

# Noninvasive Treatment for CLI with a Sequential Compression Device: Does it Work?

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CLI prognosis is dire and carries a high risk of primary major amputation within two years with subsequent morbidity and mortality in unmanaged patients. The clinical efficacy of SCBD therapy imparts essential benefit to patients who otherwise would be at impending risk of limb loss.

The aim of our study is to find out the long term outcome of the use of the SCBD as an alternative treatment for patients with CLI who are unfit for revascularisation, either due to un-reconstructable PVD, due to the nature and distribution of the disease or due to severe co-morbidity scores and expected poor intervention outcome.

Patients were assessed on an intention to treat basis. Composite-primary endpoints were limb-salvage, sustained clinical improvement, rest-pain resolution, and 90-day mortality. Second endpoints were hemodynamic outcomes with increase in popliteal artery flow and toe pressure, ulcer healing, QTWIST, QALY and cost-effectiveness. From 2004 to 2009, we reviewed more than 4500 patients with PVD. 707 of them presented with CLI, 518 had one or more intervention for their PVD, while 189 were not candidates for surgery. Only 170 patients had joined the SCBD programme for three months at three hours bi-daily. We matched controlled 75 primary amputations which were performed in the previous five years.

Demographic data was recorded according to the International Classification of Disease code. Patients were assessed regarding cardiovascular risk factors and severity of Peripheral Vascular Disease. Imaging was primarily by Duplex Ultrasound Arterial Mapping with popliteal artery flow assessment, resting ankle brachial-pressure and digital pressure measurement. Follow up was at 30, 90 days and regular 6-month intervals.

All patients were Rutherford category 4 or 5 with multilevel disease. All patients received best medical treatment. The median follow up was 13 months with average of 18.3 months (ranged from 1 to 62 months).

Sustained clinical improvement was reported in 68% of patients. Sustained hemodynamic improvement were noted with; Mean toe pressure increase from 39.9mmHg to 55.42mmHg post 12 months of treatment with mean difference in Toe Pressure of 15.49mmHg (95%CI=8.06 to 22.92, SD=30.92) P=0.0001; and Mean Popliteal flow increase from 35.44cm/sec to 55.91cm/sec 12 months post treatment with Mean Difference in Popliteal Flow of 20.47cm/sec (95%CI=14.02 to 26.91, SD=46.22) P<0.0001.

30 day mortality was 99.4%. Mean Amputation free survival rate was 18 months with limb salvage rate at 5years of 94%. Freedom from MACE at 5 Years was 62.5%. All cause survival was 68.4% at 5 years. Ten patients underwent AKA and one had BKA. Out of fifty four who died from their co morbidities only five patients lost their legs before death.

Cox proportional hazard ratio showed that smoking, DM, CRF, hypertension and hypercholesterolemia did not have a significant impact on limb salvage or toe pressure improvement.

Estimated median Inpatient/Total cost of managing a primary-amputation patient is €29,815 compared to €3985 for SCBD.

Cost per Quality for artassist was €1756. Q-TWiST was 20.48 for a total of 708 months of ArtAssist usage. We treated 170 patients with artassist at a cost of €681,965 with superior limb salvage rate. However primary amputation for 75 patients had cost €2,236,125 with poor QALY and lower QTWiST.

Art-Assist SCBD is a valuable tool in the armamentarium for dealing with CLI patients with un-reconstructable PVD. It gives superior limb salvage, ameliorates amputation free survival, enhances ulcer healing rates, reduces length of hospital stay and provides rapid relief of rest pain without any intervention in patients with limited life expectancy.