The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire : Translation and Reliability Study of The Thai Version

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Abstract

In the past decade, increasing attention is being given to more systematic and quantitative ways to evaluate explicitly the impact of disease and medical interventions on quality of life (QOL). Pertaining to the field of oncology, two relatively new instruments- the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and the FACT-G, have received growing attention and appear to be excellent QOL instruments in clinical settings. FACT-G has already been validated and has been used in Thailand. Thus in the present study, the English version of the EORTC quality of life questionnaire (QLQ-C30) was translated into Thai and the initial descriptive statistic and scale reliability were reported. Mean score in this study of 75 cancer patients was comparable with the original report. Cronbach's alpha coefficient for multi-item scales range from 0.64 to 0.89. The validity of this translated version will be reported at a later date. The initial findings of the present study indicate that the Thai version of the EORTC QLQ-C30 is reliable. A validating process of this version is in progress with active patients accrual ongoing at present.

Key word : Quality of life, EORTC QLQ-C30 Thai version

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The pace of research in health-related quality of life (HRQOL) pertaining to clinical oncology has increased rapidly over the past decade. The underlying reason for using quality of life measures in clinical practice is to ensure that treatment plans and evaluation focus on the patient rather than the disease. For example, the traditional endpoints in cancer clinical trials are tumor response, survival, and/or time to disease progression, and treatment-related toxicity. While these outcome parameters remain essential, the impact of disease and treatment on the patient's overall well-being and function is a topic of growing interest in clinical research and practice[1-3]. Besides, health care authority mandate, as well as expensive new medical technology, competing demands for limited economic resources, and funding source emphasized on documenting treatment effectiveness are the driving forces in the movement to develop outcome measures for health care. Outcomes of particular interest for health sciences include symptoms, mood, functional status, general health status, and health-related quality of life (HRQOL).

Several questionnaires have been developed which measure HRQOL, some of these questionnaires are designed for the assessment of non-disease groups, while others were developed to be used for specific disease groups. Generic measures may fail to capture those aspects of patients' experience that are of major clinical interest in a specific disease setting. In order to address this problem, state of the art in QOL assessment in cancer trials is the modular approach. Among the QOL instruments for cancer patients, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC QOL-C30) and the Functional Assessment of Cancer Therapy-General (FACT-G) are probably the most commonly used. The former was developed by EORTC, an international work group focusing mainly on European countries[4,5] The latter instrument, the FACT-G, may be viewed as the United States counterpart of the EORTC instrument[6,7]. Both instruments have been found to exhibit adequate levels of reliability and validity (construct and discriminate) and the psychometric properties are consistent across various languages and countries. The authors have recently translated Cella's FACT-G into Thai and studied its reliability and validity. The results suggested that the FACT-G multi-dimensional construct of QOL domains was applicable to Thai cancer patients and that the QOL questionnaires from Western countries could be used in Thailand[8].

The first-generation of the EORTC QOL was developed in 1987. It was designed to be cancer specific, multidimensional in structure, appropriate for self-administration, applicable across a range of cultural settings, and suitable for use with additional site or treatment-specific modules[9]. The EORTC QOL-C30 (version 3) reported by Aaronson et al[10] is currently available in more than 40 languages. The authors decided to translate the English version of the QLQ-C30 into Thai for the first time for use as a standardized measure in clinical trial since there is a growing demand for the EORTC QOL information as part of many international phase III trials in Thailand.

This paper reports the initial data on the feasibility and reliability of the Thai version of the EORTC QLQ-C30 and the data relating to the validity of the instrument will be reported later when the planned subject number is achieved.

MATERIAL AND METHOD

Questionnaire

The EORTC QLQ-C30 is a 30-item questionnaire composed of multi-item scales and single items that reflect the multidimensionality of the quality of life construct[11,12]. It incorporates five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea and vomiting), and a global health and quality of life scale. The remaining six single items assess additional symptoms commonly reported by cancer patients (dyspnea, appetite loss, sleep disturbance, constipation, and diarrhea) and also the perceived financial impact of the disease and treatment[10]. The first 28 items have a 4-point response scale that range from 0 to 4 which correspond to "Not at all", "A little", "Quite a bit" and "Very much", respectively. The last 2 items employed a 7-point response scale from 0 to 7 with "0" being "very poor" and "7" being "excellent". The questionnaire is to be completed by each individual patient.

Written consent from the EORTC study group on quality of life was obtained prior to translation (modules are copyrighted), good quality translations are required to produce translations that are clear, conceptually equivalent to the original and expressed in Thai. This requires an iterative forward-

backward process[13,14]. The whole translation process was documented and submitted to peer review, pretested and revised. Its final form was approved by the EORTC Study Group on Quality of Life; and subsequently it was used in the present study. Inform consent was obtained from all patients, and the study received approval from the local institutional review board.

Population sample and method

The EORTC QLQ-C30 information was collected as part of a prospective longitudinal study in the Medical Oncology Unit, Ramathibodi Hospital, Bangkok, Thailand. Eligible patients must have had a diagnosis of cancer irrespective of histologic types, disease status or types of treatment modality being received. Additional criteria for inclusion were age greater than 16 years and no known psychiatric disorder. The patients had to be physically and cognitively capable of filling in the questionnaire, as well as being fluent in the Thai language. All patients were informed about the purpose of the study and gave consent to their participation. Patients completed the questionnaires themselves in the presence of clinical trial nurse.

Analysis plan

Standardization of the raw scores in the questionnaire into a uniform scale from 0 to 100 was done according to the scoring procedure described in the EORTC QLQ-C30 Scoring Manual[15]. If the patients missed out one question of a multi-item scale, the raw score was calculated using the simple imputation method given that at least half of the items from that scale have been answered[15,16]. All calculations were then performed after the raw scores were linearly transformed. Higher scores for the global QOL scale and the functioning scales represent better functioning, while higher scores on the symptom and item scales indicate a higher level of symptoms.

Since this is a preliminary report of 75 patients from a total plan of 500 patients, only descriptive statistics and scale reliability of the QLQ-C30 are presented and compared with the original version[10] as well as the reports from a Japanese[17] and Iranian group[18]. The reliability (internal consistency) of the multi-item questionnaire scale was assessed by Cronbach's alpha coefficient[19]. As recommended, internal consistency of a magnitude of 0.70 or greater was sought[20].

RESULTS

Feasibility of the EORTC QLQ-C30 for Thai cancer patients

The current analysis is based on the data collected from 75 cancer patients drawn from routine oncology practice. Sixty patients were under active treatment with chemotherapy, 7 with chemoradiation, and 1 patient with hormonal therapy. The rest of the patient population were either in remission or being cared for with supportive treatment for advanced disease. Their demographic and clinical characteristics are listed in Table 1 and Table 2, respectively. Item content of the EORTC QLQ-C30 and the numbers of missing data in each item are listed in Table 3. Overall, there were 11 unanswered items which accounted for 0.48 per cent of the total numbers of items. Owing to such a small proportion of unanswered questions, no cases were omitted from the analyses due to missing data.

Descriptive statistics and scale reliability

For the ease of interpretation, all scales and item scores were linearly transformed to a 0 to 100 scale. For the five functional scales and the global quality of life scale, item response were recorded so that a higher score represents a better level of functioning. On the contrary, for the symptom-oriented scales and items, a higher score corresponds to a higher level of symptoms. Cronbach's alpha coefficients for eight multi-items scales, except for cognitive functioning scale, were greater than 0.70 indicating satisfactory internal consistency. For the cognitive functioning scale, the Cronbach's alpha coefficient was 0.64 for the group of patients undergoing active treatment and 0.69 for the entire group of patients. The value for role function score was 0.68 for the group receiving active treatment and 0.72 for all 75 patients. The present results were comparable with the original English version and are presented in Table 4.

The mean and standard deviation for the multi-item and single-item measures in the present study were concordant with the mean score of the EORTC study during the treatment phase, since the majority of the presented patients were under active treatment (90.6%). A comparison with the translated Iranian study[18] and the Japanese study[17] is listed in Table 5. The Iranian study included only breast cancer patients, whereas, the Japanese study included only lung cancer patients.

DISCUSSION

The present paper presents the Thai adaptation of the EORTC QLQ-C30 questionnaire. Levels of compliance were good, with very few missing data, indicating that the instrument was well-accepted by the patients. The QOL questionnaire employed in this study could be completed by a large majority of patients quickly without assistance. The EORTC QLQ-C30 rating suggests that patients perceived their health-related QOL (HRQOL) as relatively good as measured by the function and symptom scales. The group of patients in the present study was heterogeneous with regard to the diagnosis and treatment. Nevertheless, internal consistency was satisfactory, which shows that the items of the EORTC QLQ-C30 measure homogenous concepts. While all multi-item scales in this study met the 0.70 criterion for internal consistency reliability, this was not the case for the cognitive functioning scale. This particular scale reached the value of 0.64 for the group of patients during treatment phase and 0.69 for overall patients. However, since the current consensus is that QOL is not a unidimensional construct, a high overall internal consistency coefficient might not always be necessary to infer reliability of measurement. Cella et al set 0.60 as an acceptable coefficient for group comparisons[21]. This same cognitive scale has also shown limitations in the first assessment of the EORTC study (alpha = 0.56) which improved on the second measurement (alpha = 0.73)[10]. A similar finding was also noted for the role functioning scale, however, this scale was described by Aaronson et al as the weakest scale from a classic psychometric perspective. It was also among the briefest scales within the QOL-C30 and has the most restricted range of possible responses[10]. The EORTC result was in line with other studies in which the reliability coefficients have also increased at the second administration compared to baseline[22,23]. However, in this current report, there is no such information to make similar comparison due to the nature of the study which is a single cross-sectional evaluation. The authors are eagerly awaiting the longitudinal results on the breast cancer QOL study whether the same finding would occur.

The mean and standard deviations for the multi-item measures in the present study were similar to the mean score of the EORTC study during the treatment phase, since the majority of the patients were under active treatment (90.6%). Comparison with the Japanese study[17] and Iranian study[18] was also

Table 1. Demographic data (n=75).

	N	%
Sex		
Male	26	34.7
Female	49	65.3
Social Status		
Single	10	13.3
Married	56	74.7
Separated, divorced, widowed	9	12.0
Education		
Elementary	21	28.0
High school	10	13.3
Vocational education	10	13.3
University/college	35	25.4
Type of work		
Unemployed	5	6.7
Agriculture	5	6.7
Self-employed	7	9.3
Unskilled worker	17	22.7
Official (Government employees)	19	25.4
Retired/pensioner	12	16.0
Other	10	13.3
Financial problem		
Yes	15	20
No	60	80

Table 2. Clinical characteristics (n=75).

	N	%
Cancer Type		
Breast	38	50.7
Colon	20	26.7
Lung	9	12.0
Stomach	3	4.0
Head and neck	2	2.6
Other	3	4.0
Disease stage		
Stage I	9	12.0
Stage II	22	29.3
Stage III	16	21.3
Stage IV	28	37.3
Performance status (ECOG)		
0 (normal activity)	34	45.3
1 (symptomatic)	38	50.7
2 (sometimes in bed)	3	4.0
Treatment modality		
Chemotherapy alone	60	80.0
Chemotherapy + Radiation	7	9.3
Symptomatic treatment	3	4.0
No treatment/in remission	4	5.3
Hormonal	1	1.3
Comorbidity		
Yes	25	33.3
No	50	66.7

performed and similar results were obtained as shown in Table 5. However, the global QOL scores were at a somewhat low level for all studies. One reason could be that there are some other aspects of life not included in the questionnaire set that could have a negative influence on patient ratings of the overall QOL. The other possibility is that patients weigh the importance of some symptoms in a manner that is not evident from the present dataset[24]. However, the findings of lower scores on global ratter than on functional scores correspond well with the results from other studies among patients with a variety of cancer diagnosis[25-27].

Fatigue is a subjective experience that affects everybody. For patients with cancer, fatigue has been described as a major concern during treatment and in the advanced stages of the disease[28,29]. In recent QOL reports, fatigue has been described as a frequent complaint by disease-free cancer patients after their curative treatment has been completed[30,31]. In all EORTC QLQ-C30 studies, the fatigue symptom scales appeared to have a high score even before the initiation of the treatment. This could possibly be explained by the fact that cancer itself, particularly those with clinically significant tumor burden, can bring about many ill consequences through many aspects of life, may it be physical, psychological, spiritual, social, cognitive, and behavioral factors, which might altogether contribute to fatigue even before the treatment for cancer has been initiated. Although fatigue is the most common unmanaged symptom of patients who are receiving radiation

Table 3. Item content of the EORTC QLQ-C30 and number of missing items (n=75, 2,250 items).

Item	Subscale	Missing
1. Do you have any trouble doing strenuous activities, like carry a heavy shopping bag or a suitcase?	Physical (PF)	0
2. Do you have any trouble taking a long walk?	Physical (PF)	0
3. Do you have any trouble taking a short walk outside the house?	Physical (PF)	1
4. Do you have to stay in bed or a chair for most of the day?	Physical (PF)	0
5. Do you need help with eating, dressing, washing yourself, or using the toilet?	Physical (PF)	0
6. Are you limited in any way in doing either your work or doing household jobs?	Role (RF)	0
7. Are you completely unable to work at a job or to do household jobs?	Role (RF)	1
8. Were you short of breath?	Dyspnea (DY)	0
9. Have you had pain?	Pain (PA)	3
10. Did you need to rest?	Fatigue (FA)	1
11. Have you had trouble sleeping?	Sleep disturbance	0
12. Have you felt weak?	Fatigue (FA)	0
13. Have you lacked appetite?	Appetite loss	0
14. Have you felt nauseated?	Nausea/vomiting (NV)	0
15. Have you vomited?	Nausea/vomiting (NV)	0
16. Have you been constipated?	Constipation	0
17. Have you had diarrhea?	Diarrhea	0
18. Were you tired?	Fatigue (FA)	0
19. Did pain interfere with your daily activities?	Pain (PA)	1
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	Cognitive (CF)	0
21. Did you feel tense?	Emotional (EF)	0
22. Did you worry?	Emotional (EF)	0
23. Did you feel irritable?	Emotional (EF)	0
24. Did you feel depressed?	Emotional (EF)	1
25. Have you had difficulty remembering things?	Cognitive (CF)	1
26. Has your physical condition or medical treatment interfered with your family life?	Social (SF)	0
27. Has your physical condition or medical treatment interfered with your social activities?	Social (SF)	0
28. Has your physical condition or medical treatment interfered with your financial difficulties?	Financial impact	0
29. How would you rate your overall physical condition during the past week?	Global QOL (GL)	1
30. How would you rate your overall quality of life during the past week?	Global QOL (GL)	1
	Total missing	11 (0.48%)

Table 4. Reliability and QOL score : Comparison of the original and Thai version.

	Item number	Aaronson NK (N=313)						Thai version					
		Before treatment			During treatment			Overall patients (N=75)			During treatment (N=68)		
		Mean score	SD	Cronbach's alpha coefficient	Mean score	SD	Cronbach's alpha coefficient	Mean score	SD	Cronbach's alpha coefficient	Mean score	SD	Cronbach's alpha coefficient
Functional scale													
Physical	1-5	65.8	27.1	0.68	62.3	28.3	0.71	77.8	17.3	0.75	78.3	17.1	0.74
Role	6,7	57.3	38.6	0.54	53.6	38.4	0.52	80.9	20.4	0.72	80.9	20.0	0.68
Cognitive	20,25	83.6	20.5	0.56	80.2	24.1	0.73	82.7	21.8	0.69	84.5	19.8	0.64
Emotional	21-24	70.0	22.3	0.73	73.6	22.1	0.80	75.0	18.6	0.89	75.5	18.3	0.89
Social	26, 27	77.3	27.6	0.68	73.6	28.9	0.77	80.6	22.5	0.75	81.4	22.6	0.75
Global quality of life	29, 30	56.7	23.5	0.86	55.2	23.3	0.89	64.8	20.2	0.84	65.8	19.2	0.85
Symptom scales and/or items													
Fatigue	10, 12, 18	39.4	25.4	0.80	45.6	25.8	0.85	41.9	19.7	0.75	42.0	19.4	0.73
Nausea and vomiting	14, 15	6.7	15.5	0.65	19.6	25.1	0.73	20.0	19.9	0.72	20.6	20.4	0.72
Pain	9, 19	29.3	30.8	0.82	22.3	25.7	0.76	21.6	20.1	0.75	20.6	19.5	0.73
Dyspnea	8	41.0	28.7		37.5	28.6		21.3	23.0		20.6	22.3	
Sleep disturbance	11	31.9	33.1		30.9	32.5		34.2	28.9		33.8	29.0	
Appetite loss	13	26.9	35.1		32.6	37.0		33.3	26.8		33.3	26.4	
Constipation	16	20.1	31.0		23.7	32.6		20.4	22.5		20.1	22.4	
Diarrhea	17	4.2	14.0		4.6	14.4		21.3	23.1		11.8	16.0	
Financial impact	28	12.4	24.8		14.4	26.3		21.3	25.5		21.1	25.0	

Table 5. Comparison of the descriptive statistic and scale reliability of the 3 translated versions of EORTC QLQ-C30.

	Iranian (N=151)			Japanese (N=92)			Thai version, (N=68)		
	Mean score	SD	Cronbach's alpha coefficient	Mean score	SD	Cronbach's alpha coefficient	Mean score	SD	Cronbach's alpha coefficient
Functional scale									
Physical	62.9	22.4	0.71	48.6	36.5	0.83	78.3	17.1	0.74
Role	63.2	25.5	0.77	51.1	43.6	0.74	80.9	20.0	0.68
Cognitive	73.2	19.5	0.51	64.7	28.0	0.63	84.5	19.8	0.64
Emotional	59.9	24.4	0.83	71.5	27.8	0.90	75.5	18.3	0.89
Social	81.6	20.9	0.52	65.4	27.8	0.72	81.4	22.6	0.75
Global QOL	59.4	30.4	0.98	53.5	24.8	0.88	65.8	19.2	0.85
Symptom scales and/or items									
Fatigue	33.0	26.1	0.83	46.6	29.8	0.90	42.0	19.4	0.73
Nausea/vomiting	29.8	30.0	0.81	16.6	24.9	0.87	20.6	20.4	0.72
Pain	6.0	13.1	0.67	35.1	32.7	0.86	20.6	19.5	0.73
Dyspnea	11.3	18.8		30.5	31.0		20.6	22.3	
Sleep disturbance	25.4	29.5		31.9	32.2		33.8	29.0	
Appetite loss	36.6	32.8		33.7	34.6		33.3	26.4	
Constipation	9.4	20.1		26.2	34.4		20.1	22.4	
Diarrhea	2.4	10.2		8.7	20.0		11.8	16.0	
Financial impact	25.4	29.5		23.7	27.9		21.1	25.0	

therapy, chemotherapy, or biotherapy[32,33], improvement in fatigue scale as well as global QOL have been reported recently in a group of metastatic breast cancer patients who responded to Trastuzumab plus chemotherapy with objective reductions in tumor size, a longer time to disease progression, and a longer maintenance of tumor response[34].

In summary, the initial result of the EORTC QLQ-C30 Thai version is in line with the original version previously reported. The present study is still in the ongoing process with a projected target of 500 patients, with the objective of validation of 3 EORTC supplementary questionnaire modules, namely; Breast (QLQ-BR23), Head/Neck (QLQ-H&N35), and Lung (QLQ-L13) module. With the FACT-G instrument already validated in the Thai version by the authors [8], the future EORTC QLQ-C30 validated Thai version will further enhance collaboration with the international study group that incorporates the QOL questionnaire as part of the phase III randomized trial.

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การแปลและทดสอบหาค่าความสอดคล้องภายในของแบบวัดคุณภาพชีวิต The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire : ฉบับภาษาไทย

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ในช่วงทศวรรตที่ผ่านมา การสร้างแบบวัดคุณภาพชีวิตเพื่อนำมาใช้ประเมินผลการดูแลรักษาผู้ป่วยได้มีกระบวนการสร้างเครื่องมือวัดที่มีเกณฑ์มาตรฐานและเป็นระบบมากขึ้น สำหรับผู้ป่วยมะเร็งเครื่องมือวัดคุณภาพชีวิตที่แพร่หลายและเป็นที่ยอมรับในระดับนานาชาติ คือ The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) และ The Functional Assessment Cancer Therapy-General (FACT-G) ในประเทศไทยได้มีการแปลแบบวัด FACT-G และสามารถนำมาใช้ประเมินผลผู้ป่วยไทยได้ การศึกษาครั้งนี้จึงได้แปลแบบวัด EORTC QLQ-C30 โดยมีขั้นตอนการแปลตามมาตรฐานการแปลเครื่องมือจากภาษาต่างประเทศและนำมาทดสอบกับผู้ป่วยมะเร็ง 75 ราย โดยหาค่าความเชื่อมั่นด้วยวิธีการหาค่าสัมประสิทธิ์แอลฟ่า (Cronbach's alpha coefficients) ได้ค่าความเชื่อมั่นในแต่ละด้านของ functional scale และ symptom scale เท่ากับ 0.64 ถึง 0.89 ซึ่งเมื่อเปรียบเทียบผลการทดสอบหาค่าความเชื่อมั่นกับภาษาต้นฉบับเป็นที่น่าพอใจ รายงานผลการศึกษานี้เป็นระยะขั้นต้นของขบวนการทดสอบคุณภาพแบบวัด EORTC QLQ-C30 ฉบับภาษาไทย ซึ่งขณะนี้อยู่ในขั้นการศึกษา Construct validity ให้ได้จำนวนผู้ป่วยที่เพียงพอสำหรับการทดสอบทางสถิติ factor analysis ในลำดับต่อไป

คำสำคัญ : คุณภาพชีวิต, EORTC QLQ-C30 ฉบับภาษาไทย

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