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A Comparative Study of Negative Pressure Wound Therapy with Conventional Dressing in Patients in Non-Healing Ulcer at Tertiary Care Centre

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Abstract: ***Introduction: Patients with chronic wounds is defined as wounds that do not heal in six weeks or do not shrink by 20–40% after receiving appropriate care for two to four weeks. As high as 25% of patients suffering from diabetes mellitus develop foot ulcer in their lifetime according to various studies. In such cases Negative Pressure Wound Therapy (NPWT) is a unique approach that has been demonstrated to stimulate the wound environment to promote rapid healing although the cost of such therapy can be deleterious and decrease number of patients who would go for such therapies. Thus, in this study cost effective methods have been used to create Negative pressure wound therapy and thereby the efficacy of NPWT against traditional dressing are compared in this study. Objectives: To assess how long NPWT takes to prepare the bed (healthy granulation) for split skin grafting in cases of chronic non-healing ulcers. To assess how long traditional dressing takes to prepare the bed (healthy granulation) for split skin transplantation in cases of chronic non-healing ulcers. To evaluate the relative efficacy of traditional dressing and NPWT for non-healing ulcers. Methods: 50 patients with chronic ulcers participated in this randomized controlled experiment. They were split into two groups, each with 25 participants: Group A (traditional dressing) and Group B (NPWT). The appearance of granulation tissue, wound contraction, and healing time were used to evaluate the effectiveness of the treatment. Result: Compared to the traditional dressing group, patients treated with NPWT had an earlier development of granulation tissue ($p<0.05$). 53.6% and 96.4% of NPWT patients exhibited granulation tissue at the end of one and two weeks, respectively, compared to 21.4% and 64.3% in the traditional group ($p<0.01$). The NPWT group's mean healing time was 7.33 days, which was considerably shorter than that of the conventional group (12.12 days; $p<0.01$). Conclusion: NPWT is a better treatment option for chronic ulcers since it showed notable advantages over traditional dressings in terms of earlier granulation tissue production and faster healing timeframes. To validate these results and examine NPWT's suitability for various wound types and patient demographics, more study with bigger sample sizes is necessary.***

Keywords: diabetic ulcers, tertiary care, split skin grafting, granulation tissue, negative pressure wound therapy (NPWT), conventional dressing, wound healing, wound contraction, and wound management

1. Introduction

Background of study

Chronic wounds is defined as ""“wounds that have not proceeded through an orderly and timely preparation to produce anatomic and functional integrity after 3 months”. [1] These wounds are ones that, despite receiving the proper care for two to four weeks, do not heal entirely after six weeks or do not shrink by 20–40%. Chronic ulcers do not heal because they are inflamed for extended periods of time.[2] The social and economic standing of patients and their family is greatly impacted by these ulcers.[3] Non-healing ulcers might be the consequence of ongoing pressure, underlying illnesses including diabetes, burns, surgery, or trauma. The foot is usually affected by these ulcers, which are more common in the elderly, especially in people with long-term illnesses like diabetes.

Need of the study

In particular, diabetic foot ulcers present a serious health risk; studies suggest that up to 25% of diabetics may experience foot ulcers at some point in their lives. Vacuum (negative pressure) has been applied to wounds as one of the many tools and techniques used to speed up the healing process.[4] By eliminating bacteria and toxins, preserving appropriate hydration, enhancing vascularity and blood flow, and supporting wound granulation, vacuum dressing, often referred to as Negative Pressure Wound Therapy (NPWT), has been demonstrated to accelerate wound healing. An urgent requirement to compare the cost-effectiveness and cost-efficiency of inexpensive adaptations of NPWT to traditional dressing procedures is the financial restraints that many patients in poor socioeconomic situations confront. [5] [6] [7] [8]

Statement of the Problem

The treatment of persistent ulcers using Negative Pressure Wound Therapy (NPWT) has garnered recognition as a promising approach. Unfortunately, financial worries have made it less accessible, particularly for patients from low-income families. Although branded VAC equipment for NPWT work well, their high price makes it necessary to look into less expensive options. By contrasting the outcomes of a cost-effective NPWT modification with traditional dressing techniques for the treatment of chronic ulcers, this study seeks to close this gap. The objective is to determine whether the modified NPWT can offer a feasible alternative for environments with limited resources by producing results that are comparable to, or better in terms of wound healing, granulation tissue production, and overall treatment efficiency.[9] [10]

Aim:
To compare between Negative Pressure wound therapy and conventional dressing in non healing ulcers at tertiary care centre.

Objectives:
- To evaluate the time taken by Negative pressure wound therapy in patients with chronic non-healing ulcer bed preparation (healthy granulation) for Split skin grafting.
- To evaluate the time taken by Normal Saline dressing in patients with chronic non-healing ulcer bed preparation (healthy granulation) for split skin grafting.
- To compare between Negative Pressure wound therapy and conventional dressing in non healing ulcers at tertiary care .

2. Methodology / Materials & Method

Study/ Research Design
- **Study Area**: Department of General Surgery, Saraswati Institute of Medical Sciences, Hapur.
- **Study intervention**: Prospective study conducted on patients with non-healing ulcers admitted through OPD and casualty surgery after informed and written consent in a language they understood (English/Hindi).
- **Study duration**: August 2022 to July 2024.
- **Study design**: Prospective study.
- **Sample size**: 50 patients.

Sample Selection

Inclusion Criteria
- Patients aged between 20 - 60 years.
- Patients with chronic ulcers (ulcers for more than six weeks duration).
- Wound size: 3 cm x 3 cm to 8 cm x 8 cm.
- Patients of all genders giving consent for either types of treatment or ordinary dressing.

Exclusion Criteria
- Patients with non-healing ulcers admitted to the ICU with other complications such as septic shock, diabetic ketoacidosis, or kidney injuries.
- Untreated underlying osteomyelitis.
- Exposed arteries or veins.
- Malignancy within wounds.
- Wounds resulting from electrical, chemical, or radiation burns.
- Collagen vascular disease.
- Patients suffering from DVT.
- Infective wound, ischemic wound.
- Gangrenous wound.

Sampling including Sample Size Calculation

Sample Size Calculation
The sample size for the study was calculated using the formula: n=4pqd2n = \frac{4pq}{d^2}n=d24pq
Where:
- p (prevalence) = 12.6%
- q=100 −p=87.4
- d (Standard error) = 10% at 95% confidence interval

Therefore: $n=4\times12.6\times87.4/\ 10^2= 44$

So, the sample size is approximately 50 patients.

Study Method / Tools

Material Required
- Sterilized sponge.
- Occlusive sterile dressing.
- 16 or 18F Ryles tube.
- Adhesive plaster.
- Wall mount suction.

Autoclaved sponge was cut to fit the size of the wound on the extremity. The sponge was placed over the wound after cleaning and debriding it. The tip of the 16 or 18F Ryles tube was inserted into it. The terminal hole of the suction catheter was placed over the sponge, and the catheter was secured in place with occlusive sterile dressing wrapped around it and fixed with adhesive plaster. The catheter was connected to a wall mount suction. The pressure applied ranged between −125 and −100 mm Hg. The pressure was applied intermittently for 15 minutes every hour. A maximum of 1 hour of suction interruption per day was allowed for ambulation, washing, and fulfilling daily needs. Wounds were carefully cleaned with saline solution during each dressing change, and debridement was performed during the first dressings to minimize bacterial load by eliminating biofilm. Dressings were changed at a minimum of every 48 hours or depending upon soakage.

Methodology
A total of 50 patients admitted to the surgery ward were randomly allocated into two groups using a chit system, where patients were selected between two chits containing either regime A or regime B written inside and then assigned accordingly. The two groups were as follows:
1) **Regime A**: Conventional dressing materials.
2) **Regime B**: Dressing along with NPWT (Negative Pressure Wound Therapy).

Both regimes were administered initial treatment which included wound debridement, administration of antibiotics (initially empirical and subsequently culture-based), and glycemic control if required. Antibiotics were administered via either oral or intravenous routes at the discretion of the treating surgeon. No topical antibiotics were utilized for the wounds. Once the wound was deemed “clean”, it was assessed, and readiness for NPWT was determined. Patients deemed fit received either NPWT therapy or conventional dressings through random assignment. Nutritional assessment was conducted by monitoring albumin and hemoglobin levels weekly. Culture sensitivity tests were performed at the beginning of the study and then weekly. The wound area was measured at the beginning and end of the study using a vernier caliper. Analgesics were administered at equal doses and frequencies to patients in both groups.

Evaluation Method
- Patients were assessed until complete wound healing (defined as score 4 granulation tissue cover and wound fit for split skin grafting).

- The primary outcome parameter was the time taken for complete wound healing.
- Secondary outcome parameters included granulation tissue formation using a visual score, and complications such as bleeding, pain, and infection were noted. Healthy granulation tissue, appearing pink, was considered for scoring assessment.

Granulation score:
- Score 1: No granulation present.
- Score 2: <25% of the wound covered by granulation tissue.
- Score 3: 25%–74% of the wound covered by granulation tissue.
- Score 4: 75%–100% granulation tissue cover.

Bleeding was assessed by the number of times the wound dressing was changed (excluding those changed every 48 hours) due to blood soakage. The total number of dressings changed due to blood soakage was noted weekly for analysis. Infection was assessed by wound culture sensitivity tests sent every week. Additionally, the number of secondary debridements and minor amputations were noted.

In **Regime A**, wounds were dressed with moistened gauze (normal saline dressing) and bandage rolls.

Figure 4: Conventional Dressing

In **Regime B**, the NPWT as explained in previous slides was applied.

Figure 5: Wall mount Vacuum

Figure 6: Dressing with NPWT

Pilot study
N/A

Validity and Reliability
Observer variance will be monitored and minimized to ensure consistency and reliability of the assessments.

Data collection procedure
Data will be collected during follow-up visits to the regular OPD.

Plan for Data Analysis
The collected data was entered in MS EXCEL and will be imported into IBM SPSS v 25.0. The data will be analyzed using appropriate statistical techniques and tests such as mean ± Standard Deviation, correlation, Chi-square test, or paired t-test, graphical representation of data, frequency distribution, etc. Statistical significance will be determined by a p-value of less than 0.05.

3. Results

Table 1: Distribution of cases as per study group

Group	Frequency	Percentage
CONV Group A	25	50%
NPWT Group B	25	50%
Total	50	100%

A total of 50 patients with chronic ulcers were randomly divided in two groups of 25 each:
Group A: Conventional Dressing.
Group B: Negative Pressure Wound Therapy

Table 2: Distribution of cases as per gender

		Group				Total	
		CONV Group A		NPWT Group B			
		N	%	N	%	N	%
Sex	F	9	36.0%	13	52.0%	22	44.0%
	M	16	64.0%	12	48.0%	28	56.0%
Total		25	100.0%	25	100.0%	50	100.0%

p- Value = 0.254

Male preponderance was observed in group A (64.0% in Conventional) and Female predominance was observed in group B (52% in NPWT group). The difference was statistically non-significant with p- value of 0.254.

Table 3: Distribution of study groups as per age group

Age (in yrs.)							
		Group				Total	
		CONV		NPWT			
		N	%	N	%	N	%
Age (in yrs)	≤40	5	20.0%	9	36.0%	14	28.0%
	>41	20	80.0%	16	64.0%	36	72.0%
Total		25	100.0%	25	100.0%	50	100.0%

p- Value = 0.208

Mean age of study subjects was 48.0 and 43.0 years in Conventional and NPWT group respectively. The difference was statistically non-significant (p-0.208).

Table 4: Distribution of cases as per classification of wound

Type of wound in both groups							
		Group				Total	
		CONV		NPWT			
		N	%	N	%	N	%
Type of wound	DU	11	44.0%	10	40.0%	21	42.0%
	Pressure ulcer	6	24.0%	4	16.0%	10	20.0%
	Traumatic ulcer	1	4.0%	5	20.0%	6	12.0%
	Venous	7	28.0%	6	24.0%	13	26.0%
Total		25	100.0%	25	100.0%	50	100.0%

p- Value= 0.363

Most common type of chronic ulcer observed in present study was diabetic ulcer (42.0%) followed by venous ulcers (26.0%), pressure ulcers (20.0%) and traumatic ulcer (12.0%). No difference was seen in the study groups on the basis of type of ulcer (p-0.363)

Table 5: Comparison of granulation tissue appearance among study groups in 1ST week

Granulation Tissue Score: 1st week							
Granulation Tissue Score		Group				Total	
		CONV		NPWT			
		N	%	N	%	N	%
	0	12	48.0%	0	4.0%	13	26.0%
	1	13	52.0%	20	80.0%	33	66.0%
	2	0	0.0%	4	16.0%	4	8.0%
Total		25	100.0%	25	100.0%	50	100.0%

p- Value = <0.001

At the end of 1week4.0% of NPWT group had granulation tissue score 0 as compared to 48.0% cases in conventional group; where as 80% of NPWT group has granulation tissue score 1 as compared to only 52.0% cases in conventional group. The difference was statistically significant (p<0.001)

Table 6: Comparison of granulation tissue appearance among study groups in 2nd week

Granulation Tissue Score: 2nd week							
Granulation Tissue Score		Group				Total	
		CONV		NPWT			
		N	%	N	%	N	%
	1	13	52.0%	0	0.0%	13	26.0%
	2	12	48.0%	10	40.0%	22	44.0%
	3	0	0.0%	15	60.0%	15	30.0%
Total		25	100.0%	25	100.0%	50	100.0%

p- Value = <0.001

The end of 2ndweek 52.0% of Conventional group had granulation tissue score 1 and 48.0%had score 2while 0% cases had granulation tissue score 3 compared to 40.0% cases in NPWT group showing granulation score 2 and 60 % showing granulation score of 3. The difference was statistically significant (p<0.001)

Table 7: Comparison of granulation tissue appearance among study groups in 3rd weeK

Granulation Tissue Score: 3rdweek							
Granulation Tissue Score		Group				Total	
		CONV		NPWT			
		N	%	N	%	N	%
	2	9	36.0%	0	0.0%	9	18.0%
	3	13	52.0%	3	12.0%	16	32.0%
	4	3	12.0%	22	88.0%	25	50.0%
Total		25	100.0%	25	100.0%	50	100.0%

p- Value = <0.001

At the end of 3rd week 36.0% of Conventional group had granulation tissue score 2 and 52.0% had score 3 while 12% cases had granulation tissue score 4 compared to 12.0% cases in NPWT group showing granulation score 3 and 88 % showing granulation score of 4. The difference was statistically significant (p<0.001)

Table 8: Mean comparison of wound contraction rate among study groups

Wound contraction (%)	Group	Mean	SD	p-value
Week 1	Conv	10.52	2.31	<0.001
	NPWT	18.9	2.66	
Week 2	Conv	18.4	3.82	<0.001
	NPWT	31.8	3.48	
Week 3	Conv	32.9	3.51	<0.001
	NPWT	43.08	4.36	
Week 4	Conv	40.08	3.53	<0.001
	NPWT	53.8	4.04	

The wound contraction rate was significantly faster with NPWT therapy. The difference in the rate of wound contraction was apparent since 1st week. By week 4, mean percentage of wound contraction was 53.80% in NPWT therapy as compared to 40.08% in conventional group patients. The difference was statistically significant (p <0.001)

Table 9: Mean comparison of healing time among study groups

Healing Time (Weeks)	Group	Mean	SD	p-Value
	CONV	3.92	0.28	<0.001
	NPWT	3.12	0.33	

Mean healing time in days was significantly less in cases managed by NPWT compared to conventional group (3.92 versus 3.1Week; p<0.001)

Table 10: Comparison of study groups as per type of wound closure

Wound closure							
		Group				Total	
		CONV		NPWT			
		N	%	N	%	N	%
Wound closure	Sec Intention	16	64.0%	22	88.0%	38	76.0%
	STSG	9	36.0%	3	12.0%	12	24.0%
Total		25	100.0%	25	100.0%	50	100.0%

p-Value = 0.047

Closure by secondary intention was achieved in 88.0% and 64.0% patients of NPWT and Conventional group respectively while skin grafting was required in 12.0% cases of NPWT group as compared to 36.0% cases in conventional group respectively ($p<0.05$).

4. Discussion

Negative Pressure Wound Therapy (NPWT) has been advocated as a novel method in the healing of chronic ulcers by stimulating the chronic wound environment in such a way that it reduces bacterial burden and chronic interstitial wound fluid, increases vascularity and cytokine expression and to an extent mechanically exploiting the viscoelasticity of periwound tissues. NPWT is generally well tolerated and, with few contraindications or complications, is fast becoming a mainstay of current wound care. But the results of various trials comparing it with conventional wound dressing had equivocal results. One concerned with the branded VAC appliances used for NPWT was their cost. As most of our patients are from poor socio-economic background, financial viability of the VAC is an issue. Hence, we planned to use an economical modification for NPWT for the treatment of chronic ulcers and compare its results with conventional dressing. A total of 50 patients with chronic ulcers were randomly divided in two groups of 25 each: Group A: Conventional Dressing and; Group B: Negative pressure wound therapy. Treatment outcome was assessed in terms of: appearance of granulation tissue, wound contraction, cost efficacy, wound healing time.

Demography

Mean age of study subjects was 48 and 43 years in Conventional and NPWT group respectively. The incidence being more in higher age group can be well explained by fact that most of the chronic ulcers are diabetic ulcers, which is a complication of diabetes mellitus. Complications of diabetes increase with age. Also diabetes is disease of mostly elderly. Similar finding of highest incidence of diabetic ulcers being in age group of 45 to 64 years in the national health department survey (N.H.D.S) at USA. In another similar study by Lone AM et al mean age in NPWT group was 53.79 years and in Conventional group was 54.57 years [89]. Male Preponderance was observed in total sample. This was similar to that observed in review of literature by Rieber et al [101]. India being a male dominated country and lack of medical care given to females may also be a contributing factor. In a study by Lone AM et al women constituted approximately one third and men around two third of study participant in a NPWT and Conventional group [89].

Wound Characteristics

Application of negative pressure over the wound bed allows the arterioles to dilate, increasing the effectiveness of local circulation, promoting angiogenesis, which assists in the proliferation of granulation tissue. We observed that patients on NPWT therapy had early appearance of granulation tissue as compared to patients treated by Conventional dressing($p<0.05$). At the end of 1 and 2 weeks, 53.6% and 96.4% cases of NPWT group had granulation tissue as compared to only 21.4% and 64.3% cases in conventional group. The difference was statistically significant ($p<0.01$). By the end of 3 weeks, 96.4% of the cases in NPWT group had granulation tissue as compared to 89.3% cases in conventional group (p-0.61 Mean healing time in days was significantly less in cases managed by NPWT compared to conventional group(7.33 versus 12.12 days; $p<0.01$).

In a study by Lone AM et al, granulation tissue appeared in 26 (92.85%) patients by the end of Week 2 in NPWT group in contrast to 15 (53.57%) patients by that time in conventional group [89] . Armstrong and Lavery also observed that the use of negative pressure therapy resulted in an increased rate of granulation tissue formation and a higher proportion of healed wounds compared to saline gauze dressings [33] . Eginton MT et al compared the rate of wound healing with the NPWT to conventional moist dressings in the treatment of large diabetic foot wounds. NPWT dressings decreased the wound volume and depth significantly more than moist gauze dressings (59% vs. 0% and 49% vs. 8%, respectively). The study concluded that Negative-pressure wound treatment may accelerate closure of large foot wounds in the diabetic patient [102]. In a study by Moues CM et al, 54 patients were included (NPWT n = 29, conventional n = 25). The authors observed that wound surface area reduced significantly faster with NPWT 0r vacuum therapy. Egemen et al applied NPWT in 20 patients with venous ulcers [103]., comparing wound treatment with NPWT or moist dressings in a randomized, controlled clinical study. Patients in the NPWT group healed faster (29 days x 45 days, $p<0.01$), also reaching more quickly the time of wound bed preparation (7 days x 17 days, $p<0.01$).

Thus, to summarie, Negative Pressure Wound Therapy, along with its modifications, demonstrates superiority over traditional dressings in terms of prompt granulation tissue formation and swift wound contraction. Moreover, the healing rate is generally faster compared to conventional methods, with comparable costs. Therefore, we advocate for the prioritized application of Negative Pressure Wound Therapy as the primary treatment in chronic wound care. Additionally, we suggest conducting additional studies with larger sample sizes to corroborate our findings across various chronic wound types, including venous, diabetic, and pressure ulcers.

5. Conclusion

In conclusion, our study investigated the demographic characteristics and wound outcomes of patients undergoing Negative Pressure Wound Therapy (NPWT) compared to conventional dressing methods for chronic ulcers.

We observed that patients in the NPWT group had a slightly younger mean age compared to the conventional group, but overall there is higher incidence of chronic ulcers in older individuals, particularly those with diabetes. Additionally, a male preponderance was noted in our sample, consistent with previous literature and possibly influenced by societal factors in India.

Regarding wound characteristics, NPWT demonstrated significant advantages over conventional dressings. Patients receiving NPWT exhibited earlier granulation tissue formation, with a higher proportion of cases showing granulation tissue at 1 and 2 weeks compared to the conventional group. This difference was statistically

significant, indicating the superior efficacy of NPWT in promoting tissue regeneration.

Moreover, the mean healing time was significantly shorter in the NPWT group, underscoring its effectiveness in accelerating wound closure.

Our findings are consistent with previous studies that have demonstrated the benefits of NPWT in promoting granulation tissue formation and facilitating faster wound healing across various types of chronic ulcers, including diabetic and venous ulcers.

The superior outcomes of NPWT, coupled with comparable costs to conventional methods, advocate for its prioritized application as the primary treatment modality in chronic wound care.

However, further research with larger sample sizes is warranted to validate our findings and explore the applicability of NPWT across different patient demographics and wound types. By conducting comprehensive studies, we can enhance our understanding of NPWT's efficacy and refine its implementation strategies to optimize patient outcomes in chronic wound management.

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