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Original article

The Spanish Version of the Health-Related Quality of Life Questionnaire for Children and Adolescents With Heart Disease (PedsQL™)

Teresa González-Gil,[a] Alberto Mendoza-Soto,[b] Fernando Alonso-Lloret,[c] Rosalía Castro-Murga,[d] Clotilde Pose-Becerra,[e] and M. Concepción Martín-Arribas[f,*]

[a] Departamento de Enfermería, Obstetricia y Ginecología, Pediatría y Psiquiatría, Universidad Rey Juan Carlos, Madrid, Spain
[b] Servicio de Cardiología Infantil, Hospital-Materno Infantil 12 de Octubre, Madrid, Spain
[c] Unidad de Cuidados Intensivos Pediátricos, Hospital-Materno Infantil 12 de Octubre, Madrid, Spain
[d] Servicio de Cardiología Pediátrica, Hospital Materno-Infantil 12 de Octubre, Madrid, Spain
[e] Departamento de Enfermería, Área Materno-Infantil, Hospital Materno-Infantil 12 de Octubre, Madrid, Spain
[f] Subdirección de Terapia Celular y Medicina Regenerativa, Instituto de Salud Carlos III, Madrid, Spain

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ABSTRACT

Introduction and objectives: To adapt the Pediatric Quality of Life Inventory (PedsQL™) (General Module and Cardiac Module, 3.0 version) into Spanish.
Methods: Forward and back translation methodology. Cognitive interviewing was used to check the pre-test version. Psychometric properties were computed for the PedsQL™ Cardiac Module Scales. Cross-informant variance between children and parents was assessed.
Results: The Spanish version has some format changes to make it easier to read and to clarify response choices (version for 5-7 years age group). Some semantically complex terms were replaced with synonyms and others illustrated with examples. Some "out of context" problems were identified with respect to some items (version for children 2-4 and 5-7 years). The percentage of missing item responses ranged from 0% to 5.9%. A high ceiling effect was found, especially in the Cardiac Module, which ranged from 19% to 48.6%. Internal consistency was higher than 0.7, except for Physical Appearance Scale and School Functioning in children. Agreement between information given by children and parents was generally very high. A decreasing trend in scores on all scales was observed in relation to the severity of heart disease, but the differences were only statistically significant in some dimensions.
Conclusions: The Spanish version of the PedsQL™ differs somewhat from the original version, particularly on the School Functioning and Physical Appearance Scales, as observed in cognitive interviews. Predictive validity was not demonstrated.
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Versión española del cuestionario de calidad de vida para niños y adolescentes con cardiopatías (PedsQL™)

Palabras clave:
Instrumentos de medición
Validación
Calidad de vida
Cuestionario
Fiabilidad
Validez
Versión española

RESUMEN

Introducción y objetivos: Adaptar al español el cuestionario de calidad de vida *Pediatric Quality of Life Inventory* (PedsQL™) (Módulo General y Módulo Cardiaco, versión 3.0).
Métodos: Metodología de traducción directa e inversa. La entrevista cognitiva se utilizó para probar la versión previa al test. Se realizó la evaluación de las propiedades psicométricas de la versión española.
Resultados: La nueva versión contiene algunos cambios de formato con intención de facilitar la lectura de los enunciados y la comprensión de las instrucciones de respuesta (versión para niños de 5-7 años). Se identificaron algunos problemas de «descontextualización» en relación con el desarrollo evolutivo de los niños en las versiones para los niños más pequeños y sus padres (2-4 y 5-7 años). El porcentaje de ítems sin respuesta osciló entre 0 y el 5,9%. Se encontraron efectos techo elevados, especialmente en el Módulo Cardiaco, donde osciló en un 19-48,6%. La consistencia interna fue $>$ 0,7, excepto en la dimensión de Apariencia Física y Funcionamiento Escolar en los niños. Los grados de acuerdo entre la información dada por los niños y la dada por los padres fueron en general muy altos. Se observó una tendencia de descenso de las puntuaciones en todas las escalas en relación con la gravedad de la cardiopatía, pero sólo en algunas dimensiones las diferencias fueron estadísticamente significativas.
Conclusiones: La versión española del PedsQL™ presenta algunas diferencias con la versión original, concretamente con las dimensiones de Funcionamiento Escolar y Apariencia Física, como se observó en las entrevistas cognitivas. Por otro lado, no se ha demostrado que tenga validez predictiva.
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* Corresponding author: Subdirección de Terapia Celular y Medicina Regenerativa, Instituto de Salud Carlos III, Pabellón 5, Monforte de Lemos 5, 28029 Madrid, Spain.
E-mail address: comartin@isciii.es (M.C. Martín-Arribas).

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Abbreviations

HRQOL: health-related quality of life
PedsQL™: Pediatric Quality of Life Inventory

INTRODUCTION

This article presents part of a wider research study aimed at determining the health-related quality of life (HRQOL) of children with severe congenital heart disease, following surgery. Heart defects are the most common congenital malformations with an incidence estimated between 4 per thousand and 12 per thousand live births, according to different authors. Taking into account that in 2003 there were 438 000 births in Spain, it is estimated that about 4000 children were born with a heart defect.[1,2] Recent advances in medical and surgical treatment have greatly improved the life expectancy of these children; 85% to 90% reach adulthood, although many of them require lifelong follow-up.[3,4] As a result, not only terms such as survival should be included in health outcome indicators, but also aspects related to quality of life.

The Pediatric Quality of Life Inventory (PedsQL™) is one of the main instruments for measuring children's quality of life. This questionnaire consists of a general module which addresses the quality of life of the general population of children, and a specific module[5-7] which addresses the quality of life of children with heart problems. The validity and reliability of this questionnaire has been confirmed in different populations of children with chronic health problems and in children with congenital heart disease,[7] but the specific version for children with heart problems has not been translated into Spanish for use in Spain.

The linguistic-cultural validation of a questionnaire attempts to preserve the semantic content of the source instrument and ensure its adaptation to the new context in which it is applied. To obtain equivalent and comparable versions, the adaptation process requires a systematic methodology[8–10] that includes an initial translation stage, followed by the semantic and conceptual adaptation of the new version to the original source, and finally, the assessment of its psychometric properties (reliability, validity and sensitivity to change). The aim of this study was to obtain a Spanish version of the PedsQL™ that is semantically and culturally equivalent to the original English version and assess its psychometric properties in a sample of children with heart disease between 2 years and 18 years of age.

METHODS

Design

The adaptation process was conducted in three stages. The first consisted in adapting the questionnaire using a forward and backward translation methodology consistent with international guidelines and the recommendations of the authors of the original instrument (Mapi Research Institute: http://www.pedsql.org/translations.html) (Fig. 1). We used a qualitative methodology for the semantic and conceptual adaptation stage. Cognitive interviewing was used to check the pre-test version to assess completion problems. In the third stage we analyzed its psychometric properties; specifically, the reliability and validity of the Spanish version.

Study Population

The following inclusion criteria were applied during the second and third stages: children between 2 years and 18 years of age diagnosed with severe congenital heart disease, at least 1 year after corrective or palliative surgical repair conducted within the pediatric cardiology and surgery service. Their parents were also included.

We excluded children with developmental problems that limited understanding and/or verbal communication.

An intentional sampling strategy was applied for semantic and conceptual adaptation. Families of children who had been admitted to a pediatric surgery ward or who had attended a cardiology clinic for an examination between July 2007 to December 2007 were recruited. The sample consisted of 14 parents (4 parents of children aged 2-4, 6 parents of children aged 5-7, 2 parents of children aged 8-12, and 2 parents of children aged 13-18) and 10 children (5 children aged 5-7, 2 children aged 8-12, and 3 children aged 13-18). All families were of Spanish origin.

To assess the psychometric properties, the sample consisted of the total number of children registered in the cardiology service database who fulfilled the inclusion criteria, embracing a total of 346 families.

The PedsQL™ Questionnaire

The PedsQL™ is a modular system that measures HRQOL in a wide age group ranging from 2-year-old children to 18-year-old adolescents.

It consists of a 23-item General Module with 4 scales: *a)* physical functioning (8 items); *b)* emotional functioning (5 items); *c)* social functioning (5 items), and *d)* school functioning (5 items). It also has a specific module for children with heart problems (Cardiac Module), with 6 dimensions divided into 25 questions: *a)* heart problems-symptoms (7 items); *b)* adherence to treatment problems (3 items); *c)* physical appearance (3 items); *d)* anxiety, fear, or worry about clinical follow-up (4 items); *e)* cognitive problems (5 items), and *f)* communication skills (3 items).

Both modules (general and cardiac) are presented in different formats for children in 3 age groups (5-7 years, 8-12 years and 13-18 years) and for parents of children in 4 age groups (2-4 years, 5-7 years, 8-12 years and 13-18 years). The questions in both formats are effectively the same, although they are presented in language appropriate to the developmental level and in the first or third person, respectively.

A 5-point Likert-type scale is used for children aged 8-18 years and their parents and a 3-point scale for younger children, for ease of use. For obvious reasons, information on children aged 2-4 years was collected only from the parents.

To calculate HRQOL, items are linearly transformed to a scale of 0 to 100 (0=100, 1=75, 2=50, 3=25, 4=0), with higher scores indicating better HRQOL. The scale scores are calculated by dividing the sum of the items by the number of items answered. If more than 50% of the items are not answered the scale scores are not calculated.[5,11] A summary score of physical health can be calculated, which is the same as that obtained for physical functioning, and a summary psychosocial health score, which is the mean calculated as the sum of the items on the emotional, social, and school scales divided by the number of items answered on each scale.

Based on the original model, the validation procedure was performed following the guidelines of the Mapi Research Institute and the Scientific Advisory Committee of the Medical Outcomes Trust.[12]

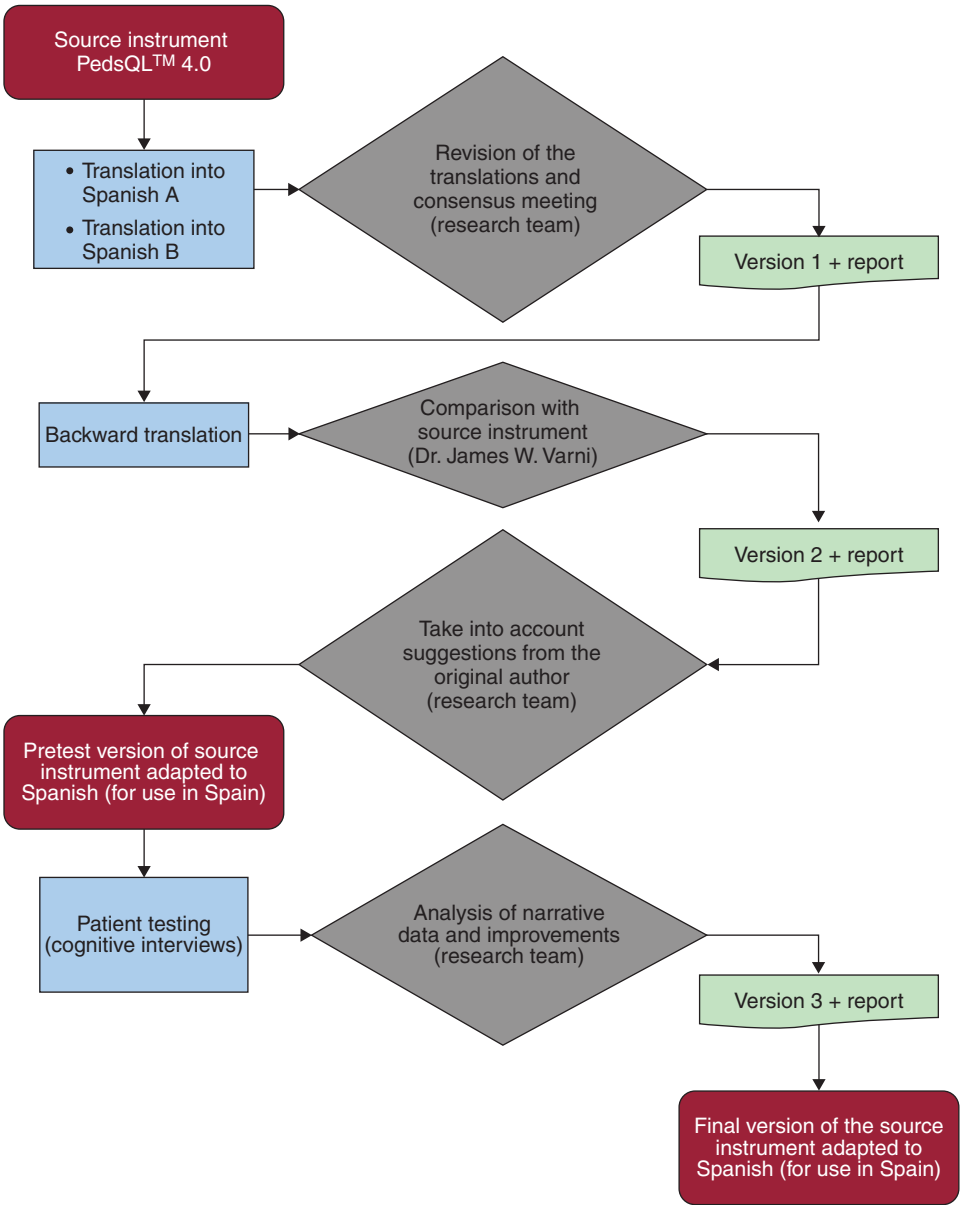

Figure 1. Diagram of the methodology used to translate the instrument from English to Spanish (adapted from the authors based on the schema presented by the Mapi Research Institute). PedsQL™: Pediatric Quality of Life Inventory.

The Spanish Version of the PedsQL™: Adaptation Process

The PedsQL™ 3.0 Cardiac Module was independently translated into Spanish by 2 professional translators who were native speakers of the target language and bilingual in the language of origin. Two versions were discussed with the 2 translators, a pediatric cardiologist, a pediatrician, a pediatric cardiology nurse, and a teacher, and the final combined version was back-translated into English by a bilingual native-English speaker. The author of the original instrument offered some suggestions that were added to the pre-test version.

For semantic and conceptual adaptation, data were collected using individual cognitive interviews in the case of children, and individual or group interviews in the case of the parents. The interview followed a "thinking aloud"[13,14] approach to the questionnaire either by the parents, children, or a researcher, during which the interviewees attempted to answer the questions. Concurrently, the researcher asked some previously prepared open questions based on the Probing Questions interview guidelines,[15–17] which sought to address some aspects of the questionnaire the research team expected to be challenging. The interviews were audiotaped and transcribed for subsequent data analysis.

In the third phase the resulting questionnaire, an explanatory letter, and informed consent form were sent by post to 346 families. We conducted telephone follow-up to reinforce the importance of completing the questionnaire.

Data Analysis

Qualitative Analysis

Consistent with the guidelines proposed in the literature,[15–18] the classification of potential problems in completing questionnaires

proposed by Conrad et al.[15] was used as a reference, using latent thematic analysis to allow for emergent issues.[19]

Initially, all interviews were analyzed by generational group (parents and children) and by age (2-4 years, 5-7 years, 8-13 years, and 14-18 years) to develop a general scheme of the different problems identified and the relationships between them.

Subsequently, specific problems were identified and collected in a report. The research group, by consensus, made a set of changes to the different versions to solve the problems identified. The Mapi Research Institute approved both modules of the Spanish version of the psychometric study.

Assessment of the Psychometric Properties of the Adapted Version

The feasibility of the Spanish version was determined by analyzing the distribution of scores, the proportion of missing values, and the frequency of floor and ceiling effects for each dimension. The percentage of floor and ceiling effects considered acceptable was 15% or less.[12]

Internal consistency was analyzed using Cronbach's alpha coefficient. A value $\geq$0.70 was considered acceptable.

To analyze agreement between the parents' and children's replies, the intraclass correlation coefficient, standardized differences, and 95% confidence intervals were used.

Construct validity was assessed by examining correlations between scores on the Cardiac Module scales and scores on the relevant scales of the General Module. Based on the questionnaire authors' model, the following hypotheses were constructed:

1. Heart problems would correlate with physical functioning.
2. Physical appearance would correlate with psychosocial functioning.
3. Cognitive problems would correlate with school functioning.
4. The management of anxiety, fear, or worry would correlate with psychosocial functioning.
5. Cardiac symptoms would correlate with the summary quality of life score.
6. Cardiac symptoms would correlate with disease severity as measured using the Aristotle method.[20]

Correlation between the scales of both modules was estimated using the Pearson correlation coefficient.

Ethical Considerations

Participants were fully informed and provided signed consent for their participation. The study was approved by the Research Ethics Committee of the *Hospital 12 de Octubre* (Madrid, Spain).

RESULTS

Semantic and Conceptual Adaptation

The results of the cognitive interviews and analysis of the data derived from them led to the identification of various problems that could have compromised the correct completion of the new version of the questionnaire.[14] In addition, as a result of the inductive analysis of the data, problems emerged that were categorized as "decontextualization" problems in the Cardiac Module. These relate to the lack of consistency between the items and the neuromaturation and developmental level of the children. The decontextualization problems appeared in the physical appearance and communication sections of the module. In the physical appearance section, the statements "He or she doesn't feel good-looking" or "He or she is embarrassed to be seen naked by others" were considered unsuitable by the parents, who believed that at this age children always see themselves as good-looking and do not feel "physical shame."

In the communications skills section, parents thought that the children would reply to all the items with "never"; however, this would not be a valid reply insofar as we are assessing communication with healthcare professionals and not with their interlocutors, that is, the parents. Regarding the item "They find it hard to explain their heart problem", children in the lower age ranges are unaware of their problem. To maintain the integrity of the original source, these items were not eliminated. After analyzing the data from the cognitive interviews, the proposed changes to the rest of the items were added.

Psychometric Properties of the Adapted Version

Sample Characteristics

Of the 346 families registered in the database, 106 children aged 5-18 years completed the questionnaire and 174 parents of children aged 2-18 years. If we exclude 72 children who could not be located, 7 who died and 20 with cognitive problems, the overall participation rate was 70.4%. Forty-four children were under medical treatment. Table 1 shows the distribution of participants by sex and age groups. The sample represented families from almost all the autonomous regions of Spain. The mean age of the parents was 39 years; 45% had completed secondary school and 22% of the fathers and 30% of mothers had completed university; 96% of the children were attending school. Fifty percent of the parents reported a low-medium or medium income and 27% a medium-high income.

Table 2 presents the comparison between the groups of participants and non-participants. Of the variables analyzed, the only difference was that the pre-surgery risk level was greater among the participants (P=.029).

Feasibility. Missing Values. Ceiling and Floor Effects

To assess the feasibility of applying the questionnaire, we calculated the percentage of unanswered items in each of the scales. These ranged between 0% and 1.8% on the General Module scales (Table 3) and between 0% and 3% in the case of children and between 0% and 5.9% in the case of parents on the Cardiac Module scales (Table 4).

For the core scales (summary score, physical health, and psychosocial health), the ceiling effect ranged between 3.8% and 15.4% in children. Elevated ceiling effects of nearly 30% were found in social functioning in both children and parents, and of 24.4% in physical health in parents. These effects were around 15% or less on the other dimensions of the General Module (Table 3). On the

Table 1
Distribution of All Participants by Sex and Age Groups

Age groups, years	Children			Parents
	Total	Male	Female	
2-4	68 (39.1)*	37 (36.3)	31 (43.1)	68 (39.1)
5-7	57 (32.8)	39 (38.2)	18 (25)	57 (32.8)
8-12	40 (23)	21 (20.6)	19 (26.4)	40 (23)
13-18	9 (5.2)	5 (4.9)	4 (5.6)	9 (5.2)
Total	174 (100)	102 (58.6)	72 (41.4)	174 (100)

* Information from parents only.

Table 2
Differences Between Participants and Nonparticipants

	Participants (n=174)	Nonparticipants (n=172)	*P*
Sex			.456
Male	102	94	
Female	72	78	
Age groups, years			.088
2-4	68	50	
5-7	57	69	
8-12	40	36	
13-18	9	17	
Aristotle class[*]			.029
1	10	8	
2	54	80	
3	44	37	
4	66	47	
Corrective surgery			.920
Yes	146	145	
No	28	27	
Number of surgical procedures			.124
1	120	134	
2	34	27	
3	20	9	
Bypass surgery			.017
Yes	173	164	
No	1	8	

[*] Higher values indicate greater complexity, greater surgical risk.

Cardiac Module scales (Table 4), higher ceiling effects were observed in practically all the dimensions, both in children (19% to 48.6%) and parents (12.6% to 33.9%). Floor effects were low, ranging from 0% to 8.6%.

Internal Consistency-Reliability

The internal consistency-reliability values of the 2 modules are presented in Table 5 and Table 6, respectively. The recommended standard value of 0.7 was reached on the General Module core scales. Internal consistency was less than 0.7 for some dimensions in the different age groups. Children in all age groups presented low values in school functioning. Children and parents presented the lowest values on the physical appearance scale, which may be related to the decontextualization problems mentioned above.

Construct Validity

We explored construct validity under the hypothesis described in the Methods section. Heart problems were significantly correlated with physical functioning (r=0.606 in children and r=0.685 in parents) and with the summary quality of life score (r=0.650 in children and r=0.681 in parents), on both the scales for children and for parents ($P<.001$). The physical appearance scale and psychosocial functioning scale were significantly correlated (r=0.243 for children and r=0.227 for parents; $P<.01$). Scores on the cognitive problems scale and school functioning scale were significantly correlated (r=0.611 for children and r=0.728 for parents, $P<.001$). The management of anxiety, fear, or worry scale and psychosocial functioning scale were significantly correlated (r=0.279 for children and r=0.337 for parents, $P<.001$).

Since it was not possible to conduct comparisons with a group of healthy children, we analyzed differences according to disease severity (Table 7). The scores were lower the greater the severity for all dimensions. The only statistically significant differences were found for the summary score and the physical health and social functioning dimensions, based on the information provided by parents.

In the Cardiac Module, scores on the heart problems dimension (symptoms scale) in both children and parents decreased depending on the severity of the heart disease. In the information provided by parents, this trend was maintained for the nonphysical dimensions (physical appearance and communication skills) and for cognitive problems, but in the information provided by children the nonphysical dimensions (physical appearance, fear, and cognitive problems) were not related to disease severity.

Parent-Child Concordance

Given the differences in the scores, we analyzed parent-child reproducibility using the intraclass correlation coefficient

Table 3
Descriptive Analysis, Percentage of Missing Values and the Frequency of Floor and Ceiling Effects for Each Dimension. PedsQL™ General Module

	No.	Mean (SD)	Missing values, %	Floor, %	Ceiling, %
Children's report					
Summary score	103	76.8 (14.9)	1	0	3.8
Physical health	104	81.5 (16.9)	0	0	15.4
Psychosocial health	103	74.2 (15.9)	1	0	3.8
Emotional functioning	103	74.1 (18)	1	0	15.4
Social functioning	104	78.6 (33.1)	0	1	29.8
School functioning	103	69 (19.7)	1	0	7.7
Parent's report					
Summary score	168	78.5 (16.3)	0	0	3.6
Physical health	168	81.3 (19.5)	0	0	24.4
Psychosocial health	168	76.9 (16)	0	0	3.6
Emotional functioning	168	74.5 (17.5)	0	0	8.3
Social functioning	168	82.8 (19.6)	0	0	33.6
School functioning	168	73.2 (21.2)	1.8	0	13.1

PedsQL™, Pediatric Quality of Life Inventory; SD, standard deviation.

Table 4
Descriptive Analysis, Percentage of Missing Values and the Frequency of Floor and Ceiling Effects for Each Dimension. PedsQL™ Cardiac Module

	No.	Mean (SD)	Missing values, %	Floor, %	Ceiling, %
Children's report					
Heart problem	103	79.8 (16.9)	3	0	19
Physical appearance	103	84.7 (20.5)	2	1	48.6
Fear/worry	105	66.8 (34.2)	0	8.6	30.5
Cognitive problems	104	69.4 (24.4)	1	2.9	14.3
Communication skills	103	57.6 (29.7)	2	4.8	19
Parent's report					
Heart problem	174	77.7 (18)	0	0	12.6
Physical appearance	173	76 (26.9)	0.6	3.4	33.9
Fear/worry	174	68.8 (32.1)	8	8.6	25.9
Cognitive problems	172	69.5 (27.9)	1.2	1.7	16.1
Communication skills	165	73.8 (28)	5.9	4	28.2

PedsQL™, Pediatric Quality of Life Inventory; SD, standard deviation.

Table 5
Reliability: Internal Consistency (Cronbach's Alpha) of the General Module Scales for Children's and Parents' Reports by Age Group and Total Sample

General Module	2-4 years	5-7 years	8-12 years	13-18 years	Total
Children's report					
Summary score		0.85	0.88	0.95	0.88
Physical health		0.75	0.76	0.87	0.78
Psychosocial health		0.78	0.83	0.93	0.82
Emotional functioning		0.48	0.71	0.81	0.62
Social functioning		0.74	0.84	0.95	0.81
School functioning		0.70	0.63	0.68	0.67
Parent's report					
Summary score	0.92	0.93	0.89	0.84	0.91
Physical health	0.89	0.87	0.75	0.81	0.87
Psychosocial health	0.86	0.89	0.84	0.68	0.87
Emotional functioning	0.63	0.72	0.79	0.81	0.73
Social functioning	0.77	0.79	0.87	0.76	0.79
School functioning	0.66	0.81	0.71	0.89	0.79

and the mean standardized difference (Table 8). For the total sample, the correlations were high on both scales, with higher scores on the General Module. Consistent with other studies, overall agreement was higher for the physical health and heart problems dimensions, reflecting observable behaviors. For the psychosocial health scale and its dimensions, agreement was somewhat lower in the 13-to 18-year-old group.

Table 6
Reliability: Internal Consistency (Cronbach's Alpha) of the Cardiac Module Scales for Children's and Parents' Reports by Age Group and Total Sample

Cardiac Module	2-4 Years	5-7 Years	8-12 Years	13-18 Years	Total
Children's report					
Heart problem		0.71	0.63	0.81	0.70
Physical appearance		0.38	0.55	0.77	0.50
Fear/worry		0.91	0.93	0.73	0.92
Cognitive problems		0.81	0.73	0.86	0.79
Communication skills		0.75	0.57	0.94	0.73
Parent report					
Heart problem	0.82	0.76	0.76	0.76	0.79
Physical appearance	0.44	0.60	0.66	0.73	0.65
Fear/worry	0.96	0.97	0.96	0.96	0.96
Cognitive problems	0.67	0.91	0.84	0.80	0.88
Communication skills	0.88	0.89	0.80	0.88	0.86

Table 7
Mean (Standard Deviation) of the PedsQL™ by Disease Severity (Aristotle Score)

Scales	Complexity of surgery levels			*P*
	1 and 2* (n=64)	3 (n=44)	4 (n=66)	
General Module				
Children's report				
Summary score	78.30 (13.37)	73.35 (13.91)	75.11 (16.80)	
Physical health	83.65 (14.58)	77.95 (18.04)	82.25 (16.71)	
Psychosocial health	75.44 (14.54)	70.38 (14.73)	71.88 (17.99)	
Emotional functioning	72.73 (16.78)	72.31 (18.96)	72.15 (17.71)	
Social functioning	82.79 (19.58)	75.37 (18.88)	75.38 (29.36)	
School functioning	70.81 (19.20)	65.19 (16.95)	68 (21.95)	
Parent's report				
Summary score	82.36 (13.92)	72.27 (15.32)	72.07 (19.72)	3<1. *P*<.05
Physical health	86.70 (15.20)	75.99 (20.91)	75.87 (23.07)	3<1. *P*<.05
Psychosocial health	79.74 (14.01)	70.25 (15.35)	70.03 (19.04)	
Emotional functioning	75.13 (17.98)	71.90 (18.14)	73.75 (17.71)	
Social functioning	87.14 (14.11)	77.50 (20.93)	82.32 (21.59)	3<1. *P*<.05
School functioning	77.77 (19.36)	68.53 (23.70)	72.55 (20.80)	
Cardiac Module				
Children's report				
Heart problem	80.39 (15.74)	76.39 (19.16)	78.43 (16.05)	
Physical appearance	86.38 (16.44)	82.97 (21.97)	85.89 (22.33)	
Fear/worry	62.34 (39.13)	71.19 (33.48)	76.84 (29.06)	
Cognitive problems	72.78 (26.39)	67.83 (21.31)	64.81 (26.73)	
Communication skills	66.38 (27.91)	46.44 (26.13)	58.07 (33.23)	
Parent's report				
Heart problem	79.36 (18.23)	75.14 (18.20)	76.23 (14.53)	
Physical appearance	79.60 (20.08)	73.81 (26.58)	79.57 (22.30)	
Fear/worry	66.12 (31.20)	65.39 (33.23)	69.23 (30.66)	
Cognitive problems	69.68 (26.51)	65.60 (27.29)	54.62 (27.96)	
Communication skills	72.26 (30.79)	67.20 (31.80)	64.26 (34.11)	

PedsQL™: Pediatric Quality of Life Inventory.
* 1, n=10; 2, n=54.

Table 8
Intraclass Correlation Coefficient Between the Data Reported by the Parents and Children for the PedsQL™ and Cardiac Module Scales

Scales	Age groups, years				Effect size (95%CI)
	5-7	8-12	13-18	Total	
General Module					
Summary score	0.86	0.91	0.94	0.87	0.06 (−0.21 to 0.34)
Physical health	0.78	0.86	0.95	0.82	0.10 (−0.17 to 0.38)
Psychosocial health	0.86	0.91	0.85*	0.87	−0.06 (−0.34 to 0.21)
Emotional functioning	0.71	0.94	0.85*	0.81	0.16 (−0.11 to 0.44)
Social functioning	0.86	0.88	0.77*	0.85	−0.09 (−0.37 to 0.18)
School functioning	0.81	0.79	0.75*	0.75	−0.05 (−0.33 to 0.23)
Cardiac Module					
Heart problems	0.82	0.73	0.92	0.81	0.18 (−0.11 to 0.46)
Physical appearance	0.53	0.82	0.95	0.54	0.21 (−0.07 to 0.49)
Fear/worry	0.62	0.71	0.96	0.74	0.05 (−0.22 to 0.34)
Cognitive problems	0.58	0.86	0.94	0.65	0.11 (−0.16 to 0.40)
Communication skills	0.53	0.52	0.94	0.53	0.31 (−0.60 to 0.03)

95%CI, 95% confidence interval; PedsQL™, Pediatric Quality of Life Inventory.
Effect size: negative values indicate lower scores in children.
* Correlations significant at *P*<.05; the others are significant at *P*<.001.

DISCUSSION

Conducting interviews, collecting feedback during the initial adaptation phase, and analyzing the feedback allowed us to assess whether the contents of the questions had been correctly understood and to improve the adaptation process. The problems identified were easily resolved and ensured that the adapted version met the needs of parents and children, although the

"decontextualization" problems, which were particularly evident in the 2- to 4-year-old and 5- to 7-year-old groups, could not be addressed as this would have involved major changes to the original version.

The questionnaires were easy to complete, as shown by the low percentage of unanswered items. On several scales and on the majority of Cardiac Module scales, the ceiling effect was notable, which is consistent with the findings of other authors[5,21–23]; however, the observed ceiling effect could limit the capacity of some subscales to detect differences in the quality of life of children. This lack of variability in the measurements also could explain the high internal consistency.

The results on reliability were acceptable for most dimensions and were similar to those of the original English version.[5] Varni observed high alpha coefficients in relation to the information provided by parents and children, except for the fear and communication dimensions, and standard values (0.70) for physical appearance. In our case, the physical appearance scale presented low values, which may be related to the decontextualization problems described, especially in the lower age ranges. The low consistency found in school functioning, also present in other studies, indicates the need to revise these items. This is an issue that needs to be discussed with the authors of the original version, and will require the Spanish version to be revised.

The majority of the hypotheses regarding the construct validity of the instrument were confirmed, with results similar to those obtained in the original version, in these versions for both children and parents. The capacity to discriminate between groups could not be demonstrated, although the scores were lower the more severe the disease, a trend that was observed on all scales.

In future phases of the PedsQL™ assessment process, the equivalence of the factorial structure should be compared to that of the original and the sensitivity of both scales and test-retest assessment of these instruments should be studied.

The high level of agreement achieved on the General Module scales between the information collected from children and parents supports the idea that the assessment of parent-reported HRQL would be sufficient to ascertain the quality of life of children with heart problems in these age ranges. However, the fact that the information was collected by mail might raise concerns regarding the parents being over-involved in the children's responses, although there were differences particularly in the 13- to 18-year-old group and in the percentages of ceiling effects on various dimensions. This could be a limitation and thus it may be advisable to conduct the tests face-to-face, especially with children.

A potential limitation of our study is the small number of participants, particularly those in the 13- to 18-year-old group (30 children of this age group were registered in the database).

On the other hand, it should be noted that the participants in the cognitive interviews were families and children of Spanish origin belonging to different regions and that no immigrant groups were represented. This could be considered a limitation. Although sociocultural strata were not taken into account for sampling purposes, we believe that the Spanish version is valid for use in the established immigrant population in Spain, as supported by the fact that no special problems in comprehension were observed in the participant population during telephone follow-up. The children interviewed were attending school with an average of 4 years of schooling. However, the scale may need to be validated for use in Latin American countries.

CONCLUSIONS

The Spanish version of PedsQL™ differs from the original version in some respects, particularly in the dimensions of school functioning and physical appearance in children, as observed in cognitive interviews; it has not been shown to have predictive validity.

This tool continues to be refined. The results indicate the need to compare the equivalence of the factor structure to the original scale. Factor analysis could confirm the problems detected in the cognitive interviews. The results could be used as a guide for future studies.

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CONFLICTS OF INTEREST

None declared.

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