Role of Vacuum Assisted Closure Therapy Compared to Standard Moist Wound Dressing in the Treatment of Diabetic Foot Ulcers

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Introduction: Amputation rates have dropped and diabetes awareness has increased due to several diabetic foot treatment suggestions. Diabetic foot ulcers (DFUs) may now be properly treated with a range of cutting-edge medicines, allowing practitioners the greatest local therapy available. One is negative pressure wound therapy.

Aim of work: Assessment of vacuum assisted closure clinical efficacy compared with the standard moist wound dressing in the treatment of diabetic foot ulcers.

Patients and methods: A total of 30 diabetic patients with diabetic foot ulcers were enrolled, after consenting each of them and divided into two groups; group A (standard moist wound dressing) (SMWD) (control group) included fifteen cases who were treated with conventional moist dressing and group B (vacuum assisted Closure) (NPWT) (experimental group) included fifteen cases who were treated vacuum assisted closure. Progress of healing was evaluated and documented in the form of change in wound diameter, depth, up or down scaling along University of Texas wound classification (UTWC), wound status at 2, 4, 8, and 12 weeks and 4 weekly thereafter till complete epithelialization with diligent recording of time required for complete epithelisation and number of dressings required in the process for both groups.

Results: Vacuum assisted wound closure is associated with better healing and diminished ulcer depth after 8 weeks of treatment with amount of change 100.00 ± 0.00 vs. 93.79 ± 5.55%. It is also associated with higher incidence of complete granulation after 6 weeks of treatment 12 (80.0%) vs. 6 (40.0%). There are no differences were noted between study groups as regard age, sex., special habits and medical co morbidities, laboratory investigations, ulcer site, ucler grading regarding University of Texas before and after treatment.

Conclusion: VAC is safer and more effective than moist dressing for diabetic foot ulcers. VAC therapy speeds wound healing, accelerates granulation tissue production, and reduces ulcer area compared to standard dressing.

Key words: Vacuum Assisted Closure Therapy; Standard Moist Wound Dressing; Diabetic Foot Ulcers.

Introduction

Globally, diabetes is expanding rapidly, and diabetic foot surgery is increasing.[1]

Diabetes patients' foot troubles lead to a disproportionate number of hospital days due to frequent surgeries and lengthier hospitalizations. Foot problems are a major admission reason.[2]

Diabetics may experience foot difficulties, known as diabetic foot. The most common, complicated, and costly complications of diabetes mellitus include foot ulcers, infections, and gangrene.[3]

The best diabetic foot ulcer treatment is uncertain. Traditional gauze bandages have been saturated with saline, but they have been difficult to keep moist over time.[4]

Several hydrocolloid wound gels now retain moisture better. Refinements have incorporated growth hormones and enzymatic debridement agents to topical ointments.[5]

Other wound remedies include hyperbaric oxygen therapy and culture skin substitutes.[6]

All of these therapies are expensive and sometimes used without enough scientific evidence.[7]

A new noninvasive adjunctive therapy system, Negative Pressure Wound Therapy (NPWT), uses controlled negative pressure using Vacuum-Assisted Closure device (VAC) to promote wound healing by removing fluid through a sealed dressing and tubing connected to a collection container. Sub-atmospheric pressure dressings, available as VAC devices, can expedite wound healing.[8]

Today, nothing is known about how negative pressure dressing heals diabetic foot ulcers. Thus, we investigated the effects of negative pressure dressing on VAC-treated diabetic foot ulcers.

Aim of work

The aim of this work was to assess of vacuum assisted closure clinical efficacy compared with the standard moist wound dressing in the treatment of diabetic foot ulcers.

Patients and methods

Patients

This prospective comparative randomized study was conducted on 30 diabetic patients with diabetic foot ulcers attended Ain Shams University Hospitals & Ahmed Maher Teaching Hospital with the following criteria.

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Inclusion criteria

1. Age: any age group.
2. Both sexes.
3. Diabetic patients with diabetic foot ulcers.
4. With adequate tissue perfusion defined as ankle brachial index between 0.7 and 1.2., or palpable distal pedal pulses.
5. University of Texas wound stages 1 and 2.
6. Presence of the wound in an anatomical position feasible for creating an air-tight seal for (Negative pressure wound therapy) (NPWT).

Exclusion criteria

1. Patients using immunosuppressive drugs, steroids or chemotherapy.
2. Wounds due to chronic venous insufficiency.
3. Autoimmune disease causing peripheral vascular insufficiency.
4. Limbs deemed unsalvageable.
5. Active Charcot foot syndrome.
6. University of Texas wound stages 3 and 4.
7. Malignant ulcers.
8. Patients refusing to participate.

Patients and methods

Before therapy, co-morbidities, wound depth, diameter, infection, vascularity, etiology, and initial ulcer grading were recorded using University of Texas wound Classification.

Ulcers in the plantar metatarsal head, heel, hammer toe tips, and other conspicuous locations were inspected, as were hammertoes, brittle nails, calluses, and fissures.

After sharp debridement to remove necrotic tissue, 30 subjects were divided into two groups: group A (standard moist wound dressing) (SMWD) (control group) included 15 cases treated with conventional moist dressing, and group B (vacuum assisted closure) (NPWT) included 15 cases treated with vacuum assisted closure.

On the first visit, wound depth, diameter, infection status, vascularity, etiology, and initial ulcer grading were recorded using University of Texas wound classification (UTWC) and vascular assessment including pulse examination and ABPI measurements.

At the follow-up visit, wound diameter, depth, up or down scaling along UTWC, wound status at 2, 4, 8, and 12 weeks and 4 weekly thereafter until complete epithelialization were evaluated and documented, along with the time and number of dressings needed for both groups.

The study patients' wounds were sharply debrided to eliminate necrotic tissue and slough. Randomization placed them in either group.

Group A received daily saline-moistured gauze dressings

Group B wounds were dressed with foam-based dressing after debridement in aseptic circumstances. For airtightness, an adhesive drape covered the dressing. A portable vacuum/suction machine's fluid collection canister was attached to a foam-embedded evacuation tube.

Sub atmospheric pressure was delivered intermittently three times a day from –50 to –125 mmHg. NPWT dressings were replaced as needed.

Ulcer floor cultures were obtained weekly to examine bacterial flora.

All patients received broad-spectrum antibiotics initially and later according on culture sensitivity.

Ulcers were managed until surgical or spontaneous wound closure or study follow-up duration evaluation, whichever came first.

Complete healing meant 100% wound closure, re-epithelialization or scab, no drainage, and no dressing.

Cases were examined every two weeks until complete granulation (maximum 8 weeks).

At follow-up visits, wound diameter, depth, up or down scaling along UTWC, wound status at 2, 4, 8, and 12 weeks and 4 weekly thereafter until complete epithelialization were assessed and recorded, along with the time and number of dressings needed for both groups.

All patients received tight glycaemic management, wound offloading, nutritional counseling, broad-spectrum antibiotics in infected wounds until culture results are available, and multiple bedside or surgical debridements as needed.

To treat wounds with granulating bases and minimal necrotic tissue, use 0.9% saline and antiseptic povidone iodine. Apply Clostridopeptidase A (Iruxol mono-Smith and Nephiew Ltd. Hessel Road Hull, UK) topical ointment for enzymatic wound debridement and tissue formation.

The NPWT group initially dressed twice weekly for 2 weeks, then once weekly if needed, depending on wound status and exudate.

An objective wound assessment and progress score was calculated using wound diameter, depth, and University of Texas Wound Classification.

Version 23.0 of SPSS (Chicago, Illinois, USA) was used to analyze data. Quantitative data were shown as mean±SD and ranges. Additionally, qualitative characteristics were reported as numbers and percentages.

Results

There was no statistically significant difference between groups according to demographic data, about age "years" and sex, with p-value (p>0.05) **(Table 1).**

There is no statistically significant difference between groups according to co morbidities about smoking, DM, HTN and renal insufficiency; also cigarettes (Days) and cigarettes (Months), with p-value (p>0.05) **(Table 2).**

There was no statistically significant difference between groups according to lab. Investigations, about HGB, TLC, CRP, ESR, HbA1c, Creat and Alb, with p-value (p>0.05) **(Table 3).**

Regarding ulcer site, there is no statistically significant difference between groups, with p-value (p>0.05) **(Table 4).**

There is no statistically significant difference between groups according to Ulcer depth category, about before, follow up in 2 weeks, follow up in 4 weeks, follow up in 6 weeks and Follow up in 8 weeks, with p-value (p>0.05) **(Table 5).**

There was statistically significant higher mean value of Ulcer depth (mm) at follow up in 6 weeks in SMWD group was 12.47±7.34 comparing to NPWT was 5.27±3.13, with p-value (p=0.009). Also, statistically significant higher mean value of Ulcer depth (mm) at follow up in 8 weeks in SMWD group was 2.07±1.12 comparing to NPWT was 0.00±0.00, with p-value (p=0.003). As for the amount of change, there was statistically significant higher change of follow up comparing to before in NPWT group than SMWD group, with p-value (p<0.05) **(Table 6).**

There was no statistically significant difference between groups according to University of Texas, about before, follow up in 2 weeks, follow up in 4 weeks, follow up in 6 weeks and follow up in 8 weeks, with p-value (p>0.05) **(Table 7).**

There was a statistically significant higher frequency of complete granulation at follow up in 6 weeks in NPWT group was 12 patients (80%) comparing to SMWD group was 6 patients (40%), with p-value (p=0.025). Also, higher frequency complete granulation of the over the period in NPWT group than SMWD group, but insignificant, with p-value (p>0.05) **(Table 8).**

Table 1: Comparison NPWT patients group and SMWD group according to demographic data

Demographic data	NPWT Group (n=15)	SMWD Group (n=15)	Test value	P-value
Age "years"				
Mean±SD	60.73±8.60	61.87±10.49	-0.324	0.749
Range	47-75	44-78		
Sex				
Female	4 (26.7%)	6 (40.0%)	0.600	0.439
Male	11 (73.3%)	9 (60.0%)		

Table 2: Comparison NPWT patients group and SMWD group according to co morbidities

Comorbidities	NPWT Group (n=15)	SMWD Group (n=15)	Test value	P-value
Smoking	5 (33.3%)	5 (33.3%)	0.000	1.000
DM	15 (100.0%)	15 (100.0%)	0.000	1.000
HTN	9 (60.0%)	5 (33.3%)	2.143	0.143
Renal Insufficiency	1 (6.7%)	2 (13.3%)	0.370	0.543
Cigarettes (Days)				
Mean±SD	26.27±15.24	28.27±13.56	-0.380	0.707
Range	11-62	11-62		
Cigarettes (Months)				
Mean±SD	782.80±417.97	873.27±375.96	-0.623	0.538
Range	305-1810	305-1810		

Table 3: Comparison NPWT patients group and SMWD group according to lab investigations

Lab investigations	NPWT Group (n=15)	SMWD Group (n=15)	Test value	P-value
HGB				
Mean±SD	12.45±1.83	12.23±2.58	0.270	0.789
Range	10.5-16.2	9.7-17.7		
TLC				
Mean±SD	13.47±5.64	12.52±4.64	0.502	0.620
Range	7-22	6.8-19		
CRP				
Mean±SD	13.73±12.28	17.31±23.07	-0.530	0.600
Range	3.98-53	2.6-99		
ESR				
Mean±SD	71.33±37.53	72.73±43.96	-0.094	0.926
Range	37-135	9-145		
HbA1c				
Mean±SD	8.89±1.62	8.98±1.57	-0.160	0.874
Range	6.6-11.7	6.4-12.3		
Creat				
Mean±SD	1.03±0.25	1.48±0.99	-1.675	0.105
Range	0.9-1.9	0.8-4.6		
Alb				
Mean±SD	3.55±0.60	3.49±0.63	0.297	0.768
Range	2.7-4.6	2.6-4.7		

Table 4: Comparison NPWT patients group and SMWD group according to ulcer site

Ulcer site	NPWT Group (n=15)	SMWD Group (n=15)	Test value	P-value
Forefoot	4 (26.7%)	5 (33.3%)	0.159	0.690
Midfoot	4 (26.7%)	3 (20.0%)		
Hindfoot	0 (0.0%)	2 (13.3%)		
Sole	4 (26.7%)	2 (13.3%)		
Heel	2 (13.3%)	2 (13.3%)		
Leg	1 (6.7%)	1 (6.7%)		

Table 5: Comparison NPWT patients group and SMWD group according to Ulcer depth category

Ulcer depth category	NPWT Group (n=15)	SMWD Group (n=15)	Test value	P-value
Before				
Grade 2	1 (6.7%)	3 (20.0%)	1.154	0.283
Grade 3	14 (93.3%)	12 (80.0%)		
Follow up in 2 weeks				
Grade 1	2 (13.3%)	4 (26.7%)	0.919	0.632
Grade 2	10 (66.7%)	9 (60.0%)		
Grade 3	3 (20.0%)	2 (13.3%)		
Follow up in 4 weeks				
Grade 1	12 (80.0%)	6 (40.0%)	5.333	0.069
Grade 2	2 (13.3%)	4 (26.7%)		
Grade 3	1 (6.7%)	5 (33.3%)		
Follow up in 6 weeks				
Grade 1	6 (40.0%)	10 (66.7%)	4.091	0.129
Grade 2	6 (40.0%)	5 (33.3%)		
Grade 3	3 (20.0%)	0 (0.0%)		
Follow up in 8 weeks				
Grade 0	11 (73.3%)	11 (73.3%)	0.000	1.000
Grade 1	4 (26.7%)	4 (26.7%)		

Table 6: Comparison NPWT patients group and SMWD group according to Ulcer depth in mm

Ulcer depth (mm)	NPWT Group(n=15)	SMWD Group (n=15)	Test value	P-value
Before				
Mean±SD	33.73±9.17	27.40±7.80	2.038	0.054
Range	22-52	17-42		
Follow up in 2 weeks				
Mean±SD	20.60±11.71	20.27±6.78	0.095	0.925
Range	7-42	12-37		
Follow up in 4 weeks				
Mean±SD	15.73±6.21	16.13±8.61	-0.095	0.925
Range	3-33	2-40		
Follow up in 6 weeks				
Mean±SD	5.27±3.13	12.47±7.34	-2.831	0.009*
Range	2-12	2-32		
Follow up in 8 weeks				
Mean±SD	0.00±0.00	2.07±1.12	-3.775	0.003*
Range	0-0	0-7		
Amount of change 2 weeks	13.13±4.09	7.13±2.20	5.008	<0.001**
% 2 weeks	43.13±20.56	26.51±5.48	3.024	0.005*
Amount of change 4 weeks	18.00±3.63	11.27±5.19	4.120	<0.001**
% 4 weeks	57.39±19.70	48.90±30.60	1.992	0.047*
Amount of change 6 weeks	28.47±6.23	14.93±2.69	7.724	<0.001**
% 6 weeks	85.45±4.88	59.78±21.03	4.603	<0.001**
Amount of change 8 weeks	33.73±9.17	25.33±5.89	2.986	0.006*
% 8 weeks	100.00±0.00	93.79±5.55	4.335	<0.001**

Table 7: Comparison NPWT patients group and SMWD group according to University of Texas

University of Texas	NPWT Group (n=15)	SMWD Group (n=15)	Test value	P-value
Before				
Grade 2 Stage 1	0 (0.0%)	2 (13.3%)	5.714	0.057
Grade 3 Stage 1	10 (66.7%)	4 (26.7%)		
Grade 3 Stage 2	5 (33.3%)	9 (60.0%)		
Follow up in 2 weeks				
Grade 1 Stage 1	2 (13.3%)	4 (26.7%)	3.067	0.547
Grade 2 Stage 1	8 (53.3%)	7 (46.7%)		
Grade 2 Stage 2	2 (13.3%)	2 (13.3%)		
Grade 3 Stage 1	2 (13.3%)	0 (0.0%)		
Grade 3 Stage 2	1 (6.7%)	2 (13.3%)		
Follow up in 4 weeks				
Grade 1 Stage 1	9 (60.0%)	6 (40.0%)	5.743	0.219
Grade 2 Stage 1	3 (20.0%)	4 (26.7%)		
Grade 2 Stage 2	2 (13.3%)	0 (0.0%)		
Grade 3 Stage 1	1 (6.7%)	3 (20.0%)		
Grade 3 Stage 2	0 (0.0%)	2 (13.3%)		
Follow up in 6 weeks				
Grade 1 Stage 1	12 (80.0%)	9 (60.0%)	1.629	0.443
Grade 2 Stage 1	2 (13.3%)	3 (20.0%)		
Grade 2 Stage 2	1 (6.7%)	3 (20.0%)		
Follow up in 8 weeks				
Grade 0 Stage 1	8 (53.3%)	7 (46.7%)	0.133	0.715
Grade 1 Stage 1	7 (46.7%)	8 (53.3%)		

Table 8: Comparison NPWT patients group and SMWD group according to Complete granulation

Complete granulation	NPWT Group (n=15)	SMWD Group (n=15)	Test value	P-value
Follow up in 2 weeks	0 (0.0%)	0 (0.0%)	0.000	1.000
Follow up in 4 weeks	7 (46.7%)	3 (20.0%)	2.400	0.121
Follow up in 6 weeks	12 (80.0%)	6 (40.0%)	5.000	0.025*
Follow up in 8 weeks	15 (100.0%)	13 (86.7%)	2.143	0.143
Follow up in 10 weeks	15 (100.0%)	15 (100.0%)	0.000	1.000

Discussion

Our study found that vacuum-assisted wound closure, a negative pressure wound therapy, outperformed moist wound dressing in managing diabetic foot ulcers, resulting in faster healing and reduced ulcer depth after 8 weeks (Change of 100.00 ± 0.00 vs. 93.79 ± 5.55%). Vacuum-assisted wound closure also increased full granulation after 6 weeks (12 (80.0%) vs. 6 (40.0%)).

Age, sex, special habits and medical co morbidities, laboratory investigations, ulcer site, and University of Texas ucler grading did not change between research groups before and after therapy.

Yadav et al., 2023 concurred that VAC dressing is the optimum dressing for faster recovery and a shorter hospital stay. VAC had the shortest treatment time (31.17 days; 24.13 days; 15.17 days). The VAC group had considerably fewer debridements (2.37, 2.43, and 1.60). Although small, the VAC group needed the fewest additional procedures like flaps or skin grafts.[9]

Chen et al., 2021 tested negative pressure wound therapy for diabetic foot ulcers. They agreed with us that negative pressure wound therapy speeds wound healing and is safe with routine treatment.[10]

Ravisankar et al., 2022 compared moist gauze dressings to negative pressure wound treatment for foot ulcers. They informed us that VAC therapy improves graft take rate (p=0.05) in DFU compared to normal wound care. Interventions significantly affect ulcer area on day 21.The study subjects' day 1 ulcer states were 16% healthy, 14% necrotic, and 50% pale.[11]

Armstrong and Lavery (2005) found that VAC group median time to closure was 56 days compared to 77 days for traditional saline dressing group.[12]

In an Indian study of sixty DFU patients, Vaidhya et al. (2015) found that VAC group healed in 17.2 days compared to 34.9 days for standard saline dressing group.[13]

Blume et al. (2008) showed that most VAC patients had complete skin closure or 100% reepithelization.[14]

Etoz et al. (2007) revealed that VAC wound closure took 11.25 days compared to 15.75 days for traditional dressing.[15]

Liu et al., 2017 found that VAC significantly lowers DFUs compared to standard dressing.[16]

All 11 patients' wounds healed after VAC therapy, according to Nather et al. (2010). Nine wounds were split-skin-grafted and two secondary-closed.[17]

Huang et al. (2014) showed that NPWT improves wound microenvironment, microvascular hemodynamics, wound infection, and endothelial cell regeneration.[18]

Everett and Mathioudakis (2018) recommend assessing the history of peripheral arterial disease, recognizing infection and treating it with antibiotics in diabetic foot infections, optimizing blood glucose to improve wound healing and limit adverse effects on cellular immunity and infection, and using multidisciplinary care to avoid amputation.[19]

In addition, Frykberg et al., 2020 found that NPWT may impact gene expression changes in diabetic patients, which may be a new NPWT research direction.[20]

In contrast, Seidel et al., 2020 found that NPWT was not better than SMWC in diabetic foot wounds in German clinical practice. The wound closure rate and time to closure were similar between treatment arms. 191 patients (NPWT 127; SMWC 64) had missing endpoints, premature therapy termination, or unapproved treatment adjustments.[21]

Gurtner et al. (2018) discovered that vacuum dressing resulted in shorter hospital stays.[22]

A 2018 study by Blume et al. compared negative pressure wound therapy with advanced moist wound care for diabetic foot ulcers, involving 342 patients (Mean age 58 years, 79% male).[23]

To improve chronic wound healing, Priyatham et al. (2016) found that vacuum assisted closure had better graft take up than conventional moist wound dressings.[24]

Thomas (2012) found that negative pressure wound therapy improved granulation tissue production, graft uptake and survival, and patient adherence.[25]

Kaya et al. (2005) also found that negative pressure wound therapy reduced hospital stay and post-op problems. Thus, negative pressure wound therapy is better for chronic wounds.[26]

Conclusion

VAC is safer and more effective than moist dressing for diabetic foot ulcers. VAC therapy speeds wound healing, accelerates granulation tissue production, and reduces ulcer area compared to standard dressing.

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Conflict of interest

There are no conflicts of interest

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