RESEARCH COMMUNICATION

Validation Study of a Quality of Life (QOL) Questionnaire for Use in Iran

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Abstract

Introduction: Recently, it has been recognized that a more comprehensive assessment of the cancer patient is necessary and that the evaluation of outcomes must move beyond traditional biomedical endpoints to include assessments of the impact of disease and its treatment on patients' quality of life. The European Organization for Research and Treatment of Cancer has developed a 30-item quality of life questionnaire to obtain information about the impact of disease and treatment on the daily living of cancer patients. This questionnaire has been translated into many languages and used in various countries. However, version 3.0 has not yet been validated for use with Iranian patients. The aims of the present study were therefore to evaluate the reliability and validity of the new QLQ-C30 questionnaire. Method: We conducted a cross-sectional study on 132 random samples of breast cancer patients. Reliability was evaluated through the internal consistency of multi-item subscales. Pearson's correlations of an item with its own scale (corrected for overlap) and other scales were calculated to evaluated convergent and discriminant validity. Clinical validity was evaluated by known-group comparisons. All calculations were performed using SPSS.V.13 software. Results: In the reliability analysis, most scales fitted the criteria except the fatigue (Alpha 0.65), pain (Alpha 0.69) and nausea and vomiting scales (Alpha 0.66). Convergent validity was evidenced by item own subscale correlation above 0.40 for all multi-item subscales. Item discriminant validity was successful in all analyses except for item 4 of the physical functioning scale. Results of the group based analysis show significant differences in QLQ-C30 functioning and symptom scores, where patients with higher grade have the worst outcome(P<0.05). Conclusion: The Iranian version of EORTC QLQC30 is a reliable and valid QOL measure for cancer patients which indicates that it can be used in clinical and epidemiological cancer research.

Key Words: Validity - reliability - EORTC QLQ-C30 - Iran

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Introduction

Quality of life (QOL) has become a part of the evaluation criteria for cancer therapy (Aaronson et al., 1988). Recently, it has been recognized that a more comprehensive assessment of the cancer patient is necessary and that the evaluation of outcomes must move beyond traditional biomedical endpoints to include assessments of the impact of disease and its treatment on patients' quality of life (Aaronson et al., 1993).

Different reasons for assessing quality of life have led to the development and use of any different generic and disease-specific measures (Arraras et al., 2002; Bjordal et al., 1999).

The European Organization for Research and Treatment of Cancer (EORTC) has a study group on QOL. One of their major tasks is the development of questionnaires for the assessment of QOL in international clinical trials (Cheung et al., 2004; Chie et al, 2004).The EORTC has developed a 30-item quality of life questionnaire (QLQ-C30) which is a brief, self-reporting, cancer-specific measure of health-related quality of life (HRQL) (Hoopman et al., 2006). Its purpose is to obtain information about the impact of disease and treatment on the daily living of cancer patients (Huang et al., 2007). QLQ-C30 was translated into many languages and used in various countries. Even the EORTC was developed in western culture, it was found to be suitable when using in eastern countries such as China (Knobel et al., 2003),Taiwan (Kobayashi et al., 1998), Japan (Kyriaki et al., 2001), Korea (Lee et al., 2000), Singapore (Levine et al., and Iran (Arraras et al., 2002). To be useful in research and clinical applications, HRQL measures, like other scientific measures, must be relevant,quantifiable, reliable and valid. There is a growing literature supporting the reliability and validity of the QLQ-C30 (Levine et al., 1988). Version 2.0 of the QLQ-C30 has been validated for use in Iran with a sample of breast cancer patients (Arraras et al., 2002). But, version 3.0 has not yet been validated for use with Iranian patients. The aims of the present study are to evaluate the reliability and validity of the QLQ-C30 (version 3.0) questionnaire when applied to an Iranian sample of breast cancer patients.

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Materials and Methods

Subjects

We conducted a cross-sectional study on 132 random samples of breast cancer patients that were admitted and treated in the chemotherapy ward of Namazi hospital in Shiraz city, Iran during Jan to Feb 2006. Any patients with a diagnosis of breast cancer, according to pathology report, under chemotherapy were eligible to enter the study.

The exclusion criteria were: life expectancy of less than 2 months; cognitive impairment; other previous or concurrent malignancies.

Questionnaire

The EORTC QLQ-C30 was used in this study for assessing quality of life. The QLQ-C30 is multidimensional, made up of 30 items (five functional domains: physical, role, emotional, cognitive, and social, one global QOL domain, three symptom domains: fatigue, nausea-vomiting, pain, and six single items). The scores are transformed into 0–100 point scales. In the case of the five functional scales and the global QOL scale, the high score means: 'high level of functioning or global QOL'. On the other hand, in the case of symptom scales and single items, the higher score implies the 'higher level of symptoms or problems'(McLachlan et al., 1998). Sociodemographic data included age, education, occupation and marital status. Clinical data including grade of tumor, metastasis and etc. gathered by additional questionnaire.

Statistical analyses

A range of statistical analyses was performed to establish reliability and the validity of the Iranian questionnaire. Reliability was evaluated through the internal consistency of multi-item subscales. Preferable reliability was indicated by Cronbach's alpha coefficient greater than 0.70 (Kobayashi et al., 1998). Construct validity was confirmed when: convergent validity – indicating the correlation between an item and its own scale – was moderately high (recommended correlation value by the EORTC $r \geq 0.40$), and discriminant validity – indicating the correlation between an item and any of the other scales – was low. A definite scaling error was assumed if the correlation of an item with another scale exceeded the correlation with its own scale. To test for item convergence and discriminative validity we examined the above mentioned item-scale correlations. Pearson's correlations of an item with its own scale (corrected for overlap) and other scales were calculated (Levine et al., 1998).Clinical validity was evaluated by known-group comparisons. This could indicate the extent to which the questionnaire scores were able to discriminate between subgroups of patients differing in clinical status (Levine et al., 1998). The known-group comparisons were conducted by comparing patients with different grades, under the hypotheses that patients with higher degree of grade may have higher symptomatic scores.

Kruskalwallis and ANOVA were used for between group analysis. All tests were two-sided and P values less than 0.05 were considered as statistically significant. All calculation was performed by using SPSS.V.13 software.

Table 1. Demographic Features and Clinical Information of Study Subjects

Characteristics		Frequency	%
Age	<40	34	25.8
	40-60	79	59.8
	>60	19	14.4
Marital status	married	35	26.5
	other	97	73.5
Education	illiterate	37	28.0
	primary	40	30.3
	secondary	45	34.1
	college /university	10	7.6
Occupation	housewife	120	90.9
	other	12	9.1
Menopause	yes	62	48.4
	No	66	51.6
Tumor grade	well differentiated	43	32.6
	moderately differentiated	55	41.7
	poorly differentiated	34	25.8
Metastasis	yes	103	78.0
	no	29	22.0

Results

In total 132 patients with breast cancer were interviewed. The demographic and clinical characteristics of the baseline sample are shown in Table 1. The mean age was 48.61 (SD=11.22) years, and most of the patients were married (73.5%) and had enjoyed primary or secondary education (64.4%). The grade of tumor was as follows: 32.6% well differentiated, 41.7% moderately differentiated and 25.8% poorly differentiated.

Table 2 shows the means and standard deviations for the multi-item and single-item measures. Score

Table 2. Descriptive Statistics and Scale Reliability of the QLQ-C30

	Items[1]	Mean scores	SD	Cronbach's alpha[2]
Functioning scales[3]				
Physical	1-5	56.57	23.81	.76
Role	6-7	65.91	34.76	.77
Cognitive	20,25	71.84	27.17	.77
Emotional	21-24	56.33	30.63	.77
Social	26-27	69.57	33.05	.73
Global quality of life	29-30	63.26	25.70	.82
Symptoms scales[4]				
Fatigue	10,12,18	41.67	26.85	.65
Nausea and Vomiting	14-15	15.66	27.99	.69
Pain	9,19	34.34	28.89	.66
Dyspnea	8	16.67	27.47	
Insomnia	11	42.93	40.67	
Appetite loss	13	25.50	36.81	
Constipation	16	15.40	29.53	
Diarrhea	17	4.04	16.49	
Financial difficulties	28	51.26	41.68	

*[1]Numbers correspond to the item numbers in the questionnaire [2]Cronbach's alphas can only be determined for multi item symptom scales [3]Scores range from 0 to 100 with a higher score representing a higher level of functioning [4]Scores range from 0 to 100 with a higher score representing a greater degree of symptoms

Table 3. Convergent and Discriminant Validity for Multi item Scales of the QLQ-C30

	Convergent validity	Discriminative validity
Functioning scales		
Physical	0.41 - 0.79	0.170 - 0.70
Role	0.89	0.072 - 0.71
Cognitive	0.74 - 0.87	0.160 - 0.58
Emotional	0.77 - 0.88	0.190 - 0.63
Social	0.94 - 0.95	0.120 - 0.74
Global quality of life	0.99	0.078 - 0.35
Fatigue	0.67 - 0.85	0.027 - 0.53
Nausea and Vomiting	0.93 - 0.95	0.027 - 0.39
Pain	0.78 - 0.83	0.052 - 0.48

distributions were approximately asymmetrical for the majority of the functioning and symptoms scales, except for the physical and emotional functioning scales. In the reliability analysis, most scales fitted the criteria except the fatigue (Alpha 0.65),pain (Alpha 0.69) and nausea and vomiting scales (Alpha 0.66) (Table 2).

Convergent validity was evidenced by item own subscale correlation (corrected for overlap) above 0.40 for all multi-item subscales. Item own subscale correlation higher than item other subscale correlation meant adequate discriminative validity. Item discriminant validity was successful in all analyses except for item 4 of the physical functioning scale that showed a higher correlation with the role functioning scale (r = 0.7) and social functioning scale (r = 0.64) compared to its own (r = 0.62) (Table 3).

Results of the group based analysis show significant differences in QLQ-C30 functioning and symptom scores, where patients with higher grade have the worst .There were statistically significant group differences in the expected direction for almost all functioning and symptom scores expect role and social functioning scales. In other words ,those with a well differentiated grade reported significantly higher levels of functioning scores, a significantly higher global quality of life and a lesser intensity of symptoms (Table 4).

Table 4. Group Comparison Analysis

Scales	Grade of Tumor			P value
	Well (n=43)	Moderate (n=55)	Poor (n=34)	
Mean (SD)	Mean (SD)	Mean (SD)		
Physical	65.1 (22.3)	54.7 (24.2)	48.8 (22.3)	0.008
Role	75.2 (30.1)	59.1 (37.9)	65.2 (36.8)	0.073
Cognitive	79.5 (25.2)	73.9 (25.4)	58.8 (28.5)	0.003
Emotional	63.5 (30.1)	57.2 (30.6)	45.8 (29.3)	0.04
Social	77.1 (30.9)	66.1 (32.2)	65.7 (6.21)	0.189
Global quality of life	84.7 (8.12)	67.9 (10.8)	28.7 (21.9)	<0.0001
Fatigue	32.9 (25.5)	43.2 (26.6)	50.3 (26.3)	0.014
Nausea and Vomiting	7.8 (21.0)	14.5 (27.8)	27.5 (32.5)	0.008
Pain	24.0 (25.5)	36.7 (28.4)	43.6 (30.4)	0.008

Discussion

When treating cancer patients, preservation and/or improvement of quality of life is an important goal. There is an emerging consensus that a pragmatic definition of quality of life be adopted and operationalised as an outcome in clinical trials. HRQL is a functional representation of patients' physical, psychological, and social response to disease and its treatment. The QLQ-C30 has been developed as a quantitative measure of HRQL for the clinical research setting. As is the case for other scientific tests, application is dependent on the instrument's consistency and accuracy. Validation is relative and its evaluation is an iterative process. Tests of validity do not provide absolute proof or rejection but rather a continuum of support and are best applied in the context in which the instrument is intended to be used, as was the case in this analysis.

This study shows that the Iranian version of EORTC QLQC30 is reliable and valid QOL measure for cancer patients which indicate that it can be used in clinical and epidemiological cancer researches.

Levels of compliance were good, with few missing data, indicating that the instrument was well accepted by patients. The internal consistencies of most scales, except for fatigue, pain and nausea & vomiting symptom scales, as assessed by Cronbach's a coefficients were above the acceptable level of 0.7. Multitrait scaling analysis showed that all item scale correlation coefficients met the standards of convergent and discriminant validity. Most scales have low to moderate correlation coefficients with the other scales, indicating that these areas are related but represent different elements of QOL. The psychosocial subscales of the QLQ-C30 appear to be measuring what they are intended to measure.

We conclude that the EORTC QLQ-C30 (version3.0) questionnaire has satisfactory psychometric properties when applied to a sample of Iranian patients with breast cancer. Its reliability and validity levels are satisfactory, and the structure of the questionnaire is confirmed. These results are in line with the results of the validation studies of versions 2.0 for Iranian (Levine et al., 1998),and those of the validation study carried out by the EORTC QOL Study Group. However, the interpretation of our results is limited due to using exclusively breast cancer patients. Studies with other diagnostic groups of cancer patients are needed to confirm our results and to allow their generalization. Also, further research comparing QOL instruments is needed to provide information on the differences of the individual questionnaires and recommendations regarding their specific range of application.

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