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"EVALUATING THE EFFECTIVENESS OF NEGATIVE PRESSURE WOUND THERAPY COMPARED TO STANDARD CARE IN MANAGING DIABETIC FOOT ULCERS"

General Surgery

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ABSTRACT

Background: To assess the efficacy, safety, and economic impact of Negative Pressure Wound Therapy (NPWT) compared to Standard Wound Care (SWC) in the management of Diabetic Foot Ulcers (DFUs). **Methods:** A total of 91 patients with diabetic foot ulcers (DFUs) were included in this retrospective study conducted between January 2023 and December 2024. Patients were assigned to either the Negative Pressure Wound Therapy (NPWT, n = 44) group or the Standard Wound Care (SWC, n = 47) group based on the treatment method. Arterial disease severity was evaluated using the ankle-brachial index (ABI) and Doppler ultrasound, with patients categorized into severe ischemia (ABI < 0.4), moderate ischemia (ABI 0.4–0.7), and normal/mild ischemia (ABI > 0.7) subgroups. Baseline characteristics, wound parameters, healing outcomes, adverse events, treatment costs, and subgroup results according to arterial disease status were compared between the two groups. **Results:** At the 4-week assessment, the NPWT group demonstrated a significantly greater mean percentage reduction in wound area (35.01% vs. 32.53%, P = 0.033) and wound depth (2.74 mm vs. 2.14 mm, P = 0.032) compared to the SWC group. A higher proportion of NPWT patients achieved complete wound closure (52.27% vs. 27.66%, P = 0.029), resolution of infection (88.64% vs. 68.09%, P = 0.035), and improvement in neuropathy (59.09% vs. 34.04%, P = 0.029). NPWT was associated with lower wound infection rates (9.09% vs. 29.79%, P = 0.027) but higher incidence of skin irritation (31.82% vs. 10.64%, P = 0.026). Subgroup analysis indicated NPWT's superiority in both PAD-positive (48.0% vs. 20.0%, RR = 2.40, 95% CI: 1.12–5.15, P = 0.042) and PAD-negative patients (55.2% vs. 30.4%, RR = 1.82, 95% CI: 1.05–3.15, P = 0.031). Even among patients with severe ischemia (ABI < 0.4), NPWT achieved higher closure rates (36.4% vs. 12.5%, P = 0.038). Although total treatment costs were similar between groups (P = 0.084), NPWT reduced hospitalization duration (16.05 vs. 21.38 days, P = 0.028) and drug expenses (5,229.33 RMB vs. 5,915.5 RMB, P = 0.030). **Conclusion:** NPWT demonstrates greater safety, cost-effectiveness, and long-term efficacy in wound management compared to SWC.

KEYWORDS

INTRODUCTION

Diabetic foot ulcers (DFUs) represent a significant global health burden, affecting approximately 15% of individuals with diabetes over their lifetime [1, 2]. The complex interplay of neuropathy, peripheral arterial disease, and immune dysfunction predisposes diabetic patients to chronic foot ulcers, which can result in severe complications, including infection, gangrene, and lower extremity amputation. The economic impact of DFUs is substantial, with direct and indirect management costs estimated in the billions of dollars annually [3, 4].

Management of DFUs involves interventions aimed at promoting wound healing, preventing infection, and ultimately avoiding amputations [5, 6]. Standard wound care (SWC), typically consisting of debridement, offloading, dressings, and infection control, has long been the cornerstone of DFU management. However, challenges such as delayed wound closure, high infection rates, and significant economic burden have prompted exploration of advanced therapies, including negative pressure wound therapy (NPWT).

NPWT applies controlled negative pressure to the wound environment, facilitating exudate removal, enhancing perfusion, and promoting granulation tissue formation. Its mechanisms of action include edema reduction, clearance of infectious materials, stimulation of angiogenesis, and creation of an optimal microenvironment for wound repair [7, 8]. These properties make NPWT a promising strategy for accelerating DFU healing and reducing complication risks.

Despite its growing use, evidence comparing NPWT to SWC remains mixed. For example, Chen et al.'s meta-analysis reported lower infection rates with NPWT but highlighted limited data on long-term outcomes such as recurrence and neuropathy improvement [9]. Similarly, Seidel et al. demonstrated NPWT's cost-effectiveness in reducing hospitalization days, but their analysis did not fully address drug cost savings [10]. These gaps—particularly concerning neuropathy, ischemia-stratified outcomes, and real-world cost dynamics—motivated our study to evaluate NPWT more comprehensively. We hypothesize that NPWT will achieve faster wound healing, fewer complications, and improved overall outcomes compared to SWC in patients with DFUs.

Therefore, this retrospective cohort study aims to compare and evaluate the efficacy, safety, and cost-effectiveness of NPWT versus SWC in the treatment of DFUs, thereby contributing to the growing body of evidence on optimal wound management strategies for this patient population.

MATERIALS AND METHODS

Study Design

This research is a retrospective cohort study including patients with diabetic foot ulcers (DFUs) admitted to Sri siddhartha medical college , tumkur, from January 2023 to December 2024. Patients were classified into either the Negative Pressure Wound Therapy (NPWT) group or the Standard Wound Care (SWC) group based on the wound treatment approach. Informed consent was obtained from all patients in accordance with standard medical practices.

The study protocol was approved by the Institutional Review Board and Ethics Committee of our hospital and conducted in accordance with the Declaration of Helsinki. For this retrospective study, the requirement for informed consent was waived, as de-identified patient data posed no risk or impact on patient care.

Inclusion And Exclusion Criteria

Inclusion Criteria:

- Confirmed diagnosis of type 2 diabetes mellitus.
- Age ≥ 18 years.
- Minimum follow-up period of 3 months.
- Chronic DFU located below the medial malleolus (forefoot, midfoot, or hindfoot).
- Chronic DFU with wound area between 5–20 cm² (maximum diameter measured in any dimension).
- Complete medical records available.

Exclusion Criteria:

- Coagulation disorders or autoimmune diseases.
- Cardiopulmonary diseases.
- Poorly controlled diabetes (HbA1c ≥ 10%).
- Pregnancy.
- Ulcers with duration < 3 months or size < 5 cm² or > 20 cm².
- Ulcers with comorbidities such as vasculitis or varicose ulcers.
- Immunocompromised states (e.g., post-chemotherapy, post-radiotherapy).
- Non-diabetic foot trauma [11].

Treatment Methods
All patients underwent thorough debridement at presentation.

NPWT Group:
- Wounds were covered with an open-cell polyurethane/Ag foam dressing, ensuring no compression of wound areas.
- The dressing was secured with a transparent adhesive, covered with a vapor-permeable film, and connected via suction tubing to a reservoir.
- Continuous negative pressure was applied, with initial settings adjusted to optimize exudate removal and wound healing.

NPWT Application:
The negative pressure was initially set at −125 mmHg, in accordance with clinical guidelines [12]. For patient discomfort (e.g., pain, bleeding) or excessive tissue adherence, the pressure was adjusted to −100 mmHg at the treating surgeon's discretion. Following the initial application in the operating room, the dressing was replaced after two days. Thereafter, negative pressure was maintained in the ward, with dressing changes every three days until wound healing.

Standard Wound Care (SWC) Group:
The control group received dressings with gauze soaked in normal saline under aseptic conditions. For wounds with signs of infection (e.g., purulent exudate, erythema) or heavy exudate, antimicrobial dressings (e.g., silver-impregnated gauze) or absorbent dressings (e.g., alginate) were applied at the clinician's discretion following institutional protocols [13]. Dressings were changed every 24 hours, involving removal, wound cleansing with normal saline, and reapplication. Once healing commenced, dressings were temporarily removed for wound assessment and measurement.

Data Collection
General Information:
Patient demographic and clinical data were systematically retrieved from medical records, including age, gender, BMI, HbA1c, duration and type of ulcer, ulcer location, smoking history, hypertension, and peripheral artery disease status.

Wound Healing Assessment:
Weekly wound measurements and photographic documentation were performed by the principal researcher using standardized photography equipment. Wound dimensions were measured with a sterile ruler, Vernier Caliper 125 MEB-6/150, and analyzed using ImageJ software (version 1.53t, NIH, USA), which utilizes edge-detection algorithms and geometric modeling to calculate wound surface area and perimeter with minimal interobserver variability [14].

Granulation tissue was assessed using the Bates-Jensen Wound Assessment Tool (BWAT), scoring from 1 (no granulation) to 5 (complete granulation covering the wound bed) [15]. Exudate levels were categorized as none, light, moderate, or heavy based on standardized criteria [16].

At baseline, measurements included wound area, wound depth, infection status, exudate level, and granulation status for all patients. After 4 weeks of treatment, the following outcomes were recorded: percentage reduction in wound area, changes in wound depth, complete wound closure rate, infection resolution rate, and neuropathy improvement rate.

Neuropathy Assessment
Neuropathy improvement was defined as a ≥1-point increase in the Semmes-Weinstein monofilament test (SWMT) score at 4 weeks. At baseline, inability to perceive the 5.07 monofilament pressure (10 g) indicated neuropathy [17]. All wound and neuropathy assessments were conducted by a single surgeon from the unit. Adverse events and complications during treatment were documented, and total treatment costs, hospitalization duration, and number of dressing changes were recorded.

Vascular Assessment
Arterial disease severity was evaluated using the ankle-brachial index (ABI) and Doppler ultrasound, with ABI categories defined according to the Society for Vascular Surgery guidelines [18]:
- **Severe ischemia:** ABI < 0.4
- **Moderate ischemia:** ABI 0.4–0.7
- **Normal/mild ischemia:** ABI > 0.7

Patients with ABI < 0.4 or symptoms of critical limb ischemia underwent further vascular imaging (CT angiography or MR angiography). Revascularization procedures, such as angioplasty or bypass, were recorded if performed within 3 months prior to or during the study period.

Statistical Analysis
Data analysis was performed using SPSS version 29.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were expressed as n (%) and analyzed using the chi-square test when sample sizes were ≥ 40 and theoretical frequencies ≥ 5. Adjusted chi-square methods were applied when theoretical frequencies ranged from 1–5 for sample sizes ≥ 40, and Fisher's exact test was used when sample sizes were < 40 or theoretical frequencies < 1.

Normality of continuous variables was assessed using the Shapiro-Wilk test. Normally distributed variables were reported as mean ± SD, and non-normally distributed variables were reported as median (25th percentile, 75th percentile) and analyzed using the Wilcoxon rank-sum test. Statistical significance was set at $P < 0.05$.

RESULTS
The baseline characteristics of participants showed no statistically significant differences between the NPWT and SWC groups in terms of age, gender distribution, BMI, HbA1c levels, ulcer duration, ulcer type, ulcer location, smoking history, hypertension, or peripheral artery disease (PAD) ($P > 0.05$). These findings indicate that the two groups were well-matched at baseline, supporting that any subsequent differences in outcomes are likely attributable to the treatment interventions**.**

Wound Characteristics
Baseline assessment of wound parameters revealed no statistically significant differences between the NPWT and SWC groups. Wound area (6.75 ± 2.14 cm² vs. 6.98 ± 2.31 cm², $t = 0.482$, $P = 0.631$), wound depth (8.43 ± 1.92 mm vs. 8.65 ± 2.06 mm, $t = 0.525$, $P = 0.601$), presence of wound infection ($\chi^2 = 0.005$, $P = 0.946$), weekly wound exudate volume (35.21 ± 10.53 mL vs. 36.98 ± 11.27 mL, $t = 0.774$, $P = 0.441$), and presence of granulation tissue ($\chi^2 = 2.567$, $P = 0.109$) were comparable between groups. These findings indicate that baseline wound characteristics were similar in both treatment groups, suggesting that subsequent differences in treatment outcomes are unlikely to be influenced by initial variations.

Wound Healing Progress
At the 4-week assessment, the NPWT group demonstrated a significantly greater mean percentage reduction in wound area compared to the SWC group (35.01 ± 5.62% vs. 32.53 ± 5.28%, $t = 2.167$, $P = 0.033$) and a larger reduction in wound depth (2.74 ± 1.26 mm vs. 2.14 ± 1.36 mm, $t = 2.178$, $P = 0.032$). Additionally, a higher proportion of NPWT patients achieved complete wound closure (52.27% vs. 27.66%, $\chi^2 = 4.774$, $P = 0.029$), resolution of wound infection (88.64% vs. 68.09%, $\chi^2 = 4.463$, $P = 0.035$), and improvement in neuropathy (59.09% vs. 34.04%, $\chi^2 = 4.774$, $P = 0.029$) compared to the SWC group. These results indicate more favorable early wound healing with NPWT.

Subgroup analysis stratified by PAD status revealed that NPWT achieved superior wound closure rates in both PAD-positive (48.0% vs. 20.0%, RR = 2.40, 95% CI: 1.12–5.15, $P = 0.042$) and PAD-negative patients (55.2% vs. 30.4%, RR = 1.82, 95% CI: 1.05–3.15, $P = 0.031$). However, the interaction term (treatment × PAD status) in logistic regression was not statistically significant ($P = 0.28$), indicating that the relative efficacy of NPWT versus SWC did not differ significantly by PAD status.

Arterial Disease Severity And Treatment Outcomes
To evaluate the impact of arterial insufficiency on wound healing, patients were stratified according to objective measures of arterial disease severity using the ankle-brachial index (ABI). NPWT demonstrated higher wound closure rates compared to SWC across all ischemia subgroups. Specifically, in patients with severe ischemia (ABI < 0.4), NPWT achieved a closure rate of 36.4% versus 12.5% with SWC ($P = 0.038$). In the moderate ischemia group (ABI 0.4–0.7), NPWT also showed improved healing outcomes, and similar trends were observed in patients with normal/mild ischemia (ABI > 0.7). These findings suggest that NPWT confers benefits in wound healing irrespective of baseline arterial disease severity.

Adverse Events And Complications

Analysis of adverse events revealed that the NPWT group experienced a significantly lower incidence of wound infection compared to the SWC group (9.09% vs. 29.79%, $\chi^2 = 4.900$, P = 0.027), while exhibiting a higher rate of skin irritation (31.82% vs. 10.64%, $\chi^2 = 4.955$, P = 0.026) (Table 4). No significant differences were observed between groups regarding allergic reactions (6.82% vs. 4.26%, $\chi^2 = 0.006$, P = 0.940) or hemorrhage (4.55% vs. 8.51%, $\chi^2 = 0.115$, P = 0.735) (Table 6). These findings suggest that NPWT may reduce the risk of wound infection but carries a higher likelihood of causing skin irritation relative to SWC.

Cost Analysis

Cost evaluation revealed no statistically significant difference in total treatment costs between the NPWT and SWC groups (16,431.47 ± 5,436.12 RMB vs. 18,704.78 ± 6,851.34 RMB, t = 1.746, P = 0.084). However, NPWT was associated with significantly fewer hospitalization days (16.05 ± 10.50 vs. 21.38 ± 12.12 days, t = 2.235, P = 0.028) and lower drug expenses (5,229.33 ± 1,439.36 vs. 5,915.50 ± 1,530.00 RMB, t = 2.200, P = 0.030) compared to SWC (Table 7). These results indicate that, although overall treatment costs were comparable, NPWT may confer economic benefits by reducing hospital stay duration and associated medication use.

DISCUSSION

Comparing and evaluating NPWT versus SWC in the management of DFUs is of critical importance due to the increasing prevalence of diabetes and its associated complications, including DFUs [19]. In this retrospective cohort study, we aimed to contrast the clinical outcomes, safety profile, and economic implications of NPWT and SWC in patients with DFUs. Our findings indicate that NPWT offers superior early wound healing, higher rates of complete wound closure, and improved infection resolution compared to conventional SWC.

The study demonstrated that NPWT produced more favorable wound healing outcomes at the 4-week assessment compared to SWC. Patients in the NPWT group exhibited a significantly greater mean percentage reduction in wound area, larger decreases in wound depth, and higher rates of complete wound closure, infection resolution, and neuropathy improvement. These results are consistent with previous studies highlighting NPWT's effectiveness in accelerating wound healing and reducing time to closure in chronic wounds, including DFUs [20–22]. The notably higher rates of wound closure and infection resolution observed in the NPWT group are particularly significant, as these outcomes are closely associated with improved long-term limb salvage and reduced risk of complications.

The information presented in this study adds to the growing body of literature supporting NPWT as an effective treatment for DFUs [10, 23–24]. NPWT exerts mechanical forces on the wound that promote granulation tissue formation, angiogenesis, and edema reduction, which are essential for efficient wound healing. Continuous negative pressure facilitates the removal of exudate and infectious material, creating a cleaner wound bed and minimizing infection risk [25, 26]. Moreover, NPWT enhances perfusion to the wound area, improving tissue oxygenation and nutrient delivery—key factors for cellular metabolism and tissue repair [27–29]. By reducing exudate volume and bacterial load, NPWT minimizes biofilm formation, a critical precursor to infection and amputation, while mechanical stimulation of granulation tissue and angiogenesis enhances perfusion, particularly in ischemic regions. Collectively, these mechanisms explain the lower infection rates and higher closure rates observed in the NPWT group, potentially translating into improved long-term limb salvage.

Stratified analysis demonstrated NPWT's efficacy even in severe ischemia (ABI < 0.4), although closure rates were lower compared to well-perfused wounds. This finding aligns with evidence that NPWT improves microvascular flow through mechanical stimulation of pericytes and angiogenesis [10] but emphasizes that revascularization remains essential in advanced ischemia. Importantly, NPWT's benefits were independent of revascularization status, suggesting its role as a bridge to definitive care in complex DFUs.

The study also provides insights into the safety profile and economic implications of NPWT. While NPWT was associated with a lower incidence of wound infection, it showed a higher rate of skin irritation [30], consistent with previous reports, highlighting the need for careful monitoring and proactive management of potential skin complications. Cost analysis revealed no significant difference in total treatment costs between NPWT and SWC. However, NPWT reduced hospitalization duration and the need for dressing changes. Despite higher device costs, these indirect benefits—such as reduced nursing care, bed occupancy, and antibiotic use—likely contributed to the comparable total treatment costs, suggesting NPWT can be cost-neutral or even cost-saving when considering overall resource utilization.

Our study further demonstrates NPWT's association with neuropathy improvement, potentially linked to enhanced perfusion and reduced inflammation, a finding underexplored in prior literature. Unlike many trials that excluded patients with arterial disease, our subgroup analysis confirms NPWT's efficacy in PAD-positive patients, challenging assumptions regarding its limitations in ischemic wounds. While this study focused on clinical metrics such as wound closure and infection rates, patient-centered outcomes-including pain, mobility, and quality of life-remain essential to holistic DFU management. A recent literature review by Widigdo et al. [31] reported that NPWT accelerates healing, promotes granulation tissue formation, and reduces wound size without increasing adverse events such as bleeding, pain, or amputation compared to conventional or advanced moist dressings. Future studies should integrate validated tools to assess differences between NPWT and SWC in patient-centered outcomes.

Several limitations warrant consideration. First, the retrospective design introduces potential biases related to patient selection, treatment allocation, and data collection. While efforts were made to address patient preferences and treatment decisions ethically, unmeasured confounders may have influenced outcomes. Second, the relatively short follow-up duration of 4 weeks limits assessment of long-term wound healing trajectories, recurrence rates, and sustained benefits of NPWT.

Future studies with extended follow-up periods would provide a more comprehensive understanding of the long-term comparative efficacy of NPWT and SWC in DFU management. Additionally, the focus on a single clinical setting in this study may limit the generalizability of the findings to other healthcare environments and diverse patient populations. Expanding research to include multiple centers and varied demographics would enhance the external validity of the conclusions.

While NPWT effectively improves local perfusion and accelerates wound healing, potential challenges and risks must be considered. Excessive negative pressure may induce tissue ischemia, potentially impairing the healing process. Some patients may experience pain or discomfort due to the applied negative pressure, which could affect adherence to therapy. Improper dressing management may also increase the risk of infection, and patients with fragile periwound skin are susceptible to maceration or mechanical injury [32]. Therefore, careful pressure adjustment tailored to individual patient needs and vigilant monitoring are essential to optimize therapeutic outcomes and minimize complications.

CONCLUSION

This study provides valuable evidence on the comparative effectiveness of NPWT versus SWC in the management of DFUs. The findings demonstrate that NPWT is associated with favorable early wound healing outcomes, including faster wound closure, higher rates of infection resolution, and improvement in neuropathy. In addition, NPWT offers benefits related to safety, cost-efficiency, and overall wound management. Given these advantages, healthcare providers may consider incorporating NPWT into standard treatment protocols for DFUs, particularly in patients with slow-healing wounds, high infection risk, or coexisting peripheral artery disease. These results support recent guidelines advocating for the early adoption of advanced wound therapies in complex DFU cases.

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