Title: Efficacy of Percutaneous vs Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder Syndrome, a Randomized Clinical Trial

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ABSTRACT

Introduction: Overactive bladder (OAB), a symptom syndrome consisting of urgency, frequency and nocturia, is a common urologic disorder. Percutaneous posterior Tibial Nerve Stimulation (PTNS) is a minimally invasive, well-tolerated and effective treatment of OAB. Recently, Transcutaneous posterior Tibial Nerve Stimulation (TTNS) with surface electrodes has been used, which is entirely non-invasive. The purpose of this study is to examine and compare the efficacy of these two methods of therapy.

Material & Methods: In this randomized clinical trial, 44 patients with OAB were randomly assigned to one of two groups. In both groups (PTNS and TTNS), the therapeutic interventions were performed three times a week for four weeks a total of 12 sessions. Incontinence Quality of Life questionnaire (I-QOL) and Overactive Bladder Symptom Score (OABSS) were evaluated before the intervention, one week and four weeks after completing the sessions.

Results: Of the 44 patients, 41 females and three males, the mean age of the subjects was 51.95 in the PTNS group and 56.86 in the TTNS group (P-value: 0.9). In our study, patients' urinary symptoms and quality of life improved in both groups over time. There was no significant difference between the two interventions (P-value of 0.796 and 0.372, respectively).

Conclusion: Both PTNS and TTNS effectively improved patients' symptoms of OAB and their quality of life. TTNS can be considered as effective as conventional PTNS and be used as a less invasive alternative for PTNS in OAB treatment.

Mesh Terms: Overactive Bladder, Nerve stimulation.

INTRODUCTION

Based on the International Continence Society (ICS), OAB is urinary urgency, with or without urge incontinence, usually with urinary frequency and nocturia, in the absence of urinary tract infection (UTI) or other pathologies that would explain these symptoms(1). The overall prevalence of overactive bladder in the United States is reported 16.0% and 16.9% for men and women respectively, while, in another EPIC study in 5 countries(Canada, Germany, Sweden, Italy and UK) similar prevalence, 11.8%, is reported in men and women (2, 3).

OAB is associated with significantly lower quality-of-life scores, higher depression scores, poorer sleep quality, sexual satisfaction, and work productivity (2, 4). ICS recommended initial management includes lifestyle modification, bladder training, pelvic floor muscle training, antimuscarinics, anti-diuretic or alfa blockers medications and intermittent catheterization when PVR >30% of bladder capacity, which may differ based on symptoms severity and sex. Invasive therapies such as neuromodulation and botulinum toxin injections in case of initial management failure and markedly disrupted quality of life are being considered(5).

Neuromodulation can be accomplished by invasive implantable sacral nerve roots stimulation systems with relatively high complication rates or less invasive perineal, perianal or tibial nerve stimulation (6). Stoller described Percutaneous Tibial Nerve Stimulation (PTNS) technique in the late 1990s to treat overactive bladder syndrome (7). Posterior tibial nerve (PTN) is a mixed sensorimotor nerve originating from L4 to S3 lumbosacral nerve roots, while Sacral S3-S4 spinal segments contribute to pelvic floor, bladder and urethra autonomic and somatic innervations. Theoretically, PTN stimulation at the medial malleolus directly stimulates the upper sacral segments' afferent fibres(S1-S2). Although the exact mechanism of the urinary inhibitory response generated by PTN stimulation is unclear, it's been reported that it has an inhibitory effect on spinothalamic tract neurons(8). More recently, specific spinal receptors and

the micturition pathway's central neuroplasticity are considered to be involved(9). To date, there are several reports of its effectiveness in treating OAB (10-17).

A 34-gauge needle electrode is inserted 4–5 cm cephalad to the medial malleolus, a neural access point for the regulation of bladder and pelvic floor function, for 20 Hz, 200 µs duration electrical stimulation. In an even less invasive manner, Transcutaneous Tibial Nerve Stimulation (TTNS) performed with two surface electrodes for electrical stimulation is suggested to be effective in OAB treatment (18, 19). This study evaluates the possible therapeutic effect of TTNS and compares it with the PTNS technique for OAB management.

METHOD

This clinical trial has been approved by the Ethics Committee of the University of Medical Sciences, and the registry of clinical trials.

We enrolled 44 patients of OAB who were diagnosed clinically based on the American Urological Association guideline 2019 (5). The inclusion criteria were age>18 and not having anticholinergic medication from one week and in the course of the study. All participants have received the initial treatment (lifestyle modification, pelvic floor muscle training with or without pharmacologic treatments). Participants were not included in case of any of these conditions: diabetes mellitus, pregnancy or attempting to get pregnant, implanted pacemaker, active or recurrent (>4 times per year) UTI and neurologic disease.

All participants were informed and provided with the consent form. They were randomly assigned to one of the two groups, using a randomization table. In the PTNS group, a 34-gauge needle electrode was inserted 5 cm cephalad to the medial malleolus and posterior to the tibial bone (Figure 1). The needle electrode was connected to the active pole, and a surface reference electrode was placed on the medial malleolus. Bi-phasic constant current with 200 µs pulse

width, 0.5- 9 mA, 20 Hz was applied to induce big toe plantar flexion for 30 minutes each session, three times per week for four weeks.

In the TTNS group, instead of needle insertion, an active surface electrode was used with the same stimulation parameters (Figure 2). Self-reported Incontinence Quality of Life (I-QOL) questionnaire and Overactive Bladder Symptom Score (OABSS) form was filled out by the participants before, one week and four weeks after the termination of intervention sessions.

The I-QOL contains 22 items, each with a five-point response scale, yielding a total score and three subscale scores for avoidance and limiting behaviour, Psychosocial impacts and Social embarrassment (20). The OABSS quantify four symptoms of OAB in the past week, which conclude daytime frequency, night-time frequency, urgency and urinary incontinence (21).

The data reviewer, alike the data analyst, was blinded to the participant's groups, despite the physician who was involved in the therapy sessions.

For statistical analysis, the mixed ANOVA test was used to compare intervention efficacy between groups. P values of less than 0.05 were considered statistically significant.

RESULT

We treated 44 patients, 41 females and three males, with no significant difference in mean age, sex, BMI and patients' symptom duration between the two groups (Table 1).

OABSS questionnaire:

In the within-group analysis, we observed a significant difference in this scaled score in all three intervals (before intervention-week 1, before intervention- week four and week1-week 4) in both groups (P values < 0.001), therefore TTNS and PTNS both were effective in patients' symptoms improvement (Table 2).

Between-group analysis showed no statistically significant difference between the changes in two groups at three intervals (P-value: 0.79), which means both interventions have the same therapeutic effect (Figure 3).

(I-QOL) questionnaire:

The total scores and three subscale scores for avoidance and limiting behaviour, psychosocial impacts and social embarrassment were analyzed separately. Within-group analysis of total scores showed that both interventions had made a statistically significant difference in three intervals of follow up (P values < 0.001) which indicates both interventions were effective in QOL improvement (Table 3).

The result of the between-group analysis of the I-QOL questionnaire total scores also showed no statistically significant difference between the changes of the two groups at all time intervals (P-value: 0.37), which means both interventions have acted similarly in refining patients' QOL (Figure 3). We observed the same results as total scores in all three I-QOL questionnaire subscales (Tables 4,5,6 and Figure 3).

DISCUSSION

OAB affects a significant proportion of the population with a weighty public health burden. Aside from psychological impacts and physical activity limitations, which affect the individual and the economic system for routine treatment and care, occupational productivity is also affected(22, 23). Subjects with OAB had shorter times to disability than those without OAB(24).

Conventional first-line treatment includes the combination of behavioural and pharmacologic therapy (anticholinergic and ß3 agonists), which can induce better efficacy, lesser drug dosage

and side effect than pharmacologic treatment alone. PTNS, as a less invasive peripheral neuromodulator, is considered for the third-line treatment based on AUA/SUFU Guideline(25).

In 1999, Yamanishi et al. used vaginal/perianal electrical stimulation to treat refractory OAB-induced incontinence and reported increased bladder capacity measured urodynamically(26). Published reviews in 2005 and 2009 on PTNS clinical trials found it encouraging, less invasive, economic, and negligible risks to offer to manage a wide range of pelvic floor dysfunction symptoms (6, 14). In 2012 Staskin et al. evaluated the aspects of PTNS, including effectiveness, adverse effects and cost-effectiveness with other treatment options and suggested that it should be considered early in the care algorithm of OAB patients(17). Eventually, the evidence reported OAB PTNS therapy as level 1 in 2013(10).

TTNS, an even lesser invasive intervention than PTNS, is also being investigated and reported effective in recent trials as a neuromodulation method for OAB treatment. This method could provide greater benefits than behavioural therapy reported by two studies(27). Two 30-minute sessions of TTNS showed a similar outcome as 10 mg of extended-release oxybutynin after12 weeks of therapy(19). In the study of Ammi et al, home-based daily TTNS for 1 month was successful in 53% of patients with previous failed anticholinergic therapy(18), and interestingly, it could also be effective by being used once a week for 3 months(28). The number of therapy sessions per week, as well as different stimulation characteristics which may alter the therapeutic result, needs to be enlightened by further trials.

In line with our study, other researchers have reported encouraging results from comparing two methods of TNS for OAB treatment. In a review of 4 trials (142 patients) comparing PTNS and TTNS by Yang et al, TTNS showed the same effectiveness as PTNS for the treatment of OAB patients(29). Similarly, a recent clinical trial has also compared PTNS and TTNS for OAB treatment in a 12 weeks therapy course and both have concluded the same effectiveness of these two methods (30).

In this study, we found TTNS and PTNS both equally effective in OAB. We evaluated the effectiveness of 30 minutes of tibial nerve stimulation for 12 sessions, 3 times a week (4 weeks totally). All three symptoms of OAB (frequency, urgency and incontinency) were improved one week after the treatment and kept the progressive trend to the fourth week after the intervention in both groups, together with the QOL improvements related to OAB-induced avoidance and limiting behaviour, psychosocial impacts and social embarrassment. Comparing the study of Ramírez-García et al(30) with ours, 12 sessions of P/TTNS with similar stimulation parameters, but at different intervals (1 and 3 times a week), both were effective in controlling OAB symptoms.

Considering the anticholinergic side effects of medications used in non-responders to behavioural therapy alone and the reported similar effects of PTNS and medication(19), it may be rational to investigate TTNS therapy as a second-line treatment after behavioural therapy.

Regarding the safety and feasibility of TTNS, it can also be suggested as a home-based modality for the initial treatment course or even for long-term maintenance therapy(31-33). This may extend its therapeutic effects while lessening the time-consuming process of inpatient PTNS and its burden on the patient and health care system. In the study of Martin-Garcia et al., home-based TTNS is reported as effective as maintenance PTNS treatment for previously PTNS responders(34). Near 50 % of patients who completed inpatient sessions, are said to discontinue long-term PTNS therapy(35, 36). Thus, it would be hypothesized that home-based TTNS may potentially improve patient adherence to the treatment which needs to be further investigated.

CONCLUSION:

TTNS could be effective in the management of OAB symptoms, same as PTNS.

The relatively equal effectiveness of both methods and the less invasive, more feasible process of TTNS make it an excellent option to be considered early in the management of OAB patients.

STRENGTHS AND LIMITATIONS:

This RCT has a triple-blind design with properly-matched controls. Our limitation is that the long-term effectiveness of P/TTNS in OAB syndrome is not evaluated.

CONFLICTS OF INTEREST: None.

DISCLOSURES: None.

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Table 1 Caption: Groups Demographic Statistics for age, BMI and symptom duration

Table 2 Caption: Group-time interaction with OABSS parameter evaluated in two groups

Table 2 Alt Text: *Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Table 3 Caption: Group-time interaction with Incontinence Quality of Life parameter in two groups

Table 3 Alt Text: *Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Table 4 Caption: Group-time interaction with avoidance and limiting behaviour parameter in two groups

Table 4 Alt Text: *Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Table 5 Caption: Group-time interaction with psychosocial impact parameter in two groups

Table 5 Alt Text: *Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Table 6 Caption: Group-time interaction with social embarrassment parameter in two groups

Table 6 Alt Text: *Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Figure 1 Electrode positions for PTNS

Figure 2 Electrode positions for TTNS

Figure 3 Caption: Score means evaluated in two groups.

Figure 3 Alt Text: OABSS: Over Active Bladder Symptom I-QOL: Incontinence Quality of Life ALB: Avoidance and limiting behaviour PSI: Psychosocial impact SE: Social embarrassment

Table 1 Groups Demographic Statistics for age, BMI and symptom duration

Group Statistics table						
	group	N	Mean	Std. Deviation	Std. Error Mean	P-value
Age (Yrs.)	PTNS (needle)	22	51.9	13.9	2.9	0.911
	TTNS (patch)	22	56.8	13.6	2.9	
BMI	PTNS	22	28.5	4.4	.9	0.649
	TTNS	22	28.5	5.2	1.1	
Duration (months)	PTNS	22	58.5	53.0	11.3	0.084
	TTNS	22	72.6	90.7	19.3	

Table 2 Group-time interaction with OABSS parameter evaluated in two groups

Pairwise Comparisons							
Measure: OABSS							
group	(I) time*	(J) time*	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
needle	1	2	2.4	.3	.000	1.6	3.3
		3	3.8	.3	.000	2.8	4.8
	2	1	-2.4	.3	.000	-3.3	-1.6
		3	1.4	.2	.000	.7	2.0
	3	1	-3.8	.3	.000	-4.8	-2.8
		2	-1.4	.2	.000	-2.0	-.7
patch	1	2	2.2	.3	.000	1.4	3.1
		3	3.9	.3	.000	2.9	4.9
	2	1	-2.2	.3	.000	-3.1	-1.4
		3	1.6	.2	.000	1.0	2.3
	3	1	-3.9	.3	.000	-4.9	-2.9
		2	-1.6	.2	.000	-2.3	-1.0

*Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Table 3 Group-time interaction with Incontinence Quality of Life parameter in two groups

Pairwise Comparisons							
Measure: I-QOL							
group	(I) time*	(J) time*	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
needle	1	2	-17.3	3.6	.000	-26.4	-8.2
		3	-26.3	3.8	.000	-35.9	-16.7
	2	1	17.3	3.6	.000	8.2	26.4
		3	-9.0	1.7	.000	-13.4	-4.5
	3	1	26.3	3.8	.000	16.7	35.9
		2	9.0	1.7	.000	4.5	13.4
patch	1	2	-11.2	3.6	.011	-20.3	-2.1
		3	-22.5	3.8	.000	-32.1	-12.9
	2	1	11.2	3.6	.011	2.1	20.3
		3	-11.2	1.7	.000	-15.6	-6.8
	3	1	22.5	3.8	.000	12.9	32.1
		2	11.2	1.7	.000	6.8	15.6

*Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Table 4 Group-time interaction with avoidance and limiting behaviour parameter in two groups

Pairwise Comparisons							
Measure: IQOL ALB							
group	(I) time*	(J) time*	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
needle	1	2	-17.3	3.6	.000	-26.3	-8.3
		3	-18.6	3.7	.000	-27.9	-9.2
	2	1	17.3	3.6	.000	8.3	26.3
		3	-1.2	2.1	1.000	-6.6	4.0
	3	1	18.6	3.7	.000	9.2	27.9
		2	1.2	2.1	1.000	-4.0	6.6
patch	1	2	-13.4	3.6	.002	-22.4	-4.5
		3	-16.4	3.7	.000	-25.8	-7.1
	2	1	13.4	3.6	.002	4.5	22.4
		3	-2.9	2.1	.519	-8.3	2.3
	3	1	16.4	3.7	.000	7.1	25.8
		2	2.9	2.1	.519	-2.3	8.3

*Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Table 5 Group-time interaction with psychosocial impact parameter in two groups

Pairwise Comparisons							
Measure: IQOL PSI							
group	(I) time*	(J) time*	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
needle	1	2	-17.4	4.0	.000	-27.4	-7.4
		3	-18.1	4.1	.000	-28.4	-7.9
	2	1	17.4	4.0	.000	7.4	27.4
		3	-.7	1.0	1.000	-3.3	1.8
	3	1	18.1	4.1	.000	7.9	28.4
		2	.7	1.0	1.0	-1.8	3.3
patch	1	2	-8.0	4.0	.1	-18.0	1.9
		3	-10.2	4.1	.0	-20.4	.0
	2	1	8.0	4.0	.1	-1.9	18.0
		3	-2.1	1.0	.1	-4.7	.4
	3	1	10.2	4.1	.0	-.0	20.4
		2	2.1	1.0	.1	-.4	4.7

*Times 1, 2, and 3 are before, one week and four weeks after the intervention.

Table 6 Group-time interaction with social embarrassment parameter in two groups

Pairwise Comparisons							
Measure: IQOL SE							
group	(I) time*	(J) time*	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
needle	1	2	-17.2	4.2	.001	-27.9	-6.5
		3	-19.0	4.4	.000	-30.2	-7.9
	2	1	17.2	4.2	.001	6.5	27.9
		3	-1.8	1.9	1.000	-6.7	3.1
	3	1	19.0	4.4	.000	7.9	30.2
		2	1.8	1.9	1.000	-3.1	6.7
patch	1	2	-13.4	4.2	.010	-24.0	-2.7
		3	-17.9	4.4	.001	-29.0	-6.8
	2	1	13.4	4.2	.010	2.7	24.0
		3	-4.5	1.9	.080	-9.4	.3
	3	1	17.9	4.4	.001	6.8	29.0
		2	4.5	1.9	.080	-.3	9.4

*Times 1, 2, and 3 are before, one week and four weeks after the intervention.

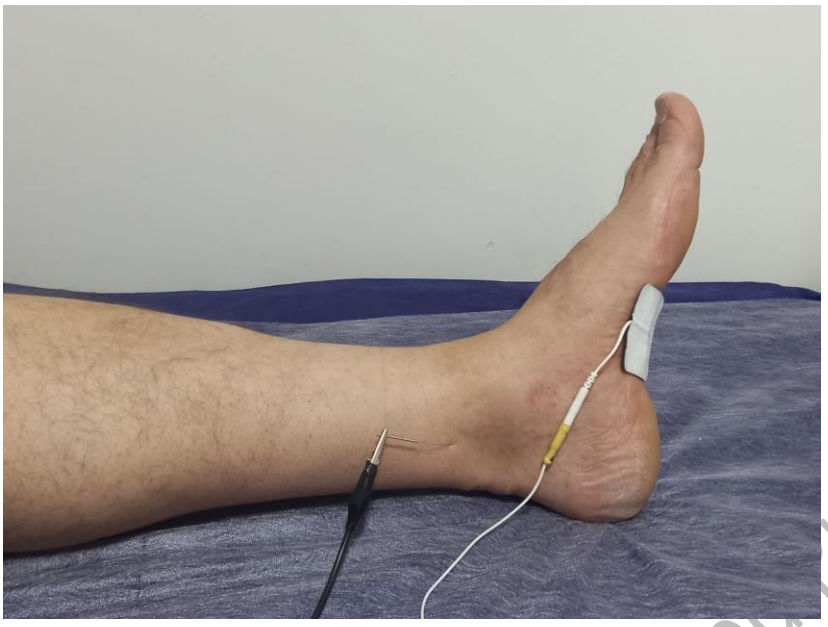

Figure 1 Electrode positions for PTNS

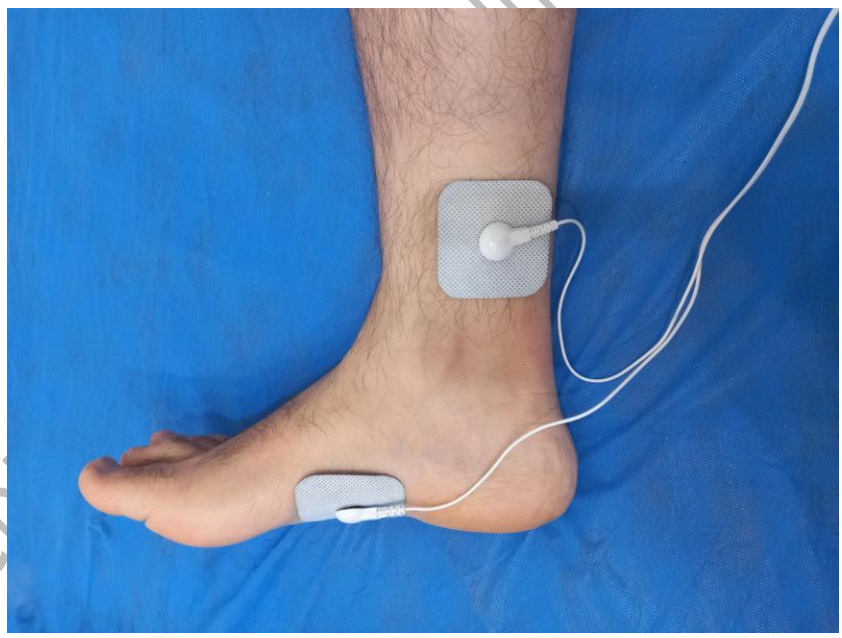

Figure 2 Electrode positions for TTNS

Figure 3 Score means evaluated in two groups.

OABSS: Over Active Bladder Symptom I-QOL: Incontinence Quality of Life ALB: Avoidance and limiting behaviour PSI: Psychosocial impact SE: Social embarrassment