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SACRAL VS. PUDENDAL NERVE STIMULATION FOR VOIDING DYSFUNCTION: A PROSPECTIVE, SINGLE BLINDED, RANDOMIZED, CROSSOVER TRIAL

Hypothesis / aims of study

Sacral nerve stimulation (Interstim, Medtronic Inc., Minneapolis, MN) has been FDA approved since 1997 for the treatment of urinary urge incontinence, urgency, frequency, and refractory retention. One limitation of the selection of S3 is that only one of the three afferent pathways inducing the inhibitory reflex is stimulated.

The pudendal nerve originates from the S2, S3, and S4 sacral nerve roots. Selection of the pudendal nerve as a site of stimulation provides afferent stimulation of S2, S3, and S4. The purpose of the present study was to compare sacral nerve stimulation (SNS) to pudendal nerve stimulation (PNS) for voiding dysfunction.

Study design, materials and methods

Thirty subjects who were undergoing sacral nerve stimulation to treat their voiding dysfunction consented to having a second electrode placed at the pudendal nerve as part of this institutional review board approved study. Baseline voiding diaries were obtained including urinary frequency, voided/catheterized volumes and incontinent episodes. All procedures were performed by a single surgeon. The InterStim (Medtronic, Inc) quadripolar tined lead was used. An electrode was placed at the S3 nerve root in the standard fashion and externalized. After placing a tined lead at S3, all subjects had a second electrode placed at the pudendal nerve via a posterior approach. Briefly, needle electrodes were placed in the external anal sphincter and complex muscle action potentials were measured (C-MAP). The ischial tuberosity was palpated and a foramen needle was passed medial to this toward the ischial spine using fluoroscopic guidance. The needle was stimulated from 0-10 mA until a c-map consistent with pudendal stimulation was found. Typical motor response was an anal contraction and sensory response consisted of pulsating in the vaginal or scrotal area. Once the pudendal nerve was identified, the directional guide wire followed by the lead introducer was advanced toward the nerve and the quadripolar lead was positioned. Radiographic films were taken to document the sacral and pudendal lead position. The quadripolar lead was connected to a standard percutaneous extension lead and externalized. Subjects were discharged with the standard external stimulation box and randomized in a single-blinded fashion to begin stimulation on either the sacral or pudendal electrode. Each lead was stimulated for 7 days and subjects completed voiding diaries and global response assessment (GRA) which asked patients to rate frequency, urgency, pelvic pain and bowel function on a 7-point scale from markedly worse to markedly better. Subjects rated their percent improvement on each lead in a blinded fashion and chose the one to be implanted to a permanent generator based on clinical response. An overall 50% improvement in symptoms was considered a positive response. Patients not responding to either lead had the electrodes explanted; the others had the best lead connected to the implantable pulse generator. An independent t-test was used to analyze time implant time. Exact Fisher test analyzed if there was a bias to choosing a lead based on whether a particular lead was tested first or second. Analysis of variance (ANOVA regression model) in a cross-over design was used to determine if there was a carry-over effect based on which lead was initiated first or second.

Results

Thirty subjects were enrolled in this trial, mean age 50.6 years (range: 25-80 years). Twenty-seven subjects had urgency, frequency or incontinence. Three subjects had urinary retention. A quadripolar tined lead was successfully placed at the sacral and pudendal sites in all subjects. The time to place the sacral lead was 25.85 minutes vs. pudendal lead 23.71 minutes (p=.57). Twenty-four of 30 (80%) subjects had a significant clinical response and had an IPG implanted, with 19/24 (79.2%) choosing pudendal and 5/24 (20.8%) choosing sacral. One patient with retention and 5 patients with urgency/frequency had no response to either lead. The order in which the lead was stimulated had no impact on the final lead implanted.

Pudendal nerve stimulation had significantly higher improvement in symptoms than sacral nerve stimulation 51% vs. 37% (p=.02). On a 7-point scale from markedly worse to markedly better, the PNS was superior to SNS for pelvic pain (p=0.024), urgency (p=0.005), frequency (p=0.007) and bowel function (p=0.049). No differences between SNS and PNS were seen for vaginal pain, sexual function or incontinence. Voiding diary data is presented in the table. Two of the three retention patients were implanted, both to the pudendal electrode. No intraoperative complications occurred. Two subjects developed sterile seromas around the IPG that were drained in the office with a sterile needle. All subjects had follow-up x-rays prior to the stage II implant. There was no migration of the sacral lead and one forward migration of a pudendal lead. No infections or erosions occurred.

Voiding Diary	Baseline	SNS*	p-value	PNS*	p-value
Voids/24 hr	21.37	12.97	0.001	12.15	0.001
Mean volume (cc)	88.96	146.94	0.001	153.79	0.001
Smallest volume (cc)	26.35	39.62	0.039	56.00	0.012

*Different from baseline but not each other.

Interpretation of results

Sacral nerve stimulation has been used for years to treat voiding dysfunction. This is the first blinded, cross-over comparative trial of sacral nerve stimulation vs. pudendal nerve stimulation. All subjects had a successful placement of a tined quadripolar electrode at the pudendal nerve and this was confirmed with electrodiagnostic monitoring. The time to implant the electrode did not differ from the sacral lead. The order in which the electrodes were stimulated demonstrated no impact on clinical result and no carry-over effect was seen. The majority of subjects chose the pudendal lead over the sacral lead for final implantation. The pudendal lead demonstrated greater subjective improvement for pelvic pain, urinary frequency, urgency and bowel movements. Voiding diary data demonstrated significant improvements in voiding frequency and volume for both the sacral and pudendal leads over the baseline values. However, no significant differences were seen between SNS and PNS for these variables. Adverse events were minimal. The major limitation to this trial is the relatively small number of subjects. Currently prospective follow-up is ongoing of those implanted with a pudendal or sacral electrode to determine the long-term improvement in symptoms and adverse events.

Concluding message

Pudendal nerve stimulation is feasible using a tined quadripolar lead. This is the first blinded, cross-over trial of sacral vs. pudendal stimulation for voiding dysfunction. Seventy-nine percent chose the pudendal lead as the superior lead. Prospective post-implant follow-up is ongoing to assess durability of response, complications, and reoperation. Additional studies are needed to confirm these promising results.

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