

# Urgent<sup>®</sup> PC Clinical Data

**Finazzi-Agrò, E. et al. (2005). Percutaneous tibial nerve stimulation (PTNS) in the treatment of urge incontinence: A double blind placebo controlled study. Poster, SIUD National Congress, Italy.**

**OBJECTIVE:** To evaluate the efficacy of Percutaneous Tibial Nerve Stimulation (PTNS) in the treatment of urge incontinence using a double blind, placebo controlled study, based on an original placebo technique.

**MATERIALS AND METHODS:** Sixteen female patients with urge incontinence and proven detrusor overactivity were randomly assigned to either PTNS or to the control group. Each group underwent twelve 30-minute sessions. The PTNS group (8 patients, mean age 43.5 yrs) received ongoing electrical stimulus throughout the treatment session per the usual PTNS techniques. The control group (8 patients, mean age 45.8 yrs) underwent a placebo treatment in which the electrical stimulator was turned on for a few seconds, then turned off for the remainder of the 30 minutes. Following the initial randomization, the control group was treated with PTNS.

All patients were evaluated with voiding diaries, I-QoL and urodynamics before and after treatment. Results of the two groups were collected by a physician blinded to their treatment and statistically compared.

**RESULTS:** Six of 8 PTNS patients were defined as successful. In contrast, no patients in the Control group were defined as successful. The mean decrease in incontinence episodes/day was -3.7 for PTNS group compared -0.7 for the control group ( $p=0.01$ ). The decrease in the number of micturitions/day was -4.5 for PTNS group compared to -1.3 for the control group ( $p=0.03$ ). The severity of leakage defined using a three-point scale, was -0.87 for the PTNS group compared to 0.2 for the control group ( $p=0.01$ ). The I-QoL was +25 for PTNS group compared to +6 for the control group ( $p=0.01$ ). The PTNS group also had an increased bladder capacity of +85 compared to +15 for the control group ( $p=0.01$ ).

For the control group subsequently treated with PTNS, 5 of 8 patients had successful response. These results were not statistically different than the group initially treated with PTNS.

**CONCLUSION:** PTNS is an effective treatment for urge incontinence due to detrusor overactivity. According to our series, the relevance of a placebo effect seems to be negligible. The placebo technique described in our study seems to lack therapeutic effect.

Source: Uroplasty summary of original poster