

COMPARISON OF EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY VS CONVENTIONAL NORMAL SALINE DRESSING IN DIABETIC FOOT

¹Dr. Koli Nikhil Vanura, ²Dr. Arun Kumar T.

¹Senior Resident, ²Professor and Head
General Surgery
ESIC Medical College, Kalaburagi, India.

Abstract -

Introduction: Wounds are a major source of morbidity and sometimes, mortality and there are several ways to treat them. Negative pressure wound therapy (NPWT) is one way, and this involves the use of a suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue and wound healing. Another way is with the use of conventional wound dressings.

Methods: A total of 40 patients of Diabetic foot ulcer who were admitted in the department of general surgery were included in the study. Study group A received negative pressure dressing therapy. Dressing was changed every 3rd day. Control group B received daily dressing changes with saline-moistened gauze. Treatment outcome and patient satisfaction was assessed in terms of time taken for wound closure and reduction in the bacterial burden of the wound.

Results: 13 wounds became pus culture negative for organisms in 3rd culture sample in NPWT group, but in conventional group, only 9 patients attained pus culture negativity in 8th sample. And this showed the power of NPWT in reducing the bacteriological burden of diabetic wounds. 11 out of 20 patients, wound closure was attained within or equal to 2 weeks in NPWT group. 7 out of 20 patients, wound closure was attained within or equal to 4 weeks in conventional dressing group. And this showed the power of NPWT in reducing the duration of wound closure mainly by skin grafting. Complete clearance of aerobic flora and anerobic flora was observed much earlier in patients who received NPWT.

Interpretation & Conclusion: NPWT is effective in reduction of bacterial flora of diabetic wounds as the wound showed pus culture & sensitivity negative for growth. NPWT enhanced granulation tissue formation leading to earlier wound healing and faster recovery compared to conventional wound dressings.

Keywords: Negative pressure wound therapy (NPWT); Wound healing; Granulation tissue

INTRODUCTION

Diabetic foot ulcers are among the most common complications of patients who have diabetes mellitus which is not well controlled. The treatment and healing of wounds are some of the oldest subjects discussed in the medical literature. In the past few years there have been significant advances in complex acute and chronic wound management. One of the most significant discoveries was the improvement in wounds with negative pressure assisted wound closure.

The new method of placing a wound to sub-atmospheric pressure for an increased period to induce healing and removal of exudative fluid was first described by Fleischman et al in 1993(1). Morykwas et al(2) in their seminar paper, based on a series of experiments, reported that there was increase in blood flow at ~125mmHg that was equivalent to 4 times the of the baseline pressure. Deva Boone et al (3), in their study conducted on a porcine infected wound model, showed that NPWT with either standard NPWT foam or silver NPWT foam caused noticeable improvements in local wound morphology, but this occurred inspite of having a high level of bacterial burden for an extended time," thus the healing that occurred in these wounds cannot be explained by a change in the bacterial load". Chester DL et al (4) recommended close surveillance of bacterial flora of the wound, during the course of vacuum assisted closure (VAC) treatment as they observed worsening of anaerobic infection with NPWT, which settled with antibiotics and cessation of NPWT.

This study was undertaken in ESIC Medical College and Hospital, Kalaburagi to compare the effect of NPWT and conventional saline dressing on duration of wound closure and reduction in the bacterial burden of the wound.

AIMS AND OBJECTIVES

To compare the efficacy of negative pressure wound therapy (NPWT) and conventional saline dressing in patients with diabetic foot in the following aspects:

- (i) Duration of wound closure.
- (ii) Reduction in the bacterial burden of the wound.

MATERIALS AND METHODS

A prospective study was carried out in ESIC Medical College and Hospital, Kalaburagi from January 2022 to December 2022 on comparison of efficacy of negative pressure wound therapy vs conventional normal saline dressing in diabetic foot.

Inclusion criteria:

- Age group 20-75 years.
- Ulcer area ranging between 5cm² and 10cm²
- Diagnosis of diabetes mellitus made by American Diabetes Association Criteria.

Exclusion criteria:

- Age < 20 years or > 75 years.
- Septicemia
- Osteomyelitis.
- Wounds resulting from venous insufficiency/arterial disorders.
- Malignant disease in a wound.
- Patients being treated with corticosteroids, immunosuppressive drugs or chemotherapy.
- Pre-existing cardiovascular, pulmonary and immunological disease.

A total of 40 patients with diabetic foot ulcer who were admitted in the department of general surgery in our institute were included in the study. These cases were randomly divided into study and the control group. Patients were made to understand and sign the consent form. Study group (A): 20 Received negative pressure dressing therapy. Dressing was changed every 3rd day. Control group (B): 20 Received daily dressing changes with saline-moistened gauze. Both the groups underwent sharp surgical debridement initially and during subsequent dressing change to remove necrotic tissue and slough.

After debridement, foam-based dressing applied over the wounds of the study group covered with an adhesive drape to create an airtight seal. Evacuation tube embedded in the foam connected to a vacuum pressure within a range of 80–125 mmHg on a continuous basis for 72 hours after which dressing was changed with similar procedure. Patients in control group received once daily saline dressing. After every 3 days, wound cultures were sent in both groups, which was taken from the floor of the ulcer to assess the bacterial burden.

Standard antibiotics were given to all patients, which consisted of broad-spectrum antibiotics initially and later changed based on culture & sensitivity. Blood glucose levels were monitored strictly during treatment and controlled by appropriate doses of insulin. Ulcers were treated until the wound closed spontaneously, surgically or until completion of the 8-week period, whichever was earlier. Treatment outcome and patient satisfaction was assessed in terms of time taken for wound closure. Treatment success was defined as wound closure within a period of 8 weeks and failure, as inability of wound closure within 8 weeks. Assessment of parameters included a) duration for wound closure and b) pus culture and sensitivity report.

RESULTS

40 patients with diabetic foot ulcer admitted in the Department of General Surgery in ESIC Medical College and Hospital, Kalaburagi in the period of January 2022 to December 2022 and who are conforming into the inclusion criteria, data was collected using a profoma and where included the study.

PATIENT PROFILE

Men (32/40,80%) outnumbered women (8/40,20%) with a male to female ratio of 4:1 in the entire study population. The gender distribution (M:F) was 16:4 in both conventional and study groups. The mean (mean \pm SD) age of patients in conventional group was 54.40 \pm 13.63 yrs (ranging from 40-68 yrs with a median of 54 yrs.) and in NPWT group was 51 \pm 10.052 yrs (ranging from 41-61 yrs with a median median of 51yrs).The mean age and gender were comparable in both the study groups.

PARAMETERS STUDIED:**DURATION OF WOUND CLOSURE: (TABLE 1)****WOUND CLOSURE IN NPWT GROUP:**

- In the NPWT group the duration of wound closure was found to be hastened when compared to conventional group.
- In our study 11 out of 20 patients wound closure was attained within a period of two weeks by SSG.
- 8 out of 9 remaining patients attained wound closure at the end of third week of NPWT.
- The remaining 1 patient attained in the fourth week.
- Ulcer shrinkage was significantly noted in NPWT group compared to conventional group.

WOUND CLOSURE IN CONVENTIONAL GROUP:

- In the conventional group the duration of wound closure was found to be prolonged when compared to NPWT.
- In our study 7 out of 20 patients wound closure was attained within a period of 4 weeks.
- 5 out of 13 remaining patients attained wound closure at the end of 6 weeks. 5 out of 20 attained wound closure by 8 weeks.
- 3 out of 20 attained wound closure by more than 2 months.

TABLE 1: COMPARISON OF DURATION OF WOUND CLOSURE IN NPWT AND CONVENTIONAL GROUP.

Wound Closure		Groups		Total
		NPWT Group	Conventional Group	
2 weeks	Count	11	0	11
	% within Groups	55%	0%	27.5%
3 weeks	Count	8	0	8
	% within Groups	40%	0%	20%
4 weeks	Count	1	7	8
	% within Groups	5%	35%	20%
6 weeks	Count	0	5	5
	% within Groups	0%	25%	12.5%
8 weeks	Count	0	5	5
	% within Groups	0%	25%	12.5%
>2 months	Count	0	3	3
	% within Groups	0%	15%	7.5%
Total	Count	20	20	40
	% within Groups	100%	100%	100%

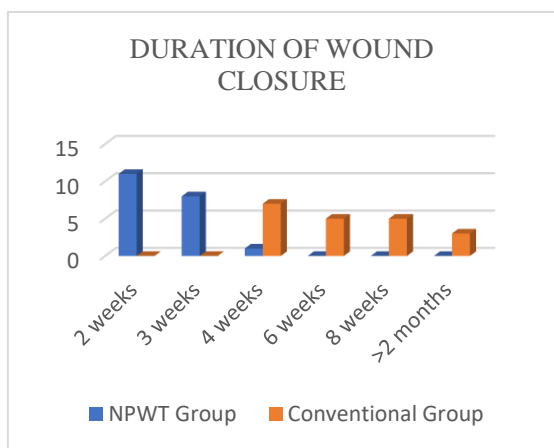


FIGURE 1: DURATION OF WOUND CLOSURE IN NPWT AND CONVENTIONAL GROUP.

PUS C&S: (TABLE 2)

- 13 wounds became pus culture negative for organisms in 3rd culture sample in NPWT group, but in conventional group, only 9 patients attained pus culture negativity in 8th sample.
- Pseudomonas aeruginosa was the most common organism isolated..
- In NPWT , Clearance of anaerobic organisms was excellent .
- NPWT was able to clear the uncommon wound contaminants such as proteus mirabilis, klebsiella pneumonia, providencia rettgeri and beta haemolytic streptococci.

TABLE 2: PUS C& S NEGATIVE REPORTS IN NPWT AND CONVENTIONAL GROUP

Pus Culture Sample		Groups		Total
		NPWT Group	Conventional Group	
3 rd Sample	Count	13	0	13

	% within Groups	65%	0%	32.5%
4 th Sample	Count	6	0	6
	% within Groups	30%	0%	15%
5 th Sample	Count	1	0	1
	% within Groups	5%	0%	2.5%
8 th Sample	Count	0	9	9
	% within Groups	0%	45%	22.5%
12 th Sample	Count	0	4	4
	% within Groups	0%	20%	10%
16 th Sample	Count	0	6	6
	% within Groups	0%	30%	15%
20 th Sample	Count	0	1	1
	% within Groups	0%	5%	2.5%
Total	Count	20	20	40
	% within Groups	100%	100%	100%

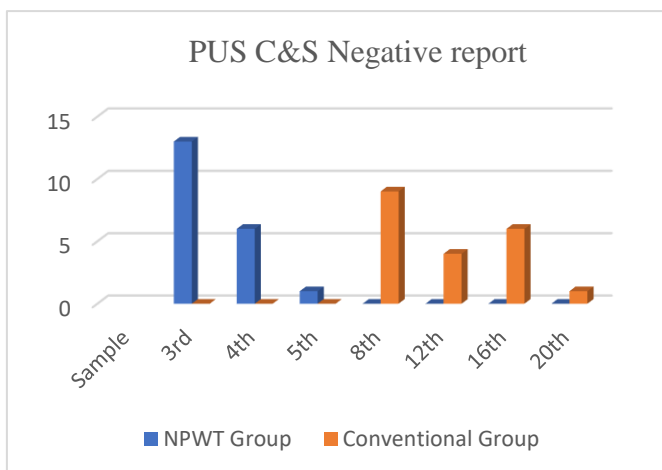


FIGURE 2: PUS C& S NEGATIVE REPORTS IN NPWT AND CONVENTIONAL GROUP

DISCUSSION

This study was done in forty consecutive patients with diabetic foot where NPWT can be applied and those patients were admitted in department of General Surgery as inpatients after randomly selecting into two groups of twenty patients each. The sample size was fixed to be twenty in each group with a power of study of 90% using open-epi software 2.3 for sample size calculation. Allocation concealment was done using serially numbered opaque sealed envelopes. Randomization and sealed envelopes were prepared by a person, independent of the investigators or anyone involved inpatient care and statistician. After decoding, Group A(study group) received NPWT and Group B (conventional group) received conventional normal saline dressings. After debridement NPWT was applied using controlled application of sub-atmospheric pressure to the diabetic wounds, using foam based dressings with a nasogastric tube in between, and the whole dressings is sealed using a sterile transparent plastic sheet and it is connected to the vacuum suction device. Comparison of effect of NPWT over conventional saline based dressings in reducing the bacteriological burden of wound in terms of pus culture negativity and in duration of wound closure.

In our study all the wounds were include in both the groups were infected prior to the start of treatment. In the conventional group the duration of wound closure was found to be prolonged when compared to NPWT group. In conventional group 7 out of 20 patients wound closure was attained ≤ 4weeks,5 out of 20 attained wound closure at ≤ 6weeks, 5 out of 20 by ≤ 8 weeks and 3 out of 20 by > 8 weeks. In study group (NPWT) 11 out of 20 patients wound closure ≤ 2 weeks, 8 out of 20 by ≤3 weeks and 1 out of 20 attained wound closure by 4th week. Bacteriological clearance was studied by using pus culture negativity. Pus cultures were

taken under strict aseptic precautions on every 3rd day and sent to Department of Microbiology, ESIC Medical College and Hospital, Kalaburagi. In conventional group pus culture negativity was attained by 9 patients by 8th sample, 4 patients by 12th sample, 6 patients by 16th sample and 1 patient by 20th sample. In study group pus culture negativity was attained in 13 patients by 3rd sample, 6 patients by 4th sample and 1 patient by 5th sample.

Complete clearance of both aerobic and anaerobic flora was attained within a shorter period of time in study group as compared to conventional group. *Pseudomonas aeruginosa* was the most common organism isolated from the wounds in both study and conventional group. 7 patients in conventional group and 11 patients in NPWT had growth of *Pseudomonas aeruginosa* in pus culture. We observed that NPWT decreased the duration of hospital stay and the time taken for definitive treatment like skin grafting both causing an overall decrease in efficient man hour lost due to delayed wound healing and prolonged hospital stay. In our study, mainly all the wounds were closed by skin grafting.

CONCLUSION

NPWT is effective in reduction of bacterial flora of diabetic wounds as the wound showed pus culture & sensitivity negative for growth. NPWT was effective in clearing aerobes and anaerobic bacteria well. Very effective in clearing *Pseudomonas* which was the most common organism isolated from the wound. NPWT although it created an anaerobic atmosphere around the wound, did not induce proliferation of anaerobes. NPWT caused an increase in proliferation of granulation tissue which was essential for wound closure especially by skin grafting. Hence we found that NPWT is effective in reducing the bacterial burden of the wound and caused proliferation of granulation tissue needed for wound closure and decreased the duration of wound closure and hospital stay.

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