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A Prospective Study on Efficacy of Various Dressings in the Management of Diabetic Foot Ulcers

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ABSTRACT

Diabetic foot ulcers (DFUs) are a serious complication of diabetes that results in significant morbidity and mortality. The standard practices in DFU management include surgical debridement, dressings to facilitate a moist wound environment and exudate control, wound off-loading, vascular assessment, and infection and glycemic control. The objective of the present study to evaluate and compare the efficacy of conventional dressing, foam dressing and vacuum-assisted closure (VAC) in the management of DFUs. A total of 120 patients with DFU were enrolled in the study. Group I patients (n=40) were treated with conventional dressing, group II (n=40) with foam dressing, and group III (n=40) with VAC dressing. Demographic profile were analysed and relevant investigation was done. The duration of treatment, number of debridement, need for the secondary procedure, cost of treatment and duration of hospital stay were compared between the three groups.

Results: There was no significant difference between the mean age, gender, duration of diabetes and ulcer size among the three groups ($P>0.05$). The majorities of the ulcers were located on the lateral malleolus among all three groups. The mean hospital stay was significantly less in VAC dressing (16.64 days) as compared to conventional dressing (30.26 days) and foam dressing group (24.37 days) ($p<0.05$). The mean number of debridement's was significantly low in VAC group compared to the others ($p<0.05$). The healing rates among conventional, foam and VAC groups were 90%, 92.5%, and 95%, respectively ($p>0.05$), The mean cost of the treatment was significantly higher among VAC group then conventional or foam dressing group ($p<0.05$). VAC dressing is the best option amongst the available dressing modalities in terms of faster healing, required less no of debridement's and a short hospital stay. Foam dressing does provide an economically viable option with better results than conventional dressing.

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Key Words

Diabetic foot ulcer, vacuum-assisted closure, foam dressing, conventional Dressing, cost-effective, hospital stay

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INTRODUCTION

Globally, the prevalence of diabetes is estimated to be approximately 10% of the adult population[1]. Studies suggest that 2.5% of patients with diabetes develop diabetic foot ulcers (DFUs) each year and a staggering 25% develop diabetic foot ulcers at some point in their lifetime[2]. If not managed promptly, it leads to infection and sepsis, which later on may necessitate a limb amputation[3]. Diabetic foot ulcers (DFU) are a common and debilitating complication of diabetes that can lead to significant morbidity and mortality[4]. Foot ulcer in the patient living with diabetes is a multifactorial problem associated with peripheral neuropathy, foot deformities, minor trauma, infection, and peripheral vascular disease. The management of diabetic foot ulcers includes relieving the wound using suitable therapeutic footwear[5]. Other recommendations include the use of daily saline or similar dressings that allow a moist wound environment, debridement, antibiotic therapy if osteomyelitis or cellulite is present, optimal control of blood glucose level, and assessment and correction of peripheral arterial insufficiency[6]. Appropriate, effective and timely treatment of DFUs reduces the risk of amputation and death[7]. Application of appropriate dressings is considered an effective treatment of DFUs[8]. Commonly used clinical dressings include saline, hydrogel, film, alginate, hydrophilic colloid, silver dressing, and so on[9]. However, there is no definitive evidence indicating the most efficient dressings for the treatment of DFUs. Annual foot examinations are advised for all diabetic individuals to detect high-risk foot conditions such as peripheral vascular insufficiency, structural foot abnormalities, and diminished protective sensation, for which targeted interventions have proven effective in mitigating the risk of amputation[10]. Dressings are essential in the treatment of persistent wounds, especially diabetic foot ulcers (DFUs), as they reduce exudates, control infection and promote wound healing. A variety of advanced dressings have been newly introduced, such as gel dressings, enzymatic debridement dressings, silver ion dressings, iodine-infused dressings, platelet-rich plasma dressings, and epidermal growth factor dressings. Collagen dressings have been used to manage foot ulcers associated with diabetes (DFU). Collagen elements, such as fibroblasts and keratinocytes are significant components of skin formation[11]. There is a vast choice of dressings available to treat chronic wounds, such as foot ulcers, in people with DM, categorized based on their primary material.

Aims and Objectives: In this study, we aimed to evaluate the efficacy of various dressings for treating foot ulcers in individuals with type 2 diabetes.

MATERIALS AND METHODS

This prospective study was conducted at the Department of General Surgery in a tertiary care hospital, India. Written informed consent was obtained from all the patients who participated in the study.

Inclusion Criteria:

- Patients≥20 years of age, with both gender.
- Patients admitted with a diabetic foot ulcer (>1 cm) slough, foul smell, and minimal granulation tissue.
- Patients who provided consent for the study.

Exclusion Criteria:

- Patients who had ulcers of Grades 3, 4 and 5 of Wagner's classification.
- Patients with Coagulopathies, peripheral arterial/venous disease and no peripheral pulses
- Immunocompromised, malnourished, malignancies and metabolic disorders patients.
- Patients who not provided consent for the study.

A complete medical history was obtained and relevant investigations were performed from all study patients. Status of the wound including size, grade, presence of slough or debris and depth of the wound were recorded on admission. To evaluate the vascularity of the diabetic foot, trans-cutaneous partial oxygen tension (tcpO2) and Doppler wave were measured.

All Patients Randomly Divided into Three Groups:

Group 1: Daily dressing of the patient with a normal saline-soaked gauge was done after thorough cleaning of the wound. The wound was examined for slough or debris and cleaned with hydrogen peroxide if needed.

Group 2: The dressing was changed every third day with hydrophilic foam with 2 layers of dry gauge on top of it, after thorough cleaning of the wound with hydrogen peroxide if needed.

Group 3: VAC was used with 125 mm hg of continuous pressure sessions. The wound was cleaned with normal saline or hydrogen peroxide as indicated and VAC was reapplied every 5th day.

Patients' wounds were monitored until complete re-epithelization or complete healing (defined as 100% healthy granulation and wound fit for split skin grafting) was achieved. The outcome of the three different modalities was assessed and compared.

Statistical Analyses: The categorical data were expressed as rates, ratios and percentages, and the comparison was made using Chi-square test. Continuous data were represented as mean ± standard deviation. P <0.05 was considered statistically significant.

Table 1: Socio-Demographics Characteristics of Study Patient

Demographics Characteristics		Conventional Dressing	Foam Dressing	VAC Dressing
Age Group	20-40 years	5 (12.5%)	7 (17.5%)	6 (15%)
	41-60 years	14 (35%)	13 (32.5%)	12 (30%)
	>60 years	21 (52.5%)	20 (50%)	22 (55%)
Mean ± SD (in years)	61.86 ± 8.56	60.31 ± 7.14	59.42 ± 6.18	
Gender	Male	25 (62.5%)	27 (67.5%)	26 (65%)
	Female	15 (37.5%)	13 (32.5%)	14 (35%)
Socio-economic Class	Lower	10 (25%)	13 (32.5%)	12 (30%)
	Middle	18 (45%)	17 (42.5%)	19 (47.5%)
	Upper	12 (30%)	10 (25%)	9 (22.5%)
Side of Foot	Right	23 (57.5%)	24 (60%)	26 (65%)
	Left	17 (42.5%)	16 (40%)	14 (35%)
Duration of Diabetes (Mean ± SD)		13.86 ± 3.56	14.14 ± 5.74	13.94 ± 4.36
Surface Area in sq cm (Mean±SD)		46.86 ± 21.56	40.60 ± 23.74	44.26 ± 4.36

Table 2: Comparison of Various Dressing Results of DFU Among the Study

Demographics Characteristics		Regular Dressing	Foam Dressing	VAC Dressing	P -value
Hospital Stay (Mean ± SD days)		30.26 ± 3.36	24.35 ± 2.14	16.64 ± 2.18	< 0.001
Number of Debridement (Mean±SD)		3.22 ± 0.76	2.73 ± 0.84	1.65 ± 0.23	< 0.001
Secondary Procedures	Done	12 (30%)	13 (32.5%)	18 (45%)	0.325
	Not Done	28 (70%)	27 (67.5%)	22 (55%)	
Final Outcome	Healed	36 (90%)	37 (92.5%)	38 (95%)	0.786
	Amputation	4 (10%)	3 (8.5%)	2 (5%)	
Cost of Treatment (Mean±SD)		3146.86 ± 521.56	3840.64 ± 923.74	9964.78 ± 2348.36	< 0.001

RESULTS AND DISCUSSIONS

A total of 120 DFUs patients were equally divided into three groups (40 in each). Group I treated with normal saline dressing, group II treated with foam dressing, and group III was treated with VAC dressing.

Majority of the patients were >60 years age group, predominantly males. Most of the DFUs affect the right side foot and the minimum duration of diabetes was ten year. There was no significant difference between the average ages of proportion, gender, duration of diabetes and ulcer size among the three groups (P>0.05). The details of demographics characteristics of the patients participating in the study are shown in Table 1.

The majorities of the ulcers were located on the lateral malleolus followed by medial malleolus among all three groups (Figure 1). VAC dressing was predominantly performed in DFUs present in the dorsum of the foot.

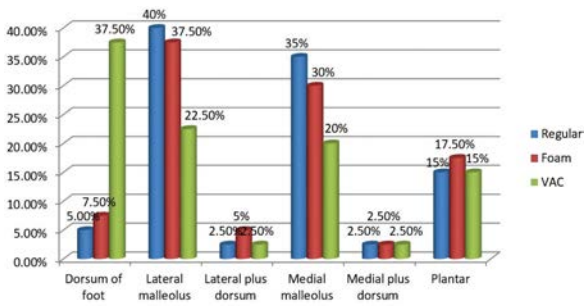

Fig. 1: Location of Diabetic Foot Ulcer Amongst the Study Patients

The mean hospital stay was significantly less in VAC dressing (16.64 days) as compared to conventional dressing (30.26 days) and foam dressing group (24.37 days) (p<0.05). The mean number of debridements in the study subjects was significantly low in the VAC group compared to the other two groups (p<0.05). No significant difference was noted between conventional dressing and foam dressing groups. About 30% in the conventional dressing group, 32.5% in the foam dressing group and 45% of the cases in the VAC group underwent secondary procedures like a local flap or split skin graft. The healing rates among conventional, foam and VAC groups were 90%, 92.5% and 95%, respectively, with no significant difference between the three groups. The mean cost of the treatment was significantly higher among VAC dressing group then conventional dressing or foam dressing group in the present study (p<0.05). Table 2

The current concept of an "ideal wound dressing" is the one that removes excess exudate, maintains a moist environment, protects against contaminants, causes no trauma on removal, leaves no debris in the wound bed, relieves pain, provides thermal insulation, induces no allergic reactions and should be cost-effective[12].

In our study, the majority of the patients were more than 60 years age group with male predominance, mean age and proportion regarding the gender of the patient was comparable among the groups, similar findings also reported by R. L. Valencia[13].

There was no significantly difference in the average size and grade of the wound between the groups. The duration of diabetes was also comparable, in agreement with the A. Ko[14].

Present study found the majority of the DFUs were located over the lateral malleolus and dorsum of the foot, our results comparable with the Everett and Mathioudakis[15].

Current study observed that VAC was the most effective with the least mean hospital stay, followed by hydrophilic foam dressing. Normal saline dressing had the maximum duration of treatment and was significantly more than the other groups, accordance with the Blume PA[16] and Vaidhya[17].

In this study the mean number of debridement needed was significantly less in the VAC group compared to the other two groups (foam dressing and saline dressing), our results correlates with the other studies: S. Subramanian[18] and Nather[19]].

Secondary procedures like a local flap or split skin graft was commonly required in VAC dressing group as compared to other two, but this was not significant statistically (p>0.05), consistent observation seen by Shimikore[20].

In our study the higher wound healing rate was found in VAC dressing group compared to conventional and foam dressing but it's not significant (P>0.05), concordance with the Anthony[14].

There was no direct correlation of reamputations with VAC in our study, constant report observed by Sepúlveda[21], in their study also did not find any significant difference with regard to amputations among patients treated with VAC.

The average cost of VAC treatment was significantly higher than normal saline dressing in the current research; this was comparable with a study done by AK Yadav[22]. The cost of VAC is its greatest limitation currently, especially in developing countries.

CONCLUSION

This original research highlights the crucial role of dressings in managing diabetic foot ulcers (DFUs). There is no difference in ultimate healing among the three groups, but with VAC there is early healing, required less number of debridement's and a decrease in the hospital stay. However, looking at the cost, foam dressing is a good option with a good healing rate as compared to conventional dressing, and lower costs as compared to VAC dressing.

Conflict of Interest: none.

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