Sounding Board

International Continence Society [1] Best Practice Statement for Use of Sacral Neuromodulation

Howard B. Goldman, Jessica C. Lloyd, Karen L. Noblett, Marcus P. Carey, Juan Carlos Castaño-Botero, Jerzy B. Gajewski, Paul A. Lehur, Magdy M. Hassouna, Klaus E. Matzel, Ian M. Paquette, Stefan G. de Wachter, Michael J. Ehlert, Emmanuel Chartier-Kastler, Steven W. Siegel

KEY WORDS: sacral neuromodulation, sacral nerve stimulation, overactive bladder, overactive bladder, fecal incontinence, best practices

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This document was approved by all members of the ICS board, as well as the chairs of the Education Committee and the Standardization Steering Committee.

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International Continence Society Best Practice Statement for Use of Sacral Neuromodulation

Aims

Sacral neuromodulation (SNM) is an accepted therapy for a variety of conditions. However, despite over 20 years of experience, it remains a specialized procedure with a number of subtleties. Here we present the recommendations issued from the International Continence Society (ICS) SNM Consensus Panel.

Methods

Under the auspices of the ICS, eight urologists, three colorectal surgeons and two urogynecologists, covering a wide breadth of geographic and specialty interest representation, met in January 2017 to discuss best practices for neuromodulation. Suggestions for statements were submitted in advance and specific topics were assigned to committee members, who prepared and presented supporting data to the group, at which time each topic was discussed in depth. Best practice statements were formulated based on available data. This document was then circulated to multiple external reviewers after which final edits were made and approved by the group.

Results
The present recommendations, based on the most relevant data available in the literature, as well as expert opinion, address a variety of specific and at times problematic issues associated with SNM. These include the use of SNM for a variety of underlying conditions, need for pre-procedural testing, use of staged vs single-stage procedures, screening for success during the trial phase, ideal anesthesia, device implantation, post-procedural management, trouble-shooting loss of device function, and future directions for research.

Conclusions:
These guidelines undoubtedly constitute a reference document, which will help urologists, gynecologists, and colorectal surgeons optimize their use of SNM for refractory urinary urgency and frequency, UUI, NOR, and FI.

INTRODUCTION

Sacral neuromodulation (SNM) is an accepted therapy for refractory urinary urgency and frequency, urgency urinary incontinence (UI), non-obstructive urinary retention (NOR), and fecal incontinence (FI).

- These indications for SNM are approved by the FDA in the United States. In other parts of the world there are some other approved indications for various pelvic floor conditions.
- A need was identified for a comprehensive document reflecting best practices across indications related to SNM

A panel of experts from the fields of urology, gynecology, and colorectal surgery was convened to determine best practices for use of this therapy.

- Eight urologists, three colorectal surgeons and two urogynecologists, covering a wide breadth of geographic and specialty interest representation, met for two days in Chicago, Illinois, USA on January 19-20, 2017 to discuss best practices for neuromodulation. Suggestions for statements were submitted in advance and specific topics were assigned to committee members. Committee members prepared each assigned topic and presented supporting data to the group at which time each topic was discussed in depth. Best practice statements were formulated based on available data and expert opinion and then each member prepared a discussion section for each particular topic which reflected the current literature and expert opinion. Another urologist was added to the group during the initial writing process. After multiple rounds of editing within the group the highlights of the statements were presented at the ICS meeting in Florence, Italy in September 2017. This document was then circulated to multiple external reviewers after which final edits were made and approved by the group.
- The meeting and editing expenses were supported by the ICS. Funding to support this project was based on an unrestricted society-initiated grant made by Medtronic to the ICS.
- As many of the recommendations herein are based on expert panel consensus, the recommendations in this document, while meant to aid clinical decision-making, do not pre-empt physician judgment in individual cases.

The statements and recommendations included in this document pertain to SNM in its present form (Interstim, Medtronic) They may or may not have relevance for future SNM products or therapies which become available for clinical use.

- At the time this document was created, the only sacral neuromodulation device commercially available was the Medtronic Interstim (Minneapolis, MN). Thus, the data and statements discussed pertain to this device. However, it is clear that other sacral neuromodulation devices will be available in the near future. Accordingly, many of the concepts contained within this document will likely apply to newer devices as well.
- The panel used the International Consultation on Urological Diseases (ICUD) method when determining levels of evidence and grades of recommendation. Table 1 summarizes the criteria used for determining levels of evidence and grades of recommendation.[1]

DEFINITIONS

SNM: a technique that electrically stimulates a sacral spinal nerve root to modulate a neural pathway with the aim of treating bladder and/or bowel dysfunction.

- The term neuromodulation vs. neurostimulation was preferred by the committee since SNM, through electrically stimulating nerves, effectively functions by modulating the lower urinary tract or bowels.

Neurogenic lower urinary tract dysfunction (NLUTD): includes all bladder/urinary sphincter dysfunction related to any relevant neurological disease

Peripheral nerve evaluation (PNE) lead: a monopolar, temporary lead which is always removed after an SNM test period and is not designed for long-term therapy.

Staged (tined) lead: a quadripolar lead which is designed for potential long-term use after a successful test period.

BACKGROUND

SNM is not indicated as a first line therapy for either urinary or bowel disorders.

- Typically, conservative measures (behavioral, physical therapy) and medical treatment are recommended prior to treatment with SNM.

In the absence of a comparative study with recommended doses of onabotulinum toxin A (BTX-A) and contemporary SNM tined leads, no recommendations can be made as to whether BTX-A or SNM should be used over the other for the management of refractory overactive bladder (*OAB).*

- *The Rosetta trial is a prospective randomized trial that compared SNM to Botulinum toxin.*[2] *It showed a slight short-term advantage to Botulinum toxin, however, it did not utilize currently recommended doses of Botulinum toxin (200u as opposed to the recommend 100u dose) or the currently available SNM lead technology and thus no conclusions can be drawn relative to contemporary practice.*

SNM is a minimally invasive technique with good long-term outcomes. SNM can be offered to patients with OAB with or without incontinence who fail to respond to or are intolerant of conservative and medical therapies. (Level of Evidence: I; Grade of Recommendation: A)

OAB Without Incontinence

The initial SNM prospective, randomized, 12 center study enrolled 51 patients for severe urgency-frequency syndrome. This group reflects the present definition of OAB "dry" (urinary urgency and frequency without urinary urgency incontinence). Subjects who demonstrated a satisfactory response to PNE were randomly assigned either to immediate treatment or implant following a 6-month delay (control group). At 6 months, voiding diary results demonstrated statistically significant improvements in the immediate implant group in comparison to the control group with respect to the number of daily voids, volume per void and degree of urgency.[3] At 2 years follow-up, 29 urgency-frequency patients showed significant reduction in the number of voids per day, with 56% of patients showing 50% or greater reduction in the average voids per day, including 32% who returned to a normal range of 4 to 7 voids per day.[4]

OAB With Incontinence

The initial prospective, randomized, multicenter trial included 34 patients with severe urgency incontinence (OAB "wet") who underwent immediate implantation of SNM after a positive trial test and 42 patients (delayed group) who received standard medical therapy (SMT) for 6 months and then were offered implantation. At 6 months, the number of daily incontinence episodes, severity of episodes and absorbent pads or diapers replaced daily due to incontinence were significantly reduced in the early stimulation compared to the delayed group. In the early stimulation group, 16 patients (47%) were completely dry and an additional 10 (29%) demonstrated a greater than 50% reduction in incontinence episodes 6 months after implantation. Efficacy appeared to be sustained for 18 months. Surgical revision was required in 32.5% of patients.[5]

In this cohort, the long-term efficacy of SNM for refractory urinary urge incontinence remained high. At 3 years, leaking was significantly reduced, with 59% of patients reporting 50% or greater reduction in leaks per day and 46% of patients reporting that they were completely dry.[2] As compared to baseline, the group of 96 implanted patients demonstrated significant reductions in urge incontinence symptoms at an average of 30.8 (range 12-60) months with respect to the number of urge incontinence episodes per day, severity of leaking, and the number of absorbent pads/diapers replaced per day due to incontinence. About 10% of patients underwent device explant due to lack of efficacy, pain or bowel dysfunction but no permanent injuries associated with the devices or therapy were reported.[3] Others demonstrate that after 3 years, 59% of urinary urgency incontinent patients showed greater than 50% reduction in leaking episodes per day with 46% of patients being completely dry.[2] A single center study with median long-term follow-up of 50.7 months showed a success rate of 84.8% for urgency UI. Overall 39% of patients needed revision of the SNM neuromodulation implant.[6] SNM showed superior subjective and objective results compared to pharmacologic–SMT treatment for OAB, at 6 months. SNM is shown to be a safe and effective treatment for OAB patients.[7] Ultimately, a 2009 Cochrane review concluded that implantable neurostimulators have benefits for some patients with OAB symptoms, retention without organic obstruction, and in those for whom other methods of treatment have failed.

SNM is an effective treatment for Fowler's Syndrome, voiding dysfunction and NOR. (Level of Evidence: I; Grade of Recommendation: A)

Non-Obstructive Urinary Retention (NOR)

The initial SNM prospective, randomized, 12 center study enrolled 177 patients for NOR. All patients had PNE and 38.4% eventually received the implant. Of the 68 patients who qualified for implantation 37 were randomly assigned to an immediate treatment and 31 to a 6-month delayed implant (control group). At 1.5-year follow-up 70% of 42 implanted patients (immediate or late) showed greater than 50% reduction in volume per catheterization.[2] Further publication of 18-month

follow-up showed that of the patients treated with implants 69% eliminated catheterization at 6 months and an additional 14% had a 50% or greater reduction in volume per catheterization. Therefore, successful results were achieved in 83% of the implant group with retention compared to 9% of the control group at 6 months. Temporary inactivation of SNM therapy resulted in a significant increase in residual volumes but effectiveness of SNM was sustained through 18 months after implantation.[8] Extension of this study with 5-year follow-up showed significant reduction in the mean volume per catheterization and the mean number of catheterizations. The clinical success rate of 71% was observed at 5 years after implantation.[9] In another single center study, out of 60 women implanted there was a spontaneous voiding rate of 72% over a mean follow-up of 4 years. After surgery, of the 43 women who voided, 13 required the continued use of clean intermittent self-catheterization up to twice a day, but this was less than before surgery. Women with abnormal EMG did better, with 76% of patients experiencing restoration of voiding.[10] Another study confirmed that the presence of Fowler's syndrome is a positive predictive factor for SNM in female urinary retention.[11] Several single center studies reported good long-term outcomes between 73%[12] and 87%.[5]

SACRAL NEUROMODULATION FOR INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME

There is limited evidence supporting the role of SNM for patients with interstitial cystitis (IC)/bladder pain syndrome (BPS).

SNM is an option for IC/BPS non-responsive to conservative therapies after appropriate assessment. (Level of Evidence: III; Grade of Recommendation: C)

IC/BPS is a condition characterized by bladder, urethral and pelvic pain along with urinary frequency, urgency and nocturia.[13] SNM may be considered for patients with IC/BPS who do not sufficiently respond to first, second or third-line treatments. However, SNM has approval for pelvic pain conditions in only a few countries, and is not approved specifically for IC in any nation. There is limited evidence supporting the role of SNM for patients with IC/BPS - typically small observational case series all reporting different criteria for success. Based on these small observational studies, the success rate for SNM for IC/BPS using intention to treat analysis was 48% to 72%.[14,15,16,17,18,19]

Based on the available limited evidence, SNM may be an option for IC/BPS non-responsive to conservative therapies after appropriate assessment and multidisciplinary team review. The AUA IC/BPS Guidelines lists SNM as a 4th line therapy.[20]

There is a lack of evidence supporting SNM as a treatment option for patients with non-IC/BPS chronic pelvic pain. (Level of Evidence: III; Grade of Recommendation: C)

Chronic pelvic pain is defined as “chronic or persistent pain perceived in structures related to the pelvis of either men or women. It is often associated with negative cognitive, behavioral, sexual and emotional consequences as well as with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor or gynecological dysfunction. Pain must have been continuous or recurrent for at least 6 months”.[21]

There is minimal evidence reporting the efficacy of SNM for chronic pelvic pain.[22] Based on available evidence, SNM cannot be recommended as a treatment option for patients with non-IC/BPS chronic pelvic pain. However, pelvic pain is not necessarily a contraindication in patients with concomitant voiding symptoms such as frequency and urgency, if those voiding symptoms improve during the trial period and the patient endorses an associated improvement in quality of life.

SACRAL NEUROMODULATION (SNM) FOR NEUROGENIC LOWER URINARY TRACT DYSFUNCTION (NLUTD)

SNM is an option for symptom control in patients with NLUTD who are at low risk of upper urinary tract deterioration. (Level of Evidence: III, Grade of Recommendation: C)

SNM for NLUTD is of growing interest, although it is still as an "off-label" indication. There have been many reports of good outcomes in NLUTD but with a lack of standardized criteria in terms of patient selection, success definition, etc. Most of the evidence is focused on incomplete SCI and multiple sclerosis (MS) but patients with cerebrovascular accident, brain trauma, cerebral palsy, and Parkinson's disease have been implanted as well with similar outcomes as in patients with non-neurogenic indications.[23,24]

SNM has been utilized in the treatment of detrusor overactivity (DO), NOR, detrusor sphincter dyssynergia (DSD) and FI due to incomplete SCI. Although there are no clinical or urodynamic criteria to select ideal candidates for SNM in SCI, in one study ASIA D (incomplete injury with some preservation of motor function below the lesion) and E (normal sensory and motor functions below the injury level) lesions and sensation of bladder filling were associated with higher success rate during the test trial.[25] We recommend that in SCI patients, SNM should be limited to ASIA D and E patients with preserved bladder filling sensation.[33]

The success rate of SNM in patients with upper motor neuron injury may be higher than in patients with lower motor neuron injury since the former preserves afferent integrity and contractility of the detrusor. One study demonstrated an improvement in bladder emptying with SNM in patients with acontractile or hypocontractile bladder, but the mechanism of action is unclear.[26]

In patients with MS, SNM has demonstrated good results treating DO and NOR due to DSD but a low success rate in treatment of NOR has been reported in those with an acontractile or hypocontractile bladder.[27] Patients with MS being considered for SNM should have stable disease without an expected requirement for frequent or routine magnetic resonance imaging (MRI); patients with rapidly progressive MS typically should not have SNM systems implanted.

The most recent studies in SNM for NLUTD utilize longer periods of the test trial than for patients with idiopathic dysfunctions.[28] Longer test periods might be more appropriate for more complex conditions such as NOR[29] as well as NLUTD.

Since SNM is used after all other therapies have failed and prior to more invasive procedures, a 50% improvement during the trial period is adequate to define success. Most studies define success with the same parameters as in non-neurogenic patients, such as reduction of urinary frequency, urgency incontinence episodes, number of catheterizations, volume per catheterization and FI episodes.

NEED FOR URODYNAMIC TESTING PRIOR TO SNM

There is a lack of evidence to suggest that urodynamic testing can predict SNM outcomes. (Level of Evidence III, Grade of Recommendation C).

Patient characteristics such as age, sex, comorbidities, duration and severity of symptoms, and results of examination and testing such as cystoscopy, imaging and urodynamic studies (UDS) have shown insignificant value in predicting which patients will respond to a trial of SNM. Indeed, in some parts of the world, UDS are commonly performed prior to SNM trial, whereas in other areas, they are not, without an obvious difference in outcomes.

With regard to clinical studies, while some case series[30] have shown that older patients and longer duration of symptoms are less likely to respond, others[31,32] have contradicted this. One study suggested that combining traditional urodynamics and ambulatory monitoring might have additional predictive value[33] over conventional studies alone. None appear to be more sensitive, specific, or cost effective for the prediction of response to SNM as the screening trial, consisting of a PNE or a staged lead implant.[34,35,36] There is however a single recent prospective study showing that children with bowel and bladder dysfunction who had detrusor overactivity on videourodynamic testing had significantly greater improvement in symptoms with 2 stage SNM implant.[37]

The trial phase of SNM is the single most valuable tool for predicting the potential therapeutic success of SNM for urinary indications. (Level of Evidence II, Grade of Recommendation B).

Several large, multicenter trials have shown that the PNE[4] and the staged trial[6] predict which patients are likely to respond, and also which will likely have long term benefit from the therapy.[1.8,9,39] A unique advantage of SNM is this inherent ability to predict which patients are likely to benefit with its own specific trial. **UDS is unlikely to add significant diagnostic benefit in the evaluation of routine idiopathic OAB.[38]**

The index patient suffering from refractory OAB is female, has no neurologic disease, has not had prior pelvic surgery, and has no or minimal SUI. On physical exam there is no significant pelvic organ prolapse or urinary residual. She has failed first and second line options, and has significant bothersome symptoms. In this scenario, the panel agreed that there is scant evidence that the result of a UDS is likely to change the third line therapy options or outcomes. Patients with neurologic disease, an unclear degree of SUI or bladder emptying symptoms, significant prolapse, male patients, and prior pelvic surgeries including outlet reduction procedures (e.g. transurethral resection of prostate) and slings are more likely to benefit from UDS to aid in the correct differential diagnosis.

Pressure flow study or Video UDS may be valuable in the diagnosis of NOR. (Expert Opinion).

Urodynamics is particularly helpful to rule out obstruction when considering the diagnosis of NOR or incomplete bladder evacuation.[39,40] Another study showed that SNM treatment response in male patients with impaired bladder emptying can be predicted with a bladder outlet obstruction (BOO)-contractility nomogram.[41] In this study of 18 men, the authors found that only 20% of patients below the 10th percentile of contractility, but 86% of men between the 10 and 25th percentiles of the Maastricht-Hannover nomogram were treated successfully with SNM. All successfully treated patients voided without needing self-catheterization. Other studies have shown that EMG study of the external urethral sphincter may be helpful in defining Fowlers syndrome.[42] In females, the combination of video imaging and real time urodynamic data has been determined to be the best method of defining BOO.[43] Video studies in men may also be useful in determining the level of obstruction, for example benign prostatic hypertrophy vs. pseudodyssynergia.[44]

In cases where SNM has been tried and failed, UDS may be considered to further define the underlying disorder. (Expert Opinion)

Considering that the PNE or staged lead placement have the best predictive value for determining which patients will benefit from long term treatment with SNM, patients who fail screening, or those who have declining efficacy over time may benefit the most from initial or repeat urodynamic assessment, which may reveal bladder pathologies not amenable to SNM and direct another therapeutic course.

FECAL INCONTINENCE (FI)

SNM should be considered as a second line treatment option for bothersome FI in patients who have failed conservative measures. (Level of Evidence: 2, Grade of Recommendation: B)

Conservative medical measures are the first line treatment for FI, however, SNM should be considered as the second line of treatment in most patients with FI.[45,46,47] Physicians should consider SNM if the patient has failed medical measures, as SNM has been shown to be superior to best medical management in a randomized trial.[13] Results of pooled analysis has suggested that 79% of patients with permanent implant for chronic stimulation experience ≥ 50% improvement in incontinence episodes in the short-term, while 84% achieve this endpoint with 3 years of follow-up.[48] Comparative studies are scarce. One study compared 23 patients randomized to SNM vs. 17 randomized to percutaneous tibial nerve stimulation.[49,50] Though short-term outcomes were acceptable in both groups, the design of the study did not allow statistical comparison between groups. One study compared 15 patients treated with SNM to 15 historical controls treated with the artificial bowel sphincter. Postoperative incontinence scores were slightly better with the artificial sphincter, though constipation scores were worse.[51] Importantly, both the artificial bowel sphincter and the magnetic sphincter, another recent option for FI, are currently unavailable. There are no comparative studies of SNM vs. sphincteroplasty, the major competing procedure for FI.

An anal sphincter muscle defect is not a contraindication for SNM. (Level of Evidence: 3, Grade of Recommendation: C)

There is a large and growing body of evidence that a defect of the internal or external sphincter is not a contraindication for SNM for FI.[50,52,53,54,55,56,57,58,59,60,61] Though clinical success has been reported in patients with sphincter defects up to 180 degrees,[13,57,62] most would agree that the size of the defect does not matter and should not affect decision making.[50,54] This is likely because the proposed mechanism of action relies more on sensory nerve fibers and bowel motility than on muscular contraction.[63,64] Given the extent of the available evidence stating that a sphincter defect does not impact the success of SNM, some authors have advocated using preoperative ultrasound only in selected patients with FI.[65]

In a patient who is a good candidate for a sphincter reconstruction, typically in a younger woman with relatively recent obstetric injury, it is appropriate to have a full discussion of risks and benefits of a sphincteroplasty vs. SNM. Though there is no evidence to compare the outcomes of these two techniques, many young women with new onset obstetric sphincter defect may be good candidates for sphincter muscle repair.

Other factors such as pudendal neuropathy and the presence of a prior sphincter repair do not predict the outcome for SNM and should not be among the factors considered when deciding which patients to test for SNM.[45,65]

Patients who have FI after Low Anterior Resection for rectal cancer may be a candidate for SNM test lead implantation if conservative treatment fails. (Level of Evidence: 3, Grade of Recommendation: D)

As treatment for rectal cancer has evolved and sphincter preservation strategies have emerged, many of these patients are cured of their disease, but as many as 50-90% will suffer at least some

degree of bowel dysfunction.[66] Many patients will suffer from debilitating low anterior resection syndrome (LARS), a constellation of fecal urgency, clustering of bowel movements, and FI. As these patients have altered anatomy after resection of the rectum, it is unclear how much benefit SNM may play in achieving relief of symptoms. Two separate studies were conducted on the utility of SNS in LARS.[67,68,69] Success was noted in 47-100% of patients subjected to a test implantation and QOL was generally improved.[67] The difficulty in interpreting this data is that the patient groups are heterogeneous. Some, but not all, of the patients had radiation for rectal cancer, and the rectal resections were done for different disease processes such as cancer or Crohn's disease. Additionally, LARS is a constellation of symptoms with many dimensions such as bowel movement clustering, urgency, and incontinence. Though most studies report on improvement in continence, further research should use a more comprehensive scoring system such as the LARS score[70] to determine which elements of the overall syndrome are improved by SNM. Though it is reasonable to consider SNM test stimulation in the clinical setting of LARS, conservative treatment such as medical bowel management and lifestyle modification should be attempted first.

SNM is the preferred therapy in an appropriate patient with combined urinary and bowel symptoms. (Level of Evidence: III, Grade of Recommendation: C)

Combined Urinary and Bowel Symptoms

Early studies of 14 patents with FI and associated urinary disturbances showed encouraging results with permanent SNM implant.[71] A study of 24 female patients with combined FI and UI showed improvement in both symptoms after SNM implant in 31.8% of patients with a mean follow-up of 28 months. SNM may be beneficial in selected patients with FI and UI.[72] A recent study showed improvement of bowel dysfunction in patients implanted with SNM for urinary urgency incontinence. There was significant improvement in mean urinary and bowel symptom scores, though only urinary quality of life (QOL) scores improved.[73]

SNM for combined urinary and fecal incontinence has been also explored in children with a positive response. Based on prospective clinical data and patient-reported measures, 29 patients showed between 55% and 91% improvement in both bowel and bladder dysfunction.[74]

SNM should be considered for combined urinary and FI after the work-up for both conditions has been completed.

OTHER BOWEL CONDITIONS

SNM for constipation should only be considered for patients who have had symptoms for more than one year and have failed conservative treatment, as results of clinical studies have been disappointing. There should be no mechanically correctable cause. (Level of Evidence: 4, Grade of Recommendation: D)

Reported outcomes of SNM in patients with constipation have been mixed,[75,76,77,78,79,80] thus this remains an area of considerable debate. Success rates with test lead implantation have been reported at 42-100%, and extended testing periods of 2-3 weeks are often necessary.[81] Contradictory studies have emerged, suggesting much lower rates of clinical success. A study by Graf et al[82] indicated that only 11% of patients were improved at 24 months. A double-blind randomized trial of SNM vs. Sham indicated that only 28% of SNM patients met the criteria for device implantation and there was no benefit of this therapy over sham treatment.[83] Additionally, this therapy is not approved by the US Food and Drug Administration, and is not universally covered by

insurers in Europe. Best evidence suggests that all less invasive medical and surgical measures should likely be taken prior to proceeding with SNM in these patients.

NEED FOR BOWEL TESTING PRIOR TO SNM

A 2-3-week bowel diary is necessary prior to SNM test for bowel dysfunction. Anorectal physiology testing (manometry, anorectal sensation, volume tolerance, compliance) can be considered to help define the elements of dysfunction and guide management. (Level of Evidence: 4, Grade of Recommendation: C)

It is difficult to identify from the literature the optimal work-up prior to SNM in bowel indications. Some clinicians even consider the PNE test itself as a part of the pre-SNM work-up in FI patients, as there is no known physiologic predictor of success of SNM in these patients.[84]

However before embarking on an SNM trial, common bowel investigations are typically done to identify those patients for whom such a test could be of greatest potential benefit.[85] Typically, the patient proposed for SNM test has chronic, severe FI which is defined as more than "one leak per week, over a 3 to 4-week period, lasting for more than 6 months" and that has failed conservative measures. A 2-3-week bowel diary is the most important document prior to SNM test for bowel dysfunction. The following is recorded and will be compared with a similar diary done during the test phase: leaks (minor and major), normal evacuated stools, time to defer as a mean by day, and medications taken. The Bristol stool chart is useful to characterize the bowel habits and to allow exclusion of patients with diarrhea from SNM since a normalized stool pattern has not been reached.

Additional investigations **may** include the following:

- Anorectal physiology testing (manometry, anorectal sensation, rectal volume tolerance and compliance) can be considered to help define the elements of dysfunction and guide management. It is usually done before surgical decision-making, as part of the FI work-up and plays a role to guide pelvic floor retraining.
- Endoanal ultrasound is the recommended tool to assess the anal sphincter complex and to identify any sphincter defects. It would guide the discussion to proceed for repair vs. SNM trial according to the different aspects of the defect.
- Dynamic defecography, either standard or MRI, is nowadays also a test to consider prior to SNM trial.[86] This exam allows for identification of any posterior pelvic floor disorder including high-grade rectal intussusception, which can be clinically difficult to identify and a potential cause of FI. In such a case, many clinicians would first correct the rectal prolapse followed by an SNM trial if FI persists.
- Neurophysiology testing may be performed in some neurologic conditions, but is not part of the usual investigations.
- A/P and lateral views of the sacrum could exclude some abnormalities/malformations making the needle and electrode placement difficult for instance in the case of sacral agenesis associated with anorectal malformations.

SNM FOR THE PEDIATRIC POPULATION

SNM may be considered in children who have failed an extended period of behavioral modification, biofeedback, and pharmacologic therapy and should be considered before irreversible surgery.

Safety and effectiveness have not been established for pediatric indications. (Level of Evidence: III, Grade of Recommendation: C)

Anatomical differences and somatic growth make implantation technically more challenging (Level of Evidence: IV, Grade of Recommendation: D)

SNM has been reported to be effective in children in several single center pilot studies. In one, a total of 23 patients, ranging from 6 to 15 years old with presenting symptoms of dysfunctional voiding, enuresis, incontinence, urinary tract infections, bladder pain, urinary retention, urgency, frequency, constipation and/or fecal soiling were followed for a mean of 13.3 months after SNM. The overall patient satisfaction rate was 64%, while that of the caregiver was 67%. Explantation rate was 10%.[87] Another study with 30 children with refractory bowel and bladder dysfunction showed significant improvements.[37]

There are only two prospective randomized trials utilizing SNM in children. The first study of 42 children with incontinence due to neurogenic LUTD showed subjective improvement in about half of children undergoing SNM, including improved bowel function in 9 children, resolution of urinary tract infections in 5 children, and improved bladder sensation in 6 children.[88] The other randomized study of 33 patients (24 boys) with mostly neurogenic LUTS and with a mean age of 12.2 years compared SNM to standard conservative treatment. Incontinence was mixed urinary and fecal in 19 cases, urinary only in 9 and fecal only in 5. Overall positive response rate was more than 75% for urinary and bowel dysfunction.[89]

A study with longer follow-up (average 3.2 years) in consecutive children with UI, constipation, frequency and/or urgency, and nocturnal enuresis from a single center showed that nearly all children (99 of 105) experienced improvement of at least 1 symptom. Reoperations occurred in 56% of children, mainly for device malfunction. Explantation was performed in 35%, mainly for complete symptom resolution.[90] Of note, certain health preventive measures are of greater importance in children, mainly reduced radiation exposure. Also, anatomical differences and somatic growth must be considered with SNM implantation in the pediatric population.

CONTRAINDICATIONS FOR SNM IMPLANTATION

Absolute contraindications for SNM includes: Inadequate clinical response to a therapeutic trial, inability to operate the device with lack of supportive caregivers who could otherwise offer assistance, and pregnant patients (Level of Evidence: IV, Grade of Recommendation: C).

Relative contraindications for SNM includes: patients with severe or rapidly progressive neurologic disease, patients with established complete SCI, patients with known anticipated need for MRI of body parts below the head and patients with abnormal sacral anatomy (Level of Evidence: III, Grade of Recommendation: C).

The manufacturer of the currently most widely available system (InterStim II) has approved the safety of the current device for 1.5 Tesla MRI of the head. See manufacturer's website for further detail.[91] Recent studies have shown that the risk of heating is low for clinical lumbar and pelvic MRI at 1.5-Tesla, both in an intact SNM system and with a fractured lead.[92]

In pregnant women, no negative effects of SNS on the fetus, mother or device have been reported. However, further studies are needed to conclude if it is a safe practice to implant or to leave a device activated in a pregnant woman.[93,94] Indeed, a recent review that included 16 Cesarean and 9 vaginal deliveries, comprising 25 pregnancies with SNM devices in situ (8 with device left on during gestation, 18 with device deactivated, typically between 3-12 weeks gestation) reported that post-delivery SNM dysfunction was present in 32%, with 3 after vaginal delivery and 5 after c-section. Ultimately, the authors suggested that "within the current limited evidence, the decision regarding SNM activation or deactivation should be individualized [in pregnancy]."93 Until more data is available, for example from a patient registry, the panel recommends not implanting a SNM device in a pregnant woman and deactivating the device when a patient already on SNM therapy becomes pregnant.

TIPS FOR INTRODUCTION OF SNM TO PATIENTS

SNM therapy should be discussed with all patients as part of their bowel or bladder control treatment pathway. (Level of Evidence: IV, Grade of Recommendation: C)

Surgeons should review the need for life-long follow-up, eventual battery replacement, complications, and expected symptom improvement. (Level of Evidence: IV, Grade of Recommendation: C)

SNM is classified as a 3rd line option for treating OAB symptoms,[95] and as a 2nd line therapy for FI. Medications and non-invasive interventions comprise first line therapy. It is known that many patients will not respond to initial therapies and will potentially be offered neuromodulation as an option. There is no documented 'best practice' for introducing SNM to patients, however at least one study showed that group-education visits made patients more informed and prepared for the test phase, which translated into improved patient-reported outcomes compared to those undergoing standard preoperative counseling, despite voiding diary outcomes being no different between the groups.[96] As no reliable predictor for patient response to more conservative therapies exists, it is our recommendation that all patients be informed of this therapy as early as possible in the treatment pathway. Similarly, for FI, where limited therapies exist beyond pelvic-floor therapy and modification of stool consistency, patients should be alerted that SNM therapy exists.[97] Patients with dual bladder and bowel disorders stand to benefit with respect to both symptoms,[73] which may direct the clinician to educate the patient about SNM almost at the first encounter. This is discussed in further detail elsewhere in this consensus statement.

As patients are introduced to SNM is it important to review the limitations and implications of the therapy. Currently, the InterStim II device is labeled for an expected battery life of 3-5 years, though some have shown longer periods with lower energy settings.[5] Long-term follow-up, the need for battery replacement, possible revision of the lead or programming changes are all important aspects of SNM therapy,[98] and should be communicated to the patient, in particular given that a recent study using contemporary technology found a 32% rate of surgical intervention at 3 years following implantation.[31] Furthermore, while symptom improvement can be dramatic in some patients, the target response of >50% improvement both objectively and subjectively as the implant threshold indicates this is not a cure in most patients. Expectations for the patient are important and should be balanced against the known response to trial and long-term implant success.

PREOPERATIVE COUNSELING - ADVERSE EVENTS

Preoperative counseling prior to SNM should include a discussion of risks including implant site pain, infection, paresthesia, leg pain, and/or need for reprogramming or for device revision. (Level of Evidence: 3, Grade of Recommendation: C)

Though SNM is a relatively safe surgical procedure, adverse events do occur. The most complete report on adverse events comes from the North American Multi-Center trial, as investigators were required to report all adverse events. The most common adverse events were implant site pain (32.5%), paresthesia (19.2%), implant site infection (10%), leg pain (5.8%) or buttock pain (5.0%).[99] The 5-year clinical data on implants for bowel indications from Hull et al[16] suggest that preoperative counseling and long-term follow-up are necessary, as 24.4% required revision or replacement by 5 years, and 19% were permanently explanted by 5 years. Close follow-up with programming parameter optimization, may increase clinical efficacy, while decreasing paresthesias and leg pain.[100]

In a recent multicenter trial, the infectious complication rate was 3.3%.[101] It may be helpful to distinguish between early (<1 month after implantation) vs. late (>1 month after implantation) infections. Wexner et al[102] reported that in colorectal patients, 5/7 early device infections resolved with antibiotics, while all 4 late infections required device explantation. As testing strategies evolve over time, there is increasing interest in the percutaneous office approach to testing, as at least one publication suggested an overall infection incidence of 0% in patients tested via office PNE vs. 10.5% in patients who received a staged approach in the operating room (OR).[103]

RATIONALE for PNE *vs* STAGED PROCEDURE

Both PNE and staged trial play a role in SNM. The advantages and disadvantages of each must be taken into consideration when selecting the approach. (Level of Evidence: II, Grade of Recommendation: C)

One of the unique aspects of SNM is that patients are allowed to undergo a trial period to evaluate whether the therapy is efficacious and provides adequate symptom relief.

Both PNE and the staged trial play a role in SNM. The advantages and disadvantages of each must be taken into consideration when selecting the approach.[2,6,104,105] An ideal candidate for PNE is one who is comfortable undergoing a procedure under local anesthesia (LA) and who is able to tolerate the potential, mild discomfort related to the procedure. Patients with heightened levels of anxiety or a low pain threshold may benefit from a staged procedure in the OR under monitored anesthesia care (MAC) sedation /local or general anesthesia (GA).[106]

PNE is less invasive, less costly and can provide reliable sensory responses. (Level of Evidence: III, Grade of Recommendation: C)

This form of test stimulation may be required by insurance carriers and may also act as a bridge to therapy acceptance. However, PNE lead migration can be problematic, and there may be limitations in pediatric populations and patients with NLUTD. (Level of Evidence: II, Grade of Recommendation: C)

Overall, the PNE approach is less invasive, less costly if performed in an office setting, and can provide reliable sensory as well as motor responses.[107] As it is generally performed in the office setting, it may also be more convenient for the patient as it has the potential to avoid one trip to the OR. This advantage would reduce the risks associated with anesthesia and hospital admission by

having only one procedure in the hospital vs. two. Additionally, this form of test stimulation may be required by insurance carriers as well as acting as a bridge to accepting therapy. However, there are issues with PNE lead migration, and it may have limitations in a pediatric population and patients with neurogenic voiding dysfunction.[93]

Staged implant is superior to PNE with regards to conversion rates to chronic therapeutic stimulation in OAB and FI. (Level of Evidence: II, Grade of Recommendation: B)

> ***This approach also has the advantage of a longer trial period.***
>
> ***However, this approach may be more costly, may require two trips to the OR and may be associated with a greater rate of adverse events.***

The advantage of the staged implant is that the there is a longer trial period, and the lead that is being tested is the lead the patient will use long-term. The patient is also allowed to trial multiple programs to achieve optimal outcomes. The conversion to permanent implant is consistently higher in the staged vs. the PNE at rates of 80% vs. 44-52%, respectively.[2,93,94,103, 108] Now with the use of fluoroscopy at the time of PNE lead placement, the PNE conversion rate may be higher, however there is no current data to support this supposition.

More data is needed to identify ideal candidates for PNE vs. staged implant. Reliable predictors of test stimulation success are currently lacking in both bladder and bowel dysfunction. (Level of Evidence: III, Grade of Recommendation: D)

> ***For patients with FI who have continent periods of >5-7days punctuated by intermittent episodes of FI, a staged implant may be preferable to ensure an adequate trial period. (Level of Evidence: IV, Grade of Recommendation: D)***
>
> ***Since NLUTD is a complex condition and given the lower rate of positive tests using PNE, a staged procedure should be considered for the majority of NLUTD patients. (Level of Evidence: III, Grade of Recommendation: D)***

In patients with underlying neurological conditions, since NLUTD is a complex condition and given the lower rate of positive tests using PNE, a staged procedure should be considered for the majority of NLUTD patients. The majority of studies recently published in this area reported exclusively on the use of tined lead electrodes for the test trial in NLUTD patients.[36] Even though these studies do not report comparative results between the two techniques it has been demonstrated that PNE testing has disadvantages compared to the staged procedure such as lead migration 11-18%,[2] lower rate of positive tests 46% vs 88%[109] (9) and different responses between temporal and definitive lead – up to 20%.

SCREENING FOR SUCCESS DURING THE TEST PERIOD

Patients who achieve ≥ 50% improvement in one or more of their bothersome urinary or bowel parameters during PNE or Stage 1 test period may be offered a full system implantation.

For both PNE and stage 1 trials, both objective and subjective measures of improvement should be assessed. Success during the SNM trial is defined as at least 50% improvement in one or more of the bothersome parameters.[9] Patients who achieve this benchmark should be offered full implantation.

PNE duration is typically 7 days for bladder indications. As the PNE leads are not anchored with tines, there has historically been concern regarding lead migration causing an inconclusive trial; thus, PNE trials are typically not done for more than about 7 days. However, some implanters do utilize longer PNE trials with little ill effect (in particular European implanters for bowel indications).

PNE test stimulation period is typically 7 days for bladder and 10-21 days for bowel indications. (Level of Evidence: III, Grade of Recommendation: 3)

PNE duration for urinary urgency/frequency and urgency incontinence is typically 7 days. This can be extended in cases of NOR. The period for SNM trial recommended by the manufacturer is two-weeks for bowel indications. It has been strictly applied in the US with a 10-14 day trial in the major published studies.[16] However, in Europe this is considered too short a duration as stated in the published consensus statement based on a Delphi process in 2015.[54] Assuming the lead remains viable without significant migration, a 3-week trial period has been chosen as an empirical compromise.[110]

Thus, for bowel indications, it is suggested that SNM test duration last from 10 days to 4 weeks, allowing for testing of various stimulation programs, which may be beneficial when a satisfactory result is not immediately achieved.[111] Ultimately, the goal of any trial (whether PNE or staged), is to provide an adequate duration to determine whether at least a 50% improvement in symptoms has been achieved.

Stage 1 test period duration is typically 2-3 weeks.

Stage 1 testing can be attempted if PNE is inconclusive, particularly if a longer test period is required for screening.

A repeat stage 1 test may be performed at the physician's discretion.

Stage 1 duration is typically 2-3 weeks. There are some experts who do utilize up to four weeks, in part to avoid any possible placebo effect, or in instances when it is unclear if the patient has met the 50% improvement criterion, or for patients with incomplete emptying.[112] Kessler and colleagues followed a series of 44 patients who underwent prolonged tined lead testing for a median of 30 days, with 70% proceeding to full implantation. The complication rate was 5% during the prolonged tined lead testing, but none of these were attributable to the extended testing itself.[113]

Patients should be encouraged to adjust the stimulation settings during their test period to optimize the trial.[2] If PNE testing is inconclusive, it is reasonable to consider a Stage 1 trial, in particular if a longer duration of testing is required. Stage 1 trials are typically not repeated, but can be attempted at the physician's discretion in select circumstances.

REMOVAL OF SCREENING LEAD

PNE electrode(s) removal preferably occurs in the clinician's office, but may be removed by patient/family at home.

Stage 1 tined leads can be removed under local anesthetic (in the office or OR) with or without sedation to ensure patient comfort during removal of all components.

There are no published studies regarding removal of the PNE lead at home by the patient versus in the office by the clinician. Removal at home is convenient for patients, especially those who travel a great distance to their clinician's facility; however, removal in the office allows for both confirmation

that the lead was removed intact, as well as an opportunity to review outcomes of the trial (though this could also be done via phone in conjunction with home lead removal). The panel agrees that removal of a PNE lead can likely be safely performed in either setting

Stage 1 tined leads should be removed by a physician.[114] These can be removed under local anesthetic in the office or the OR setting, with or without sedation, as needed to ensure patient comfort.

PREVENTION OF SURGICAL SITE INFECTION (SSI)

A perioperative antibiotic aimed at coverage of skin flora should be given intravenously within 60 minutes of incision for both bowel and bladder indications.

The specific antibiotic of choice should be guided by the local antibiogram and the patient's allergy profile. (Level of Evidence: IV, Grade of Recommendation D)

The most significant complication after SNM device implantation is wound infection. Reported wound infection rates range from 2–11% and are most commonly caused by Staphylococcus aureus.[115] A recent large multicenter trial reported a wound infection rate of 3.3%.[116]

No defined perioperative or postoperative antibiotic protocol is uniformly agreed upon for neurostimulator implantation; instead, this decision should be guided by the local antibiogram and surgeon discretion. For the staged procedure, preoperative intravenous antibiotics should be given within 60 minutes prior to the incision and aseptic techniques should be closely followed.

The AUA Best Practice Statement for perioperative antibiotic prophylaxis recommends the use of a first-generation cephalosporin for open surgical procedures that do not involve entry into the urinary tract and does not recommend prolonged antibiotic usage, since there is no evidence to support it.[101] Prostheses implantation surgeries are recommended to receive prophylaxis with an aminoglycoside plus a first-/second-generation cephalosporin or vancomycin. It is debatable how to categorize the SNM procedure because it is an open surgical procedure not entering the urinary tract as well as an implanted procedure.

In a study done by Haraway et al,[104] the use of cefazolin as the preoperative antibiotic was the only significant risk factor for subsequent infection and explanation of the SNM device. Indeed, cefazolin was less effective than vancomycin with or without gentamicin in preventing infection in this study, likely due to resistant organisms.

Antibiotic recommendations for bowel and bladder indications are similar. The European consensus statement for sacral nerve stimulation for FI and constipation recommends a single dose of prophylactic antibiotics before both the tined lead and the IPG implantation procedures, and suggests that routine postoperative antibiotics are not required.[54]

Chlorhexidine-based skin prep is commonly used for perioperative cleansing of the patient's back and upper buttocks, but this varies between clinicians. Care should be taken in preparation of the buttocks and anus. If the implanter chooses to visualize the anus during test stimulation to observe the anal sphincter contraction, it should be covered with a separate plastic drape until visualization is required during surgery.

Other investigators suggest minimizing the risk of SSI with a preoperative shower with antiseptic, as well as allowing the dressing to remain in place for 48 hours postoperatively following stage 2 procedures.[117]

IDEAL ANESTHESIA

No data suggest superiority of local anesthesia (LA) with IV sedation vs. general anesthesia (GA) for a successful staged neuromodulation trial.

Muscle relaxants with GA and regional anesthesia causing neuromuscular blockade must be avoided.

LA is preferred for PNE, and LA with IV sedation for IPG implant. GA may be considered.

There are two current methods for trialing SNM to screen for efficacy.

The first is the PNE, which is generally done in the office under LA. There is the option to perform the PNE in an ambulatory surgical center (ASC) or even in the hospital and provide monitored anesthesia care (MAC) or GA. The second method is the staged approach, which is typically done in an ASC or hospital setting under MAC or GA. When SNM was first approved, this involved a PNE screening trial, and if the patient was determined to be a success, they then underwent implant of the long-term device. This required a large cut-down to the posterior aspect of the sacrum and was routinely performed under GA with high success rates. This suggests that the use of GA does not negatively impact the success of SNM.

In general, LA is considered to be safer than MAC, which is itself considered safer than GA. There is no current data that suggests any type of anesthesia is superior over another in terms of outcomes for SNM. As one of the parameters for determining a successful implant is appropriate motor response (bellows and great toe flexion), the use of a paralytic agent should be avoided if using GA. ***(Level of Evidence: V, Grade of Recommendation: C)***

LA is preferred for PNE if patients are able to tolerate it, and LA with IV sedation (MAC) for tined lead and IPG implant. GA may be considered under certain circumstances according to physician discretion, however there is no evidence that the choice of anesthesia impacts outcomes ***(Level of Evidence: II, Grade of Recommendation: B***).[9,97]

IMPLANT TECHNIQUE

The clinician should strive to achieve appropriate motor and/or sensory responses on all 4 contacts at stimulus amplitudes of <2 volts. (Level of Evidence: II, Grade of Recommendation: B)

The concept of "Optimal Lead Placement" derives from the notion that while the overall success of SNM is excellent,[118] there is a potential for an individual patient to experience an incomplete benefit, or a "false negative" response due to technique and imprecise lead positioning[2]. Although it remains to be proven scientifically, logically it is hard to dispute that the quality of the interface between the neuromodulation device and the nervous system is of general importance to the therapeutic outcome of SNM. The current 3023 tined lead is an electrode array, consisting of four equally spaced contacts in a flexible assembly. By taking readily reproducible steps to steer the lead into position it is often possible to follow the course of the sacral nerve target, and achieve similar motor and sensory responses at each individual contact.[119,120,121] Some have demonstrated more accurate placement with the curved lead.[121] These electrode contacts may then be employed singly or in combination to achieve neuromodulation for clinical benefit.

The closer the lead is to the intended target, the lesser is the amount of energy that will be required to obtain a neuromodulation response. On one level, effective programing at lower

thresholds is more efficient, and is likely to result in longer lasting battery life and less frequent need for replacement thus increasing the cost efficacy of the therapy and reducing risks related to re-operation.[122,123] On another, electrode placement near the nerve means that the chance of stimulation of unwanted tissues (ie, the piriformis muscle), which may trigger uncomfortable stimulation or paresthesias, will be minimized. In turn, the need for reprogramming or re-operation to resolve uncomfortable stimulation should be lessened.

Leads that require higher thresholds or offer responses at fewer than 4 contacts can be successful. (Level of Evidence: II, Grade of Recommendation: B)

Sub-optimal lead placement can be therapeutically beneficial. Initial techniques for chronic lead placement were performed in a "blind" fashion, guided only by anatomical landmarks, without the routine use of fluoroscopy.[4] The depth of lead placement, lead direction, and even the final sacral level of placement was not standardized. Many subsequent series have shown excellent symptom benefit before the concept of lead optimization was widely suggested. However, it is unknown if the overall degree of symptom relief could potentially have been greater, and the rate of screen failure, re-operation, or eventual therapy abandonment might have been reduced within these study populations, had lead optimization been a standard.[124,125] Another unknown is whether the demands for precise lead placement may differ for various indications. An example of this concept is the notion that the target for lead placement for the indication of FI seems to be more robust, with a relatively large neuromodulation target (S3 or S4), while placement for urinary frequency and urgency without urge incontinence, and with a component of pelvic pain, may require hitting a narrower target (S3 or pudendal lead placement).

S3 is the preferred target for SNM. Bellows and toe dorsiflexion are the motor responses consistent with S3 placement. Thresholds for bellows should be lower than for toe. Leads placed in S4 may be appropriate in some cases. S2 should be avoided due to the risk of aberrant sensation and motor response in the leg. (Level of Evidence: 3, Grade of Recommendation: C)

From the initial studies on SNM, S3 is the preferred target for SNM. A typical S3-mediated response is a contraction of the pelvic floor along with plantar flexion of the first and second toes, whereas S4 stimulation does not produce any toe response.[126] There is individual variation in composition of the sacral roots. A direct ventral sacral root electrical stimulation study measuring bladder contraction by means of intravesical pressure showed that in 100% of the patients, bladder pressure increase was measured upon stimulation of the S3 anterior sacral root, but also in 60%, upon stimulation of S4, 40% on S2 and around 15% at S5. There is an individual difference in distribution of bladder efferent fibers.[127] It is unknown if the distribution of motor nerves activated directly by neurostimulation is similar to the distribution of the rootlets stimulated for the indirect neuromodulation effect.

In a retrospective study on patients with FI however, there was no difference in success rate upon S3 or S4 stimulation during a 3-week PNE test.[128] These findings are also supported by reports of accidently or deliberately implanted leads in S4.

S2 stimulation produces outward rotation of the leg and sensation running down the leg.[116] These effects may bother the patient, and S2 stimulation should therefore be avoided.

The clinician should consider both sensory and motor responses important for success. (Level of Evidence: IV, Grade of Recommendation: C)

The most readily quantifiable responses are motor (bellows and toe) with the patient under sedation. It is easier to obtain sensory responses than motor during a PNE, when the patient may not be able to relax and is fully conscious.[116,129] A purported mechanism of action of SNM is sensory afferent neuromodulation, so the sensory side of the response may be meaningful. Indeed, given that sensory responses are used when reprogramming, having appropriate sensory responses during initial placement may help guide successful reprogramming and eliminate the need for revisions.

Motor responses alone may be utilized in patients who undergo GA. (Level of Evidence: IV, Grade of Recommendation: C)

With patients under heavy sedation or GA, sensory responses are unlikely to be elicited. The pattern of motor responses can be helpful in predicting where paresthesias will be felt. For example, all bellows and no toe, or toe only at a significantly higher threshold than bellows, is likely to be associated with anal sensation, while bellows followed by toe response immediately or at slightly higher thresholds is more likely to be associated with genital sensation. Toe movement at a lower threshold than bellows is likely to be associated with uncomfortable sensation down the leg.

Sensation down the leg or in the buttock and discomfort in the anal, perianal, or genital areas should be avoided. ***(Level of Evidence: II, Grade of Recommendation: B)***

Although sub-sensory thresholds are potentially associated with good patient outcomes, generally patients tend to do better when the stimulation is comfortable. One of the most common adverse events of SNM is uncomfortable stimulation.[105] Most patients find stimulation in the buttocks or down the leg less comfortable, than in the anal, perineal, or genital areas.[116] Patients are more likely to require reprogramming when stimulation is uncomfortable.[105] It is unclear whether anal, perineal, or genital sensations are associated with higher success in individual patients or between patient groups depending on diagnosis, ie, FI vs. urinary frequency with or without a component of pelvic pain.

Standard frequency and pulse width settings of 10-20 Hz should be used. (Level of Evidence: II, Grade of Recommendation: B)

Other frequencies and pulse widths can be used during troubleshooting procedures. (Level of Evidence: IV, Grade of Recommendation: D)

There are no studies which show definitive advantages of specific programming settings over others for a condition or indication. Low frequency stimulation of 10-20 Hz, with pulse width between 180-210 μs, has been associated with therapeutic success for all the indications approved for SNM. These settings should be used initially. If patient comfort or therapeutic efficacy is not achieved, it is reasonable to experiment with alternative programming, though consistent success is anecdotal.

ROLE OF FLUOROSCOPY

Fluoroscopy is recommended for staged lead positioning to control depth of foramen puncture and optimize placement of the lead. (Level of Evidence IV, Grade of Recommendation D)

Fluoroscopy may be used for PNE to confirm proper lead placement. Alternatively, use of bony landmarks to determine lead placement is acceptable if fluoroscopy is not available. (Level of Evidence III, Grade of Recommendation C)

Fluoroscopy is a key element underlying quality tined lead placement, allowing the surgeon to control both depth of puncture and the placement of the lead. In many countries, labeling of the therapy indicates that fluoroscopy must be used for tined lead placement. Fluoroscopy may also be used during PNE, but not all clinicians do this during their office procedures.

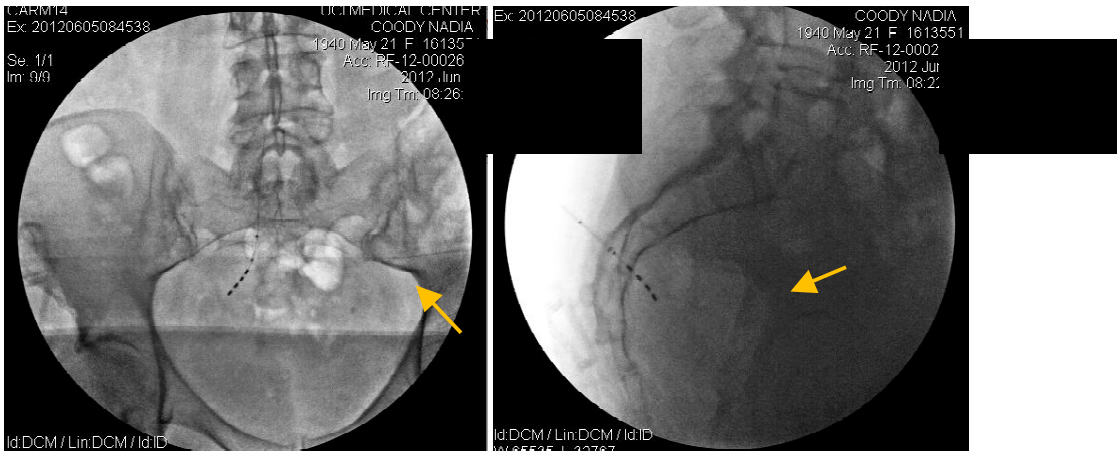
Siegel and colleagues first described fluoroscopic lead placement in 1992.[130] Their description is still useful today, and very much in keeping with the modern technique; however, they described an open surgical procedure, which contrasts with the modern, minimally-invasive approach to tined lead placement. The role of fluoroscopy has become even more crucial following conversion to the minimally-invasive placement technique, as it allows for consistent, reproducible and optimal positioning of the lead in the foramen, as well as confirming curvature along the path of the S3 nerve, plausibly avoiding multiple punctures, minimizing bleeding, infection risk, post-operative pain and surgical time.

- **Active lateral fluoroscopy should be used during final tined lead deployment.**
- **The distal end of the lead introducer should be placed only ½ to 2/3 through the sacral bone table.**
- **The motor and sensory responses and the stimulus amplitude at which they occur, along with AP and lateral x-ray images associated with final deployment, should be recorded in the medical record.**
- **Radiographic appearance consistent with ideal lead placement entails:**
    - **In the lateral view, the lead parallels the fusion plane between third and fourth sacral segments, enters above the hillock, and curves caudally. Distal lead contacts appear to be spaced more closely together than proximal contacts.**
    - **In the AP view, the lead starts close to the medial edge of the foramen, and curves out mediolaterally. Proximal contacts appear to be spaced more closely together than distal contacts.**
    - **The curved stylet may be able to increase the number of responding contacts at lower stimulus amplitudes. (Level of Evidence IV, Grade of Recommendation C)**

There remains debate regarding optimal lead placement, and no prospective studies exist to correlate clinical response (in bowel or bladder conditions) with lead positioning. Jairam et al[131] from Masstricht retrospectively reviewed lead placement in 189 patients, and found no correlation between the position of the tined lead in the Stage 1 trial, with regard to depth, angle, and deflection, and the number of active electrodes, and the likelihood of a successful trial in either the OAB group or the NOR group. Nonetheless, expert consensus dictates that placement close to the nerve may reduce voltage used and improve programming options and long-term battery life.

Figure 1a: A/P image demonstrating medial placement in the S3 foramen (arrow)

Figure 1b: Lateral image demonstrating 3 contacts below the sacral plate



IPG PLACEMENT

IPG buttock placement in the lateral upper quadrant is preferred but abdominal placement may be required in some cases. (Level of Evidence: 3, Grade of Recommendation: C)

IPG should be placed above the muscle layer, no deeper than 2.5 cm (1 in). (Level of Evidence: 3, Grade of Recommendation: C)

When SNM was first introduced, the IPG was placed in the anterior abdominal wall. This required repositioning of the patient during surgery and prolonged the procedure, and, of note, the lead extension required for this type of placement is no longer manufactured. Buttock placement of the IPG was described by Scheepens et al[132] in 2001. This technique simplified the procedure and reduced operative time in all 39 trial patients by approximately 1 hour, given that no repositioning of the patient was required during surgery. Pain was reduced and there were no infections.[121] It is, however, difficult to assess the true advantage of buttock vs. abdominal placement, since no direct randomized trials have been published. In some patients with very limited fat, an abdominal placement might be utilized.

Because of the distance limitation of the wireless communication with the programmer, the IPG should be placed no deeper than 2.5 cm (1 in). [Product information data]

POST PROCEDURAL PATIENT RESTRICTIONS

PNE test stimulation is associated with a risk of lead migration. Limited physical activity during the trial is advised to reduce this risk. (Level of Evidence: 3, Grade of Recommendation: C)

Risk of lead infection is greater with Stage 1 testing than with PNE. Operative dressings should not be removed during the test period, unless permitted by the surgeon. (Level of Evidence: 3, Grade of Recommendation: C)

Following Stage 1 and Stage 2 procedures, patients should be encouraged to minimize vigorous activity for several weeks to allow the tined lead to scar in place and prevent lead migration. (Level of Evidence: 3, Grade of Recommendation: C)

Besides the manufacturer's recommendations (Manual InterStim 3889, 3058, etc.*)* very limited data has been published regarding specific post procedural patient restrictions. However, the two main risks to the implants are infection and dislodgement.

For test stimulation with temporary leads, which are only secured by external dressing and not by internal fixation like the tined lead, secure fixation with splash-resistant, transparent dressing allowing for washing and showering after disconnection of the external pulse generator is advised.[133] Patients should be instructed to avoid strenuous physical activities, which result in tension on the electrode.

For test stimulation with a tined lead, the risk of dislodgement appears to be less;[134] however, the risk of infection becomes more relevant. In a retrospective review of 669 SNM procedures, one group did find substantial decreases in infection rates after instituting an at-home chlorhexidine washing protocol.[135] The removal of the dressing throughout the test period should, however, still be avoided unless the physician has concern upon inspection of the dressing for infection or bleeding. There is no consensus on the use or efficacy of continued antibiotics during the trial period.

In one study[136] of 235 patients, lead migration occurred 1 subject when using a tined lead. In another study, with 2 years follow-up after tined lead implantation, there was a 10% rate of lead migration following tined lead implantation.[137] Regardless, after implantation, vigorous activity and excessive bending or twisting at the waist should be avoided for sufficient time to allow scarring and fixation of the implanted device.

POST-OPERATIVE AND FOLLOW-UP CARE

Routine follow up should include a clinical examination, symptom evaluation, system check of the stimulation device and confirmation that it is functioning. (Level of Evidence: III, Grade of Recommendation: C)

In patients with urinary retention, a post-void residual should be assessed.

Suggested routine follow up consultations during the first year should occur at 1, 6 and 12 months postoperatively, then annually thereafter. (Level of Evidence: IV, Grade of Recommendation: D)

Follow up consultations on demand should also be available. (Level of Evidence: IV, Grade of Recommendation: C)

The purpose of post-operative follow-up care is to confirm adequate functioning of the therapy and to address potential complications/side effects. Different patterns of follow up visits have been described.[100]

It is recommended that the initial follow-up visits and subsequent follow-up visits should be spaced at least 1 month apart because full evaluation of setting changes may not be meaningful if the interval is less.[138] Based on the experience that a proportion of patients requires reprogramming in the early phase of follow-up, more than one follow-up visit in the first year is recommended.[100,139]

Subsequent yearly follow-up visits are advised by international expert groups,[100,125] but no consensus on the timing and interval of follow-up was determined on recent systematic review.[54] Follow up visits are uniformly recommended when problems occur.[54,100,125] A clinical evaluation of the efficacy of SNM (eg, bowel and bladder diaries, scoring of the severity of symptoms,

measurement of the impact of symptoms on QOL) and evaluation of the correct functioning of the neurostimulation device (eg, stimulation settings, impedances and side effects) are considered minimum requirements of follow-up.[100]

Radiological imaging of the tined lead is advised at final implantation, which allows for comparison and evaluation of lead migration in case of dysfunction or unexpected loss of efficacy. (Level of Evidence: 3, Grade of Recommendation: C)

Whether postoperative radiological imaging after temporary lead insertion may be helpful to confirm the position remains controversial.[54] Intraoperative fluoroscopic monitoring/documentation during the implantation phase and/or postoperative documentation of the implanted hardware is recommended to document positioning of the electrode in the sacral foramen. Post-implantation radiological imaging at routine follow up is not required, unless there is loss of efficacy potentially due to electrode dislodgement or breakage.[140]

SUCCESSFUL OUTCOME—BLADDER AND BOWEL

A patient who is satisfied with the treatment is considered to have a successful treatment outcome. (Level of Evidence: III, Grade of Recommendation: C)

For SNM, the most commonly used criterion for successful test stimulation is an improvement in the patient's bothersome symptoms of ≥ 50% during the period of observation monitored by bladder or bowel diaries.[54,100] Some data suggest that greater improvement during test stimulation may predict better long-term outcomes.[141,142,143] Regardless, the symptom improvement should be associated with concomitant patient satisfaction before pursuing full implantation.

For patients with voiding dysfunction or NLUTD, further evaluations may be necessary to ensure long-term safety of the urologic tract. (Level of Evidence: III, Grade of Recommendation: C)

Of note, in patients with voiding dysfunction in the setting of NLUTD, further evaluation may be necessary to ensure the long-term safety of the upper urinary tract. The clinical evaluation of patients' LUT symptoms often includes a bladder diary, uroflowmetry followed by measurement of post-void residual urine volume in spontaneous voiders, urinalysis, renal-bladder ultrasonography, assessment of renal function, quality-of-life measurements and sometimes urodynamic investigations and/or cystoscopy.[144] UDS, with or without fluoroscopy, can at times be essential in these patients as a means to assess detrusor and bladder outlet function and give fundamental information about detrusor pressure and thus the risk factor for upper tract damage.[145] Additional interventions, ranging from oral medication or intradetrusor BTX-A injections, to augmentation cystoplasty or even urinary diversion, may be required and are not contraindicated in the setting of SNM.

SNM INFECTION

Explantation of the IPG and lead and debridement of the infected tissue is recommended in instances of SNM infection. The wound should be irrigated and a course of oral antibiotics can be considered. (Level of Evidence: III, Grade of Recommendation: C)

Infection rate of SNM is low at 2-11% for urinary indications,[2] as well as for FI.[102] In one large investigational trial of SNM for FI, in which patients were followed for an average of 28 months

(range 2.2-69.5), 10.8% of subjects reported infection with SNM implant. One infection spontaneously resolved and five were successfully treated with antibiotics. Seven infections (5.8%) required surgical intervention, with infections in six patients requiring full permanent device explanation.[102]

A study of staged SNM implantation revealed lead infection in 12% and IPG infection in 11%. The only significant difference in clinical/surgical characteristics between infected and non-infected patients was a longer operative time for Stage 2 in infected patients.[146] A prolonged first stage implant trial with permanent quadripolar electrode has shown colonization in 13/34 electrode extension leads with the mean stage 1 SNM evaluation period of 52.3 (27–116) days but this was not associated with an increased risk of wound infection. The most frequent colonization was with Staphylococcus epidermidis, Staphylococcus capitis, Peptostreptococcus spp., Enterococcus faecalis and Micrococcus luteus.[101] In the urinary literature, one study demonstrated that Cefazolin alone was less effective in preventing infection compared with the other antibiotic regimens, with 88% of infections that required explantation stemming from Staphylococcus aureus species resistant to cephalosporins.[104]

There are no specific published reports regarding treatment of SNM device infections. Based on common general surgical principle, guidelines and expert opinion the infected device must be removed in its entirety, the wound irrigated/drained and oral/systemic antibiotic therapy started. The choice of the antibiotic should depend on local institutional guidelines. In very rare instances, removal of only one component of SNM implant may be contemplated with adequate antibiotic coverage. The choice to close the wound primarily or allow it to heal by secondary intention should be decided on a case by case basis. Other techniques to combat infection can be considered.[147]

A 3-month waiting period prior to reimplantation is advised and use of the contralateral side for the IPG pocket should be considered. (Level of Evidence: IV, Grade of Recommendation: D)

There is no reliable data regarding the waiting period for reimplantation after removal of the infected device. The recommendation of a 3-month waiting time is based on expert opinion.

TROUBLESHOOTING DEVICE MALFUNCTION – LOSS OF EFFICACY & PAINFUL STIMULATION

Patients with declining efficacy or painful stimulation should undergo device assessment. Turning off the device will differentiate painful stimulation vs. local pain at site of IPG. Changing program voltage or lead configuration may correct painful stimulation prior to attempting lead revision. (Level of evidence III, Grade of Recommendation C)

After permanent implantation, patients should be followed considering their primary reason for implant and clinical effect obtained at the time of their trial. Common complaints include discomfort at the site of the IPG, painful stimulation, recurrence of symptoms, absent stimulation, and stimulation in non-target areas.[5,148]

Such complications can be related either to the device, implantation technique, or parameters of stimulation. The most recent prospective, controlled data with 3 year follow-up is now available,[31] reporting a global device-related adverse event rate of 16%. Concerning the IPG, 47% of patients in the series reported adverse events, of which 91% were resolved at the time of analysis. These included an undesirable change in stimulation (49/272, 18%), implant site pain (34/272, 13%) and lack of efficacy

(16/272, 6%). Loss of efficacy may develop either due to failure of the therapy to achieve significant clinical improvement of symptoms (> 50%) or due to a depleted battery.

Little has been published regarding the troubleshooting of sacral neuromodulation systems since the description by the Cleveland Clinic in 2005. As such, the following algorithm is recommended:

(Figure 2 about here)

When a patient presents with a side-effect which may be related to stimulation, such as declining efficacy, painful stimulation, or aberrant neurological stimulation, the first action by the clinician should be to turn off the IPG. Should symptoms disappear, the IPG may be turned back on and reprogrammed, trying to avoid return of the presenting symptom. Pain related to stimulation should disappear when turning off the IPG and reprogramming, which may include decreasing voltage, decreasing frequency and/or changing the lead configuration. This can be done by the physician, or by a physician assistant or dedicated nurse if they are adequately trained in programming as well as clinical analysis of patient complaints. If pain persists after the IPG is turned off, the pain is may be due to the position of the IPG itself and IPG repositioning may be required, or it may be unrelated to the device. At minimum, other etiologies should be considered.

Device programming should be performed by experienced clinicians targeting comfortable low sensory thresholds to the perineum. (Level of Evidence IV, Grade of Recommendation C)

Follow-up of patients undergoing permanent SNM depends somewhat on the local health care system. As most of the adverse events require the clinician to analyze symptoms and then try to correlate those symptoms with any device malfunction, office evaluation (rather than a telemedicine visit) is usually required.

Patients given a complement of programs should try a new program for at least 1 week, unless it is not tolerable secondary to unpleasant stimulation or severe worsening of symptoms. (Level of Evidence IV, Grade of Recommendation C)

Since voiding and bowel disorders are not always constant over time, any new program should be tested for at least one week unless the patient experiences side effects from the new program. In a recent prospective trial[118] 22% of patients needed reprogramming due to an undesirable change in stimulation, decrease in therapeutic efficacy, or pain, within 5 years of implantation.

If reprogramming does not improve the patient's symptoms, radiographic imaging should be performed to assess for lead breakage or migration. (Level of Evidence IV, Grade of Recommendation C)

X-ray images can reveal lead fractures or migration of system components that subsequently necessitate replacement of the system. Moreover, impedances > 4000 ohms are also diagnostic of a lead fracture or microfracture (which may not be visible on imaging) and likely requires lead replacement, although evidence from a large retrospective series shows many abnormal impedances can be programmed around to salvage a lead.[98]

WHEN TO STOP SNM TESTING/THERAPY

SNM testing or therapy should be discontinued if the patient no longer wishes to proceed, or if in the judgment of the clinician, further testing/lead revision will not lead to symptom improvement. (Level of Evidence: III, Grade of Recommendation: C)

The only documented predictor for treatment success is the response to a trial of stimulation. Since implanted patients may experience declining efficacy over time,[39] therapy may need to be altered. As outlined elsewhere in this text, patients may elect to undergo device interrogation, re-programming, or surgical revision when symptoms are not well controlled with SNM. If at any time the patient does not desire to continue with SNM, or would prefer to transition to other 3rd line treatments, then therapy should be discontinued. Furthermore, once a patient has exhausted the possible revisions and alterations of therapy (lead location and side, programming options) and the clinician determines that no further benefit can be expected, then SNM should be discontinued.

DEPLETED IMPLANTABLE PULSE GENERATOR (IPG)

Exchange of IPG should occur when end of service is confirmed and the patient has maintained a successful response to SNM prior to battery depletion.

Check the impedance of the lead and, if indicated, replace the lead when exchanging the IPG. (Level of Evidence: III; Grade of Recommendation: C)

Patients with a depleted IPG battery (end of service) will usually present with loss of SNM stimulation and/or loss of efficacy of SNM. Occasionally, increased stimulation may be experienced. When patients present with a depleted IPG battery, confirm end of service by running a battery check with a physician programmer. Exchange the IPG when the end of service is confirmed and the patient has maintained a successful response to SNM prior to battery depletion. Check the impedance of the lead and, if indicated, replace the lead when exchanging the IPG.

NON-FUNCTIONING SYSTEM

When patients present with a non-functioning system, confirm impedances by checking all combinations with a physician programmer. If all of the combinations are non-functional, then the IPG should be turned off to conserve battery life and the lead replaced. The lead should also be replaced if there is a therapy-limiting number of programming options. (Level of Evidence: III; Grade of Recommendation: C)

Patients with a non-functioning lead will usually present with loss of SNM stimulation and/or loss of efficacy of SNM. When patients present with a non-functioning lead, confirm by an impedance check all combinations with a physician programmer. At least one functioning lead electrode is required for a lead to operate unipolar and two functioning leads for bipolar stimulation. If all of the combinations are non-functional, the IPG should be turned off and the lead replaced.

When assessing the lead with the physician programmer, run an impedance check at 2.0 volts to deliver sufficient energy for a complete check and assess all the seven possible circuit combinations. A non-functioning combination will return a reading above 4,000 ohms or 0 ohms. If all of the combinations are non-functional, the IPG should be turned off and the lead replaced (consider a trial of unipolar stimulation if only one electrode is functioning). If not all of the combinations are non-functional then, by a process of elimination, the non-functioning electrode(s) can be identified and not used in future programming. Many devices with non-functional electrodes can be salvaged and used to provide continued therapy after programming around the broken lead.[98]

Before replacing a non-functioning lead, the clinician should discuss the implications of lead removal, including the risk of retained fragments. Confirmation of the lead site should be sought, in the form of a sacral X-ray if the prior operative reports or intraoperative films are not available. It is

recommended that the lead be removed through the pre-sacral incision. When removing the lead through the pre-sacral incision, use gentle traction in a straight-line direction with respect to the lead tines. If too much resistance is encountered during lead removal, further dissection through lumbosacral fascia and pre-sacral periosteum may be required. The prevalence of lead breakage during lead removal is 1-3.6%.[103,149,150] Of note, some anecdotally report successful lead removal through the buttock incision using gentle traction on the lead. Nonetheless, leads left in for prolonged periods of time may be more challenging to remove this way and strong consideration should be given to midline removal.

RESIDUAL LEAD FRAGMENTS FOLLOWING LEAD REMOVAL

Patients with residual lead fragments should be advised of the presence, nature and safety of the residual fragments. Current evidence suggests it may be safe for residual lead fragments to remain long-term. (Level of Evidence: III, Grade of Recommendation: C)

Patients with residual lead fragments should be advised of the presence, nature and safety of the residual fragments. This should include providing patients with information regarding composition, size and location of residual lead fragments. Although not reported for SNM, migration, infection, and injury to surrounding structures from residual lead fragments are theoretical risks. Current evidence suggests it is generally safe, for residual lead fragments to remain *in situ* long-term, including in patients undergoing MRI.[85]

BILATERAL AND PUDENDAL LEADS

During PNE testing, bilateral temporary lead placement is recommended to reduce the risk of test failure due to lead migration. (Level of Evidence: III, Grade of Recommendation: C)

There is no published evidence that bilateral tined lead placement is more efficacious than unilateral placement. (Level of Evidence: 3, Grade of Recommendation: C)

For PNE test, a non-tined electrode is used. The currently available version is a thin wire without any anchoring system and is prone to migration. The risk of migration is related to the duration of the test and thus only a few days of reliable stimulation are possible. Placing bilateral PNE leads increases the possibility of a correctly placed lead, and increases the possibility of a successful test. Tined leads are more expensive than non-tined, and it may be difficult in some countries due to insurance to place bilateral tined leads for testing. In a retrospective study of55 patients with unilateral tined leads and 69 with bilateral tined leads, 76% of patients with bilateral leads went on to full implantation, versus only 58% of those trialed with a unilateral lead. It should be noted that in patients with bilateral leads, both leads were consecutively stimulated—not simultaneously.[151]

Theoretically, bilateral stimulation may be more efficacious than unilateral. This hypothesis is supported by animal experiments which demonstrate that with bilateral stimulation more nerve fibers can be stimulated enhancing the neuromodulatory effects.[152] However, in a prospective randomized trial on 25 patients, no beneficial effect was found with bilateral PNE lead stimulation compared to unilateral stimulation.[153] In patients with loss of efficacy, adding a contralateral PNE lead to achieve bilateral stimulation resulted in a significant decrease in the number of voids and pads per day. However, no benefit was found between bilateral or contralateral stimulation.[154] In FI, a study exploring the benefit of bilateral over unilateral sacral neuromodulation had to be

discontinued prematurely after an interim analysis of 20 patients demonstrated no additional benefit in symptom score, quality-of-life score, or findings on anorectal manometry.

Placement of pudendal leads can be considered as an alternative option if SNM fails after sacral lead positioning and programming has been optimized, especially if the IPG is already in place or if the patient is refractory to other minimally-invasive treatments. (Level of Evidence: III, Grade of Recommendation: Grade C)

The currently available system for SNM can be used off-label for pudendal stimulation. However no long-term data are yet available. A retrospective study in a mixed patient group including OAB wet/dry, NOR and painful bladder syndrome showed successful responses upon pudendal stimulation in 93% of patients failing SNM.[155] In two prospective studies, patients (OAB wet/dry; painful bladder) were implanted with leads at both S3 and close to the pudendal nerve. Of the patients responding successfully to the test, 78% subjectively favored the pudendal lead for chronic stimulation; however, it should be noted that the pudendal leads were placed with EMG guidance, while the sacral leads were not.[156,157]

MRI CONSENSUS STATEMENT

For current devices, manufacturer labeling should be followed for MRI imaging of the head or extremities. (Level of evidence: Grade IV, Grade D)

MRI imaging is used to diagnose and monitor an increasing number of conditions. There are three magnetic fields during MRI that can react with implanted neuromodulation devices including mechanical force and torque induced by a static magnetic field, induced voltages and current on leads by a pulsed gradient field, and current induced into the generator body by the radiofrequency magnetic field.[158,159,160]. These forces could potentially result in local tissue injury or damage to the implanted devices. Until the development of MR conditional neuromodulation systems, it is necessary to consider explantation of entire systems in order to perform MRI, exposing the patient to loss of therapy benefit, additional surgical risks, and costs.

According to the manufacturer's labeling (2012 manufacturer's instructions for use [IFU]), non-clinical testing has demonstrated that InterStim Therapy systems have been found to be MR Conditional. If a patient is implanted with an InterStim II Model 3058 Neurostimulator or an eligible serial number of an InterStim Model 3023 Neurostimulator (when implanted as a system including a neurostimulator, lead, and extension as applicable), MRI examinations of the head only may be safely performed under the following conditions:

- 1.5-Tesla (T) horizontal closed bore
- Maximum spatial gradient of 19 T/m (1900 gauss/cm)
- RF transmit/receive head coil only (no RF transmit body coil)
- Gradient slew rate limited to 200 T/m/s
- Normal operating mode (Scanning frequency of approximately 64 MHz only)
- If possible, do not sedate the patient
- Model 3058 and eligible Model 3023 Neurostimulators: Turn the neurostimulator off
- Eligible Model 3023 Neurostimulators only: Disable the magnet switch

According to the manufacturer, scanning under different conditions may result in severe patient injury or device malfunction, and is currently not recommended by FDA labelling. As a matter of course, implant surgeons and radiologists should recognize these guidelines.

There appears to be an increasing body of evidence that axial MRI imaging can be performed safely with present devices under certain circumstances. (Level of Evidence: II, Grade of Recommendation: B)

Two separate studies have shown that MRI studies of the extremities other than the head and body MRI scanning including the lumbar spine and pelvis can be performed safely with earlier and current InterStim devices. Elkelini[147] as well as Chermanski[161] reported the results from individual small series of patients studied without event using the interstim I device, using 1.5 and 0.6 Tesla machines. In one case, a generator (IPG) was found to be damaged after study due to leaving the magnet switch on, and both studies recommended setting the amplitude to zero and turning the magnet switch off.

In an ex vivo phantom model simulator study of the contemporary InterStim II device,[162] there was no significant heating, defined as in increase in temperature of >1°C, found using an intact system or with a 5cm distal lead fragment meant to simulate a retained lead fragment after partial extraction. Significant heating was found when a full-length lead, not connected to an IPG, was evaluated. Based on these findings, a prospective in vivo study was performed[163] wherein a pelvic or lumbosacral MRI was performed on a series of eleven patients with their devices in situ, and turned off (no magnet switches as part of these devices). No serious adverse events were reported during the MRI study and there were no changes in the devices after, though two patients did report a sensation of warmth at the IPG site during the scan, which resolved afterward. A caveat is that the patients were studied on the same MRI machine used to study the phantom model, and they were not willing to generalize to other machines and specific locations.

Alternative forms of imaging should be considered carefully before device removal for MRI imaging. (Level of Evidence: IV, Grade of Recommendation: D)

Although it appears that less restrictive use of MRI may be safe in certain clinical settings, it is recommended that implanting physicians and radiologists follow the manufacturer's guidelines at the present time. Thoughtful discussion and planning with radiologists may be helpful in obtaining MRI imaging of extremities that are geographically separate from the pelvis, using the principles outlined in the manufacturers' IFU for study of the head only. It remains prudent to consider imaging modalities that can serve as a substitute for MRI whenever appropriate; indeed, a study by Lloyd et al suggests that up to 24% of patients who undergo SNM device removal for MRI ultimately do not go on to receive an MRI study, and that only 56% of MRIs lead to a change in clinical management, emphasizing that it is of paramount importance to confirm the necessity of MRI before removing a functional SNM device.[164] Clearly, full body MRI conditional safety will be a highly valuable feature if and when it becomes available with future systems and devices.

FUTURE RESEARCH

Future research, including newer technologies, mechanisms for patient-response driven programming, and techniques for optimal lead placement, is needed.

This research will be aided by a better understanding of the mechanism of action of SNM

Attention should also be directed toward the development of better composite measures of therapy outcomes.

This consensus statement highlights the complex nature of neuromodulation therapy. Broadly, we have a low level of evidence for many of our recommendations. Patient selection is based on

symptoms, not biochemical or functional testing. Pelvic floor, urinary and bowel studies have not reliably predicted the best candidates for SNM, nor have patient symptoms.[165] One study has shown an association of treatment satisfaction with pudendal nerve terminal motor latency in FI[128] and and another suggests that strong toe responses at as many electrodes as possible intraoperatively may reduce the risk of future lead revision,[166] but only response to a trial of stimulation can currently predict response to treatment. This opens the door to newer technologies which incorporate the lead trial into long-term therapy, possibly with a one-step implant if costs can be contained. The current IPG (InterStim, Medtronic) is costly which is the reasoning behind a staged-implant approach. Other perceived weaknesses of this device, including lead fracture, battery life, clinician-dependent programming, and MRI compatibility, need to be addressed, as does the long-term effect of SNM on bladder and bowel physiology.

Surgical technique has not changed much since the introduction of the tined-electrode, which eliminated the need to suture directly to the periosteum. There remains debate regarding how precisely the lead must be positioned. Some studies suggest that only one active electrode is needed for a clinical response[114], though most advocate for 4-electrodes targeted at low voltages.[167] CT guidance has been used for those with complex anatomical findings,[168] while others have shown intra-operative EMG to be of help.[169] Nevertheless, further outcomes-based research is needed to clarify the best method for placing the lead. ***(Level of Evidence: III, Grade of Recommendation: C)***

Furthermore, there are no specific programming recommendations besides the 4-program settings and patient selection based on perceived symptom improvement. More novel approaches may incorporate a patient's "vote" for a program or a setting based on bowel/bladder diaries kept in real time. There are already available smart-phone applications for patients to track their symptoms which may be utilized in device programming.[170]

Economic modeling suggests that SNM becomes cost-effective relative to intradetrusor botulinum toxin injections for idiopathic OAB after about 5 years of treatment.[171] At 10 years, models suggest that SNM is also cost-effective relative to oral medical therapy for OAB.[172] There is little data on SNM cost-effectiveness relative to other treatments for urinary retention and fecal incontinence. Such studies would need to incorporate patient reported outcome measures to best characterize therapeutic benefit versus the cost of therapy.

TABLE: International Consultation on Urological Diseases (ICUD) modification of The Oxford Centre for Evidence-Based Medicine guidelines on the levels of evidence that generate the subsequent grades of recommendations

Level of Evidence	**Criteria**	**Grade of Recommendation**	**Criteria**
I	Meta-analysis of RCTs or high-quality RCT	A	Usually consistent with level I evidence
II	Low-quality RCT or good-quality prospective cohort study	B	Consistent level II or III evidence or "majority evidence" from RCTs
III	Good-quality retrospective case-control study or cohort	C	Level IV evidence or "majority evidence" from level II or III studies,

	study		Delphi processed expert opinion
IV	Expert opinion	D	No recommendation possible because of inadequate or conflicting evidence

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