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Research Paper

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) is a symptom syndrome consisting of urgency, frequency, and nocturia. It is a common urologic disorder. Percutaneous posterior tibial nerve stimulation (PTNS) is a minimally invasive, well-tolerated, and effective treatment of OAB. Recently, transcutaneous PTN stimulation (TTNS) with surface electrodes has been used, which is non-invasive. This study examines and compares the efficacy of these two therapy methods.

Methods: In this randomized clinical trial, 44 patients with OAB were randomly assigned to PTNS and TTNS groups. In both groups, the therapeutic interventions were performed thrice a week for four weeks, 12 sessions. Incontinence quality of life questionnaire (I-QOL) and OAB symptom score (OABSS) were evaluated before the intervention, then one week and four weeks after completing the sessions.

Results: Of 44 patients (41 females and 3 males), the mean age of the subjects was 51.95 years in the PTNS group and 56.86 years in the TTNS group (P=0.9). In our study, the patients' urinary symptoms and QOL improved in both groups over time. Both interventions had no significant difference (P=0.796, P=0.372, respectively).

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

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Highlights

• Both percutaneous tibial nerve stimulation (PTNS) and transcutaneous tibial nerve stimulation (TTNS) effectively improve the patients' symptoms of overactive bladder (OAB) syndrome.

• TTNS can be considered an effective, less invasive alternative for conventional PTNS.

Plain Language Summary

Stimulation of a sensorimotor nerve at the ankle can effectively treat the OAB. Throughout this specific nerve, which is superficial and reachable at the ankle, we can co-stimulate the deep pelvic nerves which control the bladder contraction and manage the OAB symptoms. This article investigates the most non-invasive TTNS and found it as effective as the previous more invasive nerve stimulations for OAB.

1. Introduction

Based on the International Continence Society (ICS), overactive bladder (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 (Wein & Rovner, 2002). The overall prevalence rates of OAB in the United States are reported to be 16.0% and 16.9% for men and women, respectively. However, in another EPIC study in 5 countries (Canada, Germany, Sweden, Italy, and the UK), a similar prevalence of 11.8% was reported for men and women (Irwin et al., 2006; Stewart et al., 2003).

OAB is associated with significantly lower quality-of-life (QoL) scores, higher depression scores, poorer sleep quality, sexual dissatisfaction, and work productivity (Coyne et al., 2008; Stewart et al., 2003). ICS recommends that initial management should include lifestyle modification, bladder training, pelvic floor muscle training, antimuscarinics, anti-diuretic or α-blockers medications, and intermittent catheterization when the post-void residual volume (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 QoL are being considered (Lightner et al., 2019).

Neuromodulation can be accomplished by invasive implantable sacral nerve root stimulation systems with relatively high complication rates or less invasive perineal, perianal, or tibial nerve stimulation (Cooperberg & Stoller, 2005). Stoller described the percutaneous tibial nerve stimulation (PTNS) technique in the late 1990s as a treatment for OAB syndrome (Stoller, 1999). 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 fibers (S1-S2). Although the exact mechanism of the urinary inhibitory response generated by PTN stimulation is unclear, it may exert an inhibitory effect on spinothalamic tract neurons (Chung et al., 1984). More recently, specific spinal receptors and the micturition pathway's central neuroplasticity are considered to be involved (van der Pal et al., 2006). Several reports show its effectiveness in treating OAB (Burton et al., 2012; Finazzi-Agrò et al., 2010; Gaziev et al., 2013; MacDiarmid et al., 2010; MacDiarmid & Staskin, 2009; Peters et al., 2009; Staskin et al., 2012; van Balken et al., 2001).

A 34-gauge needle electrode is inserted 4–5 cm cephalad to the medial malleolus, a neural access point for regulating bladder and pelvic floor function, for 20 Hz, 200 μs duration electrical stimulation. In an even less invasive manner, transcutaneous tibial nerve stimulation (TTNS) with two surface electrodes for electrical stimulation is suggested to be effective in OAB treatment (Ammi et al., 2014; Manríquez et al., 2016). This study evaluates the therapeutic effect of TTNS and compares it with the PTNS technique for OAB management.

2. Materials and Methods

We enrolled 44 patients of OAB who were diagnosed clinically based on the 2019 American Urological Association (AUA) guideline (Lightner et al., 2019). The inclusion criteria comprised patients older than 18 who had not used anticholinergic medication for one week be-

Table 1. Groups demographic statistics for age, BMI, and symptom duration

Group Statistics Table					P
Variables	**Group**	**No.**	**Mean±SD**	**SEM**	
Age (y)	PTNS (needle)	22	51.9±13.9	2.9	0.911
	TTNS (patch)	22	56.8±13.6	2.9	
BMI (kg/m^2)	PTNS	22	28.5±4.4	0.9	0.649
	TTNS	22	28.5±5.2	1.1	
Duration (mo)	PTNS	22	58.5±53.0	11.3	0.084
	TTNS	22	72.6±90.7	19.3	

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fore and during the study. All participants have received the initial treatment (lifestyle modification, pelvic floor muscle training with or without pharmacologic therapies). Participants were omitted if they were inflicted with 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, and 20 Hz was applied to induce big toe plantar flexion for 30 minutes each session, thrice weekly for four weeks.

In the TTNS group, instead of needle insertion, an active surface electrode was used with the same stimulation parameters (Figure 2). The participants filled out the self-reported incontinence quality of life (I-QOL) questionnaire and OAB symptom score (OABSS) form before, 1 week, and 4 weeks after the termination of intervention sessions.

The I-QOL contains 22 items with a 5-point response scale, yielding a total and three subscale scores for avoidance and limiting behavior, psychosocial impacts, and social embarrassment (Patrick et al., 1999). The OABSS quantifies four symptoms of OAB in the past week, which include daytime frequency, night-time frequency, urgency, and urinary incontinence (Homma et al., 2006).

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

The mixed analysis of variance (ANOVA) test was used for statistical analysis to compare intervention efficacy between groups. $P<0.05$ were considered statistically significant.

3. Results

We treated 44 patients, 41 females and 3 males, with no significant difference in mean age, sex, body mass index (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 vs week 1, before intervention vs week 4, and week 1 vs week 4) in both groups ($P<0.001$). Therefore, TTNS and PTNS effectively improved patients' symptoms (Table 2).

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

I-QOL questionnaire

The total and three subscale scores for avoidance and limiting behavior, psychosocial impacts, and social embarrassment were analyzed separately. Within-group analysis of total scores showed that both interventions showed a statistically significant difference in three inter-

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

Pairwise Comparisons							
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	0.3	0.000	1.6	3.3
		3	3.8	0.3	0.000	2.8	4.8
	2	1	-2.4	0.3	0.000	-3.3	-1.6
		3	1.4	0.2	0.000	0.7	2.0
	3	1	-3.8	0.3	0.000	-4.8	-2.8
		2	-1.4	0.2	0.000	-2.0	-0.7
Patch	1	2	2.2	0.3	0.000	1.4	3.1
		3	3.9	0.3	0.000	2.9	4.9
	2	1	-2.2	0.3	0.000	-3.1	-1.4
		3	1.6	0.2	0.000	1.0	2.3
	3	1	-3.9	0.3	0.000	-4.9	-2.9
		2	-1.6	0.2	0.000	-2.3	-1.0

*Times 1, 2, and 3 are before, 1 week, and 4 weeks after the intervention, respectively.

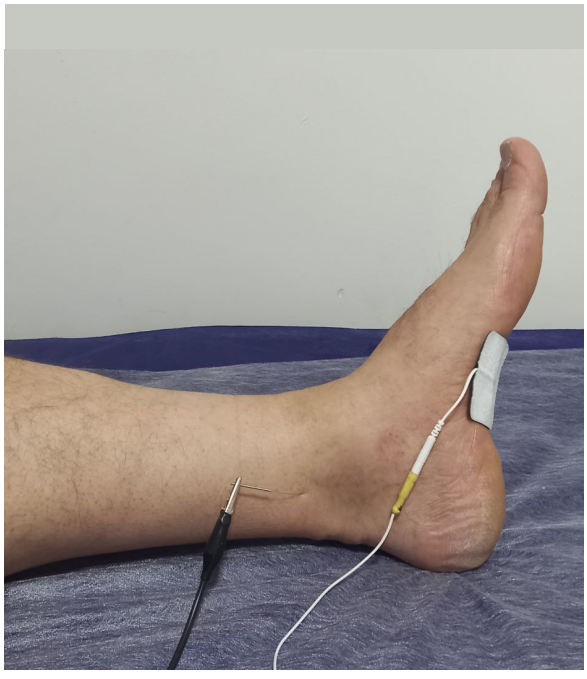

Figure 1. Electrode positions for PTNS

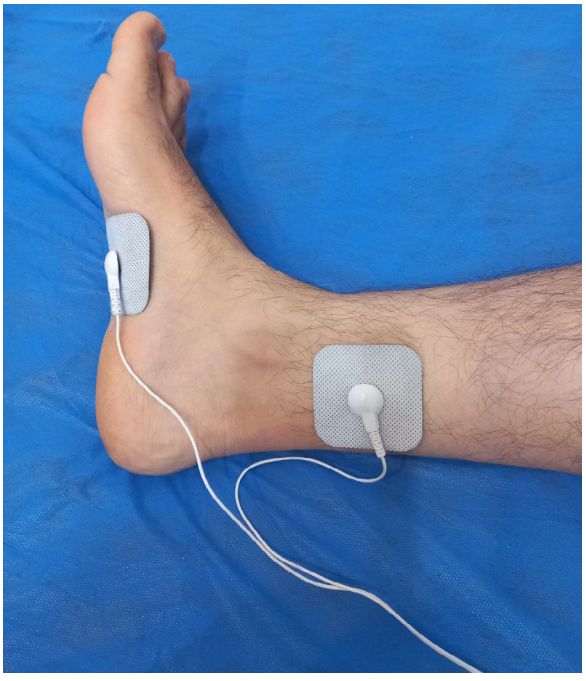

Figure 2. Electrode positions for TTNS

Table 3. Group-time interaction with I-QOL parameter in two groups

Pairwise Comparisons							
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	0.000	-26.4	-8.2
		3	-26.3	3.8	0.000	-35.9	-16.7
	2	1	17.3	3.6	0.000	8.2	26.4
		3	-9.0	1.7	0.000	-13.4	-4.5
	3	1	26.3	3.8	0.000	16.7	35.9
		2	9.0	1.7	0.000	4.5	13.4
Patch	1	2	-11.2	3.6	0.011	-20.3	-2.1
		3	-22.5	3.8	0.000	-32.1	-12.9
	2	1	11.2	3.6	0.011	2.1	20.3
		3	-11.2	1.7	0.000	-15.6	-6.8
	3	1	22.5	3.8	0.000	12.9	32.1
		2	11.2	1.7	0.000	6.8	15.6

*Times 1, 2, and 3 are before, 1 week, and 4 weeks after the intervention, respectively.

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vals of follow-up (P<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=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, and 6; Figure 3).

4. 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 (Reynolds et al., 2016; Tang et al., 2014). Subjects with OAB had shorter times to disability than those without OAB (Wu et al., 2005).

Conventional first-line treatment includes behavioral and pharmacologic therapy (anticholinergic and ß3 agonists), which can induce better efficacy, lesser drug dosage, and side effects than pharmacologic treatment alone. PTNS, as a less invasive peripheral neuromodulator, is considered for the third-line treatment based on the AUA/SUFU guideline (Lightner et al., 2019).

In 1999, Yamanishi et al. used vaginal/perianal electrical stimulation to treat refractory OAB-induced incontinence and reported increased bladder capacity measured urodynamically (Yamanishi et al., 2000). Published reviews in 2005 and 2009 on PTNS clinical trials found it encouraging, less invasive, economical, and negligible risks in managing a wide range of pelvic floor dysfunction symptoms (Cooperberg & Stoller, 2005; MacDiarmid & Staskin, 2009). In 2012, Staskin et al. evaluated the aspects of PTNS, including effectiveness, adverse effects, and cost-effectiveness with other treatment options. They suggested that it should be considered early in the care algorithm of OAB patients (Staskin et al., 2012). Eventually, the evidence reported OAB PTNS therapy as level 1 in 2013 (Gaziev et al., 2013).

Table 4. Group-time interaction with avoidance and limiting behaviour (ALB) parameter in two groups

Pairwise Comparisons							
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	0.000	-26.3	-8.3
		3	-18.6	3.7	0.000	-27.9	-9.2
	2	1	17.3	3.6	0.000	8.3	26.3
		3	-1.2	2.1	1.000	-6.6	4.0
	3	1	18.6	3.7	0.000	9.2	27.9
		2	1.2	2.1	1.000	-4.0	6.6
Patch	1	2	-13.4	3.6	0.002	-22.4	-4.5
		3	-16.4	3.7	0.000	-25.8	-7.1
	2	1	13.4	3.6	0.002	4.5	22.4
		3	-2.9	2.1	0.519	-8.3	2.3
	3	1	16.4	3.7	0.000	7.1	25.8
		2	2.9	2.1	0.519	-2.3	8.3

*Times 1, 2, and 3 are before, 1 week, and 4 weeks after the intervention, respectively.

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Table 5. Group-time interaction with psychosocial impact (PSI) parameter in two groups

Pairwise Comparisons							
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	0.000	-27.4	-7.4
		3	-18.1	4.1	0.000	-28.4	-7.9
	2	1	17.4	4.0	0.000	7.4	27.4
		3	-.7	1.0	1.000	-3.3	1.8
	3	1	18.1	4.1	0.000	7.9	28.4
		2	0.7	1.0	1.0	-1.8	3.3
Patch	1	2	-8.0	4.0	0.1	-18.0	1.9
		3	-10.2	4.1	0.0	-20.4	0.0
	2	1	8.0	4.0	0.1	-1.9	18.0
		3	-2.1	1.0	0.1	-4.7	0.4
	3	1	10.2	4.1	0.0	-0.0	20.4
		2	2.1	1.0	0.1	-0.4	4.7

*Times 1, 2, and 3 are before, 1 week, and 4 weeks after the intervention, respectively.

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Table 6. Group-time interaction with social embarrassment (SE) parameter in two groups

Pairwise Comparisons							
I-QOL 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	0.001	-27.9	-6.5
		3	-19.0	4.4	0.000	-30.2	-7.9
	2	1	17.2	4.2	0.001	6.5	27.9
		3	-1.8	1.9	1.000	-6.7	3.1
	3	1	19.0	4.4	0.000	7.9	30.2
		2	1.8	1.9	1.000	-3.1	6.7
Patch	1	2	-13.4	4.2	0.010	-24.0	-2.7
		3	-17.9	4.4	0.001	-29.0	-6.8
	2	1	13.4	4.2	0.010	2.7	24.0
		3	-4.5	1.9	0.080	-9.4	0.3
	3	1	17.9	4.4	0.001	6.8	29.0
		2	4.5	1.9	0.080	-0.3	9.4

*Times 1, 2, and 3 are before, 1 week, and 4 weeks after the intervention, respectively.

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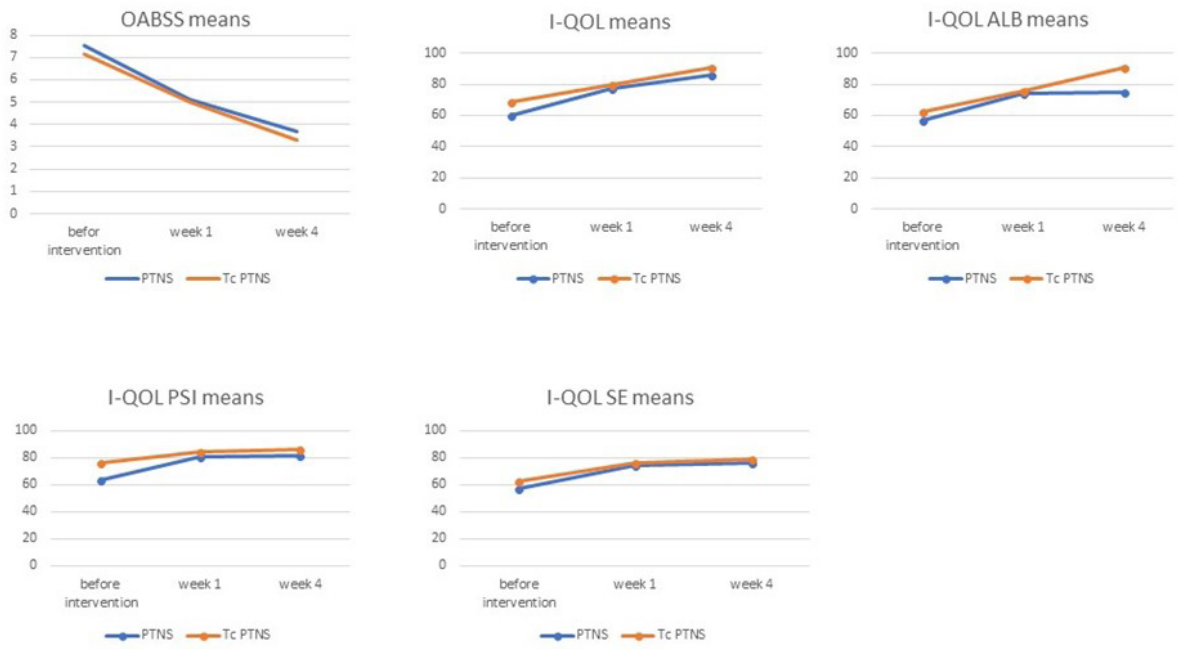

Figure 3. Score means evaluated in two groups

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Abbreviations: OABSS: Overactive bladder symptom; I-QOL: Incontinence quality of life; ALB: Avoidance, and limiting behaviour; PSI: Psychosocial impact; SE: Social embarrassment.

TTNS, an even less invasive intervention than PTNS, is also being investigated and reported effective in recent trials as a neuromodulation method for OAB treatment. Two studies reported that this method could provide greater benefits than behavioral therapy (Booth et al., 2018). Two 30-minute sessions of TTNS showed a similar outcome as 10 mg of extended-release oxybutynin after 12 weeks of treatment (Manríquez et al., 2016). In the study of Ammi et al., home-based daily TTNS for one month was successful in 53% of patients with previous failed anticholinergic therapy (Ammi et al., 2014), and interestingly, it could also be effective by being used once a week for 3 months (Moratalla Charcos et al., 2018). The number of therapy sessions per week and different stimulation characteristics that may alter the therapeutic result must 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., (2021). TTNS showed the same effectiveness as PTNS for treating OAB patients (Yang et al., 2021). Similarly, a recent clinical trial compared PTNS and TTNS for OAB treatment in a 12-week therapy course and concluded the same effectiveness of these two methods (Ramírez-García et al., 2020).

In this study, we found that TTNS and PTNS are 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 in total). 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 behavior, psychosocial impacts, and social embarrassment. Comparing the study of Ramírez-García et al. (2020) with ours, 12 sessions of P/TTNS with similar stimulation parameters, but at different intervals (1 and 3 times a week), were effective in controlling OAB symptoms.

Considering the anticholinergic side effects of medications used in non-responders to behavioral therapy alone and the reported similar effects of PTNS and medication (Manríquez et al., 2016), it may be rational to investigate TTNS therapy as a second-line treatment after behavioral therapy.

Regarding the safety and feasibility of TTNS, it can also be suggested as a home-based modality for the initial treatment course or long-term maintenance therapy (Seth et al., 2018; Van Der Pal & Van Balken, 2006; Yoong et al., 2013). This method may extend its therapeutic effects while lessening the time-consuming process of inpatient PTNS and its burden on the patient and healthcare system. In the study of Martin-Garcia and Crampton, (2019) home-based TTNS is reported as effective as maintenance PTNS treatment for previous PTNS responders. Almost 50% of patients who completed inpatient sessions are said to discontinue long-term PTNS therapy (Gordon et al., 2020; Jung et al., 2020). Thus, it would be hypothesized that home-based TTNS may improve patient adherence to the treatment, which needs further investigation.

5. Conclusion

TTNS could effectively manage OAB symptoms in the same way 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.

Study strengths and limitations

This RCT has a triple-blind design with properly matched controls. However, the long-term effectiveness of P/TTNS in OAB syndrome was not evaluated.

Ethical Considerations

Compliance with ethical guidelines

This clinical trial was approved by the Ethics Committee of Iran University of Medical Sciences, Tehran, Iran (Code: IR.IUMS.REC1395.94115240080). Also, the study was registered by Iranian Registry of Clinical Trials (IRCT) (Code: IRCT2016101730339N1).

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Authors' contributions

Study design: Gholamreza Raissi and Tannaz Ahadi; Data interpretation: Ismaeel Noori and Shayesteh Khalifeh Soltani; Data analysis: Shayesteh Khalifeh Soltani: Data acquisition: Ismaeel Noori and Pouya Ghaboosi; Writing: Gholamreza Raissi, Shayesteh Khalifeh Soltani and Tannaz Ahadi; Final approval: All authors.

Conflict of interest

The authors declared no conflict of interest.

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