Original Article

The reliability and validity of Lymphedema Quality of Life Questionnaire-Arm in Turkish patients with upper limb lymphedema related with breast cancer

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ABSTRACT

Objectives: This study aims to adapt Lymphedema Quality of Life Questionnaire-Arm (LYMQOL) into Turkish and to test its reliability and validity in Turkish patients with upper limb lymphedema related with breast cancer.

Patients and methods: Between June 2015 and November 2015, the Turkish LYMQOL-Arm was obtained using forward-backward translation method and administered to a total of 135 female patients (mean age 51.8±9.8 years; range, 31 to 82 years) with upper limb lymphedema with European Organization for Research and Treatment of Cancer-QoL Breast Cancer-specific version (EORTC QLQ-BR23) and Functional Assessment of Cancer Therapy-Breast-4 (FACT-B+4) questionnaires. A test-retest interval of seven-days was used to assess the reliability. The validation studies were carried-out by means of construct-validity using Spearman's rank correlation-coefficient. Internal consistency and test-retest-reliability were assessed using Cronbach's alpha and intra-class correlation-coefficient (ICC), respectively.

Results: 135 patients completed the questionnaire with upper limb lymphedema related with breast cancer completed the questionnaires. The mean lymphedema duration was 21.1±28.7 (median: 6) months. Internal consistency and reliability of the Turkish LYMQOL-Arm was good with Cronbach's alpha (0.88-0.90) and test-retest ICC (0.45-0.71). External construct validity was highly confirmed by expected correlations with comparator scales, EORTCQLQ-BR23 and FACT-B+4 (p<0.01).

Conclusion: The Turkish version of the LYMQOL-Arm is a valid and reliable tool for evaluating QoL in female patients with upper limb lymphedema related with breast cancer.

Keywords: Lymphedema Quality of life Questionnaire-Arm; lymphedema; quality of life; validity; Turkish.

Breast cancer is the most frequent cancer among women in Turkey.[1] Cancer treatments comprising resection of lymph nodes and/or radiation therapy can damage lymph drainage pathways causing accumulation of lymph fluid in the interstitial tissue of related limbs and body areas, known as secondary lymphedema.[2,3] In recent years, more effective screening modalities and advances in therapeutic procedures have resulted in significant improvements in the survival of cancer patients.[4] The long-term side effects and treatment-related adverse effects during the survivorship may impair the quality of life (QoL) of the patients. Lymphedema has been described as one of the most significant survivorship complications after the surgical treatment of breast cancer.[4-6]

Lymphedema may have severe consequences in terms of patients' functional and psycho-social aspects of life. Accurate information on health-related QoL outcomes among patients with lymphedema is critically needed to determine evidence-based decision making and indicate the impact of disease on survivors' lives.[1,5,6] A number of questionnaires has been presented to assess the QoL in cancer patients

with lymphedema. Generic instruments comprising; European Organization for Research and Treatment of Cancer QoL Breast Cancer (EORTC-QLQ-30), its specific version for breast cancer (EORTC-QLQ-BR23), the World Health Organization Quality of Life (WHOQOL)-BREF, Functional Assessment of Cancer Therapy-Breast (FACT-B) as well as Short Form-36 (SF-36) or Nottingham Health Profile (NHP) have been used in previous studies.[7-10] In recent years, there has been more interest in developing lymphedema-specific QoL instruments. Due to the specific symptoms and difficulties of the patients with lymphedema, it is important to use a questionnaire specifically developed for patients suffering from this chronic condition. However, few are developed to measure specific QoL in patients with lymphedema. The Upper Limb Lymphedema-27 (ULL-27),[11] Lymphedema Quality of Life Inventory (LyQLI),[12] Lymphedema Functioning, Disability and Health Questionnaire (Lymph-ICF),[13] and Lymphedema Life Impact Scale (LLIS)[14] were specifically designed and validated for assessing health related-QoL in patients with upper limb lymphedema. However, we are impressed with the short and simple questionnaire named Quality of Life measure for Limb Lymphedema (LYMQOL) developed by Keeley et al.[15] It consists of two questionnaires: for upper and lower lymphedema LYMQOL-Arm and LYMQOL-Leg. We are surprised to find very little published translated versions in the literature.

The LYMQOL is a disease specific patient reported outcome measure developed in the United Kingdom (UK), consisting of 28 perceived items. The Turkish language is spoken by nearly 85 million individuals worldwide. Previously several generic questionnaires comprising EORTC-QLQ-30, its specific version for breast cancer-EORTC-QLQ-BR23,[7] SF-36,[16] and FACTB-4[17] have been translated to Turkish and validated for breast cancer patients. However, no specific instrument for lymphedema has been tested for validity and reliability in Turkey. In this study, we aimed to translate and validate the LYMQOL-Arm for Turkish breast cancer patients with lymphedema.

PATIENTS AND METHODS

In this study, we conducted a descriptive and methodological study for validation of the LYMQOL-Arm among Turkish patients with breast cancer-related lymphedema (BCRL). The study was conducted at Lymphedema Unit, Physical Medicine and Rehabilitation Department of a university hospital, between June 2015 and November 2015. A total of 135 female patients (mean age 51.8±9.8 years; range, 31 to 82 years) were included. The study was approved by the Clinical Research Ethics Committee of the University School of Medicine. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The BCRL patients with having mental incapacity, having psychiatric diagnoses requiring medications, patients with other types of cancer, those younger than 18 years and older than 65 years were not included. Patients were excluded, if they were illiterate or involved in intensive lymphedema treatment during the test period. All patients completed their chemotherapy and radiotherapy sessions and did not have active malignancy. The diagnosis of BCRL was verified by bilateral volumetric measurements depending on the circumferential measurements.[18] Circumferential measurements were performed by a standard 1 cm retractable tape at 4 cm intervals along the arm and converted to an approximate arm volume using the truncated cone formula to enable estimation of volume. The presence of lymphedema was assessed by inter-limb volume difference (>10%) based on the serial circumferential measurements in both affected and non-affected extremities.[19] Also, the circumferential measurements of second finger base and metacarpophalangeal areas were recorded for patients with hand edema. Lymphedema was defined as an increase in hand circumference at any level by 1.5 cm or more compared to the contralateral side.[20]

The demographic properties (age, sex, education, and marital status, occupation, Body Mass Index) and clinical characteristics (duration of lymphedema, involvement side, treatments, type of surgery, grade of lymphedema) were recorded.

Translation and cross-cultural adaptation

After obtaining written permission from the researcher who developed the LYMQOL, the forward-backward translation method was initiated. Four steps were used in the linguistic validation of the questionnaire. Two lecturers graduated from departments of foreign languages of Bilkent University and two lymphedema specialists, competent who were fully bilingual in both Turkish and English, participated in the translation process. One of the lecturers translated the English version into Turkish to produce an understandable and conceptually equivalent translation. The back translation of the Turkish version into source language was done by the second lecturer who was blind to the purpose of

translation. The original form and the one translated form from Turkish to English were compared by the two lecturers, and the final form of the Turkish version was prepared. Finally, the two lymphedema specialists, who were fully competent in both languages, controlled and revised the lecturers' final Turkish version to obtain the Turkish version used in this study. To avoid misunderstanding and to obtain difficulties in understanding, the instrument was given as a pretest to 30 patients with BCRL. Face-to-face interviews with the patients showed that all the indices were clear and the instrument was understandable. We made no cross-cultural validation in the translation, as feedback from the pretest study group did not identify any concerns. The Turkish version of LYMQOL-Arm was answered by the patients themselves. One lymphedema specialist was in the interview room to help the patients in case they needed assistance, which was the case only in a few patients with difficulty in reading. The scale was completed by each patient twice with one-week interval.

Questionnaires

The LYMQOL-Arm has been developed to assess the impact of lymphedema of the arms on the QoL of the patients. It consists of four domains with 28 items. These domains are symptoms, appearance, function, and mood. The answers were evaluated on a four-point Likert scale (1= not at all 2= a little, 3= quite a bit, 4= a lot). Each item received a score between 1 and 4, with higher scores indicating a worse QoL. Domain totals were calculated by adding the individual scores and dividing the total by the number of questions answered (If >50% of questions per domain were not answered this cannot be calculated *and =0). If the item was not scored and left blank or not applicable, this was scored with a 0. The four domains and their corresponding questions are: Function 1 (a-h), 2,3, Appearance 4,5,6,7,8 Symptoms 9,10,11,12,13,14 and Emotion 15,16,17,18,19,20. Overall QoL (Q21) is scored as the value marked by the patient, between 0-10. Previous reports indicated that the LYMQOL-Arm was easy to complete with clear face validity and good internal consistency.[15]

Patients with BCRL were also administered the Functional Assessment of Cancer Therapy-Breast-4 (FACT-B+4)[21] and EORTC-BR23[22] QoL tools, for comparisons with the new instrument. They were chosen as criterion standards, since they are suggested for QoL studies for lymphedema patients and their Turkish versions have previously been evaluated for test-retest reliability and validity.[10,16]

The European Organization for Research and Treatment of Cancer QoL Breast Cancer-specific Version (EORTC QLQ-BR23) is a 23 item self-administered cancer specific questionnaire designed to measure QoL in breast cancer population at various stages and with patients with differing treatment modalities. The assessment is comprised of eight domains (body image (BRBI), sexual functioning (BRSEF), sexual enjoyment (BRSEE) and future perspective (BRFU); symptom scales-arm symptoms (BRAS), breast symptoms (BRBS), systemic therapy side effects (BRST) and upset by hair loss (BRHL).[23] The EORTC-QLQ-BR23 is found effective and suggested in clinical studies for assessing breast cancer-specific QoL.[22]

The FACT-B+4 questionnaire was developed by adding a four-item Arm subscale to the well-validated FACT-B (Functional Assessment of Cancer Therapy–Breast)[21] and was been translated and field-tested in Turkish subjects. The 40 items in FACT-B+4 evaluated patients' physical, social, emotional and functional well-being; specific breast cancer concerns; arms symptoms; as well as their overall QOL. Previous reports indicated excellent reliability, internal consistency and sensitivity to change among patients with BCRL.[17,21]

Procedure

The participants completed the LYMQOL-Arm, FACT-B and EORTC BR23 concurrently, while the LYMQOL-Arm was completed for patients twice with seven-day intervals.

Statistical analysis

For the reliability and validity studies, the sample size is determined as at least five-fold of item numbers. Based on these data, 135 patients were required to study. A total of 20% of these patients was evaluated for retest procedure.[24] Descriptive analyses were performed to calculate means and standard deviations and median of the demographic variables.

For test-retest reliability, 65 patients completed the questionnaires, as a second time within seven days, at the same time of day, during a non-treatment period. Intra-class correlation coefficients (ICC) with one-way random effects model, were used to determine test-retest reliability of the scores on five domains of LYMQOL and of the score on each question separately. Cronbach alpha coefficients were used to determine internal consistency of the entire questionnaire and of each domain. As recommended, the internal consistency of a magnitude of ≥0.70 was sought. The Cronbach alpha was determined as high correlation,

if values in range of 0.80 to 0.95 were obtained, where a value >0.95 indicated excessive internal consistency.

Confirmatory factor analysis was used to show the convenience of factor structure to the original scale. Construct validity was tested by convergent-divergent validity approach comparing the correlation of the similar scales of the LYMQOL-Arm and EORTC-BR23 and FACT-B4. It was expected that conceptually related scales would correlate better with the functioning scales of the LYMQOL and vice versa. We used the Pearson correlation coefficient for normally distributed scores and the Spearman correlation coefficient for the other scores. The correlation coefficients are interpreted as follows: <0.4 was weak, 0.4-0.74 was moderate,

0.75 to 0.9 was strong, and >0.9 was very strong.[24] Statistical analysis was performed using the SPSS version 15.0 statistical software (SPSS Inc., Chicago, IL, USA). A *p* value of <0.05 was considered statistically significant.

RESULTS

Of 135 patients with BCRL, 65 completed test 1 and 2 for LYMQOL-Arm for test-retest analyses. The time between test 1 and 2 was within seven days. The demographic and clinical characteristics of the patients are shown in Table 1. All patients underwent breast cancer surgery. A great number of them were married and housewives. A number of participants (65%) were

Table 1. Demographic and clinical characteristics of patients (n=135)

	n	Mean±SD	Median	Min-Max
Age (year)		51.8 ±9.8		31-82
Marital status				
Unmarried	18			
Married	110			
Divorced/widowed	7			
Education				
Primary school	49			
Secondary school	15			
Lycee	36			
University	35			
Occupation				
Housewife	86			
Retired	21			
Officer	23			
Self-employer	5			
Involved side				
Right	70			
Left	65			
Body Mass Index (kg/m²)		29.2± 5.4		19.2-45.1
Duration of lymphedema (months)		21.1±38.7	6	0.2-164
Dominant hand				
Right	128			
Left	7			
Surgery	135			
Modified radical mastectomy	98			
Lumpectomy	7			
Simple mastectomy	30			
Lymphedema stage				
1	39			
2	84			
3	2			
Treatment				
Surgery	135			
Chemotherapy	128			
Radiation therapy	96			
Hormone therapy	97			
Time since surgery (month)		41.4±44.5		0.75-164

SD: Standard deviation; Min: Minimum; Max: Maximum.

Table 2. Internal consistency and test-retest reliability of the Turkish LYMQOL-Arm instrument (n=65)

	Test-retest		Consistency
LYMQOL-Arm scores	ICC	95% CI	Cronbach alpha
Function	0.611	0.373-0.773	0.880
Appearance	0.665	0.449-0.808	0.881
Symptom	0.714	0.521-0.838	0.886
Mood	0.451	0.165-0.666	0.853
Overall	0.627	0.379-0.790	0.900

LYMQOL: Lymphedema-Quality-of-Life-Questionnaire; * p<0.001. ICC: Intra-class correlation-coefficient.

high school or university graduated. Radiation therapy and chemotherapy were completed prior to entry into the study. The median duration of lymphedema was six months.

Reliability

The internal consistency (based on a Cronbach alpha score of (0.85-0.90) and test-retest reliability (based on an intra-class correlation coefficient of 0.45-0.74 of the LYMQOL-Arm were found to be high (p<0.001; Table 2). The test-retest reliability of the symptom, appearance, and mood scores was strong and the function and overall scores were moderate to strong.

Confirmatory factor analysis

The confirmatory factor analysis was applied to the factor structure. Specifically, we expected a best-fit model with the following indices: a Satorra-Bentler scaled chi-square $(S\text{-}B\chi^2)$/degrees of freedom ratio (CMIN/DF) of 2.0 or less; a Trucker Lewis Index

(TLI) of 0.90 or higher; a Comparative Fit Index (CFI) of 0.90 or higher; a Goodness-of-Fit Index (GFI) of 0.90 or higher; a Incremental Fit Index (IFI) of 0.90 or higher and a low root mean square error of approximation (RMSEA) of 0.08 or less. These values were calculated as CMIN/df: 1.733, RMSEA: 0.074, GFI: 0.782, IFI: 0.904, CFI: 0.902, TLI: 0.888. Accordingly, this factor structure was found to be acceptable.

Construct (convergent-divergent) validity

Table 3 shows an overview of inter-scale Spearman correlation coefficients between the different domains of LYMQOL-Arm and the EORTC-BR23 and FACT-B4. All patients completed the three questionnaires. All domains of LYMQOL-Arm had the strongest correlation with the expected domains of EORTC-BR23 (future, systemic complications, breast symptoms, arm symptoms). Concurrently, all sub-scores of LYMQOL-Arm had strongest correlations with the corresponding domains of FACT-B4. By means of divergent validity, no correlation between

Table 3. Correlation between the EORTC-BR23 and FACT-B4 questionnaires and the LYMQOL-Arm questionnaire (construct validity)

	LYMQOL-Arm function	LYMQOL-Arm appearance	LYMQOL-Arm symptom	LYMQOL-Arm mood	LYMQOL-Arm overall
FACT-B4 physical	-0.440**	-0.407**	-0.504**	-0.530**	0.471**
FACT-B4 social	-0.100	-0.173*	-0.102	-0.161	0.239**
FACT-B4 emotion	-0.356**	-0.377**	-0.354**	-0.512**	0.487**
FACT-B4 function	-0.282**	-0.363**	-0.296**	-0.363**	0.450**
FACT-B4 arm symptom	-0.318**	-0.395**	-0.371**	-0.430**	0.341**
EORTC-body image	-0.320**	-0.347**	-0.248**	-0.403**	0.370**
EORTC-sexual function	0.026	-0.034	-0.022	-0.017	0.192*
EORTC-sexual satisfaction	0.116	0.086	0.008	-0.064	0.095
EORTC-future	-0.255**	-0.320**	-0.214*	-0.406**	0.203*
EORTC-systemic completed	0.279**	0.284**	0.287**	0.390**	-0.335**
EORTC-breast symptoms	0.341**	0.331**	0.373**	0.429**	-0.215*
EORTC-arm symptoms	0.612**	0.637**	0.602**	0.561**	-0.389**
EORTC-hair loss	-0.092	0.106	-0.096	0.214	-0.102

EORTC: European Organization for Research and Treatment of Cancer; FACT-B4: Functional-Assessment-of-Cancer-Therapy-Breast-4; LYMQOL: Lymphedema-Quality-of-life-Questionnaire; * p<0.05; ** p<0.01.

sexuality and hair loss domains of EORTC-BR23 and domains of LYMQOL-Arm (except correlation between overall score) was detected (Table 3).

DISCUSSION

Lymphedema research has gained acceleration recently. Breast cancer-related lymphedema is an important argument to assess and monitor different therapeutic approaches and has a significant impact on QoL.[3,4,8,10,16] A systematic review investigated the quality and appropriateness of patient-reported outcome instruments and indicated that lymphedema-specific QoL instruments had strong psychometric properties and offered greater reliability and validity for use in BCRL survivorship researches.[10] As it is well-known, the perceived health status and QoL show variability in BCRL patients with different ethnic origins. In addition, factors such as socioeconomic status, as well as number and quality of medical services vary from country to country and affect the perception of QoL.[3,8,10,16,17] Until now, there is no validated Turkish patient-reported QoL instrument for lymphedema patients. The LYMQOL is a relatively short instrument for patient-reported outcome measures that evaluates QoL in lymphedema patients and was originally developed in the UK.[15] The transcultural validation of LYMQOL was reported previously only for Dutch patients,[25] but was used in several studies.[26-29]

In this study, we tested the reliability and validity of LYMQOL-Arm in Turkish BCRL patients. In our study, there was a strong correlation between all items of the Turkish LYMQOL questionnaire, which demonstrates good internal consistency. We found that all subscales of Turkish LYMQOL had good internal consistency and test-re-test reliability. The Turkish version was reliable and internally consistent for the total questionnaire and subclass domains. (Cronbach alpha: 0.90). The reliability of the Turkish LYMQOL was good to excellent for patients with BCRL. Similar to van de Pas et al.[25] who tested the validity of Dutch LYMQOL, we found Cronbach alpha coefficients higher than the recommended level of 0.70. Our results were comparable with findings from the original validation study in UK patients with BCRL.[15] In the reliability analysis of the present study, the Cronbach alpha values of all subscales of LYMQOL-Arm were satisfactory which were consistent with other validation studies.[11-14,25]

The test re-test correlation coefficient measured by ICC showed the stability of LYMQOL-Arm in the Turkish sample. Our results were quite similar to those reported by van de Pas[24] who found test-retest reliability to be excellent and internal consistency to be good. In the original study, Keeley et al.[15] showed an internal consistency using Cronbach alpha scores ranging from 0.83 to 0.88 across all domains of the instrument in patients with upper limb lymphedema. Better than the original study internal consistency in this present study was observed to be between 0.85-0.90 which can be explained by the use of more specific breast-cancer QoL questionnaire (EORTC-BR23) rather than EORTC-30, as suggested in previous studies.[22]

In the present study, we used EORTC-QLQ-BR23 and FACT-B+4 for validity analysis. The EORTC QLQ-BR23 is a health-related QoL instrument that has been designed for patients with different stages of breast-cancer.[23] The FACT-B+4 was recommended by the Breast Cancer Edge Task force to assess QoL in patients with BCRL.[21] The Turkish LYMQOL-Arm showed significant correlation with FACT-B+4 and EORTC-BR23. Construct validity was tested in two ways and provided good results in our patient group. There was a good convergence between functional, symptom, appearance, mood scales of LYMQOL-Arm and domains of FACT-B+4 and EORTC-BR23. Symptom, function appearance and mood domains of LYMQOL-Arm had strong to moderate correlations with the expected domains of FACT-B+4 and EORTC-BR23. None of the domains (except overall score) of LYMQOL-Arm correlated with sexuality and hair loss scores in EORTC-BR23 questionnaire.

The results of this validity study can be compared favorably to those of other prior studies.[15,25,30,31] In the original study Spearman's correlation coefficients between the common scores of the LYMQOL and EORTC-30 ranged from-0.68 to 0.93 were relatively close to the range of correlations found in our study.[15] Similar to some previous studies, a more significant correlation was observed between the LYMQOL-Arm and FACT-B+4 scores supporting the external validity of the LYMQOL.[30,31]

By means of divergent validity, the LYMQOL scores were weakly correlated or showed no correlation with perceived sexuality and hair loss domains of EORTC-BR-23, as we predicted. The low or lack of correlation of some domains of EORTC-BR23 (sexuality and hair loss) with the LYMQOL subscale scores indicates that these are specific problems that may not affect the QoL in Turkish lymphedema patients. The relationship between breast cancer and sexual life

in Turkish patients was investigated previously and shown that sexual life has far less importance than survival.[5] Demirci et al.[7] demonstrated that sexuality was not an important factor for QoL in breast cancer patients living in Turkey. These issues can be explained by several reasons such as sociocultural status of the Turkish women, body image, pain, fear of recurrence. Another explanation may be that the instruments measure different aspects, LYMQOL concerns the lymphedema, others the QoL-related breast cancer and treatments.[5-7,15,21,32]

There is an unmet need for a specific instrument like LYMQOL to establish patients' QoL aspect for lymphedema and to measure and monitor improvement in the treatments. Appropriate translation of lymphedema-specific QoL tools into local language to meet the needs of the community is important. To the best of our knowledge, our study is the first to investigate the Turkish validity of a specific QoL measure for lymphedema patients in Turkey. Nonetheless, the study may have potential limitations. First, it was a cross-sectional study with the lack of responsiveness data. Therefore, further studies are needed for responsiveness of this tool. Another limitation was the exclusion of patients with psychiatric diagnoses and elderly. These patients were excluded based on the perception that they were unable to have a full comprehension of all questions. These selection criteria might have caused some limitations in the generalizability of our results for all BCRL patients.

In conclusion, the Turkish translated version of LYMQOL-Arm is a valid and reliable tool for the assessment of the QoL in patients with BCRL. The Turkish BCRL patients found the Turkish version of LYMQOL-Arm questionnaire to be easy to understand. Based on our study results, we recommend the use of LYMQOL-Arm in Turkish BCRL patients in further clinical researches and suggest the investigation of the responsiveness of this questionnaire.

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