

OUTCOMES OF VAC VERSUS CONVENTIONAL DRESSING IN MANAGEMENT OF DIABETIC FOOT ULCER

By

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ABSTRACT

Background: Foot wounds in people with diabetes mellitus (DM) are common and serious global health issue. Negative pressure wound therapy can be used to treat these wounds and a clear and current overview of current evidence is required to facilitate decision-making regarding its use.

Objective: To assess 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: This prospective randomized comparative study was conducted in the General and Vascular Surgery Departments at Al-Azhar university hospitals and Al-Ahrar teaching hospital, in the period from January 2019 to May 2020. The study included 30 patients randomized into two equal groups: VAC therapy and conventional dressing suffering from diabetic foot wounds. All chronic wounds where conventional dressings indicated were included in the study.

Results: Wound bed showed signs of healing by granulation tissue formation in 11 among 15 patients (73.3%) in VAC therapy group. In conventional treatment, 4 showed granulation among 15 patients (26.7%) one week after initiation of treatment. (P=0.01). There was a statistically significant difference between average granulation as % of ulcer area and it was significantly high in vacuum dressing. It was 50.2 ± 18.9 in Conventional treatment compared with 77.4 ± 19.3 in NPWT group (p- value = 0.005). Also, at the end of the study, we found that the total mean cost in conventional dressing group was 1993 ± 193 EP compared to 2261 ± 183 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.

Conclusion: Negative pressure wound therapy (NPWT) using vacuum-assisted closure (VAC) was more efficacious than conventional therapy in the management of foot ulcers in diabetic patients. Hospital stay was significantly shorter in NPWT patients, so less consuming of hospital service than conventional dressing. This is finally decreasing the total budget to the hospital.

Keywords: Diabetic Foot Ulcer, NPWT, VAC.

INTRODUCTION

As a new generation of negative pressure drainage technology, vacuum-assisted closure (VAC) can provide stable and persistent negative pressure, and there

are several modes to choose from. VAC plays an important role in closing wounds quickly, controlling infection, promoting angiogenesis, increasing blood flow, and promoting granulation tissue growth of wounds. It is now widely applied in all

kinds of acute, chronic, and special wounds in clinic with good therapeutic results. However, there is a need to pay attention to contraindications and complications of VAC when it is used, avoiding secondary damage due to improper treatment (*Xie et al., 2017*).

Topical negative pressure (TNP) therapy is widely used in the treatment of acute wounds in vascular patients on the basis of proposed multifactorial benefits. However, numerous systematic reviews have concluded that there is an inadequate evidence to support its benefits at a scientific level (*Chiang et al., 2017*).

In course of treatment of diabetic foot with ischemic origin, beyond effective medical treatment revascularization (open vascular surgery or endovascular procedures) has paramount importance for prevention of limb loss (*Kolossvary et al., 2017*). VAC therapy, together with debridement and appropriate antibiotic therapy, enables a higher rate of limb salvage (*Ulusal et al., 2011*).

Studies have shown that application of a sub atmospheric pressure in a controlled manner to the wound site has got an important role in assisting wound healing (*Xie et al., 2017*).

The present work aimed to compare the efficacy of negative pressure wound therapy with that of a control group using conventional moist wound dressings, in healing of diabetic foot ulcers.

PATIENTS AND METHODS

This prospective randomized comparative study was conducted in the General and Vascular Surgery Departments at Al-Azhar University

Hospitals and Al-Ahrar Teaching Hospital, in the period from January 2019 to May 2020. Clearance from the ethical committee was obtained. All chronic wounds where conventional dressings indicated were included in the study.

Inclusion criteria: Patients with age between 12 - 75 years, diabetic foot wounds, wound size: 2 cm² and patients giving consent for either types of treatment vacuum therapy or ordinary dressing.

Exclusion criteria: Untreated underlying osteomyelitis, exposed arteries or veins, malignancy within wounds, dry gangrene, wounds resulting from electrical, chemical, or radiation burns and those with collagen vascular disease.

Randomized case-control study enrolling 30 patients randomly divided into two equal groups: Group A treated with VAC and group B treated with conventional dressings). 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 were 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.

The application of topical negative pressure moist dressings needs synthetic hydrocolloid sheet, vacuum suction apparatus and transparent semi permeable adhesive membrane sheet.

The VAC dressing was a combination of sponge dressing with vacuum assisted wound closure systems. All the patients included in Group B were subjected to these six steps:

1. The wound was thoroughly debrided and devitalized tissue removed.
2. The foam with the surrounding normal skin was covered with adhesive, semi-permeable and transparent membrane. A good air seal was thus ensured around the wound.
3. 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").
4. This was achieved by wall suction apparatus, computerized devices or mobile suction drain devices.
5. Once vacuum was applied, the sponge collapsed into the wound bed, thus giving the surface a concave appearance.
6. The fluid from the wound was absorbed by the sponge and 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. Once adequate granulation tissue was formed the dressing was removed and definitive wound closure was achieved by skin

grafting. At the end of two days the wounds in both groups were inspected after removal of the dressings from the NPWT group. The wounds were compared based on the following parameters. They rate of granulation tissue formation as percentage of the ulcer surface area, present dimensions and surface area of the ulcer once these parameters were assessed. Both groups were subjected to split thickness skin grafting.

Both groups were given the same systemic antibiotics during the postoperative period. The wounds were reassessed at the end of the fifth postoperative day and the following parameters were accounted for skin graft taking as a percentage of ulcer surface area and number of days of hospitalization.

The changes in surface area and complications were evaluated when using negative pressure wound therapy (NPWT) compared with conventional dressings in patients with diabetic foot wounds. Patients were followed up on a daily basis in both test and conventional treatments. The conventional treatment was subjected to twice-daily dressings by conventional methods whereas the test group was subjected to topical negative pressure dressings and was left undisturbed for 2 days and wound was inspected twice daily. Patients were followed up after 1 week (for detection of early granulation tissue formation), 3 weeks (for wound size measurement) and 3 months later (for detection of any complications e.g. amputation).

Statistical analysis:

Analysis of data was done using Statistical Package for the Social Science version 22 (SPSS Inc., Chicago, IL, USA). Quantitative variables were described in the form of mean and standard deviation. Qualitative variables were described as number and percent. In

order to compare parametric quantitative variables between two groups, Student t test was performed. Qualitative variables were compared using chi-square (X²) test or Fisher's exact test when frequencies were below five. P value < 0.05 was considered significant.

RESULTS

4 of 15 (26.7%) in the Conventional treatment were females whereas 11 of 15 (73.3%) in the Conventional treatment were males. 2 of 15 (13.3%) in the NPWT group were females and 13 of 15 (86.7%) were males.

4 of 15 (3 males & 1 female) (26.7%) in the Conventional treatment were at the

age of 60 or below and 11 of 15 (8 males & 3 females) (73.3%) were above 60 years of age. 4 of 15 (3 males & 1 female) (26.7%) in the NPWT group were at or below 60 years and 11 of 15 (10 males & 1 female) (73.3) % were above 60 years of age (**Table 1**).

Table (1): Age and sex distribution of the patients in both groups

Demographic variables	Groups	Conventional treatment (n = 15)	NPWT (n = 15)	p-value
Age (years)				
Mean ± SD		56.5 ± 9.9	57.1 ± 10.8	0.875
Sex				
Male		11 (73.3%)	13 (86.7%)	0.361
Female		4 (26.7%)	2 (13.3%)	

Patients of both groups were classified according to Wagner's grading system. Majority of patients had Wagner's grade 2 ulcer (60 % in Conventional group and 73.3 % in NPWT group, P = 0.438) (**Table 2**).

The use of NPWT may be an effective initial wound therapy to achieve faster

wound bed granulation showing signs of healing in 11 among 15 patients (73.3%) compared to Conventional treatment 4 showed granulation among 15 patients (26.7%) one week after treatment. (P = 0.01) (**Table 2**).

Table (2): Wagner's grade of Wounds in both groups and Granulation tissue formation in the wound bed

Wagner's grade	Conventional treatment (n = 15)	NPWT (n = 15)	p-value
I	6 (40 %)	4 (26.7 %)	0.438
II	9 (60 %)	11 (73.3 %)	
Granulation tissue formation one week after treatment	4 (26.7%)	11 (73.3%)	0.01

There is a highly statistically significant difference between average granulation in % of ulcer area and it is significantly high in vacuum dressing. The incidence of secondary higher amputation

in NPWT group is 3/15 (20%), the Conventional treatment 4/15 (26.7%). There was no significant difference between both groups (P=0.666) (Table 3).

Table (3): Comparison of Granulation as % of ulcer area Mean ± SD Between Study And Control Group and Amputation results in both groups

Parameters	Conventional dressing (n = 15)		NPWT (n = 15)		P-value
	Mean	SD	Mean	SD	
Granulation as % of ulcer area	50.2	18.9	77.4	19.3	0.005
	N	%	N	%	
Need for amputation					0.666
Need	4	26.7%	3	20%	
Not need	11	73.3%	12	80%	

Period of hospital stay till the wound was fully granulated or ready for skin grafting was 23.9 ± 7.3 in NPWT compared to 31.1 ± 8.9 in the conventional group. There is a statistically significant difference between average duration of hospital stay and it is reduced significantly in vacuum dressing (Table 4).

It was found that the total mean cost in conventional dressing group was 1993 ± 193 EP compared to 2261 ± 183 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 (Table 4).

Table (4): Comparison of Average time for hospital stay and Average cost Between Study And Control Group

Parameters	Conventional dressing (n = 15)	NPWT (n = 15)	p-value
Hospital stay: Average period (days)	31.1 ± 8.9	23.9 ± 7.3	0.022
Total cost (Egyptian Pound): MEAN COST	1993 ± 193	2261 ± 183	0.005

DISCUSSION

Negative pressure wound therapy (NPWT) is one of the most important treatments for diabetic foot ulcers (*Wang et al., 2017*).

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 costs (*Putnis et al., 2014*). It plays an important role in closing wounds quickly, controlling infection, promoting angiogenesis, increasing blood flow, and promoting granulation tissue growth of wounds (*Xie et al., 2017*).

El-Nagar (2017) concluded that NPWT and PRP are effective in treatment of chronic wounds. Another study at found that the mean wound surface area was reduced significantly in VAC therapy group of patients (*Bayoumi et al., 2018*). *Abdelhafez et al. (2015)* showed reduction in the wound volume and wound surface area after treatment for both groups. There was a significant difference in wound surface area between the two groups after the treatment. This study concluded that negative pressure wound therapy was found to facilitate rapid granulation tissue formation and shorten healing time of the lower limb ulcers (*Abdelhafez et al., 2015*).

Our study proved the hypothesis that NPWT is more efficacious than conventional treatment for the treatment of DFU. 26.7% in the conventional treatment group were females whereas 73.3% in the conventional treatment group were males. 13.3% in the NPWT group were females and 86.7% were males. In

the conventional treatment group, 26.7% were at age of 60 or below and 73.3% were above 60 years of age. 26.7% in the NPWT group were at or below 60 years of age.

Wound bed showed signs of healing by granulation tissue formation in 73.3% compared to conventional treatment, 26.7% showed granulation one week after initiation of treatment. Granulation of the wounds was > 50% in 73.3% patients underwent NPWT, whereas only 13% in the conventional treatment had shown > 50% granulation. There was a statistically significant difference between average Granulation as % of ulcer area and it was significantly high in vacuum dressing.

Paola et al. (2010) demonstrated that treating DFU with VAC therapy results in a faster wound bed preparation and a faster closure when compared to standard wound care.

There was a statistically significant difference between wound size before and after in NPWT.

A significant shrinkage of wound area was observed over a period of 16 days in a study performed by *Kilic et al. (2011)*. Other studies carried out by *Dzieciuchowicz et al. (2010)*, *Sepúlveda et al. (2011)*, *Sajid et al. (2015)* and *Ubbink et al. (2010)* found that NPWT is superior to conventional gauze dressings in decreasing wound dimensions, achieving complete wound healing, wound bed preparation at a faster rate and lower incidence of re-amputations.

At the end of our study the incidence of secondary higher amputation in NPWT group was 20% and the conventional treatment 26.7%. There was no significant

difference between both groups. There was a difference in the total cost finally. There was a statistically significant difference between average duration of hospital stay and it reduced significantly in vacuum dressing.

Paola et al. (2010) demonstrated that treating DFU with VAC therapy results in a better graft take rate when compared to standard wound care.

Gestring and Sanfey (2014) 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.

These results provide evidence for effectiveness of NPWT as cited in by *Alzahrani et al. (2013)*. NPWT now widely applied in all kinds of acute, chronic, and special wounds in clinic with good therapeutic results (*Xie et al., 2017*). 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 (*Anghel and Kim, 2016*).

CONCLUSION

The rate of granulation tissue formation, wound surface area, overall graft survival was better in NPWT group as compared to conventional dressing group. The overall hospital stay and amputation rate were less in the NPWT group. Thus, NPWT can be considered as a superior option in the management of diabetic foot wounds. Cost of VAC

therapy was higher than conventional dressing.

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مقارنة نتائج التضميد بواسطة استخدام الضغط السالب الموضعي مقابل التضميد التقليدي في علاج قرحة القدم السكري

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خلفية البحث: هناك عوامل أساسية في حدوث القدم السكري وعوامل ثانوية ومسببات للمشكلة اما العوامل الأساسية فهي: التهاب الأعصاب الطرفية الذي يؤدي عادة إلى فقدان الإحساس أو نقصه لدى مرضى السكري، مما يؤدي إلى فقدان بعض الوظائف اللازمة للحفاظ على سلامة القدمين، خاصة الإحساس بالألم وإفراز ما يكفي من العرق من أجل ترطيب الجلد وضيق أو انسداد الشرايين الطرفية التي تغذي الساقين تحت الركبتين والعدوى الجرثومية التي تسبب اهتراء أنسجة القدم المصابه.

الهدف من البحث: مقارنة بين تأثير العلاج بالضغط السلبي والغيرات المعتادة على التئام جروح القدم السكري.

المرضي وطرق البحث: أجرى البحث على ثلاثين مريضاً يعانون من جروح مزمنة. وتم تقسيمهم إلى مجموعتين متساويتين. وتم قياس مساحة الجروح قبل العلاج وبعده. وتم تقييم الجروح بناء على نسبة الالتئام ومساحة الجروح ونسبة حدوث عملية بتر ونسبة تقبل الجرح للترقيع الجلدي وتكلفة العلاج بالضغط السلبي مقارنة بالغيرات المعتادة بالجنيه المصري والمدة اللازمة للعلاج بالمستشفى حتى جاهزية الجروح لعمل الترقيع الجلدي.

نتائج البحث: أظهرت الجروح علامات الشفاء عن طريق تشكيل أنسجة التحبيب في 11 بين 15 مريضاً (73.3%). في مجموعة العلاج باستخدام الضغط السلبي للجروح. وفي العلاج التقليدي، أظهر 4 تحبيبات بين 15 مريضاً (26.7%) أسبوع واحد بعد بدء العلاج ($P= 0.01$). كان هناك فرق مهم إحصائياً بين متوسط التحبيب كنسبة مئوية من منطقة القرحة وكان مرتفعاً بشكل ملحوظ في خلع الملابس. كان 18.9 ± 50.2 في العلاج التقليدي مقارنة مع 19.3 ± 77.4 في

مجموعة NPWT (ع - قيمة = 0.005) أيضا، في نهاية الدراسة، وجدنا أن التكلفة الإجمالية متوسط في مجموعة الملابس التقليدية كان $EP \ 193 \pm 1993$ مقارنة مع $EP \ 183 \pm 2261$ في مجموعة VAC. كان هناك فرق في التكلفة الإجمالية في النهاية. يجري أعلى في التكلفة، والعلاج VAC على الرغم من أن لديه أقصر الإقامة في المستشفى وأسرع وقت الشفاء بالمقارنة مع خلع الملابس التقليدية.

الاستنتاج: أظهرت النتائج فاعلية أكبر للعلاج بالضغط السلبي مقارنة بالغيارات المعتادة بالنسبة لجروح القدم السكري وذلك من حيث سرعة التئام الجروح، وانخفاض مساحتها بشكل أسرع، قبولها للترقيع الجلدي بنسبة أكبر، انخفاض نسبة عمليات البتر، وانخفاض مدة الإقامة بالمستشفى للعلاج. وقد تمت دراسة متوسط التكلفة اليومية، والتكلفة الكلية في نهاية الدراسة، وأظهر بحثنا ارتفاع تكلفة العلاج بالضغط السلبي مقارنة بالغيارات المعتادة.