Original Research Article

Comparative study between mandakini off-loading and conventional gauze dressing in the management of diabetic foot plantar ulcers

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) are a major complication of diabetes mellitus and a leading cause of morbidity, hospitalization, and lower-limb amputation. Effective off-loading is essential for optimal wound healing, but conventional methods remain costly, complex, and less patient-friendly in resource-limited settings.
Materials and Methods: This prospective comparative study was conducted over 18 months at Navodaya Medical College Hospital and Research Centre, Raichur. A total of 154 patients with Wagner grade 1 and 2 plantar DFUs were enrolled and divided into two groups of 76 each. Group A received Mandakini off-loading dressing, while Group B received conventional wet gauze dressing. Outcomes assessed included wound healing time, wound size reduction, granulation tissue formation, infection rate, recurrence, and amputation rate. Statistical analysis was performed using SPSS version 25, with $p < 0.05$ considered significant.
Results: Baseline characteristics were comparable between both groups. Mean healing time was significantly shorter in Group A (4.3 ± 1.1 weeks) compared to Group B (5.8 ± 1.3 weeks) ($p < 0.001$). Infection rate (13.2% vs 28.9%) and ulcer recurrence (7.9% vs 21.1%) were significantly lower in Group A. Wound contraction and granulation tissue formation were also significantly better in the Mandakini group ($p < 0.001$). Although amputation rates were lower in Group A (2.6% vs 7.9%), the difference was not statistically significant.
Conclusion: Mandakini off-loading dressing is a simple, cost-effective, and clinically superior alternative to conventional gauze dressing, providing faster healing and better overall outcomes in diabetic plantar ulcers.

Keywords
Diabetic foot ulcer, Mandakini dressing, Off-loading, Wound healing, Plantar ulcer, Gauze dressing, Diabetes mellitus.

Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder and a major global public health concern due to its rapidly increasing prevalence and multisystem complications. Among its complications, diabetic foot ulcers (DFUs) are one of the most serious and disabling conditions, contributing substantially to morbidity, healthcare costs, and reduced quality of life. According to the International Diabetes Federation (IDF), approximately 537 million adults were living with diabetes worldwide in 2021, and this number is projected to rise to 783 million by 2045[1]. In India, the burden is also rising rapidly, increasing from 26 million cases in 1990 to nearly 65 million in 2016, and is expected to reach 70 million by 2025 and 80 million by 2030[2].DFUs represent a major cause of hospitalization among diabetic patients and are a leading cause of non-traumatic lower-limb amputations. Nearly 15–25% of individuals with diabetes develop a foot ulcer during their lifetime, most commonly at pressure-bearing plantar areas[3]. Healing is often delayed due to infection, poor perfusion, and impaired tissue regeneration, leading to chronic non-healing wounds. The pathogenesis of DFU is multifactorial, involving peripheral neuropathy, peripheral arterial disease, foot deformities, and repetitive mechanical stress[4]. Among these, neuropathy is central, as chronic hyperglycemia leads to sensory loss, impaired proprioception, and abnormal gait, resulting in repeated unnoticed trauma and ulcer formation[5].

Peripheral arterial disease further worsens outcomes by reducing blood flow, oxygen delivery, and nutrient supply to tissues, thereby delaying wound healing. When combined with infection and metabolic dysfunction, these factors contribute to chronic, non-healing ulcers[6]. Approximately 80% of diabetic patients develop neuropathy, and a significant proportion progress to foot ulceration, with many eventually requiring amputation[7]. DFU is therefore a complex biomechanical and vascular disorder rather than a simple wound.

Abnormal plantar pressure distribution is a key etiological factor in DFU development, with common ulcer sites including the first metatarsophalangeal joint, metatarsal heads, and heel[8]. Effective management therefore requires not only infection control and wound care but also mechanical off-loading to redistribute plantar pressure and promote healing. Off-loading is a fundamental principle in DFU management along with optimization of perfusion and infection control[9,10].Various off-loading modalities have been described, including bed rest, crutches, therapeutic footwear, felt padding, and total contact casting (TCC)[11,12]. TCC is considered the gold standard due to its ability to evenly distribute plantar pressure and immobilize the foot, thereby enhancing healing rates[13]. However, its use is limited by cost, technical complexity, restricted mobility, and need for frequent follow-up, making it less suitable in resource-limited settings[14].DFUs also impose a substantial economic burden. Patients may spend approximately 10% of their annual income on diabetes care, which increases to around 30% with ulcer development and exceeds 50% in cases requiring hospitalization or management of infection[15]. Beyond financial strain, DFUs significantly affect mobility, independence, psychological health, and overall quality of life, leading to major social and healthcare burdens[16].In low-resource settings like India, there is a need for simple, cost-effective, and patient-friendly off-loading strategies that can be easily implemented in outpatient settings. Ideal methods should be affordable, practical, and suitable for long-term use[17]. In this context, indigenous innovations are increasingly being explored to address these challenges.The Mandakini off-loading technique is a low-cost, locally developed method designed to redistribute plantar pressure and enhance wound healing. It uses readily available materials to provide customized cushioning, thereby reducing focal pressure, promoting granulation tissue formation, and accelerating epithelialization[18]. When combined with moisture-retentive dressings, it helps maintain an optimal wound-healing environment. Compared to rigid casting, it offers improved mobility, easier application, and better patient compliance, especially in rural healthcare settings[19].In contrast, conventional gauze dressings, although widely used due to affordability, have significant limitations. They tend to adhere to the wound surface, causing pain and trauma during dressing changes, require frequent replacement, disrupt the moist wound environment, and do not provide mechanical off-loading, thereby failing to address the primary biomechanical cause of plantar ulcers[20].

Therefore, considering the limitations of conventional approaches and the need for effective, affordable, and patient-friendly alternatives, the present study was undertaken to compare the clinical efficacy of Mandakini off-loading dressing versus conventional gauze dressing in the management of diabetic plantar ulcers.

MATERIALS AND METHODS

All outpatients and inpatients presenting with plantar diabetic foot ulcers to the Departments of Medicine and Surgery at Navodaya Medical College Hospital and Research Centre, Raichur, were included in the study population. Data were collected from patients who fulfilled the eligibility criteria during the study period.This study was conducted as a prospective comparative study.

Sample Size Calculation

The sample size was calculated using a single-proportion formula based on the healing rate reported by Naaz et al. (2024)[79]. A 95% confidence level was assumed ($Z = 1.96$) with a 10% margin of error ($d = 0.10$). The expected proportion of healing in the reference group was taken as $p = 0.725$ (72.5%), and q was calculated as $1 - p = 0.275$.

Based on the calculation, the sample size was estimated as 76 patients per group. A total of 154 patients who met the inclusion criteria were enrolled and subsequently divided into two groups of 76 each.

Study Population

Inclusion Criteria

Patients included in the study were:

- All patients presenting with diabetic foot ulcers on the plantar aspect.
- Patients who provided informed consent.

Exclusion Criteria

Patients were excluded if they had:

- Diabetic foot ulcer with peripheral vascular disease (ABPI < 0.4).
- Diabetic foot ulcer associated with osteomyelitis.
- Charcot’s foot.
- Wagner’s grade 3, 4, or 5 ulcers.
- Patients receiving radiotherapy or immunosuppressant therapy.

Methodology

Ethical Considerations and Consent

The study protocol, including objectives, methodology, and potential risks, was explained to all participants. Written informed consent was obtained prior to enrollment. Confidentiality of patient data was maintained, and participants were informed that they could withdraw from the study at any stage without affecting their treatment.

Patient Optimization

All enrolled patients were optimized over a period of two weeks prior to allocation. This included assessment of HbA1c, initiation of antibiotics based on culture and sensitivity reports, surgical debridement of ulcers when required, and correction of associated comorbid conditions.

Group Allocation

Eligible patients were allocated into two groups based on patient preference until the required sample size was achieved:

Group A (Study Group): Mandakini off-loading dressing was applied.

Group B (Control Group): Conventional wet gauze dressing was used.

Intervention Procedures

Mandakini Off-loading Dressing (Study Group)

Patients in the study group received the Mandakini pressure off-loading dressing, which was changed weekly. The dressing was prepared by rolling paired gloves (similar to autoclaving gloves) and placing them over the adhesive surface of Dynaplast. These rolled gloves acted as a soft air-cushion to redistribute plantar pressure and off-load the ulcer area. The edges of the Dynaplast were secured using firm circumferential pressure. For forefoot and hindfoot ulcers, the cushions were placed proximally and distally to the lesion to ensure effective off-loading. The number of gloves used was adjusted according to patient body weight to achieve optimal pressure redistribution.

Conventional Gauze Dressing (Control Group)

Patients in the control group received conventional wet gauze dressings, which were changed daily either by the patient or by the treating physician as per routine wound care protocol.

Outcome Assessment

Primary and Secondary Outcomes

The primary outcomes assessed were wound size (cm) and Wagner grading of ulcers. Assessments were performed at baseline and then weekly for six weeks. Wound size was measured using the longest diameter of the ulcer.

Wound Healing Assessment

The duration of complete wound healing was recorded in weeks. The percentage of granulation tissue and non-viable tissue was assessed using a structured scoring system during baseline and weekly follow-up for six weeks.

Granulation Tissue Scoring (1–4 scale)

1: Nil (≤25%)

2: 26–50%

3: 51–74%

4: 75–100%

Wound Surface Scoring for Necrotic Tissue (1–6 scale)

1: 76–100% slough

2: 51–75% slough

3: 26–50% slough

4: 11–25% slough

5: 0–10% non-viable tissue

6: No necrotic tissue

Dressing was discontinued once complete re-epithelialization occurred or at six weeks if healing was incomplete.

Investigations

All patients underwent the following routine investigations:

- Complete blood count
- Fasting blood sugar
- Postprandial blood sugar
- HbA1c
- Random blood sugar
- Wound culture and sensitivity
- X-ray of foot
- Color Doppler study

Statistical Analysis

Statistical analysis was performed using SPSS version 25. Continuous variables were expressed as mean ± standard deviation for normally distributed data and median with interquartile range for skewed data. Categorical variables were expressed as frequencies and percentages.

Intergroup comparisons for continuous variables were performed using the Independent Student's t-test for normally distributed data and the Mann–Whitney U test for non-normal data. Categorical variables were analyzed using the Chi-square test, and Fisher's exact test was used when expected cell counts were small.

Repeated measures ANOVA was used for intra-group comparisons over time for variables such as wound size, granulation tissue score, and necrotic tissue score. The McNemar test was applied for paired categorical data. A p-value < 0.05 was considered statistically significant.

Results:

The baseline characteristics of the study participants are presented in Table 1. The mean age was comparable between Group A (56.4 ± 9.8 years) and Group B (57.1 ± 10.2 years), with no statistically significant difference (p = 0.68). Similarly, sex distribution, duration of diabetes, presence of peripheral neuropathy, baseline wound size, footwear practices, and Wagner grade distribution were comparable between both groups (p > 0.05 for all), indicating homogeneity of the study population at baseline.

The clinical presentation and comorbidities of patients are summarized in Table 2 and illustrated in Figure 1. Pain was the most common presenting complaint in both groups (76.3% vs 78.9%), followed by discharge and swelling, with no statistically significant difference between groups (p > 0.05). The mode of ulcer onset (traumatic, spontaneous, or pressure-related) was also comparable between Group A and Group B (p > 0.05), indicating similar etiological distribution.

The primary outcomes are shown in Table 3 and depicted in Figure 2. The mean duration of wound healing was significantly shorter in Group A (4.3 ± 1.1 weeks) compared to Group B (5.8 ± 1.3 weeks), with a highly significant difference (p < 0.001). The median healing time also supported this finding (4.0 vs 6.0 weeks, p < 0.001).

Wound infection was significantly lower in Group A (13.2%) compared to Group B (28.9%) (p = 0.02). Similarly, ulcer recurrence was significantly reduced in Group A (7.9% vs 21.1%, p = 0.03). Although amputation rates were lower in Group A (2.6% vs 7.9%), the difference was not statistically significant (p = 0.14), as shown in Table 3.

The wound healing progression at 6 weeks is presented in Table 4. Necrotic tissue scores, granulation tissue scores, and wound surface area showed significantly better improvement in Group A compared to Group B (p < 0.001 for all).

At 6 weeks, the mean necrotic tissue score was higher in Group A (5.9 ± 0.3) than Group B (5.0 ± 0.7), indicating faster necrotic tissue resolution. Granulation tissue formation was also superior in Group A (4.0 ± 0.0 vs 3.6 ± 0.5, p < 0.001).

Wound surface area reduction was significantly greater in Group A (0.4 ± 0.6 cm²) compared to Group B (1.3 ± 0.9 cm²) (p < 0.001).

The requirement for debridement was lower in Group A (0%) compared to Group B (5.3%), though not statistically significant (p = 0.12). However, the need for topical antiseptic at 6 weeks was significantly lower in Group A (5.3% vs 23.7%, p < 0.001), as shown in Table 4.

Table 1. Baseline Characteristics of Study Participants

Parameter	Group A (Mandakini) n = 76	Group B (Gauze) n = 76	p-value	Statistical Test
Age (years), Mean ± SD	56.4 ± 9.8	57.1 ± 10.2	0.68	Independent t-test
Age, Median (IQR)	57.0 (50.0–64.0)	58.0 (49.0–65.0)	0.71	Mann–Whitney U
Male, n (%)	48 (63.2%)	50 (65.8%)	0.74	Chi-square test
Female, n (%)	28 (36.8%)	26 (34.2%)	0.74	Chi-square test

Duration of Diabetes (years), Mean ± SD	8.6 ± 4.2	8.9 ± 4.5	0.68	Independent t-test
Peripheral Neuropathy, n (%)	52 (68.4%)	54 (71.1%)	0.71	Chi-square test
Baseline Wound Size (cm), Mean ± SD	4.8 ± 1.2	4.9 ± 1.3	0.61	Independent t-test
Appropriate Footwear, n (%)	22 (28.9%)	20 (26.3%)	0.72	Chi-square test
Wagner Grade 1, n (%)	34 (44.7%)	36 (47.4%)	0.79	Chi-square test
Wagner Grade 2, n (%)	42 (55.3%)	40 (52.6%)	0.79	Chi-square test

Table 2. Clinical Presentation and Comorbidities

Parameter	**Group A (n=76)**	**Group B (n=76)**	**p-value**	**Statistical Test**
Pain, n (%)	58 (76.3%)	60 (78.9%)	0.69	Chi-square test
Discharge, n (%)	34 (44.7%)	38 (50.0%)	0.51	Chi-square test
Swelling, n (%)	22 (28.9%)	25 (32.9%)	0.59	Chi-square test
Trauma-related onset, n (%)	34 (44.7%)	36 (47.4%)	0.74	Chi-square test
Spontaneous onset, n (%)	18 (23.7%)	16 (21.1%)	0.70	Chi-square test
Pressure-related onset, n (%)	22 (28.9%)	20 (26.3%)	0.72	Chi-square test

Table 3. Primary Outcomes of the Study

Outcome	**Group A (Mandakini)**	**Group B (Gauze)**	**p-value**	**Statistical Test**
Healing time (weeks), Mean ± SD	4.3 ± 1.1	5.8 ± 1.3	<0.001	Independent t-test
Healing time, Median (IQR)	4.0 (3.5–5.0)	6.0 (5.0–7.0)	<0.001	Mann–Whitney U
Wound infection, n (%)	10 (13.2%)	22 (28.9%)	0.02	Chi-square test
Ulcer recurrence, n (%)	6 (7.9%)	16 (21.1%)	0.03	Chi-square test

Amputation, n (%)	2 (2.6%)	6 (7.9%)	0.14	Fisher's exact test

Table 4. Wound Healing Progress at 6 Weeks

Parameter	**Group A (Mandakini)**	**Group B (Gauze)**	**p-value**	**Statistical Test**
Necrotic tissue score, Mean ± SD	5.9 ± 0.3	5.0 ± 0.7	<0.001	RM-ANOVA
Granulation tissue score, Mean ± SD	4.0 ± 0.0	3.6 ± 0.5	<0.001	RM-ANOVA
Wound surface area (cm^2), Mean ± SD	0.4 ± 0.6	1.3 ± 0.9	<0.001	RM-ANOVA
Patients requiring debridement, n (%)	0 (0%)	4 (5.3%)	0.12	Chi-square/Fisher
Patients requiring antiseptic at 6 weeks, n (%)	4 (5.3%)	18 (23.7%)	<0.001	Chi-square test

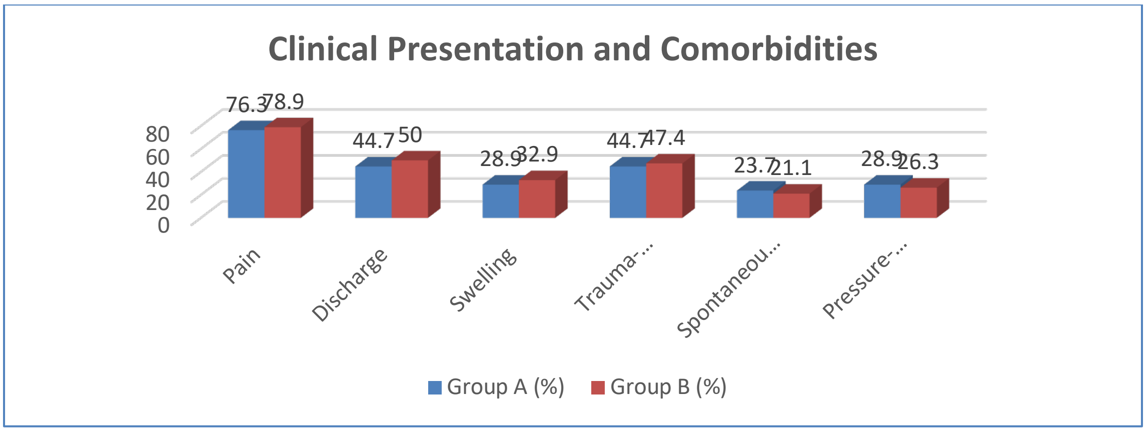

Figure 1 Clinical Presentation and Comorbidities

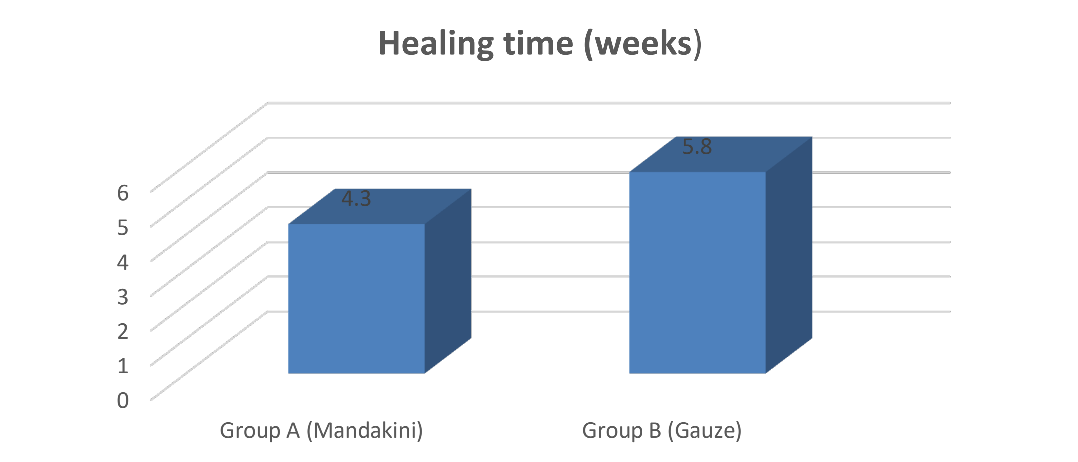

Figure-2 Healing time comparison

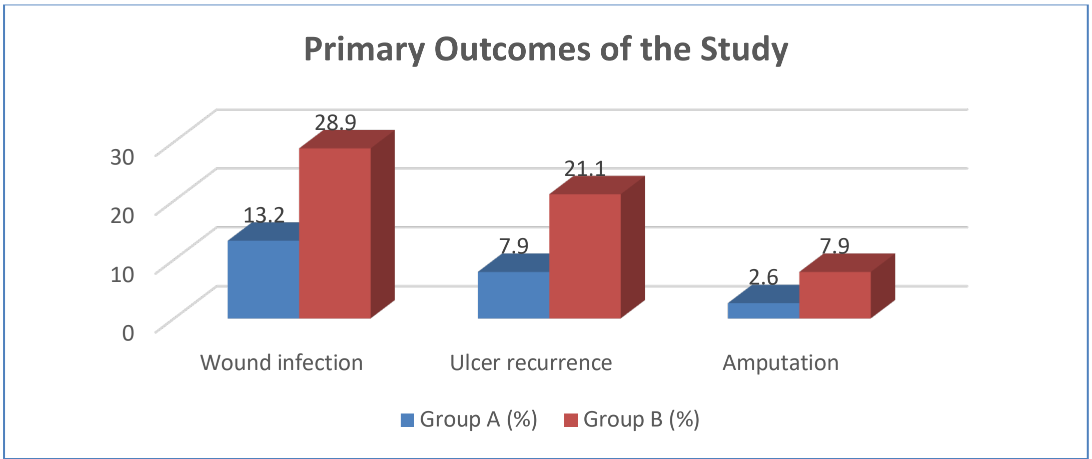

Figure 2 Primary Outcomes of the Study

Discussion:

Diabetic foot ulcer (DFU) is a major complication of diabetes mellitus, associated with prolonged morbidity, infection risk, and potential limb loss. The present prospective comparative study assessed the effectiveness of Mandakini off-loading dressing versus conventional gauze dressing in 154 patients with Wagner grade 1 and 2 plantar DFUs. Overall, Mandakini dressing demonstrated superior healing outcomes with reduced infection, recurrence, and improved wound resolution.Baseline characteristics were comparable between both groups, ensuring valid comparison. Mean age was similar in Group A (56.4 ± 9.8 years) and Group B (57.1 ± 10.2 years; p = 0.68). Similar age distribution has been reported by Modi et al. (2022)[21] (mean 53.97 ± 10.10 years) and Sanjeev et al. (2019)[22], confirming that DFU predominantly affects middle-aged and elderly populations. Male predominance observed in the present study (63.2% vs 65.8%) aligns with Ahmad et al. (2022)[23] and Sharma et al. (2025)[24], who reported higher DFU incidence in males due to occupational exposure, delayed care, and neuropathy risk.Clinical features such as pain (76.3% vs 78.9%) and discharge were similar across groups. Comparable findings were reported by Sanjeev et al. (2019)[22] and Semitha et al. (2023)[25], confirming homogeneous baseline presentation. Peripheral neuropathy was the most common comorbidity (68.4% vs 71.1%), consistent with Sharma et al. (2025)[24], who reported neuropathy prevalence of 60–80% in DFU patients. Similar comorbidity patterns were also reported by Ranade et al. (2021)[26].Duration of diabetes was comparable (8.6 ± 4.2 vs 8.9 ± 4.5 years), reflecting long-standing disease as a major risk factor, as supported by Modi et al. (2022)[21] and Elraiyah et al. (2016)[27]. Trauma-related onset was the leading cause (44.7% vs 47.4%), consistent with Ranade et al. (2021)[26], who emphasized minor trauma and repetitive pressure as key etiological factors.Baseline ulcer severity was comparable, predominantly Wagner grade 2, similar to findings of Modi et al. (2022)[21] and Kumbha et al. (2023)[28], ensuring unbiased outcome assessment.A key finding was significantly faster healing in the Mandakini group (4.3 ± 1.1 vs 5.8 ± 1.3 weeks; $p < 0.001$). Similar results were reported by Sanjeev et al. (2019)[22] and Modi et al. (2022)[21], demonstrating improved wound contraction with off-loading strategies. Infection rates were significantly lower in the Mandakini group (13.2% vs 28.9%), consistent with Naaz et al. (2024)[29] and Kumbha et al. (2023)[28], who reported improved wound bed conditions and reduced infection burden with off-loading dressings.Ulcer recurrence was significantly reduced (7.9% vs 21.1%), supporting findings of Sharma et al. (2025)[24] and Elraiyah et al. (2016)[27], who emphasized the importance of sustained off-loading in preventing recurrence. Although amputation rates were lower in the Mandakini group (2.6% vs 7.9%), the difference was not statistically significant, though Sanjeev et al. (2019)[22] reported better limb salvage with off-loading.Additionally, Mandakini dressing showed superior granulation tissue formation, reduced necrotic burden, and greater wound surface area reduction (0.4 ± 0.6 vs 1.3 ± 0.9 cm^2), consistent with Sanjeev et al. (2019)[22] and Kumbha et al. (2023)[28]. Reduced need for debridement further reflected improved wound healing dynamics, as also reported by Ranade et al. (2021)[26].

Conclusion

The present study demonstrated that Mandakini off-loading dressing is more effective than conventional gauze dressing in the management of diabetic plantar ulcers. It significantly reduced healing time, wound infection, recurrence rates, and improved wound healing parameters such as granulation tissue formation and wound contraction. Although amputation rates were lower in the Mandakini group, the difference was not statistically significant. Overall, Mandakini dressing provides a simple, cost-effective, and efficient off-loading method for improving clinical outcomes in diabetic foot ulcers.

Limitations of the study

The present study had a relatively short follow-up period of six weeks, which may not fully capture long-term outcomes such as late recurrence and sustained healing. The study was conducted at a single tertiary care center, which may limit the generalizability of the findings to other populations. Patient allocation was based on preference, which may introduce selection bias despite comparable baseline characteristics. Additionally, microbiological and biomechanical parameters of off-loading were not evaluated in detail, which could further strengthen the findings.

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