

EFFICACY OF COMBINED ALGINATE AND HYDROCOLLOID SURGICAL DRESSING IN THE QUICKER HEALING OF DEBRIDED INFECTED DIABETIC FOOT ULCERS

Qaviullah Mian, Tayyaba Ayaz, Muhammad Naeem, Rashid Waheed, Mushtaq Ahmad, Ameer Hamza

1.MTI Khyber Teaching Hospital Peshawar.

Corresponding Email: qaviullahmian@gmail.com

ABSTRACT

BACKGROUND: Diabetes is one of the more serious diseases afflicting our world today. Since of 2019, it has been estimated that 8.8% of the total world population is suffering from diabetes mellitus and the incidence pattern indicates that these rates will continue to increase. Of the wide assortment of complications associated with diabetes mellitus, the diabetic foot ulcer in the most challenging. On one hand, mere glycemic control may prevent the occurrence of this debilitating condition while on the other it may progress to full blown gangrene, necessitating amputation. It is estimated that in the year 2025, Pakistan will be 4th on the list with about 14.5 million people suffering from diabetes mellitus.

OBJECTIVE: To assess the effectiveness of a combination of alginate and hydrocolloid dressing in diabetic foot ulcer in terms of wound healing in comparison with the routine pyodine dressing.

METHODOLOGY: This descriptive study was carried out over 110 patients. After written consent, all the patients were treated with intravenous antibiotics according to culture and sensitivity reports and were then followed by oral antibiotics for a period of 2 weeks. Patients were divided into two groups, A and B. Group A patients underwent dressing with traditional pyodine. Group B patients underwent dressing using a combination of alginate and colloid gel. The dressings were performed till the complete healing of the wound after one month time.

RESULTS: In this study, 110 patients were observed. Average age was 50.64 years + 9.24 SD. Two groups were created, Group A and Group B. Patients were randomly allocated to each group, 55 to group A and 55 to group B. Group A patients underwent multiple dressings using a combination of alginate and hydrocolloid till the complete healing of the wound after one month time. Group B patients underwent the traditional pyodine dressing and the effectiveness of group A was compared against group B. The mean pre-treatment wound diameter was 4.81 ± 0.85 cm in the Group B, while it was 4.84 ± 0.81 cm in Group A. $P = 0.875$). The mean post-treatment wound diameter was 3.90 ± 0.76 cm in the pyodine group, while it was 2.46 ± 0.57 cm in the alginate plus hydrocolloid group (CI 0.44–0.58, $P = 0.022$). The mean wound difference was 0.91 ± 0.25 cm in the pyodine group, while it was 2.4 ± 0.34 cm in the alginate plus hydrocolloid group (CI 0.40–0.20, $P = 0.041$). The mean percent reduction in wound diameter was $19.2 \pm 4.6\%$ in the pyodine group, while it was $49.7 \pm 5.2\%$ cm in the alginate plus hydrocolloid group (CI 10.6–6.1, $P = 0.001$).

CONCLUSION: A combination of colloid and alginate dressing shows increased effectiveness in healing diabetic foot ulcers in comparison to the normal traditional pyodine dressing.

KEYWORDS: Efficacy, Alginate, Colloid dressing, Diabetic Foot Ulcer, Diabetic

INTRODUCTION:

Diabetes is one of the more serious diseases afflicting our world today. Since 2019, it has been estimated that 8.8% of the total world population is suffering from diabetes mellitus and the incidence pattern indicates that these rates will continue to increase.¹ Of the wide assortments of complications associated with diabetes mellitus, diabetic foot ulcer is the most challenging. On one hand, mere glycemic control may prevent the occurrence of this debilitating condition while on the other it may progress to full blown gangrene, necessitating amputation. It is the extreme nature of this complication which warrants special attention. Research shows that the entire

lifetime risk of developing foot ulcers in a diabetic patient is 15% and it may reach as high as 25%², with high incidence of amputation.³

The phrase 'Diabetic Foot' encompasses within its domain an extensive number of pathologies which include peripheral vascular disease, diabetic neuropathy, foot ulceration, Charcot's neuropathy, osteomyelitis and ultimately limb amputation.⁴ Diabetic foot has a bad prognosis and eventually results in amputation.⁵ In spite of efforts to control diabetes and ameliorate limb salvage, the incidence of amputations has continued to rise.⁶ It is because of this and the preventable nature of this disease which requires early recognition of risk factors and adequate

management.⁷ Effective diabetic control and timely detection of foot complications will decrease the number of major amputations performed in the diabetic community.⁸

Wound dressings are widely used to treat diabetic foot infections. Moist dressings perpetuate a wound habitat which promotes healing. However, dressings vary widely in effectiveness as well as cost. Choosing suitable wound dressings can effectively enhance wound healing and eventually reduce morbidity and financial implication experienced by patients.⁹ Every effort should be made to stave off diabetic foot ulceration and treat existing ulcers by a multidisciplinary team in order to decrease amputations. Even when healed, a false sense of security should not be established: the diabetic foot should be considered a life-long condition and managed accordingly to prevent recurrence.¹⁰

In 2021, 33 million adults in Pakistan have diabetes.¹¹ However, it is estimated that in the year 2025, Pakistan will be 4th on the list with about 14.5 million people suffering from diabetes mellitus.¹² Diabetics are more likely to be admitted to the hospital with a foot ulcer than with any other complication of diabetes and are 30 times more likely to undergo a lower limb amputation than the general population. For the current rate of 125 amputations carried out per week, up to 80 % of these are potentially preventable.¹³ Due to lack of education and awareness of foot care in diabetics, there is high amputation rate and morbidity. Limb loss leads to disability and disability leads to poor quality of life. Treating the diabetic foot can be quite taxing where not only physical and psychological demands are placed on the patient but monetary as well. Dressings are relatively cheaper than other means of treating the diabetic foot and if used skillfully can altogether reduce the need for amputations.

Pakistan is among the developing countries and if the means of treating diabetic foot can fall on the more affordable side it would be revolutionary. Moreover, repeated debridement can leave patients in a demoralized and weak state. Dressings circumvent that, reducing the need for regular debridement by a long number. The rationale of this study is to assess effectiveness of a combination of alginate and hydrocolloid dressing in diabetic foot ulcer in terms of wound healing, compared with the traditional pyodine dressing. If a combined dressing of alginate and hydrocolloid leads to a better outcome, the entire principle on which we treat diabetic foot ulcers can be revised.

METHODOLOGY

This interventional study was conducted in Department of Surgery, Khyber Teaching Hospital, Peshawar after taking approval from the ethical board and research committee of the of the institute. This study was performed from April 3rd 2015 to October 4th 2019 and including 110 patients calculated via OpenEpi. All admitted patients that consented to participate were incorporated in the study. After taking history and doing clinical examination the patients were investigated by doing complete blood counts and blood sugar levels. Patients with RBS levels of > 200mg/dl after an oral glucose tolerance test were

considered diabetic. All the patients were treated with I/V antibiotics empirically first with a combination of cefoperazone + sulbactam 2gm BD and then according to culture and sensitivity reports. The patients were then started on oral antibiotics for 2 weeks. The patients were randomly divided into two groups, A and B. Group A patients (intervention group) underwent multiple dressings using a combination of alginate and hydrocolloid till the complete healing of the wound after one month time. Group B patients (placebo group) underwent the traditional pyodine dressing and the effectiveness of group A was compared against group B.

Diabetic foot ulcer was evaluated by the investigators at day 0, day 5, day 10, and day 14. Before commencing treatment, the ulcer was mapped out, and the initial size and depth of ulcer was recorded. The size was measured separately by two members of the investigating team. The mean of both these measurements was calculated and considered as the final size of the wound. The second measurement of ulcer size was made 1 week after initiation of treatment. The recordings were carried for a period of 2 weeks and $\geq 50\%$ reduction in the size of the ulcer was considered significant. Strict glycemic control was maintained in all the patients before the study, and underlying anemia and hypoproteinemia were evaluated and corrected. The dead necrotic tissue attached to the wound was surgically debrided. All the wounds were thoroughly washed with 0.9% normal saline before applying the dressing.

During the course of dressing, the wound was observed for granulation tissue, wound discharge and control of infection. The outcome was measured in terms of reduction in wound size between the two groups. Data were tabulated, and the two groups were compared with reference to area and percentage reduction in the size of the ulcer.

All diabetic patients having unilateral or bilateral foot amputations or immunocompromised status, pregnant patients and patients having any lower limb malignancy were excluded from the study. Strict exclusion criteria were followed to control confounders and bias in study results. Data were analyzed by using SPSS version 17 on computer. All the results were presented in the form of tables and charts.

RESULTS

A total of 110 patients of either gender presenting with diabetes mellitus for the last 5 years were included in the study. There were 40 (36.36%) females and 70 (63.63%) males. Male to female ratio was 1.75:1. Average age of the patients was 51.34 years \pm 9.24 SD with range 30-65 years.

Patients were distributed equally into both intervention group (group A) and placebo (group B). In our study (as shown in Table 1), the mean pre-treatment ulcer size was 4.84 ± 0.81 cm in the group A while it was 4.81 ± 0.85 cm in group B (CI 0.29–0.35, P = 0.875). The mean post-treatment ulcer size at the end of study, i.e., 2 weeks was 3.9 ± 0.76 cm in group B, while it was 2.4 ± 0.57

cm in the group A (CI 0.44–0.58, P = 0.022).

The mean difference in ulcer size was 2.4 ± 0.34 cm in group A, while it was 0.91 ± 0.25 cm in group B (CI 0.40–0.20, P = 0.041). The mean percent reduction in wound diameter was $49.76 \pm 5.2\%$ cm in group B, while it was $19.2 \pm 4.6\%$ in group A (CI 10.6–6.1, P = 0.001). Statistical analysis of percent reduction in size of ulcer is shown in Table 2. This difference was statistically significant P < 0.01.

TABLE 1: Ulcer Size Variation in Placebo and Intervention Groups

Group	N	Mean	Median	SD
Pre-Treatment Wound Size:				
Pyodine dressing	55	4.81	4.9	0.85
Intervention	55	4.84	4.8	0.81
Post-Treatment Wound Size:				
Pyodine dressing	55	3.9	4.03	0.76
Intervention	55	2.4	2.5	0.57
Percent Reduction in Ulcer Size:				
Pyodine dressing	55	19.2	18.4	4.6
Intervention	55	49.7	48.3	5.2
Mean Difference:				
Pyodine dressing	55	0.91	0.85	0.25
Intervention	55	2.4	2.3	0.34

TABLE 2 : Statistical Analysis of Percent Reduction in Size of Ulcer

t test for equality of means				
	df		Sig. (2 tailed)	Mean diff
Percent reduction in size of ulcer				
Equal variances assumed	108		.000	- 8.63636
Equal variances not assumed	91.863		.000	- 8.63636
Mean Difference				
Equal variances assumed	108		.000	- .30436
Equal variances not assumed	101.430		.000	- .30436
Post-treatment wound size				
Equal variances assumed	108		.022	.31527
Equal variances not assumed	107.976		.022	.31527

Comparison of percent reduction in size of ulcer between two groups was found to be statistically P < 0.01

DISCUSSION

Foot ulcers and infections are the main culprits behind morbidity in the diabetic community. It is estimated that around 15% of people suffering from DM eventually develop a foot ulcer and significant subset of these will end up with amputation (14% to 24% risk with one ulcer or subsequent ulceration).¹⁴ Studies show that worldwide every 30 seconds a lower limb is lost because of diabetes and its incidence will increase because of the expected rise in type 2 diabetes in the future.¹⁵ Over the course of a thousand years innumerable substances have been discovered which were used to cover wounds, bleeding tissue, reduce swelling, diminish pain, remove damaged tissue, treat infections and promote healing.¹⁶ In 19th century the discovery of chemical preservatives and disinfectants, gave better understanding of the nature of infection and inflammation, allowing increased control of wound infection.¹⁷ The birth of the modern use of alginates occurred in the early 1980s which quickly led to the production of various products.¹⁸

Wound dressings are widely used to treat diabetic foot infections. Moist dressings perpetuate a wound habitat which promotes healing. However, dressings vary widely in effectiveness as well as cost. Choosing suitable wound dressings can effectively enhance wound healing and eventually reduce morbidity and financial implication experienced by patients. The identification and use of low-cost and effective dressings has paramount importance in the management of diabetic foot ulcers because of the ever-rising incidence of DM and the fiscal burden it imposes.

In the current study the age of the study population ranged from 35-65 years with mean age of 50.64 years \pm 9.24 SD, which is younger than some reported age in literature.¹⁹ Male to female ratio was 2.11:1 in this study which is comparable with other published studies, may be due to male dominant society.^{19,20} A study presented of diabetic foot disease with 200 patients of diabetic foot ulcers; there were 65% males and 35% females with average age of 53.40 years.²¹ In our study there were 63 (32.14%) females and 133 (67.86%) were males. Male to female ratio was 2.11:1. Our study matches with this study regarding presentation of age and male to female ratio.

A study concluded many factors which directly affect wound healing like hypertension, venous disease and diabetes mellitus, which strengthen the findings of our current study.¹⁹ Majority of population in the above-mentioned study were staying in rural area of China and India, where the patients used traditional medicines and avoided visiting hospitals, ignoring their wounds which affects the overall health. A similar picture is reflected here, where the lack of education further worsens the scenario.^{22,23}

A study included 375 patients which compared alginate dressings with basic wound contact dressings, foam dressings and silver containing, fibrous hydrocolloid dressing.⁹ Meta analysis of two studies found no statistically significant difference between alginate dressings and basic wound contact dressings: risk ratio (RR) 1.09 (95% CI 0.66 to 1.80). Pooled data from two studies

comparing alginate dressings with foam dressings found no statistically significant difference in ulcer healing (RR 0.67, 95% CI 0.41 to 1.08). There was no statistically significant difference in the number of diabetic foot ulcers healed when a silver hydrocolloid dressing was compared with a standard alginate dressing (RR 1.40, 95% CI 0.79 to 2.47). All studies had short follow ups of six to 12 weeks, and small sample sizes.²⁴ When comparing this to our study which showed efficacy in response to a combination of alginate and hydrocolloid dressing, the necessity for further research exposes itself.

A significant number of amputations in diabetic patients can be prevented by patient education, foot care and increased awareness on the part of diabetes care teams of effective strategies in ulcer, however, are amenable to successful conservative limb salvage treatment; a number of patients require amputation. In a study of 100 patients with diabetic foot, 48% total amputation rate was reported.²⁵ Another study presented a series of 210 diabetic foot patients; 52% of patients required limb amputation.²⁶ In a series by Shabbir E et al out of 94 diabetic patients, 39 (43.8%) patients underwent amputation, 24 major and 15 minor.²⁷

Amputation rate in our study is low as compared to other studies. Major amputations can be reduced by combined efforts and management by multidisciplinary diabetic foot care team. Improved foot care and diabetic education can reduce the rate of diabetes related amputations by 50% to 70%.²⁸

A meta analysis conducted on 2159 patients concluded that amniotic membrane and hydrogels were superior over other contact wound dressings in treating diabetic foot ulcers.²⁹ Again, this study examined the efficacy of hydrogels and alginates individually not as a combination. As a combination the two dressings promote healing of DFU. In 2016 a study conducted by Michael Saco showed that hydrogels were effective in healing diabetic foot ulcers than basic contact wound dressings, and non-adherent dressings are more cost-effective than hydro-fiber dressings.³⁰ This study did not compare the additive effect of both alginate and hydrocolloid in treating diabetic foot infections whereas our study showed efficacy in response to the dual dressing.

The limitation of the current study was lack of follow up after complete wound healing and comparison of patients on different stages of the disease in respect to their response to the given intervention.

CONCLUSION

Today complications due to diabetes are not only the most prevalent, but are the most challenging issue in this era of diabetic management. Our study has shown that a combination of colloid and alginate dressing shows increased effectiveness in healing diabetic foot ulcers in comparison to the normal traditional povidone dressing. Optimal management of diabetic foot ulcers involves a multimodality approach directed at

regular foot care, blood glucose control, and early recognition of foot problems. Appropriate surgical management, administration of systemic antibiotics, and offloading techniques are necessary to prevent the progression of these ulcers.

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