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Comparing the effect of different acupoints stimulating methods on nerve conduction velocity in diabetic neuropathy: A randomised controlled study

Porównanie wpływu różnych metod stymulacji akupunktów na prędkość przewodnictwa nerwowego w neuropatii cukrzycowej: randomizowane badanie kontrolowane

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Abstract

Purpose. To investigate the effect of needle versus laser acupuncture on nerve conduction velocity on diabetic neuropathies in type two diabetes. Methods. Fifty-five patients of both genders with age ranged from 40-60 years were diagnosed with lower extremities diabetic polyneuropathy. Patients were divided randomly into two equal groups; Group (A) (control group) treated by needle acupuncture and group (B) treated by laser acupuncture at same acupoints. All patients in both groups received two sessions per week for 6 weeks. The measurement variables were the tibial motor nerve conduction velocity (NCV) and sural sensory NCV, they were measured bilaterally, pre- and post-treatment for all patients. Results. At the acupuncture group only there was significant increase in NCV of tibial and sural nerves in both sides at post treatment in compare to pre treatment. Conclusion. acupuncture has a significant effect on improving the motor and sensory nerves function in patients with diabetic polyneuropathy. So it may be considered an appropriate safe and nonpharmacological complementary treatment option for type 2 diabetic polyneuropathy.

Key words:

acupuncture, nerve conduction velocity, diabetes mellitus, diabetic polyneuropathy

Streszczenie

Cel. Badanie wpływu akupunktury igłowej w porównaniu z akupunkturą laserową na prędkość przewodnictwa nerwowego w neuropatiach cukrzycowych w cukrzycy typu 2. Metody. U pięćdziesięciu pięciu pacjentów obu płci w wieku od 40 do 60 lat rozpoznano polineuropatię cukrzycową kończyn dolnych. Pacjenci zostali losowo podzieleni na dwie równe grupy; Grupa (A) (grupa kontrolna) leczona akupunkturą igłową i grupa (B) leczona akupunkturą laserową w tych samych akupunktach. Wszyscy pacjenci w obu grupach mieli po dwie sesje tygodniowo przez 6 tygodni. Zmiennymi pomiarowymi były prędkość przewodzenia nerwu piszczelowego ruchowego (NCV) i czuciowego łydkowego NCV, które były mierzone obustronnie, przed i po leczeniu u wszystkich pacjentów. Wyniki. Tylko w grupie otrzymującej akupunkturę zaobserwowano znaczny wzrost prędkości przewodzenia NCV nerwów piszczelowych i łydkowych po obu stronach po leczeniu w porównaniu ze stanem przed leczeniem. Wniosek. Akupunktura ma istotny wpływ na poprawę funkcji nerwów ruchowych i czuciowych u pacjentów z polineuropatią cukrzycową. Może więc być uważana za odpowiednią, bezpieczną i niefarmakologiczną opcję leczenia uzupełniającego polineuropatii cukrzycowej typu 2.

Słowa kluczowe

akupunktura, prędkość przewodnictwa nerwowego, cukrzyca, polineuropatia cukrzycowa



Introduction

Neuropathy is the commonest complication of diabetes mellitus that may cause neurological disorder, sensory deficit, osteomyelitis, limb ulcers and amputation [1]. The nerve damage that occurs due to neuropathy causes a complex and chronic pain called neuropathic pain, which is different than pain from damaged tissue by fall, cut or arthritis [2]. Neuropathic pain is moderate to severe pain that causes sleeping disturbance because it becomes worse at night [3]. This pain may remain for years and hinders normal daily activity [4].

Early and precise diagnosis of diabetic polyneuropathy is necessary to prevent its progression. The nerve conduction study is used to confirm the presence of diabetic polyneuropathy [5]. Sural nerve is pathognomonically affected in diabetic neuropathy and is used to monitor presence and severity of peripheral neuropathy. So the neurophysiological parameters that help in diagnosis of diabetic polyneuropathy should include measurements of the sural nerve [6].

The treatment of diabetic neuropathy is a challenge. It requires early recognition, glycemic control, and psychological therapy in addition to symptomatic treatment [7]. Oral medical treatment is most commonly used. However, it is associated with the risk of adverse effects due to drug interaction that may alter drug metabolism [8]. Complementary and alternative medicine interventions as acupoints stimulation are being used to treat symptoms of diabetic neuropathy. Acupuncture is proved to be effective and relatively safe in pain management in many conditions and it could also prevent the side effects of pharmaceuticals [9]. Acupuncture depends on the belief that stimulating certain acupoints can correct any imbalances in the flow of Qi through the body meridians (channels of energy) and thereby re-establish the body balance. The China medicine has different types of acupuncture including manual acupuncture, auricular acupuncture, acupoint injection, electroacupuncture and scalp acupuncture [10]. More recently, different method of stimulating the acupoints have been introduced including laser acupuncture by using low-level laser therapy LLLT at acupoints. The mechanism of action of LLLT is related to the ability of the treated cell to absorb the photon and converting the energy into ATP by forming singlet oxygen and reactive oxygen species [11]. So the aim of this article was to investigate the effect of needle versus laser acupuncture on NCV on diabetic neuropathies in type two diabetes mellitus.

Materials and Methods

Study Design

A randomized control trail was conducted to investigate the effect of needle acupuncture versus laser acupuncture on NCV in patients with diabetic polyneuropathy. This study was carried out between June 2019 and January 2021, (stopped between March and July 2020 for COVID-19). Data were collected from all patients at pre and post treatment. Research Ethics Committee with No: [P.T.REC/012/002235] was obtained before starting the study.

Participants

Sixty patients (males and females) with age ranged from 40 to 60 years old were diagnosed as type two diabetic polyneuro-

pathy and were recruited from outpatient clinic of faculty of Physical Therapy, Cairo University, Cairo, Egypt. Exclusion criteria included poly neuropathy caused by conditions other than diabetes, using of acupuncture during the last 3 months, history of epilepsy, bacterial infection or other skin diseases, opiate, analgesic, or drug abuse, pregnant or breast-feeding women, patients with haemophilia and patients with artificial heart pacemaker [12].

Randomization

Fifty-five patients signed consent form then patients were randomly assigned into two equal groups. A single blind randomization was carried out by assigning the odd numbers to group (A) (needle acupuncture group) and the even numbers were assigned to group (B) (laser acupuncture group). Following randomization, there was no dropping out of subjects from the study, Figure 1.

Interventions

Group (A): 27 participants received needle acupuncture two sessions per week for 6 weeks, whereas group (B): 28 participants received laser acupuncture two sessions per week for 6 weeks. The treatment was combination between two treatments protocols (1&2). All patients received each protocol one session per week.

Needle acupuncture

Acupuncture was performed by using pure stainless-steel sterilised metal acupuncture needle for single use (size 0.3×5 cm, made in China). Total points were 20 acupuncture points at the bilateral and the needles were left in place for 20 minute. Protocol (1) was applied on the following acupuncture points bilaterally (4Bafeng, 5Qiduan and Lianqiu). While protocol (2) was applied on the following acupuncture points bilaterally (LI 4, LI 11, ST36, ST41, SP6, SP9, GB34, KI 1, KI 27, LR 3) [13]. Acupuncture needles may produce needle sensation that the Chinese called de qi. This sensation was traditionally described as having four components (numbness, distension/extension/fullness, heaviness and sour ache "like a feeling of muscular fatigue") [14]. These de qi sensations can usually be identified separately from the sensations of simply being pricked with a needle - sharpness or pain. Patients may feel either, or both, but it is the de qi sensation that marks the successful stimulation of the nerve.

LASER acupuncture

Laser acupuncture was performed with LLLT Device (ASA), Device type: PAGANI, model 2014, LP1–LASER SCANNER. Laser beam was applied perpendicular for the acupoints at distance of 50 cm with local disinfection of the skin. Laser beam concentrate over each point for one minute. Wavelengths between 660 nm and 905 nm have been used and they have the ability to penetrate skin, and soft/hard tissues. Laser acupuncture was applied on the same pointes as needle acupuncture with same protocols on group B.

Outcome measures

Nerve Conduction Velocity

It is a measurement of the speed of conduction of an electrical impulse through a nerve, which can determine nerve damage





Figure 1. Flow chart of the study

and destruction. It was used to measure how fast and how strong the electrical activity in a nerve. It was done by neurophysiologist professor before and after 6 weeks of treatment for both limbs in both groups. Nihon Kohden Corporation, Model:SN 01308 (Made in Japan) was used for measurement of motor NCVof tibial nerve and sensory NCV of sural nerve. The nerve conduction study is well-known as valid and reliable measurement for estimation of NCV.

The neurophysiologist puts electrode patches on the skin over the investigated nerve then the stimulating electrodes send a mild electrical impulse. The other electrodes record the nerve-'s response. If the signal travels at a slower rate than it should in a healthy nerve, it means the nerve is probably damaged. For measuring the tibial motor NCV, the active recording electrode is placed over the abductor hallucis muscle, 1 cm below and behind the navicular tubercle, 8 cm from the stimulating electrodes. The inactive electrode is placed on the muscle tendon at the level of the first digit. The ground is placed over the dorsum of the ankle. The nerve is stimulated distally behind and above the medial malleolus and proximally at the level of the knee in the lower border of the popliteal space near the popliteal artery.

For measuring the sural NCV, the active recording electrode is placed immediately behind the lateral malleolus with the inactive electrode 3-4 cm away on the lateral surface of the foot. The ground is placed on the posterior lateral surface of the ankle. The nerve is stimulated on the posterior surface of the lower leg 1-3 cm lateral to the mid-line at 7, 14, and 21 cm from the recording electrodes [15].

Statistical analysis

Results were expressed as median (interquartile range (IQR)). Test of normality, Shapiro Wilk test, was used to measure the data distribution before analysis. Accordingly, comparison between not normally distributed data, comparison between variables in both groups was conducted using Mann Whitney test. While comparison between pre and post treatment data in the same group was conducted using Wilcoxon Sign Ranks test. Statistical Package for Social Sciences (SPSS) computer program (version 25 windows) was used for data analysis. P value ≤ 0.05 was considered significant.

Results

The groups were similar pre training (p > 0.05) regarding age, BMI, fasting blood sugar, post prandial blood glucose, HbA-1C, duration of diabetes and sex distribution (Table 1).

Table 1. Baseline characteristics of participants in both groups

Items	Group A	Group B	Comp	Comparison				
	Mean ± SD	Mean ± SD	t-value	P-value				
Age (years)	54.96 ± 4.98	52.6 ± 4.62	1.8642	0.068				
BMI (kg/m2)	28.25 ± 1.43	$28.25 \pm 1.43 \qquad \qquad 28.48 \pm 2.29$		0.648				
Fasting blood sugar	164.4 ± 43.59	172.07 ± 69.24	-0.508	0.613				
Post Prandial blood glucose	228.43 ± 50.23	243.25 ± 80.27	-0.849	0.4				
HbA1c	8.46 ± 1.93	8.77 ± 2.40	-0.533	0.599				
Duration of Diabetes	8.26 ± 4.1	8.17 ± 3.59	0.087	0.931				
Sex distribution N (%)								
	Group A	Group B	X ²	P-value				
Males	10 (37%)	10 (35.7%)	0.276	0.500				
Females	17 (63%)	18 (64.3%)	0.270	0.399				

 χ^2 : *Chi-square test.* **SD*: *standard deviation, P*: *probability*

Within group analysis in group A revealed that there was significant increase in NCV of tibial and sural in both sides at post treatment in compare to pre treatment. While regarding group B, there was non-significant difference in NCV of tibial and sural in both sides at post treatment in compare to pre treatment. Comparing the results between both tested groups, it was revealed that there was non-significant difference of the post-treatment in NCV of tibial and sural in both sides. In spite of this between groups non-significant difference, there was clinical difference and higher score in favor to group A (Table 2).

Table 2. Descriptive statistics and non-parametric tests for NCV tibial and sural in both sides at different measuringperiods at both groups

		Group (A) (n = 27)	Group (B) (n = 28)	P value*
	Pre treatment	41.9 (6.975)	41.17 (6.2)	0.714 ^{NS}
NCV right tibial	Post treatment	43.1 (1.9025)	44.35 (12.25)	0.858 ^{NS}
	P value**	0.001 ^s	0.069^{NS}	
	Pre treatment	41.3 (7.9)	44 (6.8)	0.051 ^{NS}
NCV left tibial	Post treatment	45.65 (8.825)	44.3 (7.55)	0.484^{NS}
	P value**	0.001 ^s	0.15 ^{NS}	
	Pre treatment	23.3 (25.125)	24.8 (24.825)	0.932 ^{NS}
NCV left sural	Post treatment	33.65 (28.9)	24.5 (12.875)	0.096 ^{NS}
	P value**	0.001 ^s	0.178^{NS}	
	Pre treatment	23.6 (17.3)	22.9 (25.7)	0.756 ^{NS}
NCV right sural	Post treatment	29.65 (18.025)	23.975 (21.125)	0.15^{NS}
	P value**	0.001 ^s	0.142 ^{NS}	

* Inter-group comparison; ** intra-group comparison of the results pre and post treatment

NSP > 0.05 = non-significant, SP < 0.05 = significant, P = Probability



Discussion

Polyneuropathy is a common problem for people with type 2 diabetes mellitus, leading to pain, weakness and impaired sensation. Most of pharmacological managements are regularly related with systemic aftereffect and do not slow down or impede progression of the neuropathy [16]. Additionally, these drugs are ineffective in management of decreased sensation. Therefore, attention was turned to look for non-pharmacological treatments. Multiple complementary and alternative medicine therapies such as acupuncture and yoga have shown efficacy in the treatment of painful peripheral neuropathy [17]. Acupuncture needles have been documented to modulate the activity of peripheral and central neural pathways, so it may effectively improve some diabetic polyneurapathy symptoms, such as aching pain, burning pain, prickling sensation, numbness, and allodynia [18].

Acupoints therapy can improve local nerve ischemia and hypoxia, increase the flow of blood, and promote the growth of micro-vessels [19]. There are different modalities for application of acupoints therapy including manual acupuncture, auricular acupuncture, acupoint injection, electroacupuncture and laser acupuncture [10]. So this article was designed to investigate the effect of needle versus laser acupuncture on NCV on diabetic neuropathies in type two diabetes mellitus.

The results of the current study revealed that in group A, there was significant increase in NCV of tibial and sural nerves in both sides at post treatment in compare to pre treatment. While regarding group B, there was non-significant difference in NCV at post treatment in compare to pre-treatment in all measurements. Meyer-Hamme et al. [20] study was in agreement with the results of the current study. In this randomized trial, 172 adults with type 2 diabetes-induced polyneuropathy were divided into three groups to be treated by 10 sessions (one session every week) of needle acupuncture or laser acupuncture or placebo laser acupuncture. Treatment was applied at bilateral acupoints (Ex-Bafeng, Qiduan and Lianqiu). Nerve conduction studies of sural and tibial nerves were measured in all patients. The neurophysiological outcome was sural sensory nerve action potential in addition to sural and tibial NCV. All these variables were improved significantly after 10 sessions in a needle acupuncture group when compared with placebo, while the laser acupuncture group did not have significant different when compared with placebo. Moreover, needle acupuncture group showed earlier onset of improvement than laser acupuncture one. The conclusion was that the needle acupuncture had significant effects on diabetic polyneuropathy [20].

Additionally, our finding is supported by high-quality research conducted by Wang et al. [21]. A total of 210 patients with diabetic polyneuropathy were randomly assigned into two groups, study group (received needle acupuncture) or control group (received sham acupuncture). All treatments were administered 3 times per week for 6 weeks. The Neuropathy Disability Score, NCV and the total symptom score were the outcome measurement. All outcome measures were assessed at the baseline, 3 weeks, 6 weeks and 14 weeks. The conclusion was that the needle acupuncture was effective for the treatment of diabetic polyneuropathy. Additionally, stimulating acupoints can free channels and networks vessels, improve distal lower extremity blood circulation and increase metabolism and nerve excitability [21].

The non-significant effect of laser acupuncture was in agreement with the results of the study conducted by Zinman et al. [22]. In that study 50 patients with painful diabetic polyneuropathy received sham therapy over a 2-week baseline period. Then patients were randomized to receive either sham or LLLT for 4 weeks. The efficacy parameters were the difference in the weekly mean pain scores, Toronto Clinical Neuropathy Score, nerve conduction studies, sympathetic skin response, or quantitative sensory testing. There was a decrease in weekly mean pain scores during sham treatment in both groups. After the treatment period, the LLLT group had more reduction in weekly mean pain scores. But LLLT group had no effect on the nerve conduction studies, Toronto Clinical Neuropathy Score, sympathetic skin response, or quantitative sensory testing. So it concluded that the study results do not provide sufficient confirmation to recommend LLLT for treatment of diabetic neuropathy [22].

However, the results of laser acupuncture are not in agreement with the results of the systematic review conducted by Anju et al (2019). Six studies were included in this systematic review. The outcome measures were pain score, nerve conduction velocity and quality of life questionnaire. The evidence obtained shows a moderate efficacy of LLLT on controlling the diabetic peripheral neuropathy. The wavelength used in most studies range in between 800 and 900 nm for treatment period ranged from 10 days to 4 weeks. There is a methodological difference between our study and the studies that were included in this systemic review. In the current study a wider range of wave length was used (660 nm and 905 nm) which may be not specific for neurological impairment [23].

The current study found superiority in the effect of needle acupuncture on laser acupuncture; however, it was in disagreement with Litscher and Schikora, [24] which found that the effects of both manual needle acupuncture and laser needle acupuncture were similar. Twenty-seven healthy volunteers were investigated to compare between laser needle acupuncture (685 nm wavelength) and manual needle acupuncture in some cerebral parameters. The results showed that the mean blood flow velocity (vm) was significantly increased in the ophthalmic artery as a result of both techniques. The difference in the results may be due to the difference in the measurement variables. This study focused on the vascular changes while our study focused on the neurological changes [24].

The unexpected non-significant effect of laser acupuncture that was found may be explained by the insufficient period of treatment time (two sessions per week for 6 weeks). As the LLLT effect in this short duration of treatment may be limited to small nerve fibers which are difficult to be assisted accurately. More definitive results might have been obtained with more frequent and/or longer duration of laser treatments [23].

Considering the effect of the tested group there was non-significant difference of the post-treatment between both groups. In spite of this between groups non-significant difference, there



was clinical difference and higher score in favor to group A. This better clinical effect of needle acupuncture may be explained by the mechanical effects of needle acupuncture which cannot be produce by LLLT. This mechanical effect includes collagen fibre reorganization, which may cause mechanical activation of signal transduction pathways [25]. The improvement in nerve conduction study values following acupuncture therapy may indicate structural neuroregeneration. These improvements were accompanied by reduced myelinated nerve fibre damage that indicated structural enhancement [20].

Study limitations

The study was limited by evaluating the measurement variables pre and post treatment only. So the follow up of the effect of treatment was not measured. Additionally, it was limited by measuring the NCV only without measuring any functional or pain scales.

Conclusion

It was concluded that, needle acupuncture has a significant increasing effect on both motor and sensory NCV. So it may be considered an appropriate safe and nonpharmacological complementary treatment option for type 2 diabetic polyneuropathy.

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