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Research

Reliability and validity of the Quality-of-Life Measurement for Limb Lymphedema (LYMQOL) for Japanese women with upper extremity lymphedema

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ABSTRACT

Objective : This study examined the reliability and validity of the Japanese version of the Lymphedema Quality-of-Life Questionnaire-Arm (LYMQOL-Arm) to assess the quality of life (QOL) of women with upper extremity lymphedema after breast cancer treatment.

Methods : Forty female patients diagnosed with upper limb lymphedema after breast cancer treatment answered two self-administered questionnaires (LYMQOL-Arm and the Japanese version of the EORTC QLQ-C30). Participants were recruited from two rehabilitation centers and one lymphedema research institute in Japan between January 2023 and May 2024. Data on demographic characteristics, duration of edema, lymphedema severity, and questionnaire responses were collected and analyzed.

Results : The internal consistency of LYMQOL-Arm was strong, with Cronbach's α coefficients ranging from 0.799 to 0.924. Test-retest reliability analysis revealed high intraclass correlation coefficients (ICC), particularly for the total score (ICC=0.915; 95% confidence interval=0.835-0.957). Criterion-related validity was evaluated between the LYMQOL-Arm and EORTC QLQ-C30. The function domain of LYMQOL-Arm was negatively significantly correlated with four QLQ-30 function scales (physical, role, social, and cognitive, with r values of -0.385 to -0.565, $p<0.01$). Significant differences exist in the scores of three domains appearance ($p=0.006$), symptoms ($p=0.003$), overall QOL ($p=0.042$) and total scores ($p=0.031$) between the groups with International Society of Lymphology (ISL) stage 0-1 and ISL stage 2-3.

Conclusion : The Japanese version of LYMQOL-Arm is a reliable and valid instrument for assessing the QOL of Japanese women with breast cancer-related lymphedema.

KEY WORDS : lymphedema, quality of life, reliability, validity, upper extremity

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Introduction

According to the Cancer Information Service of the National Cancer Center, breast cancer has the highest incidence rate among women in Japan compared to other types of cancer, and incidence is increasing every year.[1] Women with breast cancer undergoing treatment have a 10-year relative survival rate of 92.1%.[2] However, long-term breast cancer treatment has side effects, including lymphedema, which impairs physical function and causes fatigue, pain, and psychological distress, affecting the ability to perform activities of daily living and reducing the quality of life (QOL). Furthermore, the disease is associated with decreased self-confidence and increased self-consciousness.[3] Therefore, accurately assessing the QOL of affected women is crucial for prompt treatment.

The QOL of women treated for breast cancer can be measured using several questionnaires, including the European Organization for Research and Treatment (EORTC) QOL Questionnaire (QLQ-C30), EORTC QLQ-BR23 (breast cancer specific module), and Functional Assessment of Cancer Therapy-Breast (FACT-B).[4-6] However, it is unknown whether these questionnaires adequately assess the QOL of patients with lymphedema. The QOL of women with upper extremity lymphedema can be evaluated using the Upper Limb Lymphedema-27 (ULL-27),[7] Lymphedema Quality of Life Inventory (LyQLI),[8] Lymphedema Functioning, Disability and Health Questionnaire (Lymph-ICF),[9] and Lymphedema Quality-of-Life Questionnaire (LYMQOL).[10] Recent systematic reviews have identified the ULL-27 and the LYMQOL as the most frequently cited and psychometrically validated instruments for assessing health-related quality of life (HRQOL) in patients with lymphedema.[11][12] Both tools comprehensively address the physical, psychological, and social dimensions of QOL. However, a closer comparison of the item composition reveals that the LYMQOL employs more familiar and accessible language, allowing respondents to intuitively reflect on and respond based on their daily experiences. This feature facilitates the elicitation of patients' personal narratives and enhances the scale's applicability as a communication tool in nursing practice and clinical care settings. In contrast, instruments such as the LyQLI and Lymph-ICF place a stronger emphasis on functional assessment based on the WHO's International Classification of Functioning, Disability and Health (ICF). While these frameworks provide a valuable structure for evaluating disability and function, their content is often more technical, which may limit their immediate usability in clinical nursing contexts. Specifically, they may not fully capture the nuanced everyday challenges and subjective concerns that are central to nursing care. Therefore, LYMQOL may offer a more practical and patient-centered approach for evaluating QOL in individuals with lymphedema, especially within nursing settings. LYMQOL-Arm and LYMQOL-Leg assess the QOL of women with upper and lower limb lymphedema, respectively. LYMQOL-Arm has been translated into Turkish, Swedish, and Chinese, and its validity and reliability have been verified.[13-15] Although LYMQOL-Arm and LYMQOL-Leg have been translated into Japanese, the reliability and validity of the former have not been evaluated.[16] This study assessed the reliability and validity of the Japanese version of LYMQOL-Arm to determine its utility for measuring the QOL of Japanese women with lymphedema after breast cancer treatment.

Methods

1. Participants and Settings

Participants were recruited from two rehabilitation centers and a lymphedema research institute in Japan between January 2023 and May 2024. Outpatients were recruited by therapists and research assistants using pamphlets. The inclusion criterion was patients with breast cancer aged 20–75 years. The exclusion criterion was patients with breast cancer and active malignancy or undergoing chemotherapy or radiotherapy. This study included ISL Stage 0 patients, as they often experience limb discomfort and functional limitations despite the absence of visible swelling, which may affect their QOL. Given the importance of early intervention and the clinical significance of QOL assessment in this stage, as supported by previous studies, their inclusion was deemed appropriate.[17] The required sample size was determined using the Steel-Dwass test, in consultation with a statistical expert. A sample size of at least 30

participants was estimated to provide a statistical power of 80%.

2. Questionnaires

1) LYMQOL-Arm

The LYMQOL-Arm evaluates four domains: function 1 (a-h), 2,3; appearance 4,5,6,7,8; symptoms 9, 10, 11, 12, 13, 14; and mood 15, 16, 17, 18, 19 20. Each item is rated on a 4-point Likert scale ranging from 1 to 4.[10] The total score was calculated by summing item scores and dividing by the number of responses. Higher scores indicated higher disease severity and lower QOL. If more than 50% of the items in a domain were unanswered, the total score for that domain was considered zero. The last item evaluates overall QOL (Q21) on a scale from 0 (lowest) to 10 (highest). The validity, cultural appropriateness, and translation accuracy of the LYMQOL-Arm were confirmed by two experts in the field and a native English speaker fluent in Japanese. Since the original English expressions had corresponding Japanese expressions, no modifications were made for cultural adaptation.

2) EORTC QLQ-C30

The EORTC QLQ-C30 was developed by Aaronson et al.,[4] and the reliability and validity of the Japanese version were assessed by Kobayashi et al.[18] The EORTC QLQ-C30 is a widely utilized instrument for assessing the quality of life in cancer patients and has been extensively employed in oncology clinical trials. Furthermore, the validity of the original LYMQOL and the Japanese version of the LYMQOL for the lower limb has also been evaluated using this scale. The questionnaire contains five functioning scales (physical, role, cognitive, emotional, and social), a global health status scale, eight symptom scales (nausea and vomiting, fatigue, dyspnea, pain, insomnia, appetite loss, constipation, and diarrhea), and a financial difficulties scale. The five functional functioning scales and the global health status scale are combined to form a function scale, and higher scores indicate better QOL.[19] The eight symptom scales and the financial difficulties scale are combined to form a symptom scale, and higher scores indicate worse QOL.

3. Data collection and analysis

The participants were asked to complete LYMQOL-Arm twice. A research assistant added medical record data on lymphedema staging to the questionnaire and then distributed it to the participants who expressed interest in the study. Data on age, weight, height, the duration of edema, and International Society of Lymphology (ISL) lymphedema staging and the responses to LYMQOL-Arm and EORTC QLQ-C30 (Japanese versions) were collected and analyzed. Participation in the study was confirmed by signing a written consent form and completing the first questionnaire. The participants were asked to answer the LYMQOL-Arm questionnaire again within a period of two to four weeks.

4. Statistical analysis

Data were analyzed after excluding missing values from questionnaire responses. Data analysis was performed using Microsoft Excel and SPSS version 29.0 (IBM Corp., Armonk, NY). Normally distributed continuous variables were expressed as the mean ± standard deviation. Non-normally distributed continuous variables were expressed as medians and interquartile ranges. P-values of less than 0.05 indicated statistical significance.

1) Reliability

Internal consistency was assessed using Cronbach's alpha coefficient, and values higher than 0.7 indicated good reliability.[20] The test-retest reliability of total and subscale scores was evaluated using intraclass correlation coefficients. The level of reliability was determined based on the 95% confidence interval of the ICC estimate, following the general guideline: values less than 0.5 indicate poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability.[21]

2) Validity

Criterion-related validity was evaluated by calculating the Pearson correlation coefficients between the LYMQOL-Arm and EORTC QLQ-C30 domains. Construct validity was examined by dividing the participants into two groups based on lymphedema severity according to ISL staging (subclinical or mild [stage 0 or Ⅰ], moderate or severe [stage Ⅱ or Late-Stage Ⅱ or Ⅲ]) and comparing domain scores using the Mann-Whitney U test.[22] The reason for selecting this method is that, theoretically, it is expected that QOL decreases

Table 1 Socio-demographic and Clinical characteristics of the study sample

N = 40

Socio-demographic		M ± SD. n (%)
Age (years)		59.8 ± 9.1
Length (cm)		156.5 ± 4.9
Weight (kg)		60.3 ± 11.6
BMI (kg/m^2)		24.6 ± 4.6
ISL staging	Stage 0	2 (5.0%)
	Stage Ⅰ	9 (22.5%)
	Stage Ⅱ	18 (45.0%)
	Late-Stage Ⅱ	2 (5.0%)
	Stage Ⅲ	1 (2.5%)
	Unknown	8 (20.0%)
Edema site	Left side	22 (55.0%)
	Right side	18 (45.0%)
Duration of edema (year)	Less than 1	12 (30.0%)
	1 to less than 3	14 (35.0%)
	3 to less than 6	8 (20.0%)
	More than 6	6 (15.0%)

Note. ;
ISL staging: International Society of Lymphology staging
Stage 0 = A subclinical state where swelling is not evident despite impaired lymph transport. This stage may exist for months or years before edema becomes evident.
Stage 1 = This represents early onset of the condition where there is accumulation of tissue fluid that subsides with limb elevation. The edema may be pitting at this stage.
Stage 2 = Persistent pitting edema is manifest, and limb elevation alone does not reduce swelling.
Late Stage 2 = Persistent swelling, there may or may not be pitting as tissue fibrosis is more evident.
Stage 3 = The tissue is hard (fibrotic) and pitting edema may be absent. Skin changes such as thickening, hyperpigmentation, increased skin folds, fat deposits and warty over growths develop. The most severe changes are also known as elephantiasis.

as the ISL stage progresses. Furthermore, this approach was also employed in the validation of the Japanese version of the LYMQOL-Leg in a previous study, demonstrating its consistency and applicability.[16)]

5. Ethical considerations

This study was approved by the Research Ethics Committee of Fujita Health University (Approval No. HM23-305). All patients gave written informed consent after being informed about the study objectives.

Results

1. Patient characteristics

Forty-two women were recruited from three facilities. Among them, 40 consented to participate and completed the first questionnaire, and 36 completed the second questionnaire. The demographic characteristics of the participants are represented in **Table 1**.

The mean age of the participants was 59.8 ± 9.1 years, and the mean body mass index was 24.6 ± 4.6 kg/m^2. The percentage of patients with lymphedema stages 0, I, II, late-stage Ⅱ, Ⅲ and an unknown stage was 5%, 22.5%, 45%, 5. 0%, 2. 5%, and 20%. Moreover, 55% of the participants had edema in the left arm and 45% in the right.

2. Questionnaire reliability

The results of the internal consistency analysis of

Table 2 Reliability (Internal Consistency)

N=40

LYMQOL-Arm Domain	Number of items	Cronbach α
Function	10	0.882
Appearance	5	0.826
Symptoms	6	0.866
Mood	6	0.799
Total score	27	0.924

Table 3 Reliability (Stability)

N=36

LYMQOL-Arm Domain	Test-retest		
	First scores	Second scores	ICC (95% CI)
Function	2.2	2.3	0.831* (0.671-0.914)
Appearance	2.4	2.6	0.847* (0.702-0.922)
Symptoms	2.7	2.8	0.932* (0.868-0.965)
Mood	2.4	2.3	0.757* (0.526-0.876)
Total score	16.2	16.8	0.915* (0.835-0.957)
Overall QOL	6.5	6.8	0.827* (0.662-0.911)

Note.; ICC: Intra-class correlation coefficient. Cronbach's alpha coefficient. *p <.05

LYMQOL showed that Cronbach's alpha values for Function, Appearance, Mood and Symptoms were higher than 0.7 (**Table 2**). The intraclass correlation coefficient of total scores was 0.915 (95% confidence interval=0.835–0.957, p<0.05) (**Table 3**).

3. Questionnaire validity

The Pearson correlation coefficients (r) between the corresponding domains of LYMQOL-Arm and EORTC QLQ-C30 are shown in **Table 4**. The "appearance" domain was not compared because EORTC QLQ-C30 lacked this domain. The symptoms, mood, and overall QOL domains of LYMQOL-Arm were significantly correlated with the corresponding subscales in EORTC QLQ-C30, with r values of 0.698, -0.485, and 0.652, respectively (p<0.001). However, the function domain of LYMQOL-Arm was not significantly correlated with the emotional subscale of EORTC QLQ-C30 (r=-0.301). The function domain of LYMQOL was negatively significantly correlated with four QLQ-30 function scales (physical, role, social, and cognitive, with r values of -0.385 to -0.565, p<0.01).

Appearance, symptom, overall QOL, and total scores differed significantly between the severity groups (**Table 5**). Although there were no significant between-group differences in functioning and mood scores, the medium effect size was 0.30 and 0.32, respectively. Total scores were positively significantly associated with ISL stages, although the between-group differences in median scores in each domain were small (0.4–0.7).

Discussion

This study examined the criterion-related and construct validity and reliability of the Japanese version of the LYMQOL-Arm to promote its use in clinical practice and research to measure the QOL of Japanese women with lymphedema after breast cancer treatment.

The reliability of the questionnaire was high, with Cronbach's alpha coefficients ranging from 0.799 to 0.924.[20] Furthermore, test-retest reliability was good to excellent, with intraclass correlation coefficients varying from 0.757 to 0.932.[21] These findings align with those of studies from other countries, suggesting consistent reliability across cultures.[13-15]

Table 4 Validity (Criterion-related validity)

N=40

LYMQOL-Arm	EORTC QLQ-C30						
	Physical	Role	Social	Cognitive	Emotional	Symptoms	Overall
Function	-.443**	-.434**	-.565**	-.385*	-0.301	.500**	-.547**
Appearance	-0.171	-.481**	-.338*	-0.226	-0.027	.461**	-.480**
Symptoms	-.513**	-.408**	-.529**	-0.258	-0.207	.698**	-.596**
Mood	-0.272	-.445**	-.422**	-.514**	-.485**	.426**	-.484**
Overall QOL	0.31	.516**	.529**	0.301	0.127	-.599**	.652**

Note.; Pearson's correlation coefficient. $^{**}p<.001$ $^{*}p<.01$
The values that are underlined indicate the results of comparisons between corresponding items on the two scales.

Table 5 Construct validity

N=32

ISL Stage / LYMQOL-Arm	Stage 0 ~ I	Stage Ⅱ ~ Ⅲ	P-value	R
	Median (IQR)	Median (IQR)		
Function	1.9 (1.5-2.5)	2.3 (2.3-2.8)	0.104	0.30
Appearance	2.0 (1.5-2.4)	2.6 (2.2-3.1)	0.006	0.48
Symptoms	2.3 (2.0-2.8)	3.0 (2.7-3.3)	0.003	0.51
Mood	2.2 (1.9-2.6)	2.7 (2.4-2.9)	0.061	0.32
Overall QOL	7.0 (6.5-9.0)	6.0 (5.0-7.0)	0.042	0.36
Total score	9.1 (7.8-10.0)	10.6 (10.1-11.7)	0.031	-0.39

Note.; Mann Whitney U test

This study validated LYMQOL-Arm using the Japanese version of EORTC QLQ C-30. The functioning domain of LYMQOL-Arm was negatively significantly correlated with four functioning scales of EORTC QLQ C-30 (physical, role, social, and cognitive; r=-0.443, -0.434, -0.565, and -0.385). Similarly, there was a good correlation between the emotion domains (r=-0.485, $p<0.001$). Moderate-to-good correlations exist between symptoms and global domains ($0.4<r<0.7$, $p<0.001$). These findings agree with studies from other countries,[13-15] demonstrating that LYMQOL-Arm is a valid tool for measuring QOL in Japanese patients with lymphedema.

In this study, we examined the construct validity of the LYMQOL-Arm by conducting a group comparison based on ISL staging. Previous studies on translated versions of LYMQOL have used varying approaches, with many relying on correlation analyses with existing scales.[13)14)23)] Given this lack of consistency, we adopted a group comparison approach based on ISL staging to maintain methodological alignment with previous research on the LYMQOL-Leg.[16)] This approach was chosen to better capture quality of life (QOL) differences according to the progression of lymphedema. However, a previous study reported no significant association between LYMQOL scores and ISL staging.[24)] The study classified participants into three groups (Stages Ⅰ, Ⅱ, Ⅲ), which may have made it difficult to detect clear differences between groups. In contrast, our study categorized participants into two groups (Stages 0 – Ⅰ vs. Stages Ⅱ – Ⅲ) to more clearly identify the impact of disease progression on QOL. Furthermore, differences in the distribution of ISL stages among participants between the present study and previous study may have contributed to the variation in results. Therefore, differences in both the classification method and stage distribution could have influenced the discrepancies in findings.

ISL stages negatively correlate with QOL. We observed that LYMQOL scores positively correlated with ISL stages. Significant differences were observed in the scores of three domains (appearance, symptom, and overall QOL) and total scores between stages 0 – Ⅰ and Ⅱ – Ⅲ. These findings demonstrate that LYMQOL-Arm shows high sensitivity to detect changes in lymphedema severity and that the Japanese version of LYMQOL-Arm can assess QOL across disease severity stages. However, although the scores of the function and emotion domains were not significantly different between these groups, moderate effect sizes (0.30 and 0.32, respectively) suggest that these domains are clinically relevant. Thus, additional studies with larger sample sizes can increase statistical power and assess the impact of lymphedema severity on all aspects of QOL.

Despite significant differences in several domains between the severity groups (stage 0 – Ⅰ and stage Ⅱ – Ⅲ), the clinical significance of these differences is unknown. In addition, although QOL was lower in the group with stage Ⅱ – Ⅲ than in the group with stage 0 – Ⅰ, the between-group differences in median scores were small (0.4–0.7), which may be attributed to the small sample size or the distribution of the number of patients across each ISL stages.

The mean age of the participants was 59.8 ± 9.1 years, consistent with previous data from patients with breast cancer-related lymphedema (58.5 ± 10.7 years).[25] No significant difference was observed in the incidence of edema between the two arms.

This study has limitations. First, although the cohort included patients with different ISL stages, only 2.5% had stage III, potentially leading to selection bias. Therefore, the effect of severe lymphedema on QOL could not be assessed. Second, 20% of the participants had an unknown stage, potentially leading to selection bias. Therefore, the results should be generalized with caution. Third, although the participation rate was high (40 of 42 patients eligible for inclusion in the study agreed to participate), selecting participants willing to cooperate may have caused selection bias. Fourth, in this study, the LYMQOL-Arm was re-administered 2 to 4 weeks later for test-retest reliability assessment. However, there is a possibility that changes in the lymphedema stage over time may have influenced the reliability of the LYMQOL-Arm scores.

Conclusion

The Japanese version of LYMQOL-Arm is a valid and reliable tool for measuring QOL in Japanese patients with breast cancer-related lymphedema. The results indicate that LYMQOL-Arm can be used in the clinic to assess breast cancer treatment outcomes.

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Conflict of interest statement

The authors declare that they have no conflicts of interest to disclose.

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上肢リンパ浮腫を有する日本人女性を対象とした the Quality-of-Life Measurement for Limb Lymphedema（LYMQOL）の信頼性と妥当性の検討

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要　旨

目的：本研究では、乳がん治療歴のある上肢リンパ浮腫患者の生活の質（QOL）を評価するための日本語版 Lymphedema Quality-of-Life Questionnaire-Arm（LYMQOL-Arm）の信頼性および妥当性を検討した。

方法：乳がん治療後に上肢リンパ浮腫と診断された女性 40 名を対象に、2 回の自己記入式質問票（LYMQOL-Arm および日本語版 EORTC QLQ-C30）にてデータ収集を行なった。参加者は、2023 年 1 月から 2024 年 5 月までの間に、日本国内の 2 つのリハビリテーションセンターと 1 つのリンパ浮腫研究所から募集された。また、人口統計学的特性、浮腫の罹患期間、リンパ浮腫の重症度などについてデータ収集した。

結果：LYMQOL-Arm の内的一貫性は高く、Cronbach's α では 0.799 から 0.924 であった。テスト－再テスト法による信頼性は、特に総合スコアにおいて高いクラス内相関係数（ICC）が示された（ICC＝0.915、95%信頼区間＝0.835～0.957）。基準関連妥当性は LYMQOL-Arm と EORTC QLQ-C30 の間で評価され、LYMQOL-Arm の function は、QLQ-C30 の 4 つの function scales（physical、role、social、cognitive）と有意な負の相関を示した（r ＝－0.385～－0.565、p<0.01）。国際リンパ学会（ISL）のステージ 0 － 1 群とステージ 2 － 3 群の間で、appearance（p＝0.006）、symptoms（p＝0.003）、overall QOL（p＝0.042）、および総合スコア（p＝0.031）に有意差が認められた。

結論：日本語版 LYMQOL-Arm は、乳がん関連リンパ浮腫を有する日本人女性の QOL を評価するための信頼性が高く、妥当性のある尺度であることが示された。

キーワード：リンパ浮腫、生活の質、信頼性、妥当性、上肢