Research Article

Effects of transcutaneous tibial nerve stimulation for overactive bladder symptoms in adults: a randomized controlled trial.

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ABSTRACT

Background: Overactive bladder (OAB) is characterized by urinary urgency, frequency, and nocturia, often accompanied by urinary incontinence. OAB significantly impacts the quality of life of affected individuals. Transcutaneous Tibial Nerve Stimulation (TTNS) is a non-invasive treatment option used to manage overactive bladder (OAB) symptoms. Objective: to determine the effects of Transcutaneous Tibial Nerve Stimulation on overactive bladder symptoms in adults.

Methods: A randomized controlled trial was held at the Sindh Institute of Physical Medicine and Rehabilitation with a non-probability purposive sampling technique. After screening for inclusion criteria 60 patients were randomly allocated into two Group A received Transcutaneous tibial nerve stimulation (TTNS) combined with traditional physiotherapy, while Group B just received traditional physiotherapy. Both interventions were given for six weeks. The overactive Bladder Symptom Score was used as an outcome measure tool.

Results: Group A improved in all OAB parameters, including daytime frequency (p=0.008), nocturia (p=0.006), urinary urgency (p=0.002), and urge urinary incontinence (p=0.008) with a significant improvement p<0.05. All OABSS parameters in group B also showed a considerable improvement (p<0.05), except for urge urinary incontinence (p=0.08).

Conclusion: the daytime frequency, nocturia, and urgency parameters of the overactive bladder symptoms score significantly decreased in both the TTNS+PFM group and the Traditional physiotherapy group. However, urge urinary incontinence showed significant improvement only in the TTNS+PFM group.

Keywords: Lower urinary tract symptoms; neuromodulation therapy; nocturia; overactive detrusor; pelvic floor disease; urge incontinence.

Trial Registration: NCT05464589.

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Citation

Subhan S, Ahmad I, Mithani MHA, Baig AAM, Kashif M, Siddiqu MA. Title of study. Effects of transcutaneous tibial nerve stimulation for overactive bladder symptoms in adults: a randomized controlled trial. 2023:07(03); 36-41. doi: 10.52567/trehabj.v7i03.7

Article History

Received on: 20-07-2023
Revision on: 10-09-2023
Published on: 30-09-2023

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INTRODUCTION

More than 400 million individuals are affected by overactive bladder (OAB), all over the world. Its prevalence makes it a major health concern[1]. OAB is diagnosed symptomatically in the presence of urgency, with or without urge urinary incontinence (UUI), which commonly interrelates urinary frequency and nocturia, as defined by the International Continence Society (ICS) [2]. Epidemiological surveys done in 11 Asian countries, including Pakistan, concluded a high frequency of OAB in both males and females, while fewer treatment-seeking responses of the individuals because of the perception of the condition as a social taboo[3].

The normal bladder fills and empties in cycles. During the filling phase, the detrusor (bladder muscle) is relaxed and the bladder neck, sphincter complex, and pelvic floor muscles (PFM) are contracted to maintain continence[4]. During the emptying or voiding phase, the bladder neck, sphincter complex, and PFM relax, and simultaneously, the detrusor muscle contracts. Detrusor overactivity (DO) results in an urge to urinate and urinary incontinence. DO is known to be associated with pelvic floor relaxation or weakness. It is suggested that during relaxation or weakness of PFM, there is decreased afferent nerve activity that can cause involuntary detrusor contractions leading to OAB [5, 6]. Urination is a physiological process that involves the lower urinary tract's anatomical components and, the higher cortex of the brain, the pons, the spinal cord, and the lower urinary tract's peripheral autonomic, somatic, and sensory afferent innervation[7]. Any of these systems or structures may have issues that lead to the OAB [8].

For individuals with urinary symptoms, including OAB symptoms of neurogenic or idiopathic origin and incontinence, standard physical therapy (Pelvic Floor Muscles (PFM) training-Kegels) is an effective treatment[9]. The American Urological Association (AUA) advises PFM training as the initial therapy for all people with OAB[10]. Voluntary PFM contractions can effectively inhibit involuntary bladder contractions and improve the symptoms of OAB[11]. The electrical stimulation of the tibial nerve (Peripheral application of TTNS) is also one of the treatment alternatives for OAB symptoms. TTNS, often referred to as retrograde stimulation, is a procedure that includes stimulating the nerve's distal branch to indirectly stimulate the nerve roots. The tibial nerve, a posterior distal branch of the sciatic nerve originating in the pelvis (L4–S3 spinal roots), is the target of this treatment. The pelvic floor's nerve supply also originates from this site (S2-S3). The sacral plexus is the target of tibial nerve stimulation. The function of the sacral plexus is to contract the PFM and the regulation of bladder function [12, 13]. Internationally, studies were carried out by physical therapists for the therapy of OAB patients through peripheral electrical stimulation, including TTNS or percutaneous tibial nerve stimulation (PTNS) with or without PFM strengthening and they majorly included elderly women only[14, 15].

As far as the authors' knowledge is concerned, in the local population, only sacral neuromodulation is evaluated to treat children with OAB. There is no local literature found to date regarding the TTNS to manage OAB symptoms (neurogenic or idiopathic origin) in adults including both males and females despite being a prevalent condition. The objective of this study is to determine the effects of TTNS on overactive bladder symptoms in adults. **So**, the hypothesis of the study is that there is a statistically significant difference between the effects of TTNS along with PFM strengthening and PFM strengthening alone to treat OAB symptoms in adults..

METHODOLOGY

This study is a two-armed, parallel-group, single-blinded, randomized controlled trial (NCT-05464589). The study was conducted at the Institute of Physical Medicine and Rehabilitation and Urology Department of Dow University Hospital, Karachi, Pakistan within the duration of eight months, from August 2021 to March 2022. Ethical Approval was obtained from the Institutional Review Board, with Ref. No. IRB-1997/DUHS/Approval/2021/414.

A sample size of n=52 participants was estimated using Open Epi version 3.0. The confidence interval was 95% and the power of the test was 80% with after intervention mean of 2.55 and a standard deviation of 1.23 in group A and after treatment mean of 1.65 and a standard deviation of 1.04 in group B using an Overactive Bladder Symptom Score (OABSS) of previous study [15]. Due to the small sample size to ensure sufficient statistical power, n=60 subjects were considered after including approximately 12% of the drop rate due to any reason. A total of n=68 participants were evaluated on selection criteria, out of which n=8 participants did not fulfill the criteria. So, n=60 participants were randomly allocated to Group A (n=30) and Group B (n=30). There was no loss of follow-up, and all participants were included in the data analysis. (Figure 1)

The inclusion criteria were patients of both genders who were 30-65 years old, clinically diagnosed with Overactive Bladder (OAB) by Urologist symptoms for at least one month or more than one month, with a total OABSS score of 3 or more and an urgency score of 2 or more. Patients who are pregnant or have acute urinary tract

https://doi.org/10.52567/trehabj.v7i03.7

infection within 15 days, any surgical procedure for urinary incontinence, Genito-urinary cancer history, stage II pelvic organ prolapse according to pelvic organ prolapse-quantification system, skin lesion on the site of stimulation or around it, pelvic pacemakers, lower limb prostheses, patients not be able to perform Kegel's exercises, impaired sensation at the site of the stimulation, impaired mental status, high blood pressure, benign prostatic hyperplasia, diabetes mellitus, patients receiving any treatment other than the prescribed medications by the referring physicians were excluded.

Before the start of the study written informed consent was obtained from all participants. All the participants were randomly allocated into the interventional group A and the control group B. The simple randomization was done through SPSS by an independent biostatistician who was unaware of the interventions and was not involved in the study. The outcome assessment was done by another physiotherapist assessor who was blinded to the interventional group of patients who were assessed.

The OABSS was used as an outcome measure to measure the symptom severity of OAB at baseline and after six weeks of treatment. The outcome measure used in this was the Overactive Bladder Symptom Score (OABSS). OABSS is a validated instrument that evaluates the four cardinal symptoms including day and nighttime frequency, urgency, and urge incontinence) of OAB in one score[16]. The intra-class correlation coefficient of the total OABSS score was 0.74 (weighted kappa coefficients of individual item score, 0.55-0.84), and the Cronbach coefficient was 0.56 [17]. The cut-off value recommended to diagnose OAB is a total OABSS of at least 3 or more with an urgency score of at least 2 or more. The total score is 15, while 3-5 will be considered mild, 6-11 moderate, and 12 or more severe OAB [18].

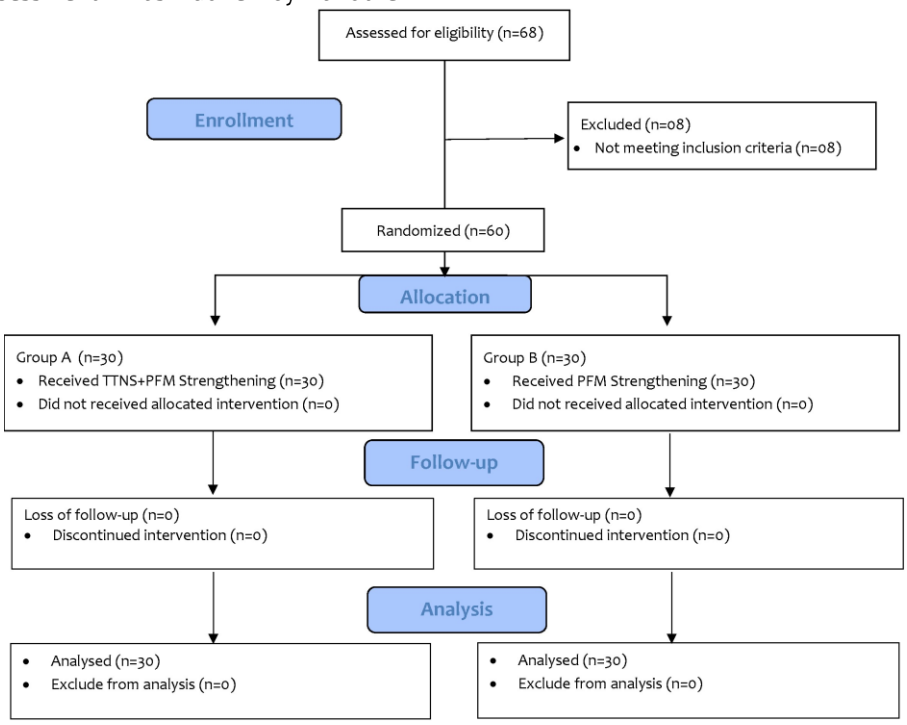

Figure 1: CONSORT diagram

Pelvic floor muscle strengthening (PFM) – Kegel exercises: The patient was instructed to lie supine with the knee flexed. Then, the patient was requested to contract PFM and maintain the position for 5 seconds, for ease of understanding, the patient was asked to contract the muscles which helps to avoid passing out the gas. Then, the patient was asked to relax for 3-5 seconds and repeat the contraction. In this way, the patient was instructed to do 15 contractions at a time and repeat this thrice daily for three weeks.

Electrical Stimulation – TTNS: Electrical stimulation was given through the Transcutaneous Electrical Nerve Stimulator (TENS Model Comfy Stim EV-806) once a week. Two electrodes were used, one electrode was applied on the medial malleolus of the right foot, and the other electrode was placed 5-10 cm proximal to the first electrode ipsilateral along the pathway of the tibial nerve. When stimulation was given, in some patients right big toe started to mobilize while some patients felt sensations at the sole of the foot showing that the nerve had started to be stimulated. The tibial nerve was electrically stimulated for 30 minutes; the pulse duration was 200 ms while the frequency was 10 Hz in continuous mode.11 No side effects related to treatment were reported by the patients.

https://doi.org/10.52567/trehabj.v7i03.7

Data were stored and analyzed using IBM-SPSS version 23.0. The frequency with percentages were reported for the baseline qualitative characteristics including gender and type of overactive bladder based on cause. The means with standard deviations were given for age, height, weight, Body mass index, and parameters of OAB symptoms in each treatment group. The normality of data was checked with the Shapiro-Wilk test which shows a value >0.05 suggesting that data is normally distributed that's we used a parametric test which is a t-test. The data assume the assumptions of the parametric tests, so a paired sample t-test was used to compare the within-group treatment effect, and between groups analysis was done using an independent sample t-test. The $p<0.05$ was considered statistically significant, bar diagrams were also used to give a graphical presentation of data.

RESULTS

The total number of participants was n=60 Adults with Overactive Bladder Symptoms, out of them, n=33 were male and n=27 were female. The mean BMI of Group A was 23.5± 5.1 and in Group B was 24.4± 2.7 (Table 1).

Table 1: Baseline Characteristics of Studied Samples (n=60)

Characteristics		Group A (n=30)		Group B (n=30)		p-value
		n/ $\bar{x}$	%/ σ	n/ $\bar{x}$	%/ σ	
Gender	Male	17	56.7	16	53.3	0.79
	Female	13	43.3	14	46.7	
Age (years)	-	43.4	8.0	45.3	10.7	0.45
Height (m)	-	1.6	0.09	1.6	0.11	0.50
Weight (kg)	-	65.4	16.6	66.6	10.0	0.74
BMI (kg/m^2)	-	23.5	5.1	24.4	2.7	0.43
Type of OAB on the Basisof Cause	Idiopathic	24	80.0	23	76.7	0.74
	Neurogenic	6	20.0	7	23.3	

Significance level- p<0.05, p<0.01** & p<0.001***; n- frequency; $\bar{x}$- Mean; σ-standard deviation; OAB-overactive bladder*

All components of OABSS including daytime frequency, Nocturia, Urinary urgency, urge urinary incontinence, and overall OABSS were significantly improved ($p<0.05$) in both groups after a 6-week intervention. While in group B which only received PFMS, urge urinary incontinence did not significantly ($p=0.08$) improve after the 6-week intervention. (Table 2)

Table 2: Mean Comparison of OABSS in Group A & B (TTNS Group)

Parameters	Group A (n=30)				Group B (n=30)			
	Baseline	after the 6-week	t-value(29)	p-value	Baseline	after the 6-week	t-value(29)	p-value
	$\bar{x}$ ± σ	$\bar{x}$ ± σ			$\bar{x}$ ± σ	$\bar{x}$ ± σ		
Day time frequency	1.3±0.59	0.43 ±0.50	9.35	0.008**	1.23±0.43	0.93 ±0.36	3.52	0.004**
Nocturia	2.1±0.59	1.0±0.37	10.79	0.006**	2.1±0.66	1.5±0.67	5.75	0.006**
Urinary urgency	3.1±0.80	1.8±0.71	9.41	0.002**	3.0±0.78	2.4±0.85	4.26	0.005**
Urge Urinary Incontinence	1.4±1.0	1.0±0.82	-1.71	0.06	0.73±0.94	0.63±0.85	-8.11	0.08
Total score of the OAB	7.9±1.9	4.3±1.42	13.72	0.007**	7.0±1.7	5.4±1.71	7.95	0.004**

Significance level- p<0.05, p<0.01** & p<0.001***; $\bar{x}$- Mean; σ-standard deviation; OAB-overactive bladder; df= degree of freedom.*

The result of the independent t-test showed that group A showed significantly ($p<0.05$) better results than group B in all components except urinary urgency, which was not statistically different ($p=0.051$) between both groups. (Table 3)

Table 3: Mean Comparison of OABSS parameters and Total Score between Groups after Treatment

Parameters	Group A	Group B	MD (95% CI)	t-value (58)	p-value
	$\bar{x}$ ± σ	$\bar{x}$ ± σ			
Day time frequency	0.43 ±0.50	0.93 ±0.36	-0.50 (-0.72, -0.27)	-4.40	0.002**
Nocturia	1.0±0.37	1.5±0.67	-0.56 (-0.84. -0.28)	-4.01	0.007**
Urinary urgency	1.8±0.71	2.4±0.85	-0.60 (-1.00, -0.19)	-2.95	0.051
Urge UrinaryIncontinence	1.0±0.82	0.63±0.85	-0.43 (-0.00, -0.86)	2.00	0.004**
Total score of the OAB Symptoms	4.3±1.42	5.4±1.71	-1.13 (-1.94, -0.34)	-2.78	0.021*

Significance level- p<0.05, p<0.01** & p<0.001***; $\bar{x}$- Mean; σ-standard deviation; OAB-overactive bladder; df= degree of freedom; MD-Mean Difference; CI- Confidence Interval.*

DISCUSSION

This study was conducted to evaluate the effectiveness of TTNS to treat OAB symptoms in adults including both males and females. It was found out that both PFM strengthening lone and TTNS along with PFM strengthening were effective for reducing OAB symptoms but the TTNS along with PFM strengthening showed more improvement in OAB symptoms comparatively.

The comparison between the two groups from the baseline to the sixth week showed the most improvement in urinary urgency in the favour of the TTNS group. TTNS along with PFM strengthening was also more effective than PFM strengthening alone for reducing daytime urinary frequency and

https://doi.org/10.52567/trehabj.v7i03.7

nocturia. The previous study conducted by Polat Dunya in which fifty-five patients of mean age 43.49 with overactive bladder symptoms were included. One group received TTNS for six weeks while the other group received pelvic floor muscle training exercises twice a day for six weeks. This study showed TTNS and PFMT as equally effective for overactive bladder symptoms. When both groups were compared from baseline to six weeks of intervention, the TTNS more effectively improved daytime frequency, nocturia, and urgency[19]. However current study found that the TTNS combined with the PFMT was more effective in treating UUI when compared with PFMT alone. This finding was different from Polat Dunya's findings. In this study, there were more patients with less severe UUI, which can be a possible reason for these findings.

A meta-analysis of 16 studies conducted by Wibisono and Rahardjo concluded that more than one session a week of percutaneous electrical stimulation of the tibial nerve is not an indicator of the success of the treatment or more benefits from the technique [20]. It was also supported by the study done by Pierre ML in which they applied TTNS once a week to treat OAB symptoms. Their study showed that only once-a-week application of TTNS did not alter the outcomes of the treatment or impede the recovery of the symptoms [21].

Schreiner L and fellows conducted a study in which they included 52 females of 60 and more than 60 years of age with the complaint of urge urinary incontinence. There were two groups with 26 patients in each group. Their study had two groups, one received PFM training while the other received PFM training along with TTNS. They used a three-day bladder diary, Kings Health Questionnaire (KHQ), and International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF) as outcome measures to evaluate symptom severity, health-related quality of life and frequency, severity, and impact on quality of life (QoL) of urinary incontinence, respectively[11]. Their results showed improvement in symptoms in both groups but more significant improvement was seen in the TTNS group. Similar improvements were observed in the current study which may be because of the application of two treatments with different mechanisms at the same time.

In the current study TTNS was applied once a week for 6 weeks and found statistically significant improvement in OAB symptoms. Similarly, Surbala L and Patrícia Lordêlo applied TTNS for less than twelve weeks and reported good results like our study. It has been established that TTNS can be effective for OAB symptoms within six weeks of application as well [22].

We used non-invasive (transcutaneous) electrical stimulation to treat OAB symptoms and yielded good results as a previous study by Pierre and colleagues reported that invasive (percutaneous) electrical stimulation significantly treated OAB symptoms [21]. The effectiveness of TTNS in the current study established that transcutaneous application of electrical stimulation can be preferred over percutaneous stimulation for OAB symptoms because it is more comfortable for the patients. It is also in correspondence with the conclusion drawn from the systematic review conducted by Gonzalez in which they concluded that both TTNS and percutaneous tibial nerve stimulation (PTNS) were equal in terms of outcome variables. However, TTNS is preferred over PTNS as it is more comfortable for patients. They also concluded that it should be the treatment of choice due to being cost-effective as well [23].

Both genders were included in the study, as there are gender differences may exist, so the results can be influenced by these differences.

CONCLUSION

This study concluded that both PFM strengthening and TTNS ensured patient safety and easy application. Also, both methods reduced the severity of OAB symptoms. The effectiveness of TTNS for OAB symptoms makes it considerable as a first-line treatment for OAB along with PFM strengthening as TTNS was easy to apply, cost effective and showed no systemic or local side effects.

DECLARATIONS & STATEMENTS

Author's Contribution

SS: substantial contributions to the conception and design of the study.
SS and SIA and MAS: acquisition of data for the study.
MHAM and AAMB: interpretation of data for the study.
MK: analysis of the data for the study.
SS, MK, SIA and MAS: drafted the work.
MK and MAS: revised it critically for important intellectual content.
SS, SIA, MHAM, AAMB, MK and MAS: final approval of the version to be published and agreement to be accountable for all aspects.
of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors contributed to the article and approved the submitted version.

Ethical Statement

The study was conducted after ethical approval from the Institutional Review Board of Institute of Physical Medicine and Rehabilitation, Karachi and Urology Department of Dow University Hospital, Karachi, Pakistan (IRB-1997/DUHS/Approval/2021/414).

Consent Statement

The written informed consent was obtained from

https://doi.org/10.52567/trehabj.v7i03.7

patients to participate in the study.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author.

Acknowledgments

There is no acknowledgment to declare

Conflicts of Interest

The authors declare no conflict of interest.

Funding

This research received no funding. The authors declare that no funds, grants, or other support were received during the conduction of research and preparation of this manuscript.

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