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ORIGINAL ARTICLE

# Efficacy of transcutaneous posterior tibial nerve stimulation in women with an idiopathic overactive bladder

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## ABSTRACT

**Objective:** The aim of this study is to assess the efficacy of transcutaneous posterior tibial nerve stimulation (TTNS) in women with urge incontinence.

**Material and Methods:** The study included twenty patients with an idiopathic overactive bladder (OAB) refractory to anticholinergic treatment. TTNS was applied to all patients on 3 days/week for 8 weeks; each session lasted 30 min. Pelvic floor muscle strength, urinary frequency, and the number of episodes of urge urinary incontinence were recorded before and after the treatment.

**Results:** After 8 weeks of TTNS treatment, a statistically significant increase was found in pelvic floor muscle strength, assessed by digital palpation (p=0.008), whereas there was no significant improvement in perineometry values (p=0.118). Bladder diary assessment revealed that patients experienced a significant reduction in the average number of incontinence episodes and voiding frequency (p=0.003 and p=0.001, respectively). There were no adverse effects during the treatment.

**Conclusion:** This study results showed that TTNS is an effective and well-tolerated treatment in women with an idiopathic OAB who have not benefited from anticholinergic medications. Further studies need to be performed to determine a standardized treatment protocol and long-term efficacy.

**Keywords:** Overactive bladder, posterior tibial nerve, urge incontinence.

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## INTRODUCTION

Overactive bladder (OAB) syndrome is a clinical syndrome. It is defined as urinary urgency mostly related with increased frequency of urination and nocturia with or without urgency incontinence in the absence of any other underlying causes.[1] The prevalence is higher in elderly women.[2] Urge incontinence is a type of urinary incontinence that involves sudden urges to void and results in an involuntary leakage of urine. It is a serious social problem for women. Early diagnosis and treatment should be applied to avoid great socioeconomic burdens and high morbidity. The role of the interdisciplinary team is important in evaluating urge incontinence and improving recommendations for patients with this condition.[3]

There are several treatment modalities for OAB. Although there are many treatment options for urge urinary incontinence, behavioral therapies such as lifestyle modifications, dietary changes, toileting habits, bladder training, and pelvic floor muscle training are recommended as the first-line treatment options. The second-line treatment option includes the use of pharmacological agents (antimuscarinic and beta-3 agonist therapy). In additon, posterior tibial nerve stimulation, temporary chemical denervation of the bladder detrusor muscle, and sacral neuromodulation are recommended as third-line therapies.[4]

Neuromodulation is the electrical or pharmacological modification of neuronal activity in the central, peripheral, or autonomic nervous system. Neuromodulation can be applied through central (sacral) or peripheral (percutaneous or transcutaneous) routes. Peripheral stimulation of the posterior tibial nerve provides electrical stimulation to the sacral voiding center through the S2–S4 sacral nerve plexus. Bladder innervation can be modulated by retrograde stimulation of the posterior tibial nerve.[5] In percutaneous posterior tibial nerve stimulation (PTNS), stimulation can be performed percutaneously with a needle placed just above the medial aspect of the ankle. Transcutaneous posterior tibial nerve stimulation (TTNS), which provides stimulation through non-skin-penetrating surface electrodes, is also available. TTNS is particularly effective in the treatment of drug-resistant OAB individuals and besides that, it contributes to increase the quality of life by improving symptoms.[6,7] Since TTNS is a non-invasive, safe, low cost, and easily tolerated treatment modality, it should be considered in the treatment of individuals with urge incontinence.[5,8] Therefore, the aim of this study was to assess the efficacy of treatment with TTNS in women with urge incontinence refractory to first-line treatment.

## MATERIAL AND METHODS

In this observational study, forty consecutive patients who were admitted to Istanbul University, Faculty of Medicine, Urogynecology Division, and treated for an idiopathic OAB after first-line anticholinergic treatment were recruited. Among these patients, twenty patients who met the eligibility criteria were included. The inclusion criteria were: non-pregnant women aged 18–60 years, clinical diagnosis of idiopathic OAB, no benefit from previous anticholinergic treatment, and accept to participate in the study. Exclusion criteria were the following: women who had surgery for the pelvic floor; women diagnosed with neurogenic incontinence; the presence of an acute urinary tract infection on urine culture at baseline; a history of malignancy; evidence of pelvic organ prolapse higher than grade II on the Pelvic Organ Prolapse Quantification system; an unable to perform the Kegel exercises; the presence of active implants or skin damage at the stimulation site. All the participants were advised to maintain their usual habits and medical treatments throughout the follow-up period. The study protocol was approved by the Istanbul University Ethics Committee (204708/2021) in conformity with the Declaration of Helsinki. All of the participants provided informed written consent before being enrolled in this study.


**Figure 1:** Application of transcutaneous posterior tibial nerve stimulation.

TTNS was performed with a transcutaneous nerve stimulation device (Chattanooga Group, USA). TTNS was applied with a frequency of 10 Hz and a pulse width of 200 μs for 30 minutes. The amplitude intensity increased gradually below the patient's discomfort threshold. TTNS was applied unilaterally using two surface electrodes on the leg, which were placed along the posterior tibial nerve path. One electrode was placed behind the medial malleolus and the other one 10 cm cranial to the medial malleolus (Fig. 1). TTNS was performed on 3 days/week for 8 weeks under the supervision of the investigator. A pelvic floor muscle exercise (Kegel exercise) program was organized with a gradually increasing intensity. The total number of pelvic floor muscle exercises was increased from a minimum of 3 sessions with 10 repetitions/day to a maximum of 6 sessions with 10 repetitions/day over 8 weeks. All participants were instructed on how to do the pelvic floor muscle exercises by palpation of the levator ani muscles and the patient was directed where to contract the muscles with feedback from the therapist.[9] The bladder training was applied to all individuals.

The socio-demographic characteristics of the patients and the duration of symptoms were recorded. The outcome measures were recorded at baseline and after the treatment. All patients underwent physical examinations, and the muscle strength of the pelvic floor was measured by digital palpation. The muscle strength of the pelvic floor was graded according to the modified Oxford grading system (from 0 [no contraction] to 5 [strong contraction]). In addition, pelvic floor muscle strength was measured with perineometer (Peritron TM 9300). Urinary frequency and the number of episodes of urge urinary incontinence were obtained and evaluated from a 3-day voiding diary in which the participants completed prior to each of the study visits were evaluated.

Statistical analyses were made using the Statistical Package for Social Sciences software version 22.0 for Windows (IBM Corp., Armonk, NY, USA). For the descriptive statistics of the data, the mean±standard deviation, median, minimum-maximum, frequency, and ratio values were used. The normality of distribution was determined using the Kolmogorov-Smirnov test for all variables at the baseline and follow-up measures. The Wilcoxon signed-rank test (p=0.05) was used for the analysis of the dependent variables.

## RESULTS

A total of thirty patients, with a mean age of 51.7±13.7 years and a mean body mass index of 22.5±3.4 kg/m$^2$, were enrolled in the study. Patient baseline characteristics are summarized in Table 1. Pelvic floor muscle strength, evaluated by digital palpation, was significantly increased at 8 weeks (p=0.008). However, there was no significant improvement in perineometer values at the end of the treatment (p=0.118). A significant improvement was found in the average number of incontinence episodes and voiding frequency in the 3-day bladder diary at 8 weeks compared to the pre-treatment values (p=0.003 and p=0.001, respectively). No side effects were noticed with the TTNS. The changes in outcome values from the baseline to 8 weeks are shown in Table 2.

**Table 1: Baseline characteristics of the patients (n=20)**

| | Mean±SD | Median (Min.–Max.) |
|---|---|---|
| Age (years) | 51.7±13.7 | 54.5 (20–70) |
| BMI (kg/m$^2$) | 22.5±3.4 | 29.3 (22.5–36.7) |
| Duration of symptoms, years | 3.4±1.4 | 3.1 (1.0–6.0) |
| Number of vaginal birth | 2.1±1.2 | 2.0 (0–4) |
| **Anticholinergic treatment** | **n (%)** | |
| Fesoterodine | 7 (35) | |
| Tolterodine | 4 (20) | |
| Solifenacin | 6 (30) | |
| Trospium chloride | 3 (15) | |

SD: Standard deviation; Min.: Minimum; Max.: Maximum; BMI: Body mass index.

**Table 2: Changes in outcome values from the baseline to 8 weeks**

| Outcome measures | Baseline Mean±SD | Week 8 Mean±SD | p |
|---|---|---|---|
| PFMS (digital palpation) | 2.40±0.99 | 2.95±0.94 | 0.008 |
| Perinometry value (cm$H_2O$) | 23.65±11.86 | 27.3±11.07 | 0.118 |
| Voiding frequency | 12.06±8.41 | 7.17±1.32 | 0.001 |
| Number of incontinence episodes | 2.77±2.22 | 0.98±1.74 | 0.003 |

SD: Standard deviation; PFMS: Pelvic floor muscle strength.

## DISCUSSION

The present study evaluated the effects of TTNS with a frequency of 10 Hz and a pulse width of 200 µS for 30 min at 3/week for 8 weeks in women with idiopathic OAB. Based on the results of this study, a significant improvement was reported in the mean incontinence episodes and voiding frequency in the 3-day bladder diary at 8 weeks compared to the pre-treatment values. In addition, a significant improvement was found in pelvic floor muscle strength, as assessed by digital palpation, after the TTNS intervention.

In accordance with our results, a systematic review demonstrated that TTNS provides significant improvements in OAB symptoms, as reported by 48–93% participants and urinary incontinence cure rates of 25–45%.[10] The authors also found limited evidence that TTNS is an effective and safe intervention in adults with idiopathic OAB.[10] In addition, a randomized controlled trial by Schreiner et al.[11] showed decreases in daily micturitions, nocturia, and urge urinary incontinence episodes with TTNS treatments and standard training consisting of bladder retraining and pelvic floor muscle exercises in older women. Similarly, some studies have reported the positive effects of pelvic floor exercises and bladder training on OAB symptoms in patients with urge incontinence.[9,12] Based on these findings, pelvic floor exercises were also integrated into the TTNS treatment for urge incontinence in all patients. In the current study, digital palpation scores of pelvic floor muscle strength were significantly increased compared to the pre-treatment values, whereas no significant difference was observed in perineometer scores. The lack of significant change in perineometer values may be due to the patients not being able to cooperate the instructions or unable to perform the appropriate contractions of pelvic floor muscles during the measurement.

TTNS is an effective and well-tolerated treatment in patients with urge incontinence.[13] Contrary to the other conservative treatments for incontinence, TTNS can be applied more easily due to having a shorter preparation time and not requiring a vaginal application. TTNS has a noninvasive nature and higher rates of patient satisfaction. Moreover, two recent randomized, controlled trials comparing the effectiveness of either the transcutaneous technique or PTNS found no significant differences in the urgency incontinence episodes, daytime frequency, the symptoms identified during the 3-day voiding diary, or the quality of life.[14,15] Despite the positive effects of both techniques, adherence to the treatment and the patient satisfaction levels were higher in the TTNS group.[14,16] Therefore, it has been suggested that TTNS is a preferable technique due to its ease of application and lower discomfort levels.[15] In addition, one of the most important advantages of TTNS is the lack of side effects, such as dry mouth and constipation, which are common with anticholinergic drugs. Moreover, no adverse events were reported with TTNS in women with idiopathic OAB in the current study.

There is no consensus on the optimal stimulation parameters in terms of pulse duration, frequency, intensity, and intervention

protocols for TTNS therapy. Therefore, the comparison of these studies is complicated, which may partially account for the differences in the results.[17] In our study, patients received TTNS 3 times a week for 30 min/session for 8 weeks with a pulse width of 200 μs and a frequency of 10 Hz. Additionally, the amplitude intensity was a controversial parameter for interpreting the effects of TTNS. A randomized controlled clinical trial that examined the effect of TTNS at two different current amplitude reported no difference between the sensitivity and motor thresholds.[18] In our study, the amplitude intensity was administered at the sensitivity threshold.

The main limitations of our study were its small sample size and the absence of a control group. Although the results of the present study are promising, the follow-up period was relatively short. Therefore, this period may not have been long enough for a valid assessment of the long-term effects of TTNS on the outcome measures. However, other studies have reported the long-term efficacy and safety of peripheral neuromodulation. The long-term effect of posterior tibial nerve stimulation was investigated in the Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation study. The mentioned study demonstrated that OAB symptoms were significantly improved in the 77% of participants and this improvement continued until 3 years after the 12 weekly percutaneous tibial nerve stimulation treatments with an average of one treatment per month.[19] Moreover, it should be considered that anticholinergics have well-recognized side effects, and they lose their clinical effectiveness after stopping treatment.[20]

## CONCLUSION

TTNS is an effective and well-tolerated treatment option in women with OAB symptoms who have not benefited from anticholinergic medications. However, further studies are essential in determining the efficacy of TTNS with a larger number of participants and longer-term findings. Moreover, the exact mechanism of action of TTNS is not yet clear and there is no standardized treatment protocol or stimulation parameters. Hence, future studies of TTNS should determine the most effective stimulation dosage, duration of effect, and help to develop data on the long-term effects of treatment as well as costs for specific patient groups.

### Statement

**Ethics Committee Approval:** The İstanbul University Clinical Research Ethics Committee granted approval for this study (date: 07.05.2021, number: 204708/2021).

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

**Peer-review:** Externally peer-reviewed.

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