

Vacuum Assisted Closure vs. Conventional Therapy in Diabetic Foot: A Comparative Study

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) represent one of the most challenging complications of diabetes mellitus, often leading to prolonged morbidity, disability, and increased healthcare costs. Conventional wound care remains the mainstay of treatment, but limitations in healing efficacy necessitate adjunctive therapies. Vacuum-assisted closure (VAC), also known as negative pressure wound therapy, has gained attention as a potential modality to accelerate wound healing and improve outcomes.

Objective: To compare the efficacy of VAC therapy versus conventional wound management in patients with Wagner's grade I and II diabetic foot ulcers.

Methods: This prospective comparative study was conducted at Hayatabad Medical Complex, Peshawar, from July to September 2024. A total of 62 patients with type II diabetes mellitus and Wagner's grade I-II DFUs were randomized into two groups: Group A (VAC therapy, n=31) and Group B (conventional therapy, n=31). Outcomes assessed over four weeks included pain severity (VAS), ulcer size reduction, granulation tissue formation, complete wound healing, time to healing, and surgical debridement requirement.

Results: VAC therapy significantly improved pain relief and ulcer size reduction compared to conventional therapy ($p < 0.001$ for both). Median VAS score was lower in Group A (3 vs. 7), and mean ulcer size was smaller at four weeks ($11.6 \pm 1.2 \text{ cm}^2$ vs. $13.4 \pm 1.1 \text{ cm}^2$). However, no statistically significant differences were observed in granulation tissue scores, Wagner's grade improvement, complete healing rates, healing time, or debridement requirements.

Conclusion: VAC therapy provides superior short-term benefits in pain reduction and ulcer size shrinkage compared to conventional management, though its impact on complete healing requires further investigation.

Keywords: Diabetic foot ulcer, vacuum-assisted closure, negative pressure wound therapy, wound healing, conventional therapy.

INTRODUCTION

Diabetes mellitus (DM) is one of the rising health issues in the world, and over 537 million patients currently suffer worldwide, and up to 643 million are projected by 2030¹. Diabetic foot ulcer (DFU) is one of the most disabling complications of diabetes, and it poses as a significant source of morbidity, expenditure, and decrease in quality of life²⁻³. According to epidemiological research, as many as 25 percent of diabetic patients will in their own lives experience a foot ulcer, and almost 15 grounds (20 percent) of those will further develop lower extremity amputation in the absence of appropriate treatment⁴⁻⁵. This issue is especially critical in low- and middle-income nations where few healthcare resources and a low educational level of patients contribute to increasing DFUs⁶⁻⁷. DFUs pathophysiology is multifactorial, bone slides, peripheral neuropathy, peripheral arterial diseases and low immune response usually affect wound healing⁸⁻⁹. Standard wound care interventions, like saline dressing, moist wound care, and routine debridement, are considered the foundation of therapy but do not result in optimal recovery, particularly in chronic ulcers with high exudates or having an infection¹⁰. As a result, new adjunctive treatments have received attention with the aim to optimize wound healing, decrease complications, and improve patient outcomes¹¹⁻¹².

Negative pressure wound therapy (NPWT) or vacuum-assisted closure (VAC) has been proposed to be a promising modality used in managing complex wounds, including DFUs¹³⁻¹⁴. It entails the regulation of a wound bed with a sealed system of dressing a pressurized down below the air through the use of sub-atmospheric pressure, ensuring diminished exudate, edema, augmented blood flow of the area as well as the growth of granulation tissue¹⁵. Moreover, VAC therapy assists in the maintenance of a moist wound area and bacterial load reduction,

which is important to the active wound healing process¹⁶⁻¹⁷. Clinical trials and meta-analyses indicated that NPWT has a potential to improve wound closure or reduce granulation time or amputation risks when compared to standard therapy¹⁸⁻¹⁹. Nonetheless, other studies have also pointed in variability of references in the outcomes, with some stating lack of significance in complete healing rates or long term consequences.

VAC therapy application in diabetic wound care is especially applicable to the surgical and tertiary care context, wherein the complexity of DFUs requires a multidisciplinary approach²⁰. Although VAC is becoming more commonly used in clinical practice, concerns exist on its comparative efficacy in early-stage DFUs (Wagner grade I and II) compared to the other wound care options. Most of the current research has centered on advanced ulcers or more heterogeneous groups of patients, and it is challenging to generalize the findings to less severe, but still, clinically significant situations²¹⁻²². Besides, there are issues of cost-based and access differences, which present a further difficulty to the mass adoption of the concept in resource constrained settings.

Comparative research comparing VAC with traditional wound maintenance is needed in this regard to offer evidence-based recommendations to particular groups of patients. Through the evaluation of block outcomes like pain relief, reduction in the size of the ulcer, the development of the granulation tissue, and the standard healing rates, the clinicians can make improvements in deciding the place of the VAC therapy in the usual regimen of healing DFUs.

This knowledge gap can be bridged in the present study through comparison of the efficacy of VAC therapy versus a traditional wound management in people with Wagner grade I and II DFUs. The study assesses short term objective by examining pain level, ulcer size changes, granulation score, healing duration and surgical debridement requirement, through meta comparative design by the prospective approach. In this way, it aims to make quality contributions of new evidence to better management strategies of DFU and lessens the heavy money incidence of the cost of diabetic foot complications.

METHODOLOGY

This would be a prospective comparative study carried out at the Department of Surgery, Hayatabad Medical Complex (Peshawar),

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between July 2024 and September 2024. Sixty-two patients with type II diabetes mellitus, over the age of 46 years, and admitted with Wagner grade I or II diabetic foot ulcers were consecutively recruited. We were able to select patients who fit the inclusion criteria into two categories: Group A that had wound care management performed using vacuum-assisted closure (VAC) and Group B having the conventional wound care treatment. The simple lottery approach was used to randomize the assignment to minimize a selection bias. The exclusion criteria were as follows: patient with Wagner grade III or combination of III and IV, severe peripheral vascular disease or overlapping disease, or previously undergone surgical treatment of the same ulcer. The patients were all therapeutically tracked in relation to the four weeks of time and routine wound care practices were observed. The clinical outcomes were observed and compared between the two groups based on the pain level, size of the ulcer, changes in Wagner classification, granulation tissue development, full wound healing, time of healing and pressure ulcer requiring surgical debridgements. Pain levels were rated by use of the Visual Analog Scale (VAS), measurement of ulcer size was done using calibrated rulers which had centimeters, and finally, the granulation scores were rated by an expert surgeon who was unaware of the modality of therapy. They were measured at week one and week by week until the study terminated.

RESULTS

A total of 62 patients with type II diabetes mellitus and Wagner’s grade I–II diabetic foot ulcers were included in the study. The mean age of participants was 57.8 ± 6.1 years (range 46–66 years). Among them, 23 (37.1%) were males and 39 (62.9%) were females. The median duration of diabetes was 13 years (IQR: 11–15 years). Patients were equally divided into two groups: Group A (VAC therapy, n=31) and Group B (conventional therapy, n=31). Both groups were comparable at baseline in terms of age, gender distribution, ulcer size, and Wagner’s grade, with no statistically significant differences (p>0.05).

Pain Assessment: Pain levels were significantly lower in the VAC group compared to the conventional therapy group after 4 weeks. The median pain score in Group A was 3 (IQR: 1–4) compared to 7 (IQR: 6–8) in Group B (p<0.001).

Ulcer Size Reduction: Ulcer size reduction was more pronounced in Group A compared to Group B. At baseline, the mean ulcer size was comparable between both groups (p=0.412). After 4 weeks, the mean ulcer size reduced to 11.6 ± 1.2 cm² in Group A versus 13.4 ± 1.1 cm² in Group B, showing a significant difference (p<0.001).

Wagner’s Grade and Granulation Tissue: There was no significant difference between the two groups with respect to change in Wagner’s grade (p=0.116). Similarly, the mean granulation tissue score at week 4 was 2.8 ± 0.7 in Group A and 2.7 ± 0.6 in Group B, which was statistically insignificant (p=0.692).

Wound Healing and Debridement Requirement: Complete wound healing at 4 weeks was achieved in 8 (25.8%) patients in Group A compared to 6 (19.3%) patients in Group B (p=0.487). The mean time to healing was slightly shorter in Group A (3.6 ± 0.8 weeks) compared to Group B (3.8 ± 0.7 weeks), though this difference was not statistically significant (p=0.549). Requirement for surgical debridement was observed in 9 (29%) patients in Group A and 11 (35.5%) in Group B (p=0.41

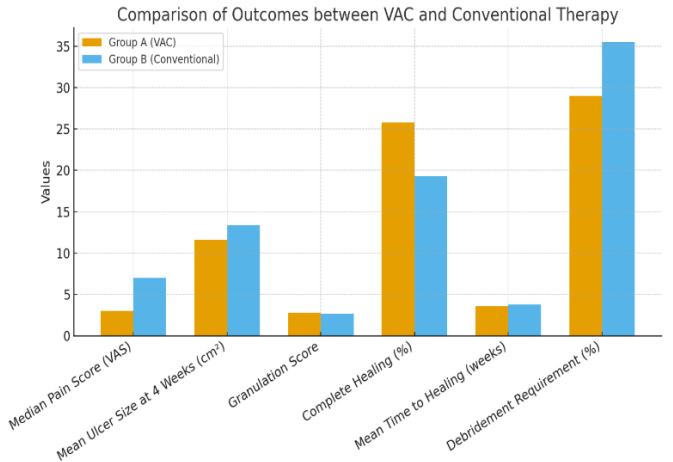
Table 1: Baseline Demographic Characteristics of Patients

Variable	Group A (VAC) n=31	Group B (Conventional) n=31	p-value
Mean Age (years)	57.9 ± 6.3	57.7 ± 5.9	0.884
Gender (Male/Female)	12/19	11/20	0.796
Median Duration of DM (years)	13 (12–15)	13 (11–14)	0.665
Mean Ulcer Size (cm ²)	13.2 ± 1.3	13.1 ± 1.4	0.412
Wagner’s Grade I/II	15/16	14/17	0.812

Table 2: Comparison of Outcomes Between Groups

Outcome	Group A (VAC) n=31	Group B (Conventional) n=31	p-value
Median Pain Score (VAS)	3 (1–4)	7 (6–8)	<0.001
Mean Ulcer Size at 4 Weeks (cm ²)	11.6 ± 1.2	13.4 ± 1.1	<0.001
Granulation Score	2.8 ± 0.7	2.7 ± 0.6	0.692
Complete Healing (n, %)	8 (25.8%)	6 (19.3%)	0.487
Mean Time to Healing (weeks)	3.6 ± 0.8	3.8 ± 0.7	0.549
Debridement Requirement (n, %)	9 (29%)	11 (35.5%)	0.412

Figure 1



The findings indicate that VAC therapy significantly improved pain relief and accelerated ulcer size reduction compared to conventional therapy. However, no statistically significant differences were observed in Wagner’s grade improvement, granulation tissue formation, complete healing rates, time to healing, or debridement requirement.

DISCUSSION

The current investigation evaluated the effectiveness of vacuum-assisted closure (VAC) therapy versus the traditional wound management of diabetic foot ulcers of the grade I and II of Wagner. Our results confirm that the VAC therapy is correlated with marked differences in the pain reduction, shrinkage of ulcer size after four weeks, but other variables, such as the formation of granulation tissue, the proportions of complete healing, the timing of healing and the need of debridement processes did not demonstrate statistically significant differences between the two. These findings support the possibility that VAC therapy is a useful adjunct treatment in diabetic wound management that can be successful in control of symptoms and early prevention of ulcer size.

The issue of pain management is the significant part of diabetic foot management because the presence of persistent pain worsens the quality of life and compliance with treatment adherence. Patients using VAC therapy scored significantly lower than those who used conventional therapy on pain in this study. Previous clinical trials have previously documented this upon the use of negative pressure wound therapy (NPWT) observed to reduce discomfort in the wound, by reducing local edema and enhancing microcirculation. The process of this activity is thought to be the stabilization of the wound climate, elimination of exudates, and decrease in inflammatory factors, all of which are united in alleviating pain.

The other area in which VAC therapy was superior was ulcer size reduction. The efficacy of NPWT to reduce the size of the wound is not new and studies have noted increased contraction in the wound, quicker healing rate in wounds when NPWT is used as compared to moist wound dressings. This and other pieces of evidence support our claim that ulcer size decreases significantly under VAC therapy and so may serve as a critical factor in

advancing faster wound bed readiness to a final closure or surgeries. VAC promotes angiogenesis and granulation tissue deposition that are fundamental in wound healing by developing a sub-atmospheric pressure in controlled environment.

Interestingly, the grade progression, granulation tissue score, and complete healing rate at four weeks did not show any notable differences between the two groups in Wagner. This observation can be explained by the follow-up time of only four weeks that might not be adequate to measure the long-term effects of VAC therapy. Higher rates of complete wound closure and less recurrence were shown in the previous research involving longer periods of observation involving VAC over conventional management. In addition, the nature of patient comorbidities, Glycemic control or vascular conditions, which were not adequately stratified in the current study might have contributed to the outcome of the healing processes.

Whether surgery debridement was also not considered significantly more demanded in the two groups also conforms to reports that VAC accelerates granulation and reduces wound size, but does not accelerate the necessity of surgery in any patients. Regardless of the adjunctive therapy administered, debridement has remained a foundation of diabetic foot management to aid the fight against the infection and debride the necrotic tissue.

The conclusions made by the pooling of the results are that the VAC therapy has considerable clinical benefits when combined in the short-term, particularly in terms of not just reduction in symptoms, but also reduction in wound size. However, it may take more time to be medically treated and incorporated into more profound diabetic management like careful glycemic control, vascular examination, and infection treatment, than its role in the experience of the whole process of full healing.

The strong points of this research are that it is prospective and that wound outcomes were assessed using standard methods in a prospective design. Nevertheless, constraints must be remembered. The single-location study and the limited sample size could be objections to generalisation. In addition, the period of follow up was not very long and so limited the verification of long term healing effects of the therapy and recurrence rates. Multicenter randomized controlled trials involving larger groups and a superior follow-up should be employed in future to determine more the efficiency of VAC therapy in management of diabetic foot.

In conclusion, the current study presents the information proving the fact that the VAC therapy is many more effective than the

conventional wound care with the reference to the reduction of the pain and to the sooner results in the reduction of the ulcer size in patients with diabetic foot ulcers. Though the results are not generalizable in the short run, further research is required to determine the impact on the complete wound remediation, recurrence as well as cost-benefit in the long run. VAC therapy can serve as an alternative to a multidisciplinary approach to the management of diabetic foot.

CONCLUSION

This paper highlights the comparative benefits of using vacuum-assisted closure (VAC) management over conventional wound management in management of Wagner grade I and II diabetic foot ulcers. Its findings show that VAC has significant advantages in efforts focused on pain control and enhanced reduction of the ulcer size-related issues that can be critical in terms of uber patient comfort and promoting uber gasping bed preparation. However, there are no significant differences observed based on granulation tissue growth, full healing or debridement requirement over the short period of the four weeks follow-up. The results suggest that although VAC therapy can be considered as an effective supplement therapy to the primary therapy to help alleviate the initial symptoms and to be able concerning the wound size, the role of this medical technique in completion of the treatment process with closed wounds and the probability of recurrence need further elaboration. Further multistage random trials in the long perspective are needed to lend it a permanent surname in the routine management systems of diabetic feet.

Authors' Contribution

SK: Concept & study design, data collection and drafting of the manuscript.

SH: Data entry, statistical analysis, interpretation of the results.

SA: Manuscript editing and critical revision of the manuscript.

All authors approved the final version of the manuscript to be published.

Conflict of Interest

The authors declared no conflict of interest.

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Data Availability

Data is available with authors and can be provided on request.

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