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Original Article

The effect of Tecar therapy on neurological disorders and nerve conduction velocity of lower limbs in peripheral neuropathy of type 2 diabetic patients: A six-week follow-up study

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ABSTRACT

Objectives: This study aimed to investigate the effect of Tecar therapy on neuropathy symptoms and tibial nerve conduction velocity in individuals with diabetes.

Patients and methods: The single-blind, randomized, sham-controlled clinical trial was conducted between January 2019 and October 2019. Twenty-four type 2 diabetics (8 males, 16 females; mean age: 60.4±8.9 years; range, 40 to 78 years) with peripheral neuropathy were randomly allocated to control (n=12) and study (n=12) groups. The study group received the capacitive Tecar therapy with 10 to 30% intensity and infrared radiation in 10 sessions. The controls received the same protocol with zero intensity. The neuropathy symptoms and nerve conduction velocity were evaluated at baseline, after 10 sessions, and six weeks after the end of sessions.

Results: There were no significant differences in variables ($p>0.05$). In this way, the homogeneity of the data variables was confirmed. Moreover, the results of two-way mixed analysis of variance showed that improvement of neuropathy symptoms in the study group was significantly more than controls in all stages ($p<0.001$). After 10 sessions, the results of post hoc analysis showed that the neuropathy symptoms and tibial nerve conduction velocity were significantly improved in both groups ($p<0.001$). The improvements were still present at six weeks in the study group ($p<0.05$). However, there was no change in these outcomes after six weeks in the control group ($p>0.05$).

Conclusion: Tecar therapy could improve neuropathy symptoms and tibial nerve conduction velocity in diabetic individuals with peripheral neuropathy. Therefore, the use of this method to control the symptoms of diabetic patients can be recommended.

Keywords: Diabetic neuropathy, nerve conduction velocity, neuropathy symptoms, Tecar therapy.

Diabetes mellitus is a long-term metabolic disease that presents a worldwide public health burden.[1] In 2017, it was estimated that there were 451 million adults with diabetes. This number will increase to 693 million by 2024.[2] Type 2 diabetes affects approximately 90% of diabetic patients in the world.[3] The prevalence of type 2 diabetes is rapidly increasing in all countries in recent decades.[4] Diabetes can result in many complications in the body.[5] Diabetic neuropathy (DN) is one of the most prevalent complications of diabetes observed in 50% of patients with a more than 10 years history of disease.[6] It commonly behaves as a predominantly distal axonopathy at early stages, progressing to a proximal impairment at advanced stages. Additionally, chronic hyperglycemia causes demyelination, manifesting with decreased nerve conduction velocity (NCV).[7]

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Physiotherapy modalities, such as electrical stimulation, laser therapy, infrared radiation (IR), and magnetic fields have been suggested to relieve the symptoms in diabetic patients.[8] Swislocki et al.[9] confirmed the short-term effect of IR on improving lower extremity sensory symptoms in DN. They applied 7 min of IR with a wavelength of 870 nm and energy density of 1.8 J/cm$^{2.m}$ on the surface of each foot. Due to the nervous system's electrical nature and the dependence of the secretion of hormones and neurohormones, electromagnetic fields can effectively improve the function of the hormonal system, cell growth, and differentiation.[10] Studies evaluating low-frequency electromagnetic fields' effect on neuropathy symptoms[11,12] and nerve conduction study parameters[13,14] in DN have reported controversial results.

The discrepancies in the low-frequency electromagnetic field results affecting patients with DN have been discussed.[12,14] Tecar therapy (TT) is a high-frequency electromagnetic field (0.3 to 1.2 MHz) that can improve blood flow and release hemoglobin by producing deep heat in the tissues.[15] Capacitive-resistive electromagnetic fields, known as Tecar today, have been used in clinical cases for the last 20 years, and there are systematic studies on their therapeutic effects.[16] Most studies in this field have reported reduced pain and improvement in musculoskeletal disorders, such as back pain[17] and muscle fatigue.[18] Recently, a novel method of TT has been developed, using an innovative mechanism resulting in endorphin release and nervous system improvement.[19] Tecar therapy reduced DN pain and ameliorated sensory tactile thresholds in a randomized study compared to sham intervention.[19] To our knowledge, the effect of TT has not been studied on the other neuropathic symptoms in diabetic patients. The present research aimed to apperceive how capacitive TT affected neuropathy symptoms and signs, as assessed by Michigan Neuropathy Screening Instrument (MNSI) and motor NCV in these patients.

PATIENTS AND METHODS

The single-blind, randomized clinical trial was performed on 24 individuals (8 males, 16 females; mean age: 60.4±8.9 years; range, 40 to 78 years) with type 2 diabetes and symptoms of peripheral neuropathy in both feet at a diabetes therapeutic center in the Imam Hossain Hospital between January 2019 and October 2019. Inclusion criteria were as follows: age between 18 and 78 years, at least one year of type 2 diabetes, Grade 1 and 2 neuropathy symptoms based on the classification of Thomas[20] in the lower extremities, which is divided into the first degree (asymptomatic), second degree (symptomatic), and third degree (disability), a pain score of 3 or more (according to the visual analog scale), and a NCV <40 m/sec.[9] It should be noted that the clinical symptoms of polyneuropathy, such as diabetic foot symptoms and paresis of the dorsal foot muscles, and diagnostic signs of electroneurophysiology are evaluated in the Thomas classification. In addition, central and peripheral vascular system disorders, kidney disorders, pregnancy, infectious wounds, use of a pacemaker or insulin pump, severe anxiety, and unwillingness to cooperate were the exclusion criteria.[19] The patients were randomly allocated into two groups: the study group (n=12) and the control group (n=12). A pilot study of 10 participants was conducted to calculate the sample size. Considering the mean and standard deviation of response time outcome in two groups, the number of individuals required per group was calculated as 24, with a 95% confidence level, 0.05 probability level (α), and 80% power. For the randomization, 24 cards with a number ranging from 1 to 24 were assigned to each patient. Even cards entered the treatment group, and individuals entered the control group by card shuffling. No patient was withdrawn up to the follow-up phase, but if a patient was lost to follow-up, their data was removed from the analysis. The primary outcome was the NCV, and the secondary outcome was the neuropathy symptoms, which were evaluated three times in both groups: before treatment, after 10 treatment sessions, and six weeks after the end of sessions.

The process was conducted in two stages, IR (first stage) and capacitive TT (second stage), in both groups for 10 sessions (three times a week, every other day, for four weeks). Infrared has several advantages for clinical use. It can be arranged in large flat arrays to treat wide surfaces. In addition, as IR light does not emit heat, there is no risk of heating damage to treated epithelial tissues.[9] The main reason for using IR as the first line of therapy is to improve pain and sensation in the feet, following a substantial reduction in the incidence of foot ulcers.[21] Diabetic patients with neuropathic symptoms were treated with IR and TT in the study group, while patients in the control group were given IR and sham TT.

First, each foot of the patients was treated with IR with a wavelength of 870 nm and density of 1.3 J/cm$^{2.m}$. Patients lied on their sides, and surfaces of their feet were treated with a distance of 80 to 90 cm

for a total of 30 min (Figure 1).[19] Then, a TT by model TEKRA XCRT (New Age, XCRT Model, Lugo RA, Italy) in capacitive mode was applied. The patient was positioned in the prone position, and TT was performed on both sides of the tibial nerves with an intensity of 10 to 30%. The cream of the device was impregnated on the surface of two active and inactive electrodes and the patient's skin. The inactive electrode was placed on the anterior surface of the leg, and an active electrode was moved in the tibial pathway from the popliteal fossa to the medial malleolus. It was continuously moved for 20 min on each foot (Figure 2). The protocol of the sham group was similar to the study group. However, the intensity applied for this group was set at zero.[18] After 10 sessions of interventions and a six-week follow-up, the neuropathy symptoms and the tibial NCV (TNCV) were evaluated in both groups.

The neuropathy symptoms were assessed using the MNSI validated in the Persian language, with a specificity of 80 to 95%, a standard tool for diabetic peripheral neuropathy approval.[22] This questionnaire consists of two parts. One part is completed by the patient and another by the examiner. The first part, which the patient answers, contains 15 questions about burning sensations, numbness, open sores, temperature sensations, and pain during walking in lower limbs. A score of seven is considered abnormal. The second part includes a physical examination of the feet, the presence of an ulcer, vibration test, Achilles tendon stretch reflex, and monofilament test. A standardized tuning fork, a 128 Hz range diapason, was utilized to produce the vibration stimulus at the distal interphalangeal joint of the great toe and medial malleolus bilaterally. At the same time, the examiner began counting the seconds. The individual was instructed to tell the examiner when they felt the vibration stop. The start time of the vibration sense and time of cessation were recorded by a stopwatch.

In addition, the monofilament test was performed by the 5.07/10 g Semmes-Weinstein monofilament. The monofilament was placed on 10 points of the plantar and dorsal surfaces of the foot, and the patient reported the feeling of perceiving the stimuli with yes or no. If the patient was able to distinguish eight points out of 10 points applied by the monofilament, the test was considered normal. If a person recognized one to seven points, it meant a decrease in tactile sensation of the feet. When the scores from the two parts are finally added together, the highest achievable total score is 8, and in the scoring algorithm, a score of 2.5 is considered abnormal. Higher scores suggest more lesions in the mention symptoms.[23]

Nerve conduction velocity is a valuable method for assessing the severity of diabetic peripheral neuropathy. Considering the relationship between increasing the thickness of the basement membrane in the endothelial layer vessels and decreasing the thickness of myelin fibers,[24] TNCV was assessed at all stages of the study. The present study evaluated intratester reliability for the assessor using electroneuromyography in 10 patients with type 2 diabetes. Measurement of TNCV was performed by one assessor twice a day with an interval of 30 min by disconnecting and reconnecting the electrodes on the skin at baseline and after 10 sessions to calculate the correlation coefficient of TNCV. It was assessed

Figure 1. Method of applying infrared radiation on the surfaces of feet.

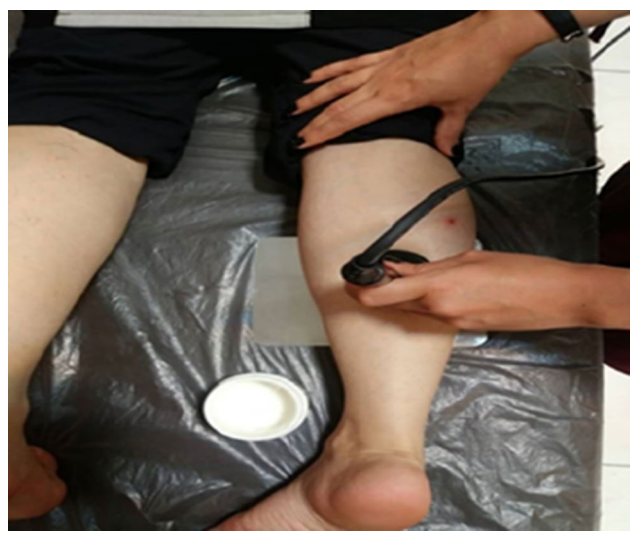

Figure 2. Method of applying Tecar therapy on the tibial nerve.

by Synergy T2 Plinth (Medelec, Surrey, UK). The amplifier was set to record the motor nerve conduction with frequency characteristics of 8 Hz to 10 kHz, a sampling frequency of 20 kHz, a duration of 200 μsec, an excitation frequency of 1 Hz, with the notch filter on, and at supramaximal intensity. Nerve conduction velocities below 40 m/sec were considered DN.[25]

Statistical analysis

Data were analyzed using IBM SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). The data are described by the mean and standard deviation. The Kolmogorov-Smirnov test was utilized to determine the normality distribution of the variables. Levene's test was used to assess the homogeneity of variances among groups. The main effects of the group (treatment), time, and the interaction effect of treatment and time were assessed using two-way mixed analysis of variance. Pairwise comparisons of variables in each group were evaluated using post hoc analysis. Interclass correlation (ICC), standard error of measurement, and minimal detectable change indices were also used for the reliability of NCV. A *p*-value <0.05 was considered statistically significant.

RESULTS

None of the patients withdrew from the study, leaving the data of 24 patients available in the analysis, as illustrated in Figure 3. Before the intervention, there was no discernible difference in demographic characteristics between the groups (Table 1). The analysis of the data distribution was normal in both groups. The homogeneity of variances among groups was confirmed by Levene's test (p>0.05).

The results of interclass correlation

The statistical indices of reliability in TNCV in two groups were presented before and after 10 sessions. The level of agreement was evaluated according to six levels, including poor (0.00), slight (0.00-0.20), fair (0.21-0.40), moderate (0.41-0.60), substantial (0.61-0.80), and almost perfect (0.81-1.00). Since all ICC coefficient values were above 0.80, the reliability of the TNCV data was perfect. In addition, scores less than 1 of the standard error of measurement, which estimates how repeated measures of a person on the same instrument tend to be distributed around the true score, and minimal detectable change, defined as minimal change that falls the measurement error in the score of an instrument used to measure a symptom, are also indicative of this point (Table 2).[26]

The results of the neuropathy symptoms from MNSI

The mean and standard deviation of the variables in the groups are shown in Table 3. The MNSI score had a statistically significant decrease after 10 sessions of treatment compared to the baseline in both groups (p<0.001). The difference between the two groups was significant after 10 sessions, meaning that patients in the study group experienced

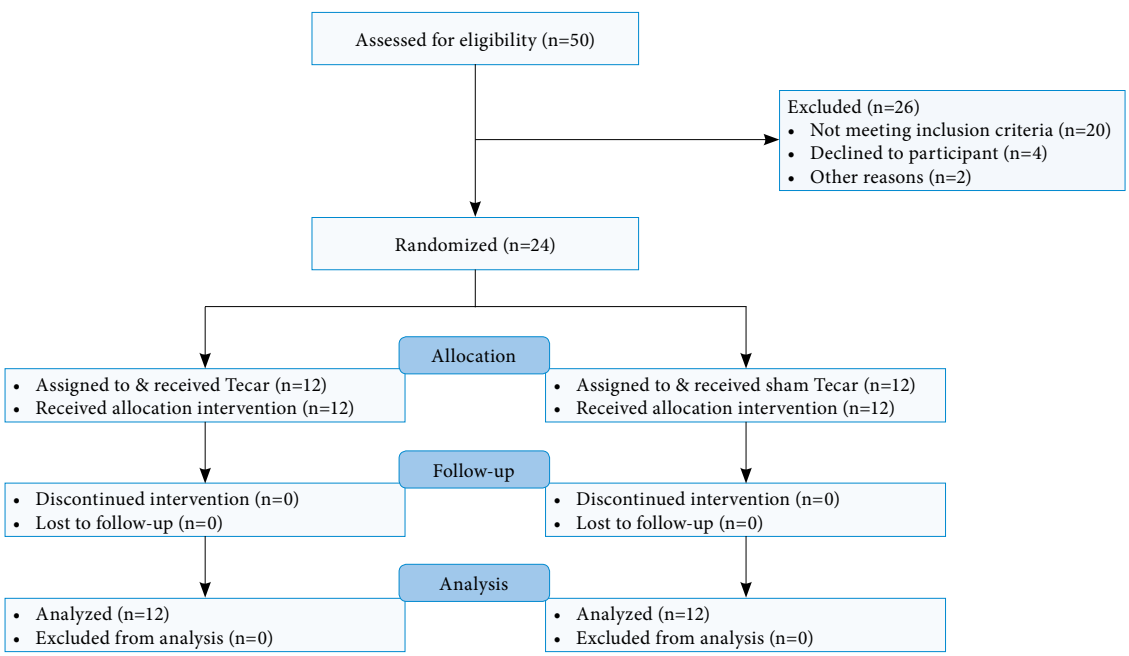

Figure 3. CONSORT flowchart of patient recruitment.

TABLE 1
Demographic characteristics of the participants

Variables	Control group Mean±SD	Study group Mean±SD	*p*
Age (year)	60.5±9.1	59.6±8.6	0.803
Height (cm)	159.00±7.32	159.58±8.15	0.855
Weight (kg)	72.91±12.45	77.04±8.51	0.341
Body mass index (kg/cm^2)	28.81±4.15	30.32±3.44	0.341
Duration of involvement (year)	7.6±4.8	10.7±6.6	0.211
Fasting blood sugar (mg/dL)	159.75±25.24	166.58±20.34	0.473
HbA1c (%)	6.63±0.37	6.68±0.43	0.766

SD: Standard deviation; HbA1c: Hemoglobin A1c.

TABLE 2
Absolute and relative coefficients of TNCV measurement reliability

Time	ICC coefficient	MDC	SEM
Before intervention			
Control group	0.978 (0.915-0.995)	0.579	0.209
Study group	0.950 (0.8130-0.987)	0.846	0.306
After intervention			
Control group	0.983 (0.935-0.996)	0.491	0.177
Study group	0.983 (0.935-0.996)	0.495	0.178

TNCV: Tibial nerve conduction velocity; ICC: Interclass correlation; MDC: Minimal detectable change; SEM: Standard error of measurement.

TABLE 3
Comparison of neuropathy symptoms and NCVs of patients in the two groups

	Pre-test (baseline)	Post-test (10 sessions)	Follow-up (6 weeks)	The main effect of time		The main effect of group		Interaction effect	
	Mean±SD	Mean±SD	Mean±SD	*p*	F	*p*	F	*p*	F
MNSI score									
Control group	11.95±1.13	4.29±1.35	3.45±1.03	<0.001*	788.81	<0.001*	22.67	<0.001*	30.59
Study group	12.91±2.03	7.58±1.52	7.33±1.3						
TNCV (m/s)									
Control group	36.50±1.28	37.26±1.22	37.53±1.10	<0.001*	231.16	0.848	0.037	<0.001*	79.39
Study group	36.74±1.46	37.10±1.43	37.01±1.44						

NCVs: Nerve conduction velocities; SD: Standard deviation; MNSI: Michigan Neuropathy Screening Instrument; TNCV: Tibial nerve conduction velocity; * p<0.001.

a more remarkable improvement in neuropathy symptoms than the controls (p<0.001). A significant ordinal interaction between time and the group was also observed (p<0.001), indicating that despite a slight increase in scores after six weeks compared to the 10th sessions in the control group, there was a considerable reduction in the mean scores compared to the baseline (Figure 4a). However, the decrease in the study group's mean scores continued after six weeks, and a more significant decrease in score disorders was observed compared to the baseline (Table 4).

The results of the tibial nerve conduction velocity

The results showed a significant increase in mean scores TNCV after 10 sessions of treatment compared

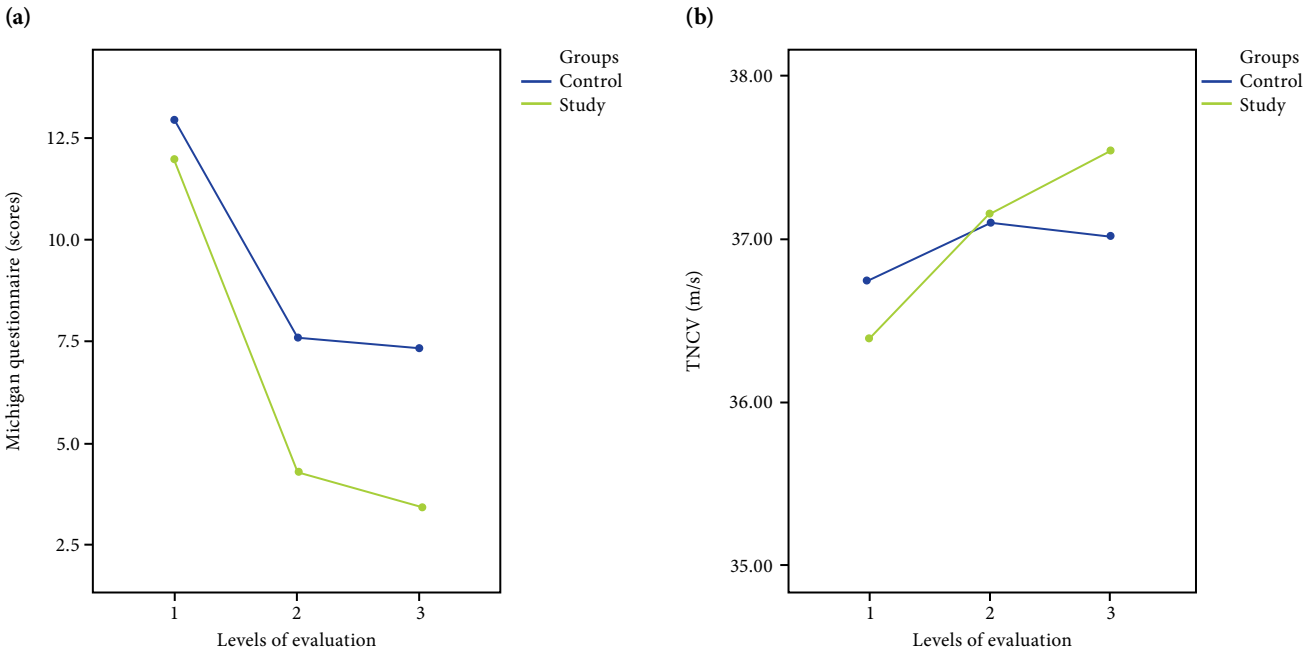

Figure 4. Changes in **(a)** neurological disorders and **(b)** TNCV at baseline (1), after 10 sessions (2), and six weeks of follow-up (3).
TNCV: Tibial nerve conduction velocity.

TABLE 4
Pairwise comparisons of variables in each group

			MNSI score	TNCV
	Pairwise comparisons		*p*	*p*
Control group	Pre-test (baseline)	Post-test (10 sessions)	<0.001*	<0.001*
		Follow-up (6 weeks)	<0.001*	<0.001*
	Post-test (10 sessions)	Post-test (10 sessions)	1.000	0.390
Study group	Pre-test (baseline)	Post-test (10 sessions)	<0.001*	<0.001*
		Follow-up (6 weeks)	<0.001*	<0.001*
	Post-test (10 sessions)	Follow-up (6 weeks)	0.003**	0.000

MNSI: Michigan Neuropathy Screening Instrument; TNCV: Tibial nerve conduction velocity; * p<0.001; ** p<00.05.

to the baseline in both groups (p<0.001, Table 3). Nerve conduction velocities for the tibial division of the sciatic nerve in the healthy adult person is 52.8±4.7 m/sec (46.7-59.6 m/sec).[27] Although the main effect of group was not significant, a significant interaction between time and group was observed. Thus, the results of post hoc analysis showed that TNCV significantly improved after 10 sessions in both groups compared to baseline (Figure 4b, Table 4, p<0.001). These improvements in the study group continued at six weeks (Figure 4b, Table 4, p<0.05). However, there was no change in these outcomes at six weeks in the control group (p>0.05).

DISCUSSION

This study was one of the recent trials performed to test electromagnetic therapy with high frequency in symptoms of peripheral neuropathy in type 2 diabetic patients. A previous review has confirmed the effect of TT on improving pain, disability, and function in people with musculoskeletal disorders.[26] Recently, the short-term efficacy of this modality on foot pain and tactile sensation in patients was expressed.[19] To the best of our knowledge, limited studies have been performed on the effect of TT on the improvement of neuropathy symptoms, particularly

in DN. The findings of the current study suggest that administration of capacitive TT and IR could result in significant reduced MNSI scores at six weeks. Furthermore, patients who received the TT reported a significant increase in TNCV compared to controls at six weeks. The Tecar device establishes the current with two separate active and inactive electrodes in both capacitive and resistive methods.[28] In this study, due to the lower extremity nerve symptoms, capacitive TT was utilized to improve blood flow, increase local heat, and dilate tissue vessels.[29] The basic principles of this protocol, such as parallel placement of electrodes on sides, were based on a previous study.[17] However, this method was applied in the present study due to the effectiveness of capacitive mode on foot pain and tactile sensation.[19]

Decrease in tactile and temperature sensations associated with diabetic peripheral neuropathy can result in notable complications, including burning pain, paresthesia, and anesthesia.[30] The effects of TT on neuropathy symptoms of DN at all stages of the evaluation were notable, with significantly reduced MNSI scores compared to controls. Moreover, follow-up after the intervention showed that the therapeutic effects continued to an acceptable level until six weeks later. Nevertheless, the combination of IR and capacitive mode had more success in reducing this complication. Some findings of the present study, such as improved pain and tactile foot sensation, agree with Bosi et al.,[31] who examined pulsed electromagnetic fields with 1-50 Hz for 10 sessions on the lower extremity of type 1 and 2 diabetics. In the study, the intervention significantly reduced the pain and tactile sensation disorders in the feet by gradual stimulation of the potential of the tissue membrane. However, the findings of the present study are inconsistent with the results of another study,[12] in which researchers examined electromagnetic fields with frequency modulation of 1 to 1000 Hz on the feet since the MNSI scores of diabetic patients did not show a significant change after three periods of 10 sessions with a one-year follow-up.[12] Different severity of DN in the populations of two studies may explain the method's ineffectiveness in that research. Consequently, neuropathy symptoms in those patients were at mild grade. Therefore, the effect of electromagnetic fields on the improvement of this level of symptoms may not be significant. Accordingly, TT could reduce neuropathy symptoms. It can improve the neurovascular system's function and decrease foot pain in a diabetic patient with mild or moderate grade of neuropathy.[19]

An essential finding of the current study was the significant improvements in the TNCV for the study group at 10th session of treatment compared to the baseline, which had perfect reliability with ICC indices higher than 0.9 in all stages. Diabetic neuropathy leads to impaired nerve conduction with progressive axonal degeneration or demyelination of peripheral nerve fibers.[32] After 10 sessions, the effect of treatment on nerve conduction was considerable, with a significant increase in TNCV in both groups. This improvement in the study group, which received TT with 10 to 30% intensity on the tibial nerve pathway in 10 sessions, significantly continued at six weeks. However, the beneficial effect on the NCV was not sustained in the control group since the TNCV scores had returned toward the baseline value at the six-week follow-up.

The combination of IR and capacitive treatment significantly affected the TNCV, while IR and sham TT with short-term action were not effective in controlling NCV. It can be stated that TT helps improving NCV by stimulating the nervous system and modulating the action of neurotransmitter receptor.[18] These findings agree with Battecha´s[33] study, which indicated that electromagnetic fields with a frequency of 50 Hz and intensity of 20 Gauss could increase TNCV by stimulating the nervous and vascular system in the lower limbs in 12 sessions, along with exercise. While in another study, despite using an appropriate period and long-term follow-up, no significant effect of modulated electromagnetic fields with frequencies 1 to 1000 Hz on sensory and motor NCV was found, which may be since only patients with mildly impaired symptoms were treated.[12] Therefore, patients with moderate to severe neuropathy are likely to benefit more than patients with mild symptoms of NCV.

There are some limitations to this analysis that should be noted. Two limitations are the short-term follow-up and the single-blinded design. Additionally, it should be stated that the use of MNSI to evaluate clinical improvement might be a potential limitation, as it was conceived as a screening instrument that gives a global score without grading the severity of the distinct symptoms. The other limitation is the usage of tibial NCV only as the main NCS outcome parameter due to the difficulty of sensory NCV recording. It can be more accurate to use the sensory potential amplitude (sural sensory nerve action potential) as an outcome measure in future studies.

In conclusion, the combination of IR and capacitive TT has reduced the lower extremities' neuropathy symptoms and improved the TNCV, indicating enhancement of the metabolism and cell regeneration. Based on the findings, the use of this method can be suggested as an effective method in improving the symptoms of peripheral neuropathy in type 2 diabetes with other physiotherapy modalities.

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Ethics Committee Approval: The ethics committee approved this plan of Shahid Beheshti University of Medical Sciences with the code IR.SBMU.RETECH.REC.1397.713. Also, this trial was registered in the Iranian clinical trial registration database with the code IRCT20190726044337N1. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, design, data collection and/or processing,, writing the article: M.N.; Design, control/supervision: M.M.R.; Data collection and/or processing, writing the article: A.D.; Idea/concept, design,control/supervision, writing the article: S.S.N.; Literature review, writing the article: M.J.A.

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