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Effect of sympathetic ganglion transcutaneous electric stimulation on actual claudication distance in peripheral arterial disease: A Randomized controlled trial

Wpływ przezskórnej elektrycznej stymulacji zwoju współczulnego na rzeczywisty dystans chromania w chorobie tętnic obwodowych: randomizowane badanie kontrolowane

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Abstract

Aim. This study was conducted to assess the effect of transcutaneous electrical nerve stimulation on Sympathetic ganglion in Leriche-Fontaine stage II peripheral arterial disease. Materials and Methods. Forty patients with unilateral PAD (Leriche-Fontaine stage II) were chosen from the Vascular Outpatient Clinic, El Sahel Educational Hospital. All patients were randomly divided into two groups of the same number. Study group and control group. Study group: received low-frequency 45 min per session, 3 times per week and 12 weeks. Control group: the placebo stimulation was delivered by same TENS device but with a voltage level falling to zero after 10 s of stimulation. Ankle peak systolic velocity (APSV), Arterial diameter (AD) and Actual claudication distance (ACD) were measured. Results. Descriptive statistics, such as standard deviation, mean, maximum and minimum, have been calculated for both groups. The t-test was conducted to compare the mean difference between the two groups after and before intervention and revealed a significant difference between the two groups. Conclusion. It was concluded that application of TENS to sympathetic ganglion enhances in Ankle peak systolic velocity (APSV), Arterial diameter (AD) and Actual claudication distance (ACD) in patients with intermittent claudication.

Key words:

Sympathetic ganglion, transcutaneous electric nerve stimulation, Ankle peak systolic velocity

Streszczenie

Cel. Badanie to przeprowadzono w celu oceny wpływu przezskórnej elektrycznej stymulacji nerwów na zwój współczulny w stadium II choroby tętnic obwodowych Leriche-Fontaine. Materiały i metody. Czterdziestu pacjentów z jednostronną chorobą tętnic obwodowych (stadium II Leriche-Fontaine) zostało wybranych z Poradni Naczyniowej Szpitala Edukacyjnego El Sahel. Wszyscy pacjenci zostali losowo podzieleni na dwie grupy o tej samej liczbie. Grupa badana i grupa kontrolna. Grupa badana: poddawana stymulacji o niskiej częstotliwości 45 minut na sesję, 3 razy w tygodniu przez 12 tygodni. Grupa kontrolna: poddawana stymulacji placebo przez to samo urządzenie TENS, ale z poziomem napięcia spadającym do zera po 10 s stymulacji. Mierzono szczytową prędkość skurczową (APSV), średnicę tętnic (AD) i rzeczywisty dystans chromania (ACD). Wyniki. Dla obu grup obliczono statystyki opisowe, takie jak odchylenie standardowe, średnia, wartość maksymalna i minimalna. Test t został przeprowadzony w celu porównania średniej różnicy między dwiema grupami po i przed zastosowanej terapii i wykazał istotną różnicę między dwiema grupami. Wniosek. Wywnioskowano, że zastosowanie stymulacji zwoju współczulnego zwiększa szczytową prędkość skurczową (APSV), średnicę tętnic (AD) i rzeczywisty dystans chromania (ACD) u pacjentów z chromaniem przestankowym.

Słowa kluczowe

Zwój współczulny, przezskórna elektryczna stymulacja nerwów, szczytowa prędkość skurczowa

Introduction

Peripheral artery disease affecting limbs arteries by forming atherosclerotic plaques within them with partial or total obstruction of one or even more distal arteries, the eventual deficit in oxygenated blood creates disintegration of the vasculature nerves as well as other tissues triggering intermittent claudication ache at rest tingling and numbness of the extremities and the creation of the crucial limb [1]. It is expected to affect 202 million people worldwide, between the ages of 45- to 50-years by 5.3% and that from 85- to 90-years by 18.6%. These percent vary in developing world where people aged from 45 to 50 are affected by 4.6% and those from 85 to 90 by 15% [2].

Ache, poikilothermic, pallor, paralysis and absence of pulse rate are the main characteristics describing acute limb ischemia (ALI) (> 2weeks) due to extreme hypo perfusion of the extremity. Crucial limb ischemia (CLI) is described by persistent (> 2weeks) ischemic ache at rest, non-healing scar/ulcers, as well as gangrene with one or both legs. [3].

Improving segmental flow of blood by stimulating sympathetic nerve outflow has been successfully accomplished though a regional blockage of sympathetic system with an invasive tool. In particular, the stellate ganglion may be selectively obstructed to temporarily inhibit unilaterally sympathetic innervation to the head, neck, and upper extremity 50 percent reduction in sympathetic outflow and amplification in blood flow in subjects suffering from peripheral vascular disease was reached through this method [4].

The application of TENS is commonly practiced in clinical practice as a non-invasive treatment modality. Relieving pain, blood flow and temperature improvement are considered the therapeutic effect of TENS. The effects of TENS on blood flow have led researchers to investigate the relationship between the peripheral vascular system and this method in order to confirm the efficacy of TENS as an adjuvant technique for physical activity in vascular claudication patients to enhance walking ability [5].

To our pleasure few studies used the Ankle peak systolic velocity (APSV) as a determent of progression in peripheral vascular treatment instead of ankle brachial pressure index which is either unable to measure ankle pressure in case of arterial calcification or gives false high results. (APSV) is not affected by those restrictions [6]. Therefore, this study intends to investigate changes in ankle peak systolic velocity, arterial diameter and actual claudication distance after 36 sessions of transcutaneous electrical nerve stimulation on sympathetic ganglion in patients with Leriche-Fontaine peripheral arterial disease.

Materials and methods

Design of the study

The study was designed as a prospective, randomized, pre-post-test, controlled trial.

Participants

Forty patients of both sexes, aged between 50 and 60 years, were chosen from an outpatient vascular clinic in the El Sahel Education Hospital. Patients have been examined and referred to by a vascular specialist. All patients were diagnosed with unilateral stage-II Leriche-Fontaine PAD, without any other pathologies noted except for intermittent claudication.

The participants were divided randomly into two groups of equal numbers. The study group got low frequency TENS (4 Hz frequency, pulse duration 200 μs) which was administered through surface electrodes for 45 min per session, supramaximal stimulation for T12, L1, and L2 sympathetic ganglions that innervate the lower extremity for 45 min per session, three times per week and for 12 weeks. Control group that received placebo stimulation as provided by the same TENS device but with a zero volt after 10 s of stimulation. Written informed consent was obtained from each participant. This study was performed according to the Statement of the Declaration of Helsinki.

Randomization

All patients were assigned randomly into to 2 equal groups using a computer-based randomization program. After randomization, no subject dropped out of the study. Both the patients and the examiner were blinded to which group of patients had been assigned.

Interventions

Transcutaneous electric nerve stimulation

Therapeutic sessions were held at an outpatient physical therapy treatment unit in the El Sahel Education Hospital. Dynatron 438 device (Enraf, Rotterdam, Netherlands) model transcutaneous electrical nerve stimulation, low frequency (4 Hz frequency, 200 μs pulse duration) burst mode was used by surface electrodes for 45 min per session for the study group over the sympathetic ganglions on T12, L1, and L2 innervating the lower extremity with supramaximal stimulation. Whereas control group received placebo stimuli supplied by the same TENS device, but with a zero input voltage. Study group: received low-frequency 45 min per session, 3 times per week and 12 weeks. Control group: the placebo stimulation was delivered by same TENS device but with a voltage level falling to zero after 10 s of stimulation.

Outcome measurements

Ankle Peak Systolic Velocity and Arterial diameter

The Doppler ultrasound (ACUSON X700 Ultrasound System Germany) model was carried out for each patient to calculate peak systolic velocity (PSV) as well as arterial diameter. It has significant clinical implications for early diagnosis, prevention, and therapy as in patients suffering from lower extremity vascular disease where it is considered as a preferred technique for examination [7]. The evaluation is usually initiated with such a convex transducer with a lower frequency to assess the aorto-iliac portion within the pelvic cavity. Following an examination of the femoro-popliteal and tibio-pedal parts using a linear transducer with a higher frequency of 9-15 MHz. Both of these segments evaluation process is usually started in the supine position, with slightly abducting and externally rotating the patient's hip, and flexing knees as well to be able toassess: common femoral artery (CFA), its bifurcation in the superficial and deep femoral artery (SFA; DFA), perennial artery (PA) to-

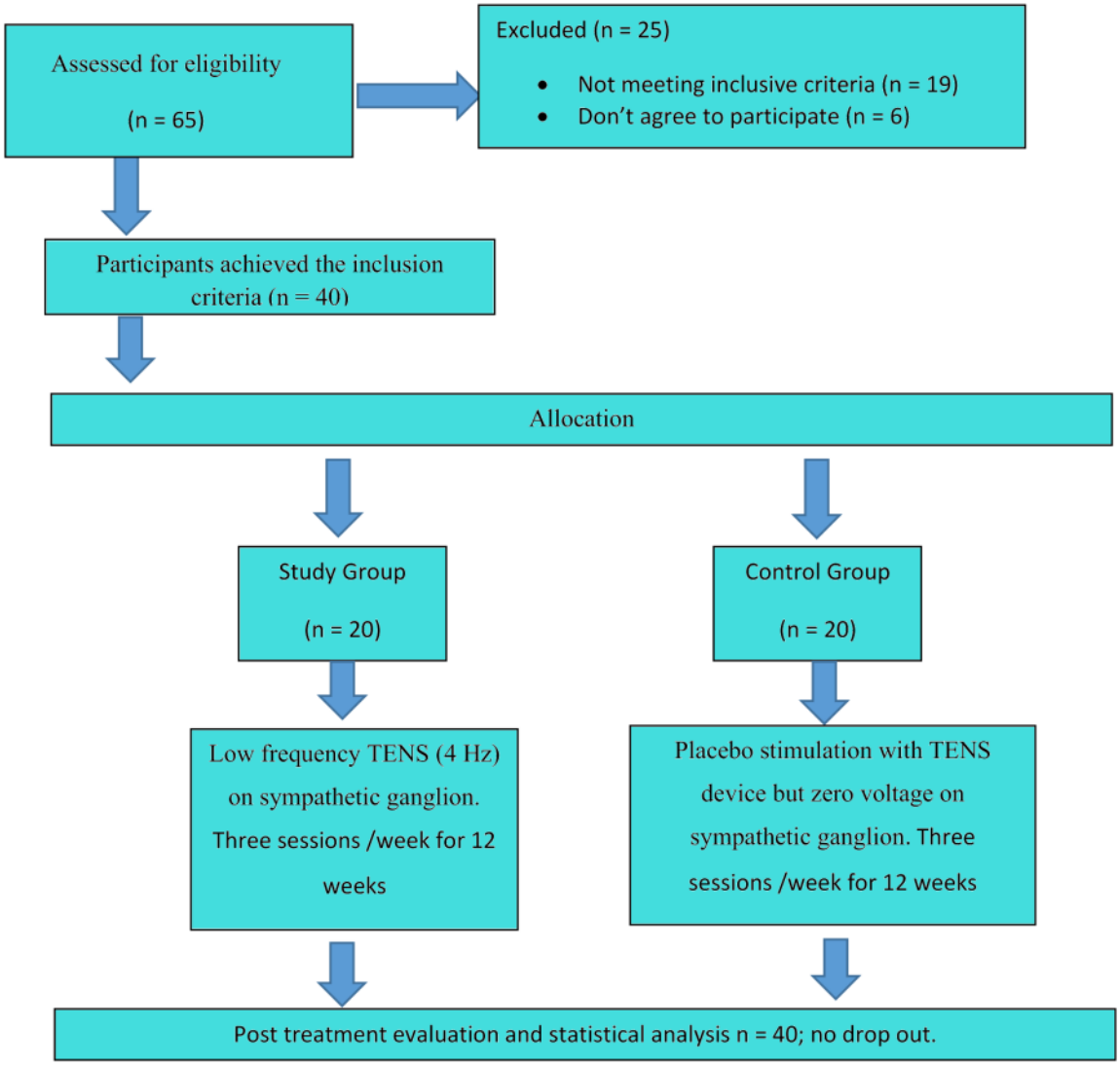

Figure 1. Flow chart of the study

gether with the anterior and posterior tibial artery (ATA, PTA), and plantar artery (PPA) and dorsal pedial artery (DOA). Recording of blood speed in both the distal anteriortibial artery and the distal posterior tibial artery at the ankle level, which are the main arteries supplying the foot was the purpose to be able to measure the degree of foot perfusion [8].

Claudication distance test

This testing is conducted on a treadmill:(NORDICTRACK T23.0 TREADMILL 2013) to measure claudication pain distance, with a steady speed of walking which is 2 miles/hour at 0 percent grade, and the grade gradually rise is 2.0 per cent every 2 minutes [9]. Two independent researchers supervised all patients during performing the treadmill test where actual claudication distance (ACD) was being measured. The onset of claudication pain, the point they preferred to stop, and the point at which the maximum walking distance was achieved were all indicated by the patients.

Actual claudication distance (ACD) is the distance where the patient stops walking due to the claudication. It is considered as a valid and reliable measurement for participants suffering from functional impairment due to intermittent claudication. Intra-class correlation coefficient (ICC) was 0.959 [10].

Statistical analysis

Prior to the study, APSV, AD and ACD were collected for every individual in both groups. The data gathered were entered on a computer to analyze the statistics. Descriptive statistics, such as standard deviation and mean have been calculated for both groups. The independent t-test was conducted to compare the mean difference between the two groups after and before intervention, as well as paired t –test was used to compare between before and after within each group. The alpha value of 0.05 was used as the level of significance.

Results

The groups were similar pre training ($p > 0.05$) regarding age, BMI, and outcome measures (Tables 1–2).

Table 1. Demographic characteristics of patients in both groups

General characteristics	Group (A) Mean ± SD	Group (B) Mean ± SD	Comparison t-value	Comparison P-value	Significance
Age [year]	55.80 ± 2.63	54.95 ± 2.91	0.9694	0.3385	NS
BMI [kg/m^2]	34.69 ± 3.69	33.04 ± 2.4	0.67	0.50	NS

SD: standard deviation; BMI: Body Mass Index

Table (2) revealed a marked significant increase in ankle peak systolic velocity (APSV), pre-and post-treatment, respectively with an increased percentage of 40.32 per cent. There was a significant rise in arterial diameter with an increased percentage of 15.78 per cent. There was a significant increase in the actual claudication distance with an increased percentage of 153.27%. Whereas control group showed a non-significant difference in mean pre-and post-treatment ankle peak systolic velocity (APSV), with a reduced percentage of 0.89. It also reveals a non-significant difference in arterial diameter (AD) with an increased percentage of 5.5, and finally a non-significant difference in actual claudication distance (ACD) with an increased percentage of 0.19.

Table 2. Comparison of mean Ankle peak systolic velocity, arterial diameter and actual claudication distance before and after treatment in study groups and control group

Dependent variables		Study Group (n = 20)	Control Group (n = 20)	group Vs. control group p- value*
Ankle peak systolic velocity (APSV)	Pre-treatment	26.36 ± 4.35	25.78 ± 4.12	0.6951^{NS}
	Post-treatment	36.99 ± 2.89	26.01 ± 4.04	0.00001^{S}
	p- value**	0.00001^{S}	0.4141^{NS}	
Arterial diameter (AD)	Pre-treatment	1.9 ± 0.09	1.8 ± 0.10	0.3082^{NS}
	Post-treatment	2.2 ± 0.14	1.9 ± 0.11	0.00001^{S}
	p- value**	0.00001^{S}	0.2966^{NS}	
Actual claudication distance (ACD)	Pre-treatment	134.03 ± 11.7	130.55 ± 8.64	0.2903^{NS}
	Post-treatment	287.30 ± 55.90	130.80 ± 10.71	0.00001^{S}
	p- value**	0.00001^{S}	0.7887^{NS}	

** Inter-group comparison; ** intra-group comparison of the results pre- and post-treatment. Data expressed by mean ± SD, NS p > 0.05 = non-significant, S p > 0.05 = significant, p = Probability.*

Discussion

Application of low frequency TENS which is considered as a cheap, portable and noninvasive tool on lumber sympathetic ganglion aiming to lower its activity and therefore lowering distal vascular resistance [11] and improving blood flow to lower extremity was our target which was proved by results. Previous studies was carried by direct application of TENS on calf muscle to improve distal blood flow as that done by Senan et al. [12] claiming that the achievement of walking in subjects suffering from intermittent claudication was improved by the help of tens modality when active tens was placed to the lower extremity during a comparison with another placebo group.splitting subjects into two sets, giving one set a TENS with high frequency whereas the other one received low frequency TENS they noticed that the distance walked before absolute claudication distance reached was greater during measuring the functional claudication distance, absolute claudication distance and initial claudication distance on two isolated testing times 40 participators suffering from PAD and IC finished a graded treadmill.

However a first and only study done to compare between the application of TENS on different regions: at the thoracolumbar sympathetic ganglions, acupuncture points, and mid-calf area, reached that the best improvement in blood flow of the left first toe was significantly gained by low frequency TENS application at the levels of T12, L1, and L2 of sympathetic ganglions [13]. This present study supports the previous one in TENS application on lumber sympathetic ganglion but with determining the stage of intermittent claudication which is stage II where claudication occurs after walking a distance of 200m.and using the ankle peak systolic velocity as a predictor on improvement of peripheral blood flow in ischemic limb which is more accurate, novel and not affected by arterial wall calcification as ankle brachial pressure index does [14].

Partially opposing our results, a study reporting that stimulation of the spinal cord in terms of (limb) survival might not

greatly enhance the outcome. In patients with ischemic skin wounds (ulcerations or gangrene), the hazard of amputation is greater than in patients with resting pain only subgroup of patients that could directly be treated through applying a stimulation to the spinal cord SCS were not identified by them randomized trials with enough power are needed if clinically applicable results are expected in patients suffering from critical extremity ischemia cli comparing it to the medicinal treatment alone data indicate inadequate proof of greater success of SCS management [15].

So it was interesting to investigate the impact of the application of TENS on the sympathetic lumber ganglion to solve this dilemma by assessing: Ankle peak systolic velocity, Arterial diameter and Actual claudication distance in peripheral arterial disease patients. Depended on the intensity of stimulation, vasodilation in the leg was induced by burst-mode TENS which was proofed by Julie et al. [16], application of TENS at or even below the motor threshold, circulation was not affected.

Practically in this study, calculated by enhanced laser Doppler imaging, transient vasodilatation occurred and lasted almost 5 to 10 minutes after TENS was released, when TENS was applied at an intensity of 25 percent just above the motor threshold, the period when vasodilatation lasts after removal of TENS was not recorded by previous researches. The results of this study showed a significant increase in ankle peak systolic velocity, arterial diameter and actual claudication distance which comes with a research that found that during a cardiopulmonary workout test tolerance which could be enhanced by raising distal blood flow to muscles when TENS was applied over the satellite ganglion was associated with a reduction in sympathetic activation and expanded distal oxygen levels in the muscles. [17].

Thus, it can be concluded that this increment in ankle peak systolic velocity, arterial diameter and actual claudication distance demonstrated in the study can be directly linked to a reduction in arterial wall vasoconstriction, which promotes the antisympathetic impact of TENS on peripheral vascular resistance when applied to thoracolumbar sympathetic ganglion rather than either directly to the calf muscles or on the acupuncture point. However, this study was limited by the lack of follow up due to the outbreak pandemic of covid-19 which ban the patients from follow up after the treatment programme. Therefore, more studies are recommended for farther follow up, also application on different stages of intermittent claudication is needed.

Conclusion

This study suggests that transcutaneous electrical nerve stimulation application on sympathetic ganglion improves APSV, AD and ACD and on Leriche-Fontaine stage-II prephiral arterial disease patients.

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Piśmiennictwo/ References

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