Percutaneous Posterior Tibial Nerve Stimulation in the treatment of Overactive Bladder: long term effectiveness

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Introduction

Overactive bladder (OAB) is a chronic condition that significantly impairs the quality of life of women affected, with considerable social and financial costs. The first lines of treatment are typically behavioral interventions followed by antimuscarinic or anticholinergic drugs; however, side effects such as dry mouth, blurred vision, constipation, fatigue and urinary retention are significant in many patients. When behavioral therapy or pharmacology is not effective in the treatment of this pathology, the modulation of bladder reflex pathways has been acknowledged as the next logical step in the algorithm of care. Neuromodulation techniques is percutaneous tibial nerve stimulation (PTNS) is commonly utilized using intermittent (weekly) stimulation of the tibial nerve at the ankle with no permanent lead or stimulator implanted.

The purpose of this study was to demonstrate the long term effectiveness and safety of 12 months of PTNS therapy at 3, 6 and 12 months of follow-up in the improvement of OAB symptoms.

Methods

Two hundred and fifty-four patients with OAB symptoms submitted to percutaneous tibial nerve stimulation sessions were analyzed. We recorded history, physical and urogynecological examination before the treatment. The patients had weekly outpatient bilateral treatment session, each lasting 30 min for 12 weeks; the they continued to receive 2 sessions of PTNS therapy monthly for 3 months and then 1 session monthly for 6 months.

Data from Overactive Bladder Questionnaires (OAB-q) and voiding diaries were completed at baseline, at 3, 6 and 12 months. Subjects completed Global Response Assessments (GRA) at 3, 6 and 12 months.

Technique

PTNS therapy was provided in the outpatient clinic setting. A 34-gauge needle electrode was inserted approximately 5 cm cephalad to the medial malleolus and posterior to the tibia with a surface electrode on the arch of the foot. The needle electrode was then connected to the handheld Urgent® PC stimulator. A current level of 0.5 to 9.0 mA at 20 Hz was then selected based on the participant's motor and/or sensory responses.

Figure 1. Urgent® PC Stimulator system

Figure 2. Percutaneous tibial nerve stimulation in the outpatient setting

Results

Of the 254 patients at baseline, 225 subjects completed the PTNS session at 3 months, 218 and only 188 patients continued PTNS therapy until 6 and 12 months, respectively. Of those who did not complete the study, 18 withdrew for unknown reasons, 12 for ineffectiveness, 16 were lost to follow up, 20 withdrew for unrelated medical reasons . The median age was 56.8 years.

The 3 months subject Global Response Assessment (GRA) for overall bladder symptoms demonstrated that PTNS subjects achieved statistically significant improvement in bladder symptoms with 78.4% reporting moderately or greatly improved responses from baseline ($p<0.001$). Compared to 3 months results, subject's GRA showed a further improvement at 6 and 12 months, 85.3% and 87.7% respectively. The objective improvements in voiding diary parameters demonstrated at 3 months were sustained at 6 and 12 months. The change from baseline on the OAB-q at 3, 6 and 12 months showed statistically significant improvement in both symptoms severity and overall quality of life ($p<0.001$). No serious device related adverse events were reported; 19 patients have complained about some minor ailments with an unknown relation to treatment, as leg pain, diarrhea, pelvic pain, urinary tract infection.

Conclusion

Our experience suggest that PTNS therapy is safe and effective in long term treating OAB symptoms. The therapeutic effect is demonstrated in the early phase (3 months) of the treatment and it is sustained when we performed the prolonged therapy up to 12 months. PTNS may be considered a therapeutic option alternative to drug, particularly considering the high rate of discontinuation of OAB drug therapies due to their considerable side effect profile. PTNS is also minimally invasive and improves quality of life. Long-term follow-up studies are needed to verify these preliminary results

References

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