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Original Research Article

Comparison of the mean healing time of wound after vacuum assisted closure versus conventional dressing in diabetic foot ulcer patients

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ABSTRACT

Background: Diabetic foot ulcers (DFU's) are chronic wounds in diabetics resulting from ischemia, angiogenesis defects and impaired immunity. Vacuum assisted closure (VAC) provides a new paradigm for diabetic wound dressing. This study compares the mean healing time of wound after VAC versus conventional dressing (CD) in DFU patients.
Methods: This randomized controlled trial carried out at surgery department, at tertiary teaching hospital over a period from 28th February-27th August 2020. Total 60 patients of age (25-75 years), both genders having DFU were included. Patients were placed randomly into two groups i.e., group A (VAC therapy) and group B (CD), by using lottery method. Mean healing time noted in both groups. For statistical analysis, SPSS version 20.0 was used. Independent 't' test used to compare the mean healing time of both groups and $p \leq 0.05$ considered significant. Effect modifiers were controlled through stratification and post-stratification independent 't' test, to see their effect on healing time. $P \leq 0.05$ was considered significant.
Results: The mean age of patients in group A was 53.13±9.09 years and in group B was 53.53±9.09 years. Out of 60 patients 41 (68.33%) were males and 19 (31.67%) were females. The mean healing time of wound in DFU patients after VAC closure (group A) was 12.07±2.15 days and after CD (group B) was 17.50±3.16 days with p=0.0001.
Conclusions: Study concluded that mean healing time after VAC is less in DFU patients as compared to CD.

Keywords: DFU, VAC, Healing time

INTRODUCTION

DFUs are chronic wounds in diabetics resulting from ischemia, angiogenesis defects and impaired immunity.[1] Different treatment modalities are available for treating DFUs.[2] Amongst them VAC provides a new paradigm for diabetic wound dressing.[3,4] Different studies concluded that DFUs treated with VAC are more likely to heal than CD.[5]

The average healing time varies greatly among different studies conducted. Therefore, we conducted this study to compare the mean healing time of wound after VAC and CD in DFU patients. Based on these results, the method with lesser healing time can be opted for our routine practice guidelines for DFU patient's management protocol.

METHODS

This randomized controlled trial was conducted at department of general surgery, at a tertiary teaching hospital, over duration of six months from 28th February 2020 to 27th August 2020. The calculated sample size was 60 i.e., 30 cases in each group, with 5% level of significance, 80% power of study and taking mean healing time with VAC therapy as 11.366±3.488 days and with conventional dressing as 16.41±3.104 days. 6

non-probability, consecutive sampling technique was used. The inclusion criterion of our patients was: 1. All patients with diabetic foot ulcer of >2 weeks duration, 2. Size of ulcer >3 cm, 3. Well controlled diabetes (HbA1C=6-8.3%), 4. Age 25-65 years and 5. Both genders.

While the exclusion criteria were: 1. Anemic patients (hemoglobin<10 g/dl), 2. Patients with history of steroid intake, 3. Patients with chronic renal failure (assessed on history and s/creatinine >1.5 mg/dl), 4. Patients with history of immunosuppressive therapy and 5. Ulcers involving bone as well.

After taking permission from ethical review committee and CPSP, total 60 patients who were presented in outpatient Department of Surgery, at a tertiary care hospital, fulfilling the inclusion criteria was selected. After informed, written consent, all selected cases were offered to pick up a slip from total mixed up slips (half-slips contained letter 'A' and other half-slips contained letter 'B') and he/she was placed in that respective group. In group A patients, VAC dressing was applied while in group B conventional dressing was applied. In patients undergoing vacuum assisted closure a drainage tube was placed in the wound followed by dressing with sterile foam sheet and application of occlusive transparent film over the whole assembly. The drainage tube was connected to a suction machine. Intermittent negative pressure of -125 mmHg was applied every 15 min; the suction was stopped for 10 min. The dressing was changed every 48 hours. In patients with conventional dressings, after wound wash, pyodine soaked gauze pieces were used for initial 48 hours followed by dressings of normal saline soaked gauze pieces, twice daily. All patients were followed regularly by the single researcher and mean healing time was noted in every patient of both groups. This all data (age, gender, duration of ulcer, and size of ulcer, BMI, and healing time) was recorded on a specially designed Performa designed beforehand.

All the data was entered and analysed by using SPSS version 20.0. The quantitative variables like age, duration of ulcer, size of ulcer, BMI and healing time were presented as mean and standard deviation. The qualitative variables like gender were presented as frequency and percentage. Independent 't' test was used to compare the mean healing time of both groups and $p \leq 0.05$ was considered as significant.

Effect modifiers like age, gender, duration of ulcer, size of ulcer, BMI were controlled through stratification and post-stratification independent 't' test was applied to see their effect on healing time. $P \leq 0.05$ was considered as significant.

While DFU was defined as all diabetic patients (having BSR>180 mg/dl) who have developed wounds involving skin and subcutaneous tissue on any part of the foot as assessed clinically. While healing time was measured in days. The start time was the application of first VAC and end time will be the day of wound healing (appearance of granulation tissue over wound as assessed clinically). BMI: was calculated by following formula; BMI=weight in kilograms (measured by weight machine)/height in meters^2 (measured by measuring tape) and >27 was taken as obese and ≤27 as non-obese.

RESULTS

Age range in this study was from 25 to 65 years with mean age of 53.33±9.01 years. The mean age of patients in group A was 53.13±9.09 years and in group B was 53.53±9.09 years. Majority of the patients 49 (81.67%) were between 46 to 65 years of age. Out of 60 patients 41 (68.33%) were males and 19 (31.67%) were females with male to female ratio of 2.16:1.

The mean duration of ulcer in group A was 4.67±1.18 weeks and in group B was 4.53±1.14 weeks. The mean size of ulcer in group A was 5.30±1.21 cm and in group B was 5.13±1.20 cm while combine size in both groups was 5.22±1.20. Mean BMI in group A was 28.70±2.69 and in group B it was 28.47±2.53 kg/m^2 while combine BMI was 28.58±2.60 kg/m^2.

In this study, mean healing time of wound in diabetic foot ulcer patients after vacuum assisted closure (group A) was 12.07±2.15 days and after conventional dressing (group B) was 17.50±3.16 days with p=0.0001.

Stratification of mean healing time between both groups with respect to age groups showed that among 25-45 mean healing time in group A was 12.00±3.16 days and in group B it was 16.83±3.06 days with a p=0.032while in 46-65 in group A it was 12.08±1.98 and group B it was 17.67±3.23 days with a p=0.0001which showed significant difference in mean healing time in all age groups among both groups. Statistically significant difference was also found among both genders in mean healing time, in males; group A it was 12.19±2.46 days and in group B it was 17.15±3.42 days with p=0.0001, similarly female; group A had mean healing time of 11.78±1.20 days and group B had 18.20±2.57 with p=0.0001.

Stratification of mean healing time with respect to duration of ulcer also showed significant difference among both groups and among duration of ulcer. Among patients who had ulcer for ≤4 weeks, group A patients had mean healing time of 11.87±2.03 days, while group B had mean healing time of 17.50±3.03 days, with statistically significant p=0.0001. While among those having ulcer longer than 4 weeks duration, their mean healing time in group A was 12.27±2.31 days and in group B it was 17.50±3.41 days with a p=0.0001.

Similarly, statistically significant difference was found in mean healing time in different size of ulcer among both

groups, patients who had ulcer size ≤5 cm their mean healing time in group A was 12.19±2.56 days while in group B it was 18.44±2.77 days with a p=0.0001. Those having ulcer size >5 cm, had a healing time in group A as 11.93±1.64 days and in group B it was 16.08±3.29 days with a p=0.0012. Stratification of mean healing time between both groups with respect to BMI, is shown in Table 1.

Table 1: Stratification of mean healing time with respect to BMI, (n=30).

BMI (kg/m^2)	Group A Healing time (days)		Group B Healing time (days)		P value
	Mean	SD	Mean	SD	
≤27	12.10	1.91	17.22	3.03	0.0001
>27	12.05	2.31	17.62	3.28	0.0001

DISCUSSION

VAC is a wound management technique that exposes wound bed to negative pressure by way of a closed system.[7] The application of VAC therapy to a wound provides a moist wound-healing environment which is the standard of care for wound healing.[7,8] This technique has been developed and popularized world-wide by prof. Louis Argenta and prof. Micheal Morykwas from the USA and by Dr. Win Flieschmann from Germany.[9] This form of therapy has been found to be effective for chronic open wounds (diabetic ulcers and stage 3 and 4 pressure ulcers), acute and traumatic wounds, flaps and grafts and sub-acute wounds i.e., dehisced wounds.[10]

VAC therapy facilitates rapid granulation of wounds and reduces bacterial colonization rates.[11] Complex effects at the wound-dressing interface following application of a controlled vacuum force have been documented. These include changes on a microscopic, molecular level and on a macroscopic, tissue level: interstitial fluid flow and exudates management, oedema reduction, effects on wound perfusion, protease profiles, growth factor and cytokine expression and cellular activity, all leading to enhanced granulation tissue formation and improved wound-healing parameters.[12]

The VAC technique is simple. It involves the application of an open - pore foam dressing to the wound. This foam dressing is then sealed using transparent adhesive drape. A negative pressure or suction force is then applied across the wound via a drainage tube embedded in the foam.[13] In a similar study performed in Los Angeles, U.S.A. on diabetic foot wounds, it has been observed that satisfactory healing i.e., 100% granulation tissue in the VAC. group was achieved in 22.8 (±17.4) days, compared to 42.8 (±32.5) days in the normal saline dressing group. Surface area changes of 28.4% (±24.3) average decrease in wound size in the VAC group, compared to a 9.5% (±16.9) average increase in the control group during measurement period.[14]

We have conducted this study to compare the mean healing time of wound after vacuum assisted closure versus conventional dressing in diabetic foot ulcer patients. Age range in our study was from 25 to 65 years with mean age of 53.33±9. 01years.The mean age of patients in group A was 53.13±9.09 years and in group B was 53.53±9.09 years. Out of 60 patients 41 (68.33%) were males and 19 (31.67%) were females with male to female ratio of 2.16:1. In this study, mean healing time of wound in diabetic foot ulcer patients after vacuum assisted closure (group A) was 12.07±2.15 days and after conventional dressing (group B) was 17.50±3.16 days with p=0.0001. In a study, the average time to complete ulcer closure was lower in VAC group (41.2 [8.5] days vs. 58.9 [14.5] days), a statistically significant difference (p=0.003).[15] In another study, patients with VAC therapy achieved healing in 11.366±3.488 days which was earlier than in conventional dressing group (16.41±3.104).[6]

In a case-control study, a total of 56 patients with DM and grade 2-3 DFU were randomly assigned to either VAC or conventional dressing.[1] The age of patients was between 47 and 64 years in group A with a mean age of 53.79 years and between 48 and 62 years in group B with a mean age of 54.57 years. Men constituted 35.71% and women around 64.28% in each group. By week 4, wound discharge disappeared in 44.4% of cases versus none in the control group. Wound discharge disappeared in two (7.4%) patients in group A, and seven (28%) in group B in week 8. Granulation tissue appeared in 26 (92.85%) patients by the end of week 2 in group A in contrast to 15 (53.57%) patients by that time in group B. 100% granulation was achieved in 21 (77.8%) patients by the end of week 5 in group A as compared to only 10 (40%) patients by that time in group B. Wound size decreased in 22 (78.6%) patients in group A as compared to 15 (53.6%) patients in group B. The majority of wounds in group A (81.8%) got closed in 5 weeks as compared to only 60% in group B in 8 weeks. One patient required amputation in group A as compared to three in the group B.[1]

In a prospective, randomized, clinical study, Mouës et al, observed that vacuum-assisted closure therapy was more effective in the management of infected wounds as it caused a faster reduction of wound surface area and faster formation of red granulation tissue within the wound than the conventional dressings.[16]

In a meta-analysis, total eight articles were selected.[17] The studies were found to be homogeneous. The eight studies included a total of 669 patients with DFU's. NPWT was found to significantly improve the proportion of healed ulcers compared with standard wound care (relative risk, 1.52; 95 percent CI, 1.23 to 1.89; p<0.001). In addition, there was a significant difference found in ulcer area reduction (p=0.003), time to wound healing (p=0.003), and reduction of major secondary amputation (p=0.006).[18] Eginton et al reported a 49% and 59% reduction in the wound depth and volume, respectively,

of 6 VAC-treated DFU's.[18] This was significantly greater than the 7.7% reduction in wound depth and 0.1% reduction in wound volume achieved when the same wounds were treated with moist gauze dressings.[20] However, when the wound area before and after VAC therapy was compared, Eginton et al found no significant reduction in the area. The greater reduction in wound dimension had been attributed to the three-dimensional stress which VAC exerted across.[20]

Blume et al carried a multicentre randomized control trial comprising of 342 patients.[21] Complete closure was assessed after a period of 112 days. Results showed that a greater proportion of foot ulcers achieved complete ulcer closure with VAC (73 of 169, 43.2%) than with advanced moist wound therapy (AMWT) (48 of 166, 28.9%) within the 112-day active treatment phase (p=0.007). Significantly more VAC patients (105 of 169, 62.1%) achieved 75% ulcer closure than AMWT patients (85 of 166, 51.2%; p=0.044).

Riaz et al studied-on total of 54 patients divided between group A (vacuum assisted closure therapy, VAC) and group B (saline dressing).[20] Patients with VAC therapy have achieved healing in 18±3.4 days while normal saline dressing group took 38±3.8 days in comparison. El-Marakbi et al studied 64 patients with diabetic foot infection. More patients healed on the VAC dressing than in the control group (68.7%) vs. (46.6%.[21]

Vikatmaa et al studied 14 RCTs and reported that in all trials, NPWT was at least as effective, and in some cases, more effective than the control treatment.[22] In a study, it was found that VAC therapy was more effective than conventional dressings in the wound bed preparation of DFU's. It resulted in healthier granulation tissue formation and decrease wound in all dimensions. VAC therapy appears to be more efficacious than conventional dressings in the preparation of diabetic ulcers.[23,24]

We observed that the patients on VAC therapy had the early appearance of granulation tissue as compared to the patients treated by moist saline gauze dressings. Complete (100%) granulation was achieved earlier and in a higher proportion of patients in group A as compared to group B.

CONCLUSION

This study concluded that mean healing time of wound after vacuum assisted closure is less in diabetic foot ulcer patients as compared to conventional dressing. So, we recommend that VAC therapy should be used routinely in DFU's for rapid healing which will in turn reduce the morbidity and improve the quality of life of these particular patients.

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