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COMPARATIVE STUDY OF VACUUM ASSISTED CLOSURE (VAC) THERAPY AND CONVENTIONAL DRESSING ON WOUND HEALING IN DIABETIC FOOT IN PATIENTS WITH UNCONTROLLED SUGARS.

Billal Rashid Post-graduate Resident, Department Of Medicine, SKIMS Soura

John Mohd* Registrar, Department Of Orthopaedics, Government Medical College Anantnag
*Corresponding Author

ABSTRACT **Introduction:** Diabetes burden is ever increasing. The incidence of diabetic foot is high in patients with persistently uncontrolled sugars. VAC is a novel modality of treatment with promising results. **Materials and Methods:** In the present study we demonstrated a comparison between the management of diabetic foot wounds using VAC and conventional wound management. 54 patients included in the present study were divided into two groups of 27 each. The comparative outcome was studied and analyzed. **Results:** Distribution of Wagner grade 1 & 2 DFUs was unequal in the two groups; eight grade 1 DFUs were in conventional dressing group while only two grade 1 DFUs were in the NPWT group. However, the possibility that this distribution favour results in the NPWT group was unlikely as both these grades were superficial. Also, when the primary objective in the two groups was compared by stratifying on the basis of grade, results were n favour for NPWT for both Wagner grade 1 and 2 DFUs. **Conclusion:** The present study showed that VAC therapy significantly decreases the time to complete wound healing when compared to conventional dressing. The study showed significant reduction in the ulcer size in the VAC group compared to the conventional dressing group and the reduction was more pronounced in the ulcer DFU of >10cm size.

KEYWORDS :

INTRODUCTION

Diabetes mellitus, characterised by hyperglycemia either due to absolute insulin deficiency or relative insulin deficiency is the most common metabolic disorder in general population.[1-3] There is a total loss of functions of beta cells of pancreas in absolute deficiency that leads to low insulin level resulting in hyperglycemia.[4-7] The beta cells of pancreas functions normally in relative insulin deficiency where the peripheral resistance to insulin action at tissue level varies.The most important complication of diabetes that leads to major mortality and morbidity is diabetic foot ulcer. [8,9] The metabolic abnormalities that characterize diabetes mellitus particularly hyperglycemia, free fatty acids and insulin resistance provoke macrovascular and microvascular complications which may lead even a trivial trauma in foot to end in major amputation. Nearly 25% of diabetic patients are prone to develop foot ulcer during their lifetime wherein the etiologies may be either arterial, neuropathy, pressure sore and foot deformity.[10-13] The mainstay of diabetic foot ulcer therapy is debridement of all necrotic tissues, callus and fibrous tissue with a primary goal to obtain wound closure Wagner grading system
Grade 1 Superficial ulcer
Grade 2 Deep ulcer, no bony involvement or abscessGrade 3 Abscess with bony involvement (as shown by Xray)
Grade 4 Localized gangrene eg. Toe, heel etc
Grade 5 Extensive gangrene involving the whole foot

Negative pressure wound therapy (NPWT) is a newer noninvasive system that uses controlled negative pressure using vacuum assisted closure (VAC) devices to help promote wound healing by macro –deformation and microdeformation of tissues, reducing edema, promoting formation and perfusion of granulation tissue and stabilisation of wound environment.Low socioeconomic status, inadequate facilities for diabetic foot care, low education, barefoot walking are major risk factors for diabetic foot ulcer.[13-17] Amputation of limb leaves a major impact on the individual Leading to increased dependency, social isolation, loss of social life and unemployment

MATERIALS AND METHODS

This study; designed as a prospective parallel randomized controlled trial was carried out in the Department of between and after being approved by the Institute Ethical Committee (IEC). With a power of 80%, a error of 5%, and expected difference of 20 days in the time taken for complete granulation cover18, the sample size was calculated to be 54 with 27 in each group.

Inclusion Criteria

All diabetic patients >18 years of age

Exclusion Criteria

1. Coagulopathy
2. Venous disease
3. DFU patients with underlying osteomyelitis
4. DFU patients with Charcot's joint
5. DFU classified under Wagner-Meggit classification as grade III, IV and V
6. Peripheral Vascular Disease
7. DFU involving both feet

Randomization Of Patients

Stratified Block randomization was carried out with randomly selected block sizes of 4 and 6. Further after randomization of patients in two groups, the patients in the respective groups were stratified into two groups of ulcer size <10 cm in and of ulcer size >10cm in the longes tdimension, considering size of ulcer as a known confounding variable.

Study Procedure

All patients with a DFU in were enrolled into the study after fulfilling exclusion criteria and after informed written consent. The nature, methodology and risks involved in the study were explained to the patient and informed consent was obtained. All the information collected was kept confidential and patient was given full freedom to withdraw at any point during the study. All provisions of the Declaration of Helsinki were followed in this study. nitial treatment including necessary surgical debridement of the wound, appropriate antibiotic based on culture sensitivity and glycemic control was done. The wound was defined fit to be included in the study when the DFU was deemed “clean” by the treating surgeon and the wound culture shown no growth or skin flora, all patients were also checked for strict glycemic control defined as having AC (ante-cibum) and PC (post-cibum) values of less than 120mg/dL and 180 mg/dL respectively before including in the trail. After satisfying the said criteria, the enrolled patients were then randomized into two groups to receive eithe conventional dressings or Vacuum Assisted Closure (VAC) therapy. The atients in the study group received VAC therapy while those in the control group received conventional dressing. Further patients in the two groups were stratified in to groups of patients with DFUs of <10cm and >10cm in the longest dimension. Wagner's grade of the DFU, duration of diabetes (in years), whether the patient was on Insulin/OHAs/both prior to study, HbAlc, baseline albumin, hemoglobin, BMI and comorbidities were recorded in both the groups before starting the intervention. Assessment of nutrition was done by monitoring albumin and hemoglobin levels every week. Culture sensitivity was sent at the start of the study and then every week. In the study group, the wound bed was filled with a saline soaked gauze piece after it was thoroughly cleaned. VAC was applied by placing sterile pads in two layers with a 16Fr Ryle'tube placed between the two layers and then the wound was sealed by a sterile transparent polyurethane sheet. The tube was connected to a wall mounted suction device and the pressure was set at -125mm Fig. Mode of Negative Pressure WoundTherapy (NPWT) was continuous. This dressing was changed

every 48 hrs. At any point of time during the study if the treating surgeon notices any adverse wound parameters, the VAC therapy was immediatelydiscontinued. In the control group conventional dressing was given. This consisted of placing a saline soaked gauze piece over the wound bed after cleaning the wound. Two layers of sterile gauze piece was placed on the dressing and secured with roller bandages. The dressing was changed daily and assessment of the wound was done every 48 hours by the treating surgeon for improvement or any adverse wound parameters. The outcome parameters were recorded in a specified proforma. Photographic documentation was also done at the start of the study and then followed weekly. Patients were assessed till satisfactory wound healing was achieved which is defined when the wound is completely filled with granulation tissue and is fit for split-skin grafting (SSG). Primary Outcome measure The time needed for satisfactory wound healing was calculated by the number of days from the start of the study till the wound was fit for grafting.

RESULTS

This study was a single-centre, prospective, parallel arm randomized control trial conducted in the Department of ,between and . 128 patients were assessed for eligibility to include in the study. 28 patients were having Wagner's grade of III or more and hence were excluded from the study. 14 patients were having associated peripheral vascular disease and three patients had osteomyelitis of the foot. Three patients had bilateral diabetic foot infection and 20 patients declined participation in the study. Following the assessment for eligibility,60 patients satisfying inclusion and exclusion criteria we enrolled into the study and randomized into two roups each with 30 patients each. Study group received VAC therapy while the control group received conventional dressing. In none of the patients in the control group, VAC therapy had to be discontinued. Three patients in conventional group and two patients in the VAC group withdrew consent from the study within the first week of therapy. One patient in the VAC group absconded during the second week of treatment and hence was excluded from the study, leaving 27 patients in each group for analysis at the end of the study.As a whole, demographic characteristics and factors which affect wound healing was comparable between the two groups The age distribution was noted to be normal in both the study and control groups with One Sample Kolmogorov-Smimov (KS) test showing a p-value of 0.125 and 0.150 respectively. The mean age in the patients who received VAC therapy was 55.85 years while those among patients who received conventional dressing was 52.89 years. The age between the two groups was compared using unpaired t-test, which showed no difference between the two groups with a p value of 0.359. Most of the patients were noted be in the ages between 40-60 years (55.6% and 77.8% in the study and control group respectively). Out of the 54 patients, 31 were male an23 were female. Of these 16 males and 11 females received VAC therapy, while 15 males and 12 female received conventional dressing. The gender distribution was uniform between the two groups with Pearson Chi test giving as p value of 0.783. Duration of diabetes in the two groups was also assessed and mean duration was found to be 7.29 years in the study group and 6.24 years in the control group. Overall the duration of diabetes in patients in the two groups was comparable with a p value of 0.462 by unpaired t test.Of the 54 patients included in the study, one patient had new onset diabetes mellitus and hence was not on any treatment for sugar control prior to hospitalization. 40 patients (74.1%) were on OHA, 11 were on insulin (20.4) and 2 were on both OHA and insulin (3.7%). In the study group, 1 patient was_newly diagnosed of diabetes, 20 patients were on OHAs, 5 on insulin and 1 on both OHA & insulin; in the control group 20 were on OHAs, 6 on insulin and 1 patient was on both OHA and insulin. This was comparable between the two groups with Pearson Chi2 test showing a p value of 0.779. Assessing comorbidities in the patients, 42 (77.8%) patients had no other comorbidities, 6 (11.1%) had HTN alone,2 (3.7%) had CAD alone, 3(5.6%) had both HTN & CAD and 1 (1.8%) patient had BA. Comorbidities were comparable in the two groups with a p value of 0.067. The mean BMI, haemoglobin, albumin and HbAlc in the study group was 22.99, 10.28, 2.77 and 8.74 respectively while in the control group it was 23.26, 10.18, 2.72 and 8.54 respectively. These parameters were uniform in the two groups with p values of 0.7780, 0.8163, 0.5287 and 0.6525 respectively. Distribution of Wagner grade 1 & 2 DFUs was unequal in the two groups; eight grade 1 DFUs were in conventional dressing group while only two grade 1 DFUs were in the NPWT group. However, the possibility that this distribution favour results in the NPWT group was unlikely as both these grades were superficial. Also, when the primary objective in the two groups was compared by stratifying on the basis of grade, results were n favour for NPWT for both Wagner grade 1 and 2 DFUs. Considering that size of the ulcer could affect the time to wound healing the patients in the groups were stratified as those having ulcers <10cm in longest dimension and those with ulcer >10cm in the longest dimension. A total of 21 of the 54 patients had ulcers >10cm, of these 11 were in the study group and 10 in the control group. Of the 33 patients with ulcer size <10cm; 16 were in the study group and 17 were in the control group. These numbers were comparable between the two groups with a p value of 0.780 as given by Pearson Chi2 test. Ulcer surface area calculated at the start of the study was normally distributed in both the patients receiving VAC therapy and conventional dressing. The mean surface areas were 70.97 cm2 and 80.44 cm2 in the study and control groups respectively; and comparable between the two groups with a p value of 0.5675 The primary objective of the study i.e. time to healing, was found to be significantly better in the study group with a p value of <0.0001. The mean and median time to healing were 22.52 days and 21 days respectively in the study group while these were 33.85 days and 34 days respectively in the control group. The maximum time to heal was 36 days and 55 days in the study and control groups respectively. The time to healing when compared between ulcers with sizes <10cm and >10cm between the study and control groups were also found to be significant. This was more pronounced in patients with ulcers <10cm where p value was found to be <0.0001 while in patients with ulcer size >10cm this was found to be <0.0042. The primary objective was also compared between the study and control groups with respect to grade. For Wagner grade 1 DFUs, the meanand median time to healing was 15.75 days and 15.5 days respectively in the NPWT group; while for the conventional dressing group these were both 30 days; and this was statistically significant (p=0.0361). Time to healing was even better for Wagner grade 2 DFUs in the NPWT group with mean and median values of 25.37 days and 27 days respectively, while these were 34.16 days and 36 days respectively in the conventional dressing group. 5As noted from table 3 the area of the ulcers reduced significantly in the patients who received VAC therapy when compared to those who received conventional dressing. The mean and median reduction in surface area of ulcers was 14.29 cm2 and 10.34 cm in the study group while in the control group it was 4.78 cm2 and 3.5 cm respectively. The p value calculated by Mann Whitney test was found to be very significant with a p value of <0.0001. Reduction in surface area of ulcer was significant when this was compared separately for patients with ulcer sizes <10cm and10cm between the study and control groups. This was found to be better in those with ulcer size >10cm where the p value was 0.0005, while this in the other group was 0.0018.

DISCUSSION

This study was a prospective parallel randomised control trial,conducted in the Department of between to ; to compare the efficacy and safety of Cost-Effective Vacuum Assisted Closure therapy versus conventional dressing in diabetic foot ulcer patients. A total of 128 patients with DFUs were assessed for eligibility, of which 60 patients fulfilled inclusion and exclusion criteria and gave consent. These 60 patients were randomized into two groups, 30 in each group; one received VAC therapy and one received conventional dressing for wound management. During intervention 5 patients withdrew consent, two in study group and three in the control group; one patient absconded, hence intervention was not continued in these patients and analysis was done for 27 patients in each group. The primary objective of the study was to compare the time to healing which was defined as the time taken for the wound to be fit for grafting. The other variables compared were reduction in surface are, granulation tissue formation, incidence of minor amputations & debridement and complications commonly attributed to VAC therapy as pain, bleeding and infection. All factors which affect wound healing were comparable between the two groups. Though Wagner grade 1 and 2 DFUs were not equally distributed in the two groups, their effect as a confounding factor was minimal considering few differences between the two groups and this was confirmed by comparing the primary objective between the two groups based on the Wagner grade.Time to healing was significantly less in the study group as compared to the control group (mean time to healing of 22.52 days vs 33.85 days respectively, p=<0.0001). When comparison between the two groups was Hone on the basis of Wagner's grade, this was also significantly less in the VAC therapy group with respect to both groups. For Wagner grade 1 DFUs, the mean time to healing was 15.75 days and 30 days (p=0.0361) in the study and control group respectively. For Wagner grade 2 DFUs this was 25.37 days and 34.16 days (0.0012)respectively. The reduction in ulcer area was significantly more in the VAC therapy groups with a mean reduction of 14.29 cm2 vs 4.78cm2compared to the control group (p=<0.0001).. Bleeding which is one of the most common and feared complication was comparable between the two groups with the

number of patient who had bleeding were 14 and 16 in the VAC therapy group and conventional dressing group respectively (p=0.584). Staphylococcus aureus was the most common organism group in the both roups. Other major organisms were Streptococcus spp, Pseudomonas aeruginosa and Escherichia coli. The number of patients with no growth (12 vs 11) and CONS (5 vs 4) was comparable between the two groups(p=0.783, 0.715 respectively). VAC therapy group demonstrated significantly less Gram-negative growth (10 vs 23, p=0.0003) and polymicrobial growth (8 vs 22, p=<.001). Thus, the results of the studied shows that VAC therapy is anefficacious and safe method of managing diabetic foot ulcers.

CONCLUSION

The present study showed that VAC therapy significantly decreases the time to complete wound healing when compared to conventional dressing. The study showed significant reduction in the ulcer size in the VAC group compared to the conventional dressing group and the reduction was more pronounced in the ulcer DFU of >10cm size.The present randomized controlled trial comparing VAC therapy with conventional dressing for DFU shows that VAC therapy is effective in reducing the time to complete wound healing and improving granulation cover with no increase in the complications such as bleeding and infection. Further RCTs with a larger number of patients is recommended toextrapolate the results of the present study.

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