

Short-Term Efficacy of Percutaneous Posterior Tibial Nerve Stimulation in Treatment of Overactive Bladder

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Abstract: Objectives: To assess the efficacy and safety of percutaneous posterior tibial nerve stimulation (PTNS) in the treatment of patients with over active bladder (OAB). **Patients and Methods:** In a prospective manner, over a one year period, we evaluated all patients with OAB symptoms for possible study participation. All patients underwent thorough medical history with voiding diary, clinical examination, urine analysis, measurement of blood glucose level, pevi-abdominal ultrasonography and urodynamic study. Only patients with urodynamically confirmed detrusor overactivity were included in the study. Patients with neurologic disorders, diabetes mellitus, urinary tract infection, crystalluria and those on pharmacological treatment for OAB were excluded. PTNS was performed 2 times weekly for 12 weeks. Patients were followed-up by medical history with voiding diary one week after completion of the treatment course. Baseline pre-treatment symptoms were compared with the post-treatment symptoms. Reduction of symptom by 50% was considered improvement. **Results:** The study included 20 patients (11 females and 9 males) with a mean age of 42.4 ± 17.90 . Seventeen patients, 17 (85%) were comfortable with the treatment. Eleventh patients (55%), 15 (75%), 16 (80%) and 15 (75%) showed improvement of the micturation frequency, urgency episodes, urgency and urge incontinence, respectively. Eighty percent of patients reported mild tolerable pain. No serious adverse effects were reported. **Conclusions:** The study results showed that PTNS is an effective, less invasive treatment option for OAB. It can be easy applied safely to treat OAB symptoms with minimal morbidity.

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1. Introduction:

Overactive bladder (OAB) is defined as a symptom complex comprising urinary urgency, with or without urgency incontinence, usually with frequency and nocturia in the absence of local pathological factors (1). Urgency is the hallmark of OAB, and is defined as the sudden compelling desire to urinate which is difficult to defer. OAB is a clinical diagnosis, distinct from the diagnosis made on urodynamic assessment of detrusor overactivity (DO). The overlap between urodynamically-defined DO and subjectively-reported OAB is substantial, but many people with OAB do not have DO and people with DO do not always have urgency (2).

There are a variety of treatment options available for the treatment of OAB. The simplest involve advice on fluid intake. Bladder retraining is often beneficial in short term, but many patients relapse. Supervised pelvic floor muscle training can reduce particularly urgency in some patients (3).

The mainstay of treatment currently is the use of anticholinergic drugs. Although there has been considerable development in these drugs over the last decade, with more bladder specific preparations available, many patients even if they find them effective can struggle with side-effects. These commonly include dry mouth, constipation and

heartburn. Of particular concern in the elderly, is possible side-effects seen with some drugs such as confusion or memory loss which may limit their use. New approaches such as using a transdermal route of administration may be helpful in reducing the side-effects although skin irritation can be a problem (4).

Newer options include the use of intravesical botulinum toxin, sacral nerve stimulation and posterior tibial nerve stimulation (PTNS) (5). Percutaneous PTNS is a technique that was developed a decade or more ago but which does not appear to have become widely adopted into clinical practice. It is currently enjoying much interest with improved equipment and marketing. At a time when conservative and non-surgical treatment options are being encouraged for the management of many conditions, it seems reasonable to consider PTNS. The mechanism of action is not well understood and most of knowledge comes from studying sacral nerve stimulation. There may be different modes of action in different clinical conditions. Some may involve the gate theory, by restoring control at the spinal segment gate as well as some supra spinal sites. Others may involve restoration of the balance between inhibitory and excitatory control systems both centrally and peripherally (6). Side-effects appear almost negligible, being limited to minor discomfort at the needle

insertion site. Another problem seems to be the need for maintenance treatment after the initial 12 week course of therapy (7).

In the present study we presented our experience with PTNS to evaluate its efficacy and safety in treatment of patients with OAB.

2. Patients and Methods:

Over a one year period, all patients with OAB symptoms (urinary frequency, urgency, nocturia and urge incontinence) were prospectively evaluated for possible study participation. All patients underwent the following: (a) complete medical history taking included 3 days voiding diary, (b) thorough physical examination, included neurological assessment of perianal sensation, anal sphincter tone, and a brief screening for any neurological factors as parkinsons' disease or cerebrovascular stroke, (c) complete urine analysis, (d) random blood sugar, (e) pelvi-abdominal ultrasonography, and (f) urodynamic evaluation.

We included only patients with urodynamically diagnosed detrusor overactivity, unresponsive to behavioral and rehabilitation therapy or antimuscarinics with no pharmacological treatment for at least 30 days before beginning the study. Patients with urinary tract infection (UTI), crystalluria, diabetes mellitus and neurological problems as cerebrovascular stroke, parkinsons disease, etc., were excluded.

The included patients were subjected to electrical percutaneous PTNS. Patients were asked to evacuate their bladder before starting the treatment session. Hands were washed and sterile disposable gloves were worn before starting the session. The area surrounding the medial malleolus was cleaned by using sterilizing solution, and the electrodes were placed in this area. The nerve was reached by insertion of a fine needle or a surface electrode approximately 3 fingers breadth cephalic to the medial malleolus, posterior to the tibia. The needle electrode or a surface electrode was placed under the heel of the same foot by a sticky pad that was connected to low voltage stimulator with adjustable pulse intensity from 0-9mA. The amplitude was slowly increased until the large toe start to flex or the toes fan. The nerve was then stimulated at a slightly lower sitting for 30 minutes for each session, frequency at 1-10 Hz, pulse width of 250 micro seconds, biphasic continuous wave of faradic type, maximum tolerable intensity that the patient can stand. The lead wire was connected properly to the stimulator unit. If the large toe was not curl or there was pain at the insertion site the stimulation, the device had been was switched off and the needle repositioned. The treatment is repeated 2 times weekly for 12 weeks.

The treated patients were followed-up one week after completion of the treatment course by voiding diary with evaluation of frequency, urgency, urge incontinence and nocturia symptoms. The subjective success was defined as the patient's positive response resulting in the request for continuing treatment to maintain the response. The objective response was based on bladder diary variables. The success was defined as 50% reduction in symptoms.

The gathered data organized, tabulated and statistically analyzed using statistical software for social science (SPSS) version 20 (SPSS Inc, USA. For qualitative data, frequency and percent distributions calculated, while quantitative data presented as mean and standard deviations.

3. Results:

The study included 20 patients with OAB symptoms; 11 females and 9 males with a mean age of 42.4 ± 17.90 . Out of the 20 patients, 17 (85%) were comfortable with the treatment and requested to continue therapy and the other 3 (15%) chose not to continue therapy.

All the patients completed their bladder diaries at base line and the follow-up. Eleventh patients (55%) showed improvement of the micturation frequency, 15 (75%) showed improvement in the urgency episodes, 16 (80%) showed improvement of the urgency and 15 (75%) showed improvement of the urge incontinence episodes (Table 1).

No serious side effects were reported, although transient pain at the stimulation site was noticed in most of patients (16; 80%) and required no analgesia.

Table 1. Improvement of urinary symptoms, after 12 weeks course of posterior tibial nerve stimulation, in 20 patients with overactive bladder.

Urinary symptoms	Number	%
Frequency of micturation	11	55
Urgency episodes	15	75
Urgency	16	80
Urge incontinence episodes	15	75

4. Discussion:

OAB is a common condition in adult population, with impact on physical, psychological and social well-being, and presents an important burden to the economy of health service (8). OAB symptoms are frequent complaints of patients attending urology and gynecology clinics. In many patients, the cause for these symptoms is DO, which in most cases is idiopathic with no obvious underlying neurological abnormality. Patients with DO suffer from sleep disturbance, psychological distress from embarrassment due to incontinence and disruption to social and work life (9).

Anticholinergic therapy is the first line treatment for OAB but is limited by side effects or lack of therapeutic goal attainment. Neuromodulation is an effective treatment alternative and its efficacy has been well established (10).

Neural stimulation is being used more frequently as a modality of treatment of wide spectrum of voiding dysfunction that failed to respond to conventional pharmacological manipulations. It was noticed that long term electrical stimulation of the peripheral nerves with sufficient intensity to result in an appropriate response in the effector organ did not induce neural damage. PTNS was chosen as the physiotherapeutic method because it is an interesting alternative for the treatment of overactive bladder, which is effective and without side effects, despite the fact that pharmacological treatment is currently the first option for the treatment of patients with the clinical symptoms of OAB, adherence to the treatment is low, especially due to side-effects which lead to discontinuation in 60% of cases. PTNS is considered to be a simpler, less invasive and easy to apply form of

peripheral sacral stimulation that is well tolerated by patients and more affordable (11).

Inhibition of detrusor activity by peripheral neuromodulation of the posterior tibial nerve was first described by *McGuire and colleagues in 1983* (12) then by other authors (13-15). They confirmed a 60–80% positive response rate after 10–12 weekly treatments with PTNS.

PTNS is one of the least invasive forms of neurostimulation, since posterior tibial nerve shares the sacral roots with bladder afferent. It is currently used for a variety of urologic conditions including interstitial cystitis, incontinence, chronic pelvic pain and overactive bladder (16). PTNS is a technique of electrical neuromodulation for the treatment of voiding dysfunction in patients who have failed behavioral and/or pharmacological therapies. While the posterior tibial nerve is located near the ankle, it is derived from the lumbar-sacral nerves (L4-L3) which control the bladder detrusor and perineal floor. Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding dysfunction and control (7).

Table 2. Summary of studies that are consistent with our results

Studies	No. of patients	Conclusions
(13)	53	Success rate (defined as patients with at least 25% reduction in daytime and/or night time frequency) = 71%
(15)	90	Subjective response = 64.4% (58/90) (defined as a patient request for continuous chronic treatment to maintain the response) Objective response (primary outcome - reduction in number of urinary leakage episodes of 50% or more per 24 hours) = 56.7% (34/60).
(17)	51	Statistically significant improvement in frequency, day time voiding volume and nocturia.
(6)	83	Subjective response = 55% (defined as a patient request for continuous chronic treatment to maintain the response) Objective response = 37% (defined as a decrease in symptoms over 50%)
(18)	35	Symptom free after treatment = 54% (19/35) Symptom free at 1 year = 23% (8/35)
(19)		Subjective efficacy=63-64% Objective efficacy= 46-54%
(10)	33	12 sessions of PTNS were offered additional treatment sessions at varying intervals for a further 9 months. 94% (30/32) of patients considered themselves to be cured or improved at 6 months and 96% (24/25) at 12 months.
(20)	83	Subjective response = 55% (defined as a patient request for continuous chronic treatment to maintain the response) Objective response = 37% (defined as a decrease in symptoms of over 50%).
(21)	100 (comparing PTNS with medication)	80% improvement in PTNS group compared to 55% improved in medication group.
(22)	220 (comparing PTNS with Sham)	55 % (60/110) of PTNS group showed moderate to marked improvement compared to 21% (23/110) of sham group.
Our study, 2017	20	Subjective response= 85% (defined as a patient request for continuous chronic treatment to maintain the response). Objective response= patients showed improvement of frequency (55%), urgency (75%) and urge incontinence (75%) and nocturia (80%).

PTN is a mixed nerve containing sensory and motor nerve fibers. Correct placement of the needle electrode induces a motor and sensory response. Centrally, the PTN project to the sacral spinal cord in the same area where the bladder projection is found (the sacral micturition center and the nucleus of Onuf). These are most probably the area where the therapeutic effect of neuromodulation of the bladder through PTNS takes place (15). Stimulation of the (S3) nerves at the level of the medial malleolus of the ankle has been made clinically applicable. Since then several publication report promising early results regarding OAB. This type of therapy seems to depend on physiological process commonly known as neuromodulation, in which influence of activity in one neural pathway modulates the pre-existing activity in another through synaptic interaction. Little is known about the actual mechanism underlying the success of this treatment in man (14).

The result of this study showed that, after 12 weekly sessions of PTNS, remarkable clinical results were obtained 85% of the patients with OAB reported a subjective success. These patients chose to continue treatment to maintain the response. The patients also showed improvement of urinary frequency in 55%, urgency in 75% and urge incontinence in 75% and nocturia in 80%. No serious side effects were reported. The results of our study are consistent and supported by the results reported by others (Table 2).

Conclusions:

From the previous discussion of our results and according to the reports of other investigators, we claim that PTNS which is minimally invasive and easy applied induce improvement of OAB symptoms with negligible side effects.

Conflicts of Interest:

The author has nothing to disclose.

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