

Predictors of glycemic control in children with Type 1 diabetes mellitus in Assiut-Egypt

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ABSTRACT

Background: Type 1 diabetes mellitus (T1DM) may lead to severe long-term health consequences, such as renal failure, blindness, as well as heart and cerebrovascular disease. Although a direct relationship between blood glucose control and diabetes complications remains to be established beyond doubt, most diabetologists aim to achieve the best possible glucose control in their patients with T1DM. The aim of this study was to detect the predictors of glycemic control among children with T1DM in Assiut Governorate-Egypt. **Materials and Methods:** We enrolled 415 children aged 2 to 18 years with type 1 diabetes of >1-year duration. They were subjected to full history including demographic factors and disease-related factors. Examination was done with determination of the body mass index, and assessment of stage of maturity. Investigations included hemoglobin A1c (HbA1c) and lipid profile. Patients with HbA1c above the recommended values for age by the American Diabetes Association were considered as poor glycemic control group. **Results:** Of the studied cases, 190 cases (45.8%) were of poor glycemic control. Patients with poor control had significantly higher mean age (16.83 ± 3.3 vs 9.77 ± 3.7 , $P < 0.000$). Girls aged 15 years or more had significantly higher prevalence of poor glycemic control than males of the same age group. As regard the disease-related factors, patients with poor control had significantly longer duration of disease (7.94 ± 2.6 vs 2.40 ± 2.0 , $P < 0.000$) and were older in age at onset of disease. Insulin regimen which consists of basal bolus insulin plus three injections of regular insulin was associated with more frequency of good glycemic control than other regimens. Patients with poor control had significantly higher mean of cholesterol, triglyceride (TG), high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol than patients with good control. Adjusting for other variables, age of the patients, duration of disease, and serum TG level were significant independent risk factors of poor glycemic control. **Conclusions:** This study concluded that children more than 15 years, duration of disease more than 5 years, and high serum TG level are the predictors of poor glycemic control of children with T1DM in Assiut-Egypt. Pediatricians need to be aware of factors associated with poor glycemic control in children with T1DM, so that more effective measures can be implemented to prevent deterioration in diabetes control.

Key words: Predictors, Type 1 diabetes, glycemic control, hemoglobin A1c

INTRODUCTION

Improved glycemic control in children with type 1 diabetes mellitus (T1DM) has unequivocally been demonstrated to delay the onset and slow the progression of microvascular complications.^[1] The Diabetes Control and Complications

Trial (DCCT) demonstrated that the goals of treatment of diabetes should be to achieve glycemic control as close to normal as possible.^[2] The American Diabetes Association (ADA) published the target age-specific Hg A1c as follow: <6 years, 7.5%-8.5%; from 6 to 12 years, $\leq 8\%$; from 13 to 18 years, $\leq 7.5\%$.^[3] Achieving glycemic targets in children with T1DM poses a difficult challenge. Increasing the intensity of diabetes management is, however, only one method of improving metabolic control.^[4] Some western studies have examined numerous demographic and diabetes-related characteristics on control of diabetes in pediatric populations.^[5,6] As the diabetes-management strategies and the demographic characters differ between centers, it is necessary to assess these variables in our setting.

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The health insurance covers most of children in Egypt and provides insulin for all diabetic children freely. However, the healthcare provider to diabetic patients is not always a pediatric endocrinologist. The Endocrine Unit of Assiut University Children Hospital started its activity since 1 year. Among the essential programs of the unit is to set a policy for strict follow up of diabetic patients aiming at reaching near optimal glycemc control to reduce the potential diabetic complications. The aim of this study was to assess the glycemc control as measured by hemoglobin A1c in a group of children with type I diabetes mellitus in Assiut governorate, and to identify the predictors of glycemc control among these children.

MATERIALS AND METHODS

This cross-sectional study was conducted on children with T1DM attending the Pediatric Endocrinology Clinic of *Assiut University Children Hospital and the Paediatric Health Insurance clinics in Assiut Governorate*. Patients were classified as Group I with good glycemc control and Group II with poor glycemc control according to the target level of HgA1c for age, recommended by the ADA.^[3]

Children were eligible for inclusion in the study if:

- Definite diagnosis of T1DM according to the definition of the World Health Organization.^[7]
- Currently insulin dependent.
- Age range 2-18 years.
- At least 1-year duration of the disease to decrease the potential impact of residual insulin production.

Exclusion criteria

- Children with secondary DM
- Children with type 2 DM.
- Age <2 years >18 years.
- Children with chronic-related diseases like hypothyroidism or hypoadrenalism.

A written consent was obtained from all cases for participation in the study. The study was approved from ethical scientific committee of *Assiut University*.

Full history was taken from all cases by structured questionnaire including:

1. Demographic factors: age, sex, residence, family history of diabetes and its degree, and socioeconomic state of the family which covered crowding index and income. The socioeconomic level was determined according to scoring system of Fahmy and El-Sherbiny.^[8]
2. Disease-related characteristics: age at onset of disease, duration of the disease, type and frequency of insulin injection, checking of blood glucose, and regular clinic attendance for follow up.

Examination was done for each patient with emphasis on weight and length. The body mass index (BMI) was calculated as: weight (kg) /height (m)². According to BMI percentile charts for age,^[9] patients were considered as normal, under weights, or over weights. Stage of maturity was assessed using sex maturity rating or Tanner staging.^[10]

Investigations done included:

- Serum C peptide level was done in clinically suspected cases with type 2 DM as those with obesity and acanthosis nigricans.
- Serum T3, T4, and cortisol levels were done in those with suggestive clinical picture of hypothyroidism or hypoadrenalism.
- Lipogram including total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C). They were estimated after 10-12 hours of fasting by autoanalyzer BM/Hitachi 911 using kits manufactured by Roche.^[11]
- HbA1c % was measured for all cases in hemolysates prepared from whole blood sample using Hitachi autoanalyzer by turbidimetric inhibition immunoassay.^[12] The ADA published the target age-specific Hg A1c as follow: <6 years, 7.5%-8.5%; from 6 to 12 years, ≤8%; from 13 to 18 years, ≤7.5%.^[3] According to the target level of HgA1c for age, recommended by the ADA,^[3] patients were classified as Group I with good glycemc control and Group II with poor glycemc control.

Statistical analysis

The data were coded, processed, and analyzed using SPSS (version 16). Continuous variables were presented as mean±standard deviation and categorical variables were presented as percentage. Pearson Chi-square test, Fisher exact test, and unpaired *t*-test were used to examine the relationships between various demographic and disease-related characteristics and diabetes control. Predictors of poor glycemc control were examined by using multivariate logistic regression. For all analyses, *P* value of <0.05 provide statistical significance.

RESULTS

This study included 415 children with type I diabetes mellitus. The mean age was 12.7 ± 3.7 years and male to female ratio was 1 : 1. 87.8 of children aged 15 years or more have tanner stage 2 or more. Of the studied 415 cases, 225 (54.2%) were of good glycemc control and the remaining 190 cases (45.8%) were of poor glycemc control. Table 1 shows the demographic characters of the good control group compared with the poor control group.

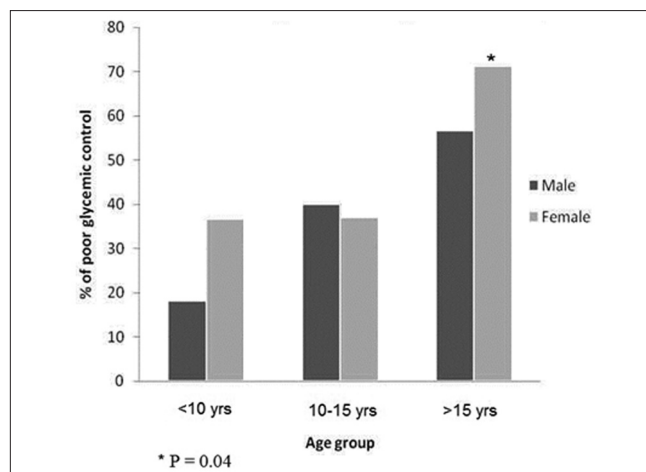
Table 1: Distribution of good controlled and poor controlled diabetic patients by demographic characters

	Total (n=415)	Good control (n=225) (%)	Poor control (n=190) (%)	P
Age (m±SD)	12.7±3.7	11.77±3.7	13.83±3.3	0.000
2-<10 year	82	61 (74.4)	21 (25.6)	0.000
10-<15 year	177	109 (61.6)	68 (38.4)	
≥15 year	156	50 (32.1)	98 (67.9)	
Sex				
Male	208	117 (56.2)	91 (43.8)	0.40
Female	207	108 (52.2)	99 (47.8)	
BMI				
Normal	179	81 (45.3)	98 (54.7)	0.002
Overweight	215	135 (62.5)	81 (37.5)	
Overweight/ obese	20	9 (45)	11 (55.0)	
Birth order				
1 st	122	63 (51.6)	59 (48.4)	0.08
2 nd	88	57 (64.8)	31 (35.2)	
3 rd or more	205	105 (51.2)	100 (48.8)	
Family history of DM				
1 st degree	76	42 (55.3)	34 (44.7)	0.38
Other related	193	98 (50.3)	95 (49.2)	
No family history	146	85 (58.2)	61 (41.8)	
Residence				
Urban	66	34 (51.5)	32 (48.5)	0.36
Rural	349	191 (54.7)	158 (45.3)	
Mother education				
No education	230	122 (53.0)	108 (47.0)	0.63
<secondary	62	32 (51.6)	30 (48.4)	
Secondary/ higher	123	71 (57.7)	52 (42.3)	
Father education				
No education	166	85 (51.2)	81 (48.8)	0.56
<secondary	77	42 (54.5)	35 (45.5)	
Secondary/ higher	172	98 (57.0)	74 (43.0)	
Socioeconomic state				
High class	12	5 (41.7)	7 (58.3)	0.66
Middle class	353	192 (54.4)	161 (45.6)	
Low class	50	28 (56.0)	22 (44.0)	

BMI: Body mass index, DM: Diabetes mellitus

Age was found to be highly significant factor of glycemc control. Patients with poor control had significantly higher mean age than the group with good control. Stratification of patients according to the age showed that glycemc control decreases with advancement of the age. Children aged 15 years and more (67.9%) had poor glycemc control compared with (25.6%) children aged less than 10 years old.

Sex was not significantly associated with glycemc control. Stratification of patients by age and sex [Figure 1] shows that girls 15 years or more had significantly higher percentage of poor glycemc control than males of the same age group (71.2% *vs* 56.7%, $P = 0.04$). Patients with BMI below normal had significantly higher percentage of good control than patients with normal BMI and over weights (62.5% *vs* 45.3% and 45.0%, $P = 0.002$).


Figure 1: Percent of children with poor glycemc control by their age and sex

Although not significantly differ, higher level of education of the mother and father were associated with higher rate of good glycemc control than lower levels of education. No significant association was noticed between socioeconomic state of the family and glycemc control. Birth order of the patient, first degree relative with diabetes, and residence were not significant factors in disease control. Table 2 shows the disease-related characters in the good controlled group compared with the poor controlled group. Patients with poor control had significantly longer duration of disease than patients with good control (4.94 ± 2.6 *vs* 3.40 ± 2.0 , $P < 0.000$). Stratification of patients according to the duration of the disease showed that the rate of poor control increases with increasing the duration. As regard age at onset of the disease, patients 10 years or more at onset of disease were more presented in the group of poor control (55.6%), whereas young patients at onset of disease (<5 years) were more presented in the group of good control (87.0%).

In the present study, 66.2% of the cases were on twice injections of premixed intermediate-acting and regular insulin/day (regimen 1), 23.7% were on twice injections of intermediate-acting insulin + one or more injections of regular insulin/day (regimen 2), while 10.1% of cases had once injection of insulin glargine and three injections of regular insulin/day (regimen 3). It was noticed that the rate of good glycemc controlled patients was significantly higher in regimen^[3] than the other two regimens, also it was significantly higher in patients with daily glucose checking (69.8%) than those with monthly checking (21.1%); on the other hand, diet control and clinic visits for follow up were not significant factors of glycemc control.

Table 3 shows the mean serum lipid levels in patients with good control compared with patients with poor control.

Table 2: Disease related characters in the good controlled group compared with the poor controlled group

	Total (n=415)	Good control (n=225) (%)	Poor control (n=190)	P
Age at onset of disease				
<5 years	23	20 (87.0)	3 (13.0%)	0.000
5-<10 years	160	102 (63.8)	58 (36.2%)	
≥10 years	232	103 (44.4)	129 (55.6)	
Duration of disease	4.1± 2.4	3.40± 2.0	4.94±2.6	0.000
<5 years	258	168 (65.1)	90 (34.9)	0.000
5-<10 years	146	55 (37.7)	91 (62.3)	
≥10 years	11	2 (18.2)	9 (81.3)	
Regimen of insulin*				
Regimen (1)	275	129 (46.9)	146 (53.1)	0.042
Regimen (2)	98	63 (64.3)	35 (35.7)	
Regimen (3)	42	31 (73.8)	11 (26.2)	
Glucose check				
Every day	224	156 (69.8)	68 (30.2)	0.032
Every week	120	56 (46.7)	64 (53.3)	
Every month	71	15 (21.1)	56 (78.9)	
Diet control				
Yes	271	147 (54.2)	124 (45.8)	0.95
No	144	78 (54.2)	66 (45.8)	
Medical follow up				
Regular	312	166 (53.2)	146 (46.8)	0.15
Irregular	103	47 (45.6)	56 (54.4)	

*Regimens of insulin: Regimen (1): Twice injections of pre-mixed intermediate-acting and regular insulin/day, Regimen (2): Twice injections of intermediate-acting insulin + one or more injections of regular insulin/day, Regimen (3): Once injection of insulin glargine + three injections of regular insulin/day

Table 3: Serum lipids in patients with good control compared with patients with poor control

	Total	Good control (n=225)	Poor control (n=190)	P
Total cholesterol (m±SD) mg/dl	127.18±35.45	119.3±31.9	136.5±37.3	0.000
Normal level (%)	401	219 (54.6%)	182 (45.4%)	0.38
Raised level (%)	14	6 (42.9%)	8 (57.1%)	
Triglyceride(m±SD) mg/dl	120.47±42.11	112.2±38.6	130.2±44.0	0.000
Normal level (%)	364	208 (57.1%)	156 (42.9%)	0.001
Raised level (%)	51	17 (33.3%)	34 (66.7%)	
HDL-C (m±SD) mg/dl	48.74±8.95	47.5±8.1	50.2±9.7	0.000
Normal level (%)	409	223 (54.5%)	186 (45.5%)	0.41
Raised level (%)	6	2 (33.3%)	4 (66.7%)	
LDL-C (m±SD) mg/dl	92.53±23.55	90.35±23.0	95.1±24.0	0.04
Normal level (%)	406	222 (54.7%)	184 (45.3%)	0.312
Raised level (%)	9	3 (33.3%)	6 (66.7%)	

HDL-C: High-density lipoprotein cholesterol, LDL-C: Low-density lipoprotein cholesterol

Poor controlled patients had significantly higher serum TC, TG, HDL-C, and LDL-C than patients with good control. On classification of patients according to the upper limit of normal of serum lipids, we found a significant proportion of patients with raised TG levels in the poor controlled group than the good controlled group (66.7% *vs* 33.3%, $P = 0.001$). Table 4 shows the predictors of poor glycemetic control and adjusted odds ratio estimated by multivariate logistic regression. Adjusting for other variables, we found that age of patients and duration of disease were most significant predictors of poor glycemetic control. Patients 15 years old or more were 2.5 times more vulnerable to poor glycemetic control than patients younger than 10 years old (aOR, 2.6; $P = 0.002$). Also, patients with disease duration, 5 years and more, were 3 times more vulnerable to poor control than those with shorter duration (aOR, 3.0; $P = 0.000$). It is noticed also that patients with raised serum TG

than the upper limit of normal were two times more liable to be uncontrolled than patients with lower levels (aOR, 2.2; $P = 0.002$). Age at onset of disease, sex, BMI, and insulin regimen were not significant factors of glycemetic control in the multivariate analysis.

DISCUSSION

In the present study, age was found to be highly significant factor of glycemetic control. Patients with poor control had significantly higher mean of age than the group with good control. Furthermore, stratification of patients according to the age showed that glycemetic control decreases with advancement of the age. This result is supported by several studies.^[13,14] Vanelli *et al.*^[15] who studied children and adolescents with diabetes stated that increasing age was associated with a higher mean HgA1c and a decreased

Table 4: Predictors of poor glyceemic control and adjusted odds ratio estimated by multivariate logistic regression

Variable	B	Adjusted OR	P	95% CI
Age group (r:<10 years)				
10-<15 years	1.05	2.9	0.024	1.15-7.11
≥15 years	0.97	2.6	0.002	1.45-4.83
Triglyceride (r=normal)	0.78	2.2	0.020	1.13-4.23
Raised TG	1.08	2.9	0.000	1.91-4.60
Duration (r=<5 years)	-2.23	0.11	0.001	
≥5 years				
Constant				

r: reference group, TG: Triglyceride

likelihood of attaining HgA1c in the target range regardless of insulin regimen.

Studied patients aged 15 years and more were 2.5 times more likely to be uncontrolled than younger patients (aOR, 2.6; $P = 0.002$). Of this group, 87.8% of the cases were at least tanner stage 2 of sexual maturity; the earliest stage of puberty detectable on physical examination (breast buds, fine pubic hair, and testicular enlargement). Adolescents tend to have worse glyceemic control than younger children or adults with DM.^[16] Striking changes in normal physiology occur at puberty, including the acceleration and cessation of somatic growth, the development of secondary sexual characteristics, and onset of reproductive capacity.^[17] Furthermore, exposure to stressful conditions associated with puberty may aid to the poor glyceemic control through stimulation of the autonomic nervous system to induce hyperglycemia.^[18] Several studies have demonstrated that insulin sensitivity decreases early in puberty in non-diabetic children and in patients with DM, which returns to normal once somatic growth and sexual maturation are completed.^[19] Sex steroids seem unlikely to be the cause, because these hormones are at even higher levels in adults when insulin sensitivity improves. One study have found a relationship between insulin sensitivity and the growth hormone-insulin growth factor axis (GH-IGF-I axis), suggesting an increased tissue GH effect as the cause of this phenomenon.^[20]

It has been argued that poor control in adolescents relates to the rapid biologic changes of puberty along with challenging of adapting to life style that require self-management of dietary practices, exercise behaviors, and insulin adjustment.^[21] However, poor adherence to treatment regimens and poor attendance to outpatient visits may add to the poor glyceemic control in our setting.

It was noticed in this study that sex was not associated with glyceemic control. When we compared patients of different age groups according to sex, we found that

female patients aged ≥15 years had significantly higher percent of poor glyceemic control than males of the same age group (71.2% *vs* 56.7%, $P = 0.04$). This result has been recorded by Setoodeh *et al.*^[22] who attributed this result to greater depression and psychological problems in girls. Furthermore, susceptibility of females to poor glyceemic control during adolescence may be attributed to the high fat content of their bodies with subsequent increase in adipocytokines as leptin and adiponectin which decreases insulin sensitivity.^[23]

It is noteworthy to mention that patients with BMI below normal had significantly higher proportion of good control than patients with normal BMI or overweight. However, in the multivariate logistic regression analysis, BMI was not found to be a significant factor for glyceemic control. This could be explained by the presence of other confounding factors in the group of low BMI as the short duration of the disease and younger age of the patients.

Duration of the disease was found to be highly significant factor of glyceemic control. Patients with good control had significantly shorter duration of disease than patient with poor control. This finding was obvious when we stratified patients according to duration where prevalence of poor control increases as the duration of the disease increases. Moreover, patients with disease duration 5 years and more were 3 times more vulnerable to poor control than those with shorter duration (aOR, 3.0; $P = 0.000$). This finding is supported by Craig *et al.*^[24] The worsening glyceemic control with increasing duration of T1D is due in part to progressive loss of beta cell function and the difficulty for the patients to continue monitoring the blood glucose level and adjust to the regimen of treatment, diet, and exercise.^[25]

Patients who are young at onset of disease (<5 years) were more presented in the group of good glyceemic control, whereas patients who are old at onset of disease (>10 years) were more presented in the group of poor control. Svensson *et al.*^[26] stated that the pre-pubertal duration is protective in diabetic patients and the youngest age-groups at diagnosis may have a relative protection during childhood or a longer time to development of complications.

In the present study, it was noticed that the prevalence of good glyceemic control was significantly higher in the insulin regimen which consisted of one basal dose of insulin glargine and three injections of regular insulin than the other two regimens. Sharplin *et al.*^[27] found good control of patients with T1DM after switch from pre-mixed insulin to glargine-based insulin regimen. Alemzadeh *et al.*^[28] found that the use of flexible multiple daily insulin therapy with glargine among preschool-aged children with

type 1 DM was associated with improved overall glycemic control and decreased frequency of severe hypoglycemia. However, the optimal insulin regimens that are essential to improve clinical outcomes remain unclear. While some studies document that the use of insulin pump has been associated with lower HgA1c, fewer episodes of severe hypoglycemia, and improvement of quality of life,^[29] the international multicenter study from the Hvidovre Study Group^[30] found that no association were found between the frequency of insulin dosing or the use of insulin pump with HgA1c value. This may raise the possibility of genetic or environmental factors that may add to the glycemic control.

In the present study, the glycemic control was significantly higher in patients with daily glucose checking than those with weekly or monthly glucose checking. This finding is supported by Haller *et al.*^[31] The frequent glucose testing will allow patients to identify, prevent, or manage episodes of hypo- and hyperglycemia and avoid missing the marked day-to-day excursions in plasma glucose from high to low values that characterize T1DM in children.^[32]

In the present study, no significant difference was found between good and poor glycemic control as regard regularity of clinic visit for follow up. Kaufman *et al.*^[6] found a relationship between fewer clinic visits and poorer control in a sample of children followed at diabetes center, while Urbach *et al.*^[13] found that increased frequency of clinic attendance is associated with worse control and explained this as the frequent visits was a result of the poor control and not a cause. The frequent clinic visits were recommended to allow for more frequent adjustments of insulin regimens, and increased number of opportunities for education and motivation.^[6]

In the study, poor controlled patients had significantly higher serum TC, TG, high-density lipoprotein-cholesterol, and low-density lipoprotein-cholesterol than patients with good control. Patients with raised serum TG than the upper limit of normal were two times more liable to be uncontrolled than patients with lower levels (aOR, 2.2; $P = 0.020$). Pettiti *et al.*^[33] found significant association between poor glycemic control and higher concentrations of TC, LDL-C, and TG even in children and youth aged, 10 to 22 years, in all major ethnic/racial groups in the United States. Poor glycemic control and increased serum lipids are risk factors for micro-and macro-vascular complication of T1DM. It is possible that both glycemic control and lipid concentration are markers for the quality of diabetes care either at the individual level or the level of the healthcare system. Children with limited access to healthcare may be those more likely to have poor glycemic control and, at the same time, may be less likely to be tested and treated for lipid abnormalities.^[25,33]

A limitation of this study was the cross-sectional observational design which cannot delineate the cause-effect relationship. Also, many of the collected data were self-reported by the patients or their guardians, which may result in overestimation of the actual frequency of insulin administration and blood glucose testing. However, this study was the first in our locality on this number of patients with T1DM. These results will direct attention to points of further studies required. Prospective studies on impact of regimens of insulin therapy and adequacy of medical follow-up is recommended.

CONCLUSIONS

This study concluded that children more than 15 years, duration of disease more than 5 years, and high serum TG level are the predictors of poor glycemic control of children with T1DM in Assiut-Egypt. Pediatricians need to be aware of factors associated with poor glycemic control in children with T1DM, so that more effective measures can be implemented to prevent deterioration in diabetes control.

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