

RESEARCH COMMUNICATION

Turkish Validity and Reliability of a Pediatric Quality of Life Cancer Module for Children Aged 8-12 and Parents

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Abstract

This descriptive study was conducted to determine the validity and reliability in Turkey of the Pediatric Quality of Life Inventory Cancer Module (PedsQL 3.0) for children aged 8-12 in the hematology-oncology polyclinics of two university hospitals in Istanbul during the period 2006-2007. The data collection instruments were the Pediatric Quality of Life Inventory (PedsQL 4.0), the Pediatric Quality of Life Inventory Cancer Module (PedsQL 3.0) and a socio-demographic questionnaire, applied for 146 children diagnosed with cancer and 146 parents. Cronbach's alpha coefficients for the PedsQL 3.0 were found to be 0.602-0.982 for sub-groups with the children's form, 0.644-0.966 with the parents' form. The scale was found to give a significantly high level of reliability ($0.60 \leq \alpha < 0.80$). Significant and directly proportional correlations were demonstrated between the forms for children and parents. It was concluded that the PedsQL 3.0 cancer module is a valid and reliable tool for assessing the quality of life of Turkish children, aged 8-12, diagnosed with cancer.

Keywords: PedsQL 3.0 cancer module - quality of life - children diagnosed with cancer

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Introduction

Quality of life comprises such components as satisfaction with life, individual wellness, happiness, functional adequacy and social wellbeing (Varni et al., 2001; Varni et al., 2002a). At the same time, the concept also indicates how individuals react to the physical, mental and social conditions of their daily life and to the illnesses that may have an impact on the personal satisfaction they could derive within the context of their life circumstances (Varni et al., 2001).

Measuring an individual's quality of life with psychological testing tools, determining the extent of quality of life in patients before and after therapy, assessing the effectiveness of medical interventions and evaluating side effects are all important in terms of medical research and in providing guidance in the formulation of health policies (Tazaki et al., 1998; Eiser and Morse, 2001).

Although evaluations of the quality of life in children were initially at simplified levels, these methods pioneered the way for the development of general and disease-specific scales. A review of pediatric quality of life scales (QLS) shows that these can be assessed in two separate groups-those that have been developed for a specific disease and those that measure general levels of wellbeing (Eiser and Morse, 2001; Aydın Demirağ, 2009). The use of QLS for specific illnesses is beneficial in comparing different methods of therapy, evaluating approaches to

treatment and contrasting the effectiveness of different therapies and side effects (Eiser, 1997).

The objective of the present study was to inquire into the validity and reliability of one of the health-related quality of life scales frequently used for children and adults in other countries, the Pediatric Quality of Life Inventory Cancer Module (PedsQL 3.0), and to test whether the module's forms for children aged 8-12 and parents, could be used in Turkey for Turkish children diagnosed with cancer.

Materials and Methods

Sampling and Population

The study was conducted over the period September 2006-December 2007 in the hematology-oncology polyclinics of two university hospitals in Istanbul. The scope of the research involved a group of 146 children, aged 8-12, diagnosed with cancer, and 146 parents. The recruitment criteria for the children in the study were determined as: being between the ages of 8-12, having been diagnosed with cancer at least six months prior to the study, willingness to participate, and exhibiting no problems with sight, hearing or mental perception. Parents were asked to sign informed consent forms after they and their children were provided with information about the study. It is emphasized that an adequate number of samples should be used in scale studies to facilitate factor analysis,

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the reservation being stated that correlation coefficients derived from validity-reliability studies conducted with small samples are less reliable. Having at least five or even ten times more variables than sample size, it is said, will increase validity (Tavşancıl, 2005). It was for this reason that in the present study, samples were not used but rather, all of the children and their parents willing to participate who presented for check-ups at the polyclinic at the time of the study were recruited into the research.

Data collection tools

Three data forms were used for data collection in the study: the Socio-demographic Questionnaire, the Pediatric Quality of Life Inventory (PedsQL 4.0) and the Pediatric Quality of Life Inventory Cancer Module (PedsQL 3.0).

Socio-demographic questionnaire

The information sheet for the children in the study was prepared by the researchers on the basis of the current literature (Hicks et al., 2003) and consisted of 25 questions about the children's demographic characteristics and medical history. Another form was prepared by the researchers, again on the basis of the current literature, and was devised to collect information on the parents and the family (Hockenberry and Wilson, 2007). This form was made up of 17 questions that probed the socio-demographic characteristics of the family.

Pediatric Quality of Life Inventory (PedsQL 4.0)

The PedsQL 4.0 is a quality of life inventory that was developed by Varni et al in 1999 to measure health-related quality of life in children and adolescents, aged 2-18. The scale queries the areas of physical functioning, emotional functioning and social functioning, which are the characteristics defined by the World Health Organization as components of the state of wellness. The scale also assesses academic functioning. Scores are calculated in three areas. A calculation is first made of the scale's total score (STS), then a total score is found (PFTS) for physical functioning. Thirdly, emotional, social and school functioning scores (ESSFS) are calculated to find the total psycho-social functioning score (PSFTS) (Varni et al., 2001). PedsQL, one of the inventories for assessment of general quality of life, is a 23-item scale that is suitable for application both in the case of healthy children and adolescents and in those with a health condition, across large populations such as schools and hospitals. In the inquiry into the internal consistency reliability of PedsQL, the Cronbach alpha coefficient value was found to be 0.93; construct and clinical validity were also assessed (Varni et al., 1999; Eiser et al., 2000). Internal consistency of PedsQL was found to be high, and many studies have affirmed the validity, reliability and sensitivity of the scale (Varni et al., 1999; Varni et al., 2001; Varni et al., 2002b; Varni et al., 2003; Varni et al., 2006).

The validity and reliability of PedsQL 4.0 in Turkey was tested in the 8-12 age group by Sönmez and Başbakkal (2004). These researchers found Cronbach's Alpha coefficients for the 8-12 age group to be 0.78 (children's form) and 0.83 (family form) (Varni et al., 1998; Üneri and Memik Çakın, 2007). The Cronbach Alpha values in

this study (Cronbach's Alpha: 0.881 in children's form; 0.884 in parents' form) are consistent with those revealed in other studies.

Pediatric Quality of Life Inventory Cancer Module (PedsQL 3.0)

Before beginning to test the validity and reliability of the scale in Turkey, contact was established with the creator of the scale, James Varni, from whom permission was obtained to use the instrument in Turkey. The letter received was presented to the board of ethics and approved.

The PedsQL 3.0 cancer module was developed and tested for validity and reliability by Varni et al in 2001. This module is a multidimensional inventory that encompasses a total of 27 items on 1-pain and hurt (2 items), 2-nausea (5 items), 3-procedural anxiety (3 items), 4-treatment anxiety (3 items), 5-worry (3 items), 6-cognitive problems (5 items), 7-perceived physical appearance (3 items) and 8-communication (3 items). The format, instructions, likert response options and scoring method are similar to the Pediatric Quality of Life Inventory 4.0. The inventory comprises two parallel forms for Children and for the Family. The inventory is based on a five-response likert system where the answers asked are marked as 0 = Never a problem, 1= Almost never a problem, 2= Sometimes a problem, 3= Often a problem and 4= Almost always a problem. The items are scored between 0-100 (0: 100, 1:75, 2:50, 3:25, 4:0).

Internal consistency reliability in both the children's and the parent forms in the original scale were found to be 0.91-0.92. The PedsQL 3.0 cancer module was also found to have excellent internal consistency reliability and clinical validity. The PedsQL 3.0 cancer module was developed on the basis of pediatric cancer research and clinical practices (Erefe, 2002).

A pilot application of the PedsQL 3.0 cancer module was conducted in Turkey with 10 children and 10 parents. After the pilot application and consultation with experts, the research team made revisions in some of the statements in line with the suggestions that were made to improve the way the statements were expressed. When corrections were completed, the inventory was printed and the actual study began. Only one implementation was conducted in determining the validity and reliability of the inventory.

Data analysis

Windows SPSS 11.5 (Statistical Package for Social Sciences) was used for the statistical evaluation of the data. Besides descriptive statistical methods (means, standard deviation), mean comparisons of quantitative data were made by using the one-way Anova for more than two groups and the Student t-test for comparisons of two groups. The Cronbach Alpha Reliability Coefficient was used in the reliability analyses of the internal consistency assessment of the scale and its sub-scales. A 95% reliability interval was found, with significance found to be $p \leq 0.05$.

Ethical approach

Permission for the study was obtained from the

ethics boards as well as from the hematology/oncology departments of the two university hospitals (Reg. No. 2006-0091 and Reg. No. 2006-18108) where the research was to take place. Subsequently, the purpose of the study and information about the methodology was explained to the doctors, nurses and other healthcare professionals working at the departments concerned and their cooperation was requested. The children and their parents were informed about the purpose, plan and benefits of the research and then asked to sign a patient informed consent form. The study started after the children and parents wishing to participate in the study had signed the consent forms.

Results

The children in the study were between the ages of 8-12, their mean age standing at 10.11 ± 1.53 years. Of the children, 41.8% (n=61) were girls and 58.2% (n=85) were boys. As far as school status was concerned, all of the children were attending school and their class distribution indicated that 6.2% were in the first grade of primary school, 16.4% in second grade, 23.3% in third grade, 9.6% in fourth grade, 14.4% in 5th grade while another 30.1% were in the first year of middle school. An analysis of family socio-demographic characteristics showed that the mean age of mothers was 37.06 ± 5.41 years while fathers were age 39.26 ± 5.93 . It was established that 39.0% (n=57) of the mothers and 47.3% (n=69) of the fathers were high school graduates.

Validity Findings

a) Language Validity: In the first step of the adaptation of the inventory, the scale was translated from English into Turkish by two individuals, independent of each other, one an independent translator and the other a teaching assistant in anesthesiology and reanimation. After the most effectively expressed statements were chosen for the items on the scale, the translation was back translated and then turned into the final Turkish language version by an English language specialist and three specialists in their fields who were native Turkish speakers fluent in both languages but who had not seen the English version of the scale.

b) Content Validity: To evaluate the face and content validity and reliability of the Turkish version of the scale items, 15 specialists in different fields were consulted. For the numerical assessment of content validity, the Content Validity Index developed by Waltz and Bausell was used as an example, after which the researchers prepared gradation criteria which they submitted to the consultants (Erefe, 2002; Gözümlü and Aksayan, 2003; LoBiondo-Wood and Haber, 2006). Changes were made in line with the recommendations of the specialists and the questionnaire was given its final form.

When a statistical analysis was made of the data that was collected with the help of the specialists, the Content Validity Index (CVI) for the Pediatric Quality of Life Inventory Cancer Module (PedsQL 3.0) was found to demonstrate the high value of minimum 73%.

Table 1. Cronbach's Alpha Coefficients for the PedsQL 3.0 Cancer Module

Sub-Scales of the Scale	Children's Form	Parent Form
	Cronbach's Alpha Coefficient	Cronbach's Alpha Coefficient
Pain and Hurt	0.731	0.721
Nausea	0.843	0.879
Procedural anxiety	0.921	0.910
Treatment anxiety	0.982	0.966
Worry	0.795	0.834
Cognitive problems	0.789	0.758
Perceived physical appearance	0.602	0.644
Communication	0.915	0.959

The items close to the lower boundary of 70% determined by the researchers were examined in the light of the remarks of the specialists and the necessary adaptations were made to achieve content validity.

c) Construct Validity: Factor Analysis: It has been accepted that a reliability coefficient of .70 and higher is adequate for scales of this kind (Büyükoztürk, 2002; Özdamar, 2004). The variance for the 8 factors in the scale was calculated to be 77.04%; variance for scales is considered adequate at 30% or over. The higher variance points to a successful measurement in terms of concept and construct (Büyükoztürk, 2002).

The results of the factor analysis of the PedsQL 3.0 Cancer Module determined that the eigen value of all eight factors was greater than five factors explained 10% or more of the variance; the remaining three factors explained 6% or more. The cumulative variance representing all of the factors indicates that the eight variables together explain 77.05% of the variance. The total variance explained in the present study was at a good level.

Reliability-related Findings: The reliability of the scale was assessed using the Cronbach alpha internal consistency coefficient. Cronbach's Alpha coefficient values were in the range of 0.602-0.982 for the children's sub-scales and 0.644-0.966 in the parent form, both excellent levels of reliability (Table 1).

Findings on Scale Comparisons for Pediatric Socio-demographic characteristics

When the PedsQL 3.0 Cancer Module and the PedsQL 4.0 mean scores were compared by gender, the sub-scales on the PedsQL 3.0 cancer module of pain and hurt, nausea, procedural anxiety, treatment anxiety, worry, cognitive problems, perceived physical appearance and communication scores did not show statistically significant differences between the genders ($p > 0.05$). The PedsQL 4.0 sub-scale scores as well did not show significant differences across the factors of physical functioning, emotional functioning, school-related problems and total scores according to gender ($p > 0.05$). However, the social functioning score was found to be significantly lower in girls ($p < 0.05$) (Table 2).

When the PedsQL 3.0 Cancer Module and the PedsQL 4.0 mean scores were compared by age, the sub-scales on the PedsQL 3.0 cancer module of pain and hurt, nausea, treatment anxiety, cognitive problems, perceived

Table 2. Comparison of Mean Scores in the PedsQL 3.0 Cancer Module and PedsQL 4.0 by Children's Gender (N=146)

Measurement areas	Gender		Testing value: p:
	Girls	Boys	
PedsQL 3.0	$\bar{X} \pm SD$	$\bar{X} \pm SD$	
Pain and hurt	73.77±24.86	76.02±20.70	t:-0.597; p:0.551
Nausea	71.31±20.63	69.88±23.40	t:0.382; p:0.703
Procedural anxiety	37.97±31.67	34.21±31.75	t:0.707; p:0.481
Treatment anxiety	62.15±33.76	62.15±34.37	t:0.000; p:1.000
Worry	89.07±20.66	85.49±20.97	t:1.024; p:0.308
Cognitive problems	73.52±20.25	69.05±21.02	t:1.285; p:0.201
Perceived physical appearance	64.07±22.69	61.27±25.18	t:0.689; p:0.492
Communication	66.39±33.74	62.74±33.02	t:0.652; p:0.515
PedsQL 4.0			
Physical functioning	49.69±24.41	52.94±23.84	t:-0.804; p:0.423
Emotional functioning	67.70±21.72	69.17±21.69	t:-0.404; p:0.687
Social functioning	85.00±13.72	78.47±19.08	t:2.281; p:0.024*
School-related problems	62.86±18.69	57.00±19.65	t:1.816; p:0.072
Total score	71.85±13.54	68.21±14.95	t:1.509; p:0.133

t: Student t test; *p<0.05

physical appearance and communication scores did not show statistically significant differences across the age distribution (p>0.05). There was, however, a significant difference in procedural anxiety across the different ages (p<0.05). The older a child was, the higher were the procedural anxiety scores. Procedural anxiety scores in the 8-12 age groups were found to be significant. Similarly, worry scores also exhibited a significant difference across the ages (p<0.01); as age increased, worry scores decreased. The scores in this item of 8 year-olds were significantly higher than those of 11 year-olds. The PedsQL 4.0 sub-scale scores did not show significant differences across ages in terms of physical functioning,

emotional functioning, social functioning, school-related problems and total points (p>0.05).

When the PedsQL 3.0 Cancer Module and the PedsQL 4.0 mean scores were compared by children's school status, the scores on the PedsQL 3.0 cancer module for pain and discomfort, nausea, therapy anxiety, worry, and perceived body image did not show significant differences in terms of school status (p>0.05). Procedural anxiety scores, however, exhibited significant differences according to school status (p<0.01). Procedural anxiety points rose as the school grade increased and it was established that the procedural anxiety scores of primary school first-grade children were significantly lower than in all the other grades. The procedural anxiety scores of middle school first-year students were found to be significantly higher than in all of the other classes. The score for cognitive problems also showed significant differences according to school status (p<0.05). While the scores for cognitive problems were found to be significantly higher in the case of primary school fourth-grade students, there was no other significant difference across the other grades. Communication scores were also found to show significant differences according to class status (p<0.05). The communication scores of primary school first-graders were seen to be significantly lower than the other classes. The PedsQL 4.0 sub-scale scores do not show statistically significant differences in terms of physical functioning, emotional functioning, social functioning, school-related problems and total points across the different classes (p>0.05).

Examining the correlation of the PedsQL 3.0 Cancer Module Children's Form with the sub-scale scores of PedsQL 4.0 showed that there was a positive and highly significant correlation between the physical functioning scores and the pain and hurt scores in the PedsQL 4.0 (p<0.01). Again, there was also a highly significant correlation observed between these scores and nausea scores (p<0.01). No significant correlation was seen between procedural anxiety scores and therapy anxiety or perceived physical appearance scores (p>0.05). There was, however, a positive statistically significant correlation, albeit a weak one, with worry scores (p<0.05). While another positive significant correlation was found in terms of cognitive problems (p<0.01), the correlation with communication scores was weak (p<0.05). Emotional functioning scores on the PedsQL

Table 3. Correlation Between Sub-scale Scores of the PedsQL 3.0 Cancer Module Children's Form and PedsQL 4.0 Correlation (N=146)

PedsQL 3.0 Cancer Module	PedsQL 4.0									
	Physical functioning		Emotional unctoning		Social functioning		School-related problems		Total score	
	r	p	r	p	r	p	r	p	R	P
Pain and hurt	0.643	0.001**	0.394	0.001**	0.181	0.028*	0.260	0.002**	0.385	0.001**
Nausea	0.532	0.001**	0.393	0.001**	0.167	0.044*	0.347	0.001**	0.419	0.001**
Procedural anxiety	0.141	0.090	0.199	0.016*	0.087	0.294	0.069	0.408	0.165	0.046*
Treatment anxiety	0.115	0.166	0.239	0.004**	0.104	0.214	0.142	0.086	0.225	0.006**
Worry	0.192	0.020*	0.341	0.001**	0.308	0.001**	0.159	0.055	0.365	0.001**
Cognitive problems	0.292	0.001**	0.347	0.001**	0.377	0.001**	0.517	0.001**	0.556	0.001**
Perceived physical appearance	0.140	0.093	0.292	0.001**	0.290	0.001**	0.158	0.058	0.332	0.001**
Communication	0.177	0.033*	0.206	0.013*	0.138	0.097	0.048	0.567	0.179	0.031*

r: Pearson correlation coefficient; *p<0.05; **p<0.01

4.0 were found to have a positive and strong significant correlation with pain and discomfort scores ($p < 0.01$); the same positive strong correlation was also seen with nausea scores ($p < 0.01$). There was, however a significant positive but weak correlation with procedural anxiety ($p < 0.05$). The correlation with therapy anxiety scores was significant but moderately positive ($p < 0.01$). There was a statistically significant positive correlation between worry scores and scores for cognitive problems and perceived physical appearance ($p < 0.01$); a moderately significant correlation was seen with communication scores ($p < 0.05$). A significantly positive but weak correlation was seen between the social functioning scores on the PedsQL 4.0 and the scores for pain and hurt and nausea ($p < 0.05$). Scores for functional anxiety did not show a statistically significant correlation in terms of treatment anxiety and communication ($p > 0.05$). There was a very strong significant correlation between worry scores and the scores for cognitive problems and perceived physical appearance ($p < 0.01$). School-related scores on the PedsQL 4.0 showed a very strong positive correlation with pain and hurt scores ($p < 0.01$); another very strong positive correlation was observed with nausea scores ($p < 0.01$). A significant correlation was seen between school-related problem scores and the scores for emotional anxiety, treatment anxiety, worry, perceived physical appearance and communication ($p > 0.05$). There was a strong positive correlation with scores for cognitive problems ($p < 0.01$). The PedsQL 4.0 total score reflected a significantly positive and very strong correlation with the pain and hurt scores ($p < 0.01$); another positive and very strong significant correlation with nausea points was observed ($p < 0.01$). A positively significant, albeit weak, correlation was seen with procedural anxiety ($p < 0.05$); a positive but moderately significant correlation was found in terms of treatment anxiety scores ($p < 0.01$). A positively significant correlation was seen in terms of worry, cognitive problems and perceived physical appearance scores ($p < 0.01$); There was a moderately significant correlation with communication scores ($p < 0.05$) (Table 3).

Discussion

Studies accept that the Cronbach's Alpha internal consistency coefficient value range of .60-.80 is an indication of excellent reliability (Çavuşoğlu, 2002; Tavşancıl, 2005). In the present study, the internal consistency analysis found Cronbach's Alpha coefficient to be in the range of 0.602-0.982 for the sub-scales in the children's questionnaire and 0.644-0.966 in the parents' questionnaire, both ranges indicating a high level of reliability.

The Cronbach's Alpha values found in the study were considerably close to those found in the original study (0.91-0.92) and higher than in the PedsQL 4.0 used in healthy children. It can be said then in this context that the PedsQL 3.0 Cancer Module is significantly comprehensive and effective as a tool to measure the quality of life level of Turkish children with cancer.

No statistically significant differences were found in the sub-scales of the PedsQL 3.0 cancer model in

terms of gender differences. The PedsQL 4.0 sub-scale scores showed only that social functioning scores were significantly lower in girls ($p < 0.05$). Restricted activity, social isolation and depression are factors that may develop in children with chronic ailments (Çavuşoğlu, 2002). It may be suggested that this is the cause of the lower quality of life scores in this area.

Looking into the impact of age on quality of life showed that as children's ages increased, scores for the sub-scales of pain and hurt, treatment anxiety, cognitive problems, perceived physical appearance and worry in the PedsQL 3.0 cancer module dropped. The study of Sitaremsi et al (2008) reported that the PedsQL 3.0 cancer module sub-scales of treatment anxiety, procedural anxiety and communication revealed lower scores the younger the child. It can be said that there is more tolerance toward the painful procedures experienced in cancer therapy as children get older.

While the one-way ANOVA test revealed that the scores in the PedsQL 3.0 cancer module sub-scales of pain and hurt, nausea, treatment anxiety, worry and perceived physical appearance did not show significant differences according to the school status of children ($p > 0.05$), there were significant differences across the school grades in terms of procedural anxiety scores ($p < 0.01$). It was seen that procedural anxiety scores increased as grade status grew. It was determined that the procedural anxiety scores of primary school first-grade students were significantly lower than in all the other classes. By the same token, the procedural anxiety scores of middle school first-year students were significantly higher than in all the other classes. The scores for cognitive problems also showed significant differences in terms of class status ($p < 0.05$); while the cognitive problems scores of primary school 4th grade students were significantly higher than primary school first-grade students, there were no significant differences in this item between other classes. The communication scores also showed significant differences across school classes ($p < 0.05$); the communication scores of primary school first-grade students were significantly lower than those of the students in the other classes. The result is thus similar to the result obtained in terms of age.

The sub-scales of the PedsQL 3.0 cancer module were examined in terms of a correlation with the sub-scales of the PedsQL 4.0 scale and a significant positive correlation was found (see Table 3). The study by Scarpelli et al (2008) also revealed a similar correlation between the sub-scales of the two instruments.

The results of the study conducted to establish the extent of validity and reliability of the Turkish version of the PedsQL 3.0 cancer module, used to assess the quality of life of children with cancer, indicated that the Turkish version of the scale questionnaire was valid and reliable. It is recommended that more studies be carried out to implement the scale in wider populations across different group samples.

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