COMPARISON OF VACUUM ASSISTED CLOSURE VERSUS CONVENTIONAL DRESSINGS IN TREATMENT OF DIABETIC FOOT ULCERS

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ABSTRACT

Objective: To compare Vacuum Assisted Closure Versus Conventional Dressings in diabetic foot ulcers, in terms of mean number of days of wound healing.

Materials and Methods: This was a randomized control trial conducted from 02-10-12 to 02-04-13 in General Surgery Department, Federal Government Services Hospital Islamabad. A total of 120 patients were allocated into two groups by consecutive sampling (non propability) technique, enrolled from the Out Patient Department (OPD) and admitted patients.Patients meeting the inclusion criteria were randomly divided into two groups, Group A (Vacuum Assisted Closure therapy) and Group B (Conventional Dressings). All patients were put on antibiotics after debridement and blood sugar levels were kept optimal. Duration of wound healing was recorded in all patients.

Results: Patients in group A (Vacuum assisted closure therapy) achieved healing in 11.366 ± 3.488days which was earlier than in group B (conventional dressing) (16.41 ± 3.104) . Results were statistically significant with a P-value 0.000.

Conclusion: Vacuum assisted closure is better than conventional dressing in treatment of diabetic foot ulcers in term of mean number of days of wound healing.

Key words: diabetes, diabetic foot ulcer, suction dressing, mean no. of days of wound healing.

INTRODUCTION

Diabetes mellitus has become a global major health issue. Global prevalence of diabetes in 2003 was estimated to be 194 million.[1] Due to sedentary life style and dietary factors the incidence of this disease is on continuous rise.[2] Diabetes mellitus lead to numerous complications, out of which foot complication is the one that is encountered on surgical floor.[3] Foot complications include non-healing chronic ulcer and foot infection with or without an obvious ulcer. Diabetic foot infections are considered as the main cause of all non-traumatic amputation worldwide.[4]

Due to impaired immunity, malnourishment, simultaneous multi system involvement by diabetes, the management of diabetic foot is a challenging problem for clinicians.[5]In this part of the world where poverty and illiteracy predominates, the patients are not well aware of their disease and its complications. Patients come with very large and badly infected wounds which sometimes are life threatening due to spreading cellulitis or gas gangrene with high mortality rate.[6] These patients are malnourished and are usually anaemic. Due to disproportion between the health resources and the population, the patient disease process is further aggravated. Even once admitted for the management of diabetic foot their prolong admission cannot be tolerated. So managing these patients is even more challenging with such a level of resources and patient awareness.

Management of diabetic foot includes the assessment of ulcer grade and then proceeding accordingly. Grade I doesn't need hospital admission and Grade V would require limb amputation.The majority of diabetic ulcers present in grade II & III. After the assessment patients are administered antibiotics according to their C/S report once available, insulin on sliding scale and wound dressing.[7,8]

Dressing the diabetic foot wounds is important part in its management. Many studies had been conducted internationally to see the best dressing modality over the one that had been conventionally used in diabetic foot. Many new dressing techniques has been introduced out of which one newer technique is vacuum assisted closure also called negative pressure therapy/ dressing.[9,10] It was 1st introduced in 1993 at a School of Medicine in USA.[11] Many studies have been conducted to show its superiority over the conventional dressing

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while only few have shown conflicting results.

The advantages of vacuum dressing over conventional dressing are that it increases the local blood flow, hastens the granulation tissue formation, decreases tissue edema, reduces the exudate and bacterial load thus achieving quicker recovery.[12,13] All these effects make it more cost effective dressing technique.[14]

The vacuum dressing has newly been introduced in our hospital and it's still not widely practiced in most of hospitals locally. Although its efficacy has been well established by international studies but local data is scarce. Furthermore as discussed earlier the local condition differs from the affluent countries as most of patients are anemic, malnourished, less complaint to treatment and less aware of their disease status. For these reasons this study was conducted to see which dressing modality is more effective in achieving earlier healing.

MATERIALS AND METHODS

This was a Randomized controlled trail conducted in the General Surgery Unit I –Federal Government Services Hospital Islamabad from 2nd October 2012 to 1st April, 2013 (6 months duration). For this study total of 120 patients were allocated and randomly divided between groupA (Vacuum Assisted Closure therapy) and Group B (Conventional Dressings for wound closure). Sample size was calculated by using WHO sample size calculator taking level of significance 5 %, power of test 80 %, population standard deviation = 3.715, test value of population mean = 9.64 and anticipated population mean = 14.222.[11]Sampling was done byConsecutive sampling (non probability) technique. An inclusion criterion was all patients aged 20-65 years of age, either gender having Grade II – III Diabetic ulcers.Those patients with age less than 20 years or more then 65 years, patients with Grade I, IV and V diabetic ulcers, moderate to severe peripheral vascular disease (on Doppler studies), Hepatitis B and C (to avoid contamination of suction machine) were excluded from the study.Patients in both groups were administered insulin therapy according to their blood sugar levels and injectable antibiotics empirically initially and then according to the culture and sensitivity report. Necessary debridement and wound toilet will precede the application of dressings in both groups.

After obtaining approval from the hospital ethical committee, informed consent was taken from all the patients with all the relevant information. All patients who met the inclusion criteria presenting in Out-Patient and Emergency department of Federal Government Services Hospital having Diabetic ulcers, were selected for the study. The dressings were applied by a single selected team of surgeons. The patients were divided in two groups by lottery method.

1. Group A patients underwent Vacuum Assisted Closure therapy.

2. Group B patients underwent Conventional Dressings for wound closure.

Patients in both groups were administered with insulin therapy according to their blood sugar levels and injectable antibiotics started empirically initially and then according to the culture and sensitivity report. Necessary debridement and wound toilet done before application of dressings. 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 -125mmHg was applied every 15 minutes; the suction was stopped for 10 minutes. The dressing was changed every 48 hours.

For 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. Duration of healing was taken in days. Both types of dressings were applied on respective groups after their selection and all necessary information for performa were collected from both groups.

All the data was entered in SPSS for windows version 17. Mean and standard deviation were calculated for quantitative data like duration of wound healing and age. Frequency and percentages calculated for qualitative variables like gender. Comparison of duration of wound healing in both groups was analyzed by student t- test. A p-value < 0.05 was considered statistically significant.

RESULTS:

Out of total 120 patients studied (N=120) mean age of patients in group A (N=60) (vacuum assisted closure therapy) was found to be 55.45 with a SD of ± 6.279 and mean age of patients in group B (N=60) (conventional dressing for wound closure) was found to be 55.23 with a standard deviation of ± 6.220, which was statistically not significant as shown in table 1.

Out of total 120 patients studied (N=120) in group A (vacuum assisted closure therapy) 63.3 % were males and 36.7 % were females. In group B (conventional dressing for wound closure) 71.7 % were males and 28.3 % were females (table 2).

Mean duration of wound healing in days was found to be 11.366 with SD of ± 3.488 in group A while it was found to be 16.41 with a SD of ± 3.104. Healing was achieved in minimum of 5 days and maximum of 18 days in group A and minimum of 10 days and maximum of 22 days in group B. Mean duration of wound healing in the two groups (A and B) was compared using student t test. It was found that wound healing was achieved earlier in group A with a P-value of 0.000 which

Table 1: Age distribution in both groups

Variable	group A (vacuum assisted closure therapy) N=60 (Mean ± SD)	group B (conventional dressing for wound closure) N=60 (Mean ± SD)
Age (years)	55.45 ± 6.279	55.23 ± 6.220

Table 2: Gender distribution in both groups

Variable	Group A (vacuum assisted closure therapy) N=60	Group B (conventional dressing for wound closure) N=60
Gender	55.45 ± 6.279	55.23 ± 6.220
Male	38 (63.3%)	43 (71.7%)
Female	22 (36.7%)	17 (28.3%)
Total	60 (100%)	60 (100%)

Table 3: Duration of wound healing in term of mean no. of days

Variable	Group A (vacuum assisted closure therapy) N=60 (Mean ± SD)	Group B (conventional dressing for wound closure)N=60 (Mean ± SD)	P – value
Duration of wound healing (days	11.366 ± 3.488	16.41 ± 3.104	0.000

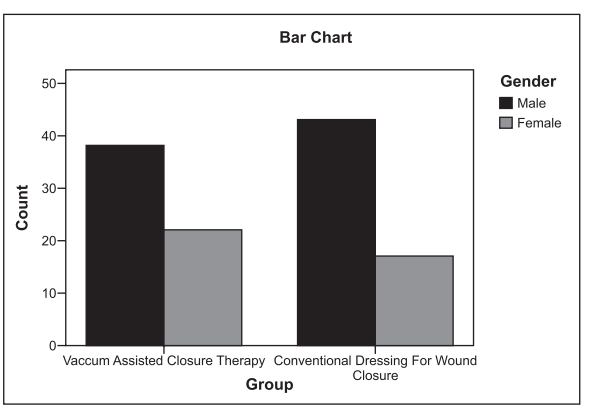

Figure 1: Gender distribution in both groups

is highly significant (table 3). So it can be concluded that significant number of patients in group A achieved wound healing earlier in comparison to group B.

DISCUSSION

Diabetes has become a major health problem globally. The main complication observed on surgical floor is diabetic foot infections and ulcers. It constitutes a major bulk of hospitalization and hence burden on hospital resources. Life time risk of diabetic foot ulcer is 15% and main cause of all non-traumatic amputation worldwide.[4] Healing in these patients is delayed due to multiple factors that increase their hospital stay and cause significant patient morbidity.

Achieving early healing in these patients is quiet challenging. It consists of antimicrobial agents, good glycemic control, correction of nutritional deficiencies and dressing. Dressing these wounds is important in achieving healing and multiple debates are done in literature regarding the best dressing technique.[5]VAC is generally well tolerated and with few contraindications or complications, is becoming very popular in wound management and care.[10]

Many studies have shown that vacuum dressing is superior over conventional dressing while few have shown conflicting results saying that there is no much difference in time of wound healing.Wanner and colleagues studied the effectiveness of vacuum dressing and compared with conventional dressing in patients with bed sores. They found no difference in days of healing in two groups.[15]Masden D and colleagues studied the effect of negative pressure on surgical closure mostly lower limb closure wounds in patients with multiple comorbidities. Eighty one patients were included in the study. 44 patients received vacuum dressing while 37 patients received conventional dressing. Overall, 35% of the dry dressing group and 40% of the negative pressure group had a wound infection, dehiscence or both and the results were statistically not significant.[16] Although this study negates the superiority of vacuum dressing but there was some important differences from our study. This study was conducted on freshly closed surgical wounds where surface area exposed to negative pressure is not widely open to be fully exposed to negative pressure while in our study it was all open wounds to make negative pressure more effective.

Mohammad Usman Riaz and colleagues studied on total of 54 patients divided between group A (vacuum assisted closure therapy, VAC) and group B (saline dressing). Patients with VAC therapy have achieved healing in 18±3.4 days while normal saline dressing group took 38±3.8 days in comparison.[17]The results were quiet significant and supported our study. Another study by Abdullah Etozon 45 patients with diabetic foot, the mean number of days of wound healing was 9.64 days ± 4.65 in the vacuum dressing group and 14.22 days± 2.78 in the control group (P =0.05)[11]comparable to our study.

Peter A Blume and colleagues conducted a similar study on 342 patients with a mean age of 58 years; 79% were male. They found that a greater proportion of foot ulcers achieved complete ulcer closure with NPWT (73 of 169, 43.2%) than with conventional dressing (48 of 166, 28.9%) within the 112-day active treatment phase (P=0.007).[12]Another study was conducted in India by Prabhdeep Singh Nain and colleagues on total of 30 patients with diabetic foot.Group A (VAC Dressing) promised better outcome (80% complete responders) as compared to conventional dressing Group B (60% complete responders).[13]

Ahmed El-Marakbi and colleagues studied 64 patients with diabetic foot infection. More patients healed on the VAC dressing than in the control group [68.7%] vs. [46.6%]. The rate of wound healing, based on the rate of granulation tissue formation and time to complete closure, was faster in the VAC group than in control group.[18]These results supported our study.

Present study was conducted to compare the effectiveness of vacuum dressing modality which was not routinely practiced locally with the conventional dressing using normal saline or pyodine guaze dressing in patients with diabetic foot. Patient age, gender and grade of the diabetic foot were comparable in both groups. Patients in both groups were administered insulin therapy and their blood sugar levels were well maintained. Choice of antibiotics was according to the C/S report of individual patients. It was observed that mean number of days in group A (VAC therapy) was lesser than in group B (conventional dressing). So in light of results of our study vacuum dressing technique can subsequently be employed as sole dressing technique in our hospital thus achieving quicker recovery, reducing patient morbidity and hospital cost.

CONCLUSION

This study has shown that wound healing of diabetic foot ulcer is affected by the choice of dressing. Wound healing as defined by appearance of granulation tissue over whole wound surface is achieved significantly earlier in vacuum assisted closure therapy group than in conventional dressing group.

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