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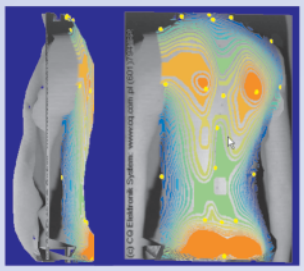

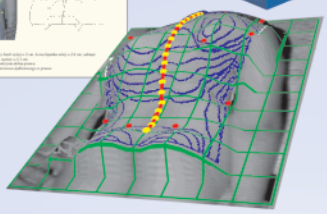

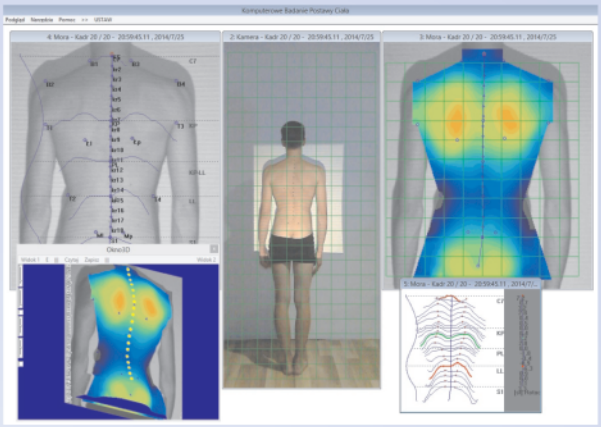

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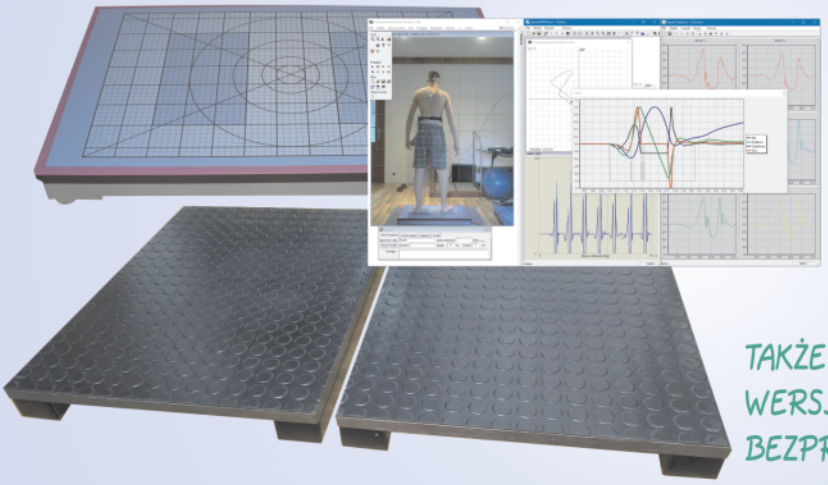

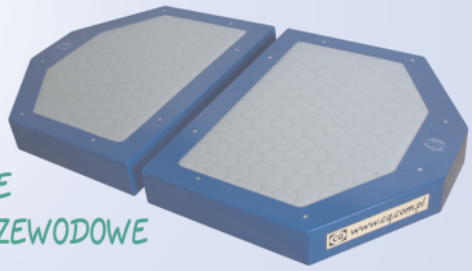

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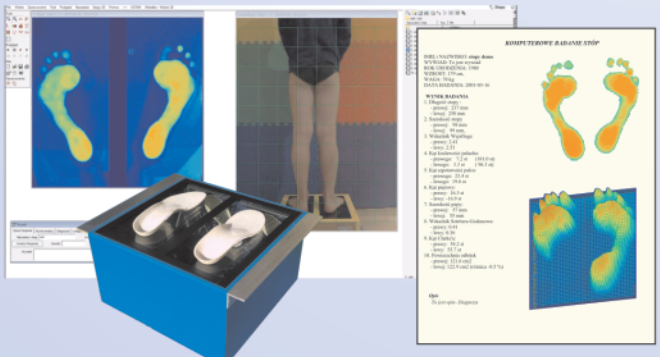

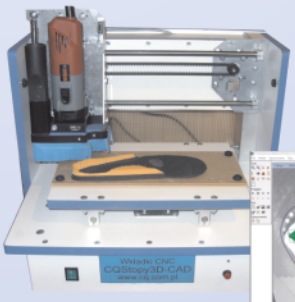

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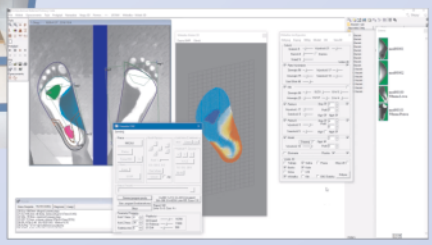

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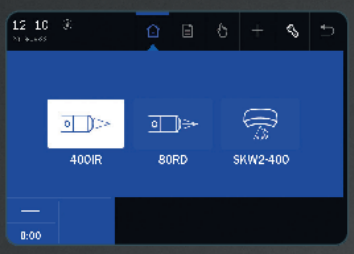

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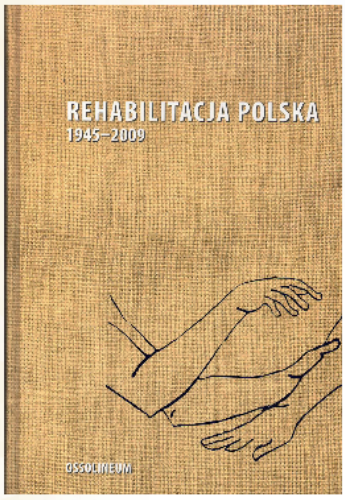

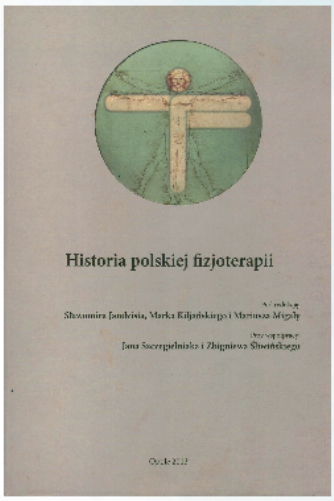

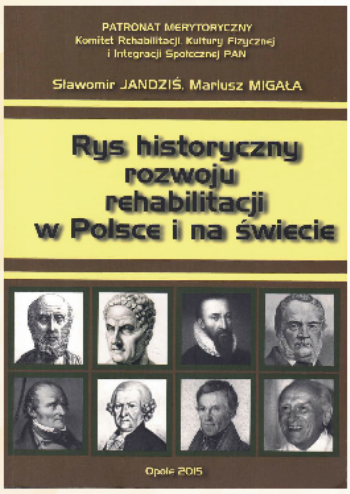

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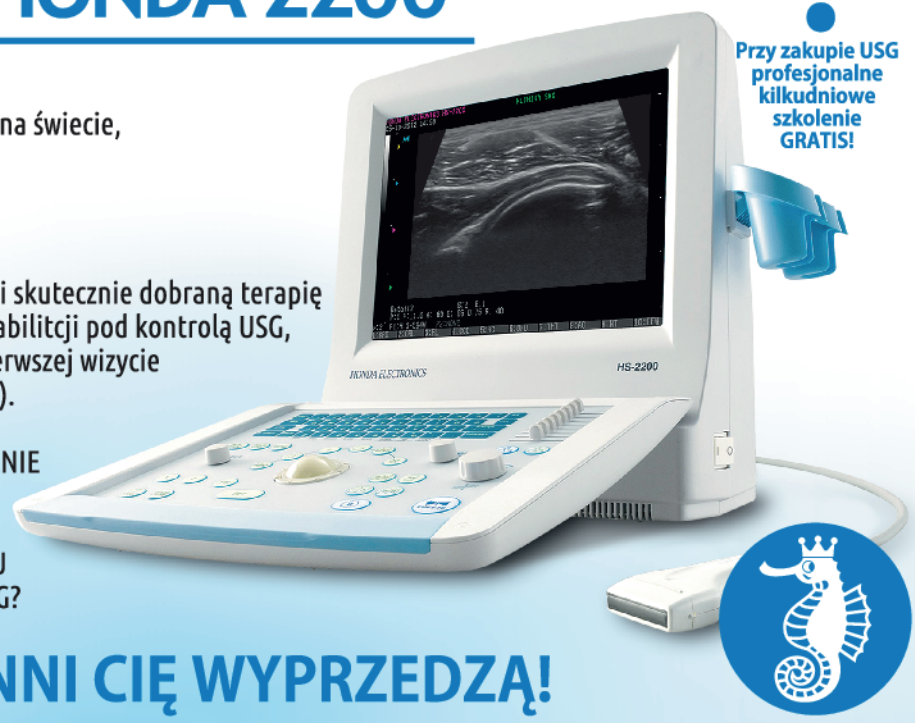

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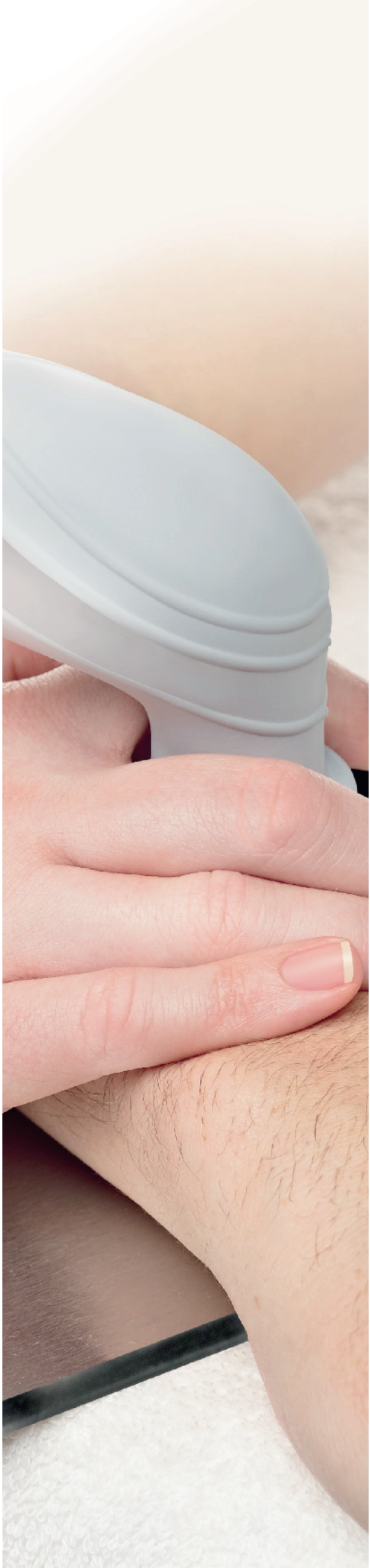

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Laser Acupuncture: Could it be a New Complementary Intervention in Management of Peripheral Arterial Disease?

Akupunktura laserowa: czy może stanowić nowy model leczenia uzupełniającego w przypadku choroby tętnic obwodowych?

Abeer Ahmad Farghaly[1(A,B,C,D,E,F)], Hesham Mostafa[2(A,B,C,D,E,F)], Hasnaa Ahmed Abdel-Aziz[3(A,B,C,D,E,F)], Hamada A. Hamada[4(A,B,C,D,E,F)]

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Abstract

Laser acupuncture has produced promising results in the management of many medical conditions; it has been used as a non-invasive therapy with no puncture pain which represents a major advantage over traditional acupuncture or electroacupuncture. The research question of this study is: Does the Aluminum Gallium Arsenide (AlGaAs) LASER acupuncture affect the lower limb blood supply and functional walking ability in patients with peripheral arterial disease (PAD)? Thirty male patients' diagnosis with PAD were recruited from Kasr El-ainy Hospital, and were randomly divided into two equal groups: study group and control group. Both groups received the routine medical treatment whereas study group received laser acupuncture therapy twice weekly for five weeks. Ankle brachial pressure index (ABPI), six-minute walk test (6MWT), and rating of perceived exertion using modified Borg scale were measured. The 2x2 mixed design MANOVA showed that laser acupuncture has induced highly statistically significant improvements in all the measured outcomes ($p < 0.05$). However, results revealed no significant difference between the two groups except for modified Borg scale. It was concluded that, AlGaAs Laser acupuncture could be an effective non-pharmacological intervention for improving circulation and functional walking performance in PAD patients and may be recommended as a complementary therapy in the management protocols of PAD.

Key words:

Laser acupuncture, peripheral arterial disease, Ankle brachial pressure index, six-minute walk test

Streszczenie

Akupunktura laserowa dała obiecujące wyniki w leczeniu wielu schorzeń. Była stosowana jako nieinwazyjna terapia bez nakłuwania, co stanowi dużą przewagę nad akupunkturą tradycyjną lub elektroakupunkturą. Pytanie badawcze postawione w ramach niniejszego badania brzmi: Czy akupunktura LASEROWA przy użyciu aluminium arsenku galu (AlGaAs) wpływa na ukrwienie kończyn dolnych i funkcjonalną wydajność chodu u pacjentów z chorobą tętnic obwodowych (PAD)? Do badania wybrano trzydziestu mężczyzn z rozpoznaniem PAD będących pacjentami szpitala Kasr El-ainy i losowo podzielono ich na dwie równe grupy: grupę badawczą i grupę kontrolną. Obie grupy poddawano rutynowemu leczeniu, natomiast grupa badawcza była poddawana również akupunkturze laserowej dwa razy w tygodniu przez pięć tygodni. Dokonano pomiaru wskaźnika kostkowo-ramiennego (ABPI), przeprowadzono test sześciominutowego marszu (6MWT) oraz dokonano oceny odczuwanego wysiłku przy użyciu zmodyfikowanej skali Borga. Zastosowano model mieszany 2 x 2 MANOVA, który wykazał, że akupunktura laserowa doprowadziła do wysoce statystycznie istotnej poprawy w zakresie wszystkich mierzonych wyników ($p <0,05$). Jednak wyniki nie wykazały znaczącej różnicy między dwiema grupami, z wyjątkiem zmodyfikowanej skali Borga. Stwierdzono, że akupunktura laserowa AlGaAs może być skuteczną niefarmakologiczną metodą leczenia poprawiającą krążenie i funkcjonalną wydajność chodu u pacjentów z PAD i może być zalecana jako terapia uzupełniająca w protokołach leczenia PAD.

Słowa kluczowe:

Akupunktura laserowa, choroba tętnic obwodowych, wskaźnik kostkowo-ramienny, test sześciominutowego marszu (6MWT)

Introduction

The prevalence of peripheral arterial disease (PAD) is estimated as15% of ischemic Egyptian patients and 12% among adult population in the developed world [1]. PAD is an indicator of systemically widespread atherosclerosis affecting arteries of lower limbs and arteries in other vascular regions such as coronary and cerebral arteries; about 10-15% of PAD patients with intermittent claudication die of ischemic heart disease and/or cerebrovascular disease within five years of diagnosis [1]. In Egyptian population, the symptomatic PAD patients were 1.831 times as likely to die as those without PAD, and 1.646 times in asymptomatic PAD patients after controlling other factors. Those with symptomatic or asymptomatic PAD were more than twice as likely to die of cardiovascular disease as those without PAD [2].

Patients with PAD experience functional limitations in daily life in the form of poor walking performance, decline in mobility and increased dependency; which would ultimately lead to morbidity with increasingly frequent hospitalization or even death [3, 4, 5].

Physiotherapy program has a major role in the management of PAD; supervised exercise training has been considered as the first-line treatment for PAD patients with intermittent claudication in the 2005 guidelines. According to the 2016 guidelines, a supervised exercise program recommended to improve the functional limitations, decrease claudication and improve quality of life. A community-based walking program is a second option that has gained attention due to the limitations of supervised walking exercise [6]. However, not all patients can enroll in exercise training programs due to a number of treatment barriers such as lack of transportation to clinical centers and lack of insurance reimbursement, thus alternative forms of physiotherapy interventions should be considered. Non-invasive acupuncture therapy such as laser acupuncture has recently gained more attention than traditional acupuncture [7]. Laser acupuncture therapy has been successfully used in the treatment of pain and cardiovascular conditions such as hypertension and diabetic foot ulcers [8]. In patients with PAD, Aluminum Gallium Arsenide (AlGaAs) LASER has previously proved to have favourable outcomes for patients with PAD when applied at acupuncture sites [9]. As Cunha et al. [9] assessed the effect of laser acupuncture on arterial pressure and Revascularization Index and not assessed its effect on functional performance. Therefore, the purpose of this study is to further investigate the effects of AlGaAs laser acupuncture in patients with PAD in regard with functional walking performance measured by 6MWT and arterial blood supply to the lower limbs measured by ankle-brachial pressure index.

Methods

Ethical consideration

The protocol of this study was approved by Ethics committee of Scientific Research of Faculty of Physical Therapy at Cairo University, (approval No. P.T.REC/012/001771). Patients provided their Informed consents for participation in the study.

Study design

A prospective, parallel randomized, single-blind, controlled trial was conducted following the Guidelines of Declaration of Helsinki on the conduct of human research.

Subjects

A Convenient sample of thirty male patients with a diagnosis of peripheral arterial disease (PAD) voluntarily participated in this study. They were referred by a medical professional after screening them to the eligibility criteria. They were recruited from the Outpatients Clinic of Vascular disorders at Kasr Al-Ainy Hospital, Cairo, Egypt. They were randomly divided into two groups: the study group (n = 15) and the control group (n = 15). Inclusion criteria included ankle-brachial pressure index < 0.9, only male patients, Fontine's classification stage IIa and IIb Rutherford's classification grade I, category 1 and 2. BMI ranged between 25 kg/m^2 and 30 kg/m^2 and age group between 50-70 years. Clinical history was obtained from patients. Exclusion criteria included; patients with neuroflogical or chest problems, patients with uncontrolled hypertension or uncontrolled diabetes mellitus, patients with contraindications to laser therapy (i.e. metal implants or pacemakers).

Randomization

A computer generated randomized table of numbers was used for concealed allocation. Sequentially numbered index cards with the randomly assigned intervention group were folded and placed in sealed, opaque envelopes. A second therapist blinded to the examination findings opened the envelope and proceed with the treatment according to the group assignment.

Outcome Measurements

Age and anthropometric measurements

Age of each patient was recorded; body mass and height of patients were measured by using standard, calibrated scales and stadiometers, and body mass index (BMI) was calculated and expressed as kg/m^2 [10].

Ankle-brachial pressure index (ABPI)

A hand-held 8 MHZ doppler probe (Hi.dop, made in Germany) was used to measure ABPI. It was measured for the right and left lower limbs before and after the interventions according to Aboyans et al. [11].

Six minutes walk test (6MWT)

The six-minute walk test has been validated as a meaningful outcome measure in patients with PAD for walking performance ability [12]. Prior to the test, the patient rested comfortably for 10 minutes and was instructed to walk as far as possible for 6 minutes without jogging along a 30-meters track; the patient was permitted to slow down his walking pace and/or to stop and rest on a chair if necessary, but he was instructed to resume walking again as soon as he could. The researcher used a stop watch during the test and set the lap counter to zero and timer to 6 minutes. The patient was informed about the time each minute. After 6 minutes, the test was ended and the patient was instructed to rate his subjective feelings of exertion using modified Borg scale (m-Borg) and the entire walking distance (i.e. 6-MWD) was recorded.

Rating of perceived exertion

The RPE scale is used as a subjective, self-reporting level of exertion. The modified Borg RPE scale is a numerical scale that ranges from 0 to 10, where 0 means "no exertion at all" and 10 means

"maximal exertion." When a measurement was taken, a number was chosen from the following scale by an individual that best describes their level of exertion during 6 minutes walk test [13].

Interventions

Laser therapy

The treatment sessions were applied at the Outpatient Clinic of Faculty of Physical Therapy, Cairo University. Patients in the study group received AlGaAs (Aluminium gallium arsenide-Handy-laser Sprint Model 50655) laser on 10 acupuncture points [9]. The emission of laser was at a wave length of 655 nm and a power out put of 41 mW, with spot size 0.08 cm2 using an energy density of 2 J/cm2. The laser acupuncture treatment was carried out for 60 seconds to each point, with a frequency of 2 days/week, and for 5 consecutive weeks. Laser acupuncture therapy was applied to the following points:LV2, ST41, UB25, UB40, UB60, UB61, GB30, GB34, GB38, and GB40 [9]. According to White et al. [14], the locations of these points are as follows:

1. Liver 2 (LV2): in liver meridian, on the dorsum of the foot proximal to the margin of the web, between the first and the second toes.
2. Stomach 41 (ST41): in stomach meridian, on the dorsum of the foot in a depression between the extensor digitorum longus and hallucis longus tendon, at the midpoint of the transverse crease of the ankle joint, corresponding to the tip of external malleolus.
3. Urinary bladder 25 (UB25): in Urinary bladder meridian, on the back, 5 cm lateral to the inferior border of the spinous process of the fourth lumbar vertebra.
4. Urinary bladder 40 (UB40): in urinary bladder meridian, located at the midpoint of the transverse crease of the popliteal fossa.
5. Urinary bladder 60 (UB60): located on the lateral aspect of the foot behind the external malleolus, in the depression between the tip of external malleolus and tendo Achilles.
6. Urinary bladder 61 (UB61): directly located below UB60 by 5cm, posterior and inferior to the external malleolus.
7. Gall bladder 30 (GB30): located on a line between the greater trochanter and the sacro-coccygeal hiatus, at 1/3 of from the greater trochanter.
8. Gall bladder 34 (GB34): located in a depression anterior to and below the head of the fibula.
9. Gall bladder 38 (GB38): On the lateral side of the lower leg, about 13 cm above the tip of the external malleolus, slightly in front of the anterior border of the fibula between peroneous brevis and extensor digitorum longus.
10. Gall bladder 40 (GB40): located in a depression on the lateral aspect of the tendon of extensor digitorum longus, anterior and inferior to the external mallelous.

Medical treatment

All patients were under the same medical treatment including; anti-Coagulant e.g. Aspirin and clopedogril, antihypertension e.g. ACE inhibitors and Calcium channel blockers, lipid lowering drugs e.g. Statins.

Sample size and Statistical analysis

Test size estimation was performed preceding the investigation utilizing G*POWER statistical programming (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany) [F tests- MANOVA: Special effects and interaction, $\alpha = 0.05$, $\beta = 0.20$, Pillai V = 0.23, and effect size = 0.29] and revealed that the appropriate sample size for this study was N = 30]. This effect size calculated from pilot study on10 participants (5 in each group) (figure 1).

The study included two independent variables. The first independent variable (between subject factor) was the tested group with two levels: study group and control group. The second independent variable (within subject factor) was the testing time with two levels: pre-treatment and post-treatment. The four dependent variables were the (ankle brachial pressure index at both sides, 6-minute walking and rating of perceived exertion). The homogeneity of variance using Levene's test revealed that there was no significant difference with p values > 0.05, that reflect the data was homogenous. Normality test of data using Shapiro-Wilk test was used, that reflect the data was normally distributed (p > 0.05). So, parametric analysis was performed. 2 x 2 mixed design Multivariate Analysis of Variance (MANOVA) was used to compare all dependent variables within and between both groups. The variable of interest was the group-by- time interaction at an a priori alpha level of 0.05 and 95% confidence interval. Reported data was analyzed using Statistical Package for Social Sciences (SPSS) computer program (version 23 windows) (Charles R Flint, New York, USA).

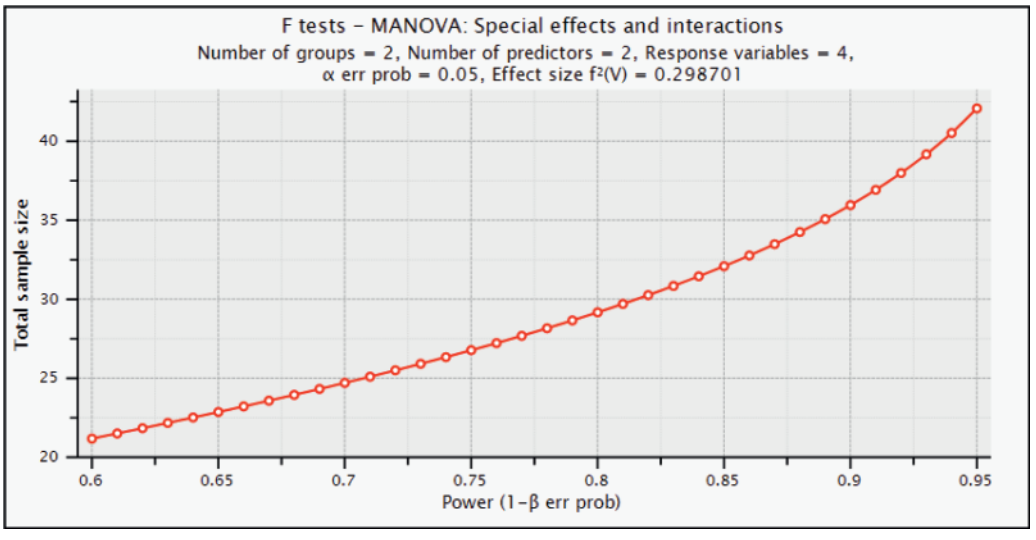

Figure 1. Plot of sample size calculation

Results

A total of 37 patients with Peripheral Arterial Disease were eligible for inclusion, and 30 were randomized to study intervention (fig 2). The study group of 15 patients who received routine medical treatment and laser acupuncture therapy. The control group consisted of 15 patients who only received routine medical treatment. No subjects dropped out of the study after randomization. The independent t-test revealed that there was no significant difference (P > 0.05) between subjects in both groups concerning age, body mass, body height and BMI (Table 1).

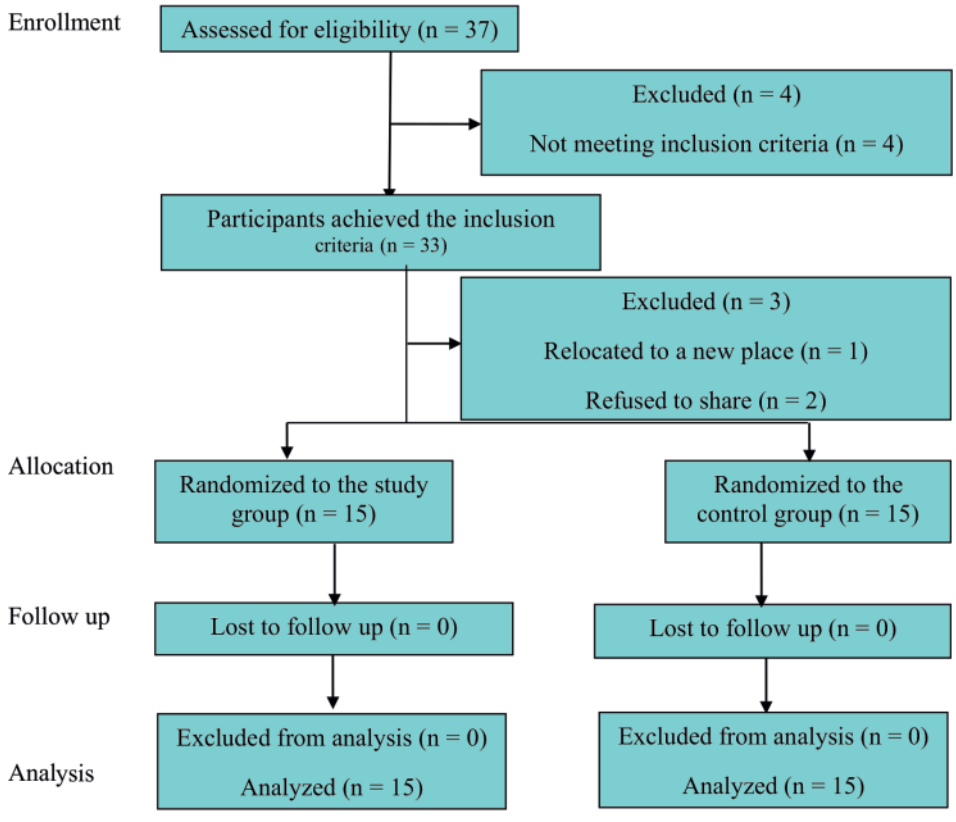

Figure 2. Flow chart of the participants during the trial

Table 1. Participants characteristics at both groups

Characteristics	Group A (n = 20) Mean ± SD	Group B (n = 20) Mean ± SD	p-value
Age [years]	64.53 ± 3.52	65.60 ± 3.25	0.395
Body mass [kg]	79.73 ± 13.81	82.67 ± 8.99	0.496
Body height [m]	1.77 ± 0.07	1.79 ± 0.07	0.382
BMI [kg/m^2]	25.44 ± 3.12	25.89 ± 2.63	0.669

Data are expressed as means ± standard deviations; BMI: Body mass index

Multivariate tests for outcome measures indicate no statistically significant effects for group (Wilk's Lambda = 0.796, F (4,25) = 1.598, p = 0.206, Partial η^2 = 0.204). While there was significant effect for time (Wilk's Lambda = 0.205, F (4,25) = 24.21, p = 0.001, Partial η^2 = 0.795), and group-by-time interaction (Wilk's Lambda = 0.284, F (4,25) = 15.753, p = 0.001, Partial η^2 = 0.716). Within subject effect, the multiple pairwise comparison tests (post hoc test) revealed a statistical significant increase (p < 0.05) in in ankle brachial pressure index at both sides and 6-minute walking test while there was significant reduction (p < 0.05) in rating of perceived exertion at study group only in the post treatment condition compared with the pretreatment. Regarding between subject effects multiple pairwise comparisons (post hoc test) revealed that there was significant reduction (p < 0.05) in rating perceived exertion at study group in compared to control group. While there were no significant differences (p > 0.05) in ankle brachial pressure index at both sides and 6-minute walking test between both groups (Table 2).

Table 2. The 2 x 2 mixed design Multivariate Analysis of Variance (MANOVA) for all dependent variables at different measuring periods at both groups

Dependent variables		Study group (n = 15)	Control group (n = 15)	Between groups Mean difference (95% CI)	Between groups p- value* (Cohen's d)	Minimal Clinically Important Difference
ABPI at right side	Pre-treatment	0.771 ± 0.134	0.777 ± 0.107	-0.006 (-0.097:0.085)	0.89^{NS} (0.04)	0.024
	Post-treatment	0.804 ± 0.123	0.788 ± 0.102	0.016(-0.069:0.101)	0.70^{NS} (0.13)	0.022
	p-value** (Cohen's d)	0.001^{S} (0.24)	0.168^{NS} (0.1)			
ABPI at left side	Pre-treatment	0.756 ± 0.135	0.824 ± 0.112	-0.068 (-0.161:0.025)	0.146^{NS} (0.5)	0.025
	Post-treatment	0.804 ± 0.116	0.816 ± 0.127	-0.012 (-0.103:0.079)	0.79^{NS} (0.1)	0.024
	p-value** (Cohen's d)	0.001^{S} (0.35)	0.331^{NS} (0.07)			
6-MWD (meters)	Pre-treatment	214.0 ± 59.68	260.7 ± 90.96	-46.7 (-104.2: 10.87)	0.108^{NS} (0.78)	15.06
	Post-treatment	318.6 ± 77.17	268.3 ± 96.65	50.3(-15.08: 115.74)	0.126^{NS} (0.65)	17.38
	p-value** (Cohen's d)	0.001^{S} (1.75)	0.651^{NS} (0.08)			
RPE (scores)	Pre-treatment	7.47 ± 1.41	6.93 ± 0.80	0.54 (-0.323: 1.389)	0.212^{NS} (0.38)	0.221
	Post-treatment	5.00 ± 1.25	7.13 ± 1.77	-2.13 (-3.279: -0.987)	0.001^{S} (1.70)	0.302
	p-value** (Cohen's d)	0.001^{S} (1.75)	0.426^{NS} (0.25)			

** 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, CI: Confidence Interval, ABPI: Ankle brachial pressure index; 6-MWT: 6-minute walking test; RPE: Rating of perceived exertion.*

Discussion

In PAD, since not much improvement in walking function could be seen in patients receiving medical treatment alone, searching for complementary therapies is an important issue. Laser acupuncture is an effectively non-noninvasive therapy, the patient does not experience stress from pain caused by acupuncture point stimulation during treatment; this represents a major advantage over electro-acupuncture or the traditional acupuncture therapy. Moreover, laser acupuncture is a safe intervention which has a low risk of collateral damage when combined with other medical treatments [8], and no known harmful effects to the irradiated tissue [15]. Based on that, it could be promising to investigate whether laser acupuncture would effectively be a non-pharmacological and non-invasive therapeutic intervention complementing the medical treatment in the management of patients with PAD especially those who are not eligible to treadmill exercise training. Therefore, the purpose of this study was to assess the effect of AlGaAs laser acupuncture on blood circulation to the lower limbs and functional walking ability in patients with PAD. The major findings in this study are: (a) AlGaAs laser acupuncture has induced statisti-

cally significant improvement in ABPI ($p < 0.01$); this improvement had a clinically meaningful impact on functional walking ability of the patients measured by 6MWD and Rating of perceived exertion after 6MWT. (b) AlGaAs laser acupuncture has induced statistically significant improvement in 6MWD ($p < 0.01$); this change was highly clinically meaningful (I.e. a change of > 100 meters) (c) AlGaAs laser acupuncture has induced statistically significant improvement in Rating of perceived exertion (I.e. modified Borg scale) ($p < 0.01$). (d) Except for the changes in Rating of perceived exertion, there was no statistically significant difference between the study and the control groups.

In regard with our first finding, the significant improvement in ABPI of both lower limbs is supported by an earlier study by Cunha et al. [9]. This study [9] has utilized a similar treatment protocol with the same acupuncture points, and demonstrated that AlGaAs laser acupuncture was successful in inducing a significant increase in the systolic arterial pressure of lower limbs in PAD patients with resultant improvement in ABPI. In addition, this finding could be consistent with other two studies,all of which have shown that traditional acupuncture therapy improves blood flow to the ischemic lower limbs in patients with PAD [16, 17].

The underlying mechanism is that acupuncture therapy increases the level of regional nitric oxide (NO) in the treated areas with subsequent improved local blood supply [18]. Recently, Jiang et al. [19] have shown that laser acupuncture stimulates nitric oxide release in treated points which induces local vasodilatation and enhancement in regional circulation. Other possible mechanism could be laser-induced elevation of Cyclic guanosine monophosphate (cGMP) which relaxes vascular smooth muscles leading to vasodilation and increased blood flow [20].

There is evidence that this vasodilator effect of NO is mediated by activation of guanylyl cyclases (GCs) and the Cyclic guanosine monophosphate (cGMP)-cGMP-dependent protein kinases type I (cGKI) axis in vascular smooth muscle cells [21,22].

In regard with 6MWD, this study has shown that AlGaAs laser acupuncture has induced statistically significant improvement in 6MWD ($p < 0.01$). Worth noting, this improvement in 6 MWD was above 100 meters (I.e. from 214.0 ± 59.68 to 318.6 ± 77.17) which is considered to be clinically significant [23,24]. To our knowledge this is the first study to measure 6MWD after laser acupuncture therapy in patients with peripheral arterial disease. Similarly to this finding, a previous study has shown that laser acupuncture treatment for only 10 days has induced significant improvement in 6MWD in patients with chronic respiratory disease [25]. Another recent study has reported a significant increase in 6MWD after two-weeks laser acupuncture intervention in COPD patients [26]. Despite the discrepancy in subjects and methodology between our study and each of these two studies, the positive result of laser acupuncture therapy in improving the functional walking ability of patients, manifested by increased 6MWD, has been similarly reported.

With regard to Rating of perceived exertion after 6MWT, this study has reported a statistically significant reduction in the mean values of modified Borg (m-Borg) scale scores after laser acupuncture therapy. This improvement was statistically different from the control group. This finding reflects the clinically important role of Laser acupuncture in reducing the susceptibility to fatigue of the lower limbs and increasing tolerance to walking for patients with PAD. This finding may indirectly supported by Susuki et al. [27], who found that traditional acupuncture had significantly produced better results on the Borg scale when combined with medications than medications alone in patients with chronic obstructive pulmonary disease.

The improvements in both 6MWD and rating of perceived exertion or modified Borg scale could be explained by: (a) laser acupuncture-evoked increases in NO and cGMP with subsequent local vasodilatation and improved blood flow to the ischemic limbs as we discussed earlier. The increased blood supply would increase bioavailaibility of oxygen, facilitate the transport of nutrients to tissues and help in removal of metabolites which harm muscular contractions [9]. (b) laser acupuncture-induced pain relief [28], which could reduce the claudication pain during the six-minutes walking, permitted walking for longer distance, and/or reduced the subjective feeling of exertion. Yasuno et al. [16], have shown that acupuncture therapy led to easiness of pain and numbness experienced by patients with peripheral arterial disease. (c) laser acupuncture-induced reduction in oxidative stress and inflammation [29]. Recently, it has been reported that limb ischemia and claudications in PAD are not only due to impaired blood flow, but also due to metabolic changes in the ischemic limb muscles, [30] in the form of dysfunction of mitochondrial bioenergetics associated with increased oxidative stress [31, 32]. The production of reactive oxygen species (ROS) is increased in the compromised mitochondria of the affected muscles of the lower limbs [33].

Limitations of the study

The primary limitation was that, no follow up was conducted to know the long lasting effect and recurrence of symptoms. Secondly, certain secondary outcome variables such as, Revascularization Index. Thirdly, the finding of potential within and between group differences with the Rating of perceived exertion, may be weakened and given the subjective nature of the variable so we recommended to use an objective variable instead of it. Finally, post hoc power analysis revealed that the power of this study is 42% however the priori power analysis that used to calculate the sample size is 80%. So we may be had type II error. Therefore, we considered the small sample size is one of our limitation.

Conclusion

Laser acupuncture induced significant improvements in lower limb circulation and functional walking ability, manifested by significant improvements in ABPI, 6MWD, and rating of perceived exertion. Nevertheless, compared to the control group, Laser acupuncture has induced a statistically significant difference in rating of perceived exertion only after 6MWT measured by modified Borg scale. These observations can be taken into account by researchers interested in seeking non-pharmacological alternatives in the clinical management of patients with PAD.

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Piśmiennictwo/ References

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