

Effect of Vacuum-Assisted Closure Therapy on Diabetic Wounds Management

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Abstract

Background: Diabetic wounds are considered a medical, psychological, social, and economic burden and are associated with decreased patients' quality of life. Vacuum-assisted closure (VAC) therapy is widely established in managing several types of wounds. VAC therapy is a method used for wound management that enhances overall wound healing. **Aim:** Assess the effectiveness of vacuum-assisted closure therapy on diabetic wound management. **Subjects:** - A purposive sample of (n=50) patients with diabetic wounds. **Research design:** A quasi-experimental design using a one-group posttest-only design was conducted in this research. **Setting:** The study was conducted at Alexandria Main University Hospital, in the inpatient surgical department. **Tools:** Wound Healing Assessment Tool (WHAT) was used for data collection. **Results:** Most patients who had partial wound healing after one month of VAC dressing application. There was a statistically significant wound healing improvement related to wound size reduction, granulation tissue formation, decrease in wound exudates amount, absence of wound odor, absence of local wound infection signs, and absence of tissue necrosis. **Conclusion:** VAC therapy has a significant impact on diabetic wound healing and had promising results with Diabetic wound management exhibiting faster wound healing. Most patients had partial wound healing after one month of VAC application. **Recommendations:** Vacuum-assisted closure Therapy is recommended for difficult and non-healing wounds that do not respond to traditional dressing techniques.

Keywords: Vacuum-Assisted Closure Therapy, Diabetic Wounds

Introduction

Diabetes mellitus is one of the most important common health problems associated with a high rate of mortality and morbidity (Hassan et al., 2018). Diabetes mellitus causes many serious common complications in diabetic people such as diabetic wounds which are a high mortality risk. More than a quarter of diabetic patients develop diabetic foot ulcers throughout their lifetime, as well as 20% of moderate to severe diabetic foot ulcers lead to limb amputation if left without treatment (Parizad et al 2021).

Complicated wounds are considered an economic burden on healthcare systems and are

associated with decreased patients' quality of life (Lo et al., 2020).

The wound is defined as a disruption in the continuity of tissue with various etiology, and it can have a significant effect on the patient if it is not well-treated. The complexity of wounds, bacterial load, ineffective wound management, and a shortage of wound care supplies make these wounds challenging (Yassin et al., 2024).

Healing wounds is a complex process in which certain acute wounds may not heal effectively and become chronic wounds. In cases of large-size wounds, especially with the presence of comorbid conditions such as diabetes. Non-healing wounds can cause

significant suffering to patients and hurt their physical, psychosocial, and economic well-being (Norman et al.,2020)

The prevalence of adults' lower extremities chronic wounds of between 0.18% and 1.3% worldwide. Chronic wounds are defined as wounds that take a long time to heal and last at least two weeks without decreasing in size (Martinengo et al., 2019).

Diabetic wounds and ulcers are chronic wound types that continue to rise in their rate. Chronic and Diabetic wounds are riskier of becoming infected which may lead to readmissions to hospital, severe sepsis, and even death. Diabetic wounds may lead to limb amputations in severe health conditions (Fitzpatrick et al., 2022).

According to the Egyptian studies conducted among diabetic patients, it is reported that (29.3%) of diabetics had diabetic foot ulcers, (63.3%) had vascular complications and neuropathy was estimated in (88.0%) of those complications (Salah Ead et al., 2019)

Vacuum-assisted closure (VAC) therapy is a method used for wound management using negative-pressure wound therapy (Zhou et al., 2015). VAC therapy is a sterile and sealed VAC foam dressing that is connected to a suction device that creates negative sub-atmospheric in the bed of the wound which speeds the healing through several mechanisms as a bio-mechanical effect. It can be used on different types of wounds including acute clean wounds and chronic dirty wounds (Veale et al., 2023) & (Morgan et al., 2023).

VAC therapy is a technique that enhances the healing of wounds by promoting the growth of tissue proliferation, increasing the local wound perfusion, minimizing the burden of microorganisms, reducing the edema site, and decreasing the inflammatory process (Lenet et al., 2022).

The effect of VAC therapy consists of two main actions or responses, the first is physical action by approximating the edges of the wound together and removing drainage, thus

diminishing wound swelling and improving local blood flow. Also, the second response is the biological action that creates tissue micro-deformation, causing stretching of cells that causes cell migration and proliferation that leads to granulation tissue formation (Veale et al., 2023).

This technique aims to reinforce the healing process of the wound by facilitating the transition of wounds from the phase of inflammation to the proliferation phase if the wound cannot heal by primary intention (Astasio-Picado et al., 2022).

Effective wound care and management require a multidisciplinary team approach between nurses and healthcare professionals based on evidence-based intervention guidelines for patients with diabetic wounds aiming to improve outcomes and reinforce patient quality of care (Tuuli et al., 2020).

Significance of the study:

A lack of application of modern and innovative methods for caring for diabetic wound patients are at higher risk of non-healing wounds due to the complicated healing process associated with many contributing factors affecting the healing process such as wound infection and low immunity when compared to other simple wounds which managed by conventional wound care, making it urgent to apply techniques to care for them for better wound dressing outcomes, decreasing hospitalization stay and cost.

Negative Pressure Wound Therapy (NPWT) is expensive worldwide, which suggests that healthcare providers who have limited resources modify this technique. The literature explained many conversions were done with successful accomplishments (Yassin et al., 2024). The previously mentioned points were the driving force for the researchers to use economic materials and supplies for developing low-cost VAC therapy types used in this study to assess its effect as fitting therapeutic wound care solutions in low-income countries. For these reasons, applying wound care dressing using VAC therapy adds value to the existing

literature. So, the current study was carried out to assess the effectiveness of vacuum-assisted closure therapy on diabetic wound management.

Aim of the Study

Assess the effectiveness of vacuum-assisted closure therapy on diabetic wound management.

Research Hypothesis:

Patients who receive vacuum-assisted closure therapy will exhibit faster wound healing in diabetic wound management.

Subjects and methods

Research design: A quasi-experimental design using one-group posttest-only was conducted in this research. In a one-group posttest-only design, the intervention was implemented (or an independent variable was manipulated) and then a dependent variable was measured. The post-test results help establish the effectiveness of the intervention proposed in the study.

Setting: The study was conducted at the inpatient surgical department of Alexandria Main University Hospital. The inpatient surgical department is located on surgical building on the third floor and has a total capacity of 38 beds.

Sample: A purposive sample of (n=50) patients with diabetic wounds.

Inclusion criteria included: Adult patients with diabetic wounds of both genders aged from 18 to 60 years. Patients only have Diabetes Mellitus without other chronic diseases comorbidities, and patients who did not receive medication that could interfere with the wound healing process such as corticosteroids, radiotherapy, chemotherapy or any immunosuppressive therapy, anticoagulant medication and bone infections in addition to any factors that could affect with research process as impairment in communication or mental disorders.

The sample study estimation was based on the Epi Info 7 program, which was used to determine the sample size using the following parameters: Total Population were 200 adult patients with chronic Diabetic wounds over the year 2022. Confidence Level at 95%, Acceptable error at 5%, Expected frequency at 50 %, Minimum sample size were 44 Patients. After adding 10% dropout, the total final sample size was 50 patients.

Tool for data collection:

The study tool: Wound Healing Assessment Tool (WHAT)

Development tool: The study tool was developed by the researchers after a recent related literature review; **Mohammed et al., (2022); El-den et al., (2021); and Hassan et al., (2018).**

The study tool was wound healing observation checklist utilized to assess the healing process of the wound for adult patients who had diabetic wounds using the Vacuum-Assisted Closure Therapy technique. It contained four parts as follows: -

Part I: Patient's demographic characteristics: -

It includes information related to age, gender, education, occupation, marital status, and patient residence.

Part II: Patient's clinical data: -

Clinical data such as patient's body temperature, laboratory results such as hemoglobin, and some inflammatory markers included WBCs, ESR, and CRP. In addition to albumin, coagulation profile, and body mass index.

Part III: Wound healing observation checklist: -

This wound healing observation checklist was utilized for diabetic wound assessment after the first VAC application after 5 days of the dressing and post-VAC dressing

application after one month through follow-up wound assessment of the healing process over one month regarding the effect of VAC therapy on healing of the diabetic wound.

This part described the morphological wound condition against certain parameters such as wound size, wound depth, granulation tissue formation, exudates type, exudates amount, wound odor, wound infection clinical signs, presence of necrotic tissue, condition of wound surrounding, wound edges and wound healing extent as completely wound healing or partial wound healing or non-healing.

Part IV: Photographic pictures: -

Photographic clinical pictures were captured to compare follow-up stages of the process for wound healing by healthy granulation tissue formation to be ready for further intervention for wound closure as skin graft if indicated.

Scoring system: -

The wound healing observation checklist was used to score as follows:

1- The wound size was measured and scored in centimeters.

2- Wound depth, it was scored as: -

- 0 = heeled.
- 1= superficially epithelialization.
- 2= Partially thickness skin loss which includes the epidermis &/ or dermis layer.

3- Granulation tissue formation including type, color, and amount, was scored as:

- 0 = normal, intact surface 100% covered the wound.
- 1= (75% -100%) fills the wound&/or tissue overgrowth with bright red beefy color.
- 2 = (< 75% & > 25%) fills the wound with bright red beefy color.
- 3 = (\leq 25%) fills the wound with pinky &/or dull, dusky red color.
- 4 = absence of granulation tissue.

4- Wound exudates type, it was scored as: -

- 0 = no exudates.
- 1 = bloody exudates.
- 2 = serosanguineous exudates.
- 3 = serous exudates.
- 4 = purulent exudates.

5- Wound exudates amount, it was scored as: -

- 0 = absent amount.
- 1 = scanty amount (< 100 ml of exudates).
- 2 = small amount (\geq 100 to \leq 200 ml of exudates).
- 3 = moderate amount (> 200% to \leq 300 ml of exudates).
- 4 = profuse amount (>300 ml of exudates).

6- Wound odor, it was scored as: -

- 0 = no odor.
- 1 = foul odor.

7- Clinical wound infection signs, it was scored as:-

- 0 = no clinical local wound infection signs.
- 1 = presence of clinical local wound infection signs. (wounds' redness, hotness, tenderness, swelling, and purulent exudates).
- 2 = presence of clinical systemic wound infection signs (fever, high WBCs, high ESR, high CRP).

8- Tissue necrosis was scored as: -

- 0 = no necrotic tissue.
- 1 = presence of necrotic tissue.

9- The wound surrounding, it was scored as:

- 0 = no signs of inflammation.
- 1 = presence of signs of inflammation (redness, tenderness, hotness, and peri-wound swelling).

10-Edges of the wound, it was scored as: -

- 0 = attached wound edges.
- 1 = non-attached wound edges.
- 2 = edematous wound edges.

11-Wound healing extent, it was scored as: -

A. Complete wound healing:

- 0 = Formation of healthy granulation tissue with formation of fibrous scar and complete wound epithelialization.

B. Partial healing of wound:

1 = Formation of healthy granulation tissue without completing a fibrous scar formation and decreased wound size and wound depth.

C. Non-healing:

2 = No repair of connective or granulation tissue formation within the wound space represented by no improvement in wound characteristics, no reduction in wound size and wound depth and no fibrous scar tissue formation.

Data collection:

The content validity was tested for the adapted tool by five specialized experts in vascular surgery and the medical-surgical nursing field for its clarity and comprehensiveness; accordingly, necessary amendments were made.

The reliability of tool was tested using Alpha Cronbach's statistical test: reliability coefficients were (0.864, and 0.982; respectively).

Pilot Study

A pilot study was carried out on 10% of the total study sample to test the tool's feasibility, clarity, and applicability and to face any problems in the data collection process. The pilot sample was excluded from the original study participants.

Ethical Considerations:

Official written approval was obtained from the Ethical Research Committee and Research Affair Committee, at the Faculty of Nursing, University of Alexandria. In addition, the official permission was obtained from the director and head of the department of the selected hospital settings after an explanation of the study's aim. The nature and the aim of the research were explained to the patients. Confidentiality and anonymity for patients were maintained. Privacy was respected and asserted.

The studied patients were informed about their right to withdraw from the study at any time.

Fieldwork:

Data collection started in January 2023 and continued until May 2023 for over 5 months.

The researcher conducted data collection for this study through the study tool.

1.VAC therapy was composed of materials such as sterile foam for VAC dressing, sterile tubes for connection, and sterile adhesive transparent tapes. The vacuum pressure was achieved by a suction device which was connected to the VAC foam dressing through a connecting tube to bed of wound. The negative pressure was in the range of 125-200 mmHg according to the wound condition and the patient's tolerance.

2.VAC dressing was applied and continued for one month with VAC dressings change every 5 days over one month. The patients were assessed two times for the wound healing process; the first wound assessment was after 5 days of VAC application focusing on assessing the inflammatory phase of wound healing, the second wound assessment was done at the end of the last dressing time after one month for the overall wound healing assessment focusing on assessing the proliferative phase. To assess the effectiveness of the VAC dressing as implemented intervention in the study.

3.The pervious selected timing for assessing the difference in the phases of wound healing because this dressing technique aims to reinforce the healing process of the wound by facilitating the transition of wounds from inflammatory phase to the proliferation phase. (Astasio-Picado et al., 2022).

4.The patient was prepared before VAC application through the following steps: - wound debridement may be carried out if devitalized necrotic tissue was detected and washing and irrigation of the wound by normal saline 0.9% and dryness for the wound followed by disinfection by betadine 10%.

5. Assessment of the wound was recorded, and clinical photographs were obtained after the first VAC application after 5 days and in the last VAC application after one month to assess and make comparison in the different phases of the healing process.

6. VAC application continued until the next following VAC dressing change was done, intermittent mode was used sequentially for one hour of negative pressure on and one hour off over the day.

Statistical analysis of the data

Data was fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using numbers and percentages. The **Shapiro-Wilk** test was used to verify the normality of distribution.

Quantitative data were described using range (minimum and maximum), mean, standard deviation, and median. The significance of the results obtained was judged at the 5% level.

The tests used were

1 - McNemar and Marginal Homogeneity Test

Used to analyze the significance between the different stages.

2 –Wilcoxon signed ranks test

For abnormally distributed quantitative variables, to compare between two periods.

Results

Table (1): Illustrate the distribution of patients according to demographic characteristics. As regards age, it was revealed that 80% of patients were aged from 40 years to less than 60 years followed by ages between 18 to less than 40 years old with 20% percentage. According to gender, 70% of patients were male. Regarding patient education, 58% of the study participants were illiterate. 84% of the

patients were married. As for occupation, 78% of the patients studied were manual workers. 66% of the patients studied come from rural areas.

Table (2): shows patients' clinical data, 84% of patients had a normal body temperature. Concerning laboratory results 82 % of studied patients had a normal range of HB. As regards WBCs, 80% of studied patients were above the normal range, while 20% of them had normal range of WBCs. In relation to CRP 78% of patients had above the normal range of CRP, while 22% of them had normal range of CRP. Regarding ESR, more than three quarters (76%) of patients had ESR above normal, while less than one quarter 24% of them had a normal range of ESR.

Concerning albumin laboratory value, 88% of studied patients had a normal albumin value, The result showed that 100% of patients had normal coagulation profiles. Concerning the body mass index 68% of patients were overweight, while 32% of studied patients had a normal body mass index.

Table (3): This table shows that as regards diabetic wound size in centimeters for length after 5 days of the first VAC application, the wound size ranged from (15 cm to 50 cm) with a mean length of (32.40 ± 10.63) , while size of the wounds in centimeters for length in the last VAC application after one month ranged from (10 cm – 44 cm) with a mean length of (25.42 ± 10.43) . Superficial epithelialization in wound depth was represented by 86 % of patients after one month of VAC application while partial thickness skin loss includes the epidermis &/ or dermis in 14% of patients after one month of VAC application. As for granulation tissue formation, it was found that 88 % of patients had (75% -100%) filled the wound&/or tissue overgrowth with bright red beefy color in the last VAC application after one month while 12 % of patients had (< 75% &> 25%) fills the wound with bright red beefy color.

Table (4): the table illustrates the type of wound exudates. After 5 days of the first VAC application, 94 % of patients had purulent

exudates, while 6 % of patients had serous discharge. As for wound exudates in the last VAC application, after one month 92 % of the patients had no wound exudates, while 6% of studied patients had serous exudates. Only 2% of patients had a purulent discharge.

Concerning wound exudates amount in the first VAC application after 5 days, 72 % of patients had a moderate amount (> 200 ml to ≤ 300 ml of exudates) and 14% of patients had a small amount (≥ 100 to ≤ 200 ml of exudates) only 4% of patients had scanty amount (< 100 ml of exudates), while 10 % of patients had profuse amount (> 300 ml of exudates). Compared with the last VAC application after one month, the study results revealed that 92% of patients had no exudates. Only 8% of patients were scant (< 100 ml of drainage).

Regarding wound odor, 82% of the patients had foul wound odor in the first VAC application after 5 days. Compared with the last VAC application, after one month 96 % of the patients had no wound odor.

Table (5): shows clinical wound infection signs in the first VAC application. After 5 days it was found that 80% of patients had the presence of clinical local wound infection signs, while 16% of patients had the presence of systemic wound infection signs (fever, elevated WBCs, elevated ESR, and elevated CRP). Only 4% of patients had the absence of clinical local wound infection signs. Compared with the last VAC application after one month, the findings revealed that 96 % of patients had the absence of local wound infection signs. Only 4% of patients still had local signs of wound infection in their wounds.

As for the presence of necrotic tissue, the table revealed that around two-thirds of the studied patients had the presence of necrotic tissue in the first VAC application after 5 days, while 34% of patients had an absence of

necrotic tissue. Compared with the last VAC application after one month, the study findings revealed that 98% of patients had an absence of necrotic tissue and only 2% of patients still had necrotic tissue in their wounds.

More than three-quarters of patients had the absence of local wound infection signs surrounding the wounds after 5 days in the first VAC application. After one month of the last VAC application, 96% of patients did not have local wound infection signs.

Concerning wound edges, the table showed that 78 % of patients had not attached wound edges while 22 % of patients had edematous wound edges in the first VAC application after 5 days. In the last VAC application after one month, 96% of patients still had not attached and only 4% of patients had edematous wound edges.

Table (6): Displays a comparing between the different studied periods according to the extent of diabetic wound healing by the end of the follow-up periods after one month in the last VAC application, it found that 96 % of studied patients had partial diabetic wound healing represented by formation of healthy granulation tissue without completing a fibrous scar formation and decreased wound size and wound depth, while the remaining 4% still complained of no wound healing.

In addition to the result portrayed statistically significant differences that were found after the VAC dressing application for one month where p value < 0.001 .

Concerning clinical photographic pictures were captured to compare follow-up stages of the wound healing process by the formation of healthy granulation tissue to be ready for further intervention for wound closure as skin graft if indicated as shown in Figures (1, 2, and 3).

Table (1): Percentage distribution of patients according to demographic characteristics (n=50)

Demographic characteristics	No.	%
Age (years)		
18 <40	10	20.0
40 <60	40	80.0
Gender		
Male	35	70.0
Female	15	30.0
Level of education		
Illiterate	29	58.0
Educated	21	42.0
Marital status		
Single	8	16.0
Married	42	84.0
Divorced	0	0.0
Widow	0	0.0
Occupation		
Manual work	39	78.0
Employee	8	16.0
Not work	3	6.0
Retired	0	0.0
Residence		
Urban	17	34.0
Rural	33	66.0

Table (2): Percentage distribution of patients according to clinical data (n=50)

Patient's clinical data	No.	%
Patient body temperature		
Normal	42	84.0
Hyperthermia	8	16.0
Hypothermia	0	0.0
laboratory results:		
Hemoglobin		
Normal	41	82.0
Above normal	0	0.0
Below normal	9	18.0
White blood count		
Normal	10	20.0
Above normal	40	80.0
Below normal	0	0.0
C-reactive protein		
Normal	11	22.0
Above normal	39	78.0
Below normal	0	0.0
Erythrocyte sedimentation rate		
Normal	12	24.0
Above normal	38	76.0
Below normal	0	0.0
Albumin		
Normal	44	88.0
Above normal	0	0.0
Below normal	6	12.0
Coagulation profile		
Normal	50	100.0
Above normal	0	0.0
Below normal	0	0.0
Body mass index (kg/m²)		
Normal weight (18.5<25)	16	32.0
Underweight (<18.5)	0	0.0
Overweight (25 < 30)	34	68.0

Table (3): Comparison between the different studied periods according to wound size, depth, and formation of granulation tissue (n = 50)

Wound healing assessment	After the first VAC application (5 days)		After the last VAC application (one month)		Test of Sig.	P
	No.	%	No.	%		
Wound size in centimeters: -					Z= 6.174*	<0.001*
Min. – Max.	15.0 – 50.0		10.0 – 44.0			
Mean ± SD.	32.40 ± 10.63		25.42 ± 10.43			
Median	33.50		24.0			
Wound depth: -					McN= 41.023*	<0.001*
Healed	0	0.0	0	0.0		
Superficially epithelialization	0	0.0	43	86.0		
Partial thickness skin loss that includes the epidermis &/ or dermis layer	50	100.0	7	14.0		
Formation of granulation tissue: -					MH= 131.000*	<0.001*
Normal, intact surface 100% covered the wound (75% -100%) fills the wound&/or tissue overgrowth with bright red beefy color.	0	0.0	0	0.0		
(< 75% & > 25%) of fills the wound with bright red beefy color	0	0.0	44	88.0		
(≤ 25%) of fills the wound with pinky &/or dull, dusky red color	0	0.0	6	12.0		
Absence of granulation tissue	0	0.0	0	0.0		
	50	100.0	0	0.0		

McN: McNemar test MH: Marginal Homogeneity Test SD: Standard deviation Z: Wilcoxon signed ranks test
p: p value for comparing between after the first VAC application 5 days and one month *: Statistically significant at $p \leq 0.05$

Table (4): Comparison between the different studied periods according to type, amount, and odor of wound exudates (n = 50)

Wound healing assessment	After the first VAC application (5 days)		After the last VAC application (one month)		Test of Sig.	p
	No.	%	No.	%		
Type of wound exudates: -					MH= 101.000*	<0.001*
None	0	0.0	46	92		
Bloody	0	0.0	0	0.0		
Serosanguineous	0	0.0	0	0.0		
Serous	3	6.0	3	6		
Purulent	47	94.0	1	2		
None	0	0.0	0	0.0		
Wound exudates amount: -					MH= 74.000*	<0.001*
None	0	0.0	46	92		
Scanty amount (<100 ml of exudates)	2	4	4	8		
Small amount (≥ 100 to ≤ 200 ml of exudates)	7	14	0	0.0		
Moderate amount (> 200 %to ≤ 300 ml of exudates)	36	72.0	0	0.0		
Profuse amount (>300 ml of exudates)	5	10.0	0	0.0		
Wound odor: -					McN= 37.026*	<0.001*
None	9	18	48	96.0		
Foul	41	82.0	2	4.0		

McN: McNemar test MH: Marginal Homogeneity Test
p: p value for comparing between after the first VAC application 5 days and one month
*: Statistically significant at $p \leq 0.05$

Table (5): Comparison between the different studied periods according to the presence of wound infection, necrotic tissue, wound surrounding, and wound edges (n = 50)

Wound healing assessment	After the first VAC application (5 days)		After the last VAC application (one month)		Test of Sig.	p
	No.	%	No.	%		
Signs of wound infection: -						
No clinical local wound infection signs	2	4.0	48	96.0	MH= 29.000*	<0.001*
The presence of clinical local wound infection signs. (wounds' redness, hotness, tenderness swelling, and purulent exudates).	40	80.0	2	4.0		
Presence of clinical systemic wound infection signs (fever, high WBCs, high ESR, high CRP)	8	16	0	0.0		
Necrotic tissue: -						
Absent	17	34.0	49	98.0	McN= 30.031*	<0.001*
Present	33	66.0	1	2.0		
Wound surrounding: -						
No signs of inflammation.	38	76.0	49	98.0	McN= 3.321*	0.001*
Presence of signs of inflammation (redness, tenderness, hotness, and peri-wound swelling).	12	24.0	1	2.0		
Edges of the wound: -						
Attached	0	0.0	0	0.0	McN= 7.386*	0.004*
Not attached	39	78.0	48	96.0		
Edematous	11	22.0	2	4.0		

McN: McNemar test

MH: Marginal Homogeneity Test

p: p value for comparing between after the first VAC application 5 days and one month

*: Statistically significant at $p \leq 0.05$ **Table (6): Comparison between the different studied periods according to the extent of wound healing (n = 50)**

Wound healing extent	After the first VAC application (5 days)		After the last VAC application (one month)		MCN	p
	No.	%	No.	%		
Complete healing (Formation of healthy granulation tissue with formation of fibrous scar and complete wound epithelialization)	0	0.0	0	0.0	46.021*	<0.001*
Partial healing of wound (Formation of healthy granulation tissue without completing a fibrous scar formation and decreased wound size and wound depth)	0	0.0	48	96.00		
Non-healing (No repair of connective or granulation tissue formation within the wound space represented by no improvement in wound characteristics, no reduction in wound size and wound depth and no fibrous scar tissue formation.)	50	100.0	2	4.0		

McN: McNemar test

p: p value for comparing between after the first VAC application 5 days and one month

*: Statistically significant at $p \leq 0.05$

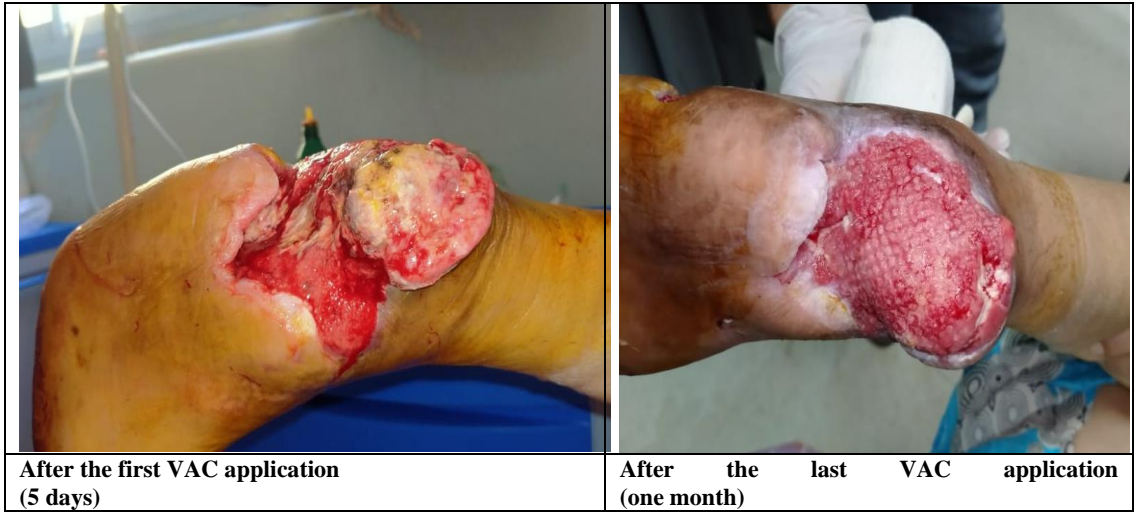


Figure (1): photographic pictures

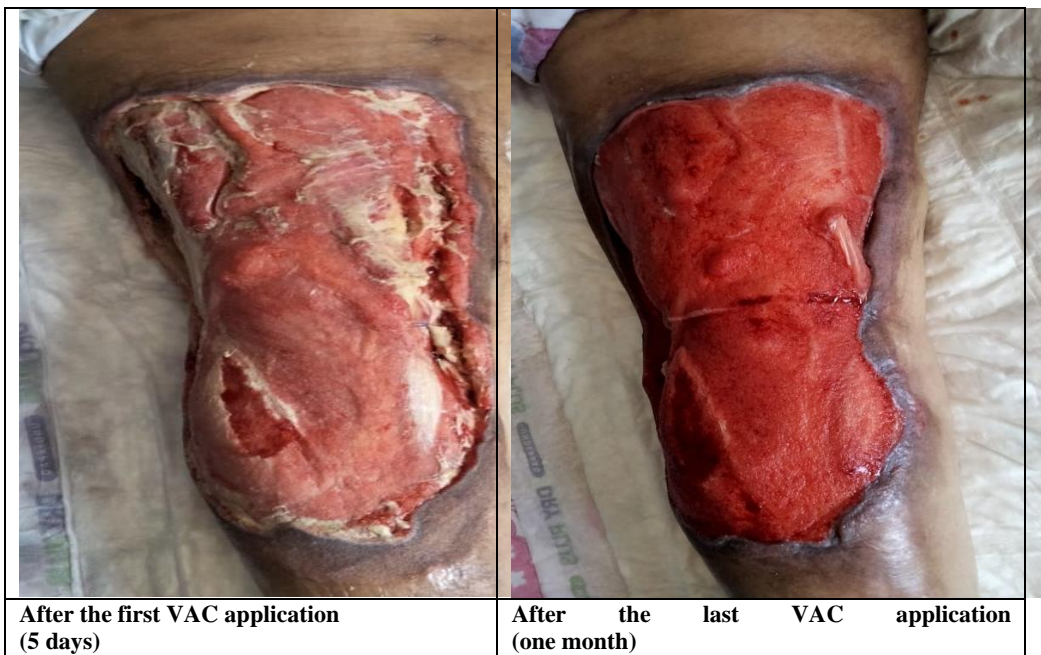


Figure (2): photographic pictures



Figure (3): photographic pictures

Discussion

There are several modalities for wound care to manage acute or chronic wounds, and their effect depends on multiple factors such as the size of wounds, wound causes, and quality of wound care. Diabetes patients are at an increased risk of chronic wounds due to neuropathy and poor wound healing. The multidisciplinary team approach can lead to the closure of wounds and fewer readmissions (Fitzpatrick et al., 2022). Specialized nurses identify the appropriate dressing technique for wound care based on wound assessment and patient conditions (Mohammed et al., 2022).

VAC is a well-established effective and safe wound care modality for complicated diabetic wounds and could lead to a higher proportion of wound healing process, rapid rates of healing, and fewer potential complications than conventional wound care dressing (Veale et al.,2023) & (Zhou et al., 2015). Therefore,

the current study was conducted to assess the effectiveness of vacuum-assisted closure therapy on diabetic wound management.

Regarding the demographic data, the study findings revealed that most of the studied patients were aged between 40 to less than 60 years. These results may be due to increasing patients' age being risky for delayed wound healing and the changes in skin structure such as loss of elasticity and easily fragile skin combined with immunocompromised status caused by diabetes. The study results were consistent with Ibrahim et al., 2023 who reported the survey revealed that the majority of in the same adult age group. The highest percentage of study cases were male patients who mostly performed hard work and prolonged times. this finding was in accord with (KautzkyWiller, Harreiter, & Pacini, 2016); who found that adult diabetic male patients are at risk for lower extremity complications than females.

Most patients were illiterate and married. Illiteracy could be due to the lack of knowledge to inspect any abnormalities and compliance with wound care. This finding aligned with the study done by **Armstrong et al., 2006** who illustrated that illiterate patients were more at risk for developing wound ulceration than educated patients.

In the same line with **Ibrahim et al., 2023** more than half of the sample was married. However, this contradicted in terms of the educational level of most patients who had completed secondary education.

In relation to patients' occupations and residences, it was found that most patients were manual workers, and they came from rural areas. This finding is in accord with **Shahi et al., 2012**, who reported that more than two-thirds of patients had hailed from rural areas. This may be due to the nature of rural area work with uncovered and unprotected feet on roads more prone to foot ulcers than in urban areas can lead to chronic wounds also, the unavailability of specialized hospitals.

Concerning the patient's clinical data, the majority of the patients had a normal body temperature. This could be due to the presence of only local wound infection and not systemic infection or septicemia.

As regards laboratory investigations, the majority of the patients had laboratory markers that indicated wound infection and inflammation. This is due to the presence of local signs of wound infection only or systemic signs of infection. This result is supported by **Chatterjee and Butina (2020)**, who reported that biomarker detection can identify disease states while also providing information about the progression of infection and prognosis for recovery, laboratory indicators for infection and inflammation such as WBCs, CRP, and ESR.

Regarding body mass index more than two-thirds of patients were overweight because of a lack of a healthy lifestyle such as nutrition and exercise for many Egyptian people. This result is supported by **Anaya and Dellinger**

(2006) who found that obesity interferes with the wound-healing process.

In terms of wound size and depth, the study illustrated that there was wound size and depth reduction in most studied patients. VAC increased the rate of epithelial tissue growth and caused a reduction in wounds. This was agreed by **Ahmed et al., 2019** who found that the reduction in wound size among patients care after the intervention of a negative pressure wound, leads to tissue stretching force that stimulates cell proliferation in the wound microenvironment, which improves the wound-healing process by cell division stimulation, angiogenesis, and the release of growth factors.

Regarding granulation tissue formation, most studied patients had healthy granulation tissue characterized by (75% -100%) filling the wound&/or tissue overgrowth with bright red beefy color.) after one month of follow-up VAC application. These results aligned with the findings of recent studies which reported that negative pressure wound therapy enhances the angiogenesis and proliferation of granulation tissue growth in the wound bed (**Miyanaga et al., 2023**) & (**Astasio-Picado et al., 2022**)

Concerning wound exudate type and amount, most studied patients were free from wound discharge one month after the VAC application. This was in accord with **Yu et al., 2023** Who illustrated that during nursing care of wounds, NPWT assists in removing discharge from the wound that contains metabolites, bacterial contamination, and toxins to facilitate wound healing.

As regards wound odor, the majority of studied patients had absent wound odors. This may be due to the VAC reduction of bacteria amount from the wound this was in line with **Yu et al., 2023**.

Concerning wound infection signs and surroundings, the findings found that most of the patients had local only or local and systemic wound infection signs and the presence of tissue necrosis in the first VAC application.

This may be due to diabetic patients having highly developed wound infections due to high blood glucose levels and low immunity status. While following up on VAC application after one month most of the studied patients had an absence of local wound infection signs and absence of tissue necrosis. This is agreed by **Yu et al., 2023** & **Hasan et al., 2015** who found that wounds managed with NPWT exhibited a more rapid suppression in the growth and multiplication of bacteria and enhanced clearance of infections from the wound.

Regarding wound edges, the study illustrated that most of the patients had non-attached wound edges at the end of the VAC application after one month. This may be due to the main role of VAC was enhanced healthy granulation tissue growth and minimized wound infection in large sized raw areas of the wounds to be ready for skin graft. This was in accord with **Gupta et al., 2016** who found that NPWT assisted wounds in preparation for closure by secondary closure or skin grafting in less time. It is the therapeutic option for the treatment of infected and non-healing wounds, not responding to conventional wound care.

In terms of the wound healing process, most of the studied patients had partial healing characterized by formation of healthy granulation tissue without completing a fibrous scar formation and decreased wound size and wound depth at the last VAC application after one month of wound dressing and follow up. This reflects the same previously mentioned rationale about the role of VAC enhanced healthy granulation tissue growth and minimizing wound infection in large-sized raw areas of the wounds to be ready for skin graft which is in the same line with **Gupta et al., 2016**, and no patients had complete wound healing. Also, in the same alignment with **Ramula et al., 2020** who reported that VAC improves wound size reduction, enhances wound granulation, and inhibition the bacterial load the key to the wound healing process, revealing better wound outcomes and faster healing of ulcers than standard methods.

Conclusion

This study sought the effectiveness of vacuum-assisted closure therapy on diabetic wound management. Most patients had partial wound healing after one month of VAC application. There was a statistically significant wound healing improvement related to wound size reduction, granulation tissue formation, decrease in wound exudates amount, absence of wound odor, absence of local wound infection signs, and absence of tissue necrosis, where partial wound healing was represented by formation of healthy granulation tissue without completing a fibrous scar formation and decreased wound size and wound depth.

The application of Vacuum-Assisted Closure Therapy had significant and promising results with Diabetic wound management exhibiting faster wound healing throughout the follow-up dressing period compared with pre-VAC application.

Recommendations

Based on the current study findings, the following recommendations are made:

- Vacuum Assisted Closure is recommended for difficult and non-healing wounds that do not respond to traditional dressing techniques.
- Vacuum Assisted Closure Therapy is considered a cost-effective and easily applied dressing technique that is used as a management option for diabetic wounds.
- Further studies focus on the impact of Vacuum Assisted Closure Therapy compared with other wound dressing treatment modalities.
- Application of In-service education programs for nurses regarding using Vacuum-assisted Closure Therapy.

References

Ahmed, Z., Husain, N., Nour, S., & Yee, S. H. (2019). Efficacy of vacuum-assisted closure

- (VAC) in wound healing. *Surgical Science*, 10(6), 173-215.
- Anaya, D. A., & Dellinger, E. P. (2006). The obese surgical patient: a susceptible host for infection. *Surgical infections*, 7(5), 473-480.
- Astasio-Picado, Á., Montero, M. D. M., López-Sánchez, M., Jurado-Palomo, J., Cobos-Moreno, P., & Gómez-Martín, B. (2022). The effectiveness of negative pressure therapy: Nursing approach. *Journal of Personalized Medicine*, 12(11), 1813.
- Chatterjee, U., & Butina, M. (2019). Biomarkers of Infection and Inflammation. *American Society for Clinical Laboratory Science*, 32(4), 149-155.
- El-den, S., Reizian, A., Yahia, A., Zedan, A., & Shorman, M. (2021). Effect of Negative Pressure Wound Therapy on Post-traumatic Wound Healing. *International Journal of Novel Research in Healthcare and Nursing*, 7(3), 590-608.
- Fitzpatrick, S., Hawkins, S., Dunlap, E., & Nagarsheth, K. (2022). Nurse driven outpatient wound center: Reducing readmission with wound care excellence. *Journal of Vascular Nursing*, 40(2), 100-104.
- Frykberg, R. G., Zgonis, T., Armstrong, D. G., Driver, V. R., Giurini, J. M., Kravitz, S. R., ... & Vanore, J. V. (2006). Diabetic foot disorders: a clinical practice guideline (2006 revision). *The journal of foot and ankle surgery*, 45(5), S1-S66.
- Gupta, S., Shaikh, T. P., Wani, J. B., Gujar, A., Bagul, A., & Gautam, R. (2016). Role of vacuum assisted closure therapy in chronic wound: For some cases in Navi Mumbai. *Int J Res Med Sci*, 4, 95-9.
- Hasan, M. Y., Teo, R., & Nather, A. (2015). Negative-pressure wound therapy for management of diabetic foot wounds: a review of the mechanism of action, clinical applications, and recent developments. *Diabetic foot & ankle*, 6(1), 27618.
- Hassan, N., Rezian, A., Jamal Al Deen, A., Yakout, R., & Ibrahim, H. (2018). Impact of hyperbaric oxygen therapy and wound care on clinical outcomes for patients with diabetic foot ulcer. *J Nurs Health Sci*, 7, 28-38.
- Ibrahim, M. H., & Allawy, M. E. A. (2023). Effect of Nursing Intervention Guidelines on Wound Status Outcomes for Patients Undergoing Negative Pressure Wound Therapy.
- Kautzky-Willer, A., Harreiter, J., & Pacini, G. (2016). Sex and gender differences in risk, pathophysiology and complications of type 2 diabetes mellitus. *Endocrine reviews*, 37(3), 278-316.
- Lenet, T., Gilbert, R. W., Abou-Khalil, J., Balaa, F. K., Martel, G., Brind'Amour, A., & Bertens, K. A. (2022). The impact of prophylactic negative pressure wound therapy on surgical site infections in pancreatic resection: a systematic review and meta-analysis. *HPB*, 24(12), 2035-2044.
- Lo, Z. J., Lim, X., Eng, D., Car, J., Hong, Q., Yong, E., ... & Heng, B. H. (2020). Clinical and economic burden of wound care in the tropics: a 5-year institutional population health review. *International wound journal*, 17(3), 790-803.
- Martinengo, L., Olsson, M., Bajpai, R., Soljak, M., Upton, Z., Schmidtchen, A., ... & Järbrink, K. (2019). Prevalence of chronic wounds in the general population: systematic review and meta-analysis of observational studies. *Annals of epidemiology*, 29, 8-15.
- Miyanaga, A., Miyanaga, T., Sakai, K., Konya, C., Asano, K., & Shimada, K. (2023). Patient experience of negative pressure wound therapy: A qualitative study. *Nursing open*, 10(3), 1415-1425.

- Mohammed, S., Akel Rajjoub, R., Elsaïd Abdelaziz, A., & Mohamed Abdelaziz, T. (2022). The Efficacy of Negative Pressure Wound Therapy versus Conventional Dressing on Diabetic Foot Wound Healing. *Egyptian Journal of Health Care*, 13(1), 678-690.
- Morgan, T., & Page, T. (2023). The effectiveness of prophylactic closed incision negative pressure wound therapy compared to conventional dressings in the prevention of periprosthetic joint infection post hip and knee revision arthroplasty surgery: A systematic review. *International Journal of Orthopaedic and Trauma Nursing*, 101048.
- Norman, G., Shi, C., Goh, E. L., Murphy, E. M., Reid, A., Chiverton, L., ... & Dumville, J. C. (2022). Negative pressure wound therapy for surgical wounds healing by primary closure. *Cochrane Database of Systematic Reviews*, (4).
- Parizad, N., Hajimohammadi, K., & Goli, R. (2021). Surgical debridement, maggots therapy, negative pressure wound therapy, and silver foam dressing revive hope for patients with diabetic foot ulcer: a case report. *International journal of surgery case reports*, 82, 105931.
- Ramula, M., & Arivzhagan, N. (2020). VAC (Vacuum assisted closure) in the management of chronic non-healing wounds: Institutional study. *International Journal of Surgery*, 4(4), 82-86.
- Salah Ead, H., Ahmed Mohammed, H., & Hidayat Morad, A. (2019). Factors Affecting Healing Process of Patients with Diabetic Foot Ulcer. *Egyptian Journal of Health Care*, 10(1), 634-648.
- Shahi, S. K., Kumar, A., Kumar, S., Singh, S. K., Gupta, S. K., & Singh, T. B. (2012). Prevalence of diabetic foot ulcer and associated risk factors in diabetic patients from North India. *The journal of diabetic foot complications*, 4(3), 83-91.
- Tuuli, M. G., Liu, J., Tita, A. T., Longo, S., Trudell, A., Carter, E. B., ... & Harper, L. (2020). Effect of prophylactic negative pressure wound therapy vs standard wound dressing on surgical-site infection in obese women after cesarean delivery: a randomized clinical trial. *Jama*, 324(12), 1180-1189.
- Veale, R. W., Kollmetz, T., Taghavi, N., Duston-Fursman, C. G., Beeson, M. T., Asefi, D., ... & May, B. C. (2023). Influence of advanced wound matrices on observed vacuum pressure during simulated negative pressure wound therapy. *journal of the mechanical behavior of biomedical materials*, 138, 105620.
- Yassin, A. M., Mohamed, M., Dirar, M., Ahmed, M., Elsir, K., & Alhadi, A. (2024). Modified intermittent low negative pressure wound therapy for complex injuries: A case series. *International Journal of Surgery Case Reports*, 116, 109356.
- Yu, L., Wang, Y., Ma, D., Pan, L., Liu, X., Chu, T., ... & Xu, X. (2023). In-hospital nursing care intervention increasing the effect of vacuum sealing drainage on wound healing: a meta-analysis. *International wound journal*, 20(8), 3371-3379.
- Zhou, Z. Y., Liu, Y. K., Chen, H. L., & Liu, F. (2015). Wound management with vacuum assisted closure in surgical site infection after ankle surgery. *International Journal of Surgery*, 17, 15-18.