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The Effectiveness of Calf Muscle Electrostimulation on Vascular Perfusion and Walking Capacity in Patients Living With Type 2 Diabetes Mellitus and Peripheral Artery Disease

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Abstract The aim of the study was to explore calf muscle electrostimulation on arterial inflow and walking capacity in claudicants with peripheral artery disease and diabetes mellitus. A prospective, 1-group, pretest-posttest study design was used on 40 high-risk participants (n = 40) who exhibited bilateral limb ischemia (ankle brachial pressure index [ABPI] <0.90), diabetes mellitus, and calf muscle claudication. A program of calf muscle electrical stimulation with varying frequency (1-250 Hz) was prescribed for 1 hour per day for 12 weeks. Spectral waveforms analysis, ABPI, absolute claudication distance (ACD), and thermographic temperature patterns across 4 specified regions of interest (hallux, medial forefoot, lateral forefoot, heel) at rest and after exercise, were recorded at baseline and following intervention to evaluate for therapeutic outcomes. A significant improvement in ACD and ABPI was registered following the intervention (P = .000 and P = .001, respectively). Resting foot temperatures increased significantly (P = .000) while the post exercise temperature drops were halved across all regions at follow-up, with hallux (P = .005) and lateral forefoot (P = .038) reaching statistical significance. Spectral Doppler waveforms were comparable (P = .304) between both serial assessments. Electrical stimulation of varying frequency for 1 hour per day for 12 consecutive weeks registered statistically significant improvement in outcome measures that assess arterial inflow and walking capacity in claudicants with diabetes mellitus. These results favor the use of electrostimulation as a therapeutic measure in this high-risk population.

Keywords electrical stimulation, diabetes mellitus, peripheral artery disease, intermittent claudication

Exercise has been the cornerstone of noninvasive management of peripheral arterial disease (PAD) for the past 40 years1. Indeed, several collaborative authorities, including the Trans-Atlantic Inter-Society Consensus (TASC) II

PAD management working group2, the American Heart Association/American College of Cardiology,3 and the Society of Vascular Surgery,1 recommend exercise as a first-line therapy in claudicants. Despite the known efficacy of exercise in patients living with PAD, not all patients can follow a prescribed exercise regime. A number of physical and psychosocial factors may preclude adherence of patients to any form of exercise program.1 Comorbid conditions like osteoarthritis, musculoskeletal problems, foot/limb pain, foot ulcers, and other factors like bad weather, age, and lack of motivation may all discourage any form of cardiovascular exercise.4 Another significant

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barrier to exercise is intermittent claudication, which is experienced by 25% to 35% of patients with PAD.
Furthermore, in the context of diabetes, a cross-sectional study5 on a multigender cohort of 460 patients with PAD (147 with diabetes) aged 55 years and older with medical histories consistent of PAD (ankle brachial pressure index [ABPI] <0.90) demonstrated that patients with diabetes and PAD have poorer lower extremity functions than patients presenting with PAD only. All these factors preclude adherence to exercise therapy creating a lacuna for the effective management of this vulnerable population. In this context, electrical stimulation (ES) targeted on ischemic muscles has been proposed as a potential passive alternative to exercise training. However, to date, only a few studies have evaluated the sustained effectiveness of this therapeutic modality on patients living with diabetes and PAD.6,7 Moreover, those studies that provide evidence on the effects of intermittent ES have been conducted on laboratory ischemic animal models8-11 while those including PAD patients had methodological limitations, including poor sample sizes, fixed low frequency of stimulation, and short duration of intervention.6,7 Therefore, the aim of this study was to explore the efficacy of longer term variable frequency (1-250 Hz) calf muscle ES on arterial inflow and walking capacity in claudicants with PAD and diabetes mellitus.

Results

Out of a total of 71 prospective participants, 40 participants (30 males; 10 females) with a mean age of 70.83 years (SD 7); mean body mass index 28.88 kg/m2 (SD 3.7); mean diabetes duration 15 years
(SD 6); mean HbA1c 8.2% (SD 1.56) (66 mmol/mol), were included in the study. Thirty-one participants were excluded during screening due to elevated ABPI readings or because they did not reach claudication distance within the maximal walking distance or timeframe stipulated in the protocol. The Veinoplus Arterial device (Ad Rem Technologies, France) was used for a consecutive mean duration of 91.68 days (SD 6.23) as quantified through the patient log-sheets. Seventy-five percent of participants were on aspirin, 10% on clopidogrel, and 22.5% on dipyridamole.

Arterial Flow

The ABPIs of 80 limbs were recorded with each limb scored separately for each participant at baseline (mean 0.702, SD 0.12) and follow-up (0.743, SD 0.16). Following intervention, a statistically significant increase in ABPI was detected (paired sample t test, P = .001; 95% CI, 0.02-0.07). Figure 2 presents the mean baseline and follow-up ABPI scores. Qualitative spectral waveforms of the posterior tibial and dorsalis pedis arteries of both limbs (N = 80) were also evaluated. Table 1 illustrates the waveform classification for each artery. Spectral waveform changes at follow-up relative to baseline are comparable (McNemar test, posterior tibial, P = .304; dorsalis pedis, P = .117).

Walking Capacity

The mean ACD at baseline was 333.71 m (SD, 208.44), which increased to 470.73 m (SD, 278.75) at 12-week follow-up. This translated to a mean walking capacity that was 41% better at follow-up relative to baseline. This mean improvement (137 m, SD = 136) in ACD was found to be statistically significant (Wilcoxon signed rank test, P = .000). The post hoc power analysis of the ABPI and ACD result was 90% and 94%, respectively, exceeding the minimum level of power required of 80%.

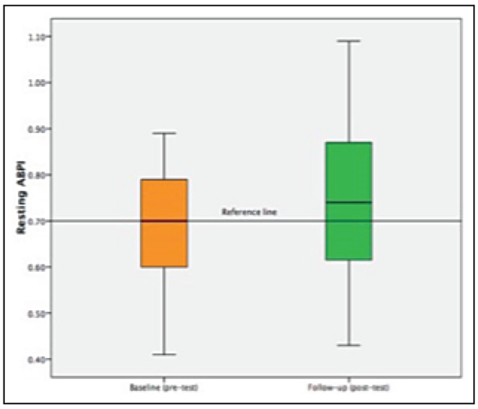

Figure 2. Baseline versus follow-up resting ankle brachial pressure index (ABPI) with means (N=80). Reference lines indicate baseline and follow-up means.

Table 1. Comparison of Spectral Doppler Waveforms at Preintervention ans Postintervention.

Anatomcal Artery	Waveform Type	Baseline n (% frequency)	Follow-up n (% frequency)
Posterior tibial	Monophasic continuous	15 (18.8)	16 (20)
	Monophasic	60 (75)	59 (73.8)
	Biphasic	5 (6.3)	5 (6.3)
Dorsalis pedis	Monophasic continuous	26 (32.5)	24 (30)
	Monophasic	49 (61.3)	52 (65)
	Biphasic	5 (6.3)	4 (5.1)

Resting Temperature and Post exercise Temperature Change

The resting temperatures and eTC derived from the regions of interest at baseline and follow-up are presented in Table 2. In both measures, the mean resting temperature was lowest in the hallux ROI and highest in the medial forefoot ROI; however, these differences were not found to be statistically significant (baseline, P = .451; follow-up, P = .259, one-way analysis of variance).

Table 2. Comparison of Infrared Thermal Temperatures at Baseline and at 12 Weeks Following Intervention.

Description	Region of Interest	Baseline (N=80), °C		Follow-up (N=80), °C	
		Mean	SD	Mean	SD
Resting temperatures	Hallux	27.71	3.19	30.14[2]	2.45
	Medial	28.38	2.59	30.74[2]	2.07
	Lateral	28.19	2.58	30.66[2]	2.04
	Heel	28.06	2.21	30.43[2]	1.75
Exercise temperature change (eTC)	Hallux	- 0.82	1.35	- 0.41[2]	1.22
	Medial	- 0.50	1.38	- 0.25[2]	1.16
	Lateral	- 0.57	1.42	- 0.29[2]	1.08
	Heel	- 0.30	1.26	- 0.11	1.05

[a]*P*< .05, relative to baseline

At the follow-up, a statistically significant increase (paired-sample t test) in resting temperature of around 2°C was recorded across all ROIs for the hallux (P = .000, 95% CI, 1.86-2.99), medial (P = .000, 95% CI = 1.89-2.84), lateral (P = .000, 95% CI, 2.00-2.95), and heel ROI (P = .000, 95% CI 1.93-2.82). Following exercise, drops in temperatures were registered across all ROIs at both baseline and follow-up as presented in Table 2. The reduction in temperature drops following the 12-week intervention was approximately halved in all regions and found to be statistically significant in the hallux (P = .005, 95% CI, −0.10 to −0.72) and lateral forefoot (P = .038, 95% CI, 0.03 to −0.58) ROI. In the medial (P = .063, 95% CI, 0.07 to −0.56) and heel (P = .091, 95% CI, 0.09 to −0.47), no statistical significance was found.