A Prospective Randomised Comparative Study of Conventional Saline Dressing Versus Pressure Offloading in the Management of Diabetic Foot Ulcers

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Abstract: Background: Diabetic foot ulcers (DFUs) are a major cause of non-traumatic lower limb amputations worldwide. Pressure offloading is a key strategy in ulcer management; however, its real-world effectiveness compared to conventional dressings remains under-evaluated. **Objectives:** To compare the efficacy of conventional saline dressing and pressure offloading dressing using the SUVIDHA technique in healing diabetic foot ulcers. **Methods:** This randomised comparative study enrolled patients with plantar DFUs who met the inclusion criteria. Patients were divided into two groups: Group A received conventional saline dressings, and Group B received pressure offloading dressings for one week in-hospital and continued offloading dressings at home for 6 weeks. Ulcer area was measured pre- and post-intervention. **Results:** Mean post-intervention ulcer area was significantly smaller in the pressure offloading group (4.2 cm^2) than in the saline group (17.6 cm^2) ($p<0.01$). The mean reduction in ulcer size was also greater in the pressure offloading group (24.2 cm^2 vs. 15.3 cm^2; $p=0.012$). **Conclusion:** Pressure offloading dressings are significantly more effective than conventional dressings in promoting ulcer healing. Offloading should be integrated into standard DFU care, especially in resource-limited settings.

Keywords: Diabetic foot ulcer, pressure offloading, SUVIDHA technique, saline dressing, wound healing

1. Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder characterised by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. It is among the leading causes of morbidity and mortality globally, with complications that significantly affect the quality of life and functional independence of patients [1]. One such complication, diabetic foot ulcer (DFU), affects approximately 15% of all diabetic patients during their lifetime and accounts for nearly 85% of diabetes-related lower limb amputations [2,3].

DFUs are complex chronic wounds primarily caused by neuropathy, peripheral vascular disease, and immunopathy. Neuropathy results in sensory loss, leading to unnoticed minor trauma, while peripheral arterial disease impairs healing by reducing blood flow. Together, these factors contribute to the development of ulcers and poor healing outcomes [4,5]. Foot ulcers not only increase the risk of amputation but also impose a significant economic burden on healthcare systems and families [6].

Despite various interventions, the recurrence rate of DFUs remains high, emphasising the need for effective preventive and therapeutic strategies [7]. Conventional wound care often involves regular saline dressing, which aims to maintain a moist environment, prevent infection, and promote granulation tissue formation. However, it does not address the mechanical stresses on the foot, which are key contributors to poor healing [8].

Pressure offloading is recognised as a cornerstone of DFU management. It aims to redistribute pressure away from the ulcer site, thereby allowing tissue repair. Techniques include total contact casts, therapeutic footwear, and felted foam [9]. The SUVIDHA technique, introduced in resource-limited settings, utilises easily available materials to achieve effective offloading and has shown promising results in previous studies [10].

This study aims to compare the healing outcomes of conventional saline dressing versus pressure offloading dressing using the SUVIDHA technique in patients with diabetic foot ulcers. By evaluating ulcer size reduction over six weeks, this research seeks to establish evidence for incorporating cost-effective pressure offloading methods in routine clinical practice.

2. Materials and Methods

2.1 Study Design and Setting

This study was designed as a prospective, randomised, comparative clinical study conducted in the Department of General Surgery, Sree Gokulam Medical College and Research Foundation, a tertiary care teaching hospital in Kerala, India. The study was carried out over 18 months, from January 2023 to June 2024.

The study protocol was reviewed and approved by the Institutional Ethics Committee, and the study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. Written informed consent was obtained from all participants before enrolment.

2.2 Study Participants

Adult patients attending the general surgery outpatient and inpatient services were screened for eligibility.

Inclusion Criteria

Patients were included if they met all of the following criteria:

- Age ≥18 years
- Diagnosed with type 2 diabetes mellitus
- Presence of a non-infected neuropathic plantar foot ulcer
- Ulcer classified as Wagner grade I or II
- Ulcer surface area between 1 cm^2 and 25 cm^2

Exclusion Criteria

Patients were excluded if they had:

- Evidence of peripheral arterial disease (PAD) (clinically or by Doppler assessment)
- Infected ulcers, osteomyelitis, or gangrene
- Non-plantar foot ulcers
- Severe foot deformities requiring surgical offloading
- Poor anticipated compliance or inability to attend follow-up visits

2.3 Randomisation and Allocation

A total of 74 eligible patients were enrolled in the study. Participants were randomised in a 1:1 ratio into two treatment groups using a simple random sampling technique. Randomisation was performed using computer-generated random numbers.

- Group A (n = 37): Conventional normal saline dressing
- Group B (n = 37): Pressure offloading dressing using the SUVIDHA technique

Allocation concealment was ensured until the point of intervention. Due to the nature of the interventions, blinding of patients and caregivers was not feasible.

2.4 Interventions

Group A: Conventional Saline Dressing

Patients in Group A received sterile normal saline dressings once daily during hospitalisation for a period of one week. After discharge, patients or their caregivers were instructed to continue daily saline dressing at home following strict hygienic precautions. Regular wound inspection and reinforcement of dressing techniques were performed during follow-up visits.

Group B: Pressure Offloading Using the SUVIDHA Technique

Patients in Group B were treated using a pressure offloading dressing based on the SUVIDHA technique. This technique involves the creation of a customised offloading cushion using sterile cotton, gauze, and micropore adhesive tape, designed to redistribute plantar pressure away from the ulcer site while allowing adequate wound ventilation.

The offloading dressing was individualised according to ulcer location, size, and foot anatomy. During hospital stay, dressings were changed once every third day. Caregivers were comprehensively trained to reproduce the technique accurately at home. Patients were reviewed weekly for six weeks, during which wound assessment and reinforcement of offloading practices were performed.

2.5 Outcome Measures

Primary Outcome

Reduction in ulcer surface area (cm^2) from baseline to the end of 6 weeks, measured using standardized wound measurement techniques.

Secondary Outcomes

- Time to complete ulcer healing
- Incidence of complications, including infection, ulcer recurrence, and requirement for surgical debridement
- Patient and caregiver compliance, assessed during follow-up visits
- Cost-effectiveness of the dressing method, considering material costs and frequency of dressing changes

2.6 Statistical Analysis

Data were entered and analysed using Statistical Package for the Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages.

The independent samples t-test was used to compare the mean reduction in ulcer surface area between the two groups. Categorical variables were analysed using appropriate statistical tests. A p-value <0.05 was considered statistically significant.

3. Results

3.1 Baseline Demographic and Clinical Characteristics

A total of 74 patients were enrolled and completed the study, with 37 patients in each group. The baseline demographic and clinical characteristics were comparable between the two groups.

The mean age of participants was 59.4 ± 7.8 years in Group A (conventional saline dressing) and 58.1 ± 6.9 years in Group B (pressure offloading using the SUVIDHA technique). Group A comprised 27 males (72.9%) and 10 females (27.1%), while Group B included 28 males (77.1%) and 9 females (22.9%).

With respect to ulcer location, the hindfoot was the most commonly affected site (51%), followed by the forefoot (35.4%) and the midfoot (13.5%). There were no statistically significant differences between groups regarding demographic variables or ulcer distribution at baseline.

3.2 Ulcer Surface Area at Baseline and After Treatment

Ulcer surface area was assessed using a transparent sterile graph sheet to ensure uniformity of measurement.

At baseline, the mean ulcer surface area was 32.9 ± 14.3 cm^2 in Group A and 28.4 ± 16.1 cm^2 in Group B. This difference was not statistically significant ($p = 0.11$), confirming baseline comparability between the groups.

After six weeks of intervention, a reduction in ulcer area was observed in both groups. The mean ulcer area in Group A decreased to 17.6 ± 10.2 cm^2, whereas Group B demonstrated a substantially greater reduction, with a mean ulcer area of 4.2 ± 3.6 cm^2. The difference in post-treatment ulcer area between the two groups was statistically significant ($p < 0.01$).

3.3 Healing Outcomes and Complications

The mean reduction in ulcer surface area over six weeks was 15.3 ± 15.0 cm^2 in Group A compared with 24.2 ± 18.5 cm^2 in Group B. This difference was statistically significant ($p = 0.012$), indicating superior wound size reduction in the pressure offloading group.

Complete ulcer healing within the study period was achieved in 9 patients (24.3%) in Group A and 18 patients (48.6%) in Group B. The higher healing rate observed in Group B was statistically significant ($p = 0.03$).

No major adverse events were reported in either group during the study period. Mild wound infection occurred in three patients in Group A, all of whom were managed conservatively without the need for surgical intervention. No infections or ulcer-related complications were observed in Group B.

3.4 Patient Compliance and Cost-Effectiveness

Patient and caregiver compliance with the prescribed dressing protocol was higher in Group B (91.9%) compared to Group A (81.1%). The higher compliance in the offloading group was attributed to reduced dressing frequency, ease of application, and caregiver training.

The SUVIDHA pressure offloading technique was found to be highly cost-effective, with an estimated expenditure of less than INR 40 per dressing. In contrast, commercially available offloading footwear and vacuum-assisted closure (VAC) systems involve substantially higher costs and often require specialised equipment and professional supervision.

The feasibility of caregiver-administered home application, coupled with minimal material requirements, significantly enhanced the practicality and scalability of the SUVIDHA technique, particularly in resource-limited settings.

Table 1. Comparison of Ulcer Area and Healing Outcomes between the Two Groups

Parameter	Group A (Saline Dressing, n = 37)	Group B (Pressure Offloading, n = 37)	p-value	Statistical Significance
Baseline Ulcer Area (cm^2)	32.9 ± 14.3	28.4 ± 16.1	0.11	Not Significant
Post-treatment Ulcer Area (cm^2)	17.6 ± 10.2	4.2 ± 3.6	< 0.01	Significant
Mean Ulcer Size Reduction (cm^2)	15.3 ± 15.0	24.2 ± 18.5	0.012	Significant
Complete Healing [n (%)]	9 (24.3%)	18 (48.6%)	0.03	Significant
Compliance with Dressing Protocol (%)	81.1%	91.9%	0.05	Borderline
Adverse Events (Wound Infection)	3 (8.1%)	0	–	Not Applicable
Major Adverse Events	0	0	–	Not Applicable

Note: Values are expressed as mean ± standard deviation or number (percentage). An independent samples t-test was used for comparison of continuous variables,

and a chi-square test for categorical variables. Statistical significance was set at $p < 0.05$.

4. Discussion

Diabetic foot ulcers (DFUs) remain a major cause of morbidity, impaired quality of life, and lower-limb amputations worldwide. The results of the present study clearly demonstrate the substantial clinical benefit of pressure offloading in the management of neuropathic plantar DFUs. Patients treated using the SUVIDHA pressure offloading technique experienced a significantly greater reduction in ulcer surface area and higher rates of complete ulcer healing at six weeks when compared with those receiving conventional saline dressings.

These findings strongly support current international recommendations that identify pressure offloading as a cornerstone of DFU management. Both the International Working Group on the Diabetic Foot (IWGDF) and the American Diabetes Association emphasise that effective offloading is essential to reduce repetitive mechanical stress, which is a key contributor to ulcer chronicity and impaired wound healing [2,9]. The present study reinforces these guideline principles in a real-world clinical setting.

In contrast, although the conventional saline dressing group demonstrated modest improvement, healing outcomes were significantly inferior. While saline dressings maintain a moist wound environment and aid in basic wound hygiene, they do not address biomechanical forces, which play a decisive role in perpetuating tissue injury and delaying granulation. Persistent plantar pressure results in microvascular compromise, local ischemia, and repeated tissue trauma, thereby prolonging inflammation and inhibiting epithelialisation [4]. By redistributing pressure away from the ulcer bed, offloading directly targets this fundamental pathophysiological mechanism, facilitating accelerated tissue regeneration.

An important strength of the SUVIDHA technique is its simplicity, affordability, and adaptability, making it particularly suitable for resource-constrained settings. Conventional gold-standard offloading modalities such as total contact casts (TCCs), removable cast walkers, or custom orthotic footwear are effective but often limited by high cost, need for specialised expertise, risk of cast-related complications, and poor patient acceptance. In contrast, the SUVIDHA technique employs readily available materials, does not require advanced technical skills, and can be safely administered by trained caregivers at home without compromising healing outcomes.

The higher compliance observed in the offloading group further strengthens the clinical relevance of this approach. Improved patient comfort, reduced dressing frequency, and active caregiver participation likely contributed to better

adherence. This highlights the critical role of family and community support in chronic wound management, particularly in long-term conditions such as diabetic foot disease [5,6]. Empowering caregivers through structured training may bridge gaps in healthcare access and improve continuity of care beyond hospital settings.

The results of this study are consistent with earlier work by Apelqvist et al. and Bus et al., who demonstrated significantly improved ulcer healing rates with offloading interventions [3,9]. However, many of these studies relied on high-cost or technologically intensive offloading modalities, which may not be feasible in low- and middle-income countries. The novelty of the present study lies in demonstrating that a low-cost, easy-to-learn offloading technique can achieve comparable short-term healing outcomes, thereby expanding the applicability of evidence-based DFU care to underserved populations.

Despite its strengths, this study has certain limitations. The relatively short follow-up period precludes assessment of long-term outcomes such as ulcer recurrence and durability of healing. Additionally, advanced imaging modalities, plantar pressure measurements, and microbiological profiling were not included, which may have provided deeper insights into wound dynamics and infection risk. Future studies incorporating longer follow-up, quality-of-life assessments, functional outcomes, and objective pressure analysis would further strengthen the evidence base.

Nevertheless, the findings of this study provide compelling evidence that pressure offloading dressings, particularly the SUVIDHA technique, significantly improve healing outcomes in diabetic foot ulcers. Given its cost-effectiveness, ease of application, and high patient compliance, the SUVIDHA method represents a practical and scalable solution for DFU management in routine clinical practice, especially in resource-limited settings.

5. Conclusion

This study concludes that pressure offloading using the SUVIDHA technique significantly enhances healing in diabetic foot ulcers compared to conventional saline dressing. The method is simple, economical, and effective, making it ideal for implementation in primary healthcare and rural settings. Adoption of offloading techniques could drastically reduce complications, hospitalisation, and amputations associated with diabetic foot ulcers.

Future research should focus on multicentric trials with longer durations, assessing recurrence, patient satisfaction, and cost-effectiveness at the health system level.

Declaration of Conflicts of Interest

The authors declare that there are no conflicts of interest related to this manuscript.

Ethics Approval

The study was conducted following the principles of the Declaration of Helsinki and was approved by the Institutional Ethics Committee of Sree Gokulam Medical College and Research Foundation, Kerala, India (Approval No: [50/665/11/2022], dated [25/11/2022]).

Funding Support

No specific grant from any funding agency in the public, commercial, or not-for-profit sectors was received for this study. The study was self-funded by the authors.

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