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RETROSPECTIVE STUDY COMPARING TWO-YEAR OUTCOMES OF DIFFERENT VAGINAL MESH KITS: A SINGLE TERTIARY CENTRE EXPERIENCE

Academic Medicine
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INTRODUCTION

- Pelvic organ prolapse (POP) is a very common problem and is expected to continue to increase with the aging population.
- Lifetime risks of women affected by POP needing correction surgery is about 11.1%.[1]
- Patients who undergo native tissue repair have increased anterior compartment recurrence and the need for repeat surgery in 2-9% of women.[2]
- Transvaginal mesh kits have been found to reduce recurrence rates but have been banned by the US FDA since April 2019 due to its association with serious complications.
- However, mesh kits are still being used in certain European and Asian countries.
- Our centre has used four different vaginal mesh kits over a time course of 13 years.

AIMS & OBJECTIVES

Our study aims to:

- Compare the two-year objective and subjective outcomes of four different transvaginal mesh kits
- Assess the complications rates associated with each mesh kit

METHODOLOGY

- This is a retrospective study of 572 patients with Baden-Walker Grades 3 or 4 anterior compartment prolapse who underwent one of four vaginal mesh kits, namely (Gynecare Prolift system (Ethicon, Inc.), Elevate™ Anterior mesh kit (American Medical System Inc.), Restorelle®Direct Fix™ (Porges Coloplast) and Uphold™ system (Boston Scientific), from 1 January 2006 to 30 April 2019 in KK Hospital, Singapore. We have used Group A, B, C and D to represent each mesh respectively.
- Patient demographics, pre-operative symptoms, examination findings, peri-operative and post-operative outcomes were recorded
- Data collected was saved anonymously and results analysed via Microsoft Excel and IBM SPSS Statistics 19. Chi-square, Fisher's Exact and Mann-Whitney U tests were used
- CIRB approval obtained on 28 February 2020 (2020/2124)

RESULTS - PATIENT DEMOGRAPHICS

- The mean age for each group was between 64.7 and 65.9 years
- Mean BMI between 25.1 to 25.8
- Less than one third were sexually active
- Most had at least one vaginal delivery and were post-menopausal
- There were no significant differences in age, AMI, parity, menopause status and years post-menopause between groups

RESULTS – PRE-OPERATIVE & INTRA-OPERATIVE

- Most complained of lump at introitus, a few had dyspareunia. D had significantly more concurrent SUI compared to A and B. C had significantly more concurrent UUI symptoms and voiding difficulty. A had significantly more with Grade 4 cystocele.

Table 1: Pre-operative Symptoms and Examination

Parameters	Group A (n = 107)	Group B (n = 270)	Group C (n = 58)	Group D (n = 137)
Lump at introitus n (%)	100 (93.5)	268 (99.3)	58 (100)	136 (99.3)
Lump at introitus months, Mean ± SD (range)	32.2 ± 67.5 (0.7 – 480)	n = 262 29.4 ± 41.0 (0.16 – 240)	35.6 ± 48.1 (0.7 – 240)	-
Stress Urinary Incontinence, n (%)	33 (30.8)	79 (29.3)	23 (39.7)	62 (45.3)
Urge Incontinence, n (%)	17 (15.9)	53 (19.6)	24 (41.4)	33 (24.1)
Faecal Incontinence, n (%)	3 (2.8)	0	n = 56 1 (1.8)	-
Voiding difficulty, n (%)	28 (26.2)	49 (18.1)	n = 57 23 (40.4)	17 (12.4)
Previous gynae/urogynae surgery, n (%) (a) Prolapse corrective surgery	28 (26.2) 21 (75.0)	39 (14.4) 12 (30.8)	18 (31.0) 4 (22.2)	-
Cystocele, n (%) (a) Grade 3 (b) Grade 4	23 (21.5)+ 78 (72.9)	183 (67.8) 87 (32.2)^	37 (63.8) 21 (36.2)	99 (72.3) 38 (27.7)
Stress Test Positive, n (%)	12 (11.2)	6 (2.2)	n = 57 4 (7.0)	0

*6 patients had Grade 2 cystourethrocele.
^31 patients were diagnosed with Grade 4 cystourethrocele intra-operatively.

- Mean duration of surgery was between 71.2 to 118.1minutes, significantly shorter in Group A. Estimated blood loss was significantly lesser in Group A and B compared to C and D. Rectal perforation occurred in 4 (1.5%) in Group B and none in the other groups. Bladder perforation occurred in 2 (0.7%) in B, 2 (3.4%) in C and 2 (1.5%) in D. 5 (4.7%) in A, 6 (2.2%) in B, 22 (37.9%) in C and 41 (29.9%) in D had post-op fever.

RESULTS – 2 YEAR OUTCOMES

- No patients complained of a recurrent lump. De novo SUI was significantly less in B compared to A and D and de novo UUI was also significantly less in B compared to the rest. Overall satisfaction rates were near 100%. Subjective cure rate was 100%.
- Wound dehiscence occurred in 3 (4.5%) in A. Mesh extrusion occurred in 9 (13.4%) in A, none in B, 4 (8.3%) in C and 2 (3.1%) in D. Recurrent cystocele occurred in 2 (3.0%) in A, none in B, 2 (4.2%) in C and 1 (1.6%) in D. Recurrent vault prolapse occurred in 3 (4.5%) in A, none in B, 1 (2.1%) in C and 2 (3.1%) in D. Overall objective cure rate ranged from 95.8% to 100%.

Table 2: 2 years outcome

Parameters	Group A (n = 107)	Group B (n = 270)	Group C (n = 58)	Group D (n = 137)
Follow-up rate, n (%)	67 (62.6)	216 (80.0)ᶜ	48 (82.8)	64 (46.7)
Lump., n (%)	NA	0	0	0
De novo SUI, n (%)	8 (11.9)	3 (1.4)	3 (6.3)	6 (9.4)
De novo U/UI, n (%)	7 (10.4)	2 (0.9)	3 (6.3)	8 (12.5)
Wound dehiscence, n (%)	3 (4.5)	0	0	-
Pelvic Pain, n (%)	0	0	1 (2.1)	-
Dyspareunia, n (%)	0	0	1 (2.1)	1 (1.6)
Satisfaction, n (%)	67 (100)	215 (99.5)	48 (100)	64 (100)
Subjective Cure Rate, n (%)	NA	216 (100)	48 (100)	64 (100)
Mesh Extrusion, n (%)	9 (13.4)	0	4 (8.3)	2 (3.1)
Recurrent cystocele, n (%) (a) Grade 1 (b) Grade 2 (c) Grade 3 (d) Grade 4	0 1 (1.5) 1 (1.5) 0	1 (0.5) 0 0 0	6 (12.5) 2 (4.2) 0 0	1 (1.6) 1 (1.6) 0 0
Recurrent vault prolapse, n (%) (a) Grade 1 (b) Grade 2 (c) Grade 3 (d) Grade 4 (e) Unknown	0 0 1 (1.5) 1 (1.5) 1 (1.5)	0 0 0 0 0	3 (6.3) 0 1 (2.1) 0 0	1 (1.6) 2 (3.1) 0 0 0
Objective Cure Rate, n (%)	65 (97.0)	216 (100)	46 (95.8)	63 (98.4)

ᶜ29 patients were followed up with phonecall. 52 patients were defaulted. 2 deceased.

DISCUSSION AND CONCLUSION

- All 4 meshes had satisfactory subjective and objective cure rates at 2-years follow up with no significant differences between them.
- This high success rate may be contributed by single surgeon experience, patient selection and perioperative counselling. The lack of heterogeneity in an operator dependent procedure would confound our results and is a weakness of our project.
- Complication rates were fairly low. Nonetheless, we recognize the potentially devastating complications which could lead to significant compromise on patient's lives.
- The use of vaginal mesh kits has been highly contentious and even banned in some countries. However, good patient selection and surgical experience performed in a high-volume centre can achieve good outcomes with low complications.

References
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