Revision of the lymphedema functioning, disability and health questionnaire for upper limb lymphedema (Lymph-ICF-UL) : reliability and validity

Title page

Revision of the Lymphedema Functioning, Disability and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL): Reliability and Validity

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Tables. Tables should be formatted in Word, numbered consecutively, and placed together at the end of the manuscript. In tables that describe characteristics of 2 or more groups:
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Condensation

Assessing reliability and validity of the Lymph-ICF-UL questionnaire in patients with breast cancer-related lymphedema

Abstract

Background. Lymphedema is associated with significant physical and psychosocial problems. The Lymphedema Functioning, Disability and Health questionnaire for upper limb lymphedema is a valid and reliable tool used to quantify the amount of problems in functioning in patients with breast cancer-related lymphedema. Although, patients suggested a revision of the scoring system to facilitate completion of the questionnaire. Therefore, adjustment of the questionnaire was carried out by implementing a numeric rating scale instead of the existing visual analogue scale.

Objective. Purpose of this study was to investigate reliability and validity of the revised Lymph-ICF, called the Lymph-ICF-UL.

Design. A multicenter, cross-sectional study.

Methods. Reliability and validity of the Lymph-ICF-UL was examined on 56 participants with objective upper limb lymphedema.

Results. Intraclass correlation coefficients for test-retest reliability ranged from .79 to .95. Cronbach's alpha coefficients for internal consistency were higher than .80. There were no systematic changes in-between the two test occasions, and measurement variability was acceptable. Face and content validity were very good because the scoring system was clear for all participants (100%), questions were understandable for 98% of the participants, and all complaints due to arm lymphedema were mentioned by 79% of the participants. Construct validity was good. Convergent validity was established since 4 out of 5 expected domains of the Lymph-ICF-UL showed a moderate correlation with expected domains of the 36-Item Short-Form Health Survey questionnaire. There was good divergent validity because 7 out of 9 hypotheses assessing divergent validity were accepted.

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Word count: 275

Conclusion. The Lymph-ICF-UL is a reliable and valid questionnaire using a simplified and clearer scoring procedure to assess impairments in function, activity limitations, and participation restrictions of patients with breast cancer-related arm lymphedema.

Keywords: Breast cancer, lymphedema, Lymph-ICF-UL, reliability, validity

Introduction

Upper limb lymphedema is a debilitating morbidity affecting more than 16% of the woman treated for breast cancer[1]. The swelling can be caused by destruction of the lymphatic vessels due to surgery or radiotherapy, resulting in a reduced lymphatic transport[2]. Lymphedema can be assessed objectively with different assessment methods that all are valid and reliable[3]. Examples of commonly used assessment methods are different kind of water displacement methods[4 5], and circumference measurements using a tapeline[6] or perimeter[7] after which the calculated volume can be determined[6]. However, an objective assessment of the amount of lymphedema volume lacks the power to encounter the real burden of lymphedema. Besides swelling, patients can suffer from problems in physical, social and mental functioning[8]. Additionally, breast cancer-related lymphedema (BCRL) can cause a lower quality of life [9-11]. Therefore, the Lymphedema Functioning, Disability and Health questionnaire for the upper limb (Lymph-ICF) was developed[7]. This questionnaire aims to quantify impairments in function, activity limitations and participation restrictions which are related to lymphedema in the upper limb. In contrast to other lymphedema-related questionnaires it is based on terminology of the International Classification of Functioning, Disability and Health (ICF) as introduced by the World Health Organization[12]. As confirmed by Viehoff et al, the ICF provides a valuable reference frame to identify and quantify meaningful concepts focusing on individuals with lymphedema[13].

The quality and usefulness of a questionnaire is determined by its clinical properties, such as validity, reliability and responsiveness. The reliability and validity of the Lymph-ICF have already been examined and it has shown to be a valid and reliable Dutch questionnaire for assessing functional problems in patients with BCRL developed after axillary dissection[7]. However, patients mentioned that the use of a scoring system with gradation, for instance a

Met opmerkingen [TDV3]: (1) Title page,
(2) Abstract,
(3) Body of article,
Introduction
Methods
Results
Discussion
(4) Acknowledgments, (+ Funding + Conflicts of Interest)
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(6) Tables,
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numeric rating scale (NRS), would be an easier scoring method instead of a visual analog scale (VAS), hence facilitating the completion of this questionnaire. Therefore, in 2014 when the Lymph-ICF-LL questionnaire for lower limbs was developed, the scoring mechanism was revised by implementing a NRS instead of a VAS[14]. This revision had not yet been extended to the Lymph-ICF questionnaire for upper limb lymphedema. As an answer to this, a revision of the Lymph-ICF questionnaire was established by implementing a NRS instead of the existing VAS. Although scores are not interchangeable, both VAS and NRS have proven to be valid, reliable and sensitive[15 16]. Moreover, NRS showed to be the recommended scale based on a higher compliance, better responsiveness with lower error rate, and better applicability compared to VAS[15]. Clinimetric properties of this revised questionnaire have not been investigated yet. Therefore, the aim of this study was to examine different aspects of reliability and validity of the Lymph-ICF-UL with NRS related to upper limb lymphedema after breast cancer treatment.

Methods

Study design

Included subjects were participants of the EFforT-BCRL trial (n= 42)[17] and were recruited in the University Hospitals of Leuven and the Antwerp University Hospital in Belgium. To shorten the inclusion period, also a small group of participants (n= 14) was recruited in the Lymphovenous Center of the University Hospitals of Leuven. Approval for this trial was obtained by the Ethical Committee of the University Hospitals of Leuven (main Ethical Committee) and received positive advice from the Ethical Committees of all other participating centers (CME reference S58689, EudraCT Number 2015-004822-33).

This cross-sectional study is reported following the COSMIN (COnsenus-based Standards for the selection of health Measurement INstruments) guidelines[18].

Participants

56 participants with BCRL were included between December 2016 and August 2017. Eligibility criteria were: 1) subjects diagnosed with unilateral lymphedema of the arm and/ or hand, developed after treatment for breast cancer, 2) chronic lymphedema stage I to IIb (duration of >3 months), 3) at least 5% difference between both arms and/ or between both hands at start of the treatment (in case of participation in EFforT-BCRL trial) or at the day of the consultation at the Lymphovenous Center, adjusted for limb dominance. Participants were excluded when 1) they had edema of the upper limb from other cause than breast cancer treatment, or 2) when they were not native Dutch speaking or able to read and fully understand the Dutch language.

Procedure

To analyze the clinimetric properties of the revised version of the Lymph-ICF questionnaire, the same methodology was applied as for the investigation of the clinimetric properties of the original questionnaires[7 14]. The revised Lymph-ICF is called the Lymph-ICF-UL.

Lymph-ICF-UL questionnaire

In the introduction of the Lymph-ICF-UL questionnaire, the scoring system is explained. Then the patient is asked to score her average impairments in function, activity limitations, and participation restrictions during the past 2 weeks. Furthermore, the patient is asked not to

discuss the questions with anyone to maintain the self-assessment characteristics of the questionnaire. The Lymph-ICF-UL questionnaire takes about 5 to 10 minutes to complete.

Different scores are obtained from the questionnaire. Each of the 29 questions has to be scored on an 11-point Likert scale between 0 and 10 (instead of a VAS between 0 and 100). The total score of the Lymph-ICF-UL is equal to the sum of the scores on the questions divided by the total number of answered questions, and multiplied by 10. In addition, a score is determined for each of the 5 domains of the Lymph-ICF-UL: (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-UL and the score on the 5 domains range between 0 and 100. According to the World Health Organization taxonomy, impairments in function, activity limitations, and participation restrictions can 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[12].

The Lymph-ICF-UL has already been translated into the English and French language according to established international guidelines described by the World Health Organization[19]. For more details about the establishment of the original version of the Dutch Lymph-ICF questionnaire, we refer to Devoogdt et al[7].

Reliability

To analyze test-retest reliability, patients completed the adapted questionnaire twice; once at the hospital and once at home with an interval of 24 to 48h after the first test. This time interval was chosen given the fact that problems related to arm lymphedema may change from one day to another. Since the questionnaire consists of 29 questions, the risk for recall bias is negligible. This second questionnaire needed to be returned by mail.

Validity

To analyze construct validity, patients also completed the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) once at the hospital. The SF-36 a valid, reliable and commonly used questionnaire to measure a person's health related quality of life[20 21]. It is a generic health status instrument, consisting of 36 questions. Eight domains are examined; i.e. physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health, and scores range between 0-100[21]. The higher the score on the SF-36, the better the quality of life of a subject.

Furthermore, to analyze face and content validity of the Lymph-ICF-UL questionnaire, each participant completed an additional questionnaire, developed by one of the authors (ND) in the original investigation[7]. This questionnaire consisted of following questions: (1) Was the scoring system clear? (yes/no), (2) Was each question of the Lymph-ICF-UL understandable? (yes/no), and (3) Were all complaints related to your lymphedema mentioned in the questionnaire? (yes/no). If a participant answered "no" to any of these questions, an explanation was asked.

Descriptive data such as participant'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, hormonal therapy or target therapy) and duration of lymphedema were collected by interviewing the participants and by consulting their medical records. The volumes of both affected and non-affected arms were calculated from limb circumferences, using a truncated cone formula[6]. Circumference measurements were performed using a perimeter, after which the volume of the arm was calculated using

following formula for each segment: $4 \times (C_1^2+C_1C_2+C_2^2)/12\pi$, where C_1 is the upper circumference and C_2 is the lower circumference of each segment. These measurements were performed by one of three physical therapists specialized in edema therapy (ND, LV, TDV).

Data analysis

Statistical analyses were performed using the software Statistical Package for the Social Sciences (SPSS for Windows version 24.0). The .05 level of significance was applied. Descriptive analyses were applied to describe the participants of this study .

Reliability

Intraclass correlation coefficients (ICCs) were used to determine test-retest reliability of the total score of the Lymph-ICF-UL, of the scores on the 5 domains, and of the score on each question separately[22]. ICC estimates and their 95% confident intervals (CIs) were calculated based on a single rating (k=1), absolute agreement, 2-way mixed-effects model[23 24]. Cronbach's alpha coefficients were used to determine internal consistency of the entire questionnaire as well as of each domain[25]. The ICCs and Cronbach's alpha coefficients were interpreted as follows: <.4 was weak, .4 to .74 was moderate, .75 to .9 was strong and >.9 was very strong[26 27].

To calculate significant changes in the mean between the two test occasions, Wilcoxon signed rank tests were performed since the One-Sample Kolmogorov-Smirnov test revealed non-normal distribution of data.

Met opmerkingen [GN4]: Ik heb dit nog eens opgezocht:
Wanneer gebruik ik Two Way Mixed?
Het Two Way Mixed model gaat ervan uit dat er een vast aantal beoordelaars zijn die een sample van alle patiënten beoordelen. Dit is bijvoorbeeld het geval als dezelfde samples een keer handmatig en een keer computergestuurd worden afgelezen. We zijn daarbij geïnteresseerd in de overeenstemming tussen deze twee specifieke technieken en willen dit niet extrapoleren naar een derde techniek oid.
Wanneer gebruik ik Two Way Random?
Het Two Way Random model gaat ervan uit dat de beoordelaars niet vast zijn, maar ook een random sample zijn van alle mogelijke beoordelaars. Dit is bijvoorbeeld het geval als er bij patiënten twee maal de temperatuur gemeten wordt. We zijn daarbij geïnteresseerd in de overeenstemming tussen de twee herhaalde metingen. Maar we willen hiermee ook iets kunnen zeggen over toekomstige herhalingen van temperatuurmetingen.
Wanneer gebruik ik One Way Random?
Het One Way Random model gaat ervan uit dat de beoordelaars een random sample zijn van alle beoordelaars, maar dat nu alle patiënten (of in het algemeen targets) beoordeeld worden. Omdat er in medisch onderzoek meestal gewerkt wordt met een sample uit de totale patiëntenpopulatie, wordt dit model daarbij niet vaak gebruikt.

Volgens dit is het dus two way random maar in het design waren de raters wel dezelfde.

Met opmerkingen [TDV5R4]: Advies statisticus L-BioStat hierover:
Shrout and Fleiss suggest that 2-way mixed-effects model is appropriate for testing intrarater reliability with multiple scores from the same rater, as it is not reasonable to generalize one rater's scores to a larger population of raters. Similarly, 2-way mixed-effects model should also be used in test-retest reliability study because repeated measurements cannot be regarded as randomized samples…

Dus welk advies opvolgen?

To interpret the magnitude of the within-subjects variation of the 2 scores, the standard error of measurement (SEM) was calculated using following formula: SEM = SD$\sqrt{(1 - ICC)}$, where SD was the average standard deviation of the 2 ratings[22]. To evaluate clinically important changes, we calculated the smallest real difference (SRD) using the formula: SRD = 1.96 x SEM x $\sqrt{2}$ [22]. 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 ± SRD.

Validity

Face 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. Face validity was examined by asking the participants whether the scoring system was obvious and whether the questions in the Lymph-ICF-UL were understandable. Content validity of the Lymph-ICF-UL was examined by analyzing the answers given by the participants to the question about the comprehensiveness of the questionnaire. First, the number of positive answers on each of the 3 questions was counted. Next, the participants' explanations on the negative answers were discussed.

To investigate construct (convergent and divergent) validity of the Lymph-ICF-UL, the relationship between scores on domains of the Lymph-ICF-UL and scores on domains of the SF-36 was examined. Spearman rank correlation coefficients were used since data was non-normal distributed. To determine convergent and divergent validity and based on the content of the questions of each domain of Lymph-ICF-UL and SF-36, we used the same hypotheses as

Met opmerkingen [TDV6]: De hypotheses zijn hetzelfde gebleven als in de originele studie in 2011; enkel waren deze toen strenger en moest er soms per hypothese aan 2 voorwaarden voldaan zijn. Nu zijn deze opgesplitst waardoor het in totaal 14 hypothesen zijn ipv 10.

formulated in the validation study of the original Lymph-ICF[7]. In case of agreement between the questions in a specific domain of the Lymph-ICF-UL and SF-36, these domains were included in a hypothesis for assessing convergent validity. In case of disagreement, they were included in a hypothesis for assessing divergent validity. Table 1 shows an overview of the various hypotheses for determining convergent validity and divergent validity and the rationale for the various hypotheses. Correlation coefficients were interpreted as follows: <.4 was weak, .4 to .74 was moderate, .75 to .9 was strong and >.9 was very strong[26]. If a moderate to very good correlation was found between two corresponding domains, the hypothesis for convergent validity was accepted. In case of a weak correlation between two disagreeing domains, the particular hypothesis for divergent validity was accepted. Construct validity was defined as very good if more than 90% of all 14 hypotheses were confirmed, was defined as good if between 75% and 90% of the hypotheses were confirmed, and was defined as moderate if between 40% and 74% of the hypotheses were confirmed. We assumed that the reliability and validity of the Lymph-ICF-UL after revision of the scoring procedure (using NRS) was going to be equal or even more reliable and valid than the original Lymph-ICF (using VAS).

(Please insert here Table 1)

Results

56 volunteers with objective unilateral BCRL participated in this study. All participants had undergone breast surgery with axillary dissection (SLNB and/or ALND). Radiotherapy and chemotherapy were completed prior entering the study. All patients were female. Mean

lymphedema volume of the arm was 410 mL (±351). For more details about the participant characteristics, see Table 2.

(Please insert here Table 2)

Reliability

Table 3 gives an overview of the ICCs, Cronbach's alpha coefficients, SEMs and SRDs for the total score on the Lymph-ICF-UL and for the scores on each domain separately. Test-retest reliability of the total score and of the mental function and mobility activities scores were very strong (ICC > .90). The other scores (i.e. physical function score, household activities score and life and social activities score) were found strong (ICC >.75). Test-retest reliability of the scores on 26 questions (90%) were strong to very strong (data not shown). Reliability of scores on the other 3 questions (about the abilities to cook, to iron and to wear clothes) were moderate (ICC= .60-.74).

Internal consistency of the Lymph-ICF-UL also ranged between strong and very strong. The Cronbach's alpha coefficient for all questions was .98 and ranged for the different domains between .89 and .98.

There were no statistical differences between the means of the total score, as well as of the separate domain scores of the Lymph-ICF-UL, between the two test occasions which were calculated with Wilcoxon signed rank analyses (Table 3).

The total score on the Lymph-ICF-UL had a variation from one test occasion to the other of

4.9. A decrease or an increase in score of 10 or more could be considered (with 95% certainty) a statistically significant change. Furthermore, a decrease or increase in score of 14 or more could be considered a clinically relevant change. The variability in each of the 5 domain scores was evaluated in the same way. The household activities domain showed the greatest variability (12.3), and the SRD was 34.1 (Table 3).

(Please insert here Table 3)

Validity

The questionnaire concerning face and content validity of the Lymph-ICF-UL was completed by all participants. All participants (100%) found that the scoring system was clear. Fifty-five participants (98%) mentioned that the questions of the Lymph-ICF-UL were understandable; 1 participant found that the 2 questions about the ability to sport and to work were too vague. Forty-four participants (79%) mentioned that all complaints were addressed in the questionnaire. Complaints related to the physical function domain not covered in the questionnaire were: pain in the breast, hypersensitivity of the skin, presence of paresthesia and number of episodes of erysipelas. Complaints related to the mental function domain not covered in the questionnaire were: feeling annoyed/embarrassed about wearing compression garment (mentioned by 3 participants). Complaints related to the mobility activities domain not covered in the questionnaire were: ability to perform more powerful activities and a question about a delayed onset of complaints after performing a task (i.e. not at the moment itself). Complaints related to the life and social activities domain not covered in the questionnaire were: possibility of wearing any kind of bra and the ability to meet the former (pre-surgery) sports/activity level. Lastly 1 participant mentioned that the distinction between

limb dominance within the questions was not covered. Nevertheless, perceived missing complaints did not have to be included in the questionnaire.

Table 4 provides an overview of the Spearman rank correlation coefficients between the different domains of the Lymph-ICF-UL and the SF-36. All participants completed both questionnaires. Concerning convergent validity, 4 out of 5 domains of the Lymph-ICF-UL correlated at least moderate with the expected corresponding domains of the SF-36. The correlation coefficients of these 4 ranged from -.42 to -.66 (moderate correlations). One hypothesis could not be accepted since there was a weak correlation between the household activities domain of the Lymph-ICF-UL and the physical function domain of the SF-36 (-.24). Therefore, 4 out of 5 hypotheses for assessing convergent validity were accepted. Concerning divergent validity, 7 out of 9 domains of the Lymph- ICF-UL showed a weak correlation with the expected corresponding domains of the SF-36. The correlation coefficients of these 7 ranged from -.19 to -.37 (no to weak correlation). Two hypotheses, between the mental function domain of the Lymph-ICF-UL and the role-physical domain of the SF-36 and between the life and social activities domain of the Lymph-ICF-UL and the physical functioning domain of the SF-36, could not be accepted as these were moderate correlations (-.53 and -.43 respectively). Consequently, 7 out of 9 hypotheses for assessing divergent validity were accepted, resulting in an overall good construct validity of the Lymph-ICF-UL (79%).

(Please insert here Table 4)

Discussion

Met opmerkingen [TDV7]: *The Discussion section ideally should contain no more than 5 paragraphs and should address:*
• Statement of principal findings
• Strengths and weaknesses of the study
• Strengths and weaknesses in relation to other studies, discussing important differences in results
• Meaning of the study: possible explanations and implications for clinicians and policymakers
• Unanswered questions and needs for future research

In 2011, the original version of the first Dutch questionnaire based on terminology of the ICF to assess the impairments in function, activity limitations, and participation restrictions of patients with BCRL, was shown to be valid and reliable. The revised version, the Lymph-ICF-UL questionnaire, is also found appropriate and useful in clinical practice by showing very good (reliability) to good (validity) clinimetric properties.

Reliability of the Lymph-ICF-UL was very good. The ICCs of the total score on the Lymph-ICF-UL and the different domain scores varied between strong and very strong, showing over all higher ICC values than those shown in the original study, except for the household activities score[7]. However, this ICC value is still high enough to speak of good test-retest reliability. Moreover, the ICC value of life and social activities improved remarkably. Consequently, the test-retest reliability of this domain improved from moderate to strong. Compared to the original version of the Lymph-ICF-UL, also Cronbach's alpha coefficients are increased for both the total score as for the scores on the different domains, with exception of the household activities score where Cronbach's alpha remained stable. If we look at the differences in SEMs and SRDs between this revised version and the original version, we found similar SEMs and SRDs for the total score as for the different domains. Except for the household activities domain we found a higher SEM and SRD, and for the mental function domain as well as the life and social activities domain we found remarkably lower SEMs and SRDs in present study.

Face and content validity of the Lymph-ICF-UL was very good for participants with BCRL. All participants (100%) found the revised scoring system (NRS) clear, in contrast to the original version in which the scoring system (VAS) was clear for only 88% of the participants and

whereby participants mentioned preferring a scoring system with gradation. Thus, revision of the scoring system by using the same anchors as in the original version, although implementing a NRS from 0 to 10 instead of a VAS, resulted in an improved face validity of the questionnaire.

Only 1 participant did not fully understand all questions, since she found that the 2 questions about the ability to sport and to work were too vague. In the original version, however, all patients mentioned that the questions were understandable.

Seventy-nine percent of the participants reported that all complaints were addressed in the questionnaire. Twelve participants mentioned missing a complaint in the Lymph-ICF-UL. However, after discussing the reported complaints with a team of experts (ND, LV, TDV), we decided that these reported complaints did not have to be included in the questionnaire. In the original version, 85% of the participants mentioned that all complaints were addressed in the Lymph-ICF. Complaints that were lacking in the original study, were comparable with the ones in current study and therefore were not relevant to be included in the questionnaire either. The mentioned complaints in present version concerning pain in the breast[28], wearing any kind of bra, and paresthesia or hypersensitivity of the skin[29 30], were complications related to the treatment of breast cancer and not due to the arm lymphedema. These participants found it difficult to distinguish between complications related to lymphedema developed after breast cancer treatment and complications related to the treatment of breast cancer itself, which can weaken the results of the content validity analyses of the questionnaire. The complaint 'number of episodes of erysipelas' is not part of the questionnaire because during the development phase of the Lymph-ICF questionnaire, none of the patients reported erysipelas as complaint. In contrast, with the development of the Lymph-ICF-LL questionnaire, this was reported by patients with lower limb lymphedema and

so it was included. The complaint 'feeling annoyed/embarrassed about wearing compression garment' could be scored with the question "Due to your arm problems, do you feel stressed?". The complaint 'ability to perform more powerful activities' could be scored with the questions "Are you able to lift or carry heavy weights?" or "Are you able to work in the garden?" (if applicable). The complaint 'delayed onset of complaints after performing a task (i.e. not at the moment itself)' could be scored with the question that examines the particular activity because the questions rely upon a recall period of two weeks. The complaint 'ability to meet the former (pre-surgery) sports/activity level' could be scored with the questions "How well are you able to perform your hobbies/How well are you able to practice sports?". Lastly, the complaint 'lack of distinction between limb dominance within the questions' is not necessary to include as a separate question since limb dominance is an item that is collected separately from the lymph-ICF-UL questionnaire.

Construct validity of the Lymph-ICF-UL was tested in terms of convergent and divergent validity and gave good results. Concerning convergent validity, 4 out 5 domains (or 80%) of the Lymph-ICF-UL correlated at least moderately with the expected corresponding domains of the SF-36 (between -.42 to -.66). In the original study, all 5 hypotheses concerning convergent validity could be accepted. In this current study, 4 out of 5 hypotheses were accepted since the household activities (-.24) domain of the Lymph-ICF-UL did not show a moderate or strong correlation with the expected physical function domain of the SF-36. The remaining 4 hypotheses did show moderate correlations with the expected domains of the SF-36. Noteworthy, this moderate correlation was also present between the life and social activities domain of the Lymph-ICF-UL and the social functioning domain of the SF-36, although this correlation was weak in the previous version (-.61 and -.33, respectively).

Concerning divergent validity, 7 out of 9 hypotheses (78%) were accepted in current study, whereas 3 out of 5 hypotheses (60%) were accepted in the original study. Unexpected, the mental function domain of the Lymph-ICF-UL showed a moderate correlation with the role-physical (-.53) domain of the SF-36, in contrast with the previous version where this correlation was weak (-.25).

A strength of this study is that different aspects of reliability and validity of the Lymph-ICF-UL were investigated. However, our study did not investigate responsiveness of the Lymph-ICF-UL. Research to determine this clinimetric property is undertaken.

Our study had a few limitations. First, the sample size of this study consisted of only 56 participants. However, as stated by Shrout and Fleiss, researchers should try to obtain at least 30 heterogeneous subjects for reliability studies[24]. The sample of our study is heterogeneous since participants with BCRL stages I, IIa or IIb, with a broad range of duration in months (at least 3 months) and a broad range of lymphedema volume were enrolled to accommodate this. Second, testing of face and content validity occurred with an author-developed questionnaire. This questionnaire was constructed to assess impairments in function, activity limitations, and participation restrictions of patients with lymphedema developed after the treatment of breast cancer. Although, as previously stated, 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. This weakens the results of the content validity analyses of the questionnaire.

In conclusion, the Lymph-ICF-UL is a reliable and valid Dutch questionnaire using a simplified and clearer scoring procedure to assess functional problems of patients with arm lymphedema developed after breast cancer treatment. This tool enables a better understanding of a patient

in total since not only clinical aspects regarding lymphedema are being evaluated but also the impact of these on someone's daily physical and mental functioning. This provides important treatment goals where both therapist and patient are able to monitor long-term results of this treatment and self-care. For the interpretation of follow-up assessments with the Lymph-ICF-UL, a change (decrease or increase) of 14 or more in the total score should be considered a clinically relevant change. Further research into the responsiveness, as well as into the clinimetric properties of the French version of this questionnaire, is undertaken.

Word count: 4150

Met opmerkingen [TDV8]: Max 4000 woorden… dus nog iets in te korten

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Conflicts of interest

The authors have no conflicts of interest to declare.

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Tables

Table 1. Fourteen Hypotheses and Rationale for Hypotheses for Assessing Construct Validity[a]

Hypothesis	Rationale
Convergent validity	Considering all correlation coefficients for various domains of the Lymph-ICF-UL and the SF-36, at least moderate correlation coefficients would occur between:
1: Lymph-ICF-UL physical function and SF-36 bodily pain	Lymph-ICF-UL physical function: Does your arm: feel heavy, feel stiff, feel swollen, feel like it has lost strength, tingle, hurt or have a tensed skin? SF-36 bodily pain: How much bodily pain have you had during the past 4 wk? During the past 4 wk, how much did pain interfere with your normal work?
2: Lymph-ICF-UL mental function and SF-36 mental health	Lymph-ICF-UL mental function: Due to your arm problems, do you feel sad, do you feel discouraged, do you have a lack of self-confidence, do you feel stressed? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?
3: Lymph-ICF-UL household activities and SF-36 physical functioning	Lymph-ICF-UL general tasks/household activities: How well are you able to: clean (scrub, vacuum, mop), cook, iron, work in the garden? SF-36 physical functioning: Does your health limit you in the following activities: vigorous activities, such as lifting heavy objects; moderate activities, such as moving a table, pushing a vacuum, lifting or carrying groceries, climbing several flights of stairs, climbing 1 flight of stairs, bending, kneeling, stooping, walking more than a mile, walking half a mile, walking 100 yd (91.44 m), and bathing or dressing yourself?
4: Lymph-ICF-UL mobility activities and SF-36 physical functioning	Lymph-ICF-UL mobility activities: How well are you able to: perform tasks with the arm elevated (e.g. hang out the laundry), lift or carry heavy objects (e.g. a filled bucket or shopping bags), sleep on the affected side, perform computer work (>30 min), sunbathe, drive a car, walk (>2 km), ride a bike? SF-36 physical functioning: Does your health limit you in the following activities: vigorous activities, such as lifting heavy objects; moderate activities, such as moving a table, pushing a vacuum, lifting or carrying groceries,

	climbing several flights of stairs, climbing 1 flight of stairs, bending, kneeling, stooping, walking more than a mile, walking half a mile, walking 100 yd, and bathing or dressing yourself?
5: Lymph-ICF-UL life and social activities and SF-36 social functioning	Lymph-ICF-UL life domains/social life: How well are you able to: go on vacation, perform your hobbies, practice sports, wear your clothes of choice, do your job, do social activities (e.g. going to parties, concerts, restaurant)? SF-36 social functioning: During the past 2 wk, to what extent have your physical health or emotional problems interfered with your normal social activities with family, neighbors, or groups? During the past 2 wk, how much of the time have your physical health or emotional problems interfered with your social activities?
Hypothesis	**Rationale**
Divergent validity	Considering all correlation coefficients for various domains of the Lymph-ICF-UL and the SF-36, weak correlation coefficients would occur between:
6-7: Lymph-ICF-UL physical function and SF-36 role–emotional and mental health	Lymph-ICF-UL physical function: Does your arm: feel heavy, feel stiff, feel swollen, feel like it has lost strength, tingle, hurt or have a tensed skin? SF-36 role–emotional: During the past 4 wk, how much time have you had problems with your work or other regular daily activities as a result of emotional problems? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?
8-9: Lymph-ICF-UL mental function and SF-36 physical functioning and role-physical	Lymph-ICF-UL mental function: Due to your arm problems, do you feel sad, do you feel discouraged, do you have a lack of self-confidence, do you feel stressed? SF-36 physical functioning: Does your health limit you in the following activities: vigorous activities, such as lifting heavy objects; moderate activities, such as moving a table, pushing a vacuum, lifting or carrying groceries, climbing several flights of stairs, climbing 1 flight of stairs, bending, kneeling, stooping, walking more than a mile, walking half a mile, walking 100 yd, and bathing or dressing yourself?

	SF-36 role-physical: During the past 4 wk, have you had any of the following problems with your work or other regular daily activities as a result of your physical health; cut down the amount of time you spent on work or other activities, accomplished less than you would like, were limited in the kind of work or other activities, had difficulty performing the work or other activities (for example, it took extra effort)?
10-11: Lymph-ICF-UL household activities and SF-36 role-emotional and mental health	Lymph-ICF-UL general tasks/household activities: How well are you able to: clean (scrub, vacuum, mop), cook, iron, work in the garden? SF-36 role–emotional: During the past 4 wk, how much time have you had problems with your work or other regular daily activities as a result of emotional problems? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?
12-13: Lymph-ICF-UL mobility activities and SF-36 role-emotional and mental health	Lymph-ICF-UL mobility activities: How well are you able to: perform tasks with the arm elevated (e.g. hang out the laundry), lift or carry heavy objects (e.g. a filled bucket or shopping bags), sleep on the affected side, perform computer work (>30 min), sunbathe, drive a car, walk (>2 km), ride a bike? SF-36 role–emotional: During the past 4 wk, how much time have you had problems with your work or other regular daily activities as a result of emotional problems? SF-36 mental health: How much time during the last 2 wk have you been a very nervous person, have you felt so down in the dumps that nothing would cheer you up, have you felt calm and peaceful, have you felt downhearted and low, and have you been a happy person?
14: Lymph-ICF-UL life and social activities and SF-36 physical functioning	Lymph-ICF-UL life domains/social life: How well are you able to: go on vacation, perform your hobbies, practice sports, wear your clothes of choice, do your job, do social activities (e.g. going to parties, concerts, restaurant)?

	SF-36 physical functioning: Does your health limit you in the following activities: vigorous activities, such as lifting heavy objects; moderate activities, such as moving a table, pushing a vacuum, lifting or carrying groceries, climbing several flights of stairs, climbing 1 flight of stairs, bending, kneeling, stooping, walking more than a mile, walking half a mile, walking 100 yd, and bathing or dressing yourself?

[a] Lymph-ICF-UL= Lymphedema Functioning, Disability and Health Questionnaire for Upper Limb Lymphoedema with Numeric Rating Scale; SF-36 = 36-Item Short-Form Health Survey questionnaire.

Table 2. Characteristics of the included subjects (n=56)

Variable	Outcome
Age (y)	62 (10)
Body Mass Index (kg/m^2)	27 (4)
Lymphedema volume arm (mL)	410 (351)
Duration lymphedema (mo)*	34.5 (13.5, 79.5 [66])
BCRL Stages	
I n(%)	10 (17.9%)
IIa n(%)	33 (58.9%)
IIb n(%)	13 (23.2%)
Breast Surgery	
Mastectomy n(%)	36 (58.1%)
Breast-conserving surgery n(%)	20 (32.3%)
Surgery on the dominant side n(%)	29 (46.8%)
Radiotherapy[a] n(%)	54 (87.1%)
Chemotherapy[a] n(%)	50 (80.6%)
Antihormonal therapy[a] n(%)	45 (72.6%)
Target therapy (Herceptin)[a] n(%)	13 (21%)

[a]n=55 since medical data of 1 patient is unknown due to previous treatment abroad; y= years, kg= kilogram, m^2= square meters, mL= milliliter, mo= months, BCRL= breast cancer-related lymphedema stages as described by the International Society of Lymphology; Descriptives are presented as "mean (standard deviation)" except when indicated with * where "median (25th, 75th percentile [interquartile range])" is shown.

Met opmerkingen [TDV9]: Tabel vergeleken met patiëntkarakteristiek uit originele studie:
- Leeftijd, BMI, LO volume gelijkwaardig in beide populaties
- Time interval since surgery is nu groter dan in de originele studie (84mo vs 55mo)
MAAR: in originele studie werd gemiddelde weergegeven, maar in deze studie zijn deze tijdswaarden niet-normaal verdeeld; waardoor ik hier eigenlijk de median + IQR telkens moet weergeven ipv mean en dit dus niet rechtstreeks vergelijkbaar is..
- Groter % aan ptn die chemo hebben gekregen in deze studie (81% vs 57%) en aan ptn die hormoontherapie krijgen (73% vs 59%) dan in de originele studie

Use "mean (SD)" rather than "mean ± SD" notation
Report percentages to one decimal place (ie, xx.x %).
• Report averages with standard deviations when data are normally distributed.
• Report median (minimum, maximum) or median (25th, 75th percentile [interquartile range, or IQR]) when data are not normally distributed.

Table 3. Reliability on the total score of the Lymph-ICF-UL and the scores on the 5 domains[a]

Score		*Mean*			*Test-retest*		*Internal consistency*	*Variability*		*Clinically important changes*	
	N	*X1*	*X2*	*P - value*	*ICC*	*95% CI*	[a]	*SEM*	*95% CI*	*SRD*	*95% CI*
Lymph-ICF-UL total score	**56**	**27.50**	**27.45**	**0.98**	**0.95**	**0.91-0.97**	**0.98**	**4.89**	**-9.57 to 9.61**	**13.56**	**-13.54 to 13.58**
Physical function score	56	24.30	22.76	0.26	0.90	0.83-0.94	0.92	6.76	-11.70 to 14.78	18.73	-17.19 to 20.27
Mental function score	56	18.97	19.69	0.67	0.93	0.88-0.96	0.98	6.31	-13.09 to 11.65	17.49	-18.21 to 16.77
Household activities score	56	33.02	34.60	0.71	0.79	0.66-0.87	0.89	12.31	-25.71 to 22.55	34.13	-35.71 to 32.55
Mobility activities score	56	30.68	31.03	0.84	0.91	0.85-0.95	0.89	7.63	-15.31 to 14.61	21.16	-21.51 to 20.81
Life and social activities score	55	28.30	30.65	0.22	0.88	0.80-0.93	0.92	8.28	-18.58 to 13.88	22.96	-25.31 to 20.61

[a] X1= mean at time point 1, X2= mean at time point 2, P-value is resulting out of Wilcoxon signed rank analyses, ICC= intraclass correlation coefficient, CI= confidence interval, a= Cronbach's alpha coefficient, SEM= standard error of measurement, SRD= smallest real difference.

Table 4. Correlation between the SF-36 and the Lymph-ICF-UL to determine convergent and divergent validity (Spearman rank correlation coefficient; n= 56)

	Spearman Rank Correlation Coefficient ($r_{s\ (p\text{-}value)}$) for:				
SF-36 domain	**Lymph-ICF-UL domains**				
	Impairments in function		**Activity limitations and participation restrictions**		
	Physical function Correlation Coefficient (Sign.)	Mental function Correlation Coefficient (Sign.)	Household activities Correlation Coefficient (Sign.)	Mobility activities Correlation Coefficient (Sign.)	Life and social activities *(n=55)* Correlation Coefficient (Sign.)
Physical functioning	-.249 (.640)	**-.311 (.020)**	-.244 (.070)	**-.415 (.001)**	-.426 (.001)
Role-physical	-.266 (.470)	-.526 (≤.001)	-.400 (.002)	-.428 (.001)	-.495 (≤.001)
Bodily pain	**-.440 (.001)**	-.292 (.029)	-.454 (≤.001)	-.437 (.001)	-.586 (≤.001)
General health	-.390 (.003)	-.388 (.003)	-.511 (≤.001)	-.471 (≤.001)	-.541 (≤.001)
Vitality	-.265 (.045)	-.542 (≤.001)	-.375 (.004)	-.384 (.003)	-.558 (≤.001)
Social functioning	-.399 (.002)	-.599 (≤.001)	-.522 (≤.001)	-.534 (≤.001)	**-.607 (≤.001)**
Role-emotional	**-.191 (.158)**	-.488 (≤.001)	**-.306 (.022)**	**-.369 (.005)**	-.419 (.001)
Mental health	**-.195 (.150)**	**-.661 (≤.001)**	**-.234 (.083)**	**-.341 (.010)**	-.431 (.001)

[a]Lymph-ICF-UL= Lymphedema Functioning, Disability and Health Questionnaire for Upper Limb Lymphedema with Numeric Rating Scale; SF-36 = 36-Item Short-Form Health Survey questionnaire; Values with bold frame= hypotheses for expected moderate correlations assessing convergent validity; Values with double frame= hypotheses for expected moderate correlations assessing divergent validity; Bold values= accepted hypotheses regarding convergent validity (Correlation Coefficient ≥0.4) or regarding divergent validity (Correlation Coefficient ≤0.4).

Appendixes

LYMPHOEDEMA FUNCTIONING, DISABILITY AND HEALTH QUESTIONNAIRE

FOR LYMPHOEDEMA OF THE UPPER LIMB (LYMPH-ICF-UL)

Surname and first name: … Date: …

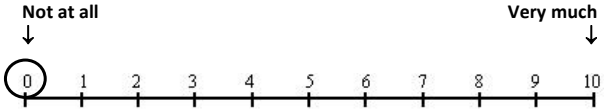
A lymphoedema of the arm and/or hand can cause physical and mental complaints, as well as activity restrictions and problems participating in social life.

This questionnaire consists of **29 questions** and is constructed from information given by subjects suffering from this condition.

Next to each question the numbers 0 to 10 are given. Please indicate to which extent you experience problems related to your arm lymphoedema and to which extent you can perform activities of daily life and participate in society by **circling the number that fits the best**. The number '0' corresponds with "no problems/pain" or "no trouble et all" to perform activities and the number "10" corresponds with "unbearable problems/pain" or "not able to perform". Cross the empty circle if it is not applicable.

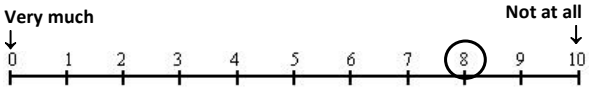
For example:

1. Does your arm hurt?



If you do not feel any pain at all in your arm, encircle '0'.

2. Are you able to iron?



○ **Not applicable**

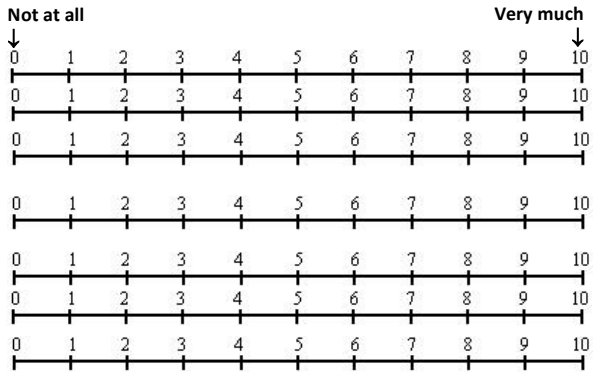
If you can hardly iron as a result of your arm lymphoedema, you encircle '9'. I you have never ironed, because you have a domestic help or you iron with your other arm, you put a cross in the little circle '⊗ not applicable' next to the numbers.

Choose an answer according to your **complaints during the last 2 weeks**. Try not to think too long about answering a certain question. Please do not leave any questions unanswered.

This is a **personal questionnaire**, to be filled in by you alone. Do not discuss these items with others in your immediate surroundings.

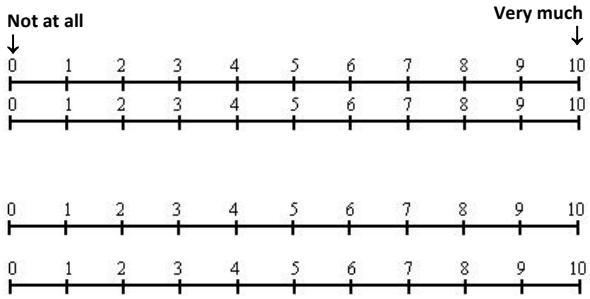
Physical functions

Does your arm:



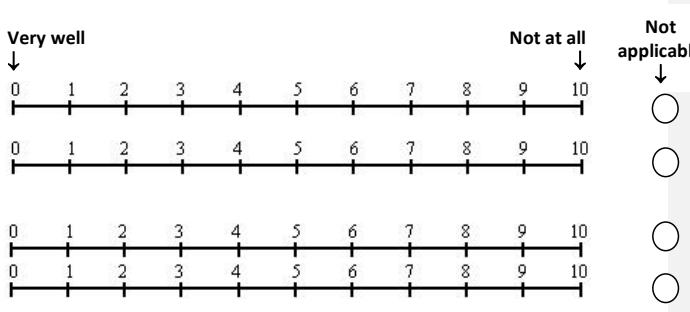
Mental functions

Due to your arm problems:



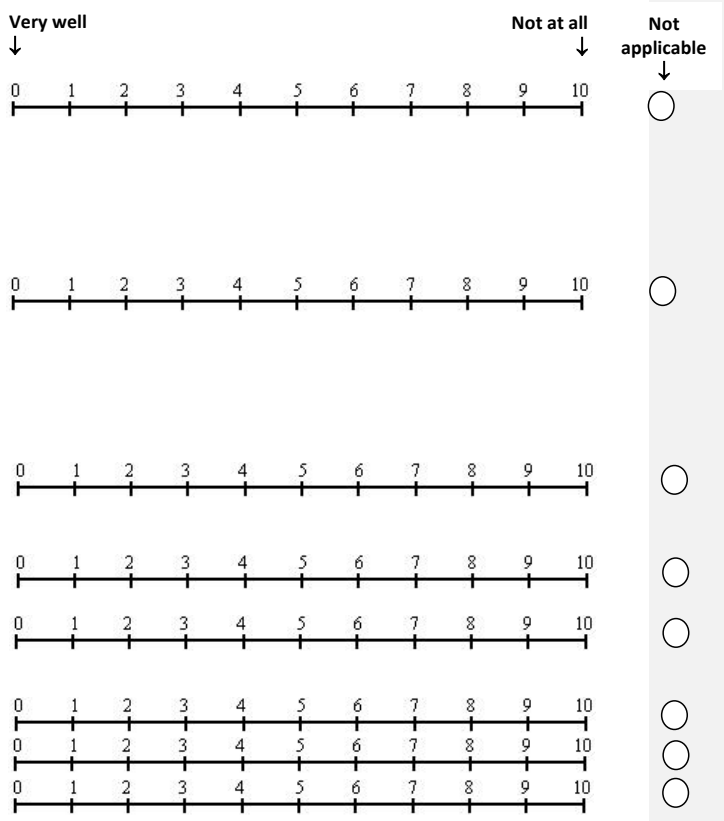
Household activities

How well are you able to:



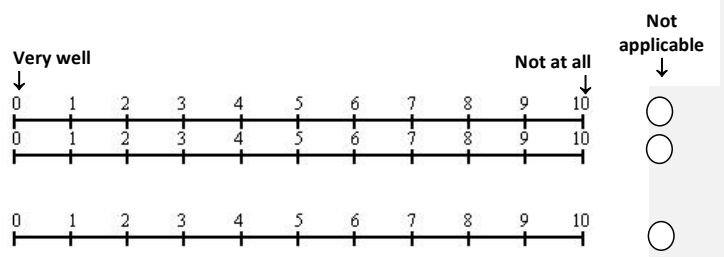
Mobility activitities

How well are you able to:

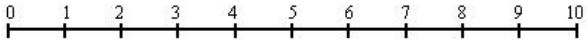


Life and social activities

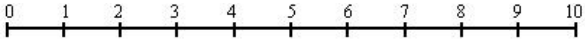
How well are you able to:



27. Wear your clothes of choice?



28. Do your job?



29. Do social activities (e.g. going to parties, concerts, restaurants)?