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The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30): translation and validation study of the Iranian version

Abstract The objective of this study was to test the reliability and validity of the Iranian version of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ-C30). The English-language version of the questionnaire was translated into Persian (Iranian language), and its final form was approved by the EORTC Study Group on Quality of Life before it was used in this study. The questionnaire was administered at two time points to a consecutive sample of 168 newly diagnosed breast cancer patients, and almost all of them (99%) found the questions easy to understand and acceptable. Crohnbach's alpha coefficient for multi-item scales (to test reliability) ranged from 0.48 to 0.95 at baseline and from 0.52 to 0.98 at follow-up administration of the questionnaire. Validity was checked using two methods: inter-scale correlation and known-groups comparison. Almost all inter-scale correlations were statistically significant in the expected direction. Known-groups comparison analysis showed that all functioning and symptom scales discriminated between subgroups of patients differing in clinical status as defined by their performance status and disease stage. In general, the findings of this study indicate that the Iranian version of the EORTC QLQ-C30 is a reliable and valid measure of quality of life in cancer patients and can be used in clinical trials and studies of outcome research in oncology.

Key words Quality of life · Validation study · Breast cancer · EORTC QLQ-C30 · Iran

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Introduction

Measuring quality of life in cancer patients is rapidly becoming more widespread, although some conceptual and methodological issues remain to be settled [7, 13, 18, 20]. Different reasons for assessing quality of life have led to the development and use of many different generic and disease-specific measures. The European Organization for Research and Treatment of Cancer (EORTC) is one of the oldest and largest clinical trial groups in Europe to have developed a core cancer-specific quality of life questionnaire (QLQ), and a number of supplementary questionnaire modules to evaluate quality of life in cancer patients in general and in specific cancer patient populations in particular. The first generation of the EORTC QLQ was developed in 1987, and the most recent version of the questionnaire, known as the EORTC QLQ-C30 version 2.0, has been disseminated by the EORTC since early March 1995 [2, 12]. The early version of this new questionnaire was first validated in an international field study of lung cancer patients, and it was found to be a reliable and valid measure of the quality of life assessment in cancer patients [3]. It is argued that the best developed quality of life measure for use with cancer patients is currently the EORTC QLQ-C30 [6]. According to the EORTC Data Centre, there are 27 EORTC clinical trials in which the QLQ-C30 is currently in use. In addition to these, the questionnaire is being used in over 100 clinical investigations being carried out by other clinical trial groups [4]. Despite the cultural differences that exist between Europe and Asia, in our centre (Iranian Centre for Breast Cancer-ICBC) we decided to translate the English-language version of the QLQ-C30 and its supplementary breast-cancer-specific instrument (QLQ-BR23) [22] into Persian (Iranian language) for the first time, for use as a standardized and valid measure in clinical trials and epidemiological studies.

No such questionnaire is currently available in Iran. This paper reports data on the reliability and validity of the Iranian version of the EORTC QLQ-C30, and the data relating to the breast-cancer-specific questionnaire will be reported in a later paper.

Methods

Questionnaire

The EORTC QLQ-C30 is a 30-item core-cancer-specific questionnaire measuring quality of life in cancer patients, and the conceptual and methodological issues underlying the construction of the questionnaire are described in detail elsewhere by the workers who pioneered it [1, 2]. 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 single items assess additional symptoms commonly reported by cancer patients (dyspnoea, appetite loss, sleep disturbance, constipation, and diarrhoea) and also the perceived financial impact of the disease and treatment [3]. After obtaining written consent from the EORTC Study Group on Quality of Life, the standard “forward-backward” translation procedure [11] was used to translate the English-language version of the questionnaire into Persian. The translated questionnaire was then reviewed, pretested and revised, and its final form was approved by the EORTC Study Group on Quality of Life; and subsequently it was used in this study.

Patients and data collection procedure

Data were collected during one complete calendar year, the declared intention being to interview all new breast cancer patients attending the breast clinic of a large teaching and medical centre in Tehran, Iran. Any patients with a suspected diagnosis of breast cancer were identified by the specialist consultants and were interviewed before the diagnosis was made. Thus, both patients and the interviewer were blind to the final diagnosis at the time of the prediagnosis interview. Follow-up assessments were carried out 3 months after completion of the patients’ initial treatment. Permission was obtained from clinicians and from the patients. All patients who were diagnosed as having conditions other than breast cancer were excluded from the analysis. There were no restrictions on patient selection in terms of histological type of breast cancer, age, or performance status.

Additional measures

Sociodemographic data included age, education, and marital status. Clinical data including disease stage and type of initial treatment were extracted from case records. The Eastern Cooperative Oncology Group (ECOG) performance status was also rated for each patients at both prediagnosis and follow-up assessments. This is a five-point scale ranging from 0 to 4. Zero indicates that the patient is able to carry out all normal activities and 4, that the patient is completely disabled [24].

Statistical analyses

A range of statistical analyses was performed to establish reliability and the validity of the Iranian questionnaire. Statistical analyses were conducted for the prediagnosis and the follow-up assessments.

Reliability

The internal consistency of the multi-item scales was assessed by Cronbach’s alpha coefficient [10]. As recommended, internal consistency of a magnitude of 0.70 or greater was sought [19].

Validity

Two methods were used to test the validity of the QLQ-C30. The first method involved examining the correlations among various QLQ-C30 scales. It was expected that conceptually related scales would correlate with one another (Pearson’s $r \geq 0.40$). In contrast, those scales with less in common were expected to show lower correlations (Pearson’s $r < 0.40$). Second, the method of known-groups comparison was used to evaluate the extent to which the QLQ-C30 was able to discriminate between subgroups of patients differing in clinical status [16]. The clinical parameters used to form subgroups of patients at both baseline and follow-up analyses included disease stage and initial and posttreatment ECOG performance status. One-way analysis of variance (ANOVA) was used to test for statistical significance of group differences.

Results

Patients’ sociodemographic and clinical characteristics

In total 316 patients with suspected breast cancer were interviewed. Of these, 168 patients were diagnosed as in fact having breast cancer. The demographic and clinical characteristics of the baseline sample are shown in Table 1. The mean age was 47.2 (SD = 13.5) years, and most of the patients were married (68%) and had enjoyed primary or secondary education (66%). According to case notes the vast majority of cases (83%) underwent mastectomy and the disease stage was as follows: 17% local, 45% loco-regional and 38% metastatic.

Table 1 Demographic and clinical characteristics of the study sample ($n = 168$)

	No.	%
Age groups (years)		
24–34	33	20
35–44	46	27
45–54	40	24
55–64	28	16
64>	21	13
Mean (SD)	47.2 (13.5)	
Range	24–81	
Educational status		
Illiterate	38	23
Primary	79	47
Secondary	33	19
College/university	18	11
Marital status		
Single	15	9
Married	117	68
Widowed	36	23
Disease stage		
Local	29	17
Loco-regional	76	45
Metastatic	63	38
Initial management		
Mastectomy	139	83
Conservative surgery	15	9
Chemotherapy	11	7
Best supportive care	3	1
ECOG performance score		
0 (normal activity)	64	38
1 (symptoms)	51	31
2 (sometimes in bed)	44	26
3 (need to be in bed)	9	5
4 (confined to bed)	0	0

At follow-up 151 breast cancer patients were interviewed, and the remaining 17 patients were excluded from the study. Of these 17 patients, 6 refused to be re-interviewed, 1 was terminally ill, 8 were lost to follow-up, and 2 were dead. However, there were no statistically significant differences between baseline and follow-up samples in terms of patients' demographic and clinical characteristics.

Acceptability of the questionnaire

As the study design required this and because many of the patients were illiterate (23%), the questionnaire was routinely administered as an interview. The average time required to complete the QLQ-C30 (including the breast cancer-specific questionnaire) was 14.2 (SD 3.1) min for the prediagnosis interview and 13.4 (SD 3.6) min for the follow-up interview. Almost all patients (99%) found the questions easy to understand and acceptable.

Descriptive statistics and scale reliability

Table 2 shows the means and standard deviations for the multi-item and single-item measures for both prediagnosis and follow-up assessments. Score distributions were approximately symmetrical for the majority of the functioning scales, except for the cognitive and social functioning scales, which showed a positive skew. The scores on symptom scales and single-item measures were rather skewed, especially at the prediagnosis assessment. As is clear, most of these symptoms are not specifically associated with breast cancer.

The reliability coefficient for multi-item scales ranged from 0.48 (social functioning) to 0.95 (global quality of life) at prediagnosis and from 0.51 (cognitive functioning) to 0.98 (global quality of life) at follow-up assessments (Table 2).

Validity results

The results of validity analysis by the two methods will be presented in the following sections.

Inter-scale validity

Table 3 shows the correlations among the nine scales of the QLQ-C30 for both the prediagnosis and the follow-up assessments. The closest correlations at both prediagnosis and follow-up assessments were observed between physical functioning, role functioning, and fatigue. Conversely, relatively weak correlations were observed between physical functioning, pain, and nausea and vomiting at the prediagnosis assessment and between physical functioning, emotional functioning, social functioning, and nausea and vomiting at the follow-up assessment. The global quality of life scale correlated significantly with most of the other scales.

Known-groups comparison

The results of the ANOVA of prediagnosis and follow-up QLQ-C30 functioning and symptom scores with performance status (as the grouping variable) are shown in Tables 4 and 5. There were statistically significant group differences in the expected direction for almost all functioning and symptom scores. In other words, those with a better performance status reported significantly higher levels of functioning scores, a significantly higher global quality of life and a lesser intensity of symptoms at both prediagnosis and follow-up administrations of the QLQ-C30. When the same analysis was performed for subgroups of patients on the basis of dis-

Table 2 Descriptive statistics and scale reliability of the QLQ-C30

	Prediagnosis ($n=168$)				Follow-up ($n=151$)		
	No. of items	Mean score	SD	Cronbach's alpha coefficient[a]	Mean score	SD	Cronbach's alpha coefficient
Functioning scales[b]							
Physical	5	68.9	24.7	0.69	62.9	22.4	0.71
Role	2	69.4	26.9	0.83	63.2	25.5	0.77
Cognitive	2	79.7	19.4	0.53	73.2	19.5	0.51
Emotional	4	60.6	22.8	0.78	59.9	24.4	0.83
Social	2	85.9	17.9	0.48	81.6	20.9	0.52
Global quality of life	2	65.7	28.5	0.95	59.4	30.4	0.98
Symptom scales and or/items[c]							
Fatigue	3	17.8	18.8	0.65	33.0	26.1	0.83
Nausea and vomiting	2	1.9	8.9	0.82	29.8	30.0	0.81
Pain	2	4.9	9.4	0.54	6.0	13.1	0.67
Dyspnoea	1	6.5	15.6		11.3	18.8	
Sleep disturbance	1	27.2	29.1		25.4	29.5	
Appetiteloss	1	21.0	28.8		36.6	32.8	
Constipation	1	2.9	10.8		9.4	20.1	
Diarrhoea	1	0.4	3.6		2.4	10.2	
Financial impact	1	20.0	27.1		25.4	29.5	

[a] Alpha values ≥0.70 indicate adequate scale reliability
[b] Scores range from 0 to 100, with a higher score representing a higher level of functioning
[c] Scores range from 0 to 100, with a higher score representing a greater degree of symptoms

Table 3 Correlations (Pearson's r) among the QLQ-C30 scales before diagnosis ($n=168$) and at follow-up[a] ($n=151$)

	PF	RF	CF	EF	SF	F	P	NV	QL
Physical functioning (PF)		0.82	0.42	0.34	0.28	–0.44	–0.40	–0.11[b]	0.50
Role functioning (RF)	0.96		0.55	0.53	0.36	–0.48	–0.23	–0.28	0.53
Cognitive functioning (CF)	0.53	0.58		0.62	0.45	–0.64	–0.20	–0.31	0.60
Emotional functioning (EF)	0.69	0.70	0.59		0.67	–0.48	–0.10[b]	–0.40	0.63
Social functioning (SF)	0.46	0.46	0.36	0.51		–0.26	–0.14[b]	–0.14[b]	0.53
Fatigue (F)	–0.50	–0.50	–0.47	–0.49	–0.20		0.21	0.38	–.55
Pain (P)	–0.16	–0.15	–0.21	–0.18	–0.12[b]	0.34		0.11[b]	–.23
Nausea and vomiting (NV)	–0.10[b]	–0.11[b]	–0.17	–0.13[b]	–0.24	0.10[b]	0.10[b]		–.34
Global quality of life (QL)	0.57	0.60	0.61	0.73	0.23	–0.54	–0.13[b]	–0.13[b]	

[a] Before treatment under the diagonal; after treatment above the diagonal. Negative correlations are artefacts of the scoring procedures
[b] Correlation not statistically significant; all not so marked are significant

ease stage, a similar pattern of results emerged for all functioning and symptom scales. (These results are not shown and are available from the corresponding author.)

Discussion

Although it is argued that the process of producing high-quality translation of quality of life questionnaires can be extremely complex and time consuming [14, 15], there is increasing interest in the translation and validation of health status questionnaires [5, 8, 9]. This paper reports the findings recorded in a validation study of a quality of life measure conducted in cancer patients (EORTC QLQ-C30) in Iran following its translation into Persian. Despite the fact that this questionnaire was originally developed in Europe and the sample in this study stemmed from a culturally diverse population, the questionnaire was translated successfully and it was well accepted by patients. In addition, for the first time we have introduced a quality of life instrument to health professionals in Iran that can be used in clinical trials or other studies of outcome research. For example, the Iranian version of the EORTC QLQ-C30 is currently in use in a prospective trial comparing different regimens in a group of breast cancer patients receiving adjuvant chemotherapy. In spite of many ad-

Table 4 Summary of ANOVA of the QLQ-C30 functioning, global quality of life, and symptom scores by the prediagnosis ECOG performance status[a] ($n = 168$)

	ECOG = 0 ($n = 64$) Mean (SD)	ECOG = 1 ($n = 51$) Mean (SD)	ECOG = 2 ($n = 44$) Mean (SD)	ECOG = 3 ($n = 9$) Mean (SD)
Physical functioning	93.4 (10.1)	66.3 (11.6)	46.8 (12.2)	17.8 (6.7)
Role functioning	96.1 (7.1)	69.9 (11.5)	41.3 (11.6)	14.8 (5.6)
Cognitive functioning	89.1 (16.3)	83.3 (15.6)	67.0 (17.4)	53.7 (13.9)
Emotional functioning	76.0 (17.3)	61.8 (18.0)	43.7 (16.3)	26.8 (17.1)
Social functioning	95.1 (9.7)	82.7 (18.2)	80.7 (18.3)	64.8 (25.6)
Global quality of life	74.7 (26.5)	64.5 (24.6)	39.8 (25.2)	16.7 (16.7)
Fatigue	9.4 (15.0)	15.7 (15.4)	29.6 (17.6)	30.1 (20.4)
Pain	.2 (7.2)	5.2 (10.3)	5.6 (8.3)	5.7 (11.3)
Nausea and vomiting	0.0 (0.00)	0.8 (4.6)	1.3 (7.3)	3.8 (14.3)

[a] A higher score represents a higher level of functioning, global quality of life and a greater intensity of symptoms; and a lower ECOG score represents a better performance status. All P-values < 0.0001 except for pain ($P = 0.8$) and nausea and vomiting ($P = 0.3$)

Table 5 Summary of ANOVA of the QLQ-C30 functioning, global quality of life and symptom scores by the follow-up ECOG performance status[a] ($n = 151$)

	ECOG = 0 ($n = 35$) Mean (SD)	ECOG = 1 ($n = 56$) Mean (SD)	ECOG = 2 ($n = 55$) Mean (SD)	ECOG = 3 ($n = 5$) Mean (SD)
Physical functioning	86.5 (9.6)	68.2 (13.6)	45.8 (17.5)	24.0 (8.9)
Role functioning	96.7 (7.9)	67.8 (12.3)	42.1 (11.9)	10.0 (9.1)
Cognitive functioning	82.8 (17.4)	78.6 (17.3)	64.5 (16.9)	40.0 (9.1)
Emotional functioning	71.9 (20.6)	65.3 (22.3)	50.3 (22.3)	20.0 (12.6)
Social functioning	86.3 (18.8)	85.2 (20.9)	76.9 (20.9)	53.3 (13.9)
Global quality of life	80.0 (21.7)	73.8 (24.5)	53.0 (27.0)	15.0 (14.9)
Fatigue	20.0 (23.9)	26.0 (23.1)	44.6 (22.6)	75.6 (29.3)
Pain	1.4 (4.7)	3.4 (7.4)	4.1 (10.7)	10.9 (17.3)
Nausea and vomiting	18.1 (26.0)	29.4 (27.7)	35.8 (33.2)	50.0 (20.4)

[a] A higher score represents a higher level of functioning and better global quality of life and a greater intensity of symptoms; and a lower ECOG score represents a better performance status. All P-values < 0.0001 except for pain ($P = 0.003$) and nausea and vomiting ($P = 0.01$)

vances in measuring quality of life in clinical research worldwide and in countries such as Japan [17], it is not surprising that to our knowledge this is the first study of its type in Iran.

The data in this study were collected by an interview-administered approach, and it took 13–14 min to carry out each interview. There were no incomplete questionnaires at all, nor was there any missing information. The study has shown that the mode of administration of the EORTC QLQ-C30 (self-completion versus interview) does not influence patients' responses to the questionnaire [3]. Furthermore, this was a double-blind study. At the time of baseline assessment of quality of life, both patients and the interviewer were blind to the final diagnosis. The advantage of this method of data collection is that it reduces both interviewee and interviewer bias, which could contribute to the robust nature of the findings.

The internal consistency as assessed by Cronbach's alpha coefficient varied according to assessment point. In general, the translated module was found to be reliable, although a low alpha value was observed for social functioning (alpha = 0.48) and pain (alpha = 0.54) at prediagnosis assessment and for cognitive and social functioning at follow-up assessment (alpha = 0.51 and 0.52, respectively). However, the results were very similar to the findings of the original validation study that was reported by the pioneering authors of the EORTC QLQ-C30 [3]. The best value for alpha coefficient was found for global quality of life at both prediagnosis and follow-up assessments (alpha = 0.95 and 0.98, respectively). This, however, could reflect a culturally unique concept of health and quality of life perceived by Iranian patients and that inherent in the questionnaire items. Compared with the original study, the most important findings of our study were related to the improvements in the role functioning alpha coefficient (alpha = 0.83 and 0.77 at the prediagnosis and the follow-up assessments, respectively). This was recognized because in the latest version of the EORTC QLQ-C30 (which was used in our study) the role functioning items were revised by the EORTC Study Group on Quality of Life.

In terms of questionnaire validity two methods were used: inter-scale correlations and known-groups comparison. The findings indicated that the conceptually related scales of the QLQ-C30 (e.g. physical functioning, role functioning and fatigue) and those scales that have less in common with these (e.g. physical functioning, role functioning and nausea and vomiting) were correlated in the expected direction both at prediagnosis and at follow-up administration of the questionnaire, although a few correlations were not statistically significant (see Table 3).

The validity of the Iranian version of the EORTC QLQ-C30 was made evident in its ability to discriminate between subgroups of patients known to differ in their disease stage and performance status. The results of known-groups comparison analysis showed strong validity both before diagnosis and at follow-up. When the ECOG performance status was used as a proxy indicator of patients' clinical status, statistically significant group differences were observed (Tables 4, 5). This was also true for analysis that carried out on the basis of patients' disease stage.

It is argued that because the majority of the available quality of life questionnaires have been developed in English-speaking countries, the extent to which these measures are applicable to other languages and cultures and the extent to which they exhibit adequate level of cross-cultural validity are unknown [21, 23]. The study findings lend support to the cross-cultural validity of the EORTC QLQ-C30 in a population outside Europe. Overall, the Iranian version of the EORTC QLQ-C30 was found to be a reliable and valid measure of quality of life in cancer patients, and it can now be used in clinical and epidemiological cancer research. To improve the psychometric properties of this translated questionnaire further studies will be needed, and it is hoped that the present study and other research activities in this area could contribute to the use of standard quality of life measures in Iran and other developing countries, since we have shown that it is possible to translate and validate such instruments even within a culturally diverse population.

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