RESEARCH ARTICLE

THE EFFECT OF USING INSULIN PEN DEVICE ON GLYCEMIC CONTROL AND QUALITY OF LIFE IN CHILDREN WITH TYPE 1 DIABETES

*Rasha Shawky Fathy AL –Ashry, Rahma Soliman Bahgat, Adel Ali Erfan and Ebtisam Mohamed El-sayed

Department of Pediatric Nursing, Faculty of Nursing, Tanta University, Egypt

ARTICLE INFO	ABSTRACT
	Insulin pen device helps diabetic children to manage their diabetes. It offers an easier method for insulin administration that is more accurate, less painful, and more discreet compared with vials and syringes. It improves adherence, enhance quality of life, glycemic control, and decrease costs. The aim of this study was to evaluate the effect of using insulin pen device on glycemic control and quality of life in children with type I diabetes mellitus. A sample of 60 children with type 1 diabetes mellitus included in this study. The study was conducted at Diabetic Outpatient Clinic and Inpatient Diabetic Unit of Pediatric Department at Tanta University Hospital. The tools of data collection were; a structured questionnaire sheet to collect socio demographic data of diabetic children, assessment of glycemic control, diabetes fear of self-injection questionnaire sheet, diabetes treatment satisfaction about insulin delivery devices, patient preferences about insulin delivery devices, and pediatric quality of life inventory scale. The results revealed that there was statistical significant difference between pen and syringe group regarding their glycemic control variables and their quality of life. The diabetic children reported significant preference, and satisfaction with the using of insulin pen, and expressed less fear of self injection compared with the using of syringe. The study concluded that the use of insulin pen device was associated with significant improvement in glycemic control variables and quality of life in children with type I diabetes mellitus. The study recommended improving awareness among Egyptian health care professionals and diabetic children about the characteristics of insulin pen devices.

INTRODUCTION

Diabetes mellitus type 1 is a form of diabetes mellitus that results from the autoimmune destruction of the insulin-producing beta cells in the pancreas. Type 1 diabetes is usually diagnosed in children and young adults, and was previously known as juvenile diabetes (Hockenberry and Wilson, 2003). More than 79,000 children developed type 1 diabetes in 2013 worldwide. Diabetes is increasing in every country, 77% of people with diabetes live in low- and middle-income countries (World Diabetes Day 2014). In the United States approximately 1 in every 400 children and adolescents is affected with type 1 diabetes (James *et al.,* 2013). In Egypt, Diabetes is an emerging public health problem. There were 7.5 million cases of diabetes in Egypt in 2013 (Center for Disease Control and Prevention, 2014). Type 1 diabetes mellitus is manifested by the classic initial signs of hyperglycemia: polyuria, polydipsia, polyphagia. If the condition progresses without intervention, the child exhibit signs and symptoms of diabetic ketoacidosis (Atkinson *et al.,* 2014).

*Corresponding author: Rasha Shawky Fathy AL –Ashry
Department of Pediatric Nursing, Faculty of Nursing, Tanta University, Egypt.

Diagnosis of type 1 diabetes is made on the basis of a classical picture of hyperglycemia combined with the laboratory data of fasting blood glucose exceeding 126 mg/dl, random blood glucose equal to or greater than 200 mg/dl, postprandial (two hours after eating) blood glucose level equal to or greater than 200 mg/dl. The glycosylated hemoglobin equal to or greater than 6.5 % (American Diabetes Association, 2014). Diabetic children need care in team approach. Nursing personnel has a pivotal role in managing and educating children and their family members regarding different aspects of care. Management of DM involves combination of insulin therapy, dietary management, physical exercise, prevention of complications, promotion of growth, emotional, and social development (Kyle and Carman, 2013; Brooker and Nicol, 2011). Consistent glycemic control is important because it lead to less long term diabetes –related complications. Two important methods for monitoring glycemic control include: blood glucose monitoring and monitoring of glycosylated hemoglobin levels (Kyle and Carman, 2013; Mauras *et al.,* 2013; American Diabetes Association, 2013). The increased number of patients with type I diabetes and technological advances have allowed for alternative therapies, whose main objective is to offer patients greater comfort and well-being.

The insulin pen device was developed to simplify subcutaneous insulin injection (Heinemann *et al.,* 2013). Insulin pens offer several significant advantages over insulin syringes: including improved patient satisfaction and adherence, greater ease of use, superior accuracy for delivering small doses of insulin, greater social acceptability, and less reported injection pain. Thus improving quality of life for patient with insulin treated diabetes mellitus and encouraging treatment compliance (Asamoah, 2008; Clark *et al.,* 2010).

The aim of the study was to evaluate the effect of using insulin pen device on glycemic control and quality of life in children with type I diabetes mellitus.

Research Hypothesis

The use of insulin pen device will improve glycemic control and quality of life in children with type I diabetes mellitus. The greater proportion of diabetic children will express their satisfaction and preference to continue using the pen for insulin injection.

MATERIALS

Research design: Quasi experimental research design was used in this study.
Setting: The study was conducted at Diabetic Outpatient Clinic and Inpatient Diabetic Unit of Pediatric Department at Tanta University Hospital.

Subject

The sample consists of sixty children having the following criteria

- Diagnosed with type I DM for at least 3 months.
- Receiving subcutaneous insulin injection by syringe.
- Injecting themselves with insulin
- Their age ranged from 8 - 12 years.
- Both sexes.

Exclusion criteria

- Type II Diabetes Mellitus**.**
- Diabetes mellitus associated with genetic syndrome.
- Sever systemic disease such as: (cardiac, renal, and hepatic diseases).
- Emotional stress.

The study sample was divided into two groups (30 children for each):

A- Group I :(Pen Group) changed over to use insulin pen for subcutaneous injection for 12 weeks.
B- Group II: (Syringe Group) continued to use syringe for insulin-injection during the same period.

Tools of data collection:

Tool I: A structured questionnaire sheet; it was comprised of two parts:

Part I: Socio-demographic data of diabetic children.
It included age, sex, birth order, and residence. Medical history as: diabetes duration, frequency of insulin injection per day, daily insulin dosage, frequency of blood glucose monitoring per day, and the presence of diabetic complications.

Part II: Assessment of glycemic control:
The blood samples were collected by the researcher and sent to the lab for measurement of fasting, postprandial blood sugar level, and glycosylated hemoglobin. These tests were carried out at the beginning of the study and after 12 weeks for the both groups.

Tool II: Diabetes fear of self-injection questionnaire sheet

(Eline *et al.,* 2000) The two groups of the study completed the eight-item diabetes fear of self-injection questionnaire after 12 weeks of the study, to indicate to what extend self injection of insulin was a cause of distress either by using syringe or pen device. Items was rated on a 4 point Likert scale (1 = almost never, 4 = almost always) with a maximum fear score of 32. Diabetic children fear of self injection was categorized into three categories: mild fear when the total score was 8-15,moderate fear when the total score was 16-24,and sever fear when the total score was 25-32.

Tool III: Diabetes treatment satisfaction about insulin delivery devices (Lewis *et al.,* 1988)

The diabetic children satisfaction about insulin delivery devices (syringe or pen) was evaluated after 12weeks of the study by using the diabetes treatment satisfaction questionnaire. The questionnaire consists of 8 items assessing total diabetes treatment satisfaction, treatment satisfaction in specific areas, and perceived frequencies of hyperglycemia and hypoglycemia. Each item was scored on a scale of 0 to 6 (0 = worst, 6= best). The diabetic children satisfaction about insulin delivery devices was categorized into 3 categories: mild satisfaction when the total score was 0-15, moderate satisfaction when the total score was 16-31, and high satisfaction when the total score was 32-48.

Tool IV: Patient preferences about insulin delivery devices (Korytkowski *et al.,* 2003)

After 12week of the study, diabetic children preferences about the use of syringe or pen device for insulin injection were evaluated using patient preferences questionnaire about insulin delivery devices. Answers were scaled from 0 to 10, representing least to most preference, respectively. The diabetic children preference about the insulin delivery devices was categorized into 3 categories: mild preference when the total score was 0-39, moderate preference when the total score was 40-59, and high preference when the total score was 60-80

Tool V: Pediatric quality of life inventory scale (Varni *et al.,* 2003)

It used to assess quality of life in children with type I diabetes mellitus at the beginning of the study and after 12 weeks. It consists of 23 items divided into four subscales including

physical, emotional, social and school functioning's with 8, 5, 5 and 5 items, respectively. Likert response scale with five categories was used, ranging from never to almost always a problem. Each question scored as follow (0, 1, 2, 3, and 4). The question was scored (0) when the child answered no problem, scored (1) if the response was almost never a problem, scored (2) if the response was sometimes a problem, scored (3) if the response was often a problem, and finally scored (4) if the response was almost always a problem. Children's quality of life was categorized into three categories: good when the total score was 0 to 29, fair when the total score was 30 to 59, and poor when the total score was 60 to 92.

METHODS

- An official permission to conduct the study was obtained from the responsible authorities
- Children and their parents consent for participation in this study was obtained after explaining the aim of the study.
- Data was collected over a period of 1 year starting from October 2012 to September 2013.
- A pilot study was carried out before starting the data collection. It was done on a sample of 6 children to test the validity and reliability of the study tool and to estimate the time required for each interview.

The actual study

The initial interview

Each child, who met the criteria of the sample selection, was interviewed individually either at the inpatient diabetic unit or in the out-patient clinic. They were asked to answer the questitionaires using the personal interview method. The time required for each interview ranged from 30- 45 minutes. The basic data about the diabetic children was collected by using (Tool I). During the study period, all the diabetic children in the two groups were kept the same frequency for daily insulin injections. The diabetic children wee asked to choose one group of the study.

Group I (pen group): was asked to switch from traditional syringe to insulin pen for 12 weeks. The researcher explained to the children and their parents the advantage of insulin pen, its types, and how to use it.
Group II (syringe group): continued to use traditional syringe for insulin injection during the study period.

The second interview

For the 2 groups of the study blood samples were collected by the researcher and sent to the lab for measurement of fasting blood sugar level, then the diabetic children were informed to have their breakfast and after 2 hours, the blood samples were collected for postprandial blood sugar level, and glycosylated hemoglobin to determine glycemic control. (Tool I) The diabetic children quality of life was assessed by using pediatric quality of life scale. (ToolV)

The third interview: (After 12week of the study)

- The diabetic children in the 2 groups had completed the questionnaires about diabetes fear of self-injection to

indicate to what extend self injection of insulin was a cause of distress either by using syringe or pen device. (Tool II)
- The patient satisfaction, convenience, and flexibility with insulin delivery devices (either syringe or pen) were evaluated by using the diabetes treatment satisfaction questionnaire.(Tool III)
- Patient preference about using either syringe or pen for insulin injection was determined at the end of the study by using patient preferences questionnaire about insulin delivery devices. (Tool IV)
- Blood samples were collected for measurement of fasting, postprandial, and glycosylated hemoglobin. Finally, the diabetic children completed a questionnaire on health related quality of life. (Tool I, V)

RESULTS

Table (1) shows percentages distribution of the diabetic children according to their biosocio- demographic data. It was found that the mean age was 10.50±1.72 years for pen group, 9.60±17.3 years for syringe group. It was noticed that more than half (56.7%) of pen group were females, while almost three quarters (70%) of syringe group were males. The table also showed that the majority of pen group (83.3%) and almost three quarter (70%) of syringe group were living in rural area. Regarding frequency of insulin injection per day, the table presented that 60% of pen group and 80% of syringe group had insulin injection 3 times per day. As regards frequency of blood glucose monitoring, it was found that 43.3% for each group checked their blood glucose level 3 times per day.

Table (2) presents mean distribution of the diabetic children according to their glycemic control variables. It was observed that, there was significant improvement in glycemic control variable associated with the using of insulin pen. As regards fasting blood glucose, this table presented that the mean fasting blood glucose level in pen group was 212.27±87.38% at the beginning of the study and decreased to 161.67±63.32% after 3 months of using insulin pen with statistical significant difference, while there was no significant difference in syringe group (P=0.109). As regards glycosylated hemoglobin, this table showed that the mean of glycosylated hemoglobin in pen group was 8.73±1.74%at the beginning of the study and decreased to 7.86±1.79% after 3 months of using insulin pen with statistical difference (P=0.018), while it was 8.22±1.77%and increased to 8.45±1.86 %after 3 months in syringe group, with no significant difference.

Figure (1) shows mean scores of diabetic children fear of self injection. It was observed that diabetic children reported significantly less fair of self injection in pen group compared with syringe group, as the mean score of diabetic children fear of self injection was 10.50±2.22%in pen group, while it was 20.70±6.77% in syringe group with statistical significant difference (P=0.0001).

Table (3) presents mean scores of diabetic children satisfaction about insulin delivery devices. It was found that 5.23±0.68 % of the diabetic children in pen group was satisfied with using insulin pen compared to only 3.03±1.97% who was satisfied with using syringe with statistical significant difference (P=0.001).

Table 1. Percentage distribution of the diabetic children according to their biosocio-demographic data

Biosociodemograhic data	Group I (pen group) (n=30)		Group II (syringe group) (n=30)	
	No	%	No	%
Age (years):				
Range	8-12		8-12	
Mean ±SD	10.50±1.72		9.60±1.73	
t-test		2.020		
P		0.048*		
Sex:				
Females	17	56.7	9	30.0
Males	13	43.3	21	70.0
Residence:				
Urban	5	16.7	9	30.0
Rural	25	83.3	21	70.0
Duration of illness (years):				
< 1 year	14	46.7	15	50.0
1< 2 years	6	20.0	4	13.3
2< 3 years	5	16.7	6	20.0
3 years and more	5	16.7	5	16.7
Frequency of insulin injection /day:				
Three	18	60.0	24	80.0
Four	12	40.0	6	20.0
Insulin units/day:				
15-20	4	13.3	7	23.3
21-30	9	30.0	14	46.7
31-40	6	20.0	5	16.7
41-50	11	36.7	4	13.3
Frequency of blood glucose monitoring /day:				
-One	6	20.0	4	13.3
-Two	6	20.0	7	23.3
-Three	13	43.3	13	43.3
-Day after day	1	3.3	3	10.0
-If there is hypoglycemia or hyperglycemia	4	13.3	3	10.0
Sites of insulin injection:				
Arms	26	86.7	25	83.3
Legs	15	50.0	14	46.7
All the above sites	4	13.3	5	16.7
Problems occurred in injection sites:				
At the beginning of the study	15	50.0	20	66.7
3 months after the study	8	26.7	18	60.0

*Significant (P<0.05)

Table 2. Mean distribution of the diabetic children according to their glycemic control variables

| Glycemic control variables	Group I (pen group) (n=30)		Group II (syringe group) (n=30)	
	At the beginning of the study	3 months after the study	At the beginning of the study	3 months after the study
Fasting blood glucose(mg/dl):				
Range	54-446	80-345	78-397	80-366
Mean±SD	212.27±87.38	161.67±63.32	197.57±84.46	186.63±72.83
Paired t-test		4.084		1.653
P		0.0001*		0.109
Post-prandial blood glucose (mg/dl):				
Range	112-438	86-460	67-500	71-305
Mean±SD	224.33±79.43	171.93±79.24	186.60±93.15	179.63±67.60
Paired t-test		4.524		0.751
P		0.0001*		0.459
Glycosylated HB:				
Range	6.50-12.40	5.20-13.10	5.80-12.90	6.00-12.50
Mean±SD	8.73±1.74	7.86±1.79	8.22±1.77	8.45±1.86
Paired t-test		2.501		0.779
P		0.018*		0.442
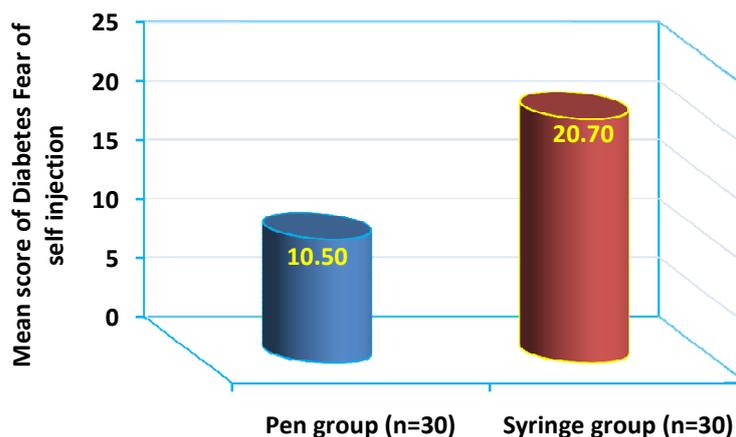
Fig. 1. Mean scores of the diabetic children fear of self injection

Table 3. Mean scores of the diabetic children according to their satisfaction about insulin delivery devices (syringe or pen)

Satisfaction about insulin delivery devices	Group I (Pen group) (n=30)	Group II (Syringe group) (n=30)	t-test	P
	Mean ±SD	Mean ±SD		
Satisfied with current treatment	5.23±0.68	3.03±1.97	5.773	0.0001*
convenient treatment	5.27±0.64	3.07±1.93	5.930	0.0001*
flexible treatment	5.40±0.62	3.33±1.37	7.511	0.0001*
Satisfied with understanding his/her diabetes	4.63±0.67	3.47±1.04	5.162	0.0001*
Recommend this form of treatment to someone else	5.67±0.48	3.43±1.87	6.338	0.0001*
Satisfied to continue with the present form of treatment	5.70±0.47	2.87±2.22	6.829	0.0001*
felt blood sugar levels have been unacceptably high recently	2.23±1.04	3.70±1.51	4.377	0.0001*
felt blood sugar levels have been unacceptably low recently	1.77±0.90	2.93±1.23	4.197	0.0001*
Total	35.90±2.60	25.83±8.76	6.032	0.0001*

Table 4. Mean scores of the diabetic children preferences about insulin delivery devices

| Preferences about insulin delivery devices	Group I (Pen group) (n=30)	Group II (Syringe group) (n=30)	χ^2	P
	Mean ±SD	Mean ±SD		
Confidence in injecting correct dose	9.13±0.78	8.23±1.16	3.521	0.001*
More stable	9.10±0.71	8.07±0.98	4.672	0.001*
Confidence in setting dose	9.70±0.47	8.50±1.25	4.918	0.001*
More discreet in public	9.03±0.76	5.40±1.65	10.928	0.001*
Easier to handle	9.67±0.55	7.57±1.19	8.757	0.001*
Confidence in glycemic control	8.87±0.82	7.80±0.71	5.372	0.001*
Easier to use	9.70±0.59	7.9±1.34	6.698	0.001*
Easier to read dose	9.80±0.55	8.80±0.92	5.089	0.001*
Total	75.00±3.66	62.27±6.11	9.796	0.001*
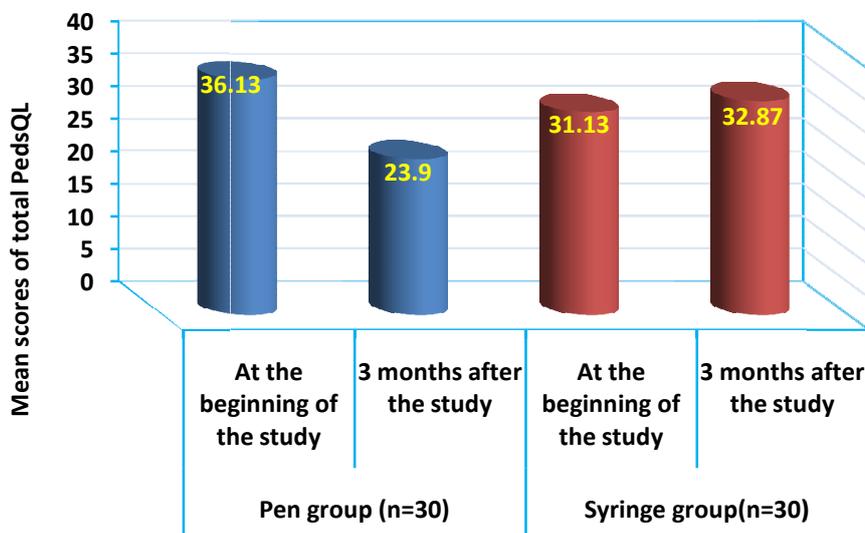
Fig. 2. Mean scores of the diabetic children according to their total quality of life at the beginning of the study and after 3 months

It was noticed that 5.67±0.48% of pen group recommended insulin pen to someone else, compared to 3.43±1.87%of syringe group with statistical significant difference. This table showed also that the overall satisfaction regarding using insulin pen was high (35.90±2.66%) corresponding to the syringe (25.83±8.76%) with statistical significant difference (P=0.0001).

Table (4) presents mean scores of the diabetic children preferences about insulin delivery devices. It was noticed that insulin pen was more discreet in public than syringe as the mean score was 9.03±0.76% for insulin pen while it was 5.40±1.65% for the syringe with statistical significant difference (P=0.001). It was found that insulin pen was easier to use than syringe as the mean score was 9.70±0.59% for insulin pen, while it was 7.9±1.34% for the syringe with statistical significant difference (P=0.001). The same table also clarified that the mean score of total preference regarding using insulin pen was 75.00±3.66 % while it was 62.27±6.11% for syringe, with statistical significant difference (P=0.001).
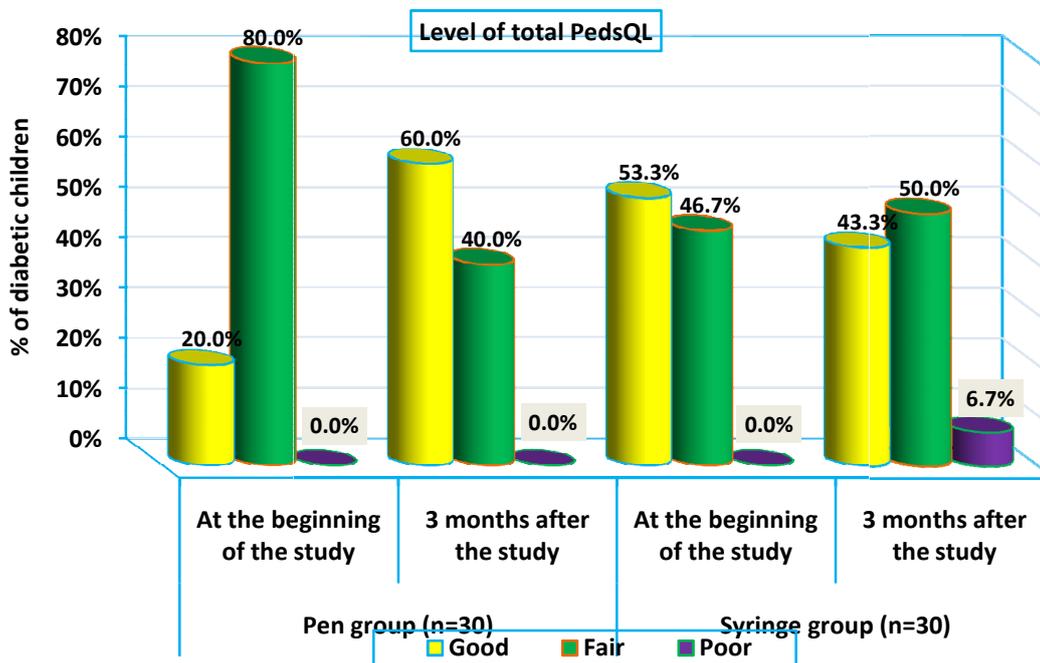
Figure (2) illustrates mean scores of the diabetic children according to their total quality of life at the beginning of the study and after 3 months**.** It was noticed that there was significant improvement in total quality of life by using insulin pen (P=0.0001) as the mean score was 36.13±10.56% at the beginning of the study and decreased to 23.90±12.89% after 3 months of using the pen, while the total quality of life was decreased by continuation of using syringe

3 months of using insulin pen, in addition, those who had fair quality of life decreased from 80% at the beginning of the study to 40% after 3 months with statistical significant difference (P= 0.004). On the other hand, it was noticed that there was reduction in quality of life of diabetic children who continued to use syringe as the percentage of diabetic children who had good quality of life decreased from 53.3% at the beginning of the study to 43.3% after 3 months.

Figure (4) shows correlation between diabetic children preferences about using insulin pen and their glycosylated hemoglobin. It was observed that there was negative significant correlation between diabetic children preferences about using insulin pen and their glycosylated hemoglobin (P= 0.007), this means whenever there was increase in diabetic children preference about using insulin pen; there was a decrease in glycosylated hemoglobin.

Figure (5) presents correlation between total quality of life of diabetic children who using pen for insulin injection and their glycosylated hemoglobin. It was clear that there was significant correlation between the total quality of life of diabetic children who using pen for insulin injection and their glycosylated hemoglobin.

Figure (6) shows correlation between total quality of life scores of diabetic children, their fear of self injection, and their preferences regarding using insulin pen.

Fig. 3. Categories of the diabetic children according to their total quality of life at the beginning of the study and after 3 months

Figure (3) presents categories of the diabetic children according to their total quality of life at the beginning of the study and after 3 months. It was observed that there was improvement in total quality of life after using insulin pen, as the percentage of children who had good quality of life increased from 20% at the beginning of the study to 60% after

It was found that there was positive significant correlation between total quality of life scores and diabetic children fear of self injection by using insulin pen (P=0.0001),which mean whenever the score of fear of self injection decreased, there was a decrease in total quality of life score, which mean improvement in total quality of life. This figure also illustrated

that there was negative significant correlation between diabetic children preference regarding using insulin pen and their total quality of life scores (P=0.009),which mean whenever the preference score of using insulin pen increased, there was a decrease in total quality of life score which mean improvement in quality of life

DISCUSSION

The incidence of type 1 diabetes in the pediatric population is a growing concern, and the optimization of glycemic control is a fundamental aspect of diabetes management.
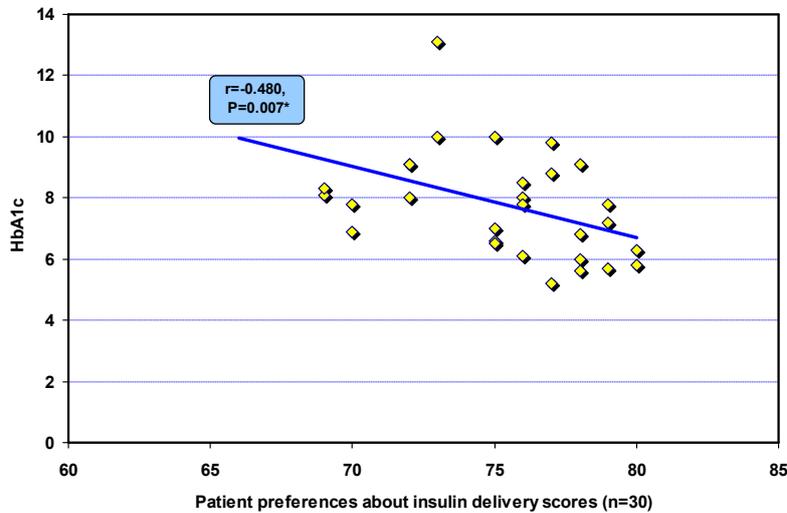

Fig.4. Correlation between diabetic children's preferences about using insulin pen and their glycosylated hemoglobin level
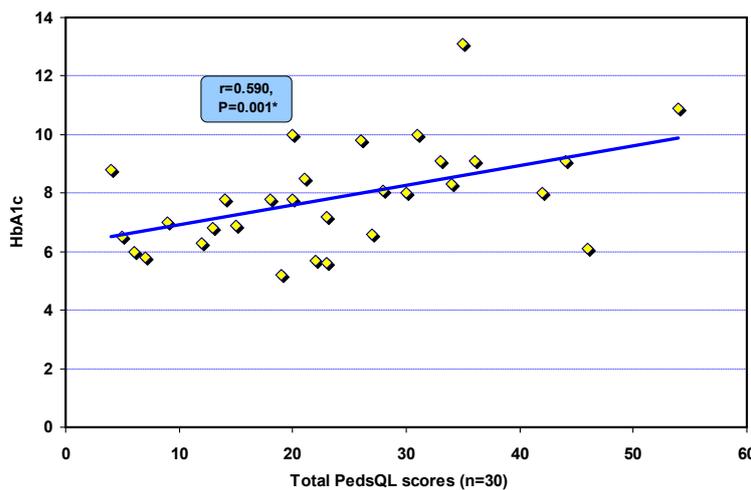

Fig.5. Correlation between total quality of life scores and glycosylated hemoglobin level among the diabetic children using insulin pen
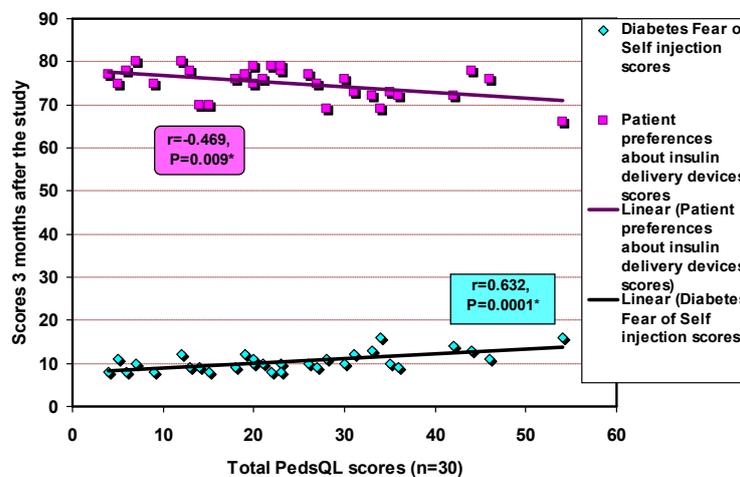

Fig.6. Correlation between total quality of life scores of diabetic children, their fear of self injection, and their preferences regarding using insulin pen

As a consequence, demand for insulin delivery devices that are simple, accurate, and tailored for the pediatric population will also increase. Insulin pen devices are designed to provide a convenient and easy means of insulin administration for the patient (McCoy and Wright, 2010). The results of this study revealed that the mean age for pen group was 10.50±1.72 years, while for syringe group was 9.60±17.3 years. The finding of the present study showed that the higher percentage of diabetic children were from rural area (Table1). This results agree with El-Ziny MA (2014) who found that with incidence and prevalence of type 1 diabetes were higher in females and more cases were found to originate from rural areas (El-Ziny *et al.,* 2014). This could be explained on the basis that rural population with low socioeconomic standards usually received therapeutic treatment from inpatient, and outpatient governmental clinics because of leakage of hospitals and health care services in rural areas.

Insulin therapy is the cornerstone in treatment of type 1 diabetes in children and adolescents. In order to prevent long-term complication multiple daily injections are required (Potts and Mandleco, 2012). In this respect, the finding of the present study revealed that 60% of pen group and 80% of syringe group had insulin injection 3 times per day. Self monitoring of blood glucose has improved diabetes management and is used successfully by children from the onset of their diabetes. Diabetes management depends to a great extent on self monitoring of blood glucose (Kyle and Carman, 2013). In this respect, the finding of the current study revealed that nearly half for each study group checked their blood glucose level 3 times per day. This study demonstrated that the use of insulin pen was associated with statistical significant reduction in problems that occurred at the insulin injection sites compared with the using of syringe, this can be explained on the basis that pen needle is thinner, sharper, shorter than syringe needle which lead to fewer problems.

Insulin pen devices were developed in an effort to overcome barriers to adherence with insulin self-administration and to improve convenience and ease of use for patient and reduce the occurrence of hypoglycemic events (Pisano, 2014). The finding of this study revealed that, there was significant improvement in glycemic control parameters after 3 months of using insulin pen. This could be explained on the base that insulin pen give diabetic children the confidence to overcome issues of needle anxiety and the social embarrassment associated with self injection and, therefore, may lead to improved adherence to recommended insulin dosing schedules and compliance with multiple injection regimen. Similar results were reported by Magnotti *et al.* (2007) who stated that the use of insulin pen leads to increase patient compliance and cause potential improvement in glycosylated hemoglobin (Magnolti, 2007). Piscopo *et al.* (2003) revealed in their study that the use of insulin pen is associated with an improvement in glycosylated hemoglobin; they stated that glycosylated hemoglobin decreased from 8.4% to 7.3 % (P less than 0.05) within the first 6 months of Novopen therapy (Piscopo *et al.,* 2003). In addition, Korytkowski *et al.* (2003) demonstrated in their study that there was a statistical significant improvement in glycemic control with average reduction of glycosylated hemoglobin values from 8.7at base line to 8.4 after the use of insulin

pen.[16]The results of this study presented that there was significant reduction in the fasting blood glucose concentration after 3 months of using insulin pen (P=0.0001). This result was agreed with Lee *et al.* (2009) who indicated in their study that fasting glucose level significantly decreased after the use of insulin pen for 12 weeks, and the reduction was significantly greater than that in the syringe group (Lee *et al.,* 2009). In addition ,this finding was in-line with Plevin and Sadur (1993) who revealed in their study that fasting blood glucose concentration decreased from 197mg∕dl to 171mg∕dl after using insulin pen (p<.05) (Plevin and Sadur, 1993).

Extreme fear of self injection and negative response to needles can affect patient's attitude toward diabetes and their ability to cope with injections. Insulin pen may be preferable and help to facilitate adherence in the pediatric population (Robert and Sarah, 2013). In this respect the finding of the current study revealed that there was statistical significant difference between pen group and syringe group regarding their fear of self injection. The results also presented that the mean score of diabetic children who tried to postpone the insulin dose in pen group were significantly less than in syringe group. Our results can be justified by the fact that pen device needles are available in 4-6 mm lengths, while the shortest syringe needle is 8 mm. The pen needles are also thinner than syringe needles: the gauge of syringe needles is usually 30, while pen needle designed for the pediatric population are available in 31 or 32gauge. In addition, the needle in the pen system does not have to puncture a stopper before injection as in the syringe and vial system; therefore, the needle retains its sharpness and beveled angle. In consistence with these results Stock *et al.* (2007) found that patients using the insulin pen device reported less fear of self injection compared with vial and syringe (Stockl *et al.,* 2007). Graff *et al.* (1998) indicated in their study that 85%of pen users never missed a scheduled injection, compared with 72%of patient using the vial and syringe (Graft and McClanahan, 1998).

The results showed that there was statistical significant difference between the pen and syringe group regarding their satisfaction about insulin delivery devices. On these, diabetic children in pen group indicated that they found insulin pen convenient, flexible and they recommended the use of insulin pen to others. These results can be justified on the basis that insulin pen meet the diabetic children needs for convenience, freedom, and flexibility. In consistent with this study, Bultman *et al.* (2011) clarified in his study that diabetic patient reported significantly greater satisfaction with diabetes treatment after using NovoPen 4 for 12 weeks, compared with their previous use of other insulin delivery devices (Bultman *et al.,* 2011). Bohannon *et al.* (2000) found in their study 76% of patients were somewhat or extremely satisfied with pen device, 78%probably or definitely would continue to use the pen device, and 80%of patients probably or definitely would recommended the pen device to others (Bohannon *et al.,* 2000).

The finding of the current study revealed that diabetic children reported significantly greater preference about using insulin pen, compared with those who used syringe for insulin injection. On these, diabetic children in pen group indicated that they found insulin pen easier to use than vial /syringe, and

found the numbers on the pen easier to read than the syringe, and they reported that insulin pen allowed them for more discreet injection in social situation. In my opinion, all these advantages make the insulin pen more convenient method of insulin administration and will lead to an improved attitude toward the use of insulin therapy. In consistent with this study, Bultman *et al.* (2011) clarified in his study that diabetic patients found Novo Pen4 easy to use, simple to learn, and convenient when handling daily (Bultman *et al.*, 2011). Stock *et al.* (2007), Summers *et al.* (2004), revealed in their studies that the majority of diabetic patients prefer the insulin pen device, citing social acceptability and ease of use as the major reasons (Stockl *et al.*, 2007; Summers *et al.*, 2004).

Intensive treatment of type 1 diabetes often disrupts a child's usual activities, and potentially impacts overall quality of life. Insulin pens are devices realized with the aim of simplifying insulin administration (Ausili *et al.*, 2007). In this support the finding of this study demonstrated that there was significant improvement in total quality of life by using insulin pen. This result can be explained on the basis that patient may experience increased opportunities to live a more flexible life due to the multiple–injection therapy provided by the pen device, i.e., experience greater freedom, eat, exercise physically and participate in ordinary social life in a manner that differs from the conventional method. In consistence with the current study Piscopo *et al.* (2003) demonstrated in his study that insulin pen was experienced as a progress which made a multiple injection regimen acceptable and provided an improvement in the quality of life (Piscopo *et al.*, 2003). The current study also showed that there was statistical significant correlation between the total quality of life of diabetic children who using pen for insulin injection and their glycosylated hemoglobin. In consistence with these finding, Lawrence *et al.* (2012) revealed in his study that glycosylated hemoglobin scores were correlated with quality of life total score (Lawrence *et al.*, 2012). Ausili *et al.* (2007) revealed that higher number of glycemic controls/day, better metabolic control was associated with better physical and psychological aspects of quality of life (Ausili *et al.*, 2007).

The finding of the present study also clarified that there was negative significant correlation between diabetic children preferences about using insulin pen and their glycosylated hemoglobin, this mean whenever there was increase in patient preference about using insulin pen; there was a decrease in glycosylated hemoglobin This can be explained on the basis that, whenever the diabetic children prefer the insulin pen they became more competent regarding their insulin therapy schedule and they didn't delay or even refuse their insulin dose, which will affect positively on their glycemic control.

Conclusion

Based on the findings of the present study, it can be concluded that

- The use of insulin pen device was associated with significant improvement in glycemic control parameters in children with type I diabetes mellitus.

- The use of insulin pen device was significantly associated with higher level of satisfaction and preference in children with type I diabetes mellitus compared with syringe.
- Children with type I diabetes mellitus expressed less fear of self injection by using insulin pen compared with syringe.
- There was significant improvement in total quality of life associated with the using of insulin pen device in children with type I diabetes mellitus.
- There was statistical significant correlation between the total quality of life of diabetic children who using pen for insulin injection and their glycosylated hemoglobin.

Recommendations

For diabetic children

- Health education should be provided to all diabetic children to improve their awareness of the characteristics of insulin pen devices.
- Educational material such as pamphlets, booklets and videos should be carefully prepared in diabetic units to explain types of insulin pen and how to use it.

For health care providers

-The advantages of insulin pen device mentioned in this study should be considered by health care providers when they counsel diabetic children regarding treatment options

For the community

-The health insurance should provide coverage for the insulin pen devices as well as the cartridges of insulin for refillable pens for all diabetic patients
-Mass media should explain the benefits of insulin pen devices to increase awareness of diabetic patients about treatment options

For further researchers

-Evaluate the health care costs of converting from administration of insulin therapy by a vial/syringe to an insulin pen device

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