RESEARCH COMMUNICATION

Validation of the Turkish Versions of EORTC QLQ-C30 and BR23 Modules in Breast Cancer Patients

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Abstract

Purpose: To test the validity and reliability of The European Organization for Research and Treatment of Cancer (EORTC) core (QLQ-C30) and breast cancer module (QLQ-BR23) for Turkish breast cancer patients. Patients and Methods: A total of 127 patients treated with radiotherapy (RT) enrolled to this prospective study. EORTC QLQ-C30 and QLQ-BR23 modules applied to patients before initiation of RT and at follow-up period. Statistical analyses were performed by SPSS 13.0. Results: Questionnaires' were found reliable and valid for Turkish breast cancer patients. Six of the 8 multi-item scales of QLQ-C30 had a high reliability (Cronbach's α >0.7); where physical functioning and pain scores were less reliable (Cronbach's α of 0.66 and 0.68 respectively). In the QLQ-BR23, 3 of 5 multi-item scales were reliable; less reliable were breast and arm symptoms scale (Cronbach's α of 0.65 and 0.61 respectively). In our analysis the most determinative subscales of QLQ-C30 on global health was emotional functioning followed by fatigue, role functioning and appetite loss (respectively $p=0.002$, $p=0.01$; $p=0.03$ and $p=0.08$). Among QLQ-BR23 scales systemic therapy side effects, future perspective and upset by hair loss subscales had high impact on global health status (respectively $p=0.006$; $p=0.01$ and $p=0.03$). Conclusions: The Turkish version of EORTC QLQ-C30 and QLQ-BR23 modules are reliable and valid tools to assess quality of life of Turkish breast cancer patients.

Keywords: Breast cancer - quality of life - validation - EORTC QLQ-C30 - QLQ-BR23

Introduction

Breast cancer is the most frequent cancer among women in Turkey (Eser et al., 2010). Screening and better treatment prolonged the survival of breast cancer patients in the last two decades (Chu et al., 1996). Cancer diagnosis itself and intensive treatment period seriously affect the well being of the patient. Treatment related acute side effects during the treatment period and the long term side effects during the survivorship may impair the quality of life (QoL) of the patient.

Since the quality of life is the subjective evaluation of the patient rather than the objective evaluation of the physician, patient oriented questionnaires were developed to better understand the quality of life (Sloan et al., 2002). The European Organization for Research and Treatment of Cancer (EORTC) developed a cancer-specific core questionnaire (QLQ-C30) which is common to all cancer sites, and also developed site-specific questionnaires for the measurement of QoL of patients with specific cancers. EORTC questionnaires were proved to have good reliability and validity and were gained widespread use in many countries (Aaronson et al., 1993; Apolone et al.,1998; McLachlan et al., 1998; McLachlan et al.,

1999; Hjermstad et al.,1995; Groenvold et al., 1997). However, the original questionnaires are in English, and they should be translated and validated for other languages to be used for non-English speaking countries. Many of the questionnaires have already been translated to common languages and validated as well (Aaronson et al., 1993; Apolone et al.,1998; McLachlan et al., 1998; 1999; Hjermstad et al., 1995; Groenvold et al., 1997).

Turkish language is spoken by some 83 million people worldwide (http://en.wikipedia.org/wiki/Turkish_language). Although QLQ-C30 was previously translated to Turkish and validated for lung cancer patients, it was not validated for Turkish breast cancer patients (Guzelant et al., 2004; Ozturk et al., 2009). The breast specific QLQ-BR23 questionnaire was not validated for Turkish patients as well. The aim of the present study was to test reliability and validity of the Turkish versions of QLQ-C30 and QLQ-BR23 questionnaires for Turkish breast cancer patients.

Materials and Methods

Study population
The study population consisted of 127 breast cancer

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patients treated with radiotherapy (XRT) at the Ege University Hospital between January 2002 and December 2005. Sociodemographical features of the patients were analyzed. Median age of the patients was 50 (range: 30-75). The vast majority (93.7%) of the patients were married and 87 (68.5%) of the patients were urban residents.

Treatment

All patients underwent surgery, either tumorectomy in 66 (51.9%) or mastectomy in 61 (48.1%), followed by adjuvant XRT. Axillary dissection was performed in 110 (86.6%), sentinel lymph node biopsy in 12 (9.4%) and no axillary intervention was used in 5 (3.9%) patients. Chemotherapy was administered to 85% of the patients depending on the tumour stage and the prognostics. The dose of XRT was 50 Gy to chest wall with 2 Gy daily fractions in 5 weeks for the patients with mastectomy and 50 Gy to breast and a boost of 10-16 Gy to tumor bed in 6-7 weeks to those with tumorectomy. Ninety patients (70.9%) received hormonal therapy with the most frequent used agent of tamoxifen.

Instrument and procedure

The QLQ-C30 and QLQ-BR23 questionnaires were handed out to the patients and they were requested to fill-in the forms. This procedure was carried out by nurses whose tasks were to deal with the social and psychological issues of the patients.

Structure of the both questionnaires have four point response format for individual items (not at all, a little, quite a bit, very much). QLQ-C30 is composed of 30 items assessing global perceived health status and QoL. These items are grouped in five functional scales - physical functioning (PF), role functioning (RF), emotional functioning (EF), cognitive functioning (CF) and social functioning (SF); three symptom scales - fatigue (FA), nausea & vomiting (NV) and pain (PA); six single item scales - dyspnea (DY), insomnia (SL), appetite loss (AP), constipation (CO), diarrhoea (DI) and financial difficulties (FD).

QLQ-BR23 questionnaire has 23 items to assess functional scales - body image (BRBI), sexual functioning (BRSEF), sexual enjoyment (BRSEE) and future perspective (BRFU); symptom scales - systemic therapy side effects (BRST), breast symptoms (BRBS), arm symptoms (BRAS) and upset by hair loss (BRHL).

The QoL scores were calculated according to the QLQ-C30 scoring manual and missing data were treated according to the published recommendations (Fayers et al., 2001). All scales are converted to a score ranging from 0 to 100. The higher the scores of the overall QoL and functioning scales indicate the better the overall QoL and functioning; however the higher the scores of the symptom scales indicate the lower QoL.

Statistical analyses

Statistical analyses were done with SPSS 13.0 (Statistical package for social sciences, Chicago, IL, USA). Patient and treatment characteristics were analyzed with descriptive statistics using mean, median and standard

Table 1. Overall QoL, Functional and Symptom Scales with Floor and Ceiling Effects and Cronbach's alpha Values (n:127)

Scale (n of items)	Mean±SD[a]	Floor (%)	Ceiling (%)	IC (α)
Global Health Status (2)	62.8±22.4	3.1	8.7	0.91
Functional scales				
Physical functioning (5)	75.4±15.7	0.0	5.5	0.66*
Role functioning (2)	83.5±23.3	1.6	52.8	0.77
Emotional functioning (4)	67.3±23.9	3.1	8.7	0.87
Cognitive functioning (2)	76.9±25.3	1.6	36.2	0.70
Social functioning (2)	73.6±27.2	3.1	36.2	0.73
Symptom scales				
Fatigue (3)	36.8±22.2	9.4	1.6	0.82
Nausea and vomiting (2)	13.7±25.3	65.1	4.8	0.85
Pain (2)	20.6±21.1	33.1	0.0	0.68
Dyspnoea (1)	8.2±20.1	81.1	2.4	NA
Insomnia (1)	26.9±32.5	48.4	10.3	NA
Appetite loss (1)	15.6±23.7	63.5	2.4	NA
Constipation (1)	18.7±27.4	61.1	4.0	NA
Diarrhoea (1)	7.9±16.5	79.4	0.0	NA
Financial Difficulties (1)	33.8±33.5	40.0	9.6	NA
Functional scales				
Body image (4)	69.5±28.9	5.6	25.4	0.88
Sexual functioning (2)	19.0±23.2	52.1	0.8	0.88
Sexual enjoyment (1)	51.1±23.3	2.3	9.3	NA
Future perspective (1)	50.1±31.8	18.4	14.4	NA
Symptom scales				
Therapy side effects (7)	35.9±20.8	3.2	0.0	0.73
Breast symptoms (4)	15.4±15.0	23.2	0.0	0.65
Arm symptoms (3)	23.0±18.6	16.8	0.0	0.61
Upset by hair loss (1)	40.0±39.4	38.7	0.0	NA

SD, Standard deviation; IC, internal consistency-Cronbach's alpha; *if item no 5 deleted Cronbach α value reached 0.68; for functional scales, higher scores indicate better functioning, for symptom scales higher scores indicate high levels of symptoms, Cronbach's a-coefficient values >0.70 indicates adequate scale reliability; NA, not applicable

deviation. Floor & ceiling effects of the QLQ-C30 and QLQ-BR23 were analyzed and a cut-off value of 20% was considered as presence of a floor or ceiling effect (Everitt, 2002). Internal consistency reliability was evaluated using Cronbach's α coefficient for each domain (LJ, 1951). As recommended, internal consistency of a magnitude of 0.70 or greater was sought (JC, 1994).

The validity of the questionnaries were evaluated by two methods: Construct validity (convergent-divergent validity), and criterion validity. Construct validity was tested by convergent-divergent validity approach comparing the correlation of the similar scales of the QLQ-C30 and QLQ-BR23. It was expected that conceptually related scales would correlate with each other. We hypothesized that the functioning scales of the QLQ-BR23 should correlate better with the functioning scales of the QLQ-C30, but not with the symptom scales of the QLQ-C30 and vice versa. Scale to scale correlation was done by Spearman's Rho bivariate correlation. Criterion validity of each of the C30 and BR23 were tested by stepwise multiple linear regression models, Global Health Status score being as a dependent variable. All tests were two tailed and conducted at p<0.05 significance level.

Table 2. Interscale Correlations among QLQ-C30 and QLQ-BR23 (Spearman rho Correlation Coefficients)

EORTC QLQ-BR23	GH	PF	RF	EF	CF	SF	FA	NV	PA	DY	SL	AP	CO	DI	FD
Functional scales															
BRBI	0.25**	0.28**	0.33**	0.39**	0.31**	0.48**	-0.28**	-0.13	-0.27**	-0.11	-0.16	-0.14	-0.12	-0.08	-0.29**
BRSEF	-0.01	0.19*	-0.02	-0.16	0.01	-0.008	-0.10	-0.06	0.08	0.02	-0.04	-0.24**	0.07	0.05	0.03
BRSEE	0.02	-0.05	0.18	-0.01	-0.05	0.12	0.19	0.22	-0.14	0.04	0.07	0.12	-0.04	-0.12	0.04
BRFU	0.33**	0.15	0.23*	0.53**	0.28**	0.46**	-0.28**	-0.05	-0.19*	0.03	-0.16	-0.16	-0.01	0.01	-0.32**
Symptom scales															
BRST	-0.25**	-0.40**	-0.31**	-0.43**	-0.57**	-0.26**	0.59**	0.44**	0.40**	0.25**	0.33**	0.32**	0.33**	0.14	0.09
BRBS	-0.20*	-0.36**	-0.34**	-0.43**	-0.43**	-0.32**	0.34**	0.11	0.38**	0.34**	0.20*	0.20*	0.20*	0.15	0.21*
BRAS	-0.28**	-0.39**	-0.32**	-0.46**	-0.40**	-0.31**	0.46**	0.17	0.47**	0.29**	0.14	0.21*	0.17	0.18*	0.25**
BRHL	-0.10	-0.12	-0.05	-0.41**	-0.38**	-0.30**	0.27**	0.23**	0.22*	0.16	0.12	0.07	0.15	0.03	0.12

The table has a spanning header: "EORTC QLQ-C30 scales" over all data columns; "Functional scales" over GH PF RF EF CF; "Symptom scales" over SF FA NV PA DY SL AP CO DI FD.

*,**correlation is significant at the 0.05, 0.01 level (2-tailed); negative correlations are due to scoring procedures

Results

Reliability

Internal consistency: Six of the 8 multi-item scales of QLQ-C30 had a high reliability (Cronbach's α >0.7); where physical functioning and pain scores were less reliable. In the QLQ-BR23 three of 5 multi-item scales were reliable; less reliable were breast and arm symptoms scale (Cronbach's α of 0.65 and 0.61 respectively) (see table 1).

Ceiling & Floor effects: In the QLQ-C30 the ceiling effect was present in three functional scales (role, cognitive and social functioning) but in none of the symptom scales; instead there was floor effect in almost all symptom scales (8 out of 9, exluding fatigue) with high ratios – 33.1% to 81.1% – whereas there was no floor effect in functional scales. In the QLQ-BR23 the ceiling effect was present only for body image; and the floor effect was present in sexual functioning, breast symptoms and upset by hair loss (see Table 1)

Validity

Construct validity/Convergent validity: The interscale correlations between certain QLQ-C30 and QLQ-BR23 scales were presented in Table-2 to display the construct validity of the QLQ-BR23. General health status subscale and several other QLQ-C30 subscales displayed weak to moderate correlation with QLQ-BR23 subscales. We can conclude that our hypothesis was verified except that of sexual related scales (BRSEF and BRSEE). (see table 3)

Table 3. Stepwise Multiple Linear Regression reduced final model for QLQ-C30 and QLQ-BR23 domains (Dependent Variable: Global health status/QoL) (R2= 0.312and 0.325)

	Standardised Beta	p-value
QLQ-C30 (Constant)		0.001
Role Function	0.19	0.038
Emotional Function	0.29	0.002
Fatigue	-0.26	0.012
Appetite loss	0.15	0.080
QLQ-BR 23 (Constant)		0.000
Future perspective	0.40	0.011
Systemic therapy side effects	-0.48	0.006
Hair loss	0.39	0.032

Criterion Validity: The reduced final model results are presented in the tables 3. Emotional functioning, fatigue, role functioning and appetite loss (respectively p=0.002, p=0.01; p=0.03 and p=0.08) were the determinative scales of QLQ-C30 on global health. Regarding QLQ-BR23 systemic therapy side effects, future perspective and upset by hair loss (p=0.006; p=0.01 and p=0.03 respectively) scales could explain the variance of the global health score.

Discussion

The transcultural validation of EORTC QLQ-C30 and BR23 modules for breast cancer patients was reported previously for various countries such as India, Japan, Korea, China, United Arab Emirates, Singapore, Taiwan, and Iran (Montazeri et al., 2000; Chie et al., 2003; Okamoto et al., 2003; Yun et al., 2004; Luo et al., 2005; Parmar et al., 2005; Wan et al., 2007; Awad et al., 2008). In the reliability analysis of the present study Cronbach's α values of all subscales of QLQ-C30 (range: 0.66-0.91) and QLQ- BR23 (0.61-0.88) were satisfactory which were consistent with the other validation studies (Montazeri et al., 2000; Chie et al., 2003; Okamoto et al., 2003; Yun et al., 2004; Luo et al., 2005; Parmar et al., 2005; Wan et al., 2007; Awad et al., 2008).

Since QLQ-BR23 displayed no serious floor or ceiling effects (except for sexual functioning) compared to QLQ-C30; we suppose that QLQ-BR23 is a more sensitive tool for measuring QoL in breast cancer patients than QLQ-C30. There was a good convergence between functional scales of QLQ-C30 and QLQ-BR23; and between symptom scales of QLQ-C30 and QLQ-BR23. It should be noted that out of 127 patients only 43 of them filled in the question of sexual enjoyment (BRSEE) and these sexual related subscales were not correlated with other QLQ-C30 subscales. The relationship between breast cancer and sexual life in Turkish breast cancer patients was investigated previously in other studies and was shown that sexual life is impaired, but has far less importance than survival (Alicikus et al., 2009; Onen Sertoz et al., 2004). Takahashi et al evaluated the sexual functioning after cancer diagnosis and demonstrated that sexuality is ignored after cancer diagnosis in Japanese patients (Takahashi et al., 2005).

There are several reasons about the losing sexual interest, such as change in body image, pain, treatment

related side effects (fatigue, nausea and vomiting) and fear of recurrence (Schover et al., 1995). It is obvious that breast cancer patients on treatment and the survivors might have sexual related problems and psychosexual consultation might be considered.

Stepwise multiple linear regression analyses were conducted in order to investigate the potential contributions of the scales of both of the instruments on general health. The reason of conducting seperate regression analyses instead of a pooled analysis was sample size problem and colinearity problem- especially existing between some scales of QLQ-C30 and QLQ-BR23. Each of the regression models could explain about 32% of the variance of the General Health. In our analysis the most determinative subscales of QLQ-C30 on global health was emotional functioning followed by fatigue, role functioning and appetite loss. Among QLQ-BR23 scales systemic therapy side effects, future perspective and upset by hair loss subscales had high impact on global health status. Of note, 85% of the patients completed questionarries after chemotherapy and they were experiencing the side effects of chemotherapy. Jaiyesimi et al analyzed 35 Nigerian women receiving radiotherapy for breast cancer and indicated that the overall QoL was significantly related to physical, cognitive and social functioning. There was also significant inverse relation between the scores of fatigue, nausea and vomiting, pain, insomnia and financial difficulty (Jaiyesimi et al., 2007).

Similarly Kootstra et al evaluated breast cancer patients' QoL before and after surgery and suggested that complications and chemotherapy had a significant negative effect on role, emotional and cognitive functioning (Kootstra et al., 2008).

Turkish breast cancer patients found the Turkish version of the EORTC QLQ-C30 and BR23 questionnaires easy to understand and the both questionnaire were found to be reliable and valid. We recommend the use of EORTC QLQ-C30 and BR23 modules in Turkish breast cancer patients in further clinical cancer research.

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