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Research Article

COMPARISON BETWEEN THE EFFICACY OF VACUUM ASSISTED DRESSING VERSUS MOIST DRESSING IN TREATMENT OF DIABETIC FOOT ULCER

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Abstract:

Introduction: Foot infections are the most common cause of morbidity in patients with diabetes mellitus. The important triggering agent is minor trauma. Peripheral neuropathy is the commonest risk factor. Most are polymicrobial with gram positive cocci being the most common. Management involves multidisciplinary treatment.

Objective: To compare efficacy of vacuum assisted dressing versus moist dressing in treatment of diabetic foot ulcer.

Material and methods: A Randomized clinical trial in Surgical Department of P.O.F Hospital Wah Cantt, in which 64 patients with diabetic foot infections, from December 2014 to May 2015 were admitted and randomly divided in two groups with 32 each. Group A received VAC dressing and group B received moist wound dressing along with standard wound management. Efficacy was assessed on 02 weeks with presence of granulation tissue.

Results: Data was analyzed using SPSS version 18. Among VAC group mean age was 53.53 years as compared to 55.21 years in moist dressing group. Among all the patient 39 (60.9%) patients were male and 25 (39.1%) were female patients. All the patients included in the study presented with active ulceration of foot. The history of ulceration ranged from 02 to 37 days in VAC group and from 02 to 45 days in moist dressing group. Among all patients 24 had good glycaemic control while rest of 40 patients showed uncontrolled levels. All the patients of VAC group showed full recovery at the end of treatment however only 07 patients recovered in moist dressing group and rest of 25 patients required longer duration for recovery. Mean duration of treatment required for VAC group was 7.6 days with standard deviation of 2.40. However, it was a lot higher for moist dressing group which turned out to be 20.6 days with standard deviation of 6.80. After applying all the statistics especially chi-square test the results are significant as P value is 0.0001.

Conclusion: VAC is relatively a new technique to our part of the world. Vacuum aided wound closure method, provides faster and more comfortable treatment for all chronic wounds. VAC therapy should be encouraged by other institutes in Pakistan as well.

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INTRODUCTION:

Foot ulcers and their related further disabling complications are the most common difficulties of diabetes mellitus. 1 Diabetic foot ulcers (DFUs) are a chronic, non-healing complication of diabetes that lead to increased hospital costs and in extreme cases, amputation. Diabetic neuropathy, peripheral vascular disease, abnormal cellular and cytokine/chemokine activity are among the main factors that hinder diabetic wound healing. DFUs represent a current and important challenge in the development of novel and efficient wound dressings. 2 Patients with diabetes have at least a 25% lifetime risk of developing a foot ulcer. Many of these infections go on to amputation. 3 These patients have a 50% mortality rate in the 5 years following the initial amputation. 4 The optimal therapy for diabetic foot ulcers remains ill-defined. Saline-moistened gauze has been the standard method; however, it has been difficult to continuously maintain a moist wound environment with these dressings. This has led to the development of various hydrocolloid wound gels, which provided more consistent moisture retention. 5 Negative-pressure wound therapy (NPWT) is a well-known treatment modality for chronic, difficult, non-healing wounds. 6 NPWT can be safely applied in acutely debrided DDFI. The mechanism of this therapy is delivery of continuous subatmospheric pressure, through a specified pump, which is connected to the resilient, foam-surfaced dressing that collects the wound exudates. VAC therapy also provides a sterile, more controlled resting environment to large, exuding wound surfaces. 7 Large diabetic foot ulcers were thus made more manageable. No patient in the VAC group underwent major or minor amputation and (70%) patients were cured completely. Among the patients in the moist dressing group, (38.5%) and (7.69%) individuals underwent major and minor amputation, respectively, and only four patients (30.76%) had complete healing. 1 Currently, there are different types of commercially available wound dressings that can be used for DFU treatment which differ on their application modes, materials, shape and on the methods employed for production. Till today, very limited data is available on the role of negative pressure dressing in healing of diabetic foot ulcers. Therefore, we endeavor to put forward a study to evaluate the role of negative pressure dressing in healing of diabetic foot ulcers using VAC device and compare it with conventional saline soaked moist dressings in our target population.

MATERIAL AND METHODS:

A Randomized clinical trial in Surgical Department of P.O.F Hospital Wah Cantt, in which 64 patients with

diabetic foot infections, from December 2014 to May 2015 were admitted and randomly divided in two groups with 32 each. Group A received VAC dressing and group B received moist wound dressing along with standard wound management. Efficacy was assessed on 02 weeks with presence of granulation tissue. All patients with diabetic foot ulcer of both genders and having age from 40 to 60 years. Patients having duration of diabetic foot ulcer < 12 months were included in the study. All patients with renal failure if they were on dialysis, with history of poor compliance with medical treatments, receiving radiation therapy or chemotherapy and an ischemic ulcer that need any open or endovascular revascularization, were excluded from the study.

DATA COLLECTION PROCEDURE:

The study was started after taking approval from hospital ethics committee. Informed written consent was taken from each patient. Patients were randomly divided into two groups by using computer generated tables. One group received vacuum assisted dressing and the other received saline soaked moist dressing. The NPWT system used in this study was VAC therapy. This system consisted of two components, a negative pressure-generating unit with a disposable canister and a pad with an evacuation tube. The vacuum-assisted closure of this system unit is programmed to deliver controlled negative pressure up to 125 mmHg. Also, the suctioning and dressing were done simultaneously. In addition, the VAC dressing was changed once every three days. The moist dressing was performed twice daily after washing the ulcer with sterile serum and bandage. Elevation of wound was done every third day till two weeks by post graduate trainee for formation of granulation tissue and findings were documented in predesigned perfoma and the number of days at which full granulation tissue appear were calculated. During whole procedure blood sugar control were maintained by insulin and monitored by BSF and BSR.

DATA ANALYSIS PROCEDURE:

The data was entered in SPSS version 20. Descriptive statistics were used to calculate means \pm standard deviation for age, duration of foot ulcer and number of days for formation of granulation tissue. Frequencies with percentage were calculated for gender and efficacy. Chi-square test was used to compare the two groups in term of efficacy. P value < 0.05 was considered significant. The effect modifiers like age, duration of foot ulcer, diabetes mellitus, control of diabetes mellitus and gender was controlled by stratification. Post stratification chi-square test was applied keeping P value \leq 0.05 as significant.

RESULTS:

During the study period 64 patients were enrolled in the study; 32 were allocated to VAC group (Group A) and 32 were allocated to Moist dressing group (Group B). The age distribution among the two groups was found to be similar. Among VAC group mean age was 53.53 years as compared to 55.21 years in moist dressing group. In VAC group range was from 44 to 62 years and in moist dressing group it was from 45 to 68 years.

Among all the patient 39 (60.9%) patients were male and 25 (39.1%) were female patients. Results showed similar duration of diabetes for both groups. In VAC group patients were having diabetes diagnosed for 13 years on average, ranging from 06 years to 21 years of history of diabetes. In moist dressing group duration of illness was 12.3 years on average, ranging from 4 years to 24 years.

All the patients included in the study presented with active ulceration of foot. The history of ulceration ranged from 02 to 37 days in VAC group and from 02 to 45 days in moist dressing group. On average history of ulceration for VAC group was 12 days as compared to 10 days for moist dressing group. The nature of

disease control after daily medication was observed by HbA_{1c} level which is significant marker of long term glycaemic control. The results showed that among all patients 24 had good glycaemic control while rest of 40 patients showed uncontrolled levels.

All the patients of VAC group showed full recovery at the end of treatment however only 07 patients recovered in moist dressing group and rest of 25 patients required longer duration for recovery. In VAC group patients showed recovery in minimum of 04 days as compared to minimum of 09 days for moist dressing group. Similar results were seen concerning maximum duration of days of treatment required for full recovery of the patient. It was 32 days for moist dressing group as compared to 12 days for VAC group.

Mean duration of treatment required for VAC group was 7.6 days with standard deviation of 2.40. However it was a lot higher for moist dressing group which turned out to be 20.6 days with standard deviation of 6.80. After applying all the statistics especially one sample T test the results are significant as P value is 0.0001 which is less than 0.05 so the results are significant.

TABLE No. 1: Demographic Profiles Of Patients In Two Groups

Parameters	VAC Group	Moist Dressing Group
Age of patients	53.53+3.80	55.21+5.76
Duration of Diabetes	13+3.87	12.31+5.33

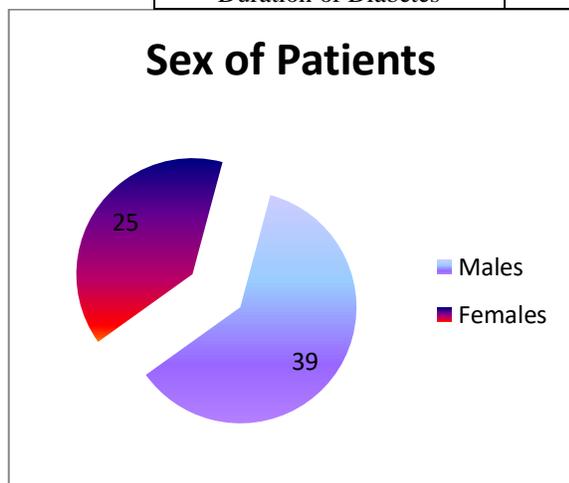


Figure No. 01: Sex Distribution of Patients

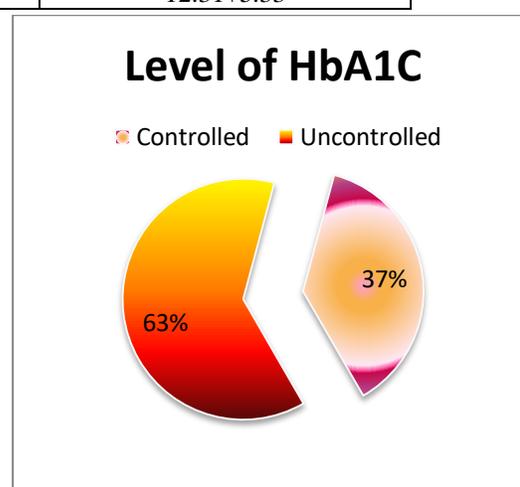


Figure No. 02: Level of HbA_{1c} in both groups

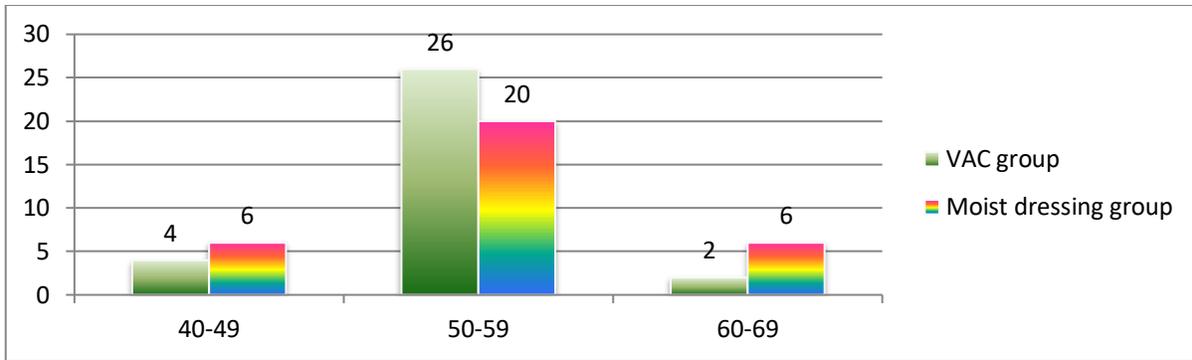


Figure No. 03: Age Distribution of Patients in Both Groups

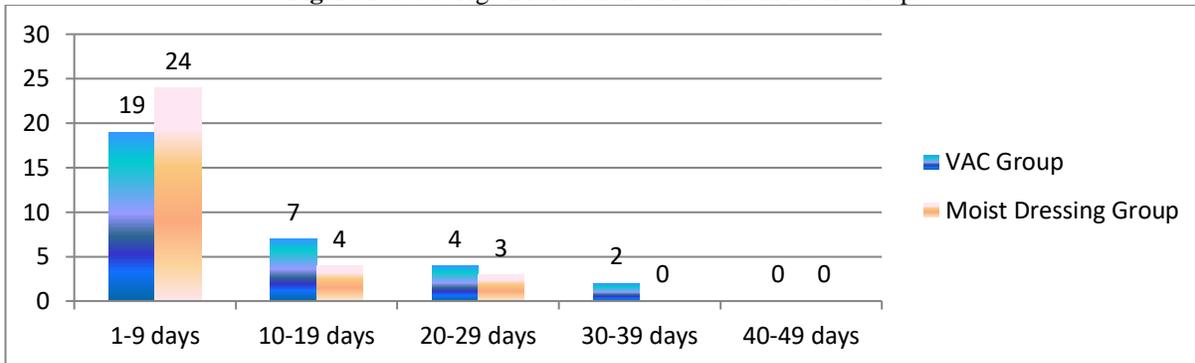


Figure No. 04: Duration of Ulceration in Both Groups

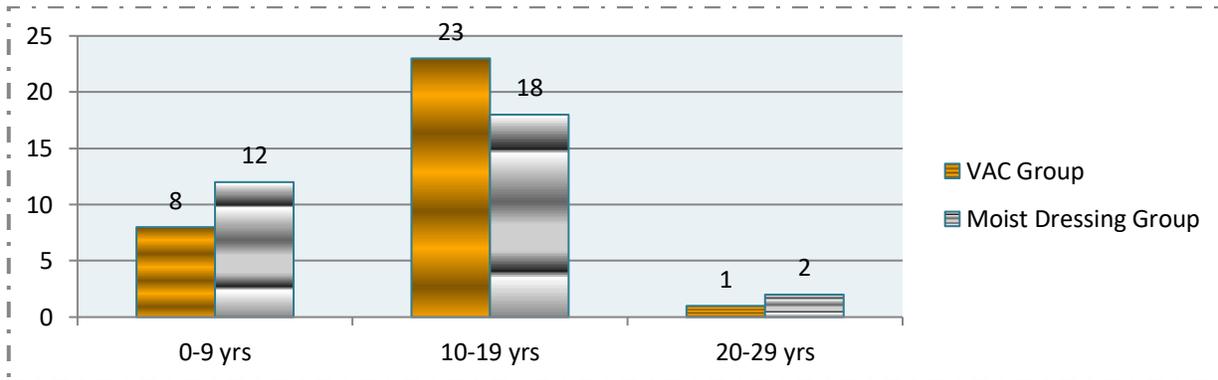


Figure No. 05: Duration of Diabetes in Both Groups

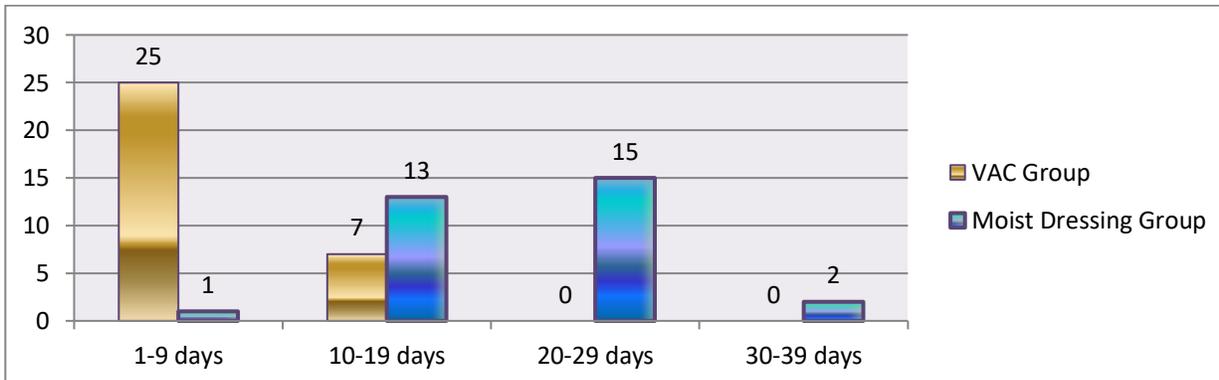


Figure No. 06: Number of Days required for Recovery of Patients in Both Groups.

TABLE No. 2: recovery data of patients in two groups

Parameters	VAC Group	Moist Dressing Group
Duration of Ulceration	11.96+8.85	9.93+9.03
Number of days to Recovery	7.62+2.43	20.62+6.79

DISCUSSION:

Vacuum treatment as a method that has been used in the past, for superficial tissue losses such as burns and pressure injuries, it has found new areas of use in severe soft tissue losses associated with orthopedic infections, diabetic foot as well as tumor surgery, in recent years.^{91,92} For those injuries that require long term administration of antibiotics and special techniques such as free tissue transplantation, care is a complicated process.⁹³

VAC therapy provides an occlusive environment which increases the rate of granulation, reduces edema, bacterial colonizations and reduces the pain caused by the wound. It has been suggested that successful healing correlates with less than 10^5 organisms per gram of tissue. The number achieved with wound VAC therapy is usually less than 10^3 .⁹⁴

Chronic wounds are one of the main causes of hospitalization of patients in surgical departments resulting in high cost for management, utilization of resources and man power. Still wounds don't respond to conventional methods of dressings. VAC therapy has revolutionized the management. In a study of 1500 general body trauma patients by Kaplan et al which is the most extensive series in its class, VAC therapy was shown to decrease the time and cost of hospitalization to almost the half.⁹⁵ Recently a randomized controlled trial comparing VAC with modern wound dressings for leg ulcer has been carried out by Vuesstaek et al.⁹⁶ The VAC proved superior with respect to the time to complete healing and wound-bed preparation time compared with conventional wound care.

For acute open wounds, NPWT is associated with a reduced time to wound closure.^{97, 98} As an example, one trial randomly assigned 54 patients with open wounds to receive either NPWT or moist saline dressings.⁹⁸ Similar results were seen in our study as the time required for recovery was far less for VAC group i.e. mean duration of 7.6 days as compared to moist dressing group which showed mean duration of 20.6 days. Similar results were seen concerning maximum duration of days of treatment required for full recovery of the patient. It was 32 days for moist dressing group as compared to 12 days for VAC group.

One multicenter trial randomized 342 patients with diabetic foot ulcers (stage 2 or 3 Wagner ulcers, and

adequate vascular perfusion) to negative pressure wound therapy or moist wound therapy (ie, hydrogel, alginate).⁸³ All ulcers were debrided (as needed) within two days of randomization, and the majority of the patients also received off-loading therapy. The primary endpoint was wound closure. A significantly greater percentage of patients treated with negative pressure wound therapy achieved wound closure within the 16 week timeframe of the study compared with alternative medical therapy (43 versus 29 percent). The negative pressure wound therapy group also demonstrated significantly fewer amputations compared with the alternate medical therapy group (4 versus 10 percent).

Another multicenter trial followed 162 diabetic patients for 16 weeks following partial foot amputation.⁸⁴ The percentage of patients with healed wounds (56 versus 39 percent) and time to complete closure (42 versus 84 days) were significantly improved in patients randomized to vacuum-assisted wound closure group compared with the control group. VAC therapy was reported in the treatment for open abdomen, and it promotes rapid wound healing and helps manage costs.⁹⁹

A large multi-centre RCT was developed to clarify the role of NPWT in the management of diabetic foot wounds following partial amputation up to the trans-metatarsal level. 162 patients were enrolled and randomly assigned to either NPWT or moist wound therapy post-operatively. Results revealed that significantly more patients healed in the NPWT group (56% vs 39%, $p=0.04$). The time to heal was also faster in the NPWT group ($p<0.005$), and was associated with faster granulation tissue formation ($p=0.002$).⁸⁴ A retrospective case-control study compared NPWTi to gentamycin beads in the treatment of post-traumatic osteomyelitis. The study demonstrated significantly reduced rates of infection recurrence in the NPWTi group (10%) compared to the control group (59%). Whilst preliminary reports regarding this novel therapy are encouraging, there is a distinct lack of robust evidence supporting it. A prospective randomized trial including NPWT, NPWTi and standard dressings has yet to be completed.¹⁰⁰

Recent advances in NPWT have focused on the practical aspects of its use and the development of ultraportable, single use devices such as the PICO™ system (Smith & Nephew Medical Ltd, Hull, UK). This modality is very new and the research supporting it is

sparse. One prospective non-comparative study of 20 patients with high risk surgical wounds was undertaken to see if such devices were safe and effective.¹⁰¹ All but one patient was recorded as having a wound that had healed or was healing at two weeks.

CONCLUSION:

VAC is relatively a new technique to our part of the world. It is very effective in promoting healing. Surgeons in all fields treat complicated wounds. Healing by secondary intent can be a prolonged, labour-intensive process often requiring longer hospitalisation. vacuum aided wound closure method, provides faster and more comfortable treatment for all chronic wounds including diabetic foot, sternal and spinal wounds, infected wounds, degloving injuries after RTA, plastic surgery and orthopaedic surgery wounds and bed sores. VAC therapy is easy to apply, safe and cost-effective method with very good results so application of VAC therapy should be encouraged by other institutes in Pakistan as well.

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PERFORMA

S.no: _____ Hospital no: _____

Name of patient: _____

Age: _____ years,

Sex:

- Male
- Female

Duration of foot ulcer: _____

Duration of Diabetes Mellitus: _____ yrs.

Hb A₁C levels: Controlled rolled

Type of bandage 1 Vacuum Dressing _____

 2 Moist Dressing _____

No of days at which granulation tissue appear _____

Complete healing of the wound (Efficacy):

- Yes
- No