RESEARCH PAPER

Relationship between glycemic control and different insulin regimens in pediatric type 1 diabetes mellitus

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Abstract

Background: Important health issues are diabetes mellitus and its comorbidities. Insulin can be delivered by several regimens including twice daily injections or multiple daily injections. This study aimed to determine what affects the state of glycemic control (age of patient, gender).

Patients and methods: A prospective study was conducted in the Department of Pediatrics in Al-Kadhmain Medical City in a period from the 1st of January 2021 to the 31st of June 2021(6 months). Data was collected from their parents or caregivers by direct questionnaire. According to American Diabetes Association criteria, patients were divided into two groups (good glycemic control, and poor glycemic control) and a comparison between insulin regimens was done.

Results: Among a total number of 98 children in this study, the mean age ± standard deviation (10.5 ± 3.5) years, 50 of them were newly diagnosed. most of the patients were females 55 (56.1%) versus 43(43.9%) males. There is no significant association between gender and glycemic control. Increasing the age of the patients associated with poor glycemic control, The highest percentage of children with good control was for those on basal regimen. The percentage of children with good control increased with follow-up visits, it starts with only 25.5% in the baseline visit and increased to 75.5% in the third visit. There is a significant difference in the growth parameter with different insulin regimens, the best growth pattern was found in those on basal-bolus, followed by pre-mixed and finally the intermediate (lente) and soluble regimen.

Conclusion: Insulin therapy which uses a multiple daily insulin injection regimen has favourable results in children and adolescents with diabetes mellitus type 1 in comparison to a twice insulin injection regimen.

Key words: Type 1 diabetes mellitus, HbA1c, anthropometric measures.

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Introduction

Diabetes mellitus is a chronic metabolic disease characterized by hyperglycemia as a cardinal biochemical feature, the major types of diabetes are differentiated by insulin deficiency versus insulin resistance, diabetes mellitus type 1 caused by a deficiency of insulin secretion because of pancreatic β-cell damage, diabetes mellitus type 2 is a result of insulin resistance occurring at the level of skeletal muscle, liver and adipose tissue, with various degrees of β-cell impairment. [1] T1DM usually develops during childhood and adolescence, the disease is caused by insulin production deficiency and requires the administration of insulin injections for long-term insulin therapy. [2] Diabetes type 1 can be diagnosed at any age of childhood, peaks in presentation occur between

5–7 years of age and near puberty. [3] The precise cause of type 1 diabetes is unknown but there are many possible contributory factors which include genetics, Autoimmunity, and many Environmental factors.[5] The decreasing β-cell mass with decreased insulin, progressively increased blood sugar, and ketoacidosis all imply that symptoms steadily increase, from early intermittent polyuria to DKA and coma, over weeks rather than months.[6] Most symptoms are nonspecific, the most important clue is inappropriate polyuria in any child with dehydration, poor weight gain, and glucose and ketone in urine can be determined quickly.[7]

Criteria for diagnosis

1. Fasting blood glucose ≥126 mg/dL Fasting is defined as no caloric intake for at least 8 h. OR
2. Hours postprandial glucose ≥ 200 mg/dL during an OGTT. OR
3. HBA1C ≥ 6.5% OR
4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random blood glucose ≥ 200 Mg/dl.[8]

Insulin is effective in decreasing blood glucose levels of diabetes type 1. The factors that affect the insulin dose (food, physical activity, illness, stress) need management daily.[9] Insulin treatment is initiated at the time of diagnosis for all patients with type 1 diabetes mellitus. The starting dose may range from 0.4 to 1.2 units/kg/day and is calculated based on several factors including age, pubertal stage, and the presence or absence of DKA.[10]

Many types of insulin are available, including:

- Rapid-acting insulin treatments example lispro (Humalog), aspart (NovoLog) and glulisine (Apidra) start working within 15 minutes, peak in about 60 minutes and last 4 hours.
- Short-acting insulin treatments for example human insulin (Humulin R) should be injected 20 to 30 minutes before a meal, peak in 1.5 to 2 hours and last 4 to 6 hours.
- Intermediate-acting insulin treatment like NPH insulin (Humulin N) start acting within about one hour, peak in about 6 hours and last 12 to 24 hours.
- Long-acting insulin treatments like insulin glargine (Lantus) and insulin detemir (Levemir) have no peak and action last for 20 to 26 hours.[10]

The aim is to determine the factors which affect glycemic control status as the age of the patient, and gender. And to evaluate the insulin regimen which offered good glycemic control.

Method

This was a prospective longitudinal study carried out in a Pediatric endocrine outpatient in Al-Kadhmain Medical City. To estimate the efficacy of different types of insulin regimens on glycemic control among type 1 Diabetes Mellitus in children below 15 years old. The data was collected over 6 months period from the 1st of January 2021 to the 31st of June 2021. The study includes 98 patients with a known case of type 1 DM. Their age was less than 15 years, 50 of them were newly diagnosed and other patients were already on specific insulin regimens, they were selected during their visit to the endocrine outpatient clinic. the patients were met on three occasions, in the first visit direct interview was done with patients' families through a questionnaire, a full medical examination was done also, and height and weight measurements and blood samples were collected for HbA1C estimation. On the second visit after three months and the third visit after six months, the same steps as the first visit were taken here. A special questionnaire form was developed for the present study which includes the Age,

gender, Regimen and types of insulin therapy and duration of specific regimen. The regimen was divided into conventional regimens either mixtard insulin regimen (30/70) or intermediate (lente) and soluble insulin regimen or Basal bolus regimen. After completing the interview, each participating child was examined and Growth measures were done: weight and height. And the results are plotted on a growth chart. A venous blood (2ml) from each participant was collected into an EDTA tube with an anticoagulant and it was estimated after 10-15 minutes of blood collection by Atellica CH 930 analyzer. HbA1c was done 3times for all patients during this period. Good glycemic control and Poor glycemic control according to American Diabetes Association (ADA) criteria: **(1)** HbA1c - < 8.5% patients less than 6 years of age; **(2)** HbA1c < 8% patients between 6–12 years of age; and **(3)** HbA1c < 7.5% patients between13–18 years of age. In each visit, there were changes in the dose of insulin and diet control and recommendations about the method of injection and exercise in patients with abnormal follow-up (e. g high HbA1c). The exclusion criteria include the presence of underlying chronic diseases of the liver, kidney, thyroid, gastrointestinal tract (celiac disease), and severe anaemia excluded by history and investigations (5 patients were excluded). Also, the use of medications other than insulin such as (vitamins, and thyroxine). If the insulin regimen was changed during the 6 months of the study, or those had neonatal Diabetes mellitus, all were excluded.

Statistical Package for the Social Sciences (SPSS) program version 20 was to code and analyze the data of the study. P-value ≤ 0.05 was significant.

Results

Results in 98 diabetic children were included in this study, most of the sample were females 55 (56.1%) and 43 (43.9%) males as presented in Figure-1. The sample age ranged between 3-15 years, and the mean ± standard deviation (10.5 ± 3.5 years). majority of the children above 10-15 years old 57.2% while those 5 and below form only 12.7%. In this study, 72. 4% of children were on pre-mixed insulin while only 10.2% were on basal-bolus regimen. Figure-2.

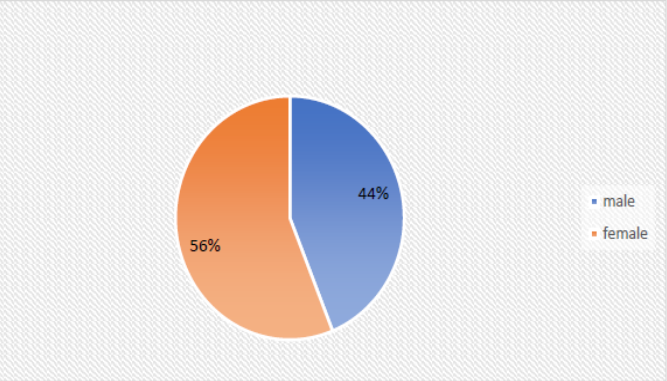

Fig 1. Distribution of type I diabetes patients according to the gender.

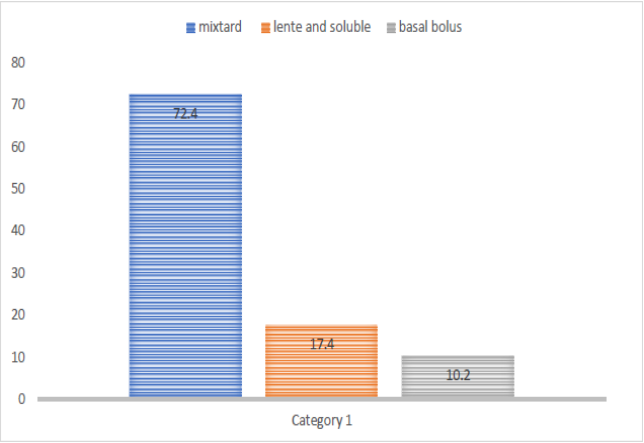

Fig 2. Distribution of type I diabetes patients according to the insulin regimen

There is a significant difference between the HbA1C level and the different regimens of insulin in the baseline visit and 6 months follow-up visit, (Table-1), shows the P-value = 0.001, and the lowest mean HbA1c in the basal-bolus regimen (= 8.9). There's a significant decrease in the mean to reach its lowest value after 6 months of follow-up in the basal-bolus regimen the mean was (=7.9) as show in (Table-2).

Table 1. The mean of HBA1C level for the different insulin regimens in the baseline visit.

The insulin type	Mean	Standerd deviation	p-value
Mixtard	10.6	±1.88	0.001
Lente & Soluble	12.1	±1.77	
Basal bolus	8.9	±1.11	

Table 2. The mean of HBA1C level for the different insulin regimens in the six month follow up visit.

The insulin type	Mean	Standerd deviation	P-value
Mixtard	10.6	± 1.88	0.001
Lente & Soluble	12.1	± 1.77	
Basal bolus	8.9	± 1.11	

To correlate the insulin regimen with the glycemic control level, (Table-3), shows that, in the baseline visit there is a significant association between different insulin regimens and the control since the p-value is less than 0.05 or the three subsequent visits. The percentage of children with good control increases with follow-up visits, it starts at only 25.5% in the baseline visit to increase to 75.5% in the third visit. The highest percentage for children with good control was those on basal-bolus regimen.

Table 3. The Association between the level of glycemic control and insulin regimen for the baseline and the follow up visits.

Variables		Good control		Poor Control		P-value
		No.	%	No.	%	
First visit	Mixtard	14	20.0	56	80.0	0.021
	Lente and Soluble	5	27.8	13	72.2	
	Basal bolus	6	60.0	4	40.0	
Total		25	25.5	73	74.5	
Second visit	Mixtard	31	44.3	39	55.7	0.001*
	Lente and Soluble	6	33.3	12	66.7	
	Basal bolus	10	100.0	0	0.0	
Total		47	48.0	51	52.0	
Third visit	Mixtard	54	77.1	16	22.9	0.029*
	Lente and Soluble	10	55.6	8	44.4	
	Basal bolus	10	100.0	0	0.0	
Total		74	75.5	24	24.5	

In this study, the 6-month follow-up study is considered the reference one for the following comparisons. Among the diabetes patients, there was a significant association between increasing age and poor control. with a significant p-value of 0.047 as shown in (Table-4).

Table 4. Association between the level of glycemic control and the age groups.

Variables		Good control		Poor Control		Total		P-value
		No.	%	No.	%	No	%	
Age	≤ 5	11	91.7	1	8.3	12	100.0	0.047
	> 5-10	25	86.2	4	13.8	29	100.0	
	> 10-15	38	66.7	19	33.3	57	100.0	

Regarding the correlation between glycemic control and gender, most of the patients with good control were 42 (56.8%) females versus the male patients 32 (43.2%) but the p-value shows no association between the glycemic control and gender as in (Table-5).

Table 5. Association between the level of glycemic control and gender

Variables		Good control		Poor Control		P-value
		No.	%	No.	%	
Gender	*Male*	32	43.2	11	45.8	0.824
	Female	42	56.8	13	54.2	
Total		74	100.0	24	100.0	

To study the effect of different insulin regimens on children's growth. The association between different regimens and weight and height centile were studied in baseline visit as shown in (Table-6), and after 6 months follow-up visit as shown in (Table-7). There is a significant difference in the growth parameter with different insulin regimens since the p-value is less than 0.05 for both height and weight. The best growth pattern was found in those on basal-bolus, followed by a conventional regimen (mixtard then intermediate lente and soluble).

Table 6. The association between the insulin regimens and the growth centile in baseline visit.

Parameter		Weight centile						P-value
		25th		50th		75th		
		No.	%	No.	%	No.	%	
Insulin regimen	Mixtard	21	30.0	48	68.57	1	1.43	0.002*
	Lente and Soluble	9	50.0	9	50.0	0	0.0	
	Basal bolus	0	0.0	4	40.0	6	60.0	
Parameter		Height centile						P-value
		25th		50th		75th		
		No.	%	No.	%	No.	%	
Insulin regimen	Mixtard	10	14.29	59	84.29	1	1.42	0.003*
	Lente and Soluble	8	44.4	10	55.6	0	0.0	
	Basal bolus	0	0.0	8	80.0	2	20.0	

Table 7. The association between the insulin regimens and the growth centile after 6 months follow up visit.

Parameter		Weight centile						P-value
		25th		50th		75th		
		No.	%	No.	%	No.	%	
Insulin regimen	Mixtard	17	24.3	51	72.9	2	2.9	0.001*
	Lente and Soluble	6	33.3	12	66.7	0	0.0	
	Basal bolus	0	0.0	3	30.0	7	70.0	
Parameter		Height centile						P-value
		25th		50th		75th		
		No.	%	No.	%	No.	%	
Insulin regimen	Mixtard	8	11.4	61	87.1	1	1.4	0.002*
	Lente and Soluble	6	33.3	12	66.7	0	0.0	
	Basal bolus	0	0.0	7	70.0	3	30.0	

Discussion

Good glycemic control is critical in patients with type 1 diabetes mellitus. A target < 7.5% is recommended in the Clinical Practice Consensus Guidelines of the ISPAD for all pediatric groups.[11] The females were predominant in this study, and these results were agreed with Turkish Demirbilek H.[12] In this study the mean age (10.5 ± 3.5) years ranged from 3 to 15 years and the highest proportion of studied patients was aged above10 years (56.2%) & < 5 years (12.2%), this agrees with Birkebaek NH[13] and Archinkovaa M[14] in Bulgaria who found (49.6%) 13-18 years and (32.5%) was from 6-12 years. The total glycemic control improved more at 3 months and 6 months from 25% to 75% after modification of the dose of insulin and through intense efforts in counselling about diet, exercise, and method of injection.

In the study, age was an important factor in glycemic control, with increasing age the incidence increase in patients with poor control diabetes 19(33.3%), so adolescents tend to be poorer glycemic control when compared with younger children or adults with type 1 DM, changes in normal physiology at puberty,

including the increment and cessation of somatic growth, secondary sexual characters development, and appearance of reproductive capacity may decrease insulin sensitivity.[15] Also, other studies like Mounir GM in Egypt [16] and Urbach SL[17] agree with this result, but Yazidi M.in tunis [18] and mostofizaden N.[19] in Iran show no difference between age and glycemic control. Also regarding the association between glycemic control and gender we found that there was no significant difference between males and females. These results agreed with mostofizaden N.[19] In Iran and archinkova M. et al. [14] while disagreeing with other studies like Setoodeh et al.[20] who showed poor glycemic control was higher in females than males due to different sample sizes. This study revealed that the patients who use multiple daily insulin regimens had good control than those who use twice daily insulin regimens either mixtard soluble or intermediate which agreed with the findings of another research done in Oman 2015,[21] which revealed that Improved glycemic control using multiple injections insulin therapy compared to twice-daily insulin therapy.[22,23] In the study there was an important relationship between both height and weight measures and types of insulin, all patient's growth parameters were more than 25th centile, and the best growth pattern was found in those on the basal-bolus regimen, followed by mixtard and finally the Lente and soluble regimen. Donaghue found a relationship between less frequent insulin injections and a reduction in height SDS.[24] Rudolf and Jackson found that patients with high levels of glycemic control and multiple insulin injections had a normal growth rate.[25,26] The average HbA1c in the diabetic center in AL-Mustansirya Medical collage / Baghdad was 9.18 versus 8.9 in patients who were on mixtard, 7.9 in those who were on basal-bolus, while those on intermediate (lente) and soluble insulin the mean HbA1c was 9.1 after 6 months follow up, another study done in Children Welfare hospital in Baghdad found that 23.8% of the patients visit the centre had good diabetic control (versus 25.5% of our sample).[27,28]

Conclusion & Recommendations, age was a significant factor in the control of glucose in the blood, with increasing age there is an increase in poor control diabetes incidence. Insulin therapy using a multiple injections regimen has a favourable outcome on the control of children and adolescents with T1DM for recent months of treatment compared to a twice injections regimen. The best growth pattern was found in those on basal-bolus, followed by a conventional regimen (Mixtard and finally the Lente and soluble). Encouragement of basal bolus regimen because it offers greater lifestyle flexibility (around mealtimes, sports etc.) and also had better glycemic control and growth outcome although poor compliance from some families and it is more expensive than other regimens.

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العلاقه بين مراقبه نسبه السكر في الدم وانظمة الانسولين المختلفه في داء السكري من النوع الاول عند الاطفال

الخلفية: داء السكري من النوع الاول ومضاعفاته من القضايا الصحية المهمة. يمكن أن يتم توصيل الأنسولين بعدة طرق بما في ذلك الحقن مرتين يوميًا أو الحقن اليومي المتعدد. تهدف هذه الدراسة إلى تحديد أي منها يؤثر على حالة التحكم في نسبة السكر في الدم (مثل عمر المريض والجنس).

طريقة البحث: أجريت دراسة مستقبلية في قسم طب الأطفال في مدينة الكاظمية الطبية في الفترة من ١ يناير ٢٠٢١ إلى ٣١ يونيو ٢٠٢١ (٦ أشهر). تم جمع البيانات من والديهم أو مقدمي الرعاية لهم عن طريق استبيان مباشر. وفقًا لمعايير جمعية السكري الأمريكية، تم تقسيم المرضى إلى مجموعتين: التحكم الجيد في نسبة السكر في الدم والتحكم السيئ في نسبة السكر في الدم ، وتم إجراء مقارنة بين أنظمة الأنسولين.

النتائج: من بين إجمالي ٩٨ طفلاً في هذه الدراسة ، كان متوسط العمر (١٠,٥ ± ٣,٥) سنوات ، وكان ٥٠ منهم حديثي التشخيص. كان معظم المرضى من الإناث ٥٥ (٥٦,١٪) مقابل ٤٣ (٤٣,٩٪) من الذكور. لا يوجد ارتباط معتد احصائيا بين الجنس والتحكم في نسبة السكر في الدم. ارتبط زيادة عمر المرضى بالتحكم السيئ في نسبة السكر في الدم. كانت النسبة الأعلى للأطفال الذين لديهم تحكم جيد هي أولئك الذين خضعوا لنظام القاعدي . زادت نسبة الأطفال الذين لديهم تحكم جيد مع الزيارات المتابعة ، حيث بدأت بـ ٢٥,٥٪ فقط في الزيارة الأساسية وزاد إلى ٧٥,٥٪ في الزيارة الثالثة. يوجد فرق كبير في مقياس النمو مع أنظمة الأنسولين المختلفة ، حيث تم العثور على أفضل نمط نمو لدى أولئك الذين يستخدمون نظام الانسولين القاعدي، يليهم الانسولين المخلوط وأخيراً نظام الانسولين متوسط التاثير.

الاستنتاج: يؤدي استعمال الأنسولين التي تستخدم حقن الأنسولين اليومي المتعدد إلى نتائج إيجابية في الأطفال والمراهقين المصابين بداء السكري من النوع الاول مقارنة بنظام حقن الأنسولين مرتين يوميًا.

الكلمات المفتاحية: داء السكري من النوع الاول، فحص الهيموغلوبين السكري، مقاييس النمو