

EFFICACY OF PROGRESSIVE RESISTIVE EXERCISES ON ANKLE BRACHIAL INDEX IN CHRONIC LOWER LIMB ISCHEMIA

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ABSTRACT

Individuals with peripheral arterial disease (PAD) could experience increased pain, intermittent claudication (IC), disability, decreased gait distance, activity limitations in activities of daily living. The current study was aimed to investigate the efficacy of progressive resistive exercises on ankle brachial index in patients with chronic lower limb ischemia. Thirty male patients with symptomatic PAD aged from 50 to 60 years old were selected. They were randomly assigned into two groups equal in number; Patients in Group (A) received resistive exercise training program in the form of series of exercises using free weights in addition to their regular medical treatment, while Group (B) patients received their regular medical treatment only. Sessions were carried out three times per week, for a total of twelve week period. Ankle brachial pressure index (ABI) and body mass index (BMI) were recorded in the two groups at two intervals: the starting of the study (pre-training) and at the end of the 12 week (post training).

It was observed that there was non-significant change in ABI of study and control groups ($p > 0.05$). While there was a significant decrease in BMI of the study group post treatment compared with that pre-treatment ($p < 0.001$); and there was non-significant change in BMI of control group ($p > 0.05$). It could be concluded that application of progressive resistive exercise couldn't affect ankle brachial index in patients with peripheral arterial disease.

Key Words: Peripheral arterial disease, ankle brachial index , Resistive exercises.

INTRODUCTION:

Peripheral Arterial Disease (PAD) is a co circulatory problem arising from decreased blood flow, and is usually secondary to

atherosclerosis in the arteries of the lower limbs, (**Criqui and Aboyans, 2015**).

The most common sites for PAD are the iliac artery (in the lower torso), the femoral artery (in the groin), the popliteal artery (at the knee), and the tibial arteries (at the shin and calf), (**American Heart Association, 2011**).

The main recognized clinical presentations of PAD are intermittent claudication (IC) and critical limb ischemia (CLI). IC describes the symptoms of pain in the muscles of the lower limbs brought on by physical activity which is rapidly relieved by rest. CLI is a more severe manifestation of PAD, which presents as rest pain, ischemic ulceration or gangrene of the foot. Patients with CLI have a high risk of limb loss and fatal or non-fatal vascular events, such as myocardial infarction (MI) and stroke, (**Subherwal et al., 2015**).

If screened in its early stages, individuals with asymptomatic PAD can be effectively treated with appropriate exercise protocols or medications to prevent further complications, (**Garg et al., 2006 and Barak et al., 2009**).

Peripheral arterial disease associated atherosclerosis limits blood flow to the lower limbs and reduces functional capacity, lowers quality of life, and increases the risk of morbidity and mortality, (**Gerhard-Herman et al., 2017**).

Lower extremity peripheral arterial disease (PAD) affects 8.5 million men and women in the United States >200 million people worldwide, (**Fowkes et al., 2013 and Benjamin et al., 2017**) (Prevalence of PAD increases with age, with estimates of approximately 5% to 6% for ages 50 to 54 and climbing to almost 20% at age 90 years (**Fowkes et al., 2013**) (In people older than 70 years, estimation ranges from 15% to 20% of the world's population, (**Fowkes et al., 2013**). Prevalence is similar between men and women, although clinical presentation may differ, (**Srivaratharajah and Abramson, 2018**).

Current and former smoking and other cardiovascular disease both double the odds of PAD. The presence of diabetes significantly raises the odds ratio to 1.7 and hypertension to approximately 1.5, (**Fowkes et al., 2013**). Mortality in patients with PAD is around two to three-fold higher than in age-matched controls, with a five-year mortality of about 30%, (**Poredos and Jezovnik, 2015**). In 2015 PAD resulted in about 52,500 deaths, which is an increase from the 16,000 deaths in 1990, (**Rosamond et al., 2016**).

Most previous researches applied programs involving weight-bearing or aerobic exercise (e.g. walking, rowing and cycling) to try improving the maximum walking distance and ankle brachial index. Due to the increased risk of cardiovascular accidents in patients with

PAD, the underlying atherosclerosis and the aversion to strenuous exercise by most patients, an alternative exercise program that does not involve high-impact aerobic exercise regimes may be more appropriate than the afore-mentioned cycling and rowing programs. Supervised exercise programs have been shown to benefit patients, (*Zwierska et al., 2005* and *Bendermacher et al., 2006*)

METHODS:

Thirty male patients with symptomatic peripheral arterial disease (PAD) were recruited in the current study. The patients were selected from the outpatient clinic of vascular department in Sayed Galal University hospital, Alazhar University where the study was conducted, after they had fulfilled the inclusion criteria of the study as the following; male patients with intermittent claudication due to peripheral arterial occlusive disease, Their ages ranged from 50 to 60 years old, their ankle brachial pressure index $0.5 < \text{ABI} < 0.9$ and fontaine classification grade II. However, patients were excluded from the study if they had; unstable cardio/respiratory condition, such as uncontrolled hypertension, cardiovascular accident or myocardial infarction within the last 2 months, surgery within 6 weeks of enrolment, major amputation of one or more lower limbs ,uncontrolled diabetes, tissue necrosis or gangrene, obesity (body mass index $> 30 \text{ kg/m}^2$) and Ischemic rest pain.

Design of the study:

The present study was designed as a randomized single-blinded parallel study with active treatment groups. Clinical examiner was blinded to treatment. The study was proactively approved by the ethical committee of Faculty of Physical Therapy, Cairo University (P.T.REC/012/001404).

The study was conducted in compliance with the declaration of Helsinki ethical principles for medical research involving human subjects.

Before participation in the study, patients received a full explanation about the nature, purpose, and benefits of the study. All patients signed an informed consent form and it was clearly stated that they have the right to refuse or withdraw from participation in the study at any time, and their personal information was to be kept confidential.

The patients who fulfilled the inclusion criteria of the study were randomly assigned into two groups equal in number (A and B). Group (A) or study group included fifteen patients who received resistive isotonic exercise training of five specific muscle groups in each leg using free weights and planter flexion pedal device three times per week for 12 week in addition to their regular medical treatment . While group

(B) or control group included fifteen patients who received their regular medical treatment only.

Instrumentation and tools:

For evaluation:

Sphygmomanometer: Riester diplomat-presameter, made in Germany was used to assess brachial, dorsalis pedis and posterior artery blood pressure.

Doppler Ultrasound: A hand-held Doppler probe (Hi dop bistos co, ltd model BT 260, made in KOREA) was used to obtain systolic blood pressure in dorsalis pedis and posterior tibial arteries and was used to calculate Ankle Brachial Pressure Index .

Standard weight and height scale: (Floor type, Health scale, made in China) It is used for measuring the weight and height of each patient and to calculate the BMI for every one $BMI = \text{weight (kg)} / \text{height (m}^2\text{)}$

For training:

Free weights: Number of variable sand weights to add resistance for muscle strength training.

Outcome measures:

Both groups underwent an identical battery of tests: baseline (before training) and after 12week exercise training program (after training).

The following measurements were done before starting treatment training sessions and at the end of the whole training sessions (after 12 week) for both groups as follows:

-Body Mass Index (BMI): each patient was asked to stand on the floor type health scale for measuring the weight in kilo grams and then measuring height in meter then calculate BMI by dividing weight in kilograms on height per meter square
 $BMI = \text{weight (kg)} / \text{height (m}^2\text{)}$

-Measuring ankle brachial pressure index (ABI): It was measured by using sphygmomanometer to obtain systolic blood pressure in brachial artery And hand held Doppler probe to obtain systolic blood pressure in dorsalis pedis and posterior tibial arteries. The ankle brachial index (ABI) was calculated by dividing systolic blood pressure on each lower limb by the higher systolic blood pressure in the arm according to specific guideline

$$(ABI = \frac{SBP \text{ ankle}}{SBP \text{ brachial}}). (Guo et al., 2008 and Aboyans et al., 2012)$$

Procedures:

Study group (group A):

The training program consisted of applying a resistance to each muscle group with a cuff weight secured to the appropriate part of the leg . On entry, the weight that caused fatigue in the muscle group after six contractions (maximum-intensity repetitions, or 6rep-max) will be

established. Every 2 weeks, the 6rep-max reassessed, and the weights changed accordingly. Patients subjected to supervised resistive exercise program for the lower limbs, three times per week for 1-hour per session. The training program began with 5 minutes of warm-up and ended with 5 minutes of cool down in the form of active free exercises. During the remaining 50 minutes, patients performed six contractions in the form of resistive, isotonic training of five specific muscle groups (Gluteus maximus, Gluteus medius, Quadriceps femoris, Hasmstring, Gastrocnemius and soleus and anterior tibial group) on a given leg, followed by a rest period for 2 minutes and then repeating this circuit for a total of three sets per session. Training in the other leg will be performed in an identical manner

Statistical analysis

Unpaired t-test was conducted for comparison of subject characteristics between groups. Normal distribution of data was checked using the Shapiro-Wilk test. Levene's test for homogeneity of variances was conducted to test the homogeneity between groups. Mixed design MANOVA was performed to compare within and between groups effects on ABI and BMI. Post-hoc tests using the Bonferroni correction were carried out for subsequent multiple comparison. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

RESULTS

- Subject characteristics:

Table (1) shows the subject characteristics of the study and control groups. There was no significant difference between groups in the mean age and BMI ($p > 0.05$).

Table 1. Comparison of subject characteristics between the study and control groups:

	Mean \pm SD		MD	t- value	p-value
	Study group	Control group			
Age (years old)	54.93 \pm 3.49	55.53 \pm 3.54	-0.6	-0.66	0.51
BMI (kg/m ²)	27.66 \pm 1.07	27.48 \pm 1.24	0.18	0.62	0.53

SD, Standard deviation; MD, Mean difference; p value, Probability value

Effect of treatment on ABI and BMI:

Mixed MANOVA revealed that there was a significant interaction of treatment and time ($F = 27.19$, $p = 0.001$). There was a significant main effect of time ($F = 198.14$, $p = 0.001$). There was a significant main effect of treatment ($F = 10.9$, $p = 0.001$).

Within group comparison

There was a significant decrease in BMI of the study group post treatment compared with that pre-treatment ($p < 0.001$). While there was no significant change in BMI of control group ($p > 0.05$). There was no significant change in ABI of study and control groups ($p > 0.05$). (Table 2).

Between group comparison

There was no-significant difference between groups pre-treatment ($p > 0.05$). Comparison between groups post treatment revealed there was non-significant difference in ABI and BMI between groups ($p > 0.05$). (Table 2).

Table 2. Mean ABI and BMI pre and post treatment of the study and control groups:

	Study group	Control group	
	Mean \pm SD	Mean \pm SD	P value
ABI			
Pre treatment	0.64 \pm 0.1	0.65 \pm 0.12	0.68
Post treatment	0.65 \pm 0.1	0.66 \pm 0.11	0.69
	$p = 0.09$	$p = 0.14$	
BMI (kg/m²)			
Pre treatment	27.66 \pm 1.07	27.48 \pm 1.24	0.53
Post treatment	27.07 \pm 1.23	27.36 \pm 1.41	0.39
	$p = 0.001$	$p = 0.11$	

SD, Standard deviation; p value, Probability value

DISCUSSION:

The present study showed no-significant change in ABI of study and control groups ($p > 0.05$). Although there appeared to be a trend for ABI to increase. While there was a significant decrease in BMI of the study group post treatment compared with that pre-treatment ($p < 0.001$). There was no-significant change in BMI of control group ($p > 0.05$).

The results of the study are supported by **Park *et al*, (2020)**, who studied the combined effect of aerobic and resistance-exercises on body composition, cardio metabolic risk factors, blood pressure, arterial stiffness, and physical functions in older obese men. Combined aerobic and resistance-exercises showed significant decreases in body weight, body mass index, and %body fat ($p < 0.05$). The exercise program significantly reduced BP, mean arterial pressure, pulse pressure, and brachial-ankle pulse wave velocity

The results of the study are contradicted by **Gibbs *et al*, (2013)**, who investigated participants with uncomplicated T2DM, and without

known cardiovascular disease or PAD . They were randomized to supervised aerobic and resistance training 3 times per week for 6 months or to a usual care control group. ABI was measured before and after the intervention. Baseline ABI was 1.02 ± 0.02 in exercisers and 1.03 ± 0.01 in controls. At 6 months, exercisers vs. controls improved ABI by 0.04 ± 0.02 vs. -0.03 ± 0.02 ($p=0.001$). This change was driven by an increase in ankle pressures (with no change in brachial pressures ($p=0.747$)). In subgroup analysis, ABI increased in exercisers vs. controls among those with baseline $ABI < 1.0$ which contradicts our results in the current study may be because of combination of aerobic and resistance training and better included ABI participants.

The results of this study coincided with results of the study done **Akerman et al., 2019**. They studied volunteers with PAD who were randomized to 12 weeks of heat or exercise. Systolic blood pressure was reduced more following heat than following exercise and diastolic and mean arterial pressure decreased by 4 mmHg in both groups. There were no significant changes in blood volume, ankle-brachial index, or measures of vascular health. There were no differences in the improvement in functional or blood pressure outcomes between heat and exercise in individuals with PAD.

The absence of a significant ABI may be because exercise interventions do not resulted in a change in ABI (**Parmenter et al ., 2019**)(but rather, may improve perfusion by promoting the growth of collaterals (**Gardner et al .,2001**) as opposed to having any measurable effect on pressure gradients in the large- and medium-sized arteries.

Some limitations of the present study should be considered. First, the sample size was relatively small to generalize. We did not compare genders as only male patients were studied. Also longer duration studies are required

Resistance training (RT) can improve capillary density, strength, and quality of life among individuals with symptomatic and asymptomatic PAD. An inspection of the literature reveals that studies that include higher-intensity, progressive RT of the lower extremity, are more likely to result in positive outcomes. (**McDermott et al .,2009**)

CONCLUSION:

The application of resistive exercise is an effective physical therapy modality for improving body composition in patient with peripheral arterial disease but not improving ankle brachial index.

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تأثير تمرينات المقاومة المتدرجه علي مؤشر الكاحل العضدي في القصور المزمن للدوره الدمويه في الأطراف السفليه

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يعاني مرضي انسداد الشرايين الطرفيه من ألم العرج المتقطع والعجز وعدم قدره علي المشي لمسافات طويله وعدم القدره علي القيام بانشطه الحياه اليوميه. تم دراسته تأثير المقاومة المتدرجه علي مؤشر الكاحل العضدي في القصور المزمن للدوره الدمويه في الأطراف السفليه. تم استخدام ثلاثون مريض من الذكور يعانون من ألم العرج المتقطع نتيجة انسداد الشرايين الطرفيه. تتراوح اعمارهم بين 50 و 60 سنه. تم اختيارهم من العياده الخارجيه لقسم الاوعيه الدمويه بمستشفى سيد جلال الجامعي (باب الشعريه). تم تقسيم المرضي بشكل عشوائي الي مجموعتين متساويتين في العدد مجموعه الدراسه (أ) تكونت من 15 مريض تلقوا تمارين مقاومه لمدته 12 اسبوع بالاضافه الي علاجهم الطبي المنتظم أما المجموعه الضابطه (ب) تكونت من 15 مريض تلقوا علاجهم الطبي المنتظم فقط. وقد تم قياس مؤشر الكاحل العضدي و مؤشر كتله الجسم قبل وبعد تنفيذ البرنامج العلاجي. أظهرت النتائج عدم وجود تغيير ملحوظ في مؤشر الكاحل العضدي في كلا المجموعتين الضابطه والدراسيه بينما يوجد انخفاض ملحوظ في مؤشر كتله الجسم في المجموعه الدراسيه بعد تنفيذ البرنامج العلاجي ولكن لا يوجد تغيير ملحوظ في مؤشر كتله الجسم في المجموعه الضابطه. يمكن استنتاج ان استخدام المقاومه المتدرجه لا يؤثر علي مؤشر الكاحل العضدي في الاشخاص الذين يعانون من انسداد الشرايين الطرفيه.