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Original Research Article

Is vacuum assisted closure dressing better than conventional management of diabetic wounds?

Abhijit Bagul, Nandkishor Narwade*, Ankit Bhupatkar, Sridevi Murali, Yashraj Shah

Department of Surgery, D. Y. Patil School of Medicine, Navi Mumbai, Maharashtra, India

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***Correspondence:**
Dr. Nandkishor Narwade,
E-mail: nandkishorn54@gmail.com

ABSTRACT

Background: Foot ulcers are a major cause of hospitalization in patients with Diabetes Mellitus (DM) which increases hospital stay because of multiple surgical procedures, prolonged length of stay. The objectives of this study were to test the conventional therapy for diabetic wounds with respect to time and wound healing, to compare the outcomes of the two methods after a stipulated period and to prove the efficacy of one method over the other by appropriate statistical methods at the end of data collection.
Methods: A prospective randomized hospital based observational study of 47 patients was conducted at the Hospital of D. Y. Patil University School of Medicine, Nerul, Navi Mumbai, Maharashtra, India for a period of 24 months (June 2014 to June 2016). All these 47 patients were studied, and the data was statistically evaluated to determine the efficacy of vacuum assisted closure in healing of diabetic wounds and to compare it with conventional method of treatment of diabetic wounds. The patients were divided into 2 groups, Group 'A' which consisted of 22 who received Vacuum Therapy (VAC), Group 'B' which consisted of 25 and received conventional dressing.
Results: The patients on VAC therapy had early appearance of granulation tissue as compared to patients treated by Conventional dressing (90.9% Vs 76% at the end of one week. All patients developed granulation tissue by the end of 2 weeks.
Conclusions: We thus conclude that VAC appears to be superior compared to conventional dressings in the treatment of diabetic foot ulcers in terms of early appearance of granulation tissue and decrease in wound depth.

Keywords: Diabetic wounds, VAC dressing

INTRODUCTION

Foot ulcers are a major cause of hospitalization in patients with Diabetes Mellitus (DM) which increases hospital stay because of multiple surgical procedures, prolonged length of stay.[1] Diabetics have 25% risk of developing a foot ulcer, which precedes amputation in up to 85% of cases.[2] The management of the DFU is largely determined by its severity (grade), vascularity of the limb, and the presence (6-8) of infection.[3]

Conventional dressing is the standard method; however, maintaining a moist wound environment is difficult. Subsequently, various hydrocolloid wound gels, growth factors, enzymatic debridement compounds, hyperbaric oxygen therapy, cultured skin substitutes, and other

wound therapies have been advocated. These therapies are not only expensive but also don't show sufficient scientific evidence in favour of their efficacy.[4] Negative pressure wound therapy (NPWT) is a newer non-invasive adjunctive therapy system that uses controlled negative pressure, using vacuum assisted closure (VAC) device, to help promote faster wound healing by removing fluid from open wounds, preparing the wound bed for closure, reducing oedema, and promoting formation of granulation tissue. The use of sub atmospheric pressure devices, available commercially as VAC devices, has been shown to be an effective way to accelerate healing of various wounds.[5,6] The data available on the role of NPWT for the management of DFU (Diabetic Foot Ulcer) is limited. Therefore, we conducted a study to compare the effectiveness of VAC with conventional dressings in the healing of DFU, in terms of healing rate (time to prepare the wound for closure either spontaneously or by surgery).

Table 1: UT wound classification.

University of Texas Diabetic Wound Classification System				
Stage	Grade			
	0	I	II	III
A (no infection or ischemia)	Pre or post ulcerative lesion completely epithelialized	Superficial wound not involving tendon, capsule or bone	Wound penetrating to tendon or capsule	Would penetrating to bone or joint
B	Infection	Infection	Infection	Infection
C	Ischemia	Ischemia	Ischemia	Ischemia
D	Infection and ischemia	Infection and ischemia	Infection and ischemia	Infection and ischemia

Classification system

A variety of classifications have been proposed which take into account the depth of the wound, presence or absence of infection, vascular changes or vascular involvement and presence or absence of tendon joints or capsular involvement. The comparative study was done based on the University of Texas (UT) wound classification 7 as given in the Table 1.

METHODS

Study design and area

An open labelled randomized control trial was conducted in the department of Surgery of a tertiary care hospital of Mumbai.

Study duration

The study period was one year in total and both methods were tested out over a period of three weeks.

Sampling technique and sample size

All the eligible subjects fulfilling the inclusion and exclusion criteria were included in the study (initial sample size -56). An informed consent was obtained from the patient in their local language before randomizing into the two groups.

- Group A (study group): modified vacuum assisted closure technique-27 patients
- Group B (control group): Conventional Dressing-29 patients

Inclusion criteria

- All male and female patients with diabetic foot ulcers between the age group of 30-60 years.
- Selection was done according to the University of Texas Classification of Diabetic Foot Ulcers, Stage A or B, Grade 2 i.e. without infection and ischemia.

Exclusion criteria

- Any patient who refused to participate in the trial.
- Any stage or grade of wound apart from the above mentioned stage/grade as per Texas University Classification of Diabetic Foot Ulcers.

A detailed history, clinical examination and relevant investigations were performed in all patients. Patients were classified under University of Texas Classification using "probe to bone test" to rule out penetration to bone and ischemic wounds were excluded based on ankle brachial index more than or equal to 0.8. Wounds of all the patients included in the study underwent sharp surgical debridement initially and no further significant debridement was done.

After 24 hours of debridement in the operation theatre, a negative suction sponge dressing (Singh et al) was applied over the wounds of (80) the study group patients under aseptic conditions. The wound surroundings were inspected daily to check for any spreading cellulitis

without removing the opposite layer. Sponge was changed every 3 days along with Bactigras to check progress of healing. Interface dressing with Bactigras was invariably used under the sponge to prevent sponge adhesion to wound. Negative pressure was maintained using constant suction with the VAC machine and with specific instructions to keep the pressure maintained at 125 mmHg. The control group received once daily conventional method of dressing. Standard antibiotic regimens were administered to all patients, which consisted of broad-spectrum antibiotics initially and later guided by the culture sensitivity reports.

Ulcers were treated until the wound was closed spontaneously, surgically or until completion of the 3-week period, whichever was earlier. Blood glucose levels were monitored strictly. Treatment outcome was assessed in terms of time taken for appearance of granulation tissue and measurement of wound depth and area at subsequent follow up. Wound depth was measured using a sterile thread vertically in the deepest part of the wound crater to the skin surface level.

Figure 1: A case of wound over dorsum of the foot before and during vac dressing.

Figure 2: A case of carbuncle over thigh after 2nd MVAC dressing change.

A total of 9 patients had to be excluded from the study, 4 patients from the Control group expressed desire of shifting to the mVAC therapy, 1 patient from the mVAC group did not follow up after the 1st mVAC dressing done on outdoor basis, and 4 patients from the mVAC group developed wound bed infections, hence had to be converted to the Conventional therapy and excluded from the study.

Figure 3: mVAC apparatus applied to a wound post fasciotomy and debridement.

Final sample size: 47 patients

- Group A (study group): modified vacuum assisted closure technique (22 patients)
- Group B (Control Group): Conventional Dressing (25patients).

Figures 1, 2 and 3 provide the status of the wound at different points during the treatment.

RESULTS

Statistics

All the collected data was entered in Microsoft Excel sheet. All the Quantitative data was presented as mean and standard deviation and compared using student 's t-test. Qualitative data was presented as frequency and percentage and analysed using chi-square test (Continuity correction was applied in case of 2 × 2 contingency tables). P-value of <0.05 was considered as significant.

Distribution of patients based on age group

Mean age of study subjects was 53.6 and 53.1 years in Conventional and VAC group respectively.

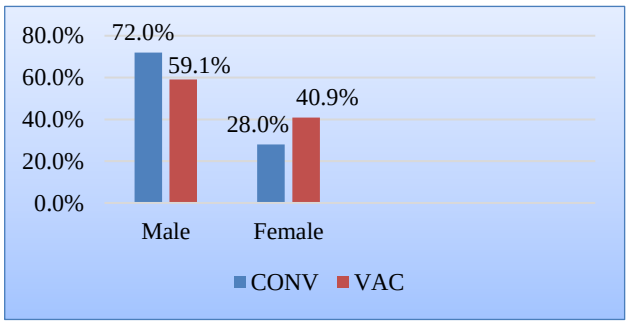

Figure 1: Distribution graph of patients based on age.

Distribution of patients based on gender

Male Preponderance was observed in both groups (81.8% in Conventional and 84% in VAC group respectively).

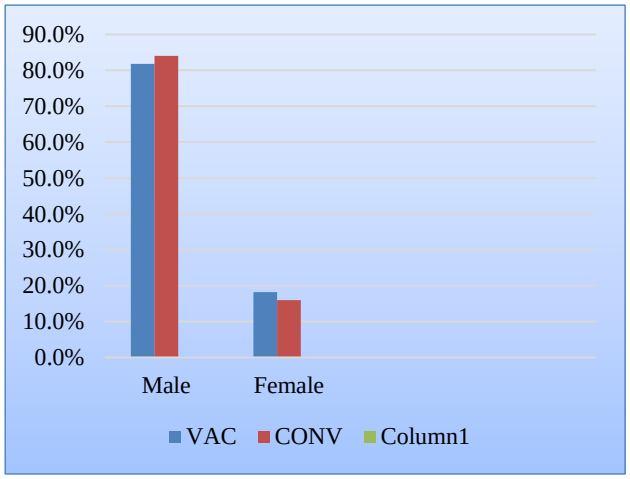

Figure 2: Distribution graph of patients based on gender.

Distribution of patients based on co-morbidities

Hypertension was the most common morbidity observed in study subjects (40% and 45.5% in conventional VAC group respectively) followed by IHD (24% versus 13.6%).

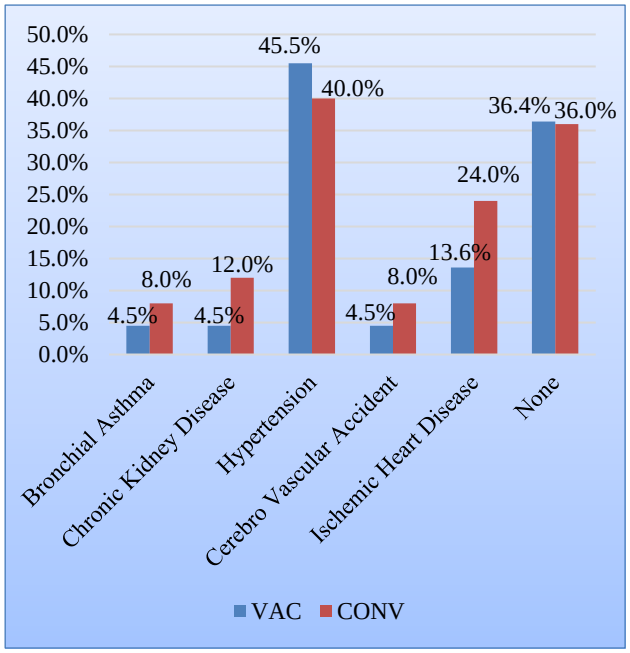

Figure 3: Distribution of patients based on co-morbidities.

Most of the wounds belonged to Stage B grade 2 according to UT classification (64% Vs 63.6%), while 28% and 18.2% were of stage B grade 1.

Table 2: Distribution of patients based on UT classification.

University of Texas Classification	Group		
	CONV	VAC	Total
Stage A Grade 1	0	2	2
	0%	9.1%	4.3%
Stage A Grade 2	2	2	4
	8%	9.1%	8.5%
Stage B Grade 1	7	4	11
	28%	18.2%	23.4%
Stage B Grade 2	16	14	30
	64%	63.6%	63.8%
Total	25	22	47
	100%	100%	100%
p-value = 0			

Table 3: Distribution of patients based on wound depth.

Wound Depth	Group	N	Mean	SD	p-value
Before debridement	VAC	22	2.44	1.49	
	CONV	25	2.05	0.76	0.26
After debridement	VAC	22	3.01	1.50	
	CONV	25	2.56	0.90	0.21
Week 1	VAC	22	2.36	1.24	
	CONV	25	2.17	0.83	0.54
Week 2	VAC	22	1.74	1.12	
	CONV	25	1.72	0.77	0.94
Week 3	VAC	22	1.42	0.90	
	CONV	25	1.33	0.74	0.71

The percentage decrease in wound depth was more in VAC group than conventional dressing at the end of 3rd week (41.8% versus 35.1%).

Table 4: Distribution of patients based on granulation tissue.

Granulation tissue	Group		Total	p-value
	Conv	VAC		
Week 1	19	20	39	
	76%	90.9%	83.0%	0.33
Week 2	25	22	47	
	100%	100%	100%	1
Week 3	24	18	42	
	96.0%	81.8%	89.4%	0.27

The patients on VAC therapy had early appearance of granulation tissue as compared to patients treated by Conventional dressing (90.9% Vs 76% at the end of one week). All patients developed granulation tissue by the end of 2 weeks.

DISCUSSION

Negative Pressure Wound Therapy (NPWT) has been advocated as a novel method in the healing of Diabetic

Foot Ulcers (DFU) by stimulating the chronic wound environment in such a way that it reduces bacterial burden and chronic interstitial wound fluid, increases vascularity and cytokine expression and to an extent mechanically exploiting the viscoelasticity of peri-wound tissues. Vacuum Assisted Closure (VAC) is generally well tolerated and, with few contraindications, is fast becoming a mainstay of current wound care.

A Randomized control trial was conducted with the aim of studying the efficacy of vacuum assisted closure in healing of diabetic wounds and to compare it with conventional method of treatment of diabetic wounds. A total of 47 patients were randomly divided in two groups:

Group A: Vacuum assisted closure and Group B: Conventional dressing.

Epidemiology

Co-morbidity

Hypertension was the most common morbidity observed in study subjects (40% and 45.5% in Conventional VAC group respectively) followed by IHD (24% Vs 13.6%). The findings can be well explained as Diabetes mellitus and hypertension are both common geriatric diseases, the two are often associated clinically as part of the insulin resistance syndrome or as a manifestation of renal diseases.[10] Elevated systemic blood pressure accelerates the progression of both micro-vascular and macro-vascular complications in diabetic ulcers due to similar pathophysiological properties.[11]

Wound characteristics

Application of negative pressure over the wound bed allows the arterioles to dilate, increasing the effectiveness of local circulation, promoting angiogenesis, which assists in the proliferation of granulation tissue.[12] We observed that patients on VAC therapy had early appearance of granulation tissue as compared to patients treated by conventional dressing (90.9% versus 76% at the end of one week. All patients developed granulation tissue by the end of 2 weeks. The percentage decrease in wound depth was more in VAC group than conventional dressing at the end of 3rd week (41.8% versus 35.1). In a study by Lone et al, granulation tissue appeared in 26 (92.85%) patients by the end of week 2 in VAC group in contrast to 15 (53.57%) patients by that time in conventional group. Armstrong and Lavery also observed that the use of negative pressure therapy resulted in an increased rate of granulation tissue formation and a higher proportion of healed wounds compared to saline gauze dressings.[13]

Eginton et al compared the rate of wound healing with the Vacuum Assisted Closure device (VAC) to conventional moist dressings in the treatment of large diabetic foot wounds. Diabetics with significant soft tissue defects of the foot were considered for enrolment. Patients were randomized to receive either moist gauze dressings or VAC treatments for 2 weeks, after which they were treated with the alternative dressing for an additional 2 weeks. Percent change in wound dimensions were calculated and compared for each weekly assessment and over 2 weeks of therapy with each dressing type. VAC dressings decreased the wound volume and depth significantly more than moist gauze dressings (59% versus 0% and 49% versus 8%, respectively). VAC dressings were associated with a decrease in all wound dimensions while wound length and width increased with moist dressings. In summary, over the first several weeks of therapy, VAC dressings decreased wound depth and volume more effectively than moist gauze dressings. They conclude that negative-pressure wound treatment may accelerate closure of large foot wounds in diabetic ulcers.[14]

Outcome

The primary endpoint in present study was a granulated wound or a wound ready for skin grafting or healing by secondary intention. Primary closure of the wound or split thickness skin grafting was done in patients of conventional and VAC group respectively. Lone et al observed that in 86.4% of patients, wounds were closed by a split-thickness skin graft in VAC group as compared to 90.9% of patients in conventional.[10] The rest of the patient's wounds were closed spontaneously.

Our observations were consistent with those of Prabhdeep et al. who also reported a split-thickness skin graft as the most common mode of wound closure.[15]

CONCLUSION

A randomized control trial was conducted for a period of one year in the department of surgery of a tertiary care hospital with the aim of studying the efficacy of vacuum assisted closure in healing of diabetic wounds and to compare it with conventional method of treatment of diabetic wounds.

A total of 47 patients between age 30-60 years with stage A or B, Grade 2 diabetic ulcers (i.e. without infection and ischemia or with only infection, wound penetrating to tendon or joint capsule) according to Texas University Classification of Diabetic Foot Ulcers were randomly divided in two groups: Group A: Vacuum Assisted Closure and; Group B: Conventional Dressing. Following observations were made during the study:

- Hypertension was the most common morbidity observed in study subjects (40% and 45.5% in Conventional VAC group respectively) affecting the wound healing time.
- The percentage decrease in wound depth was more in VAC group than conventional dressing at the end of 3 week (41.8% versus 35.1%).

- The patients on VAC therapy had early appearance of granulation tissue as compared to patients treated by Conventional dressing (90.9% versus 76% at the end of one week), but the difference was not statistically significant. All patients developed granulation tissue by the end of 2 weeks.

We thus conclude that VAC appears to be superior compared to conventional dressings in the treatment of diabetic foot ulcers in terms of early appearance of granulation tissue and decrease in wound depth.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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