

Transcutaneous tibial neurostimulation and Solifenacin in urgent incontinence of postmenopausal women

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Abstract

Symptoms of overactive bladder syndrome (OAB), including urinary incontinence, affect a person's quality of life and cause many personal, social and economic problems. Patients were randomly divided into three groups and received transcutaneous tibial nerve stimulation (cTTNS) with fixed parameters or with variable parameters (vTTNS) and Solifenacin drug. The main outcomes including quality of life questionnaire and OAB score and other secondary outcomes were evaluated before and after treatment for 6 weeks. ANOVA test did not show any significant difference between the three groups in quality of life score ($p=0.672$), OAB symptom score ($p=0.159$) and incontinence severity ($p=0.422$). The t-test demonstrated that the post treatment average quality of life score, OAB score, and incontinence severity were significantly different when compared with before treatment in all three groups ($p < 0.05$). All three methods were effective in treating symptoms of OAB. However, based on the clinical symptoms, cTTNS is recommended as a preferred and acceptable and safe strategy for the treatment of OAB in women over 50 years old.

Key Words: overactive bladder; posterior tibial nerve stimulation; treatment; Solifenacin.

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Overactive bladder (OAB) is a chronic disease characterized by urinary urgency with or without incontinence, usually related to frequency and nocturia.¹ Prevalence of OAB syndrome in the general population has been reported between 14-16%.^{2,3} The prevalence of OAB syndrome increases with age and there is no significant difference between the two sexes.⁴ Urinary incontinence is a common health problem in women. In many studies, the maximum prevalence has been reported during menopause, which varies between 8% and 56%, depending on the type of study. The prevalence of urinary incontinence in women over fifty years old was reported as 37.8% in a community-based study in Tehran.⁵ OAB symptoms, including urinary incontinence, affect a person's quality of life, ultimately leading to social isolation, anxiety, depression and decreased self-confidence. This problem imposes a

large economic burden.⁶ According to the guidelines of the American Urology Association, behavioral therapy is recommended as the first line of treatment. In the second line, oral drug therapy including antimuscarinic drugs and β_3 agonists is recommended. Onabotulinum toxin A, sacral neuromodulation and posterior tibial nerve stimulation (PTNS) are in the third line of treatment.⁷ PTNS is an effective minimally invasive treatment that not only is used in cases of non-response to treatment, but also can be placed in the first line of treatment.^{8,9} Transcutaneous tibial nerve stimulation (TTNS) is a non-invasive method, the effects of which are similar to PTNS.¹⁰ It should also be noted that there are uncertainties about the stimulation method and parameters of PTNS stimulation in the treatment of OAB.^{10,11-13} This study aimed to assess the effect of TTNS with fixed and variable parameters, and

Solifenacin therapy in postmenopausal women over 50 years old.

Materials and Methods

The study was performed in accordance with relevant regulations of ethics research committees of the University of Medical Sciences or declaration of Helsinki. This study has been approved by the Deputy of Research and Technology of Hamadan University of Medical Sciences (approval code: 9804182948). The project was carried out after approval by the research council of the Faculty of Medicine and receiving the code of ethics, IR.UMSHA.RES.1398.217. Written introduction letters were obtained from the officials of the university and researcher's centers. The purpose of the study was explained to all research units and written consent was obtained from them. The information of all patients was kept confidential. This randomized clinical trial was conducted on postmenopausal women over 50 years old with clinical symptoms of overactive bladder syndrome. Patients who met the inclusion and exclusion criteria were included in the study. Inclusion criteria include: menopausal women over 50 years of age, urinating at least 8 times a day based on the history or voiding diary and more than once feeling of urgency with or without incontinence. Exclusion criteria included: hypersensitivity to sulphenazine or its components, presence of micra leadless pacemaker, urinary retention, gastric retention, nerve damage or neuropathy, uncontrolled narrow-angle glaucoma, positive urinary tract infection test, and fasting blood glucose above 100 mg/dL. During the initial examination, with the withdrawal of 6 patients due to various reasons, 48 patients were randomized to receive treatment in three ways: cTTNS, vTTNS, or SOL. Block randomization method was used for randomization. The sample size was estimated to be approximately 16 people for each group with a type I error of 5% and a power of 80%. At first, the demographic information of the patients including: age, height, weight, level of education, occupation, marital status, number of pregnancies and type of delivery were taken and the subjects completed a written consent form to participate in the study. Patients with clinical symptoms suspected of OAB who were referred to the Women's Medical Clinic of Hamadan University of Medical Sciences were included after a thorough examination by a gynecologist and filling out the written consent. In this study, randomized block method was used to assign patients to treatment groups. Due to the existence of three treatment groups, blocks of 6 were used and there were equal numbers of each treatment in each block. In the next step, out of the total number of possible states of 6 blocks, 8 blocks were randomly selected using a table of random numbers. In order to protect the randomization process in this study, the concealment process was implemented as follows. Sealed envelopes were used for concealment. In this

way, there were 48 sealed envelopes with only a predetermined code written on it without any indication of the type of treatment. So when the patient came to the clinic, the therapist received a code from the researcher, which was written on one of the sealed envelopes. After opening that envelope, the type of treatment of the patient was determined by the therapist and that treatment was assigned to the patient. In the same way, this process was implemented for the next patients. Therefore, the type of treatment of the next patient could not be predicted for the therapist. Before the start of the intervention and after the completion of the treatment, the bladder diary was filled by the patient for one day. Electrical stimulation of the posterior tibial nerve was performed for 30 minutes every other day for 18 sessions in two groups in two different ways. In these two groups, one of the electrodes (6x4 rubber type) was placed in the lower and posterior area of the inner ankle and the other electrode was placed 5 cm higher. In the first group (cTTNS), electrical stimulation was performed with constant frequency (20 Hz) and constant diversion (200 microseconds). In the second group (vTTNS), electrical stimulation was performed with an initial frequency of 20 Hz and a diversion of 200 microseconds, within two seconds the frequency decreased from 20 Hz to 14 Hz and the diversion increased to 300 microseconds and returned to the first state within two seconds. In both groups, the intensity of stimulation was raised to the patient's tolerance level. In the third group (SOL), patients received sulfinacin with a daily dose of 5 mg for 6 weeks. The diary was completed before and after the treatment, including the volume of fluids consumed and the volume of urine excreted, as well as the number of urges, the number of incontinence, the number of urination and the intensity of incontinence. The severity of incontinence was given from 0 to 3 points. Score 0 = no incontinence, score 1 = few drops of leakage, score 2 = small amount of leakage, and score 3 = severe leakage of urine and need to change clothes. The Incontinence Quality of Life (I-QOL) questionnaire consists of 22 questions *each* with a *five-point* ordinal response scale, ranging from ratings of 1 (extremely) to 5 (not at all) for *each* item. The overall score ranges from 22 (the lowest quality of life) to 110 (the highest quality of life). The OAB symptom questionnaire consists of 4 questions assessing OAB symptoms with scores ranging from 2 to 5: daytime frequency (0-2 points), nocturnal urinary frequency (0-3 points), urgency (0-5 points), and UUI (0-5 points). The total score ranges between 0 and 15, where a score ≤ 5 indicates mild OAB, a score of 6 to 11 indicates moderate overactive bladder, and a score ≥ 12 indicates severe OAB.^{14,15} Quantitative data were reported with mean and standard deviation and qualitative data with frequency and percentage. Shapiro-Wilk test was used to test the normality of quantitative variables. The mean and standard deviation of the desired outcomes (quality of life, overactive bladder and incontinence severity)

Table 1. Characteristics of study participants.

Variable		vTTNS	cTTNS	SOL
Age		56.18 (5.4)	60.56 (8.85)	58.38 (6.2)
BMI		28.63 (3.63)	29.01 (4.01)	28.39 (4.21)
Number of people (percentage based on job)	Housewife	14 (87.5)	16 (100%)	11 (68.75%)
	Employee	1 (6.25)	0 (0%)	3 (18.75%)
	Retired	1 (6.25)	0 (0%)	2 (12.5%)
Number of people based on education (percentage)	Lack of education	6 (37.5)	12 (75%)	3 (18.75%)
	High school	6 (37.5%)	3 (18.75%)	6 (37.5%)
	Diploma	3 (18.75%)	1 (6.25%)	2 (12.5%)
	Excellent	1 (6.25%)	0 (0%)	5 (31.25%)
Pregnancy number		5.06 (2.64%)	5.56 (2.6%)	5 (2.65%)
Delivery number		4.81 (2.28%)	5.31 (2.49%)	4.87(2.82)
Delivery type	Normal	13 (81.25%)	13 (81.25%)	11 (68.75%)
	Cesarean section	1 (6.25%)	2 (12.5%)	0 (0%)
	Both	2 (12.5%)	1 (6.25%)	5 (31.25%)

were reported separately for the study groups. According to the correlation coefficient higher than 0.5 between the score before and after the intervention of the studied outcomes, the change score approach was used to compare the groups. One-way ANOVA test was used to compare the results between the three groups. Paired t-test was used to compare the results (quality of life, OAB and incontinence severity) before and after the intervention in each study group. A significance level of $p < 0.05$ was considered. The data analysis approach in this study was intention to treat. Statistical calculations were performed using SPSS software version 16.0 (Chicago, Ill., USA).

Results

A total number of 48 patients with an average age of 58.37 ± 7.06 and an average BMI of 28.68 ± 3.88 were included in the study (Table 1). Quantitative variables

had normal distribution. Among all volunteer patients, 85.45% were housewives, 43.75% had no degree of education and 75.3% had higher education. These patients had an average of 5.2 ± 2.63 pregnancies and 4.99 ± 2.53 deliveries. 77.08% of the patients had only natural delivery and the rest experienced either cesarean section or both types of delivery (Table 1). The average changes in quality of life scores in the cTTNS, vTTNS and SOL groups were 19.56 (22.92), 14.94 (22.02) and 13.75 (10.91), respectively. The average score changes of overactive bladder symptoms in the cTTNS, vTTNS and SOL groups were 1.68 (1.35), 1.5 (1.15) and 2.12 (1.89), respectively. The results showed a significant difference between the three groups in the scores of quality of life ($p = 0.672$) and symptoms of OAB ($p = 0.159$) and the severity of incontinence ($p = 0.422$) (Table 2). The t-test showed a significant change in the average quality of life score in cTTNS ($p = 0.004$),

Table 2. Comparison of the studied groups in terms of quality of life, OAB and incontinence.

Variable	vTTNs	cTTNs	SOL	p-value
Quality of Life	14.94 (22.02)	19.56 (22.92)	13.75 (10.91)	0.672
Irritable bladder	-4.31 (4.25)	-3.93 (3.54)	-2.12 (1.89)	0.159
Severity of incontinence	-1.5 (1.15)	-1.68 (1.35)	-1.12 (1.14)	0.422

Table 3. Comparison of treatment outcomes before and after the intervention by groups.

Variable	vTTNs			cTTNs			SOL		
	before	after	<i>p</i> -value	before	after	<i>p</i> -value	before	after	<i>p</i> -value
Quality of Life	72.06 (22.44)	87 (23.06)	0.016	49.50 (17.59)	69.06 (27.07)	0.004	54.62 (20.81)	68.38 (25.27)	0.001
Irritable bladder	9 (2.98)	4.68 (3.96)	0.001	10.12 (3.57)	6.18 (4.44)	0.0005	10.31 (2.72)	8.18 (3.44)	0.0004
Severity of incontinence	2 (1.21)	0.5 (0.82)	0.0001	0.87 (1.36)	2.56 (0.89)	0.0002	2.06 (1.43)	0.93 (1.06)	0.0014

vTTNS group ($p = 0.016$) and SOL groups ($p = 0.0001$) after treatment compared to before treatment. The t test showed that the average score of OAB in cTTNS ($p = 0.0005$), vTTNS ($p = 0.001$) and SOL ($p = 0.0004$) groups had significant changes after treatment compared to before treatment. The t-test demonstrated that the average intensity of incontinence after treatment has decreased significantly in all three groups compared to before treatment ($p < 0.05$) (Table 3). In the cTTNS and vTTNS treatment groups, no side effects or discomfort were reported by the patients, but in the SOL treatment group, 8 patients complained of drug side effects such as dry mouth, constipation, headache, and nausea.

Discussion

This study has examined the treatment of OAB with three treatment methods, where TTNS using adhesive skin surface electrodes was compared with sulfinacin drug therapy, for the first time. Previous studies have shown the relative superiority of PTNS method over sulfinacin drug.^{8,16} Vecchioli et al investigated the effectiveness and durability of Solifenacin (SS) versus PTNS versus combination therapy (PTNS+SS) on the treatment of OAB. According to their findings, PTNS showed more effectiveness than SS, but PTNS+SS was more effective than SS and PTNS separately. In addition, PTNS+SS showed a longer duration of effectiveness than PTNS and SS.¹⁶ The results of the present study show that the use of TTNS or the use of sulfinacin can be effective in the treatment of OAB. These two methods were able to not only improve the quality of life and the OAB score as the main variables, but also improved the number of urges, the number of incontinence, the number of urination and the severity of incontinence as secondary variables that are in line with the previous studies.^{8,17} On the other hand, the results of the present study show that electrical stimulation using cTTNS and vTTNS methods did not have a statistically significant difference with the SOL group in terms of influencing the quality of life variable, but clinically there was a significant difference between the cTTNS group and the SOL group. Also, between the cTTNS group and the vTTNS group, where cTTNS is

preferable to other. Considering the side effects of Sulphenazine and patients' resentment, TTNS was chosen as the treatment method. On the other hand, it has been clarified that the positive effects of the TTNS treatment method are similar to the PTNS method,¹⁰ but it does not have the possible side effects of the PTNS method, such as tingling, bruising, and possible bleeding.¹⁸ In another parallel study, it has been shown that TTNS is effective in reducing daytime frequency compared to PTNS and has caused a decrease in urgency incontinence episodes and improved the quality of life of patients.¹⁹ A review of 15 articles found that TTNS is a promising management option for treating patients with urinary incontinence, especially in the elderly and for those with neurogenic bladder. In addition, this method can relieve the symptoms of urinary incontinence, frequency and nocturnal enuresis, while it does not have side effects compared to PTNS treatment and avoids invasive or pharmaceutical treatments to a great extent.²⁰ According to a systematic review, four studies found TTNS and antimuscarinic treatment to be equally effective. In two studies, TTNS was better than behavioral interventions where it was found to be effective in improving symptoms of OAB. Also, a study showed the same effect of TTNS and sacral foramen stimulation.²¹ Evaluation of the effect of TENS and solifenacin succinate versus solifenacin alone in the treatment of OAB has shown that maximum bladder volume and OAB symptoms were significantly improved in both methods after treatment. The improvement of maximum bladder volume and symptoms in the TTNS and solifenacin group was significantly better than the solifenacin group alone.²² In the present study, cTTNS was more effective than vTTNS.

The justifiable reason can be the creation and maintenance of the high level of nervous system excitability in the second method, where the process of nerve adaptability does not occur and the person experiences agitated conditions. One of the limitations of this study was the lack of knowledge of referring patients about electrical stimulation methods for the treatment of OAB. Considering the preference,

acceptability and safety of cTTNS for the treatment of OAB in women over 50 years of age, adequate information about this treatment method should be provided to patients before prescribing the treatment. In conclusion our findings revealed that all three methods are effective in treating symptoms of OAB. More clinical studies can contribute to more accurate results. According to clinical symptoms, cTTNS method is recommended as a most efficient, safe and acceptable option for treating overactive bladder in women over 50 years old.

List of acronyms

OAB - overactive bladder syndrome,
TTNS - transcutaneous tibial nerve stimulation
I-QOL - Incontinence Quality of Life
SS - Solifenacin

Contributions of Authors

All authors have read and approved the final edited typescript.

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Conflict of Interest

The authors declare no conflicts of interest.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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