



Comparative study of various dressing techniques in diabetic foot ulcers in the Indian population: a single-center experience

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Abstract

Introduction A prospective randomized study was conducted to evaluate and compare the efficacy of conventional dressing, foam dressing, and vacuum-assisted closure (VAC) in the management of diabetic foot ulcers (DFUs).

Material and methods Ninety patients with DFU were included in the study conducted between 2018 and 2021 at a tertiary care center. Group 1 patients ($n=30$) were treated with conventional dressing, group 2 patients ($n=30$) with foam dressing, and group 3 patients ($n=30$) with VAC dressing. 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 a significant difference in the duration of treatment among the three groups with VAC being the least (group 1, 31.17 days; group 2, 24.13 days; group 3, 15.17 days). The mean number of debridement was also significantly less in the VAC group (2.37, 2.43, and 1.60, respectively). The need for the secondary procedure, like flap or skin graft, was also the least in the VAC group, although insignificant. The mean hospital stay of the study subjects was 31.17 days, 24.13 days, and 15.17 days in the 3 groups, respectively. The mean cost of the treatment was 3076.67 INR, 3717.33 INR, and 10,680 INR, respectively.

Conclusion VAC dressing is the best option amongst the available dressing modalities in terms of faster healing and a short hospital stay. Foam dressing does provide an economically viable option with better results than conventional dressing.

Keywords Diabetic foot ulcer · Vacuum-assisted closure · Foam dressing · Conventional dressing · Cost-effective · Hospital stay

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, 3]. If not managed promptly, it leads to infection and sepsis, which later on may necessitate a limb amputation [4, 5]. Infected diabetic wounds are responsible for 84% of all non-traumatic amputations in patients with diabetes mellitus [6]. Dressing remains the mainstay of management of DFU aided by antibiotics and debridement as and when needed. Currently, negative-pressure wound therapy/vacuum-assisted closure (VAC), foam dressing, and conventional dressing are three common modalities of management available.

We have not come across any Indian study that compares the outcome of these three treatment methods in a comprehensive way. Our study was aimed at comparing these

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modalities of treatment with regard to healing rate, duration of hospitalization, need for secondary procedures, and cost of treatment.

Materials and methods

The study was designed and conducted as a single-center, prospective study between January 2018 and December 2021. Written informed consent was obtained from all the patients who participated in the study. Patients' data were kept confidential, and they were given full freedom to leave the study at any point in time.

Patients more than 18 years of age, admitted with a diabetic foot ulcer, were included in the study. Patients with coagulopathy, peripheral arterial/venous disease, ulcer with the underlying osteomyelitis, connective tissue disorders, sickle cell disease, diseases with a poor prognosis (including malignant tumors), treatment with corticosteroids or immunosuppressive agents, and severe malnutrition (serum albumin $G3.0$ g/dL), treated with biological or biochemical therapy, including growth factors or cells, were excluded from the study. Also, patients with ulcers with Wagner's [7] grade I, III, IV, and V and bilateral involvement were excluded from the study.

Of the 95 patients included in the study initially, 5 dropped off the study due to COVID-19 infection-related illness. The remaining 90 were finally enrolled in the study. Patients were randomized into 3 groups (30 patients in each group) using the random table generated using Microsoft XL. Group 1 patients were treated with standard saline gauze dressing, group 2 patients were treated with a hydrophilic foam dressing, and group 3 patients were treated with VAC dressing.

A complete medical history was obtained at the time of admission. General blood tests including complete blood counts, blood glucose, liver, and renal profile and inflammatory markers were performed. 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, transcutaneous partial oxygen tension (tcpO₂) and Doppler wave were measured.

Peripheral pulses were not well felt in all cases. However, SPO₂ of the toes was documented in all cases. And in patients where SPO₂ was not measurable, these cases were excluded. A wound swab for culture sensitivity was sent for all patients as a routine. Whenever necessary, intravenously administered antibiotics were administered empirically, and they were changed according to the results of culture and sensitivity tests. Initial surgical debridement was carried out as standard for all patients at the bedside or in the operating room, as per the wound condition. Proper glycemic control of all patients was ensured. Appropriate off-loading was

provided according to the location of the ulcer. Debridement was done if the infection was deemed to be spreading.

Method of dressing

In group 1, the daily dressing of the patient was done with a normal saline-soaked gauze [8] after thorough cleaning of the wound. The wound was examined for slough or debris and cleaned with hydrogen peroxide if needed. Saline-soaked gauze piece was placed over the wound, covered with 2 layers of dry gauze, and then secured with a micropore/roller gauze dressing.

In group 2, the dressing was changed every third day with hydrophilic foam [9] with 2 layers of dry gauze on top of it, after thorough cleaning of the wound with hydrogen peroxide if needed.

In group 3, VAC [10] 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 with respect to healing rates, duration of hospital stays, the number of debridement done, need for the secondary procedures, and mean cost of treatment. Statistical analyses were performed using MedCalc for Windows, version 19.1.7 (MedCalc Software, Ostend, Belgium).

Results

The demographics of the patients participating in the study are shown in Table 1. There was no significant difference between the average age or proportion with regard to gender among the three groups (Table 1). There was no significant difference in the duration of diabetes among the three groups ($p = 0.7195$). There was no significant difference in ulcer size among the three groups ($p = 0.6427$) (Table 1). The majority of the ulcers were located on the lateral malleolus in the conventional and foam group and were located on the dorsum of the foot in the VAC group (Table 2). About 6.67%, 3.33%, and 6.67% of the cases among conventional, foam, and VAC groups, respectively, did not have a digital pulse.

The mean hospital stay of the study subjects was 31.17 days, 24.13 days, and 15.17 days among the conventional dressing group, foam dressing group, and VAC dressing group, respectively in the present study (Table 3 and Fig. 1). There was a statistically significant difference in the hospital stay among the three groups ($p < 0.001$) with the least stay in the VAC group.

Table 1 Demographics of patient in the study

Age group	Regular		Foam		VAC		<i>p</i> value
	Number	%	Number	%	Number	%	
40 to 50	1	3.33	2	6.67	3	10.00	0.9061
51 to 60	7	23.33	7	23.33	7	23.33	
61 to 70	7	23.33	10	33.33	12	40.00	
More than 70	15	50.00	11	36.67	8	26.67	
Total	30	100.00	30	100.00	30	100.00	
Mean	66.83		66.03		63.07		
Gender	Number	%	Number	%	Number	%	0.9520
Female	10	33.33	11	36.67	10	33.33	
Male	20	66.67	19	63.33	20	66.67	
Total	30	100	30	100	30	100	
Duration of diabetes	Mean	SD	Mean	SD	Mean	SD	0.7195
	13.37	3.53	14.97	6.23	14.63	5.93	
Surface area	Mean	SD	Mean	SD	Mean	SD	0.6427
In sq. cm	47.87	42.31	39.37	28.88	44.93	33.93	

Table 2 Location of wound amongst the patients

Location of Ulcer	Regular		Foam		VAC	
	Number	%	Number	%	Number	%
Dorsum of foot	1	3.33	1	3.33	12	40.00
Lateral malleolus	12	40.00	12	40.00	7	23.33
Lateral plus dorsum	0	0	1	3.33	0	0
Medial malleolus	12	40.00	7	23.33	6	20.00
Medial plus dorsum	0	0	1	3.33	0	0
Plantar	5	16.67	8	26.67	5	16.67
Total	30	100	30	100	30	100

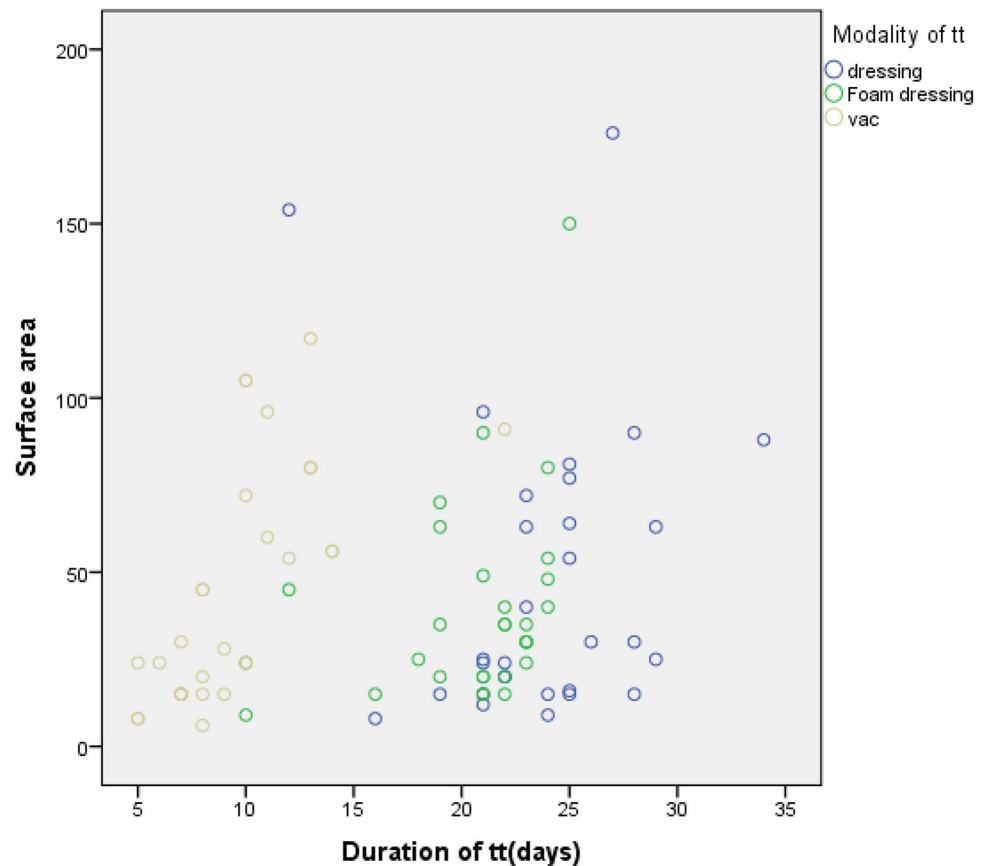
Table 3 Comparison of results of the study

Hospital stay	Regular		Foam		VAC		<i>p</i> value
	Mean	SD	Mean	SD	Mean	SD	
	31.17	3.82	24.13	2.83	15.17	3.74	<0.001
Number of debridement	Mean	SD	Mean	SD	Mean	SD	<0.001
	2.37	0.61	2.31	0.52	1.60	0.72	
Secondary procedures	Number	%	Number	%	Number	%	0.4551
Done	9	30.00	9	30.00	13	43.33	
Not done	21	70.00	21	70.00	17	56.67	
Total	30	100	30	100	30	100	
Final Outcome	Number	%	Number	%	Number	%	0.8565
Healed	27	90.00	28	93.33	28	93.33	
Amputation	3	10.00	2	6.67	2	6.67	
Total	30	100	30	100	30	100	
Cost of treatment	Mean	SD	Mean	SD	Mean	SD	<0.001
	3076.67	445.42	3717.33	984.81	10,680	3358.98	

The mean number of debridements in the study subjects was significantly low in the VAC group compared to the other two groups (Table 3). No significant difference was noted between conventional dressing and foam dressing

groups. About 30.00% in the conventional dressing group, 30.00% in the foam dressing group, and 43.33% of the cases in the VAC group underwent secondary procedures like a local flap or split skin graft (Table 3). The healing

Fig. 1 Correlation of healing time and surface area among different groups



rates among conventional, foam and VAC groups were 90%, 93.33%, and 93.33%, respectively, with no significant difference between the three groups. The rate of amputation among the three groups was also insignificant (Table 3). The mean cost of the treatment of the study subjects was 3076.67 INR, 3717.33 INR, and 10,680 INR among the conventional dressing group, foam dressing group, and VAC dressing group, respectively, in the present study ($p < 0.001$) with VAC costing almost thrice than that the other two groups.

Discussion

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 [11, 12]. Normal saline dressing, hydrophilic foam dressing, and vacuum-assisted closure are the 3 modalities of dressing being used most commonly these days, and our study aimed at comprehensively comparing these in terms of duration of treatment, number of debridements, or secondary procedure needed, final outcome, and cost of treatment.

In our study, the mean age and proportion regarding the gender of the patient were comparable among the groups. There was no difference in the average size and grade of the wound between the 3 groups. The duration of diabetes in the 3 groups was also comparable. The majority of the wounds were located over the lateral malleolus and dorsum of the foot.

When comparing the duration of treatment in terms of period of hospitalization, it was found in our study that VAC was the most effective with the least mean hospital stay (15.17 ± 3.53 days), followed by hydrophilic foam dressing (24.13 ± 6.23 days). Normal saline dressing had the maximum duration of treatment (31.17 ± 5.93 days) and was significantly more than the other 2 groups. Armstrong and Lavery [13] in their study have stated median time to closure in VAC group was 56 days opposed to 77 days in conventional saline dressing group. Vaidhya et al. [14] in an Indian study with sixty patients with DFU showed a mean time to healing of 17.2 days in VAC group compared to 34.9 days in normal saline dressing group. Blume et al. [15] had found that major proportion of patient receiving VAC therapy achieved complete skin closure or 100% reepithelization. Etoz A. et al. [16] found mean time to complete wound closure of 11.25 days in VAC group compared to 15.75 days in conventional dressing group. Roberts et al.

Table 4 A review of literature on management of diabetic foot ulcers

Sl. no	Author	Year of publication	Number of patients	Objective	Conclusion
1	James SM et al. [21]	2019	54 (27 in each group)	Comparison of vacuum-assisted closure therapy and conventional dressing on wound healing in patients with diabetic foot ulcer: a randomized controlled trial	VAC therapy significantly decreases the time to complete wound healing, hastens granulation tissue formation, and reduces the ulcer area compared to conventional dressing. The study did not find any significant increase in the bleeding and infection in the VAC therapy group
2	Erhan Sukur et al. [22]	2018	26 (12 patients in VAC group, 14 patients in saline dressing group)	Vacuum-assisted closure versus moist dressings in the treatment of diabetic wound ulcers after partial foot amputation: a retrospective analysis in 65 patients	The results of this study allowed us to conclude that VAC therapy system appears to be an effective treatment for patients with complex DFUs who had previously undergone partial foot amputation
3	Jae-A Jung et al. [23]	2016	208 (137 in foam dressing group, 71 in saline dressing group)	Evaluation of the efficacy of highly hydrophilic polyurethane foam dressing in treating a diabetic foot ulcer	These results indicate that the highly hydrophilic polyurethane foam dressing may provide an effective treatment strategy for diabetic foot ulcers
4	Vaidhya et al. [14]	2015	60 (30 in each group)	A new cost-effective method of NPWT in diabetic foot wound	Economically modified NPWT is more cost-effective to the patients in our setup
5	Gunjal et al. [24]	2014	21 (10 in VAC group and 11 in GranuloFoam group)	The use of vacuum-assisted closure and GranuloFoam silver dressing in the management of diabetic foot ulcer	With the results of the study, it was concluded that VAC GranuloFoam silver dressing can be superior to conventional GranuloFoam dressing in reducing the recurrence rate of infected diabetic foot ulcers
6	Ali M Lone et al. [2]	2014	56 (28 in each group)	Vacuum-assisted closure versus conventional dressings in the management of diabetic foot ulcers: a prospective case-control study	VAC appears to be more effective, safe, and patient satisfactory compared to conventional dressings for the treatment of DFUs
7	Ravari H et al. [19]	2013	23 (13 in saline dressing group, 10 in foam dressing group)	Comparison of vacuum-assisted closure and moist wound dressing in the treatment of diabetic foot ulcers	VAC appears to be as safe as and more efficacious than moist dressing for the treatment of diabetic foot ulcers
8	Jo C Dumville et al. [9]	2013	6 studies (157 cases) Cochrane Database Study	Foam dressings for healing diabetic foot ulcers	Currently there is no research evidence to suggest that foam wound dressings are more effective in healing foot ulcers in people with diabetes than other types of dressing however all trials in this field are very small. Decision makers may wish to consider aspects such as dressing cost and the wound management properties offered by each dressing type, e.g., exudate management
9	Ulusal et al. [25]	2010	35 (20 in normal saline group, 15 in VAC group)	Negative pressure wound therapy in patients with diabetic foot	VAC therapy, together with debridement and appropriate antibiotic therapy, enables a higher rate of limb salvage, especially in Wagner grade 3 and grade 4 ulcers

Table 4 (continued)

Sl. no	Author	Year of publication	Number of patients	Objective	Conclusion
10	Etoz A. et al. [16]	2007	24 (12 in each group)	Negative-pressure wound therapy on diabetic foot ulcer	The use of NPWT may be an effective initial wound therapy to achieve faster wound bed granulation in diabetic foot ulcers. Further studies are needed to clarify the effects and indications and to modify the technique of this alternative treatment for use on nonhealing wounds
11	Current Study	2022	90 (30 patients in each group)	Comparative study of various dressing techniques in Diabetic Foot Ulcers in the Indian population: a single-center experience	There is no significant difference in final outcome among the three groups but with VAC there is early healing, and a decrease in the hospital stay. However, looking at the cost of VAC, foam dressing is a viable option with comparable healing rates and good overall outcome

[17] in their study comparing hydrophilic foam dressing and saline-soaked dressings in diabetic foot ulcers showed that time to healing was comparable in the two groups. Liu et al. [18] in their study also showed that VAC significantly reduces DFUs compared to standard dressing.

The mean number of debridement needed was significantly less in the VAC group (1.6 ± 0.72) compared to the other 2 groups (2.31 ± 0.52 in foam dressing and 2.37 ± 0.61 in saline dressing). But there was no difference in outcome and rate of need for secondary procedures among the 3 groups in our study. In a study by Nather et al. [6] on 11 patients followed over the course of VAC therapy, healing was achieved in all wounds. Nine wounds were covered by split-skin grafting and two by secondary closure.

Although few studies have shown VAC to reduce the need for reamputations, there was no direct correlation of reamputations with VAC in our study [19]. Sepúlveda et al. in their study also did not find any significant difference with regard to amputations among patients treated with VAC [20]. Armstrong et al. [13] found a 90.3% limb salvage rate without amputation in a study on the effects of VAC on 31 subjects. In an 11-patient study by Nather et al., 100% limb salvage was achieved.

The average cost of VAC treatment was INR 10,680 (140 USD) per hospitalization, which was significantly higher than normal saline dressing (INR 3076/ 40 USD) and hydrophilic foam dressing (INR 3717/ 48 USD) in our study. The cost of VAC is its greatest limitation currently, especially in developing countries.

A review of literature on management of diabetic foot ulcer is shown in Table 4. In our search of literature, we have not come across any Indian study that compares all the three forms of dressing in a comprehensive manner.

The limitation to our study is that there may be a bias because our study center hospital is a tertiary referral center for complex diabetic foot ulcers. Therefore, the outcomes of our study might not be applicable to small hospitals or primary care centers.

Conclusion

There is no difference in ultimate healing among the three groups, but with VAC there is early healing 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.

Data Availability Data supporting the finding of this study are available within the article text and tables.

Declarations

Ethical approval Approval of ethical committee at our institute was obtained prior to the study.

Informed consent Written informed consent was obtained from all the patients who participated in the study.

Conflict of interest The authors declare no competing interests.

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