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Comparison between Continuous Subcutaneous Insulin Infusion and Multiple Daily Insulin Injections, its Effects on Quality of Life among Children with Type 1 Diabetes

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Abstract
Type 1 diabetes mellitus (T1DM) is a common chronic disease in childhood. Fifty percent of subjects with T1DM are diagnosed within the first 15 years of life. Continuous Subcutaneous Insulin Infusion (CSII) and Multiple Daily insulin Injections (MDI) are both strategies aiming to achieve a tight glycemic and metabolic control. However, the choice between them remains controversial. The aim of the present study was to compare between continuous subcutaneous insulin infusion and multiple daily insulin injections and assess its effects on quality of life among children with type 1 diabetes. A comparative randomized design was conducted at maternal and children's hospital in Sakaka city of Aljouf area. Twenty five children with type 1 diabetes mellitus on CSII and 25 children on MDI were selected randomly, glucosylated Hemoglobin (HbA1c), frequency of hypoglycemia, frequency of hyperglycemia, body weight and number of hospital admissions were evaluated at baseline and after 6 months in both groups. In addition, the children answered the Ped QOL questionnaire **Results:** there is a significant difference between both groups at the onset of the study and after six months (p=0.0001) regarding mean glycelated hemoglobin with no difference in body weight. Also there was significant difference between the both groups after six months of the study to all subscales and total scores of all diabetic modules of PedQOl except communication subscale. **Conclusions**: CSII is effective in improving the glycemic control with no difference in metabolic control and a significant difference in the associated complication with time in type 1 diabetic Saudi children than using multiple daily insulin injection. Also the results expressed better quality of life among diabetic children using CSII than those using MDI. **Recommendation**: we recommend the implementation of this mode of intensive insulin therapy in all diabetic Saudi children.
Keywords: continuous subcutaneous insulin infusion, multiple daily insulin injection, type 1 diabetes, quality of life**.**

1. Introduction

Type 1diabetes is one of the most common chronic diseases in childhood with 480,000 children estimated affected globally. The incidence is increasing at 3% per year and annually 76,000 children aged less than 15 years old develop Type 1 Diabetes worldwide**(**International diabetes federation 2011). TYPE 1 Diabetes Mellitus is the most frequent endocrinology disease in children. The chronic course of the disease and life-long substitution of insulin- therapy that must be coordinated with the food, physical activity and the results of monitoring blood glucose are factors that make life of these children and their families very difficult (Abdul-Rasoul et al. 2012).

Incidence and prevalence of pediatric diabetes may differ from one country to another; there is clear epidemiological evidence that the incidence is high in many Arab countries particularly in the gulf areas which have been classified to very high and intermediate category according to the diamonds world health organization study classification (WHO 1990 & Abdulla 2005**)**. In Saudi Arabia the prevalence of type one diabetes mellitus among children and adolescent is 109.5 per 100,000 which are considered as high prevalence in2008 (Al-Herbish et al. 2008), On the other hand, recent reports have documented higher incidence rates of T1DM in children as 27.5/100,000 per year in specific region, which was differ from one region to another (Abduljabbar et al. 2010). But now the prevalence of DM is hospital based. The statistical department in Prince Abde alrhman Alsedery in Sakaka city of Aljouf area at the north of Saudi Arabia revealed that about 1500 pediatric cases admitted to hospital from disease complication and blood glucose levels irregularity (Statistical department 2012).

Multiple daily injection treatment is the most widely used method of insulin administration, and comprises intermediate or long acting insulin once or twice a day as a basal dose and rapid-acting insulin at each meal time, and patients are required to have at least 3 or more injections a day. A technological alternative to this method of insulin delivery is the continuous subcutaneous insulin infusion(Ben-Abas et al. 2005 & Wu et al. 2010 **)**.A key cited advantage of insulin pumps is improving blood glucose levels, as insulin pumps better mimic pancreatic insulin delivery and provide a more predictable insulin effect on blood glucose levels than injections. However,

there is still a worldwide debate among diabetologists concerning the advantages of continuous subcutaneous insulin infusion over multiple daily injections (Churchill et al .2009).

Socio culture's factors can profoundly influence diabetes control among diabetic children. In Saudi Arabia, important socioeconomic factors that results from rapid urbanization, excessive consumption of fast food, sedentary life style that led to an epidemic of obesity and vitamin D deficiency appear to have negative influence on diabetes control (Soliman et al. 2013). The Saudi government in its effort to build the welfare state through providing all the health services free of charge, this develop a negative attitude of dependency on the government and hospital from parents and their children without taking their role for self monitoring and control (Al- Shammari et al.2013).

Quality of life is the degree of well-being felt by an individual or group of people. Unlike standard of living, it is not tangible thing, and so cannot be measured directly. It consists of two components; physical and psychological. The physical aspect includes; things such as health, diet, and protection against short and long term complications. The psychological aspect includes stress, worry, pleasure and other positive or negative emotional states (Costanza et al. 2008 & Mohmoud et al. 2013). Monitoring quality of life in clinical practice for chronic illness, including diabetes, has been repeatedly advocated. The development and use of pediatric HRQoL measures are important for identifying at-risk children and applying early intervention programs (Varni et al .2005).

Quality of life for children with diabetes mellitus refers to subjective well-being focuses on the health related component of life satisfaction and wellbeing (Kalyva et al .2011). So trained pediatric nurses play a critical role in empowering diabetic children to better manage diabetes by using the safest method in insulin delivery for these diabetic children and providing them and their families with the required information and consultations as well as advantages and disadvantages of insulin administration methods (Peimani et al .2010).

1.2 **Significant of the Study:**
Several studies have suggested that intensive therapy with continuous subcutaneous insulin infusion could provide better glycemic control, with a lower risk of severe hypoglycemia and a lesser weight gain than multiple daily insulin injections, and most of these studied were done in adults (Skogsberg et al .2008). However a few of studies were done on diabetic Saudi children using different method of insulin mode, and how these modes affect on children quality of life. So, the present study is conducted to compare between continuous subcutaneous insulin infusion and multiple daily insulin injections, assess its effects on quality of life among children with type 1 diabetes

1.3 Research Question:

1- Is there a difference between using CSII and MDI on glycemic, metabolic and adverse effects of disease among children
2- What are the effects of using CSII and MDI on children quality of life

2. Subjects and Methods
2.1 Design:
A comparative randomized design was used in this study.

2.2 Setting:
The study was conducted at maternity and children's hospital in Sakaka city of Aljouf area at the north of Saudi Arabia is a tertiary central hospital which has an Endocrine and Diabetes unit.

2.3 Subject:
50 participants of middle and high school children (ages 12–17 years) with type 1 diabetes who attend a medical appointment were selected randomly and divided equally into two groups. One group was using the pump and the other group was using MDI. The children were selected if they were Saudi, had been recently used the current insulin regimen, were free from any other medical or psychiatric disease diagnosed by physician, and willing to participate in the study. The children were interviewed during their follow up clinical visit at the entry of the study and after 6 months.

2.4 Tools of data collection:
Data were collected using the following three tools:
1-Interview questionnaire that cover the following parts:

Part (1): Demographic data that were designed by the researcher and include information about children and their families such as age, sex, residence, occupation and educational level.

Part (2): Clinical data obtained from participants' medical records about disease duration (date of diabetes diagnosis), their diabetes regimen, A1C levels and body weight, number of hospitalization and frequency of hypo or hyperglycemic attacks as well as presence of technical problems.

2-Pediatric Quality of Life Inventory; Diabetes Module, is a multi-dimensional diabetes-specific instrument that assesses children and adolescents (2–18 years). A 5-poin Likert scale ranging from zero to four points; never=4, almost never=3, sometimes=2, often=1 and almost always=0.This 28 questions assess 5 scales of HRQOL, which include: (1) diabetes symptoms (11 items) (scored 0-44), (2) treatment barriers (4 items)(scored 0-16), (3) treatment adherence (7 items)(scored 0-28), (4) worry (3 items)(scored 0-12), and (5) communication (3 items)(scored 0-12), with total score ranged from 0-112. The lower score indicate better quality of life.

3-Generic Core Scale of ped QOL, a child self-report consisted of 23 items divided into 4 subscales: (1) physical function (8 items) (scored 0-32), (2) emotional function (5 items) (scored 0-20), (3) social function (5 items) (scored 0-20) and (4) school function (5 items) (scored 0-20), with total score ranged from 0-92. The lower score indicate better quality of life.

Both instruments were translated into Arabic and showed good internal consistency reliability and constant validity with Cronbach's alpha value (0.840).

2.5 Methods of data collection:

Ethical consideration:

- Official permission from the authorized directors in the selected setting was obtained to conduct the study.
- Children with type 1 diabetes mellitus how fulfill the criteria were invited to participate in the study during their regular visits to outpatient clinics.
- Verbal consent for participation was obtained from children after explaining the aim of the study and assuring them that these data will be confidential.

Pilot study:

- A pilot study was carried out on 10 children with their mothers to test the feasibility and applicability of the tools, and the necessary modification was done.
- Every child in both groups was interviewed to collect the baseline necessary data, and privacy was considered as possible; mothers were asked when indicated.
- An instructional session was conducted for both groups to maintain ordinary lifestyle activities and to adjust insulin dose in relation to glucose level, physical activities, extra meals, illness and other significant daily events. The only difference was for children and their families who use pump therapy assuring that they were trained well on insulin pump operation and programming and was psychologically accepting it and had realistic expectations of CSII. They were instructed to change the infusion set every 2-3 days and if there is any sign of insertion site infection.
- At each visit, the following parameters were registered: body weight, Hemoglobin A1c (HbA1c), insulin dosage, number of contacts with the hospital for ketoacidosis (defined as pH, 7.30), severe hypoglycemic episodes and cannula insertion site were checked and any technical problems for CSII group.
- All participants completed the Pediatric Quality of Life Inventory, diabetes module and generic Core Scale of PedsQL at the beginning of the study as a baseline and after 6 months.

2.6 Statistical analysis:

The collected data were organized, tabulated and statistically analyzed using SPSS software (Statistical Package for the Social Sciences, version 16, SPSS Inc. Chicago, IL, USA). For quantitative data, the range, mean and standard deviation were calculated. For qualitative data, comparison between two groups and more was done using Chi-square test ($\chi 2$) and Fisher Exact test (FE). For comparison between means of both groups, parametric analysis (t-test) was used. For comparison between means of two related groups (at onset of the study & after six months) of parametric data, paired t-test was used. Significance was adopted at $p<0.05$.

2.7 Limitation of the study:

A limitation of this study is the small sample size which may not represent the general population of children

with type 1 diabetes mellitus at the study area as most of families prefer taking their children to a large hospital or specialized centers at another area. The small sample size also reduced the power of our statistical analyses to detect significant differences where they really exist

3. Results:

Table (1): Basic data of the study diabetic children and their parents (n=50).

Variables	The study diabetic children (Type I) (n=50)				χ^2	P
	Group 1 (n=25)		Group 2 (n=25)			
	n	%	n	%		
▪Age (years):						
12-<15	10	40.0	11	44.0	0.082	0.774
15-17	15	60.0	14	56.0		
▪Sex:						
Males	11	44.0	13	52.0	0.321	0.571
Females	14	56.0	12	48.0		
▪Residence:						
Rural	11	44.0	11	44.0	0.000	1.000
Urban	14	56.0	14	56.0		
▪Family dynamics:						
Both parents	15	60.0	13	52.0	0.325	0.569
Single parent	10	40.0	12	48.0		
▪School performance:						
Poor	4	16.0	1	4.0	5.930	0.115
Average	7	28.0	7	28.0		
Good	8	32.0	15	60.0		
Excellent	6	24.0	2	8.0		
▪Caregiver education:						
Educated	10	40.0	14	56.0	1.282	0.258
Non-educated	15	60.0	11	44.0		
▪Caregiver occupation:						
Working	10	40.0	9	36.0	0.085	0.771
Housewife	15	60.0	16	64.0		
▪Disease duration (years):						
1-<4	7	28.0	4	16.0	1.671	0.434
4-6	8	32.0	12	48.0		
>6	10	40.0	9	36.0		

Group 1: (MDI) Group 2: (CSII)

Table (1) shows that more than half of diabetic children, 60% in MDI group (G1) and 56% in CSII group (G2) their age were between 15-17 years, 65% of them were females in G(1) while 52% of G(2) were male and 56% of both group were from urban areas. Also 60% in group one and 52%in group two had both parents. As regard caregivers education and occupation, 60% of them were non-educated and housewife in group one while in group two 56%of them were educated and 64% of them were housewife. School performance among group one nearly equal with 32%of them had good performance and 40% of them their disease duration more than 6 years, while in group two 60% of them had good school performance and 48% of them their disease duration range from 4-6 years.

Table (2): Mean body weight and HgA1c of the study diabetic children at onset of the study and after six months (n=50).

Variables		The study diabetic children (Type I) (n=50)		χ^2	P
		Group 1 (n=25)	Group 2 (n=25)		
		Range Mean±SD	Range Mean±SD		
▪Body weight (kg)	At onset of study	4.00-80.00 52.64±17.57	33.00-78.00 53.52±14.94	0.191	0.850
	After 6 months of the study	35.00-79.00 54.20±14.72	32.00-75.00 52.60±14.49	0.387	0.700
Paired t-test P		1.084 0.289	2.009 0.056		
▪HgA1c:	At onset of study	6.90-8.50 7.71±0.40	6.50-7.90 7.08±0.31	6.208	0.0001*
	After 6 months of the study	6.60-9.70 7.60±0.61	6.30-7.70 6.92±0.32	4.920	0.0001*
Paired t-test P		1.453 0.159	4.615 0.0001*		

***Significant (P<0.05)**
Group 1: (MDI) Group 2 :(CSII)

Table (2) shows that the mean bodyweight of diabetic children treated by multiple daily insulin injections at the onset of the study was 52.64±17.57 and after six months increased to 54.20±14.72 with no significant difference (p=0.289).While the mean body weight among group two treated by insulin pump at the onset of the study was 53.52±14.94 and after six months decreased to 52.60±14.49 with no difference between both groups at the onset and after six months of the study. Regarding the mean glycelated hemoglobin (HgA1), it was 7.71±0.40 in group one at the onset of the study and decreased to 7.60±0.61 after six months, while in group two the mean HgA1 was 7.08±0.31 at the onset of the study and decreased to 6.92±0.32 after six months with a significant difference between mean HgA1 among group two at the onset and after six months of the study (p=0.0001).Also there was a significant difference between both groups at the onset of the study and after six months (p=0.0001).

Table (3): Associated complications among the study diabetic children at onset of the study and after six months (n=50).

Variables	The study diabetic children (Type I) (n=50)								χ^2 P	
	Group 1 (n=25)				Group 2 (n=25)					
	At onset of study		After 6 months of the study		At onset of study		After 6 months of the study		At onset of study	After 6 months of the study
	n	%			n	%				
▪No. of hospitalization:										
No hospitalization	4	16.0	4	16.0	5	20.0	10	40.0	1.110	8.570
1-2	14	56.0	15	60.0	14	56.0	15	60.0	0.774	0.014*
3-4	6	24.0	6	24.0	6	24.0	0	0.0		
5	1	4.0	0	0.0	0	0.0	0	0.0		
χ^2	1.03				7.700					
P	0.793				0.021*					
▪No. of hypoglycemic attacks:										
No attacks	6	24.0	7	28.0	18	72.0	22	88.0	15.477	19.009
One	7	28.0	13	52.0	6	24.0	3	12.0	0.001*	0.0001*
Two	9	36.0	5	20.0	1	4.0	0	0.0		
Three	3	12.0	0	0.0	0	0.0	0	0.0		
χ^2	6.022				2.400					
P	0.111				0.301					
▪No. of hyperglycemic attacks:										
No attacks	12	48.0	10	40.0	5	20.0	8	32.0	7.660	1.513
One	11	44.0	14	56.0	11	44.0	17	68.0	0.054	0.469
Two	2	8.0	1	4.0	7	28.0	0	0.0		
Three	0	0.0	0	0.0	2	8.0	0	0.0		
χ^2	0.880				10.980					
P	0.645				0.012*					

***Significant (P<0.05)**
Group 1 :(MDI) Group 2: (CSII)

As regard the associated complications among the study diabetic children in **table (3)**, it was found that there was no significant difference within group (1) treated by multiple daily insulin injection to number of hospitalization at the onset and after six months of the study p=0.793.While in group (2) using insulin pump, there was a significant difference regarding number of hospital admission at the onset and after six months of the study p=0.021. There was also significant difference between both the studied groups regarding the number of hospital admission at the onset and after six months of the study (p=0.014). Concerning numbers of hypoglycemic attacks, it was noticed that there was no significant difference within group (1) and also within group (2) at the onset and after six months of the study. But there was a significant difference between both groups at the onset of the study (p=0.001) and after six months of the study (p=0.0001). Regarding number of hyperglycemic attacks, there was no significant difference within group (1) at the onset and after six months of the study (p=0.645).While there was a significant difference within group (2) regarding number of hyperglycemic attacks at the onset and after six months (p=0.012), with no significant differences between both studied groups at the onset (p=0.054) and after six months of the study (p=0.469).

Table (4): Mean scores of the Pediatric Quality of Life Inventory (Diabetes Module) of the study diabetic children (n=50).

Peds QL Diabetes Module main items	The study diabetic children (Type I) (n=50)				t-test P	
	Group 1 (n=25)		Group 2 (n=25)			
	At onset of study	After 6 months of study	At onset of study	After 6 months of study	At onset of study	After 6 months of study
▪Diabetes symptoms (0-44):						
Range	7-37	12-36	6-24	5-19	6.208	6.917
Mean±SD	23.40±6.86	20.44±6.61	15.84±5.70	10.24±3.27	0.0001*	0.0001*
Paired t-test	2.851		5.509			
P	0.009*		0.0001*			
▪Treatment barriers (0-16):						
Range	4-16	5-16	3-14	3-12	3.317	4.858
Mean±SD	10.16±3.05	8.72±3.03	7.40±2.83	5.20±1.98	0.002*	0.0001*
Paired t-test	4.272		5.092			
P	0.0001*		0.0001*			
▪Treatment adherence (0-28):						
Range	9-23	2-23	7-22	4-20	2.833	3.961
Mean±SD	16.08±4.51	13.64±4.57	13.88±3.96	9.20±3.24	0.003*	0.0001*
Paired t-test	4.163		6.715			
P	0.0001*		0.0001*			
▪Worry (0-12):						
Range	3-11	1-10	3-11	1-9	3.018	5.770
Mean±SD	7.76±1.88	7.08±2.12	6.12±1.96	3.84±1.84	0.004*	0.0001*
Paired t-test	1.705		7.817			
P	0.101		0.0001*			
▪Communication (0-12):						
Range	2-10	1-10	1-9	0-7	0.853	1.368
Mean±SD	5.44±2.16	3.64±2.18	4.88±2.47	2.84±1.95	0.398	0.178
Paired t-test	4.700		5.696			
P	0.0001*		0.0001*			
Total (0-112)						
Range	30-90	32-83	24-73	15-62	3.667	6.857
Mean±SD	62.84±14.51	53.52±13.29	48.12±13.8	31.32±9.24	0.001*	0.0001*
Paired t-test	5.216		7.687			
P	0.0001*		0.0001*			

***Significant (P<0.05)**
Group 1 (MDI) Group 2 (CSII)

Table (4) shows mean score of Pediatric quality of life (diabetic module items) of the study diabetic children, it was noticed that there was a significant difference within group (1) treated by multiple daily insulin injection regarding the mean scores of all diabetic module subscale (diabetes symptoms, treatment barriers, treatment adherence, communication and the total score) at the onset and after sex month of the study (P<0.05), except worry subscale of diabetic module, there was no significant difference. While within group (2) using insulin pump there was a significant difference in the mean score of all diabetic module subscale and the total score at the onset of the study and after six months(P<0.05). Comparing the mean scores of the PQOL diabetic module at the onset and after six months there was significant difference between the both groups at the onset of the study to all subscales and total of all diabetic modules except communication subscale. Also there was significant difference between the both groups after six months of the study to all subscales and total scores of all diabetic modules except communication subscale (P>0.05).

Table (5): Mean scores of the generic code scale of Ped QOL of the study diabetic children (n=50).

Peds QL generic code scale Module main items	The study diabetic children (Type I) (n=50)				t-test P	
	Group 1 (n=25)		Group 2 (n=25)			
	At onset of study	After 6 months of study	At onset of study	After 6 months of study	At onset of study	After 6 months of study
▪Physical health (0-32):						
Range	3-19	3-22	4-19	4-18	2.513	4.057
Mean±SD	12.36±4.50	11.92±4.86	9.44±3.67	7.24±3.10	0.015*	0.0001*
Paired t-test	0.507		3.701			
P	0.617		0.001*			
▪Emotional functioning (0-20):						
Range	9-20	6-18	4-17	2-17	6.871	5.010
Mean±SD	15.00±3.24	12.84±3.92	8.92±3.01	7.12±4.15	0.0001*	0.0001*
Paired t-test	3.154		3.464			
P	0.004*		0.002*			
▪ Social functioning (0-20):						
Range	3-14	0-15	3-11	2-12	1.215	3.373
Mean±SD	8.20±3.32	8.68±4.45	7.24±2.15	5.24±2.49	0.230	0.001*
Paired t-test	0.844		4.364			
P	0.407		0.0001*			
▪ School functioning (0-20):						
Range	5-18	5-20	5-14	2-13	1.736	3.890
Mean±SD	10.52±3.71	9.76±4.52	9.00±2.33	5.68±2.66	0.089	0.0001*
Paired t-test	2.074		7.093			
P	0.049*		0.0001*			
Total (0-92)						
Range	23-70	20-67	17-55	13-51	4.072	4.944
Mean±SD	46.08±11.32	43.20±14.88	34.60±8.41	25.28±10.35	0.0001*	0.0001*
Paired t-test	1.609		5.515			
P	0.121		0.0001*			

***Significant (P<0.05)**
Group 1 (MDI) Group 2 (CSII)

As regard the mean score of the generic code scale of the PedOL (a child self report) of the study diabetic children in **table (5)**, it was noticed that there was no significant difference within group (1) treated by multiple daily insulin injection regarding the mean scores of physical health subscale, social functioning subscale and the total mean scores (P>0.05) at the onset and after six months of the study, but there was significant difference regarding emotional functioning subscale (p=0.004) and school functioning subscale (p=0.049). While within group (2) using insulin pump there was a significant difference in the mean score of all modules subscales and the total mean scores at the onset of the study and after six months(P<0.05). Comparing the mean score of the PQOL generic code scale at the onset and after six months there was significant difference between both groups at the onset of the study to physical health; emotional functioning subscale and total mean scores except social functioning and school functioning subscale. As well as there was significant difference between the both groups after six months of the study regarding all subscales and total scores of the generic code scale of the PedsQL (P<0.05).

Table (6): Relationship between Pediatric Quality of Life and basic data of the study diabetic children

Variables	Mean scores of Peds QL			
	Group 1 (n=25)	t-test P	Group 2 (n=25)	t-test P
	Mean±SD		Mean±SD	
▪Age (years):				
12-<15	70.60±14.61	2.386	55.00±13.43	2.411
15-17	57.67±12.34	0.026*	42.71±12.01	0.024*
▪Sex:				
Males	71.45±11.24	3.052	48.38±16.57	0.097
Females	56.07±13.40	0.006*	47.83±10.92	0.923
▪Disease duration (years):				
1-<4	72.57±10.45	F-value	53.50±11.47	F-value
4-6	61.37±15.29	0.705	51.00±15.69	1.536
>6	57.20±14.01	0.089	41.89±10.28	0.237

***Significant (P<0.05)**

able (6) shows the relationship between Ped QL and basic data of diabetic children, concerning age the mean score of Peds Ql in group (1) decreased from 70.60 ±14.61 among children aged 12 to less than 15 years to 57.67± 12.34 among children aged 15-17 years which indicate better quality of life with a significant relation between quality of life and child age (p= 0.026). Also in group (2) there was improvement in QOl with increased age with a positive relation (p=0.024).As regard sex, the mean score ofQOl is better among female in both group with a significant relation in group (1) (p=0.006) and no significant relation in group 2 (p=0.923).Regarding disease duration the score of QOl decreased with increased disease duration among both group which indicate better quality of life with no significant relation in both group.

4. Discussion

The results of the present study found a decrease in glycelated hemoglobin which achieve glycemic control when compare mean HgA1 in group use MDI to group use CSII with no significant difference in group using MDI at the onset and after six months of the study, while a significant difference was founded in mean HgA1 within group using CSII at the onset and after six months of the study .The lower HbA1c values during CSII on repeated measures were accounted for the lower HbA1c value at the start of the treatment but there was significant difference between modes of therapy in the change over time. (p=0.0001).This results agreed with Alhyak et al(2014**)** we found that when compared diabetic module of QOl with HbA1c value, positive differences were observed in diabetes symptoms, treatment barriers, treatment adherence, worry, communication and total HRQoL. Also, regression analysis of the study also showed that HbA1c was the independent influencing factor for diabetes symptoms, treatment barriers, and total HRQoL. However these findings disagreed with Lawrence et al (2012**)** who found that youth with poor glycemic control based on their age-specific hemoglobin A1C target values and those with depressive symptoms had significantly lower PedsQL-T1DM scores than their counterparts with good control and no or limited depressive symptoms.

Another concern of adolescent who achieve improved glycemic control with intensive therapy of insulin pump is weight gain (Sulli & Shashaj (2003). In our study there was no significant difference between mode of insulin therapy and body weight at the onset and after six month in both studied group. The most possible explanation for the lack of a significant difference in improved metabolic control might be that the study period was too short to detect a difference in outcome because many patients could have had adverse effect attacks that might require hospital admission. These findings corresponded with Skogsberg et al (2008) who mentioned that the CSII treatment group showed significantly greater treatment satisfaction but without any difference in metabolic control when compared with MDI treatment during the study period of 24 months. Also Pozzillip et al (2003) showed no difference in metabolic control between the CSII and the MDI treatments in a pilot study of patients with newly diagnosed type 1diabetes.While Weintrob et al (2003**)** found a significant interaction between mode of therapy and change in BMI , with no change during CSII and a significant, albeit slight, increase during MDI.
As regard the associated complication among the study diabetic children, the results revealed no significant difference within group (1) treated by multiple daily insulin injection regarding number of hospitalization at the onset and after six months of the study p=0.793.This lack of difference due to repeated adverse effect of diabetes that require hospital admission for interventions. While in group (2) using insulin pump, there was a significant difference regarding number of hospital admission at the onset and after six months of the study p=0.021. There was also significant difference between both the studied groups regarding the number of hospital admission at

the onset and after six months of the study (p=0.014).This may due to children experience with the disease particularly with long duration.

The frequency of hypoglycemic attack within group using CSII was obviously lowered than in group using MDI with no significance difference within both groups. This might be secondary not only to the different modes of therapy but also to the different short-acting insulin used in the 2 treatment modalities. But there was a significant difference between both studied groups at the onset (p=0.001) and after six month of study (p=0.0001). Many studies have been conducted to compare the efficacy of MDI versus CSII. In a systemic review of 22 studies, Jeitler et al (2008**)** found that CSII resulted in a greater reduction of HbA1c and a reduction in hypoglycemic episodes. In a retrospective chart review, Beatajoo et al (2012) & Al saleh et al(2013) found that CSII is safe, effective and a superior alternative to MDI. Other studies have shown no difference in the glycemic control in these two modalities of treatment.

Regarding number of hyperglycemic attacks, there was no significant difference within group (1) using MDI at the onset and after six months of the study (p=0.645).While there was a significant difference within group (2) regarding number of hyperglycemic attacks at the onset and after six months (p=0.012). This may because noncompliance to treatment regimen and the possible hazards of CSII is the susceptibility of children to the rapid development of DKA secondary to pump or infusion-set failure. With no significant differences between both studied groups at the onset (p=0.054) and after six months of the study (p=0.469).study made by Juliusson et al (2006) who stated that the most common cause of DKA in children on insulin pump is interruption of insulin delivery caused by catheter occlusion, battery failure, depleted insulin supply, patient error or inadequate training. The risk of DKA can be minimized by frequent self-monitoring of blood glucose and taking the emergency necessary steps in the event of unexplained hyperglycemia. The effectiveness of intensive insulin therapy including CSII appears to decrease with a decreased frequency of blood glucose self-monitoring and insulin dose adjustment.

Significant positive differences were found in all domains and total of the QoL(diabetic module) within group (1) treated by multiple daily insulin injection at the onset and after sex month of the study , except worry subscale there was no significant difference. This may explained that adolescent more concerned about his body image changed and the long term complication of the chronic disease. Also families of children with poor metabolic control had high burden and much worries than those with good control .While within group (2) using insulin pump there was a significant positive difference in all diabetic module subscale and the total score at the onset of the study and after six months. Previous study made by Valenzuela et al (2006) reported that the insulin pump gives patients more flexibility in the timing of their meals and children on the pump can adjust for snacks and meals, as well as for exercise and physical exertion. As well as the insulin pump reduces the occurrence of serious hypoglycemic episodes. Also significant positive differences were found in all domains and total of the QoL (diabetic module) between both groups except communication subscale, this may due to absence of afternoon clinics appointment for follow up and Arabian culture restriction and beliefs about chronic disease like diabetes .Hanberger et al (20009) stated that the score for the MDI group was expected as a baseline finding for children on long-term MDI treatment, whereas the CSII group had a significantly higher score. The patients using CSII were more satisfied with their treatment option and therefore were likely to find diabetes less difficult to manage. It can be expected that these patients will have fewer worries about their disease and that there will be a reduced negative impact of diabetes in daily life. Also Al- Hayek et al (2014) found that when compared to MDI significant positive differences were found in all domains of the HRQoL of insulin pump users except communication.

Comparing the mean score of the PQOL generic code scale between both groups, there was significant difference to all subscale and total mean scores except social and school functioning subscale, there was no significant difference at the onset of the study. This results disagreed with Kalyva et al (2011**)**who illustrated that cultural and social factors associated with support from extended family might at least partly have helped these children to cope socially within and, subsequently outside their family. Another results made by De Wit (2007) revealed that The school functioning of children and adolescents withT1DM is impaired as well partly because of many absences from school and that poorly controlled diabetes is associated with subtle neuropsychological deficits that may reduce academic achievement. As well as children and adolescents with T1DM did not report compromise social HRQoL. But after six months there was significant difference to all subscale and total mean scores. This may due to the use of injectable devices (pens, pumps), and more flexible school schedules accommodating diabetes management may help children and adolescents to adapt to their condition and socialize with minimal intervention. A study made by Al-Akour et al (2010) indicated that frequent absence from school and the subtle neurophysiologic changes associated with poor glycemic control

was overcome in some places by having afternoon clinics and frequent educational sessions. Also Al-Hyak et al (2014) reported that PedsQL 3.0 DM when compared with those receiving MDI, insulin pump adolescents had significantly higher levels for all domains.

The age of the child was an important predictor of level of QoL , the results indicated better quality of life with a significant relation with increase child age in both studied group which corresponded with Chaplin et al (2009 **)** who indicate that as children got older the scores of QOl improved. This could be explained by the fact that adolescents manage their disease more subjectively and independently than younger children. These results disagreed with Lawrence(2012) &Abdul-Rasoul et al (2013) the PedsQL-T1DM total score was negatively and significantly associated with younger age.

As regard gender the present study reported better QOl among girls than boys, it has been suggested that the differences in QOL score between males and females during adolescence are due to the social context of and internal expectations of gender identity. This findings is contradicted with the previous researches (Nansel et al 2008) that indicated that male gender predicted better QoL than girls as girls have been shown to have more diabetes-related worries and take responsibility for their disease earlier because they tend to enter puberty and mature earlier than boys .While Al-Yaarubi et al (2014**)** did not find a relationship between gender and QoL. Also s study made by Al-Hayek et al (2014**)** found insignificant but lower HRQoL among females on the PedsQL 3.0 DM subscale of diabetes symptoms, treatment barriers, treatment adherence, and worry than their male counterparts. However, compared with male a significant difference was found in female gender on the subscale of communication. This lower level of HRQoL in females may be due to culture, as males have easier access to medical treatment than females.

Also the results indicated that the quality of life is better with prolonged disease duration among both children using multiple daily insulin injection and children using insulin pump. This finding also disagreed with Abdul-Rasoul et al (2013**)** who mentioned that early onset and longer duration of diabetes were associated with poorer QoL, which is consistent with earlier reports illustrated that longer duration of diabetes was associated with more psychological and behavioral problems and worse QoL. Al-hyak et al(2014) found that when compared with adolescents with a shorter duration of T1DM, significant negative differences were observed in the PedsQL 3.0 DM subscales of diabetes symptoms and communication of longer duration on T1DM adolescents. However, in the regression analysis, there were no significant differences between HRQoL and diabetes duration of T1DM (Verma et al 2010).

5. Conclusion

The present showed that CSII is effective in improving the glycemic control with no difference in metabolic control and a significant difference in the associated complication with time in type 1 diabetic Saudi children than using multiple daily insulin injection. Also the results expressed better quality of life among diabetic children using CSII than those using MDI that motivate the implementation of this mode of intensive insulin therapy in all diabetic Saudi children.

6. Recommendations

-Diabetes education must not be given once to the diabetic children and their families, but must be regular follow up programs to be applied in fixed times monthly.
-Assessment of QoL after diagnosis of T1DM should be a routine practice in patients with diabetes to facilitate communication, identify early problems and implement early intervention.
-Conducting more prospective researches to emphasize the factors affecting quality of life of diabetic children and adolescents and how to deal with it for developing and refining interventions to ensure their QOL.

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