THE EFFECTIVENESS OF VACUUM ASSISTED WOUND CLOSURE (VAC) IN DIABETIC FOOT

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ABSTRACT

OBJECTIVES: To determine the mean healing time of vacuum assisted wound closure in diabetic foot ulcer patients.
STUDY DESIGN: An interventional case Series.
PLACE AND DURATION: Department of General Surgery, The Royal Oldham Hospital, Oldham, U.K from 1st September 2012 to 30th March 2013.
METHODOLOGY: All patients with diabetic foot ulcer of any size and duration were included in the study that fulfills inclusion criteria. Patients were subjected to VAC dressing which involved the controlled application of sub-atmospheric pressure to the local wound environment, using a sealed wound dressing connected to a vacuum pump. Patients were followed by disappearance of exudates and appearance of granulation tissue and the time of healing of wound.
RESULTS: Among 40 patients studied, 45.0% were between 41 to 50 years of age with male to female ratio was 1.6:1. The mean duration of diabetes in patients was an average of 14 ± 5.65 years. Duration of diabetic foot was 24 ± 6.0 and initial average wound area was 50.6 ± 27.6cm^2. After VAC therapy, the wound area ranged from 3.4 to 92.35 cm^2, the average area being 41.75 cm^2. The actual reduction in wound area attained by VAC therapy varied from 3.4 to 38.6 cm^2, with an average reduction of 11.4 ± 4.55 cm^2. The percentage reduction in wound area ranged from 10.3% to 62.11%, with an average reduction of 27.9 ± 13.7%. Wounds were healed after VAC therapy for an average of 21.75 ± 10.55 (range, 14 to 40) days.
CONCLUSION: VAC therapy is very effective and useful in the treatment of diabetic foot and ulcers and has an effective role in promotion of proliferation of granulation tissue, reduction in the wound size and healing of wound in lesser time.
KEYWORDS: Diabetes Mellitus, Diabetic Foot, Vacuum Assisted Closure (VAC), Wound area, Healing time.

INTRODUCTION

Diabetic foot is one of the major complications of diabetes mellitus, that can be difficult to treat and may require amputation if treated improperly[1]. Diabetic foot occurs in 15-25% of all diabetic patients and between 14% to 20% of these patients undergo amputation [2,3]. Majority of lower leg amputations (84%) are due to diabetic foot[2]. The risk of amputation is higher if the ulcer is infected or having ischemia. With multidisciplinary team approach, 80–90% of amputations due to ischemia and 95% with infection could be prevented[3,4].

The optimal and ideal management for diabetic foot still remains ill-defined and varies from wide range of traditional dressing, debridement, antibiotics[5,6] to saline-moistened dressings with equivocal results. Alternatively, various types of hydrocolloid, alginate dressings, wound gels and dressings are used which provided more consistent moisture retention but these dressing have equivocal results[7,8]. Similarly, use of antibiotics along with topical ointments and dressings containing growth factors and enzymatic debridement compounds are effective but proved not ideal in treatment of diabetic foot[9]. Alternatively, hyperbaric oxygen and culture skin substitutes have also been recommended. All these treatments are being utilized in some situations but are costly and without sufficient scientific evidence of their efficacy[10,11]. Due to this reason, the search for a therapy which is convenient, efficacious and cost-effective therapy continues[12]. To fulfill this criteria advanced moist wound therapy (AMWT), bioengineered tissue or skin substitute and Negative Pressure Wound Therapy (NPWT), or Vacuum Assisted Closure (VAC) therapy is also used to treat diabetic foot[9,13,14].

Professor Louis and Micheal from the USA invented the VAC therapy at the wake Forest[15]. The VAC therapy is a therapeutic technique which promotes wound healing by using a vacuum dressing after debridement over exposed tendon, fascia or bone[13]. In this technique, controlled sub-atmospheric pressure is applied to the wound environment by using a sealed wound dressing which is connected to a vacuum pump [16,17]. It promotes wound closure by producing mechanical effects and also promoting the granulation tissue formation in the wound. This is achieved by removing the excessive exudates[18].

The technique of VAC therapy is simple which involves the application of dressing which is open - pore foam over the wound. The dressing is then sealed by using a adhesive, transparent drape and then the drain is connected to the pump with a tubing. After sealing the dressing, the vacuum pump is adjusted to deliver intermittent or continuous negative pressures varying between -125 and -75 mm Hg[18].

VAC has been used by researchers and appraised as well, but the healing time varies greatly among different authors[10,14,19]. Therefore, keeping in mind all the above facts, We have

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conducted this study to determine the healing time of wound after vacuum assisted closure in diabetic foot ulcer patients. The objective of the study was to determine the mean healing time of vacuum assisted wound closure in diabetic foot ulcer patients.

METHODOLOGY

This case series study was conducted at General Surgery Department, the Royal Oldham Hospital, Oldham, U.K. from 26th September 2012 to 25th March 2013. Through Non-probability purposive sampling patients were selected for study. The inclusion criteria comprises of all diabetic patients of either sex between 30-70 year of age presented with diabetic foot ulcer of any size and duration, with well controlled diabetes (HbA1C=6-8.3%). Exclusion criteria comprises of patients with osteomyelitis. anemia (Hb% <10mg/dl), macro vascular diseases, patients with any chronic disease i.e. chronic renal failure, chronic liver disease and malignancy on any part or organ of body. Diabetic patients taking steroids for any other illness like asthma etc.

After approval from ethical committee, patients presented in the emergency and outpatient department fulfilling the inclusion/exclusion criteria were admitted after taking informed consent. The demographic data, relevant history, duration and size of the wound were noted. Blood sample of every patient for serum sugar levels and urine sample for presence of any sugar were sent.

After necessary wound debridement, vacuum assisted closure dressing applied to the wound. In debridement all infected and necrotic tissue excised thoroughly till bleeding healthy tissue. The wound was then thoroughly irrigated by jet levage. After debridement, a sealed wound dressing connected to a vacuum pump to provide sub-atmospheric pressure to the local wound environment. The application entailed placing a polyurethane foam dressing over wound defect. Adhesive drape was applied over the foam and over the additional 3 to 5 cm of surrounding normal skin. About 1 to 2 cm long slit was made in the drape and a non-collapsible tube connected to electronic vacuum pump was directly placed over the drape hole. Finally, negative pressure was applied to the wound via vacuum pump which collapses the dressing into the wound. A continuous or intermittent (5 min “on”, 2 min “off”) negative pressure of -125 mmHg was applied to the wound. If patient complains of pain or continuous bleeding was observed from wound, then a continuous pressure of about -75 to -100 mmHg was applied alternatively. The VAC dressings were kept for up to 120 hours. The dressing was changed after every 24 to 48 hours in the ward by the registrar or trained medical officer. The wound was carefully examined to assess weather the wound is clean, healthy and granulating or not. Patients were then followed on outdoor basis for any exudates, granulation tissue formation and time of healing. This all data was recorded on a specially designed performa.

DATA ANALYSIS PROCEDURE

All information was analyzed through SPSS 16. Mean and standard deviation was calculated for quantitative variables i.e. age, size of wound, duration of wound, duration of Diabetes mellitus and time of healing. Frequencies and percentages were calculated for qualitative variables i.e. sex and site of wound. Effect modifiers like age, wound size and duration of wound and duration of Diabetes mellitus were controlled through stratifications. Post stratification chi square was applied to see their effect on outcome and p value = 0.05 was considered significant.

RESULTS

A total of 40 patients were included in the study. Among them 62.5% (n=25) were male and 37.5% (n=15) were females with male female ratio of 1.67:1. Age range was from 30 to 70 years with mean age of 50 ± 9.75 years. Majority of the patients (45.0%, n=18) were between 41 to 50 years of age as shown in Table- I. Majority of patients (67.5%,n=27) were presented with Type II diabetes mellitus and 70.0% (n=28) patient were on insulin and remaining 30.0% (n=12) was on oral hypoglycemic drugs.

During treatment the negative pressure applied continuously in 92.5% (n=37) patients and intermittently in 7.5% (n=03) wounds. A pressure of -125 mmHg was applied in majority (70%, n=28) wounds followed by a pressure of -75 mmHg in 10 (25%) wounds. The frequency of VAC dressing change was after 24-48 hours for 75% (n=30) wounds, every 72 hours for 15% (n=06) and every 24 hours for 10% (n=04) wounds. Majority of patients (92.5%, n=37) does not require additional debridement during the course of VAC therapy (Table-II).

Table –III shows that the duration of diabetes in patients ranged from 2 to 25 years with an average of 14 ± 5.65 years. The average duration of wound was 24 ± 6.0 (range, 12 to 40) days and average size of ulcer was 50.6±27.6 cm^2 (range, 5.6 to 104 cm^2. Average reduction in wound area observed was 11.4 ± 4.55 cm^2 (range, 3.4 to 38.6cm^2) and the average time of healing observed was 21.75±10.55 days (range, 14 to 4 days). Table –II shows that the initial average wound area which was 50.6±27.6 cm^2, reduced to average size of 11.4 ± 4.55 cm^2 after VAC therapy.

TABLE-I: AGE AND SEX DISTRIBUTION (n=40).

Age (years)	MALE		FEMALE		TOTAL	
	No. of Patients	%age	No. of Patients	%age	No. of Patients	%age
31-40	05	12.5	02	5.0	07	17.5
41-50	10	25.0	08	20.0	18	45.0
51-60	07	17.5	05	12.5	12	30.0
61-70	03	7.5	00	0	03	7.5
Total	25	62.5	15	37.5	40	100

TABLE-II: DESCRIPTIVE STATISTICS FOR DIFFERENT VARIABLES BEFORE AND AFTER TREATMENT. (n=40)

	Minimum	Maximum	Mean	SD
Age(years)	30	70	50	9.75
Duration of Diabetes(years)	02	25	14	5.65
Duration of Wound(days)	12	40	24	6.0
Size of Wound(cm2)	5.6	104	50.6	27.6
Reduction in Wound Area(cm2)	3.4	38.6	11.4	4.55
Time of Healing (days)	14	40	21.75	10.55

TABLE-III: DETAIL OF VAC TREATMENT (n=40)

Modality of Treatment	Detail	No of Patients	Percentage
Negative pressure	Continuous	37	92.5%
	Intermittent	03	07.5%
Pressure applied	-150mmHg	02	05%
	-125mmHg	28	70%
	-75mmHg	10	25%
Change of Dressing	After 24hrs	04	10%
	24-48 hrs	30	75%
	48-72 hrs	06	15%
Additional debridement	No	37	92.5%
	Once	02	05%
	Twice	01	02.5%

DISCUSSION

Prevalence of Diabetes is rapidly increasing worldwide and along with other complications the diabetic feet is the commonest, leading to surgical intervention and prolong hospitalization[20].

Negative Pressure Wound Therapy (NPWT) is a newer noninvasive adjunctive therapy system that uses controlled negative pressure using Vacuum-Assisted Closure device (VAC) to help promote wound healing by removing fluid from open wounds through a sealed dressing and tubing which is connected to a collection container[21]. The intent is that negative pressure in the wound will cause quick reduction in swelling, wound cleansing and improvement circulation. Hence, the wound healing processes (granulation and epithelialization) will accelerate[13,21]. An advantage of vacuum assisted closure therapy is that the wound needs to be dressed every second or third day instead of daily, as is the case with conventional treatment.[14,15] VAC is generally well-tolerated with few contraindications or complications.

The mean age of patients in our study was 50 ± 9.75 years. Different multicenter trial and studies shows that the diabetic foot is more common in 6th decade of life[10,13,14,22]. Literature review shows slightly higher male prevalence which is also observed in our patients (1.6:1) and may be due the fact that male are more involvement in active and manual work, they are more prone to trauma leading to diabetic foot[1,10,20,22]. The mean duration of diabetes in our patients is more (14 ± 5.65 years) while different studies shows upto10.2 years[1,13,14] This is probably due to the control of diabetes and awareness about the complication of disease in their respective population.

The VAC therapy is particularly effective in the treatment of

large diabetic foot ulcers. The average surface area of wounds in our patients was 50.6 cm^2. In our patients the wound size was 2 to 3 times larger than the average wound area of 20.7 cm^2 reported by Armstrong [23] but comparable to the study reported by Nather et al[13]. All studies conclude that VAC therapy obviated the need for daily dressing change in large ulcers. This has advantage of obviating the problem of daily dressing, which may be painful, difficult to perform regularly and may lead to more fluid loss[13,22,23].

VAC therapy has reported to cause significant reduction in wound size as compared to the conventional dressings. A 49% and 59% reduction in wound depth and volume has been reported by Eginton et al in literature[24]. This is significantly greater than the reduction in wound depth (7.7%) and volume (0.1%) treated with moist gauze dressings[22,24]. At the other end, Eginton et al have reported no significant reduction in wound area after VAC therapy[24]. In our study, we found 11.4 ± 4.55 cm^2 of reduction in wound size which is almost comparable with the studies by Nain et al[13] and Nather et al[10] (i.e.16.14 cm^2 and 10.1 cm^2 respectively). Some studies reported greater reduction in wound area (up to 28%) as compared to our study[5,13,23,25].

Another advantage of VAC therapy reported in literature is that it encourages the wound healing by stimulating the granulation tissue formation. Morykwas et al[26] reported that more granulation is produced if wound is treated by continuous or intermittent negative pressure as compared to the wounds treated with conventional dressing[25]. Another additional benefit of VAC therapy observed is to alleviate the wound infection. The Morykwas et al, has reported a significant reduction in bacterial load in chronic wounds after application of VAC therapy by the 5th day[26].

The VAC therapy completed from 14 to 40 days, (average 21.75 ± 10.55 days) in our patients which is consistent with other studies[5,14]. Literature review shows that this time is significantly less than the average time taken by Armstrong et al (32.9 days)[23] and Clare et al (57.4 days)[27]. This study is consistent with the study conducted by Armstrong and colleagues who had observed that VAC therapy is safe and effective in complex diabetic foot wounds and could lead to faster healing rates, high percentage of healed wounds and potentially fewer re-amputations as compared to the wounds treated through standard care.

Nonetheless, in our study we observed that after only few days of VAC treatment, a well cleansed and healthy granulation tissue were achieved, even among those patients who have very little or absent granulation tissue at the time of enrolment in study. The presence of granulation tissue is critical in determining the further changes in therapeutic approach and the clinical decision to promote the wound closure first or second intention, skin grafting or with bioengineered autologous / heterologous tissues[7,19].

CONCLUSION

VAC therapy is very effective and useful in the treatment of diabetic foot infection and ulcers and has a definitive role enhancing granulation tissue formation, wound size reduction and healing of wound in lesser time.

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