248

Peters K[1], Bennett R[1], Sherer K[1]
1. William Beaumont Hospital

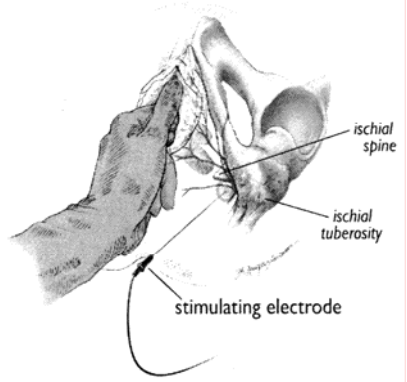
ACUTE STIMULATION OF THE PUDENDAL NERVE INCREASES CYSTOMETRIC VOLUMES

Hypothesis / aims of study

The bion® (Advanced Bionics, Valencia, California) is an implantable microstimulator placed at the pudendal nerve that is in clinical trials for urinary urgency, frequency, and urge incontinence. Since this is a leadless device, the challenge was to develop a test to see who may benefit from a permanent implantation of the bion®. A percutaneous screening test was developed to determine if acute pudendal stimulation would alter cystometric volumes. To qualify for a permanent implant, a 50% increase in volume of first desire to void (FDV) or maximum cystometric capacity (MCC) with temporary pudendal nerve stimulation is required. The aim of this study is to present our experience with the first 18 subjects who underwent a percutaneous screening test with pudendal nerve stimulation.

Study design, materials and methods

The institutional review board approved the study. Subjects with refractory urinary urgency/frequency (≥12 voids/day) or urge incontinence (≥2 episodes/day) were enrolled in this trial. Baseline voiding diaries and questionnaires were performed. Prior to implantation of a bion® device, a percutaneous screening test was performed in the office. The subjects were placed in the lithotomy position, sitting at a 45-degree angle. The vaginal and perineal area were prepped and draped and the bladder was emptied. A computerized urodynamic catheter was passed and filling cystometry performed. The bladder was filled at 25 cc/min and subjects reported their first desire to void, strong desire, and maximum cystometric capacity. After these variables were determined, the bladder was drained and electromyographic surface electrodes were placed at the external anal sphincter and monitored. The ischial tuberosity was palpated and a site 1 cm medial to this was infiltrated with 1% lidocaine. The ischial spine was palpated vaginally and a stimulating needle was advanced through the perineum to the ischial spine. Electrical current was delivered through the needle ranging from 1-10 mA while measuring complex muscle action potentials (C-MAP) (see figure). Muscle contractions were assessed by direct vision and palpation. Typical motor responses were contraction of the bulbocavernosus muscle and external anal sphincter. Sensory response was described as a pulsating or tingling in the vaginal, vulvar, or anal regions. The pudendal nerve was confirmed by demonstrating a classic C-MAP, motor and sensory responses. Once needle placement was confirmed, the pudendal nerve was stimulated for 15 minutes at a pulse frequency of 20 Hz, pulse width of 200 μsec, 50% duty cycle and pulse amplitude up to 10.0 mA. The bladder was emptied and the urodynamic catheter replaced. The filling cystometry was repeated while pudendal stimulation was continued and the previously described variables were determined.



Results

Eighteen subjects consented to the percutaneous test. The pudendal nerve was identified in all 18 subjects. Sixteen of 18 (89%) demonstrated at least a 50% increase in FDV or MCC and qualified for a permanent implant. Patients qualified on FDV *only* in 26.5%, MCC *only* in 26.5%, *both* FDV and MCC in 47%. The first urge to void increased 98%: pre-stimulation= 102cc (range: 21-191); post-stimulation= 202cc (range: 93-384). Maximum cystometric capacity increased 66%: pre-stimulation= 203 cc (range: 76-358); post-stimulation= 336 cc (range: 127-552). Fifteen of 16 subjects had a bion® implant, mean time to implant the permanent device was 28 minutes (range 5-55 min).

Interpretation of results

The pudendal nerve originates from the S2, S3, and S4 sacral nerve roots. The main trunk passes over the ischial spine and enters Alcock's canal. Selection of the pudendal nerve as a site of stimulation provides afferent stimulation of S2, S3, and S4. It was possible to find and stimulate the pudendal nerve in an office setting with only local anesthetic. In subjects with voiding dysfunction refractory to behavioral and pharmacologic therapy, 89% demonstrated at least a 50% improvement in FDV and/or MCC with acute pudendal nerve stimulation. Additional follow-up is needed to determine if this acute test predicts long-term efficacy with a permanent bion® implant.

Concluding message

Acute stimulation of the pudendal nerve significantly increases the cystometric FDV and MCC in subjects with voiding dysfunction. Prospective follow-up of permanent implants is ongoing to see if this acute test predicts long-term efficacy.

FUNDING: Advanced Bionics, Valencia California