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Original Research Article

EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY VERSUS CONVENTIONAL DRESSING IN THE MANAGEMENT OF CHRONIC ULCERS: A RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Background: Chronic ulcers are associated with prolonged morbidity, recurrent infections, and substantial healthcare expenditure. Negative Pressure Wound Therapy (NPWT) has emerged as an effective adjunct in wound management; however, evidence comparing its efficacy with conventional dressing in resource-constrained settings remains limited. This study aimed to compare the effectiveness of NPWT with conventional dressing in the management of chronic ulcers.

Materials and Methods: A prospective randomised controlled trial was conducted in the Department of General Surgery at a tertiary care hospital over 18 months. A total of 108 patients with Wagner grade ≥2 ulcers were randomised using block randomisation into NPWT (n=54) and conventional dressing (n=54) groups. The primary outcome was reduction in ulcer size. Secondary outcomes included granulation tissue formation, ulcer depth reduction, complete healing rate, duration to complete healing, duration of hospital stay, requirement for debridement and skin grafting, and post-treatment Wagner grade. Statistical analysis was performed using Student's t-test and Chi-square test. A p-value <0.05 was considered statistically significant.

Results: Baseline demographic and clinical characteristics were comparable between groups. NPWT resulted in significantly greater reduction in ulcer size at 6 weeks (2.12±0.74 cm^2 vs 4.42±2.18 cm^2; mean difference [2.30] cm^2, 95% CI [1.67 to 2.92]; p<0.0001). Granulation tissue formation was significantly higher in the NPWT group (94.26±4.72% vs 74.38±13.84%; p<0.0001). Complete healing was achieved in 83.3% of patients receiving NPWT compared with 57.4% in the conventional dressing group (p=0.003). NPWT significantly reduced time to complete healing (3.14±1.28 vs 4.86±1.94 weeks; p<0.0001), hospital stay (13.84±4.36 vs 20.28±5.74 days; p<0.0001), requirement for repeated debridement (p=0.034), and need for skin grafting (p=0.023).

Conclusion: NPWT is superior to conventional dressing in promoting wound healing, enhancing granulation tissue formation, reducing hospital stay, and improving overall clinical outcomes in patients with chronic ulcers.

Keywords: Negative pressure wound therapy; Chronic ulcer; Vacuum-assisted closure; Conventional dressing; Wound healing; Randomised controlled trial.

INTRODUCTION

Chronic ulcers represent a major healthcare challenge worldwide and are associated with significant morbidity, impaired quality of life, prolonged hospitalization, and increased healthcare costs. Chronic wounds fail to progress through the normal stages of healing and frequently remain arrested in a persistent inflammatory phase due to factors such as infection, ischemia, neuropathy, and impaired angiogenesis.[1,2]

Conventional wound management strategies, including moist dressings, surgical debridement, topical agents, and adjunctive therapies, remain the cornerstone of treatment. However, these modalities are often associated with prolonged healing times, frequent dressing changes, and variable outcomes.[3]

Negative Pressure Wound Therapy (NPWT), also known as vacuum-assisted closure, is an established therapeutic modality that applies controlled sub-atmospheric pressure to the wound bed. NPWT promotes wound healing by reducing edema, removing exudate, improving local perfusion, stimulating angiogenesis, and enhancing granulation tissue formation. Several studies have demonstrated superior outcomes with NPWT compared with standard wound care, particularly in diabetic foot ulcers and complex wounds.[4,5]

Despite growing evidence supporting NPWT, data from randomised trials conducted in developing countries and resource-limited settings remain limited. Therefore, this study was undertaken to compare the efficacy of NPWT with conventional dressing in the management of chronic ulcers.

The primary objective of this study was to compare reduction in ulcer size between NPWT and conventional dressing groups. Secondary objectives included assessment of granulation tissue formation, ulcer depth reduction, complete healing rate, duration of healing, hospital stay, and requirement for additional surgical interventions.

MATERIALS AND METHODS

Study Design and Setting: This prospective, open-label, parallel-group randomised controlled trial was conducted in the Department of General Surgery at a tertiary care teaching hospital over a period of 18 months. Clinical trial registration number: CTRI/2026/06/112581. The study was designed to compare the effectiveness of NPWT with that of conventional wound dressing in the management of chronic ulcers.

Study Population: Patients admitted to the General Surgery wards with chronic ulcers of Wagner grade 2 or higher were screened for eligibility. Consecutive patients meeting the eligibility criteria during the study period were enrolled after providing written informed consent.

Sample Size: Assuming a mean difference in ulcer-size reduction of [X] cm^2 (SD [Y] cm^2) between groups, based on [reference study], a minimum of [n] participants per group was required to achieve 80% power at a two-sided alpha of 0.05, calculated using [software/formula]. Allowing for anticipated attrition, the minimum calculated sample size for the study was 108 patients. Eligible participants were recruited until the required sample size was achieved.

Eligibility Criteria: Patients aged more than 18 years with Wagner grade 2 or higher ulcers who provided written informed consent were included in the study. Patients younger than 18 years, those with malignant ulcers, compromised vascular supply (ankle-brachial index <0.8), gangrenous foot, untreated osteomyelitis, the presence of necrotic tissue, active bleeding, wounds with exposed blood vessels, or fistulas communicating with body cavities or internal organs were excluded from participation.

Randomisation and Allocation: After enrolment, participants were randomly allocated in a 1:1 ratio to either the NPWT group (Group A) or the conventional dressing group (Group B) using a computer-generated block randomisation technique (block size of [state block size], generated by [state who generated the sequence, e.g. an investigator independent of enrolment and outcome assessment]). Randomisation ensured balanced allocation of participants between the two treatment arms throughout the study period. Allocation concealment was maintained using [state actual method, e.g. sequentially numbered, opaque, sealed envelopes prepared by an independent investigator], opened only after the participant's details were recorded on the enrolment log.

Blinding: Because of the nature of the interventions, blinding of patients and treating surgeons was not feasible. Outcome assessors were also not blinded to group allocation. Therefore, the study was conducted as an open-label randomised controlled trial; the potential for performance and detection bias arising from the absence of blinding is discussed in the Limitations.

Interventions: Patients allocated to the NPWT group underwent wound cleansing with povidone-iodine solution before application of polyurethane foam cut according to the dimensions of the wound. A perforated Ryle's tube was embedded within the foam, which was then sealed with an adhesive drape to create an airtight environment. The dressing was connected to a suction device delivering a negative pressure of −125 mmHg, applied either continuously or intermittently (5 minutes on and 2 minutes off), depending on the clinical condition of the wound. NPWT dressings were changed every 72 hours.

Patients in the conventional dressing group received routine wound care consisting of cleansing with povidone-iodine solution followed by dressing with EUSOL or mercurochrome, according to institutional protocol. Conventional dressings were changed daily. In both groups, surgical debridement was performed whenever clinically indicated, and systemic antibiotic therapy was administered according to wound culture and antibiotic sensitivity reports. All patients

received standard supportive care throughout the treatment period.

Outcome Measures: The primary outcome measure was the reduction in ulcer size, expressed in square centimeters (cm^2), after 6 weeks of treatment.

Secondary outcome measures included the extent of granulation tissue formation, reduction in ulcer depth, complete wound healing rate, time required for complete healing, duration of hospital stay, number of debridement procedures performed, requirement for skin grafting, and post-treatment Wagner grade.

Granulation tissue formation was assessed using two complementary measures: a semi-quantitative 0–10 clinical granulation-tissue score recorded weekly throughout the six-week follow-up period (Table 3), and the percentage of the wound bed covered by granulation tissue, recorded before and after treatment [Table 4].

Statistical Analysis: Data were entered into Microsoft Excel and analysed using the Statistical Package for the Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were presented as frequencies and percentages. Comparisons between groups were performed using the independent Student's t-test for continuous variables and the Chi-square test or Fisher's exact test, as appropriate, for categorical variables. A two-tailed p value of less than 0.05 was considered **statistically significant:** For all primary and key secondary outcomes, effect sizes are reported as mean differences (or proportions) together with 95% confidence intervals, in addition to p values.

RESULTS

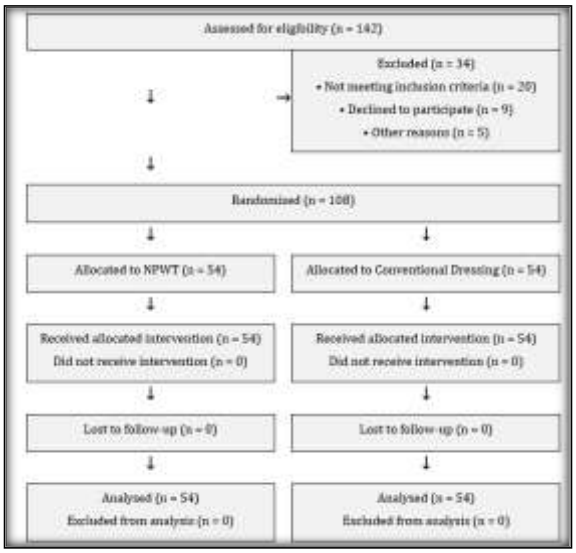

Figure 1: CONSORT Participant Flow Diagram (Placeholder).

Table 1: Baseline Demographic and Clinical Characteristics of the Study Participants

Variable	Group A (n=54)	Group B (n=54)	P value
Age (years), Mean ± SD	52.47 ± 12.36	53.18 ± 11.92	0.918
Gender			
Male	37 (68.52%)	39 (72.22%)	0.673
Female	17 (31.48%)	15(27.78%)	
BMI (kg/m^2), Mean ± SD	25.12 ± 4.46	24.84 ± 4.91	0.911
Comorbidity			
Diabetes mellitus	40 (74.07%)	38 (70.37%)	0.959
Hypertension	24 (44.44%)	22 (40.74%)	
Dyslipidaemia	15 (27.78%)	17 (31.48%)	
Chronic kidney disease	6 (11.11%)	5 (9.26%)	
Smoking	23 (42.59%)	21 (38.89%)	0.695
Alcohol consumption	18 (33.33%)	20 (37.04%)	0.686

[Table 1] showed the baseline demographic and clinical characteristics of the study participants. A total of 108 patients were included in the study, with 54 patients in each group. The mean age was comparable between Group A and Group B (52.47 ± 12.36 vs. 53.18 ± 11.92 years; P = 0.918). Similarly, the mean BMI was also comparable between the two groups (25.12 ± 4.46 vs. 24.84 ± 4.91 kg/m^2; P = 0.911). The majority of participants were male in both groups (68.52% vs. 72.22%; P = 0.673). Diabetes mellitus was the most common comorbidity, followed by hypertension, dyslipidaemia, and chronic kidney disease, with no significant difference between the groups (P = 0.959). Smoking (42.59% vs. 38.89%; P = 0.695) and alcohol consumption (33.33% vs. 37.04%; P = 0.686) were also comparable between the groups. Overall, no statistically significant differences were observed in the baseline characteristics between Group A and Group B.

Table 2: Baseline Clinical Characteristics and Ulcer Profile of the Study Participants

Variable	Group A (n=54)	Group B (n=54)	P value
Extremity Involved			
Right	29 (53.70)	26 (48.15)	0.563
Left	25 (46.30%)	28 (51.85%)	
Etiological factors			
Diabetic ulcer	32 (59.26%)	34 (62.96%)	0.99
Traumatic ulcer	9 (16.67%)	8 (14.81%)	
Trophic ulcer	8 (14.81%)	7 (12.96%)	

Venous ulcer	3 (5.56%)	3 (5.56%)	
Others	2 (3.70%)	2 (3.70%)	
Clinical Presentation			
Pain	35 (64.81%)	40 (74.07%)	0.56
Swelling	29 (53.70%)	34 (62.96%)	0.53
Discharge	26 (48.15%)	32 (59.26%)	0.43
Wagner Grade			
Wagner Grade II	30 (55.56%)	31 (57.41%)	0.977
Wagner Grade III	18 (33.33%)	17 (31.48%)	
Wagner Grade IV	6 (11.11%)	6 (11.11%)	

[Table 2] showed the distribution of clinical characteristics of chronic ulcers among the study participants. A total of 108 patients were included, with 54 patients in each group. The side of extremity involvement was comparable between Group A and Group B, with right-sided ulcers in 53.70% vs. 48.15% and left-sided ulcers in 46.30% vs. 51.85% of patients, respectively (P = 0.563).Diabetic ulcer was the most common etiological factor in both groups (59.26% vs. 62.96%), followed by traumatic, trophic, venous, and other causes, with no significant difference between the groups (P = 0.99).Clinical features such as pain (64.81% vs. 74.07%), swelling (53.70% vs. 62.96%), and discharge (48.15% vs. 59.26%) were also comparable between Group A and Group B.Regarding severity, most ulcers were classified as Wagner Grade II, followed by Grade III and Grade IV, with a similar distribution in both groups (P = 0.977). Overall, no statistically significant differences were observed in the clinical presentation between the two groups.

Table 3: Serial Comparison of Wound Healing Parameters Including Granulation Tissue Score (0–10 Scale), Ulcer Size, and Ulcer Depth Over 6 Weeks between Group A and Group B

Parameter	Group	Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Granulation Tissue (0–10 scale) (Mean ± SD)	Group A	0.28 ± 0.14	1.02 ± 0.46	2.16 ± 0.84	4.82 ± 1.74	7.34 ± 2.16	8.92 ± 1.86	9.68 ± 1.42
	Group B	0.26 ± 0.12	0.74 ± 0.39	1.22 ± 0.63	2.08 ± 0.96	4.11 ± 1.58	5.84 ± 1.74	6.62 ± 1.66
	P value	0.731	0.0038	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Ulcer Size (cm^2)	Group A	10.86 ± 5.42	9.48 ± 4.96	7.82 ± 3.18	5.94 ± 2.46	4.38 ± 1.62	3.18 ± 1.28	2.12 ± 0.74
	Group B	10.34 ± 5.88	9.96 ± 5.64	9.12 ± 4.36	8.14 ± 4.12	6.96 ± 2.74	5.64 ± 1.72	4.42 ± 2.18
	P value	0.658	0.673	0.082	0.0029	<0.0001	<0.0001	<0.0001
Ulcer Depth (cm)	Group A	1.86 ± 0.58	1.54 ± 0.46	1.18 ± 0.42	0.84 ± 0.36	0.56 ± 0.28	0.32 ± 0.24	0.18 ± 0.14
	Group B	1.82 ± 0.54	1.71 ± 0.48	1.54 ± 0.46	1.28 ± 0.42	1.02 ± 0.38	0.84 ± 0.34	0.62 ± 0.26
	P value	0.711	0.062	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

[Table 3] showed the serial comparison of wound healing parameters, including the granulation tissue score as-sessed on a 0–10 scale, ulcer size, and ulcer depth, between Group A and Group B over a 6-week follow-up period. At baseline, all parameters were comparable between the two groups. Granulation tissue scores in-creased progressively in both groups; however, Group A demonstrated significantly higher scores compared to Group B from Week 1 onwards (P = 0.0038 at Week 1 and P < 0.0001 thereafter). Ulcer size showed a gradual reduction in both groups, with a significantly greater decrease in Group A from Week 3 onwards (P = 0.0029 at Week 3 and P < 0.0001 thereafter). Similarly, ulcer depth decreased progressively, with Group A showing significantly greater reduction compared to Group B from Week 2 onwards (P < 0.0001). Overall, serial assessment demonstrated superior wound healing progression in Group A compared with Group B.

Table 4: Comparison of Pre- and Post-Treatment Changes in Granulation Tissue Growth Rate, Ul-cer Size, and Ulcer Depth between Group A and Group B

Parameter	Group A	Group B	P value
Rate of Growth of Granulation Tissue (%)			
Before Treatment	3.12±1.24	3.08±1.16	0.862
After Treatment	94.26±4.72	74.38±13.84	<0.0001
Ulcer size (cm^2)			
Before Treatment	10.86 ± 5.42	10.34 ± 5.88	0.633
After Treatment	2.12 ± 0.74	4.42 ± 2.18	<0.0001
Ulcer depth (cm)			
Before Treatment	1.86 ± 0.58	1.82 ± 0.54	0.711
After Treatment	0.18 ± 0.14	0.62 ± 0.26	<0.0001

[Table 4] showed the comparison of pre- and post-treatment changes in granulation tissue growth rate, ulcer size, and ulcer depth between Group A and Group B. At baseline, all parameters were comparable between the two groups (P > 0.05). After treatment, Group A showed significantly higher granulation tissue growth compared with Group B (94.26 ± 4.72% vs. 74.38 ± 13.84%; P < 0.0001). Ulcer size and depth were significantly reduced in both groups, with greater improvement observed in Group A (ulcer size: 2.12 ± 0.74 cm^2 vs. 4.42 ± 2.18 cm^2; ulcer depth: 0.18 ± 0.14 cm vs. 0.62 ± 0.26 cm; P < 0.0001). Overall, Group A demonstrated significantly better wound healing outcomes compared with Group B.

Table No.5: Comparison of Clinical Outcomes between Group A and Group B

Outcome	Group A	Group B	P value
≤5 Debridements	47 (87.04%)	38 (70.37%)	0.034
Skin graft required	12 (22.22%)	23 (42.59%)	0.023
Wagner Grade 0 after treatment	46 (85.19%)	34 (62.96%)	0.03
Complete healing achieved	45 (83.33%)	31 (57.41%)	0.003
Duration to complete healing (weeks)	3.14 ±1.28	4.86 ±1.94	<0.0001
Hospital stay (days)	13.84 ±4.36	20.28 ±5.74	<0.0001

[Table 5] showed the comparison of clinical outcomes between Group A and Group B. A significantly higher proportion of patients in Group A required ≤5 debridements compared to Group B (87.04% vs. 70.37%; P = 0.034). The need for skin grafting was significantly lower in Group A (22.22% vs. 42.59%; P = 0.023). A higher proportion of patients achieved Wagner Grade 0 after treatment in Group A compared to Group B (85.19% vs. 62.96%; P = 0.03). Similarly, complete wound healing was significantly more frequent in Group A (83.33% vs. 57.41%; P = 0.003). The duration to complete healing was significantly shorter in Group A (3.14 ± 1.28 weeks vs. 4.86 ± 1.94 weeks; P < 0.0001), and the mean hospital stay was also significantly reduced in Group A compared to Group B (13.84 ± 4.36 vs. 20.28 ± 5.74 days; P < 0.0001). Overall, Group A demonstrated better clinical outcomes than Group B.

DISCUSSION

The present randomised controlled trial demonstrated that NPWT significantly improved wound healing outcomes compared with conventional dressing in patients with chronic ulcers.

The mean age of patients in the present study was 52.47 ± 12.36 years in the NPWT group and 53.18 ± 11.92 years in the conventional dressing group, with no significant difference between the groups (p = 0.9184). Most patients belonged to the 51–60-year age group, indicating that chronic ulcers predominantly affect middle-aged and older adults. Patil O et al.6 similarly reported a mean age of 53 years among patients with chronic non-healing ulcers. Rohan C et al.7 also observed comparable mean ages of 55.87 years in the NPWT group and 58.60 years in the conventional dressing group, supporting the similarity in baseline characteristics [Table 1].

Male predominance was observed in both groups, similar to the findings of Patil O et al.6 and Lone AM et al.8, who reported that approximately two-thirds of their study population were males. Diabetes mellitus was the most common comorbidity in the present study, followed by hypertension, which is consistent with the observations of Cao Z et al.9 who found diabetes to be the predominant associated comorbidity among patients with chronic ulcers [Table 1 and 2].

Granulation tissue formation was significantly greater in the NPWT group from the first week onward (p < 0.0001), indicating faster wound bed preparation. Shreeram GK et al,[10] similarly reported earlier development of healthy granulation tissue in the NPWT group (9.8 ± 2.9 days) compared with conventional dressing (13.9 ± 3.6 days; p < 0.001). Likewise, Deb M et al,[11] demonstrated that granulation tissue coverage increased from 40% to 88% in the NPWT group, whereas it increased only from 22% to 42% in the conventional dressing group. Lone AM et al.8 also observed healthy granulation tissue in 92.85% of NPWT-treated wounds by the end of the second week compared with 53.57% of conventionally treated wounds. These findings support the ability of NPWT to enhance angiogenesis and accelerate granulation tissue formation [Table 3].

Both treatment groups showed progressive reduction in ulcer size during follow-up; however, the reduction was significantly greater in the NPWT group from the third week onward. By six weeks, ulcer size was significantly smaller in the NPWT group than in the conventional dressing group (p < 0.0001). Guo Q et al,[12] also reported significantly greater reductions in wound area and depth after four weeks of NPWT compared with standard wound care. Similarly, Thakur P et al,[13] observed an 83.56% reduction in ulcer area with NPWT compared with 53.88% with conventional dressing, confirming the superior wound contraction achieved with NPWT [Table 3 and 4].

Patients treated with NPWT required significantly fewer debridement procedures than those managed with conventional dressing. Similar observations were reported by Wang R et al,[14] who demonstrated faster wound closure and improved healing with NPWT, thereby reducing the need for repeated wound procedures. In contrast, Sugiyama J et al,[15] reported more debridement procedures in the NPWT

group; however, their study included patients with severe necrotizing fasciitis and gas gangrene, which likely accounted for this difference [Table 5].

Patients in the NPWT group achieved complete healing in a significantly shorter time and had a shorter hospital stay than those receiving conventional dressings. Guo Q et al,[12] likewise reported significantly shorter hospitalization (16.05 vs. 21.38 days; p = 0.028) with NPWT. Similarly, Mogal K et al,[16] found that NPWT reduced hospital stay because of earlier granulation tissue formation and faster wound contraction. These findings suggest that NPWT not only improves wound healing but also reduces hospitalization and enhances overall treatment efficiency [Table 5].

The strengths of this study include its randomised design, adequate sample size, and comprehensive assessment of clinically relevant outcomes.

No treatment-related adverse events were observed in either the NPWT group or the conventional dressing group during the study period. No participant discontinued treatment because of adverse events, and no serious adverse events requiring additional intervention were reported.

However, several limitations should be acknowledged. First, the study was conducted at a single centre, which may limit the generalisability of the findings. Second, blinding of patients and treating surgeons was not feasible because of the nature of the intervention, and outcome assessors were also not blinded, introducing the potential for performance and detection bias. Third, a formal sample-size calculation was not reported, which may have affected the statistical power of the study. Fourth, the conventional dressing protocol included EUSOL and mercurochrome, which are no longer considered standard wound-care agents in many healthcare settings, potentially limiting the applicability of the findings to current clinical practice. Finally, long-term follow-up to evaluate ulcer recurrence and sustained wound healing was not performed. Future multicentre studies with adequate sample-size estimation, blinded outcome assessment, contemporary comparator treatments, and longer follow-up are warranted to validate these findings.

CONCLUSION

Negative Pressure Wound Therapy is superior to conventional dressing in the management of chronic ulcers. NPWT significantly enhances wound healing, promotes granulation tissue formation, reduces ulcer size and depth, shortens hospital stay, decreases the requirement for additional procedures, and improves overall clinical outcomes. NPWT should be considered an effective therapeutic modality for the management of chronic ulcers.

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