30 MONTH STUDY RESULTS USING PERCUTANEOUS TIBIAL NERVE STIMULATION: LONG TERM EFFICACY OUTCOMES

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Introduction and Objectives:

Neuromodulation has become increasingly recommended in the treatment algorithm for patients with OAB and is suited following failure of pharmacotherapy options. Percutaneous Tibial Nerve Stimulation (PTNS) treatment, using Urgent® PC, is a minimally invasive, office based neuromodulation system designed to deliver neuromodulation to the sacral nerve plexus through the posterior tibial nerve via temporary insertion of a 34 gauge needle electrode near the medial malleolus. The objective of this review is to evaluate the treatment efficacy and interval through 30 months of continued therapy from the **S**ustained **T**herapeutic **E**ffects of **P**ercutaneous Tibial Nerve Stimulation (STEP) Study.

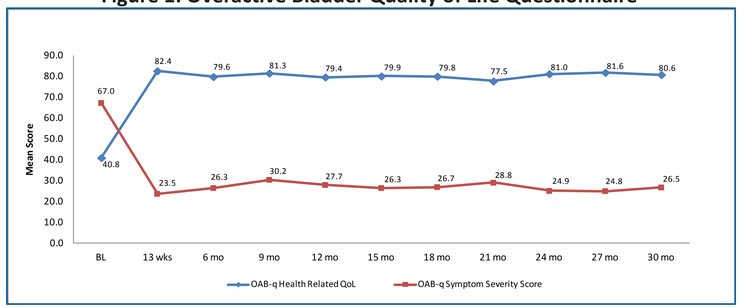
Methods:

Subjects participating in the multi-center, randomized, double-blind SUmiT Trial who met the primary endpoint of success after 12 weekly PTNS treatments were invited to participate in the long term STEP Study. Subjects were prescribed a tapering protocol of PTNS for 3 months and then received ongoing therapy according to a Personal Treatment Plan. The frequency of treatment was determined by the investigator and subject to maintain improvement of subject's OAB symptoms. The mean ± SD and median PTNS treatments per month were calculated at 3-month intervals through 30 months. Follow-up questionnaires were completed every 3 months, and 3-day voiding diaries were completed every 6 months from initial treatment baseline. Adverse events were recorded throughout the trial.

Results:

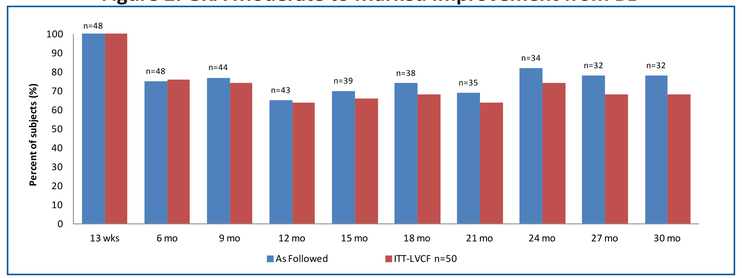
Of the 60 subjects eligible to continue, 87% (52/60) enrolled in the STEP Study. Of 52 subjects enrolled, 34 continued enrollment through 30 months. Eighteen subjects withdrew due to various reasons. The mean number of days between treatments by follow up interval varied from 21.6 to 40.5. Mean number of treatments received per month ranged from 1.1 to 1.3 following the initial and prescribed treatment phase.

Figure 1: Overactive Bladder Quality of Life Questionnaire



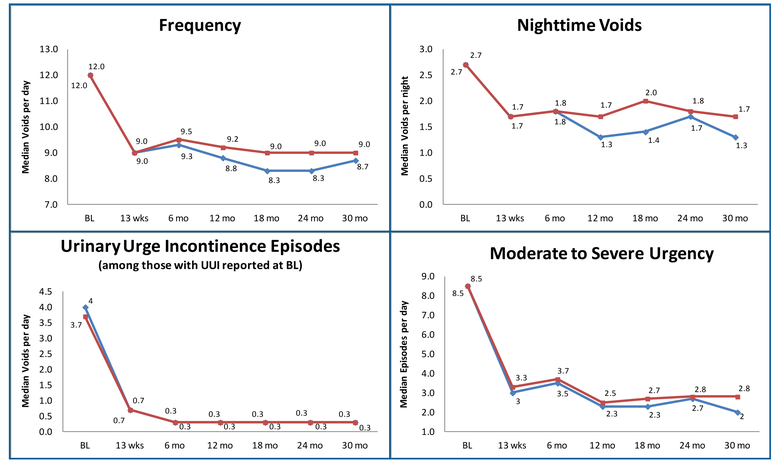
OAB Quality of Life Intent-to-Treat Last Value Carried Forward (ITT-LVCF, n=50) results. p<0.0001 for statistically significant change from BL to all time points for all domains.

Figure 2: GRA Moderate to Marked Improvement from BL



Voiding diary parameters at 6, 12, 18 and 24 months were significant for improvement compared to baseline for frequency, incontinence episodes, nighttime voids and moderate to severe urgency episodes (Figure 3). The OAB-q was also statistically significant for improvement at each follow up interval compared to baseline (Figure 1).

Figure 3: Voiding Diary Results



p< 0.0001 for statistically significant change from BL for all time points and for all analyses.

Conclusion:

Sustained efficacy of PTNS was demonstrated over 30 months with a mean of 1.2 treatments a month following initial success at 12 weeks. Clinicians should consider PTNS treatment in the continuum of care for OAB patients.

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