

**Original Research Article****A Study on Evaluation of Custom made Vacuum Assisted Closure in the Management of Non-Healing Ulcers**

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Abstract

Introduction: Non-healing ulcers are a major health problem globally and affect the individual personally, professionally and socially. They also pose a burden on the individual and the health care system. Refractory non-healing ulcers are one of the major cause of lower limb amputations attributable to non-traumatic etiology. Wound healing requires frequent and regular dressings which can be done either by conventional method or by Vacuum Assisted Closure (VAC).

Aim of the study: To evaluate custom made VAC therapy efficacy as compared to conventional dressings in the treatment of non-healing ulcers.

Materials and Methods: A total of 60 patients with non-healing ulcers were put equally into two groups as Group A with 30 patients who received (VAC) dressings and 30 patients in Group B who were given conventional dressings. The cause of the ulcers, the effectiveness of VAC, the cost of treatment, the duration of hospital stay and patient satisfaction were studied and compared.

Results: The VAC group had improved wound healing and better patient satisfaction as compared to the conventional dressing group.

Conclusion: The application of Vacuum Assisted Closure to non-healing wounds is a good alternative to conventional dressings. It facilitates better wound healing and is cost effective and has overall benefits as compared to conventional dressings.

Keywords: Vacuum Assisted Closure (VAC), Non-healing ulcers, Conventional Dressings, Diabetic Ulcers, Pressure Sores.

Introduction

Non-healing ulcers are a major health problem globally and affect the individual personally, professionally and socially. They also pose a burden on the individual and the health care

system. Refractory non-healing ulcers are one of the major cause of lower limb amputations attributable to non-traumatic etiology.^[1]

“Chronic wounds” are those that have not healed appropriately and have not produced anatomic and

functional integrity even after 3 months. It can be defined as a wound that lacks a 20-40% reduction in size after two to four weeks of optimal treatment or when there is no complete healing even after six weeks^[2]. Such wounds persist having the inflammatory response for prolonged periods and don't show healing.^[3]

The management of difficult to heal wounds has always been a cause of concern for the treating clinicians.^[4] The conventional techniques have been in use since the long time for the management of these wounds, yet desired results are not achieved always. The relatively newer techniques like negative pressure wound therapy (NPWT) using the vacuum assisted closure (VAC) are very promising and are also useful in the management of non-healing ulcers. The use of controlled levels of negative pressure application has been shown to accelerate debridement and promote healing in various types of wounds.^[4] Non-healing of ulcers are a significant health problem, particularly in elderly.^[5] The VAC treatment applies localized negative pressure to a special dressing positioned within the wound cavity that assists with the removal of interstitial fluid thereby decreasing localized edema and increasing the blood flow. The mechanical deformation of cells increases the rate of cell proliferation due to protein and matrix molecule synthesis and enhanced angiogenesis. In this study we have compared the VAC method with the conventional dressing method.

Aim of the study

To evaluate custom made VAC therapy efficacy as compared to conventional dressings in the treatment of non-healing ulcers.

Materials and Methods

This was a prospective study conducted in department of General Surgery at NRI INSTITUTE OF MEDICAL SCIENCES, Visakhapatnam over a period of 1 year from 1/7/21 to 1/7/22.

Informed consent was taken from all the study participants prior to the study and there were no ethical issues involved in the study.

The study group comprised of patients with diagnosis of non-healing ulcers admitted in the Indoor Patients ward of department of General Surgery at NRI INSTITUTE OF MEDICAL SCIENCES, Visakhapatnam.

Inclusion criteria

- Patients in age range of 25 to 65 years
- Patients of both genders
- Patients having chronic non-healing ulcers with chronic ulcers of more than six weeks duration due to diabetes mellitus, lacerating trauma, pressure sores were included

Exclusion criteria

- Patients with peripheral vascular disease
- Patients with thromboembolic phenomenon as the cause of non-healing ulcers
- Anemic patients (hemoglobin <10 g/dl).
- Patients with history of steroid intake.
- Patients with chronic renal failure (assessed on history and s.creatinine >1.5 mg/dl).
- Patients with history of immunosuppressive therapy.
- Ulcers involving bone as well.
- Malignant ulcers
- Critically ill patients

The study included a total of 60 patients with non-healing ulcers of which 30 patients were in the study group and who received vacuum assisted closure. The control group had 30 patients who were matched for age, gender and type of wound who received dressing with normal saline moistened gauze, povidine iodine and bandage roll. After debridement of the wound, and cessation of bleeding, VAC dressing was applied. Here we used more conventional methods such as a wall suction apparatus or surgical vacuum

bottles for creating the negative pressure. Pre VAC and post VAC culture and sensitivity was taken. Dressing was changed every 72 hours. Intermittent suction was given with interval of ten minutes for every two hours, daily for 12 hrs with a negative pressure ranging from 100 to 125 mm of mercury. Rest of the time drain of the VAC dressing was left connected to the VAC suction drain. Control group patients were given conventional dressings. The outcome variables studied included rate of healing, hospital stay, cost of treatment and patient satisfaction.

The VAC Method involved a 6 step method as follows:

- 1) The foam dressing was cut to the approximate size of the wound with scissors and placed gently into position
- 2) The perforated drain tube was then placed on top of the foam and a second piece of foam was placed over the top.
- 3) The foam, together with the first few inches of the drainage tube and the surrounding area of healthy skin, was then covered with the adhesive transparent membrane [IOBAN/STERI DRAPE]. It was ensured that the membrane formed a good seal both with the skin and the drainage tube.
- 4) The distal end of the drain was connected to the wall vacuum or vacuum machine, which was programmed to produce the required level of pressure. We used 100-125 mm Hg pressure.
- 5) Once the vacuum is switched on, the air is sucked out of the foam causing it to collapse inwards drawing the edges of the wound in with it.

- 6) Fluid within the wound is taken up by the foam and transported into the disposable container.

Conventional Method: In participants with conventional dressings, after through wound wash, povidine iodine soaked gauze pieces were used for initial 48 hours and then dressings were done with normal saline soaked gauze pieces, twice daily.

Descriptive statistics and Graphical presentation of data and values are expressed as Frequency, percentage, mean and SD. Comparisons of study parameters mean values between study groups made using students t-test. In all analysis, $P < 0.05$ was considered to be significant. All statistical analyses were performed using SPSS statistical software, version 22.

Results

A total of 60 patients with 30 patients in the study group and 30 patients in the control group were studied. The patient age ranged from 25 to 65 years. There were 18 (60%) males and 12(40%) females in each group and the male to female ratio was 1.5:1.

Distribution based on etiology of non-healing ulcers: There were 16 (53.3%) cases of diabetic foot ulcers, 8 (26.6 %) cases of pressure sores and 6 (20%) cases of road traffic accident trauma with lacerating wounds in each group.

Based on appearance of granulation tissue: Granulation tissue appeared in 28 (93.3%) of patients in VAC group and only 2 (6.6%) patients presented with less development of granulation tissue over the tendon which is devoid of paratenon.

Majority of wounds in VAC group covered with good granulation tissue and reduction in wound size was observed with a mean of 2.5 days.

Table 1 Distribution of appearance of healthy granulation tissue in study groups

Group	Appearance of granulation tissue in 2 to 3 days	
	No. of patients	Percent (%)
VAC dressing	28	93.3%
Conventional dressing	12	40%

Table 2 Variable mean value comparison between study groups of hospital stay in days and of cost of treatment

Variable	Group	Mean±SD	Mean difference	t-value	p- value
Hospital stay in days	VAC dressing	56.30±14.75 days	14	2.18	0.0430*
	Conventional dressing	42.30±14.01 days			
Cost of treatment in rupees	VAC dressing	375.50±65.00 Rs	-71.50	-2.35	0.0300*
	Conventional dressing	447.00±71.00 Rs			

*-P<0.05; Variable mean values are statistically significant between study groups by using student un-paired t-test.

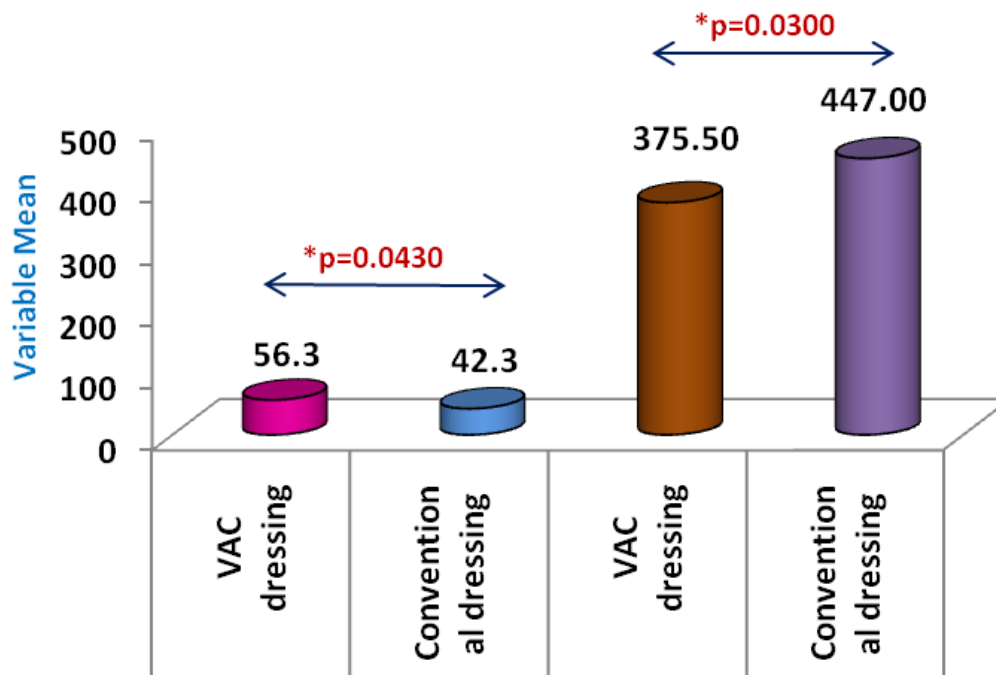


Figure 1 Variable mean value of hospital stay and cost comparison between study groups

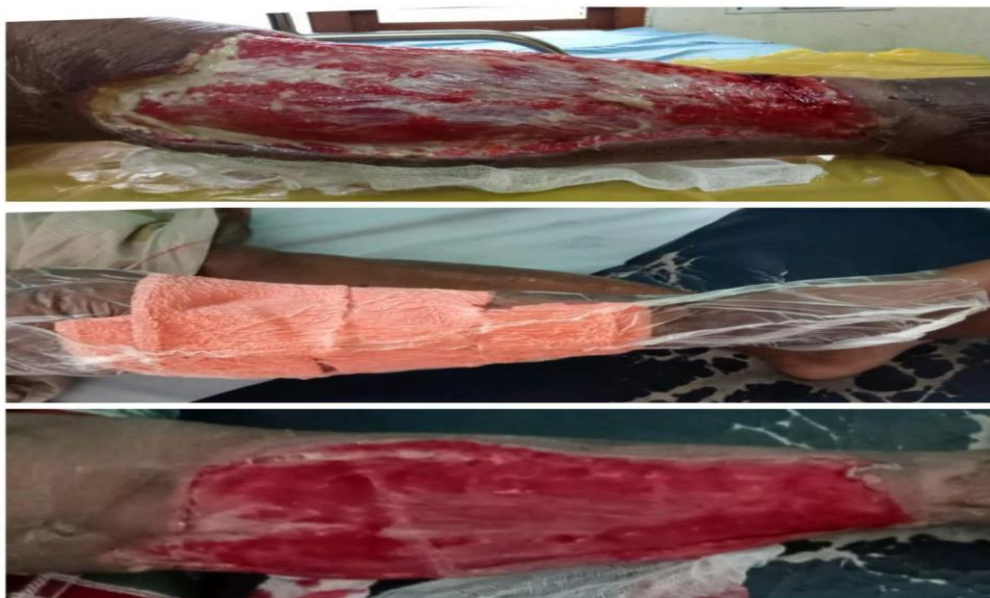


Figure 2 Panel 1 shows pre VAC large wound area of lower limb. Panel 2 shows the VAC. Panel 3 shows healthy wound bed after removing VAC.



Figure 3 Panel 1 shows pre VAC large non healing wound on back of neck. Panel 2 shows VAC applied. Panel 3 shows reduction in size of wound and healthy wound bed post VAC

Discussion

In the present study, we have attempted to compare the Vacuum assisted closure of non-healing ulcers with conventional method of healing.

The vacuum-assisted closure is a non-pharmacologic/non surgical means for modulating wound healing and it was first proposed by Argenta and Morykwas in 1997. Large wounds contribute to major morbidity, disability and loss of quality of life in patients. They impact the general public health and also the health care resources. Wound healing is assisted by Vacuum Assisted Closure (VAC) dressings that use negative pressure to hasten the healing. The negative pressure that is generated removes excess fluid from the wound thereby removing the substrate for the growth of microorganisms. Negative pressure also stimulates the growth of healthy granulation tissue and aids in new vessels formation. It also creates mechanical stimulation due to tensile forces and helps in cell stimulation and protein synthesis. Negative Pressure Wound Therapy (NPWT) involves the use of a negative pressure or suction device to remove the fluids, debris and infectious materials from the wound bed to promote the formation of granulation tissue.^[6]

Age distribution of the patients: In the present study, the patient age ranged from 25 to 65 years and the male to female ratio was 1.5:1. In a similar study done by Krishna Girish et al^[7] the age of the patients ranged from 35 to 75 years and the male to female ratio was 3.7:1. Zameer A et al^[5] in their study had 60 patients with ranging from 40 to 70 years.

Etiology of non-healing wounds: Most common causes of non-healing wounds are diabetic ulcers, pressure ulcers, venous ulcers/stasis ulcer, poor circulation, neuropathy of any kind, restricted mobility, underlying systemic diseases, increasing age, and repeated trauma. Some of the associated conditions that predispose to chronic wounds are vasculitis, use of immunosuppressants, and ischemic diseases.^[8] Immune suppression can be caused by illnesses or medical drugs used over a long period, for example steroids.^[9] Continuous emotional stress may raise the blood pressure and cortisol thereby lowering the immunity and delaying wound healing.^[10]

Patients having chronic fibrosis, edema, sickle cell disease, peripheral vascular disease, atherosclerosis are more likely to have non-healing wounds.^[11] One of the important and preventable causes for chronic ulcers is recurrent

physical trauma as the inflammatory response does not subside and continues as long as the traumatic factor continues.^[12] Infectious causes include bacterial, viral, parasitic and fungal infections. More ominous are the malignant wounds and sometimes hematopoietic disorders may also cause non-healing wounds.^[13]

In the present study, there were 16 (53.3%) cases of diabetic foot ulcers, 8 (26.6 %) cases of pressure sores and 6 (20%) cases of road traffic accident trauma with lacerating wounds in each group. VAC was used for the study group. Gokhale Y et al^[14] studied 40 cases of chronic ulcers in the lower limb in non diabetic patients and observed that 10 (25%) cases were due to venous ulcers, and 40% were due to vasculitis. In 3 (7.5%) cases, the cause could not be found out.

Comparison of VAC and Conventional dressing: (Table 1) Lone AM et al^[15] in their study on comparing VAC with conventional dressing observed appearance of granulation tissue in 26 (92.85%) patients by the end of second week in VAC group, while it appeared in 15 (53.57%) patients by that time in Conventional dressing group. They also observed that in 21 (77.8%) patients, 100% granulation was achieved by the end of fifth week in VAC group as compared to only 10 (40%) patients by that time in conventional dressing group. In our study the VAC group showed better healing with appearance of granulation tissue in 93.3% cases compared to its appearance in only 40% cases within 2.5 days.

Comparison of cost of the treatment: (Figure 1, Table 2) In the present study, the cost of VAC treatment was 375.50±65.00 Rs and the cost of conventional treatment was 447.00±71.00 Rs. Custom made VAC dressing is cost effective as compared to the commercially available VAC unit and conventional treatments.

It involves the expenditure of disposable foam, suction catheter, vacuum set and adhesive drapes, which together cost around 300-400 Rs for 2-3

days period. In the study by Patil O et al^[16] the mean cost of VAC was Rs 1,140/- and the mean cost of conventional dressing was 920/-. However, as they found shorter hospital stay in VAC group it was overall more beneficial. Some authors have even designed their own VAC systems to cater to low socioeconomic classes as the commercial systems are little expensive.^[5]

Duration of hospital stay: (Figure 1, Table 2) In the present study, the duration of hospital stay in VAC dressing group was 56.30±14.75 days and for conventional dressing group it was 42.30±14.01 days. In the study by Krishna Girish et al^[7] The mean duration of hospital stay in Study group was 40.3 days and 18.1 days in the control group.

Patient satisfaction: Though this is a subjective parameter, in our study we observed that all the patients in the VAC group were satisfied with the VAC method of dressings as compared to the conventional group patients. Similar results were observed by Krishna Girish et al^[7] The common indications for VAC are diabetic foot ulcers, pressure sores or bed sores, skin graft fixation, flap salvage, burn ulcers, traumatic crush injuries, wound dehiscence, fasciotomy wounds, extravasation wounds, animal bites like dog bites and frostbite.

VAC is contraindicated and should never be used in cases of malignancy related ulcers, infection of bones/ osteomyelitis, when visceral fistulae are present, in cases of necrotic tissue, etc. Other contraindications are relative like, bleeding tendencies, ongoing anticoagulant therapy and actively bleeding wounds.^[6]

The advantages of VAC are that it requires less number of dressing changes, improves patient comfort, decreased duration of hospital stay, decreased bacterial load and infections, perfusion to skin and wound bed is better, reduced oedema and it provides a closed moist environment for tissue healing.^[6]

Though VAC is a useful method to promote faster healing, it may have a few complications like failure of the VAC system due to improper seal, power failure, or a blocked drainage system. Also sometimes there could be infection of the wound, excess pain due to the vacuum effect, bleeding or oozing, allergic reaction to the adhesive drape, restricted mobility, severe pain while change of VAC dressing as it may adhere to the tissue, non compliance of patient.^[8] VAC therapy leads to reduced rate of dressing changes, patient comfort, reduced hospital stay, reduced bacterial load, improved skin perfusion, reduction of edema and provision of a closed moist wound healing environment.^[6]

The literature supports that VAC is a good alternative to standard wound care especially for difficult non-healing wounds. It reduces the extent of reconstructive surgical procedures. There are logistic benefits of VAC over conventional wound care methods and cost of VAC is comparable to standard wound care methods and in long term it demonstrates cost effectiveness.^[6]

Conclusion

The application of Vacuum Assisted Closure to non-healing wounds is a good alternative to conventional dressings. It facilitates better wound healing and is cost effective and has overall benefits as compared to conventional dressings.

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