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WILEY Neurourology Urodynamics ICS SUFU

International continence society best practice statement for use of sacral neuromodulation

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SACRAL NEUROMODULATION CONSENSUS STATEMENT

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).

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

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.

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

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)
- 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)

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)

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

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

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)
- An anal sphincter muscle defect is not a contraindication for SNM. (Level of Evidence: 3, Grade of Recommendation: C)
- 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)
- SNM is the preferred therapy in an appropriate patient with combined urinary and bowel symptoms. (Level of Evidence: III, Grade of Recommendation: C)

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)

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)

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)

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).

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)

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)

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)
- 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)
  - 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.
  - 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)

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.
- 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)
- 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.

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.

PREVENTION OF SURGICAL SITE INFECTION (SSI)

- A perioperative antibiotic aimed at coverage of skin flora should be given intravenously within 60 min 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)

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.

IMPLANT TECHNIQUE

- The clinician should strive to achieve appropriate motor and/or sensory responses on all four contacts at stimulus amplitudes of ≤2 volts. (Level of Evidence: II, Grade of Recommendation: B)
  - Leads that require higher thresholds or offer responses at fewer than four contacts can be successful. (Level of Evidence: II, Grade of Recommendation: B)
- 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)
- The clinician should consider both sensory and motor responses important for success. (Level of Evidence: IV, Grade of Recommendation: C)
  - Motor responses alone may be utilized in patients who undergo GA. (Level of Evidence: IV, Grade of Recommendation: C)
  - 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)*

- 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)

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)
  - 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)

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)

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)

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)3
  - Follow up consultations on demand should also be available. (Level of Evidence: IV, Grade of Recommendation: C)
- 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)

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 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)

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)
- 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)

TROUBLESHOOTING DEVICE MALFUNCTION – LOSS OF EFFICACY & PAINFUL STIMULATION

- Patients with declining efficacy or painful stimulation should undergo device interrogation. 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)
- Device programming should be performed by experienced clinicians targeting comfortable low sensory thresholds to the perineum. (Level of Evidence IV, Grade of Recommendation C)
- Patients given a complement of programs should try a new program for at least one week, unless it is not tolerable secondary to unpleasant stimulation or severe worsening of symptoms. (Level of Evidence IV, Grade of Recommendation C)
- 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)

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)

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)

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)

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)

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)
- 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)

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)
- 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)

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

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.

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