Eur J Vasc Endovasc Surg (2016) 51, 565–571

The Role of Sequential Pneumatic Compression in Limb Salvage in Non-reconstructable Critical Limb Ischemia

M. Zaki [a,b], M. Elsherif [a], W. Tawfick [a], M. El Sharkawy [a], N. Hynes [a,c], S. Sultan [a,c,*]

[a] Western Vascular Institute, Department of Vascular and Endovascular Surgery, University Hospital Galway, National University of Ireland, Galway, Ireland
[b] Vascular Surgery Department, Ain Shams University, Cairo, Egypt
[c] Galway Clinic, Royal College of Surgeons of Ireland Affiliated Hospital, Doughiska, Galway, Ireland

WHAT THIS PAPER ADDS

Critical limb ischemia (CLI) is an increasingly alarming presentation of an advanced stage of underlying generalized circulatory failure. Most of the patients presenting with CLI have profound cardiovascular comorbidities that hinder surgical intervention. Moreover, some of the patients present with no suitable outflow or reconstructable arterial anatomy. For this vulnerable cohort of patients, primary amputation is often the only available treatment option. Alternative treatments for patients who are unsuitable for open or endovascular intervention are limited, with approximately 50% undergoing primary amputation and 50% receiving medical treatment only. This study aimed at answering the question: Can SPC preclude limb loss?

Objective: Critical limb ischemia (CLI) is an increasingly alarming presentation of advanced generalized circulatory failure. Most patients presenting with CLI have profound cardiovascular comorbidities that hinder surgical intervention. Moreover, some patients present with non-reconstructable arterial anatomy. For this vulnerable cohort, primary amputation is often the only available option. This study aims at answering the question: Can sequential pneumatic compression (SPC) preclude amputation?

Methods: A retrospective analysis of 187 patients (262 limbs) prescribed the Artassist SPC compared outcomes between the group of patients who acquired the device and those who did not. The primary end point was limb salvage; secondary end points were amputation-free survival and improvement in toe pressures.

Results: The mean age was 74.78 years, the median follow-up was 16 months, and the median duration of usage was 4 months. 81.72% of the patient acquired the device and 18.28% did not. The mean toe pressure was 61.4 mmHg pre-application, and 65 mmHg after application ($p = .071$). Amputation-free survival was 98% and 96% for those who acquired the device and 90% and 84% for those who did not at 6 and 12 months, respectively. There was a non-significant association between limb salvage and device acquisition ($p = .714$); however, there was a significant improvement in rest pain ($p < .0001$), reduction in minor amputation ($p = .023$), and amputation-free survival associated with using the device ($p = .01$).

Conclusions: Although limb salvage is the paramount ambition for patients referred to vascular services, some patients with CLI are better served with primary amputation. Although the mechanism of SPC action is still ambiguous, there is strong evidence to support its role in preventing minor amputation, prolonging amputation-free survival, and improving rest pain in patients with non-reconstructable CLI; nevertheless, its role in prevention of major amputation lacks statistical significance.

Article history: Received 21 September 2015, Accepted 21 December 2015, Available online 11 February 2016
Keywords: Critical limb ischemia, Sequential pneumatic compression, Artassist, Limb salvage

INTRODUCTION

Critical limb ischemia (CLI) is an increasingly alarming presentation of an advanced stage of underlying generalized circulatory failure. Subsequently, a considerable number of patients present with advanced stages of systemic comorbidities that form a paramount impediment, and create grave risks in any endeavor for revascularization. The Trans-Atlantic Inter-Society Consensus (TASC) II reported that amputation rates in CLI patients are as high as 30%, and mortality is as high as 25%.[1] One of the main

* Corresponding author. Clinical Vascular Lead Soalta Hospital Trust, Western Vascular Institute, Department of Vascular & Endovascular Surgery Galway University Hospital, Newcastle Road, Galway, Ireland.
E-mail address: sherif.sultan@hse.ie (S. Sultan).

1078-5884/

http://dx.doi.org/10.1016/j.ejvs.2015.12.025

reasons for the high mortality and amputation rates that accompany CLI is the relatively modest attempts of revascularization owing to either inacceptable risk condition, absence of a suitable run-off, or non-reconstructable arterial anatomy. Revascularization attempts were recently estimated as 56% of patients presenting with CLI.[2] Long-term follow-up of patients with CLI is extremely pessimistic, with amputation rates reported up to 42% and mortality rates of 8.3% in patients presenting with Rutherford Category 6.[2] Alternative treatments for patients who are unsuitable for open or endovascular intervention are limited, with approximately 50% undergoing primary amputation and 50% receiving medical treatment only.[3] The efficacy of pharmacotherapy in this latter group is limited, however, with trial data showing a 20% mortality rate and 60% amputation rate at 6 months.[1] In addition, the superimposed social, economical, and vocational drawbacks necessitate that any alternative treatment sought to alter outcome should definitely be worth investigation.

Sequential pneumatic compression (SPC) has been proposed as an adjunct to best medical care, aimed at preventing amputation, relieving pain, and promoting wound healing by increasing arterial blood flow in distal limbs.[3] The mechanism of action of SPC in circulatory promotion remains ambiguous. Numerous postulated theories include emptying of the plantar venous plexus and reduction of the venous leg pressure, increasing the arteriovenous pressure gradient, and increasing shear stress in endothelial cells of the lower limb vascular beds.[4] An additional suggested mechanism is the momentary delay in the local vasoregulation resistance of the venoarteriolar response and the transient suspension of the arteriovenous reflex hyperemia, which improves endothelial function and induces collateral arterial formation.[5] Moreover, long-term effects were deduced from the enhanced angiogenesis and collateral formation in response to the generation and release of nitric oxide (NO), tissue factor pathway inhibitor (TFPI), and endogenous tissue plasminogen activator (tPA), secondary to increased shear stress following rapid cyclic blood flow.[6]

The aim of this study is to investigate the role of SPC in limb salvage among a selected population of patients with non-reconstructable CLI.

PATIENTS AND METHODS

Study aim

The aim of this study was to compare the amputation-free survival rates in non-operable patients with critical limb ischemia using sequential pneumatic compression with the rates of those who do not use it. The ultimate goal is to formulate enough data to support or deny the use of this treatment modality exclusively on patients with non-reconstructable CLI.

The primary end point was amputation-free survival; secondary end points were limb salvage and improvement in toe pressures.

Study design and population

This is a retrospective study involving all patients who were prescribed sequential pneumatic compression devices for CLI in a high-volume tertiary referral vascular center. Ethics committee approval was obtained before the start of the study. The study included patients prescribed the device either as inpatients at University College Hospital, Galway, or on an outpatient basis from 2010 till 2015. During this interval, we reviewed 912 patients with CLI, 643 of whom had revascularization procedure(s) and 269 who were not candidates for revascularization. Among the patients who were not candidates for revascularization, 62 had a primary amputation due to late presentation, and 20 patients did not fulfill the inclusion criteria, which left a total number 187 patients (262 limbs). For those who agreed to participate, hospital records, vascular laboratory scans, and investigations were reviewed in addition to a questionnaire filled by the patients to derive the necessary data.

Each patient had a duplex scan done using a HDI 5000 machine (ATL Ultrasound, Bothell, WA, USA) or a Phillips IU22 (Philips Medical Systems) in the vascular laboratory. In case the duplex scan was inconclusive, a computed tomography angiogram was performed if the estimated glomerular filtration rate was above 50 ml/min. In case of severe renal impairment and inability of the arterial duplex to conclude sufficient data, such as in heavily calcified vessels, magnetic resonance angiography was carried out. Radiological findings were examined and reported by a radiology consultant, and then assessed by two vascular surgeons, at least one of them is a consultant, in order to suggest a management plan. If intervention is warranted, the patient was assessed by the anesthetics team, and in light of their risk estimation all patients' data and scans were discussed on weekly basis in the vascular surgery department meeting in the presence of at least three consultants and professors, and five registrars.

The device used was the Artassist (ACI Medical Inc, San Marcos, CA, USA). This device applies compression to both the calf and foot, at a pressure of 120 mmHg for 3 seconds per cycle, and this continues for three cycles per minute with a 1-second delay between different segment inflation. The treatment regimen was recommending device usage for 3 hours twice daily for 3 months. Some patients purchased the machine and continued its domiciliary daily use beyond the recommended duration. Additional medical treatment was maintained in the form of a single antiplatelet (acetyl salicylic acid 75 mg once daily), naftidofuryl 200 mg three times daily, and a statin according to blood lipid levels, in addition to diabetic control. Patients with infected foot ulcers were admitted, started on intravenous antibiotics (empirical broad spectrum initially, then according to culture). Necessary drainage and debridement were done, and exposed wounds were managed using negative pressure wound therapy.

Patient follow-up was through the hospital's vascular surgery clinic, and a designated in-hospital clinic for patients using the device. For patients with rapid clinical