

A RANDOMISED CONTROL TRIAL ON COMPARISON OF OUTCOMES OF NEGATIVE PRESSURE WOUND THERAPY AND CONVENTIONAL STANDARD WOUND CARE IN NON-HEALING CHRONIC ULCERS OF LOWER LIMB

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Abstract

Background: To see the outcome of Negative pressure wound therapy (NPWT) on non healing chronic ulcers and compare with conventional method of wound care with respect to efficacy. To evaluate the efficacy of NPWT as compared to conventional therapy, in the management of Chronic Ulcers. **Materials and Methods:** Patients were randomized into 2 groups, one receiving NPWT and the other treated by conventional dressing. Wound healing was compared at 2, 3 & 4 weeks in terms of percentage reduction in wound size. **Result:** In our study on 14th, 21st and 28th day NPWT showed a wound contraction of 67% and 89.47% against 45% and 77.36% in patients treated with conventional therapy. (P-value). **Conclusion:** NPWT is found to be useful in enhancing the wound healing in chronic ulcers without any adverse events. Significant healing and contraction of wound noted from 14th day onward of NPWT application as compared to conventional therapy.

INTRODUCTION

Damage to the normal anatomical structure and function is referred to as a wound. It may just involve a minor breach in the skin's epithelial integrity, or it may go deeper and affect subcutaneous tissue as well as tendons, muscles, blood vessels, nerves, and even bone.^[1]

It's vital to keep in mind that wound healing is not linear and that, depending on the internal and extrinsic factors operating within the patient, wounds frequently advance both ahead and backward through the phases.^[2]

The stages of healing a wound are:

- Inflammatory phase
- Proliferation phase
- Maturation phase

Chronic non-healing wounds are those that have not healed or that have healed but have not returned to anatomical and functional outcomes.

The most prevalent chronic wounds in the world are pressure ulcers, diabetic foot ulcers, and venous leg ulcers. Over 40 million new chronic wounds are recorded each year. At least 70% of leg ulcers are

brought on by chronic venous insufficiency, and some are combined venous and arterial diseases [3]. Traditional dressings with saline, betadine following peroxide injection, and occasionally Eusol baths have been utilised for years, and recently, sofra tulle has also proven to be a useful adjunct in reducing wound damage.

A non-invasive adjunctive therapeutic system is negative pressure wound therapy (NPWT). In order to drain fluid from open wounds, lessen edema, and encourage the growth of healthy granulation tissue, vacuum-aided closure devices apply a sub-atmospheric pressure.^[4]

NPWT consists of an adhesive-draped open cell foam dressing that is coupled to a vacuum pump that generates sub-atmospheric pressure. The most popular NPWT gadget is the VAC.^[5]

MATERIALS AND METHODS

Patients admitted in surgical ward of Northern Railway Central Hospital for chronic non healing ulcers in lower limbs of duration more than 4 weeks between 2021 to 2024.

The study group consisted of all patients with chronic non healing ulcers in lower limbs as per inclusion criteria.

Randomization of patients was done into two groups by computer generated randomised allocation.

Following primary parameters was measured by vernier calliper at each dressing change:

- Wound area, using a length breadth and depth.
- Wound depth, measured in accordance with vernier caliper.

The following secondary parameter was measured:

- Exudates removal, assessed by visual inspection of fluid in the collection canister

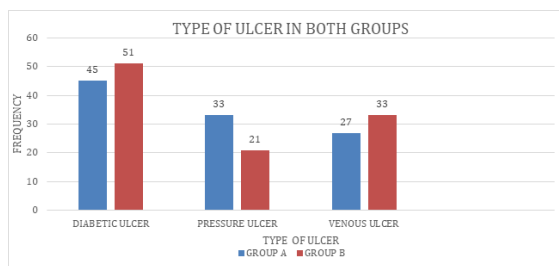
-The postoperative VAS scores and patient satisfaction scores was recorded in an excel sheet. Patients undergoing this trial was made familiar with the visual analogue scale

- (VAS) for pain before the surgery after obtaining a proper written informed consent for this trial. The patient's pain relief scores (VAS) will also be evaluated on a scale of 1 to 10, with 1 indicating that minimal pain and 10 indicating maximum pain imaginable. Each patient was asked to answer a 10 item instrument to measure. A quantitative study's key result is the effect magnitude.

RESULTS

The type of ulcers in affected people out of 105 patients of GROUP A is 45(42.9%) of diabetic ulcer, 33(31.4%) of pressure ulcer 27(25.7%) of venous ulcer.

The type of ulcers in affected people out of 105 patients of GROUP B is 51(48.6%) of diabetic ulcer, 21(20%) of pressure ulcer 33(31.4%) of venous ulcer.



The mean of initial size in Group A was 9.2251 and 0.97994 standard deviation.

The mean of initial size in Group B was 9.5357 and 0.97162 standard deviation.

The p value is 0.187 (insignificant) and both groups are comparable.

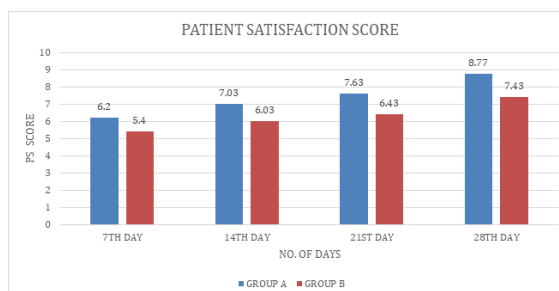
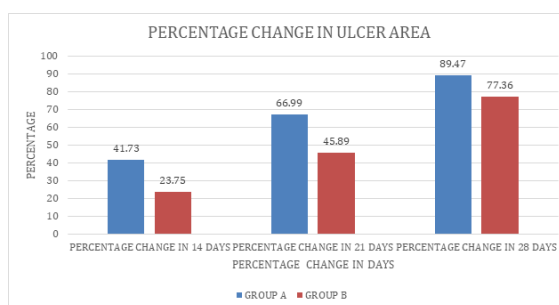


Table 1: Comparison of initial size between groups.

	Group name	N	Mean	STD. deviation	STD. error mean	P-value
Initial size	GROUP A	105	9.2251	0.97994	0.16564	0.187
	GROUP B	105	9.5357	0.97162	0.16423	

The mean reduced ulcer area after 14days was 5.3691 in group A.

The mean reduced ulcer area after 14days was 7.2780 in group B.

The p-value is 0.007 (significant) and the two groups are comparable.

The mean reduced ulcer area after 21days was 3.0589 in group A.

The mean reduced ulcer area after 21days was 5.1877 in group B.

The p-value is 0.003 (significant) and the two groups are comparable.

The mean reduced ulcer area after 28days was 0.9820 in group A.

The mean reduced ulcer area after 28days was 2.1966 in group B.

The p-value is 0.002 (significant) and the two groups are comparable.

Table 2

Group name	N	Initial size	Observed size	Mean reduction in ulcer area 14th day (cm2)	Percentage reduction from initial size	P- value
Group A	105	9.2251	6.4382	2.7869	41.739754	0.007
Group B	105	9.5357	8.2308	1.3049	23.757524	

Group name	N	Initial size	Observed size	Mean reduction in ulcer area 21st day (cm2)	Percentage reduction From initial size	P- value
GROUP A	105	6.4382	4.3793	2.0589	66.999955	0.003

GROUP B	105	8.2308	6.1405	2.0903	45.897813	
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Group name	N	Initial size	Observed size	Mean reduction in ulcer area 28th day (cm2)	Percentage reduction from initial size	P- value
GROUP A	105	4.3793	2.3024	2.0769	89.478870	0.002
GROUP B	105	6.1405	3.1494	2.9911	77.367715	

DISCUSSION

Wound healing is a complex process that is regulated by interactions between a large number of cell types, extracellular matrix proteins and mediators such as cytokines and growth factors. Chronic ulcers typically occur in lower extremities that do not respond to initial therapy or continue despite adequate care and do not progress towards healing within a defined time span which may be associated with systemic disease or regional disorders. Conventional treatment of chronic ulcers includes systemic and regional treatment. Systemic treatment includes blood glucose regulation, infection control and regional treatment includes wound washing, necrotic tissue debridement, infection mechanical off-loading, and regional dressing ulcer care. Following despite treatment, most chronic ulcers fail to heal or linger for months/years and/or recur after healing, requiring additional advanced wound care therapies for sufficient healing. A wide range of innovative non-healing ulcer treatments include negative pressure wound therapy. Over the past two decades, negative pressure wound therapy have gained significant interest for their potential use in regenerative medicine. A randomised study was conducted in 210 patients (Group A 105 Patient – negative pressure wound therapy; Group B 105 Patient – Conventional therapy) at Northern Railway Central Hospital, Department of General Surgery, to assess the outcome of NPWT in chronic non healing ulcers in lower limb over and above standard of care. In our study the initial mean size (largest dimension) of ulcer in Group-A was 9.225 cm and in Group-B was 9.53cm. The p value is 0.187. It shows that ulcer size of patients is comparable between the two groups. The etiology for chronic non healing ulcers was diabetic ulcer, pressure ulcer, venous ulcer in both group of patients. Our Primary objective was to assess the timing of contraction of wound size in largest dimension to 50% of original size in both the group. In our study 67% wound contraction at 21 st day of NPWT and in ulcers treated with conventional therapy only 45% of ulcer size reduction occur at 21 st day. At 28 th day Group-A mean ulcer size reduces by 89.47% and Group-B ulcer size reduces by

77.36% as compared with initial mean ulcer size of largest dimension.

CONCLUSION

In our study, NPWT is found to be useful in enhancing the wound healing in chronic ulcers without any adverse events. Significant healing and contraction of wound noted at 14 th day of NPWT application. The mean percentage size of reduction of ulcer in the study is 67% at 21 st day and 89.47 % at 28 th day treated with NPWT and 45.8% at 21 st day and 77.36 at 28 th day treated with conventional method which is a significant difference in reduction in the size of the ulcer treated with NPWT as compared with treated with conventional method. During the period of study no side effect was noted. NPWT proves to be an effective and safe method in healing of chronic ulcers as compared to other methods. The results of the study justify further research into the use of negative pressure wound therapy in treatment of various wounds and ulcers.

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