# Understanding the reliability and validity of the EORTC QLQ-C30 in Turkish cancer patients

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Quality of life (QOL) has become an important area to address. The most commonly used QOL tool in oncology is the European Organization for Research and Treatment of Cancer QOL measure (EORTC QLQ-C30). The aim of this study is to examine the reliability and validity of this widely used questionnaire in Turkish language. A total of 114 cancer patients were recruited in this study. The internal consistency of the subscales, concurrent validity between EORTC QLQ-C30 version 3.0 and Short Form-36 (SF-36), the correlations between the subscales of EORTC QLQ-C30 and Hospital Anxiety and Depression scale-Anxiety (HADS-A), and Hospital Anxiety and Depression scale-Depression (HADS-D) were also evaluated. Cronbach's  $\alpha$ -coefficient for multi-item scales ranged from 0.56 to 0.85, with emotional functioning having the highest Cronbach's  $\alpha$ -coefficient. General health/QOL subscale was correlated significantly with all other subscales. Modest correlations were found between relevant subscales of SF-36 and EORTC QLQ-C30 scales indicating good convergent validity. Although score of emotional functioning subscale was significantly correlated with HADS-A, no correlation was found with HADS-D. The correlations between general health/QOL and HADS-A and HADS-D were significant though Pearson's coefficients were below 0.4. The EORTC QLQ-C30 version 3.0 is a reliable and valid instrument and suitable for measuring the QOL in cancer patients in Turkey.

Keywords: EORTC QLQ-C30, quality of life, cancer, reliability, validity, Turkish language.

#### INTRODUCTION

The diagnosis and subsequent treatment of cancer is often associated with considerable psychological and social

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© 2007 The Authors Journal compilation © 2007 Blackwell Publishing Ltd difficulties for patients. Quality of life (QOL) has become an important area to address, with the hope that chemotherapeutic agents may improve the patients' QOL, as well as survival.

Although it can be argued that QOL is a difficult concept to define and to measure, considerable progress has been made over the last decade by developing robust and standardized QOL measures. The most commonly used QOL tool in oncology is the European Organization for Research and Treatment of Cancer QOL measure (EORTC QLQ-C30) (Garratt *et al.* 2002). This is a core

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cancer-specific QOL questionnaire (QLQ-C30) developed to be used alone, or with additional questionnaire modules which can be site- or treatment-specific (Aaronson *et al.* 1993). Since the first development of EORTC QLQ-C30 in 1987, different versions of questionnaire have been developed by the EORTC Quality of Life Group (Fayers *et al.* 2002). It has been translated to over 55 languages (Cull *et al.* 2002) and its psychometric properties have been studied in different cultures (Fayers & Bottomley 2002).

Professionals in Turkey are usually interested in understanding the psychosocial impact of cancer and its treatment within the Turkish culture so the research on QOL is increasing in Turkey. While the validity and reliability of the Turkish version of the EORTC QLQ-C30 has been studied, this was restricted to lung cancer patients and only with version 2.0 (Guzelant et al. 2004). Given that the QLQ-C30 version 3.0 is now the recommended version for all clinical trials, and this is increasingly being used in Turkish studies (Ozer et al. 2003), it is important to provide a psychometric evaluation of this version. It must be also noted that the validity and reliability of version 2.0 in Turkish was reported previously not in heterogeneous cancer types but only in lung cancer patients. The aim of this prospective study is therefore to examine the reliability and validity of the latest version of this widely used questionnaire in Turkish language.

#### METHOD

#### Study sample and procedure

Of the 126 consecutive cancer patients who attended Ankara Oncology Education and Research Hospital between November 2004 and March 2005, 114 participated in the study, after providing verbal informed consent. The refusals were primarily relevant to the physical limitations of patients. No local ethics committee approval was given in Turkey because such approval is not required.

All of the patients and clinicians were informed of this study. The inclusion criteria are to attend to Ankara Oncology Education and Research Hospital between November 2004 and March 2005 with a diagnosis of cancer, to be within 18–75 years of age. No exclusion criteria was applied with regard to the type of cancer, the treatment status or the performance status. The only exclusion criteria were not to be diagnosed with any disease that disrupts consciousness like delirium during the study interval and not to be illiterate. The patients were asked to complete the questionnaire either at the outpatient clinic or during their hospitalization. All patients completed three questionnaires at the first assessment and only EORTC QLQ-C30 version 3.0 again for test-retest reliability after 7 days from the first assessment. All of the questionnaires are self-administered. Socio-demographic data, including age, education, marital status, occupation, were collected. The clinical data including type of treatment, time since diagnosis were extracted from case records.

#### Instruments

The EORTC QLQ-C30 version 3.0 is a 30-item core cancer-specific questionnaire measuring QOL in cancer patients (Aaronson et al. 1993; Garratt et al. 2002) which is the most commonly used QOL instrument in cancer trails. This self-administered questionnaire incorporates five functional scales [physical (PF), role (RF), cognitive (CF), emotional (EF) and social (SF) functioning scales] and three symptom scales (fatigue, pain and nausea/vomiting), a global health/QOL scale, and several single items for the assessment of additional symptoms commonly reported by cancer patients (e.g. dyspnea, appetite loss, sleep disturbance, constipation and diarrhea), as well as the perceived financial impact of the disease and treatment. All items are scored on 4-point Likert scales, ranging from 1 (not at all) to 4 (very much). As an exception, two items (items 29 and 30) in the global health/QOL subscale were scored on a modified 7-point linear analogue scale (Favers et al. 2001). All functional scales and individual item scores are transformed to a 0-100 scale with higher values indicating a higher functioning in functional scales and an increased presence of symptoms in symptom scales. An approval was obtained from the EORTC Quality of Life Group. We used the Turkish form of the questionnaire provided from sources of EORTC Quality of Life Group.

Satisfying reliability and validity results were reported for Short Form-36 (SF-36) which has been worldwide used for assessing QOL in medical illness (Stewart et al. 1988; McHorney et al. 1994). Thirty-six questions yield eight multi-item subscales (physical functioning, role functioning-physical, role functioning-emotional, bodily pain, vitality, social functioning, mental health and general health). Six subscales are formed of Likert scales with three to six answer categories and verbal anchors for each answer category. Two subscales are designed as Gutman scales (with four yes/no items each). The scores for each subscale are transformed to a 0-100 scale with lower values representing a lower functioning or a lower presence of symptoms. The validity and reliability of SF-36 for Turkish patients was evaluated (Koçyiğit et al. 1999).

To evaluate if EORTC QLQ-C30 version 3.0 is a predicting instrument also for psychological distress, the correlations between the subscale of EORTC QLQ-C30 and Hospital Anxiety and Depression Scale-Anxiety (HADS-A), and HADS-D (-Depression) were also assessed. The Hospital Anxiety and Depression scale (HADS) is one of the most commonly used instruments for screening clinically significant anxiety and depression in patients attending a general medical clinic with physical illness (Zigmond & Snaith 1983). This self-administered scale consists of two subscales, one assessing anxiety (HADS-A) and another evaluating depression (HADS-D). Each subscale consists of seven items. The items scored from 0 (no distress) to 3 (maximum distress). Total score ranges between 0 and 21 for each subscale. The validity and reliability of HADS in Turkish language was reported by Aydemir et al. (1997).

# Statistical analysis

The EORTC QLQ-C30 version 3.0 Scoring Manual was used to calculate the item scores of the EORTC QLQ-C30 (Fayers *et al.* 2001). After the scoring procedures, all subscale and single-item scores were linearly transformed to a 0-100 scale.

# Reliability

The internal consistency of the multi-item subscales were assessed by Cronbach's alpha coefficient. An internal consistency of 0.70 was sought, as recommended (Nunnally & Bernstein 1994). To assess test–retest reliability, the patients were requested to complete the EORTC QLQ-C30 once again, a week after the first assessment and Pearson's correlation coefficient was used to test the stability of test over time.

# Validity

Several different methods were conducted to examine validity.

Construct validity (interscale validity) of the scale was assessed by examining the correlations among subscales of EORTC QLQ-C 30 by Pearson's correlation coefficient. It was expected that conceptually related scales would correlate with one another and vice versa. The correlations of an item with its own scale and other scales were calculated. Convergent and discriminant validity and linear regression analysis in which general health/QOL subscale was the dependent variable were performed.

Concurrent validity between EORTC QLQ-C30 and SF-36 was also assessed by evaluating the correlation of relevant subscales of each instrument. The correlations

between the subscales of EORTC QLQ-C30 and HADS-A, HADS-D were also evaluated.

The statistical software program Statistical Packages of Social Sciences (SPSS) for Windows (version 13.0) was used.

# RESULTS

#### Socio-demographic and clinical characteristics

In total, 114 patients with various cancer types in Ankara Oncology Education and Research Hospital completed the questionnaires. The demographic and clinical characteristics of patients are detailed in Table 1. Of the 114 patients who participated in the study, 68 (59.6%) were female. The mean age was  $49.1 \pm 13.6$  years (range: 18–75). Most of the patients were married (88.6%). Breast cancer was the most prevalent cancer type (40.4%). The mean time period since diagnosis was  $9.64 \pm 10.02$  months. Cancer diagnoses were made 6 months or less before the interviews for 55.3% of patients and 12 months or less for 83% of the all patients. Only two patients had metastases. All patients were on treatment (either chemotherapy or radiotherapy or both and surgery).

# Reliability

For reliability, Cronbach's  $\alpha$ -coefficient for multi-item scales ranged from 0.56 to 0.85 (Table 2), the cognitive

 Table 1. The demographic and clinical characteristics of the patients

	Number	%
Age (years)		
Mean (SD)	$49.1 \pm 13.6$	
Range	18-75	
Gender		
Female	46	59.6
Male	68	40.4
Educational status		
Primary/secondary	105	92.1
Collage/university	9	7.9
Marital status		
Married	101	88.6
Single	5	4.4
Widowed	8	7.0
Primary site of cancer		
Breast	46	40.3
Lung	13	11.7
Gastro-intestinal	17	14.9
Head and neck	8	7.0
Other sites	30	26.1
Treatment		
Chemotherapy	16	14
Radiotherapy	41	36
Both and surgery	57	50
Time since diagnosis		
Mean (months) (SD)	$9.64 \pm 10$	

	Item number	Mean (SD)	Cronbach's α-coefficient
Global quality of life (QOL)	29, 30	$49.0 \pm 21.8$	0.81
Physical (PF)	1–5	$59.5 \pm 24.9$	0.81
Role (RF)	6, 7	$65.7 \pm 33.5$	0.83
Emotional (EF)	21, 22, 23, 24	$69.2 \pm 33.5$	0.85
Cognitive (CF)	20, 25	$75.7 \pm 25.0$	0.56
Social (SF)	26, 27	$54.2 \pm 32.8$	0.74
Fatigue (F)	10, 12, 18	$42.0 \pm 27.1$	0.84
Nausea and vomiting (NV)	14, 15	$21.3 \pm 29.0$	0.77
Pain (P)	9, 19	$41.8 \pm 30.4$	0.74
Dyspnea(D)	8	$22.5 \pm 31.1$	
Sleep disturbance (SD)	11	$35.9 \pm 32.6$	
Appetite Loss(AL)	13	$29.2 \pm 34.9$	
Constipation (C)	16	$24.8 \pm 29.3$	
Diarrhea (DI)	17	$12.8 \pm 25.6$	
Financial impact (FI)	28	$61.6 \pm 37.6$	

Table 2. Cronbach's  $\alpha$ -coefficient for multi-item scales in the Turkish version of EORTC QLQ-C30

Cronbach's α-coefficient values >0.70 indicates adequate scale reliability.

EORTC QLQ-C30, European Organization for Research and Treatment of Cancer QOL measure.

Table 3. The correlations between subscales of EORTC QLQ-C 30 version 3.0

	QOL	PF	RF	CF	EF	SF	F	Р	NV	D	SD	AL	С	DI
PF	0.38													
RF	0.39	0.69												
CF	0.29	0.32	0.45											
EF	0.46	0.34	0.49	0.54										
SF	0.54	0.46	0.40	0.30	0.41									
F	-0.48	-0.72	-0.65	-0.42	-0.47	-0.48								
Р	-0.46	-0.50	-0.43	-0.38	-0.37	-0.53	0.62							
NV	-0.25	-0.37	-0.34	-0.19	-0.40	-0.27	0.41	0.26						
D	-0.20	-0.22	-0.33	-0.12*	-0.28	-0.24	0.23	0.16*	0.10*					
SD	-0.37	-0.37	-0.24	-0.13*	-0.30	-0.36	0.42	0.46	0.24	0.26				
AL	-0.25	-0.34	-0.37	-0.25	-0.36	-0.33	0.46	0.29	0.56	0.25	0.29			
С	-0.10*	-0.24	-0.22	-0.29	-0.37	-0.04*	0.33	0.18*	0.26	0.12*	0.09*	0.25		
DI	-0.30	-0.17*	-0.17*	-0.22	-0.43	-0.21	0.08*	0.13*	0.40	0.11*	0.06*	0.26	0.09*	
FI	-0.31	-0.39	-0.23	-0.17*	-0.26	-0.45	0.32	0.35	0.30	0.19	0.20	0.24	0.08*	0.16*

\*Correlation not statistically significant; all not so marked are significant.

Negative correlations are due to scoring procedures.

QOL, global quality of life; PF, physical Functioning; RF, role functioning; CF, cognitive functioning; EF, emotional functioning; SF, social functioning; F, fatigue; P, pain; NV, nausea and vomiting; D, dyspnea; SD, sleep disturbance; AL, appetite loss; C, constipation; DI, diarrhea; FI, financial impact; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer QOL measure.

functioning being the only subscale less than 0.70 and emotional functioning having the highest Cronbach's  $\alpha$ -coefficient (0.85). When item 5 was deleted, Cronbach's  $\alpha$ -coefficient for physical functioning increased from 0.81 to 0.86. No change was detected in the Cronbach's  $\alpha$ -coefficient for other scales when relevant items were deleted.

The stability of the test over time was assessed by using test–retest procedure. For the test–retest reliability, Pearson's correlation coefficients were significant at 0.01 level for functional scales, ranging between 0.58 and 0.75 and for multi-item symptom scales ranging between 0.62 and 0.68 and for the other items 0.47–0.62.

# Validity

#### Construct (Interscale) validity

Table 3 shows correlations between subscales of EORTC QLQ-C30 for interscale validity. Most of the interscale correlations were significant at the 0.01 level. General health/QOL subscale was correlated significantly with all other subscales; however, only EF, SF, pain and fatigue

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	SFGH	SFPF	SFRF	SFEF	SFSOF	SFVIT	SFPAIN	SFMHE	HADS-A	HADS-D				
QOL	0.32**	0.37**	0.17	0.21*	0.45**	0.52**	0.38**	0.48**	-0.24*	-0.33**				
PF	0.24**	0.57**	0.44**	0.19*	0.50**	0.46**	0.45**	0.43**	-0.21*	-0.26**				
RF	0.13	0.46**	0.44**	0.21*	0.35**	0.42**	0.37**	0.31**	-0.26**	-0.25**				
CF	0.24**	0.19*	0.2*	0.28**	0.36**	0.27**	0.24**	0.36**	-0.08	-0.13				
EF	0.21*	0.15	0.15	0.24**	0.31**	0.27**	0.26**	0.36**	-0.31**	-0.17				
SF	0.25**	0.34**	0.16	0.24**	0.42**	0.35**	0.33**	0.42**	-0.20*	-0.27**				
F	-0.13	-0.41**	-0.33**	-0.24**	-0.40**	-0.46**	-0.36**	-0.34**	0.17	0.20*				
Р	-0.33**	-0.33**	-0.18	-0.16	-0.27**	-0.40**	-0.64 * *	-0.42**	0.18	0.26**				
NV	-0.21*	-0.15	-0.24*	-0.15	-0.31**	-0.24**	-0.29**	-0.23*	0.00	0.09				
D	-0.21*	-0.19*	-0.19*	-0.24**	-0.07	-0.24**	-0.19*	-0.22*	0.16	0.00				
SD	-0.20*	-0.22*	-0.15	-0.17	-0.26**	-0.39**	-0.30**	-0.33**	0.12	0.10				
AL	-0.12	-0.18*	-0.20*	-0.07	-0.17	-0.22*	-0.16	-0.14	-0.01	-0.05				
С	0.02	-0.14	-0.03	-0.12	-0.17	-0.05	-0.08	-0.19*	0.08	0.00				
DI	-0.19*	-0.04	-0.1	-0.04	-0.26**	-0.07	-0.20*	-0.23*	0.12	0.12				
FI	-0.26**	-0.20*	-0.15	-0.13	-0.35**	-0.17	-0.33**	-0.31**	0.09	0.29**				
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Table 4. The correlations between subscales of SF-36, HADS and EORTC QLQ-C 30 version 3.0

\*Correlation is significant at the 0.05 level. Negative correlations are due to scoring procedures. \*\*Correlation is significant at the 0.01 level.

The correlation between relevant subscales of SF-36 and EORTC QLQ-C30 are in bold.

QOL, quality of life; SF, Short Form; SFGH, SF-36 general health; SFPF, SF-36 physical functioning; SFRF, SF-36 role functioning (physical); SFEF, SF-36 role functioning (emotional); SFSOF, SF-36 social functioning; SFVIT, vitality; SFPAIN, SF-36 bodily pain; SFMHE, SF-36 mental health. HADS-A, Hospital Anxiety Depression-Anxiety subscale; HADS-D, Hospital Anxiety Depression-Depression subscale; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer QOL measure.

were correlated at more than 0.40 Pearson's coefficients. Linear regression analysis showed that EF, SF and fatigue altogether explained 40% of variance.

Correlations between physical functioning and role functioning (0.69), physical functioning and fatigue (-0.72), role functioning and pain (-0.65), pain and fatigue (0.62) subscales were highest. The weakest correlations were between nausea/vomiting and other subscales (ranging between -0.19 and -0.41) except appetite loss (0.56). Correlation coefficients between the items and their own subscales were satisfactorily high (Pearson's coefficients ranging between 0.93 for item 7 and RF, -0.46 for item 5 and PF). Correlations were moderate with the items and the other subscales.

# Concurrent validity between EORTC QLQ-C30 and SF-36

The correlations between relevant subscales of SF-36 and EORTC QLQ-C30 are shown at Table 4. Modest correlations were found between relevant subscales of two QOL scales (r = 0.32 to -0.64) indicating good convergent validity. The correlations of the subscales with their corresponding counterpart were higher than the correlations of them with the unrelated subscales except general health/QOL and SF. But higher correlates for unrelated subscales were observed for QOL and three of the other subscales (SF, vitality and mental health).

# Correlation with HADS

The mean scores for HADS-D and HADS-A were 11.96 (SD = 3.5) and 10.39 (SD = 3.17), respectively, where cutoff values determined in Turkish study (Aydemir *et al.* 1997) are 7/8 and 10/11 for depression and anxiety respectively. Although EF score was significantly correlated with HADS-A (r = -0.31), no correlation was found with HADS-D. As high EF scores reflect better functioning whereas high HADS scores mean more distress, the observed correlation coefficients are negative. The correlations between general health/QOL and HADS-A and HADS-D were significant though Pearson's coefficients were below 0.4 (r = -0.240, -0.333) (Table 4).

#### DISCUSSION

This study was designed to explore the reliability and validity of the Turkish form of EORTC QLQ-C30 version 3.0 for heterogeneous cancer types. Our results indicate that the reliability analysis for multi-item subscales yielded very similar results to the Western, Iranian, Korean and Japanese studies (Aaronson *et al.* 1993; Koba-yashi *et al.* 1998; Montazeri *et al.* 1999; Yun *et al.* 2004). The low Cronbach's alpha-coefficient for cognitive functioning subscale is also found in the original (Aaronson *et al.* 1993) and other studies of different cultures (Koba-yashi *et al.* 1998; Montazeri *et al.* 1999; Yun *et al.* 2004; Luo *et al.* 2005; Silpakit *et al.* 2006). Although this sub-

scale has poor psychometric properties, it is proposed to include clinically relevant items (Luo *et al.* 2005). Therefore, the construction of the scale is justifiable from this perspective.

When item 5 was deleted, it was found that Cronbach's  $\alpha$ -coefficient for physical functioning increased. This item asks how much help is needed for eating/dressing/ washing or using the toilet. However, it was not concluded that this item had to be omitted from the subscale, as it was considered a consequence of the lack of normal distribution for item 5 (83% of the patients reported very low limitation).

The test could be accepted as stable over time as the correlation coefficients of all multi-item subscales and items were over 0.40 between the first assessment and the one a week later. Although the assumption of stability over time is tentative as physical performance of the patients was not analysed with a standardized measure in either assessment, the interval was adequately short for ruling out a significant change.

The general health/QOL displayed only modest correlation with the other subscales, similar to the findings in the study of Kuenstner et al. (2002) with the exception of EF, SF, pain and fatigue which displayed strong correlation in our study. Regression analysis showed that SF, EF and fatigue were significant explanatory variables for general health/QOL subscale. A similar observation except fatigue was reported in the cross validation study of Kobayashi et al. (1998) which was not reported in the Aaronson et al. (1993) study. The satisfactory correlation found between EF and general health/QOL deserves further consideration. Fayers et al. (1997) proposed that the EF is an effect indicator of QOL rather than a causal indicator. The general consideration is that an effect indicator reflects the level of QOL at a higher degree than a causal indicator. They also suggested that item 24 of EF dimension ('Did you feel depressed?') reflects general health/QOL more than the other three questions. Similarly we found a higher correlation of general health/QOL with HADS-D than HADS-A which results of Skarstein et al. (2000) supported this view as well.

Kuenstner *et al.* (2002) studied the comparability of SF-36 and EORTC QLQ-C30 and has concluded that the subscales of these instruments can be equated except general health/QOL domain. The correlation between general health domain of SF-36 and EORTC QLQ-C30 was found to be only moderate in our study as Kuenster *et al.* (2002) stated. All the subscales other than general health/QOL and EF correlated significantly with their corresponding counterparts at Pearson's coefficients above 0.4. Fayers *et al.* (1997) found a relatively poor relation between EF and relevant dimension of SF-36, as well.

Emotional functioning dimension of EORTC QLQ-C30 is expected to reflect psychological distress. However, in our sample in which most of the patients had high depression scores as detected by HADS-D, EF was correlated with anxiety scores but not with depression scores. It is a repeated finding in other studies (Massie & Popkin 1998; Ozer et al. 2003), though in Grassi et al. (1996) study significant but modest relation was found between depression and EF. In another study, psychological distress (anxiety state and/or depressive illness) was found in 27% of patients by HADS, however, in 22% of patients by a QOL scale (Rotterdam Symptom Check List) (Hopwood & Howell 1991). One explanation of could be that EF dimension consists three questions addressing anxiety whereas only one question for depression (Did you feel depressed?). However, HADS-D covers the three basic issues of depression (depressed mood, loss of interest or pleasure and decreased energy) (Zigmond & Snaith 1983). Moreover, importantly, the EF dimension is not fundamentally designed for the assessment of depressive symptoms and is far less suited than HADS-D to evaluate clinically significant depression. If depression is sought to be evaluated in cancer patients, it is then a necessity to screen with an additional specific questionnaire. The detection of depression and its subsequent treatment is very important in cancer patients which is implicated by the significant, though moderate correlation of HADS-D with general health/QOL particularly and other dimensions (PF, pain, RF, SF and fatigue). Fatigue in cancer patients was found to be strongly correlated with HADS-D in several studies (Kasa et al. 1993; Haghighat et al. 2003). Pain was weakly correlated with HADS-D in some studies (Grassi et al. 1996; Skarstein et al. 2000). Anxiety is found to be correlated with only general health/QOL, PF, EF and SF, weakly. Skarstein et al. (2000) suggested that anxiety assessed by HADS-A may qualitatively differ from the psychological distress observed in patients with physical illness other than cancer, which might be a rational explanation.

This study has some limitations. For example, our sample size while large, may have benefited from additional patients to give more robustness and generalizability to the findings. In addition, the classification of the disease stage could not be obtained from all patients and performance status was not assessed. Nevertheless, we believe that these results provide important insights into using EORTC QLQ-C30 version 3.0 in Turkish population.

Validation of QOL measurements is becoming increasingly important especially after the encouragement of Food and Drug Administration of USA (2006) for validation studies for patients from different cultures attending to the clinical trials for drug approval. As it is known that the Turkish population is increasing in most of European countries, the information about the validity and reliability of this instrument in Turkish is a need for the researches not only in Turkey but also in other European countries. To conclude, the Turkish version of the EORTC QLQ-C30 version 3.0 is a reliable and valid (in terms of construct and criterion validity) instrument and suitable for measuring the QOL in cancer patients.

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