

PUDENDAL NEUROSTIMULATION IS A VIABLE ALTERNATIVE TO SACRAL NERVE STIMULATION FOR VOIDING DYSFUNCTION

Hypothesis / aims of study

Chronic pudendal neurostimulation (PNS) presents a logical alternative particularly in those who fail to respond to sacral stimulation. We evaluated patients after pudendal neuromodulation to determine complications, changes in symptoms and treatment satisfaction.

Study design, materials and methods

We retrospectively reviewed patients having a tined lead placed at the pudendal nerve from November 2003 to December 2008. Demographic, history, voiding diary and complications data were collected. A follow up survey was mailed to treatment responders (those who had $\geq 50\%$ improvement in symptoms) to assess symptom changes on a 7-point scale (markedly worse to moderately improved) and treatment satisfaction. Interstitial Cystitis Symptom and Problem indices (ICSI-PI) were evaluated in a subset also enrolled in our ongoing prospective study.

Results

84 patients (78.6% female; mean age 51.8 ± 16.9 years) who had a pudendal lead placed, 44 had previously failed sacral neuromodulation. Diagnoses included interstitial cystitis/painful bladder syndrome (42), urgency/frequency or urge incontinence (26), non obstructive urinary retention (13), pelvic pain (2), and tethered sacral nerve (1). Twelve subjects also had a neurologic diagnosis and 3 had pudendal nerve pathology. Overall, 55/84 (65.5%) responded to pudendal neuromodulation and had an implantable pulse generator placed. Forty one of 44 previous sacral failures had positive results with a pudendal lead (93.2 %). Mean follow up was 23.3 months. Complications requiring revision occurred in 5/55, and an additional 2 had events that resolved with reprogramming or treatment. Over time, frequency, voided volume, incontinence episodes ($p=0.0002$ for all), urgency ($p=0.0051$), and ICSI-PI scores ($p<0.0001$) improved. Survey response rate was 72.7% (40/55). The majority still had a device (35/40; 87.5%) continuously in use (27/35; 77%), and reported improvement in overall bladder, pelvic pain, incontinence, urgency, and frequency symptoms. Treatment satisfaction was reported by 14/30 (46.7%), and 31/37 (83.8%) would recommend neuromodulation to a friend.

Interpretation of results

The results of this study indicate that by adapting the current procedure used for chronic sacral neuromodulation a tined lead can be safely and effectively placed at the pudendal nerve with neurophysiologic guidance. In addition, over 92% of patients who failed to respond to sacral nerve stimulation responded to pudendal stimulation suggesting that pudendal nerve stimulation may be a good alternative for sacral failures. The majority of the follow up data collected within the first two years after lead placement showed improvements in objective and subjective symptom assessments (voiding diaries and GRA). Patients continued to use their device, were generally satisfied and indicated that if given the chance they would recommend the treatment to a friend. Complications (lead migration, painful stimulation, and infection) and reoperations were minimal in comparison to published studies on sacral neuromodulation. For the majority of these patients, pudendal neuromodulation represented a last resort for managing symptoms and improving quality of life. These patients were very complex in that they often had urinary urgency, frequency, pain and neurologic diagnoses.

Concluding message

Pudendal neuromodulation is a reasonable alternative in complex patients refractory to other therapies. More research is needed to fully assess long-term outcomes and identify predictors of success.

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	William Beaumont Hospital Human Investigation Committee
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes