Quality of Life Assessment in Radiotherapy Patients by WHOQOL-BREF-THAI: A Feasibility Study

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Objective : *To determine the feasibility and sensitivity of the WHOQOL-BREF-THAI assessment tool in measuring the quality of life in cancer patients treated with radiotherapy in routine clinical practice.*
Method : *A cross-sectional analytical study including the consecutive radiotherapy patients at Songklanagarind Hospital from October to December 2000 was conducted. The participants completed a Thai version of the brief form of the WHO quality of life assessment instrument (WHOQOL-BREF-THAI).*
Results : *The majority of the patients (80.7%) were able to complete the questionnaire, 19 (12.6%) by themselves, 4 (2.6%) with the help of their relatives and 128 (84.8%) through the interview. Almost all of them could understand the questions very well. The mean and standard deviation of time requirement in completing it were 13.0 $\pm$ 4.0 minutes. The WHOQOL-BREF-THAI instrument was sensitive enough to discriminate the QOL in patients with differences in all analyzed clinical parameters, which were hospitalization, stage of disease, treatment aim and ECOG performance status.*
Conclusion : *The present results supported the feasibility of using the WHOQOL-BREF-THAI assessment tool in radiotherapy cancer patients with good sensitivity and patient understanding within an acceptable time requirement. One practical barrier of concern was a low self-assessment percentage in this particular group of patients, necessitating the interviewer system.*

Keywords : *Quality of Life, Cancer, Radiotherapy, WHOQOL-BREF-THAI*

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Quality of life (QOL) assessments are increasingly being used in cancer patients receiving treatments[1] that result in not only eradication of the disease but also some morbidity and complications to the patients. It is hoped that the use of such QOL indicators can encourage a more holistic approach to clinical practice[2]. Patients treated with radiotherapy are among the groups of interest due to their serious illness and the time-consuming treatment that can produce a broad range of toxicity. This consideration is particularly important in Thailand where the patients frequently present at the later stages of disease leading to treatment only for palliation, and have to spend lengthy periods of time during treatment at a distance from their home. QOL enables better evaluation of the costs and benefits of this treatment compared with other modalities or only the palliative care.

A variety of QOL assessment tools have been developed. Some are disease-specific measures for cancer patients, while others are generic which can apply to all people. Although more specific measures will be more sensitive to changes in a particular condition, using generic instruments has the advantage of allowing comparisons between disease groups and to inform decisions, for instance, on resource allocation[3].

The WHOQOL-100 is one of the generic instruments initiated by the World Health Organization to be an international QOL assessment for a cross-cultural perspective[4]. Its development and psychometric properties have been collaboratively established in 15 different centers worldwide including Thailand[5]. The 26-item abbreviated version of WHOQOL instrument (WHOQOL-BREF) has been demonstrated to be a valid and reliable brief assessment of QOL[6]. The

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Thai version of this brief measure (WHOQOL-BREF-THAI) has been tested for its psychometric properties in a large population against the WHOQOL-100 and found to be a shorter and more convenient to use, and also has better comprehensibility[7]. It has also been tested in elderly people living in Songkhla province, and found to have acceptable internal consistency and validity[8]. However, its sensitivity, practicality and feasibility in measuring QOL in cancer patients have not been evaluated. The present study aimed to assess these considerations in a specific group of patients treated with radiotherapy during the course of routine daily clinical practice.

Material and Method

Design

A cross-sectional analytical study.

Subject selection

The study was carried out in the radiotherapy division of Songklanagarind Hospital, the only university hospital in Southern Thailand. It has 700 beds, and provides a comprehensive cancer service for the people in this area. Data from the hospital-based tumor registry indicated that approximately 40% of cancer patients are treated with radiotherapy[9]. The radiotherapy division treats about 1,200 new patients annually with a distinct demographic background, containing a mixture of Buddhist and Islamic people.

All cases of patients with cancer attending for radiation treatment during the study period were selected. Patients younger than 15 years old, those who could not understand the questionnaire owing to physical or communication problems, and those who were not willing to discuss this issue after informed consent were excluded from the study.

Instrumentation

The WHOQOL-BREF-THAI is the Thai version of a brief form (WHOQOL-BREF) of a generic and transcultural QOL assessment instrument developed by WHO (WHOQOL-100). It is a 26-item scale with 5-point Likert responses, having four subscales measuring physical health, psychological well-being, social relationships and satisfaction with the environment.

The four subscale scores are calculated by summing up the scores of the corresponding items in each subscale. The overall score is the summation of all subscale scores and two global item scores. The scores then are classified into three QOL groups by the criteria according to Mahatnirunkul (Table 1)[10].

Data collection

All the patients were assessed by the radiation oncologists for physical and/or communication problems. Those who could understand what was being requested were then informed about a brief definition of the QOL and how important it is by a nurse who specialized in radiotherapy. The standardized instructions on how to answer the WHOQOL-BREF questionnaire were then given by a research assistant. The patients who were willing to participate in the study completed the questionnaire by themselves or with the help of their relatives or it was carried out as a structured interview by the research assistant. They were also asked about their understanding in each item question. The time spent in each process was recorded for every patient in integer of minutes by the nurse who informed about QOL and by the research assistant who instructed how to answer the questionnaire and facilitated the questionnaire answering process until the patient finished it.

Study Variables

The independent variables analyzed were age, gender, religion, marital status, level of education, patient status, stage of disease, treatment aim and performance status of the patients.

The dependent variables included: subscale and overall QOL scores, patient understanding ability of each question and time spent in each process of the assessment.

Statistical analysis

The sample size was calculated to test the difference of good overall QOL proportion between the two groups of patients; the proposed percentages were 15% in good and 0% in poor performance status in the proportion of 2:1, at $\alpha = 0.05$ and power = 0.90 (one sided). About 96 patients were targeted for

Table 1. Subscale and overall QOL scoring criteria of WHOQOL-BREF-THAI[10]

Subscales	Items	Bad	Average	Good
Physical health	7	7-16	17-26	27-35
Psychological well-being	6	6-14	15-22	23-30
Social relationship	3	3- 7	8-11	12-15
Satisfaction with the environment	8	8-18	19-29	30-40
Overall	26*	26-60	61-95	96-130

* Another 2 global subscales for overall QOL and general health condition are included in overall scores

the good performance group, which was defined as patients with an ECOG performance status = 0-1, and 48 patients for the poor performance group, defined as those with an ECOG performance status = 2-4[11].

The percentages of patients of each independent variables and those who could understand each question were recorded. Means and standard deviations of time requirement in each process of the study were also calculated.

Mean, standard deviation and the percentage of patients with categorized levels of each subscale and overall QOL scores were reported. Percentage and odds ratio with 95% confidence intervals of good overall QOL patients comparing the groups of patients in each independent variable using univariate analysis were calculated. The differences of mean overall scores and good QOL proportions between the groups were analyzed using the Student's t test and X^2 test respectively.

Results

Patient characteristics

One hundred and eighty-seven patients came for radiation treatment at the Radiotherapy Division of Songklanagarind Hospital between October 3 and December 8, 2000. 36 patients were excluded from the study; the reasons for exclusion are summarized in Table 2. The final sample consisted of 151 patients (80.7%), who were all willing to participate in the present study; their characteristics are shown in Table 3. Only 19 patients (12.6%) could complete the questionnaire by themselves, another 4 (2.6%) did it with the help of their relatives, and the remaining 128 patients (84.8%) were interviewed by a research assistant. The time requirement in each process of QOL assessment is shown in Table 4.

Table 2. Patients excluded from the study

Reasons for exclusion	Number	%
Physical problems:		
- age younger than 15 years	13	36.1
- alteration of consciousness	6	16.7
- old age	4	11.1
- speaking difficulty from head and neck cancer	4	11.1
- dyspnea	3	8.3
Communication problems:		
- Islamic patients, unable to understand Thai language	4	11.1
- unable to understand the questionnaire	2	5.6
Total	36	100.0

Table 3. Demographic and clinical characteristics of 151 patients

Patient characteristics		Number	%
Age	Range (mean ± SD) years 17-86 (55.9 ± 15.0)		
Gender	Female	76	50.3
	Male	75	49.7
Religion	Buddhism	132	87.4
	Islam	19	12.6
Marital status	Single	12	8.0
	Married	101	66.9
	Separated/divorced	38	25.2
Level of education	None	14	9.3
	Primary school	103	68.2
	Secondary school	19	12.6
	Higher than secondary school	15	10.0
Patient status	Out-patient	89	58.9
	In-patient	62	41.1
Stage of disease	Loco-regional	117	77.5
	Recurrence/metastasis	34	22.5
Treatment aim	Curative	109	72.2
	Palliative	42	27.8
Performance status	ECOG 0	24	15.9
	ECOG 1	76	50.3
	ECOG 2	31	20.5
	ECOG 3	16	10.6
	ECOG 4	4	2.7

Table 4. Time requirement in QOL assessment process by the WHOQOL-BREF-THAI

Process	Time in minutes Range (mean ± SD)
Nurse informs about QOL	1-4 (1.2 ± 0.5)
Research assistant instructs how to answer the questionnaire	1-8 (1.3 ± 0.9)
Questionnaire completion (total number = 151)	7-29 (13.0 ± 4.0)
Patient themselves (number = 19)	8-27 (12.2 ± 4.7)
Assisted by relatives (number = 4)	9-14 (12.0 ± 2.4)
Interviewed by a research assistant (number = 128)	7-29 (13.1 ± 4.0)

Almost all of the 151 participants understood the WHOQOL-BREF-THAI item questions. There was only one patient who did not feel certain about the meaning of "health service", "physical environment" and "sex life" per each question concerning social welfare and health services, physical environment and sexual activity respectively.

Patient quality of life

Mean, standard deviation and the percentage of patients with categorized levels of each subscale and overall QOL scores are shown in Table 5.

Psychometric properties of WHOQOL-BREF-THAI

Reliability

The internal consistency tested by Cronbach alpha coefficient for overall QOL was good at 0.85. Subscale alphas ranged from 0.45, 0.62, 0.64 and 0.67 for social relationship, physical health, satisfaction with the environment and psychological well-being respectively.

Sensitivity

Table 6 presents the mean, standard deviation and percentage of patients with different levels of overall QOL stratified by clinical parameters. The result of statistical significance and odds ratio with 95% confidence intervals of good QOL patients comparing the groups in each independent variables using univariate analysis is also shown. The WHOQOL-BREF-THAI questionnaire was sensitive enough to discriminate the QOL in patients with differences in all analysed clinical parameters - patient status, stage of disease, treatment aim and ECOG performance status.

Table 5. QOL scores and levels of 151 patients

Subscale	Score Mean±SD	QOL levels Number of patients (%)		
		Bad	Average	Good
Physical health	20.9 ± 3.1	9 (6.0)	139 (92.0)	3 (2.0)
Psychological well-being	21.3 ± 3.1	3 (2.0)	95 (62.9)	53 (35.1)
Social relationship	9.4 ± 1.8	27 (17.9)	110 (72.8)	14 (9.3)
Satisfaction with the environment	25.7 ± 3.3	4 (2.7)	129 (85.4)	18 (11.9)
Overall	83.4 ± 9.7	3 (2.0)	133 (88.1)	15 (9.9)

Discussion

The main objectives of this study were to determine the feasibility of introducing one generic QOL assessment tool, the WHOQOL-BREF-THAI, in daily radiotherapy clinical practice, and determine its sensitivity in discriminating between subgroups of patients differing in clinical status. Four major outcomes were of interest: patient understanding ability, self-assessment ability, time requirement in the assessment process and sensitivity of the assessment tool.

Patient understanding ability

Most of the patients (81%) could participate in the study. Poor physical condition was the main reason for being excluded. Of the communication problems, those who were completely unable to understand the questionnaire were mostly the native Islamic people in Southern Thailand who were not acquainted with the Thai language.

Among the study participants, although the majority education level was only primary school (68.2%) and some did not have any formal education at all (9.3%), almost all of them could understand the questionnaire very well. Only a few words were considered to be difficult to understand for one patient each, and all belonged to a formal language such as

Table 6. QOL overall scores and levels stratified by clinical characteristics of 151 patients

Patientcharacteristics	Total No.	Score Mean ± SD	QOL levels Number of patients (%)			OR (95%CI) of Good QOL
			Bad	Average	Good	
Patient status						
Out-patient	89	84.9 ± 10.1	1 (1.1)	74 (83.1)	14 (15.7)	
In-patient	62	81.3 ± 8.8#	2 (3.2)	59 (95.2)	1 (1.6)	0.09 (0.00-0.54)**
Stage of disease						
Loco-regional	117	84.4 ± 9.8	2 (1.7)	100 (85.5)	15 (12.8)	
Recurrence/metastasis	34	80.2 ± 8.7#	1 (2.9)	33 (97.1)	0 (0.0)	0.00 (0.00-0.79)*
Treatment aim						
Curative	109	84.7 ± 9.9	2 (1.8)	92 (84.4)	15 (13.8)	
Palliative	42	80.0 ± 8.2##	1 (2.4)	41 (97.6)	0 (0.0)	0.00 (0.00-0.59)*
Performance status						
ECOG 0-1	100	84.9 ± 9.6	2 (2.0)	84 (84.0)	14 (14.0)	
ECOG 2-4	51	80.5 ± 9.2##	1 (2.0)	49 (96.1)	1 (2.0)	0.12 (0.00-0.76)*

Student's t test # p value < 0.05, ## p value < 0.01

X^2 test * p value < 0.05, ** p value < 0.01

"health service", "physical environment" and "sex life" in questions concerning social welfare and health services, physical environment and sexual activity respectively.

Patient self-assessment ability

Patient self-assessment ability is a critical concern in administering QOL assessment as a routine process in clinical practice, as it is rather impractical to interview patients in a busy, heavy workload situation, which is common in most of the public hospitals in Thailand. In the present study, the majority of the patients (84.8%) could not complete the questionnaire by themselves and needed to be interviewed by a research assistant. This finding was the same as a QOL study in Hong Kong cancer patients by Yu using FACT-G Chinese version and WHOQOL-BREF-HK, wherein a high level of illiteracy necessitated interviewers[12]. These findings were quite different from studies in Western countries, in which most of the patients could complete their self-assessment[13,14]. During the development of the WHOQOL-100 in 15 countries (including Thailand), the working group had also reported a small minority who needed to be interviewed, but unfortunately the numbers had not been recorded by each center[5].

The low self-administered percentage raised another concern of the validity of the results. At an interview, there was the risk of misinformation, as the patients might not tell what they really thought or chose not to answer some items that were rather private and sensitive. Both QOL studies in Eastern countries, Ratanatharathorn in Thailand[15] and Yu in Hong Kong[12], reached the same conclusion, that both Thai and Chinese people are often characterized as being inhibited, obedient, and more hesitant in their emotional expression, and less forthcoming to strangers about sensitive topics like sex. This Eastern way of life might affect the response to their FACT-G item "I am satisfied with my sex life" which corresponded with the WHOQOL-BREF question "How satisfied are you with your sex life?"

Time requirement in the assessment process

To inform the patient about the QOL issue and instruct them how to complete the questionnaire by a familiar nurse and the research assistant took only a few minutes, and this could be done for individuals or a group.

Completion of the questionnaire in the present study required, on average, 12.2 minutes for self-administration and 13.1 minutes for the research assistant's interview. These results were comparable to the WHOQOL-BREF study in older persons conducted in Taiwan, which required 10.6 and 15.3 minutes respectively[16]. In the present study, the authors added an additional question concerning patient understanding in each item, so the actual time requirement to complete only the questionnaire would be less than the reported figures. Such times, however, were in an acceptable range of less than 15-20 minutes that would not cause ill patients to become overtired[17] and could easily be accomplished during available waiting time for a doctor in an out-patient clinic situation.

Studies from the Netherlands have demonstrated that the introduction of individual QOL assessments in routine out-patient oncology practice is feasible, and also indicate that the QOL assessment need not lengthen the duration of contact between doctor and patient, perhaps due to the increased efficiency in focusing on issues that require further discussion quickly[14,18].

Sensitivity of the assessment tool

With the advantage of allowing comparisons across conditions and interventions, the authors decided to use a generic instrument in the present study. Even excluding patients with very poor physical condition from the beginning of the study, the mean overall QOL score in the presented sample (83.4) seemed to be lower than in a large sample from the general population during Thailand's economic crisis in 1998 (86.2) done by Mahatnirunkul[10], and in middle-aged female staff officers with chronic disease in the Royal Thai Navy Base in Bangkok (94.3) done by Suparp[19] with the same instrument. The good QOL percentage of the presented sample (9.9%) was also much lower than their results (20.5% in Mahatnirunkul's and 38.2% in Suparp's studies).

The main limitation of generic instruments is that they are not sensitive enough and may fail to capture some aspects of patient experiences that are of clinical interest in a specific clinical setting[20]. Although there has been consistent evidence that the WHOQOL-BREF has the ability to discriminate between subjects with different health conditions[6,21-24], and good responsiveness in detecting QOL change over time in people in some situations such as earthquakes[25,26], liver transplants[27] and elderly people[16], its discriminative validity in cancer patients with different conditions has not been well established. The present study

is the first one to demonstrate the sensitivity of this tool in discriminating the QOL in radiotherapy cancer patients with different major clinical characteristics, such as hospitalization, staging, treatment aim and performance status.

Although the tool also had an acceptable psychometric property of internal consistency with a high Cronbach alpha coefficient for overall QOL at 0.85, which was comparable with the result of 0.84 from the study conducted by Mahatnirunkul[7], the alphas of the subscale scores were rather low, especially the social relationship subscale which was only 0.45. These findings led to one of the present study's limitations, that the authors did not evaluate the QOL in the detail of each subscale to show the negative effect of cancer and treatment in those domains.

Another limitation was the cross-sectional design of the present study. This was insufficient to investigate test-retest reliability and responsiveness to detect changes over time. Although the longitudinal results in some of the presented patients who could do their self-assessment were also accumulated after the study and showed its responsiveness to detect changes in overall and subscale scores that could facilitate the discussion of QOL issues and can heighten physicians' awareness of their patients' QOL as reported by Detmar SB[18]. The number of patients was too small to confirm this assumption and a longitudinal study with more patients is needed to test this important advantage of QOL assessment in screening for less observable QOL problems in daily clinical practice using the WHOQOL-BREF.

In conclusion, the present results support the feasibility of using the WHOQOL-BREF-THAI assessment tool in cancer patients with good sensitivity and patient understanding within an acceptable time requirement. One practical barrier remaining of concern is the low self-assessment percentage found in this particular group of patients necessitating the interviewer system, which is not easy to organize in a busy radiotherapy clinic.

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การศึกษาความเป็นไปได้ในการใช้แบบประเมินคุณภาพชีวิตฉบับย่อภาษาไทยขององค์การอนามัยโลกในผู้ป่วยรังสีรักษา

เต็มศักดิ์ พึ่งรัศมี, รัชมล คติการ, สมชาย วัฒนอาภรณ์ชัย, ดวงใจ แสงถวัลย์

วัตถุประสงค์ *: เพื่อศึกษาความเป็นไปได้และความไวของแบบประเมินคุณภาพชีวิตฉบับย่อภาษาไทยขององค์การอนามัยโลก ในการวัดคุณภาพชีวิตผู้ป่วยมะเร็งรังสีรักษาในเวชปฏิบัติประจำวัน*

วิธีการ *: การศึกษาเชิงวิเคราะห์แบบตัดขวางในผู้ป่วยรังสีรักษาโรงพยาบาลสงขลานครินทร์ ที่มารับการรักษาตามลำดับช่วงเดือนตุลาคมถึงธันวาคม พ.ศ. 2543 โดยผู้ร่วมในการวิจัยตอบแบบประเมิน คุณภาพชีวิตฉบับย่อภาษาไทยขององค์การอนามัยโลก*

ผลการวิจัย *: ผู้ป่วยส่วนใหญ่ (80.7% ของผู้ป่วยทั้งหมด) สามารถตอบแบบสอบถามได้ โดย 19 ราย (12.6%) ตอบด้วยตนเอง 4 ราย (2.6%) มีญาติช่วย และ 128 ราย (84.8%) ใช้การสัมภาษณ์ ผู้ป่วยเกือบทั้งหมดเข้าใจคำถามเป็นอย่างดี ค่าเฉลี่ยและส่วนเบี่ยงเบนมาตรฐานของเวลาในการตอบเท่ากับ 13.0 $\pm$ 4.0 นาที แบบประเมินคุณภาพชีวิตฉบับย่อภาษาไทยขององค์การอนามัยโลกมีความไวเพียงพอ ในการแยกคุณภาพชีวิตของกลุ่มผู้ป่วยที่มีตัวแปรเกี่ยวกับโรคทุกตัวที่วิเคราะห์แตกต่างกัน ซึ่งได้แก่ การอยู่ในโรงพยาบาล ระยะของโรค เป้าหมายของการรักษาและสภาพร่างกายตามระบบ ECOG*

สรุป *: ผลการศึกษาครั้งนี้สนับสนุนความเป็นไปได้ในการนำแบบประเมินคุณภาพชีวิตฉบับย่อ ภาษาไทยขององค์การอนามัยโลกมาใช้ในผู้ป่วยมะเร็งรังสีรักษา โดยมีความไวดี ผู้ป่วยเข้าใจคำถามดี และใช้เวลาไม่นาน อุปสรรคในทางปฏิบัติประการหนึ่งที่ต้องคำนึงถึงคือ ร้อยละของผู้ป่วยที่สามารถตอบแบบ ประเมินด้วยตนเองต่ำ ทำให้จำเป็นต้องอาศัยระบบการสัมภาษณ์*