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Original Article

Assessment of the Relative Effectiveness of Negative Pressure Wound Therapy versus Standard Wound Dressing in Treatment of Pressure Ulcers

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Abstract

Introduction: A pressure ulcer (PU) is a localized injury to the skin and/or underlying tissue usually over a bony prominence. It occurs as a result of pressure or pressure in combination with shear and/or friction. In this study, the effect of negative pressure wound therapy (NPWT) on the outcome of PUs compared to Standard Wound Dressings (SWD) was observed.

Materials and Methods: The study was carried out in the Department of General Surgery and Department of Plastic Surgery, The Calcutta Medical Research Institute, Kolkata. A total of 58 consecutive patients having PU (of Stage 2, Stage 3, and Stage 4 according to the US National PU Advisory Panel Staging System, 2007) and fulfilling inclusion criteria were enrolled.

Results: The mean reduction in area of ulcer after treatment of the patients treated with SWD was significantly lower than that of the patients treated with NPWT ($P = 0.022$). The mean duration of treatment in days until granulation tissue appearance of the patients treated with NPWT was significantly lower than that of the patients treated with SWD ($P < 0.0001$). The cost of treatment was higher with NPWT than with SWD, but there was no significant difference in mean cost of the treatment of the patients ($P > 0.05$).

Conclusion: We conclude that NPWT is a better modality of treatment than SWD in healing of PUs. RCTs with a large sample size, longer duration of follow-up, and cost benefit analysis taking into account factors outside direct therapy costs need to be done to establish the superiority of NPWT over SWD.

Key words: Negative pressure wound therapy, Pressure ulcer, Standard Wound dressing

INTRODUCTION

A pressure ulcer (PU) is a localized injury to the skin and/or underlying tissue usually over a bony prominence. It occurs as a result of pressure or pressure in combination with shear and/or friction. Factors that contribute to the development of PUs are immobility, reduced sensation, shearing forces, moisture, friction, nutritional deficiency, and infection. PUs vary in severity and range from Stage I – non-blanchable erythema, Stage II – partial thickness loss of dermis, Stage III – full-thickness skin loss to Stage IV – full-thickness tissue loss with exposed bone, tendon or muscle, with Stages III and IV being severe.[1]

Surgery is an integral part of the treatment of PUs, but all patients are not fit for surgery. Apart from surgery, the treatment strategies for these wounds include the use of pressure-relieving devices, wound dressings, and, more recently, negative pressure wound therapy (NPWT).

Wound dressing with gauze has become the most widely used surgical dressing since Johnson and Johnson began mass-producing a sterile surgical dressing by sterilizing cotton yarn and thread in 1891.[2] Although wet-to-dry

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dressings have gained popularity throughout much of the 20th century, many investigations have published reports on the negative aspects of this method. Ovington states, "removal of a wet-to-moist dressing that has dried may then cause re-injury of the wound, resulting in pain and delayed wound healing." Gauze dressings have been reported to cause local tissue cooling during the evaporation period in wet-to-dry dressings. This cooling results in reflex vasoconstriction, hypoxia, impaired leukocyte, and phagocyte activity and increased affinity of hemoglobin for oxygen; all of which contribute to impaired wound healing. Removal of these dressings when dry can also lead to patient discomfort and pain.[3] The mechanical debridement during removal of these dressings can lead to cross-contamination of wounds by dispersion of bacteria into the air on removal. The non-selective mechanical debridement of healthy adjacent tissue is among another negative aspect of this wound care method8. Lawrence demonstrated that bacteria can pass through up to 64 layers of dry gauze in an *in vitro* study. It is permeable to exogenous bacteria and is associated with a higher infection rate than with transparent films or hydrocolloids.[4] While the materials are inexpensive, they do require frequent changes and the related nursing expense needs to be factored in when determining their true cost. Systematic reviews by Westby *et al.*[5] were unable to determine, in which dressings or topical agents are the most likely to heal PUs, and it is generally unclear whether the treatments examined are more effective than saline gauze. More research is needed to determine whether particular dressings or topical agents improve the probability of healing of PUs.

NPWT, which was developed at Wake Forest University (Winston-Salem, North Carolina) in the early 1990s, consists of an open-cell foam dressing covered with an adhesive drape. In spite of these claims, there is a growing recognition of a lack of high-quality research evidence to support the use of NPWT.[6] Several systematic reviews were unable to draw conclusions about the relative effectiveness of NPWT for the treatment of any wound including PUs, and they recommended that independent better quality research is needed.

This study aims to observe the effect of NPWT on the outcome of PUs compared to standard wound dressings (SWD). This will help us find whether NPWT is better than SWD and, therefore, provide the patients with better treatment options, to reduce their morbidity. This study will also provide information to PU patients about ulcer care and prevention of PUs. It will also provide an opportunity to train medical personnel to detect and treat adequately while helping to decrease economic and psychological trauma to the patient by improving the quality of life.

Aims and Objectives

Aim

The aim of this study was to assess the relative effectiveness of NPWT versus standard wound dressing in treatment of PUs.

Objectives

The objectives if this study were to assess and to compare the following between the two groups:

1. Reduction of surface area (length × breadth) of the wound.
2. Duration of treatment until granulation tissue appearance.
3. The cost of treatment (out of pocket expense for availing either approach).

MATERIALS AND METHODS

Study Site

The study was conducted at the Calcutta Medical Research Institute, Kolkata.

Study Population

The source of data for study was the patients of PU (of Stage 2, Stage 3, and Stage 4 according to the US National PU Advisory Panel Staging System, 2007), who were admitted during the period of 12 months commencing from June 2016 in the Departments of General surgery and Plastic Surgery at the Calcutta Medical Research Institute, Kolkata.

Inclusion Criteria

The following criteria were included in the study:

- Age between 18 and 85 years.
- Either sex.
- The patients having PU (Stage 2, Stage 3, and Stage 4 according to the US National PU Advisory Panel Staging System, 2007).

Exclusion Criteria

The following criteria were excluded from the study:

Patients with

- Grossly infected wounds
- Bleeding disorders
- Necrotic tissue in eschar
- Untreated osteomyelitis
- Actively bleeding wound.

Study Design

This study was prospective, observational, parallel-arm, and outcomes study. To avoid bias, each patient was alternatively allocated into two groups. Hence, the patients in two groups were in the ratio of 1:1.

RESULTS AND DISCUSSION

The present study is a prospective, observational study aimed to assess the relative effectiveness of NPWT versus standard wound dressing in the treatment of PUs. With reference to study done by Ashby *et al.*[7] with 99% power at 1% level of significance, in each group, 29 patients were included in the study.

The mean age (Mean ± SD) of patients in the NPWT group was 65.24 ± 8.37 years and in the Standard Wound Dressing group was 64.28 ± 8.13 years. Chi-square (χ^2) test showed that there was no significant association between age and patients of the two groups ($P = 0.98$). t-test showed that there was no significant difference between the mean age of the two groups ($P = 0.36$). Thus, the patients of the two groups were age matched, and hence, the patients of the two groups were comparable with reference to age.

In our study, Stage 3 PUs were more as compared to Stage 4 and Stage 2. The percentage of Stage 3 ulcer was higher in NPWT group, whereas the percentage of Stage 4 ulcer was higher in standard group; however, this distribution was statistically identical in the two groups with *P* value = 0.85. Thus, the stages of ulcers were more or less equally distributed among the two groups.

A majority of patients of this study were admitted for neurological disorder (21 out of 58) followed by trauma (15 out of 58), chronic renal diseases (eight out of 58), cardiovascular disorder (five out of 58), chronic respiratory illnesses (four out of 58), and for other reasons (five out of 58). There was no significant difference between comorbidity among patients of the two groups ($P = 0.42$), and hence, they were comparable in terms of comorbidity. Type II Diabetes Mellitus (T2DM) was found in 12 patients as comorbidity. There was no significant association between status of T2DM and patients of the two groups ($P = 0.99$). Thus, the patients of the two groups were comparable for presence or absence of T2DM.

Anemia was found in eight patients of NPWT group and in five patients of the Standard Wound Dressing group. Total 13 (22.41%) of patients had anemia. Statistically, the distributions of anemic patients in the two groups were similar with *P* value of 0.34. Furthermore, in the study out of 58 patients, 10 (17.2%) of the patients had low serum albumin. There was no significant difference in distribution of low serum albumin patients in the two groups ($P = 0.49$).

Wound culture revealed presence of microorganisms in 55 patients. Most common organism isolated was *E. Coli*, followed by *Pseudomonas*, *Staphylococcus*, *Klebsiella*, *Acinetobacter*, *Citrobacter,* and *Streptococcus*. No micro-organisms were isolated in three cases and all of which belonged to Stage 2 PUs. The association of micro-organisms in the two groups was found to be nearly identical ($P = 0.79$).

The mean area of ulcer before treatment (Mean ± SD) in patients of NPWT group was 74.68 ± 30.81 cm2 (range 15–132 cm^2), and in standard wound dressing group, it was found to be 73.51 ± 30.40 cm^2 (range 24–144 cm^2). t-test showed that there was no significant difference between the mean area of ulcer before treatment of the two groups ($P = 0.85$). Thus, the patients of the two groups were similar with respect to area of ulcer before treatment.

The mean area of ulcer (Mean ± SD) after treatment of patients with NPWT group was 36.58 ± 25.01 cm^2 (range 5–92 cm^2), and with standard wound dressing group, it was found to be 44.57 ± 23.37cm^2 (range 0–90 cm^2). t-test showed that the mean area of ulcer after treatment of the patients treated with Standard Wound Dressing was significantly higher than that of the patients treated with NPWT ($P = 0.011$) (Table 1).

The mean reduction in area of ulcer after treatment (Mean ± SD) of the patients with NPWT group was 37.58 ± 19.54 cm^2 (range 5–80 cm^2) and with standard wound dressing group was 28.95 ± 17.96 cm^2 (range 4–78 cm^2). t-test showed that the mean reduction in area of ulcer after treatment of the patients treated with Standard Wound Dressing was significantly lower than that of the patients treated with NPWT ($P = 0.022$) (Table 2).

The mean number of surgical debridement (Mean ± SD) of the patients with NPWT group was 2.24 ± 1.43, and with standard wound dressing group, it was 4.28 ± 2.22. t-test showed that the mean number of surgical debridement of the patients treated with NPWT was significantly lower than that of the patients treated with Standard Wound Dressing ($P < 0.0001$) (Table 3).

The mean duration of treatment until granulation tissue appearance (Mean ± SD) of patients with NPWT was 21.45 ± 5.81 days (range 10–32 days) and with standard wound dressing group, it was 36.24 ± 14.16 days (range 8–53 days). t-test showed that the mean duration of treatment in days until granulation tissue appearance of the patients treated with NPWT was significantly lower than that of the patients treated with Standard Wound Dressing ($P < 0.0001$) (Table 4).

The mean number of dressing change (Mean ± SD) of patients with NPWT group was 5.34 ± 1.37 (range 3 – 8) and with standard wound dressing group, it was 36.24 ± 14.16 (range 8–53). t-test showed that the mean number of dressing change of the patients treated with NPWT was

significantly lower than that of the patients treated with Standard Wound Dressing ($P < 0.0001$) (Table 5).

The mean cost of the treatment (Mean ± S.D) of the patients treated with NPWT group was INR 32,836.21 ± 10,874.75 and that of the patients treated with Standard Wound Dressing was INR 32,682.59 ± 16,529.11. t-test showed that there was no significant difference in mean cost of the treatment of the patients treated with NPWT and that of the patients treated with Standard Wound Dressing ($P > 0.05$). The cost of treatment was higher with NPWT than with standard wound dressing (Table 6).

The area of ulcer after treatment was significantly decreased ($P = 0.011$) in NPWT group as compared with Standard Wound Dressing which was in concordance with study conducted by Dwivedi *et al.*,[8] where length and width of ulcer decreased significantly ($P < 0.01$) in NPWT group.

The mean reduction in area of ulcer after treatment of the patients treated with Standard Wound Dressing was significantly lower than that of the patients treated with NPWT ($P = 0.022$). Similar findings were observed in studies done by Srivastava *et al.*,[9] Moues *et al.*,[10] and Dwivedi *et al.*[8] comparing NPWT with Standard Wound Dressing by moist gauze (*P* value=0.0001, <0.05 and <0.01, respectively). In study conducted by Ford *et al.*,[11] it was found that the mean percent reduction in ulcer volume was 42.1% with gel products compared to 51.8% with VAC ($P = 0.46$). Isago *et al.*,[12] in their study, observed that following NPWT treatment, wound area reduced by an average of 55%. Our study result is equivocal with that of above two studies[11,12] with respect to percent reduction, as there is 40% reduction in area with standard wound dressing and 51% with NPWT considering the mean area of ulcer before initiation of treatment were 74.68 ± 30.81 cm^2 and 73.51 ± 30.40 cm^2 and following treatment was 36.58 ± 25.01 cm^2 and 44.57 ± 23.37 cm^2, respectively, for NPWT and standard wound dressing.

The mean duration of treatment (in days) until the appearance of healthy granulation tissue in patients treated with NPWT was significantly lower than that of the patients treated by Standard Wound Dressing ($P < 0.0001$) which was in agreement with study conducted by De Laat *et al.*[13] ($P < 0.001$). In another study conducted by Dwivedi *et al.*,[8] they found that conversion of slough into red granulation tissue was significantly higher in NPWT group ($P = 0.001$). In the present study, appearance of healthy granulation tissue was faster in NPWT group, and hence, closure of wound was earlier in NPWT group than standard wound dressing group; an observation which is in agreement with the study of Mody *et al.*,[14] who conducted a randomized controlled trial comparing a locally constructed TNP device with wet-to-dry gauze dressings on varied wound etiologies, including diabetic foot ulcers, PUs, cellulitis/fasciitis, and other types of ulcers. In PU sub-set, the authors found statistically significant differences ($P = 0.05$) in the time of closure of wound between the two treatment groups, TNP group closing earlier than gauze dressing group. Moues *et al.*,[10] in their study, found a tendency toward a shorter duration of therapy with NPWT, which was most prominent in

Table 1: Distribution of area of ulcer after treatment of the patients of the two groups

Area of ulcer (cm^2)	NPWT	Standard wound dressing	Total
0–5	0	0	0
Row %	0.0	0.0	0.0
Col %	0.0	0.0	0.0
6–29	14	7	21
Row %	66.7	33.3	100.0
Col %	48.3	24.1	36.2
30–54	8	10	18
Row %	44.4	55.6	100.0
Col %	27.6	34.5	31.0
55–79	5	9	14
Row %	35.7	64.3	100.0
Col %	17.2	31.0	24.1
80–92	2	3	5
Row %	40.0	60.0	100.0
Col %	6.9	10.3	8.6
Total	29	29	58
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±SD	36.58±25.01	44.57±23.37	
Median	31.68	36.00	
Range	5–92	12–90	

Table 2: Distribution of reduction in area of ulcer after treatment of the patients of the two groups

Reduction in Area of ulcer (cm^2)	NPWT	Standard wound dressing	Total
4.0–9.9	2	2	4
Row %	50.0	50.0	100.0
Col %	6.9	6.9	6.9
10.0–29.9	9	15	24
Row %	37.5	62.5	100.0
Col %	31.0	51.7	41.4
30.0–49.9	10	7	17
Row %	58.8	41.2	100.0
Col %	34.5	24.1	29.3
50.0–79.9	6	5	11
Row %	54.5	45.5	100.0
Col %	20.7	17.2	19.0
80.0–100.0	2	0	2
Row %	100.0	0.0	100.0
Col %	6.9	0.0	3.4
Total	29	29	58
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±SD	37.58±19.54	28.95±17.96	
Median	34.00	24.00	
Range	5–80	4–78	

Table 3: Distribution of number of debridement of the patients of the two groups

Number of debridement	NPWT	Standard Wound Dressing	Total
0–2	18	6	24
Row %	75.0	25.0	100.0
Col %	62.1	20.7	41.4
3–4	9	10	19
Row %	47.4	52.6	100.0
Col %	31.0	34.5	32.8
5–6	2	8	10
Row %	20.0	80.0	100.0
Col %	6.9	27.6	17.2
7–8	0	5	5
Row %	0.0	100.0	100.0
Col %	0.0	17.2	8.6
Total	29	29	58
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±SD	2.24±1.43	4.28±2.22	
Median	2	4	
Range	0–5	1–8	

Table 4: Distribution of duration of treatment till granulation tissue appearance of the patients of the two groups

Duration of treatment till granulation tissue appearance (in days)	NPWT	Standard Wound Dressing	Total
<10	0	1	1
Row %	0.0	100.0	100.0
Col %	0.0	3.4	1.7
10–14	3	3	6
Row %	50.0	50.0	100.0
Col %	10.3	10.3	10.3
15–21	13	0	13
Row %	100.0	0.0	100.0
Col %	44.8	0.0	22.4
22–28	10	2	12
Row %	83.3	16.7	100.0
Col %	34.5	6.9	20.7
29–35	3	9	12
Row %	25.0	75.0	100.0
Col %	10.3	31.0	20.7
>35	0	14	14
Row %	0.0	100.0	100.0
Col %	0.0	48.3	24.1
Total	29	29	58
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±SD	21.45±5.81	36.24±14.16	
Median	20	35.00	
Range	10–32	8–53	

late-treated wounds, but the difference was statistically not significant ($P = 0.19$). Our study was also similar to studies like Isago *et al.*[12] and Ashby *et al.*,[7] in which it was found that duration of therapy was less with NPWT compared with standard wound dressing. In the present study, the mean duration of treatment until granulation tissue appearance of patients with NPWT was 21.45 ± 5.81 days

Table 5: Distribution of number of dressing change of the patients of the two groups

Number of dressing change	NPWT	Standard Wound Dressing	Total
<10	29	1	30
Row %	96.7	3.3	100.0
Col %	100.0	3.4	51.7
10–29	0	7	7
Row %	0.0	100.0	100.0
Col %	0.0	24.1	12.1
30–49	0	14	14
Row %	0.0	100.0	100.0
Col %	0.0	48.3	24.1
50–59	0	7	7
Row %	0.0	100.0	100.0
Col %	0.0	24.1	12.1
TOTAL	29	29	58
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±SD	5.34±1.37	36.24±14.16	
Median	5	35.00	
Range	3 – 8	8 – 53	

Table 6: Distribution of cost of the treatment of the patients of the two groups

Cost of the treatment (in Rs.)	NPWT	Standard wound dressing	Total
5000–10000	0	4	4
Row %	0.0	100.0	100.0
Col %	0.0	13.8	6.9
10001–20000	4	4	8
Row %	50.0	50.0	100.0
Col %	13.8	13.8	13.8
20001–30000	10	8	18
Row %	55.6	44.4	100.0
Col %	34.5	27.6	31.0
30001–40000	8	1	9
Row %	88.9	11.1	100.0
Col %	27.6	3.4	15.5
40001–56000	7	12	19
Row %	36.8	63.2	100.0
Col %	24.1	41.4	32.8
Total	29	29	58
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±SD	32,836.21 ± 10,874.75	32,682.59 ± 16,529.11	
Median	34500.00	28500.00	
Range	15,000–54,000	8,554–55,168	

which was in concordance with study conducted by Gupta *et al.*,[15] where robust granulation tissue formation was found after 3–4 weeks of treatment with NPWT. In a case report by Batra *et al.*,[16] VAC was applied every 5th day until near-complete healing was achieved, and it took six cycles, a finding which was in agreement with our study. Wanner *et al.*[17] compared NPWT with a traditional wound dressing with gauze soaked in Ringer's solution. They found that the decrease in wound volume was similar in the two groups

and the two methods were found equally effective in the formation of granulation tissue.

Even though the cost of treatment was higher in NPWT group, but the difference in the mean cost of the treatment of the patients treated with NPWT group (INR 32,836.21 ± 10,874.75) and that of the patients treated with Standard Wound Dressing (INR 32,682.59 ± 16,529.11) was statistically insignificant ($P > 0.05$). Higher cost of treatment in NPWT group was also observed in studies done by Moues *et al*.[10] and Gupta *et al*.[15] Moues *et al*.,[10] in their study, found that vacuum therapy had higher material costs and the mean material expenses for wounds treated with vacuum therapy compared with conventional therapy was significantly higher ($P < 0.0001$), but on contrary, there was significantly lower mean nursing expenses for vacuum therapy than conventional therapy ($P < 0.0001$). Hospital stay costs were lower in the vacuum therapy group than in the conventional treatment group ($P < 0.043$). Overall, there was no significant difference in total costs per patient between the two therapies with conventional therapy being equally as expensive as NPWT. In our study, we considered the direct therapy costs (cost of consumables) which were higher for NPWT patients, but on contrary the cost of surgical debridement, nursing expenses and hospitalization costs were lower in NPWT group. However, studies such as Srivastava *et al*.,[9] Dwivedi *et al*.,[8] and Mody *et al*.[14] found that direct therapy costs are lower with NPWT but not significant. In these studies,[8,9,14] the investigators used locally constructed low cost NPD or TNP devices, whereas in our study, standard NPWT machine of Datt Mediproducts Pvt. Ltd. and VEL NeXT dressing materials for NPWT group were used.

We observed that the mean number of dressing change of the patients treated with NPWT was significantly lower than that of the patients treated with Standard Wound Dressing ($P < 0.0001$), a finding which is in agreement with various other similar studies.[10,13] It was also found that the mean number of debridement of the patients treated with NPWT was significantly lower than that of the patients treated with Standard Wound Dressing ($P < 0.0001$) which has not been analyzed in other studies.

CONCLUSION

In our study, we have found that NPWT brings more reduction in ulcer area, early appearance of granulation tissue, lesser need of surgical debridement, and lesser need of change of dressing compared to standard wound dressing in all stages of PUs. All these parameters are statistically significant and are in favor with NPWT. In our study, we observed that effectiveness of NPWT is more in higher stages of PU such as Stage 3 and Stage 4.

We did not find any complication in all cases of NPWT. We also did not find any technical difficulty with NPWT. Thus, NPWT is easy to apply and safe method of wound therapy.

Regarding cost of treatment, we found that it is on higher side with NPWT but not significant. In our study, we have taken the direct therapy costs. Future studies should focus on factors outside direct therapy costs also such as hospitalization costs, nursing personnel costs, and costs for surgical procedures.

We conclude that NPWT is a better modality of treatment than standard wound dressing in healing of PU. RCTs with a large sample size, longer duration of follow-up, and cost benefit analysis taking into account factors outside direct therapy costs need to be done to establish the superiority of NPWT over standard wound dressing.

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