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ORIGINAL ARTICLE

Validation study of the EORTC information questionnaire (EORTC QLQ-INFO25) in Iranian cancer patients

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Abstract
Introduction Developing a tool for measuring patient's needs is a vital step in the process of cancer treatment and research. In recent years, the European Organization for Research and Treatment of Cancer (EORTC) made a questionnaire to measure cancer patients' received information. Since validity and reliability of any instrument should be evaluated in the new environment and culture, the aim of this study was to assess the validity and reliability of the EORTC QLQ-INFO25 in Iranian cancer patients.
Materials and methods One hundred seventy-three patients with different stages of cancer filled questionnaire EORTC QLQ-INFO25, EORTC QLQ-C30, and EORTC IN-PATSA T32. Twenty-five patients answered the questionnaire twice at an interval of 2 weeks. Reliability and validity of the questionnaire was measured by Cronbach's alpha, interclass correlation, test retest, inter-rater agreement (IRA), and exploratory factorial analyses.
Results Using a conservative approach, the IRA for the overall relevancy and clarity of the tool was 87/86% and 83.33 %, respectively. Overall appropriateness and clarity were 94.13 and 91.87 %, respectively. Overall integrity of the instrument was determined to be 85 %. Cronbach's alpha coefficients for all domains and total inventory were top 70 and 90 %, respectively. Interclass correlation index ranges between 0.708 and 0.965. Exploratory factorial analyses demonstrate six fields suitable for instrument. Correlation between areas of the questionnaires EORTC QLQ-INFO25 and EORTC in-Patsat32 represents the convergent validity of the questionnaire. Also, results show a standard divergent validity in all domains of the questionnaire (Rho <0.3). Low correlation between the areas of the questionnaires EORTC QLQ-INFO25 and EORTC QLQ-C30 (<0.3) demonstrates the divergence validity of the questionnaire.
Conclusion The results showed that Persian version of the questionnaire EORTC QLQ-INFO25 is a reliable and valid instrument for measuring the perception of information in cancer patients.

Keywords EORTC QLQ-INFO25 · Cancer · Validity · Reliability · Inventory

Introduction

Patient's information is a key factor for facilitating the treatment of cancer, giving appropriate information about diagnosis, treatment, and short-term and long-term complications of the disease, leading to evidence-based and informed decision-making, as well as reducing stress levels, leading to increasing patient's satisfaction and good control of the disease [1–4].

Patient's satisfaction from received information is an essential component in their quality of life. And this group of patients experience better psychological outcomes and it is probably easier to get medical advice and treatment [5–8]. Several studies have shown that the majority of cancer patients are willing to get maximum information about the disease regardless of whether it is good or bad [9, 10]. The literature review suggests that more information needs of cancer patients have not been met. Ultimately, the unmet

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needs of patients lead to emotional disorders and discordance with a disease [6, 11].

To measure the amount of received information about cancers, developing a tool is a step to achieve the clinical and research improvements in this field [2]. Several questionnaires were designed to assess cancer patients' information based on patients' needs and satisfaction [12–17].

The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Group has developed an information module, EORTC QLQ-INFO25, which assesses cancer patients' perception of information received during different phases of care. The structure, validity, and reliability of the EORTC QLQ-INFO25 have been tested in a large international and multicultural sample of cancer patients at different stages of the disease and treatment [18]. Due to the specific conditions of Iran and recommendations from the EORTC Quality of Life Group based on testing validity and reliability in different environments, we examined the validity and reliability of the EORTC QLQ-INFO25 in cancer patients in Iran.

Materials and methods

Patients were selected from four main referral hospitals in Tehran, the capital of Iran. Eligibility criteria for participating in the study were patients older than 18 years, with cancer diagnosis as any tumor site and disease stage, receiving radiotherapy and/or chemotherapy, mentally fit, and with the linguistic capacity to complete the questionnaires. The number of samples was calculated almost 173 people based on the Tabachnik and Fidell's [19] estimate of minimum of 5 cases per a variable for multivariate statistical techniques.

Patients completed the EORTC QLQ-INFO25, the EORTC QLQ-C30 [18], and the information scales of the inpatient satisfaction module EORTC IN-PATSAT32. Both questionnaires EORTC QLQ-C30 [20] and EORTC IN-PATSAT32 [21] had been previously translated and standardized in Iran. Also, a demographic questionnaire was filled by participants. Questionnaires with less than 70 % of the items answered were excluded.

The EORTC QLQ-INFO25 module was designed by the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Group in order to use among patients with various types of cancer at different stages of the disease. It has 25 questions, composed of multiple-item scales and two single items. It is organized into four scales—information about the disease (four items), medical tests (three items), treatment (six items), and other services (six items), and eight single items. The response format is a 4-point Likert scale (1: not at all, 2: a little, 3: quite a bit, 4: very much), except items 50, 51, 53, and 54, which have a dichotomous response (yes/no).

The EORTC QLQ-C30 is a 30-item questionnaire consisting of multi-item scales and single items. It evaluates areas common to different tumor sites and treatments and contains five functional, three symptom, and one global QL scale, as well as single items that evaluate additional symptoms and the perceived financial impact of the disease and treatment. The information scales of the EORTC inpatients' satisfaction questionnaire IN-PATSAT32 [22] are provision of information by doctors and nurses, kindness of hospital personnel, helpfulness, and information giving.

After permission from the questionnaire designer, as recommended by Cull et al. [23], the original English version of the questionnaire was translated into Persian by two independent expert translators. One translator was aware of the content of the questionnaires and other was not. The two translations were reviewed by the translators and the plan researchers and compared with the original English version. Any discrepancies between the concepts of the translated and original version questionnaire were detected and the necessary changes were made in the Persian translation. The Persian version was back-translated to English independently by two translators, unaware of the content of the original English version of the questionnaire. All translation and cultural adaptation were revisited and reviewed by a selected specialists' team, and the final Persian version was produced [24].

To check the content and face validity, the Persian version of the questionnaire was sent to five oncologists with enough experience and one methodologist. Validity indicators for each question and whole questionnaire were calculated. To equalize the experts' conception of content validity indices (relevancy, clarity, and comprehensiveness of the instrument), the definitions of these indices were sent along with the questionnaire. Relevancy, clarity, and comprehensiveness were respectively defined as follows: ability of selected questions to reflect the content, questions' lucidity concerning their wording and concept, and eventually, the instrument ability to include all content domains. Then, the experts were asked to compare the Persian version with the original one, and after reviewing every item, assess its clarity and relevancy from 1 to 4 (1= inappropriate, 2=somewhat appropriate, 3=appropriate, 4= quite appropriate).

The inter-rater agreement (IRA) is the degree of observed agreement among the experts who participated in the study about the appropriateness and clarity of the instrument questions. A conservative approach was chosen to determine the inter-rater agreement (IRA) for the instrument relevancy and clarity. In this approach, the number of the questions which all (100 %) of the experts (psychiatrists, neurologists, lay experts) chose "quite appropriate" and "appropriate" or "somewhat appropriate and "inappropriate" for relevancy (in other words, the number of questions that all experts agreed on the rate of their appropriateness for relevancy) was divided by the total number of items. IRA for the instrument clarity was exactly

calculated by the same method. The acceptable level (cutoff point) of this index was considered 80 % in this study [25].

To calculate the clarity of each question, the total number of experts who chose "appropriate" or "quite appropriate" for the clarity of each item was divided by the total number of the experts. Calculation of the relevancy of each item was performed exactly the same way.

To measure the relevancy of the total instrument, the Scale-Content Validity Index/Universe Agreement approach (S-CVI/UA), in which the total number of the questions with appropriate relevancy was divided by the total number of the items, was used. In different studies, the minimum acceptable relevancy for a new instrument has been suggested about 80 %. Total clarity of the instrument was computed by dividing the sum of the questions with clarity (0–1) or sum of I-CVIs by the total number of questions (mean of the clarity of questions or mean of I-CVIs). The instrument comprehensiveness was achieved via dividing the number of experts who judged the comprehensiveness of instrument as appropriate by the total number of experts [26].

The convergent validity of each item was defined as an item-own-scale correlation of 0.40 (corrected for overlap). For item discriminant validity, the correlation between an item and its hypothesis scale (corrected for overlap) was expected to be higher than its correlation with other scales.

The correlations were calculated between the selected scales (and its individual items) of the EORTC IN-PATSA T32 and the four scales and two items of the INFO module that were hypothesized to be related. Higher correlations (Spearman's (Rho) $p>0.40$) were expected among areas with closer content (disease, medical tests, and treatment), information that was supposed to be offered at a specific time during the treatment process (disease, medical tests and admission, other services) and between the item on satisfaction and the three scales of IN-PATSAT32.

The correlations between the EORTC QLQ-INFO25 module and the EORTC QLQ-C30 scales/single items were calculated. Low correlations (Spearman Rho <0.30) were expected given that each instrument evaluates different concepts.

Construct validity is the extent to which the measurement corresponds to theoretical concepts concerning the phenomenon under study. For this purpose, we used exploratory factorial analysis. Factor analysis is a statistical technique used to identify a small number of groups or clusters that represent relationships among a set of interrelated variables. These correlation patterns are expressed in terms of unobservable or latent variables called "factors." The goal of factor analysis is to identify the not-so-observable factors from the set of observable variables. For the construct validity of the EORTC QLQ-INFO25, principal component analysis was used with promax rotation. The test of sphericity and the Kaiser-Meyer-Olkin measure of sampling adequacy were used for determining the assumptions and adequacy of sampling. The factors that have eigenvalue over one were selected as factors of questionnaire [22].

The internal consistency for each scale was estimated using the Cronbach's alpha coefficient and alpha≥0.70 was considered satisfactory [27]. Intra-class correlation coefficient (ICC) was used to evaluate test-retest reliability. Values of 0.60–0.80 were regarded as the evidence of good reliability and those higher than 0.80 were considered excellent reliability [28, 29]. Data was collected during 3 months between February 2013 and April 2013 while 178 patients participated in the study and completed the questionnaires. All analysis was done by running SPSS software version 19.

Results

Five (8.2 %) questionnaires were excluded due to less than 70 % completion rate. Study population mean age was 48.37(SD 16.38). Clinical and demographic characteristics of the sample are shown in the Table 1.

The degree of consensus (inter rater agreement) using a conservative approach, based on content experts' comments on the appropriateness and clarity of the questions were determined 86.87 % and 83.33 %, respectively. Tool's overall appropriateness was 94.13 % and its overall clarity was 91.87 % and overall integrity was 85 %. The appropriateness and clarity of each question was in the range from 80 to 100 %.

Results of multi-trait scaling analysis showed measurements of the correlation of each item with its own scale and also with other areas (Table 2). The correlation of each item with its own scale (Rho ≥0.4) represented a high convergent validity. As well, the correlation of each item with its own hypothesized domain was greater than its correlation with other areas of the questionnaire, which reflects the discriminant validity of the instrument.

The correlation between selected areas of the EORTC in-Patsat32 questionnaire and four main domains and two selected items of the EORTC-info25 questionnaire was evaluated (Table 3). Pearson correlation coefficients between areas that have similar contents demonstrate a high convergent validity of the assessed questionnaire.

To assess the divergent validity, correlation between different areas of the EORTC-QLQ-C30 questionnaire and the EORTC-info25 questionnaires was calculated (Table 4). Low correlation between the areas of two questionnaires (Spearman Rho <0.3) indicated that these two questionnaires measure different concepts.

To investigate the structure of the questionnaire, confirmatory factor analysis was used. After ensuring about the meaningfulness of Bartlett test of sphericity (p value <0.001) and the sampling adequacy by using Kaiser-Meyer-Olkin measure of sampling adequacy, six factors with eigenvalue of more than 1 were selected. Items 1

Table 1 Demographic information of patients included in the study

Patients' characteristics		Male *N* (%)	Female *N* (%)	Total *N* (%)	*p* value
Age group	15–44 years	46 (26.5)	32 (18.5)	78 (45)	0.01
	45–65 years	25 (14.4)	44 (25.4)	69 (39.8)	
	>65 years	16 (9.3)	10 (5.7)	26 (15)	
Education status	Illiterate or elementary	37 (21.3)	27 (15.6)	64 (36.9)	0.11
	High school	21 (12.1)	33 (19.1)	54 (31.2)	
	University	29 (16.7)	26 (15)	55 (31.7)	
Tumor site	Blood	0 (0)	6 (3.4)	6 (3.4)	0.001
	Respiratory system	7 (4)	7 (4)	14 (8)	
	GI and liver	36 (2)	14 (8)	50 (28.9)	
	GU	23 (13.2)	34 (19.6)	57 (32.9)	
	Head and neck, CN	14 (8)	5 (2.8)	19 (10.8)	
	Breast	0 (0)	7 (4)	7 (4)	
	Etc.	7 (4)	13 (7.5)	20 (11.5)	
Comorbidity	Yes	27 (15.6)	38 (21.9)	65 (37.5)	0.052
	No	60 (34.6)	48 (27.7)	108 (62.5)	
Treatment aim	Curative	67 (38.7)	72 (41.6)	139 (80.3)	0.179
	Palliative	20 (11.5)	14 (8)	34 (19.6)	
Treatment type	Chemo/radiotherapy	21 (12.1)	26 (15)	47 (27.1)	0.233
	Surgery + adjuvant	66 (38.1)	60 (34.6)	126 (72.8)	

to 4 were considered as the subscales of the questionnaire's first component, called information about disease; second component was named as information about medical tests (items 5 to 7); third component was called information about treatment advantageous (items 8, 9, and 11); fourth component was information about treatments' probable effects or side effects (items 10, 12, 13); fifth component was information about other services (items 14, 15, 17, 18); and the last component was disease management (items 16 and 19). Items 20 to 25 were considered as single items. Table 5 shows these five selected factors for the questionnaire of cancer patients' understanding of the information. As shown in the Table 5, these six factors have explained in total 79.6 % of the variance.

Table 2 The results of multi-trait scale analysis

EORTC-info25 items	Scale 1	Scale 2	Scale 3	Scale 4
1	*0.809*	0.541	0.015	0.653
2	*0.908*	0.537	0.118	0.546
3	*0.746*	0.415	0.245	0.486
4	*0.741*	0.446	0.278	0.380
5	0.657	*0.938*	0.352	0.512
6	0.643	*0.942*	0.362	0.339
7	0.539	*0.833*	0.518	0.275
8	0.512	0.614	*0.657*	0.008
9	0.407	0.629	*0.883*	0.432
10	0.422	0.503	*0.895*	0.436
11	0.384	0.387	*0.896*	0.296
12	0.369	0.362	*0.910*	0.214
13	0.250	0.311	*0.875*	0.361
14	0.214	0.452	0.542	*0.529*
15	0.136	0.502	0.540	*0.676*
16	0.112	0.600	0.217	*0.864*
17	0.104	0.150	0.319	*0.675*

Italic numbers represents that the correlation of that item with its own hypothesized scale was greater than its correlation with other areas of the questionnaire, which reflects the discriminant and convergent validity of the instrument

Cronbach's alpha coefficients for all domains and whole the questionnaire were between 70 and 90 %. Cronbach's alpha coefficient for the total scale and the whole questionnaire is shown in the Table 6.

The whole questionnaire and all items were significantly valuable (p value <0.001) except for items 15, 23, and 24. The intra-class correlation (ICC) ranged between 0.708 (willingness of receiving more information) and 0.965 (the effects of the treatment on sexual activity). The intra-class correlation (ICC) of the total scales and items of the questionnaire is shown in the Table 6.

Discussion

Results showed that the Persian version of the questionnaire EORTC QLQ-INFO25 was a valid and reliable instrument to measure the cancer patients' perceptions of information. High completion rate of the questionnaires (>90 %) and patients' compliance showed good understanding of the content and a desired writing style of the questionnaire.

Table 3 The results of convergent validity

EORTC-info25 questionnaire	Scale and items' name	EORTC in-patsat32 questionnaire	Scales and items' name	Spearman's RHO	*p* value
Scale 1	Information about disease	Question 7	Information provided by doctors about disease	0.217	0.004
Scale 1		Question 25	Information provided on patients' admission to the hospital	0.152	0.047
Scale 2	Information about medical tests	Question 8	Information provided by doctors about medical tests	0.340	0.001
Scale 2		Question 18	Information provided by nurses about medical tests	0.332	0.001
Scale 2		Question 25	Information provided on patients' admission to the hospital	0.085	NS✵
Scale 3	Information about treatment	Question 9	Information provided by doctors about treatment	0.352	0.001
Scale 3		Question 20	Information provided by nurses about treatment	0.407	0.001
Scale 4	Information about other services	Question 26	Information provided on patients' discharge from the hospital	0.115	NS✵
Question 19	Information about things that the patient can do to help him/herself get well (rest, contact with others…)	Question 26	Information provided on patients' discharge from the hospital	0.397	0.001
Question 22	Satisfaction with the amount of information the patient had received	Scale 3	Information provided by doctors	0.234	0.002
Question 22		Scale 7	Information provided by nurses	0.392	0.001
Question 22		Scale 9	Information provided by other hospital personnel	0.198	0.010

Patients' perceptions of their care are an important pointer of quality in health care and present vital medical or clinical information about the extent of patients' needs [22].

Cronbach's alpha coefficients for each domain have met the criteria (≥0.7), which proved that the tool could be used to compare different groups. Cronbach's alpha coefficient for the whole questionnaire was 0.919, which overall indicates that the reliability of the instrument was satisfactory. Results of other studies had also confirmed the questionnaire's high reliability. For example, in the international study that was conducted in seven

Table 4 The results of divergent validity

	EORTC-info25			
	Information about other services (scale 4)	Information about treatments (scale 3)	Information about medical tests (scale 2)	Information about the disease (scale 1)
EORTC-QLQ-C30 physical functioning scale	0.21	0.51*	0.30	0.13
EORTC-QLQ-C30 role functioning scale	0.26	0.24	0.34*	0.14
EORTC-QLQ-C30 emotional functioning scale	0.33*	0.02	0.29*	0.32*
EORTC-QLQ-C30 cognitive functioning scale	0.29	0.16	0.25	0.28
EORTC-QLQ-C30 social functioning scale	0.41*	0.28	0.18	0.17
EORTC-QLQ-C30 global health/QL scale	0.15	0.14	0.23	0.25
EORTC-QLQ-C30 measuring fatigue scale	0.20	0.26*	0.19	0.42*
EORTC-QLQ-C30 measuring vomiting scale	0.23	0.43*	0.16	0.19
EORTC-QLQ-C30 measuring pain scale	0.32*	0.27	0.22	0.39*

*p value >0.05: insignificant

European countries and Taiwan in order to assess the validity and reliability of this instrument, the Cronbach's alpha coefficient for each scale was more than 0.73 and for the whole questionnaire was greater than 0.90. Test-

Table 5 The results of construct validity

Items During your current disease or treatment, how much information have you received on:	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
1) The diagnosis of your disease?	0.89[a]	0.24	0.28	0.11	0.18	−0.31
2) The extent (spread) of your disease?	0.66[a]	0.33	0.42	−0.02	0.42	0.13
3) The possible causes of your disease?	0.86[a]	0.26	0.19	0.13	0.23	0.24
4) Whether the disease is under control?	0.78[a]	0.47	−0.03	0.44	0.19	0.60
5) The purpose of any medical tests you have had or may undergo?	−0.50	0.91[a]	−0.19	0.27	0.20	0.11
6) The procedures of the medical tests?	−0.33	0.85[a]	−0.45	0.41	−0.03	0.07
7) The results of the medical tests you have already received?	−0.15	0.76[a]	0.44	0.02	0.40	0.01
8) The medical treatment (chemotherapy, radiotherapy, surgery, or other treatment modality)?	0.26	0.56	0.83[a]	0.21	−0.33	0.39
9) The expected benefit of the treatment?	0.32	0.49	0.85[a]	0.14	−0.18	0.27
10) The possible side-effects of your treatment?	0.19	0.28	0.39	0.59[a]	0.15	−0.19
11) The expected effects of the treatment on disease symptoms?	0.43	−0.03	0.92[a]	0.16	0.21	−0.15
12) The effects of the treatment on social and family life?	0.17	0.08	0.28	0.80[a]	0.29	−0.41
13) The effects of the treatment on sexual activity?	0.22	0.25	0.35	0.79[a]	0.25	0.32
14) Additional help outside the hospital (e.g., help with daily activities, self help groups, district nurses)?	0.34	0.43	0.41	0.25	0.74[a]	0.24
15) Rehabilitation services (e. g., physiotherapy, occupational therapy)?	0.42	0.24	0.09	0.32	0.81[a]	0.15
16) Aspects of managing your illness at home?	0.21	0.51	0.05	0.14	0.56	0.92[a]
17) Possible professional psychological support?	0.06	0.18	0.17	0.29	0.68[a]	−0.12
18) Different places of care (hospitals/outpatient services/home)?	0.01	0.30	0.06	0.51	0.75[a]	−0.41
19) Things that you can do to help yourself get well (rest, contact with others …)?	−0.07	0.17	0.45	0.22	0.32	0.87[a]
Eigenvalue	11.463	2.888	1.887	1.512	1.112	1.055
% of variance	45.85	11.55	7.54	6.05	4.44	4.21

[a] All meaningful loadings (i.e., loadings greater than 0.40)

Table 6 EORTC-info25 scales, mean, standard deviation, internal consistency reliability, and intra-class correlations

EORTC-info25 scales		Mean	S.D.	Cronbach's alpha coefficient	ICC	% floor	% ceiling
Scale 1	Information about disease	51.76	23.45	0.816	0.927	7	8.2
Scale 2	Information about medical tests	32.19	13.39	0.922	0.827	19.9	24.6
Scale 3	Information about treatment advantageous	50.09	5.85	0.845	0.919	17	12.3
Scale 4	Information about treatments probable effects or side effects	30.15	20.91	0.792	0.879	25.1	20.5
Scale 5	Information about other services	40.97	24.18	0.767	0.861	44.4	0
Scale 6	Information about disease management	56.04	19.05	0.864	0.842	26.3	12.3
Whole questionnaire		55.74	16.80	0.919	0.895	7	0

retest reliability for the whole questionnaire was 0.944 and for each question was reported more than 0.7, which also confirms the findings of previous studies.

Inter-rater agreement is a controlling factor in the process of content validity whose acceptable range is 70 to 80 %. If the calculated measure is inappropriate, then it will be necessary to do a fundamental reconsideration of the tool's questions. Appropriateness and clarity of the questionnaire was determined to be about 86.87 and 83.33 %, respectively, which represent the experts' high consensus over the appropriateness and overall transparency of the tool. As well, the appropriateness and clarity of each item met the desired value of at least 80 % which was recommended in other articles. The questionnaire's integrity was determined to be around 85 %; thus, in comparison with the minimum recommended standard (80 %), we can conclude that selected items represent all the questions which could comprise the complete final questionnaire.

The results of the confirmatory factor analysis did not confirm the findings of other studies. The EORTC Quality of Life Group who designed the module recommended four components for the instrument while in our study, six multi-item scales and eight single items were identified, and it possibly seems to put these eight single items into two new domains (a desire to receive more information and a desire to receive less information).

Results show a standard divergent validity in all domains of the questionnaire (Rho <0.3) which confirms that two evaluated questionnaires were assessing different concepts. This result is similar to other EORTC study [30].

Study limitations were due to the cross-sectional design of the study. Therefore, questionnaire's responsiveness to changes was not possibly assessed; however, the instrument's ability to distinguish patients at different stages of the disease is shown as an indicator of sensitivity to changes [9], which seems the necessity of longitudinal studies to confirm this. Another limitation of this study was convenience sampling (i.e., samples were selected among only those patients who were willing to fill out the questionnaires).

Conclusions

Results have shown that the Persian version of the EORTC QLQ-INFO25 questionnaire is a reliable and valid instrument to measure the perceptions of cancer patients of the information received.

Conflict of interest The authors declare no conflict of interest.

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