

## INTERMITTENT PNEUMATIC FOOT & CALF COMPRESSION IN VASCULAR CLAUDICATION: A RANDOMIZED TRIAL

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**AIM:** Peri-operative mortality, graft failure and limitations of balloon angioplasty mitigate against active intervention for claudication, with the exception of exercise programs, conservative treatments yield modest results. Intermittent pneumatic compression (IPC) of the foot used daily for over three months enhances the walking ability and pressure indices of stable claudicants significantly. Although IPC applied to the foot and calf simultaneously (IPC<sub>foot+calf</sub>) is far superior to IPC of the foot haemodynamically, its long-term effects in claudicants have never been studied. This prospective randomized study evaluates the effects of IPC<sub>foot+calf</sub> on the walking ability, arterial haemodynamics and quality of life in patients with intermittent claudication.

**MATERIALS AND METHODS:** 41 stable claudicants, meeting stringent inclusion and exclusion criteria, were randomized to receive either IPC<sub>foot+calf</sub> and 75mg of aspirin (Group A; n=21), or 75mg of aspirin alone (Group B; n=20), with stratification for diabetes and smoking. Groups matched for age, sex, initial [ICD] and absolute [ACD] claudication distances, pressure indices [ABI], popliteal artery flow [Q], and quality of life (SF-36). IPC<sub>foot+calf</sub> (120mmHg, 3 cycles/min, inflation 4 sec, proximal inflate delay 1 sec) was used for 2.5 hrs daily, 5 consecutive months. Both groups were advised to exercise unsupervised. Evaluation of patients, after randomization, included a) ICD and ACD on a treadmill b) resting and post-exercise ABIs c) Q using duplex and d) quality of life\*. Study time-points were: baseline\*, 1/12,2/12,3/12,4/12,5/12\* and 17/12. Compliance was based on logbooks and built-in machine counters. The Wilcoxon and Mann-Whitney tests (with Bonferroni corrections) were used in the statistical analysis of data.

**RESULTS:** Following 5 months of IPC<sub>foot+calf</sub> the median ICD, ACD, resting and post-exercise ABIs in Group A increased by 197%, 212%, 17% and 64% (all  $p < 0.001$ ) respectively; changes in Group B were all non-significant ( $p > 0.1$ ). On intergroup comparison at 5/12, Group A was better than Group B in ICD, ACD, resting and post-exercise ABI (all  $p < 0.01$ ). Q changes within this period were non-significant in both groups; so were inter-group Q differences ( $p > 0.1$ ). Associated changes in the quality of life within Group A at the end of 5<sup>th</sup> month were significant; non-significant changes were noted in Group B. At 5 months, Group A patients enjoyed a better quality of life than Group B ( $p < 0.01$ ). IPC<sub>foot+calf</sub> use did not result in any complications. The daily IPC<sub>foot+calf</sub> compliance (2.5 hrs/day) was  $>82\%$  in the first month and  $>85\%$  in 2-5 months.

One year after the end of IPC<sub>foot+calf</sub> application, Group A patients maintained their ABIs and walking benefits.

**CONCLUSIONS:** IPC<sub>foot+calf</sub> emerged as effective, high-compliance, uncomplicated method for improving the walking and pressure indices in 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 some limited benefit noted in some individuals, unsupervised exercise had a non-significant impact overall.