

# Urgent<sup>®</sup> PC Clinical Data

**Peters, K.M., Leong, F.C., Shobeiri, S.A., MacDiarmid, S.A., Rovner, E.S., Wooldridge, L.S., et al. (2008). Randomized multicenter study comparing percutaneous tibial nerve stimulation with pharmaceutical therapy for the treatment of overactive bladder. Presentation, Late Breaking Science Forum, American Urologic Association, Annual Meeting, Orlando, FL.**

**INTRODUCTION AND OBJECTIVE:** The multicenter study compared the effectiveness of Percutaneous Tibial Nerve Stimulation (PTNS) versus pharmacological therapy for the treatment of Overactive Bladder (OAB). Both therapies are approved treatments of OAB symptoms in the United States. PTNS is administered using a battery operated stimulator (Urgent<sup>®</sup> PC, Uroplasty Inc.) providing a fixed electrical waveform of variable amplitude ( $\leq 9$  mA) to the tibial nerve during a 30 minute treatment session.

**METHODS:** A total of 100 patients (94 female) across 11 U.S. centers were randomized 1:1 to either PTNS treatment or tolterodine tartrate (Detrol<sup>®</sup> LA, Pfizer). Inclusion criteria included diagnosis with OAB with a minimum of 8 voids per day. Patients randomized to the PTNS arm were treated weekly for 12 consecutive weeks. Patients were randomized to pharmacologic therapy were given a 90 day prescription for either 2 mg or 4 mg daily of Detrol LA. All patients completed a 2 day voiding and bladder control diary at baseline and 12 weeks follow-up. Secondary assessments included a physician and patient global assessment of improvement. All patients were queried on a weekly basis to identify ongoing adverse events.

**RESULTS:** Twelve week follow-up data in this ongoing study was available for 44 PTNS and 43 Detrol patients (41 PTNS and 43 Detrol patients completed voiding diary). Baseline characteristics were homogenous across each treatment group. Comparable reductions in voiding episodes and urge incontinence were achieved in PTNS and Tolterodine LA patients. At 12 weeks follow-up, 80% (35/44) of PTNS patients considered themselves cured or improved versus 55% (23/42) Detrol patients ( $p=0.01$ ). Physicians considered 80% (35/44) of PTNS patients cured or improved versus 61% (26/43) of Detrol patients at 12 weeks ( $p=0.53$ ). The adverse event profile was similar between treatment groups with a statistically lower frequency of dry mouth ( $p<0.01$ ) and constipation ( $p=0.04$ ) in the PTNS arm. QoL scores (overall and subscales) showed statistically significant improvement from baseline for both treatment groups ( $p<0.01$  for all comparisons).

**CONCLUSION:** PTNS provides comparable effectiveness to pharmaceuticals and may be considered a first line therapy for the treatment of OAB.

Source: Original presentation.