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Randomised Controlled Trial: Potential Benefit of a Footplate Neuromuscular Electrical Stimulation Device in Patients with Chronic Venous Disease

R. Ravikumar [*], **K.J. Williams, A. Babber, T.R.A. Lane, H.M. Moore, A.H. Davies**

Academic Section of Vascular Surgery, Department of Surgery and Cancer, Imperial College London, UK

WHAT THIS PAPER ADDS

This pilot randomised clinical trial investigates the novel use of neuromuscular electrical stimulation (NMES) in treating patients with venous disease. NMES is a non-invasive method of activating the calf muscle pump to alter venous flow parameters. This is the first trial investigating the use of the REVITIVE device in the management of venous disease.

Objectives: Chronic venous disease (CVD) is common, affecting a quarter of the population. Current conservative methods of treatment aim to prevent progression of disease by reducing ambulatory venous pressure. Neuromuscular electrical stimulation (NMES) refers to the use of electrical impulses to elicit muscle contraction. This pilot randomised controlled trial investigates the effect of a footplate NMES device (REVITIVE) on venous flow parameters, limb oedema, and quality of life outcome measures in patients with CVD.

Methods: Twenty-two patients with Clinical Etiological Anatomical and Pathophysiological (CEAP) clinical class C2–C4 venous disease were randomised to receive a sham or test device. The recommended duration of use was for 30 minutes daily for 6 weeks. Venous flow parameters (duplex ultrasound), limb volume (optoelectric volumeter), and quality of life outcome measures were measured at baseline and after 6 weeks.

Results: The mean age of participants was 62 years, body mass index 28.6, with a 15:7 female preponderance. There was a significant difference in the percentage change in femoral vein flow parameters (from baseline) between the test and sham group while using the device (Week 0 time-averaged mean velocity 102.4% vs. −9.1%, $p < .0001$; volume flow 107.9% vs. −3.7%, $p < .0001$; peak velocity 377.7% vs. −6.7%, $p < .0001$). Limb volume was observed to increase significantly in the sham group (2.0% at Week 0 and 1.2% at Week 6; $p < .01$). This was prevented in the test group (+0.8% at Week 0 and 1.0% at Week 6; $p = .06$). There was a significant difference in the Aberdeen Varicose Vein Questionnaire between the two groups over the 6 weeks.

Conclusions: This trial demonstrated a significant difference in venous flow parameters and prevention of orthostatic limb oedema with NMES. There was a positive effect on quality of life. Larger studies are required to determine the clinical significance of this in patients with venous disease.

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INTRODUCTION

Chronic venous disease (CVD) is a common condition affecting the lower limbs.[1] Its clinical manifestations range from asymptomatic varicose veins to venous ulceration. Up to 50% of the general population have varicose veins, of whom 15% suffer from venous oedema and 5% from skin changes or ulceration.[2,3] Venous ulceration affects 2.9% of the population and is a significant financial burden to the NHS.[4]

Ambulatory venous hypertension leads to the progression of venous disease, resulting in venous ulceration. The muscle pumps of the lower limbs are an important mechanism of reducing ambulatory venous pressure.[5,6] Activation of the calf muscle pump can reduce ambulatory venous pressure by 50%.[1] Current therapies used to treat venous disease aim to reduce ambulatory venous pressure by activating or augmenting the calf muscle pump through passive (e.g., graduated compression stockings [GCSs], multilayered bandaging and intermittent pneumatic compression [IPC]), and active mechanisms (e.g., exercise therapy[7]). However, patients with venous disease often

* Corresponding author. Room 4N13C, Charing Cross Hospital, Fulham Palace Road, London W6 8RF, UK.

E-mail address: r.ravikumar@imperial.ac.uk (R. Ravikumar).

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have several co-existent pathologies such as lack of ankle range of motion and muscle weakness, which impair the effect of the calf muscle pump.[5,6]

Neuromuscular electrical stimulation (NMES) has been shown in healthy individuals to increase venous blood flow parameters by artificially activating the muscle pumps of the lower limb.[8] This pilot randomised controlled trial was conducted to investigate the effect of a NMES device on venous flow parameters, limb volume and quality of life of patients with chronic venous disease.

METHOD

Patient recruitment

This study was a single-centre randomised controlled trial conducted at Charing Cross Hospital, London, between February and September 2014. Ethics approval for the study was obtained from the National Research Ethics Committee (NRES ref: 13/YH/0295) and the trial protocol was published on clinicaltrials.gov (NCT02114307).

Patients with Clinical Etiological Anatomical and Pathophysiological (CEAP) clinical class C2–C4 and duplex ultrasound scan-confirmed diagnosis of superficial and/or deep venous disease were recruited from the vascular outpatient department. CEAP assessment, venous flow parameters, and limb volumes were measured in the affected or worse affected limb. Following written informed consent, patients were screened according to the inclusion and exclusion criteria (supplementary data). Medical history, medications, and anthropometric measurements were recorded at baseline. Patients in both groups were advised to continue with best medical therapy as prescribed by the clinical team. This includes compression stockings.

Eligible patients were randomised on a 1:1 ratio with block randomisation, using a web-based randomisation service (www.sealedenvelope.com) to either a sham or test group.

Sample size

A power calculation was not available for this pilot trial as it was investigating a novel intervention.

The neuromuscular electrical stimulation (NMES) device: REVITIVE IX

The device investigated is a class IIa medical device, CE marked for use in healthy individuals (REVITIVE, Actegy Health Ltd, Bracknell, UK). It is used in the seated position, with the users' bare feet placed on a pair of conductive footplate electrodes (Fig. 1). Electrical impulses are delivered to the muscles and nerves of the feet, which cause foot and calf muscle contraction at sufficient intensity. Direct contact between skin and electrodes is required for stimulation, precluding the use of compression stockings. Both feet have to be placed on the conductive footplates for the device to work.

Patients were expected to use the device for 30 minutes daily over a 6-week period. A patient diary card was used to monitor compliance. This was compared with a data logger, which monitored the electrical activity of the device.

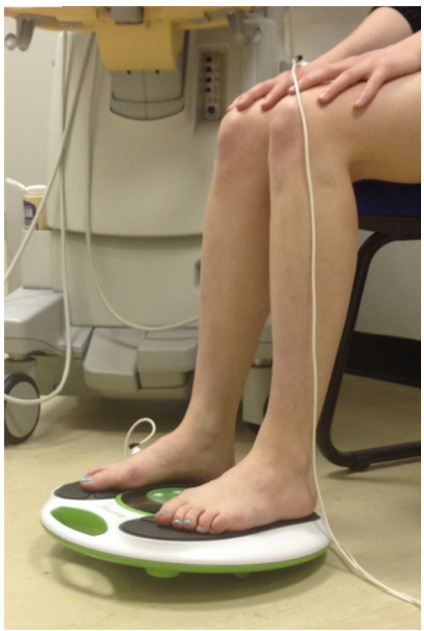

Figure 1. Illustration of patient position while using the device.

Patients were required to continue with best medical therapy (e.g., compression stockings) as prescribed by the clinical team, which was independent from the trial. The investigator was not blinded to the allocation as this would not be possible.

Test device

The test device runs a 30-minute programme of NMES consisting of 15 different waveform patterns, each with varying electrical output characteristics. The intensity of stimulation ranges from 1 to 99 units, delivering a maximum current of 13 mA (r.m.s., root mean square) at 500 Ω resistance. Stimulation intensity is increased by the subject until visible contraction is seen. This threshold intensity level is then doubled for the purposes of stimulation in this trial. The intensity of stimulation varies for each individual, and is affected by oedema and moisture. Patients were advised to use the highest intensity that was comfortable for them. The additional isorocker feature involves a fulcrum across the middle of the device over which the device can pivot to an angle of up to 15°. This allows the foot to remain in contact with the conductive footplate electrodes during ankle flexion and dorsiflexion. The isorocker can be disabled by pulling out the lever of the fulcrum, which sets the device at a 15° inclination.

Sham device

The sham device was identical to the test device, but delivered no electrical impulses. Patients were advised to set the intensity to 25 and to disable the isorocker. Hence, it simulated the effect of sitting still for 30 minutes. Patients were blinded as they were not informed which group they

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