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CONVENTIONAL DRESSING VERSUS MANDAKINI DEVICE FOR DIABETIC FOOT ULCERS: A COMPARATIVE CLINICAL STUDY.

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Abstract

Background: Diabetic foot ulcer (DFU) is a major complication of diabetes mellitus and is associated with prolonged hospitalization, increased risk of infection, amputation, and healthcare expenditure. Effective wound management is essential for improving healing outcomes. The Mandakini device has emerged as a novel adjunctive modality aimed at enhancing wound healing through improved wound bed preparation and tissue regeneration. ***Aim:*** To compare the effectiveness of conventional dressing and the Mandakini device in the treatment of diabetic foot ulcers. ***Materials and Methods:*** This prospective comparative study was conducted over a period of 10 months in the Department of General Surgery. A total of 90 patients with diabetic foot ulcers fulfilling the inclusion criteria were enrolled and randomly allocated into two groups of 45 patients each. Group A received conventional wound dressing with normal saline and standard wound care, while Group B was treated using the Mandakini device in addition to routine diabetic foot management. Baseline demographic characteristics, ulcer characteristics, wound size, duration of diabetes, and associated comorbidities were recorded. Patients were followed periodically for assessment of wound healing and duration of hospital stay. Data were analyzed using appropriate statistical methods, and a p-value <0.05 was considered statistically significant. ***Results:*** The mean percentage reduction in ulcer area was significantly higher in the Mandakini device group (72.8 ± 11.6%) compared to the conventional dressing group (48.5 ± 13.4%) (p<0.001). Healthy granulation tissue developed in 40 (88.9%) patients treated with the Mandakini device compared to 29 (64.4%) patients receiving conventional dressing (p=0.006). Complete wound healing was achieved in 31 (68.9%) patients in the Mandakini group and 19 (42.2%) patients in the conventional dressing group (p=0.011). The incidence of persistent infection was lower in the Mandakini group, and fewer patients required secondary surgical procedures. The mean duration of hospital stay was significantly shorter in the Mandakini group (11.2 ± 2.9 days) compared to the conventional dressing group (15.4 ± 3.8 days) (p<0.001). No major device-related complications were observed. ***Conclusion:*** The Mandakini device demonstrated superior efficacy compared to conventional dressing in the management of diabetic foot ulcers. The findings suggest that the Mandakini device is a safe, effective, and valuable adjunct in diabetic foot ulcer management.

Keywords: Diabetic foot ulcer, Granulation tissue, Hospital stay, Mandakini device, Ulcer healing, Wound dressing.

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INTRODUCTION

Diabetes mellitus is one of the most prevalent chronic metabolic disorders worldwide and is associated with numerous microvascular and macrovascular complications.1 Among these, diabetic foot ulcer (DFU) remains one of the most challenging complications, contributing significantly to morbidity, disability, prolonged hospitalization, and healthcare expenditure. The lifetime risk of developing a diabetic foot ulcer is estimated to range between 15% and 25% among individuals with diabetes.2 Poor glycemic control, peripheral neuropathy, peripheral arterial disease, immunological dysfunction, and repetitive trauma are major factors involved in the pathogenesis of diabetic foot ulcers.3

Diabetic foot ulcers develop as a result of a complex interaction between neuropathy, ischemia, and infection. Sensory neuropathy predisposes patients to unnoticed trauma, while motor neuropathy causes foot deformities that increase plantar pressure.4 Autonomic neuropathy reduces sweating, resulting in dry and cracked skin that facilitates bacterial entry. In addition, peripheral vascular disease compromises tissue perfusion and oxygen delivery, impairing wound healing. These factors contribute to chronic non-healing ulcers and increase the risk of infection, gangrene, and lower limb amputation.5,6 Effective wound management is a cornerstone in the treatment of diabetic foot ulcers. Conventional dressing methods have long been employed as standard wound care practices.7 These dressings aim to maintain a moist wound environment,

absorb exudates, prevent contamination, and facilitate tissue repair. However, despite advances in wound care, healing of diabetic foot ulcers often remains slow and incomplete because of persistent infection, poor vascularity, and impaired cellular response associated with diabetes.8

Recent developments in wound management have focused on innovative techniques and devices that enhance wound healing by improving wound bed preparation, promoting granulation tissue formation, facilitating exudate removal, and reducing bacterial colonization.9 The Mandakini device is one such emerging modality that has gained attention for its potential role in accelerating the healing process of chronic wounds, including diabetic foot ulcers. The device is designed to create an optimal wound healing environment through effective wound drainage, improved local circulation, and enhanced tissue regeneration.10 By promoting healthy granulation tissue formation and reducing wound contamination, it may provide superior healing outcomes compared to conventional dressing methods.11

Several studies have demonstrated that advanced wound care modalities can significantly reduce wound size, decrease healing time, and lower the risk of complications in diabetic foot ulcers. Improved wound healing not only reduces the duration of hospital stay but also minimizes the need for repeated debridement procedures, skin grafting, and limb amputations. Early wound closure further contributes to improved patient quality of life and reduced healthcare costs.12Despite the increasing use of advanced wound care technologies, evidence regarding the effectiveness of the Mandakini device in comparison with conventional dressing remains limited, particularly in the Indian population.

AIMS AND OBJECTIVES

- To compare the effectiveness of conventional dressing and the Mandakini device in the treatment of diabetic foot ulcers.

MATERIALS AND METHODS

This prospective comparative study was conducted in the Department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Tamil Nadu, over a period of 10 months from August 2024 to May 2025. Written informed consent was obtained from all participants prior to enrollment.

Inclusion Criteria

- Patients aged 18 years and above.
- Patients with Type 1 or Type 2 diabetes mellitus.
- Patients presenting with diabetic foot ulcers classified as Wagner Grade I, II, or III.
- Patients willing to provide written informed consent and comply with follow-up.

Exclusion Criteria

- Patients with Wagner Grade IV and Grade V diabetic foot ulcers requiring immediate major amputation.
- Patients with severe peripheral arterial disease requiring vascular intervention.
- Patients with osteomyelitis confirmed radiologically or clinically.
- Patients with active malignancy involving the lower limb.
- Patients receiving immunosuppressive therapy or suffering from immunodeficiency disorders.
- Pregnant or lactating women.
- Patients unwilling to participate in the study.

A total of 90 patients diagnosed with diabetic foot ulcers and attending the surgical outpatient department or admitted to the surgical wards were included in the study. Patients fulfilling the eligibility criteria were consecutively recruited and allocated into two groups of 45 patients each. Group A received conventional wound dressing with normal saline-soaked gauze and standard diabetic foot care, while Group B underwent wound management using the Mandakini device along with standard diabetic foot ulcer treatment protocols. All patients received appropriate glycemic control, antibiotic therapy based on clinical assessment and culture sensitivity whenever indicated, regular wound debridement, and management of associated comorbidities.

A detailed clinical history was obtained from each patient, including age, sex, duration of diabetes mellitus, glycemic status, associated comorbidities, duration of ulcer, history of previous ulceration, smoking status, and treatment history. Thorough clinical examination of the ulcer was performed, documenting ulcer site, size, depth, presence of slough, discharge, granulation tissue, cellulitis, and evidence of peripheral neuropathy or peripheral vascular disease. Baseline laboratory investigations including complete blood count, fasting and postprandial blood glucose levels, HbA1c, renal function tests, and wound culture when required were carried out. The ulcer dimensions were measured at baseline and during follow-up visits using a standardized wound assessment method. Wound healing parameters including percentage reduction in ulcer area, granulation tissue formation, wound discharge, infection status, need for debridement, duration of hospitalization,

and final wound outcome were recorded and compared between the two groups. Patients were followed regularly throughout the treatment period until satisfactory wound healing, discharge from the hospital, or completion of the study period. The collected data were entered into a structured proforma and analyzed using appropriate statistical software. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Comparison between groups was performed using the Chi-square test for categorical variables and Student's t-test for continuous variables. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 90 patients with diabetic foot ulcers were included in the study. They were equally distributed into the Conventional Dressing Group (n=45) and the Mandakini Device Group (n=45). Baseline demographic and clinical characteristics were comparable between the groups. Majority of patients belonged to the age group of 51–60 years and males constituted the predominant proportion of the study population. No statistically significant differences were observed, ensuring homogeneity of study participants before intervention. (Table 1).

Table 1. Baseline Demographic Characteristics of the Study Population

Variable	Conventional Dressing (n=45)	Mandakini Device (n=45)	p-value
Mean Age (years)	56.8 ± 8.7	55.9 ± 9.2	0.642
Male	29 (64.4%)	29 (64.4%)	1.000
Female	16 (35.6%)	16 (35.6%)	1.000
Duration of Diabetes >10 years	24 (53.3%)	26 (57.8%)	0.668
HbA1c >8%	27 (60.0%)	25 (55.6%)	0.669

Ulcer severity and wound characteristics at presentation were similar in both groups. The absence of significant differences indicates that treatment outcomes could be attributed to the intervention rather than baseline disparities. (Table 2).

Table 2. Baseline Ulcer Characteristics

Variable	Conventional Dressing (n=45)	Mandakini Device (n=45)	p-value
Mean Ulcer Area (cm^2)	14.8 ± 4.5	15.2 ± 4.8	0.682
Wagner Grade I	12 (26.7%)	13 (28.9%)	0.817
Wagner Grade II	22 (48.9%)	21 (46.7%)	0.832
Wagner Grade III	11 (24.4%)	11 (24.4%)	1.000
Presence of Slough	31 (68.9%)	29 (64.4%)	0.651

Patients treated with the Mandakini device demonstrated significantly superior wound healing outcomes. Greater ulcer size reduction, enhanced granulation tissue formation, and higher complete healing rates were observed compared to conventional dressing. (Table 3).

Table 3. Comparison of Wound Healing Outcomes

Outcome Variable	Conventional Dressing (n=45)	Mandakini Device (n=45)	p-value
Mean Percentage Reduction in Ulcer Area	48.5 ± 13.4%	72.8 ± 11.6%	<0.001*
Healthy Granulation Tissue Formation	29 (64.4%)	40 (88.9%)	0.006*
Complete Wound Healing	19 (42.2%)	31 (68.9%)	0.011*
Persistent Infection	14 (31.1%)	5 (11.1%)	0.021*

The Mandakini device significantly reduced hospital stay and the requirement for additional surgical procedures. Patients managed with the device showed faster wound bed preparation and improved clinical recovery. (Table 4).

Table 4. Hospital Stay and Need for Surgical Intervention

Variable	Conventional Dressing (n=45)	Mandakini Device (n=45)	p-value
Mean Hospital Stay (days)	15.4 ± 3.8	11.2 ± 2.9	<0.001*
Repeat Debridement Required	12 (26.7%)	4 (8.9%)	0.026*
Skin Grafting Required	10 (22.2%)	3 (6.7%)	0.035*
Minor Amputation	5 (11.1%)	1 (2.2%)	0.091

A significant association was observed between use of the Mandakini device and complete wound healing. Patients treated with the device had a substantially higher probability of achieving complete ulcer closure. (Table 5).

Table 5. Correlation Between Treatment Modality and Complete Wound Healing

Treatment Modality	Complete Healing n (%)	Incomplete Healing n (%)	p-value
Conventional Dressing (n=45)	19 (42.2%)	26 (57.8%)	0.011*
Mandakini Device (n=45)	31 (68.9%)	14 (31.1%)	

Better wound healing was significantly associated with good glycemic control, smaller ulcer size, use of the Mandakini device, and absence of persistent infection. Poor glycemic control and larger ulcers adversely affected healing outcomes. (Table 6).

Table 6. Correlation of Clinical Variables with Complete Wound Healing

Variable	Complete Healing (n=50)	Incomplete Healing (n=40)	p-value
HbA1c ≤8%	33 (66.0%)	5 (12.5%)	<0.001*
HbA1c >8%	17 (34.0%)	35 (87.5%)	
Ulcer Area <15 cm²	36 (72.0%)	12 (30.0%)	<0.001*
Ulcer Area ≥15 cm²	14 (28.0%)	28 (70.0%)	
Mandakini Device Use	31 (62.0%)	14 (35.0%)	0.011*
Persistent Infection Present	6 (12.0%)	13 (32.5%)	0.019*

DISCUSSION

Diabetic foot ulcer (DFU) remains one of the most challenging complications of diabetes mellitus and is associated with delayed wound healing, recurrent infections, prolonged hospitalization, and increased risk of lower-limb amputation. The study population predominantly comprised middle-aged and elderly individuals, with a mean age of 56.4 ± 9.8 years. Males accounted for 58 (64.4%) patients, reflecting the higher prevalence of diabetic foot complications among men. Similar demographic patterns were reported by Modi S et al.12 who observed a mean age of 53.97 ± 10.10 years among patients with diabetic foot ulcers. Baseline characteristics, including age, gender distribution, duration of diabetes, glycemic status, ulcer size, and Wagner grade, were comparable between the two groups. More than half of the patients had diabetes for over 10 years, and 52 (57.8%) patients had HbA1c levels greater than 8%, indicating poor glycemic control and a higher risk of impaired wound healing. Modi S et al.12 similarly reported poor glycemic control in a substantial proportion of patients and highlighted its adverse impact on ulcer healing outcomes.

Wound healing outcomes were significantly superior in patients managed with the Mandakini device. The mean percentage reduction in ulcer area was 72.8 ± 11.6% in the Mandakini group compared with 48.5 ± 13.4% in the conventional dressing group. Healthy granulation tissue formation was observed in 40 (88.9%) patients receiving Mandakini therapy compared with 29 (64.4%) patients receiving conventional dressing. Comparable findings were reported by Sanjeev S et al.13 who demonstrated a significantly greater reduction in ulcer size and faster healing among patients treated with Mandakini dressing. Similarly, Arun T et al.14 observed significantly improved healing rates in off-loaded diabetic foot ulcers managed using the Mandakini technique. Complete wound healing was achieved in 31 (68.9%) patients treated with the Mandakini device compared with 19 (42.2%) patients in the conventional dressing group. Persistent infection was observed in only 5 (11.1%) patients in the Mandakini group, whereas 14 (31.1%) patients in the conventional group continued to show signs of infection.

Improved wound drainage, pressure redistribution, and maintenance of a favorable wound-healing environment may explain the lower infection rates and enhanced healing outcomes. Miyan Z et al.15 also reported high healing rates exceeding 94% with various off-loading techniques, emphasizing the importance of pressure relief in ulcer management. Likewise, Lázaro-Martínez JL et al.16 demonstrated high healing rates among patients receiving advanced off-loading interventions. The need for additional surgical procedures was lower in the Mandakini group. Repeat debridement was required in only 4 (8.9%) patients compared with 12 (26.7%) patients receiving conventional dressing. Skin grafting was necessary in 3 (6.7%) patients in the Mandakini group and 10 (22.2%) patients in the conventional group. Minor amputation was performed in only 1 (2.2%) patient treated with Mandakini therapy compared with 5 (11.1%) patients managed conventionally. These findings indicate that improved ulcer healing translates into reduced procedural interventions and lower morbidity.

The mean duration of hospital stay was significantly shorter in the Mandakini group (11.2 ± 2.9 days) compared with the conventional dressing group (15.4 ± 3.8 days). Faster wound healing and fewer complications likely contributed to earlier discharge and reduced healthcare utilization. Sanjeev S et al.13 similarly reported shorter healing times and improved

patient satisfaction among patients treated with Mandakini dressing. Furthermore, Lee MY et al.17 demonstrated that the Mandakini device effectively reduces plantar pressure and pressure-time integral, thereby promoting ulcer healing through improved off-loading. The importance of off-loading in DFU management is further supported by the systematic review of Elraiyah T et al.18 which identified off-loading as a key intervention for enhancing healing rates and reducing ulcer size.

CONCLUSION

The Mandakini device was found to be an effective and safe modality for the management of diabetic foot ulcers. Its use resulted in significantly greater wound contraction, enhanced granulation tissue formation, higher rates of complete wound healing, reduced infection, and decreased need for additional surgical interventions when compared with conventional dressing. Patients treated with the Mandakini device also experienced shorter hospital stay and faster clinical recovery. Good glycemic control and smaller ulcer size further contributed to favorable healing outcomes. The findings suggest that the Mandakini device is a valuable adjunct in diabetic foot ulcer care and may improve overall patient outcomes.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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