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Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on Patients with Restless Legs Syndrome (RLS): A Short Report (randomized clinical trial)

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Abstract

Purpose: *Restless Legs Syndrome (RLS) is a motor and neurological disorder that is associated with a sense of urgency to move the legs. It is necessary to use non-pharmacological treatments to reduce the symptoms of this syndrome.*

Methods: *The present study is a two-group clinical trial, in which transcutaneous electrical nerve stimulation (TENS) intervention was performed on 20 patients (10 patients in each group) for 3 sessions in 3 consecutive days. The aim of this research was to evaluate the effect of TENS on RLS in patients with this complaint referring to a private medical center.*

Results: *The mean age of participants was 46.56 ± 9.16 years. There was a significant difference in RLS levels before and after the final intervention in each group. There was no significant difference of RLS rate between the two groups after final intervention.*

Conclusion: *If future studies with a larger sample size confirm the results of the present study, patients can use a portable TENS according to the advice of a physician at home to reduce nocturnal symptoms associated with RLS syndrome.*

Keywords: *Transcutaneous Electrical Nerve Stimulation (TENS); Restless Legs; Willis-Ekbom Disease*

Introduction

Restless legs syndrome (RLS), also known by its newer name Willis–Ekbom disease (WED), is one of the most prevalent neurological disorders in Europe and North America, affecting approximately 10% of the population, with women suffering almost twice as often as men (1). RLS has a high prevalence among the Iranian population (2, 3). RLS is a sensorimotor disorder that is characterized by an uncomfortable urge to move the legs (4), as well as a hyperkinetic movement disorder that can lead to insomnia, which is sometimes equally or even more disabling. In addition to sleep impairment, these patients also deal with a plethora of symptoms leading to extreme discomfort and disruption of their normal daily activities and are therefore challenged to overcome these incapacities (5). The paresthesia, which is associated with an impulse to move the limbs (usually the legs but can reach other parts of the body such as the arm), generally following a circadian variation. People with RLS may develop mood swings, anxiety, or depression (6), and the pathogenesis of this disease is uncertain. As there are no biomarkers or definitive measurable clinical findings to clearly indicate RLS/WED, its diagnosis is based primarily on subjective complaints (1). Apart from drug therapy, conservative treatments are used for RLS patients. Two modes of action, namely enhancement of circulation and counter stimulation, are introduced in this regard. Medical devices using enhancement of circulation as their mechanism of action include whole body vibration, pneumatic compression, and near-infrared light. Transcutaneous electrical nerve stimulation (TENS) and vibration relaxes pad are medical instruments that use counter stimulation (1, 5). TENS seems to be able to inhibit the transmission of nerve impulses through A-delta and C fibers via stimulating A-beta filaments. Biochemical mechanisms such as increasing levels of substance P and 5-hydroxytryptamine in

cerebrospinal fluid using TENS can also be effective (1, 7, 8).

The purpose of this study was to answer the following question: can TENS reduce the symptoms of RLS, which often occur at night and interfere with patient's activities and sleep at night? On the other hand, we aimed to investigate the efficacy of TENS on RLS in patients referring with this complaint.

Materials and Methods

This was a randomized clinical trial (RCT), which was conducted in a private clinic in Esfarayen city on 20 patients from 2019 up to February 2021. The inclusion criteria were as follows: persons aged 35 and over, having RLS based on patient's self-declaration and the diagnosis by a neurologist and internal medicine specialist, obtaining a score higher than 4 with IRLSS, no history of mental illness, no vascular diseases, no neuromuscular disorders (difficulty in performing the technique), and lack of crisis during the last 3 months (9). Exclusion criteria were severe stress experience by a person or family (death of others), intensification of RLS, use of antispasmodics, anticonvulsants, antidepressants, sedatives, herbal medicines or any other medicines to treat this syndrome during the last two weeks.

The data collection instrument was the international questionnaire of restless legs syndrome (IRLSS) that was completed by subjects through their interview by the researcher. This questionnaire is a standard tool, the validity and reliability of which have already been confirmed (10).

After obtaining permission from the ethics committee, first the severity of RLS in referred people was determined by IRLSS questionnaire and then to affirm this diagnosis, different neural and motor exams were carried out by neurologists and internal medicine specialist to confirm the existing syndrome. Then, the patients were divided into two groups using permissive blocks for random allocation of patients (10 patients in each group).
TENS with two frequencies was used for the two groups. One of the groups received TENS with high frequency and the other TENS with low frequency, namely 100 Hz and 20 Hz for case and control groups, respectively, in three times within three consecutive days for 20 minutes. IRLSS questionnaire was completed by patients in both groups in four stages: before the first, second, third interventions, and the day after the third intervention. In this study, the correlation between BMI of 20 patients and RLS before the first intervention also was examined.

Results

The results showed that the mean age of participants was 46.56±9.16 years. Most of the participants were women, married, and resident of the city, including 16 (80.0 %), 19 (95.0%), and 16 patients (80.0%), respectively. There was no significant difference in RLS between the two groups in the day after every intervention ($p>0.05$), except on the second day (before the second intervention, which was nearly significant (P=0.051). However, with the passage of days from the first to the third intervention, the score of RLS significantly decreased in each group separately ($p<0.05$). No significant correlation was observed between BMI and RLS before the first intervention (r=-0.19, p=0.46) [Table 1].

Group	First day	Second day	Third day	Fourth day	p.value*
Case	23.71±6.82	13.00±4.72	16.57±4.57	15±6.29	0.027
Control	23.00±3.67	19.11±6.29	15.67±5.43	17.78±6.92	0.019
p.value**	0.079	0.051	0.729	0.422	
*Repeated measure anova					
**Independent sample t test					

Table 1: The relation between TENS and RLS After three interventions in Case AND Control groups.

Discussion

In this study, the interventions were performed for 3 consecutive days. The results of the present research showed that TENS can significantly reduce RLS in patients with this complaint in the two groups (high dose and low dose). This finding has also been confirmed in the study of Heide et al. which used transcutaneous spinal direct current stimulation (TSDCS) to reduce pathologically enhanced spinal excitability in RLS patients and therefore ameliorate clinical symptoms (11). Also, Waldinger et al. evaluated the effect of TENS on restless genital syndrome and indicated that conventional TENS treatment is a promising therapy for ReGS (7).

It is predicted that if we could perform the study on a larger number of infected people (in the absence of COVID-19 virus), the difference in RLS rate between the case and control groups at the end of the study becomes significant. Based on the results, it also seems that if the study was performed in a larger number of sessions, the difference of RLS before the first intervention and at the end of the study would be more significant.

Conclusion

The findings of the present study and previous studies indicate the impact of TENS on the symptoms of RLS. It seems that if TENS intervention can be performed using a portable device by the patients themselves after providing the necessary training at home upon sunset (i.e. the time of symptoms onset in most patients) on a larger number of patients with RLS, we can advise the use of a portable device with a frequency prescribed by a physician at certain times of the day (before the onset of symptoms) for reducing the symptoms of RLS.

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Limitations

The outbreak of COVID-19 virus prevented people from coming to the treatment centers and the sampling process was disrupted. Also, we could not connect the turned off device to the patients in control group, which could be the reason why the difference in RLS in the day after the final intervention was not significant in the two groups.

Conflict of interest: None

Any of the authors do not have

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