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SUMIT TRIAL OUTCOMES: CLINICAL INSIGHTS INTO PERCUTANEOUS TIBIAL NERVE STIMULATION

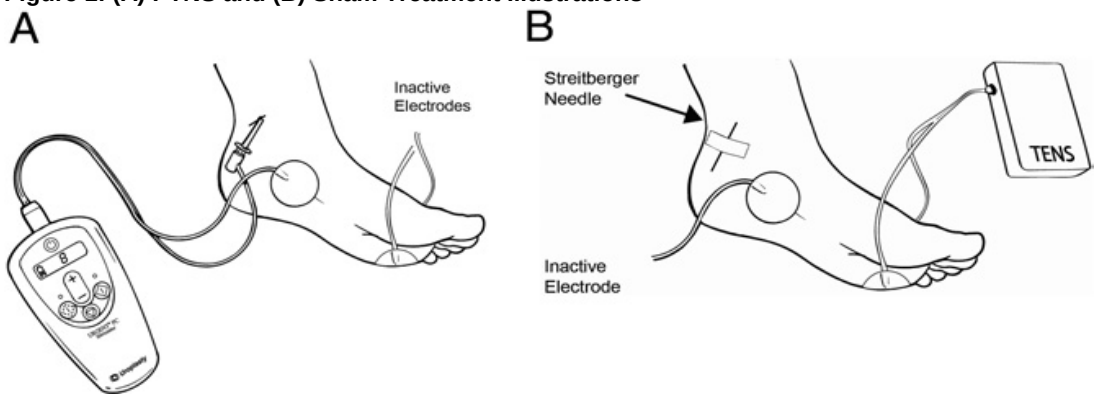
Hypothesis / aims of study

Overactive bladder syndrome (OAB) affects the lives of millions of people. Neuromodulation therapy uses electrical stimulation to target specific nerves in the sacral plexus controlling bladder function. Urgent® PC percutaneous tibial nerve stimulation (PTNS) targets the sacral plexus from an accessible, minimally invasive entry point into the nervous system via the posterior tibial nerve. The objective of this review is to present information about clinical outcomes of PTNS in the 23-center SUmiT Trial for 6 vs. 12 interventions, and for subjects stratified by age.

Study design, materials and methods

This is an IRB-approved, validated sham-controlled trial evaluating the efficacy of PTNS conducted at 23 U.S. urology and urogynecology centers. 220 subjects (174 females, 46 males) were randomized 1:1 to receive PTNS or validated sham interventions during 30-minute weekly sessions over 12 weeks. PTNS was percutaneously delivered through a 34-gauge needle electrode inserted near the posterior tibial nerve using the Urgent PC device. The active surface electrode and 2 sham electrode pads were placed to mimic the sham. The sham used a Streitberger placebo needle providing the sensation of a needle, but without piercing the skin. TENS electrode pads placed above and below the small toe provided the sensation of stimulation without tibial nerve activation, and an inactive surface electrode was placed to mimic PTNS. The audible PTNS device sounds were also reproduced in the sham intervention to diminish auditory variation between groups. See Figure 1 for illustration of interventions. Subjects completed the Global Response Assessment (GRA) and OAB-q questionnaires after 6 and 12 interventions and 3-day voiding diaries after 12 interventions. Data analysis was stratified for GRA response and OAB-q response after 6 and 12 treatments at the 7 and 13 week follow-up intervals, and the 13 week data was stratified by age. Sexual function (FSFI and SHIM) was analyzed for men and women at 13 weeks.

Figure 1: (A) PTNS and (B) Sham Treatment Illustrations



Results

In an intent-to-treat analysis at week 13 following 12 treatments, the GRA found 54.5% were responders (moderately or markedly improved) in the PTNS group compared to 20.9% in the sham group (p<0.001). All PTNS as-followed GRA outcomes were statistically significant at 13 weeks compared to baseline, but outcomes were not significant at 7 weeks (after only 6 PTNS treatments). See Table 1. Similarly, OAB-q quality of life questionnaires outcomes were statistically significant for improvement at 13 weeks, but not significant at 7 weeks between treatment groups. Analysis of the 3-day voiding diary parameters show PTNS is statically significant compared to sham in reducing frequency, nighttime voids, moderate to severe urgency episodes, and urge incontinence episodes after 12 interventions compared to baseline, p <0.0001 for all parameters and time intervals. See Table 2. The mean age of trial subjects was 62.5 years and 60.2 years, PTNS and sham, respectively. When GRA and OAB-q results were stratified by age, <65yrs vs. ≥65 yrs, no significant difference in efficacy was found in either study arm No significant changes in sexual function indices were reported by either study arm or gender. No serious treatment related adverse events were reported throughout out the trial.

Table 1: Comparison of PTNS to Sham at Follow-Up after 6 and 12 Interventions

GRA Outcome	Group	7 Weeks after 6 interventions	p-Value	13 Weeks after 12 interventions	p-Value
Overall Bladder Symptoms	PTNS Sham	28/105 (26.7%) 17/107 (15.9%)	0.07	60/103 (58.3%) 23/105 (21.9%)	<0.001
Frequency	PTNS Sham	29/105 (27.6%) 19/107 (17.8%)	0.10	49/103 (47.6%) 23/105 (21.9%)	<0.001
Urgency	PTNS Sham	23/105 (21.9%) 20/107 (18.7%)	0.61	44/103 (42.7%) 24/103 (22.9%)	0.003

Urge Incontinence	PTNS Sham	14/103 (13.6%) 13/106 (12.3%)	0.84	39/103 (37.9%) 23/104 (22.1%)	0.02

Table 2. Voiding Diary Episodes Per Day Comparison of PTNS to Sham at Baseline and 13 Weeks

Voiding Diary Parameter	Group	Baseline	13 weeks after 12 Interventions	p-Value
Frequency (mean intentional voids)	PTNS Sham	12.3 ± 3.2 12.4 ± 3.0	9.8 ± 2.8 11.0 ± 3.1	0.01
Nighttime Voids (mean waking episodes)	PTNS Sham	2.9 ± 1.6 2.9 ± 1.7	2.1 ± 1.4 2.6 ± 1.6	0.04
Moderate to Severe Urgency (median)	PTNS Sham	8.3 8.0	3.7 5.0	<0.001
Urge Incontinence (median)	PTNS Sham	3.0 1.8	0.3 1.0	0.002

Interpretation of results

Although patients may have improvements after six treatments, twelve 30-minute weekly sessions are needed for subjects to achieve significant, clinically meaningful improvements to their OAB symptoms. Equivalent results were seen in people of younger age, as well as for those ≥65 years of age.

Concluding message

Based upon the GRA and OAB-q quality of life response outcomes at 7 and 13 weeks, 12 weekly sessions of PTNS treatments are needed for the treatment to be efficacious for those suffering with OAB syndrome. PTNS therapy is a safe and efficacious treatment for those suffering with OAB syndrome, regardless of age above or below 65.

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	**ClinicalTrials.gov NCT00771264**
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	**HIC Beaumont**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**