Effect of Ozone Olive Oil Ointment Dressing Technique on the Healing of Superficial and Deep Diabetic Foot Ulcers

Hend Abdelmonem Elshenawie[1], Wael Elsayed Ahmed Shalan[2], Aziza Elsaeed Abdelaziz[3]

[1]Lecturer, Medical Surgical department Faculty of Nursing
[2] Assistant professor, Vascular Surgical department, Faculty of Medicine
[3] Teacher in Technical Institute of Nursing, Alexandria University – Egypt
sscopyprint2012@yahoo.com

Abstract: Diabetic foot ulcers and other foot problems such as, infection, and gangrene are a major cause of morbidity and mortality in diabetic people through the world.[1, 2] In diabetic patients the presence of neuropathy and ischemia make the consequence of minor trauma leading to cutaneous ulceration and wound healing failure. [3]These problems lead to serious complications which usually have an effect on patients quality of life, and are the leading cause of hospitalization. Management of patients with diabetic foot ulcer can prevent the most serious complications. In order to prevent these complications and promote healing the nurse needs to understand physiology of wound healing, as well as treatment modalities to be able to select the appropriate technique and solution for wound management. such as Honey, Der magran (Zinc-saline) and Ozonated olive oilIn addition, educating the patients about the proper foot management systems[4]. Therefore the aim of this study is measuring the effect of ozonated olive oil ointment technique on the healing of superficial and deep diabetic foot ulcers.The study was conducted at Alexandria Main University Hospital and followed up for 3months.The sample comprised 30 adult patients who had foot ulcers.. The sample was divided equally into two groups, study and control groups. The study group was treated by ozonated olive oil ointment 0.9%, once /day and control group was treated by hospital routine solutions (saline 0.9%, betadine 10%) once /day. This study revealed that, ozonated olive oil solution had better healing effect than conventional solution on all grades of foot ulcers. Based on the results of the study, it is recommended that, ozonated olive oil ointment should be used on a daily basis time to treat deep diabetic foot ulcers, and increase nurses' awareness about ozonated olive oil ointment dressing technique.

[Hend Abdelmonem Elshenawie, Wael Elsayed Ahmed Shalan and Aziza Elsaeed Abdelaziz. **Effect of Ozone Olive Oil Ointment Dressing Technique on the Healing of Superficial and Deep Diabetic Foot Ulcers**. *J Am Sci* 2013;9(11):235-250]. (ISSN: 1545-1003). http://www.jofamericanscience.org. 32

1.Introduction

Diabetes is a disorder of metabolism and of the circulation. Chronic metabolic irregularities linked to circulatory impairments, neurological deficits, tissue injury, and immunological compromise. Diabetic foot ulcers are common serious complications associated with diabetes mellitus, which is the one of chronic lesion that affect the leg due to combination of diabetic neuropathy and peripheral vascular disease. Diabetic foot ulcer is a full-thickness penetration of the dermis of the foot in a person with diabetes. which predisposes to infection. Infection is a major factor in the pathogenesis of diabetic foot lesions. When infection is associated with micro thrombi in the arterioles which further impair the circulation. In toes, the vessels become end arteries and cause gangrene of toes it leads to amputation[3-6].

Wagner, (2009)[7] classified foot ulcer severity into Grade 1 ulcers; are superficial ulcers involving the full skin thickness, but no underlying tissues. Grade 2 ulcers; are deeper, penetrating down to ligaments and muscle, but not involving bone or abscess formation. Grade 3 ulcers; are deep ulcers with cellulites or abscess formation, often complicated with osteomyelitis. Ulcers with localized gangrene are classified as Grade 4, and those with extensive gangrene involving the entire foot are classified as Grade 5.[8-9]

Diabetic foot ulcer is divided into two distinct syndromes, Neuropathic ulcers which develops on the surface of the toes and on the planter of the metatarsal heads and are preceded by callus formation.these ulcer often occur in the presence of good blood circulation and will often heal well once weight-bearing pressure is removed from them. While the other type of diabetic foot ulcer is ischemic ulcer which caused by poor circulation. These ulcers most commonly involve the toes rather than the bottom of the foot and the margins.Which lead to deep space infection and gangrene.this needs a surgical emergency which requiring hospitalization, immediate incision, drainage and intravenous antibiotics.[10-13]

The healing of the infected wound of diabetic foot ulcer is described by the type of tissue forming epithelial, collagen or by the cell involved in the healing process (e.g. fibroblast, leukocyte). It can be classified into three overlapping phases, inflammatory phase, proliferative phase and maturation phase which may occur in different parts of the wound. This can be influenced by local and systemic factors. Local factors

include local blood supply, wound oxygen tension, temperature, infection and the effects of dressing or topical applications. Systemic factors include age and the presence of disease, particularly vascular disease, and level of blood sugar, systemic infections or immunological incompetence..[7] Healing process occurs either complete or partial.Moreover, there are factors that affect healing of wound which include size, locationdepthand presence of necrotic tissue, amount of wound dressing technique, the appropriate use of addressing material or antiseptic technique and adequate debridement of dead tissue.[14-17]

The management of infected diabetic foot ulcer play an important role in prevention of further complication. In addition, It depends on several factors: the size of the wound, the presence or absence of dead tissue, the presence of wound infection, position of ulcer in relation to the weight bearing area, the extent of vascular compromise, quality of the medical diabetic management and the degree of patient adherence to treatment regimen.[9,18]

The nursing role is the cornerstone for management of diabetic foot ulcer through assess ulcer for site, size, depth, edge, surrounding areas for presence of necrotic tissue and exudates. Also, assess the feet for sensation, pulsation, color, skin temperature, callus formation and pressure points. Second nurse plays an important role in caring of the wound, educating the patients about the proper foot management system, how to maintain mobility, restore the emotion, increase physical capacity, improve nutritional status and provide measures to prevent wound infection, gangrene and amputation.[20,21] Many researchers illustrated that, the important role of nurses is to teach diabetic patients how to control blood sugar level and how to control infection through selecting the appropriate foot ulcer wound dressing technique which enhances the wound healing and saves the foot threatening and decrease the cost on the patient[18-22].

Ozone is a chemical compound consisting of three oxygen atoms(O_3) (i.e. tratomic oxygen), a highly energetic form of normal (diatomic) atmospheric oxygen (O_2).At room temperature O_3 is a colorless gas with a characteristic odor.[23] Ozone had pan-bactericidal, pan-viricidal, antifungal and antiprotozal therapeutic effect. In addition, it improves oxygen supply in tissues so leading to rapid healing process Ozonized oil had been used locally for disinfecting lesions and promoting their healing. It is prepared by budding ozone oxygen gas through pure olive oil until it solidifies; this process starts by warmth in water bath at 300°C. Oxygen gas containing ppm (per eubic per meter) then ozone is bubbled through the olive oil at a rate of 1.0L/min for 50 hours to give ozonated olive oil as Vaseline with the distinctive odor of ozone. The ozonated olive oil should be stored in a refrigerator.[20]

Dressing techniques require a positive enthusiastic approach. Furthermore, There are many dressing techniques of foot ulcer wound dressing as wet, dry, wet to dry and wet to wet dressing technique. The techniques used are selected based on the severity of wound of foot ulcer, its size and depth. Many studies revealed that bad nursing intervention during dressing technique may cause wound infection that lead to many complications. So The nursing profession is and always has been at the cutting edge of research for the development of innovative and effective methods to treat, manage and enhance wound regeneration.[21-24]

2. Materials and methods

Research design used in the present study: Quasi experimental

Setting: This study was conducted in the Vascular Surgery Unit and Diabetic Foot Ulcer Unit at Alexandria Main University Hospital.

Subject:

A convenient sample comprised of 30 adult diabetic patients was included in the study according to the following inclusive criteria:

1- Admitted within 24 hours for early intervention and prevent deterioration
2- Age: adult 21-60 years
3- Free from associated diseases (renal failure, foot ischemia, anemia or previous incidence of foot ulcer)
4- Having all grades of foot ulcer,
5- Infected wound diabetic foot ulcer (under control).
6- Having controlled diabetes mellitus to control over such variable which affect wound healing. According to American Diabetes Association (ADA) controlled diabetic Patient should have fasting blood sugar ranged from 80-110mg/dl, post prandial>200mg/dl.
7- Not receiving immunosuppressive drugs that might interfere with the study therapeutic protocol (through delaying the healing process)

The study subjects were divided alternatively into 15 patients each.

Group1 (Study group): was managed by using ozonated olive oil dressing method.

Group II (Control group): was managed by using routine conventional hospital dressing method (saline, povidon-iodine (betadine 10%)

Tools of the study:

Two tools were used in this study:

Tool I: Diabetic Foot ulcer Assessment interview schedule. It was developed by the researcher after reviewing of related literature to assess ulcer area. It comprised two parts; first part: Biosocio-

demographic data for diabetic patients, second part: Foot and ulcer assessment sheet: to identify abnormal foot changes, and foot ulcer assessment that include

- **Number of ulcers, site, Size** in centimeters[45]
- **Depth of ulcer (floor)** this indicated by percentage out of 1oo% as a total (epithelial tissue cover the surface and granulation tissue, type and amount). [19]
- **Surrounding area necrotic tissues (Margin) are** examined by absence or presence of the following:

Tool II: Ulcer wound healing assessment schedule. Developed by the researcher to asses ulcer wound healing it comprised four parts: First part: Wound healing observation check list, second part: Abnormal findings of the wound healing assessment sheet, third part: Wound culture swab. Fourth part: Photographic pictures were taken to compare wound healing process before and after dressing for both groups in order to determine ulcer healing progress

Methods

1- Approval to conduct the study was obtained from the responsible authorities of units (Diabetic Unit and Vascular Unit) after providing an explanation of the study aim.
2- The tools were developed by the investigator based on the recent relevant literature. Content validity was tested by 5 experts in the field of medical surgical nursing staff and Medicine (endocrinologist and vascular surgery specialists). The needed modifications were done.
3- Tool was tested for reliability using test retest method for testing fifty patients.
4- A written patients consent for participation in the study was obtained after informing the patients about the purpose of the study.
5- A pilot study was carried out on 5 patients in Diabetic Unit to test feasibility of the tool.
6- Patients were selected according to ulcer criteria (superficial and deep, ulcer involving all the skin layer.
7- Patients were assigned to either the study group or the control group according to inclusive criteria. The first 15 patients were assigned to the study group whereas the other 15 patients were assigned to the control group. Matches of patients in both groups were done related to biosocio – demographic characteristics such as age, sex, and ulcer size and body mass index (BMI).
7- At initial meeting, assessment of patient condition was done for both groups using Tool I- first part. This assessment was concerned with biosocio –demographic characteristics and clinical data included the following: age, sex, occupation, marital status, level of education, type of diabetes laboratory investigations((haemoglobin level, hematocrate, RBCs, WBCs, platelet, fasting blood sugar and post prandial blood sugar)and prescribed medications. Tool II- first part: Wound healing observation check list, second part: Abnormal findings of the wound healing assessment sheet, third part: Wound culture swab, fourth part: Photographic pictures to evaluate healing progress.
8- Assessment of wound ulcer was done using Tool I –second part and by photo graphic at the initial meeting using Tool II- fourth part.
9- Dressing was done by the researcher for patients in the study group by ozonated ointment in dressing room daily for five weeks
10- Patients in the control group were exposed to the hospital conventional dressing technique by applying (povidon-iodin (betadine 10%)) solution.
11- Healing process of diabetic foot ulcer in both groups was evaluated every week for both groups using Tool II- first part for five weeks.

Statistical Analysis

The clinical and laboratory results obtained are statistically analyzed using SPSS/PC* (Statistical package for social science for personal computers). using number and percentage were used for presenting qualitative variable, and Chi-square (X^2)). T he 0.05% level of significance was used.

3.Results:

Table (I). Shows frequent distribution of both studied groups according to socio-demographic characteristics.As regards age; it was found that the majority of patient's age in both studied groups was ranged from 40-50 years

According to sex, the majority of the patients in the both groups (study and control) were males (66.7%, 53.3% respectively). In relation to marital status, the majority of the patients in both studied groups (study and control) were married (93.0% and 80.0% respectively). As for occupation, it was found that 3% and 0% respectively of patients in both studied groups (study and control) were not working while, 40.0%, and 46.0% respectively had skilled work. Regarding the educational level in both studied groups (study and control) the majority of patients of study group were read and write (60%) while about of 46.7% of controlled patient are illiterate. Moreover, the statistical significance differences were found between both studied groups in relation occupation and educational level (11.744, 11.143) respectively

Table (2). shows frequent distribution of both studied groups according to type of disease, treatment and body mass index (BMI) As regards type of diabetes it was found that, the majority of studied patients had non independent diabetes mellitus NIDDM (86.7%,60%) respectively. As for the

treatment More than half of both studied groups used hypoglycaemic agent (66.7, 66.7%) respectively. In relation BMI, 60% of patients in the study group were obese as compared to 33.3% of patients in the control group were normal weight.

There was no statistical significant difference between both studied groups regarding the type of diabetes, body mass index and treatment at $p \leq 0.05$

Table (3). Shows Comparison between the two studied groups according to diabetic foot ulcer assessment. Regards foot sensation it was found that,more than two third of both groups had foot sensation to touch(93.3,73.3) respectively. As for skin temperature, 33.3% of patients in study group and 46.7% in control group felt cold skin. Concerning pulsation of studied patients, the majority of the studied patients (study and control) groups had pulsation in the foot ulcer (66.7%,53.3%) respectively. No significant differences were found between both studied groups regarding foot sensation, skin temperature and pulsation at ($p \leq 0.05$)

Table (4) Shows Comparison between the two studied groups according to foot skin assessment condition. In study group, 40.0% of the patients had pink callus, 86.7% of them had foot skin dryness and 60 % had fissure.In control group, 40% of patients had pale callus, 66.7% had foot skin dryness and 60% of them had fissure. No statistical significant difference was found between both studied groups in relation to foot skin condition.

Table (5). Shows frequent distribution of both studied groups according to the ulcer assessment. In relation to the site of ulcer, about (66.7%,33.3%)of the studied patients had ulcer in plantar surface of 1st metatarsal head of foot respectively. Regarding to the size of ulcer the studied patients in both groups their ulcer size more than 2-4cm. As regards depth of ulcer it was found that the patient's in both studied groups was ranged from grade III and grade IV. No statistical significant difference were found between both groups regarding ulcer site, size and depth at level $p \leq 0.05$.

Figure(1). Shows frequent distribution of both studied groups according to assessment ulcer surrounding area. Regards the rednessit was found that, About two third(73.3%) of the study group patients' had redness surrounding area as compared to 46.7% in control group Less than quarter of studied group patients(study and control) had tenderness and swelling necrotic tissue (13.3%, 3.3%, 13.3%, 20%). There was a statistical significant difference between both studied groups regarding assessment ulcer surrounding area at ($p \leq 0.05$)

Figure (2). Shows Comparison between the two studied groups according to ulcer wound healing during follow up period. As regards study group, 40 % of patients had partial ulcer wound healing after 3 weeks as compared to 13.3 % only in control group. After 5weeks (the end of follow up) majority of patients in the study groups (60.0%) had complete wound healing....while 40% of them had partial healing. As for control group it was found that, at the end of follow up period, 66.7% of patient had partial ulcer wound healing, while 33.3% of them complained of lacking healing. A statistical significant difference was found between the study group and control group in relation to healing process after 2, 3, 4, and 5weeks at Level of significant at $p \leq 0.05$.

Table (6), Figure (3a, b). Shows Comparison between the two studied groups according to abnormal findings of ulcer wound healing during follow up period. In study group(,40%,26.7%,13.3 %) of patients had unchanged surface areas of wound moist granulation tissueand clinical signs of infection after 3 weeks respectively. As compared no abnormal findings were detected After 5weeks (the end of follow up) As for control group, 46.7% of patients had increased surface area measurements, 40% of them had absence of healing epithelial edges after the third week of follow up period.At the end of follow up period, only 46.7% of patients had unchanged surface area of wound and about 13.3% of patient complain from signs of infection. A statistical significant difference was found between the study group and control group in relation to abnormal findings of ulcer wound healing process after first, third, and fifth weeks at Level of significant at $p \leq 0.05$.

Figure (4) Shows relation between depth of ulcer and duration of follow up period during wound healing process. After two week of follow up period it was found that, there were no one had complete healing while as 83.3% of patients had partial wound healing process for grade III foot ulcer. At the end of fourth weeks about 100% of study patients had complete wound healing for grade III foot ulcer As compared with patients had complete wound healing for grades (II, III V)foot ulcer (2.2%, 44.4%, 11.1%) respectively, After 5weeks (the end of follow up)

Figure (5) Shows of relation between depth of ulcer and duration of follow up period during wound healing process in the control group. There were detected that, the patients' had not complete wound healing with all grades(II, III,IV,V) foot ulcer at the end of follow up period. after two week of follow up period it was found that, 40%the patients of control group had no healing for grade III foot ulcer while After 5weeks (the end of follow up)about 40%,30%20% of patients had partial wound healing process for grades V,III,IV foot ulcer respectively.

4.Discussion:

The diabetic foot ulcer is one of chronic lesion which affect the leg due to combination of diabetic neuropathy and peripheral vascular disease, which

decreases the supply of oxygen to the affected lower extremity. Diabetic foot ulcer predisposes to infection which lead to serious complications. The managements of diabetic foot ulcers requires a multidisciplinary approach, including surgical, topical, and systemic interventions. Topical antibiotics often fail to penetrate far enough into the wound and frequently cause secondary dermatitis and allergy in their own right.

Table (1): Frequent distribution of both studied groups according to socio-demographic characteristics

	Study (n = 15)		Control (n = 15)		χ^2	*p*
	No.	%	No.	%		
Age						
20–	0	0.0	0	0.0		
30–	2	13.3	1	6.7		
40–	6	40.0	7	46.7	1.521	0.823
50–	6	40.0	7	46.7		
60-	1	6.7	0	0.0		
Sex						
Male	10	66.7	8	53.3	0.556	0.456
Female	5	33.3	7	46.7		
Marital status						
Single	1	6.7	3	20.0	1.154	0.283
Married	14	93.3	12	80.0		
Occupation						
Not working	3	20.0	0	0.0		
Unskilled work	0	0.0	4	26.7		
Skilled work	6	40.0	7	46.7	11.744*	0.019
Clerical work	2	13.3	4	26.7		
Housewife	4	26.7	0	0.0		
Educational level						
Illiterate	6	40.0	2	13.3		
Read & write	9	60.0	5	33.3		
Primary	0	0.0	7	46.7	11.143*	0.011
Secondary	0	0.0	1	6.7		
University	0	0.0	0	0.0		

χ^2: Chi square test *: Statistically significant at $p \leq 0.05$

Table (2): Frequent distribution of both studied groups according to type of disease, treatment and body mass index (BMI)

	Study (n = 15)		Control (n = 15)		χ^2	*p*
	No.	%	No.	%		
Type of diabetes						
IDDM	2	13.3	9	60.0	2.143	0.143
NIDDM	13	86.7	6	40.0		
Treatment						
Insulin	5	33.3	5	33.3	0.0	1.000
Hypoglycaemic agents	10	66.7	10	66.7		
Body mass index(BMI)						
Obese	9	60.0	6	40.0		
Over weight	3	20.0	4	26.7	1.243	0.537
Normal weight	3	20.0	5	33.3		

χ^2: Chi square test; *: Statistically significant at $p \leq 0.05$

Table (3): Comparison between the two studied groups according to diabetic foot ulcer assessment

	Study (n = 15)		Control (n = 15)		χ^2	*p*
	No.	%	No.	%		
Foot sensation						
To touch	14	93.3	11	73.3		
To pain	1	6.7	4	26.7	2.160	0.142
To manipulation	0	0.0	0	0.0		
Skin temperature						
Felt Cold	5	33.3	7	46.7	0.556	0.456
Felt Hot	10	66.7	8	53.3		
Pulsation						
Present	10	66.7	8	53.3	0.556	0.456
Absent	5	33.3	7	46.7		

χ^2: Chi square test; *: Statistically significant at $p \leq 0.05$

Table (4):Comparison between the two studied groups according to foot skin condition

Foot skin condition	Study (n = 15)		Control (n = 15)		χ^2	*p*
	No.	%	No.	%		
Color of callus						
Red	2	13.3	1	6.7		
Pink	6	40.0	5	33.3	0.715	0.870
Brown	2	13.3	3	20.0		
Pale	5	33.3	6	40.0		
Dryness						
Present	13	86.7	10	66.7	1.667	0.195
Absent	2	13.3	5	33.3		
Fissure						
Absent	6	40.0	6	40.0	0.0	1.000
Present	9	60.0	9	60.0		

χ^2: Chi square test

Table (5): Frequent distribution of both studied groups according to the ulcer assessment.

Ulcer assessment	Study (n = 15)		Control (n = 15)		χ^2	*p*
	No.	%	No.	%		
Site of ulcer						
Plantar surface 1st toe	1	6.7	1	6.7		
Plantar surface 1st metatarsal head	10	66.7	5	33.3		
Plantar surface 2nd toe	1	6.7	0	0.0		
Plantar surface 4th toe	0	0.0	2	13.3	8.667	0.193
Plantar surface 5th toe	0	0.0	4	26.7		
Sole	1	6.7	1	6.7		
Heel	2	13.3	2	13.3		
Size of ulcer						
1 – 2 cm	0	0.0	0	0.0	-	-
>2 -4 cm	15	100.0	15	100.0		
Depth of ulcer						
Grade I	0	0.0	0	0.0		
Grade II	4	26.7	1	6.7		
Grade III	7	46.7	6	40.0	3.820	0.282
Grade IV	3	20.0	4	26.7		
Grade V	1	6.7	4	26.7		

χ^2: Chi square test

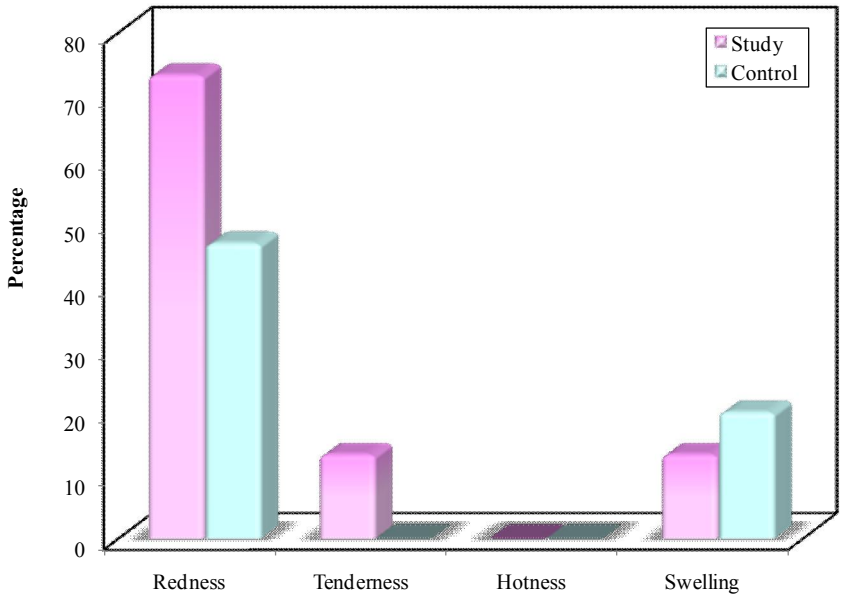

Figure (1): Shows frequent distribution of both studied groups according to assessment ulcer surrounding area

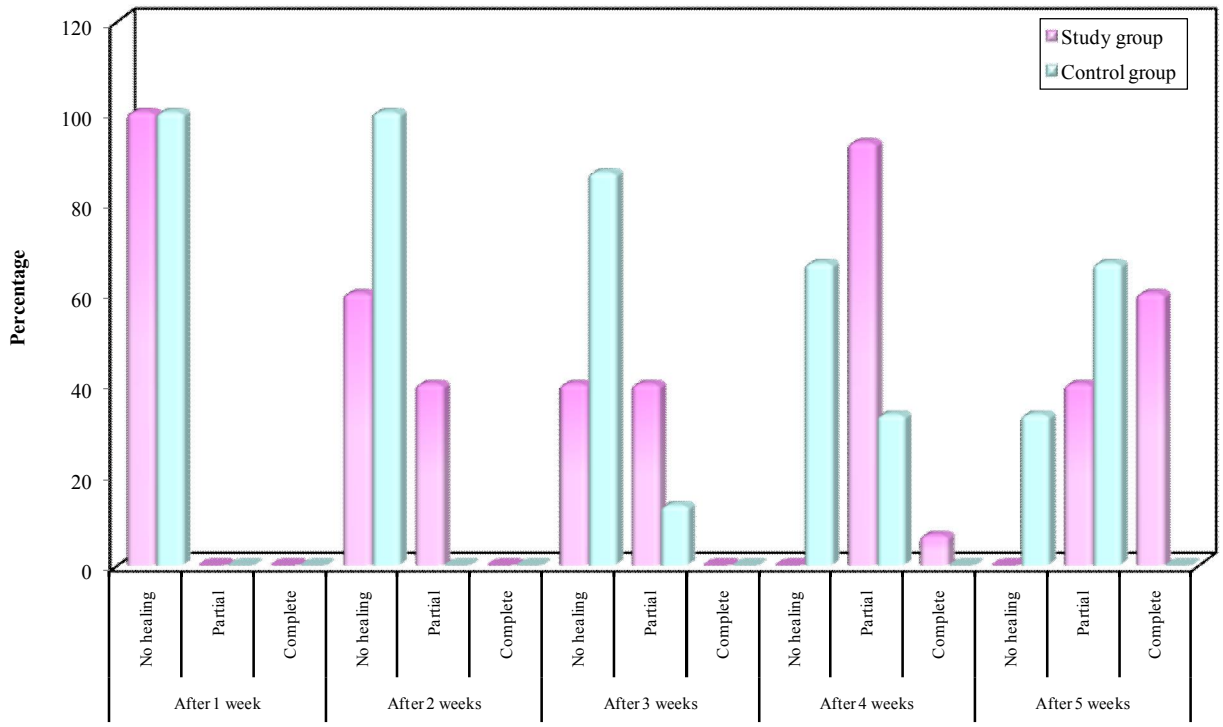

Figure (2): Shows Comparison between the two studied groups according to ulcer wound healing during follow up period

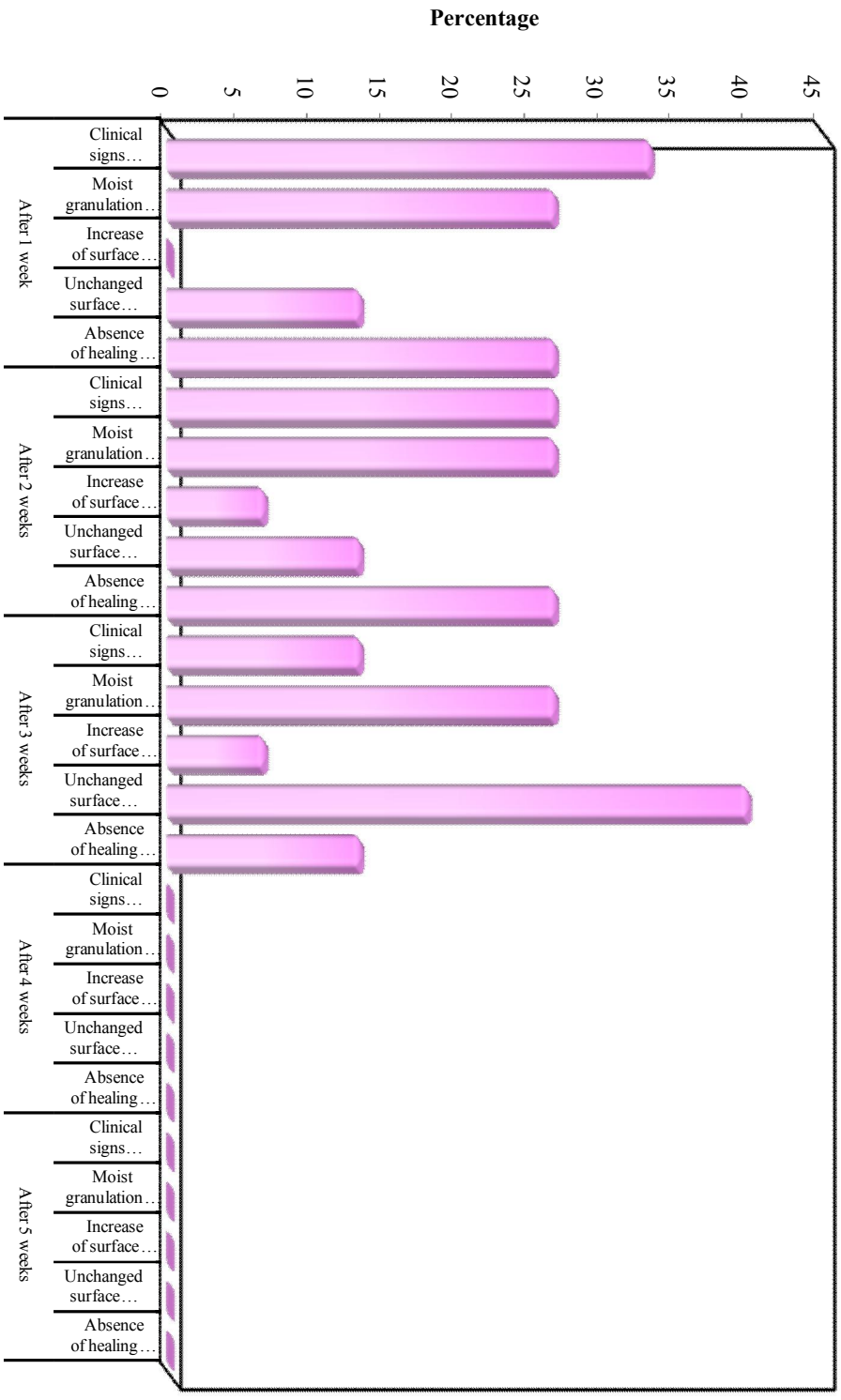

Figure (3 a): Ulcer wound healing of follow up in study group

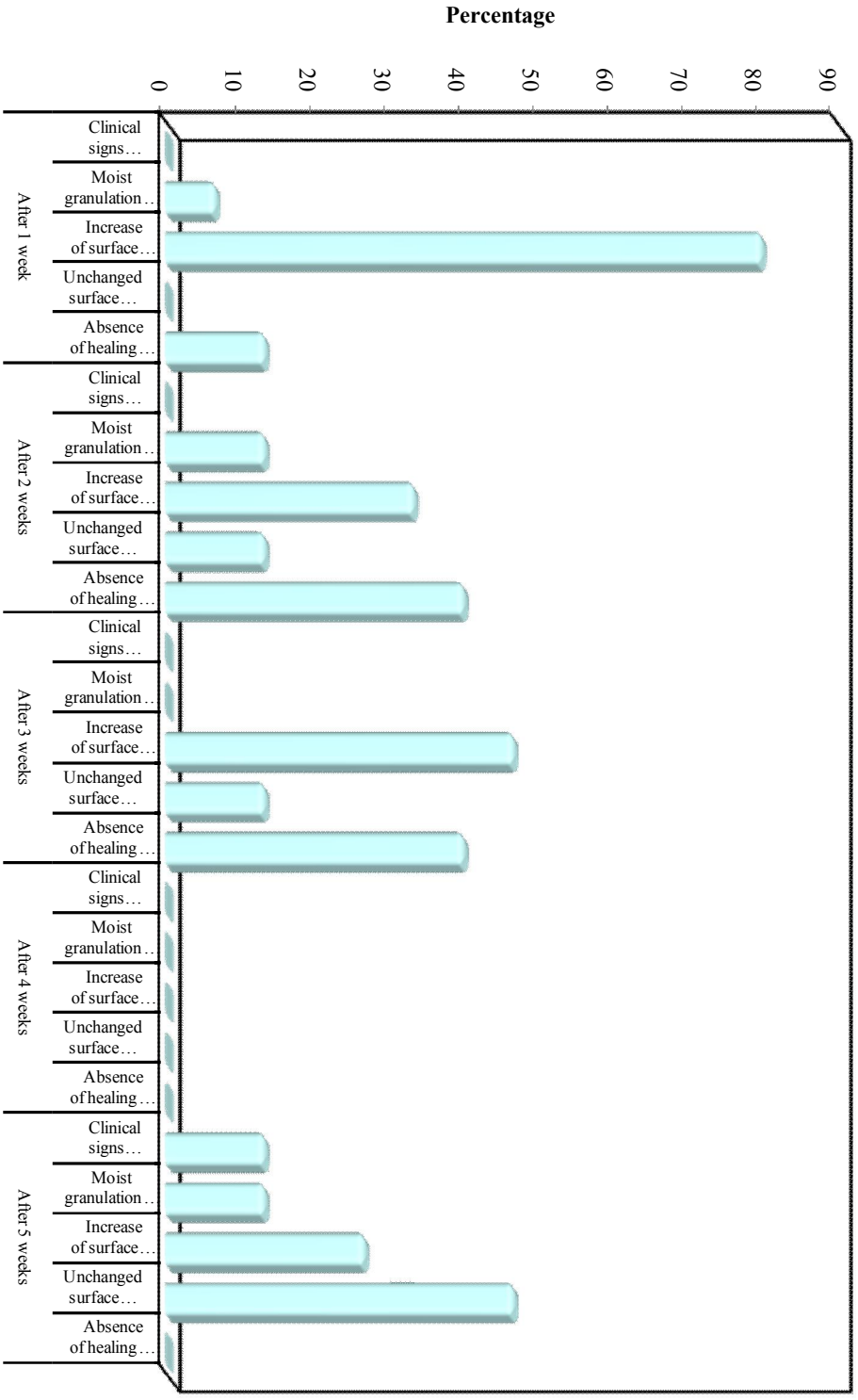

Figure (3 b): Ulcer wound healing of follow up in control group

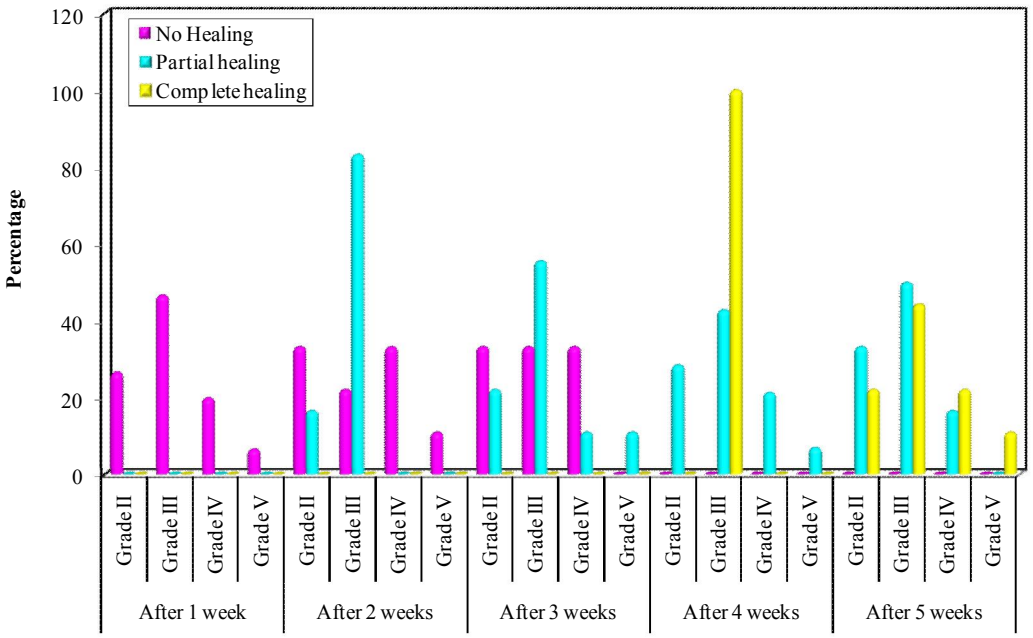

Figure (4): Shows relation between depth of ulcer and duration of follow up period during wound healing process

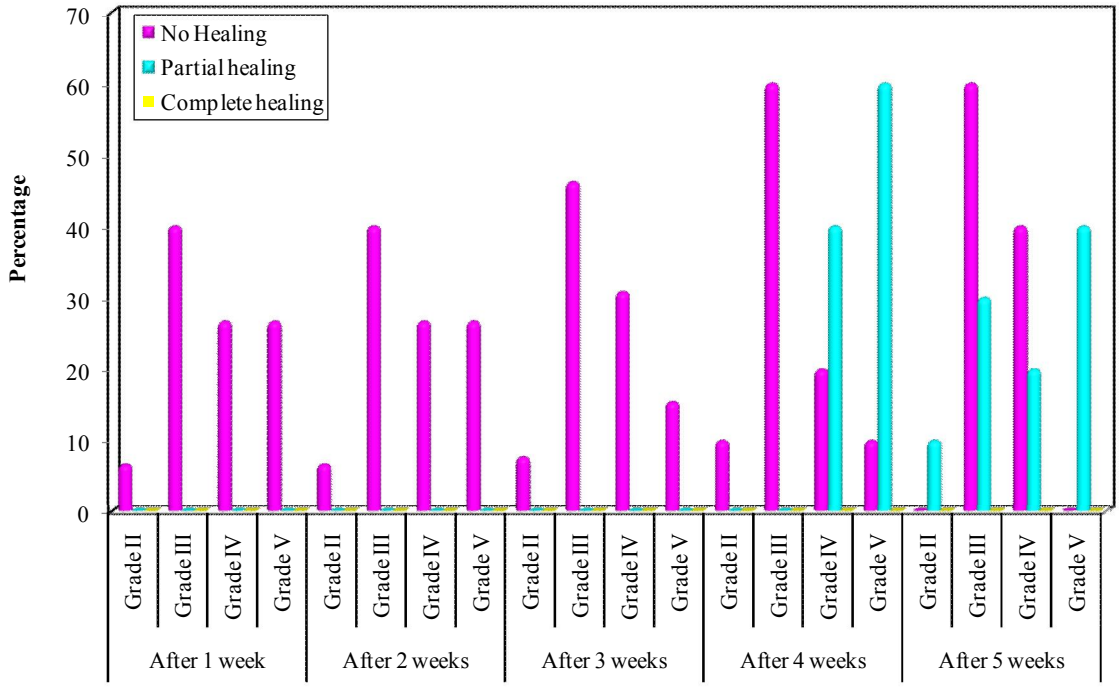

Figure (5): Shows of relation between depth of ulcer and duration of follow up period during wound healing process in the control group

A_1) largest size of ulcer was 70cm^2 before dressing with Ozona Ointment

A_2) largest size of ulcer of 70 cm^2 after 2 weeks of dressing with Ozona Ointment

Dorsal Site Of Ulcer Before Dressing With Ozona Ointment

Of Dressing Ozona Ointment

Continue: illustration sites of ulcer and response to dressing

C_1) lateral aspect of mid foot site of ulcer before dressing with Ozona ointment

C_2) lateral aspect of mid foot site of ulcer after2 weeks from dressing with Ozona ointment

Figure (6) Illustrate size of ulcers and response to dressing

Table (6): Comparison between the two studied groups according to abnormal findings of ulcer wound healing during follow up period

Abnormal finding of ulcer wound healing	After 1 week		After 2 weeks		After 3 weeks		After 4 weeks		After 5 weeks	
	No.	%	No.	%	No.	%	No.	%	No.	%
Study group										
Clinical signs of wound infection changes of color of wound exudates and amount	5	33.3	4	26.7	2	13.3	0	0.0	0	0.0
Moist granulation tissue	4	26.7	4	26.7	4	26.7	0	0.0	0	0.0
Increase of surface area measurments	0	0.0	1	6.7	1	6.7	0	0.0	0	0.0
Unchanged surface areas of wound	2	13.3	2	13.3	6	40.0	0	0.0	0	0.0
Absence of healing epithelial edges	4	26.7	4	26.7	2	13.3	0	0.0	0	0.0
Control group										
Clinical signs of wound infection changes of color of wound exudates and amount	0	0.0	0	0.0	0	0.0	0	0.0	2	13.3
Moist granulation tissue	1	6.7	2	13.3	0	0.0	0	0.0	2	13.3
Increase of surface area measurments	12	80.0	5	33.3	7	46.7	0	0.0	4	26.7
Unchanged surface areas of wound	0	0.0	2	13.3	2	13.3	0	0.0	7	46.7
Absence of healing epithelial edges	2	13.3	6	40.0	6	40.0	0	0.0	0	0.0
χ^2	21.467*		7.733		14.500*		-		30.00*	
p	<0.001		0.102		0.006*		-		<0.001	

χ^2: Chi square test
*: Statistically significant at $p \leq 0.05$

So, the control of infection is a strategy for management through using sterile equipment, applying appropriate technique and solution for wound management with aseptic technique control blood glucose level In addition frequent swabs should taken to detect microorganism early and Systemic antibiotics, should prescribed for infections[1,6,18]

Ozone applications in diabetic ulcers provide essential dual functions of topical broad-spectrum coverage and circulatory stimulation. In addition, ozone, able to penetrate into deeper tissue layers where anaerobic bacteria are apt to reside and improves oxygen supply in tissue leading to rapid healing process. [19]

The results of the present study revealed that, most of the studied patients in both groups were married males and their ages were ranged between >40--50 years. These results are supported by Richard(2010) [25] who stated that, diabetic foot ulceration occurs most commonly in older adults.. And in accordance with Yakout (2009)[26] who found that the males affected by foot ulcer more than the

females. Also, these results were contradicted by Jamil (2010)[27] who found that the majority of the patients affected by foot ulcer were divorced in the present study where most of the studied patients in both groups were skilled workers as framers,. So their jobs necessitated long hours of standings on feet, which lead to continuous pressure on feet also their feet exposed to wet muddy or sandy floor which increase risk for feet injury These results are supported by Hewitt *et al.* (2003) [28]who stated that diabetic patients who have hard work and working over time and excessive standing are at risk for developing lower extremity problems.

Furthermore, there were significant differences between study and control group related to educational level. So the control group patients' neglected their condition may due to lack of awareness about their health problem.This finding was in agreement with Armstrong *et al.* (2006) [29] who found that, illiterate patients were at risk for diabetic foot ulceration more than the educated patients as a result of lack of knowledge about diabetes and its complications and they ignored daily inspection of foot for skin abnormalities.

Concerning type of diabetius mellitus, the majority of studied patients(study, control) had type II Non insulin dependent diabetes mellitus (NIDD) (86.7%,60%) respectively This finding was advocated with American diabetic Association (2004), who reported that about 90-95% of people with diabetes had type II and high risk for foot ulceration. [30] In relation BMI, 60% of patients in the study group were obese as compared to 33.3% of patients in the control group were normal body weight. This supported by Bassl (2005) [31] who ascertained that over weight play a significant role in diabetic foot ulceration. This may due to lack of patient's knowledge about balanced diet and Egyptian dietary bad habit.

Moreover In the present study, most of the selected patients in both groups had pulsation in foot ulcer, dry skin, warm feet sensitive to touch and had pink callus and fissure which occurred as result of repetitive pressure on their feet during ambulation.These results were agreement with Daniels *et al.* (2007) [32] who found that the majority of patients the both groups had pulsation on both dorsalis pedis and posterior tibial arteries.[33] Also had warm feet sensitive to touch and pain. Moreover this results in the line with Jamil (2010), Eneroth *et al.* (2004) [27, 34] who reported that the majority of patients had pulsation on the same arteries.

As the ulcer depth and size at the initial assessment, the highest percentage of ulcer size in both groups was more than4cm and and ranged from grade III and grade IV depth. These results also were in line Margolis,*et al.*(2005) [35] who illustrated the importance of measuring wound size and depth in determining healing outcomes for different wound types. Tennvall and Apelqvist (2001)[36] and Enerothet *al.* (2004) [34] were stressed that ulcer size (>2cm), duration (>two months) and ulcer depth (penetration through to exposed tendon ligament bone or joint) were the three most important factors for predicting out come.

In relation skin surrounding the ulcer, most of the studied patients in study group and less than half of the control group had redness also less than quarter of studied patients in both groups had, tendernessand swelling.In this aspect, Tennvall and David(2009) [37] reported thatmore than third of study patients in both groups had redness. Moreover all the findings of initial physical assessment and lab investigations indicated control of infection in both studied groups

During follow up period after application of dressing technique by ozone oil ointment solution daily for study group whilethe control group treated with routine hospital solution the result revealed that, after 2 and 3 weeks during follow up period the ozonated olive oil dressing had significant effect on wound healing than conventional dressing technique, the number of patients who had partial ulcer healing were increased and the number of patient who complained of lacking ulcer wound healing were decreased in both studied groups. The progress of ulcer wound healing improved until the end of the study period.Moreover, At the end of follow up period after 5weekes, the majority of patients in study groups had complete ulcer healing 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 as 60% had complete healing as compared to 0% in control group patients. Moreover, in study group, no patients complained of lacking ulcer wound healing which revealed that patients who treated with ozonated olive oil ointment had better healing process. In control group, ten patients had incomplete healing at the end of follow up period the researcher investigated that the wound culture and daily assessment play an important role to detect the type of organism by send the culture to the lab to control infection occurred.This result may be due to patient's uncontrolled behavior such as walking barefoot and sometimes removes dressing, need more time for healing and exposure to infection.

In this aspect, El Medany (2009) [38] stated that, ozone as a strong antimicrobial agent has haemostatic effects that stop bleeding, accelerates wound healing, activates immune system response. So, the high antimicrobial activity of ozone makes it one of the most effective antibacterial and antiviral agents. In addition, Ozone improves oxygen supply in tissues and stimulate cellular metabolism and leading to rapid

healing process Also, Tennvall and David(2009) [37]found that, in patients treated with ozone olive oil ointment complete wound healing was obtained after 6-21 days.

The study results showed that, after 3 weeks during follow up period the abnormal findings of ulcer wound healing in study group were significant decrease than in control group. Also, The results revealed no abnormalities or sign and symptoms of infection were found at the end of follow up period in study group. while in the control group at the third week and fifth week of follow up period, presence of some abnormalities such as increased of surface area measurements of the wound, unchanged surface area of the wound and absence of healing epithelial edge were observed. This findings may be due to the irritant effect of povidon-iodine. This findings was advocated by Abbass H (2009) [33] and Thomas (2005) [39] who emphasized that, daily dressing technique permit daily inspection of wound, thus any signs of inflammation or discharge is detected immediately and culture can be obtained to determine the type of microorganism and needed specific antibiotic to be prescribed. Daily dressing is effective in healing process as a result of daily changing wound environment resulting in preventing the organisms to be colonized easily.

The study results showed the presence of relation between depth of ulcer and duration of follow up period during wound healing process in studied group patients" in the study group, after three weeks of follow up period the patient with grade III of foot ulcer had complete healing while the patient with grade V of foot ulcer had complete healing at the end of follow up period As control group, there were no one of all grades of diabetic foot ulcers had complete healing during follow up period while as, the majority of patients had partial healing with grade III at the end of follow up period This finding was illustrated by Willem(2011) [40] who found that Duration of healing and foot ulcer depth (penetration through to exposed tendon, ligament bone or joint) were the most important factor for predicting out come. Moreover, American diabetic association(2007) [41] stated that diabetic patients with deep foot ulcer require selection the proper dressing technique with appropriate antiseptic solution with guidance of the nurse to decrease time in healing process. Also these results were in the line of Zidan (2006) [42] who stated that, ozone ointment is more effective and help in rapid healing process.

Finally these results concluded that the nurse has an important role in assessment and caring patient with diabetic foot ulcer to prevent further complications In addition, the application of ozonated olive oil ointment dressing techniques is more effectiveness and safety in healing of all grades diabetic foot ulcer, Wounds with potential for infection, infected wounds, and poorly healing wounds.

Conclusion & Recommendations

Conclusion

From the present study, it can be concluded that ozone ointment has shown effectiveness and safety dressing technique on the healing process of all grades of diabetic foot ulcer, which has Wounds with potential for infection, infected wounds, and poorly healing wounds. While as the conventional dressing technique is an antibacterial agent but it retards ulcer healing than ozone ointment dressing.

Recommendations

Based on the results of the present study, the following recommendations are suggested

- Ozonated olive oil ointment should be used on a daily based time to treat diabetic foot ulcer.
- In the vascular out –patient clinics should be used Ozonated olive oil ointment dressing technique in the management of patients with deep diabetic foot ulcer.
- Continuing education for nursing staff through in services training program to improve their knowledge about diabetic foot ulcer preventionproper technique and solutions used in ulcer dressing, factors affecting ulcer healing and how to control diabetic foot ulcer infection
- Increase nurses' awareness about ozonated olive oil ointment dressing technique.
- Training the nurses about how to use ozone ointment in dressing.

Investigated other ozone modalities such as using ozone in dentistry and dermatology fields studies

References

1. Willem H. Foot ulceration and lower limb amputation in type 2 diabetic patients in Dutch primary health care. WHO. American Diabetic Association 2011 Available at: http://www. Foot Ulceration and Lower Limb Amputation in Type 2 Diabetic.htm
2. Fonseca V. Effects of Metformin and Rosiglitazone combination therapy in patients with type 2 diabetes mellitus: A randomized controlled trial. Journal of the American Medical Association 2000; 283(13): 1695-1702.
3. Ramchandani N. Type 2 diabetes in children. American Journal of Nursing 2004; 104(3); 65.
4. Laurence P, Cheely J. Deterioration of diabetic patient's knowledge and management skills as determined during out patients visits. Diabetes Care 1990; 23(13): 214-18.

5. Hernandez F, Menendez S, Wong R. Decrease of blood cholesterol and stimulation of antioxidative response in cardiopathy patients treated with endovenous ozone therapy. Free rad Biol Med 1995; 19:115-19
6. Food and Drug Administration. (2002). Clinical chemistry and clinical toxicology devices panel meeting summary for October 29, 2001. Available: http://www.fda.gov/cdrh/panel/summary/chem110601.html
7. Wagner K. Management of wound healing India, Japee Brothers: 2009; 1679
8. Whittier S. Effective diabetes management: The cost and quality equation. Geriatric Nursing 200; 25(3): 188-9.
9. Winslow EH, Jacobson AF. Saving limbs with the Semmes. Weinstein monofilament. American Journal of Nursing 1999; 99(2): 76.
10. Pharmacological Research, J Am Pharmacology Association 2001; 44 (5): 391-396.
11. Quinn L. Educating patients with diabetes about cardiovascular disease risk. Progressive Cardiovascular Disease Nursing 2004; 19(3): 107-113.
12. Goldwag R, Berg A, Yuyal D, Benbassat J. Predictors o patient Dissatisfaction with emergency care.Israel, IMAJ 2002; 4:603-6.
13. Margolis D, Berlin J, Strom B. Risk factors associated with the failure of venous leg ulcer to heal. Arch Dermatology 2007;135: 920-26.
14. Feinglos M and Bethel M.Type 2 Diabetes Mellitus: An Evidence –Based Approach to Practical Management. 1st ed. Totowa: Humana Press 2008;1.16
15. Anderson DKG, Svardsud K. Lower extremity skin care for the diabetic patients. Diabetes Care: 2000; 23:77-86
16. Hirnell. Phases of Wound Healing bimeco.org/images /ICON –Wound. jpg. htt www2006.
17. Carrico T. Biology of Wound Healing. Sug Clin North American, 1999;64(4):72133
18. Lash P. Wound Management, Critical Care Nursing: In Sherry K; Tornto: Philadelphia W.B Sounders, 2000 361.68.
19. Stotts N, Sparacino P. Assessing the patient with a wound as the basis for home wound care management. Home healthcare nurse 2005; 23 (2):82-92
20. Russell R. Wound Infection: Bailey and Loves Short Practice of Surgery.23rd ed. London: Nick Dunton, 2000; 89-90.
21. Pecoraro RF, Reiber GE, Burgess EM. Pathways to diabetic limb amputation: basis for prevention. Diabetes Care 1999: 22:513-21.
22. Romo T. Wound healing, skin last updated, Medicine Specialties December 2005(5).
23. Levin E.Prevention and treatment of diabetic foot wounds.J.Wound Ostomy Continence Nurse. 1998 May; 25 (3): 129.46
24. Aksenova SV, Klimenko ND, Yakupova GM. Ozone treatment of localized surgical infection. Novgorod State University 2000; 76: 321-26.
25. Richard J. Targeting Plasma Glucose Post Prandial Feature Artical Medicl, Cade July 2010 Available: http://www
26. Yakout R. The effect of semiclosed 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, 2009.
27. Jamil E. Assessment of self foot care among diabetic patients' unpublished master thesis, Faculty of Nursing. Alexandria University 2010.
28. Hewitt A, Flekser, R, Harcourt, D, Sinha S. The Evolution of a Hospital based leg ulcer clinic, Primary Intention 2003; 11 (2); 75-85
29. Armstrong DG, Driver VR, Giurini JM, Kravitz SR, Landsman AS, Lavery LA, Moore JC, Schuberth JM, Wukich DK, Andersen C, Vanore JV. American College of Foot and Ankle Surgeons. Diabetic foot disorders. A clinical practice guideline (2006 revision). J Foot Ankle Surg 2006; 45 (Suppl.): S1–66.
30. American Diabetes Association. Clinical practice recommendations. Diabetes Care 2004; 27
31. Bassl A. comparative study between three wound dressing techniques for patients with diabetic foot ulceration unpublished. Doctorate dissertation, Faculty of Nursing, Tanta University.2005.
32. Daniels R, Rn, PhD, Nosek L. Contemporary Medical –Surgical Nursing. 4th ed. United State, 2007.
33. Abbass H, Effect of honey tulle dressing versus the conventional dressing Technique on Healing of Moderat Burns. unpublished Master Thesis, Faculty of Nursing, Alexandria University 2009.
34. Eneroth M, Larsson J, Apelqvist J. The challenge of multicenter studies in diabetic patients with foot infections. Foot 2004;14 (4): 198-203

35. Margolis D, Berlin J, Strom B. Risk factors associated with the failure of venous leg ulcer to heal. Arch Dermatology 2007;135: 920-26.
36. Tennvall R, Apelqvist J. Prevention of diabetes – related foot ulcers and amputation: a cost – utility analysis based on Markov model simulations. Diabetologia 2001; 44 (11);2077-87.
37. David M, Nathan MD, Jean E, MulderMD. Last literature review version This topic last updated: June 7 17-1: 2009
38. El medany S. A clinical study of management of dermal burned hands. Unpublished Master Thesis, Faculty of Medicine, Alexandria University 2009.
39. Thomas H.Managment of the patient with a venous ulcer.Advances in skin& Wound Care Mar/Apr2005.
40. Williams. Wound care. 1st ed. New York. A Wolters Luwer Company. 2008; p. 72-74.
41. American Diabetes Association. Standards of medical care for patients with Diabetes Mellitus J Diabetes care 2007; 25: 533.
42. Zidan SH. Treatment of post operative wound infection using topical dressing with ozonated olive oil. Unpublished master thesis, Faculty of Medicine, Alexandria University 2006.

9/15/2013