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Pełna oferta:



Effect of Pulsed Electromagnetic Field on Walking Capacity in Patients with Peripheral Arterial Disease

Wpływ pulsującego pola elektromagnetycznego na chód u pacjentów z chorobą tętnic obwodowych

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Abstract

Background. Peripheral arterial disease (PAD) is a common vascular disorder characterized by intermittent claudication with costly complications and marked reduction in functional capacity. The pulsed electromagnetic field (PEMF) has been used widely for different patient populations owing to its analgesic, anti-inflammatory, and angiogenetic effects, however, its use in the management of PAD has been recently introduced. **Aim.** this study aimed to assess the effect of PEMF on functional walking parameters in patients with PAD. **Material and Methods.** Sixty patients with PAD (Fontaine stage II), aged from 45-65 were divided into two groups A & B. Group (A) received pulsed electromagnetic field for 60 minutes/session, 3 sessions/week, and for 8 weeks plus drug treatment, whereas, group (B) only received the traditional drug treatment for 8 weeks. The endpoints of the study were claudication pain distance (CPD), maximal walking distance (MWD), claudication pain time (CPT), maximal walking time (MWT), and ankle-brachial index (ABI). **Results.** There were significant changes in all measured variables compared to the baseline in the two groups. There were significant differences between the two groups in CPD, MWD, CPT, MWT, and ABI in favor of the PEMF group ($P < 0.05$). **Conclusion.** PEMF could be an effective therapeutic modality that can help improve the functional walking capacity in patients with PAD (Fontaine stage II).

Key words:

Pulsed electromagnetic field, peripheral arterial disease, walking capacity, Intermittent claudication

Streszczenie

Wstęp. Choroba tętnic obwodowych (PAD) jest powszechnym zaburzeniem naczyniowym charakteryzującym się chromaniem przestankowym z poważnymi powikłaniami i znacznym zmniejszeniem wydolności funkcjonalnej. Pulsujące pole elektromagnetyczne (PEMF) jest powszechnie stosowane w różnych populacjach pacjentów ze względu na jego działanie przeciwbólowe, przeciwzapalne i angiogenetyczne, natomiast ostatnio zaczęto stosować je również w leczeniu PAD. **Cel.** Badanie miało na celu ocenę wpływu PEMF na funkcjonalne parametry chodu u pacjentów z PAD. **Materiał i metody.** Sześćdziesięciu pacjentów z PAD (stadium II wg klasyfikacji Fontaine'a), w wieku 45-65 lat, podzielono na dwie grupy A i B. Grupa (A) była poddawana działaniu pulsującego pola elektromagnetycznego przez 60 minut/sesję, 3 sesje/tydzień przez 8 tygodni oraz leczeniu lekami, podczas gdy grupa (B) była poddawana wyłącznie tradycyjnemu leczeniu farmakologicznemu przez okres 8 tygodni. **Kryteria oceny** obejmowały dystans chromania (CPD), maksymalny dystans chodu (MWD), czas chromania (CPT), maksymalny czas chodu (MWT) oraz wskaźnik kostkowo-ramienny (ABI). **Wyniki.** Wystąpiły znaczące zmiany we wszystkich mierzonych zmiennych w porównaniu z wartościami wyjściowymi w obu grupach. Między grupami wystąpiły istotne różnice w zakresie CPD, MWD, CPT, MWT i ABI na korzyść grupy poddawanej PEMF ($p < 0,05$). **Wniosek.** PEMF może być skuteczną metodą terapeutyczną, która może pomóc poprawić funkcjonalną zdolność chodu u pacjentów z PAD (stadium II wg klasyfikacji Fontaine'a).

Słowa kluczowe

pulsujące pole elektromagnetyczne, choroba tętnic obwodowych, zdolność chodu, chromanie przestankowe

Introduction

Peripheral arterial disease (PAD) is an increasingly serious health problem in the world, particularly, in developing countries [1]. A total of 236·62 million people were having PAD in 2015, among whom 72·91% were in the low-income and middle-income countries [1]. PAD is a progressive disease affecting the arteries of lower extremities characterized by narrowing of arterial lumen owing to atherosclerotic pathophysiological process and is associated with increased risk for cardiovascular mortality [2]. Clinically, over 50% of patients with PAD are asymptomatic and nearly about 40-45% of PAD patients are presented with intermittent claudication [3]. Intermittent claudication is characterized by walking-induced cramping pain in the muscles of the lower extremities with consequently impaired walking ability, restricted mobility, and/or reduced physical activity [4].

Supervised walking exercise has been recommended as first-line therapy for the treatment of PAD, particularly PAD patients with intermittent claudication and walking disability [5]. Interestingly, it was reported that supervised exercise training could be equally or more effective in improving walking ability than the balloon and stent procedure [6]. However, not all PAD patients can participate in exercise training programs because of personal, social, or environmental barriers; because of this, searching for other feasible alternatives should be considered for such patients [6].

Electromagnetic therapy carries the promise to heal numerous health problems even where conventional medicine has failed [7]. Magnetotherapy is now a non-invasive, effective, and simple way to treat the site of an injury and the cause of pain and inflammation. Millions of people around the world have received help in the treatment of peripheral, vascular, and musculoskeletal disorders, as well as for pain management [8]. In magnetotherapy, pulsed electromagnetic fields are an effective modality. PEMF application provides an advantage by altering biological and physiological systems using a low-energy, non-ionizing electromagnetic field [8].

The pulsed electromagnetic field (PEMF) has vasodilator, anti-inflammatory, and angiogenetic effects and has been successfully applied to patients with endothelial dysfunctions and ischemic conditions resulting in significant improvements in blood flow and ischemic symptoms [9,10]. Recently, PEMF has induced beneficial effects in PAD patients with intermittent claudication in terms of improving the arterial blood flow and reducing the intimal thickness [11]. Nevertheless, there is a lack of studies investigating the potential role of the pulsed electromagnetic field in the management of PAD. Therefore, this study was conducted to assess the effect of PEMF on functional walking parameters and ABI in symptomatic PAD patients. The results of this study may guide physiotherapists to a new non-invasive treatment modality that may improve symptoms of PAD patients particularly those who cannot adhere to exercise training and consequently avoiding the complications of PAD.

Participants and methods

Design

The present study was designed as a prospective, randomized, controlled trial. It was carried out between September 2018

and December 2020. The present study followed the Guidelines of the Declaration of Helsinki on the conduct of human research.

Ethical considerations

The protocol of the current study was approved by the Ethics Committee of Scientific Research of the Faculty of Physical Therapy at Cairo University, Egypt P.T.REC/012/002122. Informed consent was obtained from each patient before the start of the study.

Participants

Sixty patients with PAD were allocated into two equal groups (group A & B). They were recruited from the vascular department at Alexandria Police Hospital, Alexandria, Egypt. The age ranged from 45 to 65 years. All participants were ABI < 0.9, Fontaine stage II PAD, diagnosed with PAD since at least (6 months to 1 year). They were medically, psychologically stable and Only ambulant patients without any aids. Any participant was excluded if were Fontaine Stage I (Asymptomatic disease), Stage III (leg pain at rest), or Stage IV of PAD (Critical ischemia, Gangrene or Trophic lesions), coronary artery or cerebrovascular disease, congestive heart failure, chest disease, uncontrolled blood pressure, musculoskeletal or neurological problems, current smoking, any previous vascular operations or angioplasty within the previous year, presence of any contraindications to electromagnetic field (e.g. pregnancy, malignancy, implanted electrical device, bleeding disorders, soft tissue infection, cellulitis).

Randomization

Each patient was informed about the nature, purpose, and benefits of the study, the right to refuse or withdraw at any time, and the confidentiality of any obtained data. Patients were randomized into two groups (A & B) equal in number by a computer-based randomization program. After randomization, there was not any dropping out of subjects from the study [12].

Measurements

Demographic and anthropometric measurements

The age, body weight, height, and body mass index of each patient were recorded at the baseline.

Outcome measures

Ankle brachial index (ABI)

ABI was measured by a portable Doppler (siemens acuson x300 ultrasound system, made in Germany) for each participant in both groups (A & B), at the baseline and after the interventions. First, the dorsalis pedis artery and posterior tibial artery were assessed in each limb for systolic blood pressure (SBP), and the highest value was recorded as the ankle systolic pressure. Then, the brachial arteries of both upper limbs were assessed for SBP and the highest reading was reported as the brachial systolic pressure. The ABI of each limb was calculated according to the following equation: $ABI = \text{Ankle systolic pressure (mmHg)} / \text{Brachial systolic pressure (mmHg)}$. The lower ratio of ABI in either limb was considered the patient's overall ABI [13].

Graded treadmill exercise testing

Functional walking variables were measured for each participant in both groups at the baseline and after the interventions by Graded Treadmill Exercise Testing, the patients started walking on an electric treadmill with 2 mph (3 km/h) and a 0 grade (Weslo Cadence 1005, Model NO.WLTL 39093, made in the USA). Then, the inclination was gradually increased (3.5% increase every 3 minutes) till maximal claudication pain was reached and the patients were forced to end the test [14,15]. The longest possible walking distance reached by the patient before the appearance of pain was measured as the pain-free walking distance or claudication pain distance (CPD). The maximal distance at which walking could not continue due to maximal pain (the moment the test had to stop) was measured as the maximal walking distance (MWD). The walking time at which the patient first experienced pain was recorded as claudication pain time (CPT) and the walking time at which the patients could not continue walking due to maximum pain was defined as the maximal walking time (MWT).

Interventions

Group A (study group) received Pulsed electromagnetic field in addition to traditional Medical Treatment 3 sessions per week for 8 weeks, while group B (control group) only received the traditional medical treatment.

Pulsed electromagnetic field (PEMF)

Patients in group A received PEMF generated by a magnetic therapy unit (BTL-5000 Series – made in the UK). Patients were in a relaxed supine lying position over the motorized bed and were asked to remove any metal objects, watches, chains, belts before lying over the bed. They were asked not

to move and to be stable during the session. The solenoid was adjusted to be over the calf muscles of both lower limbs, The PEMF parameters were 4.5 ms rectangular pulses at a low frequency of 15 Hz, with a magnetic flux density changing from 0 to 2 Mt (20 Gauz) in 200 ms and returning to 0 in 24 ms [16]. The PEMF was applied for a duration of 60 minutes [17], using the solenoid 70 cm applicator. The sessions were performed 3 days per week for 8 weeks.

Statistical analysis

Descriptive statistics were conducted to describe the data as means \pm standard deviation. The Shapiro Wilk test of normality was done at first to assess the distribution of data before treatment. Paired t-test was carried out for comparison of mean values of variables before and after interventions in each group. Independent t-test was conducted to compare the mean values of variables between the two groups at the baseline and post interventions. Also, the percent change from baseline to post intervention was calculated for each measure to compare between the two groups. The significance level for all statistical tests was set at $p \leq 0.05$. The statistical analysis was conducted using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp).

Results

A total of sixty patients having PAD were allocated for the study intervention. Group (A) included 30 patients who received PEMF in addition to traditional medical treatment for 8 weeks. Group (B) included 30 patients who received only traditional medical treatment for 8 weeks. There were no significant differences between the two groups at the baseline regarding age, weight, height, BMI, and outcome measures ($P > 0.05$) as shown in Table 1 and Table 2.

Table. 1 Baseline characteristics of participants in both groups

	PEMF group (group A, $n_1 = 30$)	Control group (group B, $n_2 = 30$)	P-value
Age [yrs.]	55.93 \pm 5.37	55.70 \pm 4.91	0.861 ^{NS}
Weight [kg]	78.33 \pm 5.06	79.47 \pm 4.73	0.371 ^{NS}
Height [cm]	169.85 \pm 5.43	171.47 \pm 5.24	0.245 ^{NS}
BMI [kg/m ²]	27.06 \pm 2.63	27.70 \pm 3.78	0.446 ^{NS}

Data are expressed as Means \pm SD. BMI: Body mass index, ^{NS} $P > 0.05$ = non-significant, P = Probability

The CPT revealed a statistically significant increase within both groups ($P < 0.05$). The post-treatment comparison of both groups showed a statistically significant difference ($P < 0.05$). Also, there was a greater improvement percentage concerning CPT in group (A) (52.53%) than in group (B) (8.50%). As well as, the MWT revealed a statistically significant increase within both groups ($P < 0.05$). The post-treatment comparison of both groups showed a statistically significant difference ($P < 0.05$). Also, there was a greater improvement percentage concerning MWT in group (A) (73.45%) than in group (B) (16.94%). Additionally, the CPD revealed a statistically significant increase within both groups ($P < 0.05$). The post-treatment comparison of both groups showed a statistically

significant difference ($P < 0.05$). there was a greater improvement percentage concerning CPD in group (A) (54.85%) than in group (B) 4.29%). The MWD revealed a statistically significant increase within both groups ($P < 0.05$). The post-treatment comparison of both groups showed a statistically significant difference ($P < 0.05$). Also, there was a greater improvement percentage concerning MWD in group (A) (64.57%) than in group (B) (15.22%). Also, the ABI revealed a statistically significant increase within both groups ($P < 0.05$). The post-treatment comparison of both groups showed a statistically significant difference ($P < 0.05$). Also, there was a greater improvement percentage concerning ABI in group (A) (9.59%) than in group (B) (1.54%) (Table 2).

Table. 2. Results of the two groups before and after the interventions

		PEMF group (group A, n ₁ = 30)	Control group (group B, n ₂ = 30)	P-value
CPT [min]	Pre treatment	4.95 ± 1.04	4.91 ± 0.87	0.885 ^{NS}
	Post treatment	7.36 ± 1.01	5.31 ± 0.86	< 0.001 ^S
	% of change	↑52.53 ± 24.32	↑8.50 ± 5.15	
	t – value	18.801	9.255	
	P value**	< 0.001 ^S	< 0.001 ^S	
MWT [min]	Pre treatment	8.76 ± 0.96	8.62 ± 0.85	0.562 ^{NS}
	Post treatment	15.09 ± 0.89	10.06 ± 0.81	< 0.001 ^S
	% of change	↑73.45 ± 12.58	↑16.94 ± 3.78	
	t – value	54.315	31.474	
	P value**	< 0.001 ^S	< 0.001 ^S	
CPD [meters]	Pre treatment	157.73 ± 44.91	154.37 ± 34.06	0.745 ^{NS}
	Post treatment	237.03 ± 49.86	160.73 ± 34.64	< 0.001 ^S
	% of change	↑54.85 ± 22.76	↑4.29 ± 2.55	
	t – value	20.622	8.527	
	P value**	< 0.001 ^S	< 0.001 ^S	
MWD [meters]	Pre treatment	262.93 ± 38.08	261.33 ± 34.19	0.865 ^{NS}
	Post treatment	429.73 ± 45.92	300.37 ± 35.0	< 0.001 ^S
	% of change	↑64.57 ± 11.19	↑15.22 ± 4.35	
	t – value	44.198	22.532	
	P value**	< 0.001 ^S	< 0.001 ^S	
Overall ABI	Pre treatment	0.70 ± 0.06	0.70 ± 0.04	0.847 ^{NS}
	Post treatment	0.76 ± 0.06	0.71 ± 0.05	< 0.001 ^S
	% of change	↑9.59 ± 3.87	↑1.54 ± 2.16	
	t – value	14.624	3.805	
	P value**	< 0.001 ^S	0.001 ^S	

Data are expressed as Means ± SD. * Inter-group comparison; ** intra-group comparison of the results at the baseline and post treatment. CPD: claudication pain distance; MWD: maximum walking distance; CPT: claudication pain time; MWT: maximum walking time; ABI: ankle-brachial index. ^{NS} P > 0.05 = non-significant, ^S P < 0.05 = significant, P = Probability

Discussion

The current study was conducted to determine the effect of Pulsed electromagnetic field on functional walking parameters in patients with PAD after eight weeks of treatment. The results obtained from this study positively revealed the significant effect of using Pulsed electromagnetic field in the management of claudication symptoms and improving the functional capacity that may delay the complications of the disease. The present study showed that PEMF induced a statistically significant increase in CPD, MWD, CPT, MWT, and ABI compared to the baseline and the controls in patients with PAD. The percentages of improvement for CPT, CPD, MWT, MWD, and ABI were 52.53%, 54.85, 73.45%, 64.57%, 9.59% respectively for group (A), while they were 8.50%, 4.29%, 16.94%, 15.22%, 1.54% for group (B).

In accordance with these findings, Mohamed et al. [18], reported a significant increase in absolute claudication distance, peak walking time, and ABI in the PEMF group. The results of the study were also in agreement with Giusti et al. [19], who reported that PEMFs significantly improved gait characteristics, self-selected gait speed, and stride duration in older adults with low BMD, with improved functional outcomes in patients with PMOP. The significant improvement of walking parameters in the PEMF group compared to the baseline and the controls may be attributed to multiple physiological effects of PEMF such as anti-inflammatory, pain-relieving, vasodilatory, angiogenetic effects that in combination could ease claudication pain and, consequently increase the functional walking capacity and performance.

Regarding the anti-inflammatory effect of PEMF, Esmael et al [20], have shown that pulsed electromagnetic field was more effective than treadmill training in reducing the inflammatory level by decreasing C Reactive Protein in patients with polycystic ovary syndrome, (i.e., ↓ 60.7% of CRP after PEMF versus ↓ 20.88% of CRP after treadmill training), helping in the suppression of inflammatory response that may delay the progression of the disease. These results proved the significant anti-inflammatory effect of PEMF and its role in improving the blood flow and delaying the circulatory complications related to peripheral arterial disease.

Furthermore, Kwan et al. [21], reported that PEMF has an anti-inflammatory effect and enhances cell proliferation through its assured effect on capillaries and it also has a positive effect on improving microcirculation in people with diabetes and atherosclerosis. In addition, PEMF application has significantly increased the diameter of the capillaries (14%) and has significantly improved blood flow velocity (28%). They concluded that PEMF may be a valuable modality for the management of diabetic patients with ischemic injury [20]. Jacobson et al., also reported that The anti-inflammatory effect of pulsed magnetic fields was due to their magnetic activity, which was independent of any heat generated by the fields themselves, and was most likely accomplished by altering cell membrane potential and affecting ionic flux which reduces inflammatory edema and hematoma development [22].

Regarding the Antioxidant effect of PEMF, Mert et al. [23] reported that PEMF has grown in popularity as a non-invasive treatment for diabetes and its complications. PEMF was

shown to affect MDA, NO, MPO, SOD, and GSH levels, as well as regulation of diabetes-related harm by reducing oxidative stress and increasing antioxidant levels. PEMF affects the levels of oxidants including malondialdehyde (MDA), nitric oxide (NO), and myeloperoxidase (MPO), as well as antioxidants like glutathione (GSH) and superoxide dismutase (SOD) [23].

Regarding the pain-relieving effect of PEMF, Sweeney et al [24], reported that pulsed electromagnetic field has Myorelaxation and Spasmolytic effects (blood flow improvement, blood vessel relaxation, washing out of acidic metabolites that cause painful irritation), both of which could have a role in relieving muscle pain and/or increasing pain threshold during walking with consequent improvements in walking distance. Rohde et al [25] reported numerous mechanisms that might explain the pain-relieving effects of PEMF treatment. They showed that PEMF treatment increases the anti-inflammatory cytokine interleukin (IL)-1 and decreases the proinflammatory cytokine IL-1b, which is a strong hyperalgesic mediator and a nociceptors stimulator, through direct and indirect pathways. Besides, IL-1b was reported to modify the neuronal excitability through an effect on neuronal receptors such as gamma-aminobutyric acid receptors and glutamate receptors, and ion channel protein found in nerve cells, and through its influence on the release of nociceptive molecules such as IL-6, and prostaglandins [25].

Furthermore, PEMF was shown to have a strong analgesic effect by its significant effect on the synthesis and release of nitric oxide (NO), as there was an inverse correlation between pain intensity and NO levels. PEMF has been also suggested to enhance the endogenous opioid precursor proteins [26]. Awa et al. [27] also, reported that PEMF was more effective than aerobic exercise in the management of pain and improvement of quality of life in patients with primary dysmenorrhea, with statistically significant difference regarding VAS and Quality of life [27].

Concerning the vasodilatory effect of PEMF, it has been shown that within the muscles under the magnetic field, there was an efflux of the Ca^{2+} ion from muscle cells which causes relaxation of muscle blood vessels and precapillary sphincters inducing a vasodilating effect [24]. Also, Bragin et al [28] reported that PEMF treatment for thirty minutes induced vasodilation of cerebral arterioles that leads to an increase in microvascular blood flow and tissue oxygenation. The effects of PEMF were mediated by NO, the most important vasodilator that leads to the improvement of microcirculation and enhancement of functional transport of blood. Smith et al. [29] also reported that PEMF application can elicit significant arteriolar Vasodilation with, a significant increase of arterial diameter with 8.7% percentage, after one hour of application of PEMF. They also reported that there was no difference in response to PEMF between small and large arterioles [29].

With regard to the angiogenetic effect of PEMF, it was shown that PEMF induced collateral growth that reflected vascular structural remodeling, which was based on both growth factor activity and increased nitric oxide bioavailability, explained by Roland et al. [30], who reported a significant increase in angiogenesis in vivo model of neovascularization after PEMF application. The application of PEMF increased the endothelial

cell proliferation coupled by an acceleration in the process of wound healing [30]. Besides, PEMF was reported to enhance ischemia-related perfusion and endothelial dysfunction and angiogenesis, associated with upregulating fibroblast growth factor (FGF)-2 expression and activating the extracellular signal-regulated kinase (ERK)1/2 pathway [31]. In addition, PEMF was reported to be a useful supplementation to diabetic patients with lower limb vascular occlusion and amputation, as a result of, their ability to greatly improve ischemia-related perfusion and neovascularization [32].

The circulatory effect of PEM was explained by the increased response of fibroblast growth factor-2 (FGF-2), angiogenesis, and the induction of endothelial proliferation [9]. Besides, it could be attributed to the increased response of nitric oxide cascades. PEMFs have been shown to influence the calcium-binding kinetics to calmodulin, which increases the rate of Ca^{2+} binding to CaM, which then catalyzes cNOS (e.g., eNOS), resulting in an immediate (seconds) production of NO, resulting in increased blood and lymph flow. NO, on the other hand, regulates cGMP production (within minutes), which cascades to the appropriate growth factor release dependent on the stage of healing (eg., FGF-2 for angiogenesis) [33].

Furthermore, Kim et al. [34] concluded that PEMF can be successfully applied to patients with circulatory disorders inducing significant improvement of blood flow and management of the symptoms associated with these conditions. Besides, Nikolaeva et al. [35] have clarified that PEMF stimulation could promote neovascularization and improve perfusion. Rikk et al. [36] also reported a significant reduction in both systolic and pulse blood pressure, which might be related to improvements in peripheral vascular resistance or, circulation and this, in turn, has a positive impact on the overall patient's well-being due to improved walking distance, which directly enhances a greater motivation for movement and less claudication pain, and better quality of life [36].

It worth mentioning that, Jiahui et al. [37] reported a significant increase in peripheral blood flow velocity in the dorsal foot following PEMF stimulation, which explained the effect

of PEMFs on peripheral blood circulation. In addition, Markov [38], reported beneficial effects of PEMF in terms of increased production of ATP, increased oxygen and nutrient supply through the vascular system, improved waste products removal through the lymphatic system, and enhanced ions distribution across the cell membrane. These effects can have a role in pain reduction and muscle power improvement resulting in improvement in the functional walking capacity in patients with PAD (fontaine stage II) who cannot share in exercise therapy.

There are some limitations in the current study that include a short treatment period and lack of long-term follows up for patients after treatment. Also, there was a lack of assessment of the effect of PEMF on PAD biomarkers (NO level, CRP level), Flow-mediated dilation (FMD), arterial diameter, and/or blood flow velocity in patients with PAD.

Recommendations

Further studies are needed to examine the effect of PEMF on endothelial biomarkers (nitric oxide and c-reactive protein level) and quality of life (Walking Impairment Questionnaire) in patients with PAD. Similar studies should be extended to a longer period of time than 2 months to confirm the efficacy of PEMF, and also to evaluate the effect of PEMF on different stages of PAD.

Conclusion

PEMF could be suggested as a new and effective noninvasive therapeutic modality that may help patients with PAD (Fontaine stage II) to improve their functional walking capacity. Also, PEMF can be proposed as an alternative to exercising especially for PAD patients who cannot adhere to exercise training programs. Nevertheless, further studies are needed to confirm our results.

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