# Prospective Evaluation of Sacral Neuromodulation in Children: Outcomes and Urodynamic Predictors of Success

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**Purpose:** Sacral neuromodulation has been demonstrated to improve refractory bowel bladder dysfunction in children. The purpose of the current study was to determine whether results are durable in children after longer followup, whether children with a lower body mass index are at risk for device failure and whether pretreatment urodynamic evaluation can predict posttreatment outcome.

**Materials and Methods:** Pediatric patients with refractory bowel bladder dysfunction were enrolled following informed consent and followed prospectively. All patients underwent preoperative videourodynamic evaluation and a 2-stage implantation procedure. Validated questionnaires were used to assess symptom severity and quality of life. Complications were analyzed with regard to treatment required and patient body mass index.

**Results:** During 45 months 30 patients were enrolled. Median age was 8.3 years at enrollment. Median followup was 14.8 months. Patients had significant improvement in quality of life and symptom scores, which persisted at the most recent followup. Patients who had uninhibited detrusor contractions on preoperative urodynamic assessment had significantly greater improvement in symptoms. Of the patients 23% had a complication requiring reoperation, most commonly neurostimulator lead breakage in those with a significantly lower body mass index.

**Conclusions:** Sacral neuromodulation significantly improves quality of life and symptom severity in children with refractory bowel bladder dysfunction. Children gain greater benefit if they show uninhibited bladder contractions on preoperative urodynamic evaluation. Children have a high rate of lead breakage requiring operative revision, which was seen after minor trauma in those with a lower body mass index.

**Key Words:** urinary bladder, electric stimulation, lower urinary tract symptoms, quality of life, questionnaires

**Abbreviations and Acronyms**

BBD = bowel bladder dysfunction

BMI = body mass index

FDA = Food and Drug Administration

MRI = magnetic resonance imaging

QOL = quality of life

SNM = sacral neuromodulation

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Sacral neuromodulation is approved by the FDA for the treatment of urinary and fecal symptoms in adults. Many studies have demonstrated the efficacy of SNM in adults but few groups have investigated SNM in children. Studies of SNM in children with nonneurogenic BBD have shown promising results with improvement in symptoms and subjective assessment of patient satisfaction but significantly high rates of reoperation estimated at 11% to 56%.[1–5]

Our group has previously reported our results of SNM in children with refractory BBD using validated

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questionnaires to assess the severity of BBD and patient QOL.[6] The purpose of the current study was to determine whether SNM results are durable in children after longer followup, whether children with a lower BMI are at risk for device failure and whether pretreatment urodynamic evaluation can predict posttreatment outcome.

## METHODS

### Patient Population

After receiving approval from our institutional review board (No. 140834) we identified patients eligible for SNM. Inclusion criteria were age at least 5 years and BBD refractory to conservative measures, including behavioral and dietary modification, treatment of constipation, medical therapy (including anticholinergics or α-blockers) and pelvic floor rehabilitation with biofeedback when indicated. All patients underwent preoperative multichannel videourodynamic evaluation. Spinal MRI was performed in any patient with concern of neurological etiology (coexisting significant bowel symptoms or lower extremity dysfunction). All patients were counseled that SNM treatment in children is still considered investigational and it is not FDA approved. All families participating in the study provided written informed consent and were followed prospectively. BMI calculations were performed using height and weight measurements recorded on the day of the stage 1 SNM procedure.

### Operative Procedure

All patients underwent 2-stage implantation of an InterStim II® SNM device. At stage 1 patients under general anesthesia underwent placement of a tined quadripolar stimulator lead under fluoroscopic guidance. The bellows response and great toe flexion were observed to ensure appropriate unilateral stimulation of the S3 nerve. Patients were sent home the same day with an external pulse generator. After a 1-week trial period patients underwent placement of an implantable pulse generator if they reported improved symptoms, satisfaction with treatment and no significant side effects, and elected to proceed.

### Outcome Assessment

We used 2 previously validated questionnaires, including the Vancouver NLUTD/DES (Nonneurogenic Lower Urinary Tract Dysfunction/Dysfunctional Elimination Syndrome) questionnaire to assess BBD severity and the PedsQL™ 4.0 generic core scales to assess QOL.[7,8] The Vancouver NLUTD/DES questionnaire contains 14 Likert scale questions, each scored from 0 to 4. Ten questions address urinary symptoms, 3 address bowel symptoms and the final question addresses the ease of answering the questionnaire with the latter not included in the symptom score. A total score of 0 to 52 is possible, a score of at least 11 indicates BBD and higher scores indicate worse symptoms. The PedsQL questionnaire consists of 23 Likert scale questions, each scored from 0 to 4. The questions assess physical, emotional, social and school related elements of QOL. The questionnaire provides a physical QOL score, a psychosocial QOL score and a total QOL score, each ranging from 0 to 100 with higher scores indicating better QOL. Patients completed these questionnaires before the stage 1 SNM procedure, 1 week after the stage 1 procedure and at every subsequent followup visit.

Medication use before and after SNM treatment was recorded as use or nonuse of daily antibiotic prophylaxis and use or nonuse of anticholinergics and/or α-blockers. Patients were not instructed to discontinue use of these medications at the time of SNM but rather were allowed to discontinue use after sufficient symptom improvement. Complications after SNM were analyzed with specific attention given to complications requiring operative intervention. BMI in patients with a complication related to device breakage was compared to BMI in the remainder of the cohort.

An estimate of the number of initial visits for BBD at our pediatric urology clinic during the study period was obtained by querying our institutional administrative billing database for ICD-9 codes, including 596.59 (other bladder dysfunction), 788.1 (dysuria), 788.21 (incomplete bladder emptying), 788.30 (urinary incontinence not otherwise specified), 788.36 (nocturnal enuresis), 788.41 (urinary frequency), 788.63 (urgency of urination), 788.31 (urge incontinence) and 788.64 (urinary hesitancy).

All data were managed using REDCap (Research Electronic Data Capture) tools hosted at our institution.[9] REDCap is a secure, web based application designed to support data capture for research studies.

### Statistical Analyses

Statistical analyses were performed using Prism® 6 for Windows®. Total questionnaire scores, domain questionnaire scores and individual question responses were compared preoperatively, after the stage 1 procedure and at followup using repeated measures 1-way ANOVA. Questionnaire score improvement in patient groups with or without specific urodynamic findings as well as the BMI of patient groups with or without specific complications were compared using the unpaired t-test and the Welch correction with $p < 0.05$ considered statistically significant.

## RESULTS

From July 2011 to April 2015 approximately 8,000 new patients were seen for a BBD diagnosis at our pediatric urology clinic, of whom 24 females and 6 males were prospectively enrolled in the study during this time frame. Median age at study enrollment was 8.3 years (range 5.5 to 17.4, IQR 7.2–12.6). Patients had a median of 7 clinic visits during 27 months before proceeding to SNM. Spinal MRI was performed in 21 patients (70%) and revealed no relevant findings. No patients were excluded from study due to MRI findings. All patients met inclusion criteria and all enrolled in the study underwent the stage 2 procedure with implantation of the internal pulse generator. Median followup was 14.8 months (IQR 4.7–21.0).