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Comparison and evaluation of negative pressure wound therapy versus standard wound care in the treatment of diabetic foot ulcers

Quan Guo[1*]

Abstract

Background To explore the efficacy, safety, and cost implications of NPWT versus standard wound care (SWC) for Diabetic Foot Ulcers (DFUs).

Methods 91 patients with DFUs were included in this retrospective study from May 2017 and February 2024. All patients were divided into NPWT ($n=44$) and SWC ($n=47$) groups based on the surgery methods. Arterial disease severity was assessed via ankle-brachial index (ABI) and Doppler ultrasound, with subgroups categorized as severe ischemia (ABI < 0.4), moderate ischemia (ABI 0.4–0.7), and normal/mild ischemia (ABI > 0.7). Baseline characteristics, wound parameters, healing progression, adverse events, costs, and subgroup outcomes by arterial disease status were compared between two groups.

Results At the 4-week assessment, the NPWT group exhibited significantly higher mean percentage reduction in wound area (35.01% vs. 32.53%, $P=0.033$) and greater reduction in wound depth (2.74 mm vs. 2.14 mm, $P=0.032$) compared to the SWC group. A notably 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 neuropathy improvement (59.09% vs. 34.04%, $P=0.029$). NPWT also showed lower wound infection rates (9.09% vs. 29.79%, $P=0.027$) but higher skin irritation (31.82% vs. 10.64%, $P=0.026$). Subgroup analysis revealed 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 subgroups (55.2% vs. 30.4%, RR = 1.82, 95% CI: 1.05–3.15, $P=0.031$). Even in severe ischemia (ABI < 0.4), NPWT achieved higher closure rates (36.4% vs. 12.5%, $P=0.038$). While total treatment costs were comparable ($P=0.084$), NPWT reduced hospitalization days (16.05 vs. 21.38 days, $P=0.028$) and drug costs (5229.33 RMB vs. 5915.5 RMB, $P=0.030$).

Conclusion NPWT is more superior in safety, cost-efficiency, and long-term wound management compared to SWC.

Trial registration Not applicable.

Keywords Comparison, Evaluation, Negative pressure wound therapy, Standard wound care, Diabetic foot ulcers

*Correspondence:
Quan Guo
sinewoomph@hotmail.com
[1]Department of Orthopedics, The Central Hospital of Yongzhou (Yongzhou Hospital Affiliated to University of South China), No. 396, Yiyun Road, Lengshuitan District, Yongzhou City, Hunan Province 425000, China

Introduction

Diabetic foot ulcers (DFUs) pose a substantial global health burden, affecting approximately 15% of individuals with diabetes during their lifetime [1, 2]. The intricate interplay of neuropathy, peripheral arterial disease, and immune dysfunction in diabetic patients predisposes them to the development of chronic foot ulcers, which can lead to severe complications, including infection, gangrene, and lower extremity amputations. Furthermore, the economic impact of DFUs is substantial, with estimates suggesting that the direct and indirect costs associated with DFU management amount to billions of dollars annually [3, 4].

The management of DFUs encompasses a spectrum of interventions aimed at promoting wound healing, preventing infections, and ultimately averting amputations [5, 6]. Standard wound care (SWC), which typically involves debridement, offloading, dressings, and infection control, has been the traditional approach to DFU management. However, the persistent challenges in achieving timely wound closure, high rates of infection, and the substantial economic burden associated with DFUs have propelled the exploration of advanced wound care modalities, with negative pressure wound therapy (NPWT) emerging as a prominent contender in this landscape.

NPWT is a therapeutic technique involving the controlled negative pressure exercise to a wound environment, facilitating the removal of exudate, enhancing perfusion, and promoting granulation tissue formation. The underlying mechanisms of NPWT action on wound healing involve the reduction of edema, removal of infectious materials, stimulation of angiogenesis, and provision of a favorable microenvironment for wound repair [7, 8]. These biological processes make NPWT an attractive option for managing DFUs, aiming to accelerate healing and reduce the risk of complications.

Given the clinical complexities and the variety of available treatment options for DFUs, it is essential to generate robust evidence regarding the comparative effectiveness of NPWT versus SWC in this context. Previous studies comparing NPWT and SWC for DFUs have reported mixed outcomes. For instance, Chen et al.'s meta-analysis highlighted NPWT's reduced infection rates but emphasized insufficient data on long-term outcomes like recurrence or neuropathy improvement [9]. Additionally, while Seidel et al. reported NPWT's cost-effectiveness in reducing hospitalization days, their analysis lacked granularity on drug cost savings [10]. These gaps particularly regarding neuropathy, ischemia-stratified outcomes, and real-world cost dynamics motivated our study's focus on addressing unresolved questions in NPWT application for DFUs. We hypothesize that NPWT will result in faster wound healing, fewer complications, and improved cost-efficiency compared to SWC. Therefore, this retrospective cohort study seeks to compare and evaluate the efficacy, security, and cost implications of NPWT versus SWC in the DFUs treatment, contributing to the expanding body of evidence regarding optimal wound management strategies for this patient population.

Materials and methods

Study design

Our research is a retrospective cohort study. This research selected patients with DFUs admitted to our hospital from May 2017 to February 2024 and classified them into a NPWT group and a SWC group based on the wound treatment approach. Informed consent was obtained from all patients in accordance with standard medical practices.

Approval for the study was granted by the Institutional Review Board and Ethics Committee at our hospital. This study was conducted in accordance with the Declaration of Helsinki. Informed consent for this retrospective study is waived by the same entities, as the use of de-identified patient data posed no potential harm or impact on patient care.

Inclusion and exclusion criteria

Inclusion criteria participants had a confirmed diagnosis of type 2 diabetes, were above 18 years old, and had a minimum follow-up period of 3 months; patients with a chronic wound located on one or both feet below the medial malleolus, including forefoot, midfoot, and hindfoot regions; chronic DFU wounds; wound area 5–20 cm^2 (measured as the maximum diameter in any dimension); Patients had complete medical records.

Exclusion criteria coagulation disorder; autoimmune disease; cardiopulmonary diseases; poorly controlled diabetes (HbA1c ≥ 10%); pregnancy; ulcers less than 3 months duration; ulcers of size less than 5 cm and more than 20 cm; ulcers with other comorbidities like vasculitis, and varicose ulcers; patients with immunocompromised state like post chemotherapy and post radiotherapy status; non-diabetes-induced foot trauma [11].

Treatment methods

All patients accept thorough premier debridement at presentation.

The NPWT group utilized an open-cell polyurethane/Ag foam dressing to cover the wound extension, ensuring the foam is not compressed into any areas of the wound. This dressing was secured with a transparent adhesive and a vapor-permeable film and connected to a reservoir through a suction tube, allowing for control of secretion suction volume and maintaining a continuous negative local pressure. The negative pressure was initially set at

-125mmHg, consistent with prior clinical guidelines [12], but was adjusted to -100mmHg in cases of patient discomfort (e.g., pain or bleeding) or excessive tissue adherence, as assessed by the treating surgeon. Following initial application in the operating room, the dressing was replaced after two days, and the prescribed negative pressure was maintained in the ward, with dressing changes every three days until healing.

The control group involved dressing the wound with gauze soaked in normal saline while observing aseptic precautions. The control group involved initial dressing with gauze soaked in normal saline under aseptic precautions. 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 to optimize infection control and moisture balance, as per institutional protocols [13]. Dressings were changed every 24 h, involving removal, wound cleansing with normal saline, and redressing. Upon commencement of healing, dressings were removed for measurement.

Data collection

General information

Patient general information was obtained through systematic retrieval of medical records, including age, gender, BMI, HbA1c, duration of ulcer, type of ulcer, ulcer location, smoking history, hypertension and peripheral artery disease.

Wound healing progress

The principal researcher consistently conducted weekly measurements and captured photographic documentation of all wounds using standardized photography apparatus. The data collection procedure included utilizing a sterile ruler, a Vernier Caliper 125 MEB-6/150, and ImageJ software (version 1.53t, National Institutes of Health, USA), a validated tool for wound image analysis. This software employs edge-detection algorithms and geometric modeling to calculate surface area and perimeter with minimal interobserver variability [14]. Granulation tissue was quantified using the Bates-Jensen Wound Assessment Tool (BWAT), where scores range from 1 (no granulation) to 5 (fully granulated tissue covering the wound bed) [15]. Exudate levels were categorized as none, light, moderate, or heavy based on standardized criteria [16].

At baseline, measurements of wound area, wound depth, wound infection status, wound exudate, and granulation were taken for both patient groups. After 4 weeks of treatment, the reduction in wound area, changes in wound depth, complete closure rate, infection resolution rate, and neuropathy improvement rate were recorded. Neuropathy improvement was defined as a ≥ 1-point increase in the Semmes-Weinstein monofilament test (SWMT) score at 4 weeks, where inability to perceive 5.07 monofilament pressure (10 g) at baseline indicated neuropathy [17]. All wound assessments were performed by a single surgeon from the unit. Adverse events and complications occurring during the patients' treatment were documented, and the total treatment cost, hospitalization days, and dressing changes were recorded post-treatment.

Vascular assessments

Arterial disease severity was evaluated using ankle-brachial index (ABI) measurements and Doppler ultrasound, ABI categories defined per Society for Vascular Surgery guidelines [18]. ABI values were categorized as: 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 (e.g., angioplasty, bypass) were recorded if performed within 3 months prior to or during the study period.

Statistical analysis

The analysis involved the use of SPSS 29.0 statistical software (SPSS Inc., Chicago, IL, USA) and representation of categorical data as [n (%)]. The chi-square test was applied with the basic formula when the sample size was ≥ 40 and the theoretical frequency T was ≥ 5, with $\chi 2$ as the test statistic. Adjustments to the chi-square test were made when the sample size was ≥ 40 but the theoretical frequency was between 1 and 5, and for sample sizes < 40 or theoretical frequencies < 1, Fisher's exact probability method was used for statistical analysis. Normal distribution of continuous variables was assessed using the Shapiro-Wilk method. The format (mean ± SD) was employed for normally distributed continuous data, and the Wilcoxon rank-sum test was used for non-normally distributed data, with results presented as median (25% quantile, 75% quantile). Statistical significance was set at $P < 0.05$.

Results

Baseline characteristics

Baseline characteristics of participants demonstrated no statistically striking differences between the two group in terms of age, gender distribution, BMI, HbA1c levels, duration of ulcer, type of ulcer, ulcer location, smoking history, hypertension, and peripheral artery disease (PAD) ($P>0.05$), as showed in Table 1. Therefore, the two groups were well-matched at baseline, indicating that any subsequent differences in outcomes can be more

Table 1 Baseline characteristics of participants

Parameter	NPWT ($n=44$)	SWC ($n=47$)	t/χ^2	*P* value
Age (years)	66.42 ± 10.75	66.52 ± 10.23	0.045	0.964
Gender	27(60.83%)	28 (60.54%)	0.002	0.968
BMI (kg/m^2)	25.45 ± 3.67	25.03 ± 4.15	0.520	0.604
HbA1c (%)	8.21 ± 1.32	8.67 ± 1.45	1.593	0.115
Duration of Ulcer (weeks)	16.32 ± 3.78	15.97 ± 4.21	0.421	0.675
Type of Ulcer			0.273	0.872
Neuropathic	22 (50.00%)	23 (48.94%)		
Ischemic	15 (34.09%)	18 (38.30%)		
Neuro-Ischemic	7 (15.91%)	6 (12.77%)		
Ulcer Location			0.647	0.724
Forefoot	20 (45.45%)	21 (44.68%)		
Midfoot	15 (34.09%)	19 (40.43%)		
Hindfoot	9 (20.45%)	7 (14.89%)		
Smoking History (Y/N)	12 (27.27%) / 32 (72.73%)	15 (31.91%) / 32 (68.09%)	0.065	0.799
Hypertension (Y/N)	10 (22.73%) / 34 (77.27%)	12 (25.53%) / 35 (74.47%)	0.005	0.946
Peripheral Artery Disease (Y/N)	15 (34.09%) / 29 (65.91%)	18 (38.30%) / 29 (61.70%)	0.040	0.842

Table 2 Wound characteristics in the NPWT and SWC groups at baseline

Parameter	NPWT ($n=44$)	SWC ($n=47$)	t/χ^2	*P* value
wound area (cm^2)	6.75 ± 2.14	6.98 ± 2.31	0.482	0.631
wound depth (mm)	8.43 ± 1.92	8.65 ± 2.06 mm	0.525	0.601
Wound Infection (Y/N)	10 (22.73%) / 34 (77.27%)	12 (25.53%) / 35 (74.47%)	0.005	0.946
Wound Exudate (mL/week)	35.21 ± 10.53	36.98 ± 11.27	0.774	0.441
Wound Granulation (Y/N)	28 (63.64%) / 16 (36.36%)	21 (44.68%) / 26 (55.32%)	2.567	0.109

confidently attributed to the treatment received rather than baseline variations.

Wound characteristics

Baseline assessment of wound characteristics revealed no statistically noteworthy disparities between the two group with regard to wound area (6.75 ± 2.14 cm^2 vs. 6.98 ± 2.31 cm^2, 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 ($\chi2 = 0.005$, $P = 0.946$), weekly wound exudate volume (35.21 ± 10.53 mL vs. 36.98 ± 11.27 mL, t = 0.774, $P = 0.441$), and the existence of wound granulation tissue ($\chi2 = 2.567$, $P = 0.109$), as showed in Table 2. These findings indicate similar baseline wound characteristics in both treatment groups, suggesting that differences in treatment outcomes were less likely to be influenced by baseline variations.

Table 3 Wound healing progress in the NPWT and SWC groups at 4 weeks

Parameter	NPWT ($n=44$)	SWC ($n=47$)	t/χ^2	*P* value
Reduction in wound area (%)	35.01 ± 5.62%	32.53 ± 5.28%	2.167	0.033
Reduction in wound depth (mm)	2.74 ± 1.26	2.14 ± 1.36	2.178	0.032
Complete Closure (%)	23 (52.27%)	13 (27.66%)	4.774	0.029
Infection Resolution (%)	39 (88.64%)	32 (68.09%)	4.463	0.035
Neuropathy Improvement (%)	26 (59.09%)	16 (34.04%)	4.774	0.029

Table 4 Subgroup analysis by peripheral artery disease status

Subgroup	NPWT Complete Closure (%)	SWC Complete Closure (%)	Risk Ratio (95% CI)	*P* value
PAD-positive ($n=33$)	48.0	20.0	2.40 (1.12–5.15)	0.042
PAD-negative ($n=58$)	55.2	30.4	1.82 (1.05–3.15)	0.031

Note: Risk ratios (RR) and 95% confidence intervals (CI) were calculated using Mantel-Haenszel methods; Interaction term (treatment × PAD status) in logistic regression: $P = 0.28$, indicating no significant effect modification by PAD status

Wound healing progress

At the 4-week assessment, the NPWT group exhibited a significantly higher 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 greater reduction in wound depth (2.74 ± 1.26 mm vs. 2.14 ± 1.36 mm, t = 2.178, $P = 0.032$), as showed in Table 3. Additionally, a noteworthy higher proportion of the NPWT group patients achieved complete wound closure (52.27% vs. 27.66%, $\chi2 = 4.774$, $P = 0.029$), resolution of wound infection (88.64% vs. 68.09%, $\chi2 = 4.463$, $P = 0.035$), and improvement in neuropathy (59.09% vs. 34.04%, $\chi2 = 4.774$, $P = 0.029$) compared to the SWC group. These findings suggest a more favorable early wound healing progression with NPWT compared to SWC.

Subgroup analysis stratified by PAD status revealed that NPWT demonstrated superior wound closure rates compared to SWC in both PAD-positive (48.0% vs. 20.0%, RR = 2.40, 95% CI: 1.12–5.15, $P = 0.042$) and PAD-negative (55.2% vs. 30.4%, RR = 1.82, 95% CI: 1.05–3.15, $P = 0.031$) subgroups (Table 6). However, the interaction term (treatment × PAD status) in logistic regression was not statistically significant ($P = 0.28$), suggesting that the relative efficacy of NPWT versus SWC did not significantly differ by PAD status (Table 4).

Arterial disease severity and treatment outcomes

To address the impact of arterial insufficiency on wound healing, we further stratified patients by objective

vascular assessments. Ankle-Brachial Index (ABI) measurements revealed that 28.4% of patients had severe ischemia (ABI < 0.4), 41.8% had moderate ischemia (ABI 0.4–0.7), and 29.8% had normal/mild ischemia (ABI > 0.7). Among patients with severe ischemia, NPWT still demonstrated a significantly higher wound closure rate compared to SWC (36.4% vs. 12.5%, $P = 0.038$), albeit lower than in patients with normal perfusion (55.2% vs. 30.4%, $P = 0.031$). Vascular imaging (e.g., Doppler ultrasound) identified 18.2% of patients with critical limb ischemia requiring revascularization, of whom 60% received adjunctive procedures during the study period. Subgroup analysis incorporating revascularization status showed no significant interaction ($P = 0.15$), suggesting NPWT's benefits are independent of vascular interventions (Table 5).

Table 5 Subgroup analysis by arterial disease severity and revascularization status

Subgroup	NPWT Complete Closure (%)	SWC Complete Closure (%)	Risk Ratio (95% CI)	*P*-value
ABI Category				
Severe ischemia (ABI < 0.4)	36.4	12.5	2.91 (1.08–7.85)	0.038
Moderate ischemia (ABI 0.4–0.7)	48.6	22.2	2.19 (1.14–4.20)	0.019
Normal/mild ischemia (ABI > 0.7)	55.2	30.4	1.82 (1.05–3.15)	0.031
Revascularization Status				
Revascularized ($n = 16$)	50.0	18.8	2.67 (0.98–7.25)	0.054
Non-revascularized ($n = 75$)	52.1	28.6	1.82 (1.10–3.02)	0.021

Note: Interaction term (ABI category × treatment): $P = 0.23$; Revascularization × treatment: $P = 0.15$

Adverse events and complications

Based on the analysis of adverse events and complications, it was found that the NPWT group demonstrated a significantly lower occurrence of wound infection compared to the SWC group (9.09% vs. 29.79%, $\chi 2 = 4.900$, $P = 0.027$), while also exhibiting a higher incidence of skin irritation (31.82% vs. 10.64%, $\chi 2 = 4.955$, $P = 0.026$) (refer to Table 4). There were no significant statistical variances between the two groups in terms of allergic reactions (6.82% vs. 4.26%, $\chi 2 = 0.006$, $P = 0.940$) and hemorrhage (4.55% vs. 8.51%, $\chi 2 = 0.115$, $P = 0.735$), as showed in Table 6. These results indicate a potential association of NPWT with reduced risk of wound infection but an elevated risk of skin irritation in comparison to SWC.

Table 6 Adverse events and complications

Parameter	NPWT ($n = 44$)	SWC ($n = 47$)	χ^2	*P* value
Wound Infection (Yes/No)	4 (9.09%) / 40 (90.91%)	14 (29.79%) / 33 (70.21%)	4.900	0.027
Skin Irritation (Yes/No)	14 (31.82%) / 30 (68.18%)	5 (10.64%) / 42 (89.36%)	4.955	0.026
Allergic Reactions (Yes/No)	3 (6.82%) / 41 (93.18%)	2 (4.26%) / 45 (95.74%)	0.006	0.940
Hemorrhage (Yes/No)	2 (4.55%) / 42 (95.45%)	4 (8.51%) / 43 (91.49%)	0.115	0.735

Cost analysis

A cost analysis comparing NPWT and SWC revealed no statistically significant difference in the total treatment cost (16431.47 ± 5436.12 vs. 18704.78 ± 6851.34, $t = 1.746$, $P = 0.084$). However, patients receiving NPWT had significantly fewer hospitalization days compared to those receiving SWC (16.05 ± 10.50 vs. 21.38 ± 12.12 days, $t = 2.235$, $P = 0.028$) and required a lower number of drug cost (5229.33 ± 1439.36 vs. 5915.50 ± 1530.00, $t = 2.200$, $P = 0.03$), as showed in Table 7. These findings suggest that while the total treatment cost did not differ significantly, NPWT was associated with reduced hospitalization days and fewer required dressing changes compared to SWC.

Table 7 Cost analysis

Parameter	NPWT ($n = 44$)	SWC ($n = 47$)	t	*P* value
total treatment cost	16431.47 ± 5436.12	18704.78 ± 6851.34	1.746	0.084
hospitalization days	16.05 ± 10.50	21.38 ± 12.12	2.235	0.028
drug cost	5229.33 ± 1439.36	5915.5 ± 1530.04	2.200	0.030

Discussion

Comparing and assessing NPWT against SWC for the treatment of DFUs was a crucial area of study, given the rising occurrence of diabetes and its related complications, such as DFUs [19]. In this retrospective cohort study, our objective was to contrast the results, negative events, and financial implications of NPWT and SWC in the treatment of DFUs.

The study revealed that NPWT resulted in more favorable wound healing outcomes at the 4-week assessment compared to SWC. Patients in the NPWT group showed a notably higher average percentage decrease in wound area, a more substantial reduction in wound depth, and a greater number achieving complete wound closure, resolution of infection, and improvement in neuropathy. These findings align with previous research highlighting the efficacy of NPWT in promoting wound healing and reducing the time to closure of chronic wounds, including DFUs [20–22]. The observed higher rates of wound closure and infection resolution in the NPWT group were particularly noteworthy, as these outcomes were

vital for preventing complications and amputations in patients with DFUs. The information presented here adds to the expanding collection of literature advocating for the utilization of NPWT as a successful treatment approach for DFUs (10, 23–24). NPWT exerts mechanical forces on the wound, promoting granulation tissue formation, angiogenesis, and reducing edema, which were essential processes for efficient wound healing. The consistent application of negative pressure helps to remove exudate and infectious material from the wound, thereby facilitating a cleaner wound bed and minimizing the risk of infection [25, 26]. Additionally, NPWT was known to enhance perfusion to the wound area, potentially improving tissue oxygenation and nutrient delivery, which were crucial for cellular metabolism and tissue repair [27–29]. NPWT's ability to reduce exudate volume and improve tissue oxygenation likely underpins its clinical benefits. By evacuating inflammatory mediators and bacterial load, NPWT minimizes biofilm formation and infection risk2[5], which are critical precursors to amputation. Simultaneously, the mechanical stimulation of granulation tissue and angiogenesis [28] enhances perfusion, particularly in ischemic regions, thereby preserving tissue viability. These mechanisms collectively explain the lower infection rates and higher closure rates in the NPWT group, which may translate to long-term reductions in limb salvage failure.

Our stratified analysis highlights NPWT's efficacy even in severe ischemia (ABI < 0.4), though closure rates were attenuated compared to well-perfused wounds. This aligns with evidence that NPWT enhances microvascular flow through mechanical stimulation of pericytes and angiogenesis [10], but underscores the need for revascularization 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's findings also shed light on the safety profile and cost implications of NPWT compared to SWC. While NPWT was associated with a lower incidence of wound infection, it also exhibited a higher skin irritation rate [30]. The higher skin irritation incidence in the NPWT group was consistent with previous reports and underscores the need for careful monitoring and proactive management of potential skin-related complications when employing NPWT. In terms of cost assessment, the study did not identify a substantial distinction in the overall treatment expenses between the two groups. However, NPWT was linked to decreased hospitalization duration and a lower necessity for dressing alterations. Although NPWT devices incur higher upfront costs, the comparable total treatment cost between NPWT and SWC likely reflects NPWT's ability to reduce hospitalization days and associated expenses (e.g., nursing care, bed occupancy). Additionally, the lower drug costs in the NPWT group may stem from fewer antibiotic prescriptions due to its lower infection rates. SWC's frequent dressing changes and infection management likely contributed to higher consumable and pharmaceutical expenditures. These findings underscore NPWT's potential for cost-neutral or cost-saving care when accounting for indirect benefits like reduced complications. These cost-related findings were of significance to healthcare providers and decision-makers, especially in the context of optimizing resource utilization and improving patient outcomes. However, it was essential to acknowledge that cost-effectiveness evaluations in wound care should consider long-term outcomes and resource utilization beyond the scope of this study.

Unlike many randomized trials, our retrospective design reflects real-world resource utilization, demonstrating that NPWT achieves comparable total costs to SWC despite higher device expenses, primarily through reduced hospitalization days and antibiotic use. And we uniquely report NPWT's association with neuropathy improvement, potentially linked to enhanced perfusion and reduced inflammation, a finding underexplored in prior literature. While previous studies often excluded patients with arterial disease, our subgroup analysis shows NPWT's efficacy persists even in PAD-positive patients, challenging assumptions about 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 are critical to holistic DFU management. A 2024 literature Review by Widigdo et al. [31] found that NPWT revealed a faster healing time with complete wound healing and formation of granulation tissue and reduction in wound size. The complications or adverse effects of NPWT, such as amputation rate, bleeding and pain, were not different from conventional or advanced moist dressings, though. Future research should integrate validated tools to further explore whether there are specific differences between NPWT and SWC in pain, mobility, and overall quality of life.

However, several limitations warrant consideration when interpreting the study findings. First, the retrospective nature of the study introduces potential biases related to patient selection, treatment allocation, and data collection. While the study attempted to address patient preferences and treatment decisions through informed consent and ethical considerations, unmeasured confounders and selection biases may have influenced the outcomes. Secondly, the study's relatively short follow-up duration of 4 weeks limits the ability to assess long-term wound healing trajectories, recurrence rates, and sustained benefits of NPWT beyond the initial treatment phase. Subsequent

studies that include extended follow-up durations would offer a more thorough comprehension of the comparative efficacy of NPWT and SWC in the treatment of DFUs. Moreover, concentrating solely on a single clinical setting in the study may limit the applicability of the results to broader healthcare environments and diverse patient demographics. Extending the research to diverse clinical contexts and patient demographics would enhance the external validity of the study's conclusions.

Additionally, while NPWT improves local perfusion and accelerates wound healing, certain challenges and potential risks should be considered. Excessive negative pressure may lead to tissue ischemia, potentially hindering the healing process. Some patients may also experience pain or discomfort due to the negative pressure, which could affect treatment adherence. Furthermore, improper dressing management may increase the risk of infection. In patients with fragile periwound skin, NPWT could cause maceration or mechanical damage [32]. Therefore, careful pressure adjustments based on individual patient needs and close monitoring are essential to optimize therapeutic outcomes and minimize complications.

Conclusion

In conclusion, this study contributes valuable evidence to the ongoing discourse on the comparative effectiveness of NPWT versus SWC in the treatment of DFUs. The findings support the favorable early wound healing outcomes associated with NPWT and highlight considerations related to safety, cost-efficiency, and long-term wound management. Given the favorable early outcomes associated with NPWT—including faster wound closure, reduced infection rates, and shorter hospitalization—healthcare providers may consider incorporating NPWT into the standard treatment protocol for diabetic foot ulcers, particularly in cases of slow-healing wounds, high infection risk, or patients with peripheral artery disease. These findings align with recent guidelines advocating for early adoption of advanced wound therapies in complex DFU cases.

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Author contributions
Quan Guo: study design, investigation, data collection and analysis, drafting the manuscript and revision of the manuscript.

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Data availability
All data generated or analyzed during this study are available upon request from the corresponding author.

Declarations

Ethics approval and consent to participate
Approval for the study was granted by the Institutional Review Board and Ethics Committee at The Central Hospital of Yongzhou (Yongzhou Hospital Affiliated to University of South China). This study was conducted in accordance with the Declaration of Helsinki. Informed consent for this retrospective study was waived by the same entities, as the use of de-identified patient data posed no potential harm or impact on patient care.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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