

# Effect of Applying Topical Insulin in Healing Process of Diabetic Foot Ulcer among Diabetic Patients

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**Abstract:** Diabetic foot ulcers (DFUs) contribute significantly to the morbidity and mortality of patients with diabetes mellitus and still one of the commonest sequelae following trauma or infection mainly around the distal ends of limbs where the vascularity is relatively decreased due to effects of diabetes. **Aim:** was to evaluate the effect of applying topical insulin in healing process of diabetic foot ulcer among diabetic patients. **Subject and Method:** Quasi-experimental design was utilized in this study on a purposeful sample of (60) diabetic foot ulcer patients, divided into two equal groups, study group who receive topical insulin dressing and control group who receive routine hospital dressing at diabetic foot unit at Mansoura University Hospital. The data collection period was extended from 1/4/2017 to the end of February 2018.

**Tools:** Two tools were used in this study; (1) Socio-demographic characteristics and medical data; (2) Diabetic foot Ulcer Scale for Healing (DFUSH). **Results:** There was a significant improvement in diabetic foot ulcer healing for the study group compared to their control, where p value (<0.05). **Conclusion:** Topical application of insulin has a very powerful effect in healing process for diabetic foot ulcer. **Recommendation:** Using topical insulin dressing for patients with Diabetic foot ulcer.

**Keywords:** Healing process, Diabetic Foot ulcer, Topical insulin, Diabetes.

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## 1. INTRODUCTION

Diabetes mellitus (DM) is one of the most common and important metabolic disorders affecting about 2–5% of the population in Europe and about 20% of the population in various other parts of the world. The diabetes mellitus incidence is increasing worldwide; by 2030, it will grow up to 366 million. This estimation occurred because of longer life expectancy and changing diet habits. Although there are many complications affecting the person with diabetes, none are more devastating than those complications involving the foot. Diabetic foot lesions have significant health and socioeconomic problems holding adverse effects on the patient's quality of life and imposing a heavy economic burden on the society, patients and their families (Mariam et al., 2017).

The diabetic foot syndrome encompasses a number of pathologies, including diabetic neuropathy, peripheral vascular disease, Charcot's neuroarthropathy, foot ulceration, osteomyelitis, and the potentially preventable end point, amputation. Subjects with diabetic foot problems are also likely to harbor other associated complications of diabetes such as nephropathy, retinopathy, ischemic heart disease and cerebrovascular disease. The burden of diabetic foot ulcer is set to increase in the future since the contributing factors to foot disease, such as peripheral neuropathy and vascular disease, are present in more than 10% of people at the time of diagnosis of type 2 diabetes (Assaad-Khalil et al., 2015).

Amputation is a serious consequence of diabetes. Lower limb amputation is performed 10–30 times more frequently among diabetic than among general population. Every 30 s, somewhere in the world, a lower limb is lost as a complication of diabetes. One report noted that more than 80% of non-traumatic lower extremity amputations (LEAs) are

performed in diabetic patients and more than 85% of these were precipitated by a foot ulcer that subsequently progressed to a severe infection (Assaad-Khalil et al., 2015).

Individuals are at high risk for amputation of the contralateral limb if they have already undergone amputation of one limb. Furthermore, 30–50% of first-episode amputations will progress to subsequent amputations within 1–3 years. Amputation carries with it a significantly elevated mortality at follow-up, ranging from 13% to 40% at 1 year to 39–80% at 5 years (Singh et al., 2005). With regard to diabetic foot ulcers, 12% of all hospitalized diabetic patients have foot ulceration in Africa. Research indicates that diabetics' patients with foot ulcers encounter stigma, loss of social role, social isolation, and unemployment. Limb amputation causes distortion of body image, increase independency, loss of productivity, and increase in costs of treating diabetic foot ulcers (Mbanya and Sobngwi, 2003).

The mechanisms of poor healing in diabetic foot ulcer are not fully understood. However, studies suggest that impaired leukocyte function, cytokines and growth factors dysregulation, neuropathy, and vasculopathy have important roles in non-healing diabetic foot ulcers (Pradhan et al., 2009). According to CDC, 6 million patients use insulin to control their diabetes (Centers for Disease Control and Prevention, 2014 and Hrynyk & Neufeld, 2014). Besides controlling glucose levels, insulin has been shown to have wound healing effects. Management of diabetic foot ulcer the local wound care is inevitable one. There are numerous antibiotic ointments used for improve healing of it, recently topical insulin was used in wound dressing, because Insulin stimulates the growth and development of keratinocytes, endothelial cells and fibroblasts, help proliferation, and promote tissue healing (Swaminathan, 2014).

#### Significance of the study

The International Diabetes Federation estimated that in 2013, 381 million people had diabetes mellitus (International Diabetes Federation, 2018). This number is estimated to be almost doubled by 2030 (Richard and Schuldiner, 2008). Egypt was ranked ninth in the world, where there are 7 million and a half million Egyptians are living with diabetes (Centers for Disease Control and Prevention, 2008). A systematic literature review of papers published on diabetes prevalence and complications in North Africa from January 1990 to July 2012 reveals that diabetes prevalence ranged from 2.6% in rural Sudan to 20.0% in urban Egypt (International Diabetes Federation, 2013). Up to 15% of those with diabetes developed a foot ulcer during their lifetime (Mbanya and Sobngwi, 2003).

While the statistical rate of diabetic foot ulcer in the diabetic foot unit at Mansoura university hospital was 42% of cases from 2017 and 2018 years. For these reasons, there was an urgent need to conduct this study to test evidence for using topical insulin as a method of diabetic foot ulcer. It is also hoped that this effort will generate attention and motivation for further studies into this topic.

#### Aim of the Study

The aim of this study was to evaluate the effect of using topical insulin in healing process of diabetic foot ulcer among diabetic patients.

#### Research hypothesis:

**H (1)** Applying topical insulin on diabetic foot ulcer for diabetic patients exhibit fewer microorganisms than the patients who do not

**H (2)** Applying topical insulin on diabetic foot ulcer for diabetic patients exhibit faster wound healing than the patients who do not.

## 2. SUBJECTS & METHOD

#### Study Design:

A quasi-experimental design was utilized to achieve the purpose of the present study.

#### Setting:

This study was conducted at diabetic foot unit at Mansoura University Hospital. This unit consisted of two units, unit (A) diabetic foot ulcer grade I & II and Unit (B) diabetic foot ulcer grade III & IV and infected wound. This hospital located in delta region diabetic foot care were performed on a regular basis, daily at diabetic foot unit with an average number of 103 cases weekly.

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**Subjects:**

A purposive sample was collected for a period about one year; it was comprised of 60 patients of both sexes. Patients were selected and distributed randomly and equally into two groups

**Study group:** consisted of 30 adult patients who receive topical insulin dressing.

**Control group:** consisted of 30 adult patients, who receive routine hospital dressing.

**Subject Dropout:** Subject were divided into study group (30 patients) and control group (30 patients) by the end of data collection four patients from the control group dropout, three patients died and one patient discharge before one week. In study group, seven patients discharged before complete one week. So, replications of these cases were carried out.

**Sample size:** was calculated using epidemiological information (EPI info.) program version 6.02 after taking into consideration the total number of diabetic patient admitted to diabetic foot unit, alpha error 5% (=confidence level=95%) Beta error 20% (=study power=80%).

$$\text{Sample Size} = \frac{Z^2 * (p) * (1-p)}{c^2}$$

Where: Z=Z value (e.g. 1.96 for 95% confidence level), P = Percentage picking a choice, expressed as decimal, (.5 used for sample size needed), C = Confidence interval, expressed as decimal.

**Criteria for selection of the subjects:**
**Inclusion criteria:**

- Adult patients(20-60 years)
- Diabetic foot ulcer grade A and B
- Both sex
- Patients who are agreed to participate in the study.

**Exclusion criteria:**

- Patients who have been operated for diabetic foot earlier
- Uncontrolled diabetes.
- Other clinically significant medical conditions that would impaired wound healing including renal, hepatic, hematological, immunological, neurological diseases, malignancies, and infected ulcer.
- University of Texas wound Classification System stage C and D, grade 3.
- Pregnancy

**Tools**

Two tools were used in this study by the researcher for collection of necessary data and achieving the aim of the study as follows;

**Tool I: An interviewing questionnaire sheet;** This tool was consisted of two parts.

Part I: Socio-demographic data.

Part II: Medical data.

**Part I: Demographic data:**

This part developed by the researchers, it was used for collection of personal data such as age, sex, occupation, level of education and marital status based on review of related literature.

**Part II: Medical data sheet: (Goenka et al., 2014)**

**Category (1):** patient health status data such as date of admission, patient diagnosis, past medical history, foot hygiene, level of mobility, presence of urinary incontinence, presence of stool incontinence, moisture, degree of ulcer, using hemoglobin level, WBCs, culture swab results, Random Blood Glucose level based on review of related literature.

**Category (2):** "Mini Nutritional Assessment (MNA)". The "MNA" test was adapted from (Gauglitz et al., 2010 and National Decubitus Ulcer Advisory Panel 2016), which consisted of six items, one simple measurement and five brief questions that can be completed in short time.

**Screening score of (MNA)"** ranged from zero to fourteen, it classified as:

- From zero to seven refer to malnourished
- From eight to eleven described risk of malnutrition
- From twelve to fourteen refer to normal nutritional status.

**Tool II: Diabetic foot Ulcer Scale for Healing (DFUSH)**

It was adopted from (NPUAP, 2017), as a quick tool to monitor changes in DFUSH status over time, this tool classified Diabetic foot ulcer with respect to **surface area, exudates, and type of wound tissue**. Record sub-score for each of these ulcer characteristics; add the sub-scores to obtain the total score and the comparison of total scores measured over time provides an indication of the improvement or deterioration in foot ulcer healing. *If "DFUSH " increase this refer to deterioration but reduction in "DFUSH" refer to improvement as the following:*

LENGTH X WIDTH (in cm <sup>2</sup> )	0	1	2	3	4	5	Sub-score
	0	< 0.3	0.3 – 0.6	0.7 – 1.0	1.1 – 2.0	2.1 – 3.0	
		6	7	8	9	10	
		3.1 – 4.0	4.1 – 8.0	8.1 – 12.0	12.1 – 24.0	> 24.0	
EXUDATE AMOUNT	0	1	2	3			Sub-score
	None	Light	Moderate	Heavy			
TISSUE TYPE	0	1	2	3	4		Sub-score
	Closed	Epithelial Tissue	Granulation Tissue	Slough	Necrotic Tissue		
							TOTAL SCORE

**Method**

**Validity and Reliability:**

- Tools: were developed by the researcher based on recent relevant literature review except tool I Category two, tool II was adopted. All tools were written in English form.
- All tools were tested for content validity by five experts (jury) in the field of the study including faculty staff members from Faculty of Nursing \_Alexandria (1 members), Faculty of Nursing \_ Mansoura University (3 members), and surgery specialist in the diabetic foot unit. The necessary modifications were done.
- Reliability testing was done using Cronbach's alpha on a sample of 10 of the subjects that measures the degree of reliability for the entire form. This techniques showed high reliability of the final version of the tool The correlation coefficient were:
  - Tool I ( r )=0.89
  - Tool II (r) =0.93

***Pilot study:***

The pilot study was carried out on 10% of subjects for testing the feasibility, applicability, and timeframe of the tools applications. The needed modification, omission and addition were made. They were excluded from the study sample.

***Fieldwork:***

This study was carried out through three consecutive phases: interviewing & assessment phase, implementation phase and evaluation phase. The data collection period was extended from 1/4/2017 to the end of February 2018.

**1) The interviewing and assessment phase:**

During this phase, the researchers explained the purpose of the study, instruments components, preventive measures, technique and the importance of using insulin in wound dressing. The time needed for completing the questionnaire was ranged from 30 - 45 minutes for each patient.

**2) The implementation phase:**

- In this phase, the selected patients who were recruited are randomly assigned to two equal groups (30 patients per each).
- Each patient was interviewed pre dressing intervention for both groups to collect the necessary data using study tools.
- Culture swab was taken before the researcher start her intervention for both groups.
- In first day of dressing for study group random blood sugar (RBS) level was measured 10 minute pre dressing and one hour post dressing in the first morning dressing.
- In morning dressing of second day for study group RBG level was measured 10 minutes pre dressing and one hour post dressing.
- Dressing was applied twice per day for both groups. One in the morning and other in evening.
- Dressing was applied twice daily for one week.
- **Dressing the wound for the study group:** It started with cleaning the wound with saline, then cleaning with (10ml of insulin in 1000 ml of normal saline), then applying gauze soaked with insulin the gauze was left to dry and then covered with sterile dressing. Infection control and principle of aseptic technique were use during the dressing, the time needed to complete each dressing was about 15 minute.
- **Dressing the wound for the control group:** the patient received the usually routine hospital dressing; cleaning the wound with saline or betadine then applying glycerin, finally covered the wound with sterile dressing .This dressing done by the nurses

**3) The evaluation phase:**

This phase was emphasized on estimating the effect of the intervention on the wound healing which was evaluated for both groups for 2 times using first tool (part II) and second tool:

- a) First time: immediately on the first day pre dressing.
- b) Second time: one week post dressing

A comparison was done between study and control group to determine effect of using topical insulin dressing on improving diabetic foot ulcer healing.

***Ethical Considerations:***

- Ethical approval was obtained from the research ethics committee of the Faculty of Nursing at Mansoura University.
- Approval to conduct this study was obtained from the administrator of Neurological Department at Mansoura University Hospital after explaining the aim of study.

- A verbal consent was taken from the study sample before inclusion in this study, after explaining the purpose of the study. The researcher emphasized that participation in this study was entirely voluntary, anonymity, and the patient can withdraw at any time without any effect of researcher on them. Privacy and confidentiality was respected and assured

**Statistical analysis:**

- After collection of the data, it was analyzed using the statistical package of social science “SPSS” software. Descriptive statistics in the form of frequencies and percentages for qualitative data, and means and standard deviations and medians and inter quartile ranges for quantitative variables. Quantitative continuous data were compared using the non- parametric Mann-Whitney test. Qualitative categorical variables were compared using chi-square test. Statistical significance was considered at p-value <0.05.

**3. RESULTS**

**Table (1): Socio-demographic characteristics of study and control groups (n= 60)**

Socio-demographic data	Groups				X <sup>2</sup>	P
	Study group (n= 30)		Control group (n=30)			
	No	%	No	%		
<b>Age group</b>	54		53		P	0.812
	Z		(-0.238)			
<b>Gender</b>					(1.148)	0.284
▪ Male	9	30	13	43.3		
▪ Female	21	70	17	56.7		
<b>Marital status</b>					(1.273)	0.529
▪ Single	1	3.3	0	0		
▪ Married	22	73.3	21	70		
▪ Widow	7	23.3	9	30		
<b>Education level</b>					(0.0)	1.0
▪ Illiterate	17	56.7	17	56.7		
▪ Read and write	6	20	6	20		
▪ Secondary school	3	10	3	10		
▪ University	4	13.3	4	13.3		
<b>Occupation</b>					(4.750)	0.314
▪ Manual work	7	23.3	4	13.3		
▪ Employee	1	3.3	6	20		
▪ House wife	19	63.3	18	60		
▪ Retired	2	6.7	1	3.3		
▪ Others	1	3.3	1	3.3		

Count [Percent] and p value (X<sup>2</sup> value) through **Chi-square test**. - Median and p value (Z value) through **Mann-Whitney test**

Table (1), showed a total of 60 patients (30 per each group) with median age, for study and control groups was (54 year and 53year) respectively. Related to gender, (70% and 56.7%) of study and control groups respectively were females. The majority of participants in the study and control groups (73.3% and 70%) respectively were married. Above half of participants (56.7%) were illiterate in each group.

Table (2): Percentage distribution of both study and control groups patients according to medical data

Medical data	Study group (n=30)		Control group (n=30)		(X <sup>2</sup> )	P
	No	%	No	%		
<b>Past medical history:</b>						
- Hypertension	22	73.3	12	40	(87.002)	<0.0001
- DM	30	100	30	100		
- Heart disease	6	20	7	23.3		
- Chest disease	0	0	1	3.3		
<b>Level of mobility:</b>						
- Immobile	30	100	29	96.7	(1.017)	0.313
- Mobile with assistant	0	0	1	3.3		
<b>Foot hygiene:</b>						
- Clean	28	93.3	29	96.7	(0.351)	0.554
- Unclean	2	6.7	1	3.3		
<b>Method of feeding:</b>						
- Oral feeding	30	100	30	100	(0)	1

(X<sup>2</sup>): Chi-square test.

P ≤ 0.050 (significant)

Table (2), revealed that 73.3% and 40% in both study and control groups had hypertension respectively, while for both of them 100% had DM. according to mobility, all study participants 100% were immobile, while 3.3% of control group was mobile with assistance. As regard to foot hygiene, the same table showed that 93.3% of the study group had clean foot but only 3.3% of the control group had unclean foot.

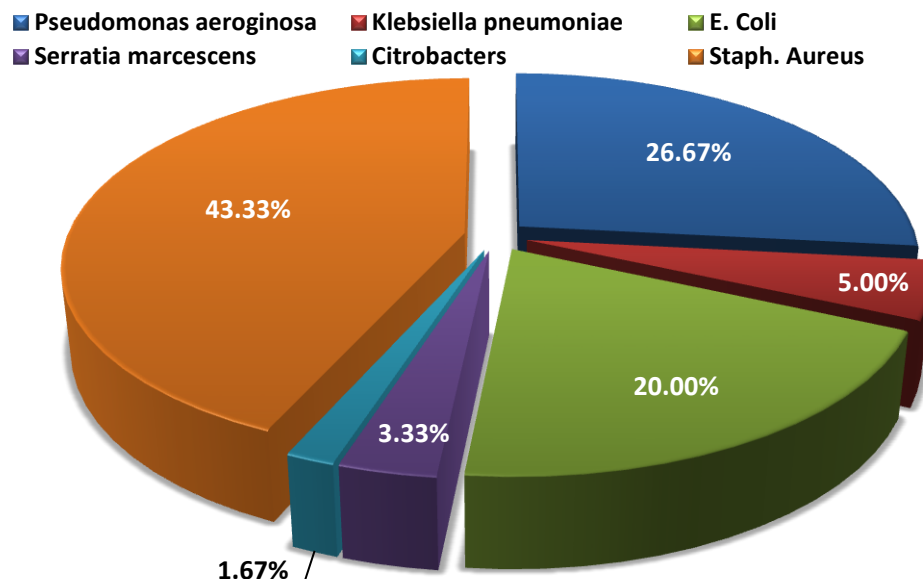


Figure (1): Distribution of microorganisms types presented in diabetic foot ulcer among study group pre dressing (n=30).

Figure (1), explained that the most common microorganism 43.33% was for staph aureus organism while 26.67% and 20% for pseudomonas aeruginosa organism and E.Coli respectively. On the other hand, the lowest proportion involved klebsiella pneumonia, serratia marcescens and citrobacters 5%, 3.33%, and 1.67% respectively.

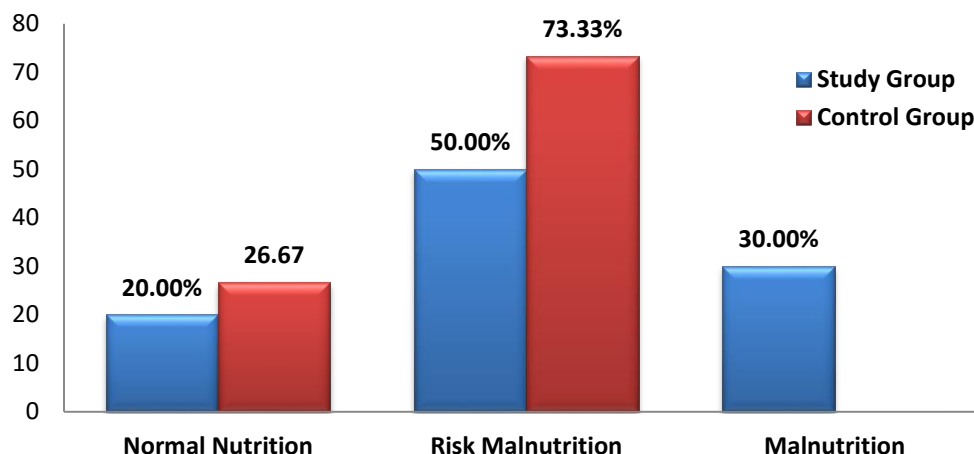


Figure (2): Percentage distribution of patients of the study and control groups according to Mini Nutritional Assessment (MNA) pre dressing (per each n=30).

Figure (2): Clarified that, 20.00% and 26.67% from the study and control group had normal nutritional state respectively. On the other hand the same figure proved that, control group had a higher percentage 73.33% for risk of malnutrition while 30.00% of the study group was had already malnutrition.

Table 3: Comparison between study and control group in relation to laboratory results (hemoglobin levels and WBCs counts) pre dressing (No=60).

Parameter	Study group (n=30)	Control group (n=30)	*p (t)
	Mean ± SD		
Hemoglobin	10.25 ± 1.77	11.84 ± 1.86	0.001 (-3.407)
WBCs	10.52 ± 3.53	8.66 ± 2.84	0.28 (2.247)

P (t): P value (t value) through Independent samples t-test.

Table (3), illustrated that there was a significant difference between two levels of Hg in the study and control groups where p value was (0.001) but, no significant difference in WBCs count between study and control group patients.

Table (4): Difference between RBG level pre/post dressing among study group at the 1<sup>st</sup> and 2<sup>nd</sup> day (n=30):

Time of measurement	Mean ± SD of Random Blood Sugar (mg/dl)	p*
<b>Day 1</b>		
Ten minutes pre dressing	190.7 ± 78.7	<b>0.050</b>
One hour post dressing	177.2 ± 67.7	
<b>Day 2</b>		
Ten minutes pre dressing	180.7 ± 68.2	0.588
One hour post dressing	178.3 ± 60.5	

p\*: Paired-samples t-test

Table (4), reflected the RBG values in first day pre dressing was (190±78.7) whereas post dressing was (177.2±67.7) which was statistically significant lower level (p=0.050). This mean a significant decrease in RBG level was observed in some participants in first day, but in second day no significant difference was observed in random blood sugar level pre/post dressing.



**Table (5): Comparison between patients of the study and control group with relation to diabetic foot ulcer healing (n=60):**

Timing	Study group (n=30)	Control group (n=30)	p*
	Mean ± SD, Median		
Day 1	11 ± 2.2, 11	10.3 ± 2.4, 11	0.354
Day 7	8.7 ± 3.9, 9.5	10.7 ± 2.8, 11	<b>0.030</b>
P**	<b>&lt;0.0001</b>	0.090	

p\* : mean Whitney test

p\*\* : mean Wilcoxon test

Table (5), clarified that, there was a significant improvement in diabetic foot ulcer healing for patients in the study group than their control where p value was <0.0001. This proved that insulin dressing had an effective action in improving diabetic foot ulcer healing according to research hypothesis. Where, there is no significant difference in diabetic foot ulcer healing score between the study and control groups at day one, while there was a statistically significant decreased in study group at day 7 where p value was 0.030.

**Table (6): Correlation between diabetic foot ulcer healing score for patients of the study and control group at day one and laboratory parameters (n=60):**

Parameter	Diabetic foot ulcer healing for the study group (n=30)		Diabetic foot ulcer healing for the control group (n=30)	
	R	P	R	P
Duration of foot ulcer in days	0.532	<b>0.002</b>	0.148	0.436
Mini nutritional assessment	0.101	0.596	-0.300	0.107
Hemoglobin level	-0.096	0.613	0.088	0.644
White blood cell count	0.403	<b>0.027</b>	-0.086	0.650

Pearson correlation coefficient

Table (6), found that there was a positive correlation between diabetic foot ulcer healing score of the study group, duration of foot ulcer, and white blood cells count where p values were p= 0.002, 0.027 respectively. While there was no significant correlation existed between diabetic foot ulcer healing score of control group and all laboratory parameters in day one.

**Table 7: Correlation between diabetic foot ulcer healing score for patients of the study and control group at day seven and laboratory parameters (n=60):**

Parameter	Decubitus ulcer healing for the study group (n=30)		Decubitus ulcer healing for the control group (n=30)	
	R	P	R	P
Duration of foot ulcer in days	0.576	<b>0.001</b>	0.063	0.740
Mini nutritional assessment	0.122	0.519	-0.146	0.442
Hemoglobin level	-0.191	0.312	0.019	0.919
White blood cell count	0.459	<b>0.011</b>	-0.207	0.273

Pearson correlation coefficient

Table (7), showed that, there was no significant correlation between diabetic foot ulcer healing score of control group and laboratory parameter in day seven, but there was a significant correlation between diabetic foot ulcer healing score of study group and some parameters that included duration of foot ulcer in days and white blood cells count where p values were  $p=0.001, 0.01$  respectively. Whereas insulin decrease neutrophils infiltration and promote neutrophils functions and reduces the hospital stay of patient. It has a high-quality impact on patient's lives and on the provider's capability to render suitable care to patients.

#### 4. DISCUSSION

Diabetic foot ulcer (DFU) is significant health issues and one of the biggest challenges that organizations faces daily. DFU contributed to a significant level of disability, pain, and financial expense for those affected and the community as a whole, on the other hand it require long hospitalization and carry risk of limb amputation (Lyder and Ayello 2017). So preventing foot ulcer has continually been a challenge, not only for caregivers, however for the health care organization as an entire (Lima 2012 and Cooper, 2013). Now days, the topical application of insulin in Diabetic foot ulcer promote the ulcer healing. It's used in animal studies for long times to find out the effectiveness of insulin in its healing. The results reported that topical application of insulin is very powerful in healing process (Apikoglu-Rabus et al., 2010).

Therefore; this study was aimed to evaluate the effect of applying topical insulin in healing process of diabetic foot ulcer among diabetic patients.

Discussion of the present study covered two main areas: **First**, Sociodemographic characteristics, medical data, immobility, foot hygiene, degree of foot ulcer, (hemoglobin, WBCs, Random Blood Glucose) level & culture swab results and Mini Nutritional Assessment scale for patients under the study; **Second**, Effect of applying topical insulin dressing on diabetic foot ulcer healing by using Diabetic foot Ulcer Scale.

***Part I: Sociodemographic characteristics, medical data, immobility, foot hygiene, degree of foot ulcer, laboratory investigation and Mini Nutritional Assessment scale for patients under the study***

The finding of this study revealed that less than three quarter of the study subjects were females, this was in harmony with (Perneger, 2018) they mentioned that, above half of his studied sample were females. In contrast to (Nangole, 2016) who illustrate, the majority of his studied sample was males. Concerning marital status the results of the current sample showed that more than two third of the study participants were married, this result in the same line with (Ikechukwu et al., 2012) they reported , less than three quarter of their sample was married.

As regard to, level of education, the present study revealed that above half of the participants was illiterate. On other hand (Taha et al., 2015) who mentioned that, more than one third of the study group with primary education. This may be related to the fact that the majority of the study subjects came from rural areas with low socioeconomic status and had low education level. Moreover the findings of current study emphasized that less than two third of participants were housewives, this may be related to the high prevalence of females who came from rural areas with unemployment status.

A study carried out by (Adegoke et al., 2013) they reported that, the age of patients with Diabetic foot ulcer was above forty seven years. This finding agreed with the current study, who found that the median of age was fifty four years old. On the other hand (Borghardt et al., 2016) they reported that, patients developed Diabetic foot ulcer with a length of stay greater than ten days, it's in agreement with the present study that revealed, the median length of hospital study was 15.5 day. This might be due to the fact that infection increases the length of hospital stay.

The current study revealed that, less than three quarter of study participants had hypertension and DM and the majority of patients with history of DM developed Diabetic foot ulcer. This is compatible with (Abo Seda, 2018) who illustrated that, the highest incidence of Diabetic foot ulcer was in the hypertensive and DM. this finding is not corresponding with (Ikechukwu et al., 2012) who mentioned that the majority hadn't DM and they had paraplegia. This might be due to decrease sensory perception caused by neuropathy.

**In relation to mobility level**, all study participants were immobile. In the same context (Sharp et al 2006) that proved, immobility is thought to be one of the essential risk elements for Diabetic foot ulcer development and Diabetic foot ulcer have been most possibly to be developed within the more immobile patients. This might be due to facts of diabetes complications as; Neuropathy and vascular complications which may lead to develop of diabetic foot ulcer, if patient become immobile, it may participate for faster chance to develop it.

According to (Ersser et al., 2005) they were proved a positive relation between both incontinence and Diabetic foot ulcer occurrence. In addition to our study which revealed that, only small percentage of patients had urinary incontinence and less than quarter had stool incontinence in study group. This might be the pathophysiology of incontinence; urinary urea decomposes on the pores of skin to form ammonium hydroxide, an alkaline substance that raises the skin PH and favors bacterial proliferation. Feces contain enzymes which includes; proteases and lipases that degrade the skin barrier characteristic.

**In relation to moisture**, in present study almost all participants had dry skin. On the same line (El Din et al., 2016) they reported that about one third of their study sample had dry skin with fungus and light calluses in left and right foot. This finding was in the same finding of (Helfand, 2003) who mentioned that, more than one third of the patients have dry skin and callus. It is possible that dry thick skin could reduce the sensitivity to monofilament testing leading to inappropriate estimation of the prevalence of neuropathy. On the other hand the majority of our participants had clean foot. In contrary to (El Din et al., 2016) they found that, more than half of their studied patients were not adequately cared for their feet. This might be due to our participants were hospitalized and received great nursing care for diabetic feet.

**Regarding method of feeding**, the results of present study proved that all participants had enteral feeding. This might be attributed to the fact that most diabetic patients suffering from dysphagia. In the same way a study carried out by (Dhandapani et al 2014) they found that, the delayed attainment of enteral feeding influence the occurrence of Diabetic foot ulcer. This might be related to the delayed calories replacement along with hyper metabolism result in muscle atrophy, diminished into subcutaneous fat, and finally leading to Diabetic foot ulcer development.

**In relation to nutritional status**, the results of current study showed that about half of the study group and about three quarter of the control group were at risk of malnutrition, this results is in harmony with (Alhaug et al., 2017) they proved that, malnourished patients had a higher prevalence of Diabetic foot ulcer than adequately nourished patients. Also his results indicated that nutritional status was significantly associated with Diabetic foot ulcer. This might be due to most diabetic patients suffering from dysphagia.

**Concerning microorganisms** found in Diabetic foot ulcer, the results of present study revealed that less than half of our participants had found staph aureus organism in Diabetic foot ulcer. This in consistence with (Dana and Bauman, 2015) who found, in their study the most common organism was staph aureus. Also, (Bhosle et al., 2017) they mentioned that, most common microorganisms grown from culture taken from the lesion was staph auras followed by pseudomonas.

**As regard to Hg level**, there was a significant difference in Hg level. In the same direction (Feuchtinger et al., 2005) who reported that increased risk for Diabetic foot ulcer associated with reduced Hg and hematocrit level and occurrence of anemia. This may be related to deficiency of oxygen reaching the tissue and difficult of swallowing which contribute to malnutrition and anemia.

**Regarding to the correlation** between diabetic foot ulcer score of the study group and control group with laboratory parameters. The present study showed that there was a significant correlation between diabetic foot ulcer of study group and WBCs. In consistency with (Chen et al., 2012) they illustrated that, low-dose of topical insulin application decreased wound neutrophils infiltration and advanced wound neutrophils attenuation, that's intently related to insulin-regulated, decreased MIP-2 expression. Additionally, there's a sensitive regulation of insulin on wound inflammatory reaction during the healing process. This might be due to facts regarding action of insulin in facing infections.

The findings of current study showed that, there was significant difference in random blood glucose (RBG) level before and after insulin dressing in first day. This might be due to the association between the presence of wound infection and increased blood glucose level which reflected that after cleaning the wound and minimize infection, the blood glucose level decreased. This is in disagreement with (Goenka et al., 2014) they studied the role of topical use of insulin in healing of chronic ulcer, all diabetic patients were brought under glycemic control with appropriate anti diabetic therapy in his study. So that was no statistically difference into RBG values before and post dressing and no significant side effects or reactions were observed and none of the participants experienced adverse systemic effects such as hypoglycemia, headache and vertigo.

**Part II: Effect of applying topical insulin dressing on diabetic foot ulcer healing by using Diabetic foot Ulcer Scale.**

In the present study, there was a significant improvement in diabetic foot ulcer for study group as compared with control group, this mean that Diabetic foot ulcer had better healing among insulin group than control group. This might be due to the physiology of insulin of accelerating wound healing. This finding was in accordance with (Stephen et al., 2016) who demonstrated that, diabetic foot ulcer score decreased for insulin group than saline group. Also, (Rezvani et al., 2009) they reported that, wound healing rates were significantly accelerated in insulin group than control group. Thus, insulin dressing decreases time required for healing. This proved that treatment with topical insulin was found to be safe and effective in reducing Diabetic foot ulcer size.

Finally, there was a positive correlation between diabetic foot ulcer healing score of study group and duration of foot ulcer from start. In the same direction (Venkatapuram et al., 2015) who proved that, topical insulin dressing improve healing rate and it significantly reduces the hospital stay. This might be due to minimize wound infection through proper insulin dressing which improve wound healing and reduce wound complications which lead to early hospital discharge.

## 5. CONCLUSION

According to the results of the present study, it could be concluded that topical insulin dressing provides favorable outcome in patients with diabetic foot ulcer by significant reduction in wound area when compared to routine hospital dressing.

## 6. RECOMMENDATIONS

*In light of the study findings, the following recommendations are proposed:*

- Application of skin assessment from admission until discharge.
- Using topical insulin dressing for patients with Diabetic foot ulcer.
- Developed booklet to learn diabetic patient for using topical insulin dressing.

**Further studies are needed to:**

- Replication of this study using large probability sample from different geographical areas.
- Study the effect of nutrition on healing of decubitus ulcer.

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