

Original Research Article

Comparison of vacuum assisted closure therapy with conventional dressing in the management of necrotizing fasciitis wound

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ABSTRACT

Background: The purpose of our study was to compare the effect of vacuum assisted closure (VAC) therapy and conventional dressings in patients with open wounds due to necrotizing fasciitis (NF) on the basis of healing rate, infection control, frequency of dressing and pain score.

Methods: The study evaluated 50 patients admitted with NF requiring surgery over a period of 18 months. The patients were randomized to two groups. In group A patients, the wounds were managed with conventional dressings and in group B patients, negative pressure wound therapy (NPWT) was applied. Serial assessment of both groups was done for four weeks. The parameters including size of wound, wound bed, granulation tissue formation, color, amount and odor of exudate, edema, frequency of dressing, re-debridement and pain were monitored and analysed.

Results: In our study, patients with NF wounds who underwent VAC therapy had earlier granulation tissue formation, resolution of infection and readiness for skin grafting. The frequency of dressing, requirement of re-debridement, resolution of edema, odor, skin maceration, inflammation around wound and pain significantly reduced in group B (VAC) when compared to conventional dressing group.

Conclusions: When compared to the conventional dressing on NF wound, application of VAC helped in early appearance of granulation tissue, significant reduction of inflammation, wound odor, exudate, need for re-debridement, frequency of dressing and pain. Thus, VAC dressing can be considered as a better option in the management of NF wounds.

Keywords: NF, Necrotizing soft tissue infections, NPWT, VAC therapy, Conventional dressing

INTRODUCTION

Necrotizing soft tissue infection (NSTI) is a bacterial infection characterized by rapidly spreading inflammation and necrosis of skin, subcutaneous tissue and superficial fascia. This includes necrotizing forms of fasciitis, myositis, and cellulitis.^{1,2}

These infections lead to fulminant tissue destruction, systemic signs of toxicity, and high mortality. The progression of disease is aggressive and rapid; early diagnosis and treatment are crucial to survival. NSTIs are

commonly seen in the extremities, perineum, chest, abdomen and genitalia, but can occur in any part of the body. This requires inoculation of the pathogen into the subcutaneous tissue, via any break in epithelial or mucosal surface.

The standard treatment consists of broad-spectrum antibiotics covering gram-positive cocci, gram-negative rods and anaerobic organisms, wide surgical debridement, and supportive care.^{1,3,4} Most patients require repeated surgical debridement, and survivors often have large and complex wounds requiring soft

tissue coverage and prolonged hospitalization. Even with optimal treatment, NSTIs portend significant morbidity and have mortality rates of 25% to 35% in recent series.⁵

Now a days, many surgeons have started using NPWT for fast and effective wound closure. NPWT as a facilitator in creating an ideal wound healing environment through several putative mechanisms has been a breakthrough in complex and difficult wounds by creating a faster wound bed granulation.^{6,7} VAC® device improves wound healing by providing macrostrain and micro-strain to wound.

Under negative pressure, foam dressing applies both mechanical and biological forces to the wound to create an environment that promotes wound healing.⁸⁻¹⁰ Most of the NPWT studies are on diabetic foot, peripheral vascular disease (PVD), chronic wounds or obstetric wounds.

There are a few studies published over NPWT on NSTI. The purpose of our study is to compare and evaluate the efficacy of NPWT with conventional dressing in the debrided NSTI wounds in terms of complete healing of wound, readiness for grafting, decrease in size, resolution of infection, frequency of dressing and associated pain.

Aims and objectives

Aim of our study is to achieve adequate and early wound healing in patients with open wounds due to NF. Objective includes assessment of the effect of VAC therapy when compared to conventional dressings in patients with open wounds due to NF on the basis of healing rates or readiness for split thickness skin grafting, infection control, frequency of dressing and pain score.

METHODS

The study was conducted on 50 patients admitted under the department of surgery, Safdarjung hospital, Delhi with NF requiring surgery over a period of 18 months from November 2017 to April 2019. The sample size for the study sample size was calculated according to the statistical test for comparison of two sample proportions based on post-operative outcomes. Assuming a clinically meaningful significant difference of 20% in outcomes between the two groups (VAC and conventional dressing), with 80% power and 5% level of significance, a minimum sample size of 25 subjects in each group were required in the study (Figure 1). Institutional ethical clearance was obtained for the study.

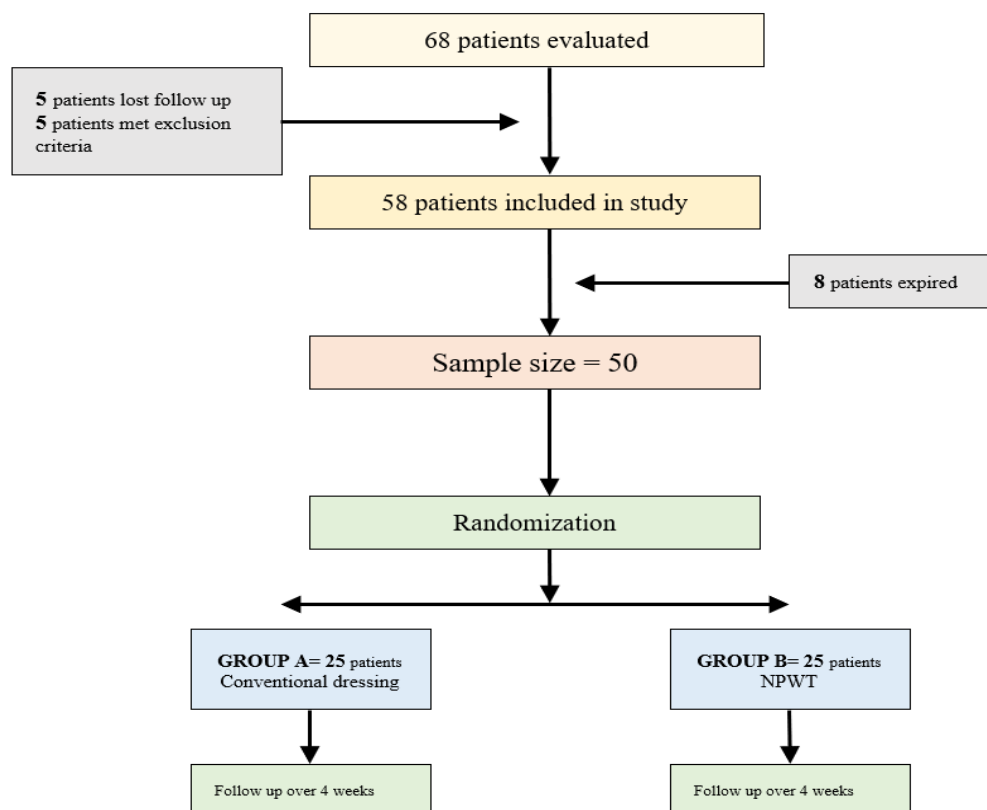


Figure 1: Flowchart of study procedure.

Inclusion criteria

All the patients undergoing emergency surgery for NF

of upper or lower limbs will be evaluated and patients with age between 12 to 75 years. All critically ill patients (GCS<10), severely immune-compromised, pregnant

patients, patients with pre-existing life-threatening comorbidities, bleeding disorders and Fournier's gangrene were excluded from the study. After admission, detailed history of patients was recorded and then subjected to a thorough clinical examination. Information about the surgery, anesthesia, pain control, mobilization and nutritional management was explained to the patient before surgery.

All appropriate investigations including hemogram, blood sugar, blood urea, serum electrolytes, arterial blood gas analysis (ABG), chest X-ray and electrocardiography were done. Following initial assessment and simultaneous resuscitation patients were taken up for surgery. After obtaining an informed written consent, adequate excision and debridement of dead and devitalized tissue was done. The wound was dressed with antiseptic solution, adequate adsorbent, cotton pads and bandage. The enhanced recovery after surgery guidelines was followed in the post-operative period. First dressing was done 48 hours after surgery and patients who meet inclusion criteria were randomized into conventional dressing (CD) (group A) and VAC (group B) by sequentially numbered opaque sealed envelope (SNOPE) method using computer generated randomization table. Regular monitoring of patients in both groups were done.

Parameters measured

Parameters measured were-1. Site of wound, 2. Wound size, 3. Related to signs of infection-wound bed, necrotic tissue/ slough/ Eschar/ granulation tissue, exudate amount, color of exudate, presence of any odor, condition of surrounding skin, edge of wound and presence of edema. 4. Requirement of re-debridement and frequency, 5. Pain score by visual analogue scale (VAS) and 6. Frequency of dressing.

Serial assessment was done weekly till the end of four weeks or until the appearance of healthy granulation tissue whichever happens early and outcomes were compared with respect to above parameters.

After gently cleaning the wound with warm normal saline, all slough and dead tissue was removed surgically under mild sedation. Frequency of dressing was depending on the type of exudates, soiling/soakage, loss of air seal/leakage etc. At each change the condition of the patient and wound was assessed in detail. The amount and type of contents of aspirate in NPWT was also noted. Since majority of these patients were suffering from severe sepsis with varying degree of disease severity, the incidence and types of complications including deaths was noted and graded as per Clavein and Dindo classification.

Technique of conventional dressing

Wound was dressed using nano silver-based (Quiron),

hydrocolloid, alginate-based dressing solution or gel for creating a moist wound environment for healing. Wound was then covered with dry cotton gauzes and cotton pads and held in place with cotton bandages and adhesive tape.

Technique of VAC

Special foam with pore size of 400-600 micron was cut to the shape of wound and filled in the wound. Care was taken to cut it away from the wound to avoid small pieces falling into it. After cleaning and drying of the surrounding skin wound was covered with adhesive film. A small circular hole was then made in the center of the adhesive film. Sensal TRAC™ sensor with tube was then applied over this particular hole and connected to VAC. VAC pump through its canister. VAC unit was then switched on with set pressure (A negative pressure of -80-125 mmHg) for continuous negative pressure therapy. Sealing of wound was checked by collapse and shrinking of foam.

In both groups dressing was continued till a maximum of four weeks and wound was assessed at regular intervals. Patients who developed any of the exclusion criteria postoperatively were excluded from statistical analysis.

Statistical analysis

Descriptive statistics was performed by calculating mean and standard deviation for the continuous variables. Categorical variables are presented as absolute numbers and percentage. Nominal categorical data between the groups were compared using chi-square goodness-to-fit test. The software used for the statistical analysis was SPSS (statistical package for social sciences) version 21.0 and Epi-info version 3.0.

The statistical tests used were ANOVA (Analysis of variance) test, unpaired or independent t test, Chi-square test. $P < 0.05$, was taken significant.

RESULTS

The study was conducted in VMMC as Safdarjung hospital over 18 months duration during which 68 patients were evaluated. A total of 50 patients were included in the study for analysis with 25 patients in group A and 25 in group B. All patients included in the study had NF wound over the extremities.

Our study included patients in the age group of 12 to 75 years. Majority of patients belong to 41-50 years (26%) (Table 1). 82% (41) patients were males with equal distribution of patients based on sex in each group (Table 2).

The most common etiology of NF of extremities identified in our study was trauma (42%) followed by idiopathic infection (18%), insect bite (14%), intravenous

cannulation (8%), abscess (8%) and minor laceration (6%). No definite etiology could be identified in 4% of

patients. There was no difference in the etiology between two groups (Figure 2).

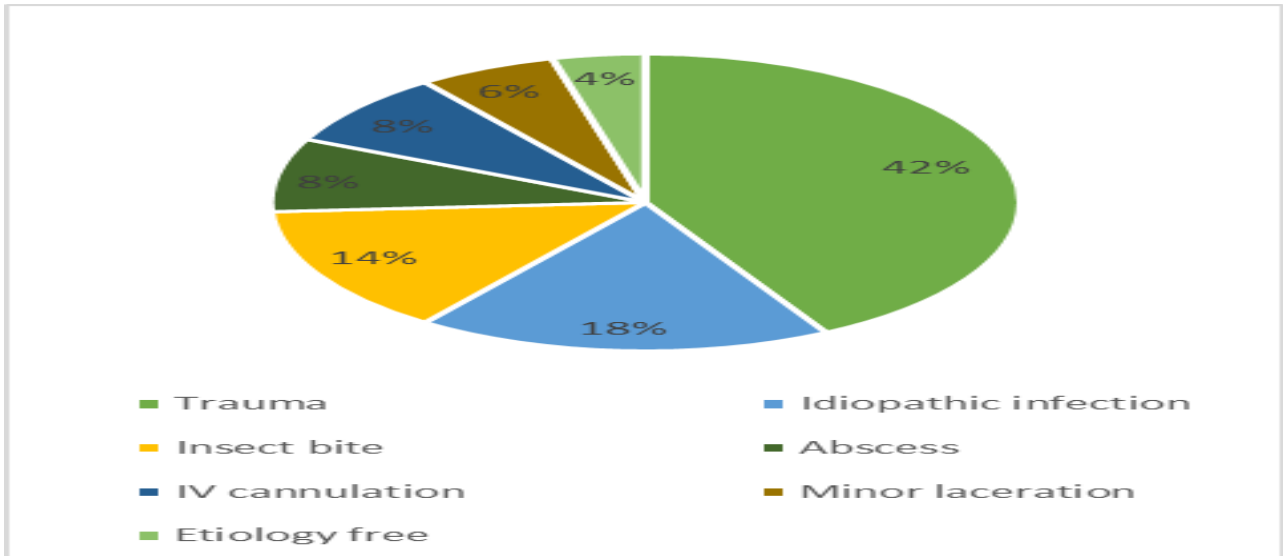


Figure 2: Etiology of NF.

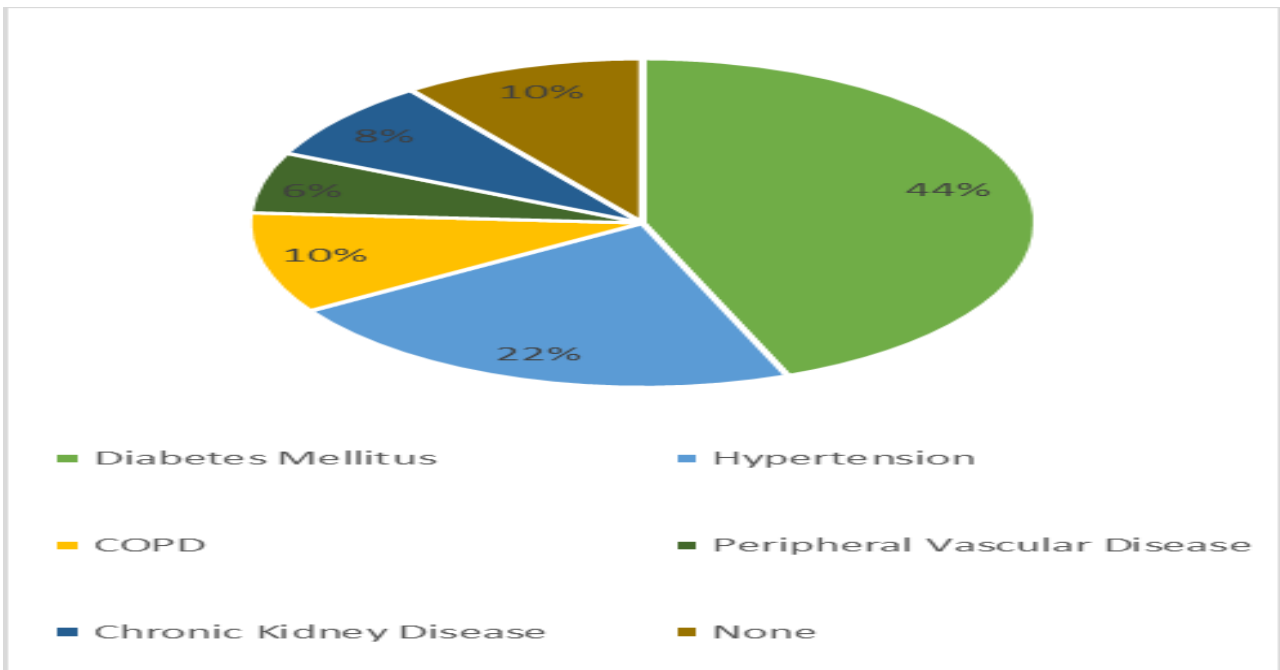


Figure 3: Comorbidities associated with NF.

Table 1: Age distribution of patients.

Age (Years)	Group A, (%)	Group B, (%)	Total, (%)	P value
≤30	5 (20)	6 (24)	11 (22)	0.243
31-40	5 (20)	3 (12)	8 (16)	
41-50	6 (24)	7 (28)	13 (26)	
51-60	2 (8)	4 (16)	6 (12)	
61-70	6 (24)	1 (4)	7 (14)	
>70	1 (4)	4 (16)	5 (10)	
Total	25 (100)	25 (100)	50 (100)	

Table 2: Gender distribution of patient.

Gender	Group A, (%)	Group B, (%)	Total, (%)	P value
Sex F	3 (12)	6 (24)	9 (18)	0.463
M	22 (88)	19 (76)	41 (82)	
Total	25 (100)	25 (100)	50 (100)	

Diabetes mellitus (DM) (44%) was found to be the most common co-morbidity associated with NF in the present study followed by hypertension (22%), chronic obstructive pulmonary disease (COPD) (10%), chronic kidney disease (CKD) (8%), PVD (6%). The 10% of patients didn't have any co-morbidity (Figure 3). The common clinical findings observed in this study included tenderness over wound (80%) followed by raised local temperature (76%), erythema (76%), fever (72%), skin necrosis (68%), tachycardia (68%), bulla formation (62%), hypotension (52%) and crepitus (10%).

While evaluating the mean size of the wound in our study, both the groups have similar change in wound size at the end of week 1 ($186.56 \pm 117.18 \text{ cm}^2$ in group A and $207.52 \pm 148.64 \text{ cm}^2$ in group B). By the end of second week, there was an increase in size of the wound in both groups. At the end of four weeks, wound size reduced in both the groups compared to week 1 but no significant difference was seen between the groups. After initial debridement and dressing, the wound score was significantly in favor of group B ($p=0.0001$). This trend in wound score improvement continued till the end of four week. the early granulation tissue formation was seen in group B wounds (Figure 4 and 5).

**Figure 4: NF wound before NPWT dressing.****Figure 5: NF wound after 4 weeks of NPWT dressing.**

In the present study both the groups needed repeated debridement till the end of first week. However, by the end of week 2, there was no need for debridement in group B ($p=0.0001$) whereas group A still needed repeated debridement.

By the end of third and fourth weeks both the groups needed similar frequency of debridement ($p=1.000$) (Table 3).

Table 3: Frequency of dressing and re-debridement.

Duration	Group A, (Mean±SD)	Group B, (Mean±SD)	P value
Frequency of changing dressing			
Week 1	4±0	2±0	<0.0001
Week 2	3.04±0.2	1.84±37	
Week 3	2.96±0.2	1.04±0.2	
Week 4	2.08±0.28	1±0	
Frequency of re-debridement			
Week 1	2±0	2±0	1.000
Week 2	1.56±0.51	1.02±0.2	<0.0001
Week 3	1±0	1±0	1.000
Week 4	1±0	1±0	1.000

In our study, most wounds were polymicrobial 30 (60%) and 14 (28%) were monomicrobial. While in 12% of the patients no microbes could be cultured.

Among monomicrobial, β - hemolytic *Streptococci* was the most common micro-organism cultured 7(50%) followed by *Staphylococcus* 3(21.43%). *E. coli* (14.28%) and *Klebsiella* were (14.28%).

In polymicrobial infection both gram positive (33%) and gram-negative organisms (67%) were present. Anaerobes could be cultured only in 2 patients.

There was a significant change in the color and odor of exudate in group B by the end of second week ($p=0.002$), which becomes comparable in both groups by the end of fourth week. The surrounding skin was less macerated and inflamed in group B at the end of first week, but this was statistically not significant.

By the end of second- and third-week group B patients showed a significant reduction in maceration and inflammation of surrounding skin ($p=0.0002$).

After 4 weeks both groups were evenly matched with respect to maceration and inflammation. There was early resolution of edema around the wound in group B seen after second week ($p=0.0005$).

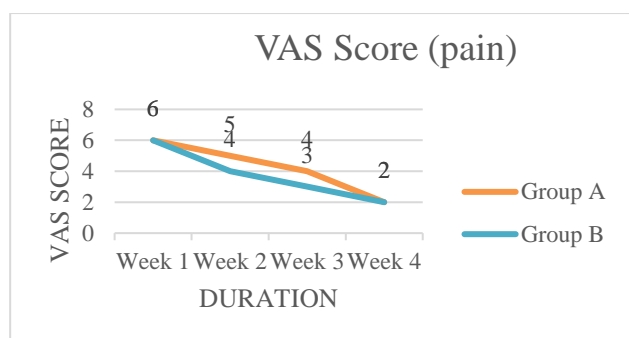


Figure 6: Weekly pain assessments.

From the date of surgery till the completion of study, patients in group B required less frequency of dressing change ($p=0.0001$) when compared to patients underwent conventional dressing (Table 1). Patients in group B also experienced significantly less pain in first week as assessed by VAS score, although it was not significant thereafter ($p=0.082$) (Figure 6). Among the 58 patients included in the study 8 patients expired (13.8% mortality rate).

DISCUSSION

NF is a common problem especially in a developing country like India. The clinical presentation is very vague and if left untreated it progresses rapidly within hours causing high morbidity and mortality. Early diagnosis and treatment are therefore critical in the management of these patients. Our study composed of 50 patients of age ranging from 12 to 75 years with a mean age of 47.5 years who were randomly categorized to two groups. Group A patients underwent conventional dressings and group B patients underwent NPWT.

NSTI can affect any age group but more common in middle age. Comorbidities are more prevalent in the middle and elderly age group thus making them more susceptible for NSTI. These findings were comparable to other studies conducted by Anaya et al, Kucharzewski et al and Muqim et al.^{3,11,12}

There was a definite male preponderance with almost 41 (82.00%) patients being males in our study. Such predominance of NF among male population has no particular reason but can be due to them being more prone to trauma. The most common etiological factor for NF in our study was trauma (44%) of vivid nature and severity. Other causes included insect bite (14%), abscess (8%), minor laceration (6%), intra venous cannulation (8%), and none (2.58%). The infection was idiopathic in (18%) of the patients.

In our study, the most common site involved by NSTI is lower limb (84%) followed by upper limb (16%). Both the lower limbs were involved in 4% of the patients. We excluded other sites from the study. Many studies have observed a similar pattern where limbs were the most

common site of NF.

Higher rates of NF are usually seen in patients having various co-existing morbidities and this was seen in this study as well. Most commonly associated co-morbidity was DM (44%). Hypertension was found in 22% COPD 10%, CKD 8%, PVD 6%. Results of our study matched with those of Chen et al who also showed that the most common etiology was DM (41%).¹³ Swain et al in their study showed 33% suffered from diabetes, 40% were hypertensive, 13% had morbid obesity and suffered from chronic renal failure.¹⁴

High blood sugar levels produce good culture medium for bacterial growth. It also causes defective phagocytosis, decreased cellular immunity and micro-vascular disease with resultant ischemia. The other common co-morbidity in our study was hypertension, which might cause disruption of the microvascular supply with reduction of tissue oxygenation and antimicrobial delivery.

The most common physical finding in our study was tenderness over the affected body part (80%) followed by raised local temperature (76%), erythema (76%), fever (72%), skin necrosis (68%), tachycardia (68%), bulla formation (62%), hypotension (52%) and crepitus (10%). Similar clinical presentation has also been reported in other studies.

Radical debridement of all the necrotic tissue leaves a large soft tissue defect which is surgical challenge. This was also observed in our study with wound size ranging from 186 to 207 square centimeter. Dressing of these wounds until they are ready for split thickness skin graft is the end point in the management of these wounds.

We observed that application of VAC dressing had no significant impact in reducing the wound size compared to patients receiving conventional dressing at the end of 4 weeks. Various other studies have shown a wound size reduction varying between 25% to 60%.¹⁵⁻¹⁷ This disparity in our study may be due to large infected wounds which require more than 4 weeks before they start healing and reduce in size. Most of these studies had varied etiologies for wound formation and therefore may not be exactly comparable to our patients. Lone et al observed that the VAC dressings resulted in an increased rate of granulation tissue formation and wound healing compared to conventional dressings.¹⁸ We observed that the resolution of infection started as early as the end of first week in patients with VAC dressings. Group B patients had appearance of healthy granulation tissue by the end of second week compared to patients in the conventional dressing group, which was statistically significant ($p=0.0001$).

It has been reported that regular debridement is associated with rapid healing of ulcers. In a retrospective cohort study, Wilcox et al indicated that frequent debridement healed wounds in a shorter time ($p<0.001$).

In fact, the more frequent the debridement, better is the healing.¹⁹ In our study the requirement for debridement was identical in first week in the both the groups. By the end of second week, the need for debridement significantly reduced in group B (VAC) patients. ($p=0.0001$). Beyond second week there was no significant difference ($p=1.000$). Thus, VAC dressing helped in reducing the need for debridement earlier than conventional dressing.

Bacterial colonization is a major factor affecting wound healing. NPWT reduces the bacterial burden and hence hastens the healing process. In our study, most patients (60%) had polymicrobial infection (Type I) NF, followed by monomicrobial (Type II) in 28%. No microbe was cultured in 12% patients. Results were comparable with the studies conducted by Swain et al and McHenry et al.^{14,20} In polymicrobial infections a wide range of bacteria were seen and included *Enterobacteriaceae* group, *Staphylococcus*, *Streptococcus*, *Pseudomonas* and *Acinetobacter*. In monomicrobial infections, group A β -hemolytic *Streptococci* was the most common micro-organism (50%) followed by *Staphylococcus* (21.43%). This is in accordance to what has been reported in the past.

Our study showed an early resolution of edema around the wound in VAC group by the end week 2 ($p=0.0005$). Even though there are only few supporting studies but there is a widespread consensus among clinicians that NPWT eliminates tissue edema.^{9,21,19} Patients in group B (VAC) required significantly less frequency of dressing right from date of surgery till the end of fourth week ($p=0.0001$). Arti et al and El-Sabbagh observed that VAC dressing should be changed every two to five days.^{22,23} Due to the proper sealing of the wound and collection of the exudates in sterile container, the need for frequent dressing change is overcome. The device manufacturer also advises dressing change once in 2-3 days. Pain is a major factor in wound management as it affects wound healing also. In present study, patients in group B experienced significantly less pain when compared to conventional dressing VAS score (mean) 3.00 vs 3.92; ($p=0.001$). A randomized controlled trial study conducted by James et al on wound healing in patients with diabetic foot ulcer also appreciates that VAC therapy had significantly reduced pain at week 3 (vas score 3 vs. 4; $p=0.004$).²⁴ In our study, 8 patients (13.8%) died before the completion of the study. Mortality rate in our study was comparable to other studies reported in the literature. Studies conducted by Gozal et al and Swain et al showed 12% and 20 % mortality respectively.^{14,25}

Our study has certain limitations. The sample size was small which could be a source of bias and might have affected the results. The majority of NF wounds evaluated in our study were of large size which require more than 4 weeks for healing and hence we cannot assess the reduction in wound size. Also, unable to predict an appropriate duration of therapy required for

complete wound healing.

CONCLUSION

In our study NF was more commonly seen in middle aged male patients with DM, hypertension, COPD, kidney disease and PVD, as commonly associated comorbidities. Tenderness, raised local temperature, skin necrosis, bullae, crepitus, tachycardia and hypotension were the common clinical presentations. Majority of cases found to have polymicrobial type 1 infections.

In the present study it was concluded that, application of VAC helped in early appearance of granulation tissue and reduced the need for debridement. It also helped in reducing surrounding skin maceration, wound edema and wound odor. The need for frequent dressing was also reduced significantly resulting in patients experiencing less pain. In our study, the defects resulting from NF were very large and there was no visible impact of VAC in reducing the size of the wound till 4 weeks.

Thus, VAC dressing can be considered as a better option in the management of NF wounds. Further studies with larger population and well-defined end points will be needed in the future before VAC dressing can be considered as a standard treatment modality in the management of NF wounds.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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