
Outcomes of sacral neuromodulation in male patients with overactive bladder, chronic pelvic pain, and fecal incontinence

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Introduction: Despite the growing body of literature on sacral neuromodulation (SNM) outcomes, research focusing on male patients remains limited and often represented by small cohorts nested within a larger study of mostly women. Herein, we evaluated the outcomes of SNM in a male-only cohort with overactive bladder (OAB), fecal incontinence (FI), chronic bladder pain, and neurogenic lower urinary tract dysfunction (NLUTD).

Materials and methods: This retrospective cohort study included 64 male patients who underwent SNM insertion between 2013 and 2021 at a high-volume tertiary center. Indications for SNM therapy included OAB, FI, chronic pelvic pain, and NLUTD. Descriptive statistics, Fisher's and t-test were used in analysis.

Results: The mean age was 57.7 ± 13.4 years, and the most frequent reason for SNM insertion was idiopathic OAB (72%), FI (16%), pelvic pain (11%), and NLUTD (11%). A majority (84%) of men received treatment prior to SNM insertion. 84% reported satisfaction and 92% symptom improvement within the first year, and these improvements persisted beyond 1 year in 73% of patients. Mean follow up was 52.7 ± 21.0 months. The complication rate was 23%, and the need for adjunct treatments was significantly reduced (73% to 27%, $p < 0.001$). Treatment outcomes did not differ significantly between various indications for SNM therapy or the presence of benign prostatic hyperplasia (BPH).

Conclusion: SNM is an effective and safe procedure for male patients with neurogenic and non-neurogenic OAB, pelvic pain, and FI. Over 70% of patients experienced symptomatic improvement and remained satisfied in the mid to long term follow up. BPH does not seem to hinder treatment outcomes.

Key Words: men, overactive bladder, pelvic pain, sacral neuromodulation

Introduction

Overactive bladder (OAB), fecal incontinence (FI), neurogenic lower urinary tract dysfunction (NLUTD),

and chronic pelvic pain represent prevalent urological conditions that significantly affect the quality of life of millions of individuals worldwide.¹⁻³ Sacral neuromodulation (SNM) is a well-established, minimally invasive, and largely reversible surgery for OAB and FI and has shown promising results in patients with NLUTD.⁴⁻⁷ Although SNM is not FDA-approved for chronic bladder pain and neurogenic bladder, it may be offered to selected patients, especially those with overlapping OAB symptoms.

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Despite the growing body of literature on SNM outcomes, research focusing on male patients remains limited and often represented by small cohorts nested within a larger study of predominantly female patients.

There is a common misconception that OAB predominantly affects women. However, the prevalence is comparable between genders (16% men vs. 16.9% women), with women having a similar prevalence between dry and wet OAB (9.3% vs. 7.6%), while men have a higher prevalence of dry OAB (13.4% vs. 2.6%).⁸ Similar prevalence between men and women is also observed in FI (7.7% and 8.9%, respectively).⁹ Despite the comparable overall burden of these diseases between sexes, females are more likely to undergo SNM implantation and experience higher success rates.^{10,11} A study evaluating 2,322,060 Medicare patients who could potentially be treated with SNM identified that female, white, and younger than 65 years patients were more likely to be treated with SNM.¹⁰ There is an unmet need to assess the outcomes of SNM in men, especially considering their distinct anatomy and the potential influence of factors such as benign prostatic hyperplasia (BPH) and its long term effect on the bladder.¹¹

Therefore, this study aims to evaluate the safety and effectiveness of SNM outcomes in a male cohort with bladder (OAB, neurogenic) and non-bladder complaints (pelvic pain and FI). By focusing on patient satisfaction, improvement, and safety, our findings will contribute to a better understanding of the long term benefits of SNM for this patient population

Materials and methods

Study design

This is a review of a prospectively collected cohort evaluating male patients who underwent SNM insertion by a single high-volume urologist at an academic tertiary hospital (Toronto, ON, Canada) between 2013 and 2021.

Ethics statement

The institutional research ethics board approved data collection as a medical quality review, and the requirement to obtain patient consent was waived.

Patient population

The population of interest included patients diagnosed with OAB (with or without urge incontinence), neurogenic bladder dysfunction (spinal cord trauma or multiple sclerosis), FI, pelvic pain, and chronic pelvic pain with urinary or bowel symptoms. Patients' symptoms persisted for at least 6 months and failed

conservative treatments prior to SNM therapy. We excluded patients with follow ups shorter than 12 months or incomplete medical records. Patients were followed at 1-, 3-, 6- and 12-months post-implantation and yearly after that.

Data collection

The collected data included patient demographics (age and sex), the primary reason for SNM indication, treatment before SNM, requirement of additional first-stage SNM testing post percutaneous nerve evaluation (PNE), procedural complications, and clinical outcomes (patient satisfaction, symptom improvement, postoperative complications, and adjunct therapies).

A successful lead placement was defined as the presence of bellows or toe dorsiflexion in at least 3 electrodes on stimulation using < 2mA current. Patient satisfaction and treatment success were measured by patient-reported bladder and/or bowel diaries and review of medical charts. Symptom improvement was defined as continuous improvement > 50% of baseline symptoms in one or more bothersome parameters such as urinary frequency, incontinence episodes, bowel seepage, and bowel warning during follow up. Treatment failure was defined as the presence of complications, lack of symptom improvement, or patient satisfaction. Complications of interest were infection, pain (battery or lead), lead migration, revision, battery replacement, and explantation. All patients received a 5 to 7-day antibiotics course after lead implantation.

Statistical analysis

Descriptive statistics were used to summarize demographic and clinical characteristics. Patients were categorized into cohorts given SNM indication (OAB non-neurogenic and neurogenic, FI, and pelvic pain) to compare outcomes in efficacy, satisfaction, and complication profile. Categorical outcomes were assessed using Chi-square or Fisher's given expected cell frequency and McNemar's test for matched pairs. T-test or Wilcoxon rank-sum analyzed association of continuous outcomes given normality distribution. Two-sided $p < 0.05$ was considered statistically significant. Statistics analyses were performed using Stata version 17BE (StataCorp, TX, USA).

Results

Baseline characteristics

A total of 64 men underwent SNM insertion between 2013 and 2021. They had a mean age of 57.7 ± 13.4

TABLE 1. Patients characteristics prior SNM therapy

Characteristics	(n = 64)	
Age mean ± SD (range), years	57.7 ± 13.4 (32-84)	
Diabetes	5	(8%)
Previous treatments	55	(86%)
Physiotherapy	9	(14%)
Anticholinergics only	7	(11%)
Beta-3 agonist only	2	(3%)
Anticholinergics and Beta-3 agonists	38	(62%)
Botox	19	(30%)
BPH oral medications	20	(31%)
BPH surgery	10	(16%)
PNE	64	(100%)
Staged SNM evaluation	10	(16%)

BPH = benign prostatic hyperplasia; PNE = in-office percutaneous nerve evaluation; SNM = sacral neuromodulation
 Values are presented in absolute number and percentage or mean standard ± deviation. Preoperative characteristics of the 64 patients who underwent sacral neuromodulation treatment.

(32-84) years. The primary indication for SNM therapy was OAB (72%, 40/64), followed by FI (16%, 10/64), pelvic pain (11%, 7/64), and neurogenic bladder (11%, 7/64). In addition, 27 (42%) patients had BPH, managed with oral medication or surgery. Prior to SNM insertion, 86% of patients had a suboptimal response to behavioral or pharmacotherapy, Table 1. All patients underwent an in-office PNE trial before the SNM impulse generator device and lead implantation, with only 10 (16%) requiring a subsequent staged SNM trial post-PNE. The need for a staged SNM trial was not associated with patient age ($p = 0.830$), treatment indication ($p = 0.814$), diabetes ($p = 0.585$), previous BPH surgery ($p = 0.340$), or concomitant BPH pharmacological treatment ($p = 0.755$). Patient follow up ranged from 1 to 8 years with a mean follow up of 52.7 ± 21.0 months.

Procedural outcomes and complications

Overall, 54 (84%) patients reported satisfaction, and 59 (92%) experienced symptom improvement within the first year after SNM insertion. Beyond 1 year, 47 (73%) patients remained satisfied and improved with SNM. There was no difference in patient satisfaction rate between single or staged SNM insertion ($p = 0.649$). Satisfaction ($p = 0.508$) and improvement rates ($p = 0.779$) during the first year or afterward ($p = 0.440$) did not differ between reasons for SNM indication. Additionally, having BPH did not affect the rate of

satisfaction ($p = 0.300$) or improvement ($p = 1.00$) during the first year or afterward ($p = 0.156$).

Regarding safety outcomes, no intraoperative complications were observed. In total, 15 (23%) patients experienced one or more complications: 8 developed battery and/or lead pain, 5 had technical problems with IPG calibration, 2 had infections, and one experienced lead migration.

Overall, 39 (61%) patients did not require adjunct treatment after SNM insertion. Adjunct treatment rate was 27% (17/64) for beta-3 agonists and/or anticholinergics and 9% (5/64) for Botox application. However, there was a highly significant reduction in OAB oral medication utilization after SNM (73% to 27%, $p < 0.001$).

Subgroup analysis

Overactive bladder

Fifty-three patients in this cohort had a diagnosis of OAB. Twenty cases of wet OAB, 26 dry OAB, and 7 with neurogenic bladder. Preoperative treatment management, subgroup characteristics, and outcomes can be found in Table 2. Within the first year of treatment, 91% patients were satisfied, and 94% reported improvement. Over a year, 81% of patients were satisfied and experienced mid to long term improvement. Finally, there was no difference in treatment outcomes rates between OAB types and neurogenic bladder for

TABLE 2. Characteristics and outcomes of patients with OAB

	Wet OAB (n = 20)		Dry OAB (n = 26)		Neurogenic (n = 7)	
Age mean ± SD (range), years	61.8 ± 13.2 (32-84)		59.5 ± 16.0 (34-82)		47.0 ± 10.5 (33-63)	
Treatment prior						
Anticholinergics and/or beta-3 agonists	17	(85%)	19	(73%)	6	(86%)
Botox	2	(10%)	9	(35%)	3	(43%)
Physiotherapy	4	(20%)	3	(12%)	0	(0%)
BPH treatment	12	(60%)	11	(42%)	2	(29%)
PNE	20	(100%)	26	(100%)	7	(100%)
Staged test	4	(20%)	0	(0%)	2	(29%)
Satisfaction in the 1 st year	17	(85%)	24	(92%)	7	(100%)
Improvement in the 1 st year	18	(90%)	25	(96%)	7	(100%)
Satisfaction and improvement > 1 year	16	(80%)	21	(81%)	6	(86%)
Adjunct therapy						
No treatment needed	4	(20%)	11	(42%)	2	(29%)
Anticholinergics and/or beta-3 agonists	2	(10%)	3	(12%)	0	(0%)
Botox	0	(0%)	2	(8%)	0	(0%)
Physiotherapy	2	(10%)	0	(0%)	0	(0%)
BPH treatment	2	(10%)	0	(0%)	0	(0%)

OAB = overactive bladder; BPH = benign prostatic hyperplasia; PNE = in-office percutaneous nerve evaluation; SNM = aacral neuromodulation

Values are presented in absolute number and percentage or mean standard ± deviation. Analysis of characteristics and outcomes of 53 patients diagnosed with overactive bladder.

TABLE 3. Complications after SNM insertion in each sub-group

Complications, n (%)	Wet OAB (n = 20)		Dry OAB (n = 26)		Neurogenic (n = 7)	
Battery pain	4	(20%)	1	(4%)	0	0%
Lead pain	3	(15%)	1	(4%)	0	0%
Infection	0	(0%)	2	(8%)	0	0%
Migration	0	(0%)	0	(0%)	0	0%
Failure	2	(10%)	2	(8%)	0	0%
Battery change	0	(0%)	0	(0%)	0	0%
Revision	0	(0%)	1	(4%)	0	0%
Explantation	2	(12%)	3	(12%)	0	0%
Overall	5	(25%)	7	(27%)	0	0%

OAB = overactive bladder; SNM = sacral neuromodulation

Values are presented in absolute number and percentage. Analysis of complication rates between subgroup of 53 patients diagnosed with overactive bladder.

TABLE 4. Study characteristics descriptions and satisfaction of FI and pelvic pain sub-group with an SNM insertion

	FI (n = 10)		Pelvic pain (n = 7)	
Age mean \pm SD (range), years	55.7	10.2 (40-77)	59.0	6.2 (50-69)
Treatment prior	6	(60%)	5	(71%)
PNE test	10	(100%)	7	(100%)
Staged test	0	(0%)	1	(14%)
Satisfaction in the 1st year	8	(80%)	5	(71%)
Improvement in the 1st year	9	(90%)	5	(71%)
Satisfaction and improvement > 1 year	8	(80%)	2	(29%)
Adjunct treatment post SNM				
No	9	(90%)	2	(29%)
Yes	1	(10%)	5	(71%)

FI = fecal incontinence; PNE = in-office percutaneous nerve evaluation; SNM = sacral neuromodulation

Values are presented in absolute number and percentage or mean standard deviation. Analysis of characteristics and outcomes of subgroup of 17 patients diagnosed with fecal incontinence and pelvic pain.

satisfaction ($p = 0.627$) or improvement ($p = 0.791$) during the first year. The sample size was insufficient to detect differences between these subgroups for improvement after 1 year or the effect of BPH on outcome rates. Twenty-two percent of patients reported complications. Table 3 summarizes complication rates by SNM indication. Postoperatively, 35% of patients needed adjunct treatment after SNM insertion.

Fecal incontinence

Ten men were included in the FI sub-group. All patients underwent PNE, and none required a stage insertion,

Table 4. Sixty percent of this cohort failed previous treatment before SNM insertion. The satisfaction rate was 80% in the first year and, beyond a year, 80% of patients were satisfied and improved. Complications included: pain with the device (20%) and failure (9%), Table 5. One patient required adjunct treatments.

Pelvic pain

In the pelvic pain sub-group all 7 patients underwent PNE, and 14% required stage insertion, Table 4. Seventy-one percent of this cohort tried at least one treatment before SNM insertion. Within the first year

TABLE 5. Complications after SNM insertion in FI and pelvic pain sub-group

Complications, n (%)	FI (n = 10)		Pelvic pain (n = 7)	
Battery pain	2	(20%)	1	(10%)
Lead pain	0	(0%)	0	(0%)
Infection	0	(0%)	0	(0%)
Migration	0	(0%)	0	(0%)
Failure	1	(10%)	1	(20%)
Battery change	0	(0%)	0	(0%)
Revision	0	(0%)	0	(0%)
Explantation	0	(0%)	0	(0%)
Total patients with complications	2	(20%)	2	(29%)

FI = fecal incontinence; SNM = sacral neuromodulation

Values are presented in absolute number and percentage. Analysis of complication rates of subgroup of 17 patients diagnosed with fecal incontinence and pelvic pain.

of SNM insertion, 71% patients were satisfied and experienced pain improvement. However, only 29% of men remained satisfied and improved beyond a year. Complications included pain with the device (10%) and failure (20%), Table 5. Seventy-one percent of patients required adjunct treatments to manage symptom control.

Discussion

The present study investigated the effectiveness and safety of SNM in a male cohort with OAB, FI, chronic bladder pain, and neurogenic bladder. The primary findings indicated that most of the patients experienced (84%) satisfaction and symptom improvement (92%) within the first year following SNM insertion, and these improvements (73%) persisted beyond 1 year in a mid to long term perspective. The complication rates were relatively low at a rate of 23%, and the need for adjunct treatments was significantly reduced (73% to 23%, $p < 0.001$). Moreover, there was no significant difference in treatment outcome rates between the various indications for SNM therapy or presence of BPH.

Our results are consistent with other studies from the literature. A study evaluating non-neurogenic OAB treated with SNM had success rates ranging between 61% to 90% and a significant improvement in urgency and frequency but analysis by sex was not available.¹² A multicentric, double-blinded, placebo-controlled trial found SNM improved symptoms in 76% of patients with NLUTD after 2 months of therapy, which was sustained despite the neurostimulator being switched off for 2 months.⁵ After SNM insertion, 27% required OAB medication, 9% Botox injection, 4% pelvic physiotherapy, and 4% BPH treatments. With the additional therapies, improved symptom control was seen. The need for further treatment was also described in one study that evaluated the combination of intermittent percutaneous needle sacral nerve stimulation in women with idiopathic overactive bladder treated with tolterodine and showed significant symptom control.¹³

Moreover, FI management remains challenging, and the available treatments have varying clinical significance. SNM has been used as a treatment for FI regardless of the etiology. Little published literature exists on gender-related success rates; studies have predominantly described female patients. Our results for male patients with FI showed a higher success rate than a comparable single-center study performed in the Netherlands, where the improvement was sustained in 48 patients out of 77 (62%) patients after 1 year of follow up.¹⁴ Results were also corroborated by a

meta-analysis of 13 studies that showed FI improved in 83.3% of patients after SNM.¹⁵ Regarding adjustment and additional treatments, we found that 90% of our study group did not require any adjustments, re-operation, and no removal performed in any of the FI subgroup, compared to a 29% rate in the literature.⁷

Pelvic pain or bladder pain syndrome is debilitating, with complex pathology and equally challenging treatment approach.¹⁶ Managing pelvic pain commonly involves various treatment modalities and may escalate to major interventions at an earlier timeline. Although it is not common to affect male patients, we found that 11% of our cohort had pelvic pain, in which only 29% were satisfied and improved pain control beyond a year of SNM therapy. The unsatisfied cohort required hydrodistension, Botox or transurethral resection of the prostate to aid with pelvic pain. A meta-analysis with 583 patients with pelvic pain and 89% women found pooled SNM success rates of 84% (95% CI, 76% to 91%) on up to 86 months follow up.¹⁷ Our lower satisfaction rate when compared to the literature can be explained by the multifactorial pathogenesis of pelvic pain in our population. Our subgroup analysis lacked sufficient power to identify whether BPH affected satisfaction rate in this group.

Our study demonstrated a low complication rate with SNM in men with no infection rate. Two patients developed infection on the battery site secondary to other surgical procedures. The main complication was device pain. Published literature showed that the infection rate was higher in the male subgroup who had undergone SNM for FI.¹⁸ Regarding revision rate, it was seen only in 2% of our OAB sub-group compared to the 30% revision rate in published literature.¹⁹

The present study provides a comprehensive analysis of SNM outcomes for multiple urological conditions, with almost half of the patients having BPH. However, there are some limitations to the present study. First, satisfaction and improvement were self-reported and did not use a structured and validated questionnaire. Second, conducting the study in a high-volume single center might limit the generalizability of our findings. Third, the relatively small sample size, particularly for subgroups such as fecal incontinence, neurogenic bladder, and pelvic pain, may have reduced the robustness of the results, as some assessments might have been underpowered. Despite these limitations, this study highlights the potential for SNM therapy in improving outcomes in patients with different urological conditions, emphasizing the importance of patient-centered outcomes (satisfaction) when evaluating treatment effectiveness (improvement).

Our study has several strengths - it addresses a significant gap in the literature by specifically focusing on a male cohort, which has been underrepresented in previous research. This highlights the importance of considering gender-specific factors when evaluating the effectiveness of SNM therapy, as these factors may have implications for patient selection, therapy indication, and treatment outcomes. Additionally, the comprehensive data collection over a long follow up period provides valuable insights into the mid to long term outcomes of SNM in men. The use of a high-volume tertiary center ensures a level of expertise and consistency in the surgical technique and postoperative management, which adds credibility to our findings.

To further build on our findings and address the study's limitations, we propose future prospective cohort studies with larger sample sizes and multi-center participation to validate the outcomes of SNM in men. Employing stratified random sampling and incorporating standardized and validated questionnaires for outcome assessment will enhance the reliability and generalizability of the results. Extended longitudinal follow up periods will provide a more comprehensive understanding of the long term efficacy and safety of SNM. Collaborative multi-center studies will further improve the generalizability of our findings to diverse patient populations and clinical settings. By addressing these limitations and incorporating these future directions, we aim to enhance the quality and impact of research on SNM in male patients.

Conclusion

SNM is an effective and safe procedure in men with neurogenic and non-neurogenic overactive bladder, pelvic pain, and fecal incontinence. Over 70% of patients symptomatically improve and remain satisfied in the mid to long term follow up. Additionally, this study suggests no association between presence of BPH and treatment outcomes.

Disclosures

Dr. Elterman is a consultant/investigator for Boston Scientific, Procept Biorobotics, Olympus, Urotronic, Prodeon, and Zenflow. Dr. Chughtai is a consultant for Boston Scientific, Olympus, Procept, and Prodeon. Dr. Zorn is a consultant/investigator for Boston Scientific and Procept BioRobotics. Dr. Bhojani is a consultant/investigator for Boston Scientific, Procept BioRobotics, and Olympus. Other authors have no potential conflicts of interest to disclose. □

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