

Urgent[®] PC Clinical Data

MacDiarmid, S.A., Peters, K.M., Leong, F.C., Shobeiri, S.A., Rovner, E.S., Wooldridge, L.S., Siegel, S.W., et al. (2009). Long term sustained therapeutic effect of percutaneous tibial nerve stimulation in the management of Overactive Bladder. Presentation, American Urological Association Annual Meeting, Chicago, IL.

INTRODUCTION AND OBJECTIVE: Overactive Bladder (OAB) is a chronic syndrome characterized by urinary urgency, with or without urge incontinence, usually associated with frequency and nocturia. Neuromodulation therapy targets specific nerves controlling bladder function with demonstrated efficacy in OAB management. Percutaneous tibial nerve stimulation (PTNS) with Urgent[®] PC targets the posterior tibial nerve for OAB treatment. This study assesses the sustained therapeutic effect of PTNS in OAB patients over one year.

METHODS: The OrBIT Trial was an RCT comparing effectiveness of PTNS to extended-release tolterodine. Patients randomized to PTNS received 12 weekly office-based treatments of 30 minutes. After the initial 12 weeks, only subjects with a successful response to PTNS (N=35) continued treatment in an extension study at intervals tapered to individual rates for sustained relief of OAB symptoms. Outcome measures at 6 and 12 months included voiding diaries, global assessments and safety assessments.

RESULTS: Of the 35 subjects classified as treatment success after 12 weekly PTNS treatments, 32 and 25 subjects finished 6 and 12 months of treatment, respectively; only two discontinued due to lack of efficacy. Subjects received a mean of 11.4±5.6 additional treatments over an average of 249 days; mean of 22.6 days between treatments. One subject had two treatment-related adverse events of abdominal pain. At 6 and 12 months, physicians classified subject OAB symptoms as improved for 31/32 (97%) and 24/25 (96%), respectively. Similarly, 30/32 (94%) and 24/25 (96%) of subjects classified their symptoms as improved at 6 and 12 months, respectively. All outcome measure changes from baseline were significant (p<0.05).

CONCLUSIONS: The sustained therapeutic effect of PTNS therapy in OAB patients over one year demonstrates excellent durability with statistically significant clinical improvement.

Source: [Original Presentation](#)