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Health-Related Quality of Life of Youths with Type 1 Diabetes: Reliability and Validity of the Hungarian Version of the PedsQL 3.0 Diabetes Module

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Abstract

Background: In the routine care of diabetes, mostly the clinical parameters are controlled and little attention is paid to the quality of life assessment. A questionnaire must be culturally adapted in the country where it is intended to be used. The aim of the study was to assess health-related quality of life in youths with type 1 diabetes using the PedsQL 3.0 Diabetes Module and to evaluate the psychometric properties in patient and control subjects.

Methods: Diabetes and Generic Module were administered to 355 youths with type 1 diabetes (8-18 y/o) and their parents. Generic Module was completed by 294 age-matched control participants and their parents. Feasibility, internal consistency reliability, reproducibility, convergent, discriminant and concurrent validities were evaluated.

Results: Minimal floor and moderate ceiling effects and hardly any missing item responses proved the feasibility. Cronbach's α was gretaer than 0.70 in all subscales and met the criterion of 0.90 in total-items reliability. Test-retest reliability was demonstrated with Pearson coefficients. We found good agreement between the children's and parents's answers, although parents underestimated their diabetic children in all subscales. The instrument was able to differentiate between the health-related quality of life of optimal, suboptimal and high risk metabolic control. The Diabetes Module subscales and the Generic Module total scale correlated well, except the worry subscale.

Conclusions: Diabetic youths had similar health-related quality of life as their non-diabetic peers. Parents underestimated their diabetic child's quality of life, but this was not the case in the healthy population. Both diabetic and healthy boys had better perception of quality of life than girls. The nationally adapted version of the Pediatric Quality of Life Inventory 3.0 Diabetes Module designed for children and adolescents was reliable and valid instrument for assessing health-related quality of life in youths with type 1 diabetes.

Keywords: Health-related quality of life; Type 1 diabetes mellitus; Children; Adolescents; Psychometric properties

Abbreviations: T1DM: Type 1 Diabetes Mellitus; HRQoL: Health-Related Quality of Life; PedsQL: Pediatric Quality of Life Inventory; DM: Diabetes Module; GCS: Generic Core Scale; CSR: Child Self-Report; PPR: Parent Proxy-Report; y/o: Years Old; HbA1c: Haemoglobin A1c; ICCs: Intra-Class Correlations

Background

Type 1 diabetes mellitus (T1DM) is one of the chronic diseases that are life threatening without proper clinical care and self-management. The incidence of T1DM is on the rise worldwide approximately by 3% per year, and this draws the attention to the seriousness and public health impact of the disease [1]. It is predicted that the number of cases will double within ten years in young children [2]. The health-related quality of life (HRQoL) measurements that focus on the patients' own perception of disease provide additional information for the physicians and health care experts [3]. In the routine visits mostly the clinical parameters are measured, such as the body composition, metabolic control, complications, and hardly any attention is paid to the quality of life assessment. The children's positive attitude towards life can help to maintain the good metabolic control which contributes to the prevention of long-term complications, such as retinopathy, nephropathy and neuropathy. In order to evaluate the HRQoL of paediatric patients with T1DM in a specific country a culturally adapted questionnaire must be used.

The aim of the present study was to assess HRQoL of youths with type 1 diabetes using the validated and nationally adapted Pediatric Quality of Life Inventory 3.0 Diabetes Module and to evaluate the psychometric properties of this instrument in patient and control subjects.

Patients and Methods

Patients and settings

A total of 355 children and adolescents (aged 8-18 years) with T1DM and their primary caregivers (n = 328) took part in this survey including 171 girls (13.16 ± 3.17 y/o) and 184 boys (13.44 ± 3.18 y/o). The participants have had T1DM for more than six months. The mean duration of the diabetes was 5.69 ± 3.44 years in girls and 5.15 ± 2.93 years in boys. The mean glycated haemoglobin value was 8.86 ± 1.41 % in girls and 8.45 ± 1.72 % in boys. The diabetic patients were from diabetes-based summer camps which were supported by foundations; so the participation was made possible for everyone regardless of financial background of the families. There were 294 randomly chosen

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non-diabetic children and adolescents (aged 8-18 years) from primary and secondary schools of different parts of Hungary including 157 girls (13.93 ± 2.63 y/o) and 137 boys (13.87 ± 2.47 y/o) and their parents (n = 294). All the study participants were white/non-Hispanic by ethnicity. The age of the patients and the controls did not differ significantly.

The participants and their parents were informed about the purpose and methods of the study verbally and in writing, as well as about the voluntary nature of the participation in the study. Before completing the questionnaires the parents and youths with age of 18 gave written consent, and the children and adolescents gave their assent.

This research study was approved by the Borsod-Abaúj-Zemplén County Regional Scientific and Research Ethics Committee.

Measures

Pediatric Quality of Life Inventory 4.0 Generic Core Scale: PedsQL 4.0 Generic Core Scales (GCS) were designed to measure the core health dimensions in both healthy and patient populations [4]. The GCS included physical functioning (8 items), emotional functioning (5 items), social functioning (5 items) and school functioning (5 items). The participants rated how much of a problem there has been in the previous month on a five-point Likert-type response scale. (0 = never a problem; 1 = almost never a problem; 2 = sometimes a problem; 3 = often a problem; 4 = almost always a problem.) Items were reverse-scored and linearly transformed to a scale ranging from 0 to 100 (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0). Total scores and subscale scores were computed as the sum of the items divided by the number of items answered. The higher score indicated better quality of life. If more than 50% of the items on the scales were missing, the scale score was not computed [5]. This HRQoL measurement can be used in clinical practice, clinical trials and research and school health settings [6]. The PedsQL™ 4.0 GCS has previously been validated in Hungary [7].

Pediatric Quality of Life Inventory 3.0 Diabetes Module: PedsQL 3.0 DM was developed to measure diabetes-specific HRQoL for youths with T1DM. The original scales were developed through focus groups, cognitive interviews, pretesting and field testing [8]. The multidimensional DM encompassed 5 subscales including Diabetes symptoms (11 items), Treatment barriers (4 items), Treatment adherence (7 items), Worry (3 items) and Communication (3 items). The scoring method is the same as the one of GCS.

Both modules were created as a self-administered instrument. Scales are comprised of parallel child self-report (CSR) and parent proxy-report (PPR) formats. The questionnaires of CSR and PPR are virtually identical, differing in first and third person tense and in the appropriate language for adults. There were no essential differences between the questionnaires designed for children and adolescents; the only difference was the use of terms 'child' for 'teen' [9].

Diabetic participants and their parents completed both the GCS and the DM, the healthy peers and their parents completed only the GCS.

Glycated haemoglobin

The haemoglobin A1c (HbA1c) values were extracted from medical records. HbA1c levels are recorded as a percentage of the total haemoglobin. Currently there is not a scale to determine the clinical severity of T1DM, as our participants had no complications. Therefore, the disease status was determined according to the target indicators of glycemic control recommended by ISPAD: HbA1c values below 7.5% were considered as optimal metabolic control, values between 7.5-9% were considered as suboptimal metabolic control, and values above 9% were defined as high risk metabolic control [10].

Statistical analysis

Data are given as means and standard deviations (SD). SPSS 19.0 statistical analysis software was used for data analyses, and p- values ≤ 0.05 were considered statistically significant. In our study, the psychometric properties of the questionnaires designed for children and adolescents were analyzed jointly. Feasibility was determined from the percentage of missing values for each subscales of the PedsQL 3.0 DM and the floor and ceiling effects for both CSR and PPR versions [11,12]. Internal consistency reliability was characterized by Cronbach's coefficient alpha using total-items and inter-subscales methods [13]. Reliability coefficient of 0.70 or higher is considered acceptable between groups and 0.90 or higher are acceptable for interpreting individual scores [14,15]. Reproducibility was measured with test-retest reliability using the Pearson correlation coefficient between total scales and subscales. The construct-related evidence was assessed using convergent and discriminant validities. The convergent validity was determined through correlation coefficients between CSR and PPR. The Pearson correlation coefficient effect sizes are designated as small (0.10-0.29), medium (0.30-0.49), and large (≥ 0.50) [16]. Intra-class correlations (ICCs) were also computed, designated as ≤ 0.40 poor to fair agreement, 0.41–0.60 moderate agreement, 0.61- 0.80 good agreement, and 0.81-1.00 excellent agreement [17,18]. The discriminant validity was evaluated through the metabolic control and the DM total scores, whether HbA_{1c} was related to HRQoL of the patients. We used one-way ANOVA and LSD post-hoc multiple comparisons. In order to establish concurrent validity we selected the PedsQL GCS, that measure different aspect of the HRQoL and we tested if scores on the subscales of the DM would correlate with the total scores of the GCS. Inter correlation was expected to demonstrate moderate to large effect sizes [19]. In order to compare the diabetes and the healthy control groups as well as the different age groups of the diabetes patients we used t-test and one-way ANOVA.

Linguistic validation

The linguistic validation of the 3.0 DM was carried out according to the linguistic validation guidelines of PedsQL and in close ongoing collaboration with the Mapi Research Institute's translation team [20,21]. The linguistic validation process consisted of 3 phases: forward translation, backward translation and patient testing. The last work phase was the cognitive interviewing using the PedsQL Cognitive Interviewing Methodology℠ (Clauzoni, S. personal communication, Mapi Research Institute, Lyon, France, September 2, 2010). The goal of the cognitive interviewing was to understand the thought processes and to pass this knowledge on to the author who can construct, create and ask better questions. We used the think-aloud interviewing technique [22]. The patients and their parents were interviewed separately during the outpatient visits. The interview took 45-60 minutes per participant. Item 20 ('It is hard for me to wear id bracelet.') had to be adjusted to the Hungarian custom, since the Hungarian diabetic youth used diabetes identity cards instead of id bracelets. The reports of the linguistic validation and the cognitive interviews were sent to the translation team for approval. The Hungarian version of the PedsQL DM is compatible and took 5-10 minutes to complete, just like the original version. The Mapi Research institute accepted the Hungarian version and gave the approval for the psychometric evaluation of the Hungarian PedsQL 3.0 DM.

Results

Feasibility of the PedsQL 3.0 Diabetes Module

For the PedsQL 3.0 DM, the percentage of missing item responses as a whole was 1.10% for CSR and 0.61% for PPR, respectively. The scale range was 0.00-4.23% in CSR and 0.35-1.16% in PPR. There were minimal floor effects in both versions (ranged 1.07-3.10% in CSR and 1.13-3.70% in PPR). However, moderate ceiling effects existed; the largest effects were for Treatment adherence (56.46% in CSR and 55.49% in PPR) and for Communication (48.17% in CSR and 46.50% in PPR). Table 1 displays the descriptive statistics of the mean subscales scores for CSR and PPR versions as well as the floor-ceiling effects and missing data in percentage. (Table 1).

Internal consistency reliability

The total-items and subscales reliability is demonstrated in Table 2. Cronbach's alpha coefficients for the subscales of the DM ranged from 0.698 to 0.795 in CSR and from 0.747 to 0.848 in PPR. Subscales scores on the module exceeded the 0.70 standard. The Cronbach's alpha in total-items reliability approached the criterion of 0.90 recommended for analyzing individual patient scores (0.904 in CSR and 0.892 in PPR) (Table 2).

Reproducibility

To examine test-retest reliability, a random sample of 29 respondents (16 girls, aged 14.33 ± 2.66 y/o and 13 boys, aged 14.01 ± 3.33 y/o) and their parents were selected. The participants completed the questionnaires 3-4 weeks apart. The health condition of the children was clinically similar in the second administration. Test-retest reliability was assessed through Pearson correlation coefficient between the total scores and between the subscales scores. The Pearson correlation coefficient ranged between 0.586-0.840 in CSR subscales, and 0.432-0.822 in PPR subscales. The correlations between the total scores were 0.877 in CSR and 0.834 in PPR. The lowest correlation (0.432) was found in the Communication subscale in PPR.

Convergent validity

Concordance between CSR and PPR is demonstrated in Table 3. The effect size was large in all subscales of the DM; the Pearson correlation coefficients were between 0.617 and 0.764 in all subscales and 0.807 between the total scores ($p \leq 0.001$). The ICCs were between 0.763 and 0.865 in the subscales and 0.893 in the total items (Table 3).

Discriminant validity

To assess whether the measure could differentiate between patients with varying degrees of disease severity, patients were categorized into 3 groups according to the HbA_{1c} values as having optimal (< 7.5%) (n = 70), suboptimal (7.5-9%) (n = 166) and high risk metabolic control (>10%) (n = 119). Using one-way ANOVA we found significant differences among three sizes of HRQL, $F(2, 352) = 3.099$, $p = 0.046$ in CSR and $F(2, 325) = 3.080$, $p = 0.047$ in PPR. LSD post-hoc multiple comparisons of the three groups indicate that the group of optimal metabolic control (M = 74.73, 95% CI [72.09, 77.37]) in CSR and (M = 72.31, 95% CI [69.54, 75.07]) in PPR gave significantly higher HRQoL scores than the group of suboptimal metabolic control (M = 70.73, 95% CI [68.77, 72.69]); $p = 0.027$ in CSR and (M = 68.03, 95% CI [66.09, 69.98]); $p = 0.018$ in PPR; and the group of high risk metabolic control (M = 70.33, 95% CI [67.92, 72.74]); $p = 0.021$ in CSR and (M = 68.31, 95% CI [66.13, 70.48]); $p = 0.034$ in PPR, respectively.

Concurrent validity

The concurrent validity was examined through an analysis of the intercorrelation between the PedsQL GCS total scores and the PedsQL 3.0 DM subscales scores. Intercorrelations ranged from 0.463 to 0.593 in CSR and from 0.440 to 0.692 in PPR with medium to large effect size range. The smallest intercorrelations were observed between the GCS and Worry subscale both in CSR and PPR. The intercorrelation between GCS and DM total scores were 0.689 in CSR and 0.762 in PPR.

HRQoL of children and adolescents with type 1 diabetes measured with the PedsQL 3.0 Diabetes Module

When we compared the HRQoL of diabetic boys and girls with the PedsQL DM, we observed that boys had significantly better quality of life than girls (boys (n = 184): 72.77 ± 12.95 vs. girls (n = 171): 69.89 ± 12.31; $p = 0.033$). This was confirmed by the parents' answers (boys (n = 170): 70.82 ± 11.24 vs. girls (n = 158) 66.86 ± 12.16; $p = 0.002$). The parents significantly underestimated their children's HRQoL globally (CSR: 72.08 ± 12.35 vs. PPR: 68.91 ± 11.84; $p = 0.000$) and in all subscales except of Communication subscale (Diabetes symptoms: CSR: 64.57 ± 13.27 vs. PPR: 62.60 ± 12.30; $p = 0.000$, Treatment barriers: CSR: 70.27 ± 19.81 vs. PPR 65.47 ± 20.03; $p = 0.000$, Treatment adherence: CSR: 83.58 ± 13.32 vs. PPR: 80.10 ± 14.17; $p = 0.000$, Worry: CSR 69.87 ± 20.43 vs. PPR: 62.91 ± 21.30; $p = 0.000$, Communication: CSR:78.30 ± 22.17 vs. PPR: 76.93 ± 22.39; $p = 0.123$). Analyzing the subscale scores of the DM we found that patients with T1DM had no problem with the treatment adherence and communication, but they had low scores in the diabetes symptoms, treatment barriers and the worry subscales. Similar pattern was found in the PPR (Figure 1).

Diabetic and control groups

Comparing the diabetic and the non-diabetic groups by gender on the basis of PedsQL GCS we found no statistically significant differenc-

Total score and subscale scores of the 3.0 DM mean ± SD	Mean score		Floor effect (%)		Ceiling effect (%)		Missing data (%)	
	CSR	PPR	CSR	PPR	CSR	PPR	CSR	PPR
Total score	71.38 ± 12.71	68.91 ± 11.84	1.91	2.08	37.0	36.10	1.10	0.61
Diabetes symptoms	63.77 ± 13.56	62.45 ± 12.57	1.74	1.82	23.62	22.91	0.47	0.35
Treatment barriers	69.51 ± 19.94	65.33 ± 20.12	3.10	3.70	34.48	33.98	0.00	0.53
Treatment adherence	82.53 ± 14.46	79.90 ± 14.58	1.07	1.13	56.46	55.49	1.56	1.16
Worry	69.17 ± 20.50	62.78 ± 21.36	2.77	3.17	32.83	31.70	0.67	0.47
Communication	77.36 ± 22.43	76.77 ± 22.53	2.10	2.03	48.17	46.50	4.23	0.57

Table 1: Subscales descriptive statistics, floor and ceiling effects, missing data of the child self-report (n = 355) and parent proxy-report (n = 328) in the PedsQL Diabetes Module.

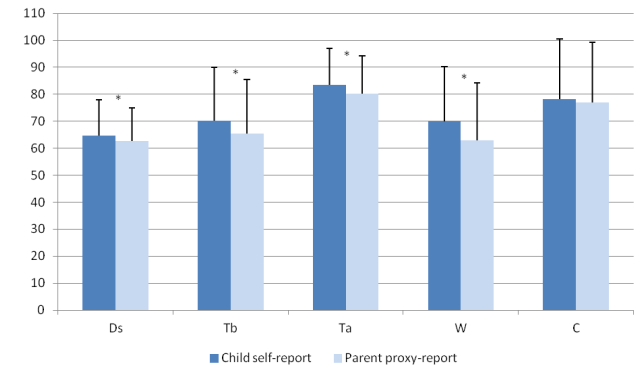
N = 355	items	Cronbach's α	Cronbach's α
3.0 DM	CSR/PPR	CSR	PPR
Total-items	28	0.904	0.892
Diabetes symptoms	11	0.775	0.767
Treatment barriers	4	0.707	0.763
Treatment adherence	7	0.742	0.747
Worry	3	0.698	0.769
Communication	3	0.795	0.848

Table 2: Subscales and total-items internal consistency reliability for PedsQL 3.0 Diabetes Module in child self-report (CSR) and parent proxy-report (PPR).

PedsQL 3.0 DM	Pearson correlation coefficients	ICCs
Total scores/total items	0.807*	0.893*
Diabetes symptoms	0.757*	0.860*
Treatment barriers	0.725*	0.841*
Treatment adherence	0.764*	0.865*
Worry	0.617*	0.763*
Communication	0.740*	0.851*

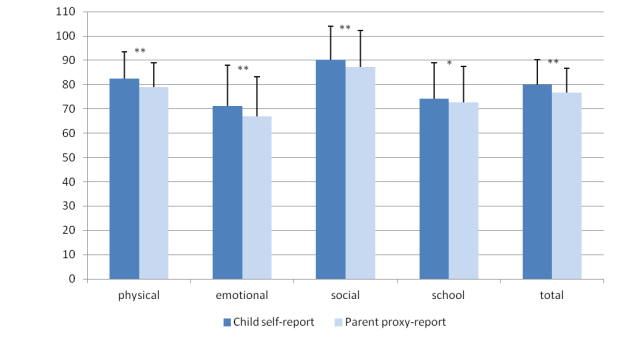
p ≤ 0.001 (2-tailed)

Table 3: Intercorrelations between the child self-report and parent proxy-report in PedsQL 3.0 Diabetes Module with Pearson correlation coefficients and intra-class correlations



*Child self-report vs. parent proxy-report in Ds = Diabetes symptoms; Tb = Treatment barriers; Ta = Treatment adherence; W=Worry subscales; p ≤ 0.001
C = Communications

Figure 1: Diabetic children and their parents' concordance on the basis of the Diabetes Module subscales (N = 328; mean with SD line).



*Child self-report vs. parent proxy-report in school functioning subscale; p ≤ 0.01
**Child self-report vs. parent proxy-report in physical, emotional, social functioning and total score; p ≤ 0.001

Figure 2: Diabetic children and their parents' concordance on the basis of the PedsQL Generic Core Scale subscale scores and total score (N = 328; mean with SD line).

es in quality of life neither in CSR nor PPR, except for the Physical functioning in boys by the PPR. The parents rated the physical functioning significantly better for control boys than diabetic boys (p = 0.005) (Table 4). The children and the parents' concordance showed similarity in healthy groups. The parents of the diabetic group significantly underestimated their children' HRQoL in all subscales of the GCS (Figure 2).

Discussions

Developing a new HRQoL instrument is time consuming and expensive, therefore researchers prefer to use a previously validated instrument [23]. However an instrument must be culturally adapted in the country where it is intended to be used [24]. The PedsQL 3.0 DM designed for children and adolescents has been translated into Hungarian and accepted by the Mapi Research Institute. We fulfilled the requirements of the validation process for both CSR and PPR. Based on the results of the psychometric evaluation, it was confirmed that the Hungarian versions of the PedsQL 3.0 DM are generally comparably feasible, reliable and valid. There were hardly any unanswered items on the DM. Both patients and parents were able to complete the questionnaires and provide sufficient data regarding the child's HRQoL. The instrument has excellent internal consistency reliability. We demonstrated the test-retest reliability of the questionnaires. We found great agreement between the children's and the parents' answers. The PedsQL 3.0 DM was able to differentiate between HRQoL of optimal, suboptimal and high risk metabolic control in the young patients. This result is underpinned by the answers of the parents. Good metabolic control is important primarily to avoid complications; furthermore, favourable metabolic control may be associated with good perception of HRQoL [25,26]. The diabetic participants and their parents completed the PedsQL GCS and the DM on the same occasion, beginning with the GCS. The DM subscales and the GCS total scale correlated well, except for the Worry subscale, both in CSR and PPR. The intercorrelations were from medium to large effect size that confirmed the concurrent validity of the instrument. The worry about the short- and long-term complications and the worry about the treatment efficacy are special characteristics of the diabetes disease, which explains why this subscale does not match the generic total score.

Both our diabetic and non-diabetic female groups denoted significantly poorer HRQoL perception than males. Multiple studies have shown these gender differences not only in healthy population [27,28], but in chronic diseases as well [29-31] including diabetes [32,33]. These differences are rather due to perception of health than the actual health status as there were no differences in clinical parameters in our patients. These should be taken into consideration in analyses of the HRQoL in healthy and chronically ill population. We found that parents underestimated their diabetic children's HRQoL. This parental underestimation is known from the literature [32-34] and our survey confirms these findings on the basis of both DM and GCS. We did not find this underestimation in the healthy youths. It raises the assumption that the parents may overprotect their diabetic children.

The diabetic patients cope with the treatment adherence very well, but the presence of the diabetes symptoms and the worry about the short-term and long-term consequences of the disease have negative impact on their quality of life. When we compared the HRQoL of the diabetic youths with the GCS we found great similarity to their healthy peers. Physical and psychosocial factors could not show differences between the diabetic and healthy youths, indicating that patients live similar lives, as their non-diabetic peers. This may be due to the appropriate care of diabetes including proper continuous patient and parent education. Laffel et al. and Emmanouilidou et al. using the PedsQL GCS also found remarkably similar quality of life to a nondiabetic youth population in their researches [35,36].

	Girls				Boys			
	CSR		PPR		CSR		PPR	
	diabetic n = 171	control n = 157	diabetic n = 158	control n = 157	diabetic n = 184	control n = 137	diabetic n = 170	control n =1 37
Physical	81.05 ± 70.74	80.06 ± 12.45	78.05 ± 10.35	77.66 ± 13.98	84.20 ± 10.80	84.63 ± 12.82	79.56* ± 10.10	83.55 ± 13.92
Emotional	66.87 ± 10.74	66.11 ± 14.92	64.68 ± 16.24	67.51 ± 13.70	74.02 ± 16.73	73.72 ± 16.90	69.09 ± 16.23	71.72 ± 15.55
Social	88.83 ± 15.60	86.18 ± 14.32	86.35 ± 16.00	86.78 ± 13.62	90.04 ± 12.84	87.49 ± 13.65	88.06 ± 14.17	87.41 ± 15.85
School	72.66 ± 15.33	70.82 ± 15.17	73.48 ± 13.72	73.22 ± 15.35	74.12 ± 14.51	73.67 ± 14.23	71.91 ± 15.68	71.82 ± 15.65
Total	77.89 ± 10.23	76.35 ± 10.17	75.93 ± 10.10	76.45 ± 10.58	81.07 ± 10.02	80.51 ± 11.39	77.49 ± 9.96	79.27 ± 11.92

* Diabetic boys vs. control boys in physical functioning by PPR; $p \leq 0.01$

Table 4: PedsQL Generic Score Scales in diabetic and the comparison groups in child self-report (CSR) and parent proxy-report (PPR) by gender (mean ± SD).

The main strength of this study is that we have measured the psychometric properties of the PedsQL 3.0 DM with a wide range of the validation methods and statistical analyses. We had appropriate sample size representing the whole country. The potential limitation is that we have examined the questionnaires designed for children and adolescents, but did not measure the psychometric properties of the questionnaires for toddlers (aged 2-4) and young children (aged 5-7). These imperfections may limit the possibility to generalize the results.

In conclusion, HRQoL is similar in diabetic and non-diabetic children and adolescents; however, optimal glycemic control is associated with better quality of life in diabetic youths. Both diabetic and healthy boys have better HRQoL than girls. Parents underestimate HRQoL of their diabetic children, but this is not the case in the healthy population. The nationally adapted versions of PedsQL™ 3.0 DM designed for children and adolescents are reliable and valid instrument for assessing HRQoL of children and adolescents with type 1 diabetes.

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