

Evaluation of reliability and validity of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30, Albanian version) among breast cancer patients from Kosovo

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Patients and methods: A sample of breast cancer patients (n=62 women) were interviewed for the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) in Albanian. Reliability of the questionnaire was considered acceptable if Cronbach's alpha was ≥ 0.70 . Item convergent-discriminant validity was tested through multitrait scaling analysis. Construct validity was tested under the hypotheses that QLQ-C30 interscale correlations would have an acceptable value of ≥ 0.40 and as well as by known group comparisons assessing differences of patient subgroups with reference to disease stage and education level.

Results: The mean age of the patients was 50 years (standard deviation: 10.9 years). Cronbach's alpha ranged from 0.54 for the cognitive functioning scale to 0.96 for the global health quality of life (GH/QoL) scale. In multitrait scaling analysis, the strength of Spearman's correlations between an item and its own subscale was ≥ 0.40 , with the exception of item 5 ($\rho=0.22$); results for item discriminant validity were satisfactory, with the exception of item 5, which showed higher correlation with other subscales than with its own physical functioning. The Spearman's interscale coefficients generally were correlated with each other. Results of known group comparisons did not show significant differences in terms of disease stage. Regarding education level, patients with high school/university education had better functional scales scores only in certain subscales compared to other subgroups; furthermore, patients with secondary school education had better GH/QoL compared to other subgroups of patients.

Conclusion: The EORTC QLQ-C30 (v3.0) in Albanian was found to be valid and reliable for women with breast cancer and could be considered as a starting point for further evaluation study.

Keyword: women, oncology, internal consistency, functional scale, symptom scale, HRQoL

Introduction

Breast cancer is the second most common cancer in the world and, by far, the most frequent cancer among women, with an estimated 1.67 million new cancer cases diagnosed in 2012 (25% of all cancers).¹ Kosovo is located in the central Balkan peninsula and has a resident population of 1.8 million, of whom 92.9% are of Albanian ethnicity.² In Kosovo, cancer care is mainly provided at the Institute of Oncology of the University Clinical Centre of Kosovo (UCCK). It is a national institute for cancer treatment and provides only outpatient care for cancer patients in Kosovo. According to the annual report for 2011 by the Kosovo Institute of Public Health (IPH), the most

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common diagnosis in tumors group classification was breast cancer (11.8%).³ The diagnosis and subsequent treatment of cancer is often associated with considerable psychological and social difficulties for patients.⁴ Quality of life (QoL) has become a part of the evaluation criteria for cancer therapy besides the classical biomedical criteria. It is the most frequently used outcome measure in oncology research.⁵ In Kosovo, there is very little information available about the QoL of cancer patients.

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) is a questionnaire to assess the QoL in cancer patients. The QLQ-C30 questionnaire has been used worldwide.⁶ The Albanian QLQ-C30 version has been translated by EORTC, and to our knowledge, this is the first evaluation of the questionnaire. Therefore, the purpose of the current study was to evaluate the validity and reliability of the QLQ-C30 in Albanian women with breast cancer.

Patients and methods

A random sample of 62 breast cancer women patients, who were attending the Institute of Oncology of the UCCK were included in the study. The study period was between the end of February 2014 until the middle of May 2014. The study was approved by the ethics committee from UCCK. Patients were informed about the purpose of the study questionnaire and were voluntarily included in the study and gave verbal informed consent. The personal interview with patients was conducted by the clinician. Only patients who were able to follow the questions and give answers were interviewed. Patients were interviewed only once during the study. There were no exclusions in patient selection in terms of disease stage, age, and the type of treatment at the time of the interview. Sociodemographic data of patients (age, marital status, and education status) were taken during the interview and clinical information (disease stage, metastasis, and types of treatment) was collected from patients' medical records. Obtained results were analyzed with current published literature.

Questionnaire

The EORTC QLQ-C30 (v3.0) in Albanian and the scoring manual were kindly sent to us by the EORTC Quality of Life Group, Brussels, Belgium. The questionnaire contains five functional scales, three symptom scales, a global health (GH)/QoL scale, and six single items, and measures health-related QoL (HRQoL) over the past week.⁶ This is the core cancer-specific questionnaire (QLQ-C30) developed to be used alone, or with additional questionnaire modules, which

can be site- or treatment-specific.⁷ Item scores of the EORTC QLQ-C30 and missing data were managed according to the EORTC QLQ-C30 scoring manual.⁸ After the scoring procedures, all scale and single-item scores were linearly transformed to a 0–100 scale. Higher scores for five functional scales and the global QoL scale, indicate 'higher level of functioning or global QoL', while for symptom scales and single items, a higher score indicates a 'higher level of symptoms or problems'.⁹

According to published studies,^{10–12} a problematic group was defined if GH/QoL or the functional scales score were ≤ 33 and symptom scale score was ≥ 66 on the EORTC QLQ-C30.

The EORTC QLQ-C30 was developed to be self-administered; however, interviewer administration is also recommended.¹³ In our study, most of the patients had no basic education or had only primary school education, making self-administration of the questionnaire difficult. Hahn et al¹⁴ showed that the mode of administering questionnaires, whether via interview or self-administration, does not interfere with the scores reported by patients.

Statistical analysis

Categorical and continuous variables were expressed with frequencies and percentages, and means and standard deviations, respectively. Reliability (internal consistency) of the questionnaire was tested by Cronbach's alpha coefficient and the acceptable value to be met was ≥ 0.70 .¹⁵ Multitrait scaling analysis was used for item convergent and discriminant validity.¹⁶ Convergent validity was predicted if the correlation value of an item and its own scale was ≥ 0.40 and discriminant validity if the correlation of an item with its own scale was higher than with other scales.¹⁷ Construct validity was evaluated under the hypothesis that the QLQ-C30 subscales were correlated with each other (acceptable correlation coefficients were ≥ 0.40) and by known groups comparisons analyzing the correlation between subgroups of patients differing in disease stage and education level. The underlying hypothesis was that patients with stage III–IV cancer would report higher symptom scores than patients in earlier disease stages and patients with high school/university education would report higher functional scores and better GH/QoL than other patient subgroups. The Kruskal–Wallis test was used for between subgroup comparison analysis.

All data analyses were performed using SPSS (v20) software and $P < 0.05$ was considered to be statistically significant.

Results

Sociodemographic and clinical characteristics

Sixty-two women with breast cancer were interviewed. The patients' mean age was 50.0 years (standard deviation [SD]: 10.9), with a range of 32–80 years. Most of the patients were married (91.9%) and had completed primary or secondary education (71%), while 16.1% had completed high school/university. Most of the patients had undergone chemotherapy (96.8%) and 82.3% of the patients had undergone surgical treatment (mastectomy). The disease stage of the patients were as follows: 11.3% stage 0–I, 30.6% stage II, 58.1% stage III–IV, while 29% had distant metastasis. Sociodemographic and clinical characteristics of the patients are presented in Table 1.

Reliability of the Albanian version of the EORTC QLQ-C30

Mean scores and standard deviations of each subscale/item, and Cronbach's alpha coefficients for the multi-item scales of the EORTC QLQ-C30 are shown in Table 2.

Table 1 Sociodemographic and clinical characteristics of the study sample (n=62)

Characteristics	Number of patients	%
Age (years)		
20–39	11	17.7
40–59	38	61.3
60–80	13	21
Education level		
No school	8	12.9
Primary	31	50
Secondary	13	21
High school/university	10	16.1
Marital status		
Single	5	8.1
Married	57	91.9
Chemotherapy		
No	2	3.2
Yes	60	96.8
Surgery		
No	6	9.7
Mastectomy	51	82.3
Lumpectomy	1	1.6
Quadrantectomy	4	6.5
Radiotherapy		
Yes	49	79
No	13	21
Disease stage		
0–I	7	11.3
II	19	30.6
III–IV	36	58.1
Distant metastasis		
No	44	71
Yes	18	29

Table 2 Mean scores and internal consistency of each subscale/item of EORTC QLQ-C30 (n=62)

	Mean score (SD)	Cronbach's alpha coefficients ^a
Functional scale^b		
Physical (1–5) ^c	82.58 (16.34)	0.81
Role (6, 7) ^c	65.6 (20.88)	0.81
Emotional (21–24) ^c	57.13 (21.6)	0.86
Cognitive (20, 25) ^c	65.05 (27.61)	0.54
Social (26, 27) ^c	54.53 (19.67)	0.8
Global health quality of life (29, 30) ^c	78.9 (17.63)	0.96
Symptom scale and/or items^d		
Fatigue (10, 12, 18) ^c	19.61 (24.6)	0.91
Nausea and vomiting (14, 15) ^c	6.99 (19.21)	0.77
Pain (9, 19) ^c	20.16 (23.2)	0.83
Dyspnea (8) ^c	19.35 (28.01)	
Insomnia (11) ^c	40.33 (40.1)	
Appetite loss (13) ^c	21.5 (34.2)	
Constipation (16) ^c	1.61 (12.7)	
Diarrhea (17) ^c	6.45 (19.87)	
Financial difficulties (28) ^c	92.47 (22.92)	

Notes: ^aAlpha ≥ 0.70 indicates acceptable scale reliability; ^bscores range from 0 to 100 – higher score indicates better functioning or GH/QoL; ^cnumbers in brackets correspond to the item numbers in the questionnaire; ^dscores range from 0 to 100 – higher score indicates a higher rate of symptoms or problems.

Abbreviations: EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire; GH/QoL, global health quality of life; SD, standard deviation.

The mean scores for the GH/QoL, physical, role, emotional, cognitive, and social functioning subscales were above 33, suggesting that there were no problems regarding their functioning. The mean scores of the symptom scales were less than 66 for almost all of the symptom scales and/or items suggesting lack of severe symptomatology among patients, with the exception of financial difficulties, with a mean score of 92.47, indicating financial problems for women with breast cancer.

Eight subscales achieved the acceptable standard of reliability (≥ 0.70), the only exception was the cognitive scale which had a Cronbach's alpha coefficient of 0.54. The highest score of internal consistency was 0.96 for GH/QoL.

Validity of the Albanian version of EORTC QLQ-C30

Multitrait scaling analysis: convergent and discriminant validity

The convergent validity testing showed that all correlation coefficients between an item and its own subscale were ≥ 0.40 with the exception of item 5 (self-care; $\rho = -0.22$). Spearman's correlation coefficients between each item and its

Table 3 Spearman's correlation coefficients between the items and the subscales of the EORTC QLQ-C30

Item correlations		Subscales								
Item no ^a	Short description ^b	PF	RF	EF	CF	SF	GH/QoL	FA	NV	PA
1	Strenuous activities	-0.79^c	-0.37	-0.3	-0.34	-0.17	-0.65	0.63	0.21	0.54
2	Long walk	-0.77	-0.34	-0.32	-0.26	-0.41	-0.45	0.5	0.34	0.44
3	Short walk	-0.60	-0.11	-0.34	-0.23	-0.28	-0.58	0.51	0.29	0.44
4	Stay in bed/chair	-0.70	-0.08	-0.20	-0.30	-0.27	-0.55	0.68	0.44	0.56
5	Self-care	-0.22	-0.23	-0.21	-0.20	-0.23	-0.23	0.22	0.33	0.23
6	Limited in work	-0.30	-0.82	-0.21	-0.13	-0.42	-0.23	0.25	0.06	0.17
7	Hobbies/limited leisure activities	-0.33	-0.96	-0.30	-0.19	-0.31	-0.25	0.24	0.05	0.20
21	Tense	-0.22	-0.18	-0.75	-0.20	-0.15	-0.12	0.18	0.19	0.17
22	Worried	-0.26	-0.19	-0.85	-0.39	-0.43	-0.26	0.11	0.29	0.28
23	Irritated	-0.30	-0.16	-0.84	-0.16	-0.18	-0.22	0.15	0.26	0.22
24	Depressed	-0.40	-0.31	-0.74	-0.37	-0.36	-0.38	0.35	0.24	0.31
20	Concentration	-0.18	-0.06	-0.25	-0.76	-0.34	-0.41	0.29	0.20	0.39
25	Memory difficulties	-0.35	-0.11	-0.32	-0.89	-0.40	-0.41	0.32	0.20	0.18
26	Family life	-0.33	-0.41	-0.35	-0.39	-0.85	-0.25	0.23	0.26	0.19
27	Social life	-0.41	-0.36	-0.39	-0.44	-0.84	-0.42	0.42	0.52	0.29
29	Physical condition	0.71	0.18	0.34	0.48	0.36	0.98	-0.73	-0.45	-0.69
30	General QoL	0.62	0.21	0.34	0.51	0.40	0.98	-0.69	-0.40	-0.60
10	Need to rest	-0.57	-0.26	-0.22	-0.27	-0.37	-0.60	0.89	0.48	0.60
12	Felt weak	-0.61	-0.20	-0.26	-0.35	-0.41	-0.68	0.83	0.54	0.60
18	Felt tired	-0.71	-0.07	-0.26	-0.30	-0.21	-0.63	0.78	0.47	0.62
14	Nausea	-0.41	-0.02	-0.26	-0.25	-0.44	-0.43	0.49	0.95	0.45
15	Vomiting	-0.31	0.02	-0.30	-0.14	-0.17	-0.33	0.28	0.71	0.30
9	Had pain	-0.52	-0.13	-0.26	-0.36	-0.27	-0.59	0.59	0.46	0.90
19	Pain interfered	-0.65	-0.20	-0.32	-0.25	-0.28	-0.60	0.68	0.38	0.89

Notes: ^aThe item number corresponds to the number of each item in the questionnaire; ^bShort description, explains briefly the questions asked in each item of the questionnaire; ^cSpearman's correlation coefficients between the subscales and items within the same subscale (in bold).

Abbreviations: CF, cognitive functioning; EF, emotional functioning; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire; FA, fatigue; GH/QoL, global health quality of life; NV, nausea and vomiting; RF, role functioning; PA, pain; PF, physical functioning; QoL, quality of life; SF, social functioning.

own subscale are presented in Table 3. The correlation coefficients ranged from -0.22 to 0.98. Item 7 (hobbies/limited leisure activities) had the strongest negative correlation with its corresponding role functioning subscale, as well as item 25 (memory difficulties) with its corresponding cognitive functioning subscale. Items 29 (physical condition) and 30 (general QoL) had the strongest positive correlation with their corresponding GH/QoL as well as item 14 (nausea) with its corresponding nausea and vomiting subscale. The results for item discriminant validity were satisfactory, with the exception of item 5 (self-care), which showed higher correlation with other subscales (role functioning, social functioning, GH/QoL, vomiting and pain) than with its corresponding physical functioning subscale.

Construct validity

Generally, the QLQ-C30 subscales showed moderate-to-strong correlation with each other. The exception was a strong relationship between fatigue and GH/QoL ($\rho=0.73$), fatigue with physical functioning ($\rho=0.72$), and pain with

fatigue ($\rho=0.70$). Spearman's correlation coefficients among nine subscales are presented in Table 4.

Findings of known group comparisons according to the disease stage generally showed that patients with advanced stages of breast cancer (stages III-IV) had higher symptomatic scores than those in early stages. However, none of these differences was statistically significant in the present study (Table 5).

In terms of education level, patients with high school/university education reported higher cognitive functioning compared to the other subgroups ($P=0.03$); other functional scales differences were not statistically significant. Interestingly, patients with secondary school education showed better GH/QoL than patients with high school/university education ($P=0.009$; Table 6).

Discussion

This initial study was designed to evaluate the reliability and validity of the EORTC QLQ-C30 (v3.0) in Albanian and is an attempt to provide initial information regarding its validity

Table 4 Spearman's correlation coefficients of subscales in the Albanian version of the EORTC QLQ-C30

Scales	PF	RF	EF	CF	SF	GH/QoL	FA	NV
PF								
RF	0.34**							
EF	0.38**	0.28*						
CF	0.34**	0.13	0.36**					
SF	0.42**	0.37**	0.38**	0.44**				
GH/QoL	0.68**	0.19**	0.35**	0.50**	0.38**			
FA	-0.72**	-0.22	-0.23	-0.37**	-0.38**	-0.73**		
NV	-0.40**	-0.02	-0.25*	-0.25	-0.45**	-0.43**	0.50**	
PA	-0.64**	-0.17	-0.32*	-0.34**	-0.29*	-0.66**	0.70**	0.46**

Notes: *Correlation is significant at the 0.05 level (two-tailed); **correlation is significant at the 0.01 level (two-tailed); negative correlations are due to scoring procedures.

Abbreviations: CF, cognitive functioning; EF, emotional functioning; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire; FA, fatigue; GH/QoL, global health quality of life; NV, nausea and vomiting; RF, role functioning; PA, pain; PF, physical functioning; SF, social functioning.

and reliability in women with breast cancer in Kosovo. As an initial study, a sample size of 62 was selected since it can identify correlations of ≥ 0.35 with a power of 80% at a P -value of 0.05.^{18,19}

The translation of the EORTC QLQ-C30 into Albanian was carried out by the EORTC Group. Our results indicate that internal consistency is acceptable, with the exception of the cognitive functioning scale ($\alpha = 0.54$); this has been reported in other studies as well.¹⁹⁻²² The predicted convergent validity was supported, regarding hypothesized correlation coefficients between an item and its own subscales, with the exception of item 5 (self-care). To an extent, similar findings regarding item 5 were reported in published studies.^{23,24} The results of discriminant validity were satisfactory, with the exception of item 5 (self-care), which showed a higher correlation with role and social functioning, GH/QoL subscale, nausea/vomiting, and pain than with its corresponding physical functioning subscale. Total item-discriminant validity success was 89.1%.

Interscale construct validity was generally supported by confirmation of predicted correlations between subscales that

are theoretically related, although strong correlations were found between fatigue with physical functioning, fatigue with pain, and fatigue with GH/QoL, which are considered unacceptable and may question the diversity of the notions being measured. The only possible explanation for these high correlations is that patients correlated fatigue (felt weak, felt tired, needed to rest) with their ability to accomplish a strenuous activity, take a long walk, necessity to stay in bed/chair, presence of pain, or their physical condition. Nevertheless, further studies are recommended.

Results of known group comparison analysis showed that there were no statistically significant differences between patients differing in disease stage. Our results were compatible with studies that reported that the stage of disease is not associated with QoL.^{25,26} In terms of education level, our findings showed that patients with high school/university education reported higher cognitive functioning compared to other subgroups; other functional scale differences were not statistically significant. Interestingly, patients with secondary school education showed better GH/QoL than patients with high school/university education. Many studies found that

Table 5 Summary of the EORTC QLQ-C30 subscales by disease stage

Disease stage	0-I	II	III-IV	P-value*
	n=7	n=19	n=36	
Symptom scale	Mean (SD)	Mean (SD)	Mean (SD)	
Fatigue	10.9 (13.0)	19.6 (23.7)	21.3 (26.8)	0.68
Nausea and vomiting	0.0 (0.0)	5.3 (13.7)	9.3 (23.0)	0.44
Pain	11.9 (15.9)	21.0 (24.1)	21.3 (24.1)	0.63
Dyspnea	14.3 (17.8)	12.8 (27.7)	24.1 (29.4)	0.16
Insomnia	42.9 (46.0)	42.1 (41.3)	38.9 (39.4)	0.94
Appetite loss	4.8 (12.6)	19.3 (33.9)	25.9 (36.6)	0.26
Constipation	0.0 (0.0)	0.0 (0.0)	2.8 (16.7)	0.70
Diarrhea	4.8 (12.6)	7.0 (23.8)	6.5 (19.2)	0.95
Financial difficulties	85.7 (26.2)	96.5 (15.3)	92.5 (22.9)	0.29

Note: * $P < 0.05$ is considered statistically significant.

Abbreviations: EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire; SD, standard deviation.

Table 6 Summary of the EORTC QLQ-C30 subscales by education level

Education level	No school	Primary	Secondary	High school/university	P-value*
	n=8	n=31	n=13	n=10	
Functional scale	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Physical functioning	78.3 (6.9)	82.6 (14.1)	86.7 (12.5)	80.7 (29.4)	0.17
Role functioning	66.7 (25.2)	65.6 (15.5)	71.8 (21.9)	56.7 (29.6)	0.42
Cognitive functioning	47.9 (18.8)	61.3 (28.7)	71.8 (21.9)	81.7 (28.8)	0.03
Emotional functioning	60.4 (23.9)	55.4 (15.6)	56.4 (29.5)	60.8 (26.7)	0.27
Social functioning	56.3 (15.3)	62.9 (14.8)	68.0 (25.9)	71.7 (26.1)	0.31
GH/QoL	65.6 (10.4)	77.7 (15.9)	86.6 (13.4)	83.3 (26.0)	0.009

Note: *P<0.05 is considered statistically significant.

Abbreviations: EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire; GH/QoL, global health quality of life; SD, standard deviation.

education level affects QoL of cancer patients.^{27,28} Pinar et al²⁹ found that university-educated patients had the highest QoL scores. Another research reported that women with college education showed better overall QoL.³⁰ On the other hand, there are studies that reported no significant differences between the educational level of patients and QoL^{31–33} and to some extent, our results were similar with their findings.

However, the results of the present study should be considered with caution since it is a preliminary study with a small number of patients; further studies are recommended to assess the findings.

Conclusion

In this initial study, the EORTC QLQ-C30 (v3.0) in Albanian was found to be reliable and valid for women with breast cancer.

Although the sample size was small and the study only included women with breast cancer, it is still important due to its preliminary findings on the validity and reliability of the EORTC QLQ-C30 in Albanian. It provides the basis for future studies of the EORTC QLQ-C30 in Kosovo and other countries in Albanian-speaking cancer patients. Studies with larger numbers of patients, including male patients as well as other groups of cancer patients and test–retest reliability are recommended to assess the results of this initial study.

Author contributions

Selvete Shuleta-Qehaja and Zoran Sterjev designed the study and all authors interpreted the data and revised the manuscript. Selvete Shuleta-Qehaja and Zoran Sterjev managed the statistical analysis. All authors read and approved the final manuscript.

Disclosure

The authors report no conflicts of interest in this work.

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