Comparison of Vaccum Assisted Closure Therapy with Vaseline Gauze Dressing in Healing of Diabetic Foot Ulcers

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ABSTRACT

Background: Delayed wound healing in diabetic patients prolong morbidity and may ultimately end up in loss of part or whole of the foot. Vaseline Gauze dressing is in common practice but Vaccum-assisted closure (VAC) therapy is not in routine use in the treatment of diabetic foot ulcers and different studies have shown conflicting results.

Objective: To compare efficacy of VAC therapy with Vaseline Gauze dressing in healing of diabetic foot ulcers.

Material & Methods: Sixty type 02 diabetic patients with Grade 1 and Grade 2 diabetic foot ulcer was selected and randomized into Group A (Vaseline Gauze Dressing) and Group B (VAC therapy) with 30 patients in each group. The quantitative variables are Age, Area of Wound at baseline at time of presentation (1st week) and after 8 week time and depth of wound were measured. Qualitative variables are Gender, Efficacy, grade of Ulcer were measured. Percentage of Healing between these two groups was analyzed to compare the difference.

Results: The mean age of Diabetic foot ulcer was 50.8 years, the proportion of male & female was 58% and 42% respectively, while the proportion of Grade 1 and Grade 2 was 45% and 55% respectively, in GroupA 46% patients have > 50% decrease in wound size and 54% has <50%. In Group B 87% patients have > 50% decrease in wound size and 13% patients have <50 % decrease. P value is 0.001 for efficacy of both groups.

Conclusion: VAC is better in efficacy in the treatment of Diabetic Foot Ulcer (DFU) as there is more rapid healing in the patients who were treated with VAC therapy as compared to patients treated with Vaseline gauze dressing. Thus VAC is a good alternative to the Vaseline gauze dressing.

Keywords: *Diabetic foot ulcer, VAC, Vaseline Gauze Dressing, Amputation.*

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INTRODUCTION

Diabetic foot ulcer is a major complication of diabetes mellitus, and occurs in 15% of all patients with diabetes and precedes 84% of all diabetes-related lower-leg amputations[1]. So far, it is a common trend in diabetic foot care domain to use advanced moist wound therapy, bio-engineered tissue or skin substitute, growth factors and negative pressure wound therapy[2].

No therapy is completely perfect as each type suffers from its own disadvantages. Moist wound therapy is known to promote fibroblast and keratinocyte proliferation and migration, collagen synthesis, early angiogenesis and wound contraction. At present, there are various categories of moist dressings available such as adhesive backing film, silicone coated foam, hydrogels, hydrocolloids etc. Unfortunately, all moist dressings cause fluid retention; most of them require secondary dressing and hence are not the best choice for exudative wounds[3].

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Wound healing may be delayed due to abnormal cell function, hyperglycemia, peripheral neuropathy, peripheral vascular disease, susceptibility to infections and abnormal planter foot pressures. Delayed wound healing causes prolong morbidity and may ultimately end up in loss of part or whole of the foot. The use of sub-atmospheric pressure dressings, available commercially as the vacuum-assisted closure (VAC) device, has been shown to be an effective way to accelerate healing of various wounds[4].

Animal studies have demonstrated that this technique optimizes blood flow, decreases local tissue edema, and removes excessive fluid from the wound bed. These physiologic changes facilitate the removal of bacteria from the wound[5,6]. In diabetic wounds, there are clinical reports to suggest that VAC therapy aids bacteria clearance[7].

In a study by Nathar et al results showed that with VAC therapy, wound healing occurred in all patients. The number of dressings required ranged from 8 to 10. The baseline average wound size was 23.1 cm^2. All subjects achieved 100% wound bed granulation with an average length of treatment of 33 days. Microbial clearance was achieved in all cases[6].

Additionally, sub-atmospheric pressure alters the cytoskeleton of the cells in the wound bed, triggering a cascade of intracellular signals that increases the rate of cell division and subsequent formation of granulation tissue. This is evident in the VAC device's wide range of clinical applications, including treatment of infected surgical wounds, traumatic wounds, pressure ulcers, wounds with exposed bone and hardware, diabetic foot ulcers, and venous stasis ulcers[8]. VAC is generally well tolerated and, with few contraindications or complications, is fast becoming a mainstay of current wound care[9]. The wound VAC has been used successfully in many different anatomic locations[10,11].

VAC therapy is new and not routinely used in management of diabetic foot ulcers. It is claimed to have faster healing rates and can be used bedside as well. This study is undertaken to check the efficacy of VAC therapy in the treatment of diabetic foot ulcer in our population.

MATERIAL AND METHODS

This randomized control trial was conducted at Surgical Department of Saidu Teaching Hospital, Swat over a period of two and half years from January, 2016 to July, 2018 after approval from local ethical committee of the Hospital. Informed consent was taken from all the participants. Demographic data was recorded on proforma including phone number and address. All type 02 diabetic patients included in study were divided in two equal groups randomly by Lottery method. The sample size was 60 and 30 patients in each group. Consecutive (Non probability sampling) sampling technique was used. All diabetic patients with wound of Wagner grade I, II severity on foot for more than 04 weeks duration and control of diabetes with oral hypoglycemics or Insulin based on fasting blood sugar of 110-130 mg/dl were included.

Patients with history of hepatic and renal diseases, steroid use, patients with impalpable dorsalis pedis or posterior tibial arteries were excluded from the study.

Swab for culture and sensitivity was taken from all ulcers. Systemic antibiotics were given according to culture and sensitivity report.

Area of ulcer was measured. We used a transparent tracing paper for making wound tracings. The tracing was then placed under the transparent graph paper. These were taken from Canson Transparent Graph Paper Pad. The tracing was then transferred on to the graph paper.

The number of small squares inside the tracing was measured. This gave the area in mm^2. Depth of the wound was measured with the help of measuring scale, from the edge of the wound up to maximum depth inside wound in mm. The percentage reduction in depth was assessed over 8 weeks in the same way as given below for area. For depth (A) replaced with (D) in the formula.

Both groups received standard treatment for wound care in terms of wound debridement. .

Group A following the first debridement received routine dressing with Pyodine bath and normal Saline and Vaseline gauze dressing was placed. Dressings were done daily or on alternate days depending upon dressing soakage and patients comfort.

Group B was given VAC system following the first debridement and washing of the necrotic and infected wound. Patients were exposed to -125 mmHg continuous negative pressure.

A piece of Molty foam 2 cm thick and cut 1 cm larger than the wound dimensions were placed over the wound. Embedded in the foam was a fenestrated evacuation tube, which was connected to a suction plastic bottle. The site was then be sealed with an adhesive drape of Opsite. Prior to application of the drape, prepare the peri-wound skin and ensure that it is dry. The VAC dressing was changed every fourth day. This was continued till there was evidence of granulation tissue in the wound. After 2-4 weeks depending on the appearance of granulation tissue we used resort to routine dressing with Pyodine bath and normal Saline and Vaseline gauze. A telephonic follow up was done. It was assessed at the baseline (A_0) and at 8^{th} week (A_8).

The percentage reduction in the area over 8 weeks was assessed as follows; Percentage reduction in wound area= $\frac{(A_0) - (A_8)}{(A_0)} \times 100$

The healing percentage was calculated and recorded on the proforma. Collected data was recorded and analyzed on SPSS version 20. Qualitative variable were gender, efficacy, grade of ulcer and was measured in terms of frequency and percentage. Quantitative variables were age, area and depth at base line (1st week) and after 08 weeks time and was measured in terms of mean ± SD. Chi Square test was used to compare efficacy between two groups. P value ≤ 0.05 was considered significant.

RESULTS

A total of 60 patients were studied in which 35(58.3%) were male and 25(41.7%) were female. The proportion of male and females in group A were 19(63 %) and 11(36%) respectively, and in group B it was 16(53%) and 14(46%) respectively. The mean ±SD age of the patient was 50.8 ±27 years and the age range was 26 - 85 years. 27(45%) patients have grade 1 ulcers and 33(55 %) patients was having grade II ulcers.

The efficacy of group A was 14(46 %) patients were having greater than 50% of decrease in wound size and 16(54 %) were having less than 50% decreases in wound size. In group B, 26(86.6%) patients were having greater than 50% decrease in wound size and 4(13.4%) were having less than 50% decrease in wound size at end of 8weeks.

The mean ±SD for decrease in size of wound in group A was 4.41 ±0.675 and group B was 4.8 ±0.627. There was more healing in patients receiving VAC therapy as compare with patients having Vaseline gauze dressings. In group A 46% patients had healing >50% in size and 54% had < 50% decreases in wound size. In group B 87% patients had >50% decrease in wound size and 13% patients had <50% decrease in wound size.

In both Group A and Group B, >50% decrease in the depth of wound has been observed in 8 weeks time were 100%.

The efficacy of VAC therapy was more and the P value is <0.05. In both group A and group B > 50% decrease in wound size were noted. In both the cases granulation tissues were present at the end of 8 weeks with P-value 0.001.

DISCUSSION

Diabetes mellitus is a common disorder and diabetic patients have lifetime risk of developing foot ulcers from 15% to 25%. The treatment of diabetic foot ulcers are very difficult and take long time to heal or get worse and result in limb loss[1].

Foot ulcers and related complications account for approximately 16% of all hospital admissions and 23% of all hospital days among diabetic patients[12]. Various treatment modalities of diabetic foot ulcer include assessment, wound debridement, treatment of infection, revascularization if indicated, sufficient off-loading of the foot and various dressing materials are used for healing of diabetic foot[13]. Debridement is the key component of the healing process by removing devitalized and necrotic tissue[14].

VAC therapy has been used in small size studies in the treatment of open wounds since 1980[15]. VAC therapy is limited in their usage as they are only suited with low-to-moderate exudates levels restricting their use in large diabetic foot wounds[16]. The VAC system include an open cell polymer foam dressing for wound bed, a transparent sheet to seal the dressing air tight, a plastic drainage tube connected to reservoir for collection and a vacuum pump that provide pressure ranging from -25mm Hg to -200 mmHg either in continuous or an intermittent form which causes contraction of dressing, deformation of cells and stimulate neo-angiogenesis and formation of granulation tissues. It also remove exudates from wound and reduces edema which help to improve perfusion[17].

Blume study showed 100% reepithelialization[2]. Sepulveda and colleagues defined 90% granulation in their study[18]. In our study at the end of 8th weeks all the patients of both groups were having granulation tissue visible in their wounds which promote healing process.

Armstrong and colleagues, in their study showed that the rate of wound healing and granulation tissues formation were faster in the VAC group than in the control group. More patients were healed with VAC than with control group, 56% versus 39% (P= 0.040)[19].

In our study the wound size and depth of patients were measured in mm at the first visit and then on 8 weeks after giving treatment. In group A 46% patients were having more than 50% decrease in area of wound and in 54% patients area of wound decreases were less than 50%. In group B 87% of patient were having greater than 50% decrease in Size of wound and 13% patients had less than

50% decrease in wound size. Thus VAC has performed better in decreasing the wound size with P- value less than 0.05. In both the groups the depth of wound decreases at end of 8weeks was more than 50%, so in term of depth both dressing's had same performance. The efficacy of both are measured using chi-square test with the P value is 0.00105.

Similar results were noted by Bagul A et al. They found that patients on VAC therapy had early appearance of granulation tissue as compared to patients treated by Conventional dressing (90.9% versus 76% at the end of one week), but the difference was not statistically significant. All patients developed granulation tissue by the end of two weeks[20].

Chiummariello described their experience with the VAC dressing used to manage acute and chronic wounds in a series of 135 patients, with excellent results together with satisfaction of the patients[21]. In a study by Eginton et al, found that VAC dressings decreased the wound volume and depth significantly more than moist gauze dressings (59% vs. 0% and 49% vs. 8%, respectively)[22].

Thus according to our study the VAC dressing is a better option for treatment of diabetic foot ulcers as it promote rapid healing of the wound. The VAC is a better alternative to Vaseline gauze dressings used.

The limitation of our study was that we were unable to study various patient's characteristics, type 01 diabetic patients, co-morbidities considered a potential risk factors for healing of wound, duration of ulcer and cost effectiveness. We recommend a large multicenter prospective studies to generate local statistical data.

CONCLUSION

Vacuum assisted closure therapy is a better dressing option for diabetic foot ulcer grade 1 and 2. More and rapid healing is achieved through VAC therapy. Thus VAC therapy is a good alternative to Vaseline gauze dressing.

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