

# Role of Negative Pressure Wound Therapy in Healing of Diabetic Foot Ulcers

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## INTRODUCTION

Diabetes is rapidly increasing in prevalence worldwide and surgery in patients with diabetic foot is becoming more common. Foot complications are a major cause of admissions in diabetic patients, and comprise a disproportionately high number of hospital days because of multiple surgical procedures and prolonged length of stay in hospital.<sup>[1]</sup>

Diabetic foot is an umbrella term for foot problems in patients with diabetes mellitus. Foot disorders such as ulceration, infection and gangrene are the most common, complex and costly sequelae of diabetes mellitus.<sup>[4-6]</sup>

The optimal therapy for diabetic foot ulcers remains ill-defined. Saline-moistened gauze has been the standard method; however, it has been difficult to continuously maintain a moist wound environment with these dressings. This has led to the development of various hydrocolloid wound gels, which provided more consistent moisture retention. Refinements in topical ointments have resulted in the addition of various pharmacological agents including growth factors and enzymatic debridement compounds. Hyperbaric

## ABSTRACT

**Introduction:** Foot disorders such as ulceration, infection and gangrene are the most common, complex and costly sequelae of diabetes mellitus.<sup>[1-3]</sup> Even for the most superficial wounds, treatment is often difficult with poor healing responses and high rates of complications. The purpose of this study is to compare the rate of ulcer healing with the negative pressure dressing technique to conventional moist dressings in the treatment of diabetic foot ulcers. **Materials and Methods:** The study was conducted on 30 patients, which were divided into two groups. One group received negative pressure dressing while other group received conventional saline moistened gauze dressing. Results were compared for rate of wound healing. **Results:** There was a statistically significant difference in the rate of appearance of granulation tissue between the two groups; with granulation tissue appearing earlier in the study group. The study group promised a better outcome (80% complete responders) as compared to the control group (60% complete responders). **Conclusions:** Negative pressure wound therapy has a definitive role in healing of diabetic foot ulcers.

**Key words:** Healing, negative pressure dressing, ulcer

oxygen therapy and culture skin substitutes are other wound therapies that have been advocated. All these therapies are associated with significant expense and are being utilized in some situations without sufficient scientific evidence demonstrating their efficacy. Therefore, the search for an efficacious, convenient and cost-effective therapy continues.

Negative Pressure Wound Therapy (NPWT) is a newer noninvasive adjunctive therapy system that uses controlled negative pressure using Vacuum-Assisted Closure device (VAC) to help promote wound healing by removing fluid from open wounds through a sealed dressing and tubing which is connected to a collection container. The use of sub-atmospheric pressure dressings, available commercially as a VAC device, has been shown to be an effective way to accelerate healing of various wounds.<sup>[7-10]</sup>

Till today, very limited data is available on the role of negative pressure dressing in healing of diabetic foot ulcers. Therefore, we endeavor to put forward

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a study to evaluate the role of negative pressure dressing in healing of diabetic foot ulcers using VAC device.

## MATERIALS AND METHODS

The present study was done on 30 patients at Dayanand Medical College and Hospital, Ludhiana. Patients were randomly divided into two groups - study group and control group. Patients were made to understand and sign the informed consent form.

Study group (A): Received negative pressure dressing therapy.

Control group (B): Received twice daily dressing changes with saline-moistened gauze.

### Inclusion criteria

- Age group 20-75 years.
- Ulcer area ranging between 50cm<sup>2</sup> and 200cm<sup>2</sup>.
- Diagnosis of diabetes mellitus made by American Diabetes Association Criteria.

### Exclusion criteria

- Age < 20 years or > 75 years.
- An obvious septicemia.
- Osteomyelitis.
- Wounds resulting from venous insufficiency.
- Malignant disease in a wound.
- Patients being treated with corticosteroids, immunosuppressive drugs or chemotherapy.
- Any other serious pre-existing cardiovascular, pulmonary and immunological disease.

Wounds of the subjects included in the study underwent initial sharp debridement to remove necrotic tissue and slough as far as possible. They were then randomized to either of the groups.

After the debridement, foam-based dressing was done over the wounds of the study group under all aseptic conditions. The dressing was covered with an adhesive drape to create an airtight seal. An evacuation tube embedded in the foam was connected to a fluid collection canister contained within a portable vacuum/suction machine [Figures 1 and 2]. Subatmospheric (negative) pressure was applied within a range of -50 mmHg to -125 mmHg intermittently three times a day. NPWT dressings were changed as and when required.

Subsequently the control group received twice daily saline-moistened gauze dressings. Weekly cultures were taken from the floor of the ulcers to assess for the bacterial flora. Standard antibiotic regimes were administered to all the patients which consisted broad spectrum antibiotics initially and later according to the culture sensitivity report. Ulcers were treated until the wound got closed surgically or spontaneously, or until completion of the 56-days (8 weeks) assessment whichever was earlier.

Complete healing was defined as 100% wound closure with re-epithelialization or scab with no wound drainage present and no dressing required.

At the end of the study period patients were categorized as:

1. Complete responders: Complete healing of lower limb ulcers.
2. Partial responders: 50% or greater reduction in product of the two longest perpendicular diameters from baseline.
3. Noncomplete responders: Less than 50% reduction in the product of the two longest perpendicular diameters from baseline.
4. Nonresponders: No reduction in ulcer or increase in ulcer area over base line.

The observations were noted and all results were tabulated and analyzed by using Student *t*-test for age, fasting blood sugar and percentage change in wound size from 1st to 8th week. The appearance of granulation tissue and the primary study end point were tested for significance by applying  $\chi^2$  test. The analysis for time status of wound was drawn by applying Z-test.

## RESULTS

The present study was conducted in a total of 30 patients aged between 20 and 75 years of age, of either sex, having ulcer area ranging between 50 and 200 cm<sup>2</sup> and fulfilling the diagnostic criteria of Diabetes Mellitus made by American Diabetes Association.<sup>[11]</sup>

### Age and sex

The mean age of patients in Group A was 61.33 ± 7.63 years and in Group B was 55.40 ± 11.54 years. The age distribution was comparable and statistically insignificant in both the groups ( $P > 0.10$ ). In Group A, 80% of the patients were males whereas 20% were females while in Group B 86.67% of the patients were

males and 13.33% were females.

### Wound discharge

At first week it was observed that all the patients in Group A and B had discharge from the wound. The discharge kept on decreasing over the period of observation in both the groups; however, Group A subjects had faster rate of disappearance of discharge. Wound discharge was present in only 13.33% of patients in 7th and 8th week in Group A as compared to 33.33% and 26.67% in Group B.

### Granulation tissue

From the study it was observed that during the first week granulation tissue was absent in 4 patients (26.67%) in Group A and 10 patients (66.67%) in Group B. It was seen that granulation tissue appeared at 2nd week in three out of four patients (75%) and 4th week in the remaining 1(25%) patient in Group A (Plate 4). The appearance of granulation tissue in patients of Group B was at 2nd, 4th and 5th week in three (30%), 3(30%) and two (20%) patients, respectively. It was also noted that in two (20%) patients granulation tissue remained absent even at the end of observation period. This suggested early appearance of granulation tissue in patients of Group A which was also found to be statistically significant

### Wound size

The wound size showed no change in 1 (6.67%) patient of Group A as compared to 3 (20%) patients of Group B. It was also observed that 2(13.33%) patients of Group B showed increase in wound size. The percentage decrease in the wound size was more in patients of Group A as compared to Group B. The mean decrease in the wound size in patients of Group A was  $-16.14 \pm 13.04 \text{ cm}^2$  and that of Group B was  $-5.98 \pm 14.41 \text{ cm}^2$ . The observation was found to be statistically significant ( $P < 0.05$ ).

### Bacterial load

We observed that patients of Group A showed rapid clearance of bacterial load as compared to Group B. This was suggested by 40% of the cultures in Group A having no growth by 3rd week as compared to 20% in Group B. *Staphylococcus aureus* was the found to be most prominent in patients of Group A whereas cultures from Group B mostly showed mixed growth

and Acinetobacter.

### Time to wound closure

Although statistically the time status of wound closure was comparable in both the groups ( $P > 0.10$ ), it was seen that the patients in Group A showed faster healing as compared to the patients of Group B. This was suggested by wounds of 9 (5+1+3) (60%) patients of Group A getting closed by the end of 4th week as compared to only 3 (0+2+1) (20%) patients of Group B. The patients who underwent below knee amputation were excluded from this analysis.

Both the groups had received similar treatment for the closure of wound, the most common mode of wound closure being STSG. Although statistically the primary study endpoint was comparable in both the groups ( $P > 0.10$ ), Group A promised better outcome (80% complete responders) as compared to Group B (60% complete responders).

## DISCUSSION AND CONCLUSIONS

The role of negative pressure dressing in healing of diabetic foot ulcers has been proposed as a novel method of manipulating the chronic wound environment in a way that it reduces bacterial burden and chronic interstitial wound fluid, increases vascularity and cytokine expression and to an extent mechanically exploiting the viscoelasticity of peri wound tissues.<sup>[12]</sup> VAC is generally well-tolerated and, with few contraindications or complications, is fast becoming a mainstay of current wound care. Hence we planned to use NPWT for the treatment and fast healing of diabetic foot ulcers.

The demographical profile was statistically studied and found comparable with no significant difference between the groups. The mean age of patients in study group was  $61.33 \pm 7.63$  years and in control group was  $55.40 \pm 11.54$  years which was comparable to the multicenter randomized controlled trial enrolling 342 patients done by Blume *et al.*,<sup>[13]</sup> who had a mean age of 58 years. The sex distribution was also similar to the above quoted study that had 79% males.

We observed that there was a decreasing trend in the presence of wound discharge in both the groups. However, it was noted that the rate of disappearance of wound discharge was faster in the study group as compared to the control. Only 13.33% of patients in



Figure 1: Showing application of negative pressure wound therapy



Figure 2: Showing machine used to create negative pressure



Figure 3: Diabetic ulcer treated with negative pressure wound therapy



Figure 4: Postoperative picture of the healed ulcer

study group had discharge at the end of 7th and 8th week as compared to 33.33% and 26.67% of patients in control group, respectively. This could be attributed to the faster rate of wound closure in the study group. In a similar study conducted by Tamhankar *et al.*,<sup>[14]</sup> in four patients with mesh-related infection after abdominal wall hernia repair which were treated by NPWD therapy, it was seen that NPWD therapy allows salvage of infected exposed mesh by clearing the purulent discharge promoting granulation tissue formation.

Application of negative pressure over wound bed allows the arterioles to dilate, so increasing the effectiveness of local circulation, promoting angiogenesis, which assists in the proliferation of granulation tissue.<sup>[15]</sup> We have also found that the patients on NPWD therapy had earlier appearance of granulation tissue. Of all the patients who initially did not have granulation tissue, 75% of those in the study group promised its appearance by the end of 2nd week as compared to 30% in the control group and this was also found to

be statistically significant ( $P < 0.05$ ). Shrestha *et al.*,<sup>[16]</sup> in their prospective study of nine patients of renal transplantation who had developed wound infections following RT, observed progressive reduction in the size of wound and development of healthy granulation tissue in all the cases.

We found a statistically significant difference in the percentage change in the wound size between both the groups ( $P < 0.05$ ). The mean decrease in the wound size was more in the study group ( $-16.14 \pm 13.04 \text{ cm}^2$ ) as compared to the control group ( $-5.98 \pm 14.41 \text{ cm}^2$ ). Our study is consistent with McCallon *et al.*,<sup>[17]</sup> who had observed average decrease of 28.4% ( $\pm 24.3$ ) in wound size in the VAC group as compared to 9.5% ( $\pm 16.9$ ) average increase in wound size in control group. Mark Eginton *et al.*,<sup>[18]</sup> had also observed that the wound volume and depth decreased significantly in VAC dressings as compared to moist gauze dressings (59% vs. 0% and 49% vs. 8%, respectively).

We observed that patients of study group showed rapid clearance of bacterial load as compared to control

group. This was suggested by 40% of the cultures in study group having no growth by 3<sup>rd</sup> week as compared to 20% in control group. The decrease in the bacterial load could have been attributed to the antibiotic regimes administered during the study. Hence we were unable to eliminate this bias. However, *S. aureus* was the found to be most prominent in study group whereas cultures from control group mostly showed mixed growth and Acinetobacter. Our study correlates with the study by Moues *et al.*,<sup>[19]</sup> who had observed that nonfermentative Gram-negative bacilli showed a significant decrease in vacuum-assisted closure-treated wounds, whereas *S. aureus* showed a significant increase in VAC-treated wounds.

Although statistically the time status of wound closure was comparable in both the groups ( $P > 0.10$ ), it was seen that the study group showed faster rate of wound closure as compared to control group. McCallon *et al.*,<sup>[17]</sup> also observed satisfactory healing in VAC group in  $22.8 \pm 17.4$  days, compared to  $42.8 \pm 32.5$  days in control group.

The endpoint taken was a granulated wound or a wound ready for skin grafting or healing by secondary intention spontaneously whichever was earlier. Both the groups had received similar treatment for the closure of wound, the most common mode of wound closure being STSG [Figures 3 and 4]. It was also observed that the failure rate was higher in patients of control group as compared to study group. Our study correlates with the study conducted by David Armstrong *et al.*,<sup>[12]</sup> who had observed that NPWT delivered by VAC device was safe and effective treatment for complex diabetic foot wounds and could lead to higher proportion of healed wounds, faster healing rates and potentially fewer re-amputations than standard care. Similarly, Robert Frykberg *et al.*,<sup>[20]</sup> have also reported overall progressively increasing wound debridement depth and amputation rates in control groups; however the same increasing trend did not occur in the NPWT group.

At the end of the study, although the primary endpoint was statistically comparable in both the groups ( $P > 0.10$ ), the study group promised a better outcome (80% complete responders) as compared to the control group (60% complete responders) [Table 1].

Analyzing the results of our study, we opine that NPWT has a definitive role in promotion of proliferation of granulation tissue, reduction in the wound size,<sup>[21]</sup> rapid clearing of the wound discharge and bacterial load.

Our data demonstrates that negative pressure wound dressings decrease the wound size more effectively than saline gauze dressings over the first 4 weeks of therapy. It is suggested that NPWT is a cost-effective, easy to use and patient-friendly method of treating diabetic foot ulcers which helps in early closure of wounds, preventing complications and hence promising a better outcome.

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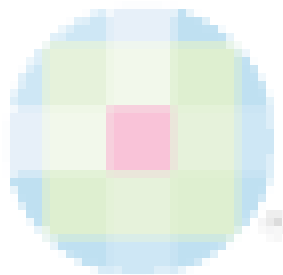
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