

Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF): Reliability and Validity

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Background. Lymphedema occurs frequently after axillary dissection for breast cancer and causes significant physical and psychosocial problems. To plan the treatment for lymphedema and monitor the patient's progress, arm swelling and arm function need to be assessed.

Objective. The purpose of this study was to investigate the reliability (test-retest, internal consistency, measurement variability) and validity (content and construct) of data obtained with the Lymphoedema Functioning, Disability and Health questionnaire (Lymph-ICF).

Methods. The Lymph-ICF is a descriptive and evaluative tool and consists of 29 questions about impairments in function, activity limitations, and participation restrictions of patients with breast cancer and arm lymphedema. The questionnaire is divided into 5 domains: physical function, mental function, household activities, mobility activities, and life and social activities. Reliability and validity were examined on 60 patients with lymphedema and 30 patients without lymphedema.

Results. Intraclass correlation coefficients for test-retest reliability ranged from .65 to .93. Cronbach alpha coefficients for internal consistency were higher than .70. There were no systematic changes from the first test to the second test, and measurement variability was acceptable (standard errors of measurement = 4.8–12.5). Content validity was good because all questions were understandable for all participants, the scoring system (visual analog scale) was clear for 88% of the participants, and all complaints due to arm lymphedema were mentioned by 85% of the participants. Construct validity was good. There was good convergent validity because 5 expected domains of the Lymph-ICF had the strongest correlation with 5 expected domains of the 36-Item Short-Form Health Survey questionnaire (SF-36). Thus, the 5 hypotheses assessing convergent validity were accepted. There was acceptable divergent validity because 3 of 5 hypotheses assessing divergent validity were accepted. There was good known-groups validity because patients with lymphedema had a higher total score on the Lymph-ICF and had a higher score on each domain and on each question (except one) compared with patients without lymphedema.

Conclusion. The Lymph-ICF is a reliable and valid questionnaire to assess impairments in function, activity limitations, and participation restrictions of patients with arm lymphedema after axillary dissection for breast cancer.



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Lymphedema is caused by a reduced transport capacity of the lymphatic system.¹ This complication occurs frequently after an axillary lymph node dissection for breast cancer: prevalence of arm lymphedema ranges between 10%² and 34%.³ In addition, patients experience significant physical, psychological, and social problems due to their lymphedema,⁴ leading to a low quality of life.⁵

The World Health Organization's taxonomy in the *International Classification of Functioning, Disability and Health* (ICF)⁶ provides an appropriate framework that allows systematic categorization of clinical observations. In research and in practice, lymphedema volume usually is measured by the water displacement method or calculated from circumference measurements.⁷ Consequently, in terms of the ICF, only one impairment (ie, swelling) is measured. However, when a patient with lymphedema is seen by a physical therapist, a complete examination and evaluation should include an evaluation of other impairments such as pain, impaired shoulder mobility, skin stiffness, weakness of the affected arm, anxiety, depression, and reduced body image.⁸ Patients with lymphedema also can experience activity limitations and participation restrictions, including decreased ability to iron, cook, clean (scrub, vacuum, mop), lift weights, perform tasks with an elevated arm, perform hobbies and sports, find clothing that would accommodate their swollen arm, and drive long distances.⁹ Currently, there is no comprehensive examination tool to determine impairments in function, activity limitations, and participation restrictions and to monitor progress of treatment for these patients.¹⁰

Various disease-specific questionnaires have been constructed to measure the consequences of lymph-

edema development following axillary dissection for breast cancer, including the Wesley Clinic Lymphedema Scale (WCLS),¹¹ the Freiburg Life Quality Assessment (FLQA-I),¹² and the Upper Limb Lymphedema 27 (ULL-27),¹³ although each questionnaire has a few limitations. The WCLS consists of only 5 questions, and its reliability and validity have not been determined.¹¹ The FLQA-I consists of 92 items and aims to assess the impact of primary and secondary lower-limb and upper-limb lymphedema, not just lymphedema developed after breast cancer treatment.¹² The ULL-27 is a Dutch and French questionnaire with demonstrated internal consistency and construct validity, but not test-retest reliability or content validity.¹³ Furthermore, none of these questionnaires are based on the terminology of the ICF.

The aim of our study was to examine different aspects of reliability and validity of the newly developed Lymphoedema Functioning, Disability and Health questionnaire (Lymph-ICF), which assesses impairments in function, activity limitations, and participation restrictions related to lymphedema developed after axillary dissection for breast cancer and which is based on the terminology of the ICF.

Method

The Lymph-ICF was constructed in 3 phases. In the first phase, information on impairments in function, activity limitations, and participation restrictions was collected in 20 patients with subjective or objective lymphedema after axillary dissection for breast cancer. These patients were recruited in the Department of Physiotherapy of the University Hospitals Leuven, where they were receiving treatment for their arm lymphedema. Other patient characteristics are missing.

The patients were asked (by means of open-ended questions) to write down all impairments in function, activity limitations, and participation restrictions related to their lymphedema, and this information was clarified afterward with the patients by 2 of the authors (N.D. and M.VK.). The patients mentioned the following impairments in function: arm feels heavy (61%), feels swollen (33%), tingles (17%), hurts (39%), and has a tensed skin (28%). They mentioned the following activity limitations and participation restrictions: they are less able to clean (33%), cook (6%), iron (33%), garden (17%), perform tasks with the elevated arm (22%), lift heavy objects (50%), work on the computer (11%), walk more than 2 km (11%), cycle (11%), go on vacation (6%), perform hobbies (11%), practice sports (28%), wear clothes of choice (11%), do a job (17%), and do social activities (11%). Impairments in mental function were not mentioned. Based on the literature, we included the following impairments in mental function: feeling sad, feeling discouraged, having a lack of confidence, and feeling stressed.^{8,13} We also included the following activity limitations and participation restrictions: being less able to wash and less able to drive a car and experiencing difficulties in emotional life with spouse or partner, in social life with family, and in work tasks.⁹

With both the information from the patients and the information from the literature, the pilot version of the



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Lymph-ICF was developed. The structure of the questionnaire was based on the Chronic Fatigue Syndrome Activities and Participation Questionnaire developed by Nijs et al.¹⁴ The pilot version of the Lymph-ICF consisted of 29 statements, and each statement was scored on 2 different 4-point scales. The first scale indicated to what degree the statement corresponded to the patient's situation, with scores ranging from 1 ("totally not agree") to 4 ("totally agree"). The second scale indicated how important the patient found each statement, with scores ranging from 1 ("very unimportant") to 4 ("very important"). The score on each statement was the product of the scores on both scales (score between 1 and 16), and the total score on the pilot Lymph-ICF was the sum of all scores divided by the number of answered statements (score between 1 and 16). A higher score on the pilot Lymph-ICF indicated more problems with functioning related to arm lymphedema.

In the second phase, reliability and validity of data obtained with the pilot version of the Lymph-ICF were investigated on a second group of patients with lymphedema following axillary dissection for breast cancer. We included 29 patients with objective or subjective lymphedema, as determined by the water displacement method. *Objective lymphedema* was defined as a difference in volume of 200 mL or more between the affected arm and the unaffected arm.^{15,16} If a patient stated that her arm was swollen, although the difference between both arms did not reach 200 mL, the edema was defined as *subjective lymphedema*.

To analyze test-retest reliability, the patients completed the pilot version of the Lymph-ICF twice, with an interval of 24 to 48 hours between tests because problems with functioning related to arm lymphedema

may change from one day to another. Furthermore, to analyze content validity of the pilot version of the Lymph-ICF, they completed a questionnaire developed by 2 of the authors (N.D. and M.VK.) that consisted of 3 questions: (1) Was each question of the Lymph-ICF understandable? (2) Was the scoring system clear? and (3) Were all complaints related to your lymphedema mentioned in the Lymph-ICF? If a patient answered "no," she was asked to explain her answer. Finally, to analyze construct validity, the patients completed the Medical Outcomes Study 36-item Short-Form Health Survey questionnaire (SF-36). The SF-36, consisting of 36 questions, is known to be a reliable and valid questionnaire that examines the general health of the patient. Eight domains of quality of life are examined: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health (scores range between 0 and 100).¹⁷ A higher score on the SF-36 indicates a better quality of life.

The mean age of the patients was 59.8 years (SD=8.2), the mean body mass index was 27.4 kg/m² (SD=4.5), and the median time interval since surgery was 53 months (range=12-198). The pilot version of the Lymph-ICF was found to have moderate to strong test-retest reliability (intraclass correlation coefficient [ICC]=.49-.92), strong internal consistency (Cronbach alpha=.75), and good construct validity (correlation between total score on the Lymph-ICF and different domains of the SF-36 ranged between -.52 and -.72). However, content validity was not acceptable. For 38% of the patients, the scoring systems were not clear. First, they experienced problems with double negations. Second, they often mentioned during a discussion afterward that they had misunderstood the

principle of the 2 scoring systems. In addition, 38% of the patients mentioned missing complaints related to their lymphedema, such as "arm feels stiff," "arm feels like it has lost strength," "inability to sleep on the affected side," and "inability to sunbathe." The following activity limitations and participation restrictions were not frequently mentioned (less than 10% of the patients): "being less able to wash," "experiencing difficulties in emotional life with spouse or partner," "experiencing difficulties in social life with family," and "experiencing difficulties in work tasks."

In the third phase, based on the results from the analyses of the pilot version and discussions between 2 of the authors (N.D. and M.VK.), a final version of the Lymph-ICF questionnaire was developed (Appendix). Instead of the 29 statements of the pilot version, the final version is composed of 29 questions. Two impairments in function ("arm feels stiff" and "arm feels like it has lost strength") and 2 activity limitations and participation restrictions ("inability to sleep on the affected side" and "inability to sunbathe") were added. Four activity limitations and participation restrictions ("inability to wash," "experience problems in emotional life with spouse," "experience problems in social life with family," and "inability to perform work tasks") were removed. In addition, we changed the scoring system. Each question is scored on a visual analog scale (VAS) ranging from 0 to 100 mm. The anchors for the impairments in function (eg, "Does your arm hurt?") are "not at all" and "very much," and those for the activity limitations and participation restrictions (eg, "Are you able to carry heavy weights?") are "very well" and "not at all." Table 1 gives an overview of the impairments in function and activity limitations and participation restrictions questioned in the Lymph-ICF; for

each question, the ICF domain and the ICF code⁶ are mentioned. In the introduction of the Lymph-ICF, the scoring system is explained. Then the patient is asked to score her average impairments in function, activity limitations, and participation restrictions during the previous 2 weeks. Furthermore, the patient is advised not to discuss the questions with anyone to maintain the self-assessment characteristic of the questionnaire. The Lymph-ICF takes 5 minutes to complete.

Different scores are obtained from the questionnaire. Each of the 29 questions corresponds to a score between 0 and 100. The total score of the Lymph-ICF is equal to the sum of the scores on the questions divided by the total number of answered questions. In addition, a score is determined for each of the 5 domains of the Lymph-ICF: (1) physical function, (2) mental function, (3) household activities, (4) mobility activities, and (5) life and social activities. Thus, the total score on the Lymph-ICF and the score on the 5 domains range between 0 and 100. The final version of the Lymph-ICF, which was used in this study, was developed in the Dutch language. The Lymph-ICF has already been translated into the English language according to established international guidelines described by the World Health Organization.¹⁸ The Dutch version was translated into English by 2 individuals working independently and translated back into Dutch by a third person.

Participants

The present study investigated the reliability and validity of data obtained on the final version of the Lymph-ICF. Ninety patients with breast cancer participated in the study: 60 with objective or subjective lymphedema following axillary dissection and 30 without lymphedema. The patients were

Table 1.

Overview of the Impairments in Function, Activity Limitations, and Participation Restrictions and Their *International Classification of Functioning, Disability and Health* (ICF) Domains and ICF Codes

Impairments in Function		
Domain	Question	Code
Physical (b2, b4, b7, b8) ^a	1. Heavy	b4552
	2. Stiff	b7101
	3. Swollen	b439
	4. Lost strength	b7301
	5. Tingle	b840
	6. Hurt	b28014
	7. Tensed skin	b840
Mental (b1)	8. Feel sad	b152
	9. Feel discouraged	b152
	10. Lack of self-confidence	b1266
	11. Feel stressed	b152
Activity Limitations and Participation Restrictions		
Domain	Question	Code
Household (d6)	12. Clean	d6402
	13. Cook	d6300
	14. Iron	d6403
	15. Garden	d6505
Mobility (d4)	16. Tasks with elevated arm	d4452
	17. Lift heavy objects	d4301
	18. Sleep on affected side	d4150
	19. Work on computer	d4458
	20. Sunbathe	d4250
	21. Drive a car	d4751
	22. Walk more than 2 km	d4501
	23. Cycle	d4750
Life domains (d8)/social life (d9)	24. Go on vacation	d9209
	25. Perform hobbies	d9204
	26. Practice sports	d9201
	27. Wear clothes of choice	d5404 ^b
	28. Do a job	d850
	29. Do social activities	d9205

^a Physical=other than mental: pain (b2), functions of the immunologic system (b4), functions of the movement system (b7), and functions of the skin (b8).
^b ICF domain: self-care.

recruited between September 2006 and July 2007 from the Multidisciplinary Breast Clinic (n=51), the Department of Physiotherapy (n=18), and the Vascular Center (n=10) of the University Hospitals Leuven and from the practice of

physical therapists outside our hospital (n=11). Only patients with breast cancer who had undergone a unilateral axillary dissection at least 12 months prior to the study were included. The patients had to be Dutch speaking.

Study Design

At the Department of Physiotherapy of our hospital, to investigate the content validity of the Lymph-ICF, each patient completed 3 questionnaires—the SF-36, the Lymph-ICF, and the author-developed questionnaire—while waiting for her arm measurement. Thereafter, the following data were collected by interviewing the patient: patient's age, body weight and height (to determine body mass index), date of surgery, type of breast surgery, side of surgery, hand dominance, type of adjuvant treatment (radiotherapy, chemotherapy, or hormonal therapy), region of arm lymphedema (upper arm, lower arm, or complete arm), hand lymphedema, and interval between development of lymphedema and inclusion in the study. The volume of each of the patient's arms then was measured by the water displacement method to determine whether she had objective or subjective lymphedema. If a patient had neither objective nor subjective lymphedema, she was classified as having no lymphedema. Finally, patients received a second Lymph-ICF questionnaire to complete at home (with an interval of between 24 and 48 hours) and return to our department by mail.

Data Analysis

We used SPSS version 17.0* to perform statistical analyses. To analyse reliability and content, convergent and divergent validity of the Lymph-ICF we only used data from the patients with objective or subjective lymphedema. For the analysis of known groups validity, we also included patients without lymphedema.

Reliability. Intraclass correlation coefficients (ICC [1,1]) were used to determine test-retest reliability of the

total score of the Lymph-ICF, of the scores on the 5 domains, and of the score on each question separately.¹⁹ Cronbach alpha coefficients were used to determine internal consistency of the entire questionnaire and of each domain.²⁰ The ICCs, Cronbach alpha coefficients, and correlation coefficients for convergent and divergent validity were interpreted as follows: $<.4$ was weak, $.4$ to $.74$ was moderate, $.75$ to $.9$ was strong, and $>.9$ was very strong.²¹

To calculate systematic changes in the mean for the test-retest analyses, Bland-Altman analyses were carried out.²² A graph was drawn for the total score on the Lymph-ICF, for scores on the 5 domains, and for scores on each question. The x-axis represented the mean of the 2 test occasion scores. The y-axis represented the difference between the 2 scores. If zero fell within the 95% confidence interval, this was an indication that there were no significant systematic changes.

To interpret the magnitude of the within-subjects variation of the 2 scores, the standard error of measurement (SEM) was calculated using the formula: $SEM = SD_{12} \sqrt{1 - ICC}$, where SD_{12} was the average standard deviation of the 2 ratings.¹⁹ To evaluate clinically important changes, we calculated the smallest real difference (SRD) using the formula: $SRD = 1.96 \times SEM \times \sqrt{2}$.¹⁹ To obtain a reference range for the mean difference of the scores of the 2 test occasions, we calculated 95% SRD as the mean difference between the 2 test occasions \pm SRD.

Validity. Content validity and construct validity were examined. It was not possible to examine criterion validity, because the impairment in function, activity limitation, and participation restriction dimensions of the ICF had been introduced by the World Health Organization and we

were unaware of a gold standard for measuring this dimension.

Content validity examines the extent to which a questionnaire represents the universe of concepts or domains, that is, whether the questionnaire offers an adequate sample of the content of a construct.²³ Content validity of the final version of the Lymph-ICF was examined by analyzing the answers of the patients with lymphedema on the questions about content validity. First, the number of positive answers on each of the 3 questions (whether the questions were understandable, the clarity of the scoring system, and completeness of the questionnaire) was counted. Next, 2 of the authors (N.D. and M.VK.) discussed the patient's explanations on the negative answers.

Construct validity is a process in which validity is evaluated in terms of the extent to which a measure correlates with variables in a manner consistent with theory.²³ Construct validity of the Lymph-ICF was investigated in 2 ways. First, the relationship between scores on domains of the Lymph-ICF and scores on domains of the SF-36 was examined, and this finding was used to investigate convergent and divergent validity. We used the Pearson correlation coefficient for normally distributed scores and the Spearman correlation coefficient for the other scores. To determine convergent and divergent validity and based on the content of the questions of each domain of Lymph-ICF and SF-36, we formulated 10 hypotheses (Tab. 2). Second, the total score of the Lymph-ICF, the scores on the 5 domains, and the score on each question were compared between patients with lymphedema (objective or subjective) and patients without lymphedema, and this comparison was used to investigate known-groups validity. The nonparametric

* SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.

Table 2.
Hypotheses to Assess Construct Validity^a

Convergent Validity	Considering all correlation coefficients between different domains of the Lymph-ICF and the SF-36, the highest correlation coefficients would occur between: <ol style="list-style-type: none"> 1. Lymph-ICF physical function and SF-36 bodily pain 2. Lymph-ICF mental function and SF-36 mental health 3. Lymph-ICF household activities and SF-36 physical functioning 4. Lymph-ICF mobility activities and SF-36 physical functioning 5. Lymph-ICF life and social activities and SF-36 social functioning
Divergent Validity	Considering all correlation coefficients between different domains of the Lymph-ICF and the SF-36, the lowest correlation coefficients would occur between: <ol style="list-style-type: none"> 6. Lymph-ICF physical function and SF-36 role-emotional and mental health 7. Lymph-ICF mental function and SF-36 physical functioning and role-physical 8. Lymph-ICF household activities and SF-36 role-emotional and mental health 9. Lymph-ICF mobility activities and SF-36 role-emotional and mental health 10. Lymph-ICF life and social activities and SF-36 physical functioning
Known-Groups Validity	Patients with lymphedema (objective or subjective) have: <ol style="list-style-type: none"> 11. A higher total score on the Lymph-ICF 12–16. A higher score on each domain of the Lymph-ICF 17–45. A higher score on each question of the Lymph-ICF than patients without lymphedema

^a Lymph-ICF=Lymphoedema Functioning, Disability and Health Questionnaire, SF-36=Medical Outcomes Study 36-Item Health Survey questionnaire.

Mann-Whitney *U* test was used because almost all scores of the patients without lymphedema were not normally distributed. We hypothesized that patients with lymphedema would have a higher total score on the Lymph-ICF, a higher score on each domain, and a higher score on each question compared with patients without lymphedema (Tab. 2). Construct validity was defined as very good if more than 90% of all 45 hypotheses (or 41 or more hypotheses) were confirmed, was defined as good if between 75% and 90% of the hypotheses (or 34 to 40 hypotheses) were confirmed, and was defined as moderate if between 40% and 74% of the hypotheses (or 18 to 33 hypotheses) were confirmed.

Furthermore, the scores of patients with objective and subjective lymphedema were compared using the parametric independent *t* test (scores of both groups were normally distributed). The .05 level of significance was applied.

Role of the Funding Source

This study was supported by a grant from the Agency for Innovation by

Science and Technology (Applied Biomedical Research).

Results

Thirty patients with objective lymphedema, 30 patients with subjective lymphedema, and 30 patients without lymphedema participated in the present study. All patients had undergone breast surgery with axillary dissection. The groups were comparable in age, body mass index, type of breast surgery, and type of adjuvant treatment (radiotherapy, chemotherapy, or antihormonal therapy) (Tab. 3). Radiotherapy and chemotherapy were completed prior to entry into the study, and antihormonal therapy was completed in 29%, 13%, and 15% of the patients with objective lymphedema, those with subjective lymphedema, and those without lymphedema, respectively ($P=.35$).

Lymphedema volume ranged from 200 mL to 2,486 mL (median=467 mL) for patients with objective lymphedema and from -149 mL to 182 mL (median=86 mL) for patients with subjective lymphedema. The time interval since breast surgery was significantly larger in the group

with objective lymphedema compared with the other groups. Seven percent of the patients with objective lymphedema had swelling of the upper arm, 23% had swelling of the lower arm, and 63% had swelling of the whole arm. Forty-seven percent of the patients also mentioned swelling of the hand. For patients with subjective lymphedema, these proportions were 44%, 22%, 26%, and 37%, respectively. Objective lymphedema was present for 41 months on average (range=7–220 months). Subjective lymphedema was present for 19 months on average (range=3–116 months).

Reliability

Four patients did not fill in the Lymph-ICF questionnaire a second time, and their data could not be included in the test-retest analyses. Table 4 gives an overview of ICCs, Cronbach alpha coefficients, SEMs, and SRDs for the total score on the Lymph-ICF and for the score on each domain. Test-retest reliability of the total score on the questionnaire and of the physical function and household activities scores was very strong ($ICC>.90$), that of the mental function and mobility activities scores

Lymphoedema Functioning, Disability and Health Questionnaire

Table 3.

Characteristics of the Patients With Objective Lymphedema (n=30), Those With Subjective Lymphedema (n=30), and Those Without Lymphedema (n=30)^a

Variable	Lymphedema			P
	Objective	Subjective	Without	
Age (y)	61.2 (10.0)	56.7 (9.3)	58.3 (11.9)	.25
Body mass index (kg/m ²)	27.0 (6.2)	25.3 (4.2)	24.6 (3.7)	.15
Lymphedema volume (mL)	467 (620)	86 (139)		<.01
Region of arm lymphedema				.01
Upper arm	7%	44%		
Lower arm	23%	22%		
Total arm	63%	26%		
None	7%	7%		
Hand lymphedema	47%	36%		.46
Presence of lymphedema (mo)	41 (64)	19 (34)		.03
Time interval since surgery (mo)	55 (74)	34 (45)	36 (33)	.01
Breast surgery				.73
Mastectomy	57%	63%	53%	
Breast-conserving surgery	43%	37%	47%	
Surgery on the dominant side	63%	43%	43%	.20
Radiotherapy	90%	87%	87%	.90
Chemotherapy	57%	50%	43%	.59
Antihormonal therapy	59%	80%	67%	.20

^a Age and body mass index analyzed with analysis of variance test, mean (SD); presence of lymphedema and time interval since surgery analyzed with Kruskal-Wallis test, median (interquartile range); other variables analyzed with chi-square test, percentages.

was strong (ICC>.75), and that of the life and social activities score was moderate (ICC=.65). Test-retest reliability of scores on 23 questions (79%) was strong to very strong (data not shown). Reliability of scores on

the other 6 questions (about stiffness, lack of self-confidence, sleeping on the affected side, driving a car, performing hobbies, and performing social activities) was moderate (ICC=.65-.75).

Internal consistency of Lymph-ICF scores ranged between moderate and very strong. The Cronbach alpha for all questions was .92 and ranged for the different domains between 0.72 and 0.92.

Differences in the total score on the Lymph-ICF, the scores on the 5 domains, and the score on each question in the Bland-Altman analyses between test occasions were distributed randomly above and below the mean, and zero fell within the 95% confidence interval (data not shown).

The total score on the Lymph-ICF had a variation from one test occasion to the other of 4.8. A decrease of the VAS score of more than 11 and an increase of more than 9 could be considered (with 95% certainty) a statistically significant change. Furthermore, a decrease of the VAS score of 15 or more and an increase of 13 or more could be considered a clinically relevant change. The score on each of the 5 domains was evaluated in the same way (Tab. 4).

Validity

The questionnaire about the content validity of the final version of the Lymph-ICF was completed by all patients. All patients mentioned that the questions of the Lymph-ICF were

Table 4.

Reliability of the Total Score on the Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF) and of the Scores on the 5 Domains (n=56)^a

Score	Test-Retest		Consistency	Variability		Clinically Important Changes	
	ICC	95% CI	α	SEM	95% CI	SRD	SRD 95%
Lymph-ICF total score	.93	.89 to .96	.92	4.8	-10.5 to 8.4	13.4	-14.4 to 12.4
Physical function score	.91	.85 to .95	.87	7.0	-15.4 to 12.0	19.4	-21.1 to 17.7
Mental function score	.87	.78 to .92	.92	9.0	-21.0 to 14.2	24.9	-28.2 to 21.5
Household activities score	.91	.86 to .95	.91	7.7	-13.5 to 16.6	21.3	-19.8 to 22.8
Mobility activities score	.87	.78 to .92	.72	7.7	-14.7 to 15.4	21.2	-20.9 to 21.6
Life and social activities score	.65	.47 to .78	.79	12.5	-25.0 to 24.0	34.6	-35.2 to 34.1

^a ICC=intra-class correlation coefficient, CI=confidence interval, α =Cronbach alpha coefficient, SEM=standard error of measurement, SRD=smallest real difference.

understandable. Fifty-three patients (88%) found the scoring system (VAS) clear: 3 patients preferred a scoring system with gradation, 2 patients found it difficult to score their complaints because the complaints were not always present or because many of the tasks could be performed but not for a long time, and the other 2 patients gave no comment.

Fifty-one patients (85%) mentioned that all complaints were addressed in the Lymph-ICF. Complaints not covered in the Lymph-ICF were: pain in the breast, edema in the axilla, loss of sensation, shooting pain in the arm, stress caused by visiting the physical therapist (mentioned by 2 patients), shopping, and writing.

Table 5 gives an overview of Pearson correlation coefficients between the different domains of the Lymph-ICF and the SF-36. All patients completed both questionnaires. The five domains of the Lymph-ICF had the strongest correlation with the expected domains of the SF-36. We found moderate correlation coefficients, except for the life and social activities domain, which correlated weakly with the social functioning domain of SF-36. The 5 hypotheses assessing convergent validity were accepted. The physical function, mental function, and household activities domains of the Lymph-ICF had the weakest correlations with the expected domains of the SF-36. The mobility activities domain of the Lymph-ICF had the weakest correlation with the role-emotional domain of the SF-36, but not with the mental health domain. The life and social activities domain of the Lymph-ICF had the weakest correlation with the role-emotional domain of the SF-36, but not with the physical functioning domain. Three of the 5 hypotheses assessing divergent validity were accepted.

Table 5.

Correlation Between the Medical Outcomes Study 36-Item Health Survey Questionnaire (SF-36) and the Lymphoedema Functioning, Disability and Health Questionnaire (Lymph-ICF) to Determine Convergent and Divergent Validity (Pearson Correlation Coefficient; N=60)

SF-36 Domain	Lymph-ICF				
	Impairments in Function		Activity Limitations and Participation Restrictions		
	Physical Function	Mental Function	Household Activities	Mobility Activities	Life and Social Activities
Physical functioning	-.26	-.24 ^a	-.51 ^b	-.62 ^b	-.25
Role-physical ^c	-.20	-.25 ^a	-.37	-.47	-.29
Bodily pain	-.52 ^b	-.45	-.40	-.52	-.32 ^b
General health	-.35	-.43	-.43	-.38	-.35 ^b
Vitality	-.23	-.59	-.34	-.45	-.29
Social functioning ^c	-.30	-.46	-.50 ^b	-.46	-.33 ^b
Role-emotional ^c	.03 ^a	-.31	-.22 ^a	-.15 ^a	-.19 ^a
Mental health	-.14 ^a	-.70 ^b	-.27 ^a	-.42	-.25

^a Weakest correlation.

^b Strongest correlation.

^c Not normally distributed: Spearman correlation coefficient.

In Table 6, the total score on the Lymph-ICF, the scores on the 5 domains, and the score on each question are compared between the patients with and without lymphedema. The total score on the Lymph-ICF and the scores on the 5 domains were significantly higher for patients with lymphedema than for those without lymphedema. In addition, the scores on 26 (of 29) questions were significantly higher. Patients with and without lymphedema had a comparable score on the question about walking. Construct validity of the final version of the Lymph-ICF was good, as 89% (40 of 45) of the hypotheses were confirmed.

We also made a comparison between the patients with objective and subjective lymphedema (data not shown). Both patient groups had a comparable total score on the Lymph-ICF and had comparable scores on the 5 domains and on all questions, except on the questions about the amount of swelling, the

ability to perform tasks with the elevated arm, and ability to wear clothes of choice. For these 3 questions, patients with objective lymphedema had a significantly higher score than patients with subjective lymphedema.

Discussion

The Lymph-ICF is the first reliable and valid Dutch questionnaire based on the terminology of the ICF to assess the impairments in function, activity limitations, and participation restrictions of patients with breast cancer and arm lymphedema (developed following axillary dissection).

Reliability of the final version of the Lymph-ICF was good for patients with arm lymphedema. The ICCs of the total score on the Lymph-ICF and the score on each domain varied between strong and very strong. Augustin et al¹² also mentioned high test-retest reliability for their questionnaire, but they used a correlation coefficient for their analyses. It is more accurate to use the ICC

Table 6. Comparison Between Patients With Lymphedema (Objective or Subjective) and Without Lymphedema to Determine Known-Groups Validity (Mann-Whitney *U* Test)^a

Score	With Lymphedema		Without Lymphedema		P
	N	Median (Q1,Q3)	N	Median (Q1,Q3)	
Lymph-ICF total score	60	33 (19,43)	30	9 (4,20)	<.001
Physical function score	60	38 (17,54)	30	6 (3,11)	<.001
1. Heavy	60	43 (17,71)	30	3 (0,11)	<.001
2. Stiff	58	29 (4,59)	30	3 (0,9)	<.001
3. Swollen	60	49 (21,63)	30	2 (0,5)	<.001
4. Lost strength	59	46 (19,73)	30	17 (2,31)	.01
5. Tingle	59	16 (1,51)	29	1 (0,11)	.01
6. Hurt	59	27 (4,58)	30	5 (0,15)	<.001
7. Tensed skin	59	27 (3,56)	30	4 (0,7)	<.001
Mental function score	60	19 (5,36)	30	3 (0,24)	.01
8. Feel sad	59	15 (2,46)	30	2 (0,8)	.01
9. Feel discouraged	60	17 (3,44)	30	2 (0,32)	.01
10. Lack of self-confidence	60	13 (1,32)	30	0 (0,5)	.01
11. Feel stressed	60	21 (5,53)	30	1 (0,25)	.01
Household activities score	60	27 (10,48)	30	4 (0,19)	<.001
12. Clean	55	38 (7,67)	27	8 (0,28)	.01
13. Cook	59	9 (1,26)	28	0 (0,4)	<.001
14. Iron	57	16 (3,53)	28	1 (0,17)	.01
15. Garden	43	48 (21,74)	22	11 (2,41)	.01
Mobility activities score	60	38 (15,47)	30	11 (3,29)	<.001
16. Tasks with arm elevated	59	29 (5,64)	30	9 (0,46)	.07
17. Lift heavy objects	57	55 (16,82)	30	24 (4,59)	.02
18. Sleep on affected side	57	22 (3,51)	30	4 (0,22)	.01
19. Work on computer	33	22 (4,66)	17	0 (0,7)	.01
20. Sunbathe	37	74 (37,96)	19	4 (0,75)	.01
21. Drive a car	47	17 (2,37)	25	0 (0,4)	<.001
22. Walk	60	9 (1,37)	28	4 (0,42)	.38
23. Cycle	46	16 (2,47)	26	5 (0,13)	.04
Life and social activities score	60	26 (9,44)	30	5 (0,20)	.01
24. Go on vacation	51	9 (0,26)	27	0 (0,9)	.01
25. Perform hobbies	46	18 (3,51)	23	0 (0,9)	.01
26. Practice sport	36	48 (9,86)	16	8 (0,59)	.07
27. Wearing clothes of choice	60	24 (1,60)	30	0 (0,9)	<.001
28. Do a job	23	30 (9,91)	17	5 (0,37)	.04
29. Do social activities	57	12 (0,25)	28	0 (0,7)	.01

^a Lymph-ICF=Lymphoedema Functioning, Disability and Health Questionnaire, Q1=first quartile, Q3=third quartile.

because this statistical test shows how strongly 2 variables resemble each other, not just correlate.²⁴ Similar to Viehoff et al,¹³ who tested ULL-27, we found Cronbach alpha coefficients higher than the recommended level of .70. The Cronbach alpha coefficient of the FLQA-I was beneath the recommended level for 3 of 6 domains.¹² None of these studies examined changes of the mean, measurement variability, and clinically important changes, as recommended by Lexell and Downham.¹⁹

Content validity of the final version of the Lymph-ICF was very good for patients with arm lymphedema following axillary dissection. All patients found the questions understandable, and only a few patients found the scoring system unclear. According to the WHO taxonomy, impairments in function, activity limitations, and participation restrictions have to be quantified with the following scale: 0% to 4% is no problem, 5% to 24% is a small problem, 25% to 49% is a moderate problem, 50% to 95% is a severe problem, and 96% to 100% is a very severe problem.⁶ Because of the gradation of this scale, we chose a VAS as scoring system and preferred not to use a Likert scale, as others did.^{11-13,25}

For patients who experienced scoring problems because their complaints were not always present or not present for a long time, the therapist had to emphasize that they had to score their average complaints during the previous 2 weeks, as mentioned in the introduction of the questionnaire. Furthermore, a pilot version of the Lymph-ICF was constructed based on information from the literature and from complaints of patients with arm lymphedema. Afterward, the patients gave their comments on the questionnaire, which led to the construction of the final version of the Lymph-ICF. Only a few patients mentioned missing a

complaint (concerning their arm lymphedema) in the final version of the Lymph-ICF, but the mentioned complaints did not have to be included in the questionnaire. The complaints of pain in the breast,²⁶ edema at the axilla,^{27,28} and loss of sensations^{2,29} were complications related to the treatment of breast cancer and not due to the arm lymphedema. The complaint "shooting pain in the arm" could be scored with the question "Does your arm hurt?" The complaint "stress from visiting the physical therapist" could be scored with the question "Due to your arm problems, do you feel stressed?" The complaint "not able to go shopping" could be scored with the question "Are you able to lift or carry heavy weights?" To score the inability to perform a static activity with the arm and hand, we chose to question the ability to work on the computer and not the ability to write, because in the future, the activity "writing for >30 minutes" will be performed less frequently and will be replaced by the activity "working on the computer for >30 minutes." Other studies did not analyze content validity.

Construct validity was tested in 2 ways and gave good results in the patients with arm lymphedema. Each domain of the Lymph-ICF (except the life and social activities domain) had the strongest correlation (between $-.51$ and $-.70$) and 3 of 5 domains had the weakest correlation with the expected domains of the SF-36, confirming good convergent and divergent validity, respectively. Other studies found comparable¹³ or slightly higher correlations¹² between their questionnaire and a questionnaire already tested on reliability and validity. The ULL-27 and the RAND 36-Item Health Survey (RAND36) showed correlations between $.45$ and $.69$,¹³ and comparable domains of the FLQA-I on one hand and of the ALLTAG and the

Nottingham Health Profile on the other hand showed correlations between $.66$ and $.77$.¹² Concerning the second method of the construct validity analyses, patients with arm lymphedema had a significant higher total score on the Lymph-ICF, higher scores on the 5 domains, and higher scores on almost all questions. Only the inability to walk seemed not specific for patients with lymphedema, although this activity was mentioned by a number of patients in the first phase of the construction of the questionnaire. Whether the removal of this question from the Lymph-ICF is necessary needs to be further investigated.

In the present study, patients with subjective and objective lymphedema had equal scores on the Lymph-ICF. This finding confirms the results of a study by Viehoff et al,¹³ who could not find an association between the severity of the swelling and the score on the ULL-27. Time interval since surgery was significantly larger in the group with objective lymphedema (55 months) than in the group with subjective lymphedema (34 months). To our knowledge, it is unknown whether breast and axillary surgery-related complaints still change between 35 and 55 months postsurgery. If breast and axillary surgery-related complaints still decrease between 35 and 55 months after surgery, patients with objective lymphedema have fewer complaints related to breast and axillary surgery compared with patients with subjective lymphedema. Thus, the score on a number of breast and axillary surgery-related questions in the group with objective lymphedema may be underestimated.

A strength of our study was that different aspects of reliability and validity of the Lymph-ICF were investigated. Our study did not investigate responsiveness of the Lymph-ICF.

This topic warrants further examination. Further investigation of the reliability and validity of the English-language version of the questionnaire also is needed. Our study had a few limitations. Four patients did not complete the Lymph-ICF a second time, so test-retest reliability was based on 56 patients instead of 60 patients. Because this is only a small proportion (7%) of the included patients and their age range (44–71 years) was comparable to the age range of the included patients (42–79 years), this limitation did not affect the results of the reliability testing. Only a limited number of patients participated in the first phase ($n=20$) and second phase ($n=29$) of the development of the questionnaire, and the characteristics of the included patients in the first phase were missing. In addition, testing of content validity in the second and third phases of development of the Lymph-ICF occurred with an author-developed questionnaire. These limitations weaken the results of the content validity analyses of our questionnaire. Finally, our questionnaire was constructed to assess impairments in function, activity limitations, and participation restrictions of patients with lymphedema developed after the treatment of breast cancer. Patients find it difficult to distinguish between complications related to lymphedema developed after breast cancer treatment and complications related to the treatment of breast cancer itself. However, patients with lymphedema had a higher score for all questions (except one) on the Lymph-ICF than patients without lymphedema. In conclusion, the final version of the Lymph-ICF is a reliable and valid Dutch questionnaire to assess functional problems of patients with arm lymphedema developed after axillary dissection.

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Lymphoedema Functioning, Disability and Health Questionnaire

Appendix.

Continued

Pain, skin sensations, and functions of the immunologic and movement systems

Does your arm:

	Not at all		Very much
	↓		↓
1. Feel heavy?	_____		_____
2. Feel stiff?	_____		_____
3. Feel swollen?	_____		_____
4. Feel like it has lost strength?	_____		_____
5. Tingle?	_____		_____
6. Hurt?	_____		_____
7. Have a tensed skin?	_____		_____

Mental function

Due to your arm problems:

	Not at all		Very much
	↓		↓
8. Do you feel sad?	_____		_____
9. Do you feel discouraged?	_____		_____
10. Do you have a lack of self-confidence?	_____		_____
11. Do you feel stressed?	_____		_____

Household activities

How well are you able to:

	Very well		Not at all		Not applicable
	↓		↓		↓
12. Clean (scrub, vacuum, mop)?	_____		_____		○
13. Cook?	_____		_____		○
14. Iron?	_____		_____		○
15. Work in the garden?	_____		_____		○

(Continued)

Appendix.

Continued

Mobility activities

How well are you able to:

	Very well	Not at all	Not applicable
	↓	↓	↓
16. Perform tasks with the arm elevated (eg, hang out the laundry)?	_____		○
17. Lift or carry heavy objects (eg, a filled bucket or shopping bags)?	_____		○
18. Sleep on the affected side?	_____		○
19. Perform computer work (>30 min)?	_____		○
20. Sunbathe?	_____		○
21. Drive a car?	_____		○
22. Walk (>2 km)?	_____		○
23. Ride a bike?	_____		○

Life and social activities

How well are you able to:

	Very well	Not at all	Not applicable
	↓	↓	↓
24. Go on vacation	_____		○
25. Perform your hobbies?	_____		○
26. Practice sports?	_____		○
27. Wear your clothes of choice?	_____		○
28. Do your job?	_____		○
29. Do social activities (eg, going to parties, concerts, restaurant)?	_____		○

^aThe Lymphoedema Functioning, Disability and Health (Lymph-ICF) Questionnaire may not be used or reproduced without written permission of the authors.