

The results of the sequential compression biomechanical device in patients with critical limb ischemia and nonreconstructible peripheral vascular disease

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Sherif Sultan, MD, FRSC,^{a,b} Nader Hamada, MRCS, MCH,^a Esraa Soylu, MBBCh,^a
Anne Fahy, MPPM,^a Niamh Hynes, MD, MRCS,^{a,b} and Wael Tawfick, MRCSI,^a Galway, Ireland

Objectives: Critical limb ischemia (CLI) patients who are unsuitable for intervention face the dire prospect of primary amputation. Sequential compression biomechanical device (SCBD) therapy provides a limb salvage option for these patients. This study assessed the outcome of SCBD in severe CLI patients who otherwise would face an amputation. Primary end points were limb salvage and 30-day mortality. Secondary end points were hemodynamic outcomes (increase in popliteal artery flow and toe pressure), ulcer healing, quality-adjusted time without symptoms of disease or toxicity of treatment (Q-TwiST), and cost-effectiveness.

Methods: From 2004 to 2009, we assessed 4538 patients with peripheral vascular disease (PVD). Of these, 707 had CLI, 518 underwent intervention, and 189 were not suitable for any intervention. A total of 171 patients joined the SCBD program for 3 months.

Results: All patients were Rutherford category >4. Median follow-up was 13 months. Mean toe pressure increased from 39.9 to 55.42mmHg, with a mean difference in toe pressure of 15.49mmHg ($P<.0001$). Mean popliteal flow increased from 35.44 to 55.91 cm/s, with mean difference in popliteal flow of 20.47 cm/s ($P<.0001$). Mortality at 30 days was 0.6%. Median amputation-free survival was 18 months. Limb salvage at 3.5 years was 94%. Freedom from major adverse clinical events (MACE) at 4.5 years was 62.5%. We treated 171 patients with SCBD at a cost of €681,948, with an estimated median per-patient cost of treatment with SCBD of €3988.

Conclusion: SCBD therapy is a cost-effective and clinically efficacious solution in CLI patients with no option of revascularization. It provides adequate limb salvage and ameliorated amputation-free survival while providing relief of rest pain without any intervention.

From the Department of Vascular and Endovascular Surgery, Western Vascular Institute, University College Hospital, Galway (UCHG)^a; and the Department of Vascular and Endovascular Surgery, Galway Clinic.^b
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All of the devices used in this study are the ArtAssist® device made by ACI Medical, LLC.