Impact of negative pressure wound therapy in complete healing rates following surgical debridement in heel and ankle regions in diabetic foot infections

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Aim
The aim was to evaluate 120-day complete wound healing rates in negative pressure wound therapy (NPWT) versus conventional dressings in anatomically challenging areas (the heel and ankle regions).

Patients and methods
A retrospective, cohort study that included diabetic patients having acute (<30 days) challenging wounds at the area of the heel and ankle after surgical debridement and achieved complete wound healing or 120-day follow-up whichever occurs first. Forty-four patients were identified and were divided into two groups according to the method of wound therapy. Group A (NPWT, n=18) and group B (conventional moist daily dressings, n=26). The primary end point was complete wound healing rates within 120 days. Distribution of characteristics between study groups and healing rates among different risk groups were reported. Kaplan–Meier curve on the basis of time-to-event strategy followed by a log rank test to measure difference among study groups were performed.

Results
Complete wound healing within a 120-day assessment period was achieved in 72.3% (group A) and 30.8% in group B (P=0.019). There was no overall significant difference in the distribution of characteristics among two groups except for BMI (P=0.03) and albumin level (0.02). However, HgA1c levels (P=0.01) and wound treatment method (P=0.007) were only factors that significantly affected the healing rate.

Conclusion
On the basis of current data analysis, the use of NPWT should be recommended for acute diabetic foot wounds in the heel and ankle regions to obtain faster complete healing and desired wound closure in such critical areas.

Keywords:
healing, negative pressure, wound

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Introduction

Diabetes mellitus is a well-recognized disease for its multiple complications including diabetic foot ulcers [1]. About 82% of patients who undergo lower extremity amputations are diabetic [2]. The lifetime incidence of developing foot ulcers in diabetic patients is about 25% [3]. Diabetic foot ulcers, especially challenging wounds, carry a high risk for mortality and major amputation with the following high socioeconomic burden [4–6].

Negative pressure wound therapy (NPWT) began as an adjunctive treatment for patients with chronic wounds [7]. Through the last decade, this innovative way of treatment was shown to be effective in promoting wound healing in many studies [8–10]. However, the scientific evidence for effectiveness of NPWT is still lacking, especially in patients with multiple diseases and challenging foot wounds [11].

It is postulated that NPWT works through many mechanisms including increased blood flow and tissue perfusion to the target wound [12,13]. It also induces wound contraction and edge approximation [7,13,14]. Vacuum therapy was shown to be better than regular dressings in promoting granulation tissue formation [15,16]. Reduction of edema was one of the important benefits of NPWT as this reduces bacterial colonization and improves the microenvironment of the wound [7,17,18]. Angiogenesis and endothelial proliferation are also induced by NPWT [19].

This study aimed to evaluate 120-day complete wound healing rates in NPWT versus conventional dressings in anatomically challenging areas (heel and ankle region) after surgical debridement in diabetic foot infections.

Patients and methods

This is a retrospective cohort study. Analysis of a prospectively collected data from the local patient registry at the Vascular Surgery Department of a Tertiary Referral Hospital between April 2017 and May 2018 was performed. The study was approved by the ethics committee and all patients had provided written consent before surgical debridement.

Search targeted all diabetic patients aged over 18 years, having acute (<30 days) challenging wounds at the area of the heel and ankle, underwent surgical debridement, and finally achieved complete wound healing or completed 120-day follow-up whichever occurs first.

The excluded patients were those who presented with active Charcot ankle arthropathy, untreated osteomyelitis, ischemic wound, uncontrolled hyperglycemia (HgA1c >12), or interrupted treatment. All wounds were of stages 2 and 3 according to Wagner's classification. They were adequately perfused as shown by ankle brachial index of more than 0.9 or toe brachial index of more than 0.5. Patients on corticosteroids or chemotherapy were also excluded from this study.

Forty-four patients were identified. The study design assigned two groups according to the method of wound therapy. Group A (n=18) received treatment with NPWT and group B (n=26) used the conventional moist daily dressings.

Patient characteristics and demographics with potential influence on wound healing were considered. Data on age, sex, BMI, and type of diabetes were reported. Blood samples were drawn from patients for routine laboratory tests plus renal, liver functions, albumin, and HgA1c levels. All wounds in the current study were surgical debridement around the ankle and heel areas with or without partial calcanectomy. Initial wound surface area was carefully measured.

Negative pressure wound therapy (Renasys EZ Max; Smith & Nephew, Hull, UK) was set to patients in the following manner: in complete aseptic conditions (operative theater), the edges of the wound were protected with an adhesive barrier, then the wound surface was covered with black hydrophobic foam. Deep areas of the wounds were also filled with foam, then covered with adhesive airtight drapes. The connection tube is connected to the foam and to a vacuum. A subatmospheric pressure of 125 mmHg was then applied in a continuous mode. Dressing was changed every 72 h in the same manner. Group B patients received daily moist gauze dressing. Both groups received broad-spectrum antibiotics according to the culture and sensitivity tests and received off-loading therapy as indicated.

The patients were followed up till wound closure or completion of a 120-day assessment period. Surgical debridement was allowed to remove necrotic tissues during the follow-up period. The primary end point was the complete wound healing within 120 days defined as 100% epithelization of tissue defect after either NPWT or conventional moist daily dressings.

Statistical analysis

Demographic data and patient characteristics were expressed as mean±SD for continuous variables and n (%) for categorical variables. The significance of the difference in the distribution of characteristics between groups was evaluated with Pearson's χ^2-test for categorical variables. Fisher's exact test was used when the numbers of observations in one or more cells were small. Comparisons of univariate continuous variables between the two groups were computed via the Student's t-test. Significant difference in healing rates among different risk groups was measured using Pearson's χ^2-test and Kruskal–Wallis. Survival functions were plotted with Kaplan–Meier curve on the basis of time-to-event strategy followed by a log rank test to measure the difference among study groups. Significance was detected at a P value of 0.05. All tests were conducted with SPSS 20 software (SPSS Inc., Chicago, Illinois, USA).

Results

The study included 44 patients, 26 (57%) men and 18 (43%) women. The mean age was 48.13±7.74 and ranges between 30 and 63 years. Eighteen patients received treatment with NPWT (group A), and 26 patients were treated with conventional dressings (group B). There was no overall significant difference in the distribution of characteristics among the two groups except for BMI (P=0.03) and albumin level (0.02). Demographics and patient characteristics in both groups are shown in Table 1.

During the follow-up period (120 days), 21 wounds showed complete healing (47.7%) with a mean healing time of 2.8±1 months. Detailed description of healing in the two study groups is demonstrated in Fig. 1. In group A: 72.3% of wounds were completely healed, while in group B, the wound healing rate was 30.8% (P=0.007). The healing rate among different risk groups are shown in Table 2. HgA1c levels (P=0.01) and wound treatment method (P=0.007) were only factors that significantly affected the healing rate.

Running log rank (Mantle–Cox) test comparing time to healing between the study groups showed a significant difference in favor of the NPWT group (P=0.019; see Fig. 2).

Discussion

Treatment of diabetic foot wounds is of major concern for vascular surgeons due to their unpredictable time of healing [11]. A mainstay of therapy is debridement of all infected and necrotic tissues, with a primary goal to obtain wound closure [20]. Saline-moistened gauze has been the standard method of treatment [9]. Subsequently, various hydrocolloid wound gels, growth factors, enzymatic debridement compounds, hyperbaric oxygen therapy, cultured skin substitutes, and other wound therapies have been advocated. All of these therapies are associated with significant expense and are being utilized in some situations without sufficient scientific evidence in favor of their efficacy [21].

NPWT is an alternative noninvasive adjunctive therapy using a vacuum-assisted closure (VAC) device to create controlled negative pressure. The VAC device was

Table 1 Demographics and patient characteristics

	NPWT (N=18) [n (%)]	Conventional dressing (N=26) [n (%)]	P value
Age (mean±SD) (years)	49.22±7.6	47.38±7.8	0.4
Sex: male [n (%)]	11 (61.1)	15 (57.7)	0.9
BMI (mean±SD) (kg/m^2)	30.39±3.4	28.23±3	0.03
Diabetes type II [n (%)]	14 (77.8)	20 (76.9)	0.4
HgA_{1C}	7.75	8.19	0.2
Albumin (g/dl)	30.72	33.13	0.02
Wound area (cm^2)	23.56	25.92	0.3

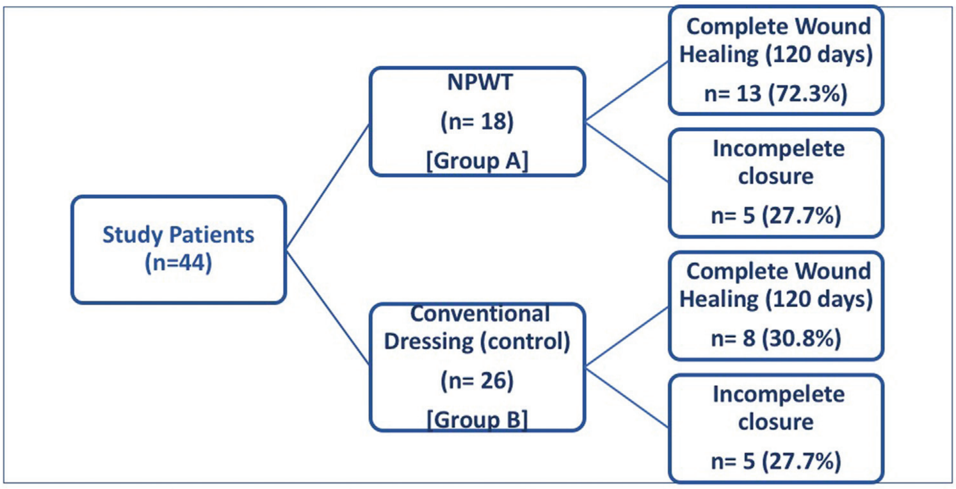
NPWT, negative pressure wound therapy.

Table 2 Healing rate among different risk groups

Variables	Healing rate (%)	P value (Pearson χ^2)
Age groups		
30–40	37.5	0.823 (Kruskal–Wallis test)
40–50	56.2	
50–60	43.8	
60–70	50	
Gender		
Male	50	0.717
Female	44	
BMI		
19–25	42.9	0.694
25–30	43.5	
>30	57.1	
Diabetes type		
Type I	40	0.578
Type II	50	
HgA_{1C}%		
≤7	63	0.011
>7	23.2.5	
Treatment method		
NPWT	72.2	0.007
Conventional dressing	30.8	

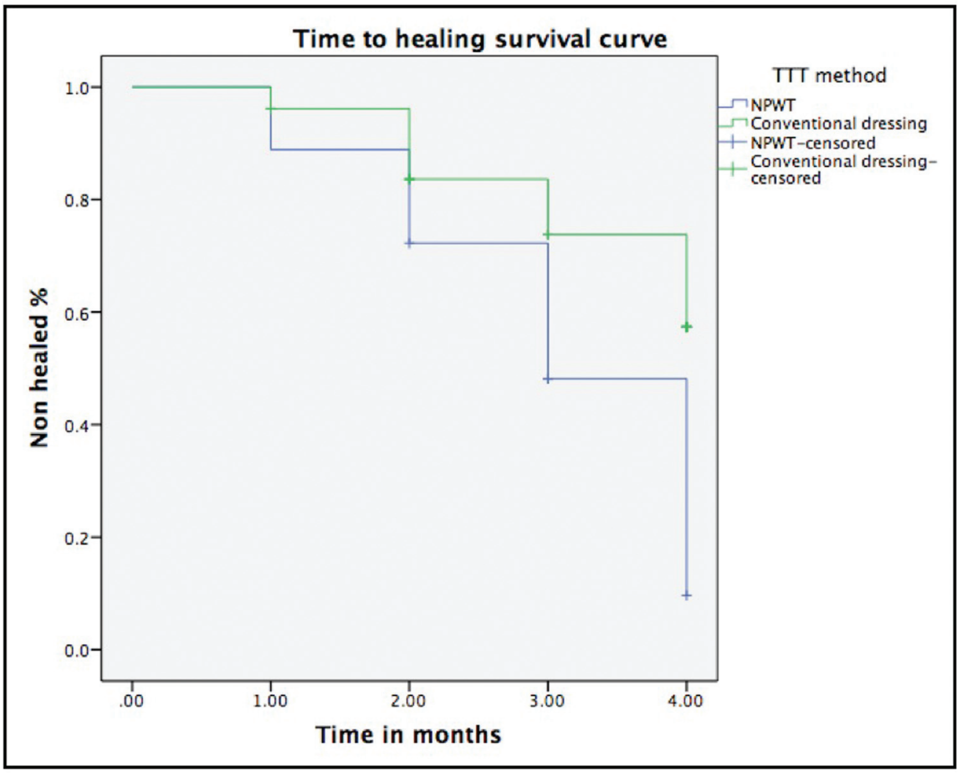
NPWT, negative pressure wound therapy.

Figure 1



Flowchart of wound healing in this study.

Figure 2



Kaplan–Meier survival curve for negative pressure wound therapy versus conventional wound dressing.

found to be a safe and effective treatment for complex diabetic foot wounds and could lead to higher and faster wound healing rates [22].

The clinical practice guidelines by the Society for Vascular Surgery on the management of diabetic foot recommended (grade 2B) the use of NPWT for chronic diabetic foot wounds that do not demonstrate expected healing progression with standard or advanced wound dressings after 4–8 weeks of therapy [23]. Randomized clinical trials have focused only on smaller chronic wounds and systematically eliminated large acute wounds from the evaluation [24].

The current study aimed to evaluate complete healing rates in acute (<30 days) wounds in NPWT versus conventional dressings in the heel and ankle regions. These areas present difficulty and draw surgeon's attention for their proximity to critical joints with risk of major amputation if get affected, besides the longer healing periods with conventional moist dressings compared with other foot regions. Two groups were identified: group A (NPWT, n=18) and group B (conventional, n=26). Complete wound healing within a 120-day assessment period was achieved in 72.3% (group A) and 30.8% in group B (P=0.019). All patient analysis demonstrated that HgA1c levels and wound treatment method were only factors that significantly affected the healing rate; however, the HgA1c levels were not significantly different among both groups (group A=7.75 and group B=8.19, P=0.2) making the wound therapy method the only significant factor in group analysis.

Several studies have reported very promising results in favor of NPWT. Chiang *et al.* [11] reported better healing rates in the NPWT group by demonstrating a reduction in maximum wound depth at day 14 (36.0% NPWT vs. 17.6% control, P=0.03). Also Mark *et al.* [25] had observed that the wound volume and depth decreased significantly in VAC dressings as compared with moist gauze dressings.

Lone *et al.* [9] in their study observed that the majority of wounds in the VAC group (78.6%) decreased in size as compared with 53.6% that in the conventional group. McCallon *et al.* [26], observed an average decrease of 28.4% in wound size in the VAC group as compared with 9.5% in the control group (treated by saline-moistened gauze dressings).

In a randomized, controlled study of 162 patients by Armstrong *et al.* [24], the patients were randomized to either VAC-assisted wound closure or moist dressings.

They included both acute and chronic wounds. The study end point was 100% re-epithelization before 112 days. There was no significant difference in the proportion of acute and chronic wounds achieving complete wound closure in either treatment group. Despite this, the Kaplan–Meier curves demonstrated statistically significantly faster healing in the NPWT group in both acute (P=0.030) and chronic wounds (P=0.033).

The current study limitations include nonrandomization and small sample size. Inherent deficiencies of retrospective studies are seen in reporting single study outcomes (complete wound healing) as we could not find measurement data or photos for wounds in the follow-up period. However, we justify the need to report our results for paucity of studies focusing on acute wound healing in such challenging areas.

On the basis of current data analysis, the use of NPWT should be recommended for acute wounds in the heel and ankle regions to obtain a faster complete healing and desired wound closure in such critical areas.

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Conflicts of interest
There are no conflicts of interest.

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