

## Original Article

# Health-related quality of life (HRQoL) of children with type 1 diabetes mellitus (T1DM): self and parental perceptions

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The aim of the study was to evaluate health-related quality of life (HRQoL) in children and adolescents with type 1 diabetes mellitus (T1DM) in Greece compared with healthy controls and to identify the effect of age, gender, age of onset of disease, and metabolic control on perceptions of HRQoL. A total of 117 children and adolescents with T1DM aged 5–18, their parents, and 128 matched healthy children and adolescents participated. Children and adolescents completed PedsQL™ 4.0 Generic Core Scales. Children and adolescents with T1DM also completed the PedsQL™ 3.0 Diabetes Module, while their parents completed the proxy-reports of both the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Diabetes Module. The results demonstrated that children and adolescents with T1DM had lower general HRQoL compared with healthy matched children and adolescents. Parents of children and adolescents with diabetes reported that the illness has a greater affect on their children's lives than the children themselves. Finally, the results indicated that later age of onset of diabetes, less hyperglycemic episodes, lower glycosylated hemoglobin (HbA1c), older age, and male gender were associated with better general HRQoL and diabetes-specific HRQoL. The findings have implications for designing effective therapeutic interventions aimed at improving the HRQoL of children and adolescents with T1DM.

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Type 1 diabetes mellitus (T1DM) is one of the most common chronic childhood illnesses, affecting approximately 1 in every 400–600 children and adolescents (1,2). Because T1DM is caused by the failure of pancreatic beta cells to produce insulin (3,4), patients with T1DM have to rely on daily subcutaneous injections of insulin or insulin infusion to meet their metabolic needs (5). Moreover, treatment includes a multifaceted regimen with daily blood glucose monitoring, carbohydrate counting, dietary plan, and physical activity (6).

The intensive treatment of T1DM is essential to prevent or delay potential complications, including impaired cognitive functioning, intellectual deficits,

and neurological impairment (7–10). These may be more severe for children who develop diabetes before the age of 4 or 5 (7,11). Although effective management of the illness is the desired outcome, the complexity of managing T1DM can be overwhelming even for the most competent patient (12), let alone for children who might feel abnormal or different from peers given the need for self-care activities that disrupt their daily lives (13). Despite the fact that both young patients and their parents have to make behavioral adjustments to their daily routines, most studies up to date have focused on the physical aspects of the disease, overlooking the effect on the quality of life (QoL) of patients (14).

Although medical advances have resulted in better management of many lifelong diseases, daily painful and intrusive regimens still exist (15), with implications for health-related quality of life (HRQoL) of patients (13,16,17). Indeed, there is considerable evidence that children and adolescents with T1DM experience poorer HRQoL in comparison to healthy peers (18–21). Although parents perceive their children as having lower HRQoL than children themselves (19), there is some evidence of greater agreement between parents and children about externalizing compared with internalizing functioning (15). HRQoL is higher among male patients with better glycemic control and shorter diabetes duration who were diagnosed at a younger age (22,23). Because the adherence to self-management that ultimately leads to good glycemic control requires good self-preparation to integrate the experience of the chronic disease (24), it is essential to explore the HRQoL of children and adolescents with T1DM.

All of the research described above was conducted in Australia, North America, or UK, and there is a lack of research conducted elsewhere. In Greece, more than 35 000 children and adolescents suffer from diabetes (25). Differences in health care delivery; family relationships and attitudes and an awareness of diabetes mean that this research may have applicability mainly to Greece. It is, however, generally agreed that comprehensive care of diabetes must include attention to child and family HRQoL that has been generally understudied (14,15,26,27), and therefore the aim of this study was to examine the HRQoL of Greek children and adolescents with T1DM. Based on the previous findings, it is expected that: (i) children and adolescents with T1DM would have lower generic HRQoL compared with a matched healthy sample of Greek children and adolescents; (ii) children's and adolescents' self-reported generic and disease-specific HRQoL would be better than parents' proxy-reported generic and disease-specific HRQoL; and (iii) older age, male gender, later age of onset of diabetes, lower glycosylated hemoglobin (HbA1c), less hypoglycemic episodes, and less hyperglycemic episodes would predict higher generic and diabetes-specific HRQoL in children and adolescents with T1DM.

## Methods

### Participants

A total of 117 children and adolescents with T1DM aged 5–18 (53 boys and 64 girls) and one parent of each child participated in the study. All children had been diagnosed with T1DM at least 1 yr previously. Participants were recruited from two sites:

the Pediatric Diabetes Clinic at the University General Hospital of Heraklion and an event organized by the association of parents of children with T1DM in Crete.

In addition, a total of 128 matched healthy children and adolescents aged 5–18 (65 boys and 63 girls) participated as controls. They were recruited from a primary school and a high school from the municipality of Heraklion.

### Measures

Generic HRQoL both of children with T1DM and healthy children was measured using the PedsQL™ (Pediatric Quality of Life Inventory™) 4.0 Generic Core Scales (28), which are standardized into Greek (29). Developmentally appropriate forms (5–18) were used for child self-reports and parent proxy-reports. The questionnaires took approximately 5–10 min to complete. Diabetes-specific HRQoL of children with T1DM was assessed using PedsQL™ 3.0 Diabetes Module (30).

Prior to the completion of the questionnaires, parents were interviewed to obtain demographic information; they gave information about the age of their child, his/her gender, the age of onset of diabetes, and the number of hypo- and hyperglycemic episodes over a period of 1 month. Hypoglycemic episodes occur when blood glucose levels fall below 60 mg/dL and hyperglycemic episodes when blood glucose levels rise above 150 mg/dL – without necessarily accompanying seizures or coma (31,32). It should be noted that these are estimations of the parents that might be more than optimistic. Moreover, HbA1c was DCCT aligned (normal range 4.4–6.3%, mean 5.4%, and interassay SD 0.15%, Tosoh method), with measurements recorded from medical notes on blood tests that were run every 2 months (32). All the participants were following multiple daily injection (MDI) insulin therapy, except from one who followed CSII therapy.

### Procedure

A total of 93 children and adolescents and their parents were approached during their routine clinical visits in the endocrinology wing of the hospital. Their general practitioner (GP) introduced them to the researchers and briefed them about the aim of the study. A total of 88 parents and their children agreed to participate in the study and filled in the corresponding questionnaires.

Another 35 children and their parents were approached during an event, which was organized by the local branch of the Greek Association of Parents of Children with T1DM. Their GP introduced them

again to the researchers and briefed them about the aim of the study. The 29 children and adolescents and their parents who agreed to participate in the study made an appointment to visit the clinic at the hospital and there they had the opportunity to fill in the questionnaires. The non-respondents offered lack of time as an excuse, while they did not seem to have any specific characteristic according to the medical records or demographic data that differentiated from the respondents. All parents and their children gave signed informed consent and then they were administered the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ Diabetes Module, the appropriate forms for their chronological age; for the children aged 5–7, the researchers recorded their answers. Throughout the time they were encouraged to ask any questions about the study.

The sample of children without diabetes was obtained from the school. In order to match the two samples for age, the researchers went to the respective classes in primary school and high school. A gender balance was obtained by randomly choosing boys and girls from each classroom. After obtaining oral consent from the selected children to participate, they were given consent forms for their parents to sign. The researchers returned the following morning to gather the consent forms and give the questionnaires to the children to complete.

MANOVAs were conducted to look at differences in generic HRQoL between children and adolescents with T1DM and healthy controls, and paired-samples t-tests were run to measure differences in generic HRQoL and diabetes-specific HRQoL according to self- and proxy-reports. Finally, regressions were used to explore the effect of age, gender, age of onset of diabetes, hypoglycemic episodes, hyperglycemic episodes, and HbA1c on self-reported generic and diabetes-specific HRQoL.

**Results**

Cronbach reliability for both PedsQL™ 4.0 Generic Core Scale ( $\alpha = 0.87$ ) and PedsQL™ 3.0 Diabetes Module ( $\alpha = 0.81$ ) is very satisfactory. For the PedsQL™ 4.0 Generic Core Scale, the Cronbach is equally high for all the three age groups ( $\alpha = 0.83$  for 5–7 yr old;  $\alpha = 0.88$  for 8–12 yr old; and  $\alpha = 0.84$  for 13–18 yr old). However, for the PedsQL™ 3.0 Diabetes Module, Cronbach is substantially lower (albeit satisfactory) for the younger age group ( $\alpha = 0.81$  for 5–7 yr old;  $\alpha = 0.92$  for 8–12 yr old; and  $\alpha = 0.93$  for 13–18 yr old).

One hundred and twenty-two questionnaires were administered to children with diabetes and their families, and 117 were returned fully completed (response rate 91%). The mean age of onset of

diabetes was 4.8 yr (SD = 2.59, range 1–14). The mean percentage of HbA1c was 8.05% (SD = 1.39, range = 5.5–11.9%). Finally, the mean number of hypoglycemic episodes was 5.82 (SD = 1.08, range = 0–7), and the mean number of hyperglycemic episodes was 5.38 (SD = 2.04, range = 0–7). The mean age of children with diabetes was 10.91 yr (SD = 3.98), and the mean age of children without diabetes was 10.93 yr (SD = 3.77). There were no age ( $t_{(243)} = 0.46, p = 0.96$ ) or gender ( $\chi^2 = 0.74, df = 1, p = 0.44$ ) differences between children with and without diabetes.

Comparison of generic HRQoL between children and adolescents with T1DM and healthy controls

MANOVA showed that children with T1DM reported poorer physical HRQoL ( $F_{(1,243)} = 11.08, p = 0.001$ ), poorer emotional HRQoL ( $F_{(1,243)} = 5.00, p = 0.026$ ), poorer school HRQoL ( $F_{(1,243)} = 7.88, p = 0.005$ ), and poorer total generic HRQoL ( $F_{(1,243)} = 7.02, p = 0.009$ ) in comparison to healthy controls. There was no difference in the level of social HRQoL ( $F_{(1,243)} = 0.314, p = .57$ ) reported by children with and without T1DM.

Generic HRQoL and diabetes-specific HRQoL as reported by children and adolescents with T1DM and their parents

Paired-samples t-test revealed that there was a statistically significant difference between the generic HRQoL of children and adolescents with diabetes as reported by themselves and their parents as shown in Table 1.

Moreover, paired-samples t-test revealed that there was a statistically significant difference between the diabetes-specific HRQoL of children and adolescents as reported by themselves and their parents as shown in Table 2.

Table 1. Means and standard deviations of generic HRQoL reported by children and adolescents with T1DM and their parents

HRQoL	Self-reports, mean (SD)	Proxy-reports, mean (SD)	t
Physical	79.61 (13.85)	75.57 (16.99)	4.05*
Emotional	70.66 (16.17)	61.84 (16.79)	6.99*
Social	81.88 (15.04)	77.58 (17.38)	2.98*
School	72.58 (12.45)	68.98 (15.66)	2.99*
Total	76.63 (10.99)	71.59 (13.03)	6.14*

HRQoL, health-related quality of life; T1DM, type 1 diabetes mellitus. Higher scores indicate better HRQoL. \*p < 0.05.

Table 2. Means and standard deviations of the diabetes-specific HRQoL reported by children and adolescents with T1DM and their parents

HRQoL	Self-reports, mean (SD)	Proxy-reports, mean (SD)	t
Diabetes symptoms	59.91 (13.31)	53.85 (11.97)	6.22*
Treatment barriers	59.56 (19.84)	50.64 (16.95)	6.85*
Treatment adherence	64.79 (15.84)	59.50 (14.92)	5.10*
Worry	61.19 (22.78)	52.80 (21.57)	5.38*
Communication	58.49 (25.76)	52.95 (22.93)	2.66*
Total	61.07 (13.43)	54.59 (12.07)	9.64*

HRQoL, health-related quality of life; T1DM, type 1 diabetes mellitus.

Higher scores indicate better HRQoL.

\*p < 0.05.

Age, gender, age of onset of diabetes, hypoglycemic episodes, hyperglycemic episodes, HbA1c, and generic HRQoL

Generic HRQoL scores were regressed on gender, age of onset, number of hypoglycemic episodes, number of hyperglycemic episodes, and HbA1c. These five predictors accounted for almost a quarter of the variance in generic HRQoL scores ( $R^2 = 0.23$ ). HbA1c ( $\beta = -0.27$ ,  $p = 0.000$ ), the number of hyperglycemic episodes ( $\beta = -0.25$ ,  $p = 0.006$ ), the age of onset of diabetes ( $\beta = 0.20$ ,  $p = 0.040$ ), and gender ( $\beta = -0.20$ ,  $p = 0.021$ ) demonstrated significant effects on the generic HRQoL scores, while age and the number of hypoglycemic episodes were not associated with HRQoL ( $r_{(116)} = 0.12$ ,  $p = 0.109$  and  $r_{(116)} = -0.06$ ,  $p = 0.456$ ), respectively. Intercorrelations between the variables are presented in Table 3.

Age, gender, age of onset of diabetes, hypoglycemic episodes, hyperglycemic episodes, HbA1c, and diabetes-specific HRQoL

Diabetes-specific HRQoL scores were regressed on gender, age of onset, number of hypoglycemic episodes, number of hyperglycemic episodes, and HbA1c. These five predictors accounted for more than one-third of

the variance in diabetes-specific HRQoL scores ( $R^2 = 0.35$ ). HbA1c ( $\beta = -0.33$ ,  $p = 0.000$ ), the number of hyperglycemic episodes ( $\beta = -0.31$ ,  $p = 0.000$ ), age ( $\beta = 0.22$ ,  $p = 0.019$ ), the age of onset of diabetes ( $\beta = 0.21$ ,  $p = 0.020$ ), and gender ( $\beta = -0.16$ ,  $p = 0.040$ ) demonstrated significant effects on the diabetes-specific HRQoL scores, while the number of hypoglycemic episodes was not associated with diabetes-specific HRQoL ( $r_{(116)} = -0.05$ ,  $p = 0.537$ ). Intercorrelations between the variables are presented in Table 4.

### Discussion

Children and adolescents with T1DM in Greece report lower generic HRQoL than healthy controls, as reported by research in other countries (19,20), probably because of the number and complexity of different tasks involved in managing T1DM (12,33). Moreover, children and adolescents with T1DM in Greece reported lower diabetes-specific HRQoL than peers from Holland (17) and USA (34), according to self- and proxy-reports using the same measures; this could be because of the fact that diabetes is treated in Greece mainly with MDI insulin therapy that is known to adversely affect HRQoL (17) and to the mean age of the sample that was higher.

The preoccupation of children and adolescents with T1DM with themes such as long-term complications of their chronic illness and their lack of autonomy may account for their lower emotional HRQoL (35). The school functioning of children and adolescents with T1DM is impaired as well partly because of many absences from school (36), and that poorly controlled diabetes is associated with subtle neuropsychological deficits that may reduce academic achievement (37).

The only unexpected finding of this study is that children and adolescents with T1DM did not report compromised social HRQoL, as was the case in other studies (13,26). This could be because of the cultural differences in the way that the social network supports children and adolescents with T1DM and their families,

Table 3. Means, standard deviations, and intercorrelations among the study variables

Variables	Mean	SD	1	2	3	4	5	6	7
Age	10.91	3.99	1.00						
Gender*	1.54	0.49	-0.04	1.00					
Onset	4.80	2.59	0.46**	-0.04	1.00				
HbA1c	8.06	1.39	0.32**	0.08	-0.03	1.00			
NHyper	5.38	2.04	0.07	0.14	-0.12	0.18**	1.00		
NHypo	5.82	1.09	0.01	0.13	-0.12**	0.01	0.32**	1.00	
GHRQoL	76.63	10.99	0.11	-0.25**	0.28**	-0.30**	-0.32**	-0.06	1.00

HbA1c, glycosylated hemoglobin; HRQoL, health-related quality of life.

\*Boys reported better GHRQoL than girls ( $t_{(115)} = 2.76$ ,  $p = 0.007$ ).

\*\*p < 0.05.

Table 4. Means, standard deviations, and intercorrelations among the study variables

Variables	Mean	SD	1	2	3	4	5	6	7
Age	10.91	3.99	1.00						
Gender*	1.54	0.49	-0.04	1.00					
Onset	4.80	2.59	0.46**	-0.04	1.00				
HbA1c	8.06	1.39	0.32**	0.08	-0.03	1.00			
NHyper	5.38	2.04	0.06	0.14	-0.12	0.18**	1.00		
NHypo	5.82	1.09	0.01	0.13	-0.21**	0.01	0.32**	1.00	
Diabetes HRQoL	61.07	13.43	0.23**	-0.23**	0.35**	-0.33**	-0.38**	-0.05	1.00

HRQoL, health-related quality of life.

\*Boys reported better diabetes HRQoL than girls ( $t_{(115)} = 2.53$ ,  $p = 0.013$ ).

\*\* $p < 0.05$ .

because the vast majority of the participants in this study use MDI insulin that could adversely affect socialization. Moreover, in Greece, the school day is relatively short (a mean of 5 h/d), in comparison with UK (approximately 7 h), which may reduce the need for Greek children to inject insulin during the day, and most children have lunch at home, so they do not 'stand out' if they follow a specific diet.

Because in many cases parents provide information about their children (especially younger children), it is essential to explore the agreement between children's and adolescents' self-reported generic and disease-specific HRQoL and their parents' proxy-reported generic and disease-specific HRQoL. The finding that parents report worse generic and disease-specific HRQoL than their children was consistent with that of other studies (19,27,38,39). This disagreement in self- and parent-proxy reports underlines the importance of collecting information directly from children and not relying solely on proxy informants whenever feasible.

The variables that were used to predict generic and diabetes-specific HRQoL accounted for 23.1 and 35.3% of the variance, respectively. It was found that both generic and diabetes-specific HRQoL could be predicted by gender, age of onset of diabetes, HbA1c, and number of hypoglycemic and hyperglycemic episodes. Analysis revealed that later age of onset of diabetes, lower HbA1c level, fewer hyperglycemic episodes, and male gender in this order predict better generic and disease-specific HRQoL; the number of hypoglycemic episodes was not a predictor. The age of the patient was a predictor only for diabetes-specific, but not for generic, HRQoL – with older children reporting better diabetes-specific HRQoL than younger children. This could be partially explained by the fact that adolescents start to manage their disease more autonomously and subjectively (40). The importance of these predictor variables has been highlighted also in previous studies (23,27), although they all have never been examined in a single study. Early onset and long duration of diabetes have been associated with poorer HRQoL (36) together with poor

metabolic control (13,41) and frequent hyperglycemic episodes (42). Girls have previously been shown to report lower HRQoL, more diabetes-related worries, less satisfaction, and have poorer perceptions of their own health compared with boys (38). Other factors that were not studied at present but might have enhanced the accounted variance are parent-child interactions (43), responsive parenting (44), school experiences (45), and other psychosocial factors (e.g., educational level of the parents).

The main strengths of this study are the recruitment of matched healthy controls and the measurement of both generic and disease-specific HRQoL. The limitations of this study are as follows: (i) all patients were recruited from a single pediatric hospital; thus caution is necessary when generalizing the findings to children and adolescents being managed in other settings; (ii) the study was carried out in the island of Crete, so the findings might not be easily generalized to children and adolescents with T1DM who live in other places in Greece – although there is no such evidence; (iii) because of time and money restrictions, data collection was based on questionnaires and not on qualitative methods (e.g., interviews, observations), which permit the acquisition of more in-depth information. However, it should be pointed out that the Cronbach  $\alpha$  was high for both scales and for all age groups, despite some concerns that were expressed about the ability of young children to provide valid ratings (46–48).

The findings of this study highlight the broad range of areas in which children's and adolescents' lives are adversely affected by T1DM. It is noteworthy that although most patients with T1DM experience psychological problems (49), only a few receive psychological treatment (50). Interventions targeting psychosocial adjustment should be considered as an important part of diabetes management and offered along with interventions designed to improve glycemic control (51) and inform future research.

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