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ORIGINAL ARTICLE

Influence of the informal primary caretaker on glycemic control among prepubertal pediatric patients with type 1 diabetes mellitus☆

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KEYWORDS
Type 1 diabetes;
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Abstract
Objectives: In prepubertal type 1 diabetic patients (DM1), the availability of an informal primary caregiver (ICP) is critical to making management decisions; in this study, the ICP-related risk factors associated with glycemic control were identified.
Patients, materials, and methods: A comparative cross-sectional study was performed. Fifty-five patients with DM1 under the age of 11 years were included. The patient-related factors associated with glycemic control evaluated were physical activity, DM1 time of evolution, and adherence to medical indications. The ICP-related factors evaluated were education, employment aspects, depressive traits (Beck questionnaire), family functionality (family APGAR), support of another person in patient care, stress (Perceived Stress Scale), and socioeconomic status (Bronfman questionnaire). Multivariate logistic and linear regression analyses were performed.
Results: The patients' median age was 8 years; 29 patients had good glycemic control, and 26 were uncontrolled. The main risk factor associated with glycemic dyscontrol was stress in the ICP (OR 24.8; 95% CI 4.06–151.9, $p = 0.001$). While, according to the linear regression analysis it was found that lower level of education (β 0.991, 95% CI 0.238–1.743, $p = 0.011$) and stress (β 1.918, 95% CI 1.10–2.736, $p = 0.001$) in the ICP, as well as family dysfunction (β 1.256, 95% CI 0.336–2.177, $p = 0.008$) were associated with higher levels of glycated hemoglobin.

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Conclusions: Level of education and stress in the ICP, as well as family dysfunction, are factors that influence the lack of controlled blood glucose levels among prepubertal DM1 patients.

PALAVRAS-CHAVE
Diabetes tipo 1;
Cuidador;
Pediatria

Influência do cuidador familiar principal sobre o controle glicêmico entre pacientes pediátricos pré-púberes com *diabetes mellitus* tipo 1

Resumo
Objetivos: Em pacientes pré-púberes com diabetes tipo 1 (DM1), a disponibilidade de um cuidador familiar principal (CFP) é fundamental para tomar decisões de administração; neste estudo, foram identificados os fatores de risco relacionados a CFPs associados ao controle glicêmico.
Pacientes, materiais e métodos: Foi realizado um estudo transversal comparativo. Foram incluídos 55 pacientes com DM1 menores de 11 anos de idade. Os fatores relacionados aos pacientes associados ao controle glicêmico avaliados foram atividade física, tempo de evolução da DM1 e adesão às indicações médicas. Os fatores relacionados a CFPs avaliados foram escolaridade, aspectos profissionais, traços de depressão (questionário de Beck), funcionalidade familiar (APGAR familiar), ajuda de outra pessoa no cuidado do paciente, estresse (Escala de Estresse Percebido) e situação socioeconômica (questionário de Bronfman). Foram realizadas análises de regressão logística multivariada e de regressão linear.
Resultados: A idade média dos pacientes era de 8 anos; 29 pacientes apresentavam bom controle glicêmico e 26 não tinham controle. O principal fator de risco associado ao descontrole glicêmico foi o estresse no CFP (RC 24,8; IC de 95% 4,06–151,9, p = 0,001). Ao passo que, de acordo com a análise de regressão linear, constatamos que: o menor nível de escolaridade (β 0,991, IC de 95% 0,238–1,743, p = 0,011) e estresse (β 1,918, IC de 95% 1,10–2,736, p = 0,001) do CFP, bem como a disfunção familiar (β 1,256, IC de 95% 0,336-2,177, p = 0,008), foram associados a níveis maiores de hemoglobina glicosilada.
Conclusões: O nível de escolaridade e o estresse do CFP e a disfunção familiar são fatores que influenciam a falta de níveis glicêmicos controlados entre pacientes pré-púberes com DM1.

Introduction

Type 1 diabetes mellitus (DM1) is one of the most common chronic diseases of childhood and adolescence. It is characterized by chronic hyperglycemia and impaired metabolism of carbohydrates, proteins, and lipids. The physiopathology of this type of diabetes is autoimmune destruction of pancreatic β cells accompanied by deficiency of insulin production.[1]

Maintaining the best glycemic control possible, avoiding complications in the short, medium and long term, and allowing adequate psychological and emotional development are the main objectives of treatment of DM1.[2] To reach these objectives, DM1 patients require the use of insulin, control of their diet, and exercise.[3] Usually, these patients are actively involved in their treatment on a daily basis, which includes performing various procedures and analyzing information to make decisions for insulin administration, diet, and physical activity. However, glycemic control may be complicated and challenging, even for those patients with a good understanding of their illness and complications. In pediatric patients with DM1, the participation of an informal primary caregiver (IPC) is needed in the decision-making process because their mental and physical capacity is not optimal, particularly in younger children.[4]

An IPC is a person in the environment of a patient who is voluntarily responsible for the patient without any remuneration. Interventions that IPC must provide when they are caring for children with DM1 include: application and adjustment of the dose of insulin, properly providing the type and amount of food, exercise supervision, monitoring capillary blood glucose, and managing hypoglycemia and hyperglycemia.[5] IPC activities are often very demanding; the more time spent in the care of a diabetic child, the more she/he sacrifices her/his own resources, which can alter her/his health and welfare.[6] The caregiver may experience anger, fear, emotional ambivalence, social isolation, pathological grief, anxiety, or stress.[7–9]

DM1 itself creates a crisis situation, with abrupt changes in lifestyle, both for the patient and his/her family from the time of diagnosis, during treatment and complications.[10] In this context, glycemic control may be affected when there is no appropriate adaptation process, leading to abnormal behavior, such as lack of treatment adherence.[11] In particular, it has been described that when the IPC participates in treatment, her/his own emotional characteristics may affect the maintenance of optimal glycemic control for

children with DM1.[12] It has also been observed that IPCs with reasonable reading and mathematical skills have a positive influence on glycemic control,[13] which also occurs when the whole family participates in the treatment or when there are more people who support the IPC's activities.[14]

In pediatric patients with DM1, information about the impact of the IPC is scarce. Therefore, the aim of this study was to determine whether IPC characteristics may be related to glycemic control.

Patients, materials, and methods

A cross-sectional study was performed. DM1 patients treated in the Pediatric Endocrinology service of the Children's Hospital, XXI Century National Medical Center, Mexican Institute of Social Security (IMSS) were included. All patients were prepubertal and predominantly managed by an IPC. Patients within the period of DM1 remission (''honeymoon period''), those with concomitant uncontrolled chronic illness (such as hypothyroidism, depression, or epilepsy), using steroids, with anemia, or those with a history of hospitalization or more than three infectious events over the past three months were excluded.[3] The following selection criteria were considered for the IPC: adults who could read and write, and who undertook specific activities (food preparation, application of insulin, and blood glucose monitoring) for the care of DM1 patients. Glycemic control was assessed by glycosylated hemoglobin (HbA1C); patients were considered controlled or uncontrolled according to the recommendations of the American Diabetes Association (ADA). Children under 6 years of age were controlled with HbA1C <8.5%, and patients between 6 and 12 years of age with levels <8%.[1,3] IPCs were scheduled for an interview and to complete questionnaires within the first two weeks after taking the blood sample for HbA1C from the DM1 patient.

The following IPC variables related to glycemic control were studied: age, sex, patient relationship, occupation, length of working hours, education, support of another person for patient care, and the presence of anxiety or stress. Socioeconomic status (Bronfman questionnaire)[15] and family functionality were also assessed.

Depression in the IPC was identified through the Beck questionnaire, a self-administered instrument validated for Spanish-speaking adults. Depressed patients were defined as having a score $\geq$10.[16] The Perceived Stress Scale was used to assess self-perceived stress; this scale consists of 14 questions with five options. Scores range from 0 (none or minimal perceived stress) to 56 (maximum perceived stress); values <30 characterized subjects without stress. This scale has also been validated in the Mexican population.[17,18] The Family APGAR questionnaire was used to determine family functionality. It consists of five components: adaptability, cooperation, development, affection, and resolution capacity. A score $\geq$7 defined good family functionality.[19,20]

The study was approved by the hospital Health Research Committee; parents signed an informed consent form, and children older than 8 years signed a letter of assent.

Statistical analysis

Quantitative variables are presented as medians, minimum values (min.), and maximum values (max.); qualitative variables are presented as absolute numbers and percentages. The chi-squared test, Fisher's exact test, and the Mann–Whitney *U* test were used for comparisons between the group with adequate glycemic control and the uncontrolled group. The association of factors associated with uncontrolled blood glucose was determined using odds ratios (OR) and 95% confidence intervals (95% CI). A multivariate logistic and a linear regression model were built to control for confounding variables. All analyses were performed using SPSS (SPSS for Windows, version 15.0, USA).

Results

Sixty-three eligible patients were identified in the Pediatric Endocrinology Service. Eight were excluded, three because the IPC declined to participate, four patients were in remission, and one patient was on steroid therapy for eosinophilic colitis. Thus, a total of 55 patients were included with ages ranging from 2 to 11 years. There were more female patients, with a 2:1 ratio. The time evolution of DM1 ranged from eight months to 11 years nine months. Only eight patients had concomitant diseases (three primary hypothyroidism, three epilepsy, and two depression), which were under control. All of the IPCs were women; 53 (95%) were the patients' mothers. Their age ranged from 21 to 54 years, and most (42%) had studied through high-school or a technical school. With respect to the composition of families, most were nuclear ($n = 43$, 78%) and 20% were single parent. The insulin regimen for all patients was based on multiple injections during the day. No patient used an insulin infusion pump. In addition, the usual frequency of self-monitoring blood glucose was before and two hours after each meal.

Comparison of the characteristics according to glycemic control

Patients were divided in two groups according to glycemic control based on the levels of HbA1C. Twenty-nine patients (53%) comprised the controlled group, and 26 (47%) were in the uncontrolled group. Table 1 compares the characteristics of both the patients and the IPC associated with glycemic dyscontrol. As noted, there were statistically significant differences in some patient-related factors: longer duration of DM1, non-adherence to medical indications, and dietetic transgression. It was also determined the following ICP factors were associated with uncontrolled glycemia: lower educational level, presence of depression, stress, and family dysfunction.

To closely examine the factors that can contribute to the glycemic control in patients with DM1, the ICP characteristics were analyzed in greater depth. The proportion of ICPs without depression or stress (56.1% vs. 21.4%) was higher in the controlled group. Conversely, in the uncontrolled group (53.8% vs. 6.9%) a larger proportion of ICPs had both depression and stress ($p < 0.01$). Furthermore, there was a trend toward longer time of DM1 evolution and increasing numbers of ICPs with depression and stress. Among the ICPs without stress or depression, the median time of evolution was 1.8 years, while among ICPs with stress or depression the median time of evolution was 2.8 years. In the ICPs who scored highly for both stress and depression, the median was 3.5

Table 1 Comparison of factors related to glycemic control of pediatric patients with type 1 diabetes mellitus.

Characteristic	Controlled $n = 29$ n (%)	Uncontrolled $n = 26$ n (%)	p
Glycosylated hemoglobin (%)	7.6 (6.5–8.5)[a]	9.2 (8.6–13)[a]	<0.01
Gender			
Male	19 (65.5)	17 (65.4)	0.67
Female	10 (34.5)	9 (34)	
Patient age (years)	7.6 (2–10)[a]	8.7 (4–11)[a]	0.37
DM time of evolution (years)	1.7 (0.6–9.1)	3.1 (0.7–9.7)	0.008
ICP age (years)	35 (24–47)[a]	34 (21–54)[a]	0.71
ICP educational level			
Primary	3 (10.4)	2 (8)	0.09
High school or technical career	8 (27.6)	15 (58)	
Undergraduate	5 (17.2)	3 (11)	
University education or higher	13 (44.8)	6 (23)	
ICP grouped educational level			
High school/technical school or primary	11 (38)	17 (66)	0.045
ICP employment			
Housewife	18 (62.1)	13 (50)	0.74
Office employee	4 (13.8)	9 (34.6)	
Seller	1 (3.4)	0	
Manager	4 (13.8)	4 (15.4)	
Teacher	2 (6.9)	0	
Depressive traits in ICP	9 (31)	17 (65)	0.013
Stress in ICP	2 (7)	17 (65)	<0.001
Socioeconomic status			
Good	28 (89.1)	23 (88.5)	0.24
Fair	1 (3.4)	3 (11.5)	
Family functionality			
Normal	26 (89.6)	16 (61.5)	0.049
Mild family dysfunction	2 (7)	6 (23.1)	
Severe family dysfunction	1(3.4)	4 (15.4)	
Support of another person in patient care	25 (86.2)	16 (61.5)	0.036
Inadequate physical activity	8 (27.5)	5 (19.2)	0.46
Non-adherence to medical indications	3 (10)	9 (35)	0.03
Dietary transgression	6 (21)	22 (85)	<0.001

ICP, informal primary care.
[a] Median (minimum and maximum values).

years. However, this trend was not statistically significant ($p > 0.05$).

This study also assessed whether the presence of another person to support the care of DM1 patients may influence glycemic control. The proportion of ICPs with stress or depression was lower when there was support from another person compared with those without such support (21.4% vs. 53.1%). Furthermore, the presence of another person involved in patient care was more prevalent among functional families (81.0% vs. 19.0%) than dysfunctional families (53.8% vs. 46.2%). This difference was statistically significant ($p = 0.05$).

Table 2 shows that presence of stress in the ICP (OR 24.85, 95% CI 4.064–151.96) was the main factor associated to uncontrolled blood glucose, according to the logistic regression analysis, in which the factors related to the primary caregiver were included. However, it must be noted that the ICP educational level (primary or high school) did not reach statistical significance even though the OR was 4.34 (95% CI 0.929–20.267).

Interestingly, in the linear regression model (Table 3), taking into account the quantitative value of glycated hemoglobin as outcome measure, it was determined that lower level of education (β 0.991, 95% CI 0.238–1.743, $p = 0.011$) and stress (β 1.918, 95% CI 1.10–2.736, $p = 0.001$) in the ICP, as well as family dysfunction (β 1.256, 95% CI 0.336–2.177, $p = 0.008$) were associated with higher levels of glycated hemoglobin.

Discussion

The metabolic control of diabetes mellitus is associated with the development, progression, and severity of its

Table 2 Multivariate logistic regression analysis of factors associated to uncontrolled glycemic levels in prepubertal patients with type 1 diabetes mellitus.

Factor	OR	95% CI	*p*
Education: primary or high-school	4.34	0.929–20.267	0.062
Lack of support from another person in patient care	0.623	0.0936–4.149	0.625
Family dysfunction	4.86	0.716–33.10	0.106
Depressive traits	0.762	0.716–2.472	0.651
Stress	24.854	4.064–151.96	0.001

complications. In pediatric patients, the comprehensive management of this disease requires the active participation of the patient and his/her family.[21] The physical and emotional health of the ICP and his/her ability to make decisions may influence the care of children with diabetes. To the authors' knowledge, this is the first study reported in the Latin-American population on the role of the ICP in DM1 pediatric patients; similar studies have been reported in populations from the United States or Europe.[22–24]

The results of this study should be considered reliable because different factors were controlled. Only prepubertal patients were included because the ICP has a very important role in that age group, as well as to avoid confusion related to hormonal changes in the various pubertal stages. Glycemic control (according to HbA1c levels) was the main outcome measure because very few of the patients had additional metabolic alterations, as expected in this type of diabetes in prepubertal patients. To determine the effects of the variables directly linked to the ICP, this study included variables known to alter glycemic control.[25]

Each patient included in this study is granted free medical treatment and consultation on diet and exercise, as part of the services offered by the Institution (IMSS). These families, in general, have a socioeconomic status that allows them to follow medical advice. The mothers of patients were the ICP in 95% of the cases studied; it is noteworthy that 42% worked outside of the home, but this condition did not influence the patients' glycemic control. In developed countries, approximately 15% of the ICPs of DM1 patients are the father, not the mother.[24,26] Unlike American or European populations,[10,12,23,26] in the present study, mothers not only stated that their spouses' employment status did not allow them to participate in the care of children with diabetes but also that they believed that care had to be provided exclusively by the mothers.

DM1 is a chronic and currently incurable disease that leads to complications in the medium and long term, requiring the active participation of patients and their families in treatment. All of these aspects affect families, particularly the ICP. Usually, after the first year of diagnosis, most families accept the disease and incorporate it into their daily lives. When this does not happen or family dysfunction is present, the risk of uncontrolled blood glucose is high.[27] Family dysfunction (often accompanied by inequitable distribution of responsibilities among members), the need to make daily decisions for the patient, and lack of adaptation to the disease can cause the ICP to develop stress or depression.[28,29] As demonstrated in the present study, these two conditions are factors associated with uncontrolled patient blood glucose levels. This finding is consistent with previous studies in other populations.[22,23] This observation supports the utility of psychological and educational interventions with patients and their families, in which skills to solve problems – not only those related to the disease itself – and those that can encourage teamwork are promoted.[28]

Additionally, physicians should emphasize that when both parents are involved and trained in DM1 treatment, decision-making that results in the best treatment is increased.[30] Physicians must also investigate the presence of certain psychological factors in the patient or his/her environment that require evaluation by a mental health expert.

It might be expected that ICPs with more years of schooling would have a better understanding of the disease, its complications, and the decision-making process. In this study ICP schooling influenced the levels of HbA1C. Other authors reported that ICPs with low educational levels can achieve good glycemic control in DM1 pediatric patients.[22] It is possible that numerical and reading skills rather than education itself positively influence the glycemic control of the patient.[13] In addition, the disease evolution time may favor glycemic control for two main reasons: the ICPs improve their skills, and patients learn and participate more in their own treatment. However, in the latter situation, the pediatric patient is less supervised, which can lead to lack of adherence to all medical recommendations, including diet and physical activities. Dietary transgression of 21–95% has

Table 3 Linear regression analysis of factors associated to glycated hemoglobin levels in prepubertal patients with type 1 diabetes mellitus.

Factor	β	95% CI	*p*
Education: primary or high-school	0.991	0.238 to 1.743	0.011
Lack of support from another person in patient care	−0.403	−1.331 to 0.524	0.386
Family dysfunction	1.256	0.336 to 2.177	0.008
Depressive traits	−0.078	−0.552 to 0.365	0.725
Stress	1.918	1.10 to 2.736	0.001

been reported for children under 8 years old.[31] These transgressions may occur because most children make decisions independently.

To put the obtained results into perspective, the limitations of this study must be taken into account. One is the design; this was a cross-sectional study, so HbA1C was measured only once, which does not necessarily reflect actual glycemic control, at least in the last year. This, in addition to small sample size, could prevent conclusive determination regarding whether depression in ICPs is associated with glycemic dyscontrol.

In conclusion, this study found that uncontrolled glycemia in prepubertal children with DM1 is associated with factors directly related to the ICP, such as stress and family dysfunction. Therefore, to improve the clinical condition of these patients, it will be necessary to strengthen the role of the ICP in each of the aspects of comprehensive care.

Conflicts of interest

The authors declare no conflicts of interest.

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