Sacral neuromodulation for the treatment of refractory urinary urge incontinence after stress incontinence surgery

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Objective: This study was undertaken to evaluate the response to sacral neuromodulation in women with refractory, nonobstructive urinary urge incontinence after stress incontinence surgery.

Study design: We reviewed the medical records of women in whom sacral neuromodulation was performed for worsening or de novo urinary urge incontinence after a stress incontinence procedure. All patients had undergone preliminary test stimulation. Demographics, surgical and urogynecologic history, including bladder diary and pad weight test, and urodynamic parameters were evaluated.

Results: Of 34 women, 22 (65%) responded to the test stimulation and underwent permanent lead implant. There was no difference between responders and nonresponders with respect to type of stress incontinence surgery. Incontinence or urodynamic parameters were not different between responders and nonresponders. Factors that were predictive of a positive response were women aged less than 55 years (P = .01), the test stimulation performed within 4 years of the stress incontinence procedure (P = .01), and evidence of pelvic floor muscle activity (P = .03).

Conclusion: Sacral neuromodulation is a viable option for the treatment of refractory urinary urge incontinence that occurs after stress urinary incontinence surgery. Older women with no pelvic floor activity who are remote from their incontinence surgery may have a suboptimal response.

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incontinent episodes and voiding frequency, many are not improved significantly. In the past, those with refractory urgency, frequency, and urge incontinence either accepted their condition or underwent sling take-down or revision, augmentation cystoplasty, detrusor myectomy, or denervation procedures.

Recently, patients with intractable UUI, urgency-frequency, or nonobstructive urinary retention have been reported to show improvement after undergoing sacral neuromodulation (InterStim Continence Control System, Medtronic, Inc, Minneapolis, MN). To date, the efficacy of sacral neuromodulation has not been reported in women who underwent SUI surgery and who have de novo or worsening UUI develop.

In this study, we look at the use of sacral neuromodulation for the treatment of refractory UUI after stress incontinence surgery. We also examine whether demographic or pretest stimulation variables predict a positive response to sacral neuromodulation.

**Material and methods**

Institutional review board approval was obtained for this retrospective analysis. The medical records of all women undergoing sacral neuromodulation test-stimulation between October 2000 and September 2004 were reviewed. Those with severe OAB symptoms, which appeared de novo or persisted or worsened after their stress incontinence surgery, were eligible for this study. All had been referred to our Female Urology and Urogynecology clinic because of the severity of their OAB symptoms and having failed behavioral therapy, pelvic floor re-education, and anticholinergic treatment. Their evaluation included completion of a urogynecologic questionnaire, a pelvic examination with assessment of pelvic floor muscle strength based on a modified, validated pelvic floor muscle grading system, a 3-day bladder diary recording micturition frequency, voided volumes and incontinent episodes (IE) per day, a 24-hour pad weight test, cystoscopy, and a video-urodynamic study. Women with urethral obstruction, based on evidence of a retro-pexed urethra on pelvic examination, poor sagittal rotation of the urethra during cystoscopy, and/or obstruction on the micturition study underwent urethrolysis or incision and release of their sling. Nonobstructed women were candidates for a test stimulation because of the severity of their symptoms and unresponsiveness to medical and behavioral therapy.

Similar criteria were used for our study cohort as is used when offering sacral neuromodulation in previously studied InterStim groups. Before offering a test stimulation, all women underwent extensive pelvic floor re-education and had tried at least 2 anticholinergic medications to improve their symptoms. Those women with less than a 50% improvement in their symptoms and still requiring the use of multiple protective pads per day because of UUI were offered a test stimulation. The test stimulation period lasted between 5 and 7 days and was performed either as an outpatient procedure via a percutaneous electrode (PNE) or a 2-stage approach as previously described.

During the testing period, women completed a bladder diary recording voiding frequency, voided volumes, IE per day, severity of leakage, and number of pads used. In addition, a 24-hour pad weight test was collected the day before evaluation. A positive response was defined as a 50% or more improvement in baseline urge incontinent episodes or a 50% or more reduction in pad weight during the testing period. All positive responders were offered permanent implantation. Permanent implantation consisted of a tined lead placed in the S3 sacral foramen that was connected to a pulse generator implanted in the fatty tissue of the buttock.

Age, time since incontinence surgery, and urodynamic measurements, all continuous variables, were changed to categorical variables with 2 responses (age older than 55 years and age 55 years or less) that best discriminated between responders and nonresponders. Two-way $\chi^2$ tests were computed between these variables and responders and nonresponders, young responders and older responders, and older respondents and older non-responders. A logistic regression model was created to find which independent variable(s) best predicted response or nonresponse in the older age group because there were no nonresponders in the younger age group.

**Results**

A total of 107 women underwent sacral neuromodulation test stimulation between October 2000 and September 2004. Of the 107 women tested whose OAB symptoms appeared de novo or persisted or worsened after their stress incontinence surgery, 34 (32%) were included in the study.

Of the 34 women in this study cohort, 22 (65%) responded to the sacral neuromodulation test stimulation and all had a permanent lead and pulse generator implanted. Twelve patients (35%) did not have greater than a 50% improvement in incontinent episodes or greater than 50% reduction in pad weights during the testing period and were classified as nonresponders, and therefore were not implanted. There were no other alternative therapies or surgical treatments offered to these 12 non-responders.

The average age of the responders was 58 (range 35-82 years) and 66 (range 56-80 years) for the nonresponders (Figure). There was a difference between the responders and nonresponders with respect to age and length of time from incontinence surgery to the test stimulation. All the nonresponders were older than 55 years and 62% were 4 or more years from their incontinence surgery. Type of stress incontinence surgery and whether a sling incision
and release was performed were not statistically significant factors between responders and nonresponders (Table I).

Because a younger age has been previously shown to be an independent variable for success with sacral neuromodulation and this was reproduced in our study, we re-evaluated previously determined variables using the age of 55 as a cutoff between the 2 groups. The only parameter that was statistically significant between the 2 groups was that women older than 55, who responded to sacral neuromodulation, had more IE per day than the younger responders. All urodynamic and incontinence symptom parameters were similar. Interestingly, whether the woman was young or old, few responded to sacral neuromodulation if their surgery had been performed more than 4 years before the test stimulation procedure (Table II).

All the nonresponders were in the group of women older than 55 years. When one compared this older group of responders and nonresponders, lack of pelvic floor muscular activity best correlated with nonresponding to sacral neuromodulation (Table III). After logistic regression, if the woman is older than 55 years with no pelvic floor activity, she has a 100% chance of not responding to sacral neuromodulation in this cohort of women (Table IV).

**Comment**

The incidence of OAB symptoms after SUI surgery depends on the surgical technique used, and can be as high as 31%, although usually less than 10%. Even with the newer minimally invasive approaches for stress incontinence, the risk of OAB symptoms postoperatively persists. In this study, 7 of the 28 slings were placed by using a minimally invasive technique. Although SUI may be resolved, the presence of OAB symptoms proves to be a source of continued patient dissatisfaction after incontinence procedures.

It is not clear why OAB symptoms sometimes occur after stress incontinence procedures. Possible causes include undiscovered preexisting detrusor overactivity, a neurogenic dysfunction resulting from surgical interference with autonomic bladder innervation, increased striated urethral sphincter activity, or structural urethral obstruction. In the latter, sling incision and revision or other urethrolysis procedures are considered. In these cases, postoperative voiding symptoms (frequency, urgency, and urge incontinence) occur in conjunction with the finding of a retropexed urethra and/or an obstructive voiding pattern on urodynamics. One third of the women in our study group had undergone sling release that had relieved obstructive voiding symptoms but OAB symptoms had persisted. Interestingly, having had a sling incision and release did not affect response to neuromodulation.

The mechanism by which neuromodulation works is not completely understood, it has been shown to be efficacious in idiopathic refractory urge incontinence and nonobstructive urinary retention. It is believed that neuromodulation treats bladder overactivity by altering the activity and basal tone of the pelvic floor as well as modulating the afferent signals delivered to the spinal cord. The cause of nonobstructive urinary...
Retention is believed to be due to a primary failure of relaxation of the striated urethral sphincter.\textsuperscript{19,23} The mechanism of action for neuromodulation in retention patients is believed to be an activation of somatic afferent axons in the sacral spinal roots causing an inhibition of reflex pathways to the urethral outlet. This ultimately relieves pelvic floor spasticity, releasing the detrusor from inhibition to allow for spontaneous voiding.\textsuperscript{24} In this study, the overall response to sacral neuromodulation is similar to that which is reported by other groups treating refractory idiopathic urge incontinence with neuromodulation.\textsuperscript{22} There are no pretest stimulation urodynamic variables to predict success of sacral neuromodulation and similarly in this cohort no urodynamic variables seemed predictive of success. This study duplicates our earlier results, specifically, that younger women responded better to sacral neuromodulation.\textsuperscript{7} In addition, the presence of pelvic floor muscular activity, evaluated by voluntarily contracting the pelvic floor, was also found to predict a positive response to neuromodulation in our cohort. Because the believed mechanism of action of sacral neuromodulation relies on afferent input from the pelvic floor, this might explain the better response in these women compared with those who demonstrated no voluntary pelvic floor muscle contractile ability.

Our data show that a short duration between stress incontinence surgery and sacral neuromodulation was predictive of a positive response in both the younger and older groups. There may be unidentified pathologic or neurologic bladder changes that occur and limit success when time to intervention is prolonged.

This is a small cohort study and findings regarding correlation with time from surgery, pelvic floor muscle denervation, and age need to be confirmed with a larger cohort. Our results have led us to offer test stimulation for sacral neuromodulation to women who have refractory OAB symptoms after a SUI procedure. Nevertheless, older women with no pelvic floor activity who are remote from their incontinence surgery may be counseled to a probable suboptimal response.

### Conclusion

Response to sacral neuromodulation for the treatment of refractory urge incontinence after SUI surgery is comparable to its use in idiopathic urge incontinence.
The type of stress incontinence surgery, incontinence parameters, and preimplantation urodynamics do not help predict response to neuromodulation. Our study suggests that a younger age, a shorter time from the incontinence surgery and evidence of pelvic floor muscular activity appear to predict a better response. Sacral neuromodulation should be considered in women with severe OAB symptoms after SUI surgery having failed medical and behavioral therapy and after urethral obstruction has been ruled out.

References