International Journal of Multidisciplinary Research and Development
Online ISSN: 2349-4182, Print ISSN: 2349-5979
Impact Factor: RJIF 5.72
Received: 12-03-2018; Accepted: 17-04-2018
www.allsubjectjournal.com
Volume 5; Issue 4; April 2018; Page No. 188-193

Comparative study between vacuum assisted closure and traditional moist dressing in the treatment of diabetic foot infection

Mahmoud S Shehata[1], Mahmoud E Nagaty[2], Ayman H Ebrahim[3], Yasser H Metwally[4], Ibrahim S Bakr[5]
[1, 2, 3] Lecturer of General Surgery, Faculty of Medicine, Al-Azhar University, Egypt
[4, 5] Assistant Professor of General Surgery, Faculty of Medicine, Al-Azhar University, Egypt

Abstract
Aim: To compare the efficacy of vacuum assisted closure therapy and traditional moist wound dressings in improving the healing process in chronic diabetic foot wounds.
Study Design: A prospective randomized study.
Place and Duration of study: General Surgery Department, Al-Hussein hospital, Faculty of Medicine, Al-Azhar University from January 2017 to December 2017.
Patients and Methods: A total of 100 patients, with chronic diabetic foot wounds were included in this study. After surgical intervention of the wound either debridement and/or amputation, all patients were randomly classified by the closed envelope technique into 2 groups, with 50 patients in each group. Patients in Group A underwent vacuum assisted closure therapy and Patients in Group B underwent traditional moist dressings respectively. Wounds were evaluated every week for six weeks as regard size and depth of the wound, timing of healthy granulation tissue formation, number of debridement sessions and local wound complications (cellulitis–secondary amputation).
Results: There was a significant reduction in the size of the wound in group A compared to group B with mean 66.36 % for VAC group and mean 36.68 % for the traditional moist dressing group. As regards the timing of healthy granulation tissue formation, it was more rapid in group A than in group B with mean 6.04 days for VAC group and mean 9.67 days for the traditional moist dressing group. As regards the number of debridement sessions, it was significantly less in Group A compared to group B with mean 0.20 for VAC group and mean 2.86 for the traditional moist dressing group. Regarding local wound complications, Group A has less wound infection and cellulitis than Group B with mean 16 % for VAC group and mean 64.0 % for the traditional moist dressing group.
Conclusion: VAC therapy appears to be safe and more effective than traditional moist dressing for the treatment of diabetic foot infections; as it provides faster wound healing and less wound complication rates.

Keywords: vacuum assisted closure, VAC, traditional moist dressings, chronic diabetic foot infection

Introduction

As the incidence of diabetes mellitus continues to increase, the treatment of diabetic foot ulcers (DFU) has become a major public health concern. Regarding Egyptian society nowadays, Diabetes is widespread in many families, nearly 10.4 % of the Egyptian population (aged 10 - 79 years) have Diabetes [1].

Currently, the standard of care for diabetic foot ulcers includes adequate and frequent debridement, proper offloading, treatment of infection, revascularization of ischemic limb, glucose control and moist dressings [2].

Despite recent advances in moist dressings, only 24 to 30 percent of DFU's heal within an adequate time frame of between 12 and 20 weeks. The decreased healing time associated with chronic DFU's increases the risk for serious complications such as hospitalization, infection, osteomyelitis and cellulitis **[3]**.

During the last two decades a wide variety of innovative dressing have been introduced. Negative pressure wound dressing is a new technology that has been shown to accelerate granulation tissue growth and promote faster healing, thereby decreasing the period between debridement and definite surgical closure in large wounds. Recent 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 **[4]**.

Despite the early clinical success and widespread empirical introduction of topical negative pressure into clinical practice, it is not known exactly how this may exert effects on the wound. Topical negative pressure is said to increase local blood flow and reduce oedema and bacterial colonisation rates. It is thought to promote closure of the wound by promoting the rapid formation of granulation tissue as well as by mechanical effects on the wound. It concurrently provides a moist wound environment and removes excess wound exudates thus aiding in the creation of the "ideal wound healing environment" [5].

The present study was conducted to compare the efficacy of vacuum assisted closure therapy and traditional moist wound

dressings in improving the healing process in chronic diabetic foot wounds and to demonstrate that vacuum assisted closure therapy can provide a better treatment option in the treatment of chronic diabetic foot wounds.

Patients and Methods

A prospective randomized study was carried out in the General surgery department in Al-Hussein hospital, Al-Azhar University; Cairo, Egypt; From January 2017 to December 2017 and after acceptance of the ethical committee.

A total of 100 patients, with chronic diabetic foot wounds were included in this study. After surgical intervention of the wound either debridement and/or amputation, all patients were randomly classified by the closed envelope technique into 2 groups, with 50 patients in each group. Patients in Group A underwent vacuum assisted closure therapy and Patients in Group B underwent traditional moist dressings respectively.

Inclusion Criteria

1. Patients with age between 16 - 77 years
2. Patients giving consent for vacuum assisted closure therapy

Exclusion Criteria

1. Patients with acute ischaemia
2. Patients with completely neglected limb or with dry, wet or gas gangrene
3. Patients with osteomyelitis
4. Patients with Charcot joint
5. Patients with exposed arteries or veins
6. Patients with malignancy within wounds

All patients were subjected to

1. Detailed history including

personal data, history of the present wound (onset, duration, history of trauma, previous surgical interventions in the same foot, for example debridement or drainage or amputation), history of diabetes mellitus (onset, duration, control, family history of diabetes), history of other medical conditions (hypertension, heart diseases, hepatic diseases, renal diseases, etc.), special habits; smoking.

2. Clinical examination

- Detailed general examination.
- Local examination;

1. Wound examination*:* site, size, number, shape, discharge, necrotic tissues.
2. Vascular examination: pulse, pallor, paresthesia, coldness, trophic changes.
3. Neurological examination: paresthesia, loss of sensations.

3. Investigations

- Laboratory; complete blood count, coagulation profile, liver and renal function tests, fasting and postprandial blood glucose and glycosylated hemoglobin level (HbA_1C), culture and sensitivity test from the wound discharge.
- Imaging studies: colored duplex study of both limbs and Plain x- ray film (antero-posterior, lateral, oblique) to exclude osteomyelitis of the affected foot.

Materials Used

VAC group (A)

1. Vacuum suction apparatus; automatic vacuum pump (negative pressure unit), canister (2000 ml capacity), tubing to connect the dressing to the pump.
2. Synthetic hydrocolloid sheet
3. Transparent adhesive membrane sheet
4. Fenestrated evacuation tube (Redivac 18)

Traditional moist dressing group (B)

1. Normal saline
2. Bovidone iodine solution 10%
3. Topical healing stimulator cream (NATARIA Cream ^{R})
4. Sterile gauze
5. Adhesive tapes

Technique of application

All wounds were thoroughly debrided and the dimensions (vertical, transverse and depth) of the wounds were assessed and adequate hemostasis was achieved.

- VAC group (A): After the healthy skin surrounding the ulcer was made dry and clear, A Fenestrated evacuation tube (tube of Redivac 18) was placed in the wound bed and the distal end was brought out away from the wound. The synthetic hydrocolloid sheet soaked in povidone iodine solution was remodeled to fit the shape of the wound and applied over the fenestrated tube. The wound area with the surrounding normal skin was wrapped with transparent adhesive membrane sheet. The whole area was ensured to be both air and fluid sealed. The other end of the tube drain was connected to the automatic vacuum pump and a negative pressure of -125 mmHg was created in an automatic intermittent manner (30 minutes on, 10 minutes off). The shape of the hydrocolloid sheet was shrunk after the device was on so, the discharge is absorbed by the foam and removed by the apparatus. The dressing was changed and the wound is inspected after 3 days except if the dressing was in need to be changed earlier. Debridement was done if needed before the vacuum dressing.

Fig 1 A: vacuum suction apparatus – B; the shape of the wound while suction is off – C; the shape of the wound while suction is on.

- Traditional moist dressing group (B): A daily dressing was done using normal saline and bovidone iodine solution 10 % and local application of healing stimulator cream (NATARIA Cream $^{R)}$. Debridement was done if needed before dressing and the wound was left open

when there was healthy granulation tissue and no discharge. Dressing was done two or three times daily when needed.

Follow-up

Wounds were evaluated every week for six weeks. Follow up were conducted through clinical evaluation of the wound regarding:

1. Size and depth of the wound
2. Timing of healthy granulation tissue formation (days)
3. Number of debridement sessions
4. Local wound complications (cellulitis–secondary amputation).

Wounds which had incomplete healing but had healthy granulation tissue were prepared for definitive closure by skin graft during follow up period.

Statistical Analysis

Results in both groups were compared and statistically analyzed using two by two table, Chi-square was used when appropriate. P value ≤ 0.05 is considered significant.

Results

100 patients, with chronic diabetic foot wounds were included in this study. All patients were randomly classified into 2 equal groups. Patients in Group A underwent vacuum assisted closure therapy and Patients in Group B underwent traditional moist dressings respectively.

1. Personal Data: the studied population included 40 females and 60 males. Their ages ranged between 30 and 77 years with a mean of 53.65 years. There was no significant difference between both groups as regards gender, age, as shown in (Table 1).

Table 1: Comparison of gender and age distribution between both groups

Personal Data	Vacuum		Traditional		P value
	No.	%	No.	%	
Gender					
Male	32	64.0	28	56.0	0.852
Female	18	36.0	22	44.0	
Age (years)					0.698
Min. – Max.	33.0 – 76.0		30.0 – 77.0		
Mean ± SD.	55.24 ± 13.50		52.44 ± 13.46		

2. Duration of DM: as regards duration of diabetes, the patients who underwent VAC were diagnosed diabetic between 1 year and 22 years, patients who underwent traditional dressings were diagnosed diabetic between 1 year and 20 years. There was no significant difference between both groups as regards duration of diabetes, as shown in (Table 2).

Table 2: Comparison of duration of diabetes distribution between both groups

Duration of diabetes (years)	Vacuum	Traditional	P value
Min. – Max.	1.0 – 22.0	1.0 – 20.0	0.777
Mean ± SD.	7.52 ± 5.80	7.88 ± 5.96	

3. Local wound examination (before treatment): by local wound examination before treatment, the duration of the presence of the wounds before this study was between 1 month and 6 months in VAC group, and between 1 month and 4 months in the traditional group.

The largest dimension of the wounds in VAC group was between 5 cm and 26 cm and between 3 cm and 25 cm in the traditional dressing group. The depth of the wound in VAC group and traditional group was nearly the same; it was between 1 cm and 3 cm.

According to the site of the wounds in VAC group there were 10 wounds in the front of the foot, 10 in the medial side of the sole, 16 in the lateral side of the sole, and 14 in the heel, while the site of the wounds in the traditional dressing group were 10 wounds in the front of the foot, 8 in the medial side of the sole, 16 in the lateral side of the sole, and 16 in the heel.

There was no significant difference between both groups as regards the duration, size, depth and site of the wound before treatment, as shown in (Table 3).

Table 3: Comparison of duration, size, depth and site of the wound before treatment between both groups

Wound	Vacuum		Traditional		P value
	No.	%	No.	%	
Duration (months)					
Min. – Max.	1.0 – 6.0		1.0 – 4.0		0.996
Mean ± SD.	3.31 ± 0.92		2.97 ± 1.17		
Largest dimension					
Min. – Max.	5.0 – 26.0		3.0 – 25.0		0.540
Mean ± SD.	13.16 ± 3.25		15.40 ± 4.97		
Depth					
Min. – Max.	1.0 – 3.0		1.0 – 3.0		0.631
Mean ± SD.	2.22 ± 0.41		2.12 ± 0.58		
Site					
Front	10	20.0	10	20	1.000
Med. Sole	10	20.0	8	16	
Lat. Sole	16	32.0	16	32	
Heel	14	28.0	16	32	

4. Size and depth of the wound (after six weeks): The percentage of size and depth reduction of the wounds after six weeks of intervention were tabulated and compared, revealing that there was a significant reduction in the size and depth of the wounds in VAC group compared to the traditional dressing group, as shown in (Table 4).

Table 4: Comparison of percentage of size and depth reduction of the wound after six weeks of treatment between both groups

Follow-Up (After six weeks)	Vacuum (n = 50)	Traditional (n = 50)	P value
Size (cm)			0.005*
Min. – Max.	1.5 – 9.0	2.0 – 16.0	
Mean ± SD.	4.80±2.44	9.56±5.72	
Percentage of size reduction (%)	66.36±6.55	36.68±5.36	<0.001*

Depth (cm)			<0.001*
Min. – Max.	0.25 – 1.0	0.50 – 2.0	
Mean ± SD.	0.71± 0.28	1.29± 0.34	
Percentage depth reduction (%)	69.12±6.25	38.92±9.97	<0.001*

*The test was significant

5. Timing of healthy granulation tissue formation (days): healthy granulation tissue was developed in all patients in group A and developed faster unlike group B where 4 patients underwent secondary amputation as they had not developed healthy granulation tissue and developed slower in the other patients, as shown in (Table 5).

6. Number of debridement sessions: the number of debridement sessions was significantly less in VAC group compared to the traditional dressing group, as shown in (Table 5).

7. Local wound complications (cellulitis–secondary amputation): Regarding local wound complications (cellulitis–secondary amputation), it was significantly less in VAC group compared to the traditional dressing group, as shown in (Table 5).

Table 5: Comparison of timing of healthy granulation tissue formation, number of debridement sessions, Local wound complications after six weeks of treatment between both groups

Follow-Up (After six weeks)	Vacuum		Traditional		P value
	No.	%	No.	%	
Timing of healthy granulation tissue (days)	(n = 50)		(n = 46)		<0.001*
Min. – Max.	4.0 – 12.0		5.0 – 22.0		
Mean ± SD.	6.04 ± 1.93		9.67 ± 3.73		
Number of debridement sessions	(n = 50)		(n = 50)		<0.001*
Min. – Max.	0.0 – 2.0		0.0 – 6.0		
Mean ± SD.	0.20 ± 0.50		2.86 ± 2.35		
Wound infection	(n = 50)		(n = 25)		<0.001*
No	42	84.0	18	36.0	
Yes	8	16.0	32	64.0	
2nd amputation	(n = 50)		(n = 50)		<0.001*
No	50	100.0	46	92.0	
Yes	0	0.0	4	8.0	

*The test was significant

Fig A **Fig B**

Fig 2: Case 1 VAC therapy; A, before intervention & B, after 6 weeks

Fig A **Fig B**

Fig 3: Case 2 VAC therapy; A, before intervention & B, after 6 weeks

Fig A **fig B**

Fig 4: Case 3 VAC therapy; A, before intervention & B, after 6 weeks

Fig A **Fig B**

Fig 5: Case 1 Traditional therapy; A, before intervention & B, after 6 weeks

Fig A **Fig B**

Fig 6: Case 2 Traditional therapy; A, before intervention & B, after 6 weeks

Fig A **Fig B**

Fig 7: Case 3 Traditional therapy; A, before intervention & B, after 6 weeks

Discussion

The prevalence of diabetic ulcers is rising at 9% annually. Regardless of the etiology, wounds are difficult to treat if coexisting factors (e.g. infection or diabetes mellitus) prevent regular wound healing and generally take longer time to heal and care is enormously variable [6].

In past few centuries medicine is so much advanced, in spite of that, management of chronic wounds remains a tough challenge. To solve this, lot of modalities of dressings and local applicants have been developed and lot of studies are still going on. Many chronic wounds around the world are treated sub-optimally with general wound care products designed to cover and absorb some exudates. Although wound dressing have been used for at least two millennia, there exists no ideal dressing. Surgical dressing of both open and closed wounds is based mainly on tradition, training and the surgeons own philosophy [7].

Vacuum assisted closure (VAC) therapy involves applying a controlled sub-atmospheric pressure environment across the surface of a wound in an airtight dressing. A pump is used to maintain negative pressure, usually between -75 and -125 mmHg, in a consistent or intermittent manner [8].

The application of topical negative pressure (vacuum) removes blood and serous fluid, reduces infection rates (closed/sealed system creates a hypoxic environment) and increases localized blood flow, there by supplying the wound with oxygen and nutrition to promote accelerated healing. Alternative names for VAC include topical negative pressure, sub-atmospheric pressure, sealed surface wound suction, vacuum sealing and foam suction dressing [4].

In the present study, the efficacy of VAC was compared to traditional moist wound dressings in improving the healing process in chronic diabetic foot wounds.

In this study, VAC had better results in reducing wound size and depth than traditional method. It was noted also that the use of VAC decreases the need of debridement sessions than traditional methods. We reviewed many studies which were consistent with those results.

Joseph *et al*. [9]. observed that after six weeks, chronic diabetic foot wounds treated with VAC had a significantly greater percent reduction in wound volume and depth than wounds treated with traditional method (p=0.038 and p=0.00001, respectively), Arti *et al*. [10]. found that the VAC group proportion was significantly (P=0.007) greater for complete ulcer closure than that for the conventional wound therapy group. In a controlled randomized multicenter trial, Armstrong *et al*. [11]. have demonstrated the superiority of VAC in treating outcomes of surgical wounds from minor amputations compared to local standard therapy.

As regards wound complications, wound infection and cellulitis develop more in traditional method than VAC, corresponding to these results, Paola *et al*. [12]. found that infection control was better and faster in the VAC group than in the conventional group (p=0.05).

Conclusion

This study showed that, VAC appears to be safe and more effective than traditional methods for the treatment of diabetic foot ulcers; as VAC has better results in wound healing than traditional method, as it provides significant reduction in the size and depth of the wounds, faster healthy granulation tissue formation, less number of debridement sessions and less incidence of local wound complications compared to the traditional dressing group.

References

1. Soliman AO. Diabetes Mellitus in Egypt in Short. J Diabetes Metab, 2013**;** 4: 318. doi:10.4172/2155-6156.1000318.
2. Yazdanpanah L, Nasiri M, Adarvishi S. Literature review on the management of diabetic foot ulcer. World Journal of Diabetes. 2015**;** 6(1):37-53.
3. Zhang J, Hu ZC, Chen D, Guo D, Zhu JY, Tang B. Effectiveness and safety of negative-pressure wound therapy for diabetic foot ulcers: a meta-analysis. Plastic and Reconstructive Surgery. 2014**;** 134(1):141-151.
4. Pham C, Middleton P, Maddern G. Vacuum-Assisted Closure for the Management of Wounds: An Accelerated Systematic Review. Adelaide Australian Safety and Efficacy Register of New Interventional Procedures-Surgical; ASERNIP-S Report, 2003, 37.
5. Dang CN, Boulton AJM. Changing perspectives in diabetic foot ulcer management. Int J Lower Extremity Wounds. 2003; 2:4-12.
6. Banwell PE, Teot L. Topical negative pressure (TNP): the evolution of a novel wound therapy. J Wound Care. 2003; 12:22-8.
7. Vermeulen HU, Goossens Ade, Vos R Legemate DA. Systematic review of dressings and topical agents for surgical wounds healing by secondary intention. Br J Surg. 2005; 92(6):665- 672.
8. Greer N, Foman NA, MacDonald R, Dorrian J, Fitzgerald

P, Rutks I, *et al*. Advanced wound care therapies for nonhealing diabetic, venous, and arterial ulcers: a systematic review. Ann Intern Med. 2013; 159(8):532-42.
9. Joseph E, Hamori CA, Bergman S, Roaf E, Swann NF, Anastasi GW. A prospective randomized trial of vacuum-assisted closure versus standard therapy of chronic nonhealing wounds. Wounds. 2000; 12(3):60-67.
10. Arti H, Khorami M, Ebrahimi-Nejad V. Comparison of negative pressure wound therapy (NPWT) & conventional wound dressings in the open fracture wounds. Pak J Med Sci. 2016; 32(1):65-9.
11. Armstrong DG, Lavery LA, Abu-Rumman P, Espensen EH, Vazquez JR, Nixon BP, *et al*. Outcomes of sub atmospheric pressure dressing therapy on wounds of the diabetic foot. Ostomy/Wound Management. 2002; 48(4):64-8.
12. Paola LD, Carone A, Ricci S, Russo A, Ceccacci T, Ninkovic S. Use of Vacuum Assisted Closure Therapy in the Treatment of Diabetic Foot Wounds. JDFC. 2010; (2):33-44.