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Abourjila A. Gamal Eldin
National Institute of Urology and Nephrology, abourjilag@gmail.com

Amr M. Elsofy
National Institute of Urology and Nephrology

Ayman M. Gabr
National Institute of Urology and Nephrology

Emad K. El Tair
National Institute of Urology and Nephrology

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Original Article

Role of percutaneous tibial nerve stimulation in the management of the detrusor overactivity

Emad K. El Tair, Abourjila A. Gamal Eldin, Ayman M. Gabr, Amr M. Elsofy
Department of Urology, National Institute of Urology and Nephrology, Cairo, Egypt

Abstract

Introduction
Percutaneous tibial nerve stimulation (PTNS) is a technique that was developed a decade or more ago, but it does not seem to have become widely adopted into clinical practice.

Aim
The purpose of this study is focused on the efficacy of PTNS for the treatment of an overactive bladder.

Patients and methods
Between September 2016 and October 2019, this study included 40 patients who are complaining of irritative voiding symptoms, such as frequency, urgency, nocturia, enuresis, and urge incontinence. Those patients are divided into two equal groups subjected to PTNS and sham groups.

Results
Only 40 patients completed the study, and they were divided into two groups A and B. Group A included 20 patients, 17 females and three males with a mean age of 24 years (SD 5.09) subjected to PTNS. Group B included 20 patients, 16 females and four males with a mean age of 27.65 (SD 7.10) as a placebo group. There was a highly significant change in frequency along the treatment course among PTNS. Urge incontinence manifestations in group A (PTNS): at 3 months, 57% of the patients (8/14) showed improvement. At 1 year: 50% of the patients (7/14) showed improvement. Group B (sham): at 3 months, 27% (5/18) only showed improvement. At 1 year, 22% of the patients (4/18) only showed improvement.

Conclusion
Posterior tibial nerve stimulation (PTNS) is an effective, minimally invasive option for the treatment of patients complaining of an overactive bladder with an easily accessible stimulation site and minimal side effects.

Keywords: Detrusor overactivity, overactive bladder, posterior tibial nerve stimulation, urgency incontinence, urgency

Introduction

Overactive bladder symptoms, according to International Society of Incontinence (ICS) definition (urgency, frequency, and nocturia with or without urge incontinence), are frequent complaints of patients attending urology and gynecology clinics. In many patients, the cause for these symptoms is detrusor overactivity (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. Quality of life scores are consistently reduced in this group of patients [1]. There are a variety of treatment options available for the treatment of DO, including advice on fluid intake encouraging an adequate but not excessive fluid intake (~1.5 l per day), avoidance of caffeine,

Correspondence to: Abourjila A. Gamal Eldin, MD, PhD,
Department of Urology, National Institute of Urology and Nephrology,
Mataria, Cairo, Egypt.
Tel: +20 115 681 0883;
E-mail: abourjilag@gmail.com

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bladder retraining, and supervised pelvic floor muscle training that can reduce particularly urgency in some patients [2].

Although there has been considerable development in anticholinergic drugs over the last decade, with more bladder-specific preparations available, many patients, even if they find them effective, can struggle with side effects [3]. Urgency is the hallmark of over-active bladder (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 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 [4]. Percutaneous tibial nerve stimulation (PTNS) is a technique that was developed a decade or more ago. At a time when conservative and nonsurgical 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 our 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 segmental gate and at some supraspinal sites. Others may involve restoration of balance between inhibitory and excitatory control systems both centrally and peripherally [5]. Stimulation of the posterior tibial nerve was pioneered by Stoller and colleagues with the introduction of the Stoller afferent nerve stimulator, which delivers electrical stimulation to the posterior tibial nerve through a 34-G needle just cephalad to the medial malleolus [6]. It has also been demonstrated that PTNS treatment of lower urinary tract dysfunction can improve associated altered sexual function, no doubt contributing to improved quality of life [7]. The lower urinary tract receives innervation from three sources: sympathetic and parasympathetic division of the autonomic nervous system and the neurons of the somatic nervous system [8].

The preganglionic sympathetic neurotransmitter in the sympathetic nervous system is acetylcholine. However, the main postganglionic neurotransmitter is a catecholamine, norepinephrine, which affects adrenergic receptors [9].

Aim

The purpose of this study is focused on the efficacy of PTNS for the treatment of an overactive bladder.

Patients and methods

The study was conducted according to Declaration of Helsinki (1996) and was approved by our Institute Ethical committee.

Between September 2016 and October 2019, this study included 45 patients who were complaining of irritative voiding symptoms, such as frequency, urgency, nocturia, enuresis, and urge incontinence. They are selected randomly from the National Institute of Urology and Nephrology. Those patients are divided into two equal groups subjected to PTNS and sham groups. Inclusion criteria were (a) ages ranged from 20 to 40 years old. (b) The patients were suffering from urgency and one symptom or more such as frequency, nocturia, and urgency incontinence with or without enuresis.

Patients with the following diseases were excluded: urinary tract infections, diabetes mellitus, stress incontinence, urolithiasis, and other neurological lesions. All patients were followed for at least 1 year after informed consent. All patients were subjected to complete history, including urological symptoms such as frequency, urgency, nocturia, enuresis or incontinence, brief screening for any neurological factors or cerebrovascular stroke. Medical history included drug treatment, previous operations, especially pelvic surgeries, and/or neurological surgeries. Detailed analysis of the present urinary symptoms was carried out. A bladder diary was included in the history. Also, all patients underwent physical examination, which includes neurological assessment of perianal sensation, anal sphincter tone, and urological examination. Urological examinations were carried out to exclude any genitourinary lesion that might cause lower urinary tract symptoms. Relevant laboratory investigations, such as serum creatinine and complete urine analysis were carried out to exclude urinary tract infection. Imaging investigations were performed such as plain urinary tract in case of enuresis to exclude spina bifida, abdominopelvic ultrasound lumbosacral imaging, and intravenous urography if needed. Urodynamic studies were carried out before intervention to confirm the diagnosis of an overactive bladder by the presence of uninhibited detrusor contraction in the filling phase of cystometry and after the intervention to evaluate the efficacy of treatment modalities. This procedure was performed by using ANDROMEDA Ellipse urodynamic investigation system made in Germany by testing multichannel cystometry.

Patients were classified into two groups: group A (PTNS group) consists of 20 patients, who were subjected to electrical stimulation of the posterior tibial nerve. Patients should experience a tolerable but not painful sensation, particularly in the region of the large toe. The treatment was repeated for two sessions every week for 12 weeks, then on a maintenance basis, after that depending on the patients' response to previous PTNS once every 2 weeks for 1 year or once monthly for 1 year.

The device used in PINS was Hometech Electric Neuromodulator (made in Taiwan), which is a low-voltage stimulator with an adjustable pulse intensity (from 0 to 9 mA), its frequency is 50 Hz, with a pulse width of 200 μ/s, and has a continuous biphasic wave of faradic type. The nerve was reached by the placement of a surface electrode, approximately three fingerbreadths cephalad to the medial malleolus and posterior to the tibia.

The other surface electrode was placed on the calcaneus of the same foot by a sticky pad, which was connected to a low-voltage stimulator with adjustable pulse intensity (from 0 to 9 mA). The amplitude slowly increased until the large toe starts to flex or the toes fan. The nerve is then stimulated

at a slightly lower setting for 30 min for each session, at a frequency at 50 Hz, pulse width of 200 μ/s, a continuous biphasic wave of faradic type, and maximum tolerable intensity. The lead wire will be connected properly to the stimulator unit.

Group B (sham): this group consists of 20 patients who were treated by fixation of the surface electrode to the posterior tibial nerve with stimulator unit switched off. The course was extended up to 12 weeks. This course included patient education about lower urinary tract (LUT) function, lifestyle changes such as fluid restriction and avoidance of irritants, bladder training, and pelvic floor physiotherapy.

Results

Our study included a total of 45 patients complaining of OAB symptoms (urgency, frequency, nocturia, and urge incontinence). Only 40 patients completed the study, and they were divided into two groups: group A (PTNS group). This group included 20 patients, 17 females and three males with a mean age of 24.25 (SD 5.09) subjected to PTNS and group B (sham group), which included 20 patients, 16 females and four males with a mean age of 27.65 (SD 7.10) as a placebo group. There was no significant difference in age among PTNS versus sham. There is a difference between male and female sex, with a considerable increase in females compared with the male with a *P* value of 1; 40 out of 45 patients of our study completed the research and their bladder diaries at baseline, week 13, and at 1 year when the overactive bladder symptoms were evaluated. Considering the urgency, group A (PTNS) patients at 3 months showed that 14 (70%) patients improved, and only six (30%) patients still complain of urgency. After 1 year, 13 (65%) patients were free of urgency, while seven (35%) patients complained of urgency (Table 1). In group B (sham), at 3 months and at 1 year, six (30%) patients improved, and 14 (70%) patients still complaining of urgency. There was statistical difference ($P = 0.011–0.027$) between the two groups at 3 months and after 1 year.

Considering frequency, 70% of the patients (14/20) of group A (PTNS) showed improvement at 3 months, while 30% of patients (6/20) still complain of frequency. At 1 year, 60% of the patients (12/20) showed improvement, while 40% of patients (7/20) still complain of frequency; 35% (7/20) of patients only showed improvement in group B (sham) at 3 months while 25% (5/20) of patients only showed improvement after 1 year (Table 2).

There was a significant difference between frequency symptoms after 3 months as well as after 1 year among PTNS versus sham. Considering nocturia, at 3 months, 75% of the patients (6/8) showed improvement, and at 1 year, 50% of the patients (4/8) showed improvement in group A.

In group B (sham), at 3 months, 11% (1/9) of patients only showed improvement. At 1 year, only 11% (1/9) of patients showed improvement (Tables 3 and 4).

Table 1: Urgency distribution along treatment course among percutaneous tibial nerve stimulation and sham

Urgency	PTNS [*n* (%)]	Sham [*n* (%)]	*P*
Preintervention	20 (100.0)	20 (100.0)	-
3 months postintervention	6 (30.0)	14 (70.0)	0.011**
1 year postintervention	7 (35.0)	14 (70.0)	0.027**

PTNS, percutaneous tibial nerve stimulation. **Highly significant at $P \leq 0.01$.

Table 2: Frequency along treatment course among percutaneous tibial nerve stimulation and sham

	PTNS			Sham			*P*
	No	Mean	SD	No	Mean	SD	
Preintervention	20	11.80	2.89	20	12.50	4.41	0.556
3 months postintervention	6	7.85	1.69	13	10.90	4.78	0.013*
1-year postintervention	8	8.60	2.11	15	11.50	4.90	0.022*

PTNS, percutaneous tibial nerve stimulation. *Significant at $P \leq 0.05$.

Table 3: Nocturia distribution along treatment course among percutaneous tibial nerve stimulation and sham

Nocturia	PTNS [*n* (%)]	Sham [*n* (%)]	*P*
Preintervention	8 (40.0)	9 (45.0)	0.749
3 months postintervention	2 (10.0)	8 (40.0)	0.028*
1-year postintervention	4 (20.0)	8 (40.0)	0.0168

PTNS, percutaneous tibial nerve stimulation. *Significant at $P \leq 0.05$.

Table 4: Urge incontinence distribution along treatment course among percutaneous tibial nerve stimulation and sham

Urge incontinence	PTNS [*n* (%)]	Sham [*n* (%)]	*P*
Preintervention	14 (70.0)	18 (90.0)	0.235
3 months postintervention	6 (30.0)	15 (75.0)	0.004**
1-year postintervention	7 (35.0)	16 (80.0)	0.004**

PTNS, percutaneous tibial nerve stimulation. **Highly significant at $P \leq 0.01$.

Table 5: Sensation distribution along treatment course among percutaneous tibial nerve stimulation and sham

Sensation	PTNS [*n* (%)]	Sham [*n* (%)]	*P*
Preintervention			
Early	9 (45.0)	7 (35.0)	0.524
Intact	11 (55.0)	12 (60.0)	
Delayed	0	1 (5.0)	
3 months postintervention			
Early	5 (25.0)	6 (30.0)	0.723
Intact	15 (75.0)	14 (70.0)	
Delayed	0	0	

PTNS, percutaneous tibial nerve stimulation.

Urge incontinence showed improvement in 50% of patients (7/14) at 1 year and in group B (sham), at 3 months, 11% (2/18) only showed improvement at 1 year (Table 5).

There was no significant difference in the improvement of sensation after 3 months among PTNS versus sham.

Cystometric capacity showed improvement in group A (PTNS) at 3 months. There was an improvement in mean bladder capacity from 256.7 to 342.3 ml, but in group B (sham), there was nearly no improvement in mean bladder capacity postintervention from 268.1 to 276.5 ml (Table 6).

Statistical analysis

Analysis of data was performed using Statistical Package for the Scientific Studies (SPSS 17, IBM, 1 New Orchard Road Armonk, New York 10504-1722, United States) for Windows. Comparison between quantitative variables was carried out by Student's *t* test. Comparison between qualitative variables was carried out by χ^2 test. Fisher's exact test was used instead of the χ^2 test when one expected cell or more were with a value less than or equal to 5.

Discussion

Overactive bladder symptoms are frequent complaints of patients attending the 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 [10].

Anticholinergic therapy is the first-line treatment for an overactive bladder, but it is limited by side effects or lack of therapeutic goal attainment. Neuromodulation is an effective treatment alternative, and its efficacy has been well established. [1]. Inhibition of detrusor activity by peripheral neuromodulation of the posterior tibial nerve was first described by McGuire and colleagues and more recently Govier *et al.* [1], van Balken *et al.* [11], and Vandoninck *et al.* [12] have confirmed a 60–80% positive response rate after 10–12 weekly treatments with PTNS.

Peters *et al.* [13] i a randomized controlled trial of 100 patients comparing PTNS with medication, 80% (35/44) of the patients in the PTNS group and 55% (23/42) of patients in the medication group considered themselves to be cured or improved. Both groups showed a similar statistically significant decrease in the number of voids per day, nocturia, urge incontinence, and the number of moderate-to-severe urgency episodes per day. Quality of life was also significantly improved in both groups. While in our patients complaining of frequency, group A (PTNS) showed that 70% of the patients (14/20) improved after 3 months. While after 1 year, 60% of the patients (12/20) improved, group B (sham) showed that 35% (7/20) of patients only improved after 3 months while only 25% of patients improved after 1 year postintervention.

Van Balken *et al.* [5], in a case series of 83 patients reported a subjective response of 55% (defined as a patient request for continuous chronic treatment to maintain the response) and an objective response of 37% (defined as a decrease in symptoms (such as the number of voids per 24 h and number of incontinence episodes per 24 h) of more than 50%.

Scaldazza *et al.* [14] found a reduction in the number of daily micturitions both with ES + PFMT and with PTNS with a significant difference in the group of patients undergoing PTNS. Kasman *et al*. [15], in a systematic review of the literature, found that, overall, 22.7% of the study population with overactive bladder syndrome were found to restart an anticholinergic after PTNS. In persons combining the two modalities, 84.2% were noted to have significant improvement compared with PTNS therapy alone, though this was based on subjective patient reports only and did not include more robust outcome measures.

However, in our patients complaining of nocturia, group A (PTNS) showed that 75% of the patients (6/8) showed improvement after 3 months, while after 1-year postintervention, 50% of the patients (4/8) improved. Group B (sham) showed that 11% (1/9) patients improved after 3 months and after 1-year postintervention.

MacDiarmid *et al.* [16] in another series, 33 patients who responded to an initial 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. In our study, patients complaining of urge incontinence, group A (PTNS) showed that 57% of the patients (8/14) improved after 3 months, while after 1 year, 50% of the patients (7/14) improved. Group B (sham) showed that 27% (5/18) of patients only improved after 3 months, while after 1 year, 22% improved postintervention. McGuire *et al.* [17], Stoller [18], Van Balken *et al.* [11], and Vandoninck *et al.* [12] reported that PTNS on patients with overactive bladder symptoms had good results and urodynamic parameters were improved after treatment and a statistically significant decrease in leakage episodes, frequency, and nocturia. In our patients complaining of an unstable bladder, in group A (PTNS), 70% of the patients (14/20) improved after 3 months. In group B (sham), none of the patients improved after 3 months postintervention.

Safety of PTNS: most studies reported no serious adverse events associated with PTNS for overactive bladder syndrome.

Table 6: Capacity along treatment course among percutaneous tibial nerve stimulation and sham

Capacity	PTNS		Sham		*P*
	Mean	SD	Mean	SD	
Preintervention	265.70	102.69	268.15	123.29	0.946
3 months postintervention	342.35	102.48	276.55	100.18	0.047*

PTNS, percutaneous tibial nerve stimulation. *Significant at $P \leq 0.05$.

Coolen *et al.* [19], in their review article, reported that there was a 71% median reduction of urgency urinary incontinence episodes during follow-up with 4.2 urgency urinary incontinence episodes per day at baseline and 1.5 at 6 months with PTNS patients.

Peters *et al.* [13] in the randomized controlled trial comparing PTNS with anticholinergic medication, 16% (8/49) of patients in the PTNS group and 14% (7/49) of patients treated with medication reported at least one moderate adverse event that was considered to be related to the treatment. In the PTNS group, there was one report each of generalized swelling, worsening of incontinence, headache, hematuria, inability to tolerate stimulation, leg cramps, and intermittent foot/toe.

Conclusion

Posterior tibial nerve stimulation (PTNS) is an effective, minimally invasive option for the treatment of patients complaining of overactive bladder with an easily accessible stimulation site and minimal side effects.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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