

DORSAL GENITAL NERVE STIMULATION FOR THE TREATMENT OF REFRACTORY OVERACTIVE BLADDER SYMPTOMS

Hypothesis / aims of study: The dorsal genital nerves, a component of the pudendal nerve, carries afferent sensory information to the sacral spinal roots. Previous studies indicate that electrical stimulation of this nerve can abolish overactive bladder contractions and increase bladder capacity in patients with an overactive bladder. The purpose of this study was to evaluate the acute effects of electrical stimulation on cystometric parameters and the pudendal anal (PA) reflex and to determine if electrodes could be properly placed and be effective and tolerated by subjects during a 1-week home use testing period

Study design, materials and methods: This was a prospective, multicenter study. The primary diagnosis was urge incontinence in the recruited subjects. After a 5 day anticholinergic wash out period, baseline data including demographics, a 3 day bladder diary, and a 24 hr. pad test were obtained. Subjects underwent percutaneous placement of a coiled fine-wire electrode using local anesthetic in the clinic procedure room. Test stimulation was applied to confirm electrode placement and cystometry was conducted with and without application of electrical stimulation. In addition, pudendal anal reflex activity was observed visually and using surface electromyography electrodes. A 7 day testing period with the electrode connected to an external pulse generator was performed as well as a 3 day post treatment period. Bladder diaries, 24 hr pad tests and adverse events queries were obtained during these periods.

Results: 21 females were enrolled with an average age of 52.7 years. Average duration of incontinence was 6 years, 52% were Caucasian, 33% African American, and 14% Hispanic. The average body mass index was 33.8 (range 19.2 to 47.1). Electrode placement was well tolerated requiring 5 to 10 minutes to achieve correct placement. The stimulation sensation was also well tolerated by subjects. There were no relationships between the effect of stimulation on cystometry and the clinical results during the home use testing period. In addition, the PA reflex was not a reliable indicator for placement nor did the presence of a PA reflex correlate with continence during the testing period. Pad weight was reduced by 50% or greater in 13 of 17 subjects (77%) and 47% of subjects reported 50% or greater reduction in leaks. Further, 81% of subjects who reported severe urgency at baseline experienced a 50% or greater improvement. Symptom relief appeared to continue during the 3 day post treatment period for many subjects. 7 subjects experienced 9 mild adverse events which ranged from skin irritation under the surface electrode or tape to pain and bruising around the electrode exit site

Interpretation of results: This study confirmed that electrodes can be placed near the dorsal genital nerves using a minimally invasive pre-pubic approach which is well tolerated by the subject. Cystometry and PA reflex information did not predict response during the testing period.

Concluding message: Results from home use testing suggest that dorsal genital nerve stimulation via a minimally invasive approach may reduce overactive bladder symptoms.

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DISCLOSURES: NONE

HUMAN SUBJECTS: This study was approved by the Cleveland Clinic IRB and followed the Declaration of Helsinki. Informed consent was obtained from the patients.