Lymphology 48 (2015) 128-138

VALIDATION OF THE LYMPHEDEMA LIFE IMPACT SCALE (LLIS): A CONDITION-SPECIFIC MEASUREMENT TOOL FOR PERSONS WITH LYMPHEDEMA

J. Weiss, T. Daniel

CoxHealth Outpatient Rehabilitation (JW) and RStats Institute (TD), Missouri State University, Springfield, Missouri, USA

ABSTRACT

Evidence-based practice supports the use of validated outcome measures to assess the impact of lymphedema; however, condition-specific lymphedema assessment measures are needed. The Lymphedema Life Impact Scale (LLIS) was developed as a comprehensive, lymphedema-specific instrument to assess the effects of lymphedema in any extremity. The LLIS is an 18-item measure of physical, psychosocial, and functional impairments caused by lymphedema. The purpose of this multicenter, cross sectional study was to investigate the reliability and validity of the LLIS. Test-retest reliability was assessed in a subgroup of 17 participants. Internal consistency and validity was assessed in 71 participants with upper (n_{UE} = 37) or lower limb (n_{LE} = 34) lymphedema, and a control group of 31 participants without lymphedema.

Intraclass correlation coefficients for test-retest reliability ranged from .965 to .990. Cronbach's alpha coefficients for internal consistency ranged between .841 and .926. Construct validity of the LLIS was upheld with symptoms, but not with edema severity. The LLIS correlated highly with other comparison measures used in this study. Minimal clinically important difference of the LLIS was 7.31; MDC_{95} = 11.53. Our results showed the LLIS to be a valid and reliable tool for the assessment of severity of impairment among patients with lymphedema.

Keywords: lymphedema, impairment, quality of life (QOL), impact scale, validity, reliability

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 (1-3). The diminishing effect of lymphedema on quality of life has been most often measured using either generic quality of life instruments or cancer-specific instruments (4-8). Assessment of lymphedema using either generic quality of life instruments, or cancer-specific outcome measures (especially to assess non-cancer-related lymphedema, or post-cancer lymphedema), fails to capture lymphedema-specific impairment. Lymphedema therapists often resort to simply using rehabilitation outcome measures, forgoing quality of life 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).

Among the existing lymphedema-specific questionnaires, most measure only the impact of upper limb lymphedema, typically following breast cancer. The only known English-language outcome instruments measuring both upper and lower limb lymphedema outcomes are the LYMQOL (11) and the Lymph-ICF (12,13), neither of which

Patient Name _____

Listed below are symptoms or problems many individuals with lymphedema report. Please indicate to what extent these problems associated with your lymphedema have affected you in the past 2 weeks. If both limbs are swollen, compare symptoms in the swollen limbs to any non-swollen limbs.
Circle the number which best describes your symptom level.

I. Physical Concerns

1. The amount of pain associated with my lymphedema is:
2. The amount of limb heaviness associated with my lymphedema is:
3. The amount of skin tightness associated with my lymphedema is:
4. In comparison to my unaffected limb, the size of my swollen limb seems:
5. In comparison to my unaffected limb, the skin texture of my swollen limb feels:
6. Lymphedema affects movement of my swollen limb:
7. The strength in my swollen limb compared with the unaffected limb is:
8. How often have you become ill with an infection in your swollen limb requiring oral antibiotics or hospitalization in the past 2 YEARS?

II. Psychosocial Concerns

9. Lymphedema affects my body image (i.e. "How I think I look."):
10. Lymphedema affects my socializing with others:
11. Lymphedema affects my intimate relations:
12. Lymphedema "gets me down" (i.e. I have feelings of depression, frustration, or anger due to the lymphedema.):

III. Functional Concerns

13. Lymphedema affects my ability to perform duties at home:
14. Lymphedema affects my ability to perform duties at work (if applicable):
15. Lymphedema affects my performance of preferred recreational activities:
16. Lymphedema affects the proper fit of clothing/shoes:
17. Lymphedema affects my sleep:
18. I must rely on others for help due to my lymphedema:

Fig. 1. Components of the Lymphedema Life Impact Scale (LLIS) (Version 1). The full version with scoring scale can be found in the supplementary materials and further information on working copies with the G-Code calculator can be found at http://klosetraining.com/resources/llis/

inquire about incidence of infection, a common and serious complication of lymphedema. Additionally, the U.S. Centers for governmental insurance programs, Medicare and Medicaid, now require documentation of functional outcomes and impairment coding for rehabilitation reimbursement; however, no current rehabilitation impairment ("G code") calculators include lymphedema-specific measures. We developed a new lymphedema-specific instrument – the Lymphedema Life Impact Scale (LLIS) – to (a) assess lymphedema-specific impairment, (b) measure any extremity lymphedema, (c) inquire about infection incidence, and (d) satisfy U.S. Medicare documentation requirements by calculating functional outcomes with its own G code calculator (*Fig. 1*). The purpose of this study was to assess the reliability and validity of the LLIS.

METHODS

LLIS Development

The LLIS was originally created from concerns expressed by patients with lymphedema about lymphedema's impact upon their quality of life. The author of the questionnaire interpreted the patient concerns, developed questionnaire items, and categorized the items into physical, functional, and psychosocial areas of impairment. Following item development, patients with lymphedema and lymphedema practitioners reviewed the instrument for clarity and comprehensiveness, and changes were made according to recommendations.

Subjects

All patients recruited for this study were over age 18, with either upper or lower limb, bilateral or unilateral lymphedema (except controls), and were recruited from lymphedema therapy clinics across the U.S. between May 2013 and March 2014. 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 17 patients with stable lymphedema, undergoing no active treatment was recruited to assess the test-retest reliability of the LLIS. A second group of 71 patients with lymphedema was recruited at the time of initiating Complete Decongestive Therapy (CDT) treatment. They provided self-report measures necessary to assess construct, content, and criterion validity, and reliability. An additional group of 62 participants underwent full CDT treatment, completing LLIS questionnaires on the first treatment day and upon discharge once they were wearing compression garments. These LLIS questionnaires were used to analyze psychometrics. Finally, LLIS scores from a control group of 31 patients were used to assess discriminant validity. These patients had diagnoses placing them at risk for lymphedema, but did not have swelling.

Self-Report Measurements

After providing informed consent, patients completed a demographic survey, a symptom scale checklist of six symptoms frequently associated with lymphedema, and four questionnaires. All patients completed the Lymphedema Quality of Life (LYMQOL) (11), a lymphedema-specific, self-report assessment tool measuring four domains of quality of life (symptoms, appearance, function, and emotion); the European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire – Core 30 (EORTC QLQ-C30) (14), a self-report instrument measuring physical symptoms and functioning (physical, role, emotional, cognitive, and social) designed to assess the impact of cancer on quality of life; and the LLIS, comprising 18 questions measuring physical, psychosocial, and functional domains with responses ranked 1-5, where 1 = *no impairment*, and 5 = *severe impairment*.

Patients with upper extremity lymphedema were additionally assessed with the Disability of Arm, Shoulder, and Hand (DASH) (15). The DASH is a self-report measure assessing upper extremity function and symptoms in patients with any upper extremity impairment. Patients with lower extremity lymphedema were additionally assessed with the Lower Extremity Functional Scale (LEFS) (16), a self-report measure assessing lower extremity function in patients with any lower extremity impairment.

Circumferential Measurements

Bilateral circumferential measurements of the hands at the thumb web space and every 10 cm from the ulnar styloid process to axilla were measured in cases of upper extremity lymphedema, or at the arch of the foot and every 10 cm from malleoli to groin in the lower extremity.

TABLE 1
Demographics of the Participants by Involved Region

	UE lymphedema	LE lymphedema	Control	Total
N	37	34	31	102
Age[a]	62.36 (12.23)	60.34 (13.32)	52.21 (15.39)	58.73 (14.1)
BMI[a]	29.37 (6.03)	35.52 (12.12)		32.31 (9.87)
Gender (female)	36 (97.3%)	28 (82.4%)	23 (74.2%)	87 (85.3%)
Race (White)	36 (97.3%)	34 (100%)	30 (100%)	100 (99%)
Employed (Yes)	19 (51.4%)	17 (50.0%)	18 (58.1%)	54 (52.9%)
Cancer etiology	33 (89.2%)	12 (35.3%)	7 (22.6%)	52 (51.0%)
Edematous region				N= 71
RUE	13 (35.1%)			13 (18.3%)
LUE	23 (62.2%)			23 (32.4%)
BUE	1 (2.7%)			1 (1.4%)
RLE		5 (14.7%)		5 (7.0%)
LLE		9 (26.5%)		9 (12.7%)
BLE		20 (58.8%)		20 (28.2%)
Cause of edema				
Primary Lymphedema		9 (26.5%)		9 (12.7%)
CVI		3 (8.8%)		3 (4.2%)
Trauma	1 (2.7%)	2 (5.9%)		3 (4.2%)
Other	3 (8.1%)	6 (17.6%)		9 (12.7%)
Obesity		3 (8.8%)		3 (4.2%)
Cancer (non-breast)		11 (32.4%)		11 (15.5%)
Breast CA	33 (89.2%)			33 (46.5%)
Duration of edema				
0-6 months	4 (10.8%)	4 (11.8%)		8 (11.3%)
6-12 months	1 (2.7%)	1 (2.9%)		2 (2.8%)
1-2 yrs	4 (10.8%)	1 (2.9%)		5 (7.0%)
3-5 yrs	12 (32.4%)	2 (5.9%)		14 (19.7%)
6-10 yrs	16 (43.2%)	21 (61.8%)		37 (52.1%)
>10 yrs		5 (14.7%)		5 (7.0%)

Note. RUE = right upper extremity, LUE = left upper extremity, BUE = both upper extremities, RLE = right lower extremity, LLE = left lower extremity, BLE = both lower extremities, CVI = chronic venous insufficiency, [a] = reported as mean and (SD).

Content Validity

Patients and experts evaluated the LLIS for clarity and pertinence to lymphedema. Four 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 (CVI) (17). The mean ranking of question pertinence from the four expert reviewers was ≥ 3.00 out of 4.00 for all questions, and the overall CVI for the LLIS was .94, 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, NY) was used to compute demographic frequencies and for the reliability/validity analysis. Intra-class correlation coefficients (ICC) were calculated for test-retest measures. The internal consistency of each domain in the LLIS was determined by Cronbach's alpha. Construct validity was assessed using Pearson's correlation between LLIS scores and lymphedema symptoms, and edema

TABLE 2
Reliability Coefficients for the Domains of the LLIS Scales

	n	alpha	Test-Retest (n=17)	ICC	95% CI	p-value
Physical	71	.888	.941	.970	.918 - .989	< 0.001
Psychosocial	71	.841	.973	.978	.931 - .992	< 0.001
Functional	40	.850	.949	.965	.892 - .988	< 0.001
Total	40	.926	.983	.990	.969 - .996	< 0.001

severity (as measured by limb volume difference in those with unilateral lymphedema). Pearson correlation analysis was also used for criterion validity when comparing the physical, psychosocial, and functional domains of the LLIS to comparable domains of four other outcome measures used in this study. Correlations were assumed to be moderate if between r = .50-.69, high r = .70-.89, and very high r = .90-1.00 (18). Alpha levels for all tests were statistically significant beyond p = 0.05. Discriminant validity comparing those with and without lymphedema was analyzed from one-way ANOVAs. Minimal detectable change (MDC) was calculated from ICC and repeated-measures t tests, and minimally clinically important difference (MCID) was calculated based on half a standard deviation of the pretest mean, as recommended by Norman et al (19).

RESULTS

Subjects

The sample used for validation consisted of 102 patients. Approximately one third (36%, n = 37) of the participants had been diagnosed with upper extremity (UE) lymphedema, one third (33%, n = 34) with lower extremity (LE) lymphedema, and the remaining third (31%, n = 31) comprised patients at risk for – but not manifesting – lymphedema. The final third of the participants were used as a control group. Participants averaged 58.73 years of age, 85.3% were female, and were almost exclusively white (99.0%). Demographics are contained in *Table 1*.

Reliability

All scales on the LLIS produced Cronbach's alpha reliability values above .840. All test-retest values were above .940 and all ICC values exceeded .964. Upon review, it was noted that the question about number of infections, with its categorical answer options, reduced the internal consistency of the physical subscale. The infection question was re-categorized as a separate scale and removed from the physical subscale for subsequent analysis. The question about effects of lymphedema on work had a low response rate because many of the respondents were unemployed or retired. The missing data for this question resulted in some portions of the analysis being based on n = 40 and not n = 71. Reliability results are in *Table 2*.

Construct Validity

Construct validity was measured through examination of six symptoms frequently associated with lymphedema. The LLIS total scores correlated highly (r = .706 to r = .830) with heaviness, stiffness, and tightness in all participants, and also for swelling in those with upper limb lymphedema. Severity of swelling as determined from initial limb volume difference in patients with unilateral lymphedema, did not correlate well with LLIS scores (r_{UE} = .361; r_{LE} = .347).

TABLE 3
Correlations Between LLIS Domains, Total Score, Six Lymphedema Symptoms, and Limb Volume Difference

	Heaviness	Swelling	Stiffness	Tightness	Pain	Numbness	Limb volume difference
LLIS scores UE Patients (n = 37)							
Physical	.812**	.790**	.743**	.757**	.669**	.562**	.314**
Psychosocial	.601**	.621**	.597**	.477**	.252	.406**	.215**
Functional	.713**	.686**	.590**	.604**	.495**	.466**	.291**
Total	.805**	.792**	.729**	.706**	.558**	.547**	.361**
LLIS scores LE Patients (n = 33)							
Physical	.766**	.691**	.826**	.731**	.509**	.315	.420**
Psychosocial	.742**	.563**	.673**	.623**	.426*	.389*	.482**
Functional	.812**	.532**	.751**	.672**	.590**	.495**	.357**
Total	.830**	.649**	.811**	.731**	.546**	.422**	.347**

Note. **Correlations significant at the .01 level; *correlations significant at the .05 level. One patient was excluded pairwise for missing data reducing sample size for lower extremity patients to n = 33. Correlations with limb volume difference was based on patients with unilateral involvement (n_{UE} = 37, n_{LE} = 14).

TABLE 4
Correlations Between LLIS Domains, Total Score, and UE Measures

	EORTC functional	EORTC symptom	DASH total	LYMQOL functional	LYMQOL appearance	LYMQOL symptoms	LYMQOL emotion
UE Patients (n = 37)							
Total	.760**	.728**	.803**	.815**	.758**	.831**	.653**
Physical	.651**	.639**	.762**	.818**	.663**	.832**	.583**
Psychosocial	.698**	.568**	.520**	.556**	.755**	.571**	.584**
Functional	.723**	.750**	.847**	.772**	.644**	.788**	.598**

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

TABLE 5
Correlations Between LLIS Domains, Total Score, and LE Measures

	EORTC functional	EORTC symptom	LEFS total	LYMQOL functional	LYMQOL appearance	LYMQOL symptoms	LYMQOL emotion
LE Patients (n = 34)							
Total	.790**	.821**	-.779**	.845**	.753**	.787**	.638**
Physical	.634**	.682**	-.652**	.676**	.618**	.736**	.472**
Psychosocial	.795**	.812**	-.745**	.835**	.757**	.684**	.673**
Functional	.804**	.826**	-.835**	.879**	.757**	.775**	.675**

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

Lymphedema symptoms correlated more strongly with the LLIS than with limb volume difference (*Table 3*).

Criterion Validity

Each of the domains of the LLIS correlated with their respective domains on the comparison measures and all correlations with LLIS total scores were statistically significant at the 0.01 level (*Tables 4 and 5*).

TABLE 6
MDC and MCID for the LLIS Scales

	Pre-*SD*	*r*	SEM	Pre-*M*	M_D	MDC_{95}	MCID	*d*
Physical	6.14	.85	2.38	24.68	9.30	6.60	3.07	1.64
Psychosocial	4.59	.81	2.00	9.85	2.45	6.79	2.30	0.69
Functional	5.73	.86	2.14	16.31	3.16	5.93	2.87	0.65
Total	14.62	.92	4.16	50.85	14.91	11.53	7.31	1.21

Note. The MCID was based on half a standard deviation of the pretest mean. The MDC_{95} was calculated using the formulas SEM = pre-SD ($\sqrt{1 - r}$) [where *r* = 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, M_D = mean difference from pretest to posttest, *d* = Cohen's *d* effect size.

The LLIS physical scale correlated more strongly with the LYMQOL symptoms scales (r_{UE} = .832; r_{LE} = .736) than with the other scales. The LLIS functional scale correlated most strongly with the LYMQOL functional scale (r_{UE} = .772; r_{LE} = .879) than with other scales with the exception of the DASH for patients with upper extremity lymphedema (rDASH = .847). Total LLIS scores correlated highly with all comparison scales at $r \geq \pm .727$ except with the LYMQOL emotion domain (r_{UE} = .653; r_{LE} = .638). Despite higher correlations with like domains of the LYMQOL than with other instruments, a follow-up analysis of differences between correlations showed no statistically significant differences (z scores all less than ± 1.96) between correlations from the EORTC, LEFS, DASH, and LYMQOL, supporting the criterion validity of the LLIS with each of the measures.

Discriminant Validity

Discriminant validity was demonstrated by comparing LLIS total and subscale scores from the known group (patients with lymphedema) to the control group (patients at risk for lymphedema but without swelling). Although in some cases it was difficult to entirely separate the effects of edema from other comorbidities, patients with lymphedema were instructed to complete the questionnaire as accurately as possible with regard to only the effect of lymphedema on their QOL. Because of the lymphedema-specific wording of the LLIS, patients without lymphedema uniformly answered 1 (no impairment) indicating that the LLIS focuses on lymphedema etiology of symptoms and not those of other comorbidities. Three independent measures ANOVAs were conducted to assess differences between known groups and control on each LLIS subscale. Each ANOVA was statistically significant: the physical scale, $F(2,90) = 42.10$, MSE = .499, $p < 0.001$; the psychosocial scale, $F(2,90) = 24.33$, MSE = .692, $p<0.001$; and the functional scale, $F(2,90) = 29.25$, MSE = .609, $p<0.001$. Post hoc tests conducted with Tukey HSD showed that in all three scales, the patients with lymphedema formed homogeneous subsets distinct from the control group.

Psychometrics

The group with pre- and post-treatment scores had mean pre-treatment LLIS scores of 50.85, and mean pre-to post differences of 14.91. (*Table 6*) Minimal detectable change (MDC) was 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. Minimally clinical important difference (MCID) was calculated based on

one-half standard deviation of the pretest mean based on the recommendation of Norman et al (19), who described the half SD standard as having "remarkable universality" (20). MCID was calculated as 7.31 for the total LLIS. The mean difference and the lower boundary of the 95% CI were larger than both the MCID and the MDC95 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 0.65 to 1.64: meaning that post-test scores improved by two-thirds of a SD to over one and half SDs. These effect sizes ranged from medium (>.50) to very large (>1.00) following Cohen's guidelines (21). Measures needed to calculate the MDC and MCID values are contained in *Table 6.*

DISCUSSION

This study demonstrated that the LLIS is a reliable and valid measure of quality-of-life impairment caused by lymphedema. Reliability was confirmed through excellent internal consistency and test-retest reliability. Construct validity was upheld through strong LLIS correlation with symptoms most commonly associated with lymphedema (heaviness, stiffness, tightness, swelling), and is also confirmed by other researchers. Ridner et al noted that substantial symptom burden accompanies lymphedema (1). Hayes et al found approximately 50% of women following breast cancer treatment reported at least one moderate to extreme symptom at 6 and 18 months post operatively, with numbness and swelling being most common (22). Armer et al found self-reported symptoms of "heaviness in the past year", and "swelling now", best predicted the presence of lymphedema (23).

Also consistent with literature about subjective experience of lymphedema symptoms, this study found weak correlation between LLIS scores and edema severity as measured by pre-treatment limb volume difference in unilateral lymphedema cases. Edema severity was not measured in bilateral cases. 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 quality of life. Hormes et al and Pain et al found arm symptoms and physical limitations adversely impacted quality of life more than arm swelling (2,24). Keeley, Weiss, and Viehoff also reported no significant correlations between amount of edema and quality of life in their studies (11,25,26). These studies support the contention that quality of life is not reliably decreased simply by the amount of swelling, so clinicians should focus on assessing other relevant factors to evaluate the overall impact of lymphedema on the individual. 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 (14.91), considerably exceeded the MCID (7.31), indicating improvement in QOL. Although post-treatment circumferential measures were not a focus of this study, it is likely that improvement in LLIS scores were related to factors beyond mere reduction of edema.

Content validity was established through patient and expert feedback on the pertinence of LLIS questions to experiences with lymphedema and is supported by numerous authors who have reported on the effects of lymphedema on quality of life (4,5,10,27-30). Bogan et al reported that participants measured success of lymphedema treatment by decreased frequency of infections, increased mobility and social participation, and fitting into regular clothes (27). Capturing the impact of impairments associated with lymphedema is an important feature of assessment, and treatment success is gauged, in part, by reduction of those impairments. The LLIS is particularly well suited to assessing pre- to post- treatment changes in those impairments.

In the absence of a gold standard against

which to perform criterion validity, this study validated a lymphedema-specific instrument against four other measures: a cancer quality of life measure, UE and LE functional measures, and a lymphedema-specific measure. The EORTC, DASH, and LEFS were used for criterion validity due to the frequent use of these instruments in lymphedema QOL literature (4-8,22,31). The LYMQOL, though less reported in lymphedema literature was used as an important condition-specific measure appropriate for validating a new lymphedema instrument. Although correlations between measures did not differ statistically significantly, the LLIS correlated more strongly with like-domains of the LYMQOL than with any of the other measures except the functional domain on the DASH. Overall, these findings suggest the benefit of using a validated, condition-specific measure when assessing criterion validity of a new instrument.

Having demonstrated validity and the ability to discriminate between patients with and without lymphedema, the LLIS offers a new comprehensive lymphedema outcome instrument for both upper- and lower-extremity lymphedema. The inclusion of the question about frequency of infection, offers a highly useful clinical tool for the lymphedema practitioner to include in the assessment of the patient. With the chronicity of lymphedema and need for recurrent clinical follow-up, the information as to whether a patient is having fewer or greater episodes of infection since the previous course of care, is agreed by therapists to be very important information. Having to re-categorize the infection question for purposes of reliability analysis does not diminish its importance to the instrument, and that question is unique among lymphedema QOL tools. The LLIS further facilitates ease of documentation of functional outcomes reporting for Medicare patients in the U.S. 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, OTR/L, CLT-LANA; Therapeia Lymphedema Center, LLC, Hamden, CT) 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.

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 (11,13), and there is no theoretical reason to think that lymphedema impairment should act differentially across gender or ethnicity. Another limitation was that two questions (infection and work-related questions) did not perform well during analysis. These questions will be reformatted in a future version of the LLIS. This study did not explore the relationship between edema volume reduction and change in LLIS scores as a result of treatment, which 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. The LLIS 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.

ACKNOWLEDGMENTS

The authors appreciate project assistance from lymphedema therapists and patients across the U.S.

REFERENCES

1. Ridner, SH, J Deng, MR Fu, et al: Symptom burden and infection occurrence among individuals with extremity lymphedema. Lymphology 45 (2012), 113-123.
2. Hormes, JM, C Bryan, LA Lytel, et al: Impact of lymphedema and arm symptoms on quality of life in breast cancer survivors. Lymphology 43 (2010), 1-13.
3. Morgan, PA, PJ Franks, CJ Moffatt: Health-related quality of life with lymphedema: A review of the literature. Int. Wound J. 2 (2005), 47-62.
4. Pusic, AL, Y Cemal, C Albornoz, et al: Quality of life among breast cancer patients with lymphedema: A systematic review of patient-reported outcome instruments and outcomes. J. Cancer Surviv. 7 (2013), 83-92.
5. Cemal, Y, S Jewell, CR Albornoz, et al: Systematic review of quality of life and patient reported outcomes in patients with oncologic related lower extremity lymph-edema. Lymphat. Res. Biol. 11 (2013), 14-19.
6. Schiefke, F, M Akdemir, A Weber, et al: Function, postoperative morbidity, and quality of life after cervical sentinel node biopsy and after selective neck dissection. Head & Neck 31 (2009), 503-512.
7. De Vries, M, HJ Hoekstra, JE Hoekstra-Weebers: Quality of life after axillary or groin sentinel lymph node biopsy, with or without completion lymph node dissection, in patients with cutaneous melanoma. Ann. Surg. Oncol. 16 (2009), 2840-7284.
8. Ferrendina, G, G Mantegna, M Petrillo, et al: Quality of life and emotional distress in early stage and locally advanced cervical cancer patients: A prospective, longitudinal study. Gynec. Oncol. 124 (2012), 389-394.
9. Klernas, P, LJ Kristjanson, K Johansson: Assessement of quality of life in lymphedema patients: Validity and reliability of the Swedish version of the Lymphedema Quality of Life Inventory (LQOLI). Lymphology 43 (2010), 135-145.
10. Williams, AF, CJ Moffatt, PJ Franks: A phenomenological study of the lived experiences of people with lymphedema. Intern. J. Palliative Nurs. 10 (2004), 279-286.
11. Keeley, V, S Crooks, J Locke, et al: A quality of life measure for limb lymphedema (LYMQOL). J. Lymphoedema 5 (2010), 26-37.
12. Deevoogdt, N, M Van Kampen, I Geraerts, et al: Lymphoedema functioning, disability and health questionnaire (Lymph-ICF): Reliability and validity. Phys. Ther. 91 (2011), 944-957.
13. Devoogdt, N, A De Groef, A Hendrickx, et al: Lymphoedema functioning, disability and health questionnaire for lower limb lymphedema (Lymph-ICF-LL): Reliability and validity. Phys Ther. 94 (2014), 705-721.
14. Aaronson, NK, S Ahmedzai, B Bergman, et al: The European Organization for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. J. Natl. Cancer Inst. 85 (1993), 365-376.
15. Hudak, PL, PC Amadio, C Bombardier: Development of an upper extremity outcome measure: The DASH (Disabilities of the Arm Shoulder and Hand). Am. J. Industrial Med. 29 (1996), 602-608.
16. Binkley, JM, PW Stratford, SA Lott, et al: The Lower Extremity Functional Scale (LEFS): Scale development, measurement properties, and clinical application. Phy. Ther. 79 (1999), 371-383.
17. Lawshe, CH: A quantitative approach to content validity. Personnel Psychology. 28 (1975), 563-575. doi:10.1111/j.1744-6570.1975.tb01393.x
18. Munro, BH: *Statistical Methods for Health Care Research*, 5th Ed., Philadelphia, 2005.
19. Norman, GR, JA Sloan, KW Wyrwich: Interpretation of changes in health-related quality of life: The remarkable universality of half a standard deviation. Medical Care. 41 (2003), 582-592. doi:10.1097/01.MLR.0000062554.74615.4C.
20. Norman, GR, JA Sloan, KW Wyrwich: The truly remarkable universality of half a standard deviation: Confirmation through another look. Expert Rev. Pharmaco-economics Outcomes Res. 4 (2004), 581-585. doi: 10.1586/14737167.4.5.581.
21. Cohen, J: *Statistical Power Analysis for the Behavioral Sciences*, 2nd Ed., Hillsdale, New Jersey, 1988.
22. Hayes, SC, S Rye, D Battistutta, et al: Prevalence of upper-body symptoms following breast cancer and its relationship with upper-body function and lymphedema. Lymphology 43 (2010), 178-187.
23. Armer, JM, ME Radina, D Porock, et al: Predicting breast cancer-related lymphedema using self-reported symptoms. Nurs. Res. 52 (2003), 370-379.

24. Pain, SJ, SL Vowler, AD Purushotham: Is physical function a more appropriate measure than volume excess in the assessment of breast cancer-related lymphedema (BCRL)? Eur. J. Cancer 39 (2003), 2168-2172.
25. Weiss, JM, BJ Spray: The effect of complete decongestive therapy on the quality of life of patients with peripheral lymphedema. Lymphology 35 (2002), 46-58.
26. Viehoff, PB, FR van Genderen, H Wittink. Upper Limb Lymphedema 27 (ULL27): Dutch Translation and validation of an illness-specific health-related quality of life questionnaire for patients with upper limb lymphedema. Lymphology 41 (2008), 131-138.
27. Bogan, LK, JM Powell, BJ Dudgeon. Experiences of living with non-cancer-related lymphedema: Implications for clinical practice. Qual Health Res. 17 (2007), 213-224.
28. Ryan, M, MC Stainton, C Jaconelli, et al: The experience of lower limb lymphedema for women after treatment for gynecologic cancer. ONF. 30 (2003), 417-423.
29. Johansson, K, H Holmstrom, I Nilsson, et al: Breast cancer patients' experiences of lymphedema. Scan. J. Caring Sci. 17 (2003), 35-42.
30. Ahmed, RL, A Prizment, D Lazovich, et al: Lymphedema and quality of life in breast cancer survivors: The Iowa Women's Health Study. J. Clin. Oncol. 26 (2008), 5689-5696.
31. Park, JE, HJ Jang, KS Seo: Quality of life, upper extremity function, and effect of lymphedema treatment in breast cancer related lymphedema patients. Ann. Rehabil. Med. 36(2012), 240-247.

Jan Weiss, PT, DHS, CLT-LANA
E-mail: weissfour@sbcglobal.net
Todd Daniel, Ph.D.
E-mail: ToddDaniel@MissouriState.edu
Missouri State University
Springfield, Missouri USA