The Effect of Vacuum Assisted Closure Dressing Technique versus Conventional Dressing on Diabetic Foot Wound Healing

Hend Abdel Monem Elshenawie, Lecturer
Medical Surgical Nursing, Faculty of Nursing, Alexandria University

Soheir Weheida, Professor
Medical Surgical Nursing, Faculty of Nursing, Alexandria University

Aziza El Said, Teacher
Medical Surgical Nursing, Institute of Nursing, Alexandria University

Abstract

Diabetic foot ulcers affect millions of people in all the world and impose tremendous medical, psychosocial and financial loss. They also represent a major use of health resources, incurring costs not only for dressings, but also staff costs (for podiatrists, nurses, doctors), tests and investigations, antibiotics and specialist foot wear. Therefore, nurses need up to date knowledge concerning managing wounds with using appropriate strategies to control infection, promote wound healing and prevent recurrence to ensure successful out comes for those patients. Negative pressure wound therapy (NPWT) is generally well tolerated and appears to stimulate a granulation tissue response compared with other wound healing modalities. This device may be a cost-effective adjunctive wound healing therapy. ***Objective:*** *Determine the effect of vacuum assisted closure dressing technique versus conventional dressing on diabetic foot wound healing**:** the present study follows aquasi-experimental research design*. ***Setting:*** *The study was conducted at Diabetic Foot Care Unit of Alex University and Royal Vascular Center*. ***Subjects:*** *The study was conducted on a convenient sample of 40 patients, who were divided into two sequential groups. One group received VAC dressing while the other group received conventional saline moistened gauze dressing.* ***Tools:*** *Tool I: Diabetic Foot Wound Assessment Structural Interview Schedule and Tool II: Wound Healing Assessment Observational Checklist.* ***Results:*** *There was a statistically significant difference in the rate of appearance of granulation tissue between the two groups; with granulation tissue appearing earlier in the study group. The study group promised a better outcome as compared to the control group*. ***Conclusion:*** *Using of VAC therapy yield improved wound healing in comparison to their control in patient with diabetes mellitus more over the majority of studied patients who had faster and more effective wound healing*. ***Recommendations:*** *Study of the effect of VAC therapy on infected diabetic wound healing VAC therapy should be used in all grades of diabetic foot wound*.

Keywords: Vacuum Assisted Closure Dressing, Diabetic Foot.

Introduction

Diabetes is increasingly becoming a major chronic disease burden all over the world. The cost of treatment of the various complications of diabetes is increasingly higher. This requires a shift in healthcare priorities in all regions of the world to help plan and prioritize health programs. Diabetes mellitus is a serious health problem because of the associated glucose-related complications of the disease, including the specific 'microvascular' complications such as retinopathy, nephropathy and neuropathy. Coupled with this, insulin resistance increases the risk of macrovascular complications including cardiovascular, cerebrovascular and peripheral arterial disease (PAD) as well as neuropathy which can occur separately, or

in combination. Foot ulceration is reported to affect 15% or more of people with diabetes mellitus M at some time in their lives[1,2]. Estimates of the prevalence of foot ulceration vary, but around 1% to 4% of people with diabetes mellitus have foot ulcers at any given time[3,4]. A person with diabetes mellitus in receipt of US Medicare, the prevalence of the presence of least one foot ulcer was 8%[5].

The particular combination of peripheral neuropathy and peripheral vascular disease contributes to the development of foot ulceration, which may lead to surgical debridement or amputation of the foot or lower limb. Diabetic foot disorders such as ulceration, infection and gangrene are the most common complications associated with the disease. The most superficial wounds, has a complex in its treatment and is often with poor healing responses and high rates of complications[6,7], which leads to no healing, or difficulty to treat. Moreover, diabetic foot wounds are significant considered risk factors for non-traumatic foot amputations for individuals with diabetes. No doubt, foot wounds in people with diabetes mellitus have a serious impact on health related quality of life, particularly with respect to physical functioning and role limitations due to physical and emotional issues[7].

The Wagner wound classification system was one of the first described and has, historically, been widely used, although it is now rarely used in clinical practice. This system assesses ulcer depth and the presence of osteomyelitis or gangrene and graded them as: grade 0 (pre- or post-ulcerative lesion), grade 1 (partial/full-thickness ulcer), grade 2 (probing to tendon or capsule), grade 3 (deep with osteitis, grade 4 (partial foot gangrene) and grade 5 (whole foot gangrene)[8].

Wound healing is a highly or chestrated process, which commences with getting rid of debris and combating infection. Inflammation clears the area for angiogenesis to occur to increase blood flow to the wound site. Subsequently, the wound heals through deposition of granulation tissue, wound contraction and maturation. When one of these steps fails, the wound is unable to heal[6,9].

Foot wounds in people with diabetes mellitus have a serious impact on health-related quality of life, particularly with respect to physical functioning and role limitations due to physical and emotional issues[10,11]. They also represent a major use of health resources, incurring costs not only for dressings, but also staff costs, time tests and investigations, antibiotics and specialist footwear.

The risk of lower limb amputation is much greater for people with diabetes mellitus than for those without. The major underlying pathophysiology associated with amputation is neuropathy and ischemia. Lower limb amputation can have devastating consequences for people's health status and health-related quality of life[12], as well as having a large financial impact on healthcare providers and users. In the UK, from the beginning of April 2007 to 31 March 2010, a total of 16,693 lower limb amputations were recorded in people with diabetes mellitus[13]. Of these 10,216 were classed as minor amputations (usually defined as below the ankle joint), and 6,477 as major amputations (usually defined as above the ankle joint). The UK cost of 'foot procedures related to diabetes or arterial disease and procedures to amputation stumps' was estimated at approximately GBP 17 million over 2009/10. In the US, the 2008 prevalence of lower extremity amputation in Medicare recipients was 1.8%, with a total mean annual Medicare reimbursement cost for each person with diabetes mellitus and a lower extremity amputation estimated at USD 54,000. Ulcers are often considered to be chronic wounds, whilst post-surgical amputation sites are considered to be acute wounds, unless they do not heal[14].

Standard wound management consists of initial surgical debridement, which is a rapid and effective technique to remove devitalized tissue, then dry or moist gauze dressings can be used to cover the wound,[6] which need to be changed frequently. These dressings are relatively inexpensive, readily available and easy to apply. However, there have some disadvantages: non-selective debridement with dressing removal and possible wound desiccation[15].

Amputation debridement is regarded as an important component of the treatment of 'chronic' foot wounds, such as ulcers or non-healing surgical wounds. It can sometimes be undertaken as a surgical procedure. Debridement involves removal of dead tissue and callus along with pressure-relief/off-loading as well as treatment of infection and revascularization, where necessary. As in other areas of wound care, sharp surgical debridement of diabetic foot wounds is recommended in order to promote wound healing by 'converting' a chronic wound to an acute wound via removal of dead tissue and slough[16]. While this practice is common, there is little evidence that surgical debridement promotes healing of diabetic foot wounds[17,18], but debridement of necrotic tissue with eschar from wounds, can sometimes be a priority to the use of wound treatments such as negative pressure wound therapy (NPWT).

The nurse plays an important role in wound healing and the total care of the patient, coordinating activities with other disciplines such as occupational and physical therapy. So, optimal care of the WOUND requires a distinctive multidisciplinary approach. Positive patient outcomes are dependent on the composition of the wound care team and close collaboration among its members. At the center of this team is the nurse, the coordinator of all patient care activities. At the same time, the nurse is also a specialist in wound care. As a wound heals, either spontaneously or through excision and grafting, the nurse is responsible for wound care and for noting changes that require immediate attention, prevention of infection and pain management[19].

The key for successful wound care depend on nurses who should have the critical skills as well as the abilities to plan strategies for patient care staring with patient assessment on admission to patient to discharge plan. The nurse is considered the corner stone for promotion of wound healing through assessing the patient conditions, planning patients care, and providing efficient care for respiratory and circulatory systems maintaining mobility, restoring the patients emotional and physical capacity, providing, wound care and preventing of infection through using the efficient method for wound healing less costly by using vacuum assisted therapy[20,21].

Vacuum assisted closure (VAC) therapy is a noninvasive, closed system that applies negative pressure to wound tissue. The vacuum assisted closure (VAC) therapy was first reported in 1990s. It has revolutionized the clinical management of the wounds[22]. It acts by removing excess tissue fluid from the extravascular space, which promotes microcirculation during the early stages of inflammation. Vacuum therapy induces increased peripheral blood flow and improves local oxygenation[23]. It promotes angiogenesis, endothelial proliferation, the integrity of the capillary basement membrane, and stimulates granulation tissue, decreasing interstitial edema and bacterial colonization[24].

The technique of vacuum therapy is very simple; a piece of foam with an open cell structure is introduced into the wound and a wound drain with lateral perforation is laid on top of it then, the entire area is then covered with a transparent adhesive membrane, which is firmly secured to the healthy skin around the wound margins. When exposed end of the drain tube is connected to a vacuum source, fluid is drawn from the wound through the foam

into a reservoir for subsequent disposal. The plastic membrane prevents the ingress of air and allows a partial vacuum to form within the wound, reducing its volume and facilitating the removal of fluid, the foam ensures that the entire surface area of the wound is uniformly exposed to this negative effect, prevents occlusion of the perforations in the drain by contact with the base or edges of the wound and eliminates the possibility of localized areas of high pressure and resultant tissue necrosis[25].

Vacuum assisted closure (VAC) therapy is used as treatment used to promote healing in acute and chronic wounds by applying negative pressure to the wound bed. These NPWT devices work through application of a disposable, open-cell antimicrobial gauze dressing with a non - adherent contact layer or foam dressing to the wound base, which is covered with a semi permeable film drape or transparent adhesive film dressing. An evacuation tube embedded in the dressing is connected through an adjustable vacuum pump to remove effluent to a remote collection container. Microprocessor controls can be programmed or varying pressures and cycles of constant and intermittent suction. The application of sub atmospheric pressure to the dressing results in multiple benefits including: increased local blood flow via enhancement of capillary blood flow increased angiogenesis with profuse granulation formation, increased number of active fibro blasts and macrophage, enhanced epithelial cell migration; decreased bio burden at the same time, the nurse is also a specialist in wound care. As a wound heals, either spontaneously or through excision and grafting, the nurse is responsible for wound care and for noting subtle changes that require immediate attention, prevention of infection and pain managements, bacterial toxins, and subsequent, cessation/delay of healing and decreased tensile strength of the wound, as well as decreased harmful, chronic wound fluid and by - products and subsequent senescent cells and tissue damage[26].

Finally, uses of Vacuum assisted closure (VAC) therapy system reduce cost, time consumed and promotes wound healing by delayed primary or secondary intention through creating a moist wound environment, preparing the wound bed for closure, reducing edema, and promoting formation and perfusion of granulation tissue[27].

Aim of the Study

The aim of the study was to determine the effect of vacuum assisted closure dressing technique versus conventional dressing on diabetic foot wound healing on diabetic foot wound healing.

Research Hypothesis:

Diabetic foot wound managed by the VAC technique will demonstrate faster healing lesser infection rates as well as wound healing compared to who managed conventionally therapy.

Materials and Method

Materials

Design: A quasi experimental research design was utilized in this study.

Setting: The study was conducted at the Foot Ulcer Care Unite the Main University and Royal Vascular Center Alexandria.

Subjects: A convenience sample of 40 diabetic patients were included in the study, they were divided into two equal groups: study and control group 20 patients in each group:

Study group (I): the study group exposed to vacuum assisted closure dressing technique by the researcher.

Control group (II): the control group exposed to hospital conventional dressing technique

Inclusion criteria for the diabetic patients were as follows[6,9]:

1. Adult 21-60 year.

2. Patients able to communicate.
3. The patient has either 2nd 3rd, 4th degree diabetic foot wound infection.
4. Patients were selected according to certain wound ulcer criteria; (superficial, involving only the epidermis, the skin appears dry and erthematous without blister and sensitive to air) which are considered as characteristics of grade II, III, IV foot ulcer[6].
5. The patients free from any associating feet deformities: by checking feet for presence of hallux valgus, hammer toes.
6. The patient body mass index were calculated by measuring patients height and body weight then use the equation; BMI[29].
7. Under-weight patients; Less than 20-24 Kg is considered below ideal body weight and excluded from the study, this is indicated for nutritional status so that will delay healing process[6,9].

Tools: Two tools were used for this study purpose:

Tool I: Diabetic Foot Wound Ulcer Assessment Structure Interview Schedule

This tool was developed by researcher after reviewing of related literature to assess the diabetic wound area[28]. It comprised two parts:

First Part:

Biosocio-demographic data for patient which included information's related to age, sex, occupation, marital status and education. Clinical data included onset of ulcer, ulcer site, grade of obesity using BMI (patients weight (in kg) Grade (0) BMI 20 - 24.9 Kgm/m2= desirable weight, Grade (1) BMI 25-29.9 Kgm/ m2=over weight, Grade (2) BMI 30-39.9 Kgm/m2=obese, Grade (3) BMI 40 and over Kgm/m2=morbid obesity and patients height (in meters), lab investigations (serum fasting blood glucose level, post prandial blood glucose level, complete differential blood count (CBC), date of admission , vital signs, type of diabetes and medication used [29].

Second Part:

This part included Foot and wound assessment: to identify initial foot and wound assessment.

It included two sections namely:

A- Data related to Foot:

These data comprised:

1- Foot Sensation; these items were assessed according to the following categories: Sensitive to touch, pain**,** skin temperature: (hot, cold) and manipulation.

2- Pulsation: pulse in dorsalis pedis (DPP), posterior tibial (PTP).

3- Callus color (red, pink, brown, pale).

4- Formation of callus (thick, skin).

5- Presence of dryness.

6- Presence of fissure.

7- Presence of deformities such as hallux valgus, hammer toes.

B- Wound assessment:

These sections included;

1- Number of ulcers.

2- Site: plantar surface of1st, 2nd, 3rd, 4th, and 5thtoe, and whether Sole or Heel ulcer or both.

3- Size in centimeters using a ruler[28].

4- Depth of wound (floor) this was measured a percentage out of a total (Epithelial tissue covering the surface and granulation tissue; type and amount)[8,28].

- The Wagner wound classification system was one of the first described and has, historically, been widely used, although it is now rarely used in clinical

practice. This system assesses ulcer depth and the presence of osteomyelitis or gangrene and graded them as: grade 0 (pre- or post-ulcerative lesion), grade 1 (partial/full-thickness ulcer), grade 2 (probing to tendon or capsule), grade 3 (deep with osteitis, grade 4 (partial foot gangrene) and grade 5 (whole foot gangrene)(8).

5- Surrounding area necrotic tissues (Margin); these areas were examined for absence or presence of the following: tenderness, redness, hotness, swelling**.**

Tool II: Wound Healing Assessment Observational Checklist

This tool was developed by the researcher after reviewing of related literature to evaluate the effect of dressing techniques on the healing process of diabetic foot wound within 4week; which means every week check healing process by Wound healing observation check list, it included 4 parts: (28)

First Part: Wound healing observation check list:

It contained the following items:

• Complete healing formations which is indicated by presence of healthy granulation tissue covered by migration and proliferation of epithelial cells within the wound space and formation of scar tissue

• Partial healing formation which is indicated by presence of healthy granulation tissue within the wound space or decrease of wound size without formation of scar tissue.

• Incomplete healing: which are detected by absence of improvement in wound characteristic, no scar tissue formation s or unhealthy granulation tissue.

Second Part: Abnormal findings of the diabetic wound healing assessment.

The wound was assessed in relation to the following criteria:

1- Clinical signs of wound infection: redness, hotness, painful sensation, unhealthy cells, tenderness, edema, and maceration, change color of the wound exudates or discharge. **Types of exudates** "Bloody: thin bright red; Serosanguineous: thin watery, pale red to pink, Serous: thin, watery, clear. Purulent: thin or thick opaque to yellow, Foul purulent: thick, opaque yellow to green". **Amount of exudates** "Scanty, Small, Moderate and Large“ color, **Odor** “absent, present".
2- Moist granulation tissues.
3- Increased of surface area measurements.
4- Absence of healing epithelial edges.

Third Part: Wound culture (Swab):

Swab culture was performed to patient in the study group and control group (2 groups), whenever signs and symptoms of infection occur.

Fourth Part: Photographic pictures:

Photographic pictures were taken to compare wound healing process before and after dressing for both groups in order to determine diabetic wound healing progress.

Method

1. Permission to carry out the study was obtained from the directors of the study settings (Diabetic Unit and Vascular Unit) and Royal vascular center after explaining the aim of the study.
2. The tools were developed after reviewing related literature.
3. The tools were tested for content validity by five experts in the field of Medical-surgical Nursing and vascular surgery specialists. The needed modifications were introduced.
4. Reliability of the tool (1) and tool (2) were tested using test retest method for fifty patients.
5. Written patients consent for participation in the study was obtained after informing the patients about the purpose of the study.

6. A pilot study was carried out on 5 patients in Diabetic Unit to test applicability & feasibility of the developed tool.
7. Patients were assigned to either to the study group or the control group according to inclusive criteria. The first 20 patients were assigned to the study group whereas the other 20 patients were assigned to the control group. Matches of patients in both groups were done related to biosocial demographic characteristics such as age, sex, and ulcer size and body mass index (BMI).
8. At initial assessment of patients condition were done for both groups using Tool I:

- First part: This assessment was concerned with biosocial demographic characteristics.
- **Body mass index was** calculated by measuring each patients height and body weight then using the equation; BMI =weight /height =Kg/m^2 this calculation was done to determine the grade of obesity[30].
- **Diabetic wound Assessment**: This assessment was carried out using Tool I- second part which included:

A- Identifying the diabetic wound site:

Wound site was identified by dividing the foot into dorsum, plantar of toes, plantar of metatarsal heads, sole, heel, medial and lateral aspect of foot.

B- Measuring wound size in centimeter:

These measurements were carried out following as follow as:

Steps:

- Using standard precautions perform hand hygiene, put on sterile gloves.
- Moist a sterile flexible applicator with saline
- Mark the point on the swab applicator with surrounding skin then grasp the applicator with thumb and forefinger at the point corresponding to the wound margin. Remove the swab applicator and measure the size with ruler.

C- Assessing the surrounding area of the diabetic wound for:

Signs of inflammation as redness hotness, tenderness and swelling, skin condition as moist or dry.

D- Measure the depth of the foot ulcer:

The researcher observing the depth, or thickness if the ulcer is superficial (epidermis) or partial thickness or skin loss that involve epidermis and /or dermis **by using** sterile cotton swab applicator inserted into the deepest point of the wound and marking it at the skin surface level then the swab applicator is measured by using ruler.

E- Assessing Floor of diabetic wound:

The presence of granulation tissue or necrotic tissue or exposure to tendon was recorded[32,33].

F- Assessment of abnormal findings of wound healing:

- Clinical signs of wound infection these signs included: as redness, hotness, painful sensation unhealthy cells, tenderness, swelling, maceration, cellulites, edema, and eczema).
- Foot ulcer exudates (type, amount and odor).
- Assessment of neurovascular condition included[34]:

a- Neuro Sensation: Assess feet sensation to touch, pain and manipulation:

- Assess sensation to touch by asking the patient to close his eyes and the researcher touch the dorsal and plantar surface of the patients feet by the palm, then the patients was asked about the article that touching his feet to know his feet sensation.
- Assess sensation to pain by asking the patient to close his eyes and the researcher used blunt point object such as metal object which moved on planter and dorsal surface of the patients feet then the patient was asked to express his feeling for pain or no feeling of pain.
- Assess sensation to manipulation by asking the patient to close his eyes and manipulate his/her big toe away from the second toe upward and downward position, the patient is asked to point in what direction was the toe moved, if his answers immediately, so his sense for position is intact, but if he hesitated or do not know the direction of the toe, so his sense to manipulation considered absent.

b- Assess circulation of patient's feet:

Palpating the pulse at dorsal is pedis and posterior tibial arteries.

c- Assess the temperature of patient's feet[(35)]:

Palpating using palm of the hand temperature of the involved patient's feet was assessed with other feet to reflect the efficiency of arterial circulation. Also, the patient was asked about his feet temperature during hot weather (worm or cold).

d- Assess any abnormalities in the patient's feet: This assessment was done through observation of the condition of the skin for normal skin, dry or moist, for presence of callus (thick skin), and colure, (red, pink, brown or pale) as well as presence of dryness.

9. Assessment of wound area was done using Tool I –second part and by photo graphic at the initial meeting using Tool II- fourth part.
10. Dressings were done by the researcher for both groups as follows: (Appendix III).

- The study group: The patients in the study group were managed by VAC at dressing room using the following steps:

1. Wash hands with soap and water and dries it well then wears the sterile gloves to prevent cross infection.
2. Clean the wound are with normal saline using antiseptic technique.
3. Debridement of the wound was done by removing dry skin around the wound area; dead tissue was removed by scalpel and forceps till floor of wound bleeds.
4. Washing the wound area by normal saline 0.9%.
5. Clean the area around the wound with normal saline solution 0.9%.
6. Dry the wound.
7. Study group subjects were dressed by VAC therapy dressing technique once daily till healing occurs or discharge of patients (2week or 4week-). A sterile open cell sponge is placed in the wound, a tube is passed through it then sealed with an adherent film, and sub atmospheric pressure is applied by suction machine or

Redivac. This dressing was changed every 3 days.

Wound swab cultures for microorganisms were obtained before dressing and weekly there after till the end of VAC therapy.

The control group: patients in the control group were exposed to the hospital conventional dressing technique which included: the same previous steps but applying (povidon-iodin) solution on the wound then covering the area with gauze to help hold the gauze in the place and to absorb drainage[31].

Steps followed by the researcher before performing the dressing for both groups:

A-preparation of the environment:

Maintain clean hygiene environment in dressing room.

Keep windows and doors at the dressing room closed to prevent air drafts.

B- Preparation of the equipment:

Equipment were prepared for the two dressing techniques included disposable mask, disposable gloves, plastic bag, tap measure, camera, scissor, artery forceps, antiseptic solutions, scalpel blade, cotton sponge gauze, dressing and Elastoplast bandage.

C- Preparation of patients:

- Explain the procedure to the patient.
- Place the patient in a comfortable position.
- Place a water resistant pad under the leg.
- Set up disposable plastic bag in a suitable location to the wound.

Steps followed at the end of dressing:

- Clean all used equipment used.
- Supplies are wasted.
- Wash hands to prevent cross infection (while the patients still in hospital).

Evaluation:

Frequency of evaluation:

Wound culture:

According to the steps as following: (for both groups):

- Wash hands with soap and water and dry well then wear the gloves before culture procedures to prevent cross infection.
- Expose the wound area.
- Using the cotton – tipped applicator swab and collect as much exudates as possible from the center of the lesion.
- Place the swab immediately in the appropriate tube, transport culture tube and send to laboratory, labeled clearly with name of patient, date room number, bed number specifying anatomic part from where the specimen was obtained.
- Record any abnormality if occurred.

11. Calculate the frequency of wound healing and performance of dressing in each dressing technique which performed once daily until healing occur.
12. Collection of data was done through a period of 10 months from the beginning of March 2014 to end of December 2014.

Ethical considerations:

Confidentiality and privacy of patient's data were asserted. Participation in the study was voluntary, with the patient right to withdraw at any time.

Statistical Analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), means and, standard deviations. Comparisons between groups for categorical variables were assessed using Chi-square test and Fisher's Exact or Monte Carlo correction. Significance of the obtained results was judged at the 5% level[36].

Results

Table (1) illustrated that of patients according to their socio demographic variables. For group II it was 12 (60%) were male and females were 8 (40%) while in group I there males were 15 (75%) and females were 5 (25%).

Age from 18-25 in conventional group was 12 (60%) and from 26-35 was 8 (40%). In VAC therapy, age from 18-25, and from 26-35 was the same 10 (50%).

Regarding education, half of the patients were illiterate 10 (50%) in conventional group II and 9 (45%) read & write in group I. Regarding, the most frequent number was manual workers 14 (70%), 16 (80%) in both group respectively.

Table (2) shows distribution of patients of both group study and control according to Type of diabetes, treatment received and body mass index. Type of diabetes NIDDM was higher in both study groups control 17(85%), 16(80%) respectively, treatment with hypoglycemic agents was higher in both study groups 14(70%), 15 (75%) respectively.

Normal body mass index was higher in both study groups 11(55%), 12(60%) study and control groups respectively. There was no statistical significant difference regarding to type of diabetes, treatment and body mass index (P>0.05).

Table (3) shows comparison between the two studied groups according to wound assessment. Regarding **site of ulcer**, heel was higher in conventional occlusive dressing group 7(35%) and in VAC therapy dressing group, plantar surface 1st metatarsal head 5(33.3%) was higher. There was statistical significant difference between the two studied groups according to site of ulcer (P<0.5).

Size of ulcer was 2-4 cm was 10(50%) and 11(55%) in both group control and study respectively and size > 4-6 cm was 10(50%) and 9(45%) in both group respectively. Grade III, IV was higher in both group 7(35%), 6(30%) and 7(35%), 7(35%) respectively.

Regarding color of callus, read pink was higher in both group control and study 7(35%), 8(40%) respectively and present dryness was higher in both groups control and study 17(85%), 16(80%) respectively. Present fissure was higher in both groups with the same number 16(80%).

There was no statistical significant difference between the two studied groups according to size of ulcer, depth of ulcer, color of callus, dryness and fissure (P>0.05).

Table (4) shows percentage distribution of patients of both group control and study according to bacterial wound culture according to bacteriological culture results before dressing, positive cases was higher in conventional groups 12(60%), respectively. while in VAC group lower. There was statistical significant difference between two studied groups and bacterial wound culture (P>0.05).

Table (5) shows Percentage distribution of patients of both group according to wound morphology and sign of infection at 3 different intervals (1-3 weeks) according to wound morphology and sign of infection per weeks. There was no statistical significant difference between the conventional occlusive dressing and VAC gloves groups of diabetic foot ulcer

according to wound morphology and sign of infection per weeks (P>0.05).

Table (6) shows distribution of patients of both groups according to wound healing during hospital stay period. There was statistical significant difference regarding wound healing after second week, after third week and before discharge (P<0.05).

Table (7) shows mean and standard deviation according to, cost of dressing and time consumed until complete healing. Cost of dressing in conventional group ranged 437.00–969.00 with mean value 715.65±166.93 and in VAC group ranged 338.00–699.50 with mean value 508.93±130.59. Time consumed in conventional group ranged 76.0–120.0 with mean value 94.07±6.20 and in VAC group ranged 19.0–55.0 with mean value 42.49±7.68.

Discussion

The role of negative pressure dressing (VAC) in healing of diabetic foot ulcers has been proposed as a novel method of manipulating the chronic wound environment in a way that it reduces bacterial burden and chronic interstitial wound fluid, increases vascularity and cytokine expression and to an extent mechanically exploiting the viscoelasticity of per wound tissues[37]. VAC is generally well-tolerated and, with few contraindications or complications, is fast becoming a mainstay of current wound care. Hence study aim to determine the effect of vacuum assisted closure dressing technique versus conventional dressing on diabetic foot wound healing on diabetic foot wound healing.

The demographical profile was statistically studied and found with no significant difference between the two groups. The mean age of patients in study group was the same the study findings done by and which was comparable to the multicenter randomized controlled trial enrolling 342 patients done by Blume et al. (2005)[38] who had a mean age of 58 years. The sex distribution was also similar to the above quoted study that had 75% males.

The result revealed that there was a decreasing trend in the presence of wound discharge in both the groups. However, it was noted that the rate of disappearance of wound discharge was faster in the study group as compared to the control. Only less than half of patients in study group had discharge after third week as compared to zero% of patients in control group. This could be attributed to the faster rate of wound closure in the study group. In a similar study conducted by Tamhankar et al. (2009)[39] in patients which were treated by VAC therapy, it was seen that VAC therapy allows salvage of infected exposed mesh by clearing the purulent discharge promoting granulation tissue formation.

Application of negative pressure over wound bed allows the arterioles to dilate, so increasing the effectiveness of local circulation, promoting angiogenesis, which assists in the proliferation of granulation tissue[40]. Also found that the patients on VAC therapy had earlier appearance of granulation tissue. Of all the patients who initially did not have granulation tissue, half of those in the study group promised its appearance by the end of 2nd week as compared to minority of the control group and this was also found to be statistically significant (P<0.05). Shrestha et al. (2007)[41] found in their prospective study of nine patients of renal transplantation wound infections following Renal Therapy, progressive reduction in the size of wound and development of healthy granulation tissue in all the cases.

Furthermore there were a statistically significant difference in the percentage change in the wound size between both the groups (P<0.05). The mean decrease in the wound size was more in the study groups compared to the control group. Current study is consistent with McCallon et al. (2000)[42] who had observed average decrease in wound size in the VAC group as

compared to average increase in wound size in control group. Mark Eginton et al. (2003)[43] had also observed that the wound volume and depth decreased significantly in VAC dressings as compared to moist gauze dressings 59% vs. 0% and 49 % vs. 8%, respectively.

On the other hand the result indicated that patients of study group showed rapid clearance of bacterial load as compared to control group. This was suggested less than half of the cultures in study group having no growth by 3rd week as compared to 20% in control group. The decrease in the bacterial load could have been attributed to the antibiotic regimes administered during the study. Hence we were unable to eliminate this bias. However, S. aureus was found to be most prominent in the study group whereas cultures from control group mostly showed mixed growth and Acinetobacter. Correlates with the study by Moues et al. (2004)[44] observed that non fermentative Gram-negative bacilli showed a significant decrease in vacuum-assisted closure-treated wounds, whereas S. aureus showed a significant increase in VAC-treated wounds.

Although statistically the time of wound closure was comparable in both the groups (P>0.10), it was seen that the study group showed faster rate of wound closure as compared to control group. McCallon et al. (2000)[42] also observed satisfactory healing in VAC group in 22.8±17.4 days, compared to 42.8±32.5 days in control group.

The endpoint taken was a granulated wound or a wound ready for skin grafting or healing by secondary intention spontaneously whichever was earlier. Both the groups had received similar treatment for the closure of wound, the most common mode of wound closure being. It was also observed that the failure rate was higher in patients of control group as compared to study group. Current study correlates with the study conducted by David Armstrong et al. (2005)[37] they had observed that NPWT delivered by VAC device was safe and effective treatment for complex diabetic foot wounds and could lead to higher proportion of healed wounds, faster healing rates and potentially fewer re-amputations than standard care. Similarly, Robert Frykberg et al. (2007)[45] have also reported overall progressively increasing wound debridement depth , amputation rates in control groups; however the same increasing trend did not occur in the NPWT group.

At the end of the study, the study group promised a better outcome as compared to the control group (60% complete responders).

Analyzing the study result concluded that VAC has a definitive role in promotion of proliferation of granulation tissue, reduction in the wound size[46], rapid clearing of the wound discharge and bacterial load. Current data demonstrates that negative pressure wound dressings decrease the wound size more effectively than Iodine gauze dressings over the first 4 weeks of therapy.

Conclusion

In the light of the study findings it can concluded that using of VAC therapy yield improved wound healing in comparison to their control in patient with diabetes mellitus more over the majority of studied patients who had faster and more effective wound healing (healing time, cost effectively, reduction time surface skin healing).

Recommendations

- In service education program should be carried out for nurses regarding to:
  - Using VAC therapy technique.
  - Wound dressing.

Table (1): Distribution of patients according to their sociodemographic variables

Variables	Group I (study group_ VAC therapy dressing) (n = 20)		Group II (control group_ Conventional occlusive dressing) (n = 20)	
	No.	No.	No.	%
Sex				
Male	15	75.0	12	60.0
Female	5	25.0	8	40.0
Total	20	100.0	20	100.0
Age				
18 – 25	10	50.0	12	60.0
26 – 35	10	50.0	8	40.0
Total	20	100.0	20	100.0
Education				
Illiterate	6	30.0	10	50.0
Read & Write	9	45.0	5	25.0
Diploma	5	25.0	5	25.0
Bachelor degree	0	0.0	0	0.0
Total	20	100.0	20	100.0
Occupation				
Manual	16	80.0	14	70.0
Clerical	0	0.0	0	0.0
No work	4	20.0	6	30.0
Total	20	100.0	20	100.0

Table (2): Distribution of patients of both group study and control according to type of diabetes, treatment received and body mass index

Items	Group I (study group_ VAC therapy dressing) (n = 20)		Group II (control group_ Conventional occlusive dressing) (n = 20)		χ^2	p
	No.	%	No.	%		
Type of diabetes						
IDDM	4	20.0	3	15.0	0.173	^{FE}p=1.000
NIDDM	16	80.0	17	85.0		
Treatment						
Insulin	5	25.0	6	30.0	0.125	0.723
Hypoglycaemic agents	15	75.0	14	70.0		
Body mass index						
Normal (18.5 – 24.9)	12	60.0	11	55.0		
Overweight (↑ 14.9)	8	40.0	9	45.0	0.102	0.749
Underweight (↓ 18.5)	0	0.0	0	0.0		
Total	20	100.0	20	100.0		

χ^2: value for Chi square test FE: Fisher Exact test

Table (3): Comparison between the two studied groups according to wound assessment

Wound assessment	Group I VAC therapy dressing (n = 20)		Group II Conventional occlusive dressing (n = 20)	
	No.	%		
Site of wound				
Plantar surface 1st toe	1	6.7	3	15.0
Plantar surface 1st metatarsal head	5	33.3	3	15.0
Plantar surface 2nd toe	0	0.0	3	15.0
Plantar surface 4thtoe	2	13.3	0	0.0
Plantar surface 5th toe	4	26.7	0	0.0
Sole	1	6.7	4	20.0
Heel	2	13.3	7	35.0
χ^2(^{MC}p)	13.112* (0.019*)			
Size of ulcer				
2 – 4 cm	11	55.0	10	50.0
>4 - 6 cm	9	45.0	10	50.0
χ^2(p)	0.100 (0.752)			
Depth of ulcer				
Grade I	0	0.0	0	0.0
Grade II	3	15.0	4	20.0
Grade III	6	30.0	7	35.0
Grade IV	7	35.0	7	35.0
Grade V	4	20.0	2	10.0
χ^2(^{MC}p)	0.987 (0.887)			
Color of callus				
Red	4	20.0		
Pink	8	40.0		
Brown	3	15.0		
Pale	5	25.0		
χ^2(^{MC}p)	0.371 (1.000)			
Dryness				
Present	16	80.0	17	85.0
Absent	4	20.0	3	15.0
χ^2(^{FE}p)	0.173 (1.000)			
Fissure				
Present	16	80.0	16	80.0
Absent	4	20.0	4	20.0
χ^2(^{FE}p)	0.0 (1.000)			

χ^2: value for Chi square test

Table (4): Percentage distribution of patients of both group control and study according to bacterial wound culture

Bacterial wound culture	Group I VAC therapy dressing (Study) (n = 20)		Group II Conventional occlusive dressing (Control) (n = 20)	
	No.	%	No.	%
1st culture (before dressing)				
Positive	12	60.0	12	60.0
Negative	8	40.0	8	40.0
Total	20	100.0	20	100.0
1st culture (after dressing)				
Positive	0	0.0	8	40.0
Negative	20	100.0	12	60.0
Total	20	100.0	20	100.0
χ^2 (p)	10.0*(0.002*)			

χ^2: value for Chi square test *: Statistically significant at $p \leq 0.05$

Table (5): Percentage distribution of patients of both group according to wound morphology and sign of infection at 3 different intervals (1-3 weeks)

Items	1st week				2nd week				3rd week			
	Group I VAC therapy dressing (n = 20)		Group II Conventional occlusive dressing (n = 4)		Group I VAC therapy dressing (n = 20)		Group II Conventional occlusive dressing (n = 4)		Group I VAC therapy dressing (n = 20)		Group II Conventional occlusive dressing (n = 4)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Appearance of wound Granulation	0	0.0	0	0.0	11	55.0	8	40.0	2	100.0	4	100.0
χ^2 (p)	-				1.600 (0.206)				-			
Re-epithelialization	12	60.0	8	40.0	20	100.0	17	85.0	2	100.0	4	100.0
χ^2 (p)	1.758 (0.185)				3.243 (0.072)				-			
Sign of infection												
Tenderness	3	15.0	5	25.0	1	5.0	2	10.0	0	0.0	0	0.0
Erythema	2	10.0	5	25.0	1	5.0	2	10.0	0	0.0	0	0.0
Purulent exudates	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Conversion of 2nd degree to 3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Brown or black discoloration	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
MCp	1.000				-				-			

χ^2: Chi square test MC: Monte Carlo test

Table (6): Distribution of patients of both groups according to wound healing during hospital stay period

Wound healing during hospital stay period	After First week		After Second week		After Third week		Before discharge	
	No.	%	No.	%	No.	%	No.	%
Group I (VAC dressing) Study group	**(n = 20)**		**(n = 20)**		**(n = 15)**		**(n = 10)**	
Complete	0	0	0	0.0	7	46.7	8	80.0
Partial	0	0	10	50.0	6	40.0	2	20.0
No healing	20	100.0	10	50.0	2	13.3	0	0.0
Group II (Conventional dressing)	**(n = 20)**		**(n = 20)**		**(n = 17)**		**(n = 15)**	
Complete	0	0	0	0.0	0	0.0	4	26.7
Partial	0	0	3	15.0	5	29.4	6	40.0
No healing	20	100.0	17	85.0	12	70.6	5	33.3
χ^2	-		5.584*		14.602*		7.150*	
p_{MC}	-		0.018*		0.001*		0.025*	

χ^2: value for Chi square MC: Monte Carlo test
*: Statistically significant at $p \leq 0.05$
#: The remaining numbers of patients in each type of technique were discharged

Table (7): Mean and standard deviation according to, cost of dressing and time consumed until complete healing

Items	Group I VAC therapy dressing (n = 20)	Group I Conventional occlusive dressing (n = 20)
Cost of dressing		
Range	338.00 – 699.50	437.00 – 969.00
Mean ± SD	508.93 ± 130.59	715.65 ± 166.93
Time consumed (days)		
Range	19.0 – 55.0	76.0 – 120.0
Mean ± SD	42.49 ± 7.68	94.07 ± 6.20

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