ORIGINAL ARTICLE

Comparison of Vacuum Assisted Closure Versus Normal Saline Dressing in Healing Diabetic Wounds

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ABSTRACT

Objective: To compare vacuum assisted closure with simple saline soaked dressing in duration of healing wounds in diabetic patients.
Study design: Randomized control trial.
Place and duration of study: General Surgery Department, Nishter Hospital, Multan.From 28- 03- 2009 to 27 -09- 2009.
Methodology: 54 patients of age between 30-60 years of either sex presented with history of superficial diabetic wound involving skin and subcutaneous tissue on any part of body were included in study. They were randomized into 2 groups i.e. A and B. Group A was subjected to vacuum assisted closure and group B to normal saline dressings. Both groups were followed until appearance of 100% granulation tissue over wound surface. Number of days taken were noted.
Results: Appearance of granulation tissue was more rapid in vacuum assisted closure group as compared to normal saline dressing group i.e. mean 17.5 days for VAC group and mean 37.5 days for saline soaked gauze dressing (P=0.000).
Conclusion: Healing is more rapid in VAC group as compared to normal saline soaked gauze dressings.
Keywords: Negative pressure wound therapy, Diabetic foot, Occlusive dressings.

INTRODUCTION

Wound and their management are fundamental to the practice of surgery.[1]Dressings are applications for wounds, burns, ulcers and other skin lesions to provide the ideal environment for wound healing[2]. Vacuum-assisted closure provides a new paradigm for wound dressings[3]. Vacuum-assisted wound closure (VAC) is a wound management technique that exposes wound bed to negative pressure by way of a closed system[4]. The application of VAC therapy to a wound provides a moist wound-healing environment which is the standard of care for wound healing[4,5].

This technique has been developed and popularized world-wide by Prof. Louis Argenta and Prof. Micheal Morykwas from the USA and by Dr Win Flieschmann from Germany[6].

This form of therapy has been found to be effective for chronic open wounds (diabetic ulcers and stage 3 and 4 pressure ulcers), acute and traumatic wounds, flaps and grafts and subacute wounds i.e., dehisced wounds[7]

VAC therapy facilitates rapid granulation of wounds and reduces bacterial colonization rates.[5,8]. Complex effects at the wound-dressing interface following application of a controlled vacuum force have been documented. These include changes on a microscopic, molecular level and on a macroscopic, tissue level: interstitial fluid flow and exudates management, edema reduction, effects on wound perfusion, protease profiles, growth factor and cytokine expression and cellular activity, all leading to enhanced granulation tissue formation and improved wound-healing parameters[9].

The VAC technique is simple. It involves the application of an open - pore foam dressing to the wound. This foam dressing is then sealed using transparent adhesive drape. A negative pressure or suction force is then applied across the wound via a drainage tube embedded in the foam[10].

In a similar study performed in Los Angelos, U.S.A. on diabetic foot wounds, it has been observed that satisfactory healing i.e. 100% granulation tissue in the VAC. group was achieved in 22.8 (+/-17.4) days, compared to 42.8 (+/-32.5) days in the normal saline dressing group. Surface area changes of 28.4% (+/-24.3) average decrease in wound size in the VAC group, compared to a 9.5% (+/-16.9) average increase in the control group during measurement period[11].

As the outcome of wound closure is different in different in different studies and no local data is available on the subject which could document healing rates of both techniques i.e. normal saline dressing and VAC. The results of this study will help in establishing that healing rate is more rapid in VAC as compared to normal saline dressings and it will

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help healthcare professionals to develop guidelines for using the better option.

METHODOLOGY

In this study 54 patients presented in the surgical unit through emergency and out patient
department randomized into group A and B, each group comprising 27 patients on the basis of envelop with assign treatment picked up by the patient. The demographic information like name, age sex and address recorded. After taking informed consent from the patient. Group subjected to VAC and Group B to normal saline dressings by the researchers. Both VAC and saline soaked dressing changed according to dressing soakage and discharge from the wound by the researchers. Patients were followed by researchers on outdoor basis daily. Time taken in number of days for wound healing i.e. disappearance of exudates and appearance of 100% granulation tissue over wound noted by the researchers.

The collected information entered and analyzed through SPSS version 10.Descriptive statistics used to calculate mean and standard deviation for age and days taken for wound healing. Frequencies and percentages calculated for sex. Two sample t-test applied for comparison between two groups by days of healing. P-value equal or less than 0.05 ($P \leq 0.05$) taken as significant. Stratification undertaken on age, sex, wound size and duration of wound to study the effect of these variables on study.

RESULTS

Fifty four patients were divided into two groups i.e. A and B. Group A which was subjected to vacuum assisted closure have patients with mean age 54±standard deviation (SD) = 6.30. Group B which was subjected to normal saline soaked dressing has patients with mean age 53±SD=5.30 (Table 1,2). 19(70%) were males and 8 (30%) were females both in group A and B 9 (Table 3,4).

100% granulation tissue appearance was observed on wound bed after initiation of either mode of therapy. Patients with VAC therapy have achieved the desired criteria in mean 18±SD=3.4 days. Mode for achievement of healing was 14 days. Normal saline dressing group took 38±D=3.8 days in comparison. P value is significant in the favor of VAC group with value of 0.00 (Table 5,6).

Wound size in group A was maximally 20 cm^2 (calculated as height × width=cm^2) and in group B was 25cm^2. But most of the wounds in both groups were in the range of 11–15cm^2 i.e. 13(48%) in group A and B (Fig.1,2).

Table 1: Age distribution in Group A

Age	Frequency	%	Valid %	Cumulative %
38	1	3.7	3.7	3.7
39	1	3.7	3.7	7.4
45	2	7.4	7.4	14.8
48	1	3.7	3.7	18.5
49	1	3.7	3.7	22.2
51	1	3.7	3.7	25.9
52	1	3.7	3.7	29.6
53	1	3.7	3.7	33.3
54	2	7.4	7.4	40.7
56	2	7.4	7.4	48.1
57	2	7.4	7.4	55.6
58	5	18.5	18.5	74.1
59	4	14.8	14.8	88.9
60	3	11.1	11.1	100.0
Total	27	100.	100.0	

Most frequent wound site in both groups were foot i.e. 67% (n=18) in group A and 78% (n=21) in group B. This is followed by legs and back in both groups (Fig. 3,4). Most wounds in both groups are 3-4 months old (85%, n= 23) (Table 7,8).

Table 2: Age distribution in group B

Age	Frequency	%	Valid %	Cumulative %
39	1	3.7	3.7	3.7
45	1	3.7	3.7	7.4
47	1	3.7	3.7	11.1
48	3	11.1	11.1	22.2
49	1	3.7	3.7	25.9
51	2	7.4	7.4	33.3
52	3	11.1	11.1	44.4
54	1	3.7	3.7	48.1
55	2	7.4	7.4	55.6
56	3	11.1	11.1	66.7
57	2	7.4	7.4	74.1
58	2	7.4	7.4	81.5
59	2	7.4	7.4	88.9
60	3	11.1	11.1	100.0
Total	27	100	100.0	

Table 3: Sex distribution in group A

Sex	Frequency	%	Valid %	Cumulative %
Male	19	70.4	70.4	70.4
Female	8	29.6	29.6	100.0
Total	27	100	100.0	

Table 4: Sex distribution in group B

Sex	Frequency	%	Valid %	Cumulative %
Male	19	70.4	70.4	70.4
Female	8	29.6	29.6	100.0
Total	27	100.	100.0	

Fig. 1: Wound size in group A:

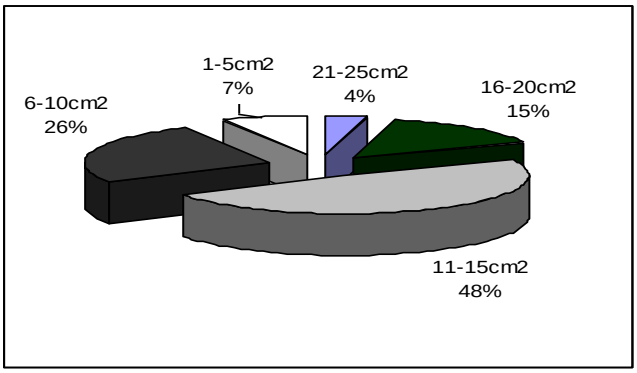

Fig. 2: Wound size in group B:

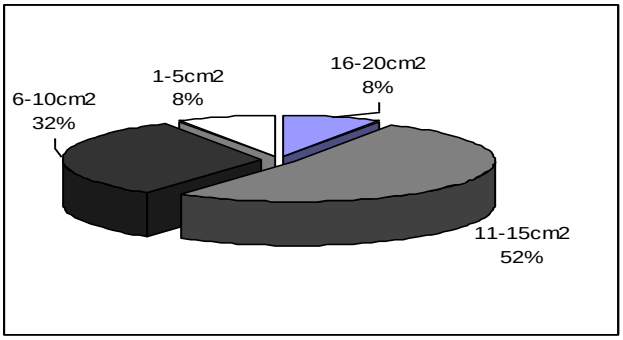

Table 5: Wound healing in days in group A:

Days	Frequency	%	Valid %	Cumulative %
12	2	7.4	7.4	7.4
14	7	25.9	25.9	33.3
16	2	7.4	7.4	40.7
18	6	22.2	22.2	63.0
20	4	14.8	14.8	77.8
22	6	22.2	22.2	100.0
Total	27	100	100.0	

Table 5 showing days of wound healing with even number of days because VAC was needed to be changed after 2 days.

Table 6: Wound healing in days in group B:

Days	Frequency	%	Valid %	Cumulative %
32	2	7.4	7.4	7.4
33	3	11.1	11.1	18.5
34	1	3.7	3.7	22.2
35	4	14.8	14.8	37.0
36	3	11.1	11.1	48.1
37	2	7.4	7.4	55.6
38	2	7.4	7.4	63.0
39	3	11.1	11.1	74.1
40	2	7.4	7.4	81.5
42	2	7.4	7.4	88.9
43	1	3.7	3.7	92.6
45	1	3.7	3.7	96.3
46	1	3.7	3.7	100.0
Total	27	100	100.0	

Fig. 3: Location wise distribution of wounds in group A

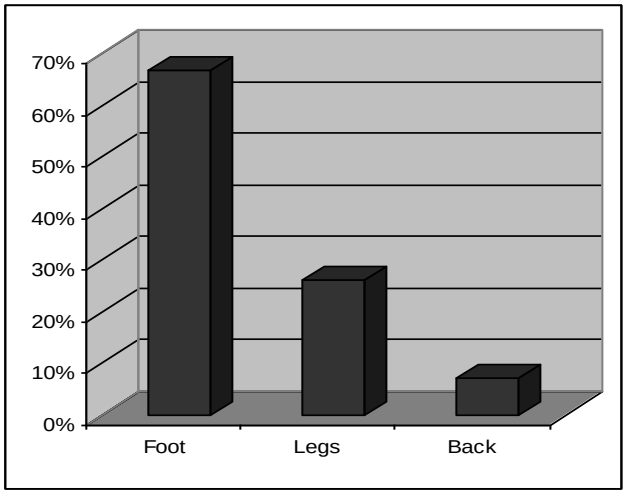

Figure 3 showing foot to be most commonly involved area i.e. 67% (n=18), followed by legs i.e. 26% (n=7) and back i.e. 7% (n=2)

Fig. 3: Location wise distribution of wounds in group B

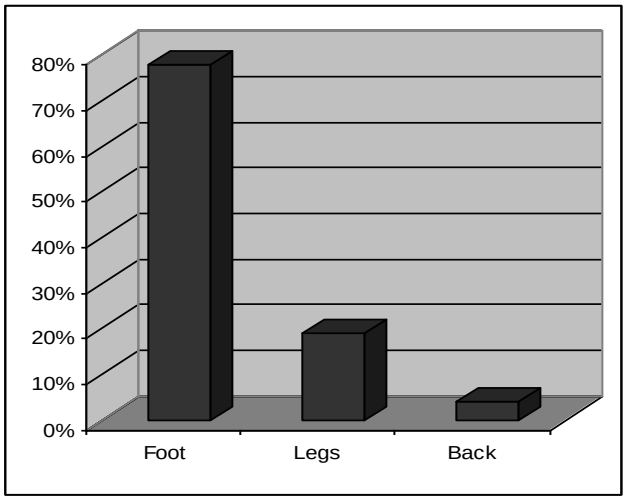

Fig. 3 showing foot to be most commonly involved area i.e. 78% (n=21), followed by legs i.e. 19% (n=5) and back i.e. 4% (n=1)

Table 7: Duration of wounds before starting therapy in group A.

Duration	Frequency	%	Valid %	Cumulative %
3-4months	23	85.2	85.2	85.2
4-5months	4	14.8	14.8	100.0
Total	27	100	100	

Table 8: Duration of wounds before starting therapy in group B.

Duration	Frequency	%	Valid %	Cumulative %
3-4months	23	85.2	85.2	85.2
4-5months	4	14.8	14.8	100.0
Total	27	100.	100	

DISCUSSION

VAC has been widely used to increase the healing rate of a variety of wounds. It has been reported that VAC decreases interstitial edema and increases capillary blood flow. Localized negative pressure removes fluid from the wound and promotes the formation of granulation tissue, which is required for wound closure. Furthermore, it reduces wound surface area by the traction force of negative pressure, which increases mitosis of tissue around the wound[12,13].

In a prospective, randomized, clinical study, Mouës et al[14], observed that vacuum-assisted closure therapy was more effective in the management of infected wounds as it caused a faster reduction of wound surface area and faster formation of red granulation tissue within the wound than the conventional dressings. Weed et al [15] reported similar conclusions.

In a study conducted by Tauro LF et al[16] in Mangalore, India moist gauze dressing was compared with VAC in chronic wounds. Among chronic wounds, diabetic wounds were main category. Patients were assessed at 10th post application day of dressing to check for granulation tissue formation on percent of wound surface area and at 5th postoperative days for percent of graft uptake by the wound after split thickness skin grafting. Study included 112 patients. 90% granulation was achieved in 22 patients in VAC group after 10 days compared to 5 patients in normal saline group. It was consistent with our study where mode of healing days was 2 weeks. In a similar study performed in Los Angelos, U.S.A. on diabetic foot wounds by M Callon SK et al, it has been observed that satisfactory healing i.e. 100% granulation tissue in the VAC. group was achieved in 22.8 (+/- 17.4) days, compared to 42.8 (+/- 32.5) days in the normal saline dressing group[11].

Armstrong DG et al[17] performed retrospective analysis of wounds of diabetic foot which were treated with VAC. Most of the wounds in this analysis were belonging to University of Texas grade 3 which corresponds to involvement of bones and joints. Data were collected from 31 consecutive patients with diabetes, 77.4% male, aged 56.1±11.7 years presenting for care at two large, multidisciplinary, referral-based wound care centers. Sub atmospheric pressure dressing therapy was used for a mean 4.7±4.2 weeks (mode=2 weeks) until the wound bed approached 100% granular tissue. This difference in mean wound healing between our study and this study was probably due to the fact that we have taken only wounds that have only subcutaneous tissue involved. But in this study majority of wounds were involving bones and joints and wounds with exposed tendon and bone present a challenging problem for the wound care surgeon. They are difficult to heal and bit late in showing up granulation tissue formation[18].

Lavery LA et al[19] conducted a study comparing diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care which is saline moistened gauzes. It was a retrospective analysis. Results of study were in the favor of VAC modality of treatment. They further added that the treatment success rate for wounds treated with VAC did not differ between the various wound durations. Similarly study showed that VAC was disproportionately used for larger wounds, and the results showed substantial benefit with VAC in such cases. However, the results also suggest that VAC may provide clinical benefit for small wounds, which tended to heal faster than larger wounds. Although not surprising, this finding strongly supports the use of VAC on small wounds. Future studies should evaluate potential differences in the efficacy of this treatment based on wound size. Eginton MT et al[20] also carried out analysis on ten diabetic patients and concluded that VAC therapy is effective in formation of granulation tissue and reduction in wound size and depth.

One of the potential deficits in our study was comparison of VAC with normal saline gauze dressings; which is conventional method used for centuries. In this modern era new moistened gauze dressings are available which are using new mediums such as alginates and hydrogels. These agents have shown greater efficacy than normal saline dressings in trials. So a comparison between these agents and VAC would have been a better protocol in current wound management strategies. On review of literature on comparison of VAC with modern dressings revealed that VAC mode of therapy is still better than these dressings. Blume PA et al[21] carried a multicentric randomized control trial comprising of 342 patients. Complete closure was assessed after a period of 112 days. Results showed that a greater proportion of foot ulcers achieved complete ulcer closure with VAC (73 of 169, 43.2%) than with Advanced moist wound therapy (AMWT) (48 of 166, 28.9%) within the 112-day active treatment phase (P=0.007). Significantly more VAC patients (105 of 169, 62.1%) achieved 75% ulcer closure than AMWT patients (85 of 166, 51.2%; P= 0.044). In another study by Armstrong DG et al [22] comprising of 162 patients with already partial amputated diabetic foot also showed that a greater proportion of patients had healed wounds in the VAC group than in the control group (43 [56%] versus 33 [39%], p=0·040). The time to reach 76–100%

granulation tissue for patients receiving VAC (median time to event 42 days [Range 40–56]) was faster than that for controls (84 days [57–112]; p=0·002). Median time was high than our study because of the fact that patients who have already amputation done have already received some sort of vascular and neural compromise.

Another problem with the study is the potential for performance bias. Because the VAC device setup is a large device set up and markedly different from moistened gauze and often has a rapid effect on wound appearance, it is difficult to adequately mask the direct caregivers and patients to group allocation and bedside wound assessment.

Another limitation with our study was that the standard for VAC therapy is vacuum assisted device from Kinetic Concepts Inc. (KCI, San Antonio, Texas). It is quiet expensive and running cost is also very high which could not be afforded by patients in our set up. So we used a modified form with suction drain as vacuum device. So that is why results might not be standardized in comparison to KCI device.

CONCLUSION

Foot ulcers are a leading cause of hospitalization for patients with diabetes and are a major source of morbidity and health care resource usage. This study proved that VAC therapy is more effective than normal saline soaked gauze dressings in healing superficial diabetic wounds. Though VAC therapy is giving birth to a new era in diabetic wounds care; many aspects still remained to be revealed. Future work should look at the effect of rapid healing on cost efficacy, length of hospital stay, and effectiveness. Quality of life should be addressed as free mobility is a big issue with VAC device in place.

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