Original Research Paper

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General Surgery

COMPARATIVE STUDY TO EVALUATE THE EFFECTIVENESS OF NEGATIVE PRESSURE WOUND THERAPY WITH INSTILLATION OF NORMAL SALINE VERSUS WITHOUT INSTILLATION OF NORMAL SALINE IN NON-HEALING ULCERS

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ABSTRACT **Background and Objective:** Extremity wounds pose significant challenges in surgical practice, often resulting in delayed healing, increased morbidity, and healthcare costs. This study aimed to compare the efficacy of Negative Pressure Wound Therapy (NPWT) with and without normal saline instillation (NPWTi) in promoting wound healing outcomes. **Methods:** A prospective observational study was conducted at Navodaya Medical College Hospital and Research Centre, Raichur, over 18 months. One hundred patients with chronic ulcers, venous ulcers, pressure sores, diabetic foot ulcers, or traumatic wounds were randomly divided into two groups of 50 each. The control group received continuous NPWT at -125 mmHg, while the study group received NPWTi with 0.9% normal saline instillation (20-minute dwell time followed by two hours of negative pressure). Primary outcomes included time to final procedure, hospital stay duration, wound closure rates, and bacterial culture positivity. **Results:** The mean age was comparable between groups (NPWT: 49.00±17.47 years; NPWTi: 47.98±16.87 years). NPWTi demonstrated significantly shorter hospital stays (11.78±4.76 vs 13.66±4.47 days, p=0.009) and reduced time to final procedure (5.34±1.93 vs 9.72±3.09 days, p=0.008). Initial wound closure rates were similar (NPWT: 60%; NPWTi: 54%), but one-month closure rates favored NPWTi (70% vs 66%, p<0.001). Diabetes affected 40% of NPWT and 38% of NPWTi patients, while 46% of participants were obese. Streptococcus pyogenes was the most prevalent organism (14 cases), with different bacterial distribution patterns between groups. **Conclusion:** NPWTi demonstrated superior clinical outcomes compared to standard NPWT, showing accelerated wound bed preparation, reduced hospitalization, and improved long-term healing rates. The addition of normal saline instillation enhanced infection control and wound hydration, making NPWTi a more effective and cost-efficient wound management strategy for complex extremity wounds.

KEYWORDS : Negative Pressure Wound Therapy, NPWTi, wound healing, saline instillation, chronic wounds, diabetic foot ulcers, wound closure, extremity wounds, infection control, hospital stay

INTRODUCTION

Extremity wounds are common problems in surgical practice. Delayed wound healing is an important aspect in management as it results in Increased patient morbidity and mortality, length of hospital stay, and costs are associated with infection in both acute and chronic wounds.

Wound infection management strategies include the use of antibiotics and the removal of infectious materials. Apart from conventional moist saline gauze dressings, various modalities of local wound therapy described to improve wound healing are ultrasound therapy[1],infrared therapy[2], platelet rich plasma. Negative pressure wound therapy (NPWT) remains an established means to manage acute and chronic extremity wounds, especially challenging wounds, as an adjunct to debridement, systemic antibiotic therapy, topical antiseptics / antimicrobials.[3]

Non-healing wounds cause severe discomfort and distress to the patient while consuming a large number of resources from the medical system. The Indian Epidemiological Data has reported chronic wounds to be 4.5 per 1000 population and acute wounds to be nearly double that is 10.5 per 1000 population. Non healing wounds have resulted in increased rate of amputations, longer hospital stay, sepsis and even death. Treating large chronic wounds till date poses a significant challenge to the health practitioners, more over to the patients by adding to their disease burden with immense health expenditures.[4,5]

NPWT has evolved to include the periodic instillation of topical wound solutions directly over the wound bed, followed by removal using negative pressure. This NPWT with instillation and dwell time (NPWTi-d) utilizes the same properties of NPWT with the added benefit of wound cleansing.[6] NPWTi-d has been reported to promote wound cleansing, granulation tissue development, and healing in wounds that did not respond to traditional NPWT.[7]

The primary effects of NPWT on wound healing include wound contracture and size reduction; stabilization of wound environment and protection from contaminating microorganisms; reduction of edema and improvement in perfusion; removal of exudates, and cellular proliferation with improved granulation tissue.[8] Topical irrigation solutions like normal saline (NS) have been used in wounds for cleansing of wound beds, removing exudate/debris and controlling microbial growth.

Combining NPWT with instillation (NPWTi) of topical solution influences wound healing owing to cyclic cleansing, dilution of wound debris, disruption of biofilm, accelerated granulation tissue and thus earlier reduction in wound size.[9,10]

However, studies analyzing these two techniques on wound healing are lacking. Hence, the aim of the study was to compare and evaluate the efficacy of wound healing using negative pressure wound therapy with(NPWTi) or without instillation of normal saline(NPWTi).

MATERIALS AND METHODS

Source of Data:

Patients admitted with chronic or venous ulcer, pressure sore, diabetic foot, traumatic or infected wound in surgical wards of Navodaya Medical College Hospital and Research Centre, Raichur.

Study Design: Prospective observational study

Study Setting: Navodaya Medical College Hospital and Research Centre, Raichur

Study Duration: 18 months

Sample Size: 100 samples (50 in each group)

Inclusion Criteria

1) Patients above 18 years and willing to participate
2) Patients with chronic or venous ulcer, pressure sore, traumatic or infected wound
3) Patients with diabetic foot

Exclusion Criteria

1) Age less than 18 years

2) Pressure ulcers with necrotic tissues, eschar or necrotic bone
3) Patients with limited life expectancy e.g., end-stage palliative care
4) Pressure ulcer located where vacuum seal cannot be obtained, e.g., the anus,
5) Indeterminate depth of ulcer, pressure ulcer too close to exposed blood vessels and/or organs, anastomotic sites and/or nerves.
6) Patient not receiving adequate nutrition for NPWT treatment

Method of Study

a) As per institutional protocol, data will be collected using a pre-made questionnaire on the day of admission which include demographics, complete history, general physical examination, etiology of wound, comorbidities, factors affecting wound healing, or drug history (immunosuppressive drug) will be included.
b) The study's execution will receive permission from the institution's ethical committee.
c) All patients will undergo excisional debridement in the operating room and received parenteral or oral antibiotics.
d) The control group will receive continuous negative pressure at -125 mmHg using NPWT (INFOV.A.C.™ Therapy System, KCI, San Antonio, TX) [13].
e) The study group will receive NPWTi-d (V.A.C. VERAFLO™ Therapy, KCI, San Antonio, TX) with instillation of 0.9% normal saline with a dwell time of 20 minutes followed by two hours of negative pressure (-125 mmHg) [14].
f) Wound assessment will be done once in 3 days.
g) Outcomes assessed will include the time taken to heal / ulcer bed preparation, number of positive culture reports and length of hospital stay.

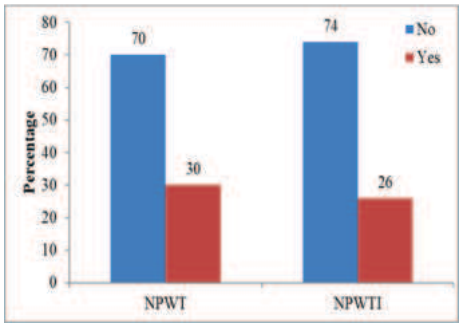
Statistical Analysis

Data will be entered into Microsoft excel data sheet and analyzed using SPSS software Categorical data will represented in the form of frequencies and proportions. Chi square test will used as test of significance for qualitative data. Categorical variables were analyzed using Fishers exact test while continuous variables were compared using Student 't' test. P value (probability that the result is true) of<0.05 will be considered as statistically significant.

Table 1: Distribution According to Smoking Among Study Groups

Smoking	NPWT		NPWTI	
	Frequency	Percent	Frequency	Percent
No	35	70	37	74
Yes	15	30	13	26
Total	100	100.0	100	100

$X^2 = 200.397$, df=4, p = <0.001

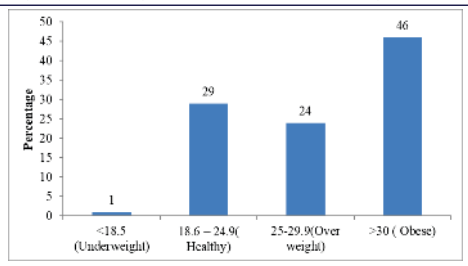


Graph 1: Distribution According to Smoking Among Study Groups

In the present study, around 26% of the patients were smokers. Among the study population, 30% of NPWT patients and 26% of NPWTi patients were smokers. The remaining 70% in NPWT and 74% in NPWTi were non-smokers. This difference was statistically significant ($X^2 = 200.397$, $p < 0.001$).

Table 2: Distribution According to BMI

BMI	Frequency	Percent
<18.5 (Underweight)	1	1.0
18.6 – 24.9(Healthy)	29	29.0
25-29.9(Over weight)	24	24.0
>30 (Obese)	46	46.0
Total	100	100.0



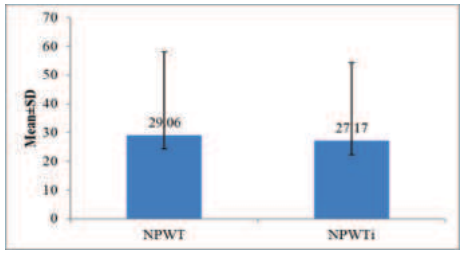
Graph 2: Distribution According to BMI

Among the participants, 46% were obese (BMI >30), 24% were overweight (BMI 25-29.9), 29% were in the healthy range (BMI 18.6-24.9), and only 1% were underweight (BMI <18.5).

Table 3: Mean BMI Between the Study Groups

BMI	Mean±SD
NPWT	29.0680±4.57060
NPWTi	27.1720±4.90968

$X^2 = 79.467$, df=68, p = 0.161



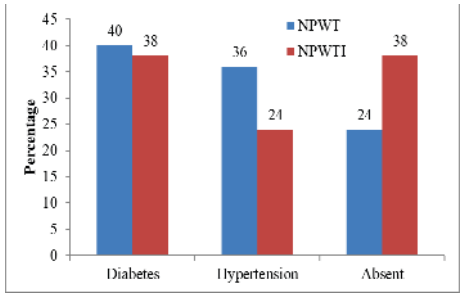
Graph 3: Mean BMI Between the Study Groups

The mean BMI in the NPWT group was 29.07±4.57, while in the NPWTi group, it was slightly lower at 27.17±4.91 ($X^2 = 79.467$, p = 0.161).

Table 4: Distribution According to Co-morbidities

Co-morbidities	NPWT		NPWTi	
	Frequency	Percent	Frequency	Percent
Diabetes	20	40	19	38
Hypertension	18	36	12	24
Absent	12	24	19	38
Total	100	100.0	100	100

$X^2 = 205.613$, df=6, p = <0.001



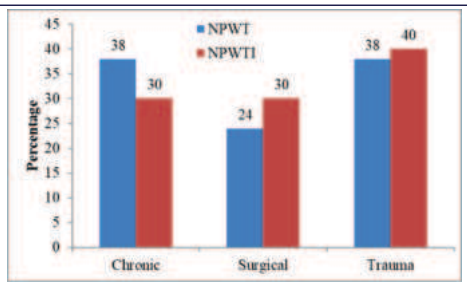
Graph 4: Distribution According to Co-morbidities

Diabetes was present in 40% of NPWT patients and 38% of NPWTi patients. Hypertension affected 36% of NPWT patients and 24% of NPWTi patients. Meanwhile, 24% of NPWT and 38% of NPWTi patients had no co-morbidities. The difference was statistically significant ($X^2 = 205.613$, $p < 0.001$).

Table 5: Distribution According to Type of Wound

Type of wound	NPWT		NPWTi	
	Frequency	Percent	Frequency	Percent
Chronic	19	38	15	30
Surgical	12	24	15	30
Trauma	19	38	20	40
Total	100	100.0	100	100

$X^2 = 201.659$, df=6, p = <0.001



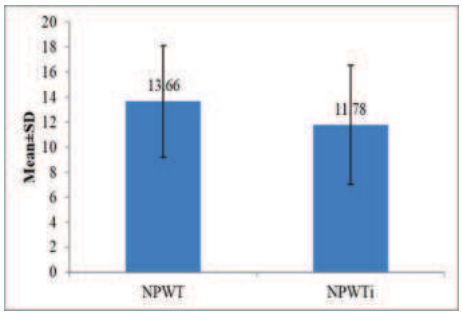
Graph 5: Distribution According to Type of Wound

Chronic wounds were found in 38% of NPWT and 30% of NPWTi patients. Surgical wounds accounted for 24% in NPWT and 30% in NPWTi, while trauma-related wounds were observed in 38% of NPWT and 40% of NPWTi patients. This difference was statistically significant ($X^2 = 201.659$, $p < 0.001$).

Table 6: Distribution According to Mean Length of Hospital Stay

Mean hospital stay (days)	Mean±SD
NPWT	13.66±4.47
NPWTi	11.78±4.76

$X^2 = 229.719$, df=182, $p = 0.009$



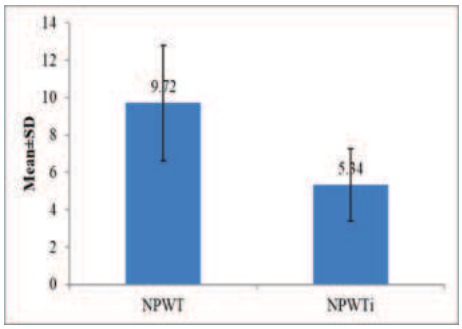
Graph 6: Distribution According to Mean Length of Hospital Stay

The mean hospital stay was significantly lower in the NPWTi group (11.78±4.76 days) compared to the NPWT group (13.66±4.47 days) ($X^2 = 229.719$, $p = 0.009$).

Table 7: Distribution According to Time to Final Procedure

Time to final procedure (days)	Mean±SD
NPWT	9.72±3.09
NPWTi	5.34±1.93

$X^2 = 79.699$, df=80, $p = 0.008$



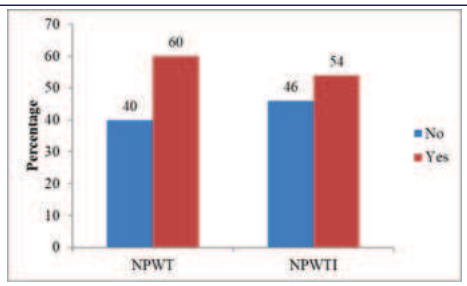
Graph 7: Distribution According to Time to Final Procedure

The NPWTi group had a significantly shorter time to final procedure (5.34±1.93 days) compared to the NPWT group (9.72±3.09 days) ($X^2 = 79.699$, $p = 0.008$).

Table 8: Distribution According to Wound Closure/Coverage

Wound closure/ coverage	NPWT		NPWTI	
	Frequency	Percent	Frequency	Percent
No	20	40	23	46
Yes	30	60	27	54
Total	100	100.0	100	100

$X^2 = 200.734$, df=4, $p = <0.001$



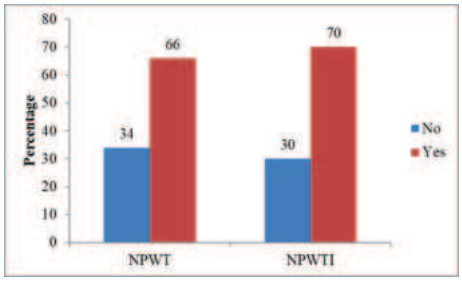
Graph 8: Distribution According to Wound Closure/Coverage

At the end of the study, 60% of NPWT patients had achieved wound closure compared to 54% in NPWTi patients ($X^2 = 200.734$, $p < 0.001$).

Table 9: Distribution According to Wound Closing After 1 Month

Wound closed after 1st month	NPWT		NPWTi	
	Frequency	Percent	Frequency	Percent
No	17	34	15	30
Yes	33	66	35	70
Total	100	100.0	100	100

$X^2 = 200.368$, df=4, $p = <0.001$



Graph 9: Distribution According to Wound Closing After 1 Month

After one month, 66% of NPWT patients had fully closed wounds, while 70% of NPWTi patients showed complete healing. This difference was statistically significant ($X^2 = 200.368$, $p < 0.001$).

Table 10: Distribution According to Bacterial Species

	NPWT	NPWTi	Total
Acinetobacter baumannii	7	6	13
Enterococcus spp.	5	6	11
Escherichia coli	5	3	8
Klebsiella pneumoniae	5	3	8
Morganella morganii	5	4	9
Proteus mirabilis	7	4	11
Pseudomonas aeruginosa	1	6	7
Serratia marcescens	6	2	8
Staphylococcus aureus	3	8	11
Streptococcus pyogenes	6	8	14
	50	50	100

The most prevalent bacteria in the NPWT group were Acinetobacter baumannii and Proteus mirabilis (7 cases each), while Streptococcus pyogenes and Staphylococcus aureus were most common in NPWTi (8 cases each). Streptococcus pyogenes had the highest overall occurrence (14 cases), highlighting differences in bacterial distribution between the two treatment modalities.

DISCUSSION

Wound infections significantly impair healing and increase healthcare costs. Advanced wound therapies like NPWT have revolutionized wound management by utilizing negative pressure to remove exudates, reduce edema, and promote angiogenesis. The addition of saline instillation (NPWTi) provides enhanced wound cleansing capabilities, though limited evidence exists for its use in infected wounds.

This comparative study of 100 patients demonstrated NPWTi's superior clinical outcomes. The age distribution showed no significant difference between groups (NPWT: 49.00±17.47 vs NPWTi: 47.98±16.87 years), consistent with previous studies. Gender distribution slightly favored males in both groups, aligning with literature reporting male predominance in wound studies.

Critical factors affecting healing included smoking (30% NPWT vs 26% NPWTi), which impairs oxygenation and immune function, and obesity (46% of participants), associated with delayed healing through inflammatory responses and poor vascular supply. Diabetes, present in approximately 40% of patients, represented a major comorbidity affecting outcomes.

NPWTi demonstrated significant advantages including shorter hospital stays (11.78±4.76 vs 13.66±4.47 days, p=0.009), reduced time to final procedure (5.34±1.93 vs 9.72±3.09 days, p=0.008), and improved one-month closure rates (70% vs 66%). These findings suggest NPWTi's enhanced wound bed preparation through continuous cleansing and debris removal, making it a superior wound management strategy with potential for reduced healthcare costs and improved patient outcomes.

CONCLUSION

The study found that while both NPWT and NPWTi were effective in wound healing, NPWTi demonstrated distinct advantages. NPWTi demonstrated faster wound bed preparation and shorter hospital stays, indicating improved wound hydration and infection control. While both groups achieved similar wound closure rates at the end of the study, NPWTi had a higher closure rate after one month. Factors such as smoking, diabetes, and BMI influenced healing outcomes, highlighting the need for individualized treatment. NPWTi proved to be more effective in accelerating healing and reducing hospital stay. Saline instillation enhanced infection control and promoted better wound hydration. Further research is needed to refine NPWTi protocols for broader clinical application. In conclusion, NPWTi is a superior alternative to standard NPWT, offering improved healing outcomes and more cost-effective wound management.

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