIGN, MATERIALS AND METHODS

Retrospective analysis of 68 electronic medical records of patients who underwent open (46) and robotic (22) SRP at a single high-volume center for relapsed PC, between May 2004 and June 2017. All patients underwent confirmatory prostate biopsy prior to SRP.

Data was collected from our electronic medical record and prospective database.

Patients who had at least one year of follow-up were included.

Continence was assessed at 12 months and defined as the use of no pads. Mild incontinence was defined as the use of 1 pad, moderate: 2 pads and severe 3 or more pads per day.

Demographic data is presented in Table 1.

Univariate analysis was performed by logistic hazard regression. Regression results were expressed as odds ratio (OR) with 95% confidence interval (CI 95%). All of the analyses were considered significant at a two-tailed P-value of ≤0.05.

All statistical tests were performed using statistical software SPSS 23.0TM for Microsoft (SPSS Inc; IBM, Chicago, IL) and STATA 8.0TM version for Microsoft (Statacorp LP, College Station,TX).

RESULTS

At one year, 18 patients (26.4%) presented UI. The UI rate in open surgery was 34.2% (16/46) and in the robotic approach, 9.1% (2/22) (p 0.01).

The open approach was a predictor of UI (OR 5.9, 95% CI 1.2-28, p 0.002). In 6 cases (8.8%) UI was severe, all were open surgeries (13%), OR 7.2 (95% CI 0.3-134, p 0.184). For this degree of UI, urethro-vesical anastomosis stenosis was a predictor of UI (OR 7.2, 95% CI 1-52, p 0.05), as well as the time to probe extraction (OR 1.3, 95% CI 1-1.7, p 0.05).

Of 67 patients followed at 2 years, 17 (25.4%) presented UI. The open approach remained as a predictor of UI, (OR 5, 95% CI 1.03.24, p 0.046), as well as hypertension (OR 3.5, 95% CI 1-12.3, p 0.049) and BT (OR 4.8, 95% CI 1.1-20).

INTERPRETATION OF RESULTS

In SRP, the open approach increases the risk of UI 5 times, both at one year and two years of follow-up, compared to the robotic approach. At one year, urethrovesical anastomosis stenosis and time to probe removal were predictive factors for severe UI. Both the history of hypertension and brachytherapy were predictive factors of UI in the long-term follow-up.

CONCLUDING MESSAGE

After Salvage Radical Prostatectomy, open approach vs robotic represents a Risk Factor for urinary incontinence.

FIGURE 1

	Total (n=68)
Age, (SD)	63,8 (5.9)
Approach (%)	
Open	46 (67,6)
Robotic	22 (32.4)
Radiotherapy Subtype (%)	
Brachytherapy	9 (13.2)
3 D External Beam Radiation Therapy	54 (79,4)
Intensity Modulated Radiotherapy (IMRT)	5 (7.4)
Prostate Volume, (SD)	24.2 (21.2)
Positive Surgical Margin (%)	20 (29.4)
Tumor Staging (%)	
T2	23 (33.8)
T3a	20 (29.4)
T3b	21 (30.9)
T3b N1 M0	4 (5.9)
Surgical Time, minutes, (SD)	193,2 (40.2)
Anastomotic stricture (%)	6 (8.8)
Diabetes Mellitus (%)	10 (14.7)
Hypertension (%)	37 (54.4)
Obesity (%)	4 (5.9)
Time to probe removal (DE)	16.7 (4.1)

REFERENCES

1. Gontero, P. et al. Salvage radical prostatectomy for recurrent prostate cancer: morbidity and functional outcomes from a large multicenter series of open versus robotic approaches. J. Urol. 101097JU0000000000000327 (2019)
2. Clery R, Grande P, Seisen T. Outcomes after salvage radical prostatectomy and first-line radiation therapy or HIFU for recurrent localized prostate cancer: results from a multicenter study. World J Urol. 2019
3. Lepor H and Kaci L: The impact of open radical prostatectomy on continence and lower urinary tract symptoms: a prospective assessment using validated self-administered outcome instruments. J Urol 2004; 171: 1216.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité de Etica Hospital Italiano de Buenos Aires **Helsinki** Yes **Informed Consent** Yes

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INVOLVEMENT OF AUTOPHAGIC DYSREGULATION IN PROSTATIC ENLARGEMENT WITH CHRONIC INFLAMMATION IN HIGH FAT DIET INDUCED OBESITY RAT MODEL

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HYPOTHESIS / AIMS OF STUDY

There are increasing evidence that indicates positive relationship between metabolic syndrome and symptom severity in benign prostatic hyperplasia (BPH). However, the underlying pathophysiological mechanism is still unclear. Metabolic syndrome is known to induce oxidative stress in several tissues which can lead to chronic inflammation (1). Also, It has been reported that oxidative stress can interfere the autophagic process, resulting in augumentation of obesity-related pathologies in multiple organs (2) and that SQSTM1/p62, which is an autophagy receptor, has anti-inflammatory effect (3). However, it is uncertain whether autophagic system is inhibited in the prostate involved in obesity or not. Therefore we investigated changes in gene expression of SQSTM1/p62 and its related inflammatory cytokines in the prostate using high fat diet induced obesity rat model.

STUDY DESIGN, MATERIALS AND METHODS

Male Wistar rats (8 weeks old) were divided into a normal diet group (ND, n=5) and a high fat diet induced obesity group (HFD, n=5). The high fat diet contains 32% fat. After the rats were maintained on these diets for 12 weeks, voiding behavior analysis was performed by metabolic cage system to analyze single voided volume and voiding frequency. The prostate was harvested after voiding behavioral analysis to investigate changes in prostate volume, histological profile and mRNA expression of SQSTM1/p62, IL1β, NLRP3, TGFβ1 by qPCR. Furthermore, to detect localization of autophagosome expression in the prostate, immunohistostain-

ing for LC3 (Microtubule-associated protein 1 light chain 3) was performed.

RESULTS

Prostate volume was significantly increased in HFD compared to ND. In voiding behavior analysis there was significantly decreased single voided volume in HFD compared to ND. Gene expression of SQSTM1/p62 was significantly decreased in HFD compared to ND whereas mRNA expression level of IL1β, NLRP3, TGFβ1 was significantly increased in HFD compared to ND. Hematoxylin and eosin staining showed increased stromal infiltration of inflammatory cells as well as collagen fiber in HFD compared to ND. In immunohistostaining, a positive immunoreactivity was shown in inflammatory cell in the prostate in both group.

INTERPRETATION OF RESULTS

Rats with high fat diet exhibited not only significantly increased prostate volume and prostatic inflammation as evidenced by inflammatory cell infiltration in HE staining but also bladder over activity as evidenced by significantly decreased single voided volume compared to rats with normal diet. These results indicates high fat diet induced obesity can induce BPH in association prostatic inflammation, leading to bladder symptoms. Furthermore, in molecular expression profiles, there were significant upregulation in gene expression of IL1β, NLRP3, TGFβ1 whereas SQSTM1/p62 was significantly downregulated in HFD group compared to ND in association with LC localization in inflammatory cell in the prostate. These results suggested that oxidative stress by obesity induced activation of NLRP3 inflammasome as evidenced by increased expression of IL1β, which is an downstream cytokine, which lead to tissue inflammation and fibrosis in association with TGFβ1 upregulation. Furthermore, autophagic dysregulation in inflammatory cell is potentially implicated to chronic inflammation in the prostate because SQSTM1/p62, which is autophagic receptor, is reported to have anti-inflammatory effect.

CONCLUDING MESSAGE

High fat diet induced obesity model showed bladder over activity as well as prostatic enlargement with chronic inflammation in association with downregulation of SQSTM1/p62 and inflammatory cytokines, suggesting that autophagic dysregulation induced by obesity can lead BPH in association with prostatic inflammation. Therefore SQSTM1/p62 could be an potential molecular target of BPH with bladder symptoms.

FIGURE 1

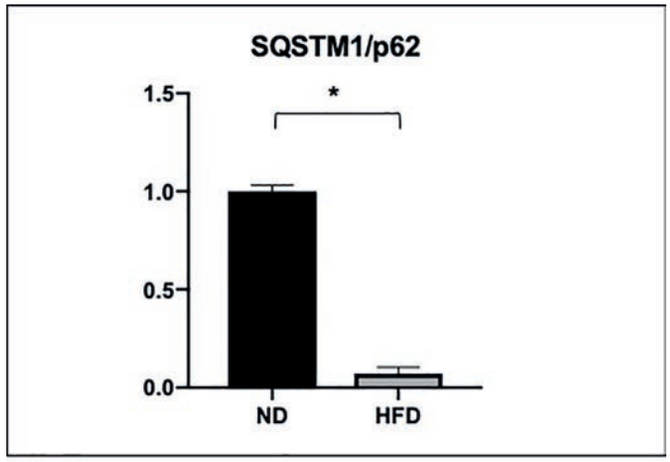

Figure.1
Relative mRNA expression of SQSTM1/p62 normalized to GAPDH in the prostate
Gene expression of SQSTM1/p62 in the prostate was significantly decreased in HFD group compared to ND group.
HFD ; high fat diet, ND ; normal diet, * ; $p < 0.01$ unpaired t test

REFERENCES

1. Tyagi P, Motley SS, Koyama T, Kashyap M, Gingrich J, Yoshimura N, et al. Molecular correlates in urine for the obesity and prostatic inflammation of BPH/LUTS patients. Prostate. 2018;78(1):17-24.
2. Namkoong S, Cho CS, Semple I, Lee JH. Autophagy Dysregulation and Obesity-Associated Pathologies. Mol Cells. 2018;41(1):3-10
3. Mylka V, Deckers J, Ratman D, De Cauwer L, Thommis J, De Rycke R, et al. The autophagy receptor SQSTM1/p62 mediates anti-inflammatory actions of the selective NR3C1/glucocorticoid receptor modulator compound A (CpdA) in macrophages. Autophagy. 2018;14(12):2049-64.

Funding None **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Oita university institutional animal care and use committee

SESSION 23 (PODIUM SHORT ORAL) - PELVIC FLOOR DYSFUNCTION 1
Abstracts 354-365
13:30 - 15:00, Brasilia 2
Chairs: Dr Anna Rosamilia (Australia), Lauri Romanzi (United States)

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FACTORS CONTRIBUTING TO RECURRENT OBSTETRIC FISTULAS POST-SURGICAL REPAIRS AMONG WOMEN

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HYPOTHESIS / AIMS OF STUDY

The high incidence of obstetric fistulas in sout east of India and in Sub-Saharan Africa result mostly from poor management of the pregnant woman.

Several factors may contribute to persistent incontinence after surgical fistula treatment.(1)

The aim is to Determine the factors involved in the recurrence of obstetric fistulas post-surgical repairs.

STUDY DESIGN, MATERIALS AND METHODS

This is a cross-sectional study which took place from October 1 to 31, 2019, using a convenience sample of 62 women diagnosed with obstetric fistulas. Data were obtained from patients' registers from outpatient consultations, emergency department as well as obstetric records, and any other hospital registers. These documents made possible to obtain necessary information on the women from their admission to the various centers of provenance until the day of the campaign. We used the interviews to supplement socio-demographic and clinical data. The physical examination included gynecological and urological assessments(2). Fistula types were determined using Kees Waldjik classification (1). Statistical analysis: Data were recorded using Microsoft Excel 2013 software, and analyzed with SPSS v.22 (Chicago, IL, USA). Continuous data were summarized using means and standard deviations whilst categorical data were presented as proportions (%) by means of tables or figures. Student's t-test was performed to assess differences between two means. Either Chi-square test with and without trend or Fischer's exact test was used to test the degree of association of categorical variables. The factors associated with the recurrence of obstetric fistulas were obtained using logistic regression models. Unadjusted odds ratios (ORs) were initially calculated to screen for inclusion in multivariate models while multivariate ORs (95% CI) were computed after adjusting for confounding univariate factors with a p-value <0.05 considered as significant.

RESULTS

The mean age of the patients was 31.0 ± 7.4 years (range 20-34 years). The majority of patients came from areas located far than 60 km (61.3%) in average while 25.8% of women were residing in areas located at a distance ≤30 km. The majority of participants (48.4%) were multiparous. Labor duration exceeded 64 hours for 64.5% of women. The majority of fistulas (45.2%) were of type 1. followed by type IIBb(42%). About less than 64.5% of the patients had fistulas of less than 2 cm. The most common location of fistula was trigonal (35.5%) followed by pericervical (32%) . Age ≥35 years ($p = 0.012$), FVV >2 Cm of dimension ($p = 0.001$), presence of vaginal septum ($p = 0.007$) and fibrosis ($p = 0.008$) were respectively 3.5-fold, 3-fold, 4-fold and 4.6-fold as likely to be associated with the recurrence of obstetric fistulas, leading to multiple surgical repairs. Other risk factors included labor duration >8h ($p<0.01$), hysterectomia ($p = 0.007$), and type III fistula ($p = 0.004$).

INTERPRETATION OF RESULTS

Recurrence of obstetric fistulas leading to multiple surgical repairs were found to occur in older women who developed type III fistulas, whose labor period was prolonged. Fibrosis developed post-surgery was also a major risk factor for subsequent surgical repairs. Hysterectomy was also seen to be frequently associated with fistulas with complicated initial repairs, hence leading to subsequent surgical procedures.

CONCLUDING MESSAGE

Labor duration should be monitored. Precautions must be taken to avoid complex fistulas and post-surgical development of fibrosis. Hysterectomy should be performed with caution to prevent the occurrence of fistulas during this surgical procedure.

FIGURE 1

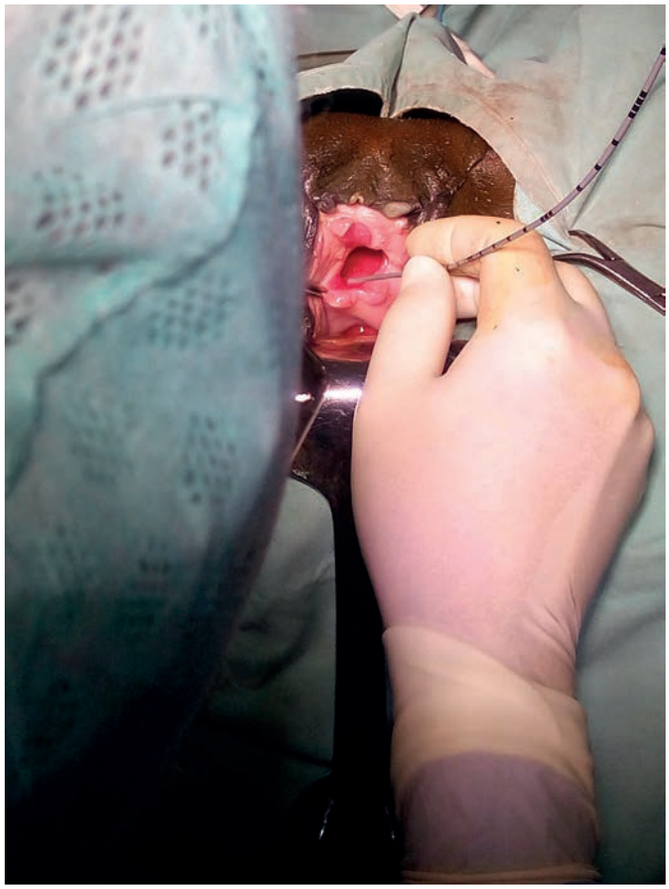

FIGURE 2

Tab 1. Factors associated with multioperability in patients with obstetric fistula.

Variables	Univariateanalysis p	Univariateanalysis OR (IC95%)	Multivariateanalysis p	Multivariateanalysis ORa (IC95%)
Age group				
<35 years		1		1
≥35 years	0,001	7,00(2,19-22,42)	**0,012**	3,47(1,71-17,01)
Multiparity				
No		1		1
Yes	0,025	3,25(1,69-5,28)	0,967	0,98(0,40-2,39)
KeesWaaldjik type III				
No		1		1
Yes	0,000	2,43(1,48-4,01)	0,215	1,56(0,65-2,34)
Vaginal septum				
No		1		1
Yes	0,000	10,80(2,85-20,87)	**0,007**	4,13(1,87-9,62)
Dimension of FVV>2 cm				
No		1		1
Yes	0,000	4,50(1,06-10,96)	**0,001**	3,15(1,61-6,98)
Intense fibrosis				
No		1		1
Yes	0,002	10,28(2,42-23,61)	**0,008**	4,61(1,83-6,37)

REFERENCES

1. Sjovelan S ET al. Surgical outcome of obstetric fistula : a retrospective analysis of 595 patients. Acta obstet GynecolScand. 2011 Jul; 90(7).753-60 doi: 10.1111/j.1600-0412.2011.01162. May 25.
2. Loposso et al. Predictors of recurrence and successful treatment following obstetric fistula surgery. Urology.2016 Nov; 97: 80-85 doi: 10.1016/J.Urology2016.03.079.EPUB 2016. Aug 2.

Funding UNFPA FUNDED THE OBSTETRIC FISTULA TREATMENT CAMPAIGN. **Clinical Trial** Yes **Public Registry** No **RCT** Yes **Subjects** Human **Ethics Committee** This study obtained the approval of ethics committee of our medicine faculty. **Helsinki** Yes **Informed Consent** Yes

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PREVALENCE AND CHARACTERISTICS OF DETRUSOR OVERACTIVITY WITH IMPAIRED CONTRACTILITY IN ELDERLY WOMEN: COMPARISONS AMONG THE COMMUNITY-DWELLING ELDERLY WITH NONNEUROGENIC LUTS

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HYPOTHESIS / AIMS OF STUDY

The symptoms of detrusor overactivity with impaired contractility (DOIC) are not a little encountered in clinical practice, however, its pathogenesis and clinical characteristics have not yet been clearly identified. Using large-scale, urodynamic database, we aimed to identify the prevalence and patient characteristics of DOIC in comparison with that of detrusor overactivity (DO) and detrusor underactivity (DU) in the community-dwelling elderly women with nonneurogenic lower urinary tract symptoms (LUTS).

STUDY DESIGN, MATERIALS AND METHODS

Based on a 11-year urodynamic database of the single institute, female elderly patients aged 65 or older who received a urodynamic evaluation for nonneurogenic LUTS were selected. Among these, data of 688 women were analyzed except for those who had impaired general health or could not perform daily tasks by themselves within 3 months prior to the examination, who had history of surgery or anatomical abnormality (urethral stricture, prolapse grade ≥3…) on the lower urinary tract, who were regularly using a catheter for urine drainage, or who could not void during a pressure-flow study (PFS). DOIC was defined when DO is observed in a filling cystometry and detrusor pressure at maximal flow (PdetQmax) is less than 30cmH2O and maximal flow rate (Qmax) is less than 10mL/s in a PFS. The prevalence rate of DOIC was identified and the characteristics of women with DOIC were compared with those with DO or DU only.

RESULTS

DOIC was identified at 5.5%, DO at 32.6% and DU at 13.1% in the total population. When age was divided by five years in order of age, prevalence rate of DOIC was 2.7%, 7.8%, 5.7%, and 13.9%, showing a significant increase with age ($p = 0.005$). The prevalence rate has also tended to increase in recent years, depending on the year in which the studies were

conducted. Compared to women with DO only, DOIC group had significantly smaller Qmax and voiding efficiency in free uroflowmetry (UFM), smaller volumes at first sensation at bladder filling, first desire to void, and strong desire to void, and smaller maximum cystometry capacity (MCC). However, there were no significant differences in patient age, amount of post-void residual (PVR), and detrusor compliance between the two groups. When compared to women with DU only, volumes at first sensation at bladder filling, first desire to void, and strong desire to void, and MCC were significantly smaller in those with DOIC. PdetQmax was significantly higher in this group than in DU only group. While, there were no statistical differences in patient age, Qmax, amount of PVR, and voiding efficiency in free UFM, and detrusor compliance between women with DOIC and DU only.

INTERPRETATION OF RESULTS

So far, the pathogenesis and patient characteristics of DOIC have not yet been clearly identified. We tried to determine the prevalence and patient characteristics of DOIC in comparison with that of DO and DU in the community-dwelling elderly women with nonneurogenic LUTS using large-scale, urodynamic database. While some urodynamic features were different between groups, the specific urodynamic features of women with DOIC were more similar to those of individuals with only DU than those with only DO.

CONCLUDING MESSAGE

The prevalence of DOIC in the community-dwelling elderly women increases with age, and urodynamic features of the elderly women with DOIC may be more similar to those of individuals with DU only than those with DO only. The amount of PVR does not reflect the characteristics of DOIC in this population.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** The Institutional Review Board of Seoul National University Bundang Hospital **Helsinki** Yes **Informed Consent** No

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OVERACTIVE BLADDER IN WOMEN: CORRELATION BETWEEN 24-HOUR BLADDER DIARY AND LOWER URINARY TRACT SYMPTOM SCORE QUESTIONNAIRE

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder (OAB), a multifaceted symptom complex, is most common in women and comprised of urinary urgency, frequency, nocturia and urge incontinence [1]. It is defined as a symptom complex due to its unknown etiology [2]. In this novel study, we aim to evaluate the correlation between symptom questionnaires and bladder diaries with respect to urgency void incidents (UVI) in women. This study was completed using a mobile app* in which patients completed the Lower Urinary Tract Symptom Score (LUTSS) questionnaire and a 24-hour bladder diary (24HBD) that documented each micturition accompanied by UVI.

STUDY DESIGN, MATERIALS AND METHODS

In this IRB approved study, an established database was searched to identify women ≥18 years of age who completed a 24-HBD and/or LUTSS questionnaire from 2015 through 2018. The LUTSS questionnaire is a validated 14 item symptom questionnaire consisting of a total and 6 sub scores – voiding dysfunction, storage symptoms, OAB, incontinence, nocturia and bother [3]. The OAB sub score is comprised of seven questions relating to OAB - urgency, frequency, urge incontinence, and bladder control. The score ranges from 0 - 24, with 24 being maximum symptom severity.

Data from OAB sub score of the LUTSS and 24HBD were contemporaneously matched within a two-week period. Women with significant changes in symptoms or management during the two-week period and/or had incomplete data entry were excluded. The 24HBD documents the time and volume of each void and whether it was accompanied by a UVI. The total number of voiding incidents in 24 hours accompanied by UVI was correlated with the OAB sub score using Pearson's correlation coefficient (r).

RESULTS

262 women completed the LUTSS questionnaire, of whom 145 had a contemporaneous 24HBD. 5 patients were excluded due to incomplete/inaccurate data entry. 140 female patients were included (mean age 54, SD 15) in the study. A scatter-plot of the number of UVI micturition incidents versus the OAB sub score is shown (Figure 1). Three significant observations were found: 1) The correlation between the UVI

and OAB sub score is a positive weak correlation, with a coefficient (r) = .13 of p< .01. 2) Some patients recorded up to 14 UVI but only reported mild symptoms with an OAB sub score of < 5. 3) Other patients reported no UVI but more severe symptoms with an OAB sub score of > 10.

INTERPRETATION OF RESULTS

The weak correlation between reported symptom scores and bladder diaries shows a lack of alignment between the perception of symptom severity and results from an objective tool, such as a bladder diary. Possible explanations for this include: 1) differences in patients' perception of symptoms, 2) variations of symptoms that are better illustrated by patients' recollection over a period of time rather than a time-limited diary, or 3) patients' difficulties in expressing personal experiences into a symptom score and bladder diary.

One weakness in this study is that only one 24HBD was utilized rather than the 3 day bladder diary used in most clinical studies. We accepted a lower test-retest reliability in return for a higher compliance rate and because of the well documented lower compliance with longer bladder diaries [3].

CONCLUDING MESSAGE

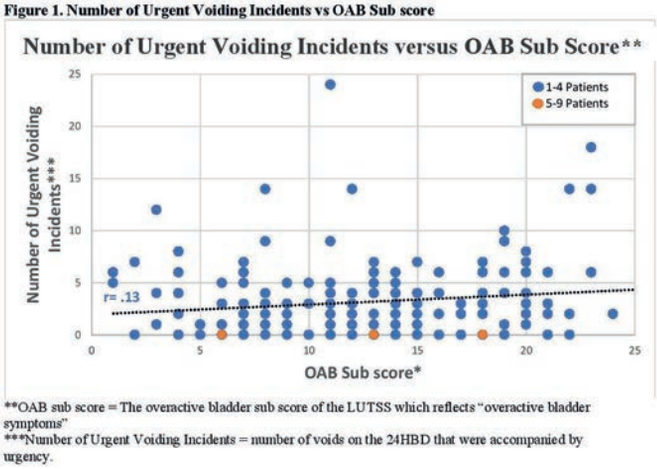
This study disclosed an unexpected disparity between the OAB sub scores of the LUTSS questionnaire and 24HBD due to a weak correlation. Based on this, patients' perceptions of symptom severity do not align with results from a more objective tool such as a bladder diary.

The 24HBD offers a snapshot of the patient's symptoms while the LUTSS reflects the patient's recollections over an extended time period. Clinical conclusions based on either instrument alone appear to be unreliable and should be interpreted with caution. We believe the two instruments are complementary. So, as clinicians - what is the best approach to evaluate patients: a questionnaire, bladder diary or both?

*WeShareUro by Symptelligence Medical Informatics LLC.

FIGURE 1

Figure 1. Number of Urgent Voiding Incidents vs OAB Sub score



**OAB sub score = The overactive bladder sub score of the LUTSS which reflects "overactive bladder symptoms"
***Number of Urgent Voiding Incidents = number of voids on the 24HBD that were accompanied by urgency.

Number of Urgent Voiding Incidents vs OAB Sub score

REFERENCES

1. Abrams P, Cardozo L, Fall M, et al. The standardization of terminology in lower urinary tract function: report from the standardization sub-committee of the International Continence Society. Urology 2003; 61:37-49
2. Blaivas, J. (2003), Overactive bladder: symptom or syndrome?. BJU International, 92: 521-522. doi:10.1046/j.1464-410X.2003.04445.x
3. Blaivas JG, Tsui JF, Mekel G, et al. Validation of the lower urinary tract symptom score. Can J Urol. 2015;22(5):7952-7958.

Funding Institute for Bladder and Prostate Research **Clinical Trial** No **Subjects** None

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DO WE NEED TO BETTER ASSESS PAIN IN UROGYNAECOLOGY?

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HYPOTHESIS / AIMS OF STUDY

There is no comprehensive questionnaire to assess pelvic pain in women. Chronic pelvic pain (CPP) accounts for 20% of women's health outpatient appointments, making it the most common indication for referral to secondary care (1). CPP is a debilitating condition which often hinders patient quality of life (QoL). It is difficult to identify whether pain is associated with, or separate to, other presenting symptoms such as those of the lower urinary tract. It is also important to fully assess pain quality and its impact on QoL to be able to plan clinical management and manage expectations. There is no single questionnaire assessing CPP. This study uses a single questionnaire to identify whether there is an associ-

ation between presence of pelvic organ symptoms and pelvic/body pain, such as dysuria, dysmenorrhoea and dyspareunia, and QoL scores in women.

STUDY DESIGN, MATERIALS AND METHODS

The questionnaire was developed using the ICS standardisation for terminology document following a literature review of established pain assessment questionnaires currently in use. Content validity of the new questionnaire was assessed in consultation with urogynaecology and urology consultants. Face validity was assessed in a pilot test with 20 patients attending outpatient clinic.

Pain location was assessed using body maps. Pain triggers such as bladder habits, menstruation and sexual intercourse were assessed using frequency and severity scales. Effect of pain on lifestyle was assessed using frequency scales and converted into a QoL score, which ranged from 0 – 48, with a higher score indicating a lower QoL. These scores were then converted into categories: good (0-10), average (11-20), poor (21-30), very poor (31-40) and extremely poor (41-48).

All women attending the urogynaecology outpatient department at a large tertiary centre were asked to anonymously complete a newly devised questionnaire assessing pelvic pain, its exacerbating factors, and its impact on QoL. Completed questionnaires from women with no pain became the control group.

Statistical analysis was performed using SPSS version 26.

RESULTS

In total, 75 women completed the questionnaire. Of these, 57 (76%) reported having pelvic pain and 18 (24%) described no pelvic pain and were the control group.

Of the women with pelvic pain:

• 3% reported no dysuria, dysmenorrhea or dyspareunia.

• 20% reported 1 associated symptom (dysuria (92%), dysmenorrhea (8%))

• 56% reported 2 associated symptoms (dysuria and dysmenorrhea (30%), dysuria and dyspareunia (61%), dysmenorrhea and dyspareunia (9%))

• 20% reported 3 associated symptoms of dysuria, dysmenorrhea and dyspareunia

Women complaining of dysuria associated with dysmenorrhea or dyspareunia had a higher QoL score of 20 (average). Dysuria specifically, or associated with both dysmenorrhea and dyspareunia, had a reported average QoL score of 20 (average). Dysmenorrhea exclusively or associated with dyspareunia was correlated with a QoL score of 7 (good) and 15 (average) respectively. (Table 1)

INTERPRETATION OF RESULTS

The presence of dysuria, dysmenorrhoea and/or dyspareunia significantly decreases QoL compared with controls, and a combination of two or more of these symptoms significantly decreases QoL further. Interestingly, women with three types of pain were associated with a lower QoL score than women with 2 types of pain (20 vs 25, 25 and 15).

Women reporting one or more types of pain had a higher QoL score than woman who did not report any pain (Chi-square = 26.182, $p<0.005$).

Women reporting 2 or more types of pain had a higher QoL score than women who only had one type of pain (Chi-square = 14.633, $p<0.005$).

Women reporting 2 or more types of pain had a lower QoL score than women who had 3 types of pain (Chi square = 3.017, $p=0.594$).

CONCLUDING MESSAGE

Pelvic pain is common in women and frequently occurs with dysuria, dysmenorrhoea and dyspareunia. The most common combination of symptoms reported with pelvic pain in women attending urogynaecology outpatient clinic was dysuria with dyspareunia, reported in 27% of women. Women with pelvic pain who report symptoms of dysuria, dysmenorrhoea and dyspareunia have a poorer QoL than women without these symptoms.

QoL does not worsen with increasing categories of pain reported. This suggests different sources of pain may have differences in impact on the woman. This new questionnaire allows for a detailed assessment and understanding of pelvic pain and its impact on patient QoL. It could also be used to direct and evaluate the success of pelvic pain management, as well as being a valuable validated tool in research.

FIGURE 1

Table 1: Pelvic pain symptoms and pelvic pain QoL			
	Frequency of women (% of total women)	Average QoL score	QoL category
Dysuria	11 (15%)	20	average
Dysmenorrhoea	1 (1%)	7	good
Dysuria and dysmenorrhoea	10 (13%)	25	poor
Dysuria and dyspareunia	20 (27%)	25	poor
Dysmenorrhoea and dyspareunia	3 (4%)	15	average
Dysuria and dysmenorrhoea and dyspareunia	12 (16%)	20	average
No symptoms	18 (24%)	0	good

REFERENCES
1. BMC Public Health. 2006 Jul 6;6(1):177.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It was a service evaluation **Helsinki** Yes **Informed Consent** Yes

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PREVALENCE OF CHILDHOOD TRAUMA AND ITS ASSOCIATION WITH LOWER URINARY TRACT SYMPTOMS IN WOMEN AND MEN

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HYPOTHESIS / AIMS OF STUDY

To describe the number and type of childhood traumas reported by women and men presenting with lower urinary tract symptoms (LUTS) and to describe associations between LUTS and the number, type, and self-reported impact of trauma experiences. We hypothesized that childhood traumatic events are common and associated with a person's experience of LUTS.

STUDY DESIGN, MATERIALS AND METHODS

This is a cross-sectional analysis of data prospectively collected in the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) Observational Cohort Study. Women and men with LUTS were recruited from 6 US tertiary centers and administered the LUTS Tool and Childhood Trauma Events Scale (CTES). The validated 22-item LUTS Tool surveys presence and bother of LUTS. The CTES asks about 6 traumatic events (death in family, divorce, sexual assault, violence, major illness, and other) that occurred prior to age 17 and their impact (rated 0-7, range 0-42) on the individual's life. Baseline LUTS Tool results were combined to create a LUTS Severity Score, using the Euclidean distance between all questions, weighted by the inverse of the ratio of average correlation of each item to average correlation between all items, to account for redundancy between items. Comparisons were made using Kruskal-Wallis and Chi-square tests, and Pearson correlations were used to assess associations between scores.

RESULTS

1011 participants (520 [51%] women and 491 [49%] men) completed the CTES and LUTS Tool. Mean±SD age of the participants was 58±14, 82% were Caucasian and 66% had college degree or higher. Death of a close friend or family member, followed by parental separation, were the most commonly reported traumas in both women and men; however, 75% of women reported at least 1 trauma compared to 64% of men ($p<0.001$). Women were more likely to have experienced >3 traumatic events (26% vs 15%, $p<0.001$) and childhood sexual trauma (23% vs 7%, $p<0.001$). Women also reported a higher life impact from those traumatic events (median CTES score 10, IQR 5-15) compared to men (6, IQR 4-12, $p<0.001$). Of participants who experienced at least 1 childhood trauma, both women and men who reported sexual trauma were more likely to have reported at least 1 additional trauma than those with a different type of childhood trauma (women: 75% vs 51%, men: 81% vs 50%, $p<0.001$ for both).

Women with childhood sexual trauma had higher LUTS tool scores compared to those without (47±14 vs 42±14, $p=0.003$), and women with any childhood trauma had higher LUTS tool scores compared to those without (45±14 vs 40±12, $p=0.008$). These associations were not present for men. Among participants who experienced any childhood trauma, total CTES scores correlated with the severity of their LUTS ($r=0.36$ and 0.61, both $p<0.001$, for women and men respectively). For those with past sexual trauma, the self-reported impact of this trauma and severity of LUTS was not correlated ($r=0.14$, $p=0.19$ in women and $r=0.33$, $p=0.08$ for men).

INTERPRETATION OF RESULTS

While childhood trauma is common in both men and women presenting with LUTS, women are more likely to have experienced sexual trauma, multiple traumas and report a greater impact on their life due to trauma. In women, the experience of sexual trauma is specifically associated with more LUTS, although there is not a direct correlation between the patient's self-reported impact from her trauma and her LUTS severity score. In men, there is a stronger correlation between the reported impact of trauma on their lives and the severity of their LUTS symptoms.

CONCLUDING MESSAGE

Some form of childhood trauma is present in most patients presenting with lower urinary tract symptoms and is associated with the number and severity of lower urinary tract symptoms experienced by the patient. Trauma should be further explored as a mediator of the severity and response to treatment for patients with LUTS.

Funding NIH **Clinical Trial** No **Subjects** Human **Ethics Committee** Multicenter IRBs at 6 institutions **Helsinki** Yes **Informed Consent** Yes

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RADIATION INDUCED BLADDER DYSFUNCTION IN WOMEN DURING THE ACUTE AND CHRONIC PHASES FOLLOWING PELVIC RADIOTHERAPY IN A PROSPECTIVE OBSERVATIONAL COHORT

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HYPOTHESIS / AIMS OF STUDY

Radiation induced bladder dysfunction is a common problem after gynecologic oncology radiation. Genitourinary radiation toxicity in the acute phase includes urinary urgency, frequency, nocturia, dysuria, bladder spasm, urothelial ulceration and hemorrhage with an incidence of 20 to 80% depending on dose of radiation. Following an asymptomatic latent period, epithelial atrophy, reduction in capacity, loss of compliance and bladder necrosis manifests as a result of progressive vascular damage, obliterative arteritis, ischemia and fibrosis. Long term urinary adverse events following radiotherapy represent a significant disease burden. Given the close proximity of the cervix and vaginal cuff to the bladder, RTOG grade 1 and 2 urinary adverse events are present in up to 45% of patients at 5-years and major complications related to grade 3 adverse events noted in 14% of patients at 20-years. Our overarching aims were to prospectively (i) characterize changes in storage and voiding dysfunction during the acute phase of radiotherapy [brachytherapy, combination, external beam (EBRT)] in women treated with radiotherapy for endometrial and cervical cancer; and (ii) systematically quantify the burden of storage and voiding dysfunction in women presenting to a moderate volume practice specializing in chronic radiation induced bladder dysfunction.

STUDY DESIGN, MATERIALS AND METHODS

Women undergoing (i) pelvic radiotherapy and (ii) presenting with bladder complaints following pelvic radiotherapy were prospectively enrolled in an observational cohort. Women with endometrial and cervical cancer treated with radiotherapy [brachytherapy, combination, EBRT] were enrolled from radiation oncology clinic prior to first radiation exposure, with plan for at least 1-year follow-up to assess changes in lower urinary tract symptoms following exposure to radiation. In order to assess long term changes following radiotherapy, women with chronic radiation induced bladder dysfunction were enrolled from urology clinic. History was recorded and participants answered self-administered questionnaires including the American Urological Association Symptom Score (AUASS), the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms (ICIQ FLUTS), and the 12 item short form health survey (SF12). Primary outcome was change in LUTS before, during and after radiotherapy. Data were analyzed using Statistical Analysis System software (SAS, Cary, NC) and presented as mean +/- standard deviation. Spearman's rho was used to test for non-parametric correlations between corresponding questionnaire items. A p-value <0.05 was considered statistically significant.

RESULTS

Following IRB approval, twenty women signed consent and were prospectively enrolled over the 10 month study period (May 2019 to February 2020). There were a total of 40 unique patient encounters and 38 complete questionnaire sets which were completed (AUASS, ICIQ FLUTS, SF12). Mean age was 59.1 +/- 14.8 years (range 19-77). Cancer diagnoses included: 4 cervical cancer, 13 endometrial cancer, and 3 other pelvic malignancies (ovarian cancer, sarcoma). Radiotherapy treatments included 11 women who underwent brachytherapy, 3 EBRT, and 6 combination radiotherapy (brachytherapy + EBRT). Prior pelvic surgical treatments included 14 women treated with radical hysterectomy (with bilateral salpingo-oophorectomy and pelvic lymph node dissection). There were 2 women who were pre-menopausal, and the remaining 18 women were post-menopausal at time of radiotherapy. Women previously had a median number of 2 (range 0-8) pregnancies and 2 (range 0-5) deliveries. Mean BMI was 30.1 +/- 8.5 kg/m^2.

For the LUTS storage domains (daytime frequency, urinary urgency, nocturia), there were differences in the magnitude of change over time when contrasting the AUASS against the ICIQ-FLUTS (Figure 1). Daytime frequency (AUASS #2, FLUTS #5) was decreased by 1-2 AUASS points in approximately 50% of the women during brachytherapy, meanwhile FLUTS score increased in most patients over time (AUASS #2 vs. FLUTS #5 Spearman r=0.443, p=0.005). Similarly for the urgency domain (AUASS #4, FLUTS #3) AUA scores had dramatic 2 to 4 point changes in all directions, while FLUTS scores were more consistently changed across patient groups, and

were worse in combined radiotherapy (AUASS #4 vs. FLUTS #3 Spearman r=0.700, p<0.001). For the nocturia domain (AUASS #7, FLUTS #2) there were high baseline AUA scores in the brachytherapy group, where some had paradoxical improvement and some worsened following radiotherapy, meanwhile the FLUTS scores appeared more consistent (AUASS #7 vs. FLUTS #2 Spearman r=0.832, p<0.001). Generally, women undergoing combination radiotherapy had worse or unchanged nocturia during treatment, and following radiotherapy there was consistently greater nocturia reflected in both the AUASS and FLUTS.

For the LUTS voiding domains (weak stream, urinary hesitancy, straining, intermittency), there were again differences in the magnitude of change over time when contrasting the AUASS against the ICIQ-FLUTS (Figure 2). Urinary hesitancy (FLUTS #6) was not a common problem during brachytherapy, however manifest more long-term after EBRT and combination radiotherapy, although this may reflect a referral pattern for these groups. Similarly, straining (AUASS #6, FLUTS #7) was not a common problem during brachytherapy, as reflected by FLUTS scores, but was more pronounced during and after EBRT and combination radiotherapy. Straining scores were closely correlated (AUASS #6 vs. FLUTS #7 Spearman r=0.753, p<0.001). Intermittency domain (AUASS #3, FLTUS #8) scores fluctuated over the acute time course, with brachytherapy group having fairly high AUA baseline scores which seemed to improve during/after radiotherapy, meanwhile FLUTS scores did not show this trend through the course of radiotherapy. Women undergoing combination radiotherapy had higher AUA scores, but only a mild increase in FLUTS scores during radiotherapy, meanwhile at long term follow-up after EBRT there were consistently higher scores in both the AUASS and FLUTS. Intermittency scores were closely correlated (AUASS #3 vs. FLTUS #8 Spearman r=0.827, p<0.001).

For the LUTS incontinence domains, women had relatively high incontinence scores at baseline (FLUTS #9-12). There were paradoxical changes in incontinence score during/after brachytherapy, discordant with expected pathophysiology. Combination treatment was associated with increased or no change in incontinence during radiotherapy, meanwhile on long-term follow-up combination and EBRT women usually had high incontinence scores, although this may reflect a referral pattern. Bladder pain (FLUTS #4) was temporarily increased during brachytherapy and combination radiotherapy, whereas on long-term follow-up bladder pain was much greater in each of these groups. For the overall quality of life domains, perception of overall health (SF12), was reported as good or very good by most brachytherapy patients, with no clear trend during treatment and improvement after treatment has ended (Figure 2). Combination radiotherapy and EBRT patients had generally worse perception of overall health (SF12) and AUASS QOL, and overall for all groups scores between these domains were moderately correlated (AUASS QOL vs. SF12 Spearman r=0.450, p=0.005).

INTERPRETATION OF RESULTS

In women who underwent brachytherapy and combination radiotherapy, the ICIQ-FLUTS storage and voiding domains scores were more consistent than the AUA scores with respect to the expected pathophysiology of radiation induced bladder dysfunction. Incontinence was prevalent at baseline, during and after radiotherapy. Pain was mostly a problem for combination radiotherapy and EBRT. Perception of overall health was generally better with brachytherapy than in combination or EBRT groups. Paradoxical changes in LUTS scores observed over the course of radiotherapy warrant further clinical discussion and clarification should be sought in women regarding changes in LUTS before, during and after radiotherapy.

CONCLUDING MESSAGE

Both FLUTS and AUA scores have utility at characterizing change in storage, voiding and incontinence during the course of radiotherapy. Classically radiotherapy has been associated with urinary urgency, frequency and worsening incontinence, which appear to be better captured by the FLUTS questionnaire. Both the AUASS and FLUTS demonstrate paradoxical changes over time which warrants further research.

FIGURE 1

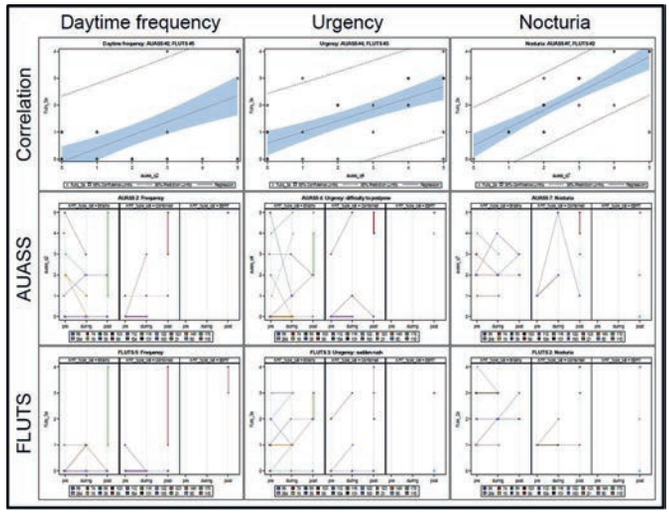

Figure 1: Change in storage domain symptom scores over time following radiotherapy [brachytherapy, combination, external beam (EBRT)] and overall correlation between AUASS versus FLUTS (daytime frequency, urgency, nocturia).

FIGURE 2

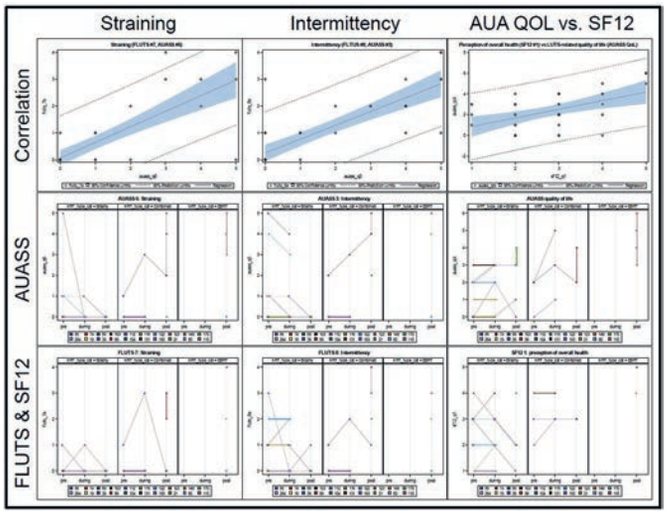

Figure 2: Change in voiding domain symptom scores over time following radiotherapy [brachytherapy, combination, external beam (EBRT)] and overall correlation between AUASS versus FLUTS (straining, intermittency) and SF12 (perception of overall health)

Funding NIH 1L30DK115056-01, Seed Grant **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional IRB protocol # 45362 **Helsinki** Yes **Informed Consent** Yes

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SPORT AND PELVIC FLOOR DYSFUNCTION IN MALE AND FEMALE ATHLETES: A SCOPING REVIEW

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HYPOTHESIS / AIMS OF STUDY

The aim of this scoping review is to systematically map and summarize the literature in order to identify the available evidence concerning pelvic floor dysfunction (PFD) among athletes.

STUDY DESIGN, MATERIALS AND METHODS

This scoping review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews [1] and the Joanna Briggs Institute methodology [2].

Inclusion criteria: any studies involving male and female athletes of any age and performance level. Studies dealing with any PFD, according to the ICS-IUGA Standards Terminology, and any type of sport were included. Any context and setting were considered for inclusion. MEDLINE, Cochrane Central, Scopus, CINHAL, Embase and PEDro database were searched from inception to March 2020. Additional records were identified through searching in grey literature (e.g. Google scholar, direct contact with experts in the field of pelvic floor dysfunction and sport medicine) and the reference lists of all relevant studies. No study design and language restrictions were applied. Two reviewers independently screened all abstracts and full-text studies for inclusion. An ad-hoc data collection form was developed by the research team to extract the characteristics of included studies.

RESULTS

2609 records were identified with an initial search. 99 studies met criteria for inclusion. [Figure 1]

The number of studies and the interest about the topic increased over the years. In particular, 6 studies were published between 1990 and 1999, 23 in the years 2000-2009 and 70 between 2010 and March 2020.

United States and Brazil yielded the largest number of publications (n=26; n= 16, respectively). The majority of study design were cross-sectional (n=70), while 17 were narrative review.

Participants represented a variety of sport participation level: 21 studies focused only in elite athletes and 6 in amateur/recreational athlete. In 50% of cases performance level is not specified. The target study population included female athlete (n= 82) practicing multiple sports (n= 57).

Considering studies that focused only in one sport, cycling (n=11), running (n=5) and crossfit (n=5) were the most investigated.

Among male athletes, 12% of studies explored pelvic floor disfunction in this population. Only 5 studies included both genders.

Urinary incontinence was the most common pelvic floor symptom; it is considered in 64 studies. 25 studies reported results about multiple PFD.

There is limited evidence related to male population, certain sports and other PFD (e.g. anal incontinence, pelvic organ prolapse, pelvic pain).

INTERPRETATION OF RESULTS

Pelvic floor dysfunction among athletes is an important medical issue, but what is known from the existing literature?

This scoping review highlighted a broad spectrum of studies dealing with sport and PFD.

Clinicians addressing musculoskeletal disorders and sports medicine should be encouraged to assess the presence of potential pelvic floor dysfunction in all athletes, both male and female. Not only as regards the high impact sports. From a researcher's prospective, further research is needed to better evaluate the overall pelvic floor among athletes, in a larger number of sports and more specifically in male athletes.

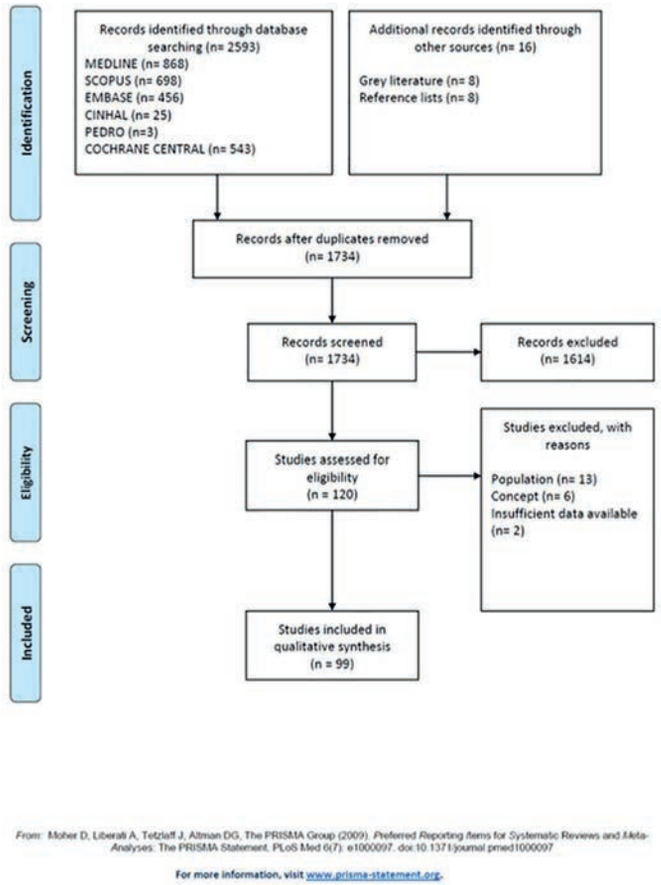
CONCLUDING MESSAGE

This study is the first scoping review to provide a comprehensive overview of the topic.

Pelvic floor disfunction among athletes is an evident issue that should be carefully evaluated by clinicians.

The sharp rise in published work in recent years is encouraging, however gaps in the literature are still evident.

FIGURE 1



PRISMA Flow Diagram

REFERENCES

1. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Ann Intern Med 2009;151(4):264-9
2. The Joanna Briggs Institute Reviewers' Manual 2015: Methodology for JBI Scoping Reviews. Adelaide, Australia: Joanna Briggs Institute; 2015 [Available from: http://joannabriggs.org/assets/docs/sumari/Reviewers-Manual_Methodology-for-JBI-Scoping-Reviews_2015_v2.pdf accessed 18th March 2020]

Funding None **Clinical Trial** No **Subjects** None

361 www.ics.org/2020/abstract/361

EVALUATION OF THE EFFECT OF ABDOMINAL SACROCOLPOPEXY ON URETHRAL ANATOMY AND CONTINENCE MECHANISM USING DYNAMIC MRI

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HYPOTHESIS / AIMS OF STUDY

Treatment of Pelvic organ prolapse (POP) associated with stress urinary incontinence (SUI) is a surgical challenge. Surgeons may perform combined prolapse and incontinence surgery or may correct prolapse first and evaluate incontinence afterwards. We present a prospective study to evaluate the effect of ASC on urethral anatomy and continence using Dynamic MRI

STUDY DESIGN, MATERIALS AND METHODS

Twenty females with concomitant apical prolapse and SUI due to urethral hypermobility were included. Patients with fixed urethra or ISD were excluded. All patients underwent ASC operation as a sole treatment without anti-incontinence procedure. Patients were informed that they may need anti-incontinence procedure afterwards.

Symptom-specific questionnaires were administered in the form of Urogenital Distress Inventory (UDI-6), International Consultation on Incontinence Questionnaire short form (ICIQ-UI-SF) to evaluate incontinence, and Pelvic Organ Prolapse and Incontinence Sexual Function questionnaire (PISQ-12) short form to evaluate sexual function. All patients underwent urodynamic study (UDS) in the form of free uroflowmetry with PVR estimation, and pressure flow study with estimation of Valsalva leak point pressure (VLPP) before and after surgery.

The following parameters were assessed in the MRI:

1-Degree of bladder descent: which is the vertical distance between PCL & the bladder base.

2-Posterior urethro-vesical angle (PUV): It is the angle between the urethral axis & the posterior border of the bladder base or the trigone (15), normally it is less than 115º

3-Angle of urethral inclination (UI): It is the angle of the urethral axis in relation to the vertical plane, normally it is less than 30º (17).

4-Leading edge of the vaginal cuff (in cases of previous hysterectomy) or the location of the cervix (in cases of preserved uterus) in relation to the PCL

5-The anorectal junction in relation to the PCL

RESULTS
Mean age was 53 years. All patients had apical prolapse; 4 with cystocele, and 5 with rectocele. Urethral hypermobility was positive in all patients. After performing ASC, all patients reported significant improvement of all prolapse and incontinence questionnaires as well as QoL and sexual function. Significant improvement of incontinence parameters on dynamic MRI (bladder neck descent, posterior urethrovesical angle and urethral inclination angle) was observed after ASC. Similarly, significant change in the position of the leading edge of prolapse and the anorectal junction was observed.

INTERPRETATION OF RESULTS
18 patients had no leak postoperatively (cured from SUI). They had a mean of 86.16 ± 13.76 cmH2O. Only two patients had postoperative SUI; however, they both reported improvement of their SUI. They showed improvement of their VLPP (mean of 86 ± 2 pre-operatively, which became 101 ± 8.49cmH2O). One of them underwent TOT insertion as she was bothered by her symptoms and she was continent after TOT. The other patient refused to undergo TOT insertion as her SUI symptoms were occasional and were of no bother to her.

CONCLUDING MESSAGE
In patients with prolapse and urethral hypermobility, ASC may return the bladder neck and urethral anatomy towards normal as proved by dynamic MRI. However, further studies on a larger number of patients with a longer follow up period are required

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Alexandria University Ethics committee **Helsinki** Yes **Informed Consent** Yes

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PELVIC FLOOR MUSCLE MECHANICAL PROPERTIES IN FEMALE RUNNERS WITH AND WITHOUT RUNNING-INDUCED URINARY INCONTINENCE: A PRELIMINARY ANALYSIS

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HYPOTHESIS / AIMS OF STUDY
More than one in five women experience the embarrassment of urine leakage while exercising, and this is a substantial barrier to exercise [1]. As many as one in three women with urinary incontinence report that they limit their physical activity due to their incontinence; this includes not exercising at all (11.6%), exercising less (11.3%) or changing the type of exercise they perform (12.4%) [2]. Urine leakage during exercise is experienced predominantly as stress urinary incontinence (SUI), which is characterized by urine leakage which occurs when bladder pressure exceeds urethral closure pressure in the absence of detrusor contraction. As with SUI in general, neuromuscular damage and structural damage to the urethra and the levator ani muscles (PFMs) as well as their associated connective tissues are likely implicated, yet repetitive loading of the pelvic floor may, over a bout of exercise, lead to muscle fatigue or tissue strain as contributing factors. The main goal of this study is to understand the mechanistic factors associated with SUI when it is experienced predominantly during exercise. More specifically, we aim to investigate differences in and compare the effects of an acute bout of running on pelvic floor morphology and function between female runners who do and do not regularly experience urinary incontinence while they run.

STUDY DESIGN, MATERIALS AND METHODS
This paper reports a preliminary analysis of data from an ongoing cross-sectional, observational case-control study which received approval from the local institutional research ethics board. Women aged 18 years and over with no known risk factors related to physical activity (PAR-Q+), who run at least 5 km in under 50 minutes, twice per week and more than 10km a week, and who have done so for at least one year, are being recruited into two cohorts: females who regularly (≥ 1 per month) experience urine leakage while exercising, and those who do not. An a priori power calculation estimated that a minimum of 26 women per group would be necessary to detect within-group differences. Women are being recruited from local running groups and physiotherapy clinics, and are excluded if they have a history of urogenital surgery, symptoms of the female athlete triad, dyspareunia, a neurologic disorder, are pregnant or have delivered a baby within the previous year. All eligible females provide demographic information and are asked to complete the International Consultation on Incontinence - Female Lower

Urinary Tract Symptoms (ICIQ-FLUTS) and the International Physical Activity Questionnaire (IPAQ).

All participants undergo an ultrasound imaging evaluation of their pelvis. 3D volume images of the levator ani are acquired using a transperineal probe while participants remain in quiet standing. Next, participants are instrumented with an intravaginal dynamometer in standing and are asked to perform three repetitions of a maximal voluntary contraction (MVC) using a dynamometric anteroposterior diameter of 35mm. In supine, passive forces are recorded while the anteroposterior diameter of the dynamometer arms moved from 15mm to 40mm at a constant speed of 50mm/s. Pelvic floor muscle elongation is held for 7s at the maximum (40mm) diameter before the arms return to their initial position. Three repetitions of passive tissue elongation are performed. Participants then run on a treadmill for 37 minutes using a standardized protocol: 2 minutes at 7km/h, 2 minutes at 10 km/h, 2 minutes at 15 km/h, 30 minutes at a self-selected pace, followed by 30 seconds at 10 then 7 km/h. Following the run, the ultrasound imaging and dynamometer protocols are repeated. Outcomes include levator hiatal area at rest, and maximum relative peak forces and rate of force development during MVC and during tissue elongation. Stress relaxation is measured using the force data acquired by the dynamometer arms once they are opened to 40mm and held for 7s, quantified using the coefficient of the exponential decay function. Based on data acquired to date, all outcomes were tested for normality using the Kolmogorov-Smirnov test. A mixed-model ANOVA was used to compare dynamometry and ultrasound outcomes between group (continence status) and across time (pre-run vs post-run). Effect sizes (Cohen's f) were calculated using partial eta-squared values, and statistical power was determined for each variable.

RESULTS

To date, 23 experienced female runners have participated out of the targeted n=52. Demographic information is presented in Table 1. The runners with and without leakage do not differ on any variables except the ICIQ-FLUTS score, which is significantly higher in the runners with running-induced SUI.

All outcomes are normally distributed. Table 2 describes the results for all outcomes. No significant two-way interactions between factors (continence status) and within-participants (pre-run vs post-run) were found for any outcome ($p > 0.05$). To date, no difference in force generating capacity of the PFMs is evident between participants with and without running-induced SUI. While the rate of force development during MVC does not appear to change after the acute bout of running, a significant small increase in the relative peak force achieved during MVC is observed after the run compared to before the run in both groups. To date, women with running-induced SUI demonstrate a slower decay in passive force during the stress relaxation response than those without SUI. After the run, there is a significant difference in relative peak forces and rate of force development measured during tissue elongation—forces were lower after the run for both groups. The effect sizes computed for the interaction between continence status and time suggest that there may be moderate effect sizes for changes in relative peak force measured during tissue elongation and for changes in levator hiatal area at rest (effect size=0.35 and 0.26 respectively), while the effects sizes may be small for the other outcomes (<0.13). There appears to be a change in the shape of the levator hiatus after the run, and we are currently developing a method to quantify this change for further investigation.

INTERPRETATION OF RESULTS

Although this study is currently underpowered, this interim power analysis suggests that this study will be adequately powered to detect differences in most outcomes in terms of the morphological and mechanical changes observed after an acute bout of running (power ranging from 82 to 93% for 4 of 6 outcomes). Based on these preliminary findings, PFM strength and fatigue appear to play a limited role, if any, in running-induced SUI in experienced female runners. Although no significant interaction effect between continence status and time (before/after the run) is evident, the moderate effect size for the interaction between relative peak force at 40mm dynamometer diameter and time suggests that changes in the mechanical properties of the supportive connective tissues may be associated with running-induced SUI in females.

CONCLUDING MESSAGE

These preliminary results do not indicate significant differences in PFM strength between female runners with and without running-induced SUI, nor any PFM fatigue induced by an acute bout of running. The effect sizes suggest that differences between runners with and without SUI may exist in the passive properties of PFMs and surrounding connective tissues. These differences might have implications in terms of the support offered to the pelvic organs and urethra in response to repetitive loading during running. These are preliminary results only, recruitment is ongoing.

FIGURE 1

Table 1. Demographic information

	Runners without running-induced		Runners with running-induced		p-value
	Mean	SD	Mean	SD	
Age (years)	38.3	9.22	44.2	11.3	0.191
Parity (0=nulliparous; 1=parous)	0.45	0.52	0.58	0.51	0.558
BMI (kg/m^2)	21.37	1.82	23.19	4.78	0.248
Hip-waist ratio	0.76	0.07	0.78	0.03	0.452
ICIQ-FLUTS Score (/48)	4.64	4.01	10.33	3.11	0.001
Running experience (years)	16.41	10.49	19.02	18.33	0.683
Self-selected pace (miles/hour)	6.67	0.68	6.01	1.29	0.143
IPAQ Score (MET-minutes/week)	4287.91	2300.87	6638.54	9851	0.449

BMI=body mass index; ICIQ-FLUTS= International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms
IPAQ=International Physical Activity Questionnaire; MET=metabolic equivalent of task; SD= standard deviation

FIGURE 2

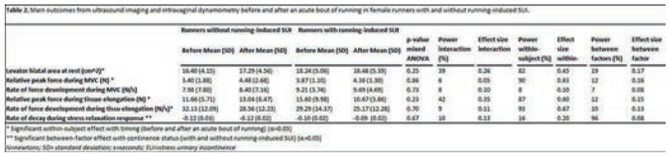

Table 2. Main outcomes from ultrasound imaging and intravaginal dynamometry before and after an acute bout of running in female runners with and without running-induced SUI.

	Runners without running-induced SUI		Runners with running-induced SUI								
	Before Mean (SD)	After Mean (SD)	Before Mean (SD)	After Mean (SD)	p-value mixed ANOVA	Power interaction (%)	Effect size interaction	Power within-subject (%)	Effect size within-	Power between factors (%)	Effect size between factor
Levator hiatal area at rest (cm²)*	16.40 (4.15)	17.29 (4.56)	18.24 (5.06)	18.48 (5.39)	0.25	39	0.26	82	0.45	19	0.17
Relative peak force during MVC (N) *	3.40 (1.88)	4.48 (2.68)	3.87 (1.10)	4.36 (1.30)	0.86	6	0.05	90	0.61	12	0.16
Rate of force development during MVC (N/s)	7.98 (7.80)	8.40 (7.16)	9.25 (5.74)	9.69 (4.49)	0.73	9	0.10	8	0.10	7	0.08
Relative peak force during tissue elongation (N) *	11.66 (5.71)	13.04 (8.47)	15.60 (9.98)	16.67 (3.86)	0.23	42	0.35	87	0.60	12	0.15
Rate of force development during tissu elongation (N/s)*	32.13 (12.09)	28.56 (12.23)	29.29 (14.37)	25.17 (12.26)	0.70	9	0.11	93	0.67	10	0.13
Rate of decay during stress relaxation response **	-0.12 (0.03)	-0.12 (0.02)	-0.10 (0.02)	-0.09 (0.02)	0.67	10	0.13	16	0.28	96	0.68

* Significant within-subject effect with timing (before and after an acute bout of running) (α=0.05)
** Significant between-factor effect with continence status (with and without running-induced SUI) (α=0.05)
Abbreviations: SD= standard deviation; s=seconds; SUI=stress urinary incontinence

REFERENCES

1. S. Almousa and A. Bandin van Loon, "The prevalence of urinary incontinence in nulliparous adolescent and middle-aged women and the associated risk factors: A systematic review.," Maturitas, vol. 107, pp. 78–83, 2018.
2. I. Nygaard, T. Girts, N. H. Fultz, K. Kinchen, G. Pohl, and B. Sternfeld, "Is urinary incontinence a barrier to exercise in women?," Obstet. Gynecol., vol. 106, no. 2, pp. 307–314, 2005.

Funding Physiotherapy Foundation of Canada **Clinical Trial** No **Subjects** Human **Ethics Committee** The Health Sciences and Science Research Ethics Board of the University of Ottawa **Helsinki** Yes **Informed Consent** Yes

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SCREENING AND IDENTIFICATION OF KEY BIOMARKERS IN PELVIC ORGAN PROLAPSE: BASED ON BIOINFORMATIC ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

Pelvic organ prolapse (POP) refers to a group of diseases in which the pelvic organs and the adjacent vaginal wall decrease due to weakened pelvic support tissue. Although it rarely causes severe symptoms or death, it has a huge impact on the quality of life of patients. Based on the diversity and heterogeneity of the pathophysiology of POP, its molecular mechanism remains unclear. In order to identify candidate genes in the occurrence and progression of POP, we have mined and analyzed some differential genes from public databases.

STUDY DESIGN, MATERIALS AND METHODS

microarray datasets GSE53868, from Prolapsed and non-prolapsed position in the vaginal wall of 12 POP patients, was downloaded from Gene Expression Omnibus (GEO) database. The differentially expressed genes (DEGs) were selected and identified, and Kyoto Encyclopedia of Genes and Genomes (KEGG) and Gene ontology (GO) function enrichment analyses were performed by the Database for Annotation, Visualization and Integrated Discovery (DAVID). The protein-protein interaction network (PPI) was constructed using STRING online website and the module analysis was performed with Cytoscape software, while hub genes were identified by MCODE plugin in Cytoscape.

RESULTS

A total of 118 differentially expressed genes were screened (P <0.05, log FC > 1 or log FC < -1), including 77 up-regulated genes and 41 down-regulated genes. KEGG and GO enrichment analysis showed that the biological process of these differentially expressed genes were mainly involved in cell apoptosis, immune response, and cell response to DNA destruction stimulation. The constructed protein interaction network suggested that these DEGs were mainly composed of 2 modules and Thrombomodulin (THBD) and zinc finger protein SNAL1 play a key role.

INTERPRETATION OF RESULTS

Thrombomodulin is a specific endothelial cell receptor responsible for the conversion of protein C to the activated protein C (protein Ca). Once evolved, protein Ca scissions the activated cofactors of the coagulation mechanism, factor Va and factor VIIIa, and thereby reduces the amount of thrombin generated. Unfortunately, we did not find a direct link between POP pathological process and coagulation function

Zinc finger protein SNAI1 Involved in induction of the epithelial to mesenchymal transition (EMT), formation and maintenance of embryonic mesoderm, growth arrest, survival and cell migration. SNAI1 participated in the activation of fibroblasts while POP is closely related to fibroblast and collagen metabolism disorders.

CONCLUDING MESSAGE

In conclusion, the present study was designed to identify DEGs that may be involved in the occurrence and progression of HCC. A total of 119 DEGs and 2 hub genes were identified and may be regarded as diagnostic biomarkers and therapeutic target for POP, especially SNAI1. However, further studies are needed to elucidate the biological function of these genes in POP

Funding The study was supported by the National Natural Science Foundation of China (No.81670695), Zhejiang Provincial medical and health technology program projects of China (Nos.2018PY031, 2018KY512, and 2019KY101), and Zhejiang Provincial Natural Science Foundation of China (No.WY20H050001) **Clinical Trial** No **Subjects** None

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EVALUATION OF MOBILE HEALTH APPLICATIONS FOR PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

With the growing use of technology by patients in managing their health, it becomes increasingly important to evaluate mobile health applications (apps) that patients use for credibility, accuracy, and utility. The aims of this study are to evaluate applications designed for Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI) using the Xcertia guidelines for medical app quality, as well as to analyze user sentiment of the apps.

STUDY DESIGN, MATERIALS AND METHODS

Mobile medical apps were found on the Apple App Store with keywords "pelvic organ prolapse," "incontinence," or "bladder." Exclusion criteria included apps that were not free or were not updated in the past year. Apps were evaluated along the Xcertia Guidelines, categories including app Operability, Privacy, Security, Content, and Usability. The number of ratings and reviews on the Apple App Store were collected for each app and a sentiment analysis of reviews was conducted. A positive review contained only positive feedback, a negative review contained only negative feedback, and a neutral review contained both positive and negative feedback.

RESULTS

From the Apple App Store, a total of 27 mobile medical apps were found and 8 apps met inclusion criteria. Based on Xcertia guidelines, all apps had simple and problem-free download/launch, visuals, and usability (Table 2). None of these apps required input of personal identifying information and none were linked to the EHR in any way. The content of the apps varied in that 62.5% of the included apps incorporated an educational or informational component. Further, only 37.5% of the apps clearly delineated the sources for their information, while the others had no way to verify the validity of the content. PRIVY-US Urinary Health and Tat: Pelvic Floor Muscle Exercises incorporated questionnaires for evaluating the degree of urinary incontinence, however only PRIVY-US Urinary Health provided users with interpretations for the results. 50% of the apps had the option of purchasing an upgrade to access additional features.

The average number of reviews among the 8 apps was 124.8, with an average of 118.5 positive reviews, 2.6 negative reviews, and 3.8 neutral reviews. Sentiment analysis showed that 5 apps had majority positive sentiment (Table 1). The percentage of positive reviews was 96% for Easy Kegel out of 225 reviews, 80% for Kegel Nation out of 5 reviews, 96% for Kegel Trainer PFM Exercises out of 741 reviews, and 100% for both PRIVY-US Urinary Health and Tat: Pelvic Floor Muscle Exercises, which each had 1 review. Only 1 app, Squeeze Time, had majority negative reviews, with 75% negative out of 4 reviews. Vesica had 50% neutral reviews out of 16 total. Kegel Trainer had equal positive, negative, and neutral sentiment in 6 reviews. Some of the complaints that users brought up in reviews across several apps included crashes, required payment for additional features, and incompatibility with other Apple devices such as the Apple Watch.

INTERPRETATION OF RESULTS

The importance of mobile health apps following Xcertia guidelines increases as patient use of mobile based technology is increasing. Apps have little oversight or regulation with the possibility of inaccurate and unreliable information being passed on to users. The quality of content in our analysis was variable. Some apps did not have any informational component and were simply instructional without explanation, limiting their utility. The incorporation of educational elements into apps would help make them well-rounded resources to consider. Additionally, only 38% cited sources from which their content was derived, therefore accuracy of educational content may be limited.

Sentiment analysis of app reviews must be considered with the total number of reviews for each app. While some apps had hundreds of reviews, others had very few, as low as 1 in some cases. There is also volunteer bias where some users may only submit a review when they come across a problem or notice significant improvement with the app. Making sure that the most popular apps are also the ones with the best content is important when considering that new users are more inclined to try apps that are positively reviewed and highly rated. In our analysis, the two highest reviewed apps had nearly almost all positive reviews (96%) for both, indicating that these are well-liked and highly utilized. Similarly, the apps with over 100 ratings had an average rating of 4.4 or higher, supporting that highly used apps are also highly rated.

CONCLUDING MESSAGE

Most apps were well received by users based on ratings/reviews and met most functional guidelines of Xcertia. However, the quality of the app content varied. Only some of the apps had an informational component, and even less had sources listed. This brings the credibility of some apps into question and leaves physicians and patients unable to verify the educational information. Optimal apps should include accurate, useful educational content with sources cited and meeting functional guidelines. Providers considering recommendation of health apps to patients should highly consider those that meet Xcertia guidelines, have an educational component, list their sources, and do not require payment

for features. For future studies, evaluation of the quality of app educational content and evaluation of mobile health apps available through other platforms is encouraged.

FIGURE 1

App	Use	Ratings		Reviews			
		Number of Ratings	Score	Number	Positive (%)	Negative (%)	Neutral (%)
Easy Kegel	Pelvic Floor Exercises	462	4.8	225	217 (96.44)	4 (1.78)	4 (1.78)
Kegel Nation	Pelvic Floor Exercises	9	3.9	5	4 (80)	1 (20)	0 (0)
Kegel Trainer	Pelvic Floor Exercises	121	4.5	6	2 (33.3)	2 (33.3)	2 (33.3)
Kegel Trainer PFM Exercises	Pelvic Floor Exercises	1700+	4.6	741	715 (96.5)	10 (1.35)	16 (2.16)
PRIVY US – Urinary Health	incontinence	8	4.5	1	1 (100)	0 (0)	0 (0)
Squeeze Time	Pelvic Floor Exercises	79	4.7	4	1 (25)	3 (75)	0 (0)
Tilt: Pelvic Floor Exercises	Pelvic Floor Exercises	1	5	1	1 (100)	0 (0)	0 (0)
Vesica	Voiding Diary	190	4.4	16	7 (43.75)	1 (6.25)	8 (50)

Table 1. Ratings and Reviews

FIGURE 2

App	Operability		Privacy	Security	Content			Usability	
	App Launch	Contact Developer/ Feedback	Personal Data Protection	Protect from External Threats, Guard Identity	Informational Component	Credible Information Sources Provided	Information Up to Date	Visually Clear, Text Readable	Easy to Use/Navigate
Easy Kegel	problem-free	available method	yes	yes	yes	no	within 6 months	yes	yes
Kegel Nation	problem-free	no available method	yes	yes	yes	yes	within 6 months	yes	yes
Kegel Trainer	problem-free	available method	yes	yes	no	no	within 6 months	yes	yes
Kegel Trainer PFM Exercises	problem-free	available method	yes	yes	no	no	within 6 months	yes	yes
PRIVY US – Urinary Health	problem-free	available method	yes	yes	yes	yes	within 1 year	yes	yes
Squeeze Time	problem-free	available method	yes	yes	yes	no	within 6 months	yes	yes
Tilt: Pelvic Floor Exercises	problem-free	no available method	yes	yes	yes	no	within 6 months	yes	yes
Vesica	problem-free	no available method	yes	yes	no	yes	within 1 year	yes	yes

Table 2. Review of Apps Alone Xcertia Guidelines

Funding NONE **Clinical Trial** No **Subjects** None

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SUCCESS AND SATISFACTION OF TENSION-FREE VAGINAL TAPE SURGERY IN FEMALES WITH STRESS URINARY INCONTINENCE: RESULTS AT 17 YEARS OF FOLLOW-UP.

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HYPOTHESIS / AIMS OF STUDY

Tension-free Vaginal Tape (TVT) Procedure is proved to be a safe and effective surgical method for stress urinary incontinence (SUI). The present study aims to evaluate the surgical outcomes at 17 years after the TVT surgery which was performed to manage females with SUI.

STUDY DESIGN, MATERIALS AND METHODS

Among 110 women with SUI who underwent the TVT procedure between March 1999 and December 2000, 51 patients were followed up for at least 17 years postoperatively. Preoperative evaluation of the patients was performed with history taking, physical examinations, one-hour pad tests, urine analysis, urine cultures and complete multichannel urodynamic studies. Long-term evaluations were performed via questionnaires on the durability of the surgical outcome and the patients' satisfaction with the procedure. All the patients were asked about their voiding symptoms as well as any recurrence by conducting detailed telephone interviews.

RESULTS

The mean follow-up period was 207.62 ± 8.46 months. Of the 51 patients who were followed up for at least 17 years, the patients were classified according to their symptom grades; grade I (n = 13, 25.49%), grade II (n = 28, 54.90%) and grade III (n = 10, 19.61%). The TVT procedure remained successful in 42 patients (82.35%): SUI was remained cured in 28 patients (54.90 %) and improved in 14 patients (27.45%) while recurred incontinence was observed in 9 patients (17.65 %). According to the telephone interviews, 26 patients (50.98 %) were very satisfied and 16 patients (31.37%) were satisfied with the TVT procedure. However, 6 (11.76%) and 3 (5.88%) patients answered 'tolerable' and 'dissatisfied', respectively, and all of these patients had recurred SUI. Among the investigated patients, no serious or long-term complications related to the procedure were observed.

INTERPRETATION OF RESULTS

According to the present results, more than 80% of the females who underwent TVT to manage SUI were remained cured or improved, and a similar rate of patients were at least satisfied at 17-years after the surgery. This implies that TVT is an effective and durable surgical procedure to manage females with SUI. However, since only 46.36% of the patients were able to be contacted to for the telephone interviews, the results of this study may not be sufficiently robust to evaluate the long-term success and satisfaction of females who underwent TVT. Further multi-institute cohort studies with prospective design are necessary to validate the precise effectiveness and durability of TVT in SUI females.

CONCLUDING MESSAGE

The TVT surgery is an effective treatment for stress urinary incontinence, with long-term durability of continence and minimal complications related to the surgery.

FIGURE 1
Table 1. Patients' preoperative and postoperative clinical data.

	n = 51
Mean age (years)	62.42 ± 16.21 (46–80)
Mean follow-up period (months)	207.62 ± 8.46 (204–210)
Mean symptom period (months)	83.23 ± 98.25 (2–280)
Mean body mass index (kg/m^2)	24.08 ± 2.41
Mean numbers of delivery	2.71 ± 1.54
Grade of incontinence	
I (n)	13 (25.49%)
II (n)	28 (54.90%)
III (n)	10 (19.61%)
Pre-operative urodynamic parameters	
Voided volume (mL)	232.65 ± 164.27
Maximal flow rate (mL/sec)	30.25 ± 9.14
Residual volume (mL)	20.27 ± 15.20
Maximal cystometric capacity (mL)	432.85 ± 101.28
Maximal detrusor pressure (cmH_2O)	26.78 ± 12.29
Surgical success rate	
Cured (n)	28 (54.90%)
Improved (n)	14 (27.45%)
Incontinence recurrence (n)	9 (17.65%)
Satisfactory status	
Very satisfied	26 (50.98%)
Satisfied	16 (31.37%)
Tolerable	6 (11.76%)
Dissatisfied	3 (5.88%)

Table 1. Patients' preoperative and postoperative clinical data.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** International review board of Pusan National University Hospital **Helsinki** Yes **Informed Consent** No

SESSION 24 (PODIUM SHORT ORAL) - SENSORY FUNCTION AND FIBROSIS
Abstracts 366-377

13:30 - 15:00, Brasilia 1

Chairs: Dr Lori A Birder (United States), Prof Georgi Petkov (United States)

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IS SOLUBLE VEGFR1 A PUTATIVE BIOMARKER AND THERAPEUTIC TARGET FOR BPS/IC?

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1. I3S and FMUP, 2. FMUP, I3S, CHSJ, 3. CHSJ

HYPOTHESIS / AIMS OF STUDY

Patients suffering from bladder pain syndrome/Interstitial cystitis (BPS/IC) have vascular fragility, reflected by the waterfall bleeding following bladder distention. Vascular endothelial growth factor (VEGF) is a molecule involved in vasculogenesis and angiogenesis. In addition VEGF also participates in the pathophysiology of pain. VEGF was shown to be increased in the lamina propria of BPS/IC bladders. However, urinary VEGF levels has been reported to be similar between BPS/IC and controls.

VEGF can bind to membrane VEGF receptors or to their soluble forms. VEGF membrane receptors include 3 subtypes: VEGFR1, VEGFR2 and VEGFR3. VEGFR1 occurs in sensory neurons and in monocyte/macrophages. VEGFR2 is expressed by endothelial cells. VEGFR1 and VEGFR2 receptors can also be found in urothelial cells.

VEGFR-2 mediates almost all of the known cellular responses to VEGF, like angiogenesis and increases vascular permeability. VEGFR1 promotes inflammation and pain, mainly by modulating VEGFR-2 signalling. Moreover, VEGFR1 soluble form act as a buffer, sequestering VEGF from binding to the membrane receptors. VEGFR-3 is associated with lymphang-

iogenesis and, since it seems to have no role in pain control, was not a subject of our study.

In the present work, we hypothesised that the sVEGFR1 can be detected in the urine of BPS/IC patients.

STUDY DESIGN, MATERIALS AND METHODS
The urine of 18 healthy control subjects and of 18 BPS/IC patients from a urine bank was analysed by ELISA to measure the urinary levels of VEGF (Enzo, ENZ-KIT156-001; detection limit 4.712 pg/ml), VEGFR1 (Abcam, ab195210; detection limit - 0.391 ng/ml) and VEGFR2 (Abcam, ab213476; detection limit - 117 pg/ml).

As VEGFR1 and R2 occur in the membrane of urothelial cells, the urine samples were centrifuged and only the supernatant was used.

Results are presented has mean values ± sd. T test was used for comparisons. Confidence intervals (CI) are presented. Whenever CI includes 0, the null hypothesis is not discarded.

RESULTS
The urinary levels of VEGF in controls and BPS/IC patients were 10.18±0.24 pg/ml and 10.28±0.26 pg/ml, respectively (p=0.241). The 95% CI ranges [-0.07013,0.2707].

The urinary levels of sVEGFR1 in centrifuged urine were 9.64±7.36 ng/ml while in patients were 3.96±3.88 ng/ml of sVEGFR1 (p=0.0044). The 95% CI ranges [-6.916,-1.387] discards the null hypothesis.

A post hoc analysis showed that 67% of BPS/IC patients had less than 6 ng/ml of VEGFR1. These patients were older than the remaining (49±9 vs 39±5 years).

VEGFR2 was not detected in the urine of controls and patients.

INTERPRETATION OF RESULTS
The presence of VEGFR1 in centrifuged samples indicates that the receptor detected belongs to the soluble form.

Our exploratory study showed a marked decrease in the urinary levels of sVEGFR 1. This results may reflect a reduction on VEGF sequestration by the VEGFR1 soluble form, which may leave VEGF free to activate the membrane attached receptors, leading to angiogenesis, pain, inflammation and urothelial changes.

This decrease seems to be age-dependent. The levels of urinary VEGF do not seem to reflect the tissue VEGF changes previously reported.

CONCLUDING MESSAGE
Urinary sVEGFR1 may be a potential BPS/IC biomarker for patient phenotyping and a potential target for future treatments.

Funding EU/EFPIA/Innovative Medicines Initiative [2] Joint Undertaking (IMI-PAINCARE) grant No 777500 **Clinical Trial** No **Subjects** None

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PEROXISOME PROLIFERATOR-ACTIVATED RECEPTOR GAMMA AGONIST AS A NOVEL TREATMENT FOR INTERSTITIAL CYSTITIS: A RAT MODEL

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HYPOTHESIS / AIMS OF STUDY
While the cause of interstitial cystitis (IC) is unknown, cellular and macroscopic urothelial changes have been characterized for many decades. Noted urothelial changes include increased solute permeability of the urinary bladder (causing pain) and decrease of urine-bladder barrier proteins including uroplakin and unique production of Frizzled-8 protein-related glycoprotein (antiproliferative factor). These changes lead to disruption of the bladder lining and slowing of the reparative process of the bladder wall, which is usually restored by cell replication and differentiation of basal cells.

Peroxisome proliferator-activated receptor gamma (PPAR-γ) agonists may offer a potential therapeutic benefit by restoring the urothelial integrity. In cell culture, PPAR-γ agonists have been shown to drive urothelial cells to differentiation and production of barrier proteins including uroplakin. This differentiation persists even when other growth factors such as epidermal growth factor are inhibited. We investigate the use of a PPAR-γ agonist, pioglitazone, as a potential reparative treatment for IC, which may offer a treatment that would target a known defect in urothelial architecture seen in patients with IC.

STUDY DESIGN, MATERIALS AND METHODS
24 female Sprague-Dawley rats were used. Baseline urinary frequency (filter paper test) and bladder capacity (via suprapubic PE-50 tubing, saline filling cystometry at 0.1 mL/min x 3 cycles) were measured. Using a previously described animal model for IC, 12 rats were treated with biweekly intraperitoneal cyclophosphamide injections (35 mg/kg) to induce cystitis. 12 rats were used as controls. Animals were divided into 4 groups (n=6 for each group): IC plus daily sham saline gavage (IC+Pio-), IC plus daily pioglitazone gavage (15 mg/kg) (IC+Pio+), normal rats with daily pioglitazone (IC-

Pio+), and normal rats with neither IC nor pioglitazone (IC-Pio- {Control}). At the end of four weeks, urinary frequency and bladder capacity were measured. Histologic examination of urothelial integrity was also performed.

RESULTS

Average voids per hour were significantly lower in IC+Pio+ (4.0±1.9) vs. IC+Pio- (10.0±2.4) rats ($p<0.01$) and were similar to IC-Pio+ (6.0±1.4) and IC-Pio- (6.0±1.5) controls. Cystometric capacity was significantly higher in IC+Pio+ (0.945±0.122 mL) vs. IC+Pio- rats (0.588±0.165 mL, $p=0.01$) and was comparable to IC-Pio- capacity (0.817±0.196 mL) and IC-Pio+ capacity (0.941±0.188 mL). Urothelial structural integrity was improved in IC+Pio+ rats versus IC+Pio- rats upon histologic observation.

INTERPRETATION OF RESULTS

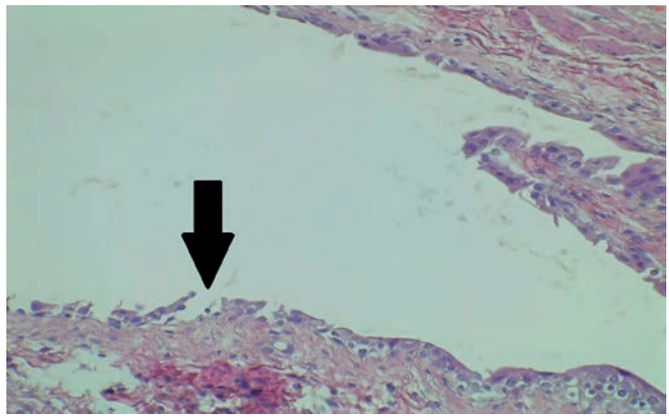
Pioglitazone is an FDA-approved medication used for treatment of diabetes mellitus. Further investigation is prudent and warranted, as hypertrophy of the bladder endothelium has been demonstrated in rat models.. In observational studies a dose dependant risk of bladder cancer has been raised in diabetics taking pioglitazone orally, though studies have shown conflicting data, as highlighted in the recent FDA brief on Pioglitazone and bladder cancer..

To date, this is the first study to address possible treatment of IC with a PPAR-γ agonist. The study reliably demonstrated changes in the rat bladder physiology, hinting at a potential benefit to patients. The current study is limited as only the feasibility of an oral dose treatment was tested in an established animal model of disease. Future studies may answer if alternative routes of administration may provide an improved risk/benefit profile. For example, bladder instillation of pioglitazone metabolites may create a therapeutic effect and minimize systemic side effects. Additional investigation into the bladder surface protein changes would illuminate if structural bladder changes were noted with treatment, however, this was not possible with the current investigation. Moving from animal to human investigation would also provide more compelling evidence for future therapeutic use.

CONCLUDING MESSAGE

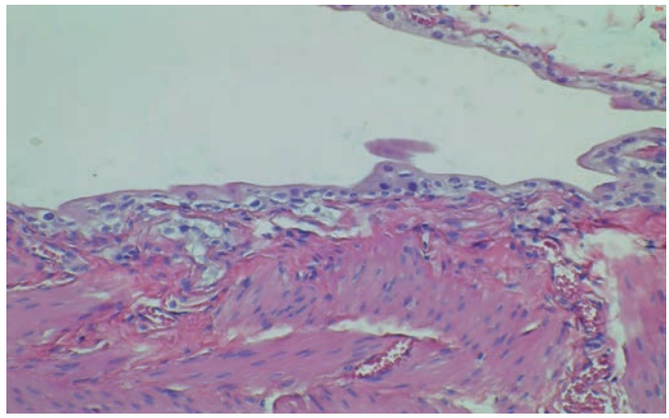
In a cyclophosphamide-induced model of IC, pioglitazone, a PPAR-γ agonist, improved bladder function. Cystometric capacity and urinary frequency (higher in rats with cystitis) were normalized following treatment with pioglitazone. In addition, the structural integrity of the urothelium was improved. While concern remains for the potential increase in urothelial carcinoma with long-term PPAR-γ agonist treatment, pioglitazone, which causes bladder mucosal proliferation, may prove useful for treating IC, and deserves further investigation.

FIGURE 1



A loss of normal urothelium and barrier thinning (arrows) is appreciated in the IC+Pio- group.

FIGURE 2



The treated cystitis (IC+Pio+) group showed amelioration of the urothelium.

Funding : Dean's Office, Stanford University School of Medicine **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** APLAC Stanford

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EFFECTS OF A SOLUBLE GUANYLATE CYCLASE ACTIVATOR, BAY 60-2770, ON NEUROGENIC LOWER URINARY TRACT DYSFUNCTION IN MICE WITH SPINAL CORD INJURY

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HYPOTHESIS / AIMS OF STUDY

Neurogenic lower urinary tract dysfunction after spinal cord injury (SCI) features detrusor overactivity (DO) and detrusor-sphincter dyssynergia (DSD), which results in inefficient voiding with high post-void residual volume. Previous studies have shown that nitric oxide (NO)-mediated pathways are involved in the control of lower urinary tract (LUT) function in multiple ways; including urethral and bladder neck smooth muscle relaxation, increased blood flow due to vascular smooth muscle relaxation and inhibition of bladder afferent activity [1]. Also, phosphodiesterase type 5 (PDE5) inhibitors, which increase cellular levels of cyclic guanosine monophosphate (cGMP), are used for the treatment of male LUT symptoms with benign prostatic hyperplasia. NO is known to promote the production of cGMP from GTP via activation of soluble guanylate cyclase (sGC); therefore, this study examined the effects of sGC activation, which can increase cGMP production independent of NO inside the cell, on bladder and urethral dysfunctions in SCI mice.

STUDY DESIGN, MATERIALS AND METHODS

Female C57BL/6N mice (9 weeks old) were used and divided into three groups: Group A of spinal cord intact mice; Group B of SCI mice treated with vehicle, and Group C of SCI mice treated with a sGC activator (BAY 60-2770). The mice in the SCI groups underwent Th8-9 spinal cord transection followed by oral administration of a vehicle or BAY 60-2770 (10 mg/kg/day) by oral gavage once a day in the morning during 2 to 4 weeks after spinal cord transection. The bladder of SCI mice was emptied via abdominal compression once daily after spinal cord transection. We evaluated the urodynamic parameters using awake cystometry (CMG) and external urethral sphincter (EUS)-electromyograms (EMGs), and the mRNA levels of mechanosensory channels, NO-related, ischemia, and inflammatory markers in L6-S1 dorsal root ganglia (DRG), urethra and bladder tissues at 4 weeks after SCI. In single-filling CMG, we measured the time to voiding, the number of non-voiding contractions (NVCs) per minute, postvoid residual volume (PVR), bladder capacity, bladder compliance, and voiding efficiency. NVC was defined as an increase in intravesical pressure more than 8 cmH2O above the baseline. In CMG and EUS-EMG recordings, we measured voiding contraction time, duration of notch-like reductions in intravesical pressure on CMG traces, and duration of reduced EMG activity. The voiding contraction time was measured as a duration between the rise of intravesical pressure beyond the threshold pressure and the point at which intravesical pressure returned to the level of threshold pressure. Reduced EMG activity was measured when EMG activity was reduced to the baseline level between tonic firings of EUS-EMG activity during voiding bladder contraction [2]. In a separate group of animals, DRG, urethra and bladder tissues were harvested at 4 weeks of SCI to evaluate the mRNA levels various markers using real-time PCR, which included mechanosensory channels markers such as TRPA1, TRPV1, acid-sensing ion channel 1-3 (ASIC1-3), and piezo-type mechanosensitive ion channel component 2 (Piezo2), NO-related markers such as neuronal & endothelial nitric oxide synthase (nNOS & eNOS), and soluble guanylate cyclase alpha 1 (sGCα1), ischemia markers such as hypoxia-inducible factor 1-alpha (HIF-1α) and vascular endothelial growth factor (VEGF), and inflammatory markers such as transforming growth factor beta 1 (TGF-β1). All values are expressed as means ± standard deviations. We used the Mann Whitney U test to evaluate statistical differences between groups. A P-value < 0.05 was considered statistically significant.

RESULTS

In single-filling CMG, time to voiding, NVCs per minute, PVR and bladder capacity were significantly larger in Group B than in Group C (time to voiding: 44.4 ± 12.3 vs 33.5 ± 9.2 sec, NVCs: 0.9 ± 0.3 vs 0.5 ± 0.1 number/min, PVR: 0.4 ± 0.1 vs 0.3 ± 0.1 mL, bladder capacity: 0.5 ± 0.1 vs 0.3 ± 0.1 mL). Voiding efficiency was significantly higher in Group C than in Group B (13.0 ± 4.0 vs 6.5 ± 1.5 %) (Fig. 1A, B). In CMG and EUS-EMG recordings, voiding contraction time was significantly smaller in Group C than in Group B (20.2 ± 1.9 vs 25.1 ± 3.5 sec). Duration of notch-like reductions in intravesical pressure on CMG traces and reduced EMG activity time were significantly longer in Group C than in Group B (notch-like reductions: 1.7 ± 0.5 vs 1.0 ± 0.3 sec, reduced EMG activity: 1.5 ± 0.2 vs 0.9 ± 0.1 sec) (Fig. 1C, D). mRNA expressions of TRPA1, TRPV1, ASIC1, ASIC2, ASIC3, and Piezo2 in L6-S1 DRG were significantly higher in Group B than in Groups A and C (Fig. 2A). mRNA expressions of nNOS, eNOS, and sGCα1 in the urethra were significantly lower in Group B than in Groups A and C (Fig. 2B). mRNA expressions of HIF-1α, VEGF, and TGF-β1 in the bladder were significantly higher in Group B than in Groups A and C (Fig. 2C).

INTERPRETATION OF RESULTS

This is the first report of examining the effects of sGC activation on lower urinary tract dysfunction in SCI mice. In this study, the sGC activator treatment, which can directly increase cGMP production independent of NO, improved DO evident as reduced NVCs as well as DSD as evidenced by an increase in reduced EMG activity time in 4-weeks SCI mice. Also, the duration of notch-like reduction and reduced EMG activity were increased in the sGC-treated group, indicating the improvement of the EUS synergic relaxation during void-

ing, resulting in better voiding efficiency after the sGC treatment. Molecular studies also showed that the sGC treatment increased mRNA expressions of nNOS, eNOS, and sGCα1 in SCI mice, suggesting that the NO-GC-cGMP function, which is impaired after SCI, is recovered after sGC activation. Previous studies in rodent SCI models suggested that the afferent limb of micturition reflexes inducing NVCs and voiding bladder contractions are controlled by C-fiber and Aδ-fiber afferent pathways, respectively, after SCI [3]. Also, it has been shown that ASICs and Piezo2 act as mechanosensitive channels in afferent pathways and that ASIC1-3 receptors are expressed in TRPV1 expressing, unmyelinated C-fiber neurons as well as in mechanosensitive, myelinated A-fiber neurons, whereas Piezo2 is expressed in mechanosensitive, myelinated A-fiber neurons. In this study TRPA1, TRPV1, ASIC1-3, Piezo2 transcripts in L6-S1 DRG were upregulated in SCI mice, and then reduced by the sGC treatment. Thus, the sGC treatment is likely to suppress excessive activities of Aδ- and C-fiber afferent pathways innervating the LUT. Moreover, the sGC treatment seems to be effective in reducing ischemia and inflammatory changes in the bladder, evident as decreased expressions of HIF-1α, VEGF, and TGF-β1 after the treatment.

CONCLUDING MESSAGE

BAY 60-2770, a soluble guanylate cyclase activator, reduced the number of NVCs, increased voiding efficiency and the mRNA expressions of NO-related markers, and decreased the mRNA expressions of C-fiber afferent markers, mechanosensitive channels, ischemia and inflammatory markers in SCI mice. Thus, sGC activation could be an effective modality for the treatment of SCI-related neurogenic LUT dysfunction such as DO and DSD.

FIGURE 1

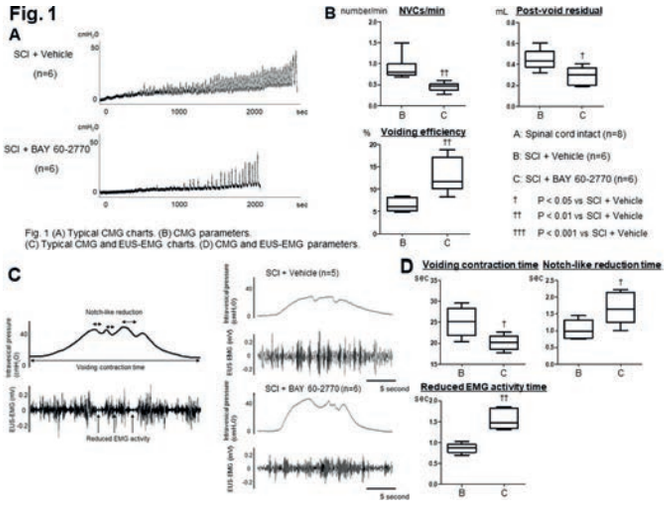

Figure 1

FIGURE 2

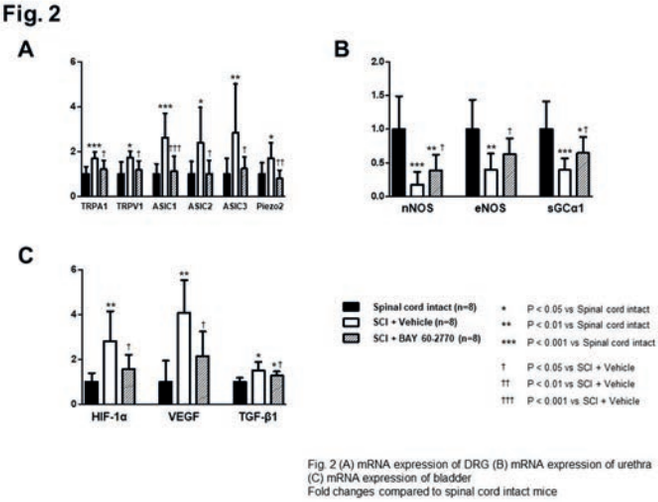

Figure 2

REFERENCES

1. Neurourol Urodyn. 30: 292-301, 2011
2. Am J Physiol Renal Physiol. 317: F1305-F1310, 2019
3. Am J Physiol Renal Physiol. 313: F796-F804, 2017

Funding DOD W81XWH-17-1-0403 **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** University of Pittsburgh Institutional Animal Care and Use Committee

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NERVE GROWTH FACTOR PRECURSOR (PRONGF) EXERTS DIFFERENT BIOLOGICAL ACTIONS ON UROTHELIAL AND SMOOTH MUSCLE CELLS OF RODENTS BLADDERS.

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HYPOTHESIS / AIMS OF STUDY

The nerve growth factor precursor (proNGF) activates p75NTR receptor and promotes cell death and degeneration in different tissues. Tissue levels of proNGF build up in conditions such as diabetes, inflammation and ischemia. Given that proNGF and p75NTR are expressed in different layers of the bladder, we aimed to identify the biological effect of proNGF/p75NTR activation on urothelial (UT) and smooth muscle (SM) cells of rodents' bladder.

STUDY DESIGN, MATERIALS AND METHODS

UT and SM cells cultured from bladder of Sprague Dawley rats (passages 2-7) were incubated with proNGF (5 or 10 nM) for different durations. Total cellular or nuclear protein extraction was performed, and the extracts were tested for

TNF-α, RhoA, p-JNK and NF-κB levels by western blotting. Nitric oxide (NO) estimation was performed on cells medium. Nuclear translocation of NF-κB was also confirmed with immunocytofluorescence. Cell viability and proliferation were assessed by MTT test and migration assay (wound healing assay).

RESULTS

proNGF decreased the viability of UT cells when incubated at concentration of 5 and 10nM for 24 hours (Figure 1.A) while SM cells showed increased viability (Figure 1.B). Treating UT cells with proNGF for 24 and 48 hours increased the expression of the transmembrane TNF-α (Figure 1.C) and reduced NO secretion. After 48 hours of incubation with 5 and 10 nM proNGF caused a significant reduction in junctional protein occludin expression. Short incubation of UT cells with proNGF (10nM) activated RhoA. On the other hand, SM did not show a reduction in viability nor an increase in TNF-α or RhoA. Interestingly, there was a significant nuclear translocation of NF-κB in the SM cells in the presence of proNGF (Figure 1.D) which was unseen in urothelial cells. Long incubation of SM cells with proNGF (48 and 72 hours) did not cause changes in contractile protein expression (smoothelin and myosin). MTT test and cell migration assay showed a significant increase in SM cell proliferation and migration when incubated with proNGF which was dose- and time-dependent. SM cell viability increased by 15-20% when incubated with proNGF [10nM] for 24 and 48 hours compared to cells incubated without proNGF (Figure 1.B). An increase of 20-40% in migration capacity of SM incubated with 5 and 10 nM of proNGF was observed after 24 and 48 hours.

INTERPRETATION OF RESULTS

The reduced viability of UT with increased expression of TNF-α and RhoA can be related to the activation of the death domain of p75NTR receptor, a member of the TNF family. The activation of these pathways through proNGF/p75NTR impacted secretory and functional integrity, as represented with lower NO and junctional protein occludin. However, p75NTR seems to promote cell survival in detrusor smooth muscle cells mostly via NF-κB activation, with enhanced proliferation and migration.

CONCLUDING MESSAGE

These results suggest that proNGF causes degenerative changes in urothelial cells and opposing effects on SMC to promote cell response to stress. Our findings also reiterate the observation that p75NTR receptor have cell-type specific response that include a wide range of responses that can promote cell apoptosis as well as cell survival and growth. Further understanding of this axis can help to identify cell-type changes in the bladder diseases in context of metabolic stress and inflammation.

FIGURE 1

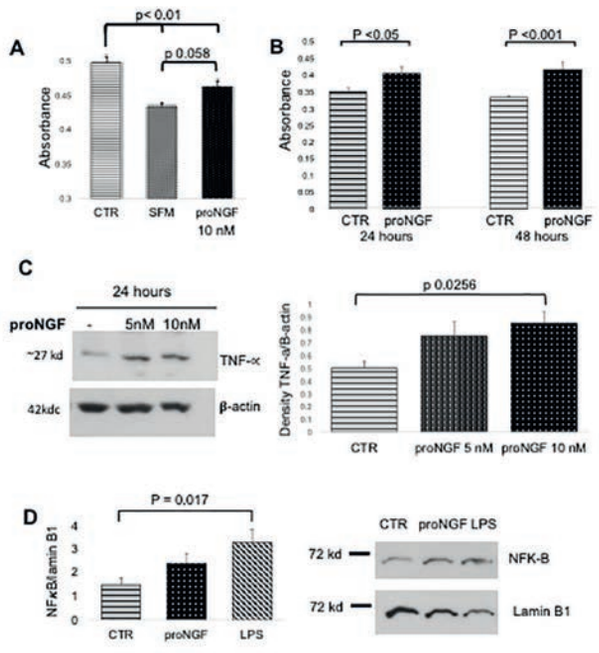

Figure 1: Urothelial (UT) and smooth muscle (SM) cells response to proNGF in cell culture conditions: A) MTT test showed a significant reduction in UT viability after 24 hours of incubation with 10nM of proNGF, SFM: serum free medium (as positive control for cell death), one-way AVONA with post hoc test., B) MTT test showed increased viability of SM cells after 24 and 48 hours of incubation with 10nM proNGF, independent t-test. C) UT cells showed increased expression of TNF-α after 24 hours of incubation with 5 and 10 nM proNGF, left; representative blotting sample, right; density estimation of blotting, one-way ANOVA. D) NF-κB nuclear translocation was seen in SM cells after 30 minutes incubation with 10 nM proNGF, LPS used as positive control for NF-κB nuclear translocation. Left; density estimation of NF-κB and lamin B1 as a housing nuclear protein, right: representative blot for NF-κB and lamin B in SM cells on nuclear extract. One-way ANOVA.

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INHIBITING MIR-21-5P ALLEVIATES BLADDER FIBROSIS AND DETRUSOR OVERACTIVITY IN SPINAL CORD INJURED RATS

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HYPOTHESIS / AIMS OF STUDY

Our preliminary experiments found that miR-21-5p was significantly up-regulated in spinal cord injured (SCI) rat by next-generation sequencing. Nevertheless, to our knowledge, no studies have investigated the role of miR-21-5p in bladder of SCI rats.

STUDY DESIGN, MATERIALS AND METHODS

Female Wistar rats underwent spinal cord transection at T9-10 and were randomly divided into negative control (NC) and experimental groups (n=10 for each group). Tail intravenous injection of miR-NC or antagomiR-21-5p were performed every three days after spinal cord transection, which were nine times in total respectively. Four weeks after transection, cystometric analyses were conducted and bladder tissues were collected for Masson staining, qRT-PCR and western-blot analyses. The normal rats were used as blank control group.

RESULTS

Compared with NC group, the level of miR-21-5p was significantly decreased in experimental group; while it was much higher in NC than blank group. In addition, Masson staining showed that bladder fibrosis was significantly lessened in experimental group. Decreased non-voiding contraction number and increased intercontraction interval were also found in experimental group. qRT-PCR and western-blot analyses showed that inhibiting miR-21-5p downregulated the levels of Smad7 mRNA and protein, which subsequently increased the levels of p-Smad3 mRNA and protein.

INTERPRETATION OF RESULTS

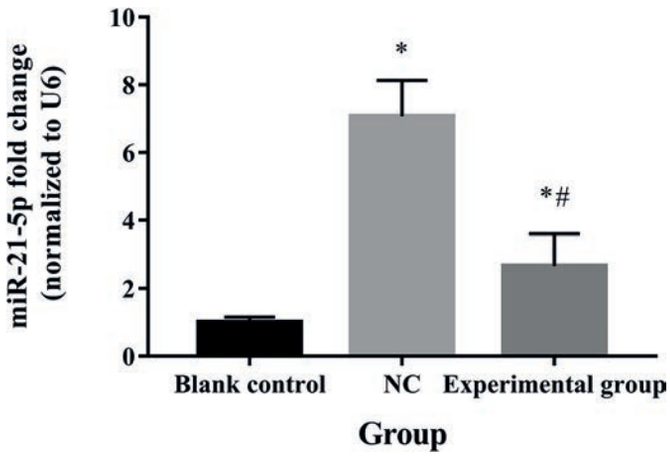
All of these days, miR-21-5p was reported to act as an oncogene through inhibiting cellular apoptosis by targeting tumor suppressor genes.(1) However, it should be noted that the over-expression of miR-21-5p abnormally activates transforming growth factor-β1 (TGF-β1) and Hedgehog signaling pathways, promoting tumor invasion by the induction of EMT. As we all know, TGF-β1 signaling pathway plays a pivotal role in EMT and fibrogenesis. Recently, the up-regulated expression of miR-21-5p was reported to be involved in the renal, myocardial, pulmonary and peritendinous fibrosis and may serve as an alternative target to directly inhibit these fibrosis.(2) Further research indicates that miR-21-5p overexpression could enhance TGF-β1 induced EMT by inhibiting smad7.(3) Moreover, proliferation, migration, and pro-fibrotic activities of fibroblasts were promoted by miR-21-5p through reducing smad7 expression. Specifically speaking, the increase of intracellular miR-21-5p induced fibroblasts differentiation into myofibroblasts and overexpression of extracellular matrix (ECM) and fibrogenic markers. What's more, tissue inhibitor of metalloproteinases (TIMPs) which was implicated in collagen synthesis and accumulation during fibrosis were also targeted by miR-21-5p.

Importantly, previous study suggests that miR-21-5p is upregulated by TGF-β1 via activation of Smad3 rather than Smad2. In normal state, Smad-3 activation can induce expression of smad7, which forms a negative feedback mechanism. Nevertheless, in pathological situations, the expression of smad7 was found to be suppressed and the negative feedback was damaged, which may due to the upregulated expression of miR-21-5p. In contrast, conditional knockout of Smad2 could enhance miR-21-5p expression. Further research is needed to explore the mechanisms underlying the interactions between miR-21-5p and TGF-β1 signaling pathway. In addition, bladder fibrosis after spinal cord injury may bear responsibility for the high intravesical pressures, low bladder compliance, bladder wall stiffer and vesicoureteral reflux. Up to now, however, there is no effective method for preventing bladder fibrosis. Therefore, it is also of great significance to investigate the functional role of miR-21-5p in bladder fibrosis after spinal cord injury.

CONCLUDING MESSAGE

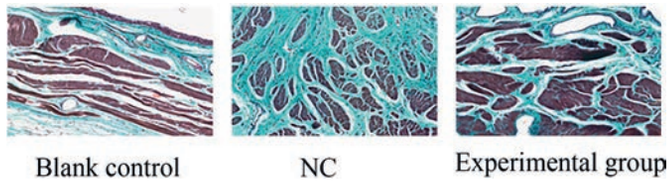
Inhibiting miR-21-5p alleviates bladder fibrosis and detrusor overactivity in SCI rats, which may potentially serve as a new molecular target for neurogenic bladder.

FIGURE 1



The level of miR-21-5p in blank, NC and experimental groups

FIGURE 2



Masson staining of bladder tissue in blank, NC and experimental groups (×10)

REFERENCES

1. Ghorbanmehr N, Gharbi S, Korsching E, et al. miR-21-5p, miR-141-3p, and miR-205-5p levels in urine-promising biomarkers for the identification of prostate and bladder cancer. Prostate 2019;79:88-95.
2. Nonaka CKV, Macedo CT, Cavalcante BRR, et al. Circulating miRNAs as Potential Biomarkers Associated with Cardiac Remodeling and Fibrosis in Chagas Disease Cardiomyopathy. Int J Mol Sci 2019;20.
3. Wang JY, Gao YB, Zhang N, et al. miR-21 overexpression enhances TGF-beta1-induced epithelial-to-mesenchymal transition by target smad7 and aggravates renal

damage in diabetic nephropathy. Mol Cell Endocrinol 2014;392:163-72.

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SEX DIFFERENCES IN BLADDER WALL FIBROSIS AND COMPLIANCE IN SPINAL CORD TRANSECTED MICE—ROLE OF ANGIOTENSIN SIGNALLING

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HYPOTHESIS / AIMS OF STUDY

Bladder wall fibrosis is associated with a variety of lower urinary tract disorders including various forms of cystitis, outlet obstruction and spinal cord injury (SCI). Fibrosis can decrease bladder compliance and capacity adversely impacting voiding and storage functions. However, many studies report contrary findings where rodents with SCI exhibit increased bladder compliance and capacity [1]. We propose that this discrepancy is due to the use of females in rodent based SCI studies and their reduced tendency to develop fibrosis. It has been demonstrated that males are predisposed to developing organ fibrosis, which appears to involve sex differences in the regulation of angiotensin II type 1 versus angiotensin II type 2 receptors (AT1Rs, AT2Rs) [2]. To our knowledge, differences in SCI-induced fibrosis have not been evaluated between male and female mice. Accordingly, our aim was to measure differences in bladder wall fibrosis in male and female mice with SCI and characterize the involvement of angiotensin receptor signalling.

STUDY DESIGN, MATERIALS AND METHODS

Male/female 8 to 12 weeks old C57Bl/6 mice were anesthetized using 2% isoflurane and their spinal cords transected between the T8-T9 segments, while sham control animals underwent a laminectomy without transection. At this time, mice were also implanted subcutaneously with micro-osmotic pumps (Alzet, model 1004) that released 1 mg/kg/day PD123319 (AT2R antagonist), 10 mg/kg/day losartan (AT1R antagonist) or vehicle (saline) for 28 days at 0.11 µl/hr. Following surgeries, animals were treated with analgesics and prophylactic antibiotics and their bladders manually expressed twice a day for up to seven days. Four to six weeks following injury, animals were sacrificed and their bladders isolated and divided into two strips that were used for length-tension recordings or saved in 10% buffered formaldehyde for histology (modified Verhoeff Van Gieson). Slides were imaged using brightfield montage microscopy (Olympus Fluoview microscope) and collagen content quantified in at least 6 comparable sections from each bladder strip using NDP and HCImage software (Hamamatsu Photonics). Experiments were carried out on $n \geq 4$ mice and the unpaired Student's t-test used to determine differences between transected versus sham controls and mice with and without drug treatment.

RESULTS

Histological evaluation of bladder sections from SCI mice showed significantly increased total collagen content in males versus females and sham controls (Fig. 1A). Male SCI mice treated with losartan showed diminished bladder collagen content compared to vehicle controls. Conversely, female SCI mice treated with PD123319 showed increased collaged content compared to vehicle treated mice (Fig 1B). The hypothetical mechanism of sex dependent differences in AT1/2R mediated bladder fibrosis and graphical representation of bladder collagen content in the test groups are summarized in Fig 1C and 1D, respectively. Functional assessments using isolated bladder strips showed that length-tension profiles were left-shifted in males (Fig. 2A) following SCI exhibiting greater passive tension indicative of increased stiffness (Fig. 2B). AT2R inhibitor treatment of females resulted in decreased compliance compared to untreated females. Alternatively, AT1R inhibitor treatment of males with SCI resulted in markedly increased compliance.

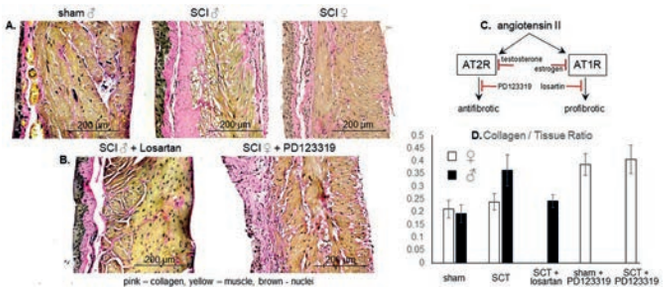
INTERPRETATION OF RESULTS

These data suggest that female mice may be protected against the development of bladder fibrosis due to altered expression and/or estrogen inhibition of AT1Rs, while males are prone to bladder fibrosis due to altered expression and/or testosterone inhibition of AT2Rs [3].

CONCLUDING MESSAGE

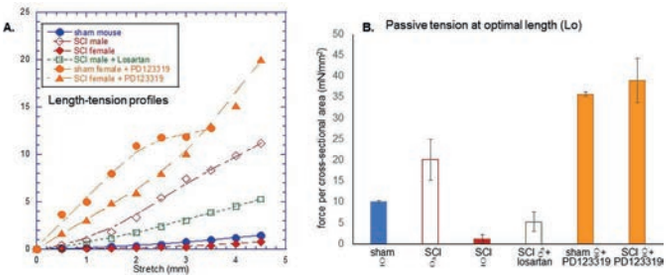
While renin-angiotensin system has well-known effects regulating systemic blood pressure, it also has a significant role in modulating tissue inflammation and fibrosis. It also is thought to have marked sex-linked differences; estrogen inhibits AT1Rs which have profibrotic actions, while testosterone inhibits AT2Rs which promote antifibrotic activity. Our data support this theory and suggests that AT1R blocker, losartan, may have therapeutic relevance in decreasing fibrosis in adult male or post-menopausal female patients with SCI.

FIGURE 1



Representative bladder wall cross-sections and collagen / tissue ratios

FIGURE 2



Length-tension profiles and passive tensions at optimal length

REFERENCES

1. Toosi et al. Ann Biomed Eng, 36(9): 1470-80, 2008
2. Toering et al. Physiol Rep, 3(7): e12434, 2015
3. Mishra et al. J Renin Angiotensin Aldosterone Syst., 17(4), 2016

Funding DOD (W81XWH1810436) **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** Institutional Animal Care and Use Committee

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LOSARTAN PREVENTS BLADDER FIBROSIS AND PROTECTS RENAL FUNCTION IN RATS WITH NEUROGENIC BLADDER

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HYPOTHESIS / AIMS OF STUDY

To investigate the role of losartan in preventing bladder fibrosis and protecting renal function in rats with neurogenic bladder (NB).

STUDY DESIGN, MATERIALS AND METHODS

Twenty-four rats were assigned to the transected spinal nerves group (TSNG, n=8), transected spinal nerves+ losartan group (LSTG, n=8), and control group (CG, n=8). In TSNG, rats' spinal nerves between L6 and S1 were transected completely. In LSTG, rats' spinal nerves between L6 and S1 were transected completely and losartan was given orally. In CG, sham operation was performed. Bladder capacity (BC), bladder compliance (ΔC) in every group, bladder leakage pressure (Pves.leak) in TSNG and LSTG and bladder threshold pressure (Pves.thre) in CG were measured by cystometry at day 30 post-operation, Renal function was evaluated by ultrasound and blood biochemistry. The expression quantity of Angiotensin II (Ang II), Ang II type 1 receptor (AT1), transformation growth factor β1 (TGFβ1), collagen III and collagen fibrin in the bladder tissue were detected by immunofluorescence, ELISA, Weston blot and Masson staining. Data are presented as the mean ± standard error of measurement. Statistical analysis was carried out with SPSS version 17.0 statistical software package. The statistical significance of differences between groups was determined by ANOVA, followed by a least significant difference test for multiple comparisons. A P-value of less than 0.05 was considered to indicate statistical significance.

RESULTS

The rats in TSNG and LSTG couldn't void voluntarily, their bladders lose the ability of autonomous contraction (Figure 1). ΔC in TSNG and LSTG decreased significantly compared to those of the CG (0.143±0.007 VS. 0.207±0.011 VS. 0.314±0.018), while, ΔC in LSTG was higher significantly than those of the TSNG, Pves.leak in TSNG and LSTG is higher significantly than Pves.thre of CG (55.373±4.015 cmH20, 43.986±2.047 cmH20 VS. 20.705±0.679 cmH20), in addition, Pves.leak in TSNG was higher than those of the LSTG. Renal function of both TSNG and LSTG decreased significantly compared to those of the CG, but renal function in LSTG was better than TSNG. Ang II of blood and bladder tissue in TSNG and LSTG increased significantly compared to CG. AT1 was expressed in bladder tissue of every group and obviously expressed in submucosa of bladder tissue. The TGFβ1, collagen III and collagen expression level (Figure 2) increased significantly in TSNG compared with LSTG and CG, while there was no significant different between CG and LSTG.

INTERPRETATION OF RESULTS

Bladder fibrosis is common in patients of NB and bladder fibrosis eventually damage renal function[1]. Currently, there is no effective drug treatment for reversing bladder fibrosis, so it is important to look for ways to prevent the neurogenic bladder fibrosis.

Losartan is an AT1 blocker which is commonly used to treat hypertension in clinic[2]. Previous studies have found Losartan could prevent colorectum, heart, liver and kidney fibrosis by blocking the combine of Ang II and AT1 in regulating TGFβ1/smads pathway. In this study, the degree of fibrosis in LSTG was significantly lower than TSNG,the expression quantity of TGFβ1 in the bladder tissues of LSTG was significantly lower thanTSNG. In addition AT1 been expressed in bladder tissues. These results indicated that losartan could

prevent bladder fibrosis in NB by blocking the combination of Ang II and AT1 in down-regulating TGFβ1 too.

It's well known that high bladder pressure for long time will lead to hydronephrosis which destroys kidney function. This study showed the rats in LSTG and TSNG produced hydronephrosis and renal impairment month 1 post-operation. These results may be because the bladders were chronically exposed to the high Pves.leak. Nevertheless, the level of hydronephrosis in LSTG was lesser than that in TSNG, which might because the Pves.leak in LSTG was slightly lower than TSNG. The reason for slightly lower Pves.leak in LSTG than TSNG may be associated with the little degree of bladder fibrosis in LSTG, because previous studies found that bladder neck fibrosis could increase the Pves.leak, however the specific mechanism needs to be study in the further. These findings may indicate that losartan could protect renal function though prevented bladder fibrosis in NB.

CONCLUDING MESSAGE

Losartan may play the role in preventing neurogenic bladder fibrosis by stop signaling Ang II / AT1/ TGFβ1, and protecting renal function. However, the exact mechanism remains to be further studied.

FIGURE 1

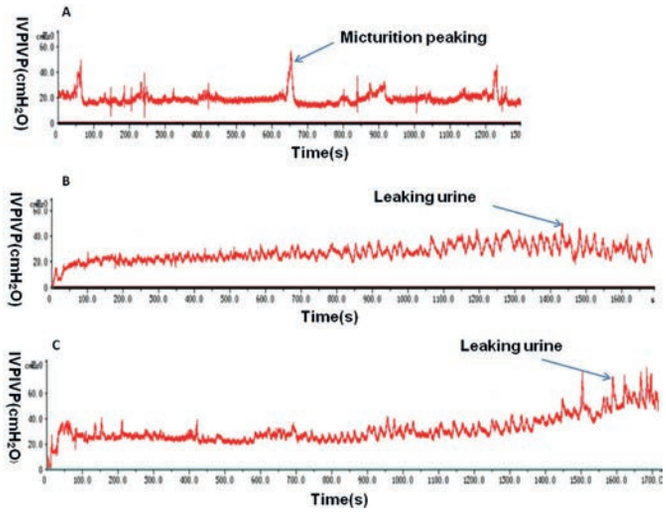

Figure 1: Bladder function. A-C: Representative curve of day 32 post-cystostomy in CG, LSTG and TSNG. The rats of CG stores urine at low pressure, when the pressure reached the Pves.thre a micturition peaking occured. The rats of LSTG and TSNG were unable

FIGURE 2

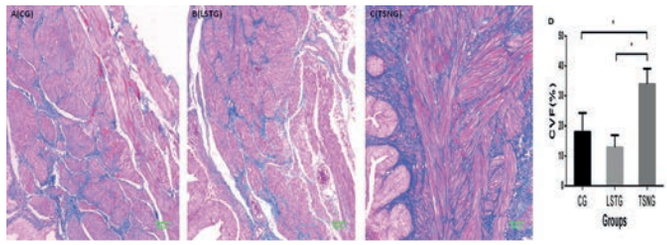

Figure 2: The result of Masson staining. A-C: The result of Masson staining of CG, LSTG and TSNG. D: he amount of collagen in the bladder tissue increased significantly in TSNG compared with LSTG and CG, while there was no significant different between CG

REFERENCES

1. Howard PS, Renfrow D, Schechter NM, et al. Mast cell chymase is a possible mediator of neurogenic bladder fibrosis. Neurourol Urodyn. 2004;23:374-82.
2. Jatic Z, Skopljak A, Hebibovic S, et al. Effects of Different Antihypertensive Drug Combinations on Blood Pressure and Arterial Stiffness. Med Arch. 2019;73:157-162.

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UROTHELIAL LYSOSOMAL DYSFUNCTION CAUSES BLADDER HYPERACTIVITY AND INFLAMMATION

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HYPOTHESIS / AIMS OF STUDY

It is well known that the prevalence of bladder pathology increases with age. For example, increased age is associated with a decrease in bladder capacity, increased bladder sensations, and increases in urinary concentrations of ATP and other pro-inflammatory mediators. These changes can lead to a clinical manifestation of bladder pathologies such as overactive bladder (OAB) and bladder pain syndrome/interstitial cystitis (BPS/IC), with symptoms such as urgency, frequency and pain. However, little is known about the cellular mechanisms that drive these pathological changes with age.

One possibility may be defects in the endolysosomal pathway of the urothelium. It is known that lysosomal function diminishes with age, especially in post-mitotic cells such as differentiated epithelia. This can lead to a buildup of undigested cellular material and damaged intracellular organelles, leading to disrupted cellular function. A previous study demonstrated that aged rats (~26 months old) exhib-

ited a marked increase in endolysosomal volume with a concurrent increase in endolysosomal pH [1]. As the function of the lysosome is directly tied to the acidic nature of its luminal pH, cathepsin B activity was also decreased. Additionally, it has been recently demonstrated that the lysosome acts as a significant store of ATP in the urothelium, and that stimulation of urothelial cells with agents such as bacterial lipopolysaccharides (LPS) can induce ATP release through lysosomal exocytosis. This has led us to hypothesize that defects in lysosomal function may play a role in bladder dysfunction and that increasing lysosomal pH artificially may result in bladder hyperactivity and inflammation in rats. Thus, alkalization of urothelial lysosomal pH may represent a new model for BPS/IC.

STUDY DESIGN, MATERIALS AND METHODS

To increase lysosomal pH, we used chloroquine (CHQ), a lysosomotropic weak base which has been shown to collect in lysosomes. Once inside the lysosome, chloroquine becomes protonated, preventing it from leaving the lysosome and decreasing lysosomal pH. To demonstrate the importance of the lysosome to a given effect, we used Gly-Phe β-naphthylamide (GPN), another agent that collects preferentially into lysosomes, where it is cleaved by cathepsin C. The cleavage product of GPN collects in the lysosome, creating an osmotic gradient that causes the lysosome to swell and eventually lyse.

The cell-based portion of our study used immortalized normal human urothelial cells (TRT-HU1) at passage number 25-35. Cells were used for experiments after 1-2 days when they had reached 50-70% confluency.

To measure extracellular ATP concentrations, TRT-HU1 cells were grown in white-walled 96-well plates. First, the media supporting the cells was first replaced with 50µl of Krebs solution alone or containing GPN (20µM, 2X final concentration) and incubated at 37°C for 20 minutes. 50µl of Krebs (for non-stimulated controls) or CHQ (200µM, 2X final concentration) was then added and the plate incubated again for 30 minutes at 37°C. 50µl of the luciferin/luciferase assay mix (Sigma-Aldrich) was then added and the luminescence measured using a plate-based luminometer. Luminescence readings were converted to ATP concentrations using a standard curve with known concentrations of ATP.

To measure lysosomal pH, TRT-Cells were grown in black-walled 96-well plates. At the time of the experiment, the media was removed and replaced with 50µl of either Krebs solution alone (control) or CHQ (100µM). After a 30-minute incubation, the extracellular solution was aspirated and the cells incubated with 5 µM LysoSensor Yellow/Blue DND 160 (Invitrogen) for 3 min followed by a 15 min post-incubation in Krebs solution. Lysosomal pH was determined from the ratio of light emitted at 450 nm vs. 510 nm (365 nm ex) using a plate reader (Tecan Spark 20M) and calibrated by exposing cells to 10µM monensin and 20 µM nigericin in a solution containing (in mM) 20 MES, 110 KCl and 20 NaCl at pH 4.0–6.0 for 15 min.

Extracellular IL-1β concentrations were measured using a commercially available ELISA kit (Abcam). Briefly, TRT-HU1 cells, grown on 35mm dishes, were stimulated with CHQ (100µM in Krebs solution) for 2 hours. To measure IL-1β, 100µl samples of the extracellular solution was used in triplicate according to the manufacturer's instructions.

For our in vivo experiments, female Sprague-Dawley rats (~200-250g) were anesthetized using isoflurane and CHQ (100µM in sterile saline, 0.5ml) was instilled in the bladder through a transurethral catheter for 1 hour. The animals were then used immediately for cystometry or plasma extravasation or allowed to recover for experiments one or three days later. For cystometry, the rats were anesthetized with urethane and catheterized through the bladder dome. Open cystometry was then performed by perfusing Krebs solution into the bladder at a rate of 0.08ml/min. For plasma extravasation, rats were anesthetized using urethane, and Evans Blue (50mg/kg) was injected through a jugular vein catheter. Fifteen minutes after dye injection, the rats were sacrificed by decapitation, exsanguinated and the bladder removed. After weighing, the bladder was placed in 3 ml formamide for 72 hours. The dye present in the formamide solution was quantified by measuring optical density and then the concentration was estimated using a standard curve.

For bladder strip experiments, bladders were removed from female Sprague Dawley rats, cut into strips longitudinally, and attached to a force displacement transducer in a tissue bath containing oxygenated Krebs solution at 37°C. Agonists and antagonists were bath applied and changes in basal tone and spontaneous contraction amplitude recorded.

RESULTS

Stimulation of TRT-HU1 urothelial cells with CHQ (100µM) increased lysosomal pH from 4.5 to 5.0 and increased extracellular ATP concentrations by 13.6%, which was prevented after pre-incubation with GPN. Extracellular concentrations of the pro-inflammatory cytokine IL-1β were also increased following CHQ treatment. During in vitro rat bladder strip experiments, CHQ increased the area of spontaneous detrusor contractions by 30.1% one hour after application. This increase was also blocked by GPN pre-treatment. Intravesical instillation of CHQ during cystometry in anesthetized rats showed a small increase in voiding frequency after 2 hours (~25%). This increase in voiding frequency was greater 24 or 72 hours after CHQ treatment. Plasma extravasation in these animals also showed a time dependent increase in bladder edema, with a maximum increase after 72 hours (~10-fold).

INTERPRETATION OF RESULTS

Our results demonstrate that alkalization of urothelial lysosomes using chloroquine can induce bladder hyperactivity and inflammation, as demonstrated by increased spontaneous detrusor contractions, increased voiding frequency and increased plasma extravasation in the bladder. The mechanism of these effects most likely includes the release of ATP through lysosomal exocytosis and release of pro-inflammatory cytokines such as IL-1β. This suggests that urothelial lysosomal dysfunction may be a plausible etiology for bladder pathology, especially in the aged where lysosomal dysfunction is more common.

CONCLUDING MESSAGE

Our study indicates that urothelial lysosomal dysfunction may be a plausible etiology for inflammatory bladder disorders such as BPS/IC, especially in the aged population where lysosomal dysfunction is more common. The effects of one intravesical treatment of chloroquine are long lasting; inducing bladder hyperactivity and inflammation that lasts for at least 3 days. This makes intravesical chloroquine instillation an easy method for inducing lysosomal dysfunction and may serve as an excellent animal model for BPS/IC.

REFERENCES

1. Truschel ST, Clayton DR, Beckel JM, et al. Age-related endolysosome dysfunction in the rat urothelium. PLoS One. 2018;13(6):e0198817. Published 2018 Jun 8. doi:10.1371/journal.pone.0198817

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ACID-SENSING ION CHANNEL 3 (ASIC3) INHIBITOR INCREASES FUNCTIONAL BLADDER CAPACITY WITH OR WITHOUT ACIDIC IRRITATION OF LOWER URINARY TRACT IN MICE WHEN ADMINISTERING INTRAPERITONEALLY BUT NOT INTRAVESICALLY

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HYPOTHESIS / AIMS OF STUDY

Acid-sensing ion channel (ASIC) is a member of sodium channel superfamily including the epithelial sodium channel/degenerin (ENaC/DEG) that play crucial roles in mechanosensation, chemosensation, and nociception. ASIC is composed of 5 subunits, ASIC1, ASIC2, ASIC3, ASIC4, and ASIC5; and ASIC1 and ASIC2 have 'a' and 'b' forms [1]. Previous study revealed that genes of ASIC subunits are largely expressed in the mouse urinary bladder (i.e., detrusor and bladder mucosa) and L6/S1 dorsal root ganglia (DRGs) innervating the bladder, suggesting the possibility that ASICs are involved in modulation of lower urinary tract (LUT) function [2]. Furthermore, the study showed that the total amounts of ASIC genes which are expressed in the bladder and the DRGs are more than those of TRPV1 genes in mice. A-317567 is a potent ASIC3 inhibitor, which has been reported to exert antidepressant and antinociception effects. We conducted this study using A-317567 to determine whether ASIC3 play a functional role in control of LUT activity.

STUDY DESIGN, MATERIALS AND METHODS

Female C57BL/6 mice (12-14 week-old) were used. The animals were anesthetized with sevoflurane during surgery including precollicular decerebration. A low midline abdominal incision was made, and a PE-50 tube was inserted into the bladder dome to record intravesical pressure. Cystometrogram (CMG) recordings conducted under unanesthetized conditions were started 2 h after decerebration, by continuously infusing saline (pH 6.3; infusion rate: 30 µl/min) at room temperature. CMG parameters evaluated were: maximal voiding pressure (MVP) and inter-contraction interval (ICI). A-317567 was dissolved in physiological saline adjusted to pH 2.8 and pH 6.0 with 1 N sodium hydroxide for i.p. injection (100 mM) and intravesical perfusion (100 µM), respectively. A-317567 was also dissolved in dilute acetic acid (A/A, pH 3.0) for intravesical perfusion (100 µM), to examine the drug effects on the bladder hyperactivity during irritation of LUT. The dose for i.p. injection was 30 µmol/kg; the dose was chosen because it has been shown to produce marked analgesic effects in previous study [1]. Effects of A-317567 were compared with those of the vehicle. All values are expressed as mean ± S.E.M. Statistical analysis was made using repeated measures two-way ANOVA followed by Sidak's multiple comparisons test when applicable. $P < 0.05$ was considered significant.

RESULTS

I.p. injection of A-317567 increased ICI by 30 % during saline infusion CMG, whereas it had no effects on MVP (***$P < 0.001$) (Table 1a). The drug ameliorated an aberrance in urine storage such as bladder hyperactivity induced by intravesical A/A perfusion, increasing ICI by 70 % (****$P < 0.0001$) (Table 1b). The effect only lasted for less than 10 min. The i.p. dose produced no changes in MVP (i.e., during bladder contraction period). The vehicle i.p. injection did not produce any effects on either normal LUT activity (during saline infusion) or A/A-induced bladder hyperactivity.

Intravesical perfusion of A-317567 (100 µM) had no effects on bladder activity with or without A/A irritation (i.e., pH3.0 or pH6.0) to the LUT (Table 2a,b).

INTERPRETATION OF RESULTS

ASIC3 is involved in afferent signal transduction of reflex bladder activity under conditions of the LUT either with or without acid irritation, showing a contribution to urine storage function; whereas it does not participate in modulation of bladder contractility (i.e., efferent modulation). The systemic injection of A-317567 exhibited a short duration in the action. Meanwhile, ASIC3 blocker given intravesically did not change the LUT activity either with or without acid irritation.

CONCLUDING MESSAGE

Block of signal transduction via ASIC3 can be useful in treatment of urine storage dysfunctions such as overactive bladder and painful bladder syndrome. Since the mouse DRGs are rich in ASIC3 gene, which is comparable to amount of TRPV1 gene [2], a site responsible for action of A-317567 is likely to be in DRGs although it is undetermined in this study. Further study is necessary to elucidate the mechanism underlying the beneficial effect of the ASIC3 blocker.

FIGURE 1

Table 1a	*Intravesical perfusion*	*pH6.3*	
	Drug (i.p.)	*Before*	*After*
ICI	A-317567	306.3 ± 22.9	398.9 ± 39.7****
(sec)	Vehicle	317.2 ± 39.9	311.4 ± 45.4
MVP	A-317567	22.7 ± 1.7	26.1 ± 3.9
(mmHg)	Vehicle	24.9 ± 2.0	24.6 ± 1.6

Table 1b	*Intravesical perfusion*	*pH6.3*		*A/A (pH3.0)*	
	Drug (i.p.)	*Before*		*After*	*10 min later*
ICI	A-317567	330.3 ± 36.0	79.2 ± 9.1	134.9 ± 12.0****	76.1 ± 12.0
(sec)	Vehicle	453.9 ± 44.5	72.7 ± 15.2	64.8 ± 9.1	64.5 ± 10.2
MVP	A-317567	25.8 ± 0.6	18.8 ± 1.7	18.8 ± 2.0	19.1 ± 1.8
(mmHg)	Vehicle	23.5 ± 2.2	15.7 ± 1.8	15.7 ± 1.0	18.0 ± 2.2

Effects of A-317567 given intraperitoneally

FIGURE 2

Table 2a	*Intravesical perfusion*	*pH6.3*	*pH6.0*
	Drug (Intravesical)	*Before*	*After*
ICI	A-317567	317.3 ± 42.8	271.3 ± 34.0
(sec)	Vehicle	315.2 ± 20.4	283.5 ± 20.2
MVP	A-317567	22.1 ± 1.2	21.6 ± 0.9
(mmHg)	Vehicle	22.4 ± 0.8	21.8 ± 1.1

Table 2b	*Intravesical perfusion*	*pH6.3*	*A/A (pH3.0)*
	Drug (Intravesical)	*Before*	*After*
ICI	A-317567	308.6 ± 25.4	66.3 ± 10.0
(sec)	Vehicle	298.5 ± 41.0	81.8 ± 13.3
MVP	A-317567	23.3 ± .12	13.5 ± 1.1
(mmHg)	Vehicle	21.0 ± 0.4	13.3 ± 1.0

Effects of A-317567 given intravesically

REFERENCES

1. Dubé GR et al. Pain 117:88-96 (2005)
2. Kobayashi H et al. BJU Int 104:1746-1751 (2009)

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MAST CELL TRYPTASE CAUSES LOWER URINARY TRACT DYSFUNCTION ASSOCIATED WITH CHRONIC ISCHEMIA

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HYPOTHESIS / AIMS OF STUDY

Uroplakin (UP) Ia, UP Ib, UP II, and UP III are known to be critical factors in normal urothelial barrier function (1). Impairment of UP II has been reported to cause mast cell infiltration in mice bladders. Current attention has focused on the association between urothelial barrier dysfunction and lower urinary tract dysfunction (LUTD). Defects in UPs lead to abnormal voiding patterns (2). Recent studies have suggested that mast cells contribute to bladder hyperactivity. Mast cells play an important role in detrusor overactivity induced by visceral hypersensitivity in rats (3). Mast cell tryptase (MCT) can regulate neuronal activity by cleaving Protease-activated Recepter 2 (PAR2), which is expressed on C-fiber. However, it has not been established whether or not urothelial barrier dysfunction causes bladder hyperactivity through PAR2 activation by MCT.

On the other hand, pelvic arterial occlusive disease, including atherosclerosis, has been suggested to cause chronic bladder ischemia, which may play a key role in the development of LUTD in both men and women. The mechanisms underlying the changes in bladder function caused by chronic ischemia have not been completely elucidated.

This study aims to investigate the effects of arterial occlusive disease-related chronic ischemia on UPs, mast cells and PAR2 in the bladder using a rat model of chronic bladder ischemia (CBI).

STUDY DESIGN, MATERIALS AND METHODS

Adult male Sprague-Dawley rats (16 weeks old) were divided into two groups (control and CBI; n = 10 each). The CBI group underwent balloon endothelial injury of bilateral iliac arteries and received a 2% cholesterol diet for 8 weeks to induce arterial occlusive disease-related chronic ischemia. The control group received a regular diet for 8 weeks. After monitoring urine output for 24 h, the bladders and common iliac arteries were harvested for pharmacological and histological examinations. Western blot analysis was used to measure the expression of UP Ia, UP Ib, UP II, UP III, MCT, PAR2 and HIF1α, an oxidative stress marker, in the bladder of this rat model. The bladders were processed for immunohistochemical and methylene blue staining. All values are expressed as mean ± standard deviation. Values of $P < 0.05$ were considered statistically significant.

RESULTS
There was no statistically significant difference in the wet weights of the bladders in the two groups (control vs CBI: 0.237 ± 0.054 g vs 0.241 ±0.055 ml, P = 0.888). Metabolic cage studies showed that the mean and maximum voided volumes were significantly smaller in the CBI group than in the control group (control vs. CBI, mean voided volume: 1.46 ± 0.33 ml vs 1.01 ±0.21 ml, P = 0.001; maximum voided volume: 2.62 ± 0.60 ml vs 2.01 ± 0.41 ml, P = 0.023). Mean arterial wall thickness was significantly greater in the CBI group (116.3 ± 23.8 μm) than in the control group (82.0 ± 26.3 μm; P < 0.001). Western blot analysis showed expression of HIF1α (P = 0.034), MCT (P = 0.024) and PAR2 (P = 0.021) were significantly increased, and UP II expression was significantly decreased (P = 0.011) in the CBI group as compared with the control group. However, no significant differences were found in UP Ia, UP Ib or UP III expression between the two groups. Immunohistochemical staining revealed that UP II-positive cells were located mostly on the urothelium. The percentage of UP II-positive cells was significantly lower in the CBI group (63.0 ± 0.11%) than in the control group (92.1 ± 0.1%, P < 0.001). Methylene blue staining revealed the number of mast cells were significantly higher in the CBI group than in the control group (P = 0.034).

INTERPRETATION OF RESULTS
In this study, increased levels of the oxidative stress marker and decreased voided volume in the CBI group indicate that pelvic arterial occlusive disease causes an ischemia/reperfusion injury and LUTD in a rat model of chronic bladder ischemia. Our results also demonstrate that expression of UP II in the urothelium was reduced in chronically ischemic rat bladders. One possible explanation is that chronic ischemia impairs urothelial barrier function through reduced expression of UP II in rats. Urothelial barrier dysfunction contributed to mast cell infiltration and increased PAR2 on C-fiber, resulting in PAR2 activation by mast cell tryptase. Activation of PAR2 may induce LUTD by stimulating C-fiber in a rat model of chronic bladder ischemia.

CONCLUDING MESSAGE
Our results suggest that chronic ischemia induced by pelvic arterial occlusive disease may cause urothelial barrier dysfunction through reduced expression of UP II. A possible explanation for this is urothelial barrier dysfunction associated with CBI induced LUTD secondary to increased expression of PAR2 and mast cell tryptase.

REFERENCES
1. Hu P, et al: Role of membrane proteins in permeability barrier function: uroplakin ablation elevates urothelial permeability. Am J Physiol Renal Physiol 2002;283:F1200-7.
2. Aboushwareb T, et al: Alterations in bladder function associated with urothelial defects in uroplakin II and IIIa knockout mice. Neurourol Urodyn. 2009;28(8):1028-33.
3. Zhang NZ, et al: Changes in mast cell infiltration: a possible mechanism in detrusor overactivity induced by visceral hypersensitivity. Int Braz J Urol. 2016;42(2):373-82.

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LONG-LASTING BLADDER HYPERSENSITIVITY WITH FREQUENT URINATION INDUCED BY INTRAVESICAL APPLICATION OF OF HYDROGEN PEROXIDE IN RATS WITH PELVIC VENOUS CONGESTION

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HYPOTHESIS / AIMS OF STUDY
The etiology of chronic pelvic pain syndrome including interstitial cystitis/bladder pain syndrome (IC/BPS) seems to be multifactorial. Recent studies have shown that pelvic venous congestion is an important cause of chronic pelvic pain in humans and animal models [1]. Furthermore, bladder-centric IC/BPS identified by bladder pathologies such as Hunner lesions is often associated with severe inflammatory changes in the bladder, and the prevalence of this type of IC/BPS seems to be higher than previously thought [2]. Thus, animal models with cystitis have been used to study the inflammation-related aspects of IC/BPS pathophysiology. However, previous experimental animal models of cystitis, for example, those induced by a single intraperitoneal or intravesical application of injection of chemical irritants such as cyclophosphamide or its metabolite, acrolein, exhibit only short-term inflammatory responses and urinary symptoms within several days. Recent studies reported that animals with an intravesical application of hydrogen peroxide (H2O2) exhibited bladder inflammation and hypersensitivity, which lasted longer than 7 days [3]. In this study, we sought to establish a new model of longer-lasting bladder hypersensitivity induced by intravesical application of H2O2 using rats with pelvic congestion.

STUDY DESIGN, MATERIALS AND METHODS
We used adult female Sprague–Dawley rats. (I) Pelvic vein congestion: Rats were anesthetized with 2% isoflurane, and an incision was made in the lower abdomen. In the pelvic vein congestion groups, the bilateral common iliac veins and uterine veins were ligated. In the sham operation groups, the bilateral common iliac veins were dissected free from the common iliac arteries [1]. (II) Intravesical H2O2 injection: Rats were anesthetized with 2% isoflurane, and a polyethyl-

ene tube (PE-50) was introduced into the bladder transurethrally and then the lower abdomen was pressed gently to withdraw urine. Thereafter, 300 µL of 1.5% H2O2 solution or vehicle was injected into the bladder through the catheter. The H2O2 solution or vehicle was drained from the bladder after 30 min by pressing the lower abdomen [3].

Rats were divided into four groups; Sham operation-Vehicle injected group (S-V; n = 8), Pelvic vein congestion-Vehicle injected group (C-V; n = 8), Sham operation-H2O2 injected group (S-H; n = 8) and Pelvic vein congestion- H2O2 injected group (C-H; n = 8). Vehicle or H2O2 solution was instilled into the bladder at 2 weeks post-pelvic congestion or sham surgery. Voiding behavior was evaluated using metabolic cages before the operation, 2-weeks after pelvic congestion or sham surgery, 1-week and 2-weeks after vehicle or H2O2 application in each animal. Cystometry was also performed at 2-weeks after vehicle or H2O2 application in each group. Under isoflurane anesthesia, a polyethylene catheter was inserted into the bladder through the bladder dome. Saline was continuously infused into the bladder at a rate of 0.04 mL/min in an awake condition. Intercontraction intervals (ICIs), basal pressure and peak pressure were measured after rhythmic bladder contractions became stable for at least 60 min.

RESULTS

The table shows the number of micturition and average urine volume per voiding at pre-operation, 2-weeks after pelvic congestion or sham surgery, 1-week and 2-weeks after vehicle or H2O2 application into the bladder. Pelvic congestion alone for 2 weeks did not alter these voiding parameters. However, the number of micturition of the C-H group was significantly increased compared to the S-V group at two weeks after bladder H2O2 or vehicle application (21.8 vs 15.7; p<0.05). The average urine volume per voiding of the C-H group is significantly decreased compared to the S-V or S-H group at two weeks after H2O2 or vehicle application into the bladder, respectively (0.26 vs 0.55 or 0.46 mL, p<0.05). In cystometry (Figure), ICIs were significantly smaller in the C-H group compared to the S-V group (4.4 vs 10.0 min; p<0.05). Basal pressure and peak pressure were not significantly difference among group.

INTERPRETATION OF RESULTS

In this study, bladder hypersensitivity evident as frequent urination with smaller voided volume lasted up to 14 days after a single intravesical application of H2O2 into rats with pelvic congestion although pelvic congestion alone for 2 weeks did not alter bladder function. It has been suggested that increased vascular permeability may be involved in lower urinary tract dysfunction due to pelvic congestion or chemical cystitis [1][3]. Thus, it is likely that two pathological changes dues to chemical irritation and pelvic congestion act synergistically to induce a longer-lasting animal model of bladder hypersensitivity than previous models including the H2O2-induced cystitis model.

CONCLUDING MESSAGE

This study revealed that a single intravesical application of H2O2 into rats with pelvic congestion induces relatively long-lasting bladder hypersensitivity with frequent urination. This model would be suitable for the study of the inflammation-related pathophysiologies of IC/BPS, especially the bladder-centric phenotype with tissue inflammation. Further studies are warranted to investigate the molecular or histological changes in relation to bladder dysfunction in this animal model.

FIGURE 1

a

	POD 0	POD 14	D 7	D 14
S-V	12.0	13.2	14.3	15.7
S-H	13.9	13.8	17.7	17.8
C-V	10.8	13.5	15.6	15.5
C-H	14.0	15.8	24.3*	21.8*

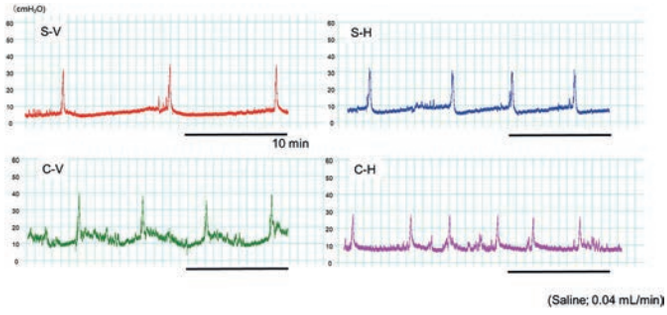
b

	POD 0	POD 14	D 7	D 14
S-V	0.42	0.44	0.62	0.55
S-H	0.44	0.43	0.30*	0.46
C-V	0.42	0.34	0.35*	0.42
C-H	0.40	0.32	0.25*	0.26**

POD: post operative days of pelvic congestion or sham surgery
D: the days after vehicle or H_2O_2 application into the rats
*$P < 0.05$, compared to the S-V group
**$P < 0.05$, compared to the S-V or S-H group
One way ANOVA with Bonferroni's multiple comparison test

Table; Metabolic cage study. (a) The number of micturition and (b) the average urine volume per voiding (mL) in each group

FIGURE 2



Figure; Representative CMG traces at 2 weeks after vehicle (V) or H2O2 (H) application into the bladder in rats with sham (S) or pelvic vein congestion (C)

REFERENCES

1. Tadalafil improves bladder dysfunction and object recognition in rats with pelvic venous congestion. Nishijima S, Sugaya K, Kadekawa K, Ashitomi K, Ueda T, Yamamoto H. Int J Urol. 2019 May;26(5):578-585.
2. Hunner lesion versus non-Hunner lesion interstitial cystitis/bladder pain syndrome. Whitmore KE, Fall M, Sengiku

A, Tomoe H, Logadottir Y, Kim YH. Int J Urol. 2019 Jun;26 Suppl 1:26-34.
3. A rat long-lasting cystitis model induced by intravesical injection of hydrogen peroxide. Dogishi K, Okamoto K, Majima T, Konishi-Shiotsu S, Homan T, Kodera M, Oyama S, Oyama T, Shirakawa H, Yoshimura N, Nakagawa T, Kaneko S. Physiol Rep. 2017 Feb;5(4). pii: e13127.

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A PILOT ANIMAL MODEL TO IDENTIFY THE INTRAVESICAL BLADDER IRRITANT CYSTOMETRIC DOSE RESPONSE THRESHOLD FOR SIX COMMON ENVIRONMENTAL EXPOSURES ASSOCIATED WITH OVERACTIVE AND PAINFUL BLADDER DYSFUNCTION IN HUMANS WITH IC/BPS

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HYPOTHESIS / AIMS OF STUDY

Interstitial cystitis / bladder pain syndrome (IC/BPS) affects 3.5 to 8.6 million women in the United States. The clinical hallmark of this disease is a chronic painful bladder which is typically worse with bladder filling, has pain poorly relieved with bladder emptying, and marked urinary urgency / frequency. There is considerable overlap between IC/BPS, and the overactive urinary urgency/frequency of overactive bladder (OAB). The underlying pathophysiology of BPS is unknown but may include chronic inflammation, autoimmune dysregulation, bacterial cystitis, urothelial dysfunction, deficiency of the glycosaminoglycan barrier, and urine cytotoxicity. Women with BPS often report a herald noxious event which results in the initial onset of painful bladder, such as cystitis, pelvic surgery, or sexual trauma. The overarching aim of our research was to evaluate an acute intravesical exposure in a pilot animal model using cystometry, organ bath myography and histology for 6 common environmental exposures and one novel agent implicated in mast cell stabilization. For this phase of our pilot study, we sought to characterize the cystometric dose response threshold in rats, for six common environmental exposures associated with overactive and painful bladder dysfunction in humans with IC/BPS.

STUDY DESIGN, MATERIALS AND METHODS

Following institutional animal protocol approval, seven female adult wild type Sprague Dawley rats (Charles River Laboratories) underwent urethane anesthetized bladder cystometry (CMG). CMG under anesthesia was performed using solutions implicated in overactive and painful bladder dysfunction. Common environmental exposures were assessed, including caffeine (0.0001 to 10 mg/mL), ethanol (0.001 to 30 %), capsaicin (0.001 to 10 uM), citric acid (0.0001 to 100 mg/mL), acetic acid (0.01 to 3 %), saccharin (0.0001 to 1 mg/mL) and one novel agent implicated in mast cell stabilization, compound 48/80 (0.01 to 100 ug/mL). CMG was performed at 50 uL/min infusion rate through PE-50 tubing placed into the dome of the bladder. Bladders were filled at a constant rate until stable cystometric contraction patterns were demonstrated with normal saline (0.9% NaCl). Baseline fills with saline were repeated at least 2 to 7 times in order to demonstrate reproducibility of baseline for each animal, and post void residual (PVR) was checked after each fill cycle. Following saline infusion, the infusion was changed to intravesical dose-escalating solutions of: caffeine, ethanol, capsaicin (the active compound in chili peppers), citric acid, acetic acid, saccharin and compound 48/80 (a mast cell secretagogue). Animals were continuously observed through all CMG cycles, non-voided contractions were annotated, and voided volume was manually measured for each void by weighing each void by the change in weight of an absorbent paper before and after each void. PVR was recorded in uL based on the weight of the residual volume removed from the bladder through the PE-50 tubing at the end of each fill cycle. PVR was used to calculate cystometric capacity and voiding efficiency for each fill cycle. All animals were comfortably anesthetized throughout each CMG cycle and there were no animals which required early euthanasia.

RESULTS

The results from CMG for the intravesical agents with known irritant (Figure 1) and suspected (Figure 2) effects were graphed over time, with intravesical exposure concentration noted on the x-axis over time, with a separate data point noted for each complete CMG fill cycle. Concentrations of zero represent saline infusion. Mean voided volumes are graphed in 1x or 10x scale in uL where indicated. PVR volumes are graphed in uL for all animals. Pre-void bladder volume was calculated for each individual void by adding the voided volume to the PVR at the end of each fill cycle in order to determine beginning bladder capacity for each measured void, with the assumption that PVR was stable throughout each CMG fill cycle. Voiding efficiency for each void was calculated by dividing pre-void bladder volume by each unique void volume, and then a mean voiding efficiency calculated for each fill cycle. In order to normalize data for graphing on a single chart, voiding efficiency (e.g. 0.01 for 1%) for each intravesical exposure are graphed in 1,000x (1k) or 10,000x (10k) scale where indicated. There were no rats and no data points excluded from any of the figures.

With respect to the acids and irritants (Figure 1), intravesical acetic acid in various concentrations has been used to induce overactivity in many animal models of overactive

bladder. On the other hand, citric acid, a common component of citric and acidic juices, is implicated as a known bladder irritant which exacerbates the painful symptoms of IC/BPS. Following exposure to acetic acid, there were stable reductions in voided volume which were 10 fold lower than that observed following exposure to citric acid. Acetic acid resulted in dose-wise reductions in PVR, with a pronounced acute exposure threshold beginning at 0.5 to 1% acetic acid, associated with increases in mean voided volume and mean voiding efficiency. Following exposure to citric acid, there was a universal increase in voided volume with marked improvement in voiding efficiency beginning at 0.001 mg/mL, continuing to 0.1 mg/mL. After the 1 mg/mL exposure threshold, there was a sudden decrease in voiding efficiency with a dose response effect which continued to worsen voiding efficiency and raise PVR, and progressively worsened with higher concentrations. Looking at the exposure to caffeine, which is implicated as a bladder irritant in humans with overactive bladder, there was a dose response threshold beginning at the 0.001 to 0.01 mg/mL concentration. With increasing concentrations of caffeine, mean voiding efficiency progressively increased and there was a dose independent loss of functional bladder capacity. Following exposure to capsaicin, there were initial improvements in voiding efficiency which began at the lowest concentration of 0.001 uM, and then beginning at the 1 uM exposure level, there was a progressive worsening in voiding efficiency concurrent with time dependent increase in PVR.

With respect to the artificial sweetener saccharin and ethanol (Figure 2), each of these agents, when administered intravesically, appear to exert a physiologic effect on bladder function. Following exposure to saccharin, beginning at the 0.01 mg/mL threshold, there appears to be a dose dependent increase in voiding efficiency as a result of loss of functional capacity and dose sensitive decrease in PVR. Ethanol has been implicated in humans as inducing diuresis as a result of increased intake volume (polydipsia) and subsequent increased urine output (polyuria), which may manifest as overactive bladder during the acute phase, or as urinary retention in the state of inebriation. Following intravesical exposure to ethanol in the rat, we found a slow loss in voiding efficiency which appeared to be dose dependent for intravesical concentrations higher than 0.1 % ethanol, meanwhile PVR was relatively stable throughout ethanol exposure. Following exposure to intravesical compound 48/80, a mast cell secretagogue implicated in mast cell destabilization, we found no obvious physiologic effect on cystometry up to 100 ug/mL in wild type rats.

INTERPRETATION OF RESULTS

Cystometric effect was demonstrated by all of the intravesical agents except compound 48/80. Regarding the acids, more consistent irritative effects were noted following exposure to citric acid. More compliant bladder filling and lower end fill pressures were noted after exposure to caffeine, ethanol and capsaicin, which appeared to have effects on both the bladder and the outlet.

CONCLUDING MESSAGE

Further research is needed to understand the complex dose response mechanism by which intravesical exposures contribute to overactive and painful bladder dysfunction in humans with IC/BPS.

FIGURE 1

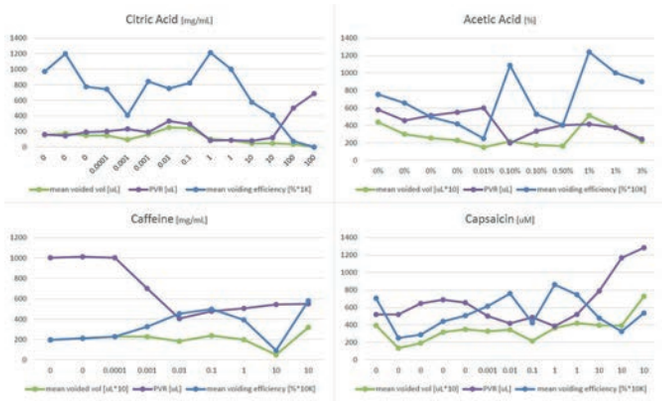

Figure 1. Cystometric effect of intravesical acids (citric, acetic) and irritants (caffeine, capsaicin) over time.

FIGURE 2

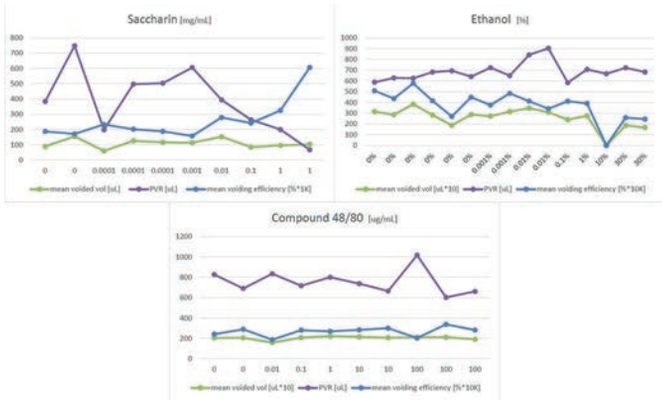

Figure 2. Cystometric effect of intravesical artificial sweetener (saccharin), ethanol and mast cell secretagogue (compound 48/80) over time.

Funding Faculty Startup Fund **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Institutional APLAC protocol # 33672

SESSION 26 (PODIUM SHORT ORAL) - MALE VOIDING DYSFUNCTION AND LUTS 2
Abstracts 405-416
15:30 - 17:00, Pavilion 9
Chairs: Prof Vincent Tse (Australia), Dr Roger Roman Dmochowski (United States)

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DO 5 ALPHA REDUCTASE INHIBITORS REDUCE THE RISK OF RECURRENT GROSS HEMATURIA AFTER A TRANSURETHRAL PROSTATECTOMY?

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HYPOTHESIS / AIMS OF STUDY
5-alpha reductase inhibitors (5ARIs) are often used for the treatment of BPH, however there is limited evidence on their efficacy after a transurethral prostatectomy (TURP); despite this they are commonly used post-TURP, as we have shown with our previous research. Our objective was to determine if 5ARI use after an episode of gross hematuria following a TURP reduces the risk of further episodes of gross hematuria.

STUDY DESIGN, MATERIALS AND METHODS
We conducted a population based retrospective cohort study using data from Ontario, Canada. Men who had a TURP between 2003-2016 were included and we excluded those with a prior TURP, prostate cancer, a bladder tumor resection, or <66yrs. We identified men who returned to the hospital/ER with gross hematuria at least 90 days after their TURP, and used the date of the initial episode of gross hematuria as the study start date. We treated the use of 5ARIs as our primary time-varying exposure. The primary outcome was recurrent hospital/emergency room visits with gross hematuria. We used an Anderson-Gill proportional hazards model to evaluate the association between 5ARI utilization and gross hematuria.

RESULTS
There were 9,449 men who had at least one episode of gross hematuria post-TURP. The median age was 80 (IQR 75-85), and most underwent an electrosurgical TURP. The median time between the TURP and the initial episode of gross hematuria was 3 years. During the study period, there were 2,713 (29%) men who had at least one prescription for 5ARIs. Our primary analysis showed that 5ARI users actually had an increased rate of emergency room visits or hospital admissions for gross hematuria compared to non-5ARI users (adjusted HR 1.22, 95% CI 1.05-1.43). However, this was no longer statistically significant in a number of sensitivity analyses (with hazard ratios closer to 1).

INTERPRETATION OF RESULTS
We did not find that 5ARI use among men with an episode of gross hematuria post TURP reduced the rate of repeat episodes of gross hematuria requiring medical attention compared to non-5ARI users. The use of 5ARIs after TURP is common, however the efficiacy is generally not proven. A single RCT did not show any benefit to 5ARIs in terms of reducing the rate of repeat TURP or reducing bleeding risk or improving voiding. Despite this, these medications are still commonly used in this setting.

CONCLUDING MESSAGE
The anecdotal use of 5ARIs for gross hematuria after a TURP should be re-evaluated. In our evaluation we did not find they led to a reduction in hospital visits for gross hematuria.

Funding St Josephs Hospital Foundation, McMaster Fund **Clinical Trial** No **Subjects** None

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TREATMENT OUTCOME OF PATIENTS WITH CNS DISORDERS AND VOIDING DYSFUNCTION AFTER BLADDER OUTLET SURGERY (TUIP, TURP, TUIBN)

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HYPOTHESIS / AIMS OF STUDY
CNS lesions have an impact on micturition, typically result in involuntary bladder contractions with coordinated sphincter function. Sensation and voluntary striated sphincter function are usually preserved, but sensation may be deficient or delayed. Urinary incontinence may occur owing to the detrusor overactivity. Bladder outlet surgeries are treatment options for voiding dysfunction secondary to bladder outlet obstruction or bladder neck dysfunction. However, LUTS may persist after these surgeries. This study focused on the therapeutic outcomes of patient with CNS lesion and voiding dysfunction who received bladder outlet surgeries and identified the predictor of satisfactory outcomes.

STUDY DESIGN, MATERIALS AND METHODS
This study is a single-center, retrospective review of VUDS database and chart review of clinical symptoms of patients from 1997 to 2019, including 51 men and 9 women who had

CNS disorders and symptoms of voiding dysfunction following bladder outlet surgery(TUR-P, TUI-P or TUI-BN). Patients with urethral stricture, history of prostate cancer, spinal cord injury or other neurological diseases were excluded. 33 patients in control group without known brain insult were enrolled. Pre-operative VUDS parameters and post-operative uroflowmetry parameters were collected. Storage and voiding symptoms were recorded by chart review. Patients' characteristics and baseline urodynamic parameters were analysed for predictive factor of outcomes.

RESULTS

The mean age of the patients was 71.06 ± 9.82 years old (range 41-87). Between three CNS groups, Parkinson's disease has better outcome in cQmax , PVR and VE. CVA group has significant improvement in frequency, PVR and VE while patients with dementia has no significant difference. Pdet is lower in dementia group while comparing to other two groups (Table.1). In total CNS group, symptoms including frequency and urinary retention have improved after surgery. About the uroflowmetry parameter, cQmax, PVR and VE have significantly improved. In patients with BPH, there is significantly improvement in frequency, urgency in control group. The similar outcomes are noted in patients without BPH (Table.2). There is no predictive factor of success found in current baseline characteristics.

INTERPRETATION OF RESULTS

Bladder outlet surgeries are effective in improving the voiding symptoms in patients with or without CNS disorder. However, there is no obvious improvement in storage symptoms in patients with CNS disorder. There is no obvious improvement in patients with dementia compare to other two groups. It may be due to that patients with dementia usually have detrusor underactivity.

CONCLUDING MESSAGE

Bladder outlet surgeries are effective to relieve voiding symptoms but not storage symptoms in patients with CNS lesions. We should have precise diagnosis before surgical intervention for the patients with CNS disorders and voiding dysfunction.

FIGURE 1

Table.1 Changes of subjective and VUDS parameters between CNS and control group, and comparison among CNS disorder groups

			Total CNS	Control	P	CVA	PD	Dementia	P
Case (N)			51	33		36	8	7	
Age (Yrs)			71.06±9.82	69.91±9.20	0.593	69.42±9.96	72.75±9.16	77.57±7.63	0.115
Storage symptoms	Frequency	Baseline	15(29.4%)	27(81.8%)	0.000	12(33.3%)	2(25%)	1(14.3%)	0.573
		Post-OP	4(7.8%)	6(18.2%)	0.599	3(8.3%)	1(12.5%)	0(0%)	0.405
		P	0.006	0.000		0.021	1.000	-	
	Urgency	Baseline	15(29.4%)	23(69.7%)	0.000	10(27.8%)	2(25%)	1(14.3%)	0.694
		Post-OP	8(15.7%)	7(21.2%)	0.612	5(13.9%)	3(37.5%)	0(0%)	0.006
		P	0.146	0.000		0.298	-	-	
	Nocturia	Baseline	11(21.6%)	16(48.5%)	0.010	9(25%)	1(12.5%)	1(14.3%)	0.651
		Post-OP	7(13.7%)	10(30.3%)	0.534	6(16.7%)	1(12.5%)	0(0%)	0.391
		P	0.375	0.109		0.625	1.000	-	
	UUI	Baseline	13(25.5%)	5(15.2%)	0.259	7(19.4%)	3(37.5%)	3(42.9%)	0.299
		Post-OP	9(17.6%)	10(30.3%)	0.979	6(16.7%)	3(37.5%)	0(0%)	0.010
		P	0.508	0.125		1.000	-	-	
Voiding	cQmax	Baseline	0.37±0.38	0.35±0.19	0.710	0.37±0.39	0.52±0.43	0.20±0.25	0.289
		Post-OP	0.55±0.46	0.81±0.31	0.003	0.56±0.44	0.68±0.53	0.20±0.25	0.313
		P	0.039	0.016		0.615	0.022	0.207	
	PVR	Baseline	191.13±224.94	97.72±114.69	0.018	202.84±233.83	107±162.09	262±261.58	0.270
		Post-OP	130.25±144.42	38.70±68.07	0.000	107.44±118.02	82.25±111.94	211.57±170.03	0.274
		P	0.024	0.548		0.048	0.003	0.068	
	VE	Baseline	0.47±0.42	0.73±0.30	0.000	0.46±0.41	0.6±0.43	0.37±0.46	0.588
		Post-OP	0.57±0.36	0.86±0.19	0.000	0.61±0.35	0.61±0.33	0.31±0.36	0.588
		P	0.004	0.002		0.004	0.040	0.140	
	Retention	Baseline	18(35.3%)	6(18.2%)	0.090	2(5.6%)	0(0%)	0(0%)	0.648
		Post-OP	4(7.8%)	0(0%)	0.030	4(11.1%)	0(0%)	2(28.6%)	0.360
		P	0.007	-		0.687	-	-	
	CIC/Foley/ cystostomy	Baseline	2(3.9%)	0(0%)	0.250	2(5.6%)	0(0%)	0(0%)	0.648
		Post-OP	1(3%)	6(11.8%)	0.007	4(11.1%)	0(0%)	2(28.6%)	0.360
		P	0.289	-		0.687	-	-	
	Pdet		40.13±31.89	40.78±22.63	0.915	40.47±28.76	54.38±40.50	22.29±31.12	0.151

CIC: clean intermittent catheterization, cQmax: correct maximal urinary flow rate, defined as $Q_{max}/V^{1/2}$, CVA: cerebrovascular accident, FS: full sensation, FSF: first sensation of filling, PD: Parkinson's disease, Pdet: detrusor voiding pressure, PVR: post-void residual volume, US: Urge sensation, UUI: urge urinary incontinence, VE: voiding efficiency

Table.1. Changes of subjective and VUDS parameters between CNS and control group, and comparison among CNS disorder groups

FIGURE 2

Table.2 Changes of subjective and VUDS parameters in patients with and without BPH

			BPH			No BPH		
			CNS(n=18)	Control(n=11)	P	CNS(n=27)	Control(n=22)	P
Age			67.45±6.81	73.72±7.68	0.035	68.71±10.90	71.14±10.11	0.425
Storage symptoms	Frequency	Baseline	8(44.4%)	9(81.8%)	0.047	7(25%)	18(81.8%)	0.000
		Post-OP	2(11.1%)	1(9.1%)	0.534	2(7.1%)	5(22.7%)	0.336
		P	0.063	0.008		0.125	0.000	
	Urgency	Baseline	8(44.4%)	9(81.8%)	0.047	7(25%)	14(63.6%)	0.006
		Post-OP	6(33.3%)	2(18.2%)	0.076	2(7.1%)	5(22.7%)	0.336
		P	1.000	0.016		0.125	0.004	
	Nocturia	Baseline	6(33.3%)	2(18.2%)	0.376	5(17.9%)	14(63.6%)	0.001
		Post-OP	3(16.7%)	0(0%)	0.062	4(14.3%)	10(45.5%)	0.125
		P	0.500	-		1.000	0.289	
	UUI	Baseline	6(33.3%)	1(9.1%)	0.319	7(25%)	4(18.2%)	0.563
		Post-OP	4(22.2%)	3(27.3%)	0.647	5(17.9%)	7(31.8%)	0.781
		P	1.000	0.500		0.687	0.375	
Voiding	cQmax	Baseline	0.45±0.45	0.32±0.15	0.350	0.36±0.35	0.36±0.21	0.965
		Post-OP	0.45±0.45	0.80±0.21	0.315	0.52±0.43	0.81±0.36	0.015
		P	0.647	0.340		0.022	0.043	
	PVR	Baseline	168.88±268.30	77.27±120.58	0.299	206.86±203.61	108.43±112.99	0.037
		Post-OP	124.61±150.73	46.73±57.49	0.061	107.14±109.03	34.68±73.73	0.007
		P	0.496	0.505		0.005	0.729	
	VE	Baseline	0.618±0.42	0.8051±0.29	0.171	0.42±0.41	0.69±0.30	0.011
		Post-OP	0.62±0.33	0.82±0.24	0.104	0.58±0.36	0.88±0.17	0.000
		P	0.076	0.510		0.019	0.120	
	Retention	Baseline	0(0%)	9(50%)	0.005	9(32.1%)	6(27.3%)	0.709
		Post-OP	2(11.1%)	0(0%)	0.138	1(3.6%)	0(0%)	0.263
		P	0.063	-		0.039	-	

BPH: benign prostate hyperplasia, CIC: clean intermittent catheterization, cQmax: correct maximal urinary flow rate, defined as $Q_{max}/V^{1/2}$, FS: full sensation, FSF: first sensation of filling, Pdet: detrusor voiding pressure, PVR: post-void residual volume, US: Urge sensation, UUI: urge urinary incontinence, VE: voiding efficiency

Table.2 Changes of subjective and VUDS parameters in patients with and without BPH

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Research **Ethics Committee**, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation **Helsinki** Yes **Informed Consent** Yes

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ALPHA-BLOCKER AND RISK OF DEMENTIA IN PATIENTS WITH BENIGN PROSTATE HYPERPLASIA: A NATIONWIDE POPULATION-BASED STUDY USING THE NATIONAL HEALTH INSURANCE SERVICE DATABASE.

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HYPOTHESIS / AIMS OF STUDY

A recent study demonstrated that use of tamsulosin increased the risk of dementia in benign prostate hyperplasia(BPH) patients. However, this study had a number of limitations. We evaluated the association between alpha-blockers and dementia in patients with benign prostate hyperplasia.

STUDY DESIGN, MATERIALS AND METHODS

From the National Health Insurance Service database, we collected and analyzed data pertaining to alpha-blockers and dementia in the entire Korean adult population with BPH between January 2011 and December 2011. These patients were followed up until September 2017. We tested the effect of alpha-blockers on the risk of dementia using propensity score-matched Cox proportional hazard regression models and Kaplan-Meier survival analysis.

RESULTS

During a mean follow-up period of 1,580 (± 674.3) days, all inclusion and exclusion criteria were met by 59,472 patients with benign prostate hyperplasia. In the unadjusted cohort, the incidence of dementia in the tamsulosin, doxazosin, terazosin, alfuzosin, and no-medication cohorts were 17.96%, 18.55%, 20.64%, 17.62%, and 22.60%, respectively. After propensity score matching, the risk of dementia did not significantly differ between the tamsulosin cohort and the doxazosin [1.038 (0.960–1.121)] or alfuzosin [1.008 (0.925–1.098)] cohorts. The terazosin [1.112 (1.052–1.196)] cohort had a higher risk of dementia than the tamsulosin cohort. However, the risk of dementia was significantly lower in the terazosin cohort than in the no-medication cohort.

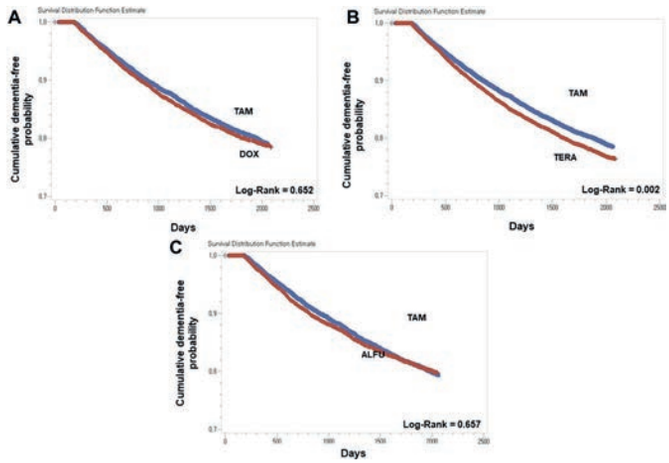
INTERPRETATION OF RESULTS

In this nationwide population-based study we found that alpha-blockers were not correlated with the risk of dementia in patients with BPH. Tamsulosin in particular did not affect the risk of developing dementia; these findings contradict those of a previous study [1]. Beyond simply not being associated with dementia, our results indicate that administering BPH medication lowers the risk of dementia in patients with BPH. The difference in these results may be due to various factors. First, it should be noted that the current study period was relatively long compared to that of the previous study (56.43 vs 19.8 months). However, as previous researchers have pointed out, the follow-up periods of previous studies were likely too short to observe the development of dementia, and may in fact represent an accelerated time to diagnosis [2]. Secondly, the mean age of the patients enrolled in this study is higher than that of previous studies (76.1–76.7 years vs 73.3–74.7 years). Indeed, age was found to be the strongest variable in the risk of dementia in all comparisons with our cohort study. However, age did not significantly affect the association between tamsulosin use and dementia risk in almost all analyses in a previous study [1]. With regard to previous findings indicating that age is associated with dementia, the current results indicate that our study cohort was representative of the general population. Moreover, we found that alpha-blockers, including tamsulosin, could lower the risk of dementia in patients with BPH. This may be explained by the following hypothesis: the no medication group in this study is not representative of the general elderly population. That is, the no medication group is likely to comprise untreated patients with BPH. Therefore, this finding should not be misinterpreted to mean that BPH medication lowers the risk of dementia in healthy individuals.

CONCLUDING MESSAGE

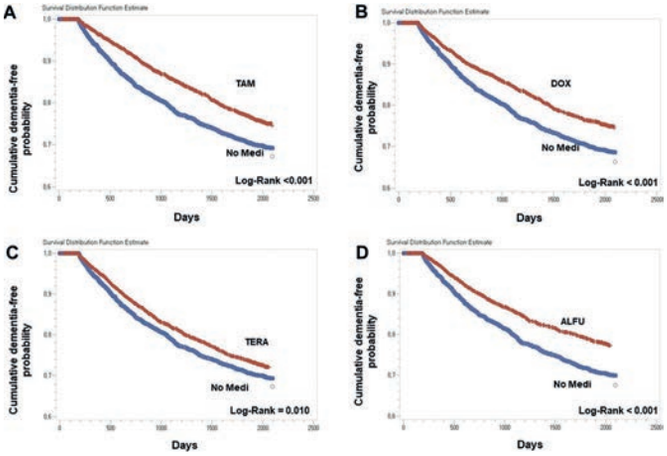
The findings of this large population-based study indicate that the use of BPH medication is not associated with an increased risk of dementia overall, by duration of use, or by medication type. Further well-designed, prospective studies are warranted to validate our findings.

FIGURE 1



Kaplan-Meier curves of dementia free probability in BPH medication matched tamsulosin (TAM, blue curves) cohort vs other BPH medication cohorts. A, vs doxazosin (DOX, red curve). B, vs terazosin (TERA, red curve). C, vs alfuzosin (ALFU, red curve).

FIGURE 2



Kaplan-Meier curves of dementia free probability in matched no BPH medication (No Medi, blue curves) cohort vs each BPH medication cohort. A, vs tamsulosin. B, vs doxazosin. C, vs terazosin. D, vs alfuzosin.

REFERENCES

1. Duan, Y., Grady, J. J., Albertsen, P. C. et al.: Tamsulosin and the risk of dementia in older men with benign prostatic hyperplasia. Pharmacoepidemiol Drug Saf, 27: 340, 2018
2. Madersbacher, S., Michel, M. C.: Re: Tamsulosin and the Risk of Dementia in Older Men with Benign Prostatic Hyperplasia. Eur Urol, 2018

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Y-V PLASTY RECONSTRUCTION FOR THE TREATMENT OF REFRACTORY BLADDER NECK CONTRACTURE: CLINICAL AND PATIENT-REPORTED OUTCOMES

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HYPOTHESIS / AIMS OF STUDY

Highly recurrent bladder neck contracture (BNC) following transurethral surgery of the prostate is rare but troublesome condition. Success rate declined considerably after repeated endoscopic treatment. With lack of standardized treatment; bladder neck reconstruction remains one of the most accepted therapeutic options for recurrent BNC. This study evaluates the success rate, functional and patient-reported outcomes (PRO) of open Y-V plasty in treatment of refractory BNC after transurethral surgery of the prostate.

STUDY DESIGN, MATERIALS AND METHODS

We present medium-term results of 15 consecutive patients with refractory BNC who underwent open Y-V plasty at a tertiary care centre between May 2017 and January 2020. All patients presented with voiding dysfunction after two or more failed attempts of endoscopic treatments. Participant information was obtained including clinical evaluation, demographics, comorbidities, and prostate profile. Perioperative evaluation, operative data and postoperative outcome were analyzed. Postoperative complications were recorded and classified according to the Clavien classification. Functional and patient-reported outcomes were evaluated using standard uroflowmetry and validated self-reported questionnaires. The questionnaires included validated IPSS, IPSS-QoL, OAB-V8 and IIEF-5 survey items.

RESULTS

Fifteen patients underwent the open Y-V plasty procedure, most of whom developed refractory BNC secondary to TURP [n=11, (73%).] Mean age at surgery age (SD) was 66.9 (5.8) years. Mean follow-up was 16.1 (6.5) months. Success rate was 100% (Table 1). Post-operative Qmax improved significantly [pre-OP 6.47 (8.6) ml/s vs post-OP was 14.74 (7.8) ml/s, $p = 0.001$]. Mean post-void residual decreased significantly [pre-OP 174.92 (206.6) ml vs post-OP 48.92 (75.7) ml, $p = 0.018$)] (Table 2). Overactive bladder symptoms were the most common postoperative complication in 47% of subjects. Mean post-operative IPSS-score was 12.3 (range 3–22) and mean post-operative IPSS-QoL was 2.4 (range 0–5). Age at surgery ($r = 0.52$) and BMI ($r = 0.52$) were positively correlated with changes in OAB-V8 score $p = <0.05$.

INTERPRETATION OF RESULTS

Highly recurrent bladder neck contracture following transurethral surgery of the prostate is a rare but troublesome condition. With lack of standardized treatment; bladder neck reconstruction remains one of the most accepted therapeutic options for recurrent BNC. The rationale for YV-reconstruction of the bladder neck is to avoid recurrent scarring by transposition of a well-vascularized bladder wall flap enabling reconstruction of a wide bladder neck. Our results confirm these considerations true: Success rate, defined as no need for further instrumentation or surgery is great along with significant improvement in objective measures as Qmax and PVR as well as health related quality of life. The IPSS-QoL of mean 2.4 is favorable. Excellent and consistent rates of bladder neck patency can, therefore, be achieved for patients suffering of refractory BNC after transurethral surgery of the prostate.

Nearly half of our patients developed persistent or de novo overactive bladder (OAB) symptoms after bladder neck reconstruction. This leads to suboptimal treatment outcomes, reduced QoL, and are associated with substantial personal and societal costs. The residual storage symptoms after treating bladder outlet obstruction is mostly attributable to

underlying bladder dysfunction for instance detrusor overactivity. It is important to recognize the risk factors for persistent OAB symptoms in order to satisfactorily council the patient before surgery, to understand how to treat these symptoms and to develop an actual clinical practice guidelines

CONCLUDING MESSAGE

Y-V plasty represents a safe and viable treatment option with high success rates and favorable patient reported outcomes for refractory bladder neck contracture. Residual storage symptoms are usually attributable to underlying bladder dysfunction leading to a suboptimal treatment outcome.

FIGURE 1

Table 1: Patients demographics		
	Mean (SD)	Range
Number of patients, *n*	15	
Age at surgery (years)	66.93 (5.85)	59-78
BMI (kg/m²)	26.95 (3.01)	23.7-34.1
Smoking status (yes)	3 (20%)	
American society of anaesthesiologists' (ASA) score	1.80 (0.41)	1-2
Charlson Comorbidity Index		
CCI 0 *n* (%)	6 (40%)	
CCI +1 *n* (%)	9 (60%)	
Etiology of BNC		
TURP *n* (%)	11 (73%)	
Greenlight laser *n* (%)	4 (27%)	
Prostate size (ml)	35.79 (22.32)	21-110
Prostate resected (gm)	12.57 (7.35)	4.4-25
PSA	1.21 (1.13)	0.1-3.8
Histopathology		
Adenocarcinoma *n* (%)	2 (13%)	
BPH *n* (%)	13 (87%)	
Preoperative Bladder management *n* (%)		
Spontaneous voiding	8 (53%)	
Suprapubic catheter	3 (20%)	
Indwelling urethral catheter	2 (13%)	
Clean Intermittent Catheterization (CIC)	2 (13%)	
Previous management *n* (%)		
Dilation + Greenlight laser resection of BNC	1 (6%)	
DVIU + Transurethral resection of BNC	4 (27%)	
Transurethral resection of BNC	7 (47%)	
Greenlight laser of BNC	3 (20%)	
Time from diagnosis to Y-V plasty (month)	20.27 (21.94)	1-95
Surgical time (minutes)	74.33 (19.19)	50-112
Hospital stay (days)	1.40 (0.51)	1-2
Follow-up period (months)	16.07 (6.54)	8-28
90-days postoperative complications (Clavien–Dindo)		
Grade I	-	
Grade II	8 (53%)	
Grade III	4 (27%)	
Grade IV–V	-	

Table 1: Patients demographics

FIGURE 2

Table 2: Pre- and postoperative parameters					
	Preoperative		Postoperative		
	Mean (SD)	Range	Mean (SD)	Range	p value
Qmax (ml/s)	6.47 (8.6)	0-35	14.74 (7.8)	7-37	<0.001
Average flow (ml/s)	2.79 (2.1)	0-7	7.30 (2.7)	3-12	<0.001
PVR (ml)	174.92 (206.6)	0-600	48.92 (75.7)	0-262	0.018
Voided volume (ml)	89.13 (110.8)	0-403	245.53 (201.2)	33-708	0.007
Flow time (sec)	22.2 (20.1)	0-58	30.73 (10.1)	16-62	0.2
IPSS	21.27 (6.7)	8-34	12.27 (6.7)	3-22	<0.001
IPSS-QoL	4.60 (1.3)	1-6	2.40 (1.7)	0-5	<0.001
OAB-V8	15.67 (8.4)	6-34	12.20 (6.6)	2-30	0.14
IIEF-5	15.86 (7.6)	6-27	7.88 (6.2)	2-22	-
p value for paired t-test comparison between preoperative and postoperative parameters					

Table 2: Pre- and postoperative parameters

Funding No **Funding Clinical Trial** No **Subjects** Human **Ethics Committee** Conjoint Health Research Ethics Board (CHREB) at the University of Calgary **Helsinki** Yes **Informed Consent** No

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BEST IN CATEGORY PRIZE "MALE LOWER URINARY TRACT SYMPTOMS (LUTS) / VOIDING DYSFUNCTION"

RESULTS FROM THE LARGE REAL-WORLD STUDY OF THE PROSTATIC URETHRAL LIFT (PUL) DEMONSTRATE CONSISTENT SAFETY AND EFFECTIVENESS FOR BPH PATIENTS

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HYPOTHESIS / AIMS OF STUDY

Minimally invasive surgical therapy (MIST) for benign prostatic hyperplasia (BPH) is designed to provide effective symptom relief with minimal morbidity. Randomized controlled trials have historically served as the gold standard for demonstrating clinical safety and efficacy, yet inconsistent real-world outcomes have reduced the use of early MISTs such as TUNA and TUMT. The Prostatic Urethral Lift (PUL) is a MIST that has been shown to provide safe, rapid, and durable symptom relief with minimal morbidity for BPH patients. Here, we expand upon effectiveness results from the large, actively enrolling Real World Retrospective (RWR) study of PUL, which continues to support results from clinical studies.

STUDY DESIGN, MATERIALS AND METHODS

2090 patients across 18 USA and Australian sites who underwent PUL following market clearance [FDA clearance Sept 2013; TGA approval Feb 2010] through May 2019 were assessed. Subjects needed a baseline IPSS score within 9

months pre-PUL and at least one IPSS score within 12 months post-PUL to be included the retrospective real-world (RWR) database. Subjects were stratified into non-retention (Group A, n=1792) and retention (Group B, n=298) groups. IPSS, QoL and Qmax were evaluated post-procedurally at 1, 3, 6, 12 & 24-months for Group A and B and absolute symptom scores compared between groups. Within Group A, outcomes were stratified for baseline prostate volume (≥80g, n=67), obstructive median lobe (OML, n=209), and prior radiation for prostate cancer (rCaP, n=62). Symptom outcomes were compared with the L.I.F.T. randomized controlled trial for PUL.

RESULTS

RWR subjects were an average of 70 ± 9 y.o (vs. 67 ± 7 y.o. L.I.F.T., p=<0.01). RWR mean baseline IPSS, QoL and Qmax were different from the L.I.F.T. population at 18.7 ± 7 (vs. 22.2 ± 6, p=<0.0001), 3.9 ± 2 (vs. 4.6 ± 1.1, p=<0.0001), and 12.1 ± 8 ml/s (7.9 ± 2, p=<0.0001). Group A IPSS scores improved significantly from baseline at all timepoints (p=<.0001). Group A and B had comparable IPSS symptom response across all timepoints. Subjects with large prostates experienced symptom improvement post-PUL (Figure 1) without elevated rates of post-operative adverse events. OML subjects experienced significant relief throughout follow-up (47% improvement at 3mo) with no increased rates of hematuria and dysuria compared to non-OML subjects. rCaP therapy subjects improved significantly at 1, 3 and 6 months and PSA remained unchanged throughout follow-up. No significant increases in specific adverse events (i.e. incontinence, UTI, stricture and urosepsis) were observed between CaP and non-CaP subjects.

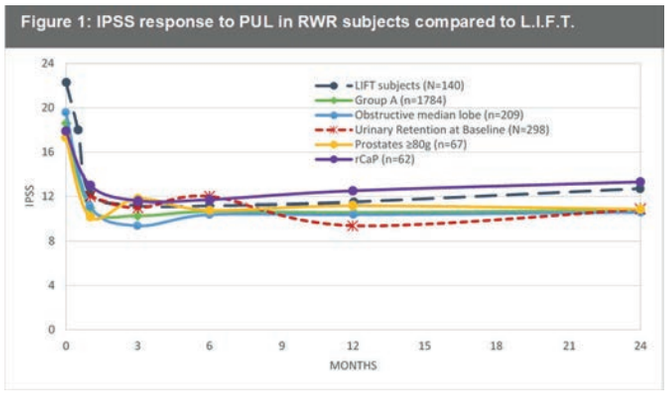
INTERPRETATION OF RESULTS

Baseline demographics for the total RWR population reveal subjects were slightly older and less symptomatic compared with the L.I.F.T. study, however outcomes are consistent across both studies. Evidence continues to support effectiveness of PUL in populations with large prostate volumes, obstructive median lobes, and prior prostate cancer treatment at procedure. None of the populations assessed demonstrated increases in specific adverse events such as incontinence, or hematuria compared to L.I.F.T. or their real-world counterparts.

CONCLUDING MESSAGE

The largest real-world investigation of PUL, a MIST, continues to confirm clinical study results and demonstrates that PUL may be offered to a broad population of patient cohorts in the real world without affecting safety outcomes.

FIGURE 1



IPSS response to PUL in RWR subjects compared to L.I.F.T.

Funding NeoTract/Teleflex **Clinical Trial** No **Subjects** Human **Ethics Committee** Sterling IRB **Helsinki** Yes **Informed Consent** Yes

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PREDISPOSING FACTORS OF THE PERSISTENT STORAGE SYMPTOMS AFTER HOLMIUM LASER ENUCLEATION OF THE PROSTATE IN BENIGN PROSTATIC HYPERPLASIA PATIENTS AND THEIR CORRELATIONS TO THE SYMPTOM RECOVERY PERIOD.

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HYPOTHESIS / AIMS OF STUDY

Bladder outlet obstruction (BOO) due to benign prostatic hyperplasia (BPH) may cause storage symptoms in men [1]. Although surgeries for BPH such as Holmium laser enucleation of the prostate (HoLEP) has been proved to improve lower urinary tract symptoms, a certain number of patients continues to complain storage symptoms [2, 3]. This study aims to investigate the predisposing factors of the persistent storage symptoms after HoLEP in BPH patients and their correlations to the recovery period of the symptoms.

STUDY DESIGN, MATERIALS AND METHODS

A total of 127 BPH patients complaining storage symptoms that underwent HoLEP from May 2014 to June 2017 were included in the study. International Prostatic Symptom Score (IPSS), overactive bladder symptom score (OABSS) questionnaire and urodynamic studies were conducted preoperatively in these patients. The patients were divided into two groups depending on the persistence of storage symptoms

(IPSS storage score > 8 or OABSS > 5) at three months after the surgery. The data of the patients with persistent storage symptoms (group I) were analyzed and compared to those without the symptoms (group II) to validate the predisposing factors for postoperative persistent storage symptoms. In group I, the correlation between the predisposing factors and recovery period of the storage symptoms was analyzed in each patient.

RESULTS

Among the 127 patients, 68 and 59 patients were sorted into group I and II, respectively. Among the compared data in the two groups (Table 1), group I presented significantly greater mean age (p = 0.015), mean peak detrusor overactivity (DO) amplitude (p = 0.039) and mean MCC (p = 0.042). Multivariable analysis which was performed by using these three variables presented that only mean age (p = 0.024) and mean peak DO amplitude (p = 0.048) were statistically significant. Among the patients from group I, storage symptoms did not recover until 12 postoperative months in 12 patients (17.64 %), and their age was the only variable that was significantly different from the other patients (77.28 ± 15.55 vs 71.81 ± 32.57 years, p = 0.045).

INTERPRETATION OF RESULTS

According to comparative analysis of the variables, patients who had older age, higher peak DO amplitude and greater MCC presented persistent storage symptoms after HoLEP at 3 months. However, multivariable analysis revealed that only advanced age and high peak DO amplitude were the predisposing factors that impeded the alleviation of storage symptoms after three months from the surgery. Most of the patients were free from storage symptoms at a year after HoLEP except 12 patients who were significantly older than others. Such results imply that age is the most critical factor that inhibits the recovery of bladder from storage symptoms after BPH surgery.

CONCLUDING MESSAGE

Old age and high peak DO amplitude were the predictors for persistent storage symptoms after HoLEP. Also, older patients were unlikely to recover storage symptoms until 12 months from the surgery.

FIGURE 1

Table 1. Comparison of preoperative characteristics between Group I and II.

	Group I (n = 68)	Group II (n = 59)	p
Mean age (years)	74.73 ± 39.28	67.21 ± 48.14	0.015*
BMI (Kg/cm²)	27.58 ± 3.76	26.39 ± 4.14	0.545
Prostate volume (g)	62.74 ± 23.97	58.84 ± 31.27	0.092
Mean Qmax (mL/s)	11.26 ± 4.35	13.21 ± 5.98	0.65
Mean PVR (mL)	41.05 ± 18.28	45.54 ± 15.42	0.112
Pdet Qmax (cmH_2O)	77.36 ± 21.43	75.89 ± 31.29	0.084
BOOI	59.76 ± 24.51	61.88 ± 31.25	0.498
BCI	112.02 ± 14.85	109.58 ± 20.24	0.581
Mean peak DO amplitude (cmH_2O)	45.79 ± 8.04	31.64 ± 10.22	0.039*
Mean MCC (mL)	258.24 ± 122.10	317.51 ± 109.47	0.042*
Mean IPSS voiding symptom score	12.24 ± 5.82	11.44 ± 7.23	0.428
Mean IPSS storage symptom score	12.45 ± 2.12	10.71 ± 4.24	0.602
Mean OABSS	13.71 ± 3.52	12.20 ± 4.04	0.367

BMI: Body mass index, Qmax: maximal flow rate, Pdet Qmax: maximal detrusor pressure at Qmax , BOOI: bladder outlet obstruction index, BCI: bladder contractility index, DO: detrusor overactivity, MCC: maximal cystometric capacity, IPSS: International Prostate Symptom Score, OABSS: Overactive Bladder Symptom Score
*p <0.05

Table 1. Comparison of preoperative characteristics between Group I and II.

FIGURE 2

Table 2. Predisposing factors of the persistent storage symptoms after HoLEP.

	OR	95% CI	p
Mean age (years)	1.59	1.02 – 3.24	0.024*
Mean peak DO amplitude (cmH_2O)	1.24	1.01 – 1.87	0.048*
Mean MCC (mL)	1.02	0.92 – 3.08	0.083

DO: detrusor overactivity, MCC: maximal cystometric capacity
*p <0.05

Table 2. Predisposing factors of the persistent storage symptoms after HoLEP.

REFERENCES

1. Dmochowski RR. Bladder outlet obstruction: etiology and evaluation. Rev Urol. 2005;7(Suppl 6):S3-13.
2. Knutson T, Edlund C, Fall M, et al. BPH with coexisting overactive bladder dysfunction--an everyday urological dilemma. Neurourol Urodyn. 2001;20: 237-47.
3. Antunes AA, Iscaife A, Reis ST, et al. Can we predict which patients will experience resolution of detrusor overactivity after transurethral resection of the prostate? J Urol. 2015;193:2028-32.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** International review board of Pusan National University Hospital **Helsinki** Yes **Informed Consent** Yes

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EFFECT OF ESCHERICHIA COLI INFECTION ON LOWER URINARY TRACT FUNCTION IN MALE PATIENTS

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HYPOTHESIS / AIMS OF STUDY

Although lower urinary tract infections (UTIs) are infrequent in men, in some clinical conditions like prostatitis the demonstration of UTI is paramount in order to correctly classify and threat this disease (1). Urine culture with or without prostate massage is essential to differentiate between bacterial and non-bacterial prostatitis. Urodynamic studies are useful in non-bacterial prostatitis in order to rule out any voiding dysfunction like bladder outlet obstruction or detrusor sphincter dyssynergia that may be present in these diseases. However, infection by Escherichia coli (E. coli) can affect the lower urinary tract function because of the effect of its endotoxin on alpha-adrenergic receptors (2). If this effect can be proved in vivo we cannot rule out that some voiding dysfunctions usually associated to non-bacterial prostatitis may result from bacterial infections. Our hypothesis is that E. coli infection can affect voiding function in male patients. The objective of our study is to compare the urodynamic findings in a sample of men with positive and negative UTI to E. coli bacteria.

STUDY DESIGN, MATERIALS AND METHODS

Study design

Cross sectional study

Materials and methods

We carried out a cross sectional study in men with UTI diagnosed by positive culture urine (>105 colony forming units per millilitre), who underwent a urodynamic study. The sample was divided into two groups: E. coli positive group: formed by 27 men with urinary culture positive for E. coli growth, and E coli negative group formed by 19 men whose urine culture showed the growth of bacteria other than E. Coli. Inclusion criteria were male, 18-year-old or over. Exclusion criteria were neurogenic lower urinary tract dysfunction, antibiotic treatment, anatomical abnormalities of the urinary tract, urolithiasis and genitourinary neoplasms. Patients were asked about the presence of lower urinary tract symptoms (LUTS), and other data like age and presence of indwelling catheters.

Urodynamic studies were performed according ICS specifications and guidelines of Good Urodynamic practices. Urethral resistance was measured by the urethral resistance algorithm (URA) and detrusor contractility by maximum value of Watts Factor (Wmax) and by the difference between the value of Watts Factor at 80% of bladder capacity minus the value of Watts Factor at 20% of bladder capacity (W8020).

Sample size was calculated based on data published by Gobish (2). Assuming that the standard deviation maximum urinary flow rate is 5 ml/s and that the difference between groups is 5 ml/s, with an alpha level of 5%, a statistical power of 80%, the minimum sample size should be 17 patients in each group.

For statistical analysis we used the Fisher exact test for qualitative variables and the t-test to compare the means of parametric data, or Mann-Whitney's U test for nonparametric quantitative data. Quantitative data were tested for normal distribution using the Kolmogorov-Smirnov test. Statistical significance was set at $p < 0.05$ bilaterally.

RESULTS

The distribution of clinical data for both groups is shown in Table 1. No clinical variable showed significant differences between both groups. The distribution of urodynamic data is shown in table 2. The parameters that showed significant differences were URA (higher in the E. coli negative group), Wmax (higher in the E. coli positive group) and W8020 (higher in the E. coli positive group).

INTERPRETATION OF RESULTS

There are several in vitro studies about the effect of E. coli bacteria on lower urinary tract function. However, to our knowledge this is the first urodynamic study that assess this influence on patients. In vitro studies have shown that

endotoxins liberated from E. coli inhibit alpha-adrenergic receptors in urethral muscle (2). This effect may explain our finding that urethral resistance was lower in patients with E. coli infection that those without it.

The action of E. coli bacteria in detrusor is more controversial. Some authors state that there is no effect on this muscle (2). While other authors claim that E. coli releases ATP that enhances bladder contractility. This release of ATP has not been shown in other microorganisms like lactobacillus bacteria. Although this mechanism has been proposed to explain the presence of overactive bladder syndrome and detrusor overactivity (DO) in women, so far no clinical study has validated this hypothesis. Our data also did not find any relationship between E. coli infection and the presence of LUTS or DO. However, this mechanism could explain the greater contrac-

tility in both contractility parameters (Wmax and W8020) found in our study in patients with E. coli infection.

Providing other non-studied effects are found, the result of E. coli infection in the lower urinary tract is positive because it reduces urethral resistance and improves bladder contractility. Some authors have advocated the deliberate colonization of human urinary tract with avirulent strains of E. in case of recurrent UTI. Although the design of our study does not allow us to stablish a cause-effect relationship, if other studies prove this effect, that procedure would be therapeutically useful.

CONCLUDING MESSAGE

Male patients with E. coli infection have less urethral resistance and more bladder contractility than male patients infected by other bacteria. The consequences of these findings could be clinically interesting.

FIGURE 1

Table 1.- Comparing the distribution of clinical data between groups

	E. coli positive group (n= 27)	E. coli negative group (n=19)	Significance
Age (years)*	67 ± 15.7	67 ± 14.5	0.950
Indwelling catheter†	4 (15%)	2 (10%)	0.516
Presence of LUTS †	19 (70%)	13 (68%)	0.570
Presence of storage LUTS †	14 (52%)	8 (42%)	0.363
Presence of voiding LUTS) †	5 (18%)	5 (26%)	0.903
Symptomatic SUI†	2 (7%)	1 (5%)	0.651

* Mean ± standard deviation. †Number of patients (percentage).

LUTS. Lower urinary tract symptoms. SUI. Stress urinary incontinence

Table 1

FIGURE 2

Table 2.- Comparing the distribution of urodynamic data between groups

	E. coli positive group (n= 27)	E. coli negative group (n=19)	Significance
Post void residual in free Uroflowmetry (ml)*	66 ± 92.5	84 ± 145.3	0.615
Maximum flow rate in free uroflowmetry (ml/s) *	12 ± 5.8	12 ± 6.9	0.470
Cystometric bladder capacity (ml)*	276 ± 120.5	147 ± 146.38	
Bladder compliance (cm H2O/ ml) *	44 ± 65.1	49 ± 67.5	0.903
Detrusor overactivity †	12 (44%)	8 (42%)	0.552
Urodynamic stress urinary incontinence †	1 (4%)	0 (0%)	0.587
URA (cm H2O) *	28 ± 17.2	36 ± 16.6	0.048‡
Wmax (Watt/M²) *	23 ± 13.9	15 ± 8.6	0.041‡
W8020 (Watt/M2) *	7 ± 9.4	1 ± 7.0	0.031‡

* Mean ± standard deviation. †Number of patients (percentage). ‡ Significant

Wmax. Maximum value of Watt Factor. W8020. Difference between Watt Factor at 80% of bladder capacity minus Watt Factor at 20% of bladder capacity.

Table 2

REFERENCES

1. Nickel JC. Classification and diagnosis of prostatitis: a gold standard. Andrologia. 2003;35(3):160-7
2. Nergårdh A, Boréus LO, Holme T. The inhibitory effect of coli-endotoxin on alpha-adrenergic receptor functions in the lower urinary tract. An in vitro study in cats. Scand J Urol Nephrol. 1977;11(3):219-24.
3. Ghobish A. Voiding dysfunction associated with "chronic bacterial prostatitis".Eur Urol. 2002;42(2):159-62.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Hospital Clínico de San Carlos Ethical Committee **Helsinki** Yes

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EFFICACY OF HOLMIUM LASER ENUCLEATION OF THE PROSTATE IN MEN WITH IMPAIRED BLADDER CONTRACTILITY: A REVIEW

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HYPOTHESIS / AIMS OF STUDY

Since Holmium laser enucleation of the prostate (HoLEP) was introduced in the 1990s as an endoscopic treatment modality for bladder outflow obstruction (BOO) secondary to BPH, several reports have concluded that HoLEP compares favourably to TURP in relieving BOO. However, there has been no consensus regarding the efficacy of surgical management of men with Detrusor Underactivity (DU) and BOO. Recently, there have been a number of reports suggesting HoLEP may be an effective treatment option for this cohort of patients. The aim of this review is to assess the current evidence in the literature in terms of the effectiveness of HoLEP in this patient population based on perioperative outcomes

STUDY DESIGN, MATERIALS AND METHODS

We performed a literature search of PubMed, Google Scholar, Scopus, and Web of Science databases. All studies that provided data on the effectiveness of HoLEP in men with BOO and DU were assessed. The primary outcome for men who were catheter-dependant preoperatively was catheter-free rate after surgery whereas the primary outcome for men not dependent upon catheter preoperatively was the change of IPSS. Secondary outcomes included changes in Qmax and PVR.

RESULTS

Results: Nine studies were identified in the literature with a follow-up range between 6 and 60 months. Only one prospective study was identified where investigators performed urodynamic studies (UDS) before and after the intervention. In addition to a significant improvement of voiding parameters, they reported partial recovery of detrusor muscle contractility in approximately 80% of patients. Two out of the nine studies reported on the number of patients who achieved catheter-free status following the intervention. In one of these studies, 95% of patients were voiding spontaneously following HoLEP without the need to do clean intermittent self-catheterization (CIC) while investigators in the other study found that 73% of patients achieved catheter-free status following HoLEP and the remaining patients needed to do CIC for high post-void residuals. Furthermore, all other studies reported an improvement in all outcome

parameters and proved the efficacy of HoLEP in patients with DU and BOO

INTERPRETATION OF RESULTS

Our review suggests that more than 80% of men with DU and BOO are likely to void spontaneously after HoLEP. This may be explained by the comprehensiveness of prostate tissue enucleation attainable with HoLEP, permitting voiding through a wide-open channel in the prostatic urethra. Therefore, patients with urodynamically proven DU should not be denied HoLEP as there is a high probability that the procedure will be successful; however, they should be appropriately counseled on the risks and benefits of the procedure and the chance of failure.

CONCLUDING MESSAGE

Conclusion: The current literature underpins the efficacy of HoLEP in patients with impaired bladder contractility. However, current research is limited and the majority of the published data are retrospective in nature. Therefore, more well-conducted prospective randomized studies are needed to reinforce high-level evidence for this hypothesis.

FIGURE 1

	Sample size	Median Follow-up (in months)	Preoperative				Postoperative			
			IPSS	PVR (ml)	Qmax (ml/s)	Catheter Dependency	IPSS	PVR (ml)	Qmax (ml/s)	Catheter Dependency
Mitchell, et al. 2014	33	24.7	21.5 (12-25.8)	244 (118.8-349.5)	9.35 (6.6-12.3)	24	3 (2-6)	53 (10.5-80)	21 (18-26.8)	1
Ryoo, et al. 2015	71	6	21.9 (+-6.7)	116.9 (+-121.3)	8 (+-33)	NP	5	38	14	NP
Jaeger, et al. 2015	27	6	18 (12.5-23)	555 (390-700)	5.1 (3-8.3)	NP	3 (1.5-6)	57 (35-136)	23 (14.8-30)	NP
Lomas, et al. 2016	17	32.5 (DU) 54 (DF)	15	390 (232-497)	2	15	5	38	14	4
Pyun, et al 2017	33	6	19.3+-8.6	94+-124.3	7.1+-3.5	NP	7+-7.6	71+-125	6.5+-7.2	NP
Woo, et al. 2017	24	6	18.7+-6.1	113+-128	7.4+-3	NP	10.7+-5.4	13.7+-41.7	18.5+-7.1	NP
Ahn, et al. 2017	105	36	NP	NP	NP	NP	NP	NP	NP	NP
Cho, et al. 2016	423	12	19.1+-7.3	61+-89	10.1+-4.2	NP	10+-1	19+-10	19+-2	NP
Cho, et al. 2019	65	60	19.08 (6.58)	58.3+-75	11.93+-5.14	NP	12	20	16	NP

Table 1: Overview of studies on the Efficacy of Holmium Laser Enucleation of the Prostate in Patients With impaired bladder contractility.

DF: Detrusor Failure, NP: Not Published.

Funding Nil **Clinical Trial** No **Subjects** None

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THE FIRST QUALITATIVE STUDY INTO THE COMPREHENSIBILITY OF THE IPSS AND TWO VISUAL ALTERNATIVES FOR MEN WITH ADEQUATE AND MEN WITH LIMITED HEALTH LITERACY SKILLS, LEADING TO A NEW, BETTER UNDERSTOOD DUTCH ALTERNATIVE: THE DUTCH REDUCED ILLUSTRATED PROSTATE SYMPTOM SCORE (DRIPSS)

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HYPOTHESIS / AIMS OF STUDY

In urology, a frequently used questionnaire to objectify subjective symptoms is the International Prostate Symptom Score (IPSS): 7 questions evaluate LUTS and 1 question addresses quality of life (QOL).

Several studies reveal difficulties with completing this questionnaire. To fill out IPSS correctly, patients need adequate health and literate skills. However, these skills are insufficient in up to 28% of people in the Netherlands, 50% in the US and 62% in eastern Europe. Thus, visual alternatives were designed: the South African Visual Prostate Symptom Score (VPSS) and the French Score Visuel Prostatique en Images (SVPI). See Figure.

For the first time, a qualitative study was performed in which participants filled out either the IPSS or one of the alternative forms while thinking aloud. Aim was to gain insight in the nature of comprehensibility problems. Based on the results of this analysis we developed a new questionnaire.

STUDY DESIGN, MATERIALS AND METHODS

Men of 40 years and older who had not previously filled out IPSS, VPSS or SVPI participated. To evaluate their health literacy status, participants completed the validated Set of Brief Screening Questions. Next, they were asked to fill out one of the three forms while thinking aloud, without time limitation nor help. Finally, an interview took place. Problems during filling out, the most probable causes and the participants' remarks were scored.

Each form was tested by participants with adequate health literacy skills (AHLS) and by participants with limited skills (LHLS). Inclusion of participants of both groups continued until no new insights were obtained per form.

Random distribution of the forms, interviewing and scoring were done by one researcher and checked by a second one.

After the interviews, problems during filling out were evaluated and the participants' comments were processed. Based on these outcomes, a new questionnaire was developed. This questionnaire was evaluated concordantly by subjects with AHLS or LHLS and adjusted in a few cycles until no new insights were gained, resulting in the definitive form: the Dutch Reduced Illustrated Prostate Symptom Score (DRIPSS, see Figure).

RESULTS

Problems during filling out and their causes are shown for each individual question of the 3 forms in the Table.

While filling out IPSS, the 23 participants (med. age 72 (41-82 yrs)) often showed difficulties understanding the terms 'past month', 'urinary stream' and 'weak'. The table design resulted in frequently filling out numeric values instead of using the answer options at top of the column, especially in the 7 LHLS-participants. Question 7 however is included in the table and should be answered by numeric values. The QOL-question was often overlooked by both groups by its isolated position.

Participants from both groups mentioned the complicated answer options (especially 'less then 1 in 5 times') and the reference period of 1 month.

One AHLS and 4 LHLS-participants considered the questionnaire more difficult than other medical forms. Three AHLS and 4 LHLS-participants wished for an introduction in clear language. Almost all participants would have given the same answers filling out the form outside this test situation. Only in the LHLS-group, 1 participant said that he would normally fill out the questions he left open in the test situation, despite not clear what is being asked.

While filling out VPSS, which consists of 4 questions with only visuals and no text, the 21 participants (med. age 69 (43-85 yrs)) often had problems understanding the first visual for daily micturition, leading to answers about mictions during work hours or only in the afternoon. Frequently, question 1 was only understood after filling in question 2. One participant missed the answer option 'no nycturia' in question 2. Question 3 lead to confusion caused by presenting the lowest score under the best urine stream and the highest score under the worst. The last visual proved to be unclear, leading to a variety of answers because of very different interpretations of what was asked.

Six out of 15 AHLS-participants and 3 men in the LHLS-group considered the questionnaire more difficult than other medical forms. Four AHLS and 4 LHLS-participants would have appreciated an introduction in clear language. No participant would have given different answers when filling out the form outside this test situation.

SVPI texts were translated into Dutch and backtranslated by 3 professional translators. The 5 visual questions, each with a verbal explanation, did not cause any comprehension problems amongst the 21 participants (med. age 65 (40-78 yrs)) as far as questions 1 and 2 were concerned. Question 3 caused difficulties understanding the alarm sign at the side of least urgency. The answer option for the least urgency a few times was not interpreted as such due to the red stripe through it. Question 4 lead to confusion because of the lowest score under the best urine stream and the highest score under the worst, with the numbers in descending order. Question 5 proved to be clear, although the figure in front was interpreted as an answer option a few times.

In the interviews, participants mentioned the visual format of question 4 was difficult to understand. Only 2 out of 16 AHLS-participants, found the questionnaire difficult compared to other medical ones. Two men, also both AHLS-participants, would have appreciated an introduction in clear language. No participant would have given different answers when filling out the form outside this test situation.

Although best understood, the SVPI still left room for improvement. We developed an alternative form, elaborating on this SVPI. Based on given comments the print was made larger for better readability and figures in front of question 3 and 5 were removed. The answer option for 'least urgency' was changed into a person standing still. Question 4 was changed to the figure of VPSS in mirrored position and numbers were left out. A comparable evaluating qualitative study with 16 participants with AHLS (6) and LHLS (10) was performed (med. age 64.5 (45-76 yrs)). Comments were processed: answer boxes were inserted, verbal questions were placed above the visuals instead of below them and the box including question 4 was made as big as the other boxes. DRIPSS was retested until no new insights were obtained.

INTERPRETATION OF RESULTS

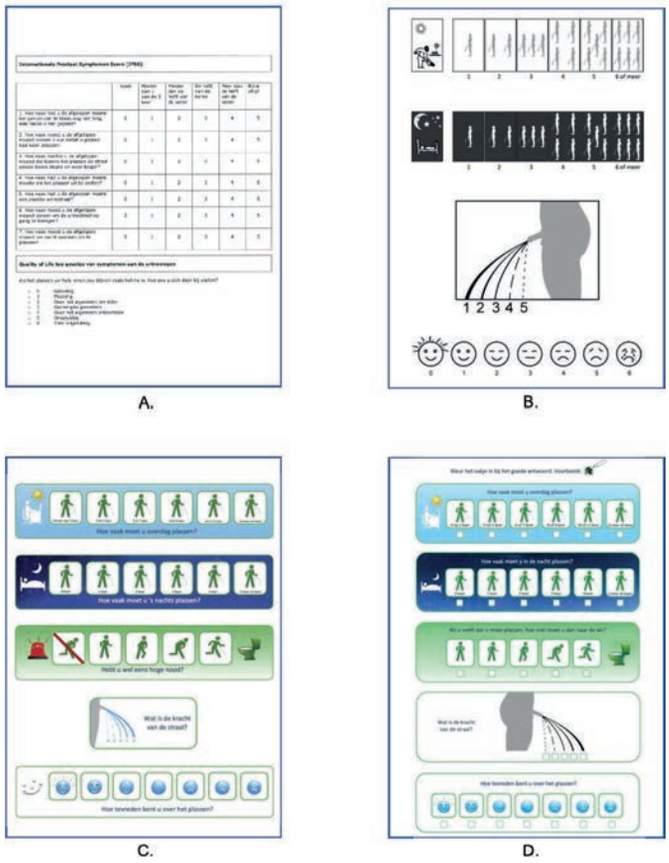
In our qualitative study we obtained insight in the comprehensibility problems of a frequently used questionnaire, something a quantitative study can't do. IPSS proved difficult to understand by the table design and difficult answer options, for men with AHLS but more so for many men with LHLS. This questions the reliability of obtained scores. The completely visual VPSS also proved hard to understand: unclear what is being asked for, it leads to answers on different interpretations of the question. SVPI showed a good balance between visuals and short verbal questions but nevertheless received some negative comments. Our qualitative study design was extremely useful to obtain insight to develop a modificated version that will lead to less comprehension problems: the Dutch Reduced Illustrated Prostate Symptom Score (DRIPSS).

CONCLUDING MESSAGE

The frequently used IPSS is difficult to understand by a large amount of men, questioning reliability. Figurative alternatives are better comprehended especially when combined with short textual questions. Based on the results of our qualitative study, we made a redesign well understood by participants with adequate ánd limited literacy skills: the DRIPSS. Next step is validation for IPSS and flowmetry to justify use in (Dutch) urological practice.

FIGURE 1

Figure 1. A. International Prostate Symptom Score (IPSS), B. Visual Prostate Symptom Score (VPSS, *van der Walt et al, 2011*), C. Score Visuel Prostatique en Images (SVPI, *Descazeaud et al, 2017*), D. Dutch Reduced Illustrated Prostate Symptom Score (DRIPSS)



Figure

FIGURE 2

Questions	Problems						Causes							
	+		±		-	0	t		q		i		d	o
IPSS 1 Emptying	14 (88)	2 (29)	2 (13)	1 (14)	-	4 (57)	-	-	2 (40)	2 (100)	2 (40)	-	-	-	1 (20)	-	-
IPSS 2 Frequency	15 (94)	1 (14)	1 (6)	-	-	5 (71)	-	1 (14)	-	-	1 (100)	4 (67)	-	-	-	2 (33)	-	-
IPSS 3 Intermittency	14 (88)	-	2 (13)	-	-	6 (86)	-	1 (14)	-	-	2 (100)	4 (57)	-	-	-	3 (43)	-	-
IPSS 4 Urgency	14 (88)	1 (14)	1 (6)	-	1 (6)	3 (43)	-	3 (43)	-	-	1 (50)	4 (67)	-	1 (17)	1 (50)	1 (17)	-	-
IPSS 5 Stream	13 (81)	1 (14)	-	-	2 (13)	2 (29)	1 (6)	4 (57)	-	3 (50)	-	1 (17)	1 (33)	1 (17)	2 (67)	1 (17)	-	-
IPSS 6 Straining	13 (81)	2 (29)	1 (6)	-	1 (6)	3 (43)	1 (6)	2 (29)	-	1 (20)	-	3 (60)	1 (33)	-	1 (33)	1 (20)	1 (33)	-
IPSS 7 Nocturia	13 (81)	4 (57)	3 (19)	1 (14)	-	2 (29)	-	-	-	-	-	3 (100)	-	-	1 (33)	-	2 (67)	-
IPSS QOL	9 (56)	4 (57)	6 (38)	-	-	-	1 (6)	3 (43)	-	-	-	1 (33)	-	-	5 (71)	2 (67)	2 (29)	-
VPSS Frequency day	7 (47)	1 (17)	6 (40)	-	1 (7)	2 (33)	1 (7)	3 (50)	-	-	-	-	-	-	8 (100)	5 (100)	-	-
VPSS 2 Frequency night	10 (67)	3 (50)	5 (33)	-	-	-	-	3 (50)	-	-	-	-	-	-	5 (100)	3 (100)	-	-
VPSS 3 Stream	12 (80)	4 (67)	2 (13)	1 (17)	1 (7)	-	-	1 (17)	-		-		-		-	1 (50)	3 (100)	1 (50)
VPSS 4 QOL	8 (53)	2 (33)	5 (33)	-	2 (13)	2 (33)	-	2 (33)	-	-	-	-	-	-	6 (86)	4 (100)	1 (14)	-
SVPI 1 Frequency night	16 (100)	4 (80)	-	1 (20)	-	-	-	-	-	-	-	1 (100)	-	-	-	-	-	-
SVPI 2 Frequency night	16 (100)	5 (100)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SVPI 3 Urgency	14 (88)	4 (80)	1 (6)	-	1 (6)	-	-	1 (20)	-	1 (100)	-	-	-	-	2 (100)	-	-	-
SVPI 4 Stream	15 (94)	4 (80)	-	1 (20)	1 (6)	-	-	-	-	1 (100)	-	-	-	-	-	-	1 (100)	-
SVPI 5 QOL	15 (94)	5 (100)	1 (6)	-	-	-	-	-	-	-	-	-	-	-	1 (100)	-	-	-

Table 1: Results filling out IPSS (AHLS 16, LHLS 7), VPSS (AHLS 15, LHLS 6) and SVPI (AHLS 16, LHLS 5) thinking aloud.
Absolute numbers (%), white: participants with adequate HLS, *grey*: participants with limited HLS, *QOL*: quality of life, +: question answered correctly, no problem, ±: question not entirely correct, but answered in an acceptable way, -: question not answered correctly and not acceptable, 0: question not answered, *t*: term misunderstood, *q*: question / sentence / text misunderstood, *i*: question ignored, *d*: deceived by design, *o*: other causes

Table

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Medical Ethical Committee Groningen, the Netherlands **Helsinki** Yes **Informed Consent** Yes

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PARALLEL OUTCOMES OF THE PROSTATIC URETHRAL LIFT FROM TWO DISTINCT MULTICENTER REAL-WORLD STUDIES

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HYPOTHESIS / AIMS OF STUDY

Numerous clinical studies have demonstrated successful outcomes of the Prostatic Urethral Lift (PUL) for the treatment of lower urinary tract symptoms, however investigation without rigid exclusion criteria is essential to assess how the technology is performing in a real-world setting. Here we compare results from two published real-world studies of PUL: the German Multicenter Retrospective Study and the large Real-World Retrospective study.

STUDY DESIGN, MATERIALS AND METHODS

The German multi-center (GM) retrospective study investigated outcomes of 86 subjects from five departments that had undergone PUL between Oct 2012 – June 2014. The Real-World Retrospective (RWR) study gathered data from 1413 subjects across 14 USA and Australian sites who had undergone PUL after market clearance. No exclusion criteria were established for baseline symptom scores, prostate size, retention history, or BPH medical therapy, as subjects needed only an IPSS before and after PUL to be enrolled. Subject baseline demographics as well as IPSS, QoL and Qmax were compared between both studies at 1, 6, 12, and 24 months after PUL.

RESULTS

At baseline, GM subjects were younger (66 vs 70yr) and had slightly higher IPSS (20.8 vs 19) and lower Qmax (11.2 vs. 13) scores compared to RWR subjects. Past publication of these studies demonstrated similar IPSS response compared with the L.I.F.T. randomized controlled trial. Here we report parallel symptom response, QoL and uroflowmetry scores at all timepoints following PUL between the two populations (Table 1). Data was also available for 14 GM and 165 RWR subjects with a history or urinary retention, defined by as having an indwelling catheter prior to PUL. Similar rates of catheter independence were achieved by retention patients in both studies with 86% of GM and 87% of RWR subjects successfully weaned from their catheters by the last available follow-up. Common adverse events experienced by subjects in both studies included hematuria, dysuria and pelvic pain, which were mild to moderate and transient in nature.

INTERPRETATION OF RESULTS

Results from this comparative analysis utilizing two large PUL retrospective studies reveal similar effectiveness and safety outcomes for non-urinary retention and retention patients. Compared to subjects in the LIFT study, GM subjects were younger and RWR subjects were less symptomatic. In the real world, it may be that men who are earlier in their disease process seek an interventional solution.

CONCLUDING MESSAGE

These consistent results reveal that patients outside of the controlled setting of a clinical trial can be treated safely and effectively with PUL and provide information from which to make clinical evidence-based recommendations.

FIGURE 1

Table 1: Comparative symptom response from real world studies of the PUL procedure

Test		1 month		6 months		12 months		24 months	
		GM	RWR	GM	RWR	GM	RWR	GM	RWR
IPSS	N (paired)	48	795	41	229	42	241	41	151
	Follow-up	11.9 ± 7.1	10.7 ± 6.6	10.6 ± 5.6	10.5 ± 6.7	10.3 ± 4.7	11 ± 7.0	10.1 ± 3.9	11.2 ± 6.3
	95% CI	9.9 –13.9	10.2 – 11.2	8.9 – 12.3	9.6 – 11.4	8.9 – 11.7	10.1 – 11.9	9.0 – 11.4	10.2 – 12.2
	p-value	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001
	*p-value**	0.2		0.9		0.5		0.2	
QoL	N (paired)	45	639	42	189	38	190	44	118
	Follow-up	2.2 ± 1.4	2.1 ± 1.5	2.1 ± 1.1	2.2 ± 1.5	2.2 ± 1.4	2.3 ± 1.5	2.0 ± 0.9	2.2 ± 1.5
	95% CI	1.8 – 2.6	2.0 – 2.2	1.7 – 2.4	2.0 – 2.4	1.8 – 2.7	2.1 – 2.5	1.7 – 2.3	1.9 – 2.5
	p-value	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001
	*p-value**	0.6		0.7		0.7		0.4	
Qmax	N (paired)	42	208	46	47	34	73	43	30
	Follow-up	15.5 ± 6.3	14.5 ± 6.4	15 ± 5.8	15.7 ± 6.8	14.1 ± 5.0	13.5 ± 6.8	14.2 ± 3.3	14.7 ± 6.3
	95% CI	13.6 – 17.4	13.6 – 15.4	13.3 – 16.6	13.8 – 17.6	12.4 – 15.8	11.9 – 15.1	13.2 – 15.2	12.4 – 16.9
	p-value	0.005	0.02	< 0.001	0.4	< 0.001	0.7	0.005	0.08
	*p-value**	0.4		0.6		0.6		0.6	

*p-value represents comparison of German multicenter study to the Real-World Retrospective PUL study

REFERENCES

1. Sievert et al (2018)
2. Eure et al (2019)

Funding Neotract/Teleflex funded RWR retrospective study **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Approved product in normal clinical setting **Helsinki** Yes **Informed Consent** No

415 www.ics.org/2020/abstract/415

A SURVEY OF THE CORRELATION BETWEEN REDUNDANT PREPUCE AND URINARY TRACT INFECTION IN URBAN AND RURAL ADOLESCENTS

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HYPOTHESIS / AIMS OF STUDY

To investigate the correlation and difference between the incidence of urinary tract infection (UTI) and redundant prepuce in urban and rural adolescents, so as to provide reference for the prevention and treatment of UTI in adolescents.

STUDY DESIGN, MATERIALS AND METHODS

During the period from September 2018 to October 2019, using the opportunity of freshmen's physical examination at the beginning of school, we selected college students from all over the country to investigate the correlation between redundant prepuce and UTI.This survey used anonymous questionnaires to collect relevant information. A total of 3800 questionnaires were sent out and 3702 valid questionnaires were collected, including 1347 urban teenagers and 2355 rural teenagers. Compared the collected data with the physical examination information, and analyzed the reliability of the questionnaire. The data were divided into urban and rural groups, and the incidence and related factors of redundant prepuce and UTI in each group were compared.The related factors include birth date, birth place, height, weight, whether phimosis and redundant prepuce, situation of wash up prepuce , whether prepuce operation, whether adhesion of prepuce, smegma, UTI, and so on. Finally, SPSS21.0 statistical software was used for correlation analysis.

RESULTS

18.04% of urban teenagers is redundant prepuce, 28.34% of rural teenagers is redundant prepuce, 0.46% of urban teenagers is phimosis, 1.35% of rural teenagers is phimosis. The difference of UTI between urban adolescents with and without redundant prepuce is statistically significant(χ^2=11.906, P<0.05); The difference of UTI between rural adolescents with and without redundant prepuce is statistically significant(χ^2=10.303, P<0.05); The difference of UTI between urban adolescents with and without phimosis is statistically significant(χ^2=8.344,P<0.05); The difference of UTI between rural adolescents with and without phimosis is statistically significant (χ^2=4.782, P<0.05); there was a significant difference between urban and rural adolescents in whether they often wash their prepuce (χ^2=123.085, P<0.05); There was no significant difference between urban and rural adolescents in the presence of smegma(χ^2=1.959, p>0.05).

INTERPRETATION OF RESULTS

The prevalence rate of redundant prepuce is very high in Chinese adolescents, Urinary tract infection is closely related to redundant prepuce .According to the survey, there is a significant difference in the incidence rate of urinary tract infection between city and rural adolescents, which is obviously related to the area where they are, whether phimosis and redundant prepuce, situation of wash up prepuce , whether prepuce operation, whether adhesion of prepuce, smegma and so on.

CONCLUDING MESSAGE

Redundant prepuce and phimosis are significantly related to the incidence of UTI. The incidence of phimosis and redundant prepuce in rural adolescents is significantly higher than that in urban adolescents, which suggests that the difference between redundant prepuce and phimosis is one of the reasons. It also suggests that strengthening the propaganda and education of rural adolescents and correcting redundant prepuce and phimosis can reduce the incidence of UTI.

REFERENCES

1. Wang Q, Zhang T, Wu J, Wen J, Tao D, Wan T, Zhu W.Prognosis and risk factors of patients with upper urinary tract urothelial carcinoma and postoperative recurrence of bladder cancer in central China[J].BMC urol,2019,19(1):24. doi:10.1186/s12894-D19-0457-5.

Funding Henan Province Medical Science Provincial-ministerial Co-construction Project (No: SBGJ2018059), Natural Science Foundation of China (NSFC) (No. 81670689) and Natural Science Foundation of China (NSFC) (No. U1904208). **Clinical Trial** No **Subjects** Human **Ethics Committee** Xin Xiang Medical University **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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AGE IS AN INFLUENCING FACTOR ON THE PERSISTENCE RATE WITH TADALAFIL IN MALE PATIENTS WITH LOWER URINARY TRACT SYMPTOMS

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HYPOTHESIS / AIMS OF STUDY

Previous clinical studies indicate that tadalafil, phosphodiesterase 5 inhibitor, is less efficacious in elderly patients. However, there are few clinical studies about the persistence rate among men treated with tadalafil for lower urinary tract symptoms (LUTS). Thus, we examined the persistence rate with tadalafil in men with LUTS and explored the influencing factors on the withdrawal.

STUDY DESIGN, MATERIALS AND METHODS

We retrospectively collected the data of patients who received tadalafil treatment for LUTS. The persistence rate and the reason for the withdrawal were investigated. Influencing factors on the withdrawal were analyzed with regard to patient's age, severity of symptoms, prostatic volume (PV), the prescription by the specialized or general urologist, drug-naïve patients, replacement of or add-on therapy to other agents for LUTS.

RESULTS

A total of 155 male patients were examined for this study. Mean age and observation period were 71.9 (48 – 93) years old and 15.1 (1 – 52) months, respectively. One hundred eleven patients (72%) had any coexisting medical conditions such as hypertension, diabetes or hyperlipidemia. The mean number of medicines for other diseases was 3.9 (0-20). In 29 patients (18%), tadalafil was used as a replacement for other agents for LUTS, and in 63 patients (41%), tadalafil was combined with other agents for LUTS. Eventually, 74 patients (48%) withdrew tadalafil during the observation period. The persistence rate at one year was 58%. The main reasons for withdrawal included insufficient efficacy (31 patients, 42%), adverse events (AEs) (21 patients, 28%), or symptom improvement (8 patients, 11%).

When excluding those patients who withdrew tadalafil due to AEs and symptom improvement, the persistence with tadalafil was significantly related only with age. Number of existing diseases or medicines for other diseases was not correlated with the persistence with tadalafil. A receiver operating characteristic (ROC) curve analysis confirmed 67 years old as the best cut-off age for the withdrawal (area under the curve=0.599). Kaplan-Meier method indicated the persistence rate at one year in patients < 67 years old and ≥ 67 years old were 82% and 65%, respectively ($p<0.05$, Figure). No influencing factors on the persistence rate were detected by the multivariate method.

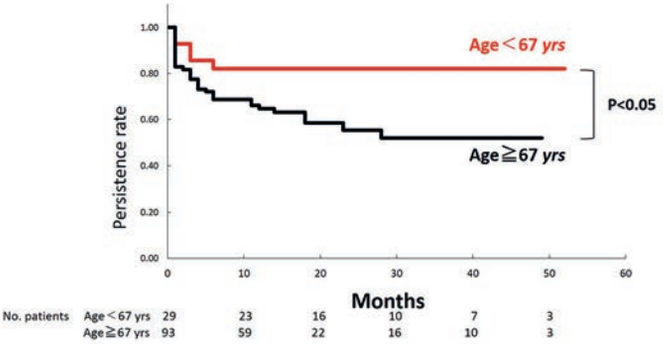
INTERPRETATION OF RESULTS

To our knowledge, this is the first report on the persistence rate with tadalafil for treatment of male LUTS. The function of NO/cGMP pathway, a main target of tadalafil, is reported to decline with aging. A meta-analysis of clinical efficacy of PDE5 inhibitor on LUTS shows that improvement of LUTS by PDE5 inhibitor is depended on age and body mass index; better in younger age and less obese patients [1]. Thus, aging seems to have a significant impact on the efficacy of tadalafil. It was reported that the improvement with tadalafil in patients over 65 years was not statistically significant compared with that of placebo-treated patients [2]. Similarly, it was showed that the efficacy of once-daily tadalafil 5 mg in the treatment of LUTS was better in men aged under 75 years than men over 75 [3].

CONCLUDING MESSAGE

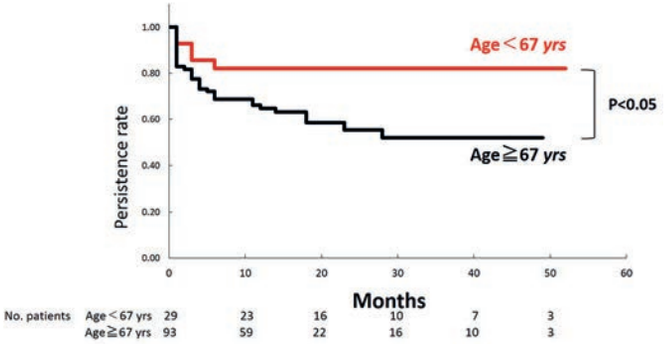
Main reason for discontinuing tadalafil was insufficient efficacy. Older patients are more likely to discontinue tadalafil treatment. It seems that tadalafil for male LUTS is more effective for younger patients and better persistence is expected in them.

FIGURE 1



Kaplan-Meier estimates of the persistence rate with tadalafil in patients of < 67 years and ≥ 67 years.

FIGURE 2



Kaplan-Meier estimates of the persistence rate with tadalafil in patients of < 67 years and ≥ 67 years.

REFERENCES

1. Gacci M, et al. Eur Urol 2012; 61: 994-1003
2. Nishizawa O, et al. Int J Urol. 2015; 22: 378-84.
3. Oelke M, et al. BJU Int. 2017; 119: 793-803.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Asahikawa Medical University **Ethics Committee Helsinki** Yes **Informed Consent** Yes

SESSION 27 (PODIUM SHORT ORAL) - GERIATRICS AND SPECIAL POPULATION
Abstracts 417-428
15:30 - 17:00, Brasilia 2
Chairs: Prof Adrian Stuart Wagg (Canada), Anne P Cameron (United States)

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IMPACT OF AN URGENT DESIRE TO VOID ON TRUNK AND PELVIS MOVEMENT IN OLDER WOMEN WITH URINARY INCONTINENCE WHO HAVE EXPERIENCED FALLS

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HYPOTHESIS / AIMS OF STUDY

Falls and urinary incontinence (UI) are major issues affecting older women age 65 and over. Urgency and mixed UI are independently associated with an increased risk of falls in older women (1). Bladder distension is hypothesized to be associated with increased trunk muscle activity (2). However, the relationship between urgency UI, and trunk and pelvis movements during gait is still not well understood. The objective of this study is to investigate the effect of an urgent desire to void (UDV) on trunk and pelvis movement during an assessment of gait kinematics in older women with urge/mixed UI, who had experienced falls.

STUDY DESIGN, MATERIALS AND METHODS

An observational pilot study was undertaken with two groups of healthy community-dwelling women age 65 and over, who experienced at least one fall in the last 12 months. Participants included in the urinary incontinent group had moderate to severe urge/mixed UI, as determined by the International Consultation on Incontinence Questionnaire on UI Short Form (ICIQ-UI SF), and >3 urine leakages/week in the 7-day bladder diary (with at least one urgency-related leakage). Participants in the continent group had an ICIQ-UI SF score equal to 0, no urine leakage reported in the past year and none in the 7-day bladder diary. Participants with a body mass index (BMI) >35 and health conditions likely to influence gait during the study were excluded. After signing a consent form and completing a 24-hour pad test, each participant partook in the experiment. Demographic data, history of falls and the results of the Montreal Cognitive Assessment test (MOCA) were collected for all participants. Participants'

gait kinematics were assessed using a Northern Digital Inc. Certus motion analysis system with markers placed on the participants' feet, shanks, pelvis and trunk, and a Bertec Fully Instrumented Treadmill (dual belt). The participant self-selected the gait speed, which was determined with no desire to void, and kept identical for all experimental trials. Participants drank water until they reported feeling an urgent desire to void (UDV), which was determined by a score of 3 on the Urinary Sensation Scale (USS). Participants were then asked to walk on the treadmill for 20 consecutive gait cycles then to go to the toilet. Immediately after emptying their bladder, the participants (with no desire to void (NDV)) were asked to walk again on the treadmill for 20 consecutive gait cycles. The mean and standard deviation (SD) of the gait parameters (treadmill gait speed, stride length and width) and of the total amplitude of trunk and pelvis movements (as measured by the trunk center of mass in the antero-posterior and medio-lateral positions [T COMAP/ML] and by pelvis center of mass in the antero-posterior and medio-lateral positions [Pel COMAP/ML]) were calculated for both groups. Descriptive statistics were obtained for demographics, cognitive and UI status, gait, and trunk and pelvis movement data. Independent t-tests and chi-square tests were used to compare the continent and UI groups for demographics, as well as cognitive and incontinence outcomes. An analysis of variance (ANOVA) with two factors and repeated measures was conducted to explore the differences between the two groups (continent and UI) for the two conditions (NDV and UDV). The p-value threshold was 0.05 and SPSS v24 was used for statistical analyses.

RESULTS

Thirty women participated in the study; 16 were continent and 14 had urgency/mixed incontinence. Both groups were similar in terms of age (74.6 years (4.1) and 73.5 years (5.9)) and MOCA scores (27/30 (3) and 28/30 (3)), respectively. BMI, number of falls, ICIQ-UI SF scores and number of urine leakages noted in the bladder diary were significantly different between groups, favoring the continent group.

There was a statistically significant interaction effect between groups (continent and incontinent) and bladder condition (NDV and SDV) for trunk and pelvis center of mass mediolateral movement (T COMML, F=5.92, p=0.02 and Pel COMML, F=8.17, p=0.00) with less displacement in the mediolateral direction of the trunk and pelvis during gait, in the incontinent women when experiencing UDV (Table 1).

For gait parameters, there was no interaction between groups and bladder condition. However, study groups were different in terms of stride length, with those with incontinence having smaller stride length F=4.64, p=0.04 and larger step width, F=4.48, p=0.04 (Table 1).

INTERPRETATION OF RESULTS

In the UDV condition, there was less change in trunk and pelvis movements for incontinent women than in continent women. This suggests an increase in trunk and pelvis 'stiffness', possibly to increase pelvic floor and trunk muscle activity. However, this trunk and pelvis stiffness may also result in reduced posture correction capacity and eventually higher risk of falls (3).

Women in the incontinence group had a smaller stride length and a larger step width, which is in line with their specific walking speed.

CONCLUDING MESSAGE

This is the first observational study of urinary incontinent and continent community-dwelling women who have experienced falls to report the influence of UDV on trunk and pelvis movement during gait at a fixed walking speed. UDV appeared to affect trunk and pelvis mediolateral displacement during gait differently in incontinent and continent older women at risk of falls. The incontinent group reduced movement of the trunk and pelvis, which appeared stiff, possibly to activate pelvic floor and trunk muscles to avoid leakage. More studies on the pelvic floor muscles using abdominal electromyography recording, in addition to rigidity tools, are necessary to confirm these results and to further understand the relationship between trunk and pelvis displacement and falls in a population of incontinent older women.

FIGURE 1

Table 1: Gait and trunk and pelvis movement parameters in both groups with urgent desire to void (UDV) and no desire to void (NDV).

ANOVA gain and trunk and pelvis movement parameter results	Continent		Incontinent				
	Mean (SD) NDV (N=16)	Mean (SD) UDV (N=16)	Mean (SD) NDV (N=14)	Mean (SD) UDV (N=14)	Inter-subject F; p (Group)	Intra-subjects F; p (Bladder)	Intra-subjects F; p (Bladder* Group)
T COM_{AP}	0.283 (0.049)	0.284 (0.043)	0.277 (0.048)	0.275 (0.040)	0.20; 0.65	0.07; 0.78	0.20; 0.65
T COM_{ML}	0.238 (0.049)	0.260 (0.063)	0.222 (0.047)	0.226 (0.050)	1.71; 0.20	13.68; **0.00**	5.92; **0.02**
Pel COM_{AP}	0.027 (0.032)	0.279 (0.031)	0.274 (0.040)	0.275 (0.033)	0.09; 0.76	0.14; 0.70	0.00; 0.94
Pel COM_{ML}	0.231 (0.045)	0.252 (0.055)	0.215 (0.036)	0.218 (0.038)	2.33; 0.13	14.78; **0.00**	8.17; **0.00**
Treadmill gait speed (m/s)	0.74 (0.25)	0.74 (0.25)	0.64 (0.13)	0.64 (0.13)	1.68; 0.20	1.19; 0.28	1.08; 0.30
Stride length (m)	0.85 (0.22)	0.88 (0.22)	0.71 (0.16)	0.71 (0.16)	4.64; **0.04**	3.58; 0.06	3.27; 0.08
Stride width (m)	0.29 (0.03)	0.29 (0.03)	0.32 (0.04)	0.32 (0.04)	4.48; **0.04**	0.00; 0.99	0.03; 0.95

significant $p<0.05$, SD: standard deviation

Table 1: Gait and trunk and pelvis movement parameters in both groups with urgent desire to void (UDV) and no desire to void (NDV).

REFERENCES

1. Chiarelli PE, Mackenzie LA, Osmotherly PG. Urinary incontinence is associated with an increase in falls: a systematic review. Aust J Physiother. 2009;55(2):89-95.
2. Castroman P, Ness TJ. Vigor of visceromotor responses to urinary bladder distension in rats increases with repeated trials and stimulus intensity. Neurosci Lett. 2001;306:97–100.

3. Smith MD, Coppieters MW, Hodges PW. Is Balance Different in Women With and Without Stress Urinary Incontinence? Neurourol. Urodynam. 2008;27:71–78.

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EXPLORING OLDER ADULTS PRIORITIES OF URINARY INCONTINENCE; A COMMUNITY PARTICIPATORY BASED RESEARCH APPROACH

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HYPOTHESIS / AIMS OF STUDY

Older adults, those most affected by UI, are often under-represented in research. The patient perspective in incontinence research is lacking. Most existing studies are quantitative in nature; existing qualitative studies are mostly driven by researchers and may not take the needs and views of people with UI into consideration. Traditionally, research studies involve older adults as subjects or participants, rather than partners in co-creation of scholarly output which meets their needs. Community Based Participatory Research (CBPR) offers a promising approach to understand the perspectives of older adults with UI, identify issues of concern to them and involve them in decision making regarding the management of UI and treatment outcomes, giving them co-ownership of the research and empowering them in the process. Specifically, here we aimed to understand the perspective of older adults in formulating a research agenda, tailored to address questions posed by them in order to improve their experience and improve outcomes from management of UI that were most important to them.

STUDY DESIGN, MATERIALS AND METHODS

Using a mixed methods approach a patients focus group (FG) was facilitated to establish UI "problems", Nominal Group Technique (NGT) was employed to achieve within-group data saturation. Group themes were developed into a questionnaire used to survey a larger sample of older adults with UI using a Delphi consensus method. Since this study took a CBPR approach, participants, instead of researchers, were encouraged to generate a list of questions requiring addressing to improve management of UI. A further FG and the NGT were employed to facilitate this process.

Advisory Group

Community dwelling and English-speaking older adults with UI were recruited. This core Patient Advisory Group worked with the researchers to plan, inform and design other stages of the research. Participants were recruited via seniors' activity centres, men's sheds, continence clinics, continence physiotherapy clinics, newsletter ads, previously conducted studies, and participants' social connections.

During the first meeting, the Advisory Group was reminded of its role as co-researcher, rather than participant. The group also received training on ethical conduct in research and participated in a FG discussion.

Focus group activities

The initial FG identified problems participants faced in managing UI in day-to-day lives. FG data were transcribed and thematically analyzed by the researchers. FG themes were fed back to achieve within-group saturation of themes. Group members were asked to silently reflect and write down ideas about important questions or concerns to address to improve their experience with managing UI. Each group member was then asked to share one idea in a round-robin until no more new ideas emerged. Each idea was recorded by the researchers. Further discussion and clarification followed to ensure that each idea was understood and documented correctly.

Prioritization

Focus group themes from the initial meeting were then presented back to the Advisory Group. Each theme was discussed to ensure that the perspective was properly conveyed and revised accordingly. Themes and ideas were combined and developed into priorities for improving outcomes of UI management. Participants were then asked to rank the list.

Delphi project

Twenty priorities identified as most important were entered into questionnaire format using Research Electronic Data Capture (REDCap), a secure database, along with demographic information, including email, age, sex and years experiencing UI. The questionnaire was presented to the advisory group for approval and consensus criteria for the Delphi method were established. Delphi participants were recruited via posters, adverts and online. The survey asked a larger panel of older adults experiencing UI and to rate the importance of each priority for improving their experience of UI management on a 5-point Likert scale, Participants could provide free-text comments to support their ranking. Priorities considered less important were discarded. The second round asked participants to re-rank remaining priorities, provided a summary of free-text comments and first round

scores. Results were analyzed by the researchers and fed back to the advisory group.

Data analyses

Priorities rated 4 - 5 by at least 80% of participants were retained, others were discarded. Results were fed back to the advisory group after each round to ensure that priorities were not excluded due to potential misunderstanding.

RESULTS

In total, eight members (3 male, 5 female) were recruited to the advisory group. Of these, 3 were recruited through seniors' activity centres, 2 through previous studies, one through a continence clinic, one through a physiotherapy clinic, and one through the social connections of another participant. The mean (SD) age of the participants was 73 (8.2) and the mean (SD) number of years that they experienced UI was 5.6 (4.7) Two female participants withdrew from the study after the first meeting;their input was still considered in the development of the survey. One additional male participant was recruited following the focus group meeting. Following thematic analysis of the FG discussion, 43 themes were identified.

Six members (3 male, 3 female) of the advisory group attended the NGT meeting. The round robin generated 28 further ideas. Discussing and clarifying the focus group themes and ideas resulted in 38 priorities for ranking. Based on the ranking results and follow-up discussion, the advisory group included 20 ranked priorities. Three which ranked highest during NGT were excluded; and three which did not make top 20 during NGT were included following discussion of the ranking results.

Delphi consensus

A total of 59 participants (19 male, 40 female) responded to the first survey round. The mean (SD) age of the participants was 72.6 (7.3), range 52-88. The number of years that participants experienced UI ranged from 1-35 with a mean (SD) of 9.8 (7.6). 15 priorities were retained for the second round. Women assigned higher ratings than men on 17/ 20 priorities. The response rate for the second round was 85% (50/59). 11 priorities were retained (Table).

INTERPRETATION OF RESULTS

Involving older adults through CBPR is a practical although time consuming method to gain older adult's perspectives in formulating a research agenda tailored to address their concerns. Through ranking and discussion, the advisory group selected 20 research, educational and outreach priorities regarding UI management. Following two Delphi rounds, 11 priorities considered most important to older adults with UI were identified. The most highly rated topic was to investigate the causes of UI. This also appeared among the four highest ranking priorities in the Delphi consensus. Such cohesion suggests that the UI Advisory Group was representative of the larger sample of older adults with UI in Canada. More importantly, many of the identified priorities reflect a gap between research knowledge and public awareness and highlight the ongoing need for public education in this area. Despite the availability of such research, four of the final 11 priorities reflected this lack of knowledge. Thus, information appears not to be reaching its intended audience or conveyed through a medium accessible to older adults.

Overall, the top 11 priorities identified by older adults reflected concerns about the impact of UI on lifestyle, a need to increase support for those with UI, and a gap in understanding of the condition and the available treatment/management.

CONCLUDING MESSAGE

A CPBR approach to the development of older adults' perspectives on problems and priorities in UI management was feasible and uncovered a continued gap in understanding and knowledge in the area.

FIGURE 1

Priorities	% Rating 4-5
Relationship between physical activity and UI, including barriers to physical activity/exercise and its role in managing/intensifying UI symptoms. →lifestyle impact	90
Causes of UI, including other health issues/medications, surgical procedures, and lifestyle hab The priorities were each rated on a scale from 1 (very unimportant) to 5 (very important). For each priority, the percentage of participants who rated the priority as a 4 or a 5 was combined. (I will delete the red print, this is just how I categorized it to help with the discussion)its. →understanding condition, education	90
Improving the quality of sleep of older adults with UI. →lifestyle impact	90
Forms of support most important to older adults when they first begin to experience UI. →seeking support	90
Accessibility of public restroom facilities across Canada, especially for seniors, and availability of UI products in these restrooms.→seeking support, future research/policy implementation	88
Impact of fluid intake, diet and lifestyle on UI. →management education	88
Cure and management strategies, including cognitive therapies and distraction techniques, for UI. →management/treatment /education	88
Factors that influence early and proper diagnosis and referral for UI (internal/external barriers). →healthcare treatment research	86
Relationship between consulting a urological specialist and improvement in the quality of life of patients with UI. →healthcare treatment /research	84
Educational resources and information to help older adults understand UI, options to manage it, and services available. →education	84
Review of the products available for UI management and their effectiveness. →management / education	80
Priorities were each rated on a scale from 1 (very unimportant) to 5 (very important). For each priority, the percentage of participants who rated the priority as a 4 or a 5 was combined.	

Table 1. Ratings of Delphi priorities, listed in order of importance.

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CAUSES AND CONSEQUENCES OF INCONTINENCE PROBLEMS FOR PEOPLE LIVING AT HOME WITH DEMENTIA: A QUALITATIVE ANALYSIS

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HYPOTHESIS / AIMS OF STUDY

The aim of this study is to characterise the causes and consequences of toilet-use and incontinence problems faced by people with dementia who live at home and their unpaid carers. This is the first study to characterise the causes and consequences of incontinence problems for people living at home with dementia. Around 50 million people are living with dementia. The majority live in their own homes and are more likely than other people of the same age to experience bladder or bowel incontinence necessitating the use of management and containment strategies, either by the person with dementia or unpaid carers (1). Incontinence has a negative impact on the health and quality of life of both the person with dementia and their carers and can contribute to the breakdown of care (2). However, there are no evidence-based conservative management interventions demonstrated to support the often devastating incontinence needs of this population. The first stage of intervention development is to understand in detail the problem being addressed.

STUDY DESIGN, MATERIALS AND METHODS

Using a qualitative design, people with dementia (PWD), unpaid carers and healthcare professionals were interviewed with semi-structured topic schedules guiding conversations on their perceptions of the causes and consequences of toilet-use and incontinence problems for PWD living at home and their unpaid carers. PWD and carer participants were invited via www.joindementiaresearch.nihr.ac.uk, dementia care groups and care teams within two English counties. Healthcare professionals (dementia care and continence care nurses) were recruited via their employers (two NHS Community Trusts and Dementia UK). Recruitment continued until no new major themes arose for two consecutive interviews and the research was deemed to be addressed sufficiently. The interviews were transcribed and framework analysis used to interpret the data based on a priori goals of determining causes and consequences. Data collection took place between January and October 2019.

RESULTS

45 people (27 family carers, 2 people with dementia, 8 continence nurses and 8 dementia nurses) took part. Considerable attempts were made to recruit further PWD without success. This limitation was in part addressed by other participants who recounted relevant conversations with PWD. Two key themes (1. Causes and exacerbating factors and 2. Consequences) and associated sub-themes were identified and are outlined in Table 1. The underlying causes and exacerbating factors of toilet-use and incontinence problems were multifaceted and complex, with six sub-themes identified: Dementia, physical, psychosocial (for either the PWD or the carer), societal, care system and containment product factors all played a role in either causing or exacerbating incontinence problems. Most participants described situations (either their own or other people's) where there were multiple causes or exacerbating factors combined. For example, a PWD might fail to recognise the signals that their bladder required emptying (dementia factor), this issue could be exacerbated by lack of adequate continence products (care system factor) and family avoidance (societal factor- stigma). Similarly, the consequences of these incontinence problems are numerous, diverse and complex. Context was important to understanding how individuals and dyads were impacted differently, for example, factors such as whether the carer lived with the PWD and the nature of their relationship (e.g. spouse or adult child) influenced how much personal support carers were willing or able to provide.

INTERPRETATION OF RESULTS

Dementia adds an extra layer of complexity to both the causes and the consequences of incontinence problems. Some of the causes and consequences can be found in the wider population, but many are specific to the dementia population. Multiple factors can come together in varying combinations and in different contexts to generate the unique problems faced by individual PWDs and their carers. Likewise, the same causal factors might lead to different consequences for different individuals. When considering how to tackle these multifaceted problems, it is likely that multi-component interventions, that can be tailored to individual situations will be required. Intervention development should be prioritised by mapping to where they are likely to make the most impact in a wide range of circumstances. We must ask which problems are potentially modifiable, how and under what circumstances?

CONCLUDING MESSAGE

This study, the first of its kind, provides detailed characterisation of the causes and consequences of incontinence problems for PWD living at home and their carers, identifying multifaceted and complex, layering dementia, physical, psychosocial, societal and care system factors. This new understanding provides the essential basis for the now underway development of urgently needed practical and implementable interventions for this underserved population.

FIGURE 1

1. *CAUSES AND EXACERBATING FACTORS OF INCONTINENCE PROBLEMS*	
Dementia Factors	• Deficit in insight or ability to use toilet/meet toileting needs, e.g. does not recognise bladder/bowel sensations in time to reach toilet. • Deficit in insight or ability to meet continence containment needs, e.g. does not recognise need for continence products. • Toilet-use/continence-related behaviours that challenge, e.g. resistance to assistance with continence care.
Physical Factors	• Bladder or bowel physiological problems. • Limited mobility or sensory abilities.
Psychosocial factors (PWD and/or carers)	• Communication difficulties, e.g. avoidance of conversations on toilet-use or incontinence. • Low self-efficacy, e.g. lack of belief in ability to cope with incontinence.
Societal factors	• Stigma, e.g. attempts to protect friends/family/others from incontinence by keeping away. • Environment and facilities, e.g. day centres not accepting people with incontinence.
Care system factors (including care professionals)	• Lack of 'expert' knowledge on managing the combination of dementia and incontinence. • Lack of support/information. • Inadequate product provision (quantity and/or design).
Containment Product Factors	• Product design limitations, e.g. confusing for PWD (e.g. pull-up pants with external seams). • Inappropriate product use, e.g. inappropriate design, size or absorbency).
2. *CONSEQUENCES OF INCONTINENCE PROBLEMS*	
Consequences for the dyad	• Social isolation for either/both carer or PWD. • Adjusting to incontinence, e.g. change in relationship. • Breakdown in care. • Difficulties staying outside the home. • Impaired home environment, e.g. damage to bed/furniture/carpets. • Financial cost, e.g. products, laundry or increased need for paid carers.
Consequences for PWD	• Health issues, e.g. incontinence associated dermatitis. • Negative emotions e.g. fear of residential care. • Threat to citizenship, e.g. access to social interaction denied in order to 'protect' dignity.
Consequences for the carer	• Health issues, e.g. exhaustion. • Negative emotions, e.g. revulsion with managing bodily waste. • Physical workload, e.g. changing containment products. • Mental workload, e.g. day-to-day planning to maintain social continence.
Consequences for care system (including care professionals	• Use of resources, e.g. increased admission to care homes. • Staff frustration, e.g. lack of knowledge on how to help.
Consequences for Society	• Hidden problem, e.g. reduced contact with PWD for family, friends and wider population, • Use of resources, e.g. increased carer workload restricts paid employment.

Table 1. Causes and consequences of incontinence problems

REFERENCES

1. Grant R, Drennan V, Rait G, Peterson I, Iliffe S. (2013) Incidence and management of incontinence in older people with and without dementia: a cohort study using a primary care database. PLOS Med 10(8):e1001505
2. Schulter PJ et al. (2017) Urinary incontinence, but not fecal incontinence, is a risk factor for admission to aged residential care of older persons in New Zealand. Neuroulogy and Urodynamics; 36: 6, 1588-1595

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EXPERIENCES OF FAMILY CAREGIVERS PROVIDING INCONTINENCE CARE TO OLDER ADULTS: A QUALITATIVE SYSTEMATIC REVIEW AND META-AGGREGATION

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HYPOTHESIS / AIMS OF STUDY

Managing incontinence in dependent older adults leads to greater burden for informal caregivers (i.e., family members and friends) and an increased risk of institutionalization for the care recipient. Understanding the perspectives and experiences of caregivers of persons with incontinence will help inform the development and evaluation of supportive programs, potentially leading to better outcomes for caregivers and care recipients. The purpose of this review was to explore informal caregivers' perceptions, experiences, and consequences (physical, psychosocial, economic) as they relate to the management of incontinence in community-dwelling older adults.

STUDY DESIGN, MATERIALS AND METHODS

Design: Prospero registered (CRD42017069185) systematic review and meta-aggregation of qualitative research studies.

Methods: The Ovid MEDLINE®, CINAHL®, PsycINFO®, Embase®, ProQuest Dissertations and Theses®, and Scopus® bibliographic databases were search for English language, peer-reviewed publications published between January 1970 and June 2019. Eligible studies had to have a qualitative design and focus on the experiences of informal caregivers caring for an older adult with urinary and/or fecal incontinence. Study participants had to be an unpaid adult (age 18 years or older) family member or friend providing the majority of care within a home setting to a community-dwelling adult aged 60 or older with urinary and/or fecal incontinence. Two independent reviewers appraised the methodologic rigor of studies using the Joanna Briggs Institute's (JBI) Critical Appraisal Checklist for Qualitative Research. A third reviewer with expertise in qualitative research methods arbitrated disagreements. The credibility of findings from each study was evaluated using the JBI ConQual process. (1) Only findings with credibility ratings of unequivocal or credible were eligible for meta-aggregation. Data was extracted and synthesized using the JBI meta-aggregation approach. (2)

RESULTS

Database searches yielded 1047 unique references; 112 full-text documents were screened and 7 articles met eligibility criteria. The studies were conducted in nine countries (i.e., Australia, China, Germany, Italy, the Netherlands, the Slovak Republic, Sweden, the United Kingdom, and the United States). Overall, there were 134 caregivers interviewed

who ranged in age from 21 to 86 years, with the majority female (69%). Over 60% were spouses of the care recipient, 37% were their adult child (son, daughter, son-in-law, or daughter-in-law), 2% were their granddaughters, and 1% were family friends. From the seven eligible studies, 51 findings were extracted with credibility ratings of unequivocal (n=27), credible (n=8), and unsupported (n=16). Only the 35 findings rated as unequivocal or credible were eligible for meta-aggregation. Eligible findings were grouped into 13 categories and further collapsed into four synthesized findings related to 1) emotional responses, 2) physical, financial, and social consequences, 3) family roles and caregiver support, and 4) management strategies. A summary of the findings appear in the table.

INTERPRETATION OF RESULTS

Informal caregivers reported that managing incontinence was emotionally and physically demanding, causing financial hardships and social isolation. They had to cope with changes in family roles and intimacy and learn practical strategies for managing incontinence. They indicated that informal and formal support was essential in helping them learn and implement incontinence management strategies, but they also identified a lack of practical support from health professionals. Caregivers also reported positive emotional experiences and coping strategies.

CONCLUDING MESSAGE

Educational and supportive programs for managing incontinence should be multi-component and tailored to meet the individual needs of informal caregivers and care recipients. Future research should incorporate strategies to cope with emotional responses, alleviate financial burdens, activate social networks, provide respite to caregivers, offer practical strategies for managing incontinence, and support positive emotional responses and coping.

FIGURE 1

Findings [Credibility Ratings]	*Categories*	*Synthesized Finding*
Synthesized Finding 1: Emotional Responses		
Dirtiness [unequivocal]	Disgust with excreta	Caregivers had positive and negative emotional responses to managing incontinence.
Consequences for carers and the need to contain excreta [unequivocal]		
Emotional responses [unequivocal]		
Feelings of shame [credible]	Shame	
Dealing with bodywork and dirty work [credible]		
Carer developed strategies and issues of acceptability [credible]		
Fluster [unequivocal]	Overwhelming demands	
Mentally Draining [unequivocal]		
Psychological burden and caregivers feelings [unequivocal]	Acceptance	
Attitude adjustment [unequivocal]		
Acceptance [unequivocal]		
Internal aspects of coping with care deficits [unequivocal]		
Synthesized Finding 2: Physical, Financial, and Social Consequences		
Caring tasks and difficulties in daily life [credible]	24-hour physical care demands on health	Caregivers experienced physical, financial, and social consequences related to incontinence management.
Physically demanding and time-consuming [unequivocal]		
Sleeping issues [unequivocal]		
Financial situation [unequivocal]	Lost income, equipment, and product costs	
Financial burden [unequivocal]		
Financial impact [unequivocal]		
Social life [unequivocal]	Social and travel restrictions	
Social isolation [unequivocal]		
Internal and external coping with care deficits [unequivocal]		
Synthesized Finding 3: Family Roles and Caregiver Support		
Family relationships [unequivocal]	Family roles and intimacy changes	Caregivers experienced changes in family roles and intimacy and needed support for managing incontinence.
Decreased intimacy [unequivocal]		
Support in Caring [unequivocal]	Caregiver support	
Externals aspects of supporting care abilities [unequivocal]		
Synthesized Finding 4: Management Strategies		
Urgency [unequivocal]	Hypervigilance and need for urgent response	Caregivers used a range of strategies to manage and cope with incontinence.
Fear of potential health hazard [credible]		
Constant watchfulness [credible]		
Strategies for becoming acceptably continent [unequivocal]	Practical management strategies	
Problem-solving [unequivocal]		
Striving for continence, coping with incontinence [credible]	Coping strategies	
Love, dedication, lifelong friendship [unequivocal]		
Internal aspects of supporting care abilities [unequivocal]		
Seeking help from health professionals [credible]	Professional caregiving support	
Learning by doing [unequivocal]		

Table. Summary of Review Findings

REFERENCES

1. Munn Z, Porritt K, Lockwood C, Aromataris E, Pearson A. Establishing confidence in the output of qualitative research synthesis: the ConQual approach. BMC medical research methodology. 2014;14:108.
2. Lockwood C, Munn Z, Porritt K. Qualitative research synthesis: methodological guidance for systematic reviewers utilizing meta-aggregation. International journal of evidence-based healthcare. 2015;13(3):179-187.

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A MULTI-SITE FOCUS GROUP STUDY OF U.S. ADULT WOMEN'S BELIEFS AND ASSUMPTIONS ABOUT BLADDER HEALTH AND FUNCTION

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HYPOTHESIS / AIMS OF STUDY

Decision-making about bladder-related behaviors occurs multiple times each day with potential significant impact over a lifetime. Beliefs and assumptions about bladder health and function may influence daily toileting behaviors and early management of lower urinary tract symptoms (LUTS) in women. Yet, little is known about how these are shaped by multilevel factors such as societal norms, media messages, health literacy, and interpersonal relationships. The aim of this study was to characterize adult women's lay beliefs and assumptions about bladder health and function to inform future prevention intervention strategies.

STUDY DESIGN, MATERIALS AND METHODS

The Study of Habits, Attitudes, Realities, and Experiences (SHARE) is a qualitative study of the Prevention of Lower Urinary Tract Symptom (PLUS) Research Consortium. It explored adolescents' and adult women's experiences, perceptions, beliefs, knowledge, and behaviors related to bladder health and function across the life course (1, 2). The SHARE study recruited participants for 44 focus groups from urban and rural areas across seven U.S. research centers. Applying a life course perspective, participants were recruited and organized into six age categories: 11-14; 15-17; 18-25; 26-44; 45-64; and 65+. The current analysis focused on data from the 36 focus groups conduced with women 18 years of age or older (N=316). To ensure having a full conceptualization of women's experiences of "healthy bladder," the study included participants without respect to LUTS status. Following focus group sessions, participants completed self-administered measures to characterize the sample in terms of demographics, physical/health conditions, and LUTS status (3). Focus groups were audio-recorded and transcribed. Following transcript and fieldnote coding for documenting nonverbal communication, multi-level qualitative content analysis was used to classify emergent themes. A transdisciplinary lens and inductive approach guided data interpretation of the "bladder beliefs and assumptions code." A team of investigators articulated interpretive insights, which were validated by a community engagement panel.

RESULTS

Table 1 summarizes demographic information on the four age groups. The sample was diverse with respect to race, ethnicity, education, socioeconomic status, physical/health conditions, LUTS status, geography (urban/rural), and language, including focus groups conducted in Spanish. 82.9% of participants reported experiencing at least one LUTS. It is not known if participants sought treatment. Table 2 summarizes reported LUTS on the LUTS Tool questionnaire (3) among adult participants. X % reported experiencing at least one LUTS. It is not known if participants sought treatment.

Women exhibited limited understanding of bladder health and function, with assumptions and beliefs shaped by personal experience and hearsay from friends, family, television commercials, etc. Except for the rare occasion when women had input from a medical professional, notions about bladder health and function were characterized by uncertainty, tentativeness, and unconfirmed impressions. Women speculated on (a) the function of the urinary tract system in cleansing or flushing the bodily system of impurities and toxins, (b) the functional relationships between and among the kidneys, bladder, urethra, vagina, and pelvic floor and (c) the impact on bladder function of medications for chronic conditions. Women's assumptions and beliefs about bladder health were framed within a "cause and effect" perspective, covering a wide array of habits/behaviors (e.g. eating and hydration habits, "holding urination", exercise), while conjecturing about the physiological mechanisms through which such practices promote or deter bladder health. Finally, there was agreement on the importance of bladder friendly habits and the inadvisability of potentially harmful practices. This was accompanied by an assumption that bladder problems could be prevented by developing community-based programs for educating women about bladder health and function, encouraging women to practice healthy bladder habits, eliminating taboos about discussing bladder health, and empowering women to speak out about their bladder-related experiences and concerns.

INTERPRETATION OF RESULTS

This is the first study to apply a socioecological, life course perspective to characterize adult women's lay beliefs and assumptions about bladder health and function. Results show a discordance between lay women's beliefs and assumptions about bladder health and function and the body of scientific knowledge used by primary care providers to screen for LUTS, as well as by clinical specialists to treat women with LUTS. Women's beliefs and assumptions about where and when to void are framed within the context of toileting socialization processes in the home and schools, which often include cautionary tales based on lay experiences. Assumptions and beliefs about delayed voiding, for example, may reflect adaptations to practical concerns such as limited toileting autonomy in the workplace and reduced toilet access in public places.

CONCLUDING MESSAGE

Across the life course, lay women's understanding of bladder health and function could benefit from input from health care professionals, particularly in preventive care settings where women could be encouraged to engage in healthy bladder habits. Additionally, community-engaged public health messaging can inform women's assumptions and beliefs about bladder health/function, educating women about the promotion of bladder health and the prevention of LUTS.

FIGURE 1

Table 1: Demographic Characteristics of the Sample.

	Overall	18-25 years	26-44 years	45-64 years	65+ years
N	**316**	**51**	**72**	**104**	**89**
Age (SD)	50.2 (19.33)	21.8 (2.11)	34.9 (5.81)	54.9 (5.9)	73.2 (6.92)
Race (%)					
White	124 (39.2%)	29 (56.9%)	22 (30.6%)	34 (32.7%)	39 (43.8%)
African-American	94 (29.7%)	11 (21.6%)	13 (18.1%)	41 (39.4%)	29 (32.6%)
Other	63 (19.9%)	9 (17.6%)	27 (37.5%)	18 (17.3%)	9 (10.1%)
Missing	35 (11.1%)	2 (3.9%)	10 (13.9%)	11 (10.6%)	12 (13.5%)
Ethnicity (%)	108 (34.2%)	10 (19.6%)	36 (50%)	35 (33.7%)	27 (30.3%)
Geographic (%)					
Rural	45 (14.2%)	11 (21.6%)	0 (0%)	7 (6.7%)	27 (30.3%)
Suburban	56 (17.7%)	17 (33.3%)	14 (19.4%)	16 (15.4%)	9 (10.1%)
Urban	215 (68%)	23 (45.1%)	58 (80.6%)	81 (77.9%)	53 (59.6%)

FIGURE 2

Table 2: Lower Urinary Tract Symptoms Reported by Participants. (Each LUTS was characterized as "Sometimes" or more except in the case of daytime urination (11 or more) or nighttime urination (2 or more)).

	Overall	18-25 years	26-44 years	45-64 years	65+ years
N	**316**	**51**	**72**	**104**	**89**
1. Urinate too frequently	185 (58.5%)	16 (31.4%)	39 (54.2%)	71 (68.3%)	59 (66.3%)
2. Daytime urination	23 (7.3%)	2 (3.9%)	9 (12.5%)	9 (8.7%)	3 (3.4%)
3. Nighttime urination	131 (41.5%)	5 (9.8%)	22 (30.6%)	45 (43.3%)	59 (66.3%)
4. Incomplete Emptying	98 (31%)	13 (25.5%)	20 (27.8%)	43 (41.3%)	22 (24.7%)
5. Dribble after urination	123 (38.9%)	20 (39.2%)	25 (34.7%)	44 (42.3%)	34 (38.2%)
6. Need to rush to urinate	163 (51.6%)	17 (33.3%)	29 (40.3%)	59 (56.7%)	58 (65.2%)
7. Delay before urination	76 (24.1%)	12 (23.5%)	14 (19.4%)	27 (26%)	23 (25.8%)
8. Intermittency	61 (19.3%)	6 (11.8%)	7 (9.7%)	30 (28.8%)	18 (20.2%)
9. Strain to urinate	34 (10.8%)	1 (2%)	5 (6.9%)	18 (17.3%)	10 (11.2%)
10. Weak stream	62 (19.6%)	5 (9.8%)	9 (12.5%)	28 (26.9%)	20 (22.5%)
11. Splitting or Spraying	57 (18%)	7 (13.7%)	14 (19.4%)	26 (25%)	10 (11.2%)
12. Sudden need urinate-fear of leaking	100 (31.6%)	7 (13.7%)	14 (19.4%)	38 (36.5%)	41 (46.1%)
13. Pain or discomfort	65 (20.6%)	10 (19.6%)	16 (22.2%)	27 (26%)	12 (13.5%)
14. Burning	26 (8.2%)	5 (9.8%)	6 (8.3%)	10 (9.6%)	5 (5.6%)
15. Leak urine	81 (25.6%)	3 (5.9%)	15 (20.8%)	38 (36.5%)	25 (28.1%)
16a. Leak just after urination	48 (15.2%)	5 (9.8%)	7 (9.7%)	22 (21.2%)	14 (15.7%)
16b. Leaked with sudden need to urinate	93 (29.4%)	6 (11.8%)	14 (19.4%)	40 (38.5%)	33 (37.1%)
16c. Leaked when laugh/sneeze/cough	106 (33.5%)	7 (13.7%)	24 (33.3%)	42 (40.4%)	33 (37.1%)
16d. Leaked with physical activity	62 (19.6%)	4 (7.8%)	10 (13.9%)	28 (26.9%)	20 (22.5%)
16e. Leaked when sleeping	32 (10.1%)	1 (2%)	8 (11.1%)	14 (13.5%)	9 (10.1%)
16f. Leaked with sexual activity	16 (5.1%)	3 (5.9%)	3 (4.2%)	5 (4.8%)	5 (5.6%)
16g. Leaked for no reason	32 (10.1%)	1 (2%)	4 (5.6%)	16 (15.4%)	11 (12.4%)
Any of the above	262 (82.9%)	39 (76.5%)	57 (79.2%)	89 (85.6%)	77 (86.5%)

REFERENCES

1. Low LK, Williams BR, Camenga DR, Hebert-Beirne J, Brady SS, Newman DK, James AS, Hardacker CT, Nodora J, Linke SE, Burgio KL Prevention of Lower Urinary Tract Symptoms Research Consortium Focus Group Study of Habits, Attitudes, Realities, and Experiences of Bladder Health. J Adv Nurs. 2019 Jul 9. doi: 10.1111/jan.14148. [Epub ahead of print] PMID:31287183
2. Williams BR, Nodora J, Newman DK Low LK, James A, Camenga DR, Hebert-Bernie J, Brady SS, Hardacker CT, Smith AL, Cunningham SD, Burgio KL; Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium. (2020) "I never knew anyone who peed on themselves on purpose:" Exploring adolescent and adult women's lay language and discourse about bladder health and function. Neurourol Urodyn. Jan;39(1):225-236. doi: 10.1002/nau.24174. Epub 2019 Oct 2.PMID:31578778
3. Coyne KS, Barsdorf AI, Thompson C, Ireland A, Milsom I, Chapple C, Kopp ZS, Bavendam T. Moving towards a comprehensive assessment of lower urinary tract symptoms (LUTS). Neurourol Urodyn. 2012 Apr;31(4):448-54. doi: 10.1002/nau.21202.

Funding None **Clinical Trial** No **Registration Number** Clinicaltrials.gov **Subjects** Human **Ethics Committee** Approved by University Institutional Review Board (IRB), which served as the central review board for six of the seven sites, and a local university IRB at the remaining site. **Helsinki** Yes **Informed Consent** Yes

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DAYTIME AND NIGHTTIME URINATION FREQUENCIES IN HEALTHY WOMEN: WHAT IS THE NORMAL RANGE?

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HYPOTHESIS / AIMS OF STUDY

There is growing interest in the promotion of bladder health and prevention of lower urinary tract symptoms (LUTS), particularly in women who are at higher risk for LUTS and associated bladder conditions. An essential step in health promotion efforts is to estimate bladder function parameters, such as daytime and nighttime urination frequencies, in women without LUTS to define the normal ranges and inform future interpretation of patient symptoms. Currently, there are no established reference ranges for urination frequencies in healthy women. A recent meta-analysis of 22 studies found wide heterogeneity across estimates of urination frequencies in healthy women, precluding generalization of reference ranges to all healthy women.1 Analyses were limited by differences in definitions of healthy women, and failure to present results separately by, or take into consideration demographic characteristics and other variables known to affect bladder function. Therefore, this study was undertaken to: 1) estimate normative reference ranges in daytime and nighttime urination frequencies in healthy women based on two operational definitions of "healthy," and separately by age, race/ethnicity, and fluid intake; and 2) examine differences by age, race/ethnicity, and fluid intake.

STUDY DESIGN, MATERIALS AND METHODS

This is a secondary analysis of data collected from the first follow-up interview of female respondents (ages 31-87 years) who participated in the Boston Area Community Health (BACH) Survey, a large, population-based study of Boston residents.2 We created two definitions of healthy participants using less restrictive ("healthy") and strict ("elite healthy") exclusion criteria. Exclusion criteria for healthy women were: pregnancy; congenital urinary tract abnormalities; urinary incontinence (UI); interstitial cystitis/painful bladder syndrome; use of LUTS medications; use of a chronic catheter; "bladder emptying problem as a result of nerve or muscle problem;" and progressive neurological disease. Additional exclusion criteria for elite healthy women were: poor to fair self-rated health; LUTS in the past 30 days; use of pads; previous UI treatment; self-report of "any bladder problem;" use of medications that could affect bladder function ("insulin or pills for sugar," heart failure, or antidepressants); use of medications for pelvic pain; gynecological conditions or comorbidities that could affect bladder function (e.g., irritable bowel syndrome, pulmonary disease, heart failure, or stroke); prior bladder or UI surgery; genitourinary cancer; current treatment for any cancer other than skin cancer; or self-reported "a lot" of health-related activity limitations.

All analyses were weighted to account for the BACH sampling design. Descriptive statistics were used to describe daytime and nighttime urination frequencies for each healthy definition, which were also stratified by age group (31-44, 45-64, 65+ years) and race/ethnicity (Black, Hispanic, White). Normative reference values were identified by the quantiles corresponding to the middle 95% of the distribution of urination frequencies for the two definitions. Reference values were also calculated by age, race/ethnicity, and fluid intake. Unadjusted and adjusted generalized linear regression with a log-link was used to estimate the rate ratio of daytime and nighttime urination frequencies by age group, race/ethnicity, and fluid intake adjusting for body mass index, number of pregnancies, hormonal status, and smoking status. Total daily fluid intake of ≥ 50 oz and ≥ 75oz with the majority consumed after 5pm was also explored in relation to nighttime urination frequency

RESULTS

Of the 2534 women who completed the BACH follow-up survey, 1505 women met healthy eligibility criteria, while 300 women met the stricter elite healthy criteria. Overall, the reference range for elite healthy women was ≤9 voids/day and ≤2 voids/night, whereas those in the relaxed healthy definition voided ≤10 times/day and ≤4 times/night (Table 1). After adjustment, there were no significant differences in daytime or nighttime urinations by age or race/ethnicity except for Black women who had 11% less daytime voids than White women (Table 2). Women who reported fluid intakes of ≤ 49oz had 29% less daytime voids on average than those who consumed the recommended amount of fluid, whereas there were no significant differences noted for those who consumed ≥ 75oz. Consuming the majority of fluids after 5 PM was associated with a decrease in nighttime voids by 23% though not found to be statistically significant.

INTERPRETATION OF RESULTS

The normative reference range for daytime urination frequency was similar in women using strict and less restrictive health definitions, whereas, nighttime urinations differed. Findings suggest that voiding up to 10 times/day and 4 times/night may be "within normal limits" for women with comorbidities and certain medication use, whereas women with elite health void up to 9 times/day and 2 times/night. These results add further support to the prior meta-analysis1 conclusion that there is a wide range of normality in healthy women and challenge the current definition of overactive bladder with respect to 24-hour urination frequency. In healthy women, when adjustments are made for key covariates, there was little influence on urination frequencies by age or race/ethnicity, except for Black women, who voided less frequently than White women. Having low daily fluid intake was associated with lower daytime frequency but consuming the majority of fluids after 5 PM had no association with nighttime frequency.

CONCLUDING MESSAGE

Normative reference values for daytime and nighttime urination frequencies in healthy women suggest wide variation in what is considered "normal." Future research is needed to examine factors that affect the lower and upper bounds of the reference ranges for urination frequency.

FIGURE 1

Table 1. Daytime and Nighttime Urination Frequencies in Healthy Women (n=1505)

Outcome	Elite Healthy (n=300)		Healthy with No or a Minor Bladder Problem (n=1505)	
	Daytime	Nighttime	Daytime	Nighttime
Urination frequency mean (sd), range	5 (1.9) 1-15	0.7 (0.8) 0-4	5.1 (2.2) 0-20	1.1 (1.1) 0-10
95% urination reference range				
Overall	2-9	0-2	2-10	0-4
Age Group				
31-44 years	2-8	0-3	2-10	0-4
45-64 years	2-9	0-2	2-12	0-4
65+ years	2-8	0-2	2-9	0-3
Race/Ethnicity				
White	2-9	0-2	2-10	0-2
Black	2-8	0-3	2-10	0-3
Hispanic	2-10	0-3	2-10	0-3
Fluid intake				
< 49 oz	2-7	0-2	2-10	0-4
50-74 oz	2-9	0-3	2-9	0-4
75+ oz	3-10	0-2	2-12	0-4

FIGURE 2

Table 2. Adjusted* Rate Ratios (RR) for Demographic Characteristics and Fluid Intake with Urination Frequencies in Elite Healthy Women (n=300)

Variable	Daytime Urination RR (95% CI)	*P value*	Nighttime Urination RR (95% CI)	*P value*
Age Group				
31-44 years	1.00	--	1.00	--
45-64 years	1.14 (0.95, 1.37)	0.160	0.77 (0.53, 1.12)	0.166
65+ years	0.88 (0.73, 1.07)	0.199	1.33 (0.65, 2.71)	0.437
Race/Ethnicity				
Black	0.89 (0.81, 0.98)	0.013	1.66 (0.89, 3.12)	0.113
Hispanic	0.93 (0.83, 1.04)	0.219	1.44 (0.73, 2.82)	0.294
White	1.00	--	1.00	--
Fluid intake				
≤ 49 oz	0.71 (0.63, 0.81)	<0.001		
50-74 oz	1.00	--	--	--
75+ oz	0.93 (0.83, 1.04)	0.185		
Total Daily Fluid Intake with Majority Consumed After 5 PM				
Not after 5 PM or < 50 oz	--	--	1.00	--
After 5 PM or > 50 oz			0.77 (0.48, 1.25)	0.293

* Adjusted for age group, race/ethnicity, body mass index group, number of pregnancies, hormonal status, daily fluid intake, and smoking status

REFERENCES

1. Wyman JF, Zhou J, LaCoursiere DY, et al. Normative noninvasive bladder function measurements in health women: A systematic review and meta-analysis. Neurourol Urodyn 2020; 39(2): 507-522.
2. McKinlay JB, Link CL. Measuring the urologic iceberg: design and implementation of the Boston Area Community Health (BACH) Survey. Eur Urol 2007; 52:389-396.

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TO TELL OR NOT TO TELL: A QUALITATIVE STUDY OF INCONTINENCE DISCLOSURE

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HYPOTHESIS / AIMS OF STUDY

Individuals with concealable stigmatized conditions may experience dilemma about whether or not to talk about their condition. Even though urinary incontinence (UI) is a common health problem, it is often under-reported and under-treated due to its stigmatized status (Mathews, 2009). Despite the risk of stigma, disclosure of UI might increase treatment seeking, ease psychological stress, increase self-efficacy, and contribute to positive aging experiences (Heintz et al., 2013). Besides stigma, there might be other reasons why people with incontinence chose to either conceal or disclose their condition. The purpose of this qualitative study is to describe the perceived risks and benefits of disclosing UI to others.

STUDY DESIGN, MATERIALS AND METHODS

Individuals who experience incontinence (n=25; 60% male) participated in focus groups about disclosure of incontinence. The mean age of participants was 68 years (SD = 14; range = 27-76 years). Institutional Review Board approval was obtained through the (institution name blinded for review) and all study participants provided informed consent prior to participation. A community-based participatory research (CBPR) team, consisting of researchers, health care providers, and people with lived experience of UI developed the research design and focus group questions collaboratively. The focus groups were jointly facilitated by two members of the CBPR team. Participants completed a brief demographic questionnaire and then responded orally to questions within the group setting. Questions were open-ended and asked participants to share their experiences with disclosure and expand upon perceived risks and benefits therein. Focus group transcripts were coded with MAXQDA 12 using inductive thematic analysis (Braun & Clarke, 2006).

RESULTS

Participants reported a range of incontinence types including urge, stress, enuresis, overflow, and mixed/ other. Many participants (84%) had told at least one person about their incontinence, most often a healthcare provider (80%) or family member (64%). The perceived benefits of disclosure included: 1) helping others gain understanding or awareness about UI, 2) getting relief from telling the secret, 3) obtaining support and accommodations, 4) strengthening relationships with others, 5) getting treatment for UI, 6) taking control and feeling empowered. The perceived risks of disclosure were: 1) gossip, 2) prejudice and discrimination (stigma), 3) embarrassment, 4) ignorant reactions from others, 5) unsupportive reactions from others, 6) others using your UI against you. In terms of prejudice, participants thought that urinary incontinence made them look weak, dependent, or old to others. Participants described incidences of discrimination including loss of a job, break-up with significant others, and travel-related hassles.

INTERPRETATION OF RESULTS

These results indicate that individuals with UI have multiple factors to consider when talking with others about their incontinence. These seem to depend largely on the reaction or perceived reaction of the person to whom they decide to disclose. In line with past research, stigma (including prejudice and discrimination) is an important consideration related to disclosure, but there are also other, more benign reactions such as lack of understanding or supportiveness that can influence this decision. Future studies could examine

how confidant reactions impact future disclosure behavior and how perceived risks and benefits of disclosure relate to disclosure behaviors such as help-seeking.

CONCLUDING MESSAGE

People with UI report both risks and benefits related to disclosure decisions. Healthcare providers, family members, and public health professionals can better engage people with UI in care when they understand the complex decision-making processes related to disclosure and the subsequent impact of each disclosure on their lives. Furthermore, people with UI may benefit from guidance on making strategic disclosures that can maximize benefits and reduce risks.

REFERENCES

1. Matthews, D. (2009). Why continence matters: A social work perspective. Aotearoa New Zealand Social Work, 21(4), 34-43.
2. Heintz, P.A., DeMucha, C.M., Deguzman, M.M., Softa R. Stigma and microaggressions experienced by older women with urinary incontinence: a literature review. Urologic Nursing, 33(6):299-305.
3. Braun, V., Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology, 3, 77–101.

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EARLY LIFE SEXUAL TRAUMA AND LATE LIFE SYMPTOMS OF GENITOURINARY DYSFUNCTION IN A NATIONAL SAMPLE OF OLDER COMMUNITY-DWELLING WOMEN

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HYPOTHESIS / AIMS OF STUDY

One in four women may experience a form of early life sexual trauma, with potentially long-lasting consequences on their health and functioning. Past research has suggested that women who are victims of sexual trauma or abuse may be at increased risk of genitourinary health problems [1,2]. However, these studies have focused almost exclusively on health outcomes in reproductive age women, with almost no research addressing potential long-term effects later in life. To address this gap, our study aimed to examine the prevalence of two types of potentially traumatic early sexual experiences in a nationally representative sample of community-dwelling older U.S. women and investigate their associations with late life symptomatic genitourinary dysfunction. We hypothesized that early exposure to sexual trauma would be associated with more frequent or persistent genitourinary symptoms in older age.

STUDY DESIGN, MATERIALS AND METHODS

We analyzed cross-sectional data from U.S. women aged 50 years and older in the second wave of the National Social Life, Health, and Aging Project, a national cohort of older community-dwelling U.S. adults. During home-based visits from 2010-2011, women answered standardized questions about exposure to two forms of early sexual trauma: a) childhood sexual abuse (being touched sexually before age 12), and b) unwanted first sexual experience (forced or coerced first sexual intercourse). Women also answered structured self-report questions about the presence and frequency of: a) urinary incontinence and b) other urinary symptoms (such as feeling of incomplete emptying, slow urinary stream, straining to begin voiding, or difficulty in postponing urination). For this analysis, urinary incontinence and other urinary symptoms were classified as being clinically significant if they occurred at least a few times a month. Women also answered questions about the presence of genital/sexual dysfunction symptoms in the past 12 months, including trouble lubricating, not finding sex pleasurable, and experiencing physical pain during intercourse (if sexually active). Genital/sexual symptoms were considered clinically significant if participants reported experiencing them for a several month period in the past year. Multivariable logistic regression models examined the odds of each genitourinary outcome predicted by each form of early life sexual trauma, adjusting for age, race/ethnicity, and education as demographic covariates that might confound associations.

RESULTS

Of 1,745 women (age range 50 to 91 years), 11% reported a history of childhood sexual abuse and 39% an unwanted first sexual experience. Forty-one percent reported urinary incontinence and 17% reported other urinary symptoms at least a few times a month, and 26% had trouble lubricating, 10% experienced pain during sex, and 17% did not find sex pleasurable for at least several months of the past year. In multivariable models, childhood sexual abuse was associated with late life pain during sexual activity [OR 1.9, 95% CI 1.1-3.3] and other urinary symptoms [OR 1.9, 95% CI 1.2-3.1]). Unwanted first sexual experience was also associated with late life symptoms of lack of pleasure with sex [OR 1.7, 95% CI 1.1- 2.5]), but not urinary incontinence or other urinary symptoms in adjusted analyses [Table 1].

INTERPRETATION OF RESULTS

Our study identified associations between two types of traumatic early life sexual experiences and multiple types of genitourinary symptoms in a national sample of older community-dwelling women. These findings raise the possibility that early life sexual trauma exposure may be an under-rec-

ognized marker of risk for late life genitourinary dysfunction in women.

CONCLUDING MESSAGE

Findings from this national sample of older community-dwelling women underline the importance of recognizing early sexual trauma exposures as a potential lifelong risk factor for adverse genitourinary health outcomes. This research provides new insights to suggest that healthcare providers may need to consider the potential impact of sexual abuse on genitourinary health and function in women across the lifespan. Early detection may help clinicians gauge female patients' risk for genitourinary or sexual decline later in life, aid in prevention, or guide delivery of trauma-informed care in older age.

FIGURE 1

Table 1: Adjusted associations between early life sexual trauma exposures and late life symptoms of genitourinary dysfunction

A. Childhood sexual abuse			
Symptom of genitourinary dysfunction	**Women without a history of childhood sexual abuse [N = 1562]**	**Women with a history of childhood sexual abuse [N = 183]**	**Adjusted odds ratio† (95% confidence interval)**
Urinary incontinence§	575 (40.4%)	86 (45.2%)	1.21 (0.78-1.88)
Other urinary problems§	234 (16.1%)	46 (27.0%)	1.91 (1.17-3.10)‡
Trouble lubricating§	290 (24.3%)	58 (39.9%)	1.82 (0.98-3.39)
Pain during sexual intercourse§	132 (9.2%)	26 (17.2%)	1.92 (1.12-3.27)‡
Lack of pleasure during intercourse§	211 (16.0%)	33 (21.6%)	1.40 (0.84-2.34)
B. Unwanted first sexual experience			
Symptom of genitourinary dysfunction	**Women without a history of unwanted first sexual experience [N = 1061]**	**Experienced unwanted first sexual experience [N = 684]**	**Adjusted odds ratio† (95% confidence interval)**
Urinary incontinence§	394 (40.1%)	267 (42.3%)	1.14 (0.86-1.51)
Other urinary problems§	163 (16.8%)	117 (18.2%)	1.15 (0.81-1.62)
Trouble lubricating§	215 (27.4%)	133 (24.5%)	0.90 (0.65-1.24)
Pain during sexual intercourse§	92 (9.9%)	66 (10.6%)	1.13 (0.74-1.73)
Lack of pleasure during intercourse§	126 (14.1%)	118 (20.9%)	1.66 (1.13-2.45)‡

*All percentages are column percentages
†Adjusting for age, race/ethnicity, education
‡Significant at P <.05.
§Data were missing for 121 women for urinary incontinence, 98 women for other urinary symptoms, 378 women for trouble lubricating, 304 women for pain during sex, and 376 women for did not find sex pleasurable.

Adjusted associations between early life sexual trauma exposures and late life symptoms of genitourinary dysfunction

REFERENCES

1. Pulverman, C. S., Kilimnik, C. D., Meston, C. M. (2018). The Impact of Childhood Sexual Abuse on Women's Sexual Health: A Comprehensive Review. Sexual Medicine Reviews, 6(2), 188-200.
2. Vézina Gagnon, P., Bergeron, S., Frappier, J., & Daigneault, I. (2018). Genitourinary Health of Sexually Abused Girls and Boys: A Matched-Cohort Study. The Journal of pediatrics, 194, 171-176.

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GENDER DIFFERENCES IN THE PREVALENCE AND RISK FACTORS OF LOWER URINARY TRACT SYMPTOMS IN ELDERLY CHINESE AMERICANS

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract symptoms (LUTS) are highly prevalent in the adult population with the most prominent symptom being overactive bladder (OAB) syndrome. To date, there are no epidemiologic studies that focus on the prevalence of LUTS for Asian Americans or their subgroups in the US. Despite the fact that Asian Americans comprise 5.6% of the US population, Asian Americans have been largely underrepresented in lower urinary tract research. Of the numerous Asian American subgroups, Chinese Americans constitute the largest subgroup of all. In order to bridge the gap of knowledge in LUTS among Asian Americans, this is the first study that aims to describe LUTS prevalence, whether or not there are gender differences in LUTS prevalence, and risk factors associated with LUTS in a community-dwelling elderly Chinese American population.

STUDY DESIGN, MATERIALS AND METHODS

We performed a secondary analysis of a prospective cross-sectional population-based survey of Chinese Americans aged 60 and older living in the Chicago area between the years 2011-2013. These surveys were conducted in English or one of the Chinese dialects, including Mandarin, Cantonese, Taishanese, or Teochew. A clinical review of system (ROS) was used to assess LUTS, which included frequency, urgency, burning or pain, blood in urine, and incontinence. Within LUTS, a subgroup of overactive bladder without incontinence (OAB-dry) was defined as urgency and/or frequency without incontinence. Descriptive statistics for demographics, risk factors, and individual general health perceptions were performed using students t-test and chi-square where appropriate. Multivariable logistic regression was used to identify independent risk factors.

RESULTS

Of the total 3,157 people queried, 1,328 (42%) were men and 1,829 (58%) were women. The mean(±SD) age was 72.8±8.3 years and 30.4% reported of at least one LUTS. There was a higher proportion of men who reported LUTS when compared to women (32.9% vs 28.7%, p=0.01). Of the individual LUTS, 27.9% of men reported frequency, 16.5% with urgency, 2.9% with burning/pain, 1.5% with hematuria, and 2.9% with incontinence. In women, 22.4% reported frequency, 12.6% with urgency, 2.2% with burning/pain, 1.7% with hematuria, and 5.6% with incontinence. When organizing these individual LUTS to meet the definition for OAB-dry, more men met the OAB-dry symptom criteria than women (28.8% vs 21.2%, p<0.0001). When compared to men with any LUTS, women with any LUTS had significantly lower rates of smoking, alcohol use, and heart disease but higher rates of frequent traditional Chinese medicine (monthly or more TCM) use, cognitive impairment, and difficulties with physical functions and activities of daily living (Table 1). Women with LUTS also had a poorer general health perception than men with LUTS (p=0.01).

In a multivariable analysis evaluating the overall population with any LUTS (Table 2), female gender (aOR 0.60, 95%CI 0.49-0.73), being married (aOR 0.79, 95%CI 0.65-0.97), and smoking (aOR 0.66, 95%CI 0.49-0.88) were found to be protective; while frequent TCM use (aOR 1.51, 95% CI 1.28-1.78), heart disease (aOR 1.54, 95%CI 1.24-1.91), and anxiety (aOR 1.69, 95%CI 1.25-2.28) were most strongly associated with increased odds of reporting any LUTS. When applying the same multivariable regression to the total population with OAB-dry, female gender (aOR 0.52, 95%CI 0.42-0.63) and smoking (aOR 0.67, 95%CI 0.49-0.90) were again found to be protective while frequent TCM use (aOR 1.51, 95%CI 1.26-1.80), heart disease (aOR 1.47, 95%CI 1.18-1.84), and anxiety (aOR 1.47, 95%CI 1.08-2.01) were also found to be most associated with increased odds of reporting OAB-dry symptom as observed in LUTS.

When examining men and women separately using the same multivariable regression model, being married was found to be protective only for women with LUTS (aOR 0.75, 95%CI 0.59-0.96), but not for men. Depression was also strongly associated with LUTS in women (aOR 1.70, 95%CI 1.28-2.26) while anxiety was associated with LUTS in men (aOR 2.74, 95%CI 1.54-4.87). Frequent TCM use was the only factor that was significantly associated with an increased odds of LUTS in both men and women. Other gender-specific factors that were associated with an increased odds of LUTS in men but not women included hypertension, heart disease, and practice of Taichi. When analyzing the OAB-dry subgroup, most associations were similar to those found in LUTS; however, smoking was found to be protective (aOR 0.72, 95%CI 0.52-0.99) in men with OAB-dry only.

INTERPRETATION OF RESULTS

In this large population-based study, LUTS were more prevalent in elderly Chinese American men than women. We also found gender-specific factors that influenced the odds of reporting any LUTS; however, frequent TCM use was the only shared characteristic between both genders reporting any LUTS. Of all the LUTS, OAB-dry was the most commonly reported symptom. OAB-dry subgroup shared similar associations as those for LUTS in general. Lastly, comparing between men and women with any LUTS, women with any LUTS were more likely to have lower baseline cognitive and physical functions than men.

CONCLUDING MESSAGE

This is the first study to specifically address LUTS in community-dwelling elderly Chinese Americans. Gender-specific differences were noted in factors associated with LUTS and OAB-dry. This study highlights the unique risk factors for elderly Chinese American men and women with LUTS and underscores the importance of expanding lower urinary tract research to incorporate greater diversity in its study populations. In addition, more longitudinal investigations are needed to elucidate the underlying mechanisms of LUTS to provide evidence-based and culturally specific clinical guidelines for the rapidly growing Chinese American population in the US.

FIGURE 1

Table 1. Risk factors and comorbidities

	Any LUTS			OAB-Dry[1]		
	Men (n=437)	Women (n=524)	*p* value	Men (n=382)	Women (n=388)	*p* value
BMI (kg/m^2), mean±SD	23.5±3.3	23.4±3.7	0.56	23.5±3.1	23.4±3.7	0.66
Current smoker	296 (67.7%)	7 (1.3%)	<0.0001	68 (17.8%)	2 (0.5%)	<0.0001
Alcohol use						
Never	327 (74.8%)	496 (94.7%)	<0.0001	286 (74.9%)	370 (95.4%)	<0.0001
Monthly or less	76 (17.4%)	20 (3.8%)		66 (17.3%)	14 (3.6%)	
2-4 times a month	9 (2.1%)	6 (1.1%)		8 (2.1%)	3 (0.8%)	
2-3 times a week	5 (1.1%)	2 (0.4%)		5 (1.3%)	1 (0.3%)	
4 or more a week	20 (4.6%)	0 (0%)		17 (4.4%)	0 (0%)	
TCM herb user[2]	163 (37.3%)	263 (50.2%)	<0.0001	145 (38.0%)	195 (50.3%)	0.0006
Taichi user[3]	63 (14.4%)	66 (12.6%)	0.41	56 (14.7%)	51 (13.1%)	0.54
Cognitive mental status[4]						
Severely impaired	7 (1.6%)	13 (2.6%)	<0.0001	5 (1.3%)	3 (0.8%)	<0.0001
Moderately impaired	16 (3.8%)	65 (13.1%)		9 (2.4%)	46 (12.5%)	
Mildly impaired	52 (12.2%)	100 (20.2%)		47 (12.5%)	76 (20.6%)	
Not impaired	351 (82.4%)	317 (64.1%)		315 (83.8%)	244 (66.1%)	
NAGI score, mean±SD[5]	3.1±4.0	5.3±4.8	<0.0001	2.8±3.5	4.8±4.5	<0.0001
ADL score, mean±SD[6]	0.6±3.0	0.8±3.2	0.02	0.3±1.9	0.4±1.7	0.11
Anxiety[7]	38 (8.9%)	88 (16.9%)	0.0003	29 (7.7%)	61 (15.8%)	0.0005
Depression[8]	87 (20.2%)	185 (35.4%)	<0.0001	67 (17.8%)	128 (33.0%)	<0.0001
Heart disease	120 (27.5%)	93 (17.8%)	0.0003	102 (26.7%)	66 (17.0%)	0.0011
Stroke	49 (11.2%)	40 (7.6%)	0.057	37 (9.7%)	29 (7.5%)	0.27
Any cancer	27 (6.2%)	39 (7.4%)	0.44	22 (5.8%)	24 (6.2%)	0.80
Diabetes	119 (27.2%)	143 (27.3%)	0.97	98 (25.7%)	104 (26.9%)	0.70
Hypertension	271 (62.2%)	327 (62.6%)	0.88	242 (63.5%)	244 (63.2%)	0.93
Osteoarthritis	163 (37.3%)	283 (54.0%)	<0.0001	141 (36.9%)	199 (51.3%)	<0.0001

1. The LUTS subgroup of OAB-dry was defined as urgency and/or frequency without incontinence.
2. TCM: traditional Chinese medicine. A TCM user here is defined as history of using either prescribed or self-medicated herbal products of any type at least monthly or more.
3. Taichi user is defined as one who practices Taichi exercises at least monthly or more.
4. Cognitive mental status is the measurement of one's cognitive impairment by a 30-question Mini-Mental Status Exam.
5. NAGI score is a physical function assessment tool with higher scores indicating higher level of difficulty in basic physical activities.
6. ADL is activities of daily living. The higher scores indicate higher level of functional assistance or support requirement.
7. Anxiety diagnosis is screened by Hospital Anxiety and Depression Scale (HADS): Anxiety subscale.
8. Depression diagnosis is screened by Patient Health Questionnaires-9 (PHQ-9).

FIGURE 2

Table 2. Regression analysis

	Any LUTS			OAB-Dry		
	Adjusted Odds Ratio (95% CI)			Adjusted Odds Ratio (95% CI)		
	Total	Men	Women	Total	Men	Women
Female	0.60 (0.49-0.73)			0.52 (0.42-0.63)		
Age	1.02 (1.01-1.03)	1.03 (1.01-1.04)	1.02 (1.00-1.03)	1.01 (1.00-1.02)	1.02 (1.00-1.04)	1.00 (0.99-1.02)
BMI	1.02 (0.99-1.04)	1.02 (0.98-1.06)	1.02 (0.99-1.05)	1.01 (0.99-1.04)	1.01 (0.97-1.05)	1.02 (0.98-1.05)
Education	1.03 (1.01-1.05)	1.03 (1.01-1.06)	1.03 (1.00-1.05)	1.02 (0.99-1.04)	1.02 (0.99-1.05)	1.01 (0.99-1.04)
Married	0.79 (0.65-0.97)	0.84 (0.57-1.24)	0.75 (0.59-0.96)	0.93 (0.62-1.34)	0.94 (0.63-1.40)	0.73 (0.56-0.94)
Current smoker	0.66 (0.49-0.88)	0.73 (0.54-1.00)	0.33 (0.07-1.56)	0.67 (0.49-0.90)	0.72 (0.52-0.99)	0.54 (0.12-2.50)
NAGI score	1.06 (1.04-1.09)	1.08 (1.04-1.12)	1.06 (1.03-1.09)	1.03 (1.00-1.05)	1.03 (0.99-1.07)	1.02 (0.99-1.06)
TCM Herb user	1.51 (1.28-1.78)	1.33 (1.02-1.73)	1.62 (1.30-2.02)	1.51 (1.26-1.80)	1.39 (1.06-1.81)	1.60 (1.26-2.03)
Taichi user	1.35 (1.05-1.74)	1.78 (1.21-2.62)	1.14 (0.81-1.61)	1.39 (1.07-1.81)	1.66 (1.13-2.45)	1.24 (0.86-1.79)
Hypertension	1.23 (1.04-1.46)	1.37 (1.05-1.78)	1.11 (0.88-1.40)	1.35 (1.13-1.63)	1.52 (1.16-1.98)	1.20 (0.93-1.54)
Heart disease	1.54 (1.24-1.91)	1.91 (1.39-2.61)	1.23 (0.91-1.67)	1.47 (1.18-1.84)	1.78 (1.30-2.45)	1.18 (0.85-1.63)
Anxiety	1.69 (1.25-2.28)	2.74 (1.54-4.87)	1.36 (0.96-1.95)	1.47 (1.08-2.01)	1.91 (1.08-3.39)	1.27 (0.87-1.85)
Depression	1.34 (1.07-1.68)	0.93 (0.64-1.36)	1.70 (1.28-2.26)	1.22 (0.96-1.55)	0.88 (0.60-1.30)	1.55 (1.14-2.11)

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EFFECT OF VITAMIN D SUPPLEMENTATION ON URINARY INCONTINENCE IN OLDER WOMEN: ANCILLARY FINDINGS FROM A RANDOMIZED TRIAL

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HYPOTHESIS / AIMS OF STUDY

Despite observational research indicating that vitamin D insufficiency is associated with increased prevalence and incidence of urinary incontinence (UI), almost no randomized trial data are available to indicate whether supplementation with vitamin D reduces UI [1-3]. Given the unique opportunity to test vitamin D supplementation as a possible preventive treatment to reduce UI among older women [3], we proposed an ancillary analysis of women enrolled in a nationwide vitamin D and omega-3 prevention trial for cancer and cardiovascular disease, the VITamin D and omegA-3 TriaL (VITAL) clinical trial. Our objectives were to evaluate the effects of vitamin D supplementation on UI incidence and prevalence at follow-up at 2 and 5 years after randomization (the years in which UI items were included in participant questionnaires). We hypothesized that older women assigned to vitamin D, especially those with low serum 25-hydroxyvitamin D (25OHD) levels at baseline, will have lower incidence and progression rates of UI than women assigned to placebos.

STUDY DESIGN, MATERIALS AND METHODS

We performed a pre-specified ancillary study to VITAL, a 2 x 2 factorial randomized trial conducted among 25,871 participants (including 13,085 women) recruited between November 2011 and March 2014 from all 50 US states. Follow-up was completed in January 2018. Randomized treatments included: 1) vitamin D3 (cholecalciferol) at a dose of 2000 IU/day, and 2) placebo. Validated UI questions were assessed in year 2 and repeated in year 5 at the trial close. The pre-specified outcomes were the prevalence of UI at year 2 and at year 5, along with UI incidence and UI progression from year 2 to year 5, with subgroup analysis for women with low baseline serum levels of 25OHD (<30 ng/mL). Among the 13,085 women randomized, we had UI data from 11,646 women at year 2 and 10,527 at year 5. For the primary analyses, women were analyzed according to their randomization to vitamin D supplementation or placebo using the intention-to-treat principle, along with similar analyses among women with 25OHD biosamples at baseline (n=2,819).

RESULTS

No sociodemographic differences were seen between all women with UI data randomized to vitamin D versus placebo or between women with low serum 25OHD randomized to vitamin D versus placebo at year 2 (mean age = 70.1 years, 29% racial/ethnic minority). At year 2, 64% reported UI, and this increased to 71% at year 5. Supplementation with vitamin D compared to placebo was not associated with lower odds of prevalent UI at year 2 or at year 5 (Table). In women with low serum 25OHD, no differences were found in prevalent UI at year 2 or at year 5 (Table). No differences were found for progression of UI or incidence of UI at year 5, including among women with low serum 25OHD (Table). For all women and women with low serum 25OHD, UI type (urge, stress, mixed, or other) did not differ between randomization groups at year 2 or at year 5 (data not shown).

INTERPRETATION OF RESULTS

Vitamin D supplementation of 2,000 IU daily in older women was not associated with decreases in UI prevalence after two years or five years, or with decreased progression or incidence of UI, even among women with low 25OHD prior to randomization.

CONCLUDING MESSAGE

This study provides novel clinical trial evidence that 2000 IU of vitamin D supplementation compared to placebo does not improve UI in older women after 2 to 5 years of treatment.

FIGURE 1

	N	Vitamin D N (%)	Placebo N (%)	Odds Ratio	95% Confidence Interval	P value
Any UI at Year 2						
All women	11,646	3740 (64%)	3740 (64%)	1.01	0.93-1.09	0.84
Low 25OHD	2,819	908 (65%)	926 (65%)	1.01	0.87-1.18	0.89
Any UI at Year 5						
All women	10,527	3782 (71%)	3740 (71%)	1.00	0.92-1.09	0.95
Low 25OHD	2,519	900 (72%)	906 (71%)	1.06	0.89-1.26	0.51
UI Progression from Year 2 to Year 5						
All women	10073	1587 (31%)	1647 (33%)	0.94	0.84-1.05	0.25
Low 25OHD	2401	360 (30%)	401 (33%)	0.94	0.75-1.17	0.55
UI Incidence from Year 2 to Year 5						
All women	3560	650 (36%)	654 (37%)	0.97	0.84-1.11	0.64
Low 25OHD	829	136 (34%)	158 (37%)	0.90	0.67-1.19	0.45

REFERENCES

1. Badalian SS, Rosenbaum PF. Vitamin D and pelvic floor disorders in women: results from the National Health and Nutrition Examination Survey. Obstet Gynecol 2010.
2. Vaughan CP, Tangpricha V, Motahar-Ford N, Goode PS, Burgio KL, Allman RM, Daigle SG, Redden DT, Markland AD. Vitamin D and incident urinary incontinence in older adults. Eur J Clin Nutr 2016.
3. Markland AD, Tangpricha V, Mark Beasley T, Vaughan CP, Richter HE, Burgio KL, Goode PS. Comparing Vitamin D Supplementation Versus Placebo for Urgency Urinary Incontinence: A Pilot Study. J Am Geriatr Soc 2018.

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PATIENT REPORT OF INTERMITTENT CATHETERIZATION EXPERIENCE (PRICE) STUDY

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HYPOTHESIS / AIMS OF STUDY

Optimally managed patients with neurogenic or non-neurogenic urinary retention utilize intermittent self-catheterization (ISC) for bladder emptying. Although ISC is the gold standard for managing chronic urinary retention (1), little is known about the patients' actual experience and quality of life (QoL), as prior research is limited to small, community-based studies performed outside of the United Sates (US). Our objective was to better understand patient practices with and attitudes towards daily ISC in a US population by interviewing patients who have been performing ISC for at least 6 months. We used a validated ISC related QoL questionnaire to determine ease of use, discreteness, difficulty with catheterization, and psychological well-being considerations with ISC. Results may assist patients, clinicians, and manufacturers in improving QoL in patients who use ISC for bladder emptying.

STUDY DESIGN, MATERIALS AND METHODS

This is a cross-sectional, multi-centric, clinical study of adult men and women performing ISC was conducted in six distinct clinical sites including urology practices and rehabilitation centers in the US. Eligible patients were 18 years or older and had been independently performing ISC for at least 6 months. Patients who were non-English speaking or could not independently complete the questionnaires were excluded. Data collected from the participant included demographics, catheter/product choice, catheterization position, frequency of use, and length of time performing ISC. Medical history related to lower urinary tract dysfunction and presence of urinary tract infections (UTIs) was collected from the patient's medical records. Specifics on self-catheterization were obtained using a general ISC habit questionnaire and a validated questionnaire aimed at assessing QoL, the Intermittent Self-Catheterization Questionnaire (ISC-Q) (2). Herein, we present findings from the ISC-Q, a 24-item questionnaire with 4 domains: Ease of use, Convenience, Discreetness, and Psychological well-being. The ISC-Q was scored according to the manual with responses graded on a scale from 0-4 with higher score corresponding to greater satisfaction. The aggregate scores were then averaged for each question, each domain, and the entire questionnaire and multiplied by 25 to put the satisfaction score on a 100-point scale.

RESULTS

A detailed breakdown of results can be found in the associated tables. A total of 200 participants were recruited from six sites; 70% were male and 73.5% were Caucasian. Nearly 90% of patients were performing ISC for 1 year or more, and nearly 49% were performing ISC for 5 years or more. More than 50% of participants had a diagnosis of urinary retention as a result of a spinal cord injury. One-hundred eighty-four participants (92%) reported using a catheter that they disposed of after a single use. Of the 16 participants (8%) that reused the same catheter for multiple catheterizations, 5 (31%) reported reusing the same catheter 1-5 times, 4 (25%) reused the same catheter 6-10 times, and 7 (44%) reused the same catheter >10 times. One-hundred twenty-four participants (62%) used a 14 Fr size catheter with 66 (33%) reported using a Coudė tip. The majority did not require assistance with catheterization (181, 91%). Only 71 (30%) of patients reported never experiencing urine leakage between catheterizations, with 29 (19%) reporting they experienced leakage "every day" and 100 (50%) reporting that they experienced leakage "sometimes/rarely". Eighty-four (44%) of participant's records experienced a UTI treated with antibiotic in the six months prior to enrollment in the study, while 20 (10%) patient records did not address UTI occurrence. As a catheter-associated UTI prevention method, it is recommended that patients perform "no-touch" catheterization; 68 (34%) patients; however, reported "touching the part of the catheter that is being inserted" (Table 1).

Results from the ISC-Q showed that the majority of participants indicated that catheters are easy to use, discreet, and that they have confidence with their ability to perform ISC. Some participants report challenges with carrying enough catheters when traveling, a feeling of self-consciousness due to the need for ISC, and concern about the risk of long-term problems from ISC. The calculated satisfaction scores for each domain were as follows: 82.0 for ease of use, 60.0 for convenience, 75.4 for discreetness, and 64.3 for psychological well-being. The overall satisfaction score was 70.4 (Table 2).

INTERPRETATION OF RESULTS

In this large, cross-sectional, multi-centric trial of ISC practices in urology practices and rehabilitation centers in the US, variability in catheter type, frequency of ISC per day and UTI experience was noted. Ninety percent of participants had been performing ISC for > 1 year, demonstrating the chronicity of the conditions that commonly lead to ISC and thus the importance of understanding the QoL impact of ISC on patients. The ISC-Q questionnaire results indicate that participants in this study had little difficulty with catheterization and were able to be discreet about their use. Further study is needed on methods to improve convenience while traveling for ISC patients as well as understanding long term sequelae and implications of ISC. UTIs were common in participants performing ISC and may contribute to concerns about long term implications of ISC. Confidence in the ability to use the catheter is important for all ISC patients and may be the results of successful patient education as well as catheter design.

CONCLUDING MESSAGE

We believe this is the first survey of its kind to be done in patients performing ISC in urology and rehabilitation centers in the US that attempted to quantify multiple components of the patient experience when performing ISC using the validated ISC-Q. Studying patient experience with ISC has the ability to facilitate QoL improvements for this large population who, for the most part, will use ISC dependent for life.

FIGURE 1

Table 1. Characteristics of participants

N=200	
Gender *n (%)*	
Male	140 (70%)
Female	60 (30%)
Age	
Median yrs. (25^{th}%,75^{th}%)	51 (33.3,68.8)
Range yrs.	19 - 90
Race *n* (%)	
White	147 (73.5%)
Black/African American	38 (19%)
Native Hawaiian/Pacific Islander	5 (2.5%)
Asian/Asian American	1 (0.5%)
Other/Multi-racial	9 (4.5%)
Medical History *n (%)*	
Spinal cord injury (paraplegia & tetraplegia)	109, (54.5%)
Retention/incomplete bladder emptying	46 (23%)
Urethral obstruction/stricture/bladder neck contracture	10 (5%)
Spina bifida	15 (7.5%)
Multiple sclerosis	5 (2.5%)
Post-operative retention	5 (2.5%)
Augmented bladder/catheterizable channel	3 (1.5%)
Transverse myelitis	2 (1%)
Other	5 (2.5%)
Length of Time Performing ISC *n (%)*	
6-12 months	22 (11%)
13 months-3-years	45 (22.5%)
3.1-5 years	35 (17.5%)
> 5 years	98 (49%)
Frequency of Catheterizations per day *n (%)*	
0-1 times/day	12 (6%)
2 times/day	6 (3%)
3 times/day	12 (6%)
4 times/day	36 (18%)
5 times/day	57 (28.5%)
6 times/day	45 (22.5%)
>6 times/day	32 (16%)
Type of Catheter used *n (%)*	
Polyvinyl Chloride (PVC)/Clear	58 (29%)
Catheter with gel lubrication	42 (21%)
Hydrophilic with water sachet	35 (17.5%)
Hydrophilic with fluid coating	29 (14.5%)
Red rubber catheter	13 (6.5%)
Other	16 (8%)
Did not know	7 (3.5%)
Usual position when catheterizing	
Sitting on a chair/Wheelchair	88 (44%)
Standing in front of or over the toilet	55 (28%)
Sitting on the toilet	44 (22%)
Sitting on the side of the bed	2 (1%)
Lying down on the bed	11 (6%)
UTI Treated with Antibiotics in the Prior 6 Months *n (%)*	
No UTI	96 (48%)
1 UTI	43 (21.5%)
2 UTIs	25 (12.5%)
3 UTIs	9 (4.5%)
4 UTIs	7 (3.5%)
Do not know	20 (10%)

Table 1. Characteristics of participants

FIGURE 2

Table 2: Results of the Intermittent Self-Catheterization Questionnaire (ISC-Q) showing the number of study participants for each response (n=200) and mean satisfaction scores, mean domain scores, and mean total ISC-Q score

Statement/Response	*Strongly Agree*	*Slightly Agree*	*Neutral*	*Slightly Disagree*	*Strongly Disagree*	*Mean Satisfaction Score*
EASE OF USE						
It is easy for me to prepare my catheter for use each time I need it	158	29	3	3	7	91.0
It is messy to prepare my catheter for use	9	33	13	32	112	75.8
It is easy to insert my catheter for use	120	53	11	7	7	84.3
I find inserting my catheter uncomfortable sometimes	14	58	17	29	82	63.3
The design of the catheter makes it easy to insert	139	36	10	8	7	86.5
The catheter is difficult to use	8	11	10	34	136	85.1
The lubrication on the catheter makes it difficult to use	15	15	23	26	119	77.7
I feel confident in my ability to use my catheter	166	20	2	7	5	91.9
					Mean Domain Score	*82.0*
CONVENIENCE						
Storage of catheters at home is inconvenient	29	28	14	21	108	68.9
Taking enough catheters for a weekend away is inconvenient	29	50	18	23	78	59.0
Taking enough catheters for a longer vacation (for 2 weeks) is very inconvenient	51	40	15	27	65	51.9
Disposal of my catheter makes it inconvenient when away from home	23	44	24	46	63	60.3
					Mean Domain Score	*60.0*
DISCREETNESS						
I find it easy to carry enough catheters around on a day to day basis	120	46	17	9	8	82.6
I find it easy to dispose of my catheter when I am away from home	86	52	22	23	17	70.9
My catheter is discreet	78	54	29	26	13	69.8
I can use my catheter discreetly when I am away from home	96	64	12	20	8	77.5
I can easily dispose of my catheter without if being obvious to people	74	62	21	31	12	69.4
My catheter allows me to feel confident when away from home	110	54	22	9	5	81.9
					Mean Domain Score	*75.4*
PSYCHOLIGICAL WELL-BEING						
I am self-conscious about my need to self-catheterize	33	39	31	23	74	58.3
I would feel embarrassed if people saw my catheter in its packet	22	43	27	23	85	63.3
My need to use a catheter sometimes makes me feel embarrassed	15	40	27	28	90	67.3
I worry that my catheter doesn't always empty my bladder fully	21	45	23	32	79	62.9
My need to use catheters stops me from visiting friends and family as often as I would like	16	19	21	29	115	76.0
I worry about the risk of long-term problems from using my catheter	29	44	34	19	74	58.1
					Mean Domain Score	*64.3*
					Mean Total ISC-Q Score	*70.4*

Table 2: Results of the Intermittent Self-Catheterization Questionnaire (ISC-Q) showing the number of study participants for each response (n=200) and mean satisfaction scores

REFERENCES

1. Drake, M.J., Apostolidis, A., Cocci, A., Emmanuel, A., Gajewski, J.B., Harrison, S.C., … Wyndaele, J.J. (2016). Neurogenic lower urinary tract dysfunction: Clinical management recommendations of the Neurologic Incontinence committee of the fifth International Consultation on Incontinence 2013. Neurourol Urodyn. 35(6):657-65. https://DOI: 10.1002/nau.23027. 2.
2. Pinder, B., Lloyd, A.J., Elwick, H., Denys, P., Marley, J., et al. (2012) Development and psychometric validation of the intermittent self-catheterization questionnaire. Clin Ther 34: 2302-2313.

Funding The study was funded as an educational grant from Wellspect HealthCare, DENTSPLY IH AB (Sweden). **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** University of Pennsylvania IRB **Helsinki** Yes **Informed Consent** Yes

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WHICH IS THE BEST TOOL TO PREDICT OUTCOME OF CLEAN INTERMITTENT SELF-CATHETERIZATION TRAINING IN PATIENTS WITH MULTIPLE SCLEROSIS?

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract symptoms, and especially voiding dysfunction are common in patients with multiple sclerosis (PwMS). Clean intermittent self-catheterization (CISC) is the reference treatment of urinary retention in PwMS. Outcome of CISC training depends on parameters related to both the patient and their environment. The patient's ability to perform CISC can be assessed using a variety of tools. Two validated instruments, the FIM (Functional Independence Measure) and the PP-Test (Pencil and Paper Test), have been found to be associated with the success for learning CISC [1]. However, no study has determined the diagnosis performance of these tests. The objective of this study is to determine and compare the performance of these tools to predict the outcome of CISC training in PwMS.

STUDY DESIGN, MATERIALS AND METHODS

All PwMS attending a tertiary neurourology department as eligible for CISC were included in this cross-sectional study. During the CISC training session, all patients were assessed by an occupational therapist and a physiatrist. Data recorded during this session included demographic and medical characteristics, as well as FIM and PP-Test scores by a continence nurse and a physiatrist. Success for learning CISC was recorded at the end of the session. Associations between FIM and PP-Test scores and success for learning CISC were assessed in univariate analysis. Diagnosis performances of FIM and PP-Test were estimated by calculating sensitivity, specificity and area under the receiver operating characteristics curve (AUC of ROC). AUC of these two tests were compared using a two-sided DeLong's test.

RESULTS

A total of 100 patients was included (mean age: 49.8(11.8) years; 68% of women). 44 % of these patients had a relapsing-remitting MS and the median Expanded Disability Status Scale score was 6. The most frequent urodynamic diagnoses were detrusor sphincter-dyssynergia (82%) followed by detrusor overactivity (75%). At the end of the session, 90% of the patients succeed to learn CISC. PP-test and FIM scores were associated with success (Table 1). Optimal cut-off values for FIM and PP-Test scores were estimated, resulting in a sensitivity of 83% and 61% and a specificity of 80% and 90% respectively. AUC of ROC curves for FIM and PP-Test total scores were not significantly different (p=0.73; Figure 1).

INTERPRETATION OF RESULTS

Both FIM and PP-Test were associated with outcome after CISC training in eligible PwMS. FIM and PP-test scores were statistically significantly higher, meaning a better functioning, in the patients who succeed at the end of the CISC training session. Cut-off values of 101 and 12 respectively led to the same diagnosis performance measured by AUC.

CONCLUDING MESSAGE

FIM and PP-Test have the same diagnosis performance for the outcome of CISC training in PwMS. The choice between these tools should be guided by the assessor's preference and the time required to perform them (PP-Test: 5' vs FIM: 45').

FIGURE 1

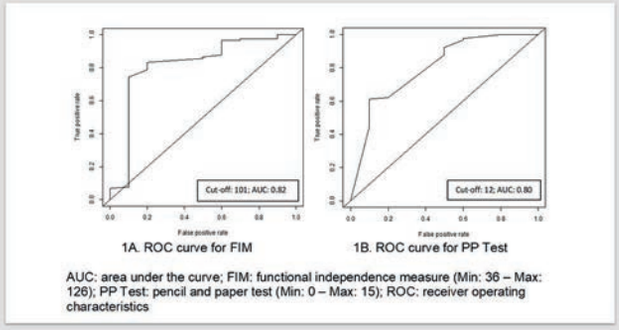

Figure 1. Receiver operating characteristics curves for FIM and PP-Test

FIGURE 2

	Success (N=90)	Failure (N=10)	p
FIM total score	114 (12.7)	98 (37.2)	0.001
Motor subscore	81 (9.7)	67 (29.7)	0.002
Cognition subscore	33 (3)	28.5 (5.7)	0.02
PP-Test total score	13.2 (4)	10 (3.9)	0.001
Prehension subscore	5 (0)	5 (2)	0.005
Perineum access subscore	5 (0)	3.7 (2)	0.003
Cognition subscore	5 (2)	1 (0)	0.0004

All results are expressed as median (IQR); FIM: functional independence measure (Min: 36 – Max: 126); IQR: interquartile range; PP Test: pencil and paper test (Min: 0 – Max: 15)

Table 1. Association between FIM, PP-Test scores and outcome after CISC training in univariate analysis

REFERENCES

1. Haddad R et al. Is disability measured by FIM a predictor for successful self-intermittent catheterization in neurological patients? Ann Phys Rehabil Med. 2016;59:e103-4.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** 1. Non interventional study 2. Retrospective study 4. The data file has been declared to the CNIL (Commission Nationale de l'Informatique et des Libertés) according to French regulations. 5. The written consent of patients for this type of research is not required, they are informed of the possible use of their data and can oppose it. **Helsinki** Yes **Informed Consent** No

SESSION 28 (PODIUM VIDEO) - VIDEO 2: URETHRA AND GENDER RECONSTRUCTION
Abstracts 429-438
15:30 - 17:10, Brasilia 1
Chairs: Prof Ervin Kocjancic (United States), Dr Ann Gormley (United States)

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INFLATABLE PENILE PROSTHESIS REIMPLANTATION FOLLOWING GENDER-AFFIRMING PHALLOPLASTY WITH RADIAL FOREARM FREE FLAP

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INTRODUCTION

Implantation of inflatable penile prosthesis (IPP) in a neophallus is a technically challenging procedure. The level of complexity increases in the revision setting. In this video, we will demonstrate IPP reimplantation in a transgender male status post phalloplasty with radial forearm free flap (RFFF).

DESIGN

Patient was a 34-year-old transgender man who had undergone RFFF phalloplasty in 2016. He underwent 3-piece, dual cylinder IPP implantation in 2018. The entire hardware had to be explanted after 3 weeks secondary to infection. Six months later, another prosthetic surgery was carried out, this time with a single cylinder and 2-piece mechanism.

Perioperative prophylaxis was based on urine culture result and consisted of vancomycin and imipenem. A 16 Fr. urethral catheter was advanced into the bladder over a cystoscopically placed guidewire. An infrapubic skin incision was made. A tunnel was created within the neophallus. This tunnel was serially dilated with Hegar dilators.Attention was given not to injure urethra or vascular pedicle of the neophallus. Measurements of the intra-phallic tunnel and neophallic dimensions were conducted. We elected to proceed with a 2-piece prosthesis (14 cm with 0.5 cm rear-tip extender) and place a single cylinder in order not to cause vascular compromise.

A cadaveric dermal allograft section was sutured in a tubular fashion over one of the cylinders, while the other cylinder was removed. A Keith needle was used to advance the cylinder into the allograft and then through the created space in the neophallus. Rear-tip extender was secured on the pubic bone. Fluoroscence angiography confirmed intact neophallic perfusion. Pump was placed into the most dependent portion of the scrotum.

RESULTS

Early postoperative course was unremarkable, he was discharged on postoperative day 2. After 1 month, a CT scan was conducted due to persistent neophallic pain which demonstrated a 3-cm seroma. He was taken to OR for incision and drainage. Wound cultures were negative. Implant remained intact and in place. Follow-up duration was 3 months at which time he reported penetrative intercourse. No other infection-related problem occurred during this time frame.

CONCLUSION

IPP revision in transgender males following RFFF phalloplasty is a complex procedure. Perioperative administration of culture-specific antibiotics, avoiding urethral and pedicle injury during tunnel dissection, adjusting cylinder number and size according to neophallic dimensions, wrapping the cylinder(s) with tissue substitutes, assessing the vascularity of the neophallus intraoperatively, and addressing postoperative fluid collections aggressively will help to minimize the risk of complications and enhance outcomes.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It is a case-presentation and informed consent has been obtained from the patient. **Helsinki** Yes **Informed Consent** Yes

430 www.ics.org/2020/abstract/430

A CASCADE OF COMPLICATIONS FOLLOWING ROBOTIC-ASSISTED VAGINOPLASTY: MANAGEMENT OF INTER-RELATED SETBACKS

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INTRODUCTION

Robotic-assisted vaginoplasty is a technically complex procedure and complications are not uncommon. Herein, we describe a case whose postoperative course was complicated by bleeding and necessitated additional procedures in order to correct neovaginal tissue loss, and urethral fistula.

DESIGN

A 43-year-old trans female presented due to her interest in gender-affirming genital reconstruction as the last step of her transitioning. Considering the limitations related to the quality of her genital skin, we decided to proceed with combined robotic and perineal approach, whereby peritoneal flaps would be used to augment the inverted penile skin flap and scrotal skin graft.

RESULTS

The procedure took 8 hours with an estimated blood loss of 250ml. Early postoperative course was unremarkable. She was discharged on postoperative day (POD) #6 after removing the Foley catheter and vaginal packing on POD #5. She did well until POD #13 at which time a sudden-onset profuse neovaginal bleeding occurred while she was resting at home. She was transferred to ER and was found to have an arterial bleeding originating from one of the distal branches of internal iliac artery. She received blood transfusions and underwent angiographic embolization by the Interventional Radiology team. Then, we did an examination under anesthesia (EUA) and confirmed the absence of ongoing bleeding. It was noted that the posterior lining of the distal neovagina was detached off the underlying surface due to the dissecting effect of pelvic hematoma. During this session, cavity was washed out, clots were partially evacuated and neovagina was packed. Two days later, EUA was repeated, the peeled-off, nonvital tissue lining the posterior neovagina was excised, skin edges were trimmed and the resultant defect was grafted with DermaPure (cadaveric dermal allograft). EUA and neovaginal packing exchanges were repeated several times in order to confirm proper graft take, monitor for recurrent bleeding, preserve neovaginal dimensions, and address additional wound-related problems. At the last EUA, that took place on POD #28, graft was in good apposition and integration with the underlying wall. However, a fistulous communication came to attention between the urethral lumen and neovaginal canal. The defect was ventral and located distal to the verumontanum, measuring 1 cm in diameter. Foley catheter was renewed and the cavity was left unpacked. 3 weeks after this EUA (POD #49), urethral fistula was repaired primarily in a multi-layered fashion. Procedure was performed with the patient in prone position for a better exposure and digital endoscopic guidance was utilized in order to ensure precise suturing, and confirm complete closure. The Foley catheter was removed in 3 weeks and then neovaginal self-dilation protocol was initiated. At 3 months follow-up, she was emptying her bladder completely and did not report any voiding difficulties. She was not complaining of urinary leakage and there was no sign of recurrent fistula on physical examination.

CONCLUSION

Many things can go wrong during and/or after robotic-assisted gender-affirming vaginoplasty. As depicted in this case, one major complication may lead the way to the devel-

opment of others. Involvement of related disciplines, staged approach to definitive repair, applying technical modifications, and utilizing technological advancements in a timely and rational way play a vital role for the effective management of these individually "difficult-to-treat" but essentially inter-related setbacks.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This is a case report. Informed consent was obtained from the patient. **Helsinki** Yes **Informed Consent** Yes

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URETHRAL RECONSTRUCTION IN MASCULINIZING GENITAL GENDER-AFFIRMING SURGERY WITH METOIDIOPLASTY

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INTRODUCTION

Metoidioplasty involves the creation of a neophallus out of a hormonally hypertrophied clitoris. The primary goal of metoidioplasty is allowing the patient to void while standing. In this video, we will demonstrate our metoidioplasty technique with particular emphasis on the surgical steps related to urethral reconstruction.

DESIGN

The patient was a 27-year-old transgender man. He was not interested in penetrative sexual intercourse and his primary aim was to stand to void. He wanted to avoid a complicated and multi-staged reconstruction which is typical of flap-based phalloplasty. Therefore, we elected to proceed with metoidioplasty. A suprapubic tube was inserted at the start of the case. The clitoris was released and lengthened by the division of its fundiform and suspensory ligaments. The urethral plate was dissected off the ventral aspect of the clitoral corpora and then divided in order to further release and lengthen the clitoris. A flap was harvested from the anterior vaginal wall to lengthen the native urethra. Remaining vaginal mucosa was treated with electrocautery, and colpocleisis was performed using spiral sutures. The vaginal wall flap was sutured to the proximal part of the divided urethral plate. The dorsal aspect of the distal neourethra was constructed by the dorsal inlay and quilting of the buccal mucosa graft (BMG) over the clitoral corpora. The medial epithelial surface of the labia minora flap (LMF) was joined to the BMG by two lateral running sutures over an 18 Fr. catheter to create the ventral aspect of the distal neourethra. The other LMF was then sutured over the proximal portion of the neourethra to create another layer of coverage. Care was taken to place extraluminal stitches during all phases of urethral reconstruction. Glansplasty, perineoplasty, and scrotoplasty concluded the procedure. Implantation of testicular prostheses was planned as a separate procedure.

RESULTS

The operation lasted 375 minutes and the estimated blood loss amount was 400 ml. The patient was discharged on postoperative day 5 after an unremarkable course. The urethral catheter was removed in 3 weeks after documenting urethral patency on retrograde urethrography. Suprapubic tube was removed after an additional 4 weeks, during which the patient voided through his neourethra without issue. Follow-up duration was 6 months and no complications were reported during this time period. He was able to void while standing and did not report any urinary issues at the last follow-up.

CONCLUSION

Metoidioplasty denotes neophallic reconstruction in the transgender men from the hormonally hypertrophied clitoris with the goal of voiding in standing position. Lengthening the native urethra in a longitudinal fashion with the use of an anterior vaginal wall flap and neourethral tubularization using a combination of BMG and LMF represent a potentially applicable way to achieve this goal.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This is a case presentation and informed consent has been obtained from the patient. **Helsinki** Yes **Informed Consent** Yes

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FOUR NEOVAGINA TECHNIQUES IN THE ANATOMICAL MODEL

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INTRODUCTION

Surgery for neovaginas in patients with vaginal agenesis is rare. The most commonly cited prevalence for vaginal agenesis in Rokitansky Sindrome is 1 in 5000 (range 1 per 4000 to 10,000 females) [1]. The incidence of androgen insensitivity syndrome in females is 1:20,000. In addition, recently with the increase in sex change surgery there is more interest in neovaginas surgery . Surgery is an option for women who have been unsuccessful with dilators or who prefer surgery after a thorough discussion of the advantages and disad-

vantages of the different techniques. In addition there are described in the literature different techniques of vaginal and laparoscopic approaches (Modified Mc Indoe, Vechietti, Davidov and vulvoperineal pediculated Flaps, …..) , all of them effective and without superiority of any of them. This relatively infrequent surgery should be performed in a few specialized centers, but the reality is that it is not regulated. Therefore, acquiring experience in this type of surgery is a challenge. Therefore, especially when dealing with rare numbers of operations of a special type, we must choose a technique that is simple, safe, and effective (2). Furthermore, rapid surgical innovation in minimally invasive procedures, devices, and surgical techniques have complicated the learning landscape. Fortunately, surgical simulation has evolved to fill the educational void. Whether it is through skill generalization or skill transfer, surgical simulation has shifted learning from the operating room back to the classroom. Educational simulation programs were necessary to improve specialist knowledge and skill and to facilitate competence in this kind of surgery. After carrying out a bibliographic search, we have not found publications on models to train these surgical techniques before performing them on patients. The aims of this abstract is to show the usefulness of Thiel-embalmed cadaver models for training the surgical steps for four different surgical tecniques of Neovagina to treat the vaginal agenesis.

DESIGN

The procedures was performed on Thiel-embalmed cadavers, which allowed the vaginal approach and abdominal cavity pneumoinsufflation and more exact reproduction of the surgical technique, by both vaginal and laparoscopic approaches, in the dissection room at the School of Medicine of our school of Medicine. Previously we made a "feminization" of male cadavers. To do this, the penis was removed together with the testicles and the lips reconstructed with the skin of the penis and scrotum. The space between the base of the scrotum and the anus was exposed to perform the "neovaginas". Four surgical tecniques of Neovaginas were done: vulvoperineal pediculated Flap, Modified Mc Indoe using Paciena prosthesis, Vechietti and Davidov . Both external camera and laparoscopic vision were used during the execution of these procedures at the dissection room in "feminized" male cadavers.

To measure the usefulness of this teaching model, we designed a course with specialists in this tecniques to train the surgical steps of the differents surgical procedures. We performed recordings of four surgical procedures to performe neovaginas (Modified Mc Indoe, Vechietti, Davidov and vulvoperineal pediculated Flaps) with an external camera for vaginal procedures and laparoscopic vision during the execution of laparoscopic procedure, allowing the visualization of anatomical elements. Afterward, a final video (video 1) was made showing the four surgical tecniques for neovaginas. Finally, we explored the opinions of our students and professors in relation to their experiences with this surgical training models.

RESULTS

All the tecniques could be done and recorded without problems. Most participants agreed that this anatomical model was useful for learning these surgical techniques because they had learned details of the surgical anatomy of these procedures .

CONCLUSION

The training in the anatomical model is useful to learn different surgical techniques of Neovaginas.

REFERENCES

1. Herlin M, Bjørn AM, Rasmussen M, et al. Prevalence and patient characteristics of Mayer-Rokitansky-Küster-Hauser syndrome: a nationwide registry-based study. Hum Reprod 2016; 31:2384
2. Wenzl R. Creation of a neovagina: what should our focus be when choosing the "right" operative technique? Fertil Steril. 2017;108(2):242.

Funding Non applicable **Clinical Trial** No **Subjects** None

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DORSAL ONLAY BUCCAL MUCOSAL GRAFT FEMALE URETHROPLASTY: ANATOMICAL PRINCIPLES FOR CONTINENCE

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INTRODUCTION

Female urethral stricture (FUS) accounts for 4-13% of all cases of bladder outlet obstruction in women. Urethral dilation typically has a low success rate whereas dorsal onlay urethroplasty with buccal mucosal graft (BMG) often succeeds in 86-94%, with no reported cases of de novo stress incontinence. However, anatomical-based surgical principles are still lacking to make this technique more widespread amongst urologists. Our aim is to show a detailed anatomically based video of a step by step technique so that it may be widely reproduced.

DESIGN

A 53-year-old woman who underwent hysterectomy in 2006 was unable to be catheterized intraoperatively. Several urethral dilations were subsequently performed between 2007 and 2010 because of recurrent straining to void and severe

voiding symptoms. Eventually, placement of a suprapubic catheter (SPC) was required. Imaging demonstrated bilateral hydronephrosis with a thickened detrusor while a distal-and-mid FUS and a bladder diverticulum were found on antegrade cystoscopy and cystourethrogram.

RESULTS

As shown in the video, the meatus was healthy. A dorsal inverted U-shaped incision was performed between the clitoris and the meatus. Perineal membrane and deeper layers were dissected with scissors and scalpel. Dorsal urethrotomy was performed at 12'-o-clock until a 30 Fr bougie-a-boule was able to pass easily. The stricture was 4 cm long. A unilateral BMG was harvested in the standard fashion. The graft was sutured with 3 interrupted 5-0 PDS at the proximal apex of the urethrotomy. Afterwards, 5-0 PDS running sutures were placed on each side, including lateral urethropelvic ligament. The graft was also quilted with interrupted sutures dorsally. The U-shaped incision was then closed with interrupted 4-0 polyglactin. A 16 Fr urethral catheter was placed for 14 days. Blood loss was <100 ml. Complete stress continence was preserved. Follow-up at 10 and 21 months after surgery showed uroflowmetry with Qmax of 26 and 19 ml/sec respectively and she only referred nocturnal urge-incontinence responding to oxibutinin BID. Figures show multiple lateral and ventral supporting structures which are always spared in this technique.

CONCLUSION

The dorsal approach with buccal mucosa to female urethroplasty can be successful and it simultaneously preserves continence likely due to preservation of the ventrolateral urethral support, as per the "hammock principle".

REFERENCES

1. Gomez RG, Segura FJ, Saavedra A, Campos R. Female urethral reconstruction: dorsal buccal mucosa graft onlay. World J Urol. 2019. DOI: 10.1007/s00345-019-02958-6

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité Ético Cientifico del SSMSO **Helsinki** Yes **Informed Consent** Yes

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FEMALE EPISPADIAS REPAIR USING BUCCAL MUCOSAL GRAFT (BMG) URETHROPLASTY: HOW WE DID IT

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INTRODUCTION

Isolated Female epispadias, without the presence of bladder exstrophy, is a very rare congenital anomaly that affects 1 in 484,000 females. In this video, we aim to describe the steps for BMG repair for a patient with female epispadias. We believe this is the first time this has been performed for this rare condition.

DESIGN

A 15-year-old female, with normal developmental milestones, had a long-standing history of urinary incontinence requiring the use of 12 pads/day (1.1 kg 24-hour pad weight). The patient had a significant history of VACTERL associations, including anorectal malformation, which was previously corrected via a 3-stage posterior sagittal anorectoplasty. She had recurrent urinary tract infections, but otherwise had normal renal function. The patient had not received prior surgery to correct the primary anatomical problem, as her parents were not keen.

Urethrocystoscopy showed a deficient anterior urethra from 11-2 o'clock with a wide open bladder neck despite multiple previous periurethral and bladder neck deflux injections. The patient underwent a single stage BMG urethroplasty. The surgery was performed through a supraurethral incision from 9-2 o'clock followed by hydro-dissection with 20ml of 0.5% bupivacaine and adrenaline. The urethra was then mobilised to the bladder neck. This was followed by urethrotomy and deepithelialisation of the deficient urethra. An inlay urethroplasty was then performed using a 2x1 cm BMG with absorbable sutures over a 18Fr catheter. The BMG was quilted to the corpora bodies anteriorly to aid imbibition and inosculation. Continence was demonstrated at the end of surgery using Crede's manoeuvre.

RESULTS

The patient's catheter was kept for a total of 3 weeks. She was able to void after removal of the catheter, with good uroflowmetry results of Qmax 18.4ml/sec, voided volume of 179ml and minimal residual urine. At 6 weeks followup, she reported much improved continence, needing only 4 pads per day. The patient had also started participating in physical sports, something that she was never able to do before.

CONCLUSION

Our attempt to alleviate incontinence in this patient with primary epidpadias is moderately successful. Further follow-up is needed to determine long term results.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** it is not required by my institution for a single case report. The study team have obtained expressed consent from the patient & her parent for this video publication. **Helsinki** Yes **Informed Consent** Yes

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DELAYED PRESENTATION OF MONS PUBIS ABSCESS FORMATION FOLLOWING MUS – CASE REPORT AND SURGICAL VIDEO

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INTRODUCTION

Midurethral slings (MUS) are considered the mainstay treatment for stress urinary incontinence (SUI), due to high efficacy with relatively low intra and/or postoperative complication rates.

A recent large cohort study found that the overall rate of sling removal was 3.3% at 9 years(1). The risk of removal was high in those who had retropubic slings. Long term complications, such as sling exposure, erosion are relatively low. However, rare cases of bladder, thigh, prepubic and pelvic abscess, were described.

We present an unusual case of MUS mesh exposure followed by mons pubis abscess formation occurring 18 years post-op.

The aim of our presentation is to:

1. Be aware of these rare long-term complications of MUS, as well as the unusual clinical presentation.

2. Describe the clinical and surgical approach for removal of sling which was inadvertently inserted superficially to the pubic bone.

DESIGN

A 75-year-old woman, presented with a gradual swelling of her mons-pubis followed by pain, and ongoing PV bleeding, with a history of MUS. Physical examination revealed a palpable, not fluctuant mass, tender to touch, extending about 10-15cm from the mons pubis to the right labia. There was a 2X2cm mesh exposure in the vagina. Ultra-sound scan described a pre-pubic arm of the TVT on the right side (Figure 1). We assumed that at the insertion of the sling the trocar diverted from the intended retropubic path to the prepubic route.

A vaginal approach was undertaken: Physical examination has revealed area of 2X2cm exposed mesh at the mid-urethral area. A 15X4cm mass was palpated on the mons pubis, extending to the right labia.

Area of the vaginal mesh dissected inwards and upwards on its route toward the pubic arch. This could only be reached a depth of 4cm. Therefore, an incision of 5cm created over the labia to reach the superficial edge of the capsule. Further dissection defined the superior border of the capsule and the top edge of the sling. The cavity of the capsule entered and pus was drained. The loose sling was identified and it snapped at its midway to the vagina just on the symphysis bone. The vaginal end of the sling was clamped and pulled downwards, allowing to identify its end which was adherent to the front end of the pubic symphysis. A sharp and blunt dissection resulted in a complete loosening of the inferior part of the right arm of the sling. The dead space was closed in several layers. The skin was closed as well and a labial draining tube was left. The exposed infected mesh at the mid-urethral site was dissected off and the underlying tissue was closed in layers. A repeated cystoscopy was done at the conclusion of the surgery and an indwelling-catheter and vaginal pack were inserted. The removed sling is seen in Figure 2.

RESULTS

Postoperatively: the surgical site was found with minimal swelling, minimal pain.

IDC and pack removed the following day and the patient had a successful trial-of-void and no further PV loss.

The patient was covered with intravenous antibiotics for 2 days followed by 7 days of oral antibiotics.

6 weeks post-operatively: Surgical sites healed well, no SUI, and no mesh exposure.

CONCLUSION

1. Although relatively rare, long term complications of MUS should be considered and recognized.

2. A thorough medical history, physical examination, and imaging are crucial for planning strategy treatment.

3. Vaginal approach for mesh removal is a safe method and should be practised in tertiary hospitals by experienced surgeons.

4. Patients should be informed on the possibility of being incontinent after sling removal.

FIGURE 1

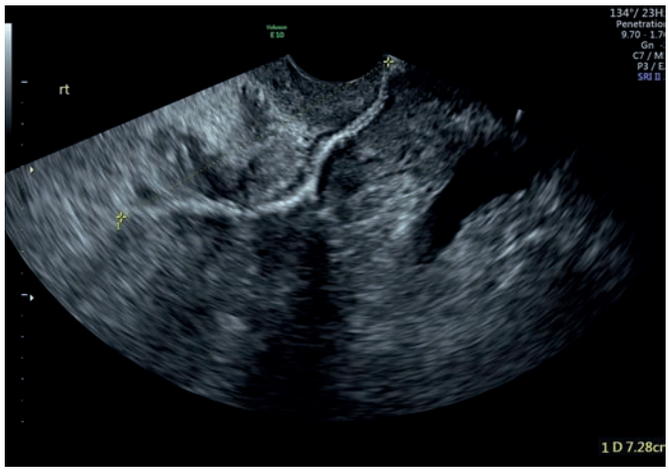
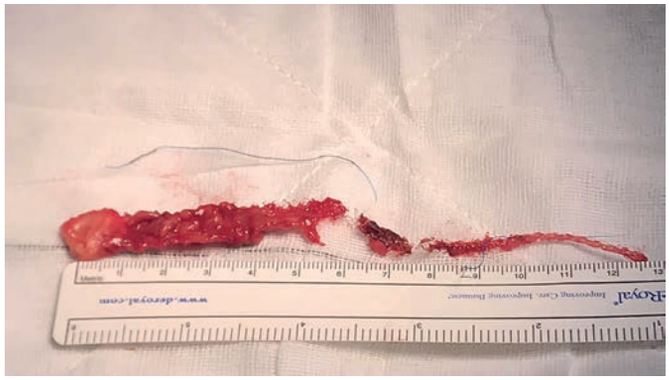


FIGURE 2



REFERENCES

1. JAMA. 2018;320(16):1659–1669. doi:10.1001/jama.2018.14997

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** No need, Patient consented **Helsinki** Yes **Informed Consent** Yes

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ROBOTIC ASSISTED DORSAL URETHRAL DIVERTICULECTOMY

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INTRODUCTION

Urethral diverticulum is rare, affecting <0.02% of women. When ventrally located, it is accessible via the anterior vaginal wall. Dorsal, proximal, circumferential, or horseshoe female urethra diverticula present more challenging dissection. In the case presented, the urethral diverticulum was dorsal and proximal. Rather than standard vaginal options including transection of the urethra, suprameatal incision, and the open retropubic "above and below" approach, a robotic assisted retropubic approach allowed the best access.

DESIGN

A 38 yo female presented with fever and a 6 month history of LUTS, post void dribbling, and recurrent UTIs. CT scan then MRI revealed a 2.5 x 1.6 cm crescenteric left dorsal urethral diverticulum at the proximal urethra with stone formation, cephalad to the pubic bone, with an elevated bladder neck. Urodynamics demonstrated bladder outlet obstruction. The patient was formally consented for the robotic approach including consent for video. Incisions were made lateral to the medial umbilical ligaments and the bladder was dropped from the anterior abdominal wall. The space of Retzius was developed. A combination of sharp and blunt dissection were used to mobilize the diverticulum circumferentially. Digital vaginal manipulation and movement of the foley balloon further defined the planes. The os was encountered in the left ventral aspect of the urethra as was consistent with cystoscopy. The urethra was repaired using a running 3-0 Vicryl suture. The suture line was watertight on testing with methylene blue. A SPTube was placed using laparoscopic guidance. The omentum was secured to the pubic peri-ostium and anterior bladder neck.

RESULTS

Operative time was 3:27 h and estimated blood loss 50 cc. Surgical finding includes a left lateral ventral ostium with the diverticulum wrapping dorsally, proximal to the pelvic diaphragm and endopelvic fascia. Post-op voiding cystourethrogram showed good healing without extravasation. The patient is currently dry with complete resolution of symptoms.

CONCLUSION

Robotic approach to urethral diverticulectomy is feasible for proximal dorsal diverticuli cephalad to the pubic symphysis. This method could be considered as an adjunct for other complex urethral diverticuli with a proximal dorsal component.

Funding None **Clinical Trial** No **Subjects** None

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IMPROVED EARLY CONTINENCE FOLLOWING ROBOTIC-ASSISTED RADICAL PROSTATECTOMY WITH A CONCURRENT RETROPUBIC VASCULARISED FASCIA SLING (ROBOSLING)

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INTRODUCTION

Urinary incontinence remains a major concern for patients when undergoing a radical prostatectomy. Although long-term continence rates exceed 90%, early continence rates are much lower, ranging between 28% to 74% at 3 months. We describe a novel technique to improve urinary function by using an autologous vascularized fascial sling (RoboSling) placed underneath the urethrovesical anastomosis at the time of robot-assisted radical prostatectomy (RARP).

DESIGN

We provide a step-by-step description of our RoboSling technique. Also included are the results of a prospective, non-randomised cohort study comparing continence rates between patients who underwent a standard RARP and those who in addition to RARP had a RoboSling procedure performed concurrently. In our hospital, between December 2016 and October 2019, 176 patients underwent RARP done by 5 different surgeons. The RoboSling procedures were performed by one surgeon. We compared pad usage and continence rates using the EPIC-urinary domain questionnaire, as well as clinical and oncological outcomes in 146 patients without a RoboSling and 30 with a RoboSling.

RESULTS

One hundred and seventeen patients (response rate 80%) filled in their 3 months postoperative questionnaires. Baseline characteristics did not differ between the two groups (see table). At three months, zero pad usage (p=0,010) was significantly higher in the RoboSling group. At 3 months, zero pad usage and continence rates remained higher in the RoboSling group. Zero pad use was 47% with and 17% without a RoboSling. Length of stay and complication rate did not differ between the two groups. Blood loss was significantly lower in the RoboSling group (P=0.015).

CONCLUSION

Patients undergoing a RoboSling procedure at the time of robotic radical prostatectomy experienced an earlier return to continence compared to the control arm without a higher complication or positive surgical margin rate. A randomized controlled trial with multiple surgeons performing the RoboSling procedure is now underway to further assess the merits of this novel technique.

FIGURE 1

	N=146	No Robosling	N=30	Robosling	p-value
Age (year)	135	64.1 (7.2)	29	61.4 (9.1)	0.072
LOS (days)	128	2.9 (4.0)	29	2.1 (1.7)	0.281
BMI	133	27 (4.4)	27	27 (5.6)	0.453
PSA (ng/ml)	118	7.5 (3.9)	28	11 (10.1)	0.061
Gleason score					
≤ 6	11	11 (7.7%)	4	4 (13.8%)	0.574
7	99	99 (69.7%)	19	19 (65.5%)	
≥ 8	32	32 (22.5%)	6	6 (20.7%)	
EPE (%)	66	66 (45.2%)	10	10 (35%)	0.313
Seminal Vesicle invasion (%)	72	6 (8.3%)	21	5 (23.8%)	0.053
Positive surgical margins (%)	42	42 (29%)	6	6 (21%)	0.496
Length of stay (days)	128	2.9 (4.1)	29	2.1 (1.7)	0.281
Blood loss (ml)	84	393 (31)	23	237 (39)	0.015
Complication rate (%)	146	6	30	2	0.627
Pad Use at 3 Months					
NONE	19	19 (17%)	8	8 (47%)	0.010
≥ 1	91	91 (83%)	9	9 (53%)	
Pad Use at 1 Year					
NONE	39	39 (52%)	8	8 (73%)	0.331
≥ 1	36	36 (48%)	3	3 (27%)	

Funding No funding **Clinical Trial** Yes **Registration Number** Australian **Clinical Trial**s, ACTRN12618002058257 **RCT** Yes **Subjects** Human **Ethics Committee** Sydney Local Health District Ethics **Helsinki** Yes **Informed Consent** Yes

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RARE CASE OF URETHRAL LEIOMYOMA

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INTRODUCTION

Leiomyomas are benign tumors of smooth muscle cells, and occur frequently in the uterus. Extrauterine leiomyomas are unusual, and even more rare in the female urethra. The differential diagnosis includes leiomyosarcomas. Computer Tomography (CT), Magnetic Resonance Imaging (MRI), 2D and 4D perineal ultrasound as well as 3D vaginal ultrasound are the imaging techniques used to aid diagnosis. Out of the given modalities, the ultrasound was perceived the most accurate in diagnosis and mapping of possible invasion of tumor into the urethral tissue. This video film shows the excision of the leiomyoma from urethra and preoperative diagnosis and postoperative followup with 2D perineal and 3D vaginal ultrasound.

DESIGN
Case report: A 48 year old healthy primipara presented with a six week history with a protruding tumor from the vaginal introitus, she had dysuria and incomplete voiding but no hematuria or pain. CT showed a 50X65 mm tumor compressing the urethra, and recommended MRI. The patient failed to come to MRI control for a year. MRI after a year showed a growth of tumor to 70x60 mm. From the cranial edge of the tumor a 20mm long triangular offshoot was seen hence, an ingrowth to the urethra could not be excluded. The radiologist recommended ultrasonography. 2D perineal ultrasond showed that the tumor deviated away from the urethra cranially and respected the urethral wall integrity. Color doppler imaging showed rich vascularity; multiple ultrasound guided biopsies showed leiomyoma cells however, due to the size of the tumor malignancy could not be excluded. Cystourethroscopy showed no invasion in the urethral lumen. The tumor was completely removed vaginally without inflicting further damage to the urethra. Peroperative urethroscopy showed an intact urethral wall. Postoperatively an indwelling caterer was kept for 14 days and the patient was able to void without any difficulties.

RESULTS
Histopathological examination showed a well circumscribed mass measuring 70x50x60 mm. Microscopically it showed interlacing fibers of smooth muscle cells, no increased mitosis was seen. Follow up with physical examination and 2D perineal and 3D vaginal ultrasound showed no recurrence of the tumor. The patient had no urinary incontinence or bladder emptying problems.

CONCLUSION
Urethral leiomyomas are difficult to diagnos and MRI can be helpful. However, 2D perineal ultrasound as well as 3D vaginal ultrasound are superior in comparison to MRI and CT imaging techniques in diagnosis of urethral leiomyomas. Complete surgical removal is recommended.

Funding Nothing to declare **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It was a clinical case at the hospital **Helsinki** Yes **Informed Consent** Yes

SATURDAY 21ST NOVEMBER

SESSION 29 (PODIUM SHORT ORAL) - OAB: MEDICATION AND SENSATION
Abstracts 439-450
09:00 - 10:30, Pavilion 9
Chair: Prof Christopher R Chapple (United Kingdom)

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COMPARISON OF URGENCY PATIENTS WITH AND WITHOUT URGENCY INCONTINENCE - RESULTS FROM THE LURN STUDY

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HYPOTHESIS / AIMS OF STUDY
Many overactive bladder (OAB) trials require that participants have at least a minimum number of urgency urinary incontinence (UUI) episodes to qualify for inclusion. Even though many patients complain of urgency with no or minimal UUI, few studies have fully characterized patients, particularly over time, with urinary urgency without significant UUI. This study compared men and women with urinary urgency with and without UUI with respect to urologic pain symptoms, pelvic floor symptoms, bowel function, mental health, sleep quality and physical function.

STUDY DESIGN, MATERIALS AND METHODS
Adult women and men seeking treatment for their lower urinary tract symptoms (LUTS) were recruited into the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) one year observational cohort study from six US tertiary care centers. Participant characteristics and clinical data were collected at study enrollment. The following patient-reported measures were completed at baseline, 3-month, and 12-month visits: the LUTS Tool, the Functional Comorbidity Index (FCI), Genitourinary Pain Index (GUPI), the Pelvic-Floor Distress Inventory (PFDI-20, for females only), the Perceived Stress Scale (PSS), the International Physical Activity Questionnaire (I-PAQ) and Patient Reported Outcomes Measurement Information System (PROMIS) Gastrointestinal (GI) bowel incontinence, GI constipation, GI diarrhea, depression, anxiety, sleep disturbance, and physical function (mobility) measures. Responses to LUTS Tool severity items were used to identify participant symptoms, with a response of "sometimes", "often", or "almost always" indicating symptom endorsement for frequency, nocturia, urgency, and urinary incontinence. Participants endorsing symptoms of urgency along with frequency and/or nocturia on the LUTS Tool were included in analysis. The UUI question on LUTS Tool was used to further characterize urgency participants into those with vs. without UUI. Clinical, demographic, and patient-re-

ported data were compared between urgency participants with vs. without UUI using two-sample independent t-tests and chi-square tests or non-parametric alternatives where appropriate. Repeated measures linear regression models were fit with the following measures as dependent variables: GUPI pain subscale, GUPI urinary symptom subscale, GUPI QOL subscale, PROMIS Depression T-score, PROMIS Anxiety T-score, PSS total score, and PFDI-20 total score (females only). In each model, urgency with vs. without UUI was included as a dependent variable along with the following covariates: age, sex, race, employment status, education, diabetes (yes vs. no), FCI total, and visit.

RESULTS

At study enrollment, there were 612 participants fulfilling the urgency criteria based on LUTS Tool responses (201 urgency without UUI [33%] and 411 urgency with UUI [67%]). Among the 612 urgency participants at enrollment, the average age was 59.8±13.7 years and most participants were females (57%) and white (79%, Table 1). Urgency participants with UUI were more likely to be female (70% vs. 31%, p-value < .001), and had significantly higher average GUPI total (17.6 vs. 15.4, p-value = 0.005), GUPI QOL subscale (7.9 vs. 6.5, p-value < 0.001), PFDI-20 total (95.3 vs. 70.8, p-value < 0.001), PROMIS GI Bowel incontinence (5.7 vs. 4.8, p-value < 0.001), and PSS total (13.6 vs. 11.8, p-value = 0.006) scores. Urgency participants with UUI also scored an average of 1.4-3.0 points higher on PROMIS GI Constipation (p-value = 0.006), diarrhea (p-value = 0.009), depression (p-value < 0.001), anxiety (p-value < 0.001), and sleep disturbance (p-value = 0.038) measures and 3.8 points higher on the physical function, mobility measure (p-value <0.001). While statistically significant differences on the PROMIS measures were seen, average scores were close to the population average of 50 and differences between urgency groups were smaller than 4-5 points, or half a standard deviation. After controlling for age, sex, race, employment, education, diabetes, FCI total, and visit, urgency participants with UUI (compared to without UUI) had significantly worse condition-specific QOL (GUPI QOL subscale adjusted mean estimate 1.27 points higher, 95% CI = [0.85-1.69]), and higher PROMIS Depression (mean adjusted estimate 3.16 points higher, 95% CI = [2.02-4.30]), PROMIS Anxiety (mean adjusted estimate 2.73 points higher, 95% CI = [1.55-3.93]), PSS total (mean adjusted estimate 2.02 points higher, 95% CI = [1.05-2.99]), and PFDI-20 total (mean adjusted estimate 29.96 points higher, 95% CI = [19.22-40.69]) scores.

INTERPRETATION OF RESULTS

Urgency patients with UUI were more likely to be female compared to those without UUI. This notable difference in demographics could be an indication that significant sex specific differences in etiologies for urgency exist resulting in increased rates of the UUI phenotype in female patients. Further investigation into potential concomitant obstructive or other conditions in these patients is warranted.

In both men and women, urgency patients with UUI had more pelvic floor dysfunction, more psychosocial issues (depression, anxiety, perceived stress) and worse QOL compared to urgency patients without UUI. The decreased patient QOL and higher scores for depression, anxiety, and stress is likely a function of the increased psychosocial burden that having UUI contributes to the patient rather than it being an intrinsic part of the UUI. Further study is necessary to determine the relationship between these phenotype defining symptoms and the etiology for their symptoms.

CONCLUDING MESSAGE

We have characterized a large cohort of women and men with urgency with vs. without UUI. Significant differences were identified in pelvic floor symptoms, bowel function, mental health, sleep quality and physical function. Further detailed studies of these co-morbidities are required to both elucidate the mechanisms underlying these urinary symptoms and improve treatment outcomes.

FIGURE 1

Variable	Total (n=612)	Urgency without UUI (n=201)	Urgency with UUI (n=411)	p-value
Age	59.8 (13.7)	59.9 (14.2)	59.8 (13.5)	0.733
Sex (% male)	263 (43%)	139 (69%)	124 (30%)	<.001
Race				0.187
Black or African American	82 (13%)	19 (9%)	63 (15%)	
White	484 (79%)	163 (81%)	321 (78%)	
Other/multi-racial	44 (7%)	19 (9%)	25 (6%)	
BMI	30.7 (6.9)	29.1 (5.3)	31.4 (7.5)	0.003
Diabetes	106 (17%)	24 (12%)	82 (20%)	0.020
Functional Comorbidity Index (FCI) total	2.6 (2.1)	2.3 (2)	2.7 (2.2)	0.052
GUPI total score	16.8 (7.9)	15.4 (7.6)	17.6 (8)	0.005
GUPI pain subscale	4.6 (5.0)	4.3 (4.7)	4.9 (5.1)	0.260
GUPI urinary symptom subscale	4.8 (2.5)	4.6 (2.3)	4.9 (2.6)	0.387
GUPI QOL subscale	7.4 (2.8)	6.5 (2.8)	7.9 (2.7)	<.001
PFDI-20 (females only)	90.9 (53.8)	70.8 (53)	95.3 (53.1)	<.001
PROMIS GI Bowel incontinence (raw score)	5.4 (2.6)	4.8 (2.1)	5.7 (2.8)	<.001
PROMIS GI Constipation (T-score)	51.3 (8.6)	49.7 (8.1)	52 (8.7)	0.006
PROMIS GI Diarrhea (T-score)	49.5 (9.3)	48.1 (8.7)	50.2 (9.5)	0.009
PROMIS Depression (T-score)	49.8 (9)	47.8 (8.4)	50.8 (9.1)	<.001
PROMIS Anxiety (T-score)	50.3 (9.5)	48.2 (8.9)	51.3 (9.7)	<.001
PROMIS Sleep disturbance (T-score)	53.7 (8.7)	52.8 (8.8)	54.2 (8.6)	0.038
PSS	13 (7.6)	11.8 (7.4)	13.6 (7.6)	0.006
PROMIS physical function, mobility (T-score)	46.9 (10)	49.5 (9.2)	45.7 (10.1)	<.001
IPAQ categories				0.009
Low activity	322 (54%)	90 (45%)	232 (59%)	
Moderate activity	79 (13%)	31 (16%)	48 (12%)	
High activity	192 (32%)	77 (39%)	115 (29%)	

Table 1. Demographics, clinical characteristics, and patient-reported measures at baseline

FIGURE 2

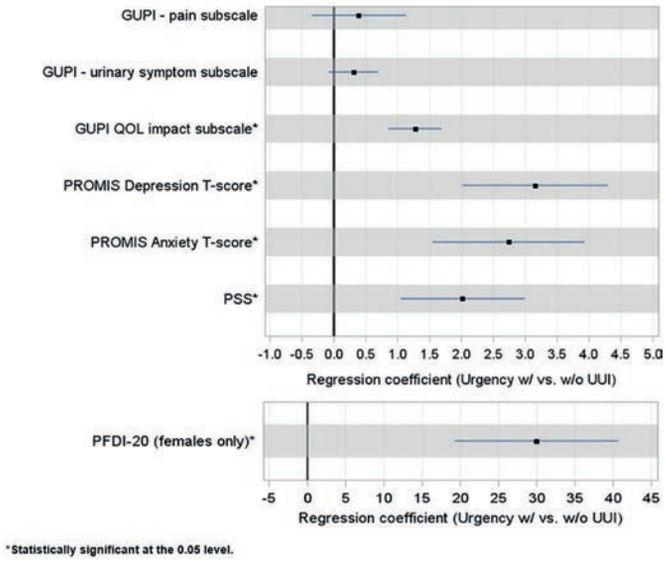

Figure 1. Forest plot of mixed regression coefficients comparing Urgency with vs. without UUI participants for self-reported measures.

Funding Disclosure: NIH/NIDDK grant numbers U01DK099879, U01DK097780, U01DK097772, U01DK097779, U01DK099932, U01DK100011, U01DK100017 **Clinical Trial** No **Subjects** Human **Ethics Committee** E&I Review **Helsinki** Yes **Informed Consent** Yes

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ONCE-DAILY VIBEGRON 75 MG IMPROVES QUALITY-OF-LIFE AND INCONTINENCE EFFICACY ENDPOINTS IN PATIENTS WITH OVERACTIVE BLADDER: DOUBLE-BLIND 52-WEEK RESULTS FROM AN EXTENSION STUDY OF THE EMPOWUR INTERNATIONAL PHASE 3 TRIAL

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HYPOTHESIS / AIMS OF STUDY

Vibegron is a novel, oral, once-daily β3-adrenergic receptor agonist being investigated for overactive bladder (OAB) treatment. In the phase 3 randomized, double-blind, 12-week EMPOWUR trial (N=1518), vibegron 75 mg statistically significantly improved co-primary OAB endpoints of change from baseline at week 12 in average number of daily micturitions and urgency urinary incontinence (UUI) episodes ($p<0.001$ for each) and key secondary endpoints vs placebo; tolterodine extended-release 4 mg was active control. Treatment was well-tolerated, with a favorable safety profile.

Presented here are results from the 40-week EMPOWUR extension study for change from EMPOWUR baseline to week 52 for quality-of-life (QOL) endpoints as measured by the Overactive Bladder Questionnaire Long Form (OAB-q LF) and for responder efficacy endpoints of ≥75% and 100% reduction from EMPOWUR baseline in UUI episodes and ≥50% reduction from baseline to week 52 in total incontinence episodes.

STUDY DESIGN, MATERIALS AND METHODS

The EMPOWUR trial enrolled adults aged ≥18 years who had OAB wet (with incontinence) or OAB dry. The planned enrollment for the extension was approximately 500 men and women who had completed the EMPOWUR trial. Those patients who received vibegron or tolterodine in the EMPOWUR trial continued that treatment in the extension. EMPOWUR patients who received placebo were randomized 1:1 to vibegron or tolterodine; the randomization was stratified by OAB type and sex. The primary objective of the extension was to evaluate vibegron safety and tolerability for up to 52 weeks. Safety assessments were summarized for all patients enrolled in the extension study using descriptive statistics. Secondary efficacy endpoints at week 52 were change from baseline for number of daily micturitions and UUI, urgency, and total incontinence episodes (not presented here). Of 23 exploratory efficacy endpoints, the following nine are presented here: change from baseline at week 52 for all OAB-q LF endpoints (Coping, Health-Related Quality of Life [HRQL], Symptom Bother, Concern, Sleep, and Social Interaction scores) and percentages of OAB wet patients at week 52 with ≥75% and 100% reduction from baseline in UUI episodes and ≥50% reduction in total incontinence episodes.

Quality-of-life efficacy endpoints were calculated for all randomized OAB patients receiving double-blind study treatment and having an evaluable change from baseline micturition measurement in the extension study. The validated OAB-q LF was administered to assess QOL endpoints, for a 1-week recall period, at weeks 12, 24, and 52 relative to start of treatment in the double-blind EMPOWUR trial. The OAB-q LF includes an HRQL scale (25 items) and a Symptom Bother scale (8 items). The HRQL scale includes 4 subscales: Coping, Concern, Sleep, and Social Interaction. Items on the HRQL scales were scored from 1 to 6, with higher scores indicating better QOL. For the Symptom Bother scale, items were scored from 1 to 6, with higher scores indicating greater symptom severity (ie, lower scores showed more improvement). For OAB-q LF scores, if <50% of the scale items were missing, the scale was retained with the mean scale score of the items present used to impute a score for the missing items.

The incontinence responder efficacy endpoints were calculated for all OAB wet patients receiving double-blind study treatment and having an evaluable change from baseline UUI measurement in the extension study.

RESULTS

Among the safety set (including those randomized from placebo) of 505 patients in the extension study (n=273, vibegron; n=232, tolterodine), the median age was 64.0 years (mean age, 61.1 years); 46.5% were aged ≥65 years; 78.2% were women; and 78.2% had OAB wet. Baseline characteristics and extension completion rates (vibegron, 85.8%; tolterodine, 84.1%) were similar. Adverse events (AEs) occurred in 62.6% (171/273) of vibegron and 54.3% (126/232) of tolterodine patients; 4 (1.5%) vibegron and 8 (3.4%) tolterodine patients discontinued study medication due to an AE. Key AEs (>5% for vibegron) for vibegron and tolterodine, respectively, were hypertension (8.8% and 8.6%), urinary tract infection (6.6% and 7.3%), and headache (5.5% and 3.9%). One death (due to arteriosclerotic cardiovascular disease, judged not related to study drug by investigators or sponsor) occurred in the vibegron group.

For the OAB-q LF scores at EMPOWUR baseline, mean scores were similar across both active treatment groups for all scales. Among patients receiving 52 weeks of active treatment, mean change from baseline in the vibegron group (n=164) was numerically better than in the tolterodine group (n=134) for all OAB-q scales (Figure 1). For the responder efficacy endpoints of reduction from EMPOWUR baseline at week 52, for which the analysis model was used, the vibegron group (N=143) demonstrated a numerically greater proportion of patients achieving the endpoints of reduction of ≥75% and 100% in daily UUI episodes and ≥50% in daily total incontinence episodes than the tolterodine group (N=106; Figure 2).

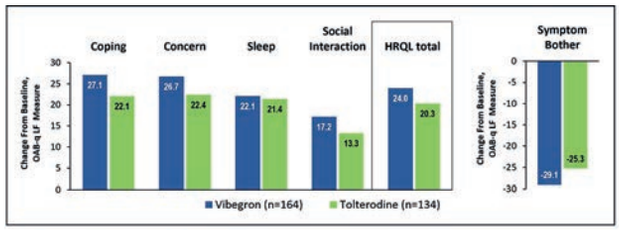
INTERPRETATION OF RESULTS

In the 40-week extension to the 12-week EMPOWUR trial, vibegron 75 mg demonstrated numerically greater QOL improvements from baseline at week 52 for all OAB-q scale scores and for proportions of patients meeting responder endpoints relative to tolterodine. Vibegron had a favorable long-term safety profile.

CONCLUDING MESSAGE

Vibegron demonstrated a favorable long-term safety profile in patients with OAB in the 52-week results from the EMPOWUR extension study. Vibegron 75 mg once daily demonstrated durable efficacy for QOL and incontinence efficacy endpoints.

FIGURE 1



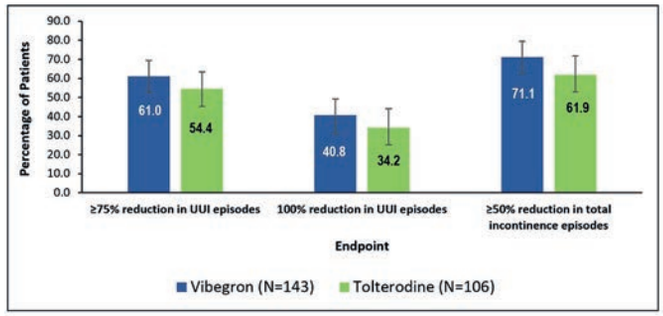
Source: Table 14.2.8.1 full analysis set extension.

[a]Mean change from baseline is calculated by: visit value minus baseline value. Baseline value was computed as value at baseline visit in the EMPOWUR trial. Weeks are relative to the start of treatment in the EMPOWUR study. For vibegron, N=176; for tolterodine, N=136. Items on the HRQL scales were scored from 1 to 6, with higher scores indicating ***better QOL***. For the Symptom Bother scale, items were scored from 1 to 6, with higher scores indicating ***greater symptom severity***.

HRQL, Health-Related Quality of Life; OAB-q LF, Overactive Bladder Questionnaire Long Form; QOL, quality of life.

Figure 1. Vibegron Demonstrated Numerically Better Mean Change from Baseline in All OAB-q LF Scores vs Tolterodine at Week 52[a]

FIGURE 2



Sources: Tables 14.2.6.1, 14.2.9.1, and 14.2.11.1 full analysis set extension for incontinence.

Error bars denote confidence intervals.

[a]Weeks are relative to start of double-blind treatment in EMPOWUR. The proportions are calculated based on the adjusted means from the mixed effects model, which included treatment, visit, baseline stratification factors, baseline value, and interaction by treatment visit. Only the patients receiving 52 weeks of active treatment were included in the model. Multiple imputation was used to estimate missing values.

UUI, urgency urinary incontinence.

Figure 2. Vibegron Demonstrated Numerically Higher Proportions of Patients Meeting Responder Endpoints at Week 52[a]

Funding Urovant Sciences **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov, NCT03583372 **RCT** Yes **Subjects** Human **Ethics Committee** Copernicus Group Independent Review Board in Cary, NC **Helsinki** Yes **Informed Consent** Yes

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THE ROLE OF MICRORNA IN OVER ACTIVE BLADDER: RELATIONSHIP AND CLINICAL CORRELATION

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder(OAB) is a disease that negatively affects the quality of life and occurs symptoms such as increased frequency of urination, urgecy and urinary incontinence. The absence of any local pathological or metabolic cause to clearly explain the symptoms and treatment is aimed at eliminating symptoms with various drugs because of unclear etiology. At this stage, epigenetic factors of the mechanism of overactive bladder have been the subject of research. miRNAs are considered important in regulation of posttranscriptional gene expression of epigenetic factors.

In our study, we aimed to determine the relationship between miRNAs, which may affect the regulation of ADRB3, the adrenergic pathway receptor gene, and ARHGEF10 and ROCK2 the cholinergic receptor pathway, genes, and and overactive bladder. We also investigated whether the detected miRNAs correlated with clinical findings and treatment responses. Additionnaly we aimed for the effective usability of miRNAs for diagnosis and treatment.

STUDY DESIGN, MATERIALS AND METHODS

This study was approved by local ethics committee to single-center clinical study. The study included 60 patients with overactive bladder and 60 healthy individuals as a control group. Detailed medical history, physical examinations, necessary laboratory tests and drug use history of all patients were obtained. In this study, patients with neurogenic bladder, bladder outlet obstruction and urinary system diseases or infections such as stones and tumors were applied as exclusion criteria. In healthy volunteers, those with pelvic surgery, any urinary complaints, or drug use were not included in the study. Turkish validated OAB questinnaire form was filled in all patients in the OAB group before and after treatment at the first month. Peripheral venous blood samples were taken from all patient and control groups and RNA isolation was performed according to the relevant commercial kit protocol. After RNA isolation, miRNA expression determination was performed by RT-PCR method. MiRNAs targeting ADRB3, ARHGEF10, ROCK2 gene regions were scanned in targetscan, mirtarbase, microrna.org, dianatools and mirDB databases. Found in four databases and have the highest level of association with these genes that 15 miRNAs were selected. For ADRB3 gene; hsa-let-7a-5p, hsa-let-7c-5p, hsa-let-7e-5p, hsa-let-7f-5p, hsa-let-7g-5p, for ROCK2 gene; için hsa-miR-138-5p, hsa-miR-135b-5p, hsa-miR-300, hsa-miR-381-3p, hsa-miR-200b-3p and for ARHGEF10 gene hsa-miR-520d-3p, hsa-miR-520e, hsa-miR-520a-3p, hsa-miR-373-5p, hsa-miR-372-3p were determined.

The data were analyzed using SPSS 25 version with Mann Whitney U test and MCNemar test for binary categorical comparison.

RESULTS

The patient group was on average 56.48 years old, while the control group was 55.82 years old. In the study, the average height and weight were 156.67 cm and 73.97 kg in the patient group, and 158.78 cm and 72.02 kg in the control group. As a result of the genetic study, the hsa-let-7a-5p (6,8 (0,02 - 97,68)), hsa-let-7c-5p (23,1 (0,31 - 259,57)), hsa-let-7e-5p (7,42 (0,34 - 44,08)), hsa-let-7f-5p (40,93 (0,03 - 484,38)), hsa-let-7g-5p (17,75 (0,44 - 855,13)) genomes associated with ADRB3 in the patient group were high with a high level of significance (p = 0.0001). miR-135b-5p (0,36 (0,04 - 79,58)), hsa-miR-300 (2,23 (0,14 - 11,63)), hsa-miR-372-3p (5,06 (0,1 - 49,77)), hsa-miR-373-5p (4,54 (0,02 - 61,18)), hsa-miR-381-3p (33,18 (5,16 - 446,39)), hsa-miR-520a-3p (0,7 (0,01 - 9,13)), miR-520d-3p (2,59 (0,03 - 72,86)), hsa-miR-520e (3,27 (0,14 - 19,53)) genomes targeting ARHGEF10 and ROCK2 gene regions were found statistically high in the control group (p = 0.0001). There was no significant difference in hsa-miR-138-5p (p=0,557) and hsa-miR-200b-3p (p=0,157) genomes in the patient and control groups.

At the end of treatment with 1 month anticholinergic agents in the patient group, a significant difference was detected in both miRNAs(hsa-let-7f-5p and miR-135b-5p) in patients with a clinical improvement of 50% and above in the OAB score. hsa-let-7f-5p genome was 147.86 (0.06 - 484.38) in patients with symptom improvement, while it was 32 (0.03 - 426.91) in the group without improvement (p = 0.045). miR-135b-5p genome was found 0.06 (0.03 - 0.21) in patients providing symptom improvement, while it was 0.3 (0.01 - 14.32) in the group without improvement (p = 0.036).

INTERPRETATION OF RESULTS

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CONCLUDING MESSAGE

OAB is a disease that can significantly reduce the quality of life and the treatment we use today is aimed at reducing the complaints because of the etiopathogenesis of the disease is not fully understood. Today, anticholinergic agents are the most preferred drugs in the medical treatment of OAB. In particular, it appears that anticholinergic drugs do not provide sufficient benefit in some patients. Some patients discontinue treatment due to their side effects. In our study, we determined a significant elevation in miRNAs associated with the adrenergic receptor gene ADRB3 in the patient group. Increased miRNA levels can lead to symptoms of OAB by inhibition of the target gene in several ways. Also, according to our study, miRNA levels effective on the genes in cholinergic pathway were found to be lower than the control group. This may be reducing the inhibition effect on the target gene and in the appearance of AAM symptoms. Better understanding of signaling pathways between the target gene and miRNAs can provide specific treatment strategies, and extensive studies are needed for this area. In the group with a decrease of 50% or more in the OAB score, the hRa-let-7f-5p associated with the ADRB3 receptor gene was higher than the other group and the miR-135b-5p associated with the ROCK2 gene region was lower than the other group. This can also assist the clinician in determining his treatment strategy that who will benefit more. Also, this may prevent patients from unnecessary anticholinergic use and exposure to their side effects, leading to the emergence of more specific treatment strategies and the discovery of new biomarkers that can be used for follow-up treatment. In addition, this study should be supported by more patients and compared with other gene polymorphisms.

FIGURE 1

	PatientGroup		ControlGroup		
		Med (min- maks)		Med (min- maks)	P value
Height (cm)	158,87±9,26	155,5 (129 - 170)	158,78±8,74	160 (140 - 172)	0,971 (z=-1,813)
Weight (kg)	73,97±16,6	73,5 (45 - 125)	72,02±13,01	70 (51 - 112)	0,472 (z=0,722)
BMI (%)	30,04±6,27	30,28 (17,78 - 45,91)	28,38±5,01	28,11 (18,2 - 43,75)	0,101 (z=-1,64)
Age (year)	58,48±13,08	60 (25 - 83)	55,82±11,83	58,5 (27 - 78)	0,397 (z=-0,72)
hsa-let-7a-5p	18,01±25,03	6,8 (0,02 - 97,68)	5,47±11,21	1,96 (0,11 - 78,21)	0,0001* (z=-4,068)
hsa-let-7c-5p	35,48±65,73	23,1 (0,31 - 259,57)	6,4±8,51	0,19 (0 - 2,3)	0,0001* (z=-8,833)
hsa-let-7e-5p	11,41±10,79	7,42 (0,34 - 44,08)	1,04±2,04	0,14 (0 - 8,41)	0,0001* (z=-6,012)
hsa-let-7f-5p	97,92±125,48	45,93 (0,03 - 484,38)	4,88±7,97	1,5 (0,13 - 33,73)	0,0001* (z=-6,818)
hsa-let-7g-5p	60,39±133,74	17,75 (0,44 - 855,13)	15,92±22,68	5,87 (0,12 - 92,41)	0,0001* (z=-5,894)
hsa-miR-135b-5p	1,93±2,86	0,24 (0,01 - 14,32)	7,54±17,33	0,36 (0,04 - 79,38)	0,0489* (z=-1,965)
hsa-miR-138-5p	0,24±0,1	0,04 (0 - 29,56)	0,47±0,83	0,03 (0 - 1,8)	0,557 (z=-0,588)
hsa-miR-200b-3p	0,12±0,22	0,04 (0 - 0,97)	0,22±0,35	0,07 (0 - 1,24)	0,157 (z=-1,417)
hsa-miR-300	0,93±3,18	0,06 (0 - 15,06)	2,84±2,55	2,25 (0,14 - 11,68)	0,0001* (z=-5,447)
hsa-miR-381-3p	4,28±5,98	2,68 (0 - 29,74)	37,18±83,14	10,18 (3,18 - 448,39)	0,0001* (z=-8,288)
hsa-miR-373-3p	0,09±0,15	0,04 (0 - 0,5)	12,6±26,27	4,54 (0,02 - 91,38)	0,0001* (z=-8,828)
hsa-miR-372-3p	4,93±11,42	1,89 (0,02 - 69,36)	9,28±11,07	5,04 (0,1 - 40,77)	0,0001* (z=-5,874)
hsa-miR-520a-3p	0,33±1,05	0,13 (0 - 5,42)	1,31±1,92	0,7 (0,01 - 9,13)	0,0002* (z=-4,118)
miR-1206-3p	1,01±1,49	0,45 (0,02 - 9,21)	9,49±15,98	2,39 (0,08 - 72,86)	0,0001* (z=-5,973)
hsa-miR-520e	0,9±1,29	0,38 (0,01 - 6,74)	4,43±4,12	3,27 (0,34 - 19,33)	0,0001* (z=-6,673)

Characteristics and miRNA results of patient and control groups

FIGURE 2

Clinical improvment	No		Yes		
		Med (min - maks)		Med (min - maks)	P value
hsa-let-7a-5p	17,46 ± 23,34	5,94 (0,02 - 97,68)	20,37 ± 22,58	9,92 (0,72 - 76,64)	0,469 (z=-0,724)
hsa-let-7c-5p	56,12 ± 67,21	19,84 (0,31 - 259,57)	52,66 ± 62,02	36,29 (0,4 - 196,72)	0,948 (z=-0,065)
hsa-let-7e-5p	11,65 ± 10,97	7,99 (0,34 - 44,08)	10,5 ± 10,17	6,53 (1,02 - 35,51)	0,914 (z=-0,107)
hsa-let-7f-5p	78,13 ± 107,58	32 (0,03 - 426,91)	184,99 ± 164,6	147,86 (0,06 - 484,38)	0,045* (z=-2,004)
hsa-let-7g-5p	65,72 ± 146,25	17,39 (0,44 - 855,13)	37,53 ± 44,93	21 (4,69 - 148,06)	1 (z=0)
hsa-miR-135b-5p	1,52 ± 3,05	0,3 (0,01 - 14,32)	0,08 ± 0,07	0,06 (0,03 - 0,21)	0,036* (z=-2,086)
hsa-miR-138-5p	6,35 ± 10,87	0,03 (0 - 29,56)	0,04 ± 0,03	0,04 (0,01 - 0,07)	1 (z=0)
hsa-miR-200b-3p	0,14 ± 0,24	0,04 (0 - 0,97)	0,04 ± 0,04	0,04 (0,01 - 0,12)	0,687 (z=-0,426)
hsa-miR-300	0,97 ± 3,25	0,06 (0 - 15,06)	0,03 ± 0	0,03 (0,03 - 0,03)	0,455 (z=-1,025)
hsa-miR-372-3p	5,52 ± 12,87	1,39 (0,02 - 69,36)	2,5 ± 1,64	1,92 (0,5 - 6,28)	0,531 (z=-0,627)
hsa-miR-373-5p	0,1 ± 0,14	0,04 (0 - 0,5)	0,04 ± 0,02	0,03 (0,01 - 0,08)	0,618 (z=-0,498)
hsa-miR-381-3p	4,83 ± 6,4	2,73 (0,02 - 29,74)	1,5 ± 1,13	1,57 (0 - 3,8)	0,123 (z=-1,543)
hsa-miR-520a-3p	0,54 ± 1,1	0,11 (0 - 5,42)	0,5 ± 0,71	0,16 (0,01 - 2,27)	0,539 (z=-0,615)
miR-520d-3p	0,91 ± 1,42	0,46 (0,03 - 9,21)	1,41 ± 1,79	0,14 (0,02 - 4,99)	0,913 (z=-0,109)
hsa-miR-520e	0,97 ± 1,4	0,38 (0,01 - 6,74)	0,63 ± 0,6	0,47 (0,08 - 2,2)	0,929 (z=-0,089)

MiRNA results of patients with and without 50% improvement after 1 month of treatment

Funding PAMUKKALE ÜNIVERSITESI BILIMSEL ARASTIRMA PROJELERI KOMISYONU **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Pamukkale University Local Ethic Commitee **Helsinki** Yes **Informed Consent** Yes

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ARE PATIENTS WITH "CONSTANT NEED TO URINATE" AND "SUDDEN NEED TO RUSH TO URINATE" DIFFERENT PHENOTYPES? – FINDINGS FROM THE LURN STUDY

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HYPOTHESIS / AIMS OF STUDY

The International Continence Society (ICS) defines urinary urgency as "a sudden compelling desire to pass urine, which is difficult to deter". Recent studies have suggested that different subtypes of urinary urgency may exist among patients who present with lower urinary tract symptoms (LUTS). The aim of this study is to examine the demographic, clinical, and psychosocial differences among participants who experience one or more of these symptoms of urinary urgency: "the sudden need to rush to urinate" (the sudden urgency group) versus "the constant need to urinate" (the constant urgency group) using data from the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN).

STUDY DESIGN, MATERIALS AND METHODS

Adult women and men seeking treatment for their LUTS were recruited into the LURN one-year observational cohort study from six US tertiary care centers. Demographic and clinical data were collected at the baseline visit. At their 12-month follow-up visit, participants completed the following self-reported measures: the LURN Comprehensive Assessment of Self-reported Urinary Symptoms (CASUS), the Genitourinary Pain Index (GUPI), the Pelvic Floor Distress Inventory (PFDI-20), the Perceived Stress Scale (PSS), and the Patient-Reported Outcomes Measurement Information System (PROMIS) Gastrointestinal (GI) bowel incontinence, GI constipation, GI diarrhea, depression, anxiety, sleep disturbance, and physical function (mobility subdomain) measures. The CASUS item, "In the past 7 days, how often did you feel a sudden need to rush to urinate?" has response options of "never," "a few times," "about half the time," "most of the time," and "every time." Participants answering "about half the time" or more were considered to have sudden urgency. The CASUS item, "In the past 7 days, did you have a constant need to urinate that did not go away?" had responses of "yes" and "no," and participants answering "yes" were considered to have constant urgency. These responses were used to group participants who experienced sudden urgency only, constant urgency only, or both sudden and constant urgency. Demographics, clinical characteristics, and patient-reported measures were compared between groups using analysis of variance (ANOVA), chi-square tests, and non-parametric equivalents where appropriate. P-values were adjusted for multiple testing using the false discovery rate (FDR).

RESULTS

Based on the 12-month follow-up CASUS responses, there were 251 participants who had sudden urgency only (n=156, 62%), constant urgency only (n=36, 14%), or both (n=59, 24%). Those with sudden urgency only were, on average, the oldest (60.6 years vs. 54.2 for the constant urgency group, and 58.4 years for both, p-value=0.014, Table 1). There was a significantly higher proportion of men who experienced constant urgency only (69%) and a higher proportion of women who experienced both sudden and constant urgency (64%, p-value=0.005). There was also a significantly higher proportion of African-Americans who experienced constant urgency only (20%) and both sudden and constant urgency (36%, p-value=0.004) compared to other racial groups.

Participants with both sudden and constant urgency reported more pain, urinary symptoms and associated distress, bowel symptoms, and psychological symptoms compared to those with only sudden urgency or constant urgency only. GUPI total scores were 19.2 (SD=8.4) on average, compared to 13.5 (SD=7.0) and 13.8 (SD=7.9) for other two groups (p<0.001). In particular, the GUPI pain subscale was 2.3-3.2 points higher (p<0.001). In females the PFDI-20 scores were 111.8 (SD 65.8) in the combined symptom group compared to 46.8 (SD=30.9) in the constant only group and 72.1 (SD=42.4) in the sudden only group (p<0.001). PROMIS measures were at or slightly below reference population means of 50 for the constant urgency only group and sudden urgency only group, while scores for the combined group were 2.9-3.9 points above the mean on average, with the exception of sleep disturbance, which was similar across groups. These measures were not significantly different between participants in the sudden urgency only group and constant urgency only group, with the exception of the PROMIS physical function T-score which was significantly lower for participants with sudden urgency only (46.3 vs. 50.8, p-value=0.005).

Patterns of urinary symptoms related to urgency and pain sensations differed across the three groups (Figure 1). In the twelve symptoms assessed, there were significant differences in the responses between urgency groups for nine of them: nocturia (p-value=0.011), fear of leaking with urgency (p-value<.001), UUI (p-value<.001), pain with bladder filling (p-value=0.015), pain while the bladder is full (p-value=0.016), satisfaction with bladder condition (p-value=0.032), overall bother of urinary symptoms (p-value=0.014), overall severity of bladder problems (p-value=0.003), and measure of bladder function (p-value=0.001). Compared to participants with both sudden and constant urgency, those with only constant urgency had significantly lower ratings for all nine of these symptoms, except for satisfaction with bladder con-

dition and bladder function which were significantly higher, while those with only sudden urgency had significantly lower ratings of pain while filling, pain while the bladder is full, overall severity of bladder problems and significantly higher ratings of bladder function. Those with only constant urgency had significantly lower ratings of nocturia, fear of leaking with urgency, UUI and significantly higher ratings of bladder function compared to participants reporting only sudden urgency.

INTERPRETATION OF RESULTS

Of the treatment-seeking participants in this study who reported urgency, the majority (62%) reported sudden urgency only. Fewer (14%) reported constant urgency only. A quarter (24%) reported both sudden and constant urgency, raising the possibilities that participants may not understand the difference between the two sensations (constant vs. sudden), and/or they have experienced both symptoms as reported. Men and African-Americans were more likely to report constant urgency. The reasons behind these demographic differences are unknown. The differences in sex may be explained by the higher rates of urgency without UUI in men compared to women. It may also be because African-Americans reported less UUI compared to White participants. Having both sudden and constant urgency adds to the overall severity and burden (both urological and non-urological – e.g., worse urinary symptoms and associated distress, more pain, worse pelvic floor dysfunction, worse GI function, and more psychosocial issues). When restricting the comparisons to the sudden urgency only and the constant urgency only groups, there were no differences in terms of their pain, GI function, anxiety, depression, or perceived stress levels. Whether there may be fundamental differences in underlying pathophysiology between the two subgroups (sudden vs. constant) is unknown, and this warrants further investigation.

CONCLUDING MESSAGE

Women and men seeking treatment for their LUTS endorsed either or both of the following symptoms: "the sudden need to rush to urinate" (sudden urgency) and/or "the constant need to urinate" (constant urgency). Participants with both sudden and constant urgency reported more pain, urinary symptoms, bowel and psychological symptoms compared to those with only sudden urgency or only constant urgency.

FIGURE 1

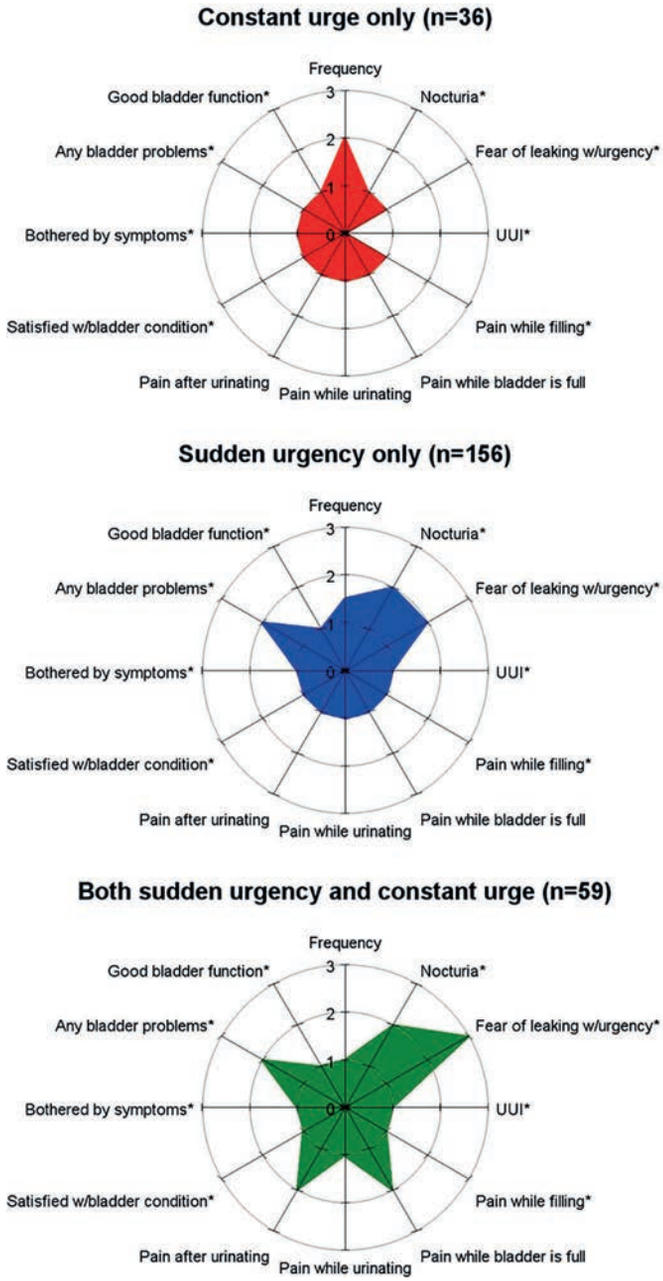

Figure 1. Radar plots of median responses to CASUS questions, paneled by participants with a) constant urgency only, b) sudden urgency only, and c) both sudden and constant urgency

FIGURE 2

Variable	Total (n=251)	Sudden urgency only (n=156)	Constant urgency only (n=36)	Both sudden and constant urgency (n=59)	p-value
Age	59.1 (12.6)	60.6 (12.4)	54.2 (12.9)	58.4 (12.3)	**0.014**
Sex (% male)	126 (50%)	80 (51%)	25 (69%)	21 (36%)	**0.005**
Race					**0.001**
Black or African American	43 (19%)	16 (11%)	7 (20%)	20 (36%)	
White	175 (76%)	118 (84%)	26 (74%)	31 (56%)	
Other/multi-racial	13 (5%)	7 (4%)	2 (6%)	4 (7%)	
BMI	31.5 (7)	32.1 (6.5)	29.9 (5.3)	31.1 (8.7)	0.115
Diabetes	44 (19%)	28 (19%)	3 (9%)	13 (23%)	0.207
Functional Comorbidity Index (FCI) total	2.6 (2.2)	2.7 (2)	1.8 (1.6)	2.9 (2.7)	**0.035**
Stress Urinary incontinence (SUI) (% yes)	45 (18%)	29 (19%)	2 (6%)	14 (24%)	**0.418**
GUPI total score	14.9 (7.8)	13.5 (7)	13.8 (7.9)	19.2 (8.4)	**<.001**
GUPI pain subscale	4.3 (4.8)	3.4 (4.3)	4.3 (4.7)	6.6 (5.4)	**<.001**
GUPI urinary symptom subscale	4.3 (2.4)	4 (2.5)	4.1 (2.2)	5.1 (2.3)	**0.031**
GUPI QOL impact subscale	6.3 (2.7)	6.1 (2.6)	5.4 (2.7)	7.5 (2.8)	**0.003**
PFDI-20 (females only)	81.9 (53.9)	72.1 (42.4)	46.8 (30.9)	111.8 (65.8)	**<.001**
PROMIS GI Bowel Incontinence (raw score)	5.6 (2.8)	5.4 (2.7)	5 (1.9)	6.6 (3.3)	**0.002**
PROMIS GI Constipation (T-score)	50.3 (8.5)	50 (8.4)	47.4 (8.1)	52.9 (8.3)	**0.011**
PROMIS GI Diarrhea (T-score)	49.8 (9.2)	49.1 (8.8)	48.6 (8.7)	52.3 (10)	0.088
PROMIS Depression (T-score)	50.1 (9.6)	49.3 (9.2)	48.3 (9.2)	53.1 (10.4)	**0.024**
PROMIS Anxiety (T-score)	50.2 (9.9)	49.1 (9.4)	48.9 (9.2)	53.9 (10.9)	**0.013**
PROMIS Sleep Disturbance (T-score)	52.5 (9.8)	51.5 (9.6)	53.3 (8.7)	54.6 (10.6)	0.093
PSS	13.8 (7.7)	12.8 (7.1)	13.7 (8.7)	16.8 (8.2)	0.007
PROMIS Physical function, mobility (T-score)	46.3 (9.6)	46.3 (9)	50.8 (9.3)	43.3 (10.5)	**0.001**
IPAQ categories					0.179
Low Activity	128 (52%)	84 (55%)	15 (42%)	29 (49%)	
Moderate Activity	27 (11%)	20 (13%)	3 (8%)	4 (7%)	
High Activity	93 (38%)	49 (32%)	18 (50%)	26 (44%)	

Table 1. Demographics, clinical characteristics and patient-reported measures by urgency group

Funding NIH/NIDDK grant numbers U01DK099879, U01DK097780, U01DK097772, U01DK097779, U01DK099932, U01DK100011, U01DK100017 **Clinical Trial** No **Subjects** Human **Ethics Committee** E&I Review **Helsinki** Yes **Informed Consent** Yes

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EFFICACY OF FESOTERODINE FUMARATE IN NEUROGENIC DETRUSOR OVERACTIVITY DUE TO SPINAL CORD LESION (SCL) OR MULTIPLE SCLEROSIS (MS) – A PROSPECTIVE STUDY

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HYPOTHESIS / AIMS OF STUDY

According to the International Continence Society (ICS) Overactive Bladder (OAB) is defined as "the presence of urinary urgency, usually accompanied by frequency and nocturia, with or without urgency incontinence, in the absence of a causative infection or obvious pathological conditions". OAB is by definition idiopathic. On the other hand, Neurogenic Detrusor Overactivity (NDO) is an urodynamically confirmed bladder dysfunction secondary to an underlying neurological pathology (i.e. SCL, MS, stroke), that causes symptoms similar to OAB. NDO is characterized by involuntary contractions, spontaneous or provoked, during filling cystometry of the UroDynamic Study (UDS) accompanied usually by low bladder compliance and capacity, and high detrusor pressure.

Patients with NDO usually suffer from recurrent urinary tract infections (UTI's), chronic bladder retention with increased residual volumes, hydronephrosis and eventually renal failure. The primary aims for the treatment of patients with NDO are the protection of the Upper Urinary Tract (UUT) and prevention of renal damage, the achievement of urinary continence, restoration of (parts of) the lower urinary tract (LUT) function and improvement of patients' Quality of Life (QoL). In patients with high detrusor pressure during the filling phase, treatment's aim is the "conversion of an active, aggressive high-pressure bladder into a passive low-pressure reservoir" despite the resulting residual urine. The reduction of the detrusor pressure contributes to urinary continence and improvement in QoL, preventing simultaneously UTI.

Antimuscarinic drugs are the first-line choice in the treatment of patients with NDO. By blocking the cholinergic/muscarinic receptors of the bladder, they promote inhibition of the parasympathetic pathways resulting in increased bladder capacity and compliance and reduced episodes of urgency and incontinence. Nevertheless, the literature for the use of anticholinergics in Neurogenic Lower Urinary Tract Dysfunction (NLUTD) is still limited and sparse and the response of individual patients to the treatment is variable. Hence, there is only one published meta-analysis about the efficacy of anticholinergics in the treatment of patients with NLUTD.

Fesoterodine fumarate is the newest anticholinergic drug. It is actually a prodrug that is broken down, by plasma esterases, into its active metabolite, 5-hydro-methyl tolterodine. The use of Fesoterodine fumarate has been approved, in many countries, for the treatment of OAB. To the best of our knowledge, no study has been yet published about the use of Fesoterodine fumarate in patients suffering from NLUTD. The aim of our study is to determine the efficacy of Fesoterodine fumarate for the treatment of patients with NDO.

STUDY DESIGN, MATERIALS AND METHODS

Eligible subjects for enrollment were considered patients between 18-80 years old suffering from NDO, confirmed by UDS, secondary to MS or SCL of at least 6 months before their enrollment. Exclusion criteria were a recent or during the study UTI, history of urothelial cancer, urolithiasis, stress incontinence, interstitial cystitis, pelvic organ prolapse (≥ III grade), prior pelvic surgery or pelvic radiation treatment, uncontrolled narrow-angle glaucoma, pregnancy and dementia. Furthermore, patients suffering from MS should have been clinically stable for at least 3 months before their en-

rollment, according to the Expanded Disability Status Scale (EDSS).

The study was designed as an open-label prospective interventional trial without a control group. All participants provided an inform consent and the study was approved by the scientific and ethics committees of our institution. It was considered as unethical to include a placebo (or a non-therapy) control group as the increased detrusor pressure could harm the UUT of the patients. On the other hand, previous studies on other antimuscarinics proved that the placebo effect is rather "limited" in such a cohort of neurological patients.

A 2-week wash-out period was requested, before enrollment for patients under drug medication for the treatment of NDO. All patients underwent a first confirmatory baseline UDS and filled the SF-Qualiveen as a QoL questionnaire. Afterwards, all subjects received a treatment of 8 mg Fesoterodine daily for 3 months. After this period, they repeated the UDS and SF-Qualiveen. Each UDS was performed with the same equipment at the same environment from the same clinician, unaware of the study hypothesis, according to ICS' good urodynamic practices and terms.

The primary endpoint of the study was the change from baseline to end of treatment in maximum detrusor pressure (Pdetmax) during the filling phase of the UDS and whether the use of Fesoterodine fumarate would decrease it. Secondary endpoints included changes from baseline to end of treatment in other urodynamic variables, particularly bladder capacity and bladder compliance. By analyzing the questionnaires, QoL, pre and post-treatment, was evaluated.

This was a pilot study since Fesoterodine fumarate has never been used in patients with NDO. Statistical analysis has been performed with the use of SPSS v.26.

RESULTS

One hundred thirty-seven patients were recruited and 124 of them, 68 males and 56 females, completed the study. Of included patients, 95 had SCL (60 paraplegics, 35 tetraplegics) and 29 MS. There was no statistical difference at baseline among the tested urodynamic parameters throughout the groups ($p > 0.05$). The urodynamic parameters Pdetmax, bladder capacity and compliance, were estimated for the whole group before and after treatment and were proved to be statistically different when compared to the baseline ($p < 0.001$ for all variables), according to Wilcoxon test for a non-parametric sample. Changes in urodynamics parameters were also significant in each of the paraplegic, tetraplegic and MS groups ($p < 0.001$).

According to all the domains of SF-Qualiveen, QoL also improved. There was a significant difference in SF Qualiveen score after treatment with Fesoterodine in all patients independently of the diagnosis (Table I).

INTERPRETATION OF RESULTS

According to our knowledge, this is the first study that evaluated the efficacy of Fesoterodine fumarate in neurogenic patients. The results of our study suggest that this treatment can improve crucial urodynamic parameters, which are mirrored in a more acceptable function of the lower urinary tract. Furthermore, this beneficial effect seems to be independent of the underlying neurological disease, as the improvement was statistically significant not only in the whole group but also in each special subgroup analysis.

CONCLUDING MESSAGE

Fesoterodine fumarate is an efficacious drag in patients with SCL and MS, as it significantly decreases detrusor pressure, increases bladder capacity and compliance, and improves QoL of the patients.

FIGURE 1

Table I. Differences between SF Qualiveen scores before and after treatment among patients according to their diagnosis

		SF QUALIVEEN PRE	SF QUALIVEEN POST	CRITERION t test
PARAPLEGICS	N=60	2,8227	1,5205	t(59) = 12,579 p=.000
TETRAPLEGICS	N=35	2,8516	1,8516	t(34) = 4,846 p=.000
MULTIPLE SCLEROSIS	N=53	2,8656	,8137	t(29) = 22,454 p=.000

Table I. Differences between SF Qualiveen scores before and after treatment among patients according to their diagnosis

REFERENCES

1. Madhuvrata P, Singh M, Hasafa Z, Abdel-Fattah M. Anticholinergic drugs for adult neurogenic detrusor overactivity: a systematic review and meta-analysis. Eur Urol. 2012; 62(5):816-30.
2. Bonniaud V, Bryant D, Parratte B, Guyatt G. Development and validation of the short form of a urinary quality of life questionnaire: SF-Qualiveen. J Urol. 2008; 180(6):2592-8
3. Schäfer W, Abrams P, Liao L, Mattiasson A, Pesce F, Spangberg A, et al. Good urodynamic practices: uroflowmetry, filling cystometry, and pressure-flow studies. Neurourol Urodyn. 2002;21(3):261-74

Funding There no **Funding** or grant for this study **Clinical Trial** Yes **Registration Number** IS**RCT**N 22433402 **RCT** No **Subjects** Human **Ethics Committee** Scientific Committee of National Rehabilitation Center, 30/11/2015, ref: 9/9-12-2015 **Helsinki** Yes **Informed Consent** Yes

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DIAGNOSTIC TOOL AND THERAPEUTIC STRATEGY FOR ACUTE COLD-INDUCED URGENCY (ACIU). ESTABLISHING ACIU IN PATIENTS.

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder syndrome (OAB) is often provoked by external cues. One particularly provocative stimulus is external cold. We have introduced the term acute cold-induced urgency (ACIU) for this phenomenon. ACIU evoked by everyday cold stimuli is a frequent complaint of patients with OAB, wet or dry, but is also common in healthy individuals. Based on literature, around 50% of patients presenting with OAB experience urgency upon daily life cold exposure events (1,2). Despite epidemiological evidence linking aggravation of OAB to cold environmental temperatures, as well as extensive anecdotal evidence from urological practice (1), acute external cold-induced bladder responses have never been directly and systematically documented in humans. ACIU can be reliably evoked with brief, non-painful cold stimuli, even in anesthetized animals, and concomitantly measured using cystometry (3). This indicates that ACIU is a conserved reflex rather than subconscious conditioning. ACIU critically depends on the activity of the cold-activated ion channel Transient Receptor Potential M8 (TRPM8) (3). These preclinical results represent proof-of-concept that ACIU can be objectively measured to serve as a novel diagnostic tool, and that TRPM8 is a potential therapeutic target to treat ACIU symptoms, and form the starting point of the current project.

The overall aim of the project is to translate these fundamental findings towards clinical applications, in order to improve the diagnosis, stratification and treatment of urinary urgency in patients.

The primary goal of this pilot project is to establish that ACIU can be provoked during urodynamic investigations in humans, and to determine the cold stimulus that is most prone/or convenient to evoke ACIU.

STUDY DESIGN, MATERIALS AND METHODS

In this pilot study we randomly selected 21 novel patients presenting in our outpatient clinic with complaints of urgency and/or urgency-incontinence. We only selected OAB patients because, based on literature, 50% of them experience urgency upon external cold (1,2).

After obtaining written informed consent, patients were asked to fill out an International Consultation on Incontinence Modular Questionnaire (ICIQ QoL and OAB), as well as a Cold Sensitivity Questionnaire (CSQ), a self-constructed questionnaire containing four questions about the influence of cold stimuli on lower urinary tract symptoms.

All patients underwent a standard urodynamic test, which was immediately followed by a repeat test during which ACIU was provoked, using a protocol adapted from our ACIU protocol established in our preclinical studies (3). The subject's bladder was filled to 80% of its capacity, at which point the infusion was halted. Subsequently, the subject was exposed to three distinct localized cold stimuli that are known to cause strong TRPM8-mediated cool sensations: immersion of one foot in 38°C-water during 30s immediately followed by immersions in 20°C-water for 30s, blowing a stream of cool air over the face for 30s, application of acetone on the skin of one forearm. These stimuli were applied in random order with 1-minute intervals, and the experiment was terminated when a voiding was evoked or all stimuli had been applied. Both subjective responses as well as urodynamic responses (detrusor contraction ≥ 15cmH2O; voiding) were recorded.

RESULTS

A total of 21 patients were enrolled in the study, 12 women and 9 men. When asked, 16 patients reported to experience an aggravation of their symptoms when exposed to cold stimuli, 5 patients did not experience ACIU. Thirteen patients (62%) showed a response on one or two of the cold stimuli, 8 patients did not show any subjective or urodynamic response. Of the 5 patients who did not experience ACIU in daily life, only one did not have a subjective or urodynamic response on the cold stimuli. Five patients (23.8%) had a subjective response on the acetone stimulus, of which one female patient had a detrusor contraction which evoked voiding. This patient did not receive the other two stimuli. Four patients (19%) had a subjective response on the cold air stimulus and one patient had a detrusor contraction on urodynamic investigation. Eight patients (38%) had a subjective response on the cold water stimulus of which three patients had a detrusor contraction as well. Only three patients (14%) showed response on two stimuli. Two of them had a subjective response on the cold air and cold water stimulus. One patient had a subjective response on acetone and cold water.

INTERPRETATION OF RESULTS

In our study 8 patients (38%) did not have any response on the cold stimuli. But 7 of those patients told us to experience an aggravation of their OAB symptoms when exposed to cold stimuli in daily life. Sixty-two percent showed a reaction on a cold stimulus of which the cold water stimulus was the most provocative stimulus with the most response (8/13 – 62%). Three of those subjective responses were associated with a detrusor contraction ≥ 15cmH2O. The cold water stimulus is known to be a very strong stimulus for activation of TRPM8 (3).

CONCLUDING MESSAGE

Based on the outcome of this experiment, we established that ACIU can be objectively measured in humans, using OAB patients as primary subjects. We determined that the cold water stimulus is the most provocative cold stimulus and this will be used to further standardize the ACIU protocol. We will use this ACIU test to evaluate ACIU occurrence and severity in various urological patient populations (patients with OAB, multiple sclerosis patients, patients with urinary stress incontinence and healthy controls).

REFERENCES

1. Ghei M, Malone-Lee J. Using the circumstances of symptom experience to assess the severity of urgency in the overactive bladder. J Urol 2005;174:972-6.
2. Kondo A, Saito M, Yamada Y, et al. Prevalence of hand-washing urinary incontinence in healthy subjects in relation to stress and urge incontinence. Neurourol Urodyn 1992;11:519-23.
3. Uvin P, Franken J, Pinto S, et al. Essential Role of Transient Receptor Potential M8 (TRPM8) in a model of Acute Cold-induced Urinary Urgency. European Urology 2015;68:655-661.

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OVERACTIVE BLADDER SYNDROME IS ASSOCIATED WITH ELEVATED URINARY PRONGF TO NGF RATIO IN AN AGING FEMALE POPULATION

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HYPOTHESIS / AIMS OF STUDY

The clinical relevance of the ratio NGF/creatinine in urine as a biomarker for overactive bladder syndrome (OAB) diagnosis is a matter of debate. ProNGF, the precursor form of nerve growth factor (NGF) was recently found to possess degenerative roles by signalling through its receptor p75NTR. The present study aims to identify the changes in concentration of NGF and proNGF, and the soluble factors involved in their proteolysis in the urine of an aging female population with OAB.

STUDY DESIGN, MATERIALS AND METHODS

Cross-sectional study in which urine samples were obtained from 20 females of 50-80 years of age with OAB and from 20 controls of the same age group. Analyses were carried out with highly specific ELISA and enzymatic kits. Participants completed a full clinical evaluation and validated self-reported questionnaires: Overactive Bladder Symptom Score (OABSS), International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), and Incontinence Impact Questionnaire (IIQ-7),as well as a one-day voiding diary.

RESULTS

The average age in the OAB group was expectedly higher than control (68.9 ± 11.38 vs 56.25 ± 5.22 years in controls) ($p<0.001$). There was no significant difference in demographics and vital signs parameters between controls and OAB subjects. Total questionnaires' scores reflecting OAB symptom severity and its impact on quality of life were significantly higher in the OAB group. (Table 1) NGF ELISA kit specificity was confirmed. We found that the proNGF/NGF ratio was significantly doubled in the OAB group. Enzymatic activity of MMP-7, the main enzyme responsible for extracellular maturation of proNGF, was significantly increased in the OAB group, however, this was counteracted by several-folds increase in the MMP-9 responsible for NGF proteolysis. On the other hand, nitric oxide and PGE2, two factors increasing expression and activity of MMP-9, also displayed higher concentrations in urine of OAB patients. (Table 1) Receiver operating characteristic (ROC) showed that proNGF/NGF ratio has high sensitivity for OAB diagnosis where the area under the curve was 0.731 (p= 0.08, 95% CI= 0.514-0.948).

INTERPRETATION OF RESULTS

The increase of proNGF/NGF ratio in OAB patients in aging female population could be a result of disturbances in the proteolytic activity. This increase could originate from the increased activity of MMP-9, enhancing NGF proteolysis in OAB. Local tissue factors in the bladder such as NO, ATP and PGE2 that increase due to metabolic stress can induce changes in proteolytic enzymes of proNGF/NGF which in turn can affect proNGF/NGF balance. Previous studies have focused on the inhibition of proNGF maturation as a principal lead to proNGF/NGF imbalance. However, in this report NGF degradation could equally contribute to proNGF/NGF imbalance in OAB.

CONCLUDING MESSAGE

The ratio ProNGF/NGF could constitute a more reliable biomarker for OAB rather than NGF level alone. Increased NGF degradation by MMP9 suggests that MMP9 inhibitors may constitute a new therapeutic target to explore for OAB.

FIGURE 1

Table 1: Demographic, serum, symptom questionnaires and urine analyses data compared in the control and OAB groups:

	CTR	OAB group	P value
Age (years)	56.25 (5.22)	68.9 (11.38)	<0.001*
BMI (kg/m^2)	29.75 (7.65)	28.82 (5.45)	0.661*
Systolic BP (mmHg)	121.4 (12.28)	123.7 (12.51)	0.561*
HOMA-IR	2.13 (1.03)	3.11 (1.18)	0.020*
Questionnaires:			
OABS (0-28)	7.3 (3.56)	17.45 (4.45)	<0.001*
ICIQ (0-22)	3.26 (3.98)	8.05 (3.83)	<0.001*
IIQ7 (0-100)	2.4 (5.2)	28.9 (23.2)	<0.001*
proNGF/NGF	0.273 (0.15)	0.414 (0.95)	0.009**
TIMP-1 (ng)	0.841 (0.97)	1.41 (2.09)	0.044**
MMP-7 (ng)	0.232 (0.31)	0.443 (0.78)	0.049**
MMP-7/TIMP-1	0.0007 (0.0008)	0.0022(0.005)	0.095**
MMP-9 (ng)	0.012 (0.79)	0.815 (2.09)	0.035**
MMP-9/TIMP-1	0.008 (0.14)	0.073 (0.44)	0.059**
PGE2 (pg)	224.2 (114.9)	340.5 (553.02)	0.114**
NO (micromole)	4.22 (1.9)	5.36 (6.7)	0.066**
ATP (nmol)	8.7 (11.38)	9.86 (10.2)	0.675**

Data are presented as mean (SD) for variables compared with parametric t-test (*) or as median (interquartile range, IQR) for variables compared with the non-parametric Mann-Whitney test (**).

Table 1

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PREVALENCE AND PREDICTORS OF CUMULATIVE ANTICHOLINERGIC BURDEN AMONG RECENTLY ADMITTED LONG-STAY NURSING HOME RESIDENTS WITH OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

Antimuscarinics, also known as oral anticholinergics, form the first-line of pharmacotherapy for overactive bladder (OAB). Among older adults (65 years of age or older), the use of antimuscarinics must be carefully considered due to known impacts of cumulative anticholinergic exposure ("anticholinergic burden"), including increased risk of falls/fractures, and cognitive concerns. However, little is known regarding the extent of anticholinergic burden among nursing home residents with OAB. This study aimed to characterize the prevalence of and factors associated with cumulative anticholinergic burden among long-stay nursing home (LSNH) residents with OAB.

STUDY DESIGN, MATERIALS AND METHODS

The study involved retrospective analysis of the Minimum Data Set (MDS) – linked Medicare claims data from 2013-2015, involving Parts A, B and D. LSNH residents (defined as having least 1 nursing home episode lasting at least 101 consecutive days), aged 65 years or older at index date (nursing home admission) were identified as having OAB based on the ICD-9/10 codes in inpatient or outpatient settings, or a claim for an OAB-specific medication (darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine, trospium chloride, mirabegron, onabotulinumatoxinA) based on prescription fill records/CPT codes during the study period. Additionally, all individuals were required to have medical/pharmaceutical coverage 6 months before and a minimum of 12 months following admission, and at least 180 days of nursing home stay after the 100th day of admission. The follow-up of 180 days post 100th day of admission was selected to capture anticholinergic burden because medication exposure in this study was ascertained using only Medicare Part D data, and medications for the first 100 days are usually covered by Medicare Part A.

Anticholinergic medication use was assessed over a 6-month period starting from the 100th day of admission, and anticholinergic burden was defined using the 4-point Anticholinergic Cognitive Burden (ACB) scale [range: 0 (none) – 3 (severe) anticholinergic activity]. Cumulative anticholinergic expo-

sure was calculated as a product of the standardized daily dose (SDD) and the ACB scale score of individual medications to yield a drug- and patient-specific measure of standardized daily anticholinergic exposure (SDACE). The SDACE for multiple medications was then used to estimate a Summative Standardized Daily Anticholinergic Exposure (SumSDACE) measure across all 6-months of follow-up per patient. The anticholinergic burden was categorized as no (0), low (1-89), moderate (90-499) or high (500 and greater), based on the distribution of SumSDACE scores. The Andersen Behavioral Model (ABM) was used to identify the predisposing (age, sex, race/ethnicity, marital status), enabling (dual eligibility, geographical region, urban-rural residence) and need factors (baseline co-medications such as anticholinergics, antidepressants, antipsychotics, anti-hypertensives; comorbidities such as fall/fracture, neurogenic bladder, multiple sclerosis, Elixhauser comorbidities, BMI, urinary incontinence, bowel incontinence, cognitive performance, depressed mood indicator) associated with high cumulative anticholinergic burden. These factors were selected based on past literature and availability in Medicare and MDS databases.

Descriptive statistics were used to summarize the prevalence and distribution of the anticholinergic burden among LSNH residents with OAB. The analysis included bivariate comparisons across levels of cumulative anticholinergic burden based on SumSDACE scores. Differences between the varying levels of cumulative anticholinergic burden were evaluated via Analysis of Variance (ANOVA) and chi-squared tests, for continuous and categorical variables, respectively. Two multivariable logistic regression models were developed. The logistic regression model aimed to identify the predictors of anticholinergic burden by grouping the outcome into two levels - moderate/high (90 and greater) vs low/no (0-89) anticholinergic burden. The multinomial logistic regression model evaluated the predictors of moderate (90-499) and high (500 and greater) burden compared to low burden (1-89). Both models were adjusted for factors included in the ABM framework.

RESULTS

A total of 124,345 individuals were identified as LSNH residents with OAB; 45.4% of patients were 85 years of age or older, 72.7% were female, and 87.3% were non-Hispanic White. Of them, 123,308 patients (99.1%) had at least one medication claim during follow-up and formed the analytical sample. Most (87.2%) of these patients had some anticholinergic burden; 12.8% had none, 18.0% had low, 41.9% had moderate, and 27.3% had high cumulative anticholinergic burden. The distribution of burden levels varied by several predisposing, enabling, and need factors.

Results from the logistic regression revealed several factors associated with moderate/high vs low/no burden (Table 1). Among the predisposing factors, age was negatively associated with moderate/high burden (age 75–84 years: odds ratio [OR] 0.75; 95% CI 0.72 - 0.78]; 85 years and older: OR 0.64; 95% CI 0.61 - 0.67), whereas females were positively associated with having moderate/high burden compared to males (OR 1.25; 95% CI 1.21 - 1.29). Compared to non-Hispanic Whites, Blacks, Hispanics and other racial groups were less likely to have moderate/high burden. Of the enabling factors, dual eligibility increased the likelihood of having moderate/high burden (OR 1.16; 95% CI 1.13 - 1.20). The odds of having moderate/high burden significantly decreased among LSNH residents located in the Northeast (OR 0.89; 95% CI 0.86 - 0.93) and West regions (OR 0.82; 95% CI 0.78 - 0.86) compared to South, and residence in urban vs rural areas (OR 0.83, 95% CI 0.81 - 0.86). Among the need factors, history of multiple sclerosis, neurogenic bladder, Elixhauser comorbidities (such as heart failure, cardiac arrhythmias, hypertension, diabetes, depression, psychoses, obesity), baseline co-medication use including anticholinergics, higher BMI levels, occasional/frequent urinary incontinence and depressed mood indicators increased the odds while cognitive impairment, bowel incontinence reduced the odds of having moderate/high burden.

These findings were maintained and often strengthened in the multinomial logistic regression model (Table 2). Females were positively associated with having moderate vs low burden (OR 1.16; 95% CI 1.11 - 1.21) and high vs low burden (OR 1.40; 95% CI 1.33 - 1.46), whereas older age groups and non-White race were negatively associated with higher burden levels. With respect to enabling factors, dual eligibility significantly increased the likelihood of moderate and high burden levels, whereas Northeast and West (vs South) regions as well as residence in urban (vs rural) areas decreased the likelihood of having moderate and high burden levels. Of the need factors, prior history of multiple sclerosis, neurogenic bladder, Elixhauser comorbidities, baseline co-medication use, higher BMI levels, and occasional/frequent urinary incontinence were positively associated with the likelihood of moderate and high burden, while cognitive impairment decreased the likelihood of higher burden. Overall, a dose-response relationship was observed with respect to the magnitude of association for high vs low burden compared to moderate vs low burden for all predisposing and enabling factors, and the above need factors.

INTERPRETATION OF RESULTS

Results from this national-level study using nursing home –linked Medicare data suggests that nearly 90% of LSNH residents with OAB were exposed to varying levels of anticholinergic burden. Although increasing age is often considered associated with increasing anticholinergic burden, in the present study, younger age in addition to prior history of co-medications and several comorbidities were significantly associated with moderate and or high anticholinergic burden.

CONCLUDING MESSAGE

Anticholinergic burden is prevalent among LSNH residents with OAB and raises concerns regarding prescribing practices in these patients because of the potential adverse effects of anticholinergics. Concerted efforts are needed to reduce anticholinergic burden in this population, particularly among those with underlying comorbidities.

FIGURE 1

Table 1. Logistic regression model for predictors of high/moderate (cumulative score: 90 and greater) vs low/no (cumulative score: 0-89) anticholinergic burden

Characteristics	Odds Ratio (OR)	95% CI	p-value
Predisposing factors			
Age categories			
65 – 74 years	Reference		
75 – 84 years	0.75	0.72 - 0.78	<.0001
85+ years	0.64	0.61- 0.67	<.0001
Sex			
Male	Reference		
Female	1.25	1.21-1.29	<.0001
Race/ethnicity			
Non-Hispanic White	Reference		
Non-Hispanic Black	0.74	0.70 - 0.77	<.0001
Hispanics	0.81	0.73 - 0.90	0.0001
Other	0.75	0.69 - 0.81	<.0001
Enabling characteristics			
Region			
South	Reference		
Northeast	0.89	0.86 - 0.93	<.0001
Midwest	0.99	0.96 - 1.03	0.61
West	0.82	0.78 - 0.86	<.0001
Urban-rural			
Rural	Reference		
Urban	0.83	0.81 - 0.86	<.0001
Need characteristics			
Elixhauser comorbidities			
Congestive heart failure	1.41	1.37 - 1.46	<.0001
Hypertension	1.11	1.04 - 1.19	0.003
Other neurological disorders	0.90	0.87 - 0.92	<.0001
Chronic pulmonary disease	1.14	1.10 - 1.17	<.0001
Diabetes	1.09	1.06 - 1.12	<.0001
Hypothyroidism	1.03	1.001 -1.06	0.04
Renal failure	1.02	0.99 - 1.05	0.16
Liver disease	0.98	0.94 - 1.02	0.33
Peptic ulcer	1.01	0.96 - 1.06	0.69
Rheumatoid arthritis	1.12	1.08 - 1.17	<.0001
Obesity	1.24	1.20 - 1.29	<.0001
Psychoses	1.10	1.07 – 1.13	<.0001
Depression	1.14	1.10 - 1.17	<.0001
Exposure to ACB level 2 or 3 medications	1.44	1.39 - 1.50	<.0001
Body mass index			
Underweight	Reference		
Normal weight	0.91	0.86 - 0.97	0.002
Overweight	1.14	1.10 – 1.18	<.0001
Obese	1.30	1.25 - 1.36	<.0001
Missing	0.93	0.84 -1.02	0.13
Urinary continence			
Always continent	Reference		
Occasionally incontinent	1.12	1.06 - 1.19	<.0001
Frequently incontinent	1.08	1.02 - 1.15	0.006
Always incontinent	1.04	0.97 - 1.12	0.25
Not rated	1.18	1.08 - 1.28	0.0001
Missing	1.02	0.58 -1.80	0.95
MDS Cognitive Performance Scale			
Intact	Reference		
Mild	1.02	0.90 - 1.16	0.72
Moderate	0.84	0.78 - 0.90	<.0001
Moderately severe	0.80	0.73 - 0.88	<.0001
Severe	0.69	0.66 - 0.73	<.0001
Missing	0.83	0.78 - 0.89	<.0001
Depressed mood indicator			
No	Reference		
Yes	1.10	1.03 - 1.18	0.008
Missing	1.17	1.09 - 1.26	<.0001

Abbreviations: ACB = Anticholinergic cognitive burden; ACE = Angiotensin-converting-enzyme; CI = confidence interval; MDS = Minimum Data Set; OR = odds ratio

FIGURE 2

Table 2. Multinomial logistic regression for predictors of moderate (cumulative score: 90-499) and high anticholinergic burden (cumulative score: 500 and greater) compared to low burden (cumulative score: 1-89)

Characteristics	Moderate to low burden Odds Ratio (OR)	95% CI	p-value	High to low burden (OR)	95% CI	p-value
Predisposing factors						
Age categories						
65 – 74 years	Reference					
75 – 84 years	0.82	0.78 - 0.86	<.0001	0.62	0.59 - 0.66	<.0001
85+ years	0.74	0.70 - 0.78	<.0001	0.47	0.44 - 0.49	<.0001
Sex						
Male	Reference					
Female	1.16	1.11 - 1.21	<.0001	1.40	1.33 -1.46	<.0001
Race/Ethnicity						
Non-Hispanic White	Reference					
Non-Hispanic Black	0.85	0.80 - 0.90	<.0001	0.71	0.66 - 0.76	<.0001
Hispanics	0.95	0.84 - 1.09	0.46	0.70	0.60 - 0.81	<.0001
Other	0.85	0.77 - 0.94	0.002	0.68	0.60 - 0.76	<.0001
Enabling characteristics						
Region						
South	Reference					
Northeast	0.90	0.86 - 0.94	<.0001	0.86	0.82 - 0.91	<.0001
Midwest	0.99	0.95 - 1.04	0.84	1.06	1.009 - 1.10	0.02
West	0.89	0.84 - 0.94	0.0001	0.88	0.82 - 0.94	0.0002
Urban-Rural						
Rural	Reference					
Urban	0.87	0.84 - 0.91	<.0001	0.76	0.73 - 0.79	<.0001
Need characteristics						
Elixhauser comorbidities						
Congestive heart failure	1.26	1.21 - 1.31	<.0001	1.55	1.49 - 1.62	<.0001
Hypertension	1.007	0.92 - 1.10	0.87	0.97	0.78 - 0.97	0.01
Other neurological disorders	0.93	0.89 - 0.96	<.0001	0.86	0.83 – 0.89	<.0001
Chronic pulmonary disease	1.08	1.04 - 1.12	<.0001	1.14	1.10 - 1.19	<.0001
Diabetes	1.07	1.04 - 1.11	<.0001	1.16	1.12 - 1.21	<.0001
Hypothyroidism	1.02	0.98 - 1.05	0.34	1.05	1.01 - 1.09	0.010
Renal failure	1.03	0.99 - 1.07	0.06	0.99	0.95 - 1.02	0.45
Liver disease	0.96	0.91 - 1.01	0.13	0.99	0.94 - 1.01	0.90
Peptic ulcer	0.99	0.93 - 1.07	0.96	0.98	0.91 - 1.06	0.59
Rheumatoid arthritis	1.04	0.99 - 1.09	0.09	1.15	1.09 - 1.21	<.0001
Obesity	1.17	1.12 - 1.23	<.0001	1.26	1.19 - 1.32	<.0001
Psychoses	1.04	1.001 - 1.07	0.04	1.03	0.99 - 1.07	0.19
Depression	1.08	1.04 - 1.13	0.0001	1.17	1.12 - 1.23	<.0001
Exposure to ACB level 2 or 3 medications	1.28	1.22 - 1.34	<.0001	1.52	1.45 - 1.60	<.0001
Body mass index						
Underweight	Reference					
Normal weight	0.92	0.86 - 0.99	0.03	0.99	0.91 - 1.08	0.80
Overweight	1.17	1.11 - 1.22	0.0001	1.09	1.04 - 1.15	0.0007
Obese	1.28	1.21 - 1.35	<.0001	1.31	1.23 - 1.39	<.0001
Missing	0.91	0.80 - 1.02	0.11	0.94	0.81 - 1.08	0.38
Urinary continence						
Always continent	Reference					
Occasionally incontinent	1.07	0.99 - 1.15	0.05	1.15	1.07 - 1.24	0.0002
Frequently incontinent	1.06	0.99 - 1.13	0.12	1.12	1.03 - 1.20	0.005
Always incontinent	1.03	0.94 - 1.12	0.51	1.08	0.98 - 1.18	0.13
Not rated	1.07	0.97 - 1.18	0.19	1.35	1.21 - 1.50	<.0001
Missing	0.83	0.41-1.70	0.63	0.85	0.39 - 1.82	0.67
MDS Cognitive Performance Scale						
Intact	Reference					
Mild	1.15	0.98 - 1.35	0.09	1.02	0.85 - 1.21	0.85
Moderate	0.83	0.76 - 0.91	<.0001	0.82	0.75 - 0.91	<.0001
Moderately severe	0.81	0.72 - 0.91	0.0003	0.75	0.65 - 0.85	<.0001
Severe	0.76	0.71 - 0.81	<.0001	0.65	0.60 - 0.70	<.0001
Missing	0.88	0.82 - 0.95	0.0008	0.79	0.72 - 0.86	<.0001
Depressed mood indicator						
No	Reference					
Yes	1.06	0.97 - 1.16	0.18	1.08	0.98 - 1.19	0.14
Missing	1.08	0.89 - 1.19	0.09	1.19	1.08 - 1.31	0.0005

Abbreviations: ACB = Anticholinergic cognitive burden; ACE = Angiotensin-converting-enzyme; CI = confidence interval; MDS = Minimum Data Set; OR = odds ratio

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INFLUENCE OF OPHTHALMOLOGICAL BACKGROUND ON THE SIDE EFFECTS OF OVERACTIVE BLADDER TREATMENT

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HYPOTHESIS / AIMS OF STUDY

It is advisable to consider ophthalmological disorders in women with overactive bladder (OAB) before the administration of pharmacological treatment in order to avoid iatrogenesis in ocular pathology.

Objectives: To describe the risk of dry eye or de novo conjunctivitis with different overactive bladder treatments in women.

STUDY DESIGN, MATERIALS AND METHODS

Retrospective multicenter observational study of 1203 women treated for overactive bladder (OAB) before January 1st, 2019. Patients should have undergone at least an ophthalmologic review in the last year. Patients with amaurosis, amblyopia and retinal pathology were excluded.

The patients were divided into three groups according to their ophtalmological background:

GA (n = 255): patients with OAB and non-glaucoma eye disease;

GB (n = 681): patients with OAB without ocular pathology;

GC (n = 267): patients with OAB and glaucoma.

Different OAB treatments were analysed (subgroups):

1: Onabotulinum toxinA,

2: Fesoterodine,

3: Mirabegron,

4: Oxybutynin,

5: Pelvic floor muscle training (PFMT),

6: Solifenacine,

7: Tolterodine.

Variables: age, BMI, evolution time, ASA, secondary diagnoses, eye health evolution.

Descriptive statistics, Student's t, Chi2, Fisher, ANOVA, multivariate analysis, risk analysis; p <0.05 was considered significant.

RESULTS

Mean age 64.48 years (range 19-85), lower in GB. Lower in GB; GA: average 70 years (41-82), lower in GA2: average GB 61.78 years (19-85), there were no differences in the subgroups; GC: average 66.02 years (49-78), was lower in GC1 and GC5.

In the general sample, OAB treatment does influence the appearance of de novo eye disease.

The risk of dry eye or conjunctivitis for each treatment in the general sample are:

- Fesoterodine: the risk is 0,12 less;

- Mirabregon: not significant;

- Oxybutynin: ethe risk is 0,53 less;

- PFMT: not significant;

- Solifenacine: the risk is 2,10 higher;

- Tolterodine: not significant.

* Group A: higher risk with solifenacin (7.32), fesoterodine (4.80), oxybutynin (4.26), mirabregon (2,75) and less with tolterodine (1,86).

* Group B: lower risk with oxybutynin (0,505), PFMT (0,279) and solifenacine (0,059).

* Group C: no treatment showed a statistical significant influence on the appearance of de novo ocular pathology.

Psychiatric pathology: depression (%): GA-48.78, GB-21.95, GC-29.27;

Anxiety (%): GA-71.43, GB-21.43, GC-7.14%.

Fibromyalgia (%): GA-19.23, GB-30.77, GC-50.00.

Prolapse (%): GA-5.88, GB-35.29, GC-58.82%.

INTERPRETATION OF RESULTS

It is well described that anticholinergics should be avoided in patients with high intraocular pressure, and that dry mouth and blurred vision may be disturbing side effects leading to treatment withdrawal. However, other ophthalmological disorders may also appear, like dry eye and recurrent

conjunctivitis. Patients with glaucoma received more often PFMT for this reason, and patients with other ophtalmological disorders were more frequenlty treated with anticholinergics (Solifenacine, Oxybutynin, Tolterodine and Fesoterodine). On the other side, botulinum toxin and mirabegron were more often indicated in the group of patients with no ophtalmological background, but a higher incidence of diabetes mellitus was found in this group that could influence the treatment choice.

CONCLUDING MESSAGE

After 3 months of OAB treatment, nearly half of women suffered dry eye or de novo conjunctivitis, more frequently if they had no previous ophthalmic problem. They appeared sooner with oxybutynin and later with fesoterodine and mirabegron. If patients had previous ocular pathology other than glaucoma, all OAB treatments favored dry eye or conjunctivitis, but they were more frequent with solifenacine.

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INCREASED SENSATION IN RESPONSE TO THE SIGHT OR SOUND OF RUNNING WATER IN INDIVIDUALS WITH OVERACTIVE BLADDER

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HYPOTHESIS / AIMS OF STUDY

The sight or sound of running water can trigger urinary urgency in some individuals with overactive bladder (OAB) [1]. There are limited studies investigating the effects of audio-visual stimuli on the sensation of bladder fullness. The purpose of this study was to test the hypothesis that individuals with OAB experience greater increases in bladder sensation in response to the sight and sound of running water compared to individuals without OAB.

STUDY DESIGN, MATERIALS AND METHODS

Participants were recruited into a prospective oral hydration study. Participants completed the International Consultation on Incontinence Questionnaire on OAB (ICIq-OAB), and their responses to question 5a about how often they rush to the toilet were used to divide them into groups with OAB (5a≥2) and without OAB (5a=0). Participants also completed a standardized trigger survey asking how often the sight or sound of running water makes them rush to the toilet using the same 0-4 scale as the ICIq-OAB (0=never, 1=occasionally, 2=sometimes, 3=most of the time, and 4=always). After filling out both the ICIq-OAB and trigger surveys, participants completed an oral hydration protocol with three complete bladder fill and void cycles (Fill1-Fill3). They drank 2L Gatorade G2 as quickly as possible during Fill1 and replaced the volume voided by drinking an equivalent volume of water during the beginning of Fill2 and Fill3 in order to maintain maximum diuresis. Throughout filling, participants recorded their sensation of bladder fullness on a 0%-100% scale using a previously-developed tablet-based sensation meter [2, 3]. After reaching 50% sensation during Fill1 and Fill3, participants watched a 3-minute trigger video showing sights and sounds of flushing toilets, running water, fountains, rain, waterfalls and swimming. (Fig. 1). The change in percent sensation from the beginning to the end of the trigger video was calculated for each group. Fisher's exact test was used to identify statistical associations between participant groups.

RESULTS

Trigger Survey Results: Twelve individuals without OAB and eleven individuals with OAB completed the trigger survey. All twelve individuals without OAB reported minimal responses to the sight or sound of running water (score of 0 or 1), while 10 of 11 individuals with OAB reported heightened responses (score of ≥2). A response of ≥2 was significantly associated with OAB (Fisher's exact test, $p<0.05$).

Trigger Video Results: Fourteen individuals without OAB and eleven with OAB completed the hydration study and were exposed to the trigger. Fill1 was slower than Fill3 for each group (10 vs. 17 ml/min for those without OAB, and 6 vs 14 ml/min for those with OAB, $p<0.05$). During both Fill1 and Fill3, none of the individuals without OAB exhibited an increase in sensation of ≥30% during the trigger video. In contrast, two of the eleven (18%) individuals with OAB reported a sensation increase of ≥30% during the trigger video in the slower Fill1, and four of eleven (36%) reported an increase of ≥30% during the trigger video in the faster Fill3. This increase of ≥30% in bladder sensation during the trigger video in Fill3 was significantly associated with OAB ($p<0.05$)

Correlation Between Trigger Survey and Trigger Video Results: Changes in sensation during the trigger video were also compared to trigger survey responses. All four individuals (100%) that exhibited an increase of ≥30% sensation during the trigger video in Fill3 responded with a survey score of ≥2 for the sight or sound of running water. In contrast, six of nineteen individuals (32%) that exhibited a <30% change in sensation during the trigger video in Fill3 responded with a survey score of ≥2 for the sight or sound of running water. A sensation increase of ≥30% during the trigger video was

significantly associated with greater survey responses for the sight or sound running water during Fill3 ($p<0.05$).

INTERPRETATION OF RESULTS

The results of this study suggest that some participants with OAB may have heightened sensation due to audio-visual stimuli of running water compared to individuals without OAB. Heightened responses to the trigger video of running water correlated with the trigger survey question results, indicating that individuals are aware of their sensitivity to this environmental trigger of urgency.

CONCLUDING MESSAGE

The results of this study indicate that the incorporation of environmental triggers into a non-invasive hydration protocol may help identify an OAB subgroup affected by triggers of urgency such as the sight or sound of running water. Further research is needed to understand the effects of environmental triggers on bladder sensation in individuals with OAB.

FIGURE 1

Fig1. Screen-shots of a flushing toilet, waterfall, running water and fountain included in the 3-minute trigger video.

Figure 1

REFERENCES

1. O'Connell, K.A., J. Singer, and S. Rajan, Stimulus-associated urinary urges in overactive bladder syndrome. Neurourol Urodyn, 2018. 37(1): p. 284-290.
2. Nagle, A.S., et al., Non-invasive characterization of real-time bladder sensation using accelerated hydration and a novel sensation meter: An initial experience. Neurourology and Urodynamics, 2017. 36(5): p. 1417-1426.
3. Sheen, D., et al., Validation of a real-time bladder sensation meter during oral hydration in healthy adults: Repeatability and effects of fill rate and ultrasound probe pressure. LUTS: Low Urinary Tract Symptoms, 2019. 11(4): p. 224-231.

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THE OVERACTIVE BLADDER BIOMECHANICAL SPECTRUM: A METHOD FOR PINPOINTING AN INDIVIDUAL BASED ON DYNAMIC ELASTICITY AND SPONTANEOUS RHYTHMIC CONTRACTIONS DURING FILLING

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HYPOTHESIS / AIMS OF STUDY

Overactive bladder (OAB) is a multi-factorial progressive syndrome [1] in many individuals, and the severity is quantified using voiding diaries and validated, subjective questionnaires. However, there is no currently available objective method to identify the degree of OAB. Recent studies have used signal analysis techniques such as Fast Fourier Transform (FFT) analysis to objectively quantify the amplitude and frequency of spontaneously rhythmic contractions identified as Detrusor Overactivity (DO) [2]. Furthermore, comparative-fill urodynamics has been used to identify and quantify acute dynamic elasticity that is present in individuals without DO and diminished or absent in individuals with DO [3]. Dynamic elasticity is characterized by a reduction in vesical pressure (Pves) (loss of elasticity) during a bladder fill due to strain-induced stress softening (strain softening) caused by previous filling and passive emptying of the bladder, and a return of Pves (restoration of elasticity) during a fill caused by active voiding during the previous fill [3]. The purpose of the present study was to develop a method to pinpoint an individual on an OAB spectrum based on both their level of dynamic elasticity and the magnitude of any rhythmic contractile activity.

STUDY DESIGN, MATERIALS AND METHODS

Participants with and without OAB were recruited into a prospective comparative-fill urodynamics study. OAB was determined based on response to the urgency question (Question 5A) of International Consultation on Incontinence Questionnaire on OAB (ICIq-OAB). The urgency question asks "How often do you have to rush to the toilet to urinate?" Individuals were considered to have OAB if $5a \geq 3$ and considered to have no OAB if $5a=0$. In the study two biomechanical properties of the bladder were calculated for each participant: the dynamic elasticity index and the maximum rhythmic amplitude. The dynamic elasticity index was calculated using previously published methods [3] by measuring pre-strain-softening pressure, post-strain softening pressure, and reversal pressure in comparative urodynamic fills. The dynamic elasticity index was defined as the sum of the loss in Pves due to strain

softening (pre - post) and the gain in Pves due to restoration of elasticity (reversal - post) divided by the change in percent capacity used to cause strain softening in the protocol (40% capacity). The maximum rhythmic amplitude of Pves was determined in the frequency range 1.75 and 8.0 cycles/minute for each participant using a previously developed FFT algorithm [2]. For each participant, maximum rhythmic amplitude was plotted on the Y-Axis and the dynamic elasticity index was plotted on the X-Axis.

RESULTS

Based on responses to the ICIq-OAB 5a question, there were 13 participants with OAB and 15 without OAB. The average dynamic elasticity index was 0.03±0.05 cm-H2O/%capacity (range -0.36 to 0.32 cm-H2O/%capacity) for participants with OAB and 0.08±0.04 cm-H2O/%capacity (range -0.23 to 0.39 cm-H2O/%capacity) for individuals without OAB. Average rhythmic amplitude participants with OAB was 2.3±0.4 cm-H2O (range 0.8 to 5.5 cm-H2O) and 1.6±0.5 cm-H2O (range 0.2 to 7.4 cm-H2O) for participants without OAB. The combined plot generates a widely distributed spectrum (Fig1A and Fig1C) for participants with OAB which appears more narrowly distributed in participants without OAB (Fig1B and Fig1C). When both datasets were analyzed together, those with maximum rhythmic amplitude >1 cm-H2O were more likely to have OAB (Fig1C, above horizontal blue line, p=0.006).

INTERPRETATION OF RESULTS

When the dynamic elasticity index is plotted against the maximal Pves rhythmic amplitude obtained from comparative fill urodynamics, individuals with OAB appear to be more widely distributed, creating an OAB spectrum. This spectrum allows an individual's position on the spectrum to be pinpointed objectively. In contrast, individuals without OAB appear to have a narrower distribution, highlighting the potential benefit of the OAB spectrum.

CONCLUDING MESSAGE

The generation of an OAB spectrum using bladder biomechanical properties of the dynamic elasticity index and the maximum Pves rhythmic amplitude obtained from comparative fill urodynamics may enable improved phenotyping of individuals with OAB. However, further research will be required to determine the clinical utility of this novel OAB spectrum.

FIGURE 1

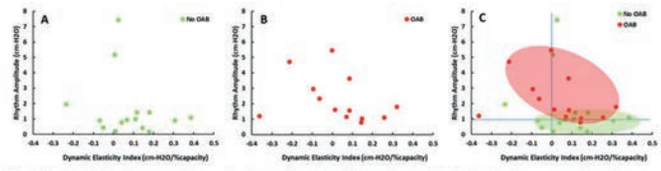

Fig 1. Plots of rhythmic contractile amplitude as a function of dynamic elasticity index for the groups of participants (A) without OAB, (B) with OAB and (C) both with and without OAB. The group without OAB is primarily clustered in the lower right portion of the graph (A and green ellipse in C). In contrast, the group with OAB covers a larger area closer to the center of the graph (B and red ellipse in C).

REFERENCES

1. Zhou F, Newman DK, Palmer MH. Urinary Urgency in Working Women: What Factors Are Associated with Urinary Urgency Progression? Journal of Women's Health (2002). 2018;27(5):575-583.
2. Cullingsworth ZE, Kelly BB, Deebel NA, Colhoun AF, Nagle AS, Klausner AP, Speich JE. Automated quantification of low amplitude rhythmic contractions (LARC) during real-world urodynamics identifies a potential detrusor overactivity subgroup. PLoS One. 2018;13(8):e0201594.
3. Cullingsworth ZE, Klausner AP, Li R, Nagle AS, Carroll AW, Roseman JT, 2nd, Speich JE. Comparative-fill urodynamics in individuals with and without detrusor overactivity supports a conceptual model for dynamic elasticity regulation. Neurourol Urodyn. 2019, DOI:10.1002/nau.24255.

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IMPACT OF BOTULINUM TOXIN-A ADD ON FOR WOMEN WITH REFRACTORY INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME SCHEDULED FOR HYALURONIC ACID INSTILLATION: IMPROVEMENT CRITERIA AND QUALITY OF LIFE

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HYPOTHESIS / AIMS OF STUDY

Interstitial cystitis/ Bladder Pain Syndrome (IC/BPS) is a chronic progressive disease of unknown etiology, characterized by pelvic pain accompanied by urinary storage Symptoms (urgency, frequency and nocturia) (1). The most accepted potential mechanism leading to IC/BPS is Injury or dysfunction of the glycosaminoglycan (GAG) layer of the urothelium with diffusion of urine toxins leading to sensory nerve activation, mast cell stimulation and bladder inflammation (1).

Intravesical instillation of Hyaluronic Acid (HA) has been proposed as a possible treatment of IC/BPS. HA may promote regeneration of GAG layer. Moreover, HA seems to have inhibitory action on mast cell degranulation (1). HA is weekly installed in the bladder till significant improvement of symptoms, which takes several weeks to achieve (1).

On the other hand, botulinum toxin-A is a fast effective well-tolerated, and safe treatment modality for patients with IC/BPS. It has very good outcomes in controlling pain symptoms and treating bladder ulcers (2). As the botulinum toxin-A effect does not exceed nine months, 88% of cases need to repeat the procedure (2).

The effects of Interstitial cystitis/ Bladder Pain Syndrome (IC/BPS) on psychological functioning and quality of life (QoL) are prevalent, insidious and damaging. Patients of IC/BPS have significant pelvic pain, sleep dysfunction, depression, anxiety and poor quality of life (3).

The aim of the present study is to evaluate the improvement criteria and Quality of life changes of combined intravesical injection of Botulinum Toxin-A with Hyaluronic Acid instillation for women complaining of refractory Interstitial Cystitis/ Bladder syndrome. A prospective randomized study.

STUDY DESIGN, MATERIALS AND METHODS

Between January 2017 till December 2019, thirty four women with IC/BPS according to the European Society for the Study of Interstitial Cystitis (ESSIC)(3) were enrolled in the present study. Eligible participants were at least 18 years old with self reported bothering urinary frequency, nocturia, urgency and pelvic pain for at least 6 months.

Exclusion criteria included pregnancy, urogenital problems (congenital anomalies, infection or stones), malignancy, or concomitant anti-coagulants.

Following the University ethical standards and a clear written consent, all women were evaluated clinically with routine laboratory tests and abdomino-pelvic ultrasound. Cystoscope with hydrodistension was carried out at least one month before starting the treatment regimens. Bladder biopsy was taken in some cases (11 cases) with suspicious bladder granulation.

The study cases were randomly divided into two groups. 17 women each group. All cases treated with intravesical instillation of 40 mg/50 ml of Hyaluronic acid every two weeks for twelve sessions. Patients of group (I) the first session was intra-vesical injection of 200 units of botulinum toxin-A (BTX-A) under local anesthesia. The 200 units BTX-A injected submucosally in 20 points of the superficial muscles of the bladder including the trigone. The second treatment session of group (I) (after 2 weeks) continue as group (II) protocol; (12) HA instillation every two weeks. All cases were evaluated after two weeks for any side effects or co-incidental morbidity

All cases of the present series were asked to fill in the following questionnaires before treatment, at the 3rd month follow up visit and at the end of study (6 months). These include, voiding diaries for 4 days, pelvic pain on visual analogue scale (0-10 VAS), International Cystitis Symptom Index and Problem Index (ICSI & ICPI), the Pelvic Pain Urgency/ Frequency Patient Symptom Scale (PUF) , as well as, the candidates quality of life, using Patient Health Questionnaire-9 (PHQ-9) (1).

Sample size was calculated from web site: clinical.com/stats/samplesize.aspx. Statistical analysis was performed with the student t-test, where $p<0.05$ was considered significant (IBM SPSS statistics).

RESULTS

A total of thirty four women (age ranged 37-63 years) completed the study, 17 patients each group. The bladder pathological study (11 biopsies) showed no abnormality away from inflammatory and mast cells infiltration. No cases of intolerance, side effects or complications were observed.

All patients of the present study completed the entire treatment protocol, as well as, the entire questionnaires; before treatment, after 3 months and at the end of treatment (6 months). On analyzing the mean values of pelvic pain scale on VAS, as well as, ICSI, ICPI, PUF and PHQ-9 questionnaires, a statistically significant improvement after treatment was reported at 3rd and 6th month evaluation in both groups compared with baseline (table,1). Moreover, there is reported faster and higher improvement in group (I) than group (II) women (table, 1).

In particular, the pain severity (VAS) was significantly decreased from 8.47 ± 1.49 to 3.88 ± 2.42 to 2.88 ± 2.13 among group (I) cases at 3 ($p=0.027$) and 6 month ($p=0.032$) follow up visits respectively. Also, pain score (VAS) significantly decreased from 8.62 ± 1.28 to 5.76 ± 1.43 to 4.32 ± 2.62 among group (II) cases after 3 ($p=0.041$) and 6 ($p=0.009$) months treatment. Moreover, there was significant lower pain criteria (VAS) among group (I) cases (BTX-A + HA) than group (II) women (HA alone) at 3 ($p=0.041$) and 6 months ($p=0.022$) (figure 1).

Furthermore, during studying patients quality of life using PHQ-9, it improved significantly from 9.65 ± 2.27 to 6.88 ± 1.91 to 5.71 ± 1.52 in group (I) women after 3 ($p=0.0002$) and 6 ($p=0.020$) months treatment respectively. Also, PHQ-9 improved for group (II) cases from 9.82 ± 2.06 to 8.24 ± 1.79 to 7.94 ± 1.92 at 3 ($p=0.007$) and 6 month ($p=0.0007$) evaluation respectively. Moreover, we reported highly significant improvement of patients quality of life (better PHQ-9) for

group (I) cases compared to group (II) at 3 (p=0.014) and 6 months (p=0.0005) (figure, 1)

INTERPRETATION OF RESULTS

Hyaluronic acid intravesical instillation alone, was successful in management of pain and bladder storage symptoms for cases complaining of refractory interstitial cystitis/ bladder pain syndrome. Adding Botulinum Toxin-A in the present study gave significantly faster and higher outcomes of pain relief, bladder storage symptoms improvement, as well as, significant improvement of quality of life than Hyaluronic acid alone.

CONCLUDING MESSAGE

In the current study, combination of Botulinum Toxin-A injection with Hyaluronic Acid instillation in the treatment of refractory Interstitial Cystitis/Bladder Pain Syndrome seems to give significantly faster, higher and satisfactory pelvic pain relief and urinary bothers and complaints improvement than Hyaluronic Acid alone. Moreover, the statistically significant improvement of quality of life among women received, Botulinum Toxin-A plus Hyaluronic Acid gave us solid lead for treatment strategy of refractory Interstitial Cystitis/Bladder Pain Syndrome.

FIGURE 1

Table (1): Reported data of the candidates of both groups (17 cases each), pre-treatment, at 3 month visit and post-treatment.

	Pre-treatment	3 month	6 month Post-treatment	p pre/post 6 month treatment	p Gp I / II post treatment
VAS (Gp I)	8.47 ± 1.49	3.88 ± 2.42	2.88 ± 2.13	0.032	
VAS (Gp II)	8.62 ± 1.28	5.76 ± 1.43	4.23 ± 2.62	0.009	0.022
VV (Gp I)	150.93 ± 26.41	185.62 ± 27.14	188.12 ± 39.92	0.002	
VV (Gp II)	149.88 ± 27.86	162.81 ± 24.04	177.81 ± 26.51	0.033	0.019
Freq. (Gp I)	16.05 ± 2.41	11.70 ± 2.21	10.41 ± 1.28	0.010	
Freq. (Gp II)	15.35 ± 2.47	12.88 ± 2.11	12.29 ± 2.02	0.0002	0.001
ICSI (Gp I)	15.35 ± 3.42	10.52 ± 2.59	7.41 ± 2.22	0.012	
ICSI (Gp II)	15.70 ± 3.33	12.53 ± 2.93	11.12 ± 2.88	0.0007	0.0008
ICPI (Gp I)	13.12 ± 2.69	7.76 ± 2.01	6.17 ± 2.03	0.007	
ICPI (Gp II)	13.52 ± 2.45	9.53 ± 2.06	8.64 ± 1.78	0.036	0.009
PUF (Gp I)	20.35 ± 3.14	13.76 ± 3.00	11.88 ± 2.61	0.0004	
PUF (Gp II)	20.12 ± 3.39	16.82 ± 2.55	15.71 ± 3.06	0.001	0.001
PHQ (Gp I)	9.65 ± 2.27	6.88 ± 1.91	5.71 ± 1.52	0.020	
PHQ (GP II)	9.82 ± 2.06	8.24 ± 1.79	7.94 ± 1.92	0.0007	0.0005

VAS: visual analogue scale, VV: voiding volume, ICSI: interstitial cystitis symptom index, ICPI: interstitial cystitis problem index, PUF: urgency/ frequency patient symptom scale, PHQ-9: patient health questionnaire-9

FIGURE 2

Figure (1): Significant improvement of pelvic pain (VAS) among Group (I) women (blue) compared to Group (II) cases (green) at 3 and 6 months. Also, better improvement of quality of life (PHQ-9) of Group (I) cases (yellow) than Group (II) candidates (red) at 3 and 6 month follow up

1,491 words

REFERENCES

1. Hung MJ, Tsai CP, Lin YH et al: Hyaluronic acid improves pain symptoms more than bladder storage symptoms in women with interstitial cystitis. Taiwanese J Obst & Gynec, 58: 417-422, 2019
2. Al-Mousa R, Alswayan Y, Alfadagh et al: Efficacy, complications and tolarability of repeated intravesical botulinum toxin-A injections in interstitial cystitis/ bladder pain syndrome. Arab J Urol (16) 10.54, 2018 Ft Abrams P, Anderson I, Birder I et al: 4th
3. Ft Abrams P, Anderson I, Birder I et al: 4th International Consultation on Incontinence: Recommendations of the International Scientific Committee: Evaluation and Treatment of Urinary Incontinence, Pelvic Organ Prolapse and Faecal Incontinence. 2009

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SESSION 30 (PODIUM SHORT ORAL) - NEW FRONTIERS
Abstracts 451-462
09:00 - 10:30, Brasilia 2
Chair: Dr Margot Damaser (United States)

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DETERMINANTS OF CONTRACTILE FUNCTION OF THE BLADDER WALL FROM CHILDREN WITH CONGENITAL ANOMALIES

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HYPOTHESIS / AIMS OF STUDY

Congenital anomalies associated with the lower urinary tract, such as posterior urethral valves (PUV), neuropathic bladders (i.e. myelomeningocoele) and bladder exstrophy, have long-term effects on bladder function, despite advances in surgical treatment and patient management. Preliminary work with biopsy samples from exstrophy bladders undergoing secondary repair showed extensive tissue fibrosis and its replacement of smooth muscle. However, there is no evidence of contractile failure of the remaining smooth muscle [1]. The underlying reason for the failure of bladder function associated with other congenital anomalies remains unknown. We hypothesised that increased fibrosis is a significant cause of bladder contractile failure for a range of congenital anomalies. This was tested with in vitro experiments on detrusor from children with and without congenital anomalies by comparing the magnitude of contractile responses and histological measurement of smooth muscle and connective tissue content.

STUDY DESIGN, MATERIALS AND METHODS

Bladder biopsy samples were from six patient cohorts: i) normal bladder function (ureteric implantation, excision of urachal cysts: n=14; 8 male, 6 female; median age 33 months); ii) PUV (n=12; all male; median age 61 months); iii) neuropathic bladder (n=10; 7 male, 3 female; median age 76 months); iv) secondary procedures for exstrophy repair (n=18; 12 male, 6 female; median age 81 months); v) primary exstrophy repair (n=5; 4 male, 1 female; 1-3 days); vi) cloacal anomaly (n=4; all female; median age 65 months). Ages were statistically similar for all cohorts, except those for primary exstrophy repair. Biopsy samples were cut from the lateral bladder wall, the mucosa removed and placed in Ca-free Tyrode's solution.

A strip was immediately dissected (≈1 mm diam; 5 mm length) for functional experiments and any remaining tissue placed in 10% formaldehyde solution for histology. The muscle strip was superfused with Tyrode's solution (including 24 mM $NaHCO_3$/5% CO_2, pH 7.4, 36°C) and isometric contractions recorded. Nerve-mediated contractions (abolished by 1 µM tetrodotoxin) were generated by electrical field stimulation (EFS) with 0.1 ms pulses delivered in 3-s trains at 1-24 Hz. Contractures to the cholinergic receptor agonist carbachol (0.1-30 µM) or the purinergic (P2X1) receptor agonist alpha, beta, ß-methylene ATP (ABMA, 10 µM) were generated in unstimulated preparations. Contraction magnitudes were normalised to cross-section area and quoted as mN.mm-2. Fixed samples were dehydrated, mounted in paraffin blocks: 5 µm sections were mounted on TESPA-coated glass slides and stained with Elastin van Gieson (collagen, red; elastin, black; muscle yellow/orange). Smooth muscle and connective tissue (collagen/elastin) areas were measured with colour filters in the Image-J program. Three separate regions (50x50 µm) were analysed and the average used.

Data are mean ± SEM (n=number of biopsies). Multiple data sets were analysed by ANOVA with Dunnett post-hoc tests to compare against data from normal bladders. A Spearman rank-order correlation coefficient, r, was calculated to assess association between variables. Force-frequency or concentration-response curves were fitted to: T=(Tmax.x^m)/(x^m+k^m); Tmax is the maximum response at high stimulation frequency (f) or agonist concentration (S); x is the different values of f or S; k is the value of x (frequency or carbachol concentration) required to achieve Tmax/2; m is a constant (^ represents raised to the power of m). Curve-fitting used an iterative program (KaleidaGraph) to estimate Tmax and k values. k-values for carbachol are equivalent to EC50 values and are expressed as pEC50 (=-logEC50).

RESULTS

Maximum contractions (Tmax) to EFS (figure 1A) or carbachol stimulation (figure 1B) were reduced in preparations from all congenital anomalies, except for cloacal anomaly, when compared to data from functionally normal bladders. The frequency-dependence of EFS contractions was similar in all preparations, as assessed by similar values of k. The concentration-dependence to carbachol was also similar in all preparations, as assessed by pEC50 values, except for samples from neuropathic bladders where carbachol was more potent (pEC50 values greater; figure 1C). Contractile responses to 10 µM ABMA showed a similar profile to those with carbachol, i.e. smaller in preparations from all congenital anomaly patients, except for those with cloacal anomaly. Atropine-resistant EFS contractions, at 16 Hz stimulation, were recorded in samples from all cohorts and the percentages of the contraction in the absence of atropine were all similar (figure 1D). The smooth muscle:connective tissue (SM:CT) ratios were greatest in detrusor from normal bladder function (2.29±0.37) and cloacal anomaly (2.12±0.40) cohorts, reduced to statistically similar values in the PUV (0.86±0.17), neuropathic (1.20±0.20) and secondary exstro-

phy (0.56±0.07) cohorts and to even smaller values for the neonatal exstrophy (0.18±0.04) cohort. A plot of EFS Tmax values as a function of SM:CT ratio (fig 2) showed a high degree of positive association between the SM:CT ratio and contraction magnitude (r=0.95, p<0.05, n=7), or a coefficient of determination (r^2) of 88%.

INTERPRETATION OF RESULTS

Reduced contractile function is a feature of detrusor smooth muscle obtained from children with a range of congenital disorders, except for cloacal anomaly. Reduced function was observed whether contractions to agonists (carbachol or ABMA) or excitation of embedded nerves was used. It is therefore unlikely that a particular pathway in contractile activation was attenuated as the normalised reduction of force was similar in all modalities. However, there was a significant association between contraction magnitude and proportion of smooth muscle in the biopsy samples. The value for the coefficient of determination between contraction magnitude and SM:CT ratio was 88%. This may be interpreted as replacement of smooth muscle with connective tissue accounts for the great majority of the loss of contractile function. Such an importance of this single factor to account for contractile dysfunction in this group of patients suggests that an understanding of why increased deposition of connective tissue occurs and how it may be avoided or reversed is of paramount importance.

CONCLUDING MESSAGE

The most important determinant of reduced contractile function in detrusor samples from children with congenital anomalies is loss of muscle tissue and replacement by connective tissue. Therapeutic strategies to reduce connective tissue content should be an effective way to improve bladder function in these patients.

FIGURE 1

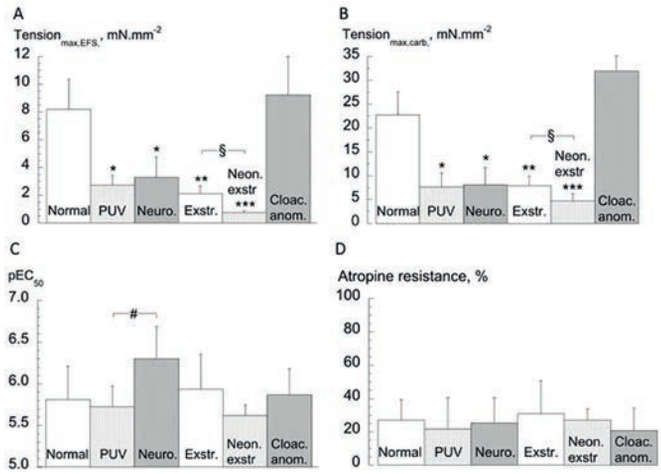

Figure 1. Contractile properties of detrusor from children with congenital anomalies. A: Maximum nerve-mediated contractions to electrical field stimulation ($Tension_{max,EFS}$). B: Maximum contractions to carbachol ($Tension_{max,carb}$). C: pEC_{50} values to carbachol. D: atropine resistance of EFS contractions at 16 Hz stimulation. Abbreviations: PUV, posterior urethral valves; Neuro., neuropathic bladders; Exstr., secondary repair of bladder exstrophy; Neon. exstr, neonatal exstrophy; Cloac. anom, cloacal anomaly. Mean data±SEM (*n* values in Methods); *p<0.05, ** p<0.01, *** p<0.005 *vs* normal; § p<0.05 neonatal vs secondary exstrophy; # p<0.05 neuropathic *vs* PUV.

Figure 1

FIGURE 2

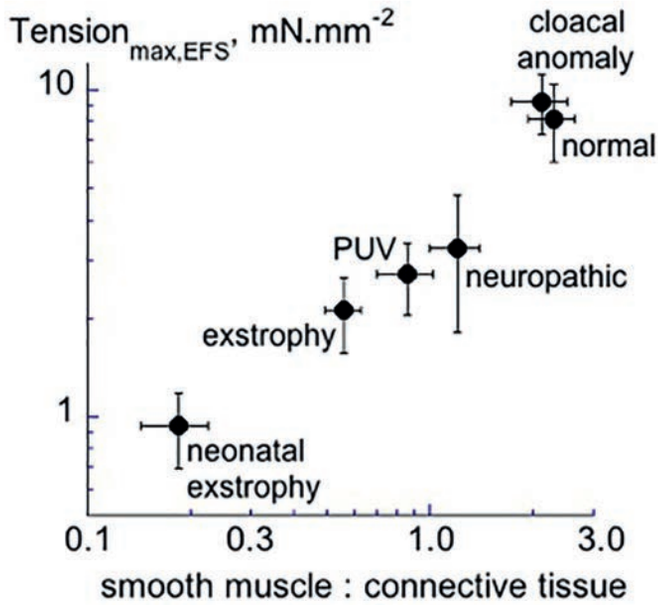

Figure 2: The relationship between maximum nerve-mediated contraction magnitude and the smooth muscle:connective tissue ratio. Mean data ± SEM (*n* values in Methods): note logarithmic axes

Figure 2

REFERENCES

1. Johal NS, Arthurs C, Cuckow P, Cao K, Wood DN, Ahmed A, Fry CH. J Pediatr Urol 2019; 15: 154.e1-154.e9.

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CHANGES WITH AGE OF HYDROGEN SULFIDE-INDUCED RELAXATION OF THE BLADDER IN SPONTANEOUSLY HYPERTENSIVE RATS

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HYPOTHESIS / AIMS OF STUDY

Hydrogen sulfide (H2S), an endogenous gasotransmitter, has a wide range of physiological functions including neuromodulation, vasorelaxation and cytoprotection. H2S is endogenously produced by three enzymes, cystathionine β-synthase (CBS), cystathionine γ-lyase (CSE) and 3-mercaptopyruvate sulfurtransferase (MPST). CBS and CSE produce H2S from L-cysteine, while MPST produces H2S from 3-mercaptopyruvate, which is synthesized from L-cysteine by cysteine aminotransferase (CAT) (CAT/MPST pathway). We previously reported that (1) at least the CAT/MPST pathway-mediated endogenous H2S production was working in the rat bladder tissues, (2) NaHS, an H2S donor, induced relaxation of pre-contracted the rat bladder tissue strips and (3) intravesically instilled GYY4137, an H2S donor, suppressed the rat micturition reflex [1]. These findings indicate a possibility that H2S can function as an endogenous relaxation factor in the rat bladder.

Recently, bladder ischemia induced by chronic hypertension has been recognized as an etiologic factor of lower urinary tract dysfunctions including overactive bladder and detrusor overactivity (DO). The spontaneously hypertensive rat (SHR) develops DO and shows frequent urination compared with a normotensive control. We recently reported that H2S donors-induced bladder relaxation and suppression of the micturition reflex were attenuated in SHRs at 18 weeks of age compared with age-matched normotensive Wistar rats [2]. On the other hand, SHRs are reported to show DO after a certain age, at lease at 17 and 21 weeks of age but not at 12 weeks of age [3] although hypertension is already detected at each age, indicating that hypertension-mediated bladder dysfunctions may be detected after hypertension is developed. Therefore, we hypothesized that responses to exogenous H2S and levels of the endogenous H2S system in the SHR bladder might be different with age. In this study, we compared effects of GYY4137 and NaHS on the micturition reflex and on the bladder contractility, and the endogenous H2S system in the bladder of SHRs at between 12 and 18 weeks of age (12W and 18W).

STUDY DESIGN, MATERIALS AND METHODS

Male SHRs at 12W and 18W were used.

(1) Under urethane anesthesia (0.8 g/kg, ip), a catheter was inserted into the bladder from the dome to instill reagents (2.4 ml/h) and to measure intravesical pressure. After detecting 4-5 micturition reflexes induced by saline instillation, GYY4137 solution (10-8, 10-7, and 10-6 M) or vehicle was instilled.

(2) Bladder dome (BL-D) and trigone (BL-T) were prepared from these rats sacrificed with an overdose of sodium pentobarbital (80 mg/kg, ip). By using 1 x 5 mm strips of the bladder, effects of NaHS (1 x 10-8 to 3 x 10-4 M) were evaluated on pre-contracted bladder strips by carbachol (10-5 M). Tissue H2S content was measured by the methylene blue method. Expression levels of CBS, CSE, CAT and MPST in the bladder tissues were investigated by Western blot.

RESULTS

(1) The baseline values of intercontraction intervals (ICI) (sec, means ± SEM) just before intravesical instillation of vehicle or GYY4137 were 916±75 at 12W (n=16) and 1324±135 at 18W (n=14). The values of SHRs at 12W were significantly shorter than those at 18W ($P<0.05$). GYY4137 significantly prolonged ICI compared to the vehicle-treated group at 12W, but not at 18W (Fig. 1).

(2) NaHS-induced relaxation on pre-contracted BL-D and BL-T strips was significantly attenuated in SHRs at 18W compared with SHRs at 12W (Table 1). The H2S content in the BL-D of SHRs at 18W was significantly higher than that at 12W (Fig. 2A). CBS, MPST and CAT, but not CSE, were detected in the bladder of SHRs at both ages (Fig. 2B). The expression levels of CBS, MPST and CAT in the SHR BL-D at 18W were significantly higher than those at 12W (Fig. 2B).

INTERPRETATION OF RESULTS

Basal values of ICI in SHRs at 18W was prolonged compared with those at 12W in line with a previous report by another group [3]. The group also reported higher bladder capacity and single voided volume in SHRs at 18W than those at 12W [3]. These lines of evidence suggest that SHRs might begin to show chronic hypertension-mediated morphological changes such as hypertrophy in the bladder after a certain age. Intravesically instilled GYY4137 prolonged ICI in SHRs at 12W and NaHS relaxed pre-contracted bladder strips of SHRs at 12W, while these H2S donors-induced changes were not detected in SHRs at 18W. These results suggest that the GYY4137-induced inhibition of the micturition reflex in SHRs at 12W might be mediated at least by relaxation of the bladder smooth muscle, and sensitivity to H2S-induced bladder relaxation in SHRs might have a close relationship with aging. Compared with bladder tissues from SHRs at 12W, higher H2S content and increased protein expression of CBS, MPST and CAT were detected in bladder tissues from SHRs at

18W. These data indicate that the endogenous H2S system might be upregulated to compensate the attenuated relaxation response to H2S in the SHR bladder after a certain age.

CONCLUDING MESSAGE

H2S-induced bladder relaxation in SHRs can be impaired in an age-dependent manner, and to compensate the less responsiveness, endogenous H2S levels are increased in the SHR bladder after a certain age. Therefore, early intervention to the endogenous H2S system in SHRs may be prevent the development of hypertension-mediated bladder dysfunctions.

FIGURE 1

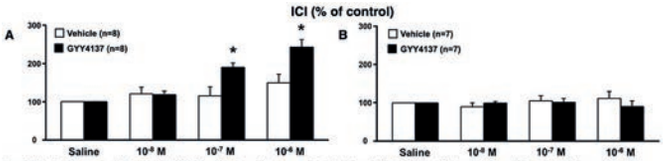

Fig. 1. Effect of intravesically instilled GYY4137 (an H_2S donor) on intercontraction intervals (ICI) in SHRs at 12 weeks (A) and 18 weeks (B) of age. Data were calculated as the ratio to the control values (Saline) before GYY4137 or vehicle instillation. Data were shown as means ± SEM. *P<0.05, significantly different from the Vehicle group (unpaired Student t-test).
Vehicle; 3.3 × 10^{-5}% *N,N*-dimethylformamide/saline. H_2S, hydrogen sulfide; SHR, spontaneously hypertensive rat.

Table 1. Data from functional studies in the SHR bladder tissues

Group	Relaxation rate (%)	EC_{50} (M)
BL-D		
12W	76.2 ± 5.4	4.8 ± 1.3 (× 10^{-2})
18W	47.5 ± 5.9*	2.6 ± 1.0 (× 10^{-2})
BL-T		
12W	83.2 ± 5.2	5.0 ± 1.2 (× 10^{-2})
18W	60.4 ± 8.1*	4.0 ± 1.2 (× 10^{-2})

Values are means ± SEM (n=12). NaHS (an H_2S donor, 1x10^{-6} to 3x10^{-4} M) was administered on the SHR BL-D and BL-T strips pre-contracted by carbachol (10^{-6} M). *P<0.05, significantly different from the 12W group (unpaired Student t-test). BL-D, bladder dome; BL-T, bladder trigone; H_2S, hydrogen sulfide; SHR, spontaneously hypertensive rat; 12W, SHRs at 12 weeks of age; 18W, SHRs at 18 weeks of age.

FIGURE 2

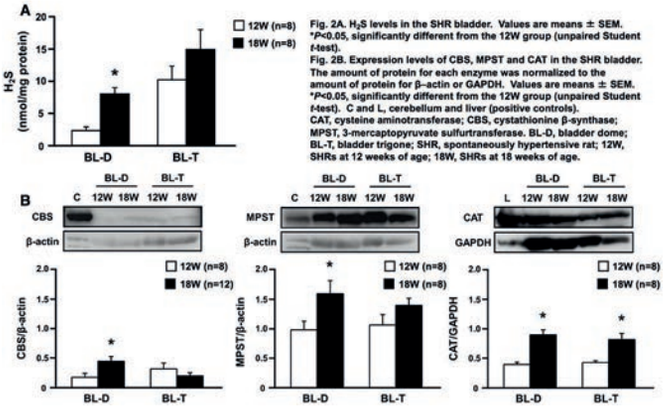

Fig. 2A. H_2S levels in the SHR bladder. Values are means ± SEM. *P<0.05, significantly different from the 12W group (unpaired Student t-test).
Fig. 2B. Expression levels of CBS, MPST and CAT in the SHR bladder. The amount of protein for each enzyme was normalized to the amount of protein for β-actin or GAPDH. Values are means ± SEM. *P<0.05, significantly different from the 12W group (unpaired Student t-test). C and L, cerebellum and liver (positive controls). CAT, cysteine aminotransferase; CBS, cystathionine β-synthase; MPST, 3-mercaptopyruvate sulfurtransferase. BL-D, bladder dome; BL-T, bladder trigone; SHR, spontaneously hypertensive rat; 12W, SHRs at 12 weeks of age; 18W, SHRs at 18 weeks of age.

REFERENCES

1. Zou S, Shimizu T, Shimizu S, et al. Possible role of hydrogen sulfide as an endogenous relaxation factor in the rat bladder and prostate. Neurourol Urodyn. 2018;37:2519-2526.
2. Zou S, Shimizu T, Yamamoto M, et al. Hydrogen sulfide-induced relaxation of the bladder is attenuated in spontaneously hypertensive rats. Int Urol Nephrol. 2019;51:1507-1515.
3. Jin JH, Lee HJ, Shin HY et al. Development and changes with age of detrusor overactivity in spontaneous hypertensive rats as observed by simultaneous registrations of intravesical and intraabdominal pressures. Int Neurourol J. 2011;15:192-198.

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Clinical Trial No **Subjects** Animal **Species** Rat **Ethics Committee** The Kochi University Institutional Animal Care and Use Committee

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INCREASED EXPRESSION OF CALCIUM-ACTIVATED CHLORIDE CHANNELS ON THE SMOOTH MUSCLE IN METABOLIC SYNDROME INDUCED OVERACTIVE BLADDER AND UNDERACTIVE BLADDER IN RATS

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HYPOTHESIS / AIMS OF STUDY

Our previous study has demonstrated the important role of chloride channels on the regulation of urinary bladder smooth muscle tone. We investigated the differences in functional expressions of calcium-activated chloride channels (CaCCs) on bladder smooth muscle (SM) among normal, and metabolic syndrome (Mets) induced overactive bladder (OAB) and underactive bladder (UAB) rats.

STUDY DESIGN, MATERIALS AND METHODS

Fructose feeding rats (FFRs) were fed a fructose rich diet while control animals received standard rat chow for 6 months. After collecting the urine samples for measurement of urinary nerve growth factor (NGF) and brain-derived neurotrophic factor (BDNF), continuous infusion cystometry (CMG) was performed. Then the bladder SM tissues were harvested for protein and mRNA expressions of CLCA4 and ANO1 chloride channels using western blot analysis and reverse transcription-polymerase chain reaction (RT-PCR). Based on the results of CMG at month 6, FFRs were categorized into NDF (normal detrusor function), OAB and UAB groups. The CMG parameters, urine NGF and BDNF levels, molecular expressions of CaCCs were compared among rats in control, NDF, OAB and UAB groups.

RESULTS

The body weight, bladder weight, serum glucose, insulin levels and insulin resistance increased significantly in FFR rats, proving the status of Mets. Among them, the serum glucose level and insulin resistance increased most in UAB group (Fig 1). When compared with control group, both urine NGF and BDNF levels increased significantly in OAB and UAB groups. However, the increases were significantly higher in OAB than in UAB groups. Western blot analysis showed significantly increased expressions of CLCA4 and ANO1 proteins on rat

bladder SM in OAB and UAB groups (Fig 2). Also, the increases were significantly higher in OAB than in UAB groups. Quantitative RT-PCR analysis demonstrated significantly increased expressions of the mRNA for CLCA4 and ANO1 in OAB and UAB groups. There was no significant change of urine NGF, BDNF levels, or molecular expressions of CaCCs on bladder SM in NDF group.

INTERPRETATION OF RESULTS

The changes of body weight, bladder weight, serum glucose, insulin levels and insulin resistance showed the effectiveness of FFR on induction of Mets in rats. The significant increase of serum glucose level and the highest increase of insulin resistance in UAB group indicated UAB group may represent the most severe condition of Mets. In OAB group, the urine NGF and BDNF levels were highest among all groups, while in UAB group, the levels were lower than OAB but still higher than control group. Meanwhile, the changes of expressions in CLCA4 and ANO1 chloride channel proteins and mRNA were parallel to those of urine NGF and BDNF levels, demonstrating the role of CaCCs on evolution of different stages of bladder pathology caused by Mets.

CONCLUDING MESSAGE

The UAB group may represent the most severe condition of Mets. The changes of urine NGF and BDNF levels, and the expressions of CLCA4 and ANO1 chloride channel proteins and mRNA on rat bladder SM in OAB and UAB groups may reflect the role of CaCCs on evolution of different stages of bladder pathology caused by Mets.

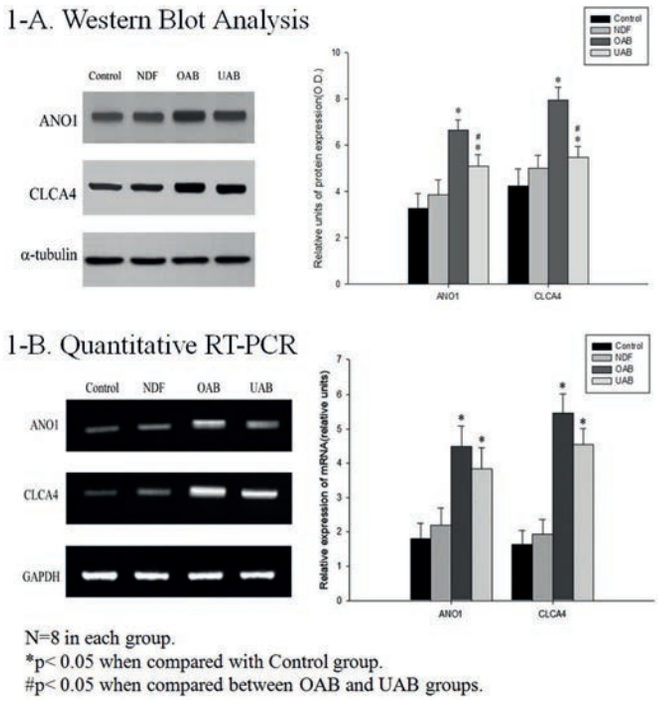
FIGURE 1

Comparison of metabolic syndrome associated variables among control, NDF, OAB and UAB groups in rats.

Variable	Control	NDF	OAB	UAB
Body Weight (g)	465 ± 11.0	560 ± 12.5*	610 ± 17.5*	605 ± 13.5*
Bladder Weight (g)	0.220 ± 0.06	0.310 ± 0.1*	0.460 ± 0.15*	0.415 ± 0.20*
Insulin (U/mL)	0.005 ± 0.001	0.008 ± 0.002	0.019 ± 0.009*	0.024 ± 0.01*
Glucose (mmol/L)	5.17 ± 0.53	5.39 ± 0.42	6.01 ± 0.37	12.36 ± 2.04*#
HOMA- IR	0.001 ± 0.0004	0.002 ± 0.0006	0.005 ± 0.0027*	0.014 ± 0.0065*#

NDF: normal detrusor function. OAB: overactive bladder. UAB: underactive bladder. (n=8 in each experiment). IR: insulin resistance.
*p< 0.05 when compared with control groups.
# p< 0.05 when compared between OAB and UAB groups.

FIGURE 2



N=8 in each group.
*p< 0.05 when compared with Control group.
#p< 0.05 when compared between OAB and UAB groups.

Funding Department of Health, Taipei City Government. **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** National Taiwan University College of Medicine and College of Public Health Institutional Animal Care and Use Committee

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IVERMECTIN-INDUCED IMPROVEMENT OF VOIDING DYSFUNCTION AND MOLECULAR AND ELECTRICAL PROPERTIES OF BLADDER AFFERENT NEURONS IN SPINAL CORD INJURED MICE WITH GENE DELIVERY OF MUTANT GLYCINE RECEPTORS USING HERPES SIMPLEX VIRUS VECTORS DRIVEN BY THE SUBPOPULATION-SPECIFIC NEUROFILAMENT 200 PROMOTER

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HYPOTHESIS / AIMS OF STUDY

The external urinary sphincter (EUS) acts cooperatively with the bladder to store and periodically eliminate urine. However, in neurogenic lower urinary tract dysfunction induced by spinal cord injury (SCI), this cooperative micturition con-

trol is disrupted, leading to detrusor overactivity (DO) and detrusor-sphincter dyssynergia (DSD), which causes inefficient voiding with high post-void residual volume. Previous studies showed that treatments targeting C-fiber bladder afferent pathways such as anti-NGF treatment or capsaicin-induced desensitization do not improve DSD [1], which led to a hypothesis that Aδ-fiber bladder afferents are responsible for the EUS hyperexcitability causing DSD. We previously reported that the herpes simplex virus (HSV)vector-mediated treatment targeting Aδ-fiber bladder afferents with double mutant glycine (G2M) receptors with increased sensitivity to ivermectin (IVM), an FDA-approved anti-parasitic drug, can improve EUS activity, resulting in increased voiding efficiency (2019 ICS meeting). Activation of G2M receptors by IVM has been shown to induce a chloride ion influx and causes hyperpolarization to reduce excitability of neuronal cells [2]. In this study, we extended our previous study to examine the relationship between functional and molecular changes in SCI-induced voiding dysfunction with DSD and the electrical properties of bladder afferent neurons in SCI mice treated with G2M-encoding HSV vectors driven by neurofilament 200 promoter (NF200p) that can selectively target A-fiber afferent pathways.

STUDY DESIGN, MATERIALS AND METHODS

All experiments were conducted in accordance with institutional guidelines and was approved by the institutional animal care and use committee. First, 8-9 weeks-old female C57BL/6N mice (n=30) were divided into 3 groups; (A) spinal intact (SI) mice, (B) SCI mice+NF200p-HSV vectors encoding wild-type glycine receptors (WT-GlyR) with IVM administration, (3) SCI mice+NF200p-HSV-G2M vectors with IVM administration. In SCI groups, the Th8/9 spinal cord was transected under isoflurane anesthesia. Thereafter, the bladder of SCI mice was emptied by perineal stimulation and bladder compression daily for 4 weeks post-SCI. Two weeks after SCI, NF200p-driven HSV vectors expressing G2M or WT-GlyR were inoculated into the bladder wall. One week after vector inoculation, IVM (50µl of 1µM solution) was intra-peritoneally injected daily for 7 days. Thereafter, SCI mice underwent single-filling cystometry (CMG) and EUS-electromyogram (EMG) recordings under an awake condition, followed by the removal of L6/S1 dorsal root ganglia (DRG) for RT-PCR studies of mechanosensitive channels such as ASIC 1-3 & Piezo2 and a C-fiber afferent marker, TRPV1.

Next, another set of female mice (n=24) were used for patch-clamp recordings and divided into 2 groups; (1) control SCI mice and (2) SCI mice+NF200p-HSV vectors encoding G2M receptors. SCI mice in Groups 1 and 2 underwent inoculation of a total of 20µl of 2.5% fluoro-gold (FG) and 3x107 plaque-forming units of NF200p-driven HSV vectors expressing G2M receptors, respectively, into the bladder wall. At 4 weeks after SCI, L6-S1 DRG, which contain cell bodies of bladder afferent neurons carried through the pelvic nerve, were dissected under isoflurane anesthesia, and enzymatically dissociated into single neurons [3]. FG-labelled afferent neurons that innervate the bladder were identified using an inverted phase contrast microscope with fluorescent attachments, and cells with a diameter larger than 35µm were selected to assess the electrical properties of presumed Aδ-fiber bladder afferent neurons, which have a larger cell size than C-fiber afferent neurons. Whole-cell patch-clamp recordings were performed at room temperature on FG-labelled neurons within 24 hours after dissociation. We evaluated the characteristics of action potentials in bladder afferent neurons from 2 groups of SCI mice as well as spinal intact (SI) control mice. After evaluating action potential characteristics including the rheobase current that is the depolarizing current size required for action potential activation, IVM (10µM/50µL) was directly applied into the cell dish, and action potentials were again induced by depolarizing currents 60 seconds later to assess the rheobase current changed by IVM-induced G2M receptors activation in large-sized bladder afferent neurons.

RESULTS

Compared to the WT-GlyR and IVM group, treatment with HSV-G2M vectors and IVM application in SCI mice significantly increased the EMG activity reduction time, leading to improvement of voiding efficiency and residual volume without affecting non-voiding contractions during bladder filling (Fig. 1-A, B, C). RT-PCR showed reductions of ASIC 1-3 & Piezo2, but not TRPV1, in L6-S1 DRG (Fig. 1-B). Patch clamp recordings showed that FG-labelled, large-sized bladder afferent neurons show a tendency of lower rheobase current sizes for action potential activation in SCI mice (Group 1) compared to SI rats (52±8.4pA vs. 56±5.5pA, p=0.20). Then, when IVM was applied to large-sized bladder afferent neurons, the rheobase current required for action potential activation was significantly increased from 46±4.0pA to 62±3.7pA ($p<0.01$) in SCI mice treated with HSV-NF200p-G2M vector (Group 2) whereas the rheobase current was not altered after IVM application in SI or SCI mice (Group 1) (Fig. 1-C).

INTERPRETATION OF RESULTS

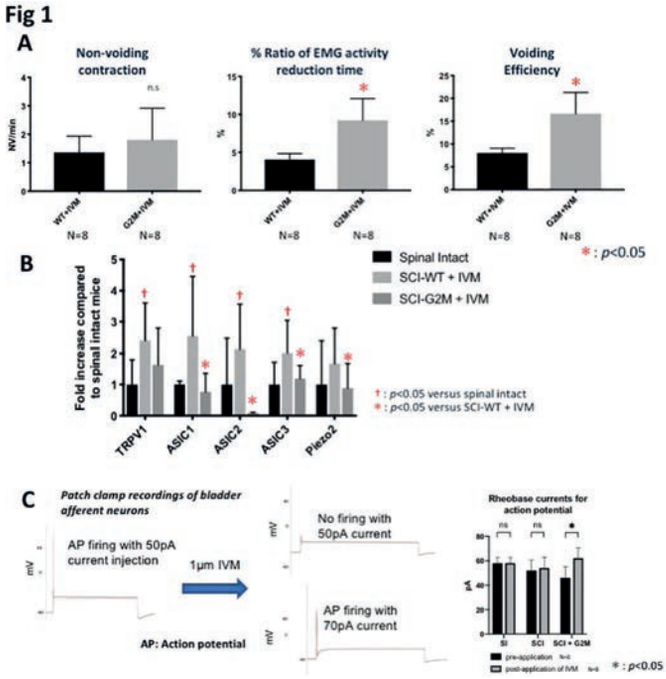
The results of this study indicate that the improvement of inefficient voiding and DSD after IVM application in SCI mice treated with A-fiber-targeting HSV-NF200p-G2M vectors was associated with reductions in expression levels of mechanosensitive channels such as ASIC 1-3 and Piezo 2, but not TRPV1, in L6-S1 DRG that contain bladder afferent neurons. It has been shown that ASICs and Piezo2 act as mechanosensitive channels in afferent pathways and that ASIC1-3 receptors are expressed in TRPV1 expressing, unmyelinated C-fiber neurons as well as in mechanosensitive, myelinated A-fiber neurons, whereas Piezo2 are expressed in mechanosensitive, myelinated A-fiber neurons [1]. Also, in patch-clamp recordings, IVM application decreased the cell excitability of large-sized, presumed Aδ-fiber bladder afferent neurons obtained from SCI mice treated with HSV-NF200p-G2M vectors,

as evidenced by the increased rheobase current for action potential activation after IVM application. Taken together, it is plausible that activation of G2M receptors expressed in Aδ-fiber bladder afferent pathways by exogenous application of IVM suppresses Aδ-fiber bladder afferent activity in association with reduced expressions of mechanosensitive channels to improve inefficient voiding and DSD in SCI mice.

CONCLUDING MESSAGE

A druggable approach using exogenous application of specific ligands such as IVM can be achieved by gene delivery of designer receptors such as IVM-sensitive mutant glycine receptors (G2M) to Aδ-fiber bladder afferent pathways for the treatment of SCI-induced voiding dysfunction and DSD by using HSV vectors driven by an A-fiber-targeting promoter (NF200p).

FIGURE 1



REFERENCES

1. Wada N et al. Therapeutic effects of inhibition of brain-derived neurotrophic factor (BDNF) on voiding dysfunction in mice with spinal cord injury. Am Journal Physiol Renal Physiol (2019); 317: F1305-F1310
2. Lynagh T, et al. An improved ivermectin-activated chloride channel receptor for inhibiting electrical activity in defined neuronal populations. J Biol Chem (2010);285:14890-7
3. Shimizu T et al. Nerve growth factor-dependent hyperexcitability of capsaicin sensitive bladder afferent neurones in mice with spinal cord injury. Exp Physiol (2018); 103: 896-904

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THE ENDOGENOUS ANTI-INFLAMMATORY ANNEXIN A1 AUGMENTS RECOVERY FOLLOWING BLADDER OUTLET DE-OBSTRUCTION

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HYPOTHESIS / AIMS OF STUDY

Due in large part to damaging changes caused by inflammation during bladder outlet obstruction, bladder dysfunction persists in many patients following de-obstruction surgery. This clinically presents as persistent lower urinary tract symptoms and post-operative urinary retention. Our lab has extensively studied the mechanisms that trigger the bladder's inflammatory response to obstruction, but the role of endogenous anti-inflammatories in the bladder, notably Annexin A1, has never been explored. In this study, we aim to assess the ability of Annexin A1 to enhance the resolution of inflammation following de-obstruction and improve functional bladder recovery.

STUDY DESIGN, MATERIALS AND METHODS

Sprague Dawley rats underwent bladder outlet obstruction via proximal urethral ligation around a 1 mm (o.d.) catheter. De-obstruction was performed after 12 days and rats were randomized to treatment with 1 mg/kg/day of AC2-26 (the active N-terminal peptide of Annexin A1) in PBS or vehicle for two days. For inflammation assays, 25 mg/kg of Evans blue dye was injected IV one hour prior to sacrifice. Bladders were then weighed and Evans blue concentrations were measured spectrophotometrically. For functional assays, suprapubic tubes were placed at the time of obstruction and awake cystometry was performed two days after de-obstruction. Functional assays included a sham surgery group while inflammation assays included a no-treatment group to establish controls. The sham cohort underwent loose urethral ligature placement and subsequent removal after 12 days.

RESULTS

Bladder weights increased from a mean of 309.7 mg after 12 days of obstruction to 390.8 mg two days after de-obstruction while treatment with AC2-26 reduced this to 255.8 mg. Inflammation measured by Evans Blue extravasation decreased following de-obstruction from 17.2 ng EB/mg to 13.5 ng EB/mg after two days; AC2-26 further decreased this

to 9.7 ng EB/mg which was significantly different from the obstructed baseline. Functionally, sham surgery resulted in intercontractile intervals of 1056.8 seconds which was significantly increased to 18888.9 seconds following obstruction and deobstruction; however, no significant increase was seen with treatment with AC2-26 with an average of 1245.2 seconds. Similarly, void volumes increased from 1335.9 µl to 2583.1 µl with obstruction and deobstruction but this normalized to 1716.0 µl with administration of AC2-26.

INTERPRETATION OF RESULTS

We demonstrate that the resolution of inflammation following bladder outlet de-obstruction is augmented significantly when treated with AC2-26, the active N-terminal peptide of Annexin A1. This is seen as a reduction in Evans blue dye extravasation and as well as bladder weights. Furthermore, the addition of AC2-26 results in normalization of micturition cycles with less urinary retention even when controlled for the effects of surgery.

CONCLUDING MESSAGE

Annexin A1 enhances the resolution of inflammation following bladder outlet de-obstruction surgery and this correlates with improved post-operative bladder function.

Funding Research support was provided by the National Institute of Diabetes and Digestive and Kidney Diseases (DK103534 to J.T.P.) and intramural funds. **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** IACUC

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EFFECTS OF FILTERED BONE MARROW-DERIVED STEM CELL LYSATE ON NEUROGENIC BLADDER

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract dysfunction (LUTD) occurs as a complication of pelvic surgery. Pelvic nerve injury is known to cause LUTD such as an underactive bladder; however, the consequences of hypogastric nerve injury remain unknown. On the other hand, a recent review reported that stem cell transplantation is effective in the treatment of LUTD. [1] However, there are many hurdles in stem cell therapy such as complicated handling of cells, high risk of immune response, and high cost, among others. In addition, many reports have suggested that the improvements following stem cell therapy are due to the paracrine effects such as growth factors or cytokines from the cells, and not the differentiation ability of the stem cells.[1] We focused on the contents of stem cells, which have the potential to solve these problems. In this study, we investigated the effectiveness of filtered bone marrow-derived stem cell lysate (FBMSCL) in a model of overflow urinary incontinence caused by bilateral hypogastric nerve injury.

STUDY DESIGN, MATERIALS AND METHODS

We collected bone marrow stem cells (BMSC) and diluted in phosphate-buffered saline (PBS) (1×10^6 cells/1 mL PBS). Subsequently, the cells were crushed by freeze-thaw method and the filtrate (FBMSCL) was collected. Seven- and eight-week-old male Wistar-ST rats were categorized into (1) Sham+PBS (n=7), (2) hypogastric nerve injury (HGNI) +PBS (n=10), and (3) HGNI+FBMSCL (n=10) groups. Bilateral hypogastric nerves were injured by pinching with reverse acting tweezers for one minute. PBS or FBMSCL (100 µl/body) was administered intravenously. After 1 week, cystometrogram was performed, and the intercontraction intervals (ICIs), maximum voiding pressure (MP), baseline, and threshold values were evaluated in each group. Bladder weight and morphology were evaluated by Masson trichrome staining. Statistical analyses were performed using ANOVA and Bonferroni multiple t-tests.

RESULTS

Representative charts are shown in Figure 1A. In the HGNI+PBS group, all rats presented with symptoms of overflow urinary incontinence. Peaks of intravesical pressure were not observed in seven of ten rats. In the HGNI+FBMSCL group, only three of ten rats presented with symptoms of overflow urinary incontinence. Peaks of intravesical pressure were not observed in seven of ten rats. ICIs in the HGNI+PBS group were significantly longer than that in the Sham+PBS group ($P<0.01$). The ICIs in the HGNI+FBMSCL group were significantly shorter than that in the HGNI+PBS group ($P<0.05$) (Figure 1B). MP, baseline, and threshold did not change among the three groups (Figure 1B). The bladder weight/body ratio of rats in the HGNI+PBS group was significantly higher than that in the Sham+PBS group ($P<0.01$), while that of the HGNI+FBMSCL group was significantly lower than in the HGNI+PBS group ($P<0.01$). Images of the stained bladder body of the three groups are shown in Figure 2A. The observations signified thinning and enlargement of the bladder body due to HGNI. The fibrotic area/total area ratio in the HGNI+PBS group was higher than that in the Sham+PBS group, while that of the HGNI+FBMSCL group was lower than in the HGNI+PBS group (Figure 2B).

INTERPRETATION OF RESULTS

Rats with HGNI exhibited overflow incontinence and prolonged urination interval. The hypogastric nerve is known to control the function of the bladder neck and urethra [2]; therefore, LUTD in this study could be attributed to impairment of function due to injury of the nerve. In this study, FBMSCL improved urinary function, suggesting that it might be involved in the repair of nerve injury. This functional improvement might prevent bladder fibrosis.

CONCLUDING MESSAGE

FBMSCL improved overflow urinary incontinence in rats, caused by injury to the hypogastric nerve, suggesting that intravesical injection of FBMSCL may be useful in the treatment of neurogenic bladder.

FIGURE 1

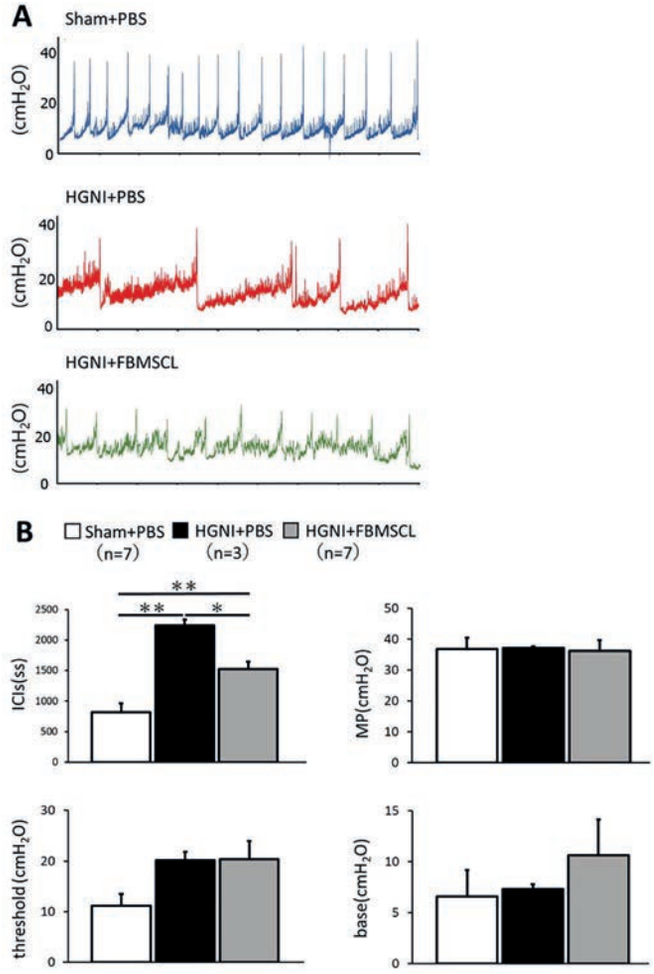

Figure 1. The results of cstometrogram in each group.
A, The representative charts in each group, B, ICIs, MP, threshold and base line in each group, and C, bladder weight/body ratio in each group. Sham+PBS group (n=7), HGNI+PBS group (n=10), HGNI+FBMSCL (n=10). ANOVA and Bonferroni multiple t-tests. **P<0.01.

Figure 1. The results of cystometrogram in each group

FIGURE 2

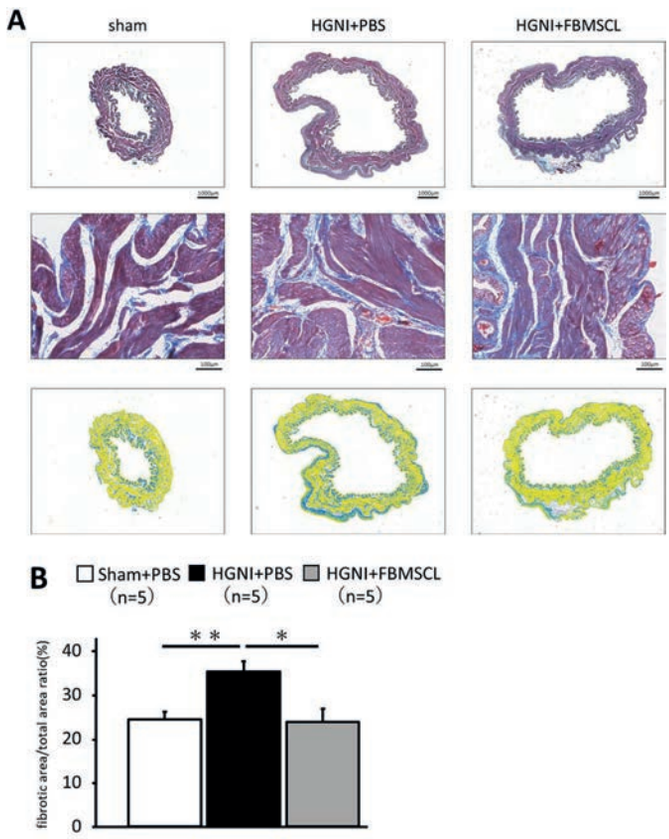

Figure 2. Results of Masson trichrome staining of bladder body in each group
A, Representative photographs of bladder body (upper line; Magnification x4, middle line; Magnification x10) in Sham (left row), HGNI+PBS (middle row) and HGNI+FBMSCL (right row). Lower line represents the results of analysis; blue is fibrotic area and yellow is other area of tissue. B, fibrotic area(blue)/total area(blue+yellow) ratio in each group. n=5, ANOVA and Bonferroni's multiple t-test. **P<0.01, *P<0.05.

Figure 2. Results of Masson trichrome staining of the bladder body in each group

REFERENCES

1. Sun DZ, et al. Harnessing the mesenchymal stem cell secretome for regenerative urology. Nat Rev Urol. 2019;16(6):363-37.5.
2. Hehemann M, et al. Pelvic and hypogastric nerves are injured in a rat prostatectomy model, contributing to development of stress urinary incontinence. Sci Rep. 2018;8(1):16432.

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BONE MARROW MESENCHYMAL STEM CELL SECRETIONS ACTIVATE VAGINAL WALL FIBROBLASTS AND FACILITATE RECOVERY FROM BIRTH INJURY RELATED INCONTINENCE IN RATS

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HYPOTHESIS / AIMS OF STUDY
The main intention of this research was to provide a new approach for birth-injury induced stress urinary incontinence (SUI), focusing on bone marrow stem cell (BMSC) secretions and fibroblast contribution. With increasing acknowledgment of the potential role of BMSC secretions in angiogenesis, tissue repair, immunomodulation, and anti-fibrotic, we hope to determine if BMSC secretions activate anterior vaginal wall fibroblasts (AVWFs), which play an important role in the progress of delivery associated SUI.

STUDY DESIGN, MATERIALS AND METHODS
Primary fibroblasts were extracted from anterior vaginal wall tissues of patient with SUI and vaginal prolapse, and identified by immunofluorescence staining. BMSC conditioned medium (BMSC-CM), which contains all secretions of BMSC, was collected and purified after two-day culture in serum-free medium. The effects of BMSC-CM in AVWFs proliferation and migration were respectively assessed by CCK8 assay and cell-scratch test compared with fibroblast-CM and serum-free medium. Reverse transcription-quantitative polymerase chain reaction (RT-PCR) and western blot were used to detect the expression of collagen I and III and the activation of signal pathway. In vivo, 15 SD rats were divided into 3 groups and received vaginal distention (VD) + periurethral injection of BMSC-CM, VD + periurethral injection of control medium, or sham VD. Leak point pressure (LPP) and periurethral histology were observed 2 weeks later.

RESULTS
The cells we extracted were indeed fibroblasts which exhibited vimentin positive and α-SMA negative, rather than smooth muscle cells. BMSC-CM significantly enhanced the proliferation and migration ability of AVWFs compared to fibroblast-CM and control medium. BMSC-CM also accelerated the expression of collagen I, but not collagen III at both mRNA and protein level. Western blot showed that p-STAT3, p-AKT and p-mTOR expressed at a higher level under the administration of BMSC-CM. LPP was obviously decreased in rats treated with VD + control medium compared to sham VD but not in those treated with VD + BMSC-CM. HE and Masson staining suggested that rats received VD + BMSC-CM had an improvement of collagen fiber arrangement more similar to sham VD group than rats received VD + control medium.

INTERPRETATION OF RESULTS
BMSC secretions (a combination of growth factors, cytokines and chemokines) successfully promote activation of anterior vaginal wall fibroblasts, which may contribute to functional and anatomic recovery of birth-injury caused stress incontinence simulated by vaginal distention.

CONCLUDING MESSAGE
In conclusion, MSC secretions facilitate recovery from SUI after simulated childbirth injury, likely via activating vaginal wall fibroblasts. BMSC secretions hold promise as a novel, noninvasive therapeutic approach for treating SUI and remain further research.

Funding The study was supported by the National Natural Science Foundation of China (No.81670695), Zhejiang Provincial medical and health technology program projects of China (Nos.2018PY031, 2018KY512, and 2019KY101), and Zhejiang Provincial Natural Science Foundation of China (No.WY20H050001) **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Experimental Animal **Ethics Committee** of Wenzhou Medical University

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EFFECTS OF LOW-DOSE INSULIN TREATMENT OR A SOLUBLE GUANYLATE CYCLASE ACTIVATOR, BAY 60-2770, ON LOWER URINARY TRACT DYSFUNCTION IN STREPTOZOTOCIN-INDUCED DIABETIC RATS

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HYPOTHESIS / AIMS OF STUDY
Diabetes mellitus (DM) is often associated with lower urinary tract dysfunction (LUTD). Although streptozotocin (STZ)-induced DM rats have been used as a rodent model of the LUTD, this is an acutely-induced, severe DM model with high glucose levels, and may not be suitable for studying the physiological condition encountered in DM patients, especially those with type II DM that is induced insufficient insulin production with insulin resistance. Thus, this study first sought to develop a more physiological rat model of DM by using low-dose insulin administration to maintain the moderately-high blood glucose level, thereby minimizing the initial diuretic effects. Also, DM is known to impair nitric oxide (NO)-cyclic guanosine monophosphate (cGMP)-dependent urethral relaxation mechanisms during micturition, resulting in inefficient voiding together with DM cystopathy [1-3]. Thus, secondly, this study examined the effects of soluble guanylate cyclase (sGC), which can increase cGMP produc-

tion, independent of NO, inside the cell, on bladder and urethral dysfunctions in STZ-induced DM rats.

STUDY DESIGN, MATERIALS AND METHODS

Female Sprague-Dawley rats (11-12 weeks) were used, and DM was induced using a single intraperitoneal injection of STZ (65 mg/kg). We divided rats into four groups: (1) non-DM (N) group, (2) DM with low-dose insulin (DI) group, (3) non-insulin DM with vehicle (D) group, and (4) non-insulin DM with sGC (GC) group. In insulin-treated DM rats (Group DI), slow-releasing insulin pellets (2 units/24 hours) were implanted 3 days after inducing DM. In Group GC, a sGC activator (BAY 60-2770,1 mg/kg/day) was orally administered from 6 to 8 weeks after inducing DM. First, in Groups DI and D, we performed 24-h voiding assay at 2, 4, and 8 weeks, cystometry and urethral perfusion pressure (UPP) recordings at 8 weeks with or without low-dose insulin treatment, and compared the data with those in Group N. In cystometry, we measured opening pressure (OP, pressure at which the urethra opens and urine flow starts), intercontraction intervals (ICI), the number of non-voiding contractions (NVCs) per minute, postvoid residual (PVR), bladder capacity, bladder compliance, and voiding efficiency [1]. NVC was defined as an increase in intravesical pressure of more than 8 cmH2O above the baseline. In UPP recordings, we measured urethral pressures (UP) at which urethra started to relax (UPUR), UP nadir which is the lowest pressure during urethral relaxation, UP reduction which is difference between UPUR and UP nadir, and high-frequency oscillation (HFO) amplitude of UP during voiding [2]. Secondly, we evaluated the effects of sGC treatment on the cystometric and UPP parameters at 8 weeks of DM in Groups D and GC. Thirdly, in a separate group of animals, the urethra and the bladder were harvested at 8 weeks of DM to evaluate the mRNA levels various markers using real-time PCR, which included NO-related markers such as phosphodiesterase type 5 (PDE5), multidrug resistance protein 5 (MRP5) and Ca2+ channels, ischemia markers such as hypoxia-inducible factor 1 alpha (HIF-1α), and inflammatory markers such as transforming growth factor beta 1 (TGF-β1) and tumor necrosis factor alpha (TNFα). All values are expressed as means ± standard deviations. We used the Kruskal-Wallis one-way analysis of variance to analyze statistical differences and Dunn's post hoc test between in Groups N, DI, and D, and the Mann Whitney U test to evaluate statistical differences between in Groups D and GC. A P-value < 0.05 was considered statistically significant.

RESULTS

Moderately-high levels of blood glucose (292.3 ± 59.5 mg/dL) were maintained in Group DI vs. Group D (495.6 ± 7.6 mg/dL). In voiding assay, 24-h voided volume was significantly higher in Group D than in Group N at 2, 4, and 8 weeks (115.0 ± 24.2 vs 6.4 ± 3.2 mL, 88.3 ± 28.7 vs 5.7 ± 2.0 mL, and 82.8 ± 17.0 vs 9.8 ± 3.5 mL, respectively). In cystometry, OP, NVCs per minute, and PVR were significantly higher in Group D than in Groups N and GC (OP: 43.2 ± 11.0 vs 24.3 ± 2.7 and 30.4 ± 8.2 cmH2O, NVCs: 0.2 ± 0.1 vs 0.0 ± 0.0 and 0.0 ± 0.0 number/min, PVR: 0.2 ± 0.1 vs 0.0 ± 0.0 and 0.1 ± 0.0 mL) (Fig. 1A, B). Voiding efficiency was significantly lower in Group D than in Groups N, DI, and GC (91.6 ± 3.5 vs 99.4 ±1.1, 99.2 ± 0.8, and 97.3 ± 0.7 %). In UPP recordings, UPUR was significantly lower in Group D than in Groups DI and GC (21.6 ± 3.0 vs 32.5 ± 5.9 and 33.5 ± 9.2 cmH2O). UP reduction and HFO amplitude were significantly lower in Group D than in Groups N and GC (UP reduction: 6.7 ± 4.1 vs 15.5 ± 2.3 and 15.5 ± 5.1 cmH2O, HFO a: 1.1 ± 0.4 vs 4.0 ± 2.0 and 3.5 ± 1.8 cmH2O) (Fig. 1C, D). In addition, mRNA expression levels of Ca2+ channels and PDE5 in the urethra were significantly higher in Group D than in Groups N and GC. MRP5 in the urethra was significantly lower in Group GC than in Group D (Fig. 2A). mRNA expression levels of HIF-1α, TGF-β1, and TNFα in the bladder were significantly higher in Group D than in Groups N, DI, and GC (Fig. 2B).

INTERPRETATION OF RESULTS

This is the first report to examine the effects of sGC on DM-induced LUTD in diabetic rats. Previous studies in rodent diabetes models demonstrated that diabetic urethral dysfunction was associated with impaired NO-mediated urethral relaxation mechanisms including reduced NO synthase activity in rats [3]. In this study, the sGC treatment, which can directly increase cGMP production independent of NO, improved bladder overactivity evident as reduced NVCs as well as urethral relaxation during bladder contraction, as evidenced by an increase in UP reduction in 8-weeks DM rats. Molecular studies also showed that the sGC treatment reduced mRNA expression of PDE5 (a cGMP degrading enzyme), MRP5 (a multidrug resistance protein to transport cGMP out of the cell) and Ca2+ channels, suggesting that sGC activation increases cGMP accumulation and reduces muscle contractility. Also, HFO activity of the urethra, which represents the pumping activity of external urethral sphincter during voiding, was increased after sGC treatment in 8-weeks DM rats, suggesting the further improvement of bladder emptying during micturition. Moreover, in this study, the sGC treatment seems to be effective in reducing ischemia and inflammatory changes in the bladder, evident as decreased expressions of HIF-1α, TGF-β1, and TNFα after the treatment. STZ-induced DM rats have been used as a DM model with LUTD. However, diuresis-induced bladder overdistention due to high blood glucose levels significantly contributes to LUTD, especially bladder overactivity in the early phase in STZ-DM rats. The results of this study revealed that the low-dose insulin treatment can control the blood glucose concentration at a moderately-high level, and significantly reduced urine overproduction and prevented the progression of bladder overactivity, urethral dysfunction and inefficient voiding during 8 weeks of DM.

CONCLUDING MESSAGE

Low-dose insulin-treated DM rats with a lesser degree of diuresis-induced bladder overdistention would be a useful model for studying the natural progression of DM-induced LUTD. Activation of sGC, which can increase cGMP levels inside the cell, would be an effective option for the treatment of DM-induced LUTD including bladder overactivity and inefficient voiding due to impaired urethral relaxation.

FIGURE 1

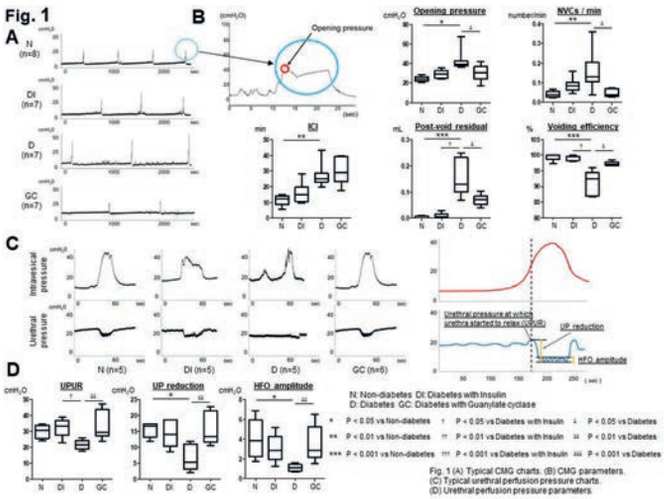

Figure 1

FIGURE 2

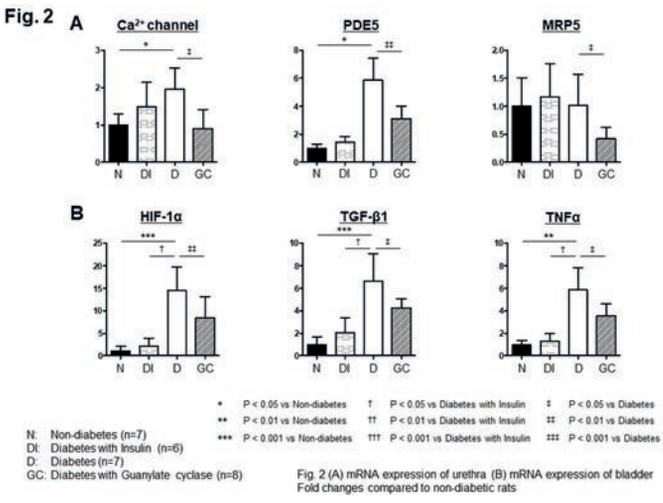

Figure 2

REFERENCES

1. Neurourol Urodyn. 37: 666-672, 2018
2. Lower Urinary Tract Symptoms. 11: 241-247, 2019
3. Life Sciences. 249: 117537, 2020

Funding None **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** University of Pittsburgh Institutional Animal Care and Use Committee

459

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NLRP3 REGULATES THE PROGRESSION FROM BLADDER OVERACTIVITY TO UNDERACTIVITY IN A MOUSE GENETIC MODEL OF TYPE 1 DIABETES (AKITA)

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HYPOTHESIS / AIMS OF STUDY

Diabetic bladder dysfunction (DBD) patients present with symptoms ranging from overactive bladder to underactive bladder/decompensation and various combinations thereof. Experimental models suggest that DBD progresses from overactive to underactive bladder but this progression has not been established in humans. We have recently demonstrated the appearance of overactive bladder symptoms (decreased voided volume and increased voiding frequency during awake restrained urodynamics) in a genetic mouse model of type I diabetes (the Akita mouse) at 15 weeks. In the present study we have extended this time frame to 30 weeks to assess progression of this complication into middle adulthood.

Counterintuitively, the Epidemiology of Diabetes Interventions and Complications Study showed that strict glycemic control does not decrease the risk of DBD in humans. This surprising result suggests that, mechanistically, this complication must arise more from the metabolic derangement in this disease than a direct effect of high glucose levels. Building on this conclusion we have recently shown that diabetic metabolites are capable of directly activating a structure known as the NLRP3 inflammasome within cultured urothelial cells. The NLRP3 inflammasome is a multimeric complex that senses such metabolites (known as Damaged Associated Molecular Patterns or DAMPS) and triggers an inflammatory response by activating caspase-1 to cleave pro-IL-1β into its active form and promote its release where it acts as a strong pro-inflammatory cytokine. Previous studies from multiple labs have also shown that NLRP3-induced inflammation underlies several other diabetic complications such as nephropathy, neuropathy and retinopathy. Recently we have demonstrated just such a central role for NLRP3 in the production of signs of overactive bladder at 15 weeks in our Akita diabetic mice through the use of these diabetic mice in which NLRP3 has been genetically deleted (NLRP3-/-). To determine if NLRP3-mediated inflammation may drive the progression of DBD from overactive bladder to underactive bladder we have examined urodynamic function at 30 weeks in the NLRP3-/- mice.

STUDY DESIGN, MATERIALS AND METHODS

All animal studies were approved by our Institutions Animal Care and Use Committee. Four groups were used: 1) control mice, 2) control mice with NLRP3-/- genotype, 3) diabetic

mice (Akita) and 4) diabetic mice with the NLRP3-/- genotype. Mice were assessed at 30 weeks for blood glucose using a glucometer (AimStrip). Inflammation was assessed by injecting mice i.v. with 10 mg/kg Evan's blue. 1 h later bladders were harvested and dye extracted with formamide (56oC overnight). Extravasated dye was calculated from a standard curve and normalized to bladder weight. Urinary function was assessed by awake restrained urodynamics.

RESULTS

30 week old diabetic mice, with or without a functional NLRP3 gene, had significantly increased blood glucose compared to controls (274 vs 128 mg/dl). Diabetes greatly increased bladder inflammation. However, this increase was completely blocked in the diabetic NLRP3 /- mice. Urodynamic analysis revealed signs of underactive bladder (an increase in voiding volume associated with a decrease in voiding frequency) in response to diabetes. These changes were not present in the diabetic mice in which NLRP3 had been deleted (NLRP3-/-).

INTERPRETATION OF RESULTS

Female Akita mice develop significant bladder inflammation and urodynamic signs of underactive bladder/decompensation after 30 weeks of age which did not develop in the absence of NLRP3.

CONCLUDING MESSAGE

The results demonstrate a central role for NLRP3-mediated inflammation in the development and progression of DBD

FIGURE 1

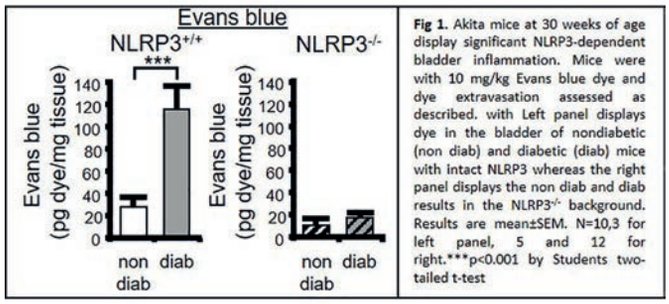

Fig 1. Akita mice at 30 weeks of age display significant NLRP3-dependent bladder inflammation. Mice were with 10 mg/kg Evans blue dye and dye extravasation assessed as described. with Left panel displays dye in the bladder of nondiabetic (non diab) and diabetic (diab) mice with intact NLRP3 whereas the right panel displays the non diab and diab results in the NLRP3$^{-/-}$ background. Results are mean±SEM. N=10,3 for left panel, 5 and 12 for right.***p<0.001 by Students two-tailed t-test

FIGURE 2

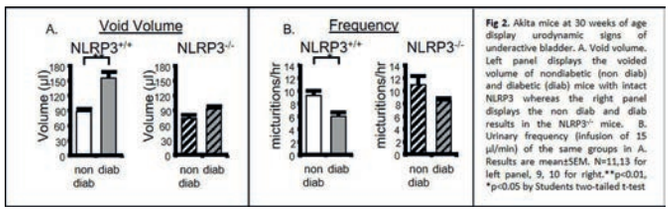

Fig 2. Akita mice at 30 weeks of age display urodynamic signs of underactive bladder. A. Void volume. Left panel displays the voided volume of nondiabetic (non diab) and diabetic (diab) mice with intact NLRP3 whereas the right panel displays the non diab and diab results in the NLRP3$^{-/-}$ mice. B. Urinary frequency (infusion of 15 µl/min) of the same groups in A. Results are means±SEM. N=11,13 for left panel, 9, 10 for right.**p<0.01, *p<0.05 by Students two-tailed t-test

Funding NIDDK: R01DK103534 **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** Institutional Animal Care and Use Committee

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EFFICACY OF VIBEGRON, A NOVEL B3-ADRENORECEPTOR AGONIST ON STORAGE AND VOIDING DYSFUNCTION IN MICE WITH SPINAL CORD INJURY

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HYPOTHESIS / AIMS OF STUDY

Chronic spinal cord injury (SCI) rostral to the lumbosacral level induces detrusor overactivity (DO) during the storage phase, which is mediated by spinal reflexes triggered by hyperexcitable C-fiber afferent pathways. In addition, during the voiding phase, inefficient voiding is commonly observed due to detrusor-sphincter dyssynergia (DSD) after SCI. Vibegron is a new β3-adrenoceptor agonist that was approved for the treatment of overactive bladder in Japan in 2018; however, it remains to be elucidated whether vibegron has any therapeutic effects on LUTD induced by SCI. Therefore, we investigated the effects of vibegron to clarify the role of β3 in storage and voiding dysfunction using SCI mice.

STUDY DESIGN, MATERIALS AND METHODS

Female C57BL/6N (8-9 weeks old) mice were used, and SCI was induced by complete transection of the Th8/9 spinal cord under isoflurane anesthesia. SCI mice were then divided into 2 groups; (1) SCI mice treated with vibegron (30mg/kg/day) (n=13), (2) control SCI mice with saline (n=7). Two weeks after SCI, vibegron or saline (treatment or control group, respectively) was administered daily by oral gavage for 14 days. After spinal cord transection, their bladders were manually squeezed to eliminate urine once daily for 4 weeks until cystometric evaluation, which was performed using cystometry (CMG) under an awake condition. In CMG recordings, the number of non-voiding contractions (NVCs), micturition pressure (MP), post-void residual volume (PVR) and voided volume (VV) were evaluated in each SCI mouse (Figure 1).

In real-time PCR analyses, another set of mice was used, and L6-S1 dorsal root ganglia (DRG) that contain bladder afferent neurons and the bladder were removed from saline-treated control SCI mice (n=10) and vibegron-treated SCI mice (n=12) as well as saline treated normal (spinal intact) mice (n=12). The bladder was divided into mucosal and detrusor

layers, and the mRNA levels of TRPV1, TRPA1, iNOS and ATF3 transcripts were evaluated by real-time PCR.

RESULTS

Compared to saline-treated SCI mice, NVCs during bladder filling were significantly reduced in vibegron-treated (Figure 1). The mRNA levels of TRPV1, TRPA1, ATF3 and iNOS mRNA in L6-S1 DRG were increased in SCI mice vs. spinal intact mice, and significantly decreased after vibegron treatment in SCI mice (Figure 2). Also, the TRPV1 and TRPA1 mRNA levels in the detrusor muscle layer were increased in SCI mice vs. spinal intact mice, and significantly decreased after vibegron treatment in SCI mice.

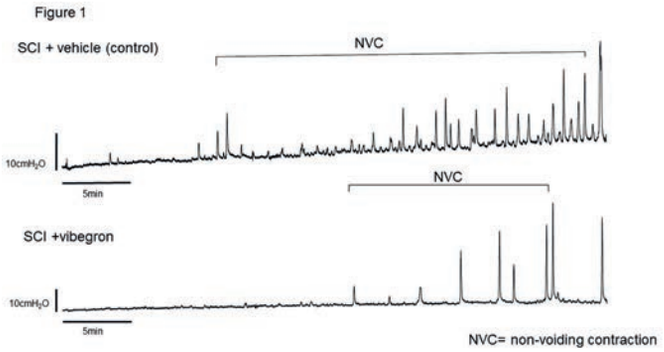
INTERPRETATION OF RESULTS

The treatment with vibegron improved DO evident as a decrease in NVCs in association with the reduction in the expression of inflammation markers such as ATF3 and iNOS as well as TRPV1 and TRPA1 in L6-S1 DRG, which contain bladder afferent neurons. Because previous studies have shown that TRPV1 and TRPA1 channels are predominantly expressed in C-fiber afferent pathways and that NVCs are significant reduced by C-fiber-targeting therapies such as anti-nerve growth factor treatment [1], it is likely that β3 adrenoceptor activation is effective to reduce activation of C-fiber bladder afferent pathways along with suppression of inflammatory responses, thereby reducing DO. Also, vibegron treatment reduced the expression of TRPV1 and TRPA1 in detrusor muscles in SCI mice. Overall, the results of this study demonstrated that vibegron significantly improves storage LUTD as well as hyperexcitability of bladder afferent pathways after SCI.

CONCLUDING MESSAGE

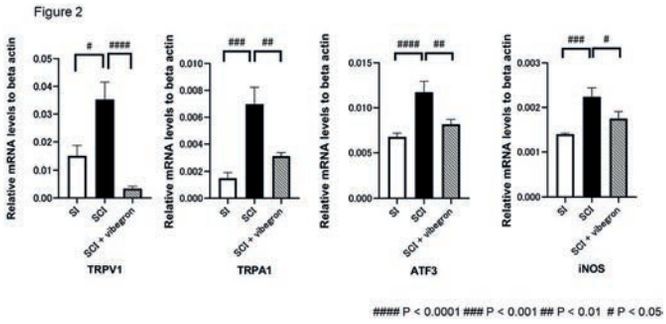
Vibegron improved SCI-induced detrusor overactivity along with significant reductions in C-fiber afferent receptors such as TRPV1, TRPA1 and inflammatory cytokines/markers such as ATF3 and iNOS in SCI mice. Thus, vibegron could be an effective therapeutic option for storage LUTD after SCI.

FIGURE 1



Representative CMG recordings in SCI mice

FIGURE 2



Real-time PCR results of C-fiber afferent receptors (TRPV1, TRPA1) and inflammatory markers (ATF3, iNOS) in spinal intact (SI) mice, vibegron-treated and saline-treated SCI mice

REFERENCES

1. Neurourol Urodyn. 2018 Aug;37(6):1889-1896.

Funding KAKENHI 18K16751 **Clinical Trial** No **Subjects** Animal **Species** Mouse **Ethics Committee** Kindai University Institutional Animal Care and Use Committee

461 www.ics.org/2020/abstract/461

STIMULATION OF BRAIN ALPHA7 NICOTINIC ACETYLCHOLINE RECEPTORS CAN INHIBIT THE RAT MICTURITION REFLEX THROUGH BRAIN GABA RECEPTORS

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HYPOTHESIS / AIMS OF STUDY

Psychological stress can induce not only frequent urination but also exacerbation of bladder dysfunction including overactive bladder (OAB) and bladder pain syndrome/interstitial cystitis (BPS/IC). Psychological stress-related information is conveyed to the brain, and then the brain recruits neuronal and neuroendocrine systems for adaptation to stressful conditions. However, the brain pathophysiological mechanisms underlying psychological stress-induced effects on bladder function are still unclear.

A previous study reported that a representative stress response, the sympatho-adrenomedullary (SA) system, is activated by centrally administered (±)-epibatidine (EP) [1], an agonist of nicotinic acetylcholine receptors (nAChRs). Although it is already reported that EP centrally inhibits the

rat micturition reflex [2], brain mechanisms for the inhibitory effect are not clarified yet. In this study, we investigated how centrally administered EP inhibits the micturition reflex focusing on the dependence on the SA system, brain nAChR subtypes and brain receptors of GABA, an inhibitory neurotransmitter, in rats.

STUDY DESIGN, MATERIALS AND METHODS

Urethane anesthetized (0.8 g/kg, ip) male Wistar rats (300-400 g) were used.

(1) Catheters were inserted into the bladder dome and the femoral artery to perform cystometry (12 ml/h saline infusion) and to collect blood samples, respectively. Two hours after the surgery, cystometry was started to evaluate intercontraction intervals (ICI) and maximal voiding pressure (MVP). One hour after the start, EP (0.3 or 1 nmol/rat) or vehicle [2.5 µl N,N-dimethylformamide (DMF)/rat] was intracerebroventricularly (icv) administered. Plasma noradrenaline (NA) and adrenaline (Ad) levels were measured at just before and at 5 min after the icv administration. We also confirmed effects of centrally pretreated mecamylamine (MEC, a non-selective antagonist of nAChRs, 100 or 300 nmol in 5 µl saline/rat, icv) on the EP (1 nmol/rat, icv)-induced responses.

(2) In some experiments, acute bilateral adrenalectomy (ADX) was performed before insertion of catheters described in (1). After the ADX, hydrocortisone was administered (5 mg/kg, im) to maintain levels of glucocorticoid. EP administration (1 nmol/rat, icv), cystometry and collection of blood samples were performed as described in (1).

(3) Effects of central pretreatment with methyllycaconitine (MLA, an alpha7 nAChR antagonist, 30 or 100 nmol in 5 µl saline/rat, icv), dihydro-beta-erythroidine (DHbE, an alpha4beta2 nAChR antagonist, 100 or 300 nmol in 5 µl saline/rat, icv) or SR95531 (SR, a GABAA antagonist, 0.1 nmol in 5 µl saline/rat, icv) on the EP (1 nmol/rat, icv)-induced responses were also investigated.

RESULTS

(1) Centrally administered EP dose-dependently prolonged ICI and elevated plasma NA and Ad without altering MVP compared to the vehicle-treated group (Fig. 1A). These EP-induced changes were significantly attenuated by central pretreatment with MEC (data not shown).

(2) The EP-induced ICI prolongation was not affected by ADX, which abolished the EP-induced elevation of plasma NA and Ad (Fig. 1B).

(3) Central pretreatment with MLA or SR significantly attenuated the EP-induced ICI prolongation (Fig. 2A and 2B), respectively, while DHbE showed no significant effect on the EP-induced response (data not shown).

INTERPRETATION OF RESULTS

Our present data indicate that EP centrally inhibits the micturition reflex through brain nAChRs as shown by centrally administered EP-induced ICI prolongation and by MEC-induced attenuation of the EP-induced response. Although NA and Ad generally induce urinary storage, the EP-induced inhibition seems to be independent of the EP-induced activation of the central SA outflow because ADX, which abolished the EP-induced elevation of plasma NA and Ad, had no effect on the EP-induced ICI prolongation. Since centrally administered EP had no effect on MVP, an urodynamic parameter of bladder efferent activity, EP might depress inputs to the micturition center, thereby inhibiting the micturition reflex. In the central nervous system, alpha7 and alpha4beta2 nAChRs are the most predominant subtypes of nAChRs and these subtypes are reported to enhance the release of various neurotransmitters including GABA, an inhibitory neurotransmitter, in the brain [3]. In this study, MLA and SR, but not DHbE, centrally attenuated the EP-induced ICI prolongation. Therefore, stimulation of brain alpha7 nAChRs might inhibit the micturition reflex through these receptors-mediated enhancement of GABA release and stimulation of brain GABAA receptors.

CONCLUDING MESSAGE

Centrally administered EP can inhibit the rat micturition reflex through brain alpha7 nAChRs and brain GABAA receptors, independently of the SA outflow modulation. Thus, brain alpha7 nAChRs could be a new target for alleviation of psychological stress-induced exacerbation of urinary bladder dysfunction such as OAB and BPS/IC.

FIGURE 1

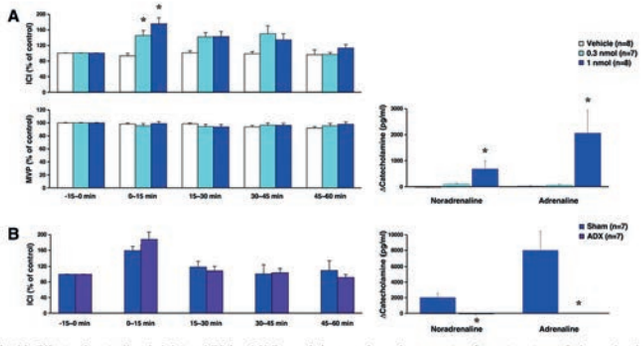

Fig. 1A. Effects of centrally administered EP (a nAChR agonist) on urodynamic parameters in cystometry and plasma levels of noradrenaline (NA) and adrenaline (Ad). Data of urodynamic parameters (ICI and MVP) were calculated as the ratio to the control values before icv administration (-15–0 min). ΔCatecholamine means increments of NA and Ad at 5 min after vehicle (2.5 µl DMF/rat, icv) or EP (0.3 or 1 nmol/rat, icv) administration in comparison with NA and Ad measured just before the administration. Values are means ± SEM. *P<0.05, when compared with the Bonferroni method to the Vehicle group. Fig. 1B. Effects of centrally administered EP (1 nmol/rat, icv) on ICI and plasma levels of NA and Ad in ADX and sham-operated (Sham) rats. Data of ICI were calculated as described in Fig. 1A. ΔCatecholamine means increments of NA and Ad calculated as described in Fig. 1A. Values are means ± SEM. *P<0.05, when compared with unpaired Student t-test to the Sham group.
ADX: acute bilateral adrenalectomy; ICI: intercontraction intervals; MVP: maximal voiding pressure; nAChR: nicotinic acetylcholine receptor.

FIGURE 2

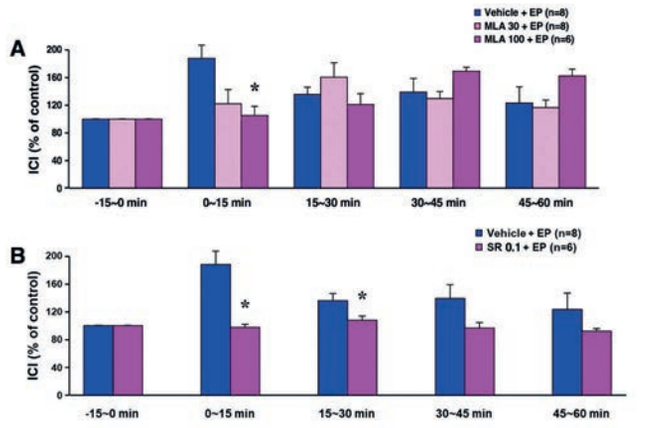

Fig. 2. Effects of central pretreatment with methyllycaconitine (A) (MLA, an antagonist of α7 nAChRs) or SR95531 (B) (SR, an antagonist of $GABA_A$ receptors) on centrally administered EP-induced ICI prolongation. Vehicle (5 µl saline/rat), MLA (30 or 100 nmol/rat) or SR (0.1 nmol/rat) was icv administered 30 min before EP administration (1 nmol/rat, icv). Data of ICI were calculated as described in Fig. 1A. Values are means ± SEM. *$P<0.05$, when compared with the Bonferroni method (A) or unpaired Student *t*-test (B) to the Vehicle + EP group.
ICI: intercontraction intervals; nAChR: nicotinic acetylcholine receptor.

REFERENCES

1. Shimizu T, Yokotani K. Brain cyclooxygenase and prostanoid TP receptors are involved in centrally administered epibatidine-induced secretion of noradrenaline and adrenaline from the adrenal medulla in rats. Eur J Pharmacol. 2009;606:77-83.
2. Lee SJ, Nakamura Y, de Groat WC. Effect of (+/-)-epibatidine, a nicotinic agonist, on the central pathways controlling voiding function in the rat. Am J Physiol Regul Integr Comp Physiol. 2003;285:R84-R90.
3. Gotti C, Zoli M, Clementi F. Brain nicotinic acetylcholine receptors: native subtypes and their relevance. Trends Pharmacol Sci. 2006;27:482-491.

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BEST IN CATEGORY PRIZE "RESEARCH METHODS / TECHNIQUES"

BEHAVIORAL, HISTOPATHOLOGICAL AND MOLECULAR EVALUATION OF USING LOW ENERGY SHOCK WAVE THERAPY IN A RAT MODEL OF EPIRUBICIN-INDUCED CYSTITIS

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HYPOTHESIS / AIMS OF STUDY

Epirubicin (EPI) is commonly used as an adjuvant intravesical therapy for treatment of non-muscle invasive bladder cancer (NMIBC). However, Its frequent instillation is mainly complicated with cystitis. Low energy shock wave (LESW) has been shown to have both anti-inflammatory and analgesic effects, so we evaluated the effect of LESW on the bladder inflammatory changes associated with EPI-induced cystitis in a rat model.

STUDY DESIGN, MATERIALS AND METHODS

30 female Fischer rats were randomly allocated into 3 groups (10 rats each); Control, EPI and EPI plus LESW groups. Saline (0.6 ml) or EPI (0.6 mg/0.3 ml diluted in saline) was instilled and retained in the bladder for 1 hour, LESW treatment (300 pulses, 0.12 mJ/mm^2) was applied simultaneously to the bladders in EPI plus LESW group. This was repeated daily for 1 week. Behavioral assessment of pain, eye movement and locomotion was performed 1 hour after instillation. Magnetic resonance imaging (MRI) was also carried out to estimate bladder wall thickness and bladder capacity. After sacrification, bladders were harvested for bladder weight estimation and histopathological examination. Molecular studies of inflammatory markers in terms of IL-6 and TNF-α relative gene expression levels were also assessed.

RESULTS

LESW treatment significantly improved pain, eye movement and locomotion scores, reduced bladder weights and down-regulated IL-6 and TNF-α relative gene expression levels (table 1). MRI of EPI plus LESW group showed that bladder wall thickness was 0.73 ± 0.25 mm vs. 1.64 ± 0.27 mm in EPI group ($p < 0.001$) and bladder capacity was 8.7 ± 1.53 µl vs. 5.07 ± 1.31 µl in EPI group ($p < 0.001$). Yet, there was no significant difference regarding the degree of bladder inflammation between EPI and EPI plus LESW groups (table 2).

INTERPRETATION OF RESULTS

Intravesical instillation of EPI up-regulated IL-6 and TNF-α expression and induced bladder inflammation, thus caused pain behavioral changes, increased bladder wall thickness and reduced bladder capacity. LESW treatment has been shown to suppress the inflammatory changes associated

with intravesical EPI instillation, by significant down-regulation of IL-6 and TNF-α relative gene expression. It also resulted in significant improvement of pain behavioral changes. EPI plus LESW group showed statistically significant lower bladder weights, less bladder wall thickness and increased bladder capacity relative to EPI group, but the degree of bladder inflammation didn't differ significantly between both groups.

CONCLUDING MESSAGE

LESW suppresses the bladder inflammatory changes induced by intravesical instillation of EPI, so LESW might be nominated as a promising method for relieving bladder inflammation associated with EPI instillation for treatment of NMIBC.

FIGURE 1

Variables Mean ± SD	Group 1 (Control)	Group 2 (EPI)	Group 3 (EPI + LESW)	P	P1
Bladder weights (mg)	59.4 ± 4.8	155.9 ± 16.8	103.5 ± 8.4	*<0.001**	*<0.001ǂ*
Pain assessment score	1.2 ± 0.42	3.2 ± 0.67	2.1 ± 0.47	*<0.001**	*0.001ǂ*
Eye movement score	1.1 ± 0.32	3.1 ± 0.74	1.9 ± 0.57	*<0.001**	*0.001ǂ*
Locomotion score	1.9 ± 0.74	4.1 ± 0.66	2.3 ± 0.67	*<0.001**	*<0.001ǂ*
IL-6 relative gene expression	0.88 ± 0.05	3.21 ± 0.65	1.96 ± 0.63	*<0.001**	*0.001ǂ*
TNF-α relative gene expression	0.81 ± 0.05	1.79 ± 0.14	1.23 ± 0.07	*<0.001**	*<0.001ǂ*

P = group 3 vs group 2 vs group 1, P1 = group 3 vs group 2.

*ANOVA.
ǂstudent's *t*-test.

Table 1: Overall results of bladder weights, pain behavioral scores and molecular studies of inflammatory markers

FIGURE 2

Scores of bladder inflammation *n* (%)	Group 1 (Control)	Group 2 (EPI)	Group 3 (EPI + LESW)	P	P1
0	10 (100)	5 (50)	6 (60)		
1	0	2 (20)	4 (40)	*0.02_*	0.32
2	0	3 (30)	0		

Scores of bladder inflammation; 0 = no evidence of inflammatory cell infilterates or interstitial edema, 1= mild inflammatory cell infilterates with little interstitial edema, 2 = moderate inflammatory cell infilterates and moderate interstitial edema. P = group 3 vs group 2 vs group 1, P1 = group 3 vs group 2.

_fisher's exact test.

Table 2: Histopathological results of bladder inflammatory changes

Funding No **Clinical Trial** No **Subjects** Animal **Species** Rat **Ethics Committee** Mansoura Faculty of Medicine - Institutional Research Board (MFM-IRB)

SESSION 31 (PODIUM) - BEST CONSERVATIVE MANAGEMENT
Abstracts 463-468
09:00 - 10:30, Brasilia 1
Chairs: Dr Kathleen Frances Hunter (Canada), Dr Diane K Newman (United States)

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BEST IN CATEGORY PRIZE "E-HEALTH"

APP-BASED TREATMENT FOR FEMALE URINARY INCONTINENCE AS EFFECTIVE AND COST-EFFECTIVE IN COMPARISON TO CARE AS USUAL IN PRIMARY CARE: A PRAGMATIC RANDOMIZED CONTROLLED TRIAL.

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HYPOTHESIS / AIMS OF STUDY

The majority of women with urinary incontinence (UI) experience barriers to seek help. Often when they do seek help, they receive suboptimal care. This may lead to inadequate treatment and unnecessary high costs for society. An eHealth application could both improve care and reduce costs. Previously, we showed effectiveness of an app-based treatment for stress-, urgency- and mixed type UI after 4 months. Until now, long-term effectiveness and cost-effectiveness were not assessed in comparison to care-as-usual.

The aims of this study are to assess effectiveness and cost-effectiveness of an app-based treatment for female stress-, urgency- and mixed type UI after 12 months in comparison to care-as-usual in primary care.

STUDY DESIGN, MATERIALS AND METHODS

We performed a pragmatic, parallel arm, randomized controlled non-inferiority trial in Dutch primary care of female patients with ≥2 episodes per week of stress-, urgency-, or mixed type UI.

Women were recruited through general practices and (social) media from 2015 through July 2018. We compared a stand-alone app-based treatment with pelvic floor muscle and bladder training to care-as-usual through a general practitioner according to Dutch and international guidelines for treatment of urinary incontinence. Assessment of the primary outcome measure, effectiveness after 4 months, was previously published.[1]

Now, we present effectiveness and cost-effectiveness after 12 months, which are defined as secondary outcomes. Outcomes of effectiveness were change of symptom severity from baseline (ICIQ-UI-SF) and change of impact on disease-specific and general quality of life (ICIQ-LUTS-QoL and EQ-5D-5L), these were assessed for superiority. Also we compared total costs, cost-effectiveness based on IIALY (Incontinence Impact Adjusted Life Years score) and cost-utility based on Quality Adjusted Life Years (QALY) score from a 1 year societal perspective.

RESULTS

In total, 262 women were eligible and randomized equally. In the app-based treatment group 89 (68%) women completed follow up, as for 83 (63.3%) women in the care-as-usual group. Both groups showed improvement with between group differences of 0.903 (95%CI -0.66 to 1.871) for severity of incontinence, 0.445 (-1.125 to 2.015) for impact of incontinence on quality of life and 0.001 (-0.041 to 0.043) for improvement of general quality of life. No treatment was superior over the other. Women in the intervention group gained, on average, 0.71 IIALYs and 0.89 QALYs. Women in the control group gained on average 0.66 IIALYs and 0.91 QALYs. Mean direct and indirect costs per participant per year in the app-based treatment group were €1520 including €87 UI specific costs and in the care-as-usual group €1680 including €191 UI specific costs. The incremental cost-effectiveness ratio was €3696 and the incremental cost-utility ratio was €-6379. In total, 65.6% of the 5000 replications in the bootstrap simulation were in the lower halve of the incremental cost-effectiveness plan, which means that they represented lower costs for the app-based treatment, shown in figure 1. The mean difference of effect between groups was minimal and smaller than the known margin for clinical relevance. Sensitivity analysis for increased costs for app-based treatment, and stratification for UI type and recruitment showed similar results.

INTERPRETATION OF RESULTS

After 12 months of treatment, both app-based treatment and care-as-usual for female stress-, urgency and mixed UI showed clinically relevant improvements of UI-symptoms and quality of life. There was no significant or clinically relevant difference between groups.

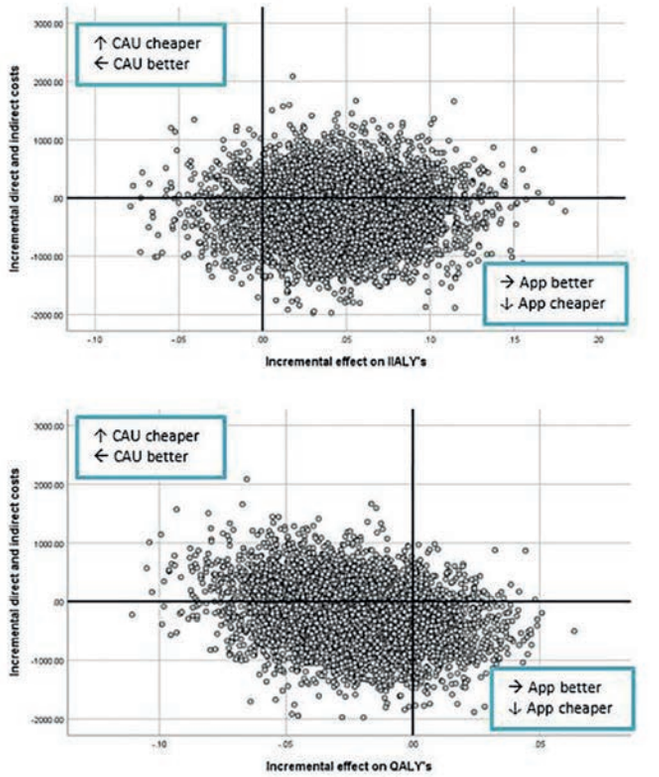
App-based treatment was less expensive than care-as-usual, with a mean difference in total costs of €161 and in UI specific costs of €87 per patient per year. These results remained steady in scenario's with higher costs for app-development and did not depend on type of incontinence (stress versus urgency) or recruitment method (through general practitioner or (social) media).

CONCLUDING MESSAGE

The app-based treatment for female stress-, urgency- and mixed UI is an equally effective, and cost-effective alternative for care-as-usual in general practice.

FIGURE 1

Figure 1. Incremental cost-effectiveness planes per outcome parameter.



REFERENCES

1. Loohuis AMM, Wessels NJ, Dekker JH, van Merode NAM, Slieker-ten Hove MC, Kollen BJ, Berger MY, van der Worp H, Blanker MH. App-based treatment for urinary incontinence non-inferior to care as usual in primary care. Results of a pragmatic, randomized controlled trial. Annals of Family Medicine 2020 (In press).

Funding Disclosures and funding: All authors declare to have no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years: no other relationships or activities that could appear to have influenced the submitted work **Clinical Trial** Yes **Registration Number** Dutch Trial Register (ID: Trial NL4948) **RCT** Yes **Subjects** Human **Ethics Committee** The Medical Ethical Review board of the University Medical Center Groningen (Netherlands) (METc-number: 2014/574) approved this study. All participants gave written informed consent. **Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE "GERIATRICS / GERONTOLOGY"

THE ELECTRIC TRIAL: ELECTRIC TIBIAL NERVE STIMULATION TO REDUCE INCONTINENCE IN CARE HOMES

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence (UI) is highly prevalent in nursing and residential care home (CH) residents and associated with high personal, social, physical and economic burden. UI treatment options are limited in this care context and predominantly rely on containment using expensive and undignified absorbent products. Transcutaneous posterior tibial nerve stimulation (TPTNS) is a non-invasive, safe and low-cost intervention with promising evidence of effectiveness for reducing UI in adults [1], including older women [2]. The ELECTRIC trial aimed to compare the clinical effectiveness of TPTNS and sham stimulation to reduce the volume of UI in CH residents.

STUDY DESIGN, MATERIALS AND METHODS

A multicentre, pragmatic, parallel group randomised controlled trial compared 24-hour volume of UI leaked in CH residents receiving TPTNS or sham electrical stimulation at 6 weeks. Trial recruitment took place between Jan 2018 and Aug 2019 in 37 nursing and residential CHs in Scotland and England. Eligible residents had weekly or more UI, wore absorbent pads and used a toilet/toilet aid for bladder emptying, with or without assistance. Excluded residents had an indwelling urinary catheter, post void residual urine (PVRU) volumes >300 ml, a cardiac pacemaker, bilateral leg ulcers, treated epilepsy, pelvic cancers or were non-English speaking.

Residents were randomised (1:1) via remote computer allocation, stratified by sex, severity of UI and care home centre. CH staff were trained to deliver a 6-week programme of 12 x 30 min stimulations to all participants using two surface electrodes and an electrical stimulator. The TPTNS group received 30 minutes' continuous stimulation to the tibial nerve (behind medial malleolus) at the highest tolerable intensity, 10 Hz frequency, pulse width 200µs-1 twice weekly for 6 weeks. Those in the sham group received identical stimulation but at a low intensity (4 mA) stimulation and delivered above the lateral malleolus, to avoid the tibial nerve.

The primary outcome was the volume of urine leaked in a 24-hour period measured by pad weight test (PWT) at 6 weeks post randomisation. Secondary outcomes were the volume of UI leaked over a 24-hr period at 12 and 18 weeks; the number of absorbent pads used in 24-hrs at 6, 12 and 18 weeks; resident, staff, and family perceptions of bladder condition; toileting skills and quality of life.

Intention-to-treat analysis was undertaken, with participants' data analysed according to their randomised group. Group differences in UI volume leaked at 6 weeks were assessed using a linear mixed model adjusting for stratification variables, UI severity, gender and baseline UI leakage, with CH centre as a random effect. Secondary outcomes were analysed using similar generalised linear models. A sample size of 278 residents randomised allowed detection of a 200 ml difference in the primary outcome with 90% power, but to account for potential differences in variability and missingness of data, the target recruitment was 400 residents.

RESULTS

406 residents were randomised from 37 CHs: 197 residents to TPTNS group and 209 to sham stimulation. Resident mean age was 85.5 years (SD 8.1) and 77.6% were female. The mean Mini Mental State Examination Score (MMSE) was 13.1 (SD 9.1) indicating moderate dementia and 76.6% of the 252 residents with a MMSE score were in the moderate or severe dementia category. The mean Barthel score was 7.6 (SD 3.9) demonstrating the high physical dependency and more than half (52%) were severely frail with 27% moderately frail. UI in 233 (57.2%) was severe (>400 ml/24 hours) and for the whole sample the mean total urine leakage was 573 ml (SD 442). The mean 24-hour pad use was 3.4 (SD 1.7).

Primary outcome data were available for 344 residents (166 TPTNS and 178 sham stimulation). Table 1 shows there was no significant difference between the groups in the 24-hour volume of urine leaked at 6 weeks post randomisation (primary outcome time point) or at 12 or 18 weeks' post-randomisation.

Sub-group analysis showed no significant effects of TPTNS at the primary outcome time point: there was no significant difference between groups by sex, severity of UI; physical dependence; mobility levels; toilet use dependence; clinical frailty; use of anticholinergic medication; or falls status.

There were no significant differences in secondary outcomes between the groups at 6-weeks for the number of absorbent pads used in 24 hours, resident quality of life, resident perception of bladder condition or family perception of bladder condition. However, there was a significant difference in staff assessment of residents' toileting skills [TPTNS mean score 14.2 (SD 6.8); sham mean score 12.5 (SD 7.4); mean difference 1.23 (95% CI 0.22 to 2.24; p = 0.017)]. The staff perception of resident bladder condition was significantly better for the TPTNS group than the sham group [TPTNS mean score 2.9 (SD 1.4); sham mean score 3.2 (SD 1.4); mean difference -0.51 (95% CI -0.96 to -0.07; p = 0.024)]. The 12-week and 18-week secondary outcomes showed no significant differences between the TPTNS and sham groups for the number of absorbent pads used in 24-hours, resident quality of life, resident, family or staff perception of resident's bladder condition. There was a significant difference in staff assessment of residents' toileting skills at 18 weeks [TPTNS mean score 15.6 (SD 6.0); sham mean score 13.7 (SD 6.8); mean difference 1.24 (95% CI 0.16 to 2.33; p = 0.024)].

INTERPRETATION OF RESULTS

In this sample of very elderly, physically and mentally frail nursing and residential care home residents, we found no evidence that TPTNS effectively reduced the volume of urine leaked in 24-hours, compared to sham stimulation.

CONCLUDING MESSAGE

In care home residents TPTNS is no more effective than sham stimulation at reducing volume of UI. Investigation of the potential role of care home contextual factors to explain the result should be undertaken.

FIGURE 1

	Total volume urine (ml) leaked [mean (SD)]					
	n	TPTNS	n	Sham	Mean difference (95% CI)	p-value
Baseline	197	559 (385)	209	586 (490)		
6 weeks	166	600 (403)	178	518 (412)	64.60 (-12.89, 142.08)	0.102
12 weeks	152	615 (453)	156	544 (426)	78.78 (-2.62,160.18)	0.058
18 weeks	133	586 (414)	156	572 (469)	28.96 -54.97, 112.89)	0.499

Table 1: Total volume of urine leaked (24-hour pad weigh tests) at 6, 12 and 18 weeks.

REFERENCES

1. Booth J, Connelly L, Dickson S, Duncan F, Lawrence M. The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: A systematic review. Neurourology and Urodynamics. 2018 Feb;37(2):528-541. doi: 10.1002/nau.23351. Epub 2017 Jul 21.
2. Schreiner L, Santos T, Knorst M. Randomised trial of transcutaneous tibial nerve stimulation to treat urge urinary incontinence in older women. Int Urogynecol J. 2010; 21:1065–1070.

Funding National Institute for Health Research Health Technology Assessment **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov, NCT03248362 **RCT** Yes **Subjects** Human **Ethics Committee** Yorkshire & The Humber Bradford Leeds Research **Ethics Committee** / Scotland A Research **Ethics Committee Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE "CONSERVATIVE MANAGEMENT"

MORPHOMETRICAL AND FUNCTIONAL CHANGES FOLLOWING PELVIC FLOOR PHYSIOTHERAPY FOR URINARY INCONTINENCE IN OLDER WOMEN

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HYPOTHESIS / AIMS OF STUDY

Evidence from recent clinical trials, including the Group Rehabilitation Or IndividUal Physiotherapy trial (GROUP trial), [1] suggests that group-based physiotherapy is not inferior to individual physiotherapy for reducing urinary incontinence (UI) episodes in older women with stress and mixed UI, making pelvic floor muscle (PFM) training more accessible and lessening the burden of UI on the health care system.

It is unclear, however, whether changes in pelvic floor morphometry and PFM function previously reported for the current standard of care (individual physiotherapy),[2] are comparable to a group-based physiotherapy approach. Furthermore, it is not known if both interventions result in similar self-perceived efficacy by women in performing PFM exercises and preventing urinary leakage. In this secondary analysis, we aim to investigate the morphometrical, functional and related self-efficacy effects of these two physiotherapy approaches (individual and group-based) to treat UI in older women.

STUDY DESIGN, MATERIALS AND METHODS

The GROUP trial (ClinicalTrials.gov, number NCT02039830) [1] is an assessor-blind, randomized, multi-centre, non-inferiority trial comparing individual versus group-based physiotherapy with respect to the average percentage reduction in UI episodes, one-year post-randomization. The study protocol was approved by the research ethics board at each recruitment site and each volunteer provided written consent prior to participation.

Eligible participants were women age 60 and over, who reported at least three episodes of stress or mixed UI episodes per week during the preceding three months. Details on the participants' inclusion/exclusion criteria are provided in the trial protocol.[3]

Pelvic floor morphometry, PFM function and self-efficacy data were acquired at baseline, immediately post-treatment and at one-year follow-up by an outcome assessor blinded to the participants' intervention allocation.

Pelvic floor morphometry was obtained from transperineal ultrasound (US) volumes using either a Siemens Acuson Antares system with a 3–5 MHz curvilinear 3D/4D probe or a GE Voluson Expert system with a 2–6 MHz curvilinear 3D/4D probe, depending on equipment availability at each study centre.

PFM function was assessed using the Montreal dynamometer, consisting of two parallel aluminium branches fixed to a base, allowing for measurements in variable vaginal apertures. The lower branch has two strain gauges mounted in a differential arrangement.

Participants' perceptions of self-efficacy in performing PFM exercises was assessed using the Broome Pelvic Muscle Self-Efficacy Scale (Part A), a 14-item questionnaire with scores ranging from 0-100.

Pelvic floor morphometrical and functional parameters in addition to perceived self-efficacy scores were compared using mixed-effects models for repeated-measures between intervention arms and over time (2 intervention arms, 3 time-points), in order to minimize the effects of missing data. The outcome was a function of the intervention arm, time-points and their interaction.

RESULTS

A total of 362 participants were randomized to either individual (184) or group-based physiotherapy (178), of which 337 (93%) completed the intervention and 319 (88%) completed the one-year follow-up assessment. The mean age of the participants was 67.9 years old (SD 5.8). Three hundred (82.9%) had symptoms of mixed UI, and 62 (17.1%) of stress UI. Mean duration of UI symptoms was 9.7 (SD 9.8) years. Mean leakage episodes per week was 14.7 (SD 14.7).

Figures 1 and 2 summarize results for pelvic floor morphometry and PFM function. No differences were found between intervention arms (individual versus group-based physiotherapy) in most of the pelvic floor morphometric and PFM functional parameters for all time-points. However, positive post-treatment changes in pelvic floor morphometry and PFM function were observed in both groups and were maintained at the one-year follow-up.

For pelvic floor morphometry, changes over time were not observed during rest or PFM maximum contraction task but were observed during cough task. Participants in each intervention arm presented less caudal movement of the PFMs and a smaller opening of the levator hiatus while coughing, both at post-treatment and at the one-year follow-up.

For PFM function, both interventions resulted in a stronger, faster, more coordinated and more endurant PFM contractions. Both at post-treatment and at the one-year follow-up, participants presented higher forces on the maximal contraction task; a higher number of valid rapid contractions with faster contraction and relaxation speeds on the rapid

contractions task; a higher area under the curve on a sustained contraction task, and higher peak and valley forces on the triple cough task. Of interest, PFM contractions were stronger and better maintained between each cough burst.

For perceived self-efficacy, both interventions resulted in significantly higher scores after treatment and in the long-term (P<0.001), with no differences found between intervention arms or between post treatment and one-year follow-up; overall, high self-efficacy was perceived by 48 (14%) of the 334 participants at baseline, 307 (92%) of the 334 participants post-intervention and 284 (90%) of the 315 participants at the one-year follow-up.

INTERPRETATION OF RESULTS

Our results show that aging women benefit significantly and equally from either individual or group PFM physiotherapy. In both intervention arms, participants presented important post-treatment gains on pelvic floor morphometry while coughing and on PFM function during rapid, maximal and sustained contractions, and while performing triple coughs. More importantly, gains were maintained in the long term. Finally, both intervention arms reported better self-efficacy in performing PFM exercises both immediately after treatment and in long term.

CONCLUDING MESSAGE

Women age 60 and over with stress or mixed UI presented long-term pelvic floor morphometrical and PFM functional changes following a standardized individual or group-based physiotherapy treatment. These changes suggest a better control of PFMs, which is supported by the participants' reported self-efficacy in performing PFM exercises.

FIGURE 1

Pelvic floor morphometric parameters

	Intervention arm	n	Baseline	n	Post-treatment	n	One-year follow-up	Interaction effect	Group effect	Time effect	Effect size
Rest task											
BN_{HEIGHT} [mm]	Individual	146	23.9 (4.4)	149	24.4 (5)	125	23.7 (4.5)	0.366	0.208	0.942	-0.02
	Group	146	24.4 (4.4)	142	24.2 (4.6)	116	24.6 (5.4)				
PFM_{HEIGHT} [mm]	Individual	143	18.3 (6.6)	150	19.3 (6.5)	127	18 (6.7)	0.957	0.307	0.097	-0.06
	Group	150	17.8 (6.4)	144	18.7 (6.7)	120	17.7 (6.1)				
LH_{AREA} [mm^2]	Individual	141	1519 (335)	143	1492 (312)	117	1494 (314)	0.998	0.566	0.626	0.01
	Group	143	1503 (364)	133	1479 (332)	119	1481 (375)				
LH_{AP} [mm]	Individual	147	54 (6.7)	151	53 (6.8)	130	53.8 (7.4)	0.682	0.223	0.564	0.09
	Group	153	53.2 (7.8)	144	53 (7.2)	127	52.7 (8)				
PFM maximal contraction task											
BN_{HEIGHT} [%]	Individual	128	9 (20)	130	8 (19)	109	9 (15)	0.356	0.483	0.601	0.02
	Group	127	7 (16)	121	10 (15)	108	6 (28)				
PFM_{HEIGHT} [%]	Individual	141	23 (40)	149	17 (48)	125	15 (141)	0.670	0.243	0.695	-0.03
	Group	148	24 (38)	142	21 (37)	118	26 (39)				
LH_{AREA} [%]	Individual	140	-16 (12)	143	-18 (12)	116	-17 (13)	0.865	0.587	0.655	0.09
	Group	139	-16 (13)	129	-17 (13)	115	-17 (12)				
LH_{AP} [%]	Individual	147	-15 (9)	151	-16 (9)	130	-16 (10)	0.941	0.677	0.793	0.05
	Group	152	-15 (10)	142	-16 (9)	126	-15 (9)				
Cough task											
BN_{HEIGHT} [%]*	Individual	141	-16 (23)	145	-15 (25)	120	-16 (21)	0.260	0.945	0.070	-0.08
	Group	145	-19 (22)	136	-12 (22)	114	-15 (27)				
PFM_{HEIGHT} [%]**	Individual	139	-17 (33)	150	-7 (37)	121	-3 (74)	0.604	0.187	0.008	-0.19
	Group	147	-17 (27)	138	-12 (32)	117	-10 (28)				
LH_{AREA} [%]**	Individual	133	13 (14)	141	7 (16)	111	7 (18)	0.868	0.806	<0.001	0.33
	Group	139	13 (15)	128	6 (16)	116	7 (16)				
LH_{AP} [%]**	Individual	142	1 (8)	150	-2 (10)	126	-2 (10)	0.668	0.839	<0.001	0.27
	Group	150	1 (8)	140	-2 (8)	125	-1 (10)				

Data are means and standard deviations (SD). Mixed models for repeated measures (2 intervention arms, 3 time-points). Cohen's dz effect sizes were based on paired t-test between the baseline and the one-year follow-up.2 *Post-hoc differences: baseline ver

FIGURE 2

PFM functional parameters

	Speculum opening	Treatment arm	n	Baseline	n	Post-treatment	n	One-year follow-up	Interaction effect	Group effect	Time effect	Effect size
Rest task												
Mean force at minimal dynamometer opening [N]	11 mm	Individual	165	1.2 (0.9)	164	1.3 (0.8)	142	1.2 (0.7)	0.440	0.941	0.539	-0.02
		Group	158	1.1 (0.9)	153	1.2 (0.8)	126	1.3 (0.9)				
Maximal vaginal aperture [mm]	-	Individual	165	36.3 (8.3)	164	37 (8.3)	143	35.8 (8)	0.332	0.405	0.463	0.08
		Group	157	37.5 (8.1)	150	36.4 (7.6)	126	36.5 (7.6)				
PFM maximal contraction task	25 mm											
Maximal force [N]*		Individual	167	5.4 (3.1)	158	6.6 (3.6)	141	6.4 (3.4)	0.868	0.892	<0.001	0.08
		Group	155	5.5 (3.2)	152	6.4 (3.2)	127	6.4 (3.3)				
PFM rapid contractions task	25 mm											
Number of valid contractions [n]*		Individual	167	7.8 (2.9)	161	9 (2.9)	141	9.1 (3.1)	0.156	0.038	0.000	-0.35
		Group	156	7.8 (2.7)	153	8.6 (2.7)	125	8.3 (2.5)				
Speed of contraction [N/s]*		Individual	167	9.9 (7.7)	160	11.1 (7.3)	141	12.1 (8.3)	0.965	0.096	0.001	-0.28
		Group	156	9 (6.3)	153	10.5 (6.3)	125	11.3 (8.3)				
Speed of relaxation [N/s]*		Individual	167	-6.2 (5)	160	-7.9 (5.9)	141	-7.9 (5.3)	0.552	0.522	0.002	0.30
		Group	156	-7 (5)	153	-7.9 (4.8)	125	-7.8 (5.2)				
PFM sustained contraction task	25 mm											
Area under the force curve [N.s]*		Individual	163	94.5 (65.2)	161	119.7 (80.3)	138	114.3 (73.4)	0.853	0.980	<0.001	-0.28
		Group	154	97.6 (67.9)	151	116.3 (74.7)	125	114.2 (68.2)				
Triple cough task	25 mm											
Peak force 1**		Individual	165	2.4 (1.9)	159	4.1 (2.8)	138	3.7 (2.7)	0.942	0.253	<0.001	-0.46
		Group	151	2.3 (1.5)	154	3.9 (2.6)	124	3.4 (2.2)				
Peak force 2**		Individual	165	2.9 (2.2)	159	3.9 (2.9)	138	3.5 (2.7)	0.96	0.28	<0.001	-0.18
		Group	151	2.8 (2)	154	3.7 (2.5)	124	3.3 (2.2)				
Peak force 3*		Individual	165	3.2 (2.2)	159	4.5 (2.9)	138	4.1 (2.6)	1.00	0.77	<0.001	-0.31
		Group	151	3.1 (2.2)	154	4.4 (2.7)	124	4 (2.6)				
Valley force 1*		Individual	165	0.9 (0.9)	159	1.7 (2)	138	1.7 (1.8)	0.97	0.72	<0.001	-0.41
		Group	151	0.9 (0.9)	154	1.7 (1.7)	124	1.6 (1.4)				
Valley force 2*		Individual	165	0.9 (0.9)	159	1.8 (1.9)	138	1.6 (1.7)	0.98	0.75	<0.001	-0.38
		Group	151	0.9 (0.9)	154	1.7 (1.7)	124	1.5 (1.5)				

Data are means and standard deviations (SD). Mixed models for repeated measures (2 intervention arms, 3 time-points). Cohen's dz effect sizes were based on paired t-test between the baseline and the one-year follow-up.2 *Post-hoc differences baseline vers

REFERENCES

1. Neurourol. Urodyn., vol. 38, 2019, p. S359–61.
2. Neurourol Urodyn 2013;32:1086–95. https://doi.org/10.1002/nau.22370.
3. Trials 2017;18:544. https://doi.org/10.1186/s13063-017-2261-4.

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EFFECTS OF PHYSIOTHERAPY TREATMENT ON THE PELVIC FLOOR MUSCLE FUNCTION AND MORPHOLOGY IN GYNECOLOGICAL CANCER SURVIVORS WITH DYSPAREUNIA: A PROSPECTIVE STUDY

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HYPOTHESIS / AIMS OF STUDY

Gynecological cancer treatments often result in pelvic floor muscle (PFM) dysfunctions that could contribute to the development of pelvic floor disorders significantly affecting the quality of life of women and their partners (1). Although pain during sexual intercourse (dyspareunia) affects more than half of cancer survivors, very few evidence-based treatment options are available for this population. Prospective studies and randomized clinical trials support the effectiveness of physiotherapy (PT) which could be recommended as a first-line treatment for women suffering from vulvar pain with no history of cancer (2). Also, data in gynecological cancer survivors with dyspareunia are limited to a single prospective study conducted by our team. Statistically and clinically significant changes in pain symptoms and sexual function were found after PT treatment targeting PFM dysfunctions (3). However, there is a gap in knowledge about treatment mechanisms in this oncological population as no study thus far has investigated the changes in PFM function and morphology after PT treatment. Therefore, the aim of the study is to evaluate the effects of PT on PFM function and morphology in gynecological cancer survivors suffering from dyspareunia.

STUDY DESIGN, MATERIALS AND METHODS

Data of this study were derived from the prospective study investigating the effects of PT in 31 gynecological cancer survivors with dyspareunia (endometrial cancer = 20 (64.5%), cervical cancer = 11 (35.5%)). Women were included if they had completed cancer treatments for at least three months and presented vulvovaginal pain (intensity of ≥5 on a numerical rating scale), for at least 80% of sexual intercourse attempts, for more than three months. A standardized pelvic examination was performed by a gynecologic oncologist from our team to confirm the eligibility of participants. PT treatment consisted of 12 weekly 1-hour sessions, including education, PFM exercises with biofeedback using an intra-vaginal probe, manual therapy such as stretching techniques, in addition to home exercises (five times per week). Participants were asked to refrain from using other treatments that could influence pain symptoms or PFM outcomes during their participation in the study.

Women underwent individual baseline and post-treatment assessments with an experienced physiotherapist not involved in the treatment. The physiotherapist taught the participant how to perform PFM contractions correctly. Then, the assessment of the PFM function and morphology was performed in a supine position after the participant had emptied her bladder.

PFM function was assessed using an intra-vaginal dynamometric speculum to measure the following five parameters. 1) Passive resistance at the minimal aperture (N). 2) Tissue flexibility in accordance to patient tolerance of the stretch to the maximal aperture (mm). 3) PFM maximal strength (N) according to a 10-s PFM maximum voluntary contraction (MVC). 4) PFM coordination, extracted from a 15-s rapid-repeated PFM MVCs, and described as the number of rapid contractions and speed of contraction (N/s). 5) PFM endurance using a 90-s sustained PFM MVC, defined as the normalized area under the force curve ([area/maximal force]·100) (%·s).

PFM morphology was evaluated with 3D/4D transperineal ultrasound imaging from GE Healthcare, model Voluson E8 Expert BT10 equipped with the convex probe RM6C. Measurements were taken in the mid-sagittal and axial planes under two conditions: rest and PFM MVC. The following six parameters were measured. 1) Bladder-neck (BN) position according to the horizontal (x-axis) and vertical position (y-axis) in cm. 2) Anorectal angle (°). 3) Levator plate angle (°). 4) Levator hiatal (LH) area (cm2). 5) LH anterior-posterior (AP) diameter (cm). 6) LH left-right (LR) diameter (cm).

PFM dynamometric and morphologic parameters were shown to be valid, reliable, and sensitive to change in previous studies with similar populations. All data analyses were processed offline. As data were normally distributed, paired t-tests were conducted to investigate the changes from baseline to post-treatment.

RESULTS

Participants' mean age was 55.9 (SD 10.8), and body mass index was 28.5 (SD 5.3) kg/m2. Stages of cancer were 1 (n=19) (61%), 2 (n=6) (19%), 3 (n=5) (16%) and 4 (n=1) (3%). As for cancer treatments, 24 women (77%) had surgery (total hysterectomy and bilateral salpingo-oophorectomy=23, total hysterectomy=1), 19 (61%) had brachytherapy, 15 (48%) had external beam radiation therapy, and 16 (52%) had chemotherapy. The median of time since cancer treatments to baseline assessment was 38 months (quartile Q1=9, quartile Q3=70). Table 1 and Table 2 show PFM dynamometric and morphologic measures at baseline and post-treatment assessments. Of the 31 women assessed at baseline, one withdrew from the study (disease in the family) and two were lost at follow-up.

INTERPRETATION OF RESULTS

Significant changes in PFM function were found from baseline to post-treatment. Participants showed a reduction in passive resistance at the minimal aperture, an increase in tissue flexibility as well as improvements in PFM coordination and endurance. However, the change in PFM maximal strength from baseline was not statistically significant. This was expected as PT treatment emphasized muscle relaxation and motor control rather than strength training.

Regarding PFM morphology, results demonstrate significantly greater anorectal angle, smaller levator plate angle as well as larger LH dimensions at rest following PT, suggesting a lower PFM tone. At PFM MVC, the BN was positioned superiorly and anteriorly after PT. Furthermore, a significant decrease in LH area and LH AP diameter were detected.

CONCLUDING MESSAGE

To our knowledge, this is the first study to evaluate the effects of PT on PFM function and morphology in gynecological cancer survivors with dyspareunia. Findings support the rationale that PT treatments contribute to improving the PFM function and morphology in this population, which may represent a key treatment mechanism to reduce pain symptoms. However, a well-designed randomized clinical trial is needed to confirm these findings.

FIGURE 1

	Baseline (n=30)†	Post-treatment (n=28)	P
Passive resistance at the minimal aperture (N)	1.53 (0.61)	1.18 (0.61)	.006*
Maximal aperture (mm)	22.60 (8.09)	31.73 (7.99)	<.001*
Maximal strength (N)	4.43 (2.29)	5.14 (2.38)	.134
Number of rapid contractions	6.6 (2.3)	9.7 (3.5)	<.001*
Speed of contraction – Ascending slope (N/s)	6.54 (6.36)	9.12 (6.84)	.012*
Speed of contraction – Descending slope (N/s)	-6.21 (5.03)	-8.54 (6.49)	.027*
Endurance (%·s)	1771.03 (761.23)	2403.77 (706.79)	<.001*

All measurements are expressed as mean (SD). Significant difference: p<.05*
†One participant was not able to complete the dynamometric assessment due to pain.

Table 1: Baseline and post-treatment dynamometric measurements

FIGURE 2

	Baseline (n=31)	Post-treatment (n=28)	P
Rest			
X-axis – BN position (cm)	-0.15 (0.40)	-0.11 (0.53)	.497
Y-axis – BN position (cm)	2.99 (0.45)	3.02 (0.46)	.700
Anorectal angle (°)	106.78 (9.77)	112.64 (8.94)	<.001*
Levator plate angle (°)	23.56 (6.56)	20.03 (6.55)	<.001*
LH area (cm^2)	13.44 (3.02)	15.40 (3.41)	<.001*
LH AP diameter (cm)	5.19 (0.82)	5.47 (0.76)	<.001*
LH LR diameter (cm)	3.46 (0.42)	3.78 (0.45)	<.001*
PFM MVC			
X-axis – BN position (cm)	-0.71 (0.43)	-0.90 (0.59) (n=27)†	.032*
Y-axis – BN position (cm)	3.16 (0.49)	3.30 (0.52) (n=27)†	.029*
Anorectal angle (°)	101.91 (8.66)	98.71 (5.88) (n=27)†	.096
Levator plate angle (°)	32.16 (6.58)	32.50 (8.39) (n=27)†	.510
LH area (cm^2)	10.71 (2.13) (n=30)†	10.18 (2.15) (n=27)†	.032*
LH AP diameter (cm)	4.33 (0.66)	4.21 (0.63) (n=27)†	.022*
LH LR diameter (cm)	3.33 (0.42) (n=30)†	3.29 (0.43) (n=27)†	.464

All measurements are expressed as mean (SD). Significant difference: p<.05*
†Data of one participant was not recorded.

Table 2: Baseline and post-treatment morphologic measurements

REFERENCES

1. Cyr M. P., Dumoulin C., Bessette P., Pina A., Gotlieb W. H., Morin M. (2019). Altered Pelvic Floor Muscle Function in Gynecological Cancer Survivors Suffering from Dyspareunia: a Case-Control Study. Annual Scientific Meeting on Pelvic Pain of the International Pelvic Pain Society (IPPS), Toronto, Canada. October 17-20, 2019.
2. Morin M., Dumoulin C., Bergeron S. B., Mayrand M. H., Khalifé S., Waddell G., Dubois M. F., Dubois O. (2016). Efficacy of Multimodal Physiotherapy Treatment Compared to Overnight Topical Lidocaine in Women with Provoked Vestibulodynia: A Bi-center Randomized Controlled Trial. The Journal of Sexual Medicine, 13(6), S243.
3. Cyr M. P., Dumoulin C., Bessette P., Pina A., Gotlieb W. H., Lapointe-Milot K., Mayrand M. H., Morin M. (2020). Feasibility, Acceptability and Effects of Physical Therapy Treatment for Gynecological Cancer Survivors with Dyspareunia. Annual Meeting of the International Society for the Study of Women's Sexual Health (ISSWSH), Orlando, USA. March 2-8, 2020.

Funding Quebec Network for Research on Aging **Clinical Trial** Yes **Registration Number** ClinicalTrials.gov, NCT03935698 **RCT** No **Subjects** Human **Ethics Committee** Comité d'éthique de la recherche en santé chez l'humain du Centre intégré universitaire de santé et de services sociaux de l'Estrie - Centre hospitalier universitaire de Sherbrooke **Helsinki** Yes **Informed Consent** Yes

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PELVIC FLOOR DYSFUNCTION, RISK FACTORS AND KNOWLEDGE OF THE PELVIC FLOOR IN NORWEGIAN MALE AND FEMALE POWER- AND OLYMPIC WEIGHTLIFTERS

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HYPOTHESIS / AIMS OF STUDY

Strenuous work and exercise have been suggested as possible risk factors for pelvic floor dysfunction (PFD) in women (1). Female athletes/exercising women have three times the risk of experiencing urinary incontinence (UI) compared to non-exercising controls (2). However, most of these studies are in sports including running and jumping activities and there is sparse knowledge on prevalence and risk factors for PFD in female and male power- and Olympic weightlifters. These athletes train and compete with high external loads, often exceeding their own body weight, and the sports may therefor serve as a model to study heavy load and PFD. The aim of the present study was to investigate prevalence and risk factors for PFD in power- and Olympic weightlifters. Furthermore, to investigate impact and bother of PFD and knowledge of the pelvic floor.

STUDY DESIGN, MATERIALS AND METHODS

This cross-sectional study addressed all male and female athletes of >=18 years of age, who had competed in at least one National Championship in power- or Olympic weightlifting in Norway in 2018/2019. Background data, symptoms of bladder/bowel and pelvic organ prolapse (POP), potential risk factors (age, BMI, parity, hypermobility, female athlete triad, straining on toilet, training frequency, years specializing in power- or Olympic weightlifting) and knowledge of the pelvic floor were collected via an electronic questionnaire. ICIQ–UI-SF, ICIQ-BS and ICIQ-V were used to assess PFD (3). Prevalence is reported as frequency and percentage. Risk factors for PFD was estimated by logistic regression analysis and reported as Odds ratio with 95% CI. P-value was set to 0.05.

RESULTS

One hundred and ninety-one female (response rate: 54.1%) and 204 male (response rate: 37.7%) power- and Olympic weightlifters answered the questionnaire. Eleven female athletes who reported ongoing pregnancy, history of surgery for UI/POP or neurological disease were excluded from the analysis. Mean age was 31.0 (SD: 10.7) and 34.0 (SD: 13.5) and mean BMI 26.1 (SD: 4.4) and 29.5 (SD: 4.0) for females and males respectively. Forty-nine (27.2%) of the females had given birth with mean parity of 2.2 (SD: 1.4, range: 1-9). Mean years of specializing in power- or Olympic weightlifting were 4.1 (SD: 3.6) for females and 10.1 (SD: 11.7) for males. Four or more days with weightlifting/week was reported by 143 (79.4%) of the females and 154 (75.5%) of the males.

Prevalence of PFD is presented in Table 1. Among females, increasing age (OR: 1.03, 95%CI: 1.00-1.07, p = 0.03), increasing BMI (OR: 1.09, 95%CI: 1.01-1.18, p = 0.03) and being at risk of the female athlete triad (OR: 2.08, 95%CI: 1.02-4.23, p = 0.04) were shown to be significantly associated with SUI. Only occasional and daily straining on voiding was significantly associated with POP (OR: 2.44, 95% CI:1.07-5.55, p = 0.03 and OR: 9.49, 95%CI: 2.26-39.85, p = 0.02). No significant associations between expected risk factors and anal incontinence (AI) were found in females. In males, increasing age was significantly associated with AI (OR: 1.03, 95%CI: 1.00-1.07, p = 0.04).

Seventy-four (90.2%) of the females reporting SUI or mixed urinary incontinence (MUI) experienced leakage during power- and Olympic weightlifting. Seventy-two (87.8%) reported negative effect of UI on sport participation. Fear of visible leakage (N=48, 58.5%) and loss of concentration (N=42, 51.2%) were the most common complaints. Accidental loss of gas was the most commonly reported type of AI, and 123 (89.1%) of the females and 105 (91.3%) of the males experienced leakage during sports. Twenty-three percent of the females reported symptoms of POP, but bother was low (mean: 1.0, SD: 2.1).

Seventy-seven (42.8%) females and 150 (73.5%) males did not know why, and 80 females (44.4%) and 148 males (72.5%) how, to train the pelvic floor muscles. However, 141 (78.3%) females and 101 (49.5%) males responded they would do pelvic floor muscle training to prevent PFD, if they knew how.

INTERPRETATION OF RESULTS

As far as we have ascertained, this is the first study in power- and Olympic weightlifting including questions on AI and POP in addition to UI and targeting both men and women. We found high prevalence of both SUI, AI and POP in the female population and AI in the male population. Significant associations between SUI and increasing age, increasing BMI, risk of female athlete triad in females were found. Both BMI and age have previously been found to be associated with UI in female athletes, but results are inconsistent across different studies (2). High BMI scores in strength athletes is more likely to be a result of high muscle mass than overweight and obesity. Few risk factors, except age in males and straining on voiding in females, could explain the high prevalence of AI and POP respectively.

A limitation of our study is the low response rate with a possible selection bias. Small numbers in some categories may also have negatively influenced the regression models.

CONCLUDING MESSAGE

The prevalence of PFD was high in both female and male power- and Olympic weightlifters. Risk factors found to increase the odds for PFD were high age, high BMI and risk of female athlete triad for SUI, straining on voiding for POP in females, and high age for AI in males. Few athletes had any knowledge of the pelvic floor, supporting a potential for both prevention and treatment strategies.

FIGURE 1

	Females, N (%)	Males, N (%)
Overall UI	90 (50.0)	19 (9.3)
SUI	75 (83.3)	2 (10.5)
UUI	3 (3.3)	3 (15.8)
MUI	7 (7.8)	-
Other UI	12 (13.3)	17 (89.5)
Overall AI	144 (80.0)	126 (61.8)
Liquid	59 (41.0)	51 (40.5)
Solid	13 (9.0)	14 (11.1)
Gas	138 (95.8)	115 (91.3)
POP	42 (23.3)	-

Table 1: Prevalence of pelvic floor dysfunction in female (N=180) and male (N=204) power- and Olympic weightlifters

REFERENCES

1. Milsom I, Altman D, Cartwright R, Lapitan MCM, Nelson R, Sjöström S, et al. Epidemiology of urinary incontinence (UI) and other lower urinary tract symptoms (LUTS), pelvic organ prolapse (POP) and anal (AI) incontinence. In: Abrams P, Cardozo L, Wagg A, Wein A, editors. Incontinence. 1. Tokyo: 6th International Consultation on Incontinence; 2017. p. 1-141.
2. Bo K, Nygaard IE. Is Physical Activity Good or Bad for the Female Pelvic Floor? A Narrative Review. Sports Med. 2020;50(3):471-84.
3. Diaz DC, Robinson D, Bosch R, Constantini E, Cotterill N, Espuna-Pons M, et al. Patient-reported outcome assessment. In: Abrams P, Cardozo L, Wagg A, Wein A, editors. Incontinence. 1. 6 ed. Tokyo: 6th International Consultation on Incontinence; 2017. p. 541-98.

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BEST IN CATEGORY PRIZE "QUALITY OF LIFE / PATIENT AND CAREGIVER EXPERIENCES"

READABILITY ASSESSMENT OF DECISION AIDS FOR UROLOGIC DYSFUNCTIONS

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HYPOTHESIS / AIMS OF STUDY

A growing number of patients use online patient decision aids (PtDAs) due to their easy accessibility. To serve their purpose of assisting patients in shared decision making, PtDAs should meet the NIH recommendation that readability of all patient educational materials be no greater than a 6th grade reading level. However, PtDAs that are found on the Internet are not regulated and vary in their readability and quality. The aim of this study is to determine the readability and quality of online PtDAs for benign urologic conditions including pelvic organ prolapse, urinary incontinence, overactive bladder, and benign prostate hyperplasia.

STUDY DESIGN, MATERIALS AND METHODS

The four urologic conditions were entered into the Google search engine, and the first two pages of the search results were used for the study. Thirty-one PtDAs met the inclusion criteria of being patient-oriented and being informative about the condition and treatment options without having misleading claims about any services or products. The PtDAs were analyzed using five readability assessment tools: Coleman Liau Index (CLI), Flesch-Kincaid (FKI), Automated Readability Index (ARI), Simple Measure of Gobbledygook (SMOG), and Gunning Fog Index (GFI). An average of the five scores were taken for each PtDA to calculate the percentage of PtDAs meeting the readability requirements. In addition, the validated DISCERN instrument, a health-information specific tool assessing reliability, dependability and trustworthiness, was used to judge the overall quality of the PtDAs.

RESULTS

The average readability score of all thirty-one PtDAs was 11.58 grade level with a standard deviation of 1.98. None met the NIH recommendation of being at or below the sixth grade level, but four were at or below the eighth grade level, the average reading level of Americans. The average DISCERN score was 46.8 with a standard deviation of 8.6, which is classed as 'fair.' While 39% were classed as 'good,' none was classed as 'excellent.'

INTERPRETATION OF RESULTS

The result of this study indicates that on average, the PtDAs are written at five grade levels above the recommended reading levels and three grade levels above the reading level of an average American. This is particularly concerning given the elderly population possess a lower literacy level,

yet a higher risk for the four urologic conditions examined in the study. In addition, the average DISCERN score was 46.8, which is classed as 'fair'. Given that the score ranges from 16 to 75 points, with the range 64 to 75 points classed as 'excellent,' the PtDAs have room for improvement in terms of overall quality.

CONCLUDING MESSAGE

None of the online PtDAs met the recommended readability guidelines, and on average, they were of moderate quality. Such shortcomings limit the overall utility of the PtDAs. Continued efforts are needed to improve the readability and the quality of online PtDAs.

FIGURE 1

Table 1.

	Organisations	Title	CLI	FKI	ARI	SMOG	GFI	Average of All Indices	DISCERN Score
Pelvic Organ Prolapse	Healthwise	Pelvic Organ Prolapse: should I have Surgery	8.32	7.95	5.94	9.93	9.63	8.35	55
	NICE	Surgery for uterine prolapse	10.56	12.01	10.76	13.35	14.02	12.14	58
	NICE	Surgery for vaginal vault prolapse	10.46	11.06	9.93	12.8	13.24	11.50	55
	Mayo Clinic	Uterine prolapse	13.03	11.78	11.11	12.51	12.58	12.20	42
	ACOG	Surgery for Pelvic Organ Prolapse	11.48	10.16	8.64	11.85	12.12	10.85	36
	NHS	Pelvic organ prolapse	11.10	14.81	14.89	14.23	16.24	14.25	47
	NAFC	What is pelvic organ prolapse	13.25	12.62	12.37	13.72	13.85	13.16	34
Urinary Incontinence	NICE	Surgery for stress urinary incontinence	9.49	10.78	9.52	12.16	12.75	10.94	55
	Healthwise	Taking Control: Non-Surgical Treatment Options for Urinary Incontinence in Women	9.82	8.73	7.23	10.78	11.01	9.51	57
	NHSAAA	What matters to you when choosing surgery for stress urinary incontinence?	8.56	12.37	10.48	13.63	15.01	12.01	55
	RNAO	What can I do about urinary incontinence?	9.31	9.52	7.94	11.11	11.16	9.81	56
	WWL NHS	Treatment for Stress Urinary Incontinence Patient Decision Aid	11.8	12.45	12.09	13.77	14.99	13.02	47
	UCF	What is Stress Urinary Incontinence (SUI)?	9.88	9.12	7.71	10.84	10.55	9.62	51
	CM	Stress Incontinence	13.97	10.64	10.72	12.14	12.89	12.07	32
	Mayo Clinic	Urinary Incontinence	13.8	12.58	11.58	13.30	14.12	13.08	52
Overactive	FHS	Overactive Bladder Syndrome (OAB)	10.12	9.1	7.45	10.2	9.4	9.25	30
	Mayo Clinic	Overactive Bladder	13.51	12.95	12.39	11.38	13.98	13.24	46
	UCF	What is Overactive Bladder (OAB)?	8.99	7.97	6.84	9.56	9.22	8.52	48

FIGURE 2

Bladder	Cleveland Clinic	Overactive Bladder	12.31	10.23	9.28	11.6	11.65	11.01	45
	WebMD	OAB: -- Helping a Confused Bladder	10.35	9.2	8.36	10.59	10.37	9.77	32
	Healthline	Everything you need to know about overactive bladder	12.32	11.72	10.93	12.30	12.85	12.02	49
	MNT	What can I do about an overactive bladder?	12.52	11.55	11.21	12.57	12.93	12.16	41
	Cedar Sinai	Overactive Bladder	14.22	15.35	15.36	15.31	16.64	15.38	30
Benign Prostate Hyperplasia	Drugsite Trust	Decision Aid for Benign Prostatic Hyperplasia	8.64	8.3	6.41	9.94	9.46	8.55	48
	JHM	Benign Prostatic Hyperplasia (BPH)	13.48	14.56	14.36	15.32	16.57	14.86	48
	NIDDK	Prostate Enlargement (Benign Prostatic Hyperplasia)	14.80	14.14	13.63	14.80	16.4	14.75	53
	MedicineNet	Facts you should know about enlarged prostate (BPH)	13.69	13.40	12.96	14.29	15.37	13.94	59
	Mayo Clinic	Benign Prostatic Hyperplasia (BPH)	13.32	11.97	11.08	12.87	13.1	12.47	54
	UCF	What is Benign Prostatic Hyperplasia (BPH)?	10.5	9.53	8.43	11.30	11.39	10.23	48
	Cleveland Clinic	Benign Prostatic Enlargement (BPH): Management and Treatment	12.29	11.18	10.45	12.49	12.87	11.86	49
	URMC	Benign Prostatic Hyperplasia (BPH)	9.46	7.77	6.77	9.77	8.93	8.54	39

Abbreviations: (ACOG: The American College of Obstetricians and Gynecologists; ARI: Automated Readability Index (ARI); CLI: Coleman Liau Index (CLI); CM: Continence Matters; FHS: Fairview Health Service; FKI: Flesch-Kincaid Index (FKI); GFI: Gunning Fog Index (GFI); JHM: Johns Hopkins Medicine; MNT: MedicalNewsToday; NAFC: National Association for Continence; NHS: National Health Service; NHSAAA: National Health Service Ayshire and Arran; NICE: National Institute for Health and Care Excellence; NIDDK: National Institute of Diabetes and Digestive and Kidney Disease; RNAO: Registered Nurses' Association of Ontario; SMOG: Simple Measure of Gobbledygook (SMOG); UCF: Urology Care Foundation; URMC: University of Rochester Medical Center; WWL NHS: National Health Service Wrighton, Wigan and Leigh)

Funding None **Clinical Trial** No **Subjects** None

SESSION 33 (PODIUM SHORT ORAL) - PEDIATRIC UROLOGY / NOCTURIA
Abstracts 495-506
11:30 - 13:00, Pavilion 9
Chair: Prof Jian Guo Wen (China)

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BLADDER CONTRACTILITY INDEX A NEW MARKER FOR EARLY PREDICTION OF PROGRESSION TO RENAL FAILURE IN POSTERIOR URETHRAL VALVE

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HYPOTHESIS / AIMS OF STUDY

In spite of early valve fulguration nearly two third of the children may progress to chronic kidney (CKD) and bladder decompensation secondary to poor bladder contractility (under active detrusor) near puberty. Bladder stabilization remains the main modifiable factor which can alter disease progression and ultimate outcome. In this study, we hypothesized that bladder contractility index (BCI) may be an early marker for future renal deterioration in patients of PUV. CKD III or estimated eGFR of < 45 ml/min/1.73m2 has been reported to be associated with more adverse renal, cardiovascular and clinical outcome. Baseline characteristics and other urodynamic (UDS) parameters were also evaluated along with primary goal i.e. BCI

STUDY DESIGN, MATERIALS AND METHODS

Data were expressed as mean±SD (range) or n (%) and compared among the groups by Student t-test or Chi-square test as appropriate. Survival curves were computed using the Kaplan-Meier method and compared between groups using the log-rank test. Univariate and multivariate Cox proportional hazards model was used to analyze factors predicting the event (i.e. eGFR of ≤ 30 ml/min/1.73m2), and to estimate adjusted hazards ratio (HR) with 95% confidence interval (95%CI). Statistical significance was accepted at P value of <0.05. Receiver operating characteristic (ROC) curve analysis of predictors was done to determine optimal cut-off levels with maximum combination of sensitivity and specificity. All analysis was done using SPSS version 16.0 (SPSS Inc, Chicago, IL).

RESULTS

Mean follow-up period was 12.5 years (range 1-15) and median age of patients at the time of evaluation was 5.8 yrs. At the end of the study, 21.8% (59/270) patients had progressed to CKD stage IIIA or more and lifetime risk for developing CKD stage was 45% . Clinical characteristics of patients who developed CKD stage IIIA are compared with those who did not.

Nadir serum creatinine at 1 year after surgery (1.7±0.8 vs. 0.9±0.4, p<0.001) was significantly higher in patients who developed CKD stage IIIA or more (Group I). Renal survival was significantly better in patients with nadir serum creatinine of ≤ 1 mg/dl at 1 year after surgery as compared to those who had higher values (Figure 2, log rank p=0.012). High grade VUR (18/59 vs. 8/211, p=0.013) and bilateral renal scar (12/59 vs.9/211, p=0.006) were more common in group I. Patients in group I had undergone higher number of bladder augmentation procedures (12/59 vs. 8/211, p=0.001).

Various measures and calculated indices of CMG done at 1-2 years after surgery are shown and compared.. Mean follow-up period was 8.5 years (range 1-10) and median age of patients at the time of evaluation was 5.8yrs. At the end of the study, 21.8% (59/270) patients had progressed to CKD stage 4-5 and lifetime risk for developing CKD stage was 45% .

Cox regression analysis of risk factors predicting development of CKD stage IIIA or more. In the multivariate model, bladder contractility index (BCI) (HR, 0.8; p=0.004), end filling pressure (EFP) (HR, 2.1; p=0.010) and ΔC (p=0.020) were significantly associated with the event (i.e. an eGFR of <45 ml/min/1.73m2) whereas BOOI (p=0.053) and bladder BVE (p=0.267) were not (Table 1).

Additionally, nadir serum creatinine at 1 year after surgery (HR, 6.0; p=0.003), high grade VUR (HR, 3.1; p=0.023) and bilateral renal scar (HR, 2.6; p=0.002) were also associated with risk of development of CKD stage IIIA or more.

Patients were divided into tertiles according to BCI values (i.e. <65, n=94; 65-130, n=84; and >130, n=92) and EFP values (i.e. <10, n=95; 11-15, n=85; and >15, n=90); and survival curves were constructed for each tertile group. Cumulative renal survival was significantly different among the three tertile groups of BCI (, log rank p=0.025) and EFP (log rank p=0.017) indices. Further, the ROC cut-off levels ((Figure 1) for BCI and EFP were; 75 (AUC±SE, 0.73±0.03, sensitivity of 78.2%, and specificity of 62.5%) and 18 (AUC±SE, 0.65±0.05, sensitivity of 78.6%, and specificity of 64.4%), respectively.

INTERPRETATION OF RESULTS

Mean follow-up period was 12.5 years (range 1-15) and median age of patients at the time of evaluation was 5.8 yrs. At the end of the study, 21.8% (59/270) patients had progressed to CKD stage IIIA or more and lifetime risk for developing CKD

stage was 45%. Cox regression analysis of risk factors predicting development of CKD stage IIIA. In the multivariate model, bladder contractility index (BCI) (HR, 0.8; p=0.004), end filling pressure (EFP) (HR, 2.1; p=0.010) and ΔC (p=0.020) were significantly associated with the event (i.e. an eGFR of < 45 ml/min/1.73m2) whereas BOOI (p=0.053) and bladder BVE (p=0.267) were not.

CONCLUDING MESSAGE

Bladder contractility index and end filling pressure are the two important urodynamic indices which can predict early the long term risk of development of CKD stage III in children with PUV.

REFERENCES

1. M.S. Ansari , Anil Gulia, Aneesh Srivastava. Risk factors for progression to end-stage renal disease in children with posterior urethral valves. Journal of Pediatric Urology (2010) 6, 261e264
2. Ardissino G, Dacco V, Testa S, Bonaudo R, Claris-Appiani A, Taioli E, et al. Epidemiology of chronic renal failure in children. . Pediatrics 2003; 111:382
3. Glassberg KI. The valve bladder syndrome: 20 years later. J Urol. 2001;166:1406–14

Funding None **Clinical Trial** Yes **Registration Number** IEC/97/2018 **RCT** No **Subjects** Human **Ethics Committee** IEC/97/2018 **Helsinki** Yes **Informed Consent** Yes

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COMPARISON BETWEEN ESTIMATES RENAL FUNCTION BY SERUM CREATININE AND CYSTATIN C FOR PATIENTS WITH SPINA BIFIDA

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HYPOTHESIS / AIMS OF STUDY

In order to maintain renal function, it is very important for patients with spina bifida (SB) to receive feasible urological management and avoid to febrile urinary tract infection (fUTI) during their lifetime. Therefore, it is very important to evaluate renal function for SB patients. A patient's renal function is usually evaluated with serum creatinine (SCre), renal scintigram and ultrasonography comprehensively; however, SCre and the estimated glomerular filtration rate (eGFRcre), which is estimated by Scre, are strongly affected by the quantity of the patient's muscle volume. It was previously reported that for patients with spinal cord injury, renal function evaluated by eGFRcre is likely to be overestimated, because of low muscle volume1). Nowadays, cystatin C (CysC), which is not influenced by muscle mass, has been introduced clinically to estimate renal function. It should be more accurate to evaluate renal function by eGFR that is estimated using CysC (eGFRcys) for SB patients who sometimes suffer impairment in their lower limbs in comparison to evaluation by eGFRcre. Therefore, the aim of this study is to investigate whether the estimation of renal function by eGFRcre is affected by the muscle mass of SB patients more than that evaluated by eGFRcys.

STUDY DESIGN, MATERIALS AND METHODS

A total of 54 SB patients who had been admitted to our institute from 2018 to 2019 were retrospectively reviewed. Medical records of urological and orthopedic symptoms and treatment for urological diseases were investigated. Patients were divided into 2 groups; patients who were able to walk (WA) and those who required wheelchairs (WC). Discrepancies between values of estimated glomerular filtration rate with SCre and CysC were assessed in the ratio of eGRFcre and eGFRcys (eGFRcre/cys). The correlation between eGFRcre and eGFRcys was evaluated by the linear regression model. It was considered that the renal function was overestimated by eGFRcre when eGFRcre/cys was > 1.2. The value of eGFRcre and eGFRcys were calculated in formulas as follows; eGFRcre=194Cre-1.094Age-0.287(×0.739; in female) and eGFRcys={104CysC-1.019×0.996Age(×0.929; in female)}-8.

RESULTS

The cohort included 39 in the WA group and 15 in the WC group. Fifty-one patients conducted clean intermittent catheterization (CIC) and the other 3 patients performed spontaneous voiding. Eleven patients had vesicoureteral reflex (VUR). There was no significance in the ratio of conducting CIC or suffering VUR between these two groups. There were significant differences in theeGFRcre/cys between the two groups (WA : WC = 0.799 : 0.545 ; p<0.001). The value of eGFRcre/cys in all 15 patients in the WC group was more than 1.2, whereas that in 11 of 41 in the WA group was more than 1.2 (Table 1). The linear regression analysis in the scatter plotting showed a positive correlation between eGFRcre and eGFRcys in the WA group as opposed to that in the WC group.

INTERPRETATION OF RESULTS

In this study, there was no visible correlation between eGFRcre and eGFRcys in the WC group and the value of eGFRcre was much higher than eGFRcys in all cases of WC, indicating that the patients' renal function in the WC group was overestimated when the functions were evaluated by eGFRcre. Regarding eGFR in the WA group, the value of the correlation coefficient in the scatter plots was relatively low (r2=0.300), even though there was correlation between eGRFcre and eGFRcys. This is presumably because the renal function of some patients in the WA group who have a relatively lower muscle mass in their lower limbs were overestimated by eGFRcre. Patients using crutches could have potentially lower muscle mass in their lower limbs in comparison to those who walk on their own. However, there were not enough significant

differences in the ratio of eGFRcre and eGFRcys between patients using crutches and those not using them in the WA group, because the number of patients using crutches was smaller (4 of 39 patients). These results indicated that renal function of SB patients with inability at the lower limbs could be overestimated when it is evaluated by eGRFcre.

CONCLUDING MESSAGE

There were the discrepancies of eGFRcre/cyc in SB patients especially those who usually use a wheelchair. Therefore, health care provider should evaluate renal function by eGFRcys for SB patients with lower limb disability.

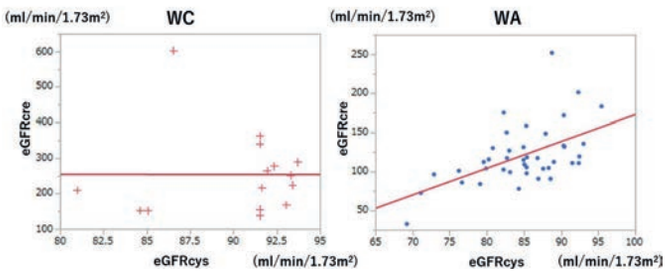
FIGURE 1

Table 1. Patient demographics

		WC		WA		P
N		15		41		
Age		20.1	(15-35)	27.3	(16-70)	0.024
Gender	M	12		21		0.0452
	F	3		20		
Voiding	spontaneous	0		2		0.1425
	CIC	15		39		
VUR	+	1		11		0.0629
	-	14		26		
	N/A			2		
f UTI	+	3		3		0.2193
	-	12		36		
	N/A			2		
eGFRCre/ Cys	0.8-1.2	0		11		0.0203
	>1.2	15		29		
	<0.8			1		

FIGURE 2

Figure1. Scatter plots ; correlation between eGFRcre and eGFRcys in the two groups



REFERENCES

1. Evaluating estimated glomerular filtration rates of creatinine and cystatin C for male patients with chronic spinal cord injury Goto T et al., Spinal Cord 2018 May;56(5) 447-452

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Independent **Ethics Committee** of Tohoku University School of Medicine **Helsinki** Yes **Informed Consent** Yes

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BEST IN CATEGORY PRIZE "PAEDIATRICS"

HIGH PREVALENCE OF DYSPLASTIC DEVELOPMENT OF SACRAL VERTEBRAL ARCHES IN PEDIATRIC ENURESIS

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HYPOTHESIS / AIMS OF STUDY

Deformity of sacral vertebral arches in the conventional pelvic plain x-ray film is sometimes seen in children with persistent enuresis. This study is the first report of comparison of the images of three-dimensional computed tomography (3D-CT) in 2 cohorts; pediatric cases with enuresis and children without voiding symptoms or enuresis who underwent pelvic CT for other reasons.

STUDY DESIGN, MATERIALS AND METHODS

From January 2019 to December 2019, 47 children with primary nocturnal enuresis underwent 3D-CT of sacrococcygeal bone (33 males, 14 females, mean age 7.9±2.0 years, range: 5 years-old to 13 years-old). For the control group, 138 children without enuresis (78 males, 60 females, mean age 10.7±4.4 years, range: 3 months-old to 18 years-old) who underwent pelvic CT for other reasons were included.

First, we evaluated the presence or absence of unfused sacral arches at S1-S3 levels in these two cohorts. Then, we selected a subset age and gender matched enuresis children and control children without enuresis for a comparison study: Children with enuresis (n=32 in total, 21 males 11 females, mean age 8.0±2.2 years, range: 5 years-old to 13 years-old) and children without enuresis (n=32 in total, 21 males 11 females, mean age 8.0±2.2 years, range: 5 years-old to 13 years-old) were compared for fusion of dorsal sacral arms 3D-CT).

All procedures in this study involving human participants were performed in accordance with the ethical standards of the Institutional Review Board and the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from each child's parents.

RESULTS

In the initial assessment in all participants, dysplastic sacral vertebral arches, evident as unfused arches at one or more levels of S1-S3 sacral arches, were observed in all cases of the enuresis group cohort (n=47) (Fig. 1A). In the control group cohort (n=138), 77 children were over 10 years-old, among whom 70 cases (91%) showed fused sacral arches at all three S1 through S3 levels (Fig.1B) whereas the remaining 7 con-

trol children over 10 years-old (9%) had one or more unfused sacral arches at S1-S3 levels. In addition, in the control group, 11 control children were under 3 years-old, and all of them showed three unfused sacral arches at S1-S3 levels.

In the comparison study of age and gender matched enuresis patients and control children from 5 to 13 years-old (n=32 each), there was only one case (3%) in the enuresis group, in whom all S1-S3 arches were fused. Also, in the enuresis group, only one arch between S1 and S3 levels was fused in 7 cases (22%), and two arches were fused in 11 cases (34%). In contrast, in the control group, 19 out of 32 control children (59%) had fused arches at all S1-S3 levels (P< 0.0001 vs. enuresis group; student t-test) (Table 1). In addition, in the remaining control children who had unfused arches, sacral arches were not fused at any of 3 levels in 2 cases (6%), one arch was fused in 3 cases (10%), and two arches were fused in 3 cases (10%).

INTERPRETATION OF RESULTS

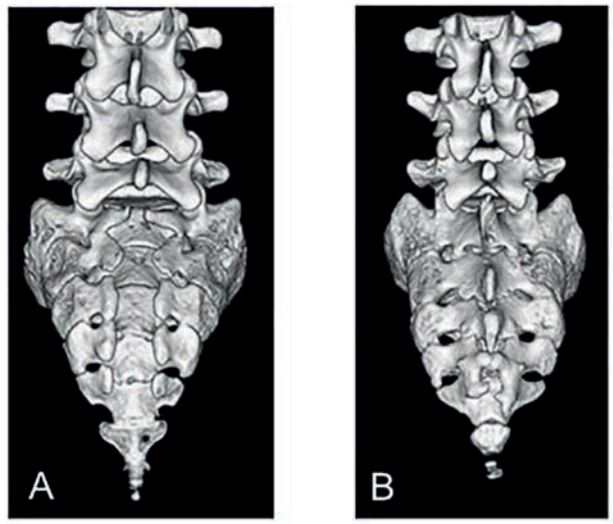
The etiology of primary pediatric nocturnal enuresis is controversial and objective diagnostic test is lacking. We hereby provide evidence for a novel hypothesis that dysplastic development of sacral bone, with occult neurological dysfunction, might be a cause of pediatric enuresis. We also found that, in the control group, the majority (91%) of children over 10 years-old showed fused sacral arches at all 3 sacral levels whereas there were no such cases among those younger than 3 years-old, suggesting that sacral arch fusion is gradually completed during childhood development.

CONCLUDING MESSAGE

Sacral vertebral arches at S1-S3 levels are normally fused by age 10 in most children. However, our study indicates that children with nocturnal enuresis exhibited a significantly higher incidence of unfused sacral arches than age and gender matched children without enuresis. Our results suggest that dysplastic development of sacral vertebral arches may play a role in the etiology of nocturnal enuresis. Further studies are warranted to investigate the natural history of children with enuresis with and without sacral dysplasia.

FIGURE 1

Fig. 1 : Representative 3D-CT images



A: 11-year-old boy with enuresis showing unfused S1-S3 sacral arches.
B: 11-year-old, non-enuresis boy with fused three sacral arches.

FIGURE 2

Groups	Fusion of sacral arm			
	S1	S2	S3	3 sacral arms fused
Enuresis group (n=32)	5	10	7	1
Control group (n=32)	22	26	23	19
P value	p<0.001	p<0.001	p<0.0005	p<0.0001

Table

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** The Ethics Commitee of Mizushima Central Hospital **Helsinki** Yes **Informed Consent** Yes

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EVENING DIETARY PROTEIN INTAKE IN THE PATHOGENESIS OF NOCTURNAL POLYURIA

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HYPOTHESIS / AIMS OF STUDY

Recent research has shown that nocturnal polyuria (NP) is a heterogeneous condition that may be driven by excess nocturnal free water and/or sodium clearance. Consistently, behavioral and pharmacologic interventions targeting both nocturnal free water and sodium production have garnered considerable traction in the management of nocturia owing to NP. Relatively less attention has been afforded to urea—the most abundant urinary solute—despite the fact that urinary urea excretion is known to be highly interrelated with dietary protein intake [1]. Mechanistically, the body maintains a low concentration level of urea in both plasma and extracellular fluid, which lends to a daily urea excretion approximately two times greater the total body urea pool (and thus proportionally far greater than sodium, wherein daily excretion reflects approximately one-fifteenth of the total body sodium pool) [1]. Accordingly, it stands to reason that excretion of a large quantity of urea, as would be expected in patients following significant dietary protein intake, may reflect an additional important mediator in the pathogenesis of NP. This study aims to explore the association between NP and estimated dietary protein intake.

STUDY DESIGN, MATERIALS AND METHODS

Post hoc analysis of prospective observational data from 170 adults who completed a renal function profile between October 2011 and February 2015. Each subject underwent a 24-h urine collection which included 8 urine samples collected at 3-h intervals (daytime: 10h-13h-16h-19h-22h and nighttime: 01h-04h-07h). Urine volume, osmolality, and urea were used to calculate urinary excretion of urea (urine urea x urine volume). Urinary urea excretion was subsequently employed to estimate dietary protein intake ([24-h urinary urea nitrogen excretion (UUN; g/day)] + 0.031 * [body weight (kg)]* 6.25) [2].

Patients were compared by NP status using two distinct cutoffs for NP in accordance with current International Continence Society terminology: 1) nocturnal urine production >90ml/h (NUP90) and 2) nocturnal polyuria index (nocturnal urine volume/24-h total urine volume) >0.33 (NPi33) [3].

Clinical and biochemical parameters were compared using the chi-square test and Mann-Whitney U test for categorical and continuous variables, respectively. A p-value <0.05 was deemed statistically significant. All continuous measures are reported as median (interquartile range).

RESULTS

A total of 170 adults were eligible for analysis (62% female, median age 66 [51-72] years), of whom 81 (47.6%) met the threshold for NP at NUP90, and 118 (69%) met the cutoff for NP at NPi33 (Table 1).

At NUP90, nighttime urea excretion higher in the NP vs. no NP group, which corresponded to a significantly higher estimated evening protein intake in subjects with NP (Table 2). No significant differences were observed in daytime urea excretion, estimated daytime protein intake, 24-h urea excretion, or estimated 24-h protein intake.

At NPi33, nighttime urea excretion and estimated evening protein intake were likewise both significantly higher in the NP group. Among subjects with NP, daytime urea excretion and estimated daytime protein intake were significantly lower compared to the non-NP subgroup, and no significant differences were observed in 24-h urea excretion or estimated 24-h protein intake between groups.

INTERPRETATION OF RESULTS

A large protein-rich meal, as reflected in the urinary urea-based estimate of dietary protein intake, lends to a period of glomerular hyperfiltration and excess urine volume. In the present analysis, an increase in nocturnal urea excretion was observed specifically during the nighttime in subjects with NP, and no such trend was seen in subjects without NP. Estimated evening dietary protein intake was correspondingly significantly higher amongst the NP subgroup, as would be consistent with a large, protein-rich evening meal, and this finding persisted across two distinct accepted cutoffs for NP. Protein intake in the hours leading to sleep may reflect an additional important mediator in nocturia owing to excess nocturnal urine production.

CONCLUDING MESSAGE

Reduction of evening protein consumption may be an effective lifestyle intervention in the management of nocturia owing to NP. Future research on the association between NP and diet is warranted.

FIGURE 1

Table 1: Clinical Characteristics

	NUP90			NPi33		
	NP (n=81)	No NP (n=89)	p-value	NP (n=118)	No NP (n=52)	p-value
Age (years)	67 (58-73)	62 (48-71)	0.030*	67 (58-73)	51 (37-66)	<0.001*
Sex (F // M)	44 // 37	61 // 28	NS	65 // 53	40 // 12	0.007*
BMI (kg/m²)	25 (23-29)	24 (21-26)	0.006*	25 (22-28)	24 (22-26)	NS
NUP (ml/h)	114 (101-139)	58 (47-74)	<0.001*	100 (71-126)	56 (44-84)	<0.001*

Note: *Denotes statistical significance. Abbreviations: NP, nocturnal polyuria; BMI, body mass index; NUP, nocturnal urine production.

*p <0.05 for $\chi 2$ test/Mann–Whitney U test.

FIGURE 2

Table 2: Urinary urea excretion and estimated protein intake

	NUP90			NPi33		
	NP (n=81)	No NP (n=89)	p-value	NP (n=118)	No NP (n=52)	p-value
Daytime urea excretion (g)	17.0 (12.5-20.2)	17.1 (12.1-20.7)	NS	15.6 (11.9-19.4)	18.3 (13.9-22.2)	0.009*
Nighttime urea excretion (g)	9.6 (8.1-12.8)	8.1 (6.6-10.2)	<0.001*	9.3 (7.7-11.8)	7.9 (6.3-9.1)	<0.001*
24-h urea excretion (g)	26.5 (22.3-33.6)	25.3 (20.7-31.3)	NS	24.7 (21.4-32.3)	26.5 (22.3-33.5)	NS
Daytime protein intake (g/kg body weight)	0.8 (0.7-1.0)	0.8 (0.7-1.0)	NS	0.8 (0.6-0.9)	0.9 (0.8-1.1)	<0.001*
Evening protein intake (g/kg body weight)	0.6 (0.5-0.7)	0.5 (0.4-0.6)	0.035*	0.6 (0.5-0.6)	0.5 (0.4-0.6)	0.005*
24-h protein intake (g/kg body weight)	1.3 (1.0-1.4)	1.2 (1.0-1.5)	NS	1.2 (1.0-1.4)	1.3 (1.1-1.6)	NS

*p <0.05 for Mann–Whitney U test.

REFERENCES

1. Bankir L, Roussel R, Bouby N. Protein- and diabetes-induced glomerular hyperfiltration: Role of glucagon, vasopressin, and urea. Am J Physiol - Ren Physiol. 2015;309(1):F2–23.
2. Teunissen-Beekman KFM, Dopheide J, Geleijnse JM, Bakker SJL, Brink EJ, de Leeuw PW, et al. Effect of increased protein intake on renal acid load and renal hemodynamic responses. Physiol Rep. 2016;4(5):1–10.
3. Hashim H, Blanker MH, Drake MJ, et al. International Continence Society (ICS) report on the terminology for nocturia and nocturnal lower urinary tract function. Neurourol Urodyn. 2019;38(2):499-508.

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NOCTURIA INDEPENDENTLY PREDICTS LEFT VENTRICULAR HYPERTROPHY AND LEFT ATRIAL ENLARGEMENT AMONG PATIENTS WITH CARDIOVASCULAR DISEASE

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HYPOTHESIS / AIMS OF STUDY

Nocturia is a well-recognized, but poorly characterized, manifestation of cardiovascular disease. Multiple studies have reported associations between hypertension and the presence and severity of nocturnal voiding [1]. Hypertension is associated with multiple cardiac abnormalities which independently heighten the risk for adverse cardiovascular outcomes [2], including left ventricular hypertrophy (LVH), left atrial enlargement (LAE), and prolonged QTc interval (p-QTc), However, the association between nocturia and these specific cardiac abnormalities is not well understood. This study aims to explore potential associations between nocturia and LVH, LAE, and p-QTc on electrocardiography (ECG).

STUDY DESIGN, MATERIALS AND METHODS

Retrospective analysis of self-reported nocturnal voiding frequencies from 153 patients evaluated at an inner-city academic cardiology practice. Patient-reported nocturnal voiding frequency was recorded in the medical record at the time of routine clinical encounter. A nocturia database was compiled with institutional review board approval via a waiver of informed consent for retrospective analysis.

ECGs concurrent with the clinical encounter were abstracted and evaluated according to current American Heart Association guidelines by a reviewer blinded to nocturia status. ECGs were assessed for the presence of LVH (using the Cornell and Sokolow-Lyon criteria), LAE (product of the amplitude and duration of the terminal negative component of the P wave in lead V1 measuring ≥1 mm by 1 mm or a total duration of the P wave ≥120 ms in the inferior leads), and p-QTc (≥460 ms in women and ≥450 ms in men). A nocturnal voiding frequency of ≥1 void was selected as the cut-off for nocturia because existing literature on nocturia and non-dipping hypertension suggests that the largest decline in nocturnal systolic blood pressure occurs between 0 and 1 nocturnal voids rather than at higher nocturnal voiding frequencies [3]. A power calculation was not performed due to the paucity of foundational literature on ECG correlates of nocturia.

Three different multiple logistic regression models were used to predict LVH, LAE, and p-QTc based on nocturia status: Model I adjusted for age; Model II adjusted for age, sex, and race; Model III adjusted for age, sex, race, body mass index (BMI), hypertension, diabetes mellitus, and diuretic utilization.

RESULTS

A total of 153 patients met the criteria for inclusion. The study sample was predominantly female (74%) and self-reported African-American race (90%), with a high prevalence of obesity (63%), hypertension (78%), diabetes mellitus (33%), and diuretic use (40%). Nocturia was present in 77% of study subjects, while LVH, LAE, and p-QTc were present in 44%, 41%, and 29% of study subjects, respectively. Bivariate analysis revealed significant associations between nocturia and older age, African-American race, obesity, hypertension, diuretic use, LVH, and LAE. No such trends were observed between nocturia and sex, diabetes mellitus, and p-QTc.

On multivariate analysis, nocturia was predictive of LVH according to Model I (OR 3.20, [1.18-8.69], p=0.022), Model II (OR 3.17, [1.16-8.69], p=0.025), and Model III (OR 2.99, [1.02-8.75], p=0.046). Nocturia also predicted LAE according to

Model I (OR 4.72, [1.56-14.30], p=0.006), Model II (OR 4.71, [1.54-14.37], p=0.006), and Model III (OR 4.24, [1.32-13.57], p=0.015). No significant associations were observed between nocturia and p-QTc according to Model I (OR 1.51, [0.56-4.10], p=4.10), Model II (OR 1.39, [0.51-3.81], p=0.517), or Model III (OR 1.19, [0.41-3.49], p=0.747).

INTERPRETATION OF RESULTS

Nocturia predicts LVH and LAE, and this finding persists even after controlling for several relevant comorbid conditions. LVH is associated with reduced left ventricular compliance (requiring higher filling pressures), whereas LAE reflects higher left ventricular preload, and both mechanisms likely predispose patients to sodium and water retention. Consistently, existing volume overload, particularly in conjunction with recumbency during sleep, would be expected to increase preload and cardiac output, lending to increased nocturnal urine production. The absence of a significant association between nocturia and p-QTc may be attributable to the association of p-QTc with multiple other factors, including electrolyte abnormalities, medications, and aging. The specific mechanisms underlying both the presence and absence of associations between nocturia and LVH, LAE, and p-QTc merit further study.

CONCLUDING MESSAGE

LVH and LAE were both independently associated with nocturia in the outpatient cardiology setting. Further investigation into nocturia as a potential marker of underlying cardiovascular disease is warranted.

REFERENCES

1. Feldstein CA. Nocturia in arterial hypertension: a prevalent, underreported, and sometimes underestimated association. J Am Soc Hypertens. 2013;7(1):75-84.
2. Ahmad MI, Mujtaba M, Anees MA, Li Y, Soliman EZ. Interrelation Between Electrocardiographic Left Atrial Abnormality, Left Ventricular Hypertrophy, and Mortality in Participants With Hypertension. Am J Cardiol. 2019;124(6):886-91.
3. Agarwal R, Light RP, Bills JE, Hummel LA. Nocturia, nocturnal activity, and nondipping. Hypertension. 2009;54(3):646-51.

Funding N/A **Clinical Trial** No **Subjects** Human **Ethics Committee** SUNY Downstate Health Sciences University Institutional Review Board **Helsinki** Yes **Informed Consent** No

500 www.ics.org/2020/abstract/500

AGE- AND GENDER-SPECIFIC NOMOGRAMS OF POST-VOID RESIDUAL URINE IN HEALTHY CHILDREN AND ADOLESCENTS

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HYPOTHESIS / AIMS OF STUDY

Purpose: To expand the previously established age- and gender-specific nomograms of post-void

residual urine (PVR) from children to adolescents.

STUDY DESIGN, MATERIALS AND METHODS

Material and Methods: Healthy children aged 2 to 16 years were enrolled for two sets of uroflowmetry and PVR. The first two consecutive PVRs of each child or adolescent with a voided volume >50 ml in participants >=6 years and >30mL in participants <=5 years were included for construction of PVR nomograms. Children with possible urinary tract infection or neurognenic lower urinary tract dysfunctions were excluded. All PVRs were assessed within 5 min after voiding with suprapubic ultrasound (Logiq Book1, GE Medical Systems, Milwaukee, WI), and estimated by the equation of height x width x depth x 0.52 ml. Bladder capacity (BC) was defined as voided volume + PVR.

RESULTS

Totally, 1663 children (841 boys and 822 girls) with a mean age of 9.9±3.9 years with 2752 PVRs were eligible for construction of PVR nomograms. The 95th percentile of PVR for all children was 32.6 ml, or 15.0% of bladder capacity (BC).

INTERPRETATION OF RESULTS

The table showed the age and gender specific percentile of PVR and PVR/bladder capacity (PVR/BC) from age 2 to 16 years. The PVR and PVR/BC decreased as age increased before age of 12 years. The PVR increased after adolescence while PVR/BC remained stable at 10%. PVR was higher in boys than girls before age of 12 years. In adolescent, PVR was higher in girls. Table Age and gender specific percentile of post-void residual urine (PVR) and PVR/bladder capacity (PVR/BC)

CONCLUDING MESSAGE

Conclusions: Age, gender, and BC should be taken into considerations at interpretation of PVR tests in children and adolescents because of gender- and age- differences in bladder function development.

FIGURE 1

Age groups	2-3 years		4-6 years		7-9 years		10-12 years		13-16 years	
Boys	(n=33)		(n=307)		(n=352)		(n=297)		(n=356)	
Percentile	ml	%BC	ml	%BC	ml	%BC	ml	%BC	ml	%BC
50th	4.40	0.04	4.29	0.03	2.45	0.02	3.53	0.02	6.33	0.02
75th	24.16	0.15	12.19	0.08	5.69	0.04	8.14	0.04	12.07	0.04
90th	39.11	0.21	25.78	0.18	16.41	0.08	15.51	0.07	17.94	0.07
95th	48.50	0.34	44.37	0.23	26.74	0.14	24.72	0.12	24.59	0.08
Girls	(n=44)		(n=297)		(n=287)		(n=257)		(n=410)	
Percentile	ml	%BC	ml	%BC	ml	%BC	Ml	%BC	ml	%BC
50th	5.84	0.04	3.90	0.03	2.17	0.02	3.83	0.02	9.16	0.03
75th	25.93	0.13	9.86	0.06	5.02	0.03	9.65	0.04	17.29	0.06
90th	35.73	0.23	18.97	0.12	12.27	0.06	19.25	0.07	29.69	0.10
95th	48.17	0.23	28.17	0.17	20.32	0.09	29.28	0.12	39.26	0.12

Table 1.

Funding Division of Urology, Department of Surgery, Taipei Tzu Chi Hospital, The Buddhist Tzu Chi Medical Foundation, New Taipei, Taiwan **Clinical Trial** No **Subjects** Human **Helsinki** Yes **Informed Consent** Yes

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CHARACTERIZING NOCTURIA AMONG BELGIAN POSTMENOPAUSAL WOMEN: PREVALENCE, BOTHER, ETIOLOGY AND POSSIBLE RISK FACTORS FOR DEVELOPING NOCTURIA

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HYPOTHESIS / AIMS OF STUDY

Nocturia, or the act to pass urine during the main sleeping period, is a common urological symptom in the elderly population. Today, little is known about nocturia in postmenopausal women. However, due to the lack of endogenous produced estrogen in these women, an increased prevalence of nocturia is expected in this population.

Equally for the global population, a multifactorial etiology for nocturia in postmenopausal women is expected, as the effect of impaired estrogen production can probably be seen through different mechanisms. Firstly, the depletion of estrogen leads to a higher incidence of nocturnal hot flushes and thus an increased risk of sleep fragmentation. Secondly, lack of estrogen leads to a lower excretion of anti-diuretic hormone (ADH) and thus an impaired nocturnal water reabsorption, resulting in a higher nighttime urine production. Moreover, impaired estrogen production will lead to atrophy of estrogen receptors, which are present in the urethra and bladder trigonum, and will therefore induce a higher incidence of lower urinary tract symptoms (LUTS). Lastly, the incidence of obstructive sleep apnea syndrome (OSAS) is higher in postmenopausal women compared to premenopausal women.

Multiple studies have shown that nocturia has severe consequences on overall health, as nocturia is an independent risk factor for depressive symptoms, a reduced productivity and increases the risk on falls and fractures. Moreover, it has been found that nocturia patients had 23% increase in the risk on all-cause mortality. A further specification of the incidence, origin and impact of nocturia in postmenopausal women, is important as it may guide the professional to an optimal assessment and treatment of nocturia.

The aim of this study is threefold: to observe the prevalence of nocturia in the Belgian postmenopausal population, to report the bother of nocturia in this population and to define risk factors for developing nocturia as a postmenopausal women.

STUDY DESIGN, MATERIALS AND METHODS

All patients in this prospective observational trial were recruited when consulting the menopause clinic between March 2015 and June 2019. Exclusion criteria were: thyroid dysfunction, the use of antihypertensive agents, history of psychiatric or neurological disorders and a history of alcohol or drug addiction.

Women were asked to complete the ICI questionnaire on nocturia (ICIQ-N). Nocturia was defined as ≥ 2 nocturnal voids. Bother linked with nocturia was reported on a VAS-scale, with '0' defined as having no bother and '10' as having high bother. Moreover, women were asked to fulfill the 'Targeting the individual's Aetiology of Nocturia to Guide Outcomes' (TANGO) screening tool to observe underlying risk factors (comorbidities, sleep characteristics, LUTS and self-reported health status) for nocturia. At last, baseline characteristics including age, weight, height and waist circumference, were collected.

Descriptive statistics are presented as median(s) (interquartile range). Differences in bother between different nocturnal frequencies were assessed using the non-parametric Mann-Whitney U test for continuous variables. Categorical variables of the TANGO were compared between 'no nocturnal voids', '1 nocturnal void' and '≥ 2 nocturnal voids' in 2 x 2 assessment using the non-parametric Chi-square test. To identify independent predictors for nocturia, a univariate and multivariate logistic regression analysis with calculation of the adjusted odds ratio was performed. This study was approved by the institution's ethical board.

RESULTS

This study recruited 191 postmenopausal women with a median age of 52 (47– 56) years. The overall median weight and height was 67 (60 – 74) kg and 165 (162 - 169) cm respectively, which corresponds with a median Body Mass Index of 23.9 (21.4– 27.5) kg/m2. The median waist circumference was 89 (84 – 96) cm.

Nocturia was reported in 23.6% (45/191) of the post-menopausal women. Twenty-nine percent (55/191) of the women slept through the night without waking up to void. One nocturnal void was seen in 47.6% (91/191) of the postmenopausal women, 18.3% (35/191) reported 2 nocturnal voids and 5.2% (10/191) reported more than two nocturnal voids. Obviously, patients who did not void during the night, reported no bother linked with nocturia. A significant difference ($p < 0.001$) in bother linked with nocturnal voiding was seen between women who had to get up once and women who voided two or more times during the night (1/10 (IQR 0/10 - 5/10) and 5.5/10 (IQR 3/10 – 7/10) respectively).

No differences among prevalence of comorbidities (intake of diuretics, presence of lower limb edema, orthostatic hypotension or diabetes) were found between women with a different number of nocturnal voids. Moreover, no different responses on the statements: 'My sleep quality is bad' and 'I report my health as bad' were reported between patients with a different nocturnal frequency. Lastly, although no differences in daytime incontinence and sleep apnea signs were reported between the aforementioned groups, a trend towards a higher prevalence of sleep apnea signs could be visualized in women with a higher nocturnal frequency. Figure 1 shows significant differences in onset and maintain insomnia, awaking in the first 3 hours of the night and daytime urgency compared between women without nocturia; with 1 and with ≥ 2 nocturnal voids.

Univariate logistic regression showed that waist circumference could be identified as an independent risk factor for developing nocturia (OR 1.04; 95% CI: 1.01 – 1.08). Secondly, a significant association between nocturia and urgency could be observed (OR 3.7; CI: 1.76 – 7.8). Different models of multivariate analyses with potential confounders were tested as shown in table 1.

INTERPRETATION OF RESULTS

The prevalence of nocturnal voiding in postmenopausal women is high. Approximately half of women in this cohort had to get up once at night to void, and 23% of this cohort report two or more nighttime voids. Equal to previous literature, getting up twice at night goes along with a significant increase in bother linked with nocturia.

After analysis of the TANGO screening tool, different underlying causes for nocturia can be suggested. Daytime urgency symptoms increased significantly with each nocturia episode, suggesting an underlying overactive bladder syndrome in patients with a high nocturnal frequency. Moreover, a non-significant trend towards a higher incidence of sleep apnea signs could be seen in women with two or more nighttime voids. Both of the aforementioned causes can be linked with an impaired secretion of estrogen during menopause. Subsequently, a significant increased risk of insomnia (both onset and maintained) linked with an increase of nighttime frequency is found. This finding seems logical, however it could be that this association is the other way around, as insomnia can induce an early night toilet visit. Lastly, the proportion of women who awakes during the first 3 hours of sleep increases linear with increase in nocturnal frequency. This early nighttime voiding can be due to a high fluid intake in the evening, impaired secretion of ADH resulting in an increased water diuresis overnight or a combination of one of both aforementioned causes in combination with a low bladder capacity. Unfortunately, information about bladder capacity, overnight diuresis and timing of voids was not available. Further research including frequency volume charts, fluid assessment and sleep observation is necessary.

CONCLUDING MESSAGE

In this cohort of postmenopausal women, the prevalence of nocturia was reported as 23%. A significant increase in bother was seen, linked with nocturnal frequency. Waist circumference and daytime urgency could be determined as potential risk factors for developing nocturia in the postmenopausal population. Different underlying causes of nocturia in the postmenopausal women were suggested, however more research is necessary.

FIGURE 1

Table 1 Different models of multivariate logistic regression analysis with nocturia (≥ 2 nocturnal voids) as a dependent, dichotomous variable.

	Model 1	Model 2	Model 3
Waist circumference	OR 1.04 (CI 1.0 – 1.07)*	OR 1.04 (CI 1 – 1.07)*	OR 1.03 (CI 0.99 – 1.07)
Urgency	OR 4.1 (CI 1.8 -9.3)*	OR 4.05 (CI 1.7 – 9.2)*	OR 4.13 (CI 1.8 – 9.5)*
Onset insomnia		OR 2.1 (CI 0.97 – 4.59)	OR 3.04 (CI 0.93 – 4.48)
Sleep apnea signs			OR 1.6 (CI 0.68-3.84

*A p-value < 0.05 was considered statistically significant.

Table 1 Different models of multivariate logistic regression analysis with nocturia (≥ 2 nocturnal voids) as a dependent, dichotomous variable.

FIGURE 2

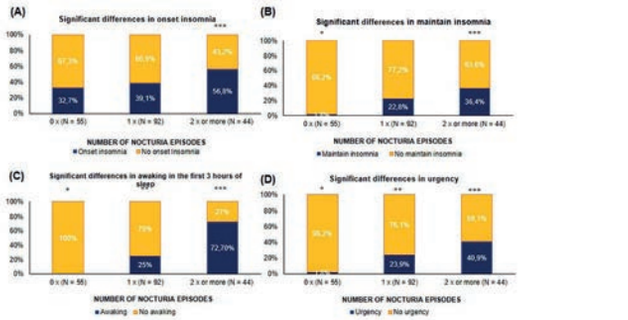

Figure 1 Frequencies among risk factors for nocturia assessed using the TANGO questionnaire for patients with 0, 1 and 2 or more nocturia episodes: A) Differences in onset (first 30 minutes of the night) insomnia, B) Differences in maintaining sleep through the night, C/ Differences in awakening in the first 3 hours of the sleep to go to the toilet, D) Differences among daytime urgency episodes. Comparisons were assessed 2 on 2 using the chi-square test for categorical variables.
* P value < 0.05 between patients with 0 and 1 nocturia episode , ** P value < 0.05 between patients with 1 and 2 or more nocturia episodes, *** P value < 0.05 between patients with 0 and 2 or more nocturia episodes

Figure 1 Frequencies among risk factors for nocturia assessed using the TANGO questionnaire for patients with 0, 1 and 2 or more nocturia episodes

Funding Ghent University Frederik Paulson Chair **Clinical Trial** No **Subjects** Human **Ethics Committee** Ghent University ethical comitee **Helsinki** Yes **Informed Consent** Yes

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EFFECT OF RENAL DYSFUNCTION ON CIRCADIAN CHANGES IN SALT EXCRETION AND URINE OUTPUT

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HYPOTHESIS / AIMS OF STUDY

Nocturnal polyuria is the most common cause of nocturia, but its pathology is not yet understood and its treatment is often difficult. Previous studies have reported that renal dysfunction is one of the factors associated with nocturnal polyuria. However, the cause and effect relationship between renal dysfunction and nocturnal polyuria remains to be elucidated. We hypothesized that a decrease in renal function leads to a carryover of salt excretion into the night time and causes an increase in night-time urine output. The aims of this study were to determine the effect of decreased renal function on circadian changes in salt excretion and urine output, and to determine the cause and effect relationship between renal dysfunction and nocturnal polyuria.

STUDY DESIGN, MATERIALS AND METHODS

Thirty-nine patients who underwent nephrectomy at our hospital between December 2018 and March 2020 were included in the study. Two days before and seven days after surgery, blood tests and 24-hour urine storage tests were performed to assess renal function, salt excretion, and urine output. Urine was collected every 12 hours from 10 o'clock to 22 o'clock (day-time urine) and from 22 o'clock to 10 o'clock (night-time urine), and salt excretion and urine volume were measured during the day time and night time, respectively. According to each parameter, night-time urine output rate (night-time urine volume/daily urine volume) and night-time salt excretion rate (night-time salt excretion/daily salt excretion) were calculated. Renal function, day-time and night-time salt excretion, and night-time urine rate were compared before and after nephrectomy.

RESULTS

The median age was 65 years, and the genders were 21 males and 18 females. The primary disease was a living kidney transplant donor in 27 cases, renal cancer in 10 cases, and renal pelvic cancer in 2 cases. Comorbidities were hypertension in 15 cases, dyslipidemia in 5 cases, and diabetes mellitus in 3 cases. The pre- and post-operative eGFR (mL/min/1.73m2) were 71.6 ± 2.27 vs. 46.3 ± 1.78 (P <0.0001), daily salt excretion (g/day) were 7.50 ± 0.45 vs. 6.75 ± 0.35 (P = 0.091), day-time salt excretion (g) were 4.65 ± 0.36 vs. 3.53 ± 0.24 (P = 0.0010), night-time salt excretion (g) were 3.00 ± 0.26 vs. 3.33 ± 0.21 (P = 0.229), night-time salt excretion rate (%) were 39.3 ± 2.57 vs. 49.7 ± 2.01 (P = 0.0009), and night-time urine rate (%) were 40.3 ± 2.37 vs. 46.4 ± 1.96 (P = 0.042) (Figure 1, 2) (means ± SEM, pre-operation vs. post-operation, paired t-test).

INTERPRETATION OF RESULTS

As a result of the nephrectomy, renal function was reduced by approximately 35%. With decreased renal function, day-time salt excretion decreased, night-time salt excretion rate increased, and night-time urine rate increased significantly. These findings suggest that a decrease in renal function is associated with a decrease in day-time salt excretion and an increase in night-time salt excretion rate, resulting in nocturnal polyuria.

CONCLUDING MESSAGE

Renal dysfunction increases night-time urine rate via increased night-time salt excretion rate.

FIGURE 1

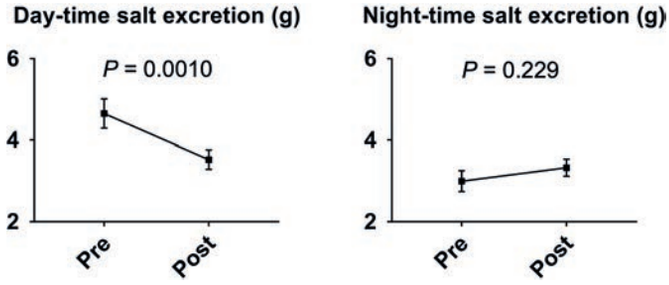

Figure 1. Changes in day-time and night-time salt excretion.

FIGURE 2

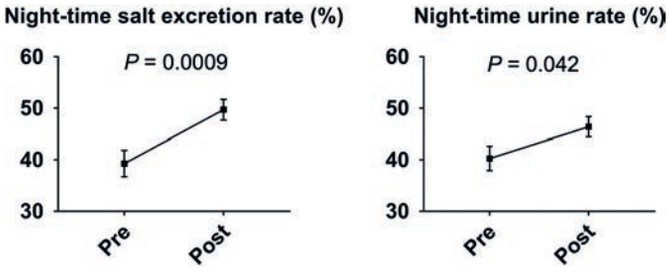

Figure 2. Changes in night-time salt excretion rate and night-time urine rate.

Funding None **Clinical Trial** Yes **Registration Number** UMIN, UMIN000036760 **RCT** No **Subjects** Human **Ethics Committee** Osaka University Medical Hospital **Helsinki** Yes **Informed Consent** Yes

503 www.ics.org/2020/abstract/503

SALT INTAKE ALTERS NOCTURNAL URINE VOLUME, BUT NOT NOCTURNAL FREQUENCY NOR BLADDER CAPACITY IN PATIENTS WITH LOWER URINARY SYMPTOMS

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HYPOTHESIS / AIMS OF STUDY

Nocturnal frequency is one of the most bothersome symptoms among lower urinary symptoms. Recently, salt restriction has been a topic for reduction of nocturnal frequency. However, it is not fully understood how much salt restriction affect nocturnal frequency, nocturnal urine volume or nocturnal bladder capacity. It is also not well-known whether excessive salt intake lead to increased nocturia. Aim of this study is to examine the effect of increasing or decreasing salt intake on nocturnal urine volume, nocturnal frequency and nocturnal bladder capacity in patients with lower urinary symptoms.

STUDY DESIGN, MATERIALS AND METHODS

This study included forty-four patients with lower urinary symptoms. They had two or more daily salt intake measurement at any time and simultaneously filled in bladder volume chart. Salt intake was estimated by morning urine using Tanaka's formula. Nocturnal frequency, nocturnal urine volume and nocturnal bladder capacity were obtained by frequency volume chart. The association of salt intake and salt intake change with urine volume, frequency and bladder capacity was evaluated by the day and night. To precisely assess these association, data with a difference of more than 300 mL in daily urine output over two days were excluded. This study was approved by local ethics committee.

RESULTS

Median age of the patients was 77 years (68-89 years). Baseline nocturnal frequency was 2.0 (0-6.5), nocturnal urine volume was 546mL (100-1350 mL), and nocturnal bladder capacity was 200mL (50-437 mL). Median salt intake was 10.5 g/day (6-14.4 g/day) and baseline salt intake was significantly associated with nocturnal frequency and nocturnal urine volume (p=0.009, p=0.001, respectively). Median change of salt intake was -0.3 g/day (-4.1 to 5.4 g/day). Salt restriction or excessive salt intake was significantly decreased or increased nocturnal urine volume (p=0.004). One-gram salt restriction lead to 36.5mL decrease of nocturnal urine volume. But, salt intake change was not significantly associated with nocturnal frequency nor nocturnal bladder capacity (p=0.29, p=0.91, respectively). Salt restriction was associated with nocturnal urine volume, but not associated with decrease of nocturnal urinary frequency. Effect of salt restriction is limited. Nocturnal frequency should be treated with salt restriction in conjunction with other treatments.

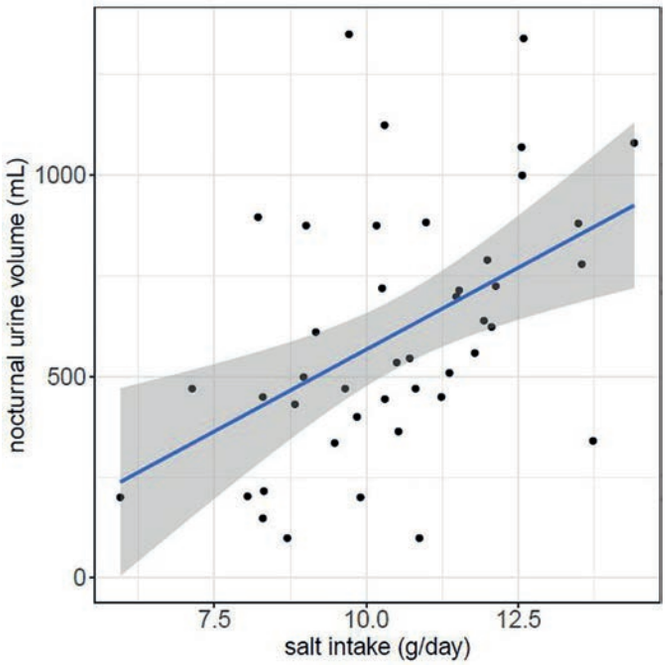
INTERPRETATION OF RESULTS

Salt restriction was associated with decreased nocturnal urine volume, but not associated with decrease of nocturnal urinary frequency nor nocturnal bladder capacity. One-gram salt restriction lead to 36.5mL decrease of nocturnal urine volume. Effect of salt restriction for the treatment of nocturnal frequency is limited.

CONCLUDING MESSAGE

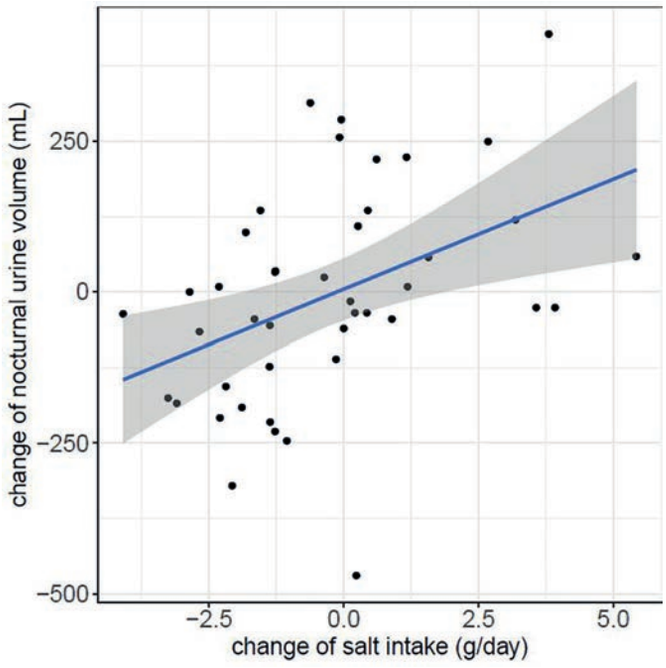
Salt restriction for the treatment of nocturnal frequency should be in conjunction with other treatments.

FIGURE 1



Association between salt intake and nocturnal volume.

FIGURE 2



Association between change of salt intake and change of nocturnal volume.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Osaka university **Ethics Committee Helsinki** Yes **Informed Consent** No

504 www.ics.org/2020/abstract/504

LONG TERM RESULTS OF ARTIFICIAL URINARY SPHINCTER IMPLANTATION FOR STRESS URINARY INCONTINENCE IN CHILDREN: A MONOCENTRIC RETROSPECTIVE STUDY

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HYPOTHESIS / AIMS OF STUDY

To report long term results and complications of artificial urinary sphincter (AUS) in children for stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD).

STUDY DESIGN, MATERIALS AND METHODS

We performed a retrospective, monocentric study. All patients under 18 years old that underwent an AUS (AMS 800) implantation between 1986 and october 2018 were included.

Pre-operative data (underlying disease, severity of SUI) were reported, as well as per and post operative complications. Complete continence was defined as 0 pad/day. Explantation-free and revision-free device survival was estimated by the Kaplan-Meier method.

RESULTS

Overall 37 patients with a median age of 12 years [IQR 9-16] were included (15 females, 22 males). Median follow up was 18,7 years (IQR 0,3-31,4).

25 had a neurogenic ISD, mostly from spinal dysraphism, 5 had a congenital sphincter agenesis, 3 had a post-prostatic rhabdomyosarcoma ISD and 2 an epispadias. 1 patient had a gunshot pelvic trauma and 1 a pelvic surgery for Hirschsprung syndroma, both resulting in ISD.

In patients with neurogenic bladder, the main preoperative voiding mode was spontaneous voiding (n=35, 95%), often with abdominal thrust (or Crédé). 2 patients practiced clean

intermittent catheterization (self-catheterization or by caregiver).

All patients had a preoperative urodynamic evaluation assessing the ISD before device implantation.

48% had previously undergone surgery, mostly for vesico-ureteral reflux or cryptorchidism.

All implantation were performed in open approach except for one young female patient (robotic approach).

In male, the cuff implantation was pericervical in 2/3 cases (n=25). For the remaining patients, the cuff was located in a

bulbar position. For all female patients, the cuff was implanted around the bladder neck.

The median size if the cuff was 6cm (IQR 4-7,5). In 81%, a 61-70 cmH2O balloon was implanted.

5 patients experienced early complications (< 30 days after implantation) : 3 patients had a urinary tract infection, 1 leading to device explantation 21 days after implantation. 2 had acute urinary retention, resolved after few days of catheterization.

At last follow-up, 83,3% (n=30) still had a functional AUS in place.

10 (27%) patients underwent explantation (appendix 1) due to erosion or infection. Only 4 patients had a second device implantation after explantation of the first one. Among those patients, 3 underwent explantation of the second device.

16 (43%) underwent revision (appendix 2), with a median delay of 114 months (IQR 0-223).

10 patients have had an augmentation cystosplasty for compliance degradation non-responding to anticholinergic treatments.

18 (49%) patients were spontaneously voiding, 17 patients were practicing self-catheterization, 1 underwent an ileal urinary derivation and 1 had an indwelling catheter.

At last follow up, the overall continence was satisfaying, with 30 patients (81%) requiring 0 pad/day, 4 patients requiring 1 pad/day and only one who was fully incontinent.

As for the patients still having a functional AUS, 27 (90%) patients wore 0 pad/day and 3 (10%) patients wore 1 pad/day.

INTERPRETATION OF RESULTS

AUS implantation remains a trigering intervention, aspecially for children. To our knowledge, this study reports the longest follow-up of patients with AUS implanted during childhood.

Erosion was the most common complication as reported in litterature.

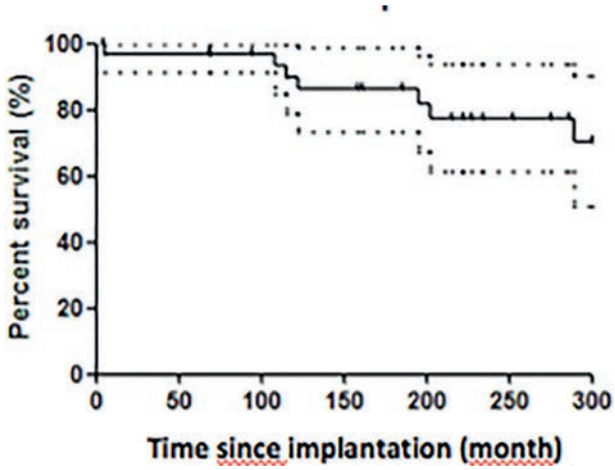
We observed a relatively high rate of revision, that may be related to the very long follow up of our patients.

CONCLUDING MESSAGE

Artificial urinary sphincter AMS 800 is a long term effective surgical treatment for SUI related to ISD in children. Its implantation remains challenging especially in this population of patients who often had undergone previous bladder neck surgery.

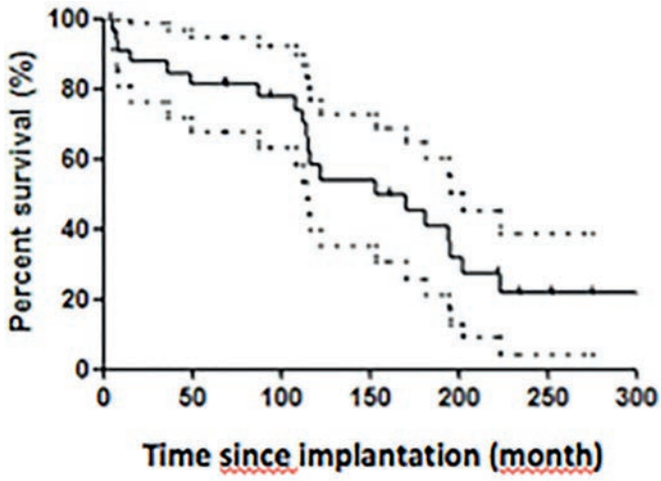
However, AUS provides a long term high rate of continence, and often a high rate of satisfaction, even if revisions are often necessary.

FIGURE 1



Explantation-free survival

FIGURE 2



Revision-free survival

Funding No **Clinical Trial** No **Subjects** Human **Ethics Committee** CNIL **Helsinki** Yes **Informed Consent** No

505 www.ics.org/2020/abstract/505

TRANSITIONAL CARE OF INCONTINENCE FROM PEDIATRIC UROLOGIST TO FUNCTIONAL UROLOGIST : CONCERNS FROM A NATIONAL SURVEY.

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HYPOTHESIS / AIMS OF STUDY

In childhood there are some causes of incontinence, requiring a life-long care, as: bladder exstrophy, posterior urethral valves, neurogenic bladder related to spina bifida, anorectal malformation, spinal cord injury or pelvic trauma realted to surgery, etc.All these conditions are rare disease, however the high rate survival , is creating worldwide an increasing specific population. Uptonow different adult Health care provider (HCP): urologist, gynecologist, coloproctologist, physiotherapist, nurse, etc are involved on the care of these patients with paediatrics (urologist, surgeon, nurses) in different program and organization. The majority of these programs are not well defined, and no single worldwide accepted document is reported defining a transitional care process from adolescence to adult life for people with lower urinary tract and pelvic floor dysfunction related either to a congenital malformation either to an acquired condition during childhood. Aim of our paper has been to define the actual situation in the main Institution involved in transitional care process in European Western Country , evaluating with a survey adult center and paediatrics ones, in order to define advantages, concerns, satisfaction.

STUDY DESIGN, MATERIALS AND METHODS

A multidisciplinary working group (WG) involving well experienced Health care Professionals (HCP) with transitional care has been created, including Urologist, pediatric urologist, gynaecologist, surgeon ,pediatric surgeon, physiotherapist, nurses. A multiple choice questionnaire (MPCQ) has been defined by two senior urologist/pediatric urologist, and submitted to the WG, for reviewing and approval . The reviewed version,of 18 MPCQ has been submitted to major adult and pediatric center involved in continence transitional care, all centers have been selected on their experience, in order to define concerns, limitations, etc on the basis of survey results. Data have been evalutatd using SPSS Windows package and statistically computed by Kruskall Wallis test.

RESULTS

A 18 items MPCQ has been sent to 20 pediatric urology and pediaric surgery deprtment , Group Pediatric (GP) and to 10 adult urology center, group adult (GA). The institution involved are similar in both groups (60% public hospital, 20 private hospital, 10% University, 10 others), with a quite similar activity for urological disease: neurogenic bladder, hypospadia, perineal malformation. In GP the majority of HCP involved are pediatric surgeon (30%) vs urologist in GA (60%). The clinical experience of these HCP has been reported higher in GP, 75%>20 yrs versus GA, 40%>20yrs. No significative statistical difference has been reported for volume activity (numer fo major urological reconstruction/year) between both groups. Only 30% in GP and GA reported a specific program for transition .These programs are active by > 5yrs only in 15% of GP and 30% GA. The team composition between adult and pediatric specialist is mainly undefined and only 20% in both groups reported a defined and structured team. Urotherapist are present in 50%of GA and only in 5% of GP. The presence of the other specialist (orthopaedic, gynaecologist,psychologist) is reported in 30% in GP vs 50% in GA. The majority of HCP is working with individual connection between centers based on personal realtionship, 80-90% without a well defined program. Most HCP avocated as useful the presence of pediatric urologist instead of pediatric surgeon and an adult urologist specialized in reconstructive/functional urologist, as "adolescent urologist "(60%, 40%). 55% of GP HCP vs 40% GA HCP are satisfied about the clinical program of transitional care in their institution, reporting an high rate of satisfaction by patients, 50% vs 70%.

INTERPRETATION OF RESULTS

The results of this survey, in a well industrialized European western country, confirmed previous investigations in paediatrics, where the lack of specific program is commonly reported. Different institution are using different program organization, where the difference could be partially explained by different logistic (pediatric urology department into pediatric hospital or into general hospital cohexisting or joined to urological (adult) department . Significant is the scant presence of urotherapist), mainly in pediatric institution, as well as the different organization of HCP team. Furthermore is interesting to observe that in many pediatric urological center the coordinator is a pediatric surgeon instead of a pediatric urologist. Moreover mostly in adult center early career professionals are involved in transitional care of continence , as for reduced clinical interest.

CONCLUDING MESSAGE

Our survey confirmed the usefulness to define a common specific program for transitional care, either in every single country either,with scientific society , worldwide. In our mind the snapshot of our single country survey could be usefull in order start an active joint WG to ameliorate assistance to these chronic complex patients and define specific educational module for physician, surgeon, nurse , physiotherapist.

REFERENCES

1. Transition of care for adults with congenital urological malformations. Curr Treat opt in Pediatrics 2016,2,35-42

2. The fate of transitional urology patients referred to a tertiary transitional care center.Urology 2014;84(6) 1544-1548

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506 www.ics.org/2020/abstract/506

MODE OF BIRTH DELIVERY AND AGE AFFECTS THE PEDIATRIC URINARY MICROBIOME

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HYPOTHESIS / AIMS OF STUDY

We previously described the existence of the pediatric urobiome in both males and females [1]. We now wish to determine if there are differences in the pediatric urobiome by age, and mode of birth delivery dichotomized by sex. Prior studies have demonstrated that the pediatric gut microbiome differs between children delivered by Caesarian section (C-section) and those delivered vaginally. This difference is apparent in the first few months following birth, but within a year the difference becomes much less apparent [2]. Other studies have reported age effects on the gut microbiome [3]. However, to date, the influence of mode of delivery on the pediatric urinary microbiome and the longevity of its potential effects have not been studied.

STUDY DESIGN, MATERIALS AND METHODS

Following IRB approval, catheterized urine samples from children less than 18 years of age without antibiotic exposure were obtained. Demographic information from the participants were obtained, including mode of birth and age. Urine specimens were assessed using the expanded quantitative urine culture (EQUC) protocol and the isolated bacteria were identified via MALDI-TOF Mass Spectrometry. Following identification, urotype was assigned based on dominant genus (i.e., 50% or greater relative abundance). Microbiome data in terms of urotype were then analyzed by age and by mode of birth delivery. The participants were sorted into three age groups 0-2 years of age, 3-11 years of age, and 12-18 years of age. Significance was determined via Fisher's exact test.

RESULTS

86 children were included in the study, including 39 females and 47 males. Mean patient age was 6.5 years (2 months – 17 years). Cultivatable bacteria were detected in the bladders of children as young as 2 months old (Figure 1). Whereas most genera were detected in all three age groups, some were only detected in infants or teenagers. Urotypes in terms of sex and mode of birth delivery are listed in Table 1. In males, we detected an association between the Enterococcus-dominant urobiome and delivery by C-section (p=0.02).

INTERPRETATION OF RESULTS

Differences were observed in the urinary microbiome by age. We only detected certain genera in the very young (i.e. Finegoldia and Morganella) and some in older children; in particular, Lactobacillus was only detected in females aged eight and older and predominantly in those aged 12 and older. Many genera were detected throughout childhood (especially Actinomyces, Enterococcus, Streptococcus, and Staphylococcus).

Like other pediatric microbiomes, based upon our pilot study, there appears to be a difference in the bacteria that constitute the urobiome between children born by C-section and vaginal delivery. Further sample collection will be necessary to confirm this observation and to see if there are other urotypes, genera, or species that are associated with either method of delivery. In studies examining mode of delivery and the gut microbiome, initial differences quickly disappear with age. At this point, we do not have the statistical power to determine if the differences we see remain with age; we need to increase our sample size.

CONCLUDING MESSAGE

Detection of some genera seems to be associated with age. A statistically significant association exists between C-section birth in males and the Enterococcus urotype. Increased sampling is required to determine if there are more associations with mode of delivery.

FIGURE 1

Table 1: Urotype by sex and mode of delivery[a,b]

	Female (n=33)			Male (n=38)		
	C-section (n=10)	Vaginal (n=23)	p value	C-section (n=11)	Vaginal (n=27)	p value
Negative	5 (50%)	8 (35%)	0.46	5 (45%)	9 (33%)	0.71
Positive	5 (50%)	15 (65%)		6 (55%)	18 (67%)	
Actinobaculum	0 (0%)	0 (0%)	1	0 (0%)	1 (4%)	1
Actinomyces	1 (10%)	4 (17%)	1	0 (0%)	0 (0%)	1
Actinotignum	1 (10%)	0 (0%)	0.3	0 (0%)	2 (7%)	1
Aerococcus	0 (0%)	0 (0%)	1	0 (0%)	1 (4%)	1
Bifidobacterium	0 (0%)	1 (4%)	1	0 (0%)	0 (0%)	1
Escherichia	1 (10%)	0 (0%)	0.3	0 (0%)	0 (0%)	1
Enterococcus	0 (0%)	2 (9%)	1	3 (27%)	0 (0%)	0.02
Lactobacillus	1 (10%)	4 (17%)	1	0 (0%)	0 (0%)	1
Micrococcus	0 (0%)	0 (0%)	1	1 (9%)	0 (0%)	0.29
Staphylococcus	0 (0%)	2 (9%)	1	0 (0%)	5 (19%)	0.29
Streptococcus	0 (0%)	1 (4%)	1	0 (0%)	5 (19%)	0.29
Unknown	1 (10%)	0 (0%)	0.3	1 (9%)	4 (15%)	1
Mixed	0 (0%)	1 (4%)	1	1 (9%)	0 (0%)	0.29

[a]Mode of delivery available for only 71 children.
[b]Values in the table represent percentage of patients with that particular urotype with significance determined via Fisher's exact test.

FIGURE 2

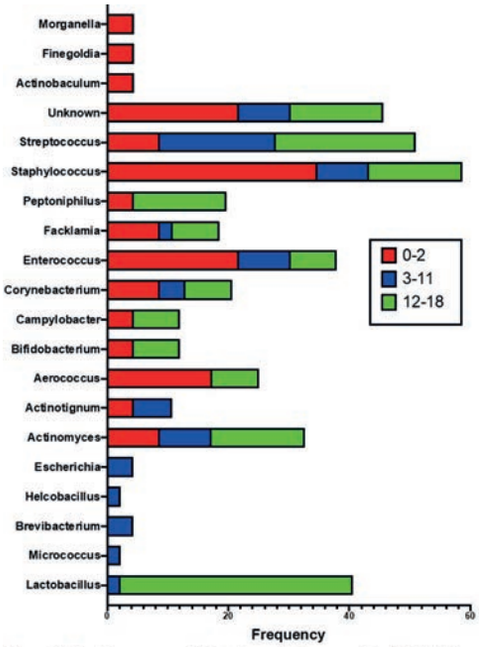

Figure 1: The frequency of detection of all genera identified. When identified in participants aged 0-2 it is shown as red, in 3-11 year olds blue, and in 12-18 year olds green.

REFERENCES

1. Thomas M Halverson, Denise Juhr, Zachery Kornberg, Hillary Copp, Douglas Storm, and Alan J Wolfe. Presence of Cultivatable Bacteria in the Bladders of children. International Continence Society (ICS) 2019, Gothenburg, Sweden, September 3-6 2019
2. Reyman M, van Houten MA, van Baarle D, et al. Impact of delivery mode-associated gut microbiota dynamics on health in the first year of life [published correction appears in Nat Commun. 2019 Nov 25;10(1):5352]. Nat Commun. 2019;10(1):4997. Published 2019 Nov 1. doi:10.1038/s41467-019-13014-7
3. O'Toole PW, Jeffery IB. Gut microbiota and aging. Science. 2015;350(6265):1214–1215. doi:10.1126/science.aac8469

Funding All funding was internal funding. **Clinical Trial** No **Subjects** Human **Ethics Committee** University of Iowa IRB and University of California, San Francisco IRB **Helsinki** Yes **Informed Consent** Yes

SESSION 34 (PODIUM SHORT ORAL) - PELVIC FLOOR DYSFUNCTION 2

Abstracts 507-518

11:30 - 13:00, Brasilia 2

Chair: Dr Kathleen C Kobashi (United States)

507 www.ics.org/2020/abstract/507

PREVALENCE, RISK FACTORS, AND QUALITY OF LIFE CONCERNING STRESS URINARY INCONTINENCE IN US FEMALE ATHLETES PARTICIPATING IN STRENGTH SPORTS.

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HYPOTHESIS / AIMS OF STUDY

Stress urinary incontinence (SUI) is a complaint of involuntary loss of urine during effort or physical exertion, or during sneezing or coughing [1]. SUI is frequently a symptom during pregnancy and in the postpartum periods. However, it also affects women in sport [2]. High prevalence of SUI has been shown in sports involving running and jumping but there is sparse knowledge on women participating in strength sports [2]. The aim of this study was to identify the scope of the problem of SUI in women participating in strength sports, movement patterns that elicit SUI, and the impact on quality of life in female athletes with SUI.

STUDY DESIGN, MATERIALS AND METHODS

This study followed a mixed methods design, with a quantitative survey and qualitative focus group interviews. The International Consultation on Incontinence Questionnaire on Urinary Incontinence Short Form (ICIQ-UI-SF) was sent to women who are United States citizens, age 18-65, and members of USA Weightlifting (USAW), USA Powerlifting (USAPL), and/or United States CrossFit affiliates [3]. In addition to the ICIQ-UI SF, several demographic questions were added to the survey: age, body mass index (BMI), sport preference (USAW, USAPL, CrossFit, or a combination), number of pregnancies, number of delivery(ies), type of delivery(ies), vaginal tears during labor and delivery, frequency and duration of exercise sessions per week, and perceptions of leakage in and outside of training. Polychoric and Spearman correlations were conducted for survey analysis. A logistic regression was performed to estimate predictors of the likelihood of women experiencing urine leakage with exercise. Wald chi-square tests were used to calculate odds ratios for each outcome. Following the survey, respondents were able to volunteer to participate in two focus groups for qualitative data. Eight women participated in the focus groups.

RESULTS

Three hundred forty-two respondents completed the online survey (5% response rate); the largest representative was from Olympic weightlifting members (n=239). A majority of respondents (n=226, 65.5%) reported leaking once per week or more often. When responding to "when does urine leak?" a majority of respondents (n=154, 44.8%) reported leakage during physical activity and exercise. There was a moderate positive correlation between parity and the interference of urine leakage with everyday life (r=.336, p<.001) and between urine leakage during exercise and urine leakage outside of exercise (r=.397, p<.001), as well as urine leakage during exercise and interference with everyday life (r=.683, p<.001). There was also a weak, but statistically significant correlation between hours per week of physical activity and urine leakage outside of exercise (r=-.122, p=.024). Sport preference was the only statistically significant predictor of urine leakage with exercise (OR 1.227 {95% CI 1.04-1.45}, p=.01), as shown in Table 1. Multiparity was the only statistically significant predictor of urine leakage outside of exercise (OR 1.402 {95% CI 1.00-1.94}, p=.04), as shown in Table 2. Qualitative reports demonstrated feelings of embarrassment, frustration, and hopelessness with urine leakage during and outside of exercise. Women reported double-unders, deadlift, running/jumping, front squats, cleans, and push press as the primarily offending movements during exercise that cause leakage during exercise. Main barriers to quality of life included adjustments to or elimination of training exercises, feelings of annoyance/irritation, and that urinary leakage is an acceptable side effect of training. Women stated that if provided education about pelvic floor muscle training they would use it, but only once the urinary leakage episodes became severely bothersome. Qualitative results show that while women have negative motions surrounding SUI, they are also not comfortable asking for more resources beyond pelvic floor muscle training from their physicians.

INTERPRETATION OF RESULTS

Quantitative results are similar to those found in previous studies that SUI is an issue within female athletes [2]. Due to the poor response rate (5%) it is not possible to generalize to the female strength population. This is one of few studies that specifically examined female athletes involved in strength sports. Qualitative results support the need for additional research examining each of these strength sports individually to truly identify the scope of the problem and the manner in which women choose to address SUI.

CONCLUDING MESSAGE

Parous women are more likely to report SUI than nulliparous women. Parity and hours of training per week are linked to urine leakage both during and outside of exercise. Despite negative feelings of shame, embarrassment, and frustration, women accept SUI as a side effect of training, and are hesitant to ask for more from their physicians beyond pelvic floor muscle training information. Additional research is needed to examine each strength sport individually.

FIGURE 1

Table 1: Odds ratios for urine leakage with exercise

	Odds Ratio (95% CI)	P-value (α<.05)
Age	0.968(0.77-1.20)	.76
Gravida	1.046(0.77-1.41)	.77
CS/VBAC	1.462(0.72-2.95)	.29
Sport preference	1.227(1.04-1.45)	***.01***
Education level	0.923(0.57-1.482)	.73
Hours/week exercising	0.955(0.73-1.24)	.73

CI = Confidence Interval

FIGURE 2

Table 2: Predicting urine leakage outside of exercise

	Odds Ratio (95% CI)	P-value (α<.05)
Age	1.212(0.95-1.54)	.11
≥ 1 pregnancy	1.402(1.00-1.94)	***.04***
CS/VBAC	1.139(0.53-2.43)	.73
Sport preference	1.150(0.96-1.37)	.12
Education level	1.114(0.65-1.90)	.69
Hours/week exercising	0.827(0.61-1.11)	.21

CI = confidence interval

REFERENCES

1. Haylen BT, Freeman RM, Swift, SE, et al. The International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery, Neurourol Urodyn, 2010; 30(1), 2-12.
2. Bø K, Nygaard IE. Is physical activity good or bad for the female pelvic floor? A narrative review. Sports Med, 2019; doi:10.1007/s40279-019-01243-1
3. Avery, K, Donovan, J, Peters, TJ, et al. ICIQ: A brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn, 2017; 23, 4, 322-330.

Funding Rocky Mountain University of Health Professions Research Grant, $350.00 **Clinical Trial** No **Subjects** Human **Ethics Committee** Rocky Mountain University of Health Professions Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

508 www.ics.org/2020/abstract/508

FATE OF OVERACTIVE BLADDER SYMPTOMS AFTER MIDURETHRAL SLING IN FEMALE STRESS URINARY INCONTINENCE PATIENTS WITH NEUROLOGICAL DISEASE

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HYPOTHESIS / AIMS OF STUDY

We investigated surgical outcomes and changes of overactive bladder (OAB) symptoms after midurethral sling placement in female stress urinary incontinence (SUI) patients with or without neurological disease.

STUDY DESIGN, MATERIALS AND METHODS

Medical records of patients who underwent midurethral sling operation for SUI between January 2009 and December 2018 at a single tertiary center were reviewed. Patients with previous anti-incontinence surgery and concurrent pelvic organ prolapse repair were excluded. Based on the presence of underlying neurological disease (cerebrovascular, neurodegenerative movement disorder, spinal cord disease, or peripheral neuropathy), patients were divided into two groups: the non-neurological disease (NND) group and the neurological disease (ND) group.

Among patients who experienced complete dryness through the final follow-up examination, baseline demographics and changes in OAB symptoms were compared, including de novo OAB in the pure SUI group, resolution rate of urgency or de novo UUI in SUI in the urgency group, and resolution rate of UUI in the MUI group. OAB symptoms between postoperative month 6 and month 12evaluated to investigate the influence of midurethral sling operation. ND patients with MUI were categorized into three subsets based on the timeline of UUI symptoms and neurological condition as pre-existing UUI, UUI as sequela of a neurological condition, or not-identifiable. The resolution rate of UUI was compared between pre-existing and neurological sequela subsets. Next, to evaluate the association between postoperative OAB symptoms and neurological disease, we performed a 1:1 matched analysis between NND and ND groups in subsets of patients with pure SUI (de novo OAB) and MUI (resolution of UUI).

RESULTS

A total of 855 patients (median follow-up: 49.8 months; mean age: 57.9±9.3 years) were included. Complete dryness was achieved 95.0% of NND and 93.7% of ND patients (p=0.440). Among 797 patients (711 NND and 86 ND) who achieved complete dryness, 227 patients had pure SUI, 198 patients had SUI with urgency, and 372 patients had mixed urinary incontinence (MUI) preoperatively. The ND patients tended to be older older (57.2±9.0 years vs. 62.8±9.2 years) and had higher proportions of diabetes (8.0% vs. 24.4%), hypertension (26.7% vs. 47.7%), and MUI (44.6% vs. 64.0%) than NND patients (p<0.001 for all). The incidence of pure SUI was higher in ND patients (5.9% vs. 18.2%, p=0.032) than in NND patients. Specifically, de novo urgency developed in 5.4% of NND patients and 18.2% of ND patients and de novo UUI developed in 0.5% of NND patients and none of the ND patients. In patients with SUI with urgency, resolution rate of urgency was similar (72.0% vs. 77.8%, p = 0.703) and de novo UUI developed in 1.5% of patients. In patients with MUI, the overall resolution rate of UUI was significantly higher in NND patients than in ND patients (75.4% vs. 60.0%, p = 0.017). The rate was significantly higher in preoperative SUI predominant NND patients than in UUI predominant NND patients (80.9% vs. 55.0%, p < 0.001). There was no significant difference in resolution rates of UUI based on preoperative predominant type of incontinence in the ND group (62.9% vs. 50.0%, p = 0.387).

The chronological association of OAB symptoms with neurological conditions was clearly identified in 79.7% of MUI patients (43 out of 55). There was no significant difference in the resolution rates of UUI between patients whose storage symptoms were associated with a neurological condition and those whose storage symptoms were not associated with a neurological condition (17 out of 28: 60.7% vs. 9 out of 15: 60.0%, p = 0.964). In a 1:1 matched analysis of pure SUI patients, 19 patients were matched and de novo OAB was significantly higher in patients with ND than in patients with NND (5.26% vs. 21.05%, p < 0.001). In a 1:1 matched analysis of MUI group, 52 patients were matched but resolution of UUI did not significantly differ between ND and NND patients (53.9% vs. 57.7%, p = 0.414).

INTERPRETATION OF RESULTS

Comparable success rates in neurological patients might be due to the patients' relatively high performance statuses. Most neurological patients in the study population were tolerable to monitored or general anesthesia and capable of caring for themselves or could perform normal activities with some difficulty. Our success rates of midurethral sling in neurological group are higher than previous literature, and this might have been becaute the etiology of SUI in our patient population was not purely due to impaired control of the external sphincter. In addition, the incidence of de novo OAB in neurological group is also higher than previous literature. This might be because our study population included 61.6% (53 out of 86) of patients with suprapontine lesions that might have influenced the tonic inhibition of the pontine micturition center, which can lead to spontaneous involuntary detrusor contractions. Significant difference in de novo OAB after 1:1 matched analysis might have occurred due to the natural course of neurological condition itself. Three-fourths of patients who developed de novo OAB had supra pontine lesion; cerebrovascular diseases (n = 2), Parkinson's disease (n = 1). In a matched analysis of MUI patients, how-

ever, there was no significant difference in the resolution of UUI between non-neurological disease and neurological disease patients (53.9% vs. 57.7%, p = 0.414). This might be because patients included in the present study were in their early stage of neurodegenerative disease and had relatively high performance status.

CONCLUDING MESSAGE

Presence of neurological disease did not affect the success rate of midurethral sling placement. De novo OAB symptoms were more likely to develop and the resolution rate of UUI seemed to be lower in patients with neurological disease. However, after matching by baseline variables including age, diabetes and hypertension, there was no difference in the resolution rate of UUI in MUI group while de novo OAB symptoms were prevalent in neurological pure SUI group. In addition, the onset of preoperative UUI was irrelevant in patients with persistent postoperative UUI in neurological MUI group.

REFERENCES

1. El-Azab AS, El-Nashar SA: Midurethral slings versus the standard pubovaginal slings for women with neurogenic stress urinary incontinence. Int Urogynecol J 2015; 26: 427.
2. Losco GS, Burki JR, Omar YA et al: Long-term outcome of transobturator tape (TOT) for treatment of stress urinary incontinence in females with neuropathic bladders. Spinal Cord 2015; 53: 544.
3. Ford AA, Taylor V, Ogah J et al: Midurethral slings for treatment of stress urinary incontinence review. Neurourol Urodyn 2019; 38 Suppl 4: S70.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Institutional Board of Asan Medical Center **Helsinki** Yes **Informed Consent** No

509 www.ics.org/2020/abstract/509

THE EFFECTS OF HIGH-INTENSITY FOCUSED ULTRASOUND (HIFU) ABLATION TREATMENT FOR UTERINE FIBROIDS ON GENITOURINARY SYMPTOMS

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HYPOTHESIS / AIMS OF STUDY

This study was aim to evaluate the effects of High-intensity focused ultrasound (HIFU) ablation of uterine fibroids on genitourinary symptoms after HIFU therapy .

STUDY DESIGN, MATERIALS AND METHODS

Seventy- five women with symptomatic uterine fibroid were scheduled for high-intensity focused ultrasound ablation for uterine fibroids. All subjects were required to perform Magnetic Resonance Imaging on Uterus in order to screen out the patients with endometrial or uterine malignancy before starting the treatment. Magnetic Resonance Imaging on Uterus follow up was also conducted three -month post HIFU therapy to assess the uterine reduction rate and fibroid reduction rate. Laboratory examination with Serum LDH, CA125 and Hemoglobin level were also performed before and three months post HIFU treatment. Genitourinary symptoms questionnaire assessment using Overactive Bladder Symptom Score (OABSS), Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire -7 (IIQ-7) , International Consultation on Incontinence Questionnaire - Short Form(ICIQ-SF) , sexual function assessment with Female Sexual Function Index (FISI) questionnaire were also conducted before and three months post HIFU treatment.

RESULTS

Among these seventy- five patients, forty -five of them presented with anterior wall uterine fibroids while thirty of them had posterior wall uterine fibroids. For the treatment result , the average sonication power was 364.52 Watt while the average total treatment time was 115.36 minutes. Total Sonication time during HIFU therapy was 919.48s with average exposure energy was 338534.27 Joule . There was a significant improvement in uterine reduction rate (27.1 ± 15.2%, $P<0.05$) and fibroid reduction rate (40.68±23.85 %, $P<0.05$) after three month HIFU treatment through Uterus Magnetic Resonance Imaging follow up .In comparison ,there was an

increase in hemoglobin level and greater reduction in serum LDH and CA125 level at baseline and three months post HIFU treatment , with no significantly difference (P>0.05) . Symptomatic improvement in genitourinary symptoms with total reduction in OABSS, UDI-6, IIQ-7, ICIQ-SF score were found postoperatively (P<0.05). The scores of all parameters of FSFI improved significantly after HIFU therapy (P<0.05) except in the satisfaction and pain domain. In comparison between anterior wall uterine fibroids located group and non-anterior wall located group, the result showed that there was no significant difference in OABSS, UDI-6,IIQ-7 ,ICIQ-SF scores.

INTERPRETATION OF RESULTS
Successful ablation of the uterine fibroids in HIFU therapy cause shrinkage of the uterine size and uterine fibroids. Less compression effects of these uterine fibroids over pelvic organ and bladder after ablation therapy subsequently relieve the patients' lower urinary tract symptoms .

CONCLUDING MESSAGE
High-intensity focused ultrasound (HIFU) ablation treatment for uterine fibroids showed significant improvement in uterine reduction rate, fibroid reduction rate after HIFU treatment .HIFU treatment also has great impact in quality of life with improvement in genitourinary symptoms and sexual function.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** **Ethics Committee** of Kaohsiung Medical University Hospital **Helsinki** Yes **Informed Consent** Yes

510 www.ics.org/2020/abstract/510

PATIENT COUNSELLING AND SURGERY FOR STRESS URINARY INCONTINENCE – AN INTERNATIONAL SURVEY

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HYPOTHESIS / AIMS OF STUDY
Stress urinary incontinence (SUI) is a common cause of urinary incontinence and negatively affects a woman's quality of life. One of the surgical options for treatment is a mid-urethral sling (MUS) comprised of monofilament polypropylene. The MUS is the most investigated procedure for SUI and considered to have a relatively low-risk safety profile. However, recent negative publicity and litigation have resulted in the decline of the use of synthetic mesh for prolapse surgery and urinary stress incontinence in recent years.

The aim of this survey is to investigate whether the current climate has resulted in a change in doctors' and their patients' preconceptions regarding the use of synthetic mesh for the treatment of SUI.

STUDY DESIGN, MATERIALS AND METHODS
An electronic survey was distributed among practitioners who provide consultation and treatment for women with SUI, which comprised a total of 16 questions: 10 assessing the patient consultation with SUI (Table 1), and 6 concerning respondents' demographics. The survey was approved by the IUGA educational committee.

RESULTS
A total of 293 participants completed the survey. Demographics (age, gender, country of practice, title and years of experience) are presented in Table 2. Despite resulting in prolongation of consultation, the majority of respondents (86%) think that patient information leaflet (PIL) should be handed out, and these will provide essential information and better understanding for their patients (73%). However, only 64% of respondents are actually providing the PIL at the time of consultation. Majority of participants would use either IUGA, or their working institute PIL (60%). Only 8% felt that patients have positive preconception of synthetic mesh for SUI. Interestingly, 83% of respondents haven't changed their recommendations for the treatment, nor their consent process. The preferred initial surgical treatment for SUI was retropubic MUS followed by transobturator MUS, and then bulking agents. Burch colposuspension and pubovaginal fascial sling were the least preferred treatment initially. According to the survey, clinicians counselling patients presenting with vaginal prolapse and SUI would initially offer vaginal repair with MUS (52%) or vaginal repair alone and MUS later if needed (21%).

INTERPRETATION OF RESULTS
Despite the negative publicity and the current medico-legal litigation involving MUS for treatment of SUI, the majority of respondents still prefer this as the initial surgical treatment for SUI. PIL are valued by majority of clinicians, and should be provided in the consultation process for patients with SUI.

CONCLUDING MESSAGE
Despite the recent negative publicity, the majority of clinicians worldwide, still believe that MUS for treatment of SUI, is considered as the preferred surgical option.

FIGURE 1

Table 1 – Survey questions (Q1-Q10)

Question number	Question number
Q1- Do you feel the majority of your patients have preconceived ideas about the use of synthetic mesh for the treatment of SUI? 1. Yes, negative preconception 2. Yes, positive preconception 3. No 4. My patients haven't heard of the use of synthetic mesh for SUI	**Q6** - Do you feel your consultation time for surgical treatment of SUI has changed in the last year? 1. Yes, it has been prolonged 2. Yes, it was shortened 3. No. There is no change
Q2 - Do you think patients should receive patient information leaflets (PIL) while consulting? 1. Yes 2. No 3. Indifferent	**Q7** - In light of the recent negative publicity for synthetic mesh, have you changed your opinion with regard to the use of synthetic mesh for surgical treatment of SUI? 1. Yes 2. No 3. Indifferent
Q3 - Do you use and/or provide patient information leaflets (PIL) while consulting about SUI? 1. Yes 2. No 3. Sometimes	**Q8** - Should your patient require surgery for SUI, and assuming she doesn`t have any significant co-morbidities, please number the following options from **first** (1) to be offered to **last** (6)? 1. Urethral bulking agents 2. Retropubic MUS 3. Trasobturator MUS 4. MUS – mini sling 5. Burch colposuspension 6. Fascial sling
Q4 - Which patient information leaflets (**PIL**) are you using? (you can choose more than one) 1. The IUGA PIL 2. Government issued PIL 3. My hospital/ Department PIL 4. My national college PIL (ACOG, RCOG etc.) 5. My own PIL 6. I'm not using PIL	**Q9** - Have you changed your consent process to include (Tick **ONE** option): 1. **A consent tool kit** 2. A consent that requires patients to initial specific complications 3. I have not changed my consent process
Q5 - Do you feel that patient information leaflets (PIL) contribute to patient understanding of the surgical treatment options for SUI? 1. Yes. They provide essential information and assist in a better understanding of the preferred surgical treatment for SUI 2. No. They cause more confusion 3. Indifferent	**Q10** - A woman with vaginal prolapse and urinary stress incontinence (tick **ONE** you relate the most): 1. I would perform a vaginal repair alone and MUS latter if necessary 2. I would perform an abdominal repair alone and MUS latter if necessary 3. I would perform a vaginal repair and bulking agents 4. I would perform an abdominal repair and bulking agents 5. I would perform abdominal repair and MUS 6. I would perform a vaginal repair with MUS 7. I would perform an abdominal repair and Burch colposuspension or fascial sling 8. I would perform an abdominal repair of prolapse alone

FIGURE 2

Table 2 – Respondents demographics

Item	N (%)				
Gender	Male 153 (52%)			Female 140 (47%)	
Age	20-29 1 (1%)	30-39 49 (31%)	40-49 41 (26%)	50-59 48 (30%)	>60 20 (13%)
Position/title	Gynaecologist with urogynaecology special interest 44 (15%)	Urogynaecologist / FPMRS / Specialist in female urology 176 (60%)	Urologist (general) 19 (6%)	Urogynaecology Trainee 28 (10%)	Gynaecology/ Urology Trainee 13 (5%)
Years of training/ experience	<2 12 (4%)	2-5 42 (14%)	6-10 70 (24%)	11-15 36 (12%)	>15 133 (45%)
Work place	Public sector 143 (49%)	Private sector 54 (18%)	Both 96 (33%)		
Region of the world	Africa 2 (1%)	Asia 23 (8%)	Oceania 60 (20%)	Europe 86 (29%)	North / South America 110 (38%)/ 7 (2%)

Funding NONE **Clinical Trial** No **Subjects** Human **Ethics Committee** IUGA educational committee **Helsinki** not Req'd Not needed, approved by IUGA **Informed Consent** No

511 www.ics.org/2020/abstract/511

MID-URETHRAL SLINGS (MUS) AT RISK OF EXTINCTION? A PROSPECTIVE SINGLE-CENTER STUDY.

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HYPOTHESIS / AIMS OF STUDY

In many countries, the mid-urethral sling (MUS) for stress urinary incontinence (SUI) is at risk of extinction as collateral damage of the mesh-war. A main criticism is the lack of real-world and long-term data. Therefore a prospective sling database was created in our center.

STUDY DESIGN, MATERIALS AND METHODS

The database was created in 09-2016. Demographics and complications were inserted into an electronic record, linked to the medical file. Patient-reported outcome measures (PROMS) were assessed through validated questionnaires (PGI-I, IIQ-7, UDI-6 and PISQ-12) at 0, 3 and 12 months (m).

RESULTS

Between 09-2016 and 10-2019, 460 MUS procedures were performed. Physician-reported data were inserted in 96%, 87% and 59% and PROMS were completed in 88%, 78% and 72% at 0, 3 and 12m respectively. TVT-O was performed in the majority of the procedures (73%). It concerned a primary sling in 89%. Simultaneous surgery was performed in 31% of patients (of which 63% cystocele repair). Success rate (PGI-I 1-2) was 88% at 3m and decreased to 83% at 12m ($p = 0.14$). IIQ-7 showed a significant improvement at 3m and 12m. According to UDI-6, SUI-related as well as irritative and obstructive symptoms improved after 3 and 12m ($p < 0.01$). In the 57% of patients who were sexually active, 68% were satisfied with their sexual life preoperatively, while this increased to 84% at 12m. For both pain and incontinence during sexual intercourse and fear of unwanted urine loss, there was a significant improvement at 3m and 12m. Peroperatively, there were 5 vaginal and 4 bladder perforations, none with consequences. At 3m, there were 10% urinary tract infections, 2% erosions, 3% retentions and 4% pain complaints. For these complications, 9 patients underwent re-intervention. After 1y there were 4% asymptomatic erosions and 1.2% persistent pain.

INTERPRETATION OF RESULTS

A linear regression analysis showed worse outcome (PGI-I) at 3m in patients with concomitant cystocele repair and higher post-void residual. Higher SIU complaints resulted in better outcome after 3m. At 12m, patients with a higher BMI and more preoperative urge complaints had worse outcome. The cystocele group had a significant lower PGI-I at 3m compared to the exclusively sling group. However, the latter had a significant decline of success at 12m.

CONCLUDING MESSAGE

A prospective sling database was created as part of daily clinical practice. With little effort a large amount of data became readily available. While the PROMS data had a satisfactory response rate (72%), only 59% of physician-data were completed at 12m. The MUS showed 83% success with a 2% re-intervention rate. These numbers are used in our center-specific informed consent. A 5 year follow-up is planned.

FIGURE 1

Variable	3m			12m		
	n	slope	p-value	n	slope	p-value
BMI	277	0.01809 ± 0.01094	0,099	199	0.04270 ± 0.01573	0,007
Parity	269	0.07092 ± 0.05206	0,174	192	0.04257 ± 0.06995	0,543
Cystocele repair	277	0.3397 ± 0.1114	0,003	199	0.3397 ± 0.1114	0,558
Pre-op SUI	248	-0.09229 ± 0.03636	0,012	168	-0.005937 ± 0.04935	0,904
Pre-op urge	249	-0.006959 ± 0.03469	0,841	168	0.09291 ± 0.04494	0,040
Post-void residual (PVR)	275	0.002647 ± 0.001155	0,023	199	0.004038 ± 0.002052	0,051
Age	277	0.005808 ± 0.003728	0,120	199	0.01083 ± 0.005651	0,057

Predictive factors

FIGURE 2

	WITH cystocele repair		WITHOUT cystocele repair		
	n	mean (sd)	n	mean (sd)	p-value
Pre-op SUI	80	4,4 (1,8)	299	6,3 (1,3)	< 0,0001
Pre-op urge	88	4,9 (1,6)	303	5,5 (1,7)	0,005
Pre-op obstructive	80	4,0 (1,8)	300	3,2 (1,4)	< 0,0001
Post-void residual (PVR)	96	49,3 (70,6)	344	11,1 (30,6)	< 0,0001
PGI-I 3m	success	75%	success	92%	0,0015
PGI-I 12m	success	84%	success	83%	1

Concomitant cystocele repair vs exclusively MUS

Funding NONE **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Commissie Medische Ethiek AZ Groeninge Kortrijk (1479206631415) **Helsinki** Yes **Informed Consent** Yes

512 www.ics.org/2020/abstract/512

PREDICTING THE RETURN OF BLADDER FUNCTION FOLLOWING VAGINAL NATIVE TISSUE REPAIR USING DATA FROM A SUPRAPUBIC CATHETER REGIMEN

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HYPOTHESIS / AIMS OF STUDY

Same day surgical discharge after vaginal reconstructive surgery is often appropriate but, in those with acute urinary retention, timing for repeat attempt at a voiding trial is not clear. Previously identified risk factors for failure of voiding trial after vaginal reconstruction come from a single retrospective study: age, degree of cystocele, intraoperative blood loss, Levator and Kelly Plication[1]. We present novel data analyzing a cohort of patients with routinely placed suprapubic catheters, providing insight into return of bladder function and risk factors for postoperative voiding dysfunction following vaginal prolapse repair. We aim to improve postoperative care by minimizing clinic visits for voiding trials.

STUDY DESIGN, MATERIALS AND METHODS

We identified 127 women undergoing native tissue vaginal reconstruction from a single surgeon between 2012 and 2019 who routinely used suprapubic catheters. These patients all followed a specific catheter regimen postoperatively, giving reliable information about postvoid residual volumes (PVR) and thus bladder function. We used a PVR of <150 cc at 4 hours to be a surrogate marker for return of bladder function. Univariate and multivariate logistic regression analyses were used to identify risk factors for return of bladder function >4 days by surrogate marker. Variables included were age, baseline PVR, history of diabetes, stroke and/or smoking, leading edge of prolapse, stage of prolapse, type of apical suspension, estimated surgical blood loss (EBL), operative duration, anesthesia duration, concomitant hysterectomy and/or incontinence procedure. Primary outcome measure was PVR >150 cc measured by suprapubic catheter after 4 hours.

RESULTS

Our cohort (n=127) had a median age of 67 yrs (IQR 61-75), median BMI of 27.3 (IQR 23.9-29.3), were 95.3% (n=121) white and 94.5% (n=120) postmenopausal. Thirteen% (n=16) were diabetic, 3.9% (n=5) had history of stroke and 26.8% (n=34) had smoking history. Prolapse stage was advanced for the majority of patients: 55 patients had Stage 3 and 24 patients had Stage 4. The leading edge of prolapse was anterior in 31.5% (n=40) and apical in 62.2% (n=79). The average time to return of bladder function was 4.1 days. Eighty% of patients with vaginal vault suspension had return of bladder function by the fifth postoperative day whereas 80% of patients with concomitant hysterectomy had return of bladder function by the seventh postoperative day (See figure 1). Eighty% of patients with operative duration ≤ 120 minutes had return of bladder function by day 4 while 80% of patients with operative duration > 120 minutes had return of bladder function by day 7. Univariate and multivariate analyses of risk factors for return of bladder function after the 4th postoperative day can be seen in Table 1.

INTERPRETATION OF RESULTS

We present several clinically relevant findings which provide guidance on timing of voiding trials following prolapse repair. First, a concomitant hysterectomy demonstrated a 2.86-fold increased risk of delayed return of bladder function >4 days compared to patients with a vaginal vault suspension.

We recommend repeating a void trial after 1 week in these patients given 80% of our cohort met criteria for return of bladder function by day 7. Second, surgical duration >120 minutes resulted in a 9.96-fold increased risk of delayed return of bladder function >4 days even when controlling for all other evaluated risk factors. We recommend considering surgical length along with other risk factors identified such as DM (5.65-fold), sacrospinous fixation (2.59-fold), and estimated blood loss (1.1-fold) when scheduling office visits. Third, in patients with an uncomplicated vaginal vault suspension and no other identified risk factors, we recommend voiding trial on postoperative day 5 as 80% of our cohort had return of bladder function by this time.

Limitations of the study are in the homogeneity of the cohort which could limit generalizability and in the retrospective design.

CONCLUDING MESSAGE

Concomitant hysterectomy, operative duration > 2 hours and diabetes were all significantly associated with delayed return of bladder function after pelvic organ prolapse repair. Based on this data, an individualized approach to post-operative voiding trials can be implemented: we recommend removal of Foley catheter on postoperative day 5 after a vaginal vault suspension and day 7 after a hysterectomy with suspension and/or after a case with operative duration>120 minutes. We believe our data allows surgeons to minimize postoperative clinic visits by stratifying patients based on risks for prolonged voiding dysfunction.

FIGURE 1

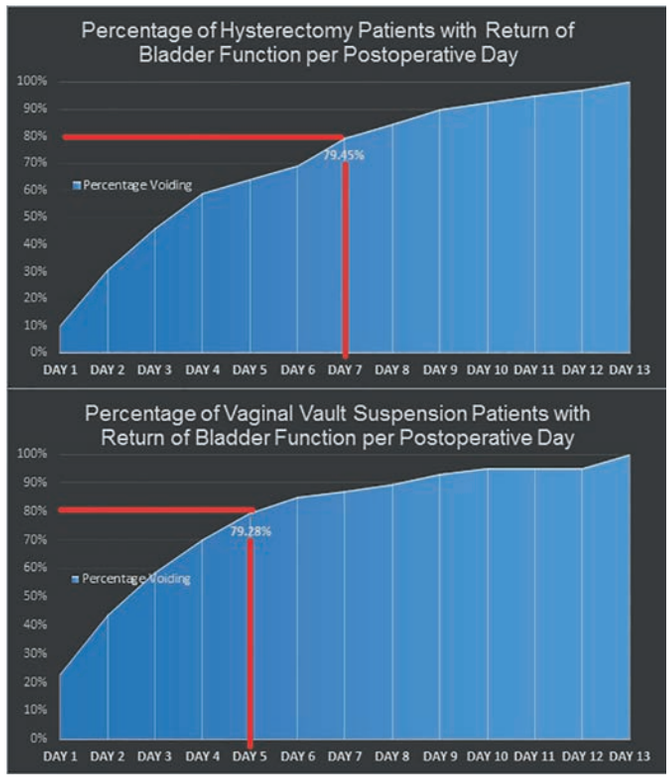

Figure 1

FIGURE 2

Univariate	OR	95% CI	P-Value
Smoking Hx	1.55	0.65 - 3.72	0.32
DM Hx	4	0.87 - 18.5	0.08
Stroke Hx	1.35	0.22 - 8.41	0.75
Post-Menopausal	5.54	1.027 - 29.88	0.04
Preop PVR	1	0.99 - 1.0	0.83
Ant/Apical Site	3.73	0.44 - 31.34	0.23
Stage 3/4 POP	1.56	0.63 - 3.89	0.34
LOS	1.04	0.91 - 1.19	0.58
Hysterectomy	2.86	1.30 - 6.29	0.009
Anterior Repair	2.11	0.49 - 8.87	0.311
EBL	1.1	1.01 - 1.20	0.03
Surgery > 120	11.07	1.43 - 18.45	0.02
Anesthesia > 180	3.13	1.29 - 7.6	0.01
UTI	1.85	0.62 - 5.51	0.27
Age	0.99	0.97 - 1.02	0.63
Race	1.45	0.59 - 3.56	0.41
BMI	0.97	0.89 - 1.05	0.44
SSLF	2.59	1.07 - 6.26	0.04
USLS	1.97	0.79 - 4.89	0.144
Mesh 1	1.08	0.49 - 2.37	0.85
Mesh 2	0.83	.311 - 2.19	0.7
Mesh 3	0.16	0.02 - 1.59	0.12
TOT Sling	1.69	0.75 - 3.8	0.2
TVT Sling	1.68	0.57 - 4.96	0.35
Multivariate	**OR**	**95% CI**	**P-Value**
DM	5.65	1.12 - 28.5	0.04
Post-Menopausal	3.69	0.42 - 32.56	0.24
Hysterectomy	1.52	0.59 - 3.89	0.38
EBL	1.03	0.99 - 1.01	0.5
Surgery Length	9.96	1.27 - 17.87	0.03
Anesthesia Time	0.51	0.20 - 1.30	0.51
SSLF	1.48	.44 - 3.95	0.43

REFERENCES

1. Hakvoort, R.A., et al., Predicting short-term urinary retention after vaginal prolapse surgery. Neurourol Urodyn, 2009. 28(3): p. 225-8.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Wake Forest Baptist Health Institutional Review Board **Helsinki** Yes **Informed Consent** No

513 www.ics.org/2020/abstract/513

ANTERIOR VAGINAL WALL PROLAPS AND STRESS URINARY INCONTINENCE: EVALUATION OF CONCOMITANT SURGERIES.

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HYPOTHESIS / AIMS OF STUDY

The surgical treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI) at the same or deferral time is still debated. Aim of this study was to evaluate the outcomes and complications of women underwent concomitant surgery for POP and SUI.

STUDY DESIGN, MATERIALS AND METHODS

This prospective study assessed women with concomitant anterior vaginal wall defect and SUI (Group 1), patients with only anterior vaginal wall defect (Group 2), and subjects with only SUI (Group 3). All women were naïve for vaginal surgery, all the patients with POP were symptomatic. Surgical procedures were: anterior vaginal wall repair (AVWR) by native tissue technique, middle urethral sling (MUS) placement. In Group 1 both the surgical treatments were performed. Allocation of women in Group 1 was based on share decision during counselling. Exclusion criteria were: previous POP/SUI surgery, previous pelvic surgery and/or radiotherapy, neurological diseases. All patients underwent preoperative physical examination, with Pelvic Organ Prolapse Quantification system (POP-Q) and stress test, urodynamics (UDS). POP objective success was defined by POP-Q stage < 2, while objective SUI success by negative stress test. Complications were ranked by Clavien-Dindo scale. Follow-up was scheduled by outpatient clinical evaluation at 1-3-6-12 months, and then yearly, with physical examination, urinalysis, abdominal ultrasound (AUS) with post-void residual (PVR) urine. Data were analysed with a 2-years follow-up.

RESULTS

Patients were recruited from January 2014 to January 2018, 197 completed 2-years follow-up and were eligible for the study. Group 1 was comprised by 42 women (21.3%) with mean age of 66.4 yrs, group 2 by 76 (38.6%) with mean age of 68.2 yrs, and group 3 by 79 (40.1%) with mean age of 64.3 yrs.

Patients characteristics are reported in table 1. In table 2 are listed mean operative time and blood loss, outcomes and complications. As expected, mean operative time was higher in concomitant surgical procedures (83 minutes), and mean hospital stay was longer in group 1 and 2 than group 3. No significant difference was found in terms of blood loss, two patients who needed blood transfusions were in group 2. POP and SUI outcomes were similar between group 1 and the control groups. The rate of de novo urgency was higher in group 1 but did not reach significant difference with the

control groups. Groin pain was comparable in group 1 and 3 (MUS placement). Re-operation rate was low in all groups. Outcomes are reported in table 2.

INTERPRETATION OF RESULTS

Women underwent concomitant POP and SUI surgical correction had success rate not inferior than control groups without higher complications rate. Thus, concomitant treatment of POP and SUI was effective and safe as the single procedures. This study showed that the association of these two surgical treatments did not mean an increase of the complications. Due to the longer operating time, also blood loos were higher when both the surgical techniques were associated. Anyway, this finding did not negatively impact on the post-operative course and on the outcomes. Furthermore, the only blood transfusions were performed in women underwent a single surgical procedure (group 2). Thus, the management of POP and SUI with a single surgical step was suitable in patients who preferred complete resolution of these conditions. Counselling was a crucial step in these women.

CONCLUDING MESSAGE

Concomitant surgical treatment of anterior vaginal wall defect and stress urinary incontinence was effective and safe. Counseling was crucial to share decision on the management of concurrent POP and SUI.

FIGURE 1

Table 1. Patients characteristics.

	Group 1 AVWR + MUS	Group 2 AVWR	Group 3 MUS
Number of patients	42	76	79
POP-Q stage 2	17 (40.5%)	35 (46%)	-
POP-Q stage 3	23 (54.8%)	37 (48.7%)	-
POP-Q stage 4	2 (4.7%)	4 (5.3%)	-
Mean VLPP (range)	58.8 (5-110) cmH_2O	-	64.6 (12-114) cmH_2O
Mean pad/day (range)	1.9 (0-4)		2.7 (2-5)
Occult SUI	7 (16.7%)	-	0

AVWR, *Anterior vaginal wall repair*; *MUS*, middle urethral sling

Table 2. Operative results, outcomes, and complications.

	Group 1 AVWR + MUS	Group 2 AVWR	Group 3 MUS	P
# of patients	42	76	79	
POP objective success rate	40 (95.2%)	69 (90.7%)	-	0.38*
IUS objective success rate	41 (97.6%)		75 (94.9%)	0.48*
Mean operative time	83 min	64 min	18 min	-
Mean blood loss	88.8 ml (± 30.2)	51.2 ml (± 47.7)	40.7 ml (± 39.6)	0.6**
Intraoperative complications	1	2 (2.6%)	2 (2.5%)	0.99*
Postoperative complications	1 (2.4%)	3 (3.9%)	2 (2.5%)	0.84*
Groin pain	2 (4.8%)	-	5 (6.3%)	0.73*
Blood transfusion	0	2	0	
Hospital stay	2.3 days (± 0.7)	2.9 days (± 1.7)	1.1 days (± 0.9)	0.41**
Preoperative OAB	30/42 (71.4%)	32/76 (42.1%)	21/79 (26.5%)	-
De-novo OAB	1/12 (8.3%)	3/44 (6.8%)	4/58 (6.9%)	0.49*
Re-operation rate	1 (2.4%)	3 (3.9%)	2 (2.5%)	0.84*

AVWR, *Anterior vaginal wall repair*; *MUS*, middle urethral sling; ** ANOVA Test; * Chi-square Test

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Department commettee **Helsinki** Yes **Informed Consent** Yes

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EXPERIENCE OF COMPLICATIONS REQUIRING SURGICAL CORRECTIONS AMONG 982 CASES OF MID-URETHRAL SLING SURGERIES

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HYPOTHESIS / AIMS OF STUDY

Although mid-urethral sling surgery in female patients with stress urinary incontinence (SUI) is proved as a simple and safe procedure with high treatment success rate, its complication rate is increasing with the growing number of the surgical cases. The present study aims to investigate and assess the complications occurred from 982 cases of mid-urethral sling surgeries that require surgical correction or intervention.

STUDY DESIGN, MATERIALS AND METHODS

Among 1,029 patients who underwent mid-urethral sling surgery (792 tension-free vaginal tape (TVT) cases and 237 transobturator tape (TOT) cases) in our department from 2002 to 2016, 982 patients who were able to be tracked by medical records were included in the study. The medical records of the 982 patients were reviewed to investigate the complications occurred from mid-urethral sling surgeries that required surgical correction or intervention. As well, the treatment options selected for each complication cases were assessed.

RESULTS

The investigated complications which required surgical correction or intervention after mid-urethral sling surgery were as follows: 1 vessel injury (0.10%), 1 peri-obturator foramen abscess (0.10%), 3 vaginal erosions (0.31%), and 12 lower urinary tract symptoms (1.22%). In the case of vessel injury, the surrounding vessel of obturator artery was injured by the trocar insertion during TVT. The vessel injury was detected directly after the sling insertion and was managed by angioembolization. The peri-obturator foramen abscess occurred at 5 months after TOT, and it was managed by antibiotics along with aspiration of abscess via anterior vaginal wall without mesh removal. All vaginal erosion cases were treated by removing the exposed mesh along with repairing the incision of the anterior vaginal wall which was made for mesh removal. The 9 cases of voiding difficulty (0.92%) and the 3 cases with de novo storage symptoms which were drug-refractory (0.31%) were also treated by mesh removal. According to the medical records, there were no nerve injuries nor organ injuries.

INTERPRETATION OF RESULTS

According to our results, only 1.73% of the patients who underwent midurethral sling surgery experienced postoperative complication which required surgical correction. Among the complications, voiding difficulty which was managed by mesh removal was most commonly occurred (0.92%). All the complications were able to be managed by simple procedures and no severe complications were reported in almost a thousand TVT or TOT cases. Such results imply that midurethral sling surgery is a safe procedure to treat females with SUI.

CONCLUDING MESSAGE

The complications following the mid-urethral sling surgeries such as vessel injury, peri-obturator foramen abscess, vaginal erosion, and voiding difficulty could effectively be managed by intervention or mesh removal. The surgeons should always be aware of the possibility of severe complications and be prepared for valid management method for each complication.

FIGURE 1

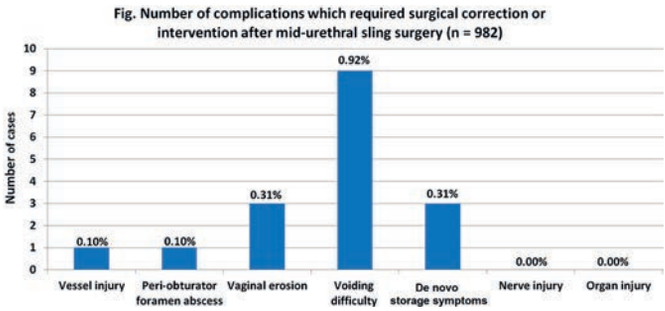

Fig. Number of complications which required surgical correction or intervention after mid-urethral sling surgery (n = 982)

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** International review board of Pusan National University Hospital **Helsinki** Yes **Informed Consent** Yes

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EFFICACY OF POLYACRYLAMIDE HYDROGEL (BULKAMID®) FOR THE MANAGEMENT OF URINARY STRESS INCONTINENCE IN WOMEN

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HYPOTHESIS / AIMS OF STUDY

Urinary stress incontinence (USI) is a common condition affecting one third of the female population [1]. There are different conservative and surgical approaches to manage such symptoms. In the recent years different surgical methods have been introduced, aiming successful results with less surgical complications.

A polyacrylamide hydrogel (Bulkamid®) injection in the urethra is a novel technique that is used for the treatment of USI. It has proven to be a safe method, but with limited research studies examining its efficacy [2].

The aim of our study was to examine how effective and safe are the polyacrylamide hydrogel (Bulkamid®) injections in controlling the symptoms of USI.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective study, conducted in a busy Trust, examining all the patients who underwent urethral injection with polyacrylamide hydrogel (Bulkamid®). 108 patients had the surgery since its introduction to our Trust in September 2016 and in the following three years.

The data were obtained from the surgical notes and BSUG (British society of urogynaecology) database.

RESULTS

108 patients underwent polyacrylamide hydrogel (Bulkamid®) urethral injection in the two main hospitals of our trusts over the period of three years. 54 procedures were performed by gynaecologists and 54 by urologists.

90 patients were having primary procedure. 18 (16%) patients were having a repeat procedure but only 10 (9%) of them had previously Bulkamid injection. 102 (94.4%) procedures were performed by consultants.

The average BMI was 31; with the exception of one patient whose BMI was 57, the rest of the patients ranged between 22.7 and 43.

The average age was 56 years (31 – 84).

Complications: There have been no intra-operative complications (0%). 5 patients experienced post-operative complications (4.6%), 3 in the form of urgency, one retention and one developed urinary tract infection. All five patients were operated by consultants.

Success of the procedure included both complete cure or improvement of symptoms and it was 78% with similar rates in both gynaecologists and urologists.

INTERPRETATION OF RESULTS

Our success rates were similar to the rates suggested in other studies (67% and 88%) while our complication rates were notably lower than the rates suggested in literature. Neither age nor BMI had an impact on the success of the procedure or incidence of complications.

In the recent years following the "mesh pause" more invasive procedures emerged again. Surgeries like colposuspension and fascial slings which had become less popular among surgeons and patients became the first options of surgical treatment of USI. In view of the invasiveness of these surgeries and the potential complications, alternative approaches became prevalent.

Nevertheless, NICE recommends that urethral bulking agents are to be offered only "if alternative surgical procedures are not suitable for or acceptable" and following a detailed counselling regarding the limited evidence about the procedure, the steps of the surgery and that repeated injections may be necessary [3].

Admittedly, previous long-term studies suggested disappointing results with collagen urethral injection . This has not been the case with polyacrylamide hydrogel (Bulkamid®) where emerging studies suggest it is a promising and safe procedure.

CONCLUDING MESSAGE

Polyacrylamide hydrogel (Bulkamid®) urethral injection is a successful alternative surgical procedure for USI. It manages to control the USI symptoms in patients of various ages and BMIs and the technique is easy to learn. Moreover, it is associated with patient satisfaction. On the downside, it is a procedure that might need repeating.

Still, given the easiness of the surgery, the success rates, the patients' approval and the ability to perform it as an outpatient procedure, polyacrylamide hydrogel (Bulkamid®) proves to be an effective alternative surgery for USI.

REFERENCES

1. Bachkangi, P., & Salman, M. (2019). Complications of Mid-Urethral Tape Insertion. Journal Of Clinical Gynecology And Obstetrics, 8(2), 44-47.
2. Kasi, A.D., Pergialiotis, V., Perrea, D.N. et al. Polyacrylamide hydrogel (Bulkamid®) for stress urinary incontinence in women: a systematic review of the literature. Int Urogynecol J 27, 367–375 (2016). https://doi.org/10.1007/s00192-015-2781-y
3. National Institute for Health and Care Excellence. Urinary incontinence and pelvic organ prolapse in women: management [Internet]. [London]: NICE; April 2019 [updated June 2019] (Clinical guideline [CG123]). Available from: https://www.nice.org.uk/guidance/ng123

Funding No funding or grants were obtained for this study. **Clinical Trial** No **Subjects** Human **Ethics not Req'd** The study was based on a retrospective audit from which the data were obtained. The audit and subsequent analyses got R&D clearance. **Helsinki** Yes **Informed Consent** Yes

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THE USE OF THE TRANSOBTURATOR ADJUSTABLE SLING FOR THE TREATMENT STRESS URINARY INCONTINENCE IN MORBIDLY OBESE FEMALE PATIENTS

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1. Akfa Medline

HYPOTHESIS / AIMS OF STUDY

Stress urinary incontinence (SUI) is the non controlled loss of urine during coughing or physical activity, mostly due to a weak pelvic floor or urethral sphincter and having a significant impact on the patient's quality of life. Sling surgery is the gold standart in the surgical treatment of SUI. Unfortunately, despite the with higher results of this surgeries, about 20% of patients are incontinent postoperatively and this situation is common in obese patients. In this study we are evaluated the results of surgical treatment of SUI in morbidly obese (BMI >40) patients with transobturator adjustable slings Urosling (Lintex).

STUDY DESIGN, MATERIALS AND METHODS

To our study we are included 70 morbidly obese female who underwent transobturator adjustable sling surgery between 2015 and 2019. Perioperatively all patients were evaluated by Stamey degree of incontinence, cough test, pad use, q-tip test, ICIQ-SF questionnaire, uroflowmetry and residual urine check. All surgeries performed by single, experienced surgeon. All cases performed under spinal anesthesia, by performing cough test with 300cc bladder filling after gentle tightening of the sling. Special attention is paid to the prevention of overcorrection

The control readjustment was performed under local anesthesia the next day after surgery if it required.

RESULTS

Mean age of patients was 67.3±9.1 years. 32 (45,7%) had prior pelvic floor surgery, 47 (67,1%) patients presented with grade 3 stress urinary incontinence, other 23 (32,8%) presented with grade 2 stress urinary incontinence according the Stamey classification. The preoperative pad use was 5,7 dail. The mean operative time was 21.3±11.4 min. No intraoperative complications like bleeding, bladder injury. 31 (44/2%) patient was continent, readjustment of sling performed next day after surgery for 39 (55,7%) patients, who had signs of urinary incontinence during cough test. All patients were continent after readjustment with no residual urine. 6 (0.08%) patient felt pain after surgery which controlled by painkillers. Hospital stay period was 2 days for all patients. Mean follow up was 12 months, overall success rate was in 66 (95%) patients, 2 (2.85%) had 1 pad during 24 hour, 1(1,4%) no feedback.

INTERPRETATION OF RESULTS
Our series demonstrates that the use of the adjustable transobturator sling is particularly beneficial for obese patients. In morbidly obese patients a considerable success rate is achievable with transobturator adjustable sling surgery. The procedure can be regarded as safe as no complications were observed in this group of patients in part with multiple risk factors

CONCLUDING MESSAGE
The individual adjustability of the sling in order to achieve an adequate degree of tension to the urethra is the key factor in restoring continence in this selected cohort of morbidly overweight patients

REFERENCES
1. Noblett KL, Jensen JK, Ostergard DR. The relationship of body mass index to intra-abdominal pressure as measured by multichannel cystometry. Int Urogynecol J Pelvic Floor Dysfunct. 1997;8:323–326.
2. Shkarupa D.D., Kubin N.D., Staroseltseva O.Y., Zaytseva A.O., Pisarev A.V., Shapovalova E.A. ADJUSTABLE TRANSOBTURATOR SLING FOR TREATING PATIENTS WITH COMPLICATED STRESS URINARY INCONTINENCE. Urology Herald. 2017;5(4):58-68.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** None

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HOW DO TAPES WORK?

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HYPOTHESIS / AIMS OF STUDY
Cure of urodynamically-proven stress incontinence (USI) by a Mid-urethral sling (MUS - tape) has been well recorded though the mechanism by which this occurs has not been clarified.We hypothesize that the intra-operative cure of stress incontinence by an MUS is achieved by bladder neck closure. To demonstrate this, we aim to correlate the perioperative reduction in the sign of stress incontinence with cystoscopic observations of increasing bladder neck closure. We aim to prove, for the first time, that the mechanism of achieving continence with an MUS is an appropriate degree of bladder neck closure.

STUDY DESIGN, MATERIALS AND METHODS
Forty consecutive women with USI were consented for: (i) MUS (Advantage Fit©- Boston Scientific) and pre/post-operative assessment of (ii) the sign of clinical stress leakage; (iii) bladder neck closure (by cystoscopy). Seven (18%) had undergone prior continence surgery. Thirty-one (78%) underwent concurrent pelvic organ prolapse (POP) surgery. Institutional ethical approval and patient consent had been obtained.

All assessments for SI were performed with patients under spinal block, in lithotomy position and asked to produce a maximum cough. The bladder had been emptied by short plastic catheter and was refilled to exactly 300mls prior to cough-testing. Cystoscopic assessment for bladder neck closure was at rest (no cough), with the cystoscope withdrawn 5mm (approx.) from a position where the full circumference of the bladder neck had been visualized. A minimum two observers (generally three) determined the following observations.

Stress incontinence grading (SIG): was scored: 0: cough, no SI; 1: cough, few drops SI; 2: cough, small SI leak; 3: cough, moderate SI leak; 4: cough, large SI leak; 5: no cough, large leak.

Bladder neck Closure (BNC): was scored: 1: 0-25%; 2: 25-50%; 3: 50-75%; 4: 75-100% closure. This represents the degree of reduction of the bladder neck aperture (full circumference having been visualized) by 5mm (approx.) cystoscopic withdrawal (see Figure 1).

RESULTS
Mean preoperative SIG was 3.6 (range 2-5); mean postoperative SIG was 0.5 (Range: 0-3) This indicates a mean reduction of SI from a moderate/ large leak with coughing to a few drops (max) with coughing. This correlated with clinical cure of SI at follow-up.

Mean preoperative BNC was 1.9 (Range 1-3); mean postoperative BNC was 3.9 (Range: 3-4). This indicates a mean improvement in bladder neck closure from 25-50% preoperatively to 75-100% postoperatively.

At the 6 week postop visit (26/40 so far), all patients were SI dry (2 patents required urodynamics for confirmation) with a mean postvoid residual of 5mL (Range 0-72mL). Two patients had a degree of urgency without urge incontinence.

INTERPRETATION OF RESULTS
The intraoperative cure of stress incontinence by MUS as judged by the reduction of the sign of SI is associated with increasing bladder neck closure (to over 75% BNC post-insertion). This is the first time that this finding has been clinically proven. The use of SIG and BNC offers two new methodologies to optimise the insertion of MUSs, particularly in combined SI-POP cases. Other continence procedures such as bladder neck elevatory procedures (e.g. colposuspension) and periurethral injectables have appeared to work by bladder neck closure, without similar confirmatory studies.

CONCLUDING MESSAGE

The intra-operative cure of stress incontinence by a MUS is achieved by bladder neck closure (generally more than 75% BNC post tape insertion). The use of the outlined SIG and BNC methodologies can optimise MUS insertion.

FIGURE 1

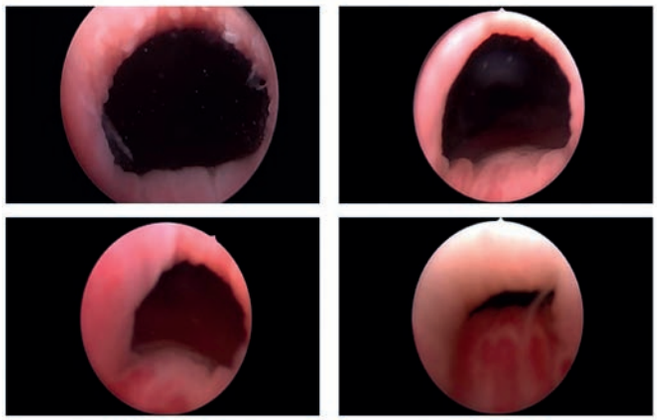
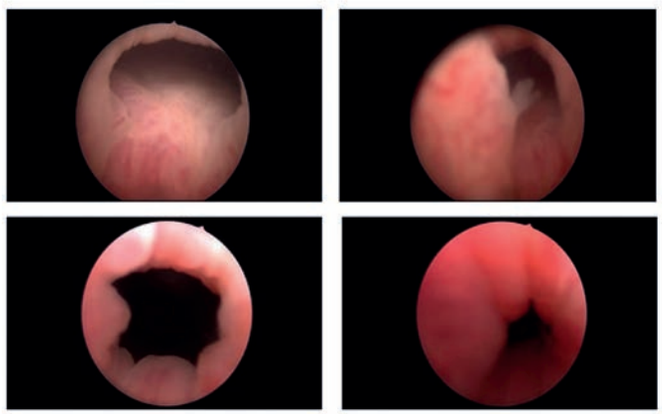


Figure 1: Bladder Neck closure 0%-25% (top left); 25%-50% (top-right); 50%-75% (bottom left); 75%-100% (bottom right)

FIGURE 2



Figures 2 A and B (top); Bladder neck closure 25-50% pre-MUS (SIG 4); 75%-100% post-MUS (SIG 0). Figures 2C and D (Bottom): Bladder neck closure 50%-75% pre-MUS (SIG 3); 75%-100% post-MUS (SIG 0).

Funding Nil **Clinical Trial** Yes **Registration Number** St Vincents Heath 2019/ETH 13412 **RCT** No **Subjects** Human **Ethics Committee** St Vincents Health, Sydney. Australia **Helsinki** Yes **Informed Consent** Yes

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NEW TECHNIQUE OF ROBOT-ASSISTED IMPLANTATION OF ARTIFICIAL URINARY SPHINCTER BY POSTERIOR APPROACH AND INTRAOPERATIVE CYSTOSCOPIC MONITORING: EARLY EXPERIENCE

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HYPOTHESIS / AIMS OF STUDY

Artificial urinary sphincter (AUS) implantation is the gold-standard surgical treatment for stress urinary incontinence (SUI) caused by intrinsic sphincter deficiency (ISD) in women. Robot-assisted AUS implantation has been recently described and several techniques have been reported with anterior or posterior approach of the bladder neck(1,2). This technique still remains challenging in particular regarding bladder-neck dissection. The objective of this study is to report the early experience of a modified technique of robot-assisted AUS implantation in women with a posterior approach to the bladder neck and intraoperative real-time cystoscopic control.

STUDY DESIGN, MATERIALS AND METHODS

We reviewed the records of patients who underwent a first robot-assisted AUS implantation between 2017 and 2019. All of the operations were performed with the Da Vinci Xi®, by transperitoneal approach and by posterior dissection of the bladder neck, in order to avoid the "blind" anterior dissection. Dissection begins between the bladder and the vagina, using a vaginal valve to expose the anterior vaginal fornix. When the dissection was low enough, a lateral dissection was initiated. The next step was to open the umbilical-retropubic space anteriorly and carry out the dissection until the right and left endopelvic fascia. Only a thin plane remained between the anterior and posterior dissection. Using the Maryland or the Cadiere forceps, a passage was made from back to front to the left and then to the right in order to exactly position the cuff sizer around the bladder neck. Real-time intraoperative cystoscopic monitoring was systematically carried out to check the correct level of dissection (sub-trigonal, at the bladder neck) and to avoid any injury to the bladder neck when moving from back to front. This endoscopy was performed with a 70° cystoscope, and monitoring was made possible by the simultaneous display of the endoscopy and laparoscopy in the surgeon console.

Perioperative and intraoperative data, functional outcomes and complications were reported. Continence was defined as 0 to 1 “confident” pad per day. Functional outcomes were also assessed with the USP-questionnaire, the PGI-I score and the satisfaction rate.

RESULTS

During the period of this study, 25 patients were included. The median age was 67 years (IQR:61-74). 24 patients (96%) had a history of pelvic surgery (80% SUI surgery, 56% prolapse surgery). The median preoperative maximum urethral closure pressure was 26cmH2O (19-37).

The median operative time was 263min (221-349). 2 conversions (8%) to open surgery were required: 1 for adhesion and significant pelvic fibrosis and 1 for poor respiratory tolerance of pneumoperitoneum. 9 intraoperative complications were reported: 5 vaginal injuries (20%), 2 bladder neck injuries (8%) (including one leading to non-implantation of AUS) and 2 urethral injuries (8%). A cystotomy was performed in 5 cases (20%), in order to better visualize the bladder neck and ureteral meatus. The median size of the implanted cuff was 7.5cm (7.5-8). The median hospital stay was 3 days (2-7).

With a median follow-up period of 15 months (13-26), 21 patients (84%) had their initial AUS in place, 3 AUS (12%) were removed for infection and/or erosion (at 1 month, 3 months and 12 months), and 1(4%) was revised due to persistent SUI (implantation of a smaller cuff).

Among the patients with an AUS in place (n=21), 15 patients (80%) were continent. The median satisfaction rate was 90% (80-100). The median USP score for SUI was 0 (0-1.5) for SUI, 5 (1.-7.7) for overactive bladder and 1 (0-3) for voiding symptoms. A PGI-I score of 1 was reported in 80% of patients.

INTERPRETATION OF RESULTS

Whatever the surgical approach (open or robotic), the circumferential dissection of the bladder neck still remains challenging, and if damage is done to it early erosion may result. The posterior approach, recently described(2), provides a safe dissection, without any "blind" passage at the posterior side of the bladder neck, and frees the surgeon from having to rely on the digital vaginal control of an experienced assistant. However, with this posterior approach, it may sometimes be difficult to locate the lower point of the dissection, but can be helped with intraoperative cystoscopic monitoring.

Thanks to this technique, we observed a low rate of bladder-neck injury, only one of which obliged us to stop the procedure, and no ureteral injury occurred.

However, 3 explantations related to erosion occurred.

This study has several limitations: its retrospective design and the short follow up period.

CONCLUDING MESSAGE

We have reported here on our early experience with robot-assisted AUS implantation in women with the posterior approach to the bladder neck and with real-time cystoscopic monitoring. This procedure appears feasible, reproducible and ensures proper cuff positioning and with a lower risk of bladder or cervical injury. Medium-term functional results appear satisfactory. Further studies with long-term results seem necessary to evaluate the benefits of this compared to robot-assisted implantation with anterior bladder neck approach or open surgery.

FIGURE 1

Table 1: Perioperative outcomes

	N=25
Median operative time (min) (IQR)	263 (241-349)
Conversion to open surgery	2 (8%)
Intraoperative complications	9 (36%)
Bladder neck injury	2
Urethral injury	2
Vaginal injury	5
Implantation failure	1 (4%)
Cystotomy	5 (20%)
Median cuff size (IQR)	7.5 (7.5-8)
Median hospital length of stay (d) (IQR)	3 (2-7)
Postoperative complications	9 (36%)
Clavien I	1
Clavien II	4
Clavien IIIa-b	4

Table1: Perioperative outcomes

FIGURE 2

Table 2: Post-operative functional outcomes

Total implanted AUS	N=24
Median fallow-up (months) (IQR)	15 (13-26)
Explantation	3 (12%)
Revision	1 (4%)
Pad number	N=20
0 or « confident pad »	16 (80%)
≥1	4 (20%)
USP questionnaire	N=15
Median SUI score (IQR)	0 (0-1.5)
Median OAB score (IQR)	5 (1.7-7.7)
Median voiding symptoms score (IQR)	1 (0-3)
Median satisfaction rate (%) (IQR)	90 (80-100)
PGI-I score	N=17
1-3	14 (82%)
>3	3 (18%)

Abbreviations: AUS, artificial urinary sphincter; USP, urinary symptom profile; SUI, stress urinary incontinence; OAB, overactive bladder; PGI-I, patient global impression of improvement

Table 2: Functional outcomes

REFERENCES

1. Peyronnet B, Capon G, Belas O et al. Robot-assisted AMS-800 artificial urinary sphincter bladder neck implantation in female patients with stress urinary incontinence. Eur Urol 2019;75:169-175
2. Gontran-Tellier B, Boissier R, Baboudjian M. Robot-assisted implantation of an artificial urinary sphincter, the AMS-800, via a posterior approach to the bladder neck in women with intrinsic sphincter deficiency. BJU Int 2019;124(6):1077-1080

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** According to French legislation, retrospective studies are not subject to IRB approval **Helsinki** Yes **Informed Consent** Yes

SESSION 35 (PODIUM SHORT ORAL) - ASSESSMENT AND PATHOPHYSIOLOGY
Abstracts 519-530
11:30 - 13:00, Brasilia 1
Chairs: Dr Chantale L Dumoulin (Canada), Dr Elizabeth R Shelly (United States)

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EXAMINATION OF PELVIC FLOOR MUSCLES HARDNESS IN PATIENTS WITH INTERSTITIAL CYSTITIS USING ULTRASOUND REAL-TIME TISSUE ELASTOGRAPHY

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HYPOTHESIS / AIMS OF STUDY

A previous study demonstrated that in patients with pain in the pelvic floor muscle (PFM), manual stretching of PFM significantly improved pain and symptoms1). The evaluation of PFM property is generally palpation of the vagina. However, this is a subjective assessment. Therefore, to evaluate the PFM property objectively, appropriate modality should be needed. Recently, several studies have investigated the hardness of PFM using ultrasound elastography in healthy subjects2). In the skeletal muscles of the extremities, hardness has been found to increase in the presence of pain. IC/bladder pain syndrome is characterized by refractory discomfort referable to the lower urinary tract and associated with urinary urgency, frequency, and pain. However, the relation between PFM hardness in patients with interstitial cystitis (IC) and PFM pain is unknown. From the above, it is expected that in patients with IC, PFM hardness may higher than in healthy adults. The aim of this study is to investigate the differences in muscle hardness of PFM between healthy female adults and patients with IC.

STUDY DESIGN, MATERIALS AND METHODS

The subjects were 18 women patients with IC (IC group; median: age 74.0 years, BMI 21.4 kg/m2) and 17 healthy women (control group; median: age 26.0 years, BMI 19.6 kg/m2). The measurements were performed in the supine position with the knees flexed. At rest and during PFM contraction, the hardness of the striated urethral sphincter was assessed using real-time tissue elastography (RTE) (ARIETTA 70, HITACHI Aloka Medical, Japan) with a linear transducer (frequency range: 7-3 MHz) placed on the perineum in the mid-sagittal plane (Figure 1a). The transducer was oriented perpendicular to the perineal skin surface and was pressed by free-hand manipulation with constant repeated pressure. The measurements were performed three times. The target region of interest (ROI) (ROI A) was set at 10 mm ventral to the mid-urethra, and 15 mm cranially from the pubic bone (striated urethral sphincter). The reference ROI (ROI B) was set at 5 to 10 mm caudal adipose tissue from ROI A (Figure 1b). The relative hardness of the striated urethral sphincter compared to that of the reference was indicated by a strain ratio, the ROI B divided by the ROI A (B/ A). Between-group (healthy women and patients with IC) comparisons of descriptive variables were made using Mann-Whitney U tests (age, at rest and PFM contraction strain ratio). The Wilcoxon test was used to compare strain ratio at rest and during PFM contraction within the groups. Spearman's rank correlation coefficient was used for the correlation between age and strain ratio (At rest and PFM contraction). Statistical significance was set at 5%.

RESULTS

• The striated urethral sphincter strain ratio at rest was significantly higher in IC group than in control group (p=0.038). The striated urethral sphincter strain ratio during PFM contraction was not significantly different between the two groups.

• The striated urethral sphincter strain ratio in control group was significantly higher during PFM contraction than at rest (p=0.003). The striated urethral sphincter strain ratio in IC group was not significantly changed between the resting and PFM contraction (Figure 2a)

• Age was significantly higher in the IC group than in the control group (p <0.001). There was no significant correlation between age and striated urethral sphincter strain ratio (at rest, during PFM contraction) (Figure 2b).

INTERPRETATION OF RESULTS

To our knowledge, this is the first study to investigate the differences in muscle hardness of PFM between healthy women and patients with IC. In this study, we have shown that striated urethral sphincter strain ratio at rest was significantly higher in IC group than in control group. The previous study has reported that increased muscle hardness is a factor in the pain of PFM in the IC3). Muscle hardness is generally found to be significantly higher in patients with low back or neck pain than in asymptomatic patients. Therefore, in patients with IC, pain in the bladder or urethra may lead to increased PFM tone, resulting in increased muscle hardness of the striated urethral sphincter.

The mechanism in which the hardness of PFM increases is considered as follows; Pain may increase muscle hardness by stimulating α-motor neurons and stimulating muscle contraction. Pressure on blood vessels due to hypertonia results

in decreased local blood flow and ischemia. These may cause a vicious circle that sustains muscle contraction.

In the current study, age was significantly higher in IC group compared to the control group. Although, there is no correlation between striated urethral sphincter hardness and age in both control and IC group. From this, we consider that age is unlikely to affect striated urethral sphincter hardness. However, further clinical studies will be necessary to examine the muscle hardness of the striated urethral sphincter in healthy elderly women.

CONCLUDING MESSAGE

We concluded that striated urethral sphincter hardness is significantly higher in patients with IC than in healthy women.

FIGURE 1

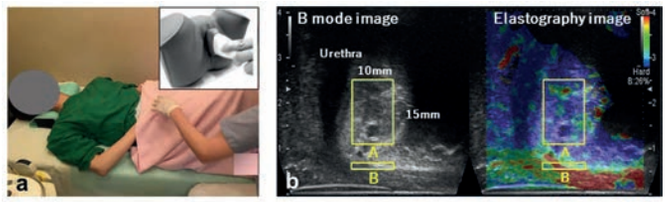

Fig 1. a: Measurement position; supine, flexion of both knees. Probe place; sagittal plane placed in the center of perineum. b: B mode image and elastography image. It is expected that striated urethral sphincter is within the area bounded by the line identified by "A" and that "B" contains adipose tissue.

figure1

FIGURE 2

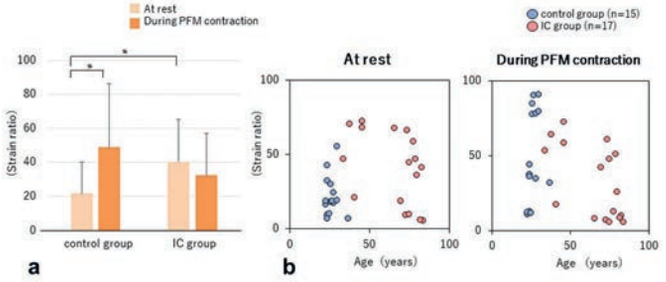

Fig 2. a: Comparison of striated urethral sphincter strain ratio B/ A in these two groups. Data shows the means ± their SD. *P < 0.05. b: Relationship between striated urethral sphincter strain ratio B/ A (at rest and during PFM contraction) and age. Spearmen rank correlation coefficient (n=32).
PFM: pelvic floor muscles, IC: interstitial cystitis.

figure2

REFERENCES

1. J Urol. 2001; 166(6): 2226–2231.
2. Neurourol Urodyn. 2018; 37(1): 206-212.
3. Scand J Urol Nephrol. 1973; 7(2): 150-152.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee Ethics Committee** of Hokkaido University Hospital **Helsinki** Yes **Informed Consent** Yes

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CORTICOMOTOR EXCITABILITY OF THE PELVIC FLOOR MOTOR REPRESENTATION IN WOMEN: FEASIBILITY AND RELIABILITY OF A NEW APPROACH TO RECORD MOTOR EVOKED POTENTIALS

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HYPOTHESIS / AIMS OF STUDY

Proper function of the pelvic floor muscles (PFMs) depends of the integrity and function of central and peripheral nerve pathways. There is a wide spectrum of dysfunctions related to the female PFMs, and, among those, certain conditions such as superficial and deep dyspareunia, urinary incontinence (UI) and dysfunctional voiding may be related to alterations within the cortical motor areas representing these muscles and/or their associated corticomotor pathways [1]. Transcranial magnetic stimulation (TMS) is a pain-free, non-invasive, approach to evaluate the excitability of corticospinal projections to the PFMs. A magnetic field generated by a stimulating coil results in current reaching the cortical neurons beneath the skull. The resulting neuronal depolarization ultimately depolarizes the motor cortical areas beneath the stimulating coil, generating evoked potentials (MEPs) in the muscles innervated by the depolarized region. TMS has been used successfully to demonstrate alterations in corticomotor excitability; studies mainly focus on the upper extremity, while some have focused on the lower limbs and trunk. However, the application of TMS to study corticomotor pathways to the PFMs remains challenging, as PFM MEP amplitudes and latencies have demonstrated poor reproducibility [2]. The aim of this study is to present a novel approach to assessing the corticomotor excitability of the PFM pathways, and to evaluate the reliability of MEP parameters using this approach.

STUDY DESIGN, MATERIALS AND METHODS

This is a feasibility and reliability study. The protocol was approved by local Research Ethics Board. Healthy females over 18 years of age were recruited from the local community. Exclusion criteria were pregnancy, menopause, diagnosed gynecologic conditions (e.g., pelvic organ prolapse, UI, vaginal infection) other than dyspareunia, tendency to faint, metal implants in head or neck and pacemaker. Participants attended two laboratory-based assessments, the first of which was within one week following the start of their menstrual cycle. In the first session, after providing informed consent, demographic data were collected and a standardized PFMs assessment was performed by a pelvic floor physiotherapist to evaluate muscle function and to instruct each participant on how to perform a correct PFM contraction. At each of the two assessments, participants were instrumented with ad-

hesive electromyography (EMG) electrodes (Delsys D.E.2.1) on the skin overlying the right tibialis anterior muscle, the abdominal muscles, and the hip adductor muscles; the latter two being beyond the scope of this report. Custom monopolar suction electrodes, similar to differential suction electrode [3], were placed intravaginally, with the active pole over the pubovisceralis (PV) muscle on the lateral sidewall and the reference pole placed anteriorly over the pubis, just within the introitus to avoid crosstalk from the urethral sphincters, Adhesive electrode pairs were placed unilaterally over the bulbocavernosus (BC) muscle and unilateralally over the external anal sphincter (EAS). A common reference electrode was placed on the skin overlying the right anterior superior iliac spine. The protocol consisted of applying single TMS pulses over the vertex using the Magstim® 200 system coupled with a double cone coil (96 mm loops, P/N 9902). Resting motor threshold (rMT) was determined using tibialis anterior as the target muscle. For the assessment, TMS pulses were delivered at 1.3 rMT while MEPs were recorded from all instrumented muscles. To assess MEP amplitude and latency characteristics, 12 TMS pulses were delivered while participants were instructed to remain relaxed. To assess the cortical silent period (sCP), 5 TMS pulses were delivered while participants were instructed to gently contract their PFMs. The outcome variables of interest were the peak to peak amplitude, latency, and cSP from MEPs recorded over the PV, BC and EAS.

RESULTS

Thirty-one women participated, with demographic data presented in Table 1. Twenty-four participants reported no history of vulvar pain, while 7 reported symptoms of vulvar pain including PVD and deep dyspareunia. The MEPs recorded from the PV, BC and EAS had distinct timing and shape characteristics (Figure 1) and were also distinct from the signals recorded from the hip adductors and the abdomen. Intra-class correlation coefficients (ICCs) showed that the TMS intensity used as well as cSP from all the muscles evaluated had excellent between-day reproducibility. The peak-to-peak amplitude of MEPs recorded from PV at rest and with PFM contraction, and those recorded from BC showed good reproducibility, whereas the other outcomes showed fair to poor reproducibility (Table 1).

INTERPRETATION OF RESULTS

These results suggest that the approach presented has adequate between-day reliability in terms of cSP to evaluate corticomotor excitability to the different female PFMs (PV, BC, EAS) and to measure changes in cSP that may indicate improvements or declines in corticomotor excitability as a result of time or intervention. Because intracortical and corticospinal excitability can modify motor output, the capacity to reliably assess the excitability of these projections may be important to our understanding of several conditions where altered corticomotor excitability is suspected to play an important role as well as a role in monitoring the effectiveness of interventions.

CONCLUDING MESSAGE

This novel approach for generating MEPs from the PFMs appears to be effective, generating distinct signals for the PV, BC and EAS all of which have adequate repeatability in cSP to assess changes in corticomotor excitability over time. This approach may help us to improve our understanding the pathophysiology of conditions such as dyspareunia, UI, anismus, and dysfunctional voiding, and to determine the effectiveness of interventions targeting central pathways.

FIGURE 1

Figure 1. Sample motor evoked potentials (MEPs) generated concurrently from the pubovisceralis, bulbocavernosus and external anal sphincter muscles. The peak seen at time=0 reflects the stimulus artifact while the signals occurring at approximately 20ms represent the MEPS. Note the distinct MEP latencies (arrows) and shapes suggesting that these signals are recorded from distinct muscles. The bottom trace shows a MEP acquired from the pubovisceral muscle during contraction, presented on a different scale from the others such that the cortically-mediated silent period (cSP) is evident.

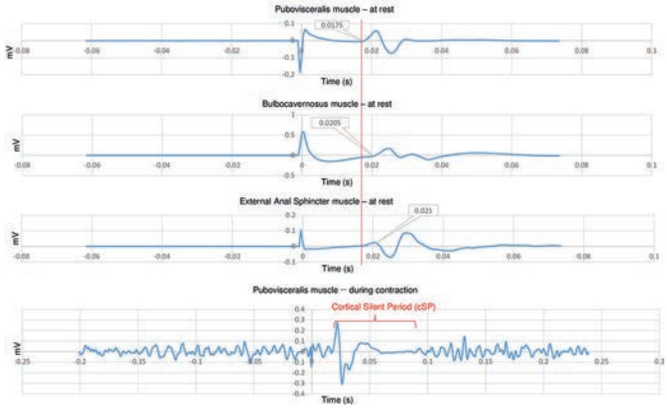

FIGURE 2

Table 1. Demographic data (n=31) and main outcome measures.

Descriptive data	Descriptive outcome
Age (years) – Mean ±SD	30.1 ±6.6
BMI (kg/cm²) – Mean ±SD	24.0 ±7.0
Parity – n (%) Nulliparous	27 (87.1)
Parity = 1	1 (3.2)
Parity = 2	2 (9.7)
PERFECT scheme score (/20) – Mean ±SD	17 ±4

n=31	Visit 1 Mean ±SD	Visit 2 Mean ±SD	ICC (95%CI)	$SEM_{95\%}$	$MDC_{95\%}$
TMS intensity (rMTX1.3)	73 ±14	77 ±13	0.86 (0.68 – 0.92)	6	17
Pubovisceralis					
MEP at rest					
Amplitude (µV)	204.2 ±217.9	220.0 ±184.2	0.66 (0.31 – 0.84)	147.6	409.1
Latency (ms)	19.1 ±3.1	18.0 ±1.9	0.55 (0.06 – 0.76)	2.3	6.3
MEP on contraction					
Amplitude (µV)	552.6 ±399.7	605.5 ±380.9	0.65 (0.28 – 0.83)	284.8	789.4
cSP (ms)	83.5 ±21.6	90.8 ±22.7	0.85 (0.62 – 0.92)	10.4	28.9
Bulbocavernosus					
MEP at rest					
Amplitude (µV)	281.1 ±259.5	590.5 ±765.3	0.37 (-0.30 – 0.67)	476.2	1319.9
Latency (ms)	21.4 ±3.1	20.8 ±5.3	0.56 (0.24 – 0.80)	3.2	8.8
MEP on contraction					
Amplitude (µV)	681.4 ±658.8	987.5 ±881.4	0.74 (0.39 – 0.86)	462.1	1280.9
cSP (ms)	96.0 ±45.4	90.5 ±34.1	0.84 (0.65 – 0.92)	20.5	56.9
EAS					
MEP at rest					
Amplitude (µV)	72.2 ±79.8	72.6 ±80.5	0.47 (-0.11 – 0.76)	71.3	197.8
Latency (ms)	22.8 ±5.6	22.2 ±4.8	0.29 (0.67 – 1.41)	5.5	15.2
MEP on contraction					
Amplitude (µV)	202.6 ±180.7	217.7 ±203.5	0.45 (-0.15 – 0.74)	171.3	474.8
cSP (ms)	123.5 ±41.0	118.7 ±37.8	0.79 (0.58 – 0.90)	22.4	62.1

Caption. SD: Standard Deviation; ICC: Intraclass Correlation Coefficient; CI: Confidence Interval; SEM: Standard Error of Measurement; MDC: Minimal Detectable Change, rMT: resting Motor Threshold; MEP: Motor Evoked Potential; cSP: cortical Silent Period; µV: microvolts; ms: milliseconds; EAS: External Anal Sphincter.

REFERENCES

1. Lefaucheur JP. Excitability of the motor cortical representation of the external anal sphincter. Experimental brain research 160, 268–272 (2005).
2. Brostrom S. Motor Evoked Potentials from the Pelvic floor. Neurourol Urodyn. 2003;22(7):620-37.
3. Keshwani, N., McLean, L., Development of a differential suction electrode for improved intravaginal recordings of pelvic floor muscle activity: reliability and motion artifact assessment. J Neurourol Urodyn 2012: 31(8): 1272-1278.

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IS THE INABILITY TO CONTRACT THE PELVIC FLOOR MUSCLES RELATED TO FEMALE URINARY INCONTINENCE?

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HYPOTHESIS / AIMS OF STUDY

The International Continence Society (ICS) defines a pelvic floor muscle (PFM) normal contractile function as the ability to constrict and do an inward movement of the pelvic openings (1). Studies have shown that more than 30% of women do not contract their PFM correctly at a first consultation, even after verbal instruction (2). Most of them contract other muscles like the gluteal, adductor or abdominal instead of the PFM, others stop breathing or try to exaggerate inspiration instead of doing a contraction and others push in a downward perineum movement. Pelvic floor muscle training (PFMT) has been recommended as the first line treatment for urinary incontinence (UI) due to the important role of the PFM in the continence mechanism (3). However, this therapeutic approach might not be a viable option for all women with UI considering that many of them may not able to contract the pelvic floor correctly at a first moment. On the other hand, even though women can perform an appropriate contraction, other important muscular aspects that could be involved in UI sometimes are ignored such as endurance, coordination, relaxation or the combination of these parameters. Therefore, the aim of this study is to know how many women with UI are unable to contract their PFM in a first assessment carried out at a Pelvic Floor Physiotherapy Outpatient Clinic of a teaching hospital and to analyze if this is related to worst UI symptoms and worst impact in quality of life. Considering all of has been published about the role of PFM in the continence mechanism, we hypothesized that the inability to contract the PFM would be associated with UI severity and worsening in quality of life.

STUDY DESIGN, MATERIALS AND METHODS

This is a cross-sectional study from medical records of women with UI who were referred to pelvic floor physical therapy after underwent a gynecological evaluation in a public teaching hospital between May 2013 to December 2019. Records included demographic data, PFMs strength through Modified Oxford Scale (MOS) and the final score of the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) from a baseline assessment. The MOS is a standardize method to assess PFM strength during a maximal voluntary contraction (MVC) by digital vaginal palpation. This scale ranges from 0 to 5: grade 0 is when there is no discernible muscle contraction; grade 1 is a flicker or pulsation felt under the examiner's finger; a grade 2 detects a contraction but without any discernible lift; in a grade 3 the muscle contraction is further enhanced and characterized by the elevation of the posterior vaginal wall; grade 4 is a good contraction with the capable of elevating the posterior vaginal wall against resistance by digital pressure applied to the posterior vaginal wall and in the grade 5 the examining finger is squeezed and drawn into the vagina against a strong resistance applied to the posterior vaginal wall. The ICIQ-SF is a validate questionnaire developed for assessing the prevalence, severity, impact on quality of life and type of UI. There are three scored questions and a visual analogue scale ranging from 0 to 10 on how much does leaking urine interfere in the patient everyday life. The overall score ranges from 0 to 21, with greater values indicating increased severity of UI symptoms. For this analysis, women were divided in two groups: those who were not able to voluntary perform a PFM contraction (grade 0 and 1 in the MOS) and those who were able to voluntary contract the PFM (grade ≥2 in the MOS). All statistical analyses were conducted using Statistical Package for the Social Sciences (SPSS) version 21 and group differences were tested using univariate t-tests. Incomplete data records were excluded from the analysis.

RESULTS

During the considered period, 617 medical records were found of women with UI who were referred by the gynecology team to a physiotherapeutic evaluation in a public teaching hospital. Of these, 111 were excluded due to incomplete data, leaving 506 records for the final analysis. The mean age was 57.38 (±11.29) years, 36.4% were not able to voluntary perform a correct MVC of the PFM (grade 0 and 1 in the MOS) after verbal command and proprioceptive digital stimulus and the most prevalent type of UI was the mixed UI in 64.6% of the cases. Characterization of the sample are presented in Table 1. As it is shown in Table 2, there is no significant difference between the variables analyzed when groups are compared, including the final score of the ICIQ-SF. This shows that regardless of whether they know how to contract the PFM or not, both groups had the same degree of UI symptoms classified as severe and the same impact in quality of life.

INTERPRETATION OF RESULTS

Women with the capacity of performing a PFM contraction appears to have the same severity of UI symptoms and impact in quality of life as women without this condition. This reinforces that other PFM aspects are important in the mechanism of continence like resistance, coordination and relaxation. Other systems also play an important role in this context, such as connective and support tissues and other aspects like hormone conditions, overweight and obesity, type of UI and daily life habits. Despite that, the fact that 36.4% of these women were not able to voluntarily contract the PFM corroborates with other studies (2) and draws our attention to the importance of evaluating the correct execution of this contraction before just orienting exercises for all women with UI. The absence of objective measures to evaluate the severity of UI, as the pad-test, is a limitation of this study. Although the ICIQ-SF is a validated questionnaire for the assessment of UI symptoms and their impact on quality of life, this tool considers only the patient's perspective regarding her clinical condition. This type of evaluation has become relevant in research and clinical practice, but the combination of objective measures would make the results more consistent. In addition, only women with UI were evaluated. It would be interesting to evaluate and compare the data also with a group of women without pelvic floor dysfunction.

CONCLUDING MESSAGE

Although the results of the present study showed that there is no association between the inability to contract the PFM and the severity of UI symptoms, it's interested that 36.4% of women were not capable to contract their PFM correctly. This finding makes us question whether it would be related to strength, lack of body perception, nervous or muscular injury or any other aspect. Other studies could be developed to better understand the incapacity of performing a PFM contraction in women with PFM dysfunction and in healthy women too.

FIGURE 1

Table 1 – Characterization of the sample

Variables		n=506		
Age (years) – Mean±SD		57.38±11.29		
BMI (kg/cm²) – Mean±SD		30.89±10.69		
Obstetric history – n (%)				
		Parity	*Vaginal delivery*	*C-section*
	0	18 (3.6)	87 (17.2)	330 (65.2)
	1	44 (8.7)	91 (18)	97 (19.2)
	2	131 (25.9)	139 (27.5)	46 (9.1)
	3	122 (24.1)	92 (18.2)	20 (3.9)
	≥4	191 (37.7)	97 (19.1)	13 (2.6)
		Episiotomy	*Forceps*	
	Yes	202 (39.9)	65 (12.8)	
	No	180 (35.6)	315 (62.3)	
	N.I	124 (24.3)	126 (24.9)	
PFM Strengtht – n (%)				
	0-1	184 (36.4)		
	≥2	322 (63.6)		
Type of urinary incontinence – n(n%)				
	SUI	130 (25.7)		
	UUI	35 (6.9)		
	MUI	327 (64.6)		
	Others	14 (2.8)		
Score ICIQ-SF - Mean±SD		15.02 (±3.8)		
ICIQ-SF scores in categories – n(n%)				
	Slight (1-5 points)	6 (1.2)		
	Moderate (6-12 points)	122 (24.1)		
	Severe (13-18 points)	279 (55.1)		
	Very severe (19-21 points)	99 (19.6)		

Subtitles: n: absolute frequency among 506 participants; %: relative frequency; SD: standard deviation; BMI: body mass index; N.I: not informed; C-section: caesarean section; PFM: pelvic floor muscles; SUI: stress urinary incontinence; UUI: urgency urinary incontinence; MUI: mixed urinary incontinence; Others: other types of urinary loss as enuresis, insensitive and overflow urinary incontinence; ICIQ-SF: International Consultation on Incontinence Questionnaire - Short Form.

FIGURE 2

Table 2. Comparisons between groups

Variables	Groups		
	MOS 0-1 (n= 184)	MOS ≥2 (n=322)	*p-value
Age (years) – Mean±SD	58.44 (±11.72)	56.77 (±11.08)	0.109
BMI (kg/cm²) – Mean±SD	30.81 (±5.56)	30.93 (±12.78)	0.906
Parity - Mean±SD	3.41 (±2.06)	3.21 (±1.77)	0.263
Vaginal deliveries - Mean±SD	2.39 (±1.90)	2.13 (±1.67)	0.120
ICIQ-SF score - Mean±SD	15.04 (±3.92)	15.01 (±3.84)	0.943

Subtitles: MOS: Modified Oxford Scale; SD: standard deviation; BMI: body mass index; ICIQ-SF: International Consultation on Incontinence Questionnaire - Short Form. *Intergroup comparisons measured by Student's t-tests; Statistical significance was p 0.05 for all analyses.

REFERENCES

1. Bo K, Frawley HC, Haylen BT, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. Neurourol Urodyn. 2017;36(2):221-244. doi:10.1002/nau.23107
2. Bø K, Larsen S, Oseid S et al. Knowledge about and ability to correct pelvic floor muscle exercises in women with urinary stress incontinence. Neurourol Urodyn. 1988;7:261-262.
3. Murray AS. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incon-

tinence in women. Res Nurs Heal. 2019;42(3):234-235. doi:10.1002/nur.21946

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comitê de Ética em Pesquisa do Hospital de Clínicas de Porto Alegre/ Research **Ethics Committee** of Hospital de Clínicas de Porto Alegre **Helsinki** Yes **Informed Consent** No

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INTRAVAGINAL PRESSURE PROFILE DURING TWO DIAPHRAGMATIC ASPIRATION TASKS IN WOMEN WITH STRESS URINARY INCONTINENCE: A CROSS SECTIONAL STUDY

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HYPOTHESIS / AIMS OF STUDY

Pelvic-floor muscle (PFM) training is recommended as first-line treatment for stress urinary incontinence (UI), in women. [1] Recently, approaches such as Abdominal Hypopressive Technique and Low Pressure Fitness have been proposed as alternatives to PFM training for the treatment of stress UI. These approaches involve a diaphragmatic aspiration (an apnea) with or without a specific body posture. Theoretically, the execution of these techniques would result in a decreased abdominal pressure leading to a reflex activation of the abdominal and PFM, thereby increasing vaginal force closure and reducing UI. To our knowledge, no mechanistic studies have compared the effect of a diaphragmatic aspiration, with or without a specific body posture, to PFM maximal voluntary contraction in regard to the pressure distribution along the vaginal cavity of women with stress UI.

The aim of this study was to compare intravaginal pressure profiles in women with stress UI during three tasks: a PFM maximal voluntary contraction, a diaphragmatic aspiration alone and a diaphragmatic aspiration associated with a body posture described in the Low Pressure Fitness approach (the Venus posture).

STUDY DESIGN, MATERIALS AND METHODS

We conducted an observational cross-sectional study. Participants were recruited through newspapers, advertisements in community centers, web and social media initiatives. Eligible participants were community-dwelling women, age 18 years and over, who reported at least three episodes of urine loss per week during the preceding three months, as noted in the 7-day bladder diary. Stress UI was confirmed using the validated Questionnaire for Incontinence Diagnosis. Exclusion criteria were: other UI type (urge or mixed UI), pregnancy, pathology/risk factor or medication likely to interfere with the study such as cardiac and respiratory conditions or high blood pressure.

The intravaginal pressure profile was assessed using the FemFit®, an 80 mm intra-vaginal pressure sensing device comprising of an array of eight independent pressure sensors, separated by nine mm gap. The device is thin (4mm) and flexible, enclosed with a soft biocompatible silicone. This device was previously tested for reliably and validity.[2] Pressure data was transmitted, via Bluetooth to an Android tablet for data logging and real-time display for user feedback.

Before an assessment session the FemFit® was disinfected and covered with a condom. A trained physiotherapist taught the participant how to effectively contract the PFM via vaginal palpation. Standardized instructions were then given via a short training video recorded by an expert (JV) on how to execute a diaphragmatic aspiration alone and a diaphragmatic aspiration associated with the Venus posture. Both tasks were practiced under supervision, prior to pressure measurement. The FemFit® was then inserted into the participant's vaginal cavity in an anterio-posterior axis by the physiotherapist. The device position in the vagina was verified after every task.

Data was acquired at rest and during three trials of each of the three tasks, in the standing position. Tasks were consecutively executed with a 15 second rest-period between each trial and task, to avoid fatigue. For each task, the peak pressure, defined as the maximum pressure achieved across the eight sensors and the peak pressure location, were identified. Delta pressure was calculated from the rest task (peak pressure – rest pressure). As the distribution of these outcomes exhibited violation of the normality assumption, main analyses relied on non-parametric tests (Friedman test and Wilcoxon test).

RESULTS

From April 2019 to August 2019, seventeen participants were recruited. The mean age of the participants was 52 years (SD 11.73), mean BMI was 29.4 kg/m2 (SD 7.05), median parity was 2, mean duration of UI symptoms was 8 years (SD 6.8) and median leakage episodes per week was 11 (Q1= 7; Q3= 27,5). Data from two participants were not usable for analysis.

Figure 1 shows the mean pressure profile for each task. Visually, each task produced a specific vaginal pressure profile with both diaphragmatic aspiration tasks producing

pressures lower than the resting pressure. The mean peak pressure was 87% and 82% higher during PFM maximal voluntary contraction task than during the diaphragmatic aspiration and diaphragmatic aspiration with the Venus posture tasks respectively ($z = -2.98$, $P < 0.01$; r (effect size) = 0.86 for diaphragmatic aspiration and $z = -2.84$, $P < 0.01$; $r = 0.86$ for diaphragmatic aspiration with Venus posture). No significant difference was found between the two diaphragmatic aspiration tasks ($z = -0.63$, $P > 0.01$; $r = 0.18$) (Figure1). Compared to rest, the mean amplitude of the peak pressure was significantly higher for maximal PFM voluntary contraction task ($z = -3.30$, $P < 0.01$; $r = 0.88$) but not for the two other tasks (Figure 2). As for the peak pressure location, no significant difference was found between the three tasks $\chi 2$ (2, n= 11) = 5.71, $P > 0.05$, with peak pressures occurring mostly between sensor 3 and sensor 6.

INTERPRETATION OF RESULTS

To our knowledge this is the first study to compare the effect of a diaphragmatic aspiration with or without a specific body posture to a PFM maximal voluntary contraction using an intravaginal pressure profile measuring instrument in women with stress UI.

All three pressure profiles were different. Our results show that PFM maximal voluntary contraction task produced a significantly higher peak pressure compared to both alternative tasks. PFM maximal voluntary contraction would therefore lead to greater vaginal closure force, an important component in maintenance of continence during effort. In line with our results, Stupp et al. [3] found higher muscle activation patterns during a PFM maximal voluntary contraction than during a diaphragmatic aspiration, using intravaginal EMG measurements.

Accordingly, only during the PFM maximal voluntary contraction task a significant higher peak pressure could be observed when compared to the rest condition. In contrast during both diaphragmatic aspiration tasks, the peak pressure achieved was not different than the one achieved at rest, questioning the proposed mechanism of action of the hypopressive approach with or without a specific body posture in producing a significant reflex activation of the PFM musculature. Finally, peak pressure location along the length of the vagina was not significantly different between tasks but amplitude pressures were, once again questioning the proposed mechanism of action of the hypopressive approach compared to direct PFM activation.

CONCLUDING MESSAGE

After initial training, diaphragmatic aspiration and the diaphragmatic aspiration associated with Venus posture produced lower peak pressure than PFM maximal voluntary contraction. Furthermore, only a maximal voluntary PFM contraction produced higher intravaginal peak pressures than the ones observed at rest. For both of the aspiration tasks the intravaginal peak pressure achieved was not different than the ones observed at rest. Adding a posture did not appear to add value to diaphragmatic aspiration. More research is needed to better understand mechanism of action of Abdominal Hypopressive Technique and Low Pressure Fitness approaches in the long term and in other body positions.

FIGURE 1

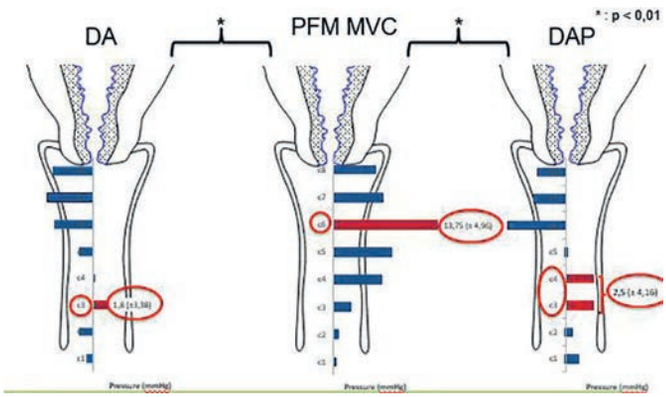
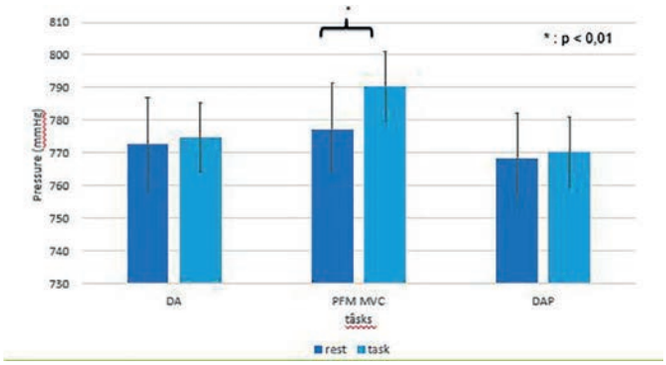


Diagram of pressure amplitude and distribution along each task. Positive values are shown on the right-hand side of the plot. Peak pressure delta (mean with SD) and its location (in red)

FIGURE 2



Means and standard deviation of peak pressure values compared to resting pressure values for each task. DA: diaphragmatic aspiration ; PFM MVC: pelvic floor muscle maximal voluntary contraction; DAP: diaphragmatic aspiration with posture.

REFERENCES

1. Neurourology & Urodynamics, 2018;37(7):2271-2272. https://doi.org/10.1002/nau.23551.
2. Neurourol Urodyn 2020;39:253–60. https://doi.org/10.1002/nau.24179.
3. Neurourol Urodyn 2011;30:1518–21. https://doi.org/10.1002/nau.21151.

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Institutional **Ethics Committee** of the Institut Universitaire de gériatrie de Montreal **Helsinki** Yes **Informed Consent** Yes

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THE IMPACT OF PSOAS MUSCLE ATROPHY ON LOWER URINARY TRACT SYMPTOMS IN ELDERLY FEMALE PATIENTS

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HYPOTHESIS / AIMS OF STUDY

Aging societies have been progressing rapidly worldwide, and the trend of growing number of elderly individuals with various range of functional capacities even among the same generation has been accelerated. Owing to the lack of pertinent evidence, we investigated the relationship between psoas muscle atrophy and lower urinary tract symptoms (LUTS) in elderly female patients.

STUDY DESIGN, MATERIALS AND METHODS

We retrospectively analyzed female patients aged ≥65 years who visited our hospital between 2008 and 2018. The psoas muscle index (PMI) was assessed by computed tomography (CT) and defined as psoas muscle area at the level of third lumbar vertebra divided by the total body surface area. Logistic regression analysis was used to assess the relationship of International Prostate Symptom Score (IPSS) with several variables, including PMI, body mass index, age, hemoglobin (Hb), albumin, and estimated glomerular filtration rate (eGFR). Receiver operating characteristic (ROC) curve analysis was performed to assess the diagnostic accuracy of variables. Patients with diabetes mellitus, neurological disease, acute cystitis, history of abdominal surgery, carcinoma, and pelvic organ prolapse and those receiving medication for LUTS were excluded. Moreover, only patients who underwent CT examination within 1 year before or after visiting our hospital were enrolled.

RESULTS

The study population comprised 158 elderly female patients. The number of patients in the ≥75 years (old age) and 65–74 years (pre-old age) age groups were 70 and 88, respectively. Lower levels of PMI and Hb showed a significant association with severe IPSS storage sub-score in the "old age" group; however, a significant relationship was not observed in the "pre-old age" group [Table]. Furthermore, none of the variables showed any significant relationship with the total IPSS and IPSS voiding sub-score in both age groups [data not shown]. In terms of diagnostic accuracy, ROC curve analysis of PMI and Hb indicated good predictive performance as markers of IPSS severe storage symptoms in the "old age" group [Figure].

INTERPRETATION OF RESULTS

Low muscle mass and anemia are known markers of sarcopenia [1]. In our study, both these variables were associated with severe storage symptoms in the "old age" group. In a previous study, aging-induced detrusor muscle change was associated with detrusor hyperactivity with impaired contractility (DHIC) [2]. Moreover, elderly individuals with sarcopenia were shown to exhibit detrusor overactivity or DHIC [3]. These theories may explain the observed association of lower levels of PMI and Hb with severe storage symptoms in the "old age" group in our study. We could not evaluate muscle function in this retrospective study, which is a study limitation; further studies are desired to explore this aspect.

CONCLUDING MESSAGE

Lower levels of PMI and Hb were found to be associated with severe storage symptoms in the "old age" group. Prevention of sarcopenia at a younger age may help control the future development of severe storage symptoms.

FIGURE 1

75 years or older (old age, n=70)

	Univariate analysis			Multivariate analysis		
	OR	95%CI	p-value	OR	95%CI	p-value
PMI	**0.33**	**0.15 to 0.74**	**0.01>****	**0.38**	**0.16 to 0.90**	**0.05>***
Age	0.98	0.85 to 1.14	0.84			
BMI	1.08	0.90 to 1.30	0.40			
Hb	**0.43**	**0.22 to 0.82**	**0.05>***	**0.38**	**0.16 to 0.84**	**0.05>***
Alb	0.42	0.11 to 1.67	0.22			
eGFR	1.00	0.96 to 1.04	0.92			

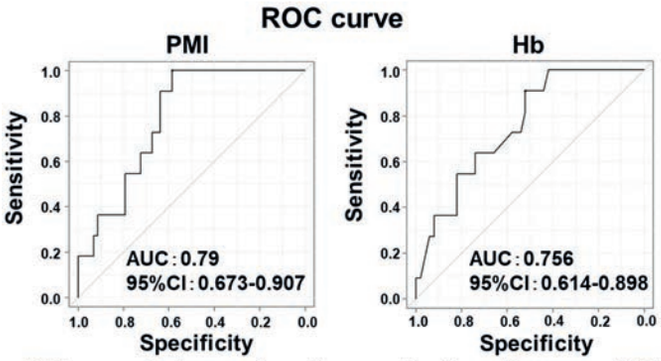
65-74 years old (pre-old age, n=88)

	Univariate analysis			Multivariate analysis		
	OR	95%CI	p-value	OR	95%CI	p-value
PMI	0.90	0.59 to 1.36	0.61			
Age	1.07	0.89 to 1.30	0.45			
BMI	1.06	0.98 to 1.15	0.14			
Hb	0.78	0.53 to 1.16	0.23			
Alb	0.72	0.15 to 3.48	0.69			
eGFR	0.99	0.96 to 1.02	0.59			

Logistic regression analysis was used to assess the relationship of IPSS storage subscore (mild or moderate vs severe) with variables.
Statistical significance was considered as follows : *P<0.05, **P<0.01
IPSS storage subscore ; mild or moderate 0-9, severe 10-15
PMI psoas muscle index, BMI body mass index, Hb hemoglobin, Alb albumin

Table

FIGURE 2



ROC curve analysis was performed to assess the diagnostic accuracy of PMI and Hb as markers of IPSS storage symptoms (mild or moderate vs severe) in the "old age" group.
ROC : Receiver operating characteristic curve,
AUC : Area under the curve, CI : Confidence interval

Figure

REFERENCES

1. J Clin Gerontol Geriatr Volume 6, Issue 4, Pages 115-119, 2015
2. Age (Dordr). 2011 Mar;33(1):81-8.
3. JAMA. 1987 Jun 12;257(22):3076-81.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Kindai University Faculty of Medicine **Ethics Committee Helsinki** Yes **Informed Consent** No

524 www.ics.org/2020/abstract/524

BEST IN CATEGORY PRIZE "REHABILITATION"

ASSESSING PELVIC FLOOR MUSCLE TONE USING DIGITAL PALPATION IN WOMEN WITH PROVOKED VESTIBULODYNIA: ASSOCIATION AND COMPARISON WITH DYNAMOMETRY AND ULTRASOUND IMAGING

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HYPOTHESIS / AIMS OF STUDY

Chronic vulvar pain or vulvodynia is a frequent chronic pain condition with a population prevalence rate as high as 7% to 16% by the age of 40. Provoked vestibulodynia (PVD), the most common type of vulvodynia, is characterized by a sharp, burning pain located at the entry of the vagina when applying pressure or attempting vaginal penetration. Alterations in pelvic floor muscle (PFM) function have been suggested to play a key role in the pathophysiology of PVD [1]. More notably, heightened PFM tone was demonstrated in women with PVD compared to asymptomatic controls using dynamometry and transperineal 3D/4D ultrasound [1]. Increased PFM tone is suspected to be a contributing factor in the development of vestibular pain as well as a perpetuating factor, which may exacerbate pain even further, due to increasing alterations of muscle tone. Primarily targeting PFM alterations, pelvic floor physiotherapy is recommended as an effective first line treatment for PVD. This highlights the relevance of PFM tone assessment in understanding the pathophysiology of PVD and evaluating the effects of treatment.

Most physiotherapists in clinical practice rely on digital palpation to assess PFM tone because it is easy to use and requires no equipment. Among the several scales available, the Reissing scale, consisting of a 7-level grade ranging from -3 (hypotonic) to +3 (hypertonic), was reported to have a good inter-rater reliability [2]. Despite the widespread use of this gradation system, the concurrent validity, evaluated by comparing the scale with other validated and objective instruments, has never been assessed. An in vitro study done recently has suggested that digital palpation may lack sensitivity amongst physiotherapists in assigning stiffness values to the tested 7-point Reissing scale [3]. While using an electromechanical instrument that aimed to replicate the stiffness perceived by the clinician, they found large variability and overlap in stiffness values on the 7-point scale. The study emphasized the relevance to carry out an in vivo study to examine the ability of physiotherapists to assess PFM tone using the Reissing palpation scale. The aim of the present study was to assess the validity of digital palpation in assessing tone using the Reissing Scale by 1) examining the association of palpation scores with dynamometry and 3D/4D transperineal ultrasound imaging in women with PVD; and 2) evaluating whether the palpation grade scale can be discriminated against dynamometry and ultrasound imaging.

STUDY DESIGN, MATERIALS AND METHODS

This cross-sectional study involved 208 nulliparous women, all having a confirmed diagnosis of PVD by a gynecologist on our team. Participants were included if they had a mean pain intensity during intercourse of ≥ 5 on the numerical rating scale for a period over 6 months. Participants were convened to an assessment session carried out by experienced physiotherapists. PFM tone was assessed intra-vaginally with one finger using the Reissing scale after participants were instructed to relax their pelvic floor musculature. The physiotherapist palpated the levator ani muscle toward the posterior fourchette (6 o'clock) and designated a score from -3 to +3, representing no resistance to very firm resistance respectively. '0' found at the centre of the scale would represent normal resting muscle tone. Thereafter, an intravaginal dynamometric speculum was used to assess PFM tone according to a validated methodology. More specifically, passive forces at a vaginal aperture of 15 mm, followed by flexibility measures (maximal tolerated aperture obtained while separating the speculum branches) were recorded. And finally, PFM morphometry was assessed at rest using trans-

perineal 3D/4D ultrasound (GE voluson e8 equipped with a convex transducer 5-9MHz) to assess the levator hiatus area.

The associations between digital palpation, dynamometric, and ultrasound assessments were investigated using Spearman correlation coefficients. The correlations were interpreted as follows: little or no relation (r=0–0.25); fair (r=0.25–0.50); moderate to good (r=0.50–0.75); and good to excellent relation (r≥ 0.75). Differences between palpation scores, dynamometry and ultrasound imaging were assessed using one-way ANOVA followed by the post hoc Scheffe tests.

RESULTS

Participants had a mean age of 23 years (SD=4) with a mean pain intensity of 7.3/10 (SD=1.5) during intercourse for an average duration of 4 years (SD=3.3). For PFM tone assessed using digital palpation, the Reissing scale scores obtained were as follows: 0=45 (21%); 1=58 (28%); 2=80 (39%); 3=25 (12%). None of participants had scores of -1, -2, or -3.

As for the association between palpation and dynamometry, a weak association was found for the passive forces (tone) (R= 0.16; p <0.05). The ANOVAs indicated that passive resistance at the 15mm aperture significantly differed across palpation score categories (F= 4.878, P< 0.01). As shown in Figure 1, there was a significant difference between passive forces at palpation scores 0-3; 1-3; and 2-3 (posthoc p<0.05). Moreover, there was a fair association between palpation and flexibility (measurement of maximal vaginal aperture obtained with the speculum) (R= 0.36; p<0.05). The ANOVAs indicated that flexibility significantly differed across palpation score categories (F=14.021, P< 0.05). The values were significantly different for scores 0-1; 0-2; 0-3; and 1-3 (posthoc p <0.05) as illustrated in Figure 2.

Regarding the association between palpation and ultrasound imaging, a weak association was found with the levator hiatus area (R=-0.19; p<0.05). The ANOVAs indicated that the levator hiatus area differed across palpation categories (F= 3.121, P< 0.05) and that a significant difference was found only for the score 0-3 (posthoc p<0.05).

INTERPRETATION OF RESULTS

The results of the correlation analyses showed weak to fair associations between the Reissing scale and both dynamometry and ultrasound imaging. With the ANOVA tests, it was shown that although mean values of dynamometry and ultrasound imaging increased or decreased across subsequent scores of digital palpation, they did not consistently differ between adjacent scales. It should however be highlighted that given the population understudied (i.e. women with pain), only the increased tone spectrum of the scale was investigated. Although several assessors were involved in the study, this should have a negligible impact on our results given that good inter-rater reliability has been shown for the Reissing scale [2].

CONCLUDING MESSAGE

Findings of this study showed that PFM tone assessed with digital palpation was weakly or fairly associated with dynamometry and ultrasound imaging. Our results also showed limited ability of the physiotherapist to discriminate between palpation scores against dynamometry and ultrasound measures. Therefore, it is important to understand that although palpation is easy, inexpensive, and widely used, it is subject to overlap in adjacent or closely related scores. For that reason, changes in muscle tone may not be captured by digital palpation. This study suggests that assessors/clinicians/researchers should be conscious of these limitations when relying solely on digital palpation as an assessment and outcome measure tool.

FIGURE 1

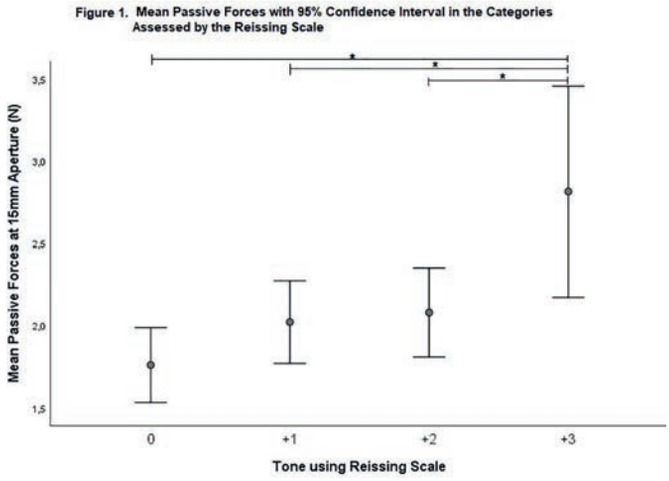

Figure 1. Mean Passive Forces with 95% Confidence Interval in the Categories Assessed by the Reissing Scale

FIGURE 2

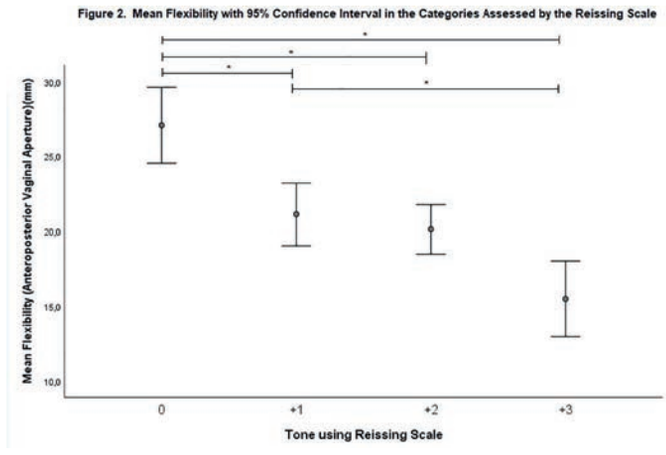

Figure 2. Mean Flexibility with 95% Confidence Interval in the Categories Assessed by the Reissing Scale

REFERENCES
1. Thibault-Gagnon S, Morin M. Active and Passive Components of Pelvic Floor Muscle Tone in Women with Provoked Vestibulodynia: A Perspective Based on a Review of the Literature. J Sex Med. 2015 Nov;12(11):2178-89.
2. Reissing ED, Brown C, Lord MJ, Binik YM, Khalifé S. Pelvic floor muscle functioning in women with vulvar vestibulitis syndrome. J Psychosom Obstet Gynaecol. 2005 Jun;26(2):107-13.
3. Davidson MJ, Nielsen PMF, Taberner AJ, Kruger JA. Is it time to rethink using digital palpation for assessment of muscle stiffness? Neurourol Urodyn. 2020 Jan;39(1):279-285.

Funding Canadian Institutes of Health Research **Clinical Trial** Yes **Registration Number** TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT01455350 **RCT** No **Subjects** Human **Ethics Committee** Comité d'évaluation scientifique du CIUSSS de l'Estrie - CHUS **Helsinki** Yes **Informed Consent** Yes

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CLITORAL BLOOD FLOW ASSESSED WITH COLOR DOPPLER ULTRASONOGRAPHY IN WOMEN WITH PROVOKED VESTIBULODYNIA

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HYPOTHESIS / AIMS OF STUDY
Provoked vestibulodynia (PVD) is defined as a "provoked vestibular pain of at least 3 months duration, without clear identifiable cause, which may have potential associated factors" [1]. This highly prevalent condition is the main cause of dyspareunia and is associated with a significant psychosocial burden [2]. However, its pathophysiology is still unclear, which may explain the lack of effective treatments. Among the proposed contributing factors, increased tone in the pelvic floor muscles was shown to be involved in PVD [3]. Due to mechanical pressure, this tensed musculature may possibly interfere with blood flow, which may, in turn, promote inflammation and increase pain sensitization. No studies thus far have investigated whether women with PVD would present a reduction in peripheral blood circulation in the dorsal clitoral artery, a branch of the pudendal artery irrigating the vulvar area. Therefore, this original research aimed to evaluate and compare the dorsal clitoral blood flow in women diagnosed with PVD and healthy controls using color Doppler ultrasonography.

STUDY DESIGN, MATERIALS AND METHODS
This cross-sectional study involved 20 women diagnosed with PVD according to Friedrich`s criteria and 21 healthy controls. A trained evaluator blinded to the participant's diagnosis performed the assessments of dorsal clitoral artery blood flow using color Doppler ultrasound. Participants were asked to abstain from sexual activities 24 hours prior to the exam. The evaluation was performed in the morning, during the follicular phase (from 1st to 3rd day of menstrual cycle), in a room with temperature set at 22 ºC. After a 10-min rest period in a supine lying position, the blood flow of the dorsal clitoral artery was assessed using the color Doppler ultrasound (Voluson, 730 Expert; linear transducer 3-8 MHz). The measures of the resistance index (RI), time-averaged maximum velocity (TAMX), peak systolic velocity (PSV), end-diastolic velocity (EDV), pulsatility index (PI) were performed at rest considering the mean value of three consecutive waveforms. Mann-Whitney tests were used to compare blood flow parameters and student t-tests were used to compare sexual function between the two groups.

RESULTS
Participants with PVD and healthy controls were comparable for socio-demographic characteristics. They were predominantly white (75.6%), non-smokers (85.4%), nulliparous (46.3%) and aged 31 (±9) years old. Patients with PVD obtained a lower score for sexual function index, according to FSFI (mean total score = 16.9±7.5, $p \leq 0.05$). When compared to controls, women diagnosed with vulvodynia showed increased values for RI (PVD: median 0.72 [0.59; 0.84] vs. control: median 0.64 [0.51;0.66], p=0.003). The PVD group also had higher values for PSV (PVD: median 11.44 [9.27;15.2] vs. control: median 8.13 [7.66;8.7], $p<0.001$); TAMX (PVD: median 5.8 [4.33;6.74] vs. control: (median 5.26 [3.91;5.28], p=0.02) and EDV (PVD: median 3.22 [2.21;5.17] vs. control: median 3.17 [2.08;3.2], p=0.17). No statistically significant difference was found in PI between the two groups ($p>0.05$).

INTERPRETATION OF RESULTS
Our findings showed that women with PVD had higher values in most doppler parameters compared to controls, which are consistent with restriction in blood flow. Higher RI and TAMX values observed in women with PVD reflects a lower blood flow and a higher downstream vascular resistance. This resistance to blood flow can be explained by a vasoconstriction or a distal occlusion. Consistent with these results, higher velocities (PSV and EDV) were observed in women with PVD and could be explained by the interrelation between velocity and area of the blood vessel. According to the following formula (Flow = Velocity x Area), resistance distal to the measurement site and vasoconstriction (i.e. reduction of the area) could be counterbalanced by an increase in velocity. In sum, our findings suggest a lower blood flow in women with PVD which could play a role in the pathophysiology of PVD. It is plausible that this blood perfusion restriction may be related to pelvic floor muscle tensions.

CONCLUDING MESSAGE
Findings of the present study contribute to advance the understanding of the pathophysiology of PVD by unveiling a novel contributing factor. Future studies should be under-

taken to further investigate the association between blood flow restriction and women's symptomatology.

REFERENCES

1. Bornstein J, Goldstein A, Coady D; International Society for the Study of Vulvovaginal Disease (ISSVD), International Society for the Study of Women's Sexual Health (ISSWSH), International Pelvic Pain Society (IPPS). 2015 Consensus terminology and classification of persistent vulvar pain. Obstet Gynecol. 2016 Apr;127(4):745-51.
2. Morin M, Binik YM, Bourbonnais D, et al. Heightened Pelvic Floor Muscle Tone and Altered Contractility in Women With Provoked Vestibulodynia. J Sex Med 2017;14:592-600.
3. Gates EA, Galask RP. Psychological and sexual functioning in women with vulvar vestibulitis. J Psychosom Obstet Gynecol 2001; 22:221.

Funding Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - CAPES and Santander Mobilidade Internacional **Clinical Trial** Yes **Registration Number** NCT02871661 **RCT** Yes **Subjects** Human **Ethics Committee Ethics Committee** of the University of Campinas **Helsinki** Yes **Informed Consent** Yes

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WHAT DRIVES NOCTURIA IN WOMEN AFTER THE MENOPAUSE?

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HYPOTHESIS / AIMS OF STUDY

To investigate nocturnal bladder parameters in women over 40 years of age and to describe the impact of hormone-related factors.

STUDY DESIGN, MATERIALS AND METHODS

A multi-centre, cross-sectional study was undertaken, involving data collection from consenting women aged 40 or over who were attending tertiary hospital continence clinics. Women who were pregnant or had end stage renal disease, bladder cancer, previous pelvic radiotherapy, an indwelling catheter or dementia requiring supervision were excluded from the study. Data was collected using a 3-day bladder diary and a study questionnaire capturing hormone status and use of known modifying agents. Clinically relevant nocturia and Nocturnal polyuria (NP) were defined as ≥ two voids and ≥33% of 24 hour urine during the main sleep period respectively (1). Nocturnal bladder capacity index (NBCi) >1.3 was considered reflective of compromised bladder storage (2).

Ethics approval was obtained. Participant data was entered into the statistical database SPPS Version 25. Descriptive statistics were used to describe the study sample overall, and by age and nocturia severity. Frequency of item endorsement on the study questionnaire was evaluated and items checked for association with nocturia severity and clinical parameters from the bladder diary. In order to assess contribution of hormonal status on nocturia parameters a binary logistic regression model was created with n≥ 2 as the dependent variable.

RESULTS

Data sets from 158 women with a mean age of 64.3 (SD 12.1) years were analysed. From bladder diary data 85% of women voided at least once per night; 49% had clinically-relevant nocturia. There was a moderate positive and significant correlation between self-report and bladder diary evidence of nocturia severity ($r=0.64$, $p<0.001$). Overall 16% of women were pre or peri menopausal.

Nocturia severity was significantly and positively correlated with night diuresis rate ($p<0.001$), NUV ($p<0.001$) and Vitamin D supplementation ($p=0.017$) but not with hormone depletion symptoms at night, consumption of phytoestrogen foods, oestrogen replacement, prolapse or self-reporting as "overweight". Reporting ≥150 minutes of physical exercise per week approached a significant association with reduced nocturia severity. There were two independent predictors of nocturia severity, Vitamin D supplementation (OR 2.33, $p=0.026$) and age (OR 1.04, $p=0.038$). After adjustment for age the significant association with nocturia ≥ 2 remained (95% CI 1.1-4.9, $p=0.03$).

Nocturnal urine volume (NUV): Women voiding twice or more per night produced 167.5mL more urine than those with less severe nocturia ($p<0.001$). NP was observed in 78% of participants with clinically relevant nocturia ($p<0.001$) and 29% of women who voided less than twice at night ($p=0.002$). Median NUV was significantly higher in women reporting use of vitamin D than in women not supplementing (635 vs 500mL, $p=0.047$).

Bladder storage: There was no difference between maximum voided volume day vs night ($p=0.398$). Overall participants with more severe nocturia demonstrated a significantly higher NBCi than those with mild nocturia (1.25 vs 0.4, $p<0.001$). NBCi was significantly higher in women reporting daytime flushes and sweating ($p=0.004$), but lower when respondents either used probiotics ($p=0.045$) or participated in 150 minutes of physical activity each week ($p=0.036$).

Hormonal factors: Hormone depletion symptoms during the day or at night were reported by 28% and 30% of women respectively; no association with time since last menses was found. Neither NUV nor NBCi were associated with time since last menstrual period. Table 1 reports the significant relationship between hormone-specific variables endorsed by ≥20% of participants and nocturia severity, bladder-diary derived NUV and bladder capacity.

The logistic regression model for nocturnal polyuria index >33% was significant (chi squared =35.82, p<0.001). There were two independently significant predictors: age increased the odds of having and NPi>33% by 7% (OR 1.07, p<0.001), while exercise was protective (OR 0.22, p=0.001). The logistic regression model for nocturia index > 2.0 was significant (chi squared =30.52, p<0.001). Four predictor variables were identified: : i) Age – OR 1.06, p=0.001) ii) self-report of use of hormone replacement therapy - OR 0.18, p=0.049 iii) 150 minutes of exercise per week – OR 0.29, p=0.002 and iv) flushes or sweating during the day – OR 2.97, p=0.014). While the logistic regression model for nocturnal bladder capacity index (NBCi) was not significant (chi squared = 8.77, p=0.187), women reporting flushes or sweating during the day were 2.8 times more likely to have an NBCi>1.3 (p=0.187).

INTERPRETATION OF RESULTS

In women > 40 years clinically-relevant nocturia is mixed, driven by both i) increased overnight urine volume and diuresis rate and ii) reduced maximum voided volumes both day and night. Future work to elucidate mechanism of Vitamin D on NUV and to test addition of >150 mins exercise and urogenital oestrogen to current therapy is warranted.

CONCLUDING MESSAGE

NP is a prevalent finding in post-menopausal women reporting clinically relevant nocturia. The possible link between hormonal depletion and bladder storage may induce bladder sensitivity. The potentially protective effect of physical activity on nocturia warrants further investigation.

FIGURE 1

	ANV	NUV	NPi	NBCi	Ni
Vitamin D	↑	↑	↑		↑
Exercise 150	↓		↓	↓	
Day Flushes	↑			↑	↑

Table 1: Variables significantly associated with clinically-relevant nocturia, high NUV or compromised bladder storage.

REFERENCES

1. Hashim H, Blanker MH, Drake MJ, Djurhuus JC, Meijlink J, Morris V, Petros P, Wen JG, Wein A. International Continence Society (ICS) report on the terminology for nocturia and nocturnal lower urinary tract function. Neurourology and urodynamics. 2019 Feb;38(2):499-508.
2. Epstein M, Blaivas J, Wein AJ, Weiss JP. Nocturia treatment outcomes: analysis of contributory frequency volume chart parameters. Neurourology and urodynamics. 2018 Jan;37(1):186-91.

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AN ONLINE SURVEY OF BLADDER HEALTH AND LUTS IN US WOMEN USING LURN-SI 29 AND A NATIONAL RESEARCH REGISTRY

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HYPOTHESIS / AIMS OF STUDY

Online research communities are becoming increasingly common and provide a low-cost resource to researchers and low burden opportunity for volunteers. These platforms are prime for studies utilizing self-reported measures to explore novel, potential risk and protective factors and can be particularly useful to understand the usability and performance of newly developed research instruments in additional populations. The objectives of this online bladder health survey were to (1) assess the response rate and feasibility of using ResearchMatch, a national online volunteer registry established by the National Institute of Health for the recruitment of study participants, (2) compare the demographics, health characteristics, and lower urinary tract symptoms (LUTS) of survey respondents to published prevalence estimates from population-based surveys, and (3) pilot the newly developed Lower Urinary Tract Research Network-Symptom Index (LURN-SI 29) in women, including its ability to detect known associations between demographics, health characteristics, and LUTS (i.e., convergent validity). Data obtained in this study will be used to inform future population based studies and intervention trials.

STUDY DESIGN, MATERIALS AND METHODS

A cross-sectional survey of women recruited through ResearchMatch was performed to assess bladder health/LUTS, known LUTS-related risk and protective factors, as well as other health characteristics and behaviors. At the time of study launch, ResearchMatch included 98,300 women 18 years of age and older (480 women 80-100 years-old) and 630 transgender participants. ResearchMatch permits contact of 1,500 participants via email at one time with additional contacts made until sample size is reached.

The web-based survey was developed by content experts in the field of bladder health and LUTS, and edited and revised by a team of investigators. LUTS were assessed using the new Lower Urinary Tract Research Network-Symptom Index (LURN-SI 29).[1] Additional validated questionnaires were used when possible but several understudied areas lacked validated items. New questions were drafted and revised by our research team taking into account the available published and unpublished literature in the field. We then tested these questions for 6th grade readability using MS Word and assessed content validity. The survey was entered

into the secure web platform REDCap and logic was used to minimize participant burden with irrelevant questions. The survey consisted of 100 questions and took approximately 14 minutes to complete. A REDCap link was provided for survey completion.

Participant demographics, health characteristics and LUTS were summarized and compared to estimates from the Epidemiology of LUTS (EpiLUTS) study [2], which used representative population-based sampling of men and women >40 years from an internet based panel of US, UK, and Swedish residents (allowing for multiple contacts and incentives to improve response rates). Participant LURN-SI total scores and sub-scores were tabulated and compared by demographics and health characteristics. Total scores and sub-scores ranged from 0 (least severe) to 100 (most severe); p-values were calculated by the non-parametric Kruskal-Wallis test. Free text entry for some fields was used to "hear" participants' voices on understudied topics (e.g., preferred terminology, effects of exercise). Free text entries were analyzed using qualitative research methods, grouping of common language and meaning, and identification of themes.

RESULTS

A random sample of 18,609 of the 99,920 registered female and transgender volunteers between the ages of 18-100 received the request to participate in the survey. Of 18,609 volunteers emailed, 2,144 agreed to participate and 1,747 (ages 18-88 years) completed the survey for a response rate of 9.4% of those contacted, and a completion rate of 81.5% of those who agreed. The response rate to EpiLUTS was 59.6%.

Table 1 shows participant demographics and LUTS characteristics among ResearchMatch volunteers compared with participants in EpiLUTS. ResearchMatch participants had a mean age of 44 years, most had completed some post-high school education, and were White/Caucasian, making the sample younger, more highly-educated with similar racial/ethnic diversity to the EpiLUTS population. Self-reported health, distribution of comorbid conditions and body mass index (BMI) were similar between the two studies while menopausal status and parity were not. ResearchMatch respondents were less likely to be postmenopausal and had lower parity consistent with their younger age. ResearchMatch respondents reported a high prevalence and bother from LUTS similar to EpiLUTS.

Table 2 shows bivariate analysis of participant characteristics and LURN-SI total scores and sub-scores. LURN-SI 29 total scores ranged from 0 to 77; median score (25th%, 75th%) was 17 (11, 26). Notably, the Nocturia sub-score had the highest median score of 29 (14, 57). LURN-SI 29 sub-scores as well as total score increased with age, BMI, medical comorbidity, parity, menopausal status, urinary symptom bother and each decrement in self-reported health, and varied with education and race, thus providing evidence of convergent validity.

Several novel areas of bladder health were evaluated with our survey and may be important in future studies; these include:

(1) Respondents used over 30 different terms to describe urine leakage. Preferred terms included: "Had an accident" (24.0%), "Peed on myself" (22.3%) and "Urinary Incontinence" (19.7%). Less preferred terms: "Urine accident" (3.0%) and "Accidental urine loss" (5.6%). 4% of participants used "Other" terms (e.g. piddle, dribble, drips, drops, sneeze pees, weak bladder, old lady bladder, mommy bladder).

(2) 24.7% of women reported that they experienced bladder pressure during certain activities (10.4% during jumping, 8.5% during running, 5.7% during fast walking, 5% during yoga, 4.6% during hard landings).

(3) 12.9% of participants avoided physical activity and 15.2% interrupted a workout due to LUTS.

(4) Adaptive behaviors were employed during exercise by 32.7% of participants (pad use 18.7%, dark clothing 8.6%, frequent toilet use 16.3%, sitting down to exercise 3.4%).

INTERPRETATION OF RESULTS

Response rates among self-identified volunteers in the ResearchMatch web-based platform for the study of bladder health and LUTS (9.4%) were similar to representative sampling of the population using postal and telephone recruitment [3] but were less than internet based incentivized sampling in EpiLUTS (59.6%). ResearchMatch participants were younger, more educated, and less parous than EpiLUTS participants. Despite this, the spectrum of LUTS was similar indicating this platform is an appropriate resource to pilot and inform the development of novel study instruments in the area of bladder health and LUTS. Respondents report a high prevalence of bladder symptoms consistent with other LUTS measures used in population-based studies. Furthermore, the novel LURN-SI 29 was capable of detecting expected associations with demographics (i.e., age) and health characteristics (i.e., comorbidity and BMI), supporting its use in future etiologic and health outcomes studies.

CONCLUDING MESSAGE

Internet-based recruitment for a bladder health survey is feasible, with similar response rates as population based postal and telephone recruitment studies. Participant demographic characteristics varied but the prevalence and spectrum of LUTS were comparable to other population-based samples. For future studies, selective sampling is feasible in ResearchMatch to allow a more nationally representative racial/educational distribution although its use is still limited in terms of achieving diversity in socioeconomic status and

related domains affecting internet access and computer and health literacy. Internet-based population use of the novel LURN-SI 29 provided data on its performance outside of LUTS patients, demonstrating its ability to detect expected associations with demographics and health characteristics. For future studies refining and validating the LURN-SI 29, use of patient preferred language and bladder symptom assessment in the context of activity may improve performance of the measure.

FIGURE 1

TABLE 1: Participant demographics and characteristics in ResearchMatch volunteers for a bladder health study compared with the Epidemiology of LUTS (EpiLUTS) study

		ResearchMatch (*n*=1,747)	EpiLUTS (Women; *n*=15,861)
Age (years)	Mean (range)	44.0 (18-88)	56.7 (40-99)
Gender (%)	Female	98.6	100
	Trans/Gender Queer/Nonconforming	1.3	NR
Education (%)	High School	5.0	54.3
	Associates/Some College	26.3	24.3
	Bachelors/Graduate Degrees	67.9	8.5
Race (%)	White/Caucasion	86.7	83.0
	Black/African American	5.4	7.1
	Asian	3.6	2.3
	Other/Mixed	4.3	1.7
Ethnicity (%)	Hispanic/Latino	6.0	5.8
Health Insurance (%)	Insured	90.5	NR
	Intermittently Insured	5.1	NR
	Uninsured	3.7	NR
Self-Reported Health (%)	Excellent	13.6	10.5
	Very Good	42.7	35.8
	Good	29.0	34.2
	Fair	12.0	15.6
	Poor	2.6	3.9
Body mass index (kg/m^2)	Mean	27.8	28.8
Medical Conditions (%)	None	20.2	NR
	Anxiety	44.2	33.4
	Depression	43.7	23.7
	Lower Back Pain	33.0	NR
	Hypertension	20.8	35.2
	Diabetes (Type 1 or 2)	6.6	10.5
	Arthritis	21.8	35.4
	Sleep Apnea	8.8	10.4 (or sleep d/o)
	Insomnia	16.7	10.4 (or sleep apnea)
	*Neurologic Disease	8.0	3.4
Pregnancy Status (%)	Currently	1.1	NR
	Never pregnant	42.2	NR
	Parity 0	59.2	16.3
	Mean Parity	0.8	2.5
Menopause Status (%)	Pre-	45.4	25.0
	Peri-menopausal	6.7	12.4
	Post-menopausal	37.7	62.6
	Unsure	10.2	NR
Nocturnal Enuresis (%)	Never	88.1	96.2[1]
	A few times	8.6	1.2[2]
	Half the time or more	3.3	2.6[3]
Urgency Incontinence (%)	Never	62.3	75.6[1]
	A few times	29.6	11.3[2]
	Half the time or more	8.0	13.1[3]
Stress Incontinence (%)	Never	47.8	68.2[1]
	A few times	37.4	17.0[2]
	Half the time or more	14.87	14.8[3]
Bladder Pain with Filling (%)	Never	82.3	92.4[1]
	A few Times	14.2	5.4[4]
	Half the time or more	3.5	2.2[5]
Urgency (%)	Never	29.0	64.3[1]
	A few Times	49.1	24.6[4]
	Half the time or more	21.9	11.1[5]
Nocturia (%)	None	34.3	24.2
	Once per night	44.4	42.1
	2 or more	21.3	33.7
Daytime Frequency (%)	3 or fewer	11.9	NR
	4-7 times	64.6	NR
	8-10 times	19.7	24.6 (perceived frequency)
	11 or more	3.8	
Incomplete Emptying (%)	Never	50.3	75.3[1]
	A few times	36.4	17.3[4]
	Half the time or more	13.2	7.4[5]
Urinary Tract Infection (%)	Never	23.4	NR
	Ever	76.6	NR
	Recurrent UTI	10.0	6.9
Urinary Symptom Bother (%)	Not at all	47.4	LUTS at least "somewhat bothersome" to >50% of participants who experienced them
	Somewhat Bothered	39.7	
	Very Bothered	8.8	
	Extremely Bothered	4.1	

*Neurologic Disease is brain ischemia, stroke, multiple sclerosis, Parkinson's or other neurologic disease
[1]Never/rarely; [2]Few times/month; [3]Few times/week or more; [4]Sometimes; [5]Often/always
LUTS, lower urinary tract symptoms; NR, not reported; UTI, urinary tract infection

FIGURE 2

TABLE 2: Median (25th%, 75th%) Lower Urinary Tract Research Network-Symptom Index 29 (LURN-SI 29) total scores and sub-scores by demographics and health characteristics in ResearchMatch volunteers for a bladder health study (*n*=1,747).

		n	LURN-SI Total	Incontinence Sub-Score	Urgency Sub-Score	Pain Sub-Score	Nocturia Sub-Score	Voiding Difficulty Sub-Score
All Participants		1747	17 (11,26)	4 (0,13)	17 (8,33)	6 (0,13)	29 (14,57)	15 (5,30)
Age (years)	18-35	699	**13.5 (9,21)***	**0 (0,8)***	**8 (0,25)***	**6 (0,13)***	**14 (0,43)***	**15 (5,25)***
	36-50	390	**18.0 (12.5,28)***	**8 (0,17)***	**25 (8,33)***	**6 (0,19)***	**43 (14,57)***	**15 (5,30)***
	51-65	440	**19.0 (12,28)***	**8 (4,17)***	**25 (8,33)***	**6 (0,13)***	**50 (29,71)***	**15 (5,30)***
	>65	218	**21.0 (15,28)***	**8 (4,21)***	**25 (17,42)***	**6 (0,13)***	**57 (29,71)***	**20 (10,30)***
Gender	Female	1724	17 (10,26)	4 (0,13)	**17 (8,33)***	6 (0,13)	29 (14,57)	15 (5,30)
	Transgender	5	25 (14,25)	8 (0,8)	**25 (25,67)***	13 (0,19)	29 (14,43)	30 (10,35)
	Gender Queer/Nonconforming	14	21 (14,29)	10.5 (0,25)	**21 (8,33)***	6 (0,25)	29 (14,43)	22.5 (15,35)
	Other	4	31.5 (23,55)	6 (2,19)	**62.5 (34,92)***	47 (19,78)	57 (29,79)	27.5 (13,65)
Education	Grade School/HS	14	**17 (14,30)***	**8 (0,8)***	**25 (17,50)***	**6 (0,19)***	22 (0,29)	**20 (10,35)***
	High School Diploma	87	**19 (12,29)***	**8 (0,26)***	**25 (8,42)***	**6 (0,13)***	29 (14,71)	**20 (5,30)***
	Associates/Some College	459	**19 (12,30)***	**8 (0,17)***	**25 (8,42)***	**6 (0,19)***	29 (14,57)	**20 (10,30)***
	Bachelors/Graduate Degrees	1187	**16 (10,24)***	**4 (0,13)***	**17 (0,33)***	**6 (0,13)***	29 (14,57)	**15 (5,25)***
Race	White/Caucasion	1485	**17 (11,26)***	**4 (0,13)***	**17 (8,33)***	6 (0,13)	**29 (14,57)***	**15 (5,30)***
	Black/African American	92	**15 (10,26)***	**4 (0,17)***	**17 (8,33)***	3 (0,13)	**29 (29,57)***	**15 (5,20)***
	Asian	62	**12 (8,18)***	**0 (0,8)***	**12.5 (0,17)***	6 (0,13)	**14 (0,29)***	**10 (0,25)***
	Other/Mixed Race	73	**17.5 (10,30)***	**4 (0,13)***	**25 (8,42)***	6 (0,19)	**29 (0,57)***	**20(10,35)***
Ethnicity	No	1640	17 (11,26)	4 (0,13)	17 (8,33)	6 (0,13)	**29 (14,57)***	15 (5,30)
	Hispanic/Latino	105	16 (10,25)	4 (0,13)	17 (0,33)	6 (0,19)	**29 (14,57)***	15 (10,35)
Health Insurance	Insured	1561	17 (10,25)	4 (0,13)	17 (8,33)	6 (0,13)	29 (14,57)	15 (5,30)
	Intermittently Insured	86	17 (11,28)	4 (0,13)	17 (4,33)	6 (0,19)	29 (0,57)	20 (10,35)
	Emergency Coverage Only	14	18 (14,35)	10.5(0,13)	25 (17,58)	6 (0,13)	29 (14,71)	15 (10,30)
	Uninsured	63	18 (10,29)	8 (0,17)	25 (8,42)	6 (0,13)	29 (14,57)	15 (5,35)
Self-Reported Health	Excellent	237	**12 (9,18)***	**4 (0,8)***	**8 (0,25)***	**0 (0,6)***	**29 (14,57)***	**10 (5,20)***
	Very Good	736	**16 (10,23)***	**4 (0,13)***	**17 (0,33)***	**6 (0,13)***	**29 (0,57)***	**15 (5,25)***
	Good	498	**18 (12,28)***	**4 (0,17)***	**17(8,33)***	**6 (0,19)***	**43 (14,71)***	**20 (10,30)***
	Fair	208	**25.5 (17,36)***	**8 (4,21)***	**25 (17,50)***	**13 (6,25)***	**57 (29,71)***	**25 (15,35)***
	Poor	46	**30 (20,39)***	**15 (0,29)***	**33 (17,50)***	**13 (6,25)***	**50 (29,71)***	**25 (20,50)***
BMI	Underweight/Normal	781	**16 (10,23)***	**4 (0,8)***	**17 (0,33)***	6 (0,13)	29 (0,57)	15 (5,25)
	Overweight	399	**17 (11,26)***	**4 (0,13)***	**17 (0,33)***	6 (0,19)	**29 (14,57)***	15 (5,30)
	Obese	400	**18 (12,28)***	**8 (0,17)***	**17 (8,33)***	6 (0,13)	**43 (14,71)***	15 (5,30)
	Morbidly Obese	125	**23 (15,30)***	**13 (4, 25)***	**25 (13,58)***	6 (0,19)	**43 (29,71)***	15 (5,30)
Medical Conditions	None	355	**13 (8,19)***	**2 (0,8)***	**8 (0,25)***	**0 (0,13)***	**29 (0,43)***	**10 (5,20)***
	1 or More Comorbidity	1387	**18 (11,27)***	**4 (0,13)***	**17 (8,33)***	**6 (0,19)***	**29 (14,57)***	**20 (10,30)***
	Anxiety or Depression	990	**18 (11,27)***	4 (0,13)	**17 (8,33)***	**6 (0,19)***	29 (14,57)	**20 (10,30)***
	Lower Back Pain	577	**21 (13,30)***	**8 (0,17)***	**25 (8,42)***	**6 (0,19)***	**43 (14,71)***	**20 (10,35)***
	Chronic Pain	279	**26 (16,36)***	**8 (0,25)***	**25 (17,50)***	**13 (6,25)***	**43 (29,71)***	**25 (15,45)***
	Hypertension	364	**22 (14,30)***	**8 (4,21)***	**25 (8,50)***	6 (0,19)	**57 (29,71)***	**20 (10,30)***
	Diabetes (Type 1 or 2)	67	**27 (21,35)***	**17 (4,25)***	**42 (17,58)***	13 (6,19)	**57 (29,71)***	25 (15,35)
	Arthritis	380	**23 (14,33)***	**8 (4,21)***	**25 (8,50)***	**6 (0,19)***	**57 (29,71)***	**20 (10,35)***
	Chronic Constipation	130	**25 (16,32)***	8 (0,17)	**25 (8,42)***	**13 (6,19)***	**57 (29,71)***	**25 (15,45)***
	Sleep Apnea	155	**25 (14,35)***	**13 (4,25)***	**25 (8,58)***	**6 (0,19)***	**43 (29,71)***	**20 (10,30)***
	Insomnia	293	**22 (12,32)***	4 (0,17)	**25 (8,42)***	**6 (0,19)***	**43 (14,71)***	**25 (10,35)***
	#Neurologic Disease	140	**26.5(14,39)***	**8 (0,25)***	**25 (8,42)***	**13 (0,25)***	**50 (22,71)***	**25 (10,45)***
Pregnancy Status	Currently	19	24 (14,26)	8 (0,17)	**25 (8,42)***	6 (0,19)	**57 (29,86)***	20 (10,30)
	Never Been Pregnant	736	**14 (9,21)***	**0 (0,8)***	**17 (0,25)***	6 (0,13)	**29 (0,57)***	15 (5,25)
	Parity 0	1035	**15 (10,23)***	**4 (0,8)***	**17 (0,33)***	6 (0,13)	**29 (0,57)***	**15 (5,25)***
	Parity 1	241	**20 (13,30)***	**8 (4,17)***	**25 (8,42)***	6 (0,19)	**43 (14,71)***	**20 (5,35)***
	Parity 2	276	**20 (12,27)***	**13 (4,21)***	**25 (8,33)***	6 (0,13)	**43 (14,57)***	**15 (5,30)***
	Partity 3+	195	**21 (13,31)***	**13 (4,21)***	**25 (8,42)***	6 (0,19)	**43 (14,71)***	**20 (5,30)***
Menopause Status	Pre-	792	**14 (10,21)***	**0 (0,8)***	**8 (0,25)***	**6 (0,13)***	**29 (0,57)***	**15 (5,25)***
	Peri-menopausal	116	**18 (12,28)***	**8 (0,21)***	**25 (8,33)***	**6 (0,19)***	**43 (14,71)***	**15 (5,30)***
	Post-menopausal	656	**21(13,29)***	**8 (0,21)***	**25 (8,42)***	**6 (0,13)***	**57 (29,71)***	**20 (5,30)***
	Unsure	178	**16 (11,27)***	**4 (0,13)***	**17 (8,33)***	**6 (0,13)***	**29 (0, 57)***	**20 (10,30)***
Urinary Symptom Bother	Not at all	826	**11 (8,16)***	**0 (0,4)***	**8 (0,17)***	**0 (0,6)***	**14 (0,43)***	**10 (5,20)***
	Somewhat Bothered	693	**21 (16,27)***	**8 (4, 17)***	**25 (17,33)***	**6 (0,19)***	**43 (14,71)***	**20 (10,30)***
	Very Bothered	153	**35 (27, 41)***	**21 (8, 33)***	**50 (33,58)***	**19 (6,31)***	**71 (43,86)***	**30 (15,45)***
	Extremely Bothered	72	**43.5 (35, 50)***	**27 (13, 42)***	**67 (42,79)***	**25 (13,44)***	**71 (43,86)***	**40 (18,55)***

*p<0.05; #Neurologic Disease is brain ischemia, stroke, multiple sclerosis, Parkinson's, or other neurologic disease; HS, some high school

REFERENCES

1. Cella D, Smith AR, Griffith JW, Flynn KE, Bradley CS, Gillespie BW, Kirkali Z, Talaty P, Jelovsek JE, Helfand BT, Weinfurt KP; LURN Study Group. A new outcome measure for LUTS: Symptoms of Lower Urinary Tract Dysfunction Research Network Symptom Index-29 (LURN SI-29) questionnaire. Neurourol Urodyn. 2019 Aug;38(6):1751-1759. doi: 10.1002/nau.24067. Epub 2019 Jun 21.
2. Coyne KS, Sexton CC, Thompson CL, Milsom I, Irwin D, Kopp ZS, Chapple CR, Kaplan S, Tubaro A, Aiyer LP, Wein AJ. The prevalence of lower urinary tract symptoms (LUTS) in the USA, the UK and Sweden: results from the Epidemiology of LUTS (EpiLUTS) study. BJU Internat. 2009 Aug;104(3):352-60
3. Czajka JL, Beyler A. Background Paper. Declining Response Rates in Federal Surveys: Trends and Implications. Mathematica Policy Research Report. June 15, 2016. https://www.mathematica.org/our-publications-and-findings/publications/declining-response-rates-in-federal-surveys-trends-and-implications-background-paper

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THE CAUSAL EFFECT OF DIFFERENT DEPRESSION SUBTYPE ON INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME: A NATIONWIDE RETROSPECTIVE COHORT STUDY

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HYPOTHESIS / AIMS OF STUDY

Interstitial cystitis/painful bladder syndrome (IC/PBS) and depression are two diseases of chronic, unknown etiology and often occur concomitantly without a reasonable reason. Past studies have suggested that the prevalence of depression in IC/PBS patients ranges from 5 % to above 50 %. Some diseases have interaction with each other and therefore be co-existed. Similarly, there may also have interaction or causal effect between depression and IC/PBS. There are many different subtypes of depression with different severity or mechanism. The effect of comorbidity and interaction may therefore different among these subtypes. We hypothesized that depression is a risk factor of IC/PBS, and the effect was related to different type of depression. This study used a nationwide database with retrospective cohort study, and aimed to investigate the causal effect of different depression subtypes on IC/PBS.

STUDY DESIGN, MATERIALS AND METHODS

Two types of newly diagnosed depression between 2002 and 2013 were identified from a nationwide database as the depression cohorts. Subjects which diagnosed of IC/PBS before depression were excluded. All depression patients were divided into two subgroups according to ICD-9 coding as Major depressive disorder, recurrent episode; and Major depressive disorder, single episode. These subjects were further matched one to one by confounding factors (including age, and other 12 comorbidities) with propensity scores as matched cohorts. All subjects were followed up during the study period to detect the event of IC/PBS. The hazard ratio (HR) of IC/PBS between depression and non-depression cohort in each type of depression was applied before and after matched by propensity scores. The duration of IC/PBS as consequence of depression and incidence density were calculated.

RESULTS

There were 21,646 depression and 607,535 depression subjects, respectively, including11,290 and 10,281 patients in recurrent type subgroup and single episode type subgroup, respectively. Each subgroup was matched one to one using propensity score for confounding factors and yielded 11,179, 10,220 depression and non-depression cohorts among two subgroups. Demographics, including age, sex and 12 comorbidities, were similar between two cohorts of the same subgroup. Subgroup with recurrent type of major depressive disorder had significant higher incidence density and shorter duration of developing IC/PBS than matched control. (6.929 per 10,000 person-years and 4.67±2.65 years). After adjusted, the risk of IC/PBS remained significantly increased in recurrent type of major depressive disorder, HR=1.54 (95% CI, 1.039-2.269; p=0.031).

INTERPRETATION OF RESULTS

After controlling the confounding factors in our cohort study, the risk of IC/PBS was significantly increased in patients with recurrent or severe depressive disorder. A cross-talk pathophysiology of depression and IC/BPS is possible. Further study to investigate the effects of other types of depression was suggested. This finding could imply valuable cues to a urological approach, and preventive measures for holistic care in depressive disorder patients. Early identification and treatment of depressive disorder were important for prevention of BPS/IC in these numerous and disabled patients.

CONCLUDING MESSAGE

The risk of IC/PBS was significantly increased in patients with recurrent or severe depressive disorder. Early identification and treatment of depressive disorder were important for prevention of BPS/IC in these numerous and disabled patients.

FIGURE 1

Table 1. Comparison on confounders between the depression and non-depression cohorts of three sub-groups

Variable	Depression	Sub-group 1 (n=22,358) Non-Depression=11,179 Depression=11,179	p	Sub-group 2 (n=20,440) Non-Depression=10,220 Depression=10,220	p
Age (years)	No	44.63 ± 15.64 (18.00-93.00)	0.525	45.42 ± 16.25 (18.00-92.36)	0.236
	Yes	44.77 ± 15.92 (18.02-101.96)		45.70 ± 17.52 (18.02-96.17)	
Sex (Female, %)	No	7,337 (65.6)	0.554	6,314 (61.8)	0.088
	Yes	7,380 (62.0)		6,409 (62.7)	
Fibromyalgia (n, %)	No	6,934 (62.3)	0.365	6,039 (59.1)	0.314
	Yes	6,960 (59.2)		6,074 (59.4)	
IBS (n, %)	No	3,203 (28.7)	0.179	2,506 (24.5)	0.085
	Yes	3,140 (28.1)		2,421 (23.7)	
Migraine (n, %)	No	880 (7.9)	0.510	655 (6.5)	0.455
	Yes	880 (7.9)		660 (6.8)	
Anxiety state (n, %)	No	7,951 (71.1)	0.506	6,424 (62.9)	0.465
	Yes	7,951 (71.1)		6,431 (62.9)	
Chronic fatigue syndrome (n, %)	No	297 (2.7)	0.195	256 (2.5)	0.091
	Yes	319 (2.9)		226 (2.2)	
Stress incontinence (n, %)	No	332 (3.0)	0.219	243 (2.4)	0.341
	Yes	353 (3.2)		253 (2.5)	
Pelvic pain (n, %)	No	200 (1.8)	0.163	172 (1.7)	0.144
	Yes	180 (1.6)		152 (1.5)	
Chronic UTI (n, %)	No	140 (1.3)	0.500	105 (1.0)	0.216
	Yes	139 (1.2)		93 (0.8)	
SLE (n, %)	No	122 (1.1)	0.423	85 (0.9)	0.299
	Yes	118 (1.1)		93 (0.9)	
Sjögren's syndrome (n, %)	No	705 (6.3)	0.126	584 (5.7)	0.172
	Yes	663 (5.9)		552 (5.4)	
Asthma (n, %)	No	2,448 (21.9)	0.224	2,181 (21.3)	0.287
	Yes	2,496 (22.3)		2,215 (21.7)	
TMD (n, %)	No	484 (4.3)	0.057	419 (4.1)	0.048
	Yes	436 (3.9)		372 (3.6)	

Values are given as mean ± standard deviation (range) or n (%). *IBS* irritable bowel syndrome, *UTI* urinary tract infection, *SLE* Systemic Lupus Erythematosus, *TMD* temporal mandibular disorder.

Table 1. Comparison on confounders between the depression and non-depression cohorts of three sub-groups

FIGURE 2

Table 2. Hazard ratio of IC/BPS in the depression cohort compared with the non-depression cohort of two sub-groups

	Depression / non-depression	*HR* (95%*CI*)	*p*
unmatched	**Sub-group 1 (n=618,825)**	1.239 [a] (0.926-1.656)	0.149
	Sub-group 2 (n=617,816)	1.135 (0.795-1.620)	0.487
matched	**Sub-group 1 (n=22,358)**	1.535 [a] (1.039-2.269)	0.031
	Sub-group 2 (n=20,440)	1.157 [a] (0.733-1.825)	0.532

IC/BPS, interstitial cystitis/bladder pain syndrome; HR, hazard ratio; CI, confidence interval.
[a] Adjusted confounders: age, sex, Fibromyalgia, irritable bowel syndrome, migraine, anxiety, chronic fatigue syndrome, stress incontinence, pelvic pain, chronic urinary tract infection, Systemic Lupus Erythematosus, Sjögren's syndrome, asthma, temporal mandibular disorder.

Table 3. Incidence density of *IC/PBS between the depression cohort and non-depression cohort in two sub-groups*

	Cohort	n	Event	Person-year	Incidence density*	*p* [a]
unmatched	**Sub-group 1**					
	Depression	11,290	50	71,493.766	6.993	<0.001
	Non-depression	607,535	1,354	6,545,824.35	2.068	
	Sub-group 2					
	Depression	10,281	32	61,413.807	5.210	<0.001
	Non-depression	607,535	1,354	6,545,824.350	2.068	
matched	**Sub-group 1**					
	Depression	11,179	49	70,721.232	6.929	0.031
	Non-depression	11,790	60	126,059.87	4.760	
	Sub-group 2					
	Depression	10,220	32	61,054.472	4.540	0.532
	Non-depression	10,220	52	114,531.704	5.241	

IC/BPS interstitial cystitis/bladder pain syndrome
*per 10,000 person-years; [a] compare with non-depression cohort, p value of K-M analysis

Table 2. Hazard ratio of IC/BPS in the depression cohort compared with the non-depression cohort of two sub-groups , Table 3. Incidence density of IC/PBS between the depression cohort and non-depression cohort in two sub-groups

Funding No **Clinical Trial** No **Subjects** Human **Ethics Committee** The Institutional Review Board of the Feng Yuan Hospital, Ministry of Health and Welfare, Republic of China, specifically (project/IRB no. 108009) **Helsinki** Yes **Informed Consent** No

529 www.ics.org/2020/abstract/529

HIGHER TONICITY OF PELVIC MUSCULATURE IN WOMEN WITH KETAMINE-INDUCED CYSTITIS

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HYPOTHESIS / AIMS OF STUDY

Ketamine, an N-methyl-Daspartate receptor antagonist, has been widely used in anesthesia, psychiatrics and veterinary medicine since 1960s. As for low prices, accessibility and addictive characteristics, it has become popular among young adults in many countries over the past decade. However, it was strongly convinced to damage urologic system. Despite the crackdown on smugglers and subsequent decreasing Ketamine abuse, refractory symptoms of ketamine cystitis, including lower abdominal pain, urinary frequency, urgency and hematuria, are difficult to treat and may destroy renal function. Despite that the mechanism of ketamine cystitis is not fully elucidated so that there is no gold standard for treatment, promising results are raised with the intravesical use of botulinum toxin. It indeed relieved of suprapubic pain and localized myofascial pain. Aim of this study is to investigate pelvic musculature hypertonicity in ketamine-induced cystitis (KIC) by magnetic resonance imaging (MRI).

STUDY DESIGN, MATERIALS AND METHODS

MRI examinations were performed in 14 female patients diagnosed with KIC between 2015 and 2016 at our institution. We recruited age-matched control group who had also received pelvic MRI. Patients with pelvic trauma or surgery were excluded. Baseline characteristics, visual analogue scale of chronic pain and renal function were recorded and analyzed by reviewing medical chart retrospectively. Two experienced and blinded radiologist measured the parameters of MRI, including the H-line, M-line, pubococcygeal line, urethral distance to pubococcygeal line, puborectalis width and length, posterior puborectalis angle and urethral area. Mann-Whitney test was applied.

RESULTS

Baseline characteristics, such as weight, height, body mass index and parity, were similar in both groups. However, more proportion in KIC group suffered from chronic pain and psychiatric conditions. In terms of parameters of MRI, M-line significantly decreased in KIC group(1.28±0.38, $P<0.01$) compared with control group (1.80±0.44). Pubococcygeal line noticeably reduced in KIC group (8.07±1.06) compared with control group (11.44±2.93, $P<0.01$). H-line decreased in KIC group without significance. In addition, urethral area increased in KIC group (2.07±0.62, $P<0.05$) compared with control group (1.54±0.63). There is no significance between

two groups in puborectalis width, puborectalis length and posterior puborectalis angle.

INTERPRETATION OF RESULTS

M-line, representing the descent of the levator from the reference pubococcygeal line, significantly decreased in KIC group. It may imply pelvic floor stay in high tension status. H-line, the puborectal line, that is the anteroposterior pelvic dimension, would be observed in patients with pelvic floor relaxation and even accompanying organ prolapse. Despite that there's no significant difference between two groups in H-line, it decreased in KIC group. Taken together, MRI might suggest hypertonicity of pelvic musculature in patients with ketamine-induced cystitis. Besides, urethral area meaningfully increased in KIC group. As we known, investigation about urethral area in cystitis was limited. We speculate it may be result from long-term inflammation and may be compatible with morphology of ketamine-induced uropathy and lower urinary tract symptoms, such as urinary incontinence.

CONCLUDING MESSAGE

MRI suggest hypertonicity of pelvic musculature in patients with ketamine-induced cystitis. For those with severe pain and lower urinary tract symptoms of KIC, therapies aimed at pelvic floor relaxation might by helpful. Further application about MRI information should be investigated.

FIGURE 1

Table 2. Parameters of MRI

	Control	KIC	P value
H line (cm)	5.18±0.70	5.12±0.92	0.9740
M line (cm)	1.80±0.44	1.28±0.38	0.0019 **
Pubococcygeal line	11.44±2.93	8.07±1.06	0.0013 **
Urethral distance to pubococcygeal line	1.46±0.47	1.42±0.37	0.7894
Right puborectalis width	0.72±0.29	0.67±0.14	0.5540
Right puborectalis length	6.76±0.81	6.62±0.64	0.5045
Left puborectalis width	0.84±0.37	0.75±0.21	0.6750
Left puborectalis length	6.73±0.72	6.65±0.64	0.7889
Posterior puborectalis angle	43.29±7.90	41.71±5.07	0.8554
Urethral area (cm2)	1.54±0.63	2.07±0.62	0.0399 *

FIGURE 2

Table 1. Baseline characteristics

Parameter	Control (mean±SD)	KIC (mean±SD)	P value
Age	26.93 (16-32)	27.14 (19-34)	0.7541
Weight	54.09 (36-77)	49.14 (39-60)	0.3652
Height	1.58 (1.41-1.68)	1.60 (1.51-1.68)	0.6240
BMI	21.42 (17.9-28.4)	19.18(16.2-26.2)	0.0780
Parity (number/range)	0 (0)	0 (0)	
Chronic pain (n/%)	8 (53%)	12 (86%)	
Comorbid metabolic syndrome(n/%)	0 %	0 %	
Comorbid psychiatric conditions (%)			
Incidence of depression (n/%)	0 %	2 (14%)	
Incidence of insomina (n/%)	0 %	4 (29%)	

REFERENCES

1. Radiographics. 2008 Jul-Aug;28(4):949-67. doi: 10.1148/rg.284075139.
2. Int Urogynecol J DOI 10.1007/s00192-015-2794-6
3. International Journal of Urology (2015) 22, 816--825 doi: 10.1111/iju.12841

Funding The study was not supported by any funding or grant. There are no conflicts of interest. **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It needs ethics committee for medical chart and image reviewing. And we are applying for ethics committee. **Helsinki** Yes **Informed Consent** No

530 www.ics.org/2020/abstract/530

A RETROSPECTIVE ANALYSIS OF VOIDING DIARY INFORMATION TO DETERMINE THE DIFFERENTIAL VOIDING PATTERN ACCORDING TO AGE AND CHEMOTHERAPY IN PATIENTS WITH NON-UROLOGICAL CANCER AND VOIDING DIFFICULTY

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HYPOTHESIS / AIMS OF STUDY

Patients undergoing chemotherapy are encouraged to drink large volumes of fluids owing to the adverse effects of chemotherapy agents and complaints of voiding difficulty, which affects not only their quality of life but also their therapeutic prognoses. Most patients with cancer are old, with lower urinary tract symptoms before and after chemotherapy. For collecting patient voiding information, a self-assessed voiding diary is a useful tool. This study aimed to describe some differential characteristics of voiding according to age and chemotherapy based on information from the voiding diary of patients with non-urological cancer who complained of voiding symptoms.

STUDY DESIGN, MATERIALS AND METHODS

The 3-day voiding diaries of 96 patients with cancer were analyzed retrospectively by a single urologist to compare the differential characteristics of voiding according to chemotherapy and age between 2013 and 2017. All patients were referred to the urologist because of voiding difficulties, and one complete 24-hour voiding diary was analyzed, including voiding volume, frequency, intervals, and nocturia, using the International Prostate Symptom Score (IPSS) voiding questionnaire. Patients were grouped according to age (≥65 vs <65 years) and the presence of ongoing chemotherapy (chemotherapy vs non-chemotherapy group). The Wilcoxon rank-sum test and generalized estimation equation were statistically utilized to determine the intrapersonal correlation.

RESULTS

The overall mean age and male-to-female sex ratio were 64.7 years and 80:16 (83.3%/16.7%), respectively. The median voiding frequency (daytime/nighttime), voided volume (VV), and daytime/nighttime VV was 10 (5/4), 2015 ml, and 990/900 ml, respectively. The median voided interval was 1.6 hours (interquartile range [IQR], 0.9–2.6), and the median daytime/nighttime interval was 1.7 (IQR, 1.0–2.7) and 1.5 hours (IQR, 0.8–2.4), respectively. The remaining information is documented in Table 1.

Comparison of the groups according to age and chemotherapy revealed that the total and nighttime frequencies were significantly affected by age and that voided volume was affected by chemotherapy ($p \leq 0.05$), whereas none of the IPSS items were affected by age or chemotherapy ($p > 0.05$; Table 2). Comparison of the chemotherapy effects within the same age subgroup revealed that the voiding characteristics of the old age group (≥65 years) were not significantly different according to chemotherapy ($p > 0.05$). In the young age group (<65 years), chemotherapy significantly affected voided volume ($p \leq 0.05$) but not voiding frequency ($p > 0.05$).

INTERPRETATION OF RESULTS

The voiding problem in patients with non-urological cancer was markedly influenced by age and chemotherapy. For those patients undergoing chemotherapy, the young-aged patients were affected much more in voided volume and frequency by the volume of water intake to reduce the adverse effects of chemotherapeutic agents, whereas the voiding problem in the old-aged group was not affected in voiding frequency by the chemotherapy itself but the underlying anatomical at the lower urinary tract.

CONCLUDING MESSAGE

This study showed that VV and voiding frequency were affected by chemotherapy or age in patients with non-urological cancer who had voiding difficulty. Large volume intake of fluids during chemotherapy might affect voiding patterns in patients in the young age group but not in those in the old age group undergoing chemotherapy who have voiding difficulty.

FIGURE 1

Table 1. Baseline characteristics

	N(%) or median (range)
Age (year-old) <65	44 (45.8)
≥65	52 (54.2)
Gender (male/female)	80/16 (83.3 /16.7)
Medications for voiding symptom	24 (25.3)
Cancer treatment	
Non-chemotherapy including surgery	76 (79.2)
Chemotherapy	20 (20.8)
IPSS total score (mean± STD/ Median, range)	20.15±9.55/20.5 (1-35)
Total voiding frequency	10 (2-35)
daytime/nighttime	5/4 (0-25/0-16)
Total voided volume	2015 (340-4620)
Maximum voided volume	300 (50-950)
Minimum voided volume	100 (5-550)
Total daytime voided volume	990 (225-2670)
Maximum daytime voided volume	265 (50-950)
Minimum daytime voided volume	100 (5-950)
Total nighttime voided volume	900 (100-2900)
Maximum nighttime voided volume	300 (25-900)
Minimum nighttime voided volume	150 (5-700)
Single voided volume	150 (5-950)
Single daytime voided volume	150 (5-950)
Single nighttime voided volume	195 (5-900)
Single interval time, IQR	1.6 (0.9-2.6)
Single daytime interval time, IQR	1.7 (1.0-2.7)
Single nighttime interval time, IQR	1.5 (0.8-2.4)

REFERENCES

1. Scand J Urol Nephrol. 2001 Oct;35(5):377-81.
2. Prog Urol. 2007 Nov;17(6 Suppl 2):1252-63
3. Int J Surg. 2016 Jan;25:164-71. doi

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** IRB of National Cancer Center, Goyang, Korea **Helsinki** Yes **Informed Consent** No

SESSION 37 (PODIUM SHORT ORAL) - URODYNAMICS AND BEST OF THE REST
Abstracts 577-588
15:00 - 16:30, Pavilion 9
Chairs: Dr Sender Herschorn (Canada), Dr Ouida Lenaine Westney (United States)

577 www.ics.org/2020/abstract/577

DO URODYNAMICS REALLY CAUSE ANXIETY AND EMBARRASSMENT? AN AUDIT OF PATIENT EXPERIENCE OF URODYNAMICS IN THE UK

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HYPOTHESIS / AIMS OF STUDY

Urodynamic studies (UDS) are invasive diagnostic tests for lower urinary tract dysfunction. The test may cause anxiety and embarrassment for many patients. In addition to utilising them for diagnosis, urology departments should aim to reduce patient anxiety and embarrassment.

We performed a prospective, multi-centre audit of patient satisfaction of UDS in the UK.

Standard

The following standards were set:

• Overall patient satisfaction rate should be greater than 60%.

• Greater than 60% of patients should be willing to undergo a repeat test, if clinically necessary.

• Anxiety rates should ideally be less than 50% of the maximum on a numerical rating scale (NRS).

STUDY DESIGN, MATERIALS AND METHODS

Data was collected prospectively via a patient questionnaire. Patients self-completed the questionnaire on the day of their procedure. Patient demographic details were collected alongside symptoms and neurological status.

Numerical rating scale (ranging 1-5) data was collected for:

• Pre-test and intra-test anxiety

• Embarrassment

• Pain

• Overall satisfaction

Data were collated and analysed using Microsoft Excel and RStudio.

RESULTS

90 patients from five large centres across the UK were included in the study. 53% of patients were male and 47% were female.

The predominant symptoms leading to UDS were storage LUTS (47% of patients), voiding LUTS (33% of patients), stress urinary incontinence (27% of patients) and urgency urinary incontinence (24% of patients).

Median anxiety levels were 3/5 and 2/5 on the NRS prior, and during the test, respectively. Mean and median pain scores were both 2/5. Levels of embarrassment were relatively low (median 2/5), whilst overall satisfaction was high (median 5/5; mean 4/5).

85% of patients were satisfied with the procedure (NRS 4/5 or 5/5) and 98% indicated they would be willing to have a repeat procedure in the future if clinically indicated.

INTERPRETATION OF RESULTS

The pattern of LUTS presenting for UDS in our cohort is different to population previously published population-based studies. Patient satisfaction with UDS is high in the UK, with the majority willing to undergo the test again. Moderate levels of pre-procedure anxiety are reduced slightly during the procedure.

CONCLUDING MESSAGE

The UDS service across the centres included are representative of UDS services across the whole of the UK. Patients in the UK are satisfied with the service they receive, although they are moderate levels of pre-procedure anxiety and mild-moderate levels of embarrassment. This anxiety existed despite the vast majority being aware of the details of the procedure (via information leaflet or having had procedure previously). Variations in LUTS compared to previous population-based studies is likely due to UDS patients being a subset of patients rather than a reflection of the whole population.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Patient questionnaire. No ethical approval required. Part of ongoing review of service. **Helsinki** Yes **Informed Consent** Yes

578 www.ics.org/2020/abstract/578

A NOVEL USE OF VIDEO URODYNAMICS: A PILOT STUDY OF STATISTICAL SHAPE MODELING TO UNDERSTAND BLADDER FUNCTION

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HYPOTHESIS / AIMS OF STUDY

Evaluation and diagnosis of multiple urologic conditions involves video urodynamic studies (VUDS). These VUDS assess the shape of the bladder via radiographic imaging and its function via multichannel urodynamics. Storage and voiding are complex processes involving coordination and alteration of bladder shape which are visualized by VUDS. Current assessment of bladder shape is performed qualitatively based on radiographic imaging by identifying trabeculations and diverticula which occur late in bladder dysfunction and are variably detected by clinical specialists. The aim of this study was 1) to develop a novel analytic approach for assessment of bladder shape using radiographic imaging and statistical shape modeling; and 2) to determine what relationships exist between bladder shape and function.

STUDY DESIGN, MATERIALS AND METHODS

This was a cross-sectional pilot study, approved by the Institutional Review Board. Radiological and functional data were obtained for female patients who underwent VUDS as part of their clinical care. Patients with active urologic malignancy, previous augmentation cystoplasty, bladder substitution, or active urinary tract infection were excluded. All studies were performed in the seated position. Demographic data were manually extracted. Single VUDS images representing a moderately full bladder (approximately 300 ml) were selected for each subject. These images were read by two independent clinicians blinded to subjects' medical history and assessed as "normal" or "abnormal" appearing based on the presence or absence of abnormal features such as trabeculations or diverticula.

The same images were also subjected to statistical shape analysis by a blinded researcher. Shape analysis has been previously utilized in other clinical areas to determine alterations in specific features of anatomic structures. Here we applied these methods to analyze bladder shape. Bladder images were traced manually in ImageJTM and converted from an image to a 2D shape format in MathematicaTM. Corresponding points were established using DeformetricaTM, ensuring respective points on each shape represent the same anatomical landmarks. The Procrustes method was used to align the shapes as closely as possible, removing the effects of orientation, position, or global scale variation. Then a principal component analysis was performed in MathematicaTM to quantify the modes of variation, which describe shape variance and are each defined by an eigenvector and eigenvalue. In this study, modes represent shape variance in different anatomic regions of the bladder. Principal component scores were calculated for each shape and mode for use in subsequent statistical analyses.

Independent samples Student's t-tests with Benjamini-Hochberg corrections for multiple comparisons were used to determine if clinically evaluated shape via radiographic imaging (normal vs abnormal), post void residual volume (normal vs elevated), or voiding ability (able vs unable) differed across any significant modes of variation of interest. Pearson's correlations were performed on continuous versions of these variables on only the normally shaped bladders to evaluate differences between subgroups of interest.

RESULTS

22 subjects have been included in this pilot study. The average age was 51 years. The primary indications for video urodynamics was severe lower urinary tract symptoms in the presence of neurogenic lower urinary tract dysfunction or previous surgery. On urodynamic testing 29% had post void residuals >300 ml. Radiographic bladder imaging was "normal" for 62.5% of subjects. All subjects had urodynamically diagnosed abnormalities of storage or emptying and severe lower urinary tract symptoms.

Shape analysis of the bladders identified 4 significant modes, which account for 43%, 19%, 14%, and 6% of the total variance in bladder shape. These modes were associated with anatomic features on radiographic imaging (Figure 1A). Qualitatively, mode 1 described changes in the proportional left to right vs superior to inferior length accounting for alterations in the lateral walls of the bladder (pink). Mode 2 and mode 3 described local variations in superior-inferior dimensions of the right (white) and left (green) walls of the bladder respectively, and mode 4 described global bladder smoothness/roundness (yellow) (Figure 1A and 1B).

Qualitative assessment of bladder modes showed separation of clinically normal and abnormal bladders for modes 1 and 3, but not for modes 2 and 4 (Figure 1B). The t-tests revealed that mode 3, which corresponds to the left superior-inferior bladder walls, differed significantly ($p=0.004$) for patients with clinically identified normal (-85.5 ± 129.9) vs abnormal (149.7 ± 210.1) bladder shapes (Figure 1C). Mode 1 was not significantly different in patients with radiographically normal and abnormal bladder shapes (Figure 1C) and there were no significant differences in post void residual volume or voiding ability for any of the groups. We then performed a subgroup analysis of subjects with radiographically normal appearing bladders; in this group a significant inverse correlation was found between mode 1 and post void residual volume with a correlation coefficient of -0.561 ($p=0.046$) (Figure 1D).

INTERPRETATION OF RESULTS

The results of this preliminary study indicate that shape analyses can be used to determine abnormalities of bladder shape similar to clinical assessment of radiographic images. In our study, mode 3 values representing the superior-inferior left aspects of the bladder wall reflect the clinical radiographic assessments. As clinical assessments identified trabeculations and diverticula, this mode is most associated with these features.

Secondly, our study demonstrates the ability of statistical shape analysis to detect alterations in bladder function in radiographically normal appearing bladders. Mode 1, representing the lateral bladder walls, is significantly correlated with post void residual volume in clinically normal appearing bladders. These results indicate that: 1) bladder function can be correlated to shape and 2) shape analysis is able to detect subtle variations in clinically relevant bladder shape features.

Additional VUDS data is needed to optimize the statistical shape model and begin correlation of additional shape features with bladder characteristics and function. This method demonstrates potential for the identification of more subtle alterations in bladder shape that may be associated with early diagnosis of abnormal bladder function.

This preliminary study is limited by the number or participants and that all subjects had severe lower urinary tract symptoms and urodynamically demonstrated abnormalities of either storage, emptying or both—consistent with abnormal bladder function.

CONCLUDING MESSAGE

This study demonstrates that statistical shape analysis can determine clinically identified abnormalities of bladder shape. Secondly, this shape model is able to detect alterations in bladder shape correlated with bladder function in radiographically normal appearing bladders. These data suggest a complex relationship between bladder function and shape. This method has the potential to identify clinically undetectable alterations in bladder shape associated with bladder dysfunction.

FIGURE 1

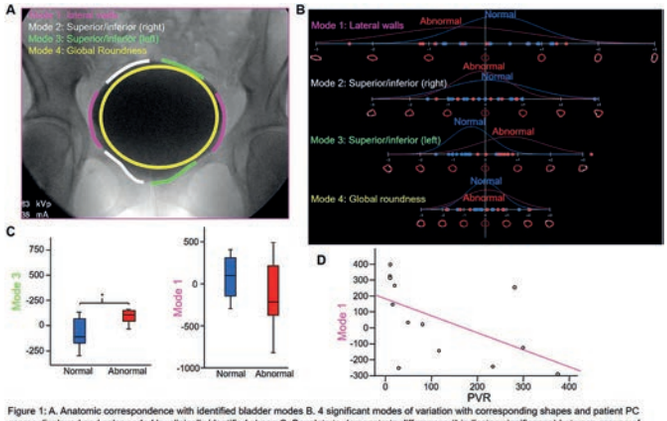

Figure 1: A. Anatomic correspondence with identified bladder modes B. 4 significant modes of variation with corresponding shapes and patient PC scores displayed and color-coded by clinically identified shape C. Boxplots to demonstrate differences (* indicates significance) between groups of interest D. Linear regression analysis of Mode 1 with post void residual (PVR) with correlation coefficient of -0.561 (p=0.046).

Figure 1

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WHICH URODYNAMIC PARAMETERS CAN PREDICT THE OUTCOME OF INTRAVESICAL INJECTIONS OF ONABOTULINUM TOXIN A FOR OVERACTIVE BLADDER?

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HYPOTHESIS / AIMS OF STUDY

Intravesical Onabotulinum Toxin A (Botox A) injections is a commonly used minimally invasive surgical procedure for treatment of overactive bladder (OAB) symptoms refractory to first and second-line therapies. Prospective randomized control studies show success rates around 60% in symptomatic OAB patients. We present the largest reported single-centre audit of long-term outcomes for Botox A injections for refractory non-neurogenic OAB. We have assessed whether patient outcomes can be predicted by pre-operative urodynamic findings.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective review of consecutive 418 patients (age range 22-94 years, median 61 years, 128 (30%) men) having intravesical Botox A injections for refractory non-neurogenic OAB symptoms under the care of 4 consultant surgeons between 2006 and 2018 was conducted. The outcome of treatment was categorized using a 5 point Patient Global Impression of Improvement (PGI-I) scale at the last follow up

appointment or when contacted by telephone if last review was over 6 months ago. Successful outcomes were defined as PGI-I scores of 1 and 2 (good effect and partially good effect). Patient outcomes were correlated with the pre-operative urodynamic findings, including presence of urge urinary incontinence (OAB-wet), idiopathic detrusor overactivity (IDO), peak DO pressure, bladder capacity at onset of first DO, and evidence of bladder outlet obstruction (BOO). Duration of voiding detrusor contraction was noted in urodynamic studies with a valid voiding phase; however, studies with no evidence of voluntary detrusor contraction, where void was initiated on top of underlying DO, or where the intra-vesical catheter was expelled part-way through the void were excluded. Statistical analysis was done by Students T-Test and Chi Square Test and significance was determined at $P < 0.05$.

RESULTS

Pre-operative urodynamic results were available for review on 309 (74%) patients; 214 women (age range 22-90 years, median 59 years) and 95 men (age range 27-94 years, median 69 years) and were a mixture of conventional cystometrograms (CMG), video-cystometrograms (VCMG) and ambulatory cystometrograms. Urodynamically proven IDO was demonstrated in 215 cases (69%) prior to Botox-A injections. The outcomes are listed in Table 1.

INTERPRETATION OF RESULTS

Intravesical Botox A was significantly more successful in women with urodynamically proven idiopathic detrusor overactivity (75%) comparing with men (60%) and women with OAB in absence of detrusor overactivity (62%). Successful outcomes were significantly associated with increased duration of voiding detrusor contractions but not with any other urodynamic parameters.

CONCLUDING MESSAGE

The gender difference is in agreement with previously published results [1,2], however our results also highlight statistically significant difference in outcomes for women with and without IDO. This is contrary to the only reported cohort study which found no difference in outcomes after intravesical Botox-A injections in patients with and without detrusor overactivity [3].

FIGURE 1

	Failure (PGI-I ≥3)	Partial Success (PGI-I 2)	Success (PGI-I 1)
Men IDO	27	8	35
Men no DO	11	3	11
Women IDO	36	13	96 *
Women no DO	26	11	32
OAB Wet Women	20	7	54
OAB Wet Men	17	7	20
Median Peak DO pressure Women (cmH2O)	33	62	34
Median Peak DO Pressure Men (cmH2O)	50.5	61.5	60
Volume at 1st DO Women (ml)	255	125	240
Volume at 1st DO Men (ml)	215	190	210
BOO Women	3	4	10
BOO Men	7	3	7
Duration Detrusor Contraction Women (s)	63**	107	85.5
Duration Detrusor Contraction Men (s)	73.5	97	93

- *P = 0.02
- **P=0.03

Table 1

REFERENCES

1. Walker et al. (2019) Onabotulinum toxin A Injections in Men With Refractory Idiopathic Detrusor Overactivity. Urology. 2019 Jan;123:242-246. doi: 10.1016/j.urology.2018.09.016
2. Hsiao et al. (2016) Factors associated with therapeutic effi¬cacy of intravesical onabotulinumtoxinA injection for overactive bladder syndrome. PLoS One. 2016;11(1):e0147137
3. Jackson et al. (2012) Intravesical botulinum toxin for overactive bladder syndrome without detrusor overactivity. British Journal of Medical and Surgical Urology 2012; 5(4): 169-173 doi: 10.1016/j.bjmsu.2011.10.003

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Audit **Helsinki** Yes **Informed Consent** No

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INFLUENCE OF VOIDING POSTURE ON UROFLOWMETRY PARAMETERS AND VOIDING EFFICACY IN MALE ADULT PATIENTS

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HYPOTHESIS / AIMS OF STUDY

Voiding posture affects uroflowmetry parameters including post-void residual (PVR) in men. Goel et al reported the impact of voiding posture on uroflowmetry parameters in men [1]. They recruited 740 men as a healthy volunteer and ask them to undergo uroflowmetry tests in the sitting and standing position. As a result, PVR among the participants aged >50 was significantly lower in the sitting voiding position, whereas voiding time (VT) was significantly longer in the sitting voiding position than the standing position. Oppositely, Yazici, et al reported PVR in men (mean age, 58.0

years old) was larger in the sitting voiding position than the standing voiding position [2]. Influence of voiding position among men for uroflowmetry parameters and PVR is still controversial. It has been still unknown that how voiding posture affect bladder voiding efficacy (BVE). Annually, we have conducted approximately 1,500 voiding tests on uroflowmetry in our outpatient clinic. In the present original study, we investigated the proportion of male patients who void on uroflowmetry in a sitting/standing voiding position and how voiding posture affected uroflowmetry parameters as well as PVR, bladder capacity and BVE.

STUDY DESIGN, MATERIALS AND METHODS

We conducted a retrospective study from 20th February 2019 to 29th February 2019 including male patients who underwent uroflowmetry and PVR at our outpatient department. Prior to the uroflowmetry, we have guided the patient, "please urinate in your usual posture". Voiding posture were automatically recorded on the uroflowmetry chart (FlowSky; TOTO AQUAENG LTD, Tokyo, Japan). We measured PVR subsequently after uroflowmetry by an ultrasound device (BVI6100; Verathon, Bothell, WA). In cases of multiple times of uroflowmetry, we selected the first data from the patient. Data of uroflowmetry included voided urine volume (VV), maximum flow rate (Qmax), average flow rate (Qave), time to Qmax, VT, time to Qmax, time of hesitancy. BVE was calculated by a following formula; VV (mL)/(VV+PVR), %. Data with insufficient voided urine volume ≤150 mL were excluded from analysis. Proportion of sitting/standing voiding posture was calculated at 10-year age intervals and evaluated using the Fisher's exact test. The uroflowmetry parameters, PVR, bladder capacity and BVE were compared between sitting and standing voiding postures by the Wilcoxon rank sum test. BVE was calculated at 10-year age intervals and evaluated using the Dunn test. The uroflowmetry parameters, PVR, bladder capacity and BVE were also evaluated by the two age groups (≤64 and ≥65 years old).

RESULTS

During the study period, 1,203 male patients underwent uroflowmetry and PVR measurement. After excluding the patients with VV ≤150 mL, data from 703 patients were included for analysis. Of 703 patients, proportion of voiding in the sitting position was 38.4% (270/703). Proportion of voiding in the sitting position was 0% in 20s, 33.3% in 30s, 47.1% in 40s, 38.8% in 50s, 42.5% in 60s, 36.2% in 70s, and 34.8% in the age group and ≥80 (P=0.409). Median voiding efficacy was highest in the 30s (92.2%) and gradually decreased thereafter (77.8% in the age group of ≥80). There was a significant difference between 30s and age group of ≥80 (P=0.013). Overall, median Qmax and BVE were significantly higher in the sitting voiding posture (19.9 mL/sec and 88.1%) than those in the standing voiding posture (17.0 mL/sec and 85.7%; P=0.022 and P=0.023). Median time of hesitancy was significantly longer in the sitting voiding posture (17.2 sec) than those in the standing voiding posture (12.5 sec; P<0.001). Among male patients aged ≥65, median Qmax and BVE were significantly higher in the sitting voiding posture (18.7 mL/sec and 88.3%) than those in the standing voiding posture (16.4 mL/sec and 85.5%; P=0.034 and P=0.022). Median time of hesitancy was also significantly longer in the sitting voiding posture (17.7 sec) than those in the standing voiding posture (12.5 sec; P<0.001). Among male patients aged ≤64, uroflowmetry parameters, PVR, bladder capacity or BVE were no longer significantly different.

INTERPRETATION OF RESULTS

The voiding posture influence in Qmax, time of hesitancy and BVE, especially in the elderly male patients aged 65 or older. For the elderly male patient, the sitting voiding posture is beneficial in terms of better Qmax and BVE.

CONCLUDING MESSAGE

Physicians need to pay attention to the voiding posture to evaluate the uroflowmetry parameters, PVR, bladder capacity and BVE in the elderly male patients.

FIGURE 1

	Sitting (n = 199)	Standing (n = 316)	P value
Voided urine volume (mL), median (IQR)	266.8 (191.2 – 365.6)	249.1 (193.0 – 331.5)	0.205
Qmax (mL/sec), median (IQR)	18.7 (12.1 – 28.1)	16.4 (12.4 – 22.9)	0.034
Qave (mL/sec), median (IQR)	10.7 (6.8 – 15.7)	9.9 (6.9 – 13.6)	0.135
Time (sec), median (IQR)	30.8 (21.5 – 44.1)	30.4 (21.1 – 46.2)	0.894
Time to Qmax (sec), median (IQR)	10.4 (6.4 – 19.4)	10.4 (6.9 – 16.9)	0.851
Hesitancy (sec), median (IQR)	17.7 (6.4 – 28.2)	12.5 (2.8 – 22.2)	<0.001
Residual urine volume (mL), median (IQR)	34.0 (20.0 – 79.0)	43.0 (22.3 – 80.0)	0.072
Bladder capacity (mL), median (IQR)	327.3 (240.6 – 424.0)	308.6 (245.6 – 426.8)	0.632
Bladder voiding efficacy (%), median (IQR)	88.3 (77.3 – 93.9)	85.5 (76.0 – 92.1)	0.022

Voiding posture and uroflowmetric parameters among the patients ≥65 years old

REFERENCES

1. Goel A, Kanodia G, Sokhal AK, Singh K, Agrawal M, Sankhwar. Evaluation of impact of voiding posture on uroflowmetry parameters in men. World J Mens Health 2017; 35: 100-106.
2. Yazici CM, Turker P, Dogan C. Effect of voiding position on uroflowmetric parameters in healthy and obstructed male patients. Urol J 2014; 10: 1106-1113.

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APPLICATION OF NON-INVASIVE MEASUREMENT OF BLADDER PRESSURE VIA MEASUREMENT OF URINATING F VALUE IN URODYNAMIC STUDY

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HYPOTHESIS / AIMS OF STUDY
At present, routine urodynamic examination for measuring bladder pressure and related values is an invasive approach, involving personnel, resources, and nosocomial infection prevention, etc., which impede urodynamic examination as a routine way for evaluating lower urinary tract dysfunction. This study introduces a novel approach with the measurement of urinating F value as a non-invasive method to measure the bladder pressure.

STUDY DESIGN, MATERIALS AND METHODS
(1) Using non-invasive urodynamic equipment to measure the urinating F value during micturition (measurement principle: using a digital camera to dynamically capture the urine line during urination, and compare the urinating line with the reference value of F value to calculate and obtain the urinating F value.), maximum urinary flow rate (Qmax), and urethral outlet pressure Po (measurement principle: during the measurement of urinary flow rate, the energy is obtained by the urine stream falling on the collecting web plate, and the leverage is transmitted to the pressure sensing device at the other end, which is calculating urethral outlet pressure Po value), the above three values were measured at the same time during measurement of urine flow rate. (2) Use the verification formula: R=258L/[], Pdif=, Pves = Pdif+Po and , to calculate the minimum urethral resistance (Rmin), urethral consumption pressure (Pdif), bladder pressure (Pves) and bladder pressure (Nves). The urethral pressure Pdif is the pressure consumed by the bladder pressure Pves to drive urine to flow through the urethra.

RESULTS
Based on the urinating F value, using the above-mentioned formula, data values such as urethral resistance Rmin, bladder pressure Pves, and bladder urination power Nves can be calculated to replace them from the routine urodynamic study. When urine volume is 300ml as a regular setting, the urinating F value is 14.5F, the maximum urinary flow rate Qmax is 20.0ml / s, the urethral outlet pressure Po is 20.0cmH2O, the urethral length L is 18cm, and the bladder pressure Pves is 30cmH2O. The actual urethral consumption pressure Pdif is 10cmH2O, the urethral resistance R is 0.025H, the urinary power Nves of the bladder pressure is 600y, the urethral resistance R calculated by the non-invasive method is 0.025H, the urethral consumption pressure Pdif is 9.861cmH2O, and the bladder pressure Pves is 29.861 cmH2O, urinary power Nves of bladder pressure is 597.212y.

INTERPRETATION OF RESULTS
Compared with the actual measured bladder pressure, the analysis from the above results demonstrated the value of bladder pressure via non-invasive urinating F-value measurement, has a smaller error and is within an acceptable range. Hence it is replaceable and feasible as a screening approach.

CONCLUDING MESSAGE
The introduced urinating F value can be used to calculate bladder pressure, and it is possible to develop a new generation of urodynamic study by the above non-invasive approach and the calculating methods.

Funding The study was supported by the National Natural Science Foundation of China (No.81670695),Zhejiang Provincial medical and health technology program projects of China (Nos.2018PY031,2018KY512,and 2019KY101),and Zhejiang Provincial Natural Science Foundation of China(No.WY20H050001) **Clinical Trial** No **Subjects** Human **Ethics not Req'd** The process of data collecting is non-invasive. **Helsinki** Yes **Informed Consent** Yes

582 www.ics.org/2020/abstract/582

THE WAY OF THE VALSALVA LEAKAGE POINT PRESSURE (VLPP) USING SYRINGE AND WITHOUT SYRINGE

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HYPOTHESIS / AIMS OF STUDY
Abdominal leakage point pressure (ALPP) including Valsalva leakage point pressure (VLPP) is one of the most crucial examination to detect stress urinary incontinence (SUI). However, there is no agreed standard way of performing ALPP. This study is aimed to compare the way of VLPP using syringe to the way without syringe by asking to increase their abdominal (intravesical) pressure in women with SUI. We investigated whether Valsalva leakage was associated with the crude straining pressure and the external – sphincter electromyography (e-EMG) amplitude.

STUDY DESIGN, MATERIALS AND METHODS
42 women were recruited who underwent urodynamic study including VLPP while external - sphincter electromyography (e-EMG) was recorded with surface electrode for their lower urinary tract symptom (mean age: 66.4±15.1 years old). UDS

were performed in standardized and reproducible manner, according to Good Urodynamic Practice (Catheter size was 6Fr, infusion speed was 50mL/min) For each patient, both the way of VLPP using syringe and without syringe were examined respectively: The way of VLPP using syringe was performed by blowing into syringe at the bladder volume of maximum desire to void during UDS each patient, and Valsalva maneuver without syringe was asking to increase their abdominal (intravesical) pressure themselves. VLPP is defined as the abdominal (intravesical) pressure at which urinary leakage occur with increased abdominal pressure in absence of detrusor contraction. We described the presence of urinary leakage and the crude straining pressure, the external – sphincter electromyography amplitude using surface electrode.

RESULTS

Crude straining pressure (above zero) 92.7±33.1 cmH2O using syringe was higher than 58.2 ± 21.7 cmH2O without syringe ($p<0.0000025$). Along with this, 10 patients (38.5%) using syringe and 4 patients (15.4%) without syringe leaked respectively (no statistical significance). Between those who leaked and who did not leak, crude straining pressure (above zero) was not different. EMG amplitude was not different between both groups. Between those who leaked and who did not leak, e-EMG amplitude was not different, either.

INTERPRETATION OF RESULTS

This study showed that the crude straining pressure using syringe was significantly higher than without syringe ($p<0.00000025$), the detection rate of the Valsalva leakage using syringe was also higher and more than twice times in patients with a complaint of urinary incontinence. In terms of the external-sphincter EMG during Valsalva maneuver, there was no significant change. It is essential that we detect not only VLPP value but also the presence of urinary leakage to diagnose SUI.

CONCLUDING MESSAGE

This study showed that the crude straining pressure using syringe was significantly higher than without syringe, and the detection rate of the Valsalva leakage using syringe was also higher while external-sphincter EMG was not clearly change. The Valsalva leakage was seemed to associated with VLPP value and may be due to the external-sphincter EMG. These result suggested that the way of VLPP using syringe might more beneficial to grasp urodynamic SUI.

REFERENCES

1. Warren K, Abram P. Leak point pressure: how useful are they?.Curr Opin Urol. 2015 Jul;25(4):317-22

Funding No grant **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Dokkyo Medical University **Ethics Committee Helsinki** Yes **Informed Consent** Yes

583 www.ics.org/2020/abstract/583

RETROSPECTIVE CLINICAL STUDY OF SPECTRAL POWER AND FREQUENCY IN URODYNAMICS PRESSURE DATA: WORKFLOW AND PRELIMINARY TESTS OF FILL-DEPENDENCE

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HYPOTHESIS / AIMS OF STUDY

The purpose of this study is to increase the utility of quantitative physiological sensing during urodynamic studies. Specifically, we hope to capture and quantify bladder pressure parameters during bladder filling to target signals that may be associated with autonomous or low amplitude rhythmic contractions.

Numerous studies have demonstrated the presence of low amplitude rhythmic contractions in in-vitro detrusor tissue strips [1], whole bladders in preclinical studies and early clinical testing [2]. These contractions, and their organization into organ-level signals, have also been implicated in dysfunctions of lower urinary tract control (see review in [3]). The efficient ability to capture and quantify these signals in clinical settings remains in its infancy. For temporal dynamics and spectral composition of pressure signals, appropriate tests and scalable clinical methods are not readily available to analyze data, link outcomes with population or diagnosis norms or to make comparisons over time within a single patient.

In this retrospective clinical study, our primary aim was to establish an initial, scalable workflow to manage and analyze temporal pressure dynamics using existing urodynamics data. A secondary aim was to test early functional implications of these measurements by testing for fill-dependent changes during cystometric filling. As a proof of concept for this approach, we specifically tested two hypotheses: 1) Does the spectral power for bladder pressure across this frequency band (1-10 cycles per minute (CPM)) change with bladder filling? 2) Does the mean weighted frequency of bladder pressure dynamics change with bladder filling?

STUDY DESIGN, MATERIALS AND METHODS

Deidentified data from 12 recent urodynamics tests performed at the clinic over a 60-day period were extracted from a Laborie Aquarius XTTM multichannel UDS system (Laborie Medical Technologies, Toronto, Canada) and converted to a suitable format for analyses in MATLAB. Each urodynamics series was divided into 300-second segments and smoothed using a 10-point moving average. Pressure changes over time were calculated for each segment to test for frequency components of both vesical and abdominal pressures (P¬ves; P¬abd). A reduction in True Volume was

used as a marker of voiding or leakage and restricted the analysis to filling-only segments. Temporal dynamics of the P¬ves and P¬abd vs time were calculated for the frequency range of 1-10 CPM using Fast Fourier Transform (FFT) with a resolution of 0.2 CPM for 300s segments. Segments abbreviated by a void were analyzed with a resolution of 0.35 to 1.55 CPM depending upon their duration. For frequencies with FFT(P¬ves) > FFT(P¬abd), the total FFT power attributable to the vesical-only signal and the weighted mean frequency for the spectral distribution were calculated for each filling segment.

RESULTS

The spectral power and weighted mean frequency were measured for a total of 48 segments in 12 data sets. Voiding was not detected in 3 data sets. For each data set we were able to measure power and mean frequency for each segment during filling, creating fill-dependent spectral analysis plots for all 12 patients.

For 10 of 12 data sets the spectral power in the final segment (just prior to void) was larger than the power measured during the initial filling duration (Fig 1). As a group, the mean spectral power significantly increased during filling (12.6 ± 3.5 vs 54.1 ± 19.0; mean ± SEM, P <0.05, Student's paired t-test, n=12).

The signal spectral composition (1-10 CPM) also changed with bladder filling. For 9 of 12 data sets the final mean weighted frequency (measured just prior to void) was less than that measured during the initial filling segment (Fig 2). Across the 12 data sets, there was a small but significant decrease in the mean weighted frequency during bladder filling (initial duration, 5.2 ± 0.3 CPM, vs final duration, 4.4 ± 0.4 CPM; mean ± SEM, P <0.05, Student's paired t-test, n=12).

For all segments across all patients, there was a weak but statistically significant relationship between the mean weighted frequency and spectral power (Pearson, P < 0.05, R = -0.312, N = 48). Higher total power was generally associated with lower mean weighted frequency.

INTERPRETATION OF RESULTS

Our workflow was useful for initial processing of clinical urodynamics data and allowed filling-dependent signal processing of relevant pressures and temporal dynamics. Initial results revealed filling-related changes in both summed spectral power as well as the mean weighted frequency with bladder filling.

While very early, the preliminary results suggest that we can capture and quantify the spectral composition of urodynamics signals captured during routine clinical testing. The filling dependent increase in spectral power in frequencies of 1-10 CPM is consistent with increasing autonomous contraction amplitudes observed during bladder filling. The small filling dependent decrease in mean frequency of the spectral distribution is more surprising; perhaps related to increased synchronization across detrusor areas during bladder filling. We will repeat and extend this study in additional retrospective and future clinical and preclinical prospective studies.

CONCLUDING MESSAGE

We have developed an early workflow process and have generated initial functional data using quantitative analytics of clinical urodynamics based upon temporal spectral composition and FFT power over the range from 1-10 CPM. Initial results suggest that these measurements may differentiate filling related activities in patients. Future work will expand these results to additional data sets and explore relationships between these measures and clinical diagnoses related to bladder dysfunctions.

FIGURE 1

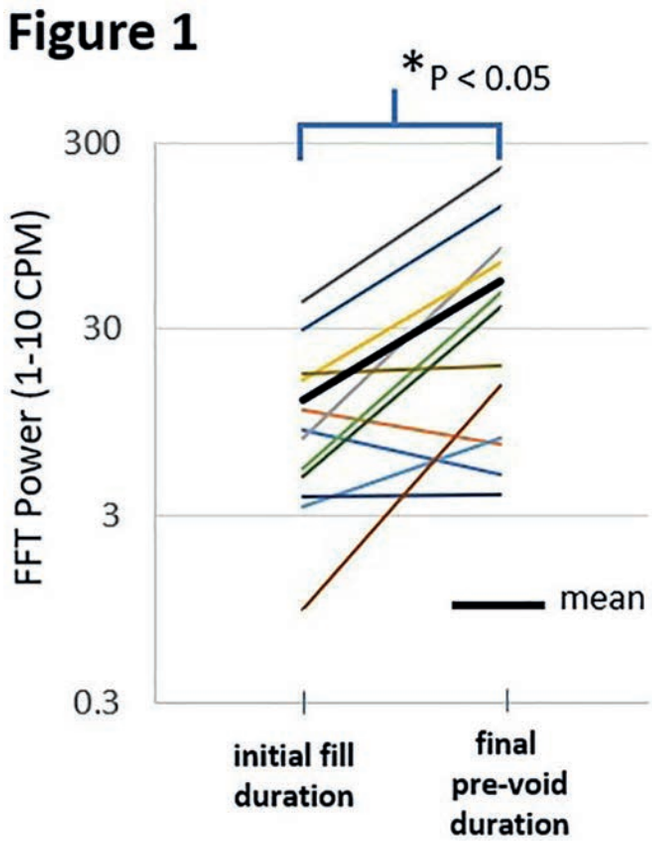

Fig. 1. Spectral Power, calculated from FFT(1-10CPM) as described, increases with bladder filling (Student's paired t-test, P<0.05, N=12). Individual data, colored lines, and mean data shown.

FIGURE 2

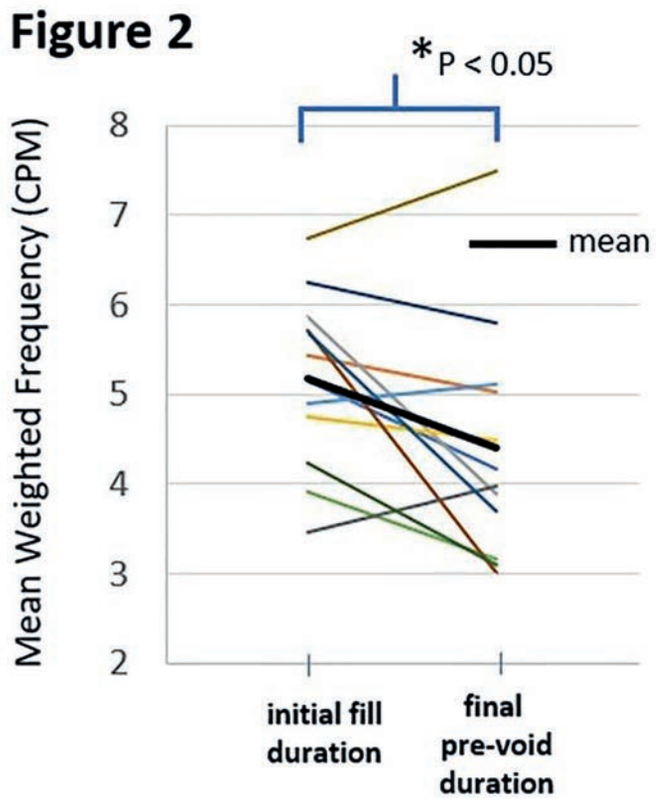

Fig. 2. Mean Weighted Frequency, calculated from FFT(1-10CPM) as described, decreases with bladder filling (Student's paired t-test, P<0.05, N=12). Individual data, colored lines, and mean data shown.

REFERENCES

1. Colhoun AF, Speich JE, Cooley LF, et al: Low amplitude rhythmic contraction frequency in human detrusor strips correlates with phasic intravesical pressure waves. World J Urol 2017; 35: 1255–1260.
2. Cullingsworth ZE, Kelly BB, Deebel NA, et al: Automated quantification of low amplitude rhythmic contractions (LARC) during real-world urodynamics identifies a potential detrusor overactivity subgroup. PLOS ONE 2018; 13: e0201594.
3. Drake MJ, Kanai A, Bijos DA, et al: The potential role of unregulated autonomous bladder micromotions in urinary storage and voiding dysfunction; overactive bladder and detrusor underactivity. BJU Int. 2017; 119: 22–29.

Funding NONE **Clinical Trial** No **Subjects** Human **Ethics Committee** University of Minnesota Institutional Review Board **Helsinki** Yes **Informed Consent** No

584 www.ics.org/2020/abstract/584

COMPARING THE PERFORMANCE OF THE NEW LASER FLOW CYTOMETER UF-5000 WITH UF-1000I AND GRAM STAIN IN PREDICTING BACTERIA GROWTH PATTERNS IN WOMEN WITH UNCOMPLICATED URINARY TRACT INFECTIONS

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HYPOTHESIS / AIMS OF STUDY

We prospectively compared the performance of the new flow cytometer UF-5000 with UF-1000i and Gram stain in predicting the bacterial patterns in urine samples obtained from community women with uncomplicated urinary tract infection (uUTI)

STUDY DESIGN, MATERIALS AND METHODS

From July, 2016 to June, 2019, women aged 20-80 years who visited urological clinics with symptoms suggestive of uUTI were invited to fill the questionnaire of Urinary Tract Symptoms Assessment questionnaire (UTISA). Patients with UTISA score 4 or more were invited to join the study, and those with urolithiasis, pregnancy, recent antibiotics use, neurogenic bladder or with urinary catheter were excluded. After signed informed consent and completion of a questionnaire for baseline characteristics, mid-stream urine sample was collected for gram staining, urine analysis and urine culture. Urine analyses were performed with the both models of laser flow cytometry (UF1000i and UF- 5000 Sysmex, Kobe, Japan). Trough the diagrams generated from laser flow cytometry, specimen was classified as none, cocci bacteria or rods/mixed growth in UF1000i. For UF- 5000 and gram staining, specimen was classified as none, cocci, rods or mixed growth. Standard urine cultures were performed, and the agreement between cultures and the UF1000i/UF5000/Gram staining interpretations was analyzed.

RESULTS

Finally, 102 samples from 102 women (age: 49.6 ± 16.6 years) with UTISA score of 10.7 ± 3.8 met the criteria for analysis. Among these samples, there were 10 gram-positive cocci, 2 gram-positive bacilli, 66 gram-negative rods, and 24 specimens with two bacteria species or more that were regarded as mixed growth. The sensitivity/specificity of UF-1000i was 81.8/91.1% for gram-negative rods and 23.5/96.9% for cocci/mixed. The sensitivity/specificity of UF-5000 was 80.0%/88.2% for gram negative rods and 70.0/86.5% for gram-positive cocci.

INTERPRETATION OF RESULTS
The results showed that the UF5000 keep a good sensitivity (80.0%) in identifying gram negative bacteria with acceptable specificity (88.2%). With regard to gram positive bacteria, UF5000 outperformed UF1000i in detecting gram positive cocci (sensitivity: 70 % and specificity: 86.5%) with good specificity which was comparable to gram staining (sensitivity: 60 % and specificity: 100%). However, the sensitivity of UF5000 for identifying mixed growth is poor. Gram staining is associated with a sensitivity rate of 88%, a specificity rate of 95%, a negative predictive value of 96%, and a positive predictive value of 84% for identifying bacteriuria.

CONCLUDING MESSAGE
UF-5000 demonstrated potential utility for the rapid screening of bacterial morphology, which inherited the good sensitivity and specificity of UF1000i for GNB bacteria and improve the sensitivity for detecting the Gram-positive cocci.

Funding Division of Urology, Buddhist Tzu Chi General Hospital, Taipei Branch, Taipei Taiwan, and Medical College of Buddhist Tzu Chi University, Hualien, Taiwan **Clinical Trial** No **Subjects** Human **Helsinki** Yes **Informed Consent** Yes

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FACTORS ASSOCIATED WITH UTI AND UROSEPSIS AFTER RENAL TRANSPLANT: A SINGLE CENTER EXPERIENCE

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HYPOTHESIS / AIMS OF STUDY
Renal transplant remains one of the most effective methods of treating end-stage renal disease in the US. However, with an increasing demand for renal transplant and extended wait times for patients receiving a renal transplant, it remains imperative to reduce complications that could decrease graft function. In renal transplant patients, urinary tract infection (UTI) remains one of the most common complications. Given its association with poorer graft function and patient survival, methods to reduce UTI in this subset of patients is important. If allowed to progress to urosepsis, the detrimental effects on graft function and patient morbidity and mortality are exacerbated. While antibiotic prophylaxis and immunosuppression adjustment have drastically reduced the incidence of UTI after renal transplant, the rate of serious complications remains high. Our objective is to evaluate factors associated with UTI and urosepsis in renal transplant patients to better identify patients at risk.

We hypothesize that there will be a correlation between a history of recurrent UTI or urinary retention with the development of postoperative UTI or urosepsis requiring hospitalization.

STUDY DESIGN, MATERIALS AND METHODS
A retrospective chart review was conducted examining 651 consecutive patients undergoing renal transplant between August 1, 2016, and July 30, 2019, at a tertiary care academic center. Patient demographics, medical history, surgical history, type and time on dialysis, and oliguria were collected. Primary outcomes examined were the occurrence of UTI and the occurrence of urosepsis with required hospitalization within one year of transplant. Variables were compared using Pearson's chi-squared test and the duration of dialysis was evaluated using a two-sample t-test in Stata.

RESULTS
Of the 651 patients undergoing renal transplant, 84 (13%) developed a UTI within 1 year of transplant. Compared to patients who did not have a UTI, those who developed a UTI post-transplant were more likely to have Diabetes Mellitus (Type 1 or 2) (56% vs 44%, p=0.033) and anuria (<100mL of urine/day, 37% vs 26%, p=0.039) prior to their transplant.

A similar trend was seen in patients who had to be hospitalized for urosepsis. They tended to be anuric (38% vs 27%, p=0.065) and were on dialysis longer (1599 vs 1244 days, p=0.0555) at the time of their transplant than patients who did not have to be hospitalized for urosepsis (Table 1). Of the 52 urosepsis patients, 6 (12%) underwent cystoscopy and 2 (4%) underwent voiding cystourethrography (VCUG).

INTERPRETATION OF RESULTS
There are identifiable risk factors associated with the development of UTI and urosepsis requiring hospitalization after transplantation. Based on the analysis for UTI, patients with a history of diabetes or who are anuric are at a higher risk of developing UTI and should be followed closely to protect their graft function. None of the measures we examined were significant factors in developing urosepsis. However, longer mean duration of dialysis for urosepsis patients did approach significance (p=0.0555). These factors may help identify patients that may require adjustment in their immunosuppression regimen and antibiotic prophylaxis.

CONCLUDING MESSAGE
UTI and urosepsis develop after renal transplantation in a small subset of patients. This is the first study to identify patient factors associated with UTI and urosepsis hospitalizations in this contemporary cohort.

FIGURE 1

	Total n=651	No Postoperative UTI n=567	Occurrence of Postoperative UTI n=84	p-value	No Postoperative Urosepsis Hospitalization n=599	Occurrence of Postoperative Urosepsis Hospitalization n=52	p-value
	n (%)	n (%)	n (%)		n (%)	n (%)	
Past Medical History							
Diabetes Mellitus (DM)	294 (45)	**247 (44)**	**47 (56)**	**0.033**	267 (45)	27 (52)	0.307
DM with end-organ complications	112 (17)	98 (17)	14 (17)	0.919	104 (17)	8 (15)	0.895
Benign Prostatic Hyperplasia	30 (5)	23 (4)	7 (8)	0.081	27 (5)	3 (6)	0.677
Prostate Cancer	27 (4)	21 (4)	6 (7)	0.14	23 (4)	4 (8)	0.181
Obstructive Sleep Apnea	69 (11)	61 (11)	8 (10)	0.732	66 (11)	3 (6)	0.238
Kidney Stones	58 (9)	53 (9)	5 (6)	0.308	57 (10)	1 (2)	0.065
Recurrent UTI	81 (12)	68 (12)	13 (15)	0.367	72 (12)	9 (17)	0.268
Past Surgical History							
Hysterectomy	55 (8)	47 (8)	8 (10)	0.704	51 (9)	4 (8)	0.838
Spinal Surgery	31 (5)	25 (4)	6 (7)	0.272	28 (5)	3 (6)	0.722
Prostate Surgery	19 (3)	15 (3)	4 (5)	0.282	17 (3)	2 (4)	0.679
Other Urologic Surgery	99 (15)	81 (14)	18 (21)	0.089	88 (15)	11 (210	0.213
Prior Renal Transplant	68 (10)	62 (11)	6(7)	0.289	63 (11)	5 (10)	0.838
ESRD-Specific Factors							
Oliguria	352 (54	302 (53)	50(60)	0.283	319 (53)	33 (63)	0.157
Anuria	179 (28)	**148 (26)**	**31 (37)**	**0.039**	159 (27)	20 (38)	0.065
Duration of Dialysis							
No Dialysis	96 (15)	88 (16)	8 (10)	0.374	91 (15)	5 (10)	0.72
Dialysis <1 year	100 (15)	89 (16)	11 (13)		92 (15)	8 (15)	
Dialysis 1-5 years	268 (41)	228 (40)	40 (48)		246 (41)	22 (42)	
Dialysis >5 years	187 (29)	162 (29)	25 (30)		170 (28)	17 (33)	
Type and Time on Dialysis							
History of Peritoneal Dialysis	110 (17)	92 (16)	18 (21)	0.235	97 (16)	13 (25)	0.104
History of Hemodialysis	456 (70)	395 (70)	61 (72)	0.581	420 (70)	36 (69)	0.894
Never on Dialysis	96 (15)	88 (16)	8 (10)	0.148	91 (15)	5 (10)	0.277
Mean Duration Dialysis (days)	1330	1257	1384	0.4112	**1243**	**1612**	**0.0555**

Table 1: Factors Associated with UTI and Urosepsis after Renal Transplant

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Exempt **Helsinki** Yes **Informed Consent** No

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MODIFIED PSOAS HITCH CAN REPLACE BOARI FLAP WITHOUT COMPROMISING VASCULARITY

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HYPOTHESIS / AIMS OF STUDY

The Boari Flap has been in the urologist's armamentarium for tension free reconstruction of mid and proximal ureteral defects for over 70 years. However, complications can occur because of compromised blood supply due to having incisions on 3 sides of the flap, and relying on the flap base as the only source of blood supply. Rates of ureteral stricture and anastomotic leak are quoted as high as 10 to 20%. We present our technique of a modified Psoas hitch that does not compromise blood supply, and can be as effectively as a Boari Flap in bridging long ureteral defects and ureteral substitutions.

STUDY DESIGN, MATERIALS AND METHODS

We retrospectively reviewed all patients who underwent our modification of the Psoas hitch performed by a single surgeon from 2008 to 2019. Our modification includes creating a semi-oblique cystotomy on the lowest part of the anterior and contralateral aspect of the bladder after complete release of the anterior surface of bladder. The contralateral superior vesical pedicle is sacrificed to allow for additional mobility if necessary. A series of short relaxing incisions at the different tethering levels in the pseudo flap segment are made until the bladder is able to reach the healthy ureter, and the ureter is anastomosed in a nonrefluxing or refluxing technique.

RESULTS

Patient demographics and characteristics are summarized in Table 1. Sixteen patients underwent this modified technique. Mean follow up was 20.4 months. Four (25%) patients had prior radiation, 3 (18.8%) underwent hyperthermic intraperitoneal chemotherapy (HIPEC) for peritoneal carcinomatosis at the same time of surgery, and 1 (6.3%) underwent repair of a transplant ureteral stricture. 8 cases involved intraoperative consults for which there was no preoperative planning. There was 1 with postoperative leak, and no patients had obstructive hydronephrosis to suggest flap ischemia. The mean length of the flap was 8.65 cm (2 cm to 16 cm).

INTERPRETATION OF RESULTS

In our experience with the modified Psoas hitch, we are able to offer patients another option for bridging large ureteral defects that is associated with low rates of complications with this simple technique.

CONCLUDING MESSAGE

Our modification of the Psoas hitch is reliable and can be used to reconstruct long ureteral strictures as well as serve as a substitution for patients with transplant ureteral strictures. It can be performed easily with a lower complication rates than traditional Boari Flap. This procedure is especially suitable in complex patients with high morbidity (such as prior radiation and peritoneal carcinomatosis) with decreased tissue vascularity.

FIGURE 1

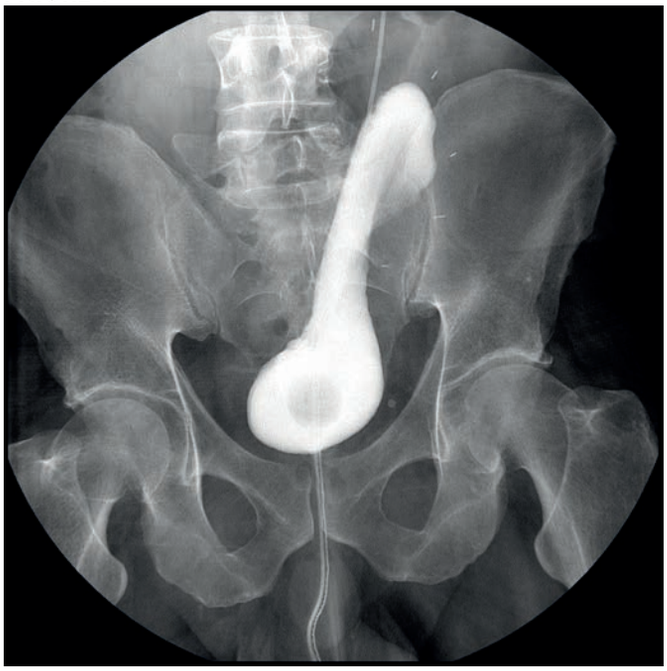

FIGURE 2

Table 1: Patient Characteristics, Demographics, Surgical Indications

Total number of patients	15	
* Males	4	
* Females	11	
Mean age (years)	58.5	(29 - 89)
Mean BMI (kg/m^2)	27.9	(16.7 - 50.9)
Left side procedures	8(53%)	
Right side procedures	6(40%)	
Transplant procedures	1(7%)	
HIPEC patients with peritoneal carcinomatosis	3(20%)	
Prior radiation history	4(27%)	
Average follow up (mo)	16.9	(1-60)
Lost to follow up	1	
Intraoperative Consultations	8	
* Ureteral injuries during hysterectomy	2	
* Ureteral resection for non-genitourinary malignancy	6	
Elective/planned Procedures	7	
* Primary procedure for urothelial ca of the ureter	1	
* Native ureteral stricture	5	
* Transplant ureteral stricture	1	

HIPEC - Hyperthermic Intraperitoneal Chemotherapy

REFERENCES

1. Wein, Alan J. et al. 1894-1968 Campbell. Campbell-Walsh Urology. 10th ed. Philadelphia, PA: Elsevier Saunders, 2012.
2. Rassweiler, Jens J. et al. "Ureteral Reimplantation for Management of Ureteral Strictures: A Retrospective Comparison of Laparoscopic and Open Techniques." European Urology, Volume 51, Issue 2, 512 – 523.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This was a retrospective study that did not require IRB approval **Helsinki** Yes **Informed Consent** No

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A TRIAL TO DEVELOP SERUM BIOMARKERS FOR INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME

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HYPOTHESIS / AIMS OF STUDY

The diagnosis of interstitial cystitis/bladder pain syndrome (IC/BPS) is still difficult because it relies on subjective symptoms and nonspecific objective findings. Until now, biomarkers have been studied mainly in urine, but none of them has been developed for practical use. Thus, we conducted a comprehensive analysis to identify serum biomarkers of IC/BPS and validate their usefulness.

STUDY DESIGN, MATERIALS AND METHODS

[Study 1] From January 2013 to February 2014, we sampled the blood from 25 patients with IC/BPS (4 men and 21 women; age: 63.2 ± 17.1 years), 10 age-matched subjects without lower urinary tract syndromes (LUTS; 10 women; age: 64.7 ± 6.8 years), and 15 younger subjects without LUTS (15 women; age: 35.5 ± 9.5 years). We used metabolomics to search for candidate substances in the serum. [Study 2] From August to December 2017, we sampled the blood from 5 female patients with Hunner-type IC (HIC; age: 58.2 ± 19.3 years) and 5 female subjects without LUTS and compared the concentration of candidate substances as a pilot prospective study. [Study 3] From January to February 2019, we sampled blood from 25 female patients with HIC (age: 70.4 ± 10.9 years) and 25 female subjects without LUTS (age: 66.1 ± 8.5 years) and compared the concentration of a candidate substance as a prospective study. In addition, the concentration of phospholipid was measured and the ratio of the candidate to phospholipid was calculated to improve the accuracy as a biomarker.

RESULTS

[Study 1] We analyzed 678 metabolites; 58 metabolites were not significantly different among generations, but they were significantly different between patients with IC/BPS and the subjects without LUTS. We selected 1-linoleoylglycerophosphocholine (1-LPC 18:2; sensitivity, 80%; specificity, 70%) as a candidate biomarker. [Study 2] For the prospective study, we estimated the sample size to be ≥13 people in each group (type 1 error, 5%; power, 90%) because the concentration of 1-LPC 18:2 was 20.0 ± 7.0 and 31.0 ± 9.8 μg/mL

in patients with HIC and subjects without LUTS, respectively. [Study 3] The concentrations of 1-LPC 18:2 were significantly different between patients with HIC and subjects without LUTS (27.9 ± 6.3 vs 40.4 ± 15.1 μg/mL, $p < 0.0003$). If we set the cutoff value of 1-LPC 18:2 at 28.4 μg/mL, the sensitivity and specificity would be 68% and 84%, respectively (Figure 1). The concentrations of phospholipid were significantly different between patients with HIC and subjects without LUTS (2146 ± 348.3 vs 2318 ± 277.5 μg/mL, $p = 0.0366$). The ratios of 1-LPC 18:2 to phospholipid were significantly different between patients with HIC and subjects without LUTS (13.1 ± 2.6 vs 17.4 ± 6.0 ‰ , $p = 0.0013$). If we set the cutoff value of the ratio at 15.7 ‰, the sensitivity and specificity would be 88% and 68%, respectively (Figure 2).

INTERPRETATION OF RESULTS

Lysophospholipids may be associated with the pathology of IC/BPS. In recent years, lysophospholipids have been recognized as the second lipid mediators next to prostaglandins and are next-generation drug targets. By focusing on lysophospholipids, it may be possible to elucidate the pathology and develop therapeutic drugs from a new perspective.

CONCLUDING MESSAGE

The serum concentration of 1-LPC 18:2 and the ratio of 1-LPC 18:2 to phospholipid are useful as candidate biomarkers of IC/BPS.

FIGURE 1

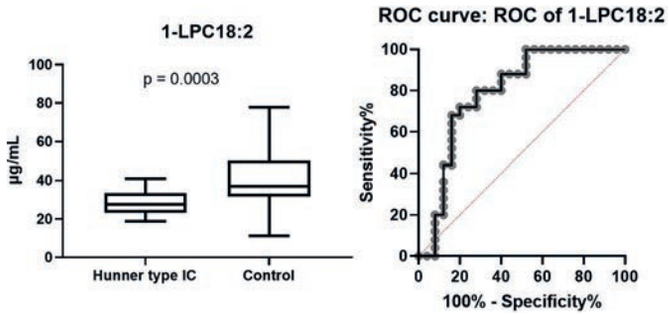
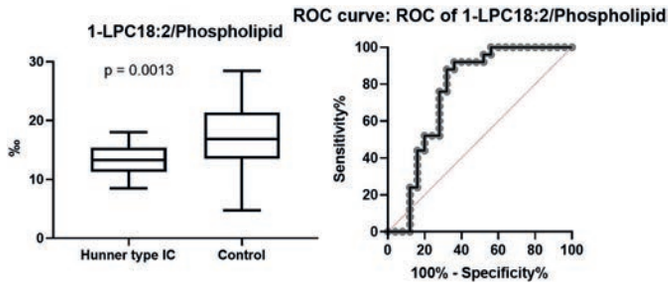


FIGURE 2



Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Nara Medical University Certified Review Board **Helsinki** Yes **Informed Consent** Yes

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A RANDOMIZED CONTROLLED STUDY COMPARING B3 AGONISTS AND ANTICHOLINERGICS IN THE TREATMENT OF THE LOWER URINARY TRACT SYMPTOMS (LUTS) IN PATIENTS WITH MULTIPLE SCLEROSIS (MS)

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HYPOTHESIS / AIMS OF STUDY

Multiple Sclerosis (MS) is the most frequent autoimmune demyelinating disease of the Central Nervous System. Patients suffering from MS usually present with overactive bladder syndrome. Most common symptoms are increased frequency, urgency, incontinence and nocturia. LUTS occur on average 6 years after the onset of MS while all patients experience LUTS within a period of 10 years since the initial diagnosis. Our objective is to evaluate the efficacy and safety of treating patients with MS and LUTS using either b3 agonist (mirabegron) or anticholinergics.

STUDY DESIGN, MATERIALS AND METHODS

This is a prospective, randomized, controlled, single center study including 91 patients with MS and LUTS. At baseline all patients underwent thorough clinical examination including neurological examination and DRE. Medical history was recorded. All patients underwent urine test, urine cultivation and abdominal ultrasound. All patients completed an urination diary (for at least 3 consecutive days) and specific questionnaires such as MusiQoL and NBSS. At second visit all patients were administered either a b3 agonist (mirabegron) or anticholinergics. More specifically, 46 patients (Group 1) received mirabegron 25mg or 50mg and 45 patients (Group 2) received solifenacin 5mg or 10mg, or fesoterodine 4mg or 8mg. The choice of the drug dosage was not random and was based on the baseline characteristics of each patient. The treatment was always carried out alongside with the MS treatment. Reevaluation was performed 3 months after the

first visit. All patients underwent the same clinical and imaging tests that were carried out at first visit. A statistical analysis was performed in both groups using the t-test.

RESULTS
We compared several clinical and imaging parameters (scores of the 2 questionnaires, potential pelvic or calyceal dilatations, increased urine residual volume, infection, Qmax flow rate) between the two groups at first visit and 3 months after treatment. In both groups improvement in LUTS was recorded in most of the tested parameters. Statistical significant difference from baseline evaluation up to reevaluation was recorded in terms of urine infection (p value≤0.01), MusiQoL score (p value <0.001), NBSS score (p value<0.05), dairy urgency episodes (p value <0.001), dairy number of urinations (p value <0.001) and urination volume (p value <0.001) in both groups. Nevertheless, comparison between Group 1 and Group 2 revealed no statistical difference. No patients discontinued medications due to side-effects.

INTERPRETATION OF RESULTS
All patients in both groups showed a statistical significant improvement in most of the tested parameters, from baseline up to reevaluation. There was no difference in symptoms improvement in the mirabegron group compared to the anticholinergic group.

Thus, all drugs tested presented similar efficacy and safety.

CONCLUDING MESSAGE
All MS patients receiving either mirabegron or antimuscarinic therapy for LUTS showed an improvement. No statistical difference was noted between the two groups in all the tested parameters.

Funding There was no funding support for the conduction of this paper. **Clinical Trial** Yes **Public Registry** No **RCT** Yes **Subjects** Human **Ethics Committee** ARETAIEION HOSPITAL ETHICS COMMITTEE **Helsinki** Yes **Informed Consent** Yes

SESSION 38 (PODIUM SHORT ORAL) - INFECTION AND POT POURRI
Abstracts 589-600
15:00 - 16:30, Brasilia 2
Chairs: Prof Nucelio L B M Lemos (Canada), Dr Vani Dandolu (United States)

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LEVATOR ANI MUSCLE AVULSION AFTER VAGINAL BIRTH BETWEEN ROUTINE VERSUS RESTRICTIVE EPISIOTOMY

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HYPOTHESIS / AIMS OF STUDY
The changes in urogenital organ morphology or tomography might have a clinical effect on the subsequent development of pelvic organ prolapse and urinary incontinence. It has been established that levator ani muscle avulsion increases the risk of pelvic organ prolapse. [1] Levator ani muscle avulsion from vaginal birth resulting in decreased pelvic floor muscle strength, vaginal hiatal enlargement and pelvic organ prolapse. [2] Vaginal birth is the strongest risk for developing pelvic organ prolapse and the prevalence of levator injury was reported approximately 13-36%. [3] The severity of sphincter tear and vaginal laceration were found to be independent clinical predictors of increased risk of levator ani muscle avulsion. To prevent pelvic organ prolapse following vaginal delivery, a reduced degree of perineal laceration may be the potential role. Therefore, we conducted the study to compare levator ani muscle avulsion following vaginal birth with routine versus restrictive episiotomy.

STUDY DESIGN, MATERIALS AND METHODS
The prospective observational study recruited postpartum primiparas women with normal vaginal delivery at a tertiary hospital between February and December 2016. Deliveries were classified as routine or restrictive episiotomy. Inclusion criteria include postpartum primiparas women with vaginal delivery at 6-12 weeks postpartum periods, age over 18 years and no pelvic surgery for prolapse or pelvic trauma before. Exclusion criteria include postpartum primiparas women who were delivered vaginally with preterm baby, non-cephalic presentation, twin delivery or instrumental delivery.

RESULTS
Sixty-one post-partum women participated in our study. Thirty-two women (52.5%) have undergone routine episiotomy. While twenty-nine (47.5%) have been performed restrictive episiotomy. The mean age + SD of routine and restrictive episiotomy were 24.8 + 4.5 and 25.0 + 5.3 years, respectively. The mean BMI + SD of routine was 21.3 + 2.3 kg/m2 and restrictive episiotomy was 22.4 + 3.4 kg/m2. There were no statistical differences in age and BMI between two groups. (p= 0.89 and p= 0.13, respectively). Right mediolateral episiotomy was performed in all cases. The rate of anal

sphincter tear after routine episiotomy was detected 12.5% and restrictive episiotomy was 13.8% (p=1.00).

Regarding the baby weight and baby head circumference, there were no statistical differences between two groups (p= 0.28 and p=0.68, respectively). No statistical differences in the duration of the first and second stages of labor between two groups (p=0.15 and p=0.72, respectively). No statistically significant differences of pelvic floor dysfunction symptoms such as stress urinary symptoms, overactive bladder symptoms, dragging sensation and vaginal laxity at 6-12 weeks after delivery.

Levator ani avulsion was detected only on right-sided after routine episiotomy (9.4%) and restrictive episiotomy (10.3%) (Figure1). No bilateral levator avulsion was found. There were no statistically significant differences regarding the incidence of avulsion between two groups (p=1.00). Regarding other pelvic floor parameters, there were no statistical differences of the bladder neck descent, cystocele descent, uterine descent, rectocele descent and the ballooning of the genital hiatus area as shown in Table1.

INTERPRETATION OF RESULTS

There were no differences in the rate of levator avulsion between routine and restrictive episiotomy. Moreover, the differences were not detected on other pelvic floor parameters.

CONCLUDING MESSAGE

The restrictive episiotomy did not reduce the rate of levator ani avulsion when comparing with the routine episiotomy. Moreover, this technique did not also improve the pelvic floor parameters.

FIGURE 1

	Routine episiotomy N=32	Restrictive episiotomy N=29	*p*- Value
Bladder neck descent (Mean± SD)	19.6 + 7.2	19.6 + 7.1	0.99
Cystocele (Mean± SD)	7.6 + 8.1	8.5 + 7.6	0.67
Uterus (Mean± SD)	22.1 + 8.2	22.7 + 10.3	0.81
Rectocele (Mean± SD)	8.6 + 8.9	9.8 + 10.0	0.61
Rectal ampulla (Median (IQR))	0 (0- 0)	0 (0- 0)	0.82
Area at rest (Mean± SD)	18.6 + 2.7	17.9 + 2.8	0.36
Area on Valsava (Mean± SD)	24.4 + 4.3	22.5 + 5.1	0.11
Area difference (Median (IQR))	5.6 (2.7-7.2)	3.3 (1.8- 7.0)	0.24
Levator ani avulsion at right side (n; percent))	3 (9.4%)	3 (10.3%)	1.00
Levator ani avulsion at left side	0 (0%)	0 (0%)	
Levator ani avulsion both sides	0 (0%)	0 (0%)	

Table 1 shows pelvic floor parameters between two groups

FIGURE 2

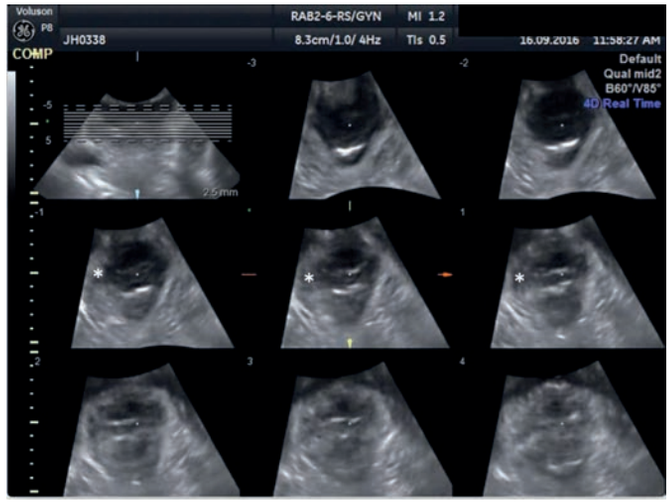

Figure 1 shows the tomographic imaging of right side levator ani avulsion

REFERENCES

1. Dietz HP. Pelvic floor ultrasound: a review. Am J Obstet Gynecol. 2010;202:321–34.
2. DeLancey JOL, Morgan DM, Fenner DE, Kearney R, Guire K, Miller JM, et al. Comparison of levator ani muscle defects and function in women with and without pelvic organ prolapse. Obstet Gynecol. 2007;109:295–302.
3. Schwertner-Tiepelmann N, Thakar R, Sultan AH, Tunn R. Obstetric levator ani muscle injuries: current status. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2012;39:372–83.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Khon Kaen University **Helsinki** Yes **Informed Consent** Yes

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FACTORS PREDICTING THE SUBOPTIMAL RESPONSE OF THE FRONTLINE MEDICAL TREATMENT IN WOMEN WITH DYSFUNCTIONAL VOIDING

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HYPOTHESIS / AIMS OF STUDY

The definition of dysfunctional voiding was made by videourodynamic result of detrusor contraction (high or normal pressure) with a narrowing outlet at the level of external sphincter. These patients can be treated with alpha blocker and/or muscle relaxant as the medical treatment. However, some patients may not have a good response to medical

treatment (i.e. suboptimal response) and require change or add-on medications, or surgical treatment. Understanding the factor predicting the suboptimal response may be helpful for early change of medications or surgical treatment. Thus the aim of this study is to elucidate the factors predicting the suboptimal response of the frontline medical treatment in women of dysfunctional voiding.

STUDY DESIGN, MATERIALS AND METHODS

Medical records of all consecutive women with dysfunctional voiding who received alpha blocker and/or muscle relaxant as the frontline medical treatment in a tertiary referral center were reviewed. A suboptimal response to the frontline medical treatment was defined as change or add-on medication, or surgical treatment after the initiation of the frontline medical treatment. Multivariable backward stepwise Cox proportional hazard modeling were performed to predict the suboptimal response to the frontline medical treatment by using all variables with $p<0.05$ in the univariate analysis.

RESULTS

Between July 2011 and November 2019, a total of 60 women with dysfunctional voiding were included in this retrospective study. Twenty-five women were found to have the suboptimal response to the frontline medical treatment, including urethral botox injection (n=11), transurethral incision of the bladder neck (n=3), add-on medication (n=3) and change of medication (n=8). Multivariable Cox proportional hazard modeling revealed Pdet.Qmax (hazard ratio = 1.010), bladder capacity (hazard ratio = 1.004) and the use of Urief (hazard ratio = 0.320) were independent factors predicting the suboptimal response to the frontline medical treatment (Table 1 and Fig 1A & 1B). Pdet.Qmax ≥37 cmH2O was determined to be the optimum cut-off value to predict the suboptimal response using receiver operating characteristic (ROC) analysis, which provided an area under the ROC curve of 0.58 (95% confidence interval = 0.42 to 0.73; sensitivity = 68.0%, specificity =51.4%, Fig 1C). Bladder capacity ≥465 mL was determined to be the optimum cut-off value to predict the suboptimal response, which provided an area under the ROC curve of 0.69 (95% confidence interval = 0.55 to 0.83; sensitivity = 40.0%, specificity =94.3%, Fig 1D).

INTERPRETATION OF RESULTS

High Pdet.Qmax and large bladder capacity were associated with the suboptimal response to the frontline medical treatment. Nonetheless, the use of Urief seems associated with optimal response to the frontline medical treatment.

CONCLUDING MESSAGE

High Pdet.Qmax and large bladder capacity were factors predicting the suboptimal response to the frontline medical treatment. In addition, Urief seems to a better choice for women with dysfunctional voiding.

FIGURE 1

Fig 1. Probability of optimal response to the frontline medical treatment in (A) all women with dysfunctional voiding and (B) between the Urief and the other medications groups

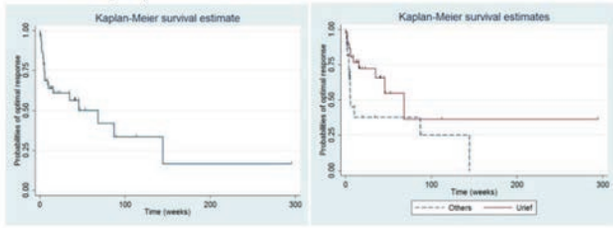

Fig 1. The receiver operating characteristic curve for (C) detrusor pressure at maximum flow and (D) bladder capacity as predictors of the suboptimal response

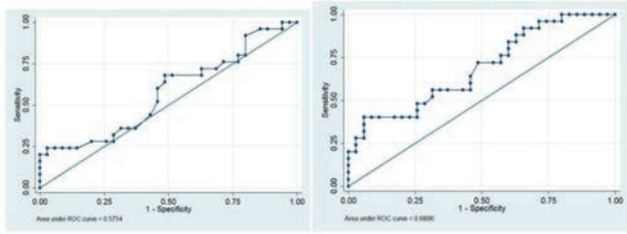

Fig. 1

FIGURE 2

Table 1. Baseline characteristics and Cox proportional hazard modeling for predicting the suboptimal response to the frontline medical treatment in women with dysfunctional voiding (n=60)

		Univariate			Multivariable		
Variable	Value	HR	95% CI	p	HR	95% CI	p
Age (years)	60.8±18.7	1.009	0.987~1.031	0.42	-	-	-
Hypertension	27 (45)	0.961	0.433~2.133	0.92	-	-	-
Diabetes	15 (25)	0.972	0.356~2.653	0.96	-	-	-
IPSS-V	7.5±4.9	1.029	0.926~1.144	0.60	-	-	-
IPSS-S	7.5±4.2	1.061	0.926~1.217	0.39	-	-	-
IPSS-V/S	1.1±0.7	1.061	0.449~2.509	0.89	-	-	-
IPSS-T	14.9±8.3	1.022	0.961~1.088	0.48	-	-	-
Frequency	31 (52)	0.779	0.343~1.768	0.55	-	-	-
Urgency	32 (53)	0.636	0.279~1.449	0.28	-	-	-
Incontinence	7 (12)	2.167	0.721~6.514	0.17	-	-	-
Nocturia	2 (3)	1.503	0.201~11.247	0.69	-	-	-
Difficult urination	25 (42)	1.654	0.746~3.557	0.22	-	-	-
Urine retention	5 (8)	3.308	1.111~9.853	0.03	-	-	-
Bladder pain	4 (7)	0.961	0.127~7.254	0.97	-	-	-
First sensation of filling (mL)	127±72	1.002	0.997~1.007	0.45	-	-	-
Pdet.Qmax (cmH_2O)	43.8±30.3	1.011	1.003~1.020	0.01	1.010	1.001~1.019	0.04
Maximum flow rate (mL/s)	9.1±5.8	1.019	0.954~1.087	0.58	-	-	-
Voided volume (mL)	183±119	1.001	0.998~1.004	0.49	-	-	-
Postvoid residual volume (mL)	130±141	1.002	1.000~1.004	0.10	-	-	-
Bladder capacity (mL)	316±140	1.004	1.001~1.007	0.01	1.004	1.001~1.007	0.02
VE	0.61±0.34	0.572	0.188~1.742	0.33	-	-	-
BOOI	25.8±34.1	1.009	1.001~1.017	0.03	-	-	-
Detrusor overactivity	30 (50)	0.745	0.332~1.671	0.48	-	-	-
Urief	38 (63)	0.411	0.184~0.915	0.03	0.320	0.134~0.749	0.009
Baclofen	17 (28)	2.129	0.908~4.994	0.08	-	-	-
Tamsulosin	15 (25)	1.727	0.742~4.019	0.21	-	-	-
OAB medication	16 (27)	1.415	0.603~3.322	0.43	-	-	-

Values are expressed as mean ± standard deviation or number (percentage). BOOI = bladder outlet obstruction index; CI = confidence interval; HR = hazard ratio; IPSS = International Prostate Symptom Score; IPSS-S = IPSS-storage subscore; IPSS-T = total International Prostate Symptom Score; IPSS-V = IPSS-voiding subscore; IPSS-V/S = IPSS voiding to storage subscore ratio; OAB = overactive bladder syndrome; Pdet.Qmax = detrusor pressure at maximum flow rate; VE = voiding efficiency.

Table 1.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** Research **Ethics Committee**, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation **Helsinki** Yes **Informed Consent** Yes

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MANCHESTER OPERATION FOR ELONGATION OF THE UTERINE CERVIX- IS IT A SAFE PROCEDURE?

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HYPOTHESIS / AIMS OF STUDY

Manchester operation for elongation of the uterine cervix was first described by Archibald Donald from Manchester England in 1888 and modified later by William Edward Fothergill in 1915 (1). The surgery was designed to treat symptomatic cervical elongation in the presence of mild uterine prolapse. The Manchester operation is a minimally invasive procedure that enables uterine preservation and thus keeping the possibility of future pregnancy and childbirth.

Following the 2019 FDA's warning regarding the use of mesh for pelvic organ prolapse (POP) repair, there has been a growing interest in classical surgical techniques that use native tissue, such as Manchester operation. However, data regarding the efficacy and safety of the Manchester operation are extremely scarce and there is a real need to get up-to-date data.

The aim of the present study was to investigate the efficacy, complications, and clinical outcomes of Manchester operation for women with POP mainly related to elongation of the uterine cervix.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective cohort study of all Manchester operations that were done between 2010 and 2019 in a single Urogynecology and Pelvic Floor Reconstruction unit of a tertiary hospital. The study was approved by the local IRB. The major surgical steps of the Manchester operation include amputation of the cervix, suspension of the cervical stump by suturing the cut ends of Cardinal Ligaments in front of cervix (Fothergill sutures), and formation of a posterior vaginal flap into the cervix (Sturmdorf suture) for re-epithelialization of the cervical canal. Care is taken through surgery to keep the cervical canal open.

Medical records of all patients who underwent Manchester operation were reviewed. Demographic and surgical data were collected in real time and stored in a computerized database. The computerized medical charts were reviewed for general characteristics, such as age, body mass index (BMI), parity, smoking status, postmenopausal status, POP staging, and surgical data including duration of operation, blood loss during surgery, length of hospital stay, early and late postoperative complications, as well as follow up visits.

RESULTS

Overall, 35 patients (mean age 54.2 ± 10.5 years) underwent Manchester operation between 2010 and 2019. Demographic and clinical characteristics of the patients are presented in table 1. Of the 35 patients, 34 had significant elongation of the uterine cervix. One other patient was scheduled for vaginal hysterectomy but due severe pelvic adhesions the procedure was converted to Manchester operation. Twenty-five patients (71%) underwent a concomitant repair such as anterior colporrhaphy, posterior colporrhaphy, or mid urethral sling procedure (TVT-O).

There were no intraoperative complications. The Operation time for patients who underwent Manchester operation only, was less than 30 minutes. Mean hemoglobin levels before and after surgery were not significantly different (12.17±1.2 g/dl versus 11.02±1 g/dl, respectively). One patient underwent surgical revision 24 hours after surgery for increased vaginal bleeding and the anterior aspect of the cervical stump was re-sutured. Mean Hospital stay was 48 hours.

There were four cases of late postoperative complications: one patient had vesicovaginal fistula that was diagnosed two months postoperatively. The second patient underwent drainage of hamatometra three months postoperatively with complete recovery thereafter. The third patient presented with abdominal pain and fever six months after surgery. Ultrasound examination revealed heterogeneous contents within the uterus. The presumed diagnosis was pyometra. The patient underwent a failed hysteroscopic attempt to drain the uterus under anesthesia and therefore total abdominal hysterectomy was undertaken. The forth patient presented nine months after surgery with small bowel evisceration through the posterior vaginal fornix. This complication was probably due to significant underweight (BMI 19) and poor tissue healing.

INTERPRETATION OF RESULTS

Manchester operation seems to be an effective and safe alternative procedure for the treatment of POP caused by true cervical elongation. The surgery is short, blood loss is minimal and without any significant early complications. In addition, the surgery enables uterine preservation in women who are interested in this option. However, there may be significant complications during the first year after surgery, especially hamatometra or pyometra due to post-operative cervical stenosis. It is therefore important, that the surgery will be carried out with a strict technique and skilled surgeons who are capable to manage unique postoperative complications.

CONCLUDING MESSAGE

The Manchester operation is an effective surgical procedure for symptomatic patients with elongation of the uterine cervix. However, this procedure is not free of complications and

therefore it is recommended that this operation will be done by surgeons who underwent formal training in pelvic floor reconstructive surgery.

FIGURE 1

Age (Yr.)	54.2±10.5
BMI	26.58±4.7
Parity	2.62±1.66
Previous Operative Delivery	3(8.5%)
Previous Cesarean Section	3(8.5%)
Previous Pelvic Floor Surgery	8(22.9%)
Menopause	14(40%)
Smoker	3(8.5%)
Pre-operative POP Q Stage:	
II	8 (22.9%)
III	27(77.1%)
IV	0
Concomitant Surgery:	
Anterior colporrhaphy	25(71.5%)
Posterior colporrhaphy	25(71.5%)
Mid Urethral Sling	25(71.5%)

REFERENCES

1. Dastur AE, Tank PD. Archibald Donald, William fothergill and the manchester operation. J Obstet Gynaecol India. 2010;60(6):484–485. doi:10.1007/s13224-010-0058-4

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THE ROLE OF THE APICAL DEFECT IN THE PATHOGENESIS OF PELVIC ORGAN PROLAPSE: CYSTOCELE WITH APICAL DEFECT.

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HYPOTHESIS / AIMS OF STUDY

The aim of current study was the examination of the influence of level I defect on building of cystocele.

The proposed approach of urogynecological examination which combines the use of the basic form of POP-Q scale and the modified clinical classification by DeLancey, taking into account the impact of level I defects on pelvic organ prolapse in level II in anterior compartment. The inclusion of the apical defect has a significant impact on the decision making process, as it alters the surgical management of pelvic organ prolapse and promotes methods that focus on repairing the anatomical cause of the defect rather than just its clinical presentation.

STUDY DESIGN, MATERIALS AND METHODS

This study includes 302 women, who reported complains connected to pelvic organ prolapse. The patients were examined using a new, simple and standardized method of urogynecological examination which assumes the simultaneous application of the basic form POP-Q System and the modified classification of lower pelvic organ prolapse by DeLancey expanded by the impact of level I defect (apical defect) on level II prolapse in anterior compartment.

In presennted study the patient was placed in the lithotomy position on a gynecological chair with an averagely-filled bladder (about 200-250 ml assessed by ultrasound measurement). The examination started with the assessment of the vulva, perineum and vagina at rest and at maximum Valsalva. Then, using two Kristeller specula, the following were evaluated:

using anterior and posterior specula - level I

using the posterior speculum - anterior compartment, level II - cystocele and level III - urethrocele. The influence of the reposition of level I defect on the cystocele.

using the anterior speculum - posterior compartment, level II - recto- or enterocele, not taking into account in current study

If the cystocele was present, the type of defect was assessed as lateral or central. For a cystocele with a lateral defect the vesical fascia is unilaterally or bilaterally detached from the arcus tendineus, vaginal rugae are preserved, whereas in the case of a cystocele with a central defect the vaginal mucosa appears smooth.

Then, after inserting both specula, the patient was asked to perform the Valsalva maneuver during which the specula were slowly pulled out of the vagina and the position of the reference point for level I was assessed. As the reference point, the authors agreed on the vaginal cuff for patients after a hysterectomy or the point where the anterior and posterior fornix merge with the vaginal portion of the cervix. This method allows to assess a defect at level I.

By detection level I defect with concomitant cystocele presence it is necessary to insert the posterior speculum which restores the leading part of the prolapse at level I. Once the level I defect has been compensated, the possible changes in the presentation of the cystocele was evaluated. It is possible that the cystocele completely disappears, if the exclusive cause for its presence at level I defect is reasoned. In case of cystocele caused of mixed defect at level I and II reposition of level I using posterior specula the cystocele get smaller but it doesn't disappear. In this situation the examiner should quote the extension of the cystocele before reposition of level I and quote the extension of the cystocele after

reposition together with determination of the type of level II defect. The cystocele caused exclusive by lateral or central defect requires lack of level I defect.

RESULTS

The 302 patients aged 27-88 years, among the study group 188 (62%) were postmenopausal women, and 114 (38%) premenopausal. In terms of their BMI, 51% of patients had a normal weight, 3% were underweight, 32% were overweight, and 14% were obese. Regarding the family history of POP, approximately one third of women (28%) had positive family history. The demographic and clinical characteristics as well as life-habits are presented in table.

The apical defect was present in 218 patients (72.2%), where the frequency of cystocele caused by apical defect, mixed central or lateral cystocele coexists with apical defect were 30.8%, 9.6% and 31.8% of all cystocele, respectively.

Thus, a lateral cystocele with concomitant defect at level I was 3-times more frequent than central cystocele coexists with defect at level I. Cystocele caused exclusive by a defect of the vesicovaginal fascia was found in 84 patients (27.8%) - central defect cystoicele was founded only in 13 patients (4.3%) and in 71 patients (23.5%) a cystocele with a lateral defect was identified. Therefore, isolated lateral defects were 5.5-times more often recognized than isolated central defects in studied population.

INTERPRETATION OF RESULTS

Analysis of differences between particular parameters and types of defects has shown that the number of pregnancies, parity, weight of the biggest newborn and age by first delivery were not statistically significant. However, for two of the parameters (age and BMI) significant differences were observed. The mean age in the mixed apical/central defect was significantly higher compared to lateral ($p<0.001$), apical ($p = 0.012$) and mixed apical/lateral ($p = 0.031$) defects. Similarly, mean values of BMI were significantly higher in the mixed apical/central cystocele than in lateral ($p = 0.002$), apical ($p = 0.003$) and mixed apical/lateral ($p = 0.005$) defects.

Besides, cystocele caused by isolated central or mixed apical/central defect were observed more often in women over 50 years of age with overweight and obesity.

In terms of the family history, the detailed examination revealed its relationship to age of onset of pelvic organ prolapse. The mean age of women with family history was significantly lower ($p = 0.035$) in relation to those without family history. Interestingly, the frequencies of women with family history in the eleven established groups were higher in younger women (up to 45 years of age).

Our approach to POP-Q system, especially regarding cystocele assessment, may be a useful tool for planning causal operative treatment of pelvic organ prolapse. However, prospective analysis of recurrence following corrective surgery according to proposed system of urogynecological examination is needed. Additionally, larger epidemiological studies should be carried out to determine the incidence of the defects specified in the modified DeLancey scale and to develop imaging methods for the apical defect, particularly in ultrasonography and magnetic resonance imaging (MRI). Currently, sonography has only limited significance in assessing the apical defect, it doesn't recognize consequently over 70 % of POP defects. MRI seems to be more promising, although MRI is not the standard procedure urogynaecological examination in planning of surgical treatment.

We postulated that the proposed system of urogynecological examination and then appropriate surgical treatment for defect repair can improve the effectiveness of surgical therapy of cystocele and significantly reduce the rate of recurrence.

CONCLUDING MESSAGE

The results of this study indicate a significant role of the apical defect in the development of pelvic floor disorders in woman, especially in the anterior compartment. Not taking the influence of apical defect at level II anterior compartment into account while planning surgical procedure exposes a large group of women to ineffective treatment.

FIGURE 1

Patient characteristics/ Variable	Type of cystocele				
	Central (C)	Lateral (L)	Apical (Ap)	Mix Ap-C	Mix Ap-L
N (%)	13 (4,3%)	71 (23,5%)	93 (30,8%)	29 (9,6%)	96 (31,8%)
Age (mean±SD)	64.1±13.3	50.4±14.9	56.3±12.3	66.6±11.3	56.9±15.7
Number of pregnancies	2.2 (1-4)	2.4 (1-6)	2.4 (1-7)	2.8 (1-10)	2.4 (1-6)
Parity, mean (range)	1.9 (1-3)	2.0 (1-5)	2.2 (1-5)	2.5 (1-10)	2.1 (1-6)
Instrumental delivery (%)	4	4.9	2.9	1.4	2.4
Caesarean (%)	4	2.8	2.4	4.1	1.5
Weight of biggest child [g], mean (range)	3,571.0 (2,700-4,690)	3,537.7 (2,275-4,700)	3,506.8 (2,640-4,900)	3,533.8 (3,000-4,500)	3,725.8 (2,900-5,100)
Age by first delivery, mean±SD /median (range)	25.0±3.6 25.0 (18-32)	24.3±7.1 25.0 (18-35)	23.3±7.7 25.0 (19-38)	23.0±5.8 23.0 (18-32)	25.0±1.0 24.5 (18-46)
BMI, mean (range)	26.8 (19-37)	25 (17.3-35.6)	25.4 (18.3-39)	28.5 (20.7-45.7)	25.3(18.3-35.4)
Menopause (n)	11	31	58	28	60
Family history of POP (n)	2	26	27	8	21
Hernia/varices/asthma (n)	1/ 4/ 3	6/ 18/ 1	2/ 23/ 3	1/ 8/ 2	5/ 22/ 0
Smoking (n)	1	7	9	2	7

Ap/C – mixed apical and central defect
Ap/L – mixed apical and lateral defect

Table Patient baseline characteristics

REFERENCES

1. Kantartzis KL1, Turner LC, Shepherd JP, Wang L, Winger DG, Lowder JL.Apical support at the time of hysterectomy for uterovaginal prolapse.Int Urogynecol J. 2014 Sep

3. [Epub ahead of print] http://www.ncbi.nlm.nih.gov/pubmed/25182150
2. Tunn R, Albrich S, Beilecke K, Kociszewski J, Lindig-Knopke C, Reisenauer C, Schwertner-Tiepelmann N, Kuhn A, Viereck V, Bjelic Radisic V, Kölle D, Umek W, Bader W, Schwandner O, Lange R. Interdisciplinary S2k Guideline: Sonography in Urogynecology: Short Version - AWMF Registry Number: 015/055. Geburtshilfe Frauenheilkd. 2014 Dec;74(12):1093-1098. PMID: 25568465
3. Summers A, Winkel LA, Hussain HK, DeLancey JO. The relationship between anterior and apical compartment support. Am J Obstet Gynecol. 2006;194(5):1438–43. [PMC free article] [PubMed] [Google Scholar]

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SACROCOLPOPEXY IN WOMEN OVER AGE 75 YEARS OLD : IS IT POSSIBLE?

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HYPOTHESIS / AIMS OF STUDY

Pelvic floor disorders are common among and disproportionately affect older women. There are limited data regarding functional and anatomic outcomes in older women undergoing laparoscopic sacrocolpopexy (LSC)

The primary aim of this study was to evaluate the functional and anatomic outcomes after laparoscopic sacrocolpopexy in women over age 75 years old with symptomatic, advanced pelvic organ prolapse.The secondary aim was to evaluate the postoperative complication.

STUDY DESIGN, MATERIALS AND METHODS

This was a prospective single centre study, on patients over age 75 years old with symptomatic POP stage >II in according to POP-Q system underwent LSC. Preoperative evaluation included: history, clinical examination, urodynamic testing, trans labial ultrasound. They completed Patients preoperatively completed self-administered Urinary Distress Inventory Short Form (UDI-6), Incontinence Impact Questionnaire–Short Form (IIQ-7), for urinary symptoms, and Female Sexual Function Index Questionnaire (FSFI) for sexual dysfunction. All surgical procedures were performed by two senior surgeons.

Anti incontinence surgery was not performed simultaneously. They were followed up at 1,3,6,12 months after surgery and then annually with the same preoperative protocol. Urodynamic testing was performed 6 months after surgery, and annually they performed uroflowmetry. At last visit they completed also PGI-I questionnaire Anatomic success was defined as prolapse stage<II for all compartments, point C≤5 and at least 7 cm for total vaginal length. Failure to correct normal support (stage 0 or I) was considered as persistence of prolapse and return to a higher stage following initial correction was considered a prolapse recurrence. The postoperative complications were classified in according to Clavien–Dindo classification.Statistic test: Nc Nemar and Chi test, $p<0.05$.

RESULTS

From January 2016 to January 2017, 20 consecutive women underwent LSC for symptomatic advanced pelvic organ prolapse sacrocolpopexy in our tertiary urogynaecological center. Age mean was 76.7±1.9,follow up median was 42.3 (36-48 months). Preoperatively, no patient was sexually active (table 1) and the FSFI was not completed, all underwent previous hysterectomy (12 abdominal hysterectomy and 8 vaginal hysterectomy).At last visit the cure rate of anterior compartment was 95.6%, 100% for central compartment and 94.3% for posterior compartment. No patients had recurrence in any compartments. One and two out of 20 patients (5% and 10%) had asymptomatic anterior and posterior persistence (stage II) respectively. None of these patients underwent reoperation. Six months after after surgery there was an improvement of all urodynamic parameters (Table 2); at last visit there was an improvement of maximum flow at uroflowmetry ($p<0.0001$).Detrusor underactivity persisted in 7 women after surgery, while the bladder outlet obstruction disappeared in all patients. The stress urinary incontinence persisted after LSC in all patients (8 pts) and there were 2 de novo cases. The urgency urinary incontinence resolved in 8 women (40%), and there were 2 de novo cases. The voiding symptoms resolved in all patients, without de novo cases; storage symptoms disappeared in 10 women (55%) with 2 de novo cases OAB symptoms were treated with beta 3 agonist. Constipation persisted in all patients with 2 de novo cases. There was one case of vaginal mesh exposure, and it was treated conservatively.PGI-I score was high in all women, 95% of patients reporting that they are “very much better” or “much better” with the surgery. According to the Clavien Dindo Classification, in there were four cases of grade I complications (nausea, vomiting, fever).

INTERPRETATION OF RESULTS

Colposacropexy as well as in young women also in elderly women has good anatomical outcomes. The stress urinary incontinence persisted in all patients after surgery probably because the intrinsic sphincter deficiency was a condition quite severe in the elderly. The storage symptoms and urgency incontinence are influenced by aging and this could explain the de novo cases. The vaginal mesh exposure rate was low probably because they were all previously hyster-

ectomized patients. The constipation did not improve in any patient, probably because they were severe cases, and in literature there is no evidence of an improvement of the outcomes after LSC

CONCLUDING MESSAGE

These results showed that the LSC remains the gold standard even in elderly patients with good anatomic and functional results and few complications, if performed by expert hands

FIGURE 1

Table 1 Demographic and clinic data

Parameters	value
Age mean ±SD	76.7± 1.9
BMI median (range)	25.8 (21.87-37.11)
Menopause n(%)	20 (100)
Parity, median (range)	2 (2-5)
Sexual activity n(%)	0
Previous hysterectomy n(%)	20(100)
Diabetes	3 (15)
Hypertension	18(90)

FIGURE 2

Functional outcomes	Preoperative	Postoperative	P value
Urodynamic stress incontinence	13(65)	4(20)	0.25
Bladder capacity ml (mean±SD)	304.9±77.7	341±71.3	0.001
PdetQmax cmH2O (mean±SD)	37.4±21.0	25.3±14.3	0.0001
Qmax ml/sec (mean±SD)	12.12±4.4	21.8±4.2	0.0001
Qmax ml/sec (mean±SD) at last follow up visit	12.12±4.4	22.3±3.5	0.0001
Bladder outlet obstruction n(%)	20(100)	0	nv
Detrusor underactivity n(%)	13(65)	7 (35)	0.63
Voiding symptoms n(%)	20(100)	0	nv
Storage symptoms n(%)	19 (95)	9(45)	0.002
Constipation n(%)	7(35)	9(45)	0.5
Stress urinary incontinence (%)	8(40)	10 (10)	0.5
Urgency urinary incontinence (%)	18 (90)	11 (55)	0.01

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** CEAS UMBRIA **Helsinki** Yes **Informed Consent** Yes

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NOTES COMBINED TRANSURETHRAL-TRANSVAGINAL APPROACH FOR VESICOVAGINAL FISTULA REPAIR.

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HYPOTHESIS / AIMS OF STUDY

Vesicovaginal fistula (VVF) is an abnormal epithelized/fibrotic connection between the bladder and vagina, with the consecuence of continuous urinary incontinence, that represents a physical, psychological, sexual, emotional, economical, debilitating, social stigma condition and affects quality of life of women. The true incidence is difficult to know due to underreports (around 0,3-2%); in developed countries it arises mainly as a complication of pelvic-gynecological surgery (80-90%), and from underdeveloped countries the main aetiology is obstetric (>90%). (1)

Although various conservative and non or minimally invasive treatments has been described (bladder drainage alone, electric or laser fistula tract fulguration, fibrin or collagen sealants application, platelet enriched plasma infiltration), the mainstay treatment for VVF is surgical repair, following basic principles such as adequate exposure and identification of structures, wide mobilization, excision of the fistula tract, tension-free closure, interposition flaps, good hemostasis and uninterrupted bladder drainage. Different surgical approaches (transabdominal, tansvaginal, transurethral) are used based on the fistula location (supra or infratrigonal), size (diameter), relation to bladder structures (ureteral meatus, bladder neck, urethra), complexity (uni or multiple), risk factors (radiotherapy), but as there is no best approach, the expertise and training of the surgeons is very important for the decision; in general, simple-infratrigonal fistulas are managed by a vaginal approach, whereas complex-supratrigonal fistulas are either repaired through abdominal or combined approachs. (2)

Among minimally invasive techniques, the NOTES Combined Transurethral-Transvaginal Approach (NOTES-CTTA) represents a good option for the management of VVF; compared to simple transvaginal approach, it could achieve a better exposure of the surgical field to facilitate a successful fistula repair, while compared to the transabdominal approach, NOTES-CTTA only used the natural body cavities (no incisions to the body surface), with the advantages of small surgical injury, minimal bleeding, and rapid recovery. (3)

The aim of our communication, is to show the efficacy and security of the NOTES-CTTA for resection and repair of a VVF, refractory to conservative management.

STUDY DESIGN, MATERIALS AND METHODS

A 33 years old women without medical antecedents, started with continuous urine leakage through vagina, 1 week after labor assisted with forceps. Cystoscopy identified a <1cm left trigonal orifice (near bladder neck and 2cm from left ureteral meatus). Vaginal exploration (filling bladder with methylene blue), show leakage through a <1cm orifice in anterior vaginal wall. With the diagnosis of simple trigonal VVF, and in consensus with the patient, placement of a 16ch urethral bladder catheter was performed; 6 weeks after (with the catheter 24hours open-connected to bag), cystography and cystography-CT scan demonstrated no contrast from bladder to vagina. Bladder catheter was retired, reappearing immediately continuous incontinence. Cystoscopy and vaginal exploration, showed the persistence of the trigonal VVF, so we decide to perform a NOTES-CTTA. In lithotomy position, under 30º cystoscopic vision, the fistula was tutorized with a guidewire and 3F fogarty balloon (introduced from the vagina into the bladder). Transurethral endoscopic excision was performed with a continuos flow 26ch resector, using Collins-knife electrode with bipolar energy and 0,9% saline irrigation; we were able to precisely surround and excise the fibrotic tissue of the fistula tract. Transvaginal closure of the defect was performed maintaining the lithotomy position, in 3 separate layers: bladder mucosa (continuous 4-0 monocryl), detrusor (continuous 3-0 vicryl), and vaginal mucosa (single 3-0 vicryl). A suprapubic bladder catheter 12ch was placed (due to bad tolerance to previous urethral bladder catheter), and an iodized-vaseline gauze package was left in the vagina. Continuous 0,9% saline bladder irrigation was left for 12 hrs (throuh suprapubic catheter and simple urethral foley). Transurethral fistula resection time was 10 minutes, vaginal closure time 15 minutes, and total surgery time 50 minutes. The patient was discharged from hospitalization 36hours after surgery, without vaginal package and foley urethral catheher, with the suprapubic catheter open-connected to bag.

RESULTS

None Clavien-Dindo >2 complications were observed. Pathology analysis confirm complete excision of fibrotic VVF. After 1 month with suprapubic bladder catheter 24hours open-connected to bag, cystography, cystoscopy, and physical exploration with methylene blue were performed, showing complete resolution of the fistula; suprapubic bladder catheter was removed, and the patient started with normal micturition without incontinence. With a 3-6 months follow up after surgery, the patient referred a complete reincorporation to normal activities (laboral, social, and sexual), and excellent quality of life.

INTERPRETATION OF RESULTS

Although this simple-small VVF was managed initially by conservative treatment with urethral bladder catheter, as no improvement happened, surgical repair was required. Delayed elective surgery was performed 2,5 months after the injury, when local inflammation and edema disappeared, and mucosal membranes became soft for dissection.

Different as described in the publication of Xie et al (3), we decide to perform this technique as a primary surgical indication for VVF; we did not place ureteral catheters; complete transurethral resection of the fistula scar was performed with the Collins-knife electrode up to the vagina; as the deffect was located on the proximal anterior vaginal wall, we suture it with cystoscopic assistance, without changing the patient to a prone position (saving time for the surgery); postoperatory hospital stay was only 36hrs, and althoug our recommendation was to remove the suprapubic bladder drainage 2 weeks after the surgery, we left it 1 month due to preference of the patient (affraid of recurrence).

In concordance with Xie et al (3), the deffect was closed in 3 layers; one month after the surgery the vaginal exploration showed no leakage when bladder was filled with normal saline stained with methylene blue, and cystography and cystoscopy demonstrated no fistula. During the follow-up period, no urinary leakage or incontinence was observed.

CONCLUDING MESSAGE

When conservative management of VVF fails, surgery repair must be performed due to personal and social implications it represents for patients, with an impact on quality of life.

In the era of minimal invasive surgery, the NOTES-Combined Transurethral-Transvaginal Approach, has the advantage of small surgical injury with better surgical field exposure, gives the surgeon an excellent view that permits a complete excision of the fistula fibrotic-epithelized tissue with control of the ureteral meatus, selective hemostasis could be performed, and repair of the defect in separate layers with satisfactory anastomosis, always following the basic principles for this kind of surgery, without significants complications and rapid postoperatory recovery.

This technique must be considered as a primary minimally invasive option for the treatment of simple, small, infratrigonal VVF, not only reserved as a rescue surgery after failure of previous surgical procedures.

REFERENCES

1. Shanmugasundaram R et al. Vesicovaginal fistula: Review and recent trends. Indian J Urol. 2019 Oct-Dec; 35(4): 250–258.
2. Huang WC et al. Surgical repair of vesicovaginal fistulas. Urol Clin North Am. 2002 Aug;29(3):709-23.
3. Xie M et al. Vesicovaginal fistula repair through combined transurethral and transvaginal approaches: a case series study. J Gynecol Obstet Hum Reprod. 2018 Nov;47(9):487-490.

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ARE UNNOTICED AND CONTINUOUS URINARY INCONTINENCE SEVERE PATTERNS OF INCONTINENCE?

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HYPOTHESIS / AIMS OF STUDY

-ICIQ-UI short form is a self administered questionnaire that aims to evaluate the frequency, intensity, impact in quality of life and pattern of urinary incontinence (UI). The first two questions about frequency and intensity of incontinence have graded answers. Quality of life (QoL) is measured as an analogical scale from 0 to 10. The last part of the questionnaire describes different UI patterns which lets us categorize into stress, urgency, mixed, enuresis or postmicturitional urinary incontinence.

-Leaking when you cough or sneeze or when you are physically active or exercising are characteristic of stress UI. Leaking before getting to the toilet is characteristic of urgency incontinence and Mixed UI has characteristics of both. But "leaking for no obvious reason" or "all the time" are not characteristic of any type of UI, but they seem to confer severity to UI. Our goal is to determine wether these last two patterns add severity to pure stress, urgency or mixed urinary incontinence

STUDY DESIGN, MATERIALS AND METHODS

-We retrospectively reviewed 395 records of women evaluated for LUTS.

-Neurogenic patients were excluded

-Patients were categorized into 3 main UI patterns: stress, urgency and mixed.

-These patterns were subcategorized as "severe" (S) if they also "leaked all the time" or "for no obvious reason" and "non-severe" (NS) if they did not.

-Frequency, intensity and quality of life scores between the 3 main patterns of UI were compared, as well as between S and NS UI patterns with Kruskal-Wallis test

RESULTS

-Sixty nine patients (17.4%) were excluded because they did not have UI and 33 (8,3%) because they did not fit in any of these patterns (3 had postmicturition UI, 23 had only unnoticed or continuous incontinence but not any of the 3 main types of UI and 7 did not have any pattern).

-A total of 293 patients were included: 62 (21,2%) had SUI (48 NS-SUI, 14 S-SUI); 75 (25,6%) UUI (57 NS-UUI, 18 S-UUI) and 156 (53,2%) MUI (66 NS-MUI, 90 S-MUI).

-In Figure 1, we show how scores for frequency, amount and QoL are significantly different for the 3 main UI patterns. MUI had the highest scores, followed by UUI and finally SUI with the lowest scores.

-S-UI patterns had significantly higher scores than NS-UI patterns for every main type of UI pattern (Figure 2).

INTERPRETATION OF RESULTS

-SUI, IUU and MUI have different partial ICIQ-UI short form scores.

-Patients with S-UI leak more frequently and a greater amount of urine than NS-UI patients and their QoL is worse for any of the 3 main patterns of UI.

CONCLUDING MESSAGE

If a non-neurogenic woman with SUI, UUI or MUI leaks for no obvious reason or all the time, her UI is worse for every aspect evaluated in the ICIQ-UI short form questionnaire.

FIGURE 1

	Median Frequency	IQR	p	Median Amount	IQR	p	Median QoL	IQR	p	Total ICIQ sum	IQR	p
SUI	3	1-4	<0,001	2	2-4	>0,001	5	3-9	<0,001	11	7-16	<0,001
UUI	4	2-4		4	2-4		8	4-9		14	9-18	
MUI	4	4-5		4	4-6		9	7-10		17	14-19	

Frequency, intensity and QoL for the main UI Patterns

FIGURE 2

	Median Frequency	IQR	p	Median Amount	IQR	p	Median QoL	IQR	p	Total ICIQ sum	IQR	p
PURE SUI	2,5	1-4	0,004	2	2-4	0,004	5	1-8	0,087	10	4-15	0,014
SEVERE SUI	4	4-4		4	4-4		6	5-10		15	12-18	
PURE UUI	4	2-4	0,001	2	2-4	0,015	7	3-9	0,005	14	9-16	0,002
SEVERE UUI	4,5	3-5		4	2-6		8,5	8-10		18	14-21	
PURE MUI	4	3-4	<0,001	4	2-4	>0,001	7	5-8	>0,001	14	11-17	>0,001
SEVERE MUI	4	4-5		4	4-6		10	8-10		18	16-20	

Comparison of Severe and Non-Severe scores for each of the main types of UI patterns

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It´s a retrospective anonymous study with general conclusions **Helsinki** Yes **Informed Consent** No

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THE IMPACT OF RADIATION TREATMENT ON THE MID-URETHRAL SLING IN WOMEN WITH GYNECOLOGY MALIGNANCIES; EXPERIENCE IN A LARGE UROLOGY/UROGYNECOLOGY PRACTICE.

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HYPOTHESIS / AIMS OF STUDY

This article aims to describe the outcomes of a mid-urethral sling(MUS) in women with gynecology malignancies and additional adjuvant radiotherapy

STUDY DESIGN, MATERIALS AND METHODS

This descriptive study was conducted retrospectively through a chart review at a large urology and urogynecology practice from May 2000 through May 2019 and approved by the institutional review board(IRB). A chart review was performed for women who underwent the treatment of gynecology malignancies and MUS. All cases were identified and collected by using the procedure code (sling placement 57288, sling revision 57287) and diagnosis code ICD-9 and -10 of gynecology malignancies and confirmed by reviewing operative records and pathology reports of each case. Demographic features, description of operative procedures, clinicopathologic results, and postoperative follow-up data, including adjuvant treatment for cancer and complications related to the procedures, were collected from the electronic medical records of the outpatient clinic. Descriptive statistical analyses were performed.

RESULTS

We identified a total of 70 women with a diagnosis of gynecology malignancies who also underwent MUS between May 2000 and May 2019.

The mean age of patients was 63 years. The most common type of cancer was endometrial (n=50, 71%), and the rest were ovarian (n=18), tubal (n=2), and cervical (n=1) in origin.

Seventy-four percent (n=52) underwent retropubic MUS, and 26% (n=18) had trans-obturator (TOT) sling. About 26% (n=18) of total patients received POP repair and MUS concurrently with staging operation for a diagnosis of cancer. There were four cancer cases (2 tubal cancers, one endometrial cancer, and one ovarian cancer) incidentally detected during MUS concurrent with POP repair. These women subsequently underwent a cancer staging procedure within four weeks.

Among patients with a history of gynecology cancer, eighteen percent (n=13, mean and median age of 72 years) were found to have undergone adjuvant radiation treatment before or after the MUS procedure; 10 patients (69%) had MUS before the treatment of cancer with adjuvant radiotherapy, with a time span between MUS and radiotherapy ranging from 53 days to 5 years (median 127 days). Three patients (23%) underwent MUS after radiation treatment, and the time interval ranged from 10 months to 3 years. The mean follow-up period after MUS and radiation treatment was 12 months. Of these, in the subset of the radiation group of 13 patients, only one patient (7%), developed mesh extrusion, eventually requiring a sling revision and reoperation. This patient had undergone a retropubic sling after external adjuvant radiotherapy for cervical cancer. The rest of the radiation group who received the adjuvant brachytherapy for endometrial cancer did not have any mesh complications, were satisfied with the outcome and did not require any additional procedure.

INTERPRETATION OF RESULTS

There is limited data on the effect of radiation on a synthetic MUS, as patients with a history of pelvic irradiation have explicitly been excluded from many of the clinical trials assessing anti-incontinence procedures. Without more data, there is a concern of a potential risk of a foreign body placement if it may be followed by pelvic radiation or if the patient had previous pelvic radiation.

We described the outcome of MUS in patients who subsequently underwent radiation treatment or had undergone radiation immediately after or years after the MUS. Only one patient underwent mesh revision and eventually re-operated on for recurrent incontinence; the complication is likely attributable to a relatively higher dose of radiation applied to the patient with cervical cancer. Most patients (n=12 out of 13) did well without complications such as mesh extrusion or reoperation; all twelve patients received vaginal adjuvant brachytherapy after surgical treatment of endometrial cancer. This outcome indicates the safety of MUS in the majority of patients who have had a sling prior to or subsequent to radiation, especially among patients with endometrial cancer.

Our study suggests that patients with gynecologic cancers that need a concomitant urogynecologic procedure should get it with minimal increase in risk regardless of a possible need for subsequent radiation.

CONCLUDING MESSAGE

Pelvic floor disorders, including urinary dysfunction, are common urogynecologic problems among the elderly population. However, these conditions are likely to be undertreated or ignored, especially in women undergoing treatment of gynecologic malignancies.

Based on the results from our descriptive study, a MUS can be performed safely in patients undergoing endometrial cancer staging and additional adjuvant radiation treatment.

Given the impact of stress incontinence on the quality of life of these patients, further studies with larger numbers are needed to confirm our findings.

REFERENCES

1. Bochenska K, Mueller M, Geynisman-Tan J, et al. Concomitant Repair of Pelvic Floor Disorders in Women Undergoing Surgery for Gynecologic Malignancies. Female Pelvic Medicine & Reconstructive Surgery. 2019;25(5):362-364.
2. Dobberfuhl AD. Evaluation and treatment of female stress urinary incontinence after pelvic radiotherapy. Neurourology and Urodynamics. 2019;38(S4):S59-S69.
3. Bodean OM, Marcu RD, Spinu DA, et al. Pelvic floor disorders in gynecological malignancies. An overlooked problem?(Report). Journal of Mind and Medical Sciences. 2018;5(1):COV7.

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IS ABNORMAL IMMUNOLOGY ASSOCIATED WITH RECURRENT URINARY TRACT INFECTIONS?

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HYPOTHESIS / AIMS OF STUDY

Urinary tract infections (UTI's) are one of the most frequent causes of infection in both community and hospital settings. (1) Diagnosis of UTI's is conducted using urinary symptoms and urine culture (1). Presently investigation of recurrent urinary tract infections includes excluding anatomical abnormalities, functional disorders of the lower urinary tract, for example voiding dysfunction and metabolic disorders including diabetes mellitus. Previous studies into recurrent UTI's describe risk factors that increase susceptibility such as: sexual intercourse, use of spermicides, previous UTI's, history of maternal UTI and age at first UTI. The latter two suggesting a genetic aspect to susceptibility. However, there have been no previous studies to assess the association of the immune system and recurrent urinary tract infections. This study aims to identify if there are any immunological markers that are associated with a patient's susceptibility to recurrent UTI's.

STUDY DESIGN, MATERIALS AND METHODS

This was a retrospective study of women attending the urogynaecology clinic in a tertiary centre. Women with vaginal prolapse, lower urinary tract symptoms or recurrent UTI can be referred to the clinic. At each visit, women had a urine analysis conducted alongside clinical evaluation. Urine microscopy and culture (UCEM) studies were requested depending on urinalysis and / or patient symptoms. Women were included in this study if they had had one or more urinary tract infection. Patients were classified as having recurrent urinary tract infections if they experienced three or more UTIs within a year, with a UTI requiring at least one microorganism to be cultured.

The following immunological investigations were also carried out as part of the regular assessment: IgA, IgM, IgG, IgG subclasses, serum diamine oxidase (DO) and mannose binding lectin (MBL). Patients requiring a cystoscopy and bladder biopsy had a mast cell analysis carried out on the biopsy sample. The mast cell count (MCC) was obtained using CD117 immuno-histochemical staining. A MCC of >28 mm2 was considered elevated.

Statistical analysis was performed using SPSS v26, Chicago, USA.

RESULTS

In total 227 women were included in the study. The age range was 18 to 91 years. 124 women were classified as experiencing recurrent urinary tract infections. 103 women had 2 or less urinary tract infections within a year.

In total 34 different organism were identified from urine culture reports. The 5 most common organisms accounted for 73.5% of all positive results. These top 5 organisms were present on average 80.0% of the time at a concentration above 100,000 cfu/ml. The incidence of organisms found in urinary tract infections is presented in Table 1.

Overall, in 50.7% of urinary tract infections only one organism was cultured. Women who experienced recurrent UTI's were more likely to have multiple organisms present during the infection, (Chi-squared = 33.852, p value = 5.946e-9). This suggests that if the urinary tract infection is caused by multiple organisms, women are more likely to be susceptible to recurrent UTI's.

We compared the women with recurrent UTI's and women with ≤2 UTI's in 1 year with overall IgG, IgM and IgA levels using a Chi-square test. No significant association was found (Table 2). A comparison with the IgG subclasses using a Chi-squared test was made (Table 2). Women with recurrent UTI's were more likely to have low IgG2 levels (<2.4 g/L) compared with women experiencing ≤2 UTI's in 1 year (Chi-squared= 8.562, p=0.003).

In addition, women with a low MBL were not at increased susceptibility to recurrent UTI's (Chi-Squared= 0.316, p value= 0.574, t-test p value = 0.250).

From bladder biopsy results, women with recurrent UTI's were not more likely to have an increased mast cell count (>28 mm2) (Chi-squared= 0.791, p value= 0.374) in the bladder mucosa.

The average age of menopause in the United Kingdom is 51 years of age. Of women experiencing recurrent UTI's, 66.1% of them were pre-menopausal. Pre-menopausal women had an increased susceptibility to recurrent UTI (p = 0.017) Chi-squared= 5.693. There was no association found with menopausal status and MBL levels.

INTERPRETATION OF RESULTS

This retrospective study has identified the association between low IgG2 levels and recurrent UTI's which has previously not been shown. IgG1 and IgG2 are the predominant subclass contributors to the IgG class (2).

Present literature states a deficiency in mannose binding lectin is due to genetic predisposition and confers an increased susceptibility to recurrent infection (3). Studies have been conducted in respiratory tract infections however there is a lack of research investigating this theory in urinary tract infections. The study findings show that MBL is not thought to be a predisposing factor to recurrent urinary tract infections in women, even when assessed independently as pre and post-menopausal groups.

CONCLUDING MESSAGE

These are the first results demonstrating that an immune deficiency of low IgG2 can be associated with developing recurrent UTI's in women.

FIGURE 1

Organism Name	Percentage Incidence (%)
Escherichia coli	34.2
Enterococcus species	24.9
Klebsiella pneumonia	5.2
Staphylococcus haemolyticus	4.8
Coliform	4.4
Beta haemolytic strep B group	3.8
Staphylococcus epidermidis	3.0
Candida species	2.6
Staphylococcus aureus	2.0
Citrobacter coseri	2.0
Other	13.1

Table 1: Incidence of organisms present in urinary tract infections. Of the Enterococcus species, 74.29% were Enterococcus faecalis.

Table 1

FIGURE 2

		Non-Recurrent Urinary Tract Infection (UTI)	Recurrent Urinary Tract Infection (UTI)	Chi-squared	p-value
IgG	Mean	10.157	9.720	0.01	1.00
	Range	9.910	12.690		
IgA	Mean	1.803	1.783	0.149	1.00
	Range	4.430	3.400		
IgM	Mean	1.382	1.304	2.465	0.254
	Range	3.110	3.550		
IgG1	Mean	6.576	6.154	1.512	0.371
	Range	7.070	6.990		
IgG2	Mean	3.327	3.471	8.562	0.003
	Range	5.880	6.740		
IgG3	Mean	0.439	0.363	0.538	0.463
	Range	1.240	0.930		
IgG4	Mean	0.513	0.436	0.999	0.448
	Range	8.770	1.840		

Table 2: Mean and range values of immunological markers in recurrent and non-recurrent urinary tract infections.

Table 2

REFERENCES

1. Foxman, B. The epidemiology of urinary tract infection. Nat Rev Urol. 2010;7:653–660. Available from: doi: https://doi.org/10.1038/nrurol.2010.190
2. Agarwal S, Cunningham-Rundles C. Assessment and clinical interpretation of reduced IgG values. Ann Allergy Asthma Immunol. 2007;99(3):281–283. Available from: doi:10.1016/S1081-1206(10)60665-5.
3. R. Colodner, O. Nitzan, B. Chazan, H. Edelstein and R. Raz. Mannose-binding lectin in pre-menopausal women with recurrent urinary tract infections. Clin Microbiol Infect. 2010;16:1394–1398. Available from: doi: 10.1111/j.1469-0691.2010.03107.x

Funding NONE **Clinical Trial** No **Subjects** Human **Ethics not Req'd** It was a retrospective service evaluation. **Helsinki** Yes **Informed Consent** Yes

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A RAPID, POINT-OF-CARE ANTIBIOTIC SUSCEPTIBILITY TEST FOR URINARY TRACT INFECTIONS

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HYPOTHESIS / AIMS OF STUDY

The lack of a rapid, point-of-care antibiotic susceptibility test(AST) has led to misuse of antibiotics in urinary tract infections (UTI). To address this issue, we present a rapid point-of-care phenotypic AST device, which can report antibiotic susceptibility/resistance of a uropathogen against a panel of antibiotics in as fast as 2hrs by utilizing fluorescent labelling chemistry and a highly sensitive particle counting instrument.

STUDY DESIGN, MATERIALS AND METHODS
BiesseBioscreen is an instrument developed by ASI that allows measuring the concentration of fluorescent particles into a liquid. Measurements were performed diluting at first 30µl of urine samples in 1ml of isotonic solution (i.s.) and incubating for 7mins at 80°C. After dilution,30µl 0.05mM of nucleic fluorescent probe (SYTOX®Orange Nucleic Acid Stain, INVITROGEN) were added to the samples. The probe entered the bacterial wall and concentrated into it allowing its recognition by the instrument. After 60sec the operator could read on the instrument screen the CFU/ml measurement. A CFU/ml≥5x104CFU/ml was considered a cut-off for positivity. A panel of 5 antibiotics(amoxicillin clavulanate, ciprofloxacin, ceftazidime, fosfomycin and nitrofurantoin) was selected. For each unique patient sample that tested positive for UTI screening, an aliquot of the raw urine sample was spiked into each of the 6 culture tubes for a final concentration of 5x104CFU/ml. At time points of 0,1,2, and 3hrs, 30µl from each tube was collected and added to a cuvette containing 3ml of i.s. plus 30µl of Sytox orange(0.05 mM), heated for 7mins at 80°C and scanned for 30sec on the particle counter unit. Tubes were incubated at 37°C between subsequent time points. Presence of at least 5x104CFU/ml was considered resistance to the selected antibiotic. Results were compared to standard urine cultures (VITEK® 2ASTinst,BioMérieux).

RESULTS
We considered 87 UTI-positive patient urine samples; using a panel of 5 common UTI antibiotics plus a growth control, a total of 1740 measurements were performed. Comparing our results to the urine cultures, it was obtained an overall sensitivity=81%, specificity=83%, a sensitive predictive value=95% and a resistant predictive value=54%.

INTERPRETATION OF RESULTS
We demonstrated the ability of BiesseBioscreen device [1] to differentiate between sensitive and resistant bacteria with specificity up to 100% to over a 2 hour growth period. By reducing the timeframe to accurately assess antibiotic resistance from 2-3 days to 2 hours, our point-of- care phenotypic AST has potential to provide critical information to clinicians prior the administration of antibiotic therapy. For all the samples measured at least one antibiotic among those chosen for the measure was in accordance for sensitive with the gold standard of the microbiology laboratory.

CONCLUDING MESSAGE
According to our preliminary data, the sensitive predictive value for a single antibiotic agent is 95%, thus allowing (in most cases) an early (within 2hrs) recognition of an effective agent in the patient. Further studies are needed to confirm these results.

REFERENCES
1. Nicolai et al., "Evaluation of BiesseBioscreen as a new methodology for bacteriuria screening", New Microbiologica, 37, 495-501, 2014.
2. Foxman B. Epidemiology of urinary tract infections: incidence, morbidity, and economic costs.Am J Med, 2002. 113 Suppl 1A: p. 5s-13s.
3. Guidelines on urological infections, EAU 2015;

Funding None **Clinical Trial** No **Subjects** None

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IS RECURRENT URINARY TRACT INFECTION IN WOMEN ASSOCIATED WITH ABNORMALITIES IN LOWER URINARY TRACT FUNCTION?

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HYPOTHESIS / AIMS OF STUDY
The incidence of urinary tract infections (UTI) is high in women and a proportion of women has recurrent UTI's. The standards in our country recommend referral to medical specialist care when UTI's recur more than 4 times per year or when UTI does not cure on usual antibiotics or recurs within a short interval. Medical specialist care guidelines are of the view that for patients referred with RUTI (cited from EAU-guideline): ... 'An extensive routine workup including cystoscopy, imaging, etc. is not routinely recommended as the diagnostic yield is low.' There is evidence for the very modest (positive and or negative) predictive value of cystoscopy or imaging in unselected women, however these modalities are recommended for specific indications. A recent study (1) (PMID: 30016804) included 12 studies for recurrent simple UTIs in a systematic analysis. These showed that (only) <1.5% of (656 reported total) women investigated with imaging or cystoscopy had life-threatening (0.15% (1) malignancy and few fistulae) pathology, but up to 67% had abnormal urodynamics; abnormal flowrate and or PVR. Only 2 studies in this review have reported the use of invasive urodynamics and especially DO has been an incident observation (≈50%) in small cohorts. Apart from these small studies the prevalence of lower urinary tract dysfunction in the cohort of women with RUTI is not reported.

On the other hand: In the era of increased attention to the urinary tract micobiome and lower urinary tract (LUT) (dys) function the association of LUTD and 'common' recurrent urinary tract infections (RUTI) is potentially relevant. Many reports suggest an association of bacterial DNA and or evidence for bladder microbiome with symptoms of dysfunction and ICI-RS suggests further research. (2,3) (PMID: 28444712 & 30133786). We report objective assessment of LUTD in a large cohort of women with RUTI with the aim to

explore the relevance of RUTI for LUTD dysfunction. To this aim we have also included an age matched cohort of women with signs and symptoms of LUTD without a history of (R) UTI.

STUDY DESIGN, MATERIALS AND METHODS

We included 208 women with mean age 51,5, range 19-96. All women had RUTI according to our national standard criteria; 43 (21%) had a uro-(gynecol-)logical history (UrolHist) (e.g. vaginoplasty, hysterectomy or vesicourethral reflux). All women underwent (invasive) urodynamics, after guideline-compatible assessment of symptoms and clinical assessment. Urodynamics (fluid fill, external pressure, urethral double lumen F8) was done when the patients had no signs or symptoms of urinary tract infection with the patient seated, after the insertion of the catheters. Cystometry was done with room temperature saline up to to strong desire to void (taking into account the data from the bladder diary). Voiding was allowed in seated position and in privacy. PVR was measured via the urodynamic catheter after voiding.

821 age matched female patients with symptoms of LUT dysfunction without history of UTI's were used as an otherwise unselected control cohort from our department, with identically performed urodynamics. The overall prevalence of DO in this 'random' control cohort of referred patients is 56.7%; the prevalence of underactive detrusor (DU) is 23,7% and bladder outflow obstruction (BOO) 1%.

RESULTS

Table 1:

The table shows that RUTI patients with or without UrolHist did not differ (t-tested:) in flowrate, voided volume, cystometric capacity, outflow resistance (BOO) or detrusor contraction. Although detrusor overactivity (DO) was associated with reduced (urodynamic and bladder diary) capacity the incidence of DO was similar in the groups with (58%) or without (56%) UrolHist.

Five (3.6%) patients without and 2 (5%) with UrolHist had bladder outflow obstruction (URA>30) and 26% and 30% had DU. The average contractility was lower in advanced age and weakly (chi2 .025) associated with DO. DO was also somewhat more incident (chi2 .031) in patients with higher grade of BOO.

Comparing this to the non RUTI control group shows that the percentages DO and DU are remarkably similar to the RUTI -group.

INTERPRETATION OF RESULTS

Patients that have no abnormalities on function testing were offered RUTI management as per current practice guidelines. Sometimes the studies provide arguments to advise to reduce too excessive fluid intake. Patients however, that have shown (concurrent? causative? resulting?) LUT dysfunction are offered specific management for the dysfunction as well.

The relevance of these observations probably twofold: Female RUTI can (or should?) be interpreted more as a sign of lower urinary tract dysfunction than as a sign of anatomical abnormalities and it should be considered to adapt the guidelines accordingly.

The other implication may be that epidemiological studies to show an association between microbiome or common UTI and LUTD or symptoms need samples that are large enough to correct for the 'background prevalence' of LUTD or symptoms.

CONCLUDING MESSAGE

Recurrent urinary tract infection is less likely a sign of anatomical abnormalities than of dysfunction. Imaging provides less likely useful information than assessment of function.

Referred patients with RUTI with or without a history of urogynecological interventions or abnormalities have a prevalence of LUT dysfunction that, when assessed objectively, is high, and similar to patients who are referred with symptoms of LUT dysfunction without recurrent urinary tract infections.

FIGURE 1

	Urol Hist	N	Mean	Std. Deviation
Qmax	No	106	19,8	12,7
	Yes	24	18,6	12,3
Vol Voided	No	106	259,9	200,2
	Yes	24	205,8	154,5
Capacity	No	163	385,5	188,1
	Yes	43	327,4	189,8
Det press endfill	No	163	9,7	12,9
	Yes	43	11,3	14,1
URA	No	130	13,4	10,4
	Yes	31	14,6	9,0
Wmax	No	133	11,7	7,6
	Yes	34	12,3	7,5

REFERENCES

1. Santoni N, Ng A, Skews R, Aboumarzouk OM. Recurrent Urinary Tract Infections in Women: What Is the Evidence for Investigating with Flexible Cystoscopy, Imaging and Urodynamics?. Urol Int. 2018;101(4):373–381.
2. Drake MJ, Morris N, Apostolidis A, Rahnama'i MS, Marchesi JR. The urinary microbiome and its contribution to lower urinary tract symptoms; ICI-RS 2015. Neurourol Urodyn. 2017;36(4):850–853.
3. Ford AA, Veit-Rubin N, Cardozo L, Khullar V. Is the microbiome influencing patient care in lower urinary tract dys-

function? Report from the ICI-RS 2017. Neurourol Urodyn. 2018;37(S4):S93–S98.

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MICROBIOME PREDICTORS OF SURGICAL TREATMENT RESPONSE IN WOMEN UNDERGOING MID-URETHRAL SLING SURGERY FOR MIXED URINARY INCONTINENCE

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HYPOTHESIS / AIMS OF STUDY

Describe pre-operative urinary and vaginal bacterial taxa associated with 12 month surgical response after mid-urethral sling in women with mixed urinary incontinence.

STUDY DESIGN, MATERIALS AND METHODS

After Institutional Board Approval and written informed consent was obtained, urine and vaginal bacterial samples (N=124) were collected from a subset of women with MUI enrolled in the ESTEEM trial (NCT01959347). All women underwent midurethral sling surgery. Objective response at 12 months was defined as ≥70% reduction from baseline in urinary incontinence episodes on 3-day diary without additional treatment. Based on mixed urinary incontinence symptoms as measured by the Urogenital Distress Inventory, as most subjects responded to treatment meeting the minimal clinically important difference threshold, subjective response was defined by change from baseline in Urogenital Distress Inventory analyzed continuously. Clinical and demographic differences in responder status were assessed with univariate generalized linear models and Fischer's exact test. Using 16S rRNA gene sequencing data, beta diversity was compared in responders vs non-responders. Differential abundance analysis of operational taxonomic units was assessed, focusing on predominant taxa defined as the most prevalent operational taxonomic units in ≥3 participants, using unadjusted and age-adjusted linear models.

RESULTS

Objective responders (N=72), compared to non-responders (N=28) were younger (51.6±10.2 y, p = 0.007), premenopausal (OR [CI] 4.22 [1.28-13.86]) and on hormone replacement therapy (HRT), (OR [CI] 6.35 [1.82-22.23]. Age (urine and vagina, p<0.001), menstrual status (urine, p=0.04; vagina, p=0.01), postmenopausal +HRT (vagina, p=0.01) and responder status (vagina, p=0.03) were associated with operational taxonomic units in beta diversity analyses. Six predominant operational taxonomic units were identified: Lactobacillus, most predominant (urine and vagina), followed by Gardnerella (urine and vagina), Tepidomonas (urine), Escherichia (urine), Streptococcus (urine and vagina), Prevotella (urine and vagina). Differential abundance analysis of urine revealed no association between predominant operational taxonomic units and responder status. Vaginal differential abundance analysis adjusting for age, found Prevotella associated with objective responder status, p=0.01; changes in Urogenital Distress Inventory (N=105) scores were not associated with vaginal operational taxonomic units (Fig. 1a, b). Lower Lactobacillus was associated with older age and higher Prevotella (Fig. 2).

INTERPRETATION OF RESULTS

In older women undergoing a mid-urethral sling for the treatment of mixed urinary incontinence, the state of the vaginal microbiome may be important in optimizing surgical outcomes.

CONCLUDING MESSAGE

Surgical responders had decreased Prevotella in the vagina. Younger women, more likely to be surgical responders, had more Lactobacillus. Further research is needed to confirm whether therapy altering the vaginal microbiome in older women impacts surgical response in women with mixed urinary incontinence.

FIGURE 1

Vagina results

response variable	feature	N	N.not.0	Objective Response Unadjusted pval	Objective Response Age adjusted pval
vagina.ObjectiveResponse	Prevotella	97	97	0.01	0.01
	Lactobacillus	97	97	0.04	0.25
	Escherichia	97	49	0.82	0.41
	Streptococcus	97	97	0.97	0.26
	Gardnerella	97	95	0.97	0.66

response variable	feature	N	N.not.0	Delta UDI Unadjusted pval	Delta UDI Age adjusted pval
vagina.DELTA_UDI	Prevotella	101	101	0.91	0.99
	Lactobacillus	101	101	0.22	0.69
	Escherichia	101	53	0.02	0.13
	Streptococcus	101	101	0.32	0.92
	Gardnerella	101	99	0.22	0.42

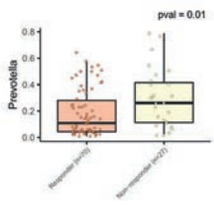

Figure 1a-b

FIGURE 2

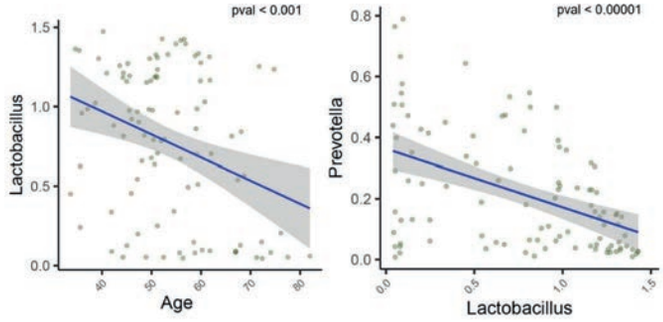

Figure 2

Funding Eunice Kennedy Shriver National Institute of Child Health and Human Development **Clinical Trial** Yes **Registration Number** NCT01959347 **RCT** Yes **Subjects** Human **Ethics Committee** Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

SESSION 39 (PODIUM SHORT ORAL) - QUALITY OF LIFE AND HEALTH DELIVERY
Abstracts 601-612
15:00 - 16:30, Brasilia 1
Chair: Dr Cristina Naranjo Ortiz (United States)

601 www.ics.org/2020/abstract/601

ASSOCIATION BETWEEN GESTATIONAL DIABETES MELLITUS AND PREGNANCY-SPECIFIC URINARY INCONTINENCE: SEVERITY AND IMPACT ON THE QUALITY OF LIFE OVER THE FIRST YEAR POSTPARTUM

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HYPOTHESIS / AIMS OF STUDY
In the light of the complex inter-relationships among diabetes mellitus, pregnancy and urinary incontinence, the hypothesis was that gestational diabetes mellitus (GDM) associated with pregnancy-specific urinary incontinence (PS-UI) will increase the occurrence and severity of UI, having a negative impact on the QoL during pregnancy and up to 12 months postpartum. The aim of this study was to investigate the severity and impact of UI on quality of life (QoL) of diabetic pregnant women over a 1-year follow-up period.

STUDY DESIGN, MATERIALS AND METHODS
This cross-sectional study was conducted in a Perinatal Diabetes Research Center and was approved by the Research Ethics Committee of the Institution. Three hundred eighty-eight women were evaluated at five-time-points: 24-28 gestational weeks (visit 1), 34-38 gestational weeks (visit 2), 24-48 hours postpartum (visit 3), 6 weeks postpartum (visit 4) and 6-12 months postpartum (visit 5). The diagnosis of Gestational Diabetes Mellitus (GDM) was established between 24th and 28th gestational weeks, by the 75 g-OGTT test according to ADA's criteria (1). Urinary incontinence was defined according to the International Continence Society (2) and the severity and impact on QoL were evaluated by ISI (Urinary Incontinence Severity Index) and ICIQ-SF (International Consultation on Incontinence Questionnaire Short Form). From the data, the pregnant women were classified into two study groups: normoglycemic incontinent (NI; normal 75-g GTT; n=168) and diabetic incontinent (DI; abnormal 75-g GTT; n=220). The NI and DI groups were compared using the Chi-square test for categorical variables and Student-t test for quantitative variables. All analyses were performed using SAS software for Windows, v.9.3.

RESULTS
The figure 1 indicates the incontinence data and questionnaire response and the figure 2 shows the classification of UI severity and its impact on the quality of life.

INTERPRETATION OF RESULTS
The responses to the ISI and ICIQ-SF questionnaires showed greater severity combined with greater bother-score in diabetic women, with severe and very severe classification, compared to normoglycemic women in all time-points. The third item of the ICIQ-SF (Impact of UI on QoL) also demonstrated higher levels of interference on daily life in diabetic women, both during pregnancy and after delivery, except at 6 weeks postpartum (P=0.1105).

CONCLUDING MESSAGE
Diabetic pregnant women tended to exhibit more severe symptoms of PS-UI as well as the worse impact on QoL during pregnancy with an excessive tendency to show a similar reaction over the first year postpartum. These study not only contradicts the old concept that the effects of GDM vanish soon after delivery but also reinforce the positive interaction between pregnancy, GDM and long-term maternal outcome.

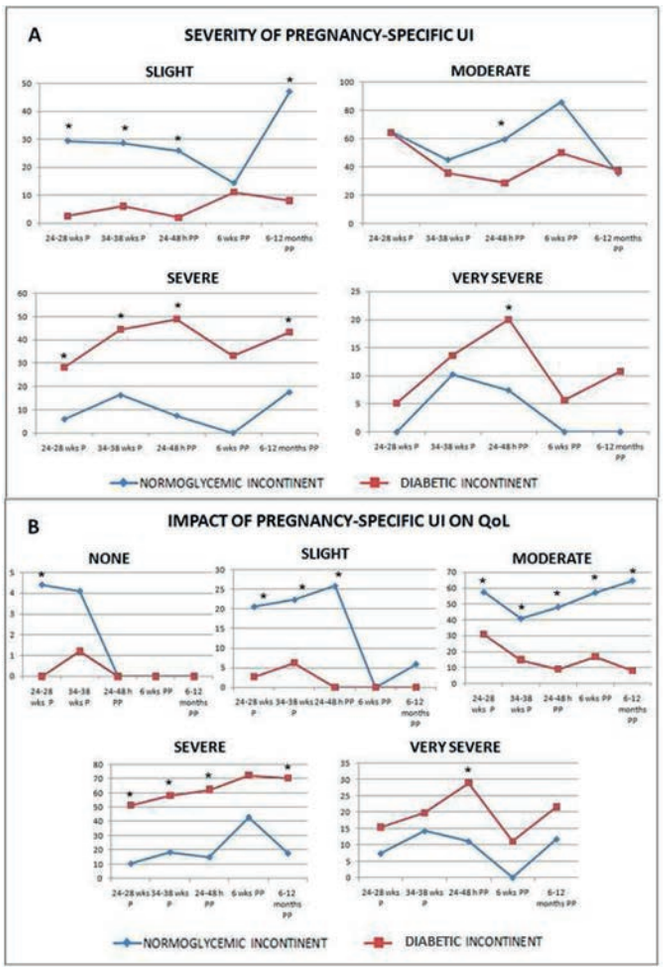
FIGURE 1

VISITS	GROUPS	SCORE ISI	SCORE ICIQ-SF	SCORE QoL
VISIT 1	NI	3.44 ± 1.71	9.04 ± 2.88	4.75 ± 2.38
	DI	5.82 ± 2.52*	12.85 ± 3.41*	7.21 ± 2.09*
VISIT 2	NI	4.71 ± 3.29	10.53 ± 4.66	5.45 ± 2.75
	DI	7.00 ± 2.90*	14.22 ± 3.70*	7.64 ± 2,42*
VISIT 3	NI	3.96 ± 2.86	10.30 ± 3.99	5.41 ± 2.52
	DI	7.71 ± 2.85*	15.76 ± 2.92*	8.51 ± 1.53*
VISIT 4	NI	3.57 ± 1.51	11.00 ± 1.73	6.29 ± 1.80
	DI	6.06 ± 2.73*	13.94 ± 2.88*	7.94 ± 1.47
VISIT 5	NI	3.65 ± 2.32	10.29 ± 3.60	5.76 ± 2.17
	DI	6.70 ± 2.81*	14.81 ± 2.73*	8.27 ± 1.37*

Values presented as means ± SD. * P<0.05 – compared to NI group (t test).

ISI, ICIQ-SF and QoL response scores

FIGURE 2



The proportions of slight, moderate, severe and very severe symptoms evaluated using the ISI (A) and ICIQ-SF (B) questionnaires among incontinent women with gestational hyperglycemia and normoglycemia. Wks, weeks; h, hours; P, pregnancy; PP, postpartum.

REFERENCES

1. American Diabetes Association (ADA). Diagnosis and classification of diabetes mellitus. Diabetes Care. 2014;37:S81–90.
2. Abrams, P.; Andersson, K.E.; Birder, L.; Brubaker, L.; Cardozo, L.; Chapple, C.; Drake, M. Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourol. Urodyn. 2010, 29, 213–240.
3. Rudge MVC, Souza FP, Abbade JF, Hallur RLS, Marcondes JPC, Piculo F, Marini G, Vesentini G, Thabane L, Witkin SS, Calderon IMP, Barbosa AMP, The Diamater Study Group. Study protocol to investigate biomolecular muscle profile as predictors of long-term urinary incontinence in women with gestational diabetes mellitus. BMC Pregnancy Childbirth. 2020; 20(1): 117. doi: 10.1186/s12884-020-2749-x.

Funding This work was supported by grant #2012/25060-3 and #2016/01743-5, São Paulo Research Foundation (FAPESP), Brazil **Clinical Trial** No **Subjects** Human **Ethics Committee** This is a cross-sectional study with the approval of the Research **Ethics Committee** of Botucatu Medical School - UNESP (CAAE20639813.0.0000.5411) **Helsinki** Yes **Informed Consent** Yes

602

www.ics.org/2020/abstract/602

BEST IN CATEGORY PRIZE "PREVENTION AND PUBLIC HEALTH"

PROMOTING UPTAKE OF PREVENTATIVE MEASURES IN OBSTETRIC ANAL SPHINCTER INJURIES

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HYPOTHESIS / AIMS OF STUDY

From 2000 to 2012, the rate of obstetric anal sphincter injuries (OASIS) in England tripled from 1.8% to 5.9%, in primiparous women (1). The Royal College of Obstetricians and Gynaecologists guidelines state that mediolateral episiotomy in instrumental deliveries (where indicated); manual perineal protection at crowning and warm compression in the second stage can prevent OASIS. Additionally, all women delivering vaginally should have a digital rectal examination (DRE- female) to identify isolated, rectal buttonhole tears (2).

In response to rates rising nationally, a prospective, observational audit of 41 deliveries was completed at our Trust in 2016 to identify areas where practice could be improved. This audit highlighted low rates of manual perineal protection and DRE- female post-delivery by midwives. In 2017, the Trust commenced 'PRactical Obstetric Multi-Professional Training' to increase OASIS preventative measures, amongst other Obstetrics emergencies and outcomes. To establish if this training had improved practice, a re-audit was completed in 2019.

The aim of this audit was to assess changes in practice and areas where OASIS preventative measures can be implemented.

STUDY DESIGN, MATERIALS AND METHODS

A prospective audit was completed from September to December 2019; all cases were observed in the Consultant lead unit. All deliveries included were observed from during the second stage, until the end of the third stage of labour. The clinician leading the delivery (midwife or doctor) was unaware of the data the observer was collecting. The pro forma collected information on parity, ethnicity, gestation, birthweight, previous OASIS, delivery position, mode of delivery,

type of episiotomy, use of manual perineal protection, use of warm compression and DRE- female post-delivery.

RESULTS
Of the fourteen deliveries, eleven were led by a midwife throughout and three involved a doctor near the end, for instrumentation. They consisted of six primiparous and eight multiparous women. Their gestation ranged from 30+3 to 42+0 weeks and the birthweight ranged from 1400 to 4100 grams. In the 14 cases (100%), good manual perineal protection was used compared to only 24 out of 41 cases (58.5%) in the 2016 audit. The use of warm compression was used in two cases in this audit and no cases in 2016. In both audits, episiotomy was medio-lateral in all cases where it was required (fifteen cases in 2016 and three in 2019). There was 100% completion of a DRE- female by the doctor after intervening for instrumentation, in both the 2016 and 2019 audits. Of the remaining deliveries (completed entirely by a midwife) there was a DRE- female post-delivery in 16 of the 26 cases (61.5%) in 2016 and in 6 of the 11 cases (54.5%) in 2019.

INTERPRETATION OF RESULTS
Both the 2016 and 2019 audits are limited by their small number of deliveries observed. Rather than analysing retrospective data (written records of the delivery entered by a doctor/midwife); all cases were observed to eliminate recording bias. Although the clinician was unaware that the observer was collecting data on their practice, the presence of an observer may alter practice.

Despite rates of OASIS at the Trust being less than the national average (1.2% in 2009); the 2016 audit was completed to optimise patient care. It highlighted that manual perineal protection and DRE- female post-delivery could be improved. Whilst 'PRactical Obstetric Multi-Professional Training' significantly improved the rates of good manual perineal protection; rates of DRE- female post-delivery remained suboptimal. Free texts notes made at the time of observation highlighted that midwives often deemed it "unnecessary" to complete a DRE- female, if examination of the vaginal wall revealed apparent minimal injury.

CONCLUDING MESSAGE
This re-audit highlights that the 2017 training programme was successful in improving manual perineal protection but requires updating to put a greater emphasis on the importance of a DRE- female. These findings have been disseminated using our local monthly quality improving meetings and monthly newsletters. Furthermore, a midwifery e-learning package could be launched on post-OASIS morbidity and preventative measures. A re-audit to assess effectiveness of these interventions should be completed in three years (2022).

REFERENCES
1. Royal College of Obstetricians and Gynaecologists (2015) Third and Fourth Degree Perineal Tears, Management (green top guideline 29) London: RCOG Available at: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg29/
2. OASI Care Bundle Project Team. Implementation guide for maternity sites in the roll-out. Available at: https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/oasi-care-bundle/oasi-care-bundle-guide-final-_-050118.pdf

Funding No funding or grant has been obtained. **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Audit of clinical practice through observation of deliveries. **Helsinki** not Req'd Audit was approved by the Trust's 'Clinical Effectiveness Department' before commencing. Verbal consent was obtained from all patients (and clinicians leading the delivery) that they were happy for the observer to be present. Presence of an observer documented on patient's medical notes. **Informed Consent** No

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QUALITY OF LIFE AFTER TREATMENT BY VAGINAL PESSARY VERSUS SURGERY IN SYMPTOMATIC PELVIC ORGAN PROLAPSED PATIENTS

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HYPOTHESIS / AIMS OF STUDY
Pelvic organ prolapse (POP) is the downward descent of one or more compartments of vagina and uterus into vagina or protrude through hymen. It is a benign condition causes vaginal bulge, pelvic pressure, voiding dysfunction, defecatory dysfunction and sexual dysfunction.[1] Symptomatic prolapse has a negative impact on quality of life. Age, parity, vaginal delivery, obesity, connective tissue diseases, chronic constipation and menopausal status are the risk factors developing POP.[1]

Beside expectant management for treating the symptomatic prolapse, vaginal pessary is the non-surgical option to relieve the pelvic organ prolapse symptoms and considered to be offered before surgery.[2]

Patients' preference plays a potential role to select the choice of treatment after receiving the counselling from the physicians.[2]

Prolapse surgery comprised of correcting all affected vaginal compartments to restore the vaginal anatomy as well as the surrounding visceral organ which technique was operated by physicians' discretion and expertise.[3]

The aim of the study was to evaluate and compare the effectiveness of vaginal pessaries and surgery among women with symptomatic pelvic organ prolapse after 3 and 6 months using validated prolapse quality of life (P-QOL) questionnaire and satisfaction score after treatment.

STUDY DESIGN, MATERIALS AND METHODS

This is a prospective observational study comparing the quality of life score after treatment between pelvic organ prolapsed patients who opted pessary versus surgery. After the ethics committee was approved and informed consent was obtained, the data were collected from an urogynecology clinic at the tertiary hospital between January 2018 and August 2020. The inclusion criteria were women with age 18 years or more, prolapse stage II or more (POP-Q system) and had been treated with vaginal pessary or surgery. Patients who did not understand Thai language were excluded.

The Prolapse Quality of Life (P-QOL) questionnaire in Thai version was used at before treatment, 3 months and 6 months after treatment. Moreover, satisfaction score using visual analog scale was also used at 3 moths and 6 months after treatment.

Based on the pilot study, the mean difference + SD after treatment with pessary was 23.50 + 31.68 and 36.8 + 42.85 in surgery. We assumed 80% power, p-value <0.05 and mean difference more than 25 points for detect statistically significant and found sample size were 40 patients per arm.

Statistical analysis was performed using STATA/SE version 10.1. Normality testing was conducted using Kolmogorov-Smirnov testing. The descriptive data were presented as percentages, means, and medians. The t-test, chi-square, Fisher's exact and Mann-Whitney U test were used as appropriate to compare between pessary and surgical groups. Generalized estimating equation (GEE) was used comparing the mean difference of QoL score between two groups. p-values of <0.05 were considered statistical significance.

RESULTS

Eighty patients were prospectively recruited in the study. Forty patients in pessary group (50%) and another forty patients in surgery group (50%). We enrolled patients by determining the number of patients in the same stage. The data were collected during the follow-up period. Contacting by phone in case of loss to follow-up. Therefore, no missing data in our study. Thirty-nine patients (97.5%) in pessary group fitted with support pessaries, while only one (2.5%) fitted with space occupying pessary. There were two surgical routes to restore pelvic floor anatomy in our study that is vaginal approach in 31 patients (77.5%) and laparoscopic approach in 9 patients (22.5%).

The mean age + SD was 65.7 + 7.7 years. The mean BMI + SD and menopausal status were 24.9 + 3.7 kg/m2 and 96.3%, respectively. There was no statistical difference between pessary and surgery groups regarding age, BMI, parity, menopausal status, underlying diseases and POP-Q stage.

The P-QOL score at baseline before treatment in each group as shown in Table1. Patients with treated symptomatic prolapse adversely affected the disease in general health perceptions, prolapse impact, role limitations, physical limitations, emotions and severity measures domains. After treatment either pessary or surgery, all P-QOL domains significantly improved at 3 months and 6 months except personal relationships and sleep/energy domains in the pessary group that had not different from baseline (Table2). When compared between two groups, general health perception and sleep/energy domains were significantly improved in the surgery group. The mean + SD of satisfaction score after treatment in pessary and surgery at 3 months and 6 months were 8.9 + 1.4 and 9.3 + 1.0 (p=0.509), 9.4 + 1.2 and 9.3 +1.1 (p=1.000), respectively.

INTERPRETATION OF RESULTS

The quality of life in symptomatic prolapsed patients after treatment significantly improved in quality of life from P-QOL questionnaire. However, personal relationships and sleep/energy domains in the pessary group had not significantly improved from baseline might be due to patients need to remove the pessary during night time to prevent complications regarding pessary use. Moreover, when compared between two groups, general health perception and sleep/energy domains were significantly improved in the surgery group. All symptomatic prolapsed patients extremely satisfied after treatment both pessary and surgery.

CONCLUDING MESSAGE

The quality of life in symptomatic prolapsed patients after treatment appeared apparently improved in quality of life from P-QOL questionnaire. General health perception and sleep/energy domains were significantly improved in the surgery group compared with the pessary group. All symptomatic prolapsed patients extremely satisfied after treatment both pessary and surgery.

FIGURE 1

Table 1 Baseline quality of life before treatment between two groups

P-QOL domain	Pessary	Surgery	*p*- value
	Median (IQR)	Median (IQR)	
1. General health perceptions	50 (25, 75)	50 (50, 75)	0.0946
2. Prolapse impact	67 (67, 100)	67 (33, 100)	0.5558
3. Role limitations	33 (0, 67)	33 (17, 67)	0.4767
4. Physical limitations	17 (0, 58.5)	33 (17, 91.5)	0.0551
5. Social limitations	0 (0, 27.5)	5.5 (0, 44)	0.2407
6. Personal relationships	0 (0, 0)	0 (0, 0)	0.4765
7. Emotions	44 (22, 67)	33 (11, 56)	0.5864
8. sleep/ energy	0 (0, 0)	0 (0, 50)	0.0229
9. Severity measures	33 (17, 37.5)	25 (12.5, 37.5)	0.7626
10.Total score	28.5 (19.5, 39)	31.5 (25, 51)	0.2021

FIGURE 2

Table 2 Comparison of P-QOL domain score between pessary and surgery groups

Domains	3 months					6 months				
	Pessary		Surgery		Difference between group (*p*-value)	Pessary		Surgery		Difference between group (*p*- value)
	Mean change from baseline	*p*-value	Mean change from baseline	*p*-value		Mean change from baseline	*p*-value	Mean change from baseline	*p*-value	
1. General health perceptions	-14.38	0.001	-31.23	0.001	-16.85 (0.010)	-15	<0.001	-30	<0.001	-15 (0.024)
2. Prolapse impact	-53.47	<0.001	-59.23	<0.001	-5.77 (0.922)	-63.47	<0.001	-60.9	<0.001	2.57 (1.000)
3. Role limitations	-37.48	<0.001	-40.84	<0.001	-3.37 (1.000)	-36.64	<0.001	-42.93	<0.001	-6.28 (0.816)
4. Physical limitations	-29.62	<0.001	-42.16	<0.001	-12.54 (0.256)	-27.95	<0.001	-42.58	<0.001	-14.63 (0.154)
5. Social limitations	-14.96	<0.001	-21.06	<0.001	-6.10 (0.624)	-14.68	<0.001	-21.62	<0.001	-6.94 (0.501)
6. Personal relationships	-4.55	0.229	-6.67	0.021	-2.12 (1.000)	-3.72	0.482	-6.25	0.036	-2.53 (1.000)
7. Emotions	-34.92	<0.001	-35.51	<0.001	-0.59 (1.000)	-37.42	<0.001	-37.18	<0.001	0.24 (1.000)
8. sleep/ energy	-6.68	0.147	-20.41	<0.001	-13.73 (0.023)	-4.18	0.765	-19.99	<0.001	-15.81 (0.007)
9. Severity measures	-20.15	<0.001	-25.93	<0.001	-5.783 (0.324)	-23.90	<0.001	-26.558	<0.001	-2.658 (1.000)
10.Total	-23.963	<0.001	-31.493	<0.001	-7.529 (0.116)	-25.159	<0.001	32.044	<0.001	-6.884 (0.166)

REFERENCES

1. Pelvic Organ Prolapse. Female Pelvic Med Reconstr Surg. 2017;23:353–64.
2. Bodner-Adler B, Bodner K, Stinglmeier A, Kimberger O, Halpern K, Koelbl H, et al. Prolapse surgery versus vaginal pessary in women with symptomatic pelvic organ prolapse: which factors influence the choice of treatment? Arch Gynecol Obstet. 2019;299:773–7.
3. Pelvic Organ Prolapse. Female Pelvic Med Reconstr Surg. 2017;23:353–64.

Funding None **Clinical Trial** Yes **Public Registry** No **RCT** No **Subjects** Human **Ethics Committee** The institutional review board of The Khon Kaen University **Ethics Committee** on Human Research **Helsinki** Yes **Informed Consent** Yes

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COMMON IS NOT THE SAME AS NORMAL – HOW WOMEN WITH SYMPTOMATIC PELVIC ORGAN PROLAPSE CAUSED BY VAGINAL DELIVERY UNDERSTAND THE CONDITION AND EXPERIENCE INTERACTION WITH HEALTHCARE PROFESSIONALS

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HYPOTHESIS / AIMS OF STUDY

To explore how women with symptomatic pelvic organ prolapse caused by vaginal delivery understand the condition and experience interaction with healthcare professionals.

STUDY DESIGN, MATERIALS AND METHODS

A retrospective text analysis with an interpretive qualitative approach was used. The data presented in this abstract stems from an original empirical dataset with the purposive sampling strategy aiming to obtain posts written by women from an online discussion thread containing conversations about experiencing symptomatic pelvic organ prolapse (sPOP) after vaginal delivery (VD). In total, posts written by 33 women were selected for analysis. The women who participated were 24 to 45 years old (mean =27). Eighteen were primiparous and twelve of the women had children younger than 1-year-old.

Written consent to undertake the study was obtained from the forum's web operations manager. An information letter with details about the research and confidentiality, the voluntary nature of participation and the right to withdraw at any time was published on the forum's website.

RESULTS

The theme "Taken by surprise" illustrated that there was a general unawareness of the existence of the POP condition until the symptoms were discovered. Unfamiliarity with pelvic floor anatomy was frequently described and this in turn made it difficult for the women to understand both the anatomical abnormalities and the symptoms that they had to deal with. The women had not realized that they could encounter this bodily condition. Vaginal delivery was expressed as the norm of discourse and no one had informed them about the risks associated with VD or prepared them for the possible complications during antenatal education courses. This left them feeling that they had been misled and the topic had been silenced.

"Yes actually. I am going to bring up the issue again at the next appointment with the midwife. And ask why prolapse is not spoken of, before, during and after the pregnancy" (Participant 33)

A second theme, "Miscommunication" showed that miscommunication between the women and their healthcare providers impacted on these women's experiences of sPOP care thus complicating decision-making and reducing the opportunity to get help. When women sought healthcare services due to existing symptoms, they were met with neglect. The women felt that the healthcare providers acted as if the women were "making a big thing out of it". Physicians explained sPOP as a prevalent, natural and expected condition after VD, using expressions that belittled the problem with phrases like "it doesn't look too bad", "minimal collapse of the front wall", "I have seen worse" and that "POP is very common". The women could not agree with such a replacement of concepts where "common" turned into "normal". This negligence led to psychological distress and drained the women. Nevertheless, the women felt that it was up to them to stop the neglect and seek care to be registered in

the medical records, which could help to make sPOP caused by VD visible.

Dissonance occurred between the women's experiences and expectations and the healthcare professionals' assessment and advice given. The women considered themselves as far too young to be experiencing any kind of POP and wanted to be treated. However, the women faced a lack of consensus among physicians regarding how sPOP should be addressed. For example, one woman reported that she had been given completely different diagnoses and advice by different physicians. The common advice was to do Kegel exercises and some women felt like they were blamed for their own injures because they had not done the exercises properly. The women were told that surgery could cause even bigger problems in comparison with their current condition and therefore, it was not a desirable option, especially for young persons. The women were advised to postpone surgery until they "were done with babies". This argument left them in an impossible situation. sPOP was believed to be a condition that could not be fixed while they were in their prime, which meant they had to live with it and suffer for a long time. Some women stated that they had been convinced to give birth vaginally and now that they have been harmed, no one took responsibility or had the competence to deal with the problem.

Additionally, when they met a physician who explained the condition and suggested a treatment plan, they became very happy, emotional and deeply impressed by that fact that someone finally could help them and praised these "good doctors". One woman described that she cried with happiness while sitting in a gynecological chair.

INTERPRETATION OF RESULTS

This study brings women´s subjective experiences into focus and highlights the importance of considering experiential knowledge without exception when evaluating and treating sPOP. Women in our study got the shock of their lives when they discovered sPOP and were angry that the information about the risks with VD had been silenced during antenatal care. Sadly, other studies focusing on women with different pelvic floor traumas confirmed these findings (1). Truthful objective information about the risks of VD is required, and it could be assumed that improved provision of information could prepare women to face potential problems postpartum.

We found that participants were unfamiliar with normal pelvic floor anatomy, which made it challenging to understand pathological changes. These shortcomings of knowledge indicate that pelvic organs are still a stigmatized part of the body and are in concordance with a study revealing that female adolescents lacked knowledge of female anatomy with only a few students knowing the number of openings in a vulva (2). In our opinion, the pelvic floor health education should be included in the school curriculum on a mandatory basis.

Our study demonstrates that although there is a growing awareness, especially when it comes to levator ani muscle (LAM) injures, which are associated with sPOP (1), the bothersome symptoms of POP are still viewed by healthcare providers as normal, expected and unavoidable issues after VD and are not investigated properly. Healthcare professionals seem to be unaware of the real impact of this condition on the quality of life and psychological health of new mothers. It has been revealed that a large number of treatments given to women with childbirth traumas have not been scientifically evaluated in reliable systematic reviews, and there are no systematic reviews addressing the acute POP associated with VD (3). It may be assumed that this lack of evidence can partly explain our findings that the healthcare professionals failed to meet the women's needs regarding diagnostic, information and treatment options.

CONCLUDING MESSAGE

The study shows that the women lacked understanding of sPOP and that the healthcare professionals failed to meet women's needs. The women indicated that sPOP is still viewed by healthcare providers as a normal condition and is not appropriately investigated. It is essential to admit the problem and address it using a standard treatment plan. Therefore, there is a need to develop national guidelines for the prevention and management of sPOP. Furthermore, information that highlights the potential risks of VD should be offered during antenatal care.

REFERENCES

1. Skinner, EM., Barnett, B., Dietz HP. (2018). Psychological consequences of pelvic floor trauma following vaginal birth: a qualitative study from two Australian tertiary maternity units. Arch Womens Ment Health, 21(3),341–51. doi:10.1007/s00737-017-0802-1
2. Hebert-Beirne, JM., O'Conor, R., Ihm, JD., Parlier, MK., Lavender, MD., Brubaker, L. (2017). A pelvic health curriculum in school settings: the effect om adolescent females' knowledge. J Pediatr Adolesc Gynecol, 30(2):188-192. doi:10.1016/j.jpag.2015.09.006
3. Swedish Agency for Health Technology Assessment and Assessment of Social Services (250/2016) Treatment of maternal birth injuries following vaginal birth. https://www.sbu.se/en/publications/sbu-kartlagger/treatment-of-maternal-birth-injuries-following-vaginal-birth/

Funding Conflict of interest- The authors reported no potential conflict of interest; Founding source-None declared **Clinical Trial** No **Subjects** Human **Ethics Committee** Ethical approval- This study was approved by the Regional Ethical Review Board Sweden (Dnr 2017/65). **Helsinki** Yes **Informed Consent** No

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EVALUATION OF THE EFFECTS OF COITAL INCONTINENCE ON FEMALE SEXUAL FUNCTION

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HYPOTHESIS / AIMS OF STUDY

Urinary incontinence (UI), the involuntary leakage of urine, is a common condition affecting 12%–46% of adult women. This circumstance is associated with significant deterioration in aspects of the quality of life,which influence social,physical,psychological and sexual behavior.Sexual dysfunction has been identified in approximately 46% of women with UI and lower urinary tract infections.Coital incontinence (CI) is the involuntary leakage of urine during sexual intercourse.

The effect of CI on the quality of sexual function is unclear and the few studies that exist lack consensus.In this study,the aim was to determine whether UI accompanied by CI affects sexual function in women.

STUDY DESIGN, MATERIALS AND METHODS

From September 2017 to September 2018,all sexually active women with UI (self-reported diagnosis) attending the outpatient gynecology clinic of a regional state hospital were consecutively interviewed about their experience of CI.Clinical evaluation consisted of the taking of medical resumes,urine analysis and physical examination.Face-to-face interviews were conducted by the same clinician and assistant nurse.Questions were asked about the women's experiences with CI.A five-point scale evaluated the frequency of CI (never, rarely, sometimes, often, and always).Women who had UI without CI were recruited as the control group.Patients underwent pelvic examination to determine the stage of pelvic organ prolapse in accordance with the POP-Q system (pelvic organ prolapse quantification system) and answered a validated questionnaire,including the Female Sexual Function Index (FSFI) questionnaire that evaluates the quality of sexual life.Sexual dysfunction was defined as an FSFI score <26.55 based on previously published and validated studies.The degree of the FSFI score is capable of predicting the extent of sexual problems.It has been validated for the Turkish population and is used to assess sexual function among women. The SPSS program version 20 was used for statistical analysis.

RESULTS

All 80 women with UI included in the study responded to the FSFI forms and none of them had a chronic disease that prevented them from participating in the study.Of the 64 women who participated in the study,24 were diagnosed with CI and the remaining 56 women were used as controls. The groups did not differ significantly in age,parity,cigarette usage,menopausal condition,birth type and pelvic floor muscle strength.No statistically significant differences in FSFI sub-domains or total scores were found among the different incontinence types.Women with CI had significantly lower FSFI scores than the controls for all subgroups.No significant differences were found in the frequency of CI based on incontinence type.

INTERPRETATION OF RESULTS

UI during sexual intercourse often causes women to avoid intercourse, and the sexual function of both themselves and their partners tend to be affected. However, no study in the literature has investigated or quantified this issue using the FSFI form. To the best of our knowledge, this is the first study to examine the effect of CI based on the FSFI scores and to compare the FSFI scores between the CI and control groups. A statistically significant difference was found for all domains (except lubrication domain) of the FSFI questionnaire. The relationship between the incidence of CI and the FSFI scores was also investigated and a decrease in scores was observed with increasing frequency as confirmed statistically by correlation tests.

CONCLUDING MESSAGE

This study shows that CI is much more prevalent than expected and has serious adverse effects on sexual function. Therefore, it is necessary to give greater attention to this issue,to use questionnaire forms when necessary and to encourage patients to express their concerns more effectively.

FIGURE 1

Table 1. Demographic and clinical characteristics of women with and without coital incontinence.

	With coital incontinence (n = 24)	Without coital incontinence (n = 56)	p
Age(range),yr, mean ± sd	44.8±5.5 (35-61)	45.5 ± 8.7 (21-69)	p=0.712[a]
Parity, mean±sd (median)	6.17 ± 2.24 (6)	5.8 ± 1.9 (6)	p=0.423[b]
Cigarette usage,n (%)	12(50%)	17(30.4%)	p=0.079[c]
Postmenopause, n (%)	9(37.5%)	22(39.3%)	p=0.543[d]
Stress test positivity,n (%)	17(70.8%)	12(21.4%)	p=0.000[c]
Pelvic Floor Muscle Strength, mean ± sd	2.62±0.58	2.7±0.60	p=0.328[b]
Incontinence type,n			
SUI	19(79.2%)	24(42.9%)	p=0.002[c]
UI	-	13(23.2%)	p=0.000[c]
MI	5(20.8%)	19(33.9%)	-
Birth type,n		-	
Vaginal delivery	21(87.5%)	46(82.1%)	-
Cesarean section	-	1(1.8%)	-
Vaginal delivery + cesarean section	3(12.5%)	9(16.1%)	-

a-student's t test
b-mann- whitney U test
c-chi-squared test
d-fisher's exact test

Table 1. Demographic and clinical characteristics of women with and without coital incontinence.

FIGURE 2

	With coital incontinence (n = 24)	Without coital incontinence (n = 56)	t	p*
Fsfi score --- desire	2.29 ± 0.8	4.05 ± 1.92	-4.322	**0.003**
Fsfi score --- arousal	4.21 ± 1.56	8.13 ±3.7	-5.019	**0.001**
Fsfi score --- lubrication	6.5 ± 1.67	9.21 ± 2.61	-4.687	0.060
Fsfi score --- orgasm	3.21 ± 1.56	5.11 ± 2.65	-3.272	**0.004**
Fsfi score --- satisfaction	3.13 ± 1.23	5.75 ± 2.55	-4.805	**0.002**
Fsfi score --- pain	4 ± 1.28	5.61 ± 2.43	-3.052	**0.023**
Fsfi score --- total	23.3 ± 4.3	37.86 ± 15.1	-4.630	**0.000**

Table 2. Comparison of FSFI scores on coital incontinence group and without coital incontinence group
*student-t test

Table 2. Comparison of FSFI scores on coital incontinence group and without coital incontinence group *student-t test

REFERENCES
1. El-Azab AS, Yousef HA, Seifeldein GS. Coital incontinence: relation to detrusor overactivity and stress incontinence. Neurourol Urodyn. 2011;30(4):520–4.
2. Preda A, Moreira E. Stress Urinary Incontinence and Female Sexual Dysfunction: The Role of Pelvic Floor Rehabilitation. Acta Med Port. 2019 Nov 4;32(11):721-726.
3. Wiegel M, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. J Sex Marital Ther. 2005;31(1): 1– 20.

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SEXUAL ABUSE: A LITTLE-KNOWN ELEMENT IN THE GENESIS OF VESICO-SPHINCTERIC DISORDERS

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HYPOTHESIS / AIMS OF STUDY
Even though urologists know that there may be an association between sexual abuse and urinary disorders, finding sexual abuse (SA) is often not part of their standardized questioning. The aim of our work is to assess the incidence of sexual abuse(SA), to understand and know how to manage the consequences of child molestation on vesico-sphincter functions.

STUDY DESIGN, MATERIALS AND METHODS
A multi-parametric, cross-sectional study was conducted by a female doctor looking for sexual assault , the latter has interviewed 214 women with bladder pain syndrome /Interstitial cystitis (BPS/IC) 14,95% (32 cases), retentionist bladder 10,28% (22cases), bladder hyperactivity without leakage 18,69% (40 cases), Nocturnal enuresis 7,9%(17 cases), Urge urinary incontinence 19,63% (42 cases), stress urinary incontinence 15,89% (34 cases) and mixed urinary incontinence 12,62% (27 cases). The authors present their experience with 214 patients (42 years, extremes 19 to 75 years), followed by specialistsbetween January 2017 and December 2019. All patients were evaluated by a voiding calendar, an MHU score (measurement of urinary handicap), bladder fibroscopy and urodynamic workup and a spinal MRI to rule out a neurological lesion.

RESULTS
The distribution of patients according to the vesico-sphincteric disorder and the number of SA are shown in Table 1 , and the characteristics of our series in Table 2 . The psychosocial impact was observed in 100% of patients, showcasing mainly feelings of discomfort, anger, sadness, frustration, fear and feelings of rejection from those around them. In 90% of the cases, patients revealed for the first time that the reason why they did not talk was shame,whilst others said they had no reason, or that they don't know why. Furthermore, Only 30% had dared to talk to someone regarding this issue. SA before 18 years of age was reported in 78% of the cases. Figures are almost identical no matter the socio-professional category, the highest prevalence reported was 10% among female executives (Tab.2).

INTERPRETATION OF RESULTS
The paradoxical attitude of the subject who refuses the examination urogyneological clinic or one that exhibits an attitude opposition during a urodynamic or coloproctological assessment can only alert us to the possibility a reminiscence of a painful memory (but there is no correlation between the painfulness of this memory and the gravity of what induced it: sometimes a simple examination may have been experienced as an assault).

The finding of a "frozen" perimeter, not contracting not in restraining effort and does not relax when pushed or when requesting relaxation, will further attract our Please note that this is a hypertonic perimeter (but we will also be wary of the possibility of a pathology central neurological).

CONCLUDING MESSAGE
Sexual abuse is very frequent and should be dealt with caution, since the latter may be the cause of physical or psychological illnesses, according to previous studies.

Sexual assault is very common, both amongst men and women, in all epidemiological studies, and in different countries: a strong causal link between SBAU and Sexual Abuse.

The urologist is at the heart of the problem, particularly in his management of pelvic static disorders and vesicosphincteric disorders.

FIGURE 1

Vesico-sphincteric disorder	Number of cases in our series	% of disorders in our population	Number of cases of sexual abuse	% of urinary disorder abuse
bladder pain syndrome /Interstitial cystitis (BPS/IC)	32	14,95 %	16	50 %
Retentionist bladder	22	10,28 %	10	45,45 %
Bladder hyperactivity without leakage	40	18,69%	17	42,5 %
Nocturnal enuresis	17	7,94%	7	41,18 %
Urge urinary incontinence	42	19,63 %	19	45,24 %
Stress urinary incontinence	34	15,89 %	7	20,58 %
Mixed urinary incontinence	27	12,62 %	13	48,14 %
Total	214	100 %	89	41,58 % (89/214)

Table 1 : The distribution of patients according to the vesico-sphincteric disorder and the number of sexual abuse

FIGURE 2

Prevalence	• 89/214 = 41.58%. • Prevalence: identical regardless of socio-professional category (the highest of 10% reported among executive girls).
Sex ratio	• 100 % of women.
Age of onset of abuse	• Before 18 : 78% (22% as an adult)
Confide for the first time	• For the first time : 90%. • The reason evoked by the patients who had not confessed was shame in 90% of the cases; no reason had been evoked by the others. • Only 30% had dared to confide in a third party.
Installation timeline	• Immediateconsequences : 45 cases. • 12-18 months : 30 cases. • The notion of resilience seems to be a protective mechanism in these cases
The type of abuse	• Moral harassment, exhibitionism or isolation, touching, incest : 30%. • 25% : physical abuse, • 55% : abuse. • 20% : sexual abuse (rape).
Déclaration	• 90 % : No declaration. • In addition, 38% of women seem to forget their sexual trauma.
Aggressor	• AS perpetrated by a family member OR entourage : 70%. • Repeated : 20%. • A single abuse : 40 %. • Isolated SA : 28 %.
Psycho-psychiatric sequelae	• < 20 % victims of childhood AS: serious psychopathological disorders. • Psychosocial repercussions : 100% (discomfort, anger, sadness, frustration, fear and the feeling of rejection from those around the • Difficulties in sexual adaptation (dyspareunia, anorgasmia) : 64%.
Medical sequelae	• Pelvic pain, irritable bowel syndrome, fibromyalgia syndrome.

Table 2 : The characteristics of sexual abuse

REFERENCES

1. Bloom DA, Knechtel J, Steinberg M (1988) Urological manifestations of sexual abuse. J Urol 139: 184A, abstract 85
2. Davila GW, Bernier F, Franco J, et al. (2003) Bladder dysfunction in sexual abuse survivors. J Urol 170: 476-9
3. Hinman F Jr (1986) Nonneurogenic neurogenic bladder (the Hinman syndrome) – 15 years later. J Urol 136: 769-77

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BEST IN CATEGORY PRIZE "NOCTURIA"

ASSOCIATION BETWEEN CARDIOVASCULAR RISK FACTORS AND NOCTURIA IN THE UNITED STATES POPULATION: THE 2005-2012 NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

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HYPOTHESIS / AIMS OF STUDY

Nocturia is highly prevalent and one of the most distressing lower urinary tract symptoms among older adults. However, the pathophysiology of nocturia is variable and difficult to confirm. In addition, to our knowledge, there is no literature to date that has analyzed their association using a nationally representative population-based database such as the National Health and Nutrition Examination Survey (NHANES) studies of the United States. Therefore, we investigated the association and influence of nocturia on the prevalence of cardiovascular disease (CVD) using the NHANES data.

STUDY DESIGN, MATERIALS AND METHODS

NHANES is operated continuously in two-year cycles conducted by the US Centers for Disease Control and Prevention (CDC), which is a cross-sectional study in which participants were sampled to represent populations living in the United States and underwent health and nutrition surveys as well as physical and laboratory tests. All protocols were approved by the Research Ethics Review Board of the National Center for Health Statistics, US Centers for Disease Control and Prevention. Among the 40,790 individuals who participated in NHANES from 2005 to 2012, only 14,365 adults were analyzed in this study.

A participant was considered to have nocturia if they answered "two or more" of the following questions: "During the past 30 days, how many times per night did you most typically get up to urinate, from the time you went to bed at night until the time you got up in the morning?" A participant was considered to have CVD if they answered yes to ≥1 of the following structured questionnaire: "Has a doctor ever told you that you had congestive heart failure?", "Has a doctor ever told you that you had coronary heart disease?", "Has a doctor ever told you that you had a heart attack (or myocardial infarction)?", or "Has a doctor ever told you that you had angina pectoris?"

A multivariate logistic regression analysis with adjustment for confounding variables, including age, sex, race, body mass index, smoking status, dyslipidemia, hypertension, and diabetes mellitus was performed with 1: 1 propensity score matching (PSM) for the confounding variables, taking into

consideration heterogeneity of demographic characteristics according to CVD.

RESULTS

A total of 14,365 adults (7,023 men, 7,342 women, mean age 52.6 years) aged 20-85 years were included in the study. There were 1,873 CVD cases (13%). Nocturia occurred in 4,727 individuals (32.9%), and the prevalence according to sex was 30.6% in men and 35.2% in women. The presence of CVD was more common in the elderly, men, those with higher BMI, smokers, and those with diabetes, hypertension, and hyperlipidemia. There was also a significantly higher prevalence of nocturia in the participants with CVD. In the multivariate analysis, the odds ratios (ORs) of mild and severe nocturia for CVD were 1.259 (95% CI, 1.12-1.417, p <0.001) and 1.996 (95% CI, 1.627-2.449, p <0.001), respectively. Taking into account the heterogeneity of participants with CVD, additional analysis was performed using 1:1 PSM. Although there was little heterogeneity of other confounding variables due to CVD, the ORs of mild and severe nocturia were 1.221 (95% CI, 1.064-1.401, p = 0.004) and 1.833 (95% CI, 1.431-2.347, p <0.001), respectively, showing maintained statistical significance.

INTERPRETATION OF RESULTS

The present nationally representative population-based study demonstrated that CVD was significantly associated with the prevalence of mild (two to three times per night)-to-severe (four or more than four times per night) nocturia in men and women after taking major confounding factors into account. In addition, in a well-balanced PSM data, our study showed that CVD was associated with prevalence of nocturia.

CONCLUDING MESSAGE

These findings indicate that nocturia may predict CVD as the number of nocturia increases. Moreover, the results provide better understanding of the underlying mechanisms of nocturia and the association between nocturia and CVD.

Funding None **Clinical Trial** No **Subjects** Human **Helsinki** Yes **Informed Consent** No

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BEST IN CATEGORY PRIZE "HEALTH SERVICES DELIVERY"

UNDERSTANDING THE IMPACT OF URINARY INCONTINENCE IN PATIENTS WITH DEMENTIA: DEVELOPMENT OF AN INTERDISCIPLINARY SERVICE MODEL

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HYPOTHESIS / AIMS OF STUDY

Dementia is estimated to affect over 1 million people in the UK by 2021 and the prevalence of concomitant urinary symptoms such as incontinence is estimated to exceed 50%. The resultant psychological and socio-economic burden for patient, family and carers can be substantial [1].

Our aim was to develop a dedicated urology service within a cognitive impairment clinic led by neurologists in order to treat and better understand the bothersome urinary symptoms suffered by these patients, with a focus on patients with dementia and urinary incontinence (UI).

STUDY DESIGN, MATERIALS AND METHODS

Patients attending this clinic were invited to be assessed and interviewed by urologist, together with their family and or/carer. As well as formal history, exam and relevant investigations, themes of importance such as impact on quality of life and select question items were drawn from validated questionnaires such as the King's Health Questionnaire (KHQ) and relevant ICIQ modules. Multi-disciplinary Team (MDT) meeting was carried on same day to discuss each case, together with neurologist, psychologist, psychiatrist and specialist nursing team. Outcomes of the first 75 patients with UI and dementia have been reported.

RESULTS

Average age was 70 years (range 58-98, male to female ratio 1.5:1). In regards to dementia subtype, the majority had a diagnosis of Alzheimer's disease (n=43, 57%) or Frontotemporal dementia (n=12, 16%). Average Montreal Cognitive Assessment (MoCA) score was 17/30 (range 5-29). 34% (n=18) reported faecal incontinence (as well as UI). The average score for how much leaking of urine interferes with everyday life was 7.7/10 (range 2-10). The commonest answer for when urine leaks was, for no obvious reason (72%, n=54) and 25.3% (n=19) reported this leakage occurred all the time. 58.7% (n=44) revealed some degree of sleep disturbance and tiredness due to the leakage. 83% (n=62) stated that their daily activities were limited due to UI. Two thirds of patients (n=50) stated their bladder problem makes them feel anxious or nervous. Over 80% stated that their daily activities were limited due to UI. 88% (n=67) felt the topic was

socially embarrassing for them to discuss, both among their families and with health professionals. All the carers stated that the persons' continence care affects care they provide and agreed that that more awareness and teaching would be beneficial. Moreover, less than one third of patients or carers (30.7%, n=23) were aware of or had been in contact with any bladder and bowel community service. More than half of carers (n=46, 65%) were concerned UI may be a principle reason for future nursing home admission. While all respondents stated that continence issues affected the care they provided, this was heightened in those who could not afford additional (self-funded) assistance compared to those who could (6.9/10 versus 8.3/10).

INTERPRETATION OF RESULTS

This co-ordinated approach to the management of dementia and bothersome urinary tract symptoms has revealed how much dementia patients can struggle with UI. Our clinic observations were consistent with previous research by Engberg et al and others, in regards to the range of adopted self-care behaviours by patients such as strict fluid restriction in an attempt to remedy UI [2]. The burden of UI appeared under-reported due to the common misconceptions that it is an inevitable part of the disease and ageing process and that no treatment strategies exist. This project, while limited by small numbers of patients, shows the potential benefits of a co-ordinated approach between specialities. In financially pressured health care systems, the next step in our hospital would be for the development of a tailored referral pathway between neurologists and urologists to identify those patients who would benefit most from urology input.

CONCLUDING MESSAGE

In patients with cognitive impairment who develop UI, it can be distressing and disrupt many facets of daily life. Moreover, it can serve as the precursor to loss of independence and even early nursing home admission. Bladder and bowel services are invaluable and awareness of the benefits of such resources should be increased across primary and secondary care. Development and expansion of models like this one and improved inter-speciality referral pathways are important steps improving patient care.

REFERENCES

1. Wagner TH, Patrick DL, Bavendam TG et al. Quality of life of persons with urinary incontinence: development of a new measure. Urology. 1996 Jan 1;47(1):67-71.
2. Engberg SJ, McDowell BJ, Burgio KL et al. Self-care behaviors of older women with urinary incontinence. Journal of Gerontological Nursing. 1995 Aug 1;21(8):7-9.

Funding National Institute Health Research (NIHR) UK **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This was a service evaluation as part of audit **Helsinki** Yes **Informed Consent** No

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CONSUMER INFORMATION ON YOUTUBE: A EVALUATION OF THE READABILITY AND CONTENT-QUALITY OF PELVIC ORGAN PROLAPSE VIDEOS

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HYPOTHESIS / AIMS OF STUDY

Nearly 90 million Americans have health literacy skills that are basic or below basic. The Centers for Disease Control define health literacy as the capacity of an individual to obtain, process, communicate, and understand health information to make appropriate medical decisions [1]. Increasingly, individuals are using YouTube, the largest video-sharing site, to acquire medical knowledge. The aim of this study was to review the readability and quality of pelvic organ prolapse (POP) YouTube videos.

STUDY DESIGN, MATERIALS AND METHODS

The search term, "Pelvic Organ Prolapse" was used to analyze the readability of the first 50 written transcripts of YouTube videos. Transcripts were excluded if they lacked narration in English or contained both no text and no audio. The readability of written transcripts was evaluated using an online software (www.readabilityformulas.com) to determine reading grade levels. The quality of videos was scored using the DISCERN quality criteria and the Patient Education Materials Assessment Tool (PEMAT). Accuracy was assessed by comparing content to accepted POP treatment guidelines.

RESULTS

The mean readability scores of all 50 videos was 13.0 (Table 1). Over 80% of the videos contained poor quality information with mean Gunning Fog, Flesch-Kincaid, and SMOG scores of 15.8, 12.6, and 10.6 respectively. The mean readability index for videos with a low PEMAT score (score < 70%) for understandability and actionability was 12.5 and 12.9 respectively (Table 1). The PEMAT understandability and actionability scores for videos with low readability (score > 9) was 73% and 61% respectively. Videos with low readability scores had an average DISCERN score of 3. The average Gunning Fog, Flesch-Kincaid, and SMOG readability scores for videos with high misinformation was 15.3, 11.9, and 10.4 respectively (Table 1).

INTERPRETATION OF RESULTS

Transcripts of POP YouTube videos are written at difficult levels with many transcripts exceeding the reading capabilities of the American population. The typical American adult reads at a seventh-grade level, yet the overall readability index of POP transcripts on YouTube requires an education grade level greater than twelve [2]. The majority of videos are low quality, with many omitting other treatment options,

risks of treatment, and/or shared decision making with medical professionals.

CONCLUDING MESSAGE

Appropriate patient understanding is essential when dispersing patient driven resources. Difficult-to-comprehend transcripts can impede upon the intended message. These findings suggest that there is an immense need for improvement in patient education materials. Efforts should be made to avoid complex terms when creating patient focused content and helping patients navigate to content of appropriate literacy online.

FIGURE 1

	Percent of Videos	Mean number of views	Mean Gunning Fog Score	Mean Flesch-Kincaid Score	Mean SMOG scores	Mean Readability Score
All Videos	100%	92,081	15.82	12.63	10.65	13.0
Moderate to poor quality (DISCERN score ≤3)	82%	111,290	15.8	12.6	10.6	13.0
High Misinformation (DISCERN score ≥3)	16%	3,460	15.3	11.9	10.4	12.5
Commercial Bias	26%	3,166	14.7	11.6	10.2	12.2
PEMAT Low Understandability	50%	177,232	15.2	11.9	10.3	12.5
PEMAT Low Actionability	64%	139,195	15.6	12.4	10.8	12.9

Table 1. The readability of pelvic organ prolapse YouTube videos with content that includes misinformation, biased data, or insufficient scientific validation.

REFERENCES

1. Rudd R. Health Literacy. Centers for Disease Control and Prevention. https://www.cdc.gov/healthliteracy/learn/index.html. Updated December 13, 2016.
2. Gaines T, Malik RD. Readability of pelvic floor dysfunction questionnaires. Neurourology & Urodynamics. 2020;39(2):813. http://search.ebscohost.com.proxy-hs.researchport.umd.edu/login.aspx?direct=true&db=edb&AN=141660718&site=eds-live.

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IT'S ABOUT TIME: THE TEMPORAL BURDEN OF LOWER URINARY TRACT SYMPTOMS AMONG WOMEN

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HYPOTHESIS / AIMS OF STUDY

Lower urinary tract symptoms (LUTS) are associated with substantial economic, social, and emotional costs, with negative impact on overall health and quality of life. The experience of LUTS impacts the day-to-day physical, emotional, and social wellbeing of women. While efforts have been made to improve the quality of life of women with LUTS, there remains a need for a contextual understanding of bladder symptoms and how LUTS affect the daily life of sufferers. An aim of the Prevention of Lower Urinary Tract Symptoms Research Consortium (PLUS) (1) is to understand better the lived experiences of women with LUTS, including psychological, social, and institutional processes. The aim of this study was to explore the lived experiences of U.S. adult women who experienced LUTS and to identify salient features of living with LUTS.

STUDY DESIGN, MATERIALS AND METHODS

This is a secondary analysis of qualitative interviews conducted with 50 women from the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) (2) (Table 1).

The purpose of this analysis was to explore the temporal burden of LUTS. All participants reported one or more LUTS, such as storage, voiding, and post-micturition symptoms (Table 1). Seventy-six percent of participants had sought treatment for LUTS.

Using directed content analysis, pairs of PLUS investigators (specialists in urology, gynecology, nursing, medical sociology, behavioral science and public health) coded the interview transcripts and identified themes related to living with LUTS. Data interpretation involved an inductive process guided by team science and informed by a transdisciplinary perspective.

RESULTS

Accounts of living with LUTS have a prominent place in the biographies of symptomatic women, taking the form of illness narratives recounting the emergence and progression of LUTS. Descriptions of the onset and temporal progression of LUTS reveal the increasing burden of symptoms and their pervasive and all-encompassing impact on daily life. Managing LUTS can become the driving organizational principle of daily life, leading to a loss of spontaneity and reduction of valued activities. Feelings of shame and embarrassment are engendered by untimely manifestations of LUTS during interpersonal encounters and in public settings. Descriptive accounts of living with LUTS emphasize the need for constant vigilance and time-consuming self-management strategies. Women with LUTS articulate a dissatisfaction with stopgap measures for relieving symptoms, underscoring a pressing need for an increased focus on prevention. (Table 2).

INTERPRETATION OF RESULTS

Articulating the temporal burden of LUTS demonstrates how constraints imposed by the interaction of time with LUTS can dictate the organization of daily life. Stories of the temporal burdens incurred by women living with LUTS can provide direction for research efforts and serve as cautionary tales in

public health messages about risk and protective factors for bladder health and function.

CONCLUDING MESSAGE

Further research is needed to develop interventions to minimize the impact and prevent the development of LUTS. Nurses have a key role in conducting routine screening, symptom assessment, and symptom management providing bladder health education

FIGURE 1

Table 1. Characteristics of Participants (n=50)

Age	
Range, yrs. (min, max)	19, 77
Mean, yrs. (SD)	51.0 (15.0)
Race n (%)	
Asian/Asian American	1 (2)
Black/African American	8 (16)
Native Hawaiian/Pacific Islander	1 (2)
White	36 (72)
Other/Multi-racial	4 (8)
Lower Urinary Tract Symptoms* n (%)	
Frequency (n=42)	10 (24)
Urgency (n=42)	34 (81)
Incontinence (41)	
Rarely	3 (7)
Sometimes or greater	27 (66)
Nocturia (n=42)	
1 time/night	13 (31)
2 time/night	22 (52)
Pain/discomfort in bladder area (n=42)	10 (24)
Burning with urination (n=42)	52 (12)

*Based on responses to individual items of the LUTS Tool questionnaire

FIGURE 2

Table 2. Women's Voices of the Temporal Burden of LUTS

Narratives of LUTS:	Stories of LUTS reveal temporal markers and anchors for keeping track of onset and progression of the burden of LUTS across the life course.	*I would say it definitely began in the early 2000s because up until then I was teaching, and I couldn't leave the classroom. Obviously, I was able to hold it until then, but then I retired in 2002.* ***It started getting bad about 2010.***
LUTS in Daily Life:	Time is a recurring theme shaping women's experiences, pointing to the salience of the temporal burden of LUTS. LUTS dominates daily thoughts and routines. Managing LUTS is time- consuming, becoming an organizing principle of daily life.	*Honestly, in my mind I am on a schedule, so it* ***controls my life*** *where I don't want to be gone for too long or to go and grab lunch and walk somewhere.*
All-Encompassing Impact of LUTS:	The burden of LUTS pervades all aspects of life, creating a "global life-style" characterized by planning ahead to forestall problems and engaging in vigilant surveillance to manage LUTS in the event of an unexpected breach of protection.	*It's sort of the* ***global lifestyle*** *of needing to make sure there's always a bathroom nearby, making sure I have sufficient pads to catch things.*
Off-Time Appearance of LUTS:	The burden of LUTS is felt acutely by women in early- and mid-life who feel they are reverting to childhood.	*Mostly just the irritation of constantly having accidents like* ***3- years old or something.***
It's About Time:	The cumulative burden of LUTS on quality-of-life can erode capacity to manage and cope with symptoms. Women reach a tipping point representing the limit of their endurance.	*The urgency is what drives me crazy, and from time to time I will have an accident because I can't get there in time. Then, of course, the frequency is no picnic either. I could go 10-15 times a day. Sometimes it seems like a normal trip to the bathroom. Other times, it's "why am I here?" I am* ***ready to get rid of this.***

REFERENCES

1. Harlow BL, Bavendam TG, Palmer MH, Brubaker L, Burgio KL, Lukacz ES, Miller JM, Mueller ER, Newman DK, Rickey LM, Sutcliffe S, Simons-Morton D. The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium: A transdisciplinary approach toward promoting bladder health and preventing lower urinary tract symptoms in women across the life course. J Womens Health (Larchmt). 2018 Mar;27(3):283-289.
2. Griffith JW, Messersmith EE, Gillespie BW, Wiseman JB, Flynn KE, Kirkali Z, Kusek JW, Bavendam T, Cella D, Kreder KJ, Nero JJ, Corona ME, Bradley CS, Kenton KS, Helfand BT, Merion RM, Weinfurt KP; LURN Study Group. Reasons for Seeking Clinical Care for Lower Urinary Tract Symptoms: A Mixed Methods Study. J Urol. 2018;199(2):528-535.

Funding Data provided by the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN). LURN supported by NIDDK (grants DK097780, DK097772, DK097779, DK099932, DK100011, DK100017, DK099879). The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium supported by NIH—NIDDK by cooperative agreements (grants U01DK106786, U01DK106853, U01DK106858, U01DK106898, U01DK106893, U01DK106827, U01DK106908, U01DK106892). **Clinical Trial** No **Subjects** Human **Ethics Committee** The study was approved by Ethical & Independent Review Services for the DCC, and by local university IRBs at the four enrolling sites. **Helsinki** Yes **Informed Consent** Yes

611 www.ics.org/2020/abstract/611

CAREGIVERS' ATTITUDES TOWARDS AN APP BASED TREATMENT FOR URINARY INCONTINENCE IN WOMEN: A MIXED METHODS STUDY

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HYPOTHESIS / AIMS OF STUDY

Mobile health (mHealth) applications (apps) provide a promising route to improve healthcare delivery and outcomes. Besides increasing adherence, health apps have the ability to reach people suffering from conditions that make them feel embarrassed or stigmatized and may lower barriers for women with urinary incontinence (UI). Recent studies show that apps for UI could be an effective and cost-effective option in the treatment of UI. Knowledge about the attitudes of stakeholders is important for successful implementation, but lacking [1].

Therefore, we aim to explore the attitudes of care providers towards the use of an app in the treatment of urinary incontinence, and to investigate the preferences and anticipated

barriers for implementation of an app-based treatment for UI according to care providers.

STUDY DESIGN, MATERIALS AND METHODS

We performed a sequential mixed methods study, consisting of focus groups followed by a quantitative questionnaire. We organized 5 focus group sessions with the main caregivers involved with UI care; general practice assistants (PA) (n=7), (resident) general practitioners (GP) (n=6), registered pelvic physiotherapists (PPT) (n=8, n=7), and (resident) uro- and gynecologists (UG) (n=6). Sessions were recorded, transcribed verbatim and coded separately by two researchers. Emerging themes were used to form a questionnaire, which was widely spread among Dutch caregivers to further investigate their attitudes towards current UI care and the possible role of eHealth applications in UI treatment. The questionnaire included 17 statements regarding the use of an app for treatment of UI in women, with 5 response categories ranging from strongly disagree to strongly agree.

RESULTS

Focusgroup sessions

Care providers explored and discussed the possible roles eHealth applications could play in the treatment of UI in women, like providing patients with reliable information, supporting treatment adherence and lowering barriers for women who don't want to visit their physician for UI.

Additionally, they discussed preconditions and barriers concerning implementation of an app for the treatment of UI. Some of them felt that a reliable party should develop such an app and effectiveness should be demonstrated before they would consider it as a treatment option. Barriers for implementation according to care providers were concerns about data safety, lack of time and financial compensation for this time, a fear of decreased or increased patient contact and a lack of clear legal guidelines for usage of eHealth applications.

Quantitative Questionnaire

In total, 741 care providers with a mean age of 45 years, completed the questionnaire (Figure 1); 87% of the participants was female, and 75% had never referred patients to treatment apps for UI.

The majority of all care providers (strongly) agreed that an app for UI can support regular treatment (68%) and that it can support treatment adherence after regular treatment (61 %)(Figure 2). 56% of all care providers and 89% of all PPTs (strongly) agreed that an app for UI should always be used with supervision of a care provider. 48% of all care providers and 15% of PPTs (strongly) agreed that an app for UI is a sound alternative for women who don't visit a care provider.

Almost all care providers (strongly) agreed that an app for UI should be developed by a reliable organization (95%) and that it should fulfil legal obligations regarding safety and privacy (93%), before they would refer patients to a treatment app for UI. Proven effectiveness was important to 83% of all care providers. There were no evident differences in subgroups.

A lack of time to get familiar with the app, was seen as a barrier by 42%, and lack of financial compensation for this time investment by 19% of participants. The majority of participants (strongly) disagreed that fear of decreased or increased patient contact would be a barrier for using an app for UI (respectively 80% and 81%). 49% of care providers (strongly) disagreed that doubts about personal benefits would be a barrier for implementation.

INTERPRETATION OF RESULTS

Our results demonstrate that many care providers in the Netherlands see a supportive role for mhealth in the treatment for UI. This is in agreement with recent literature showing that care providers have a positive attitude towards a variety of mHealth applications [2]. In an earlier study, Dutch GPs welcomed eHealth for UI as a new tool, but reported doubts regarding eHealth as a standalone therapy. This is in line with current data showing that 56% of all care providers and 47% of GPs feel that a caregiver should always supervise an app treatment.

Our study shows that several contextual factors like a lack of time, financial issues, protection of data and privacy could play a role when implementing an app for UI. A recent systematic review on mHealth adoption by professionals identified several barriers and facilitators of which 'time-issues' was the most common barrier, in n=10 out of 33 reviewed articles [3]. Reimbursement of tasks related to mHealth was mentioned as a barrier by only one publication in this review article. This might indicate a low importance, which was also seen in our study where only 19% of our participants viewed financial compensation for time investment as a barrier.

CONCLUDING MESSAGE

This study provides valuable insight into several contextual factors valued by professionals regarding implementation of an app based treatment for UI in women. Care providers see a supportive role for an app during and after regular treatment. Despite the evidence for effectiveness of eHealth for UI as a stand-alone treatment, care providers are divided towards app usage in absence of a health provider. These factors, along with other barriers and preconditions identified in this study, should be taken into account to promote future implementation of an app for the treatment of UI in women.

FIGURE 1

Table 1. Demographics of participants.

Sex, n (%)	
Female	644 (87)
Male	97 (13)
Age, years, mean (SD)	45 (10,7)
Profession, n (%)	
PA	351 (48)
GP	124 (17)
PPT	76 (10)
UG	183 (25)
Region of employment, n (%)	
North NL	397 (54)
Middle NL	205 (28)
South NL	139 (19)
Owning a smartphone, n (%)	731 (99)
EHealth, work-related, n (%)	
Usage, ≤1x per month	
o Health apps	465 (63)
o Websites	685 (92)
o E-consultation	260 (35)
Referral to digital tools for UI	
Online information	
o Never	136 (18)
o Seldom	58 (8)
o Sometimes	186 (25)
o Often	274 (37)
o Always	87 (12)
Treatment apps	
o Never	552 (75)
o Seldom	86 (12)
o Sometimes	70 (9)
o Often	24 (3)
o Always	9 (1)

NL= Netherlands, PA = practice assistant, GP= (resident) general practitioner, PPT = pelvic physiotherapist, UG = (resident)uro- and gynecologist.

FIGURE 2

**Answered by all care providers, i.e. practice assistants (PAs), (resident)general practitioners (GPs), pelvic physiotherapists(PPTs) and (resident)uro- and gynecologists (UGs). **Answered by GPs, PPTs and UGs.*

Figure 2. Results of analysis of survey questions. Numbers inside the bars show the level of agreement of care providers in percentages.

REFERENCES

1. Mair FS, May C, O'Donnell C, Finch T, Sullivan F, Murray E. Factors that promote or inhibit the implementation of e-health systems: an explanatory systematic review. Bull World Health Organ. 2012;90(5):357–364. doi:10.2471/BLT.11.099424
2. Kong T, Scott MM, Li Y, Wichelman C. Physician attitudes towards-and adoption of-mobile health. Digit Health. 2020;6:2055207620907187. Published 2020 Feb 20. doi:10.1177/2055207620907187
3. Gagnon M-P, Ngangue P, Payne-Gagnon J, Desmartis M. M-health adoption by healthcare professionals: a systematic review. J Am Med Inform Assoc. 2015;23(1):212–220. doi: 10.1093/jamia/ocv052.

Funding This work was supported by a grant from ZonMw, The Dutch Organisation for Health Research and Development. Project number: 837001508. **Clinical Trial** No **Subjects** Human **Ethics Committee** The Medical Ethical Review board of the University Medical Centre Groningen in the Netherlands **Helsinki** Yes **Informed Consent** Yes

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CORRELATION ANALYSIS OF QUALITY OF LIFE WITH DIFFERENT GROUPS OF FEMALE LOWER URINARY TRACT SYMPTOMS BASED ON 2,953 BLADDER DIARIES

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HYPOTHESIS / AIMS OF STUDY

Storage symptoms include frequency, urgency, nocturia and incontinence. Based on bladder diaries, we could get the objective data of the above symptoms. To the best of our knowledge, there is lack of correlation of quality of life (QoL) with lower urinary tract symptoms (LUTS) based on bladder dairies. Thus, we aimed to perform the above correlation.

STUDY DESIGN, MATERIALS AND METHODS

The bladder diaries and the King's Health Questionnaires of all consecutive women with LUTS, who visited urogynecologic clinics in a tertiary referral center, were reviewed.

Base on bladder dairies, women with at least one episode of urgency and urinary incontinence were allocated to the overactive bladder syndrome (OAB) & urinary incontinence (UI) group. Women with at least one episode of urgency but without incontinence were allocated to the OAB group. Women with at least one episode of urinary incontinence but without urgency were allocated to the UI group. Women with ≥2 episodes of nocturia but without urgency and urinary incontinence were allocated to the nocturia group. Women with ≥8 episodes of daytime frequency but without urgency, urinary incontinence and ≥2 episodes of nocturia were allocated to the frequency group. Women without urgency, urinary incontinence, ≥2 episodes of nocturia and ≥8 episodes of daytime frequency were allocated to the normal group.

Analysis of variance with Bonferroni correction was used to perform statistical analysis for between-group comparisons.

RESULTS

Between 2010 and 2019, medical records of 2,953 women were reviewed in this study. There was no case with isolated "≥8 episodes of daytime frequency" (i.e., the frequency group). All women with ≥8 episodes of daytime frequency also had at least one episode of urgency. Women in the OAB & UI and nocturia groups were older than the normal group (Table 1). In addition, higher parities were noted in the OAB & UI and nocturia groups, compared with the normal group (Table 1).

Compared with the normal group, the QoL scores were poorer in all groups (Table 2). In addition, the OAB & UI group had the poorest QoL scores, compared with the other groups. The OAB group had similar QoL scores with the UI group. The nocturia group had better QoL scores, compared with the OAB & UI and OAB groups (Table 2).

INTERPRETATION OF RESULTS

Based on bladder diaries, we can classify women with LUTS into five groups (i.e., the OAB & UI, OAB, UI, nocturia and normal groups). In general, after correlation with the scores of King' Health Questionnaire, the OAB & UI group had a poorest QoL score, followed by the OAB group and the UI group. The nocturia group had a better QoL score than the OAB & UI, OAB and UI groups.

CONCLUDING MESSAGE

Based on bladder diaries, we can classify women with LUTS into five groups (i.e., the OAB & UI, OAB, UI, nocturia and normal groups), and this classification is closely related to the severity in the impairment of QoL. Thus this novel classification based on bladder dairy might be used a reference of disease severity for physicians in treating women with LUTS.

FIGURE 1

Table 1. Baseline characteristics among subgroups of female lower urinary tract symptoms based on bladder diaries (n=2,953)

Variables	OAB & UI (n=726, a)	OAB (n=1,163, b)	UI (n=94, c)	Nocturia (n=737, d)	Normal (n=233, e)	†p	‡Post hoc analysis
Age (years)	62.8±12.3	58.5±12.9	58.8±11.6	62.7±11.5	57.4±12.2	<0.0001	a vs. e, p<0.001; d vs. e, p<0.001
Parity	2.9±1.8	2.4±1.3	2.5±1.2	3.0±1.5	2.6±1.1	<0.0001	a vs. e, p=0.03; d vs. e, p=0.006

Values were presented with mean ± standard deviation. OAB = overactive bladder syndrome, UI = urinary incontinence.
†Analysis of variances (ANOVA).
‡Bonferroni correction.

Table 1

FIGURE 2

Table 2. The scores of the King's Health Questionnaires among subgroups of female lower urinary tract symptoms based on bladder diaries (n=2,953)

Variables	OAB & UI (n=726, a)	OAB (n=1,163, b)	UI (n=94, c)	Nocturia (n=737, d)	Normal (n=233, e)	†p	‡Post hoc analysis
GHP	54.1±21.3	48.8±21.3	48.4±24.1	43.1±22.2	33.0±20.4	<0.0001	a, b, c & d vs. e, all p<0.001; a & b vs. d, all p<0.001; a vs. b, p<0.001
II	55.4±31.0	42.3±32.0	36.9±28.0	27.5±29.8	16.7±22.6	<0.0001	a, b, c & d vs. e, all p<0.001; a, b & c vs. d, all p<0.05; a vs. c, p<0.001; a vs. b, p<0.001
RL	49.0±31.1	35.3±31.0	26.3±25.6	21.5±27.0	13.0±20.2	<0.0001	a, b, c & d vs. e, all p<0.01; a & b vs. d, all p<0.001; a & b vs. c, all p<0.05; a vs. b, p<0.001
PL	54.9±31.3	39.0±31.2	33.9±27.7	25.5±28.6	15.4±21.7	<0.0001	a, b, c & d vs. e, all p<0.001; a & b vs. d, all p<0.001; a vs. c, p<0.001; a vs. b, p<0.001
SL	36.1±31.0	25.1±28.6	18.6±25.4	15.3±23.7	7.0±13.9	<0.0001	a, b, c & d vs. e, all p<0.01; a & b vs. d, all p<0.001; a vs. c, p<0.001; a vs. b, p<0.001
PR	24.1±31.7	20.3±30.0	13.3±25.4	14.4±26.5	7.8±15.6	<0.0001	a & b vs. e, all p<0.01; a & b vs. d, all p<0.05
E	45.7±31.3	33.3±29.9	27.7±26.2	22.1±27.6	13.9±20.0	<0.0001	a, b, c & d vs. e, all p<0.01; a & b vs. d, all p<0.001; a vs. c, p<0.001 a vs. b, p<0.001
SE	49.9±28.8	40.5±29.1	30.1±25.4	27.5±27.2	14.4±17.5	<0.0001	a, b, c & d vs. e, all p<0.001; a & b vs. d, all p<0.001; a & b vs. c, all p<0.01; a vs. b, p<0.001
SM	50.2±27.1	25.9±22.8	39.4±25.0	17.2±20.2	14.6±18.6	<0.0001	a, b & c vs. e, all p<0.001; a, b & c vs. d, all p<0.001; a & b vs. c, all p<0.001; a vs. b, p<0.001

Values were presented with mean ± standard deviation. E = emotions, GHP = general health perceptions, II = incontinence impact, OAB = overactive bladder syndrome, PL = physical limitations, PR = personal relationships, RL = role limitations, SE = sleep/energy, SL = social limitations, SM = severity measures, UI = urinary incontinence.
†Analysis of variances (ANOVA), ‡Bonferroni correction.

Table 2

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Research **Ethics Committee** of National Taiwan University Hospital **Helsinki** Yes **Informed Consent** No

SESSION 40 (PODIUM VIDEO) - VIDEO 3: CREATIVE IDEAS
Abstracts 613-621
15:00 - 16:30, Brasilia 4
Chairs: Prof Helen Elizabeth O'Connell (Australia), Dr Joanna Togami (United States)

613 www.ics.org/2020/abstract/613

COVID-19 GLOBAL EPIDEMIC- "MOBILE UROLOGIST`S BAG III" (MUBIII)- SAFETY MODIFICATIONS

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INTRODUCTION
The Mobile Urologist's Bag III (MUBIII) was developed for a rapid complication management of urogenital diseases or injuries. It is a mobile urology emergency kit which includes among others a wireless portable ultrasound probe. This short note describes how the MUBIII and the usage of its wireless ultrasound probe could be an advantage for urological examination during the global COVID-19 epidemic.

The MUBIII kit can be utilized for urological emergencies such as urinary retention, overflow bladder, voiding disorders, congested kidney, kidney and bladder stones, urosepsis, abscesses, tumor complications, postoperative complications, hematuria, priapism, bladder or rectum and urogenital injuries. The mobility of MUBIII is beneficial during the COVID- 19 epidemic, as it enables to examine patients in emergency room or during isolation.

DESIGN
In general, in order to treat COVID- 19 positive patient safely, health care professionals must use personal protective equipment (PPE)- gown, medical mask/ respirator, gloves and eye protection (goggles/face shield).

In order to use the wireless ultrasound probes safely, we suggest utilizing a sterile pair of gloves. This technic is the cheapest and available one. One glove is for covering the wireless ultrasound probe, the second one is cut to create a rubber band as a closing device.

The steps for preparation of the wireless ultrasound probe protective cover is as following :1) Take the first glove and put ultrasound gel inside the glove, then put the probe inside. 2) Close the probe- cover with the self-made rubber band. 3) Before using the probe, move the gel inside the cover (the first glove) to the tip of the probe so there is no air that can distort the image. 4) Then put a bit of gel on top of the probe to start examination.

The probe is connected to a tablet or phone. The modality has to be chosen before using the probe. Attention do not touch the screen or any other devices while using the probe, avoid any risk for contamination. The bottom on the probe is using for stop, save, freeze and record the exam.

In order to remove the cover safely after examination: Remove the rubber band and squeeze the probe out of the glove carefully without touching it. Then disinfect the probe carefully. The probe can be next restored in the MUBIII or covered again as described above for the next usage.

RESULTS
Currently known, COVID- 19 is transmitted by small droplets from the nose or mouth of an infected person. These droplets are spread by COVID- 19 infected patient and contaminate patient's clothes, skin and other objects and surfaces at the surrounding. This contamination can enhance the transmission of to COVID- 19 to other persons. Therefore, it is highly important to avoid contamination of the MUBIII kit and especially its wireless ultrasound probe.

The mobility of MUBIII is beneficial during the COVID- 19 epidemic, as it enables to examine patients in emergency room or during isolation.

CONCLUSION
Handling of the portable devices in the MUB III is a rapid and efficient way for emergency treatment even in case of outdoor patients. The application of MUB III in clinical practice saves time and reduces costs.

Funding No **Clinical Trial** No **Subjects** Human **Ethics not Req'd** No **Helsinki** Yes **Informed Consent** Yes

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PLACEMENT OF A COIN-SIZED IMPLANTABLE TIBIAL NEUROSTIMULATOR (ECOIN DEVICE) FOR URGENCY URINARY INCONTINENCE

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INTRODUCTION
The treatment of overactive bladder (OAB) with urgency urinary incontinence (UUI) symptoms follows an algorithmic pathway. Patients who fail first- and second-line treatments may be offered percutaneous tibial nerve stimulation

(PTNS), onabotulinumtoxinA injections (BOTOX) or sacral neuromodulation as a third-line treatment. An implantable tibial nerve stimulator may present a more convenient and effective treatment than these options. The coin-sized neurostimulator is subcutaneously implanted in a single visit using only local anesthesia. We present an instructional video demonstrating the brief placement of the eCoin device for the treatment of OAB with UUI.

DESIGN

The eCoin placement technique is demonstrated on a patient in an ambulatory surgery center procedure room setting. A custom marking template (Figure 1A) is provided to indicate the location of the incision and final eCoin placement. Once the markings are made, the patient is prepped for the procedure with local anesthesia. The lower leg is then sterilized and draped. The custom marking tool is used again to remark the incision site and eCoin placement location. Once the incision is made, a custom sizing blunt dissection tool (Figure 1B) is used to create a pocket for device placement. The eCoin is then easily inserted into the pocket (Figure 2A), located above the tibial nerve. A layered closure technique is completed (Figure 2B). The patient is then fitted with an ankle support to provide gentle compression for 4 weeks. During this period, the patient is instructed to comply with provided aftercare instructions and materials in order to prevent infection or eCoin device migration. After the 4-week healing duration, the eCoin device is activated.

RESULTS

A total of 133 patients across 15 study sites were implanted with the eCoin device in a clinical trial. The mean implant time from incision to closure was 20.77 minutes (SD 9.08). The median implant time was 18 minutes. All of the patients were evaluated for wound healing approximately 2 weeks post implant. There was 1 related severe adverse event, an infection resulting in uncomplicated explant at a hospital setting. At the time of this writing, patients in the study have had the device implanted for an average of 56.9 weeks. The treatment is effective and sustainable as described in other abstract submissions.

CONCLUSION

We demonstrate the use of a safe method of subcutaneous tibial nerve stimulation implant placement that is done in the office under local anesthesia. The procedure time is relatively brief resulting in minimal adverse events in a large cohort.

FIGURE 1

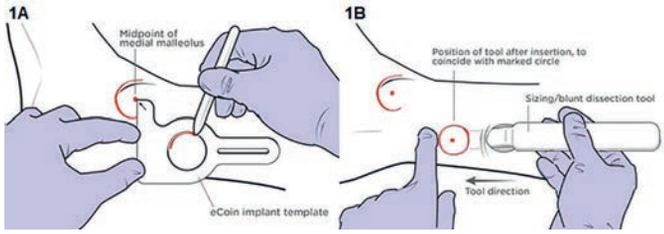
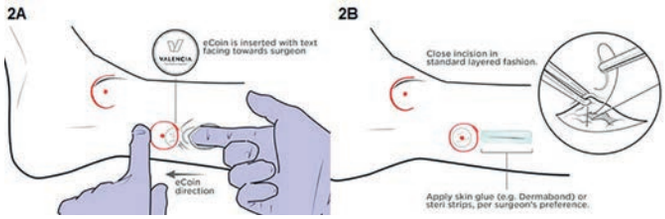


FIGURE 2



Funding Valencia Technologies Corporation **Clinical Trial** Yes **Registration Number** NCT03556891 **RCT** No **Subjects** Human **Ethics Committee** Western Institutional Review Board **Helsinki** Yes **Informed Consent** Yes

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REMOVAL OF INTERSTIM TINED-LEAD USING STRAIGHT STYLET. DESCRIPTION OF A SURGICAL TECHNIQUE.

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INTRODUCTION

In Sacral Neuromodulation (SNM) therapy approximately 20-30% of implanted patients need a surgical revision, while 15-18% of them undergo a definitive explantation. Whatever the reason for quadripolar lead removal, it is estimated that up to 7.5% of procedures are associated with a lead damage and consequently breakage. It is still unclear what the consequences of leaving fragments in the pelvis could be. Aim of our study is to describe the new technique we have been using for the last two years in our centre to remove the quadripolar lead, using the straight stylet disposable in the electrode kit.

DESIGN

We searched SNM database of our institution for all the patients that underwent a quadripolar lead removal from January 2018 to January 2020, using our standardized technique and after informed consent. The novelty of the technique consists in the use of the straight stylet, which typically

comes pre-packaged with the quadripolar tined-lead. The stylet gives the electrode greater stiffness, reducing interactions with surrounding tissues, probability of damage of the lead and its breakage during removal.

RESULTS

59 patients (41 women and 18 men) underwent a quadripolar lead removal using our standardized technique from January 2018 to January 2020. 44 out of 59 patients removed a tined-lead within 3 months from SNM-test, due to the absence of significant benefits on symptoms (negative first stage SNM). In 15 patients the electrode was removed due to failure of definitive implant. Mean time from definitive IPG implant to lead removal was 67.9 months (5.6 years). In 10 out of this cohort of patients, the lead was replaced, while it was permanently removed in 5 cases. Reasons for lead removal were a loss of efficacy of SNM with no evidence of electrode displacement or malfunctioning (6 cases); a sub-optimal electrode position at X-ray or CT-scan (5 cases); pain (1 case); need for magnetic resonance for other clinical reasons (1 case); device malfunctioning (1 case); substitution of IPG 3023 model with an IPG 3058 model (1 case). We recorded only 1 case of lead-breakage during lead-removal in the whole population: a female patient with a quadripolar lead placed 18 years before, with an open technique and a surgical fixation on periosteum of sacral bone (non-tined electrode). Lead removal by gentle traction was not possible, and it was decided not to proceed with a deeper surgical extraction.

CONCLUSION

Quadripolar lead breakage during removal procedure is not uncommon. A few data about possible adverse effects of leaving fragments in the pelvis are available. Our technique has been safely used for the last 2 years in our centre, with no episodes of lead breakage or retained fragments, except for one non-tined electrode.

Funding Nothing to declare **Clinical Trial** No **Subjects** Human **Ethics not Req'd** The video describes a variant of a pre-existent surgical technique, with safe and approved surgical matherials. No new devices or instruments have been used. Informed consent about variant of the technique was acquired from all the patients before the procedure. **Helsinki** Yes **Informed Consent** Yes

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NEW ADJUSTABLE ARTIFICIAL URETHRAL SPHINCTER (AUS) WITH AN ADDITIONAL STRESS BALLOON TO FURTHER IMPROVE TREATMENT OUTCOME IN MALE STRESS URINARY INCONTINENCE (SUI)

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INTRODUCTION

The artificial urinary sphincter (AUS) became the gold standard to treat stress urinary incontinence (SUI) in the male. The reported success rate varies between 50 to 96%. Still, certain issues seem not to be solved. The recently released AUS Victo+ from Promedon® has been developed to solve these issues: faster reaction to stress, less episodes of urine loss, adjustable cuff to ensure the critical urethral closing pressure in order to avoid atrophy of the corpora spongiosum. We demonstrate the Victo+ surgical procedure and show its safety and efficacy.

DESIGN

We retrospectively reviewed data stored in a multi-center prospective database for 46 (average age:7 0± SD 7,5y) male patients with severe SUI. The causes of SUI were related to previous TURP, radical prostatectomy and even radiation related to prostate cancer.

In the lithotomy position through a midline perineal and inguinal incision, the one-piece Victo+AUS was implanted. Patients were followed from 11 (0,9 - 20,9) months. The essential features of operation are described. Primary successful operative measurements were defined as no complications and patient satisfaction. Successful treatment outcome was defined as no pad usage or reduction of pad usage > 50%.

RESULTS

No intraoperative complications occurred. Operative time was 63 (55-78) min. After 6 weeks the patient returned for activation. 18/36 patients became continent with the initial filling, whereas the other patients needed additional fluid to reach a satisfactory outcome. The need for pads reduced from 6,4 ± 3,6 to 1,8 ± 1,8 pads/day. Overall patient satisfaction was reported at 84%. The patients were also investigated with regard to their leakage while coughing. Related to the stress balloon, leakage while coughing was not seen in any of the patients.

CONCLUSION

The initial results of the Victo+ AUS demonstrates that it can be safely and effectively performed with promising results. The number of implants and the follow-up time is still small to make a final conclusion.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Retrospective data analysis and surgical procedure **Helsinki** Yes **Informed Consent** Yes

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ATOMS ADJUSTABLE SLING: COULD IT BE CONSIDERED AS AN EFFECTIVE OPTION FOR COMPLEX MALE STRESS INCONTINENCE CASES?

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INTRODUCTION

Male stress urinary incontinence is a common complication after radical prostatectomy (4-74% at 12 months, depending on definition). Up to 5% of these patients will need surgery to regain continence. The artificial urinary sphincter (AUS) is the current gold-standard treatment, but it has considerable complication and failure rates. The slings are regarded as an option and their indications have been expanding. ATOMS (Adjustable transobturator male System ®) was created in 2008. It has an adjustable cushion that compresses the bulbar urethra achieving continence rates between 64-95% with major (Clavien III) complications in 2-4%. The market value is 40% less than the AUS. Since it has a compressing mechanism, one might expect it to cause urinary retention when used in patients with underactive detrusor.

DESIGN

We present a complex clinical case in which ATOMS was successfully implanted and we detail the surgical technique. This is a 70-year-old male, with right hemiparesis secondary to a stroke. Five years after radical prostatectomy with undetectable PSA, he complained of stress incontinence using 6 wet pads/day. Cystoscopy showed a patent anastomosis and a shortened hypotonic sphincter. Urodynamics confirmed a stable underactive detrusor, with minimal residual activity. Nonetheless, the patient was able to achieve adequate bladder emptying using Valsalva. Unfortunately, patient's impaired manual dexterity prevents him from manipulating an AUS's pump but, yet, he demonstrated he was capable of self-catheterization. In this scenario, ATOMS was chosen assuming the risk of catheterization. Daily pad count, uroflowmetry, post-void residual, along with IPSS were used during the follow-up.

RESULTS

As shown in the video, after general anesthesia the patient is placed in the lithotomy position. A standard midline perineal incision is carried out until bulbospongiosus muscle is exposed, but spared. Dissection on both sides of the muscle is done, until ischiopubic rami are exposed along with transverse perineal muscle, creating a safety triangular area. The tunneller needles are passed through the medial superior angle of the obturator foramina and the mesh arms are pulled out to place the cushion compressing atop of the bulbospongiosus muscle. The cushion is filled with saline and the port is placed under the dartos fascia in the scrotum. Estimated blood loss was 50 ml. Patient was discharged on postoperative day one, after Foley catheter is withdrawn and normal voiding is achieved. At 1-month follow-up, the patient is using no pads, with no need of self-catheterization and has a maximum flow 24 ml/sec with a few drops leaking only when the bladder is full. Two mL of extra saline are injected achieving complete dryness with no voiding symptoms at 6 months. Patient is fully satisfied.

CONCLUSION

ATOMS adjustable sling is effective for male stress incontinence, yet in severe cases. It can also have good results on complex cases, such as underactive detrusor or in patients who are not candidates for AUS. It should be considered as a part of the therapeutic armamentarium for male stress incontinence.

REFERENCES

1. Esquinas C, Angulo J. Effectiveness of Adjustable Transobturator Male System (ATOMS) to Treat Male Stress Incontinence: A Systematic Review and Meta-Analysis. Adv Ther. 2019;36(2):426-441
2. Doiron C, Saavedra A, Haines T, Nadeau G, Tu L, Morisset J, Steele S, Valiquette L, Elterman D, Maciejewski C, Rourke K. Canadian Experience with the Adjustable Transobturator Male System for Post-Prostatectomy Incontinence: A Multicenter Study. J Urol. 2019;202(5):1022-1028.

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité Ético Cientifico del SSMSO **Helsinki** Yes **Informed Consent** Yes

618 www.ics.org/2020/abstract/618

CYSTOSCOPIC RESECTION OF SQUAMOUS METAPLASIA TO TREAT RECURRENT URINARY TRACT INFECTIONS

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INTRODUCTION

We present a case study demonstrating a novel cystoscopic approach to the treatment of recurrent urinary tract infection (UTI). UTIs are a common infection with symptoms of dysuria, frequency, urgency, suprapubic pain or haematuria. Recurrent UTIs is most commonly described as at least two episodes of symptomatic infection with pyuria or positive urine culture in 6 consecutive months or three infections in the past 12 months.

UTIs are traditionally treated with antibiotics and prolonged courses of prophylaxis may be prescribed in patients with recurrent UTI. However with the growing concerns of antibiotic resistance and the era of antibiotic stewardship alternative effective approaches to recurrent UTI treatment are needed.

Patients with recurrent UTI often have 'trigonitis at cystoscopy'. This is a poorly defined term but is associated with non-keratinising squamous metaplasia accompanied by minimal to severe degrees of inflammation, oedema or cystic changes of the urothelial and lamina propria [1]. Non-keratanising squamous metaplasia at the trigone however is a common finding at cystoscopy and often warrants no further management [2,3].

Cystoscopic resection of trigonitis or squamous metaplasia is a novel treatment approach not previously described.

DESIGN

This is a case presentation of a 39 year old female presenting with a 1 year history of recurrent UTI. She had had ten culture positive UTIs in this year. Prior to the procedure she was experiencing regular dysuria, urinary frequency and urgency and three episodes of nocturia. Urinary tract ultrasound was normal.

She has been treated with repeated courses of oral antibiotics and trialled a 3 month prophylactic course of antibiotics. The frequency of UTI was not improved with this treatment. The patient has no other PMHx.

The patient underwent trans-urethral cystoscopic resection of trigonitis and squamous metaplasia under general anaesthesia. Pre-operative urine analysis was carried out to exclude active UTI. Prophylactic gentamicin was administered at the start of the procedure. The bladder was distended using glycine. A monopolar cysto-resectoscope was used to resect or peel away the squamous metaplasia layer from the trigone. The resected sample was removed from the bladder by trapping the specimen between the loop and the cystoscope and removing the cystoscope from the bladder. Fulguration was carried out for haemostasis and treatment of areas with increased vascularity over the trigone. The bladder was emptied and refilled 3 times to ensure adequate haemostasis.

Post-operatively the patient continued oral antibiotics for 6 week. Fosfomycin 3mg on alternate days was given for two weeks followed by 4 weeks of co-amoxiclav 625mg TDS. These antibiotics were selected based on patient tolerance and previous urine culture sensitivities.

RESULTS

Trans-urethral resection of the squamous metaplasia as demonstrated in the video lead to resolution of dysuria, nocturia and bothersome urinary frequency. In the following 6 months after completing this treatment the patient had had no further urinary tract infections.

CONCLUSION

Transurethral resection of trigonitis and squamous metaplasia can treat recurrent UTI with improvement in associated persistent lower urinary tract symptoms. The presence of non-keratinising squamous metaplasia should not be dismissed in symptomatic patients particularly if additional appearances of oedema, increased vascularity or cystic changes are visible.

REFERENCES

1. Sadeghi Z, MacLennan G, Childs SJ, Zimmern PE. Is trigonitis a neglected, imprecise, misunderstood, or forgotten diagnosis?. Low Urin Tract Symptoms. 2019;11(4):182–188. doi:10.1111/luts.12264
2. Lenherr SM, Crosby EC, Cameron AP. Cystoscopic findings: a video tutorial. Int Urogynecol J. 2015;26(6):921–923. doi:10.1007/s00192-014-2614-4
3. Ozbey I, Aksoy Y et al Squamous metaplasia of the bladder: findings in 14 patients and review of the literature. Int Urol Nephrol. 1999;31(4):457-61.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Case presentation with permission from the patient **Helsinki** Yes **Informed Consent** Yes

619 www.ics.org/2020/abstract/619

PRIMARY BLADDER NECK OBSTRUCTION IN WOMAN - VIDEOURODYNAMIC EVALUATION AND SURGICAL TREATMENT

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INTRODUCTION

- Primary bladder neck obstruction (PBNO) is a functional obstruction of the bladder caused by abnormal opening of the bladder neck during the voiding phase. A variety of symptoms may be present, including voiding symptoms such as hesitancy, poor stream, inttermitent stream, incomplete emptying and urinary retention; storage symptoms such as frequency, urgency, urgency incontinence and nocturia; suprapubic discomfort and urinary tract infection.

- The true prevalence of PBNO in women is not know. It is estimated that 4.6% to 16% of women presenting with obstructive voiding have PBNO (1,2).

- There are multiple theories as to the etiology of PBNO, including fibrous narrowing, hyperplasia, abnormal quantities of non-muscular connective tissue, abnormal morphologic arrangement of the detrusor/trigonal musculature and also increased sympathetic nervous system activity exerting an effect at the level of the bladder neck.

- The diagnosis can be made by videourodynamic which demonstrates high-pressure with low-flow voiding. Fluoroscopic image demonstrates obstruction at the bladder neck.

- Treatment options include conservative and pharmacologic management, and surgical intervention.

DESIGN

Case report:

Female, 60-year-old

Long-standing voiding symptoms (hesitancy, poor stream and intermittent flow)

UTI in the last 10 years

Two episodes of urinary retention

Previous history:

Two vaginal labours

No cesarian, nor abortions

No pelvic surgery

Urologic evaluation:

Ultrasound: bilateral hydronephrosis

Videourodynamic (attached in the video presentation): high-pressure, low-flow voiding dynamics with obstruction at the bladder neck and vesicoureteral reflux (Fig 1).

Qmax: 3ml/s

Pdet max: 148cmH2O

VV: 152 mL

PVR: 480 mL

RESULTS

Patient was submitted to bilateral transurethral incision of the bladder neck (attached in the video presentation).

Transurethral 5 and 7 o'clock incisions of the bladder.

The results were reviewed with follow-up of three months.

There was marked symptomatic improvement after transurethral incision of the bladder outlet.

The peak urine flow rate increased from 3.0 ml/s to 46 ml/s (Fig 2) and no signal of urinary incontinence.

CONCLUSION

Videourodynamic is a valuable tool that shows a relative high-pressure, low-flow voiding with radiographic evidence of obstruction at the bladder neck and allow to make the differential diagnosis with dysfunctional voiding.

In properly diagnosed cases, 5 and 7 o'clock transurethral incision of the bladder neck is an effective procedure for relief of bladder outlet obstruction in woman.

FIGURE 1

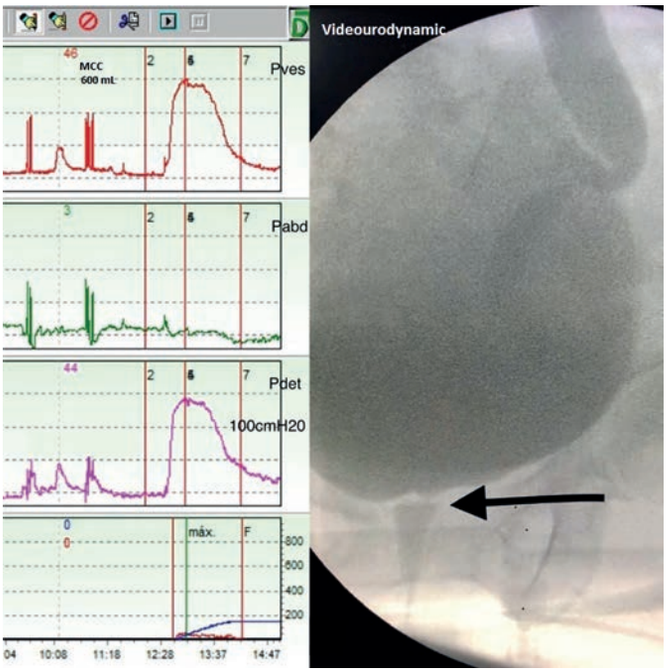
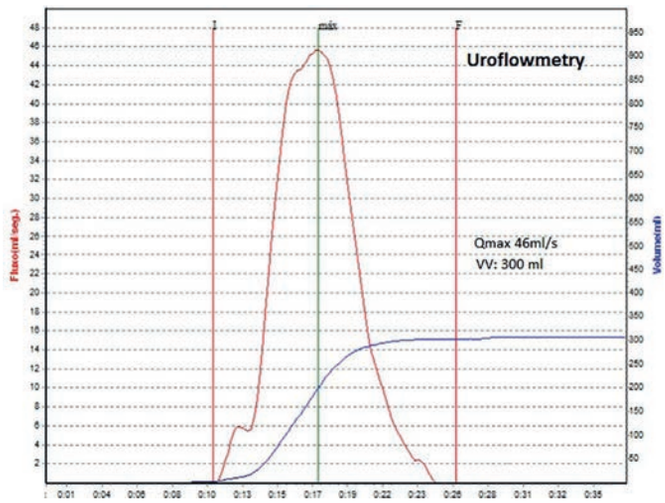


FIGURE 2



REFERENCES

1. Kuo HC. Videourodynamic characteristics and lower urinary tract symptoms of female bladder outlet obstruction. Urology. 2005;66:1005-1009.
2. Brucker BM, Fong E, Shah S, et al. Urodynamic differences between dysfunctional voiding and primary bladder neck obstruction in women. Urology. 2012;80:55-60.

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** This is a case report **Helsinki** not Req'd Is a case report **Informed Consent** Yes

620 www.ics.org/2020/abstract/620

CATHETERIZABLE CONTINENT CUTANEOUS DIVERSION WITH EXTENDED SPIRAL MONTI(ONEM): VIDEO PRESENTATION

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INTRODUCTION

In this video we define and present surgical technique of extended spiral monti (ONEM) as a new continent cutaneous diversion in seventeen years old male patients with spinal dysraphism.

DESIGN

Lower abdominal midline incision was made and abdomen was opened. In order to put the autologous rectus fascial sling placement dissection was carried out to underneath urethra through between posterior bladder wall and rectum. Endopelvic fascia was opened bilaterally in order to visualization of bladder neck and urethra. 8,5 cm and 30 cm ileum was isolated for ONEM conduit and augmentation cystoplasty. Both distal and proximal tip of 8cm ileal segment was cut into spiral shape and created 1.7 cm width, 6 cm length flap. Than 5 cm middle segment was excise antimesenteric part of ileum over 16 Fr foley catheter with stapler. Spiral flaps were tubularized over 16 fr catheter and closed as a continuation of middle part. 17 cm conduit was created (Figure-1). Fixation sutures was placed on anterior bladder wall and bladder was opened in sagittal axis direction. Urethral foley catheter and cystostomy were placed. Autologous fascial sling was placed underneath bladder neck. ONEM conduit was anastomosed on right bladder dome with submucosal tunnel creation. 30cm ileum was detubularized and hemispheric shaped was created. Watertight anastomosed were done between bladder and hemispheric ileal segment with bladder with 3-0 polyglactin suture. ONEM conduit were anastomosed right side of umbilicus. Drain was placed and abdominal incision was closed.

RESULTS

Modified extended spiral monti (ONEM) is effective and safe method.

CONCLUSION

Modified extended spiral monti (ONEM) can be used for patients with NLUTD when need upper level placement of conduit for catheterizable continent cutaneous diversion. This conduit also suitable for obese neurogenic patients due to 4,5-5 cm pedicle free channel on both tip of conduit.

FIGURE 1

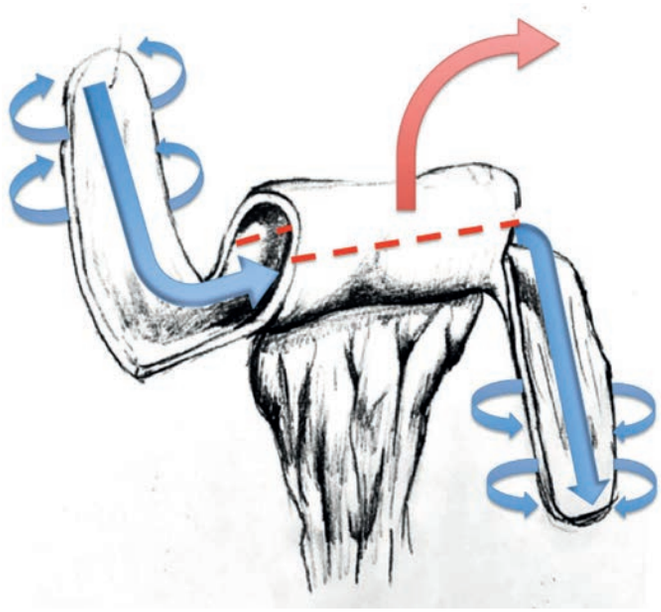

İllustration of ONEM conduit

Funding None **Clinical Trial** No **Subjects** Human **Ethics not Req'd** Not required **Helsinki** Yes **Informed Consent** Yes

621 www.ics.org/2020/abstract/621

LAPAROSCOPIC PARTIAL NEPHRECTOMY FOR DELAYED-ONSET URINARY INCONTINENCE FOR DUPLEX KIDNEY AND ECTOPIC VAGINAL IMPLANTATION

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INTRODUCTION

The duplicated renal collecting system with ectopic ureter draining in the proximal third of the vagina is a rare congenital anomaly that causes incontinence and urinary tract infections. It frequently occurs in association with a poorly functioning upper pole segment. The standard treatment is the upper pole heminephrectomy with ureterectomy.

Our objective is to describe an infrequent cause of urinary incontinence like an ectopic ureter draining into the vagina and its minimally invasive treatment.

DESIGN

A 23-year-old G0 female was referred to our hospital with complaints of continuous urine leakage not related to efforts or urgency for the past four years. Treated in another center with a transobturator sling with unfavorable results. She used four daily-pads and had urinary frequency every 1 hour. She never had urinary tract infections.

Cystoscopic evaluation of the lower urinary tract and urodynamic evaluation of bladder and urethral function were normal. Also had gynecological exam without particularities. CT scan revealed a dysplastic duplex kidney located at right upper-pole unit, drained by a dilated ureter extending to the vagina. Upper pole heminephrectomy with ureterectomy was performed. Exploration of the right kidney demonstrated a dysplastic upper-pole segment with a draining dilated ureter.

RESULTS

Mean surgical time was 80 minutes. Postoperative hospital stay was 2 days. Pathological anatomy informed stromal fibrosis and chronic inflammation. Following surgical intervention, the patient reported immediate and complete resolution of urinary incontinence and significant improvement of her quality of life.

CONCLUSION

Ectopic ureter should be considered in case of persistent urinary leakage, specially in young women. Laparoscopic upper-pole heminephrectomy with ureterectomy for an ectopic ureter is safe and reproducible and offers benefits of laparoscopic surgery.

REFERENCES

1. Toia B, Pakzad M, Hamid R, Diagnosis and surgical outcomes of ectopic ureters in adults: A case series and literature review. Neurourol Urodyn. Aug;38(6):1745-1750. 2019
2. Ming-Hsien Wang. Persistent Urinary Incontinence: A Case Series of Missed Ectopic Ureters. Urol Case Rep. Nov; 3(6): 223–225. 2015
3. Chan E, Steinbrecher H, Madden NJ. Retroperitoneoscopic left upper moiety heminephroureterectomy for dribbling incontinence. Pediatr Urol. Feb;10(1):193. 2014

Funding None **Clinical Trial** No **Subjects** Human **Ethics Committee** Comité de Etica. Hospital Italiano de Buenos Aires **Helsinki** Yes **Informed Consent** Yes

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