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Comparing Glycemic Control of Children and Adolescents with Type 1 Diabetes on Multiple Daily Insulin Injection and those on Insulin Pump Therapy in limited resource Settings

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ABSTRACT

Background: Type 1 diabetes (T1D) is one of the most common chronic diseases in children. Overall, approximately 96,000 children under 15 years are estimated to develop type 1 diabetes annually worldwide.

Aim of the work: To compare glycemic control of patients with (T1D) treated with different modalities, multiple daily injection (MDI) and continuous subcutaneous insulin infusion (CSII).

Patients and Methods: This cross-sectional study was conducted on 30 patients diagnosed with T1D following at Diabetes & Endocrine Pediatric unit at Galaa Military hospital, patients were divided into two equal groups, group (A) 15 patients on MDI, group (B) 15 patients on CSII MiniMed paradigm 715 version. Not all patients were using continuous glucose monitoring (CGM), only 2 patients used flash glucose monitoring. Demographics, clinical data, and investigations were done with special emphasis on HbA1c at the beginning of the study, at three and six months.

Results: The average blood glucose checks/day were significantly higher in patients on MDI (8.47 ± 1.68) than patients on pump (7.00 ± 1.36) with p-value = 0.014. There was statistically significant decrease in HbA1c level in patients on MDI after 6 months of glycemic control compared to that at the start of study and at 3 months with p-value < 0.001. However, there was a statistically significant increase in HbA1c level in patients on CSII after 6 months compared to that at start and at 3 months of the study with p-value < 0.001

Conclusion: Our study found no significant overall differences in glycemic control in the form of HbA1c between CSII and MDI therapy for children with T1D. It's clear that a pump with CGM will give the best glycemic index & more physiological treatment while a pump without CGM can give a false sense of security resulting in complications. So, for limited resource countries, CGM with MDI will be preferable over pump insertion without CGM.

Keywords: *Glycemic Control, Type 1 Diabetes, Multiple Daily Insulin Injection, Insulin Pump Therapy*

1. INTRODUCTION

Diabetes is a challenge to global health that respects neither socioeconomic status nor national boundaries. People living with diabetes are at risk of developing several serious and life-threatening complications, leading to an increased need for medical care, a reduced quality of life and undue stress on families. Diabetes and its complications, if not well managed, can lead to frequent hospital admissions and premature death. Globally, diabetes is among the top 10 causes of death. [1]

The International Diabetes Federation (IDF) estimates 1,211,900 cases globally in those under 20 years old. [2]

The primary goal in T1D management is optimal glycemic control to minimize complications and enhance quality of life. Standard care involves intensive insulin therapy, typically through MDI or CSII using insulin pumps. [3]

Current T1D therapy focuses on matching exogenous insulin and food intake while incorporating daily activities such as exercise and sleep. Remarkable advances have been made in insulin formulation and diabetes technology, including methods for insulin delivery and glucose monitoring. [4]

Insulin pumps, which deliver insulin through a catheter inserted into the skin, offer certain advantages, especially in pediatric cases. They allow for flexibility in meal timing, extended catheter use, and programmable basal insulin delivery. Some pumps integrate with CGM, forming an automated insulin delivery system that reduces hypoglycemia risk. Despite these benefits, insulin pumps pose challenges, such as the complexity of changing infusion sites and potential complications such as ketoacidosis due to tubing issues & also financial burden. [5]

Our main objective is to compare glycemic control of patients with T1D treated with different methods, MDI and CSII.

2. PATIENTS AND METHODS

Study design

This cross-sectional study conducted on 30 patients diagnosed with T1D, following at Diabetes & Endocrine Pediatric unit at Galaa Military hospital over 6 months from May to November 2021.

Study Population & Measurements

Children and adolescents aged up to 18 years were recruited. Patients with other associated autoimmune diseases, those receiving drugs that alter insulin sensitivity as Metformin were excluded. Patients were divided into two equal groups: group (A) including 15 patients on MDI while group (B) including 15 patients on CSII, all were using MiniMed 715 without CGM. Only 2 patients used flash glucose monitoring. The ethical committee approval code was MD- 249-2021. The following data was obtained including age, gender, onset of diabetes, presentation at diagnosis (hyperglycemia or Diabetic Ketoacidosis (DKA)), insulin regimen, doses, family history of diabetes or any chronic diseases, exercise, dietary history. Full clinical examination with special concern to anthropometric measures: weight (SDS), height (SDS) and BMI (SDS), examination of injection sites to detect lipodystrophy, tanner staging and any signs of insulin resistance. Investigations were collected from patients' files including HbA1c at the beginning of the study, at 3 and 6 months from the study.

Statistical analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 27. The quantitative data (parametric) were presented as mean, standard deviations and ranges while non-parametric data were presented as median, inter-quartile range (IQR). Qualitative variables were presented as numbers and percentages. The p-value was considered significant as the following: P-value > 0.05: Non-significant (NS), P-value < 0.05: Significant (S), P-value < 0.01: Highly significant (HS).

3. RESULTS

Over a period of 6 months, 30 patients with T1D were recruited. There was female predominance (63.3% females and 36.7% males). Mean age was 12.74±2.59 years old. Ten females (66.7%) and five males (33.3%) were on MDI while nine females (60.0%) and six males (40.0%) were on pump. Their Demographic and clinical data is shown in table 1.

Table 1: Demographic and clinical data of the studied patients

		Total no. = 30
Gender	Female	19 (63.3%)
	Male	11 (36.7%)
Age (yr)	Mean ± SD	12.74 ± 2.59
	Range	6.8 – 17.1
Onset of DM (age)	Median (IQR)	6 (5 – 9)
	Range	3 – 10
Presentation on first attack	DKA	28 (93.3%)
	Classis symptoms of diabetes	2 (6.7%)
Groups	On MDI	15 (50.0%)
	On CSII	15 (50.0%)

Table 2: Comparison between patients on MDI and those on CSII regarding Total insulin, TDD, ICR, ISF and anthropometric measures

		On MDI	**On CSII**	**Test value**	**P-value**	**Sig.**
		No. = 15	**No. = 15**			
Total insulin (units)	Median (IQR)	48 (25 – 63)	43 (35 – 67)	-0.311≠	0.756	NS
	Range	11 – 88	26 – 90			
TDD (Unit/kg/d)	Mean ± SD	1.05 ± 0.30	1.05 ± 0.30	0.036•	0.971	NS

	Range	0.57 – 1.8	0.66 – 1.89			
ICR	Median (IQR)	8.5 (7 – 12)	9 (6 – 16)	-0.022≠	0.982	NS
	Range	5 – 40	5 – 22			
ISF	Median (IQR)	33 (26 – 48)	40 (26 – 75)	-0.109≠	0.913	NS
	Range	20 – 163	7 – 80			
Weight SDS	Median (IQR)	0.4 (0.2 – 0.98)	0.34 (0.17 – 1)	-0.249≠	0.803	NS
	Range	-1.47 – 1.3	-1.6 – 2.11			
Height SDS	Median (IQR)	0.55 (-1 – 0.68)	-0.65 (-1.43 – 0.6)	-1.452≠	0.146	NS
	Range	-2.3 – 0.85	-2.3 – 1.38			
BMI SDS	Median (IQR)	0.56 (0.19 – 1.39)	0.5 (0.06 – 1)	-0.664≠	0.507	NS
	Range	-1.2 – 1.74	-0.48 – 2.16			
Puberty	Pubertal	11 (73.3%)	10 (66.7%)	0.159*	0.690	NS
	Prepubertal	4 (26.7%)	5 (33.3%)			
Lipodystrophy	No	11 (73.3%)	11 (73.3%)	0.000*	1.000	NS
	Yes	4 (26.7%)	4 (26.7%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant

TDD: Total daily dose of insulin, ICR: Insulin Carb. Ratio, ISF: Insulin Sensitivity Factor, BMI: Body Mass Index

*: Chi-square test; •: Independent t-test; ≠: Mann-Whitney test

The previous table shows that there was no statistically significant difference found between MDI group and CSII group regarding total insulin, TDD, ICR and ISF with p-values 0.756, 0.971, 0.982 and 0.913 respectively. Also, there was no statistically significant difference found between both groups regarding weight SDS, height SDS, BMI SDS, puberty and lipodystrophy with p-values 0.803, 0.146, 0.507, 0.690 and 1.000 respectively.

There was no statistically significant difference between MDI group and CSII group regarding HbA1c level at start, 3 months and 6 months after the study with p-values 0.448, 0.665 and 0.901 respectively. The attacks of hypoglycemia, hyperglycemia and DKA during follow-up didn't show statistically significant difference between both groups with p-values 1.000, 0.068 and 0.309 respectively. The average blood glucose checks/day was significantly higher in patients on MDI (8.47 ± 1.68) than patients on pump (7.00 ± 1.36) with p-value 0.014. However, there was no statistically significant difference found between both groups regarding average fasting blood glucose and average postprandial blood glucose with p-value = 0.533 and 0.974 respectively as shown in table 3.

Table 3: Comparison between patients on MDI and patients on CSII regarding the glycemic control of the studied patients

		On MDI	**On CSII**	**Test value**	**P-value**	**Sig.**
		No. = 15	**No. = 15**			
HbA1C at start	Mean ± SD	8.62 ± 1.43	8.25 ± 1.22	0.770•	0.448	NS
	Range	6.3 – 12	6.3 – 10.4			
HbA1C after 3 months	Mean ± SD	8.66 ± 1.92	8.39 ± 1.38	0.437•	0.665	NS
	Range	6.7 – 13.7	6.5 – 11.3			
HbA1C after 6 months	Mean ± SD	8.59 ± 1.48	8.65 ± 1.42	-0.126•	0.901	NS
	Range	6.5 – 10.8	6.5 – 11			
Attacks of hypoglycemia	No	12 (80.0%)	12 (80.0%)	0.000*	1.000	NS
	Yes	3 (20.0%)	3 (20.0%)			
Attacks of hyperglycemia	No	10 (66.7%)	5 (33.3%)	3.333*	0.068	NS
	Yes	5 (33.3%)	10 (66.7%)			
Attacks of DKA during follow up	No	15 (100.0%)	14 (93.3%)	1.034*	0.309	NS
	Yes	0 (0.0%)	1 (6.7%)			
Average blood glucose checks /day	Mean ± SD	8.47 ± 1.68	7.00 ± 1.36	2.621•	0.014	S
	Range	5 – 11	5 – 10			
Average FBG	Mean ± SD	129.87 ± 22.59	135.47 ± 25.90	-0.631•	0.533	NS
	Range	83 – 163	93 – 182			
Average PPBG	Mean ± SD	242.07 ± 60.81	242.79 ± 55.39	-0.033•	0.974	NS
	Range	148 – 327	167 – 315			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant

FBG: fasting blood glucose, PPBG: postprandial blood glucose

*: Chi-square test; •: Independent t-test

There was statistically significant increase in the level of HbA1c three and six months after the start of the study in the CSII group with p-value < 0.001 as shown in figure 1.

4.

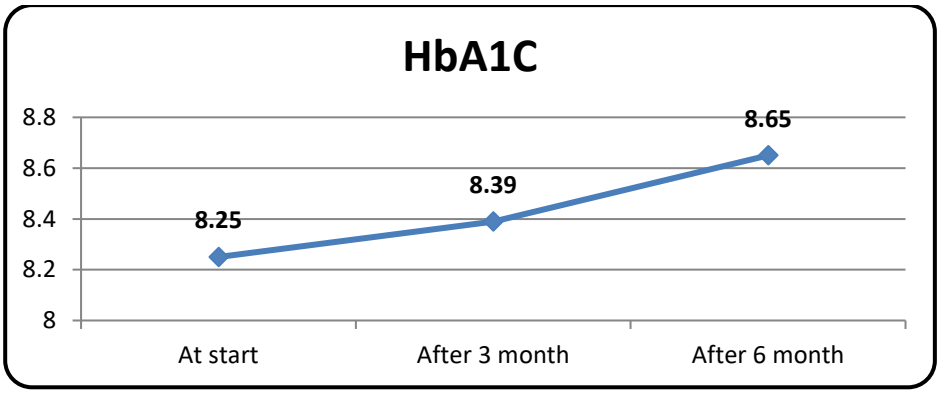

Figure 1: Comparison between HbA1C level at start, after 3 months and after 6 months among patients on CSII

There was statistically significant decrease in the level of HbA1c six months after the start of study with p-value < 0.001 as shown in figure 2.

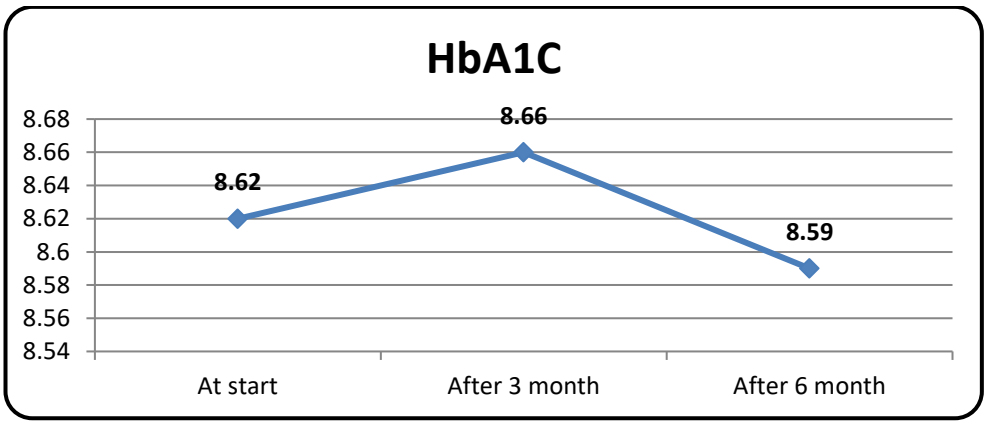

Figure 2: Comparison between HbA1C level at start, 3 months and 6 months from the start of study among patients on MDI

5. DISCUSSION

Given the rising popularity of insulin pump therapy among young patients, there is an ongoing debate about its merits compared to MDI, particularly in terms of glycemic control, hypoglycemia, and cost-effectiveness. [6]

In the present study, it was found that ten females (66.7%) and five males (33.3%) were on MDI while nine females (60.0%) and six males (40.0%) were on pump with age ranged from 6.8 – 17.1year and with mean 12.74±2.59 yr, 28 of them (93.3%) presented with DKA as first presentation & 2 (6.7%) presented with classic symptoms of diabetes, there was no statistically significant difference found between MDI group and CSII group regarding gender distribution, age of patients, onset of diabetes and presentation on first attack, with p-value = 0.705, 0.247, 0.673 and 0.143 respectively.

In agreement with the study conducted by Babiker et al. who compared glycemic control in 129(76.7%) patient on MDI and 39(23.3%) patient on pump showed there were 64 (49.6%) females on MDI &22(56.4%) on pump, there were 65 (50.4%) males on MDI, 17 (43,6%) on pump with age ranged from 10.2-16 year with mean 12.4±2.20 yr. At baseline, both groups were similar for age, male to female ratio, HbA1c, total daily dose of insulin; there was no difference in mean age and mean HbA1c at the start of the comparison. [5]

In the present study, it was found that there was no statistically significant difference found between MDI group and pump group regarding total insulin, TDD, ICR and ISF with p-values 0.756, 0.971, 0.982 and 0.913 respectively.

This was inconsistent with Karges et al. which is a population-based cohort study comparing patients with type 1 diabetes who used pump therapy and patients who used insulin injection therapy conducted in Germany. The study highlighted that total daily insulin dose was lower and prandial-to-total insulin ratio was higher in pump therapy compared with injection

therapy, significant for all age groups of the matched cohort (P <0 .001).

In the present study, it was found that there was no statistically significant difference between MDI group and pump group regarding weight SDS, height SDS, BMI SDS, puberty and lipodystrophy with p-values 0.803, 0.146, 0.507, 0.690 and 1.000 respectively.

This was consistent with study conducted by Karges et al. who reported that there was no statistically significant difference between both groups regarding BMI (p<0.005). [7]

In contrast to a study conducted in Kuwait comparing glycemic control in type 1 diabetic patients, data on 326 type 1 diabetic patients started on CSII retrospectively compared with them when on MDI, had a similar result despite a reduction in insulin daily dose, stated significant increase in BMI in patients on CSII therapy may have been due to the liberty to eat without receiving extra injections of insulin. [8]

In the present study there was no statistically significant difference found between MDI group and CSII group regarding HbA1c level at start, after 3 and 6 months from the study with p-values 0.448, 0.665 and 0.901 respectively. The average blood glucose checks/day was significantly higher in patients on MDI (8.47 ± 1.68) than patients on pump (7.00 ± 1.36) with p-value = 0.014. This may be explained that patients on pump had false sense of security, they don't monitor their blood glucose frequently, although pump used was not sensor augmented.

This was inconsistent with Karges et al. reported that mean daily frequency of self-monitoring of blood glucose level was higher with pump therapy compared with injection therapy, significant in all age groups (P < .001 for all). [7]

On MDI group there was statistically significant decrease in the level of HbA1c after 6 months of follow up compared to that done at start of the study and that done during the previous 3 months with p-value < 0.001.

In CSII group there was a statistically significant increase in the level HbA1c after 6 months of follow up compared to that done than at start of the study and that done during the previous 3 months with p-value < 0.001.

In contrast with Ribeiro et al. a longitudinal study based on data obtained retrospectively from the medical records of patients of both sexes aged 5–20 years with a diagnosis of T1D. To compare multiple doses of insulin and continuous insulin infusion therapy as treatment for type 1 diabetes, found that 14.2% of the patients had lower than 7.5% HbA1c during the use of MDI, while 35.71% showed HbA1c value lower than 7.5% with the use of CSII, demonstrating better glycemic control with the use of infusion pump therapy. [9]

Our study shows that there was no statistically significant difference found between MDI group and CSII group regarding the attacks of hypoglycemia, hyperglycemia and attacks of DKA during follow up with p-value 1.000, 0.068 and 0.309 respectively. There was no statistically significant difference found between both groups regarding average FBG and average PPBG with p-values 0.533 and 0.974 respectively.

This agreed with AbdulRasoul et al., showed there was no significant change in the rate of DKA in either group. [8]

Also, Karges et al. found that there wasn't any significant difference between both groups regarding attacks of hypoglycemia, hyperglycemia, and attacks of DKA during follow up. [7]

6. CONCLUSION

Our study found no significant overall differences in HbA1c levels or most other measured parameters between CSII and MDI therapy for children with type 1 diabetes. The results suggest that both treatment options could be effective. The observed higher frequency of blood glucose checks in the pump group might indicate increased self-management engagement.

Ultimately, the choice between CSII and MDI should be individualized based on patient preferences, lifestyle, and specific needs in consultation with a healthcare professional. It's clear that pumps with CGM will give best glycemic index & more physiological treatment but pump without continuous monitoring could be non-beneficial and can give the patient false sense of security resulting in complications so the core is in continuous glucose monitoring & for limited resource country it will be favored over pump insertion.

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