

Urgent® PC Clinical Data

MacDiarmid, S.A., Peters, K.M., Shobeiri, S.A., Wooldridge, L.S., Rovner, E.S., Leong, F.C., et al. (2010). Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. *J Urol*, 183, 234-240.

PURPOSE: The Overactive Bladder Innovative Therapy Trial during phase 1 was a randomized trial demonstrating comparable effectiveness of percutaneous tibial nerve stimulation and extended-release tolterodine during 12 weeks of therapy for frequency, nocturia, urgency, voided volume and urge incontinence episodes. In this second phase of the Overactive Bladder Innovative Therapy Trial we assessed the sustained therapeutic efficacy of percutaneous tibial nerve stimulation in subjects with overactive bladder during 1 year.

MATERIALS AND METHODS: After 12 weeks subjects randomized to weekly percutaneous tibial nerve stimulation with Urgent® PC were offered an additional 9 months of treatment with assessments at 6 and 12 months from baseline. Outcome measures included voiding diary data, overactive bladder questionnaires, global response assessments and safety assessments.

RESULTS: A total of 33 percutaneous tibial nerve stimulation responders continued therapy with 32 and 25 subjects completing 6 and 12 months of therapy, respectively. Subjects received a mean of 12.1 treatments during an average of 263 days, with a mean of 21 days (median 17) between treatments. Subject global response assessments showed sustained improvement from 12 weeks at 6 and 12 months, with 94% and 96% of responders, respectively. At 12 months mean improvements from baseline included a frequency of 2.8 voids daily ($p \leq 0.001$), urge incontinence of 1.6 episodes daily ($p \leq 0.001$), nocturia with 0.8 voids ($p \leq 0.05$) and a voided volume of 39 cc ($p \leq 0.05$). Overactive bladder questionnaire symptom severity was significantly improved from 12 weeks to 12 months ($p \leq 0.01$) as well as from 6 to 12 months ($p \leq 0.01$). No serious adverse events occurred.

CONCLUSIONS: Statistically significant overactive bladder symptom improvement achieved with 12 weekly percutaneous tibial nerve stimulation treatments demonstrates excellent durability through 12 months. The durability of response demonstrates the effectiveness of percutaneous tibial nerve stimulation as a viable, long-term therapy for overactive bladder.

Source: Original article