



## A STUDY TO EVALUATE THE CLINICAL EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY VIS-À-VIS SALINE MOIST GAUZE DRESSING

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**ABSTRACT** In the last one century, the understanding of wound healing has been remarkably improved and with that a number of advancements made to facilitate early and safer wound healing. Some of the concepts changing the perception of wound healing and driving the newer wound management strategies include wound occlusion, moist wound healing, growth accelerators, enzymatic debridement, high pressure water irrigation, bio-debridement, growth factors, skin substitutes, collagen, topical insulins, topical antioxidants and negative pressure wound therapy. In the current study we set out to study the efficacy of Negative pressure wound therapy in comparison to conventional saline moist gauze dressing in open infected wounds.

**KEYWORDS :** Negative Pressure Wound Therapy, Vacuum Assisted Dressing, NPWT, VAC

### Introduction

Acute and chronic open wounds affect at least 1% of the population. These wounds may heal or may result in hospitalization, amputation, sepsis and even death.<sup>i</sup>

Treatment and care of wounds is one of the least lucrative part of medical profession, however considering the resulting burden of morbidity and cost, it becomes one of the most important parts of patient management. Despite the relevance and importance of wound management, much of the medical establishment, whether through lack of confidence, training, interest, or remunerative potential, continues to perceive this to be under the province of someone else.<sup>ii</sup> Despite this passing the buck attitude, wound care and its management remains to be one of the most important aspects of total patient care and few advancements from time to time have been made in order to facilitate wound healing and protection from infection at the earliest possible. Though the causes of wound might be systemic as well as local, yet topical wound management is compulsory in view of the exposure of wound to environment and *per se* exposure of wound to newer risks.

Large wounds with tissue loss and chronic wounds are a major concern for health care professionals and are a big social, economic and psychological burden on the society. Psychological stress appears to influence the process of recovery.<sup>iii,iv</sup>

In the last one century, the understanding of wound healing has been remarkably improved and with that a number of advancements made to facilitate early and safer wound healing. Some of the concepts changing the perception of wound healing and driving the newer wound management strategies include wound occlusion<sup>v</sup>, moist wound healing<sup>vi</sup>, growth accelerators, debridement and infection management thus paving way to use of antibiotics and antimicrobials, silver impregnated dressings, foams, alginates, hydrocolloids, hydrofibres, hydrogels, transparent films, enzymatic debridement, high pressure water irrigation, bio-debridement, growth factors, skin

substitutes, collagen, topical insulins, topical antioxidants and negative pressure wound therapy.<sup>viii</sup>

Negative or sub atmospheric pressure (-100 to -125 mm Hg) is used in a continuous or intermittent manner<sup>ix,x</sup>. The intermittent negative pressure is delivered at wound site through a porous dressing, which applies mechanical forces known as macro strain (physical response) and micro strain (biological response) and subsequently removes exudates by an electromechanical pump.

In India, some of the clinical trials evaluating role of NPWT in various types of wounds have shown a promising response<sup>xi,xiii,xiv,xv,xvi,xvii</sup>. Considering these positive responses for NPWT in these studies, the present study was carried out with the objective to evaluate the efficacy of Negative Pressure Wound Therapy compared with the Saline Moist Gauze Dressing.

### Material & Methods

This study enrolled a total of 104 patients with a mean age of 38 years; with 71.15 being male. The patients were enrolled based on the duration and size of the wound i.e. patients with acute large wounds having  $\geq 5$  cm in shortest length were selected and in case of chronic ( $\geq 1$ -month duration), non-healing wounds, patients with a size of  $\geq 3$  cm in shortest length were selected. The patients were randomly assigned to either Group A i.e. Negative Pressure Wound Therapy (NPWT) or Group B i.e. Saline Wet Gauze Therapy (Saline) and received the therapy as needed. The patients with untreated Osteomyelitis; Non-enteric and unexplored fistulas; Malignancy in the wound; Exposed vasculature, nerves, anastomotic site or organs; patients positive for infectious co-morbidities such as HIV/HCV/HBsAg; with Multiple wounds; receiving Chemotherapy or Radiotherapy or moribund patients were not enrolled for the study.

All the patients received standard nutritional supplements including zinc and multivitamins daily. The wounds of the subjects included in the study underwent initial sharp debridement to remove necrotic

tissue and slough. After the debridement, foam-based dressing was done over the wounds of Group A under all aseptic conditions. The dressing was covered with an adhesive drape to create an airtight seal. An evacuation tube was embedded in the foam connected to a fluid collection canister contained within a portable vacuum/suction machine. Sub-atmospheric (negative) pressure was applied within a range of -50 mmHg to -125 mmHg intermittently for 15 min each. NPWT dressings were changed as and when required. The group B received twice daily saline-moistened gauze dressings.

Weekly cultures were taken from the floor of the ulcers to assess for the bacterial flora. The patients were monitored for appearance of granulation and wound closure; recurrence/persistence of infection; and for the complications, if any during the period of study. The study evaluated treatment until closure of ulcer surgically or spontaneously or the day 56<sup>th</sup> of observation. Both the groups were compared for the time taken for wound closure or the reduction in wound size & depth. Complete ulcer closure was defined as skin closure (100% reepithelization) without drainage or dressing requirements.

At the end of the study period patients were identified as Complete responders: 100% reepithelization; Partial responders: 50% or greater reduction in product of the two longest perpendicular diameters from baseline; Non-complete responders: Less than 50% reduction in the product of the two longest perpendicular diameters from baseline; and Non-responders: No reduction in ulcer or increase in ulcer area over base line.

**Results**

The data suggest that no statistically significant demographic differences existed between the two groups Table 1. The mean patient population age was 38 years and the patients were predominantly male (69.2%). The time that elapsed between initial debridement and appearance of granulation, wound closure and total duration of hospital stay was significantly (P < 0.001) shorter in the NPWT group than in the Saline group.

**Table 1 Patients Demographic**

Characteristics	NPWT Group	Saline Group	p value
n	52	52	
Sex (M/F)	37/15	35/17	0.671
Age (in years)	38.40 ± 12.64	38.23 ± 12.11	0.063
Diabetic	51.92 %	42.31 %	0.570
Necrotizing Fasciitis	21.15%	28.85%	
Pressure Sore	11.54%	17.31%	
Traumatic	15.38%	11.54%	
Wound size (cm <sup>2</sup> )	163.28±103.57	151.67±88.50	0.540
Wound depth (mm)	13.37±6.05	13.21±5.90	0.896
Exposed Bone	51.92%	44.23%	0.432
Dead/Devascularised Tissue	100%	100%	
Pus Discharge	90.38%	84.62%	0.374
Culture Positivity	98.08%	92.31%	0.169
Appearance of granulation (days)	8.35 ± 2.79	12.52 ± 6.40	0.001
Wound closure (days)	23.69 ± 6.52	34.33 ± 10.21	0.001
Hospital Stay (days)	28.25 ± 6.94	39.17 ± 10.36	0.001
Persistent infection	44.23%	78.85%	0.001
% Reduction in wound size after treatment	45.92 ± 5.42	24.07 ± 10.73	0.001
% Reduction in depth after treatment	56.86 ± 21.62	58.66 ± 24.54	0.692

**Table 2 Between Group Comparison of Hematological/Biochemical Variables**

Variables	Group A			Group B			Independent 't' test	
	n	Mean	SD	n	Mean	SD	't'	'p'
Hb (g/dl)	52	11.12	1.74	52	10.84	2.08	0.741	0.460
RBS (mg/dl)	52	154.85	51.54	52	145.46	57.62	0.875	0.383
FBS (mg/dl)	29	167.17	33.68	26	177.65	34.27	-1.143	0.258
BS_PP (mg/dl)	29	257.10	49.29	26	233.12	45.80	1.863	0.068

HbA1c (%)	29	8.07	0.71	26	8.00	0.69	0.364	0.717
Total protein (g/dl)	52	7.24	0.56	41	7.29	0.41	-0.493	0.623
Serum albumin (g/dl)	41	3.66	0.29	41	3.66	0.24	-0.170	0.866

There was a significant difference in the rate of recurrence/persistence of infection in the two groups i.e. 44.23% in NPWT group as compared to 78.85% in saline group. The difference in reduction in wound size in both the groups was 45.92 ± 5.42 and 24.07 ± 10.73 respectively. Reduction in wound depth had no significant difference in the groups.

A total of 91 cases in had non-complete response to treatment. Partial response was seen in 12 (23.08%) of NPWT and 1 (1.92%) of saline group respectively. No significant difference between two groups for flap reconstruction / split skin grafting rate was observed. Flap reconstruction was needed in 3.85% of NPWT and 9.62% of saline groups.

Comparison of haematological and biochemical variables among the groups is shown in **Table 2**.

**Conclusion**

Based on the findings of present study, it can be concluded that negative pressure wound therapy is a useful choice for treatment of wounds when compared to treatment with saline gauze therapy in terms of reduction in wound size, time taken for wound closure and duration of hospital stay.

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