Comparative Study of Ozonated Olive Oil Ointment versus Conventional Dressing Methods on the Healing of Grade I Diabetic Foot Ulcers

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Abstract: Diabetic foot ulcers are common serious complications associated with diabetes mellitus, and are the leading cause of hospitalization .These complications usually have an effect on patients quality of life .The nurse has two responsibilities ,first assess feet ulcer , second care of the wound by using appropriate sterile dressing techniques with the application of different solutions such as Honey, Der magran (Zinc-saline) and Ozonated olive oil and educating the patients about the proper foot management systems. Therefore the aim of this study is to compare the effect of ozonated olive oil ointment versus conventional dressing techniques on the healing of diabetic foot ulcers grade I .The study was conducted at Alexandria Main University Hospital and followed up for 10 months .The sample comprised 50 adult patients who had grade I foot ulcers. The sample was divided equally into two groups, study and control groups. The study group was treated by ozonated olive oil ointment, and control group was treated by hospital routine solutions (saline 0.9%, betadine 10%) once /day. This study revealed that, although the two dressing techniques (ozonated olive oil ointment and betadine 10%wet dressing techniques) were effective on the healing process of grade I diabetic foot ulcers, yet ozonated olive oil solution had better healing effect than conventional solution. 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 grade I diabetic foot ulcers, In the vascular out –patient clinics it's preferable to use both dressing techniques in the management of patients with diabetic foot ulcer and increase nurses' awareness about ozonated olive oil ointment dressing technique.

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1. Introduction:

Diabetic foot ulcer is a full-thickness penetration of the dermis of the foot in a person with diabetes. Ulcer severity is often classified using the **(Wagner, 2009)** system 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 cellulitis 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.

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. Infection is a major factor in the pathogenesis of diabetic foot lesions. When infection is associated with ischemia it leads to amputation in diabetic patients. In diabetic foot infection, there is micro thrombi in the arterioles which further impair the circulation. In toes, the vessels become end arteries and cause gangrene of toes **(Buttaro, 2008).**

The management of diabetic foot ulcer 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 **(Foster, 2006)**.

The nurse has two responsibilities toward diabetic patients to maintain foot ulcer wound healing. First, assess feet 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 caring of the wound and educating the patients about the proper foot management system including how to; maintain mobility, restore the motion, increase physical capacity, improve nutritional status and provide measures to prevent wound infection, gangrene and amputation **(Taylor, 2001, Nancy 2002)** 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 with using the application of the appropriate topicalagent (**Ragab**, **2002), (Elshatby, 2003), (Bassl,2005), (Yakout, 20009) and (Elsayed, 2000).**

There are many dressing techniques of foot ulcer wound dressing as wet, dry, wet to dry and wet to wet dressing techniques. **The** techniques used are selected based on the severity of wound of foot ulcer, its size and depth **(Aksenova and Yakupova, 2000)**

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 .Ozonated or ozonized olive oil is prepared by budding ozone oxygen gas through pure olive oil until it solidifies; this process starts by warmth in water bath at 300º C. Oxygen gas containing ppm (per cubic^3 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 (**Ledea and Rosado, 2007**) Ozone had pan-bactericidial, pan-viricidal, antifungal and antiprotozal therapeutic effect. In addition, it improves oxygen supply in tissues so leading to rapid healing process. Ozonated olive oil had a fungicidal and bactericidal effect. Ozonized oil had been used locally for disinfecting lesions and promoting their healing. In European countries the ozonated olive oil has been applied on infected wound for promoting their healing (**Viebahn, 2002**). (**Zidan, 2006**) confirmed the efficacy of ozonated olive oil dressing as a sole treatment of wound infection versus a systemic antibiotic and classical dressing.

Dressing techniques require a positive enthusiastic approach. 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 .Grade 1 ulcers are the focus of this study because their early treatment will prevent progression into other grades of ulcers. It will save the limb and decrease the health care costs of diabetic patients.

Compare the effect of ozonated olive oil ointment dressing on the healing of grad 1 diabetic foot ulcers versus the conventional dressing method.

The ozonated olive oil ointment is more effective than the conventional dressing technique on grade I diabetic foot ulcers healing**.**

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 50 adult diabetic patients was included in the study according to the following inclusive criteria:

1- Admitted within 24 hour for early intervention and prevent deterioration
2- Age: adult 21-60 years
3- Having grade I foot ulcer because the early treatment will prevent progression into other grades of ulcers. It will save the limb and decrease the health care costs of diabetic patients.
4- Free from associated diseases (renal failure, foot ischemia, anemia or previous incidence of foot ulcer) to control over such variables which affect wound healing.
5- Free from infection as indicated by normal vital signs &white blood cells as a criteria for controlled sepsis.
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 two equal groups 25 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

Tool II: Ulcer wound healing assessment schedule. Developed by the researcher to asses ulcer wound healing it compresed for 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- Permission to carry out the study was obtained from the directors of the chosen setting units (Diabetic Unit and Vascular Unit) after explaining the aim of the study.
2- The tools were developed by the researcher after reviewing related literature.
3- The tools were tested for content validity by seven experts in the field of Medical- surgical Nursing and Medicine (endocrinologist and vascular surgery specialists). The needed modifications were done.
4- Reliability of the tool was tested using test retest method for testing fifty patients.
5- A written patients consent for participation in the study was obtained after informing the patients about the purpose of the study.
6- A pilot study was carried out on 5 patients in Diabetic Unit to test feasibility of the tool.
7- Patients were selected according to ulcer criteria (superficial, ulcer involving only the epidermis, the skin appears dry and erthematous without blister and sensitive to air) which is considered as characteristics of grade I foot ulcer
8- Patients were assigned to either the study group or the control group according to inclusive criteria. The first 25 patients were assigned to the study group whereas the other 25 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).
9- 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 Body mass index calculated by measuring patients height and body weight then use the equation[1,2];

BMI =weight /(height^2) =Kg/m^2 this calculation was done to determine the grade of obesity.

Grade (0) BMI 20 -24.9 Kgm/m2= desirable weight
Grade (1) BMI 25-29.9 Kgm/ m2 =over weight
Grade (2) BMI 30-39.9 Kgm/m2=obese
Grade (3) BMI 40 and over Kgm/m2=morbid obesity.

Less than 20-24 Kg is considered under weight and excluded from the sample, this is indicated for nutritional status so that will delay healing process. Collection of data was done in 10 months from the beginning of March2009 to end of December2009. However one case was took more than4weeks till healing occurred.

Statistical Analysis

The clinical and laboratory results obtained are statistically analyzed using SPSS/PC* (Statistical package for social science for personal computers, ($\overline{X}$), (SD), "t" test, fisher and Chi-square (X^2)).

3. Results

Figure (1). Shows frequent distribution of both studied groups according to socio-demographic characteristics .As regards age; it was found that the patient's age in both studied groups was ranged from 20-50 years with a means age of 41.8±7.22 and 43.6+9.13 years for study and control groups respectively.

According to sex, the majority of the patients in the both groups (study and control) were males (56%and 68% respectively). In relation to marital status, the majority of the patients in both studied groups (study and control) were married (68.0% and 84.0% respectively). As for occupation, it was found that 36% and 16% respectively of patients in both studied groups (study and control) were not working while, 28%, and 44% respectively had skilled work. Regarding the educational level in both studied groups (study and control) the majority of patients' lies between illiterate (44 %and 20% respectively) and read and write (32% and 56% respectively)..

Figure (2). shows frequent distribution of both studied groups according to type of disease, treatment and body mass index (BMI) In relation to study group it was found that, there were only 8.0% of the studied patients had IDDM while, 92.0% of them had NIDDM. On the other hand in the control groups, 12%of the patients had IDDM while the other 88% had NIDDM. As for the treatment the majority

of both studied groups used hypoglycaemic agent (72-76.0%) respectively. There was no statistical significant difference between both studied groups regarding the type of diabetes and treatment at $p \leq 0.05$ As regards BMI, 48% of patients in the study group were over weight as compared to 60% of patients in the control group .

Table (1). Shows frequent distribution of both studied groups according to vital signs. It was found that the temperature of all patients in both study and control groups ranged between (36.5-37.3 C°) and (36.7-37.6 C°) respectively .Their pulse ranged between (80-92b/m) and (82-95b/m) respectively. Respiration ranged between (18-24c/m) and (19-23c/m) respectively, their systolic pressure ranged between (120-145mmHg) and (120-150mmHg) respectively and their diastolic blood pressure ranged between (80-95mmHg) and (85-95mmHg) respectively.

Table (2). Shows frequent distribution of both studied groups according to laboratory findings. In both study and control groups laboratory findings (haemoglobin level, hematocrate, RBCs, WBCs, platelet, fasting blood sugar and post prandial blood sugar) were found within the normal range while, fasting blood sugar (FBS) level was higher than normal in study group and control group (105-180 and 102 -178 mg/dl) respectively. As well as post prandial (151-189 and 151-190mg/dl) respectively.

Figure (3). Shows frequent distribution of both studied groups according to diabetic foot assessment. In relation to foot sensation in study group, 72 % of patients had foot sensation to touch, 52%of them had sensation to pain and 28% had sensation to manipulation. In control group 60 % of patients had foot sensation to touch, 56% had sensation to pain and 40 % of them had sensation to manipulation. As for skin temperature, 48% of studied patients in study group and 68% in control group had hot skin, while 52% of patients in study group and 32% in control group felt cold skin. Concerning dorsalis pedis pulsation of studied patients, it was felt in 52%of patients in study group and 68% of patients in control group. The posterior tibial pulsation was felt in 52% of patients in study group and 56% of patients in control group.

Table (3). Shows frequent distribution of both studied groups according to the ulcer assessment. In relation to the site of ulcer, 24 %of the studied patients in study group had ulcer in planter surface of 1st toe, also plantar surface of 1st metatarsal head respectively. In control group, 24% of patients had ulcer in plantar surface of 1st metatarsal head and plantar surface of 4th toe. Regarding to the size of ulcer 56.0% of the studied patients in study group their ulcer size ranged from 1-2 cm while, the other 44% their ulcer size were ranged from more than 2-4cm. On the other hand in control group, 32.0% of the patients their ulcer size were ranged between 1-2 cm, while the 68.0% of them their ulcer size ranged from more than 2-4 cm. As for the ulcer edge 52.0% of the studied patients in study group had regular ulcer edge while, the remaining 48.0% of them had irregular one. Also 32.0%of the patients in control group had regular ulcer, and 68.0% of them had irregular one.

Table (4). Shows frequent distribution of both studied groups according to ulcer surrounding area. In study group it was found that, 44.0% of the patients had necrotic tissue surrounding area as compared to 64.0% in control group. Twenty seven point three percent of the patients in study group had red, tender and hot necrotic tissue, while in control group, 25% of patient's respectively had red and hot necrotic tissue .

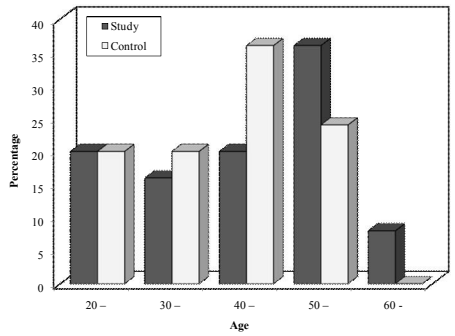
Figure (4). Shows frequent distribution of studied groups according to foot skin condition. In study group, 64.0% of the patients had callus, 68% of them had foot skin dryness and 80 % had fissure .In control group, 52.0% of patients had callus, 64% had foot skin dryness and 56% of them had fissure.

Table (5). Shows frequent distribution of both studied groups according to ulcer wound healing during follow up period. As regards study group, 68 % of patients had complete ulcer wound healing after 2 weeks as compared to 40.0 % only in control group. After 4weeks (the end of follow up) majority of patients in the studied groups (88.0%) had complete healing while only 12.0% of them had partial wound healing. As for control group it was found that, at the end of follow up period, 80% of patient had completed ulcer wound healing, 16% had Partial wound healing and only 4% 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 weeks at Level of significant at $p \leq 0.05$.

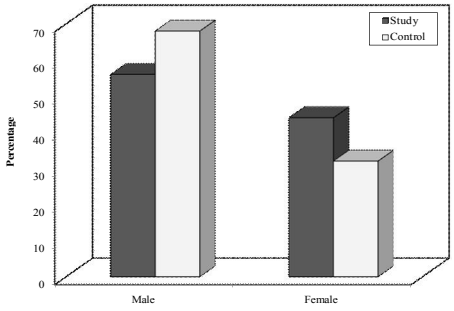
Table (6). Shows frequent distribution of both studied groups according to abnormal findings of ulcer wound healing during follow up period. In study group, no abnormal findings were detected. As for control group, 12% of patients had increased surface area measurements, 12% of them had absence of healing epithelial edges at the second week .At the end of follow up period, only 4% of patients had unchanged surface area of wound and absence of healing epithelial edges .Concerned suspected patient the result of wound culture revealed no infection was occurred.

Table (7). Shows relations between ulcer wound healing and biosocial-demographic characteristic of study group at the end of follow up period.

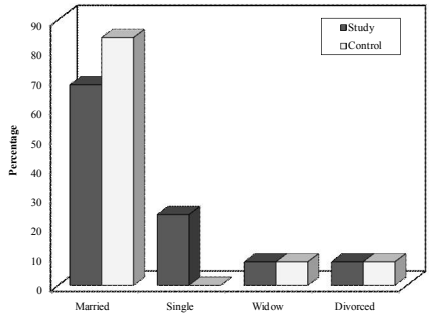
Table (8). Shows relations between ulcer wound healing and diabetic foot ulcer assessment of study group at the end of follow up period. It was found that, there were relations between ulcer wound healing and some diabetic foot ulcer assessment. The healing of ulcer was better when its site were in planter surface of 1st toe and 1st metatarsal head (22.7%, 22.7%) respectively. Also the complete healing occurred in 54.5% when the size of ulcer was 1-2cm while in 45.5% when its size was more than 2-4cm.



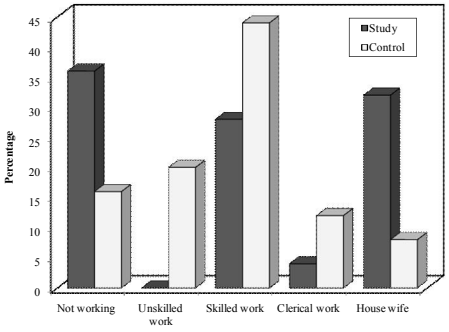
Age



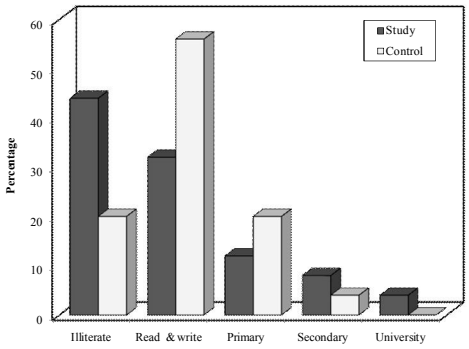
Sex



Marital status



Occupation



Education level

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

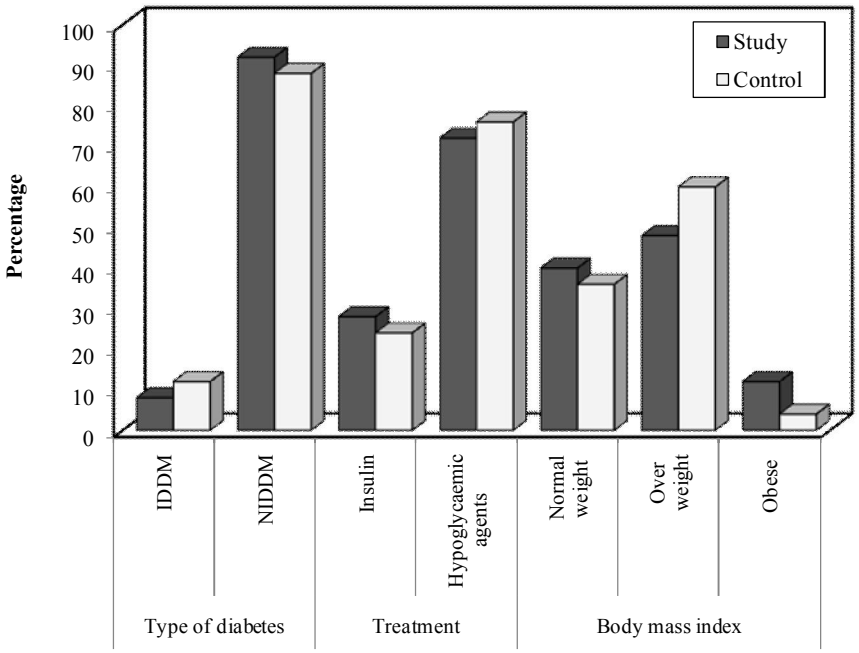


Figure (2): Frequent distribution of both studied groups according to type of disease and body mass index (BMI).

Table (1): Frequent distribution of both studied groups according to vital signs.

	Study group "n=25"	Contol group "n=25"	t-test	P
Temp Range Mean S.D.	36.5 – 37.3 37.01 0.21	36.7 – 37.6 37.1 0.13	0.62	0.25
Pulse Range Mean S.D.	80 – 92 86.6 3.98	82 – 95 87.6 4.65	0.91	0.299
Respiratory rate Range Mean S.D.	18 – 24 22.1 1.96	19 – 23 21.6 1.06	0.82	0.41
Systolic Blood pressure Range Mean S.D.	120 – 145 126.5 7.22	120 – 150 130.0 6.25	0.98	0.25
Diastolic blood pressure Range Mean S.D.	80 – 95 85.2 3.6	85 – 95 86.2 4.01	0.90	0.36

~~1.~~ Level of significant at p ≤0.05.

Table (2): Frequent distribution of both studied groups according to laboratory findings.

	Study group "n=25"	Control group "n=25"	t-test	p
Hb (mg)				
Range	10.5 - 16.5	11.5 - 16.5		
Mean	13.543	13.600	0.89	**0.216**
S.D.	1.7397	1.4860		
HCT (%)				
Range	33 – 50	33 - 50		
Mean	40.56	41.48	0.81	**0.26**
S.D.	5.650	5.680		
RBCs (million/ cm^3)				
Range	3.2 - 5.8	3.6 - 5.9		
Mean	4.756	4.776	1.03	**0.165**
S.D.	.6145	.5555		
WBCs (1000/cm^3)				
Range	4.0- 11.0	4.0 - 11.0		
Mean	7.72000	7.52000	0.89	**0.21**
S.D.	2.590367	2.417299		
Platelet (1000/cm^3)				
Range	150.0-381.0	150.0-394.0		
Mean	260.72	280.72	0.91	**0.256**
S.D.	70.174497	67.202753		
FBS (mg/dl)				
Range	105 – 180	102 - 178		
Mean	143.24	132.32	1.21	**0.069**
S.D.	21.249	23.673		
Post prandial (mg/dl)				
Range	151 –189	151 - 190		
Mean	186.24	187.60	0.109	**0.958**
S.D	24.040	21.307		

Level of significant at $p \leq 0.5$.

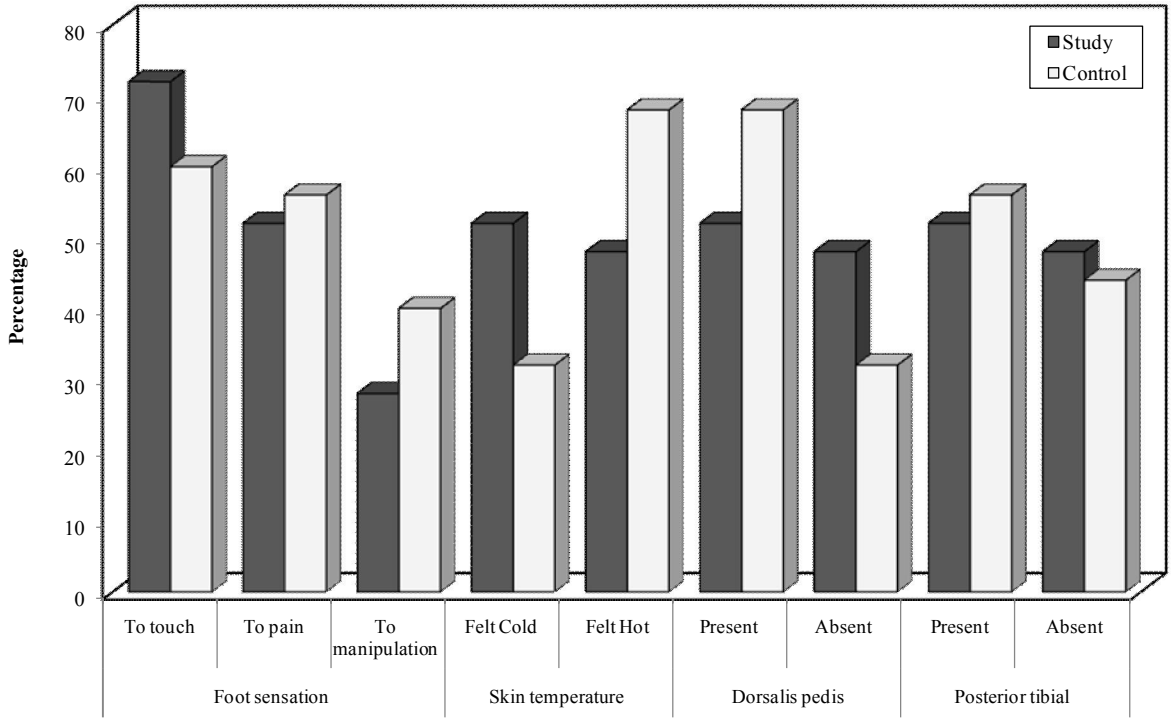


Figure (3): Frequent distribution of both studied groups according to diabetic foot assessment.

Table (3): Frequent Distribution of both studied groups according to ulcer assessment.

Ulcer assessment	Study group "n=25"		Control group "n=25"		X^2	p
	No.	%	No.	%		
Site of ulcer						
• Plantar surface 1st toe	6	24.0	5	20.0	0.21	0.930
• Plantar surface 1st metatarsal head	6	24.0	6	24.0		
• Plantar surface 2nd toe	4	16.0	3	12.0		
• Plantar surface 4th toe	3	12.0	6	24.0		
• Plantar surface 5th toe	5	20.0	4	16.0		
• Sole	1	4.0	1	4.0		
• Heel	0	0.0	0	0.0		
Size of ulcer						
1 – 2 cm	14	56.0	8	32.0	2.92	0.077
>2 -4 cm	11	44.0	17	68.0		
Ulcer edge						
Regular	13	52.0	8	32.0	2.05	0.126
Irregular	12	48.0	17	68.0		

Level of significant at p ≤0.05.

Table (4): Frequent distribution of both studied groups according to ulcer surrounding area.

	Study group "n=25"		Control group "n=25"		X^2	p
	No.	%	No.	%		
Surrounding area necrotic tissue (margin)						
Yes	11	44.0	16	64.0	1.97	0.128
No	14	56.0	9	36.0	5.584*	0.016
If yes						
Redness	3	27.3	5	31.3	0.049	0.842
Tenderness	3	27.3	3	18.8	0.274	0.601
Hotness	3	27.3	4	25.0	0.018	0.895
Swelling	2	18.2	4	25.0	0.175	0.675

*Level of significant at p ≤0.05.

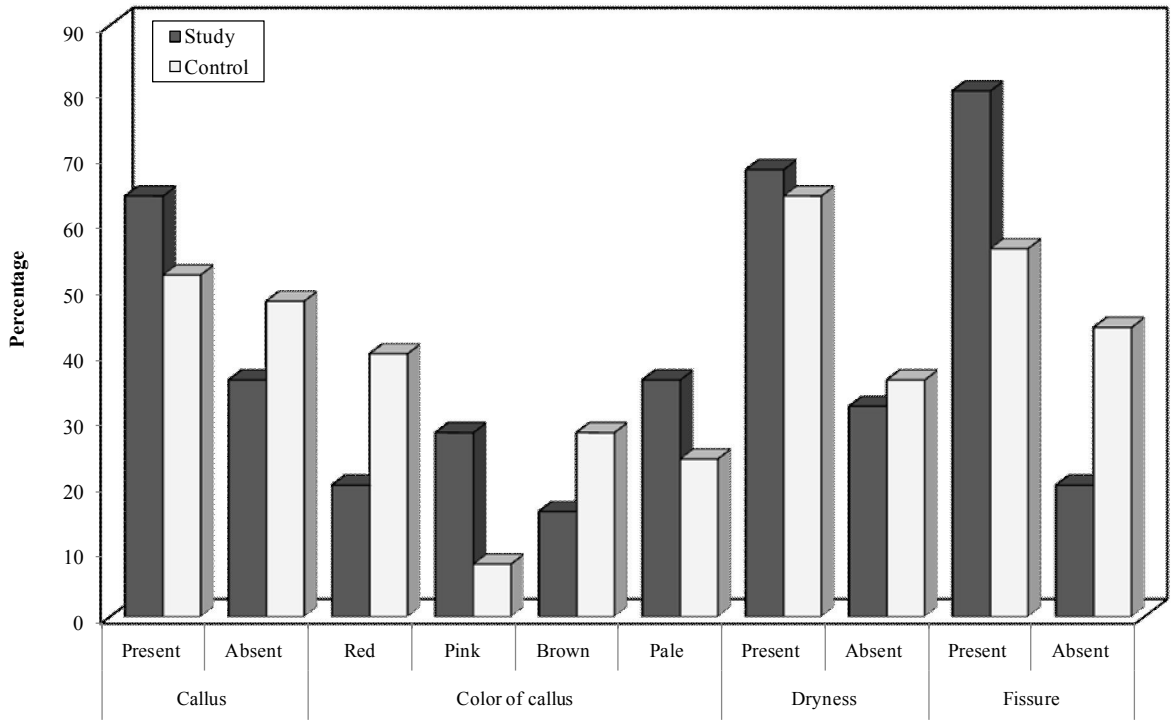


Figure (4): Frequent distribution of both studied groups according to skin condition

Table (5): Frequent distribution of both studied groups according to ulcer wound healing during follow up period

Ulcer wound healing	Follow up period							
	After 1 week		After 2 weeks		After 3 weeks		After 4 weeks	
	No.	%	No.	%	No.	%	No.	%
I Study group Complete ulcer wound healing Partial ulcer wound healing No ulcer wound healing	4 11 10	16.0 44.0 40.0	17 6 2	68.0 24..0 8.0	20 4 1	80. 16.0 4.0	22 3 0	88.0 12.0 0.0
II. Control group Complete ulcer wound healing Partial ulcer wound healing No ulcer wound healing	6 7 12	24.0 28. 48.0	10 5 10	40.0 20.0 40.0	15 6 4	60.0 24.0 25.0	20 4 1	80.0 16.0 4.0
X^2 P2	1.471 0.479		7.239 0.027*		2.914 0.233		1.24 0.53	

* Level of significant at p ≤0.05.

Table (6): Frequent distribution of both studied groups according to abnormal findings of ulcer wound healing during follow up period.

Abnormal finding of ulcer wound healing	Follow up period							
	After 1 weeks		After 2 weeks		After 3 weeks		After4 weeks	
	No.	%	No.	%	No.	%	No.	%
I Study group 1. Clinical signs of wound infection Change of color of wound exudates and amount Discharge and odour 2. Moist granulation tissue 3. Increase of surface area measurements 4. Unchanged surface areas of wound 5. Absence of healing epithelial edges.	 0 0 0 0 0 0	 0.0 00 00 0.0 0.0 0.0	 0 0 0 0 0 0	 0.0 0.0 0.0 0.0 0.0 0.0	 0 0 0 0 0 0	 0.0 0.0 0.0 0.0 0.0 0.0	 0 0 0 0 0 0	 0.0 0.0 0.0 0.0 0.0 0.0
II. Control group 1. Clinical signs of wound infection Change of color of wound exudates Discharge and odour 2. Moist granulation tissue 3. Increase of surface area measurements 4. Unchanged surface area of wound 5. Absence of healing epithelial edges.	 0 0 0 0 0 0	 0.0 0.0 0.0 0.0 0.0 0.0	 0 0 0 3 3 3	 0.0 0.0 0.0 12.0 12.0 12.0	 0 .0 0 0 1 2 2	 0.0 0.0 0.0 4.0 8.0 8.0	 0 0 0 0 1 1	 0.0 0.0 0.0 0.0 4.0 4.0

- Level of significant at p ≤0.05

Table (7): Relations between ulcer wound healing and bio socio-demographic characteristics of study group at the end of follow up period.

Characteristics	End of follow up period			
	Study group			
	Partial or no healing "n=3"		Complete healing "n=22"	
	No.	%	No.	%
Age				
20 –	0	0.0	5	22.7
30 –	0	0.0	4	18.2
40 –	0	0.0	6	22.7
50 –	2	66.7	9	31.8
60 -	1	33.3	1	4.5
Fisher exact test	5.53			
p	0.236			
Sex				
Male	2	66.7	12	54.5
Female	1	33.3	10	45.5
Fisher exact test	0.16			
p	0.69			
Type of diabetes				
IDDM	0	0.0	2	9.1
NIDDM	3	100.0	20	90.9
Fisher exact test	0.30			
p	0.58			
BMI				
Normal weight	0	0.0	10	45.5
Over weight	2	66.7	10	45.5
Obese	1	33.3	2	9.1
Fisher exact test	2.90			
p	0.406			

* Level of significant at $p \leq 0.05$.
N.S. Not significant difference

Table (8):Relations between ulcer wound healing and diabetic foot ulcer assessment of study group at the end of follow up period.

Foot ulcer assessment	End of follow up period			
	study group			
	Partial or no healing		Complete healing	
	"n=3"		"n=22"	
	No.	%	No.	%
Site of ulcer Plantar surface of 1st toe	1	33.3	5	22.7
Plantar surface of 1st metatarsal head	1	33.3	5	22.7
Plantar surface of 2nd toe	0	0.0	4	18.2
Plantar surface of 4th toe	0	0.0	3	13.6
Plantar surface of 5th toe	1	33.3	4	18.2
Sole	0	0.0	1	4.5
Heel	0	0.0	0	0.0
p	0.298			
Size of ulcer 1 – 2 cm	2	66.7	12	54.5
>2 -4 cm	1	33.3	10	45.5
p	0.412			
Ulcer edge Regular	2	66.7	11	50.0
Irregular	1	33.3	11	50.0
p	0.274			

* Level of significant at p ≤0.05 .
N.S. Not significant difference

4. Discussion:

Management of patients with grade 1 diabetic foot ulcer can prevent the most serious complications. The last two decades have focused on improving ulcer wound healing rates and control infection by using different dressing techniques with different solutions.

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 >20--50 years. This finding can be explained by the fact that, younger adults or older adults have hard work, working over time and excessive standing especially in the present study where most of the studied patients in both groups were farmers and builders. 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) who stated that, whilest diabetic foot ulceration occurs most commonly in older adults, it also affects younger. And in accordance with (Yakout ,2009) who found that the worker males affected by foot ulcer more than the females. Also this finding contradicted by (Jamil,2010) who found that the majority of the patients affected by foot ulcer were divorced.

Concerning body mass index (BMI) in the present study majority of the patients in study and control groups suffered from either over weight or obesity. This may due to lack of patient's knowledge about balanced diet and Egyptian dietary bad habit. This result was in accordance with (Willem , 2011) who found that most of diabetic patients suffered from either over weight or obesity. This supported by (Bassl ,2005) who ascertained that over weight play a significant role in diabetic foot ulceration.

Furthermore in the present study high percent of patients in both studied groups were illiterate and read & write. So they neglected their condition. This may be due to lack of awareness about their health problem .This finding was in agreement with (Armstrong et al, 2006) 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.

Regarding to type of diabetes, majority of the studied patients in both studied groups (study and control) had type II Non insulin dependant diabetes mellitus (NIDD) This finding was in agreement with

(Stotts and Sparacino ,2005) who found that the majority of patients with foot ulcer occurred in individuals with NIDDM. Also these results 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. Also these results insure that all studied patients in both groups had control diabetes mellitus according to American Diabetic Association (ADA ,2011) who stated that normal post prandial blood sugar level was up to<< 180 mg/dl. most of patients had their post prandial blood glucose level ranging from 150-180 mg/dl. This control in the blood glucose level may be due to the fact that the patients had taken their prescribed treatment both hypoglycemic agent either oral or insulin. This finding was illustrated by (Willem,2011) who found that good control of blood glucose levels may prevent the development of diabetic foot ulceration.

Moreover In the present study, most of the selected patients in both groups had dry skin, warm feet sensitive to touch and pain had callus and fissure which occurred as a result of repetitive pressure on their feet during ambulation .These results were inaccordance with (Daniels et al, 2007) who found that the majority of patients had warm feet sensitive to touch and pain. Moreover more than half of the studied patient in the both groups had pulsation on both dorsalis pedis and posterior tibial arteries.

Regarding to the morphology of the wound in the present study, most common site of ulcers in both studied groups were in planter foot and the planter surface of I st toe and I st metatarsal head . These results were explained by (Armstrong et al , 2006) who stated that one third of patients who developed ulcer in planter surface of toes especially meta-tarsal heads usually proceeded by increases foot pressure.

As fore the ulcer size at the initial assessment, the highest percentage of ulcer size in both groups was1-4cm. These results also were in line with (Elshatby , 2003) findings also explained by (Margolis,et al ,2005) who illustrated the importance of measuring wound size and depth in determing healing outcomes for different wound types. (Tennvall and David ,2009) and(Ortegon ,et al ,2004) concluded in their series papers 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.

As regards skin surrounding the ulcer, most of the studied patients in control group and less than half of the study group had necrotic tissue margin also less than third of studied patients in both groups had redness, tenderness, hotness and swelling .In this aspect,(Elshatby ,2003) reported that, most of the studied patients in control group and more than half of the study group had necrotic tissue margin also more than third of study patients in both groups had redness. Moreover all the findings of initial physical assessment and lab investigations indicated absence of infection in both studied groups.

Moreover, the results of the present study revealed the absence of any significant differences in the biosociodemographic characteristics and wound characteristics (surface area, depth, floor of ulcer and wound discharge) between the study and control groups which insure limitation of the effect of any intervening variables and measure only the effect of the solutions used in dressing on ulcer wound healing.

After implementation of the two dressing techniques, the results showed that, after 2 weeks the ozonated olive oil dressing had significant effect on wound healing than conventional dressing technique although the number of patients who had complete or 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. In the third week in study group patients who had partial or no healing were decreased more than those of second week and who treated with routine hospital solution (saline and povidon-iodin). Patients who had complete ulcer healing increased more than who treated in the control groups and also that who in second week. At the end of follow up period after 4weeks, although the majority of patients in both studied 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 88% had complete healing as compared to 80% in control group patients. Except three cases in study group and four cases in control group had partial ulcer wound healing which means presence of healthy granulation tissue within the wound space or decreased of wound size without formation scare tissue. 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, one patient had incomplete healing at the end of follow up period the researcher investigated the wound culture to detect the type of organism by send the culture to the lab. The culture result revealed that, no infection occurred .This result may be due to patient's uncontrolled behavior such as walking barefoot and sometimes removes dressing.

These results were explained by (Zidan, 2006) who stated that, ozone ointment is more effective and help in rapid healing process. Also, the same author found that, in patients treated with ozone olive oil ointment complete wound healing was obtained after 6-21 days. Consequently stated that ozonated olive oil had a fungicidal and bactericidal effect; ozonized oil had been used locally for disinfecting lesions and promoting their healing(American Diabetic Association ,2004) In this field (Matsumoto et al ,2001) stated that, ozone (O3), is an allotropic form of oxygen possesses unique properties which are being defined and applied to biological systems as well as to clinical practice as a molecule containing a large excess of energy, ozone manifests bactericidal, virucidal, fungicidal and healing promoting actions which may make it a treatment of choice in certain conditions and an adjunctive treatment in others. (El Medany ,2009) 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 the present study daily dressing permit daily inspection of the wound, and assessment of foot for temperature, pulsation, color and skin abnormality. The results revealed no abnormalities or sign and symptoms of infection were found during the study and follow up period in study group while in the control group at the third week and fourth week, 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. In this aspect (Jacobs and Rekha ,2007) reported that, povidin-ioden (betadine 10%) solution may be used to clean wound but it retard it's healing. This finding may be due to the irritant effect of povidon-iodin. (Thomas ,2005) 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.

(El medany,2009)referred the mechanism behind the promoting effect of ozone on reepithelization due to vasodilatation, enhanced oxygenation ,normalization of tissue Ph, reabsorption of edema ,active proliferation of fibroblasts and keratinocytes with excessive formation of fibronctin, collagen, chondroitin sulphate, intracellular matrix and stimulation the synthesis of cytokines.This explanation became evident to confirm the rapid progress of the wound healing in patients treated by ozone ointment. Furthermore the study results showed no statistical significant relation was found between wound healing and biosoco-demographic characteristics. In the study group ulcer healing was better in non obese, NIDDM, males less than 50 years. These results were accordance with (Willem , 2011) who reported that, age, sex, type of diabetes and patient's weight are considered the important factors in healing process.

During the application of ozonated olive oil ointment dressing technique the researcher found that, the package of ozonated ointment can cover the frequent ulcer dressing for more than six times. The dressings with ozonated ointment was expensive than conventional dressing method but the healing of the wound is faster so the period of dressing become shorter than other technique.

Conclusion:

From the present study, it can be concluded that although the two dressing techniques (ozonated olive oil ointment and povidon-iodin 10% wet dressing techniques) were effective on the healing process of grade I diabetic foot ulcer, ozonated olive oil ointment dressing had better healing effect than conventional dressing.

Povidon-iodin 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 grade I diabetic foot ulcer. In the vascular out –patient clinics it's preferable to use both dressing techniques in the management of patients with grade I diabetic foot ulcers, increase nurses' awareness about ozonated olive oil ointment dressing technique through development of procedure manual, training the nurses about how to use ozone ointment in dressing.

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