

ORIGINAL ARTICLE

Comparison of Vacuum Assisted Closure (VAC) Therapy Versus Conventional Dressing in the Management of Diabetic Foot Ulcer

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ABSTRACT

Background: Debridement of all necrotic, callus, and fibrous tissue is a mainstay of diabetic foot ulcer therapy, with the primary goal of wound closure. The best topical treatment for diabetic foot ulcers is yet unknown. To aid wound healing, a vacuum-assisted closure (VAC) device is used.

Objective: To compare the outcome of vacuum-assisted wound closure (VAC) versus conventional wound dressing in diabetic foot ulcers.

Material and methods: Study Design: Randomized Control Trial. **Setting:** Department of Surgery, Services Hospital, Lahore. **Duration of Study:** 6 months i.e. from-to-**Data Collection:** Forty patients with diabetic foot ulcer were included. Patients were randomly assigned in two groups. In group A, the dressing was applied by using adhesive drape to create the airtight seal. Conventional group received gauze dressings soaked in saline once daily. Patients were followed regularly for 2 weeks to check for appearance of granulation tissue. Outcome was determined in terms of appearance of granulation tissue.

Results: In VAC group, the mean age of patients was 42.95±9.29years. In conventional group, the mean age of patients was 46.30±9.33years. In VAC group, there were 12 (60%) males and 8 (40%) females. In conventional group, there were 16 (80%) males and 4 (20%) females. In VAC group, the mean duration of wound healing was 7.50±2.82days. In conventional group, the mean duration of wound healing was 10.60±5.55days. The difference was significant (p<0.05). In VAC group, there were 20 (100%) patients who had treatment success. In conventional group, there were 13 (65%) patients who had treatment success while 7 (93.0%) did not have complete healing within 2weeks. The difference was significant (p<0.05).

Conclusion: Thus, VAC is more successful in achieving granulation of tissues in patients with diabetic foot ulcer as compared to conventional dressing

Keywords: Type II diabetes mellitus, diabetic foot ulcerations, Vacuum-assisted wound closure, conventional dressings, Negative pressure wound therapy

INTRODUCTION

Diabetes mellitus is a common condition in Pakistan, with over 7.1 million diabetics in 2010 and 13.8 million diabetics projected by 2030.¹Foot ulcers affect 10-25% of diabetics.²

A cure for diabetic foot ulcers is not currently available, and there is no proven prevention method. Traditionally, gauze soaked in saline has been utilised; however, maintaining the moisture of this dressing has proven challenging. Many wound treatments, including hydrocolloid wound gels and growth factors, as well as enzyme debridement chemicals and hyperbaric oxygen therapy, have been developed as a result of this research and development. Although there is no scientific evidence to support the usefulness of some of these medications, they are nevertheless being prescribed despite the high cost of the medications themselves.^{2, 3}

Positive pressure wound therapy is a new noninvasive technique for treating open wounds. It works by removing fluid from the wound bed, reducing edema, and encouraging the growth and perfusion of new granulation tissue.⁴ To expedite wound healing, sub-atmospheric pressure devices, such as VAC or Suctions machines, have been shown to be beneficial.^{2, 3, 5-7}

In view of these studies it is obvious that VAC Therapy is effective treatment method for diabetic foot

ulcer's and it is commonly used method in developed countries but limited international and local data is available which actually compares the efficacy of these two methods. Therefore, this study was designed to be carried out at large tertiary care center with adequate sample size to compare VAC with conventional dressing for wound healing of diabetic foot ulcers. This study proves the superior efficacy of VAC over conventional dressing. It would help to improve knowledge and practice in future regarding better management of diabetic foot ulcer's in our Region.

Objective: To compare the outcome of vacuum-assisted wound closure (VAC) versus conventional wound dressing in diabetic foot ulcers.

MATERIAL AND METHODS

Study Design: Randomized Controlled Trial

Setting: Surgical Unit III, Services Hospital, Lahore.

Duration of Study: 6 months i.e. from-----to-----

Sample Size: Sample size has been estimated to be 40 patients based on an estimated percentage of granulation tissue formation of 92.85%³ in VAC group and 53.57%³ in conventional dressing group with 95% level of confidence and power of test = 90.

Sampling Technique: Non-probability, consecutive sampling

Inclusion Criteria: Patients of both genders aged 20-60 years with diabetic foot ulcer upto 6cm size in its longest dimension and grade 1, 2. Patients with grade 1 and 2 diabetic foot ulcer's as defined by Wagner's classification given below was included.

Grade	Lesion
0	No open lesions; may have deformity or cellulitis
1	Superficial diabetic ulcer (partial or full thickness)
2	Ulcer extension to ligament, tendon, joint capsule or deep fascia without abscess and osteomyelitis
3	Deep ulcer with abscess, osteomyelitis or joint sepsis
4	Gangrene localized to portion of forefoot or heel
5	Extensive gangrenous involvement of the entire foot

Exclusion Criteria: Patients with osteomyelitis of the underlying bone assessed from medical record and X ray, peripheral vascular disease assessed from medical record and examination, taking medications like corticosteroids, immunosuppressive agents or chemotherapy

Data Collection Procedure: Forty patients with diabetic foot ulcer as per operational definition were included in the study after informed consent. Using random tables, patients were randomly assigned to one of the two groups of VAC (A) and conventional dressing (B). Initially, the wounds were debrided with sharp instrument and during later dressings change to eradicate the necrotic tissues. After debridement, one foam-based dressing was applied on wounds under aseptic measures. In group I, the dressing was concealed within the cemented wrap to create the air-tight seal. Then evacuation tube implanted inside the foam was attached to the vacuum and pressure was applied within the range of 80-125mmHg on continuous basis for 72-hours. In group II, patients received only gauze based dressing fully soaked in saline on daily basis. Oral analgesics were given to all patients when dressing is replaced. Ulcers was managed until the wound is completely closed naturally, or until 8 weeks. Glycemic level was monitored strictly, during the study period and maintained by using regular doses of insulin. After the closure of wound, patients were followed regularly for two weeks to determine the re-appearance of granulation tissues. Bio data was entered in a predesigned structured Performa attached with the synopsis. Outcome was determined in terms of appearance of granulation tissue (timing of appearance of healthy granulation tissue on wound in both dressing groups at 2 weeks).

Data Analysis: Statistical analysis was done using SPSS version 21. Qualitative data like gender, appearance granulation tissue at 2 weeks was presented as frequencies and percentages. Quantitative data i.e., age, was presented as mean and standard deviation. The two groups were compared with respect to the frequency of appearance of granulation tissue at 2 weeks with chi square test. In all cases, p value ≤ 0.05 as significant.

RESULTS

In VAC group, the mean age of patients was 42.95 ± 9.29 years. In conventional group, the mean age of patients was 46.30 ± 9.33 years. In VAC group, there were 12 (60%) males and 8 (40%) females. In conventional group, there were 16 (80%) males and 4 (20%) females. In VAC group, the mean duration of diabetes was 5.05 ± 3.07 years. In conventional group, the mean duration of diabetes was 6.30 ± 4.35 years. In VAC group, the mean wound size was 4.03 ± 1.42 cm. In conventional group, the mean wound size was 4.27 ± 1.47 cm. Table 1

In VAC group, the mean duration of wound healing was 7.50 ± 2.82 days. In conventional group, the mean duration of wound healing was 10.60 ± 5.55 days. The difference was significant ($p < 0.05$). In VAC group, there were 20 (100%) patients who had treatment success. In conventional group, there were 13 (65%) patients who had treatment success while 7 (35.0%) did not have complete healing within 2 weeks. The difference was significant ($p < 0.05$). Table 2

Table 1: Characteristics of patients

	Group	
	VAC	Conventional
n	20	20
Age (years)	42.95 ± 9.29	46.30 ± 9.33
Gender		
Male	12 (60%)	16 (80%)
Female	8 (40%)	4 (20%)
Duration (years)	5.05 ± 3.07	6.30 ± 4.35
Wound size (cm)	4.03 ± 1.42	4.27 ± 1.47

Table 2: Comparison of both groups for duration of healing and success

	Group		p-value
	VAC	Conventional	
n	20	20	
Day of healing	7.50 ± 2.82	10.60 ± 5.55	0.032
Treatment Success	20 (100%)	13 (65%)	0.004

DISCUSSION

Diabetes Mellitus and Its Consequences Delayed wound healing is a serious health issue, especially in the elderly. Failure to heal a wound not only causes pain and suffering, but it also has social and economical consequences. The risk of having a diabetic foot ulcer is as high as 25% during the course of one's life.³ Foot problems are a leading cause of hospitalisation in diabetic patients, who spend an excessive amount of time in the hospital due to various surgical operations and a protracted stay.²

Patients with diabetes mellitus have a 25% lifetime risk of getting a foot ulcer, which in up to 85% of instances leads to amputation. Debridement of all necrotic, callus, and fibrous tissue is a mainstay of diabetic foot ulcer care, with the primary goal being wound closure. The severity (grade), vascularity of the limb, and presence of infection all play a role in the diabetic foot ulcer's treatment.^{1,2}

In our study, the mean duration of wound healing was 7.50 ± 2.82 days with VAC while 10.60 ± 5.55 days with conventional method. The difference was significant ($p < 0.05$). In VAC group, there were 20 (100%) patients who had treatment success. In conventional group, there were 13 (65%) patients who had treatment success while 7

935.0%) did not have complete healing within 2 weeks. The difference was significant ($p < 0.05$).

Lone et al., found that granulation tissue re-appeared in 26 (92.85%) patients at end of 2nd Week with VAC, while in 15 (53.57%) patients with conventional method. 100% granulation was observed in 21 (77.78%) patients with VAC as compared to only 10 (40%) patients by conventional method.³

According to another study by Ali, by the seventh week, discharge had vanished in 96 percent of VAC patients and just 54 percent in the standard dressing group. Granulation tissue was seen in 100 percent of VAC patients and only 63 percent of participants in the standard dressing group.⁵

Ravari, on the other hand, observed that after two weeks, majority of the VAC group's patients showed considerable improvement in wound diameter and depth, as well as increased granulation tissue proliferation. Wagner's Score decreased in both study groups, albeit the decrease in the moist dressing group was not significant. According to a Singapore study, all wounds healed completely. Split-skin grafting was used to close nine wounds and secondary closure was used on two others.⁶

In the VAC group, McCallon et al., found a 28.4 percent (24.3) decrease in wound size, compared to a 9.5 percent (16.9) increase in wound size in the control group (treated by saline-moistened gauze dressings).⁸

In comparison to wet gauze dressings, Mark et al., found that VAC dressings reduced wound volume and depth significantly.⁹ Priyatham et al., discovered that the rate of granulation tissue was faster in the VAC group than in the conventional moist dressing group, with a mean of 78.68 percent for VAC and 51.92 percent for conventional moist dressing. The VAC group had a shorter hospital stay than the traditional moist dressing group, with a mean of 32.48 days for the VAC group and 59.43 days for the conventional moist dressing group. The VAC group has a higher percentage of graft uptake than the conventional moist dressing group, with an average of 80.78 percent for the VAC group and 59.58 percent for the conventional moist dressing group. Consequently, VAC helps to heal the ulcer of chronic diabetic foot more rapidly and provide better graft uptake and also reduces the hospital stay than conventional saline dressing.¹⁰

According to Alam S et al.¹¹, 46% of patients who received dressings saw a reduction in wound size of 50% or more, while 54% saw a reduction of 50% or less. Patients treated with VAC saw an average reduction in wound size of more than 50%, with 13% experiencing a reduction of less than 50%.

In a study involving 135 patients and the VAC dressing, Chiummariello found excellent results and high levels of patient satisfaction with the dressing's use in the treatment of acute and chronic wounds.¹² Studies by Eginton et al. found that VAC dressings reduced wound volume and depth significantly more than moist gauze dressings (59 per cent and 49 per cent per cent, respectively).¹³

Armstrong and Lavery found that the VAC therapy group closed in 56 days on average, while the conventional saline dressing group closed in 77 days.¹⁴ More DFUs who received VAC therapy had complete skin closure or 100

percent reepithelization, according to Blume et al.¹⁵ It took the VAC therapy group an average of 41.2 days and the conventional group an average of 58.9 days to close the wounds.¹⁶

CONCLUSION

Thus, VAC is more successful in achieving granulation of tissues in patients with diabetic foot ulcer as compared to conventional dressing. Now we have got the evidence in favor of VAC for management of diabetic foot ulcer in patients with diabetes. Now in future, we will implement the use of VAC instead of conventional method for management of diabetic foot ulcer.

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