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ACUTE PUDENDAL NERVE STIMULATION IMPROVES CYSTOMETRIC VOLUMES IN URGE INCONTINENT PATIENTS

Hypothesis / aims of study

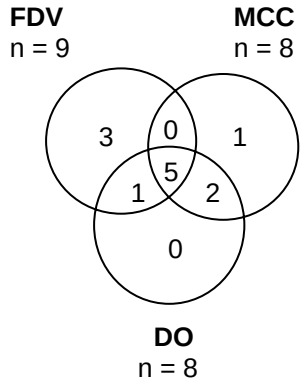
The aim of this study was to demonstrate the effectiveness of acute pudendal nerve stimulation at improving cystometric volumes in urge incontinent patients. An office percutaneous screening test (PST) is described and proposed as a useful means of determining appropriate candidates for permanent implantation of the bion® microstimulator (Advanced Bionics Corporation, Valencia, CA) at the pudendal nerve. The bion microstimulator is a leadless implantable device currently under clinical investigation (in the US) for the treatment of urge urinary incontinence and urinary urgency/frequency.

Study design, materials and methods

After obtaining Institutional Review Board approval, urinary urge incontinent women who were refractory to medical therapy and had a minimum of 2 leaks per day were enrolled in this study. A baseline cystometrogram was performed to obtain pre-stimulation values for first desire to void (FDV), maximum cystometric capacity (MCC), and volume at detrusor overactivity (DO). The office PST was subsequently performed under local anaesthesia applied at a point halfway between the ischial tuberosity and the anus on one side. At this location a 20 gauge stimulation needle was percutaneously inserted and guided towards the pudendal nerve with transvaginal palpation of the ischial spine. Appropriate pudendal nerve stimulation was confirmed by the following: 1) a motor response in the bulbocavernosus or anal sphincter muscles, 2) a sensation felt in the vagina, labia or anus, and 3) a compound muscle action potential (CMAP) recorded at the external anal sphincter with surface EMG electrodes. The pudendal nerve was stimulated for 15 minutes at 0.5 to 10 mA (based on obtaining an appropriate response defined above), 20 Hz, 200 µs pulse-width with a 50% duty-cycle (5-seconds-on, 5-seconds-off). Stimulation was then continued during a repeat cystometrogram to ascertain the stimulation induced affect on cystometric volumes. Passing criteria for the PST was defined as a 50% increase over the pre-stimulation values for FDV, MCC, or DO. Bion implantation at the pudendal nerve was subsequently performed in a surgical setting.

Results

Twelve of fourteen (85.7%) PSTs met at least one of the passing criteria. Nine of the 12 PSTs (75%) passed on the basis of FDV, 8 of the 12 (67%) passed on the basis of MCC, and 8 of 11 (73%) passed on the basis of DO. A detrusor contraction was not elicited during 1 of the 12 baseline cystometrograms. Five of the 12 PSTs (42%) passed on the basis of all three criteria (Venn diagram). Average post-stimulation cystometric volumes increased significantly: 76% for FDV, 50% for MCC, and 65% for DO (Table).



Venn diagram: Passing Criteria

	Without Stimulation			With Stimulation				
	N	*Mean*	*SD*	*N*	*Mean*	*SD*	*%*	*ρ*
FDV	14	139	38	14	245	72	76	0.0001
MCC	14	271	67	14	407	121	50	0.0005
DO	11	227	98	11	374	145	65	0.0018

Table: Percent Improvement

Interpretation of results

The pudendal nerve arises from sacral nerve roots S2-S4 and passes behind the ischial spine as it re-enters the pelvis through Alcock's canal. It is at this point, prior to branching, where the pudendal nerve is typically accessible. Percutaneous stimulation of the pudendal nerve and thereby afferents of three sacral nerve roots specific for pelvic floor function, allows for immediate and effective inhibition of detrusor contractions.

Concluding message

Short term pudendal nerve stimulation results in significant changes in cystometric parameters and thus bladder function. An acute office percutaneous screening test may be useful when considering appropriate candidates for permanent implantation of the bion® microstimulator.

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HUMAN SUBJECTS: This study was approved by the HealthONE Alliance Institutional Review Board and followed the Declaration of Helsinki Informed consent was obtained from the patients.