

Improvement in Walking Ability, Ankle Pressure Indices and Quality of Life in Vascular Claudication Using Intermittent Pneumatic Foot and Calf Compression: A Randomized Controlled Trial

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Background: Perioperative mortality, graft failure and limitations of balloon angioplasty mitigate against active intervention for claudication. With the exception of exercise programmes, conservative treatments yield modest results. Intermittent pneumatic compression (IPC) of the foot used daily for over 3 months enhances significantly the walking ability and pressure indices of stable claudicants. The prospective randomized study evaluated the effects of IPC of the foot and calf simultaneously ($IPC_{foot+calf}$) on the walking ability, arterial haemodynamics and quality of life of patients with intermittent claudication.

Methods: Forty-one stable claudicants, meeting stringent inclusion and exclusion criteria, were randomized to receive either $IPC_{foot+calf}$ and 75 mg aspirin (group 1, n=21) or 75 mg aspirin alone (group 2 n=20), with stratification for diabetes and smoking. Groups matched for age, sex, initial (ICD) and absolute (ACD) claudication distance, ankle: brachial pressure index (ABPI), popliteal artery flow (Q) and quality of life (Short Form (SF) 36 questionnaire). $IPC_{foot+calf}$ (120 mmHg, three cycles per min, inflations 4 s, proximal inflation delay 1s) was used for 2.5 hours daily for 5 months consecutively. Both groups were advised to exercise unsupervised. Evaluation of patients, after randomization, included (a) ICD and ACD on a treadmill, (b) resting and postexercise ABPIs, (c) Q using duplex imaging, and (d) quality of life. Compliance was assessed by means of a log book. Non-parametric analysis was used (Wilcoxon and Mann-Whitney tests).

Results: After 5 months of $IPC_{foot+calf}$ Median ICD, ACD, resting and post exercise ABPI in group 1 increased by 197, 212, 17, and 64 percent (all $P<0.001$) respectively; changes in group 2 were all non-significant ($P>0.1$). On intergroup comparison at 5 months, patients in group 1 were better than those in group 2 in terms of ICD, ACD, resting and

postexercise ABPI (all $P < 0.01$). Q changes within this period were not significant in either group; neither were intergroup Q differences ($P > 0.1$). Associated changes in the quality of life within group 1 at the of month 5 were significant; non-significant changes were noted in group 2. At 5 months patients in group 1 enjoyed a better quality of life than those in group 2 ($P < 0.01$). $IPC_{foot+calf}$ use did not result in any complications. The daily $IPC_{foot+calf}$ compliance (2.5 h per day) was greater than 82 percent in the first month and greater than 85 percent in months 2-5. Once year after the end of $IPC_{foot+calf}$ application, patients in group 1 maintained the improved ABPI and walking benefit.

Conclusion: $IPC_{foot+calf}$ emerged as an effective, high-compliance, uncomplicated method for improving the walking ability and pressure indices in patients with stable claudication, with a confirmed durable outcome. These changes are associated with a significant improvement in all aspects of quality of life evaluated by the SF-36. Despite a limited benefit noted in some individuals, unsupervised exercise had a non-significant impact overall.