Improvement of the Walking Ability in Intermittent Claudification with Supervised Exercise and Pneumatic Foot and Calf Compression: Results at Six Months of a Randomized Controlled Trial

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Introduction/Aim of the Study: The purpose of the prospective randomized trial is to compare the effect of unsupervised exercise, supervised exercise and intermittent pneumatic foot and calf compression (IPC) on the claudication distance and lower limb arterial hemodynamics of patients with intermittent claudication as a result of superficial femoral artery occlusion.

Materials/Methods: Thirty-four eligible patients with stable intermittent claudication and absolute claudication distance (ACD) 300m, selected out of 151 patients screened, were randomized to IPC (ArtAssist® device, model AA-1000, n=13, for 3 hr/d), supervised exercise (n=12, three hour session/week on a treadmill in the physiotherapy department) or unsupervised exercise (n=9), with stratification for age and walking distance. All patients were on antiplatelet agents and were asked to exercise daily by walking. In each patient, initial claudication distance (ICD), ACD, resting ankle brachial pressure index (ABPI) resting and reactive hyperemic calf arterial inflow (15 serial measurements, 15 seconds apart, following 5 minutes of thigh occlusion) were measured before, and six weeks and six months after randomization, using venous occlusion air plethysmography (APG). Reactive hyperemic calf arterial inflow was normalized for resting flow, while the hyperemic index (ration of the area under the hyperemic curve/peak flow) was also calculated. All results are shown as median and interquartile range.

Results: Compared with unsupervised exercise, both IPC and supervised exervise increased ICD and ACD, up to 2.6 times (Table). IPC increased arterial inflow)p<0.05 at 6 weeks) and ABPI, and decreased the reactive hyperemic flow ration at 15 seconds (at week 6, p<0.009) and 30 seconds (at week 6, p<0.01 and month 6, p<0.028). Unsupervised exercise decreased arterial inflow and increased ABPI (p<0.05 at 6 months). Unsupervised exercise had no effect on arterial inflow or ABPI.

	Group	Baseline	6 weeks	6 month
ICD (m)	Unsupervised Exercise	70 (22.5)	80 (45)	77.5 (17.5)
	Supervised Exercise	60 (26.25)	80 (35)*	70 (45)*
	IPC	60 (35)	85 (65)*	90 (85)
ACD (m)	Unsupervised Exercise	135 (87.5)	130 (130)	130 (62.5)
	Supervised Exercise	145 (108.75)	235 (142.5)**	220 (282.5)*
	IPC	145 (145)	295 (210)**	370 (732.5)*
ABPI	Unsupervised Exercise	.060 (0.24)	0.60 (0.20)	0.60 (0.13)
	Supervised Exercise	0.51 (0.14)	0.56 (0.21)	0.62 (0.15)*
	IPC	0.56 (0.16)	0.60 (0.08)	0.62 (.034
Resting Arterial Inflow (ml/sec)	Unsupervised Exercise	1024 (0.81)	1.24 (1.13)	1.28 (0.94)
	Supervised Exercise	108 (0.80)	1.32 (1.38)	1.26 (0.64)
	IPC	0.9 (0.59)	1.15 (1.04)*	1.04 (0.39)
Hyperemic Index	Unsupervised Exercise	2.05 (1.40)	1.97 (1.59)	2.73 (1.75)
	Supervised Exercise	2.26 (2.94)	2.37 (2.59)	2.67 (2.56)
	IPC	3.14 (1.27)	1.93 (3.00)	1.99 (2.38)
	Intra-group	Comparison	*p<0.05	**p<0.01

Conclusion: IPC, by augmenting leg perfusion, achieved improvement in walking distance comparable with supervised exercise. No improvement or perfusion changes were seen in patients randomized to unsupervised exercise. Long-term results in a larger number of patients will provide valuable information on the optimal treatment modality of intermittent claudication.