Improving Walking Ability Using Foot Compression Treatment

Delis KT, Nicolaides AN, Wolfe JH, Stansby G. Improving walking ability and ankle brachial pressure indices in symptomatic peripheral vascular disease with intermittent pneumatic foot compression: a prospective controlled study with one-year follow up. J Vasc Surg 2000;31:650–1.

Study Overview

Objective. To determine if a device that delivers intermittent compression to the sole of the foot improves walking ability and vascular indices in patients with stable exercise-induced lower extremity claudication.

Design. Nonrandomized, controlled clinical trial.

Setting and participants. Thirty-seven patients agreed to participate in the study. (Authors did not report details of recruitment and setting.) All subjects met inclusion criteria: unilateral, intermittent stable claudication with a maximal walking distance (MWD) of 40 to 300 m at baseline; superficial femoral artery occlusion; and absence of clinically important aortoiliac or popliteal disease. Extensive exclusion criteria eliminated individuals with cardiac and pulmonary disease or other conditions (rheumatologic, orthopedic, neurologic) that would limit walking ability. Diabetic patients on insulin for more than 5 years, obese patients, and patients with more extensive or complicated peripheral vascular disease were also excluded. Study participants were matched in groups of 3 by age, sex, claudication distance, hemodynamics, and risk factors. In each group, 2 patients were allocated to the intervention and 1 to standard care.

Intervention. Both groups of patients received standard care consisting of 75 mg of aspirin daily and advice to exercise for at least 1 hour per day. Intervention patients also received the A-V Impulse System (Novamedix, Andover, Hampshire, UK) and instructions to use it a total of 4 hours per day over 1 to 3 sessions for 4.5 months.

Main outcome measures. The principle clinical outcomes were pain-free walking distance (PFWD) and MWD assessed with a treadmill protocol. Physiologic measures included resting and postexercise ankle-brachial indices (ABIs). Technicians assessing ABIs were blind to treatment assignment; however, the authors did not indicate if the same were true of investigators assessing treadmill walking distance. It was not stated whether results were computed by intention-to-treat or treatment received. Statistical significance was set at $P \leq 0.02$.

Main results. 25 patients used the device and 12 received standard care. 86% of the intervention patients adhered to the treatment regimen as assessed by a device hidden in the equipment. One patient in each group smoked; 3 intervention patients and 1 control patient had diabetes. The average age of all of the patients was 67 years, and 65% were men. Completeness of follow-up and drop-out rates were not reported.

All patients in the intervention group increased both of their walking distances: the median PFWD in this group rose from 78 to 183 m and the median MWD rose from 124 to 245 m (both $P < 0.001$) at 4.5 months. (The improvement between 3 to 4.5 months was not significant.) The control group did not demonstrate a significant increase in either walking parameter. There was no significant decline in walking distances from 4.5 to 12 months. The intervention group had significantly higher PFWDs and MWDs at 12 months compared with the control group ($P < 0.0001$ and $P = 0.004$). ABI measurements showed a smaller but significant ($P = 0.01$ to $P < 0.001$) improvement in the intervention group and no significant change among controls. There was no or poor correlation between changes in ABIs and changes in walking distances.

Conclusion

A device that delivers intermittent pneumatic compression to the foot appears promising for the treatment of patients with intermittent claudication.

Commentary

Although this study broke several rules of good study design—most notably the lack of randomization—it offers an intriguing look at a new modality for the treatment of a common clinical problem. Besides the weaknesses mentioned above (eg, lack of intention-to-treat analysis, unblinded treadmill tests), there were a few key problems that the authors did not address. For example, the authors did not discuss adverse events. Although it was implied in the

research findings that no adverse events had occurred, Delis and colleagues did not make this information explicit. No placebo or sham intervention was used in the study. Further, the authors did not report on the amount of exercise patients did during the study period. Exercise has documented functional benefits [1] that could have substantially confounded research results. Investigators also reported excluding patients taking "vasoactive medications" but did not list which medications met this criteria and made no comment on patients' medical regimens.

Despite the questionable quality of the evidence, this study is valuable in that the effect size was as large or larger than other noninvasive interventions [1,2]. Given its low cost and lasting effects, the compression treatment examined by Delis et al should be investigated in a larger, better-designed trial, possibly including cilostazol, pentoxifylline, and/or exercise.

Applications for Clinical Practice

Delis and colleagues' research was essentially a pilot study. The low numbers and quality of evidence the authors produced do not merit a change in clinical practice at this time. Physicians should look to future trials to determine if this study's effect size can be validated and if improvements in quality of life and functional status can be reproduced in broader research contexts.

References

1. Leng GC, Fowler B, Ernst E. Exercise for intermittent claudication. Cochrane Database Syst Rev 2000;2:CD000990.
2. Beebe HG, Dawson DL, Cutler BS, Herd JA, Strandness DE Jr, Bortey EB, Forbes WP. A new pharmacological treatment for intermittent claudication: results of a randomized, multicenter trial. Arch Intern Med 1999;159:2041–50.

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