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Validation of the Arabic and Tunisian Arabic version of the KINDL questionnaires for children with diabetes type 1

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ABSTRACT

Aim: We aimed to validate the Arabic and Tunisian Arabic versions of diabetes-specific quality of life (QOL) instrument KINDL-R Diabetes Module for Tunisian children population with type 1 diabetes.

Patients and methods: This a cross-sectional study to validate Arabic and Tunisian KINDL QOL instrument that we translate in literary and dialectal Arabic. Both forward and backward translations from the German version of KINDL QOL into Arabic version were performed. Our project received a GPED grant in August 2014. After the face validity of the Arabic version was established, it was then pilot-tested. Finally, the validity and reliability of the final version of the Arabic KINDL questionnaire were evaluated.

Results: The KINDL-R Diabetes Module (DM) questionnaire of QOL was given to 212 persons : 108 children (aged 3–17 years) with T1DM and 104 parents. The Cronbach's alpha coefficients of the overall items and the main domains was about 0.7.

The mean total score of the KINDL-R DM was $69,56 \pm 14,01$ in children aged 7–13 years, $59,93 \pm 15,17$ in children aged 13–17 years and $56,6 \pm 9,9$ in parents (higher scores indicate better QOL). The parents reported lower diabetes-specific HRQOL than the children themselves ($p < 0,01$). Emotional score was correlated to environment ($p = 0,03$). Self-esteem was reported to environment ($p = 0,02$) and mother's instruction level's ($p = 0,014$).

Conclusions: The KINDL-R Diabetes Module (DM) of QOL in literary and dialectal Arabic have sufficient acceptability, reliability and validity so as to be used for the purposes of a comparative in Tunisian and Arabic populations.

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KEYWORDS

Quality of life; Type 1 diabetes; children; validation; questionnaire

1. Introduction

Health-related quality of life (HRQOL) is a multidimensional concept including well-being in terms of patient's physical, emotional, mental, and social behaviors and is defined as the way the effects of a disease and/or its treatment are perceived by the patient [1]. Assessment of HRQOL in clinical practice is important in order to evaluate the course of the disease, early detection of problems, and to determine what type of therapy would be adequate to maintain acceptable metabolic control with less impact on HRQOL in each patient [1]. HRQOL has increasingly been acknowledged as an essential health outcome measure in pediatric medicine [2]. The development and use of pediatric HRQOL measures are important for identifying at-risk children and applying early intervention programs [3].

Type 1 diabetes mellitus (T1DM) is one of the most common chronic childhood illnesses, affecting approximately 1 in every 400–600 children and adolescents [4]. It affects all aspects of patient's life, especially psychologically. Its management is complex,

requiring a high degree of responsibility and self-control to achieve an adequate metabolic control. Key aspects to succeed are the support of a multidisciplinary team, education in disease management with decision-making capacity, the possibilities offered by new technologies and the emotional sphere of the patient and family [5].

In fact, treatment guidelines recommend routine screening for emotional status and family relationships, mainly during puberty characterized by hormonal and psychosocial changes [6].

Until recently, all HRQOL research in patients with diabetes had been conducted mostly in North America, Australia and the UK [7]. No study from the Maghreb region has been reported. Since there is a great difference in the health care delivery system, religion, culture and family dynamics in different societies, there is a need to do HRQOL studies in different communities [2].

The aim of our study is to assess reliability and accomplish a limited validation of the diabetes-specific quality of life (QOL) instrument KINDL-R Diabetes

Module (DM) to the population of Tunisian and Arabic diabetic children. In addition, a second purpose was to understand the relationship between the QOL in youths with type 1 diabetes and its associated clinical and sociodemographic factors.

2. Methods

2.1. Participants and instruments

The study has received the approval of the Ethical Committee on 1 October 2014.

One hundred and eight children and adolescents, aged 3–17, diagnosed with type 1 diabetes for at least 6 months and their parents referring to our diabetes Center's, in Children's Hospital Bechir Hamza of Tunisia, pediatric emergency department and external consultation, were enrolled in the study, between January and June 2016.

All the parents and children aged more than 6 years have given their informed consent. For children under 6 years, we only had their parents' informed consent.

Exclusion criteria were less than 6 months from diagnosis of T1DM, cognitive problems that prevented comprehension of the questionnaires, and patients who declined to participate in the study. After agreeing to participate in the study, parents and child filled in the KINDL-R Diabetes Module (DM) questionnaire of QOL.

We used a questionnaire that was originally designed in German (originally developed by Bullinger et al. (1994) revised by Ravens-Sieberer & Bullinger [8], for use in clinical populations but also with healthy children and adolescents. Three versions of the KINDL-R DM questionnaire are available as self-report measures for different age groups: KIDDL KINDL (3–6 years) ($n = 19$), KID KINDL (7–13 years) ($n = 62$) and KIDDO KINDL (13–17 years). In addition, the questionnaire is available in two proxy versions for parents (3–6-year-olds and 7–17-year-olds). The KINDL-R Diabetes Module (DM) of QOL consisted of 24 items divided into six subscales including physical well-being, emotional well-being, self-esteem, family, friends and everyday functioning (school or nursery school/kindergarten). The questionnaires took approximately 15 min to be completed. Likert response scale with four categories was used, ranging from never a problem (0) to usually a problem (4). All the subscales can be combined to produce a total score (0–100 score). Higher scores represented better QOL. One of the authors was responsible for completing the questionnaire for children by face-to-face interview and she was available to clarify the possible questions of the parents about the instrument.

We obtained permission to translate the KINDL-R Diabetes Module (DM) of QOL in literary and dialectal

Arabic. The goal of this double translation was to expand the population to investigate. As a matter of fact, literal Arabic is learn at school and is accessible for parents and children who have been to school; Tunisian Arabic is the language spoken in Tunisia (and easy to understand for Libyan, Algerian and Moroccan people), it's thus more adapted for illiterate parents and young children.

Translation was performed by the Tunisian National Translation Center and was approved by a third translator and 2 pediatricians.

The Arabic version was back translated to German by another translator and the team of the KINDL questionnaires send us a file comparing German original to German back translation with one of four remarks: no differences in wording/slight changes in wording but no difference in meaning/ bigger changes in wording, maybe difference in meaning/ grave changes in wording and meaning. We changed sentences with bigger and grave changes. The final accepted version was used and is available on the site www.kindl.org (language versions: Arabic and Tunisian Arabic).

A pre-test was administrated to a sample of patients and their parents to verify that the items are understandable.

2.2. Statistical analysis

The reliability of the QOL subscales was tested using the Cronbach's alpha coefficient. An internal consistency of 0.70 was set for measures used to detect differences between groups and greater than 0.90 for interpreting individual scores. Construct validity was examined through an analysis of the intercorrelations among KINDL-R Total score and KINDL-R scale scores. Concurrent validity was assessed by calculating the intercorrelations between children's and parents' responds. The exploratory factor analysis with Varimax rotation was used to determine the construct validity of the KINDL-R. Convergent and discriminant validity was checked using Spearman correlation. The value of a correlation coefficient of greater than 0.40 between an item and its own scale is regarded as an adequate evidence of convergent validity.

Statistical analysis was performed with SPSS 12.0 for Windows. In order to assess any relationship between diabetes related QOL and sociodemographic factors, body mass index, metabolic control (HbA1c), type of family, age at onset and duration of diabetes, type of insulin regimen and educational level of the parents, the Pearson correlation coefficient was used. Unpaired *t*-tests were used for comparisons between the scores. One-way ANOVA was used for comparisons between different age groups. For all analyses, a value of $p \leq 0.05$ was considered to provide statistical significance.

3. Results

Patient demographic and diabetes-specific data are presented in Tables 1 and 2. The average age of participants was 11.02 years; 50% were girls; 4.8% came from single parent families, and 29.8% of parents had university degree.

The mean time of disease progression was 4.4 years, with 30.77% ($n = 32$) longstanding (> 5 years), and 18.26% less than 1 year. The mean annual HbA1c level was 9.15% ($SD \pm 2.07$); 26.53% of patients had good metabolic control ($HbA1c < 7\%$); 92 (85.18%) were taking 2 injections of insulin per day, 16 (14.81%) 3–4 injections, and no patient used an insulin pump. Although HbA1c values tended to increase, as children grew older we could not find a statistically significant difference between the different age's groups and between the genders ($p \leq 0.01$).

Cronbach's alpha coefficient for all subscales and total scores of both patient and parent reports of the Arabic and dialectal versions of KINDL-R DM approached or exceeded the reliability standard of 0.70, which is considered satisfactory. It was equally high for all age groups and subscales (0.69–0.77). Patient and parent

reports had an adequate level of concordance, with coefficient values of at least 0.684 (Table 3). In Table 4, underlined values represent correlations between child and parent proxy reports. Parents showed adequate level of concordance with their children and most of the correlation coefficients reached or exceeded 0.50. All of the above are statistically significant using Pearson correlation coefficient ($p < 0.01$).

No significant correlation was found between the total or all subscales score of the diabetic children and gender, BMI, HbA1c, type of family, age at onset and duration of diabetes, insulin therapy and residence. Figures 1 and 2 display the mean and range of item scores of the child and parent proxy Arabic KINDL-R DM. 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 5.

We did not find any differences in HRQOL reports among different age and gender groups. Table 6 demonstrates the comparison between HRQOL reports of male and female based on the KINDL-R DM responds. HRQOL total and all subscales scores were regressed on gender, age, number of hypoglycemic episodes, envir-

Table 1. Demographic characteristics of the participants.

Variable		N	Mean	Standard deviation	Minimum	Maximum
Weight (SD)	Male	54	[+ 1,M]	13.54	18	70.1
	Female	54	+ 1	14.69	17	72.2
Height (SD)	Male	54	[M,-1]	24.09	90	179
	Female	54	-1	22.01	88	167
IMC (kg/m ²)	Male	54	97%	8.52	15.96	24.23
	Female	54	> 97%	7.74	15.01	25.3
AGE (n)	3–6 years	19	4.82	0.68	4.40	6.70
	7–13years	62	11.2	1.12	7.00	13.90
	14–17 years	27	14.7	1.33	14.00	17.80
Incomes		104	816.92	691.32	100.00	4500.00
Uniparental families		5	–	–	–	–
Mother's age		108	43.81	4.382	24.00	56.00
Father's age		108	46.74	6.61	32.00	60.00
Mother's education	No education	4	–	–	–	–
	Primary	40	–	–	–	–
	Secondary	50	–	–	–	–
	University	14	–	–	–	–
Father's education	No education	10	–	–	–	–
	Primary	35	–	–	–	–
	Secondary	46	–	–	–	–
	University	17	–	–	–	–

Table 2. Clinical characteristics of the participants.

Characteristics	N	Mean	Standard deviation	Minimum	Maximum
Last HBA1C	108	8.37	9.48	7.08	13.00
Annual HBA1C	102	9.15	2.07	6.00	17.00
Duration of diabetes (years)	104	4.4	5.74	0.1	13.00
Hypoglycemia/ months	98	8.74	1.57	6.00	13.00
Convulsion/years	106	2.38	3.37	0	3.00
Ketoacidosis	No	72	–	–	–
	Yes	36	–	–	–
Insulin injection/day	2	92	–	–	–
	3	2	–	–	–
	4	9	–	–	–
	5	5	–	–	–
	5	5	–	–	–

Table 3. Cronbach's α coefficients values for KINDL-R diabetes module scales: parent proxy-report and child self-report.

Variables	Correlation with total	
	Correlation with total	Alpha
Physical	0.331150	0.736057
Emotional	0.542495	0.695491
Self-esteem	0.547057	0.694577
Family	0.550736	0.693838
Friends	0.185177	0.762089
School	0.286129	0.744255
Disease	0.215705	0.756775
Total_subscale_score	0.918512	0.684336

Table 4. Individual correlations between the total scores and the subscales of the KINDL-R DM.

	Correlation's coefficient of Pearson, Prob > r under H0: Rho = 0							Total_subscale_score
	Physical	Emotional	Self_esteem	Family	Friends	School	Disease	
physical	1.00000	0.26279	0.26732	0.32513	-0.04295	0.22871	-0.04225	0.44337
emotional	0.26279	1.00000	0.36592	0.35307	0.16461	0.17236	0.32138	0.61841
self_esteem	0.0526	0.0526	1.00000	0.0082	0.2298	0.2083	0.0167	≤ .0001
family	0.26732	0.36592	0.0060	1.00000	0.37146	0.11764	0.15559	0.71211
friends	0.0485	0.0060	0.0052	0.0052	1.00000	-0.03448	0.3924	≤ .0001
school	0.32513	0.35307	0.37146	0.0022	0.8027	0.40438	0.28589	0.58338
disease	0.0154	0.0082	0.0052	-0.03448	1.00000	-0.11970	0.0344	≤ .0001
Total_subscale_score	-0.04295	0.16461	0.28528	0.8027	1.00000	-0.11970	-0.03185	0.61105
	0.7556	0.2298	0.0348	0.8027	0.3841	0.3841	0.8174	≤ .0001
	0.22871	0.17236	0.11764	0.40438	-0.11970	1.00000	0.08261	0.37211
	0.0930	0.2083	0.3924	0.0022	0.3841	0.08261	0.5488	0.0052
	-0.04225	0.32138	0.15559	0.28589	-0.03185	0.08261	1.00000	0.19146
	0.7594	0.0167	0.2567	0.0344	0.8174	0.5488	0.19146	0.01614
	0.44337	0.61841	0.71211	0.58338	0.61105	0.37211	0.19146	1.00000
	0.0007	≤ .0001	≤ .0001	≤ .0001	≤ .0001	0.0052	0.1614	

Underlined values represent correlations between patient report and parent proxy report. All correlations are significant ($P \leq 0.01$, by two-tailed Pearson's correlation).

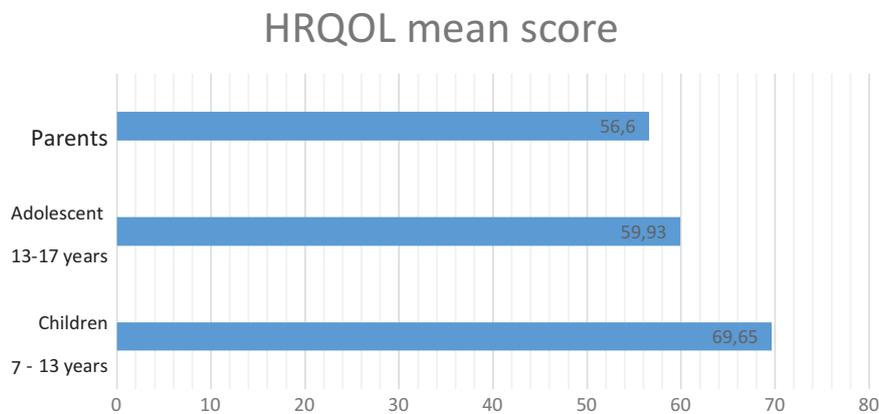


Figure 1. HRQOL mean score.

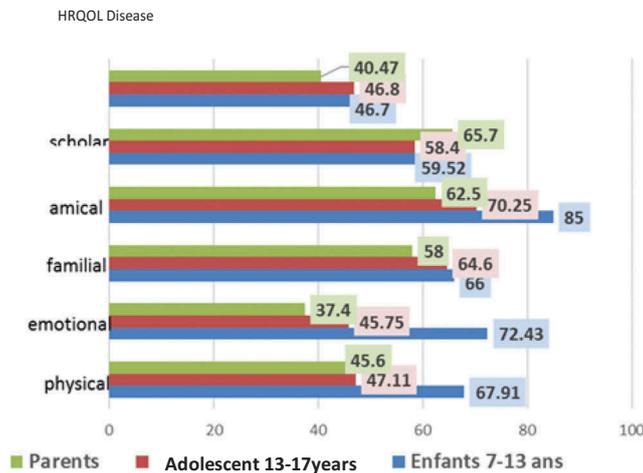


Figure 2. The mean of item scores of the child and parent.

onment, parent's instruction level's, socio-economic condition and HbA1c (Table 7). Emotional score was correlated to environment ($p = 0.03$). Physical score was related to father's instruction level's ($p = 0.04$). Self-esteem was reported to environment ($p = 0.02$) and mother's instruction level's ($p = 0.014$). Gender, large BMI, poor metabolic control, school level and

intensity of treatment did not influence QOL of children with diabetes (Tables 6 and 7).

4. Discussion

There has been an increasing need among clinicians for disease specific QOL scales in recent years [9]. While

with diabetes and for the conduction of a comparative study with non-diabetic youths in Northern Africa and Arab countries. However, it should be noted that the relatively small sample sizes possibly precluded better reliability estimates for this instrument. To additionally extend reliability and validation estimates, the KINDL-R DM could be tested with different types of methods such as test-retest [10].

In comparison with Greek [11,12], American [13], Dutch [14] and Iranian [15] children, Tunisian children with type 1 diabetes reported lower HRQOL total and all subscales scores, according to self- and proxy-reports using the KINDL-R DM questionnaire. It may be attributed to different cultures and languages. In fact, Ethnic disparities are important in determining the prevalence, care, treatment outcomes and QOL of diabetics as shown by many international studies including the San Antonio Heart Study (SAHS) [16].

The parents in our study reported that their children had lower diabetes-specific HRQOL than the children themselves. The discrepancy between patient and parent reports is consistent with previous findings [2,17,18]. It is possible that this result reflects that the parents have identified themselves with the child's diabetes. In addition to this, this may indicate the burden of diabetes on the parent, which could affect family communication and lead to parental over involvement [10]. Also, parents may be more likely to take into consideration that their child might be restricted by their diabetes.

In terms of age differences, present study showed that adolescents (between 13–17 years), reported the lower diabetes-specific HRQOL than younger children. These findings have been reported in earlier studies [19]. This may indicate an enhanced experience of being different from their peers, because these children are living with a chronic disease. This result might also reveal that a chronic disease management might interfere and complicate the process of separation and development towards maturity.

According to the present study, analysis revealed that urban environment predict better total and emotional score mainly children's self-esteem. In addition, socioeconomic condition such as parent's level instruction was predictive factor of better physical score and self-esteem. In fact, other studies had already linked a worse HRQOL in children with specific characteristics such as those from families with disadvantaged socioeconomic status [19,20]. The results of the present study reinforce this finding and the importance of knowing the social situation of the patient.

Evidence shows that better HRQOL is associated with better metabolic control although this relationship is modest, in many studies [5,21]. In our study, it is not possible to establish the directionality of

association between HRQOL and HbA1c. Also, gender, large BMI, poor metabolic control, school level and intensity of treatment was not predictor of HRQOL of children with diabetes.

This study has a number of potential limitations, which may minimally affect the power of its results. First, it had not included a control group similar in age and gender distribution to the study group, in order to compare them to diabetic children. Further Tunisian studies are required in the generic HRQOL-field comparing children and adolescents with T1DM and healthy children, or among children in different clinical groups concerning their chronic conditions.

Second, 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.

A larger study is also needed to further investigate the possible correlations between the predictive factors of HRQOL in diabetic children.

5. Conclusions

In conclusion, this study showed that the literary and dialectal Arabic version of the KINDL-R DM of QOL have sufficient acceptability, reliability and validity so as to be used for the purposes of a comparative in Tunisian and Arabic populations. Moreover, lower HRQOL in Tunisian children with diabetes indicates that youth with diabetes in Tunisia require intensive programs to increase their HRQOL, and more supportive resources should be allocated. In fact, we recommend that assessment of HRQOL after diagnosis of T1DM should be a routine practice in patients with diabetes to facilitate communication, identify early problems and implement early intervention.

WHAT IS ALREADY KNOWN ON THIS TOPIC

An increasing need among clinicians for disease specific QoL scales.

Many researches have suggested that patients with diabetes have reduced HRQoL compared to the general population

Among these numerous generic and specific questionnaires validated for the teenagers diabetics, the best in the use are the KINDL-R and the PedsQL.

While information about HRQoL is extremely important to the clinical practice of all clinicians, a diabetes-related QoL instrument was not available in Arabic and Tunisian Arabic.

WHAT THIS STUDY ADDS:

A validated Arabic version of KINDL-R diabetes module to estimate the quality of life of the young diabetics from the Maghreb and Arabic-speaking population generally.

First evaluation of Young Diabetic Tunisian quality of life

Disclosure statement

No potential conflict of interest was reported by the authors.

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Compliance with Ethical Standards

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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