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Transcutaneous calf-muscle electro-stimulation: A prospective treatment for diabetic claudicants?

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Abstract

Background: First-line therapy for claudicants with diabetes include supervised exercise programmes to improve walking distance. However, exercise comes with a number of barriers and may be contraindicated in certain conditions. The aim of this study was to evaluate whether calf-muscle electro-stimulation improves claudication distance.

Method: A prospective, one-group, pretest–posttest study design was employed on 40 participants living with type 2 diabetes mellitus, peripheral artery disease (ankle-brachial pressure index < 0.90) and calf-muscle claudication. Calf-muscle electro-stimulation of varying frequencies (1–250 Hz) was applied on both ischaemic limbs (*N* = 80) for 1 h per day for 12 consecutive weeks. The absolute claudication distance was measured at baseline and following the intervention.

Results: The cohort (*n* = 40; 30 males; mean age = 71 years; mean ankle-brachial pressure index = 0.70) registered a mean baseline absolute claudication distance of 333.71 m (standard deviation = 208). Following 91.68 days (standard deviation = 6.23) of electrical stimulation, a significant mean increase of 137 m (standard deviation = 136) in the absolute claudication distance was registered (*p* = 0.000, Wilcoxon signed rank test).

Conclusion: Electrical stimulation of varying low to high frequencies on ischaemic calf muscles significantly increased the maximal walking capacity in claudicants with type 2 diabetes. This therapeutic approach may be considered in patients with impaired exercise tolerance or as an adjunct treatment modality.

Keywords

Peripheral artery disease, type 2 diabetes mellitus, electrical stimulation, intermittent claudication

Lower extremity artery disease [peripheral artery disease (PAD)] is a highly prevalent disease estimated to affect over 200 million people worldwide.[1] Its presence increases the risk of mortality, intermittent claudication and tissue loss.[2] Patients with concomitant diabetes mellitus are considered particularly vulnerable as they carry a particular poorer prognosis than those with either disease alone.[3]

Treatment guidelines for claudicants recommend supervised exercise training as first-line therapy;[2] however, this comes with a number of barriers particularly in the elderly population.[4] Motivation to exercise, osteoarthritis, psychosocial factors, congestive heart failure or chronic obstructive pulmonary disease may be preclude adherence to any form of active exercise therapy.

In this context, electrical stimulation (ES) technology is being proposed as a potential alternative or adjunct to traditional exercise to improve claudication symptoms in a target PAD and diabetes population.

A prospective, one-group, pretest–posttest study design was conducted subsequent to University Research Ethics Committee approval. Consenting participants were assessed for eligibility after being randomly selected from a hospital database of patients with type 2 diabetes and symptomatic PAD. Inclusion criteria included the following: PAD defined with an ankle-brachial index (ABI) < 0.9, abnormal spectral waveforms on the ankle arteries of both limbs and calf-muscle intermittent claudication, reproducible on a graded treadmill test.

Exclusion criteria included: Change in cardiovascular medication within the past year or during the intervention, history of renal disease or spinal stenosis, medial artery calcification (ABI > 1.3), sensory or autonomic neuropathy, previous foot/toe amputations or history of oral claudication therapy.

To quantify claudication severity and response to treatment, the graded treadmill protocol was utilized as a serial

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measure to acquire the absolute claudication distance (ACD), defined as the distance at which claudication becomes severe so that the participant is forced to stop.[5] The treadmill was initiated and maintained at a fixed speed of 3.2 km/h while the slope was increased by 2° every 2 min up to a maximum of 10° from an initial inclination of 0°. The recorded distance was not disclosed to the participant to ensure blinding.

The ES device (Veinoplus® Arterial Model 2.1; Ad Rem Technology, France) was given to each participant for home use following a demonstration session. It consisted of a central unit with two adhesive electrodes designed to be attached transcutaneously on the calf muscle, generating ES at varying frequencies (1–250 Hz) through a series of rectangular pulses of low energy (<25 uC) and low voltage (50 V peak) within a fixed 1-h session. Subsequently, this was applied for 1 h every day for a period of 12 weeks.

The Wilcoxon signed rank test was used to evaluate the significant difference in mean ACD since the Kolmogorov–Smirnov test revealed a non-normal distribution of baseline and follow-up data sets.

From a total of 81 prospective participants, 40 participants [30 males; mean age = 71 years, standard deviation (SD) = 7; body mass index = (BMI) 28.8; SD = 3.7; mean ankle-brachial pressure index (ABPI) = 0.70, SD = 0.12; mean diabetes duration = 15 years, SD = 6; mean HbA1c = 8.22, SD = 1.56; 32.5% active smokers] satisfied the inclusion criteria and were recruited.

At baseline, the recorded mean ACD was 333.71 m (SD = 208). Following a mean intervention period of 91.68 (SD = 6.23) consecutive days, the mean ACD was 470.7 m (SD = 279). This translated to a mean improvement in the ACD of 137 m (SD = 136) reflecting an improvement in maximum walking capacity of 41% relative to baseline. Utilizing the Wilcoxon signed rank test, this improvement was found to be statistically significant ($p = 0.000$).

Findings of this study confirm a significant mean increase ($p = 0.000$) in ACD of 137 m following 91.68 days (SD = 6.23) of 1 h ES of the calf muscles. The novelty of this study is that it is the largest study stimulating ischaemic limbs ($N = 80$), for the longest intervention period to date (12 weeks), utilizing an ES device of varying frequencies in contrast to previous studies.[6,7]

The effects of ES on ischaemic muscles may include the augmentation of angiogenesis and morphological muscular adaptation.[8–10] It has been demonstrated that ES augments the endogenous production of vascular growth factors, thus facilitating angiogenesis in ischaemic muscle.[8] New capillaries increase blood flow and oxygen availability to the exercising muscle, lessening the ischaemic symptoms.[9] Additionally, muscle fibre activation is enhanced by ES, while selective recruitment of fatigue-resistant type 1 muscle fibres is also thought to contribute to the improvement in claudication symptoms.[10]

These results provide new insights on ES while opening up new treatment options for the claudicant population. Furthermore, the ability of ES to produce muscular exercise activity without gross movement of joints or whole body exercise is an added advantage particularly in patients with comorbid disease such as severe osteoarthritis, chronic heart failure or pulmonary diseases.

Given the positive results, future research constituting randomized controlled trials with a larger sample size are indicated. In this study, this was not possible due to limited number of eligible participants available. By evaluating the macro-circulatory response to ES, future studies may also reveal whether the effectiveness of ES may extend beyond reduction in claudication symptoms.

In conclusion, electrical calf-muscle stimulation significantly increased the walking capacity in claudicants living with type 2 diabetes. While urging further research in this field, this study signifies positive prospects for ES as an adjunct treatment modality for claudication symptoms particularly in those precluded from active exercise training.

Declaration of conflicting interests

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