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ORIGINAL RESEARCH

Comparative study between vacuum assisted closure dressing vs normal conventional dressing in diabetic foot ulcer

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ABSTRACT

Aim: To compare vacuum assisted closure dressing vs normal conventional dressing in diabetic foot ulcer.

Methodology: One group was treated with conventional dressing after debridement and other group was treated with vacuum assisted closure dressing.Both groups were compared in terms of outcome, duration of hospital stay and response to therapy(appearance of granulation tissue, reduction in ulcer size), presence of complications such as infection, bleeding and the need for repeated debridements, and amputation.

Results: The majority of patients in both groups (26- conventional, 28- VAC group) were treated with Oral hypoglycemic agents. Co-morbidities were systemic hypertension in 9 and 10, CAD in 3 and 3 and bronchialasthma in 0 and 1 and none in 24 and 22 patients. Wagner grading was Wagner G 1 in 16 and 15, Wagner G 2 in 19 and 20 and Wagner G 3 in 1 and 1. DFU size was <10 in 22 and 25 and >10 in 14 and 11. Area was <50 in 19 and 18 and between 50-100 in 5 and 8 and >100 in 12 and 10 patients in conventional and VAC group respectively. The difference was significant (P< 0.05). The mean HbA1C was 9.08 and 9.17, healing time (days) was 23.6 and 19.2, at the end of treatment, Mean DFU area was 62.45 among conventional dressing group, whereas it is 59.44 among VAC dressing group.Mean reduction in DFU area was 7.4 among conventional dressing group, whereas it is 11.68 among VAC dressing group.Number of debridement was 1.75 and 3.88, number of amputations was 0.08 and 0.02, VAS at 1 week was 2.0 and 13.6, 2weeks was 2.3 and 2.2, at 3 weeks was 2.7 and 110.3, at 4 weeks was 3.1 and 3.1, at 5 weeks was 3.2 and 5.2, 6 weeks was 3.2 and 3.8, 7 weeks was 3.5 and 5897.8 and 8 weeks was 4.0 and 4.0 respectively. The difference was significant (P< 0.05).

Conclusion: VAC dressing therapy to be more efficient and safer with less complications which can be utilised for treatment of diabetic foot ulcer patients and prevention of morbidity like amputations and mortality.

Keywords: conventional dressing, diabetic foot ulcer, vacuum assisted closure

INTRODUCTION

Patients with diabetic mellitus (DM) are frequently admitted to hospitals due to foot issues, which result in several surgical procedures and extended hospital stays.[1] A foot ulcer may occur in up to 25% of patients with diabetes mellitus during their lifetime; in up to 85% of

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these cases, amputation occurs first. Debridement of all necrotic, callus, and fibrous tissue is a cornerstone of diabetic foot ulcer (DFU) treatment, with the main objective being wound closure. The degree of the DFU, the limb's vascularity, and the existence of infection all have a major role in how it is managed.[2,3]

It's still unclear what the best topical treatment is for DFU. The conventional approach has been to use gauze that has been wet with saline; nevertheless, it has been challenging to keep the wound moist while using these dressings.[4] The use of growth factors, enzymatic debridement agents, hyperbaric oxygen therapy, cultured skin substitutes, hydrocolloid wound gels, and other wound remedies has since been promoted. All of these treatments come with hefty price tags and are used in certain circumstances without enough empirical data to support their effectiveness.[5]Negative Pressure Wound Therapy (NPWT) also called VAC [Vacuum Assisted Closure], Topical Negative Pressure Therapy (TNPT) or vacuum sealing is a modern surgical procedure, in which the vacuum assisted drainage is utilized to extract out blood or edema fluid from a wound or an operation site.[6]We performed this study to compare vacuum assisted closure dressing vs normal conventional dressing in diabetic foot ulcer.

METHODOLOGY

This trial included 36 diabetic foot ulcer patients (DFUs) of Wagner's Grades 1 and 2 of both genders in the department of general surgery; Velammal MedicalCollege Hospital and Research Institute. Inclusion criteria was age group 20-75 years, ulcer area ranging between 5cm2and 10cm2.Exclusion criteria was age < 20 years or > 75 years, any obvious septicemia, osteomyelitis, wounds resulting from venous insufficiency/arterial disorders, malignant disease in a wound, patients being treated with corticosteroids, immunosuppressive drugs or chemotherapy, any other serious pre-existing cardiovascular, pulmonary and immunological disease.Diagnosis of diabetes mellitus was made by American Diabetes Association Criteria

Theenrolled patients were randomized in two groups randomly. One group was treated with conventional dressing after debridement and other group was treated with vacuum assisted closure dressing after getting informed consent.Patients were furtherstratified with respect to DFU size <10 cm and <1:10 cm. Both groups were compared in terms of outcome, duration of hospital stay and response to therapy(appearance of granulation tissue, reduction in ulcer size), presence of complications such as infection, bleeding and the need for repeated debridements, and amputation. The results were compiled and subjected to statistical analysis using the Mann- Whitney U test. P value less than 0.05 was regarded as significant.

RESULTS

Table I Patients distribution

Age group (years)	Conventional	VAC
30-39	2	0
40-49	8	14
50-59	13	9
60-70	9	11
>70	4	2

Among our study groups, majority of patients were in 50-59 years age range (13 patients) in conventional dressing group, whereas in VAC dressing group most prevalent age group was 40-49 years (14 patients). Least common age group was 30-39 years in both study groups. (2, 0 patients respectively)(Table I).

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Table II Assessment of parameters

Parameters	Variables	Conventional	VAC	P value
Treatment	Insulin	6	5	0.05
	OHA	26	28	
	BOTH	4	3	
Co-morbidities	SHT	9	10	0.04
	CAD	3	3	
	BA	0	1	
	None	24	22	
Wagnergrading	Wagner G1	16	15	0.01
	Wagner G2	19	20	
	Wagner G3	1	1	
DFUsize	<10	22	25	0.03
	>10	14	11	
Area	<50	19	18	0.02
	50-100	5	8	
	>100	12	10	

The majority of patients in both groups (26- conventional, 28- VAC group) were treated with Oral hypoglycemic agents. Co-morbidities were systemic hypertension in 9 and 10, CAD in 3 and 3 and bronchialasthma in 0 and 1 and none in 24 and 22 patients. Wagner grading was Wagner G 1 in 16 and 15, Wagner G 2 in 19 and 20 and Wagner G 3 in 1 and 1. DFU size was <10 in 22 and 25 and >10 in 14 and 11. Area was <50 in 19 and 18 and between 50-100 in 5 and 8 and >100 in 12 and 10 patients in conventional and VAC group respectively. The difference was significant (P< 0.05) (Table II).

Table III Comparison of mean values

Variables	Conventional	VAC	P value
HbA1C	9.08333	9.1778	0.05
Healing time (days)	23.63889	19.2778	0.02
DFU end (area)	62.45833	59.4444	0.01
reduction in DFU area	7.40417	11.6875	0.01
Number of debridement	1.75000	3.8841	0.02
Number of amputations	0.08333	0.0278	0.05
VAS 1 week	2.00000	13.6392	0.01
2 weeks	2.33333	2.2778	0.91
3 weeks	2.72222	110.3068	0.01
4 weeks	3.11765	3.1667	0.95
5 weeks	3.23077	5.2054	0.02
6 weeks	3.27273	3.8056	0.05
7 weeks	3.50000	5897.8036	0.01
8 weeks	4.00000	4.0000	1

The mean HbA1C was 9.08 and 9.17, healing time (days) was 23.6 and 19.2, at the end of treatment, Mean DFU area was 62.45 among conventional dressing group, whereas it is 59.44 among VAC dressing group.Mean reduction in DFU area was 7.4 among conventional dressing group, whereas it is 11.68 among VAC dressing group.Number of debridement was

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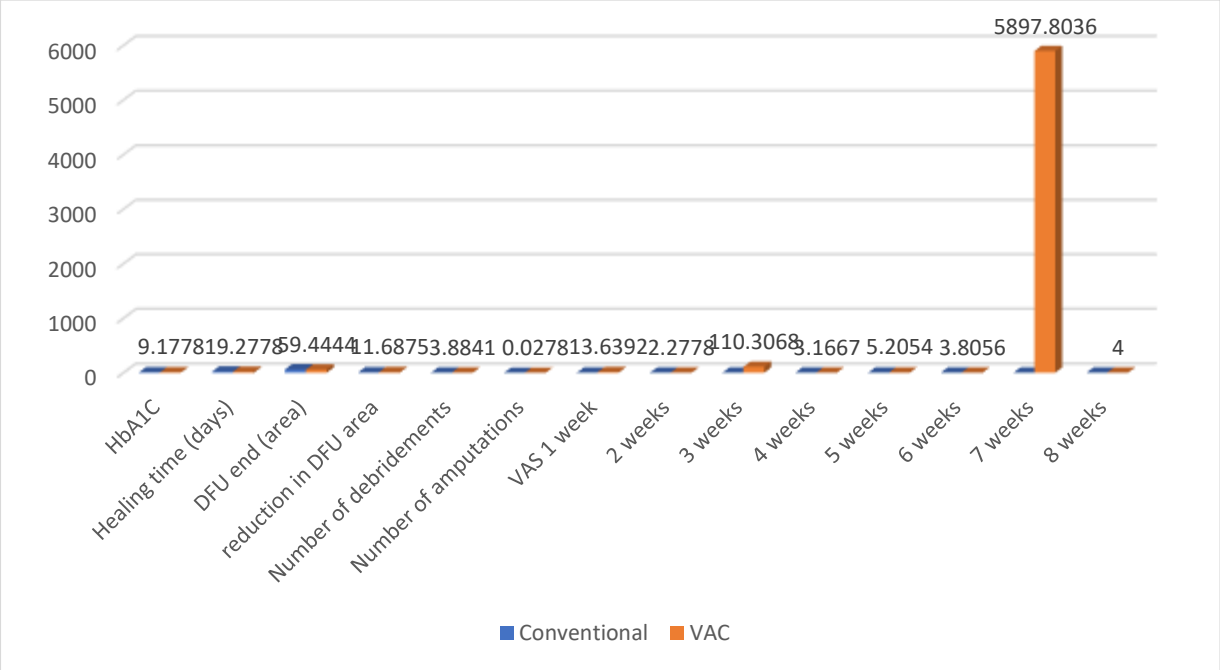
1.75 and 3.88, number of amputations was 0.08 and 0.02, VAS at 1 week was 2.0 and 13.6, 2weeks was 2.3 and 2.2, at 3 weeks was 2.7 and 110.3, at 4 weeks was 3.1 and 3.1, at 5 weeks was 3.2 and 5.2, 6 weeks was 3.2 and 3.8, 7 weeks was 3.5 and 5897.8 and 8 weeks was 4.0 and 4.0 respectively. The difference was significant (P< 0.05).

Graph I Comparison of mean values



DISCUSSION

Diabetic foot ulcer is considered as one of the major complications of diabetes mellitus with underlying multifactorial pathophysiology.[7] Particularly, in Indian population mortality due to diabetic foot ulcer was considerably high due to lack of health education and low socio-economic status.[8] Newer strategies like vacuum assisted/negative pressure dressing was found to be associated with better healing. These strategies should be studied further in larger trials and advantages and disadvantages should be evaluated.[9,10]Our study compares and contrasts vacuum assisted closure dressing with conventional dressing in diabetic foot ulcer patients and merits & demerits were documented in terms of primary and secondary outcome. We observed that majority of patients were in 50-59 years age range (13 patients) in conventional dressing group, whereas in VAC dressing group most prevalent age group was 40-49 years (14 patients). Least common age group was 30-39 years in both study groups. (2, 0 patients respectively). Akbari et al[11]evaluated vacuum-compression therapy (VCT) for the healing of diabetic foot ulcers. Eighteen diabetic patients with foot ulcers were recruited through simple nonprobability sampling. Subjects were randomly assigned to either an experimental or a control group. Before and after intervention, the foot ulcer surface area was estimated stereologically, based on Cavalieri's principle. The experimental group was treated with VCT in addition to conventional therapy for 10 sessions. The control group received only conventional therapy, including debridement, blood glucose control agents, systemic

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antibiotics, wound cleaning with normal saline, offloading (pressure relief), and daily wound dressings. The mean foot ulcer surface area decreased from 46.88 +/- 9.28 mm(2) to 35.09 +/- 4.09 mm(2) in the experimental group (p = 0.006) and from 46.62 +/- 10.03 mm(2) to 42.89 +/- 8.1 mm(2) in the control group (p = 0.01). After treatment, the experimental group significantly improved in measures of foot ulcer surface area compared with the control group (p = 0.024). VCT enhances diabetic foot ulcer healing when combined with appropriate wound care.

The majority of patients in both groups (26- conventional, 28- VAC group) were treated with Oral hypoglycaemic agents. Co-morbidities were systemic hypertension in 9 and 10, CAD in 3 and 3 and bronchialasthma in 0 and 1 and none in 24 and 22 patients. Wagner grading was Wagner G 1 in 16 and 15, Wagner G 2 in 19 and 20 and Wagner G 3 in 1 and 1. DFU size was <10 in 22 and 25 and >10 in 14 and 11. Area was <50 in 19 and 18 and between 50-100 in 5 and 8 and >100 in 12 and 10 patients in conventional and VAC group respectively. Lone et al[12]compared the effectiveness of vacuum-assisted closure (VAC) versus conventional dressings in the healing of diabetic foot ulcerations (DFUs) in terms of healing rate (time to prepare the wound for closure either spontaneously or by surgery), safety, and patient satisfaction.Randomized case–control study enrolling 56 patients, divided into two groups. Group A (patients treated with VAC) and Group B (patients treated with conventional dressings), with an equal number of patients in each group. DFUs were treated until wound closure, either spontaneously, surgically, or until completion of the 8-week period.Granulation tissue appeared in 26 (92.85%) patients by the end of Week 2 in Group A, while it appeared in 15 (53.57%) patients by that time in Group B. 100% granulation was achieved in 21 (77.78%) patients by the end of Week 5 in Group A as compared to only 10 (40%) patients by that time in Group B. Patients in Group A had fewer number of positive blood cultures, secondary amputations and were satisfied with treatment as compared to Group B.

In our study, the mean HbA1C was 9.08 and 9.17, healing time (days) was 23.6 and 19.2, at the end of treatment, Mean DFU area was 62.45 among conventional dressing group, whereas it is 59.44 among VAC dressing group.Mean reduction in DFU area was 7.4 among conventional dressing group, whereas it is 11.68 among VAC dressing group.Number of debridement was 1.75 and 3.88, number of amputations was 0.08 and 0.02, VAS at 1 week was 2.0 and 13.6, 2weeks was 2.3 and 2.2, at 3 weeks was 2.7 and 110.3, at 4 weeks was 3.1 and 3.1, at 5 weeks was 3.2 and 5.2, 6 weeks was 3.2 and 3.8, 7 weeks was 3.5 and 5897.8 and 8 weeks was 4.0 and 4.0 respectively. Sepulveda et al[13]evaluated the efficacy of NPWT compared with standard wound dressing to treat diabetic foot amputation wounds.There were 24 patients, with a mean age of 61.8 +/- 9 years (79% men), 12 in each group. The average time to reach 90% of granulation was lower in A group (18.8 +/- 6 days versus 32.3 +/- 13.7 days), a statistically significant difference (P = 0.007).

CONCLUSION

VAC dressing therapy to be more efficient and safer with less complications which can be utilised for treatment of diabetic foot ulcer patients and prevention of morbidity like amputations and mortality.

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