Sacral Nerve Stimulator Revision Due to Somatic Growth

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Abbreviations and Acronyms

DES = dysfunctional elimination syndrome

IPG = implantable pulse generator

SNM = sacral nerve modulation

Study received Stanford University institutional review board approval.

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Purpose: Sacral nerve modulation is a Food and Drug Administration approved treatment for refractory urgency, frequency, urge incontinence and nonobstructive urinary retention in adults. The sparse literature on sacral nerve modulation in children focuses on its initial efficacy in patients with neurogenic bladder and dysfunctional elimination. We describe our initial experience with sacral nerve modulation and the phenomenon of growth spurts associated with lead malfunction that necessitates revision.

Materials and Methods: After receiving institutional review board approval we retrospectively reviewed the charts of pediatric patients who underwent sacral nerve modulation surgery at our institution. Charts were examined for patient demographics, subjective success, the need for further surgery and success after revision.

Results: Four patients underwent sacral nerve modulation at an average age of 12.1 years. All patients reported initial success, defined as greater than 50% symptom improvement. Subsequently 3 patients required a total of 5 revisions due to lead malfunction with an average of 1.5 years between surgeries. In those requiring revision the average somatic growth between revisions was 8.1 cm. Return of efficacy was reported after each revision. All patients had functioning nerve stimulators in place and continued to have a positive subjective response.

Conclusions: The sparse data on sacral nerve modulation in children shows efficacy and safety similar to those in adults. Somatic growth may be associated with lead malfunction and require surgical revision. We report a small series showing that revision can be done successfully and safely. Informed consent for sacral nerve modulation in pediatric patients should include a discussion of somatic growth as a possible cause of lead malfunction necessitating revision.

Key Words: urinary bladder, urination disorders, child development, electric stimulation, prostheses and implants

SACRAL nerve modulation is a Food and Drug Administration approved treatment for refractory urgency, frequency, urge incontinence and urinary retention in adults.[1] While SNM is well established in adults, it is less frequently used in pediatric populations due to concerns over the long-term effects of nerve stimulation on bladder development, the risk of infection in the lead or generator and the possibility of lead migration with somatic growth. The published revision rate in adults is 5% to 16%.[2,3] There is a relative paucity of publications on SNM in children. Published studies show short-term safety and promising efficacy.[4–7]

In our practice we have selectively used SNM in cases refractory to behavioral and pharmacological therapy. Since we noted that lead mal-

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function required revision after growth spurts, we quantified the relationship between somatic growth and the need for lead revision in our SNM population.

METHODS AND MATERIALS

After receiving Stanford University institutional review board approval we retrospectively reviewed charts to identify pediatric patients, defined as those younger than 19 years, who underwent SNM surgery at Lucile Packard Children's Hospital, Stanford, California. Charts were examined and data were extracted on diagnoses, height, weight, age, dates of surgery and revisions, cause of failure and subjective success. Descriptive statistics and graphing were done using Excel®.

SNM was performed using the InterStim™ II 33 cm Model 3093 tined lead stimulator and Model 3058 battery. Stage 1 was done by intubating the S3 foramen and confirming correct placement under fluoroscopic guidance. Test stimulation revealed great toe flexion ipsilaterally and the bellows response. Sensation was not assessed with the patient under general anesthesia. The stylette was advanced and a dilator was passed over it. A tined lead was passed through the dilator and positioned under fluoroscopic guidance with a maximal number of electrodes to provide the motor response, typically with the large lead 1 straddling the anterior aspect of the bone at S3. The dilator was removed while maintaining the lead in position. The lead was tunneled laterally to the left gluteal region without tension and connected to the extension cable, which was tunneled medially out through the skin.

After confirming greater than 50% improvement in symptoms based on voiding diaries the permanent generator was placed at the stage 2 procedure. The left buttock incision was reopened and a pocket was created for the IPG. The extension cable was detached and removed in sterile fashion. The lead was connected to the IPG in a tension-free manner. When lead removal was required, we applied pressure to the lead from the left gluteal incision. If it did not release easily, we made an additional incision at the initial sacral access point and gently applied pressure to the lead from this position.

RESULTS

We identified 2 male and 2 female patients who underwent SNM placement at our institution between August 2007 and June 2010. In all patients behavioral therapy had failed alone and in conjunction with pharmacological therapy. Pharmacological therapy failure was due to a lack of efficacy or to medicine side effects.

In all patients urodynamics were performed preoperatively. Urodynamics revealed small capacity/significant uninhibited contractions leading to incontinence, detrusor sphincter dyssynergia/urge incontinence, overactivity/detrusor instability and overactivity in 1 patient each.

Surgery was performed by a pediatric urologist (WK) and an adult urologist trained in SNM (CVC or RA). Initial consultations were done at an average age of 9.8 years (range 6.7 to 12.0) with an average of 2.3 years of treatment (range 0.5 to 5.3) before SNM placement. The table shows patient age and diagnosis at initial placement. Mean age at initial placement was 12.1 years (range 11 to 13.2). Mean height was 151.5 cm (range 147 to 159.5) and mean weight was 50.4 kg (range 36.3 to 68.7). Mean followup since initial implantation was 2.5 years (range 1.1 to 3.6) and mean followup since the most recent surgery was 0.7 years (range 0.3 to 1.1).

There were no perioperative complications of initial placement and all patients reported greater than 50% improvement in symptoms based on voiding diaries and subjective reports. When the condition was present preoperatively, improvement was seen in frequency, urge incontinence, nocturnal enuresis and voided volume. We also noted a significant decrease in pain in our patient with chronic pelvic pain. These improved parameters were maintained until device malfunction. No adequate data were available in this retrospective study to evaluate changes in bowel function. No urodynamics were performed after SNM in these patients since invasive testing was not indicated after clinical improvement and urodynamics would not have changed management if the loss of efficacy was associated with lead or IPG malfunction.

Three of the 4 patients (75%) required lead revision due to malfunction, which presented as return to the level of symptoms before SNM. Mean time to failure after initial placement was 1.1 years (range 0.2 to 2.4). Lead revision was often noted to occur after growth spurts. When eliminating 2 procedures involving IPG adjustment exclusively, mean somatic growth between lead revisions was 8.1 cm (range 4 to 12.5) and the mean weight change was 5.8 kg (range 1.6 to 7.6). Mean time between lead revisions was 1.5 years (range 0.7 to 2.8).

A total of 13 leads were placed, including 9 on the left and 4 on the right side. All IPGs were placed in the left gluteal region. Preoperatively interrogation confirmed high impedance (values not recorded), consistent with the lead as the cause of device malfunction, in all cases in which the lead was revised. All leads were intact on fluoroscopy at revision, although 1 was noted to have a small, distal injury after removal. Fluoroscopy at revision confirmed

Patient data at initial implantation

Pt No.—Sex—Age (yrs)	Diagnoses
1—M —11.0	Urgency, urge incontinence
2—M —12.0	Low capacity bladder, detrusor-sphincter dyssynergia, incontinence
3—F —12.5	Chronic pelvic pain/spasms, overactive bladder
4—F —13.2	Urgency, frequency, urge incontinence