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**Original Research Article**

# Vacuum assisted wound healing: can it prove to be cost- effective?

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## ABSTRACT

**Background:** In search for a faster and effective method Negative pressure wound therapy (NPWT) also known as Vacuum assisted wound closure (VAC) has emerged to be a promising technology over the years. This study was carried out to determine the clinical efficacy and cost effectiveness of Vacuum assisted closure (VAC) therapy compared to conventional wound therapy.
**Methods:** A prospective randomised study using VAC was performed on cases with chronic non healing wounds using a low cost negative pressure therapy unit. The negative pressure used in the vacuum assisted closure of the wounds was provided by the wall mounted centralised suction apparatus which provided a constant average pressure of 125 mm of Hg (range being 110-200 mm Hg).
**Results:** The rate of wound healing which was exhibited by reduction in size of the wound by more than 1 cm at the end of the first 5 days was higher in the cases (82%) as compared to the control (18%) group. By end of 15 days size reduction of >3 cm was seen almost 85% of the patients treated with NPWT. The total cost incurred in the first group undergoing VAC for a period of 15 days per patient was Rs.750 ($11.16) as against the second group undergoing conventional wound dressing which was Rs.700 ($10.41) for the same period per patient. The cost- benefit analysis of the two groups statistically revealed a p value of <0.05 under 95% confidence limits, thus proving vacuum assisted closure, though slightly expensive than the conventional dressing, to be a better and cost effective modality, taking into consideration the faster wound healing rates.
**Conclusions:** In this study NPWT appeared to exhibit better wound healing and is thus a promising alternative to the conventional management and has a potential to be replicable across many hospitals with financial constraints in the low and middle income countries.

**Keywords:** Chronic lower limb ulcers, Cost-effective modality, Negative pressure wound therapy, Vacuum assisted closure therapy, Wound healing

## INTRODUCTION

Wound healing is a highly complex process, which starts with removal of dead and devitalized tissue, inflammatory changes with angiogenesis and finally deposition of granulation tissue, wound contraction and maturation. Wounds fail to heal when there is an interruption in the above mentioned process at any level. Other factors contributing to the delay in wound healing are chronic venous insufficiency, diabetes mellitus, vascular diseases and prolonged immobilization.[1] Delay in wound healing, thus, appears to be a significant burden to the overall health and wellbeing of an individual. In addition to the increased morbidity and mortality, it also imposes an enormous financial burden on the overall healthcare system.

Over the past few decades, there has been a rise in the incidence and prevalence of chronic wounds, which can be attributed to rise in the occurrence of non-

communicable diseases and increased life expectancy. In the United States, chronic wounds affect around 6.5 million patients and about US $25billion is spent annually on treatment of these wounds.[2] The prevalence of vascular ulcers in the US is estimated at 500,000 to 600,000 which increases with age.[3] A study in the UK showed wound prevalence of 3.55 per 1000 population.[4] The majority of wounds were surgical/trauma (48%), leg/foot (28%) and pressure ulcers (21%). According to the data of studies from China, reported incidence of ulcers in hospitalized patients was 1.5% to 20.3%.[5] Studies about wound prevalence have been sparse in the Indian subcontinent, with a few exhibiting chronic wound prevalence of 4.5 per 1000 population and acute wounds at 10.5 per 1000.[6]

Chronic wounds can lead to complications like intractable pain, infection and amputation making the patients permanently handicapped. These patients require assistance in performing daily activities and at the same time have to deal with additional health expenditure causing psychological problems to themselves and their dependent family members. Many patients, who do not seek early medical treatment due to orthodox beliefs or poor economic status, which is common in low and middle income countries like India, further add to the overall burden. The wound is ignored, becomes deeper and complicated, thus, making the management a challenging task.

The standard wound care methods like surgical debridement and conventional dry or moist gauze dressings are the mainstay in treatment of wounds and have proven their efficacy. These dressings, though cumbersome, have always stood the test of time. However, in the past few decades, with rapid development and emergence of sophisticated technology, there have been tremendous advances in the field of wound care, both in the high income countries as well as the low and middle income countries. The management of chronic conditions and wounds such as diabetic ulcers, venous ulcers, pressure wounds, traumatic wounds and also acquired immune deficiency syndrome (AIDS)-related wounds have benefited from improved medical knowledge and technology. These modern wound care methods have led to significant decrease in morbidity and mortality with faster healing rates and fewer painful dressing changes.

Negative pressure wound therapy (NPWT) also known as Vacuum assisted wound closure (V.A.C) has emerged to be a promising technology over the years. First described by Fleischman et al in 1993, done in 15 patients with open fractures, negative pressure therapy or vacuum assisted closure proved to be effective in cleaning and conditioning of the wound.[7] Negative pressure wound therapy (NPWT) refers to wound dressing systems that continuously or intermittently apply sub-atmospheric pressure to the surface of a wound to assist healing. Two main factors are considered to be responsible for the dramatic response seen in the wounds one being removal of fluid and other mechanical deformation. Removal of fluid decreases oedema, which decreases the interstitial pressure resulting in increased blood flow. Mechanical deformation causes a wide variety of molecular responses, including changes in ion concentration, permeability of cell membrane, release of second messengers, and stimulation of molecular pathways increasing the mitotic rate of stretched cells.[8] NPWT thus boasts to be more efficient and promotes faster healing of chronic wounds in comparison to conventional therapy of dressing.

In 1995, a negative pressure wound therapy (NPWT) system, also known as vacuum-assisted closure[9] (V.A.C™ Therapy, KCI, San Antonio, TX), became commercially available proving to be highly effective with good outcomes.[10] A randomized controlled trial was conducted in Australia in 2003 using VAC® device (KCI, San Antonio, TX) on pressure wounds, diabetic wounds, skin grafts and deep and complex wounds, which showed faster appearance of granulation tissue with early re-epithelialisation as compared to the standard dressings.[11] Though this treatment was a breakthrough in the developed world, it failed to gain ground in the low and middle income regions due to the substantial financial resources required. One of the greatest drawbacks of this commercially available V.A.C apparatus was the high cost, limiting its use on a daily basis in the financially backward regions.[12] But, as rightly said, necessity is the mother of inventions, we at our hospital, tried a low cost NPWT using the centralized suction apparatus available in the wards with some minor pressure modifications and using material like autoclaved bed foam and Ryle's tube.

The purpose of this study was to show the clinical efficacy of VAC therapy compared to conventional wound therapy and determine the cost incurred with respect to faster healing rates, fewer dressing changes and material used in both groups, also to determine the cost effectiveness of this low cost vacuum assisted closure system with that of commercially available one.

This type of vacuum assisted closure has the potential to be used on a daily basis in hospitals with budget constraints. Our study may be a step towards the wider application of this cost effective, negative pressure wound closure system which may be replicable and scalable across hospitals in low and middle income countries.

## METHODS

The present study was conducted on patients admitted with chronic non healing wounds in the General Surgery department of MGM hospital, Kamothe, New Mumbai. This was a prospective study conducted over a period of 3 months from June 2014 to August 2014 on a total of 100 patients, age 35-80 with chronic non healing wounds.

The study included patients taking into consideration their age, sex or associated medical co-morbidities. Patients were included in the study after a written, valid and informed consent and were approved by the Institutional Ethical Committee (IEC).

This study was conducted on patients with lower limb ulcers and pressure sores on below the waist, the aetiology being arterial or venous insufficiency, trophic ulcers and bed sores due to prolonged immobilization. The patients were divided into two comparable groups with 50 patients in each group. Group 1 was the test group which was subjected to vacuum assisted closure therapy and Group 2 was the control group subjected to the conventional method of dressing i.e. by debridement and using normal saline cleaning and application of antiseptic ointment.

The patients' demographic details such as age and sex were collected. Age and sex standardization was performed for the two groups in order to minimize the selection bias. Also associated co-morbidities like diabetes mellitus were noted for each patient. Patients in each of the two groups, on admission underwent a detailed clinical examination. Also all the basic routine clinical investigations like complete blood counts, fasting and post-prandial blood sugar levels, renal function tests like serum creatinine and blood urea nitrogen and liver function tests like total and direct bilirubin were performed for all the admitted patients. Those patients having large wounds with exposed blood vessels or open joint capsule, known or suspected malignancy, or osteomyelitic wounds were excluded from the study.

The patients were randomly assigned in each parallel study group without any selection bias. Randomisation was performed by creating two balanced groups of patients based on their age group and co-morbidities and then randomly assigning them to group 1, undergoing VAC and group 2 undergoing Conventional dressing for chronic wounds. For assigning the participants to the groups, a computer-generated list of random numbers was used. The patient and the medical personnel carrying out the dressing were aware of the allocation of the groups but the data analysts and outcome assessors were kept blinded.

The patients' wounds on admission were evaluated and thorough debridement was performed before assigning to any treatment modalities. The dimensions of the ulcer were measured before applying any of the above dressings. The time duration for evaluation of each wound was kept constant. After every 5 days, the wounds in each of the categories were re-evaluated and dimensions measured. This process continued for a period of 15 days in each of the categories and the rate of wound healing was measured in centimetres. The negative pressure used in the vacuum assisted closure of the wounds was provided by the wall mounted centralised suction apparatus available in the wards. It provided a constant pressure of 125 mm of Hg. The other material used for the vacuum dressings was bed foam with a pore size of 0.28 mm and about 3-4 inches in thickness which was sterilized in the hospital autoclave unit. A 16 gauze Nasogastric tube (Ryle's tube) was used along with commercially available low cost transparent adhesive film.

The technique used for application of the vacuum apparatus was as follows:

- Thorough debridement of the wound was performed with cleaning of the surrounding area with 70% alcohol (spirit).
- Sterile foam was then cut geometrically in the shape of the ulcer and placed on it.
- A Ryle's tube with its perforated ends was kept over the foam.
- An airtight dressing was given over the sponge and the Ryle's tube with the help of a transparent adhesive film with just a small opening for the emerging other end of the Ryle's tube, thus making it airtight.
- The other end of the tube was connected to the wall mounted centralized suction apparatus.
- The suction apparatus was calibrated to provide a constant suction rate of 125 mm of Hg.
- The pressure was applied continuously during the day as well as at night except for certain periods of ambulation.

The dressing was kept intact for 5 days and the wound was examined on the 5th day. Any discomfort or air leak during the period of dressing was taken care of. Care was taken to apply the vacuum dressing under strict sterile conditions. The VAC dressing was applied every 5 days for a total period of 15 days. After every 5 days, the dressing was removed and the wound dimensions measured. A re-dressing was done in a similar manner which again continued for a period of 5 days.

The patients in group 2 were controls whose wounds were managed using the conventional methods of wound dressing. In this, after initial debridement (surgical or chemical) the wound was thoroughly cleaned with normal saline and solution. Papain ointment, povidone ointment or any other antiseptic ointment was applied as per the requirements of the ulcer. It was then covered with gauze pads and sticking plaster or roller bandages. Once or twice daily dressings were performed using the same regimen. After every 5th day of dressing the dimensions of the ulcer were measured as for the vacuum dressings.

Culture and antibiotic sensitivity testing was performed for all the patients in both the categories at the time of admission. Broad spectrum, lower generation antibiotics were initially started for all patients, based on reports of resistant pathogens appropriate antibiotics were started for those multi-drug resistant wounds, this was kept

constant for both groups. The patients' general condition was noted every time and nutrition was kept to the optimum. The diabetic patients were strictly administered oral hypoglycaemic agents or insulin as per their requirement and regular blood sugar monitoring was performed.

After subjecting the patients to the above stringent wound management measures in the above two groups, the final evaluation was performed on the 15th day of admission and the rate of wound healing was determined for each group. Also the cost of the material used was calculated for each of the patients. Photographic evidence was collected before and after the above mentioned treatments for all the patients.

The data analysis of the study was performed by application of the SPSS statistical software and the results computed electronically.

## RESULTS

All the 100 patients were assigned into two groups' with 50 patients in each, group 1 including the cases subjected to vacuum assisted closure and group 2 the controls undergoing conventional dressings. The assessment of healing rates in both the groups, that is, VAC as well as the patients treated with conventional dressing was carried out for a period of 15 days with observations on every 5$^{th}$ day and the results were assessed in relation to the following parameters to determine the clinical significance:

- Rate of wound healing at 5 days- determined by observing the reduction in wound dimensions by more than 1 cm.
- Rate of wound healing after 10 days- determined by observing the reduction in wound dimensions by more than 2 cm as compared to the initial dimensions.
- Rate of healing after 15 days- determined by observing the reduction in wound dimensions by more than 3 cm as compared to the initial dimensions.
- Cost incurred in vacuum assisted closure and in conventional dressing.
- Fig. 1a and Fig. 2a show two of the lower limb ulcers presented at the beginning of VAC therapy

***Rate of wound healing at 5 days: (Table 1)***

The rate of wound healing which was exhibited by reduction in size of the wound by more than 1 cm at the end of the first 5 days was higher in the cases as compared to the control group. It has been statistically proven with a p<0.001.

**Table 1: Comparison of wound healing after 5 days in cases and controls.**

| Size reduction >1 cm after 5 days | Cases | Controls | Total | Chi-square | df | P value |
|---|---|---|---|---|---|---|
| **Yes** | 42 | 9 | 51 | | | |
| **No** | 8 | 41 | 49 | 43.577 | 1 | <0.001 |
| **Total** | 50 | 50 | 100 | | | |

***Rate of wound healing after 10 days: (Table 2)***

The rate of wound healing which was seen by reduction in size of the wound by more than 2 cm as compared to the initial size, checked at the end of 10 days was again seen to be higher in the cases as compared to the control group. It has been statistically proven with a p value of <0.001 (Figure 2b).

**Table 2: Comparison of wound healing after 10 days in cases and controls.**

| Size reduction >2 cm after 10 days | Cases | Controls | Total | Chi-square | df | P value |
|---|---|---|---|---|---|---|
| **Yes** | 41 | 9 | 50 | | | |
| **No** | 9 | 41 | 50 | 40.96 | 1 | <0.001 |
| **Total** | 50 | 50 | 100 | | | |

***Rate of wound healing after 15 days: (Table 3)***

The rate of wound healing which was seen by reduction in size of the wound by more than 3 cm as compared to the initial size, checked at the end of 15 days was again seen to be higher in the cases as compared to the control group. It has been statistically proven with a p value of <0.001 (Figure 1b and Figure 2c).

**Table 3: Comparison of wound healing after 15 days in cases and controls.**

| Size reduction > 3 cm after 15 days | Cases | Controls | Total | Chi-square | df | P value |
|---|---|---|---|---|---|---|
| **Yes** | 41 | 4 | 45 | | | |
| **No** | 9 | 46 | 55 | 55.313 | 1 | < 0.001 |
| **Total** | 50 | 50 | 100 | | | |

***Cost calculation of the vacuum assisted wound closure: (Table 4)***

The total cost incurred in the vacuum assisted wound closure system application was calculated by adding the cost of the working of the wall mounted centralized suction apparatus and the total cost of the material used like the porous bed foam including the sterilization cost, cost of the Ryle's tube and the transparent adhesive film per patient. It was calculated for an overall period of 15 days which involved three dressing changes, thus amplifying the cost of the material used to thrice the cost per dressing, per patient.

**Table 4: Cost calculation of vacuum assisted wound closure per patient.**

| Wall mounted suction apparatus | Sterilized bed foam | Ryle's tube | Transparent adhesive dressing film | Total cost for 15 days |
|---|---|---|---|---|
| **Rs. 50** | Rs.280 | Rs.120 | Rs.300 | Rs.750 |

***Cost calculation of the conventional wound dressing: (Table 5)***

The total cost incurred in the conventional wound dressing was calculated by adding the cost of the material used for dressing like gauze pads, gamjee rolls, adhesive tapes and bandage rolls as well as the various ointments used in each patient. The gauze pads and bandage rolls used were in pre sterilized packs whereas the gamjee rolls were sterilized at the hospital autoclave unit. The cost of the ointments was variable ranging from Rs. 50 per tube to Rs. 300 per tube. So, an average of Rs.175 was taken into account as the cost of the ointment for each patient. The total cost was calculated taking into consideration once a day dressing for a period of 15 days in each patient, thus amplifying the cost of the disposable material used to 15 times the daily cost.

**Table 5: Cost calculation of conventional wound dressing per patient.**

| Gauze packs | Gamjee rolls | Adhesive tape | Bandage rolls | Ointment | Total cost for 15 days |
|---|---|---|---|---|---|
| **Rs.150** | Rs.225 | Rs.50 | Rs. 100 | Rs. 175 | Rs.700 |

The total cost incurred in the first group including the cases undergoing vacuum assisted wound closure for a period of 15 days per patient was Rs.750 as against the second group undergoing conventional wound dressing which was Rs.700 for the same period per patient. The costs considered here did not include the hospital admission and investigation charges and the bed charges which were constant for both the groups. The cost-benefit analysis of the two groups statistically revealed a $p<0.05$ under 95% confidence limits, thus proving vacuum assisted closure, although slightly expensive than the conventional dressing, to be a better and cost effective modality, taking into considering the faster wound healing rates leading to shorter duration of hospital stay and fewer dressing changes.


**Figure 1: A=Lower right leg ulcer after debridement and cleaning before application of VAC therapy; B=Lower right leg ulcer on day 15 of VAC therapy.**


**Figure 2: A=Lower limb ulcer on day 0 before the start of VAC therapy; B=lower limb ulcer on day 10 of VAC therapy; C=lower limb ulcer on day 15 of VAC therapy.**

## DISCUSSION

Ulcers, being on a significant rise due to multi factorial reasons, management of wounds is a constantly developing field of science, seeking ways and methods to promote more efficient, faster, safer and cost-effective modalities.[13] The application of vacuum assisted closure is rising with advancing technology. Vacuum is seen to significantly decrease the surface area of wounds as compared to the daily dressing therapy. Certain studies like the one performed by Philbeck et al promote application of intermittent cyclical pressure over continuous pressure as it has proved to be more effective.[14] Our study, in contrast has revealed faster healing without any additional complications with the application of vacuum continuously except during performing certain essential daily tasks like bathing or mobilization to prevent complications associated with prolonged immobility.

Argenta et al has discouraged using wall suction stating large controlled volumes might induce wound desiccation, but certain other studies like the ones by Shalom et alused wall mounted suction successfully for 15 patients with chronic wounds.[15,16] This study supports the later, as no complications like wound desiccation or patient discomfort, were noticed with the centralized wall mounted suction apparatus at our hospital. Many studies using vacuum application boast about faster healing rates, however no studies done in the Indian subcontinent provide the exact dimensions and rates of wound healing. Our study exhibited more than 3 cms reduction in the wound dimensions over a period of 15 days as compared to <2 cms reduction in the wound size by the conventional dressing methods. This can be attributed to the reduction in oedema fluid by the vacuum application, thus causing wound shrinkage as also the mechanical debridement which leads to less bacterial colonisation.

The number of dressing changes with the vacuum therapy was far less, as compared to conventional daily dressings which were cumbersome as well as painful. Though, the vacuum resulted in slight restriction of mobility, it did not hamper the patients' satisfaction levels and quality of life.

To consider application of any method on a regular basis, the greatest obstacle faced in a developing country, is to have an economically cheaper modality. The cost of commercially available V.A.C is Rs. 600,000 ($7500) for the unit and Rs. 6000 ($75) for each dressing change.[17] The cost of this low cost VAC is significantly less than the commercially available device. The total cost incurred per patient for a 15day treatment of vacuum assisted therapy was only Rs.750 which was also comparable to the daily conventional dressings. Treatment with the conventional dressing was only marginally less than these low cost VAC dressings. So, the cost-benefit analysis with the vacuum treatment revealed faster healing with fewer complications at a similar cost.

However, as seen in every study, our study came with a few potential biases as well as drawbacks. Drawbacks of this low cost VAC were that the patient was restricted to one place, ambulation was limited and certain patients did exhibit minor pain and discomfort. We also did not have a gold standard method of wound measurement as serial photographs; plaster moulds and use of measuring tapes are not validated modes of measuring wound dimensions and the depth of the wound was not accounted for. Also the treatment that we imparted, was followed up sequentially only for a period of 15 days in both the groups. Though we kept a track of the wounds up to complete healing either by primary healing or secondary wound closures, the reduction in size was only noted for a 15 day period. The cost calculations done were also for the same time duration which has been a major drawback. Large pressure ulcers had to undergo longer duration (more than 15 days) of VAC therapy to show significant reduction in size.

All said and done, studies of larger dimensions and longer durations are required to sufficiently and effectively validate the results of our study, so as to be applicable in the developing resource limited nations.

This study performed at a tertiary hospital in a developing country, effectively proved the efficacy of negative pressure wound therapy (Vacuum assisted wound closure), over the conventional wound dressings.

Also, the cost-benefit analysis revealed a significant overall advantage of vacuum assisted wound healing. NPWT does appear to exhibit better wound healing and is thus a promising alternative to the conventional management. The cost-effectiveness of this low budget vacuum apparatus also has the potential to be replicable across many hospitals with financial constraints in the low and middle income countries. However, rigorous studies on a larger scale are required in order to validate the results, so that this measure of wound healing can be propagated as a cost effective and a time saving modality of wound care.

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