

Effect of Transcutaneous Electrical Nerve Stimulation Versus Interferential on Lower Limb Pain in Patients with Diabetic Peripheral Neuropathy

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Abstract: This study was conducted to investigate the effect of Transcutaneous electric nerve stimulation (TENS) versus interferential in patients with diabetic peripheral neuropathy. Sixty patients from both sexes (30 women and 30 men), suffering from diabetic peripheral neuropathy for at least five years were selected from the Diabetes Out-Patient Clinics of El-Agousa and Kaser Al-Aini Hospitals, Cairo University to participate in this study. Their age was ranged from 45 to 60 years with their BMI less than 30 kg/m². All patients were evaluated for pain intensity by Visual Analogue scale and for nerve conduction velocity by EMG pre -treatment and after eight weeks. The patients were divided into three groups equal in number, group A received transcutaneous electrical nerve stimulation on both lower limbs for 30 minutes duration each session, three times per week for eight weeks and pharmacological therapy, group B received interferential training program for the same duration each session and pharmacological therapy, three times per week for eight weeks and group C (Control group) received only the pharmacological therapy of the diabetic peripheral neuropathy for eight weeks. Results showed that the pain intensity significantly decreased by 24% for TENS group as well as for interferential group by 41.66% while non-significantly decreased in the control group. Sensory nerve conduction velocity showed non-significant change among the three groups after treatment. Conclusion: Interferential showed better results than Transcutaneous electrical nerve stimulation training in relieving pain in patients with diabetic neuropathy without any significant effect on sensory nerve conduction velocity.

Key words: Diabetic peripheral neuropathy • TENS • Interferential

INTRODUCTION

Diabetes is commonly complicated by diabetic peripheral neuropathy (DPN) that influences 30 to 50% of individuals with diabetes. Hyperglycemia is the primary risk factor for DPN. Risk factors also include age, duration of disease, cigarette smoking, hypertension, elevated triglycerides, higher body mass index, alcohol consumption and taller height [1].

Diabetic neuropathy influences sensory, autonomic and motor neurons of the peripheral nervous system, which is to say that about each kind about nerve fiber in the form is powerless. Moreover, every organ system in the body that relies on innervation for function is consequently subject to pathology. Therefore, diabetic neuropathy describes a number of exceptional syndromes that are fundamentally classified by the nerve fibers affected. Diabetic neuropathy is generally symmetrical

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and mainly affects sensory system. Side effects incorporate burning tingling sensation, numbness and pain most commonly in the lower extremities especially in the feet [2].

The first step in management of patients with DPN should aim for stable and optimal glycemic control. Neuropathic indications enhance not only for control, as well as avoidance blood glucose fluctuations. Patients with painful DPN might profit from pharmacological symptomatic medicine [3].

Transcutaneous electric nerve stimulation (TENS) is the application of a mild electrical current to the cutaneous nerve fibers using surface electrodes. TENS has been utilized in the treatment of neurologic and other disorders. The justification to the utilization for TENS is dependent upon gate theory of pain. TENS will be utilized extensively for pain relief in various disorders [4].

The mechanism of TENS for decreasing pain is explained by both neural modulation and increase in endogenous opioid-like substances (e.g., dynorphins, endorphins, enkephalins) within the central nervous system [5]. It has been proved that there is a significant decrease in pain threshold after application of transcutaneous electric nerve stimulation (TENS) [6]. Physiotherapists often decide to utilize interferential therapy to treat sub-acute and chronic pain. Interferential current is derived from the interference of two medium frequency currents. When only one pair of electrodes is utilized, the current is called pre-modulated interferential and two individual currents interfere with each other in the unit [7].

The purpose of this study was to investigate the efficacy of TENS versus interferential in patients with diabetic peripheral neuropathy.

MATERIALS AND METHODS

Subjects: Sixty patients from both sexes, suffering from peripheral neuropathy of diabetic origin for at least five years, were selected from the Diabetes Out -Patient Clinics of El Agousa and Kaser Al-Aini Hospitals, Cairo University. Their age was ranged from 45 to 60 years. All patients received their regular pharmacological therapy. The patients were divided randomly into three groups equal in number:

Study Group A (TENS group): Received TENS on both lower limbs, three times per week for eight weeks and pharmacological therapy.

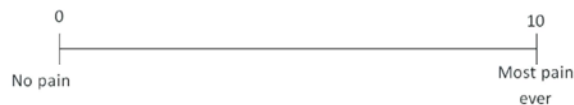


Fig. 1: Visual analogue scale [8].

Study Group B (Interferential Group): Received Interferential on both lower limbs, three times per week for eight weeks and pharmacological therapy.

Control Group C (Pharmacological Group): Received only their regular pharmacological therapy for peripheral neuropathy and oral hypoglycemic drugs or insulin.

Inclusion Criteria: The patients participated in this study had type 2 diabetes and suffering from peripheral neuropathy with sensory manifestations (pain, numbness, tingling and burning sensation in the lower limbs). The patients were ambulant and independent. The muscle strength of the lower limbs was not less than grade four according to manual muscle testing.

Exclusion Criteria: The patients excluded from this study had life threatening diseases such as renal failure, myocardial infarction and heart failure. Patients had sensory manifestations due to any other cause than diabetes (e.g. lumbar disc prolapse). Patients had circulatory problems as intermittent claudication. Patients had skin diseases or foot ulcers. Patients had obesity (BMI > 30 kg/m²).

Instrumentations:

For Evaluation:

Visual Analogue Scale (VAS): This scale was utilized to measure the pain intensity before and after treatment. The pain test was 10 cm (100 mm) length with two endpoints labeled (0=no pain) and (10=most pain ever), Fig (1).

Electromyography (EMG): The electromyography device Dantec key point 9033 (work station –two channels) was utilized to study sural nerve sensory conduction velocity before and after treatment. The device consists of:

- Stimulating unit to which the stimulating electrode was connected.
- Amplifiers to which the recording electrode and the ground electrode were connected.
- Electrodes which consist of stimulating bipolar electrode, ground electrode and two surface recording electrodes (one is active and the other is reference).

For treatment

Transcutaneous Electrical Nerve Stimulation (TENS): TENS was applied bilaterally on both lower limbs by portable TENS unit (TENS 210 – Mettler).

Interferential: Interferential was applied bilaterally on both lower limbs by portable Interferential unit.

Procedures

For evaluation

Visual Analogue Scale (VAS): All patients were evaluated for pain intensity by using Visual Analogue Scale (VAS). The patients were asked to determine the intensity of pain on the length of the pain scale according to its severity (from 0 to 10).

Nerve Conduction Studies: Sural nerve conduction studies were performed by recording the sensory nerve action potential posterior to the lateral malleolus with stimulation 14 cm proximally in the mid-calf. Surface electrodes, 20 mm in diameter were placed over the lateral dorsal surface of the foot, with the distal electrode at the base of the fourth and fifth toes and the proximal active electrode 3 cm from the distal electrode. The stimulation site was posterior to the lateral malleolus, directly over the sural nerve, with the cathode placed 12 cm from the proximal recording electrode plus oral hypoglycemic drugs.

(A) For treatment

For study group (A)

TENS Application: Each patient in group (A) was in a comfortable supine position. TENS was utilized with four adhesive electrodes applied on the skin of lower limbs as follows: One electrode placed at the lower border of medial tibial condyle, the other electrode placed three inches above medial malleolus close to the tibia of the right lower limb (*first channel*). One electrode placed at the lower border of medial tibial condyle, the other electrode placed three inches above medial malleolus close to the tibia of the left lower limb (*second channel*).

The device was switched on and the intensity was adjusted till Strong, rhythmic visible muscle contractions produced under the electrodes (moderate tolerable intensity), with low frequency equals 15Hz and pulse width 250 μ sec. Duration of the session lasted for 30 minutes, three times per week for eight weeks according to Hamaza *et al.* [9] protocol.

For Study Group (B): Interferential the use bipolar technique through the higher frequencies (90-130Hz) to stimulate the pain gate mechanisms & thereby mask the pain symptoms plus oral hypoglycemic drugs.

Setup and Application: Apply the electrodes to the treated area. Electrode positioning should ensure adequate coverage of the stimulated area. Placement of the electrodes should be such that a crossover effect is achieved in the desired area. When the electrodes are properly positioned, the stimulation should be felt only between the electrodes, not under them. If the electrodes are not placed so that a crossover is achieved, the physiological effects of interferential stimulation cannot be attained.

Stimulation can be applied using pad electrodes and sponge covers (which when wet provide a reasonable conductive path), though electro conductive gel is an effective alternative. The sponges should be thoroughly wet to ensure even current distribution. Turn on the apparatus by activating the power switch. Select the beat frequency (10Hz). Use the sweep frequency (150 Hz). Set the duration of the treatment for 30 minutes by adjusting the timer. Start the treatment by pressing the start button. Slowly increase the intensity until the appropriate current level is obtained, guided by the patient's feeling.

For Control Group (C)

Pharmacological Therapy: The patients in group (C) only received their regular pharmacological therapy of the peripheral neuropathy with oral hypoglycemic drugs.

RESULTS

General Characteristics of the Subjects: There was no significant difference between the three groups in their ages, weights, heights, BMI and durations of DPN where their F and P-values were (0.04, 0.95), (0.51, 0.65), (0.28, 0.85), (0.71, 0.52) and (0.01, 0.93) respectively.

Pain Intensity: To determine the difference in the mean value of the pain intensity between the three groups, Kruskal-Wallis test was performed. It revealed that there was non-significant difference among the three groups for the pre-treatment values as P-value > 0.05. While there was a significant difference among the three groups for the post treatment values where P-value < 0.05 as shown in Table (2) and Fig. (3).

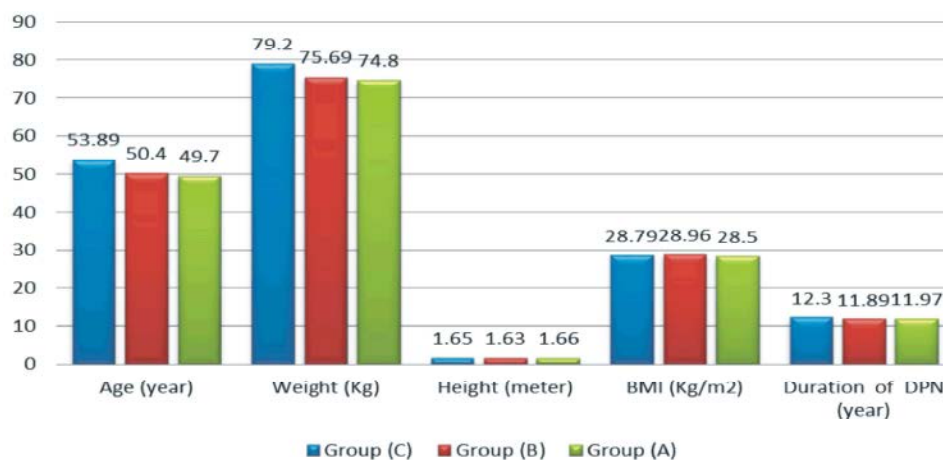


Fig. 2: Mean of groups (A, B & C)

Table 1: Mean and SD of the age, weight, height & BMI and duration of DPN of groups (A, B & C)

Items	Group (A)		Group (B)		Group ©		Comparison		
	Mean	SD	Mean	SD	Mean	SD	F-value	P-value	S
Age (year)	49.7	3.98	50.4	4.78	53.89	4.48	0.04	0.95	NS
Weight (Kg)	74.8	8.65	75.69	7.06	79.2	7.94	0.51	0.65	NS
Height (meter)	1.66	0.05	1.63	0.07	1.65	0.07	0.28	0.85	NS
BMI (Kg/m ²)	28.5	1.02	28.96	0.94	28.79	0.91	0.71	0.52	NS
Duration of DPN (year)	11.97	3.22	11.89	3.81	12.3	3.12	0.01	0.93	NS

*SD: standard deviation, P: probability, S: significance, NS: non-significant,*Significance (P < 0.05)

Table 2: Results of Kruskal-Wallis test among the three groups (A, B & C) for Pain intensity pre and post treatment.

Pain Intensity	Kruskal-Wallis value	P value	S
Pre treatment	2.71	0.52	NS
Post treatment	27.85	0.0001	S

P: probability, S: significance, NS: non-significant, S: Significant,*Significance (P < 0.05)

Table 3: Post hoc test for pain intensity among the three groups (A, B & C).

Pain intensity		Mann-Whitney		S
		U-statistic	P-value	
Post treatment	Group A vs. group B	25.6	0.015	S
	Group A vs. group C	98.0	0.0001	S
	Group B vs. group C	87.0	0.009	S

P: probability, S: Significant,*Significance (P < 0.05)

Median of Pain (VAS)	Pre treatment	Post treatment
Group A	6	4.5
Group B	6	3.5
Group C	7.5	7.5

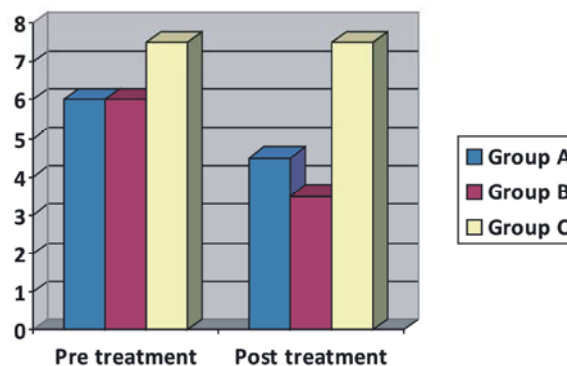


Fig. 3: Median of pain intensity pre and post treatment for groups (A, B & C).

Post-Hoc Test for Pain Intensity: To determine the difference between the three groups in the mean value of the Pain intensity at post treatment values post-hoc test was performed (Mann-Whitney test). There was a significant difference between groups A and B as P-value < 0.05. There was a significant difference between groups A and C as P-value < 0.05. Finally, there was a significant difference between groups B and C as P-value < 0.05 as shown in Table (3) and Fig. (3).

Table 4: Analysis of variance comparisons among the three groups (A, B & C) for sural nerve amplitude pre and post treatment

Sensory Amplitude (iV)	Sum of Squares	DF	Mean Square	F-ratio	P value	Significance level
Pre Treatment	Between groups (influence factor)	1.6000	2	0.8000	0.0534	0.948 NS
	Within groups (other fluctuations)	854.4000	57	14.9895		
	Total	856.0000	59			
Post Treatment	Between groups (influence factor)	0.1658	2	0.08288	217.009	0.001 S
	Within groups (other fluctuations)	0.02177	57	0.0003819		
	Total	0.1875	59			

SS: Sum of Square, MS: Mean Square, P: probability, NS: non- significance,*Significance (P < 0.05)

Sensory Amplitude (iV)	n	Pre treatment		Post treatment	
		Mean	SD	Mean	SD
A	20	49.8000	3.8058	64.0000	0.6489
B	20	50.0000	2.9019	64.4000	0.8208
C	20	50.2000	4.6971	49.8000	3.8058

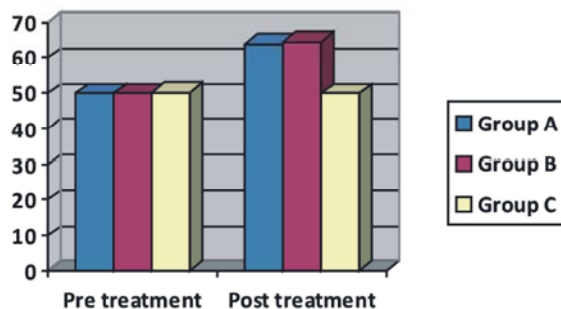


Fig. 4: Mean of sural nerve amplitude pre and post Treatment among the three groups (A, B & C)

Sural Nerve Conduction Studies: To determine the difference in the mean value of the sural nerve amplitude, analysis of variance (ANOVA) was performed. The results revealed that there was no significant difference among the three groups for the pre-treatment value as F value was (0.0534) and P value was (0.948), there was significant difference for the post treatment value as F value was (217.009) and P value was (0.001) as shown in Table (4) and Fig. (4).

DISCUSSION

This study was conducted to investigate the effect of TENS application versus interferential on pain intensity and nerve conduction velocity in patients with diabetic peripheral neuropathy.

The greater part of patients was assessed for pain intensity by using Visual Analogue scale (VAS) and for sensory nerve conduction velocity of sural nerve. Evaluation was done before starting the treatment (pre-treatment) and after eight weeks of treatment (post treatment).

In the present study, we were able to demonstrate that interferential electrical stimulation in group (B) is effective in decreasing pain in case of peripheral neuropathy.

This study agrees with Cameron *et al.* [10], their results showed that there was statistical significant relieving of foot pain after using interferential current. The improvement of electrophysiological examination (sural sensory conduction velocity, distal latency, amplitude) could be explained as follows: the increase in conduction velocity mediated by an increase in endoneural blood flow after electrical stimulation of peripheral nerves and increased nerve conduction velocity after an improvement in blood flow in the lower limbs, achieved through either revascularization or alternatively, due to action on neuron sodium channels. Other evidence suggests that sodium channel expression in primary sensory neurons is altered in diabetic neuropathy [11], indicating a possible molecular basis for neuropathic pain.

Johnson and Tabasam [12] in their study, they expressed that interferential current is essentially a deeper form of TENS. In essence, IFC modulates a high

frequency (4000 Hz) carrier waveform with the same signal produced by a TENS unit. The high frequency carrier waveform penetrates the skin more deeply than a regular TENS unit, with less user discomfort for a given level of stimulation. Deep in the tissues, the carrier waveform is cancelled out, resulting in a TENS-like signal deep under the skin.

For the analgesic impact of interferential current in the treatment of muscle soreness, the results of this study are in accordance with the findings of Schmitz *et al.* [13]. The authors found a significant decrease in perceived pain scores across treatment groups after interferential current therapy.

This study coexists with Fuentes *et al.* [14] that provided information on the effects of the current on the pain mechanisms and the optimum carrier frequency for use in the analgesia of chronic pain.

The results of the present study demonstrated that the pain intensity in study group A (TENS group) significantly decreased after treatment.

This was proved by Jin *et al.* [15]; they stated that transcutaneous electrical nerve stimulation (TENS) is therapeutic modalities that have had positive effects on Painful diabetic peripheral neuropathy. Transcutaneous electrical nerve stimulation (TENS) is a non-pharmacological, noninvasive treatment that has been utilized to treat a variety of painful conditions. The TENS technique reduces pain through peripheral and central mechanisms. This modality involves nerve stimulation by applying electrical current to the distribution of nerve fibers via skin surface electrodes. It triggers endogenous opioid release, modifies electrical transmission and dilates blood vessels, all of which lead to a reduction in neuropathic pain.

These outcomes go with Cheing and Luk [16] who compared TENS versus placebo. The results showed an improvement in pain compared to placebo. The improvement in sensitivity compared with the placebo group was measured on the seventh day of treatment and on 14th day of treatment with TENS as follow up procedures.

Likewise these effects were reliable for Forst *et al.* [17] who evaluated the treatment of TENS in comparison with placebo treatment. Electrical stimulation was performed with skin electrodes placed over the common peroneal nerve using the low-frequency mode (4 Hz) and the intensity was set individually at between five and 70 mA. Patients were advised to stimulate both legs for at least half an hour per day. After six weeks of treatment, significant improvement in the intensity of pain was seen

on visual analogue scale (VAS), which proved that TENS is effective tool for management of diabetic peripheral neuropathy.

Those outcomes of TENS in the present study were supported by the results of the study of Hamaza *et al.* [9] who utilized percutaneous electrical nerve stimulation (TENS) in the management of patients with painful diabetic neuropathy for three weeks for 30 minutes three times per week. The authors concluded that TENS is a useful non pharmacological therapeutic modality for treating diabetic neuropathic pain.

Also, the results of TENS in the present study are consistent with Alvaro *et al.* [18] as they published a case report to describe the alteration of pain in a patient with sever painful diabetic neuropathy following the application of TENS (80 Hz), delivered one to two hours a day and on the entire night through electrodes placed on the lumbar area of the back. The researchers found that after 20 minutes of TENS on the first day of treatment, the patient reported a 38% reduction in intensity of pain and after 17 days, the patients reported no pain and comfort sleep through the night

The results of this study indicated that TENS had statistical significant effect on nerve conduction velocity and are consistent with the findings of Alves-Guerreiro *et al.* [19] who examined the effect of three electrotherapeutic modalities (TENS, interferential and action potential stimulation) upon nerve conduction in the human median nerve. The results showed that only interferential therapy caused a significant increase in peak to peak amplitude (PPA) while TENS and action potential stimulation showed no significant change in peripheral nerve conduction velocity.

CONCLUSIONS

Interferential was better than transcutaneous electric nerve stimulation (TENS) in relieving pain in patients with diabetic neuropathy. On the other hand neither TENS nor Interferential showed any significant effect on sensory nerve conduction velocity in patients with diabetic neuropathy.

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