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Functional electrical stimulation improves quality of life by reducing intermittent claudication☆

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ABSTRACT

Objective: To determine if Functional Electrical Stimulation (FES) would improve ischemic pain, walking distance, and quality of life of patients with intermittent claudication.
Design: Single blind, randomized block, two factorial design.
Patients: Patients diagnosed with Peripheral Artery Disease (PAD) and intermittent claudication (IC). Ankle Brachial Index ranged 0.4-0.9 on at least one leg. Patients were randomly assigned to experimental (FES + Walk, $N = 13$) or control (WALK, $N = 14$) groups.
Intervention: Experimental group patients received FES to the dorsiflexor and plantarflexor muscles while walking for 1 h/day, six days/week for eight weeks. Control group patients received similar intervention without FES. A Follow-up period of both groups lasted eight weeks.
Outcome measures: Outcome measures were taken at baseline (T_0), after intervention (T_1), and after follow-up (T_2). Primary measures included Perceived Pain Intensity (PPI), Six minute walk (6MW), and Peripheral Arterial Disease Quality of Life (PADQOL). Secondary measures included Intermittent Claudication Questionnaire (ICQ) and Timed Up and Go (TUG).
Results: Group by time interactions in PPI were significant ($P < 0.001$) with differences of 27.9 points at T_1 and 36.9 points at T_2 favoring the FES + Walk group. Groups difference in Symptoms and Limitations in Physical Function of the PADQOL reached significance ($T_1 = 8.9$, and $T_2 = 8.3$ improvements; $P = 0.007$). ICQ was significant ($T_1 = 9.3$ and $T_2 = 13.1$ improvements; $P = 0.003$). Improvement in 6MW and TUG tests were similar between groups.
Conclusions and relevance: Walking with FES markedly reduced ischemic pain and enhanced QOL compared to just walking. FES while walking may offer an effective treatment option for the elderly with PAD and Intermittent Claudication.
Trial registration: NIH-NIA 1R21AG048001 https://projectreporter.nih.gov/project_info_description.cfm?aid=8748641&icde=30695377&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC. https://clinicaltrials.gov/ct2/show/NCT02384980?term=David+Embrey&rank=1.

1. Introduction

Over 8 million Americans suffer from peripheral arterial disease (PAD) [1] and 7% experience intermittent claudication (IC), defined as ischemic leg pain with exertion that improves with rest [2–4]. Yearly, 1.5 million patients with PAD receive medical care at a cost of >4 billion dollars [5,6] including pharmaceutical intervention which has limited benefits [7,8]. Endovascular surgeries, including atherectomy, angioplasty, stenting or drug-eluting stents, as well as surgical revascularization using bypass, can be successful in select patients but long-term benefits are limited [9]. Although the complication rate and overall

Abbreviations: 6MW, 6 Minute Walk; ABI, Ankle Brachial Index; FES, Functional Electrical Stimulation; FES + Walk, Experimental Group (FES plus walking); IC, Intermittent Claudication; ICQ, Intermittent Claudication Questionnaire; PAD, Peripheral Artery Disease; PADQOL, Peripheral Arterial Disease Quality of Life; PPI, Perceived Pain Intensity; QOL, Quality of Life; TUG, Timed Up and Go; WALK, Control Group (Walk only).

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morbidity associated with endovascular intervention are lower when compared with surgical revascularization [10], the need for repeated surgical intervention remains a significant medical and financial burden [11]. Additionally, most patients are likely to endure functional limitations in their daily activities, and their quality of life is adversely impacted [5]. Limited mobility and de-conditioning exacerbates co-morbidities including hypertension, obesity, hyperlipidemia, and hyperglycemia [4]. Spinal cord stimulation (SCS) is another surgical intervention that was shown to effectively diminish claudication and improve quality of life measures in patients with critical limb ischemia [12]. However, clear indication to implant SCS is limited to patients with severe ischemia where other surgical interventions are not warranted or have failed [13].

Dose-dependent exercise provides the best non-surgical treatment to decrease pain, improve walking distance, and enhance quality of life in patients with IC [2,14]. Research suggests self-directed walking is associated with significantly less functional decline when performed at least three times/week compared with only one-two times/week [2,15]. Supervised exercise, at sufficient intensity has been shown to increase blood flow to dorsiflexors [16,17]. However, patients with co-morbidities and ischemic walking pain are often unable or unwilling to participate in regular exercise [18].

To complement exercise, functional electrical stimulation (FES) while walking provides a novel treatment option. Non-invasive FES has been shown to minimize chronic pain, enhance muscle strength, increase muscle cross-sectional area and metabolism following trauma or disease of musculo-skeletal [19], peripheral vascular [20], cardio-pulmonary [21–24], and neurological systems [25,26]. Likewise, FES has been shown to enhance arterial, venous, and lymphatic flow [27–29]. Advanced biomedical electronics now allow electrical stimulation to be applied using wearable FES systems to help patients suffering from stroke, multiple sclerosis, and traumatic brain injury. To date, the efficacy of FES during walking has not been investigated in patients with PAD and IC.

We hypothesized that patients who walk using a new FES system will have a significant reduction in ischemic walking pain, increase walking abilities, and improve quality of life after eight weeks of training. We further hypothesized that such gains would be sustained following eight weeks of follow-up.

2. Methods

A single blind, randomized block, two factorial design compared outcomes of two cohorts: FES + Walk vs. WALK (walk only). Sample size determination was based on the effect size observed in a previous study of this FES system [23]. Randomization occurred by drawing group assignments from sealed envelopes prepared by the principal investigator. A program director drew group assignments from the envelopes and informed the PI, who enrolled all patients. Patients were blocked according to claudication severity (mild = 0/20, moderate = 21/40, severe = 41/60, or profound = 61/100) using Perceived Pain Intensity (PPI). This study was approved by the MultiCare Institutional Review Board and all subjects gave informed consent. The CONSORT (Fig. 1) diagram summarizes the recruitment, randomization, attrition, and risk factors.

Baseline (T_0) measurements were collected prior to randomization. Post-treatment (T_1) and carry-over (T_2) measures were collected by clinicians blinded to group assignment and not otherwise involved with the patients. All patients received standard care by their physician, defined as conservative (non-surgical) management of signs and symptoms of PAD, including medications to improve circulation and manage pain.

Patients were ambulatory, community dwelling adults diagnosed with PAD and IC, had Ankle Brachial Index (ABI) between 0.4 and 0.9 on at least one leg, scored 23 or higher on the Folstein Mini Mental test, and demonstrated visible muscle contractions when receiving FES, within their level of comfort for the dorsiflexor and plantarflexor muscles. Patients were excluded if they had an implanted electronic stimulator, had arthritis or CNS damage resulting in neuromuscular limitations in either leg, or had skin lesions where the FES electrodes would be placed.

At study onset patients were instructed not to talk about their intervention or treatment assignment with anyone in the clinic. To assure that the changes in walking abilities and claudication were independent of receiving FES; all data were collected without the patients wearing the FES system.

2.1. Primary outcome measures

Walking distance was established by measuring meters traveled during a 6 Minute Walk Test (6 MW). This test has been shown to be reliable for patients with PAD and IC [30].

The Perceived Pain Intensity (PPI) was used to determine the magnitude of ischemic walking pain. Within 30 s after completing the 6MW, assessors asked patients to rate their ischemic pain in their lower legs by placing a hash mark on a 0–100 mm horizontal line. Patients were instructed that 0 meant “no pain” and 100 meant “the most intense pain ever experienced.”

Primary changes in lifestyle were measured with the Peripheral Arterial Disease Quality of Life (PADQOL) questionnaire. This is a well validated measure using

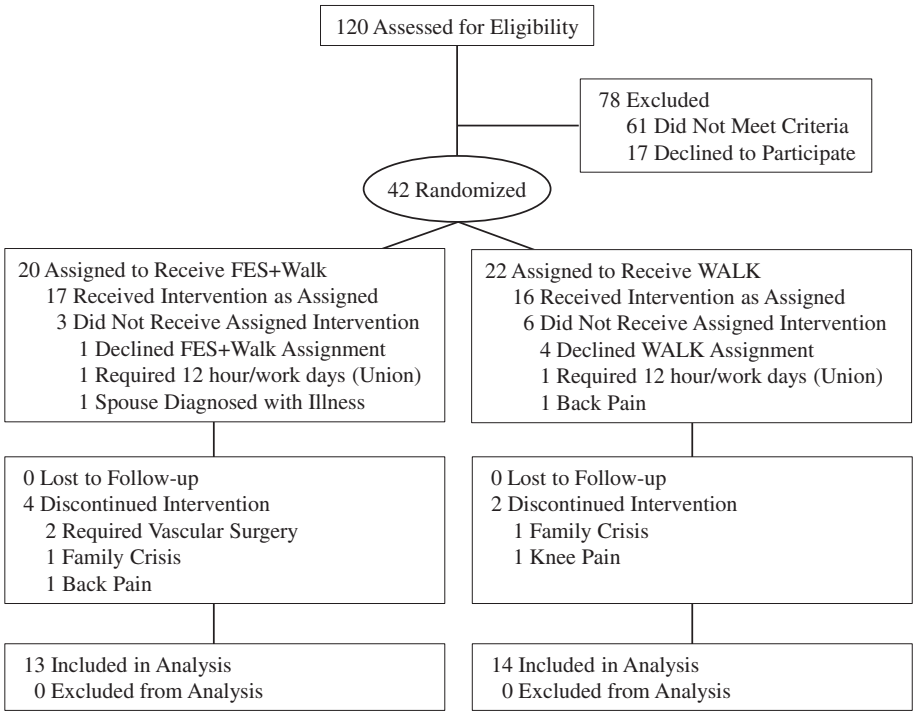

Fig. 1. CONSORT flow chart of eligibility, randomization, and intervention.

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