Improving Quality of Life with Neuromodulation:

A Novel Treatment for Incontinence

Abstract

Sacral neuromodulation (SNM) is Health Canada authorized for the management of chronic intractable (functional) disorders of the pelvis and lower urinary or intestinal tract. A minimally invasive procedure, it has excellent symptom reduction and quality of life improvement in carefully selected patients and its effects are shown to be of extended duration in long-term follow up.

Key words: sacral neuromodulation, overactive bladder, urge incontinence, fecal incontinence

Introduction

Sacral neuromodulation (SNM) is peripheral nerve stimulation used for the treatment of overactive bladder (OAB), which consists of urinary urgency with or without urge incontinence and urinary frequency. It is also used in the treatment of non-obstructive urinary retention.

SNM is recommended by both the American Urological Association (AUA) and the Canadian Urological Association (CUA) as third-line therapy for the treatment of OAB. First- and second-line therapies include conservative management and pharmacological therapies with anti-cholinergic or beta 3 agonist medications.[1,2]

Fecal incontinence (FI) is a debilitating, socially isolating condition that can have a number of etiologies, including vaginal childbirth, anal or colon surgery, spinal cord injury, or inflammatory bowel

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disease.[3] The use of SNM for fecal incontinence in those patients with failed trials of conservative management is evidence based.[4]

Sacral neuromodulation works by modulating the afferent signals in the sacral nerves that regulate and signal storage and emptying reflexes.[5]

Sacral Neuromodulation

Trial of therapy

The first step after a patient has been identified as a candidate for sacral neuromodulation is peripheral nerve evaluation (PNE). The goal of PNE is to identify the subset of patients who will respond to treatment and should therefore be considered for the operation; non-responders should not move on to implantation of a SNM device. PNE involves the insertion of a single electrode into either 3rd sacral foramen under local anesthetic. A sensation in the pelvic floor is used to identify the ideal position. Following the procedure, urinary patients go home with an external pulse generator attached for 4-7 days, recording their symptoms in a voiding diary. A 50% improvement in symptoms is needed to qualify for permanent implantation of the 4-electrode lead and implantable pulse generator in the operating room.

Key Point

Sacral neuromodulation (SNM) is peripheral nerve stimulation used for the treatment of overactive bladder (OAB) and fecal incontinence.

Implantation

Another method of identifying responsive patients is implantation of the 4-electrode lead (tined lead) in the operating room and then either the removal or the implantation of the implantable pulse generator (IPG) in a second operation two weeks later if the results are successful. This is called an Advanced or Staged Trial. When comparing PNE to initial tined lead implantation, PNE has a sensitivity of 98.5% and a specificity of 87.3% and, given the reduced cost, is recommended as initial screening for patients.[6]

Patients with fecal incontinence are considered for SNM if they suffer from bowel urgency, fecal incontinence, or regular staining. Response to PNE is considered adequate to proceed with implantation if there is a 50% objective improvement of any symptoms over a 7-day period.

Patients who don't respond to PNE are eligible to undergo staged implantation, initially with the 4-electrode lead to again evaluate response. Again, if a 50% improvement is noted, completion of the operation with the implantable pulse generator is performed, otherwise the lead is removed and the patient will need to consider other therapies.

Symptom Improvement

Urinary

Given the large number of implantations and history of the device, improvements in urinary symptoms are established and of long duration in those who respond.

In a large study of 340 patients where 272 received SNM device implantations, the urinary incontinence (UI) patients had 3.1 ±2.7 leaks per day and the urinary frequency (UF) patients had a mean 12.6 ±4.5 voids per day. Post implantation at the 12-month follow up, the UI patients

had a mean decrease of 2.2 ±2.7 leaks per day, and the UF patients a mean decrease of 5.1 ±4.1 voids per day both (P < 0.0001). This cohort was 91% female with an average age of 57.[7]

These improvements are of long duration, with same cohort at 36 months retaining a mean improvement of 2.3 ±2.3 leaks per day in the UI group and a mean improvement of 5.3 ±4.0 voids per day in the UF group (both P < .0001).[8]

Standard medical therapy (SMT) is a commonly used and proven method of improving OAB symptoms but may not be as effective as SNM. A randomized study with 147 patients demonstrated that SNM (61%) was significantly better than SMT (42%) for therapeutic success (P =0.02).[9]

Fecal

SNM use in patients with fecal incontinence is more recent, but several large studies have demonstrated significant improvement in symptoms.

A study of 100 patients (89% women with a mean age of 55 years) received SNM implantation. The average number of incontinence episodes in a 3-week period at baseline was 31.3 (3.0–142.0) and improved to 4.4 (0.0–31.0) during PNE (P < 0.0001). This result persisted at 36 months with 4.5 (0.0–20.0) episodes (P < 0.0001). Of the 100 patients, 21 were considered late failures after implantation.[10]

A continuation of this study with a larger number of patients (n=325), all with implanted sacral neuromodulators, showed fecal incontinence episodes at a baseline with an average of 16.1 ± 14.5. This improved to 3.0 ± 3.7 per 3 week interval at a mean follow up time of 7 years (P < .001). About half (52.7%) of patients initially evaluated with PNE experienced long-term results, the remainder accounting for those that failed initial PNE or experienced late treatment failure.[11]

Quality of Life

Urinary

Urinary symptoms, whether it be urge, frequency, or incontinence, can be particularly distressing for patients and impair quality of life. In addition to assessing treatment based on an objective improvement in symptoms, it is also important to understand the impact on quality of life, typically assessed through questionnaires.

Via the validated international consultation on incontinence modular questionnaire (ICIQ-OABqol) for OAB quality of life, patients are assessed on medical quality of life,

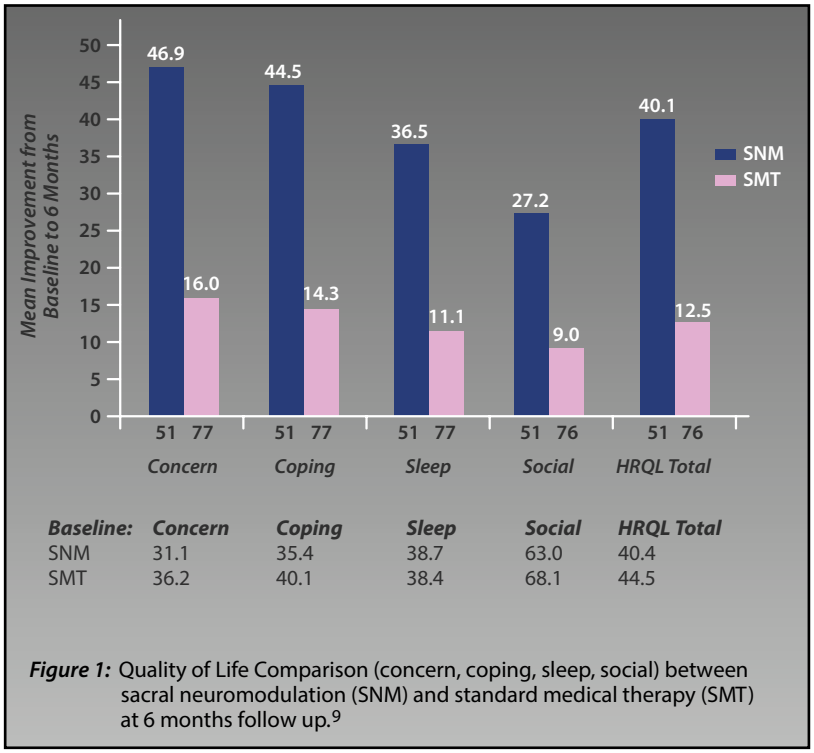


Figure 1: Quality of Life Comparison (concern, coping, sleep, social) between sacral neuromodulation (SNM) and standard medical therapy (SMT) at 6 months follow up.[9]

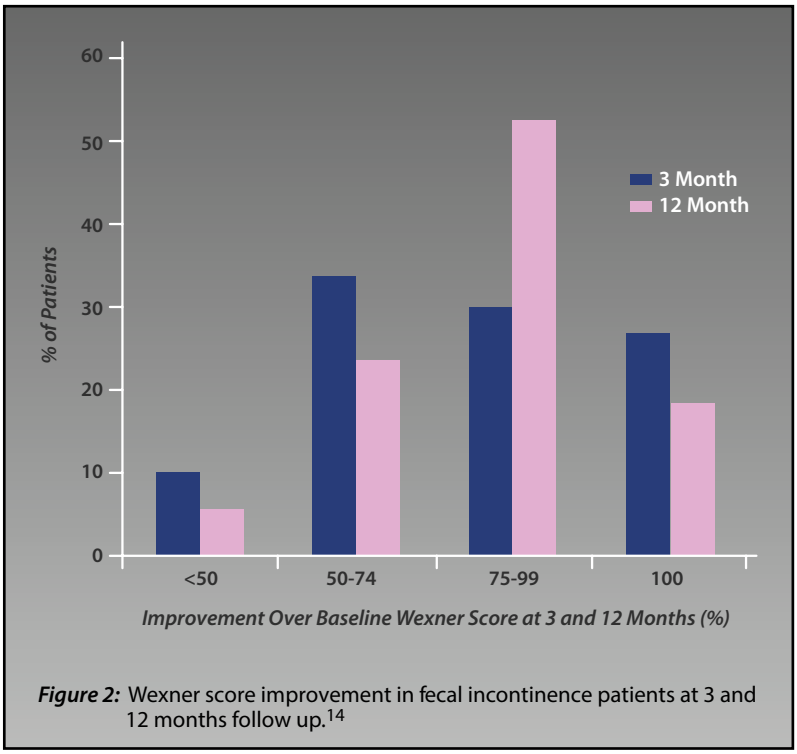


Figure 2: Wexner score improvement in fecal incontinence patients at 3 and 12 months follow up.[14]

their overall concern, coping, sleep, and social domains.

In the same long-term study mentioned previously, the 272 patients exhibited statistically significant improvements in all aspects of the ICIQ-OABqol at both 12 months and 36 months post-implantation.[7,8]

Figure 1 compares SNM to standard medical therapy and demonstrated that in 147 randomized patients there was significantly greater improvement in ICIQ-OABqol at 6 months ($P < 0.001$).

Sexual function is often impaired in patients with OAB both because of the urinary symptoms and an underlying neurological condition in some patients.[12] A small study of women with OAB demonstrated a correlation between improvement in LUTS and improvement in sexual function according to the Female Sexual Function Index (FSFI) survey.[13]

Key Point

SNM is recommended by both the American Urological Association (AUA) and the Canadian Urological Association (CUA) as third-line therapy for the treatment of OAB.

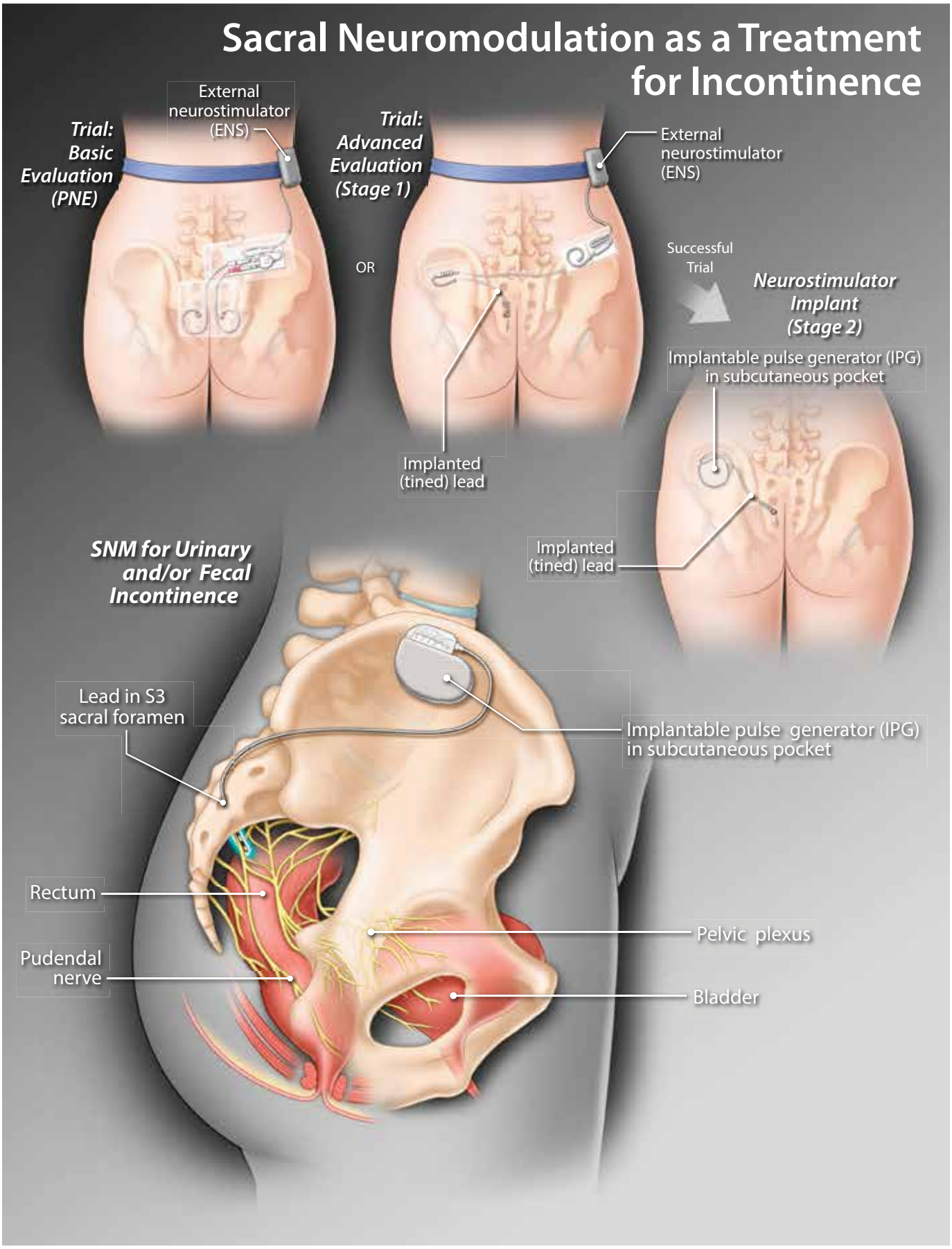
Fecal

Fecal incontinence, like urinary incontinence, can be an equally socially debilitating condition and improved patient quality of life may be considered the true marker of a successful procedure. Despite becoming an indication for SNM more recently than urinary symptoms, its improvement in quality of life has been well demonstrated. The Wexner score incorporates consistency of incontinence (solid, liquid, gas), pad use, and the impact of fecal incontinence on quality of life. A higher score is worse, with possible scores ranging from 0 to 20. A large study of 145 patients who had SNM implantation for fecal incontinence demonstrated that 94.4% of patients had at least a 50% reduction in Wexner score at 12 months and 18% of patients had 100% reduction of Wexner score. (See figure 2). The authors also showed that sphincter defect did not compromise the efficacy of SNM, suggesting that even patients with previous surgeries or anatomical contributions for their incontinence should be considered for SNM.[14]

Complications

The implantation procedure for both bowel and bladder symptoms is the same, therefore it is expected that the possible complications will be very similar, if not identical.

Complications can be broken down into surgical complications and those related to treatment failure. Surgical complications can include: infection, lead migration, and discomfort related to the location of the implanted pulse generator. Different


Sacral Neuromodulation as a Treatment for Incontinence
Trial: Basic Evaluation (PNE)
External neurostimulator (ENS)
Trial: Advanced Evaluation (Stage 1)
OR
External neurostimulator (ENS)
Implanted (tined) lead
Successful Trial
Neurostimulator Implant (Stage 2)
Implantable pulse generator (IPG) in subcutaneous pocket
Implanted (tined) lead
SNM for Urinary and/or Fecal Incontinence
Lead in S3 sacral foramen
Implantable pulse generator (IPG) in subcutaneous pocket
Rectum
Pudendal nerve
Pelvic plexus
Bladder

Key Points

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SNM is recommended by both the American Urological Association (AUA) and the Canadian Urological Association (CUA) as third-line therapy for the treatment of OAB.

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modes of treatment failure include: partial loss of response and complete loss of response.

Troubleshooting can take several forms and is on a spectrum between program adjustment which can be done wirelessly, and revision or explantation of the device, both of which require a return trip to the operating room. A recent study of 161 patients who underwent second-stage implantation experienced an explantation rate of 10.5% and a revision rate of 16.1% at an average follow up time of 16 months.[15] Battery replacement, usually done around 5 years post implantation depending upon use, also requires a trip to the operating room.

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Summary

Fecal incontinence and overactive bladder are both debilitating medical conditions that can impair quality of life and limit day-to-day activities. Sacral neuromodulation is authorized by Health Canada as treatment for both bladder and bowel conditions. Patient selection is important, primarily in instances of peripheral nerve evaluation, to provide patients with trial therapy and to confirm responders. This minimally invasive out-patient surgery has consistently been demonstrated to improve symptoms and quality of life in these challenging and refractory conditions.

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Clinical Pearls

Fecal incontinence and overactive bladder are both debilitating medical conditions that can impair quality of life and limit day-to-day activities.

Sacral neuromodulation is authorized by Health Canada as treatment for both bladder and bowel conditions.

SNM is a minimally invasive out-patient surgery that has consistently been demonstrated to improve symptoms and quality of life in patients with OAB or fecal incontinence.

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Key Point

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