



A PROSPECTIVE COMPARATIVE STUDY OF NEGATIVE PRESSURE WOUND THERAPY VERSUS CONVENTIONAL DRESSING IN THE MANAGEMENT OF DIABETIC FOOT ULCERS AT A TERTIARY CARE CENTER

General Surgery

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) are associated with infection, prolonged hospitalization, delayed wound healing and an increased risk of amputation. Negative pressure wound therapy (NPWT) is an advanced wound-care technique used to promote healing and prepare the wound bed for closure. **Objective:** To compare clinical outcomes of NPWT and conventional dressing in patients with DFU. **Methods:** In this prospective, non-randomized comparative study conducted over 24 months at a tertiary care centre, 140 patients with DFU were enrolled consecutively and allocated to NPWT (n = 70) or conventional dressing (n = 70). Wound size was measured serially at three weekly follow-up assessments; the number of debridements, method of wound closure, Visual Analog Scale (VAS) pain score, time to infection control and duration of hospital stay were recorded. Categorical variables were compared using the chi-square or Fisher's exact test and continuous variables using the Mann-Whitney U test. **Results:** Age and gender distributions were comparable between groups (p = 0.600 and p = 1.000). Median wound size was significantly smaller with NPWT at Week 1 (29 vs. 34 cm²), Week 2 (18 vs. 29 cm²) and Week 3 (9 vs. 24.5 cm²; p < 0.001 at each time point). A single debridement sufficed in 77.1% of NPWT patients versus none in the conventional group, and skin grafting was performed more often with NPWT (67.1% vs. 35.7%). NPWT was also associated with lower VAS pain scores (3.5 vs. 7), shorter time to infection control (5 vs. 8 days) and shorter hospital stay (9 vs. 14 days) (p < 0.001 for all). **Conclusion:** Compared with conventional dressing, NPWT was associated with better wound healing and more favourable clinical outcomes. Because of the non-randomized design, these findings should be interpreted with caution.

KEYWORDS

Diabetic Foot Ulcer, Negative Pressure Wound Therapy, Conventional Dressing, Wound Healing

INTRODUCTION

Diabetes mellitus has become one of the most pressing global health challenges of recent decades, with an estimated 537 million adults affected worldwide in 2021 and a disproportionate burden in low- and middle-income countries such as India (Anjana et al., 2017; International Diabetes Federation, 2021; Mohseni et al., 2019). Diabetic foot ulcer (DFU) is among its most disabling complications, with a lifetime incidence of approximately 15–25% among people with diabetes, and it remains the leading precursor of non-traumatic lower-limb amputation (Armstrong & Mills, 2013; Armstrong et al., 2017; Mohseni et al., 2019). DFU arises from the interplay of peripheral sensorimotor neuropathy, peripheral arterial disease, and impaired immune function in the hyperglycemic state, and it imposes a substantial economic and psychosocial burden through hospitalization, surgery, and prolonged wound care (Armstrong et al., 2017; Carter et al., 2023; Hasan et al., 2015; Mohseni et al., 2019; Rice et al., 2014).

Conventional wound care—typically saline- or povidone-iodine-soaked gauze changed once or more daily—remains the mainstay of DFU management in many centers because of its simplicity and low cost. However, frequent dressing changes are painful and labor-intensive, exudate control is inconsistent, and open dressing systems offer limited protection against bacterial contamination (Canadian Agency for Drugs and Technologies in Health, 2014; Frykberg & Banks, 2015).

Negative pressure wound therapy (NPWT), also known as vacuum-assisted closure, applies controlled sub-atmospheric pressure to a sealed wound bed. Proposed mechanisms of benefit include continuous removal of exudate with reduction of bacterial load, macro- and micro-deformation effects that promote fibroblast proliferation and angiogenesis, and maintenance of a moist, protected wound environment (Argenta & Morykwas, 1997; Glass et al., 2014; Orgill & Bayer, 2013; Saxena et al., 2004). Comparative and randomized studies have generally reported favorable outcomes for NPWT over standard moist wound care, although a Cochrane review emphasized the need for further high-quality evidence (Blume et al., 2008; Liu et al., 2018). Most published comparisons originate from high-income settings, and applicability to resource-constrained

tertiary care centers in low- and middle-income countries remains comparatively under-studied (International Working Group on the Diabetic Foot, 2023). The present study was therefore undertaken to compare NPWT with conventional dressing in the management of DFU at a tertiary care center, with respect to wound size reduction, need for debridement, method of wound closure, pain, infection control, and duration of hospital stay.

MATERIALS AND METHODS

Study Design and Setting

This prospective, non-randomized comparative clinical study was conducted in the Department of General Surgery of a tertiary care teaching hospital in Maharashtra, India, over a period of 24 months.

Participants

All patients admitted to the surgical ward with a diabetic foot ulcer during the study period were considered for inclusion. Patients with peripheral vascular disease, active bleeding, critical illness, uncontrolled diabetes (fasting blood sugar >160 mg/dL) or wound size <10 cm² were excluded. A total of 140 patients were enrolled consecutively and allocated to the NPWT group (n = 70) or the conventional dressing group (n = 70) according to time of presentation; no randomization was performed.

Baseline Work-up

Baseline evaluation included clinical examination, laboratory tests, blood glucose, and Doppler ultrasound. Wounds were debrided and cultured for antibiotic sensitivity.

Interventions

NPWT was applied after debridement at -80 to -125 mmHg. Conventional dressings were changed twice daily using povidone-iodine, saline, and moist gauze.

Outcome Measures

Wound size was assessed weekly for three weeks. Pain (VAS), infection-control time, hospital stay, debridement frequency, and closure method were recorded.

Statistical Analysis

Data were entered in Microsoft Excel and analysed using IBM SPSS Statistics for Windows, version 27.0. Categorical variables were expressed as frequencies and proportions and compared using the chi-square or Fisher's exact test, as appropriate. Normality of continuous variables was assessed using the Kolmogorov-Smirnov test; as these variables were non-normally distributed, they are presented as median (interquartile range, IQR) and were compared between groups using the Mann-Whitney U test. Wound size across the three sequential follow-up points was compared using the Friedman test. A p-value <0.05 was considered statistically significant.

Ethical Considerations

The study received Institutional Ethics Committee approval (No. 458). Written informed consent was obtained from all participants. The study followed the Declaration of Helsinki.

RESULTS

A total of 140 patients with diabetic foot ulcers were enrolled and allocated equally to the NPWT (n = 70) and conventional dressing (n = 70) groups.

Baseline Characteristics

Fifty-nine patients (42.1%) were aged 51–60 years, 38 (27.1%) were aged 41–50 years, 32 (22.9%) were older than 60 years and 11 (7.9%) were younger than 40 years; 84 patients (60.0%) were male. Age and gender distributions did not differ significantly between the groups (p = 0.600 and p = 1.000, respectively). Median fasting blood sugar (FBS) was significantly lower in the NPWT group than in the conventional group (137 vs. 155 mg/dL, p = 0.007), whereas median glycated haemoglobin (HbA1c) was comparable between groups (8.4% vs. 8.2%, p = 0.412) (Table 1). Doppler ultrasound demonstrated normal blood flow in all 140 patients (100%), consistent with the pre-specified exclusion of peripheral vascular disease.

Table 1. Baseline Demographic and Clinical Characteristics of the NPWT and Conventional Dressing Groups.

Characteristic	NPWT (n = 70)	Conventional (n = 70)	P value
Age group			0.600
<40 years	6 (8.6%)	5 (7.1%)	
41–50 years	22 (31.4%)	16 (22.9%)	
51–60 years	26 (37.1%)	33 (47.1%)	
>60 years	16 (22.9%)	16 (22.9%)	
Gender			1.000
Male	42 (60.0%)	42 (60.0%)	
Female	28 (40.0%)	28 (40.0%)	
FBS, median (IQR), mg/dL	137 (127–155)	155 (135–158)	0.007
HbA1c, median (IQR), %	8.4 (7.3–9.3)	8.2 (7.4–9.1)	0.412

NPWT, negative pressure wound therapy; FBS, fasting blood sugar; HbA1c, glycated haemoglobin; IQR, interquartile range. Age and gender compared using the chi-square test; FBS and HbA1c using the Mann-Whitney U test.

Microbiological Profile and Antibiotic Sensitivity

Escherichia coli was the most frequently isolated organism in the overall cohort (42 patients, 30.0%), followed by *Staphylococcus aureus* (37, 26.4%), *Pseudomonas aeruginosa* (34, 24.3%) and *Klebsiella* species (27, 19.3%). On antibiotic sensitivity testing, amikacin showed the highest sensitivity (26, 18.6%), followed by piperacillin-tazobactam (20, 14.3%) and vancomycin (17, 12.1%). Neither the distribution of isolated organisms (chi-square test, p = 0.201) nor the antibiotic sensitivity pattern (Fisher's exact test, p = 0.218) differed significantly between the two groups.

Wound Size Over Follow-up

In the overall cohort, median wound size decreased significantly over follow-up, from 32 cm² (IQR 29–34) at Week 1 to 24.5 cm² (IQR 18–29) at Week 2 and 17.5 cm² (IQR 9–24.75) at Week 3 (Friedman test, p < 0.001). Median wound size was significantly smaller in the NPWT group than in the conventional group at every follow-up point: 29 vs. 34 cm² at Week 1, 18 vs. 29 cm² at Week 2 and 9 vs. 24.5 cm² at Week 3 (Mann-Whitney U test, p < 0.001 at each time point) (Table 2, Figure 1).

Table 2. Wound Size (cm²) Over Follow-up in the NPWT and Conventional Dressing Groups.

Follow-up	NPWT (n = 70)	Conventional (n = 70)	P value
2			

Week 1	29 (27–32)	34 (25–36)	<0.001
Week 2	18 (16–20)	29 (27–30)	<0.001
Week 3	9 (8–11)	24.5 (23–26)	<0.001

Values are median (interquartile range) wound size in cm². NPWT, negative pressure wound therapy. Mann-Whitney U test at each time point.

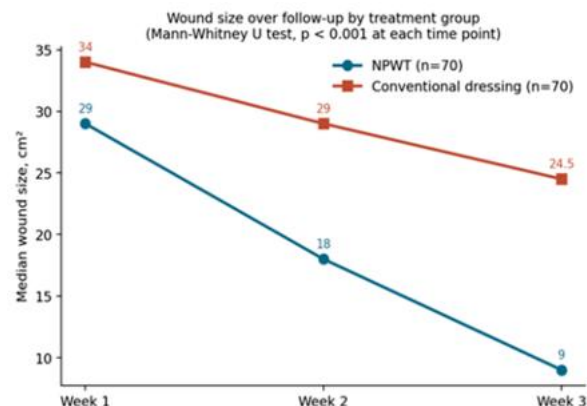


Figure 1 Wound Size Reduction Over Three Weeks in the NPWT and Conventional Dressing Groups

Debridement and Wound Closure

In the NPWT group, 54 patients (77.1%) required a single debridement and 16 (22.9%) required two, with none requiring three; in the conventional group, 43 patients (61.4%) required two debridements and 27 (38.6%) required three, with none requiring only one (Fisher's exact test, p < 0.001). Skin grafting was performed significantly more often in the NPWT group (47 patients, 67.1%) than in the conventional group (25, 35.7%), whereas spontaneous closure occurred more often in the conventional group (45, 64.3%) than in the NPWT group (23, 32.9%) (chi-square test, p < 0.001) (Table 3).

Table 3. Debridement, Wound Closure, and Clinical Outcomes in the NPWT and Conventional Dressing Groups

Variable	NPWT (n = 70)	Conventional (n = 70)	P value
Number of debridements			<0.001
1	54 (77.1%)	0 (0%)	
2	16 (22.9%)	43 (61.4%)	
3	0 (0%)	27 (38.6%)	
Wound closure method			<0.001
Skin grafting	47 (67.1%)	25 (35.7%)	
Spontaneous closure	23 (32.9%)	45 (64.3%)	
Outcome			
Hospital stay, days	9 (7–10)	14 (12–16)	<0.001
VAS pain score	3.5 (2–4.25)	7 (5.75–8)	<0.001
Time to infection control, days	5 (4–6)	8 (7–10)	<0.001

Values are n (%) for categorical variables and median (interquartile range) for continuous variables. NPWT, negative pressure wound therapy; VAS, Visual Analog Scale. Number of debridements was compared using Fisher's exact test; wound closure method using the chi-square test; hospital stay, VAS pain score, and time to infection control using the Mann-Whitney U test.

Hospital Stay, Pain and Infection Control

Compared with the conventional group, the NPWT group had a significantly shorter median hospital stay (9 vs. 14 days), a significantly lower median VAS pain score (3.5 vs. 7) and a significantly shorter median time to infection control (5 vs. 8 days) (Mann-Whitney U test, p < 0.001 for all).

DISCUSSION

Wound care is a key determinant of healing and amputation risk in diabetic foot ulcer, alongside metabolic control, infection management, and vascular assessment (Noble-Bell & Forbes, 2008). NPWT is thought to promote healing through removal of necrotic tissue and exudate, reduction of interstitial edema, enhancement of local perfusion, and stimulation of granulation tissue formation (Karatepe et al., 2011). Randomized and comparative studies from diverse settings, including a multicenter trial after partial diabetic foot

amputation (Armstrong & Lavery, 2005), a randomized trial in infected diabetic foot ulcers (Malekpour Alamdari et al., 2021), and safety data from outpatient NPWT use (Fife et al., 2008), provide useful points of comparison for the present findings.

Most patients in the present cohort were aged 51–60 years, and age and gender distributions were comparable between the two arms, supporting the internal comparability of the groups. Similar age profiles were reported by Nain et al. (2011) and Sukur et al. (2018). The male predominance observed here is consistent with James et al. (2019) and Seidel et al. (2020), whereas Lone et al. (2014) reported a female predominance, suggesting that regional or sociocultural factors may influence gender distribution in DFU cohorts. Median FBS was lower in the NPWT group although HbA1c was comparable; because impaired glycemic control compromises leukocyte function, chemotaxis, phagocytosis, and collagen synthesis, this between-group FBS difference should be regarded as a potential confounder, even though HbA1c parity suggests broadly similar longer-term glycemic status. James et al. (2019) similarly reported suboptimal glycemic control in both study arms, whereas Ravari et al. (2013) described a comparatively better-controlled cohort, which may partly explain differences in absolute healing rates across studies.

Infection resolved faster in the NPWT group, consistent with the proposed mechanism by which continuous exudate removal reduces bacterial and inflammatory burden while the sealed system limits external contamination. Reduced bacterial load or colonization with NPWT has been reported by Nain et al. (2011) and Mouës et al. (2004), although Lone et al. (2014) did not observe a significant between-group difference. The predominantly polymicrobial organism profile and the antibiotic sensitivity pattern did not differ significantly between groups, consistent with previously described diabetic foot wound microbiology (Bowler et al., 2001) and suggesting that the observed clinical benefit reflects the mechanism of NPWT rather than a difference in the underlying microbiological profile of the two groups. Infection was assessed against standard clinical criteria for identifying wound infection (Cutting, 2024) and in keeping with contemporary guideline-based principles for diabetic foot infection management (Lipsky et al., 2012).

Greater wound size reduction with NPWT at every follow-up point accords with the accelerated wound contraction reported by Maranna et al. (2021), Nain et al. (2011), and McCallon et al. (2000), and is compatible with macro-deformation drawing the wound edges together, micro-deformation promoting fibroblast proliferation and angiogenesis, and reduced edema from continuous exudate removal. A markedly lower proportion of NPWT patients required repeated debridement, suggesting that NPWT may help maintain a cleaner wound bed over time; James et al. (2019) found no significant between-group difference in debridement frequency, whereas Vaidhya et al. (2015) reported a reduced need for repeated intervention. Skin grafting was performed more often after NPWT, consistent with more rapid granulation tissue formation and earlier readiness for grafting reported by Seidel et al. (2020), Sukur et al. (2018), and Nain et al. (2011), although the present study did not independently assess graft uptake or long-term functional outcomes. Lower VAS pain scores with NPWT plausibly reflect the reduced frequency of dressing changes and protection of exposed nerve endings by the sealed system, in keeping with James et al. (2019), while the shorter hospital stay agrees with Maranna et al. (2021) and is consistent with the faster healing, earlier infection control, and fewer debridement procedures observed in this cohort.

Taken together, these findings suggest that NPWT may offer clinically meaningful advantages over conventional dressing in the management of diabetic foot ulcers in tertiary care settings where resources, contraindication screening, and trained personnel permit, as part of a broader multidisciplinary strategy that continues to include glycemic control, appropriate antibiotic therapy, and offloading (Bus et al., 2011). Strengths include direct comparison of the two modalities in 140 patients, assessment of multiple clinically relevant outcomes, and serial wound measurement over three weeks. The study is limited by its single-center, non-randomized design, short follow-up, exclusion of high-risk patients, absence of cost-effectiveness, graft-uptake, and quality-of-life assessment, and the baseline between-group difference in FBS; the observed differences therefore represent associations rather than established causal effects. Larger multicenter randomized trials with longer follow-up, standardized NPWT protocols, and formal economic evaluation are needed.

CONCLUSION

In this comparative study of 140 patients with diabetic foot ulcers managed at a tertiary care centre, negative pressure wound therapy was associated with greater and faster reduction in wound size, fewer debridement procedures, a higher rate of skin grafting, lower pain scores, earlier infection control and shorter hospital stay than conventional dressing. These findings support NPWT as a useful advanced wound care modality in this setting, while the non-randomized design underscores the need for larger, multicentre randomized studies with cost-effectiveness analysis before broader generalization.

DECLARATIONS

Ethical approval was obtained (No. 458) and written informed consent was obtained. No funding or conflicts of interest were reported. Data are available from the corresponding author on reasonable request.

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