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Article in *Quality of Life Research* · March 2006

DOI: 10.1007/s11136-005-0449-7 · Source: PubMed

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*Brief communication*

## The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30): Validation study of the Thai version

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Accepted in revised form 30 June 2005

### Abstract

The objective of this study was to assess the psychometric properties of the Thai version of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) version 3.0. The questionnaire was completed by 310 cancer patients during their follow-up at 2 teaching hospital oncology clinics. About 70% of participants had advanced stage of cancer and 72% had been receiving chemotherapy. Cronbach's  $\alpha$  coefficients of the six scales were above 0.7, except for cognitive and social function scales. All test-retest reliability coefficients were high. Multitrait scaling analysis showed that all item-scale correlation coefficients met the standards of convergent and discriminant validity. Most scales and items could discriminate between subgroups of patients with different clinical status assessed with the Eastern Cooperative Oncology Group (ECOG) scale. The results suggested that the EORTC QLQ-C30 and the Functional Assessment of Cancer Therapy – General (FACT-G) measured different aspects of quality of life and should be independently used. Testing psychometric properties of the EORTC QLQ-C30 in heterogeneous diagnostic group yield similar results as found in homogeneous group. These results support that the EORTC QLQ-C30 (version 3.0) has proven to be a reliable and valid measure of the quality of life in Thai patients with various types of cancer.

**Key words:** EORTC QLQ-C30, FACT-G, Quality of Life, Thailand, Validation

### Introduction

Quality of life (QOL) has become a part of the evaluation criteria for cancer therapy besides the classical biomedical criteria. It is the most frequently used outcome measures in oncology research [1]. The majority of clinical trials included QOL as a secondary endpoint in phase III investigations. Various instruments for measuring QOL of cancer patient have been developed [2]. The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC QLQ-C30) developed by the EORTC [3]

was translated into many languages and used in various countries. Even the EORTC was developed in western culture, it was found to be suitable when using in eastern countries such as China [4], Taiwan [5], Japan [6], Korea [7], Singapore [8] and Iran [9]. The international instruments for assessing quality of life of cancer patients available in Thai version are the Functional Living Index-Cancer (FLIC) [10], the FACT-G [11] and the EORTC QLQ-C30. The validity of the FLIC Thai version was tested in lung cancer patients [12]. The FACT-G was extensively tested for its psychometric properties in Thai sample [13]. The initial

data on the feasibility and reliability of the EORTC QLQ-C30 Thai version was demonstrated [14], however, its psychometric properties were not yet adequately explored.

The aim of this study was to determine the psychometric properties of the Thai version of the EORTC QOL-C30 in a group of Thai patients who have undergone treatment for cancer.

## Patients and methods

### *Study sample*

This is a prospective study which was carried out among 310 cancer patients who were treated at the Medical Oncology Unit, Ramathibodi Hospital and Rajavithi Hospital, Bangkok, Thailand. A written consent was obtained from all study participants. The participants were asked to complete the EORTC QLQ-C30 and FACT-G while they were waiting for their doctors. Demographic data and other relevant clinical information were collected from their medical records.

### *Instruments*

The EORTC QLQ-C30 is a 30-item core cancer specific questionnaire measuring QOL in cancer patients. The construction of the questionnaire was described in detail elsewhere [3]. The Thai version of the EORTC QLQ-C30 was previously established and approved by the EORTC Study Group on Quality of Life [14]. The Thai version of the FACT-G, another cancer specific QOL instrument was used as a comparison instrument. The FACT-G was originally developed in English by Cella et al. [11]. The Thai version of FACT-G was found to have good reliability and validity in a group of Thai cancer patients [13].

### *Analysis plan*

The internal consistency of each scale was estimated by Cronbach's  $\alpha$  coefficient [15]. Test-retest reliability was carried out in a subgroup of 28 participants who completed the questionnaire twice within 7–10 days. Pearson's correlation coefficient was used to determine its test-retest reliability. Multitrait scaling analysis, as described

by Kobayashi et al. [6], was carried out for testing convergent and discriminant validity. Items within each scale need to have a correlation above 0.40 with its own scale score to support the scale's convergent validity. In order to confirm the discriminant validity, the magnitude of correlation of an item with its own scale was compared with other scales. No item in each scale should be correlated with another scale exceeded the correlation with its own. A definite scaling error was assumed if the correlation of an item with another scale exceeded the correlation with its own.

The FACT-G was used for testing the construct of the EORTC QLQ-C30. Correlations between corresponding scales of these two instruments including physical, social, emotion and role function scales were analysed. It was expected that the correlations between corresponding scales should be higher than correlations of each scale to other non-corresponding scales.

The clinical validity was determined by the extent to which the scores were able to discriminate between subgroups of patients with different clinical status. The Eastern Cooperative Oncology Group (ECOG) score was used as the clinical parameter to categorize subgroups of patients. ANOVA was used to test for differences among subgroups.

## Results

The demographic and clinical characteristics of the sample are shown in Table 1. The mean age was 50.8 (SD=12.4) years and two-third of patients were female, finished secondary school or higher. More than one-third were diagnosed of breast cancer. Nearly 70% had advance stage of disease (stage 3–4) and 72% had been receiving chemotherapy, however, most had good performance status, about 90% had ECOG score of 0 or 1.

### *Reliability*

Table 2 showed that, except for cognitive ( $\alpha=0.50$ ) and social ( $\alpha=0.63$ ) scales, all scales had Cronbach's  $\alpha$  coefficients above the acceptable level of 0.70 [16]. The test-retest reliability measured by Pearson's correlation coefficients ( $r$ ) were

**Table 1.** Sample characteristics

	N = 310	%
Sex		
Male	123	39.7
Female	187	60.3
Education status		
Illiterate	11	3.6
Primary	92	30.1
Secondary	62	20.3
Colleges	43	14.1
Graduated	80	26.1
Postgraduated	18	5.9
No data	3	
Types of cancer		
Breast	117	37.7
Colon	66	21.3
Lung	60	19.4
Head and neck	19	6.1
Stomach	7	2.3
Other	41	13.2
Disease stage		
Stage 1	13	4.2
Stage 2	83	26.8
Stage 3	63	20.3
Stage 4	151	48.7
Treatment status		
Chemotherapy	223	71.9
Radiation	6	1.9
Hormonal therapy	12	3.9
Chemotherapy + radiation	20	6.5
Supportive treatment	9	2.9
No treatment	40	12.9
ECOG Performance status		
0	148	48.1
1	127	41.2
2	25	8.1
3	8	2.6

high for all functional scales, with a range from 0.75 for role function scale to 0.89 for physical function scale. The  $r$ -value for global scale was 0.90. The results for the symptom scales were between 0.66 for nausea/vomiting and 0.89 for fatigue.

#### Validity

All item-scale correlation coefficients were above 0.40, supporting a satisfactory item convergent validity. Furthermore, the magnitude of the correlation of each item with its own scale exceeded the correlation with another scale and hence no scaling error was found [6].

#### Comparison with FACT-G

There were moderate correlations between physical well-being scale of FACT-G to all scales of the EORTC QLQ-C30 ( $r=0.44$  to  $0.56$ ) and FACT-G emotion scale to EORTC emotion scale ( $r=0.52$ ). Functional well-being scale of FACT-G was stronger correlated to physical ( $r=0.41$ ) and emotional ( $r=0.45$ ) function scales than to role function scale of the EORTC QLQ-C30. Social domain showed no correlation ( $r=0.10$ ,  $p=0.13$ ). Summary, only two corresponding scales, namely physical and emotion scales were moderately correlated.

#### Clinical validity

Table 3 shows that the score of all functional scales were lower in parallel with a lower performance status. For the symptom scales and items, the scores were higher with the performance score. However, the scores of NV, SL, CO and DI were not different among the three groups of performance level.

#### Discussion

Most studies validating EORTC QLQ-C30 were performed in patients with a homogeneous diagnosis. However, some carried out in patients with heterogeneous diagnoses as done in this study which yielded the same results as those performed in homogeneous diagnosis [17, 18]. This supports that EORTC QLQ-C30 was designed for assessing the core characteristic of QOL of life in cancer patients and confirmed the stability of its construct across different types of cancer.

This study shows that the Thai EORTC QLQ-C30 is reliable and valid. The internal consistencies of most scales, except for cognitive and social functioning scales, as assessed by Cronbach's  $\alpha$  coefficients were above the acceptable level of 0.7 [16]. The low Cronbach's  $\alpha$  coefficient for cognitive and social functioning scales were also found in other studies carried out in patients with heterogeneous diagnosis [17, 18] as well as those conducted in homogeneous subjects [3]. This finding was consistent across different cultures.

**Table 2.** Internal consistency (Cronbach's  $\alpha$  coefficients) and test-retest of the scale items

Functional scale	Item	Mean (SD)	Cronbach's $\alpha$ (N=310)	Test-retest $r$ (N=28)
Physical (PF)	1–5	78.3 (18.2)	0.75	0.89
Role (RF)	6–7	80.1 (22.5)	0.76	0.75
Emotional (EF)	21–24	75.5 (19.5)	0.86	0.88
Cognitive (CF)	20, 25	81.9 (19.7)	0.50	0.81
Social (SF)	26–27	80.4 (22.1)	0.63	0.83
Global quality of life	29–30	62.4 (21.8)	0.90	0.90
Symptom scale/items				
Fatigue (FA)	10, 12, 18	40.3 (20.5)	0.73	0.89
Nausea and vomiting (NV)	14–15	16.2 (20.8)	0.82	0.66
Pain (PA)	9, 19	26.7 (23.5)	0.80	0.81
Dyspnoea (DY)	8	23.0 (24.8)		
Sleep disturbance (SL)	11	32.9 (29.1)		
Appetite loss (AP)	13	31.8 (29.2)		
Constipation (CO)	16	23.3 (26.8)		
Diarrhea (DI)	17	10.4 (17.9)		
Financial problem (FI)	28	25.2 (29.3)		

**Table 3.** Known group comparison using ECOG performance score

Functional scales	ECOG 0 (N=148)		ECOG 1 (N=127)		ECOG 2–3 (N=33)		<i>p</i> -Value
	Mean	SD	Mean	SD	Mean	SD	
PF	83.4	15.3	76.0	17.6	65.4	24.3	<0.001
RF	83.3	19.6	79.4	23.2	69.2	28.0	0.04
CF	84.2	16.6	78.1	24.1	74.4	26.7	0.01
EF	77.8	16.7	73.9	21.6	69.9	21.0	0.06
SF	82.3	20.6	77.4	25.6	71.7	27.8	0.04
QOL	66.2	19.3	61.8	22.8	46.8	22.9	<0.001
Symptom scales/items							
FA	35.3	17.9	44.0	22.2	48.8	19.2	<0.001
NV	14.3	19.6	17.6	21.7	20.2	23.1	0.23
PA	22.1	22.2	29.1	23.5	39.4	24.6	<0.001
DY	17.8	22.1	26.0	25.2	36.5	28.5	<0.001
SL	29.5	26.8	35.7	32.0	38.4	26.5	0.11
AP	26.6	25.2	34.1	32.5	41.4	28.9	0.01
CO	21.5	26.7	23.6	25.9	28.3	27.8	0.4
DI	8.6	14.6	13.1	21.1	9.1	17.2	0.09
FI	20.9	28.6	28.9	30.1	30.3	28.1	0.05

Similar to the previous study [19], test-retest reliability of NV was lower than those of all other scales. It is possible that this symptom changed spontaneously during the testing period although it was assumed to be stable across time or it changed accordingly with the effect of chemotherapy.

Multitrait scaling analysis showed that all item-scale correlation coefficients met the standards of convergent and discriminant validity. Ferrell et al found a moderate to strong correlation between all

corresponding scales of the two QOL measurements in cancer patients, i.e. FACT-G and the Quality of Life-Cancer Survivors (QOL-CS) [20]. This is not the case for FACT-G and EORTC QLQ-C30. This study found that PWB of FACT-G was moderately correlated to all scales of EORTC QLQ-C30 and only two scales, physical and emotional, of both questionnaires were well correlated. This could be interpreted that FACT-G and EORTC QLQ-C30 measure QOL in different aspects within the similar domain, so the results

derived from the two instruments could not be directly compared [21]. However, both EORTC QLQ-C30 and FACT-G were vigorously tested for their own psychometric properties and the results confirmed that both instruments were acceptable QOL measurements for cancer patients. To establish the validity of each instrument using comparative methodology will probably yield no benefit. However, further research comparing QOL instruments is needed to provide information on the differences of the individual questionnaires and recommendations regarding their specific range of application [22].

## Conclusion

The findings of this study add more evidences supporting the cross-cultural validity of the EORTC QLQ-C30 in other non-English speaking countries. The Thai EORTC QLQ-C30 was found to be a reliable and valid QOL measure for cancer patients which indicates that it can be used in clinical and epidemiological cancer research. To translate and validate the instrument originally developed from other culture is acceptable and this allows researcher to use the same measurement in multicultural studies. EORTC QLQ-C30 and FACT-G measure different aspects of QOL, the results derived from these questionnaires should not be compared and should be independently interpreted.

## Acknowledgements

We express our gratitude to Dr. Jedzada Maneechavakajorn, Oncology Unit, Rajavithi Hospital, for collecting data from his unit.

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