

A Study Of Some Complications Of Type 1 Diabetes Mellitus In Children And Adolescents Receiving Conventional Versus Basal Bolus Insulin Therapy

Rand Hadi Kareem

M.B.Ch.B. Iraqi board of medical specializations, Iraq

Rebee Mohsin Hasani

Assistant Professor / Babylon University College of medicine C.A.B.P., F.I.C.M.S, Consultant paediatrician, Iraq

Shawq Alaa Jabir

FIBMS paediatrics, Endocrinology, Iraq

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Abstract: Background: Diabetes Mellitus type 1 is a common chronic disorder in childhood and adolescence. In type 1 diabetes, insulin therapy is life saving. There are two insulin regimens, conventional and basal bolus, change in the type of regimen to reduce and maintain glycated hemoglobin, with relative risk reduction of attacks of hypoglycemia, diabetic ketoacidosis, microvascular and macrovascular complications.

Aim of study: To compare glycemic control and complications of type 1 diabetes mellitus in children and adolescents receiving conventional versus basal bolus therapy.

Methodology: a cross sectional study that included 100 patients diagnosed as with type 1 DM, fifty patients on conventional and fifty patients on basal bolus regimen, history of hypoglycemia, diabetic ketoacidosis in last six months, HbA1c of each regimen were compared.

Results: Episodes of moderate to severe hypoglycemia in the last 6 months were in conventional regimen 22 (44.0) while bolus regimen 10 (20.0) ($P = 0.014$). There was non-significant elevation in percentage of diabetic ketoacidosis attacks ($N=7$, 14.0%) among patients used basal bolus insulin therapy in comparison to patients used conventional insulin therapy ($p = 0.186$). HbA1c in patients on basal bolus therapy is associated with significant reduction in HbA1c ($P = 0.044$).

Conclusion: Type 1 diabetic children and adolescents, patients receiving a basal bolus regimen have less hypoglycemia episodes and better than conventional regimen in reducing HbA1c, but without significant difference in diabetic ketoacidosis episodes.

Keywords: Type1 Diabetes Mellitus, Insulin Regimen, Diabetic Ketoacidosis, Hypoglycemia.

Introduction: Type 1 diabetes mellitus (T1DM) is a chronic autoimmune disorder characterized by immune-mediated destruction of pancreatic β -cells, leading to an absolute insulin deficiency and a lifelong need for exogenous insulin therapy. It is one of the most common endocrine disorders in children and adolescents, and its incidence is rising globally,

particularly in low- and middle-income countries (1,2). The onset typically occurs in childhood or adolescence, and poor glycemic control in these patients can result in both acute complications—such as diabetic ketoacidosis (DKA) and severe hypoglycemia—and chronic complications, including retinopathy, nephropathy, and neuropathy (3).

Optimal glycemic control is essential for preventing complications and ensuring normal growth and development. The landmark Diabetes Control and Complications Trial (DCCT) demonstrated that intensive insulin therapy significantly reduces the risk of long-term microvascular complications compared to conventional therapy in patients with T1DM (4). Consequently, insulin therapy strategies have evolved to include more intensive regimens that aim to mimic physiological insulin secretion.

Conventional insulin therapy typically involves two or three daily injections of a combination of short- and intermediate-acting insulin. While simpler to administer, this regimen often provides suboptimal glycemic control and has been associated with higher complication rates (5). In contrast, basal-bolus insulin therapy—based on multiple daily injections (MDI) of rapid-acting insulin before meals and long-acting insulin for basal needs—offers better postprandial glucose control and more closely simulates natural insulin secretion patterns (3,6). However, basal-bolus therapy requires frequent blood glucose monitoring, carbohydrate counting, and greater patient and caregiver engagement, which can be challenging in pediatric populations.

Recent studies have shown that children and adolescents on basal-bolus regimens tend to have better metabolic outcomes, lower HbA1c levels, and fewer acute complications compared to those on conventional therapy (7,8). Nevertheless, the effectiveness of each regimen can vary based on patient compliance, family support, socioeconomic conditions, and access to healthcare services.

Aim of study

To compare glycemic control and some complications of type 1 diabetes mellitus in children and adolescents receiving conventional versus basal bolus therapy

Patients and Method

Study Design:

A cross sectional study had been conducted at pediatric diabetic center in Marjan hospital /Babylon governorate/Iraq during the period from November 2023 to August 2024.

Patients:

All patients attended the pediatric clinic at diabetic center during the study period (one day per week) and met the eligibility criteria had been included in this study.

Inclusion criteria:

1. Diabetes mellitus type 1.
2. Age 1-16 years.

Exclusion criteria:

1. Duration of diagnosis less than 1 year.
2. Incomplete investigations and poor follow up.
3. Patients with other chronic disease like thalassemia, congenital heart disease, and syndromic patients.

Total number of patients initially included who fulfilled the criteria was 100, fifty of them on conventional regimen while the remaining fifty patients on basal bolus regimen, no patient use insulin pump nor continuous glycemic monitoring.

Methodology

For all patients a uniform questionnaire was applied, which included the following informations: age, sex, residence, duration of DM, parental education, caregiver at home, school attendance, family

history of DM type1, family history of other autoimmune diseases, growth parameters analysis, thyroid function test, celiac screen, in addition to HbA1c, number of moderate and severe hypoglycemic attacks in last 6 months, number of DKA episodes in last 6 months and long term complication of DM include measurement of lipid profile was only done to the diabetic patients diagnosed for more than 5 years ago and patients who are more than 11 years old, while albumin / creatinine and retinal examination were done to the diabetic patients diagnosed for more than 5 years ago and patients 2 years after puberty.

Regarding regimens, conventional regimen had been achieved (twice daily injection of either lente and soluble insulin or premixed). While basal bolus regimen was achieved by multiple daily injections with glargine or degludec as basal with either rapid or short (soluble) acting insulin as bolus doses, insulin doses calculation: Bolus insulin: calculated as insulin sensitivity factor (ISF) plus insulin to carbohydrate ratio (ICR) that was taken before each meal :

ISF= 1800 (for rapid-acting analog) or 1500 (for regular insulin) divided by total daily dose.

ICR= 500 divided by total daily dose, and according to the number achieved we explained to the patients and/or their families how to calculate the dose according to the meal consumed, for example: if ICR= 30, so every 30 grams carbohydrate should be covered with 1 unit insulin, and gave them a list and figures (appendix 2) that illustrate the amount of different foods that correspond to 15g carbohydrate (serving) to facilitate dose calculation for them as there is no diabetic nurse educator.

Regarding DKA, we asked the patients or their family about any attack of acidosis that required emergency

room admission, then we summed the number of DKA to achieve the number of dkas per 6 months for each patient.

Regarding hypoglycemia, also we asked the patients or their family about the number of hypoglycemic events documented by blood sample testing) blood glucose less than 54mg/dl, disturbed level of consciousness or seizure, according to International Society for Pediatric and Adolescent Diabetes (ISPAD), then we summed the number of episodes to achieve the number of episodes per 6 months for each patient.

Lipid profile was estimated in the fasting state in biochemical laboratory, hba1c and thyroid function test were estimated at the diabetic center in Marjan hospital, celiac screen in gastroenterology center in Marjan hospital, urine albumin to creatinine ratio of first

Morning void in private laboratory, retinal eye examination in ophthalmological outpatient clinic in Al-Imam Al Sadiq hospital.

All patients weighed by the same electronic scale, and standing height had been checked by the same stadiometer. BMI results were achieved by computerized calculator and plotted on CDC chart.

After data analyzing, we compared between CR and BBR changes in hba1c, growth parameters, occurrence and frequency of hypoglycemic episodes, DKA, lipid profile, urine albumin to creatinine ratio and retinal damage.

Data Analysis

Statistical analysis was carried out using SPSS version 27. Categorical variables were presented as frequencies and percentages. Continuous variables were presented as (Means $\pm$ SD). Student t-test was used to compare means between two groups. Pearson Chi-Square test and Fisher Exact test were used to find the association between categorical variables. $P \leq 0.05$ was considered as significant.

Results

Table 1: The comparison between two regimens of insulin therapy for type 1 diabetic patients according to study variables (N=100)

Study variables	Insulin therapy		Total (N=100)	P-value
	Basal bolus (N=50)	Conventional (N=50)		
Age (years)	(10.64 $\pm$ 3.22)	(10.74 $\pm$ 3.30)	(10.69 $\pm$ 3.24)	0.878
Sex				
Male	22 (44.0)	23 (46.0)	45 (45.0)	0.841
Female	28 (56.0)	27 (54.0)	55 (55.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	
Residence				
Urban	25 (50.0)	27 (54.0)	52 (52.0)	0.689
Rural	25 (50.0)	23 (46.0)	48 (48.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	
Father education				
Illiterate	2 (4.0)	1 (2.0)	3 (3.0)	0.715
Primary and secondary	37 (74.0)	40 (80.0)	77 (77.0)	
Higher education	11 (22.0)	9 (18.0)	20 (20.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	
Mother education				
Illiterate	3 (6.0)	2 (4.0)	5 (5.0)	0.874
Primary and secondary	38 (76.0)	37 (74.0)	75 (75.0)	
Higher education	9 (18.0)	11 (22.0)	20 (20.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	

Caregiver Patient alone				
Parents	10 (20.0)	13 (26.0)	23 (23.0)	0.776
Patient and parents	27 (54.0)	25 (50.0)	52 (52.0)	
Total	13 (26.0)	12 (24.0)	25 (25.0)	
	50 (100.0)	50 (100.0)	100 (100.0)	
School attendance				
Yes	44 (97.8)	41 (89.1)	85 (93.4)	0.203
No	1 (2.2)	5 (10.9)	6 (6.6)	
Total	45 (100.0)	46 (100.0)	91 (100.0)	

Table 2: The comparison between two regimen of insulin therapy for type 1 diabetic patients according to study variables (N=100)

Study variables	Insulin therapy		Total (N=100)	P-value
	Basal bolus (N=50)	Conventional (N=50)		
Duration of DM (years)	(2.65 ± 1.83)	(3.16 ± 2.60)	(2.91 ± 2.25)	0.261
Weight SDS				
<-2	3 (6.0)	3 (6.0)	6 (6.0)	0.382
>2	0 (0.0)	1 (2.0)	1 (1.0)	
(-2)_2	47 (94.0)	46 (92.0)	93 (93.0)	
Total	50 (100.0)	50(100.0)	100 (100.0)	
Height SDS				
<-2	5 (10.0)	5 (10.0)	10 (10.0)	0.151
>2	0 (0.0)	2(4.0)	2 (2.0)	
(-2)_2	45 (90.0)	43(86.0)	88 (88.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	
BMI SDS				
<-2	0 (0.0)	1 (2.0)	1 (1.0)	0.409
>2	1 (2.0)	1 (2.0)	2 (2.0)	
(-2)_2	49 (98.0)	48 (96.0)	97 (97.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	
Family history of type 1 DM				
Present	7 (14.0)	5 (10.0)	12 (12.0)	0.538
Absent	43 (86.0)	45 (90.0)	88 (88.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	
Family history of other autoimmune diseases Present				

Absent				
Total	2 (4.0)	1 (2.0)	3 (3.0)	1.000
	48 (96.0)	49 (98.0)	97 (97.0)	
	50 (100.0)	50 (100.0)	100 (100.0)	

Table 3: The comparison between two regimens of insulin therapy for type 1 diabetic patients according to complications in the last 6 months (N=100)

Complications in last 6 months	Insulin therapy		Total (N=100)	P-value
	Basal bolus (N=50)	Conventional (N=50)		
Episodes of moderate to severe hypoglycemia				
Yes	10 (20.0)	22 (44.0)	32 (32.0)	0.014
No	40 (80.0)	28 (56.0)	68 (68.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	
Number of hypoglycemic attacks				
Once	9 (90.0)	19 (86.3)	28 (87.5)	0.011
Twice	1(10.0)	2 (9.1)	3 (9.4)	
Three times	0 (0.0)	1 (4.6)	1 (3.1)	
Total	10 (100.0)	22 (100.0)	32 (100.0)	
DKA episodes				
Yes	7 (14.0)	3 (6.0)	10 (10.0)	0.186
No	43 (86.0)	47 (94.0)	90(90.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	

Table 4: The comparison between two regimens of insulin therapy for type 1 diabetic patients according to glycemic control (N=100)

Glycemic control	Insulin therapy		Total (N=100)	P-value
	Basal bolus (N=50)	Conventional (N=50)		
HbA1c (%)	(9.11 ± 1.85)	(9.88 ± 1.91)	(9.50 ± 1.91)	0.044*

Table 5: The comparison between two regimens of insulin therapy for type 1 diabetic patients according to investigation and retinal examination (N=100)

Late complications	Insulin therapy		Total (N=100)	P-value
	Basal bolus (N=50)	Conventional (N=50)		
Lipid profile				
Hyperlipidemia	2 (6.9)	3 (10.3)	5 (8.6)	1.000
Normal	27 (93.1)	26 (89.7)	53 (91.4)	
Total	29 (100.0)	29 (100.0)	58 (100.0)	
Albumin/creatinine ratio				
Macroalbuminurea	0 (0.0)	1 (4.0)	1 (2.0)	0.138
Microalbuminurea	2 (8.0)	6 (24.0)	8 (16.0)	
Normal	23 (92.0)	18 (72.0)	41 (82.0)	
Total	25 (100.0)	25 (100.0)	50 (100.0)	
Retinal examination				
Retinal changes	1 (4.0)	1 (4.0)	2 (4.0)	1.000
Normal retina	24 (96.0)	24 (96.0)	48 (96.0)	
Total	25 (100.0)	25 (100.0)	50 (100.0)	

Table 6: The comparison between two regimens of insulin therapy for type 1 diabetic patients according to comorbidities including (thyroid function test, celiac screen) (N=100)

Comorbidities	Insulin therapy		Total (N=100)	P-value
	Basal bolus (N=50)	Conventional (N=50)		
Thyroid function test				
Hypothyroidism	1 (2.0)	0 (0.0)	1 (1.0)	1.000
Normal	49 (98.0)	50 (50.0)	99 (99.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	
Celiac screen				
Positive	6 (12.0)	3 (6.0)	9 (9.0)	0.487
Negative	44 (88.0)	47 (94.0)	91 (91.0)	
Total	50 (100.0)	50 (100.0)	100 (100.0)	

Discussion

According to growth parameters in the current study, there were no significant differences between two regimens of insulin therapy (table 2). In comparison between two regimens of insulin therapy (basal bolus and conventional) according to episodes of moderate to severe hypoglycemia in the last 6 months, there was statistically significant increase in conventional than

basal bolus regimen. The episodes in conventional regimen 22 (44.0), while in basal bolus regimen 10 (20.0) ($P=0.014$) and increased number of hypoglycemic attacks in conventional rather than basal bolus ($P=0.01$) (table 3), which is similar to study by Chou WY et al. (9), concluded that severe hypoglycemic episodes ($p < 0.001$) were significantly higher in patients receiving a premixed regimen than those

receiving a basal-bolus regimen.

In FRANCHINI S. et al. (10) study found that multiple injection treatment reduced attacks of severe hypoglycemia in pediatrics. This is due to fixed dose of insulin in conventional regimen and patients delayed meals or snacks with increased exercise activity.

There was no significant elevation in percentage of DKA attacks (N=7, 14.0%) among patients used basal bolus insulin therapy in comparison to patients used conventional insulin therapy in which only three patients (6.0%) had history of DKA attacks during last the 6 months, ($p < 0.186$) (table 3), compared to ALABEDI, Rihab F study published 2020 (11) that found that no patient on the CR developed DKA during the study period compared to 4/32 patients on BBR ($P = 0.03$), but in cohort study by Chou WY et al. (9), found that DKA was significantly higher in patients receiving a premixed regimen than those receiving a basal bolus regimen (10.62% vs. 5.31%; $p = 0.037$).

During the current study those patients who developed DKA reported missing doses of insulin as they avoid frequent blood glucose checking and frequent insulin injection, patients took insulin doses but without corrective doses, or large snack without extra insulin, limited access to medical care, omission of insulin during illness and improper storage of insulin in private sector are the most common causes in this study indicating poor compliance to basal bolus regimen.

HbA1c in patients on basal bolus therapy was associated with significant reduction in HbA1c ($P = 0.044$) (table 4), in comparison with HbA1c in conventional therapy, so there was significant difference between regimens in reduction of HbA1c. Which is similar to SABOO et al. (12) study, concluded that intensive therapy significantly reduced and maintained HbA1c compare to the conventional group and encouraged to switch to intensive treatment. Chou WY et al. (9) concluded that the median reduction of HbA1c was better with the basal-bolus regimen than with the premixed regimen in both matched ($p = 0.034$).

In a study by LIND, Marcus, et al. (13) diabetic patients treated by multiple daily insulin injections had lower HbA1c levels than those treated with conventional therapy.

There were no significant differences between two regimens of insulin therapy in lipid profile, albumin/creatinine ratio and retinal examination (table 5).

The comparison between two regimens of insulin therapy for type 1 diabetic patients including (basal bolus and conventional) according to investigations

including (thyroid function test, celiac screen), there were no significant differences between two regimens of insulin therapy according to association of other autoimmune disease, from all patients in this study only 1 patient with hypothyroidism and 9 patients with celiac disease (table 6).

Conclusion

Children and adolescents patients receiving a basal bolus regimen have less hypoglycemia episodes, basal bolus regimen also had better effectiveness in reducing HbA1C, but without significant difference in DKA episodes.

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