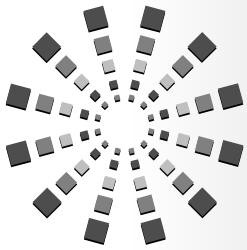

Ceren Orhan, PhD, PT
Esra Üzelpasacı, MSc, PT
Emine Baran, MSc, PT
Gülbala Nakip, MSc, PT
Serap Özgül, PT
Sercan Aksoy, MD
Türkan Akbayrak, PT

The Reliability and Validity of the Turkish Version of the Lymphedema Life Impact Scale in Patients With Breast Cancer–Related Lymphedema

KEYWORDS
Breast cancer
Lymphedema
Quality of life
Reliability
Validity

Background: Health-related quality of life is measured to detect the influence of lymphedema on physical, functional, and social aspects of life in patients with breast cancer–related lymphedema (BCRL). **Objective:** This study aimed to perform the psychometric evaluation of the Lymphedema Life Impact Scale (LLIS) in Turkish patients with BCRL. **Methods:** Patients with BCRL (n = 78) filled out the Turkish LLIS, Lymphedema Quality of Life, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30, and Quick Disability of Arm, Shoulder and Hand scales. Breast cancer survivors without BCRL (n = 35) completed only the Turkish LLIS. Psychometric properties were analyzed with the internal consistency, test-rest reliability, construct, criterion, and discriminant validity. **Results:** The internal consistency of the Turkish LLIS was strong (Cronbach's α coefficient >.70). Test-retest reliability was strong to very strong (intraclass correlation coefficients from 0.88 to 0.93; $P < .001$). Similar to the original structure of the scale, exploratory factor analysis identified 3 factors. Criterion validity was supported by moderate to strong correlations between the LLIS, Lymphedema Quality of Life, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30, and quick Disability of Arm, Shoulder and Hand. There were significant differences in the total and subscale scores of the LLIS between participants with and without BCRL ($P < .05$). **Conclusions:** The present study provided the evidence to confirm reliability and clinical validity of the Turkish LLIS.

Author Affiliations: Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences (Drs Orhan, Özgül and Akbayrak and Mss Üzelpasacı, Baran, and Nakip) and Cancer Institute (Dr Aksoy), Hacettepe University, Ankara, Turkey.

The authors have no funding or conflicts of interest to disclose.

Correspondence: Ceren Orhan, PhD, PT, Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Hacettepe University, 06100 Ankara, Turkey (cerengursen@yahoo.com).

Accepted for publication January 29, 2019.
DOI: 10.1097/NCC.0000000000000709

Implications of Practice: The Turkish LLIS is a reliable and valid condition-specific scale to measure the physical, functional, and psychological aspects of health-related quality of life in patients with BCRL.

In Turkey, breast cancer is very common among women.[1] According to the report of the Turkish Ministry of Health, the incidence of breast cancer is 46.8 cases per 100 000, with 17 000 women diagnosed in Turkey each year.[1] Although the survival rate and duration in breast cancer survivors have increased,[2] breast cancer–related lymphedema (BCRL) remains one of the most feared and burdensome complications. Based on a meta-analysis,[3] BCRL occurs in approximately 19% of the breast cancer survivors from the 12th to the 24th month after surgery. A recent study reported the prevalence rate of BCRL as 25% at the end of the first year after surgery.[4] Breast cancer–related lymphedema may be triggered by trauma or infection and develops because of reduced lymphatic transport capacity after cancer treatments, including axillary lymph node dissection or radiotherapy.[5]

In the past, lymphedema was considered as an unimportant medical complication of cancer therapies.[6] However, BCRL is a progressive and persistent condition, which negatively influences the health-related quality of life (HRQoL).[7] It was reported that breast cancer survivors suffering from lymphedema experienced lower HRQoL compared with patients without lymphedema.[8] Lymphedema can lead to physical impairments such as decreased strength and range of motion, fatigue, pain, heaviness, and discomfort, which can result in activity limitations and functional impairment in the affected arm.[6,7] In addition, patients with BCRL experience negative body image, stress, anxiety, and fear, associated with the increased severity of the lymphedema.[7,9] As a result of physical, psychological, and emotional problems, different aspects of quality of life might be negatively influenced.[7]

Health-related quality of life has been measured to determine the influence of lymphedema development on physical, functional, and social aspects of life in patients with BCRL.[10] Although generic or cancer-specific questionnaires including the Short Form 36 and the Nottingham Health Profile and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC-QLQ C30) have been used to assess HRQoL in lymphedema patients,[6,11] these instruments are nonspecific and not sensitive enough to determine the HRQoL in patients with lymphedema.[6,11,12]

Weiss and Daniel[12,13] developed the Lymphedema Life Impact Scale (LLIS) in order to evaluate lymphedema-specific impairment and to measure different aspects of HRQoL including physical, psychosocial, and functional dimensions in patients diagnosed with lymphedema on upper or lower extremities. Results of a previous study reported that the total LLIS had greater than 0.72 criterion validity with lymphedema and cancer-specific questionnaires, and its internal consistency was strong.[12] Based on their findings, the instrument was deemed accurate, time efficient, and easy to understand and administer.[12,13] Unlike other condition-specific questionnaires for lymphedema, the LLIS comprises the question regarding the infection occurrence and includes a scoring calculator to document functional outcomes and a percent of impairment using the total score of the LLIS (developer L. Hodgkins; Hartford Hospital Rehabilitation Network, Meriden, Connecticut).[12,13] The LLIS version 2 also includes a question about patient knowledge of lymphedema treatment, which measures the cognitive ability of the patient to perform self-care activities during the ongoing treatment of lymphedema.[13] Additionally, the LLIS measures HRQoL in patients with arm or leg lymphedema.[12,13] The psychometric properties of the LLIS (version 1) have been evaluated in an Iranian population, and the Persian version of the LLIS (version 1) was found to be an acceptable scale to assess HRQoL in patients with lymphedema.[14] It has been suggested that the adaptation of research instruments by translating and testing the psychometric properties is a more feasible and cost-effective method compared with the development of a new scale.[5] There are few lymphedema-specific questionnaires to detect the influence of lymphedema on HRQoL in Turkish patients with BCRL, namely, Lymphedema Quality of Life (LYMQOL) and Lymphoedema Functioning, Disability and Health Questionnaire. Further, the discriminant validity of these instruments compared with nonlymphedema population has not been studied.[10,15] Each instrument has some limitations including a lack of responsiveness,[16] difficult scoring system perceived by patients,[16] and not evaluating the skin problems related to lymphedema.[17] On the basis of the literature and our knowledge, the cultural adaptation and validation of the Turkish LLIS have not been performed. Therefore, the aim of the present study was to translate and culturally adapt the LLIS (version 2) into Turkish and perform a psychometric evaluation of the LLIS in patients with BCRL. Confirming the validity and reliability of the LLIS will help health professionals in identifying the impairment in HRQoL related to BCRL.

■ Methods

Translation

To start the validation process, we obtained permission from Weiss and Daniel,[12,13] who developed the LLIS.[12,13] The cross-cultural adaptation process of the LLIS version 2 was performed by applying the forward and back translations according to previous studies and guidelines.[18,19] In stage 1, 2 bilingual translators independently translated the LLIS from English into Turkish, and 2 translated versions (TV1 and TV2) were obtained. Then, one independent researcher made a synthesis (TV-12) of the TV1 and TV2 (stage 2). In stage 3, 2 independent translators who were not familiar with the original version of the LLIS performed the back-translation (BTV1 and BTV2) by translating TV-12 into English. In stage 4, an expert committee comprising the 6 researchers (5 physiotherapists and 1 medical

oncologist) who were experienced in the assessment and treatment of lymphedema were invited to review all the documents (TV1, TV2, TV-12, BTV1, and BTV2). The general structure and each item of the Turkish LLIS were discussed. To improve clarity, the words "arm/leg" were used instead of the word "limb" for items 4 to 6. The options of item 7 were changed to "0 = no interference" and "4 = interference completely." For item 9, an extra explanation in the brackets was added as "rate 0 if you do not have a spouse or partner." The options of item 18 were changed as follows: "1 = once, 2 = twice, 3 = 3 times, 4 = four times." Based on the suggestions of the experts, a prefinal version was produced. Then, patients with BCRL (n = 20) completed the prefinal version to evaluate the clarity of all items and their feasibility for Turkish patients (stage 5). After a pilot testing, some revisions were made, and the final Turkish version was created (Turkish LLIS).

Research Design

A cross-sectional study with a test-retest method including a comparison group (nonlymphedema) was conducted in order to determine the reliability and validity of the Turkish LLIS.

Participants

Breast cancer survivors with or without lymphedema attending the outpatient physiotherapy clinic of a large tertiary hospital in Turkey were invited to participate in the study. A detailed medical history of all patients was recorded. Demographic, physical, and lymphedema characteristics of the patients with BCRL and breast cancer survivors without lymphedema (age, weight, height, education level, work status, duration of lymphedema, affected extremity or extremities, cancer-related treatments, the symptoms of swelling, pain, and heaviness) were collected. After a baseline examination and circumferential measurements (see below), the eligibility criteria were checked. The inclusion criteria were as follows: (*a*) older than 18 years, (*b*) having a previous diagnosis of breast cancer, (*c*) completed chemotherapy and/or radiotherapy sessions, and (*d*) sufficient literacy to complete the questionnaires. Exclusion criteria were as follows: (*a*) acute infection, (*b*) metastasis, and (*c*) not able to speak and read Turkish. Additional exclusion criterion for patients with BCRL was being currently under complete decongestive treatment for lymphedema. Approval for the present study was obtained from the university ethics committee. Based on the principles stated in the Declaration of Helsinki, written informed consents were taken from all participants.

Measurements

In all study participants, the presence and severity of lymphedema were objectively evaluated by circumferential measurements. The circumferential measurements were performed bilaterally starting from the wrist to the axilla, with 5-cm intervals.[20] Then, in order to obtain the approximate arm volumes, the circumference values (in centimeters) of the limbs were converted to the volume values (in milliliters) by using the Frustum (truncated cone) formula.[7,20] Based on the result of the circumference measurement, objective lymphedema was defined as having more than 2-cm difference between the affected and unaffected extremities. Breast cancer survivors with less than 2-cm difference between the limbs and who did not indicate subjective swelling and heaviness symptoms of lymphedema were considered as having no lymphedema.

The breast cancer survivors completed the Turkish LLIS. Patients identified as having BCRL also completed the Turkish versions of the LYMQOL,[10] EORTC-QLQ C30,[21] and Quick Disability of Arm, Shoulder and Hand (Quick DASH)[22] scales. After 1 week, the patients with BCRL completed the LLIS a second time in order to determine the test-retest reliability.

LYMPHEDEMA LIFE IMPACT SCALE

In this study, LLIS version 2 was translated to Turkish language (ie, Turkish LLIS). The LLIS is a self-report questionnaire comprising of physical, psychological, and functional subscales. It includes a total of 18 item with a 5-point Likert-type scale between 0 and 4 ("0 = no impairment," "4 = severe impairment")[13]; LLIS version 2 also includes a separate domain for infection occurrence, scoring between 0 (no episodes of infection) and 4 (4+ episodes of infection in the past year). The total score of the LLIS version 2 ranges from 0 to 72.[13] The LLIS version 2 was reported to be a valid and reliable instrument (Cronbach's α = .84-.95).[13]

LYMPHEDEMA QUALITY OF LIFE

Lymphedema Quality of Life is a validated condition-specific instrument for the impact of lymphedema on HRQoL (Cronbach's α = .83-.88).[23] It evaluates the impact of arm and leg lymphedema on HRQoL with separate questionnaires consisting of 4 domains: symptoms, appearance, function, and mood.[23] Each item is scored between 1 and 4.[23] The Turkish version of LYMQOL was reported to be valid and reliable (Cronbach's α = .70-.94).[10]

EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER QUALITY OF LIFE QUESTIONNAIRE CORE 30

The EORTC-QLQ C30 is a quality-of-life questionnaire for patients diagnosed with cancer, and it consists of 30 items.[24] It includes functional scales, symptom scales, and single-item scales.[24] A scale score is calculated between 0 and 100. While the higher scores in total and functioning scales imply lower impact on HRQoL, the lower scores in symptoms scale indicate better HRQoL.[21,24] It was reported that the Turkish version of the EORTC-QLQ C30 was an acceptable questionnaire for Turkish breast cancer patients (Cronbach's α >.70).[21]

QUICK DISABILITY OF ARM, SHOULDER AND HAND

Quick DASH is a self-reported 11-item questionnaire designed for evaluating the functional level of upper extremity.[25] Each item has 5 response categories, which are scored between 1 and 5. Scores of items are converted to a summative score ranging between 0 (no disability or symptoms) and 100 (greater disability or symptoms).[25] The Turkish version of Quick DASH has very strong reliability.[22]

Data Analysis

IBM SPSS software, version 21 (IBM Corp, Armonk, New York) was used to conduct statistical analyses. The normality distribution was determined by visual (histogram and probability plots) and analytical methods (the Kolmogorov-Smirnov test). Descriptive statistics were shown using mean and SD for normally distributed continuous variables, median (25%–75% percentiles) for non–normally distributed continuous variables, or frequency (%) for categorical variables. Demographics and clinical characteristics were analyzed using the Student t test for normally distributed continuous data, Mann-Whitney U test for non–normally distributed continuous data, and χ^2 test or Fisher exact test for categorical data. Floor and ceiling effects were computed in order to analyze the percentage of the participants with lymphedema who gave the lowest and highest possible scores for all dimensions of the LLIS. To determine the reliability and construct and criterion validity of the Turkish LLIS, data obtained from the patients with BCRL were used. Data obtained from breast cancer survivors without lymphedema were used to evaluate the discriminant validity of the Turkish LLIS.[12–14] The reliability of the LLIS was examined with the internal consistency and test-retest reliability. Cronbach's α coefficient was calculated for the internal consistency of each domain and the total scale except for the infection subscale. According to the original study of the LLIS, the question related to the infections (Q18) was isolated and not included in the internal consistency calculation.[13] It was reported that Cronbach's α coefficient ≥.70 was acceptable. Intraclass correlation coefficients (ICCs) were calculated to measure the test-retest reliability. Exploratory factor analysis was performed to evaluate construct validity. Based on the Kaiser-Meyer-Olkin test and Bartlett test, the suitability for factor analysis was determined. The last question about the infection occurrence was not included in the factor analysis. Criterion validity measured by Pearson correlation analysis reveals the correlations between the domains and/or total scores of LLIS, LYMQOL, EORTC-QLQ C30, and Quick DASH. According to the previous studies,[16,26,27] Cronbach's α coefficients, ICCs, and correlation coefficients were categorized as follows: weak (0 to <0.40), moderate (0.41–0.74), strong (0.75–0.90), and very strong (>0.90). We performed the discriminant validity analysis to test the ability of the Turkish LLIS to differentiate the BCRL patients from those without lymphedema. Discriminant validity was determined comparing the differences in the subscale and total scores of LLIS between lymphedema and nonlymphedema groups with the Mann-Whitney U test because the data were non–normally distributed. $P < .05$ was accepted as a level of significance.

■ Results

A total of 138 participants were screened for eligibility between June and December 2017. Twenty participants did not meet the inclusion criteria (insufficient literacy [n = 8], acute infection [n = 2], ongoing medical treatment [n = 10]). Because 5 participants did not complete all questionnaires, they were excluded from the study. Consequently, 78 women with BCRL and 35 women without lymphedema (113 women in total) participated in the present study.

Demographic and Clinical Characteristics

There was no significant difference in demographic variables and medical characteristics (age, body mass index, education level, employment status, type of surgery, and treatment) between lymphedema and nonlymphedema groups at baseline ($P > .05$) (Table 1). The mean age, body mass index, and education level were 56.5 years, 28.5 kg/m^2, and 9.7 years, respectively. Approximately 85% of the participants had mastectomy, chemotherapy, and/or radiotherapy.

Psychometric Analysis

Descriptive statistics, internal consistency, and test-retest reliability analyses are shown in Table 2. Floor and ceiling effects of each subscale of the LLIS are presented in Table 3. Floor effect was found in the psychological domain of the LLIS as 42.7% of the participants rated the questions between Q6 and Q12 as "0" (best possible score). These results indicated that lymphedema has less impact on the psychological domain than on the other domains. Ceiling effect revealed that HRQoL was mostly influenced by the functional concerns domain in which the worst possible score (score 4) was given by 8.7% of the participants.

RELIABILITY TESTING

Internal consistency was strong. Cronbach's α coefficients ranged from .76 to .89 for all questions and domains of LLIS (Table 2). Test-retest reliability for the total score of the LLIS and for the score of each domain ranged from strong to very strong (ICC = 0.88–0.93, $P < .001$) (Table 2).

CONSTRUCT VALIDITY TESTING

The results of the Kaiser-Meyer-Olkin test (0.842) and Bartlett test of sphericity ($\chi^2 = 583.3$; $P < .001$) indicated that there was suitability to perform exploratory factor analysis. Because all diagonal elements were greater than 0.75 in the anti-image matrix, it was concluded that there was no need for the elimination of any item. After factor loadings were rotated by the varimax rotation method, 3 significant factors had eigenvalues greater than 1. These 3 factors were explained with the 55% of the total variance. When the questions in these subfactors were analyzed, it was decided that they were compatible with the structure of the original scale factors. Factor loading patterns are shown in Table 4.

In addition, correlations between volume differences and the total score on the LLIS and the scores of the 3 domains were investigated for the construct validity. However, there were weak correlations between volume differences and the scores of all domains and the total score on the LLIS ($r < 0.40$).

CRITERION VALIDITY TESTING

The correlation coefficients between the different domains or total scores of the LLIS and LYMQOL, EORTC-QLQ C30, and Quick DASH are presented in Table 5. There were moderate or strong correlations between the LLIS total/subscale scores and LYMQOL domains. Correlation coefficients ranged from 0.52 to 0.85 for the LLIS and LYMQOL. The functional and total

Table 1 • Demographic and Clinical Characteristics (n = 113)[a]

Variable	Total (n = 113)	Lymphedema (n = 78)	Nonlymphedema (n = 35)	P^b
Age, y	56.54 ± 10.21	56.82 ± 10.54	55.94 ± 9.55	.67
BMI, kg/m^2	28.59 ± 4.34	28.88 ± 4.58	27.95 ± 3.71	.29
Education level, y	11.0 (5.0–15.0)	11.0 (5.0–13.0)	11.0 (5.0–15.0)	.29
	n (%)	n (%)	n (%)	P^c
Employment status				
Unemployed	87 (77)	63 (80.8)	24 (68.6)	.15
Employed	26 (23)	15 (19.2)	11 (31.4)	
Type of surgery				
Mastectomy	97 (85.8)	67 (85.9)	30 (85.7)	.99
Lumpectomy	16 (14.2)	11 (14.1)	5 (14.3)	
Treatment				
Chemotherapy (yes)	94 (83.2)	64 (82.1)	30 (85.7)	.63
Radiotherapy (yes)	82 (73.2)	57 (74.0)	25 (71.4)	.77
Duration of lymphedema				
0 to 6 mo	16 (20.5)	16 (20.5)	—	—
6 to <12 mo	17 (21.8)	17 (21.8)		
1 to <3 y	19 (24.4)	19 (24.4)		
3 to <5 y	15 (19.2)	15 (19.2)		
5 to 10 y	9 (11.5)	9 (11.5)		
>10 y	2 (2.6)	2 (2.6)		
Affected Extremity				
RUE	39 (50.0)	39 (50.0)	—	—
LUE	38 (48.7)	38 (48.7)		
BUE	1 (1.3)	1 (1.3)		

Abbreviations: BMI, body mass index; BUE, bilateral upper extremity; LUE, left upper extremity; RUE, right upper extremity.
[a]Data are presented as Mean ± SD, median (25%-75%), or frequency (percentage).
[b]Student *t* test or Mann-Whitney *U* test for continuous variables.
[c]χ^2 Test or Fisher exact test for categorical variables.

scores of the LLIS had the strongest correlations between the LYMQOL functional and appearance scores (from 0.75 to 0.82). There was also strong correlation between the physical domain of the LLIS and the functional domain of the LYMQOL (r = 0.76).

The functional and symptom domains of the EORTC-QLQ C30 were strongly correlated with the total score of the LLIS (r = –0.85; r = 0.79, respectively) but not with the domains of the LLIS. There were moderate correlations between all domains of the LLIS and the functional and symptom domains of the EORTC-QLQ C30 (ranging from 0.67 to –0.74).

There were moderate correlations between all domains of the LLIS and the Quick DASH, ranging from 0.68 to 0.74. The total score of the LLIS had a strong correlation with the Quick DASH (r = 0.84).

DISCRIMINANT VALIDITY TESTING

In Table 6, the total score on the LLIS and the scores of all domains are compared between lymphedema and nonlymphedema groups. There were significant differences in the total score of the LLIS and in the scores of all domains between participants with and without lymphedema (P < .05).

■ Discussion

Based on the results of the present study, the Turkish version of the LLIS is a reliable and valid instrument to measure the impairment of HRQoL for Turkish breast cancer survivors with BCRL. The Turkish LLIS is an acceptable and capable tool to obtain information on the physical, functional, and psychosocial dimensions

Table 2 • Descriptive Statistics,[a] Internal Consistency, and Test-Retest Reliability of the LLIS

	LLIS Scores		Consistency	Test-Retest		
	First Test (n = 78)	Test-Retest (n = 26)	Cronbach's α	ICC	95% CI	P^b
LLIS physical	9.80 ± 4.78	11.07 ± 3.55	.78	0.88	0.76–0.94	<.001
LLIS psychosocial	7.30 ± 5.06	9.00 ± 5.29	.77	0.93	0.86–0.97	<.001
LLIS functional	7.85 ± 4.75	8.73 ± 3.96	.76	0.85	0.70–0.93	<.001
LLIS total	24.74 ± 12.46	28.73 ± 10.67	.89	0.91	0.82–0.96	<.001

Abbreviations: CI, confidence interval; ICC, intraclass correlation coefficient; LLIS, Lymphedema Life Impact Scale.
[a]Data are presented as Mean ± SD.
[b]P < .05.

Table 3 • Floor and Ceiling Effects of LLIS in Patients With Lymphedema[a]

LLIS Domains	Floor		Ceiling	
	n	%	n	%
LLIS physical	99	21.5	24	5.1
LLIS psychosocial	**200**	**42.7**	37	7.9
LLIS functional	107	27.43	**34**	**8.71**

Abbreviation: LLIS, Lymphedema Life Impact Scale.
[a]Data are presented as frequency (percentage).

of HRQoL in breast cancer survivors with BCRL. This is the first study to evaluate the validity of Turkish LLIS using disease-specific questionnaires. The present study is also the first study to reveal the discriminant validity in HRQoL between Turkish breast cancer patients with and without lymphedema.

Over the past 3 decades, HRQoL has been accepted as an essential concept in healthcare.[28] It has been reported that contemporary breast cancer management has focused on HRQoL of survivors as well as the survival rate.[29] In breast cancer survivors, lymphedema is a common problem and might cause significant loss of HRQoL by impairing the activities in daily living and limiting the participation in work and leisure activities.[2,29,30] Based on a systematic review investigating the self-reported HRQoL in patients with BCRL, body image and physical, psychological, and social functions were reported as the most affected domains of HRQoL.[2] The assessment of HRQoL is difficult because it is influenced by various factors including cultural, personal, and religious aspects of life.[28] To detect specific issues related to lymphedema and to determine the significant differences between baseline and posttreatment values or alterations in lymphedema prognosis, the use of lymphedema-specific instruments for investigating HRQoL has been suggested.[2]

There are a limited number of lymphedema-specific instruments to examine the influence of lymphedema on HRQoL in Turkish patients.[10,15] The LLIS has been validated as a condition-specific questionnaire for the assessment of the impact of lymphedema on various dimensions of HRQoL.[12,13] Unlike other condition-specific questionnaires for lymphedema, the LLIS includes a question regarding the infection occurrence and a scoring calculator (developer L. Hodgkins; Hartford Hospital Rehabilitation Network).[12,13] The clinical importance of the scoring calculator has been considered as the calculation of an impairment percentage from a total score on the LLIS.[14] The LLIS version 2 also includes a question about the knowledge of lymphedema treatment. Based on previous reports revealing positive associations between knowledge and management behaviors,[31,32] knowledge is considered an important indicator of present cognitive ability of patients to perform essential self-care activities.[13] For these reasons, our purpose was to perform the psychometric evaluation of the Turkish version of the LLIS (version 2) in breast cancer survivors with lymphedema.

Standardized and validated instruments are needed to compare the findings of the studies both nationally and internationally.[19] Where a cross-cultural adaptation is required, the original instrument should be translated and adapted into the target language considering all stages of the adaptation and validation process.[19] However, there is no international consensus on the cross-cultural adaptation process of self-reported instruments.[19] In the present study, the translation and validation process was based on the previous guidelines.[18,19]

In the present study, the reliability of the questionnaire ranged from strong to very strong. For the domains of the original LLIS version 2 questionnaire, Cronbach's α coefficients were reported as .85 to .95.[13] The ICCs for the total score of the Turkish LLIS and for the scores of physical, function, and psychological domains revealed strong to very strong test-retest reliability, comparable to the original questionnaire (ICC = 0.82-0.94).[13] Similar results were reported by Haghighat et al,[14] who revealed that the Persian version of the LLIS had strong to very strong internal consistency (Cronbach's α from .85 to .88) and test-retest reliability (ICC from 0.85 to 0.98).

In the present study, exploratory factor analysis was performed to explore the factor structure of the Turkish LLIS. Similar to the structure of the original scale, the exploratory factor analysis determined 3 significant factors, namely, physical, psychological, and functional. Similar to the present study, 3 factors with eigenvalues greater than 1 were observed in the Persian version of the LLIS (version 1). However, based on the exploratory factor analysis, the item for the infection occurrence in the Persian LLIS (version 1) was placed in different subscale (functional subscale) unlike the original scale.[14] Furthermore, it was reported that the infection occurrence item was placed to a separate subscale because the internal consistency of the physical subscale reduced.[12,13]

Consistent with the original study of the LLIS,[13] there were weak correlations between the severity of edema and the total and

Table 4 • Factor Analysis of the LLIS[a]

LLIS Domains	LLIS Questions	Factor 1	Factor 2	Factor 3
LLIS physical	Q1			0.643
	Q2			0.844
	Q3			0.536
	Q4			0.802
	Q5			0.534
	Q6			0.426
LLIS psychosocial	Q7	0.736		
	Q8	0.554		
	Q9	0.505		
	Q10	0.751		
	Q11	0.521		
	Q12	0.502		
LLIS functional	Q13		0.690	
	Q14		0.787	
	Q15		0.767	
	Q16		0.521	
	Q17		0.401	
Eigenvalues		6.44	1.66	1.38
Explained variance (%)		37.85	9.76	8.11

Abbreviation: LLIS, Lymphedema Life Impact Scale.
[a]Factor loadings >0.40 are shown. Keiser-Meyer-Olkin measure of sampling adequacy = 0.842, Bartlett test $P < .001$.

Table 5 • Criterion Validity of the LLIS

Lymphedema Patients (n = 78)	LYMQOL Functional	LYMQOL Appearance	LYMQOL Symptoms	LYMQOL Emotion	EORTC-QLQ C30 Functional	EORTC-QLQ C30 Symptom	Quick DASH	Limb Volume Difference
LLIS physical	0.76[a]	0.65[a]	0.68[a]	0.60[a]	−0.71[a]	0.68[a]	0.74[a]	0.36[b]
LLIS psychosocial	0.62[a]	0.62[a]	0.58[a]	0.52[a]	−0.74[a]	0.67[a]	0.68[a]	0.36[b]
LLIS functional	0.75[a]	0.75[a]	0.64[a]	0.62[a]	−0.73[a]	0.67[a]	0.74[a]	0.30[b]
LLIS Total	0.82[a]	0.79[a]	0.73[a]	0.69[a]	−0.85[a]	0.79[a]	0.84[a]	0.39[a]

Abbreviations: EORTC-QLQ C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; LLIS, Lymphedema Life Impact Scale; LYMQOL, Lymphedema Quality of Life; Quick DASH, Quick Disability of Arm, Shoulder and Hand.
[a]Correlation is significant at .01 level.
[b]Correlation is significant at .05 level.

subscale scores of the Turkish LLIS in the present study. Previous studies have revealed that there was a weak correlation between the severity of lymphedema and the quality of life or functional level.[11,23,33,34] In the reliability and validity studies of the Upper Limb Lymphedema 27 and LYMQOL,[11,23] there was no correlation between the quality of life and edema severity. Previous studies[33,34] have reported that functional limitations and symptoms appeared to be more strongly correlated with the quality of life than the severity of lymphedema. Similar to the original study,[13] the criterion validity of the Turkish LLIS was confirmed against the valid and reliable questionnaires including LYMQOL, EORTC-QLQ C30, and Quick DASH.[10,21,22] Moderate to strong correlations were also found between the scores of the LLIS and those of LYMQOL, EORTC-QLQ C30, and Quick DASH. In a previous study,[14] strong correlations were found between the total score of the Persian LLIS and EORTC-QLQ C30.

Similar to the validation study of the original LLIS,[12,13] we demonstrated that the Turkish LLIS could differentiate between breast cancer patients with and without lymphedema. As the LLIS focuses on the symptoms of lymphedema rather than other upper limb impairments related to breast cancer treatments[12] and has lymphedema-specific wording,[12] breast cancer survivors without lymphedema tended to mark the "0—no impairment" answer. In contrast to our findings, a study investigating the psychometric properties of the Persian LLIS reported a nonsignificant difference in the score of the psychosocial subscale between lymphedema and nonlymphedema groups.[14] The authors indicated that this nonsignificant difference might be related to multiple factors including personal, family, and social problems regarding the presence of breast cancer.[14]

Table 6 • Discriminant Validity of the LLIS[a]

LLIS	Lymphedema (n = 78)	Nonlymphedema (n = 35)	P[b]
LLIS physical	10.0 (6.0–13.0)	1.0 (0.0–2.0)	<.001[c]
LLIS psychosocial	7.0 (3.0–10.2)	2.0 (1.0–3.0)	<.001[c]
LLIS functional	7.0 (4.0–13.0)	1.0 (0.0–1.0)	<.001[c]
LLIS total	24.0 (14.7–35.2)	4.0 (3.0-6.0)	<.001[c]

Abbreviation: LLIS, Lymphedema Life Impact Scale.
[a]Data are presented as Median (25%–75%).
[b]Mann-Whitney *U* test for continuous variables.
[c]$P < .05$.

The adaptation process based on international guidelines, the investigation of different aspects of validity and reliability, and inclusion of participants without lymphedema were the strengths of the present study. Criterion validity was determined with LYMQOL, which is a disease-specific quality-of-life questionnaire. However, previous studies have reported that the Turkish versions of LYMQOL and LYMPH-ICF were correlated with the generic quality-of-life questionnaires, namely, Nottingham Health Profile and Short Form 36, respectively.[10,15] Furthermore, the present study also revealed the discriminant validity of Turkish LLIS.

The present study had some limitations. First, patients were recruited from one center, and this may influence the generalizability. However, patients from all regions of Turkey are referred to the university hospital oncology clinic, as it is one of the largest clinics in Turkey. A second limitation is that the responsiveness of the Turkish LLIS has not been investigated. Further research is needed to evaluate the responsiveness of the Turkish version of the LLIS.

Implications for Clinical Practice and Research

It has been reported that BCRL is one of the most burdensome, feared, and distractive complications after breast cancer treatment because of its progressive prognosis.[35] As reported by Hidding et al,[35] it is a common misconception that BCRL will recover over time, resulting in inadequate evaluation and monitoring of this complication. Healthcare providers should be aware that it is essential to provide special multidisciplinary attention to breast cancer survivors starting from the early postoperative period for early detection and prevention of BCRL.[36]

Health-related quality of life is an important outcome measure for the patients with BCRL. Based on the result of the present study revealing the weak correlation between the severity of lymphedema and HRQoL, all patients with BCRL should be screened in terms of the impairment in HRQoL rather than only those with severe lymphedema. Furthermore, the most effective and patient-specific treatment program may be planned after the determination of the influenced aspects of HRQoL. The Turkish LLIS is a condition-specific instrument to detect the impairments of HRQoL in patients with BCRL. However, healthcare providers should take into account that HRQoL can be

influenced by other prevalent upper limb impairments related to the breast cancer treatment including persistent pain, decreased strength, impaired shoulder range of motion, and altered muscle recruitment patterns and scapular/shoulder biomechanics. For this reason, patients should be instructed to distinguish between the impact of BCRL and other upper limb impairments when rating the items of the Turkish LLIS.

■ Conclusion

The present study provides the evidence to support psychometric properties of the Turkish LLIS for patients with BCRL. The documentation of HRQoL of patients with BCRL is needed to promote effective multidisciplinary treatment strategies. Therefore, healthcare providers can now use the Turkish LLIS in clinical practice and for the research purposes to evaluate the physical, functional, and psychological impairments in HRQoL in patients with upper limb lymphedema. However, future research should address the validity of the Turkish LLIS in patients with leg lymphedema, and its responsiveness to the treatment-related changes should be investigated.

ACKNOWLEDGMENT

The authors thank Jan Weiss for her permission to translate and adapt the LLIS in Turkish patients.

References

1. Republic of Turkey, Ministry of Health, Public Health Institution, The Department for Cancer Control. Turkey Cancer Control Programme. https://http://www.iccp-portal.org/system/files/plans/Turkiye_Kanser_Kontrol_Program_English.pdf. Accessed March 1, 2018.
2. Pusic AL, Cemal Y, Albornoz C, et al. Quality of life among breast cancer patients with lymphedema: a systematic review of patient-reported outcome instruments and outcomes. *J Cancer Surviv*. 2013;7(1):83–92.
3. DiSipio T, Rye S, Newman B, Hayes S. Incidence of unilateral arm lymphoedema after breast cancer: a systematic review and meta-analysis. *Lancet Oncol*. 2013;14(6):500–515.
4. Devoogdt N, Geraerts I, Van Kampen M, et al. Manual lymph drainage may not have a preventive effect on the development of breast cancer–related lymphoedema in the long term: a randomised trial. *J Physiother*. 2018;64(4):245–254.
5. Shi S, Lu Q, Fu MR, et al. Psychometric properties of the Breast Cancer and Lymphedema Symptom Experience Index: the Chinese version. *Eur J Oncol Nurs*. 2016;20:10–16.
6. Klernas P, Johnsson A, Horstmann V, Kristjanson LJ, Johansson K. Lymphedema Quality of Life Inventory (LyQLI)—development and investigation of validity and reliability. *Qual Life Res*. 2015;24(2):427–439.
7. Taghian NR, Miller CL, Jammallo LS, O'Toole J, Skolny MN. Lymphedema following breast cancer treatment and impact on quality of life: a review. *Crit Rev Oncol Hematol*. 2014;92(3):227–234.
8. Fu MR. Breast cancer–related lymphedema: symptoms, diagnosis, risk reduction, and management. *World J Clin Oncol*. 2014;5(3):241–247.
9. Vassard D, Olsen MH, Zinckernagel L, et al. Psychological consequences of lymphoedema associated with breast cancer: a prospective cohort study. *Eur J Cancer*. 2010;46(18):3211–3218.
10. Bakar Y, Tugral A, Ozdemir O, Duygu E, Uyeturk U. Translation and validation of the Turkish version of Lymphedema Quality of Life Tool (LYMQOL) in patients with breast cancer related lymphedema. *Eur J Breast Health*. 2017;13(3):123–128.
11. Viehoff PB, van Genderen FR, Wittink H. Upper Limb Lymphedema 27 (ULL27): Dutch translation and validation of an illness-specific health-related quality of life questionnaire for patients with upper limb lymphedema. *Lymphology*. 2008;41(3):131–138.
12. Weiss J, Daniel T. Validation of the Lymphedema Life Impact Scale (LLIS): a condition-specific measurement tool for persons with lymphedema. *Lymphology*. 2015;48(3):128–138.
13. Weiss J, Daniel T. Validation of the Lmyphedema Life Impact Scale version 2: a condition specific measurement tool for persons with lymphedema. *Rehabil Oncol*. 2018;36(1):28–36.
14. Haghighat S, Montazeri A, Zayeri F, Ebrahimi M, Weiss J. Psychometric evaluation of the Persian version of the Lymphedema Life Impact Scale (LLIS, version 1) in breast cancer patients. *Health Qual Life Outcomes*. 2018;16(1):132.
15. Kostanoglu A, Hosbay Z, Tarakci E. Lymphoedema Functioning, Disability and Health Questionnaire Turkish version: translation, cross-cultural adaptation and validation. *J Phys Ther Sci*. 2016;28(6):1728–1732.
16. Devoogdt N, Van Kampen M, Geraerts I, Coremans T, Christiaens MR. Lymphoedema Functioning, Disability and Health questionnaire (Lymph-ICF): reliability and validity. *Phys Ther*. 2011;91(6):944–957.
17. Cornelissen AJM, Kool M, Keuter XHA, et al. Quality of life questionnaires in breast cancer–related lymphedema patients: review of the literature. *Lymphat Res Biol*. 2018;16(2):134–139.
18. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976)*. 2000;25(24):3186–3191.
19. Gjersing L, Caplehorn JR, Clausen T. Cross-cultural adaptation of research instruments: language, setting, time and statistical considerations. *BMC Med Res Methodol*. 2010;10:13.
20. Pekyavas NO, Tunay VB, Akbayrak T, Kaya S, Karatas M. Complex decongestive therapy and taping for patients with postmastectomy lymphedema: a randomized controlled study. *Eur J Oncol Nurs*. 2014;18(6):585–590.
21. Demirci S, Eser E, Ozsaran Z, et al. Validation of the Turkish versions of EORTC QLQ-C30 and BR23 modules in breast cancer patients. *Asian Pac J Cancer Prev*. 2011;12(5):1283–1287.
22. Koldas Dogan S, Ay S, Evcik D, Baser O. Adaptation of Turkish version of the questionnaire Quick Disability of the Arm, Shoulder, and Hand (Quick DASH) in patients with carpal tunnel syndrome. *Clin Rheumatol*. 2011;30(2):185–191.
23. Keeley V, Crooks S, Locke J, et al. A quality of life measure for limb lymphoedema (LYMQOL). *Journal of Lymphoedema*. 2010;5(1):26–37.
24. Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst*. 1993;85(5):365–376.
25. Gummesson C, Ward MM, Atroshi I. The shortened disabilities of the arm, shoulder and hand questionnaire (QuickDASH): validity and reliability based on responses within the full-length DASH. *BMC Musculoskelet Disord*. 2006;7:44.
26. Devoogdt N, de Groef A, Hendrickx A, et al. Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema (Lymph-ICF-LL): reliability and validity. *Phys Ther*. 2014;94(5):705–721.
27. Lexell JE, Downham DY. How to assess the reliability of measurements in rehabilitation. *Am J Phys Med Rehabil*. 2005;84(9):719–723.
28. Can G, Durna Z, Aydiner A. The validity and reliability of the Turkish version of the Quality of Life Index [QLI] (cancer version). *Eur J Oncol Nurs*. 2010;14(4):316–321.
29. Velanovich V, Szymanski W. Quality of life of breast cancer patients with lymphedema. *Am J Surg*. 1999;177(3):184–187.
30. Thomas-MacLean R, Miedema B, Tatemichi SR. Breast cancer–related lymphedema: women's experiences with an underestimated condition. *Can Fam Physician*. 2005;51:246–247.

31. Deng J, Fu MR, Armer JM, et al. Self-reported information sources and perceived knowledge in individuals with lymphedema. *Lymphology*. 2013; 46(4):173–183.
32. Sherman KA, Miller SM, Roussi P, Taylor A. Factors predicting adherence to risk management behaviors of women at increased risk for developing lymphedema. *Support Care Cancer*. 2015;23(1):61–69.
33. Hormes JM, Bryan C, Lytle LA, et al. Impact of lymphedema and arm symptoms on quality of life in breast cancer survivors. *Lymphology*. 2010; 43(1):1–13.
34. Pain SJ, Vowler SL, Purushotham AD. Is physical function a more appropriate measure than volume excess in the assessment of breast cancer–related lymphoedema (BCRL)? *Eur J Cancer*. 2003;39(15):2168–2172.
35. Hidding JT, Beurskens CH, van der Wees PJ, van Laarhoven HW, Nijhuis-van der Sanden MW. Treatment related impairments in arm and shoulder in patients with breast cancer: a systematic review. *PLoS One*. 2014;9(5):e96748.
36. Gebruers N, Verbelen H, de Vrieze T, et al. Current and future perspectives on the evaluation, prevention and conservative management of breast cancer related lymphoedema: a best practice guideline. *Eur J Obstet Gynecol Reprod Biol*. 2017;216:245–253.