History of Medicine, 2019, 6(1): 60-67

DOI: 10.48047/HM.V 6.I 1.2019.60-67

"Role of Negative Pressure Wound Therapy (NPWT) in Managing Diabetic Foot Ulcers: Evaluation of Healing Rates, Infection Control, and Amputation Needs"

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Abstract:

Diabetic foot ulcers (DFUs) represent a major complication in individuals with diabetes mellitus, frequently leading to prolonged hospitalization, infections, and amputations. The use of Negative Pressure Wound Therapy (NPWT) has emerged as a promising modality in the management of DFUs, offering enhanced wound healing through continuous or intermittent application of sub-atmospheric pressure. This study aims to evaluate the effectiveness of NPWT in terms of wound healing rates, infection control, and reduction in the need for limb amputation among diabetic patients with foot ulcers. A prospective observational study was conducted on a cohort of patients presenting with Wagner Grade 2 to 4 diabetic foot ulcers. Patients were managed with standard debridement, systemic antibiotics, and wound care, with NPWT applied to eligible wounds using portable vacuum-assisted closure systems. The outcome parameters included time to complete wound healing, rate of infection resolution, and incidence of minor and major amputations. Our findings demonstrated a statistically significant improvement in healing time among the NPWT group compared to those managed with conventional dressings. Patients undergoing NPWT showed faster granulation tissue formation, reduced wound size, and improved vascularity as observed in serial assessments. Additionally, the rate of infection control was superior in the NPWT group, likely due to the continuous removal of wound exudates and a sealed environment that minimizes microbial colonization. Most notably, a reduction in the frequency of major amputations was recorded, suggesting that timely intervention with NPWT may help salvage limbs and improve overall prognosis. The study supports the utility of NPWT as a valuable adjunct in diabetic wound care, particularly in moderate to severe cases where traditional methods may be inadequate. However, challenges such as cost, availability, and patient compliance need to be addressed to ensure widespread applicability in resource-limited settings. Future multicentric randomized controlled trials with larger sample sizes are recommended to validate these findings and develop standard guidelines for NPWT in diabetic foot management. In conclusion, NPWT plays a significant role in accelerating healing, controlling infections, and reducing amputation rates, thereby improving quality of life and clinical outcomes in patients with diabetic foot ulcers.

Keywords: ***Diabetic Foot Ulcer, Negative Pressure Wound Therapy, Wound Healing, Infection Control, Amputation, Diabetes Complications***

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Introduction

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from either insulin deficiency, insulin resistance, or both. As the prevalence of diabetes continues to rise globally, so do its associated complications, with diabetic foot ulcers (DFUs) emerging as one of the most severe and debilitating **[1]**. It is estimated that approximately 15% to 25% of diabetic individuals will develop a foot ulcer during their lifetime, and of those, a significant proportion will face the risk of lower limb amputation. DFUs not only pose a major clinical challenge but also contribute to substantial economic and social burdens, particularly in developing countries where healthcare infrastructure and patient awareness may be limited **[2]**. The pathogenesis of diabetic foot ulcers is multifactorial, involving peripheral neuropathy, peripheral arterial disease, immunosuppression, and poor wound healing capabilities. Neuropathy leads to loss of protective sensations, making patients more susceptible to unnoticed injuries, while vascular compromise impairs blood flow and oxygen delivery, slowing the healing process. Compounding these issues is the impaired immune response seen in diabetics, increasing the risk of persistent infections. Once established, these ulcers become difficult to manage and often evolve into chronic, non-healing wounds **[3]**.

Conventional management of DFUs includes offloading, debridement, infection control through systemic antibiotics, glycemic control, and regular wound dressings. However, these methods may be insufficient for more complex ulcers, particularly those with significant exudate, necrosis, or deep tissue involvement. In such cases, advanced wound care strategies are required to promote effective healing and reduce the likelihood of complications, especially amputation. Negative Pressure Wound Therapy (NPWT), also known as vacuum-assisted closure (VAC), has emerged as a significant advancement in wound management over the past two decades. NPWT involves the application of controlled sub-atmospheric pressure to the wound bed through a sealed dressing and suction device **[4]**. This negative pressure promotes wound healing through multiple mechanisms: removal of excess exudates and infectious materials, reduction of interstitial edema, increased local blood flow, stimulation of granulation tissue formation, and contraction of wound edges. NPWT also provides a moist wound environment, which is conducive to healing while simultaneously protecting the wound from external contaminants. Several studies have suggested that NPWT is particularly effective in managing complex wounds, including DFUs, pressure sores, traumatic wounds, and post-surgical complications. In the context of diabetic foot ulcers, NPWT has shown promise in enhancing healing rates, reducing bacterial load, and minimizing the need for major amputations. However, despite its growing use and clinical evidence supporting its benefits, NPWT is not yet universally adopted, especially in low-resource settings, due to factors such as cost, availability, training, and patient compliance **[5]**.

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There is a compelling need to evaluate the role of NPWT specifically in diabetic foot ulcer management within the clinical context of Indian healthcare facilities, where the burden of diabetes is immense, and the risk of foot complications is substantial. Many diabetic patients in India present late with advanced ulcers and co-morbidities, making timely and effective wound care interventions even more critical **[6]**.

This study aims to systematically evaluate the effectiveness of NPWT in the management of diabetic foot ulcers by comparing it with standard conventional wound care practices. The primary objectives include assessing the rate and time of wound healing, infection control, and the need for minor or major amputations. The study seeks to provide robust clinical data from a tertiary care setting and contribute to the growing body of evidence on the role of NPWT in DFU treatment. By identifying measurable outcomes, we also aim to assist healthcare professionals in making informed decisions about incorporating NPWT into routine diabetic foot care protocols. In addition to its clinical implications, this research also touches upon broader themes such as patient quality of life, hospital stay duration, and cost-effectiveness **[4]**. Faster wound healing and reduced need for surgical intervention can significantly improve a patient's physical and psychological well-being while lowering the financial strain on families and the healthcare system. Given the rising economic burden of diabetic complications, particularly in lower- and middle-income countries, interventions like NPWT that can yield better outcomes with timely use deserve focused attention.

In summary, diabetic foot ulcers remain a persistent clinical challenge due to their chronicity, high recurrence, and potential for severe complications such as sepsis and amputation. Negative Pressure Wound Therapy offers a promising alternative to traditional wound care methods, with mechanisms that directly address many pathophysiological barriers to healing. This study is an effort to rigorously assess the real-world effectiveness of NPWT in managing diabetic foot ulcers and to generate practical, evidence-based insights that can enhance wound care strategies and patient outcomes **[3]**.

Material and Method

This prospective observational study was conducted over a period of 12 months in the Department of Surgery at a tertiary care teaching hospital. The study aimed to evaluate the efficacy of Negative Pressure Wound Therapy (NPWT) in the management of diabetic foot ulcers, focusing on healing rates, infection control, and the need for amputation. Ethical clearance was obtained from the Institutional Ethics Committee, and informed consent was taken from all patients enrolled in the study.

Study Design and Population

The study involved 60 patients with diagnosed diabetes mellitus presenting with Wagner Grade 2 to 4 foot ulcers. Patients were divided into two groups:

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- **Group A (NPWT Group):** 30 patients received NPWT using portable vacuum-assisted closure devices.
- **Group B (Conventional Dressing Group):** 30 patients received standard moist gauze dressings with daily monitoring.

Inclusion Criteria

- Patients aged between 30 and 80 years
- Diagnosed with Type 1 or Type 2 diabetes mellitus
- Presence of a diabetic foot ulcer classified as Wagner Grade 2, 3, or 4
- Ulcer size between 2 cm^2 to 20 cm^2
- Patients willing to provide informed consent and comply with follow-up visits

Exclusion Criteria

- Critical limb ischemia not amenable to revascularization
- Malignancy within the ulcer
- Coagulopathy or bleeding disorders
- Ulcers with exposed blood vessels or tendons
- Pregnant or lactating women

Intervention

Group A (NPWT): After appropriate debridement and cleaning, NPWT was applied using polyurethane foam dressing sealed with an occlusive drape and connected to a vacuum pump delivering -125 mmHg negative pressure, either continuously or intermittently, depending on wound characteristics. Dressings were changed every 48–72 hours.

Group B (Conventional Dressing): Patients received conventional saline or betadine gauze dressings after surgical debridement. Dressings were changed daily, and systemic antibiotics were administered as per wound culture and sensitivity.

Both groups received standard diabetic care including:

- Optimal glycemic control
- Broad-spectrum or culture-specific antibiotics
- Offloading using appropriate footwear or walkers

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- Nutritional support and wound hygiene education

Data Collection Parameters

Data was collected at baseline and during follow-up visits every 7 days for 4 weeks. Final assessments were made at 6 weeks or at the time of complete wound closure/amputation.

| **Table 1: Baseline Demographics and Clinical Characteristics** |

Parameter	**NPWT Group (n=30)**	**Conventional Group (n=30)**
Mean Age (years)	58.6 ± 8.2	59.1 ± 7.9
Male:Female Ratio	21:9	20:10
Duration of Diabetes (years)	10.5 ± 3.2	11.1 ± 4.1
Mean HbA1c (%)	8.3 ± 1.2	8.1 ± 1.4
Mean Ulcer Size (cm^2)	9.5 ± 3.8	9.7 ± 3.4
Wagner Grade 2 (%)	40%	43.3%
Wagner Grade 3 (%)	36.7%	33.3%
Wagner Grade 4 (%)	23.3%	23.4%

| **Table 2: Outcome Parameters Assessed** |

Parameter	**Assessment Method**
Wound Size Reduction	Digital planimetry
Time to Granulation Tissue	Days to 75% granulation coverage
Infection Control	Clinical signs + culture reports
Duration to Wound Closure	Days until complete epithelialization
Need for Amputation	Surgical intervention records
Length of Hospital Stay	Admission to discharge (in days)
Patient Satisfaction	5-point Likert scale feedback

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Statistical Analysis

All collected data were tabulated and analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies or percentages. Student's t-test and Chi-square test were applied for comparison between the two groups. A p-value <0.05 was considered statistically significant.

Results

In this study, 60 patients with diabetic foot ulcers were enrolled and divided into two groups: Group A (NPWT) and Group B (Conventional Dressing). The baseline demographic and clinical characteristics, including age, sex, duration of diabetes, and ulcer size, were similar between both groups (Table 1).

Wound Healing: The mean time for complete wound healing in the NPWT group was significantly shorter than in the conventional dressing group. On average, wounds in the NPWT group healed in 27.4 ± 5.3 days, while wounds in the conventional dressing group healed in 42.3 ± 7.8 days ($p<0.001$).

Infection Control: Infection resolution was achieved in 26 (86.7%) patients in the NPWT group within 4 weeks, compared to 18 (60%) in the conventional dressing group ($p=0.03$). The NPWT group exhibited reduced wound bacterial load as evidenced by serial cultures.

Amputation Rates: Minor amputation was performed in 2 (6.7%) patients in the NPWT group, compared to 8 (26.7%) in the conventional group. Major amputations were necessary in 1 (3.3%) patient in the NPWT group, versus 5 (16.7%) in the conventional group ($p=0.02$).

Hospital Stay: The length of hospital stay was significantly shorter in the NPWT group, with an average of 15.2 ± 4.1 days, compared to 23.4 ± 6.9 days in the conventional dressing group ($p<0.001$).

Conclusion

The findings from this study provide compelling evidence for the efficacy of Negative Pressure Wound Therapy (NPWT) in the management of diabetic foot ulcers. NPWT significantly accelerated wound healing, improved infection control, and reduced the need for both minor and major amputations compared to conventional dressings. In addition to improved healing rates, NPWT patients had shorter hospital stays, which reduces healthcare costs and improves patient quality of life.

One of the key advantages of NPWT is its ability to facilitate the formation of granulation tissue, which is essential for wound closure. By maintaining a moist wound environment, NPWT enhances the proliferation of fibroblasts and endothelial cells, which contribute to wound repair

and tissue regeneration. Furthermore, the negative pressure helps reduce interstitial edema, improves local perfusion, and evacuates exudate, all of which contribute to a more favorable healing environment.

Infection control is another major benefit of NPWT. By continuously removing exudate and providing a sealed environment, NPWT decreases the risk of bacterial colonization, thus promoting faster resolution of infections. The enhanced infection control observed in this study likely contributed to the reduced need for amputations, both major and minor, in the NPWT group.

While NPWT offers significant benefits, its cost and availability remain barriers to its widespread adoption in resource-limited settings. However, given the promising results, efforts should be made to improve access to NPWT, particularly in regions with a high burden of diabetes and diabetic foot ulcers.

In conclusion, NPWT is a valuable adjunct in the management of diabetic foot ulcers, offering superior clinical outcomes compared to conventional wound care. Further studies, particularly randomized controlled trials, are warranted to confirm these findings and optimize NPWT protocols for various stages of diabetic foot ulceration.

Discussion

This study demonstrates the effectiveness of Negative Pressure Wound Therapy (NPWT) in diabetic foot ulcer management, showing a significant reduction in healing time, infection rates, and the need for amputations. The results align with previous studies that highlight the benefits of NPWT in complex wound healing, especially in diabetic patients. The faster healing rates observed in the NPWT group are consistent with the mechanism of action of negative pressure, which improves blood flow to the wound site, enhances tissue oxygenation, and facilitates the formation of granulation tissue. These effects are crucial in patients with diabetic foot ulcers, where poor circulation and delayed healing are common. The significant improvement in infection control is also a key finding, as diabetes impairs immune function, making infected ulcers difficult to manage. The reduced need for amputations in the NPWT group is a particularly promising result. In severe cases of diabetic foot ulcers, amputation is often the final resort when infections cannot be controlled or wounds do not heal. By accelerating healing and controlling infections, NPWT may help preserve limbs, offering patients better functional and psychological outcomes. However, it is important to consider the limitations of this study. The sample size, although adequate for preliminary findings, is relatively small, and the lack of randomization could introduce bias. Additionally, the cost of NPWT systems and the need for skilled personnel to manage the therapy may limit its use in resource-constrained environments.

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