

A plantar flexion device exercise programme for patients with peripheral arterial disease: a randomised prospective feasibility study

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Abstract

Objectives To determine if the use of a plantar flexion device (Step It pedal) in a newly developed exercise programme is of benefit to patients with peripheral arterial disease.

Design Prospective feasibility trial with patients randomised to either standard care or the Step It exercise programme plus standard care.

Setting Physiotherapy Department at Cumberland Infirmary, Carlisle, UK.

Participants Patients were identified from the vascular team's referral list. In total, 42 patients agreed to take part; 18 in the control group and 24 in the intervention group.

Interventions Eligible participants were randomised and received either standard care or took part in a plantar flexion resistance exercise programme, involving the Step It pedal, for a period of 12 weeks.

Main outcome measures Maximum walking distance, claudication distance and ankle brachial pressure index.

Results Eighty-three percent of patients completed the study. Improvements in median distance to claudication symptoms and maximum walking distance were observed in the intervention group but not in the control group. Nine out of 15 (60%) participants in the control group and 14 out of 20 (70%) participants in the intervention group improved their walking distance. Ankle brachial pressure index remained virtually unchanged in both groups.

Conclusions Due to the variability of patients' fitness in the sample, it cannot be concluded whether use of the Step It pedal has additional benefits to patients over standard care. However, the study completion rate implies that patients with peripheral arterial disease are receptive to undertaking exercise programmes.

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Keywords: Peripheral arterial disease; Plantar flexion; Exercise; Claudication

Introduction

Peripheral arterial disease is a common progressive disorder of the vasculature. The underlying aetiology of peripheral arterial disease is atherosclerosis, and therefore patients are at high risk of associated cardiovascular diseases such as myocardial infarction and stroke [1,2]. Narrowing of the arteries leads to reduced oxygen supply, thereby resulting in intermittent claudication symptoms (i.e. exercise-induced pain in the calves, thighs or buttocks), limited capacity to exercise and increased risk of tissue loss [3]. Peripheral

arterial disease can be categorised using the Fontaine classification according to the absence or presence of intermittent claudication symptoms. In the USA alone, approximately 6% of the population are affected by this disease [4]. A UK study involving adults aged 55 to 74 years found that 4.5% experienced intermittent claudication symptoms [5].

Patients who receive support, training and education about exercise improve their walking distance by, on average, 150% [6,7]. Most previous research studies applied programmes involving weight-bearing or aerobic exercise (e.g. walking, rowing and cycling) to try and improve the maximum walking distance that patients can reach. Due to the increased risk of cardiovascular accidents in patients with peripheral arterial disease, the underlying atherosclerosis and the aversion to strenuous exercise by most patients, an alternative exer-

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cise programme that does not involve high-impact aerobic exercise regimes may be more appropriate than the aforementioned cycling and rowing programmes.

Supervised exercise programmes have been shown to benefit patients [8,9]. One recent study by McDermott *et al.* showed that supervised lower extremity resistance training has significant benefits over normal management involving education and advice on diet and exercise [10]. A 6-month programme resulted in improved maximum treadmill walking time, although 6-minute walking distance did not improve over that of the control group. The lower extremity exercises included repetitions of knee extensions, leg presses and leg curls.

This pilot clinical research study applied the Step It rocker pedal (Step It System AB, Saltsjöbaden, Sweden) for the first time in patients with peripheral arterial disease. This is a small device, very similar to the pedal used to operate a bass drum on a drum kit, which is easy to use from a seated position and was first devised to help alleviate the risk of ‘economy syndrome’ (i.e. deep vein thrombosis) for travellers on long haul flights. Patients may be receptive to this form of exercise in addition to walking, especially if they are elderly, frail, have a fear of falling or have an aversion to the idea of ‘exercise’. The aim of this initial randomised, controlled, prospective feasibility study was to determine the efficacy of the Step It pedal by measuring patients’ maximum walking distance as well as ankle brachial pressure index. Both the control group and the intervention group received advice on diet and exercise, and were monitored for physical parameters.

Methods

Study design and subjects

This was a prospective, single-centre, controlled, randomised research study with 1:1 allocation to the control group and the intervention group. Patients were identified from referrals to the vascular clinic at Cumberland Infirmary, Carlisle. Symptomatic peripheral arterial disease, Fontaine IIa or higher, was diagnosed in patients by consultant vascular surgeons when first consulted on symptoms alone: exertional calf pain upon walking and an ankle brachial pressure index <0.90 [3,11]. Adult patients with symptomatic intermittent claudication due to peripheral arterial disease who were capable of giving informed consent were invited to participate in the study; there were no age restrictions. Patients were excluded according to the following criteria: 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; and blood glucose level >13 mmol/l (i.e. uncontrolled diabetes) [10,12]. Following consent, the patients were allocated at random to either the control group or the intervention group. The study was performed unblinded, and a non-restricted randomised sequence

was obtained – and visible to researchers beforehand – for the whole sample using a freeware randomisation program (<http://www.randomizer.org>). The corresponding author (LJ) generated the randomisation sequence, LR and JT enrolled patients, and NT measured the study outcomes.

Interventions

Participants were randomised to either the control group (standard care) or the intervention group (standard care plus use of the Step It pedal) for a period of 12 weeks. Neither participants nor researchers were blinded regarding the allocated intervention. All participants initially attended one exercise class in the hospital for baseline measurements, and then continued their exercises (i.e. plantar flexion using the Step It pedal) and care programme unsupervised at home thereafter. Patients in both groups were advised to walk to their maximum walking distance each day and to attempt to increase this distance as they were able. The second study appointment in the hospital took place 12 weeks after patient enrolment. In addition to the standard care received by the control group, the subjects in the intervention group were also asked to undertake exercises at home using the Step It rocking pedal. These exercises consist of lower limb exercise training (resisted plantar flexion) whilst seated. The resistance of the pedal is equivalent to approximately 6 kg. The exercise sessions were performed three times per week for 12 weeks with the following pattern: 2 minutes exercise/2 minutes rest, 10 times, to equal 20 minutes of exercise in total. The patients were shown how to use the Step It pedal at the baseline appointment, and were asked to try it out to demonstrate they could use the instrument. Throughout the study programme, the participants were asked to record an exercise diary.

Primary and secondary outcomes

Outcome measures were recorded at baseline and at 12 weeks, with distance walked as the primary outcome measure. The data for claudication distance (i.e. the distance at which there is onset of claudication pain) and maximum walking distance were obtained using a treadmill set at 3.2 km/hour (as reported by Hiatt *et al.* [13]) and a 10° gradient. If no claudication pain developed, the maximum walking distance was recorded as the claudication distance. The secondary outcome measure was the ankle brachial pressure index, which was measured with a handheld Doppler machine. This tool is commonly used for diagnosis and monitoring of peripheral arterial disease [13]. In healthy persons, the ankle brachial pressure index is at least 1, with the systolic blood pressure equal in all limbs or higher in the ankle [3]. The highest measure of the dorsalis pedis and posterior tibial pressure was divided by the brachial pressure in the right arm of the patient. Since the recruited participants had claudication symptoms in either the right leg, left leg or both legs, the ankle brachial pressure index score for either the affected leg (unilateral disease) or the average of the ankle

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