Quality of Life, Functional Assessment of Cancer Therapy-General

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Abstract

Research on quality of life (QOL) in Thailand is still in its developing stages and requires cross-culturally valid QOL questionnaires to appropriately assess QOL as an endpoint in research and clinical trials. The English-language version of the FACT-G (Version 4) questionnaire was translated into Thai using an iterative forward-backward translation process. To determine if this instrument could cross a broad cultural divide and be used in Thailand, the reliability and validity of its Thai version was studied. The translated questionnaire was administered to 364 cancer patients. In evaluating its psychometric properties, internal consistency by Cronbach's alpha and test / retest reliability measured by Spearman rank-correlation coefficients were used. Cronbach's alpha coefficient ranged from 0.75 to 0.90. Spearman rank-correlation coefficient value for global QOL was 0.80. Validity was checked using two methods: factor analysis and known-groups comparison. Known-groups comparison analysis showed discrimination between subgroups of patients differing in clinical status as defined by disease stage (stage I/II vs stage III/IV, $p < 0.001$), treatment status (active treatment vs no treatment, $p < 0.05$), and financial burden (yes vs no, $p < 0.001$). In conclusion, the finding of this study indicate that the Thai version of the Functional Assessment of Cancer Therapy-General (FACT-G) is a reliable and valid measure of quality of life in cancer patients and can be used in clinical trials and studies of outcomes research in oncology.

Key word : Quality of Life, Validation, Psychometric, Functional Assessment of Cancer Therapy-General, Translation Methodology, Thai Version

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The outcomes variables within clinical oncology have primarily been survival and tumor response. This is despite the general and broad definition of health as stated by the World Health Organization, stressing that the patient's situation as a whole should be considered[1]. With the advance of oncological science and practice, complex new treatments have been introduced, achieving cure in some, and prolongation of life in many patients with common cancers. For many patients, cancer has turned from a rapidly fatal illness into a chronic disease treated over the course of months and years with complex and toxic therapies. Oncology staff are now being required to monitor and address the adverse consequences of cancer illness and treatment on a patient's physical, psychological and social performance. It is becoming essential that outcomes from cancer treatment include measures of quality of life (QOL), as well as survival and objective response to treatment. It has been claimed that QOL is as important as quantity of life in most settings[2].

There is no universally agreed-upon definition of what constitutes QOL. QOL has been defined as 'the subjective evaluation of life as a whole'[3] or 'QOL refers to patient's appraisal of and satisfaction with their current level of functioning compared with what they perceived to be possible or ideal[4]. Both definitions emphasize the subjective and evaluative nature of the concept. QOL is generally assumed to be a multidimensional construct measuring different aspects or 'domains' of life[5,6], including, for example, physical, psychological, social, and functional well-being.

While there have been numerous and substantial attempts in recent trials at incorporating and validating health-related QOL (HRQOL) instruments for cancer, at present, no tool can reasonably lay claim to the title of 'gold standard'[7,8]. A wide variety of tools are currently in use, which leaves the researcher with conflicting evidence and a confusing array of options[9,10]. Quality of life can only be measured indirectly. Any QOL instrument is by nature imperfect. The choice of an appropriate questionnaire is, therefore, dependent on many patient, disease, treatment and study variables. One ideal questionnaire for all purposes does not exist. The Functional Assessment of Cancer Therapy-General (FACT-G) scale is among the few available cancer specific QOL measures for which psychometric properties have been reported systematically

and extensively. The FACT-G was developed over a 4-year period in a multi-phase process that included focus groups and item generation, item review and reduction, scale construction, initial evaluation of factors, internal consistency, convergent and discriminant validity, and differentiating known groups, followed by test-retest reliability and sensitivity to change. All of the psychometric findings support the reliability and the validity of the FACT-G in measuring the quality of life construct[11]. The FACT-General (FACT-G) is multidimensional, consisting of subscales assessing Physical Well-Being (PWB), Emotional Well-Being (EWB), Social/Family Well-Being (SFWB), Functional Well-Being (FWB), and Relationship with Doctor (RWD)[11]. However, the last subscale (RWD) was removed from Version 4 due to its lack of response variability and because treatment satisfaction encompasses multiple dimensions[12]. The FACT-G is sensitive to important characteristics of cancer including staging (Stage I-IV)[11,13], location of services[13], and changes in a patient's clinical condition over time[11].

A review of the Thai literature on cancer points out the scarcity of specific instruments to assess QOL that have been adapted to the Thai cultural context and have undergone a detailed psychometric analysis. Most patient-centered questionnaires on quality of life have been developed in English-speaking cultures. Thus, it has been questioned as to whether or not the QOL questionnaires could cross a broad cultural divide and be used in Eastern countries[14,15]. Ideally, new scales should be developed and validated for each culture in which they will be used. Without such evidence, an instrument's capacity to assess accurately and reliably that which it is designed to measure remains uncertain, and that the resultant data is untrustworthy. In addition, the process by which such instruments are translated is often problematic. Single forward translation is limited because it tends to produce a very literal rendition of the source text rather than a translation which also conveys the underlying meaning of the original text[16]. Another limitation of this approach is the lack of verification of the single forward translator[17].

This article describes the translation and validation of the Thai FACT-G Version 4 using Thai cancer patients from three major hospitals in Bangkok, Thailand. This report focuses on the methodo-

logical approaches used to ensure equivalence of Thai and English versions of the FACT-G and to support its use with Thai cancer patients.

METHOD
Translation method

Permission from Dr. David Cella was obtained prior to the translation process. This study used the modified double back translation methodology as described by Bonomi et al[18]. Although Version 3 of the FACT-G was previously translated into Thai by CORE[19], several items were revised in Version 4 and thus required retranslation for the Version 4 Thai FACT-G. Items from the revised FACT-G and four disease-specific subscales (FACT-B, FACT-C, FACT-L, FACT-H&N, Version 4) were independently translated (forward translations) into Thai by two nurse oncologists who spoke Thai as their native tongue. Consistent with the FACIT (Functional Assessment of Chronic Illness Therapy) Translation Methodology recommendations, translators were asked to use simple language so that patients with lower reading levels would be able to understand the language of the questionnaire without assistance. Translators were also asked to capture the underlying meaning of the items rather than perform literal translations. The two forward translations were then sent to a third independent native speaking Thai translator to resolve any discrepancies. The reconciled Thai version then underwent back-translation by a fourth professional translator whose native tongue was English. The translation process is summarized in Fig. 1.

After the forward, reconciling and back-translation steps were completed, bilingual health professionals in Thailand were contacted to review all the documents. During the review process, items from the Version 3 Thai translation[19] were compared and incorporated into the new translation. As a result, a revised Thai forward translation was created. This revised Thai translation was then pretested with patients to assess the instrument's comprehensibility and acceptability. Patients were asked to complete the FACT-G and one of the four disease-specific subscales by self-administration. A subgroup of the patients were then interviewed to determine whether there were any questions which were difficult to comprehend and/or not relevant to their QOL. As a result of feedback gathered during patient interviews, certain items in the Thai version were revised to create the final Thai language ver-

sion of the FACT-G and four subscales. The initial part of this study with its reliability results was published recently[20,21], as well as the abstract form of this report[22].

Instrumentation

The finalized Thai version used in this study was translated from the English FACT-G (Version 4). This is a 27-item instrument with each item scored on 1-5 response categories: 0 = 'Not at all', 1 = 'A little bit', 2 = 'Somewhat', 3 = 'Quite a bit', and 4 = 'Very much.' The items reflect cancer treatment related impact on QOL[18,19]. The FACT-G (Version 4) has four subscales, measuring physical (PWB), social / family (SFWB), emotional (EWB), and functional well-being (FWB)[12]. While the general scale (FACT-G) allows for comparison among different cancer types, it can fail to capture important cancer specific QOL issues that can differ across current treatments. Thus, subscales specific to breast cancer (FACT-B), lung cancer (FACT-L), colorectal cancer (FACT-C), and head & neck cancer (FACT-H&N) were also used in this study to cover issues specific to each of these types of cancer[23]. For example, the Breast Cancer Subscale (BCS) is comprised of nine items specific to QOL in breast cancer but not yet included in the FACT-G. When the BCS is added to the FACT-G, the 36-item instrument is known as the FACT-Breast (FACT-B). Each disease-specific subscale is intended for use in conjunction with the FACT-G and all of these subscales were translated according to the methodology described above. Only FACT-G and FACT-B were studied in detail because both scales had a sufficient number of patients to be analyzed; however, the smaller FACT-B sample size precluded its factor analysis. FACT-L, FACT-C, and FACT-H&N were not analyzed and discussed due to the small sample size. These self-administered questionnaires have advantages over other methods; they are relatively inexpensive to produce, require minimal time and energy input from staff, and yield quantifiable responses[24,25].

Subjects

The 364 participants were cancer patients from three hospitals in Bangkok, namely: Ramathibodi Hospital, Rajvithi Hospital, and the National Cancer Institute (Thailand). To be considered for the study, patients had to meet the following criteria: (1) could read and speak Thai, for illiterate

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Start : Source document (original FACT 4 English version)

Step 1

Forward translation (native Thai-speaker residing in Thailand) : English → Thai

Result : Two independent forward translations

Step 2

Reconciliation of forward translations (native Thai-speaker not involved in forward translation process)

Result : Reconciled Thai version that includes input from both forward translations

Step 3

Back translation of reconciled version (native English speaker residing in USA)* : Thai → English

Result : Back translation into English to compare to source document

Step 4

Reviewed by bilingual health professionals residing in Thailand

Result : Revised language versions based on reconciliation of discrepancies among source document, step 2 forward translation and Step 3 back translation

Step 5

Spelling and meaning verification

Result : Revised Thai version ready for pretesting in Thailand

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* This step was accomplished through the courtesy and assistance of Dr. David Cella and his collaborators in the USA.

Fig. 1.   Translation procedure.

patients, the questionnaire was administered as an interview; (2) capable of giving informed consent; (3) not so weak that completing the questionnaires would be a burden; (4) were not impaired cognitively with overt psychosis, major depression, or delirium. The sample size was more than adequate for the conduct of factor analyses, which usually require a 1:5 item:respondent ratio[26]. A subset of these patients completed the FACT-G and FACT-B on a second occasion, 7 days after the first administration, to assess test-retest reliability (stability of the instrument over time).

Statistical analysis

The internal consistency of the translated scale was tested with Cronbach's alpha[27] and test-retest reliability (Spearman rank-correlation coefficients, a minimum of 0.05 level of statistical significance was used). The evaluation of reliability allowed the authors to gauge the amount of chance variation among the scores within the inventory. This variation will always be present within the inven-

tory, but the variation is expected to be similar in magnitude on each testing occasion[28]. The authors evaluated the test-retest reliability of individual question scores and the inventory total score between baseline testing and retesting 1 week later. Internal consistency coefficients greater than 0.70 were considered acceptable to justify discriminative use. The construct validity was tested with factor analysis and known-groups comparison. Construct validity is a measure of the inventory's ability to produce consistent results which reflect the true clinical state of the patient, i.e., whether the index agrees with expected results based on our underlying hypothesis[29]. In this case, it was hypothesized that conceptually related subscales would correlate with one another, most compatible with its domain, i.e., item 'I have a lack of energy' should load heavily on the PWB domain. The correlational effect sizes are designated as small (0.10), medium (0.30), and large (0.50) based on Cohen's statistical guidelines[30]. Burns and Grove propose that the minimum cut-off point for items that are included as elements of a

factor is 0.30[31]. To evaluate the clinical validity of the Thai FACT-G, the known-groups comparison was performed. This could indicate the extent to which the questionnaire scores were able to discriminate between subgroups of patients differing in clinical status[32]. The clinical parameters and financial burden were employed to form mutually exclusive patient subgroups. Student's *t*-test and one-way ANOVA were employed to test for the statistical significance of group differences.

RESULTS
Patient characteristics

364 patients with breast, colorectal, lung, head & neck and other cancers were studied; their characteristics are shown in Table 1. Financial burden was also included in this study as a known group factor since preliminary qualitative research suggests that socioeconomic factors may be more proximal to QOL outcomes than was thought previously, even with ethnic minority populations living in the same geographic location[33]. Almost all patients found the questions easy to understand and acceptable. FACT-G and disease specific subscale FACT-B are presented in detail since both consisted of adequate sample sizes.

Psychometric testing
Reliability

Internal consistency data are listed in Table 2 and Table 3. FACT-B is highlighted along with FACT-G since breast cancer represents the majority of patients (52.2%) in this study. FACT-G and FACT-B total score alpha coefficients were 0.90 and 0.91 respectively. These figures indicated that the 27 items constituting the FACT-G and the 36 items constituting the FACT-B are consistent internally and appear to measure a unitary construct. Test-retest correlation coefficients for subscales and aggregates were 0.80 for the FACT-G and 0.60 for the FACT-B, indicating a moderate degree of stability over the time period (7 days) during which no change would be expected.

Validity

Factor loadings are given in Table 4, where the forced 4–factor solution accounts for 55.69 per cent of the explained variance. The factor analysis using an oblique rotation resulted in factor load-

Table 1.   Demographic characteristics of sample.

Variables	Number of patients (N)	%
Age (years)		
Range	15-79	
Mean ± SD	50.92 ± 12.18	
Gender		
Male	88	24.2
Female	276	75.8
Education		
None	21	5.8
Primary school	149	40.9
Secondary school	67	18.4
Vocational	32	8.8
College graduate	88	24.2
NA	7	1.9
Marital status		
Single	63	17.3
Married	246	67.6
Divorced/separated	49	13.5
NA	6	1.6
Financial burden		
No	213	58.5
Yes	145	39.9
NA	6	1.6
Type of cancer		
Breast	190	52.2
Colon	64	17.6
Lung	51	14.0
Head & Neck	27	7.4
Other organs	32	8.8
Stage of Disease		
1	17	4.7
2	115	31.6
3	86	23.6
4	115	31.6
NA	31	8.5
Performance status (ECOG)		
0	147	40.4
1	173	47.5
2	30	8.2
3	10	2.8
NA	4	1.1
Treatment status		
Active treatment	227	62.4
No treatment	108	29.6
Supportive only	13	3.6
NA	16	4.4

ings that are equivalent to the findings reported by Cella et al[11] and the report by Yu et al[14], which assessed the FACT-G (Version 3) scale in Hong Kong Chinese cancer patients. These results are shown in Table 5. The study by Yu et al is the only published validation of the FACT-G representing Eastern culture at the time of preparation of this manuscript.

Table 2.   Reliability of Thai FACT-G version 4 subscales and overall scores.

Subscale	No. of sample	No of items	Range of scores	Mean $\pm$ SD	Alpha	r (N=25)
PWB	356	7	0-28	20.84 ± 5.53	0.81	0.60*
SFWB (include item GS7)**	262	7	0-28	18.69 ± 4.97	0.79	0.88*
SFWB (exclude item GS7)**	346	6	0-24	17.03 ± 4.31	0.75	-
EWB	353	6	0-24	17.47 ± 5.11	0.83	0.83*
FWB	358	7	0-28	17.16 ± 5.66	0.87	0.73*
Total FACT-G (include item GS7)**	250	27	0-108	74.16 ± 15.40	0.90	0.80*
Total FACT-G (exclude item GS7)**	324	26	0-104	72.50 ± 15.09	0.90	-

* p < 0.01, **23% of the patients chose not to answer this item (see discussion)
PWB, Physical Well-Being; SFWB, Social / Family Well-Being ; EWB, Emotional Well-Being;
FWB, Functional Well-Being
FACT-G = PWB+SFWB+EWB+FWB

Table 3.   Reliability of Thai FACT-B version subscales and overall scores.

Subscale	No. of sample	No of items	Range of scores	Mean $\pm$ SD	Alpha	r (N=17)
PWB	190	7	0-28	21.21 ± 5.73	0.84	0.42^{ns}
SFWB	129	7	0-28	18.94 ± 4.95	0.76	0.87*
EWB	185	6	0-24	17.27 ± 5.45	0.85	0.71*
FWB	190	7	0-28	18.05 ± 5.46	0.86	0.60**
Total FACT-G	128	27	0-108	75.47 ± 16.12	0.91	0.62*
Total FACT-B	126	36	0-144	98.45 ± 19.89	0.91	0.60**
BCS	184	9	0-36	22.98 ± 5.34	0.63	0.70*

* p < 0.01, ** p < 0.05 ; ns, not significant
PWB, Physical Well-Being; SFWB, Social / Family Well-Being ; EWB, Emotional Well-Being;
FWB, Functional Well-Being
FACT-G = PWB+SFWB+EWB+FWB
FACT-B= PWB+SFWB+EWB+FWB+BCS
BCS, Breast Cancer Subscale

Table 6 presents the clinical validity by known-groups factors that impact QOL. The method of known-groups comparison was used to evaluate the extent to which the Thai FACT-G version 4 was able to discriminate between subgroups of patients differing in clinical status. The clinical parameters used to form subgroups of patients at baseline for analyses included disease stage, treatment status, and financial burden.

DISCUSSION

This paper has described the methodology used to translate the FACT-G (Version 4) into Thai and the results of testing the Thai version with 364 patients. It is a 27-item questionnaire that can easily be completed in 15-20 minutes usually without assistance. Our adaptation of the rigorous double-back translation technique has enabled us to achieve high-quality translations of the Thai FACT-G version 4 which can be compared with other language versions. With its simplicity and brevity, it is, therefore, responsive to the realistic constraints of a clinical trial setting. Some conditions were overexpressed because the four diagnostic groups (breast, colorectal, lung, and head & neck cancer) represented the majority of the patients in this report. Besides, a survivor effect was also probably operating, with participating patients in the outpatient clinics also having better prognosis and performance status than those found in the general population.

The current study demonstrates the FACT-G Thai version, when used with Thai patients, resulted in measures of internal consistency and validity that are psychometrically sound. The Cronbach's alpha for all of the scales were ≥ 0.75, indicating sufficient reliability for research purposes. Cron-

Table 4.   Factors loading on 27-Item Thai FACT-G Version 4 (N = 250).

Items	Component			
	FWB	PWB	EWB	SFWB
Physical Well-Being				
GP1. I have a lack of energy		0.80		
GP2. I have nausea		0.67		
GP3. Because of my physical condition, I have trouble meeting the needs of my family		0.50		
GP4. I have pain		0.57		
GP5. I am bothered by side effects of treatment		0.61		
GP6. I feel ill		0.79		
GP7. I am forced to spend time in bed		0.64		
Social/Family Well-Being				
GS1. I feel close to my friends	0.58			0.37
GS2. I get emotional support from my fam family				0.81
GS3. I get support from my friends	0.55			0.37
GS4. My family has accepted my illness				0.79
GS5. I am satisfied with family communication about my illness				0.83
GS6. I feel close to my partner (or the person who is my main support)				0.80
GS7. I am satisfied with my sex life				0.51
Emotional Well-Being				
GE1. I feel sad			0.77	
GE2. I am satisfied with how I am coping with my illness	0.42		0.40	
GE3. I am losing hope in the fight against my illness			0.69	
GE4. I feel nervous			0.83	
GE5. I worry about dying			0.76	
GE6. I worry that my condition will get worse			0.82	
Functional Well-Being				
GF1. I am able to work (include work at home)	0.72			
GF2. My work (include work at home) is fulfilling	0.78			
GF3. I am able to enjoy life	0.78			
GF4. I have accept my illness	0.62			
GF5. I am sleeping well	0.56			
GF6. I am enjoying the things I usually do for fun	0.83			
GF7. I am content with the quality of my life right now	0.66			

bach's alphas for the subscales in this study ranged from 0.75 to 0.90, which are comparable to those reported by Cella et al (0.69 to 0.82)[11]. Thus, the subscales as constructed perform well as homogeneous (unidimensional) indicators. The FACT-B Physical Well-Being subscale had a somewhat low score (0.42, p = 0.09) on the test-retest analysis, this is due to the study design that the test-retest·interval is 7 days which resulted in deterioration of physical condition after the initiation of chemotherapy on day 1 for the patients under active treatment. Theoretically, the test-retest stability of the instrument and the reproducibility, implies that the scores obtained at one point in time should not differ significantly from the scores obtained at the next time of measurement, provided that the state of the patient is the same. Thus, we have modified the interval to 3 days for our future study which is still in the acceptable

range of time to perform this test[11,34]. Too short a period might bias the answers, because the patients might remember too well their responses at the first assessment. On the other hand, changes in the patients' condition are more likely to occur if the period is too long. However, the reduced quality of life after treatment as compared to baseline, provides some evidence for construct validity.

The Breast Cancer Subscale (BCS) had a somewhat low alpha coefficient (0.63), however, this result is identical to that obtained in the original report (0.63)[35] and therefore does not reflect a problem in the Thai translation. Though 0.63 falls below the acceptable cut-off point for the alpha coefficient, it is not unusual to see published scales with alpha coefficient <0.70[36]. Additionally, it is adequate for tests whose primary purpose is to evaluate groups of patients rather than individuals[37].

Table 5. Comparison of item to Factor Loading for Thai FACT-G Version 4 (N = 250) with English Version 2 and Chinese Version 3 data sets.

Items	Comparision of three studies		
	Current Study (Version 4) (N = 250)	Cella et al (Version 2)[11] (N = 545)	Yu et al (Version 3)[14] (N = 1108)
Physical Well-Being			
GP1	0.80	0.59	0.68
GP2	0.67	0.71	0.63
GP3	0.50	0.45	0.22
GP4	0.57	0.57	0.60
GP5	0.61	0.71	0.53
GP6	0.79	0.65	0.73
GP7	0.64	0.66	0.57
Social / Family Well-Being			
GS1	0.37	0.45	0.10
GS2	0.81	0.61	0.73
GS3	0.37	0.52	0.48
GS4	0.79	0.70	0.46
GS5	0.83	0.64	0.41
GS6	0.80	0.42	0.72
GS7	0.51	0.12	0.49
Emotional Well-Being			
GE1	0.77	0.56	0.73
GE2	0.40	0.44	0.13
GE3	0.69	0.56	0.51
GE4	0.83	0.57	0.75
GE5	0.76	0.75	0.75
GE6	0.82	NA	NA
Functional Well-Being			
GF1	0.72	0.61	0.82
GF2	0.78	0.74	0.85
GF3	0.78	0.53	0.50
GF4	0.62	0.57	0.07
GF5	0.56	0.70	0.21
GF6	0.83	0.37	0.56
GF7	0.66	0.49	0.45

Besides, since QOL is a multidimensional construct, a high overall internal consistency coefficient might not be necessary to obtain valid measurement. Cella et al have set 0.60 as an acceptable coefficient for group comparisons[38]. BCS is meant only as a complement to the FACT-G and is never used alone. When the BCS subscale is combined with FACT-G, the alpha coefficient is high (0.91).

Verifying that a measurement is reliable is not sufficient to demonstrate its usefulness in clinical studies. It must also be shown to be a valid measurement. The factor analysis results from this study indicated that the theoretical model of quality of life proposed by Cella et al[11] is duplicated in Thai patients. A comparison of the factor analyses between Cella et al[11] and the current study shows

great similarity. The items in this study factor analysis generally loaded on the same factors as they did in the analysis conducted by Cella et al[11]. Although the results of the factor analysis of the current study generally paralleled the original, there were notable differences. Social / Family Well-Being item GS3, 'I get support from my friends', originally loaded at 0.52 but achieved only 0.37 in this study, loading instead at 0.55 on the Functional Well-Being subscale, perhaps because the item also relates closely to Functional Well-Being. There is a close correspondence between Social / Family and Functional subscales, so some shared variance is to be expected. In the Social / Family Well-Being subscale, 23 per cent of our patients chose not to answer item GS7, 'I am satisfied with my sex life'.

Table 6.   Clinical validity of Thai FACT-G Version 4.

Variables	Mean ± SD	P - value	
Financial burden			
Yes (N=145)	69.05 ± 14.97	$P < 0.001$	
No (N= 213)	77.83 ± 14.71		
Treatment status			
Active treatment (N= 227)	73.36 ± 15.32		
No treatment (N = 108)	77.50 ± 14.60	$P < 0.05$	
Disease stage			
Stage 1+2 (N = 132)	78.44 ± 15.93	Stage 1+2 vs stage 3;	$P < 0.005$
Stage 3 (N = 86)	71.40 ± 15.25	Stage 1+2 vs stage 4;	$P < 0.001$
Stage 4 (N = 115)	70.61 ± 13.79	Stage 1+2 vs stage 3+4;	$P < 0.001$
Stage 3+4 (N = 201)	70.95 ± 14.40	Stage 3 vs stage 4;	$P = 0.94$

Thai people are often characterized as being inhibited, obedient, more hesitant in their emotional expression and less forthcoming to strangers about sensitive topics like sex, perhaps affecting responses to some items. These findings confirm the general notion that missing data can be expected when sensitive areas are addressed in a questionnaire. However, at the same time, the results indicate that inquiring about sexuality need not be avoided as long as the patients are free to leave such questions unanswered.

For clinical validity assessment, a known-groups comparison using stage of disease, treatment status, and financial burden shows very encouraging results. The results support a relationship between disease activity and QOL. The data on clinical validity shows differential sensitivity to physical health parameters. Financial burden was not addressed in the FACT-G English version because the authors believe that it is best measured by a more direct assessment of costs, charges or, perhaps more feasibly, resource utilization[18]. However, due to socio-economic differences between Eastern and Western cultures, we need to assess this financial burden in a more systematic way, i.e., creating a new domain for this particular issue. Further tests of the precision based on change in clinical status over time are necessary to advance our understanding of the usefulness of this instrument.

Results of this study demonstrate the impact of cultural differences on psychometric properties of instruments. Researchers cannot assume that simple translation of instruments from one language to another is adequate, nor can reliability and validity of

measures conducted in one culture be applied cross-culturally. A borrowed instrument needs to be adapted in a culturally relevant and comprehensible way in order to preserve the meaning of each item across the two languages. In addition, it is necessary to test psychometric properties of the adapted instrument in the target population in order to assure its reliability and validity in cross-cultural research.

Despite an increasing interest in QOL in recent years, it is still rarely included as an objective in clinical trials, nor adequately assessed. Even when QOL was studied, most of the evaluations were not adequate, usually because the assessment was unidimensional or because a non-validated instrument was used[39]. More recent studies suggested that QOL scores may have prognostic significance in advanced cancer. This has been shown in several different types of cancer and with a range of different validated self-reported multidimensional QOL instruments[40-44]. This finding provides the most powerful evidence for the validity of the QOL instruments and may have important implications for the stratification of patients into prognostic groups in future clinical trials. Even more important, several more recent studies showed that more aggressive cancer treatment can be associated with improved QOL when compared with less intensive treatment, even in the palliative care setting and despite significant toxicity[45,46]. Patients were observed to report improvement in QOL even when no traditional objective response was detectable and there was no survival benefit[47-49]. With the scales constituting QOL in the English-speaking culture extracted and found to be valid in Thai, this study indicates its

possible usefulness as an instrument that is universally applicable across cultures. Now the FACT-G can be used in internationally phase III studies, for example, in North America, Europe and Thailand. In those patients who will be selected by the strict eligibility criteria in the phase III studies, the metric equivalence will be accurately evaluated.

In conclusion, the findings of this study indicate that the Thai FACT-G Version 4 is a reliable and valid measure of quality of life in cancer patients. It is safe to say that the FACT-G Thai language translation as reported here provides sufficient assurance of equivalence to the English-language version to proceed with its use in clinical trials and clinical practice.

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การแปลและตรวจสอบคุณภาพของแบบวัดคุณภาพชีวิต The Functional Assessment of Cancer Therapy–General (FACT–G) Version 4 ฉบับแปลเป็นภาษาไทย

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คุณภาพชีวิตของผู้ป่วยมะเร็ง เป็นดัชนีชี้วัดหนึ่งที่สำคัญและจำเป็นในการประเมินผลการรักษาและการวิจัย โดยเฉพาะการวิจัยในระดับนานาชาติจำเป็นต้องหาเครื่องมือวัดตัวแปรเชิงคุณภาพที่ได้มาตรฐานในระดับสากล FACT–G เป็นเครื่องมือวัดคุณภาพชีวิตที่นิยมใช้กันแพร่หลายในต่างประเทศ ประกอบด้วยข้อคำถาม 27 ข้อแบ่งเป็น 4 ด้านคือ ความผาสุกด้านร่างกาย ความผาสุกด้านครอบครัวและสังคม ความผาสุกด้านอารมณ์ และความผาสุกด้านการปฏิบัติกิจกรรม การศึกษาครั้งนี้เป็นการตรวจสอบคุณภาพของแบบวัดคุณภาพชีวิต FACT–G Version 4 ฉบับภาษาไทยที่ผ่านการแปลอย่าง มีขั้นตอนตามมาตรฐานการแปลเครื่องมือจากภาษาต่างประเทศ และได้นำมาสอบถามกับผู้ป่วยมะเร็ง 364 ราย โดยหาค่า ความเชื่อมั่นด้วยวิธีการหาค่าสัมประสิทธิ์แอลฟา (Cronbach's alpha coefficients) และการทดสอบซ้ำด้วยการหาค่า สัมประสิทธิ์สหสัมพันธ์ (Spearman rank–correlation coefficients) การทดสอบความเที่ยงตรงเชิงโครงสร้างด้วยวิธีการทำ Factor analysis และ known–groups comparison ผลการวิจัยพบว่า ค่าความเชื่อมั่นในแต่ละด้านและทั้งฉบับอยู่ระดับที่ น่าพอใจ ค่าสัมประสิทธิ์แอลฟาเท่ากับ 0.75 ถึง 0.90 และค่าสัมประสิทธิ์สหสัมพันธ์แบบสเปียร์แมนทั้งฉบับเท่ากับ 0.80 การทดสอบความเที่ยงตรงเชิงโครงสร้างสามารถวัดตัวแปรทางคลินิกได้อย่างมีนัยสำคัญทางสถิติ ในเรื่องระยะของโรคมะเร็ง (ระยะที่ 1, 2 เปรียบเทียบกับระยะ 3, 4, p<0.001) สถานภาพของโรคและการรักษา (ระยะมีโรคและรับการรักษาเปรียบ– เทียบกับระยะปลอดโรคและไม่ได้รับการรักษา p<0.05) สถานภาพทางการเงิน (มีปัญหาค่ารักษาเปรียบเทียบกับไม่มีปัญหา ค่ารักษา p<0.001) นอกจากนี้ผลการวิเคราะห์หาค่า factor loading พบว่า ข้อคำถามส่วนใหญ่ได้ค่าคะแนนของการจัดกลุ่ม อยู่ในเกณฑ์ที่ยอมรับได้และสอดคล้องตรงตามรายด้านของแบบวัดคุณภาพชีวิต FACT–G ต้นฉบับภาษาอังกฤษ โดยสรุป แบบวัดคุณภาพชีวิต FACT–G Version 4 ฉบับภาษาไทย เป็นแบบสอบถามที่มีค่าคุณภาพเครื่องมือที่ดีได้มาตรฐานเทียบเท่า ระดับสากลของผู้นิพนธ์ต้นฉบับเดิม สามารถนำมาใช้วัดคุณภาพชีวิตของผู้ป่วยโรคมะเร็งและใช้ในการวิจัยทางคลินิกใน ประเทศไทยต่อไปได้

คำสำคัญ :   คุณภาพชีวิต, ความเที่ยงตรง, Functional Assessment of Cancer Therapy General, กระบวนการแปล, ฉบับภาษาไทย

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