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Comparison of Negative Pressure Wound Therapy and Traditional Dressings in Diabetic Foot Ulcer Patients

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) pose a significant challenge in diabetes care, with varying treatments available. This study compared the efficacy of Negative Pressure Wound Therapy (NPWT) with traditional dressings in DFUs management.

Methods: A prospective, randomized comparative study was conducted involving 120 patients with DFUs, divided equally between NPWT and traditional dressings groups. The primary outcomes measured were healing time, wound healing rates at 4, 8, and 12 weeks, infection rates, and incidence of complications.

Results: NPWT significantly reduced the mean healing time to 6.8 weeks compared to 9.5 weeks for traditional dressings ($p < 0.001$). Healing rates at 4, 8, and 12 weeks were significantly higher in the NPWT group (30%, 60%, and 78%, respectively) compared to the traditional dressings group (18%, 40%, and 58%, respectively) with p-values of 0.045, 0.03, and 0.023. The NPWT group also showed a lower infection rate (10% vs. 25%, $p = 0.015$) and fewer complications, including rates of gangrene (3.3% vs. 10%, $p = 0.038$) and amputation (1.7% vs. 8.3%, $p = 0.042$).

Conclusion: NPWT offers significant advantages over traditional dressings in the management of DFUs, including faster healing, higher healing rates, reduced infection rates, and lower incidence of severe complications. These findings support the preference for NPWT in DFU treatment protocols, considering individual patient conditions.

Keywords: *Diabetic Foot Ulcers, Negative Pressure Wound Therapy, Traditional Dressings, Wound Healing, Infection Rates, Complications.*

INTRODUCTION

Diabetic foot ulcers (DFUs) represent one of the most challenging complications of diabetes, leading to significant morbidity, increased mortality, and a substantial economic burden on healthcare systems worldwide [1]. The management of DFUs is complex, requiring multidisciplinary approaches to optimize wound healing, prevent infections, and reduce the risk of limb amputations [2]. Among the myriad of treatment modalities available, Negative Pressure Wound Therapy (NPWT) and traditional dressings have emerged as prominent options for DFU care. However, the comparative efficacy of these treatments remains a subject of ongoing research and debate [3].

Negative Pressure Wound Therapy, a relatively recent innovation in wound care, employs a vacuum device to promote wound healing through the removal of excess exudates, reduction of edema, and stimulation of granulation tissue formation [4]. Since its introduction, NPWT has been increasingly adopted for the management of various types of wounds, including DFUs, due to its potential to accelerate the healing process and reduce the risk of secondary infections [5]. Conversely, traditional dressings, encompassing a wide range of materials and methods, from simple saline-moistened gauze to advanced alginate or hydrogel dressings, have long been the cornerstone of wound management [6].

These dressings provide a moist environment conducive to wound healing, absorb exudates, and protect the wound from external contaminants [7].

The choice between NPWT and traditional dressings for DFU management hinges on multiple factors, including the wound's characteristics, patient comorbidities, and healthcare resource availability [8]. Despite the growing body of literature on this topic, healthcare professionals continue to face challenges in determining the most appropriate treatment modality for individual patients [9]. This is partly due to the variability in study designs, outcome measures, and patient populations across research studies, which complicates the direct comparison of treatment efficacies [10].

Recent meta-analyses and randomized controlled trials (RCTs) have provided valuable insights into the relative benefits of NPWT and traditional dressings in DFU management [11]. These studies suggest that NPWT may offer advantages in terms of faster wound healing rates, reduced infection risks, and lower complication rates, including amputations [12]. However, the evidence is not unequivocal, with some studies reporting minimal differences between the two modalities or highlighting the importance of patient selection and wound characteristics in determining treatment outcomes [13].

Given the significant impact of DFUs on patient quality of life and healthcare resources, there is a pressing need for comprehensive, comparative studies that elucidate the relative efficacy of NPWT and traditional dressings. Such research is essential to inform clinical practice, guide treatment selection, and ultimately improve patient outcomes in the management of DFUs [14]. This article aims to contribute to the existing body of knowledge by presenting a prospective, randomized comparative study on the efficacy of NPWT and traditional dressings in the healing of DFUs, focusing on healing rates, infection incidence, and complication rates.

Aims and Objectives

The primary aim of this study was to compare the efficacy of Negative Pressure Wound Therapy (NPWT) and traditional dressings in the healing process of diabetic foot ulcers (DFUs), with a focus on healing rates, infection incidence, and complication rates. The objectives included determining the time to complete wound closure, comparing the rate of infection between the two treatment modalities, and assessing the incidence of complications such as further infection, gangrene, or the need for amputation.

Materials and Methods

The study employed a prospective, randomized comparative design, conducted in the Department of Surgery at The Oxford Medical College, Bangalore, from February 2021 to August 2022. A total of 120 patients diagnosed with Type 1 or Type 2 diabetes, presenting with active foot ulcers classified as Wagner Grade 1, 2, or 3, and aged between 18 and 80 years, were enrolled in the study. Patients were excluded if they had severe peripheral arterial disease (ankle-brachial index <0.5), osteomyelitis in the affected limb, known hypersensitivity to materials used in NPWT or traditional dressings, or were pregnant or lactating.

Following the initial assessment, participants were randomly allocated into two groups, with 60 patients in the NPWT group and 60 in the traditional dressings group. The NPWT group received wound dressing using an FDA-approved NPWT system, with pressure settings and dressing changes according to the manufacturer’s guidelines. The traditional dressings group received wound care using standard moist dressings, changed daily or as needed based on clinical assessment. The initial assessment included measuring wound size and assessing for infection. Weekly follow-up evaluations focused on wound size reduction, signs of infection, and any adverse events.

Data collection included healing rates, time to complete wound closure, and incidence of complications, analyzed using SPSS version 26. All participants received standard diabetic foot care education, and glycemic control was monitored throughout the study period to ensure consistent management of diabetes.

This elaborate methodology aimed to provide a rigorous framework for comparing the outcomes of NPWT and traditional dressing interventions in the management of DFUs, thereby contributing to the evidence base for optimizing wound care in this high-risk patient population.

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Results

The results section of the study comparing Negative Pressure Wound Therapy (NPWT) and traditional dressings in diabetic foot ulcer patients presents a detailed analysis of the outcomes based on healing rates, infection rates, and incidence of complications, as detailed in the tables.

The baseline characteristics of the participants in both groups were well matched in terms of average age, gender distribution, mean diabetes duration, and HbA1c levels. The average age for both the NPWT and Traditional Dressings groups was 58 years, with an equal distribution of male participants (65%) in each. The mean duration of diabetes was identical at 12 years across groups, and the baseline HbA1c level was comparable, being 7.9 ± 1.3% in the NPWT group and 8.0 ± 1.4% in the Traditional Dressings group, with a p-value of 0.75, indicating no significant difference between the two groups.

The distribution of ulcer severity, based on Wagner Grade, was also similar between the two treatment modalities, with no significant difference observed in the proportions of Grade 1, Grade 2, or Grade 3 ulcers across the groups, demonstrating an equitable comparison framework for evaluating treatment outcomes.

Significant differences were noted in the wound healing outcomes between the two groups. The mean healing time was significantly shorter in the NPWT group (6.8 ± 1.5 weeks) compared to the Traditional Dressings group (9.5 ± 2.0 weeks), with a p-value of <0.001, indicating a substantial enhancement in healing speed with NPWT. Furthermore, the proportion of wounds healed by various time points also favored NPWT, with 30% of wounds in the NPWT group healed by 4 weeks compared to 18% in the Traditional Dressings group, p-value 0.045; 60% versus 40% healed by 8 weeks, p-value 0.03; and 78% versus 58% by 12 weeks, p-value 0.023.

The comparison of infection rates between the two groups revealed a lower infection rate in the NPWT group at 10% compared to 25% in the Traditional Dressings group, with a statistically significant p-value of 0.015. This result suggests a better infection control with NPWT.

In terms of complications, the overall incidence was significantly lower in the NPWT group at 5% compared to 18% in the Traditional Dressings group, p-value 0.02. Specifically, the incidence of gangrene was 3.3% in the NPWT group compared to 10% in the Traditional Dressings group, p-value 0.038. The need for amputation was also significantly reduced with NPWT, recorded at 1.7% versus 8.3% in the Traditional Dressings group, p-value 0.042.

These findings clearly demonstrate that NPWT not only significantly accelerates wound healing and reduces the mean healing time in patients with diabetic foot ulcers but also effectively lowers the infection rate and the incidence of severe complications such as gangrene and the need for amputation compared to traditional dressings.

Table 1: Baseline Characteristics

Characteristics	NPWT Group (n=60)	Traditional Dressings Group (n=60)	p-value
Average Age (years)	58 ± 9	58 ± 10	n/a
Gender (Male %)	65% (39 males)	65% (39 males)	n/a
Mean Diabetes Duration (years)	12 ± 5	12 ± 6	n/a
HbA1c Level (%)	7.9 ± 1.3	8.0 ± 1.4	0.75
Wagner Grade Distribution			
- Grade 1	20 (33.3%)	22 (36.7%)	0.7
- Grade 2	25 (41.7%)	23 (38.3%)	0.65
- Grade 3	15 (25%)	15 (25%)	1

Table 2: Wound Healing Rates and Times

Time Point	NPWT Group (n=60)	Traditional Dressings Group (n=60)	p-value
Mean Healing Time (weeks)	6.8 ± 1.5	9.5 ± 2.0	<0.001
% Wound Healed at 4 Weeks	30% (18)	18% (11)	0.045
% Wound Healed at 8 Weeks	60% (36)	40% (24)	0.03
% Wound Healed at 12 Weeks	78% (47)	58% (35)	0.023

Table 3: Infection Rates

Group	Infection Rate	p-value
NPWT Group	10% (6)	0.015
Traditional Dressings Group	25% (15)	

Table 4: Incidence of Complications

Complication	NPWT Group (n=60)	Traditional Dressings Group (n=60)	p-value
Total Complications (%)	**5% (3)**	**18% (11)**	**0.02**
- Gangrene	**3.3% (2)**	**10% (6)**	**0.038**
- Need for Amputation	**1.7% (1)**	**8.3% (5)**	**0.042**

Discussion

In the discussion of our findings, it is imperative to contextualize the results within the broader landscape of existing research on the efficacy of Negative Pressure Wound Therapy (NPWT) compared to traditional dressings in the treatment of diabetic foot ulcers (DFUs). Our study demonstrated that NPWT significantly accelerates wound healing, reduces infection rates, and lowers the incidence of severe complications like gangrene and the need for amputation. These outcomes align with and contribute to the growing body of evidence supporting the effectiveness of NPWT in DFU management.

A meta-analysis by Liu et al. [15], which included randomized controlled trials comparing NPWT to conventional dressings in treating DFUs, reported a higher rate of wound healing and a shorter healing time in the NPWT group. Similarly, our study observed a mean healing time of 6.8 weeks for NPWT, markedly less than the 9.5 weeks noted for traditional dressings, with a statistically significant difference ($p < 0.001$). The healing rates at 4, 8, and 12 weeks also favored NPWT, underscoring its potential for more rapid wound closure.

Concerning infection rates, our findings of a reduced infection rate with NPWT (10% vs. 25% in traditional dressings, $p = 0.015$) are echoed by the work of Armstrong and Lavery[16], who highlighted the role of NPWT in reducing wound bioburden and potentially mitigating infection risks. The ability of NPWT to continuously remove exudates and potentially infectious material from the wound site may contribute to this outcome.

The reduction in the incidence of complications, particularly the lower rates of gangrene and amputation in the NPWT group (3.3% and 1.7%, respectively), compared to the traditional dressings group (10% and 8.3%, $p = 0.038$ and $p = 0.042$, respectively), is of significant clinical relevance. A systematic review by Peinemann and Sauerland[17] highlighted NPWT's potential to decrease the risk of amputations in patients with DFUs, although they called for more high-quality studies to strengthen the evidence base. Our study contributes to this call by providing comparative data on these critical outcomes.

However, it is important to note contrasting findings from some studies, such as the trial by Game et al.[18], which did not find a significant difference in amputation rates between NPWT and traditional treatments. These discrepancies could be attributed to variations in study designs, sample sizes, and patient populations, underscoring the need for further research.

In summary, our study supports the growing consensus on the efficacy of NPWT in enhancing wound healing, reducing infection rates, and lowering the incidence of severe complications in DFU management. Yet, it also highlights the necessity for individualized patient assessment and consideration of NPWT's applicability based on clinical judgment and patient circumstances.

Conclusion.

Our study comprehensively demonstrates that Negative Pressure Wound Therapy (NPWT) is superior to traditional dressings in the management of diabetic foot ulcers (DFUs). The significant reduction in healing time, with an average of 6.8 weeks for NPWT compared to 9.5 weeks for traditional dressings ($p < 0.001$), highlights the efficacy of NPWT in accelerating wound closure. Moreover, the progressive improvement in wound healing rates at 4, 8, and 12 weeks, with statistically significant differences favoring NPWT (p-values of 0.045, 0.03, and 0.023, respectively), underlines its consistent benefit over time. The reduction in infection rates (10% for NPWT vs. 25% for traditional dressings, $p = 0.015$) further supports the role of NPWT in enhancing wound management outcomes. Additionally, the lower incidence of severe complications, such as gangrene (3.3% vs. 10%, $p = 0.038$) and the need for amputation (1.7% vs. 8.3%, $p = 0.042$), emphasizes the clinical advantages of NPWT. These findings advocate for the consideration of NPWT as a preferred treatment modality in the management of DFUs, tailored to individual patient needs and clinical circumstance.

References

1. Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med. 2017;376(24):2367-2375.
2. Jeffcoate WJ, Harding KG. Diabetic foot ulcers. Lancet. 2003;361(9368):1545-1551.
3. O'Meara S, Cullum N, Majid M, Sheldon T. Systematic reviews of wound care management: (5) beds; (6) compression; (7) lasers; (8) therapeutic ultrasound; (9) electromagnetic therapy; and (10) electrical stimulation for chronic wounds. Health Technol Assess. 2000;4(21):1-237.

4. Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg. 1997 Jun;38(6):563-76; discussion 577.
5. Apelqvist J, Willy C, Fagerdahl AM, et al. Negative pressure wound therapy – overview, challenges and perspectives. J Wound Care. 2017;26(3):S1-S113.
6. Queen D, Orsted H, Sanada H, Sussman G. A dressing history. Int Wound J. 2004;1(1):59-77.
7. Broussard KC, Powers JG. Wound dressings: selecting the most appropriate type. Am J Clin Dermatol. 2013;14(6):449-459.
8. Fife CE, Carter MJ, Walker D. Wound care outcomes and associated cost among patients treated in US outpatient wound centers: data from the US Wound Registry. Wounds. 2012;24(1):10-17.
9. Game FL, Apelqvist J, Attinger C, et al. Effectiveness of interventions to enhance healing of chronic ulcers of the foot in diabetes: a systematic review. Diabetes Metab Res Rev. 2016;32 Suppl 1:154-168.
10. Lipsky BA, Berendt AR, Cornia PB, et al. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. Clin Infect Dis. 2012;54(12):e132-173.
11. Lázaro-Martínez JL, Aragón-Sánchez J, García-Morales E. Antibiotics versus conservative surgery for treating diabetic foot osteomyelitis: a randomized comparative trial. Diabetes Care. 2014;37(3):789-795.
12. Armstrong DG, Lavery LA, Abu-Rumman P, et al. Outcomes of subatmospheric pressure dressing therapy on wounds of the diabetic foot. Ostomy Wound Manage. 2002;48(4):64-68.
13. Dumville JC, Hinchliffe RJ, Cullum N, et al. Negative pressure wound therapy for treating foot wounds in people with diabetes mellitus. Cochrane Database Syst Rev. 2013;(10):CD010318.
14. Uçkay I, Aragón-Sánchez J, Lew D, Lipsky BA. Diabetic foot infections: what have we learned in the last year? Diabetes Metab Res Rev. 2012;28 Suppl 1:8-20.
15. Liu Z, Dumville JC, Hinchliffe RJ, Cullum N. Negative pressure wound therapy for treating foot wounds in people with diabetes mellitus. Cochrane Database Syst Rev. 2014;(10):CD010318.
16. Armstrong DG, Lavery LA. Negative Pressure Wound Therapy After Partial Diabetic Foot Amputation: A Multicentre, Randomized Controlled Trial. Lancet. 2005;366(9498):1704-1710.
17. Peinemann F, Sauerland S. Negative-pressure wound therapy: systematic review of randomized controlled trials. Deutsches Ärzteblatt International. 2011;108(22):381-389.
18. Game FL, Apelqvist J, Attinger C, et al. Effectiveness of interventions to enhance healing of chronic ulcers of the foot in diabetes: a systematic review. Diabetes Metab Res Rev. 2016;32(Suppl 1):154-168.