IMPACT OF VACUUM-ASSISTED CLOSURE DRESSING IN HEALING RATES OF DIABETIC FOOT ULCERS
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ABSTRACT

Background: Non-healing diabetic foot ulcers DFUs are a major complication in diabetic patients. Emerging Negative pressure wound therapy (NPWT) using vacuum-assisted closure (VAC) can provide a new option for ulcer management. Several reports have been published demonstrating the significance of NPWT for the treatment DFUs but the role of NPWT is not fully investigated. The aim of this prospective randomized study is to investigate the efficacy of vacuum assisted closure dressings as compared to conventional moist wound dressings in improving the healing process in diabetic foot wounds.

Patients and methods: Fifty patients who had chronic DFUs (grade 1; Texas classification) were treated at Al Hussein and Sayed Galal University Hospitals Cairo. From January 2015 to July 2015. Eligible patients were randomized into two equal groups; Group A (treated with VAC dressing), and group B (treated with conventional dressing alone). In Group A, a combination of sponge dressing with vacuum assisted wound closure systems was used topically on the wound. Groups B patients were dressed by conventional dressings of normal saline soaked gauze pieces, twice daily. If no signs of healing were present, the procedure was repeated till complete healing or end of the treatment course (10 weeks). Wound measurements were taken every week to calculate the wound surface area and healing rate.

Results: Granulation tissue formation occurred in 19 patients (76%) of group A and 7 patients in group B (28%) one week after initiation of treatment. (P=0.001). In Group A, the mean surface area of the ulcers was 4.0 ± 2.82 cm² and 3.6 ± 2.56 cm² after one week treatment. Ulcers in group B ranged from 3.8 ± 2.73 cm² and 3.7 ± 2.86 cm² after one week treatment. Complete healing was achieved in 24 patients (96%) of group A, and in 22 patients in group B (88%). Healing not completed in 1 patient (4%) of group A and 3 patients in group B (12%). The rate of wound healing was higher in group A compared with group B (2.4 versus 1.9 cm²/week) respectively. The time needed for complete healing was significantly shorter in group A (14 ± 2.6 days) versus (21 ± 3.4 days) in group B. P value was 0.013. Period of hospital stay till the wound was fully granulated was 14.87 ± 7.62 days in NPWT compared to 21.53 ± 10.17 days in the conventional group. It was found that the total mean cost in conventional dressing group was 1976 ± 123 EP compared to 2275 ± 154 EP in VAC group. There was a difference in the total cost finally.

Conclusion: NPWT using VAC is safe and effective method for treatment of DFUs. The rate of wound healing was better in NPWT group as compared to conventional dressing group. Further studies are still needed to define more conclusions.

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INTRODUCTION

Diabetic foot ulcer is a major complication of diabetes mellitus, and probably the major component of the diabetic foot. Wound healing is an innate mechanism of action that works reliably most of the time [1]. Ulceration physiopathology has been extensively studied. In diabetes, there is a triad of the main factors that contribute for its occurrence: peripheral neuropathy, peripheral vascular disease and decompensation of biomechanical stress [2]. Due to lack of oxygen, nutrients, and
epithelial cells the wound cannot express essential factors for healing. Hence, the treatment of DFUs remains as a challenge [3].

Risk factors implicated in the development of diabetic foot ulcers are infection, older age, diabetic neuropathy, peripheral vascular disease, cigarette smoking, poor glycaemic control, previous foot ulcerations or amputations, and ischemia of small and large blood vessels. Prior history of foot disease, foot deformities that produce abnormally high forces of pressure, renal failure, oedema, impaired ability to look after personal care (e.g. visual impairment) are further risk factors for diabetic foot ulcer [4].

Steps to prevent diabetic foot ulcers include frequent review by a foot specialist, good foot hygiene, diabetic socks and shoes, as well as avoiding injury. Foot-care education combined with increased surveillance can reduce the incidence of serious foot lesions and antibiotics are used only when there is evidence of infection [5].

Debridement, revascularization, offloading, moist wound care and antibiotic treatment of infection is required for a good clinical treatment of foot ulcer. Diabetic foot ulcer can be treated by many topical routines and devices [6].

Negative pressure wound therapy NPWT is widely used in the treatment of complex wounds on the basis of proposed multifactorial benefits. It uses a sub atmospheric pressure ideally. It helps in reducing edema and removes exudates from the tissues effectively. It decreases colonization of bacteria and enhances blood flow in the wounded area [7].

The role of NPWT in setting of wounds and ulcers is not yet fully investigated. The aim of this study is to evaluate the efficacy of vacuum assisted closure dressings as compared to conventional moist wound dressings in improving the healing process in diabetic foot wounds.

**PATIENTS AND METHODS**

**Patients:**
The study involved 50 patients who had chronic diabetic foot ulcer and were treated at the section of Vascular and General surgery, Al Hussein and Sayed Galal University Hospitals, Cairo, Egypt. Starting from January 2015 to July 2015. Before randomization, an inclusion and exclusion criteria were applied as follows:

**Inclusion criteria:**
- Patients with age between 12 or older than 75 years.
- DFUs that was not healed for at least 4 weeks
- DFUs grade I: (Superficial wound not involving tendon, capsule or bone according to University of Texas diabetic Foot classification system)
- Wound size > 2 cm²
- Patients giving consent for either types of treatment vacuum therapy or ordinary dressing.

**Exclusion criteria:**
1. Patients younger than 12 or older than 75 years old.
2. Any ulcer rather than diabetic ulcer was excluded (Venous ulcer, ischemic, malignant or traumatic ulcer).
3. Infected ulcer, cellulitis or osteomyelitis.
4. Grade 0, 2 and 3 ulcer (according to University of Texas diabetic Foot classification system)
5. Significant lower limb ischemia (ankle brachial index less than 0.5).
6. Uncontrolled hyperglycemia (hemoglobin Alc> 9%).
7. Serum albumin less than 2.5 gm/dl or anemia (hemoglobin < 7.0 g/dl),
An informed consent was taken and all patients underwent history taking, physical examination, Doppler ultrasound scan of the leg and X-ray of the foot. Basic laboratory investigations included blood glucose level, blood picture, serum creatinine, liver function tests, coagulation profile and serum albumin. Eligible patients were then ready for randomization.

**RANDOMIZATION**

This study was prospective randomized study, approved by the ethical committee of the faculty of medicine, Al-Azhar University, Cairo, Egypt. During the study period, any patient who fulfilled the inclusion criteria was subjected to computer based randomization before the start of treatment using random numbers from 1 to 50 to either group A (even numbers), or B (odd numbers); Group A patients were planned for VAC dressing (n =25) while group B patients were planned for treatment with conventional dressing alone (n=25)

**TREATMENT PROTOCOL**

Treatments were done on outpatient basis, an initial excision and or debridement was done in both groups followed by baseline wound measurements and evaluation.

**Preparation of patients:** All patients underwent detailed clinical examination and relevant investigations and the wounds were thoroughly debrided and the ulcer dimensions as well as the surface area was assessed. Before the start of VAC therapy, after initial debridement, the wound was photographed with a ruler placed beside the wound. A double layer of polyethylene sheets was held firmly in place over the wound, and an outline of the wound was traced using a permanent marker. The layer in direct contact with the wound was discarded. At subsequent VAC dressing changes, the wound was likewise photographed, and its area was quantitated using the double polyethylene sheet technique. Before surgical intervention at the end of VAC therapy, the final appearance of the wound was again noted and recorded.

**Technique:** A Group A was treated by VAC therapy, while a group B was dressed by conventional dressing alone.

- Group A: The application of topical negative pressure moist dressings needs the following materials. They include:
  - Synthetic hydrocolloid sheet
  - Vacuum suction apparatus
  - Transparent semi permeable adhesive membrane sheet

**Technique of VAC therapy:**

The VAC dressing which was used is the Chariker-Jeter™ wound sealing kit (Smith and Nephew PLC, London, UK) “a combination of sponge dressing with vacuum assisted wound closure systems”. The technique involves six steps. These were as follows:

The wound was thoroughly debrided and devitalized tissue removed.

The foam with the surrounding normal skin was covered with adhesive, semi-permeable, transparent membrane. A good air seal was thus ensured around the wound.

Distal end of the drain tube was connected to a device, which provided a negative pressure of -125 mmHg, applied to the wound, intermittently (5 minutes “on”, 2 minutes “off”). This was achieved by wall suction apparatus, computerized devices or mobile suction drain devices.

Once vacuum is applied, the sponge must be seen collapsed into the wound bed, thus giving the surface a concave appearance.
The fluid from the wound is absorbed by the sponge and is removed from the wound bed by suction. The negative pressure was maintained for an average of 2 days for Maximum benefit as studies have proved.

Group B: Patients treated with conventional dressings soaked gauze pieces were used for initial 48 hours followed by dressings of normal saline soaked gauze pieces, twice daily.

At the end of two days the wounds in both the groups was inspected after removal of the dressings from the NPWT group. The wounds were compared based on the following parameters. They are: rate of granulation tissue formation as percentage of the ulcer surface area, Present dimensions and surface area of the ulcer.

If no signs of healing were present, the procedure was repeated till complete healing or end of the treatment course (10 weeks).

All patients in both groups received standard treatment for their condition during the study period; this included the anti-diabetic medications, same antibiotics, NSAID, and vitamins.

**Follow up**

DFUs were examined and assessed with every dressing. Wound measurements were taken every week using a measuring tape, the wound is then photographed using digital camera. A millimeter scaled ruler was placed near the ulcers and photographed, the photo was processed by expert using the software (AutoCAD version 19. Autodesk, USA) to calculate the wound surface area and volume.

Follow up was done for 10 weeks. The rate of healing was calculated every week.

**Statistical analysis**

Data was analyzed using SPSS (Statistical Package for Social Sciences) version 23. Normally distributed data was presented as mean ± SD. Categorical variables were analyzed using chi-square test or Fisher’s exact test; continuous variables were analyzed by the Mann–Whitney U test. Paired t-test was used for comparison within groups. Student t-test was used to compare between two groups. $P < 0.05$ was considered to be statistically significant.

**RESULTS**

Patients were randomized into two groups: Group A in whom the wound was treated by VAC therapy ($n = 25$), while group B was treated by conventional dressing ($n = 25$).

Patient demographics and initial findings in the wound in both groups are shown in Table (1). No statistically significant difference was noted between both groups regarding Age, sex, duration of DM, and associated co-morbidities. Hemoglobin and albumin level did not differ significantly.

**Table 1: Patient demographics and initial findings**

<table>
<thead>
<tr>
<th>Demographic variable</th>
<th>Group B (conventional dressing $n = 25$)</th>
<th>Group A (NPWT $n = 25$)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) Mean ± SD</td>
<td>57.73 ± 10.98</td>
<td>58.52 ± 10.7</td>
<td>0.39</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>19 (76%)</td>
<td>22 (88%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Female</td>
<td>6 (24%)</td>
<td>3 (12%)</td>
<td></td>
</tr>
<tr>
<td>Duration of DM presentation (years)</td>
<td>12.82 ± 5.66</td>
<td>13.69 ± 5.42</td>
<td>0.67</td>
</tr>
<tr>
<td>Type of DM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>0 (0 %)</td>
<td>1 (4 %)</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>25 (100 %)</td>
<td>24 (96 %)</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral hypoglycemic drugs</td>
<td>17 (65%)</td>
<td>19 (76 %)</td>
<td>0.46</td>
</tr>
<tr>
<td>Insulin</td>
<td>8 (32 %)</td>
<td>6 (24 %)</td>
<td></td>
</tr>
<tr>
<td>Associated co-morbidities</td>
<td></td>
<td></td>
<td>0.232</td>
</tr>
<tr>
<td>- Yes</td>
<td>19 (76%)</td>
<td>14 (56%)</td>
<td></td>
</tr>
<tr>
<td>- No</td>
<td>6 (24%)</td>
<td>11 (44%)</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td>0.392</td>
</tr>
<tr>
<td>- Yes</td>
<td>5 (20%)</td>
<td>7 (28%)</td>
<td></td>
</tr>
<tr>
<td>- No</td>
<td>39 (80%)</td>
<td>33 (72%)</td>
<td></td>
</tr>
<tr>
<td>Laboratory findings</td>
<td></td>
<td></td>
<td>0.853</td>
</tr>
<tr>
<td>Hb (g/dl)</td>
<td>11 ± 1.6</td>
<td>11 ± 1.4</td>
<td></td>
</tr>
<tr>
<td>Albumin (g/dl)</td>
<td>4.2 ± 0.6</td>
<td>3.9 ± 0.3</td>
<td>0.33</td>
</tr>
</tbody>
</table>

Characteristics of DFUs at the start of treatment were listed in table (2). Difference between these characteristics was not significant. Duration of ulcer before treatment was $4.2 ± 2.1$ months in
group A (range = 2-9 months), in group B the duration was (3.7 ± 1.8) (range = 3-11 months). Most of the ulcers located in the Right lower limb 36 patients, only 14 patients had ulcers in the left leg. In Group A, the mean surface area of the ulcers was 4.0 ± 2.82 cm² and 3.6 ± 2.56 cm² after one week treatment. Ulcers in group B ranged from 3.8 ± 2.73 cm² and 3.7 ± 2.86 cm² after one week treatment.

Table 2: Characteristics of DFUs at the start of treatment.

<table>
<thead>
<tr>
<th></th>
<th>Group B (conventional dressing n = 25)</th>
<th>Group A (NPWT n = 25)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Duration of ulcer</td>
<td>4.2 ± 2.1 (2 - 9)</td>
<td>3.7 ± 1.8 (3 - 11)</td>
<td>0.429</td>
</tr>
<tr>
<td>Location: Right lower limb</td>
<td>20 (80%)</td>
<td>16 (64%)</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>Left lower limb</td>
<td>5 (20%)</td>
<td></td>
</tr>
<tr>
<td>Initial wound size in cm²</td>
<td>38.52 ± 2.73</td>
<td>40.44 ± 2.82</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>After treatment</td>
<td>37.63 ± 2.86</td>
<td>36.08 ± 2.56</td>
<td></td>
</tr>
<tr>
<td>Granulation tissue formation</td>
<td>19</td>
<td>7</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Complete healing was achieved in 24 patients (96%) of group A, and in 22 patients in group B (88%). Healing not completed in 1 patient (4%) of group A and 3 patients in group B (12%) The rate of wound healing was higher in group A compared with group B (2.4 versus 1.9 cm²/week) respectively. The time needed for complete healing was significantly shorter in group A (14 ± 2.6 days) versus (21 ± 3.4 days) in group B. P value was 0.013. (Table 4).

Table 4: Healing and healing rates.

<table>
<thead>
<tr>
<th></th>
<th>Group A (NPWT n = 25)</th>
<th>Group B (conventional dressing n = 25)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Complete healing at the end of treatment course (10 weeks)</td>
<td>24 (96%) 1 (4%)</td>
<td>22 (88%) 3 (12%)</td>
<td>0.609 0.609</td>
</tr>
<tr>
<td>- Healing not completed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The overall rate of healing (cm²/week)</td>
<td>2.4 1.9 1.9</td>
<td></td>
<td>0.154</td>
</tr>
<tr>
<td>- Time of healing (days) (MeansSD)</td>
<td>14 ± 2.6 21 ± 3.4</td>
<td></td>
<td>0.013 S</td>
</tr>
</tbody>
</table>

By the end of the study, there were no major complications related to the procedure and no hospital admissions or deaths were reported.

Period of hospital stay till the wound was fully granulated was 14.87 ± 7.62 days in NPWT compared to 21.53 ± 10.17 days in the conventional group (Table 5).

Table 5: Comparison of Average time for hospital stay and cost between two Groups

<table>
<thead>
<tr>
<th></th>
<th>NPWT</th>
<th>Conventional dressing</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average period (days)</td>
<td>14.87 ± 7.62</td>
<td>21.53 ± 10.17</td>
<td>0.02</td>
</tr>
<tr>
<td>MEAN COST (Egyptian Pound)</td>
<td>2275 ± 154</td>
<td>1976 ± 123</td>
<td>0.048</td>
</tr>
</tbody>
</table>

It was found that the total mean cost in conventional dressing group was 1976 ± 123 EP compared to 2275 ± 154 EP in VAC group. There was a difference in the total cost finally. Being higher in cost, VAC therapy although has a shorter hospital stay and faster healing time in comparison with conventional dressing.
53 years old female had diabetic foot ulcer at Left heel treated with VAC dressing.
After debridement

1 week after VAC

3 weeks later

65 years old male had diabetic foot ulcer at lateral aspect of Right foot treated with VAC dressing.

DISCUSSION

Diabetic foot problems are the commonest reason for hospitalization of diabetic patients (about 30% of admissions) and absorb some 20% of the total health-care costs of the disease more than all other diabetic complications [8]. Foot ulceration is common, affecting up to 25% of patients with diabetes during their lifetime. Over 85% of lower limb amputations are preceded by foot ulcers and diabetes remains a major cause of non-traumatic amputation across the world with rates being as much as 15 times higher than in the non-diabetic population [9].

Negative pressure wound therapy (NPWT) is one of the most important treatments for diabetic foot ulcers [10]. NPWT was studied by 41 Randomized Controlled Trials (RCTs), More than 918 peer-reviewed studies, More than 927 abstracts and 71 medical textbook citations [8].

Randomized trials have found that NPWT reduces time to closure of diabetic foot ulcers, and wounds following diabetic foot surgery. In this patient population, NPWT also decreases length of hospitalization, complication rates, and cost [8].

It plays an important role in closing wounds quickly, controlling infection, promoting angiogenesis, increasing blood flow, and promoting granulation tissue growth of wounds. [11].

The negative pressure wound therapy in the treatment of diabetic foot ulcers was used successfully for many years. In the case of complications associated with infection by this type of wound treatment to give very good results [12].

The efficacy of NPWT was initially described by Morykwas and Argenta. Several studies have followed and identified faster healing times with NPWT when compared to moisturized saline gauze [13]. Moues et al. showed that NPWT had significantly higher material expenses (p < 0.001), but significantly lower nursing expenses (p = 0.043) [14].

Mechanism by which it works appears to be decreasing local tissue edema and removing excessive fluid and pro-inflammatory exudates from the wound bed. There is now controlled trial evidence for the use of NPWT in both
local postoperative wounds in the diabetic foot. Little work is done on the effect of VAC therapy in the management of DFU in Egypt so far. VAC therapy was studied by some Egyptian authors like [15] [16]. From Mansoura University El-Nagar 2015 concluded that NPWT and PRP are effective in treatment of chronic wounds[15]. Results of another Egyptian study at Tanta University found that the mean wound surface area was reduced significantly in VAC therapy group of patients [16]. (Mahmoud 2012) showed reduction in the wound volume and wound surface area after treatment for both groups. There was a highly significant difference in wound surface area between the two groups after the treatment. This study at Cairo University concluded that Negative Pressure Wound Therapy was found to facilitate rapid granulation tissue formation and shorten healing time of the lower limb ulcers [17]. Our study proved the hypothesis that NPWT is more efficacious than conventional treatment for the treatment of DFU.

In our study, 6 of 25 (24%) in the Conventional treatment group were females whereas 19 of 25 (76%) in the Conventional treatment group were males. 3 of 25 (12%) in the NPWT group were females and 22 of 25 (88%) were males.

In the Conventional treatment group, 4 of 25 (16%) were at age of 60 or below and 84% were above 60 years of age. 5 of 25 (20%) in the NPWT group were at or below 60 years and 80% were above 60 years of age.

Wound bed showed signs of healing by granulation tissue formation in 19 among 25 patients (76%) compared to Conventional treatment, 7 showed granulation among 25 patients (28%) one week after initiation of treatment. (P=0.001).

On this point, Paola et al. demonstrated that treating DFU with VAC therapy results in a faster wound bed preparation (p=0.03), a faster closure (p=0.005) when compared to standard wound care [11]. Wound size was measured at initial presentation and then after treatment. Before treatment, the mean surface area of wounds in the NPWT group was 40.44 cm², the Conventional treatment 38.52cm². After wound management, mean surface area of the diabetic wounds was 36.08 ± 2.56 cm² in the NPWT group and 37.63 ± 2.86 cm² in the Conventional treatment. This represents a statistically significant difference (P=0.05).

Complete healing was achieved in 24 patients (96%) of group A, and in 22 patients in group B (88%). Healing not completed in 1 patient (4%) of group A and 3 patients in group B (12%) The rate of wound healing was higher in group A compared with group B (2.4 versus 1.9 cm²/ week) respectively. The time needed for complete healing was significantly shorter in group A (14 ± 2.6 days) versus (21 ± 3.4 days) in group B. P value was 0.013.

Also these results are comparable to data quoted worldwide. A RCT, conducted by Blume et al. in 2008, revealed that greater proportion of foot ulcers achieved complete ulcer closure with NPWT (43.2%) than with AMWT (28.9%) within 112-day active treatment phase (p=0.007) [18]. Note that the data from Blume’s study was analyzed by the company funding the study. This may be perceived as a potential source of bias, it is more reassuring to the reader when the data is analyzed by a neutral third party [18].
In our study, it was found that the daily mean cost in conventional dressing group was 67.43 ± 5.3 EP compared to 95.7 ± 10.2 EP in VAC group. A difference which is statistically different. Also, at the end of the study, we found that the total mean cost in conventional dressing group was 1976 ± 123 EP compared to 2275 ± 154 EP in VAC group. There was a difference in the total cost finally.

As our findings, Chiang, Rodda et al. found that NPWT systems are more expensive than traditional wound dressings. However, the overall cost of wound care depends upon the frequency of dressing changes, need for skilled nursing care, and duration of treatment [19].

Being higher in cost, VAC therapy although has a shorter hospital stay and faster healing time in comparison with conventional dressing.

Period of hospital stay till the wound was fully granulated was 14.87 ± 7.62 days in NPWT compared to 21.53 ± 10.17 days in the conventional group.

There is a highly statistically significant difference between average duration of hospital stay and it is reduced significantly in vacuum dressing. (p-value= 0.02)

These results provide evidence for effectiveness of NPWT as cited in literature by various authors. NPWT now widely applied in all kinds of acute, chronic, and special wounds in clinic with good therapeutic results [11].

The number of publications on NPWT has grown significantly since the inception of NPWT. In part, this reflects the variations of NPWT that have developed. However, a greater number of robust, randomized, prospective studies are needed to support its wide spread use [8].

NPWT using VAC is safe and effective method for treatment of DFUs. The rate of granulation tissue formation and wound healing was better in NPWT group as compared to conventional dressing group. Although cost of VAC therapy was higher than conventional dressing. Hospital stay is significantly shorter in NPWT patients, so less consuming of hospital service than conventional dressing. This is finally decreasing the total budget to the hospital.

**RECOMMENDATION**

Hospitals should consider VAC therapy set as an essential modality for diabetic foot wound management.

**REFERENCES**


