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A Comparative Study between Negative Pressure Wound Therapy versus Standard Moist Wound Therapy Utilizing Vacuum Assisting Closure in the Treatment of Diabetic Foot Wound

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Abstract

Background: Foot infections are common in patients with diabetes and are associated with high morbidity and risk of lower extremity amputation. After surgical debridement, wound related complications as infection, secondary or major amputation are very common compared to non-diabetic patients. Negative pressure wound therapy (NPWT) is a new wound care therapy and present an effective tool in the management of diabetic foot wound.

Aim of Study: To compare and evaluate safety and clinical efficacy of negative pressure wound therapy compared to standard moist wound therapy (SMWT) in the treatment and management of diabetic foot wound.

Patients and Methods: This is a cohort study involving 40 patients with active diabetic foot wound, in a high-volume tertiary referral vascular center. The study included patients attending Ain Shams University hospitals and Gamal Abdel Naser Hospital, both as in-patients and on out-patient basis They were divided into 2 groups: 20 patients (group A) were prescribed NPWT, and the other 20 patients (group B) received SMWT. Comparison between the two groups according to time to full granulation tissue, infection, number of sessions of debridement and limb salvage.

Results: Patients treated with NPWT in group A showed earlier full granulation tissue in 10% of patients after 2 weeks, 68% after 4 weeks and 100% after 8 weeks, compared to 0% of patients treated with SMWT after 2 weeks, 21% after 4 weeks and 83% after 8 weeks, with a significant difference after 4 weeks (p-value 0.003). No significant difference between the two groups as regard as wound related complications.

Conclusion: According to our study results, we concluded that NPWT has a significant effect on acceleration and promotion of granulation tissue. We suggest that NPWT is most appropriate for deep, cavitary and full thickness wound which helps an early closure of wounds. Also, NPWT is safe as SMWD regarding wound related complication such as wound infection, the need of surgical debridement or amputation with no significant difference.

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Introduction

FOOT infections are common in patients with diabetes and are associated with high morbidity and risk of lower extremity amputation. After surgical debridement, wound related complications as infection, secondary or major amputation are very common because of diabetes impaired wound healing process compared to non-diabetic patients.

The diagnosis of diabetic foot infection is based on the clinical signs and symptoms of local inflammation. Infected wounds should be cultured after debridement.

Debridement is a technique aimed at removing nonviable and necrotic tissue, thought to be detrimental to healing. This is accomplished by removing abnormal wound bed and wound edge tissue, such as necrotic dermal tissue, foreign debris, and bacteria elements known to have an inhibitory effect on wound healing **[1]**.

Surgical debridement is the cornerstone of treatment for deep diabetic foot infection. Procedures range from simple incision and drainage to extensive multiple surgical debridement and amputation. As infection is controlled and the wound starts to granulate, primary closure may be successful. The wound may also be treated surgically with a flap or graft, left to heal by secondary intention, or managed with negative pressure dressings **[2]**.

Optimal therapy for diabetic foot wounds remains ill defined. Saline-moistened gauze has been the standard; however, it has been difficult to

continuously maintain a moist wound environment with these dressings. This has led to the development of various hydrocolloid wound gels which provide more consistent moisture retention. Refinements in topical ointments have resulted in the addition of various pharmacologic agents, including growth factors and enzymatic debridement compounds.

Other wound care therapies have been advocated including hyperbaric oxygen therapy and cultured skin substitutes. All these therapies, including the more elaborate ointments, are associated with significant expense and are being utilized in some situations without sufficient scientific evidence demonstrating efficacy. Therefore, the search for an efficacious, convenient, and cost-effective therapy continues.

One of the newer wound-care therapies involves the application of negative pressure to the wound. The negative pressure wound therapy provides an environment of sub atmospheric pressure to wounds and has achieved excellent anecdotal results. A randomized clinical trial in diabetic foot wounds demonstrated therapy to be associated with a more rapid decrease in wound size and a shorter time to wound healing [3].

Aim of the work:

To compare and evaluate safety and clinical efficacy of negative pressure wound therapy compared to standard moist wound therapy in the treatment and management of diabetic foot wound.

Patients and Methods

The aim of this randomized prospective study was to compare and evaluate safety and clinical efficacy of negative pressure wound therapy (NPWT) compared to Standard moist wound therapy (SMWT) in the management of diabetic foot wounds.

Primary end point of the study was to obtain clean, not infected, and full healthy granulating tissue after surgical debridement, with less of necrotic tissues, bone, or tendon exposure and without local signs of infection.

Research hypothesis:

NPWT is more effective, help us to obtain healthy, not infected granulation tissue with less time of healing and reduce the need of other sessions of debridement of necrotic tissue. Also, it had improved limb salvage rates in comparison to SMWD in management of diabetic foot wound.

Study design and population:

This was a randomized simple prospective controlled study involved 40 patients with active diabetic foot wound.

Patients were divided into two groups by random allocation based on computer generated table of random numbers. 20 patients (group A) was prescribed NPWT, and the other 20 patients (group B) received SMWD.

Inclusion criteria:

- Diabetic.
- Age >18 years.
- Adequate blood circulation based on presence of intact distal pulse and confirmed by arterial duplex.
- Ankle/brachial index >0.7.
- Serum albumin >3.

Exclusion criteria:

- Not diabetic.
- Uncontrolled hyperglycemia.
- Ischemic lower limb patients.
- Ankle/brachial index <0.7.
- Bad general condition as regard hemodynamic and metabolic status.
- Wounds resulting from untreated electrical, chemical or radiation burn.
- Presence of untreated osteomyelitis, Charcot joint, cellulitis, collagen vascular disease or ulcer malignancy.

Ethical committee approval was obtained prior to initiation of the study. The study included patients attending Ain Shams University Hospitals and Gamal Abdel Naser Hospital, both as in-patients and on out-patient basis. This study was conducted in the period between January 2021 and July 2021.

An informed consent was obtained from all patients who agree to participate in the study, and patients was offered the opportunity to withdraw from the evaluation at any time.

Study procedure:

Patients' evaluation:

Initial evaluation and clinical examination of patients was done according to patient's demographic data, laboratory investigations (complete blood count including total leucocytic count, kidney functions, blood sugar, albumin level and diabetic profile).

Grade of wound infection was described according to presence of frank purulence and/or two or more local singes of inflammation such as warmth, erythema, lymphangitis, lymphadenopathy, edema, pain, and loss of function. Wound assessment was done if surgical debridement or amputation was needed.

Proper wound description post debridement was recorded precisely including wound depth and diameter, according to Wagner classification.

Vascularity is assessed depending on one or more non-invasive values such as presence of pedal pulse, arterial doppler or Ankle Brachial Index (ABI).

Dressing's techniques in both groups:

In Group A of the patients, NPWT was applied while Group B received SMWT.

NPWT changes were performed every 48-72 hours, no less than two times per week, using Vacuum Assisted Closure device. The system consists of 3 components: A negative pressure generating unit with a disposable canister, a pad with evacuation tube, and a reticulated, open cell sterile polyurethane or a dense open-pore polyvinyl alcohol foam dressing cut to fit the wound. The system unit is programmed to deliver controlled negative pressure ranging from 50 to 200mmHg.

The technique involves six steps. as follows:

1- The wound was meticulously debrided, and necrotic tissue removed.
2- The wound was filled by a sterile polyurethane foam and wrapped with an adhesive, semi-permeable, transparent membrane. A good air seal was thus guaranteed around the wound.
3- The distal drain tube was connected to negative pressure device, which provided a negative pressure of 70-120mmHg, applied to the wound.
4- This was achieved by wall suction apparatus, computerized devices, or mobile suction drain devices.
5- Once the device is on, the sponge should be seen collapsed into the wound bed, thus giving the surface a concave appearance.
6- The fluid from the wound is absorbed by the sponge and is removed from the wound bed by suction to an external canister.

The Standard Moist wound therapy dressings were changed on daily basis using moistened surgical gauze, Conventional dressing done in traditional way to group B in using the following: Normal saline, Povidone-Iodine solution, Topical healing promotor cream, Sterile gauze and Adhesive tapes.

Follow-up and assessment:

This study evaluates the efficacy to obtain healthy full healthy granulation tissue and safety from complications when using (NPWT) compared with conventional dressings in patients with diabetic foot wounds.

Patients were followed-up in both NPWT and Conventional treatments. The Conventional treatment was subjected to daily dressings by conventional methods whereas the test group was subjected to topical negative pressure dressings and was left undisturbed for 3 days and wound was inspected twice weekly.

During follow-up visits, wounds were assessed during dressing for 12 weeks. Wound dimensions, closure, depth, diameter, and tissue quality were evaluated and documented on weeks 2,4,8 and 12.

Both techniques will be compared as regard to time of obtaining full and clean granulation tissue, infection control, need of other sessions of debridement of necrotic infected tissue and limb salvage.

Statistical analysis of the data:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

The used tests were:

1- Chi-square test: For categorical variables, to compare between different groups.
2- Monte Carlo correction: Correction for chi-square when more than 20% of the cells have expected count less than 5.
3- Student *t*-test: For normally distributed quantitative variables, to compare between two studied groups.
4- Mann Whitney test: For abnormally distributed quantitative variables, to compare between two studied groups.

Results

Table (1): Comparison between the two studied groups according to demographic data.

	NPWT (n=20)		SMWD (n=20)		Test of Sig.	*p*
	No.	%	No.	%		
Gender:						
Male	14	70.0	13	65.0	χ^2=	0.736
Female	6	30.0	7	35.0	0.114	
Age (years):						
Min. – Max.	49.0-76.0		43.0-69.0		*t*=	0.105
Mean ± SD.	59.35±7.56		55.20±8.24		1.660	
Median (IQR)	58.0 (53.0-64.0)		53.50(48.0-64.0)			

IQR: Inter quartile range.
SD : Standard deviation.
t_2 : Student *t*-test.
χ^2 : Chi square test.
p: *p*-value for comparing between the studied groups.

There were no statistically significant differences between the 2 groups as regard to age and sex.

Table (2): Comparison between the two studied groups according to investigations (laboratory investigation and ankle brachial index).

	NPWT (n=20)	SMWD (n=20)	*t*	*p*
HbA1c (%):				
Min. – Max.	5.0-13.0	5.0-12.0	0.778	0.441
Mean ± SD.	8.05±2.24	8.60±2.23		
Median (IQR)	8.0 (6.0-9.50)	9.0 (6.50-10.0)		
Hg:				
Min. – Max.	8.0-14.0	8.0-15.0	0.988	0.329
Mean ± SD.	10.65±1.79	11.20±1.74		
Median (IQR)	10.50 (9.0-12.0)	11.0 (10.0-12.0)		
Albumin:				
Min. – Max.	3.0-5.0	3.0-5.0	0.000	1.000
Mean ± SD.	3.83±0.75	3.83±0.75		
Median (IQR)	4.0 (3.0-4.0)	4.0 (3.0-4.0)		
ABI:				
Min. – Max.	0.80-1.20	0.70-1.20	1.519	0.137
Mean ± SD.	1.05±0.13	0.99±0.14		
Median (IQR)	1.05 (0.95-1.20)	1.0 (0.90-1.10)		

IQR: Inter quartile range.
SD : Standard deviation.
t : Student *t*-test.
p: *p*-value for comparing between the studied groups.

There were no statistically significant differences between the 2 groups as regard to laboratory investigations with labs within near normal range except of elevated inflammatory mediators and poor glycemic control in both groups.

Table (3): Comparison between the two studied groups according to Wound description, dimensions ad Wagner grading.

Foot description	NPWT (n=20)	SMWD (n=20)	Test of Sig.	*p*
Length:				
Min. – Max.	7.0-16.0	6.0-16.0	*t*=	0.785
Mean ± SD.	12.15±2.78	11.90±2.97	0.275	
Median (IQR)	12.0 (10.0-14.50)	12.0 (10.0-14.0)		
Width:				
Min. – Max.	4.0-10.0	4.0-11.0	U=	0.056
Mean ± SD.	6.40±1.54	5.68±1.99	129.50	
Median (IQR)	6.0 (5.50-7.0)	5.0 (4.0-6.25)		
Depth:				
Min. – Max.	2.0-4.0	2.0-4.0	*t*=	0.603
Mean ± SD.	2.50±0.61	2.60±0.60	0.525	
Median (IQR)	2.0 (2.0-3.0)	3.0 (2.0-3.0)		
Wagner C:				
Min. – Max.	3.0-4.0	3.0-4.0	U=	1.000
Mean ± SD.	3.85±0.37	3.85±0.37	200.0	
Median (IQR)	4.0 (4.0-4.0)	4.0 (4.0-4.0)		

IQR: Inter quartile range. *t* : Student *t*-test.
SD : Standard deviation. U: Mann Whitney test.
p: *p*-value for comparing between the studied groups.

There were no statistically significant differences between the 2 groups as regard to wound dimensions and Wagner classification.

Table (4): Comparison between the two studied groups according risk factors.

	NPWT (n=20)		SMWD (n=20)		χ^2	*p*
	No.	%	No.	%		
HTN:						
No	16	80.0	15	75.0	0.143	0.705
Yes	4	20.0	5	25.0		
Renal insufficiency:						
No	17	85.0	18	90.0	0.229	0.633
Yes	3	15.0	2	10.0		

There were no statistically significant differences between the 2 groups as regard to risk factors.

Table (5): Comparison between the two studied groups according to full granulation tissue formation.

Full granulation tissue formation	2 weeks	4 weeks	8 weeks	12 weeks
NPWT:	(n=20)	(n=19)	(n=19)	(n=19)
No	18 (90.0%)	6 (31.6%)	0 (0.0%)	0 (0.0%)
Yes	2 (10.0%)	13 (68.4%)	19 (100.0%)	19 (100.0%)
SMWD:	(n=20)	(n=19)	(n=18)	(n=18)
No	20 (100.0%)	15 (78.9%)	3 (16.7%)	0 (0.0%)
Yes	0 (0.0%)	4 (21.1%)	15 (83.3%)	18 (100.0%)
χ^2 (*p*)	2.105 (FE*p*=0.487)	8.622* (0.003*)	3.446 (FE*p*=0.105)	

χ^2 : Chi square test. FE: Fisher Exact.
p: *p*-value for comparing between the studied groups.
*: Statistically significant at $p \leq 0.05$.

There were statistically significant differences between the 2 groups according to achieving full granulation tissue at 4 weeks follow-up. 68.4% of group A achieve full granulation tissue in 4 th week in comparison to 21.1% of patients treated with SMWD.

Table (6): Comparison between the two studied groups according to time to full granulation tissue in weeks.

Time to full granulation tissue	NPWT (n=19)	SMWD (n=18)	*t*	*p*
Min. – Max.	1.0-7.0	4.0-12.0	6.182*	<0.001*
Mean ± SD.	3.47±1.61	7.50±2.31		
Median (IQR)	3.0 (2.0-4.0)	7.50 (6.0-8.0)		

IQR: Inter quartile range.
SD : Standard deviation.
t : Student *t*-test.
p: *p*-value for comparing between the studied groups.
*: Statistically significant at $p \leq 0.05$.

There were statistically significant differences between the 2 groups according to achieving full granulation tissue by the time in weeks.

Table (7): Comparison between the two studied groups according to infected wounds.

Infected wounds	2 weeks	4 weeks	8 weeks	12 weeks
NPWT:	(n=20)	(n=19)	(n=19)	(n=19)
No	15 (75.0%)	17 (89.5%)	18 (94.7%)	19 (100.0%)
Yes	5 (25.0%)	2 (10.5%)	1 (5.3%)	0 (0.0%)
SMWD:	(n=20)	(n=18)	(n=18)	(n=18)
No	14 (70.0%)	15 (83.3%)	17 (94.4%)	18 (100.0%)
Yes	6 (30.0%)	3 (16.7%)	1 (5.6%)	0 (0.0%)
χ^2 (*p*)	0.125 (0.723)	0.298 (FE*p*=0.660)	0.002 (FE*p*=1.000)	–

χ^2: Chi square test.
FE: Fisher Exact.
p: *p*-value for comparing between the studied groups.

There were no statistically significant differences between the 2 groups as regard to number of infected wounds by the time.

Table (8): Comparison between the two studied groups according to debridement session.

Debridement session	2 weeks	4 weeks	8 weeks	12 weeks
NPWT:	(n=20)	(n=19)	(n=19)	(n=19)
No	17 (85.0%)	17 (89.5%)	19 (100.0%)	19 (100.0%)
Yes	3 (15.0%)	2 (10.5%)	0 (0.0%)	0 (0.0%)
SMWD:	(n=20)	(n=18)	(n=18)	(n=18)
No	16 (80.0%)	15 (83.3%)	18 (100.0%)	18 (100.0%)
Yes	4 (20.0%)	3 (16.7%)	0 (0.0%)	0 (0.0%)
χ^2 (FE*p*)	0.173 (1.000)	0.298 (0.660)	–	–

χ^2: Chi square test. FE: Fisher Exact.
p: *p*-value for comparing between the studied groups.

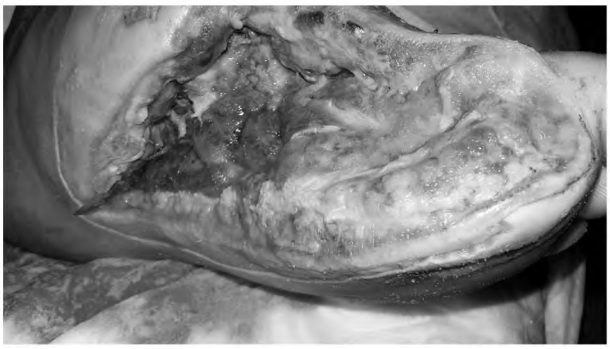
There was also no statistically significant difference between the 2 groups as regard the need for surgical debridement.

Table (9): Comparison between the two studied groups according to limb salvage.

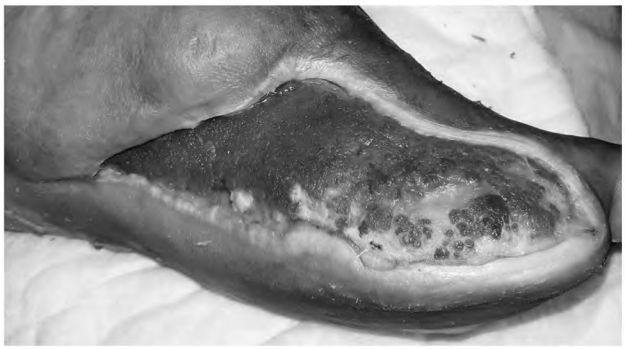
	NPWT (n=20)		SMWD (n=20)		χ^2	*p*
	No.	%	No.	%		
Limb salvage:						
No	19	95.0	18	90.0	0.360	EF*p*=
Yes	1	5.0	2	10.0		1.000

χ^2: Chi square test.
FE: Fisher Exact.
p: *p*-value for comparing between the studied groups.

There was also no statistically significant difference between the 2 groups as regard limb salvage.

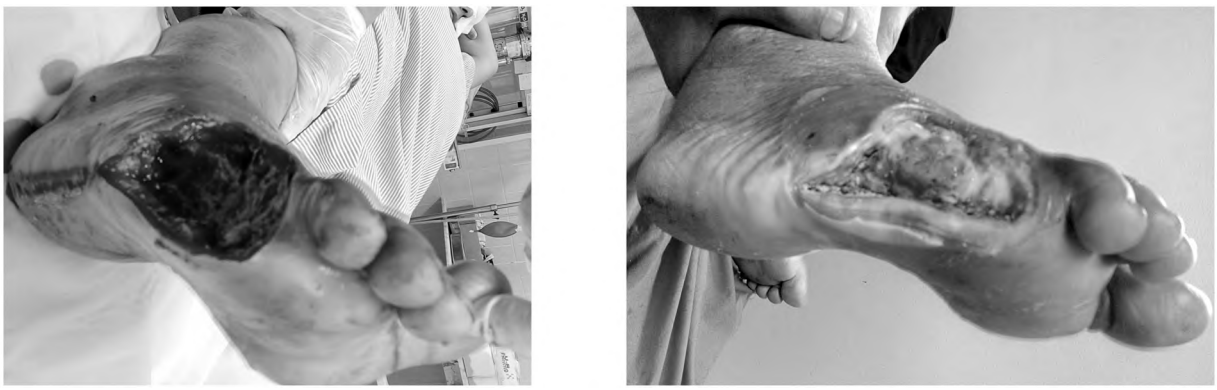


Before using NPWT



After 4 weeks of using NPWT

Fig. (1): Complete full healthy granulation tissue formation after 4 weeks of using NPWT.



Before using SMWT After 4 weeks of using SMWT

Fig. (2): Non complete full granulation tissue formation after 4 weeks of using SMWT.

Discussion

The main challenge of DFI management is limb salvage, about 25-50% of these patients get immediate amputation at admission in many levels [4].

Their risk of amputation is ≈ 56 and 155 times greater than non-diabetic patients. Most of these patients had soft tissue infection and 20% of them have bone infection or osteomyelitis [5].

Management of DFI is achieved by multidisciplinary approach and levels which reduces the incidence of major amputation. Several preventive strategies such as repeated debridement, pressure offloading, treatment of ischemia, and metabolic stabilization are initial to enhance wound healing and prevent infection and amputation.

Deep diabetic foot infection is mainly treated by surgical debridement which range from simple incision and drainage to extensive multiple surgical debridement and amputation. The affected bones should be excised in patients with osteomyelitis [6].

In most cases, surgeons leave debrided wound open without primary closure to control infection and to observe wound granulation. The wound may also be treated surgically with a flap or graft, left to heal by secondary intention, or managed with negative pressure dressings [7].

Negative pressure wound therapy was proposed as a new technique to promote wound healing. Several studies discussed the efficacy of NPWT in wound healing generally and in DFI wounds specifically.

These studies differ from each other in several point such as inclusion and exclusion criteria or the points of evaluation.

Blume et al., [11] concluded, in one of the largest randomized controlled trial , that NPWT is as safe as and more efficacious than Advanced moist wound therapy (AMWT) in the treatment of DFUs and no significant difference was observed in ulcer-related complications such as infection, cellulitis, and osteomyelitis. However, the study showed that AMWT patients had more than twice as many secondary amputations as those receiving NPWT.

In this study, they excluded Patients with recognized active Charcot disease or ulcers resulting from electrical, with collagen vascular disease, ulcer malignancy, untreated osteomyelitis, or cellulitis. Patients with uncontrolled hyperglycemia (hbA1C_12%) or inadequate lower extremity perfusion were not enrolled.

The inclusion/exclusion criteria in this study were different. They did not exclude patients with venous insufficiency and included more than twice as many patients. Patients with Wagner classification 2-4 were not excluded. Also, they did not exclude patients with impaired perfusion but required adequate therapy of the circulatory disorder.

The purpose of our study is to compare between Negative pressure wound therapy and standard moist dressing wound therapy as regards time of healing, infection control, sessions of debridement and limb salvage in the management of diabetic foot wounds in non-ischemic lower limbs. Patients with uncontrolled diabetes, severe infection, perturbated laboratory investigations or lower limbs ischemia were excluded from the study.

The demographical data between the two groups was no statistically significant difference. The mean age of patients in group A was 63.30 ±8.36 years and in group B was 61.35 ±7.56 years. The sex distribution was statistically no significant.

Regarding risk factors, hypoglycemic medications and laboratory investigations, there was no significant difference also in wound sizes, dimensions, and grading.

Morykwas et al., [8] concluded in their study that NPWT enhance granulation tissue formation which seemed more rapid and robust, also Morykwas et al., [8] demonstrated a statistically significant increase in granulation tissue formation when measured by wound volume.

In our study we found that Patients treated with NPWT in group A showed earlier full granulation tissue in 10% of patients after 2 weeks, 68% after 4 weeks and 100% after 8 weeks, compared to 0% of patients treated with SMWT after 2 weeks, 21 % after 4 weeks and 83 % after 8 weeks, with a significant difference after 4 weeks (p-value 0.003)

These results showed a significant statistically difference between the 2 groups regarding full granulation tissue formation after using NPWT in the first 4 weeks, and no significant difference between them after 8 weeks of treatment.

Our study is compatible with Sepúlveda et al., [9] study, who published his randomized controlled trial and he compared NPWT with SMWT and showed that the treatment with NPWT help reaching 90% granulation of a wound in a shorter time and with few complications.

Sajid et al., [10], published their study results on 278 patients when they compared NPWT and SMWT according to wound size reduction and they found after 2 weeks treatment that wound area reduction in both groups revealed statistically significant faster healing in NPWT group as compared to SMWT group A (p<0.001).

Also, Blume et al., [11] found that A greater proportion of foot ulcers achieved complete ulcer closure with NPWT (73 of 169, 43.2%) than with AMWT (48 of 166, 28.9%) within the 112-day active treatment phase (p_0.007). Wounds treated with NPWT were 100% healed within 96 days (95% CI 75.0-114.0) and not determinable for AMWT (p_0.001).

Also, Eginton et al., [3] had also observed that the wound volume and depth decreased significantly in VAC dressings as compared to moist gauze dressings.

Regarding wound related complications as infection, number of surgical debridement sessions and amputations were not statistically significant between the 2 groups. Major amputation was seen in 2 cases of the SMWD group, and one below knee amputation and 2 toes amputation was seen in NPWT group and none of these was statistically significant. NPWT does affect limb salvage rate in comparison to SMWT.

Wound infection in our study was evaluated according to clinical examination every follow-up visit. Consisting frank purulence and/or two or more local singes of inflammation such as warmth, erythema, lymphangitis, lymphadenopathy, edema, pain, and loss of function were considered as signs of infected wound.

It was thought that NPWT participate positively in reducing risk of wounds infection compared to SMWT, by providing a safety barrier that protects wound from environmental contaminants, reducing bacterial load and increasing antibiotics concentration.

Mouës et al., [12], studied the bacterial load in wound treated by both technique and they found that the total quantitative bacterial load was generally stable in both therapies with a significant decrease of non-fermentative gram-negative bacilli in NPWT (p<0.05), whereas Staphylococcus aureus showed a significant increase in vacuum-assisted closure-treated wounds (p<0.05). It was concluded that the quantitative bacterial load was stable in both groups without significant difference.

Lo Torto F., et al., 2017 [13], studied daptomycin concentration in wounds treated with NPWT compare with a control group treated with traditional dressing. After biopsy detection of tissue concentration of both groups, the data found an important increase of antibiotic concentration in the tissue after VAC therapy. Despite significant increase in the concentration of antibiotics in the study group tissue and improvement was sensibly lower in the control group, Statistical differences were not found between the two groups.

Conclusion:

According to our study results, we concluded that NPWT has a significant effect on acceleration and promotion of granulation tissue. The effect of Negative pressure wound dressings appears obviously over the first 4 weeks by decreasing wound size more effectively and faster rate of growth of granulation tissue than the application of moist saline gauze dressings, hence we suggest that NPWT is more appropriate for deep, cavitary and full thickness wound which helps in early closure of wounds and promising a better outcome. Also, NPWT is as safe as SMWT regarding wound related

complication such as infection, the need of surgical debridement or amputation with no significant difference.

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دراسة مقارنة بين علاج جروح القدم السكرى بواسطة الضغط السلبى وبواسطة الضمادات التقليدية الرطبة

تعد عدوى القدم شائعة لدى مرضى السكرى وترتبط بارتفا ع معدلات الاعتلال وخطر بتر الأطراف السفلية.

يعتبر التنضير الجراحى حجر الزاوية فى علاج عدوى القدم السكرية العميقة. عندما يتم السيطرة على العدوى ويبدأ الجرح فى التحبيب، قد يكون الإغلاق الأولى ناجحاً. يمكن أيضاً معالجة الجرح جراحياً بشريحة أو رقعة جلدية، أو تركه للشفاء بالضمادات الجراحية اليومية بغرض الالتئام الثانوى، أو استخدام أجهزة الضغط السلبى.

أجهزة الضغط السلبى هو أحد علاجات العناية بالجروح الأحدث التى توفر بيئة تحت الضغط الجوى للجروح وتعزز تكوين الأنسجة الحبيبية والشفاء عن طريق زيادة تدفق الدم وتقليل التورم والمشاركة فى إزالة البكتيريا للجروح والسيطرة على العدوى. يتكون النظام من ضمادة أسفنجية، وغطاء لاصق شبه مغلق، ونظام تجميع السوائل، ومضخة شفط

العديد من الدراسات قد دعمت استخدام أجهزة الضغط السلبى فى علاج جروح القدم السكرى كطريقة أكثر فعالية من الضمادات الجراحية فى دراسة لـ .Blume et al، فى واحدة من أكبر التجارب استنتج أن أنظمة الضغط السلبى آمنة وفعال أكثر من الضمادات التقليدية فى علاج جروح القدم السكرى ولم يلاحظ أى فرق كبير فى المضاعفات المرتبطة بالقرحة مثل العدوى وإلتهاب النسيج الخلوى وإلتهاب العظم.

\الهدف من در\استنا: هو مقارنة وتقييم السلامة والفعالية السريرية بين أنظمة الضغط السلبى والضمادات التقليدية الرطبة فى علاج جروح القدم السكرى.

وجدنا فى دراستنا أن المرضى الذين عو لجوا بـ أنظمة الضغط السلبى فى المجموعة الأولى أظهروا أنسجة حبيبية كاملة مبكرة فى ١٠٪ من المرضى بعد أسبوعين، و ٦٨٪ بعد أربعة أسابيع و ١٠٠٪ بعد ثمانية أسابيع، مقارنة بـ ٠٪ من المرضى الذين عولجوا بالضمادات التقليدية بعد أسبو عان، ٢١٪ بعد أربعة أسابيع و ٨٣٪ بعد ثمانية أسابيع، مع اختلاف كبير بعد ٤ أسابيع (القيمة الاحتمالية ٠.٠٠٣).

أظهرت هذه النتائج فرقاً معنوياً إحصائياً بين المجموعتين فيما يتعلق بتكوين الأنسجة الحبيبية الكاملة بعد استخدام أنظمة الضغط السلبى فى الأسابيع الأربعة الأولى، وعدم وجود فرق معنوى بينهما بعد ٨ أسابيع من العلاج.

فيما يتعلق بمضاعفات الجروح كالعدوى، فإن عدد جلسات التنضير والبتر الجراحى لم يكن ذا دلالة إحصائية بين المجموعتين. شوهد بتر للطرف السفلى حالتين من مجموعة الضمادات، وشوهد بتر واحد أسفل الركبة وبتر إصبعين فى مجموعة الغيارات الضغط السلبى ولم يكن أى من هؤلاء ذو دلالة إحصائية. لذا لا يحسن أنظمة الضغط السلبى معدل إنقاذ الأطراف بالمقارنة مع الضمادات التقليدية.

استنتجنا إلى أن فائدة أنظمة الضغط السلبى فى علاج جروح القدم السكرية تظهر فى الأسابيع الأولى بعد التنضير الجراحى. إنه يسرع تكوين الأنسجة الحبيبية ويملأ بسرعة منطقة الجروح الكبيرة والعميقة. فى دراستنا، كان لدى المجموعتين نفس معدل مضاعفات الجرح مع عدم وجود فرق معتد به إحصائياً يشير إلى نفس مستوى آمان.