



Clinical Outcome of Vacuum Assisted Dressing and Conventional Saline Dressings in Management of Chronic Non-Healing Ulcers – A Randomized Controlled Study

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(Received: 11 March 2024

Revised: 16 April 2024

Accepted: 28 May 2024)

KEYWORDS

Dressing,
Vacuum
Assisted,
Conventional,
Complication,
Ulcer, Wound
closure

ABSTRACT:

Background: Chronic non-healing ulcers are among the most common reasons for hospital admissions in surgical wards. These ulcers are challenging to treat, even when the underlying cause is identified, due to coexisting factors such as diabetes mellitus and infection.

Objective: To compare the clinical outcomes of vacuum-assisted wound dressing with conventional saline dressing in patients with non-healing ulcers.

Methods: This hospital-based, randomized controlled study was conducted over a period of 18 months among patients over 18 years of age with non-healing ulcers persisting for more than 3 weeks. These patients were admitted to the inpatient services of the Department of General Surgery at AVMC&H. Patients were divided into two groups: Group A, receiving vacuum-assisted dressing, and Group B, receiving conventional saline dressing. The study evaluated wound healing rates, granulation tissue formation, culture reports, and the total duration of hospital stay.

Results: A total of 66 patients were included, with a mean age of 54.63 ± 9.36 years, and an equal distribution of male and female participants. There were no significant differences in the demographic characteristics between the groups ($p > 0.05$). The results showed a significantly higher wound healing rate in Group A compared to Group B ($p < 0.05$). Additionally, Group A had significantly better outcomes in terms of sterile pus culture and shorter hospital stays compared to Group B ($p < 0.05$).

Conclusion: Vacuum-assisted wound dressing was associated with a shorter overall hospital stay, improved sterility of pus cultures, and superior wound healing rates and granulation tissue formation, as compared to conventional saline dressing for non-healing ulcers.



Introduction

Chronic non-healing ulcer has become one of the most common reason for admission in surgical ward.(1,2) Non-healing ulcers are difficult to treat even if the aetiology is made out, because of coexisting factors like diabetes mellitus, infection.(3,4) Majority of chronic non-healing ulcer patient's experience prolonged phase of pain, prolonged treatment requiring longer duration of stay in hospitals, morbidity and require major reconstructive surgery, amputation.(5) Looking from patient's point of view, management protocol for chronic wounds is mostly painful and uncomfortable imposing a social stigma and financial burden to the family & society. Vacuum assisted closure dressing which is now termed under negative pressure assisted wound therapy is a significant discovery in management of non-healing wounds.(5) Negative pressure wound therapy as delivered by vacuum assisted closure causes the tissue at wound bed to be stretched and drawn into the open pores of the granu foam used, fluid from the extravascular space is removed, improved circulation, increased bacterial clearance, and cell mitosis is stimulated leading to proliferation of granulation tissue contributing towards hastening of wound closure.(6–8)

The concept of using negative pressure to create a suction force thereby enabling the drainage of surgical wounds to promote wound healing is well known.(9,10) The extravascular excess fluid if not adequately removed from a wound after surgery, the fluid components will act as both physical and chemical impediment to the healing of ulcer. A buried drain can have little mechanical effect on surrounding tissue.(11,12) The development of the methodology of application whereby the suction is topically delivered across the surface of the wound to provide a solution in promoting faster healing on the nonhealing wound has been a novel concept. There has not been extensively reported studies on use of NPWT in India. Only few Indian studies have provided intuition into the usage of NPWT in Indian setting.(2) This study will provide high quality evidence of faster and improved wound healing, reduced duration of hospital stays, decreased need of repeated surgical debridement. Present study aimed to assess the clinical outcome of vacuum assisted wound dressing and conventional saline dressing in nonhealing ulcers.

Materials and Methods

This hospital-based randomized controlled study was conducted among patients over 18 years of age who presented with non-healing ulcers persisting for more than 3 weeks. These patients were admitted to the inpatient services of the Department of General Surgery at Aarupadai Veedu Medical College, Puducherry, India, between November 2022 and April 2024. The study received approval from the Institutional Human Ethics Committee (AV/IHEC/2022/095) and was registered with the Clinical Trials Registry of India (CTRI/082756). The study's objectives, procedures, and participant roles were thoroughly explained to all potential participants. They were informed that non-participation would not affect the quality of treatment provided, and that they could withdraw from the study at any time. Written informed consent was obtained after assuring participants that their responses would remain confidential.

Data were collected using a pre-tested semi-structured proforma to gather sociodemographic information. Patients with wounds showing complete necrosis, bleeding disorders, malignant ulcers, abdominal wounds, or electrical burns were excluded from the study. Non-probability sampling was used to enroll patients, who were then randomly assigned to Group A (receiving vacuum-assisted dressing) or Group B (receiving conventional saline dressing) through simple randomization using computer-generated numbers.

A detailed history was taken for both groups pre-operatively, and routine investigations such as haemoglobin (Hb), total count (TC), differential count (DC), erythrocyte sedimentation rate (ESR), random blood sugar (RBS), haemoglobin A1C (HBA1C), HIV, HBsAg, chest X-ray (PA), electrocardiogram (ECG), liver function tests (LFT), renal function tests (RFT), and pus culture and sensitivity were performed. Patients were evaluated for wound healing rate, granulation tissue formation, culture results, and total hospital stay duration. In Group B (control), conventional saline dressing was performed daily, with debridement of slough as needed. The wound was cleaned with Betadine and normal saline, dressed in moist saline gauze, and covered with layers of gauze sealed with a roller bandage. In Group A (study group), a sterile, open-cell



foam dressing was placed gently into the wound cavity, sealed with an adhesive drape, ensuring coverage of the foam and fenestrated tube inside. The drapes extended to 3 to 5 centimetres of the surrounding healthy tissue. Controlled pressure, ranging from 50 to 125 mm Hg, was applied uniformly to all tissues on the inner wound surface using a centralized vacuum pump, either continuously or intermittently. The foam dressing compressed in response to the negative pressure, which was applied continuously for the first 48 hours and then switched to continuous therapy.

Statistical Analysis: Data were manually entered into an Excel sheet and analyzed using the Statistical Package for Social Sciences (SPSS) version 23.0 on Windows 10. Descriptive statistics were presented as mean, standard deviation, frequency, and percentage using tables. The mean difference between continuous data was analyzed using the Chi-square test or Fisher's exact test for categorical variables, and the independent "t" test or Mann-Whitney U test for continuous variables. Before-and-after treatment comparisons were made using repeated measures ANOVA. Statistical significance was set at a p-value of less than 0.05.

Results

A total of 66 patients were included in the study, with 33 patients in Group A (receiving vacuum-assisted dressing) and 33 patients in Group B (receiving conventional saline dressing). The mean age of the patients was 54.63 ± 9.36 years, with an equal distribution of males and females (50% each). The mean age between the groups was comparable, with no statistically significant difference. Additionally, there were no significant differences in the demographic characteristics between the two groups ($p > 0.05$) (Table 1).

The study demonstrated a significantly higher wound healing rate in Group A compared to Group B ($p < 0.05$) (Table 2). Wound culture and sensitivity results were also significantly better in Group A (72.7%) compared to Group B (75.8%) ($p < 0.05$) (Table 3). Furthermore, patients in the vacuum-assisted dressing group had a significantly shorter duration of hospital stay compared to those in the conventional dressing group (Table 4).

Discussion

The practice of exposing a wound to sub-atmospheric pressure is relatively new and was first described by Fleischmann et al. in the year 1993, who first reported the use of sub-atmospheric pressure for an extended period to promote debridement and healing following the successful use of this technique.(5) The NPWT using the VAC is definitely having an advantage in countries like India, where the patient load on the health centers is very high.(13) In countries like India, where 40% and more of the population are earning less than one US dollar per day and also where only a small portion of government budget goes to health.(14) Hence there is an urgent need of faster and cost effective wound healing techniques.(15) The negative pressure consists of an open-cell foam dressing covered with an adhesive drape. It is connected to a vacuum pump which will create and maintain a sub atmospheric pressure which can be either continuous or intermittent therapy.

The present study showed significant higher wound healing rate in group A patients compared to group B patients ($p < 0.05$). Similarly, the pus culture sterility and shorter hospital stay was significantly better in group A compared to group B ($p < 0.05$). In corroboration with the present study, Pragadheeswaran et al., documented that the vacuum assisted closure was superior in term of wound healing and granulation tissue formation compared to conventional saline dressing.(16) Another study by Muneer et al., documented that the vacuum dressing is low cost and also reduced the healing time, hospital stay thereby reducing the total cost incurred to the patients.(17) The vacuum sealing technique is an effective option in the management of infected wounds.(18) In concordance, another study by James et al., found that VAC significantly reduced the time to complete wound healing, hasten granulation tissue formation and reduce the ulcer area compared to the conventional dressing.(19,20) This study also demonstrated that vacuum-assisted dressing is a more beneficial tool for wound healing promotion, particularly in the case of non-healing and persistent ulcers.

Conclusion

The vacuum assisted dressing reduced the overall hospital stay, improved pus culture sterility, with better wound healing rate and granulation tissue formation in comparison to the conventional dressing for non-healing



ulcers. As a result, vacuum-assisted dressing is employed as an alternative and most efficient way for ulcer and wound management. Also adds the benefit of being convenient, pain free dressing with better patient compliance and not required for daily dressing.

Financial support and sponsorship: Nil

Conflicts of interest: There are no conflicts of interest

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Table 1: Comparison of baseline parameters between the groups

	Vacuum assisted dressing		Conventional dressing		p-value
	Mean	SD	Mean	SD	
Age (in years)	54.42	9.77	54.85	9.08	0.96
Height (cm)	161.9	7.2	158.1	6.8	0.66
Weight (kg)	70.2	11.7	66.3	12.3	0.74
PR (bpm)	75.3	3.4	74.8	4.6	0.98
RR (per min)	15.2	1.3	14.9	1.0	0.64
SBP (mmHg)	109.7	14.7	114.2	10.0	0.51
DBP (mmHg)	76.7	11.4	78.5	10.0	0.69
Hemoglobin (g/dL)	11.9	2.2	12.4	2.0	0.74
Total Count (cumm)	13510.9	1568.3	15084.8	3789.2	0.12
ESR (mm/hr)	14.6	2.3	18.8	2.8	0.11
Creatinine (mg/dL)	.9	.2	.9	.1	0.99
Urea (mg/dL)	32.9	4.4	36.6	3.3	0.91

Table 2: Comparison of wound size at different interval of time between the group

	Vacuum assisted dressing		Conventional dressing		p-value
	Mean	SD	Mean	SD	
Wound size Day 0	14.7	4.4	15.8	5.6	0.65
Wound size Day 5	11.3	3.2	13.2	4.5	0.01*
Wound size Day 14	8.8	2.5	10.7	3.6	0.01*
Wound size Day 21	6.6	2.7	9.1	2.9	0.01*

Table 3: Comparison of wound culture sensitivity between the groups

		Vacuum assisted dressing		Conventional dressing		p-value
		Count	%	Count	%	
C/S before	Absent	0	0.0	3	9.1	0.69
	Present	33	100.0	30	90.9	
C/S after	Absent	9	27.3	8	24.2	0.52
	Present	24	72.7	25	75.8	

Table 4: Comparison of mean duration of hospital stay between the groups

	Vacuum assisted dressing		Conventional dressing		p-value
	Mean	SD	Mean	SD	
Hospital stay (in days)	19.5	6.0	28.7	9.1	0.01*



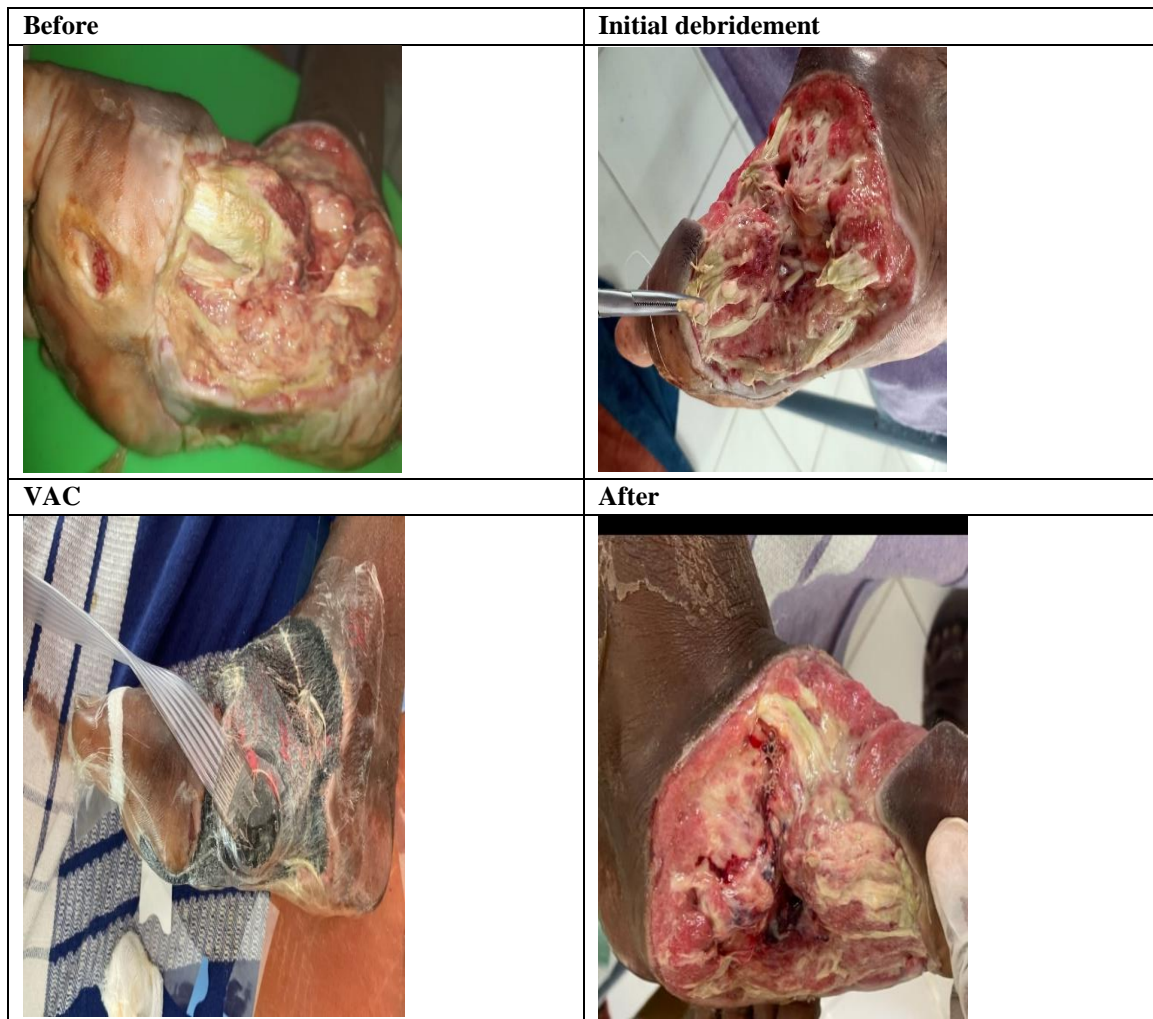


Figure 1: Clinical images