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CROSS SECTIONAL REVIEW OF EFFECT OF PERCUTANEOUS TIBIAL NERVE STIMULATION ON FECAL INCONTINENCE: RESULTS FROM TWO RECENT OVERACTIVE BLADDER TRIALS

Hypothesis / aims of study

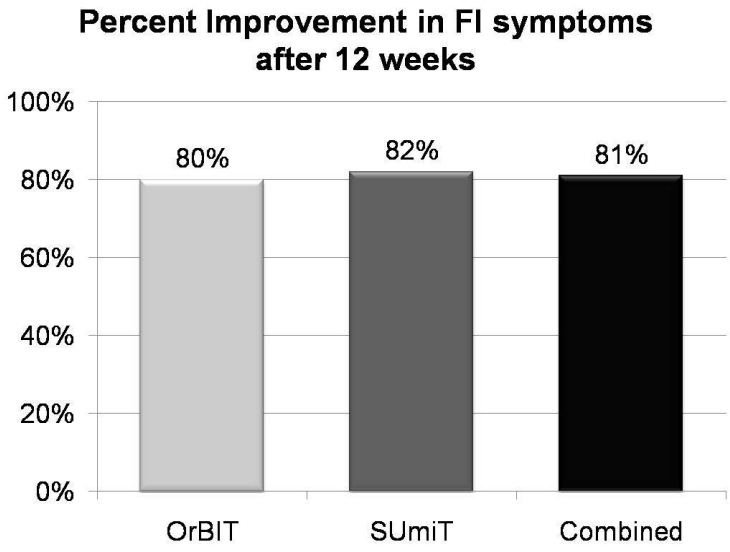
Patients with overactive bladder (OAB) frequently have concomitant fecal incontinence (FI). The exact prevalence of FI is unknown; however the literature reports that the prevalence of FI is significantly higher in those with OAB symptoms; 28.9% in men and 32.4% in women [1]. Two recent clinical trials were completed using percutaneous tibial nerve stimulation (PTNS) with subjects diagnosed with OAB. The objective of this review is to compare the efficacy of PTNS in the subset of OAB subjects experiencing FI symptoms from the two trials.

Study design, materials and methods

Two multi-center, clinical trials, OrBIT and SUmiT, were completed. The OrBIT Trial was an open-label trial of which 10% (5/50) experienced FI. The SUmiT Trial was a double-blind trial of which 13.6% (15/110) experienced FI. In each study, subjects received 12 weekly 30-minute PTNS treatments in which stimulation was delivered through a 34-gauge needle electrode inserted near the posterior tibial nerve using the Urgent® PC device. At the end of 12 weeks, questionnaires and voiding diaries were completed. All data were analyzed by an independent biostatistician using SAS® Version 9.2. Mean values were analyzed for significant change using a two-sided paired t-test and proportions were analyzed using chi-square methodology. Data were entered into a double-entry, password-protected Clindex® Clinical Trial and Data Management System.

Results

Baseline characteristics were similar across both groups in this subset cohort. In the OrBIT Trial, mean age was 61.0 years with an average OAB duration of 9.4 years. Similarly, the mean age in the SUmiT Trial was 68.0 years with an average OAB duration of 13.5 years. Average body mass index was 27.9 and 27.7 respectively. In the OrBIT Trial, the subject-completed Global Response Assessment (GRA) for FI symptoms indicated 80% (4/5) had reported improvement after 12 PTNS treatments. In the SUmiT Trial, after 12 PTNS treatments, 82% (9/11) reported improvement in FI symptoms, 4 subjects were excluded due to a “not applicable” response on their questionnaire. The combined GRA data reports 81% (13/16) had improvement in FI symptoms after 12 weekly PTNS treatments. See figure.



Interpretation of results

Although the two studies were designed for OAB patients, GRA outcomes suggest PTNS provides symptom relief for patients experiencing FI with a compelling 81% improved after receiving 12 weekly 30-minute treatments. These results are similar to those reported in a recent European PTNS FI trial where 91% (20/22) reported subjective improvement [2].

Concluding message

Although PTNS is not FDA cleared for use with those affected by FI in the United States, it suggests that this treatment has great potential for patients with fecal incontinence. PTNS therapy is safe and effective without serious adverse effects. Further research in larger study populations is needed.

References

1. Coyne K, Kopp Z, Cash B, Khullar V, Milsom I, et al. The Coprevalence of Chronic Constipation and Faecal Incontinence With Overactive Bladder. Poster #382 Presented at ICS 2009 San Francisco, CA. September 29 – October 2, 2009

2. Govaert B, et al; A Prospective Multicenter Study to investigate Percutaneous Tibial Nerve Stimulation for the Treatment of Faecal Incontinence. Colorectal Dis 2009: e-published August 8, 2009

Specify source of funding or grant	**Uroplasty, Inc.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Clinical Trials.gov Identifiers:** **SUmiT Trial: NCT00928395** **OrBIT Trial: NCT00448175**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Central (Western IRB) and Local IRBs**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**