

A Hospital-Based Assessment of the Effectiveness of This Economical Modification of Negative Pressure Wound Therapy with Conventional Dressings in the Healing of Infected Chronic Wounds

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Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to compare the effectiveness of this economical modification of negative pressure wound therapy with conventional dressings in the healing of infected chronic wounds in a Bihar region.

Material & methods: The Present study was single-center, open labelled randomised control trial conducted in the Department of Surgery. Study duration was of 12 months. 50 patients with chronic ulcers were randomly divided in two groups of 25 each as Group A (Negative Pressure Wound Therapy) and Group B (Conventional Dressing).

Results: Mean age of study subjects was 53.7 and 54.66 years in Conventional and NPWT group respectively. The difference was statistically non-significant. Male Preponderance was observed in both groups (64% in Conventional and 60% in NPWT group respectively). The difference was statistically non-significant. Most common type of chronic ulcer observed in present study was diabetic ulcer (68%) followed by venous ulcers (20%) and pressure ulcers (12%). No difference was seen in the study groups on the basis of type of ulcer. At the end of 1 and 2 weeks, 52% and 96% cases of NPWT group had granulation tissue as compared to only 20% and 64% cases in conventional group. The difference was statistically significant ($p < 0.01$). By the end of 3 weeks, 96% of the cases in NPWT group had granulation tissue as compared to 88% cases in conventional group. 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 90.82% in NPWT therapy as compared to 75.55% in conventional group patients. The difference was statistically significant ($p < 0.05$). Decrease in wound dimensions was significantly faster in NPWT group patients as compared to conventional group. The difference was statistically significant from week 2 ($p < 0.05$).

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

Chronic wounds can cause bacteria to form biofilms as a defense against unknown host cells and become resistant to topical and systemic antimicrobials. Biofilms allow pathogens to develop when microorganisms adhere to cells, colonize and increase their expansion on the wound surface. [1] It typically result from medical conditions, nutritional deficiencies, infections, and metabolic disorders, involve intensive and time-consuming treatments. Optimal management of chronic wound healing can be achieved by controlling several complex and dynamic factors, [2] which will improve the maintenance of anatomical continuity and function. [3] Furthermore, the ideal wound healing is to

restore the structure, function, and normal skin anatomy to a perfect condition. [4] Unfortunately, it takes a long time when inhibiting factors interfere with the process, including various local and systemic factors. [5]

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. [6,7] Negative-pressure wound therapy (NPWT) also called vacuum-assisted wound closure is an innovative technique in managing complex wounds. It was first described by Charikar [8] as an experimental technique for treating subcutaneous fistulas. Today, NPWT is well established for treating trauma wounds, general surgical wounds, and diabetic foot wounds.

With this technique, an open-cell foam dressing is placed into the wound cavity and a controlled sub atmospheric pressure is applied to suck fluid from the wound, with the intention of improving wound healing. [9] It deters the accumulation of fluid at wound sites through continuous drainage, makes daily dressing changes unnecessary, improves regional blood flow, and reduces bacterial proliferation, thus limiting the opportunity for infection. At the cellular level, NPWT is also known to encourage collagen synthesis, angiogenesis, and granulation tissue formation. [10-12] Unfortunately, NPWT is mainly used for wounds with controlled infection after procedures such as necrotic tissue debridement.

In present study we aimed to compare the effectiveness of negative pressure wound therapy with conventional dressings in the healing of infected chronic wounds in a Bihar region.

Material & Methods

The Present study was single-center, open labelled randomised control trial conducted in the Department of Surgery, RDJM Medical College and Hospital, Muzaffarpur, Bihar, India. Study duration was of 12 months. 50 patients with chronic ulcers were randomly divided in two groups of 25 each as Group A (Negative Pressure Wound Therapy) and Group B (Conventional Dressing). 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.

Methodology

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.

Statistical Analysis

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

Table 1: Age and gender distribution

Characteristic	Group A (NWPT)	Group B (Conventional)	Total
Age (in years)			
≤ 50	16 (64%)	17 (68%)	33 (66%)
>50	9 (36%)	8 (32%)	17 (34%)
Mean	54.66 ± 12.8	53.7 ± 12.4	52.38 ± 12.8
Gender			
Female	10 (40%)	9 (36%)	22 (39.3 %)
Male	15 (60%)	16 (64%)	34 (60.7 %)

Mean age of study subjects was 53.7 and 54.66 years in Conventional and NPWT group respectively. The difference was statistically non-significant. Male Preponderance was observed in both groups (64% in Conventional and 60% in NPWT group respectively). The difference was statistically non-significant.

Table 2: Type of ulcer and granulation tissue appearance

Type of ulcer	Group A (NPWT)	Group B (Conventional)	Total
Diabetic ulcer	16 (64%)	18 (72%)	34 (68%)
Pressure ulcer	3 (12%)	3 (11%)	6 (12%)
Venous ulcer	6 (24%)	4 (16%)	10 (20%)
Granulation tissue appearance			
Week 1	13 (52%)	5 (20%)	18 (36%)
Week 2	24 (96%)	16 (64%)	40 (80%)
Week 3	24 (96%)	22 (88%)	46 (92%)

Most common type of chronic ulcer observed in present study was diabetic ulcer (68%) followed by venous ulcers (20%) and pressure ulcers (12%). No difference was seen in the study groups on the basis of type of ulcer. At the end of 1 and 2 weeks, 52% and 96% cases of NPWT group had granulation

tissue as compared to only 20% and 64% cases in conventional group. The difference was statistically significant ($p < 0.01$). By the end of 3 weeks, 96% of the cases in NPWT group had granulation tissue as compared to 88% cases in conventional group.

Table 3: Wound contraction rate and surface area

Wound contraction	Group A (NPWT)	Group B (Conventional)	P Value
Week 1	57.73 ± 16.14	48.58 ± 21.19	< 0.05
Week 2	78.62 ± 16.84	62.38 ± 18.12	< 0.05
Week 3	90.82 ± 15.45	75.55 ± 16.94	< 0.05
Wound surface area (cm²)			
After debridement	143.97 ± 16.14	141.59 ± 20.22	0.79
Week 1	85.55 ± 17.13	115.55 ± 20.22	0.33
Week 2	52.78 ± 15.85	75.35 ± 18.12	< 0.05
Week 3	25.35 ± 15.45	43.27 ± 18.93	< 0.05

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 90.82% in NPWT therapy as compared to 75.55% in conventional group patients. The difference was

statistically significant ($p < 0.05$). 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 4: Wound closure

Wound closure	Group A (NPWT)	Group B (Conventional)	Total	p-value
Secondary intension	18 (72%)	22 (88%)	40 (80%)	< 0.01
STSG	6 (24%)	3 (12%)	10 (20%)	< 0.01

Closure by secondary intention was achieved in 88% and 72% patients of NPWT and Conventional group while skin grafting was required in 12% cases of NPWT group as compared to 24% cases in conventional group respectively ($p < 0.05$).

Table 5: Other characteristics

Characteristics	Group A (NPWT)	Group B (Conventional)	p-value
Healing time (days)	7.43 ± 2.04	12.18 ± 4.56	< 0.01
Hospital stay (days)	12.16 ± 4.36	18.22 ± 5.35	< 0.05

Mean healing time in days was significantly less in cases managed by NPWT compared to conventional group (7.43 versus 12.18 days; $p < 0.01$). Mean hospital stay was significantly more in cases managed by conventional dressing as compared to NPWT (18.22 versus 12.16 days; $p < 0.05$).

Discussion

Negative pressure wound therapy (NPWT) or vacuum assisted closure (VAC) treatment is based on evenly distributed local negative pressure applied to the wound surface. [13,14] 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 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. [15] Negative-pressure wound therapy (NPWT), which deters the accumulation of fluid at wound sites through continuous drainage, makes daily dressing changes unnecessary, improves regional blood flow, and reduces bacterial proliferation, thus limiting the opportunity for infection. At the cellular level, NPWT is also known to encourage collagen synthesis, angiogenesis, and granulation tissue formation. [16-18] Unfortunately, NPWT with polyurethane foam has the limitation that it is mainly used for wounds with controlled infection after procedures such as necrotic tissue debridement.

Mean age of study subjects was 53.7 and 54.66 years in Conventional and NPWT group respectively. The difference was statistically non-significant. Male Preponderance was observed in both groups (64% in Conventional and 60% in NPWT group respectively). The difference was statistically non-significant. Most common type of chronic ulcer observed in present study was diabetic ulcer (68%) followed by venous ulcers (20%) and pressure ulcers (12%). No difference was seen in the study groups on the basis of type of ulcer. 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. [19] At the end of 1 and 2 weeks, 52% and 96% cases of NPWT group had granulation tissue as compared to only 20% and 64% cases in conventional group. The difference was statistically significant ($p < 0.01$). By the end of 3 weeks, 96% of the cases in NPWT group had granulation tissue as compared to 88% cases in conventional group. In a study by Lone AM et al¹⁹ 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 Lavery [20] 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 [21] 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 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 90.82% in NPWT therapy as compared to 75.55% in

conventional group patients. The difference was statistically significant ($p < 0.05$). Decrease in wound dimensions was significantly faster in NPWT group patients as compared to conventional group. The difference was statistically significant from week 2 ($p < 0.05$). Closure by secondary intention was achieved in 88% and 72% patients of NPWT and Conventional group while skin grafting was required in 12% cases of NPWT group as compared to 24% cases in conventional group respectively ($p < 0.05$). In a study by Moues CM et al [22] patients were included (NPWT vacuum $n = 29$, conventional $n = 25$). The authors observed that wound surface area reduced significantly faster with NPWT vacuum therapy. Mean healing time in days was significantly less in cases managed by NPWT compared to conventional group (7.43 versus 12.18 days; $p < 0.01$). Mean hospital stay was significantly more in cases managed by conventional dressing as compared to NPWT (18.22 versus 12.16 days; $p < 0.05$). Ford et al [23] noted mean percentage reduction in ulcer volume was higher in the NPWT group (51.8% vs. 42.1%, $p = 0.46$), NPWT promotes healing and neo-vascularisation. Ashby et al [24] noted superior benefits of NPWT in comparison with moist dressing in regards to rapid development of granulation tissue and wound contraction. 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

The Present study concluded 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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