The Efficacy of Negative Pressure Wound Therapy versus Conventional Dressing on Diabetic Foot Wound Healing.

Soheir Mohammed Weheida [(1)], Rahaf Akel Rajjoub[(2)], Aziza Elsaid Abdelaziz [(3)], Thoraya Mohamed Abdelaziz[(4)]

(1) Professor of Medical Surgical Nursing, Faculty of Nursing, Alexandria University, Alexandria, Egypt.

(2) Assistant Professor, Nursing Department, College of Health Sciences, University of Buraimi, Sultanate of Oman.

(3) Lecturer at Health Technical Nursing Institute, Alexandria, Egypt.

(4) Assistant Professor of Medical Surgical Nursing, Faculty of Nursing, Alexandria University, Alexandria, Egypt. ORCID: 0000-0003-2836-1425.

Abstract

Background: Complicated wound dressings impose tremendous medical, psychosocial and financial burden for millions of diabetics all over the world. The Negative pressure wound therapy (NPWT) technique for managing diabetic wounds, compared with other wound healing modalities; intended to control infection, promote wound healing and prevent recurrence to ensure successful outcomes for those patients; is a global researchers' concern. **Aim**: Evaluate the efficacy of negative pressure wound therapy versus conventional dressing on diabetic foot wound healing. **Design:** The present study follows the quazi-experimental research design. **Setting**: The study was conducted at the Inpatient Diabetic and Vascular Surgical Departments, of Alexandria Main University Hospital. **Subjects**: A convenience sample of 40 adult patients, who were divided randomly into two sequential groups. Study group: received NPWT dressing; while the control group: received conventional saline/povidine-iodine dressing. Two **tools** entitled "Diabetic Foot Wound Assessment" and "Pain Assessment" were developed and utilized by the researchers to evaluate wound healing process. **Results**: Statistically significant difference was declared in relation to appearance of granulation tissue and the incidence of local wound infection; where none of the study group patients had existing local signs of infection post two weeks of dressing follow-up; compared with patients in control group. As well, a statistical significant difference was found concerning wound healing process starting from the second week of dressing; at $p \leq 0.05$; where the majority of study group patients (80.0%) had complete diabetic foot wound healing, compares with less than half of the controls (45.0%). **Conclusion**: The NPWT dressing has a positive effect on wound healing in comparison to conventional dressing. Where; the majority of study group patients had complete wound healing at fifth week of dressing. **Recommendations**: Replication of the study on large probability sampling.

Keywords: Efficacy**,** Negative Pressure Wound Therapy, Conventional Dressing, Diabetics foot, Wound Healing

Introduction

Wound healing is a highly orchestrated process, which commences with getting rid of debris and combating infection. Nevertheless, inflammation clears the wound area for angiogenesis to increase wound site blood flow. Subsequently, the wound heals through deposition of granulation tissue, wound contraction and maturation. As one of these steps fails; the wound becomes unable to heal efficiently **(Lewis, Dirksen & Bucher, 2017; Baranoski & Ayello, 2020).** Also, wound management is directed toward the application of new noninvasive dressing techniques, where the negative pressure wound therapy (NPWT) is considered effective closed system procedure. The NPWT was first reported in 1990s; where it has revolutionized the clinical wound management. It affects wound healing by stimulating angiogenesis to cause mechanical stress in the wound bed, removing healing inhibitors and excess tissue fluid from the extravascular space **(Kairinos, McKune, Solomons, Hudson, and Kahn, 2014; Seidel, Diedrich, Herrle, Thielemann, Marusch, et al., 2020)**.

Moreover, NPWT increases the peripheral microcirculation blood flow during the early stages of wound inflammation; eliciting local oxygenation to the wound edges, which accelerate granulation tissue formation and the healing process is provoked by creating negative pressure around the wound, lowering the pressure over the wound than in the

atmosphere, which pulls the wound edges together **(Webster, Scuffham, Sherriff, Stankiewicz & Chaboyer, 2012).** Meanwhile, NPWT induces hypoperfusion to the tissue vicinity to the wound, especially prominent the subcutaneous tissue, resulting in minimal ischemic tissue damage. This is why the application of lower negative pressure is more beneficial when treating diabetic wounds **(Costa, Achten, Knight, Bruce, Dutton, et al., 2020; Quatman Villarreal & Cochran, 2020)**.

The key for successful wound care depend on professional nursing management, where they imply critical thinking skills, as well demonstrate strategic planning abilities regarding diabetic wound care. The nurse has the corner stone role for promoting healthy diabetic wound healing process; through assessing the diabetic patient, planning care, and providing a holistic efficient care, maintaining mobility, in addition to restoring emotional and physical capacity, as well as nutritional functions (**WoundSource Editors, 2019; Unitek College Team. 2021).**

Diabetic foot wound are challenging to manage; giving a burden on healthcare management system to maintain healthy wound healing. However, a thorough systematic nursing assessment of diabetic foot wound patients is essential to develop a comprehensive plan of care, enhancing early detection for any alterations that may disrupt the healing processes, worsen tissue damage and prolong tissue repair process **(Thomas, 2019)**. Thus, the current study was conducted to highlight diabetic wound healing process comparing the two selected dressing techniques. Predominantly, the study aim is considered one of the health care facilities deliberate concerns; hoping to contribute by adding an innovative buildings block in wound dressing era of nursing science.

Aim of work

Evaluate the efficacy of negative pressure wound therapy versus conventional dressing on diabetic foot wound healing.

Research Hypothesis:

1. Patients exposed to NPWT dressing technique exhibit complete wound healing, as indicated by presence of healthy granulation tissue covered by migration and proliferation of epithelial cells and formation of scare tissue, compared to those who do not exposed.
2. Patients exposed to NPWT dressing technique exhibit less infection manifestations, than those who do not exposed.
3. Patients exposed to NPWT dressing technique exhibit reduced pain parameters, than those who do not exposed.

Operational definition:

Conventional dressing: Is the application of dressing under aseptic technique with a lay of topical antibiotic, post cleansing the wound with normal saline 0.9%, then disinfect the wound utilizing Povidone -iodine 10%, and finally secure the dressing with adhesive tape.

Method

Design: A quazi-experimental research design was utilized in this study

Setting: The study was conducted at the Inpatient Diabetic and Vascular Surgical Departments, Alexandria Main University Hospital.

Subjects: A convenience sample of 40 diabetic patients from both sexes with leg ulcers/wounds. Subjects were randomly and sequentially recruited into two equal groups (20 patients each) according to the utilized dressing technique; conventional dressing (Control) group, and Negative pressure management technique (NPWT) (Study group).

Patients' inclusive criteria:

1- Adult 18-60 years and willing to communicate.
2- Have clean diabetic 1st grade plantar leg wounds with superficial diabetic ulcer (partial or full thickness), either in plantar of toes, plantar of metatarsal heads, or sole.
3- Wound length ranging between 10-15 cm
4- Have controlled diabetes and comorbid conditions (Hypertension, renal disease. etc).

Patients' exclusion criteria:

1- Free from diabetic peripheral neuropathy, bleeding tendency, immune-compromised conditions and not receiving steroids or chemo and radiotherapy.

2- Free from fever (equals or more than 38.5°c), diarrhea, nausea, or vomiting, confusion or dizziness, bleeding, warmth, or redness around the wound.

3- Free from contaminated wounds requiring surgical debridement.

Tool: Two tools were used to attain study purpose.

Tool 1 was entitled as "**Diabetic Foot Wound Assessment".** This tool was developed by the researchers after in-depth review of relevant literatures. It aimed to evaluate the diabetic foot wound before and post application of the two study relevant dressing techniques (being mid-follow up period). It comprised three parts:

Part I: Socio-demographic data included information related to: age, sex, occupation, marital status, and education.

Part II: Diabetic foot wound characteristics: to identify diabetic foot wound assessment data post two weeks of both dressing techniques, through:

1. Depth of wound, which was indicated by estimating depth percentage out of 100% as a total epithelial tissue covering the wound surface. It was scored as:
   0 =100% wound was healed and surfaces are intact.
   1 = 75% to < 100% wound is covered &/or epithelial tissue extends > 0.5 cm into wound bed.
   2 = 50% to < 75% wound is covered &/or epithelial tissue extends < 0.5 cm into wound bed.
   3 = 25 to 50% wound covering.
   4 = < 25% wound covering.
   5 =No epithelial tissue present covering the wound.
2. Presence of abnormal findings of wound healing
   a- Assessment of wound bed color: pink, red, dark red or yellow/white.
   b- Assessment of wound exudate odor: It was scored as 0 = absent, and 1 = present.
3. Presence of granulation tissue type, color and amount, it was scored as:
   0 = normal: 100% wound covered, surface intact or partial thickness wound.
   1= bright, beefy red, 75% -100% wound fills &/or tissue over growth.
   2= bright, beefy red, < 75% & > 25% of wound fills.
   3= pink&/or dull, dusky red/or fills ≤ 25%of wound.
   4 = no granulation tissue present.
4. Local infection was examined and recorded starting from 3rd and 5th days of dressing.
   It was scored as:
   0= absence of local signs of wound infection.
   1=Presence of local signs of wound infection (redness, hotness, tenderness, purulent discharge and swelling)
   2= presence of systemic wound infection signs (fever, elevated WBCs, ESR and CRP).
5. Finally, the estimated size of wound which was scored in centimeters for length and width using ruler.

Part III: "Wound Healing Assessment": This part was developed by the researchers to describe wound morphologically against certain parameters:

1. Moist granulation tissues formation.
2. Improved healing surface area measurements (Decrease wound size).
3. Presence or absence of healing epithelial edges
4. Presence or absence of clinical signs related to wound infection: redness, hotness, tenderness, swelling, edema, change wound color, and presence of exudates or discharge (amount, color, and odor).

Scoring system: however, in this part mean items scores were calculated to present the following total wound healing score:

1 = Complete healing: indicated by presence of healthy granulation tissue covered by migration and proliferation of epithelial

cells within the wound space and formation of scare tissue.

2 = Partial healing: presence of healthy granulation tissue within the wound space or decrease of wound size without formation of scar tissue.

3 = No healing: represented by no improvement in wound characteristics or no granulation tissue formation, No decrease of wound size and depth and no fibrous scar tissue formation.

Tool II: "Pain Assessment":

This tool was developed to assess wound pain parameters namely; site, intensity, duration (documented in minutes), in addition to precipitating and alleviating factors. In order to assess the intensity of subjective pain characteristics; the visual analog scale (VAS) was adopted from its first scientific descriptors; **Hayes and Patterson, 1921,** where pain intensity was indicated on a continuous horizontal line, of 10 cm length, ranging from 0 (left, least extreme) to 10 (right, most extreme). The VAS reliability was tested by **Bijur, Silver, and Gallagher, 2001**; where r= 0.97. **Scoring system of pain intensity:** "0" means no pain; "1-3" means mild pain; "4-7" is considered moderate pain; "8 and above" is severe pain.

Data collection:

1. Data collection started in March till the end of June 2021 over a period of 4 months.
2. **Written approval:** Official written approval was obtained from the Ethical Research Committee and Research Affair Committee, at Faculty of Nursing; Alexandria University. As well official permission was obtained from the directors and head of the selected settings' departments after explanation of the study aim.
3. **Tool development:** The study tools were developed by the researchers after recent related literature review; Abdel Fattah & Sharaf, (2015); Desokey, (2017); Ibrahim, Wong, Mohamed, Mohamed, Chin, et al. (2018), and El-Den, Reizian, Yahia, Zedan, and Shormana (2021). The second tool incorporated adoption of the reliable VAS to measure wound pain intensity.
4. **Content validity:** The developed tool was revised by five experts in the field of Surgery and Medical Surgical Nursing to test its clarity and comprehensiveness; however necessary modifications were done accordingly.
5. **Reliability** of the developed tool one and two were tested using Alpha Cronbach's statistical test; reliability coefficients was (0.864, 0.982; respectively).
6. A pilot study was conducted on (10%) of the study subjects for testing, the feasibility and applicability of the developed tool; and modifications were done. Those patients were excluded from the study sample.
7. After obtaining participants' consent; they were recruited randomly and sequentially either in the control or study group.
8. Upon patients' enrollment in the study based on the inclusion and exclusion criteria: The researchers assessed and recorded each group patient's wound assessment and healing process through:
   - Initial meeting for both group patients' assessment was conducted using **tool I-first part.**
   - Moreover, **morphological wound assessment** was done by the researchers in conjunction with surgeons in charge; utilizing **tool I-second part** prior and post two weeks of the two dressing techniques start time.

It aimed to:

a) Measure the depth of the diabetic foot wound:

The researchers observed the depth or thickness if the wound is superficial (epidermis) or partial thickness or skin loss that involves epidermis and /or dermis by Epithelialization process.

b) Assess local findings of abnormal wound healing

- Assess presence of local wound infection clinical signs: wound color, hotness, tenderness, and swelling.
- Diabetic foot wound exudates (type, amount and odor) either: ○ Bloody: thin bright red
  ○ Serosanguineous: thin yellow watery

- Pale: red to pink. ○ Serous: thin, watery, clear ○ Purulent: thin or thick opaque to yellow
- Foul purulent: thick, opaque yellow to green

c) Assess granulation: The presence of healthy granulation tissue formation, with fibrous scare, was recorded by the researchers.

d) Assess the surrounding area of the wound: The researchers assessed signs of inflammation (redness, hotness, tenderness and swelling), and skin condition (moist or dry).

e) Identify wound size in centimeters through:

- Perform hand hygiene, put on latex gloves.
- Moist a sterile flexible applicator with saline.
- Mark the point on the swab applicator with surrounding skin then grasp the applicator with thumb and forefinger at the point corresponding to wound margin.
- Remove the swab applicator and measure the wound size with ruler.

- In addition, **wound healing** was monitored 5 times; starting from first week and weekly till the fifth follow up week using the study **tool I- third part**; to evaluate:
  a. Granulation tissues formation.
  b. Improved healing surface area size.
  c. Presence of thin healing epithelial edges
  d. Absence of wound infection clinical signs; where complete wound healing occurred indicated by: the formation of healthy granulation tissue (development of thin epithelium layer/blue film at wound edges).
- Patients' **wound pain** was assessed by the researchers for both groups at five follow up periods; starting from admission till the fourth week of the two dressing techniques; utilizing the study **tool II**.
- Both groups (conventional and NPWT) dressings were changed twice/week until healing occurred or within maximum five weeks.
- **Control group patients** were exposed to routine hospital dressing by nurses in the above mentioned units.
- **The NPWT diabetic foot patient's dressing was performed by the researchers via the following steps:**

1- Wash hands with soap and water and dry it well, then wear surgical gloves to prevent cross infection.

2- Cleanse the wound and the area around the wound under aseptic technique with normal saline solution 0.9%; the researchers ensured wound dryness.

3- Debridement was done by removing all necrotic tissues by scalpel and forceps till floor of wound bleeds.

4- One millimeter layer of antibiotic ointment was applied directly on wound surface.

5- Study group patients were managed by NPWT dressing by applying a vacuum pressure through a special transparent nonpermeable sealed dressing. Sterile open cell foam was placed in the wound, whereas a tube is passed through it then sealed with an adherent film as sub-atmospheric pressure was applied by suction machine that contains a fluid collection canister; which provides a positive pressure to the surface of a wound.

6- The vacuum applied intermittently, on a pressure of 50-150 mmHg, the mode cycle was alternating between one hour suction pump on and one hour off until the next following vacuum dressing.

7- The researchers wrapped the wound using light regular bandage dressing with minimum pressure to secure it in place.

8- However, the old stuck foam dressing was carefully loosened with normal saline 0.9%; while gently lifting it under aseptic technique to avoid wound irritation.

Ethical consideration:

1- Written informed consent was obtained from each patient after explanation of the study aim. The participants' right to

withdraw from the study at any time was explained and assured.

2- Confidentiality of the collected data was assured; as well as patients' privacy and anonymity was maintained for all participants.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. Qualitative data were described using number and percent Quantitative data were described using range (minimum, maximum & median), means and standard deviations. Comparisons between groups for categories variables were assessed using Chisquare test and Fishers Exact or Monte Carlo correction. Significance of obtained results was judged at the 5% level (**IBM Corp., 2011).**

Results:

Table (1): Shows distribution of both studied groups' patients according to sociodemographic characteristics. As regards **age**; it was found that 40.0% of the study group patients' age ranged from 30 to less than 40 years, compared to an equal proportion of (30.0%) were ranging between 20 to less than 30 years and 40 to less than 50 years of control group; respectively.

According to **sex**, the majority of both the study and control group patients were males representing 75.0% and 80%; respectively. As for **occupation**, it was found that an equal proportions representing; 45.0% of both studied groups were manual workers.

In relation to **marital status**, the majority of the patients in both studied groups (study and control) were married 60.0%; respectively. Regarding the **educational level** the majority of both negative pressure wound therapy (NPWT) and control groups were illiterate represented by; 50.0% and 90.0%; respectively.

Statistically significance differences were found between both studied groups in relation to level of education; where $x^2 = 33.000$ at $p \leq 0.05$.

Table (2): Shows distribution of both studied groups' patients according to wound characteristics assessment post two weeks of dressing:

This table shows that as regards to **depth** of diabetic wound, patients in the study and control group were classified into 1st superficial and 1st full thickness wound. Where, the 1st superficial depth was represented by 25.0**%** in the study group as compared to 20.0**%** in control group. While, the 1st full thickness wound were declared in 75.0**%** of the study group compared to 80.0**%** in controls.

In relation to **abnormal findings** of wound healing post two weeks of the two dressing techniques; regarding the wound **color**, the majority of patients in the study and control groups (95.0 **%** and 75.0**%;** respectively) had red color wound. While, equal proportions were declared for wound exudate **odor;** representing 55.0% in both groups.

As for presence of **granulation tissues** it was found that, the majority of patients in the study group (70.0%) had presence of granulation tissues post two weeks of dressing; compared with 35.0% of patients in the control group**.** Regarding wound **size**; in both the study and control group patients the size ranged from14 – 25 cm.

However**,** a statistically significant difference was declared between the two groups as regard to appearance of granulation tissue; where the study group showed a promising granulation tissue outcome compared to the control group; $\chi^2 = 4.912$ at $p \leq 0.05$. Also, a statistically significant difference concerning occurrence of local infection clinical signs was detected; where none of the study group patients had local signs of infection post two week of dressing, compared with nearly half (45.0%) of the controls.

Table (3): Shows comparisons between the two studied groups' patients according to wound pain assessment: As regard to **site** of pain **(**wound**);** it was found that, for all patients (100.0**%)** in the both study and control group pain was localized at the site of wound; with no related radiation.

As regards to pain **intensity**; the results revealed that nearly all the study and control group patients had severe pain at the site of wound on admission (100.0% and 95.0%; respectively). However, this percentage started to decrease in the study group patients by the end of second week from sever 85.0**%** to mild 90.0% in the fifth week of pain assessment; compared with higher intensity percentages (95.0% and 50.0% respectively); in control group patients.

It was also observed that, the mean wound pain **duration** was lowered in both the study and control groups from 43.0±4.18 and

45.50±8.26 minutes on admission; respectively, to reach 12.00±2.51and 10.75±2.45 at the end of the fifth week of both dressings; respectively**.**

There was no statistical significant difference between both studied groups patients regarding pain assessment parameters; except for pain **intensity** at the fourth follow up week; where x^2=2 7.619, at $p \leq 0.05$.

Table (4): Displays comparison between the two studied groups' patients according to extent of wound healing during follow up periods. It was observed that, after **two weeks** of both dressings; half of the study group patients (50%) had **partial wound healing** compared with only 15% in the control group. However, by the **third** week; quarter of the study group patients (25%) had **complete wound healing** compared to 0% in the control group.

Likewise, by the end of the follow up periods it can observed that; the majority of **study group** patients (80.0%) had **complete** diabetic foot wound healing, while the remaining 20.0% had **partial** healing. As for the **controls**; at the end of follow up period it was found that, less than half patients (45.0%) had **complete** wound healing, 35.0% had **partial** wound healing, while the last 20.0% complained from **no wound healing**.

A statistical significant difference was found between the study and control group in relation to healing process starting from the second week of dressing application until the fifth week; at $p \leq 0.05$; where x^2 = 5.584, 11.459, 8.006 and 6.423; respectively, at $p \leq 0.05$.

Table (1): Distribution of both studied groups' patients according to socio demographic characteristics

Socio-demographic characteristics	Negative pressure wound therapy group (n = 20)		Conventional dressing group (Control group) (n = 20)		x^2	P
	No.	%	No.	%		
Age (years)						
20–	2	10.0	6	30.0		
30–	8	40.0	5	25.0	3.926	0.416
40–	5	25.0	6	30.0		
50– 60	5	25.0	3	15.0		
Sex						
Male	15	75.0	20	80.0	0.143	1.000
Female	5	25.0	15	20.0		
Occupation						
Manual worker	9	45.0	9	45.0	0.0	1.000
Employee	7	35.0	7	35.0		
Not working	4	20.0	4	20.0		
Marital status						
Single	5	25.0	5	25.0		
Married	12	60.0	12	60.0	0.0	1.000
Divorced	2	10.0	2	10.0		
Widow	1	5.0	1	5.0		
Educational level						
Illiterate	10	50.0	18	90.0		
Read & write	5	25.0	1	5.0	33.000*	<0.001*
Primary	3	15.0	1	5.0		
Secondary	2	10.0	0	0.0		

*: Statistically significant at $p \leq 0.05$

Table (2): Distribution of both studied groups' patients according to wound characteristics assessment post two weeks of dressing.

Wound characteristics assessment	Negative pressure wound therapy group (n = 20)		Conventional dressing (control group) (n = 20)		Test of sig.	P
	No.	%	No.	%		
Depth of wound						
1st superficial	5	25.0	4	20.0		FEp=
1st full thickness	15	75.0	16	80.0	x^2= 0.143	1.000
Abnormal findings of wound healing						
a- Wound color						
Red	19	95.0	15	75.0		
Increased redness	1	5.0	5	25.0	x^2= 3.137	0.182
b- Wound exudate odor Yes	11	55.0	11	55.0	x^2=	
No	9	45.0	9	45.0	0.0	1.000
Appearance of granulation tissue						
Yes	1 4	70.0	7	35.0		
No	6	30.0	13	65.0	x^2= 4.912*	0.027*
Local infection Yes	0	0.0	9	45.0	x^2=	FEp =
No	20	100.0	11	55.0	11.613*	0.001*
Size of wound Min. –						
Max.	14.0 – 25.0		14.0 – 25.0		t = 0.253	0.802
Mean ± SD.	18.35 ± 3.46		18.60 ± 2.74			
Median	17.0		18.0			

x^2: Chi square test / FE: Fisher Exact test /t: Student t-test, *: Statistically significant at $p \leq 0.05$

Table (3): Comparisons between the two studied groups' patients according to wound pain assessment.

Wound pain assessment.	Admission		First week		Second week		Third week		Fourth week	
	No.	%	No.	%	No.	%	No.	%	No.	%
Site										
NPWT group										
Wound	20	100.0	20	100.0	20	100.0	20	100.0	20	100.0
Control group Wound	20	100.0	20	100.0	20	100.0	20	100.0	20	100.0
Intensity										
NPWT group										
Mild	0	0.0	0	0.0	0	0.0	3	15.0	18	90.0
Moderate	0	0.0	0	0.0	3	15.0	17	85.0	2	25.0
Severe	20	100.0	20	100.0	17	85.0	0	0.0	0	0.0
Control group Mild	1`	5.0	0	0.0	0	0.0	1	5.0	10	50.0
Moderate	0	0.0	0	0.0	1	5.0	19	95.0	10	50.0
Severe	19	95.0	20	100.0	19	95.0	0	0.0	0	0.0
x^2	1.026	-	1.111	1.111	7.619*					
P	1.00	-	0.605	0.605	0.006*					
Duration	**No.**	**Mean± SD**	**No.**	**Mean± SD**	**No.**	**Mean± SD**	**No.**	**Mean± SD**	**No.**	**Mean± SD**
NPWT group	20	43.0±4.18	20	20.50±7.24	20	12.00±2.51	20	12.00±2.51	20	12.00± 2.51
Control group	20	45.50±8.26	20	19.25±3.35	20	10.75±2.45	20	10.75±2.45	20	10.75± 2.45
T	0.681	0.701	1.594	1.594	1.594					
P	0.501	0.489	0.119	0.119	0.119					
Precipitating factors										
NPWT group										
Dressing	20	100.0	20	100.0	20	100.0	20	100.0	0	0
Bathing	20	100.0	20	100.0	6	30.0	0	0	0	0
Movement	20	100.0	20	100.0	0	0	0	0	0	0
Control group Dressing	20	100.0	20	100.0	20	100.0	20	100.0	0	0
Bathing	20	100.0	20	100.0	3	15.0	0	0	0	0
Movement	20	100.0	20	100.0	0	0	0	0	0	0
Alleviating factors										
NPWT group										
Rest, Post dressing and Sedative	20	100.0	20	100.0	20	100.0	20	100.0	20	100.0
Control group										
Rest, Post dressing and Sedative	20	100.0	20	100.0	20	100.0	20	100.0	20	100.0

x^2: Chi square test, t: Student t-test, *: Statistically significant at $p \leq 0.05$

Table (4): Comparison between the two studied groups' patients according to extent of wound healing during follow up periods.

Wound healing process	First week		Second week		Third week		Fourth week		Fifth week	
	No.	%	No.	%	No.	%	No.	%	No.	%
Negative pressure wound therapy group										
Complete	0	0	0	0.0	5	25.0	8	40.0	16	80.0
Partial	0	0	10	50.0	10	50.0	8	40.0	4	20.0
Incomplete healing	20	100.0	10	50.0	5	25.0	4	5.0	0	0.0
Control group Complete	0	0	0	0.0	0	0.0	1	5.0	9	45.0
Partial	0	0	3	15.0	5	40.0	9	45.0	7	35.5
Incomplete healing	20	100.0	17	85.0	15	50.0	10	15.0	4	20.0
x^2	-		5.584*		11.459*		8.006*		6.423*	
^{MC}p	-		0.018*		0.002*		0.019*		0.034*	

χ^2: value for Chi square, MC: Monte Carlo test, *: Statistically significant at $p \leq 0.05$

Discussion

Wound management is a challenging process that necessitates specialized nursing skills. Where, the wound care nurse is in charge for identifying the appropriate dressing technique; while constantly assesses patient's wound condition **(Unitek College Team, 2021**). Over the last two decades numerous dressing techniques have been utilized to improve wound healing process and control infection, in the direction of preventing its serious complications. Thus, the nurse must comprehend wound healing physiology as well as various therapeutic modalities indications; to select the best wound management approach **(Sood, Granick & Tomaselli, 2014).**

Therefore, the current study was conducted to evaluate the efficacy of NPWT versus Conventional Dressing on Diabetic Foot Wound Healing. Discussion of the present study results covered three main areas sociodemographic characteristic of the both studied groups, assessment of the wound pain and assessment of healing process after applying the specified study techniques (NPWT conventional using povidine-iodine) during the follow up period.

The results revealed that, most of the studied patients of both groups were married males and their ages ranged between 20-50 years. This finding can be explained by the fact that, younger adults mostly perform hard work, work over-time and sustain prolonged standing hours. However, in the present study most of diabetic patients in both groups were farmers and builders; their jobs necessitated long hours of standings on feet, which lead to continuous pressure in addition to being exposed to wet muddy or sandy floor which increased risk for feet injury. These results are supported by **Hewitt, Flekser, Harcourt, Sinha (2003)** who stated that, diabetic foot ulceration occurs most commonly in younger and older adults. This was also in accordance with **Yakout (2009)** who found that, the worker males are affected by foot ulcer more than the females. Likewise this finding was in agreement with (**KautzkyWiller, Harreiter, & Pacini, (2016);** who found that young adult diabetic men are at risk for developing lower extremity problems more than women. However, this finding is contradicted by **Jamil, (2010)** who found that; the majority of the patients affected by diabetic foot ulcer were divorced older adult male.

Furthermore, the present study illustrates that high percentage of patients in both studied groups were illiterate and read & write. This may explain their neglected wound condition which could be due to lack of awareness about associated diabetic health problem and its early management; if detected. This finding was in agreement with **Armstrong. Driver, Giurini, Kravitz, Landsman, et al, (2006)** who found that, illiterate patients were at risk for compound wound ulceration more than the educated patients; as a result of lack of knowledge about diabetes and its complications in turn, they ignored daily inspection of foot abnormalities. Moreover, the results of the present study revealed the absence of any significant differences in the sociodemographic characteristics and wound characteristics (surface area, depth, wound

discharge) between the study and control groups which ensure limitation of the reverse effect of intervening variables, and focusing on examining only the effect of dressing techniques on diabetic wound healing process.

The current study assess diabetic foot ulcer pain associated with the two dressing techniques, where a statistical significant difference between both studied groups at the fourth follow up week as regards pain intensity was declared. In spite minimal researches were conducted to explore NPWT-related pain; **Woo, 2010; Upton & Andrew, 2015** findings supported the NPWT effectiveness in wound healing, but stressed on pain resulted from changing wound dressing, where this pain may adversely impact patients' physical and psychological well-being. Thus patient's prior dressing should be managed for pain through analgesics as prescribed. In this respect also the **wound care center, 2016** announced that; NPWT can be very painful, especially once dressing changing initiated; however patients significantly reported a lowered pain levels as the pressure is applied, explaining the lowered pain intensity than conventional dressing.

In the present study twice weekly dressing encouraged frequent diabetic foot wound inspection and skin assessment to temperature, pulsation, color, which allowed for early skin abnormality detection. However, the results revealed no wound abnormalities nor sign and symptoms of infection during the study follow up periods in the NPWT dressing group. In this respect **Liu, He, Cai, Xing, Guo, et al, 2017** and **Webster et al, 2019** stated that; the comprehensive NPWT dressing act as surgical site infections (SSIs) prophylaxis, enhancing healing via primary closure. In addition **Jacobs and Rekha, 2007** & **Bigliardi, Alsagoff, ElKafrawi, Pyon, Wa, and Villa, 2017** reported that, Betadine 10% solution may be used to disinfect wound being a powerful bactericidal; but if used in ulcer dressing, it delays healing due to its skin irritation effect.

Whereas in the conventional dressing wound assessment post two weeks of follow up; revealed early diabetic foot ulcer abnormalities such as: presence of local signs of infection, lacking of granulation tissue development and absence of healing epithelial edge. This may be explained by; the twice weekly NPWT dressing showed its effectiveness in healing process through continuous researchers' skin assessment during changing wound dressing, resulting in preventing easily organisms' colonization. This finding was advocated by

Abbass, 2009 and **Waynne, 2018** who emphasized that, scheduled daily dressing permit constant wound cleansing and enhance inspection and early detected of any signs of inflammation or discharge.

As regard to wound healing process, a pronounce improvement in NPWT diabetic foot wound healing started by the second week, where the NPWT patients who had complete wound healing have increased apparently; than those in the control group. However post 3 weeks, the NPWT dressing had significant effect on wound healing than conventional dressing (saline and Povidone-iodine). Where, the number of patients who had complete or partial wound healing was increased; while patients lacking wound healing were decreased in both studied groups. Although the majority of patients in both studied groups, at the end of follow up period post 5 weeks, had complete ulcer healing documented by the presence of healthy granulation tissue covered by migration and proliferation of epithelial cells within the wound space and formation of scare tissue, still the result of the study group patient is better compared to control group patients. Except for minor cases in study and control groups who had partial ulcer healing, which means presence of healthy granulation tissue within the wound space or decreased of wound size without formation scare tissue.

However, **The Canadian Agency for Drugs and Technologies in Health, 2014; and Zens, Barth, Bucher, Dreck, Felsch, et al., 2020** have declared the promising benefit of NPWT in wound closure/healing outcome by secondary intention. In addition **Liu et al, 2017** and **El-den et al, 2021** stated that; NPWT has proven practical effectiveness, better health outcome, quality of life and

shortened hospital stay due to its rapid and complete diabetic foot ulcers healing.

Hence, the study findings declared that none of the NPWT group patients complained from lack of ulcer healing post 5 weeks of follow up; which goes in line with research hypothesis, that patients who are managed with NPWT have better healing process than those on conventional wound management.

Finally as revealed from this discussion, NPWT shows better diabetic foot ulcer morphological parameters. Moreover, it was more effective than the conventional dressing on wound healing process, as the period of wound healing was shorter than in conventional dressing technique. So, the present study emphasized the significance of expending the use of NPWT dressing on diabetic foot wound, to accelerate its healing and prevent or minimize its complications.

Conclusion:

The application of NPWT had significant and promising results in relation to diabetic foot wound healing in earlier time throughout the follow up period; in comparison to conventional dressing. Where complete wound healing was indicated by presence of healthy granulation tissue covered by migration and proliferation of epithelial cells within the wound space and formation of scare tissue, in addition to absence of local infection signs post two week of dressing; compared with control group. In addition, statistical significant difference was detected between both studied groups regarding wound pain **intensity** at the fourth follow up week.

Recommendation:

Replication of the study on large probability sampling.

References

Abbass H, (2009). Effect of Honey Tulle Dressing versus the Conventional Dressing Technique on Healing of Moderate Burns. Unpublished Master Thesis, Faculty of Nursing, Alexandria University.

Abdel Fattah M. & Sharaf A. (2015). Cooled Boiled Tap Water versus Sterile Normal Saline for Traumatic Wound Cleansing: a Comparative Clinical Trial. World Journal of Nursing Sciences 1 (3): 100-9

Armstrong DG., Driver VR., Giurini JM., Kravitz SR., Landsman AS., Lavery LA., Moore JC., Schuberth JM., Wukich DK., Andersen C., Vanore JV. (2006). American College of Foot and Ankle Surgeons. Diabetic foot disorders: A clinical practice guideline. J Foot Ankle Surg; 45 (Suppl.): S1–66.

Baranoski S. & Ayello E. (2020). Wound Care Essentials: practice and principles. 5th Edition. Philadilphia: Wolter Kluwer.

Bigliardi P., Alsagoff S., El-Kafrawi H., Pyon J., Wa C., Villa M. (2017). Povidone iodine in wound healing: A review of current concepts and practices. International Journal of Surgery, 44, 260-8,

Bijur PE., Silver W., Gallagher EJ. (2001). Reliability of the visual analog scale for measurement of acute pain. Acad Emerg Med.;8(12):1153-7.

Canadian Agency for Drugs and Technologies in Health. (2014). Negative pressure wound therapy for managing diabetic foot ulcers: a review of the clinical effectiveness, costeffectiveness, and guidelines [online]. 28.08.

Costa ML., Achten J., Knight R., Bruce J., Dutton SJ., Madan J., Dritsaki M., Parsons N., Fernandez M., Grant R.,

Nanchahal J.; WHIST Trial

Collaborators. (2020). Effect of Incisional Negative Pressure Wound Therapy VS Standard Wound Dressing on Deep Surgical Site Infection After Surgery for Lower Limb Fractures Associated With Major Trauma: The WHIST Randomized Clinical Trial. JAMA. ; 11;323(6):519-26.

Desoky G. (2017). The Effect of Forced Air Warming System on Post Anesthetic Recovery of Patients Undergoing Major

Abdominal Surgeries. Alexandria Scientific Nursing Journal 19 (2), 25-36

El-den S., Reizian A., Yahia A., Zedan A., Shormana 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

Hayes HS., and Patterson DG. (1921). Experimental development of the graphic rating method. Psychol. Bull; 18, 98–9.

Hewitt A, Flekser, R, Harcourt, D, Sinha S. (2003). The Evolution of a Hospital based leg ulcer clinic, Primary Intention; 11 (2); 75-85

IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.

Ibrahim N., Wong SK., Mohamed IN., Mohamed N., Chin KY., Ima-Nirwana S., Shuid AN. (2018). Wound Healing Properties of Selected Natural Products. Int J Environ Res Public Health; 25; 15(11): 2360.

Jamil E. (2010). Assessment of Self-Foot Care among Diabetic Patients, Unpublished Master Thesis, Faculty of Nursing, Alexandria University.

Kairinos N, McKune A, Solomons M, Hudson DA, Kahn D. (2014). The flaws of laser Doppler in negative-pressure wound therapy research. Wound Repair Regen; 22:424.

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.

Lewis S., Dirksen S. & Bucher L. (2017). Study Guide for Medical-Surgical Nursing -Assessment and Management of Clinical Problems. 10th Edition. US: Mosby.

Liu S., He Z., Cai, T., Xing P., Guo Z., Chen L., Su L., & Yang P. (2017). Evaluation of negative-pressure wound therapy for patients with diabetic foot ulcers: systematic review and meta-analysis. Therapeutics and clinical risk management, 13, 533–44.

Quatman CE, Villarreal ME, Cochran A. (2020). Incisional Negative Pressure Wound Therapy Following Surgical Repair of Lower Extremity Fractures. JAMA. 11; 323(6):513-4.

Seidel D, Diedrich S, Herrle F, Thielemann H., Marusch F., Schirren R., Talaulicaret R. (2020). Negative Pressure Wound Therapy vs Conventional Wound Treatment in Subcutaneous Abdominal Wound Healing Impairment: The SAWHI Randomized Clinical Trial. JAMA Surg; 155:469.

Sood, A., Granick, M.S., & Tomaselli, N.L. (2014). Wound Dressings and Comparative Effectiveness Data. Advances in wound care, 3(8), 511–29.

Thomas C. (2019). Comprehensive Patient and Wound Assessments, Advances in Skin & Wound Care; 32(6), p 287-8.

Unitek College Team. (2021). A Step-by-Step Guide to Wound Care. Unitek College Blog. Available from: https://www. unitekcollege.edu/blog/astep-by-step-guide-to-wound-care/. Accessed: February, 2022

Upton D. and Andrews A. (2015). Pain and trauma in negative pressure wound therapy: A review. International Wound Journal, 12, 100– 5.

Waynne M. (2018). HSE National Wound Management Guidelines. The Office of Nursing and Midwifery Services Director, Clinical Strategy and Programmes Division, Dr. Steevens' Hospital. Available from: https://healthservice. hse.ie/filelibrary/onmsd/hse-national-wound-managementguidelines-2018.pdf. Last updated: 2021. Accessed: February 2022.

Webster J, Scuffham P, Sherriff KL, Stankiewicz M., Chaboyer W. (2012). Negative pressure wound therapy for skin grafts and surgical wounds healing

by primary intention. Cochrane Database Syst Rev; CD009261.

Webster, J., Liu, Z., Norman, G., Dumville, J. C., Chiverton, L., Scuffham, P., Stankiewicz, M., & Chaboyer, W. P. (2019). Negative pressure wound therapy for surgical wounds healing by primary closure. The Cochrane database of systematic reviews, 3(3).

Woo K. (2010). Wound-related pain: anxiety stress and wound healing. Wounds UK; 6: 92–8.

Wound Care Center. (2016). Negative Pressure Wound Therapy. Retrieved from Wound Care Centers: Available from: http://www.woundcarecenters.org/article /wound-therapies/negative-pressurewound-therapy. Accessed: 15-2-2022.

WoundSource Editors. (2019). Understanding Diabetic Foot Ulcer Classification Systems WoundSource Practice Accelerator's blog. Available from: https://www. woundsource. com/blog/und erstanding-diabetic-foot-ulcerclassification-systems. Accessed: 13-22022

Yakout R. (2009). The effect of semi-closed compression technique as compared to no contact heat therapy dressing on the healing of chronic venous leg ulcer unpublished Doctorate dissertation Faculty of Nursing, Alexandria University.

Zens, Y., Barth, M., Bucher, H.C., Dreck K., Felsch M., Groß W., Jaschinski T., Kölsch H., Kromp M., Overesch I., Sauerland S., Gregor S. (2020). Negative pressure wound therapy in patients with wounds healing by secondary intention: a systematic review and meta-analysis of randomized controlled trials. Syst Rev; 9, 238.