




The Reliability of the Thai version of Health-Related Quality of Life Questionnaire: PedsQL 3.0 Cancer Module

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Abstract

Assessing the health-related quality of life (HRQOL) is highly recommended as a standard of care for children with cancer in conjunction with medical treatment. The Pediatric Quality of Life Inventory (PedsQL) Cancer Module is a standard tool designed to assess the HRQOL among pediatric oncology patients. This study aimed to evaluate the reliability and correlation of the PedsQL 3.0 Cancer Module in Thai version between child and parent reports. A cross-sectional study was conducted on 85 Thai children with cancer and their families. Excellent internal consistency of the PedsQL 3.0 Cancer Module of the Thai version was addressed among child and parent reports (0.92 and 0.94, respectively). Overall positive correlations were also found between child and parent reports ($r=0.61$, $P<.001$). However, the statistically significant differences of HRQOL scores between child and parent reports were determined on procedural anxiety (70.05 ± 26.67 vs 60.03 ± 25.6 , $P=.003$), treatment anxiety (88.15 ± 17.37 vs 76.82 ± 26.7 , $P=.001$), worry (66.67 ± 25.59 vs 55.34 ± 30.37 , $P=.003$) and the total score (74.37 ± 15.7 vs 70.42 ± 17.15 , $P=.034$). This study demonstrated desirable internal reliability with positive correlations between child and parent reports of the PedsQL 3.0 Cancer Module in Thai version, although possible differences between child and parent HRQOL scores should be considered.

Keywords

children with cancer, parent, health-related quality of life, Pediatric Quality of Life Inventory, reliability

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Introduction

The outcomes of children with cancer have improved over time. In Thailand, the 5-year overall survival for all childhood cancers significantly improved from 39.4% during 1990 to 2000 to 47.2% during 2001 to 2011.¹ Although childhood cancer mortality rates have declined due to advancing treatment, childhood cancer remains a leading cause of death among children and adolescents. Children with cancer always encounter physical and mental distress. These unpleasant experiences lower the patient's quality of life (QOL).² Therefore, the assessment of the health-related quality of life (HRQOL) is highly recommended as a standard of care for children with cancer in conjunction with medical treatment since firstly diagnosed through after the end of therapy.²

The HRQOL evaluation includes physical and psychosocial functional assessment,³ which is defined as “how well a person functions in their life and their

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perception in physical, mental, and social domains of health” or “self-perceived well-being that is related to or affected by the presence of disease or treatment.”⁴

The HRQOL instruments among children are employed from both patient self- and parent reports because of potential differences in their perspectives of functioning observations, cognitive development of the child, or patient statuses that might not be suited to complete an HRQOL instrument.^{5,6} Strong correlations between patient and parent reports have been addressed in domains reflecting external behaviors, such as physical functioning, while a fair correlation have been constituted in domains reflecting internal behaviors such as emotional, perception and social functioning as well as unpleasant symptoms.⁷ Therefore, disease-specific HRQOL instruments are needed to address a specific condition with a particular illness, and the impact of treatment on the patients’ QOL. Appropriate HRQOL assessment must possess clinical relevance and provide the most benefits to the specific patients and families.⁵

Nevertheless, assessments can be applied at a specific time point or further longitudinal assessment as a follow-up.⁵ Patients’ HRQOL recognition may lead to modifying and adapting treatment strategies according to the patients’ HRQOL.⁸

The Pediatric Quality of Life Inventory (PedsQL) is a modular instrumental questionnaire, combining generic and disease-specific measurements, and includes patient and parent reports.⁹ The PedsQL Cancer Module was designed to assess the HRQOL among children and adolescents with cancer aged 2 to 21 years, which has been widely used and translated in several languages.^{10,11} However, the PedsQL Cancer Module has not been previously conducted using the Thai version.

A recent report addressed the acceptable internal consistency reliability of the English version of the PedsQL 3.0 Cancer Module with an average Cronbach’s α of 0.72 and 0.87 for the child and parent reports, respectively.³ Therefore, this study aimed to demonstrate the psychometric analysis and reliability of the PedsQL 3.0 Cancer Module in the Thai version. The results would establish the standard instrumental questionnaire to evaluate HRQOL for Thai children with cancer.

Methods

Participants

Eighty-five children with cancer and their families treated primarily at the Division of Hematology-Oncology, Department of Pediatrics, Phramongkutklao Hospital from May 1, 2018 to November 30, 2019, were eligible for this study. Written informed consent and

assent forms to participate in the study were obtained from all participants including children aged ≥ 8 years as well as their parents or legal guardians before engaging in the study.

This study was approved by the Institutional Review Board, Royal Thai Army Medical Department according to the ethics principles of the Declaration of Helsinki (1964) and its revision (reference number: IRBRTA 700/2561). The study was also registered and approved by the Thai Clinical Trials Registry (TCTR <https://www.thaiclinicaltrials.org/>), number TCTR20200904001.

The study’s inclusion criteria included all pediatric oncology patients aged 2 to 18 years and their parents. Exclusion criteria included patients with a terminal illness or in palliative care, developmental disorder, intellectual disability, learning disorder, or illiterate.

Instrument

The PedsQL 3.0 Cancer Module was designed to evaluate the QOL among children and young adults with cancer aged 2 to 25 years, including both child and parent reports. The PedsQL 3.0 Cancer Module has been categorized in different age groups in 2 parallel versions: child (5-7, 8-12, 13-18, and 18-25 years) and parent (2-4, 5-7, 8-12, 13-18, and 18-25 years) reports. The PedsQL 3.0 Cancer Module consists of eight domains in 27 items covered by 5 scales: (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). A 5-point Likert scale ranges from 0=never, 1=almost never, 2=sometimes, 3=often and 4=almost always, except for the 5 to 7 years of child reports employing a 3-point Likert scale (0=never, 2=sometimes, 4=almost always) combined using with a visual aid (0=happy face, 2=neutral face and 4=sad face). The score in each item was reverse-scored and linearly transformed to a 0 to 100 scale (0=100, 1=75, 2=50, 3=25, 4=0). Scores were calculated as the sum of the items divided by the number of items answered. Higher scores indicated better HRQOL.

Procedures

After translation agreement approval was obtained from the Mapi Research Trust, a non-profit organization authorized on behalf of Dr. James W. Varni, the owner of the original version of the PedsQL 3.0 Cancer Module, the questionnaires were translated to Thai under a full linguistic validation process.¹² The forward translation was performed by 2 clinicians. Then backward translation to English was performed by an

expert linguist and subsequently reviewed by these 2 clinicians. The cognitive interviews were applied among 5 patients and families in each single age group to ensure the questionnaire's comprehension. After the full process, the Mapi Research Trust approved the use of the Thai version of the PedsQL 3.0 Cancer Module for academic purposes.

After informed consent and assent were obtained, participating patients and/or their parents completed the Thai version of the PedsQL 3.0 Cancer Module. For participating patients aged 2 to 4 years, only parents filled out the questionnaires. For participating patients aged >5 years, parents and children filled out the questionnaires separately. Children aged 5 to 7 years, filled out the questionnaires with assistance from a research nurse for ensuring reading competency and clarifying each question. Children aged 8 to 18 years obtained the questionnaires independently, or with support from the research nurse as needed.

Statistical Analysis

Demographic data were analyzed using descriptive statistics and presented as mean with standard deviation (SD) for continuous variables and demonstrated as frequency and percentage for categorical variables. Reliability was determined by internal consistency using Cronbach's coefficient alpha. Reliability of ≥ 0.70 was considered acceptable. Pearson correlation coefficients were used to assess the correlation between child and parent reports. A paired-samples *t*-test was conducted to evaluate the differences between HRQOL scores of the child and parent reports for each domain of the PedsQL 3.0 Cancer Module. Statistical analysis was performed using IBM SPSS Software for Windows, Version 23.0 (Armonk, NY: IBM Corp., USA), and a *P*-value $< .05$ was considered statistically significant.

Results

Patient Characteristics

A total of 85 children with cancer and their families were eligible and participated in this study. Patient characteristics including age, sex, diagnosis, disease status, treatment status, and household incomes are summarized in Table 1.

Among 85 pediatric oncology patients, the overall mean age was 10.82 ± 5.48 years. The male to female ratio was 1.4:1 and the most common cancer types included acute lymphoblastic leukemia, brain or central nervous system tumors, osteosarcoma and neuroblastoma, in rank.

Table 1. Patient Demographic Data (n=85).

	N (%)
Age (years)	
Mean \pm SD	10.82 \pm 5.48
Gender	
Male	50 (58.8)
Female	35 (41.2)
Diagnosis	
Hematologic malignancy	48 (56.5)
Acute lymphoblastic leukemia	32 (66.7)
Chronic myeloid leukemia	5 (10.4)
Non-Hodgkin lymphoma	4 (8.3)
Acute myeloid leukemia	3 (6.3)
Hodgkin lymphoma	1 (2.1)
Others	3 (6.3)
Solid tumors	37 (43.5)
Brain/central nervous system tumor	13 (15.3)
Osteosarcoma	10 (27)
Neuroblastoma	9 (24.3)
Wilms tumor	1 (2.7)
Hepatoblastoma	1 (2.7)
Rhabdomyosarcoma	1 (2.7)
Ewing sarcoma	1 (2.7)
Retinoblastoma	1 (2.7)
Disease status	
Newly diagnosed	60 (70.6)
Relapse/refractory	6 (7)
Remission of disease	19 (22.4)
Treatment status	
During treatment	66 (77.6)
Completed treatment	19 (22.4)
Household incomes (THB/month)	
< 15 000	33 (38.8)
15 000-30 000	20 (23.5)
> 30 000	32 (37.6)

Data are presented as mean \pm SD for continuous variables and number (%) for categorical variables.

Abbreviations: SD, standard deviation, THB, Thai baht.

In all, 66 (77.6%) patients were in the treatment process; 60 (70.6%) patients received a recent diagnosis and 6 (7%) patients experienced a relapse or refractory diseases. Nineteen (22.4%) patients had disease remission.

Regarding family income status, most patients' families (n=33, 38.8%) had household incomes less than 15 000 Thai baht monthly.

Feasibility

All questionnaires were completed with no missing data in both child and parent reports. According to the pilot

Table 2. Cronbach's Coefficient Alpha Values for PedsQL 3.0 Cancer Module Among Child and Parent Reports.

PedsQL 3.0 cancer module	Child reports (n = 65)	Parent reports (n = 85)
Pain and hurt	0.83	0.82
Nausea	0.78	0.84
Procedural anxiety	0.94	0.91
Treatment anxiety	0.90	0.95
Worry	0.85	0.92
Cognitive problems	0.77	0.82
Perceived physical appearance	0.87	0.89
Communication	0.86	0.82
Total score	0.92	0.94

Reliability was determined by internal consistency using Cronbach's coefficient alpha. Reliability of ≥ 0.70 was considered acceptable. Abbreviation, PedsQL, The Pediatric Quality of Life Inventory.

testing in 5 patients and families in each age group, the time spent to complete the questionnaires took approximately 5 to 15 minutes.

Internal Consistency

In total, 85 parent and 65 child reports constituted the data source in this study. The Cronbach's coefficient alpha of the total scores, including all age groups, was desirable among the child and parent reports (0.92 and 0.94, respectively). For child reports, the highest reliability value was found in the procedural anxiety domain. However, nausea and cognitive problems domains had lower reliability. Meanwhile, for the parent reports, the highest reliability value was found in the treatment anxiety domain. Otherwise, all domains in parent reports indicated favorable reliability (Table 2).

Correlation Between Child and Parent Reports

In all, the significant positive correlation for the total score of the PedsQL 3.0 Cancer Module between child and parent reports was addressed ($r=0.61$) at $P < .001$. In addition, the nausea domain employed the highest correlation ($r=0.67$), while the cognitive problems domain demonstrated the lowest correlation between child and parent reports with $P < .001$ (Table 3).

Agreement Between Child and Parent Reports

In all, the highest HRQOL scores of the PedsQL 3.0 Cancer Module in child reports were observed in the treatment anxiety domain (88.15 ± 17.37), while the highest HRQOL scores in parent reports were detected

Table 3. Correlation Between Child and Parent Reports of the PedsQL 3.0 Cancer Module.

PedsQL 3.0 Cancer Module	<i>r</i>	<i>P</i> -value
Pain and hurt	0.538	<.001
Nausea	0.670	<.001
Procedural anxiety	0.513	<.001
Treatment anxiety	0.425	<.001
Worry	0.481	<.001
Cognitive problems	0.354	<.001
Perceived physical appearance	0.486	<.001
Communication	0.478	<.001
Total score	0.610	<.001

The correlation between child and parent reports were calculated using Pearson correlation coefficients. $P < .05$ is considered as statistical significance.

Abbreviation: PedsQL, The Pediatric Quality of Life Inventory.

in the nausea domain (78.98 ± 18.99). In contrast, the lowest HRQOL scores in child reports were observed in the cognitive problems domain (66.31 ± 22.26), while the lowest HRQOL scores in parent reports were detected in the worry domain (55.34 ± 30.37) (Table 4).

Children with cancer reported higher HRQOL scores of the PedsQL 3.0 Cancer Module in total score and all domains, except for the perceived physical appearance and communication domains, compared with parent reports. However, the statistically significant differences between child and parent reports were determined on the procedural anxiety (70.05 ± 26.67 vs 60.03 ± 25.6 , $P=.003$), treatment anxiety (88.15 ± 17.37 vs 76.82 ± 26.7 , $P=.001$), worry (66.67 ± 25.59 vs 55.34 ± 30.37 , $p=0.003$) and total score (74.37 ± 15.7 vs 70.42 ± 17.15 , $P=.034$). The differences in HRQOL scores between children and parents are summarized in Table 4.

Table 4. Differences in Health-Related Quality of Life Scores of the PedsQL 3.0 Cancer Module Between Children and Parents.

PedsQL 3.0 Cancer Module	Parent reports (n = 85)	Child reports (n = 65)	P-value
	Mean ± SD	Mean ± SD	
Pain and hurt	76.95 ± 21.5	79.3 ± 22.85	.383
Nausea	78.98 ± 18.99	79.77 ± 19.05	.687
Procedural anxiety	60.03 ± 25.6	70.05 ± 26.67	.003
Treatment anxiety	76.82 ± 26.7	88.15 ± 17.37	.001
Worry	55.34 ± 30.37	66.67 ± 25.59	.003
Cognitive problems	64.26 ± 20.94	66.31 ± 22.26	.507
Perceived physical appearance	76.17 ± 24.97	73.83 ± 24.62	.458
Communication	73.31 ± 23.2	71.61 ± 25.32	.588
Total score	70.42 ± 17.15	74.37 ± 15.7	.034

The differences in health-related quality of life scores of the PedsQL 3.0 Cancer Module between child and parent reports were calculated using paired samples t-test. $P < .05$ is considered as statistical significance. Abbreviation: PedsQL, The Pediatric Quality of Life Inventory.

Discussion

HRQOL assessment has become a priority in pediatric oncology treatment and comprehensive care, to achieve excellent patient-centered outcomes.¹³ Moreover, patient HRQOL is a fundamental determinant for patients and families to decide treatment plans such as the end of life¹⁴ or advance care planning.¹⁵ The patient characteristics including types of cancer, disease and treatment status, and socioeconomic status among families may certainly affect the disparity of their HRQOL.^{16,17}

To our knowledge, this study constitutes the very first prospective cohort study that identified the internal consistency of the Thai version of the PedsQL 3.0 Cancer Module with desirable reliability in all domains of both child and parent reports. These results are comparable to the related psychometric properties studies of the PedsQL 3.0 Cancer Module in many languages globally such as Swedish, Brazilian, Chinese, Japanese, Pakistani and German.^{11,18-22}

Interestingly, all domains of parent reports showed desirable reliability. However, nausea and cognitive problems domains of child reports constituted acceptable reliability. These findings may be related to individual personal background, and different experiences encountered by each patient. Also, variation of ages accepted in early school admission across Thailand may be associated with question responses.

A strong correlation was found between child and parent reports in all domains of the PedsQL 3.0 Cancer Module, especially regarding nausea, pain and hurt and procedural anxiety domains. Interestingly, pain and nausea are physical health scale domains which also showed a positive correlation between children and parents in

several studies.^{18,20-23} These might be due to the physical symptoms being externalized and generally accessible for objective evaluation.

Presently, chemotherapy-induced nausea and vomiting, which is one of the most unpleasant symptoms in pediatric oncology patients, could be substantially minimized by effective anti-emetic drugs such as ondansetron.²⁴ Also, effective analgesic drugs for bedside invasive procedural sedation in pediatric oncology provided satisfaction, decreasing pain and nausea/vomiting.²⁵ These reasons might have affected the strong correlation between child and parent reports concerning nausea, pain and hurt and procedural anxiety domains.

In contrast, the cognitive problems domain demonstrated the lowest correlation between child and parent reports. This might be due to the dissimilarity or unmatched experienced situations²⁶ and miscomprehension of statements in questionnaires between children and parents.

Parents reported significantly lower HRQOL scores than patients themselves in the total score, procedure anxiety, treatment anxiety and worry domains. These findings were comparable to related studies of Sand et al.¹¹ and Matziou et al.²³ These domains comprise emotional or internalized symptoms which may either be difficult to interpret by the parents or influenced by the emotions of the parents themselves. A systematic review reported a greater agreement between child and parent reports for observable functioning (physical HRQOL), and lesser agreement for nonobservable functioning (emotional or social HRQOL) domains.⁷ Communication between parent and child may improve their understanding and support for each other.

Limitations of the Study

The study did not perform internal reliability for each age group of the questionnaires due to the small sample size in some age groups, so the small number of patients might have affected the power to identify outcomes. Heterogeneity of the studied population on diagnosis, disease and treatment statuses as well as household incomes and psychosocial statuses may also have affected the outcomes. Longitudinal HRQOL studies comparing among different treatment statuses (on treatment vs completed treatment) might improve and provide a better comprehension of pediatric oncology patients' QOL.

Conclusion

The Thai version of the PedsQL 3.0 Cancer Module had desirable internal reliability and feasibility with a strong correlation between child and parent reports. Although possible differences between child and parent HRQOL scores should be considered particularly in the procedure anxiety, treatment anxiety and worry domains, obtaining both child and parent reports of the Thai version of the PedsQL 3.0 Cancer Module are still recommended to evaluate HRQOL among pediatric oncology patients.

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Authors' Contributions

KS contributed to conceptualizing and designing the study, interpreted data, drafted and edited the manuscript. JY was involved in patient care and collected and interpreted the data. CM contributed to patient care, conceptualized and designed the study, managed the program overall, analyzed, and interpreted data, and was a major contributor in writing the manuscript. All authors contributed to patient care, collected data, and critically reviewed and approved the final version of the manuscript.

Availability of Data and Material

The datasets generated or analyzed during the current study are not publicly available due to privacy or ethics restrictions. The data are available from the corresponding author upon reasonable request.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethics Approval, Consent to Participate and for Publication

Written informed consent and assent forms were obtained from all participants. This study was approved by the Institutional Review Board, Royal Thai Army Medical Department (reference number: IRBRTA 700/2561) following the ethics principles of the Declaration of Helsinki (1964), including revisions.

The study was also registered and approved by the Thai Clinical Trials Registry (TCTR <https://www.thaiclinicaltrials.org/>), number TCTR20200904001.

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