УДК 616.13-005.4-085.849.1
DOI 10.17802/2306-1278-2025-14-2-146-154

ONLINE

ВЛИЯНИЕ ЭЛЕКТРОМАГНИТНОЙ ТЕРАПИИ НА БОЛЕВОЙ СИНДРОМ И ГЕМОДИНАМИКУ ПРИ ЗАБОЛЕВАНИЯХ ПЕРИФЕРИЧЕСКИХ АРТЕРИЙ

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Основные положения

• Перемежающаяся хромота нижних конечностей является важным симптомом, указывающим на наличие заболеваний периферических артерий.

• Импульсная электромагнитная полевая терапия в сочетании с восстановительными физическими упражнениями представляет собой новый метод, рекомендованный для лечения перемежающейся хромоты нижних конечностей, вызванной заболеванием периферических артерий.

Актуальность	Несмотря на улучшение состояния в покое, перемежающаяся хромота нижних конечностей является важным симптомом у пациентов с заболеваниями периферических артерий (ЗПА). Улучшение вазодилатация/ангиогенеза у пациентов с проблемами кровообращения и добавление импульсной электромагнитной полевой терапии к физическим упражнениям по реабилитации является новым рекомендованным способом лечения перемежающейся хромоты нижних конечностей, вызванной ЗПА.
Цель	Оценка влияния добавления импульсной электромагнитной полевой терапии к упражнениям на эллиптическом тренажере на сосудистую гемодинамику, функциональные показатели и качество жизни у пациентов с ЗПА.
Материалы и методы	Пожилые пациенты с ЗПА были рандомизированы в две группы: первая (n = 20) – тренировки на эллиптических тренажерах и фармакотерапия, назначенная врачом для лечения ЗПА; вторая (группа наблюдения, n = 20) – эллиптические тренажеры и фармакотерапия, назначенная врачом для лечения ЗПА, дополненные импульсной электромагнитной полевой терапией. Курс электромагнитной терапии и тренировок на эллиптических тренажерах длился 8 нед. (3 раза в неделю). Проанализированы следующие показатели: лодыжечно-плечевой индекс, диаметр задней большеберцовой артерии, время появления боли при хромоте в нижних конечностях, дистанция ходьбы при хромоте в нижних конечностях, модифицированная оценка функции ходьбы, краткая форма оценки здоровья SF-36, оценка качества жизни, суммарный балл краткосрочной физической работоспособности, модифицированный тест шестиминутной ходьбы и общая дистанция шестиминутной ходьбы.
Результаты	Установлено, что упражнения на эллиптических тренажерах в сочетании с электромагнитной терапией эффективнее воздействуют на гемодинамические и функциональные показатели, чем изолированные тренировки на эллиптических тренажерах.
Заключение	Полученные гемодинамические и функциональные результаты тренировок на эллиптических тренажерах у пожилых людей с ЗПА могут быть улучшены при добавлении к тренировкам электромагнитной терапии.
Ключевые слова	Электромагнитная терапия • Упражнения на эллиптическом тренажере • Перемежающаяся хромота • Заболевания периферических артерий • Пожилые люди

Поступила в редакцию: *13.09.2024;* ***поступила после доработки:*** *30.11.2024;* ***принята к печати:*** *26.12.2024*

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THE IMPACT OF ELECTROMAGNETIC THERAPY ON PAIN AND HEMODYNAMICS IN PERIPHERAL ARTERIAL DISEASE

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Highlights

• Intermittent claudication in the lower limbs is a bothersome symptom in patients with peripheral arterial disease (PAD).

• Pulsed electromagnetic therapeutic modality (PEMTM) is a newly recommended intervention for managing PAD-induced lower-limb intermittent claudication when added to exercise rehabilitation.

Background Despite the improvement with rest, lower-limb intermittent claudication is a bothersome issue/symptom in patients with peripheral arterial disease (PAD). Utilizing its benefits in increasing vasodilation/angiogenesis in patients with circulatory disorders/issues, adding pulsed electromagnetic therapeutic modality (PEMTM) to exercise rehabilitation of PAD is a newly recommended intervention in managing PAD-induced lower-limb intermittent claudication.

Aim To check the effects of adding PEMTM to elliptical exercise on vascular hemodynamics, functional outcomes, and quality of life in PAD sufferers.

Methods PAD older men were assigned randomly into the group of elliptical exercise (n = 20, received only elliptical exercise and by-physician prescribed for-PAD pharmacotherapies) or study group (n = 20, received PEMTM, elliptical exercise, and by-physician prescribed for-PAD pharmacotherapies). The eight-week PEMTM or elliptical exercise was applied 3 times weekly. The following outcomes were evaluated: PAD patients' ankle brachial index test, diameter of posterior tibial artery, lower-limb claudication pain time, lower-limb claudication pain distance, modified walking-impairment questionnaire, short-form-36 health survey, disease-specific quality-of-life evaluation by the intermittent claudication questionnaire, summation score of short physical performance battery, pain-free six-minute walked distance, and the total six-minute walked distance.

Results The present paper showed a significant effect of elliptical exercise alone or combined with PEMTM on all measured parameters with a significant superiority to the combined application of elliptical exercise and PEMTM.

Conclusion Gained hemodynamic and functional benefits of elliptical exercise in PAD elderly could be magnified by adding PEMTM to elliptical exercise.

Keywords Electromagnetic therapy • Elliptical exercise • Intermittent claudication • Peripheral arterial disease • Elderly

***Received:** 13.09.2024; **received in revised form:** 30.11.2024; **accepted:** 26.12.2024*

Список сокращений

DSQoLE-ICQ – disease-Specific Quality-of-Life – Evaluation by The Intermittent Claudication Questionnaire
PAD – peripheral arterial disease
PEMTM – pulsed electromagnetic therapeutic modality
SF36HS – short Form-36 Health Survey

Introduction

Peripheral arterial disease (PAD) is a common atherosclerotic vascular disease in the older population. It is an atherosclerotic occlusive disorder of arterial vessels, excluding coronary and intracranial arteries. PAD's worldwide prevalence exceeds 200 million people. The hallmark/main PAD symptom is the lower-limb intermittent claudication, described as reproducible physical exertion-induced cramping/spasm and/or pain in the PAD patient's lower extremities, which is rapidly relieved with rest or stopping the physical exertion [1].

PAD patients with lower-limb intermittent claudication usually avoid any physical exertion. This avoidance induces weakness of lower limb muscles, changes of gait and/or lower limb biomechanics, impairment in walking performance, decline in functional performance of daily life activities, and decline in PAD patients' quality of life [2].

The available for-PAD vascular surgical interventions are expensive, associated with repeated hospitalizations, and repeated long-term revascularization procedures. With the reported problems of vascular interventions, exercise rehabilitation is the for-PAD recommended regular first-line therapy. Exercise not only improves PAD patients' cardiovascular/physiological parameters, functional outcomes, and walking-associated pain and distance but also adds better control of abnormal cardiovascular/metabolic profile (hypertension, hyperglycemia, excess weight, and hyperlipidemia) [3].

The good choice of exercise modality has a good impact on PAD patients' adherence to exercise sessions. Due to the low impact/stress of the upper body's weight on lower limb joints and low risk of falls, the good fitting of elliptical trainers to sufferers with knee/back pains, excess weight, frailty, osteoporosis, and sedentary lifestyle makes them prefer elliptical trainers more than bicycles or treadmills during exercise rehabilitation sessions [4]. Moreover, it is documented that using elliptical trainers in the rehabilitation program of patients with cardiovascular risk factors significantly improved their hypertension, hyperglycemia, excess weight, and hyperlipidemia. Improvement of these parameters or risk factors not only improves quality of life but also may improve PAD-associated hallmark symptom, lower-limb intermittent claudication [5].

On the other hand, pulsed electromagnetic therapeutic modality (PEMTM) is a relatively new promising physiotherapeutic tool that employs an electrical current to steer successive magnetic pulses into wounds/ulcers, malfunctioning neurons, non-united fractured bones, inflamed joints, and/or partially obstructed arteries. These magnetic pulses/waves produce a very fine electrical signal that induces a local cellular repair in malfunctioning tissues. Numerous clinical physiotherapeutic trials reported a significant role of PEMTM in improving chronic disease-associated soft tissue dysfunctions, inflammatory reactions, muscular discomfort, and pain [6].

Published reports document a significant role of PEMTM in improving chronic cardiovascular disorders including those associated with vasoconstriction (e.g., coronary artery vasospasm/atherosclerosis and increased systemic/peripheral vascular resistance), thrombotic and clotting dysfunctions (e.g., elevated platelet aggregation and increased levels of coagulation factors), inflammation (e.g., increased number of leukocytes and endothelial adhesive molecules), and vascular hypertrophy/stenosis (increased accumulation of lipids on in the inner arterial walls) [7].

With the great above-mentioned benefits of elliptical exercise and PEMTM in cardiovascular disorders, this study aimed to assess: 1) the effect of elliptical exercise on PAD-associated functional outcomes, vascular hemodynamics, and lower-limb intermittent claudication-associated pain in PAD elderly which was not assessed before; 2) the effect of adding PEMTM to elliptical exercise on PAD-associated functional outcomes, vascular hemodynamics and lower-limb intermittent claudication-associated pain in PAD elderly.

Methods

Design

A randomized PAD trial.

Setting

Forty PAD men were randomly recruited from A local teaching hospital (El-Sahel Teaching Hospital).

Ethics

This PAD research was clinically/legally approved by "Cairo University Local ethical committee" (No: P.T.REC/012/004285). The included PAD men in this study were consented.

Criteria of PAD men

The random selection of 40 PAD patients whose age was ≥ 65 years old was performed by the authors. All PAD men complained of lower-limb intermittent claudication during exertion (i.e. symptomatic PAD men. The included men's value of the ankle-brachial-index test (the value achieved from dividing the PAD patient's systolic blood pressure of one of the ankle arteries by the PAD patient's systolic blood pressure of the brachial artery) ranged between 0.8 to 0.6. The PAD men's body mass index was < 30 kg/m^2.

Patients with benign/malignant malignancies, cardiac insults or pacemakers, spinal disc herniation, ischemic ulcers or gangrenous tissues in lower limbs, arthritis/amputation of lower limb(s), previous angioplasty or vascular surgical interventions, present history of current smoking, and respiratory insults, uncontrolled diabetes and/or hypertension were excluded.

Randomization

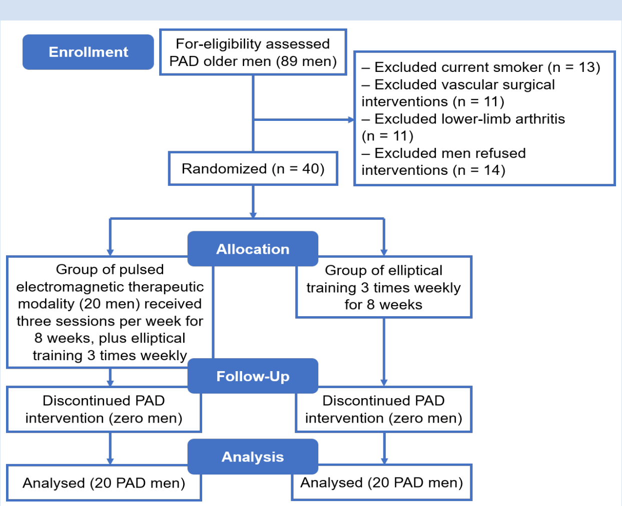
The envelop technique randomly assigned PAD older men to a group of elliptical exercise (n = 20, received only elliptical exercise and by-physician prescribed for-PAD pharmacotherapies) or study group (n = 20, received PEMTM, elliptical exercise, and by-physician prescribed for-PAD pharmacotherapies). *Figure* is the randomization chart of this PAD trial. Not participating in the implementation of the recruitment program of men, execution of elliptical exercise or PEMTM program, or examining patients was a requirement for the physical therapist carrying out the randomization mission.

Elliptical training

Both PAD groups received three sessions of low-to moderate-intensity elliptical exercise per week for 8 weeks on an elliptical trainer (made in China). Before and after every scheduled supervised elliptical exercise session, PAD men achieved a series of 5-minute lower-limb stretching/flexibility exercises. During each session of elliptical exercise, PAD men were directed to perform elliptical exercise to the point of lower-limb intermittent claudication-associated severe pain (score 8), and then take a rest on a chair. As soon as the lower-limb intermittent claudication-associated pain was relieved, they were directed to resume their elliptical exercise. The severity of lower-limb intermittent claudication-associated pain was classified/graded on a visual analogue scale of 1 – 10 : 0 = no lower-limb intermittent claudication-associated pain, 1 = onset of lower-limb intermittent claudication, 5 = lower-limb intermittent claudication-associated moderate pain, 8 = lower-limb intermittent claudication-associated severe pain, and 10 = lower-limb intermittent claudication-associated maximal claudication pain [8]. This cycle (elliptical exercise, followed with rest, then ended by elliptical exercise) was repeated several times during the one-hour supervised session of elliptical exercise.

PEMTM

PAD participants of the study group received a 3-session PEMTM per week for 8 successive weeks. The session of PEMTM intervention was continued for 60 minutes in a supine position. The 70 cm solenoid of the PhysioMG-827 electromagnetic therapy device/unit (ASTAR, Polish manufacturing) was set to be placed/directed over PAD men's legs, ankles, and feet. The PAD men's legs, ankles, and feet were positioned at the center of the space formed by the 70 cm solenoid, close to the center of the wall of the unit's applicators. Each PAD man received a detailed description of the PhysioMG-827 electromagnetic therapy device/unit and the trial's treatment plan.



Participating PAD men in group of exercise or group of electromagnetic therapy plus exercise

Note: *PAD – peripheral arterial disease.*

Primary outcome

PAD patients' ankle brachial index test

Before starting PEMTM intervention, PAD patients' resting ankle brachial index test was used to validate/confirm PAD diagnosis and to categorize the grade of lower-limb intermittent claudication for each man. After ending the PEMTM intervention, ankle brachial index test was performed again to assess the efficacy of PEMTM. Using a Doppler unit (Siemens Acuson X300, German manufacturing), under the supervision of an ultrasonography specialist, ankle brachial index test was detected. The PAD patients' right posterior tibial artery, PAD patients' right dorsalis pedis artery, and PAD patients' right brachial artery were checked for their systolic blood pressure. The perfect value of ankle brachial index test was then pointed by dividing the greater pressure magnitude between the PAD patients' dorsalis pedis artery and the PAD patients' posterior tibial artery by the PAD patients' systolic arm pressure. The PAD patients' left side underwent the identical process/steps [9]. The ankle brachial index test magnitudes measured on PAD patients on the right and left sides were recorded, and the lower number of PAD patients on each side was taken into consideration as the overall ankle brachial index test [10, 11].

Secondary outcomes

Diameter of posterior tibial artery

Using the Doppler unit, under the supervision of an ultrasonography specialist, PAD patients' diameter of the posterior tibial artery was assessed. In both groups, it was measured on the side of the lowest value of ankle brachial index test.

Lower-limb claudication pain time and lower-limb claudication pain distance

Using an electrically operated/automated treadmill, a physiotherapist supervised the PAD patients' performance of on-treadmill graded exercise testing before and after the application of PEMTM intervention to calculate lower-limb claudication pain time and lower-limb claudication pain distance. At the start of the test, all PAD patients were supervised during the 3-minute walking (start of the test) on the horizontally inclined treadmill (0% inclination and a pace/speed of 3.2 km/h). After that, the test treadmill's slope/inclination was gradually raised by 3.5% every three-minute walking while the test treadmill's speed remained unchanged/fixed. The PAD patients' walking on the test treadmill was continued until they experienced the highest non-tolerated level of leg claudication pain, at which the performance of the on-treadmill graded exercise test had to be stopped. The used treadmill has a digital screen that calculated the time taken for the appearance of lower-limb claudication pain time (if this time increased after using PEMTM intervention, it was considered an improvement in lower-limb claudication pain distance). Also, the used treadmill has a digital screen that calculated the distance taken for the appearance of lower-limb claudication pain distance (if this distance increased after using PEMTM intervention, it was considered an improvement in lower-limb claudication pain distance) [12].

PAD patients' modified walking-impairment questionnaire

Four-category walking disability were assessed in modified walking-impairment questionnaire. The first category contained two items that assessed pain/aching in calves and buttocks, respectively, with a five-Likert scaled response (zero means no difficulty/pain and 5 means great difficulty/pain). The second category contained six items that assessed pain/difficulty during around-home walking, 50-feet walking, 150-feet walking, 300-feet walking, 600-feet walking, 900-feet walking, and 1 500-feet walking. The third category contained four items that assessed pain/aching while walking one block slowly, walking one block at average speed, walking one block quickly, and running/jogging on one block. The fourth category contained four items that assessed pain/aching during climbing one, two, or three flights of stairs. All items of the second, third, and fourth categories were evaluated with six Likert-scaled responses [13].

PAD patients' Short Form-36 Health Survey (SF36HS)

In this PAD trial, we scored the total summation of all SF36HS domains (PAD patients' physical function, PAD patients' bodily pain/tenderness, PAD patients' vitality, PAD patients' mental/psychological health, PAD patients' role restrictions/limitations due to physical issues/problems, PAD patients' overall/general health satisfaction/perceptions, PAD patients' social conditioning/functioning, and PAD patients' role restrictions/limitations due to emotional issues/problems) [13].

Disease-Specific Quality-of-Life Evaluation by The Intermittent Claudication Questionnaire (DSQoLE-ICQ)

In patients with lower-limb intermittent claudication, this questionnaire is validated to be used in the assessment of sufferers' health-associated quality of life [14]. The 16-item DSQoLE-ICQ is scored from a 5-Likert or 6-Likert adjectival scale. The total score of the 16-item DSQoLE-ICQ is equally weighted and transformed to a zero-100 scale, where the minimum score, zero, is the best PAD-related possible health state, while 100 is the PAD-related worst possible health state [1].

Summation Score of Short Physical Performance Battery

The three components of this test were evaluated. The first component was a four-meter walking velocity (a reflection of PAD patients' gait speed). The second component evaluated the five repetitions of chair standing. The third component evaluated the different forms of standing balance such as side-to-side, semi-tandem, and tandem standing. The PAD patients' SS-SPPB ranges from 0–12 (0 means the lowest physical performance during the test while 12 means the highest physical performance during the test) [15].

Pain-free six-minute walk distance and total six-minute walked distance

Pain-free six-minute walked distance and the total walked distance during the six-minute walking test were assessed in PAD groups.

Statistical analysis

To analyze PAD men's data, the paired test of version-18 SPSS (Windows version 18) was used. The PAD patients' significance of any tested variable was < 0.05. As mean ± standard deviation, results of demographic data (body mass index, pack-years of smoking, age, and duration of lower-limb intermittent claudication) or paired tests (used to compare between pre- and post-values of pain-free six-minute walked distance, diameter of posterior tibial artery, DSQoLE-ICQ, ankle brachial index test, SF36HS, lower-limb claudication pain time, modified walking-impairment questionnaire, lower-limb claudication pain distance, total six-minute walked distance, and summation score of short physical performance battery) are expressed. All data showed normal distribution as support by the results of Kolmogorov–Smirnov testing.

Results

As shown in Table 1 and Table 2, a comparison of pre-treatment demographic data (pack-years of smoking, duration of lower-limb intermittent claudication, age, and body mass index) or assessed data (pain-free six-minute walked distance, diameter of posterior tibial artery, DSQoLE-ICQ, ankle brachial index test, SF36HS, lower-limb claudication pain time, modified walking-impairment questionnaire, lower-limb claudication pain distance, total six-minute walked distance, and summation score of short physical performance battery) between PAD groups showed a non-significant difference.

Table 1. Groups' mean ± SD of PAD-associated demographic and PAD-related data

	PEMTM plus elliptical exercise group	Elliptical exercise group	P value
Age of PAD men (years)	71.10 ± 3.82	70.60 ± 3.48	0.667
Body mass index of PAD men (kg/m^2)	26.42 ± 1.98	27.11 ± 1.57	0.229
Duration of intermittent claudication (months)	43.70 ± 4.60	43.65 ± 4.73	0.973
PAD men pack-years of smoking	61.90 ± 5.14	59.45 ± 4.38	0.113

Note: *P value > 0.05, hence significance is not achieved; PAD – peripheral arterial disease; PEMTM – pulsed electromagnetic therapeutic modality; SD – standard deviation.*

Table 2. PAD men's results after ending the exercise alone or exercise plus PEMTM

PAD men's parameters	PEMTM plus elliptical exercise group	Elliptical exercise group	P value (between PAD men groups)
Ankle brachial index test of PAD men	**Mean ± SD**	**Mean ± SD**	
Before	0.71 ± 0.06	0.70 ± 0.07	0.630
After	0.80 ± .07	0.75 ± .07	0.02*
p-value (within PAD group)	< 0.001 *	< 0.001*	
Diameter (mm) of posterior tibial artery (measured on the side of lowest value of ankle brachial index test in PAD men)	**Mean ± SD**	**Mean ± SD**	
Before	1.31 ± 0.20	1.27 ± 0.19	0.520
After	1.71 ± 0.18	1.37 ± 0.28	0.0001*
p-value (within PAD group)	< 0.001 *	< 0.001*	
Lower-limb claudication pain time (seconds) in PAD men	**Mean ± SD**	**Mean ± SD**	
Before	272.90 ± 53.87	275.25 ± 62.73	0.899
After	470.65 ± 61.97	411.15 ± 67.53	0.006*
p-value (within PAD group)	< 0.001*	< 0.001*	
Lower-limb claudication pain distance (meter) in PAD men	**Mean ± SD**	**Mean ± SD**	
Before	154.20 ± 32.88	149.15 ± 33.89	0.635
After	305.50 ± 33.20	245.15 ± 33.18	0.0001*
p-value (within PD group)	< 0.001 *	< 0.001 *	
Items of Four-Category Modified walking impairment questionnaire	**Mean ± SD**	**Mean ± SD**	
Before	63.8500 ± 12.27	70.30 ± 15.16	0.147
After	52.90 ± 11.90	62.55 ± 14.24	0.025*
p-value (within PAD group)	< 0.001 *	< 0.001 *	
Pain-free six-minute walked distance (meter)			
Before	153.65 ± 67.79	155.10 ± 62.41	0.999
After	254.65 ± 69.84	190.75 ± 53.94	0.002*
p-value (within PAD group)	< 0.001 *	< 0.001 *	
Total six-minute walked distance (meter)			
Before	353.65 ± 38.63	364.35 ± 44.34	0.420
After	460.55 ± 38.05	401.35 ± 49.48	0.0001*
p-value (within PAD group)	< 0.001 *	< 0.001 *	
DSQoLE-ICQ	**Mean ± SD**	**Mean ± SD**	
Before	39.30 ± 5.69	40.25 ± 5.72	0.601
After	28.40 ± 5.58	33.15 ± 7.84	0.033*
p-value (within PAD group)	< 0.001 *	< 0.001*	
PAD men's Short Form 36 Health Survey	**Mean ± SD**	**Mean ± SD**	
Before	42.80 ± 3.36	40.25 ± 6.11	0.110
After	48.35 ± 3.34	42.75 ± 6.25	0.001*
p-value (within PAD group)	< 0.001*	< 0.001*	
PAD men's summation score of short physical performance battery	**Mean ± SD**	**Mean ± SD**	
Before	6.15 ± 1.87	6.10 ± 2.04	0.936
After	9.05 ± 1.50	7.20 ± 2.04	0.002*
p-value (within PAD group)	< 0.001*	< 0.001*	

Note: ** P value < 0.05, hence significance is achieved; DSQoLE-ICQ – Disease-specific quality-of-life evaluation by The Intermittent Claudication Questionnaire; PAD – Peripheral arterial disease; PEMTM – Pulsed electromagnetic therapeutic modality; SD – Standard deviation.*

As shown in Table 2, to test the efficacy of elliptical exercise alone or combined with PEMTM, pre and post-values of PAD men's evaluated outcomes were compared within groups. The group that received elliptical exercise alone or the group that received elliptical exercise connected with PEMTM showed a significant improvement in pain-free six-minute walked distance, diameter of posterior tibial artery, DSQoLE-ICQ, ankle brachial index test, SF36HS, lower-limb claudication pain time, modified walking-impairment questionnaire, lower-limb claudication pain distance, total six-minute walked distance, and summation score of short physical performance battery but the group that received elliptical exercise and PEMTM showed the higher improvement.

Also, as shown in Table 2, to test the efficacy of elliptical exercise alone or combined with PEMTM between PAD groups, post values of PAD men's evaluated outcomes were compared between groups. The group that received elliptical exercise connected with PEMTM evoked a significant improvement in pain-free six-minute walked test, diameter of posterior tibial artery, DSQoLE-ICQ, ankle brachial index test, SF36HS, lower-limb claudication pain time, modified walking-impairment questionnaire, lower-limb claudication pain distance, total six-minute walked distance, and summation score of short physical performance battery.

Discussion

The present paper showed a significant effect of elliptical exercise alone or combined with PEMTM on PAD-associated pain-free six-minute walked distance, diameter of posterior tibial artery, DSQoLE-ICQ, ankle brachial index test, SF36HS, lower-limb claudication pain time, modified walking-impairment questionnaire, lower-limb claudication pain distance, total six-minute walked distance, and summation score of short physical performance battery with a significant superiority to the combined application of the exercise with PEMTM in older PAD men.

Many cardiovascular risk factors such as alcohol drinking, diabetes, sedentary lifestyle, obesity, smoking, repeated stress exposure, hypertension, and dyslipidemia evoke the development of PAD [16, 17]. The benefits of elliptical exercise are proven to correct cardiovascular risk factors that trigger the development of PAD and its symptoms/signs. As supported by previous recent studies [4, 5], regular elliptical training regulates/corrects body mass, insulin resistance [4], and metabolic syndrome components including local obesity of abdomen, high/uncontrolled levels of blood pressure and glucose, abnormal levels of lipids (triglycerides and/or high-density lipoprotein) [4, 5].

Exercise-induced correction of cardiovascular risk factors or metabolic syndrome components may correct the PAD-associated endothelial dysfunction of patients' lower limb vessels, hence the perception of lower-limb intermittent claudication reduces. Increased exercise-induced production of endothelial nitric oxide synthase that stimulates an increased rate of nitric oxide release improves the relaxation of lower-limb vessels. This relaxation, especially during exercise training increases blood flow to PAD patients' lower limbs. This increased blood flow not only reduces vascular inflammation burden but also decreases the frequency of the perception of the lower-limb intermittent claudication, PAD-associated pain, restricted vascular hemodynamics, low physical performance/functioning, and poor quality of life improvement [18].

Also, on the other hand, the present paper showed that adding PEMTM to elliptical exercise significantly increased the improvements in PAD-associated pain-free six-minute walked distance, diameter of posterior tibial artery, DSQoLE-ICQ, ankle brachial index test, SF36HS, lower-limb claudication pain time, modified walking-impairment questionnaire, lower-limb claudication pain distance, total six-minute walked distance, and summation score of short physical performance battery.

Multiple PEMTM-induced physiological effects may be suggested to explain the improved walking/physical performance, vascular hemodynamics, lower-limb intermittent claudication, and quality of life in PAD patients after the application of PEMTM. These effects may be justified by the increased blood flow (vasodilation due to the increased diameter of blood vessels and enhanced nitric oxide synthesis/release), formation of new blood vessels (neoangiogenesis due to enhanced proliferation/migration of vascular angiogenic endothelial cells), and decreased chronic inflammation induced by PAD-associated local ischemic effects/insults, and the corrected imbalance between increased walking-associated metabolic muscular demands (oxygen & nutrients) and limited blood supply to the working lower limb muscles [19].

The results of the presented investigation in our PAD patients were consistent with those of Markovi et al [20] whose randomized clinical trial reported a significant improvement in peak claudication distance and time after adding PEMTM to the for-PAD pharmacological interventions, interferential therapy, and low-burden kinesio-exercises.

The presented study's findings in our PAD patients were in line with those of Giusti et al [21] who reported significantly improved gait characteristics/dysfunctions (gait patterns, self-selected gait speed, and stride duration) in elderly with low bone mineral density who were treated by PEMTM. Furthermore, due to the significant improvement in blood pressure, flow-mediated dilation, and nitric oxide release, the results of Stewart et al [22] were consistent with our results after using PEMTM to enhance hypertensive sufferers' vascular activity.

These findings were consistent with the experimental study's findings of Bragin et al [23] who reported dilated cerebral arterioles after a 30-minute application of PEMTM in rats (the dilatation of vessels improved functional blood transport that mediated the positive effects of PEMTM). Again, consistent with us, improved capillary diameter and blood velocity may be the suggested causes of healed ulcers after using PEMTM in the treatment of diabetics with foot ulcers [19].

Deng et al [24] reported that PEMTM can improve increased muscular tension/claudication and spasm. PEMTM-induced elimination of acidic metabolites that induce local pain and inflammatory reactions, muscular spasm/tension, and limited blood circulation in the affected region may be the suggested explanation of the improved muscular claudication after using PEMTM. Also, the reported improvement in PAD-associated muscular spasm/claudication after the application of PEMTM may be due to the increased efflux of lactate dehydrogenase and calcium ions and lowered frequency/perception of LIC. This theory/suggestion is consistent with the findings of Pan et al [25] who found that 15-Hertz PEMTM enhanced ischemia-inducing limited blood perfusion, hence the frequency of intermittent claudication is liable to be highly improving.

Limitations

This study noticeably contained the loss of follow-up to the results of EE-plus-PEMTM or EE interventions. Also, comparing the response of PAD to pulsed electromagnetic filed versus other treatments such as laser therapy or shock wave therapy is another limitation of this trial. Future PAD trials may discuss these points/limitations.

Conclusion

The present paper showed a significant effect of elliptical exercise alone or combined with PEMTM on PAD-associated pain-free six-minute walked distance, diameter of posterior tibial artery, DSQoLE-ICQ, ankle brachial index test, SF36HS, lower-limb claudication pain time, modified walking-impairment questionnaire, lower-limb claudication pain distance, total six-minute walked distance, and summation score of short physical performance battery with a significant superiority to the combined application of the exercise with PEMTM in older PAD men.

Conflict of interest

O.S. Ahmed declares no conflict of interest. A.A. Abou Tahoun declares no conflict of interest. A.A. Ali declares no conflict of interest. M.N. Khattab declares no conflict of interest. H.A. El-Hadidy declares no conflict of interest.

Financial

Authors declare no research funding.

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Для цитирования: *Ахмед О.С., Абу Тахун А.А., Али А.А., Хаттаб М.Н., Ел-Хадидий Х.А. Влияние электромагнитной терапии на болевой синдром и гемодинамику при заболеваниях периферических артерий. Комплексные проблемы сердечно-сосудистых заболеваний. 2025;14(2): 146-154. DOI: 10.17802/2306-1278-2025-14-2-146-154*

To cite: *Ahmed O.S., Abou Tahoun A.A., Ali A.A., Khattab M.N., El-Hadidy H.A. The impact of electromagnetic therapy on pain and hemodynamics in peripheral arterial disease. Complex Issues of Cardiovascular Diseases. 2025;14(2): 146-154. DOI: 10.17802/2306-1278-2025-14-2-146-154*