Long-Term Outcome and Surgical Interventions After Sacral Neuromodulation Implant for Lower Urinary Tract Symptoms: 14-Year Experience at 1 Center

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Purpose: Few reports address the reoperation rate after sacral neuromodulation implants. We report our long-term results and reoperations during our 14-year experience with sacral neuromodulation at our center.

Materials and Methods: We retrospectively reviewed the patient database at our center to assess the long-term outcome, incidence and cause of surgical reintervention after InterStim® sacral neuromodulation implantation for lower urinary tract dysfunction between 1994 and 2008.

Results: A total of 96 sacral neuromodulation devices were implanted in 88 women and 8 men. Indications for implantation were bladder pain syndrome in 47.9% of cases, urgency urinary incontinence in 35.4% and idiopathic urinary retention in 16.7%. The explantation rate was 20.8% and median time to removal was 18.5 months. Reasons for explantation in all subgroups were poor result in 12 patients, painful stimulation in 6 and radiation of stimulation to the leg in 2. Median long-term followup was 50.7 months. The long-term success rate was 87.5%, 84.8% and 73% in patients with idiopathic urinary retention, urgency urinary incontinence and bladder pain syndrome, respectively. Overall 39% of patients needed revision of the sacral neuromodulation implant. The main reason for revision was loss of stimulation in 58.5% of cases. The revision rate decreased with the introduction of the tined lead technique from 50% using lead Model 3092 to 31% using lead Model 3893 (Medtronic, Minneapolis, Minnesota). The battery was changed in 8 patients. Mean battery life was 101.8 months.

Conclusions: Sacral neuromodulation is a minimally invasive procedure with a good long-term outcome. The reoperation rate has improved with advances in surgical technique and equipment.

Key Words: urinary bladder; pain; urinary incontinence, urge; electric stimulation; prostheses and implants

Abbreviations and Acronyms

BPS = bladder pain syndrome

FDA = Food and Drug Administration

GRA = global response assessment scale

IPG = implanted pulse generator

IUR = idiopathic urinary retention

PNE = percutaneous nerve evaluation

SNM = sacral neuromodulation

UUI = urgency urinary incontinence

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Study received institutional ethics board approval.

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THE concept of sacral nerve stimulation was introduced in 1979 by Schmidt et al.[1] Currently SNM is approved by the United States FDA for refractory UUI, urinary frequency/urgency syndrome and nonobstructive IUR.[2] SNM is also approved in other countries.

Several studies show the safety and efficacy of SNM at short-term and medium term followup but SNM remains expensive with the additional costs of reoperation, revision and battery exchanges.[3] Thus, it is important to review SNM long-term outcomes and revision rates. We re-

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viewed our experience with SNM during the last 14 years.

MATERIALS AND METHODS

We retrospectively studied the records of all patients at our department who underwent permanent InterStim SNM implantation from 1994 to 2008. The study was approved by our institutional ethics board. Patient demographics were obtained, including age, gender and indications for SNM. Evaluation included medical history, physical examination, voiding diaries, urodynamic testing and cystoscopic examination. Indications for implantation were UUI, BPS and IUR. In all patients conservative and pharmacological treatment had failed. The BPS diagnosis was based on symptoms of chronic pelvic pain related to the bladder, in addition to signs of bladder glomerulations after bladder hydrodistention, as suggested by the European Society for the Study of Interstitial Cystitis.[4] In addition to the complaint of pain, patients with BPS had symptoms of frequency (100%), urgency (96%) or nocturia (94%). IUR was defined as the inability to void without an obvious anatomical or neurological cause. UUI was defined as the complaint of involuntary leakage accompanied by or immediately preceded by urgency.[5] A voiding diary was completed for 3 days before PNE and another was completed during the PNE test period.

Patients who showed 50% or greater improvement in GRA were scheduled to receive the permanent SNM implant. Initially up to November 2005 the lead was implanted using the open technique proposed by Schmidt et al.[6] Since December 2005, we have used a percutaneous approach with the tined lead.[7] The pulse generator was initially implanted in the lower abdomen but in 1999 this was changed to the upper, outer part of the buttock.[8] The usual stimulation parameters were amplitude 0.5 to 3 V, rate 14 to 16 Hz, width 210 to 240 μseconds and stimulus duration 5 seconds on/5 seconds off. Patients were routinely followed 3, 6 and 12 months postoperatively, and yearly thereafter. Some patients were seen more often, as clinically indicated.

Clinical success criteria were based on GRA by direct patient interview, consisting of 5 levels (see Appendix). If bother symptoms improved moderately (good outcome) and above according to GRA, the outcome was recorded as long-term success. In patients with IUR a 50% or greater decrease in the number of catheterizations was considered success. All adverse events, complications and surgical interventions were recorded and analyzed. Statistical analysis was done with SPSS®, version 17. ANOVA was used for metric variables across the different groups. Categorical variables were analyzed with the chi-square test. Statistical significance was considered at $p < 0.05$.

RESULTS

A total of 196 patients underwent PNE (table 1). Differences in the PNE success rate were not statistically significant by indication ($p = 0.07$). Despite the good PNE outcome 15 patients (7%) did not proceed with the permanent implant.

Table 1. *Patient demographics and urodynamic results*

Variable	BPS	UUI	IUR
No. pts (%)	78 (39.7)	77 (39.2)	41 (20.9)
Age	42.38	54.48	43.9
No. gender (%):			
F	70 (89)	70 (91)	27 (66)
M	8 (11)	7 (9)	14 (34)
Mean ± SD max flow (ml/sec)	12.3 ± 7.3	13.87 ± 9.1	3 ± 2.1
Mean ± SD voided vol (ml)	130.7 ± 95.18	203 ± 124.8	41 ± 23
Mean ± SD post-void residual urine (ml)	54 ± 77.44	86 ± 80.2	326.5 ± 231
Mean ± SD 1st bladder filling sensation (ml)	92.5 ± 67.38	207 ± 91.8	304.3 ± 156.3
Mean ± SD max cystometric capacity (ml)	165 ± 95	326.1 ± 140	450.8 ± 158.3
No. detrusor overactivity (%)	32 (41)	45 (58.4)	6 (14.6)
No. catheterization (range)	0	0	6 (4–8)
% PNE success	66	54.4	43.9

A total of 96 patients (49%) received a permanent SNM implant (table 2). Those with BPS and IUR were significantly younger than those with UUI (42.3, 43.9 and 54.4 years old, respectively, $p = 0.01$). The SNM lead was implanted using an open technique in 70 cases (72.9%) and using the newer percutaneous approach with a tined lead in the remaining 26 (27.1%). In 5 patients (5.2%) a staged approach was used due to technical difficulty during PNE.

Median long-term followup was 50.7 months (range 12 to 157). All patients completed at least 1 year of followup (fig. 1). Patients with a mild and fair response according to GRA had the device removed (see Appendix). The long-term success rate (good and good response) was 87.5% in IUR, 84.8% in UUI and 72% in BPS cases (table 2). Success rate differences among the groups were not statistically significant ($p = 0.6$). The severity of urgency was a good predictor of long-term success in the BPS group ($p = 0.027$).

The overall explantation rate was 20.8%. The rate was highest in the BPS group and lowest in the IUR group (28.3% vs 12.5%, table 2). Time to explantation was the briefest for BPS and this difference was statistically significant ($p = 0.002$, fig. 2). Indications for explantation were a poor result in 12 patients (12.5%), painful stimulation in 6 (6.25%) and radiation of stimulation to the leg despite lead revision in 2 (2%) (table 3). The explantation risk increased with increases in the revision rate from 13.2% in those with no revision to 30.2% in those with revision ($p = 0.04$).

A total of 41 reoperations were done in 30 patients for an overall 39% revision rate. The revision rate was the highest (56%) in the IUR group (table 2). The most common indication for revision was poor response (24 procedures or 58.5%). The second most common indication for revision was local pain from the IPG device