

Original Article

Validity and Reliability of Arabic Version of the Lymphedema Functioning, Disability, and Health Questionnaire Post Mastectomy

Shimaa Tarek Shaker ^{1,*}, Hussein G. Mogahed ², Amr Abouzid ³, Mohamed M. Mazen ⁴, Marwa M. Selim ⁵ and Ahmed Mahmoud Zarraa ²

¹ Department of Physical Therapy for Surgery, Faculty of Physical therapy, Delta University, Egypt.

² Department of Physical Therapy for Surgery, Faculty of Physical therapy, Cairo University, Egypt.

³ Department of Surgical Oncology, Oncology Center, Mansoura University (OCMU), Egypt.

⁴ Department of Basic Science, Faculty of Physical therapy, Delta University, Egypt.

⁵ Medical Oncology Department, National Cancer Institute, Cairo University, Egypt.

* Shimaa Tarek Shaker, Department of Physical Therapy for Surgery, Faculty of Physical therapy, Delta University, Egypt. shimaatarek18@gmail.com. +201095965864

Abstract:

Objectives: This study's objective was to translate Arabically, test content validity, assess internal consistency reliability, and test-retest reliability of the Lymphedema Functioning, Disability, and Health Questionnaire (Lymph ICF) in its Arabic version, For those with post-mastectomy lymphedema. **Methods:** Ten specialists and eighty-six patients with grade 1 to 2 upper limb lymphedema following mastectomy participated in the study. For generating an Arabic version of Lymph ICF, Forward and backward translations were conducted, followed by development of the pre-final and final translated versions of Lymph ICF. A total of 167 forms of Arabic Lymph ICF (test and re-test forms) were completed by the patients. Statistical analysis was conducted using expert relevance proportion, content validity index, Cronbach's alpha, and Intraclass Correlation Coefficient (ICC). **Results:** For the Arabic version of Lymph ICF, the expert relevance proportion was 96.89%, with a Scale-Level Content Validity Index (S-CVI) of 96.9% and Item-Level Content Validity Index (I-CVI) ranging from 0.8 to 1.0 for individual items, the Cronbach's alpha was 0.761, and the ICC was 0.88 (95% CI: 0.744–0.935). **Conclusions:** The Arabic version of the Lymph ICF is a valid and reliable questionnaire that can significantly aid in the assessment and management of lymphedema in Arabic-speaking populations.

Keywords: Reliability; Lymphedema; Validity; Mastectomy.

Academic Editor: Ahmed Torad.

Received: December 2024, Revised: January 2025, Accepted: February 2025, Published: March 2025

Copyright: Open access publication under the terms and conditions of the Creative Commons Attribution [CC BY] license [<https://creativecommons.org/licenses/by/4.0/>].

1. Introduction

Cancer is a condition marked by altered metabolism and signaling that causes uncontrollable cell division and survival. It is one of the most devastating human diseases, with a range of clinical features and millions of deaths each year globally [1].

Globally, breast cancer (BC) is the most prevalent malignancy and the primary cause of death for women, posing a serious health threat to women [2]. Approximately 15% of patients with breast cancer get UEL, and this rate rises to 40% when axillary lymph node dissection is performed. Following breast surgery, impaired lymphatic drainage causes fluid buildup and swelling in the upper limb [3]. This leads to complications including infections, loss of limb function, pain, fatigue, and psychological issues [4,5].

Lymphedema assessment includes various factors such as patient characteristics (age, BMI, dominant side, affected side, comorbidities, etc.), type of surgery, circumferential measurements, and the Constant Murley Score. The Lymph ICF is also used to assess the condition [6].

The Lymph-ICF is a reliable and valid questionnaire based on International Classification of Functioning (ICF) terminology, utilized to evaluate participation restrictions, activity constraints, and functional impairments in patients with breast cancer who have arm lymphedema, especially following axillary dissection. It has been validated as an effective tool for assessing these limitations [7, 8]. The Lymph-ICF, originally developed by Devoogdt et al., has been translated into multiple languages, including Bahasa Malaysia by Meilani et al., Chinese by Zhao et al., Turkish by Kostanoglu et al., French by De Vrieze et al., and Danish by Grarup et al., specifically for breast cancer patients [9-14]. The absence of an Arabic version of the Lymph ICF questionnaire prompted the development of this study.

2. Materials and Methods

Study design:

The research employed a prospective observational study design. This study followed the validity and reliability assessment guidelines outlined by Borsa et al. [15] and Sousa and Rojjanasrirat [16].

Participants:

The expert panel comprised ten individuals with master's degrees or over 10 years of relevant experience, fluent in Arabic and English, and experienced with Arabic-speaking patients.

This study involved 86 Egyptian female patients, aged between 40 and 65 years, diagnosed with grade 1 to 2 upper limb lymphedema (according to the International Society of Lymphology criteria), after modified radical mastectomy (involves the removal of the entire breast, including the skin, areola, nipple, and breast tissue, primarily used to treat breast cancer) [17]. The patients had lymphedema for 3 to 6 months, which developed 6 to 9 months after surgery. All patients were oriented, literate in Arabic, and capable of understanding the questionnaire. Patients were excluded if they had severe chronic conditions (e.g., Heart failure, multiple sclerosis, rheumatoid arthritis, or neurological conditions), a history of recurrent cancer or metastasis, prior shoulder injuries or inflammatory arthritis, communication, vision, or hearing impairments, cognitive or mental health conditions.

Sample size calculation:

The sample size for Intraclass Correlation Coefficients (ICCs) was calculated using the formula provided by Walter et al. [18] Using the minimum acceptable ICC of 0.8, expected ICC of 0.9, significance level 0.05, statistical power 90% and number of repetitions 2, the minimum required sample size was about 86 subjects.

Ethical approval:

The study received approval from the Ethical Committee of the Faculty of Physical Therapy – Cairo University (No: P.T.REC/012/005386). Each participant provided signed informed consent after receiving comprehensive information about the study's goals, methodology, potential benefits, privacy policies, and data usage.

The study was registered on the Pan African Clinical Trials Registry by ID N.: PACTR202502864231115

Procedures:

The procedure for translating and adapting the Lymph ICF Questionnaire into Arabic was outlined by **Sousa and Rojjanasrirat** [16].

1. Forward Translation: The Lymph-ICF's English version was translated into Arabic by two bilingual translators, Arabic version one (Ar1) and Arabic version two (Ar2). Ar1 was familiar with the relevant concepts and terminology, while Ar2 lacked a medical background. The translations aimed to capture the intended meaning of each item.
2. Development of the Initial Draft: The two versions (Ar1 and Ar2) were compared, and inconsistencies in the translations were addressed. The final draft was created by integrating both versions and correcting any linguistic errors.
3. Blind Back-Translation: An English back-translation was made from the initial Arabic version by two translators, English version one (En1) and English version two (En2). One translator was experienced in health terminology,

while the other was knowledgeable in the cultural and linguistic subtleties of English. This step ensured the translation's accuracy.

4. Comparison of Back-Translated Versions: The two back-translated versions (En1 and En2) were compared with each other and with the original form of the questionnaire. The researchers assessed aspects such as instructions, items, sentence structure, and relevance. No further adjustments were needed, and the preliminary Arabic version was considered the pre-final version.
5. Content Validity Assessment: A panel of ten experts, each with a master's degree or ten years of experience in oncology physiotherapy or surgical oncology, evaluated the pre-final Arabic version for content validity. Each item was rated on a scale from 'irrelevant' to 'highly relevant', with suggestions for improvement. Once the expert content validity testing was completed, the pre-final version was approved as the final Arabic version.
6. Reliability Testing: Reliability testing of the final Arabic version was conducted with 167 data sheets (test-retest forms), the re-test was performed a week later.

Statistical analysis

For numerical and categorical data, descriptive statistics such as means, standard deviations, frequencies, and percentages were employed. Validity was assessed using the expert relevance proportion, the Scale-Level Content Validity Index (S-CVI), and the Item-Level Content Validity Index (I-CVI). Internal consistency reliability was measured with Cronbach's alpha, and test-retest reliability with ICC [19].

With SPSS version 25 for Windows, statistical analyses were conducted at a significance level of $p < 0.05$ with a combination of parametric and non-parametric statistical methods [20].

3. Results

Experts' Characteristics:

A multidisciplinary panel of 10 experts (seven Physiotherapists and three Surgeons) provided content validity assessments. Their professional experience ranged from 10 to 27 years, and their academic ranks varied from Assistant Lecturer to Professor, including three Associate Professors, one Professor, five Lecturers, and one Assistant Lecturer (Figure1).

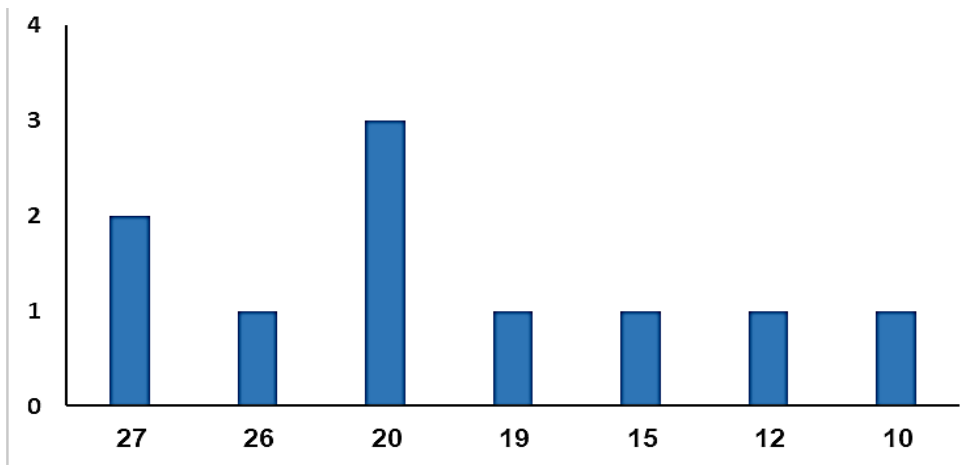


Figure 1. Expert's Experience.

Characteristics of patients:

All patients in the current study were recruited from Dar El Salam Cancer Hospital (Harmal) (46.51%) and Oncology Center at Mansoura University (OCMU) (47.68%) (Table1).

Table 1. Distribution of Patients across Hospitals.

Hospital	Frequency	Percentage
Dar El Salam Cancer Hospital Harmal	40	46.51%

Oncology Center at Mansoura University	41	47.68%
Drop out	5	5.81%

Considering the patients' clinical and demographic traits, the mean age was 52.21 (\pm 6.13) years and BMI was 29.37 kg/m² (\pm 2.06). The mean duration of lymphedema (DOL) was 4.30 months (\pm 1.12), and the mean time from operation to onset of lymphedema (TFOTOL) was 7.60 months (\pm 1.00). Lymphedema was grade 2 in 53% of the participants and grade 1 in 43% (**Table2**).

Table 2. Patient Demographics and Clinical Features.

	MEAN	SD \pm	Minimum	Maximum
Age (years)	52.21	6.13	41	65
Height (Cm)	161.45	18.12	154	165
Weight (kg)	79.35	5.15	68	97
BMI kg/m²	29.37	2.06	25.28	37.18
DOL (month)	4.30	1.12	3	6
TFOTOL (month)	7.60	1.00	6	9

Content validity I-CVI & S-CVI:

Content validity was assessed using the Item-Level Content Validity Index (I-CVI) and the Scale-Level Content Validity Index (S-CVI). The I-CVI values ranged from 0.8 to 1.0, while the S-CVI was 0.969. The mean expert relevance proportion was 96.89%, with five experts achieving perfect agreement (**Table3**) and (**Figure2**).

Table 3. Expert's proportion of relevance

Experts	No. of agreements (Relevant responses)	Expert proportion of relevance (%)
1	28	96.55
2	26	89.65
3	29	100
4	29	100
5	28	96.55
6	28	96.55
7	29	100
8	29	100
9	26	89.65
10	29	100
Mean	28	96.89

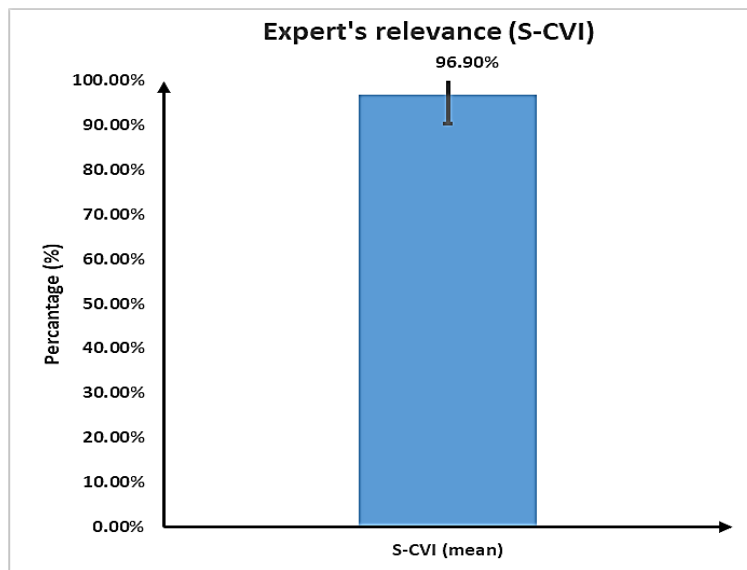


Figure 2. Expert's relevance (S-CVI)

Reliability:

Test-retest reliability was assessed through two administrations of the 29-item Arabic questionnaire, spaced one week apart. The Dropout rate was 5.81%, with only five participants failing to complete the retest phase (Table 4).

Table 4. Cases Summary

Total Cases	86
Valid cases	81
Invalid cases	5
Dropout rate	5.81%

The Internal consistency, measured by Cronbach's Alpha, was 0.764. Test-retest reliability, evaluated using ICC, showed values ranging from 0.744 to 0.935, with an average ICC of 0.88. (Figure 3) and (Table 5).

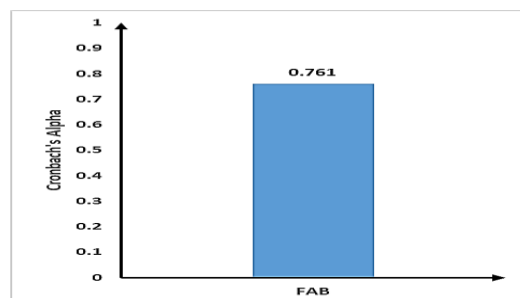


Figure 3. Cronbach's Alpha

Table 5. Average Intraclass Correlation Coefficient

Statistic	Interclass Correlation	95% Confidence Interval		F Test with True Value			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Average Measures	0.88c	0.744	0.935	6.128	79	3397	0.000

4. Discussion

The Lymph-ICF, in its Arabic version, showed strong psychometric properties, including excellent content validity, high reliability, and clinical suitability. The high expert consensus on item relevance and preservation of conceptual equivalence with the original version makes it a reliable tool for assessing upper limb lymphedema in Arabic-speaking populations.

Lymphedema assessment is crucial for early detection and intervention, allowing healthcare providers to identify the condition at an early stage and prevent complications. It also guides evidence-based clinical practices, ensuring standardized and effective care for patients. Additionally, ongoing assessment helps monitor the effectiveness of treatments, enabling adjustments as needed for optimal patient outcomes [21, 22, 23].

This study aimed to translate the Lymphedema Functioning, Disability, and Health Questionnaire (Lymph-ICF) into Arabic, test its content validity, and assess its internal consistency and test-retest reliability in patients with post-mastectomy lymphedema.

The Arabic version of the Lymph-ICF underwent a psychometric evaluation through the following parameters:

Validity:

Content validity is a key element of the psychometric assessment as it aims to ensure that the instrument measures what it is intended to measure [24].

The expert panel showed a strong consensus on the relevance of the items written for the Arabic version by determining high I-CVI values (0.8 to 1.0) and a S-CVI of 0.969, which exceeds the commonly accepted threshold of 0.90 for excellent content validity [25]. The other versions of the Lymph-ICF typically report high CVI values, with an I-CVI greater than or equal to 0.8 for individual items, and an S-CVI often exceeding the 0.90 threshold, which is considered excellent for content validity. This similarity suggests congruence between the original version and its adaptations for Arab countries, as well as the Malay [10] and Chinese versions [11] of the disability index.

The Arabic Lymph-ICF version is conceptually equivalent to the original. This was achieved by ensuring that the vocabulary and cultural aspects matched, regardless of language and cultural differences, while preserving the key concepts related to disability, functional impairment, and quality of life in relation to health.

Reliability:

Five participants only, who represent 5.81% of the total sample size, dropped out in the second round of the test-retest phase, which caused the loss of some data for the reliability analysis. However, a dropout rate of less than 10% is generally considered acceptable in studies assessing psychological properties over time [26]. New studies might suggest ways to improve follow-up rates, e.g. sending process reminders or planning follow-up visits.

The internal reliability of the Arabic version assessed by the Cronbach's alpha was 0.764, indicating good internal consistency. According to George and Mallery, values above 0.7 and up to 0.9 are considered acceptable. Higher values, which are near 0.9, appear to confer excellent consistency [27].

The test-retest reliability of the Arabic version of the Lymph-ICF was checked using ICC in the range of 0.744 to 0.935, indicating good to excellent reliability. These findings align with those of translated versions, including the

Chinese version (ICC: 0.88–0.97), Bahasa Malaysia version (ICC: 0.83–0.94), Danish version (ICC: 0.81–0.92), Turkish version (ICC: 0.79–0.91), and French version (ICC: 0.83–0.96) [9–14].

All of which also exhibited strong reliability. These results discovered that the Arabic version is helpful in the examination of upper limb lymphedema in the Arabic community due to its cross-cultural application and retest stability.

5. Conclusions

The Arabic version of the Lymphedema Functioning, Disability, and Health Questionnaire demonstrates adequate content validity, internal consistency and test-retest reliability for evaluating function, activity limitations, and participation restrictions in patients with post mastectomy lymphedema.

References

1. Upadhyay A. Cancer: An unknown territory; rethinking before going ahead. *Genes & diseases*. 2021 Sep 1;8(5):655–61.
2. Wang S, Chen R, Zheng R, Zhang S. Breast cancer and its global health implications. *Cancer Commun*. 2023;41(11):1183–94.
3. Cil T, Boileau JF, Chia S, DeCoteau MJ, Jerzak KJ, Koch A, Nixon N, Quan ML, Roberts A, Brezden-Masley C. The Canadian Breast Cancer Symposium 2023 Meeting Report.
4. Kirloskar KM, El Hawa AA, Kim KG, Dekker PK, Shaposhnik G, Fan KL. Prevention, diagnosis, and management of upper extremity lymphedema complications: altmetric analysis of online media. *Plastic and Reconstructive Surgery–Global Open*. 2022 Apr 1;10(4): e4024.
5. Anbari AB, Wanchai A, Armer JM. Breast cancer-related lymphedema and quality of life: A qualitative analysis over years of survivorship. *Chronic illness*. 2021 Sep;17(3):257–68.
6. Kostanoglu AL, Tarakçı E. Physical therapy enhances functions and quality of life in older patients with breast cancer-related lymphedema: a prospective experimental study. *Nigerian Journal of Clinical Practice*. 2021 Mar 1;24(3):387–92.
7. Augustin, Bross, Földi, Vanscheidt, Zschocke. Development, validation and clinical use of the FLQA-I, a disease-specific quality of life questionnaire for patients with lymphedema. *Vasa*. 2005 Feb 1;34(1):31–5.
8. Schaverien MV, Coroneos CJ. Surgical treatment of lymphedema. *Plastic and reconstructive surgery*. 2019 Sep 1;144(3):738–58.
9. Devoogdt N, Van Kampen M, Geraerts I, Coremans T, Christiaens MR. Lymphoedema Functioning, Disability and Health questionnaire (Lymph-ICF): reliability and validity. *Physical therapy*. 2011 Jun 1;91(6):944–57.
10. Meilani E, Zanudin A, Nordin NA. Psychometric Evaluation of the Bahasa Malaysia Version of the Lymphedema Functioning, Disability, and Health Questionnaire for Upper Limb Lymphedema in Patients with Breast Cancer-Related Lymphedema. *Lymphatic Research and Biology*. 2024 Jun 1;22(3):210–20.
11. Zhao H, Wu Y, Tao Y, Zhou C, De Vrieze T, Li X, Chen L. Psychometric validation of the Chinese version of the lymphedema functioning, disability, and health questionnaire for upper limb lymphedema in patients with breast cancer-related lymphedema. *Cancer Nursing*. 2022 Jan 1;45(1):70–82.
12. Kostanoglu A, Hosbay Z, Tarakci E. Lymphoedema functioning, disability and health questionnaire Turkish version: translation, cross-cultural adaptation and validation. *Journal of physical therapy science*. 2016;28(6):1728–32.
13. De Vrieze T, Fripiat J, Deltombe T, Gebruers N, Tjalma WA, Nevelsteen I, Thomis S, Vandermeeren L, Belgrado JP, De Groef A, Devoogdt N. Cross-cultural validation of the French version of the lymphedema functioning, disability and health questionnaire for upper limb lymphedema (lymph-ICF-UL). *Disability and rehabilitation*. 2021 Sep 11;43(19):2797–804.
14. Grarup KR, Devoogdt N, Strand LI. The Danish version of Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF) for breast cancer survivors: Translation and cultural adaptation followed by validity and reliability testing. *Physiotherapy theory and practice*. 2019 Apr 3;35(4):327–40.
15. Borsari JC, Damásio BF, Bandeira DR. Cross-cultural adaptation and validation of psychological instruments: Some considerations. *Paidéia (Ribeirão Preto)*. 2012; 22:423–32.
16. Sousa VD, Rojjanasrirat W. Translation, adaptation and validation of instruments or scales for use in cross-cultural health care research: a clear and user-friendly guideline. *Journal of evaluation in clinical practice*. 2011 Apr;17(2):268–74.
17. Jones C, Lancaster R. Evolution of operative technique for mastectomy. *The Surgical Clinics of North America*. 2018 May 21;98(4):835–44.
18. Walter SD, Eliasziw M, Donner A. Sample size and optimal designs for reliability studies. *Statistics in medicine*. 1998 Jan 15;17(1):101–10.

-
19. Gerstman BB. Basic biostatistics. Burlington (MA): Jones & Bartlett Publishers; 2014.
 20. Pallant J. SPSS survival manual: A step-by-step guide to data analysis using IBM SPSS. Routledge; 2020 Jul 16.
 21. Armer JM, Ballman KV, McCall L, Armer NC, Sun Y, Udmuangpia T, Hunt KK, Mittendorf EA, Byrd DR, Julian TB, Boughey JC. Lymphedema symptoms and limb measurement changes in breast cancer survivors treated with neoadjuvant chemotherapy and axillary dissection: results of American College of Surgeons Oncology Group (ACOSOG) Z1071 (Alliance) substudy. Supportive care in cancer. 2019 Feb; 27:495-503.
 22. Weiss J, Daniel T. Validation of the lymphedema life impact scale (LLIS): a condition-specific measurement tool for persons with lymphedema. Lymphology. 2015 Jan 28;48(3):128-38.
 23. Tan M, Salim S, Beshr M, Guni A, Onida S, Lane T, Davies AH. A methodologic assessment of lymphedema clinical practice guidelines. Journal of Vascular Surgery: Venous and Lymphatic Disorders. 2020 Nov 1;8(6):1111-8.
 24. Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. Research in nursing & health. 2006 Oct;29(5):489-97.
 25. Lenz ER. Measurement in nursing and health research. Springer publishing company; 2010 Apr 17.
 26. Terwee CB, Bot SD, de Boer MR, Van der Windt DA, Knol DL, Dekker J, Bouter LM, de Vet HC. Quality criteria were proposed for measurement properties of health status questionnaires. Journal of clinical epidemiology. 2007 Jan 1;60(1):34-42.
 27. George D, Mallery P. SPSS for Windows step by step: A simple guide and reference, 11.0 update. 4th ed. Boston: Allyn & Bacon; 2003.