

Brief communication

Quality of life of lung cancer patients: Validation of the Taiwan Chinese version of the EORTC QLQ-C30 and QLQ-LC13

Wei-Chu Chie¹, Chih-Hsin Yang², Chiun Hsu² & Pan-Chyr Yang³

¹*School of Public Health and Graduate Institute of Preventive Medicine, College of Public Health, National Taiwan University (E-mail: weichu@episerv.cph.ntu.edu.tw);* ²*Department of Oncology;* ³*Internal Medicine, National Taiwan University Hospital, Taiwan*

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Abstract

The purpose of this study was to test the validity and reliability of the Taiwan Chinese translation of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 (EORTC QLQ-C30, version 3) and Quality of Life Questionnaire Lung Cancer-13 (QLQ-LC13) questionnaires. Consecutively 51 patients with lung cancer undergoing active chemotherapy and 48 such patients undergoing regular follow-up completed the questionnaires. The intraclass correlation between test and retest ranged from 0.46 to 0.85 for the QLQ-C30 and was 0.76 for dyspnea for the QLQ-LC13. The κ coefficients between test and retest ranged from 0.51 to 0.73 for single items of the QLQ-C30 and 0.49–0.68 for five of the nine items in the QLQ-LC13. The Cronbach's α coefficients were ≥ 0.70 for all scales of the two questionnaires apart from that of cognitive functioning. The correlation coefficients between indices measuring similar dimensions of the EORTC QLQ-C30 and the SF-36 questionnaires ranged from 0.43 to 0.73, and that between the dyspnea scales of the two EORTC questionnaires was 0.70. Patients in the follow-up group revealed higher scores of global status/quality of life, and lower scores of nausea/vomiting, as also physical functioning. The questionnaires could also detect expected adverse effects of radiotherapy, cisplatin, and paclitaxel.

Key words: EORTC QLQ-C30, EORTC QLQ-LC13, Lung cancer, Quality of life

Introduction

Lung cancer is a disease that is rapidly increasing in Taiwan [1]. The high case-fatality rate (95.7%) [1] spurred oncologists to develop new therapeutic measures to prolong lung cancer patients' life [2].

More than 50 instruments measuring quality of life (QOL) for patients suffering from lung cancer emerged from 1970 to 1995 [3]. The Lung Cancer Symptom Scale (LCSS), Functional Assessment of Cancer Therapy-Lung (FACT-L) and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 (EORTC QLQ-C30) with Quality of Life Questionnaire Lung Cancer-13 (QLQ-LC13) have good

reliability and validity [3]. The EORTC QLQ-C30 includes 30 questions that measure five function scales, three symptom scales, five single symptom items and financial difficulty. All scales/items are transformed to scores ranging between 0 and 100. For all functioning scales that measure function a higher score represents better QOL; and for all symptom scales/items a lower score means better QOL. Previous studies using this instrument revealed high internal consistency in most scales except for cognitive functioning, good inter-scale correlation, good discriminant validity [4], test-retest reliability [5], patient-observer agreement [6] and cross-cultural validity except a low discriminant validity of role functioning scale in Japan [7].

The QLQ-LC13 is a supplementary module to the QLQ-C30 for patients with lung cancer and contains 13 questions to measure one symptom scale (dyspnea) and nine single symptom items. A previous study demonstrated good internal consistency for the dyspnea scale and good clinical validity for most scores [8].

The only available Chinese translation prior to this study, the Cantonese version of the EORTC QLQ-C30 [9] included vocabulary that differed from the Mandarin typically used in Taiwan. The Standard Chinese version of the QLQ-C30 (version 2) was available in 1997 and the results of validation were published in 2000 [10]. As a result of the geographical, political and cultural separation of China and Taiwan for over 50 years, each country's corresponding languages and alphabetical characters have evolved and become somewhat different. Here we present the result of translation and cross-validation of the EORTC QLQ-C30 version 3 and QLQ-LC13 questionnaires for lung cancer patients in Taiwan.

Methods

We followed the EORTC guidelines for the translation procedure and pilot testing of the questionnaire [11]. The Taiwan Standard version (version 1.0) of the SF-36 questionnaire, a generic instrument measuring eight separate dimensions of QOL [12, 13] was used as a comparison instrument. The Taiwan Standard version (version 1.0) of the SF-36 questionnaire has demonstrated good reliability and validity in Taiwan [14–17].

We consecutively contacted lung cancer patients undergoing active chemotherapy and undergoing post-therapy follow-up at the out patient clinic of the Department of Oncology of the National Taiwan University Hospital from November 2000 to December 2001 inclusively. Chemotherapy and the concurrent medical treatment data were also collected on patients undergoing active treatment. Written consent was obtained from all study participants. Patients who declined to participate, or who had participated in other studies or who had elected to amend their treatment plans were excluded. Assuming that the standard deviation of the questionnaire-derived QOL score is 20, the sample size required for each group is 50 subjects

in order to achieve 80% power for detecting a difference of 10 points between two groups at the 5% significant level for a one-sided Z-test. The final participant distribution was 51 for the active treatment group and 48 for the follow-up group after correcting for misclassified patients and the excluding non-eligible patients. The selection of the two known groups was based upon the hypotheses that patients undergoing chemotherapy typically revealed poorer QOL.

Patients were instructed to complete the questionnaires themselves. However, four patients in the active treatment group and seven patients in the follow-up group who were illiterate were assisted by two interviewers fluent in both Mandarin and Taiwanese. The illiterate subjects were kept in the study to maintain the representativeness of the sample. Patients in the follow-up group were retested with the same questionnaires 1–2 weeks after the first test, conducted by telephone interview or by mailing the questionnaires. Test/retest reliability of the translated questionnaire was carried out on the follow-up group since their medical condition was expected to be more stable than that of patients in active treatment.

Answers to the three questionnaires were scored according to the instructions and computer programs provided [12, 13, 18]. The test/retest reliability was evaluated by intraclass correlation coefficients (ICCs) for each questionnaire-determined dimension, and κ value of two repeated tests for single items. Cronbach's α coefficient was used in order to evaluate the internal consistency of each dimension. The validity of the two questionnaires was examined by Pearson's correlation coefficients between similar dimensions for the EORTC and the SF-36 questionnaires. The Wilcoxon's rank sum test was used to examine the difference in scores for each dimension, and the Cochran Mantel-Haenszel test was used to examine differences in single items between the two groups of patients. A p -value of <0.05 was considered as statistically significant.

Results

Patients in the active chemotherapy group ($n = 51$) averaged 54.3 years of age ($SD = 12.1$ years), included more men (32) than women, had about the

same number with less than a high school education (22) as with a high school education or better (29), spoke mostly Mandarin (39) or Taiwanese (39) and had adenocarcinoma or squamous cell cancer. Patients in the follow-up group averaged 55.0 years of age (SD = 12.4 years), included almost equal numbers of men and women, had the same number with less than or at least a high school education (24), spoke mostly Taiwanese (38) and had mostly adenocarcinoma (32).

The ICCs were moderate to high in most scales ($r = 0.46$ – 0.85 for the QLQ-C30 and 0.76 for dyspnea of the QLQ-LC13). The κ coefficients for and single items were moderate for the QLQ-C30 ($\kappa = 0.51$ – 0.73) and also for five items in the QLQ-LC13 ($\kappa = 0.49$ – 0.68), but low for the remaining four items of the QLQ-LC13 (hemoptysis, peripheral neuropathy, pain in arm and pain in other

part, $\kappa = 0.35$ – 0.39). All Cronbach's α coefficients for scales of the QLQ-C30 and the dyspnea scale of the QLQ-LC13 were satisfactory (≥ 0.70) apart from that coefficient for cognitive functioning ($\alpha = 0.58$). The Cronbach's α coefficient of pain-related questions was only 0.58, while that for peripheral neuropathy plus pain questions was 0.69 (Table 1).

The physical functioning, emotional functioning and pain scales of the QLQ-C30 were highly correlated ($r \geq 0.70$) with scales measuring the same domains in the SF-36. The dyspnea scale of the QLQ-LC13 was highly correlated ($r = 0.70$) with the single item of dyspnea (short of breath) of the QLQ-C30. Correlation coefficients between the remaining pairs of scales were moderate ($r = 0.43$ – 0.63). The follow-up group demonstrated a higher score for the QOL scale, a lower score for the

Table 1. Reliability of the EORTC QLQ-C30 and the EORTC QLQ-LC13

	Test-retest reliability (Follow-up group, N = 48)	Internal consistency (All patients, N = 99)
<i>QLQ-C30</i>		
Intraclass correlation coefficients		Cronbach's α
Physical functioning	0.85	0.85
Role functioning	0.58	0.92
Emotional functioning	0.76	0.81
Cognitive functioning	0.83	0.58
Social functioning	0.46	0.82
QOL	0.75	0.86
Pain	0.46	0.80
Nausea and vomiting	0.52	0.74
Fatigue	0.64	0.81
Agreement % (κ)		
Dyspnea	71% (0.53)	–
Sleep disturbance	77% (0.67)	–
Appetite loss	79% (0.66)	–
Constipation	79% (0.53)	–
Diarrhea	79% (0.51)	–
Financial difficulty	85% (0.73)	–
<i>QLQ-LC13</i>		
Intraclass correlation coefficients		Cronbach's α
Dyspnea	0.76	0.83
Agreement % (κ)		
Coughing	77% (0.62)	–
Hemoptysis	92% (0.39)	–
Sore mouth	85% (0.49)	–
Dysphagia	83% (0.51)	–
P. neuropathy	63% (0.38)	Pains + this item: 0.69
Alopecia	83% (0.68)	–
Pain in chest	75% (0.58)	All pains: 0.58
Pain in arm	63% (0.39)	–
Pain others	65% (0.35)	–

Table 2. Comparison of QOL scores of each scale in the EORTC QLQ-C30 and QLQ-LC13 among two groups of patients

	Active chemotherapy N = 51 Mean ± SD	Follow-up N = 48 Mean ± SD	Wilcoxon's test <i>p</i> -value (one-side)
Physical functioning	79.9 ± 18.3	72.2 ± 22.1	0.0262* (T > F)
Role functioning	71.6 ± 25.9	74.7 ± 31.5	NS
Emotional functioning	75.8 ± 16.1	75.0 ± 21.0	NS
Cognitive functioning	80.4 ± 18.8	78.8 ± 22.0	NS
Social functioning	69.3 ± 28.4	76.7 ± 21.4	NS
QOL	56.5 ± 19.6	63.2 ± 20.8	0.0449* (F > T)
Fatigue	39.2 ± 21.6	34.3 ± 19.7	NS
Nausea and vomiting	17.6 ± 21.7	5.6 ± 11.1	0.0004 (T > F)
Pain	24.8 ± 24.8	19.4 ± 18.3	NS
Dyspnea	20.3 ± 18.3	24.1 ± 21.8	NS

**p* < 0.05, one-sided.

nausea/vomiting scale, and a lower score for physical functioning scale than the active chemotherapy group. Scores of the two groups did not appear to differ for any other dimensions (Table 2) or single items (not shown in the table). Compared with patients who did not have the following treatments, patients who underwent radiotherapy and who received cisplatin experienced more nausea and vomiting, patients who received radiotherapy experienced more hair loss and arm/shoulder pain, and patients who received paclitaxel revealed greater level of hair loss (Table 3).

Discussion

The test/retest reliabilities of the questionnaires for the follow-up group in this study were lower than was the case for the 1995 study of Hjerstad et al. [5] but consistent with our previous study on patients with nasopharyngeal carcinoma [19]. Our test/retest interval was within the range suggested by Streiner and Norman [20]. It is possible that a patient's condition may have changed within the range even for members in the follow-up group. The results for internal consistency in this study

Table 3. Differences in nausea/vomiting scores of patients with and without certain treatments (only significant results were included)

	N	Mean ± SD	<i>p</i> -value
Nausea and vomiting			Wilcoxon's test <i>p</i> -value (one-side)
Radiotherapy			
Yes	9	25.9 ± 20.6	0.0490 (Yes > no)
No	42	15.9 ± 21.8	
Cisplatin			
Yes	28	23.8 ± 25.0	0.0161 (Yes > no)
No	23	10.1 ± 14.0	
Hair loss			Cochran Mantel-Haenszel test
Radiotherapy			
Yes	9	33.3 ± 37.3	0.0292
No	42	11.1 ± 24.0	
Paclitaxel			
Yes	10	36.7 ± 39.9	0.0059
No	41	9.8 ± 21.4	
Arm and shoulder pain			Cochran Mantel-Haenszel test
Radiotherapy			
Yes	9	44.4 ± 28.9	0.0150
No	42	19.8 ± 25.6	

were consistent with the findings of previous studies [4, 7, 8, 10]. We changed the translation peripheral neuropathy (tingling) from 'pain as having been stung' to 'like having been stung with needles' because of the unexpectedly high Cronbach's α coefficient of tingling and pain questions.

The moderate to high correlation of similar dimensions between the QLQ-C30 and the SF-36 and the high correlation between dyspnea scales of the two EORTC questionnaires imply that both EORTC questionnaires exhibited good validity. The scores for the active chemotherapy group of this study were similar to or better than for those of patients during treatment in previous studies [4, 8, 10]. The scores for the follow-up group of this study were similar to the reference values of local or locoregional non-small cell lung cancer provided by the EORTC [21], but better than that of previous studies [4, 7]. The significantly higher scores in the QOL and lower score in the nausea/vomiting scale of the follow-up group corresponded with the finding of Bergmen et al. [8]. The corresponding symptoms of cisplatin (nausea/vomiting), paclitaxel (hair loss), and radiotherapy (shoulder/arm pain) were consistent with previous knowledge of the adverse effects. The pronounced hair loss experienced by patients undergoing radiotherapy was, however, difficult to explain and warrants further investigation.

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Address for correspondence: Wei-Chu Chie, School of Public Health and Graduate Institute of Preventive Medicine, College of Public Health, National Taiwan University, Room 209, 19 Hsueh Road, Taipei 10020, Taiwan
Phone: +886-2-23920460; Fax: +886-2-23920456
E-mail: weichu@episerv.cph.ntu.edu.tw