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**Original Research Article**

# Efficacy of negative pressure wound therapy using suction drain in the management of chronic wounds

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## ABSTRACT

**Background:** Chronic non-healing wounds are one of the major burden to the patients in the present era and covers about 1% of adult population and 3.6% of the population greater than 65 years. Chronic leg wounds are the common cause of morbidity and its prevalence in the community range from 1.9 to 13.1%. Indian studies show the prevalence of chronic wounds of around 4.5/1000 population. Recent studies have shown that application of a sub atmospheric pressure in a controlled manner to the wound site helps significantly in wound healing. Aim of the present study is to assess the efficacy of topical negative pressure moist wound dressings in wound healing process in chronic wounds and to prove that negative pressure dressings can be used as a much better treatment option than conventional saline dressings in the management of chronic wounds.
**Methods:** After 10 days, in study group the mean rate of granulation tissue formation, mean graft, mean hospital stay was 81.7%,80.6%, 34.7 days respectively and the same in control group it is 41.9%. ,60.45%, 58.60 days respectively.
**Results:** To conclude, topical negative pressure dressing's help in faster healing of chronic wounds and better graft take up and reduces hospital stay of these patients.
**Conclusions:** The database of our retrospective study regarding age and sex incidence, clinicopathological features and therapeutic outcome was comparable to other studies in various literatures.

**Keywords:** Chronic wounds, Graft, Rate of granulation tissue formation, Topical negative pressure moist wound dressing

## INTRODUCTION

Wound healing has its history as long as mankind. The THREE GESTURE THEORY was described 4000 years ago on clay tablets since 2200 B.C. Seven of the 48 case reports included in the Edwin Smith Papyrus (1700 BC) describe wounds and their management.[1,2] The work of Joseph Lister and Louis Pasteur has revolutionized the modern surgical world. Louis Pasteur introduced concept of "germ theory of disease". Joseph Lister introduced concept of "antisepsis and sterility" which helps prevent infections.[3,4] Chronic non-healing wounds are one of the major burden to the patients in the present era where microorganisms have developed a very high resistance to the existing antibiotics. Chronic wounds cover about 1% of adult population and 3.6% of the population greater than 65 years.[1]

As due to sudden change in the life style of the people in present era, the incidence and prevalence of diabetes is continuously rising during the past few decades. And the most common problem encountered in diabetic patients is development of diabetic foot, especially due to its complications like diabetic neuropathy. Also, the prevalence of diabetic foot is much higher in developing countries like ours, where most of the rural population still walks bare footedly. Role of surgery specially in diabetic foot patients is rapidly increasing worldwide.[4]

The most common and most complex foot disorders are ulceration, infection and gangrene, which are difficult to treat and also costly sequelae of diabetes mellitus.[5,6]

The best therapy for management of diabetic foot ulcers remains still ill-defined. Various methods of treatment strageies are devised/ developed for its management. Treatment lines were developed both for local and for systemic use. Saline-moistened gauze has been the standard method since long period, but it usually takes longer time for wound healing and also difficult to continuously maintain a moist wound environment for long time with these dressings.

This has led to the development of various hydrocolloid wound gels, which provided more consistent moisture retention. Modifications in formulations of topical ointments have resulted in the addition of various pharmacological agents including growth factors and enzymatic debridement compounds. Recently culture skin substitutes and hyperbaric oxygen have also been advocated in in wound management.[7]

Although all these above-mentioned modalities of therapies are associated with good results but on other hand are costly and availability in rural areas an issue and over that in some situations they are being used without sufficient scientific evidence demonstrating their efficacy. Hence, the search for an efficacious, convenient and cost-effective therapy for managing wound 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.[8-10]

Till today, very limited data is available on the role of negative pressure dressing in healing of diabetic foot ulcers. Therefore, we aimed to put forward a study to evaluate the role of negative pressure dressing in healing of diabetic foot ulcers using suction device.

## METHODS

The present study was done on 82 patients at R. L. Jalappa Hospital, attached with Sri Devraj Urs Medical college,Kolar. 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 15-75 years.
- Ulcer area ranging between 10cm2 and 200cm2.
- Diabetic foot ulcers
- Bedsores or pressure sores
- Traumatic wounds

### *Exclusion criteria*

- Age < 20 years or > 75 years.
- Osteomyelitis.
- Near joint cavities or places where not feasible to apply negative suction.
- Wounds resulting from venous insufficiency, Burns.
- 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, sterile gauze/foam was used to place on ulcer bed over the wounds in study group under all aseptic precautions. The tubing's of the suction device was placed over the gauze/foam and was again covered with gauze/foam and the whole area was covered with an adhesive transparent sheet (Tegaderm), to provide an airtight seal.

An evacuation tube embedded in the foam/gauze was connected to a suction device (suction Drain). Sub atmospheric (negative) pressure was maintained by the suction drain within a range of –50 mmHg to –125 mmHg intermittently three times a day. NPWT dressings were changed as and when required usually once in 48-72 hours. 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.


**Figure 1: A) Diabetic foot post disarticulation, B) Post debridement and C) Post negative suction dressings.**

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

- Complete responders: Complete healing of lower limb ulcers.
- Partial responders: 50% or greater reduction in product of the two longest perpendicular diameters from baseline.
- Noncomplete responders: Less than 50% reduction in the product of the two longest perpendicular diameters from baseline.
- 4Nonresponders: 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 82 patients aged between 15 and 75 years of age, of either sex, having ulcer area ranging between 10 and 200 cm2 and fulfilling the inclusion and exclusion criteria.

### *Age and sex*

The mean age of patients in Group A was was 54.05 ± 15.47 years and in Group B was54.07±16.79 years. The age distribution was comparable and statistically insignificant in both the groups (P>0.10). In Group A, (73.2%) of the patients were males whereas 27.8% were females while in Group B (75.5%) of the patients were males and 24.5% were females.

### *Wound discharge*

At first week it was observed that all the patients in Group A and B had discharge from the wound. But the quality of discharge was significantly improved in Group a, i.e. from Purulent discharge to serous discharge after the end of 10 days, where as in majority of patients in Group B had persistant purulent discharge, and the amount of discharge noted in group B was much higher than those with Group A patients. Serous wound discharge noted in 90.2% of patients in Group A, compared with that of Group B in which majority had persistant purulent wound discharge 68.3%.

### *Wound size*

The average or mean size of wound in study group on Day 0 was 66.5±29.3 mm and was 70.4±30.0 mm in control group. There was significant decrease in size among cases on day 7 compared to Day 0 size. Among cases size of wound on Day 7 was 46.6 ± 21.8 mm and in controls was 63.9±28.1 mm. There was significant difference in mean wound size on day 7 between cases and controls. There was significant decrease in size among controls on day 7 compared to Day 0 size. The wound size showed no change in 1 (6.67%) patient of Group A as compared to 09 (20%) patients of Group B. It was also observed that 5 (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 -18.14±13.04 cm2 and that of Group B was -4.98±14.41 $cm^2$. The observation was found to be statistically significant (P<0.05).

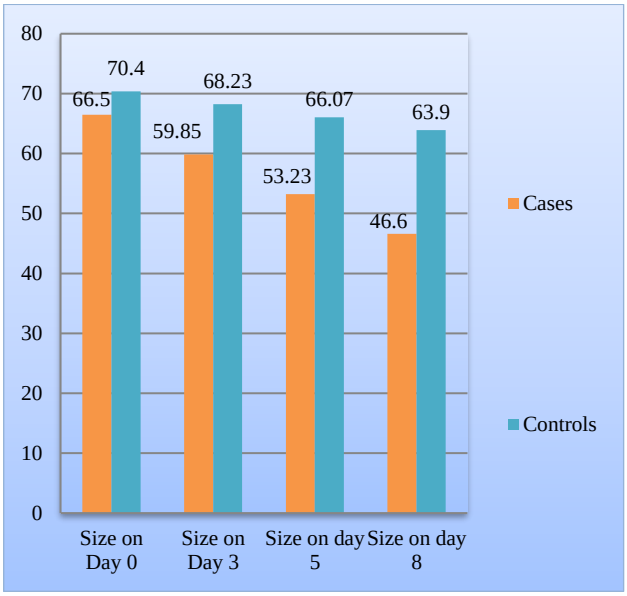


**Figure 2: Bar diagram comparing the size of wound pre and post NPWT.**

The signs of healing in terms of regularity of wound shapes, sloping of edges, regular margins, vascularity, healthy granulation formation, etc. appeared early in Group I (~1 week) compared with that in group II

(>4weeks). It was also observed that, ulcers of size < 20 cm2, (Mean 15.4Cm2) shows rapid healing of the wound < 2weeks in comparison with that of control group > 4 weeks. (4 patients) Rate of reduction of size to >2cms(>2mm/day) was noted in 10 days in study group, in comparison (25 patients) with that of the control group which took more than 3 weeks.

It was also observed in both in groups that that rate of reduction in ulcer size was less in patients who had diabetes mellitus, than in patients who are non-diabetics.

***Granulation tissue***

There was significant difference in mean Percentage of Granulation Tissue between cases and controls from day 0 to Day 8. Percentage of granulation tissue was increase in both the groups on day 3, 5 and day 8 significantly in both the groups. However, percentage of increase in granulation tissue in 1 week was highest in cases (81.7%) than in controls (41.9). Granulation tissue appeared earlier in study group around 80% in 1 week (28 patients), compared with that in control group i.e. > 4 weeks. From the study it was also observed that during the first week granulation tissue was absent in 2 patients (2.67 %) in Group A and 25 patients (66.67%) in Group B. It was seen that granulation tissue covered the whole wound area at 2nd week 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.

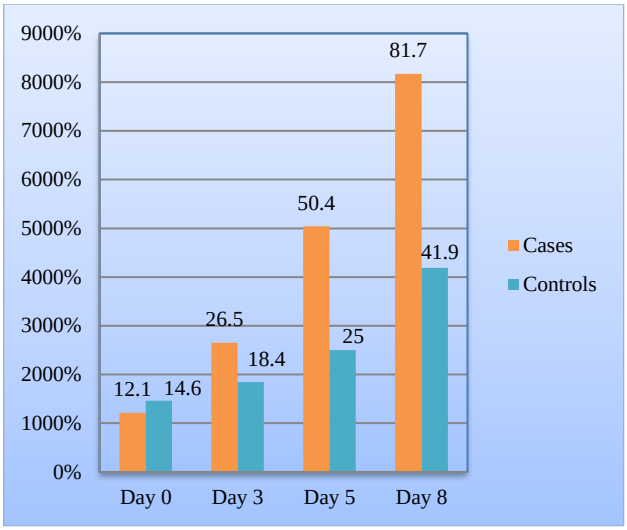


**Figure 3: Bar diagram showing Percentage of Granulation Tissue comparison between two groups on Day 0, 3, 5 and Day 8.**

***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.

**Table 1: Comparing the wound culture in both groups.**

| | | Group | | | | P value |
|---|---|---|---|---|---|---|
| | | Cases | | Controls | | |
| | | Count | % | Count | % | |
| Culture Day 0 | Present | 41 | 100.0 | 41 | 100.0 | - |
| Culture Day 10 | Present | 3 | 7.3 | 32 | 78.0 | <0.001* |
| | Absent | 38 | 92.7 | 9 | 22.0 | |

On day 0 culture was positive in all the cases and controls and on day 10, culture was negative in 92.7% of cases and in 22% of controls. This difference in culture findings on day 10 between cases and controls was statistically significant.

***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.

**Table 2: Comparison of time duration in days till wound closure in both groups.**

| | Group | | | | P value |
|---|---|---|---|---|---|
| | Cases | | Controls | | |
| | Mean | SD | Mean | SD | |
| Duration till wound closure (days) | 21.8 | 4.9 | 46.2 | 9.9 | <0.001* |

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).

Mean duration till wound closure among cases was 21.8 ± 4.9 days and among controls was 46.2±9.9 days. This difference in duration till wound closure between cases and controls was statistically significant.

***Duration of Hospital Stay***

Mean duration of hospital stay in cases was 34.7 ± 4.7 days and in controls was 58.6 ± 10.1 days. There was significant difference in mean duration of hospital stay between cases and controls.

**Table: 3: Comparison of mean hospital stays in days in both groups.**

| | Group | | | | P value |
|---|---|---|---|---|---|
| | Cases | | Controls | | |
| | Mean | SD | Mean | SD | |
| Hospital Stay (days) | 34.7 | 4.7 | 58.6 | 10.1 | <0.001* |

**Table 4: Comparison of study parameters in both groups.**

| | Cases | | | Controls | | |
|---|---|---|---|---|---|---|
| | Before | After 3 weeks | P value | Before | After 3 weeks | P value |
| Size (mean) in cm | 66.5 | 46.6 | <0.001* | 70.4 | 63.9 | <0.001 |
| Granulation tissue% | 12 | 81 | <0.001 | 14 | 41 | <0.006* |
| Wound discharge | Purulent 20 Seropurulent10 | Serous 38 | <0.001 | Purulent 19 | Purulent15 Seropurulent: 20 | <0.001 |
| Culture positivity | 41 | 3 | <0.001 | 41 | 32 | <0.001 |
| Duration till surgery | 24 days | | <0.001 | 45 days | | <0.001 |
| Duration of total stay | 34.7 days | | <0.001 | 54.6 days | | <0.001 |

The mean hospital stays in Group I was 34.70± 13.81(SD) days and that in Group II was 58.32± 16.48(SD) days. In both the groups, no complications occurred during the application of dressings, skin grafting or in the post-operative period. The patients were followed up after 1 month of discharge. The main post-operative parameters noted in both the groups during follow up are: Wound size, Contractures, Infections, pain. All these parameters were less in Group A as compared to Group B.

To summarise in few words, the rate of reduction of wound size, and rapid increase in size of granulation tissue, with decreased bacterial load, with decreased serous discharge, and decreased time till wound closure and short hospital stay was noted in group A, these changes appeared very fast in Group A compared with that in Group.

## DISCUSSION

Wound dressings was started initially from the means of providing physical protection to the wound surface, exudates absorption and local infection control by local medications to the level of providing adequate environment promoting wound healing. This has been achieved by various modern wound dressing techniques which promotes granulation tissue formation.

In the early 1990's, Fleischmann et al for the first time introduced the concept of topical negative pressure moist wound dressing in the field of chronic wound care. This type of dressing involved a combination of hydrocolloid with topical negative pressure dressings.[11]

The various mechanisms by which the negative ssuction dressings help in 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.[12]

The demographical profile was statistically studied and found comparable with no significant difference between the groups. The mean age of patients inGroup A was was 54.05±15.47 years and in Group B was 54.07±16. 79 years which was comparable to the multicenter

randomized controlled trial enrolling 342 patients done by Blume et al. 13 who had a mean age of 58 years. The sex distribution was also similar to the above quoted study that had 79% males. 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 (-18.14 ± 13.04 $cm^2$) as compared to the control group (-4.98 ± 14.41 $cm^2$). Present study is consistent with Joseph et al and McCallon et al, 14 who also had observed average decrease of 28.4% (± 24.3) in wound size in the VAC group as compared to 9.5% (± 16.9) average increase in wound size in control group.

**Table 5: Comaparison of study parameters with Blume et al, Joseph et al.**

| Variables | Peter A Blume et | | Joseph et al | | Present study | |
|---|---|---|---|---|---|---|
| | Vacuum group | Control group | Vacuum group | Control group | Vacuum group | Control group |
| Sample size | 169 | 166 | 18 | 18 | 41 | 41 |
| Mean age | 58 | 58 | 52.41 years | 53.2 years | 54.05 years | 54.07 years |
| Rate of granulation | 95% | - | 81.56% | 54.3% | 81.07% | 41.90% |
| Graft take up | 43.2% | 28.9% | 85.3% | 56.43% | 80.6% | 60.45% |
| Hospital stay | 63.6days | 78.1days | 36.24 days | 70.4 days | 34.64 days | 58.32 days |

**Table 6: Comparison between present study and Mc callon et al.**

| Variables | Mc Callon et al., | | Present study | |
|---|---|---|---|---|
| | Cases | Control | Cases | Controls |
| Percentage reduction of ulcer size | 28.4%(±24.3) | 9.5%(±16.9) | 35.4%(±10) | 10.3%(±8) |
| Duration of stay (days) | 22.8±17.4 | 42.5(±32.5) | 37.4 | 58.6 |

**Table 7: Comparison of cost between present study and with Webster J et al.**

| | Webster J et al. | | Present study |
|---|---|---|---|
| | VAC | Suction dressing | Suction dressings |
| Charges | 96.51/day | 4.22/day | 200/ 1 suction dressings |
| Mean duration | 32days | 32days | 34.5days |
| Total cost | ~$5000 | ~$200 | ~3000 INR |

Mark Eginton et al 15 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).

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.12 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, 90% 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).

We observed that patients of study group showed rapid clearance of bacterial load as compared to control group. This was suggested by 70% of the cultures in study group having no growth by 2rd week as compared to 10% 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. Present study correlates with the study by Moues et al who had observed that non-fermentative Gram-negative bacilli showed a significant decrease in vacuum-assisted closure-treated wounds, whereas *S. aureus* showed a significant increase in VAC-treated wounds.[16]

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 also observed satisfactory healing in VAC group in 22.8±17.4 days, compared to 42.8±32.5 days in control group.[14]

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 w0ound,

the most common mode of wound closure being STSG. It was also observed that the failure rate was higher in patients of control group as compared to study group. Present study correlates with the study conducted by David Armstrong et al , 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.[17] Similarly, Robert Frykberg et al have also reported overall progressively increasing wound debridementdepth and amputation rates in control groups; however, the same increasing trend didnot occur in the NPWT group.[18]

***Cost effectiveness of NPWT***

Various studies conducted by Philbeck et al have shown the cost effectiveness of topical negative pressure dressing.[19] The cost-effectiveness of this modality of treatment over conventional dressing techniques is believed to be due to

- Lesser time required for wound to heal or granulate.
- Better response to definitive treatment modalities like grafting, flaps etc. after removal of topical therapy.
- Less frequency of dressing changes thus reducing service as well as material charge.


**Figure 4: Diabetic Foot: A) Post Debridement, B) Post NPWT 2weeks, C) Post SSG.**

Philbeck et al, versus Ferrell et al, Vuerstaek et al, Akhlaq Hussain et el, Lavery et al, Mody et al also suggests that Negative pressure wound therapy(NPWT) though very effective in management of chronic wounds, as the V.A.C equipments are quite costlier, which is difficult for our rural population to afford.[20]

Present study it is believed that NPWT through low cost suction drain is as effective as providing NPWT through commercially available V.A.C systems. Studies conducted by Jeff J. Kim et al, Akhlaq Hussain et al, Mody et al, Webster J et al also concludes that NPWT through cost effective suction drain is much cheaper and effective option for people of low socioeconomic status as mentioned in one of the study mentioned above.

Analyzing the results of present study, we opine that NPWT has a definitive role in promotion of proliferation of granulation tissue, reduction in the wound size, rapid clearing of the wound discharge and bacterial load.[17]

The most important limitation of the present study is its sample size. Although a sample size of 82 patients is adeqaute for statistical analysis, a randomized controlled comparative study with a much larger population may help to further substantiate the findings or reveal variations which were not observed in the present study.


**Figure 5: Diabetic foot: On admission, post 2 weeks of suction dressings, post 4 weeks SSG.**

## CONCLUSION

In our present study it was concluded that the rate of granulation tissue formation, rate of reduction in wound size, time till wound closure, duration of hospital stay and patient compliance was better in topical negative pressure 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 topical negative pressure dressing group.

Negative pressure wound therapy using suction drain is much cheaper than the commercially available V.A.C systems and can be used as a cost-effective option for rural population in the management of chronic wounds. Thus, topical negative pressure moist wound dressing can be considered as a superior option in the management of chronic wounds.

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