Effect of Pulsed Magnetic Field Therapy Versus Aerobic Training on Peripheral Arteries in Type 2 Diabetes

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Abstract

Background: Diabetes mellitus is a group of metabolic diseases characterized by high blood glucose levels over a prolonged period of time, requiring continuous medical care and ongoing patient. Self-management education and support, to prevent acute complications and to reduce the risk of long-term complications.

Aim of Study: The main purpose of this study was to investigate and compare between the effect of pulsed electromagnetic field and aerobic exercises in treatment of atherosclerosis in type 2 diabetic patients.

Subjects and Methods: Forty atherosclerotic diabetic patients, with ages ranged from 45 to 55 years old, were recruited from Out Clinic of Faculty of Physical Therapy, Cairo University. They were assigned randomly to two equal groups; group A, which included 20 diabetic atherosclerotic patientswho received PEMF for with 15Hz frequency and 20 gauss intensity for 20min., while group B included 20 diabetic atherosclerotic patients who received aerobic exercise with 65-80% pf predicted max. heart rate. For both groups treatment conducted for 8 weeks, 3 sessions/week. Measurement of arterial blood flow and intimal thickness by Doppler ultrasonography were reported before and after 8 weeks of the treatment

Results: Within group comparison showed significant increase of arterial blood flow and significant reduction of intimal thickness in both groups in both groups (p<0.05). Comparison between post-treatment values between both groups showed non-significant difference.

Conclusion: It could be concluded that, PEMF and aerobic exercises are effective methods in treatment of arterial problems in type 2 diabetic patients.

Key Words: Pulsed magnetic field therapy – Aerobic training – Peripheral arteries – Type 2 diabetes.

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Introduction

DIABETES mellitus is a group of metabolic diseases characterized by high blood glucose levels over a prolonged period of time, requiring continuous medical care and ongoing patient self-management education and support, to prevent acute complications and to reduce the risk of long-term complications [1].

Lower extremity peripheral arterial disease is the third leading cause of atherosclerotic vascular complications in people with type 2 Diabtes Mellitus after coronary heart disease and stroke. About 10-20% of people with peripheral arteries disease have intermittent claudication, another 50% have atypical leg symptoms, and those without exertional leg pain have poor mobility compared with individuals without peripheral arterial disease. Patients with leg ischemic symptoms have roughly a three-fold increase in risk of mortality and major cardiovascular events (heart attack and stroke) compared with those without peripheral arterial disease [2].

The effect of magnetic fields suggests that in vitro EMFs may modulate some endothelial functions related to angiogenesis through the signal-transduction pathway dependent on the Vascular Endothelial Growth Factor (VEGF). Moreover, the application of weak or moderate intensity (EMFs) to intact or VEGF-A-stimulated vascular endothelial cells seems to promote or enhance arteriogenesis and effectively stimulate these cells [3].

Aerobic exercise training is an accepted therapeutic strategy in the management of type 2 diabetes mellitus because it improves the diabetic status, reduces the metabolic risk factor associated with cardiovascular diseases, and improves insulin sensitivity. Exercises has important effects on decreasing the development of cardiovascular complications, as it is defined as planned and structured activity that is aimed at improving cardiovascular health and metabolic control [4].

Subjects and Methods

Forty diabetic patients with Atheros-clerosis their ages were ranged from 45 to 55 years, they were selected from Outpatient Clinic of Faculty of Physical Therapy, Cairo University, to participate in this studywhich carried out from Jan. 2015 to May 2019 and the patients were subdivided into two equal groups. A consent form was obtained from each subject as an agreement to be included in the present study and the patients had all rights to withdraw from the study at any time without any responsibility.

This current study was designed to investigate and compare between the effect of pulsed magnetic field therapy and the effect of aerobic exercise on peripheral arteries in people with type 2 Diabetes Mellitus.

Design of the study: Two groups pre-test post-test design:

- *Group A (PEMF group):* This group included 20 diabetic atherosclerotic patients. They were received pulsed magnetic field with frequency 15 HZ and intensity 20 gauss for 20min. Treatment was conducted for eight weeks, (three sessions per week).
- *Group B (Aerobic exercise group):* This group included 20 diabetic atherosclerotic patients. They were participated in eight weeks aerobic training program (three sessions per week) with 65-80% of predicted maximum heart rate.

Criteria for patients selection: These criteria for patient selection were classified into two various criteria:

Inclusion criteria:

The patients were chosen under the following criteria:

• Age range from 45 to 55 years; 28 males and 12 femaleswere included; patients referred from physician of internal medicine diagnosed as controlled type 2 diabetes (HbA $_{1c} \le 6.5$ DCCT %) 5 years ago; suffer from mild to moderate degree of atherosclerosis and patient with BMI between 25 and 30kg/m^2 .

Exclusion criteria:

The current study excluded the following criteria:

• Pregnant women; presence of internal fixation and malignancy.

Equipment's:

Evaluating equipment's and methods:

Measurement and assessment were done before the starting of the exercise program and after 8 weeks for all groups. High resolution B-mode ultrasound device (Logic 400 CL Pro; GE Medical system, Milwaukee, WI, USA) was used to evaluate endothelialcellfunction by endothelial dependant vasodilation and atherosclerosis by measuring commonfemoral arteries intima-mediathickness.

Treatment equipment:

Pulsed electromagnetic field unit (for Group A treatment):

Pulsed electromagnetic field unit made by ASA in Italy was used in treatment of group A. It consists of an appliance, therapy bed with solenoid Ø 60cm. The device generates in low and medium frequency pulsating magnetic fields with square wave: 5-1 00Hz (E.L.F.) and 100-1000Hz (low and medium frequency) and sinusoidal wave: 1-100Hz. Peak intensity of the magnetic field: ≥100 gauss. The appliance was connected to electrical mains supplying 220v at frequency of 50HZ with earth connection.

Treadmill (for Group B treatment):

AC-Commercial AC MOTOR made in USA by American motion fitness was used for training. The maximum speed of treadmill is 61km/h. The treadmill can be inclined and lifting 150kg.

Procedures:

Patient history have been carefully taken to collect data about his general condition, physical activity and current medication.

The procedures of this study were divided in the following main parts:

Preparatory procedures:

- A- All medical and demographic data of subjects were collected and the role of physical therapy importance in improving their blood supply was explained.
- B- Before the initiation of treatment programs, a consent form was obtained from each patient as an agreement to be included in the present study.

- C- Resting heart rate (HRrest), maximum heart rate (HR_{max}) as well as target heart rate during exercise were determined for every patient.
- HR_{max}=220-age.
- Target heart rate can be calculated as a range of 65%-85% intensity according to Karvonen method. THR=((HR_{max} – HR_{rest}) X % intensity) + HR_{rest}.

Evaluation procedures:

B-mode ultrasound measurement of Intimal-medial Thickness (IMT) was used to detect the atherosclerotic process before the development of vessel stenosis. Endothelium dependent vasodiltationresponse in the common femoral arteries before and after the intervension were used to evaluate endothelial function. Blood flow velocity was assessed by pulsed Doppler spectral tracing before and after PEMF or aerobic exercise to detect the functional effect. Desired frequency of 7.5MHz transducer of a high resolution ultrasound device (Logic 400CL Pro; GE Medical system, Milwaukee, WI, USA) was used.

Treatment procedure:

Pulsed magnetic field procedures for group A:

This procedure was applied only for group A. Patient was placed in a comfortable relaxed position. The appliance was connected to electrical mains supplying 220v. The solenoid was adjusted to be over the pelvis and upper thigh area. The option of appliance was adjusted to have very low frequency (15HZ) and very low intensity (20G). The application Time was be 20min. The treatment was applied 3 times per week, for 8 weeks.

Exercise procedures in Group B:

Group B patients participated in a program of exercise with intensity of maximum heart rate with 65-80% of predicted maximum heart rate for and frequency of 3 times/week for 8 weeks. The session consisted of 5 minutes warm-up performed on the treadmill at low load followed by training period for 30 minutes and ended by 5 minutes cool down as following:

Warming up exercise:

The aerobic training program included a 5-min warm-up consisting of fast walking, slow running and stretching.

Exercise phase:

After warming up, continuous running was performed started by walking ~2.0mph increased gradually every 2 minutes to reach intensity of 60%-80% of the maximum heart rate of the partic-

ipant. The running period was 15min for the first session, and every two sessions 2 minutes were added to the running period in a stepwise manner until the running period reached 30min.

Cool down exercise:

At the end of each session, there was a cooldown period consisting of slow running and stretching for 5min.

Statistical procedures:

In this study, the descriptive statistics (the mean, the standard deviation, maximum, minimum and range) were calculated for all subjects in the study including height weight, BMI and common femoral arteries intima-media thickness variable.

Paired sample *t*-test was used to compare the difference between before treatment and after treatment results of common femoral arteries intima-media thickness in each group.

Independent sample *t*-test was used to compare the before and after treatment results in the study groups for all variable.

Correlation between variables was done using Pearson's correlation coefficient "r".

Results

The units of this chapter are presented under the following heads:

- 1- Result of statistical analysis of general characteristics of patients in both groups of the study (A and B).
- 2- Results of statistical analysis of arterial blood flow in both groups of the study (A and B).
- 3- Results of statistical analysis of intimal thickness in both groups of the study (A and B).
- 1- Result of statistical analysis of general characteristics of patients in both groups of the study (A and B): The collected data of general characteristics assessed before application of treatment (pre-treatment) for each patient in both groups of the study (PEMF group and Aerobic exercise group):
- *Group A (PEMF group):* As shown in (Table 1) Group A (PEMF group) consisted of 20 patients 15 males and 5 females, their mean age was (26.333±3.266) years, mean height was (166.067±5.548) cm, mean weight was (73.267±8.556) and mean BMI was (26.528±7.652).
- *Group B (Aerobic exercise group):* Also, Table (1) showed that Group B (Aerobic exercise group)

consisted of 20 patients 13 males and 7 females, their mean age was (26.867±4.533) years, mean height was (164.333±4.952) cm, mean weight was (71.533±7.652) and mean BMI was (26.512±2.845).

• Comparison between groups: As shown in Table (1) statistically there was non significant differ-

ence between both groups regarding age, (*p*-value =0.714), height (*p*-value=0.374), weight (*p*-value =0.563) or BMI (*p*-value=0.987).

Table (2) showed that there was non-significant difference in gender distribution between both groups (*p*-value=0.496).

Table (1): General characteristics of patients.

	Age (years)		Height (c.m)		Weight (k.g)		BMI	
Group	Group A (PEMF group)	Group B (Aerobic exercise group)						
Mean	26.333	26.867	166.067	164.333	73.267	71.533	26.528	26.512
± S.D.	3.266	4.533	5.548	4.952	8.556	7.652	2.468	2.845
Mean difference	-0.533		1.733		1.733		0.016	
<i>t</i> -value	-0.370		0.903		0.585		0.016	
<i>p</i> -value	0.714		0.374		0.563		0.987	
Level of significance	Non significant		Non significant		Non significant		Non significant	

- 2- Results of statistical analysis of arterial blood flow in both groups of the study (A and B):
- Group A (PEMF group): As shown in (Table 3) the mean value of arterial blood flow in Group A (PEMF group) before treatment was (145.419±16.267) cm/s, while the mean value of arterial blood flow after treatment was (153.538±26.685) cm/s. Statistically, there was small but significant increase of arterial blood flow after treatment (*p*-value <0.001) with percentage of improvement 5.6%
- Group B (aerobic exercise group): As shown in (Table 3) the mean value of arterial blood flow in Group B (aerobic exercise group) before treatment was (145.068±24.237) cm/s, while the mean value of arterial blood flow after treatment was (156.251±32.704) cm/s. Statistically, there was significant increase of arterial blood flow after treatment (*p*-value <0.001) with percentage of improvement 7.7%.
- Comparison between groups: Table (4) showed that there was non-significant difference in mean values of arterial blood flow before treatment between both groups (Group A (PEMF group) and Group B (Aerobic exercise group)) with (p-value=0.963) while there was non-significant difference between both groups (Group A (PEMF group) and Group B (aerobic exercise group)) after treatment (p-value=0.805).
- 3- Results of statistical analysis of intimal thickness in both groups of the study (A and B):
- Group A (PEMF group): As shown in (Table 5) the mean value of intimal thickness in Group A

- (PEMF group) before treatment was (5.36 ± 0.509) mm, while the mean value of intimal thickness after treatment was (5.12 ± 0.555) mm. Statistically, there was significant decrease of intimal thickness after treatment (p-value <0.001) with 4.5% percentage reduction.
- Group B (aerobic exercise group): As shown in (Table 5) the mean value of intimal thickness in Group B (aerobic exercise group) before treatment was (5.493±0.613) mm, while the mean value of intimal thickness after treatment was (5.16±0.643) mm. Statistically, there was a significant decrease of intimal thickness after treatment (*p*-value <0.001) with 6.1% percentage reduction.
- Comparison between groups: Table (6) showed that there was non-significant difference in mean values of intimal thickness before treatment between both groups [(Group A (PEMF group) and group B (aerobic exercise group)] with (*p*-value =0.522) again there was non-significant difference between both groups [(Group A (PEMF group) and Group B (Aerobic exercise group)] after treatment (*p*-value=0.857).

Table (2): Gender distribution in both groups.

Group		up A group)	Group B (Aerobic exercise group)		
Gender	Male F	emale	Male F	emale	
Frequency	15.000	5.000	13.000	7.000	
Percentage	0.750	0.250	0.650	0.350	
Mann-Whitney U	180.000				
Z	-0.681				
<i>p</i> -value	0.496				
Level of significance		Non significant			

Table (3): Comparison between arterial blood flow in group A (PEMF group) & group B (aerobic exercise group) before and after treatment.

Statistical tools		up A group)	Group B (Aerobic exercise group)		
Statistical tools	Before treatment	After treatment	Before treatment	After treatment	
Mean ± S.D	145.419	153.538	145.068	156.251	
	±16.267	±26.685	±24.237	± 32.704	
Mean difference	12.687		16.137		
% of improvement	6%		8%		
<i>t</i> -value	14.000		14.000		
<i>p</i> -value	0.000		0.000		
Level of significance	Significant increase		Significant increase		

Table (4): Comparison between arterial blood flow results of Group A (PEMF group) and Group B (aerobic exercise group) before and after treatment.

Theres	Before t	reatment	After treatment		
Item	Group A	Group B	Group A	Group B	
Mean ± SD	145.419± 16.267	145.068± 24.237	153.538± 26.685	156.251± 32.704	
Mean difference <i>t</i> -value <i>p</i> -value	0.351 0.047 0.963		-2.713 -0.249 0.805		
Level of significance	Non significant		Non significant		

Table (5): Comparison between intimal thickness results before and after treatment in Group A (PEMF group) and Group B (aerobic exercise group).

	Group A (PEMF group)		Group B (Aerobic exercise group)	
	Before treatment	After treatment	Before treatment	After treatment
Mean ± S.D	5.360±	5.120±	5.493±	5.160±
	0.509	0.555	0.613	0.643
Mean difference	0.128		0.223	
% of improvement	4%		6%	
t-value	14.0	000	14.000	
<i>p</i> -value	0.000		0.000	
Level of significance	Significant decrease		Significant decrease	

Table (6): Comparison between intimal thickness results of Group A (PEMF group) and Group B (Aerobic exercise group) before and after treatment.

	Before t	reatment	After treatment		
	Group A	Group B	Group A	Group B	
Mean ± SD	5.360±	5.493±	5.120±	5.160±	
	0.509	0.613	0.555	0.643	
Mean difference	-0.133		-0.040		
t-value	-0.648		-0.182		
<i>p</i> -value	0.522		0.857		
Level of significance	Non significant		Non significant		

Discussion

This study was conducted to investigate and compare between the effect of pulsed magnetic field therapy and the effect of aerobic exercise on peripheral arteries in people with type 2 diabetes mellitus.

The results of the study showed that:

The pre-treatment results of the present study revealed no significant difference between the mean values of arterial blood flow and or the intimal medial thickness of femoral arteries of the study groups. The post-treatment results of this study showed increase in the arterial blood flow after the treatment for Group (A) and (B) with a percentage of 5.6% and 7.7% respectively. Regarding intimal thickness pre and post-treatment comparison there was significant reduction in Group (A) and (B), by 4.5% and 6.1% respectively. While, the post-treatment results of the present study revealed non-significant difference of the mean values of arterial blood flow or intimal medial thickness variables between the two groups (pvalue > 0.05).

Therefore, the results of current study showed that there was a significant improvement in PEMF and aerobic exercise groups. This confirms the effectiveness of PEMF and aerobic exercise as therapeutic modality enhancing the arterial blood flow and reduce the intimal thickness in type 2 diabetic patients.

Regarding the effect of the PEMF on the arterial blood flow and internal thickness, our results came in consistnce with Smith et al., [5] results, who examined the acute effects of PEMF stimulation on arteriolar microvessel diameters in the rat cremaster muscle. The study showed that local PEMF stimulation produced significant (*p*<0.001) vasodilation, compared to pre-stimulation values, in cremasteric arterioles in anesthetized rats (n=24). This dilation occurred after 2min of stimulation (9% diameter increase) and after Ih of stimulation (8.7% diameter increase). Rats receiving "sham" stimulation (n=15) demonstrated no statistically significant change in arteriolar diameter following either "sham" stimulation period.

Our results came in agreement with Roland et al., [6] who demonstrated a significant increase in angiogenesis in vivo model of neovascularization in which rats received daily PEMF stimulation for 8-12 weeks. However, the acute vascular effects of PEMF were not investigated by these authors.

Our findings were supporting studis which proved that Extremely Low Frequency (ELF) Electromagnetic Fields (EMFs) coused activation of angiogenesis using cultured umbilical Human Vein Endothelial Cells (HUVECs). The cultures were exposed to a sinusoidal EMF to intensity of 1mT, 50Hz for up to 12h. EMFs increased the degree of endothelial cell proliferation and tubule formation, coupled by an acceleration in the process of wound healing. Also, the results suggesting that EMFs may modulate in vitro some endothelial functions correlated to angiogenesis.

Regarding the aerobic exercise group, the results of our study consistent with the works reported by Dinenno et al., [7] who conducted a study with two distinct moments, consisting of a cross-sectional analysis and an aerobic training intervention. The authors verified the influence of the aerobic training on arterial remodelling. In the first moment, the authors analysed 55 endurance-exercise trained men (47±2 years) and 53 sedentary men (47±2 years). Endurance-trained individuals were demonstrated to have a common femoral arteries lumen diameter 7% greater than sedentary individuals.

For the intervention study, Dinenno et al., [7] selected 22 individuals (51±2 years) from the sedentary group, who underwent a 3-month aerobic training. The individuals exercised 13.5±1.0 weeks, 5.3±0.3 days, 45±2min. per session, on average, at 73±1% of the maximum HR. After the training period, a 9% increase in the common femoral arteries lumen diameter was observed, along with a reduction by 14% and 20% in the intima-media thickness and in the intima-media/lumen ratio, respectively.

Our results confirmed the findings of Moreau et al., [8] who analyzed postmenopausal women and verified that both hormone replacement therapy and regular aerobic exercises were associated with a lower intima-media thickness ratio. Together, hormone replacement therapy and regular aerobic exercises promoted greater changes in the intimamedia thickness than each one separately. However, both the regular aerobic exercise group and the hormone replacement group were able to promote significant changes in the intima media thickness when compared to the sedentary group not treated with hormone replacement.

Also, our results came in agreement with Rauramaa et al., [9] who showed that atherosclerotic progression in middle-aged men who underwent

a 6-year moderate aerobic exercise program, subgroup of individuals not taking statins, and were analyzed with a carotid bifurcation ultrasonography (10MHZ). However, when a was analyzed separately, exercise was proven to be efficient in the reduction.

Our results also came in accordance with another study for Moreau et al., [10] who tested the effect of exercises on the Femoral Intima-Media Thickness (IMT) in 173 sedentary, moderately active, and endurance-trained young (20-39 years), middle-aged (40-59 years) and older (60-79 years) men. The study concluded that Femoral IMT increases with age even in habitually exercising adults. However, the age-associated increase and absolute level of IMT are smaller in middle-aged and older adults who perform regular aerobic-endurance exercise and may contribute to their lower incidence of atherosclerotic disease.

Conclusion:

It could be concluded that, PEMF and aerobic exercises are effective methods in treatment of arterial problems in type 2 diabetic patients.

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تآثير المجال المغناطيسي الكهريائي النابض مقابل التدريبات الهوائية على الشرايين الطرفية في مرضى السكرى من النوع الثاني

الغرض: كان الغرض الرئيسي من هذه الدراسة هو التحقيق والمقارنة بين تأثير المجال الكهرومغناطيسي النبضي والتمارين الهوائية في علاج تصلب الشرايين في مرضى السكري من النوع الثاني.

المواضيع: تم تجنيد أربعين مرضى تصلب الشرايين، تتراوح أعمارهم بين ٤٥ وه ه سنة، من عيادة خارجية لكلية العلاج الطبيعى جامعة القاهرة. تم تعيينهم بشكل عشوائى لمجموعتين متساويتين، المجموعة (أ)، التى تلقت العلاج المغناطيسى النبضى لمدة ٥٠ هرتز و٢٠ غاوس شدة لمدة ٢٠ دقيقة، فى حين تلقت المجموعة (ب) ممارسة التمارين الرياضية مع ٥٥-٨٠٪ وتوقع كحد أقصى. معدل ضربات القلب. لكلا المجموعتين العلاج أجريت لمدة ٨ أسابيع، ٣ جلسات/أسبوع. تم الإبلاغ عن قياس تدفق الدم الشرياني وسمك الأمعاء بواسطة الموجات فوق الصوتية دوبلر قبل وبعد ٨ أسابيع من العلاج.

النتائج: ضمن مقارنة المجموعة اَظهرت زيادة كبيرة في تدفق الدم الشرياني وإنخفاض كبير في سمك البطانة الداخلية للشرايين الطرفية في كلا المجموعتين المجموعتين المجموعتين ألمجموعتين ألمجموعتين ألمجموعتين.

الخلاصة: يمكن أن نستنتج أن العلاج المغناطيسى النبضى والتمارين الهوائية هي طرق فعالة في علاج مشاكل الشرايين لدى مرضى السكرى من النوع الثاني.