Preventing amputation using a novel device with intermittent negative pressure in a patient with severe lower limb ischemia: single case presentation

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Introduction

A 69-year-old Caucasian male, ex-smoker, with severe pain in his right thigh and both calves when walking, was referred to the Vascular lab at Oslo University Hospital - Aker, Oslo, Norway.

Since 1994, the patient had received many treatments for his condition, which included angioplasty, additional bypass surgeries, and most recently a femoral popliteal bypass (below knee) in 1996. Upon investigation, in May 2014, the right femoral bypass was found to be occluded. In June 2015, his condition became more severe, walking distance significantly reduced, body weight increased, and the right leg was numb and cold with no palpable pulse (dorsalis pedis) in the foot. At inclusion, the patient was on anti-hypertensive medications, in addition to cholesterol lowering and anti-thrombogenic drugs. He had no rest pain or leg ulcer but had an initial maximum walking distance on levels surface of 150 m. Further surgical intervention was not considered to be an option due to the long occlusion time. At inclusion, his systolic pressure on the left brachial artery and left dorsal pedis artery were 120 mmHg and 120 mmHg, respectively; and systolic pressure recorded on right brachial and dorsal pedis arteries were 120 mmHg and 45 mmHg, respectively.

Method

It was decided to offer the patient a 14-week course of intermittent negative pressure (INP) therapy, with a novel device indicated to improve microcirculation and transcutaneous oxygen pressure. The patient had to adhere to a routine using the device at home for 2 hours a day broken into timed sections. Time was recorded on a USB provided with the device and monitored by the clinician.

Results

Duplex colour scanning was used to analyse the patient's vessels at the end of intervention. It showed the development of strong functional collaterals.

After 7 days of use, the patient reported an immediate reduction in numbness of the leg and an increase in warmth. After a 4-week control period, the patient reported a subjective improvement in walking distance, reduction in pain, improved quality of life and functional status.

The patient's initial claudication time (time before onset of pain) increased 56% from week 4 to week 14. In the same time period, his absolute claudication time (maximal time before he had to stop) increased by 145% (see Table 1).

Table 1.

Recorded scores	Week 0	Week 4	Week 14
Pulse volume recording (mm)	2	4	4
Walking time (min:sec)[a]	n/a	2:45	6:00
Walking distance (m)[b]	150	147	320
Weight (kg)	117.6	115.0	111.8
BMI	34.4	33.6	32.7
Weight-to-Hip ratio	1.05	1.04	1.04
ABI left (control)	1.0	n/a	0.91
ABI right (intervention)	0.38	n/a	0.41
Ankle pressure[c] (mmHg)	45		45

a: initial walking test was not timed, but tested with patient on level surface in hallway. From week 4 to week 14 the patient was tested with a Skinner-Gardner graded treadmill protocol.
b: From week 4 to week 14 the test was performed on a treadmill with a graded exercise protocol starting at 0% incline with 2% increment every 2nd minute and constant speed of 3.2 kph).
C: Measured in the dorsalis pedis and tibialis posterior arteries

Discussion

Duplex colour scanning at week 14 revealed open collaterals in the patients treated leg. These collaterals may explain the improvement in quality of life being reported by the patient. The patient's absolute ankle pressure did not change during the course of the study despite indications of improved peripheral circulation and clinical improvement in walking distance and self-reported pain-reduction. This may be explained by the patient's weight reduction which in itself lowers the systemic blood pressure and thus may have affected the distal extremity's systolic pressure. Unfortunately we did not perform a thorough duplex colour scanning at baseline for comparison. It is therefore a limitation in the present case study whether the openings and collateral vessels occurred during the course of the study. However, the patient was operated with a bypass surgery due to severe ischemia, and it is likely, considering the patient's symptoms, that INP-therapy contributed to the observed collateralisations.

The typical treatment route for this patient would have been amputation. After he started using this novel device, the clinical condition of the patient has improved to an extent so that amputation is no longer imminent.

Conclusion

This use of this device has probably led to opening of collaterals ensuring blood flow to his leg and thereby reducing amputation risk and improving quality of life. This novel device should be investigated further as a potential alternative treatment option for patients with non-healing wounds (arterial leg ulcers) and limb ischemia. The device is designed to be used at home, which theoretically would reduce nursing costs, rehabilitation costs and provide patients with an alternative to amputation.