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Negative Suction Dressing *vs.* Normal Dressing in the Management of Diabetic Foot Ulcers – A Randomized Control Trial

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Abstract

Background: Diabetic foot ulcers (DFUs) are a major complication of diabetes mellitus, often leading to prolonged hospital stays, infections, and limb amputations. Conventional wound management strategies, such as normal saline and betadine H_2O_2 dressing, have been widely used but may not adequately accelerate healing. Negative suction dressing (NPWT) has emerged as an alternative method aimed at improving granulation tissue formation and reducing hospital stay duration. However, comparative studies assessing NPWT's efficacy *versus* conventional dressing remain limited. This study evaluates the effectiveness of NPWT *versus* normal saline and betadine dressing in diabetic foot ulcer management at a tertiary care hospital.

Methods: This randomized controlled trial was conducted at the Department of General Surgery, a tertiary healthcare center, from May 2022 to May 2024. A total of 80 patients diagnosed with diabetic foot ulcers were randomized into two groups:

- Group 1: Negative suction dressing (NPWT).
- Group 2: Normal saline and betadine H_2O_2 dressing.

Both groups received standardized diabetes management, including blood glucose control using insulin or oral hypoglycemic agents, along with systemic antibiotics. Wounds were assessed for granulation tissue formation, graft take-up percentage, duration of hospital stay, ulcer size reduction, and postoperative complications. Data were analyzed using chi-square tests and t-tests, with statistical significance set at $p<0.05$.

Results: Patients treated with NPWT demonstrated significantly shorter hospital stays (29.91 days) compared to 53.46 days in the conventional dressing group (p=0.0001). Granulation tissue formation was superior in NPWT-treated wounds, with a mean ulcer area reduction of 83.56 ± 16.88% *vs.* 53.88 ± 21.52% for conventional dressing (p=0.0001). The success rate was 100% in NPWT compared to 83.7% in normal saline and betadine dressing (p=0.006). Additionally, NPWT resulted in improved graft take-up rates, with 82.17 ± 14.44% graft survival *vs.* 61.48 ± 17.25% in the conventional dressing group (p=0.0001).

Conclusions: Negative suction dressing significantly enhances diabetic foot ulcer healing by reducing hospital stay duration, improving granulation tissue formation, increasing graft take-up rates, and minimizing treatment failures compared to conventional dressing methods. These findings underscore the superior efficacy of NPWT in DFU management, suggesting that it should be integrated into standard treatment protocols for improved patient outcomes. Further large-scale studies are recommended to validate long-term benefits and cost-effectiveness.

Keywords: Diabetic foot ulcer; Negative suction dressing; Wound healing; Granulation tissue; Randomized controlled trial

Key Findings

- Negative suction dressing (NPWT) significantly reduced hospital stays (29.91 days vs. 53.46 days for conventional dressing, p=0.0001).
- Granulation tissue formation was notably higher in NPWT-treated wounds (Mean ± SD = 83.56 ± 16.88 vs. 53.88 ± 21.52, p=0.0001).

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- NPWT demonstrated a 100% success rate, compared to 83.7% in normal saline and betadine dressing (p=0.006).

- Graft take-up rates were significantly improved in NPWT-treated patients (Mean ± SD = 82.17 ± 14.44 vs. 61.48 ± 17.25, p=0.0001).

What is known and what is new?

- Conventional dressings have been widely used in diabetic foot ulcer (DFU) management, but healing is often slow, increasing infection risks and hospital stays.

- NPWT is known to promote granulation tissue formation and accelerate healing, but comparative studies remain limited.

- This manuscript provides direct comparative evidence, highlighting NPWT's superior outcomes in healing, hospital stay duration, and graft take-up rates.

What is the implication, and what should change now?

- NPWT should be integrated into standard DFU management protocols to improve recovery and reduce hospital resource utilization.

- Further large-scale studies are needed to assess long-term efficacy, recurrence rates, and cost-effectiveness.

- Healthcare policies should consider expanding NPWT access, ensuring more patients benefit from its advantages.

Introduction

Background

Diabetes mellitus is a chronic metabolic disorder characterized by insufficient insulin production or impaired insulin function, resulting in sustained hyperglycemia. This condition affects multiple organ systems, leading to severe complications such as neuropathy, nephropathy, retinopathy, and an increased risk of cardiovascular diseases [1-3]. Among these complications, diabetic foot ulcers (DFUs) are a common and debilitating issue, often arising from poor glycemic control, neuropathy, peripheral vascular disease, and repeated trauma to pressure-bearing areas of the foot [4].

DFUs pose a significant burden on global healthcare, with an estimated annual incidence ranging from 9.1 to 26.1 million cases worldwide [5]. Nearly 15% to 25% of individuals diagnosed with diabetes mellitus will develop a foot ulcer during their lifetime [6]. As diabetes prevalence continues to rise, the incidence of DFUs is expected to increase proportionally [7]. DFUs are classified into three major types: neuropathic, neuroischemic, and ischemic ulcers [8]. Various risk factors contribute to their development, including infection, older age, diabetic neuropathy, peripheral vascular disease, cigarette smoking, inadequate glycemic control, prior ulcerations or amputations, and ischemia of both small and large blood vessels [8-10].

Rationale and knowledge gap

The management of DFUs is critical to preventing complications such as osteomyelitis, infection, and amputation. Traditional wound care involves normal saline dressing, which serves as a standard approach but may not significantly accelerate wound healing. Negative suction dressing, also known as vacuum-assisted wound closure (VAC), is an advanced dressing system that applies **sub**-atmospheric negative pressure (-125 mmHg) to the ulcer surface, reducing local edema, promoting blood flow, and accelerating granulation tissue formation. The dressing system consists of a sterile, open-pore foam dressing sealed with an occlusive drape to create a controlled wound environment. A vacuum tube is attached to facilitate the removal of excess fluid, maintaining optimal healing conditions (Figure 1). Despite its known benefits, comparative studies evaluating the effectiveness of negative suction dressing *versus* normal saline dressing remain limited, highlighting a crucial gap in evidence-based wound management strategies [11-17].

Figure 1: Pre *vs* Post Vacuum Therapy.

Objective

This study aims to compare the efficacy of negative suction dressing and normal saline dressing in managing diabetic foot ulcers. The primary objective is to evaluate:

- The rate of granulation tissue formation in both dressing methods.

- The overall graft survival and wound healing efficiency.

- Patient compliance and comfort levels with each treatment.

- Hospital stays duration and postoperative complications associated with each approach.

- By conducting this study, we aim to provide evidence-based insights into optimizing DFU management, potentially improving patient outcomes and reducing healthcare burdens related to diabetes-related complications.

Methods

This study was conducted at the Department of general surgery, in a tertiary care hospita.

The period of the study was from 1st May 2022 to 1st May 2024.

Study Type: Randomized Control Trial

Sampling technique: Randomization done by lottery method

Randomization and handling of confounders

The lottery method was used to achieve randomization; however, baseline characteristics across the two groups, such as age, gender, duration of diabetes, and ulcer severity, were assessed to ensure that both arms were comparable. Confounders were minimized by checking these variables across groups, ensuring balanced distribution to reduce potential biases [18-23].

Matching of study arms

Prior to randomization, demographic and clinical characteristics were recorded for both groups to verify they were similar. This assessment included age, gender, duration of diabetes, and ulcer-related factors, helping to ensure both arms were well-matched. Statistical methods like chi-square and t-tests were employed to confirm group similarity.

Parameters for defining ulcer

Ulcers were classified based on a standardized grading system that took into account.1.t depth, size, and presence of infection. Only diabetic foot ulcers meeting these criteria were included, ensuring uniformity in ulcer classification across groups [24,25].

Consideration of glycemic index

Glycemic control was measured through HbA1c levels at the study outset to standardize and compare glycemic control between groups. HbA1c thresholds were defined to include patients with similar glycemic profiles, reducing the influence of glycemic variability on wound healing outcomes.

Treatment modality for Diabetes Mellitus (DM)

Both groups received comparable DM management, including insulin or oral hypoglycemic agents as indicated, with blood glucose monitored and maintained within target ranges throughout the study. Uniform management protocols ensured that differences in ulcer healing were attributed to dressing type rather than variations in diabetes treatment [26].

Duration from onset of DM to ulcer development

The time elapsed from diabetes diagnosis to ulcer development was recorded to control for its impact on healing outcomes. This allowed for matching or adjustment across groups, considering that longer durations of diabetes might impact wound healing independently of the intervention [27].

Importance of pre-randomization definitions

Defining and balancing these variables prior to randomization ensured that both groups were as comparable as possible at baseline, allowing for a more accurate assessment of the dressing type's effect on ulcer healing. By controlling these factors, the study aimed to isolate the effect of the intervention from potential confounders.

Two groups will be formed by randomized sampling method:

- Group1: Negative suction dressing

Patients to be manage with Negative suction dressing.

- Group2: Normal saline and betadine H2O2 dressing

Patients to manage with normal saline and betadine H2O2 dressing.

Inclusion criteria

- All patient above 18-year age with both genders diagnosed to have an ulcer as a complication of diabetes mellitus.
- Patient is willing to give informed consent.

Exclusion criteria

- Patient with proven malignancy.
- Patient with proven venous ulcer.
- Patients not consented for inclusion in the study.
- Patients with peripheral vascular disease.
- Patients with age <18 years or >75 years, having septicemia, osteomyelitis, are on corticosteroids, immunosuppressive drugs or chemotherapy and patients who are contraindicated to silver ion dressing and normal saline dressing were excluded from the study.
- Patients with uncontrolled autoimmune connective tissues diseases.
- Patients who are currently receiving radiation therapy or chemotherapy.

Oral and written consent was taken from all participant and they will be informed that they can leave the study at any time A through history and general examination was done on all patients. Complete control of diabetes was done. Blood sugar was monitored and maintained the Euglycemic state using insulin and oral hypoglycemic agents during the therapy. All patients were administered broad-spectrum systemic antibiotics.

Investigations including complete blood count, electrocardiography, chest x- ray, HIV, HbsAg, Renal function test, Liver function test, RBS, HBA1c was done on all patients. On admission period will include electrocardiogram, noninvasive blood pressure, pulse oximeter. Vitals signs were maintained stable throughout period. After the surgical intervention of the wound either debridement and/or amputation, all patient was divided into 2 group.

Patient in Group A underwent Negative suction dressing and Group B underwent simple dressing and hospital provided antibiotics. Wounds was assessed for the presence of wound discharge, the appearance of granulation tissue, presence of slough and changes in the wound size. Wound size was measured by taking the largest transverse diameter and largest vertical diameter and All patients follow up till 6 months.

Outcome measure

Wounds were assessed for -the presence of wound discharge, - the appearance of granulation tissue, -presence of slough and -changes in the wound size at the beginning of the treatment and at the end of definitive treatment. Wound size was measured by taking the largest transverse diameter and largest vertical diameter and All patients follow up till 6 months. Occurrence of any complications such as hematoma, bleeding, nausea, vomiting and allergic reactions were also observed.

Results

The age distribution of patients undergoing negative suction dressing versus those receiving normal saline and betadine H2O2 dressing is detailed in Table 1. The majority of patients in both groups fall within the 51-60 years age bracket, with 20.9% in the negative suction group and a significant 51.2% in the saline and betadine group. Other notable age groups include 41-50 years (27.9% in negative suction) and 31-40 years (18.6% in negative suction and 14% in saline and betadine). The mean age was slightly higher for the saline and betadine group (51.22 years) compared to the negative suction group (48.33 years), but the difference was not statistically significant (Chi-square test = 10.04, p=0.08).

Table 4 presents the gender distribution between the two dressing methods. notable finding is the higher proportion of males (72.1%) in the normal saline and betadine group compared to the negative suction group (48.8%). Conversely, females comprised 51.2% of the negative suction group but only 27.9% of the saline and betadine group. The distribution of gender between the two groups was

Table 1: Wagner Classification of diabetic foot ulcer.

Grade	Lesion
0	No open lesions; may have deformity or cellulitis
1	Superficial diabetic ulcer (partial or full thickness)
2	Ulcer extension to the ligament, tendon, joint capsule, or deep fascia without abscess or osteomyelitis
3	Deep ulcer with abscess, osteomyelitis, or joint sepsis
4	Gangrene localized to the portion of the forefoot or heel
5	Extensive gangrenous involvement of the entire foot

Table 2: The University of Texas wound classification system.

Stage	Grade			
	0	I	II	III
A	pre- or post-ulcerative completely epithelized lesion	Superficial wound	Wound penetration up to tendon or capsule	Wound penetration up to bone or joint
B	Infection	Infection	Infection	Infection
C	Ischaemia	Ischaemia	Ischaemia	Ischaemia
D	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia

Table 3: Age distribution.

Age distribution	Negative suction dressing		Normal saline and betadine H2O2 dressing		Total
	N	%	N	%	N(%)
21–30	5	11.60%	2	4.70%	7 (8.1%)
31–40	8	18.60%	6	14%	14(16.3%)
41–50	12	27.90%	6	14%	18(20.9%)
51–60	9	20.90%	22	51.20%	31(36%)
61–70	8	18.60%	5	11.60%	13(15.1%)
71–75	1	2.30%	2	4.70%	3 (3.5%)
Total	**43**	**100%**	**43**	**100%**	**86(100%)**
Mean±SD	**48.33±12.48**		**51.22±11.55**		**49.77±12.04**

Chisquare test=10.04, p=0.08, Not statistically significant

Table 4: Gender distribution.

Se distribution	Negative suction dressing		Normal saline and betadine H2O2 dressing		Total
	N	%	N	%	N(%)
Male	21	48.80%	31	72.10%	52(60.5%)
Female	22	51.20%	12	27.90%	34(39.5%)
Total	**43**	**100%**	**43**	**100%**	**86(100%)**

Chisquare test=4.80, p=0.02*, Statistically significant

statistically significant (Chi-square test = 4.80, p=0.02).

The duration of hospital stays, measured in days required for healing, is summarized in Table 5. Patients treated with negative suction dressing had a shorter average hospital stay (29.91 days) compared to those treated with normal saline and betadine H2O2 (53.46 days). The majority of patients in the negative suction group required between 21-30 days (46.5%) for healing, while a significant portion in the saline and betadine group required 61-70 days (27.9%). This difference in duration was highly significant (Chi-square test = 38.54, p=0.0001). The difference might be in view of rapid recovery in patients managed with negative suction dressing and more compliance.

Granulation tissue formation, measured by percentage ulcer area reduction, is detailed in Table 6.1. Negative suction dressing resulting higher percentages of granulation, with 44.2% of patients showing 20% to 40% reduction and 18.6% showing 81% to 100% reduction. In contrast, 53.5% of patients in the saline and betadine group showed an 81-100% reduction, but 16.3% showed no granulation (failure). The overall granulation rate was significantly higher for the negative suction group (Mean ± SD = 83.56 ± 16.88) compared to the saline and betadine group (53.88 ± 21.52), and thus statistical significant (Chi-square test = 26.44, p=0.0001).

Table 6.2 illustrates the distribution of graft take up. Negative suction dressing showed a higher graft take up, with 25.6% of patients having 20% to 40% graft take up and 39.5% having 41% to 60% graft take up. On the other hand, inthesalineandbetadinegroup,48.8% had81-90% graft take up, but 16.3% experienced graft failure. The mean graft takes up was significantly higher in the negative suction group (82.17 ± 14.44) compared to the saline and betadine group (61.48 ± 17.25), with statistical significance (Chi-square test = 28.82,

Table 5: Duration of hospital stay in days/day required for healing.

Duration in days	Negative suction dressing		Normal saline and betadine H2O2 dressing		Total
	N	%	N	%	N(%)
11–20	11	25.60%	0	0.00%	11(12.8%)
21–30	20	46.50%	8	18.60%	28(32.6%)
31–40	5	11.60%	2	4.70%	7 (8.1%)
41–50	4	9.30%	4	9.30%	8 (9.3%)
51–60	1	2.30%	9	20.90%	10(11.6%)
61–70	1	2.30%	12	27.90%	13(15.1%)
71–80	1	2.30%	8	18.60%	9 (10.5%)
Total	**43**	**100%**	**43**	**100%**	**86(100%)**
Mean±SD	**29.91±13.20**		**53.46±17.26**		**41.68±19.33**

Chisquare test=38.54, p=0.0001*, Statistically significant

Table 6: Outcome.

Outcome	Negative suction dressing		Normal saline and betadine H2O2 dressing		Total
	N	%	N	%	N(%)
Success	43	100%	36	83.70%	79(91.9%)
Failure	0	0%	7	16.30%	7 (8.1%)
Total	**43**	**100%**	**43**	**100%**	**86(100%)**

Chisquare test=7.53, p=0.006*, Statistically significant

Table 6.1: Rate of granulation tissue formation.

Percentage ulcer area reduction	Negative suction dressing		Normal saline and betadine H2O2 dressing		Total
	N	%	N	%	N(%)
20–40	19	44.20%	0	0.00%	19
41–60	9	20.90%	6	14.00%	15
61–80	7	16.30%	7	16.30%	14
81–100	8	18.60%	23	53.50%	31
Failed	0	0.00%	7	16.30%	7
Total	**43**	**100%**	**43**	**100%**	**86(100%)**
Mean±SD	**83.56±16.88**		**53.88±21.52**		**67.54±24.43**

Chisquare test=26.44, p=0.0001*, Statistically significant

Table 6.2: Distribution based on graft take up.

Graft	Negative suction dressing		Normal saline and betadine H2O2 dressing		Total
	N	%	N	%	N(%)
20–40	11	25.60%	2	4.70%	13
41–60	17	39.50%	1	2.30%	18
61–80	9	20.90%	12	27.90%	21
81–90	6	14.00%	21	48.80%	27
Failed	0	0.00%	7	16.30%	7
Total	**43**	**100%**	**43**	**100%**	**86(100%)**
Mean±SD	**82.17±14.44**		**61.48±17.25**		**71.00±18.97**

Chisquare test=28.82, p=0.0001*, Statistically significant

p=0.0001). This might be as a response to better granulation tissue formation and healing wound bed formation in its treated with negative suction dressing. This in turn lead to better graft placement and uptake.

Discussion

Please kindly check that the discussion section is with necessary rigor, critical thinking, and comprehensiveness.

The study highlights significant advantages of negative suction dressing (NPWT) over normal saline and betadine dressing in managing diabetic foot ulcers (DFUs) [28,29].

- **Age Distribution:** Middle-aged adults (51–60 years) represented the highest prevalence group, consistent with findings from Sridhar et al. (2020) and Bogucka et al. (2023). The slight variation in mean age across studies suggests that inclusion criteria

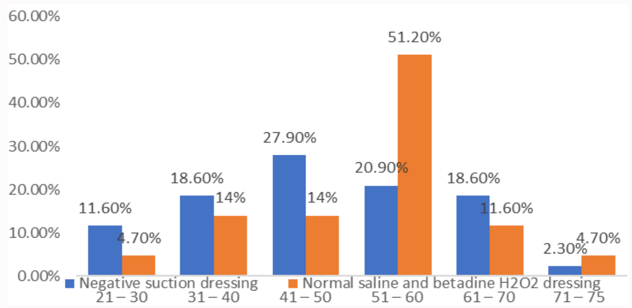

Figure 2: Age distribution.

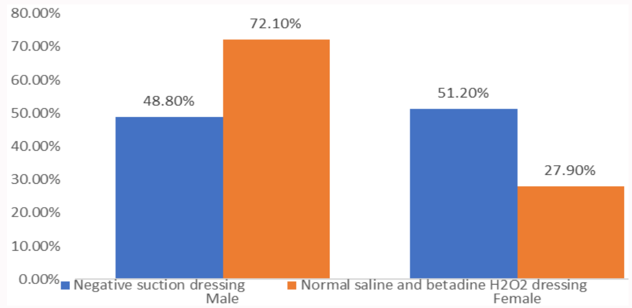

Figure 3: Gender distribution.

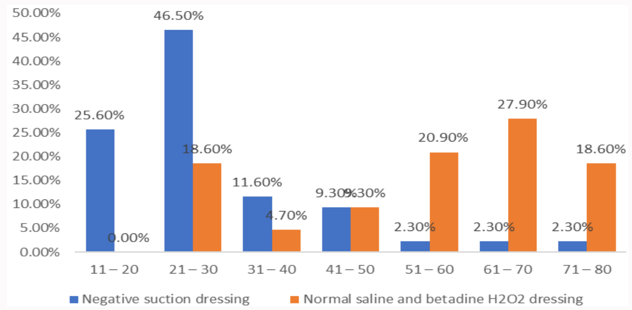

Figure 4: Duration of hospital stay in days/day required for healing.

and specific wound characteristics influence patient distribution.

- **Gender Distribution:** Male patients were predominant, particularly in the normal saline and betadine group (72.1%), aligning with previous studies (Sridhar et al., 2020; Bogucka et al., 2023). This trend reflects a higher incidence of chronic wounds in men, likely due to greater occupational exposure and higher diabetes-related complications.

- **Hospital Stay Duration:** NPWT significantly reduced hospital stay (mean = 29.91 days) compared to 53.46 days for conventional dressing. This aligns with findings from Sridhar et al. (2020) and Bogucka et al. (2023), reinforcing NPWT's role in accelerating wound healing and minimizing hospital resource utilization.

- **Outcome and Healing Rate:** NPWT demonstrated 100% success compared to 83.7% success in normal saline and betadine dressing. Its ability to enhance granulation tissue formation and reduce wound area (83.56% vs. 53.88%) was statistically significant (p=0.0001), corroborating prior research on NPWT's efficacy (Weheida et al., 2022).

Strengths

- Randomized controlled design, minimizing selection bias.

- Objective wound assessment using digital imaging and standardized scoring.

- Comprehensive analysis of hospital stay, healing rates, and complications.

Limitations

- Single-center study, limiting generalizability.

- Short follow-up period without long-term ulcer recurrence assessment.

- Potential selection bias due to strict inclusion criteria excluding patients with complex systemic comorbidities.

Findings align with Sridhar et al. (2020), who reported higher NPWT healing rates and shorter hospital stays**.** Bogucka et al. (2023) and Weheida et al. (2022) similarly documented NPWT's efficacy in reducing infection rates and enhancing granulation tissue formation. These results confirm that NPWT consistently outperforms conventional dressings across multiple clinical settings.

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- Integration of NPWT into standard diabetic foot ulcer treatment protocols.

- Further research on NPWT's long-term impact on ulcer recurrence and limb salvage.

- Cost-effectiveness analysis for broader clinical adoption.

- Awareness programs targeting male patients, given their higher prevalence of chronic wounds.

- This study underscores NPWT as a superior alternative to traditional dressings, reinforcing its role in efficient wound management and patient recovery (Figures 2-7).

Conclusions

This study provides compelling evidence that negative suction dressing (NPWT) significantly improves diabetic foot ulcer outcomes compared to normal saline and betadine dressing.

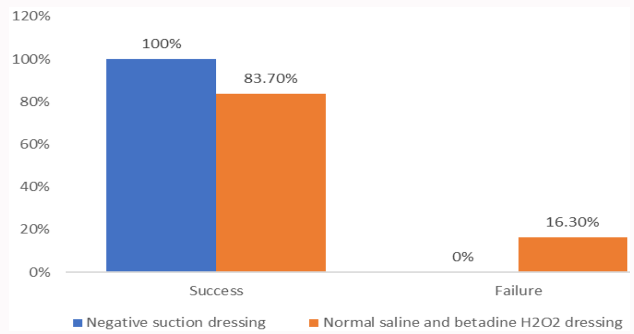

Figure 5: Outcome.

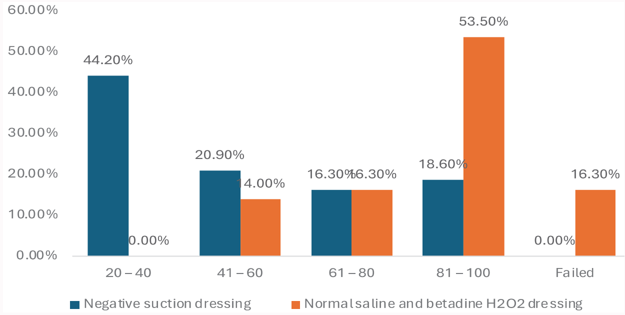

Figure 6: Rate of granulation tissue formation.

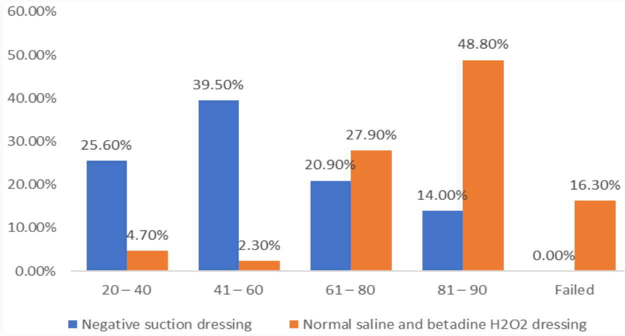

Figure 7: Distribution based on graft take up.

Age distribution

Patients aged 51-60 years formed the majority in both groups (20.9% in NPWT vs. 51.2% in conventional dressing). While the mean age was slightly higher in the saline and betadine group (51.22 years vs. 48.33 years in NPWT), the difference was not statistically significant (Chi-square test = 10.04, p=0.08), indicating that age did not independently affect dressing efficacy.

Gender distribution

Male patients were significantly more prevalent in the saline and betadine group (72.1%) compared to NPWT (48.8%), while female patients comprised 51.2% in NPWT and only 27.9% in the saline and betadine group. The gender distribution difference was statistically significant (Chi-square test = 4.80, p=0.02), suggesting potential gender-based variability in treatment preference or ulcer severity.

Hospital stay duration

Patients undergoing NPWT experienced a shorter hospital stay (mean = 29.91 days) compared to 53.46 days in the conventional dressing group. The difference was highly significant (Chi-square test = 38.54, p=0.0001), reinforcing the faster healing and higher compliance associated with NPWT.

Granulation tissue formation

The NPWT group exhibited a significantly higher granulation rate (Mean ± SD = 83.56 ± 16.88) compared to 53.88 ± 21.52 in the saline and betadine group, with strong statistical significance (Chi-square test = 26.44, p=0.0001). This suggests that NPWT promotes faster wound recovery by enhancing tissue regeneration.

Graft Take-Up

The mean graft take-up rate was significantly higher in NPWT (82.17 ± 14.44) compared to 61.48 ± 17.25 in conventional dressing (Chi-square test = 28.82, p=0.0001). The improved granulation tissue formation in NPWT patients likely contributed to better graft placement and survival.

Implications

NPWT demonstrates superior efficacy over conventional dressing in accelerating healing, reducing hospital stay, enhancing granulation tissue formation, and improving graft take-up rates. Given these findings, integrating NPWT into standard diabetic foot ulcer treatment protocols could significantly optimize patient outcomes. Further multi-center, long-term studies are necessary to evaluate its sustained benefits and cost-effectiveness.

Acknowledgments

We extend our sincere gratitude to the patients who participated in this study and the dedicated medical staff for their invaluable support in patient care and data collection. Their commitment and expertise were essential in ensuring the smooth execution of the research.

Ethical Statement

Ethical approval was taken from the college ethical committee before starting the study.

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