Impact of Partial Weight-bearing Therapy on Walking Performance in Patients with Peripheral Arterial Disease

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Abstract:

Background: Peripheral arterial disease (PAD) is a common circulatory problem. The most common presenting symptom of PAD is intermittent claudication which leads to reduced walking capacity thus representing a disability. Objective: The purpose of this study was to find out the effect of partial body weight treadmill training on walking performance among patients with intermittent claudication due to peripheral arterial disease (PAD-IC). Methods: The study was conducted on thirty patients, their age ranged from 45 to 55 years. They were divided randomly into two equal groups in number. The first group (study) performed a training program on the anti-gravity treadmill of moderate intensity (12-14 on the Borg scale for rating of perceived exertion) for 50 minutes, 3 sessions per week for 12 weeks in addition to their medical treatment. The second group (control) received their medical treatment only. Ankle brachial pressure index (ABI), walking performance (pain free walking distance (PFWD) and maximum walking distance (MWD) were measured before and after the study for both groups. Results: statistical analysis showed a significant improvement (increase) in ABI, PFWD and MWD by 6.06%, 25.32% and 12.7%, respectively in the study group compared to control group. Conclusion: It is recommended for patients with intermittent claudication to participate in partial body weight treadmill training to increase their walking performance.

Key words: Intermittent claudication, peripheral arterial disease, ABI, ant-gravity treadmill, pain free walking distance, Maximum walking distance.

INTRODUCTION

Peripheral arterial disease (PAD) is a manifestation of systemic atherosclerosis; thus, it shares its insidious and gradual progression natural course. Peripheral artery disease (PAD) is caused by atherosclerotic stenoses in the peripheral arterial tree that impair blood flow to the lower extremity(1). Presence of PAD being associated with increased risk of cardiovascular disease (CVD) and coronary artery disease (CAD) and their consequences (2). Claudication can severely limit the performance of daily physical activities and often impairs the normal personal, social and occupational functional capacity of these patients, thus representing a disability (3).
However, PAD may present in the upper extremities, the complaints of most clinicians are due to involvement of lower extremity. It can be symptomless or with pain in one or more muscle groups of the lower extremity (4). Symptoms develop as a result of blood flow reduction from the arterial lesions, causing a mismatch between the metabolic demands of the muscle upon exertion or at rest and the oxygen supply (5).

Intermittent arterial claudication most often refers to cramping pains in the buttock or leg muscles. It is caused by poor blood supply to the affected area. The poor blood flow is often a result of atherosclerotic blockages more proximal to the affected area (6).

Vascular (or arterial) claudication typically occurs after ambulation for a distance with resultant vascular insufficiency, where the muscular demands of oxygen exceed the supply. Symptoms are lower extremity cramping. Resting from activity even in a standing position may help relieve the symptoms (7). Patients with atypical symptoms or even asymptomatic patients who have PAD experience progressive functional impairment and an increased risk of becoming unable to walk for 6 minutes compared with subjects without PAD (8).

Ankle brachial index (ABI) is a noninvasive vascular screening test to clarify peripheral arterial disease by comparing systolic blood pressures in the ankle to the higher of the brachial systolic blood pressures, which is the best estimate of central systolic blood pressure (9). The majority of patients with claudication have ABIs ranging from 0.3 to 0.9. Rest pain or severe occlusive disease typically occurs with an ABI <0.5. ABIs <0.2 are associated with ischemic or gangrenous extremities (10).

Peripheral artery disease is commonly divided in the Fontaine stages, introduced by René Fontaine in 1954 for ischemia. Stage I: Asymptomatic, incomplete blood vessel obstruction, Stage II: Mild claudication pain in limb. Stage III: Rest pain, mostly in the feet. Stage IV: Necrosis and/or gangrene of the limb (4).

Supervised exercise programs have been recommended as first-line therapy for treatment of intermittent claudication (11). The process of supporting body weight when walking leads to long-term improvements and carryover in over ground walking capabilities, especially walking speed (12). The Anti-Gravity Treadmill is a revolutionary medical rehabilitation treadmill with its technology of differential air pressure that provides safe, accurate and comfortable partial weight-bearing therapy while promoting normal gait patterns and provides the opportunity to rehabilitate lower extremities (13).

SUBJECTS AND METHODOLOGY

I-Subjects

Thirty sedentary patients of both sexes with Stage II Fontaine classification of peripheral arterial disease (classic intermittent claudication) are involved in this study. Patients are clinically diagnosed. They were selected from Vascular Disease Department at AL Gala Family Military Hospital. Their ages range from 45 to 55 years old. The study was conducted at Physical Therapy Department at AL Gala Family Military Hospital.

- Inclusion criteria:

Patients with Fontaine stage II lower-extremity PAD were selected for participation according to the following criteria:

- Vascular-type intermittent limiting claudication based on the San Diego Claudication Questionnaire.
- A resting ankle brachial index more than 0.5 and less than 0.9.
- Ages range from 45 to 55 years old.
- Ability to walk on a treadmill.
- Clinical stability of PAD in the last 3 months.
- Body mass index (BMI) ranges from 25 to 29.9 kg/m² (over weight).
- All patients were under medical control and maintained their prescribed medications.

- Exclusion criteria:

- Leg pain at rest.
- Ischemic ulceration.
- Gangrene.
- Resting ankle blood pressure less than 50 mm Hg.
- Patients with cardiac instability, diabetes or have Autonomic neuropathy.
- Patients taking β-adrenergic-blocking drugs.
- Patients who had undergone vascular surgery or angioplasty within the previous year.
Table 1: Descriptive statistics for the mean age, weight, height, and BMI of both groups:

<table>
<thead>
<tr>
<th>Study group</th>
<th>Control group</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>50.8 ± 3</td>
<td>-0.24</td>
<td>0.81**</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74.38 ± 7.9</td>
<td>-0.58</td>
<td>0.56**</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>163.53 ± 5.92</td>
<td>-0.91</td>
<td>0.36**</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.74 ± 1.47</td>
<td>0.04</td>
<td>0.96**</td>
</tr>
</tbody>
</table>

SD: Standard Deviation- value: unpaired t value, P-value: Probability Level, **: Non significant.

Table 2: Results of the ABI, PFWD and MWD of both groups pre and post the study:

<table>
<thead>
<tr>
<th>Groups</th>
<th>Pre-study Mean± SD</th>
<th>Post-study Mean± SD</th>
<th>t-value</th>
<th>p-value</th>
<th>% of improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.66 ± 0.05</td>
<td>0.7 ± 0.06</td>
<td>-8.98</td>
<td>0.0001*</td>
<td>↑ 6.06 %</td>
</tr>
<tr>
<td>2</td>
<td>0.631 ± 0.08</td>
<td>0.634 ± 0.08</td>
<td>-0.84</td>
<td>0.41**</td>
<td></td>
</tr>
<tr>
<td>Between groups p-value</td>
<td>0.18</td>
<td>0.01*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>t-value</td>
<td>1.37</td>
<td>2.49</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFWD (m)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>167.13 ± 7.28</td>
<td>209.46 ± 8.5</td>
<td>0.42</td>
<td>0.0001*</td>
<td>↑ 25.32%</td>
</tr>
<tr>
<td>2</td>
<td>166.46 ± 7.46</td>
<td>169.13 ± 6.81</td>
<td>-3.48</td>
<td>0.004*</td>
<td>↑ 1.6%</td>
</tr>
<tr>
<td>Between groups p-value</td>
<td>0.8</td>
<td>0.0001*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>t-value</td>
<td>0.24</td>
<td>14.33</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MWD (m)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>364.13 ± 13.28</td>
<td>410.4 ± 19</td>
<td>-19.14</td>
<td>0.0001*</td>
<td>↑12.7%</td>
</tr>
<tr>
<td>2</td>
<td>363.53 ± 12.18</td>
<td>364.93 ± 13.09</td>
<td>-1.48</td>
<td>0.15**</td>
<td>↑0.38%</td>
</tr>
<tr>
<td>Between groups p-value</td>
<td>0.89</td>
<td>0.0001*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>t-value</td>
<td>0.12</td>
<td>7.62</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SD: Standard Deviation, ↑: increase, t-value: unpaired t value, P-value: Probability Level, **: Non significant, *: Significant.

- Patients with BMI less than 25 or more than 30 kg/m².
- Patients who are smokers.
- The patients were divided into two groups:
  - 1- Study group
  - 2- Control group

Fifteen patients were participated in a supervised exercise program using the Alter G anti-gravity treadmill trainer which provides partial body-weight training. The patients perform exercise at moderate intensity (12-14 on the Borg scale for rating of perceived exertion) for 50 minutes, 3 sessions per week for 12 weeks in addition to their medical treatment. Their mean ± SD age, weight, height and BMI were 50.8 ± 3 years, 74.38 ± 7.9 kg, 163.53 ± 5.92 cm, and 27.74 ± 1.47 kg/m² respectively.

-II- Instrumentation

A- Evaluation tools and equipment:

1- San Diego claudication questionnaire.

To confirm the classic intermittent claudication which is defined as leg muscle discomfort provoked by exertion and is relieved with rest.

2-Height and weight scale (SK-TZ 160, Made in China).

The measured height and weight was used to calculate body mass index (BMI) of each patient to fulfill the inclusion criteria of the study.

3-ABI measurement tools

Blood pressure cuff (Aneroid Sphygmomanometer Model No. SA-500 Osaka Japan) and a hand held Doppler device with vascular probe (Hi.dop.BT-200 vascular Doppler Bistos Co., Ltd Korea) was used for measuring ankle brachial pressure index.

4- Walking performance measurement tool:

- Six-minute walk test and stop watch were used for measuring the walking parameters:
  1- Maximum walking distance (MWD).
  2- Pain free walking distance (PFWD).

5- Claudication pain scale.

It is a scale which measures the intensity of claudication pain (0=no pain, 1=onset of pain, 2=moderate pain, 3=intense pain, and 4=maximal pain) (4).

6- BORG 6-20 Rate of Perceived Exertion Scale.

To ensure that patients perform the exercise at moderate intensity (12-14 on the Borg scale for rating of perceived exertion) (8).

B- Training equipment

The Alter G anti gravity treadmill

Device model (M320 Fremont, California, United States Of America) which uses Lower-Body Positive Pressure (LBPP) and Differential Air Pressure (DAP) technology to alter the weight of an individual during performing the exercise program.

III. Procedures

The study protocol was explained in details for every patient before the initial assessment. A complete history and physical examination were taken for all patients with particular attention paid to identifying long-term complications of peripheral arterial disease. A written informed consent was signed by each patient before participation in the study as an agreement to be included in the present study.

This study was reviewed and was approved by the Ethics Committee of Faculty of Physical therapy, Cairo University.

A. Evaluation procedure:

1-Stage of PAD assessment procedure

The San Diego claudication questionnaire (SDCQ) is a standardized questionnaire based on the Rose claudication questionnaire that is usually administered by certified health interviewers. This questionnaire allows for lateralization of leg symptoms (right, left, or both) and categorizes leg symptoms as either classic claudication, atypical leg pain that is exertional or no leg pain (14).

2-Body mass index evaluation

A height and weight scale was used to measure height and weight to calculate body mass index: BMI = body weight in kilograms/height in meter squared (15).

3-ABI assessment procedure

Measurement of systolic pressures of the four limbs was performed in all patients using a standard sphygmomanometer in a quiet room, with the patient supine for at least 5 min before measurement. Right and left arm and ankle (posterior tibial artery and dorsalis pedis artery) systolic blood pressures were measured by trained physicians using a handheld Doppler ultrasound (Vascular Doppler 8 MHz) and a manually operated blood pressure cuff with a 15 cm-wide bladder. A cycle of measurements (right arm, right ankle, left ankle, and left arm) was repeated, and the means of two measurements for each limb were used to calculate the ABI. Finally, the ratio of the highest systolic pressure in the ankle to the higher of the left or right brachial systolic pressure was used to define the ABI (16).

4-Six- minute walk test for walking parameters evaluation.

Six-minute walk test was done before starting the exercise program (24 hours before starting the first session) and 24 hours after completing the 12 weeks (after last session of the program). The 6-minute walk test is a measure of
walking endurance that has excellent test/re-test reliability in individuals with PAD (8).

**Test procedure**
The 6MWT took place in an indoor, 30-m-long hallway with marks on the wall every 5 m. Patients were asked to walk up and down the hallway, covering as many laps as possible in 6 minutes. Patients were permitted to stop walking if their claudication became intolerable; however, the time clock continued to run during the rest period, and patients who stopped walking were encouraged to resume walking as soon as possible. The procedure was performed under supervision, with recording of the time to the first stop, the number of non-walking periods when patients stopped because of claudication, and the total distance walked during the test. The investigator provided verbal encouragement every 2 minutes during the test (17).

The total distance patient can walk during the test (MWD) and the distance that a patient can walk before claudication pain begins (first stop) (PFWD) (18) were measured. Instructions on what to do and what not to do during the test should be provided such as, your goal is to walk as far as possible in six minutes. Please do not talk during the test unless you have a problem or if I ask you a question.

Measuring of the ankle brachial pressure index and the six-minute walk test were done at the beginning and end of the study (12 weeks) for both groups.

**B. Training procedure:**

All patients were individually instructed at the first training session about walking on the Alter G treadmill and how to stop it when they cannot walk. All instructions were given to the patients to be familiar with the Alter G machine. All of the 15 patients in the study group were performing a supervised partial body-weight treadmill training program 50 minutes, 3 sessions per week for 12 weeks. Each training session consisted of 5 minutes of warming-up activities consisting of stretching exercises for the quadriceps, hamstring, and calf muscles, 40 minutes of intermittent treadmill walking, and ended with 5 minutes of cool-down activities consisting of stretching exercises. Patients performed the exercise at moderate intensity (12-14 on the Borg scale for rating of perceived exertion) i.e. quite an effort; you feel tired but you can continue (8).

Ratings of perceived exertion are generally believed to be valid and reliable markers of physiological intensity during exercise and were recommended to monitor exercise intensity (19).

Walking on treadmill was initiated at 2 mph speed, 0% grade and 60% of total body weight. Patients were walking until claudication pain become moderately severe, i.e. a level of “3” on a 0-4 pain scale (0=no pain, 1=onset of pain, 2=moderate pain, 3=intense pain, and 4=maximal pain), at which time the subject stop the treadmill and rest until claudication pain subsides. The speed was increased by 0.5 mph to reach a moderate intensity of exercise according to Borg scale. Exercise and rest periods were repeated throughout the training session. Every 4 weeks, there were an increase in weight bearing by 20% until reaching 100% of body weight which was maintained until the end of the 12 weeks program.

**Statistical analysis:**
The data obtained from both groups were statistically analyzed to compare the difference within each group and between the two groups. The statistical package of social studies (SPSS, version 9) was used for data processing using the P-values ≤ 0.05 as a level of significance.

**RESULTS**
The purpose of this study was to evaluate the effect of partial body-weight treadmill training on patients with (PVD-IC), data obtained from both groups before and after the study, regarding ankle brachial pressure index (ABI), pain free walking distance (PFWD), and maximum walking distance (MWD) were statistically analyzed and compared.

I- General characteristics of the subjects:

Comparing the general characteristics of the patients of both groups revealed that there was no significance difference between both groups in the mean age, weight, height, and BMI pre study (p > 0.05). Table (1)

II-Results of the ABI, PFWD and MWD of both group’s pre and post the study:

Results revealed statistical significant improvement (increase) in ABI, PFWD and MWD by 6.06 %, 25.32 % and 12.7%, respectively in study group compared to control group. Table (2)

**Discussion**

Peripheral artery disease (PAD) is not a static disease and its progression from intermittent claudication to rest pain or gangrene can occur(20). The goals of comprehensive prevention strategies, including exercise, are 3-fold to
reduce limb symptoms; to decrease the occurrence of cardiovascular events and to improve exercise capacity and lessen or prevent physical disability (21). Lower-body positive pressure (LBPP) devices are comfortable, adjustable, do not impede circulation, and can be used over extended periods (13).

Lower body positive pressure (LBPP) has been found to be superior to other methods of unweighting such as upper body harnesses that partially support body weight and aquatic exercises, that is because air pressure is uniformly applied over the lower body which decreases the pressure points formation, which are common with the harness-based systems, also it maintains the normal muscle activation and gait patterns, which are altered in the aquatic activities (22). Ambulation on a lower-body positive pressure treadmill is a relatively novel exercise mode (23). It was found that patients with (PAD-IC) demonstrate reduced physiological capacity, limited lower limb mobility, poor walking performance (maximal walking distance/time), low physical activity levels, and decreased health-related quality of life compared to healthy, age-matched controls (24).

The purpose of this study was to find out the effect of partial body-weight treadmill training using the anti gravity treadmill device (Alter G) on patients with (PAD-IC). Walking programs are known to improve walking capacity but could be limited by a person's ability to carry his or her own full body weight to perform the walking. So, decreasing body weight, through unloading, might allow longer pain-free walking, thus potentially accelerating exercise training.

The current study was conducted on thirty patients with vascular type intermittent claudication (PAD-IC). They were divided randomly into two groups of equal numbers; the first group (study), participated in a supervised exercise program using the Alter G anti gravity treadmill which provides a partial body-weight training. They performed the exercise program at moderate intensity (12-14 on the Borg scale for rating of perceived exertion) for 50 minutes, 3 sessions per week for 12 weeks in addition to their medical treatment. The second group (control), received their medical treatment only and asked to maintain their habitual activities. ABI and walking performance (pain free walking distance and maximum walking distance) were measured before and after the study (12 weeks).

It was found that, patients in the study group demonstrated significantly improvement (increase) of ABI by 6.06 % and greater walking performance (25.32% improvement in pain free walking time and 12.7% improvement in maximal walking time) compared with baseline and with control group.

The improvement in this study can be explained by the ability of patients to exercise for a longer continuous duration with less body weight on the anti gravity treadmill than traditional treadmill, and this greater continuous duration and less weight were needed to improve peripheral blood flow.

The improvement of walking performance in the current study seems to be associated with the improvement of ABI. That is come in agreement with (25). Who reported that lower ABI is associated with reduced physical function (e.g. Walking speed, distance walked in 6 minutes), and this relationship exists with or without PAD symptoms.

It was reported that the 6-minute walk test is reliable in patients with lower extremity PAD and is sensitive to change in walking endurance after exercise interventions. Thus, a 6-minute walk test can serve as an alternative objective method of assessing walking endurance in older men and women (4).

Bendermacher et al., reported that the distance at which a patient prefers to stop because of claudication pain may be a better instrument by which to measure the functional impairment of patients with intermittent claudication (26). Improvement in ABI, PFWD and MWD with exercise training in PAD patients could arise from different mechanisms as increases in leg blood flow following exercise training (27), increases in shear stress that stimulate nitric oxide bioactivity (28), increase expression of vascular endothelial growth factor (VEGF) messenger RNA in skeletal muscle (29), Exercise training has the potential to enhance skeletal muscle mitochondrial function and metabolism (30) and by suppressing inflammatory activation (31).

Also, it was found that, greatest increase in angiogenesis in the gastrocnemius muscle of patients with peripheral arterial disease occurs at 3 weeks post exercise training (32).

The results of this study come in agreement with Slordahl (33) who found an increase in peripheral limb blood flow for (PAD-IC) patients at rest following an exercise program. Increased limb blood flow may result in increased oxygen supply/perfusion, reduced submaximal VO2so, improved walking economy and reduced claudication pain.

Moreover, previous studies on the Alter G technology show that the machine is capable of accurate and precise unweighting across a variety of body types, Comfortable and safe for most individuals, including those with stable cardiac, vascular, and respiratory disorders, able to reduce ground reaction force for walking and running in proportion to the amount of unweighting and it is effective in reducing pain in individuals whose lower extremity pain is related to full weight bearing ambulation or exercise (34).
It was reported that Anti-Gravity treadmill can reduce the forces acting on the musculoskeletal system while maintaining metabolic demand and kinematic timing patterns during walking, also during walking at faster velocities with body weight support, peak vertical ground reaction force can be attenuated while aerobic and neuromuscular stimuli that are similar to normal weight walking are maintained (13).

Lower body positive pressure training has an obvious increase in exercise tolerance and because patients could walk pain free during LBPP, their confidence may have improved and allowed for their activities to increase. Thus, the LBPP treadmill may be an effective tool for the rehabilitation of patients with diseases of the lower extremities (22). The findings of the present study can be supported by Grabowski (13) who found that using the Alter G lower body positive pressure training (LBPP) decreased the metabolic demand by 41% during walking at 0.25 of body weight.

Conclusion

Based on the findings of this study, it could be concluded that there is improvement (increase) in the ABI and walking performance (PFWD and MWD) after partial body weight demand by 41% during walking at 0.25 of body weight.

References