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Comparative Study of Management of Diabetic Foot by Vacuum Assisted Closure with Simple Saline Gauge Dressing

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ABSTRACT

Diabetic foot ulcer is a common complication of Diabetes Mellitus that has shown an increasing trend over the previous decade. The use of sub-atmospheric pressure devices, available commercially as Vacuum-assisted closure devices, is an effective way to accelerate the healing of various wounds. The present study is designed to compare the management of diabetic foot by vacuum-assisted closure with Simple dressing.

A study was conducted on patients with diabetes mellitus and suffering from foot ulcers. After the surgical intervention of the wound either debridement and/or amputation, all patients were divided into 2 groups. Patients in Group A underwent vacuum-assisted closure therapy and Patients in Group B Simple dressing and hospital-provided antibiotics. The depth and size of the wound were inspected and was recorded before and every three days during the study period. The simple dressing was performed twice daily after washing the ulcer with sterile saline. Type of diabetes mellitus and state of its control (in primary diagnosis, with control or without control), duration of the ulcer, previous history of the treatment of the ulcer, wound location, and frequency of underlying disease were evaluated for all the study patients.

The duration of wound healing after therapy was significantly (p=0.0001) lower in patients of Group A than Group B while the hospital stay was significantly (p=0.0001) lower in patients of Group A than Group B in this study. This study showed that Vacuum-assisted closure appears to be safe and more effective than traditional methods for the treatment of diabetic foot ulcers; as Vacuum-assisted closure has better results in wound healing than the traditional method, as it provides significant reduction in the size of the wounds, faster healthy granulation tissue formation, a smaller number of debridement sessions and less incidence of local wound complications compared to the traditional dressing group.

Key words: VAC (vacuum-assisted closure), NPWT (Negative Pressure wound Therapy), DFU (Diabetic foot Ulcer), DM (Diabetes Mellitus).

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INTRODUCTION

Diabetic foot ulcer (DFU) is a common complication of DM (Diabetes Mellitus) that has shown an increasing trend over the previous decade. In total, it is estimated that 15% of patients with diabetes will suffer from DFU during their lifetime. Although accurate figures are difficult to obtain for the prevalence of DFU, the prevalence of this complication ranges from 4%-27%. Diabetic foot ulcerations are the most common foot condition leading to lower extremity amputation.

The prevalence of diabetes mellitus (DM) is growing at epidemic proportions in the U.S. and has been reported as the most common reason for hospital admissions in western countries. People with DM develop foot ulcers because of neuropathy (sensory, motor, and autonomic deficits), ischemia, or both. The initiating injury may be from acute mechanical or thermal trauma or from repetitively or continuously applied mechanical stress.

Diabetic foot ulcerations (DFUs) are painful and costly for both the patient and the health care system. Every year, more than 1 million people with DM worldwide lose a leg as a consequence of this disease. Most DM-related amputations are preceded by a foot ulcer.

Optimal care of foot ulceration depends on the treating physician's understanding of the pathophysiology involved, familiarity with accepted principles of treatment, and the knowledge that a coordinated, multidisciplinary team approach will best accomplish the goal of limb salvage. All efforts should be made to prevent foot lesions, and when present, existing ulcers should be treated promptly and aggressively, which can often prevent an exacerbation of the problem and decrease the incidence of amputations. Even when ulcers have healed, patients with DM and a history of a lower extremity ulcer should consider it a lifelong condition that requires monitoring to prevent recurrence.

DFU is considered a major source of morbidity and a leading cause of hospitalization in patients with diabetes. It is estimated that approximately 20% of hospital admissions among patients with DM are the result of DFU. Indeed, DFU can lead to infection, gangrene, amputation, and even death if necessary, care is not provided. On the other hand, once DFU has developed, there is an increased risk of ulcer progression that may ultimately lead to amputation. Overall, the rate of lower limb amputation in patients with DM is 15 times higher than in patients without diabetes.

It is estimated that approximately 50%-70% of all lower-limb amputations are due to DFU. In addition, it is reported that every 30 s one leg is amputated due to DFU worldwide. Negative pressure wound therapy (NPWT) is a newer non-invasive adjunctive therapy system that uses controlled negative pressure, using vacuum-assisted closure (VAC) device, to help promote wound healing by removing fluid from open wounds, preparing the wound bed for closure, reducing edema, and promoting formation and perfusion of granulation tissue. NPWT can be used to treat Charcot neuroarthropathy wounds produced as a result of neuropathy and deformity, following debridement of infection or amputation, and in reconstructive soft tissue and osseous procedures. The use of sub-atmospheric pressure devices, available commercially as VAC devices, is an effective way to accelerate the healing of various wounds.

There is scarcity of data to support antibiotic treatment of chronic ulcers, even when tests are positive. Antimicrobial treatment is indicated if there are clinical criteria for systemic or local infection, either the presence of pus or two or more signs of inflammation (erythema, induration, pain, tenderness, warmth. Laboratory data are not particularly useful for diagnosing infection, except in the case of osteomyelitis.

The present study is designed to compare the management of diabetic foot by vacuum-assisted closure with Simple dressing.

MATERIAL AND METHOD

This Observational comparative study was conducted in the Department of Surgery, Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow on the patients with diabetes mellitus and suffering from foot ulcers.

Sample size

In a study, the mean wound bed preparation time was found to be 15.60 days in the conventional dressing group and 8.50 days in the VAC therapy group. The sample was calculated by using the following formula.

$$n=2*Z1-\alpha/2\ 2\ *\ SD2/d2$$

Z1-α/2=Power of the study

SD: Assumed standard deviation

d: Absolute error (Difference in means)

Assuming 80% power, 5% significance level with 95% confidence interval, and assumed standard deviation being 12 as well as absolute error is 7.1, the total sample size calculated per group is 22.

n=2*(1.96*1.96)*(12*12)/(7.1*7.1)=22 per group

Inclusion criteria

All patients with diabetes mellitus suffering from foot ulcers and infections of age groups (15 yrs-75 yrs).

- Incidental diagnosis of diabetes on admission with a diabetic foot ulcer.
- Patients with a gangrenous foot, complicated by diabetes were included in the study.
- Exclusion criteria
- Patients with foot infections without diabetes mellitus.
- Patients with gangrene foot of etiology other than infection of foot complicated by diabetes.
- Patients whose treatment could not be completed.
- Patients with renal failure if they were undergoing dialysis.
- Patients with a history of poor compliance with medical treatments.
- Patients with receiving radiation therapy or chemotherapy.
- Patients having ischemic ulcer that needed any open or endovascular revascularisation

Methods

After the surgical intervention of the wound either debridement and/or amputation, all patients were divided into 2 groups. Patients in Group A underwent vacuum-assisted closure therapy and Patients in Group B Simple dressing and hospital-provided antibiotics. Wounds were evaluated every week for six weeks as regard size and depth of the wound, timing of healthy granulation tissue formation, number of debridement sessions, and local wound complications (cellulitis–secondary amputation).

Detailed history taking, thorough physical examination, routine investigations, relevant special investigations, choosing the appropriate line of treatment were done.

The depth and size of the wound were inspected and was recorded before and every three days during the study period. The simple dressing was performed twice daily after washing the ulcer with sterile saline. Type of diabetes mellitus and state of its control (in primary diagnosis, with control or without control), duration of the ulcer, previous history of the treatment of the ulcer, wound location, and frequency of underlying disease were evaluated for all the study patients.

Depth of ulcers was measured using vernier caliper in the biggest vertical diameter of the ulcers and improvement of ulcer defined according to the Wagner scale.

4.9 Statistical analysis

Data analysis was performed using SPSS version 16.0 (SPSS Inc., Chicago, Illinois, USA). Numerical data were expressed as mean ± standard deviation (SD) or percent as proportionate to the sample size. Comparison Comparisons between the groups was done by using Chi-square/Unpaired t-test. A p-value<0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS

The present study was conducted to compare the management of diabetic foot by vacuum-assisted closure and Simple dressing and hospital-provided antibiotics. A total of 30 patients were included in each group after randomization.

Group A: Underwent vacuum-assisted closure (VAC) therapy

Group B: Simple dressing and hospital provided antibiotics

The mean age of patients of Group A and Group B was 43.77 ± 12.29 and 42.63 ± 9.66 years respectively. There was no significant (p>0.05) difference in age between the groups showing comparability of the groups in terms of age. More than half of patients of both Group A (73.3%) and Group B (66.7%) were males. There was no significant (p>0.05) difference in gender between the groups showing comparability of the groups in terms of gender. The wound area at presentation was insignificantly (p>0.05) lower among patients of Group A (156.22 ± 92.03 cm2) than Group B (176.48 ± 102.96 cm2). Wound depth at presentation was insignificantly (p>0.05) lower among patients of Group A (12.83 ± 5.24 mm) than Group B (13.07 ± 6.16 mm). Wound exposed bone was present in 50% of patients of Group A and 53.3% of patients of Group B. There was no significant (p>0.05) difference in the wound at presentation in terms of exposed bone. Wound at presentation in terms of dead & devitalized was present in all patients in both the groups.

Wound at presentation in terms of pus discharge was present in a majority of patients in both Group A (83.3%) and Group B (93.3). There was no significant (p>0.05) difference in the wound at presentation in terms of pus discharge. Wound at presentation in terms of granulation was absent in all patients in both the groups.

Hb level was insignificantly (p>0.05) higher in patients of Group A (11.01 ± 1.72 gm/dl) compared to Group. There was no significant (p>0.05) difference in blood sugar level between the groups post-intervention. HbA1c was insignificantly (p>0.05) higher in patients of Group A (7.95 ± 0.72%) than Group B (7.91 ± 0.64%) at post-intervention. Total protein was insignificantly (p>0.05) lower in patients of Group A (7.22 ± 0.56 gm/dl) than Group B (7.23 ± 0.46 gm/dl) at post-intervention. Serum albumin was insignificantly (p>0.05) higher in patients of Group A (3.61 ± 0.34 g/dl) than Group B (3.44 ± 0.36 g/dl) at post-intervention. Size after therapy was significantly (p=0.01) lower in patients of Group A (86.10 ± 48.25 cm2) than Group B (130.68 ± 79.39 cm2) (Table1) (Figure 1).

Table1: Comparison of size after therapy between the groups.

Groups	Size (cm2)
	(Mean ± SD)
Group A	86.10 ± 48.25
Group B	130.68 ± 79.39
p-value1	0.01*

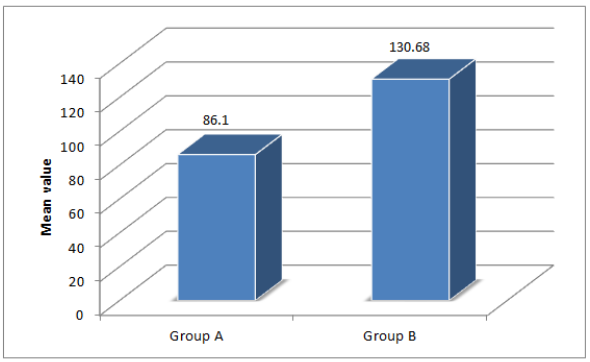

Figure1: Comparison of size after therapy between the groups.

Reduction in wound size was significantly (p=0.0001) higher in patients of Group A (43.93 ± 7.29%) than Group B (24.80 ± 10.36%) (Table 2) (Figure2).

Table2: Comparison of Reduction in wound size (%) between the groups.

Groups	Reduction in wound size (%) (Mean ± SD)
Group A	43.93 ± 7.29
Group B	24.80 ± 10.36
p-value1	0.0001*

1Unpaired t-test, *Significant

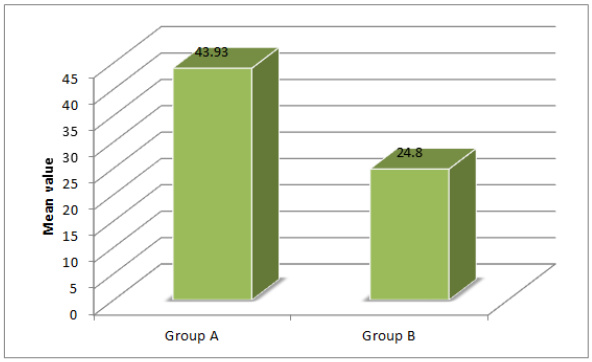

Figure2: Comparison of Reduction in wound size (%) between the groups.

Table3: Comparison of Depth after therapy (mm) between the groups.

Groups	Depth after therapy (mm) (Mean ± SD)
Group A	6.17 ± 4.03
Group B	5.77 ± 4.12
p-value1	0.70

1Unpaired t-test

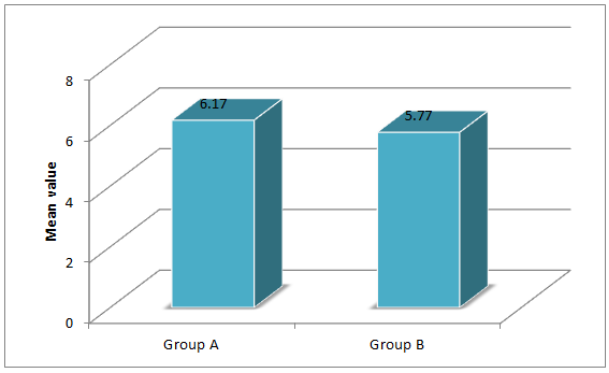

Figure3: Comparison of Depth after therapy (mm) between the groups.

Depth after therapy was insignificantly (p>0.05) higher in patients of Group A (6.17 ± 4.03 mm) than Group B (5.77 ± 4.12 mm). Reduction in Depth after therapy was insignificantly (p>0.05) lower in patients of Group A (54.72 ± 23.18%) than Group B (58.61 ± 23.40%) (Table 4) (Figure 4).

Table 4: Comparison of Reduction in depth (%) between the groups.

Groups	Reduction in depth (%) (Mean ± SD)
Group A	54.72 ± 23.18
Group B	58.61 ± 23.40
p-value1	0.52

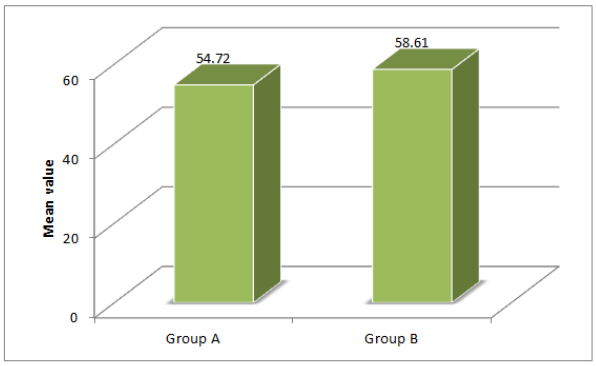

Figure4: Comparison of Reduction in depth (%) between the groups.

The appearance of granulation after therapy was significantly (p=0.0001) lower in patients of Group A (8.17 ± 2.65 days) than Group B (13.17 ± 5.87 days). (Table 5) (Figure5).

Table5: Comparison of Appearance of granulation (days) between the groups.

Groups	Appearance of granulation (days) (Mean ± SD)
Group A	8.17 ± 2.65
Group B	13.17 ± 5.87
p-value1	0.0001*

1Unpaired t-test, *Significant

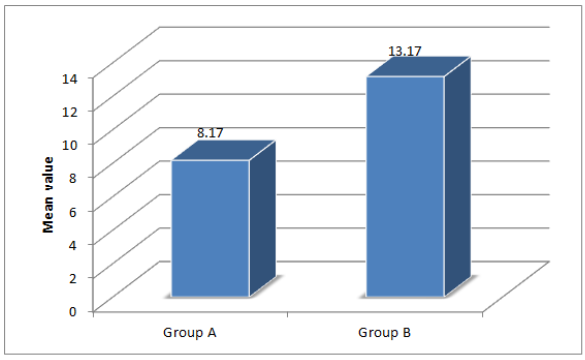

Figure5: Comparison of appearance of granulation (days) between the groups.

The recurrence/persistent infection was in 40% of patients Group A and 86.7% patients of Group B with significant (p=0.0001) difference (Table 6) (Figure 6).

Table6: Comparison of Recurrent/ persistent infection between the groups.

Recurrent/ persistent infection	Group A (n=30)		Group B (n=30)		p-value1
	No.	%	No.	%	
Yes	12	40.0	26	86.7	0.0001*
No	18	60.0	4	13.3	

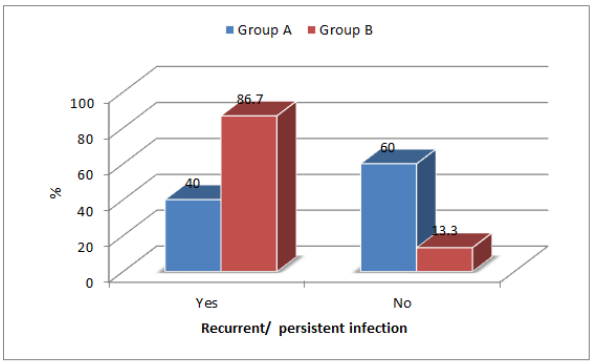

Figure6: Comparison of Recurrent/ persistent infection between the groups.

The wound closure after therapy was significantly (p=0.0001) lower in patients of Group A (23.40 ± 6.45 days) than Group B (34.50 ± 9.77 days) (Table 7) (Figure 7).

Table 7: Comparison of Wound closure (days) between the groups.

Groups	Wound closure (days) (Mean ± SD)

Group A	23.40 ± 6.45
Group B	34.50 ± 9.77
p-value1	0.0001*

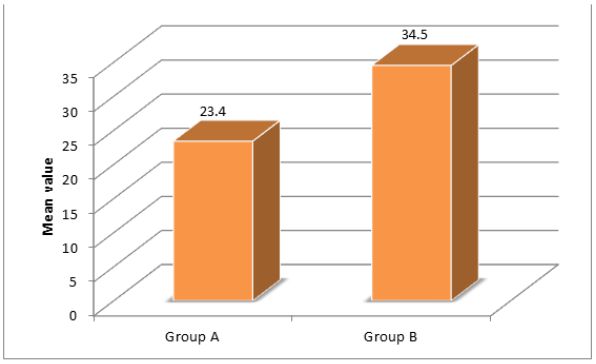

Figure7: Comparison of Wound closure (days) between the groups.

The hospital stay was significantly (p=0.0001) lower in patients of Group A (28.30 ± 6.95 days) than Group B (39.20 ± 9.82 days). (Table 8) (Figure 8)

Table8: Comparison of Hospital stay (days) between the groups.

Groups	Hospital stay (days) (Mean ± SD)
Group A	28.30 ± 6.95
Group B	39.20 ± 9.82
p-value1	0.0001*

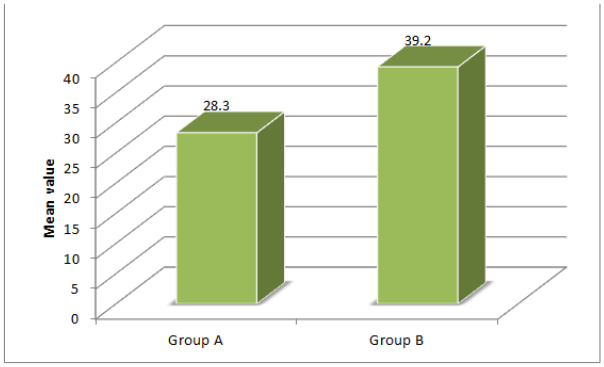

Figure8: Comparison of Hospital stay (days) between the groups.

A considerable proportion of patients with diabetes mellitus develop DFUs. The incidence of DFU ranges from 1% in the West to as high as 11% in African populations. DFUs comprise the most common cause of non-traumatic amputation preceding as high as 85% of the cases. The mortality rate among DFU patients is almost twice that in diabetics without DFU. It was found that the cost of care in patients with DFUs was over five times higher in the 1st year than in diabetics without foot ulcers. This is mainly due to the long duration of hospital stay needed in DFU patients.

Hemoglobin level, blood sugar levels, and HbA1c levels are insignificant with p>0.05 and the results were comparable with the study of James et all. Total protein level was lower in Group. A than in Group B and Albumin levels were higher in group A than in Group B at post-intervention with no statistical significance with the results being comparable to the study of James et al19.

In this study, wound size after therapy was significantly (p=0.01) lower in patients of Group A than Group B. Reduction in wound size was significantly (p=0.0001) higher in patients of Group A than Group B in the present study, depth after therapy was insignificantly (p>0.05) higher in patients of Group A than Group B. Reduction in Depth after therapy was insignificantly (p>0.05) lower in patients of Group A than Group B in this study. In the study, the time to complete wound healing was significantly better in the VAC therapy group as compared to conventional dressing. Similar results were obtained when comparison was done between the two groups stratifying the patients based on ulcer size. The time to complete healing in the VAC group was significantly better in both groups DFUs of smaller size than DFUs of larger size. This can be attributed to the fact that the time to healing is directly proportional to the size of the ulcer.

In a study, the median time to complete closure was 56 days in the VAC therapy group against 77 days in the conventional saline dressing group. It is demonstrated that a greater proportion of DFUs who received VAC therapy achieved complete skin closure or 100% reepithelization. It is showed the meantime to complete wound closure of 41.2 days and 58.9 days in the VAC therapy group and conventional group, respectively. In a similar Indian study of sixty patients with DFU showed a time to healing of 17.2 days in the VAC therapy group as compared to 34.9 days in the conventional dressing group.

In a systematic review and meta-analysis on the effect of NPWT in DFUs showed that NPWT significantly reduces DFUs compared to standard dressing. In the studies showed a reduction by 28.4%, 16.4%, and 23.6% in DFUs who received NPWT. An Indian study by Nain et al (2011) showed similar results as the present study with a mean reduction in ulcer area by 16.14 cm2 and 5.98 cm2 in DFUs treated with NPWT and conventional dressing, respectively.

The time for the appearance of granulation after therapy was significantly (p=0.0001) lower in patients of Group A than Group B in this study which is almost similar to the results showed in stating that the median time to achieve 76%-100% granulation was almost twice as faster using NPWT than conventional dressing. In a Spanish study, the meantime to achieve 90% granulation was earlier in the NPWT group than the conventional dressing group.

Hemorrhage is one of the most feared complications of NPWT and has been responsible for 12 deaths since 2007. However, such life-threatening bleeding has been reported only when NPWT was applied for sternal wounds. Major bleeding in NPWT on DFUs is mostly due to improper hemostasis following debridement, exposed large blood vessels, and high set negative pressure, all of which are avoidable causes, James19 et al showed that VAC therapy when done by trained surgical residents there was no significant bleeding reported while stress should be made on proper hemostasis after debridement to avoid bleeding complications and also negative pressure should be constantly monitored to avoid complications. This study found that the recurrence/ persistent infection was in 40% of patients Group A and in 86.7% patients of Group B with significant (p=0.0001) difference.

The duration of wound healing after therapy was significantly (p=0.0001) lower in patients of Group A (23.40 ± 6.45 days) than Group B (34.50 ± 9.77 days) while the hospital stay was significantly (p=0.0001) lower in patients of Group A (28.30 ± 6.95 days) than Group B (39.20 ± 9.82 days) in this study. This study showed that VAC appears to be safe and more effective than traditional methods for the treatment of diabetic foot ulcers; as VAC has better results in wound healing than the traditional method, as it provides significant reduction in the size of the wounds, faster healthy granulation tissue formation, a smaller number of debridement sessions and less incidence of local wound complications compared to the traditional dressing group.

One of the limitations of this study was the small sample size and short duration of the study. The studies with a larger sample size and long duration are required to have robust findings.

DECLARATION OF CONFLICT OF INTEREST

No conflict of Interest.

ETHICAL APPROVAL
Ethical Clearance: taken from Institutional ethical clearance Committee.

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