

# Translation, reliability, and validation of the Turkish version of the Lymphedema Quality-of-Life tool in Turkish-speaking patients with lower limb Lymphedema



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*The aim of this study was to translate the original English version of the Lymph Quality-of-Life Questionnaire (LYM-QoL) into Turkish language and test its reliability and validity in patients with lower limb lymphedema (LLL). A total of 119 patients (86 women and 33 men) with LLL were enrolled in this study. The Turkish version of the Nottingham Health Profile was used to evaluate the criterion validity of related domains in LYMQoL. The LYMQoL was performed after seven days to evaluate its test-retest reliability. Cronbach's alpha value was found to be 0.94 for internal consistency, and the intraclass correlation coefficient score for test-retest reliability was found to be 0.95. The intraclass correlation coefficient score of domains ranged between 0.83 and 0.92. For the criterion validity, "functional aspects" and "symptoms" domains moderately correlated significantly with the Nottingham Health Profile total score. Kappa values ranged from 0.356 to 0.715. According to the factor analysis, four factors that explain the 71% of the cumulative variance were found. In conclusion, this study indicates that the Turkish version of the LYMQoL is a reliable valid tool for the evaluation of disease-specific health-related quality of life in patients with LLL. It can be safely used in both clinical routine and research. (J Vasc Nurs 2018;37:11-17)*

Lymphedema can be described as an increase in protein-rich tissue fluid in interstitial spaces due to failure or trauma of the lymphatic system.<sup>1</sup> Primary Lymphedema, which is one of the types of Lymphedema, is caused by an incomplete developmental abnormality of the lymphatic system in addition to reduced transport capacity. Secondary Lymphedema, which is the other type of Lymphedema, is caused by external trauma, most commonly after cancer surgeries of the genitourinary system (ie, vulva, endometrium, uterus, ovary, and prostate cancer).<sup>2</sup> The incidence of primary Lymphedema under the age of 20 years

is 1.15 in 100.000, whereas the incidence of secondary lower limb Lymphedema (LLL) is reported to range from 20% to 30% in cancer-related patients.<sup>3,4</sup>

Although the severity of LLL can vary, it restricts a person's daily activities by affecting physical function, recurrent skin infections, changing gait, and mobility, and these contribute to negative psychological and social well-being.<sup>5-7</sup> Researchers reported that skin thickness and subcutaneous tissue thickness correlated significantly with the International Society of Lymphology staging, which can be interpreted as that increasing the severity of LLL not only affects one's physical abilities but also skin characteristics.<sup>8</sup> Firmness, pain, discomfort, and the feeling of heaviness might affect person's ability to move body parts.<sup>9</sup> As a result, patients with LLL might have substantial deterioration in their health-related quality of life (HRQoL).<sup>10</sup> Deterioration in physical abilities and capacity not only affects the quality of life (QoL) but also affects one's ability to find clothing and footwear, which might cause frustration, social isolation, and psychological symptoms.<sup>11</sup> Measuring HRQoL could be useful to demonstrate clinical impacts related to Lymphedema or treatment-related changes. There are both general and disease-specific questionnaire-based HRQoL tools. Generic HRQoL tools could only show a general picture of the deficit.<sup>12</sup> It is reported that disease-specific tools provide more specific information regarding patients' problems.<sup>13</sup>

Lymphedema and its deteriorating effects have been studied extensively in breast cancer survivors, which are commonly focused on physical, psychological, and social functioning. However, there is not enough study regarding the QoL of patients with LLL. To assess QoL in patients with Lymphedema might be cumbersome because both treatment and management of

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Lymphedema are quite difficult and complex due to the position of the leg(s) and larger volume of extremity. Therefore, factors that affect QoL in patients with Lymphedema should be multidimensional.<sup>10,14</sup> In this manner, evaluating disease-specific HRQoL in patients with LLL, which is multidimensional and has different symptoms, is crucial.

Lymphedema Quality of Life Questionnaire (LYMQoL) is a validated tool that can be used in both types of research or in clinical routine to detect QoL of patients with LLL.<sup>15</sup> LYMQoL has been reported as having a good feasibility, reliability, and validity in researches.<sup>16</sup> Until now, there is no validated tool regarding LLL patients' disease-specific HRQoL in the Turkish language. Therefore, our aim was to conduct the translation, validation, and reliability evaluation of the original English version of the LYMQoL into the Turkish language.

## MATERIAL AND METHODS

### *Instrument*

The LYMQoL was designed as a disease-specific HRQoL tool, which included 22 questions. It has four domains and measures the function, appearance, symptoms, and mood in patients with Lymphedema. Each item is scored on a four-point Likert scale as follows: "Not at all = 1", "A little = 2", "Quite a bit = 3", and "A lot = 4". A total score for each domain is calculated by summing up each point taken by each item then dividing the number of answered items. Score ranges 1 to 4 for both total LYMQoL and each domain. Lower scores are an indicator of better QoL. The whole-domain score is calculated as "0" if 50% of items are not answered. The overall QoL is scored on a ten-point (0 to 10) scale via the last question of LYMQoL in which higher scores are related to better QoL.<sup>15</sup> The last question of LYMQoL is not included in the total score.

### *Translation*

As soon as permission was granted from the copyright holder for translation of LYMQoL, the standard translation method was followed.<sup>17</sup> The original version was first translated separately into Turkish by two native Turkish speakers who were blinded to each other. After then, a meeting included those, along with a bilingual author (Y.B.), who reviewed the translations to put the translated Turkish version draft of LYMQoL into its final form. Thereafter, two other bilingual speakers who were specialized on health care and did not know the original version of the questionnaire translated it back into English. Authors analyzed the final version of the draft along with the translations for discrepancies. After the pilot study, which was conducted with 18 Turkish patients with LLL, it was recognized that the Turkish LYMQoL was easily understandable, and they did not report any incoherent items or expressions. Therefore, the final version of the Turkish LYMQoL was obtained.

### *The Nottingham health profile*

The Nottingham Health Profile (NHP) is used to assess perceived health problems with a total of 38 items that are scored as "yes" or "no". These items take part in specific domains in the NHP, such as energy level, pain, emotional reaction, sleep, social isolation, and physical abilities. Each domain's score ranges from 0 to 100, and higher scores indicate poor QoL or vice versa. Summing up all domains' score gives the total NHP score. The reliability and validity

of the Turkish NHP were demonstrated.<sup>18</sup> Owing to the sociocultural level of the study sample, NHP was administered as it includes simple and general questions and needs only "yes/no" answer.

### *Study sample*

A total of 144 patients with primary or secondary LLL who were diagnosed and attend our clinic led by a general practitioner were enrolled for this study from August 2013 to September 2015 at the Lymphedema outpatient clinic in the Abant Izzet Baysal University School of Physical Therapy and Rehabilitation. Thereafter, circumference measurement and subtissue fluid proportion measurements were obtained by one of the authors (A.T.) for Lymphedema. Inclusion criteria are diagnosis of primary or secondary LLL; a minimum of 6-month symptom duration; capable of reading, speaking, and understanding Turkish as a mother language; and willing to participate in this study. Those with other problems related to swelling of lower extremities (originated from internal disease), acute thrombophlebitis (in the last 2 months), diagnosis of acute infection, deep vein thrombosis within the previous six months, active malignancy, ongoing chemotherapy and/or radiotherapy, and open wounds in their affected limbs were excluded from the study. No major change occurred in participants' clinical situation during the study process. Primary and secondary endpoints were to achieve adequate number of patients according to the previous studies regarding LYMQoL and to create culturally adapted, comprehensible, and easy-to-apply Turkish version of LYMQoL.

LYMQoL and NHP questionnaires were filled out by patients at the first visit. Then, they refilled the LYMQoL a week later. Patients were informed that they must visit again. Retest evaluation of the LYMQoL was performed at the clinic. This study was approved by the local ethics committee of Bolu Abant Izzet Baysal University Ethics Committee. Written informed consent was obtained from the participants after oral and written information was provided to them. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

### *Reliability and validity*

Reliability of the LYMQoL was assessed by internal consistency by using Cronbach's alpha coefficient and test-retest analysis. Intra-class correlation coefficient (ICC) was used to analyze retest results with one week apart. A correlation coefficient ranges from "0" to "1", and approaching "1" shows an excellent reliability. Kappa coefficient was used to analyze item-based reliability parameters.

Pearson's correlation coefficient was used to analyze criterion validity of the LYMQoL by comparing the NHP scores of patients. The Pearson's *r* correlation coefficient is used for the criteria of poor ( $r < 0-0.20$ ), fair ( $r = 0.21-0.40$ ), moderate ( $r = 0.41-0.60$ ), good ( $r = 0.61-0.80$ ), and excellent ( $r > 0.81-1$ ).<sup>19</sup>

### *Statistical analysis*

Descriptive analyses were used to calculate means and standard deviations of the demographic variables. Kolmogorov-Smirnov and Shapiro-Wilk tests were used to analyze whether the data are distributed normally or not. Cronbach's alpha and Kappa coefficients along with ICC were used to evaluate reliability, whereas Pearson correlation coefficient was used to assess validity. The structure of the questionnaire was evaluated using the exploratory factor analysis based

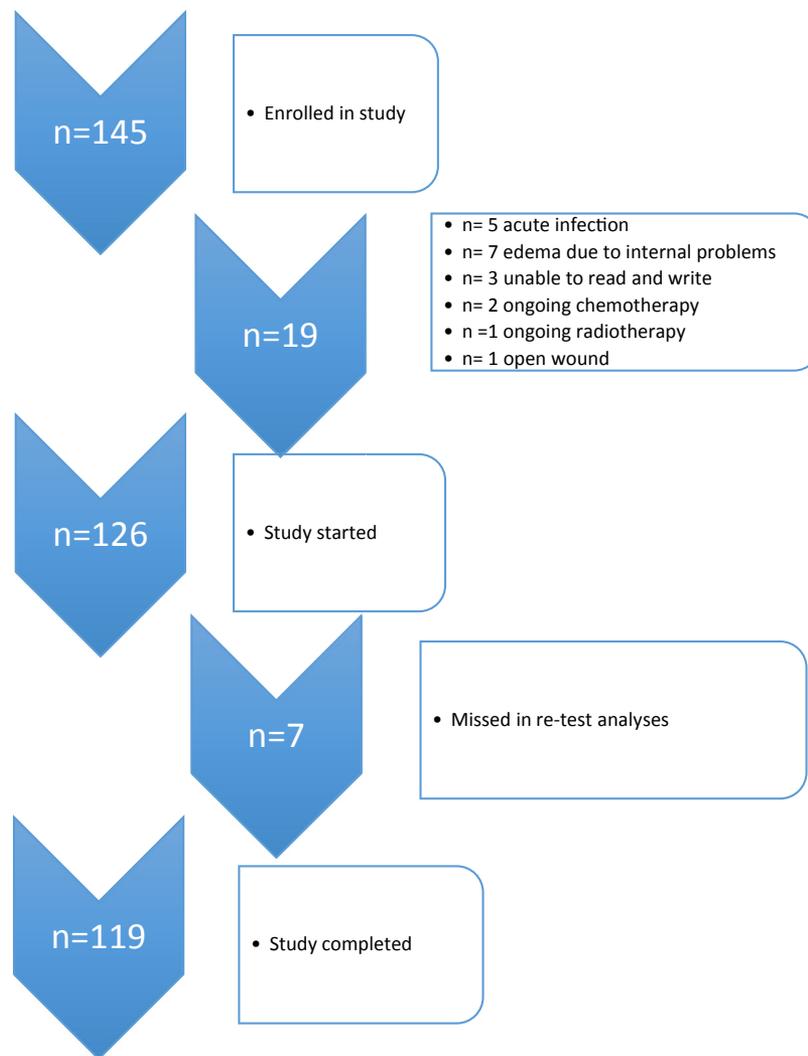


Figure 1. Flow chart of the participants’ screening, participation, and completion of the study.

on the Kaiser-Meyer-Olkin test result. A *P* value below 0.05 was accepted as the level of statistical significance. Statistical analyses were performed by using PASW (ver. 18; SPSS Institute, Chicago, IL).

**RESULTS**

A total of 145 patients with LLL participated in the study. Nineteen patients who did not meet the inclusion criteria were excluded from the study. Five patients had acute infection, seven of them had edema of the legs originated from internal problems, three of them could not read and write, two had ongoing chemotherapy, one had ongoing radiotherapy, and one had open wound in her lower leg. Second assessments could not be performed in seven participants. Thus, this study was completed with a total of 119 patients (Figure 1). Tables 1 and 2 show the demographic and clinical characteristics of patients.

LYMQoL and its domains (functional aspects, appearance/body image, symptoms, mood/emotions) were found as 0.93, 0.76, 0.89, 0.74, and 0.94, respectively, regarding their Cronbach’s alpha value. According to these values, LYMQoL has a good to excellent internal consistency. ICC value of each domain varied between 0.83 and 0.95 (95% confidence interval,

*P* < .001; Table 3); therefore, it can be interpreted from these values that the Turkish-translated LYMQoL has excellent test-retest results.

TABLE 1			
DEMOGRAPHIC CHARACTERISTICS AND CLINICAL FEATURES OF THE PATIENTS (N = 119)			
	Minimum	Maximum	X ± SD
Age (y)	12	75	49.83 ± 14.42
Height (m)	1.50	1.80	1.64 ± 0.08
Weight (kg)	50	200	82.7 ± 21.38
BMI (kg/m <sup>2</sup> )	17.96	68.68	30.88 ± 8.19
Lymphedema duration (y)	1	38	7.03 ± 6.25

BMI = body mass index; SD = standard deviation; X = mean.

TABLE 2

**SOCIODEMOGRAPHIC CHARACTERISTICS OF THE PATIENTS (N = 119)**

	<i>n</i>	<i>%</i>
Gender		
Female	86	72.3
Male	33	27.7
Affected leg		
Bilateral	67	56.3
Unilateral	52	43.7
Type of Lymphedema		
Primary	54	45.4
Secondary	65	54.6
Causatives of sec. LE		
Endometrium CA	21	32.3
Ovary CA	12	18.4
Prostate CA	14	21.5
Cervical CA	18	27.8
Staging (ISL)		
Stage I	—	—
Stage II	13	30.2
Stage III	52	69.8

CA = cancer; ISL = International Society of Lymphology; Sec. Le = secondary Lymphedema.

The total LYMQoL correlated well with the “overall QoL”; however, poor criterion validity was found between the LYMQoL and NHP. All domains of the LYMQoL significantly correlated in a negative direction with the last item “overall QoL,” yet NHP significantly correlated with the “functional aspects” and “symptoms” domains of the LYMQoL (Table 4).

The floor-ceiling effect is the term that describes most of the subjects in the study who score near the bottom as floor effect or score near the top as ceiling effect. The floor-ceiling effect was calculated for the first measurement of questions within the LYMQoL, and possibility of patients replying “not at all = 1” in the 17th and 21st questions was much more than that to other questions, whereas “a lot = 4” reply was much more than others in sixth and 15th questions.

After the exploratory factor analysis, Kaiser-Meier-Olkin test gave  $P = .745$ , and therefore, it was interpreted as suitable to conduct factor analysis. Correlations were found to be significant between the items of the LYMQoL according to the sphericity test result that was found to be not of a spherical structure ( $P < .0001$ ). As all diagonal elements were above the value of 0.50 in the anti-image matrix, item elimination was not necessary. Statistically significant four factors were achieved in the Turkish-translated LYMQoL. Factor loadings and related features are shown in Table 5.

TABLE 3

**RELIABILITY OF THE LYMPHEDEMA QUALITY-OF-LIFE QUESTIONNAIRE (LYMQOL) (N = 119)**

<i>LYMQoL Domains</i>	<i>ICC</i>	<i>P</i>
Functional aspects	0.92	<.001
Appearance/body image	0.92	<.001
Symptoms	0.83	<.001
Mood/emotions	0.90	<.001
Overall LYMQoL	0.95	<.001

ICC = intraclass correlation coefficient,  $P < .05$ .

Test-retest reliability of each item was assessed by Kappa coefficient which ranged between 0.356 and 0.715. These values could be interpreted as having moderate to substantial agreement. Kappa values are shown in Table 5.

**DISCUSSION**

The Turkish version of LYMQoL was found to be a valid and reliable tool to investigate disease-specific HRQoL in patients with LLL. These results are compatible with the original English version of LYMQoL.<sup>15</sup> Thus, the Turkish version of LYMQoL can be safely used in patients with LLL.

Diminished QoL was reported in patients with LLL.<sup>6</sup> Symptoms associated with Lymphedema not only affect physical function but also widespread psychological implications in their life.<sup>12</sup> Current evidence supports the need to evaluate QoL as the main outcome because it has been carrying a great importance.<sup>14</sup> The main symptom of Lymphedema is swelling. Yet, this is not the only contributor of decreased QoL. For instance, Sawan et al<sup>20</sup> reported no difference in QoL, although a significant improvement was observed in swelling. However, it might be an expected situation because a generic HRQoL questionnaire was used in their study. Nevertheless, their study also showed a need for disease-specific HRQoL tools as Lymphedema has drastic impacts within multiple aspects such as physical, emotional, and functional. Disease-specific HRQoL tools instead of generic HRQoL tools are needed to demonstrate an accurate view of QoL.<sup>14</sup> In this manner, we think that the LYMQoL is a proper disease-specific HRQoL tool in which afflictions in emotional, physical, functional, and body image could be obtained.

LLL has a well-known impact on one's functionality and physical performance. It was reported that activities in both daily living and work are affected due to LLL.<sup>5</sup> Patients with LLL mostly experience symptoms such as heaviness and tightness, which might also contribute to their dysfunctionality. It was reported that QoL might be more associated with the decreased physical function.<sup>4</sup> Consistent with this, our results also showed that “functional aspects” and “overall QoL” domains of the LYMQoL correlated significantly with the NHP.

TABLE 4

## CRITERION VALIDITY OF LYMPHEDEMA QUALITY-OF-LIFE QUESTIONNAIRE (LYMQoL)

<i>LYMQoL Domain</i>	<i>Overall Quality of Life, r</i>	<i>P</i>	<i>NHP, r</i>	<i>P</i>
Functional aspects	-0.595	<.001	0.223	.015
Appearance/body image	-0.394	<.001	0.009	.925
Symptoms	-0.410	<.001	0.227	.013
Mood/emotions	-0.634	<.001	0.079	.392
Overall LYMQoL	-0.605	<.001	0.119	.197

NHP = Nottingham health profile; r = Pearson correlation coefficient,  $P < .05$ .

In the original English version of LYMQoL, domain scores were reported instead of the total score. Reported domain Cronbach's alpha scores ranged between 0.874 and 0.945, whereas ICC values of domains ranged from 0.614 to 0.782.<sup>15</sup> In the translated Dutch version of LYMQoL, internal consistency was found to be excellent with a 0.89 Cronbach's alpha value.<sup>10</sup> Total Cronbach's alpha values of the Turkish version of LYMQoL were found to be 0.937 and 0.936 in total scores for test and retest, respectively. ICC values of domains in Turkish version ranged between 0.838 and 0.929. Also, the total ICC score of the Turkish LYMQoL was found to be 0.955, which is accepted as excellent. Based on these results, it can be interpreted as an excellent internal consistency and test-retest reliability values. When test-retest reliability was investigated within items, reliability of each item was found to be significant according to the Kappa coefficient that ranged between 0.356 and 0.715.<sup>21</sup> The smallest value of Kappa was found in a first item, which is "How much does your swollen leg affects the following daily activities". We think that this might be the result of the large age distribution in our population. In addition, there were also students and men who had no regular household activities compared with others. In the sixth item, which is "How much difficulty do you have finding clothes you would like to wear" was found highest regarding the Kappa value. This was also expected due to wearing clothes or having difficulty with clothes can be faced with any age or professional experience.

In our study, the NHP was used for evaluating criterion validity. Only the "functional aspects" domain of the Turkish version of LYMQoL correlated significantly with the NHP ( $r: 0.186, P: .043$ ) in the test period. In the retest period, both "functional aspects" ( $r: 0.223, P: .015$ ) and "symptoms" ( $r: 0.227, P: .013$ ) domains correlated significantly with the NHP. The "overall QoL" score of the LYMQoL correlated significantly with all domains in good to very good level. Compared with the findings of both the original version and the Dutch translated version, our significant criterion results did not comprise all domains. The main reason of this result is that the NHP is a generic HRQoL questionnaire and consists of general questions instead of disease-specific ones. Because there was no Turkish-translated and validated Lymphedema-specific tool, the NHP was used as it is easily

comprehensible and readable among the Turkish population. If a Turkish-translated and validated Lymphedema-specific tool was used, we think it could have achieved higher results regarding criterion validity. The Turkish version of Lymphedema Functioning, Disability and Health Questionnaire (LYMPH-ICF)<sup>22</sup> could have been used, yet it was published at the end of our data-collection period. We suggest that the Turkish version of LYMQoL could be compared in the future with the Lymphedema-specific HRQoL tool such as LYMPH-ICF so that much more concentrated criterion validity results might be obtained.

When the structure of the Turkish LYMQoL was investigated via an exploratory factor analysis, four factor structures were found, and the same was found with the original English version and translated Dutch version, each has four factors too.<sup>10,15</sup> Floor-ceiling effects that were not analyzed in the original English version was observed for the Turkish version of LYMQoL. In questions 6 and 15, the ceiling effect was found at 27.7% and 26.1%, whereas a floor effect was found in questions 17 and 21 at 68.1% and 65.5%, respectively. These results are in contrast to the Dutch version<sup>10</sup> in which the borderline ceiling effect was found in the 17th question, "Have you had difficulty concentrating on things, for example, reading", with 70.1%. In the Turkish version, the sixth question "How much difficulty do you have finding clothes you would like to wear" and the 15th question "Does (do) your swollen leg(s) feel weak" were found to be in the ceiling effect, in which "a lot = 4" answer was higher. It was an expected result because the main symptom of Lymphedema is swelling, and this makes it difficult to find a proper outfit and interferes with a muscle-skeletal system, which can be felt as a weakness by patients.

In our point of view, the LYMQoL is relatively short and compact so that it is easy to apply. Our patients declared that the questionnaire was easily comprehensible, and an average of five minutes is needed to complete the questionnaire according to the pilot study result. During the data study, no negative situation was observed in the direction of feedbacks taken from our patients. Patel et al<sup>23</sup> reported that LYMQoL is a useful tool to track changes throughout the Lymphedema treatment. It was indicated that QoL can be evaluated via LYMQoL in which Complex Decongestive Therapy was applied.<sup>24</sup> We think that specific

TABLE 5

## FACTOR LOADINGS AND KAPPA VALUES OF LYMQOL

	<i>Factors</i>				<i>Kappa</i>	<i>P</i>
	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>		
How much does your swollen leg affect the following daily activities?	0.338	0.126	<b>0.780</b>	0.276	0.356	<.0001
Does the swelling affect your leisure activities?	0.129	0.483	<b>0.695</b>	-0.062	0.565	<.0001
How much do you have to depend on other people?	0.416	0.281	<b>0.423</b>	0.342	0.657	<.0001
How much do you feel the swelling affects your appearance?	0.108	<b>0.813</b>	0.148	0.287	0.569	<.0001
How much difficulty do you have finding clothes to fit?	0.181	<b>0.901</b>	0.162	-0.087	0.647	<.0001
How much difficulty do you have finding clothes you would like to wear?	0.289	<b>0.891</b>	0.065	-0.119	0.715	<.0001
Do you have difficulty finding shoes to fit?	0.335	<b>0.631</b>	0.306	-0.205	0.572	<.0001
Do you have difficulty finding socks/tights/stockings to fit?	0.234	<b>0.679</b>	0.148	-0.016	0.596	<.0001
Does the swelling affect how you feel about yourself?	<b>0.541</b>	0.541	0.152	0.019	0.536	<.0001
Does it affect your relationships with other people?	<b>0.600</b>	0.266	0.234	0.307	0.702	<.0001
Does your Lymphedema cause you pain?	0.142	0.133	<b>0.840</b>	0.104	0.501	<.0001
Do you have any numbness in your swollen leg?	0.093	-0.085	0.061	<b>0.938</b>	0.409	<.0001
Do you have any feelings of "pins and needles" or tingling in your swollen leg?	0.045	0.014	0.115	<b>0.845</b>	0.411	<.0001
Does (do) your swollen leg(s) feel weak?	0.383	0.112	0.267	<b>0.389</b>	0.566	<.0001
Does (do) your swollen leg(s) feel heavy?	0.235	<b>0.616</b>	0.286	0.424	0.588	<.0001
Have you had trouble sleeping?	<b>0.826</b>	0.118	-0.022	-0.104	0.511	<.0001
Have you had difficulty concentrating on things, such as reading?	<b>0.780</b>	0.310	0.052	-0.121	0.601	<.0001
Have you felt tense?	<b>0.842</b>	0.220	0.296	0.128	0.480	<.0001
Have you felt worried?	<b>0.867</b>	0.115	0.351	0.205	0.542	<.0001
Have you felt irritable?	<b>0.869</b>	0.151	0.305	0.198	0.530	<.0001
Have you felt depressed?	<b>0.761</b>	0.433	0.014	0.118	0.513	<.0001

Highest values on each row are in bold font.

questions need to be addressed in cases of LLL, such as infection frequency could have been added in the original questionnaire. We suggest that further studies that aim to develop a Lymphedema-specific HRQoL tool should take these into account.

When considering limitations of this study, one can conclude that this is a single-center study, which may not represent the general Lymphedema patient population. However, our clinic is a major referral center, providing care to the entire North and North-West provinces of Turkey. Although using NHP could be considered as another limitation, it has been widely used in Turkey as a generic HRQoL tool due to its easy comprehensibility. We could not test the construct validity with a Lymphedema-specific tool because of lack of any Lymphedema-specific QoL tool in the Turkish language during the study period. Maybe criterion validity could be conducted again using a Lymphedema-specific tool such as the LYMPH-ICF.<sup>22</sup> However, analyzing floor-ceiling effects is a strength of this study. An item-based test-retest analysis was performed via Kappa coefficient; therefore, it can be assumed as another strength of this study.

## CONCLUSION

Findings of this study indicate that the Turkish version of LYMQoL is a reliable and valid measure for the evaluation of QoL in patients with LLL. Based on these results, we recommend the use of Turkish LYMQoL in all patients with LLL to evaluate disease-specific HRQoL in clinical routine and research as it provides an outcome score. We believe that this approach will enhance further treatment options, which can be helpful for problems of patients with LLL.

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