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**Original Research Article**

# Outcomes of VAC versus conventional dressings in patients with lower limb ulcer

**Hemant B. Janugade, Raunaq S. Chabbra*, Ankur G. Das, Aniket Surushe, Harshvardhan Saygaonkar**

Department of General Surgery, KIMSDU, P. B. Road, Karad, Maharashtra, India

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***Correspondence:**
Dr. Raunaq S. Chabbra,
E-mail: raunaq24@hotmail.com

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## ABSTRACT

**Background:** Chronic leg ulcers are a significant cause of morbidity in developing countries causing a significant burden on the health care system. The orthodox methods of dressing the wound requires long duration of hospital stay. The recent technique of vacuum assisted closure (VAC) has brought about new horizons in wound management with better outcomes.
**Methods:** A comparative randomized case control study was conducted with a total of 60 patients from November 2015 to December 2017 in patients admitted with lower limb ulcers to KIMSDU, Karad, Maharashtra.
**Results:** The mean graft uptake of Group A(VAC) and Group B (conventional dressings) was 82.23±15.60 and 70.07±18.42 respectively. Healing was achieved in minimum of 11 days and maximum of 48 days in Group A and minimum of 22 days and maximum of 59 days in Group B. The mean duration of wound healing in Group A and Group B was 27.70±9.57 and 41.93±11.58 days respectively. The duration of hospital stay was minimum of 13 days and maximum of 50 days in Group A and minimum of 24 days and maximum of 60 days in Group B.
**Conclusions:** Rate of granulation tissue formation, overall graft survival and patient compliance was better in vacuum assisted closure dressing group as compared to conventional dressing group. It was also seen that the overall hospital stay and post-operative complications were less in the vacuum assisted closure dressing group.

**Keywords:** Chronic leg ulcers, Dressings, Graft uptake, Vacuum assisted closure

## INTRODUCTION

Ulcers of the lower extremities, particularly in individuals older than 65 years, are a common cause for visits to the podiatrist, wound care specialist.[1] The incidence of ulceration is rising as a result of the ageing population and increased risk factors for atherosclerotic occlusion such as smoking, obesity, and diabetes. Leg ulcers is reported to have impact on virtually every aspect of daily life: pain is common, sleep is often impaired, mobility and work capacity tend to be restricted, and personal finances are often adversely affected. It is also known that social activities are restricted due to fear of injury and negative body image. Leg ulcers is usually associated with significant morbidity, high cost of healthcare, loss of productivity, and reduced quality of life.

Wound healing is a complex and dynamic process that includes an immediate sequence of cell migration leading to repair and closure. This sequence begins with removal of debris, control of infection, clearance of inflammation, angiogenesis, deposition of granulation tissue, contraction, remodeling of the connective tissue matrix, and maturation. When wound fails to undergo this sequence of events, a chronic open wound without anatomical or functional integrity results.[2]

Saline-moistened gauze has been the standard method; however, it has been difficult to continuously maintain a moist wound environment with these dressings. Subsequently, various hydrocolloid wound gels, growth factors, enzymatic debridement compounds, hyperbaric oxygen therapy, cultured skin substitutes, and other wound therapies have been advocated. All of these therapies are associated with significant expense and are being utilized in some situations without sufficient scientific evidence in favor of their efficacy.[3]

Negative pressure wound therapy (NPWT) is a newer non-invasive adjunctive therapy system that uses controlled negative pressure, using vacuum-assisted closure (VAC) device, to help promote wound healing by removing fluid from open wounds, preparing the wound bed for closure, reducing edema, and promoting formation and perfusion of granulation tissue.

The present study was done to assess the percentage of graft uptake in patients with chronic leg ulcer after VAC against that of conventional dressing methods.

## METHODS

A hospital based comparative Randomized Case Control Study was conducted to compare the clinical efficacy of VAC with conventional dressing materials in the treatment of lower limb ulcers. The present study was carried out with following two groups of 30 patients each.

### *Group A*

Patients treated with VAC

### *Group B*

Patients treated with conventional dressings.

Present study was a hospital based randomized case control study done on patients admitted to Surgical Units in KIMS, Karad for a period of two years

### *Inclusion criteria*

- Above 18 years of age
- An informed written consent was obtained from the patient
- Patient had to be admitted to a Surgical Unit in KIMS, Karad
- Patient with lower limb ulcers
- Patients with ulcer >4cm$^2$
- Be able and willing to comply with the study procedure in view of the investigator.

### *Exclusion criteria*

- Patients aged <18 or >70 years
- Pregnant or nursing mothers
- People on medications, such as corticosteroids, immunosuppressive agents or chemotherapy
- Patients with severe wound ischemia and severe neuropathy
- Deep infections such as osteomyelitis and septic arthritis
- Chronic ulcers not healing after 8 weeks.

Patients were divided into Group A (patients treated with VAC) and Group B (patients treated with conventional dressings), with an equal number of patients in each group. For each patient ulcers were treated till wound closure, either spontaneously, surgically, or until completion of the 8-week period.

Cases were allotted to each group randomly. All patients would have undergone adequate wound debridement. Patients were assessed by the following methods: Demographic and other information obtained, interview, wound assessment and treatment chart (used as a protocol globally for all wounds) and Visual Analogue Scale (VAS). Also, photographic and wound tracing was done at regular intervals for both groups.

### *Treatment schedule*

### *Group A*

Patients treated with vacuum assisted closure. Dressings were regularly changed every 4 days. Wound tracing and photos was taken every 8 days. Ulcers were followed up until wound closure, either spontaneously, surgically, or until completion of the 8-week period.

### *Group B*

Patients were treated with conventional dressings. Daily dressings were done. Wound tracing and photos were taken every 8 days. Ulcers were followed up until wound closure, either spontaneously, surgically, or until completion of the 8-week period.

Patients in both groups were administered with insulin therapy according to their blood sugar levels and injectable antibiotics started empirically initially and then according to the culture and sensitivity report. Necessary debridement and wound toilet done before application of dressings. In patients undergoing vacuum assisted closure a drainage tube was placed in the wound followed by dressing with sterile foam sheet and application of occlusive transparent film over the whole assembly. The drainage tube was connected to a suction machine. Intermittent negative pressure of 125 mmHg was applied every 15 minutes; the suction was stopped for 10 minutes.

For conventional dressings, after wound wash, povidonesoaked gauze pieces were used for initial 48 hours followed by dressings of normal saline soaked gauze pieces, twice daily. Duration of healing was taken in days. Both types of dressings were applied on respective groups after their selection and all necessary information for proforma were collected from both groups.

VAS was used as a measure of the bother score for symptoms such as in, immobility etc. It was used to measure patient satisfaction with the treatment plan at various intervals with the score of 0 being not satisfied and 10 being most satisfied.

### *Statistics*

Quantitative data is presented with the help of Mean and Standard deviation. Comparison among the study groups is done with the help of unpaired t test as per results of normality test. Qualitative data is presented with the help of frequency and percentage table. Association among the study groups is assessed with the help of Fisher test, student ‘t’ test and Chi-Square test. ‘p’ value less than 0.05 is taken as significant**.**

## RESULTS

Majority of the patients in Group A were in the age group of 41-50 years (33.3%) followed by 51-60 years (26.7%), 61-70 years (20%), 31-40 (13.3%) and 21-30 years (6.7%). The mean age of the patients was 49.9±11.32 years.

Majority of the patients in Group B were in the age group of 41-50 years (30%) followed by 61-70 years (26.7%), 51-60 years (23.3%), 31-40 years (16.7%) and 21-30 years (3.3%). The mean age of the patients was 50.8±10.57 years. There was no significant difference between the groups as per student t-test (p>0.05).

There was male preponderance in both the groups (56.7% and 60% respectively) while there were 43.3% and 40% female patients in Group A and Group B respectively. There was no significant difference between the groups as per Fisher test (p>0.05).

The most common type of ulcer in Group A and Group B was diabetic ulcer (43.3% and 40% respectively) followed by bedsore (26.7% and 33.3% respectively). There was no significant difference between the groups as per Chi-Square test (p>0.05).

The mean graft uptake of Group A and Group B was 82.23±15.60 and 70.07±18.42 respectively. There was significant difference between the groups as per Student t-test (p<0.05).

Healing was achieved in minimum of 11 days and maximum of 48 days in Group A and minimum of 22 days and maximum of 59 days in Group B. The mean duration of wound healing in Group A and Group B was 27.70±9.57 and 41.93±11.58 days respectively. There was significant difference between the groups as per Student t-test (p <0.05).

**Table 1: Mean graft uptake.**

| % of graft take up | Group A | | Group B | | p value |
|---|---|---|---|---|---|
| | N | % | N | % | |
| 91-100 | 14 | 46.6 | 4 | 13.3 | <0.05 |
| 81-90 | 2 | 6.7 | 6 | 20 | |
| 71-80 | 9 | 30 | 3 | 10 | |
| 61-70 | 2 | 6.7 | 10 | 33.3 | |
| 51-60 | 2 | 6.7 | 1 | 3.3 | |
| 41-50 | 0 | - | 5 | 16.7 | |
| 31-40 | 1 | 3.3 | 1 | 3.3 | |
| Total | 30 | 100 | 30 | 100 | |
| Mean±SD | 82.23±15.60 | | 70.07±18.42 | | <0.05 |

**Table 2: Duration of wound healing.**

| Duration of wound healing (days) | Group A | | Group B | | p Value |
|---|---|---|---|---|---|
| | N | % | N | % | |
| 11-20 | 6 | 20 | 0 | - | <0.05 |
| 21-30 | 14 | 46.7 | 7 | 23.3 | |
| 31-40 | 7 | 23.3 | 5 | 16.7 | |
| 41-50 | 3 | 10 | 11 | 36.7 | |
| 51-60 | 0 | - | 7 | 23.3 | |
| Total | 30 | 100 | 30 | 100 | |
| Mean±SD | 27.70±9.57 | | 41.93±11.58 | | <0.05 |

The duration of hospital stay was minimum of 13 days and maximum of 50 days in Group A and minimum of 24 days and maximum of 60 days in Group B.

**Table 3: Duration of Hospital stay.**

| Duration of hospital stay | Group A | | Group B | | p Value |
|---|---|---|---|---|---|
| | N | % | N | % | |
| 11-20 | 4 | 13.3 | 0 | - | <0.05 |
| 21-30 | 15 | 50 | 7 | 23.3 | |
| 31-40 | 7 | 23.4 | 5 | 16.7 | |
| 41-50 | 4 | 13.3 | 11 | 36.7 | |
| 51-60 | 0 | - | 7 | 23.3 | |
| Total | 30 | 100 | 30 | 100 | |
| Mean±SD | 32.03±17.40 | | 41.77±11.13 | | <0.05 |

The mean duration of wound healing in Group A and Group B was 29.23±9.17 and 41.77±11.13 days respectively. There was significant difference between the groups as per Student t-test (p<0.05).

## DISCUSSION

In the present study, majority of the patients in Group A were in the age group of 41-50 years (33.3%) followed by 51-60 years (26.7%), 61-70 years (20%), 31-40 (13.3%) and 21-30 years (6.7%). The mean age of the patients was 49.9±11.32 years. Majority of the patients in Group B were in the age group of 41-50 years (30%) followed by 61-70 years (26.7%), 51-60 years (23.3%), 31-40 years (16.7%) and 21-30 years (3.3%). The mean age of the patients was 50.8±10.57 years. There was no significant difference between the groups as per Student t-test (p>0.05).

There was male preponderance in both the groups (56.7% and 60% respectively) while there were 43.3% and 40% female patients in Group A and Group B respectively. There was no significant difference between the groups as per Fisher test (p>0.05).

Aslam R et al in a randomized control trial comparing vacuum assisted closure versus conventional dressings in diabetic foot ulcers, in terms of mean number of days of wound healing found mean age of patients in group A (N=60) (vacuum assisted closure therapy) was found to be 55.45 with a SD of ±6.279 and mean age of patients in group B (N=60) (conventional dressing for wound closure) was found to be 55.23 with a standard deviation of ±6.220, which was statistically not significant.[4] 63.3% were males and 36.7 % were females. In group B (conventional dressing for wound closure) 71.7 % were males and 28.3 % were females.

Blume PA et al study on comparison of negative pressure wound therapy using vacuum assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers found 342 patients with a mean age of 58 years; 79% were male.[5]

Singh B et al in a prospective time bound comparative study found average mean age was 54.4 years (37-74-year-old). Twenty-two patients (73.3%) were male.[6]

Singh B et al in a prospective time bound comparative study reported eight subjects (26.7%) were classified as grade III according to the Wagner classification, and twenty-two subjects (73.3 %) were classified as grade II. It was observed in our study that the mean graft uptake of Group A and Group B was 82.23±15.60 and 70.07±18.42 respectively. There was significant difference between the groups as per student t-test (p<0.05).[6]

Priyatham K et al in a prospective study assessing the efficacy of vacuum assisted closure as compared to conventional moist wound dressings in improving the healing process in chronic wounds reported better graft take up was observed in vacuum dressing group as compared to the conventional dressing group.[7]

Singh B et al in a prospective time bound comparative study reported first appearance of granulation, time to appearance of 100% granulation tissue and time to complete ulcer healing, all were attained much faster in patients under the NPWT "study" arm compared to the control arm ( 15.1, 25.1, 41.2 days versus 21.5, 41.1, 58.9 days) with a statistically significant difference ( p value = 0.0003).[6] Healing in the present study was achieved in minimum of 11 days and maximum of 48 days in Group A and minimum of 22 days and maximum of 59 days in Group B. The mean duration of wound healing in Group A and Group B was 27.70±9.57 and 41.93±11.58 days respectively. There was significant difference between the groups as per Student t-test (p<0.05).

Aslam R et al in a randomized control trial reported Mean duration of wound healing in days was found to be 11.366 with SD of ±3.488 in group A while in group B it was found to be 16.41 with a SD of ±3.104. Healing was achieved in minimum of 5 days and maximum of 18 days in group A and in group B minimum of 10 days and maximum of 22 days in group B.[4] Mean duration of wound healing was achieved earlier in group A with a P-value of 0.000 which was highly significant. Significant number of patients in group A achieved wound healing earlier in comparison to group B.

Riaz MU et al reported patients with VAC therapy have achieved healing in 18±3.4 days while normal saline dressing group took 38±3.8 days in comparison.[8] Another study by Etoz A et al in a study on negative pressure wound therapy on diabetic foot ulcers reported 45 patients with diabetic foot, the mean number of days of wound healing was 9.64 days ±4.65 in the vacuum dressing group and 14.22 days ±2.78 in the control group (P = 0.05).[9]

In the present study, the duration of hospital stay was minimum of 13 days and maximum of 50 days in Group A and minimum of 24 days and maximum of 60 days in Group B. The mean duration of wound healing in Group A and Group B was 29.23±9.17 and 41.77±11.13 days respectively. There was significant difference between the groups as per Student t-test (p<0.05).

Priyatham K et al in a prospective study assessing the efficacy of vacuum assisted closure as compared to conventional moist wound dressings in improving the healing process in chronic wounds found Shorter duration of hospital stay was observed in the vacuum dressing group.[7]

Dzieciuchowicz L et al, Sepulveda G et al, Moues CM et al and Ubbink DT et al have found that NPWT is superior to conventional gauze dressings in decreasing wound dimensions, achieving complete wound healing, wound bed preparation at a faster rate and lower incidence of re-amputations.[10-13]

## CONCLUSION

Rate of granulation tissue formation, overall graft survival and patient compliance was better in vacuum assisted closure dressing group as compared to conventional dressing group. It was also seen that the overall hospital stays and post-operative complications were less in the vacuum assisted closure dressing group.

Thus, vacuum assisted closure dressing can be considered as a superior option in the management of chronic wounds. But further studies with larger population will be needed in the future before vacuum assisted closure dressing can be added to the wide spectrum of treatment modalities available in the management of chronic wounds.

Negative Pressure Wound Therapy (NPWT) is a more effective method of treatment of lower limb ulcers as compared to Conventional Dressing with 30% faster healing rates, reduced overall complication rates and better patient acceptance.

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