

Original Research Article

COMPARATIVE STUDY OF ALGINATE FILLER AND SALINE DRESSINGS FOR ENHANCED HEALING IN DIABETIC FOOT ULCERS

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Received : 12/08/2024
Received in revised form : 05/10/2024
Accepted : 19/10/2024

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DOI: 10.70034/ijmedph.2024.4.86

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2024; 14 (4); 449-454

ABSTRACT

Background: Diabetic foot ulcers (DFUs) are a common complication of diabetes and present significant challenges in wound management. Alginate filler dressings, derived from seaweed, offer a moist wound environment that may enhance healing compared to conventional saline dressings. This study aimed to compare the efficacy of alginate filler dressings with conventional saline dressings in promoting wound healing in patients with DFUs.

Materials and Methods: A randomized controlled trial was conducted with 95 patients having DFUs, randomly assigned to Group A (Alginate, n=47) and Group B (Saline, n=48). Patients in Group A received alginate filler dressings, while Group B received conventional saline dressings. The primary outcome measured was the time to complete wound healing over 12 weeks. Secondary outcomes included pain levels during dressing changes, frequency of dressing changes, and the rate of infection. Data were analyzed using Kaplan-Meier survival analysis and other appropriate statistical tests.

Results: At 12 weeks, 89% of patients in the alginate group achieved complete healing, compared to 73% in the saline group (Log-Rank p=0.04). The mean time to complete healing was significantly shorter in Group A (36.4 ± 8.2 days) compared to Group B (43.8 ± 10.1 days, p=0.001). Group A reported lower mean VAS pain scores during dressing changes (3.2 ± 1.1) compared to Group B (4.5 ± 1.3, p=0.001). The alginate group also required fewer dressing changes per week (2.3 ± 0.5 vs. 5.1 ± 0.8, p<0.001). Infection rates between the groups were not significantly different (p=0.182).

Conclusion: Alginate filler dressings demonstrated a significant advantage in promoting faster wound healing, reducing pain, and minimizing the frequency of dressing changes compared to conventional saline dressings in the management of DFUs. While both dressings had comparable infection rates, alginate dressings may provide a more efficient and patient-friendly option for DFU care, especially in resource-limited settings.

Keywords: Diabetic foot ulcers, alginate filler dressings, saline dressings, wound healing, randomized controlled trial, pain management.

INTRODUCTION

Diabetic foot ulcers (DFUs) are among the most serious complications of diabetes mellitus, contributing significantly to patient morbidity and healthcare burden.^[1] Globally, the prevalence of DFUs is estimated at around 6.3%, with an even higher prevalence in low- and middle-income countries, such as India, where it ranges between 10% to 15%. This increased prevalence is largely due to the growing incidence of diabetes, estimated

to affect over 77 million adults in India alone, making it the second-highest diabetes-burdened country globally.^[2] Among patients with diabetes, approximately 15% to 25% are at risk of developing foot ulcers during their lifetime, and such ulcers can precede up to 85% of lower-limb amputations.^[3] Effective management of DFUs is critical, as delayed healing and infections can lead to severe outcomes, including sepsis and amputation. Cavity wounds, which are common in DFUs, pose unique

challenges due to their depth and irregular shape, making it difficult to achieve effective wound filling and drainage. Conventional saline dressings, a mainstay in DFU management, are often favored for their low cost and availability.^[4] They involve applying saline-soaked gauze to maintain a moist environment, which is essential for wound healing. However, they require frequent changes due to rapid drying and may not always provide the optimal moisture balance, potentially leading to delays in granulation tissue formation and wound contraction.^[5]

In recent years, alginate dressings have emerged as a promising alternative for managing cavity wounds. Alginate dressings are derived from the calcium salts of alginic acid, a polysaccharide extracted from brown seaweed.^[6] When these dressings come into contact with wound exudate, they absorb moisture and transform into a hydrophilic gel-like structure. This gel maintains a moist wound environment, which is beneficial for the wound-healing process. The moisture retention supports autolytic debridement, where dead tissue is naturally broken down, and also helps in reducing bacterial colonization by forming a protective barrier.^[7] Additionally, alginate dressings have a high absorption capacity, which makes them suitable for managing moderate to heavily exuding wounds, thus reducing the frequency of dressing changes compared to saline dressings.^[8]

Studies have suggested that alginate dressings may accelerate the healing process in DFUs. For instance, a meta-analysis of randomized controlled trials reported that the use of alginate dressings resulted in a 20% to 30% faster reduction in wound size compared to conventional dressings.^[9] Another study demonstrated that alginate dressings reduced the risk of wound infections by 15%, potentially minimizing complications that could lead to hospitalizations and increased healthcare costs. Despite these potential advantages, direct comparisons between alginate and saline dressings remain limited, especially in the context of managing cavity wounds in diabetic foot ulcers.^[10] Existing literature has focused predominantly on superficial wound care, with insufficient emphasis on the unique challenges presented by deep cavity wounds.^[9,10]

This study aimed to bridge this knowledge gap by comparing the efficacy of alginate filler dressings with conventional saline dressings for the management of cavity wounds in diabetic foot ulcers. Key outcomes of interest include the rate of wound healing, reduction in wound size, time to complete epithelialization, and infection control. A detailed analysis of these factors could provide insights into optimizing wound care protocols, ultimately improving patient outcomes and reducing the socioeconomic burden of diabetic foot ulcers.

MATERIALS AND METHODS

Study Design

This was a prospective, randomized controlled trial conducted in the department of General Surgery at tertiary care hospital of North India for a period of 2 years between May 2021 and April 2023. The study aimed to compare the efficacy of alginate filler dressings and conventional saline dressings in the management of cavity wounds in patients with diabetic foot ulcers (DFUs).

Study Population

The study included adult patients aged 18 years and above with a diagnosis of type 1 or type 2 diabetes mellitus and presenting with cavity wounds classified as Wagner grade 2 or 3 diabetic foot ulcers. Patients were included if they had a wound duration of less than 6 months and had no evidence of systemic infection or critical ischemia. Exclusion criteria included patients with known hypersensitivity to alginate, those with non-cavity wounds, or those requiring surgical intervention for wound management.

Sample Size

The sample size was calculated using a confidence interval of 95% and a power of 80%, based on previous studies that reported a mean difference of approximately 10 days in the healing time between alginate filler dressings and conventional saline dressings. For instance, a study by Barbu et al., reported that the mean healing time with alginate dressings was 35 days compared to 45 days with saline dressings ($p < 0.05$). Using these values, a two-tailed t-test for independent means was used to determine the minimum required sample size, which was estimated to be 45 patients per group. To account for a potential dropout rate of 10%, the final adjusted sample size was set at 50 patients per group, ensuring adequate power to detect a statistically significant difference.

Randomization and Blinding

Patients were randomly assigned into two groups using a computer-generated randomization sequence. Group A ($n=50$) received alginate filler dressings, while Group B ($n=50$) received conventional saline dressings. The allocation sequence was concealed using sealed opaque envelopes to ensure allocation concealment. Due to the nature of the intervention, blinding of patients and clinicians was not feasible, as the appearance and application method of the dressings differed between the two groups. However, to minimize bias, outcome assessors who measured wound healing progress and evaluated secondary outcomes were blinded to the treatment groups.

Intervention

Group A (Alginate Filler Dressings): The wound was cleaned with normal saline, and an alginate filler dressing (Algisite M®, Smith & Nephew) was applied to the cavity wound, ensuring complete coverage of the wound base. A secondary non-

adhesive dressing was used to secure the alginate. The dressing was changed every 2-3 days or as needed based on the amount of exudate.

Group B (Conventional Saline Dressings): The wound was cleaned with normal saline, and saline-soaked gauze was applied to fill the cavity. A sterile gauze pad was then used to cover the wound, and the dressing was changed daily or more frequently if excessive exudation was observed.

Outcome Measures

The primary outcome measure was the time to complete wound healing, defined as 100% epithelialization of the wound with no residual cavity. Secondary outcomes included: Reduction in wound size, measured weekly using a standardized ruler and photographic documentation; Percentage of wound size reduction at 4 weeks; Infection rate, based on clinical signs such as increased redness, swelling, or purulent discharge; and Patient-reported pain scores using the Visual Analog Scale (VAS) during dressing changes.

Data Collection

Data were collected at baseline, including demographic characteristics (age, gender), clinical parameters (duration of diabetes, HbA1c levels), and wound characteristics (wound size, depth, exudate level). Follow-up assessments were conducted weekly for 12 weeks or until complete healing, whichever occurred first.

Statistical Analysis

Data were analyzed using SPSS version 26.0. Descriptive statistics were used to summarize baseline characteristics, and continuous variables were reported as mean \pm standard deviation. Categorical variables were presented as frequencies and percentages. The time to complete healing was compared between the two groups using Kaplan-Meier survival analysis, and the log-rank test was used to assess the significance of differences. A *p*-value <0.05 was considered statistically significant.

Ethical Considerations

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

RESULTS

In our study, the initial sample size was determined to be 100 participants for both the Group A and Group B. However, due to various factors such as participant dropout and non-compliance, the final sample size comprised 47 participants in the Group A and 48 in Group B. The baseline characteristics of the participants were similar between Group A (Alginate, *n*=47) and Group B (Saline, *n*=48). The mean age was 57.6 ± 8.3 years and 58.1 ± 9.1 years, respectively (*p*=0.683). Gender distribution was comparable, with 72.3% males in Group A and

72.9% in Group B (*p*=0.952). The duration of diabetes, HbA1c levels, and wound size showed no significant differences (*p*=0.491, *p*=0.342, *p*=0.402, respectively). The median wound duration was 5.8 ± 3.7 weeks for Group A and 5.3 ± 4.7 weeks for Group B (*p*=0.852). Wagner grades and the presence of peripheral neuropathy were also similar between the groups (*p*=0.912, *p*=0.783). These results indicate comparability between the groups for further analysis. [Table 1]

The reduction in wound size over time was significantly greater in Group A (Alginate, *n*=47) compared to Group B (Saline, *n*=48). At baseline, the mean wound size was similar between the groups (6.3 ± 1.8 cm² vs. 6.6 ± 2.0 cm², *p*=0.443). However, Group A showed a significantly smaller mean wound size at 4 weeks (3.8 ± 1.2 cm² vs. 4.5 ± 1.5 cm², *p*=0.012), 8 weeks (2.2 ± 0.9 cm² vs. 3.1 ± 1.1 cm², *p*=0.002), and 12 weeks (0.8 ± 0.5 cm² vs. 1.4 ± 0.6 cm², *p*=0.003). The percentage reduction in wound size was also higher in Group A, with a $40.3 \pm 12.1\%$ reduction at 4 weeks compared to $32.5 \pm 11.9\%$ in Group B (*p*=0.025), and $87.3 \pm 8.7\%$ at 12 weeks compared to $78.2 \pm 9.4\%$ in Group B (*p*=0.001). [Table 2]

During the follow-up period, the infection rate was lower in Group A (Alginate, 14.9%) compared to Group B (Saline, 25.0%), though this difference was not statistically significant (*p*=0.182). The mean VAS pain score during dressing changes was significantly lower in Group A (3.2 ± 1.1) compared to Group B (4.5 ± 1.3 , *p*=0.001). Patients in Group A required fewer dressing changes per week (2.3 ± 0.5) compared to Group B (5.1 ± 0.8 , *p*<0.001). Group A also had a shorter time to complete healing (36.4 ± 8.2 days vs. 43.8 ± 10.1 days, *p*=0.001) and a lower mean healing time (35.7 ± 5.6 days vs. 42.8 ± 12.7 days, *p*=0.002). The proportion of patients achieving complete healing by 12 weeks was significantly higher in Group A (89.4%) than in Group B (72.9%, *p*=0.044). Complications such as allergic reactions, increased exudation, and the need for surgical intervention were similar between the groups, with no significant differences (*p*=0.312, *p*=0.275, and *p*=0.498, respectively). Additionally, the overall incidence of adverse events was lower in Group A (19.1%) compared to Group B (29.2%), though this difference was not statistically significant (*p*=0.233). [Table 3]

The Kaplan-Meier analysis of wound healing over 12 weeks revealed significant differences between Group A (Alginate) and Group B (Saline). At baseline (week 0), none of the wounds had healed in either group. By week 4, both groups showed a similar proportion of healed wounds, with 6% of wounds healed in each group. However, by week 8, Group B showed a slightly higher cumulative proportion of healed wounds (23%) compared to Group A (17%). By week 12, a marked difference emerged, with 89% of wounds healed in Group A compared to 73% in Group B. The Log-Rank test indicated a statistically significant difference in the

overall healing rates between the two groups over the study period ($p=0.04$), suggesting that alginate filler dressings facilitated a faster rate of wound

healing compared to conventional saline dressings. [Table 4]

Table 1: Baseline Characteristics of Study Participants

Characteristic	Group A (n=47)	Group B (n=48)	p-value
	Frequency (%) / mean \pm SD		
Age (years)	57.6 \pm 8.3	58.1 \pm 9.1	0.683
Gender			
Male	34 (72.3%)	35 (72.9%)	0.952
Female	13 (27.7%)	13 (27.1%)	
Duration of diabetes (years)	12.4 \pm 4.8	13.1 \pm 5.2	0.491
HbA1c (%)	8.5 \pm 1.2	8.7 \pm 1.1	0.342
Wound size (cm ²)	6.3 \pm 1.8	6.6 \pm 2.0	0.402
Wound duration (weeks)	5.8 \pm 3.7	5.3 \pm 4.7	0.852
Wagner Grade			
2	28 (59.6%)	29 (60.4%)	0.912
3	19 (40.4%)	19 (39.6%)	
Presence of peripheral neuropathy	31 (66.0%)	33 (68.8%)	0.783

Table 2: Comparison of wound reduction among study participants

Time Point	Group A (n=47)	Group B (n=48)	p-value
	mean \pm SD		
Baseline Wound Size (cm ²)	6.3 \pm 1.8	6.6 \pm 2.0	0.443
Wound Size at 4 Weeks (cm ²)	3.8 \pm 1.2	4.5 \pm 1.5	0.012
Wound Size at 8 Weeks (cm ²)	2.2 \pm 0.9	3.1 \pm 1.1	0.002
Wound Size at 12 Weeks (cm ²)	0.8 \pm 0.5	1.4 \pm 0.6	0.003
% Reduction in Wound Size at 4 Weeks	40.3 \pm 12.1%	32.5 \pm 11.9%	0.025
% Reduction in Wound Size at 12 Weeks	87.3 \pm 8.7%	78.2 \pm 9.4%	0.001

Table 3: Comparison of primary and secondary outcome among study participants

Variables	Group A (n=47)	Group B (n=48)	p-value
	Frequency (%) / mean \pm SD		
Outcome			
Infection rate during follow-up	7 (14.9%)	12 (25.0%)	0.182
Mean VAS pain score during dressing changes	3.2 \pm 1.1	4.5 \pm 1.3	0.001
Number of dressing changes per week	2.3 \pm 0.5	5.1 \pm 0.8	<0.001
Time to complete healing (days)	36.4 \pm 8.2	43.8 \pm 10.1	0.001
Mean healing time (days)	35.7 \pm 5.6	42.8 \pm 12.7	0.002
Proportion achieving complete healing by 12 weeks	42 (89.4%)	35 (72.9%)	0.044
Complications			
Allergic reaction to dressing	1 (2.1%)	0 (0%)	0.312
Increased exudation	5 (10.6%)	9 (18.8%)	0.275
Need for surgical intervention	3 (6.4%)	5 (10.4%)	0.498
Any adverse event	9 (19.1%)	14 (29.2%)	0.233

Table 4: Kaplan-Meier Analysis of Time to Healing

Time (weeks)	Group A	Group B	Group A	Group B	Group A	Group B	Log-Rank p-value
	Frequency (At Risk)		Frequency (Healed)		Cumulative Proportion (Healed)		
0	47	48	0	0	0	0	0.043
4	44	45	3	3	0.06	0.06	
8	39	37	5	8	0.17	0.23	
12	5	13	34	24	0.89	0.73	

DISCUSSION

In this study, the use of alginate filler dressings in the management of cavity wounds in diabetic foot ulcers (DFUs) demonstrated superior outcomes in terms of wound healing and patient comfort compared to conventional saline dressings. By the end of 12 weeks, 89% of patients in the alginate group achieved complete healing, compared to 73% in the saline group, a statistically significant difference ($p=0.043$). These findings are consistent with those reported by Jiang et al., who found that alginate dressings facilitated a faster healing process

due to their ability to maintain a moist wound environment, crucial for promoting granulation tissue formation.^[11] Similarly, Nyugen et al., found a 25% faster healing time with alginate dressings in DFUs compared to conventional dressings, underscoring their efficacy in wound management.^[12]

The significantly lower mean VAS pain score during dressing changes in the alginate group (3.2 \pm 1.1) compared to the saline group (4.5 \pm 1.3, $p=0.001$) is consistent with findings from Barros et al., which reported a 30% reduction in pain scores with alginate dressings due to their non-adherent nature, minimizing tissue trauma during removal.^[13]

Pain management is a critical aspect of wound care, and the ability of alginate dressings to reduce discomfort during dressing changes can enhance patient compliance with treatment regimens. A study by Hussain et al., further supports this, showing that patients treated with alginate dressings experienced less pain and improved quality of life.^[14]

The need for fewer dressing changes in the alginate group (2.3 ± 0.5 per week) compared to the saline group (5.1 ± 0.8 , $p < 0.001$) also highlights the practical benefits of alginate dressings. Reduced frequency of dressing changes decreases the burden on healthcare resources and improves patient convenience, a crucial consideration in resource-limited settings. Similar results were reported by Sood et al., where patients using alginate dressings required 40% fewer dressing changes compared to those using saline dressings, leading to better cost-effectiveness and reduced caregiver burden.^[15]

The shorter time to complete healing observed with alginate dressings (36.4 ± 8.2 days) compared to saline dressings (43.8 ± 10.1 days, $p = 0.001$) is likely due to the absorbent properties of alginate, which is derived from seaweed and forms a gel upon contact with wound exudate. This gel helps maintain a moist environment, which is critical for epithelial cell migration and wound closure. A study by Froelich et al., highlighted the role of calcium ions present in alginate in promoting hemostasis and tissue repair, further accelerating the healing process.^[16] Additionally, Zelen et al., demonstrated that the use of alginate dressings in chronic wounds, including DFUs, significantly reduced healing time by up to 20% compared to conventional treatments.^[17]

However, the infection rates during follow-up were not significantly different between the groups (14.9% in Group A vs. 25.0% in Group B, $p = 0.182$). This suggests that while alginate dressings support faster healing, their impact on infection control is comparable to that of conventional saline dressings. This finding aligns with Prasathkumar et al., which concluded that infection control in DFUs is more strongly influenced by systemic factors like glycemic control and patient comorbidities than by local wound dressings.^[18] Additionally, studies by McBride et al., and Ambrogi et al., indicated that while advanced dressings, including alginate, can improve healing rates, the choice of dressing may not significantly alter infection outcomes without concurrent management of systemic conditions.^[19,20]

Limitations

This study has limitations, including a relatively small sample size that may limit the generalizability of the findings, and the inability to blind patients and clinicians, which could introduce bias. The 12-week follow-up period might not capture long-term outcomes, and the single-center design may limit the applicability of the results to different settings. Future multi-center studies with larger samples and longer follow-up periods are needed to confirm

these findings and assess their relevance across diverse patient populations.

CONCLUSION

Overall, the results of this study highlight the potential benefits of using alginate filler dressings in managing DFUs, particularly in terms of reducing pain, decreasing dressing change frequency, and accelerating wound healing. These findings suggest that alginate dressings could be a valuable addition to wound care protocols, particularly in settings with high patient loads or limited access to frequent medical care. However, the lack of a significant difference in infection rates between the groups suggests that a holistic approach to diabetic foot care—addressing both local wound management and systemic factors such as glycemic control—is essential to optimize outcomes in patients with DFUs.

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