The Italian version of the PedsQL™ in children with rheumatic diseases

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Abstract

Objective

The aim of the study was to test the reliability and validity of the Italian translation of the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Rheumatologic Module in a sample of rheumatologic children in Italy.

Methods

The PedsQL 4.0 and the PedsQL 3.0 were administered to rheumatic and healthy children. 102 children 5-18 years old and 132 parents of children 2-18 years old were tested. Additionally, the Child Health Questionnaire – Parent Form 50 – was administered to the rheumatologic sample.

Results

Internal consistency reliability for group comparisons reached the recommended coefficient alpha of 0.70 for PedsQL 4.0 and PedsQL 3.0. The inter-correlation between these last ones was highly significant. The correlation between the PedsQL 4.0 and the CHQ was statistically significant.

Conclusions

The Italian version of the PedsQL 4.0 and PedsQL 3.0 Rheumatology Module demonstrate acceptable reliability and validity for both patient self-report and parent proxy-report.

Key words

Quality of life, juvenile chronic arthritis, children.

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Introduction

The importance of a comprehensive approach to treating children with chronic diseases is broadly recognized (1-4). This means considering the influence of both objective health indexes (traditionally measured in a medical setting) and subjective indicators connected to the impact of the disease on the patient's life or, in other words, health-related quality of life (HRQOL). Several instruments are available for assessing HRQOL in adults, while questionnaires for use in the pediatric field are less well developed (5, 6). HRQOL studies can help health practitioners more fully understand children's disease-specific symptoms and psychosocial functioning and development in the context of daily life from the perspectives of both pediatric patients and their parents (7, 8). The PedsQL™ 4.0 Generic Core Scales and the modules developed for various diseases are used to assess health-related quality of life in healthy children and adolescents, as well as pediatric patients with acute or chronic conditions, combining into a single system several generic scales and modules for specific diseases (9-12).

The PedsQL 4.0 Generic Core Scales are the outcome of an iterative process with healthy and ill pediatric populations (12, 13). This instrument was designed to measure the core health dimensions as delineated by the World Health Organization (14), as well as school functioning. It is considered one of the most promising HRQOL instruments, integrating generic core scales and disease-specific modules into one measurement system for children and adolescents (15). The importance of validating new translations should be emphasized to investigate the acceptability of the psychometric properties for further use in both clinical practice and research.

This is the first study of a larger multicenter research project in progress on the validation of the Italian PedsQL™ instruments in pediatrics in Italy. The aim of the present study was to demonstrate the reliability and validity of the PedsQL 4.0 Generic Core Scales (13) and the PedsQL 3.0 Rheumatology Module (16) in a sample of Italian children with rheumatic disease. The original version of the Rheumatology Module was adapted to the Italian language according to the PedsQL™ translation protocol distributed by the Mapi Research Trust in France (17). The PedsQL™ scales scores were analyzed relating to pain characteristics (frequency, intensity, duration), chronicity of illness, type of diagnosis, and impact of absences from school.

Patients and methods

Subjects and settings

The PedsQL was administered to 102 children 5-18 years old and 132 parents of children 2-18 years old. All the subjects came from Padua and its province (Italy). The dissimilar numbers of the groups was due to the different versions of the questionnaires: there were 30 parents of children 2-4 years old who filled in the proxy report form. Both versions (pediatric patient self-report and proxy proxy-report) are available for parents and children from their 5th year upwards. The PedsQL was self-administered by parents and by children 8-18 years old, and administered by an interviewer to children 5-7 years old.

Sixty-six children with rheumatic disease were recruited from the Rheumatology Unit of the Department of Pediatrics (University of Padua). The mean age for the pooled report forms (self and proxy reports) was 8.6 (SD 4.5). The sample consisted of 78.8% females and 21.2% males, the larger number of females being related to the specific dominance of female gender in rheumatic diseases (18). All the children were native Italians. The sample included 49 children (74.2%) with juvenile idiopathic arthritis (JIA), 4 (8.1%) of them with the systemic subtype, 16 (32.7%) with the polyarticular subtype and 29 (59.2%) with the oligoarticular subtype, plus 3 children (4.5%) with spondylarthritis and 14 (21.3%) with other rheumatic diseases (4 juvenile dermatomyositis JDM, 4 systemic lupus erythematosus SLE, one patient for each of the following diseases: sarcoidosis, polyarteritis nodosa, Kawasaki disease, hypermobile joint syndrome, rheumatoid nodules,

systemic sclerosis). Active disease in JIA was defined as the presence of at least one swollen, painful joint and/or high spiking fever, in JDM and SLE as an increasing value of Disease Activity Score (DAS) (19) or Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) respectively (20). For the remaining patients with various rheumatological conditions, no validated activity scores are available so we classified the disese status as active or non-active on the basis of the primary physician judgment. According with these criteria, at the time of the clinical evaluation, 13/49 JIA patients (26.5%), 2 JDM and 1 SLE patients had active disease. None of those with miscellaneous rheumatic conditions were active. Patients and parents completed the PedsQL 4.0 Generic Core Scales and PedsQL 3.0 Rheumatology Module during a rheumatology visit at the clinic.

The sample of healthy children consisted of 66 subjects recruited at primary and secondary schools in Padua. The mean age for the pooled report forms was 9.1 (SD 5.0). The distribution of males and females was exactly the same as in the group of children with rheumatic diseases. The age distribution was also identical in the two groups, *i.e.*, 15 cases (22.7%) were 2-4 years old; 12 (18.2%) were 5-7 years old; 22 (33.3%) were 8-12 years old; and 17 (25.8%) were 13-18 years old.

Measures

The PedsQL™ 4.0 Generic Core Scales include 23 items that encompass: (1) Physical functioning (8 items); (2) Emotional functioning (5 items); (3) Social functioning (5 items); (4) School functioning (5 items). The PedsQL 4.0 Generic Core Scales comprise parallel child self-report and parent proxy-report formats. Specifically, the child self-report includes ages 5-7 (young child), 8-12 (child), and 13-18 (adolescent). The parent proxy report includes ages 2-4 (toddler), 5-7 (young child), 8-12 (child), and 13-18 (adolescent). The two forms, for children and parents, are parallel providing an indication of the child's and the parent's perception. The instrument instructions ask how much of a problem each item has been during the past month. The choice of answer for each item is on a 5-point Likert scale for 8-18 year-olds' self-report and parent proxy-report (0 = never a problem, 1 = almost never a problem, 2 = sometimes a problem, 3 = often a problem, 4 = almost often a problem). For self-reports by children 5-7 years old, the Likert scale has been reduced to a 3-point scale (0 = not a problem at all; 2 = sometimes a problem; 4 = a great problem), each choice of response being attached to a happy-sad faces scale (21, 22).

The score for each item is reversed and linearly converted into a 0-100 scale (0=100, 1=75, 2=50, 3=25, 4=0), so that higher PedsQL 4.0 scores indicate a better HRQOL, while lower scores indicate a worse HRQOL. This conversion does not affect the measurement properties of the scales (16).

The total score for a given scale is computed as the sum of the items divided by the number of answers (to account for missing data). If >50% of the items in the scale are missing, the score is not calculated. Inputting the mean of the completed items in a scale when >50% of the items have been completed generally produces the least biased and most precise results (23).

The score for the Physical Functioning Scale is the same as the Physical Health Summary Score (8 items). The Psychosocial Health Summary Score (15 item) is obtained from the sum of the items divided by the number of items answered in the Emotional, Social and School Functioning Scales. The Total Scale Score is computed from the sum of all the items divided by the number of items.

The PedsQL 3.0 Rheumatologic Module consists of 22 items and encompasses the following multidimensional scales (16): Pain and Hurt (4 items), Daily activities (5 items), Treatment (7 items), Worry (3 items), and Communication (3 items). These last two scales are not included in the parent's proxy report for toddlers (2-4 year-olds). The format, instructions, Likert scale and scoring method are the same as those of the Generic Core Scales, with higher scores indicating a better HRQOL.

Before the PedsQL 4.0 Generic Core Scales and PedsQL 3.0 Rheumatology Module were administered, the translation of the latter was validated according to the officially-recommended procedure (17), which is characterized by the following steps: forward translation, backward translation, testing on 6 patients for each age range; then, on the strength of the results obtained, a final Italian version was approved. The officially-approved Italian translation of the PedsQL 4.0 Generic Core Scale was provided by the MAPI Research Institute.

The Italian version of the Child Health Questionnaire – Parent Form 50 (CHQ-PF50) (24) – was also administered in this study. The CHQ-PF50 is a paper-and-pencil measure completed by parents of children 5-18 years old. The CHQ is a multidimensional generic health status questionnaire developed for clinicians and researchers interested in measuring children's functional health and well-being. It is available as a parent proxy report for children aged 5-18 years and as a corresponding self-report for adolescents.

Table I. PedsQL 4.0 Generic Core Scores for self and proxy reports analyzed by age (ANOVA). Significant differences are marked in bold type.

PedsQL 4.0 Generic Core Scales	Mean				F	Sig.
Self report n=102	2-4 years	5-7 years	8-12 years	13-18 years		
Total		82.2	77.7	79.5	1.44	0.24
Physical health summary score		83.7	78	80.2	1.22	0.29
Psychosocial summary score		81.5	77.5	79	1.06	0.35
PedsQL 4.0 Generic Core Scales - proxy report n=132						
Total	89.3	82.9	77.5	80.2	6.10	**0.00**
Physical health summary score	88.5	81.9	78.3	79.7	2.62	**0.05**
Psychosocial summary score	89.9	83.5	77	80.4	6.86	**0.00**

Table II. The PedsQL 4.0 Generic Core Scales for self-report and proxy report between the two groups. Significant results are marked in bold type.

Generic Core Scales	No. of items	Children with rheumatic disease			Healthy children			
		No. of subjects	Mean	SD	No. of subjects	Mean	SD	*p*
Self-report								
Total score	23	51	79.35	11.30	51	79.37	10	0.99
Physical health	8	51	77.70	15.95	51	82.54	12.17	0.08
Psychosocial health	15	51	80.24	10.95	51	77.68	10.56	0.23
Emotional functioning	5	51	80.44	16.89	51	72.16	15.40	**0.01**
Social functioning	5	51	84.61	15.74	51	80.98	14.35	0.22
School functioning	5	51	75.69	15.23	51	79.90	12.58	0.13
Proxy report								
Total score	23	66	82.01	13.98	66	81.74	11.21	0.9
Physical health	8	66	80.35	18.84	66	82.99	13.41	0.35
Psychosocial health	15	66	82.95	14.23	66	81.08	11.63	0.41
Emotional functioning	5	66	80.76	15.81	66	75.53	14	**0.04**
Social functioning	5	66	87.12	18.48	66	83.79	17.84	0.29
School functioning	5	61	79.68	18.20	66	84.32	13.67	0.10

The CHQ PF50 includes 50 items divided into 15 health concepts that contribute to give an overall functioning and well-being measure for children in the context of their family and social environments. These components have been pooled in 9 different scales. Individual items require participants to respond on a Likert-type scale with higher scores indicating a better or more positive health status.

The CHQ PF50 has two available summary scores (the Psychosocial and Physical), which can be used in the evaluation of outcomes when information at the scale level is not practical. The existing literature supports the validity of the CHQ (24), and this tool proves effective in differentiating chronic illnesses (25). In Italy the parent report for children aged 5-18 has been validated to date (4).

The license agreement for the use of CHQ has been requested and approved by the author of the questionnaire.

Finally, additional information on the type of diagnosis, time of diagnosis, frequency, duration and intensity of pain in the last month, and days of absence from school in the last month were collected.

Procedure

Patients and their parents were recruited at the Rheumatology Unit of the Paediatric Department of Padua (Italy), while waiting for a scheduled visit, but before being seen by the specialist. Written parental informed consent and child assent were obtained. Parents and children separately answered the additional questions (see *Methods*) and the PedsQL 4.0 and Rheumatologic Module 3.0. The Child Health Questionnaire (CHQ) was completed by the parents, according to the available standardization of this instrument in Italy. A trained clinical psychologist was on hand to answer any questions regarding the parent self-reports. A researcher administered the PedsQL to the younger children (aged 5-7) and assisted the older children and adolescents (8-18 years old), if they had questions during the compilation of the questionnaires.

The sample of healthy children was recruited by contacting various schools in Padua, after obtaining the headmasters' permission. Parents gave their written consent to their children's participation in the study by mail, then the PedsQL 4.0 (proxy and self-report) was administered to the children during some scheduled breaks at school. The PedsQL™ Rheumatology Module and the Child Health Questionnaire were not administered to healthy children. A researcher was always present while the child completed the questionnaires, and administered the PedsQL to the 5-7 year-olds children. The PedsQL 4.0 Generic Core Scales proxy-report version and additional information were sent to the children's home by mail for completion by their parents. The parents returned their forms to the school within a week of receiving them.

Statistical analysis

The internal consistency reliability of the scales was determined by calculating Cronbach's alpha for the PedsQL 4.0 Generic Core Scales, the three summary scales (Total, Psychosocial and Physical) of the PedsQL 4.0, and the Rheumatology Module scales. Cronbach's alpha was calculated for both self-report and proxy-report. An alpha >0.70 was considered adequate for comparing different groups. Construct validity was determined using the known-groups method, which compares scale scores across groups known to differ in the health construct investigated – the comparisons of the Generic Core Scales for healthy and rheumatic children in particular. Construct validity was further examined by analyzing the correlation between the PedsQL 4.0 Generic Core total score and the PedsQL 3.0 Rheumatology Module scores. Concurrent validity was established by comparing the PedsQL 4.0 Generic Core total score and the CHQ scores. Parent-child correlation was computed to examine cross-informant variance. Correlation effects were designated as small (0.10-0.29), medium (0.30-0.49), and large (>0.50) (26). Finally, to establish whether some of the main characteristics of rheumatic disease, such as the days of absence from school, influenced the PedsQL 4.0 scores, one-way analyses of variance were calculated separately for self and proxy reports. Statistical analyses were conducted using the SPSS for Windows.

Results

Age and sex

ANOVA revealed no significant differences in any of the individual scales between males and females for healthy and ill child self-report, but gender did influence the Psychosocial Health Summary Score for parent proxy-report, with females perceived by their parents as manifesting higher HRQOL than males. This was true of healthy and ill children as perceived by their parents.

Age only influenced the parent proxy-report: the mean Physical Health Summary Score, Psychosocial Health Summary Score, and the Total Scale Score for children 2-4 years old were higher than those of older children (Bonferroni post-hoc test $p<0.05$), among both patients and healthy children. No age-related differences emerged in the self reports, however (Table I).

Internal consistency reliability

The majority of child self-report and parent proxy report scales approached or exceeded the standard alpha coefficient value of 0.70 for group comparisons. The reliability values were lower than those found by Varni (16) but, according to Dazzi (27), values between 0.60 and 0.70 can be considered adequate. The only scales that presented an alpha under 0.60 were School functioning in the PedsQL 4.0 and daily activities in the Rheumatologic Module 3.0, both for self-reports.

Construct validity

The comparisons between the PedsQL 4.0 Generic Core Scales for children with rheumatic diseases and healthy children are given in Table II. Contrary to our hypothesis, the only significant difference between the groups was associated with emotional functioning in both self and proxy reports, where children with rheumatic disease obtained a higher score. The *t*-test failed to highlight any other statistically relevant differences. These findings are not consistent with the US findings for the PedsQL™ Rheumatology Module, in which all scales were significantly different between healthy children and children with rheumatic diseases (16).

The construct validity was also tested utilizing the correlation between the PedsQL 4.0 Generic Core Scales total score and the PedsQL 3.0 Rheumatology Module scales (16) (Table III). The correlation between the PedsQL 4.0 Generic Core Scales and Rheumatology Module 3.0 reached statistical significance in almost all the scales and particularly for parent proxy-report report. The correlation for the self-report reached statistical significance in all scales except for worry. For the most part, the values indicated low or moderate correlation.

Table III. Pearson's correlation coefficients between PedsQL 4.0 Generic Core Scales and Rheumatology Module scales for self and proxy reports. (r<0.20 no correlation; <0.20 and 0.39> low correlation; <0.40 and 0.59> moderate correlation; <0.60 and 0.79> strong correlation; <0.80 and 1> very strong correlation).

PedsQL 4.0 Generic Core Scales *Rheumatology Module 3.0*	Physical health	Emotional funct.	Social funct.	School funct.	Psychosoc. health	Total score
Self-report						
Pain and hurt	0.65**	0.38**	0.28*	0.18	0.41**	0.58**
Daily activities	0.49**	0.35*	0.29*	0.19	0.41**	0.50**
Treatment	0.46**	0.36**	0.38**	0.10	0.41**	0.49**
Worry	0.17	0.32*	0.01	-0.06	0.14	0.17
Communication	0.36**	0.31*	0.24	0.03	0.29*	0.36**
Proxy-report						
Pain and hurt	0. 73**	0. 40**	0. 36**	0. 31*	0. 44**	0. 64**
Daily activities	0.68**	0.36**	0.39	0.36**	0.45**	0.62**
Treatment	0.39**	0.35**	0.25**	0.23	0.34**	0.40**
Worry	0.52**	0.36**	0.21	0.26	0.33*	0.48**
Communication	0.32*	0.36**	0.43**	0.43**	0.50**	0.50**

*p=0.05; **p=0.01.

Concurrent validity

The PedsQL 4.0 and CHQ were compared using Pearson's correlation coefficients, as shown in Table IV. The correlation between the Physical Health Scale of the PedsQL 4.0 and the Physical Scale of the CHQ, the Psychosocial Scales of both questionnaires, and their global scores were highly significant, indicating moderate or strong relationship.

Parent-child concordance

The parent-child concordance interrelations matrix is shown in Table V. The child self-report and parent proxy-report correlation for the PedsQL 4.0 Generic Core Scales and Rheumatology Module 3.0 was significant and suggested moderate or strong relationship, with large effect sizes.

Influence of other variables on the PedsQL 4.0 and Rheumatology Module 3.0.

The aim of this analysis was to establish whether any of the main features of rheumatic disease influenced the total general PedsQL 4.0 score and summary scale scores (Physical Health Summary Score and Psychosocial Health Summary Score). The following variables were analyzed: frequency, duration and intensity of pain; chronicity of disease; type of diagnosis. One-way ANOVA was performed separately for self and proxy reports.

The frequency of pain was evaluated on 3 different levels: 0=never; 1=sometimes; 2=often. The frequency of pain significantly influenced all the scales except for the Psychosocial Health Summary Score for parent proxy-report.

Duration of pain was evaluated on 3 levels too: 0 = none; 1 = a little; 2 = a lot. The longest duration strongly influenced the summary scores of the Generic Core Scales. The only exception was represented by the Psychosocial Health Summary Score for parent proxy-report, which was the only one that did not reach the statistical significance utilizing ANOVA; post-hoc analysis revealed that the scores were discriminated according to the three different levels of pain duration.

Finally, *pain intensity* – assessed as 0 = none, 1 = a little, 2 = a lot – was consistent with the previous results. The summary scores were significant higher when the pain intensity reported by children and by parents was "none", and significant lower when it was "a little" or "a lot".

The *chronicity of the illness* was scored as: 1 = more than 1 year; 2 = less than one year. ANOVA revealed no significant difference in the global scores or summary scales (Physical and Psychosocial). Finally, the type of diagnosis was assessed to establish whether this

Table IV. Pearson's correlation coefficients between PedsQL 4.0 Generic Core Scales and Rheumatologic Module and the CHQ Scales (r<0.20 no correlation; <0.20 and 0.39> low correlation; <0.40 and 0.59> moderate correlation; <0.60 and 0.79> strong correlation; <0.80 and 1> very strong correlation).

CHQ Scales *PedsQL 4.0 (proxy report)*	Global health	Physical funct.	Role/Social limitations	Pain	Behavior	Mental health	Self-esteem	Health	Family	Physical summary scale	Psychosocial summary scale
Physical health	0.63**	0.79**	0.57**	0.69**	0.26*	0.56**	0.37**	0.48**	-0.01	0.74**	0.59**
Emotional funct.	0.36**	0.28*	0.26*	0.27*	0.22	0.39**	0.13	0.38**	0.09	0.31*	0.34**
Social funct.	0.21	0.52**	0.44**	0.34**	0.25*	0.48**	0.24	0.21	0.12	0.44**	0.42**
School funct.	0.32*	0.56**	0.48**	0.38**	0.46**	0.33*	0.06	0.26	0.05	0.52**	0.39**
Psychos. health	0.38**	0.58**	0.48**	0.43**	0.40**	0.52**	0.20	0.35**	0.13	0.54**	0.51**
Total	0.55**	0.75**	0.51**	0.61**	0.37**	0.60**	0.31*	0.46**	0.08	0.70**	0.60**
Pain and hurt	0.47**	0.68**	0.59**	0.86**	0.18	0.61**	0.29*	0.28*	-0.18	0.72**	0.57**
Daily activities	0.50**	0.53**	0.42**	0.51**	0.36**	0.40**	0.22	0.28*	-0.02	0.50**	0.44**
Treatment	0.20	0.31*	0.34**	0.30*	0.32*	0.29*	-0.02	0.16	0.01	0.30*	0.34**
Worry	0.42**	0.34*	0.41**	0.47**	0.40**	0.42**	0.17	0.44**	-0.06	0.43**	0.50**
Communication	0.27	0.26	0.01	0.28	0.33*	0.39**	0.16	0.15	0.13	0.16	0.42**

*p=0.05; ** p=0.01

variable could influence the PedsQL 4.0 total score of the Physical and Psychosocial scales. The diagnostic groups were distinguished as: systemic juvenile idiopathic arthritis (SYSJIA), polyarticular juvenile idiopathic arthritis (POLJIA), oligoarticular juvenile idiopathic arthritis (PAUJIA), spondylarthritis (SPJIA), and other rheumatic diseases (OTHERS). ANOVA revealed no differences between the groups in relation to the categories considered, in either the self-report or the proxy report (Table VI).

Absences from school

The children with rheumatic disease were absent from school more often than the healthy children.

In both groups (rheumatologic and healthy children) the number of missed days at school did not correlate with any of the global or summary scales (Physical and Psychosocial) of the PedsQL™ (ANOVA). However, the not significant correlation in the sample of children with rheumatologic diseases could have been caused by the low statistical power, given the small sample size.

Table V. Pearson's correlation coefficients between self and proxy reports in the Generic Core Scales and Rheumatologic Module (r<0.20 no correlation; <0.20 and 0.39> low correlation; <0.40 and 0.59> moderate correlation; <0.60 and 0.79> strong correlation; <0.80 and 1> very strong correlation).

Rheumatology Module 3.0	r	Generic Core Scales	r
Pain and hurt	0.80**	Physical health	0.63**
Daily activities	0.63**	Emotion funct.	0.43**
Treatment	0.54**	Social funct.	0.53**
Worry	0.37**	School funct.	0.58**
Communication	0.36**	Psychos. health	0.52**
		Total	0.58**

Table VI. One-way ANOVA comparing the different types of diagnosis in the rheumatic sample, for self and proxy reports.

PedsQL 4.0 Self-report n=51	Means					F	Sig.
	Sysjia	Poljia	Paujia	Spjia	Others		
Total	84.8	79	77.7	73.4	82.5	0.62	0.64
Physical scale	78.1	76.8	77.2	68.7	81.2	0.29	0.88
Psychosocial scale	88.3	80	77.9	75.8	83.1	0.9	0.46
PedsQL 4.0 proxy-report n=66							
Total	79.5	81.8	82.8	68.1	84	0.86	0.48
Physical scale	74.2	78.9	82.3	61.4	83.7	1.07	0.47
Psychosocial scale	82.2	83.3	83.1	72.5	84.5	0.43	0.78

Discussion

This article presents the measurement properties of the Italian version of the PedsQL 4.0 Generic Core Scales and PedsQL 3.0 Rheumatology Module in the pediatric rheumatology setting. The analyses support the reliability and validity of the PedsQL as a child self-report and parent proxy report for measuring HRQOL in the Italian population, with results generally consistent with those found using the original US English version (16). For child self-report from 5-18 year-olds and parent proxy-report from 2-18 year-olds, the internal consistency reliability generally exceeded the recommended minimum coefficient alpha of 0.70 for group comparisons. An exception was represented by the School Functioning Scale in the PedsQL 4.0 Generic Core Scales and the Daily Activities Scale in the Rheumatology Module 3.0 (only in the self-report version), both of which had lower alpha values (<0.60).

Contrary to our expectations, the construct validity calculated comparing the PedsQL 4.0 Generic Core Scales for children with rheumatic diseases versus

healthy children only reached a significant difference in the emotional dimension for both self and proxy reports. This result differs from the original US findings (16) and is also counterintuitive: in fact, the healthy children had lower QoL scores on this scale than the patients with rheumatic disease. This contradicts the evidence of a construct validity obtained using other analytical methods, *i.e.* the correlation between the global scales of the PedsQL and those of the CHQ (Physical and Psychosocial Scales) was statistically significant, indicating strong relationship. In particular, the correlation between the Physical Health Scale of the PedsQL 4.0 and the Physical Scale of the CHQ, like the Psychosocial Summary Scores of both questionnaires, was high. The same was true for the comparison between the CHQ summary (Physical and Psychosocial) Scales and the PedsQL 4.0 Total Scale – all these kinds of measures were administered only to the patients. The results on the construct validity might have been influenced by the type of patients involved in this study. The patients were attending our clinic for follow-up visits, and many of them reported no acute symptoms or exacerbations of their disease, which was in remission at that time of assessment. As emerged from the pain intensity score (0-10), 46.9% of our rheumatic children (n=31) had suffered no painful episodes in the previous month, and 80% of the whole sample scored pain between 0 and 2 (0 = no pain and 2 = mild pain). The treatment regimen was considered adequate by patients and their parents (as emerged from the clinical data collected by the physician). So the most likely explanation is that when patients were assessed, they were experiencing only little or no limitation of their daily activities and the global level of their quality of life was good.

Indirect confirmation of this post hoc hypothesis comes from the significant influence of pain on the global HRQOL of these patients: children with rheumatic diseases who reported more frequent, persistent and intense pain had lower PedsQL™ scores than the healthy children and were more often absent from school (28).

The correlation between the PedsQL 4.0 Generic Core Scales and the Rheumatology Module 3.0 was significant for both self and proxy reports (except for the worry scale in the self reports) as in the previous study of Varni (16). The inter-correlation between the PedsQL 4.0 Generic Core Scales and the PedsQL 3.0 Rheumatology Module scales is consistent with the conceptualization of disease-specific symptoms as causal indicators of HRQOL. The concordance between parents and children for the Generic Core Scales and Rheumatology Module was highly significant.

In conclusion, the Italian version of the PedsQL 4.0 and Rheumatology Module 3.0 have adequate reliability and validity, although less than the original US English version (16). Moreover, almost all the summary scales of the PedsQL 4.0 were lower when higher pain was reported during the last month.

The present study has several limitations. First of all, the sample size is small for testing the psychometric properties of an instrument. The preliminary results of this study will need to be generalized to a larger population in the context of the multi-center Italian research project. On the other hand, instrument validation is an interactive process and the PedsQL scales are currently undergoing further field tests in Italy and elsewhere in the pediatric rheumatology setting. Moreover, a limit of the present study regards the lack of comparison between the PedsQL and the Childhood Health Assessment Questionnaire (CHAQ): future studies could delve into this matter especially to establish the relationship between CHAQ and rheumatologic module. Finally, administering the questionnaires to children with rheumatic during an acute phase could well produce different conclusions from those emerging from our sample of children with disease remission.

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