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Negative pressure wound therapy in patients with diabetic foot

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Objective: In this study our aim was to compare the results of standard dressing treatment to negative pressure wound therapy (NPWT) performed with a vacuum-assisted closure (VAC) device in patients with diabetic foot ulcers.

Methods: We assessed the results of 35 patients treated for diabetic foot ulcer between 2006 and 2008. Of these cases, 20 (4 women and 16 men; mean age: 66 years; range: 52-90 years) were treated with standard wet dressings and 16 feet in 15 patients (10 men, 5 women; mean age: 58.9 years; range: 42-83 years) with VAC therapy. The success of treatment was evaluated in terms of hospitalization length and rate of limb salvation.

Results: The average hospitalization period with VAC treatment was 32 days compared to 59 days with standard dressing treatment. All patients treated with standard dressings eventually had to undergo amputation. However, the amputation rate was 37% in the VAC treated group and 88% of patients had a functional extremity at the end of treatment.

Conclusion: VAC therapy, together with debridement and appropriate antibiotic therapy, enables a higher rate of limb salvage, especially in Wagner Grade 3 and Grade 4 ulcers.

Key words: Amputation; diabetes, negative pressure wound therapy; wound.

Sensory, autonomic, and motor nerve damage are usually present in diabetic foot cases. Autonomic nerve system damage accompanying the loss of protective pain sense causes abnormal capillary circulation and leads to edema and cracking and flaking of the skin. Moreover, various deformities subsequent to intrinsic motor neuropathy result in abnormal load distribution in certain regions. This, in turn, leads to the destruction of the skin integrity with time, providing a favorable base for bacterial inoculation. This is one of the reasons for high morbidity and mortality rates in patients with diabetic foot.[1]

Negative pressure wound therapy (NPWT) was initially developed to treat decubitus ulcers and wounds with vascular dysfunction, though indications for its use have gradually increased.[2] Recently, NPWT 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.[3] It has been demonstrated that NPWT is an efficient adjuvant treatment, especially in diabetic foot infections.[4-6]

NPWT exerts mechanical forces on the wound bed and has positive effects on both the contraction of the wound and the proliferation of granulation tissue. It also contributes to the healing process as it reduces excess interstitial fluid and keeps the wound moist in a sealed environment.[7] Moreover, it has

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been demonstrated in experimental studies that the NPWT technique promotes granulation tissue formation and stimulates local blood circulation. In addition to this, it significantly reduces bacteria count in the tissue.[8]

NPWT is an adjuvant treatment obtained by applying sub-atmospheric pressure between -50 mmHg and -175 mmHg on the wound, in a controlled manner. The vacuum-assisted closure (VAC) system is a wound closure device used for this purpose; it applies localized and controlled negative pressure on the wound[6] (Fig. 1). The suction effect, generated by a portable, adjustable pump, is applied on the wound cleaned by a sponge made of polyurethane or polyvinyl alcohol. These sponges are 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 µm. The polyvinyl alcohol sponge has pore sizes ranging from 200 to 300 µm.[5,6]

In this study we compared the results of standard dressing treatment to NPWT performed with a VAC device in patients with diabetic foot ulcer. The success of treatment was assessed in terms of hospitalization length and limb salvation.

Patients and methods

We assessed the clinical follow-up and results of 35 patients with diabetic foot ulcers treated between 2000 and 2008. Group 1 was composed of 20 patients (4 women and 16 men; mean age: 66 years; range: 52-90 years) treated with standard dressing (Table 1). Group 2 was comprised of 16 feet in 15 patients (10 men, 5 women; mean age: 58.9 years; range: 42-83 years) treated with NPWT (Table 2). In both groups, the patients had severely infected wounds with discharge and necrosis, most of which were Wagner Grade 3 and Grade 4 wounds[9] (Table 3). One patient in Group 2 developed a wound, following a gun shot injury. One other patient developed a wound in the postoperative (open reduction and fixation with plaque) period after a closed calcaneus fracture. The remaining 13 patients did not have any concomitant trauma.

Fig. 1. **(a)** VAC application and **(b)** VAC device. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

In Group 1, patients were treated with standard wound debridement and dressing techniques. In Group 2, VAC therapy was applied following the first debridement and washing of the necrotic and infected wound. The VAC dressing, applied on the wound, was changed every two days. The patients had an average of 15 (range: 2-68) treatment sessions. Negative pressure wound therapy was delivered through a KCI (San Antonio, TX, USA) brand-

Table 1. Summary of ‘Group 1' cases.

	Age	Sex	Hospitalization (days)	Result
1	70	M	15	Syme amputation
2	55	F	45	Below-knee amputation
3	55	F	45	Below-knee amputation
4	61	F	20	Transmetatarsal amputation
5	84	M	90	1st and 2nd toe amputation
6	90	F	30	Below-knee amputation
7	65	M	15	5th toe ray amputation
8	50	M	60	3rd toe amputation
9	73	M	25	Transmetatarsal amputation
10	80	M	15	Syme amputation
11	80	M	21	Below-knee amputation
12	64	M	190	5th toe amputation
13	53	M	15	Above-knee amputation
14	60	M	124	1st toe amputation
15	68	F	94	Below-knee amputation
16	52	M	156	1st toe amputation
17	70	F	15	Below-knee amputation
18	87	M	159	Below-knee amputation
19	56	M	15	1st and 2nd toe amputation
20	60	M	20	1st toe amputation

Table 2. Summary of 'Group 2' cases.

	Age	Sex	Main disease	Size and localisation of wound (mm)	Wagner grade	Isolated bacteria	Antibiotic	Sessions	Time of hospital stay (day)	Result
1	72	M	DM	Right heel 20x30	3	Group G streptococcus, *S. epidermitidis*, enterococcus spp.	Duocid 1 g 2x1 and Cipro 2x750 mg	10	25	Healed
2	60	F	DM	Necrotic wound on left heel 40x50	4	No bacteria	Duocid 1 g 2x1	2	6	Below-knee amputation
3	75	M	DM	Plantar aspect of right foot 30x30	2	Pseudomonas spp.	Duocid 1 g 2x1 and Cipro 750 mg 2x1	2	6	Healed
4	69	M	DM	Lateral corner of left crus 100x100	3	No bacteria	Duocid 1 g 2x1	17	34	Healed
5	81	F	DM, SVO, CAD	Whole gangrene of left foot	5	*Proteus mirabilis*, *Enterobacter cloacae*,	Duocid 1 g 2x1 and Cipro 2x750 mg	5	10	Above-knee amputation
6	52	M	DM, right open calcaneus fracture	Right heel 50x30	3	*Pseudomonas aeruginosa*, *Staphylococcus aureus* (MRSA)	Vancomycin 2x1 and Tienam 4x1	4	28	Closing with free gracilis flap
7	43	M	DM, HT, CKF	Bilateral diabetic foot						
				Dorsum and lateral plantar of right foot 30x20	3	Group B hemolytic streptococcus	Amoclavin 1 g 2x1	40	80	Healed
				Plantar wound on left foot 30x20 and necrosis of second and third toes	4	No bacteria	Maxisporin 4x1 and Proxacin 2x1	29	58	Amputation of 2nd and 3rd toes
8	50	F	DM	Dorsum of right foot 100x100	3	*E. coli*, pseudomonas spp.	Tazocin 3x 4.5 g	68	136	Healed
9	53	M	DM	Dorsal of left foot 1st toe 30x20	2	No bacteria	Amoclavin 1 g 2x1	2	7	Healed
10	53	M	DM, gunshot Injury	Right heel 100x100	3	*S. epidermidis*, pseudomonas spp, *E. coli*	Vancomycin 2x1 and Fortum 3x1	7	14	Healed
11	49	F	DM	Plantar aspect of right foot 40x40	3	Enterococcus spp, non-hemolytic streptococcus, *Klebsiella pneumoniae*	Tazocin 3x1 and Cipro 500 2x1	9	18	Healed
12	42	M	DM	Plantar aspect of left foot 100x50	3	*Pseudomonas aeruginosa*	Duocid 1 g 3x1 and Cipro 2x750 mg	14	28	Desarticulation of 4th MP joint ray and of 3rd toe
13	53	M	DM	Frontal aspect of right foot 150x200	4	*Morganella morganii*, enterococcus	Tazocin 3x1 and Cipro 500 mg 2x1	22	44	Transmetetarsal amputation
14	83	M	DM	Over the right lateral malleolus 50x50	3	*E. coli*	Meronem 1x1	3	14	Healed
15	49	F	DM	First toe of right foot 40x50	3	No bacteria	Duocid 1 g 2x1	2	10	Distal phalanx amputation of 1st toe right foot

ed VAC device (Fig. 1). In accordance with the severity of the wound, patients were exposed to -125 mmHg continuous negative pressure for the first two sessions. Intermittent treatment was then delivered at the same pressure. In this treatment, 5 minutes of negative pressure application was followed by a break of 2 minutes. The patients received antibiotic therapy in accordance with the antibiogram results (Table 2). Treatment was organized in collaboration with the endocrinology department to keep glucose levels under control.

Results

In the 20 patients treated with standard debridement dressing, (Group 1), the average hospitalization length was 59 (range: 15-181) days. Of the 15 patients treated with VAC therapy (Group 2), the average length of stay was 32 (range: 6-136) days.

Table 3. Wagner's classification for diabetic foot disease.

Grade 1	Superficial diabetic ulcer.
Grade 2	Deep ulcer (cellulitis).
Grade 3	Deep ulcer with abscess orosteomyelitis.
Grade 4	Gangrenous patches. Partial foot gangrene.
Grade 5	Gangrene of entire foot.

The limb salvage rate in Group 1was 0%, whereas in Group 2, complete wound healing was achieved in 10 out of 16 feet (63%) without any loss of extremity. The wounds were completely covered by placing split-thickness grafts following the formation of granulation tissue (Fig. 2). In the patient with an operated calcaneus fracture, the wound was closed with a free gracilis muscle flap and skin graft. Two patients in Group 2 received hyperbaric oxygen therapy in addition to the NPWT.

Fig. 2. Wagner Grade 3 patient (no. 10). **(a)** Before treatment; **(b, c)** Reduction in the wound size during treatment; **(d)** Result of treatment after split-thickness skin grafting. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

Clinical follow-up for all patients (100%) required amputation at various levels as wound healing was not achieved in Group 1. In total, 10 patients (50%) had major amputations. One patient was amputated above the knee, 7 patients below the knee, and 2 patients required a Syme's amputation. The patients had to use prostheses. A total of 10 patients (50%) received minor amputations; where 2 patients had transmetatarsal, 1 patient had a ray, and 7 patients had toe amputations (Table 1).

In Group 2, major amputations were performed on two patients (12%); one patient was amputated above the knee and the other below the knee. Four patients had minor amputations (25%); one patient had a transmetatarsal amputation (Fig. 3), one on the 1st ray and 3rd metacarpophalangeal joints, one of the 2nd and 3rd toes on the MP joints, and one on his first toe on the interphalangeal joint (Table 2). In this group, all amputations were performed at the beginning of therapy due to the necrosis detected during debridement.

Most of the patients stated that the sponge closure method in the VAC technique was more comfortable than the classical wound closure therapy since fewer dressings were required and there was less smell and leakage.

Discussion

In this study, we compared the treatment results of those patients who received NPWT to the results of other patients who did not, to demonstrate its efficiency. When comparing the two groups, we observed that wound healing was not achieved without amputation in the patients who received standard wound dressing therapy. Moreover, the length of hospital stay in these patients was significantly longer. Wound healing occurred in 63% of patients

Fig. 3. Wagner Grade 4 patient (no. 13). **(a, b)** Before therapy; **(c-e)** Transmetatarsal amputation and result of treatment after split-thickness skin grafting. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

who received NPWT using a VAC device without requiring amputation. The hospitalization period was also shortened in this group.

The treatment of infected and necrotic foot wounds in diabetic patients presents high levels of morbidity, difficulty, and cost.[2] NPWT has been widely used for the treatment of acute and chronic wounds over the last decade.[10] In this study, we showed that NPWT shortened the hospitalization period and increased the rate of wound healing and limb salvation in subjects with diabetic foot.

In a multi-centered, randomized, controlled study, Apelqvist et al. reported that VAC therapy was a more efficient, safer, and a lower-cost method than moist wound dressing in patients with complex diabetic foot.[11] Braakenburg et al. did not detect a significant difference between the success of VAC therapy and normal dressing therapy in acute and chronic wounds. However, they did find that VAC had important advantages for patients with diabetes and cardiovascular diseases and suggested that this may be the result of increased neoangiogenesis.[12]

Negative pressure wound therapy provides significant reduction in the wound size. Some studies demonstrated that wound volume could be reduced by 59%.[13] With this reduction, VAC therapy enables the secondary healing of wounds or wound closures with split-thickness skin grafts. Therefore, NPWT should be considered as an alternative therapy on the reconstructive ladder, between secondary wound healing and skin grafts. In our study, free muscle flap was used in only one subject to provide soft tissue support in the posterior and plantar heel region.

Morykwas et al. conducted experiments on animals and demonstrated that VAC therapy decreased bacteria count in tissue.[8] Weed et al., on the other hand, determined that VAC therapy did not have a consistent effect on bacterial clearance, based on serial bacterial cultures collected in their clinical study.[14] However, because VAC therapy is a closed therapy system, it facilitates the safe removal of infected drainage, protecting healthcare personnel and other patients from nosocomial infections.[2]

Armstrong et al. reported a 90.3% limb salvage rate without amputation in a study on effects subatmospheric pressure conducted on 31 subjects. In their study, 3.2% of patients were amputated below-the-knee, and the remaining 6.5% were transmetatarsal.[15] In an eleven patient study by Nather et al., 100% limb salvage was achieved.[16]

In our study, 37% of patients treated with VAC therapy were amputated; 25% required ray and transmetatarsal amputations and the remaining 12% below-the-knee (n=2) and above-the-knee (n=1) amputations. The reason for our higher amputation rates in comparison to those in the literature is that 80% of our subjects had Wagner Grade 3 and 4 wounds. In the study of Nather et al., all subjects had Wagner Grade 2 or 3 wounds.[16] Among our subjects, there was one Grade 5 wound on which vacuum therapy was tried. However, both the patient's clinical progress and the level of gangrene deterioration necessitated an urgent above-the-knee amputation. A below-the-knee amputation was performed on another subject when an advanced arteriosclerosis obliterans was detected in the distal of popliteal artery after an arterial Doppler USG examination. Other subjects did not require a high-level amputation and approximately 88% of our patients were able to walk on their own feet without using prosthesis.

In our study, the average length of hospitalization for patients who received NPWT was 32 days. Nather et al. reported an average length of stay of 23.3 days, Armstrong et al. 32.9 days, and Clare et al. 57.4 days.[15-17] This indicates that our results are below the literature average of 37.8 days.

In conclusion, our results suggested that VAC therapy, together with debridement and appropriate antibiotic therapy, enables a higher rate of limb salvage, especially in Wagner Grade 3 and Grade 4 ulcers.

Conflicts of Interest: No conflicts declared.

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