Sacral Neuromodulation as Treatment for Refractory Idiopathic Urge Urinary Incontinence: 5-Year Results of a Longitudinal Study in 60 Women

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Abbreviations and Acronyms

INS = implantable neurostimulator

LOCF = last observation carried forward

OAB = overactive bladder

PNE = percutaneous nerve evaluation

SNS = sacral nerve stimulation

UUI = urge urinary incontinence

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Purpose: We evaluated the results of sacral neuromodulation after 5-year followup in women with refractory idiopathic urge urinary incontinence.

Materials and Methods: A neuromodulation system with an original (nontined) lead was implanted by open surgery after a positive percutaneous nerve evaluation in 60 women from 1990 to 2004. Voiding incontinence diary parameters were used to evaluate efficacy. Success was defined as at least a 50% decrease in the number of incontinence episodes or pads used daily. Safety was also evaluated.

Results: The success rate gradually decreased from 52 patients (87%) at 1 month to 37 (62%) at 5 years. Complete continence persisted in 15% of patients. The system was still used by 80% of patients at 5 years. In 32 patients a total of 57 adverse events occurred, which were not severe (Clavien grade I and IIIb in 61% and 39%, respectively).

Conclusions: Sacral neuromodulation appears to be a safe technique for refractory idiopathic urge urinary incontinence in women. The success rate gradually decreased to 62% after 5 years with 15% of patients completely continent.

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

URGE urinary incontinence is usually treated with anticholinergic drugs, bladder retraining, pelvic floor exercises or biofeedback. SNS or neuromodulation is an alternative when conservative measures fail. Although the mechanism of action of the technique is still far from understood,[1,2] its efficacy for UUI is generally accepted based on a large number of case series and 1 randomized clinical trial.[3–6] However, SNS is an expensive technique with a high reoperation rate.[7] Thus, detailed information on the durability of its efficacy is relevant, especially in light of the development of alternative options.

The literature on the long-term results of SNS for UUI is sparse. We found 4 publications with a mean or median followup of at least 5 years.[7–10] The number of patients with UUI was small in 2 series[8,9] while another included neurogenic and idiopathic as well as continent and incontinent patients.[7] The remaining study included 96 men and women with idiopathic UUI.[10] Unfortunately none of the studies mentioned the incidence of patients who became completely continent.

We describe the results of a retrospective analysis of a prospectively filled database from a single center

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study of 60 women with idiopathic UUI refractory to conservative therapy who passed the 5-year followup mark. Results in the first 41 patients who passed the 10-year followup mark were also considered. Continence rates are provided.

MATERIALS AND METHODS

Since 1990, we have used sacral (S3) neuromodulation as treatment for UUI refractory to conservative management. The procedure and technical aspects were described previously.[11] The current patients were implanted if PNE revealed at least a 50% decrease in the number of incontinence episodes or pads used daily, as derived from voiding incontinence diaries.

All leads were implanted via a small mid sacral incision. An INS was placed abdominally in most of the earlier cases and at the buttock site in later cases. Postoperatively the lead position was assessed radiologically. During followup the stimulation amplitude was set just above the patient sensation threshold while pulse frequency and width were usually kept at 10 Hz and 210 μseconds, respectively.

Followup studies included voiding incontinence diaries at 1 month, every 3 months between months 3 and 18, and every 6 months thereafter. Derived from the diaries were the number of incontinence episodes and pads used daily, voiding frequency and average voided volume per void. When parameter values were missing at a followup mark, the last available value was carried forward. This was particularly true for patients who exited the study due to treatment failure. Missing 1-month values in 5 cases were imputed using 3-month values.

Similar to PNE, successful treatment was defined as a decrease of at least 50% in the number of incontinence episodes or pads used daily. A decrease of at least 90% was considered an excellent response and patients who did not record any leaks in the voiding incontinence diary were considered completely continent. A decrease of less than 50% in the number of incontinence episodes and pads used daily as well as conversion to another therapy, including INS explantation or a permanently turned off INS, botulinum toxin injections, urinary diversion and anti-stress incontinence surgery, characterized treatment failure.

Statistical analysis was done with SPSS®, release 11.0.1. Results are shown as the median and IQR. The paired t test was used to assess within patient differences with $p < 0.05$ considered significant.

RESULTS

A total of 60 women with idiopathic UUI received an implant between June 1990 and September 2004, resulting in a 53% PNE success rate. Table 1 lists patient characteristics. Median age at implantation was 48 years (IQR 41 to 54), median history of drug use for incontinence was 2.0 years (IQR 1.0 to 3.0) and mean pad use history was 6.0 years (range 2.7 to 10.0). Of the women 41 underwent a total of 77 previous operations for incontinence, excluding bladder dilation, while 9 underwent a total of 14 bladder dilations.

Table 1. *Characteristics of 60 women with INS, and status 5 and 10 years after implantation*

	No. Pts
Abdominal hysterectomy	23
Vaginal hysterectomy	17
Detrusor overactivity on preop urodynamics	57
Idiopathic urge incontinence 5 yrs postop:	60
Active SNS	45
Active SNS + anti-stress incontinence surgery	2
Active SNS + stress incontinence	1
Implantable pulse generator explantation, continent after anti-stress incontinence surgery	1
Implantable pulse generator explantation	1
Implantable pulse generator permanently turned off + left in situ	2
Suprapubic catheter after anterior + posterior repair, implantable pulse generator turned off	1
Bladder augmentation (ileocystoplasty)	1
Urinary diversion (ileal conduit)	3
Urinary diversion (ileal conduit) + cystectomy	1
Botulinum toxin type A	2
Idiopathic urge incontinence 10 yrs postop:	41
Active SNS	24
Active SNS + Burch colposuspension	1
Implantable pulse generator permanently turned off + left in situ	1
Failed implantable pulse generator + explantation	1
Botulinum toxin type A	1
Death	1
Lost to followup*	7
Failure before 5 yrs	5

* At 71 to 111 months with all patients on active SNS at last visit.

Table 2 lists voiding diary results. Statistically significant improvements were found in the number of incontinence episodes and pads used daily, the leakage severity index, voiding frequency and average voided volume per void at all followup marks. This was true using the LOCF method as well as using data only from available diaries. Table 2 also shows that the 2 methods usually resulted in slight numerical differences in parameters, especially compared with baseline. This confirmed the robustness of the results. In years 1 to 5 the mean $\pm$ SD number of stimulation parameter adjustments per patient was 3.0 $\pm$ 1.8, 1.0 $\pm$ 1.0, 0.7 $\pm$ 0.9, 0.8 $\pm$ 1.1 and 0.7 $\pm$ 1.1, respectively. Eight patients in whom treatment was about to fail received anticholinergics for a median of 8.5 months but ultimately treatment still failed. At 42 months and thereafter results were not confounded by patients with stress urinary incontinence or those who underwent surgery for stress urinary incontinence since they did not complete diaries after that followup. We also determined the leakage severity index, defined as an estimate of the daily load of incontinence to patients, who subjectively graded the amount of urine lost as small or large.