

Effect of Safety Insulin Administration Guidelines on Reducing Of Acute Complication For Diabetic Patients at Selected Hospital In Al-Taef city.

Enshrah R. Mohamed¹, Huson A. Ghalya² and lobna M. Gamal Ali

¹ Medical and Surgical Nursing Dep. Faculty of Nursing- Minia University & Assistant professor of Medical and Surgical Nursing Faculty of Nursing-Umm-Alqura University

² Critical Care NursingDep., Faculty of Nursing- Umm-Alqura university.

³ Medical and Surgical Nursing Dep. Faculty of Nursing- Minia University& Assistant professor of Medical and Surgical Nursing Faculty of Nursing-King Faisal University.

sosomohamd19@yahoo.com

Abstract: Diabetes mellitus (DM) is a chronic multisystem disease related to abnormal insulin production, utilization or both. Complications of diabetes mellitus can be classified into acute and chronic. Nursing responsibilities for the patient receiving insulin include proper administration, assess response to insulin therapy, and education of the patient regarding administration to prevent or reduce the occurrence of complications. Safety insulin guidelines are developed by American Diabetes Association to maintain safe insulin administration practices. The present study aimed to evaluate the effect of using safety measures guidelines during insulin administration on reducing of acute complication for patient with diabetes. **Subjects and methods** Subjects A convenient random sample composed of 40 female adult patients. **Setting:** The study was conducted at the medical ward and outpatient affiliated to selected hospital in Al-Taif. **Three Tools** were used to collect the data for this study **1st. Tool** were used to collect the data covering biosocial and demographic data and assessment data related to patient's insulin; **2nd. Tool** included observational checklist assessment sheet to assess presence or not of any acute complications for diabetes among study group and **3rd. Tool:** involve formulated safety insulin guidelines practices was used during insulin administrations. **Results** there is significant differences between experimental and control groups after teaching and demonstrating of safety insulin guidelines practices. It is **concluded that** application of safety insulin guidelines practices have significant effect on the reduction of acute diabetes mellitus complication, the most affected acute complication reduced are a local skin reaction dawn phenomenon and somogyi phenomenon. It was **recommended** that Information must be always available whenever patient needs clarification about insulin administration through responsible nurse and available of educational materials.

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1. Introduction

Diabetes mellitus (DM) is a major public medical health problem in a worldwide, it can affect individual's health through involvement of several body systems. Inevitable complications of diabetes mellitus may end up crippled in a way or another to a diabetic patient for: loss insight, having leg amputation and coronary artery disease (CAD)⁽¹⁾. The prevalence of diabetes in Saudi Arabia according to sex was 34.1% in males and 27.6% in females ($P < .0001$). The mean (SD) age for onset of diabetes in males and females was 57.5 (13.1) and 53.4 (13.1)⁽²⁾. Complications of diabetes mellitus develop as a result of uncontrolled blood glucose levels. It can be classified into acute and chronic. Acute complications develop either as an immediate response to blood glucose levels (low or high) or over a period of few days, and are treated as medical emergencies⁽³⁾. Most acute and severe complications of DM occur in both types of DM (type 1 and 2) mortality rate in

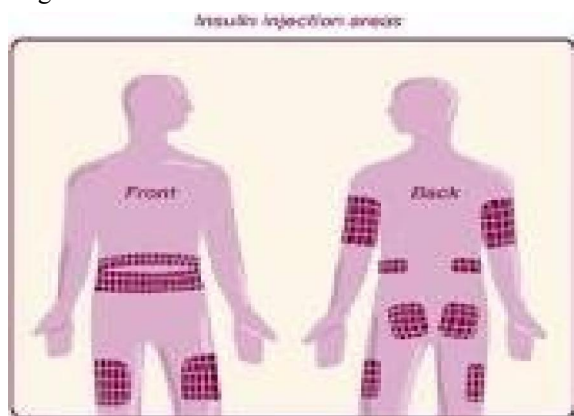
hyperketonic hyperosmolar (HHs) is raging from 10-50%, depending on underlying disease. Mortality rate in diabetic ketoacidosis (DKA) is less than 5%. A prevalence of microvascular complications was, retinopathy 23.7%, nephropathy 5.5%, neuropathy – 27.5% & prevalence of CHD 11.4% & PVD was 4%. In study from North Delhi Diabetes Centre. comprising 720 type-2 diabetics, retinopathy was seen in 21.2%, micro-albuminuria in 41%, peripheral neuropathy in 15.3%, CAD in 7% & PVD was in 7.4% of patients⁽⁴⁾.

The management of Diabetes requires a lot of learning because it is a complex condition that to manage, e.g. learn about diet modifications, glucose monitoring, lifestyle modifications, risks associated with uncontrolled glucose levels, symptoms of hypo- and hyperglycemia, treatments for hypo- and hyperglycemia and (if on insulin injections), and safely insulin injections. Educational materials should always be given, but for insulin injection, a

demonstration and return demonstration teaching plan is necessary⁽⁵⁾

Self-monitoring of blood glucose (SMBG) is a cornerstone of diabetes management, by providing a current blood glucose reading, enables the patient to make self-management decision regarding diet, exercise, and medication. SMBG is also important for detecting episodic hyperglycemia and hypoglycemia⁽⁶⁾. Insulin is a hormone, normally secreted by the pancreas, which performs a number of functions in the body, the most notably is controlling blood sugar levels⁽⁷⁾.

A skilled injection technique found to make the patient's experience less pain and avoid unnecessary complications. For all SC injections researches focus on the importance to maintain aseptic procedures. The sites suitable for administering SC injections are the lateral aspects of the upper arm are a favorable choice as the arms have fewer large blood vessels and less painful sensations, thighs and the umbilical region of the abdomen...ect⁽⁸⁾.



Figure(1):Illustrate sites used for subcutaneous injections

Assessment of the patient who is new to insulin must include an evaluation of his ability to manage this therapy safely such as assess the ability to understand the interaction of insulin, diet and activity. assess patient's cognitive skills to do these things. Many pts. are fearful when they first begin using insulin. Some pt. find it difficult to self-inject because they are afraid of needles or pain associated with an injection⁽⁹⁾.

The nurse should include the following instruction when teaching the patients about insulin therapy such as: Wash hand thoroughly ;Always inspect insulin bottle before using it. Make sure that is the proper type and concentration, expiration date has not passed, and top of bottle is in perfect condition ;If insulin solution are cloudy, the insulin bottle needs to be gently rolled between the palms of hands to mix

the insulin; Select proper injection site; Cleanse the skin with soap and water or alcohol; Pinch up the skin, and push the needle straight into the pinched-up area (90 angle).if very thin may need to use a 45 angle; Push the plunger all the way down, let go of pinched skin, leave needle in place for 5 sec to insure that all insulin has been injected, and then remove needle; and Destroy and dispose of single-use syringe safely⁽¹⁰⁾.

Aim of the study :

The study aimed is to evaluate the effect of using safety measures guidelines practices during insulin administration on reducing of acute complication for patient with diabetes.

Subjects and Methods

Research design:

A Quasi experimental research design will be used to carry out this study.

Subjects

A convenient random sample composed of 40 female adult patients, They were classified into (20) patients as a study group and other(20) patients as a control group, whereas sample was selected under the following inclusive and exclusive criteria.

Inclusion Criteria :-

- Mentally oriented, stable and able to understand information.
- Patients with current or past history of diabetes type (1) and type (2)
- Insulin administered by subcutaneous injection.

Exclusion Criteria :-

- Elderly patients >65 years.
- Patients with state of confusion or coma.
- Patients have psychological or intellectually disability.

Setting:

The study was conducted at the medical ward and outpatient affiliated to selected hospital at Al-Taifcity.

Theoretical framework

Orem's theory assumptions are that people should be self-reliant and responsible for their own care and promoting self-care behaviors. Based on Orem's theory actions of the nurses directed to help individuals or groups under their care to maintain or change conditions in themselves or their environments and health education considered one of major nursing actions that lead to patient demonstrating effective self-care^(11& 12).

This study based on Orem's self care theory assumptions as diabetic patients considered a biopsychosocial being capable of self care, and that nurses actions depended on formulated safety insulin administration guidelines practices are directed toward educating and implementing of patients for

proper and safety insulin self injection, increasing patients self reliance to maintain his health and decrease acute DM complications that may occur with them.

Study Tools

Three tools were used to collect the data for this study established in English language based on extensive literature review and designed and tested by the researcher, and pilot study was conducted.

First Tool: An interview questionnaire sheet, it was designed in English language by researcher and based on literature review **it included two parts:**

1st part covering biosocial and demographic data of the patient as age, sex, level of education, occupation,etc.

2nd part included assessment data related to patient's insulin which covering the following items: its type, duration of insulin using, dose, type of syringe, and time of injection....etc.

Second Tool included observational checklist assessment sheet used pre applying safety insulin administration guidelines practices and after one month to assess presence or not of any acute complications for diabetes among study group e.g. Local allergic reactions such as redness, swelling, tenderness, and indurations, systemic allergic reactions (generalized urticaria, edema or anaphylaxis), Lipotrophy, and Lipohypertrophy...and the other acute complication as hypoglycemia, hyperglycemia and diabetic ketoacidosis (DKA).

Third Tool: involve formulated safety measures guidelines was used during insulin administrations designed by **Siminerio, et al. (2011)⁽¹³⁾** who developed the strategies for Insulin Injection Therapy in Diabetes Self-Management and published by the American Association of Diabetes Educators. A brochure in simple Arabic language to every patient for study group was to reinforce practice and used as teaching aid was developed by researchers according to previous mentioned guidelines

Methods

- Administration permission to conduct the study was obtained from the director of selected hospital at Al-Taif city after explanation of the aim of the study.
- Development of the study tools, safety measures guidelines during insulin administration and the tools after reviewing the related literature was done.
- The tools were reviewed for clarity, feasibility, applicability, and the content validity of the tools and all the necessary modifications were done.
- Data pertinent to the study will be collected through interview and a direct observation will be utilized for data collection.

Procedure:

- The volunteers read a detailed description of the protocol and provided a written informed consent was obtained from each participating patients to be included in study clarification of the nature and purpose of the study was done on initial interview with each patients. The researchers emphasized that the participation is voluntary and confidential. The following aid was designed:
- The data collected and teaching of safety measures guideline during insulin administration were given on three sessions, which were conducted on three meetings every meeting was carried out from the first day from patients' admission at medical department or outpatient appointments in morning shift and the time spent in these sessions with each patient ranged between 30 – 60 minutes.

The Three Sessions Were:

- **The First Session:** Included information about socio-demographic data, insulin history and presence or not of acute complications of diabetes mellitus; Provided information and demonstration of practices related to safety measures guidelines practices during insulin administration (as use of insulin kits, measures of insulin dose, right rout for insulin administration and subcutaneous injection sites...ect) and giving a patient's the brochure (teaching aid).
- **The Second Session:** assess level of patients performance related to safety measures guidelines practices during insulin administration through redemonstration.
- **The Third and Last Session:** Evaluation of study group: to assess presence or not of any acute complications among diabetic patients after one month (follow-up) of patient's demonstration for safety measures practices in medical ward or outpatient clinic. Assessment of acute complications was achieved through reviewing patients clinical records, patient complaining, and through glucocheck to assess immediately random blood sugar.
- A brochure in simple Arabic language to every patient for study group its contents include instructions and pictures illustrating the safety measures guidelines practices during insulin administration were visible for illiterate patients.
- Data collection take approximately two months started from the first of The-Alqeda 1433H.

Pilot Study

A pilot study was conducted on a number of 10% (4) from patient's size to test the clarity and feasibility of assessment sheet and tools accordingly, the necessary modifications were done.

Ethical consideration:

- After approval of the ethics committee, an official permission was obtained from director and head of medical ward and outpatient department for selected hospital at Al-Taif city to collect data.
- Obtaining a voluntary acceptance the study subjects to participate in the study. The significant and purpose of the study was explained to them and confidentiality of any obtained information was ensured to them.
- Needed permission was obtained through the appropriate channels.

Statistical design

Data were collected, revised, coded, tabulated and analyzed using the numbers frequency and percentage distribution by using Statistical Package for Social Science. (SPSS) Version 16. Appropriate statistical methods tests (t-test) was used to calculate the differences between two independent variables. A significant P. value was considered when P. value was less than 0.05 and highly significant when P. value was less than 0,01

3. Results

Table (1) Distribution of the study sample according to their age.

Age	Categories	No.=40	100%
	From 18-28 years	2	5.0
	From 29-38 years	1	2.5
	From 39-48 years	5	12.5
	From 49-58 years	9	22.5
	From 59-65 years	23	57.5

Table (1): Shows distribution of the study sample according to their age. It was found that more than half of the sample were in the age group 59-65 years.

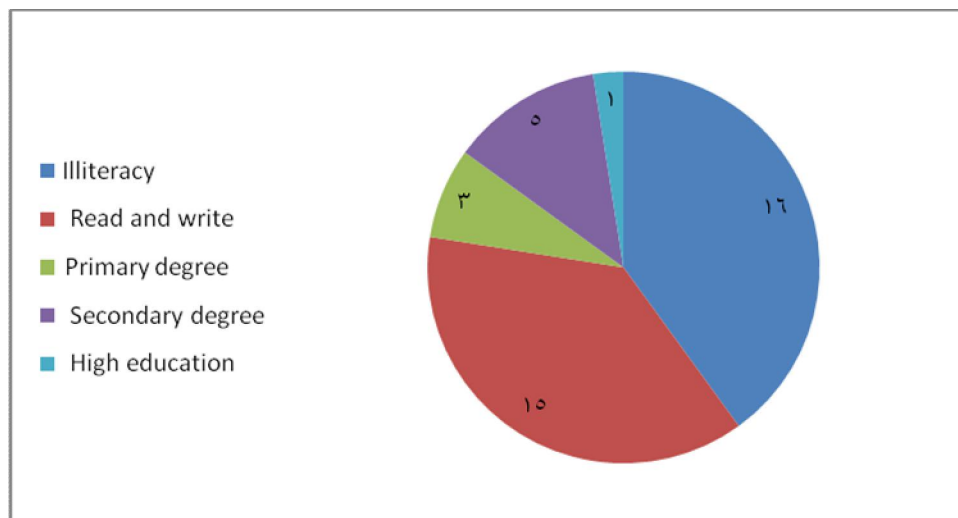


Fig.(2): Distribution of the study sample according to education level

Fig. (2): Shows distribution of the study sample according to education level. It was described that the highest percentages of the study group were (40%)& (37.5) Illiteracy and Read and write respectively.

Table (2) Distribution of the study sample according to their nutritional assessment.

Nutritional Category	No.=40	100%
1- Daily intake of Meals		
• <3 meals	13	32.5
• From 3-5 meals	20	50.0
• >5 meals	7	17.5
2- Patient's body build		
• Normal weight	18	45.0
• Thin	9	22.5
• Obese	13	32.5

Table (2) Shows distribution of the study sample according to number of meals intake. It was found that the half of study sample their meals intake were (50.0%) from three to five meals per day. Concerning Patient's body build it was stated that the highest percentage among study group were (45.0%) with normal body build while It was found that the lowest percentages (22.5%) among study group were thin

Table (3) Distribution of the study sample according to their assessment about insulin.

Insulin assessment	No. N=40	% 100%
Insulin type		
1. Rapid acting insulin	14	35.0
2. Long acting insulin	25	62.5
3. Pre-mixed Insulin	1	2.5
Time duration of insulin using		
1. Less than 6months	2	5.0
2. From 6- 24 months	0	0.0
3. 13-24 months	1	2.5
4. More than 24 months	37	92.5

Table (3) Shows Description of sample according to their insulin type intake. It was found that the highest percentages of the type were (62.5%) in the long acting insulin. It was found that the lowest percentages of the type were (2.5%) in pre-mixed insulin.

Table (4) Difference between the experimental and control group according to presence acute complications for DM before and after applying of safety measures during insulin administration.

Presence of DM complications	group	N	Mean	SD	t- value	Sig.
Before Teaching	Exp.	20	5.5500	2.28208	0.06	Not significant
	Control	20	5.5000	3.01749		
After Teaching	Exp.	20	7.7000	1.89459	2.66	0.01
	Control	20	5.5500	3.08605		

Table (4) Shows difference between the experimental and control group according to presence acute complications for DM among before and after applying of safety measures during insulin administration. It illustrated that there is no significant differences between experimental and control groups related to acute complications for DM before use of safety measures during insulin administration. while there is significant differences between experimental and control groups after teaching of safety measures during insulin administration.

Table (5) Correlation between socio-demographic characteristics of the study group and presence of acute complications for DM.

Socio-demographic characteristics	Mean	SD	t- value	Sig.
Age	3.892 3.252	4 35	1.197	Not significant
Education level	7.001 2.896	4 35	2.417	
Occupation	7.177 3.109	2 37	2.309	

Table (5) Shows the correlation between socio-demographic characteristics of the study group and presence of acute complications for DM. It revealed that there no significance correlation between socio-demographic characteristics of the study group and presence of acute complications for DM.

Table (6)Percentage distribution of acute complications for DM between the experimental and control group.

Presence of Complication	group	% Before	% After
1. Diabetes ketoacidosis (DkA)	exp.	0.35	0.35
	control	0.50	0.50
2. HyperglycaemicHyperosmolar State (HHS)	exp.	0.45	0.50
	control	0.45	0.45
3. Dawn Phenomenon	exp.	0.55	0.05
	control	0.45	0.40
4. Somogyi Phenomenon	exp.	0.60	0.20
	control	0.40	0.40
5. Hypoglycaemia	exp.	0.35	0.10
	control	0.10	0.10
6. Diabetic Coma	exp.	0.15	0.15
	control	0.50	0.50
7. Diabetic Foot	exp.	0.40	0.25
	control	0.45	0.40
8. Local skin reaction	exp.	0.70	0.00
	control	0.65	0.65
9. Systemic Allergic Reactions from insulin	exp.	0.40	0.20
	control	0.45	0.50
10. Lipotrophy or Lipohpertyrophy	exp.	0.50	0.50
	control	0.55	0.55

Table (6) Shows percentage distribution of acute complications for DM between the experimental and control group. It presented that highest percentage among both study groups were (70%) had local skin reaction before applying of safety measures during insulin administration. While after applying of safety measures during insulin administration it was found that most acute complications reduced among experimental group were local skin reaction Dawn Phenomenon Somogyi Phenomenon constituted 0% & 5% & 20% respectively.

4. Discussion

The majority of the sample size in the study group were in the age group 59-65 years this results

may related to prevalence of diabetes mellitus in urban Saudi Arabia was raised with age. there finding was supported by **Gibney, et. al (2010)**. & **American Diabetes Association (2004)**^(14& 15) that mentioned in a recent study,The results showed an overall prevalence of 4.3%. There was a rise of prevalence with age and higher-income groups. Also **National Diabetes Information Clearinghouse NIH(2011)**⁽¹⁶⁾ stated that among U.S. residents ages 65 years and older, 10.9 million, or 26.9 percent, had diabetes in 2010.

As regard to education level of the patients in this study it was found that highest percentages of the study group were illiterate and read and write respectively this results may be indicated that are a

correlation between study group age and education level. Moreover, the results of the study demonstrated that the half of study sample their meals intake were from three to five meals per day this may related to patient's want to avoid glucose level alteration. This finding is in the same line with **American journal occupational therapy(2011)**⁽¹⁷⁾ reports that for people with diabetes, eating small, frequent meals rather than three large meals may be better with for proper nutritional balance and glucose stability.

Concerning patient's body build it was stated that the highest percentage among study group were (45.0%) with normal body build while It was found that the lowest percentages (22.5%) among study group were thin this may be due to relation between numbers of diet meals and insulin therapy.

Furthermore, the study results revealed that, more than half of the study sample reported were received a long acting insulin while lowest percentages received a pre-mixed insulin this results that patients use insulin as prescribed and their condition needs⁽¹⁸⁾. The studies were similar to that of the present study were revealed that many types of insulin are available, including rapid-acting insulin, long-acting insulin and intermediate options used depending on patient's needs and doctor prescribed a mixture of insulin types with type 2 diabetes. Also **Australian Institute of Health and Welfare, AIHW (2012)**⁽¹⁹⁾ recorded that in the period 2000 to 2009, 222,544 people began using insulin to treat their diabetes. Of those people who began using insulin, the majority (77%) had Type 2 diabetes.

In addition, the results founded that there were the highest percentages of the study sample were used insulin for more than 24 months. This may related to the study group were old age. Study shows that there were no significance difference between control and experimental group before applying safety insulin administration guidelines this may be related to that both groups have nearly the same demographic characteristics,

As regard to the percentage distribution for acute complications for DM before applying safety insulin guidelines practices among control and experimental group the current study represented that diabetic local skin complications were highest percentage with both experimental and control group this could be related to lower educational level of the study sample as well as the incorrect injection technique. This not similar with another study incidence who stated local skin complications was 53% among DM patients⁽²⁰⁾.

Additionally Somogyi phenomena was found that two third of experimental group experienced somogyi phenomena this may due inadequate of patient's knowledge related to insulin dose and route

this incongruent with study that mentioned that incidence of diabetic patients on intermittent insulin injection therapy show that 30% of patients developed somogyi phenomena⁽²¹⁾.

Additionally, the current study founded that nearly half of the study sample complain from dawn phenomenon which is supported by another study that reported an Approximately 54% of patients with type 1 diabetes and 55% of patients with type 2 diabetes experience the dawn phenomenon⁽²²⁾.

Diabetic foot also seen as a common problem with study group, it range around half from experimental group, this results indicated lack of patient's education and follow up. These findings was higher with other studies who found that the lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25% and people at greatest risk of ulceration can easily be identified by careful clinical examination of the feet: education and frequent follow-up^(23& 24). Moreover on the contrary with **Boulton, et.al.(2009)**⁽²⁵⁾ shows that effect relation between blood glucose concentrations and micro-vascular complications in patients with insulin-dependent diabetes mellitus has not been established. Lastly **Singh, et.al.(2005)**⁽²³⁾ stated that cornerstones for the prevention of diabetic foot of guidelines based care are intensive glycemic control (IGC) and optimal foot care (OFC).

Less than half of the experimental group complained from systematic allergic reaction due to their type and duration of insulin used. This considered high percentage in comparison with other study which reported that highly purified human recombinant insulin, allergy to insulin has become a very rare clinical situation, encountered in less than 1% of patients⁽²⁶⁾.

Additionally, hypoglycemia occurred among one third from experimental group this may related to noncompliance from study sample with insulin therapy, diet therapy and level of activity. The findings of **Hepburn, et.al. (2009)**⁽²⁷⁾ similar to current study who stated that hypoglycemia is common in those who are intensively treated with insulin. Also another study found that rates of hypoglycemia increased as the duration of people treated with insulin therapy increased, after 25 years or more of treatment⁽²⁷⁾.

According to apply of safety insulin guidelines for the experimental group found that it had positive impact on the reduction of acute diabetic complications. The first acute complication that show the significantly influenced by applying safety insulin guidelines was the reduction of local skin reaction which is supported by another research that reported significant reduction of local skin reaction after training patients correct way of insulin

injection⁽²⁰⁾. The second acute complication reduced was Dawn phenomenon this may be due to give of correct dose of insulin in correct time appears to minimize the effects of the dawn phenomenon. This results agree with⁽²²⁾.

Also, Somogyi phenomenon had less occurrence after applying safe insulin guidelines practices among experimental group this results due to patient's glucose were controlled. This results agree with study which shows that glucose monitoring and regulation have major effect on decreasing somogyi phenomena, and the reduction of evening insulin doses reduce the occurrence of this phenomena⁽²¹⁾. Hypoglycemia was significantly reduced around one quarter among experimental group after applying safety insulin guidelines practices, but still the occurrence of diabetic coma in the same group was not affected due to increased percentage of hyperglycemia in experimental group this could be related to enhanced patients awareness of signs of hypoglycemia and early management, in addition to decreased level of activity and non-compliance with diet therapy. This found by **Hepburn, et.al. (2009)**⁽²⁷⁾ that maintaining glycemic control and correct dose, time and administration of insulin in conjugant with diet control and glucose monitoring decrease significantly the recurrence of diabetic coma.

Also occurrence of diabetic foot was slightly reduced around one quarter among experimental group this may be due to the short period of the study and diabetic foot requiring further management, although⁽²³⁾ concluded that preventing the development of foot ulcers in patients with diabetes reduces the frequency by 49–85%. Systematic allergic reaction occurrence found to be decreases during study period this may be related that this reaction was managed over time by giving small doses of insulin for desensitization. This agree with **Reichard, et.al. 1993**⁽²⁶⁾ found that the major cause of systematic allergic reaction is due to sensitivity of insulin preparation. Finally, there were no significance relationship between demographic data as age, literacy and level of occupation in relation to the presence of total acute DM complications among control and experimental group before or after applying insulin administration guidelines this may be due to demographic characteristics of study group were in age group 55–65 years with low level of education. This results disagree with **Eledrisi, et.al. (2005)** & **Castéra et.al. 2005**^(28&29) who mentioned some of these acute complications are relatively related to certain age groups^(20&25&26).

Conclusion

Application of safety insulin administration guideline have significant effect on the reduction of acute

diabetes mellitus complication in experimental group in relation to control group. It was found that most acute complications reduced among experimental group were local skin reaction Dawn Phenomenon Somogyi Phenomenon constituted 0% & 5% & 20% respectively.

Recommendations Based on the findings of the study the researchers recommends the following:

1. Provide frequent training for nurses about new information related to patient's safety and care of patients to improve their skills and knowledge.
2. Information must be always available whenever patient needs clarification through responsible nurse and available of educational materials
3. Nursing educators must reexamine current approaches to clinical teaching and seek methods to better preparation.
4. Further studies concerning patient's safety during medication administration in all hospitals.

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