Clinical Practice Assessment

Treating Urinary Incontinence with Posterior Tibial Nerve Stimulation

Clinical Question:
In patients with urge urinary incontinence (UUI) does Posterior Tibial Nerve Stimulation (PTNS) compared to placebo or anticholinergic drugs result in improved patient outcomes.

Bottom line:
PTNS is effective in the treatment of UUI in women who are intolerant to or failed anticholinergic drug therapy. PTNS does not cure UUI but continued treatment may be effective for up to 36 months in some patients. Its efficacy in men is unclear. SORT Strength of evidence B.

Synopsis:
Treatment of overactive bladder with or without urinary urge incontinence involves bladder training, pelvic floor muscle training or anticholinergic drug therapy. Patients who remain symptomatic after these treatments or who are intolerant to them may be candidates for additional therapies. These include Botulinum injection and PTNS. The exact mechanism by which PTNS relieves symptoms is unknown. The sacral micturition center is stimulated by PTNS via the S2-S4 sacral nerve plexus. The procedure is usually performed by insertion of a fine-gauge needle next to the tibial nerve above the ankle. A surface electrode is placed on the foot. A low voltage stimulator connects the needle to the surface electrode. Stimulation of the posterior tibial nerve causes a plantar flexion response or a fanning of the toes. Symptoms include tingling in the foot and toes. A typical treatment lasts about 30 minutes and treatments are usually administered weekly for an initial duration of 12 weeks. Additional treatments are typically needed for continued benefit if the initial treatments are effective.

In a randomized trial¹ of 35 female patients with detrusor overactivity not responsive to anticholinergic therapy, 18 patients were assigned to PTNS and 17 to a sham treatment. Bladder diaries and quality of life scores were recorded before and after treatments which were administered three times per week. One patient in the active treatment group and 2 in the sham treatment group did not complete the study. 12/15 patients (71%) in the treatment group and 0/15 in the sham treatment reported improvement in symptoms. There was an improvement in the number of incontinence episodes, number of voids, voiding volume and quality of life scores in the active PTNS group compared to the sham treatment group. Source of funding/conflict of interest: Uroplasty Inc.

In another randomized control trial² of 220 patients over the age of 18 (110 PTNS, 78% female and 110 sham procedure, 80% female) who had failed conservative therapy and were off anticholinergic therapy for at least two weeks, there was improvement in bladder symptoms at 13 weeks in the active treatment group (60/110, 54.5%) compared to the sham treatment group (23/110, 20.9%). Ankle bruising (1/110, 0.9%), discomfort at the needle site (2/110, 1.8%), bleeding (3/110, 2.7%) and tingling at the needle site (1/110, 0.9%) were side effects in the active treatment group. No side effects were reported in the sham treatment group. A total of 12
patients withdrew prior to study completion. 5 patients withdrew consent (4 PTNS and 1 sham), 4 lost to follow up (2 PTNS and 2 sham), 3 withdrew for other reasons (1 PTNS and 2 sham).

Source of funding/conflict of interest: Uroplasty Inc.

In a randomized controlled trial involving 100 patients with overactive bladder comparing PTNS (50, 96% female) versus extended release Tolterodine (50, 92% female): 87 patients were analyzed (44 PTNS versus 43 Tolterodine). More patients in the PTNS group reported improvement (global response assessment of overactive bladder symptom improvement) (35/44, 79.5%) compared to Tolterodine (23/42, 54.7%). Based on investigator assessment 35/44 (79.5%) in the PTNS group improved at 12 weeks compared to 26/43 (60.5%) in the Tolterodine group. Changes in voids per day, nocturia, urge incontinence, moderate to severe urge symptoms and voided volume per day at 12 weeks compared to baseline were similar in the PTNS and Tolterodine group. 8/49 PTNS patients and 7/49 Tolterodine patients reported side effects. PTNS group side effects included (1 report of each): generalized swelling, worsening incontinence, headache, hematuria, headache, cramps, foot/toe pain, and vasovagal response to placement of the needle. Tolterodine side effects included: constipation, infection, dizziness, headache, vision disturbance, diarrhea, fatigue, ear pain, abdominal pain and increased frequency. Dry mouth and constipation were reported more frequently in the Tolterodine group than in the PTNS group. 8/100 patients withdrew consent prior to 12 weeks of follow up, 5 PTNS and 3 Tolterodine). 4/100 in the Tolterodine group withdrew, 3 because treatment was not successful and 1 for ‘other reasons’. 1 patient allocated to PTNS was lost to follow up. Three patients who did not maintain a voiding diary in the PTNS group were excluded from the analysis. Source of funding/conflict of interest: Uroplasty Inc.

A prospective extension study of patients who had reported moderate to marked improvement with PTNS included 29/50 (78% female) patients in the final analysis at the end of 36 months. Patients were given a taper of PTNS over 14 weeks in which the interval between PTNS treatments were progressively increased. After 5 such treatments, an individual treatment plan was formulated for each participant to treat/prevent overactive bladder symptoms. Patients were not provided overactive bladder medications during the course of this study. Efficacy was determined by a marked or moderate improvement on the global response assessment (GRA) at 36 months. 28/29 patients met the primary efficacy end point at 36 months on the GRA. Those who did not complete the study included, 5 withdrawals for unknown reasons, 3 for ineffectiveness of therapy, 5 lost to follow up, 2 withdrew due to other medical conditions (Congestive heart failure and cancer), 2 patients moved, 2 patients had incomplete or did not return study close out form and 2 had difficulty attending follow up visits. Treatment related adverse effects reported included: 2 reports of bleeding at the needle site. Source of funding/conflict of interest: Uroplasty Inc.

In a multicenter case series of 83 patients (72% women) in the Netherlands 46/83 (55.4%) reported subjective improvement (determined as requesting continued treatment) and 31/83 (37%) had objective improvement (decrease in the number of voids in a 24 hour period and incontinence episodes in a 24 hour period). In this study patients who scored low on the Short Form 36 health survey questionnaire were less likely to have subjective or objective response. Additionally those with a low score (< 30 out of 50) on the mental component were unlikely to respond to PTNS. Source of funding/conflict of interest: Not reported.

In another case series of 35 patients (100% female) followed for 12 months after completion of therapy, the number of patients who were symptom free declined from 19/35 (54%) immediately after treatment to 8/35 (23%) a year after completion of therapy. Recurrences were
usually evident by three months. 3/35 patients (8.6%) were lost to follow up. All patients had previously undergone treatment with oxybutynin. Source of funding/conflict of interest: Not reported.

In a 2012 Cochrane review update of anticholinergic drugs versus non drug therapies for non neurogenic overactive bladder symptoms in adults the authors concluded that anticholinergic drugs were effective in the treatment of overactive bladder symptoms. They also noted that there was limited evidence from small trials that electrical stimulation was a better option in patients who had failed anticholinergic therapy (primarily PTNS). However they also noted that different modalities of electrical stimulation needed to be compared to the most effective anticholinergic drugs to establish this.

References:


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