Efficacy of Applying Topical Insulin Therapy in Healing Process of Decubitus Ulcers in Immobilized Patients: A Randomized Control Study

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Abstract:

Decubitus ulcers are important health problems and one of the maintrials that health organization facingevery day. Now a day various innovative modality of wound treatmenthave been endorsed including wound care. Recently, application of topical insulin helpsin healing ofdecubitus ulcers. Therefore, **the aim of this study** was to investigate the efficacy of applying topical insulin therapy in healing processof decubitus ulcers in immobilized patients.**Design:** ARandomized control trial research design was conducted in Neurological and Medical Departments at Alexandria Main University Hospital. **Subjects:** this study composed of 60 patients divided into two equal groups, study group who receive topical insulin dressing and control group who receive routine hospital dressing. **Results,** indicates significant improvement in decubitus ulcers healing forthe study group compared control to their where p value (<0.05)**Conclusion,** topical application of insulin has a very powerful effect in healing process for decubitus ulcers. **Recommendation:** in service education program for nurses working in neurological and medical departments

Key words: Healing, Decubitus ulcers, Topical insulin therapy, Immobilized

Introduction

Immobility refers to a control and reduction in the level of movement. It is the inability to move the whole body or one of its parts. Immobility and bedridden can lead to some complicationssuch as skin breakdown anddecubitusulcers. Decubitus ulcers are described as injuries to the skin and surrounding tissues due to a continuous pressure at one or more places on skin. This pressure wedged between the bone and a surface, which limits blood flow leading to damage the tissuesand cells of the skin and sometimes finally dying **Miller et al (2018)**. According to NDUAP it is described as localized injury to the skin only or with underlying tissue commonly over a bony prominence, because of only pressure effect, or with shear or friction and can also be known as bedsores, decubitus ulcers, and pressure injuries **National Decubitus Ulcer Advisory Panel (NDUAP) (2017).**

According to **Agency for Healthcare Research and Quality (2018),** about five% to eight % of patients with immobilized are predicted to PUs in US, and rate of exposure to it is twenty five% to eighty five% yearly. Patients with spinal cord injuries have risk for death from this problem with range seven% to eight %. The rate of acquires bedsores in hospitalized patients for immobilized patients is anticipated to be three% to eleven%. The patients have a higher risk for developing pressure injuries. These include older adults, critical care patients, patients with a

fractured hip or spinal cord accidents, individuals with DM, persons that using wheelchair or who are bed ridden, patients who are motionless, incontinent, with neuromuscular and immobilized patients **(Melter, 2017).**

Skin is a complicated tissue, which contains more than one layer. An injury to this stratified epithelium must be taken into consideration **National Decubitus Ulcer Advisory Panel (NDUAP) (2017)** have described decubitus ulcers (DUs) as localized injuries to the skin and or underlying tissue, commonly over a bonyprominence region. DUs are a common condition, which affecting three million adults in the US. It's occurrence range from 0.4 to 38% in United State ofin acute care hospitals, to twenty four% in long term nursing centers and from zero to seventeen % in home care settings [3] Every year, billions of dollars are spent for treating DUs and their related complications. The fees of treating depend on its severity which generally starting from $2,000 to $20,000 per ulcer (**Abdelkader et al. ,2017**)

According to **European Decubitus Ulcer Advisory Panel (EDUAP)and NDUAP (2017)** DUs have 4 stages and additional 2 categories. Stage I is characterized by using of non-blanchable localized erythema. Stage II has shallow open ulcer without slough. Stage III is characterized by loss of whole thickness skin. Stage IV is characterized by whole thickness tissuesare lost, tissue necrosis and damage to bone. While unstageable is characterized by complete thickness tissue loss and presence of eschar within the wound bed. Suspected deep tissue injury is characterized with maroon discoloration with intact skin.

There are risk factors that predispose to bed sores development. These factors including immobility, general skin status, poor perfusion, poor sensory perception or response, Diabetes Mellitus (DM), poor nutrition, moisture, and low albumin **(Saleh et al ., 2017)**The preventive techniques for decubitus ulcers contain use of risk assessment tools to detect people at higher threat for it, maintain circulation to relieve the decubitus, turning and moving patients, skin care via the use of creams, dressings and control of incontinence and nutritional support **Saleh et al (2017)**

The standard of care for DUs consist in most cases of specialized dressings and wound care, in addition to other interventions such as the use of decubitus redistribution assisted surfaces, patient repositioning, oral nutritional therapy and antimicrobial therapy **(Spetz et al., 2017)** .Wound healing is a complex biologic process thathas impacts on its gene and protein levels; clot formation, irritation, granulation tissue improvement and remodeling. One crucial method initiated throughout the early stages of healing is re epithelialization; this involves the proliferation, migration, and differentiation of keratinocytes from the wound margins **Coleman et al (2017)**

In the management of decubitus ulcers the wound care is inevitable one. There are numerous antibiotic ointments used for improve healing. Now a days, the topical application of insulin in DUs 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 **Agency for Healthcare Research and Quality (2018) and Goenka et al (2017).**

Using insulin for dressing in chronic ulcers, proved that insulin had positive effects on wound healing**.** Also**Green et al (2018),** two studies have

been finished to evaluate the comparative role of insulin in the hastening of wound healing. Inside the first study, six diabetic and 5 non-diabetic human volunteers had two uniform cuts created, one on every forearm. One forearm wound was treated with topical regular insulin and the opposite with normal saline four times a day until healing. The injuries handled with insulin healed quicker than the wounds handled with saline.

Insulin acts through its receptors and aids in the migration of keratinocytes in wounds without interacting with the epidermal growth factor receptors. Insulin through insulin like growth factor-1 has also been shown to inhibit apoptotic pathway, attenuates the production of anti-inflammatory cytokines and stimulates production of extracellular matrix component **Ching et al(2016)**. Insulin is one of the hormonal mediators which sharing in collagen production. It takes part in all stages of wound healing through improving the extracellular matrix and collagen synthesis by increasing the proliferation of myofibroblasts during the fibroplasias stage, elevating the macrophage activation through some methods within the inflammatory stage, and through increasing keratinocytes differentiation, migration, and proliferation in the re-epithelial stage **Karginet al (2015)**.

Insulin has been utilized in wound healing to increase wound collagen, granulation tissue, wound tensile strength, and local production of insulin-like growth elements by means of fibroblasts. Also it has the ability to enhance this re epithelialization process, especially proliferation, migration, and extracellular matrix secretion by keratinocytes, endothelial cells (ECs), and fibroblasts **Valentini et al (2018) ;Bates and Jensen(2001)**. So; this study was conducted to evaluate the effect of applying topical insulin in management decubitus ulcers healing in immobilizedpatients.

Significance of the study:

According to the Statistical Record of Alexandria Main University Hospital, **2018** the incidence of decubitus ulcer in immobilized patients at medical &neurological departments are 48 % from 2019 and 2020 years.For these reasons, there was an urgent need to conduct this study to test evidence for using insulin as method for treatment of decubitus ulcers for immobilized patients. It is also hoped that this effort will generate attention and motivation for further studies into this topic.

Aim of the Study

This study aimed to investigate the efficacy of applying topical insulin therapy in healing process of decubitus ulcers in immobilized patients

Research hypothesis:

• Applying topical insulin on decubitus ulcers for immobilized patients exhibit faster wound healing than the patients who do not

• Applying topical insulin on decubitus ulcers for immobilized patients exhibit short hospital stay than the patients who do not

• Applying topical insulin on decubitus ulcers for immobilized patients exhibit less microorganisms than the patients who do not

Method

This part represents the methodology used to gather and analyze

data related to the research.

Study Design:

This study was A Randomized Control Trial (RCT) research design.

Setting:

This study was applied atMedical and Neurological Departments ofAlexandria Main University Hospital. This department consisted of two units, unit one andunit two. Unit one contain18 beds, while unit two contain29 bed. Medical department contain 33 beds.

Subjects:

A purposive sample was collected for a period about one year; it was comprised of 60 patients of both sexes. Patients selected according to sampling criteria. 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 (30patients) 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, replication of these cases was carriedout.

Criteria for selection of the subjects:

Inclusion criteria:

- Adult patients (20-60 years) with DUs grade II orIII

- Both sex

- Patient hasimmobilized

- Patients withoutDM

- Patients who are approved to share in thestudy.

Exclusion criteria:

- Patients with history of hypersensitivity toinsulin

- Patients had any other disorders such as pneumonia, immune-deficiency, infection

- Pregnancy

- Patients who are terminallyill.

Tools

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

Tool one: Socio-demographic characteristics and medical information:

This tool was developed by the researcherconsisted of two parts.

Part I: Socio-demographic data.

Part II: Medical information.

Part I: Socio-demographic data:

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 information sheet:

Category (1): patient health status data such as date of admission, patient diagnosis, past medical history, skin hygiene, level of immobility, presence of urinary incontinence, presence of stool incontinence, moisture, site, shape and degree of bedsores, using decubitus relieving devices and types of it, hemoglobin level, WBCs, culture swab results, Random Blood Glucose level, method of feeding based on review of related literature [11]

Category (2)"Mini Nutritional Assessment (MNA) ". The ″MNA″ test adapted from **Gauglitz (2018)**; it is composed 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 nutritionalstatus.

Tool two: Wound assessment tool

This tool was developed by the investigator after reviewing the related literature. It consisted of **seven items, five of this items had adapted from ″Bates-Jensen Wound Assessment Tool, 2001 ″;**to assess the following:

1- Skin color surrounding wound:	
● Pink	
● Bright red	(1)
● White or greypallor	(2)
● Dark red orpurple	(3)
● Black	(4)
	(5)
2- Amount of exudates:	
● None	(0)
● Light	(1)
● Moderate	(2)
● Heavy	(3)
3- Exudates type:	
● None	(1)
● Bloody	(2)
● Thin,watery	(3)
● Serous	(4)
● Purulent	(5)
4- Tissue type:	
● Necrotictissue	(4)
● Slough	(3)
● Granulationtissue	(2)
● Epithelial tissue	(1)
● Wound isclosed	(0)
5- Peripheral tissueedema:	
● Noedema	(1)
● Non-pitting edema extends <4 cm aroundwound	(2)
● Non-pitting edema extends >4 cm around wound	(3)
● Pitting edema extends < 4 cm aroundwound	(4)
● Pitting edema extends >4 cmaround	(5)
6- Presence of hotness	Yes / No
7- Presence wound bad odor.	Yes / No

Tool three: Wound measurements

It was developed by investigator to measure wound length and width through using measuring instruments that include transplant paper, marker, tongue depressor, a ruler and measuring tape.

Tool four: Decubitus Ulcer Scale for Healing (DUSH Tool)

It was adapted from **NDUAP(2017),** as a quick tool to monitor the change in DUs status over time. This tool categorized DUs with respect to **surface area, exudates, and nature of wound tissue.** Record a sub-score for each of these ulcer features. Add the sub-scores to obtain the total score. The evaluation of total scores measured over time offers a suggestion of the progress or weakening in DUs healing. **If ″DUSH ″ increase this refer to deterioration but reduction in ″DUSH″ refer to improvement as the following**:

Method

Administrative preparation:

▪ The approval was obtained from the ethical committee of the Faculty of Nursing at AlexandriaUniversity to implement this study atNeurological andMedical Departments atAlexandria Main University Hospitalafter clarification the purpose and nature ofthe study.

● Informed consent was obtained from the patientspre included in this study, postexplanation thenature and aim of the study. The researcher stressed that involvement in this study was completely voluntary, anonymity, and the patient can withdraw at any time without any effect on their care. Confidentiality and privacy were assured andrespected

Tools development:

● Tools: were developed by the researcher based on recent relevant literature review except tool two, four and ″MNA″ test was adapted. All tools were written in Englishform.

Validity and Reliability:

Content validity of tools was established by giving it to five experts Medical - Surgical Nursing , Neurologic and Medical departments to ascertain their validity content and it was 98.6% .The questionnaires' reliability was assessed using Cronbach's alpha and it was reliable as indicated by the value of 0.825 for tool one, 0.895 for tool twoand 0.98 for tool three and tool four

Pilot study: the pilot study was carried out on 10% of patients for testing the applicability and feasibility of the tools. The needed modification, additionand omission were finished. They were excluded from the study sample

Data collection:

▢ Data collection extended from 1/4/2018 to the end of February2019.

Procedure:

▢ The researcher started by introducing herself to patients of both groups and their relatives, and giving them brief idea about the aim of thestudy.

▢ Each patient was interviewed before dressing intervention for both groups to collect the necessary data using studytools.

▢ Culture swab was taken before the researcher start intervention for bothgroups.

▢ In first day of dressing for study group random blood sugar (RBS) level was measured10 minutes pre dressing and one-hourpost dressing in the first morning dressing.

▢ Second day for study group random blood sugar (RBG) level was measured10 minutes pre dressing and one hour postdressing.

☐Dressing was applied twice per day for both groups. One in the morning and other in evening.

☐Dressing was applied twice daily for oneweek.

Dressing for study group: It started with cleaning the wound with saline, then applying gauze soaked with insulin (10ml of insulin in 1000 ml of normal saline) for eachtype

, the gauze was left to dry and then covered with sterile dressing.

☐The researcher used two types of insulin that included act rapid andmixtard30/70.

☐In the study group, first fifteen patients used act rapid insulin for dressing, while second fifteen patients used mixtard30/70 fordressing.

☐Comparison between 2 types of insulin was done to determine if there were differences in the effect of them on DUshealing.

Dressing the wound for thecontrol group: the patients received the usually routine hospital dressing; cleaning the wound with saline or betadine then applying topical antibiotic, finally covered the wound with sterile dressing.

Evaluation for healing process:

The wound was evaluated for both groups for 2 times using second third, and fourth tool:

a) First time: immediately on the first day pre intervention.

b) Second time: one-week post intervention.

☐A comparison was done between study and control group to determine the

outcomes of consuming insulin dressing on improving thehealingof DUs.

Statistical analysis:

Data were collected, then entered, processed, and analyzed using IBM-SPSS software (version 21.0).

Data expression:

☐Quantitative data were initially tested for normality using Kolmogorov-Smirnov test and data were considered as normally distributed if p value >0.050 then data were expressed as Mean ± SD if normally distributed or Median and interquartile range (IQR) if not normallydistributed.

Data comparison:

☐ Qualitative data: Qualitative data were compared using Chi-square or Fisher's exact test.

☐ Quantitative data: Quantitative data were compared between two groups using Independent-Samples t-test if data were normally distributed or the non-parametric Mann-Whitney-U test if not.

☐ Comparison between two paired samples: Quantitative data were compared between two reading of the same group using Paired-Samples t-test if data were normally distributed or using the non-parametric Wilcoxon Signed-Ranks test ifnot.

Correlation:

☐ Pearson's correlation test was used to study the linear relationship between two quantitative variables if normally distributed while Spearman's correlation test was used if not.

☐ Partial correlation test was used when adjustment (controlling) for confounders was needed

Results

Table (1): Percentage distribution of patients of both groups according to their socio-demographic characteristics:

This table mentioned that, no significant difference was found between study and control groups as regard to sociodemographic characteristics. Concerning age, the median 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. In relation to occupation, (63.3% and 60%) were housewives in study and control groups respectively.

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

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

▪ Count [Percent] and p value (X^2value) through **Chi-squaretest.**
▪ Median and p value (Z value) through **Mann-Whitney test**

Table II: Percentage distribution of both study andcontrol groupspatients according to medical condition:

This table revealed that (73.3% and 40%) in both study and control groups had hypertension and (70%, 46.7%) had chest diseases respectively. Concerning level of mobility, all study participants of both were immobile. No one of participants had urinary

incontinence, while (3.3%) of study group complained from urinary leakage. Also, (20% and 36.7%) of study and control groups had stool incontinence respectively. Concerning the moisture status, all participants were dry except (6.7%) were moist. As regard to skin hygiene, (93.3% and 96.7%) in the study and control groups respectively had clean skin. About (93.3% and 86.7%) of study and control groups using decubitus relieving devices respectively. All study participants were having enteral feeding. As regard to hospital stay, the median for study and control group was (15.5 and 14respectively)

Table II: Percentage distribution of both study andcontrol groupspatients according to medical condition

Medical information	Study group (n=30)		Control group (n=30)		(X^2)	P
	No	%	No	%		
Past medicalhistory:						
Hypertension	22	73.3	12	40		
- DM	0	0	1	3.3		
- immobilized	6	20	7	23.3		
- Heartdisease	2	6.6	3	10	(87.002)	**<0.0001**
- GI/liver disease	1	3.3	1	3.3		
- Renaldisease	21	70	14	46.7		
- Chestdisease						
Level ofmobility:						
- Immobile	30	100	30	100	(1.017)	0.313
Mobile withassistant	0	0	0	0		
Presence of urinary incontinence	0	0	0	0	(0)	1
Presence of urinary leakages	1	3.3	0	0	(1.017)	0.313
Presence of stool incontinence	6	20	11	36.7	(2.052)	0.152
Moisture:						
- Moist	2	6.7	2	6.7	(0)	1
- Dry	28	93.3	28	93.3		
Skinhygiene:						
- Clean	28	93.3	29	96.7	(0.351)	0.554
- Unclean	2	6.7	1	3.3		
Use of decubitus relieving device	28	93.3	26	86.7	(0.741)	0.389
Devices used (n=54):						
- Airmattress	22/28	78.6	26/26	100	(6.268)	**0.012**
- Air mattress&pillow	6/28	21.4	0	0		
Method of feeding:						
- Enternal	30	100	30	100	(0)	1
Hospital stay	15.5		14		**P** 0.614	
	Z		(-0.504)			

- (X^2):**Chi-square test**.   P ≤ **0.050(significant)**

Figure (1): Illustrated distribution of DUs sites among study participants, as shown the common site of DUs was buttock, (83.33%) followed by back, heel, and ankle that represented (10%, 5%, and 1.67%) respectively.
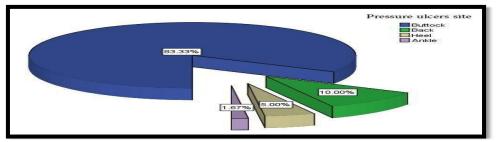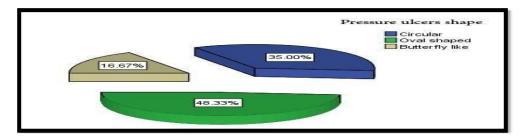

Figure (I): Percentage distribution of patients of the study groups according to decubitus ulcers sites (n=60).

Figure (II): Clarified distribution of DUs shape among study participants, (48.33%) of participants had oval shaped DUs, while (35%) had circular shaped decubitus ulcers, and the lowest proportion (16.67%) had butterfly DUsshape.

Figure (II): Percentage distribution of patients of the study groups according to decubitus ulcers shape (n=60).

Figure (III): Described distribution of DUs degree among study participants, the majority (83.3%) of participants had second degree DUs, but the lowest proportion (16.67%) had third degree DUs.
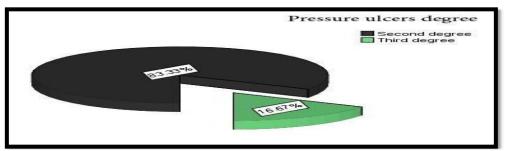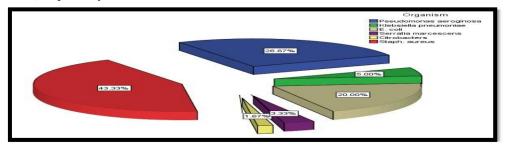

Figure (III): Percentage distribution of patients of the study groups according to decubitus ulcers degree (n=60).

Figure (IV): Discussed distribution of microorganisms types presented in DUs among study participants pre dressing. The most common microorganism was staph aurous organism (43.33%), followed by pseudomonas aeroginosa organism (26.67%) and E.Coli (20%). The lowest proportion involved klebsiella pneumonia, serratia marcescens and citrobacters (5%, 3.33%, and 1.67%) respectively.

Figure (IV): Distribution of microorganisms types presented in decubitus ulcers among study participants pre dressing (n=60).

Figure (V): Clarified distribution of study group pre dressing . About (50%) of study group was at risk of malnutrition, (30%) had malnourished and (20%) had normal nutritional status.
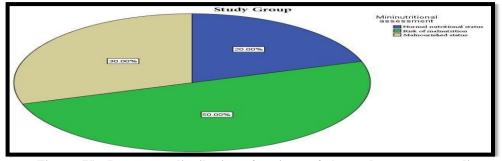

Figure (V): Percentage distribution of patients of the study groups according to Nutritional assessment pre dressing (n=30).

Figure (VI): showed percentage distribution of nutritional assessment of **control group**. The largest proportion (73.33%) was at risk of malnutrition, and (26.67%) had normal nutritional status.
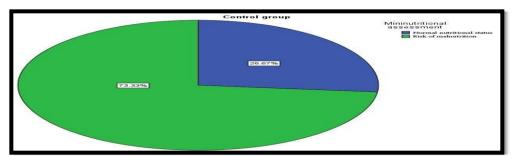

Figure (VI): Percentage distribution of patients of the control group according to Nutritional assessment

Table III: Comparison between study and control group patients in relation to laboratory findings (hemoglobin levels and WBCs counts) pre dressing

As observed from this table, there was a significant difference between two levels of Hg in study and control groups where p value was (0.001) but, no significant difference in WBCs count between study and control groups.

Table III: 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 samplest-test.**

Table IV: Difference between random blood sugar (RBS) level pre / post dressing among study group.

As shown from this table, the RBG values in first day pre dressing was (190±78.7) whereas after dressing was (177.2±67.7) which was statistically significant lower level (p=0.050) , a significant decrease in RBG level was observed in some participants in first day, but in second day no significant difference was in RBG level pre/post dressing.

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

Time of measurement	Mean ± SD of random blood sugar (RBS) (mg/dl)	p*
	Day 1	
Ten minutes before dressing	190.7 ± 78.7	
One hour after dressing	177.2 ± 67.7	**0.050**
	Day 2	
Ten minutes before dressing	180.7 ± 68.2	
One hour after dressing	178.3 ± 60.5	0.588

▪ p*: **Paired-samplest-test**

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

This table clarified that, there was a significant improvement in diabetic foot ulcer healingfor patients in the study group than their control. 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 the score was statistically significant decreased in study group at day 7 but in control group it hadn't changed significantly.

Table V: 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	**0.030**
P**	**<0.0001**	0.090	

- p* :mean **Whitney test**   p** : mean **Wilcoxon test**

Table VI: Comparison between of decubitus ulcer healing with relation to actrapid subgroups and mixtard subgroup dressing of study group at day one and day seven (n=30):

This table showed that, mixtard subgroup dressing had higher significant improvement in DUSH score than actrapid subgroup dressing where p value was (p= 0.001 and 0.002) respectively. This mean that both insulin types had improved DUs healing but, mixtard was more improver than actrapid in DUs healing.

Table VI: Comparison between of decubitus ulcer healing with relation to actrapid subgroups and mixtard subgroup dressing of study group at day one and day seven (n=30):

Timing	Act rapid subgroup dressing (n=15)	Mixtard subgroup dressing (n=15)	p*
	Mean ± SD, Median		
Day 1	10.3 ± 2.3, 11	11.7± 2, 12	0.121
Day 7	7.5±4.2, 9	9.8±3.3, 11	0.087
P**	**0.002**	**0.001**	

- p* : mean **Whitney test**   p** : mean **Wilcoxon test**

Table VII: Correlation between decubitus ulcer healing score of study and control group in day one and laboratory parameters(n=60):

As observed from this table, there was positive correlation between decubitus ulcer healing score of the study group , duration of bedsores, and white blood cells count where p values were (p= 0.002 , 0.027) respectively. Also, no significant correlation existedbetween decubitus ulcer healing score of control group and all laboratory parameters in day one.

Table VII: Correlation between decubitus ulcer healing score of study and control group in day one and laboratoryparameters.

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 bedsores in days	0.532	**0.002**	0.148	0.436
Use of decubitus relieving device	-0.008	0.967	-0.052	0.786
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	**0.027**	-0.086	0.650

▪ Pearson correlation coefficient

Table VIII: Correlation between decubitus ulcer healing score for patients ofthe study and control group in day seven and laboratory parameters.

This table commented that, there was no significant correlation between DUSH score of control group and laboratory parameter inday seven, but there was a significant correlation between decubitus ulcer healing score of study group and some parameters that included duration of bedsores in days and white blood cells count where p values were (p= 0.001 , 0.011) respectively. Whereas insulin decrease neutrophils infiltration and promote neutrophils functions and reduces the hospital stay of patient.

Table VIII: Correlation between decubitus ulcer healing score ofthe study and control group in day seven and laboratory parameters.

Parameter	decubitus ulcer healing of the study group (n=30)		decubitus ulcer healing of the control group (n=30)	
	R	P	R	P
Duration of bedsores in days	0.576	**0.001**	0.063	0.740
Use of decubitus relieving device	0.078	0.683	-0.080	0.672
Level of patient mobility	-0.071	0.721	0.120	0.528
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	**0.011**	-0.207	0.273

▪   Pearson correlationcoefficient

Table IX ,X: Correlation between decubitus ulcer healing score of study subgroups in day one and seven and laboratory parameters.

As observed from table 9 and 10, that decubitus ulcer healing scores of actrapid subgroup dressing was correlated significantly with duration of bedsores and WBCs count in day one and seven where (p= 0.012, 0.029, 0.003, 0.001) respectively. Regarding mixtard subgroup dressing, there was only significant correlation at day 7 with duration of bedsores where p value was (p= 0.031).

Table IX: Correlation between decubitus ulcer scale for healing score of study subgroups in day one and laboratory parameters.

Parameter	Act rapid subgroup dressing (n=15)		Mixtard subgroup dressing(n=15)	
	R	**P**	**R**	**P**
Duration of bedsores in days	0.630	**0.012**	0.505	0.055
Use of decubitus relieving device	0.313	0.256	-0.346	0.207
Device type	358	0.209	-0.051	0.862
Mini nutritional assessment	0.321	0.244	-0.229	0.411
Hemoglobin level	-0.207	0.460	-0.121	0.668
White blood cell count	0.564	**0.029**	0.247	0.323

▪ Pearson correlationcoefficient

Table X: Correlation between decubitus ulcer scale for healing score of study subgroups in day seven and laboratory parameters.

Parameter	Act rapid subgroup dressing(n=15)		Mixtard subgroup dressing (n=15)	
	R	**P**	**R**	**P**
Duration of bedsores in days	0.714	**0.003**	0.556	**0.031**
Use of decubitus relieving device	0.249	0.372	-0.063	0.824
Device type	-0.020	0.947	0	1
Multi nutritional assessment	0.340	0.216	-0.247	0.375
Hemoglobin level on admission	-0.365	0.180	-0.202	0.471
White blood cell count on admission	0.749	**0.001**	0.345	0.208

▪ Pearson correlationcoefficient

Discussion

Decubitus ulcers are significant health issues and one of the biggest challenges that organizations faces daily. Decubitus ulcers are localized damage to the skin and/or underlying soft tissue, commonly over bony prominences. The injury can appear as intact skin or an open ulcer and may be painful **NPUAP (2017)**.Preventing decubitus injuries have continually been a challenge, not only for caregivers, however for the health care organization as an entire, because the epidemiology of DUs varies through clinical setting.. The improvement of DUs can interfere with the patient's functional recovery, may be complicated by pain and infection, and can contribute to longer medical institution remain **Lyder and Ayello (2017)**

Wound healing process involves complex mechanisms that results in cell adhesion, migration, proliferation, and differentiation **Cooper (2017).**Recently topical insulin was used in wound

dressing, because it accelerates wound restoration. Insulin stimulates the growth and development of various cell types and impacts proliferation, migration, and secretion by using keratinocytes, ECs, and fibroblast **Lima et al (2017)** . **Therefore;** this study was aimed to evaluate the effect of applying topical insulin in healing of decubitus ulcers among immobilized patients.

Sociodemographic characteristics:

The results of the present study revealed that less than three quarter of the study subjects were females, this was in harmony with **Perneger et al (2018)** who mentioned that above half of his studied sample were females. In contrast **Nangole (2016)** reported that 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 was married, this results is in the same line with**Ikechukwu et al (2017)** reported that less than three quarter of his sample was married.

As regard to, level of education in the present study revealed that above half of the participants was illiterate. On other hand **Taha et al (2019)** 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 **Boa et al (2017)** . reported that the age of patients with DUs was above forty seven years. In

the same line, current study found that the median of age was fifty four years old. According to **Borghardtet al (2018)** highlighted that patients developed DUs with a length of stay greater than ten days. The present study revealed that the median of hospital study was 15.5 day.

A study carried out by **Abo Seda (2018)** illustrated that the highest incidence of DUs was in the hypertensive and chest diseases. The current study revealed that, less than three quarter of study participants had hypertension and chest diseases. In contrast, **Ikechukwu *et al* (2017)** mentioned that the majority hadn't DM and had paraplegia.

In relation to mobility level, all study participants were immobile. In the same point **Sharp et al (2017)** mentioned that immobility is thought to be one of the essential risk elements for DUs development and DUs have been most possibly to be developed within the more immobile patients. If someone can move independently at frequent enough durations, they're not likely to develop DUs. Repositioning is probably the oldest form of DUs prevention and remains at this moment the most crucial preventive measures of DUs

According to **Eraser et al (2016)** there was a positive relation between both incontinence and DUs occurrence. But in this study, only small percentage of patients had urinary incontinence and less than quarter had stool incontinence In the incident of incontinence, urinary urea stasis on the skin and pores to form ammonium hydroxide, an alkaline material that elevations the skin ph. and favors bacterial production. Fecal incontinence similarly plays a majorpart in skin irritation and might make a contribution to skin breakdown. Feces contain enzymes which includes; proteases and lipases that damage the

characteristic ofskin barrier.

In relation to moisture, in the present study almost all participants had dry skin. On other hand **Abo Seda (2018)** reported that there was a significant relation between moisture and DUs development. In additional to the majority of participants had clean skin, but **langemo(2016)** reported that poor personnel hygiene, the skin contains many organisms in which the warm, moist environment increase the risk for DUs development that may become infected. Also the incidence of DUs in the patients not using air mattress was higherthanpatientswho areusingairmattress,**Garg et al (2015)**recommended air mattress as an essential element of the treatment protocol of DUs. Also, in current study there was a significant relation between DUs development and using of air mattress and pillow.

Concerning method of feeding, the results of present study proved that all participants had eternal feeding. This may be attributing to the fact that most immobilized patients suffered from dysphagia. In the same way **Hartgrink et al (2016)** had proved that supplemental feeding improves the nutritional status, but there wasn't a relation with DUs development and severity. Meanwhile, a study carried out by **Dhandapani et al (2018)** found that the delayed attainment of eternal feeding influence the occurrence of DUs. This may berelated to the delayed calories replacement along with hyper metabolism result in muscle atrophy, diminished subcutaneous fat, and finally leading to DUsdevelopment.

In relation to nutritional status, the results of current study showed that the largest proportion was at risk of malnutrition, this result is in harmony with **Alhaug et al (2017)** who proved that

malnourished patients had a higher prevalence of DUs than adequately nourished patients. Also his results indicated that nutritional status was significantly associated withDUs.

The findings of this study showed also that the most common site of DUs were buttocks. This resultis in agreement with **Brito et al (2016)** thesereport that the most frequent location of DUs were the sacral region, this may due to the common dorsal position that patients assume in bed. While for DUs shape, slightly less than half of the study participants had oval shaped DUs. This was in the same line with **Taha et al (2019)** who mentioned that less than three quarter of participants had oval shaped DUs.

The finding of current study showed that the majority of participants had second degree DUs. In the same line **Jiang et al (2016)** observed that stage II had the highest prevalence forming. In contrast **Awwal et al (2018)**, illustrate that stage III and stage IV DUs occur as the common form of ulcers. This can be attributed to the reality that some health professionals dealing with the patients concerned only with the primary reason of health center admission rather than prevention of hospital secondary conditions. The ulcer is then observed at latter stages when it becomes offensive or when the patients or their relations complain.

Concerning microorganisms, the results of present study revealed that less than half had found staph aurous organism in DUs. This is in consistence with **Dana & Bauman, (2017)** who found that the most common organism was staph aurous. Also,**Bhosle et al (2017)** mentioned that most common microorganisms grown from culture taken from the lesion was staph auras followed by pseudomonas.

Regarding Hg level, there was a significant difference in Hg level. In the same direction **Feuchtinger et al (2017)** reported that an increased risk for DUs associated with reduced Hg and hematocrit level and occurrence of anemia. This may be related to deficiency of oxygen reaching the tissue.

Regarding correlation between DUSH score and laboratory parameters, the present study showed that there was a significant correlation between DUSH of study group and WBCs. In consistency with **Chen et al (2015)** illustrate that low-dose 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 healingprocess.

The findings of current study showed that, there was significant difference in RBG level before and after insulin dressing in first day. This is in disagreement with **Goenka et al (2017)**, who study role of topical use of insulin in healing of chronic ulcer, all diabetic patients were brought under glycemic control with appropriate ant diabetic therapy in his study. So that no statistically difference existed in RBG values pre/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.

In the present study, there was a significant improvement in DUSH for the study group as compared with control group, this means that DUs had better healing among insulin group than control group. This goes in line with **Goenka et al (2017)** who demonstrated that DUSH scores decreased for insulin group than

saline group. Also, **Rezvani et al (2018)** 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 DUssize.

The findings of this study also proved that both actrapid and mixtard had a significant improvement in DUSH scores, but mixtard was more effective than act rapid. This may be attributed to fact that act rapid is a neutral solution of human insulin because it recall fast acting insulin, mixtard 30/70 is a pre-mixed neutral suspension of human insulin together with neutral insulin injection (30%) and isophane insulin injection (70%) and it consider long acting insulin **European Medicines Agency (2017)**.According to **Goenka et al(2017)**using actrapid for dressing in chronic ulcers, proved that act rapid had demonstrated positive effects of insulin on wound healing. Also, **Venkatapuram et al (2016)**found that local mixtard therapy has an effective method in the treatment of chronic ulcers and issafe.

Finally, there was a positive correlation between DUSH score of study group and duration of bed sores from thestart. In the same direction **Venkatapuram et al (2016)** proved that topical insulin dressing improve healing rate and it significantly reduces the hospitalstay.

Conclusion

This study concluded that using insulin dressing was more effective and safely method to accelerate DUs healing than using hospital routine dressing. Mixtard was slightly more effective than actrapid on decubitus ulcers healing.

Recommendations

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

A. For the nurses:

- Application of skin assessment for immobilized patients from admission untildischarge.

- Conferences, workshops should be applied arranged continuously for nurses to upgrade their knowledge and practice regarding decubitus ulcer.

- Using topical insulin dressing for patients withDUs.

- In service education program for nurses working in neurological unit to update their skills

- Provision of adequate nutrition for prevention of DUs and proper treatment of it.

Further studies are needed to:

- Replication of this study using large probability sample for more evidence.

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- No.

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