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REAL-WORLD EFFECTIVENESS OF PERCUTANEOUS TIBIAL NERVE STIMULATION

Hypothesis / aims of study
The primary aim of this study is to determine the effectiveness of percutaneous tibial nerve stimulation (PTNS) in patients with overactive bladder (OAB) symptoms in a real-world setting. We will also determine the rate of patient adherence to the recommended 12 weeks of therapy. Our secondary objective is to determine the rate of conversion to maintenance PTNS therapy as a surrogate for treatment success, and to identify interval treatments offered to those patients who have not derived improvement in their symptoms.

Study design, materials and methods
This is a retrospective review of our electronic medical record (Epic Systems Corp., USA.) for the study period of 11/1/2010 through 11/5/2014 to identify all patients who underwent PTNS at our institution. We utilized billing current procedural terminology (CPT) codes to identify all of the patients. Demographic data, number of treatment visits, prior treatments, AUA symptom indices, Incontinence Symptom Index scores, and interval treatments were abstracted from the medical record. Symptom scores were obtained prior to the 12-week treatment period, during the weekly treatment sessions, and at the completion of the 12-week follow-up period. Descriptive statistics were then performed with SAS (SAS Ins, Cary, NC, USA).

All patients had been treated with the Urgent PC system manufactured by Uroplasty (Uroplasty, Inc. Minnetonka, MN, USA). A 34-gauge solid stainless steel needle electrode was inserted in the leg 3 fingerbreadths (approximately 5cm) superior to the medial malleolus at about a 60-degree angle cephalad after prep of the area with an alcohol swab. The ground electrode was placed on the ipsilateral instep [1]. The stimulator device was attached to the needle and ground pad, and the amplitude increased until a motor response was elicited and a sensory response was reported by the patient. Once the optimal amplitude was identified, the stimulation was continued for a total of 30 minutes. The treatment course was planned for 12 weeks followed by monthly maintenance therapy. Patients were encouraged to complete the full twelve week to determine efficacy and not end the therapy prematurely.

Results
A total of 75 patients were treated with PTNS during the study period. The mean patient age was 66.8 years (range 17-91 years), and 53 patients (70.7%) were female. Sixty-seven (89.3%) patients had previously been on anticholinergic medication or mirabegron and discontinued the medication. The average number of prior medications trialed per patient was 1.67. Twenty-five (33%) of the patients were started on an OAB medication as adjunctive therapy prior to the 12-week treatment period. When compared to patients who underwent stand-alone PTNS, the patients who received PTNS alongside an OAB medication were more likely to transition to maintenance therapy, which was considered a surrogate marker for treatment success ($p<0.002$, Pearson chi-squared test). Six of the 25 patients who began their 12-week treatment period with adjunctive anticholinergic therapy were able to discontinue their OAB medication at the end of the 12-week treatment period.

In the cohort, 46 patients (61.3%) completed the initial 12-week treatment period. Twenty-five of those patients who completed the 12-week induction period went on to monthly maintenance therapy. This was considered a surrogate marker for treatment success (effectiveness of 54%). All patients who completed the 12-week treatment period and went on to maintenance treatment reported at least a 50% improvement in their symptoms.

Of the 29 patients who did not complete the 12-week induction course, 12 patients (16%) dropped out because of no improvement in their symptoms, 6 (8%) dropped out because of hospital admissions or other comorbidities that prevented them from attending their appointments, and 5 patients (6.7%) dropped out because of lack of insurance coverage for their PTNS sessions. Fifteen patients (20%) were subsequently lost to follow-up. In the group of patients who did not complete the 12-week initial treatment period, the patients went on to other treatment modalities such as anticholinergic medication (N=5), mirabegron (N=11), sacral neuromodulation (N=4), botulinum toxin injections (N=5) and physical therapy (N=1).

Thirty percent of the patients who started monthly therapy reported that their symptoms began to worsen sooner than the 4 week maintenance interval between treatments. Average symptomatic return occurred 21.4 days after their maintenance PTNS session. Six patients who transitioned to maintenance therapy subsequently crossed over to another therapeutic modality. Mirabegron was started de novo in 3 patients, sacral neuromodulation in 1 patient, and Botox therapy in 1 patient.

Needle placement was uncomplicated in 74% (N=56) of sessions. The most commonly encountered difficulties with needle placement were peripheral edema, morbid obesity, peripheral neuropathies / hypersensitivities, and chronic pain conditions. The only complications (N=2) were associated with pain during needle placement requiring termination of the procedure.

Interpretation of results
This represents the first report of “real-world” institutional results of PTNS to include both male and female patients. Most patients who underwent this treatment modality at our institution had already failed treatment with at least one anticholinergic medication and many had undergone other treatment modalities for OAB. This study provides valuable information that can be useful when counselling patients. The strength of this study is that these patients did not receive any form of compensation for their time and with a median follow-up that is much longer than those reported in the current literature.

Concluding message

PTNS is an effective, easy to implement treatment modality for refractory OAB with a very low complication rate. Our success rate for the procedure, as defined by the rate of crossover to maintenance therapy after completion of the twelve-week induction period was 54%. Patients must be counselled that it takes a longer than other treatments to produce effective results and should be encouraged to finish the 12-week induction period, as there are a substantial number of them who do not make it to completion of the treatment period. A considerable percentage of patients who pursue PTNS as a treatment modality will end up crossing over to another treatment modality, most commonly beginning therapy with mirabegron either as adjunctive therapy or as another treatment modality with PTNS discontinuation. The patients who are offered PTNS as an adjunct to medical therapy appear to have the greatest overall symptomatic improvement.

References

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