

Negative pressure wound therapy versus conventional dressing in treatment of infected chronic wounds in rural hospital: A prospective case control study

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Abstract

Background: Patients with chronic wounds constitute a significant workload burden for health care organizations. Negative pressure wound therapy (NPWT) or vacuum assisted closure (VAC) treatment is based on evenly distributed local negative pressure applied to the wound surface. In present study we aimed to compare the effectiveness of this economical modification of NPWT with conventional dressings in the healing of infected chronic wounds in a rural hospital. **Material and Methods:** Present study was single-center, open labelled randomised control trial conducted in patients admitted to our hospital in surgery ward with infected chronic wounds due to diabetic ulcers, pressure ulcers, venous ulcers and pilonidal sinus ulcers willing to participate. Patients were randomly divided (by computer generated numbers) in two groups as Group A (Negative Pressure Wound Therapy) and Group B (Conventional Dressing). **Results:** 56 patients with chronic ulcers were randomly divided in two groups of 28 each. as Group A (Negative Pressure Wound Therapy) and Group B (Conventional Dressing). Age and gender distribution was statistically non-significant. NPWT group had more granulation tissue, faster wound contraction, closure by secondary intention, less healing time and less hospital stay as compared to conventional group, difference was statistically significant. Mean cost incurred by cases managed by conventional dressing was slightly lower than incurred by cases managed by NPWT, difference was however non-significant. **Conclusion:** Negative Pressure Wound Therapy with its modification appears to be superior compared to conventional dressing in terms of early appearance of granulation tissue, rapid contraction, overall faster healing, decrease in hospital stay and much more cost-effective.

Keywords: infected chronic wounds, Negative Pressure Wound Therapy, conventional dressing, granulation tissue,

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INTRODUCTION

Patients with chronic wounds constitute a significant workload burden for health care organizations. Successful

therapy should be based on knowledge of the wound etiology and the different features of the wound care products available. Various treatment modalities have been discovered over the years in forms of different types of wound dressings. Some commonly used dressing agents are povidone iodine, EUSOL, acetic acid, silver sulfadiazine etc. An ideal wound care product in addition to controlling the infection should also protect the normal tissues and not interfere with the normal wound healing.^{1,2} Negative pressure wound therapy (NPWT) or vacuum assisted closure (VAC) treatment is based on evenly distributed local negative pressure applied to the wound surface.^{3,4} The open wound is covered with a separate wound dressing (polyurethane or polyvinyl alcohol) and an air-tight film. The wound dressing is connected by means

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of a set of suction tubes to a control unit by which the primary negative pressure on the surface of the wound can be adjusted.⁵ The cost of the therapy by using branded NPWT appliances is approximately Rupees. 3000/- for 48-72 hours session which is very high, especially for patient requiring multiple sessions. In present study, we thus used an economical modification of NPWT (by using simple sofa foam, sterile plastic drape, Ryle’s tube and central suction) amounting approximately Rupees 300-350/- for one session. In present study we aimed to compare the effectiveness of this economical modification of NPWT with conventional dressings in the healing of infected chronic wounds in a rural hospital.

MATERIAL AND METHODS

Present study was single-center, open labelled randomised control trial conducted in the department of Surgery of a tertiary care Hospital. Study duration was of 18 months (November 2018 – May 2020). Study was approved by institutional ethical committee. Patients admitted to our hospital in surgery ward with infected chronic wounds due to diabetic ulcers, pressure ulcers, venous ulcers and pilonidal sinus ulcers willing to participate, were considered for study. A detailed history, clinical examination and relevant investigations were performed in all patients. The Index ulcer was defined as the ulcer with the largest area and duration of at least three months at the time of inclusion. Size of the Index ulcer was determined by volume of the wound i.e., by multiplying greatest length with greatest width and depth. Study was explained to patients and a written informed consent was taken for participation and follow-up. Patients were randomly divided (by computer generated numbers) in two groups as Group A (Negative Pressure Wound Therapy) and Group B (Conventional Dressing). Wounds of all the patients included in the study underwent sharp surgical debridement initially and during subsequent dressing change to remove necrotic tissue and slough. After debridement in the emergency operation theatre, a foam-based dressing was applied over the wounds of the study

group patients under all aseptic conditions. In Group A patients, dressing was covered with an adhesive drape to create an airtight seal. An evacuation tube embedded in the foam was connected to a vacuum and sub-atmospheric (negative) pressure was applied within a range of 80–125 mmHg on a continuous basis for 5 days. Group-B received once daily saline soaked gauze dressing. Oral analgesics were administered to all of the patients at the time of changing the dressing. Standard antibiotic regimens were administered to all patients, which consisted of broad-spectrum antibiotics initially and later guided by the culture sensitivity reports. Ulcers were treated until the wound was closed spontaneously, surgically or until completion of the 3 weeks period, whichever was earlier. Blood glucose levels were monitored strictly during treatment and controlled by appropriate doses of insulin. Treatment outcome was assessed (at week 1, 2 and 3) in terms of appearance of granulation tissue, wound contraction achieved by week, wound surface area, days of hospitalization and cost of procedure. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

RESULTS

56 patients with chronic ulcers were randomly divided in two groups of 28 each as Group A (Negative Pressure Wound Therapy) and Group B (Conventional Dressing). Mean age of study subjects was 52.8 and 53.6 years in Conventional and NPWT group respectively. The difference was statistically non-significant (p=1.0). Male Preponderance was observed in both groups (64.3% in Conventional and 57.1% in NPWT group respectively). The difference was statistically non-significant (p=0.78).

Table 1: Age and gender distribution

Characteristic	Group A (NWPT)	Group B (Conventional)	Total
Age (in years)			
≤ 50	18 (64.3 %)	18 (64.3 %)	36 (64.3 %)
>50	10 (35.7 %)	10 (35.7 %)	20 (35.7 %)
Mean	53.61 ± 11.9	52.8 ± 12.1	53.38 ± 12.3
Gender			
Female	12 (42.9 %)	10 (35.7 %)	22 (39.3 %)
Male	16 (57.1 %)	18 (64.3 %)	34 (60.7 %)

Most common type of chronic ulcer observed in present study was diabetic ulcer (69.6%) followed by venous ulcers (19.6%) and pressure ulcers (10.7%). No difference was seen in the study groups on the basis of type of ulcer (p=0.59).

Table 2: Type of ulcer

Type of ulcer	Group A (NPWT)	Group B (Conventional)	Total
Diabetic ulcer	18 (64.3 %)	21 (75 %)	39 (69.6 %)
Pressure ulcer	3 (10.7 %)	3 (10.7 %)	6 (10.7 %)
Venous ulcer	7 (25 %)	4 (14.3 %)	11 (19.6 %)

At the end of 1 and 2 weeks, 53.6% and 96.4% cases of NPWT group had granulation tissue as compared to only 21.4% and 64.3% cases in conventional group. The difference was statistically significant ($p < 0.01$). By the end of 3 weeks, 96.4% of the cases in NPWT group had granulation tissue as compared to 89.3% cases in conventional group ($p = 0.61$).

Table 3: Granulation tissue appearance

Granulation tissue appearance	Group A (NPWT)	Group B (Conventional)	Total	p-value
Week 1	15 (53.6 %)	6 (21.4 %)	21 (37.5 %)	< 0.01
Week 2	27 (96.4 %)	18 (64.3 %)	45 (80.4 %)	< 0.01
Week 3	27 (96.4 %)	25 (89.3 %)	52 (92.9 %)	0.61

The wound contraction rate was significantly faster with NPWT therapy. The difference in the rate of wound contraction was apparent since 1st week. By week 3, mean percentage of wound contraction was 90.9% in NPWT therapy as compared to 74.54% in conventional group patients. The difference was statistically significant ($p < 0.05$).

Table 4: Wound contraction rate

Wound contraction (%)	Group A (NPWT)	Group B (Conventional)	p-value
Week 1	58.76 ± 18.12	46.57 ± 20.21	< 0.05
Week 2	77.69 ± 16.83	61.34 ± 19.12	< 0.05
Week 3	90.90 ± 14.41	74.54 ± 17.94	< 0.05

Decrease in wound dimensions was significantly faster in NPWT group patients as compared to conventional group. The difference was statistically significant from week 2 ($p < 0.05$).

Table 5: Wound contraction rate

Wound surface area (cm ²)	Group A (NPWT)	Group B (Conventional)	p-value
After debridement	141.92 ± 18.12	142.57 ± 20.21	0.79
Week 1	84.52 ± 18.12	116.54 ± 20.21	0.33
Week 2	51.72 ± 16.83	74.35 ± 19.12	< 0.05
Week 3	24.37 ± 14.41	42.21 ± 17.94	< 0.05

Closure by secondary intention was achieved in 85.7% and 71.4% patients of NPWT and Conventional group while skin grafting was required in 14.3% cases of NPWT group as compared to 28.6% cases in conventional group respectively ($p < 0.05$).

Table 6: Wound closure

Wound closure	Group A (NPWT)	Group B (Conventional)	Total	p-value
Secondary intension	20 (71.4 %)	24 (85.7 %)	46 (82.1 %)	< 0.01
STSG	8 (29.6 %)	4 (14.3 %)	10 (17.9 %)	< 0.01

Mean healing time in days was significantly less in cases managed by NPWT compared to conventional group (7.33 versus 12.12 days; $p < 0.01$). Mean hospital stay was significantly more in cases managed by conventional dressing as compared to NPWT (17.23 versus 11.13 days; $p < 0.05$). Mean cost incurred by cases managed by conventional dressing was slightly lower than incurred by cases managed by NPWT (Rs 920/- Vs 1140/-; $p = 0.12$). The difference was however non-significant.

Table 7: Other characteristics

Characteristics	Group A (NPWT)	Group B (Conventional)	p-value
Healing time (days)	7.33 ± 2.02	12.12 ± 4.54	< 0.01
Hospital stay (days)	11.13 ± 4.32	17.23 ± 5.34	< 0.05
Cost (rupees)	1140 ± 191.2	920 ± 115.4	0.12

DISCUSSION

Negative Pressure Wound Therapy (NPWT) has been advocated as a novel method in the healing of chronic ulcers by stimulating the chronic wound environment in such 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 periwound tissues.^{6,7} One concerned with the branded VAC appliances used for NPWT was their cost. As most of our patients are from poor socio-economic

background, financial viability of the VAC is an issue. Hence, we planned to use an economical modification for NPWT for the treatment of chronic ulcers and compare its results with conventional dressing. Mean age of study subjects was 52.8 and 53.6 years in Conventional and NPWT group respectively. The incidence being higher age group can be well explained by fact that most of the chronic ulcers are diabetic ulcers, which is a complication of diabetes mellitus. Complications of diabetes increase with age. Also diabetes is disease of mostly elderly. Similar finding of highest incidence of diabetic ulcers being in age group of 45 to 64 years in the national health department survey (N.H.D.S) at USA.⁸ In another similar study by Lone AM *et al.*,⁶ mean age in NPWT group was 53.79 years and in Conventional group was 54.57 years. Male Preponderance was observed in both groups (64.3% in Conventional and 57.1% in NPWT group respectively). This was similar to that observed in review of literature by Rieber *et al.*,⁹ India being a male dominated country and lack of medical care given to females may also be a contributing factor. In a study by Lone AM *et al.*,⁶ women constituted approximately one third and men around two third of study participant in a NPWT and Conventional group. Application of negative pressure over the wound bed allows the arterioles to dilate, increasing the effectiveness of local circulation, promoting angiogenesis, which assists in the proliferation of granulation tissue.¹⁰ We observed that patients on NPWT therapy had early appearance of granulation tissue as compared to patients treated by Conventional dressing ($p < 0.05$). The wound contraction rate was also significantly faster with NPWT therapy Mean healing time in days was significantly less in cases managed by NPWT compared to conventional group (7.33 versus 12.12 days; $p < 0.01$). In a study by Lone AM *et al.*,⁶ granulation tissue appeared in 26 (92.85%) patients by the end of Week 2 in NPWT group in contrast to 15 (53.57%) patients by that time in conventional group. Armstrong and Lavery¹¹ also observed that the use of negative pressure therapy resulted in an increased rate of granulation tissue formation and a higher proportion of healed wounds compared to saline gauze dressings. Eginton MT *et al.*,¹² compared the rate of wound healing with the NPWT to conventional moist dressings in the treatment of large diabetic foot wounds. NPWT dressings decreased the wound volume and depth significantly more than moist gauze dressings (59% vs. 0% and 49% vs. 8%, respectively). The study concluded that Negative-pressure wound treatment may accelerate closure of large foot wounds in the diabetic patient. In a study by Moues CM *et al.*,¹³ patients were included (NPWT vacuum $n = 29$, conventional $n = 25$). The authors observed that wound surface area reduced significantly faster with NPWT vacuum therapy. Vuerstaek *et al.*,¹⁴ noted that patients in

the NPWT group healed faster (29 days x 45 days, $p < 0.01$), also reaching more quickly the time of wound bed preparation (7 days x 17 days, $p < 0.01$) [80]. Egemen *et al.*,¹⁵ applied NPWT in 20 patients with venous ulcers and found a rapid preparation of the bed, as well as an optimization of the subsequent integration of the skin graft. Ford *et al.*,¹⁶ noted mean percentage reduction in ulcer volume was higher in the NPWT group (51.8% vs. 42.1%, $p = 0.46$), NPT promotes healing and neo-vascularisation. Ashby *et al.*,¹⁷ noted superior benefits of NPWT in comparison with moist dressing in regards to rapid development of granulation tissue and wound contraction. In present study, mean hospital stay was significantly more in cases managed by conventional dressing as compared to NPWT (17.23 versus 11.13 days; $p < 0.05$). The decreased stay can be attributed to rapid healing and wound contraction rate in cases of NPWT therapy, which allowed an earlier reconstruction and reduced the days of hospitalization. Similar findings were noted by Moues CM *et al.*,¹³ Petzina *et al.*,¹⁸ Assenza *et al.*,¹⁹ Closure by secondary intention was achieved in 85.7% and 71.4% patients of NPWT and Conventional group while skin grafting was required in 14.3% cases of NPWT group as compared to 28.6% cases in conventional group respectively ($p < 0.05$). In the study by Lone AM *et al.*,⁶ most of the cases required skin grafting owing to large ulcers, the healing by secondary intention was higher in cases of NPWT as compared to Conventional dressing (23% versus 7%). Our observations were consistent with those of Prabhdeep *et al.*,²⁰ who also reported more cases requiring skin grafting in conventional group. Llanos *et al.*,²¹ in their study on traumatic wounds, observed that need for second coverage procedure was less common in the NPWT group (5 [16.7%] vs. 12 [40.0%] patients, $p = 0.045$). Mean cost of the therapy by using branded VAC appliances is approximately Rupees 3000/- for 48 -72 hours session which is very high, especially for patients requiring multiple sessions as in our study. If we superimpose this cost for the approximate of 5 days in present study, it will amount to Rupees 10,000/-. In present study, however, mean cost incurred by cases managed by NPWT was Rs 1,140/-. When we compare the cost to conventional dressing, the cost is slightly higher (Rs 920/-), but if we compute the shorter hospital stay in NPWT patients and faster recovery, meaning early return to work; the overall therapy is much more cost effective than conventional dressing. Thus Negative Pressure Wound Therapy with its modification appears to be superior compared to conventional dressings in terms of early appearance of granulation tissue, rapid contraction and decrease in hospital stay. Overall healing rate was also faster than conventional dressing while the cost was comparable. We thus recommend use of Negative Pressure

Wound Therapy in chronic wound management as first line therapy. We also recommend further studies with larger sample size to validate our observations in each specific type of chronic wounds viz. venous, diabetic and pressure ulcers.

CONCLUSION

Present study concludes that the Negative Pressure Wound Therapy with its modification appears to be superior compared to conventional dressing in terms of early appearance of granulation tissue, rapid contraction, overall faster healing, decrease in hospital stay and much more cost-effective.

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