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Journal of Surgical Case Reports and Images

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Research Article

# A Prospective Comparative study to Evaluate the Efficacy of Wound Healing using Negative Pressure wound Therapy with or Without Instillation

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**Received Date:** November 23, 2022; **Accepted Date:** December 29, 2022; **Published Date:** February 04, 2023

**Citation:** Aysha Kalim Khan, Arulvanan Nandan, Sitaram Prasad, Anil Heroor, Merene Meenu, Wafa Ibrahim Khatri, Tahoora Sarguroh, Hitesh Rajendra Singhavi. (2023). A prospective comparative study to evaluate the efficacy of wound healing using negative pressure wound therapy with or without instillation. *J, Surgical Case Reports and Images,* 6(2); DOI: **10.31579/2690-1897/137**

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## Abstract

**Objective:** NPWT has evolved as a standard treatment for chronic traumatic and infected wounds, demonstrating an increase in wound healing when compared to normal wound care treatments. The NPWTi is a combination of the traditional NPWT with various fluid instillations into the wound. The objectives of this paper were to see whether there is any benefit in administering a saline infusion in addition to the conventional NPWT.

**Method:** Around 40 patients were enrolled in our study, with 20 patients in each of the NPWT and NPWTi groups, with a mean age of 60 years. The efficacy in treatment was assessed in terms of wound bed score, the number of follow-ups to wound closure, and the wound closure methods

**Result:** There was no statistical significance in the number of follow-ups required in both groups (P value 0.622). The NPWTi group showed rapid wound healing in the initial two follow-ups with a significant P value (P=0.00), but both groups showed comparable wound healing in the third and fourth follow-ups with no statistical difference (P=0.564). The end outcome in terms of wound closure could not be compared due to differences in wound volume in patients requiring skin grafting.

**Conclusion:** In comparison to NPWT, NPWTi demonstrated accelerated wound healing, increased granulation tissue, and brought down infection, however wound closure in terms of secondary suturing or split thickness skin graft was the same in both groups.

**Keywords:** negative pressure wound therapy; vacuum-assisted closure; instillation; wound therapy

## Abbreviations:

NPWT-Negative Pressure Wound Therapy
NPWTi- Negative pressure wound therapy using instillation
WBS- Wound bed score

## Introduction

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 [1,2,3].

In the 1990s, Negative Pressure Wound Therapy (NPWT) was developed for the treatment of full thickness wounds. NPWT functions by

application of a suction force (negative pressure) applied across a wound surface via dressing. It claims to speed up the process of wound closure, reduce infection rates and decrease maintenance cost [4, 5, 6]. In 1983, Svedman used a technique that allowed for continuous irrigation and drainage of chronic wounds and reported an increase in wound blood perfusion and granulation tissue formation in comparison to standard moist wound dressings [7]. Automated controlled delivery and exit of the medicated installation solution in the wound bed was devised by Fleishmann [8]. This was the next generation of NPWT known as the infusion NPWT (NPWTi) therapy. It promotes wound healing by enhancing exudate and debris removal, maintaining a clean wound through integration of wound irrigation as a component of the therapy. It also provides a controlled delivery of antimicrobials and antiseptic solutions that helps reducing the bioburden [9]. However, studies analyzing these two techniques on wound healing is lacking. Therefore, we aim to observe the effects of infusion NPWT on chronic wound.

## Materials and methods:

It was a prospective observational study done in our tertiary care hospital, all patients above 18 years and willing to participate with diabetic, chronic or venous ulcer, pressure sore, traumatic or infected wound were included in our study. The use of NPWT is excluded in the following cases - pressure ulcers with necrotic tissues, eschar or necrotic bone, patients with limited life expectancy e.g., end-stage palliative care, pressure ulcer located where vacuum seal cannot be obtained, e.g., the anus, indeterminate depth of ulcer, pressure ulcer too close to exposed blood vessels and/or organs, anastomotic sites and/or nerves.

Patient not receiving adequate nutrition for NPWT treatment were also excluded from the study. We included 20 patients in each group. The sample size for this study was calculated to be 20 based on an alpha error of 5% (with a 95% confidence interval) and a relative precision of 23% with a 20% margin of error. As per institutional protocol, data was collected using a pre-made questionnaire on the day of admission which included demographics, complete history, general physical examination, etiology of wound, comorbidities, factors affecting wound healing, or drug history (immunosuppressive drug) were all included. The study's execution received permission from the institution's ethical committee. Study was done conforming to the declaration of Helsinki statement.

On each follow-up, the wound bed was examined using the "Vincent Falanga"[10] wound bed score and the wound was closed using secondary suturing or a split thickness skin graft, depending on the clinical assessment [3]. Patients in each group had surgical debridement and cleaning done before receiving NPWT or NPWTi, with 5-day follow-up. Wounds were clinically examined in all of the patients in our trial, and a decision was made whether to use NPWT or NPWTi. In all cases, surgical debridement was performed, prophylactic antibiotics were administered, and adequate therapy for related diseases such as diabetes, anemia, or infection was provided. In cases of chronic and infected wounds, a swab or tissue sample was sent for culture and sensitivity testing.

### Device:

Negative Pressure Wound Therapy (NPWT) employs suction to drive fluids and drainage away from an open wound. A unique dressing was used to create a vacuum environment, which increased blood flow to the wound region, kept it clean, helped it heal and avoid infection. Three various sizes of foam were available for dressing (large, medium, or small), and the appropriate size of sponge was used depending on the wound surface area. The wound was subsequently covered with a transparent, occlusive dressing. The thin dressing material is used to produce a tight seal around the wound and surrounding skin. This dressing is attached to a pump that, when turned on, exerts a negative pressure, or suction, on the wound [11].

Suction was delivered continuously or intermittently, with a pressure range of -125 to -75 mmHg according to patient needs. Normal saline was used as an installation solution in NPWTi, with a 10-minute irrigating cycle. For optimum performance and safety, NPWT/NPWTi system was appropriately maintained. The pump featured a canister for collecting fluid. Wound assessment was done on every 5 days. The surrounding skin was also kept clean, and steps were taken to avoid maceration. The tubing from the dressing to the canister was also kept free of kinks. The negative pressure seals were not compromised. At least once a day, and as needed, the device was examined to ensure it had the correct negative pressure reading.

Depending upon approximation of wound margins and granulation, wound was closed with secondary suturing or split thickness skin graft. Graft was harvested from the thigh and moist gauze dressing was done for donor site.

### Assessment:

Our study assessed variables that included wound bed score, time taken for healthy granulation tissue formation and method of wound closure. Wound Bed Score (13 points)- The scores were categorized into four quartiles: 4-9, 10-11, 12 and 13-16; an increase in wound bed score from one unit to the next increases the odds of healing by 22.8 percent [10] (Fig A)

### Statistical analysis:

Statistical methods were reported as means (standard deviation), medians (minimum and maximum) and percentages, depending on the type of variable. Categorical variables were analyzed using Fishers exact test while continuous variables were compared using Student T test. The data was analyzed using SPSS v20.0 for Windows (SPSS, Inc., Chicago, IL.).

### Results and observation:

In our prospective observational study, we enrolled 40 patients, twenty patients in each group. One patient from the NPWT group was lost to follow-up; the NPWT group had 10 males and 9 females with a mean age of 60.84 years (20-84 years) and the NPWTi group had 12 males and 8 females with a mean age of 57.05 years (30-87 years). The parameters that influence wound healing were recorded and reported, including randomized blood sugar levels, serum creatinine levels, and hemoglobin levels. Confounding factors for wound healing were similar in both the groups. As a result, the wound healing by negative pressure wound therapy (NPWT) and infusion negative pressure wound therapy (NPWTi) were comparable in both groups. The wound size (volume) was measured in centimeters. Efficacy of wound management device was analyzed by the following variables: Number of follow ups (up to wound closure), requirement of skin grafting or primary closure, wound healing was assessed using wound bed score scale. Demographic data with confounding factors is recorded in (Table 1). We included comorbidities diabetes mellitus and hypertension. Out of 39 patients, 10 were diabetic from NPWT and 5 in NPWTi group with P value of 0.105, and 12 were hypertensive in NPWT and 5 in NPWTi group with a P value of 0.025. Twelve of the patients had both diabetes and hypertension (Table 2). The average number of follow up required reveals the efficacy of therapy, wound healing was determined by wound bed score on each follow up, and the number of follow up necessary in both groups was similar with no statistical significance (P value 0.622). Each wound was followed until the wound bed was ready for secondary closure or skin grafting. The NPWTi group showed rapid wound healing in the initial two follow-ups with a significant P value (P=0.00), but both groups showed similar wound healing in the third and fourth follow-ups with no statistical difference (P=0.564) (Table 3) (Figure B). In our study, NPWT group had 15 patients required secondary suturing and 4 patients underwent superficial split skin thickness grafting. In the NPWTi group, half of them (10) needed secondary suturing and half (10) underwent skin grafts. Due to differences in wound volume of patients requiring skin grafting the final outcome in terms of wound closure cannot be compared (Table 4). On initial follow-up, wound bed score revealed that the NPWTi aids in

quick wound healing and granulation, although the end result of wound bed score was identical in both groups. Fig B shows graph comparing wound Bed score between NPWT- Negative pressure wound therapy and NPWTi- Negative pressure wound therapy (infusion)

## Discussion

Negative pressure wound therapy (NPWT) is becoming increasingly popular treatment option for traumatic and infected wounds [12]. In comparison to the open wound treatment, NPWT has an advantage of more development of granulation tissue and increase in the mechanical strain over the wound edges hence resulting in cellular proliferation. Negative pressure also avoids formation of fluid pockets in the wound.

NPWT with installation (NPWTi) is an advancement of previous therapy, specifically addressing contaminated and infected wounds which are most often associated with multiple revision surgeries, chronic pain and prolonged hospitalization.

NPWTi utilizes these same properties with the added benefit of wound cleansing with the instillation of topical wound solutions [6]. Depending on the size and characteristics of the wound, the amount of fluid and length of the different phases of the cycle can be modified individually [13]. Even after the surgical procedure, medicines such as antibiotics, antiseptics, or other fluids can be administered to the wound. The most commonly applied topical substances are saline, polyhexanide (PHMB), silver nitrates, and povidone-iodine [14,15]. Gabriel et al. demonstrated the efficiency of NPWTi in a trial that showed bioburden reduction using silver nitrate and found encouraging results in clinical infection reduction when compared to regular wet to moist dressings [16]. A study done by S.G Goss, demonstrated that debridement alone does not reduce wound bioburden. Wounds treated with NPWTi had a statistically significant reduction in bioburden, while wounds treated with NPWT had an increase in bioburden over the 7 days.[17]. A study conducted by Omar et al demonstrated that wound healing was accelerated in patients with NPWTi but there was no difference in outcome in terms of wound closure having similar results as of our study [18].

Our study showed that the number of follow ups required for wound management was equal in both the groups with no statistical significance. Wound bed score (WBS), showed that the efficacy of NPWTi over NPWT in wound healing was rapid during initial two follow ups, with statistically significant difference. This observation is novel to our study. Time to healing or readiness for grafting or secondary suturing is significantly reduced. But third and fourth follow up wound healing was similar in both the groups.

Hence NPWT with saline instillation showed rapid wound healing by angiogenesis (granulation), promoting granulation and removal of infection as compared to NPWT, however the end result of wound closure in both the groups was found to be the same. Surgical debridement followed by 5 days of NPWT is the normal protocol for wound bed preparation at our institution at present. The NPWT system that we currently use is a combination of NPWT and NPWTi machine and therefore the only additional cost of using the installation mode lies in the choice of installation solution. Saline was used in our study, which was inexpensive and cost-effective. Absolute costs were not assessed in this study; however, it appears that the benefits of reducing bioburden in chronic wounds in this patient population might outweigh the expenses which is subject to further research.

## Limitations:

Our study had a small sample size therefore the interpretation is subject to caution. Further large randomized controlled trial is warranted for its clinical application.

### Recommendation:

Effectiveness of NPWTi can be further examined by utilizing variety of installation solution such as antimicrobials. Studies in the future need to examine the efficacy of utilizing various dwell times and cycles of installation for optimal results. Studies need to evaluate the wound biofilm in order as an indication to use sensitive antimicrobials in installation solution [17].

## Conclusions:

Our study concluded that NPWTi show rapid wound healing, promotes granulation, decreases infection compared to NPWT, but the wound closure in terms of secondary suturing or split thickness skin graft were same in both the groups.

**Conflict of interest:** None

**Funding source:** None declared

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**DOI:** 10.31579/2690-1897/137

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