



Validation of the Lymphedema Life Impact Scale Version 2: A Condition-Specific Measurement Tool for Persons With Lymphedema

Jan Weiss, PT, DHS, CLT-LANA¹; Todd Daniel, PhD²

¹CoxHealth Outpatient Rehabilitation, Springfield, MO; and ²Missouri State University, Springfield, MO

Background: Evidence-based practice supports the use of validated outcome measures to assess the effect of lymphedema; however, condition-specific lymphedema assessment measures are needed. The Lymphedema Life Impact Scale (LLIS) has been validated as a comprehensive lymphedema-specific instrument to assess the effects of lymphedema in any extremity. **Objectives:** This multicenter, cross-sectional study investigated the reliability and validity of a revised version of the LLIS, known as LLIS version 2. **Methods:** Qualifying patients from lymphedema clinics across the United States completed self-report outcome measures; clinicians measured limb circumference. Test-retest reliability was assessed in a subgroup of 21 participants. Internal consistency and validity were assessed in 84 participants with upper- or lower-limb lymphedema. **Results:** Intraclass correlation coefficients for test-retest reliability ranged from 0.687 to 0.895. Cronbach α coefficients for internal consistency ranged between 0.847 and 0.953. Construct validity of the LLIS was upheld with symptoms but not with edema severity. The LLIS correlated from moderately to highly with most domains of the comparator LYMQOL (Lymphedema Quality of Life scale) used in this study. Minimal clinically important difference of the LLIS was 7.27; MDC₉₅ was 12.74. **Limitations:** Despite adequate group sizes, the vast majority of participants were white females, so generalizations to male patients or to those of different races should be done cautiously. **Conclusions:** LLIS version 2 is a valid and reliable tool for the assessment of severity of impairment among patients with lymphedema. (*Rehab Oncol* 2018;36:28–36) **Key words:** lymphedema, outcome measure, quality of life (QOL), validity

Lymphedema is a condition that manifests as tissue swelling when the lymphatic system fails to remove excess interstitial fluid. Numerous impairments, activity limitations, and infections associated with lymphedema have been shown to adversely affect quality of life (QOL).^{1–3} The diminishing effect of lymphedema on QOL has frequently been measured using either generic QOL instruments or cancer-specific instruments.^{4–8} Assessment of lymphedema using either generic QOL instruments or cancer-specific

outcome measures (especially to assess non-cancer-related lymphedema or postcancer lymphedema) fails to capture lymphedema-specific impairment. Lymphedema therapists often resort to simply using rehabilitation outcome measures or forgoing QOL assessment entirely. Several authors have identified the importance of using a condition-specific measure to assess the effects of lymphedema upon patients.^{4,5,9,10}

Known lymphedema-specific questionnaires include those measuring only the effect of upper extremity (UE) lymphedema,^{11,12} and a few that measure the effect of upper- or lower-limb lymphedema.^{9,11,13,14} These questionnaires are limited in that they do not inquire about incidence of infection, a common and serious complication of lymphedema, nor do they have a means by which functional outcomes and impairment coding can be calculated. With the current requirement by the Centers for Medicare & Medicaid Services for documentation of functional outcomes and impairment coding for

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Correspondence: Jan Weiss, PT, DHS, CLT-LANA, CoxHealth Outpatient Rehabilitation, 3545 S. National Ave, Springfield, MO 65807 (weissfour@sbcglobal.net).

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rehabilitation reimbursement, it is desirable to have both a lymphedema-specific outcome measure and the one for which impairment level can be calculated. Weiss developed the Lymphedema Life Impact Scale (LLIS), which, accompanied by its own G code calculator, addressed both of these limitations. Weiss and Daniel¹⁵ reported on the validation of the LLIS in a previous publication in 2015. Following validation of LLIS version 1, minor but beneficial changes were made to the initial version of the LLIS. Those changes became the current version of LLIS, known as LLIS version 2. This lymphedema-specific instrument meets all the goals met with LLIS version 1: (a) to assess lymphedema-specific impairment, (b) measure any extremity lymphedema, (c) inquire about infection incidence, and (d) to satisfy US Medicare documentation requirements by calculating functional outcomes with its own G code calculator. The purpose of this study was to assess the reliability and validity of LLIS version 2.

METHODS

LLIS Development

The LLIS was originally created in response to concerns expressed by patients with lymphedema about lymphedema's effect upon their QOL. The author of the questionnaire interpreted the patients' concerns, developed questionnaire items, and categorized the items into physical, functional, and psychosocial areas of impairment. Patients with lymphedema and lymphedema practitioners reviewed the instrument for clarity and comprehensiveness, and changes were made according to their recommendations. The validation of the original LLIS identified both its psychometric strengths and the need for specific changes to make the instrument more broadly applicable. Although the basic content of the LLIS was unchanged, questions were reworded for clarity, enabling ease of use of the LLIS for bilaterally affected patients and for all persons regardless of life circumstance (relationship status, employment, role). A single question regarding skin texture was removed during development of LLIS version 2, as the developer felt that skin texture more accurately reflected therapist assessment than patient assessment. In its place, a question regarding knowledge of lymphedema management was added to include an important, but often overlooked, measure of independent self-care of lymphedema. Furthermore, it was noted during analysis of the original LLIS that the question asking about the number of infections, with its categorical answer options, reduced the internal consistency of the physical subscale in the LLIS. The infection question was therefore removed from the physical scale and recategorized as a separate scale. Finally, the answer scale on LLIS version 2 was changed from the initial 1 to 5 scale to a 0 to 4 scale, as it was believed that a score of "0" better reflected "no impairment" than did a score of "1." This change did not affect statistical analysis. For the remainder of this article, any reference to LLIS refers to version 2, unless stated otherwise.

Subjects

All patients in this study were older than 18 years, with either upper-limb or lower-limb bilateral or unilateral lymphedema, and were recruited from lymphedema therapy clinics across the United States between April 2015 and September 2016. Patients with life-threatening or terminal illness, and those currently wearing compression bandages, were excluded. The study was approved by the Missouri State University Institutional Review Board. An initial group of 21 patients with stable lymphedema during their maintenance phase of treatment (including compression garment use) was recruited to assess the test-retest reliability of the LLIS. A second group of 84 patients with lymphedema was recruited at the time of attending a lymphedema clinic to either order compression garments or initiate complete decongestive therapy (CDT). After providing written informed consent, they completed self-report measures necessary to assess construct, content, and criterion validity and reliability. Forty-nine of the original 84 participants underwent full CDT, completing LLIS questionnaires on the first treatment day and again upon discharge once they were wearing compression garments. These LLIS questionnaires were used to analyze the minimal detectable change (MDC) and the minimally clinically important difference (MCID). No control group was included in this study, as discriminant validity of the original LLIS was shown to be excellent in discriminating between those with and without lymphedema. It was felt to be unlikely that of a total of 18 questions, replacing a single item with another in the current LLIS would have a significant effect on discriminant validity. For this reason, discriminant validity testing was not repeated.

Self-report Measurements

Criterion validity of the original LLIS was performed comparing the LLIS with a lymphedema-specific instrument (Lymphedema Quality of Life scale [LYMQOL]),¹³ a frequently used cancer-related QOL instrument (European Organization for Research and Treatment of Cancer–Cancer 30 [EORTC QLQ-C30]),¹⁶ and instruments measuring physical functioning (Disability of Arm, Shoulder, Hand; DASH)¹⁷ for patients with UE lymphedema and (Lower Extremity Functional Scale [LEFS])¹⁸ for patients with lower extremity (LE) lymphedema. The 3 domains of the LLIS correlated highly with like scales on all other questionnaires; the highest correlations were with the LYMQOL. For this reason, only the LYMQOL was used to assess criterion validity for LLIS version 2. Patients completed a demographic survey, a symptom scale checklist of 6 symptoms frequently associated with lymphedema, the LYMQOL, and LLIS version 2 questionnaires. The LYMQOL is a lymphedema-specific, self-report assessment tool measuring 4 domains of QOL (symptoms, appearance, function, and mood).¹³ The LLIS comprises 18 questions measuring physical, psychosocial, and functional domains with responses ranked 0 to 4, where 0 = *no impairment* and 4 = *severe impairment*. The question regarding infection is

in its own domain, with scoring 0 = *no episodes of infection* and 4 = *4+ episodes of infection* in the past year.

Circumferential Measurements

Bilateral circumferential measurements of the hands at the thumb web space and every 10 cm from the ulnar styloid process to the axilla were done in cases of UE lymphedema or at the arch of the foot and every 10 cm from the medial malleolus to the groin in LE lymphedema.

Content Validity

Patients and experts evaluated the LLIS for clarity and pertinence to lymphedema. Ten experts in the field of lymphedema management rated LLIS questions according to perceived relevance of questions to those living with lymphedema (1 = *question not pertinent to those with lymphedema*; 4 = *strongly pertaining to lymphedema*) in order to compute the average item-level content validity indices (CVIs).¹⁹ The mean ranking of question pertinence from the 4 expert reviewers was 3.00 or more out of 4.00 for all questions, and the overall CVI for LLIS version 2 was 0.91, indicating agreement among the experts that all questions pertained to, or strongly pertained to, the problems that patients with lymphedema may experience.

Data Analysis

IBM SPSS Statistics 22.0 (SPSS, Armonk, New York) was used to compute demographic frequencies and for the reliability/validity analysis. Intraclass correlation coefficients (ICCs) were calculated to measure reproducibility between test-retest measures. The internal consistency of each domain in the LLIS was determined by the Cronbach α . Construct validity was assessed using Pearson's correlation between LLIS scores and lymphedema symptoms and edema severity (as measured by limb volume difference [LVD] in those with unilateral lymphedema). Pearson's correlation analysis was also used for criterion validity when comparing the physical, psychosocial, and functional domains of the LLIS with corresponding domains of the LYMQOL used in this study. Correlations were assumed to be moderate if between $r = 0.50$ - 0.69 , high $r = 0.70$ - 0.89 , and very high $r = 0.90$ - 1.00 .²⁰ Alpha levels for all tests were statistically significant beyond $P = .05$. MDC was calculated from ICCs and repeated-measures t tests, and MCID was calculated on the basis of 0.5 standard deviation (SD) of the pretest mean, as recommended by Norman et al.²¹

RESULTS

Subjects

The sample used for validation consisted of 84 patients; $n = 37$ (44%) of the participants had a diagnosis of UE lymphedema, and $n = 47$ (56%) had LE lymphedema.

Participants who provided demographic data had an average age of 59.7 years, 82.1% were female, and they were exclusively white (100.0%), although 7 participants (8.7%) did not provide racial or age data. Demographics are given in Table 1.

Reliability

Cronbach α reliability values ranged from 0.847 (psychosocial domain) to 0.953 for the total LLIS. The question about the number of infections was in an isolated domain and was not entered into the Cronbach α reliability calculation. All test-retest values ranged from 0.687 (physical domain) to 0.895 (psychosocial), with the total LLIS test-retest value of 0.829. All ICC values equaled or exceeded 0.82. Reliability results are given in Table 2.

Construct Validity

Construct validity was measured through examination of 6 symptoms frequently associated with lymphedema. The LLIS total scores correlated moderately ($r = 0.532$ - 0.681) with most symptoms for all participants and highly ($r > 0.71$) for heaviness and tightness in participants with LE lymphedema. Severity of swelling as determined from the initial LVD did not correlate well with LLIS scores in participants with UE lymphedema ($r_{UE} < 0.177$), and those correlations were not significant. LVD appeared to correlate highly in 10 patients with unilateral LE lymphedema for whom LVD was reported ($r_{LE} > 0.753$); however, this was likely due to an extreme LVD score from 1 participant. When that score was winsorized for excessive leverage, the correlations decreased dramatically ($r_{LE} > 0.330^{**}$ - 0.412^{**}).²² Most of the LLIS scores correlated moderately ($r \geq 0.50$ - 0.69) and more strongly with symptoms than with LVD (Table 3).

Criterion Validity

Domains of the LLIS correlated with their respective domains on the LYMQOL, and all of the correlations with LLIS total scores were statistically significant at the .01 level for LE (Table 4) and for all but one of participants with UE lymphedema (Table 5). Interestingly, nearly all correlations between LLIS total and subscale scores in all participants correlated most strongly with LYMQOL functional and appearance domains. Only the correlation between LLIS physical scale and LYMQOL symptoms in the LE lymphedema group was higher than those between LLIS and LYMQOL functional and appearance domains. All correlations between LYMQOL domains and LLIS scores were higher in the LE lymphedema group than in the UE lymphedema group except for mood. Overall, correlations of the LLIS with LYMQOL mood were the weakest.

Sensitivity

The group with pre- and posttreatment scores had mean pretreatment LLIS scores of 29.63, and mean pre- to posttest difference of 18.98 (Table 6). MDC was

TABLE 1

Demographics of the Participants by Involved Region

	UE Lymphedema	LE Lymphedema	Valid Total
n (%)	37 (44%)	47 (56%)	84 (100%)
Age ^a	59.88 (11.92)	59.56 (14.13)	59.70 (13.11)
BMI ^a	29.08 (5.90)	38.89 (12.61)	34.57 (11.28)
Gender (female)	36 (97.3%)	33 (70.2%)	69 (82.1%)
Race (white)	32 (100%)	45 (100%)	77 (100%)
Employed (yes)	19 (51.4%)	16 (34%)	35 (41.7%)
Edematous region			
RUE	21 (56.8%)		21 (25.0%)
LUE	13 (35.1%)		13 (15.5%)
BUE	3 (8.1%)		3 (3.6%)
RLE		6 (12.8%)	6 (7.1%)
LLE		7 (14.9%)	7 (8.3%)
BLE		34 (72.3%)	34 (40.5%)
Cause of edema			
Primary lymphedema		10 (21.7%)	10 (12.0%)
CVI		3 (6.5%)	3 (3.6%)
Trauma		5 (10.9%)	5 (6.0%)
Other	3 (8.1%)	10 (21.7%)	13 (15.7%)
Obesity		4 (8.7%)	4 (4.8%)
Cancer (nonbreast)		12 (26.1%)	12 (14.5%)
Breast CA	33 (89.2%)		33 (39.8%)
DVT	1 (2.7%)	2 (4.3%)	3 (3.6%)
Duration of edema			
0-6 mo	9 (26.5%)	7 (15.2%)	16 (20.0%)
6-12 mo	3 (8.8%)	1 (2.2%)	4 (5.0%)
1-2 y	6 (17.6%)	4 (8.7%)	10 (12.5%)
3-5 y	7 (20.6%)	10 (21.7%)	17 (21.3%)
6-10 y	9 (26.5%)	24 (52.2%)	33 (41.3%)

Abbreviations: BMI, body mass index; BLE, bilateral lower extremities; BUE, bilateral upper extremities; CA, cancer; CVI, chronic venous insufficiency; DVT, deep vein thrombosis; LLE, left lower extremity; LUE, left upper extremity; RLE, right lower extremity; RUE, right upper extremity.

^aMean (SD).

calculated after conducting the interclass correlation and a repeated-measures *t* test on the total and subscale LLIS scores for patients before and after lymphedema treatment. MCID was calculated on the basis of 0.5 SD of the pretest mean based on the recommendation of Norman et al,²¹ who described the 0.5 SD as having “remarkable universality.”

MCID was calculated as 7.27 for the total LLIS. The mean difference for the total score was larger than both the MDC₉₅ and the MCID for the LLIS total scale, indicating that the total LLIS has the sensitivity to be clinically useful in assessing changes as the result of lymphedema treatment. The effect sizes for all scales ranged from 0.91 to 1.69: meaning that posttest scores improved by nearly 1 SD to more than 1.5 SDs. These effect sizes ranged

from large (>0.80) to very large (>1.00) following Cohen’s guidelines.²³ Measures needed to calculate the MDC and MCID values are given in Table 6.

DISCUSSION

The design of this validation study was similar to that of the original LLIS, with minor changes as described in the “Methods” section. Results were both similar and different from those of the original LLIS study. Results relating to the reliability and content validity were similar to those of LLIS version 1, with even stronger Cronbach α reliability coefficients. This finding is likely due to the redesign of the questions for improved clarity and consistency. Surprising was that the construct validity with symptoms,

TABLE 2

Reliability Coefficients for the Domains of the Lymphedema Life Impact Scale

	n	α	Test-Retest (n = 21)	ICC	95% CI	P
Physical	84	0.911	0.687	0.820	0.550-0.927	<.001
Psychosocial	82	0.847	0.895	0.942	0.858-0.976	<.001
Functional	84	0.913	0.736	0.841	0.616-0.935	<.001
Total	82	0.953	0.829	0.905	0.769-0.961	<.001

Abbreviations: CI, confidence interval; ICC, intraclass correlation coefficient.

TABLE 3

Correlations Between LLIS Domains, Total Score, 6 Lymphedema Symptoms, and Limb Volume Difference

LLIS Scores	Heaviness	Swelling	Stiffness	Tightness	Pain	Numbness	Limb Volume Difference
Patients with UE lymphedema (n = 37)							
Physical	0.660**	0.491**	0.625**	0.646**	0.667**	0.628**	0.176
Psychosocial	0.549**	0.401*	0.387*	0.443**	0.563**	0.606**	0.085
Functional	0.482**	0.353*	0.486**	0.494**	0.641**	0.605**	0.137
Total	0.605**	0.445**	0.532**	0.564**	0.666**	0.655**	0.146
Patients with LE lymphedema (n = 47)							
Physical	0.830**	0.653**	0.715**	0.761**	0.705**	0.598**	0.753*
Psychosocial	0.665**	0.432**	0.614**	0.607**	0.560**	0.667**	0.850**
Functional	0.675**	0.504**	0.549**	0.594**	0.617**	0.620**	0.779**
Total	0.786**	0.577**	0.681**	0.711**	0.681**	0.679**	0.886**

Abbreviations: LE, lower extremity; LLIS, Lymphedema Life Impact Scale; UE, upper extremity.

Note. **Correlations significant at the .01 level; *Correlations significant at the .05 level. One patient LVD was winsorized for excessive leverage. Correlations with limb volume difference were based on patients with unilateral involvement (n_{UE} = 29, n_{LE} = 10).**TABLE 4**

Correlations Between LLIS Domains, Total Score, and Lower Extremity Measures (N = 47)

	LYMQOL Functional	LYMQOL Appearance	LYMQOL Symptoms	LYMQOL Mood
Total	0.791**	0.809**	0.728**	0.547**
Physical	0.668**	0.699**	0.737**	0.416**
Psychosocial	0.757**	0.753**	0.593**	0.537**
Functional	0.774**	0.797**	0.687**	0.571**

Abbreviations: LLIS, Lymphedema Life Impact Scale; LYMQOL, Lymphedema Quality of Life (scale).

Note. **Correlations significant at the .01 level; *Correlations significant at the .05 level.

test-retest validity, and criterion validity of LLIS version 2 with LYMQOL all had somewhat lower correlations than were found with LLIS version 1. A plausible explanation for those weaker correlations could be that the participants recruited for this study had greater day-to-day fluctuations in their lymphedema than were experienced by the LLIS version 1 group. This fluctuation is consistent with the descriptions of many people living with lymphedema who describe frequent changes in their limb, necessitating daily alteration to required care. Typically, symptoms of pain, heaviness, tightness, swelling, numbness, and stiffness are reported by those living with lymphedema and would be associated with a physical domain. In this study, we found that correlations between LLIS scores and physical symptoms were lower than those previously reported with LLIS version 1. However, we also found that LLIS

total and subscale scores correlated higher with LYMQOL functional and appearance scores than LYMQOL symptom scores, except for LE LLIS physical scores. This would appear to confirm that lymphedema impacts persons in a considerably greater manner than simply physical impairments. Rather, the effect of the disease touches all domains of measure including function and perception of self. Herein lies the importance of using LLIS version 2 as an important comprehensive QOL measure for lymphedema.

Studies support the contention that QOL is not reliably decreased simply by the amount of swelling, so clinicians should focus on assessing other relevant factors to assess the overall effect of lymphedema on the individual.^{1,2,13,24-28} Construct validity was demonstrated through moderate to high LLIS correlation with most symptoms that are commonly associated with lymphedema

TABLE 5

Correlations Between LLIS Domains, Total Score, and Upper Extremity Measures (N = 37)

	LYMQOL Functional	LYMQOL Appearance	LYMQOL Symptoms	LYMQOL Mood
Total	0.654**	0.756**	0.557**	0.555**
Physical	0.661**	0.692**	0.627**	0.471**
Psychosocial	0.548**	0.705**	0.408*	0.546**
Functional	0.628**	0.722**	0.535**	0.538**

Abbreviations: LLIS, Lymphedema Life Impact Scale; LYMQOL, Lymphedema Quality of Life (scale).

Note. **Correlations significant at the .01 level; *Correlations significant at the .05 level.

TABLE 6
MDC and MCID for the LLIS

	Pre-SD	r	SEM	Pre-M	MD	MDC ₉₅	MCID	d
Physical	5.25	0.86	1.96	13.08	8.86	5.44	2.63	1.69
Psychosocial	5.54	0.60	3.50	8.06	5.04	9.71	2.77	0.91
Functional	5.32	0.85	2.06	8.49	5.08	5.71	2.66	0.95
Total	14.54	0.90	4.60	29.63	18.98	12.74	7.27	1.31

Note. The MCID was based on half a standard deviation of the pretest mean. The MDC₉₅ was calculated using the formulas $SEM = \text{pre-SD} (\sqrt{1-r})$ [where $r = \text{ICC of average measures}$] and $MDC_{95} = SEM(1.96) (\sqrt{2})$. Pre-SD = standard deviation of pretest, SEM = standard error of measurement, Pre-M = mean of pretest, MD = mean difference from pretest to posttest, $d = \text{Cohen's } d \text{ effect size (MD/Pre-SD)}$, LLIS, Lymphedema Life Impact Scale.

and was also supported in the lymphedema literature. Ridner et al¹ noted that substantial symptom burden accompanies lymphedema. Hayes et al²⁴ found that approximately 50% of women following breast cancer treatment reported at least 1 moderate to extreme symptom at 6 and 18 months postoperatively, with numbness and swelling being most common. Armer et al²⁵ found that self-reported symptoms of “heaviness in the past year” and “swelling now” best predicted the presence of lymphedema. Also consistent with literature, this study found weak correlation between LLIS scores and edema severity, as measured by pretreatment LVD in unilateral lymphedema cases. Undoubtedly, some individuals with lymphedema will report impairments as relating directly to amount of swelling as did 1 individual in this study. The lack of significant correlation of edema severity with LLIS scores may have also been due to a low sample size of patients with unilateral LE lymphedema. Edema severity could not be measured in bilateral cases because of a lack of comparison with an unaffected limb. Although limb volume is a very common outcome measure used in the treatment of lymphedema, research demonstrates weak correlation between edema volume and function or QOL.^{2,13,26-28} Hormes et al² and Pain et al²⁶ found that arm symptoms and physical limitations adversely impacted QOL more than arm swelling. Keeley et al,¹³ Weiss and Spray,²⁷ and Viehoff et al²⁸ also reported no significant correlations between amount of edema and QOL in their studies. In the group of participants who completed pre- and post-LLIS measures, significant improvement was noted in LLIS scores. The mean difference between pre- and post-LLIS scores (18.98) considerably exceeded the MCID (7.27), indicating improvement in QOL. Although posttreatment circumferential measures were not a focus of this study, it is likely that improvement in LLIS scores was related to factors beyond mere reduction of edema.

Lymphedema affects individuals at physical, functional, and psychosocial levels. Capturing the effect of impairments associated with lymphedema is an important feature of assessment, and many authors have identified that patients gauge treatment success, in part, by reduction of those impairments.^{4,5,10,29-33} LLIS version 2 is particularly well suited to assessing pre- to posttreatment changes in patient symptoms, function, or perception of self and hence an important comprehensive QOL measure for lymphedema. Content validity of the LLIS

was shown to be high through patient and expert agreement on a high level of pertinence of LLIS questions to experiences with lymphedema. Bogan et al²⁹ reported that participants measured success of lymphedema treatment by decreased frequency of infections, increased mobility, social participation, and fitting into regular clothes. Finnane et al³³ recognized a gap in the literature between frequently measured edema volume and symptoms and QOL related to lymphedema. Their investigation of QOL related to symptoms in patients with lymphedema found that more than 50% of patients had 10 symptoms commonly associated with lymphedema and the vast majority (>75%) reported heaviness, tightness, aching, reduced range of motion, and swelling. The majority of patients felt it very important that symptoms were reduced following treatment.

In the absence of a gold standard against which to perform criterion validity, the original LLIS study validated a lymphedema-specific instrument against 4 other measures: a cancer QOL measure (EORTC QLQ C-30), UE and LE functional measures (DASH and LEFS, respectively), and a lymphedema-specific measure (LYMQOL). The EORTC, DASH, and LEFS were used for criterion validity in the initial study because of the frequent use of these instruments in lymphedema QOL literature. Results showed the original LLIS correlated more strongly with like domains of the LYMQOL than with any of the other measures except the functional domain on the DASH.¹⁵ Since only minor content changes were made in LLIS version 2, and in the interest of removing patient survey “burnout,” criterion validity for LLIS version 2 was examined only against the valid LYMQOL. Having demonstrated validity and reliability, LLIS version 2 offers a new comprehensive lymphedema outcome instrument for both UE and LE lymphedema. The inclusion of the question about frequency of infection offers a highly clinically useful tool for the lymphedema practitioner to include in the evaluation of the patient and makes it unique among lymphedema QOL tools. With the chronicity of lymphedema and need for recurrent clinical follow-up, the information as to whether a patient is having fewer or more episodes of infection since the previous course of care is important. An important change to the original LLIS is that the question about infection in version 2 is in an isolated domain and is not included in the reliability analysis of the remainder of the questionnaire. The LLIS further facilitates ease of documentation of



LLIS Lymphedema Life Impact Scale

version 2

Patient name _____ Eval _____ 10th visit _____ 20th visit _____ 30th visit _____ D/C _____

Listed below are symptoms or problems reported by many individuals with lymphedema. Please indicate to what extent these problems associated with your lymphedema has affected you in **the past week**. Circle the number which best describes your symptom level.

I. Physical concerns (NOTE: If swelling and symptoms are the same in both limbs, rate them the same; otherwise, rate **only** the worst limb)

1. The amount of pain associated with my lymphedema is:	0 no pain	1	2	3	4 severe pain
2. The amount of limb heaviness associated with my lymphedema is:	0 no heaviness	1	2	3	4 extremely heavy
3. The amount of skin tightness associated with my lymphedema is:	0 no tightness	1	2	3	4 extremely tight
4. The size of my swollen limb(s) seems:	0 normal size	1	2	3	4 extremely large
5. Lymphedema affects the movement of my swollen limb(s):	0 normal movement	1	2	3	4 movement extremely limited
6. The strength in my swollen limb(s) is:	0 normal strength	1	2	3	4 extremely weak

II. Psychosocial concerns

7. Lymphedema affects my body image (how I think I look).	0 not at all	1	2	3	4 completely
8. Lymphedema affects my socializing with others.	0 no interference	1	2	3	4 interferes completely
9. Lymphedema affects my intimate relations with spouse or partner (rate 0 if not applicable).	0 no interference	1	2	3	4 interferes completely
10. Lymphedema “gets me down” (i.e., I have feelings of depression, frustration, or anger due to the lymphedema).	0 never	1	2	3	4 constantly
11. I must rely on others for help due to my lymphedema.	0 not at all	1	2	3	4 completely
12. I know what to do to manage my lymphedema.	0 good understanding	1	2	3	4 no understanding

III. Functional concerns

13. Lymphedema affects my ability to perform self-care activities (i.e., eating, dressing, hygiene).	0 no interference	1	2	3	4 interferes completely
14. Lymphedema affects my ability to perform routine home or work-related activities.	0 no interference	1	2	3	4 interferes completely
15. Lymphedema affects my performance of preferred leisure activities.	0 no interference	1	2	3	4 interferes completely
16. Lymphedema affects the proper fit of clothing/shoes.	0 fits normally	1	2	3	4 unable to wear
17. Lymphedema affects my sleep.	0 no interference	1	2	3	4 interferes completely

IV. Infection occurrence

18. In the past year, I have become ill with an infection in my swollen limb requiring oral antibiotics or hospitalization.	0	1x	2x	3x	4+
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Fig. 1. Lymphedema Life Impact Scale, version 2.

functional outcomes reporting for Medicare patients in the United States. Since generic impairment-level calculators do not include lymphedema-specific measures, it is beneficial to have a means to determine functional impairment when using a lymphedema measure. The LLIS is unique in its design to be used with an Excel “G code” calculator (developer L. Hodgkins, MS, OTRL, CLT-LANA; Hartford Hospital Rehabilitation Network, Meriden, Connecticut) for scoring to meet Medicare requirements. The “G code” calculator is able to establish a percent impairment from a summed LLIS score. This percent impairment then is equated to a Medicare modifier, indicating the patient’s level of impairment.

The principal contribution of this study was in the redesign of the original LLIS. Patients and providers agreed that the language of the new version is more understandable and applicable to all patients. Analysis was strengthened, as nearly everyone answered all questions rather than having numerous missing data. These factors could have contributed to the stronger reliability of LLIS version 2. The added question about knowledge of lymphedema management was felt to be an important indicator of the patient’s cognitive ability to perform necessary self-care activities. Although the knowledge of self-care does not ensure that one will be able to perform such activities independently, research has shown positive relationships between knowledge and recommended behaviors.^{34,35}

A limitation of this study was that despite adequate group sizes, the vast majority of participants were white females, so generalizations to male patients or to those of different races should be done cautiously. Still, the female-to-male ratios in this study were consistent with other studies,^{13,14} and there is no theoretical reason to think that lymphedema impairment should act differentially across gender or ethnicity. The study also appeared to demonstrate greater variability in participant response through the reduced test-retest and correlation scores in many areas. Although these factors may have somewhat weakened the validity compared with LLIS version 1, this should not be interpreted as a weakness of the measure; rather, the measure is accurately measuring the greater variability within participants. Despite all test-retest subjects having stable lymphedema, their age, general health and comorbidities, coping strategies, and resources, in addition to severity of lymphedema, all varied considerably. These factors would very likely affect QOL but are not necessarily easily separated when responding to a lymphedema-specific QOL measure. The design of questions on the LLIS referring specifically to the effects from the lymphedema was an attempt to separate impairments caused by lymphedema from impairments from other sources (Figure 1). Finally, this study did not explore the relationship between edema volume reduction and change in LLIS scores as a result of treatment. This was not an essential element of validation, so it was not undertaken during this study. This could be an area of future study.

CONCLUSIONS

The LLIS contributes to the field of lymphedema treatment by offering a condition-specific outcome measure for lymphedema, serving to benefit lymphedema research and clinical practice. The instrument is short and quick to administer. It measures treatment outcomes and when combined with an Excel spreadsheet calculator is able to calculate Medicare functional impairment. LLIS version 2 has demonstrated validity and reliability in the population with any extremity lymphedema and can be used in place of measures that are not condition-specific, providing additional accuracy in detecting impairment and treatment outcomes in patients with lymphedema.

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