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Original article

Comparison between Continuous Subcutaneous Insulin Infusion *versus* Multiple Daily Insulin Injection Effects on the Quality of Life in Libyan Children with Type 1 Diabetes Mellitus

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Abstract
Type 1 diabetes mellitus (T1DM) is considered a chronic autoimmune disease. Since the 1970s, the continuous subcutaneous insulin infusion therapy (CSII) via pumps has been widely used in the management of T1DM in comparison to multiple daily insulin therapy (MDI). The present study aimed to compare the quality of life among pediatric age groups with type 1 diabetes mellitus who were treated by insulin pumps versus multiple daily injections. This study was a randomized trial carried out at the pediatric departments of Tripoli University Hospital and Children's Hospital, Tripoli, Libya, between September and November 2020. The Pediatric Quality of Life Inventory 3.0 Diabetes Module was used to assess the health-related quality of life of children with diabetes. This study was statistically managed via a computerized program of the Statistical Package for the Social Sciences version 21. A total of 54 Libyan children with T1DM were included in the study; 27 were treated by MDI, compared to 27 who were treated by CSII insulin pump. This study revealed that the health-related quality of life was better among the insulin pump group compared to the MDI group according to overall PedsQL dimensions' comparison. Hemoglobin A1c readings were lower in the insulin pump group compared to the MDI group, 7.7% and 9.9%, respectively. In terms of diabetes symptoms and treatment problems, patients on CSII had better symptom control and fewer treatment barriers than the MDI group, some of which were statistically significant. Patients on insulin pumps had better communication with their health care providers. No difference had been identified between the two groups related to worry problems. This study concluded that the diabetic children who were treated by continuous subcutaneous insulin infusion "CSII" (insulin pump) had better health-related quality of life in almost all facets compared to multiple daily insulin injection "MDI". Thence, early utilization of insulin pumps among diabetic children is recommended to improve health outcomes and reduce related adverse health outcomes.
Keywords. Health-Related Quality of Life, Type 1 Diabetes Mellitus, Children, Insulin Pump.

Introduction

Type 1 diabetes mellitus (T1DM) is considered a chronic autoimmune disease as a result of progressive pancreatic beta cell destruction [1-2]. Globally, the incidence of type 1 diabetes mellitus has risen over time, with an estimated percentage was 1 in every 400-600 among children and adolescents [3-4]. In general, insulin therapy is administered by daily multiple subcutaneous injections using different insulin regimes to standard requirements, and the recommended doses are adjusted according to blood glucose level, meals, and physical activity [5-6].

Since the 1970's, the continuous subcutaneous insulin infusion therapy (CSII) via pumps had widely raised used in the management of T1DM in compare to multiple daily insulin therapy (MDI) which supported their efficacy by various studies in meta-analyses of observational and randomized controlled studies among childhood as well as adolescent [7]. Also, the CSII therapy is identified to improve the quality of life because it closely mimics daily physiological insulin characteristics [8]. Therefore, the aim of the present study was to compare the quality of life among pediatric age groups with type 1 diabetes mellitus who were treated by insulin pumps versus multiple daily injections.

Methods

This study was a randomized trial carried out at the pediatric departments of Tripoli University Hospital and Children's Hospital, Tripoli, Libya, between September and November 2020.

The study included 54 pediatric diabetic patients (aged less than 18 years) who were diagnosed with type 1 diabetes mellitus. 27 of these patients who treated with multiple daily insulin injection "MDI" versus 27 of them who were treated by continuous subcutaneous insulin infusion "CSII" (insulin pump).

The data was collected by two standardized questionnaires, including a patient characteristics questionnaire performed by investigators and another international validated questionnaire of Pediatric Quality of Life Inventory (PedsQL™) 3.0 Diabetes Module (PedsQL questionnaire) [9-10].

The PedsQL™ 3.0 Diabetes Module is a standardized questionnaire that used to evaluate the health-related quality of life (HRQoL) among diabetic pediatric patients through 28 items and 5 points Likert scale to illustrate the following scales variables as: Never = 0 (100), Rarely = 1 (75), Sometimes = 2 (50), Often = 3 and almost always = 4 (0). The higher average mean scores are considered better HRQoL. Also, the scales

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were related to the diabetes symptoms, treatment obstacles and compliance, anxiety, and communication issues [9-10].

(PedsQL™) 3.0 diabetes module composed of 4 main categories [9-10]: 1) Diabetes problems (11 questions); 2) Treatment problems (11 questions); 3) Worry problems (3 questions); and 4) Communication problems (3 questions). The data was enrollment through a face-to-face interview with the caregiver by pharmacy students who gathered the selected information.

This study was statistically managed via a computerized program of Statistical Package for the Social Sciences (SPSS) version 21. Descriptive statistics in the form of frequency and percentage, means ± SD were used. Inferential statistics in the form of an independent sample *t*-test and chi-square tests were used. The P value of less than 0.05 was considered statistically significant.

Results

A total of 54 Libyan children with T1DM were included in the study; 27 were treated on MDI compared to 27 other participants who were treated on CSII (insulin pump).

Regarding the age frequency, the mean age among the MDI group was 9.2 years, while 8.9 years was among the insulin pump group (Table 1).

Regarding the gender frequency, the frequency of male children was 11 in the MDI group and 9 in the CSII group. The frequency of female children was 16 in the MDI group and 18 in the CSII group. (Table 1). The HbA1c readings were lower in the insulin pump group compared to the MDI group, 7.7% and 9.9%, respectively (Table 1).

Table 1. Patient determinants and clinical information.

Variables (n = 54)	**MDI N=27**	**Insulin pump N=27**
Age (Year)	9.2	8.9
Gender (n) %	M= (11) 40.7% F= (16) 59.3%	M = (9) 33.33% F = (18) 66.66%
HbA1c (Mean)	9.9%	7.7%
Type of insulin	Humalog (insulin lispro) NovoRapid (insulin aspart) Lantus (insulin glargine)	Humalog (insulin lispro) Novo Rapid (insulin aspart)

On comparing the statistical differences in tests between diabetes mellitus problems among two groups of children, the health-related quality of life has been revealed to be better among the insulin pump group for most variables of the disease problems in comparison to the MDI group (Table 2).

Table 2. Diabetes problems

Variables (n = 54)	**MDI**		**Insulin Pump**		**P-value**
	Mean	**SD**	**Mean**	**SD**	
Feeling hungry	36.11	25.7	30.55	21.8	0.395
Feeling thirsty	44.44	22.9	31.48	23.1	**0.043***
Going to the bathroom too often	44.44	23.8	45.37	28.0	0.895
Having stomach-aches	76.85	27.9	63.88	25.7	0.081
Having headaches	67.59	32.4	74.07	27.6	0.432
Going low	44.44	21.8	48.14	19.1	0.510
Feeling tired	54.62	32.6	74.07	26.7	**0.020***
Getting shaky	66.66	34.0	75.92	24.0	0.252
Getting sweaty	66.66	31.1	68.51	34.4	0.836
Trouble sleeping	82.40	28.7	87.03	24.8	0.528
Getting irritable	46.29	38.9	60.18	38.0	0.190

** Statistically significant results were reported by P-value*

Regarding the treatment problems and difficulties, the children who were treated by insulin pump expressed a better health-related quality of life in comparison with the children who were treated by MDI, and significant differences were reported in 3 out of 11 variables (Table 3).

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Table 3. Treatment problems and difficulties

Variables (n = 54)	MDI		Insulin Pump		P-value
	Mean	SD	Mean	SD	
Causing pain	69.44	36.2	75.92	27.6	0.462
Getting embarrassed	77.77	32.1	82.40	31.7	0.596
Arguing about diabetes care	73.14	31.8	73.14	32.5	1.000
Sticking to the care plan	92.59	14.9	95.37	11.8	0.450
Take a blood test	90.74	15.4	95.37	13.6	0.246
Take insulin shots	52.77	24.8	99.07	4.7	**0.001***
Having exercise	48.14	24.4	62.03	27.5	0.055
Track carbohydrates	30.55	41.5	91.66	18.0	**0.001***
Carry fast carbohydrates	23.14	24.4	7.40	16.4	**0.005***
Eat snacks	34.25	21.6	28.70	23.2	0.3671

**Statistically significant results were reported by P-value*

Regarding the problems of children's groups who are worried about the disease. A statistically insignificant difference was reported in both groups. Although the children who were treated by MDI showed less worry about the areas “going low” and “complications of diabetes”. Children who were treated by an insulin pump expressed less worry problems in the area of “medical treatment” compared to children who were treated by MDI (Table 4).

Table 4. Worry problems

Variables (n = 54)	MDI		Insulin Pump		P-value
	Mean	SD	Mean	SD	
Going low	36.11	32.1	29.62	25.4	0.418
Medical treatment	77.77	33.5	89.81	22.8	0.128
Complications of diabetes	27.77	34.9	23.14	32.57	0.616

Regarding the communications problems statistically significant difference was identified with low communication problems recognized among the insulin pump group who communicate effectively with doctors, compared to the MDI group (Table 5).

Table 5. Communication problems

Variables (n = 54)	MDI		Insulin Pump		P-value
	Mean	SD	Mean	SD	
Telling the doctor about feelings	82.40	21.3	93.51	14.5	**0.029***
Asking the doctor questions	80.55	21.8	88.88	20.7	0.155
Explaining illness	75.9	26.7	89.81	17.0	**0.026***

**Statistically significant results were reported by P-value*

Regarding the overall problem dimensions outcomes in comparison between children who were treated by MDI versus insulin pump. On determining the total score in each dimension, the results revealed a statistically significant difference in diabetes problems and communication problems (P-value = 0.001) for both variables. While a statistically insignificant difference was identified regarding the treatment problems and worry problems, P-value = 0.214 and 0.965, respectively. Thence, the health-related quality of life was better among the insulin pump group compared to the MDI group (Table 6).

Table 6. Overall problem dimensions

Variables (n = 54)	MDI		Insulin Pump		P-value
	Mean	SD	Mean	SD	
Diabetes problems	57.31	14.6	59.92	17.8	**0.001***
Treatment problem	53.86	28.36	64.64	34.4	0.214
Worry problem	47.21	21.87	47.52	30.0	0.965
Communications problems	79.61	2.7	90.73	1.9	**0.001***

**Statistically significant results were reported by P-value*

Discussion

Childhood diabetes has been found to have an adverse health impact on health-related quality of life (HRQOL) for patients and their families, which is recognized to be affected by various factors, including physical, emotional, and social functions among children and adolescents. For this context, a Pediatric Quality of Life Inventory (PedsQL) questionnaire was designed to evaluate the HRQOL among children in

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many countries in the form of PedsQL™ 3.0 Diabetes Module and PedsQL™ 4.0 Generic Core Scales, which had good reliability and validity tests to assess the quality of life (QOL) among diabetic children [11-22]. The present study included 54 Libyan children diagnosed with type 1 diabetes mellitus, which divided into 27 who were treated on MDI compared to 27 others who were treated on CSII (insulin pump) at the pediatric departments of Tripoli University Hospital and Children's Hospital during 2020.

This study found that the overall health-related quality of life is better among the insulin pump group compared to the MDI group. These findings are supported by Nuboer et al study and AbdulRasoul et al study [23-24]. Also, a systematic review of both pediatric and adult diabetic patients has poses significant tight glycemic control and improvement in quality of life by CSII compared to MDI. [25]. This evidence has been supported by several observational studies among pediatric databases from the United States, the United Kingdom, Germany, and Austria, which reported a significant correlation between CSII therapy and good glycemic control outcomes [26-27]. These results are consistent with the present study, which found better diabetes symptom control for the CSII group compared to the MDI group. Interestingly, the HbA1c readings were found to have better control among the insulin pump group compared to the MDI group, and these results correspond to Johnson SR et al study [28]. Additionally, the present study had insight into important health determinants such as effective communication skills and psychological support, which were found to have crucial roles among diabetic patients to reduce adverse health outcomes and improve their health condition.

The limitation of the study was a small sample size, while the strength of the study was a good study design with the utilization of a standardized, valid questionnaire in the study.

Conclusion

This study concluded that diabetic children who were treated by continuous subcutaneous insulin infusion “CSII” (insulin pump) had better health-related quality of life in almost all facets compared to multiple daily insulin injection “MDI”. Thence, early utilization of insulin pumps among diabetic children is recommended to improve health outcomes and reduce related adverse health outcomes.

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Ethical approval

This study was ethically approved by selected hospitals with strict privacy of patients' data, and was used for research purposes only.

Conflict of interest

The authors did not have any type of conflict of interest regarding publishing this study.

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