

Sacral Neuromodulation: Improving Bladder and Bowel Dysfunction in Children

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Published online: 27 February 2018

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This article is part of the Topical Collection on *Urology*

Keywords Sacral neuromodulation · Sacral nerve stimulation · Bowel and bladder dysfunction

Abstract

Purpose of review Sacral neuromodulation (SNM) is a Food and Drug Administration-approved treatment for bowel and bladder dysfunction in adults, but use in the pediatric population remains an “off-label” indication. We aim to summarize the indications for and clinical outcomes of SNM in children.

Recent findings A PUBMED® and MEDLINE® search was conducted for articles involving pediatric patients using the keywords “sacral neuromodulation” and “sacral nerve stimulation.” We identified 14 articles; all were reviewed and the results included in this article. Refractory bowel and bladder dysfunction (BBD) was the most common indication for SNM. The S3 nerve root is the most common anatomical location for lead placement. There were no standardized methods of reporting success in the literature. In general, approximately 60–90% of patients had improvement in symptoms, and there were significant decreases in the number of bladder and bowel-related medications used with SNM therapy. Significant improvements in quality of life (QOL) were also reported. The most important reported complication was reoperation, the frequency of which tended to increase with longer duration of therapy.

Summary SNM is an effective therapy for refractory BBD in the carefully selected child. Patients and families should be counseled regarding the risk of reoperation, which tends to increase with time.

Introduction

Bladder dysfunction is one of the most frequent reasons for referral to a pediatric urologist. Conservative management typically involves behavioral modification, management of concomitant bowel dysfunction, pharmacotherapy, clean intermittent catheterization (CIC) when needed, and occasionally biofeedback. When conservative management fails, treatment options in children are limited.

In adults, sacral neuromodulation (SNM), also known as sacral nerve stimulation, was approved by the Food and Drug Administration (FDA) in 1997 for urinary urge incontinence. It later received FDA approval for urinary urgency/frequency (1999), non-obstructive urinary retention (1999), and fecal incontinence (2011). Its exact mechanism remains unclear at this time. Current

evidence suggests that sacral neuromodulation activates the somatic sacral afferents at the sacral root level. This activation then modulates both bladder storage and emptying reflexes. It has also been shown to modulate sensory outflow from the bladder through ascending pathways to the pontine micturition center [1].

The first published studies on the use of SNM in the pediatric population emerged in the 2000s, first in Europe and later in the USA. Despite multiple publications reporting its safety and efficacy in children, the use of SNM in children under the age of 16 is not yet approved by the FDA and remains an “off-label” indication at this time. In this review, we aim to summarize the indications for and clinical outcomes of SNM use in children.

Materials and methods

A PUBMED® and MEDLINE® search was conducted for scientific articles involving pediatric patients using the keywords “sacral neuromodulation” and “sacral nerve stimulation.” We identified 14 unique articles, published between 2004 and 2017 [2–8, 9••, 10, 11•, 12•, 13, 14, 15•]. Three (21%) of the articles were multi-institutional studies, all of which were prospective [3, 5, 13]. The remaining 11 articles were all single-institution studies, 7 of which were prospectively collected [2, 8, 10, 11•, 13, 14, 15•]. Five of these were published by institutions outside of the USA [2, 5–7, 13]. Each of these articles was thoroughly reviewed and the results included in this article.

Indications

SNM is approved by the FDA for use in adults with urinary urge incontinence, refractory urinary urgency/frequency, urinary retention, and fecal incontinence. Although SNM has not been approved by the FDA for use in children, the articles included in this review use the device in an “off-label” manner and demonstrate improvement in symptoms in the carefully selected child. There are no clearly defined indications for the use of SNM in the pediatric population, but most of the studies reviewed included children with dysfunctional urination and fecal elimination refractory to typical conservative management, which generally includes behavioral modifications and pharmacotherapy. The studies reviewed included patients with a broad variety of symptoms, including urinary frequency, urgency, incontinence, retention, and enuresis, as well as constipation and fecal incontinence.

The terminology used to describe this constellation of symptoms in patients without neurologic conditions has varied over the years. The

earliest literature used the term dysfunctional elimination syndrome (DES), defined as functional disturbances involving the urinary and GI system in the absence of urologic or neurologic abnormalities [3]. The term non-neurologic lower urinary tract dysfunction (NLUTD) later replaced DES. In 2013, the International Children's Continence Society's (ICCS) consensus statement recommended standardizing the terminology and advocated the use of the term bowel and bladder dysfunction (BBD) [16, 17].

The articles included in this review include patients with all of the above described indications, as well as refractory constipation. Five of the reviewed studies also included patients with neurogenic bladder and bowel dysfunction [2, 5, 7, 10, 11•], with one including patients solely with neurogenic bladder (NGB) [2]. A summary of the reviewed studies, including the indications for SNM, is included in Table 1.

Surgical technique

The sacral neuromodulation device (Interstim® system, Medtronic) is surgically implanted while the child is under general anesthesia and in the prone position. The device is typically implanted in two stages. While the initial testing phase—peripheral nerve evaluation (PNE)—can be done with a temporary lead as an office procedure under local anesthesia in adults, this is not feasible in children. The first stage of the procedure involves percutaneous placement of a tined lead using fluoroscopic guidance to confirm correct positioning. Different anatomic sites have been described for lead placement, but the most commonly used target is the third sacral nerve root (S3), although S4 can be used as an alternative lead placement [18]. The lead is then connected to a temporary external generator for a period of 2–3 weeks while the therapy is tested for efficacy. The second-stage procedure, which is also performed under general anesthesia, involves placement of a permanent battery, the implantable pulse generator (IPG). The previously implanted lead is connected to the IPG, which is placed in a pocket under the skin in an area protected by adipose tissue, typically the upper buttocks. The device is activated within 24 h after the child has recovered from anesthesia.

The purpose of the staged approach is to allow for a trial period to ensure that SNM provides the desired improvement, typically defined as at least 50% improvement in symptoms compared to baseline. The trial period is typically several weeks long, which allows for adjustment in device settings to maximize symptom improvement. All studies reviewed utilized this staged approach, although one did trial the placement of the entire device in a single stage in the carefully selected patient [9••].

Clinical outcomes

Because there is no standardized system in place to evaluate success with SNM therapy, there were variable methods of reporting outcomes with SNM across the reviewed studies, which can make interpretation and comparison of the data somewhat challenging. Each study's clinical outcomes are summarized briefly in Table 1. Reported median follow-up for the reviewed studies ranged from 4.1 to 32.6 months.

Table 1. Indications for and clinical outcomes with SNM

Authors	Date published	Indication for SNM	Included patients with neurologic conditions?	Number of patients	Mean age (years)	Median follow-up (months)	Percentage of patients that had permanent generator implanted	Clinical outcome	Changes in medication use
Guys et al.	2004	Neurogenic bladder	Yes	21	11.9	NR	100%	Significant increase in leak point pressure, total bladder capacity, and bladder compliance on UDS	NR
Humphreys et al.	2006	DfES	No	23	11.1	13.3	91%	85% improvement (16% resolution) in urinary incontinence 69% improvement (13% resolution) in nocturnal enuresis 75% improvement in urinary urgency 73% improvement in urinary frequency 60% improvement (33% resolution) in urinary retention	Mean # of medications significantly decreased from 4.5 to 1.5
Roth et al.	2008	DfES	No	20	11.0	27.0	90%	80% improvement in constipation 88% improvement (75% resolution) in urinary incontinence 69% improvement (38% resolution) in nocturnal enuresis 69% resolution of urinary urgency 89% improvement (78% resolution) in urinary frequency 25% improvement in urinary retention 70% improvement (41% resolution) in constipation 81%	30% able to stop medications completely 90% able to decrease # of medications used
Haddad et al.	2010	Urinary and fecal	incontinence	Yes	33	12.2	NR		81% improvement in urinary incontinence 78% improvement in fecal incontinence Significant improvements in bladder capacity and overactivity on UDS
All patients stopped			medications for the study						
van Wunmik et al.	2012	Refractory	functional constipation	No	13	15.2	7.3	92%	Significant increase in frequency of 1.5/weeks to 4.8/week Significant improvement in constipation symptoms on validated questionnaires
75% able to stop enemas and laxatives									
Groen et al.	2012	DfES	Yes	18	15.0	28.8	83%	75% improvement (25% resolution) in urinary incontinence 13% resolution of nocturnal enuresis	NR

Table 1. (Continued)

Authors	Date published	Indication for SNM	Included patients with neurologic conditions?	Number of patients	Mean age (years)	Median follow-up (months)	Percentage of patients that had permanent generator implanted	Clinical outcome	Changes in medication use
Stephany et al.	2013	NLUTD	No	14	10.0	6.0	100%	30% resolution of urinary urgency 40% resolution of urinary retention; significant decrease in CIC frequency from 5.2/day to 2.0/day 67% resolution in fecal incontinence Significant improvement in DES symptoms on validated questionnaires Significant improvement in QOL on validated questionnaires	NE
Dwyer et al.	2014	DES	No	105	8.8	32.6	98%	88% improvement (41% resolution) in urinary incontinence 66% improvement (28% resolution) in nocturnal enuresis 67% improvement (28% resolution) in urinary urgency/frequency 79% improvement (40% resolution) in constipation Significant improvement in DES symptoms on validated questionnaires	88% able to stop bladder-related medications; 71% able to stop laxatives
Sulkowski et al.	2015	BBD	Yes	29	12.1	4.1	100%	Significant improvement in QOL on validated questionnaires 85% improvement in constipation; 46% able to stop cecostomy flushes 65% improvement (20% resolution) in urinary incontinence 15% resolution in enuresis 100% improvement (25% resolution) in urinary retention 63% improvement in fecal incontinence Significantly fewer uninhibited detrusor contractions on UDS Significant improvement in DES symptoms on validated questionnaires	91% able to stop anticholinergics
Schober et al.	2015	BBD	Yes	26	10.8	14.0	100%	Significant improvement in QOL on validated questionnaires 85% improvement in constipation; 46% able to stop cecostomy flushes 65% improvement (20% resolution) in urinary incontinence 15% resolution in enuresis 100% improvement (25% resolution) in urinary retention 63% improvement in fecal incontinence Significantly fewer uninhibited detrusor contractions on UDS Significant improvement in DES symptoms on validated questionnaires	48% able to stop bladder-related medications; Mean # of medications significantly decreased from 2 to 0.65
Mason et al.	2016	BBD	No	30	8.3	14.8	100%	Significant improvement in QOL on validated questionnaires 90%	100% able to stop anticholinergics
van der Witt et al.	2016	Refractory	functional constipation	No	30	16.0	22.1	Significant improvement in QOL on validated questionnaires	Significant increase in mean defecation frequency from 2.0/week to 5.8/week

Table 1. (Continued)

Authors	Date published	Indication for SNM	Included patients with neurologic conditions?	Number of patients	Mean age (years)	Median follow-up (months)	Percentage of patients that had permanent generator implanted	Clinical outcome	Changes in medication use
67% able to stop Refractory			constipation requiring ACE	Yes	22	12.0	18.0	laxatives/enemas 100%	Lu et al. Significant decrease in weekly frequency of ACE use from 7 /week to 1/week 45% of patients had their cecostomy or appendicostomy closed
No significant decrease in oral laxatives overtime									
Fuchs et al.	2017	BBD	NR	63	11.5	22.8	100%	Clinical outcomes not reported; complication rates only Found no association between low BMI and lead complications	NR

DES dysfunctional elimination syndrome, *MLUTD* non-neurogenic lower urinary tract dysfunction, *BBD* bowel and bladder dysfunction, *ACE* antegrade continence enemas, *UDS* urodynamic studies, *QOL* quality of life, *BMI* body mass index, *NR* not recorded

Urinary

Incontinence

Six studies reported their rates of improvement and resolution in urinary incontinence [3–5, 7, 9••, 11•]. Rates of improvement in urinary incontinence were fairly similar across studies and ranged from 65 to 88%. Reported rates of complete resolution of urinary incontinence were highly variable, ranging from 16 to 75%; the largest series of 105 patients reported resolution rates of 41% [9••]. One study reported a significant decrease in the mean weekly frequency of incontinence episodes, improving from 23.2 episodes per week to 1.3 episodes per week [7].

Nocturnal enuresis

Five publications reported rates of improvement and resolution in nocturnal enuresis [3, 4, 7, 9••, 11•]. As with many treatment modalities for enuresis, success rates were not quite as high as for urinary incontinence, with improvement rates reported from 66 to 69% and resolution rates of only 13–38%.

Urinary frequency/urgency

Four studies reported their outcomes for urinary frequency and urgency [3, 4, 7, 9••]. Rates of improvement in these symptoms ranged from 67 to 89%, with resolution rates similarly variable to urinary incontinence, reported from 28 to 78%.

Urinary retention

Four articles reported the results of SNM as a therapy for urinary retention [3, 4, 7, 11•]. Twenty-five to 100% percent of patients were able to decrease the frequency of CIC, and 25–40% were able to stop CIC entirely. One publication reported a significant decrease in mean post-void residual (PVR) from 765 mL pre-operatively to 236 mL post-operatively [11•].

Urodynamic findings

Three publications reported on urodynamic study (UDS) findings pre- and post-SNM [2, 5, 11•]. Two studies reported a significant increase in bladder capacity with SNM. One study reported a significant increase in bladder compliance, and two studies found that SNM significantly decreased detrusor overactivity on UDS.

Medication use

The majority of the reviewed studies allowed patients to remain on bladder- and bowel-related medications, such as anticholinergics, laxatives, and enemas, during the study period. Six studies reported on changes in the use of bladder-related medications after SNM [3, 4, 9••, 10, 11•, 12•]. Thirty to 100% of patients were able to stop all bladder-related medications, with the largest study of 105 patients reporting a discontinuation rate of 88% (8). Two studies reported a

67% decrease in the mean number of bladder-related medications used per patient [3, 11•].

Validated questionnaires

Four studies reported their results as changes between pre- and post-operative scores on validated questionnaires [8, 10, 11•, 12•]; all of these studies included the Vancouver NLUTD/DES questionnaire [19]. All four studies found significant improvement in symptom scores on this questionnaire after SNM therapy. Only one of the four studies specified at what time point the post-operative questionnaires were performed (Stephany et al. [8]—1 month post-operatively).

Bowel

Constipation

Four publications reported their results on rates of improvement and resolution in constipation [3, 4, 9••, 10]. Rates of improvement in constipation were reported between 70 and 85%, with resolution rates reported at 40–46%. Two studies reported a significant increase in the frequency of defecation per week [6, 13], with one reporting an improvement in frequency of weekly bowel movements from 1.5 to 4.8, and the other reporting an improvement from 2.0 to 5.8.

Encopresis

Three studies reported the impact of SNM on fecal incontinence [5, 7, 11•]. Improvement rates ranged from 63 to 78%. One study reported a resolution rate of 67%, albeit in a population of only three patients [7].

Laxative/enema use

Four studies reported on changes in the use of enemas and laxatives after SNM [6, 9••, 13, 14]. Sixty-seven to 75% of patients were able to stop all laxatives, and 45–75% of patients were able to stop using enemas. One study reported specifically on patients that had an appendicostomy or cecostomy for antegrade continence enemas; 46% of these patients were able to have their appendicostomy or cecostomy surgically closed after therapy with SNM [14].

Validated questionnaires

Three studies reported their results as changes in pre- and post-operative scores on constipation-specific validated questionnaires [6, 10, 13]; the questionnaires utilized varied across studies. All three studies found significant improvement in symptom scores on these questionnaires after SNM therapy.

Quality of life

Three publications reported on quality of life after SNM therapy [8, 10, 12•] using validated questionnaires, which again varied across studies. All of these studies reported significant improvement in quality of life after placement of SNM by patient report.

Complications

A summary of the operative complication rates for each study can be found in Table 2. Overall reoperation rates ranged from 14.3 to 53.3% (median 23.2%). A significant positive correlation between length of follow-up and overall reoperative rate was found ($r = 0.738$, $p = 0.006$); this is demonstrated in Fig. 1. Infection rates requiring reoperation were reported between 0 and 18.2% (median 6.0%). Permanent device explantation rates secondary to complications or lack of efficacy ranged from 0 to 36.9% (median 3.8%).

Discussion

The literature demonstrates that SNM is an efficacious treatment for bowel and bladder dysfunction refractory to conservative management in children, improving both symptoms and quality of life. However, SNM use in children presents a unique set of challenges and concerns compared to adult patients.

One potential concern is the inevitable growth of young children with time; it is currently unclear how growth impacts device function. One small study of four pediatric patients found that three patients who had initial success with SNM later had device malfunction that was associated with a mean somatic growth of 8.1 cm; all underwent surgical revision and had return of efficacy after revision [20]. Our review found a greater incidence of re-operative complications, which primarily involved lead or generator revision, with a longer follow-up time. We theorize that this could be at least partially attributed to the growth of the patient over time.

In addition, there may be challenges with placement of a device into a generally smaller-sized pediatric patient. Placement of the lead into a location that allows for good stimulation at all locations on the lead may be more technically challenging in a younger patient than in a larger adult patient. In addition, lead breakage was a frequently reported cause of lead revision in the reviewed studies. Stephany et al. found a higher rate of lead complications in patients with a lower body mass index (BMI) and suggested that the lack of adipose tissue protecting the lead could increase the risk of lead breakage [8]. Pain over the generator site was a frequently reported cause of generator revision in the reviewed studies, which may also be due to lack of adipose tissue cushioning the generator. However, Fuchs et al. analyzed risk factors for complications with SNM and did not find a significant association between BMI and re-operative complications [15•], so the relationship between these factors remains unclear and merits further study.

Furthermore, dysfunction of urination and fecal elimination is quite frequently secondary to a neurologic condition in the pediatric population, and the effect of SNM in this population remains unclear. Five of the reviewed studies did include patients with neurologic conditions, but frequently the differences in response between patients with neurogenic and non-neurogenic voiding dysfunction were not reported. Groen et al. reported that only 40% of their patients with neurologic conditions had improvement in any symptoms, and the remaining 60% had their device explanted due to treatment failure [7]. In contrast, Guys et al. included only patients with neurogenic bladder in their study, and did demonstrate significant improvement in urodynamic parameters with SNM [2]. Certainly, anatomic abnormalities of the lower spinal cord and

Table 2. Complication rates with SNM

Authors	Date published	Number of patients	Median follow up (months)	Overall reoperation rate	Infection rate	Lead revision rate	IPG/device revision rate	Permanent explanation rate
Guys et al.	2004	21	NR	14.3%	4.8%	4.8%	4.8%	0%
Humphreys et al.	2006	23	13.3	14.3%	0%	4.8%	9.6%	0%
Roth et al.	2008	20	27.0	20.0%	5.0%	10.0%	5.0%	5.0%
Haddad et al.	2010	33	NR	18.2%	12.1%	6.1%	0%	12.1%
van Wunnik et al.	2012	13	7.3	25.0%	0%	8.3%	16.7%	0%
Groen et al.	2012	18	28.8	53.3%	13.3%	0%	13.3%	26.7%
Stephany et al.	2013	14	6.0	14.3%	0%	14.3%	7.1%	0%
Dwyer et al.	2014	105	32.6	48.5%	8.7%	NR	41.7%	36.9%
Sulkowski et al.	2015	29	4.1	17.2%	6.9%	0%	6.9%	3.4%
Schober et al.	2015	26	14.0	23.1%	7.7%	11.5%	7.7%	3.8%
Mason et al.	2016	30	14.8	23.3%	0%	23.0%	3.3%	3.3%
van der Witt et al.	2016	30	22.1	44.0%	3.7%	22.2%	18.5%	22.2%
Lu et al.	2017	22	18.0	27.3%	18.2%	0%	4.5%	9.1%
Fuchs et al.	2017	63	22.8	25.4%	7.9%	17.5%	0%	NR

IPG implantable pulse generator, NR not recorded

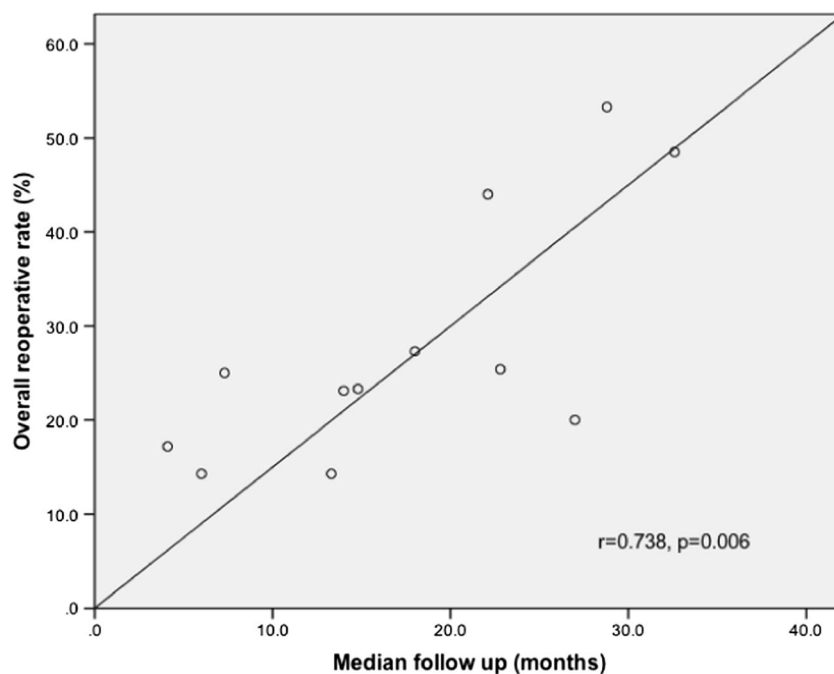


Fig. 1. Relationship between length of follow-up and reoperation rates.

sacrum remain contraindications for sacral neuromodulation, as safe and correct lead placement would not be possible in these patients. However, there has been a report of successful placement of the SNM lead adjacent to the pudendal nerve root in a pediatric patient with caudal regression and partial sacral agenesis with good results [21]. This lead placement location warrants further investigation as an option for patients with abnormalities of the lower spinal cord and sacrum.

A final concern regarding SNM use in children is the placement of a permanent device into a patient that could possibly outgrow their symptoms. Roth et al. offered all of their patients who had at least 12 months of symptom relief a trial of device deactivation; 10% of these patients did not experience a return of symptoms and subsequently had their devices explanted [4]. It is unclear if this finding is related to the child outgrowing their symptoms or simply imperfect patient selection.

Because of these challenges and concerns, patient selection in the pediatric population is paramount. A thorough medical history, physical exam, and other indicated testing should be done to rule out correctable etiologies for the child's symptoms. Finally, the child and family should be extensively counseled regarding the risks and benefits of the SNM procedure, with particular emphasis on the possible need for reoperation, as this risk increases with time.

Conclusion

Sacral neuromodulation is an effective treatment for refractory bowel and bladder dysfunction in the carefully selected child. Studies have demonstrated

not only safety similar to that of adults but also high rates of improvement in both urinary and bowel symptoms, a decrease in the number of patients requiring pharmacotherapy, and improvement in quality of life. The most important reported complication is reoperation, which tends to increase with longer length of follow-up. Although SNM is not yet FDA-approved for children under the age of 16, it is likely that its acceptance and usage will increase as more literature on its use in the pediatric population continues to emerge.

Compliance with Ethical Standards

Conflict of Interest

Kristin M. Ebert declares that she has no conflict of interest. Seth A. Alpert declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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