

Percutaneous tibial nerve stimulation associated with occipital headaches: a review of the adverse effects of percutaneous tibial nerve stimulation

Abstract

Percutaneous tibial nerve stimulation (PTNS) is an effective third line therapy for overactive bladder (OAB); however, there is a paucity of data regarding the adverse effects of PTNS. We review the published side effects of PTNS therapy, which generally are minimal and include bleeding, hematoma, lower extremity swelling, worsening of urinary incontinence, leg cramps, vasovagal response, and generalized headache. In addition, we report a rare case of PTNS induced occipital headache that led to discontinuation of therapy.

Keywords: percutaneous tibial nerve stimulation, overactive bladder, headache, adverse outcomes

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Introduction

Overactive bladder syndrome (OAB) is a common chronic condition characterized by symptoms of urinary urgency, frequency, and nocturia, with or without urinary incontinence in the absence of potential causative pathological or metabolic conditions.¹ The overall prevalence of OAB in the United States is 11-16%² and OAB has been shown to have significant impacts on the quality of life of patients and an estimated cost of 66 billion dollars in the United States.^{2,3}

The American Urologic Association (AUA) recommends a stepwise approach in the treatment for OAB.^{1,4} In patients with persistent symptoms despite adequate trials of either behavioral therapy or pharmacotherapy, third line therapies such as sacral neuromodulation, onabotulinumtoxin A (Botox®) injection, and PTNS are indicated. Medication intolerance for the treatment of OAB, is mainly due to the side effect profile of anticholinergics, which includes dry mouth, dizziness, and constipation.⁵ Mirabegron, a beta-3 agonist used to treat OAB, has a side effect profile of increased blood pressure, tachycardia, and urinary tract infections and less commonly, palpitations and atrial fibrillation.⁶ Sacral neuromodulation has been shown to cause symptom improvement in up to 88% of patients;⁷ however, it has also been demonstrated to have potential adverse effects, such as alteration in bowel habits, surgical wound complications, and the potential for lead migration.⁷ Botox injections can also provide significant improvement of urinary symptoms, but carry the risk of acute urinary retention which may require catheterization and increase the risk of urinary tract infection.⁸

PTNS is an FDA-approved, non-invasive office based procedure consisting of 12 weekly 30-minute sessions with reported urinary symptom improvement rates of greater than 80%.⁹ The mechanism of PTNS treatment is incompletely understood; however, it is proposed that PTNS disrupts abnormal spinal reflex arcs responsible for OAB.¹⁰ PTNS is similar to acupuncture treatments at the spleen 6 (SP6) region, which is located 5cm above the medial malleolus.¹¹ Although a number of clinical trials have reported minimal side effects of PTNS,

the side effects of PTNS are less well documented than other third line therapies for OAB.

A patient undergoing PTNS therapy in our office reported persistent occipital headaches shortly after treatment. We present a case report of this patient with PTNS-induced headache, and we review here the potential side effects of PTNS therapy in OAB patients.

Case presentation

A 56-year-old woman with a past medical history significant for interstitial cystitis, hypertension, hyperlipidemia, C1-C5 cervical spine disease, and overactive bladder refractory to behavioral and pharmacological therapy, presented for her first session of PTNS. She was naïve to previous bladder neuromodulation treatments, and her past medications included both mirabegron (50mg) and oxybutynin (15mg), which were both ineffective in the management of her overactive bladder symptoms.

At baseline, she was alert and oriented with normal mental status and reported no history of headaches. Her past surgical history includes colonic resection for diverticulitis, total abdominal hysterectomy, and analgesic back injections. Neurological examination and CN I-XII exam was within normal limits. Her urodynamic studies showed detrusor activity starting at 40 mL bladder volume and reduced maximum bladder capacity of 180mL. Patient had urge urinary incontinence associated with detrusor overactivity (DO) starting at volume of 79ML.

The PTNS procedure was performed in an office setting. The patient was positioned with her back on the exam table and her upper body at approximately 45 degrees to horizontal. She was comfortable and did not have any back or neck pain associated with her positioning. The posterior tibial nerve was targeted 2 fingerbreaths lateral and 3 fingerbreaths superior to the medial malleolus, as per manufacturer recommendation, and the stimulator was set to 1mA for 30 minutes. The patient initially tolerated the PTNS procedure well and reported no discomfort.

Approximately 30 minutes after the procedure, the patient began to complain of a headache in the occipital region. She described the headache as constant, stabbing 5/10 pain. Over the counter acetaminophen failed to provide pain relief. The patient reported that her occipital headache lasted for approximately 48 hours, and was not accompanied by visual changes, aura, nausea, or vomiting. While the patient has a history of cervical spine disease, and symptoms of chronic neck pain, she stated that the occipital headache she experienced following PTNS therapy was different in quality and location than her pain caused by her cervical spinal disease.

The patient proceeded to get both a second and third course of PTNS therapy and during both sessions, she experienced occipital headache episodes of similar duration, location and intensity. On physical examination, patient had no tenderness to palpation of her cervical or occipital area, and no abnormal masses or lymphadenopathy was appreciated. Due to her recurrent occipital headaches, the patient did not complete a full course of PTNS therapy. The patient has not experienced any further headaches in the seven months following her last PTNS treatment.

Materials and methods

An extensive search of the literature, published in the English language through September 31st, 2017, was performed using PubMed. The following terms were used for the search: Headache, Adverse Effects; an advanced search was performed combining these searches with the following term: Percutaneous tibial nerve stimulation OR Posterior Tibial Nerve Stimulation. We also performed a literature search combining the following terms: acupuncture, overactive bladder, adverse effects. We reviewed the titles, and as needed, the abstracts of the articles yielded by the search, and excluded review articles; animal model studies, and studies using PTNS for conditions other than OAB.

Results

Our initial search identified up to 34 relevant publications. 88 patients across 3 PTNS clinical trials were identified. The following adverse outcomes were noted from PTNS therapy: pain (5.7%), slight bleeding (4.5%), hematoma (1.1%), generalized swelling (1.1%), worsening of incontinence (1.1%), hematuria (1.1%), leg cramps (1.1%), headache (1.1%) and vasovagal response to needle placement (1.1%).^{1,9,12} Our literature search for acupuncture treatment of OAB identified 1 relevant article. No serious adverse outcomes were noted across 118 patients.¹³

Main text

The side effect profiles of PTNS therapy and acupuncture at the SP6 site appear to be minimal in their respective clinical trials. The most common adverse outcomes of PTNS—bleeding, pain, and generalized swelling are common complications of needle placement.¹⁴ In addition, localized muscle cramping has been shown to be associated with the passing of electrical current at the site of PTNS treatment.¹⁵

Some of the neurologic effects of PTNS therapy, namely headache and vasovagal response can be explained by the stimulation of the central nervous system. Studies with fMRI have demonstrated CNS effects associated with acupuncture therapy.^{16,17} Napadow et al.¹⁷ demonstrated that acupuncture therapy in patients with Carpal Tunnel

Syndrome resulted in increased hypothalamic activation compared to healthy controls. Some studies suggest that the hypothalamus is associated with numerous types of primary headache.¹⁸ Moreover, hypothalamic stimulation has also been associated with the vasovagal response.¹⁹ Another side effect of PTNS is worsening urinary incontinence. PTNS therapy is thought to increase inhibitory neuron stimulation of the bladder via afferent S3 nerve fibers.¹⁰ It is possible that it instead induced a stimulatory pathway, leading to increased incontinence. Regarding hematuria as a potential adverse event of PTNS, the literature offers no explanations.

Our patient's occipital headaches possibly occurred secondary to the patient's underlying cervical spine disease. It has been shown that cervical spinal injuries lead to a state of allodynia due to increased secretion of substance P.²⁰ Cervical spine injuries also lead to inflammation and apoptosis, which can both cause alteration of neural pathways.²¹ In addition, studies show that electro stimulation of nerves can lead to release of substance P.²² PTNS treatment, which introduces an electrical current to the tibial nerve, may have served as the trigger for headache in the occipital region. Another possible explanation for our patient's occipital headache is that her symptoms were induced through a central nervous pathway. PTNS therapy may have activated the hypothalamus, a region associated with primary headache, resulting in occipital headaches. It is also possible that the patient's headaches could have been caused by being forced to lie on her back with her upper body at 45 degrees for an extended period of time. However, as the patient had previously tolerated other medical procedures, such as analgesic back injections, which require being positioned in specific positions for extended durations of time without headaches, this explanation is less plausible.

Like other medical procedures, PTNS has the potential to induce anxiety in patients.²³ Studies have shown that cervical spine disease is associated with an increase in anxiety and other psychiatric disorders.²⁴ As a result, this patient is predisposed to anxiety, which has been shown to cause to a state of hyperalgesia.²⁵ While anxiety-induced hyperalgesia may be another potential explanation for our patient's headache symptoms, generally pain induced by anxiety is known to immediately occur after treatment and may increase in severity with time.²⁶ Our patient initially tolerated the PTNS treatment well, and she did not complain of occipital headache pain until 30minutes later. Given the patient's pain presentation, extensive medical and surgical history not associated with headache symptoms, an anxiety etiology is less likely the cause of these headaches.

Conclusion

PTNS is a third line therapy used to treat OAB with an adequate success rate of treatment. PTNS is generally considered to have an excellent side effect profile, especially compared to other forms of OAB treatment. However, it is possible that in patients with significant cervical spine disease, PTNS may induce occipital headache. Fortunately, there are additional third line therapies for OAB treatment including Botox injections and Sacral Neuromodulation.⁹ This case emphasizes the importance of individualized OAB treatment consisting of a combination of numerous behavioral, pharmacological, and procedural therapies.

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Conflicts of interest

CD, JM, GL and BG reports no conflict of interest.

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