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Sacral nerve stimulation: a promising therapy for fecal and urinary incontinence and constipation in children ☆

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ABSTRACT

Purpose: This study describes our series of children with bowel and bladder dysfunction (BDD) treated with sacral nerve stimulation in order to begin to identify characteristics associated with better outcomes and guide future therapies.
Methods: Between May 2012 and February 2014, 29 patients were evaluated before and after sacral nerve stimulator (SNS) placement. A prospective data registry was developed that contains clinical information and patient-reported measures: Fecal Incontinence Qualify of Life Scale, Fecal Incontinence Severity Scale, PedsQL Gastrointestinal Symptom Scale, and Vancouver DES Symptom Scale.
Results: The median age of patients was 12.1 (interquartile range: 9.4, 14.3) years and the median follow-up period was 17.7 (12.9, 36.4) weeks. 93% had GI complaints and 65.5% had urinary symptoms while 7% had urologic symptoms only. The most common etiologies of BBD were idiopathic (66%) and imperforate anus (27%). Five patients required reoperation due to a complication with battery placement. Six of 11 patients (55%) with a pre-SNS cecostomy tube no longer require an antegrade bowel regimen as they now have voluntary bowel movements. Ten of eleven patients (91%) no longer require anticholinergic medications for bladder overactivity after receiving SNS. Significant improvements have been demonstrated in all four patient-reported instruments for the overall cohort.
Conclusions: Early results have demonstrated improvements in both GI and urinary function after SNS placement in pediatric patients with bowel and bladder dysfunction.

Bowel and bladder dysfunction (BBD), also previously known as dysfunctional elimination syndrome (DES), is a constellation of symptoms associated with gastrointestinal (GI) and urinary function [1–3]. These symptoms present in myriad combinations with both GI and urinary dysfunction including intractable chronic constipation, urinary retention, and both fecal and urinary incontinence [4].

Neuromodulation using a sacral nerve stimulator (SNS) has been demonstrated to provide relief to adult patients with BBD [5]. Although the pediatric use of SNS is much less common than in adults, reports published thus far have demonstrated promising results for pediatric patients with both GI and urinary dysfunction [6–10]. These patients represent a complex and chronic population, for whom long term follow-up will be necessary to demonstrate durable improvements. Furthermore, the spectrum of symptoms associated with BBD are difficult to quantify and compare, therefore validated measures of quality of life and symptom improvement are important for determining clinical utility [11–14]. To this end, we have created the SNS Patient Registry to collect longitudinal prospective data, including patient-reported quality of life and symptom surveys and clinical information, on patients undergoing SNS placement at our institution. The purpose of this study is to report the short-term results of SNS on patient-reported symptoms and medical management in children with BBD in order to begin to identify characteristics associated with better outcomes and guide future treatments.

1. Methods

1.1. SNS patient registry

This prospective cohort study includes patients who had a SNS placed between May 2012 and February 2014. Indications for SNS placement included intractable chronic constipation, urinary retention associated with neurogenic bladder, and both fecal and urinary incontinence. Patient-reported measures are recorded at each visit starting with the pre-operative evaluation. These data are stored, along with

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detailed clinical information collected from the patient records, using REDCap electronic data capture tools hosted at our institution [15]. Our hospital Institutional Review Board approved this study with completion of patient questionnaires at each visit providing continued implicit consent for participation in the data registry.

It is difficult to demonstrate symptomatic improvement using medication regimens as a surrogate since each patient's baseline is so different from another. For this reason we focused on patients with cecostomies, and classified cessation of antegrade enemas or surgical closure as markers of improvement after SNS. Data elements collected include medication regimens, need for cecostomy flushes or bladder catheterizations, complications associated with SNS placement, and four validated patient-reported instruments meant to evaluate symptom severity and quality of life. Frequency of interventions such as cecostomy flushes and bladder catheterizations were categorized as follows: more than once daily, 6–7 days a week, 4–5 days a week, 2–3 days a week, less than once a day or daily. Clinical improvement was defined as moving from one category to at least the next lower category. We also defined clinical improvement as termination of anti-cholinergic medications, and improvement in at least four of the seven categories from the four validated patient surveys. The validated tools used are the Fecal Incontinence Severity Index [11], Fecal Incontinence Quality of Life Scale [12], PedsQL Gastrointestinal Symptom Scale [13], and Vancouver Dysfunctional Elimination Syndrome (DES) Symptom Score [14].

1.2. SNS procedure

The minimally invasive technique used at our institution is similar to that previously reported by Spinelli et al. and is performed by two different surgeons [16]. The patient is placed in the prone position on the operative table. The sacroiliac joints are identified using fluoroscopy and a line between them is drawn on the skin. Starting 2 cm superior and lateral to the midpoint of the line, the access needle is passed through the skin and into the 3rd sacral foramen, with correct positioning confirmed by fluoroscopy. The InterStim™ SNS System (Medtronic, Minneapolis, MN) pacing lead is then inserted into the 3rd sacral foramen using the Seldinger technique. The placement is confirmed with fluoroscopy and stimulatory testing, which demonstrates a bellows effect of the perineum along with dorsiflexion of the toes at all four electrodes. A subcutaneous pocket is then created over either the left or right lateral buttock, where the SNS pulse generator/battery is positioned after it is connected to the permanent stimulator lead.

1.3. Statistical analysis

Data are presented as medians with interquartile ranges for continuous data, and as frequencies and percentages for categorical data. The Wilcoxon signed-rank test was used to determine differences in pre-operative and post-operative objective and patient reported measures. All statistical analysis was performed using STATA 13 (StataCorp LP, College Station, TX).

2. Results

2.1. Population characteristics

Thirty-four patients have received an SNS at our institution. Two have had complex bladder and pelvic reconstructions and are not included in this analysis. Three additional patients were excluded due to lack of post-SNS follow-up at the time this report was prepared. This left a final cohort of 29 patients with a median age of 12.1 years [interquartile range (IQR): 9.4, 14.3] and a median follow up of 17.7 weeks (12.9, 36.4). The majority of patients have been white (89.7%) and female (55.1%) (Table 1).

Nearly all patients (93.1%) have had GI complaints, while 65.5% have had urinary symptoms. Seventeen (58.6%) patients reported both GI and urinary complaints (Table 1). Of those with GI complaints, five had only fecal incontinence, 18 had constipation, and four reported both. The etiology of symptoms was predominantly idiopathic, while eight patients were born with imperforate anus, one of which had myelomeningocele and another had tethered cord (Table 1). Prior to SNS placement, 13 patients had undergone placement of a cecostomy for an antegrade colonic bowel regimen, including all eight of the imperforate anus patients. No patients had retrograde enemas as a component of their home bowel regimen. Also, 11 patients were receiving anti-cholinergic medications for overactive bladders before placement of a SNS.

Table 1
Baseline characteristics of patients who underwent placement of sacral nerve stimulator (SNS).

	SNS placement participants ($N = 29$)
Male, *n* (%)	13 (44.9)
Race, *n* (%)	
White	26 (89.7)
Non-white	3 (10.3)
Age, median (IQR)	12.1 (9.4, 14.3) years
Symptoms, *n* (%)	
Gastrointestinal	27 (93.1)
Urinary	19 (65.5)
Both	17 (58.6)
History, *n* (%)	
Idiopathic	19 (65.5)
Hirschsprung's disease	1 (3.4)
Syrinx	1 (3.4)
Imperforate anus	8 (27.6)
With tethered cord	1 (3.4)
With myelomeningocele	1 (3.4)

Data are presented as medians and interquartile ranges (IQR) for continuous variables and frequencies and percentages for categorical variables.

2.2. Peri-operative outcomes

Most patients have tolerated SNS placement well. Twenty-one patients (72.4%) reported having no pain at the battery site, while one patient reported severe pain, two reported moderate pain, and five described mild pain at the most recent follow-up. Five patients have required reoperation due to a complication. Two had the battery repositioned due to discomfort and one later required SNS explant due to a wound infection with subsequent re-implantation. There was also one additional explant due to a wound infection and two additional patients have required operative management of post-operative hematomas (one required cauterization and one repositioning).

2.3. Effects of SNS on medical regimen and patient reported outcomes

After SNS placement, six patients (46.2%) have stopped using their cecostomy or had it surgically closed because they now have voluntary bowel movements and no longer need antegrade flushes and five (38.4%) have had a clinical improvement in their antegrade bowel regimen. Of the patients with a history of imperforate anus, half have stopped using their cecostomy and three (37.5%) have decreased the frequency of enemas from every day to every other or every third day since SNS placement because of improvements in their voluntary control. In addition, ten of eleven patients (90.9%) no longer require anti-cholinergic medications for bladder overactivity after receiving the SNS. Table 2 provides a summary of outcomes relating to clinical improvements as defined in the Methods for the entire group of patients as a whole and also for those who had intractable constipation, fecal incontinence, any urinary dysfunction, and imperforate anus.

Table 3 contains the results of patient reported measures. For the overall group, significant improvements were observed in all instruments. Similarly, patients whose indication for SNS placement was intractable constipation demonstrated significant improvements in all

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Table 2
Number of patients with clinical improvement based on the frequency of cecostomy flushes, use of anticholinergic medications, and results of patient-reported surveys.

Group	Cecostomy flushes	Anticholinergic use	Patient-reported survey results
Overall ($n = 29$)	11/13 (85%)	10/11 (91%)	18/29 (62%)
Constipation ($n = 22$)	9/11 (82%)	7/7 (100%)	16/22 (73%)
Fecal incontinence ($n = 7$)	5/5 (100%)	0/0	5/7 (71%)
Urinary symptoms ($n = 19$)	1/3 (33%)	10/11 (91%)	12/19 (63%)
Imperforate anus ($n = 8$)	7/8 (88%)	0/0	4/8 (50%)

Results listed as the number of patients demonstrating clinical improvement (as defined in Methods) in each category over the number of patients to whom that category applies with corresponding percentages.

four instruments, and all patients with any urinary symptoms had significant improvements in the Vancouver DES Symptom Score along with all of the GI related instruments except the Fecal Incontinence Severity Index. Patients with a history of imperforate anus did trend towards improvements in all measures however only reached statistical significance for the Embarrassment questions from the Fecal Incontinence Quality of Life Scale. Patients with fecal incontinence did not demonstrate significant improvement in any of the patient reported measures.

Table 3
Patient reported outcomes before and after placement of sacral nerve stimulator.

Test	Pre-SNS	Post-SNS	*P*-value
Overall ($n = 29$)			
Fecal Incontinence Quality of Life Scale			
–Lifestyle	3.0 (2.2, 4.0)	3.8 (3.1, 4.0)	0.002
–Coping/behavior	2.8 (1.9, 4.0)	3.8 (3.0, 4.0)	0.001
–Depression/Self-perception	3.3 (2.6, 4.1)	4.1 (3.7, 4.4)	<0.001
–Embarrassment	3.0 (1.7, 4.0)	3.7 (2.3, 4.0)	0.005
Fecal Incontinence Severity Index	15 (13,17)	18 (14,21)	0.006
PedsQL GI Symptom Scale	13 (7, 21)	8 (3, 14)	0.003
Vancouver DES Symptom Score	17 (8, 26)	10 (7, 21)	0.029
Constipation ($n = 22$)			
Fecal Incontinence Quality of Life Scale			
–Lifestyle	3.1 (2.2, 4.0)	3.8 (3.2, 4.0)	0.006
–Coping/behavior	2.8 (2.3, 3.9)	3.8 (3.2, 4.0)	0.002
–Depression/self-perception	3.3 (2.6, 4.1)	4.1 (4.0, 4.4)	0.001
–Embarrassment	3.0 (1.7, 3.7)	3.0 (3.8, 4.0)	0.002
Fecal Incontinence Severity Index	16 (13, 18)	19 (15, 21)	0.003
PedsQL GI Symptom Scale	15 (10, 21)	8 (3, 14)	0.016
Vancouver DES Symptom Score	20 (8, 25)	9.5 (7, 21)	0.029
Fecal incontinence ($n = 7$)			
Fecal Incontinence Quality of Life Scale			
–Lifestyle	2.2 (1.8, 3.6)	3.8 (3.6, 4.1)	0.209
–Coping/behavior	1.6 (1.3, 2.8)	3.6 (2.9, 3.9)	0.073
–Depression/self-perception	3.0 (2.6, 3.6)	4.1 (4.1, 4.3)	0.073
–Embarrassment	2.0 (1.2, 2.8)	3.3 (2.8, 4.0)	0.073
Fecal Incontinence Severity Index	14 (12, 16)	17 (13, 18)	0.530
PedsQL GI Symptom Scale	10.5 (2.3, 20)	10 (5.5, 14.5)	0.805
Vancouver DES Symptom Score	7.5 (5.5, 14.8)	7 (6, 8.5)	0.710
Urinary symptoms ($n = 19$)			
Fecal Incontinence Quality of Life Scale			
–Lifestyle	3.0 (1.9, 4.0)	3.8 (3.1, 4.0)	0.024
–Coping/behavior	2.8 (1.9, 4.0)	3.8 (2.9, 4.0)	0.006
–Depression/self-perception	3.3 (2.3, 4.3)	4.1 (3.6, 4.4)	0.003
–Embarrassment	3.0 (1.7, 4.0)	2.3 (3.3, 4.0)	0.034
Fecal Incontinence Severity Index	15 (14, 18)	19 (15, 21)	0.067
PedsQL GI Symptom Scale	14.5 (7, 21)	7 (3, 14)	0.006
Vancouver DES Symptom Score	22.5 (16, 27)	13 (8, 22)	0.012
Imperforate anus ($n = 8$)			
Fecal Incontinence Quality of Life Scale			
–Lifestyle	3.4 (2.7, 3.9)	3.7 (3.3, 3.9)	0.09
–Coping/behavior	2.8 (2.1, 3.9)	3.7 (3.1, 3.9)	0.16
–Depression/self-perception	3.6 (2.9, 4.1)	4.1 (3.6, 4.3)	0.08
–Embarrassment	2.8 (1.3, 4.0)	4.0 (2.7, 4.0)	0.049
Fecal Incontinence Severity Index	15.5 (12.5, 16.5)	17 (10.5, 20.5)	0.44
PedsQL GI Symptom Scale	10.5 (4.5, 11.5)	7.5 (3, 9)	0.29
Vancouver DES Symptom Score	7.5 (3, 10)	7.5 (6.5, 10.5)	0.36

Results listed as median scores (interquartile range) and comparison of means performed by Wilcoxon signed-rank test.

3. Discussion

We report here the initial results for patients who underwent SNS placement at our institution. In this series we demonstrate that in patients with GI and urinary dysfunction, sacral nerve stimulation has led to reductions in daily interventions for management of symptoms. More than half of those patients who were dependent on antegrade cecostomy flushes prior to SNS placement are no longer using the cecostomy at all and now have voluntary bowel movements and similarly more than half of patients taking anti-cholinergic medications had ceased using them after the procedure due to improvements in their urinary dysfunction. SNS also led to significant improvements in patient reported symptoms and quality of life using several validated instruments.

In addition to most patients experiencing incremental improvements in symptoms, placemment of the SNS was well tolerated. There were five patients who required reoperation due to a complication associated with the battery site. Most of these were because the upper buttock location caused the battery to interfere with childhood activities such as sitting on the floor. All patients have since recovered well, and we have started placing the battery pocket more lateral to avoid this problem.

In the United States, sacral nerve neuromodulation was first used in 1988 and FDA approved in 1997 for the treatment of adults with urinary incontinence [17] and in 2012 for the treatment of adults with fecal incontinence or constipation [18–20]. Although the exact mechanism of action remains elusive, significant improvements have been reported for a wide range of symptoms including constipation [18], fecal incontinence [19,20], irritable bowel syndrome [21], urinary retention [22], and urinary incontinence [17]. In the pediatric population, adoption of SNS placement has been slow and reports of successful outcomes are limited to small series. One of the earliest reports was from Humphreys et al., who reported on 23 patients with primarily urinary symptoms [6], while two independent studies from Europe described results in 13 patients with refractory constipation [8] and 33 patients with mixed urinary and GI symptoms, respectively [9]. All of these studies reported clinical improvements in most children undergoing treatment with SNS. Consistent with these reports, our study demonstrated clinical improvement in most children as reflected by decreases in anticholinergic medication use and antegrade enema use [10]. Furthermore, our study is the first to demonstrate significant improvements in short-term patient reported symptoms and quality of life after SNS placement and the first to report improvement in the imperforate anus subgroup.

Our current series of patients is a heterogeneous group of patients, most of whom had a history of some GI dysfunction. In particular, eight patients had a history of imperforate anus with severe constipation that required antegrade flushes via a cecostomy for bowel management. At the time of this write-up, four patients were no longer using their cecostomy and were awaiting spontaneous or surgical closure. Three of the other patients have been able to substantially diminish the frequency of cecostomy flushes from daily to two to three times

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per week. Because of the small number of patients in this subgroup, the only patient-reported measure that demonstrated a significant improvement was the Embarrassment portion of the Fecal Incontinence Quality of Life Scale with the other measures all trending towards improvement. However, the decreased need for cecostomy treatments in this group suggests a substantial improvement in function and quality of life. We anticipate that differences in other measures will reach statistical significance in the future as we accumulate larger numbers of patients within this subgroup.

At this time the number of patients who have been treated is too small to make predictions regarding which patients may benefit more than others from SNS placement. Yet our results thus far demonstrate clinical improvement in most patients across different indications for SNS placement. It is noteworthy to point out in Table 2 the patient-reported outcomes showed lower rates of improvement than the other measures, highlighting the fact that improvements in objective clinical measures may not automatically translate into improvements from the perspective of the patients themselves. This should underscore the importance of including these types of outcomes in future studies of SNS therapy. Furthermore, the potential to expand the SNS Patient Registry to include additional patients referred for fecal and urinary dysfunction from anorectal malformations, Hirschsprung's disease, spinal etiologies, and urology issues, and data from multiple institutions performing pediatric SNS placements similar to the International Serial Transverse Enteroplasty Data Registry [23], would allow for more rapid growth of the patient cohort, in addition to enhancing the generalizability of the data.

These results are limited in several ways. First, the number of patients is relatively small and our follow up is relatively short given the chronicity of these problems, both of which limit the power of our findings. However, these short term results suggest that SNS is a promising therapy for patients with BBD in that it improves symptoms, quality of life and allows for a decrease in medical regimens required to manage associated symptoms. Second, this series represents a heterogeneous group of patients, many of whom have concomitant GI and urinary symptoms. However, when looking at subgroups of patients, they all continued to demonstrate significant improvements in patient-reported measures, with the exception of the imperforate anus group, which is limited by its small sample size. Third, measurement of clinical improvement for children with BBD is difficult, with only one validated measure designed specifically for this population, and few reliable objective tests available to trend improvements [15]. The present cohort of patients did not have systematic pre- and post-SNS anorectal manometry performed, although we do plan to make this standard for all future SNS patients. Also, it is difficult to demonstrate symptomatic improvement using medication regimens as a surrogate since each patient's baseline is so different from another. For this reason we focused on patients with cecostomies, with cessation of antegrade enemas or surgical closure as classified markers of improvement. In addition, we reported changes in medication regimen by allowing patients to serve as their own controls and comparing regimens pre- and post SNS placement. Lastly, these patients are being treated at a large, tertiary pediatric hospital with a multi-disciplinary team treating both GI and urinary dysfunction, which may limit the generalizability of the results to centers without such resources.

In conclusion, the short-term improvements in medical regimens, patient reported symptoms and quality of life in this study suggest that SNS may be a promising therapy for pediatric patients with both GI and urinary dysfunction that has been refractory to standard medical management. With the accrual of additional patients and longer follow-up, future studies will be able to identify longer-term effects of SNS for patients with BBD and potentially identify subgroups of patients that are more likely to respond to sacral neuromodulation.

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