



Sacral neuromodulation in pediatric refractory bladder and bowel dysfunction

Insights from Canada's first pediatric cohort

Roseanne Ferreira¹, Dean Elterman¹, Mandy Rickard², Max Freeman², Natasha Brownrigg², Abby Varghese², Michael Chua², Armando Lorenzo², Joana Dos Santos²

¹Division of Urology, University Health Network, University of Toronto, Toronto, ON, Canada; ²Division of Urology, The Hospital for Sick Children, Toronto, ON, Canada

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ABSTRACT

INTRODUCTION: Refractory bladder and bowel dysfunction (BBD) significantly affects the health and quality of life of children and their caregivers, emphasizing the need for effective and minimally invasive treatments. This study aims to present the inaugural Canadian experience using sacral neuromodulation (SNM) as a therapeutic option for children with refractory BBD.

METHODS: Patients <18 years old with refractory BBD were prospectively followed from 2018 to the present. Preoperative evaluation included spinal MRI and video urodynamics. Two-stage SNM implantation was executed with a minimum two-week stage 1 trial. Functional outcomes and complication rates were measured following validated questionnaires.

RESULTS: Six patients completed staged implantation at a median age of 10.8 years (range 8.2–18). The median baseline Dysfunctional Voiding Scoring System (DVSS) score was 12.5 (10–22). At six months of followup, only one patient required adjunct bladder medication. Median DVSS at one-year followup was 5.5 (0–7). Symptomatic resolution was noted in three patients at six months, sustained over one year. Early surgical complications were reported in one (infection) and late complications in three (lead fracture, battery depletion, non-traumatic malfunction), requiring reimplantation at a median of 37.5 (1–49) months. Post-SNM reimplantation, oral medication and rectal therapy decreased, and DVSS scores improved by 30% (0–63.6) at six months.

CONCLUSIONS: SNM is feasible and offers promising results for refractory pediatric BBD in Canada. The significant improvement of symptoms highlights the treatment's potential, which must be balanced against the high need for revision detected at three years, possibly related to patients' growth and high activity level.

INTRODUCTION

Bladder and Bowel Dysfunction (BBD) remains a common yet under-recognized condition, affecting 20% of school-age children¹ and responsible for 40% of pediatric urology consults.^{2,3} BBD not only leads to a spectrum of physical consequences such as incontinence, constipation, urinary tract infections, and kidney scarring but also results in significant psychosocial burdens, including social isolation and academic underachievement.^{2,3} Current treatment modalities range from conservative management and behavioral interventions like biofeedback to a combination of pharmacological agents such as anticholinergics, beta-3 agonists, and alpha-blockers. Each has varying degrees of success but may have limitations and side effects.³ While most BBD cases improve with behavioral or pharmacological treatment, approximately 1% of children do not respond to first-line therapies and are considered refractory.¹

Sacral neuromodulation (SNM) is a safe, effective, and minimally invasive surgical intervention where a sacral nerve stimulator, comprising a small wire and battery, is implanted under the skin of the lower back. This device emits continuous, mild electrical impulses targeting the sacral nerves, primarily S3, which are part of the core neural pathways responsible for urinary and fecal control and pelvic floor muscle activity.⁴ While this technique has been well-documented for treating adult bladder and bowel dysfunction,^{5,6} the

KEY MESSAGES

- SNM demonstrated promising improvements in functional outcomes and reduced reliance on oral medications, with symptomatic resolution in half of the patients sustained for over a year.
- Device reimplantation appeared to be required over approximately three years. The most common reason was related to device malfunction.
- For the four patients requiring SNM reimplantation, the use of oral medications decreased, and functional outcomes improved post-procedure.

pool of evidence exploring its safety, efficacy, and long-term outcomes in pediatric patients has also shown promising results, with over 80% of patients experiencing symptom improvement.⁷⁻¹⁶ The need for minimally invasive yet effective treatments for refractory BBD in children makes SNM an intriguing avenue for exploration, particularly given the side effects of other conventional therapies.¹⁷

Despite this therapy being widely investigated in the United States and Europe, scarce funding and regulatory challenges have delayed its availability to pediatric patients in Canada. In Canada and the US, approximately 6% of children suffer from non-neurogenic urinary and fecal incontinence, with 1% of these cases proving refractory to standard treatments.⁹ This condition significantly impacts the quality of life (QoL) of both patients and their caregivers, leading to psychological distress, social isolation, and considerable healthcare and personal costs.⁹

Herein, we present the outcomes of the first Canadian pediatric cohort study focusing on the role of SNM therapy in children with refractory BBD. Building upon the results of this pilot study, our province is currently funding SNM pediatric cases in our institution. This study aims to evaluate SNM's short- and long-term outcomes in a pediatric population, providing valuable insights to expand the treatment landscape for this challenging condition.

METHODS

Study design and population

A prospective cohort of patients with refractory BBD who underwent SNM insertion in a pediatric academic center (Toronto, Canada) was evaluated between October 2018 and September 2023. This study received approval from the institutional research ethics board.

Patients underwent evaluation using videourodynamics (VUDS) for refractory urinary incontinence (UI) and spinal MRI for either refractory UI or fecal incontinence (FI). Refractory incontinence was characterized as persistent UI/FI despite six months of conservative treatment, including bladder retraining, constipation management, optional biofeedback, and pelvic floor physiotherapy, followed by no improvement after at least three months of comprehensive medical therapy. This medical therapy consisted of maximized antimuscarinics with or without beta-3 adrenoceptor agonists or alpha-blockers in cases of dysfunctional voiding with high post-void residuals.

Patients with conditions such as spinal cord abnormalities, developmental delay, immunodeficiency, bleeding disorders, inflammatory bowel disease, and anatomical constraints hindering electrode placement, as well as those who were unable to speak English or provide consent, were excluded from the study. All patients underwent transcutaneous electrical nerve stimulation (TENS) for at least 12 weeks without success.

Operative procedure

After signing informed consent, all patients underwent two-stage treatment under general anesthesia. All subjects received a sacral neuromodulation device (InterStim II, by Medtronic, Minneapolis, MN). One pediatric urologist carried out device insertions. The two-step insertion method, with fluoroscopy-guided access to the S3 nerve root, allowed placement of a tined, four-pole electrode after verifying a satisfactory neurological reaction. A successful lead placement was defined as bellows or toe dorsiflexion in at least three electrodes with <2 mA stimulation. This electrode is then linked to an external pulse generator, which undergoes adjustments during a two-week trial.

Patients completed a voiding diary during the two-week trial period to track symptoms. If the subjects exhibited more than a 50% reduction in symptoms during this trial, without adverse events, a permanent pulse generator was implanted during a second stage in the subcutaneous tissue of the buttock. Baseline ques-

tionnaires were filled out on the day of surgery. Patients were followed at two weeks; then at one, three, six, nine, and 12 months after the procedure, and yearly after that. Figure 1 summarizes our pre- and post-SNM procedure protocol.

Data collection and outcomes assessment

The collected data included patient demographics (age and sex), reason for referral, treatments used before SNM, medication used before and after SNM, procedural complications, device reimplantation reasons, and timing. Functional outcomes were evaluated via the Dysfunctional Voiding Scoring System (DVSS)¹⁸ and the Pediatric Incontinence Quality of Life measurement (PinQ).¹⁹ The DVSS quantitatively assessed the severity of voiding dysfunction. In contrast, PinQ evaluated the impact of incontinence on the QoL for both children and caregivers, offering valuable insights into the psychosocial effects of this condition.

DVSS scores of ≥ 6 for females and ≥ 9 for males were indicative of voiding dysfunction, and a PinQ score of less than 20, between 20 and 50, or greater than 50, respectively, defined a mild, moderate, or severe effect of incontinence on QoL. Symptomatic resolution was defined as DVSS scores of ≤ 6 for females and ≤ 9 for males and no impact of symptoms on daily activities.

Statistical analysis

Descriptive statistics were used to summarize demographic and clinical characteristics. Continuous variables were summarized using medians and interquartile ranges (IQR) or range. Categorical variables were summarized using frequency and percentages. Due to our small sample size and the challenge of confidently asserting the normality of the data, we opted to use non-parametric tests when comparative analysis was granted. Analyses were performed using Stata 18BE. A two-sided p-value of less than 0.05 was considered statistically significant.

RESULTS

Baseline characteristics

From October 2018 to September 2023, six patients with refractory BBD completed two-stage SNM insertion. Half of the patients were female. Surgical indications included one patient with primary bladder symptoms (UI), four mixed dysfunctions (UI, FI), and one FI. VUDS was performed in all patients with urinary symptoms. Four out of five patients presented with

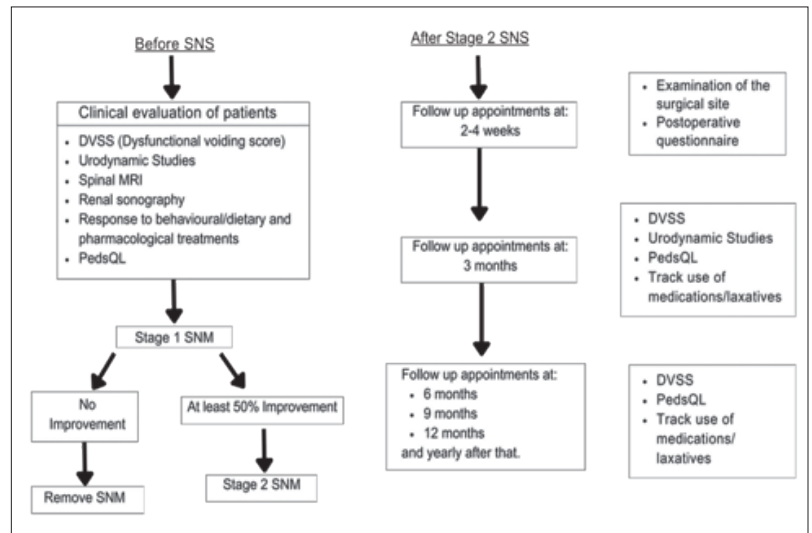


Figure 1. Sacral neuromodulation evaluation flowchart. DVSS: dysfunctional voiding score; MRI: magnetic resonance imaging; PedsQL: pediatric quality of life using PIN-Q score; RI: refractory incontinence (persistence of voiding symptoms or fecal incontinence after six months of behavioral, dietary, and pharmacological treatments); SNS: sacral neurostimulation.

detrusor overactivity and decreased bladder capacity; one had normal VUDS findings.

Regarding comorbidities, half of the patients had a diagnosis of attention-deficit/hyperactivity disorder (ADHD). Patients underwent a stepwise and combined therapy approach: those with fecal incontinence received multiple stool softeners, while those with urinary incontinence were treated with at least two bladder medications. Table 1 summarizes the medical therapies received by patients. The median baseline DVSS score was 12.5 (IQR 11.2–15.2). The impact of incontinence on QoL was 58.5 (IQR 53–65.5) for patients and 56 points (IQR 53–69) for caregivers.

Procedural outcomes and complications

All patients successfully improved symptoms during Stage 1 and proceeded to Stage 2 implantation. The median age at implantable pulse generator (IPG) insertion was 10.8 years (range 8.2–18). During followup, medication use was reduced in frequency and dose; at six months of followup, only one patient required adjunct bladder medication. Four patients had completed 12-month followups. Resolution of urinary symptoms was noted in three patients and sustained over one year. At one year followup, the median DVSS was 5.5 (IQR 3–7), highlighting a median difference of -9.5 (70%) DVSS points from baseline. All patients were no longer using retrograde enemas (i.e., Peristeen®), other rectal therapies, or medications for constipation at six and 12 months post SNM. Early surgical complications were reported in one patient (infection), and late complications in three (non-

Table 1. Preoperative patient characteristics

Patient	Sex	Age at surgery (years)	Comorbidities	SNM indication	Urodynamic findings	Spine MRI	Anorectal manometry	Medical therapy	Conservative treatment
1	Female	9.4	ADHD	UI, OAB	DO, low compliance, decreased capacity	Normal	–	Anticholinergic, B3 Agonist, laxative	Biofeedback
2	Male	8.2	ADHD	UI, OAB, FI/encopresis, constipation	DO, low compliance, decreased capacity	Normal	Normal	Anticholinergic, B3 Agonist, laxative, enema	Biofeedback, Pelvic physiotherapy
3	Female	11.5	ADHD	UI, OAB, FI/encopresis, constipation	Normal	Normal	–	B3 Agonist, alpha-blocker, laxative	Pelvic physiotherapy
4	Male	10.2	None	UI, OAB, FI/encopresis, constipation	DO, low compliance, decreased capacity	Normal	Abnormal	Anticholinergic, B3-agonist, alpha-blocker, laxative	Biofeedback, Pelvic physiotherapy
5	Female	15	None	UI, OAB, FI/encopresis, constipation	DO, decreased capacity	Normal	Normal	Anticholinergic, B3 Agonist, laxative, enema	Biofeedback, Pelvic physiotherapy
6	Male	18	Anxiety	FI/encopresis, constipation	–	Normal	Normal	Senokot, Senna, Magnesium, Pico-salax, PEG, Saline enema, Peristeen enema	Biofeedback, Pelvic physiotherapy

ADHD: attention-deficit/hyperactivity disorder; DO: detrusor overactivity; FI: fecal incontinence/encopresis; MRI: magnetic resonance imaging; OAB: overactive bladder; PEG: polyethylene glycol 3350; SNM: sacral neuromodulation; UI: urinary incontinence; – : not performed.

traumatic malfunction, lead fracture, battery depletion). Complications primarily involved device malfunction and were managed surgically by replacing the battery or the entire system (Table 2).

SNM reimplantation

Those with complications required SNM reimplantation at a median of 37.5 months (IQR 27.2–41.5) post-

implantation. At the time of reimplantation, median DVSS was 11.5 (IQR 10.7–12.2), and PinQ (38 [32.7–45.5]) score. Post-SNM reimplantation, the use of oral medications decreased (Table 3). DVSS scores decreased by 43% (-7.7% to -81.8%) and 30% (-63.6 to 0) at three and six months, respectively. Two patients had sustained symptom resolution at a one-year followup. QoL varied among patients, staying moderate at three [patient PinQ 34 (11–61)] and six months [patient PinQ 35 (9–72)].

DISCUSSION

The significant burden of refractory BBD on patients' and caregivers' health and quality of life emphasizes the pressing need for federal regulatory approval and integration of innovative therapies into Canadian pediatric care for refractory BBD. Our study demonstrated noteworthy outcomes. In alignment with prior pediatric studies demonstrating significant symptom improvement with SNM,⁷⁻¹⁶ our findings revealed a 70% improvement in lower urinary tract symptoms. Additionally, there was a notable reduction in reliance on pharmacological interventions for UI, and no patient required retrograde enemas, other rectal therapies, or medications for constipation. Despite one early and three late device-related complications leading to reim-

Table 2. Patient characteristics, neuromodulation indication, and complications

Patient	SNM Indication	Time to reimplantation (months)	Cause for reimplantation	Management
1	UI, OAB	39	Device malfunction with no reported trauma	Reimplantation of MRI-compatible lead and IPG system
2	UI, OAB, FI/encopresis, constipation	49	Battery depletion/symptom recurrence	Battery change
3	UI, OAB, FI/encopresis, constipation	36	Lead fracture after falling on the device	Reimplantation of new MRI-compatible lead and IPG system
4	UI, OAB, FI/encopresis, constipation	1	Infection	Implant removal; device replacement at a later date

FI: fecal incontinence/encopresis; IPG: internal pulse generator; MRI: magnetic resonance imaging; OAB: overactive bladder; UI: urinary incontinence.

plantation, post-SNM reimplantation outcomes showed significant improvement in QoL and bladder and bowel symptoms. These findings highlight SNM's pivotal role in managing refractory BBD, indicating its potential to improve patient outcomes and reduce dependence on more invasive interventions and surgical options.

Current alternatives for managing refractory cases involve interventions like clean intermittent catheterization (CIC), retrograde enemas, and various surgical procedures, such as botulinum toxin injections into the detrusor muscle or the urethral sphincter, appendicovesicostomy to facilitate bladder catheterization, and antegrade continence enema for fecal incontinence.³ SNM represents a minimally invasive and easily reversible option to be considered for those who did not respond to conservative treatments.

Additionally, SNM demonstrated effective results for treating both fecal and urinary incontinence instead of a combination of multiple surgical procedures that would be required to treat refractory patients suffering from both issues (i.e., detrusor botulinum injection ± CIC + transanal irrigation or MACE).⁷⁻¹⁶ Moreover, decreased utilization and, ultimately, reversal of antegrade continence enema have been described in children with severe constipation and refractory FI undergoing SNM therapy.^{20,21}

SNM has demonstrated higher success rates than botulinum toxin in improving symptoms of urinary incontinence.²² Conversely, one recent randomized trial of 381 women comparing SNM with botulinum toxin as a treatment for refractory urinary urge incontinence (UUI) showed marginally better results for botulinum toxin compared to the SNM. Still, the need for CIC and the development of UTIs was more prevalent in patients who underwent botulinum toxin injections.²³ These findings should be interpreted cautiously due to the absence of comparative data on both therapies in children with refractory BBD.

Unlike SNM devices in adults, which typically last from 5–7 years to over a decade,²⁴ in our experience, device reimplantation appeared to be required over approximately three years. The most common reason was related to device malfunction (lead fracture, battery depletion, and non-traumatic malfunction), possibly stemming from children's growth, high activity level, and related lead migration. The introduction of newer, smaller, lighter-weight SNM devices, which are also MRI-compatible,²⁵ has made SNM even more appealing for pediatric use, potentially extending its applicability to selected neurogenic cases. Furthermore, newer models with rechargeable batteries can extend the device's

Table 3. Neuromodulation reimplantation outcomes and adjunct therapy rate

Patient	Age at reimplantation (years)	Baseline	3 months	6 months	12 months
1	12.8	Anticholinergic, B3-agonist, laxative, antibiotics DVSS: 11 PIN-Q: 32	Laxative DVSS: 2 PIN-Q: 22	None DVSS: 4 PIN-Q: 9	None DVSS: 0 PIN-Q: –
2	12.3	Anticholinergic, B3-agonist, Senna, Peristeen enema DVSS: 10 PIN-Q: 33	Anticholinergic, PEG, Ex-lax DVSS: 7 PIN-Q: 11	PEG, Ex-lax DVSS: 10 PIN-Q: 24	
3	14.5	B3-agonist, alpha-blocker, laxative DVSS: 13 PIN-Q: 53	PEG, Prucalopride DVSS: 14 PIN-Q: 46	Laxative DVSS: 13 PIN-Q: 72	Laxative DVSS: 7 PIN-Q: 44
4	10.3	Anticholinergic, B3-agonist, alpha-blocker, laxative DVSS: 12 PIN-Q: 43	Cephalexin, B3-agonist, alpha-blocker, PEG DVSS: 6 PIN-Q: 61	Cephalexin, alpha-blocker, PEG DVSS: 6 PIN-Q: 46	Cephalexin, alpha-blocker, laxative DVSS: 4 PIN-Q: 28

DVSS: dysfunctional voiding scoring system; PEG: polyethylene glycol 3350; PIN-Q: Pediatric Incontinence Measurement-Quality of Life score (patient-reported); – : missing data.

lifespan to fifteen years and eliminate the need for surgical battery replacement.²⁶

Healthcare providers must thoroughly discuss the advantages and disadvantages of each device before choosing which model best suits each patient. This includes considering factors such as the need for regular recharging and its potential impact on daily life for patients and caregivers.

Despite being an expensive therapy, preliminary cost analysis conducted by our group indicates that SNM costs less than other interventions used to treat refractory BBD in children.⁹ These alternatives, such as botulinum toxin injections for urinary incontinence, cecostomy for antegrade enemas, and retrograde transanal irrigation systems for fecal incontinence, require recurrent administration or incur significant accumulative daily costs for catheters and related supplies, which can explain the higher costs.

Limitations

Our study acknowledges certain limitations. Despite its prospective nature, it lacked a control group and did not employ randomization in assigning treatment options.

Second, this was a single-center study with a small cohort of children with refractory BBD that were followed in a quaternary pediatric hospital, which can reduce the generalizability to other populations.

Additionally, while patients underwent preoperative VUDS and validated questionnaires, there has been no postoperative urodynamic evaluation to quantify and compare pre-post bladder function parameters. This is primarily due to guardians' reasonable hesitancy to undergo further invasive tests when they perceive their treatment to be effective; however, despite the study's constraints, our findings contribute to the growing body of evidence supporting SNM as a valuable component of multidisciplinary strategies for the management of complex cases of BBD.

CONCLUSIONS

SNM offers promising results for pediatric refractory BBD. Our SNM reimplantation cohort experienced an improvement in functional outcomes and reduced reliance on oral medications and rectal therapies, enhancing their quality of life. For children, device reimplantation appeared to be required over approximately three years. The most common reason was device malfunction, possibly related to patients' growth. The significant improvement in symptoms highlights the treatment's potential, which must be balanced against the high need for revision detected at three years. This study establishes the feasibility of introducing SNM for selected refractory pediatric patients with refractory BBD in Canada and beyond.

COMPETING INTERESTS: Dr. Elterman is a consultant and investigator for Medtronic. The remaining authors do not report any competing personal or financial interests related to this work.

This paper was reviewed by the CUA 2024 Scientific Program Committee Co-Chairs and was selected as one of two winning essays. As such, it was presented at the 2024 CUA Annual Meeting in Victoria, BC.

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CORRESPONDENCE: Dr. Joana Dos Santos, Division of Urology, The Hospital for Sick Children, Toronto, ON, Canada; joana.dossantos@sickkids.ca