Research Paper:

Effect of Capacitive Tecar Therapy on Foot Pain and Tactile Sensation in Patients with Type 2 Diabetes

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ABSTRACT

Objective Because of the significant prevalence of diabetes, disability of patients due to the complication of Diabeti Neuropathy (DN) has been increased. Physiotherapy is one of the methods for DN which can help control the symptoms through modalities such as infrared radiation, electrical stimulation and electromagnetic fields. Tecar therapy is a form of electromagnetic fields.This study investigated the effect of Capacitive Tecar therapy on pain and tactile sensation of the feet in type 2 diabetics with symptoms of peripheral neuropathy.

Materials & Methods This clinical trial was performed as pre-test and post-test with a control group. The samples consisted of 24 diabetics aged 17-78 years with symtoms of peripheral neuropathy allocated in the control and experimental group randomly. The patients of experimental groups participated in 10 sessions and received the Capasitive tecar therapy with 10%-30% intensity in addition to infrared radiatin; the controls received the same protocol with zero intensity of tecar. Pain and tactile sensation of the soles were evaluated before and after sessions. The collected data were analyzed by the Reapeted measure Analysis Of Variance (ANOVA). All statistical analyses were performed in SPSS V. 18. The significance level was set at $P<0.05$.

Results The results of Rearetd Measure ANOVA showed that there was a significant difference in the mean scores of pain and tactile sensation of soles in the post-test compared to the pre-test of two groups. ($P<0.001$).There was also a significant difference in the means of post-test scores of variable pain ($P=0.002$) and tactile sensation ($P<0.001$) between the two groups. The improvement of variables in experimental group was more than control group.

Conclusion The results of this study revealed that Tecar Therapy with infrared radiation can be an appropriate therapeutic program for improving pain and tactile sensation of soles in diabetic patients with symptoms of peripheral neuropathy.

Extended Abstract

Introduction

Diabetes is one of the most common metabolic disorders, in which impaired carbohydrate metabolism, deficiency in insulin production, and its effects will raise blood sugar [1]. Type 2 diabetes is the most common type accounting for 90%-95% of all diabetic cases [2, 3]. The World Health Organization (WHO) estimates the prevalence rates of type 2 diabetes in 2000 as 5.7% that will rise to 7.8% in 2025 [4]. Because its clinical diagnosis oc-

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curs 4-7 years after the onset, multiple organs of the body are adversely affected in this period [5]. Diabetic Peripheral Neuropathy (DPN) is one of the most common complications of diabetes [6]. It affects 12-50% of diabetics [7]. Gradual dysfunction of small-diameter thinly myelinated (Aδ) or unmyelinated (C) nerve fibers conveying pain, temperature, and touch is one of the important complications of the DPN [8, 9]. This disorder has two types of distal and proximal neuropathy and affects the distal ends of the body's largest nerve fibers. Therefore, the lower limbs are more prone to sensory disorders than other areas [10, 11].

One of the interventions used to control the process of DPN is low-frequency electromagnetic fields. Several studies have reported its effectiveness in improving DPN complications [12-14]. There is high electrical activity in the nervous system. Due to the dependence of hormone and neurohormone secretion on the nervous system, electromagnetic fields can affect the function of the hormonal system, growth, and cell differentiation [15, 16]. Studies on the effect of these waves on the pain and tactile perception in the soles of the feet in diabetic patients have yielded different results. Bosi et al. [18] considered pulsed electromagnetic fields with a frequency of 1-50 Hz to be effective in reducing pain and improving tactile perception in the soles due to the excitation of the membrane potential of damaged tissues. Other studies, however, have shown the ineffectiveness of electromagnetic fields on the pain [18] and its small effect on the tactile perception of the sole [13]. Despite the discrepancies in the results, the impact of high-frequency electromagnetic fields on the symptoms of DPN has also been studied.

Tecar therapy uses high-frequency electromagnetic currents (0.3-1.2 MHz) [19], which enhance blood circulation and the release of tissue hemoglobin by creating deep heat in tissues [20]. It has two methods of "resistive" and "capacitive" using two different types of electrodes. The capacitive method is used to act on superficial tissues with low-resistant muscles and nerves, while the resistive method for high-resistant deep tissues such as bone [21]. Despite few studies on the therapeutic effects of capacitive or resistive electromagnetic waves [22], most studies have reported reduced pain and improved function in musculoskeletal lesions such as low back pain [23], Achilles tendinopathy, and patellar tendonitis [24]. The physiological mechanisms of this modality are cellular regeneration, increased metabolic rate, and decreased pain with the release of endorphins [25]. Since the effect of Tecar therapy on the neuropathic symptoms of diabetic patients has not been investigated, this study aimed to examine the impact of capacitive Tecar treatment on pain and tactile perception of the soles of the feet in type 2 diabetic patients.

Materials and Methods

This research is a single-blind clinical trial with a pre-test-post-test design. The study samples were diabetic patients aged 40-78 years with DPN symptoms referred to the Diabetic Clinic of Imam Hossein Hospital in Tehran City, Iran. Sampling was based on a non-random sampling technique, and the samples were evaluated in the biomechanics laboratory of the Faculty of Rehabilitation at Shahid Beheshti University of Medical Sciences. Because of the small number of dependent variables and the detection of mean differences in two independent populations, assuming the type 1 error of 0.05, the test power of 80% according to a pilot study on 5 samples in each group, the final sample size was determined 24 feet in each group (a total of 48 feet taking into account the possible dropout, too). The inclusion criteria were having type 2 diabetes and symptoms of DPN (grade 1 or 2) in lower limbs, Visual Analog Scale (VAS) score ≥3 for the feet, having diabetes for more than one year, and tibial nerve conduction velocity <40 m/s. On the other hand, the exclusion criteria were systematic central and peripheral vascular problems, pregnancy, diabetic infectious wound, cardiac pacemaker presence, and unwillingness to continue study participation.

One examiner evaluated patients from the beginning to the end of 10 sessions of Tecar therapy. Before that, the pain and tactile sensation of the soles of the feet of patients in both study groups were evaluated using 10-cm VAS [26] and 5.07/10 g Semmes-Weinstein monofilament [27] (Figure 1). In the intervention group, infrared radiation with a wavelength of 870 nm with a density of 1.3 j/cm^2/min was used. The patients lay on their sides once with their back to the radiation and once at the front of the radiation. Then, each dorsal, plantar, medial, and lateral area of their feet with a distance of 80-90 cm was treated with this radiation for a total of 30 minutes (Figure 2). Then, they received capacitive Tecar therapy (TEKRA XCRT, New Age, Italy) (Figure 3) in the tibial nerve pathway from the popliteal area to the medial area of the ankle continuously for 20 minutes, with an intensity of less than 50% in 10 sessions for 4 weeks. One session lasted for 100 minutes in the prone position (Figure 4). The patients in the sham group received the same treatment protocol, including infrared radiation but with 0 intensity of Tecar device. Finally, the variables of pain and tactile sensation of the sole were re-evaluated after the intervention. The Kolmogorov-Smirnov test was used to check the normality of data distribution, and Levene's test to examine the equality of variances. The mean and standard deviation were used to describe the obtained data. The obtained data were analyzed using the independent t-test and repeated measures ANOVA in SPSS V. 18, considering a significance level of less than 0.05.

Figure 1. Semmes-Weinstein monofilament 5.07/10 g

Figure 2. The positions for applying infrared radiation on the feet

Results

In this study, 24 patients with type 2 diabetes suffering from mild to moderate DPN participated in the two intervention (n=12) and sham (n=12) groups. All participants had diabetes for at least 2 years and complained of lower extremity pain and sensory impairment (Table 1). At baseline, there was no significant difference between the two groups in terms of demographic factors (P>0.05). The Kolmogorov-Smirnov test presented in Table 2 showed the normality of data distribution (P>0.05). Levene's test results presented in Table 3 established the equality of variances (P>0.05). Therefore, to compare the effect of treatment methods on the two study variables (foot pain and tactile sensation) in the study groups, repeated measures ANOVA was used. The mean and standard deviation of the two groups' variables, before and after 10 sessions of intervention, are presented in Table 4.

Effect of the intervention on foot pain

The patients' foot pain scores using the VAS were compared using the independent t-test at baseline. The results showed no significant difference between the two study groups in pre-test foot pain (P=0.56) (Table 3). After the intervention, the mean foot pain in the two groups showed a significant decrease, and the difference between the two groups was significant (P<0.001) (Table 4). The patients in the intervention group experienced less foot pain than the patients in the sham group (P=0.002). In other words, both treatment methods reduced foot pain in patients; however, the combination of infrared radiation (on the foot surfaces) and capacitive Tecar therapy (on the tibial nerve pathway) was more successful. The Mean±SD scores of foot pain in the sham and intervention groups were 5.54±1.93 and 5.25±1.48 before the intervention and reached 2.17±1.68 and 0.79±0.97 after the intervention, respectively.

Effect of the intervention on foot sole tactile sensation

The results of the independent t-test showed no significant difference between the two study groups in pre-test foot sole tactile sensation (P=0.482) (Table 3). After the intervention, the mean foot sole tactile sensation score in the two groups increased, and the difference between

Figure 3. The device used for Tecar therapy

Figure 4. Applying capacitive Tecar therapy

Table 1. Demographic and clinical characteristics of the participants (n=12 per group)

Characteristics	Group	Mean±SD	t	Sig.
Age (y)	Sham	60.5±9.12	0.25	0.80
	Intervention	59.58±8.63		
Height (cm)	Sham	159.00±7.32	-0.18	0.85
	Intervention	159.58±8.15		
Weight (kg)	Sham	72.91±12.45	-0.94	0.35
	Intervention	77.04±8.51		
Body mass index (kg/m^2)	Sham	28.81±4.15	-0.97	0.34
	Intervention	30.32±3.44		
Duration of diabetes (y)	Sham	7.62±4.76	-1.29	0.21
	Intervention	10.66±6.63		
Fasting blood sugar (mg/dl)	Sham	159.75±25.24	-073	0.47
	Intervention	166.58±20.34		

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Table 2. The Kolmogorov-Smirnov test results of examining the normality of data distribution

Variables	Group	The Kolmogorov-Smirnov test	
		Statistic	Sig.
Foot pain	Sham	0.941	0.339
	Intervention	1.204	0.110
Foot sole tactile sensation	Sham	1.335	0.057
	Intervention	1.250	0.088

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the two groups was significant (P<0.001) (Table 4). Both treatment methods increased foot sole tactile sensation in patients; however, the combination of infrared radiation and capacitive Tecar therapy was more successful. The Mean±SD score of foot sole tactile sensation in the sham and intervention groups was 5.79±0.93 and 5.92±0.71 before the intervention and reached 7.79±1.41 and 9.38±0.64 after the intervention, respectively.

Discussion and conclusion

The purpose of this study was to investigate the effect of capacitive Tecar therapy on the symptoms of DPN in type 2 diabetic patients. The results showed that the combination of capacitive Tecar therapy and infrared radiation had a positive and significant effect on improving these symptoms. Using this new method, a significant improvement was achieved in the foot pain and tactile sensation of the sole compared to the infrared radiation treatment alone. No other study was found to investigate the effect of Tecar therapy on the symptoms of DPN in diabetic patients. The studies on Tecar therapy's impact on musculoskeletal lesions have indicated improvement in pain and function of damaged tissues [29]. Many studies on low-frequency electromagnetic fields have confirmed its effect on various variables in diabetic patients, and some have reported it without any therapeutic effect.

The findings of the present study showed that the use of capacitive Tecar therapy for 10 sessions led to a greater re-

Table 3. The Levene's test results of examining the equality of variances (n=12 per group)

Variables	Group	t	Sig.	F
Foot pain	Sham Intervention	0.587	0.560	5.004
Foot sole tactile sensation	Sham Intervention	0.708	0.482	0.753

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Table 4. ANOVA results of comparing foot pain and tactile sensation scores in the two study groups

Variables	Group	Mean±SD		Within-group comparison, Sig.	Between-group comparison, Sig.
		Pre-test	Post-test		
Foot pain	Sham	5.25±1.48	0.79±0.97	0.001>	0.002
	Intervention	5.54±1.93	2.17±1.68		
Foot sole tactile sensation	Sham	5.92±0.71	9.38±0.64	0.001>	0.001>
	Intervention	5.79±0.93	7.79±1.41		

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duction in foot pain of patients in the intervention group compared to the sham group. Peripheral neuropathic pain is one of the most resistant types of pain to treatment [30]. For explaining this finding, it can be stated that the combination of capacitive Tecar therapy on the tibial nerve pathway with infrared radiation affected the receptors of foot pain in diabetic patients and reduced foot pain by releasing endorphins and increasing tissue heat. According to studies, almost more than half of patients with DPN symptoms who were treated do not experience pain relief [31]. In contrast, a study showed that using electromagnetic waves with a modulated frequency of 1-1000 Hz on the nerves of the lower limbs in patients with diabetic neuropathy in 10 sessions to increase blood circulation and vascular endothelial growth led to the relief of pain and threshold of cold sensation [13]. Combination of electromagnetic radiation with a frequency of 50 Hz and the exercise therapy and further stimulation of the neurovascular system of tissues, patients' foot pain can be reduced, and their sensory nerve conduction velocity can be improved [15]. However, a study showed that pulsed electromagnetic field therapy with a frequency of 50 Hz and an intensity of 1800 Gauss was not effective in improving patients' foot pain. The low intensity of the applied current was the reason for the method's ineffectiveness [18].

Another finding of this study was the significant improvement in the tactile sensation of the soles of the feet of diabetic patients in the intervention group. This finding is consistent with the results of Stein et al.'s [33] in 2013 on the application of pulsed electromagnetic field therapy with modulated frequency on the lower limbs of diabetic patients. According to them, electromagnetic waves increase the tactile sensation of patients' foot soles by directly and indirectly activating the Aδ and C-fibers towards the distal axons. However, in another study, it was shown that despite using electromagnetic radiation with a modulated frequency of 1-1000 Hz, no significant improvement was observed in the tactile sensation of the sole, maybe because only patients with mildly impaired tactile sensation were treated [13]. DPN increases the prevalence of diabetic foot ulcers following a decrease in foot sensation. Therefore, the treatment of this disorder is very important [6].

A combination of capacitive Tecar therapy and infrared radiation therapy can reduce lower limb pain and improve the tactile sensation of the soles of the feet in diabetic patients. This method is suggested as an effective method in improving the symptoms of DPN associated with type 2 diabetes, along with other physiotherapy modalities. The use of this method for 4 weeks in 10 sessions was one of the study's limitations. If the treatment period were more prolonged, more accurate results would be obtained. Other limitations

include short-term evaluation of the effect of treatment and is a single-blind study, which can affect the results to some extent. Besides, in Iran, due to the limited insurance to cover the financial costs of this device, all diabetic patients can't use it. As a result, it is not possible to evaluate the function of this modality in detail. Further studies with long-term follow-up to assess the effect of Tecar therapy on the symptoms of DPN are suggested.

Ethical Considerations

Compliance with ethical guidelines

This study obtained its ethical approval from the Research Ethics Committee of Shahid Beheshti University of Medical Sciences (Code: IR.SBMU.RETECH.REC.1397.713) and was registered by the Iranian Registry of Clinical Trials (Code: IRCT20190726044337N1).

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Authors' contributions

Conceptualization: Asghar Rezasoltani; Methodology: Asghar Rezasoltani, Sedigheh Sadat Naeimi, Meghdad Sedaghat, Alireza Akbarzade Baghban, Maryam Niajalili; Research: Maryam Niajalili, Asghar Rezasoltani, Sedigheh Sadat Naimi; Editing and finalization: Maryam Niajalili.

Conflict of interest

The authors declared no conflict of interest.

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