Reliability and validity of the Arabic version of the PedsQL[™] 4.0 generic ore scales and PedsQL[™] 3.0 diabetes module

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ABSTRACT

Background: Health related guality of life (HRQOL) has become a field of extensive research involving children and adolescents with diabetes. There are no HRQOL instruments designed or adapted for the Arabic culture and language. The objectives of the study are to test the Arabic translated version of the PedsQL[™] 4.0 Generic Core Scales (GCS) and the PedsQL[™] 3.0 Diabetes Module (DM) in children and adolescents with type 1 diabetes (T1DM) in Kuwait and analyse their psychometric properties. Methods: After the process of translation, committee review and pre-testing (linguistic validation), 131 children and adolescents with and 104 without T1DM, with their parents completed the Arabic version of GCS. Those with T1DM completed the Arabic DM. Demographic and diabetes-related data were collected using specially designed guestionnaires. Internal consistency was checked by Cronbach's alpha coefficient. The intraclass correlations coefficient, celling and floor effects and construct validity were assessed to determine the psychometric properties of both instruments. Results: Cronbach's alpha of the child self-report and parent proxy-report was greater than 0.70, for both instruments, indicating internal consistency reliability. Items of both instruments had minimal missing responses, and required a brief time (5 - 7 minutes) to finish indicating their feasibility. No floor effect was demonstrated. Ceiling effect ranged from 5.8% to 15.8%. The GCS distinguished between healthy and diabetic children. The intraclass correlation coefficient (ICC) between child self-report and parent proxy-report of GCS scores showed good to excellent agreement, p < 0.001. However, in the DM reports, the correlation was lower, but still significant. Girls reported lower HRQOL scores in worries and communication subscales of the diabetes module than boys, p < 0.05. Conclusions: The Arabic version of the PedsQL GCS and PedsQL DM showed sufficient feasibility, reliability and validity to be used for research purposes in public health setting for children 2 -18 years old and their parents.

Keywords: Children; Quality of Life; Children and Adolescents; PedsQL[™] Generic Core Score; PedsQL[™] Diabetes Module; Type 1 Diabetes

1. INTRODUCTION

Type 1 diabetes mellitus (T1DM) is one of the most common chronic diseases in children and adolescents. Living with the requirements related to glycemic control, insulin therapy, diet plan and physical activity may have a significant impact on the psychological functioning of not only the patients but their families as well [1]. Health-related quality of life (HRQOL) has been progressively acknowledged as an essential outcome measure in clinical trials and health service research and evaluation [2]. It is now well established, that enhancing HRQOL in children with diabetes is as important as metabolic control and prevention of long term complications [3].

A number of instruments have been developed for use to assess HRQOL in children. However, most of these measures were developed in adults, with modified versions for children [4]. The diabetes quality of life for youth (DQOLY) developed by Ingersoll *et al.* [5] is adapted from the adult version of the QOL measure used in the Diabetes Control and Complications Trial. It provides information about diabetes-specific QOL in ado-

lescents but does not capture the children's HROOL with respect to the normal social, emotional and physiccal development to compare with healthy youth, and cannot be applied for children younger than 11 years. The PedsQLTM inventory instruments, developed by Varni et al. [6], include generic and disease-specific instruments. The PedsQLTM Generic Core Scales (GCS) distinguish between healthy children and those with acute or chronic diseases. The PedsQLTM 3.0 Diabetes Module (DM) measures disease specific HRQOL in children 2 -18 years of age with T1DM. Both the GCS and the DM measures have child self-reports and parent proxy reports. Literature search did not identify any diabetes-specific instrument constructed or adopted for the Arab culture and language that can be used to evaluate HRQOL in children with diabetes.

The objectives of the present study are to adapt the Arabic version of the PedsQL GCS and the PedsQL DM to children and adolescents with T1DM and to determine the feasibility, reliability and validity of the child self-report and the parent proxy-report. We hypothesized that both instruments will demonstrate satisfactory psychometric properties in the Arabic form and would differentiate between healthy childrenand those with T1DM.

2. SUBJECTS AND METHOD

2.1. Participants

Participants were 112 children aged 5 - 18 years and 131 parents/caregivers of children aged 2 - 18 years diagnosed with T1DM. They were recruited from the 6government hospitals in the country. One hundred and forty families were approached, and 93.6% agreed to participate.

The control group consisted of 104 healthy children attending clinics for their vaccines, standard check up for a sport activity or accompanying their siblings during their clinic visits.

2.2. Demographic and Diabetes Related Information Form

The demographic form contains the information on age, gender, school performance based on grade point average obtained from school report, and information required to calculate the SES [7]. The diabetes related information included age at disease diagnosis, duration of diabetes, mode of treatment and mean HbA1c over the last year.

2.3. HRQOL Measures

The PedsQL 4.0 GCS consist of four scales divided in 23 items assessing the level of physical and psychosocial functioning of children. Physical functioning consists of

8 items. Psychosocial functioning is divided into three subscales; emotional, social and school functioning, each consisting of 5 items [4]. The items for the self-report and proxy-report are essentially identical, differing in developmentally appropriate language, and first or third person tense. There are 7 forms available: child-reports for the ages 5 - 7, 8 - 12 and 13 - 18, and parent proxyreports for the ages 2 - 4, 5 - 7, 8 - 12 and 13 - 18. The instructions ask for the degree of a problem each item had been during the previous month. A five point Likert response scale is used (0 = never a problem, 4 = almostalways a problem). Items are reversed-scored and linearly transformed to a 0 - 100 scale, with higher scores indicating better HROOL. Scale scores are computed as the sum of items divided by the number of items answered (accounting for missing data).

The PedsQL 3.0 DM is the only multidimensional diabetes-specific instrument that would assess the broad age range of 2 - 18 years with both child and parent proxy-reports [6]. It encompassed five scales: 1) diabetes symptoms (11 items); 2) treatment barriers (4 items); 3) treatment adherence (7 items); 4) worry (3 items) and 5) communication (3 items). The format instructions and scoring methods are identical to the GCS.

Both instruments in their original American version showed good psychometric properties. The linguistic validation and psychometric properties of both instruments in many other languages are well documented [3, 8-12].

2.4. Procedure

Permission to translate the GCS and DM was obtained from the developer of the original English version, Dr James Varni, though Mapi Institute. The linguistic translation followed the recommended guidelines [13]. The PedsQL 3.0 DM was translated into Arabic by a clinical psychologist and a diabetes educator, both fluent in English. A single version was produced after discussion between the two translators. The first reconciled forward translation was then back-translated to the original US English by two Kuwaiti English teachers, who had no contact with the original instrument. The pre-test was conducted on 37 children and adolescents with T1DM and their parents using the cognitive interviewing technique to identify and correct errors during translation. All the results of the phases were reported to the instrument author in Mapi Research Institute.

The PedsQL 4.0 GCS had already been translated into Arabic by another team, but not validated. However, in order to use this version for the purpose of the study, a pilot study of the translated form, received from Mapi Institute, was taken on 37 children with T1DM, and 25 healthy controls. Cognitive interviewing technique was used in a similar method as for the PedsQL DM, after which the final version was produced.

The instruments were applied at the diabetes outpatient clinics in the hospitals. Children and their parents responded to the questions of the instrument while waiting for their medical assessment. The questionnaire was self-administered. Children and their parents responded to the questions separately. Trained research assistants were available to read the questions for illiterate parents, and some children in the 5 - 7 age-group.

2.5. Statistical Analysis

The feasibility of the Arabic version of the PedsQLTM GCS and the PedsQLTM DM was determined based on the percentage of missing responses for each item. Scale internal consistency reliability was assessed by measurement of Cronbach's alpha coefficient, values equal or greater than 0.70 were considered satisfactory [12].

Agreement between child self-report and parent proxyreport was determined by using intraclass correlations coefficient (ICC). Values ≤ 0.4 are considered as poor to fair agreement, 0.41 - 0.6 moderate agreement, 0.61 - 0.8 good agreement and 0.81 - 1 excellent agreement.

Ceiling and floor effects were based on the percentage of scores at the extremes of the scaling range. Floor or ceiling effects are considered to be present if more than 15% of respondents achieve the lowest or highest possible scores, respectively [14]. Effect of size was calculated to determine the magnitude of the differences. Effect sizes for differences in means are designated as small (0.2 - 0.49), medium (0.5 - 0.79) and large (≥ 0.8) in magnitude. Construct validity was tested performing the known-groups method, which compares scale scores across groups known to differ in the health construct being assessed. We hypothesized that healthy children and adolescents will report higher scores than those with T1DM.

All statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS) version 13.0. A level of significance of 0.5 was adopted.

The study was approved by the joined ethical committee of Kuwait University and Ministry of Health. Children and their parents were informed about the study, and gave signed consent and assent.

3. RESULTS

3.1. Sample Characteristics

Demographic characteristics of the diabetic and control groups are presented in **Table 1**. There was no significant difference between the groups. Of the respondents, 11 (8.4%) of the diabetics and 10 (9.6%) of the controls were from the low SES, 91 (69.5%), 68 (65.4%) were from the middle class, and 29 (22%), 26 (25%) were from the high class. Mean age, age at diabetes onset and duration of diabetes were 8.2 ± 4.1 , 5.6 ± 3.1 and 8.7 ± 3.6 years respectively.Mean value for HbA1c was 8.0% + 1.1% (normal = 4.5 - 6). There was no statistically significant difference in HbA1c between the different age groups (p > 0.05) and between the genders (p > 0.05). Respondents of parent proxy-reports consisted of mothers (n = 97.74\%), fathers (n = 20, 15.3\%) and grandparents (n = 14, 10.7\%).

3.2. Feasibility

The questionnaires took approximately 5 (for GCS), and 7 (DM) minutes to be completed. For parent selfreport, 9.1% of item responses were missing. All were in the 2-4 year-age group in the school functioning scale, because many of them did not go to school yet. The percentage of missing items for children self-reports was 1.1% on the GCS and 1.5% on the DM.

3.3. Internal Consistency Reliability

Internal consistency reliability coefficients are presented in **Table 2**. The Cronbach's α value exceeded the minimum reliability standard of 0.70 for most domains in

Table 1. The	characteristics	of the	diabetic and	control	groups.

	Diabetic group n (%)	Control group n (%)
Gender		
Female	57 (53.5)	49 (47.1)
Male	74 (56.5)	55 (52.9)
Age group (year)		
2 - 4	12 (11.5)	11 (10.6)
5 - 7	29 (22.1)	25 (24)
8 - 12	39 (29.8)	33 (31.7)
13 - 18	48 (36.6)	35 (33.7)
Insulin regimen		
2 injections	19 (14.5)	
3 - 4 injections	98 (74.8)	
Insulin pumps	14 (10.7)	
Age at diabetes onset (years, mean \pm SD)	5.7 ± 3.6	
Duration of diabetes (months, mean \pm SD)	8.7 ± 3.6	
HbA1c (mean \pm SD)	8.0 ± 1.1	

	Diabetic Children Healthy Children								
Scale	α	$Mean \pm SD$	% Floor	% Ceiling	$Mean \pm SD$	% Floor	% Ceiling		
Child Self-Report									
Total Score	0.85	82.5 ± 12.4	0.0	0.0 1.2		0.0	8.3		
Physical Health	0.79	80.2 ± 11.2	0.0	1.5	80.8 ± 15.1	0.0	7.8		
Emotional Function	0.81	70.8 ± 12.7	0.0	0.9	$82.7 \pm 12.9^{*}$	0.0	10.4		
Social Function	0.74	89.9 ± 10.7	0.0	2.4	$80.9\pm10.7^*$	0.0	5.8		
School Function	0.79	85.3 ± 14.7	0.0	4.2	87.6 ± 14.8	0.0	8.3		
Psychosocial Health	0.79	80.3 ± 12.2	0.0	3.7	$86.6 \pm 14.1^{*}$	0.0	9.6		
Parent Proxy-Report									
Total Score	0.82	81.1 ± 10.4	0.0	0.0 2.9		0.0	15.8		
Physical Health	0.76	86.4 ± 11.7	0.0	3.8	88.2 ± 13.1	0.0	9.6		
Emotional Health	0.80	65.5 ± 9.8	0.0	4.3	$89.6\pm10.4^*$	0.0	7.9		
Social Function	0.84	83.2 ± 11.4	0.0 7.4		79.3 ± 11.8	0.0	11.6		
School Function	0.79	89.5 ± 15.9	0.0	10.6	90.1 ± 16.2	0.0	8.9		
Psychosocial Health	0.82	76.2 ± 13.2	0.0	0.0 5.3		0.0	9.9		

Table 2. Scale descriptive and internal consistency reliability for PedsQL 4.0 GCS parent proxy-report and child self-report.

*p < 0.001 (independent sample testing); Higher values indicate better QOL.

the PedsQL GCS and DM module except for "worry" in parents report and "treatment adherence" in children self-report in the DM module.

3.4. Range of Measurement

Table 2 presents the percentages of scores on the PedsQL GCS for healthy children and children with T1DM. There were no floor effects for both groups, with all scales demonstrating 0.0% of respondents scoring at the minimum. Ceiling effects were minimal ranging from 0.9% of diabetic children respondents for the emotional function to 15.8% of parents of healthy respondents for the total score. The ceiling effects showed the expected trend, where healthy children reporting more ceiling effects than children with T1DM. Children with diabetes reported lower scores in the emotional and psychosocial domains, higher in the social domain and had similar scores in the physical and school function domains. The mean total scale scores (self and parent-proxy reports) were 86.2 and 91.9 for healthy children, 82.5 and 81.1 for children with diabetes.

Table 3 demonstrates mean, standard deviation of item scores of the diabetes module for children with T1DM. Again, there was no floor effect in all domains, and the ceiling effects were minimal. Mean total score was 78.3 and 76.2 for the self and parent-proxy report respectively.

3.5. Construct Validity

Table 4 demonstrates the differences between healthy

 Table 3. Scale descriptives and internal consistency reliability for PedsQL Diabetes Module parent proxy-report and child-self report.

6 J	Diabetic Children							
Scale	α	$Mean \pm SD$	% Floor	% Ceiling				
Child Self-Report								
Total Score	0.82	78.3 ± 11.4	0.0	1.8				
Diabetes Symptoms	0.81	81.4 ± 11.9	0.0	5.2				
Treatment Barriers	0.83	73.9 ± 10.4	0.0	5.9				
Treatment Adherence	0.66	68.7 ± 13.1	0.0	2.9				
Worry	0.77	80.8 ± 12.2	0.0	4.2				
Communication	0.82	86.4 ± 9.9	0.0	7.7				
Parent Proxy-Report								
Total Score	0.81	76.2 ± 13.3	0.0	10.2				
Diabetes Symptoms	0.81	70.4 ± 12.4	0.0	6.1				
Treatment Barriers	0.79	69.4 ± 11.7	0.0	4.9				
Treatment Adherence	0.77	63.7 ± 10.5	0.0	8.0				
Worry	0.67	62.4 ± 13.4	0.0	4.9				
Communication	0.72	71.5 ± 12.2	0.0	4.7				

Higher values indicate better QOL.

children and children with T1DM. Most effect sizes were in the small to medium effect size range. The intercorrelations between the DM module and the Generic Core scales total score are shown in **Table 5**.

	Children w	ith Healthy	D.66		Children with Diabetes	
Scale —	Mean \pm SD	$Mean \pm SD$	— Difference	Effect Size		
Child Self-Report						
Total Score	82.5 ± 12.4	86.2 ± 13.4	3.7	0.18	-11.32*	
Physical Function	80.2 ± 11.2	80.8 ± 15.1	0.6	0.02	-0.14	
Emotional Function	70.8 ± 12.7	82.7 ± 12.9	11.9	0.6	-6.31*	
Social Function	89.9 ± 10.7	80.9 ± 10.7	9	0.44	-5.11*	
School Function	85.3 ± 14.7	87.6 ± 14.8	2.3	0.11	-0.98	
Psychological Health	80.3 ± 12.2	86.6 ± 14.1	6.3 0		-3.33*	
Parent Proxy-Report						
Total Score	81.1 ± 10.4	87.5 ± 10.6	6.4	0.31	-3.51*	
Physical Function	86.4 ± 11.7	88.2 ± 13.1	1.8	0.12	-1.3	
Emotional Function	65.5 ± 9.8	89.6 ± 10.4	24.1	1.19	-9.34*	
Social Function	83.2 ± 11.4	79.3 ± 11.8	3.9	0.19	-2.41*	
School Function	89.5 ± 15.9	90.1 ± 16.2	0.6	0.02	-0.19	
Psychological Health	76.2 ± 13.2	89.3 ± 12.2	13.2	0.7	-6.92^{*}	

Table 4. Comparison of HRQOL between children with diabetes and healthy controls: Effect size.

Effect sizes designated as small (0.2 - 0.49), medium (0.5 - 0.79) and large (> 0.8); $p^* < 0.01$

	Tot G	Ph	Em	Soc	Sch	Psy	Tot D	DM Sy	Tx B	Tx Ad	Wo	Com
Effect size correlations	0.66 ^c	0.82 ^c	0.57 ^b	0.69 ^a	0.67 ^a	0.45 ^b	0.47 ^b	0.61 ^b	0.89°	0.21	0.19	0.69 ^c
ICC	0.81	0.78	0.76	0.82	0.79	0.67	0.51	0.69	0.71	0.41	0.31	0.59

ICC Intraclass correlation coefficient; Tot G: Total Score GCS; Ph: Physical health; Em: Emotional health; Sco: Social function; Sch: School function; Psy: Psychosocial health; Tot DM: Total score DM; DM sy: Diabetes symptoms; Tx B: Treatment barriers; Tx Ad: Treatment adherence; Wo: Worry; Com: Communication ${}^{a}p < 0.05$, ${}^{b}p < 0.01$, ${}^{c}p < 0.001$.

3.6. Self-Report/Proxy Report Concordance

The parent/child concordance intercorrelation matrix is shown in **Table 5**. Most intercorrelations of subclasses between child self-report and parent proxy were in medium to large effect size range. The result of paired sample t tests for the total sample showed that there was no significant difference between the subscale scores of selfreports and those of proxy-reports. The values of the ICCs ranged from in poor-fair and good agreement. The total scores of self-reports were higher than those of proxy-reports, both for the GCS and DM module

No difference was found in GCS report of the diabetic group among different age and gender groups (p > 0.05). In the DM report, different age groups differ only in the "treatment barrier", where the adolescents group (13 - 18 years) reported worse HRQOL than the other younger groups. Boys and girls did not demonstrate any difference in the diabetes subscale except for "communication" and "worries" subscales, where girls reported worse scores (p < 0.05).

4. DISCUSSION

Over the past few years, the assessment of HRQOL has become essential in many chronic diseases, leading to the development of various instruments. However, most of these instruments were in English [15]. No specific measure adapted to the Arabic culture and language for the evaluation of HRQOL is available. The adaptation and validation of the PedsQL DM and GCS followed the recommended guidelines [13,16]. The results indicate that both instruments are reliable in Arab children with T1DM in Kuwait. The results support the feasibility, reliability and validity of the child self-report and the parent proxy-report of both instruments.

There were minimal missing item responses, indicating good acceptability of children and their parents to PedsQL DM and PedsQL GCS. Children and adolescents with diabetes in Kuwait, reported similar HRQOL scores to those in Greece [3], USA [6], and the Netherlands [17] and higher HRQOL scores than the Iranian children [10] using the PedsQLTM 4.0 GCS and the PedsQLTM 3.0 DM.

The PedsQL GCS child and parent proxy report internal consistency reliabilities generally exceeded the minimum recommended coefficient standard of 0.70 for group comparisons. Therefore, the total scores of both reports were reliable for comparative studies. In the PedsQL DM, total score exceeded the required standard of 0.70, both in the child and proxy reports. Treatment adherence in the both reports and treatment barriers and worries subscale in the proxy-reports were less than 0.70. This was in consistence with the Greek version of the instruments [3], where the treatment barriers and treatment adherence subscales were in the 0.60 range. This level was comparable to its original version [18] as well as to other translated versions [11.12.19]. The Cronbach's internal consistency coefficient is a conservative estimate of actual reliability, and thus the Arabic version of the PedQL DM and GCS were considered reliable instruments to assess the quality of life of children and youth with type 1 diabetes, and to conduct comparative studies with non-diabetic children. However, scales that did not achieve the 0.70 standard should be used for descriptive analyses only. The Arabic version of both instruments demonstrated internal reliability coefficient α similar to that of the original Americanversion [6], Iranian [10] and the Norwegian [11], and better than that shown in the Greek version [3].

There were no floor effects and only minimal ceiling effect was indicated in most of the subscales. This was consistent with previous studies [12,20,21], and it is expected for population of healthy children and adolescents. The PedsQL 4.0 GCS distinguished between children with diabetes and healthy controls, with most effect sizes in the large range except the social functioning subscale in the child sell-report.

Construct validity of the Arabic version of both instruments were analysed by assessing the intraclass correlation between subscales of the GCS and DM scales. The results of subscales of both instruments correlated with their total scores. This supports the validity of the Arabic version of PedsQL 3.0 DM and PedsQL 4.0 GCS for conducting HRQOL research in Arabic children.

Children responses correlated with parent responses positively and correlation coefficients were medium to large. Although parents showed high level of agreement with their children in total and majority of subscales, concordance was less for emotional and psychosocial function, and worries subscale. This is consistent with current research [3,22]. It reflects parent anxiety for children's illness and underestimating their adjustment with diabetes, and other chronic diseases [22].

The main strengths of the current study include the high enrolment rate (>93%) and being conducted in all government hospitals with pediatric and adolescents diabetes clinics. This would make the sample representa-

tive of the study base population. The illiteracy of some parents was overcome by the availability of research assistant to assist in reading the question without further explanation. Furthermore, the age distribution was broad and included acceptable numbers in each age-group. The PedsQL was able to differentiate HRQOL between healthy and diabetic children.

5. CONCLUSION

Overall, this study showed that the Arabic version of the PedsQL GCS and PedsQL DM are understandable and feasible for use in Kuwait. Both instruments showed good psychometric properties, and they can be used to evaluate pediatric health outcomes in research and community setting. Having a HRQOL instrument with high validity and reliability is important to study the impact of diabetes on children and their parents. The assessment of quality of life must be part of the routine care of these children and has to be done at least annually. The high HRQOL in children with diabetes in Kuwait may reflect the standard of medical care for children with T1DM in the country, and the strength of the family unit, where grandparents and other family members may help in providing the support for the children to cope with the demands and the frustrations associated with the diagnosis of diabetes.

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