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**Original Research Article**

# A randomized controlled trial comparing low cost vacuum assisted dressings and conventional dressing methods in the management of diabetic foot ulcers

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## ABSTRACT

**Background:** Diabetic foot ulcers are chronic wounds which are difficult to heal, due to ischemia and intrinsic defects in angiogenesis and impaired immunity against infection. VAC therapy influences positive mechanical forces on the growth of tissues, especially in stimulating cell migration and mitosis, optimizes blood flow, decreases local tissue edema from the wound bed and provides an occlusive environment for wound healing under moist, clean and sterile conditions. Aims and objective was to compare the effectiveness of low cost hospital made VAC dressing with conventional dressings in healing of diabetic foot ulcers.
**Methods:** This study was a prospective, randomized controlled trial and included 60 patients with diabetic foot ulcers admitted over 3 months. Patients were randomly allocated to two groups: odd numbered patients to VAC therapy and the even numbered patients to conventional dressings. Wound swab was taken before the start of the study. The data was analyzed and presented in percentages or proportions using Chi-square test and Student-t-test wherever applicable.
**Results:** In this study it was found that in the VAC dressing group 76.7% of the ulcers had red granulation tissue at the end of therapy compared to 46.7% in conventional group. The mean wound bed preparation time was found to be 15.60 days in the conventional dressing group and 8.50 days in the VAC therapy group. In the VAC group 72.73% ulcers had no bacteria at the end of therapy.
**Conclusion:** In this study, it was found that Vacuum Assisted Closure therapy was more effective than conventional dressings in the wound bed preparation of diabetic foot ulcers.

**Keywords:** Dressings, Diabetic ulcers, Vacuum assisted dressing, VAC therapy

## INTRODUCTION

India, is ranked first in the list of the ten nations most affected with diabetes, foot ulceration is the most common complication, affecting approximately 15% of diabetic patients during their lifetime. This can be attributed to several social and cultural practices such as barefoot walking, inadequate facilities for diabetes care and education, and poor socioeconomic conditions.[1] Diabetic foot ulceration followed by amputation contributes dramatically not only to the morbidity among persons with diabetes but is also associated with severe clinical depression.[2]

According to the Vascular Society of India (2010), the number of amputations in India is 80,000 to 100,000 every year. Over 85% of lower limb amputations are preceded by foot ulcers and diabetes remains a major cause of non-traumatic amputation across the world with rates being as much as 15 times higher than in the non-diabetic population.[3] The length of hospital stay is approximately 60% longer among patients with diabetic foot ulcers, as compared with those without ulcers.[4] Diabetic foot ulcers are chronic wounds which are difficult to heal, due to ischemia and intrinsic defects in angiogenesis and impaired immunity against infection.[5]

Several techniques have been developed to induce healing in chronic diabetic foot wounds. These include new generation dressings, namely silver dressings, anodyne therapy, ultrasonic debridement and extracorporeal shockwave therapy.[5] The Vacuum Assisted Closure (VAC) entails placing an open-cell foam dressing into the wound cavity and applying a controlled sub atmospheric pressure.[6] VAC promotes wound bed healing in the following ways:

- VAC exerts a three-dimensional stress across the whole area of the wound, also known as macro-strain, that draws wound edges inwards in a centripetal fashion, thus shrinking the wound[5]
- The positive influences of mechanical forces on the growth of tissues, especially in stimulating cell migration and mitosis, are also noted[7]
- This therapy enhances clearance of bacteria colonizing the wound, and aids in wound healing.[8,9]
- Use of VAC therapy in large wounds obviated the need for a daily change of dressing, hence removing the trouble of a daily change of dressing[5]
- Studies have demonstrated that this technique optimizes blood flow, decreases local tissue edema and removes excessive fluid from the wound bed[10]
- Active reduction of excessive wound fluid also results in decompression of small blood vessels, restores microcirculation and increases oxygen and nutrient delivery to the wound. All these factors notably improve the rate of granulation tissue formation[10]
- VAC therapy has the ability to provide an occlusive environment in which wound healing could take place under moist, clean and sterile conditions. This environment increases the rate of granulation in the wound, besides reducing pain caused by the wound. Such a sterile, occlusive environment is not given by conventional dressings.[5]

Since these vacuum dressings are unaffordable to the lower socioeconomic class we used a low budget vacuum dressing using easily available materials in the wards which showed similar results as that of company VAC dressings. Aim and objectives was to compare the effectiveness of low cost hospital made vacuum assisted closure with conventional dressings in healing of diabetic foot ulcers, in terms of granulation tissue formation along with change in wound dimensions, bacterial clearance and patient satisfaction.

## METHODS

This study was a prospective, randomized controlled trial and included 60 patients with diabetic foot ulcers admitted in the Surgery and Orthopedics departments of Father Muller Medical College Hospital. The study was conducted over a duration of 3 months in 2015 and was approved by the Ethical Committee of the institution. Informed consent for the study was obtained from the patient.

### *Inclusion criteria*

- All patients with diabetic foot ulcers of size less than 15 cm
- All patients in age group between 20-80 years of age.

### *Exclusion criteria*

- Patients not willing to participate in the study
- Ulcers with underlying osteomyelitis of the bone.

Patients were randomly allocated to two groups: odd numbered patients to VAC therapy and the even numbered patients to conventional dressings. Documentation in the study included the patient's profile, diabetic history, complications and comorbidities. Wound description included size and site of ulcer, presence of exudates and presence of granulation tissue. In all patients, a wound swab was taken on admission and wound debridement done.

*VAC therapy*

After a proper debridement of the wound, polyurethane ether foam was applied to the wound. A non- collapsible drainage tube embedded in the foam was then connected to the wall suction pump. Then an airtight adhesive drape (opposite) was applied on top of the foam and a permanent negative pressure of -200 mmHg was exerted. Typically, the wall suction pump could be programmed to provide various amounts of negative pressure (100-250mmHg) on an intermittent or continuous basis depending upon the wound type. The tube drained the secretion into a collection canister. In this way, a previously open wound was converted into a controlled, closed and moist wound.

*Conventional dressing methods*

The patients assigned to conventional dressing methods received daily local wound care. The choice of dressing depended on the wound bed and the number of exudates. The dressings included Silver dressings and Betadine dressings. The VAC dressings were changed every 5-7 days and the conventional dressings every day. On the sixth day, culture sensitivity, wound size, amount of

discharge and granulation tissue were noted. This was repeated for about three weeks or till the ulcer heals or is fit for skin grafting. A wound was considered to be prepared when healthy red granulation tissue covered 100% of the surface and wound, secretion was minimal and of serous nature.

In case of insufficient wound healing, re- debridement and re- VAC was done. The wound bed preparation time (the time between surgical debridement and application of the skin grafts) for skin grafting in the patients of both the groups were noted. At the end of therapy, patient satisfaction was also noted. Patient satisfaction was assessed under 4 parameters: satisfaction of health, satisfaction of sleep, satisfaction of basic daily life activities and satisfaction of delivered health services. Patients were asked to rate their satisfaction levels from a scale of 1 to 5 with 1 being very unsatisfied, 2 being unsatisfied, 3 being no satisfaction, 4 being satisfied and 5 being very satisfied.

***Statistical analysis***

The data collected was entered in MS office Excel 2010. It was imported in SPSS, 23 version. The data was analyzed and presented in percentages or proportions using Chi-square test and Student-t-test wherever applicable.

## RESULTS

The demographic details of the patients in our study are mentioned in Table 1. Difference in the ulcer dimensions in terms of volume, surface area, length, width, depth of the ulcers between the first day and end of therapy was calculated Table 2. The mean difference in the volume and length of the ulcers between the two groups was found to be statistically significant ($p<0.05$).

**Table 1: Age distribution of patients.**

| | Conventional | VAC |
|---|---|---|
| Age (Mean) | 58 (35-82) | 58.5 (34-90) |
| **Sex** | | |
| Male | 21 (70%) | 23 (76.7%) |
| Female | 9 (30%) | 7 (23.3%) |
| **Occupation** | | |
| Agriculture | 4 (13.3%) | 3 (10%) |
| Homemaker | 6 (20%) | 6 (20%) |
| Labourer | 3 (10%) | 7 (23.3%) |
| Retired | 7 (23.3%) | 5 (16.7%) |
| Others | 10 (33.3%) | 9 (30%) |
| Duration of diabetes (mean)-months | 87 (3-264) | 102 (3-516) |
| **Comorbidities** | | |
| Hypertension | 14 (46.7%) | 9 (30%) |
| Nil | 16 (53.3%) | 19 (63.3%) |
| Others | 0 (0%) | 2 (6.7%) |
| Diabetic ulcer chronicity (mean)-months | 20.94 (0.26-120) | 3.01 (0.16-12) |
| **Site** | | |
| Foot | 11 (36.7%) | 6 (20%) |
| Leg | 11 (36.7%) | 12 (40%) |
| Toes | 2 (6.7%) | 7 (23.3%) |
| Malleoli | 4 (13.3%) | 5 (16.7%) |
| Others | 2 (6.7%) | 0 (0%) |

**Table 2: Difference in ulcer dimensions (day 1 to end of therapy).**

| Dressing | | Mean (SD) | t value | Significance |
|---|---|---|---|---|
| Difference in volume | Conventional | 1.1233 (4.76644) | -2.120 | 0.038 |
| | VAC | 10.2478 (23.08564) | | |
| Difference in surface area | Conventional | -0.1230 (0.46906) | -1.732 | 0.089 |
| | VAC | 6.0737 (19.59550) | | |
| Difference in length | Conventional | -0.0200 (0.7611) | -2.852 | 0.006 |
| | VAC | 0.1933 (0.40252) | | |
| Difference in width | Conventional | -0.0767 (0.36548) | -1.561 | 0.124 |
| | VAC | 0.3300 (1.37944) | | |
| Difference in depth | Conventional | 0.1033 (0.29300) | -2.278 | 0.0260 |
| | VAC | 0.2567 (0.22389) | | |

*Statistical significance, $p<0.05$.

In this study it was found that in the vac dressing group on day 1 46.7% ulcers had red granulation tissue and at the end of therapy 76.7% of the ulcers had red granulation tissue. In the ulcers which underwent conventional dressing 46% had red granulation tissue on day 1 and at the end of therapy, 46.7% had red granulation tissue Table 3.

Also, the mean wound bed preparation time was found to be 15.60 days in the conventional dressing group and 8.50 days in the vac therapy group. This was found to be statistically significant ($p<0.05$). In this study, in the

VAC group, on day 1, 63.33% had serous discharge and 16.67% had purulent discharge. At the end of therapy, 93.33% ulcers had serous discharge and 6.67% had purulent discharge. In the conventional group, on day 1, 70% ulcers had serous discharge and 5 (16.67%) ulcers had purulent discharge. At the end of therapy, 96.67% ulcers had serous discharge and 3.33% ulcer had purulent discharge Table 4.

**Table 3: Comparison of granulation tissue formation in the diabetic ulcers between the 2 dressing groups (day 1 to end of therapy).**

| Colour of granulation tissue | Day 1 dressing | | Total | End of therapy dressing | | Total |
|---|---|---|---|---|---|---|
| | VAC | Conventional | | VAC | Conventional | |
| Red | 14 (46.7%) | 14 (46.7%) | 28 (46.7%) | 23 (76.7%) | 14 (46.7%) | 37 (61.7%) |
| Pale pink | 15 (50%) | 12 (40%) | 27 (45%) | 7 (23.3%) | 15 (50%) | 22 (36.7%) |
| Black | 1 (3.3%) | 4 (14.3%) | 5 (8.3%) | 0 (0%) | 1 (3.3%) | 1 (1.7%) |
| Total | 30 (100%) | 30 (100%) | 60 (100%) | 30 (100%) | 30 (100%) | 60 (100%) |

**Table 4: Comparison of discharge in the diabetic ulcers between the 2 dressing groups (day 1 to end of therapy).**

| Colour of granulation tissue | Day 1 dressing | | Total | End of therapy dressing | | Total |
|---|---|---|---|---|---|---|
| | VAC | Conventional | | VAC | Conventional | |
| Red | 14 (46.7%) | 14 (46.7%) | 28 (46.7%) | 23 (76.7%) | 14 (46.7%) | 37 (61.7%) |
| Pale pink | 15 (50%) | 12 (40%) | 27 (45%) | 7 (23.3%) | 15 (50%) | 22 (36.7%) |
| Black | 1 (3.3%) | 4 (14.3%) | 5 (8.3%) | 0 (0%) | 1 (3.3%) | 1 (1.7%) |
| Total | 30 (100%) | 30 (100%) | 60 (100%) | 30 (100%) | 30 (100%) | 60 (100%) |

**Table 5: Comparison of culture sensitivity (CS) in the diabetic ulcers between the 2 dressing groups (from day 1 to end of therapy).**

| Dressing | | | CS at the end of therapy | | Total |
|---|---|---|---|---|---|
| | | | Bacteria present | Bacteria absent | |
| VAC (total number of ulcers= 30) | CS (day 1) | Nil | 0 (0%) | 8 (100%) | 8 (100%) |
| | | Bacteria present | 6 (27.7%) | 16 (72.7%) | 22 (100%) |
| | Total | | 6 (20%) | 24 (80%) | 30 (100%) |
| Conventional (total number of ulcers = 30) | CS (day 1) | Nil | 0 (0%) | 6 (100%) | 6 (100%) |
| | | Bacteria present | 5 (20.8%) | 19 (79.7%) | 24 (100%) |
| | Total | | 5 (16.7%) | 25 (83.3%) | 30 (100%) |

*Chi-square test was not applicable as many of the cells were having expected value less than 5.

In the VAC group 72.73% ulcers had no bacteria at the end of therapy. In the conventional dressing group, on day one 79.17% were rendered sterile at the end of therapy Table 5.


**Figure 1: scale.**

With regard to patient satisfaction, it was studied under 4 parameters: satisfaction of health, sleep, basic daily life activities and of delivered health services. Vac therapy showed better satisfaction levels when compared to the conventional dressing group (Figure 1-4).

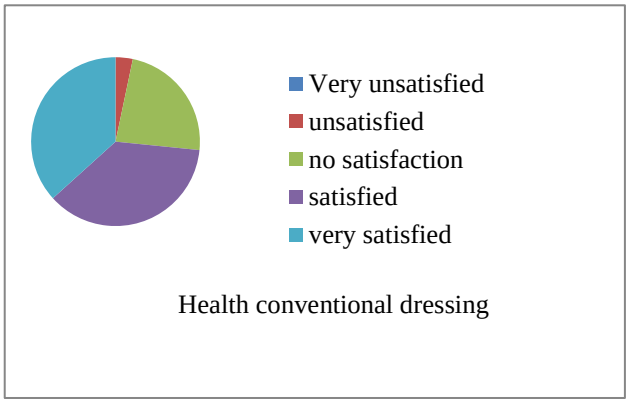


**Figure 2: diagram showing of satisfaction of health in conventional dressing group.**

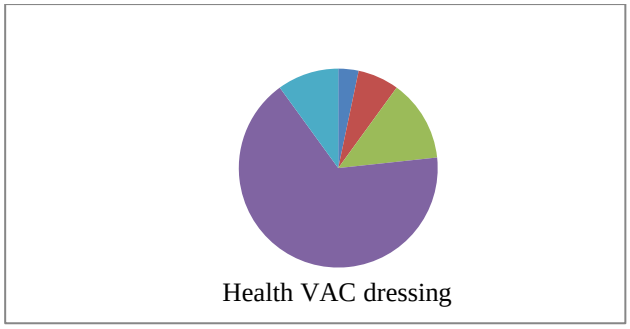


**Figure 3: Satisfaction of health in VACl dressing group.**

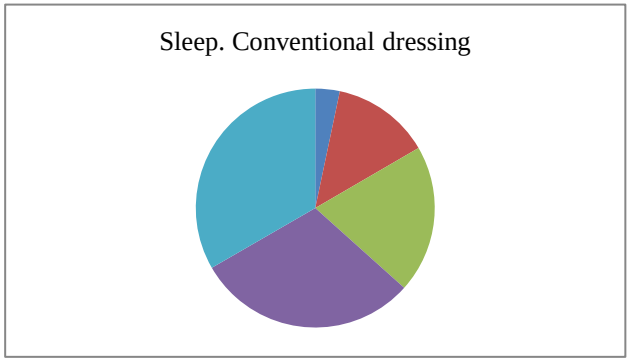


**Figure 4: sleep satisfaction in patients of conventional dressing group.**

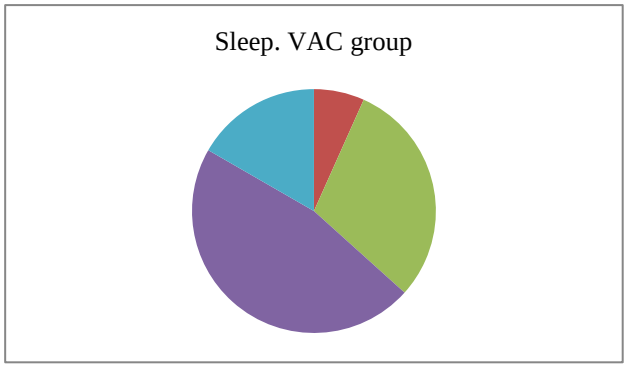


**Figure 5: Sleep satisfaction in patients of VAC dressing group.**

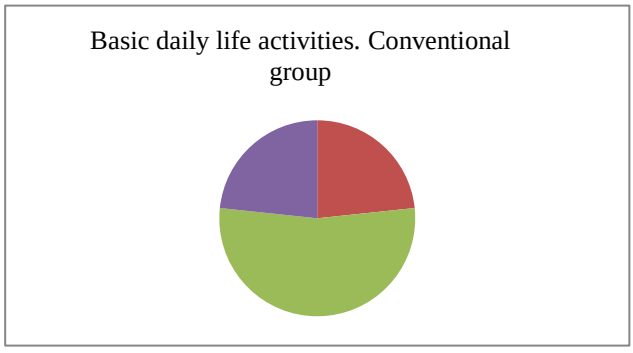


**Figure 6: Daily activities in patients of conventional dressing group.**

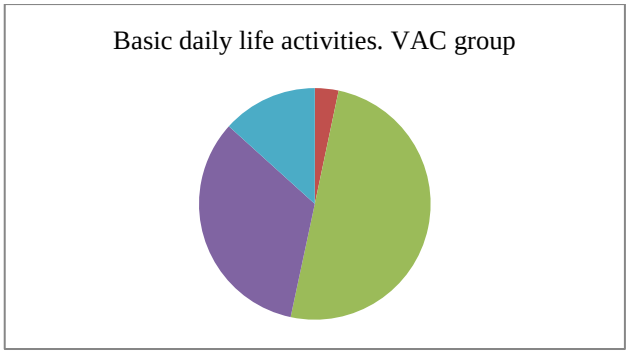


**Figure 7: Daily activities in patients of VAC dressing group.**

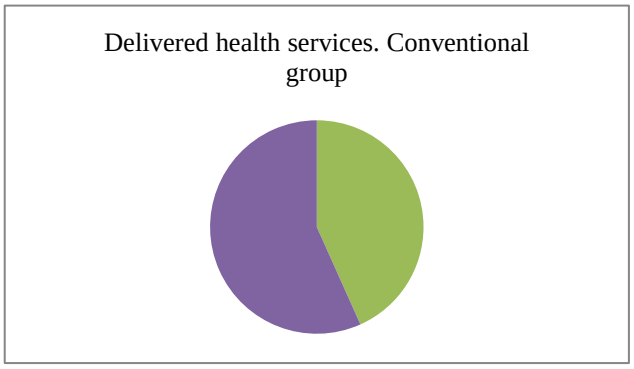


**Figure 8: Satisfactional on health services delivered in conventional group.**

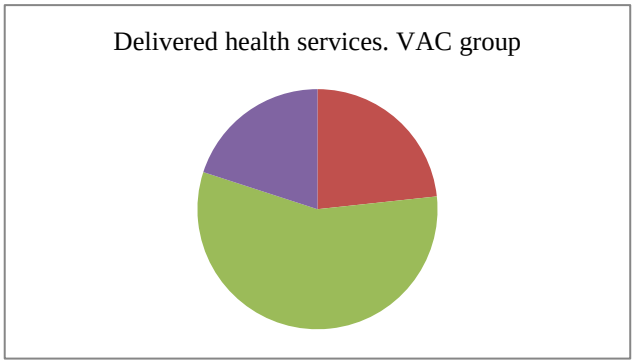


**Figure 9: Satisfactional on health services delivered in VAC group.**

## DISCUSSION

Diabetic ulcers are chronic ulcers are those which do not heal or fail to respond to treatment due to defects or disturbances in the normal wound healing mechanism. The main factors that result in delayed wound healing in chronic wounds are:

- Disturbance in microcirculation and prolonged hypoxia which interferes with angiogenesis and granulation tissue formation
- The glucose in the blood and tissues serves as a culture medium for the growth of bacteria and this

leads to coexisting infections which further delays wound healing
- Presence of edema, which further impedes microcirculation
- Further diabetic neuropathy leads to lack of sensation over the wound, which leads to neglecting of the wound, increasing the possibility of bacterial contamination which delays wound healing.

The treatment of diabetic ulcers falls into the following categories: Diagnosis, offloading, infection control, wound bed preparation, dressings, surgery, adjuvant agents (topical device, etc.) and prevention of recurrence.[11] Our study is revolving around the aspect of wound care hence it can be discussed under following headings.

**Figure 10: VAC dressing done.**

**Figure 11: Suction pump connected to dressing.**

***Wound healing***

Diabetic ulcers are usually chronic ulcers due to defects in the normal wound healing mechanism. Diabetic neuropathy directly contributes in genesis of non-healing diabetic ulcers, ischemic necrosis leads to tissue breakdown.[11]

The patient may not seek treatment until after the wound has advanced.[4] VAC therapy influences positive mechanical forces on the growth of tissues, especially in stimulating cell migration and mitosis.[7] It optimizes blood flow, decreases local tissue edema from the wound bed.[10] It also enhances bacterial clearance.[8,9] VAC therapy provides an occlusive environment for wound healing under moist, clean and sterile conditions. This promotes healthy granulation in the wound. Such a sterile, occlusive environment is not given by conventional dressings.[5]

**Figure 12: Post VAC day 5.**

In this study, it was found that all the ulcer dimensions decreased in the VAC therapy group. This resulted in decrease in ulcer volume and surface area. On the other hand, in the conventional dressing group, only ulcer volume and depth decreased. Surface area increased due to increase in length and breadth. This could be due to the increased number of times re-debridement needed to be done as seen in other studies.[13-15]

A randomized trial by Joseph et al, examining the efficacy of negative pressure wound therapy in chronic non-healing wounds had similar results, in his study the wound depth decreased by 66% as compared to only 20% for moist dressings.[16]

However, the study did not include diabetic foot wounds and therefore is not completely applicable to the patient population in this study. The amount of granulation tissue was better in VAC group which is comparable to a study done by Lone et al (refer table), this could be due to increased blood flow due to the negative pressure aiding in faster angiogenesis and increased nutrient supply, even the discharge decreased at a faster rate helping the ulcers to heal faster. This was comparable with one group, however other studies showed no significant decrease in wound healing time.[5,6,13,17-21]

**Table 6: comparison of the study results with Lone et al.**

| Measure of granulation at the end of the study in % | Week 6 | |
|---|---|---|
| | Conv | VAC |
| Our study | 46.70 | 76.70 |
| Lone et al | 40.00 | 77.78 |

### *Bacterial clearance*

Infection is usually the consequence rather than the cause of foot ulceration, but can cause substantial deterioration and delay in healing. Bacteria are omnipresent and its impact on healing is difficult to determine.[11] VAC therapy provided a sterile, more controlled resting environment to large, educating wound surfaces.[5] In various studies they found either decrease in bacterial load or no change but whatever was the bacterial load it did not have any significant impact on outcome.[8,13,14,17] Due to less wound fluid and better circulation greater amounts of oxygen is made available for the bacteria killing oxidative bursts. Concentration of immune cells is better in VAC because of foam.[22] Bacterial clearance was similar in both the groups, a tad better in conventional group (VAC : 80%, conventional : 83.3%) which is similar to certain studies but, in few other studies reduction in bacterial load was reported this can be due to improvement in circulation and oxygenation to compromised or damage tissue, which enhances the resistance to infection.[5,8,9,13,17,19,22] Increase in local tissue oxygen levels reduce or eliminate the growth of anaerobic organisms, which have been correlated to decreased healing rates. Also increased flux makes greater amounts of oxygen available to neutrophils for oxidative bursts that kill bacteria.[6] Probably, the antibiotic usage is more effective than the choice of dressing for bacterial clearance in this study and hence it cannot be made out whether it was the dressing or the antibiotic usage which lead to bacterial clearance. However, in another study by Moues et al, there was decrease in quantitative bacterial load in both the therapies and the bacterial load remained stable till the end of treatment.[14]

### *Patient satisfaction*

In this study, patients in the VAC therapy group were more satisfied than those in the conventional dressing group. VAC therapy patients did not require a daily change of dressing, thus making them feel less uncomfortable, they were ambulatory and had better quality of life which is similar to various other studies.[7,9,19] This study has several limitations, one of them being the small patient population. Also, the ulcer measurements and co morbidities were different in both the dressing groups. Further studies are needed to clarify these limitations.

## CONCLUSION

In this study, it was found that Vacuum Assisted Closure therapy was more effective than conventional dressings in the wound bed preparation of diabetic foot ulcers. It resulted in healthier granulation tissue formation and decrease wound in all dimensions. VAC therapy appears to be more efficacious than conventional dressings in the preparation of diabetic ulcers.

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