W13: Hands-on Sacral Neuromodulation with World Class Experts – Ideal Lead Placement (1)

Workshop Chair: Hashim Hashim, United Kingdom
24 October 2024 09:30 - 11:00

Start	End	Topic	Speakers
09:30	09:35	Introduction and New Innovation	Hashim Hashim
09:35	09:45	Patient Selection and Preparation: Recharge vs Battery & Neurological conditions?	Jacqueline Zillioux
09:45	09:55	How to get Ideal Lead Placement	Marcio Averbeck
09:55	10:50	3 Hands-on lead placement Stations: 1 – Accurate needle/temporary lead placement - models, 2 – Lead placement with permanent lead - models & 3 – Smart programming with programmers	Hashim Hashim Jacqueline Zillioux Marcio Averbeck Beatrice Bourchard Emre Huri Arun Sahai Salvador Arlandis Guzmán Laura Thomas
10:50	11:00	Questions	All

Description

The Sacral Neuromodulation (SNM) workshop will start with a general overview from the experts covering the current state of SNM therapy including the patient indications, clinical data, clinical guidelines, hospital set up needed for optimal therapy utilization, technology innovations covering new products (Sure Scan MRI safe leads and InterStimX) and the necessary patient follow-up. The delegates will then be divided into nine small groups of 2-3 delegates on each station and rotate after 20 minutes through insertion of percutaneous nerve evaluation leads station, advanced tined lead and battery implant station and programming. They will practice on pelvic models and there will be visual aids. Tips and tricks will also be discussed with the experts and at the end of the session.

Aims of Workshop

Sacral neuromodulation is now standard treatment for patients with OAB, idiopathic retention and fecal incontinence who have failed conservative management. This workshop will briefly review appropriate patient selection but will then focus most of the time on hands on skills to learn appropriate needle and lead placement techniques. Six very experienced experts will work with attendees on lifelike models to teach them how to achieve lead placement efficiently and appropriately. Tips and tricks for getting the best responses will be reviewed.

Educational Objectives

This is a practical hands-on workshop that will allow the participants to practice on pelvis models the different steps of performing sacral neuromodulation therapy including primary percutaneous nerve evaluation, advanced tined lead placement (using standardization technique), battery implantation and device programming and also troubleshooting.

Learning Objectives

1. Understand the role of sacral neuromodulation, recognize the latest technological developments, their clinical implications and getting the best outcome with SNM
2. Understand the patient selection process and current SNM indications
3. Review standard surgical technique for optimal lead placement and gain understanding of choices for recharge versus fixed battery (as well as use in neurological disease)

Target Audience

Urology, Urogynaecology and Female & Functional Urology, Bowel Dysfunction

Advanced/Basic

Intermediate

Suggested Learning before Workshop Attendance

Goldman HB, Lloyd JC, Noblett KL, et al. International Continence Society best practice statement for use of sacral neuromodulation. Neurourology and Urodynamics. 2018;1–26. https://doi.org/10.1002/nau.23515

Matzel KE, Chartier-Kastler E, Knowles CH, Lehur PA, Munoz-Duyos A, Ratto C et al (2017) Sacral Neuromodulation: Standardized Electrode Placement Technique. Neuromodulation 20(8):816–824

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Sacral neuromodulation update in 2024: Insights from the ICS workshop 2023

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ABSTRACT

Purpose: This review is based on the International Continence Society (ICS) Workshop on Hands-On Sacral Neuromodulation (SNM)- Ideal Lead Placement presented at the Annual Congress in 2023. This workshop briefly reviewed appropriate patient selection, focused most of the time on hands on skills to teach appropriate needle and lead placement techniques. Six very experienced experts worked with attendees on lifelike models to teach them how to achieve lead placement efficiently and appropriately. Tips and tricks for getting the best responses were reviewed.

Materials and methods : The review follows the structure adopted by workshop, where SNM-Ideal Lead Placement is discussed in four sections: main/extended indications and ideal patient profile, sacral neuromodulation techniques included basic evaluation (PNE), advanced evaluation, ideal lead placement and novel technology.

Results: The learning objectives were achieved at the end of the workshop. These were: understanding the role of sacral neuromodulation, recognize the latest technological developments, their clinical implications and getting the best outcome with SNM, stress the importance of patient selection process and current SNM indications, reviewing standard surgical technique for optimal lead placement and gain understanding of choices for recharge versus fixed battery (as well as use in neurological disease).

Conclusions: Hands-on training workshops on sacral neuromodulation is efficient training modules to ensure learning objectives for participants. Accurate needle/temporary lead placement, lead placement with permanent lead, smart programming with programmers are the main parts of hands-on training session with using realistic phantom and 3D printed models in workshop.

1. Introduction

Sacral neuromodulation (SNM) plays a critical role in the management of patients with lower urinary tract dysfunction (LUTD) and fecal incontinence. Sacral neuromodulation was approved in the United States in 1997 for the treatment of urinary urgency incontinence in patients who failed or could not tolerate oral medication. Indications quickly expanded to include idiopathic non-obstructive urinary retention and fecal incontinence.

SNM has its twentieth century origin in the trailblazing work of several dedicated clinicians and researchers. In 1975, Nashold and associates reported that direct spinal stimulation induced bladder contractions and emptying. The NIH became very interested in this area and began to work with several urologists at the University of California, San Francisco (many who became leaders in the field — Tanagho, Schmidt, Jonas, Thuroff, Bruschini) to further investigate electrical stimulation and bladder function [1]. Concurrently, G. Brindley developed a technique of sacral anterior root stimulation (SARS) to allow paraplegic patients to void. During later urodynamic investigation, Tanagho and Schmidt noted that stimulation of the sacral roots led to detrusor inhibition. Early trials on SNM were started in 1985 by Urosystems. Medtronic later acquired the rights to this technology from the University of California and Urosystems and continued clinical trials [2]. The original procedure entailed an open incision over the sacrum, blind placement and fascial fixation of the lead and tunneling to connect to a generator placed in the anterior abdominal wall.

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Interstim® became much more commonly used as it evolved into a percutaneous, fluoroscopy guided procedure. In 2002, Spinelli developed the tined lead that allowed a less invasive approach to lead placement. In 2006 a smaller battery/generator was introduced by Medtronic. In 2015, Siegel described "optimal" lead placement which allowed for improved results over time. An MRI conditional rechargeable SNM device was developed by Axonics and approved by the FDA in 2019. Medtronic followed suit with their own rechargeable device. In the last few years devices with longer lasting batteries or requiring less frequent recharges have been introduced as well.

The development of SNM has revolutionized the treatment of many bladder and bowel disorders allowing patients who formerly suffered tremendously to regain hope and the ability to function relatively normally. This review of the SNM workshop held at the 2023 International Continence Society (ICS) annual meeting in Toronto, Canada sheds further perspective on patient identification and best implant practices to continue to help us to maximize the benefit of this technology.

2. Material and methods

This review article is based on the 'Hands-On Neuromodulation with World Class Experts – Ideal Lead Placement' Workshop 23. The workshop examined ideal lead placement in sacral neuromodulation which is now standard treatment for patients with refractory overactive bladder (OAB)/detrusor overactivity, idiopathic non-obstructive retention and fecal incontinence who have failed conservative management. The workshop reviewed appropriate patient selection and focused on hands on skills to learn appropriate needle and lead placement techniques. Six experts worked with attendees on lifelike models to teach them how to achieve lead placement efficiently and appropriately.

3. Main/extended indications and ideal patient profile

SNM therapy is not indicated as a first-line therapy for either urinary or bowel disorders. The 2024 American Urologic Association Guidelines on Overactive Bladder considers SNM a third line therapy after behavioral modification and pharmacologic management with changes the concept of staged treatment to a treatment focused on pathophysiologic data [3]. This is echoed by the recommendations of the European Association of Urology and Canadian Urologic Association [4,5]. The primary indications are OAB with and without urinary incontinence, non-obstructive urinary retention, and fecal incontinence. This therapy is a particularly good option for patients with overlapping indications such as urge urinary incontinence and incomplete bladder emptying or urge urinary incontinence and fecal incontinence.

Historically, SNM has not been offered to patients who required regular, interval magnetic resonance imaging (MRI). However, in 2020, MRI conditional technology was introduced which allowed clinicians to expand these indications to a wider swathe of patients who suffer from neurogenic OAB such as those with multiple sclerosis (MS) [6]. Indeed, a recent sham-controlled multicenter trial of SNM for neurogenic NLUTD reported 52% successful test-phase, and 76% success in the treatment group compared to 42% in sham among those implanted [7]. This was a well-selected study population (incomplete spinal cord injury, cerebrovascular event, etc.), but demonstrated the feasibility and efficacy of this therapy in the setting of NLUTD.

SNM is considered an advanced therapy for Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS) as well [8], but supporting evidence is very limited and primarily includes small observational case series with variable criteria for success. In these small observational studies, the success rate for SNM for IC/BPS using intention to treat analysis was 48%–72% [9–13].

SNM is contraindicated for very few patient populations. Pregnancy remains a contraindication to implantation. There is a theoretical, but unproven, risk to the fetus to keeping the device activated during pregnancy. As such, most practitioners recommend device de-activation during pregnancy. Traditionally, advanced age was considered a contraindication to SNM but more recent data contradicts this [14]. Cognitive impairment has also been considered a relative contraindication as patients must be able to provide feedback about device efficacy and be able to use technology to manage the device; however, an involved and consistent caregiver can mitigate this. Limited data also suggests patients with mild to moderate cognitive impairment and OAB may benefit from SNM despite less use of the programming features [15].

The ICS best practice statement for use of SNM states that a patient who is satisfied with the treatment is considered to have a successful treatment outcome [16]. In practice, we combine this subjective definition with objective data from bladder and bowel diaries to select appropriate patients for permanent implant. Ideally, diaries during the test phase should demonstrate at least fifty percent improvement in symptoms such as number of voids per day or number of incontinence episodes per day. Patients must be counseled about this pre-operatively so that appropriate expectations are set prior to the test phase. Patients should also be counseled regarding postoperative expectations of potential need for reprogramming, lead and/or battery revisions such that these events are not perceived as failure.

4. Sacral neuromodulation techniques: Percutaneous & advanced evaluation

Table 1 explores the advantage and disadvantages of the basic versus advanced, or staged, evaluation approaches. In the workshop, we used the models and equipments of Medtronic company. We aimed to review the data about this system in the article.

4.1. PNE (Basic evaluation)

The percutaneous nerve evaluation (PNE) temporary test phase is usually done in the outpatient setting under local anesthesia, with or without fluoroscopy.

1. Position the patient on the table. Place a pillow under the pelvis/abdomen to flatten the back and place a pillow under the feet to flex the knees slightly (Fig. 1).
2. Prep for the procedure by swabbing the lower back, pre-sacral region and buttocks with antiseptic solution.
3. Drape the patient using the drapes supplied with the kit to allow for observation of the anus/pelvic floor and great toe motor responses. Ensure a clear view over the buttock and perineal area.
4. Pass the proximal end of the test stimulation cable to an assistant off the prepped field, and they will attach the black pin end to the ground pad and adhere the ground pad to the patient, usually over one of the heels.
5. The assistant will plug the adaptor end of the test stimulation cable into the external neurostimulator, also referred to as the ENS, and pair the controller with the ENS. They will have to confirm the connections are secure by viewing the controller screen. If connections are not secure, the check connection screen will appear.
6. Landmarks may be identified either with or without fluoroscopy. S3 is the target foramen but sometimes S4 is used.

    a. To identify landmarks without fluoroscopy: identify the midline and draw a line 15 cm long from the coccyx, then palpate the greater sciatic notches and mark their location. The S3 foramen is at the level of the sciatic notch about 2 cm lateral of midline. The S3 foramen can also be found by measuring approximately 9 cm (the length of the short needle on the pack is 9.5 cm and can be used to mark the level instead of the ruler provided) cephalad from the tip of the coccyx and 2 centimeters lateral for midline. Draw the lines 2 cm to the right and left of the midline.

Table 1
Peripheral Nerve Evaluation & Advanced Evaluation: Advantages and Disadvantages.

	Advantages	Disadvantages
Basic Percutaneous Nerve Evaluation — PNE	• Possible as office procedure • Less invasive • Less costly approach, if test fails • Easily removed in physician's office • Test on both sides • No anesthesia/sedation risk	• More easily dislodged • Symptoms reoccur during the interim period • May not capture same stimulation with implant • Lead contains only one electrode • Shorter test period
Advanced Tined Lead Evaluation	• Lead placement confirmed by fluoroscopy • No lapse in symptom control between evaluation and implant • Lead contains 4 electrodes (→ multiple program options) • Longer test period (up to 4 weeks)[5] • Test success rates seem to be significantly higher [1,2,3,4]	• More invasive than test with the temporary wire • More costly, if evaluation fails • Often removed in OR — but can be done in office

Fig. 1. Patient positioning.

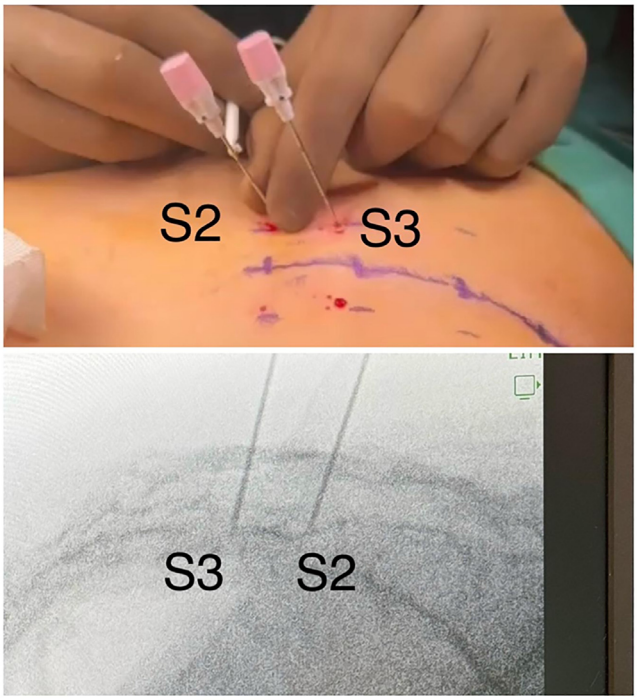

Fig. 2. Proper needle placement (S2 and S3).

b. To identify landmarks with fluoroscopy: start in the AP position to identify and mark the appropriate needle entry point which is cephalad and parallel to the S3 bone fusion seam. Place a radio-opaque straight long instrument e.g., needle or sponge-holding forceps to identify the medial border of the foramen on the right and left side of the midline and draw a line with a marker pen along the border of your instrument. The foramina usually appear as 'eye brows' in the AP position and the S3 is at the level of the sciatic notch. Then move your Xray machine C-arm to the lateral position going under the table to identify the S3 foramen and to see the trajectory of the needle. The aim is to insert the needle into the upper part of the foramen.

1. The foramen needle skin entry point will be located 2 centimeters cephalad to the S3 foramen to accommodate a 60° angle insertion. The S2 and S4 foramina are located approximately 2 centimeters cephalad or caudal to S3 (Fig. 2).
2. Inject a local anesthetic, e.g., lidocaine 1%, to numb the skin near the entry point of the foramen needle. S3 is the target foramen. The foramen needle skin entry point will be located

Table 2
Motor and Sensory responses of Sacral Nerve roots 2-4.

Innervation	Motor: Pelvic floor	Motor: Foot/Calf/Leg	Sensation/Sensory
S2: Primary somatic contributor of pudendal nerve for external sphincter, leg, foot	Clamp of anal sphincter	Plantar/Dorsi flexion of the entire foot, contraction/ cramping of the calf, leg/hip/heel rotation	Genital: Contraction of the base of the penis, vagina
S3: Virtually all pelvic autonomic functions and striated muscle (levator ani)	Bellows	Plantar flexion/Dorsiflexion of the great toe, occasionally other toes	Genital, perineal, anal. Pulling in rectum extending forward to scrotum or labia (saddle area)
S4: Pelvic autonomic and somatic. No leg or foot	Bellows	No lower extremity motor simulation	Anal: Pulling in rectum only

2 centimeters cephalad to the S3 foramen. The needle should be placed at approximately a 60° degree angle relative to the skin and should always be oriented in a cephalocaudal direction. The needle tip should be inserted to a depth just below the anterior surface of the bone.

3. To confirm the desired needle placement, connect the test stimulation cable to the non-insulated (upper part) portion of the foramen needle.
4. The assistant will press the increase key on the controller and adjust the stimulation as directed by the physician.
5. Observe for sensory and/or motor responses.
    a. The desired S3 motor response in the pelvic floor is anal bellows, a pulling inward or deepening of the intergluteal fold. The desired foot response for S3 is a plantar flexion of the great toe and occasionally other toes.
    b. For women, the S3 sensory response is often vaginal sensation extending to the perineum and rectum. In men, the common S3 sensory response is sensation in the rectum extending to the scrotum. Tapping is felt in the saddle area.
    c. Responses should be observed at low amplitude levels, preferably 2 milliamps or less.
6. Once ideal motor and/or sensory responses are observed, remove the Foramen needle stylet. Using the visual markings as a guide, insert the PNE lead through the Foramen needle until the lead electrode exits the needle tip.
7. Test for motor and sensory responses (Table 2) by hooking the test stimulation cable to the connector pin on the end of the temporary test stimulation lead. Once desired stimulation is confirmed, decrease the ENS amplitude to zero.
8. Stabilize the lead and carefully remove the needle and lead stylet. When the needle is removed, the lead stylet handle is caught in the needle hub and removed along with the needle. Once again confirm the ideal stimulation responses.
9. If desired, repeat this procedure on the contralateral side.
10. Ensure the temporary test stimulation lead (s) are secured with dressing.
11. Insert the exposed end of the left test stimulation lead into the white plug of the patient cable, marked as 1. Insert the right test stimulation lead into the red plug of the patient cable, marked as 2.
12. To ensure patient comfort, place gauze under the patient cable plugs.
13. Connect the patient cable to the ENS. Cover the temporary test stimulation leads and cable connections with dressing and secure the ENS to the patient.
14. When only one lead is placed, a patient cable with ground pad will be used to connect the temporary test stimulation lead to the ENS. Insert the exposed end of the test stimulation lead into the white plug of the patient cable. The unused plug will remain unattached.
15. Connect the black plug of the patient cable into the ground pad and attach to the patient.
16. Insert the patient cable into the ENS. When one lead is connected, regardless of whether it was placed on the left or the right, the controller will always display the stimulation settings on the left.
17. Cover the temporary test stimulation lead and cable connections with dressing and secure the ENS to the patient.
18. Instruct the patient on post-operative care, the importance of completing a voiding diary and quality of life questionnaire, how to use the programmer, when to come back for follow-up (usually 1 to 2 weeks following PNE insertion) and give them written instructions highlighting maintenance of the dressings and the importance of not removing these.

4.2. Staged (Advanced evaluation)

In advanced evaluation, evaluation of therapy is assessed with tined lead implantation rather than the removable percutaneous lead. This allows patients to try SNM therapy to assess its efficacy so they can make a final decision with their physician about whether to proceed with permanent implantation. Candidates for advanced evaluation are any PNE candidates who desire the procedure be performed with sedation or general anesthesia. In general, patients for who the indication is idiopathic retention or a neurologic disorder are good candidates for an advanced evaluation because the longer trial period this approach affords increases the chance of success. Failure of a PNE trial does not preclude an advanced evaluation for patients who still want to pursue sacral neuromodulation. As noted in the table, advanced evaluation success rates seem to be significantly higher [1–4].

The advanced evaluation (also referred to as Stage 1) is initiated through an ambulatory procedure performed in a hospital or surgical center. The patient wears an ENS during the advanced evaluation, which typically lasts up to 14 days (depending on physician guidance). Symptom diaries are used to measure results. In general, the evaluation is successful if the patient experiences a significant (50% or greater) reduction in symptoms with objective and subjective parameters.

5. Ideal lead placement and novel technology

5.1. Ideal lead placement during stage 1

Patient positioning is a crucial step to maintain successful lead placement in advanced evaluation. The head, thorax, and hips should all be properly supported while the patient is in the prone position. The prone position, with the anus, feet, and toes exposed, is necessary to observe the motor responses of the anus, pelvic floor, and feet. The reduction of lordosis with horizontal positioning of the sacrum ensures easy access to S3 foramina via needle. In contrast to the PNE lead implant, the tined lead electrode implantation is performed in the operating room, always guided by fluoroscopy.

The skin in the immediate vicinity of the sacral region is sterilized using an antiseptic solution. The surgical site and anus are enclosed in

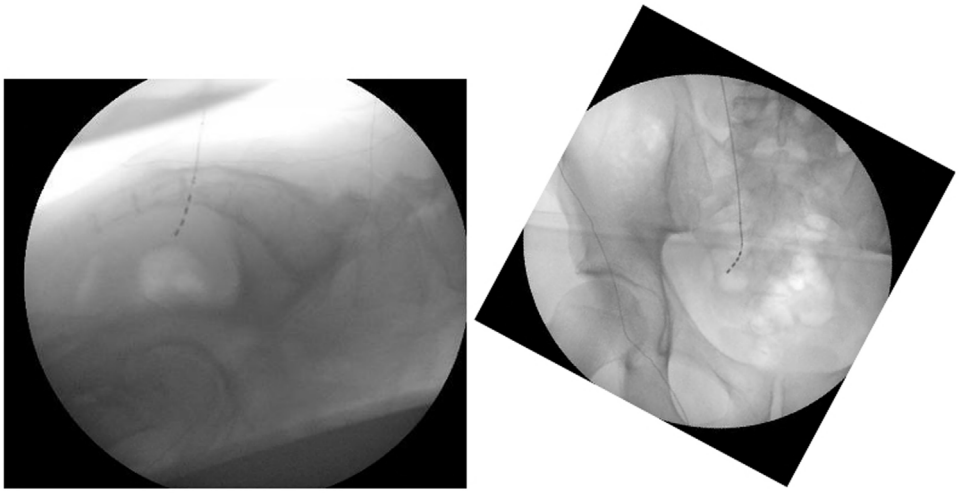

Fig. 3. Lateral and AP images of ideal placement of tined lead at S3 curving caudally and laterally.

a rectangle defined by sterile drapes. Motor responses can be directly observed without contaminating the operation field by using a clear adhesive sterile drape. Fluoroscopy to identify the appropriate landmarks and needle placement are identical to that of the PNE.

The external pulse generator can be used to test stimulation once it reaches this indicative level. The goal is to achieve low current (<2 mA) motor responses (bellows/toe). To optimize the motor response, it is generally customary to decrease the stimulation amplitude to a lower level (such as 1 mA or lower) and make minor modifications to the needle's depth. At this point, the directional guide can be inserted and the needle stylet removed. After that, the guide wire is left in place and the needle is taken out. It is important to keep the introducer from accidentally moving while the dilator is placed because this could give the permanent electrode an incorrect trajectory.

While inserting the introducer, it is also quite simple to push the guide wire further into the pelvis. It is therefore recommended to use either intermittent or continuous fluoroscopy to regulate the dilator's advancement. Placing the four contacts in close proximity to the S3 nerve is the goal of electrode implantation. This is accomplished if, depending on whether the procedure is carried out under general or local anesthesia, low-intensity stimulation produces an acceptable motor/sensory response. The easiest way to accomplish this is to avoid creating a false track and enter the foramen at its medial and upper edges. Ideally, physiological responses (both bellows and toes) should be obtained in 4/4 electrodes under low-intensity stimulation. Ideal fluoroscopic placement is illustrated in Fig. 3.

5.2. Recent innovations

SNM novel technology developments include reduced implantable pulse generator (IPG) size, MRI compatibility, recharge capacity and extended fixed battery life.

5.2.1. Implantable pulse generator (IPG) size

Reduction in IPG size is a recent advancement, which can make implantation easier and may improve patient comfort. Until recently, the only available device for administering SNM was Interstim-II (Medtronic, Minneapolis, MN, USA) which measures 14 cm^3. Notably smaller, the dimensions of the rechargeable Axonics r-SNM (Axonics Modulation Technologies, Inc., Irvine, CA) system are 5.5 cm^3. The newer InterStim-Micro technology (2.8 cm^3) is roughly 49% smaller than the Axonics rechargeable SNM device, and it has a volume reduction of around 80% when compared to the standard InterStim-II system.

The IPG is normally well tolerated in the gluteal region. However, thin patients may feel the device under their skin and express discomfort when supine or in various positions. This discomfort may not go away when the stimulation is switched off. In certain instances, a reoperation may be required to free the pseudocapsule enclosing the generator [17]. Smaller generators that are more suited to subcutaneous tissue can be used to avoid this uncommon occurrence. Conversely obese patients may have more difficulty with the smaller implantable generators. Recharging sessions may be hampered because weight increase may cause changes in the distance and angle between the IPG and recharger over time [18,19].

5.2.2. Magnetic resonance imaging (MRI) compatibility

Theoretically, lead migration or heating during MRI in the vicinity of a sacral nerve root might induce painful stimulation, harm to the entire SNM system, or thermal injury to the nerve itself. While this is a theoretical concern, to the knowledge of the authors this has never occurred. In fact, a number of studies utilizing both phantom models and live patients have shown that temperature changes in the phantom model were minimal and that a prospective group of 11 patients who underwent MRI with an older SNM device in place had no patient or device adverse events [20,21]. Despite this data many radiologic departments were very hesitant to allow MRI below the neck for patients with a sacral neuromodulation device in place. Despite therapeutic benefits being shown, the absence of MRI compatibility has been seen as a relative contraindication to SNM in certain subpopulations, such as neuro-urological patients. Over the course of their lives, half of patients with pacemakers and neuromodulation devices are expected to require an MRI. In fact, this is the present explanation for 23% of device explanations [21].

The FDA authorized the Axonics r-SNM™ System for full-body 1.5 T MRI scans in September 2019. Quickly following suit, in 2020, Medtronic received approval for their micro neurostimulator and SureScan MRI compatible lead. Thus, the need for repeated MRI's is no longer a contraindication to sacral neuromodulation therapy. The SureScan leads are made to enable full-body 1.5 and 3 T MRI-conditional scans. They are intended to be utilized both in the InterStim II, X and InterStim Micro systems.

5.2.3. Generator recharge capacity

The requirement for IPG replacement over time in existing non-rechargeable devices could be viewed as a technological constraint. The generator needs to be replaced when the battery runs out, which results in recurrent cost and patient morbidity. A new generation of rechargeable IPGs has been created that significantly increases the

device's lifespan. The Axonics r-SNM™ System is made, tested, and approved for at least 15 years of physiological operation. It includes a rechargeable IPG. The rechargeable has a similar life span.

Subsequent to the introduction of the rechargeable devices, both Medtronic and Axonics have introduced recharge-free devices that should last up to 10–15 years. Given this length of battery life, the indications for the rechargeable systems have narrowed. We typically reserve the rechargeable system for very thin patients, for whom the decreases size may be more comfortable.

6. Conclusion

Sacral neuromodulation has been a therapeutic option for nearly 30 years. In that time, the indications have expanded to include non-neurogenic urinary urgency and urge urinary incontinence, idiopathic urinary retention, and fecal incontinence. Refinement in lead placement techniques have increased surgical accuracy and thus therapeutic success. Recent innovations in MRI compatibility are allowing us to offer this therapy to patients with underlying neurologic pathology as well. Technologic advances in implantation technique and generator size continue to decrease the morbidity associated with the procedure [22]. As such, we are now able to offer a less cumbersome therapy to a wider range of patients.

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No.

Ethics approval

The authors declare that this study did not involve Humans or Animals.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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