ORIGINAL ARTICLE

VAC therapy to promote wound healing after surgical revascularisation for critical lower limb ischaemia

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Key words

Critical lower limb ischaemia; Vacuum-assisted closure therapy; Wound healing

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Abstract

Vacuum-assisted closure (VAC) therapy is a new emerging non-invasive system in wound care, which speeds up wound healing by causing vacuum, improving tissue perfusion and suctioning the exudates, and facilitating the removal of bacteria from the wound. The application of sub-atmospheric pressure on the lesions seems to alter the cytoskeleton of the cells on the wound bed, triggering a cascade of intracellular signals that increase the rate of cell division and subsequent formation of granulation tissue. The aim of this study is to analyse the results of VAC therapy used as an adjuvant therapy for the treatment of foot wounds in patients affected by critical limb ischaemia (CLI) (Rutherford 6 class) after distal surgical revascularisation, to promote and accelerate the healing of ulcers. Twenty-nine patients (20 males, 9 females; mean age 68·4) affected by CLI of Rutherford 6 class, after surgical revascularisation of the lower limb, underwent VAC therapy in order to speed up wound healing. Complete wound healing was achieved in 19 patients (65·51%), in an average period of $45\cdot4 \pm 25\cdot6$ days. VAC therapy is a valid aid, after surgical revascularisation, to achieve rapid healing of foot lesions in patients with CLI.

Introduction

Critical lower limb ischaemia (CLI) is a widespread disease, and foot ulcers in patients with Rutherford 6 lesions represent a serious problem, with high levels of morbidity, long hospital stay and high costs. Current methods of treatment are represented by endovascular and surgical revascularisation (1,2) in association with specific antibiotic therapy for infected lesions, repeated local debridement, advanced moist wound dressing (3), bioengineered tissue or skin substitutes (4), growth factors (5,6) and spinal cord stimulation (7–9). Vacuum-assisted closure (VAC) therapy represents a new emerging non-invasive system for wounds healing, based on localised delivery of continuous negative sub-atmospheric pressure through a pump

[†]These authors contributed equally to this work and share the senior authorship.

which is connected to the resilient, foam-surface dressing that collects the wound exudates.

Our experience in treatment of foot wounds with VAC therapy in patients affected by CLI with Rutherford 6 lesions, after distal surgical revascularisation, is reported.

Key Messages

- vacuum-assisted closure (VAC) therapy promotes wound healing by delivering negative pressure (a vacuum) at the wound site through a patented dressing, and this helps draw wound edges together, remove infectious materials and actively promote granulation tissue
- critical limb ischaemia (CLI) is a widespread disease, and foot wounds in patients with Rutherford 6 lesions

represent a serious socio-economic problem because of their association with morbidity and mortality rates

• in this study, application of VAC therapy in patients affected by CLI with Rutherford 6 lesions, after distal surgical revascularisation, is shown to be helpful in promoting and accelerating wound healing effectively.

Materials and methods

From January 2012 to July 2013, the VAC system was used in 29 patients (20 males, 9 females; mean age 68.4) affected by peripheral arterial disease of Rutherford 6 class, after surgical revascularisation of the lower limb, as an adjuvant therapy to accelerate wound healing. Institutional Review Board (IRB) approval was obtained.

The enrolled patients presented the following risk factors and comorbidities: diabetes mellitus (22, 75.9%), hypertension (19, 65.5%), dyslipidemia (16, 55.2%), heart failure (17, 58.6%), chronic obstructive pulmonary disease (11, 37.9%), smoke (14, 48.3%) and end-stage renal disease on haemodialysis (8, 27.6%). One patient underwent an axillo-bifemoral bypass in polytetrafluoroethylene (PTFE) 8 mm; three patients underwent a popliteal–posterior tibial artery bypass in great saphenous vein (GSV); the remaining 25 patients were submitted to a femoro-distal bypass in GSV (eight femoro-peroneal artery bypass, eight femoro-anterior tibial artery bypass, two femoro-pedideal artery and seven femoro-posterior tibial artery).

After surgical revascularisation of the lower limb, 12 patients underwent an open transmetatarsal amputation (Figure 1), 9



Figure 1 open transmetatarsal amputation.



Figure 2 Application of VAC therapy on open transmetatarsal amputation.

patients underwent minor amputations, 8 patients were submitted to surgical debridement of the calcaneal lesion.

Selection criteria for the application of VAC therapy were represented by calcaneal, dorsal or plantar foot ulcers with an area of $>3 \text{ cm}^2$; adequate distal blood flow assessed by ultrasonographic examination after revascularisation; absence of granulation tissue 7 days after surgery.

VAC therapy was applied following the first debridement and washing of wounds in patients with calcaneal lesions (8 cases), after minor amputations (9 cases) or open transmetatarsal amputation (12 cases) (Figure 2). A sub-atmospheric localised pressure was applied on the wound, in a controlled manner: the system unit is programmed to deliver controlled negative pressure ranging from 50 to 200 mmHg. The sub-atmospheric pressure generally applied is 100–125 mmHg. Suction effect, generated by a portable, adjustable pump, was applied on the wound cleaned by a sponge made of polyurethane or polyvinyl alcohol. These sponges were closed with an adhesive drape to obtain a sealed environment.

Between the drape and the device, an electrical pump is connected to a canister, which collects the wound exudate, using a flexible pipe. The polyurethane sponge has pore sizes ranging from 400 to 600 μ m. The polyvinyl alcohol sponge has pore sizes ranging from 200 to 300 μ m (10,11).

A specific antibiotic therapy in accordance with the antibiogram results was started in all patients. In accordance with the severity of the wound, patients were exposed to a continuous negative pressure ranging from -75 to -125 mmHg. Patients with severely infected wounds with discharge and necrosis were submitted to wound culture and subsequently to specific antibiotic therapy in accordance with the antibiogram results. All data for the enrolled patients are summarised in Table 1.

Age	Sex	Main disease	Size and localisation of the wound (mm)	Surgical treatment	Isolated germ	Antibiotic therapy	Time of hospital stay	Results
46	Σ	DM, Hypertension, smoke, dyslipidemia, heart failure	Left heel 70×70	Femoro-peroneal artery bp in GSV; surgical debridement of heel lesion	Enterococcus faecalis; Escherichia coli	Meropenem	45	Hyperbaric oxygen therapy; healed
63	Σ	DM, dyslipidemia, heart failure	Right heel 30 × 35	Femoro-anterior tibial artery bp in GSV; surgical debridement of heel lesion	No bacteria	Cefazolin	15	Lost during follow-up
68	Σ	Hypertension, heart failure, smoke, dyslipidemia	Necrosis of the last three toes of the right foot	Femoro-anterior tibial artery bp in GSV; amputation of the last three toes of the right foot	Staphylococcus epidermidis	Imipenem; trimethoprim sulfamethoxazole	24	Bypass occlusion and restoration Transmetatarsal amputation; healed
81	Σ	Hypertension, DM, haemodialysis, dyslipidemia, heart failure	Necrosis of the last two toes of the right foot	Femoro-pedideal artery bp in GSV; amputation of the last three toes of the right foot	Pseudomonas aeruginosa; Staphylococcus aureus	Vancomycin; imipenem	16	Healed
76	ш	Hypertension, DM, dyslipidemia, heart failure	Left heel 40×30	Femoro-posterior tibial artery bp in GSV; surgical debridement of the left calcaneal lesion	E. faecalis; Morganella morganii	Piperacillin tazobactam; ciprofloxacin	21	Healed
72	Σ	Hypertension, DM, haemodialysis, heart failure, dyslipidemia	Gangrene of all toes of left foot	Femoro-anterior tibial artery bp in GSV; open transmetatarsal amputation	S. aureus	Cefazolin	47	Healed
57	ш	Hypertension, heart failure, smoke	Gangrene of the first and second toes of the right foot	Popliteal-posterior tibial artery bp in GSV; right first and second toes ambutation	No bacteria	Cefazolin	14	Transmetatrsal amputation; healed
88	Σ	DM, hypertension, COPD, smoke, heart failure, dyslipidemia	Gangrene of all toes of the left foot	Femoro-peroneal artery bp in GSV; open transmetatarsal amputation of the left foot	S. epidermidis	Imipenem; trimethoprim sulfamethoxazole	23	Healed
72	Σ	DM, hypertension, heart failure, smoke	Gangrene of the left first toe	Popliteal-posterior tibial artery bp in GSV; left first toe amputation	P. aeruginosa	Meropenem	19	Transmetatarsal amputation; healed
78	Σ	DM, hypertension, COPD	Gangrene of all toes of the right foot	Femoro-peroneal artery bp in GSV; open transmetatarsal amputation	P. aeruginosa; E. faecalis	Amikacin; ampicillin–sulbactam	24	Healed
68	Σ	DM, smoke, heart failure	Gangrene of the first and second toes of the left foot	ieal artery bp in ation of the cond left toes	No bacteria	Cefazolin	14	Lost during follow-up
99	Σ	DM, hypertension, smoke	Gangrene of all toes of the left foot	Femoro-posterior tibial artery bp in GSV; open transmetatarsal amputation	S. epidermidis	Imipenem; trimethoprim sulfamethoxazole	24	Healed

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Table 1 Summary of 29 patients enrolled in this study

46 6	Table	Table 1 Continued							
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F Heart failure, DM, COPD, Gangrene of all toes of Fermotor tibial artery bp <i>A. baumanii</i> Colistimethate sodium; 13 haemodialysis the right foot in GSV; open transmetatarsal trimethoprim sulfamethoxazole	5	Щ	Dyslipidemia, smoke, COPD, DM	Calcaneal lesion of the right foot 40 × 35	Popliteal-posterior tibial artery bp in GSV; surgical debridement of the calcaneal	No bacteria	Cefazolin	22	Healed
	74	ш	Heart failure, DM, COPD, haemodialysis	Gangrene of all toes of the right foot	Femoro-posterior tibial artery bp in GSV; open transmetatarsal amputation	A. baumanii	Colistimethate sodium; trimethoprim sulfamethoxazole	<u>6</u>	Healed

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Table	1 Cor	Table 1 Continued						
Age	Sex	Age Sex Main disease	Size and localisation of the wound (mm)	Surgical treatment	Isolated germ	Antibiotic therapy	Time of hospital stay	Results
46	ш	Dyslipidemia, heart failure, tromboangiitis obliterans	Gangrene of all toes of the left foot	Femoro-anterior tibial artery bp in GSV; open transmetatarsal amputation	P. aeruginosa	Vancomycin	14	Bypass occlusion and restoration; healed
56	Σ	Dyslipidemia, DM, heart failure	Gangrene of all toes of the left foot	Femoro-anterior tibial artery bp in GSV; open transmetatarsal amputation	No bacteria	Cefazolin	46	Healed
64	Σ	DM, dyslipidemia, hypertension, COPD	Gangrene of all toes of the left foot	Femoro-posterior tibial artery bp in GSV, open transmetatarsal amputation	E. coli, E. faecalis	Meropenem	25	Healed
63	Σ	Heart failure, DM, COPD	Gangrene of all toes of the right foot	Axillo-bifemoral bp in PTFE; open transmetatarsal amputation	Proteus mirabilis; Citrobacter Cefazolin; piperacillin freundii tazobactam; amika	Cefazolin; piperacillin tazobactam; amikacin	31	Dead
DM, d	iabete	DM, diabetes mellitus; bp, bypass; GSV, great saphenous vein; COPD,		chronic obstructive pulmonary disease; PFTE, polytetrafluoroethylene.	se; PFTE, polytetrafluoroethylene			



Figure 3 Results at the end of the treatment.

Results

The VAC dressing was changed every 3 days in the operation room. Patients had an average of 14 (range: 4–21) treatment sessions. The duration of VAC use ranged from 7 to 51 days, and generally the treatment was continued until sufficient granulation tissue formation, with complete disappearance of signs of local infection, with an average length of stay of 31.5 ± 19.5 days (Figure 3).

During a mean follow-up of 17 months, bypass occlusion occurred in three patients. The first patient presenting an open transmetatarsal amputation underwent femoro-anterior tibial bypass restoration and subsequently wound healing. The second one with transmetatarsal amputation underwent femoro-posterior tibial bypass restoration failure, followed by above-the-knee amputation. The third patient with amputation of three toes needed a transmetatarsal amputation after femoro-anterior tibial bypass restoration and after obtaining wound healing. Among the remaining 26 patients, 2 patients already submitted to minor amputations with slow healing, underwent transmetatarsal amputation followed by wound healing during follow-up. One patient received hyperbaric oxygen therapy in addition to VAC therapy. Two patients were lost during follow-up; one patient died during hospital stay for concomitant comorbidities and another patient died during follow-up. Complete wound healing was achieved in 19 patients (65.51%) in an average period of 45.4 ± 25.6 days.

Discussion

VAC therapy was initially developed to treat decubitus ulcers and wounds with vascular dysfunction; successively the indications for its use have gradually increased (12). Recently, it has not only been used for chronic pressure ulcers but also prior to graft or flap treatments in cases of acute wounds, diabetic ulcers, burns and osteomyelites (13). In addition, VAC therapy seems to be very effective in accelerating foot wound healing in patients with arterial ulcers, after surgical revascularisation of the lower limbs, with restoration of adequate distal blood flow.

VAC therapy exerts mechanical forces on the wound bed and has positive effects on both the contraction of the wound and the proliferation of granulation tissue. Moreover, it stimulates local blood circulation and it significantly reduces bacterial counts in tissues (14). It also contributes to the healing process by reducing excess interstitial fluid and by keeping the wound moist in a sealed environment.

Various reports on the application of VAC therapy for the treatment of diabetic foot syndrome are available in the literature.

Armstrong et al. (15) carried out a study in 31 patients with diabetic foot ulcers and reported a 90.3% limb salvage rate without amputation, with an average length of stay of 32.9 days. Only 3.2% of patients were amputated below the knee, and the remaining 6.5% underwent transmetatarsal amputation. Nather et al. (16) reported a 100% limb salvage in 11 patients with diabetic foot ulcers treated with VAC therapy, presenting Wagner grade 2 or 3 wounds with an average length of stay of 23.3 days. Ulusal et al. (17) reported an amputation rate of 37% , with an average hospitalisation of 32 days. The reason for this higher amputation rates in comparison to those in the literature is that 80% of the subjects had Wagner Grade 3 and 4 wounds. Beno et al. (18) reported efficient results in the management of venous ulcers and infected wounds, and they concluded that an appropriate revascularisation is necessary prior to VAC therapy in patients with diabetic foot syndrome and peripheral arterial occlusive disease, while further studies are necessary to prove the efficiency of VAC systems in treatment of infected graft material after revascularisation.

Contrasting results on reduction of bacterial counts in tissues are reported in the literature.

Morykwas *et al.* (14) carried out experiments on animals and demonstrated that VAC therapy decreased bacterial counts in tissues. On the other hand, Weed *et al.* (19) determined that VAC therapy did not have a consistent effect on bacterial clearance, based on serial bacterial cultures collected in their clinical study.

However, because VAC therapy is a closed therapy system, it facilitates the safe removal of infected drainage, protecting health care personnel and other patients from nosocomial infections (12).

About the use of VAC therapy in the treatment of foot wounds after surgical revascularisation of the lower limb, Nishimura *et al.* (20) reported a case of severe ischaemic foot in a patient submitted to left axillopopliteal bypass and third, fourth and fifth digital amputation for gangrene, complicated with *Staphylococcus aureus* infection, in which VAC therapy markedly improved wound healing. Also, Clare *et al.* (21) reported their experience with VAC device in 17 patients with non-healing diabetic and dysvascular wounds, 6 of whom previously submitted to lower limbs revascularisation.

In our Institution, which is a primary referral centre for the treatment of peripheral arterial disease, VAC system was applied as an adjuvant therapy in 29 patients with Rutherford 6 lesions (area $>3 \text{ cm}^2$) after surgical revascularisation of the lower limb followed by transmetatarsal amputation (12 cases), local minor amputations (9 cases) and/or surgical wounds debridement of extensive calcaneal lesions (8 cases), in association with specific antibiotic therapy, to speed up foot wound healing.

Only one patient needed hyperbaric oxygen therapy in addition to VAC therapy; one patient underwent above-the-knee amputation after bypass failure; three patients already submitted to minor amputations needed a transmetatarsal amputation of the foot. Two patients were lost to follow-up and another two patients died. We recorded an average hospital stay of 31.5 ± 19.5 days, and complete wound healing was achieved in 19 patients in an average period of 45.4 ± 25.6 days.

In conclusion, our results suggested that VAC therapy, together with periodical surgical wound debridement and specific antibiotic therapy, could be helpful to promote and accelerate wound healing of foot lesions after restoration of an adequate distal blood flow through surgical revascularisation.

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