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Original Research Article

OUTCOMES OF MODIFIED NEGATIVE PRESSURE WOUND THERAPY USING STERILE SURGICAL GLOVE AND POLYVINYLALCOHOL FOAM COMPARED WITH CONVENTIONAL GAUZE DRESSING IN THE MANAGEMENT OF NON HEALING DIABETIC FOOT ULCERS

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ABSTRACT

Background: Chronic diabetic foot ulcers pose significant healing challenges and often require specialized dressings. Negative-pressure wound therapy (NPWT) can accelerate wound granulation, but commercial devices are expensive. We evaluated a low-cost modified NPWT using a sterile surgical glove and polyvinyl alcohol (PVA) foam compared to standard moist gauze dressing in non-healing diabetic foot ulcers. **Materials and Methods:** In a prospective randomized controlled study, 60 patients with chronic diabetic foot ulcers were assigned to receive either modified NPWT (n=30) or conventional saline-moistened gauze dressings (n=30). The modified NPWT system used a PVA foam dressing sealed with a sterile glove connected to continuous suction. Outcomes included percentage of granulation tissue, time to wound bed preparation, bacterial culture results, length of hospital stay, and patient treatment cost. **Result:** The modified NPWT group achieved significantly greater granulation: mean granulation percentages on days 4, 8, and 12 were 40.0%, 64.5%, and 90.5% versus 15.6%, 29.9%, and 50.1% with gauze ($p<0.001$ for all). Mean time to prepare the wound bed was 13.2±1.24 days with NPWT versus 27.6±3.22 days with gauze ($p<0.001$). Day-12 wound cultures were sterile in 80% of NPWT cases versus 26.7% with gauze ($p=0.002$), indicating markedly reduced bacterial load. Mean hospital stay was significantly shorter with NPWT (17.1±1.95 days) than with gauze (31.8±3.01 days; $p<0.001$). Mean treatment cost was higher for NPWT (Rs 8248 vs Rs 4037; $p<0.001$). **Conclusion:** The sterile glove–PVA foam NPWT system significantly enhanced healing metrics and shortened hospital stay compared to conventional gauze dressings, albeit at higher cost. This modified NPWT approach may be an effective low-cost alternative for managing chronic diabetic foot ulcers.

INTRODUCTION

Diabetic foot ulcer (DFU) remains one of the most common and debilitating complications of diabetes mellitus, contributing substantially to patient morbidity, healthcare costs, and risk of lower-limb amputation. Impaired wound healing in diabetic patients results from a complex interplay of peripheral neuropathy, vascular insufficiency, infection, and impaired immune response. Despite advances in wound care, chronic non-healing ulcers continue to pose a significant therapeutic challenge, particularly in resource-limited settings.[1,2]

Negative pressure wound therapy (NPWT) has emerged as a major advancement in the management of chronic and complex wounds. By applying subatmospheric pressure to the wound bed, NPWT facilitates continuous drainage of exudate, promotes angiogenesis, stimulates granulation tissue formation, and reduces local bacterial burden. However, the high cost of commercial NPWT systems limits their accessibility in many developing countries, making their widespread use impractical in routine clinical practice.[3,4]

To address this challenge, several cost-effective modifications of NPWT have been explored. Among these, the use of readily available materials such as sterile surgical gloves and polyvinyl alcohol (PVA) foam offers a practical and affordable alternative while maintaining the therapeutic benefits of negative pressure. Such modifications are particularly relevant in high-prevalence regions where diabetic ulcers constitute a major healthcare burden.[5,6]

The present study aims to evaluate the outcomes of a modified NPWT technique using a sterile surgical glove and PVA foam compared with conventional gauze dressing in patients with non-healing diabetic foot ulcers. The comparison focuses on key clinical parameters including granulation tissue formation, time required for wound bed preparation, bacterial load reduction, duration of hospital stay, and overall treatment cost. By assessing both clinical efficacy and cost-effectiveness, this study seeks to determine whether a modified NPWT system can serve as a viable, low-cost alternative to conventional wound care in diabetic foot management.

MATERIALS AND METHODS

Study Design and Setting: This was a prospective, randomized controlled study conducted in the Department of General Surgery, Holy Cross Hospital, Kollam, Kerala, which is a tertiary care center specializing in diabetic foot management. The study period extended from December 2017 to February 2019.

Study Population: A total of 60 patients with chronic non-healing diabetic foot ulcers were enrolled after obtaining informed consent. Eligible participants were adults aged over 20 years with diabetic foot ulcers persisting for more than four weeks and without contraindications to NPWT.

Inclusion Criteria

1. Patients aged above 20 years of either sex.
2. Clinically diagnosed diabetic foot ulcer persisting for at least four weeks.
3. Willingness to participate with informed consent.

Exclusion Criteria

1. Non-diabetic patients.
2. Healing ulcer with pink granulation tissue.
3. Patients with peripheral vascular disease, gangrenous foot, or untreated osteomyelitis.
4. Patients with systemic illnesses such as chronic kidney disease, cirrhosis, tuberculosis, connective tissue disorders, or malignancy within the past five years.
5. Patients with ulcers already showing complete granulation tissue formation.

Randomization: Patients fulfilling inclusion and exclusion criteria were randomized into two groups using a computer-generated randomization sequence. Thirty patients were assigned to the modified NPWT group and thirty to the conventional gauze dressing group. Randomization was ensured by sealed opaque envelopes containing the group allocation codes.

Intervention Procedure: After thorough wound debridement and irrigation with normal saline, patients in the intervention group received modified NPWT using sterile polyvinyl alcohol (PVA) foam and a sterile surgical glove. The foam was cut to fit the wound cavity, and a suction catheter (Ryle's tube) with multiple fenestrations was placed between two foam layers. The wound and surrounding area were sealed with a surgical glove, and airtight closure was achieved using adhesive tape. The catheter end was connected to a wall-mounted suction unit delivering continuous negative pressure between 50 and 125 mmHg. Dressings were changed every four days.

Patients in the control group received standard moist gauze dressings with sterile saline as per institutional protocol, changed once or twice daily depending on wound condition.

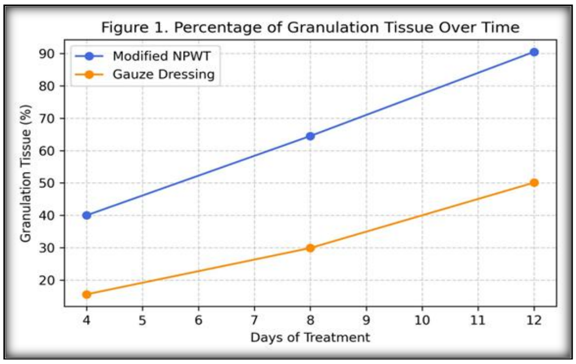
Outcome Measures: Primary outcomes included percentage of granulation tissue formation and time required for wound bed preparation. Secondary outcomes included reduction in bacterial load (assessed by wound swab cultures taken on day 1 and day 12), duration of hospital stay, and cost incurred to the patient.

Data Collection and Follow-Up: Patients were followed up during hospitalization and for a minimum period of two months. Wound assessments were performed on days 4, 8, and 12 using a standardized wound scoring system evaluating granulation area, color, and consistency. All relevant data were recorded in predesigned case record forms.

Statistical Analysis: Quantitative variables were expressed as mean ± standard deviation, and qualitative variables as frequencies and percentages. Group comparisons were made using Student's t-test or ANOVA for continuous data and Chi-square test for categorical variables. A p-value of <0.05 was considered statistically significant. Data were analyzed using SPSS software version 22 (IBM Corp., Armonk, NY, USA).

RESULTS

Granulation Tissue Formation: Modified NPWT led to significantly more granulation tissue than gauze at all assessed time points. By day 4, the mean wound score in the NPWT group corresponded to 40.0% granulation versus 15.6% in the gauze group; by day 8, 64.5% vs 29.9%; and by day 12, 90.5% vs 50.1%. All between-group comparisons were highly significant (P<0.001 for days 4, 8, and 12). [Figure 1] illustrates the trajectory of % granulation over time, and [Table 1] summarizes the numerical outcomes. These results demonstrate that modified NPWT accelerated the development of healthy granulation tissue relative to conventional dressing.

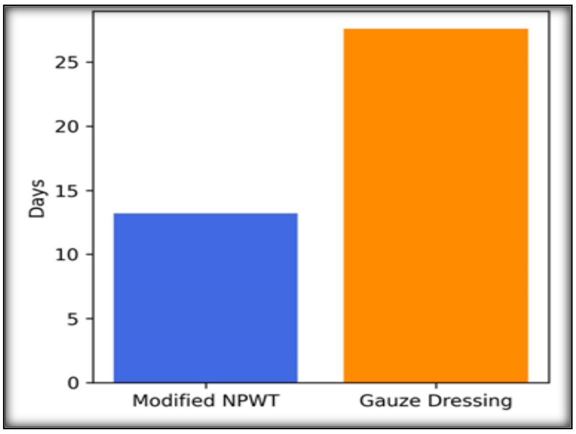


[Figure 1] Percentage of wound area covered by granulation tissue at days 4, 8, and 12. Modified NPWT (blue line) significantly outperformed gauze dressing (orange line) at each time point (P<0.001).

Table 1. Granulation tissue formation over time by dressing group. Percentages of granulation tissue (%GT) were calculated by a standardized wound scoring system. Data are mean ± SD or percentages, with P-values from between-group comparisons.

Time (day)	Modified NPWT (mean±SD)	%GT NPWT	Gauze (mean±SD)	%GT Gauze	P-value
4	2.77 ± 0.43	40.0%	0.83 ± 0.53	15.6%	<0.001
8	4.53 ± 0.51	64.5%	1.87 ± 0.51	29.9%	<0.001
12	6.63 ± 0.49	90.5%	3.23 ± 0.57	50.1%	<0.001

Wound Bed Preparation Time: The mean time to achieve a fully granulating wound bed was significantly shorter with modified NPWT. Patients in the NPWT group prepared their wound beds in 13.2 ± 1.24 days on average, compared to 27.6 ± 3.22 days in the gauze group (P<0.001). Figure 2 plots the mean preparation time by treatment. Table 2 presents these values. Thus, modified NPWT roughly halved the wound bed preparation time compared to standard dressing.



[Figure 2] Mean time (days) required for wound bed preparation. Modified NPWT (blue bar) achieved complete granulation significantly faster than gauze dressing (orange bar; P<0.001).

Table 2: Time to wound bed preparation. Mean time (in days) to achieve a healthy granulation tissue bed. Values are mean ± SD; P-value by t-test.

Dressing	Time to Wound Bed Preparation (days)
Modified NPWT	13.2 ± 1.24 **days** (SD)
Gauze	27.6 ± 3.22 days (SD)
P-value	<0.001

Bacterial Culture Results: Initial wound swabs (day 1) showed similar pathogen profiles in both groups (no significant difference, P=0.345). After 12 days of treatment, however, the NPWT group had dramatically fewer positive cultures. On day 12, 80.0% of NPWT-treated ulcers were sterile (no bacterial growth) versus only 26.7% of gauze-treated ulcers. Correspondingly, pathogenic organisms were detected in a smaller fraction of NPWT patients; for example, Staphylococcus aureus was present in 5/30 (16.7%) NPWT patients versus 11/30 (36.7%) gauze patients, and Escherichia coli in 1/30 (3.3%) vs 4/30 (13.3%). The between-group difference in overall culture positivity was significant (P=0.002), indicating that modified NPWT markedly reduced bacterial burden. Figure 3 shows the distribution of organisms at day 12.

[Figure 3] Distribution of wound culture results on day 12. Modified NPWT (blue bars) yielded a higher proportion of sterile cultures (no growth) and fewer pathogens overall than gauze dressing (orange bars; P=0.002).

Hospital Stay: Length of hospitalization was significantly shorter with modified NPWT. The NPWT group averaged 17.07 ± 1.95 days of hospital stay, whereas the gauze group averaged 31.77 ± 3.01 days. This difference was highly significant (P<0.001). Figure 4 compares the mean hospital stay between groups, and Table 3 lists the numeric values. In this study, NPWT-treated patients were discharged roughly two weeks earlier than those receiving conventional dressing, reflecting accelerated wound progress.

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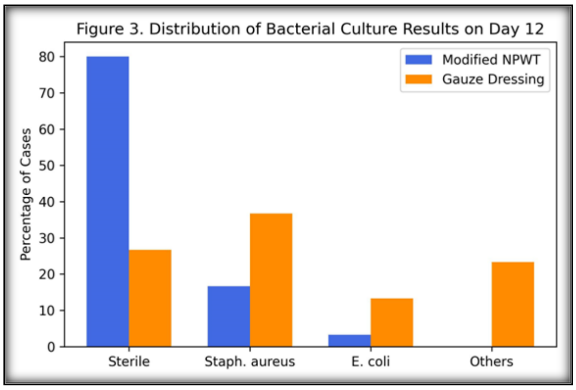

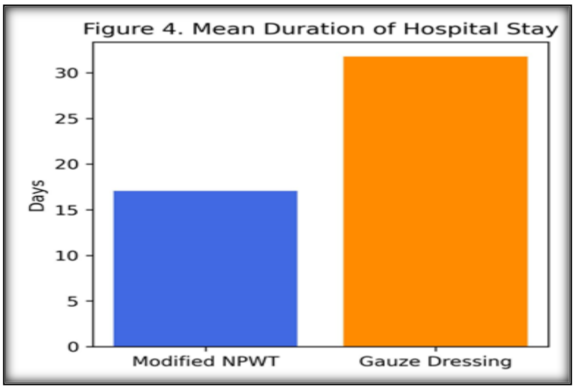

[Figure 4] Mean duration of hospital stay (days). Patients treated with modified NPWT had significantly shorter stays than those with gauze dressing (P<0.001).

Table 3: Hospital stay by treatment group. Values are mean ± SD; P-value by t-test.

Dressing	Hospital Stay (days)
Modified NPWT	17.07 ± 1.95 **days**
Gauze	31.77 ± 3.01 days
P-value	<0.001
Mean ± SD (n=30 each).	

Cost Comparison: The total direct cost per patient was significantly higher for the NPWT method. The mean cost incurred was Rs. 8247.7 ± 652.5 in the modified NPWT group, versus Rs. 4037.2 ± 481.9 in the gauze group. This two-fold difference was statistically significant (P<0.001). Figure 5 depicts the mean cost per patient. Despite higher costs, the gains in healing efficiency with NPWT may justify the expense; however, cost remained a disadvantage of the new technique.

[Figure 5] Mean total cost per patient (Indian Rupees). Modified NPWT (blue bar) incurred higher costs than gauze dressing (orange bar; P<0.001).

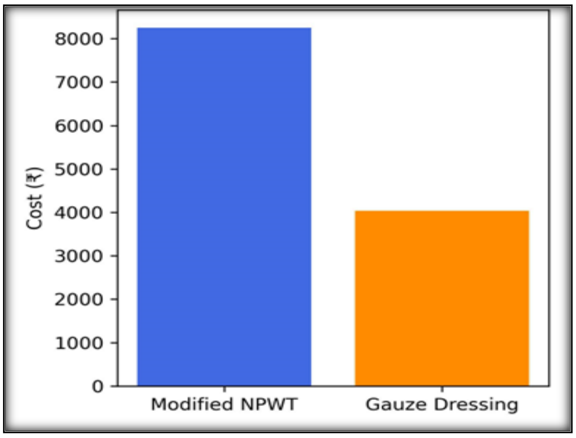

Table 4. Patient cost by dressing type. Values are mean ± SD; P-value by t-test.

Dressing	Mean Cost (₹)
Modified NPWT	8247.7 ± 652.5
Gauze	4037.2 ± 481.9
P-value	<0.001

Mean ± SD (n=30 each).

Results of Modified NPWT Dressing

Patient 1: Diabetic foot ulcer – left foot

Image 1: Diabetic foot ulcer – left foot

Image 2: patient undergoing modified NPWT for left Diabetic foot ulcer

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Image 3: Diabetic foot ulcer after modified NPWT showing a wound score of 7 Wound bed preparation time is 12 days

Patient 2: Diabetic Foot Ulcer –Right

Image 4: Diabetic foot ulcer – Right

Image 5: Post Debridement Of Right Diabetic Foot Ulcer

Image 6: Diabetic Foot Ulcer Covered With PVA Foam

Image 7:On Day 5 Diabetic Foot Ulcer Showing A Wound Score Of 3 With Pale Granulations

Image 8: On Day14 Diabetic Foot Ulcer Showing A Wound Score Of 7 wound bed preparation time is 14 days

Patient 3: Diabetic Ulcer- Left Foot

Image 9: diabetic foot ulcer – left dorsum

Image 10: On Day 32 Diabetic Foot Ulcer Showing A Wound Score Of 7

DISCUSSION

Diabetic foot ulcer continues to be one of the most challenging chronic complications of diabetes mellitus, often leading to prolonged hospitalization and significant morbidity. Conventional moist gauze dressings, though widely used, have limitations such as frequent changes, pain during removal, and inconsistent moisture balance, all of which delay granulation and wound bed preparation. In recent years, negative pressure wound therapy (NPWT) has gained wide recognition for its ability to accelerate healing by promoting angiogenesis, increasing

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perfusion, and stimulating granulation tissue formation through continuous suction of exudate.[7]

In this study, a modified, low-cost NPWT system using a sterile surgical glove and polyvinyl alcohol (PVA) foam was compared with standard saline-moistened gauze dressings in the management of chronic non-healing diabetic foot ulcers. The results demonstrated a clear superiority of the modified NPWT method in promoting wound healing, consistent with the principles and mechanisms observed in conventional NPWT systems reported in previous literature.[8,9]

The percentage of granulation tissue formation in the modified NPWT group was significantly higher than in the gauze group at all intervals (days 4, 8, and 12). By the 12th day, nearly 90% of the wound bed in the NPWT group was covered with healthy granulation tissue, compared to about 50% in the gauze group. These findings are comparable to those of Sepulveda et al. and Vaidhya et al. who also observed faster granulation and improved wound bed readiness with NPWT. Early granulation directly contributed to earlier wound bed preparation in our study—13.2 days for NPWT versus 27.6 days for gauze—which supports the role of negative pressure in enhancing local tissue perfusion and fibroblast proliferation.[10]

Bacterial culture results further confirmed the antimicrobial advantage of modified NPWT. By the twelfth day, 80% of wounds in the NPWT group showed no bacterial growth compared to only 26.7% in the gauze group. Similar bacterial clearance trends have been documented in studies by Mouës et al. and Sajid et al. indicating that controlled subatmospheric pressure not only removes exudates but also reduces bacterial colonization.[11-15]

Duration of hospital stay was significantly reduced among NPWT patients (mean 17.07 days) compared to gauze-dressed patients (mean 31.77 days). This reduction mirrors previous randomized trials showing that NPWT shortens hospitalization and decreases overall morbidity. A shorter hospital stay not only benefits patient comfort but also contributes to better bed turnover and reduced institutional burden.[16]

The only limitation noted with the modified NPWT system was the higher cost compared with gauze dressing (Rs. 8247 vs. Rs. 4037). However, considering the faster wound bed preparation, fewer dressing changes, reduced nursing hours, and shorter hospital stay, the overall cost-effectiveness remains favorable. Furthermore, this modified setup costs substantially less than commercial NPWT systems, which often range around Rs. 9,000 per single dressing, making it an accessible alternative for resource-constrained healthcare settings.[17]

Certain limitations of the present study must be acknowledged. The sample size was relatively small and limited to diabetic foot ulcers only. The study did not assess complete healing time or long-term recurrence. Ulcer size variations and subsequent reconstructive options (such as skin grafts or flaps) were not standardized, which could influence final outcomes. Future multicentric randomized controlled trials with larger sample sizes and broader wound types are recommended to validate and generalize these findings.[18]

CONCLUSION

The modified negative pressure wound therapy using a sterile surgical glove and polyvinyl alcohol foam provides an effective, affordable, and safe alternative to conventional gauze dressings in the management of non-healing diabetic foot ulcers. It significantly enhances granulation tissue formation, promotes faster wound bed preparation, reduces bacterial burden, and shortens hospital stay.

Although the initial cost per patient is higher than that of conventional dressings, the improved healing outcomes and reduced inpatient days make the overall approach economically favorable. The technique is simple, reproducible, and well-suited for implementation in low-resource clinical environments.

Further large-scale clinical studies are warranted to establish its long-term benefits and cost-effectiveness compared to commercial NPWT systems and other advanced wound care modalities.

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