Validity and Reliability of Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF) Thai Version

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ABSTRACT

Objective: The study objective is to adapt the Lymphoedema functioning, disability and health questionnaire (Lymph-ICF) for use in the Thai language and to investigate the validity and reliability of the Thai version.

Materials and Methods: This study was done in 5 stages in line with established guidelines for cross-cultural adaptation of self-report measures; 1) Initial translation 2) Synthesis of the translations 3) Back translation 4) Expert committee review and 5) Test of the prefinal version. The face validity was assessed by interview content experts. In the assessment of the validity of the construct, the Spearman correlation coefficient was used to examine the correlations between the scores of the Thai Lymph-ICF and the scores of the Thai EQ-5D-5L. The intraclass correlation coefficient (ICC) was used to establish test-retest reliability while Cronbach's alpha was used to determine the internal consistency of the whole questionnaire and of each domain.

Results: Fifty participants were evaluated for validity and reliability. Face validity was supported. Construct validity showed strong correlations between the scores of the Thai Lymph-ICF and the scores of the Thai EQ-5D-5L. Internal consistency and test-retest reliability were both excellent.

Conclusion: The Lymph-ICF Thai version was shown to be both valid and reliable for evaluating the quality of life of patients with breast cancer-related lymphoedema.

Keywords: Breast cancer; lymphoedema; lymphoedema questionnaire; quality of life; reliability; Thai; validity (Siriraj Med J 2021; 73: 268-274)

INTRODUCTION

The study of cancer in 184 countries worldwide shows breast cancer to be the most common type of cancer in women.[1] From cancer registry data in Thailand in 2010-2012[2], breast cancer has the highest incidence among other cancers in the Thai female population, which is as high as 28.6 cases per 100,000 people.

After the successful breast cancer treatment, the survival rate is 89% at the 5th year, 83% at the 10th year and 78% at 15th year.[3] But despite the high survival rate, some patients still continue to suffer substantial adverse effects. One of the most important and most common complications is lymphoedema, which potentially affects the patient's quality of life. Although no studies

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on Thailand's incidence or prevalence of lymphedema following cancer-related breast surgery exists, a systematic review and meta-analysis found that the incidence of arm lymphedema after breast cancer treatment is 21.4%.[4] From this data, we can infer that approximately one in five Thai women will eventually develop arm lymphoedema post breast cancer treatment. Affected women can experience pain, swelling, tightness, and heaviness of the arm. All of these limit the patient's ability to perform their daily life activities. Furthermore, it leads to cosmetic embarrassment and potential compromises quality of life and social participation.

As the breast cancer related lymphoedema (BCRL) affects the patient's life in many ways, the quality of life assessment, therefore, has to include every related aspect. The Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF), which was published in 2011, is the current tool to assess the quality of life of patients with lymphoedema. The study was from 2006-2007, included 60 patients and resulted in good validity and reliability.[5]

The Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF) is more context-specific for patients suffering from BCRL when compared to other quality of life assessment tools which cover a wide range of aspects of life that can be adversely affected by ill-health. For example, Patients with BCRL don't normally have trouble with mobility and ambulation. However, other quality of life assessment tools always consist of these unnecessary domains. The Lymph-ICF encompasses all aspects of functioning and health in this group of patients including 1) physical function (heavy, stiff, swollen, lost strength, tingle, hurt, tensed skin), 2) mental function (feel sad, feel discouraged, lack of self-confidence, feel stressed), 3) household activities (clean, cook, iron, garden), 4) mobility activities (tasks with elevated arm, lift heavy objects, sleep on effected side, work on computer, sunbathe, drive a car, walk more than 2 km, cycle), and 5) life and social activities (go on vacation, perform hobbies, practice sports, wear clothes of choice, do a job, do social activities). Each of the 29 questions corresponds to a score on Visual Analogue Scale (VAS) from 0 to 100 mm. The total score and scores on each domain of the Lymph-ICF is the sum of the scores on the questions divided by the total number of answered questions. Thus, the total score on the Lymph-ICF and the scores on the 5 domains range between 0 and 100. The questionnaire has been translated and tested for the validity and reliability in many languages. The Turkish and Danish versions showed good validity and reliability and demonstrated that Lymph-CF was an effective tool to assess the quality of life of lymphoedema patients.[6,7]

With no Thai version available, this study was carried out to develop one, as well as to determine if this Thai version would be effective for assessing the quality of life in every aspect for patients with BCRL.

MATERIALS AND METHODS

The Siriraj Institutional Review Board approved this study - certificate of approval number (Si 610/2017). Participation information was read to each subject and informed consent obtained prior to participation.

Inclusion criteria were: 1) Age 18 - 80 years, 2) Diagnosed with unilateral breast cancer related Lymphoedema and 3) Ability to communicate and reply to instructions in Thai. Exclusion criteria were: 1) Lymphoedema from another cause or unknown cause 2) infection or ulcer in affected upper extremity or 3) still receiving cancer treatment.

This study was done in 5 stages in line with established guidelines for cross-cultural adaptation of self-report measures; 1) Initial translation 2) Synthesis of the translations 3) Back translation 4) Expert committee review and 5) Test of the prefinal version.[8] In stage 1, the Lymph-ICF English version was independently forward-translated into Thai by 2 Thai native physiatrists who were fluent in English. In stage 2, two translators and experts synthesized the translation into one. In stage 3, the Thai translation Lymph-ICF was translated back into English by two bilingual Thai-English speakers, neither of whom had prior knowledge of Lymph-ICF. In stage 4, an expert committee comprising medical personnel who specialized in breast cancer related lymphoedema (one physiatrist, one plastic surgeon, one occupational therapist and one physiotherapist) and translators reviewed the back-translation and developed the prefinal version. In stage 5, the prefinal version was tested on 5 patients with breast cancer related lymphoedema for their understanding of each item in the questionnaire. After completing the questionnaire, the participants were asked questions related to content validity[5]: 1) Is each question easy to understand? 2) Is the scoring system easy to use? 3) Does the questionnaire include all the complaints related to your lymphoedema, and 4) any suggestions for this questionnaire? All the participants gave positive answers (yes) for questions 1 to 3. One participant suggested that some open questions would be helpful for patients to give detail of their complaint.

Sample size calculation

According to the previous validity study using physical functioning domain of SF36 for quality-of-life

assessment with physical function domain of Lymph-ICF the correlation coefficient is -0.498.[6] Instead of SF36 our study used EQ-5D-5L for quality-of-life measurement, we imply that the correlation coefficient (r) is equal to -0.5. After adding all the information into the nQuery Advisor® Version 7.0 (Statistical Solutions Ltd., Cork, Ireland) software, we found that 38 participants would be enough for this study (power of 90% with a significant level of 0.05). On the other hand, for the reliability test (test-retest reliability), from previous study we found that the intraclass correlation coefficient of Lymph-ICF total score is equal to 0.9 with a 95 percent confidence interval width of 0.2. The sample size approximation is 19.[6] For the primary outcomes of validity and reliability of Lymph-ICF Thai version, we initially estimated that 38 participants would be needed. Assuming a 30% withdrawal rate, the final calculated sample size was a total sample of 50 participants.

Evaluation of psychometric property of the Thai version Lymph-ICF

The validity and reliability of the final Thai version was evaluated by 50 patients with unilateral BCRL. All participants did the questionnaire twice at least 2 hours apart, with all domains shuffled when they did it the second time to determine test-retest reliability. The first time, patients completed the demographic data, the Lymph-ICF questionnaire Thai version, and the EQ-5D-5L questionnaire at the outpatient rehabilitation department. Two hours later, they did the Lymph-ICF questionnaire again but with the domains shuffled.

The Lymph-ICF questionnaire has 29 questions and 5 domains: 1) physical function, 2) mental function, 3) household activities, 4) mobility activities, and 5) life and social activities. The questionnaire would take about five minutes to complete. Each of the 29 questions is rated on an 11-point Likert scale between 0 and 10. The total score of the questionnaire is the sum of the score from each question divided by the total number of answers and multiplied by 10. Each of the five domains is scored by adding the score from each question, divided by the total number of answers and multiplied by 10. The total score of the questionnaire and of the 5 domains would be between 0 and 100.

The EQ-5D-5L, a self-assessed, health related, quality of life questionnaire, measures the quality of life on a 5-component scale: 1) mobility, 2) self-care, 3) usual activities, 4) pain/discomfort, and 5) anxiety/depression. Each component has a 5-level classification system. The EQ-5D-5L also has an overall health scale to describe the condition of the rater's health, where 0 indicates the worst imaginable condition and 100 the best imaginable condition. Convergent validity was demonstrated by a correlation between EQ-5D-5L and the dimensions of WHO 5, ($r=0.43$, $P<0.001$).[9] The EuroQol approach is reliable, average test-re-test reliability using inter-class coefficients with mean of 0.78 and 0.73.[10]

Data analysis

PASW Statistics for Windows, Version 18.0 (SPSS Inc., Chicago, IL, USA) were used for all statistical analyses, with a p-value < 0.05 considered to be statistically significant. Descriptive statistics were also performed. Continuous variables were reported using mean ± standard deviation (SD) for normally distributed data and median (interquartile range; IQR) for non-normally distributed data (Kolmogorov-Smirnov and Shapiro-Wilk tests). Categorical variables were presented as a number (percentage).

Assessment of validity: Face validity was investigated. One physiatrist, one plastic surgeon, one physical therapist, one occupational therapist and a breast cancer related lymphedema patient were asked to be content experts. All of these health care professionals worked in their field more than 10 years. All the experts agreed that all items in the Thai version of Lymph-ICF had face validity; they appeared to measure quality of life in BCRL patients. To establish construct validity, correlations between the scores of the Lymph-ICF and the scores of the EQ-5D-5L were examined using Pearson correlation coefficient for normally distributed score or Spearman correlation coefficient for non-normally distributed score. Correlation coefficients were rated with ≤ 0.3 indicates poor correlation, 0.31 to 0.6 indicates moderate correlation, and > 0.6 indicates strong correlation.[11] A p-value less than 0.05 was considered statistically significant.

Assessment of reliability: An intraclass correlation coefficient (ICC) was used to determine the test-retest reliability of the total score and of the scores of the 5 domains of the Lymph-ICF.[12] An ICC < 0.5 indicates poor reliability, 0.5 to 0.75 indicates moderate reliability, 0.75 to 0.9 indicates good reliability, and > 0.9 indicates excellent reliability.[13] To determine the internal consistency of the whole questionnaire and of each domain, Cronbach's alpha were used, with a value of > 0.7 indicating a reliable internal consistency.[14]

RESULTS

Fifty female participants with unilateral BCRL, aged 40-76 years (mean age 59.7±9.3 years), participated in the study; no participant dropped out. Their demographic data and clinical characteristics were shown in Table 1.

TABLE 1. Demographic data and clinical characteristics of the participants.

	Mean ± SD, n (%)	Range
Age (years)	59.7±9.3	40 - 76
Gender Female:Male	50:0 (100.0%:0.0%)	
Body Mass Index (kg/m^2)	26.6±4.4	18.1- 38.9
Education		
None	1 (2.0%)	
Primary school	24 (48.0%)	
Secondary school	6 (12.0%)	
Vocational Certificate/ High Vocational Certificate/ Diploma	3 (6.0%)	
Bachelor's degree	12 (24.0%)	
Master's degree and above	4 (8.0%)	
Dominant side (Right:Left)	42:8 (84.0%:16.0%)	
Affected side (Right:Left)	25:25 (50.0%:50.0%)	
Affected on dominant side (Yes:No)	25:25 (50.0%:50.0%)	
Region of lymphoedema		
Above elbow	50 (100.0%)	
Below elbow	48 (96.0%)	
Hand	33 (66.0%)	
Circumference of affected side		
Dorsum of hand	19.1 ± 2.6	16.5 – 32.0
Wrist	17.7 ± 2.7	13.5 – 29.0
Below elbow 10 cm	28.1 ± 5.6	20.0 – 44.0
Elbow	29.0 ± 5.1	15.0 – 38.0
Above elbow 10 cm	34.8 ± 5.9	25.0 – 47.0
Circumference of normal side		
Dorsum of hand	18.1 ± 0.8	16.5 – 20.0
Wrist	15.8 ± 2.5	7.0 – 26.0
Below elbow 10 cm	22.8 ± 2.6	17.5 – 30.0
Elbow	23.9 ± 2.9	16.0 – 29.0
Above elbow 10 cm	28.3 ± 5.7	15.0 – 42.0
Mean duration of lymphoedema (months)	55.9 ± 60.1	1 - 240
Time interval since surgery (months)	133.0 ± 95.8	1.0 – 432.0
Surgical type		
Lumpectomy	22 (44.0%)	
Mastectomy	28 (56.0%)	
Others	0 (0.0%)	
Radiation therapy	48 (96.0%)	
Chemotherapy	47 (94.0%)	
On pressure garment	42 (84.0%)	
Physical therapy program for lymphedema	37 (74.0%)	

Abbreviations: SD = standard deviation, n = number

Assessment of reliability: For the test-retest reliability of the Lymph-ICF total score and each domain using intraclass correlation coefficient (ICC), the ICC ranged from 0.76 to 0.96 indicating good to excellent reliability. The internal consistency of the whole questionnaire and of each domain using Cronbach's alpha ranged from 0.89 to 0.97, which indicates a reliable internal consistency. (Table 2)

The construct validity analysis was shown in Table 3. There were significant correlations between the scores of the Lymph-ICF and the scores of the EQ-5D-5L in all aspects except mobility. The correlation in the mental function was strong.

TABLE 2. Test retest reliability and internal consistency of Thai version of Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF).

Outcome	First assessment Median (IQR25, IQR75)	Second assessment Median (IQR25, IQR75)	Intraclass Correlation Coefficient (ICC)	95 % Confidence Interval for ICC	Cronbach's alpha
Lymph ICF total score	25.4 (7.2, 44.8)	26.0 (5.3, 44.2)	0.96	0.94 – 0.98	0.97
Physical function score	23.6 (9.6, 47.5)	24.3 (5.7, 41.8)	0.90	0.83 – 0.94	0.91
Mental function score	6.3 (0.0, 33.8)	3.8 (0.0, 26.3)	0.96	0.92 – 0.98	0.93
Household activities score	22.5 (0.0, 50.0)	25.0 (0.0, 50.0)	0.87	0.78 – 0.92	0.89
Mobility activities score	31.7 (9.4, 54.4)	30.0 (5.4, 51.3)	0.92	0.86 – 0.95	0.91
Life and social activities score	18.3 (1.7, 46.3)	16.7 (1.7, 40.8)	0.76	0.62 – 0.86	0.91

Abbreviations: IQR25 = Inter Quartile Ranges 25, IQR75 = Inter Quartile Ranges 75, ICC = Intraclass Correlation Coefficient

TABLE 3. Construct validity: correlation analysis of the Thai versions of the Lymph-ICF and EQ-5D-5L questionnaire.

Lymph ICF	Physical function		Mental function		Household activities		Mobility activities		Life and social activities	
EQ-5D-5L	r_s	p-value	r_s	p-value	r_s	p-value	r_s	p-value	r_s	p-value
Mobility	0.282	0.048	0.231	0.107	0.320*	0.025	0.247	0.087	0.321*	0.023
Self-care	0.491*	<0.001	0.464*	0.001	0.424*	0.002	0.305*	0.033	0.364*	0.009
Usual activities	0.532*	<0.001	0.543*	<0.001	0.435*	0.002	0.470*	0.001	0.473*	0.001
Pain/ discomfort	0.431*	0.002	0.384*	0.006	0.430*	0.002	0.387*	0.006	0.401*	0.004
Anxiety/ depression	0.455*	0.001	0.649**	<0.001	0.338*	0.006	0.331*	0.020	0.402*	0.004

*Moderate correlation **Strong correlation

r_s = Spearman rank correlation coefficient

DISCUSSION

This study demonstrated the Lymph-ICF Thai version to be valid and reliable for evaluating the quality of life in BCRL patients.

Baseline characteristics of our study are quite similar to the English (original)[5] and Danish versions[7] of Lymph-ICF. Mean age and body mass index (BMI) of patients in our study were 59.7±9.3 years and 26.6±4.4 kg/m^2, compared with 61.2±10 years and 27±6.2 kg/m^2 in the original English version, and 61±12.4 years and 27.7±5.4 kg/m^2 in the Danish version. Participants in the Turkish version[6] were younger and more obese compared with our study with mean age 53.8±5.8 years and BMI 30.4±4.1 kg/m^2. The age and BMI in the Turkish version, although differed from those of the other three versions, reflected age and BMI of the general Turkish population. According to data from World Health Organization, the average BMI in female in Turkey is 28.5 kg/m^2 which is substantially higher than in Thai (24.6 kg/m^2), Belgium (24.7 kg/m^2), and Denmark (24.5 kg/m^2).[15]

The original English version and the Turkish version use the Visual Analogue Scale (VAS) from 0 to100 mm while the Danish version uses the Numerical Rating Scale (NRS) from 0 to 10. A systematic review comparing the NRS, VAS, and/or Verbal Rating Scale (VRS) for unidimensional self-reporting of pain intensity found that NRS produced better compliance rates, higher responsiveness, greater ease of use, and better applicability relative to VAS and was the recommended tool in 11 studies[16], therefore, we chose NRS from 0 to 10 in this study. All three versions (English, Danish and Turkish) use the same range of final score (0 to100) for both the total score of the Lymph-ICF and each of the 5 domains.

The English and Turkish Lymph-ICF used SF-36 as the quality-of-life questionnaire to investigate correlation with Lymph-ICF. This study used EQ-5D-5L as it is the shortest and easiest questionnaire and its impletion was as good as SF-36.[17]

The construct validity analysis showed that there was a significant correlation between the scores of the Lymph-ICF and the scores of the EQ-5D-5L in all aspects except mobility. This might be due to the Lymph-ICF and the EQ-5D-5L questionnaire investigate mobility in different functions. The majority of mobility score of the Lymph-ICF (tasks with elevated arm, lift heavy objects, sleep on affected side, work on computer, sunbathe, drive a car, walk more than 2 km and cycle) investigates the upper extremities mobility whereas the mobility score of the EQ-5D-5L (walking) investigates the lower extremities mobility.

Comparing test-retest reliability of the Thai version with the other three versions (original English, Turkish and Danish), it was found that the Thai, Turkish and Danish versions had excellent reliability in the total score with ICC values > 0.9 and good to excellent reliability in scores on the 5 domains of the Lymph-ICF with ICC values > 0.75 ranging from 0.76 to 0.96, 0.80 to 0.98 and 0.84 to 0.95, respectively. The original English version had moderate reliability in life and social activities domain with ICC 0.65 and good to excellent reliability in the total score and scores on other 4 domains of the Lymph-ICF with ICC values ranging from 0.87 to 0.93.

Comparing internal consistency of the Thai version with the other three versions (original English, Turkish and Danish), it was found that all versions (Thai, original English, Turkish and Danish) had good internal consistency with Cronbach's alpha values of > 0.7 ranging from 0.89 to 0.97, 0.72 to 0.92, 0.89 to 0.99 and 0.92 to 0.98, respectively.

Study limitations

First, the follow-up period was relatively short (only 2 hours apart), however all domains of the questionnaire were shuffled the second time. Second, Lymph-ICF was a self-report questionnaire with no cognitive test for participants before their inclusion in the study. Nevertheless, ability to communicate and reply to instructions in Thai were assessed before recruitment. Third, our study compared quality of life of patients between the Thai version of Lymph-ICF scores and the Thai version EQ-5D-5L scores which differed from the previous study using SF-36, hence it cannot truly compare the outcome with the previous study. Fourth, all participants in this study were outpatients. These are patients with uncomplicated lymphedema. No Patients with complications from lymphedema participated in this study. Lastly, only unilateral breast cancer related lymphoedema (BCRL) patients were enrolled in this study so the study results cannot be applied to patients with bilateral BCRL and other causes of upper limb lymphoedema.

CONCLUSION

This study demonstrated that the Thai version of Lymph-ICF is a valid and reliable questionnaire for evaluating quality of life in BCRL patients and can be used in clinical practice and research for unilateral BCRL patients.

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