Section: General Surgery

Original Research Article

A CLINICAL STUDY OF MANAGEMENT OF CHRONIC NON-HEALING ULCER IN DIABETIC PATIENTS USING VACUUM-ASSISTED DRESSING

M. Anbu Subbiah[1], M. Nachiappan[1], A. Raghuraman[1], M. Abdul Maliq[1], M.Suresh Manikandan[2]

[1]Assistant Professor, Department of General Surgery, Government Sivagangai Medical College and Hospital, Sivagangai, Tamilnadu, India.
[2]Junior Resident, Department of General Surgery, Government Sivagangai Medical College and Hospital, Sivagangai, Tamilnadu, India.

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Corresponding Author:
Dr. M. Suresh Manikandan,
Email: dr.e.sureshmanikandan@gmail.com

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Abstract

Background: This study explores VAC therapy's potential for improving diabetic wound management, addressing the burdensome challenges of non-healing ulcers, prolonged hospital stays, and the risk of amputation. VAC's controlled negative pressure promotes granulation tissue formation and wound healing, offering a promising alternative to conventional dressings. **Material & Methods:** The study was conducted at Government Rajaji Hospital, Madurai, a tertiary care centre, with patients selected from the general surgery wards. A total of 50 cases presenting with chronic non-healing ulcers due to diabetes were included, meeting specific inclusion and exclusion criteria. Clinical examinations were performed using a predefined proforma, and the intervention involved VAC dressing application. The control group received conventional dressing, and various outcome variables were assessed, including granulation tissue formation, duration of hospital stay, pain scores, and bacterial growth in cultures. **Results:** The study found that VAC dressing led to more significant granulation tissue growth, reduced pain, shorter hospital stays, and lower amputation rates than conventional dressing. Bacterial growth was also better controlled with VAC therapy. **Conclusion:** VAC therapy is a promising alternative for managing various types of wounds, offering better healing outcomes with few complications. However, further research with larger sample sizes is needed to assess its use and cost-effectiveness for different wound types. Awareness and training on VAC application are essential for its wider utilisation.

INTRODUCTION

Non-healing ulcers are among the most common causes of admission in surgical wards. In which diabetes is the most common etiological factor. In most cases, a hospital stay of many weeks is required to manage the above. In many cases, they ultimately go for amputation. Acute and chronic wounds affect 1% of the population. Regardless of aetiology, wounds are difficult to treat if coexisting factors exist (e.g., Infection or diabetes mellitus), and it prevents regular wound healing.

Wounds represent a significant risk factor for hospitalisation, amputation, sepsis, and even death, and from a patient's perspective, wound therapy is often uncomfortable and painful. In all sense, patients become a burden for society and family.

Negative pressure wound therapy (or) vacuum-assisted closure dressing is the newer non-invasive technique that uses controlled negative pressure using a vacuum-assisted closure (VAC) device. It helps to promote wound healing by removing fluid from the open chronic wounds, preparing the wound bed for graft or other closure methods by reducing the oedema and promoting the formation of granulation tissue. VAC dressing can treat chronic non-healing ulcers following debridement of infection or amputation and in reconstructive soft tissue and osseous procedures.

Vacuum Assisted Closure is the universally accepted method for dressing. It has proved its efficacy for wound dressing. Faster wound healing and shorter hospital stay.

Still, in our hospital, the majority of dressings are conventional. We aim to show VAC's advantage over conventional dressing in our hospital.

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The aim is to study the advantage of vacuum-assisted closure dressing in managing chronic non-healing ulcers in diabetic patients.

MATERIALS AND METHODS

A study was conducted at Government Rajaji Hospital, Madurai, a tertiary care centre, with a patient selection from the general surgery wards. The study included 50 cases presenting clinically with ulcers between January 2022 and November 2022. Patients provided informed and written consent.

Inclusion Criteria

Inclusion criteria for patient selection were as follows: Patients had chronic non-healing ulcers due to diabetes with adequate blood sugar control, and they did not have any other comorbidities such as uncontrolled hypertension, uncontrolled hyperglycemia, peripheral arterial occlusive disease (PAOD), wounds with underlying osteomyelitis, advanced malignancies, or renal, cardiac, and liver dysfunctions.

Exclusion Criteria

Exclusion criteria included pregnant females and patients with chronic ulcers other than those related to diabetes (e.g., PAOD, varicose veins, burns, Hansen's disease, malignant ulcers, or osteomyelitis). Patients with severe comorbidities such as uncontrolled hypertension, uncontrolled hyperglycemia, advanced malignancies, and severe renal, cardiac, and liver dysfunctions were excluded, as were patients with acute wounds or those who did not consent to participate in the study.

Assessment of Parameters

Each case was systematically examined using a predefined proforma, and case selection was performed. The intervention involved a sequence of steps: thorough wound debridement before applying a Vacuum-Assisted Closure (VAC) dressing. After achieving hemostasis and ensuring the bleeding had stopped, the VAC dressing application was made. Pre-V.A.C and post-VAC cultures and sensitivity tests were taken. VAC dressing was applied and maintained for 72 hours, and a pre-VAC. Doppler study and X-ray of the affected limb were performed. The control group received conventional dressing, and the patient's status at discharge was recorded.

Outcome variables included the result at the end of treatment, the rate of granulation tissue formation, the number of days of hospital stay, and pus cultures and sensitivity tests before and after VAC treatment. Materials used for the study included an OPSITE cover, transparent adhesive plaster, a sterilised sponge, a Ryles tube, and a suction apparatus.

The procedure sequence involved wound preparation, including removing and discarding dressings from the wound, taking a culture swab for microbiology before wound irrigation with normal saline, performing surgical debridement, and achieving adequate hemostasis. Sterile sponge dressing was gently placed into the wound cavity, and the site was sealed with an adhesive drape, ensuring that the drapes covered the sponge, tubing, and at least three to five centimetres of surrounding healthy tissue. Controlled negative pressure was uniformly applied to all tissues on the inner surface of the wound using a portable vacuum pump with a suction pressure of 150 mm Hg, and the sponge dressing was compressed in response to the negative pressure, which was applied continuously for 72 hours.

Statistical Analysis

The collected data were analysed using SPSS software. Pearson chi-square test and Independent sample t test was performed.

RESULTS

The study involved 50 participants, divided equally into two groups: 25 with VAC dressing and 25 with Conventional dressing. The results and findings of this study are as follows:

In both the VAC and Conventional dressing groups, the mean age of participants was similar, averaging around 54.7 years, with standard deviations of 12.68 and 8.68, respectively, indicating a balanced age distribution, while the male gender predominated in both groups with 17 males and eight females in the VAC group and 20 males and five females in the Conventional group.

Table 1: Distribution of Patients' characteristics

	Group A	Group B	P value
Age (Mean/SD)	54.84 ± 12.68	54.68 ± 8.68	0.959
Male (n)	17	20	0.333
Female (n)	8	5	

The ulcers in this study were observed in various locations. Most participants (26) had ulcers on their feet, followed by 16 with ulcers on their legs. A smaller number of participants had ulcers on the back (3), forearm (2), sole (2), and abdomen (1). This diversity in ulcer locations highlights the need for tailored treatment approaches.

The study evaluated HbA1c levels as a marker of glycemic control. In the VAC dressing group, the mean HbA1c level was 7.28% with a standard deviation of 0.51; in the Conventional dressing group, it was 7.42% with a standard deviation of 0.54. These values indicate that, on average, the glycemic control was similar in both groups.

The mean ulcer surface area in the VAC dressing group was 40.21 mm^2, with a standard deviation of 2.55, and in the Conventional dressing group, it was 36.95 mm^2, with a standard deviation of 5.61. This suggests that ulcers in the VAC group tended to be slightly larger.

Participants in the VAC dressing group exhibited a higher mean granulation tissue growth of 39.33 mm (standard deviation 2.51) than the Conventional dressing group, which had a mean of 34.41 mm (standard deviation 5.52). This indicates that VAC dressing was associated with more significant

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granulation tissue growth, an important aspect of wound healing.

The average duration of hospital stay was shorter in the VAC dressing group, with a mean of 21.52 days (standard deviation 2.23), compared to the Conventional dressing group, which had an average stay of 28.68 days (standard deviation 3.64).

The reduced hospitalisation duration in the VAC group suggests faster recovery.

Participants in the VAC dressing group reported less pain, with a mean pain score of 3.72 (standard deviation 1.42), whereas the Conventional dressing group reported a higher pain score of 7.00 (standard deviation 1.35). This suggests that VAC dressing accelerates wound healing and provides a more comfortable experience for patients.

Both groups showed bacterial growth in cultures before dressing, with common organisms such as Staphylococcus, E. coli, Pseudomonas, Proteus, Streptococcus, Acinetobacter, Klebsiella, and Citrobacter. However, after dressing, the VAC group had a reduced bacterial growth rate, with 88% showing no growth, whereas the Conventional dressing group had 44% with no growth.

Table 2: Comparison of sites between groups

Site	Group A (Vacuum-assisted closure dressing)	Group B (Conventional dressing)	P value
Foot	14	12	**0.87**
Leg	6	10	
Back	2	1	
Forearm	1	1	
Sole	1	1	
Abdomen	1	0	

Table 3: Comparison of study outcome between groups

	Group A (Vacuum-assisted closure dressing)	Group B (Conventional dressing)	P value
HbA1c	7.28 ± 0.51	7.42 ± 0.54	0.342
Ulcer surface area	40.21 ± 2.55	36.95 ± 5.61	0.011
Mean granulation tissue growth (in mm)	39.33 ± 2.51	34.41 ± 5.52	<0.001
Mean duration of hospital stay (in days)	21.52 ± 2.23	28.68 ± 3.64	<0.001
Mean pain score	3.72 ± 1.42	7.00 ± 1.35	<0.001

Table 4: Comparison of culture growth between groups

Growth Identified in Culture	Group A (Vacuum-assisted closure dressing)	Group B (Conventional dressing)	P value
Before dressing	24 (96%)	25 (100%)	**0.02**
After dressing	3 (12%)	14 (56%)	

Table 5: Comparison of treatment between groups

Treatment	Group A (Vacuum-assisted closure dressing)	Group B (Conventional dressing)	Total	P value
Amputation	1 (4%)	6 (24%)	7 (14%)	**0.03**
Discharge	9 (36%)	10 (40%)	19 (38%)	
SSG	15 (60%)	9 (36%)	24 (48%)	
Total	25 (100%)	25 (100%)	50 (100%)	

In the Conventional dressing group, 36% had SSG, 40% were discharged, and 24% required amputation. These outcomes underscore the effectiveness of VAC dressing in preserving limb integrity and improving overall patient outcomes.

DISCUSSION

Managing diabetic wounds presents a significant challenge due to delayed wound healing, resulting in patient morbidity and a strain on healthcare resources. This underscores the need for advanced wound management approaches. Vacuum-assisted closure (VAC) is a novel method that employs negative pressure to facilitate wound healing, positively impacting granulation tissue formation and closure while offering an affordable wound care system.

In this study, most patients (66%) were 51-70 years old. Male patients predominated, constituting 74% of the study population, with a male-to-female ratio of 2.85:1. Wounds were most commonly found on the foot (52%), followed by the leg (32%), back (6%), and sole (4%). Staphylococcus aureus was the most frequently isolated organism in both case and control populations (42%).

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Notably, patients with sterile pre-VAC cultures did not convert to non-sterile cultures after VAC treatment, whereas 87.5% of patients with non-sterile pre-VAC cultures achieved sterile cultures after VAC application. The study revealed a highly significant difference in the rate of granulation tissue formation, with the conventional dressing group at 34.41 and the VAC dressing group at 39.33 ($p<0.001$). Pain scores were significantly lower in the VAC dressing group (3.72) compared to the conventional dressing group (7.00) ($p<0.001$).

Hospital stays were shorter for patients with VAC dressing (21 days) than those with conventional dressings (28 days). Patients with VAC dressing experienced improved comfort and satisfaction, demonstrating an overall increase in well-being and confidence. VAC-treated patients required fewer amputations and more split skin grafts, with Fischer's exact test showing statistical significance (p-value=0.03). Sixty per cent of cases received split skin graft cover compared to 36% in the control group. The amputation rate was only 4% in cases, contrasting with 24% in the control group. This study underscores the effectiveness of VAC in diabetic wound management, improving patient outcomes and reducing the need for amputation.

CONCLUSION

VAC therapy is the recent modality of treatment of wounds. Its introduction has changed the course of wound management. Based on the data from the present study and other studies available, VAC results in better healing with few serious complications. It thus looks to be a promising alternative for managing various types of wounds. The application of VAC is simple but requires training to ensure appropriate and competent use. The cost of VAC will vary and depend on the length of hospital stay and the cost of supplies. There is a lack of high-quality RCTs on VAC therapy for wound management with sufficient sample size and adequate power to detect any differences between VAC and standard dressings. More rigorous studies with larger sample sizes assessing VAC therapy's use and cost-effectiveness on different wound types are required. Awareness about VAC and training on applying VAC dressings will allow its utilisation more often.

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