Accelerating Healing: The Impact of Negative Pressure Wound Therapy on Diabetic Foot Ulcers

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ABSTRACT

Diabetic foot ulcers, a prevalent global health issue, often necessitate hospitalization due to prolonged healing times and complications. This study aimed to compare the efficacy of Negative Pressure Wound Therapy (NPWT) with Standard Moist Wound Therapy (SMWT) in treating diabetic foot ulcers. Conducted over two years at the Regional Institute of Medical Sciences, Imphal, the study enrolled 40 patients with chronic diabetic foot ulcers. The NPWT group, receiving continuous sub-atmospheric pressure via a vacuum pump, demonstrated superior outcomes compared to the SMWT group. Specifically, the NPWT group achieved 97.25% granulation tissue formation within three weeks, compared to 83% in the SMWT group, and had a significantly reduced hospital stay duration (mean 12.6 days vs. 38.3 days). Additionally, NPWT led to better glycaemic control and improved renal function. These results suggest that NPWT enhances wound healing, reduces hospital stay, and is a cost-effective alternative to traditional wound management. The study supports the use of NPWT as a recommended treatment for diabetic foot ulcers in hospital settings.

Keywords: Chronic Limb Ulcer, Diabetics, Extricare 2400, Glycaemic Control, Granulation Tissue, Negative Pressure Wound Therapy, Vacuum-assisted Closure.

INTRODUCTION

Diabetic foot ulcers, a global health issue, represent the most prevalent cause of hospitalization among diabetic patients [1]. According to reports, diabetic patients require an additional 1.99 weeks for healing compared to non-diabetic patients. In cases of chronic limb ulcers, the epithelium covering the affected area, such as the skin or mucous membrane, undergoes breakdown[2]. Chronic limb ulcers are defined as defects in the skin on the lower limb persisting for more than six weeks and showing no tendency to heal after three or more months [3]. Ulcers that do not heal remain critical and are often the reason for surgical admissions.

Ulcers that do not heal remain critical and are often the reason for surgical admissions. In most cases, diabetes is the main culprit of non-healing wounds [4,3]. Consequently, the intervention of diabetic foot ulcers requires a longer hospital stay [5]. Skin ulcers can result in complete loss of the epidermis, often portions of the dermis, and even subcutaneous fat, thereby triggering social distress and high expenses for the individual and the healthcare system[5,6]. The treatment of lower limb ulcers is complex; even when properly managed, the wounds may not heal as expected, and when they do heal, the closure is often temporary and difficult to maintain [7]. In recent years, improvements in diabetic therapy and the reinforcement of guidelines have reduced the amputation rate. The fundamentals of caring for lower limb ulcers include off-loading, frequent debridement, and moist wound healing [8]. Many new advanced topical dressings, such as polyurethane foams, capillary dressings, vacuum-assisted closure, alginates, cellular composites, non-adherent dressings, and film dressings, are emerging as means to improve wound care [9]. Such dressings are designed to modulate levels of biological molecules, such as growth factors, that may promote wound healing [10-13]. The Vacuum-assisted closure (VAC) is a new therapeutic method in managing acute and chronic wounds. Vacuum-assisted closure (VAC), also known as Negative Pressure Wound Therapy (NPWT), is a new therapeutic method in managing acute and chronic wounds. The VAC applies continuous pressure below normal to the surface of wounds to improve healing. Despite the increasing introduction of innovative applications in treating wounds, such as various dressings, local growth factors, hyperbaric oxygen, and local and systemic antiseptic agents, the treatment of serious wounds remains a clinical enigma[14].

To date, very limited data is available on the use of negative pressure dressing in healing diabetic foot ulcers. Therefore, we endeavour to conduct a study to evaluate the role of

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negative pressure dressing in healing diabetic foot ulcers using a VAC device.

METHODS

Principle of the Negative pressure wound therapy.

Negative Pressure Wound Therapy (NPWT) is a non-invasive system that operates by applying localized sub-atmospheric pressure. This therapy involves the delivery of continuous negative pressure through a specialized pump connected to a foam-surfaced dressing, which is covered with a transparent polyurethane sheet to collect wound exudates. The application of negative pressure effectively removes fluid, reduces edema, and enhances blood flow, thereby decreasing the risk of bacterial infections. Additionally, NPWT is a cost-effective alternative to the conventional management of complex wounds [15]. The technique of Negative Pressure Wound Therapy (NPWT) is relatively straightforward. A sterile absorbent foam dressing is placed directly on the wound and sealed with a sterile adhesive sheet to create a closed environment. A tube is then connected to a vacuum pump, which draws fluid through the foam into a disposable canister [16,17]Click or tap here to enter text.. The application of negative pressure, typically between 50-125 mm/Hg, reduces interstitial pressure and removes fluid and debris from the wound into the collection chamber. Initially, the vacuum is applied continuously, but as drainage decreases, it is applied intermittently. The vacuum dressing is usually changed approximately every two days [16,17]. The mechanism of action involves drawing the wound edges together and stabilizing the wound environment, thereby accelerating wound healing by promoting the formation of granulation tissue, which can either completely close the wound or improve its condition in preparation for a skin graft [18,19]. The reduction in wound edema exudates and micro-deformations of the wound surface leads to secondary effects, including increased angiogenesis, granulation tissue formation, and, in some cases, a decrease in bacterial bioburden. After three to four days of therapy, bacterial counts in the wound are significantly reduced.

Aims of the study

This non-randomized control trial was conducted over two years at the Regional Institute of Medical Sciences, Imphal, to compare the therapeutic efficacy of Negative Pressure Wound Therapy (NPWT) and Standard Moist Wound Therapy (SMWT) in the treatment of diabetic foot ulcers. The primary objective was to evaluate the effectiveness and speed of healing between the two methods. The study involved 40 candidates with lower limb ulcers, aged between 18 and 85 years

Study population

A total of 40 patients admitted to the Surgical Department from January 2021 to October 2022 with chronic diabetic foot ulcers of at least four weeks' duration were enrolled in this study, which spanned 22 months.

Inclusion criteria

1. Patients with lower limb ulcers aged between 18 and 85 years.
2. Target ulcers with an area between 2 cm^2 25 cm^2.

Exclusion criteria

1. Patients with more than Grade III Wagner classification diabetic foot ulcers.
2. Patients on anticoagulant therapy.
3. Patients with ulcers due to venous disease.
4. Patients with osteomyelitis in diabetic foot ulcers.

Study protocol

The study protocol included comprehensive documentation of the patients' profiles, diabetic history, Wagner grading, healing time, percentage of granulation tissue, and complications. Additionally, detailed descriptions of the ulcers, including their location and measurements, were recorded. The study participants were divided into two groups: the Intervention group (NPWT) and the Control group (SMWT), each comprising 20 patients.

Procedure

1. Informed and written consent was obtained from all patients.
2. A pre-designed proforma was used for data collection.
3. Diagnosis was based on a detailed patient history, physical examination, routine laboratory tests, and radiological investigations.
4. Pre-procedural biochemical and haematological investigations were conducted as needed. Data on age at diagnosis, gender, clinical presentation, predisposing factors, and management follow-up were collected.

Initial treatment included wound debridement and administration of antibiotics (oral/IV), with strict glycaemic control. Once the diabetic foot ulcer was clean, the principal investigator assessed the wound's readiness for NPWT. Suitable patients received either NPWT or SMWT based on their preference. For NPWT, the wound bed was filled with gel foam after thorough cleaning, and NPWT was applied by creating a small circular hole in the transparent sheet, covered with another transparent adhesive, and connected to the NPWT pump. The dressing was changed every four to five days. The NPWT system was programmed to deliver -125 mmHg, the optimal pressure for better healing. Patients were monitored for bleeding and sepsis throughout the treatment. Treatment continued until complete wound healing, defined as >95% granulation tissue formation ready for split-thickness graft, within a maximum of six weeks. If patients developed sepsis due to uncontrolled ulcer infection involving bone necrosis, they were offered amputation after obtaining consent.

Application of NPWT device

The application of the NPWT device (Extricare 2400 Negative Pressure Wound Therapy Pump) is depicted in Figure 1. The NPWT device comprises the following components:

1. Extricare 2400 - NPWT Pump
2. Disposable canister
3. Pad with an evacuation tube
4. Reticulated open-cell steel polyurethane or dense open pore polyvinyl alcohol foam dressing unit, customized

to fit the wound. The system was programmed to maintain a negative pressure of -125 mmHg.

Wound measurement

Wounds were photographed with a ruler placed beside them. A double layer of polyurethane sheets was applied over the wound, and the outline of the wound was traced using a permanent marker. The tracing was transferred to a graphic grid (2 x 2 mm) for area quantification to the nearest 4 mm^2.

Statistical analysis

Statistical analyses were performed using SPSS Statistics version 22.0. Variables are reported as mean ± standard deviation (SD). Group comparisons were conducted using paired t-tests and chi-square tests where appropriate. P values < 0.05 were considered statistically significant.

Ethics

The procedures followed were in accordance with the ethical standards of the Research Ethics Board of the Regional Institute of Medical Sciences, Imphal

RESULTS

The study results demonstrated that the 20 candidates in the Intervention group (NPWT) exhibited quicker healing and superior granulation tissue formation compared to the Control group (SMWT). The mean granulation tissue formation was 97.25% in the NPWT group and 83% in the SMWT group (Table 3). Additionally, the Intervention group had a significantly reduced duration of hospital stay, with a mean of 12.6 days compared to 38.3 days in the Control group. In the Intervention group, 15 candidates were discharged within two weeks, and 5 candidates were discharged within a month without complications. Conversely, in the Control

Figure-1: Application of NPWT device (Extricare 2400 Negative Pressure Wound Therapy Pump). The pressure was set at -125mmhg.

SL No.	Characteristics	Intervention (NPWT) Mean ± SD	Controls (SMWT) Mean±SD
1.	Serum creatinine	1.12±0.39	1.08±0.43
2.	HbA1C	8.76±1.35	8.52±2.20
3.	Blood Sugar (before therapy)	270.35±79.99	274.50±93.09
4.	Blood Sugar (after therapy)	216.25±47.32	230.05±54.14

Table 1: Comparison between Intervention (NPWT) and Control (SMWT) based on Serum creatinine, HbA1C, and Blood Sugar (before and after therapy)

Characteristics	Intervention (NPWT)			Controls (SMWT)		
Sex	≤ 95% granulation tissue N (%)	>95% granulation tissue N (%)	p-value	≤ 95% granulation tissue N (%)	>95% granulation tissue N (%)	p-value
Male	6 (37.5)	10 (62.5)	> 0.005	8 (47.1)	9 (52.9)	> 0.005
Female	0 (0.0)	4 (100.0)		1 (33.3)	2 (66.7)	

Table-2: Comparison between intervention and controls based on the development of more than 95% granulation tissue within 3 weeks of fully healed ulcers (N=40)

Characteristics	Intervention (NPWT)			Controls (NPWT)		
Duration of diabetes	≤ 95% granulation tissue N (%)	>95% granulation tissue N (%)	p-value	≤ 95% granulation tissue N (%)	>95% granulation tissue N (%)	p-value
≤ 7 years	1 (10.0)	9 (90.0)	> 0.005	6 (75.0)	2 (25.0)	> 0.005
>7 years	5 (50.0)	5 (50.0)		4 (33.3)	8 (66.7)	

Table-3: Comparison between intervention and controls based on healing of the diabetic ulcer (N=40)

	Sepsis during and after therapy	Referred for STSG	Discharged for Secondary Healing	Amputation, discharged	Prematurely Discharged on request
Intervention (NPWT)	Nil	17	3	0	0
Control (SMWT)	1	11	1	4	2

Table-4: Details of intervention and controls based on infection and at the end of the therapy

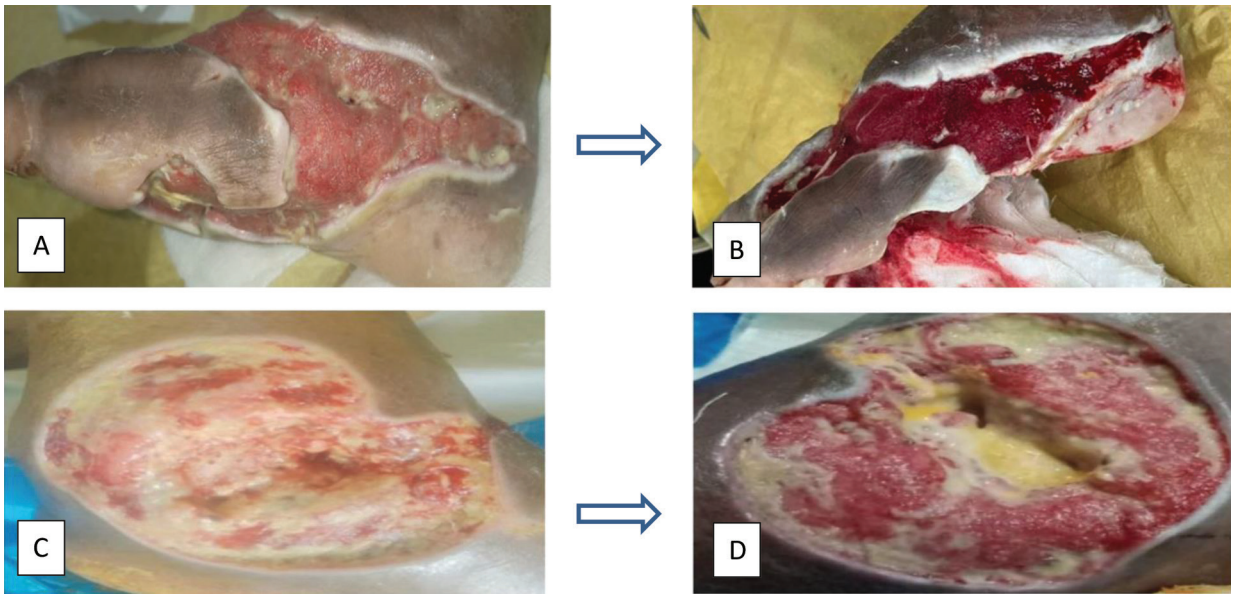

Figure-2: Chronic foot ulcer before and after application of NPWT (A) Before treatment, (B) 95% granulation tissue after single application for 5 days, (C) Before treatment, and (D) Formation of 70% granulation tissue after the treatment of single application for 5 days

group, 10 candidates were discharged within four weeks, and another 10 candidates were discharged after a month, with complications. Among the Control group, 10 candidates were completely healed, 6 were partially healed, and 3 underwent amputation, as illustrated in Figure 2. At the end of the study, the mean Wagner grading score was 2.8 in the Intervention group and 3.05 in the Control group. The Intervention group also maintained better blood sugar control, with a mean value of 216.25 ± 47.32 mg/dL, compared to 230.05 ± 54.14 mg/dL in the Control group (Table 1). Furthermore, the Intervention group exhibited good endocrine control, with an HbA1c of 8.76 ± 1.35, while the Control group's HbA1c was 8.52 ± 2.20.

DISCUSSION

It is estimated that approximately 6% of diabetic foot ulcers result in hospitalization due to infection or other ulcer-related complications. Additionally, between 14% and 24% of diabetic patients who develop a foot ulcer eventually require amputation [20]. This study confirms that foot ulcers are preventable [21]. Prolonged hospital stays not only incur significant costs but also increase the risk of acquiring healthcare-associated infections, a major global health issue [22]. To assess the efficacy of the NPWT device, an unbiased randomized sampling approach was essential. Selection criteria for diabetic candidates with foot ulcers were based on biomedical markers such as HbA1c. HbA1c levels below 5.7% are considered normal, while levels of 6.5% or higher indicate diabetes [23,240]. In this study, the HbA1c levels in the intervention and control groups were 8.76 ± 1.35 and 8.52 ± 2.20, respectively, confirming the presence of diabetes (Table 1). Additionally, selecting candidates without renal impairment was crucial, as poorly controlled diabetes mellitus often correlates with poor wound healing and an increased risk of kidney disease [25]. As a standard clinical practice, all candidates were monitored for liver and kidney function [26]. The serum creatinine levels in the intervention and control groups were 1.12 ± 0.39 and 1.08 ± 0.43, respectively (Table 1), indicating no significant renal impairment in either group. Notably, renal function improved in the intervention group following treatment. The formation of new connective tissues and microscopic blood vessels serves three primary functions: (a) providing protection against microbial invasion and additional injury, (b) facilitating wound closure by filling the wound base with new tissue and vasculature, and (c) replacing necrotic tissue until the wound is completely covered by scar tissue [27,28]. Diabetic patients are reported to have a 5.15 times higher risk of postoperative complications following a Split Thickness Skin Graft (STSG) (29). Ideally, an STSG is performed on a wound bed with predominant red granulation tissue and no visible tendon or bone [30]. Granulation tissue formation was a key treatment endpoint for both therapies in this study. Ten candidates in the intervention group achieved 95% granulation tissue formation within three weeks of treatment, with accelerated healing and no apparent risk of infection (Table 2). NPWT notably enhanced blood supply, granulation tissue formation, and bacterial clearance, effectively overcoming atherosclerosis, which is prevalent among diabetic patients [31,32]. Previous retrospective studies have similarly demonstrated that NPWT significantly improves blood supply, angiogenesis, granulation tissue formation, and bacterial clearance, and reduces infection rates at the surgical site compared to standard dressings [31-34]. The duration of diabetes diagnosis did not significantly impact ulcer healing time. Healing was more influenced by glycaemic control, ulcer size, and ulcer duration. Patients with better glycaemic control, maintaining an HbA1c range between 7.0% and 8.0% during treatment, experienced faster ulcer healing [35]. Our study observed that NPWT effectively maintained endocrine levels and blood sugar control, with random blood sugar levels of 216.25 ± 47.32 mg/dL in the

intervention group, compared to 230.05 ± 54.14 mg/dL in the control group (Table 1). The most severe complication encountered was advanced wound infection, necessitating amputation in some cases due to compromised immunity from diabetes. Four amputations were performed during the study. At the conclusion of treatment, 17 candidates in the NPWT group and 11 in the control group were referred for STSG after achieving ideal conditions, such as 95% red granulation tissue, no systemic signs of infection, and no discernible sloughing (Table 4). Overall, the NPWT group demonstrated superior outcomes compared to the SMWT group.

CONCLUSION

As demonstrated in this study, Negative Pressure Wound Therapy (NPWT) enhances blood supply, thereby promoting granulation tissue formation and bacterial clearance, which helps in preventing infections. The findings suggest that NPWT significantly reduces the duration of hospital stays for patients with diabetic foot ulcers by accelerating the wound healing process. Based on these results, NPWT is recommended as an effective treatment modality for diabetic foot ulcers in hospital settings.

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