Thi-Qar Medical Journal (TQMJ):Vol.(18),No.(2),2019

Web Site: https://jmed.utq.edu.iq Email:utjmed@utq.edu.iq

ISSN(Print):1992-92 18, ISSN (Online):1992-92 18

Factors associated with uncontrolled type 1 Diabetes Mellitus in children and adolescents in Thi-Qar 2016-2017

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Abstract

Background:- T1DM is the most common endocrine-metabolic disorder of childhood and adolescence, with important consequences for physical and emotional development. Individuals with T1DM confront serious lifestyle alterations that include an absolute daily requirement for exogenous insulin, the need to monitor their own glucose level, and the need to pay attention to dietary intake.

Objective:- to assess the main factors and patient characteristics associated with uncontrolled T1DM that should be aware by Iraqi's Pediatricians.

Patient and method:- A cross sectional analytical study had been conducted on children and adolescents with type1 DM visiting the diabetic clinic in Al- Nasiriya Diabetes and endocrine specialized center (south of Iraq), from 1st of June 2016 to the end of May 2017. The patients selected to be as uncontrolled status (fair and poor control) according to their HbA1C level results. Demographic factors, disease-related characteristics, checking of blood glucose, dietary control, type, dose and regimen of insulin injection and other related aspects, and anthropometric measures were included.

Result: - Two hundred and one(201) type 1 diabetic patients selected to be uncontrolled status with mean age of(9.530 year ±3.2526),with no significant difference in sex. Majority of them were with poor control status (71.1%), and 28.9% were with fair control status. The residence, mother education, dietary control, regular follow up and regular checking of blood glucose level, syringe use, insulin injection technique, lipodystrophy at injection sites, and person who give the insulin were the main independent factors that had a significant statistical association with the control status in this study, while multivariate analysis revealed that dietary control, person who are responsible for giving insulin and changing site of injection were significantly associated with control status.

KEY WORD : Factors , uncontrolled type 1 diabetes mellitus , children ,adolescents.

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Introduction:-

T1DM is the most common endocrine-metabolic disorder of childhood and adolescence, with important consequences for physical and emotional development [(1)]. The defect is in insulin secretion from pancreatic beta cells that results in chronic hyperglycemia with disturbances of carbohydrates, fat and protein metabolism [(2)]. It is a common disease, with evidence of gradually increasing in overall worldwide prevalence. It causes great morbidity and early mortality in a large number of people, since it is associated with many complications and lastly the cost of managing its complications is very high [(3)]. Over the world there are more than 15 million patients with type 1 DM [(1)].

The natural history of T1DM usually follows different stages : 1- Initiation of autoimmunity. 2- Preclinical autoimmune destruction of β-cell (90%). 3- Onset of clinical diabetes. 4- Transient (honey moon) remission. 5- Established disease 6- Complications (early and or chronic) [(1)].

Symptoms of hyperglycemia (polydipsia, polyuria, unexplained weight loss, nonspecific malaise) and symptoms of glucosuria and ketoacidosis are the main presented clinical problems for these patients [(4)].

Diagnosis:- diagnostic criteria for diabetes [(5)]

IMPAIRED GLUCOSE TOLERANCE (IGT)	**DIABETES MELLITUS (DM)**
Fasting glucose 100-125 mg/dL (5.6-7.0 mmol/L)	Symptoms* of DM + random plasma glucose ≥200 mg/dL (11.1 mmol/L)
	Or
2-hour plasma glucose during the oral glucose tolerance test(OGTT) ≥140 mg/dL, but <200 mg/dL 11.1 mmol/L)	Fasting plasma glucose ≥126 mg/dL (7.0 mmol/L) *or* 2-hour plasma glucose during the OGTT ≥200 mg/dL
	Or HbA1c level≥ 6.5% (repeat testing)

Glycosylated hemoglobin: medium and long-term monitoring of diabetic control is best to be assessed by HbA1c levels method measurement. An international expert committee composed of appointed representatives of the European Association for the Study of Diabetes , American Diabetes Association (ADA), and others recommended HbA1c assay for diagnosing diabetes mellitus [(1,6)].

HbA1c Values and Degree of Glycemic Control	
HbA1c value	Degree of glycemic control
<6%	Normal
6–7.5 %	Well controlled
7.6–9.9%	fairly controlled
≥10%	Poorly controlled

Glycemic control: The ADA recommends using patient age as one consideration in the establishment of glycemic goals, with different targets for pre-prandial, bedtime/overnight blood glucose levels, and hemoglobin A_{1c} (HbA_{1c}) levels in patients aged 0-6, 6-12, and 13-19 years. The target HbA1c for all age-groups is preferred to be < 7.5%. The benefit is to prevent the long-term microvascular and macrovascular complications of the disease and also avoiding sequelae of acute hypoglycemia and the CNS changes due to both hypoglycemia and hyperglycemia [7-8]. A minimum of 4 daily blood glucose measurements should be performed. HbA1c measurement reflects the average blood glucose concentration from the preceding 2-3 months, it is recommended that HbA1c measurements be obtained 3-4 times/ year to obtain a profile of long-term glycemic control [1].

Insulin therapy: All children with type 1 diabetes mellitus require insulin therapy. Most require 2 or more injections of insulin daily, with doses adjusted on the basis of self-monitoring of blood glucose levels. Insulin replacement is accomplished by giving a basal insulin and a preprandial (premeal) insulin. The basal insulin is either long-acting (glargine or detemir) or intermediate-acting (NPH). The preprandial insulin is either rapid-acting (lispro, aspart, or glulisine) or short-acting (regular). Also, a continuous subcutaneous insulin infusion regimen can be used [9].

Diet and activity:- To keep BG concentrations as normal(reference ranges) as possible; the dietary management is to balance the child's food intake with activity and insulin dose , avoiding extremes BG ranges of hypoglycemia or hyperglycemia.

within the context of the culture of the patient's, the following recommendations are most recently dietary consensus that include [1]:

- 50-55% of daily energy intake should be provided as carbohydrates (CHD). No more than 10% of CHO should be from sucrose or other refined CHO.
- Fat – arranged from 30-35% of daily energy intake.
- Protein - Should provide 10-15% of daily energy intake.

The other real benefit for children with diabetes should be practicing exercise that is considered as an important aspect of management. Regular exercise improves glucose regulation by increasing insulin receptor number [1].

Materials and Methods

A cross sectional analytical study had been conducted on children and adolescents with type1 DM visiting the diabetic clinic in Al- Nasiriya Diabetes and endocrine specialized center, during their regular checkup from 1st of June 2016 to the end of May 2017. The patients selected to be as uncontrolled status according to their HbA1C level (according to American Diabetes Association definition), which was done at least for 2 occasions (3 months apart) and its mean had been used to include the patient in this study. The data were collected by face to face meeting with the patient and his family and by studying medical record files and electronic medical recording system in the center.

Inclusion criteria for children in this study is:

- Definite diagnosis of T1DM according to the definition of the WHO [5].
- Currently using insulin.
- Age range 1 to ≤ 15 years.
- At least 6-months duration diabetes.

Exclusion criteria

- Those with secondary DM.

- Children with type 2 DM.
- Age <1 years >15 years.
- Those with HbA1c level ≤ 7.5 %.

Ethical consideration:-

A written assent was obtained from all patients in the study. The study was approved by the ethical scientific committee of the Medical college/ University of Thi-Qar, and Thi-Qar health directorate.

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

- Demographic factors: sex, age, residence, family history of diabetes and its degree, and level of the family education and patient education.
- Disease-related characteristics: duration of diabetes, attendance to education programs at the center, physical exercise.
- Regular checking of blood glucose which is desired at least 4 check per day [8]. Those who checked ≥ 4 times/day regarded good, 2-3 times/day regarded weak, and those who checked < 2 were poor checker.
- Dietary control was assessed according to the percentage of compliance of the patients from the desired dietary instructions (> 80% good, 50-80% accepted, and < 50% poor).
- We asses type, dose and regimen of insulin injection, regularity of administration, way of injection (syringe, pen, mixed), technique of injection (correct or not), person who inject insulin, changing the site of injection, any dystrophy at the site of injection, and finally insulin storage.

Physical examination was done for each patient with concerns on weight and length or height. Then (BMI) body mass index was calculated as: weight kg /height m^2. Patients were considered as normal, under weights, or over weights according to their BMI percentile charts for age and sex [10].

Investigations done including:-

- HbA1c % was measured for all cases in blood samples using Bio-Rad D-10 ™ hemoglobin testing system. For each patient at least two readings of HbAc1 level 3 months apart. Patients were classified as Group I with fair glycemic control and Group II with poor glycemic control [1].
- Serial fasting blood glucose measurements were registered for each patient (at least 6 reading).
- Serum T3, T4 and TSH level to assess thyroid function.
- Serum antitissue transglutaminase antibody level (if +ve the test repeated again in Al- Hussein teaching hospital) in order to diagnose celiac disease if +ve, then confirmed by biopsy.

Statistical analysis

The data had been expressed in the form of numbers and percentage and analyzed using SPSS (version 23). Were the student t test, ANOVA and Leavens test had been used to associate the quantitative variables. Pearson Chi-square test and Fisher exact test used to associate qualitative variables. Logistic regression analysis was used for independent variables to see the real effect on outcome. For all analyses, *P* value of <0.05 provides statistical significance.

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Result: Two hundred and one(201) T1DM patients selected to be uncontrolled status according to their HbA1C exam, with mean age of(9.530 year ±3.2526), gender proportion was 52.2 % male and 47.8 % female. Majority of them were with poor control status (71.1%), and only 28.9% were with fair control status as shown in figure 1:

Figure (1) control state of the sample

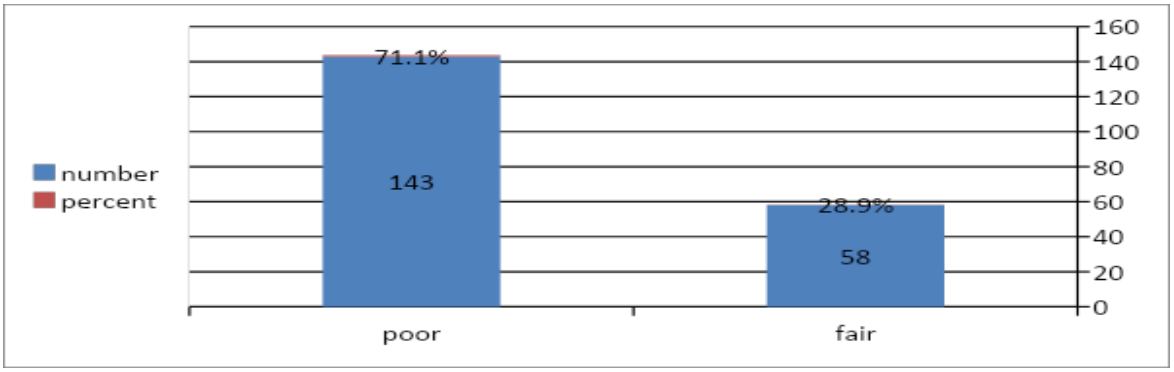


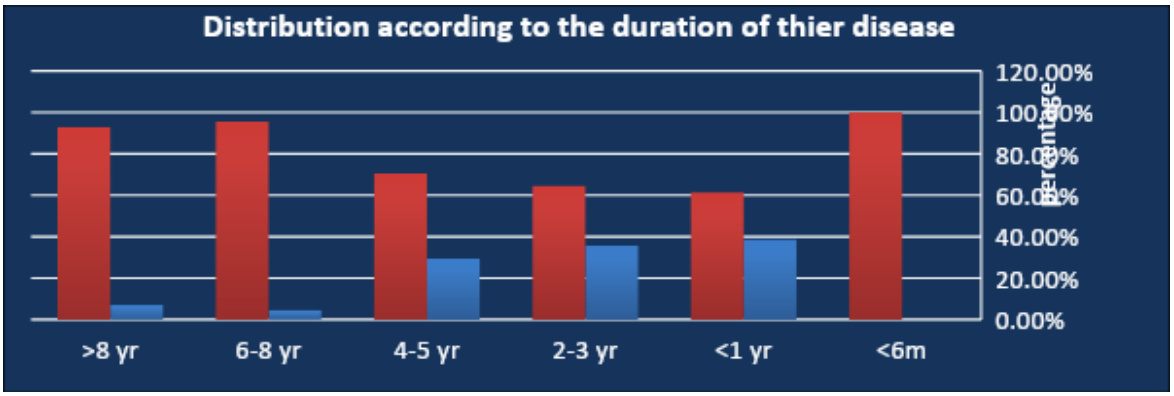
Table 1: Uncontrolled HbA1C according to the socio-demography of child factors:

Patients characters	Uncontrolled status (HbA1c)				Total	X^2 P value
	Fair		**Poor**			
Age						
Preschool age <6 years	25	80.6%	6	19.4%	31	53.258[a]
Primary school age(6-12 years)	30	24.4%	93	75.6%	123	0.0001
More than12 years	3	6.4%	44	93.6%	47	
Sex						
Female	33	34.4%	63	65.6%	96	2.727
Male	25	23.8%	80	76.2%	105	0.069
Address						
Rural	19	22.9%	64	77.1%	83	2.450
Urban semi-urban	39	33.1%	79	66.9%	118	0.075
BMI						
Normal	43	30.7%	97	69.3%	140	2.347
Underweight	14	28.0%	36	72.0%	50	
Overweight	1	9.1%	10	90.9%	11	0.321
Educational status						
Preschool & Illiterate	27	64.3%	15	35.7%	42	38.055
Primary schooling	28	25.0%	84	75.0%	112	
Intermediate schooling	3	6.4%	44	93.6%	47	0.0001
Physical activity and exercise						
No	24	27.3%	64	72.7%	88	0.191
Yes	34	30.1%	79	69.9%	113	0.114
Total	58	28.9%	143	71.1%	201	100%

Patients aged >12 years(intermediate school) seems to had poorer control (P value <0.0001), while sex and residence don't affect the control status.

There was significant association between the duration of disease and the uncontrolled status, where the vast majority of poorly controlled were in those with duration of less than 6 months and with those more than 6 years duration as shown in figure(2) .

Figure (2): Distribution of patients according to duration of their disease



Pearson Chi-Square14.857[a] , p value =0.008

Table (2):Uncontrolled T1DM patients according to their familial factors

	Uncontrolled status (HbA1c)				Total		X^2
	Fair		**Poor**				**P value**
Father education							
Primary	22	27.2%	59	72.8%	81		2.621[a]
Secondary	21	25.6%	61	74.4%	82		
Basic college and above	15	39.5%	23	60.5%	38		0.274
Mother education							
Primary	22	18.8%	95	81.2%	117		28.935[a]
Secondary	20	31.7%	43	68.3%	63		
Basic college and above	16	76.2%	5	23.8%	21		0.0001
Family history							
Positive	24	29.6%	57	70.4%	81		0.040[a]
Negative	34	28.3%	86	71.7%	120		0.123
Relative with DM							
No relative	34	28.3%	86	71.7%	120		1.437[a]
1st degree	8	36.4%	14	63.6%	22		
2nd degree	11	24.4%	34	75.6%	45		,0.853
3rd degree	2	40.0%	3	60.0%	5		
1st and 2nd degree	3	33.3%	6	66.7%	9		
Total	58	28.9%	143	71.1%	201	100%	

Higher mother education is significantly associated with improved control status (P valueL<0.001).

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Table (3): Difference between 2 group fasting blood sugar means reading

Independent samples Test					
Equal variances	Levene's Test for Equality of variances	T-test for Equality of means			
	F, Significance	T valve	Sig.(2-tailed)	Mean difference Std. Error Difference	95% Confidence interval of the difference
					Lower-Upper
Assumed	14.437 .0001	-1.109-	-.269	-.293- .264	-.814- .228
Not assumed		-9.034-	.000	-.293- .032	-.357- -.229

A very high significant statistical association had been found, when the 2 group had been compared inform of their reading for their mean blood glucose at a fasting status by comparing different age group at different situation of their fasting blood glucose in term of their final control status, where the fasting blood glucose tend to be higher among poor control with the increment in age.

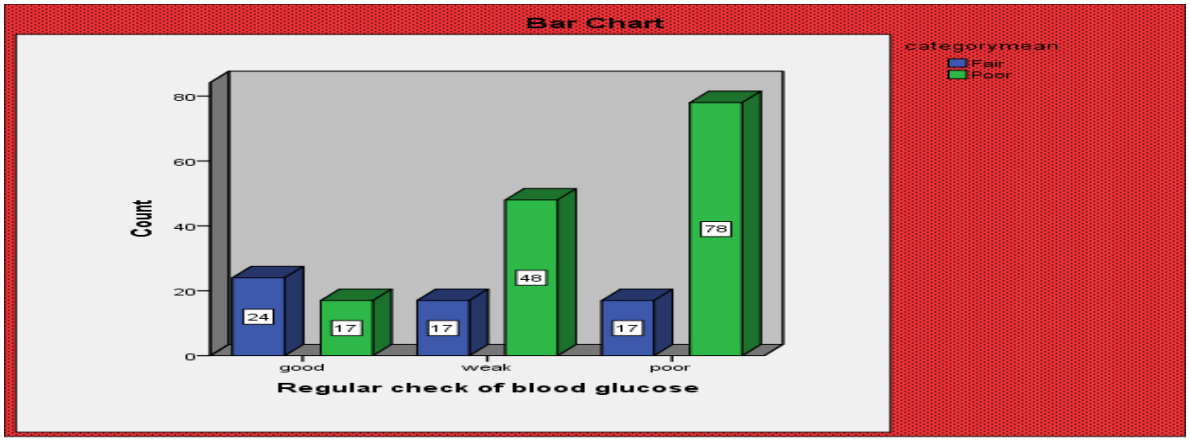
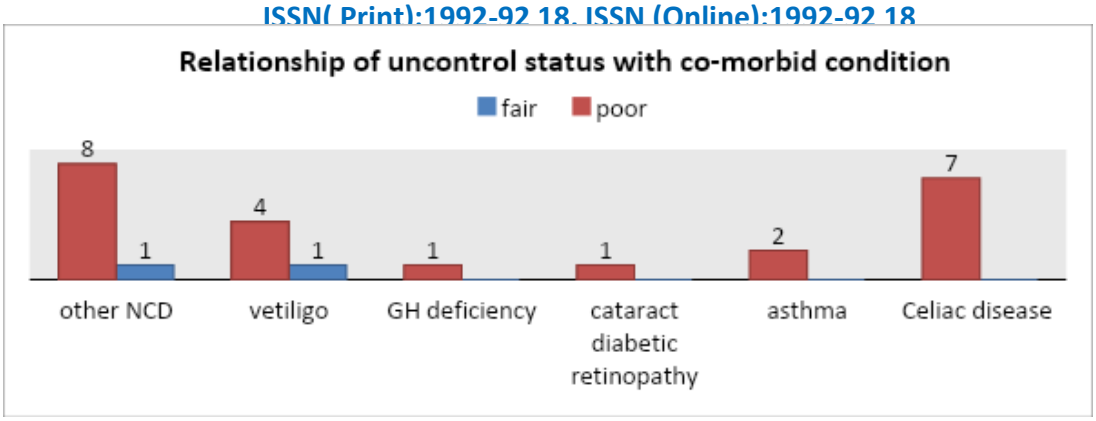


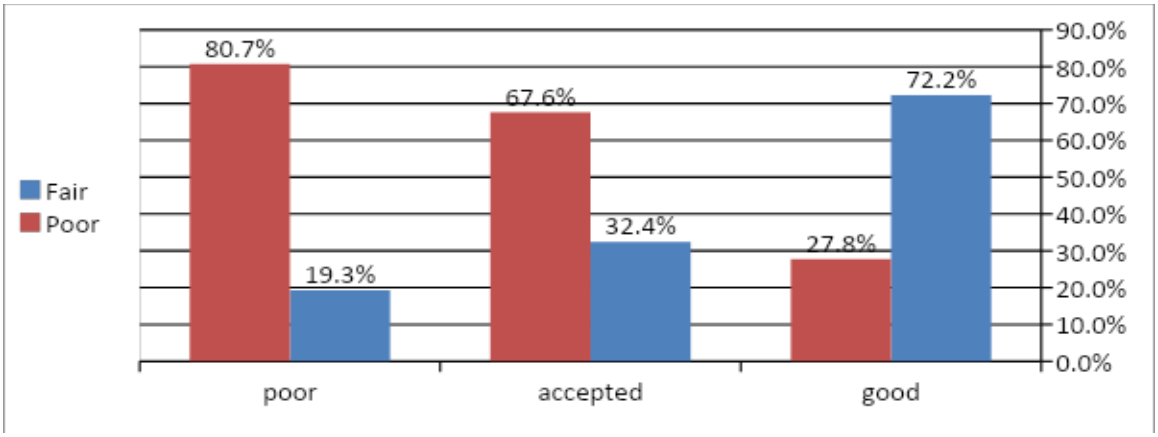
Figure (3) distribution of patients according to their checking of blood glucose
Pearson Chi-Square=23.385a P value =0.0001

Figure (4): Distribution of comorbid condition according to control status:



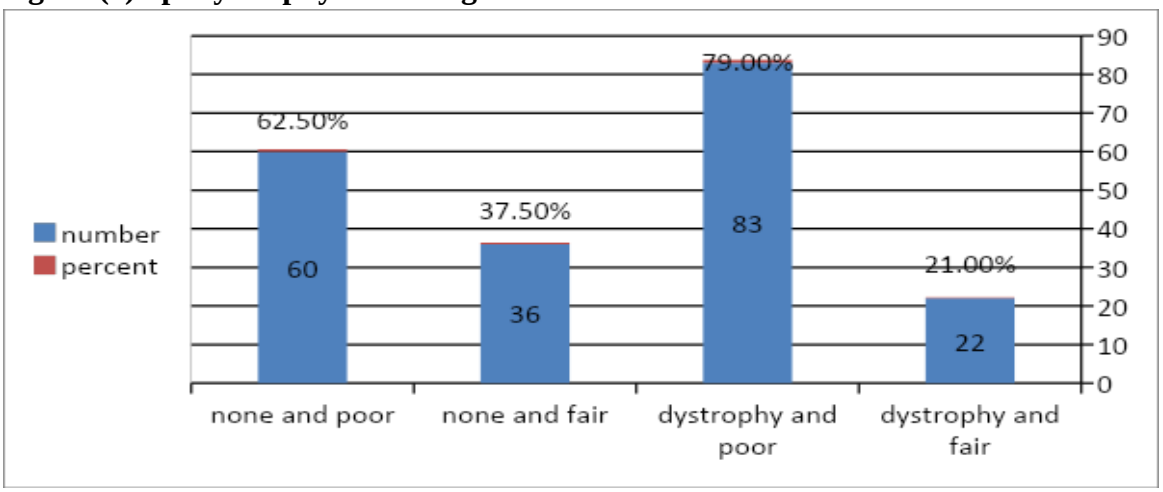
Celiac disease represents the highest comorbid chronic illness in comparison with other comorbid conditions.

Figure (5):- control status according to the dietary control



Pearson Chi-Square=7.68[a] , P value= 0.014

Figure (6) lipodystrophy according to control status



Pearson Chi-Square= 6.689[a] , Point Probability=0.004

Table (4):- Distribution according to the components of satisfy management

Control status	Fair		Poor		Total	X^2, P value
Attend education program						
Regular	21	65.6%	11	34.4%	32	7.82, 0.023
irregular	14	18.7%	61	81.3%	75	
Not attended	23	24%	71	76%	93	
Type of insulin						
premixed	58	30.5%	132	69.5%	190	4.966, 0.069
self-titrated	0	0.0%	10	100.0%	10	
mixed	0	0.0%	1	100.0%	1	
Dose U/kg						
0.5	4	30.8%	9	69.2%	13	0.944, 0.813
0.7	27	28.1%	69	71.9%	96	
1	17	33.3%	34	66.7%	51	
>1	10	24.4%	31	75.6%	41	
Type of insulin regimen						
2dose/d	57	29.4%	137	70.6%	194	0.577, 0.721
4dose/d	0	0.0%	2	100.0%	2	
Other type	1	20.0%	4	80.0%	5	
Regularity in taking of treatment						
Yes	56	29.8%	132	70.2%	188	1.229, 0.286
No	2	15.4%	11	84.6%	13	
Way of injection						
syringe	13	17.6%	61	82.4%	74	10.365, 0.006
pen	35	40.2%	52	59.8%	87	
mixed	10	25.0%	30	75.0%	40	
Technique of injection						
correct	54	31.2%	119	68.8%	173	3.364[a], 0.067
incorrect	4	14.3%	24	85.7%	28	
Person who give insulin injection						
mother	42	42.0%	58	58.0%	100	33.891, 0.0001
father	1	6.7%	14	93.3%	15	
patient	2	4.8%	40	95.2%	42	
other	1	16.7%	5	83.3%	6	
mother and father	9	42.9%	12	57.1%	21	
Mother & patient	1	8.3%	11	91.7%	12	
father & patient	1	33.3%	2	66.7%	3	
father and other	0	0.0%	1	100.0%	1	
patient and other	1	100.0%	0	0.0%	1	
Changing the site of injection						
Yes	41	38.3%	66	61.7%	107	9.978, 0.002
No	17	18.1%	77	81.9%	94	

This table showed that regular attendance to diabetes education programs, use of premixed insulin (specially pen use), when the mother gave insulin to her child, and regular change

of insulin injection sites were statistically significant factors associated with better diabetic control.

Table 5: Logistic regression analysis

Mean of HbA1C	B	Sig.	Exp(B)	95% Confidence Interval for Exp (B)	
				Lower Bound	Upper Bound
Significant: Dietary control	8.230	0.014	3753.518	0.496	28412898.445
Changing the site of injection	2.087	.029	8.063	1.233	52.729
Person who give insulin injection	-40.468-	.0.002	2.661 E-18	.000	.[b]
Non-significant:					
Sex	Age	Residence	Father education	Mother education	Patient education
Patient education	Family history of DM	Checking of blood sugar	Physical activity	Comorbid diseases	Attendance to education programs
Type of insulin	Insulin dose	Insulin regime	Technique of injection	Dystrophy at the site of injection	Duration of the disease

The dietary control, changing the site of insulin injection, and the person who gave the insulin were the main independent factors that had a real significant statistical association with the control status in this study.

Discussion:

A cross sectional analytical study had been conducted to enroll two hundred and one (201) T1DM patients selected to be as uncontrolled status according to their HbA1C level examinations, which was done at least for 2 occasions and its mean had been used to include the patient in this study. The recruited children in the final sample of the study were with a mean age of(9.530 year ±3.2526), 52.2 % male, 58.7% of urban and semi-urban residence. Majority of them were with poor control status (71.1%), and only 28..9% were with fair control status.

Patients factors:

Age: A univariate analysis show that, age very high significantly affecting the control status, through which there is advance increase in the proportion of poorly controlled with the increment of age; and inversely decrease the rate of age specific control status among the fair control group (P value=0.0001), these results were supported and comparable other studies that done in Egypt and Italy [(11-13)]. This might reflect the effect

of duration of the illness rather than real effect of the age, this demonstrated well by multivariate analysis, which proves the age as a confounder.

Sex: there was no significant statistical association between the gender and control status by both univariant and multi-variant analysis, which also similar to the result of other studies [14,15].This might reflecting that the care introduce to both sex are of equal quality.

Residence: the study shows no significant association between the geographical distribution of the place of inhabiting with control status. This result was similar to a Loveline study in Cameron [16].

Patients education: the study shows a very high significant statistical link between the two variables of interest, but a multivariate analysis does show this association, this also has been proved by other several studies [11-13]. This might be explained by the educational status here is a mirror of the age of the patient.

BMI: although the study doesn't show significant statistical association but the poorly controlled group tended to be either over or underweight rather than the fairly control group, it is also comparable with other studies [10,17].

Disease duration: Highly significant factor for glycemic control is the duration of the disease was found to be. A significantly shorter duration of disease aggregated among the fair control group than those with poor control. Stratification of the patients according to duration of their illness making an obvious finding when prevalence of poorly controlled increases with increase in the duration. Moreover, duration of 6 years and more were 1.5 time more to be poor control than those with less than 1 year duration (OR, 8.0; *P* = 0.029). Craig *et al* support this finding [18]. Increasing duration of IDDM worsening glycemic control that is due to progressive beta cell function loss and lack of the patients monitoring continuity to his blood glucose level and adjust to the treatment regimen, exercise and diet [19]. Patients with onset of disease <1 years were more presented in the fair glycemic control group, whereas old onset patients (>6 years) were more presented in the group of poor control. This is similar to Svensson *et al* [20].

Familiar factors

Father education, family history of DM and number of relatives with DM in various degrees of relatedness had no significant statistical association with controlling rate of DM regarding the level of HbA1c, these findings mimic several studies done in different occasions [14].

Mother education had very high significant statistical association by both types of analysis (uni- and multivariate), we found that mothers of higher education had better glycemic control compared with those having lower degrees of education (P value =0.0001). This finding is differ from a study done in Egypt [14], and it might be explained by the role of the mother in Iraq as a 1st caregiver for the child when being sick and explained by the cultural and social role.

Adherence to the treatment regimen:

In the present study, prevalence of fair glycemic control not significantly differ in the insulin regimen than poor controlled(1 basal dose and 3 injections of regular insulin than the other 2 regimens) which in-consisted with Sharplin *et al* and Alemzadeh *et al* , who find good control of patients with type one DM when switch from premixed insulin to glargine-based insulin regimen [9,21].

We found that (among preschool-aged children with type one DM) improved glycemic control with the use of flexible multiple daily insulin therapy with glargine. This result differs from the Svoren study [22], but is consistent with studies that were introduced by the international multicenter study from the Hvidovre Study Group [23]. This might be explained by the introduction of other factors such genetic or environmental, which had a biggest role in the control. Poorer control was seen in those patients who don't regularly change the site of insulin injection (P value=0.002) and those who had lipodystrophy at the site of injection (P value=0.04).

Regarding the regularity of checking in this study, the glycemic control was better in patients with good glucose checking than those with weak glucose checking (P value=0.0001). This finding goes with Haller *et al* study [24]. "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".

Also a significant difference was found between fair and poor glycemic control as regard regularity of endocrine center visiting for follow up. Kaufman *et al* found a "relationship between fewer clinic visits and poorer control in a sample of children followed at diabetes center" [25]. Regarding attending an education program, which was significantly associated with the control status it was comparable with other study [26].

Poor glycemic control was seen in most patients with comorbid conditions (especially those with celiac disease, P value < 0.05). Children with type 1 diabetes and celiac disease report limited availability of gluten-free products at school and restaurants, with dietary arrangements outside of the home reported as the most common issues related to gluten free diet adoption [27].

Poor diet control significantly worse the glycemic control. Wrong nutritional practices may increase the risk of long term diabetic complications [1].

However uni-variant analysis state that diabetes control status affected by multiple factors in this study but multivariate analysis by Logistic regression showed that dietary control, person who are responsible for giving insulin and changing site of injection were significantly associated with control status, that is comparable with other studies [9,21,26].

Limitation:

1-Cannot delineate the cause-effect relationship.

2-Overestimation of the insulin administration actual frequency.

Conclusion:

Poorly control T1DM was higher rate than fairly controlled.

Uni-variant analysis show age, educational status, mother education, attending education programs, technique of given insulin, way of injection, lipodystrophy, and are significantly associated with control status. Person who gave the insulin, regular changing of the site of insulin injection and the dietary control was the main determinant

of the control status that is proved by logistic regression.

Recommendation:

Poor glycemic control associated factors among children with T1DM should be aware by Iraqi's Pediatricians.

Prevention of diabetes control deterioration made by more sophisticated measures that can be implemented to save their life.

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Thi-Qar Medical Journal (TQMJ):Vol.(18),No.(2),2019

Web Site: https://jmed.utq.edu.iq Email:utjmed@utq.edu.iq

ISSN(Print):1992-92 18, ISSN (Online):1992-92 18

العوامل المرتبطة بداء السكري من النوع الأول غير المنضبط لدى الأطفال والمراهقين في ذي قار 2016-2017

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مقطعية على الأطفال والمراهقين المصابين بمرض السكري من النوع الأول أثناء زيارتهم لعيادة السكري في مركز السكري والغدد الصماء المتخصص في الناصرية من 1 يونيو 2016 حتى نهاية مايو 2017. المرضى الذين تم اختيارهم إلى أن يكون الوضع غير المنضبط وفقا لنتائج مستوى HbA1C من خلال لقاء وجها لوجه. تم جمع البيانات

الديموغرافية، والخصائص المتعلقة بالمرض، والتحقق من مستوى السكر في الدم، والتحكم الغذائي، والنوع، والجرعة، ونظام حقن الأنسولين والجوانب الأخرى ذات الصلة، و المقاييس الأنثروبومترية

النتيجة: - تم اختيار مائتين وواحد (201) مريض من مرضى السكري من النوع الأول الذين تم اختيارهم ليكونوا غير خاضعين للرقابة وفقا لفحص HbA1C ٪ 52.2 ، مع متوسط عمر (9.530 ± 3.2526 سنة)، ونسبة الجنسين من الذكور و 47.8٪ من الإناث. وكان معظمهم مع وضع سيطرة ضعيف (71.1٪)، و 28.9٪ فقط كانوا مع وضع السيطرة العادلة. أظهرت الدراسة أن مستوى تعليم الأم، التحكم الغذائي، والمتابعة المنتظمة لنسبة السكر في الدم والمراجعة المنتظمة لمركز السكري، استخدام السرنجة في زرق الانسولين، الشخص الذي يزرق الأنسولين للمريض، وتغيير مكان زرق الأنسولين بشكل منتظم هي العوامل المؤثرة على السيطرة على السكري.

وكان التحكم الغذائي والشخص الذي يعطي الأنسولين وتغيير مكان زرق الأنسولين العوامل المستقلة الرئيسية التي كان لها ارتباط إحصائي كبير حقيقي مع حالة السيطرة في هذه الدراسة.