

Research

Japanese Version of the Quality of Life Measurement for Limb Lymphedema (leg) (J-LYMQOL-I) : its Reliability and Validity

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ABSTRACT

BACKGROUND : Lymphedema is a condition that manifests as swelling when the lymphatic system fails to remove excess interstitial fluid from the tissues. Cancer treatments, such as radical surgery including lymph node dissection, chemotherapy, and radiotherapy, contribute to the risk of secondary lymphedema. To plan the treatment for lymphedema and monitor the patient's progress, leg or arm swelling and function of the limbs need to be assessed.

OBJECTIVE : The purpose of this study was to investigate the reliability (test-retest, internal consistency) and validity (criteria-related validity, construct validity) of data obtained with the Japanese version of the Quality of Life Measurement for Limb Lymphedema (leg) (J-LYMQOL-I).

METHOD : Two hundred and eleven women with lower limb lymphedema were recruited between September 2012 and October 2013 from the lymphedema outpatient services in four Tohoku areas and one Kanto area of Japan, and were assessed by self-administered questionnaires that included the J-LYMQOL-I.

RESULTS : The Cronbach's alpha coefficient of the J-LYMQOL-I was .925, and subscales ranged from .898 to .944, $p < .05$, indicating a high internal reliability of the tool. Test-retest reliability was moderate ($r = .589$, $p < .05$). A confirmatory factor analysis revealed that the four-factor model of the J-LYMQOL-I fitted the data. The Pearson correlation coefficient, between the J-LYMQOL-I and J-EORTC QLQ-C30, was .702, indicating a high criteria-related validity for all domains, except one.

CONCLUSION : The J-LYMQOL-I has high construct validity and reliability and can be used for clinical assessment of QOL in patients with lower limb lymphedema.

KEY WORDS : lymphedema, quality of life, LYMQOL, reliability, validity, condition-specific QOL

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INTRODUCTION

Lymphedema is a condition that manifests as swelling when the lymphatic system fails to remove excess interstitial fluid from the tissues. Cancer treatments, such as radical surgery including lymph node dissection, chemotherapy, and radiotherapy, contribute to the risk of secondary lymphedema. Secondary lymphedema is common in female survivors of breast or uterine cancers. Lymphedema can be associated with reduced quality of life (QOL). Female cancer survivors with lymphedema experience physical problems including fatigue, pain, and cutaneous dryness. Additionally, these survivors can experience psychological and social problems, including impaired self-esteem, negative life outlook, reduced desire to leave home, decreased activity levels, and decreased income. Secondary upper or lower limb lymphedema alters the female cancer survivor's appearance. Therefore, appropriate assessment of patient condition, including QOL, is required for timely treatment and care of lymphedema.

Initially, most investigators assessed patient QOL using a health-related quality of life (HRQOL) instrument, such as the Medical Outcome Study 36-item short form health survey (SF-36)¹⁾. The Japanese version of the SF-36²⁾ was developed in 1998. However, this general questionnaire was not suitable for determining the well-being of patients with cancer. Therefore, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core30 question (EORTC QLQ-C30)³⁾ and Function Assessment of Cancer Therapy (FACT)⁴⁾ were developed, along with several condition-specific QOL instruments. For example, the EORTC QLQ-LC13⁵⁾ and FACT-L⁶⁾ were developed for lung cancer patients, whereas the EORTC QLQ-BR23⁷⁾ and FACT-P⁸⁾ were developed for breast cancer patients. These instruments were translated and are used widely as clinical tools in Japan. The EORTC QLQ-CX24⁹⁾ and EORTC QLQ-EN24¹⁰⁾ were developed for patients with gynecological cancers. However, the EORTC QLQ-EN24 has not yet been translated into Japanese. The difficulty in using these instruments includes lack of sensitivity to issues regarding lymphedema. For example, the EORTC QLQ-EN24 consists of 13 factors and 24 items. However, it contains only two

items related to lymphedema. The two items regarding lower limb lymphedema are questions concerning "swelling of the lower limb" and "sensation of heaviness of the lower limb." It cannot be said that the QOL of patients with lymphedema is adequately evaluated using only these two items. It is important to use a condition-specific instrument to assess the patient-specific effects of all kinds of lymphedema. In recent literature, several lymphedema/chronic edema condition-specific functional or health-related QOL assessment instruments are described. The Upper Limb Lymphedema 27 (ULL27)¹¹⁾ and the Lymphedema Functioning, Disability and Health Questionnaire (Lymph-ICF)¹²⁾ are only applicable to breast cancer-related lymphedema. The Freiburg Life Quality Assessment Lymphedema (FLQA-L)¹³⁾ and the Lymphedema Quality of Life Inventory (LQOLI)¹⁴⁾ can be used for a wide range of patients with lymphedema. However, these instruments lack sensitivity towards issues that relate to upper or lower limb lymphedema. Few patient-reported outcome-measuring instruments exist to measure the impact of all types of lymphedema and lymphedema of different extremities. The Quality of Life Measure for Limb Lymphoedema (LYMQOL)¹⁵⁾ is the only known English QOL instrument available to measure all types of lymphedema. Although some health-related QOL instruments and condition-specific QOL instruments for cancer were translated into Japanese, no condition-specific QOL instrument for lymphedema has been developed and translated specifically for Japan. The purpose of this study was to create a Japanese version of the LYMQOL and test its reliability and validity in Japanese patients with lymphedema. At this time, we will focus only the results of LYMQOL (leg).

METHODS

1. Procedure

The LYMQOL¹⁵⁾ was developed by experienced healthcare professionals in the lymphedema service in Derby, UK. It consists of two instruments, one for arm lymphedema and one for leg lymphedema (the LYMQOL [arm and leg]). The LYMQOL (arm and leg) comprises self-report questionnaires consisting of 23 statements (arm ver.) or 22 statements (leg ver.).

The LYMQOL [leg] has four domains : function (8 items), appearance (7 items), symptoms (5 items), and emotion (6 items). It also includes an overall QOL value, between 0–10, as patient–indicated QOL. Except for the overall QOL, the scale indicates the patient’s perception of each item, with scores ranging from 1 (not at all) to 4 (a lot). The scores for each domain are added and divided by the total number of questions answered to provide a total score. If answered questions constituted <50% of items, the whole domain is scored as 0. A higher score on the LYMQOL indicates more functional problems related to leg lymphedema. The developer of the original LYMQOLP obtained permission to develop the Japanese version. The original LYMQOL was translated into Japanese by independent translators. The translation considered the cultural and lifestyle context, making use of appropriate idioms. Any differences in the translations were discussed, and once resolved, they were integrated into the provisional LYMQOL questionnaire. An initial back translation was done, and then, the process of forward and back translation was repeated until a satisfactory translation was achieved and the Japanese version of the LYMQOL finalized.

2. Participants

The present study investigated the reliability and validity of data obtained using the Japanese version of LYMQOL (leg). Two hundred eleven patients with gynecological cancer participated in this study. The patients were recruited between September 2012 and October 2013 from the lymphedema outpatient services in four Tohoku areas and one Kanto area, Japan. Patients over 20 years of age, who consented to take part in this study, were included. Exclusion criteria were active malignancy and current chemotherapy and radiotherapy.

3. Study design

Each patient completed three questionnaires : the LYMQOL, the EORTC QLQ C-30 (ver. 3)¹⁶⁾, and an author–developed questionnaire. The following data were collected from patient medical records : age, body weight, height, date and type of gynecological surgery, and International Society of Lymphology (ISL) lymphedema staging. Some patients received a second LYMQOL at home (with an interval of 2 weeks), which

they returned it to our department by mail.

4. Data analysis

All data were managed and analyzed using Microsoft® Excel® and SPSS (Version 22.0J for Windows ; SPSS Inc., Chicago, IL).

1) Reliability

Intraclass correlation coefficients were used to determine test–retest reliability of the total score of the LYMQOL. Cronbach’s alpha coefficients (range 0 to 1.0), a measure of internal consistency, wherein a coefficient = 1.0 indicates perfect internal consistency, were used to assess reliability. Generally, values > .70 are considered significant. Internal consistency was used to measure the correlation between questions on a particular scale. A high inter–item correlation suggests that all of the questions assess the same factor of interest.

2) Validity

The validity of LYMQOL was investigated in two ways. First, we assessed criterion validity by comparing the Japanese version of the LYMQOL with the Japanese version of the EORTC QLQ–C30 (ver. 3)¹⁶⁾. We used the Pearson correlation coefficient for all scores. Second, construct validity was assessed. We postulated that patients with more severe lymphedema would have poorer QOL. In the Japanese version of the LYMQOL, a higher domain score indicated lower patient QOL. We compared the ISL staging consensus with scores for each domain, using a nonparametric Kruskal–Wallis test. To analyze the factor structure and stability of the LYMQOL, we conducted a longitudinal confirmatory factor analysis using IBM SPSS AMOS version 22. To account for the four domains of QOL (function, appearance, symptoms, emotion), as in the original LYMQOL, we used aggregate analysis, which appropriately adjusts parameter standard errors and goodness–of–fit statistics in response to a nested data structure. The model is illustrated in **Figure 1**.

5. Ethical considerations

Ethical approval was obtained from the Ethics Committee of Tohoku University Graduate School of Medicine (No. 2011–178). Patients were asked to sign a consent form prior to participation and were informed of the risks and benefits associated with participation.

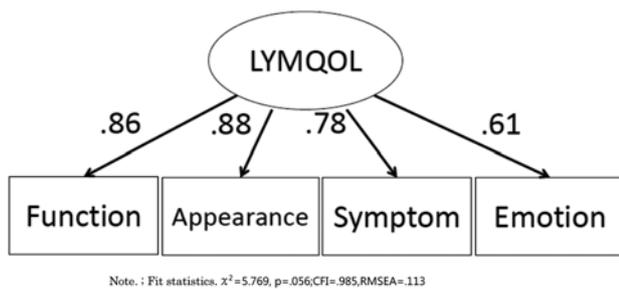


Figure 1 Longitudinal confirmatory factor analysis of the LYMQOL (leg)

RESULTS

1. Descriptive characteristics

In total, 211 patients participated in the study. All patients had undergone pelvic dissection for gynecological cancer. The patient demographics are presented in **Table 1**. All patients were stratified according to the ISL staging : 16.6% patients were stage 1, 24.4% were stage 2a, 29.9% were stage 2b, and 13.3% were stage 3. The patients in this study had a mean age of 59.53 (standard deviation [SD] = 13.08) years, a mean height of 157 (SD = 5.31) cm, a mean weight of 56.04 (SD = 9.65) kg, and a mean BMI of 22.74 (SD = 3.61).

2. Reliability

The internal consistency reliability coefficients for each domain and total LYMQOL were high (Cronbach’s alpha coefficients, 0.898 and 0.944, respectively), as shown in **Table 2**. There were no pronounced floor or ceiling effects. Test-retest reliability was examined using 25 patients (**Table 3**). The test-retest reliability of the questionnaire total score was moderate (.589, $p < .05$).

3. Validity

The content and face validity were assessed using the original version of the LYMQOL, as the Japanese version of the LYMQOL did not examine these. This time, we investigated criteria-related validity and construct validity in two ways.

1) Criteria-related validity

Table 4 provides an overview of the Pearson correlation coefficients between the different domains of the LYMQOL and EORTC QLQ-C30. Each of the four domains “function,” “symptoms,” “emotion,” and “overall quality of life” showed strong or moderate correlations with the corresponding domains of the

EORTC QLQ-C30. However, there was no corresponding domain in the EORTC QLQ-C30 for “appearance” ; therefore, no comparison could be made for this factor.

2) Construct validity

Three domains (function, appearance, and symptoms) showed significant differences in the LYMQOL score by one-way ANOVA ($p = .00$), and one domain (emotion) showed a marginally significant difference (**Table 5**). With higher ISL stages, we observed worse scores on three LYMQOL domains (function, appearance, and symptoms). **Figure 1** presents the longitudinal confirmatory factor analysis model. The model fit was acceptable, but not outstanding, with a comparative fit index (CFI) = .985, and a root mean square error of approximation (RMSEA) = .113. The Chi square model index was not significant. Nevertheless, all LYMQOL subscales maintained high loadings on LYMQOL. The lowest factor loading was for the “emotion” factor, which was still moderately strong at .61.

DISCUSSION

The purpose of this study was to translate the English LYMQOL¹⁵⁾ questionnaire into Japanese for validation in Japanese patients with lymphedema of the lower limb, and to produce a disease-specific QOL tool for patients with lymphedema that could be used in routine clinical practice and research for assessing QOL and other outcome measures in Japan. The availability of such a questionnaire also makes it possible to compare the data collected in other international studies.

1. Participant characteristics

The proportion of women with lower lymphedema in this study suggests that leg lymphedema is an essential issue post gynecologic cancer treatment. The EORTC QLQ-CX24 and EORTC QLQ-EN24 were developed for gynecological cancer patients⁸⁾¹⁷⁾, and although they have a sub-scale for lymphedema, the subscale does not adequately evaluate QOL for all patients with lower limb lymphedema.

The participants ranged from ISL stage 1 to 3, and the proportion of participants in each stage rate was similar. Consequently, this study is appropriate for assessing QOL of patients with lower limb lymphedema with a range of ISL stages.

Table 1 Socio-demographic and Clinical characteristics of the study sample (n=211)

Socio-demographic		Cause Disease		International Society of Lymphology (ISL) Lymphedema staging	
Age	59.53 (13.08)	Endometrial cancer	32.4%	ILS Stage1	16.6%
Length	157 (5.31)	Cervical cancer	31.8%	ILS Stage2a	24.4%
Weight	56.04 (9.65)	Ovarian cancer	22.3%	ILS Stage2b	29.9%
BMI	22.74 (3.61)	Others	13.5%	ILS Stage3	13.3%
				Unknown	15.8%

Note : mean (SD)

Note. ILS Staging

Stage0 = A subclinical state where swelling is not evident impaired lymph transport

Stage1 = This represents early onset of the condition where there is accumulation of tissue that

subsides with limb elevation. The edema may be pitting at the stage

Stage2a = Limb elevation alone rarely reduces swelling and pitting manifest

Stage2b = There may or may not be pitting as tissue fibrosis is more evident

Stage3 = The tissue is hard (fibrotic) and pitting is absent. Skin changes such as thickening, hyperpigmentation, increased skin folds, fat deposits and warty overgrowths develop

Table 2 Reliability (Internal consistency)

LYM QOL Domain	Number of Items	Cronbach α
LYMQOL total	26	0.925*
Function	8	0.904*
Appearance	7	0.915*
Symptoms	5	0.898*
Emotion	6	0.944*

Note. ; *p < .05

Table 3 Reliability (Stability) N=25

LYM QOL Domain	Test-retest
LYMQOL total	0.589*
Function	0.496*
Appearance	0.460*
Symptoms	0.421*
Emotion	0.247

Note. ; *p < .05

Table 4 Validity (Criterion related validity)

LYMQOL	EORTC QLQ-C30						
	Physical	Symptoms	Emotion	Overall QOL	Role	Cognition	Society
Function	0.702**	0.653**	0.483**	-0.494**	0.586**	0.396**	0.717**
Appearance	0.732**	0.522**	0.452**	-0.406**	0.447**	0.339**	0.496**
Symptoms	0.595**	0.669**	0.532**	-0.458**	0.521**	0.423**	0.570**
Emotion	0.533**	0.630**	0.738**	-0.509**	0.486**	0.510**	0.518**
Overall QOL	-0.541**	-0.627**	-0.607**	0.613**	-0.438**	-0.294**	-0.596**

Note. ; **p < .01

2. Reliability

We investigated Cronbach's alpha coefficients and test-retest reliability in two ways. The reliability of the LYMQOL (leg) was good for patients with lower limb lymphedema. Cronbach's alpha coefficient showed good reliability of >.925 for all domains in the Japanese

version of the LYMQOL (leg), compared with >.8 in the original version¹⁵. The Japanese version also showed high internal consistency. The test-retest reliability of the total score in the questionnaire was moderate (>.589), but those of function, appearance, and symptoms were weak (>.42). Test-retest reliabil-

Table 5 LYMQOL score in each ILS staging

	Stage1	Stage2a	Stage2b	Stage3	unknown	F-value	P-Value
Function	1.95 (0.73)	2.29 (0.71)	2.53 (0.78)	2.95 (0.74)	1.95 (0.75)	7.72	0.000
Appearance	1.76 (0.64)	2.33 (0.78)	2.85 (0.76)	3.14 (0.63)	1.65 (0.89)	17.10	0.000
Symptoms	1.96 (0.64)	2.44 (0.63)	2.64 (0.65)	2.97 (0.67)	2.19 (0.99)	8.71	0.000
Emotion	2.23 (0.92)	2.31 (0.62)	2.40 (0.79)	2.77 (0.67)	2.40 (0.77)	2.33	0.058
Total	51.07 (15.49)	60.90 (13.95)	66.65 (15.96)	77.20 (17.49)	48.58 (19.33)	9.78	0.000
Overall QOL	6.68 (2.47)	6.44 (2.10)	5.70 (2.31)	4.21 (2.41)	6.62 (5.91)	6.14	0.000

Note. : One-way ANOVA

ity results were not satisfactory. One reason for this is that the time interval between testing and retesting was 2 weeks, which is rather long, and QOL changes may occur during this time period. However, in the study by Marx et al.¹⁸⁾, there was no significant difference in test-retest results when comparing intervals between 2 days and 2 weeks. Therefore, another reason may be that the measurement of emotion is susceptible to various influences, and generally, its stability may be low.

3. Criteria-related validity

Since the original LYMQOL was compared with the EORTC QLQ C-30, the Japanese version EORTC QLQ C-30 was also used to determine criterion validity in the development of the Japanese version of the LYMQOL. As a result, the “function” in the LYMQOL and the “physical” of the EORTC QLQ-C30 showed the highest correlation; “symptom,” “emotion,” and “overall QOL” were similar. However, there is no comparable domain in the EORTC QLQ-C30 or the other disease-specific HRQOL instrument for the “appearance” domain of the LYMQOL; therefore, although “appearance” showed the highest correlation with “physical”, it was weakly correlated with other domains. On the basis of the above result, we verified the reference validity of the Japanese LYMQOL (leg).

4. Construct validity

Patients with higher ISL staging tended to have higher LYMQOL scores. This supports our hypothesis that “patients with more severe lymphedema have lower QOL.” In the original LYMQOL, the developers did not extract the four-factor structure using exploratory factor analysis; however, in this study, a confirma-

tory factor analysis revealed that data fit the four-factor model of the LYMQOL in the same manner as the original LYMQOL. Therefore, the model fit was extremely good, and the Japanese version of the LYMQOL (leg) is considered a validated QOL assessment tool.

A number of other condition-specific QOL tools for lymphedema have been developed and reported. However, these tools have not been translated into Japanese and contain many questions. The LYMQOL is a short tool, covering both arm and leg edema.

5. Implications for further research

Improving both QOL and disease condition in cancer survivors is one of the most important issues in cancer care. Consequently, HRQOL assessments are becoming an essential component of research that focuses on medical outcomes in various situations, especially in cancer care. Although lymphedema has no direct effect on the health of the cancer survivors, it has a great impact on their QOL. Further research is required to integrate QOL assessments with lymphedema care outcomes.

Since the original LYMQOL is the only measurement tool with both arm and leg versions, future examinations of the Japanese version should be considered the reliability and validity of the LYMQOL (arm).

CONCLUSION

The Japanese version of the LYMQOL (leg) is a validated condition-specific QOL assessment tool that can be widely used both for clinical assessment of QOL and as a measure of treatment outcomes in Japan.

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Conflict of interest statement

My coauthors and I do not have any interests that might be interpreted as influencing the research. We do not have any relation with the manufacture or distributor of the product.

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Japanese Version of the Quality of Life Measurement for Limb Lymphedema (leg)

(J-LYMQOL-l): 日本語版の信頼性と妥当性の検討

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要 旨

背景：がん患者はリンパ節摘出を伴う手術，化学療法や放射線治療によりリンパ浮腫を発症することがある。リンパ浮腫の発症は患者のQOLの低下を招くことから，その経過によるQOLを知るためにも，特異的疾患QOLを評価する指標が必要である。

目的：英国で開発されている上肢，下肢両方のリンパ浮腫患者のQOLを評価するLYMQOL (Arm & Leg)のうち，本研究は日本語版LYMQOL (下肢)を開発するために，その信頼性と妥当性を検討した。

方法：東北および関東地方のリンパ浮腫外来のある医療機関で211名の下肢リンパ浮腫に罹患している女性に対し，口頭と書面による説明と同意のもとにLYMQOL (下肢)を含む自記式質問紙に回答をしてもらった。信頼性はCronbach's α およびテスト-再テスト法で確認した。また妥当性は基準関連妥当性をEORTC-QLQ-C30の日本語版で，また構成概念妥当性は確認的因子分析法を用いて検討した。

結果：信頼性はCronbach's α では，全体では0.925各因子においては，0.898-0.915， $p < 0.05$ で非常に高い信頼性であったが，再テスト法では全体で $r = 0.589$ ， $p < 0.05$ で中程度であった。妥当性はEORTC-QLQ-C30との相関が高かったが，「appearance」はLYMQOLの独自の因子であることから低い相関であった。また，構成概念の因子的妥当性では，確認的因子モデルにおいてオリジナルと同様に4因子でありCFI=0.985でモデル適合度はよい結果となった。

結論：以上より日本語版LYMQOL (下肢)の信頼性，妥当性は十分確保され，今後臨床，研究で用いるには，適している評価指標であることが示された。

尚，日本語版LYMQOLを希望される場合は，著者へご連絡ください。

キーワード：リンパ浮腫， quality of life，LYMQOL，信頼性・妥当性，特異的疾患QOL