

Effectiveness of an Evidence Based Insulin Injection Guidelines Application on Diabetic Children Mothers' Awareness about insulin injection: A quasi experimental study

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Abstract: Type 1 Diabetes Mellitus is one of the most frequent chronic diseases where its incidence increased from birth to 12 years with a peak between 10-14 years of age. Insulin therapy is a drug of choice and become a routine part of daily life for diabetic children /families . However, errors in injection technique and self-dosing increase the likelihood of serious adverse events as lipohypertrophy, hypo and hyperglycemia that can be avoided through increase mothers and diabetic children awareness Study aim was evaluate effect of an Evidence Based Insulin Injection Guidelines Application on Mothers' Awareness about insulin injection and its complication on their diabetic children. Methodology: A quasi experimental design was used Setting: inpatient department and outpatient clinic of endocrinology. Subjects was 61 mothers of school age diabetic children. Four tools were used; I was an interview questionnaire that assessed sociodemographic characteristics of mothers and also children plus children clinical data ;II was insulin Injection Technique Questionnaire (ITQ) that assessed mothers' insulin injection knowledge ,attitude and skills ;III was insulin injection checklist that assessed mothers' pen and syringe insulin injection techniques and tool IV lipohypertrophy checklist that assessed presence and grades of diabetic children lipohypertrophy. Results: regarding total percentage score of mothers Knowledge, Attitude and Practices about insulin injection pre, immediately and post 6 months from Evidence-Based Insulin Injection Guidelines Application were improved with statistically significant differences $p < 0.001$;while complication of insulin injection among diabetic children as lipohypertrophy, hypo and hyperglycemia and bleeding had no statistically significant differences where pain 98.0% of children had no pain pre Evidence-Based Insulin Injection Guidelines Application compared to 57.5% post 6 months with statistically significant differences $p = 0.001$ and the rational of this variation returned to improper insulin injection rotation that leading to painless feeling with injection (lipohypertrophy). Conclusion: Evidence-Based Insulin Injection Guidelines Application improved diabetic children mother awareness about insulin injection .Recommendation: insulin injection remain a crucial part in management of insulin dependent diabetes mellitus and a gap in mothers' awareness about insulin injection and its complication need basic education of proper insulin injection that not requires a major changes in health care system.

Keywords: T1DM= Type 1 Diabetes Mellitus, IDDM= Insulin Dependent Diabetes Mellitus, EBIIGA= Evidence-Based Insulin Injection Guidelines Application, KAP = Knowledge, Attitude and Practices, LH= lipohypertrophy.

1. INTRODUCTION

Type 1 diabetes mellitus (T1DM) is one of the most common endocrine and metabolic disorders which considered as second most common chronic disease in childhood where a destruction of pancreatic β cells that responsible about insulin secretion and this distraction caused by autoimmune destruction of the pancreas or idiopathic process. (**kkooorns et al., 2017** and **Smith. M, Simmons.M and Cambier C,2017**)^(1,2) The diabetic children usually have a permanent and sever insulin deficiency results in decrease insulin utilization so their bodies cannot make enough insulin on its own and depending on the daily insulin injection where the insulin therapy is the choice of treatment while hepatic glucose production increase and leading to hyperglycemia (**Dawood and Qadori 2018**)⁽³⁾.

In Egypt, incidence and prevalence of insulin dependent diabetes mellitus (IDDM) where nearly 1 in every 400 to 600 children with increasing over the past 18 years (**El Ziny et al., 2014**)⁽⁴⁾. Worldwide, the incidence was increased to be around 3% in children under age 15 years. According to (**Craig ME, Hattersley A and Donaghue KC 2009 & IDF 2013 and Levy 2016**)^(5,6,7) diabetic teenagers represents 80%-90% of diabetes children due to genetic and environmental factors. There are two main peaks of incidence in diabetic children, the first one occurred between age of 5 to 9 years and the second at 10 to 14 years and the peak occurs 2 to 3 years earlier in girls than in boys in older age group.

American Diabetes Association ADA,(2014)⁽⁸⁾ mentioned that the disease often starts suddenly with polyuria, polydipsia, polyphagia, excessive fatigue, lack of energy, sudden weight loss, slow of wounds healing, blurred vision, frequent infections, diabetic ketoacidosis following severe dehydration in addition the diabetic children may have other autoimmune diseases as, Addison's disease, myasthenia gravis, pernicious anemia, Graves' and Hashimoto's thyroiditis.

Unproper management of IDDM may expose the diabetic children for life threatening or acute complication as hypoglycemia with prevalence of 25% - 55% in Africa which associated with poorer cognitive function and diabetic ketoacidosis that represent 15% - 70% of newly diagnosed children and adolescents with T1DM and considered as a major cause of morbidity and mortality while long term or chronic complication (micro and macro-vascular) where microvascular includes neuropathy, nephropathy and retinopathy in addition to macrovascular as peripheral vascular, cerebrovascular and cardiovascular disease complication (**Usher-Smith 2011 and Niba 2016**)^(9,10)

ADA (**2014&2016**)^(11,12) estimated that most of the diabetic children requires two or more injections of insulin daily as an exogeneous insulin which is an effective drug in controlling blood sugar level. Chronic under or over treatment with insulin injection exposure the child for longstanding poor diabetes control, from undertreatment as; weight loss, poor growth and delay skeletal and pubertal maturation where insulin overtreatment leads to impaired linear growth or poor weight gain and excessive weight gain that coexistence or development of a comorbidity as celiac disease and hypothyroidism (**Siminerio et al 2018**)⁽¹³⁾.

Diabetic children and their families may face many problems from insulin injection which could be interrelated to difficulty of insulin injection preparation, wrong of insulin injection practice, unavailability of insulin and its supplies, high cost and or psychological problems as fear of needle pain, embarrassment of taking insulin in public places and suffering from dermatological side effects of insulin injection such as lipohypertrophy or lipoatrophy (**Neu et al., 2015**)⁽¹⁴⁾. Lipohypertrophy of skin is defined as an accumulation of fat which leading to bulging of an area of skin which caused by diabetic patient/care givers keeps injection insulin into the same spot, continue injection into the lumpy area that delays the absorption of insulin, poor glycemic control and unpredictable hypoglycemia and the diabetic patient preferring this lumpy area due to painless feeling with insulin injection (**Hambridge (2017)**)⁽¹⁵⁾

Insulin is very sensitive drug and may affected by external factors as left it in unconducive environment that easily destroyed and lose its efficacy in addition to negative diabetic children and caregivers' attitude towards insulin administration may compromise their interest to look for appropriate instructions of proper insulin handling techniques and storage (**Netere et al (2020)**)⁽¹⁶⁾. **La Banca et al (2020)**⁽¹⁷⁾ revealed that outlining educational strategies which focused on insulin therapy for diabetic children has shown a gap that, once filled, will contribute to evidence-based practice and the improvement of pediatric diabetes education. Therefore, to encourage diabetic children and their parents to comply with multi-dose of insulin therapy, diabetes education should range from availability of insulin types, their respective action profile, peak and duration of therapeutic effect, concentration and aspects of safe practices of the insulin injection technique. Thus, guidelines on storage, needle selection, application sites and absorption rate, pen or syringe handling, indication of skin fold, mixture of two types of insulin in the same syringe and disposing of waste materials are essential for proper insulin regimen adherence⁽¹⁷⁾

The proper management of the diabetic children and adolescents has been a challenge due the presence of knowledge ,skills and attitude that donate to non-adherence to treatment and so the long-term complications increased . Not only the management of IDDM is complex treatment and key elements for the successful implementation is a multidisciplinary team or a single professional education and the pediatric nurse served as the leaders when addresses to the following issues related to blood glucose monitoring , acute complications resolutions ,assessment of caregivers' knowledge and skills related to insulin application and monitoring of chronic complications but also the proper diabetes education for diabetic children /families is intense and complex and need that the educators to be skillful and good in communication, sensitivity, humor, in-depth knowledge about childhood IDDM and the delivered information must be pediatric specific and appropriate for caregivers and children sociodemographic characteristics **Phelan et al (2018)**⁽¹⁸⁾

Diabetic school age children had lack of abstract thinking and able only to manage hypoglycemia but had a limits management choice and dictates that family/caregivers makes most of the treatment decisions and still need close knowledgeable adult supervision and support **Salem et al (2018)**⁽¹⁹⁾. Several studies revealed that a child's early independent participation in management of IDDM was significantly associated with poorer control^(12, 20,21). Mostly the primary caregiver for diabetic school age children is the mother who most intimately assured to the details of the disease, problems and how to cope with its **Al-Odayani et al., (2013)**⁽²²⁾.

When the nearest and adherent care providers (mothers) of the diabetic child had inaccurate information, the result may be potentially harmful, so accurate knowledge and positive attitude are the first steps in formulating a preventive program of insulin injection complication where a positive correlation between total knowledge of the studied mothers and their total reported insulin injection practices **Hussien H A , saleh S and Tantawi H (2019)**⁽²³⁾.

The health care providers may not be in position to give detailed instructions to parents /diabetic children about proper insulin injection techniques when specific guidelines /recommendation on insulin therapy were absent and recently those recommendations globally, had little or no scientific underpinning and based as much on habit and tradition as on evidence so to improve T1DM outcomes ,minimize its complication and support the diabetic children and their mothers an international evidence-based guidelines and consensus recommendations will ideally provide additional important information , optimal insulin injection techniques in treatment of diabetic children and leading health care decision for health care stakeholders which in turn reduces mortality ,hospital stay duration ,disease complication and so enhancing healthy status of diabetic children ^(24,25) .So this study evaluate effect of an evidence based insulin injection guidelines application on mothers' awareness about insulin injection and its complication on their diabetic children .

Aims of the study: this study aims to evaluates (before and after)the effect of an evidence-based insulin injection guidelines application(EBIIGA) on ;

- Mothers' knowledge, Attitude and Practices (KAP)related to insulin injection among diabetic children
- Mother's ability to assess lipohypertrophy for their diabetic children.
- Occurrence of diabetic children insulin injection complication as pain ,bleeding ,hypo and hyperglycemia.

Research hypothesis:

- Mothers of children with T1DM who exposure for(EBIIGA) their KAP related to care of their diabetic children with insulin injection will be improve
- Mothers of children with T1DM who exposure for(EBIIGA) their ability to assess lipohypertrophy will be improve
- Mothers who exposure for (EBIIGA) their diabetic children insulin injection complication will be decrease

Methodology:

Research design: A quasi experimental design was utilized.

Setting of the study:

This study was conducted at inpatient diabetic department and outpatient diabetic clinic at Mansoura University Children's Hospital. This is a specific place that provides health services for children with endocrinology problems for free.

Subjects:

A purposeful sample of 61 mothers of children with type 1 DM at the previously mentioned setting and fulfilled the following criteria:

Inclusion criteria

- Children ages 6 up to 12 years and taken insulin injection by their mothers for more than one year by syringe/pen or both
- Children /mothers accepted to participate in this study and attend follow up visit regularly
- Mothers didn't attend any educational program about insulin injection
- Both gender children

Exclusion Criteria:

- Mothers with physical , intellectual ,emotional or social impairment

Tools of the study were four tools :

- **Tool I** : An interview questionnaire sheet that developed by the researchers and had two parts ;**part I** that assessed mothers and children sociodemographic characteristics as age, gender, level of education and mothers work; **second part** that assessed diabetic children clinical data as duration of the disease, types of devices used, duration of insulin injection , time of injection and number of insulin injection per day .
- **Tool II:** The Arabic version of the insulin Injection Technique Questionnaire (ITQ) That developed by **Frid et al (2016)**⁽²⁶⁾ to assess mothers' knowledge ,attitude and skills about insulin injection for their diabetic children .
- **Tool III:** Insulin injection checklist for reported practice of insulin injection that adopted from **American Association of Diabetes Educators, (2017)**²⁷ to assess insulin injection practices and determine areas of educational need as complication of insulin injection as hypoglycemia if (blood glucose <70 mg/dL) and hyperglycemia if (blood glucose more than 250 mg/ dL);injection process and disposal procedure.

Tool IV: lipohypertrophy observational check list that developed by **Kordonouri et al (2002)**⁽²⁸⁾ to assess presence and a grade of lipohypertrophy among diabetic children.

2. METHODOLOGY

- Research study approval was gained from Research Ethics Committee at the Faculty of Nursing , Mansoura University. Also, an official approval was gained from the director of hospital and the head of the outpatient and inpatient department after an explanation the study aims, tools, period and the advantages. Additionally, oral consent was obtained from the subjects who agree to participate in the study after specifying the purpose of the study and informing the subjects that the collected data was only for research and it was be confidential and they have a right to withdraw at any time from the study .
- A pilot study on 10% of the sample size was performed to test questions clarity, the feasibility, objectivity and accuracy of the instruments based on the pilot study; the necessary modifications were done to the study instruments.

The study was taken three phases to be completed:**Phase I(pre -test) :**

- In this phase the researchers assessed mothers' knowledge ,attitude and skills (pre -test) about insulin injection ; mothers' (KPA)was assessed by using **tool (II)** including 17questions ;7question for knowledge as (proper needle length ,time needed of insulin evacuation ,needle numbers of uses, causes of extra number needle use, mixing of insulin); while 10 question for mothers attitude as appreciation of proper needle length, alternation of injection sites and how to be follow, storage of open insulin vial and checking of expiry dare in addition to proper selection of insulin injection sites ;in addition to mothers' practice of insulin injection and lipohypertrophy assessment using **tool (III)** (pen and syringe check list that had 11 steps for each one and 3 steps for lipohypertrophy presence .
- Assessment of previous last 6 months insulin injection complication before EBIIGA as pain ,bleeding hypoglycemia and hyperglycemia that need medical help or hospitalization and covered by 2 question for each one using **tool (II)**.

- Lipohypertrophy grades that covered by one question before starting the study **using tool (IV)** .

Phase II intervention : Intervention phase where the researchers collect all evidence base practices and consensus statements guidelines that were previously published by ADA(2019)⁽²⁰⁾ related to insulin injection in children in forms of a leaflet, photographs, insulin injection rotation forms an insulin injection handouts and checklist as an educational materials .Mothers were divided into groups each groups had from 5–8 mothers and attend two educational sessions each one taken (45 min) .The first session covered knowledge about insulin injection (storage ; devices criteria , injection sites ,injection rotation and process)in addition to complication of insulin injection as (pain ,bleeding ,lipohypertrophy , hypo and hyperglycemia) while the second one handled practical part where the mothers taught easy-to-follow rotation scheme using insulin injection rotation form, skin lifting technique ,using pen and syringe administration steps of insulin and examination steps of insulin injection sites , presence and grades of lipohypertrophy. A conclusion and answering the mothers' questions was done after each session .

Phase III(immediate & six month post-test evaluation): Evaluation phase (post -test)which was done twice (immediately post and post 6 months from application of (EBIIGA)which evaluated mothers' KPA and lipohypertrophy technique and grading using **tool II , III and IV** while assessment of insulin injection complication as (pain ,bleeding ,hypo and hyperglycemia that need care, medical help or hospitalization in addition to grades of lipohypertrophy was done once after 6 month from application of mothers to EBIIGA through follow up and via mothers' WhatsApp or mobile from starting the study **using tool II and IV** .

3. SCORING SYSTEM

1. The mothers' knowledge about insulin injection ,the overall (ITQ) score for 7 knowledge questions was taken 21 grads . The responses of mothers were evaluated using the model response sheet designed by the researchers and evaluated by Nursing Outcomes classifications scale by **Morhead (2013)**⁽²⁹⁾ after slight modification by the researchers from five-point Likert scale to be three -point Likert scale where the each item from participants' answer scored as the following :

- Zero marks = no information
- One to 2 marks = moderate information
- 3 marks = Extensive Independently
- If the total scores >75 means good knowledge, 50-75 score means average knowledge and <50 score mean poor knowledge(Surendranath, et al 2012)⁽³⁰⁾

2. Mothers' attitude⁽²⁶⁾ was taken one grade if her response was positive and take zero if was negative ,the overall mothers' positive attitude was taken 10 grades for each evaluation .

3. An observational checklist ⁽²⁷⁾that assessed insulin injection techniques for both pen and syringe (11 steps) .each step was taken zero for not done , one grade for incomplete done step and two grads for complete done, so 22 were the total grades .The mothers' skills were competent if taken more than 75% from total score while not competent if less than 75 grades also the same in assessment of lipohypertrophy(3 steps) taken 6 grades . .

4. Scoring of lipohypertrophy grades was scored as grade 0= no changes; grade 1 = visible hypertrophy of fat tissue but palpably normal consistency; grade 2 = massive thickening of fat tissue with firm consistency; and grade 3 = hypertrophy.

4. RESULTS

Table 1: Sociodemographic characteristics of the studied sample (diabetic children/ mothers (No=50) as age, gender, level of education and mothers work

Study sample site Sociodemographic characteristics	Outpatients N=10(100.00)	Inpatients N= 40 (100.00)	Total 50 (100.00)	Chi Square Test (P-value)
Maternal:				
Age				
18 less than 30	6(60%)	9(22.5%)	15(30.0)	2.474* (0.047)
30 less than 40	4(40%)	19(47.5%)	23(46.0)	
40+	0 (0.0)	12(30.0)	12(24.0)	

Mothers' education				
Not educated	0 (0.0)	16(40%)	16(32)	4.188* (0.02)
Read &write	10(100%)	24(60%)	34(68)	
Mothers' work				
Worked	0 (0.0)	17(42.5)	17(34)	4.685* (0.01)
Not worked	10(100)	23(57.5)	33(66)	
Children				
Age				
6-less 9	10(100)	29(75.50)	28(56)	2.105 (0.15)
9- less 12	0 (0.0)	11(27.50)	22(44)	
Gender				
Male	10(100)	18(45.0)	28(56.0)	7.716* (0.005)
Female	0 (0.0)	22(55.0)	22(44.0)	
Insulin injection duration:				
1 to Less 2 y	10(100.0)	21(52.5)	31(62.0)	5.778* (0.02)
2 y +	0 (0.0)	19(47.5)	19(38.0)	
Insulin injection type:				
Syringe	2(20.0)	39(97.5)	41(82.0)	27.515* (<0.001)
pen	8(80.0)	1(2.5)	9(18.0)	
Insulin injection number/day:				
Once morning	8(80.0)	19(47.5)	27(54.0)	≠ FET P 0.09
Twice /daily	2(20.0)	21(52.5)	23(46.0)	

≠ FET P means the P value for Fisher Exact Test.

Table (1) : Sociodemographic characteristics of the mothers and their diabetic children. it shows that the majority of inpatients' diabetic children mothers age ranged from 30 to less than 40 and above 40 years was 46.0% and 24.0% compared to 60% of them their age ranged from 18 to less than 30years in outpatients .All mothers (100%)in outpatient clinic were read and write while in inpatient was 60% and the rest of them not educated .Regarding mothers work 66% not working while the rest(34%) of them were working .above 50% from children were males and their age ranged between 6 to less than 9 years and the rest 44% of them were females and their age ranged from 9 to less than 12 years .The majority of children(82%) used syringe while the rest of them used pen. There were a statistically significant differences observed between inpatients and outpatient's clinic sociodemographic characteristics of both mothers and their diabetic children except in childrens' age.

Table 2: Mothers' KAP level and percent scores about insulin injection regarding (pre, immediately, and 6 months post) of EBHGA.

KAP \ EBHGA Phases	Pre No 50(%)	Immediately No 50(%)	6 months No50(%)	Friedman Test (P-value)
Knowledge of insulin storage & administration techniques (7Qs):				
Levels of mothers' knowledge				
Poor	46(92.0)	31(62.0)	37(74.0)	
Average	4(8.0)	16(32.0)	10(20.0)	
Good	0(0.00)	3(6.0)	3(6.0)	
Total percent scores of mothers' knowledge :				
Min.-max.	9.52-61.90	28.57-90.48	14.29-76.19	81.716* (<0.001)
Mean ±SD	27.62±11.63	48.10±12.14	44.10±13.87	
Median (IQR)	26.19(14.29)	47.62(14.29)	42.86(19.05)	
Attitudes about insulin storage & administration techniques (10Qs):				
Mothers' attitude:				
Negative	40(80.00)	0(0.00)	1(2.00)	
Positive	10(20.00)	50(100.00)	49(98.00)	

Total scores of mothers' attitude:				
Min.-max.				
Mean ±SD	1-7	6-8	4-8	89.571*
Median (IQR)	3.38±1.47	7.52±0.56	6.72±0.93	(<0.001)
	3.50(2)	8(1)	7(1)	
Practice of insulin injection technique (11Qs.):				
Mothers' level of practicing pen insulin injection				
Competent	0(0.00)	24(48.0)	33(66.6)	
Not competent	50(100)	26(52.0)	17(34.0)	
Total percent scores mothers' level of practice pen insulin injection:				
Min.-max.				
Mean ±SD	22.73-40.91	50.00-86.36	59.09-100.00	85.849*
Median (IQR)	34.73±5.26	74.27±8.74	78.27±9.86	(<0.001)
	36.36(9.09)	72.72(13.64)	77.27(14.77)	
Mothers' level of practicing of practice syringe insulin injection: :				
Competent	0(0.00)	20(40.00)	17(34.00)	
Not competent	50(100)	30(600)	23(16.00)	
Total percent scores of mothers practice syringe insulin injection:				
Min.-max.				
Mean ±SD	4.17-29.17	25.00-33.33	16.67-33.33	88.080*
Median (IQR)	14.50±5.79	31.17±2.42	28.17±4.00	(<0.001)
	16.67(8.33)	33.33(4.17)	29.17(8.33)	

Table 2 : Mothers' KAP about care of diabetic children regarding (pre, immediately, and 6 months post) of EBIIGA.it shows that the majority 92% from mothers their knowledge was poor before and decreased immediately post and post 6 months from EBIIGA to be 62.0% and 74% respectively and Median (IQR) was 26.19(14.29), 47.62(14.29) and 42.86(19.05) respectively with statistical significant differences where p = <0.001 . Regarding mothers' attitude about insulin injection in their diabetic children the table

Table 3: Inpatient and outpatient Diabetic childrens' insulin injection complication regarding pre and 6 months post of EBIIGA

EBIIGA	Pretest of EBIIGA				6 months after of EBIIGA			
	Outpatients N=10	Inpatients N= 40	Total 50	Chi Square Test (P-value)	Outpatients N=10	Inpatients N= 40	Total N= 50	
Pain				LHR				FET
Yes	0.0	2.5	2.0	0.451	40.0	42.5	42.0	---
No	100.0	97.5	98.0	0.5	60.0	57.5	58.0	1.0
Sign Rank Test "P" <0.001*								
Bleeding				FET				FET
Yes	0.0	47.5	38.0	---	20.0	52.5	46.0	---
No	100.0	52.5	62.0	0.008*	80.0	47.5	54.0	0.09
Sign Rank Test "P" =0.4								
Hypo:				FET				FET
Yes	60.0	57.5	58.0	---	40.0	67.5	62.0	---
No	40.0	42.5	42.0	1.0	60.0	32.5	38.0	0.2
Sign Rank Test "P" 0.8								
Frequency of hypoglycemia				LHR				LHR
Never		85.0	80.0	3.040		82.5	74.0	6.782*
Twice	60.0	5.0	8.0	0.2	40.0	40.0	18.0	0.03
From 3 - 5 times	20.0	10.0	12.0		20.0	12.5	8.0	
5+	20.0	0.00	0.00		0.00	5.0	8.0	
	0.00					0.00	0.00	
Sign Rank Test "P" =0.3								
Hyper:				FET				FET
Yes	60.0	42.5	46.0	---	60.0	52.5	54.0	---
No	40.0	57.5	54.0	0.5	40.0	47.5	46.0	0.7
Sign Rank Test "P" =0.5								
Frequency of Hyperglycemia/6m				LHR				LHR
Never		42.5	46.0	4.689				0.696
1 to 2 times	60.0	2.5	2.0	0.2	60.0	50.0	52.0	---
3 to 5 times	0.0	2.5	2.0		0.0	2.5	2.0	
More than 5	20.0	5.0	8.0		0.0	0.0	0.0	
	20.0	50.0	44.0		40.0	47.5	46.0	
Sign Rank Test "P" =0.6								

FET= Fisher Exact Test only have p value

LHR=Likelihood-Ratio Test= value and p value

SRT= Sign Rank Test only have p value only

KWT=Kendall's W Test

Table3: Shows correlation between inpatient and outpatient childrens' insulin injection complication pre and post 6 months of EBIIGA, the majority of diabetic children in both setting 98% had no pain pre 6 months compared to above half of them 58% post 6 months from EBIIGA with statistically significant differences where P= 0.001 while other insulin injection complication as bleeding ,hypoglycemia and hyperglycemia in both settings pre 6 months were (38.05% , 58.0% and 46.0%)compared to (46.0%,67.5% and 54.0%) respectively post 6 months from EBIIGA with no statistically significant differences. Regarding frequency of hypoglycemia 80.0% of children had no hypoglycemia pre 6 months and the rest of them their frequency of occurrence ranged between(8.0 % and 12.0 %) twice and from 3 to 4 times compared to 82.5% had no and the rest their occurrence ranged between (12.5% and 5.0%) post 6 month with statistically significant differences where P= 16.782 and p value was 0.03.On the other hand less than half of diabetic children never had hyperglycemia occurrence 46.0% and the rest of them 54.0% the occurrence were more than 5 times (44.0%) then from 3 to 5 (8.0%) and from one to two times 2.0%) in the previous 6 month of EBIIGA compared to (52.0%) never while the rest of them (48.0%) the frequency of hyperglycemia ranged between more than 5 ,(46.0%) , 1 to 2 times(2.0%) post 6 months from EBIIGA with no statistically significant differences where p= 0.696 and p value = 0.7.

Table 4: Percent distribution of diabetic children lipohypertrophy mothers' assessment and calculation at three intervals (pre ; immediately, and post 6 months after)of EBIIGA

EBIIGA phases	Before EBIIGA				Immediately after EBIIGA				6 months after EBIIGA			
	Outpatients N=10	Inpatients N= 40	Total 50	Chi Square Test (P-value)	Outpatients N=10	Inpatients N= 40	Total 50	Chi Square Test (P-value)	Outpatients	Inpatients	Total	Chi Square Test P-value
Lipohypertrophy assess& grades												
Positioning				FET				FET				FET
Not done	40.0	30.0	32.0	---	40.0	7.5	14.0	---	0.0	0.0	0.0	---
Incomplete	60.0	70.0	68.0	0.7	60.0	92.5	86.0	0.02*	0.0	12.5	10.0	0.6
Complete	0.0	0.0	0.0		0.0	0.0	0.0		100.0	87.5	90.0	
Kendall's W Test related $\chi^2=80.053$ * P<0.001												
Sites examination				FET				FET				FET
Not done	82.5	60.0	78.0	---	40.0	25.0	28.0	---	0.0	0.0	0.0	---
Incomplete	17.5	40.0	22.0	0.2	60.0	75.0	72.0	0.4	20.0	32.5	30.0	0.7
Complete	0.0	0.0	0.0		0.0	0.0	0.0		80.0	67.5	70.0	
Kendall's W Test related $\chi^2=84.974$ * P<0.001												
Feel of hardness				FET				FET				FET
Not done	87.5	80.0	86.0	---	20.0	20.0	20.0	---	0.0	0.0	0.0	---
Incomplete	12.5	20.0	14.0	0.6	80.0	80.0	80.0	1.0	40.0	30.0	32.0	0.7
Complete	0.0	0.0	0.0		0.0	0.0	0.0		60.0	70.0	68.0	
Kendall's W Test related $\chi^2=91.797$ * P<0.001												
Grades of LPT				FET				LHR				LHR
Not visible	70.0	65.0	66.0	---	80.0	0.0	16.0	36.450	100.0	27.5	42.0	20.976**
Visible	30.0	35.0	34.0	1.0	20.0	52.5	46.0	<0.001	0.0	40.0	32.0	<0.001
Massive	0.0	0.0	0.0		0.0	40.0	32.0		0.0	27.5	22.0	
Hypertrophy with density	0.0	0.0	0.0		0.0	7.7	6.0		0.0	5.0	4.0	
Kendall's W Test related $\chi^2=36.150$ * P<0.001												

FET= Fisher Exact Test only have p value

LHR=Likelihood-Ratio Test= value and p value

SRT= Sign Rank Test only have p value only

KWT=Kendall's W Test

Table 4: Illustrates mothers' assessment and calculation of lipohypertrophy on their diabetic children at three intervals (pre ; immediately and post 6 months after)of EBIIGA .Regarding step of positioning above half of diabetic childrens mothers 68.0% performed it incompletely and the rest not done pre while immediately post 86.0% and the rest 14.0% not done but improved after 6 months of EBIIGA to be 87.5% completely done and the rest of them 12.5% performed it incomplete with a statistically significant differences where $\chi^2=80.053$ and P<0.001.Concerning insulin injection sites examination of nodules; pre EBIIGA more than two third (78.0%)of mothers not performed it, while immediately post 72.0% of them did it incompletely and 67.5% of them did it completely after 6 months from EBIIG with a statistically significant differences where $\chi^2=84.974$ and P<0.001.Regarding feeling of diabetic children insulin injection sites skin hardness ;pre 6 months the majority of mothers (86.0 %)not did it and the rest of them 20.0% did it incompletely while immediately post was (80.0%) incomplete done and the rest of them 20.0% not performed it while post 6 months (70.0%)did it completely and the rest 30.0% did it incompletely with a statistically significant differences where $\chi^2=91.797$ and P<0.001.Concerning lipohypertrophy grades pre EBIIGA (66.0 %)of mothers said that there was no childs' skin visible changes and the rest of them (34.0%) mentioned a visible change compared to immediately post was (16.0%) no visible changes , (46.0%) visible, (32.0%) was massive changes and the rest (6.0%) of diabetic children had

insulin injection sites hypertrophy ;while post 6 months from EBIIGA(42.0 %) of mothers said that no shin visible changes were found while visible was 32.0% ,massive was 22.0% and hypertrophy with density represent (4.0%);and regarding the three phases of EBIIGA a statistically significant differences was found where $X^2=36.150$ and $P<0.001$.

Data analysis

After data collection, it was coded and tabulated using SPSS program version 27 was used for data processing⁽³¹⁾. Descriptive statistics are carried out through data presentation in tables, graphs and mathematical presentations. Analytic statistics and interpretation are done through selection of the proper statistical tests and finally decision taking according to the significance depending on the P (probability of the chance) values. The 5% level of significance was used. Number and percent were used for presenting and interpreting the qualitative variables according to the categories and the quantitative variables according to the intervals. Tests of normality were carried out for the quantitative variables. Accordingly, if this test is significant ($P\leq 0.05$) the quantitative variables are described to be abnormally distributed, otherwise it is normally distributed. Hence, for abnormally distributed quantitative variables, mainly the scales and scores, the median and inter quartile range was used for mathematical presentation. On the other hand, for normally distributed quantitative variables, the mean and standard deviation was used for mathematical presentation. The analytical tests of significance are used for either the difference between groups or association within one group. Fisher Exact test or Chi square with Yetes correction was used for comparisons of percentages for the qualitative variables if Chi Square test is not valid. If the distribution of the quantitative variables is abnormally, the non-parametric tests were used for analysis. For comparisons of the median for the same groups during the period of follow up, Wilcoxon's test (for two) and Friedman's test (for more than two) are used. On the other hand, Mann Whitney test and Kruskal Wallis test were used for comparison of the median between two or more than two **different** groups respectively. The corresponding parametric tests of difference are paired t-test, student t-test and ANOVA or F-test respectively. Regarding scoring system and after summation of the scores corresponding to each sub item, it was divided by the total scores and multiplied by 100 to calculate the percent scores then , the obtained value is further classified into categories.

Limitation of the study

- 1- The sample size was 61 mothers with the beginning of the study while in the follow up phase 11 mothers were excluded from the study due to irregularity of follow up to the hospital , children were attended with others personal rather than the mothers or not responding to what sup or mobile massages.
- 2- Neither mothers' KPA improvement nor insulin injection complication occurrence was affected only by EBIIGA but there are other underlying factors could contribute and need a further research studies which need to be identified
- 3- No generalization for this study due to small sample size .

5. DISCUSSION

Egypt is largest settled population among the Arab countries and the most densely populated on it is the Nile Delta which constituted nine governorates from 28 egyptian governorates .Regionally, the largest contribution of estimated childhood T1DM cases comes from Egypt which accounts a quarter of the region's total **El-Zanaty and Way (2009)**⁽³²⁾ and **El-Ziny et al (2017)**⁽⁴⁾. There are a lack of evidence based practices specialized in diabetic children care and few researches handled this issue and mentioned that EPP or guidelines which focused in age appropriate educational interventions and continues are effective in awareness of children /families and caregivers bout care of T1DM and improved diabetic children disease outcomes and decrease expenditure **Calliari ;et al (2018)**⁽³³⁾. Education of both the diabetic child and caregivers is the critical corner stone in ensuring adherence of the complex tasks involved in effective management of T1DM **Niba (2016)**⁽³⁴⁾. Insulin therapy remains the cornerstone of diabetes management; but the art of injecting insulin is still poorly understood in many health facilities and therefore science of injection technique has now become an integral part of diabetology and accordingly the different developmental stage a specialized approach to insulin injection are required .Admitted diabetic children needs from four to five days in the hospital for blood glucose regulation and education leaves very little time for the educators to get to know the families and ensure that everyone involved with the child's diabetes control has been educated , in these instances education and insulin regulation must be accomplished on an outpatient basis **Dawood, and Qadori(2018)**⁽³⁾ and this results in the same line with the present study where outpatients sample represent only ten cases in outpatient while the majority from inpatient word where study setting may affect in mothers' KPA and also all sociodemographic characteristics and clinical data of study sample statistically were significant except children age in relation to the study setting, **table (1)**.

Regarding mothers' age; near half of them their age ranged between 30 and less than 40 years and above half of them not working that disagree with a study done by **Rahman et al (2021)**⁽³⁵⁾ in the part of mothers' age where 40% of them their age above 46 years but in harmony of their working 80% of them were household. The worldwide reported that female's attendance to diabetic clinic is higher than males^(4,36) and this result in contrary with the present study where above half of them was males and the rest was females, **table (1)** .

Children 6–12 years old had a lack of abstract thinking and had limited management choices and dictates their parents to make most of the treatment decisions and those children have a two peak of IDDM at 5 to 9 years and at 10 to 14 years **Nicole et al (2019)**⁽³⁷⁾. The present study revealed that the majority of them taken insulin by syringe while the rest of them used pen only those findings in agreement with a study done by **Calliari (2018)**⁽³³⁾ where 78% from children used syringe and 17.2% used pen and the rational of syringe preference may related to inexpensiveness and simplicity of uses , **table (1)**.

key components in the management of type 1 diabetes was therapeutic education about diabetes and regular visit of diabetic clinic . Therapeutic education is a process where the competencies of KAP was integrated into the diabetes treatment plan via the diabetic educators to support diabetic children and their families **Allen et al (2017)**⁽³⁸⁾ . Poor knowledge about subcutaneous tissue anatomy ,diabetic childrens' body response of insulin , disease complication and its management for both patients and health care providers was the major obstacle to optimum diabetes control, health agencies insulin budget exhaustion , frequent hospitalization and emergency clinic visit **Srollo & Gentile (2018)**⁽³⁹⁾ .

In the present study the majority of the mothers had poor knowledge about care of their diabetic children and this result in agreement with **Hussien , saleh and Tantawi (2019)**⁽²³⁾ where 64.9% from diabetic childrens' mothers had unsatisfactory total knowledge score about care of their children but in contrary with **Karilena et al (2016)**⁽⁴⁰⁾ whom found that 72% from mothers of diabetic children had a satisfactory knowledge score .Our study results found that the mean total score of knowledge before EBIIGA was slightly more than one quarter and improved after EBIIGA to be near half with statistical significant differences ;($p < 0.001$) and this results in congruence with a study done **Salem , Hafez Shabaan(2018)**⁽¹⁹⁾ that mentioned improvement of mothers' knowledge mean score from (52.023) before educational session to be (66.023) after with highly statistical significant differences where $P = 0.000$ and also with a study done by **Abdel Megeid and El-Sayed(2012)**⁽⁴¹⁾ that showed significant improvement in the mothers' knowledge regarding pre and post educational session about diabetic care with statistical significant differences $p < 0.001$. **Almualm et al (2015)**⁽⁴²⁾ found that 72.1 % of participants had poor score of knowledge pre; while (89.2 %) had good knowledge immediate post-test and (83.8 %) had good knowledge score in follow up phase and the rest was(14.4 %) had poor with statistically significant for every topic ($p < 0.05$) that disagree with our results where the majority of mothers pre had poor knowledge ;immediately post near two third of them had poor while post 6 months near three quarters as in **table 2** .The researches^(23,25,33) that studied diagnosed diabetic children for more than 5years with insulin injection ,highly educated mothers , previous health teaching of mothers could the causes of highly improvement of mothers' levels of knowledge that was in conflicting with the present study where the majority of the studied sample diagnosed with T1DD for less than 2 years and near third of mothers not educated as in **table 1**

The primary goal to manage diabetes is to achieve the blood glucose level within the normal range which can be accomplished by appropriate delivery of insulin by comprehensive education which should be appropriate for children/family's needs ;appropriate insulin injection techniques and inappropriate insulin injection as (excess needle reuse, lack of injection sites rotation ,insulin bad transportation /storage and prolonged duration of insulin use) **Strollo & Gentile (2018)**⁽³⁹⁾. Insulin is effective only if administered appropriately .In the present study all mothers not competently performed insulin injection pre EBIIGA while done competently by above half of them immediately post and decreased to be one third of them after 6m of EBIIGA with statistically significant differences $p < 0.001$ (**table 2**) and this results in agreement with **Ramzy H and Atalla A (2016)**⁽⁴³⁾ whom concluded that statistical difference with practicing insulin injection after one week of intervention among study group and also in contract with studies done by **Hussien H A , Saleh S and Tantawi(2019)**⁽²³⁾ and **Rahman et al (2021)**⁽³⁵⁾ that mentioned above 50.0% of diabetic children mothers performed insulin injection incorrectly and **Abdel Megeid and El-Sayed (2012)**⁽⁴¹⁾ illustrated that practicing mothers to insulin injection pre intervention was (31%) poor while post intervention was improved to be good (69.0%) with statistically significant differences $p < 0.00$ also other study done by **Nascimento et al (2011)**⁽⁴⁴⁾ mentioned that diabetic children caregivers showed poor performance of insulin injection and need continues educational and training sessions about insulin injection to encouraging a positive attitude in fighting the disease while negative attitudes which delivered from their beliefs and perceptions compromise caregivers interest to look for the instruction appropriately for insulin

handling technique and storage and both negative and positive attitude affecting diseases outcomes. Our study illustrated that the majority of mothers had negative attitude pre EBIIGA compared to all of them their attitude was positive immediately after and slightly decrease after 6 months from EBIIGA with statistically significant differences (**table 2**) where p -value = 89.571; <0.001 and this results in agreement with a study done by **Abdel Megeid and El-Sayed (2012)**⁽⁴¹⁾ whom expose that mothers attitude about insulin injection and daily insulin screening was negative (99.0%) pre educational sessions and improved post to be (100%) with statistically significant differences $p < 0.001$, and also **Vimalavathini, Agarwal, and Gitanjali (2018)**⁽⁴⁵⁾ showed that planned educational intervention programs improved caregivers' attitudes components scored about insulin injection with statistically significant differences where $P < 0.001$.

Many studies apparent that factors as poor education of the families, failure of them to follow up properly and failure of them to follow the instructions given during educational session their children have insulin injection complication compared to families without those factors and the most common complication were lipohypertrophy, hypoglycemia, hyperglycemia and pain **Niba (2016)**⁽³⁴⁾; **Dawood and Qadori (2018)**⁽³⁾ and **Chen et al (2021)**⁽⁴⁶⁾. The present study illustrated that the majority of mothers said that their children didn't had pain pre EBIIGA while post 6 months decrease to be slightly above half of their children and our rational may be related to the majority of mothers give insulin in arms of their children and not follow insulin injection rotation guidelines before EBIIGA that led to lipohypertrophy painless feeling so they continued injection by this way while after instructing them to follow insulin injection rotation technique near half of the mothers used different sites rather than arms and this result in the same line with **Dawood and Qadori (2018)**⁽³⁾ and **Kalra et al (2018)**⁽⁴⁷⁾ whom stated that repeated use of the same injection site increase the risk of lipoatrophy-with time, patient learn that these areas are relatively pain free and continue to use them. Other insulin injection complication was hypoglycemia that considered the major limitation to fitted control of glucose levels. The present study found that (8.0% and 12.0%) from children exposure to it twice and from 3 to five-episode 6 months pre EBIIGA compared to (12.5% and 5.0%) 6 months post with statistically significant differences where p -value was 6.782 0.03 as in **table 3** this result contract with **Kalra et al (2018)**⁽⁴⁷⁾ who stated that 6.1% from school age children hospitalized by hypoglycemia in last 6 month by weekly mild; moderate few times each year and every few years sever hypoglycemia and the rational of little improvement in our study or occurrence by **Kalra et al (2018)**⁽⁴⁷⁾ may be due other risk factors as exercise and delayed children meals /snakes time; also **Demir et al (2019)**⁽⁴⁸⁾ agree with the present study where mean \pm SD of hypoglycemic occurrence was 6.7 ± 3.6 before educational session and decreased to be 4.2 ± 2.8 0 after with statistically significant differences where $p = 0.03$.

Chronic hyperglycemia that affecting school age children leads to white matter structural changes and overall poorer cognitive performance; the present study stated that above half of children were affected by hyperglycemia pre EBIIGA compared to less than half of them post with no statistically significant differences **table 3** and this result in harmony with **Wherrett et al (2018)**⁽⁴⁹⁾ who showed that hyperglycemia can be decreased with family support, health education and as well as telephone services access available 24 hours; while in disharmony with by **Kalra et al (2018)**⁽⁴⁷⁾ where mean \pm SD of hyperglycemia frequency among diabetic children pre educational session was 14.9 ± 7.1 while after was 21.9 ± 13.0 .

Other complication not mentioned in research studies and not evaluated after education intervention of insulin injection as rotation of the application sites, lipohypertrophy and needle reuse that considered as a fundamental issue in controlling of glucose level and minimizing complication. Many studies mentioned that lipohypertrophy considered the most common insulin injection skin complication among diabetic children than adults that could results from improper insulin injection, poor education and training from professional health care providers and other not fully established the causes. Our study evaluates mothers' abilities to classifying lipohypertrophy where two third of them mentioned their children didn't have skin change and their rational was no body informed them how to be assess it? and one third of them visibly observed it pre EBIIGA while immediately post the details classification was found 16.0%, 46.0%, 32.0% and 6.0% no visible skin change, visible, massive and hypertrophy and post 6 months was same classification by 42.0%, 32.0%, 22.0% and 4.0% as in **table 4**. Finding of more than one third in the all EBIIGA phases in our present study lipohypertrophy was visibly that in concurrent with **Tsadik et al., (2018)**⁽⁵⁰⁾ who mentioned that, more than one third of the studied children had LH and supported also by **Strollo and Gentile et al., (2018)**⁽³⁹⁾ (21) who reported that almost half of the studied children had lipohypertrophy and also **Deeb et al; (2019)**⁽⁵¹⁾ who highlighted that (39%) from diabetic children had LH specially in their arms and those students preferred arms as a site of injection and not follow guidelines of injection site rotation and this result in contract with the present study where immediately post EBIIGA only below one

quarter of children had no LP while the majority had different grades of LH and the rationale of this result may be returned to negative attitude of all mothers to change injection site and mainly used arms for injection and also had incompetent insulin injection technique as in **table 2**.

6. CONCLUSION

Based on the findings of the current study, EBIIGA improved mothers' KPA and their abilities to assess of LH, while insulin injection complication (injection sites bleeding, hypo and hyper glycemia) had not statistically significant differences rather than children pain feeling and mothers' abilities to grades LT had a statistically significant difference in relation to EBIIGA phases.

7. RECOMMENDATIONS

Mothers of diabetic children educational strategies that focused on insulin therapy were shown a gap, once filled, it will contribute to evidence-based practice and will improve diabetic children insulin injection and disease outcomes. Our recommendations in relation to injection techniques are in concordance with the newly published multi-country survey practice implications that mentioned evidence-based practice is conscientious and well-judged utility of up to date best evidence in combination with clinical expertise and patient principles to lead health care stockholders to proper health care decision.

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