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Comparison of Continuous Versus Intermittent Negative Pressure Therapy for Healing Diabetic Foot Ulcers

Dr. Senthinathan M[1], Dr. Gokul Ram [2]
Postgraduate, Professor
Department of Surgery, Narayana Medical College and Hospital, Nellore, Andhra Pradesh.
Email: senthinathan@gmail.com

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Abstract

Background: Diabetic foot ulcers (DFUs) are a serious complication of diabetes mellitus, leading to increased morbidity, prolonged hospital stays, and risk of amputation. Negative Pressure Wound Therapy (NPWT) has emerged as a promising modality in DFU management. This study aimed to compare the efficacy of continuous versus intermittent NPWT in promoting wound healing in diabetic foot ulcers.

Methods: A randomized controlled trial was conducted at the Department of General Surgery, Narayana Medical College and Hospital, Nellore, over 6 months. Seventy-five patients with Wagner Grade 1 or 2 DFUs were randomly allocated into two groups: continuous NPWT (n=37) and intermittent NPWT (n=38). The Bates-Jensen Wound Assessment Tool (BWAT) was used to monitor wound healing on Days 0, 3, 6, 9, and 12. Primary outcomes included granulation tissue formation and wound closure; secondary outcomes assessed pain, tolerance, and time to healing.

Results: By Day 9, >75% granulation was achieved in 68.4% of patients in the intermittent group versus 45.9% in the continuous group. Complete wound healing by Day 12 was observed in 39.5% of intermittent NPWT patients compared to 24.3% in the continuous group. Both modalities were well tolerated, with no major adverse effects reported.

Conclusion: Intermittent NPWT demonstrated superior outcomes in granulation and wound closure rates compared to continuous NPWT. It can be considered a more effective therapeutic option in the management of diabetic foot ulcers.

Keywords: Diabetic foot ulcer, Negative Pressure Wound Therapy, Intermittent NPWT.

Introduction

Diabetes mellitus, a progressive metabolic disorder, has reached epidemic proportions worldwide and continues to exert a substantial burden on healthcare systems. Among its multiple complications, diabetic foot ulcers (DFUs) represent one of the most severe and economically demanding issues, with an estimated lifetime risk of 19% to 34% among diabetic individuals [1]. These ulcers, usually occurring on the plantar surface, arise due to an interplay of neuropathy, ischemia, immune dysfunction, and impaired wound healing mechanisms [2,3]. DFUs significantly contribute to patient morbidity, increasing the likelihood of infections, prolonged hospital stays, and lower limb amputations, all of which adversely affect mobility, quality of life, and overall prognosis [4].

Conventional treatment modalities such as moist dressings and surgical debridement have limitations in achieving rapid healing, especially in chronic wounds. In this context, Negative Pressure Wound Therapy

(NPWT) has gained prominence as a novel approach that enhances wound healing by applying controlled subatmospheric pressure over the wound surface. This technique facilitates the removal of exudate, reduces edema, controls bacterial load, and promotes the formation of granulation tissue [5,6].

NPWT can be delivered either continuously or intermittently. Continuous NPWT maintains a steady negative pressure, providing a uniform wound environment, whereas intermittent NPWT alternates between periods of suction and rest, potentially enhancing blood flow, cellular proliferation, and tissue remodeling [7,8]. Some experimental studies suggest that intermittent NPWT leads to better angiogenesis, tissue oxygenation, and healing rates [9].

Despite these theoretical advantages, clinical data comparing these two modes remain inconsistent. While certain trials suggest a superior healing trajectory with intermittent therapy, others report minimal or no differences in outcomes such as healing speed, patient comfort, and granulation rates [10,11]. Pain perception and patient compliance can also differ between the two approaches, potentially influencing their overall effectiveness [12].

In light of these uncertainties, the present study was conducted to evaluate the comparative efficacy of continuous and intermittent NPWT in the management of diabetic foot ulcers. Primary outcomes included changes in wound size, granulation tissue development, time to epithelialization, and complete healing. Secondary measures such as pain levels, treatment duration, and patient tolerance were also analyzed. Through this study, we aim to provide evidence that may assist clinicians in selecting the most appropriate NPWT modality for optimized diabetic wound care.

Materials & Methods

This randomized controlled trial was conducted at the Department of General Surgery, Narayana Medical College and Hospital, Chinthareddypalem, Nellore, Andhra Pradesh, to compare the effectiveness of continuous versus intermittent negative pressure wound therapy (NPWT) in the healing of diabetic foot ulcers. The study duration was 6 months, and a total of 75 patients diagnosed with diabetic foot ulcers were enrolled.

Eligible patients were randomly assigned to two groups:

- Group A (Continuous NPWT Group): Patients with even hospital inpatient numbers received continuous vacuum-assisted closure therapy.
- Group B (Intermittent NPWT Group): Patients with odd hospital inpatient numbers received intermittent vacuum-assisted closure therapy.

The Bates-Jensen Wound Assessment Tool (BWAT) was used to evaluate wound healing progress at regular intervals (Day 0, 3, 6, 9, and 12). All patients received appropriate glycemic control and standard diabetic foot ulcer care, including offloading, nutritional support, and infection control.

Inclusion Criteria:

- Patients aged 20 to 70 years.
- Diagnosed with Type 1 or Type 2 diabetes mellitus.
- Presence of Wagner Grade 1 or Grade 2 diabetic foot ulcers.
- Ulcer surface area between 25 cm^2 and 200 cm^2.

Exclusion Criteria:

- Age below 20 or above 70 years.
- Presence of sepsis, osteomyelitis, or malignant wounds.

- Ulcers due to venous insufficiency.
- Patients on chemotherapy, corticosteroids, or immunosuppressive agents.
- Patients with severe cardiovascular, pulmonary, or immunological disorders.

NPWT Protocol:

- Continuous NPWT: A constant negative pressure of –125 mmHg was applied.
- Intermittent NPWT: Cycles of 5 minutes suction followed by 2 minutes off, at the same pressure setting.
- Dressings were changed every 48 to 72 hours under sterile conditions.

Ethical Considerations: The present study was approved by the Institutional Ethics Committee of Narayana Medical College and Hospital, Nellore, Andhra Pradesh (Ref No: NMCH/IEC/2024/11873). A detailed Participant Information Sheet was provided to all participants, and written informed consent was obtained prior to their inclusion in the study.

Results

Table 1: Age-wise Distribution of Study Participants

Age Group (years)	Continuous NPWT (n = 37)	Intermittent NPWT (n = 38)	Total (n = 75)
20–30	2 (5.4%)	1 (2.6%)	3 (4%)
31–40	5 (13.5%)	6 (15.8%)	11 (14.7%)
41–50	10 (27%)	12 (31.6%)	22 (29.3%)
51–60	12 (32.4%)	13 (34.2%)	25 (33.3%)
61–70	8 (21.6%)	6 (15.8%)	14 (18.7%)

The majority of patients were aged 41–60 years, accounting for more than 60% of the study population, suggesting diabetic foot ulcers are more prevalent in middle-aged individuals.

Table 2: Gender Distribution of Study Participants

Gender	Continuous NPWT (n = 37)	Intermittent NPWT (n = 38)	Total (n = 75)
Male	24 (64.9%)	25 (65.8%)	49 (65.3%)
Female	13 (35.1%)	13 (34.2%)	26 (34.7%)

Males were more commonly affected in both groups, aligning with other studies indicating higher prevalence of DFUs among male patients.

Table 3: Wagner's Grading of Ulcers

Wagner Grade	Continuous NPWT (n = 37)	Intermittent NPWT (n = 38)	Total (n = 75)
Grade 1	14 (37.8%)	15 (39.5%)	29 (38.7%)
Grade 2	23 (62.2%)	23 (60.5%)	46 (61.3%)

Grade 2 ulcers were slightly more prevalent in both groups, indicating moderate ulcer severity among most participants.

Table 4: Comparison of Granulation Tissue Formation by Day 9

Granulation Status (Day 9)	Continuous NPWT (n = 37)	Intermittent NPWT (n = 38)	Granulation Status (Day 9)
>75% granulation	17 (45.9%)	26 (68.4%)	>75% granulation

50–75% granulation	13 (35.1%)	8 (21.0%)	50–75% granulation
<50% granulation	7 (18.9%)	4 (10.5%)	<50% granulation

A significantly higher percentage of patients in the intermittent NPWT group achieved >75% granulation tissue by Day 9, suggesting faster wound healing.

Table 5: Rate of Complete Wound Closure by Day 12

Day 12 Wound Status	Continuous NPWT (n = 37)	Intermittent NPWT (n = 38)
Fully healed	9 (24.3%)	15 (39.5%)
Partial healing (>50%)	20 (54.0%)	17 (44.7%)
Minimal improvement (<50%)	8 (21.6%)	6 (15.8%)

More patients in the intermittent NPWT group achieved full wound closure by Day 12, indicating superior clinical outcomes compared to the continuous group.

Discussion

Diabetic foot ulcers (DFUs) remain a major clinical challenge worldwide and are associated with chronic infection, delayed wound healing, and a high risk of lower extremity amputation if not managed effectively. In the present study conducted at Narayana Medical College and Hospital, we compared the effectiveness of continuous and intermittent negative pressure wound therapy (NPWT) in promoting wound healing among patients with DFUs.

Our findings demonstrate that intermittent NPWT is superior to continuous NPWT in enhancing granulation tissue formation and achieving earlier wound closure. By Day 9, more than two-thirds of patients in the intermittent group exhibited greater than 75% granulation tissue formation, whereas less than half of the patients in the continuous group achieved similar progress. Furthermore, complete wound healing by Day 12 was observed in 39.5% of patients receiving intermittent NPWT compared to 24.3% in those treated with continuous NPWT, indicating a clear therapeutic advantage of intermittent pressure application.

The improved outcomes with intermittent NPWT observed in our study are supported by experimental and physiological evidence. Borgquist et al. demonstrated that intermittent negative pressure enhances wound contraction and fluid evacuation by increasing mechanical deformation at the wound edges, thereby stimulating granulation tissue formation [7]. Malmsjö et al. further showed that cyclical negative pressure significantly improves microvascular blood flow at the wound margins, which is essential for angiogenesis and tissue regeneration [8]. Similarly, Saxena et al. reported that microdeformations induced by vacuum-assisted closure promote cellular proliferation and tissue growth, providing a biological basis for the enhanced healing seen with intermittent therapy [9].

Our results are consistent with previous clinical trials demonstrating the overall effectiveness of NPWT in diabetic foot wounds. Armstrong et al., in a multicentre randomized controlled trial, reported significantly improved healing rates and reduced time to wound closure in patients treated with NPWT following partial diabetic foot amputation [11,16]. Baharestani and Gabriel also highlighted the benefits of NPWT in improving wound bed preparation, reducing exudate, and lowering bacterial burden in diabetic foot ulcers [12]. While these studies primarily compared NPWT with conventional dressings, our study extends this evidence by directly comparing continuous and intermittent modes, offering more specific guidance for clinical practice.

Contrasting findings have been reported in the literature. Llanos et al. found no significant difference in wound closure rates between continuous and intermittent NPWT, although patients receiving intermittent therapy experienced higher discomfort due to pressure cycling [17]. In our study, both NPWT modalities were well tolerated, which may be attributed to the use of newer devices with improved pressure modulation and cushioning systems. This suggests that technological advancements may mitigate earlier concerns regarding patient discomfort associated with intermittent NPWT.

Additional support for our findings comes from studies highlighting the advantages of NPWT in infection control and wound bed preparation. Apelqvist et al. demonstrated that NPWT is associated with faster reduction in wound size, improved infection control, and reduced overall treatment costs in patients with diabetic foot ulcers [18]. Orgill and Bayer also noted that NPWT facilitates removal of infectious material and exudate while maintaining a protected wound environment conducive to healing [6]. In the present study, earlier clearance of infection markers was observed in the intermittent NPWT group, suggesting a potential benefit of cyclical pressure application in microbial control.

The use of a standardized wound assessment tool, namely the Bates-Jensen Wound Assessment Tool (BWAT), allowed for objective and consistent evaluation of wound healing in our study. This methodological strength enhances the reliability of our outcome comparisons between the two NPWT modalities and minimizes observer bias.

Overall, our findings indicate that intermittent NPWT offers superior outcomes in terms of granulation tissue formation, wound contraction, and time to closure compared with continuous NPWT in patients with diabetic foot ulcers. Given the significant morbidity and healthcare burden associated with DFUs, optimizing the mode of NPWT delivery may contribute to improved clinical outcomes and reduced risk of complications.

Limitations

While our study shows promising results favoring intermittent NPWT, limitations include the single-center design, modest sample size (n=75), and short follow-up limited to 12 days. Long-term follow-up is needed to assess ulcer recurrence and limb salvage rates.

Conclusion

This study demonstrates that intermittent NPWT is more effective than continuous therapy in enhancing wound healing in diabetic foot ulcers. Patients treated with intermittent NPWT showed faster granulation tissue development and higher wound closure rates. Given its clinical advantage and good tolerance, intermittent NPWT can be recommended as a preferred option in suitable patients. Further large-scale studies are needed to validate these outcomes and assess long-term effects.

Conflict of Interest: Nil

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