# Comparison between Two Vascular Rehabilitation Training Programs for Patients with Intermittent Claudication as a Result of Diabetic Atherosclerosis

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## ABSTRACT

***Background and purpose:*** *intermittent claudication is a chronic disabling condition causing physical limitations and pain. Lower limb exercise has consistently been shown to improve pain-free and maximal walking distances so the aim of the present study was to compare between Allen-Burger exercises alone or combined with treadmill walking exercises on posterior tibial artery diameter, walking distance and economy.* ***Subjects and methods:*** *sixty male patients suffering from intermittent claudication as a result of diabetic atherosclerosis participated in this study. Patients were randomly assigned into three groups; group (A) received Allen-Burger exercises and treadmill walking exercises, group (B) received Allen-Burger exercises, and group (C) received medical treatment. Maximal walking distance and pain free walking distance, walking economy and posterior tibia artery diameter were measured pre and post the three months period for all groups.* ***Results:*** *All measured parameters were improved in all groups with the greatest improvement been in group (A) and the least improvement in group (C) except for posterior tibial artery diameter that was improved in group (A) and (B).* ***Conclusion:*** *supervised treadmill walking exercise combined with Allen-Burger exercises could be an effective vascular rehabilitation training program for improving walking efficiency and vascular remodeling in patients with diabetic atherosclerosis suffering from intermittent claudication.*
***Key words:*** *Treadmill walking; Allen-Burger exercise; Intermittent claudication; Doppler.*

## INTRODUCTION

Peripheral arterial disease (PAD) is a progressive atherosclerotic occlusive disease[1,17]. Insufficient arterial blood flow to lower extremities result in skeletal muscle ischemia-induced debilitating pain associated with walking (claudication). This contributes to significant reduction in aerobic capacity and peak oxygen consumption similar to that of individuals with stage III heart failure[24]. Intermittent claudication is a cramp like pain that occurs during walking, when the ability to deliver and utilize $O_2$ is inadequate to meet the metabolic requirement of the active skeletal muscle causing reduction in health related-quality of life[4,20]. Diabetes and smoking are the strongest risk factor for PAD. Other well-known risk factors are advanced age, hypertension and hyperlipidemia. In people with diabetes, the risk of PAD is increased by age, duration of diabetes and the presence of peripheral neuropathy[2]. The goals of comprehensive preventive strategies, including exercise, are 3-fold: (1) to reduce limb symptoms; (2) to improve exercise capacity and prevent or lessen physical disability, and (3) to decrease the occurrence of cardiovascular events[9]. Peripheral arterial disease can be readily identified by the ankle-brachial index (ABI), a simple test comparing systolic blood pressure measured in the arm and in the ankle by Doppler, but this index might not be sensitive enough to reflect the effect of exercise training program[26].

Combined with the ABI, Duplex ultrasonography provides all the information necessary for management decisions in the majority of patients with lower extremity artery disease, confirms the diagnosis, and provides information on lesion location and severity. The lesions are located by two-dimensional (2D) ultrasonography[23].

Walking efficiency is reduced in patients with claudication in that walking patterns change to favor stability over speed. As a result of this less efficient alternation in biomechanics, the oxygen cost of walking is increased[15]. Calf muscle strength and endurance has been shown to be improved following treadmill-walking training and this is associated with improved walking capacity [28]. On the other hand, the therapists notes that the effectiveness of Burger-Allen exercises has not been established; however, there may be some physiological basis for their use. It was hypothesized that through positional changes and muscle contraction, postural exercises could increase local collateral circulation and circulatory flow, thus enhancing tissue nourishment and blood supply[6].

Therefore, the purpose of the present study was to compare between the effect of two different exercise programs; Allen-Burger exercise alone and combined with treadmill walking training on diameter of posterior tibia artery, pain free walking distance (PFWD), maximal walking distance (MWD), and walking economy in diabetic patients suffering from intermittent claudication.

## SUBJECTS AND METHODS

### Subjects

A total of 60 men patients with symptomatic intermittent claudication as a complication of type-2-diabetic atherosclerosis with grade 1 and 2 according Rutherford classification or stratification of PAD[16]. The patients were selected from Faculty of Physical Therapy, outpatient clinic.

Eligible patients included 60 men, ranging in age from 43 years to 59 years. The patients had long standing type 2 diabetes (mean duration about seven years). Patients were diagnosed according to American Diabetes Association with diagnostic criteria, fasting blood glucose > 126mg/dl and postprandial more than 200 mg/dl. They had lifestyle-limiting claudication with an ankle-brachial index < 0.90 and/or a decrease of > 10% of ABI following symptom-limited treadmill exercise test. They were able to walk at a rate of 2 mile/hour on treadmill. Exclusion criteria included: unstable glycemic control, uncontrolled hypertension (blood pressure > 200/100), ischemic rest leg pain, foot ulceration or impending gangrene, obese, smoker, exercise capacity limited by causes other than claudication such as angina pectoris, severe arthritis, unstable coronary heart disease, and lower extremity revascularization within the past three months. The study procedures were explained and informed consent was obtained from eligible participants. Patients were randomly assigned into three groups; group (A); received Allen-Burger exercises and treadmill walking exercises, group (B); received Allen-Burger exercises and group (C); control group who received medical treatment prescribed by the physician and instructions about the disease and its complications, dietary habits and medication compliance. All patients were under medical control using oral hypoglycemic and anti thrombolytic drugs throughout the study.

### Instrumentation

Assessment instrument

- Doppler ultrasonography (B mode): It was used to assess ankle brachial pressure index as a criteria for diagnosis and to measure the diameter of posterior tibial artery (Toshiba medical system, Xario, SSA-660A).
- Computerized electronic treadmill. It was used to assess PFWD, MWD using graded treadmill testing.
- Cardiopulmonary exercise testing unit. It was used to assess walking economy (ZAN 680, ergospirometry system, Germany).
- Glucometer: It was used to monitor blood glucose level before during and after exercise training sessions.

Training instrument

- Computerized electronic treadmill: it was used to conduct treadmill walking program.

### Procedure

Before starting the study, a complete history and medical examination were taken to identify any long term complications of diabetic atherosclerosis. Maximal and pain free walking distances, walking economy and posterior tibial artery diameter were measured in all patients upon entry in to the study and after three months of training.

Assessment procedure:

Ankle brachial pressure index (ABPI):

Ankle brachial pressure index (ABPI) was measured, by specialized radiologist who was blinded to group assignment, for all patients from supine lying position, using cuff of 12 cm wide that was placed just above the malleolus. The Doppler probe was adjusted to provide the optimal signal for systolic pressure at the ankle, measurement was made for both the dorsalis pedis and posterior tibial and the highest value was used. For brachial systolic blood pressure, the pressure was measured from both upper limbs and the highest was used [12]. Then ankle-brachial index was obtained by diving ankle systolic blood pressure by brachial systolic one. Patients with index < 0.9 were eligible for the study. The diameter of the most obstructive area of the posterior tibial artery was determined behind the medial malleolus at the end of diastole.

Graded treadmill exercise testing:

The testing protocol consisted of walking on treadmill at a speed of 2 mile per hour, starting at 0% grade, the grade was increased 3.5% every 3 minutes until 10.5% grade was obtained, at which time, the speed was increased by 0.5 mile per hour every 3 minutes, while maintaining the grade at 10.5%. Patients were only permitted to hold the handrails lightly in order to maintain balance[24].

During the test, patients rated their claudication pain severity every 30 seconds, using the following claudication pain scale: 0 = no pain, 1 = initial onset of mild claudication pain, 2 and 3 = moderate pain, 4 = sub maximal and 5 = maximal claudication pain (point at which the patient requested to stop). The distance walked before initial onset of pain was defined as PFWD; the distance at which the patients stopped the test due to claudication pain was defined as MWD.

Walking economy test:

Oxygen uptake was measured using cardiopulmonary exercise testing, using constant sub-maximal exercise testing, protocol at treadmill speed of 2mph and a grade of 0% until maximal claudication pain for a maximum of 20 minutes at baseline and after three months[8].

Training procedure:

Patients in group (A) participated into treadmill walking program for one hour, three times per week for three months. The program began with 2 mph, 0% grade. They walked until their claudication pain became moderately severe (4 of 5 on the claudication scale); they then rested and sat down until the pain subsided. This exercise/rest cycle was repeated throughout each 60 minutes exercise session. When the patient was able to walk for 8 minutes at the initial work load without having to stop, the grade was increased by 0.5% until 8-10% grade was achieved. After that, exercise intensity was increased by increasing the speed about 1 – 2 mph (0.2-0.3 kilometer per hour) as tolerated [24]. In addition to the fore mentioned treadmill walking exercise, group (A) and group (B) participated into Allen-Burger exercise (4th and 5th progression), the fourth progression included active free ankle exercises in the elevated and dependent positions, while the 5th progression included active resisted ankle exercises in the elevated and dependent positions. These exercises were done for three times per day, every day. After the 4th progression was successful (increase in elevation time-induced blanching, decrease in time for rubor coloration), the patient graduated for 5th progression. The patient performed the Allen-Burger exercise with the therapist three times per week and the other times were done at home by the patient himself.

**Statistical analyses**

All data were expressed as mean ± SD. Statistical significance was evaluated using one way ANOVA to compare between three groups and least significant difference (LSD) post hoc analysis statistical analyses were done using SPSS.

## RESULTS

This study was conducted on 60 patients with intermittent claudication as a complication of diabetic atherosclerosis. The demographic profile of the patients was shown in Table 1 at baseline; there were no statistically significant differences in age, body mass index, duration of diabetes, ankle brachial pressure index among the three groups.

***Table (1): Mean and standard deviation of the age, height and weight of groups (A, B and C).***

| Items | Group (A) | | Group (B) | | Group (C) | | Comparison | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | ±SD | Mean | ±SD | Mean | ±SD | F-value | P-value | S |
| Age (yrs) | 48.2 | ±5.12 | 47.75 | ±3.86 | 48.0 | ±3.97 | 0.05 | 0.94 | NS |
| BMI (Kg/m$^2$) | 28.91 | ±0.25 | 28.92 | ±0.44 | 28.95 | ±0.21 | 0.07 | 0.93 | NS |
| Systolic blood pressure (mmHg) | 121.75 | ±4.06 | 122.25 | ±4.12 | 121.25 | ±2.22 | 0.39 | 0.67 | NS |
| Diastolic blood pressure (mmHg) | 78.2 | ±3.9 | 77.5 | ±5.25 | 77.5 | ±4.44 | 0.15 | 0.85 | NS |
| Duration of disease (year) | 7.5 | ±2.544 | 7 | ±2.15 | 8 | ±2.534 | 0.856 | 0.43 | NS |
| ABPI (mmHg) | 0.730 | ±0.04 | 0.72 | ±0.06 | 0.74 | ±0.05 | 0.21 | 0.52 | NS |

NS: non significant. BMI: Body mass index ABPI: Ankle brachial pressure index.

**Doppler results**

At pre-treatment, no significant difference was found between groups for posterior tibial artery diameter; see Table 2, 3 and Fig. 1. In post-training measurement, there was a statistical significant difference among groups, and group (A) had the greatest improvement( increase) with a percentage of 45.13%, while group (C) showed the least increase of about 2.06% with a non-statistical significant difference between pre and post treatment for group C. On the other hand, group (B) showed an increase about 26.84 % as regards to posterior tibial artery diameter.

***Table (2): Results of ANOVA among the three groups for posterior tibial artery diameter.***

| Posterior tibial artery diameter | | SS | MS | F | P value | S |
|---|---|---|---|---|---|---|
| Pre Treatment | Between groups<br>Within groups<br>Total | 0.26<br>1.536<br>1.562 | 0.013<br>0.027 | 0.48 | 0.61 | NS |
| Post Treatment | Between groups<br>Within groups<br>Total | 3.854<br>0.873<br>4.727 | 1.927<br>0.015 | 125.82 | 0.0001 | S |

SS: Sum of Square, MS: Mean Square, P: Probability, S: Significance, NS: non-significant.

***Table (3): Post hoc test among the three groups for posterior tibial artery diameter.***

| Posterior tibial artery diameter | | Mean difference | P value | S |
|---|---|---|---|---|
| Post treatment | Group A vs. group B | 0.2 | 0.0001 | S |
| | Group A vs. group C | 0.61 | 0.0001 | S |
| | Group B vs. group C | 0.4 | 0.0001 | S |

S.: Significant.

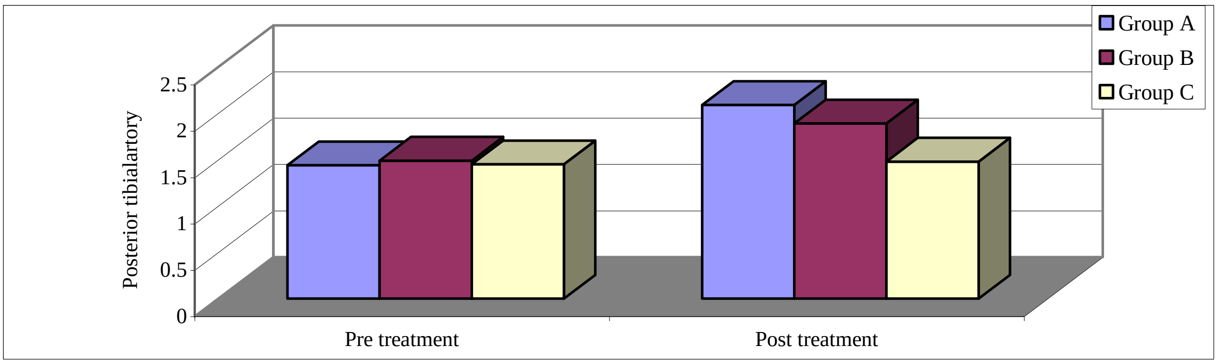


***Fig. (1): Mean of posterior tibialartery diameter for the three groups pre and post treatment.***

**Pain free walking distance and maximal walking distance**

As regards to pain free walking distance and maximal walking distance, at pre-treatment, no significant difference was found between groups, see Table 4, 5 and Fig. 2, 3. In post-training measurement, there was a statistical significant difference among groups, and group (A) had the greatest improvement (increase) with a percentage of 33.78% and 48.32%, respectively while group (C) showed the least increase of about 0.86% and 9.46%, respectively. On the other hand, group (B) showed an increase about 26.7 % and 40.78, respectively.

***Table (4): Results of ANOVA among the three groups for pain free and maximal walking distance.***

| Pain free walking distance | | SS | MS | F | P value | S |
|---|---|---|---|---|---|---|
| Pre Treatment | Between groups<br>Within groups<br>Total | 0.433<br>449.750<br>450.183 | 0.217<br>7.890 | 0.02 | 0.97 | NS |
| Post Treatment | Between groups<br>Within groups<br>Total | 36676.800<br>404.050<br>37080.850 | 18338.4<br>7.089 | 2587.02 | 0.0001 | S |
| Maximal walking distance | | SS | MS | F | P value | S |
| Pre Treatment | Between groups<br>Within groups<br>Total | 1.033<br>809.550<br>810.583 | 0.517<br>14.203 | 0.03 | 0.96 | NS |
| Post Treatment | Between groups<br>Within groups<br>Total | 333844.90<br>831.950<br>334676.85 | 166922.45<br>14.596 | 11436.48 | 0.0001 | S |

SS: Sum of Square, MS: Mean Square, P: Probability, S: Significance, NS: non-significant.

***Table (5): Post hoc test among the three groups for pain free and maximal walking distance.***

| Pain free walking distance | | Mean difference | P value | S |
|---|---|---|---|---|
| Post treatment | Group A vs. group B | 12.6 | 0.0001 | S |
| | Group A vs. group C | 57.6 | 0.0001 | S |
| | Group B vs. group C | 45.0 | 0.0001 | S |
| Maximum walking distance | | Mean difference | P value | S |
| Post treatment | Group A vs. group B | 33.05 | 0.0001 | S |
| | Group A vs. group C | 172.15 | 0.0001 | S |
| | Group B vs. group C | 139.1 | 0.0001 | S |

S.: Significant.

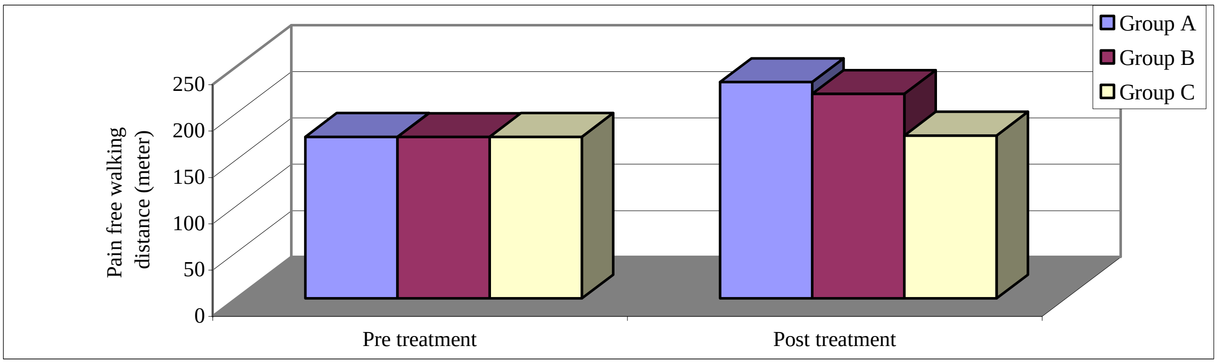


***Fig. (2): Mean of pain free walking distance for the three groups pre and post treatment.***

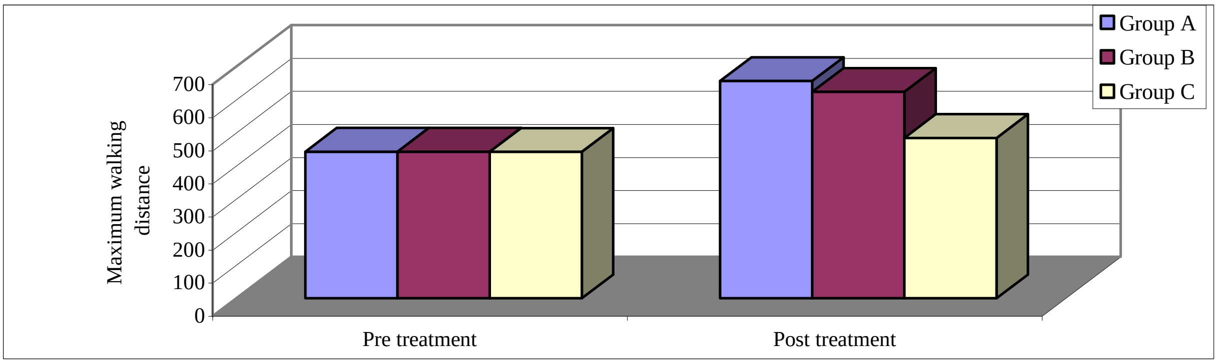


***Fig. (3): Mean of maximum walking distance for the three groups pre and post treatment.***

## Walking economy results

As regards to walking economy results at pre-treatment, no significant difference was found between groups, see Table 6, 7 and Fig. 4. In post-training measurement, there was a statistical significant difference among groups, and group (A) had the greatest improvement (decrease) with a percentage of 14.06% respectively while group (C) showed the least increase of about 0.55%. On the other hand, group (B) showed a decrease about 6.67%.

***Table (6): Results of ANOVA among the three groups for walking economy measured by maximal oxygen consumption.***

| Walking economy measured by maximal oxygen consumption | | SS | MS | F | P value | S |
|---|---|---|---|---|---|---|
| Pre Treatment | Between groups<br>Within groups<br>Total | 2.72<br>54.28<br>57.01 | 1.36<br>0.95 | 1.43 | 0.24 | NS |
| Post Treatment | Between groups<br>Within groups<br>Total | 18.52<br>55.95<br>74.47 | 9.26<br>0.98 | 9.43 | 0.0001 | S |

*SS: Sum of Square, MS: Mean Square, P: probability, S: significance, S: Significant.

***Table (7): Post hoc test among the three groups for walking economy measured by maximal oxygen consumption.***

| Walking economy measured by maximal oxygen consumption | | Mean difference | P value | S |
|---|---|---|---|---|
| Post Treatment | Group A vs. group B | 0.63 | 0.04 | S |
| | Group A vs. group C | 1.36 | 0.0001 | S |
| | Group B vs. group C | 0.73 | 0.02 | S |

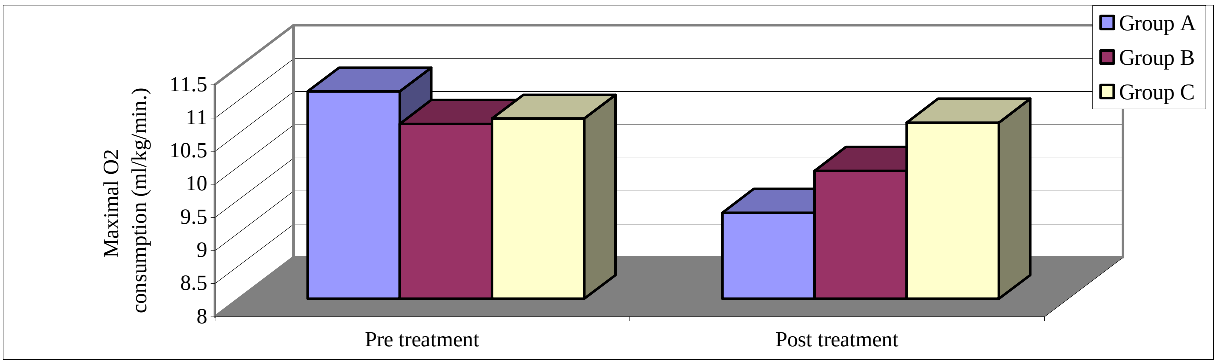


***Fig. (4): Mean and SD of walking economy measured by maximal oxygen consumption for the three groups pre and post treatment.***

## DISCUSSION

Impaired walking ability has several important clinical implications. Patients with peripheral arterial disease have markedly reduced health- related quality of life and higher prevalence of depression, which is largely related to leg symptoms[18,21]. Functional measures including the 6-minute walk test and treadmill walking time have been associated with increased mortality and risk of cardiovascular events in PAD[14]. Together, these findings suggest that interventions that augment exercise performance in PDA may have wide-ranging health benefits. This study was designed to examine the effect of Allen-Burger exercise alone or with treadmill walking exercise to treat patients with intermittent claudication as a result of diabetic atherosclerosis. The outcome measurements are considered to increase the diameter of posterior tibial artery, increase the pain free and maximal walking distance, improve walking economy and to be measured objectively through Doppler ultrasonography, graded treadmill exercise testing, and cardiopulmonary exercise testing, respectively. The study results showed that posterior tibial artery diameter was increased in group A and B but the greatest improvement was achieved in group (A) who received treadmill walking exercise in addition to Allen-Burger exercise with no change in group (C). Also maximal and pain free walking distances and walking economy were significantly improved in all study groups with the greatest improvement (increase in maximal and pain free walking distances and decrease in walking economy) seen in group (A).

The improvement in posterior tibial artery diameter coincided with the results of Sabatier et al.,[19] who evaluated the effect of 14 weeks of aerobic exercises in sedentary healthy women in the form of ten 2-minute alternating intensity bouts (high and low, high intensity was 75-90% of heart rate reserve and low intensity was 55-65% of heart rate reserve) on femoral artery diameter and blood flow independent of changes in adiposity. This remodeling may be a result of reduction of sympathetic adrenergic out flow to the legs that would result in increased dilation and consequently an increase in artery diameter.

As regards to increased maximal and pain free walking distances, these results were confirmed by Treat-Jacobson et al.,[24] who used the same exercise testing and training protocols used in the present study, but their study was conducted mainly to compare between treadmill, arm ergometry training and combination of both training modalities in patient with claudication with only 15 patients were diabetics in their sample. On the other hand, their study showed a greater percentage of improvement as regards to the maximal and pain-free walking distances. The improvement achieved may be a result of systemic central cardiorespiratory and local skeletal muscle adaptation. The mechanisms by which exercise training yields improvement in walking ability remain speculative. Exercise training improves oxygen extraction and muscle carnitine metabolism in the leg[15]. Human studies in PAD patients with improved walking ability following exercise training have not demonstrated increases in leg blood flow, suggesting other mechanisms[22]. Exercise training stimulates endothelial dependent vasodilatation by periodic exposure to repeated episodes of exercise-induced hyperemia; the increased blood flow augments vascular expression of nitric oxide and prostacyclin, there by promoting vasodilatation. Meta analysis from the Cochrane Collaboration evaluating only randomized, controlled trials concluded that exercise improved maximal walking ability[13]. Improvements were most often attained when exercise sessions lasted longer than 30 minutes, took place at least three times per week, when the exercise modality was walking to near maximal pain and when the program lasted at least 6 months[11]. The improved walking distance seen also in group (B) who received only Allen-Burger exercises may be attributed to that these postural exercises with alternating emptying and filling of the blood vessels increases circulatory efficiency and local collateral circulation through stimulation of peripheral vascular system[3]. Furthermore, the possible mechanisms of treadmill walking exercise with respect to improved functional capacity were due to the following effects: (1) exercise-induce capillary growth and mitochondrial biogenesis through enhanced peroxisome proliferator activated receptor-gamma coactivator 1 which is a key regulator, (2) suppression of the endothelial inflammatory activation, (3) enhancement of nitric oxide bioavailability and hence vasodilatation[5,9].

Regarding the decrease in walking economy revealed in the present study, it can be hypothesized that after exercise training and/or Allen-Burger exercise, the muscles can use oxygen more efficiently and there should be less deficit in oxygen supply, so delayed onset of claudication pain and improved walking capacity[7].

Following a program of exercise training, walking economy has been shown to improve in PAD patients as evidenced by a decrease in oxygen consumption at sub maximal workloads[10].

Calf muscle strength and endurance had been shown to be improved following treadmill walking training and this was associated with improved walking capacity[28]. The reduced relative load could also have improved the stability of patient when walking, thereby leading to a reduced demand for oxygen when walking[25].

The findings of the present study was supported by Wang et al.,[27] who concluded that supervised exercise training on treadmill with speed 3.2 Km/h with an individualized incline to elicit moderate claudication pain combined with natural herbal product did not produce greater beneficial effects than exercise training alone as regards to walking economy. The improvement seen in the present study regarding functional measures could be the result of reduced fasting and blood glucose level in all study group and this can also explains the small improvement seen in the control group; group (C) who received counseling about nutrition for controlling blood glucose level, frequent monitoring of blood glucose, adherence to medication, risk factors or atherosclerosis and potential complications of cardiovascular disease. Broadly speaking, the improvement seen in the present study in the trained groups (group A, B) can occur in response to enhanced $O_2$ delivery, $O_2$ utilization or a combination of the two.

## Conclusion

Treadmill walking exercise combined with Allen-Burger exercise program is the most effective one in causing vascular remodeling in the form of increased posterior tibial artery diameter, increasing walking distance and decreasing energy cost for walking (improving walking economy) in diabetic atherosclerotic patients suffering from intermittent claudication. On the other hand, Allen-Burger exercise program alone was also effective but its impact was less than the first program.

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## الملخص العربي

يعد العرج المتقطع من الأمراض المزمنة التي تسبب نقص المجهود البدني والآلام . وتعد تمرينات الطرف السفلي من أحد الوسائل الطبيعية لتحسين أقصى مسافة للمشي وكذلك المسافة المقطوعة بدون آلام ، ولهذا فإن هدف الدراسة هو المقارنة بين "Berger" وتمرينات "Berger" مع المشي على السير الكهربائي وتأثيرهما على قطر شريان الساق ، المسافة المقطوعة واقتصادية استهلاك الطاقة أثناء المشي .
أجريت الدراسة على ستون مريضاً من الرجال المصابين بالعرج المتقطع نتيجة لمرض البوال السكري وقد تم تقسيمهم إلى ثلاث مجموعات ، تلقت المجموعة الأولى برنامج مكون من تمرينات "Berger" بالإضافة إلى برنامج المشي على السير الكهربي ، وتلقت المجموعة الثانية تمرينات "Berger" فقط ، والمجموعة الثالثة كانت هي المجموعة الضابطة والتي تلقت جلسات تعليمية عن مرض البوال السكري ، ومضاعفاته وكيفية تجنب هذه المضاعفات من خلال نصائح خاصة بالتغذية الصحيحة لمرض البوال السكري .
وأظهرت النتائج تحسن ملحوظ في جميع المجموعات في صالح المجموعة الأولى ماعدا قطر شريان الساق الذي لم يظهر تحسن ملحوظ في مرضى المجموعة الضابطة ، وهذه النتائج تدل على أن إضافة تمرينات المشي على جهاز السير المتحرك إلى تمرينات "Berger" ذات فائدة كبيرة في زيادة قطر شريان الساق وكذلك المسافة المقطوعة بدون الآلام والمسافة القصوى للمشي في مرضى العرج المتقطع الناتج عن مرض البوال السكري .