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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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

Table 2. *Long-term results by group and surgical intervention*

Variable	BPS	UUI	IUR	p Value
No. pts (%)	46 (48)	34 (35.4)	16 (16.7)	
Mean age	40.7	54.2	38.6	0.001
No. gender (%):				0.067
F	44 (95)	32 (94)	12 (75)	
M	2 (5)	2 (6)	4 (25)	
% SNM success	72	84.8	87.5	0.6
% Explantation	28	14.7	12.5	0.22
Mean time to explantation (mos)	15.1	41.5	58.2	0.002
% Revision	50	32	56	0.17
Mean time to revision (mos)	23.6	23.7	33.1	0.5
Mean No. battery exchanges	5	1	2	0.36
Mean battery durability (mos)	91	113	124	0.22

(box pain) in 7 procedures (17%). Other causes for revision included painful stimulation or radiation of stimulation toward the leg in 5 procedures each (each 12%) (table 3). Median time to revision was 26.5 months (table 2). Median time to revision based on adverse events was 13.1, 18.2, 26.9 and 40.9 months for IPG pain, painful stimulation, poor outcome and stimulation radiation to the leg, respectively ($p = 0.28$). The revision rate decreased from 50% using lead Model 3092 to 31% using tined lead Model lead 3893 ($p = 0.1$) with the introduction of the percutaneous technique. Median time to revision also increased from 15.76 months with old lead Model 3893 to 21 months with tined lead Model 3893 ($p = 0.4$).

The IPG battery had to be changed in 8 patients. Battery life was 90.8, 113 and 124 months (average ± SD 101.8 ± 23.4) in those with BPS, UUI and IUR, respectively ($p = 0.22$).

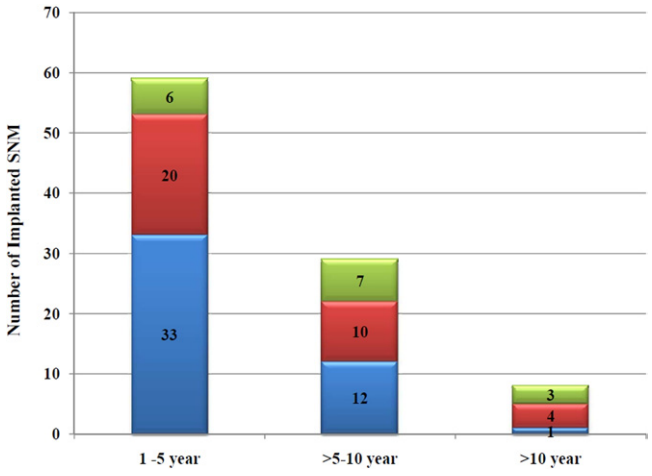

Figure 1. Average SNM followup after implantation by indication. Green bars indicate IUR. Red bars indicate UUR. Blue bars indicate BPS.

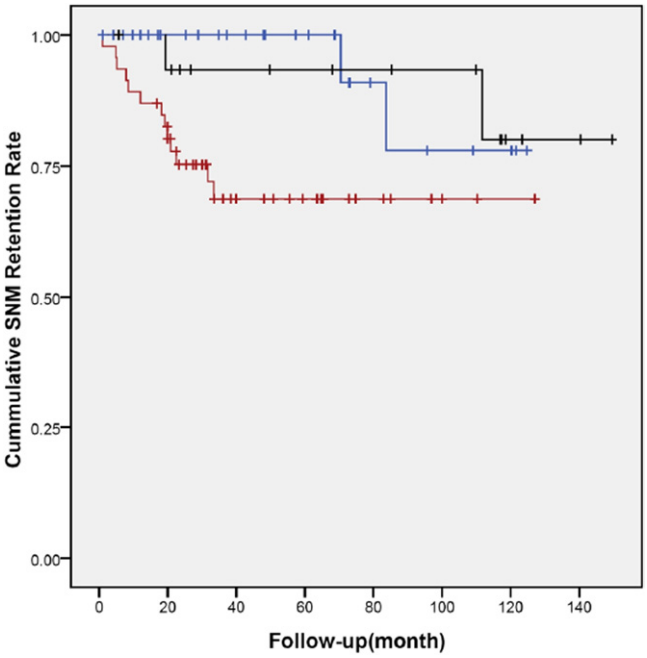

Figure 2. Kaplan-Meier graph of SNM retention rate. Blue curve indicates UUI. Red curve indicates BPS. Black curve indicates IUR.

DISCUSSION

Since SNM approval by the FDA in 1997, more than 60,000 patients have received an SNM implant worldwide.[9] It is hypothesized that SNM inhibits sacral interneuronal transmission and the afferent limb of the micturition reflex. In patients with IUR SNM induces the voiding reflex by interrupting the somatic excitatory outflow to the sphincter, interfering with the guarding reflex, halting voiding reflex inhibition and, thus, facilitating voiding.[10]

The screening phase through the PNE or the stage 1 of 2-stage implantation is still the most important step to select the most appropriate patient for a permanent implant. Our PNE results are similar to previously reported results at around a 50% success rate.[11] Younger age (39.2 vs 47.5 years) was a good predictor of PNE success in the IUR group. Scheepens et al found that intervertebral disk prolapse and UUI were positive predictors of PNE success while the duration of complaints and neurogenic bladder dysfunction were negative predictors of PNE success in patients with lower urinary tract dysfunction.[12] Cohen et al reported that the intraoperative motor response was the most important factor in PNE success.[13] Goh and Diokno noted that the ability to void greater than 50 cc and IUR duration were good predictors of PNE success.[14] In a multicenter, prospective, worldwide study 11 patients (7%) refused implantation despite successful screening,[15] which was similar to our finding.

Table 3. *Reasons for surgical intervention*

Reason	No. 1–5 Yrs		No. Greater Than 5–10 Yrs		No. Greater Than 10 Yrs		Total No. (%)	
	Removal	Revision	Removal	Revision	Removal	Revision	Removal	Revision
BPS:								
Symptom deterioration	9	5	0	6	0	0	9 (69)	11 (58)
Painful stimulation	3	2	0	0	0	0	3 (23)	2 (10.5)
IPG pain	0	3	0	1	0	0	0	4 (21)
Stimulation radiation to leg	1	1	0	1	0	0	1 (8)	2 (10.5)
UUI:								
Symptom deterioration	1	4	0	3	0	0	1 (20)	7 (64)
Painful stimulation	0	1	2	0	1	0	3 (60)	1 (9)
IPG pain	0	0	0	0	0	0	0	0
Stimulation radiation to leg	1	0	0	2	0	1	1 (20)	3 (27)
IUR:								
Symptom deterioration	1	1	1	0	0	5	2 (100)	6 (55)
Painful stimulation	0	0	0	1	0	1		2 (18)
IPG pain	0	0	0	1	0	0		1 (9)
Stimulation radiation to leg	0	1	0	1	0	0		2 (18)

More recent studies concluded that the staging technique would improve the pre-implantation success rate and eliminate false-positive results.[16] However, Washington and Hines recently reported that a staging procedure had a 13.5% infection rate compared to 6.1% for PNE.[17] There was no infection in our series. The staging technique was done electively in 10 patients at our center with a 50% success rate. However, it was done only in patients in whom there were technical difficulties during PNE or in those who could not tolerate the PNE procedure under local anesthesia.

Our long-term followup shows that a good outcome was maintained in most patients at a mean of 50.7 months. The highest success rate was in the IUR group but the difference was not statistically significant. Recently van Kerrebroeck et al reported the long-term results of SNM in a multicenter, worldwide clinical trial.[15] Of the patients 68% with UUI, 56% with urgency frequency and 71% with IUR had a successful outcome 5 years after implantation. van Voskuilen et al reported a good outcome in 59.7% of 149 patients at a mean followup of 5.3 years, including 71.8% with overactive bladder and 28.2% with IUR.[18] Of 41 patients Elhilali et al found that only the IUR group maintained the good long-term result (78%) while SNM failed in 52% of the frequency-urgency group at 78-month followup.[19] White et al followed 202 patients, including 55% with urgency frequency, 28.5% with UUI and 16.7% with IUR, for a mean of 36.7 months and reported an 85.1% success rate.[20]

Urgency was a good predictor of success in patients with BPS in our study. van Voskuilen et al found no positive predictive factors for definitive implant success.[18] Everaerdt et al noted that psychological factors have a role in year 1 after SNM implantation.[21] Age less than 55 years or fewer than 3 chronic conditions was associated with a good outcome in patients with UUI.[22]

The 20% explantation rate in our study was higher than the 8.5% to 14% in previous reports.[18,23,24] There were no differences in operative technique, age or gender that may underlie the differences in the explantation rate. However, the explantation risk increased with an increase in the revision rate. In a recent study of 214 patients implanted between 2002 and 2004 Hijaz et al observed that 10.5% required explantation.[23] Indications for implant removal were infection in 5% of cases and implant failure to maintain function in 5.5%. Blendon et al found that followup was the best predictor of revision or explantation.[24] Our study shows that the highest explantation rate and the shortest time to explantation were in patients with BPS. This difference was statistically significant. However, 72% of patients in this group were satisfied with the outcome and they retained the device at a mean followup of 52 months. Loss of efficacy was the commonest reason for explantation in the studies by van Voskuilen[18] and Hijaz[23] et al (85% and 52%, respectively).

There were 41 surgical re-interventions in a total of 30 patients (39%), consistent with long-term results in worldwide clinical studies of SNM.[3,15] van Kerrebroeck et al reported on a total of 152 patients implanted with InterStim at 17 centers worldwide.[15] At 5-year followup 39.5% of patients experienced adverse events that required surgical intervention, including device exchange in 23.7%, implant revision in 14.5% and lead repositioning in 13.1%. The surgical intervention rate in our study is lower than the 48% in the series by van Voskuilen et al in 149

patients with SNM at a mean followup of 64.2 months.[18] Those investigators linked this high reoperation rate to a considerable learning curve in patient selection and equipment still under development. A similar higher reoperation rate was reported by Datta,[25] Dasgupta[26] and Elhilali[19] et al (53%, 53% and 44%, respectively).

In our study the reoperation rate in patients implanted with the fascial anchoring lead was 50%, higher than the 31% in patients implanted with the tined lead. The availability of the tined self-anchoring quadripolar lead allows a minimally invasive procedure and decreases operative time, postoperative adverse effects and lead migration.[27] A similar decrease in the reoperation rate was reported around 1994 when the new electrode became available. In the study by van Voskuilen et al the mean number of reoperations was 1.56 in patients implanted between 1990 and 1995, which decreased to a mean of 0.49 in those implanted between 1995 and 2003.[18] Sutherland et al reported differences in success and adverse events depending on implanted lead type in 104 patients at a mean 22-month followup.[28] The nontined lead had a 3 times poorer outcome and more complications than the tined lead (74% vs 28%). However, more long-term studies are needed to confirm the advantages of the tined lead.

Loss of efficacy was the most common reason for reoperation (58.5% of cases). This was also a finding in the long-term reports by van Voskuilen[18] and Hijaz[23] et al. However, it is unclear why patients lose the positive response with time despite SNM reprogramming. In some cases repositioning the lead, replacing the extension cord or replacing the pulse generator can help regain SNM efficacy. X-ray can facilitate assessing lead migration and evaluating impedance can detect a system short circuit.[23]

The second most common indication for re-intervention was IPG related pain (17% of cases). In a worldwide clinical study van Kerrebroeck et al found this problem in 7.9% of patients.[15] White et al reported a higher incidence (17.4%) and found that it is 1 of the predictors of an adverse event.[20] Relocating the SNM pulse generator from the lower abdomen to the upper buttock has shortened operative time, decreased the reoperation rate and decreased the incidence of pain at the device site from 42% to 16%.[13] On the other hand, Dasgupta et al reported less IPG related pain when the implant was located in the abdomen compared to the buttock site (2 of 17 vs 4 of 9 cases).[26]

Interstim II was approved by the FDA in 2006.[29] It is 50% lighter, the incision for implantation is 3.5 cm shorter and the whole surgery is shortened by 10 minutes.[30] In our opinion the learning curve of the surgical technique may not be long but gaining experience with patient evaluation and complication management is a more lengthy process.

The mean durability of the IPG battery in our study was 101.8 months. It was shortest in the BPS group (91 months). The higher voltage use in this group may explain this difference. Reported battery durability in 68 women with IUR was 7 to 10 years.[26] In patients with overactive bladder mean durability of the battery was 73.7 months.[18] To our knowledge no report discusses the effect of different stimulation settings on battery life. In our study patients with IUR seemed to have the longest battery life. It is unclear whether increasing the cycle spacing of the SNM stimulus can increase battery life.

CONCLUSIONS

This study shows that SNM produces long lasting, sustained, subjective improvement in patient symptoms. Although the reoperation rate was high, it improved with advances in surgical technique and equipment.

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APPENDIX

GRA

Response	Grade (%)	Therapy Outcome
Unchanged	0	Failure
Mild improvement	Greater than 0–24	Failure
Fair improvement	Greater than 25–49	Failure
Good outcome	Greater than 50–74	Success
Very good outcome	Greater than 75–100	Success

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