Disability and Rehabilitation

ISSN: 0963-8288 (Print) 1464-5165 (Online) Journal homepage: https://www.tandfonline.com/loi/idre20

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To cite this article: Tessa De Vrieze, Jacqueline Frippiat, Thierry Deltombe, Nick Gebruers, Wiebren A.A. Tjalma, Ines Nevelsteen, Sarah Thomis, Liesbeth Vandermeeren, Jean-Paul Belgrado, An De Groef & Nele Devoogdt (2020): Cross-cultural validation of the French version of the Lymphedema Functioning, Disability and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL), Disability and Rehabilitation

To link to this article: https://doi.org/10.1080/09638288.2020.1716271

DISABILITY AND REHABILITATION
https://doi.org/10.1080/09638288.2020.1716271

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ORIGINAL ARTICLE

Cross-cultural validation of the French version of the Lymphedema Functioning, Disability and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL)

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ABSTRACT

Purpose: Upper limb lymphedema is a vexing morbidity that can occur after the treatment for breast cancer. The Lymphedema Functioning, Disability and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL) is a valid and reliable tool assessing problems in functioning in patients with breast cancer-related lymphedema. Until now, a French-language version was lacking. The aim of this study was to perform a cross-cultural validation of the French version of the Lymph-ICF-UL questionnaire.

Methods: A forward–backward translation process between the original language (Dutch) and the target language (French) was performed. Psychometric properties of this final French version were examined in 50 participants.

Results: Intraclass correlation coefficients for test–retest reliability ranged from 0.66 to 0.95. Cronbach's alpha coefficients for internal consistency were higher than 0.77. Face and content validity were very good because the scoring system was clear for all participants (100%), questions were understandable (100%), and all complaints due to BCRL were mentioned by 78% of the participants. Construct validity was moderate. Convergent validity was established since 3 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. There was satisfactory divergent validity as 6 out of 9 hypotheses assessing divergent validity were accepted.

Conclusion: The French version of the Lymph-ICF-UL is a reliable and valid questionnaire and ready for use in clinical as well as in scientific practice.

ARTICLE HISTORY
Received 11 September 2019
Revised 19 December 2019
Accepted 11 January 2020

KEYWORDS
Breast neoplasms; rehabilitation; lymphedema; surveys and questionnaires; reliability and validity

➤ IMPLICATIONS FOR REHABILITATION

- Since the introduction of more effective treatment modalities increasing the number of breast cancer survivors, the amount of patients dealing with lymphedema is rising likewise up to a pooled incidence rate of more than 16% of the women treated for breast cancer.
- The French version of the Lymph-ICF-UL is a reliable and valid questionnaire for assessing problems in functioning of patients with breast cancer-related lymphedema of the arm and/or hand.
- As the questionnaire provides patient information in the different domains of the International Classification of Functioning, Disability and Health, it facilitates evaluating the impact of breast cancer-related lymphedema on daily functioning.
- Based on the outcomes of the Lymph-ICF-UL treatment goals can be set, where after the questionnaire can be used to monitor long-term results of this treatment and self-care.

Introduction

The Lymphedema Functioning, Disability and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL) is a lymphedema-specific questionnaire which aims to quantify impairments in function, activity limitations and participation restrictions that are related to upper limb lymphedema. In contrast to other lymphedema-related questionnaires, it is based on terminology of the International Classification of Functioning,

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Supplemental data for this article can be accessed here.

Disability and Health (ICF) [1] as introduced by the WHO [2]. In this questionnaire, a total score is determined as well as a score for each of the five domains of the Lymph-ICF-UL: (1) physical function, (2) mental function, (3) household activities, (4) mobility activities, and (5) life and social activities. For more details about the establishment of the original version of the Dutch Lymph-ICF-UL questionnaire, we refer to Devoogdt et al. [3] According to a recently independent published systematic review, the Lymph-ICF and the Lymphedema Quality of Life Inventory (LyQLI) are the most complete and accurate questionnaires available to asses self-reported problems in functioning and quality of life in patients with breast cancer-related lymphedema (BCRL) [4]. This original questionnaire [3] has been translated into Turkish [5], which revealed very good reliability and good construct validity. However, recently the questionnaire has been revised by altering the scoring procedure through implementation of a numeric rating scale instead of the existing visual analog scale. This revised version showed to be a valid and highly reliable questionnaire in its original, Dutch language, using an easier and simplified scoring procedure [6]. Lately, this revised version has been translated into Danish and subsequently tested on reliability [7]. Although French is the fifth most spoken language in the world representing more than 300 million people [8], a French-language version of this questionnaire is still lacking. Therefore, the aim of the current study was to perform a cross-cultural validation of the Lymph-ICF-UL French version in patients with BCRL of the arm and/or hand.

Materials and methods

This cross-sectional study is reported following the COSMIN guidelines [9]. Approval for this trial was obtained by the Ethical Committee of the University Hospitals of Leuven (main Ethical Committee) as well as by the Ethical Committees of all other participating centers (CME reference S58689, EudraCT 2015-004822-33). All participants provided written informed consent.

Study design

This study was conducted in two phases: (1) translation of the original Dutch version of the Lymph-ICF-UL questionnaire into French, and (2) investigation of the psychometric properties of this translated version.

Participants

Subjects were partly recruited from a cohort of participants of the EFforT-BCRL trial in three university hospitals in Belgium: at the Lymphology Clinic of Brussels in Saint-Pierre University Hospital ($n = 6$), at the Department of Physical Medicine and Rehabilitation of the University Hospitals of Leuven ($n = 3$) and at the Multidisciplinary Breast Clinic of the Antwerp University Hospital ($n = 1$) [10]. Furthermore, additional eligible participants were recruited at the Lymphology Clinic of Brussels in Saint-Pierre University Hospital ($n = 9$) and at the Center de Référence du Lymphoedème at CHU UCL Namur site Godinne ($n = 31$).

Participants were recruited between December 2016 and January 2019 during a consultation or treatment for their lymphedema at one of the hospitals. Eligibility criteria were: (1) patients with unilateral BCRL of the arm and/or hand, (2) chronic lymphedema stage I to IIb (duration of $\geq$3 months), (3) at least 5% difference between both arms and/or between both hands, adjusted for limb dominance, (4) native French-speaking. Patients were excluded when: (1) they had edema of the upper limb from another cause than breast cancer treatment, or (2) when they were not able to read and fully understand the French language.

Procedure

Translation process

A sequential approach was applied for the translation process from the Dutch version of the Lymph-ICF-UL questionnaire [3,6] into a French-language version [11,12]. This was established in different stages following a standard forward–backward translation process according to international guidelines, which has become standard in health status assessments [11,13–15].

First, two translators independently translated the original Dutch version of the Lymph-ICF-UL into the target language, French. These translators were bilingual speakers of the target language as well as of the original language. Each of the two translators performed a forward translation. After a consensus meeting, a reconciled translation was developed. To do so, the cultural and lifestyle context of the target language was taken into account, making use of appropriate idioms if required [13]. Subsequently, a native Dutch speaker who was fluent in the target language then translated the reconciled form back into Dutch. Comparison of this backward translation with the original Dutch version of the Lymph-ICF-UL was performed, and modifications were provided to the translation as needed.

Before investigating the psychometric properties of the French version of the Lymph-ICF-UL, the questionnaire was proofread by a small number of French-speaking patients ($n = 3$) to check for any gross ambiguities or difficulties.

Reliability and validity of the Lymph-ICF-UL French version

In assessing the psychometric properties of the French version of the questionnaire, the same methodology was applied as was done in the original questionnaires [3,6], as this facilitates comparison between the results [16].

To analyze test–retest reliability, participants completed the final French version of the Lymph-ICF-UL twice individually; once at the hospital and once at home with an interval of 24 to 48 h after the first test. This second questionnaire was returned by mail.

To analyze construct validity, participants also completed the 36-item Short-Form Health Survey (SF-36) once at the hospital. This generic questionnaire, originally developed and validated in English, has been translated into French [17].

To analyze content and face validity of the French Lymph-ICF-U, each patient completed an additional questionnaire, developed by one of the authors (ND) [3]. This questionnaire consisted of the 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.

This additional questionnaire was also translated into French following the forward–backward translation by three separate translators as recommended.

Collection of medical history of participants and excessive arm volume

Descriptive data were collected by interviewing the participants and by consulting their medical records. Circumference measurements of the edematous and non-edematous arm were performed using a perimeter, after which the volume of both arms

was calculated using a truncated cone formula [18]. Excessive arm volume was calculated by reducing the volume of the edematous limb with the volume of the non-edematous limb, corrected for limb dominance [19]. Measurements were performed by one of four physical therapists specialized in edema therapy (JF, KD, TDV, LV).

Data analysis

Statistical analyses were performed using SPSS for Windows version 24.0. The 0.05 level of significance was applied. Descriptive analyses were applied to describe the participants.

Reliability

Intraclass correlation coefficients (ICCs) were used to determine test–retest reliability of the total score of the French Lymph-ICF-UL, of the scores on the five domains, and of the score on each question separately [20]. Cronbach's alpha coefficients were used to determine internal consistency of the entire questionnaire as well as of each domain [21]. To calculate significant changes in the mean between the two test occasions, Wilcoxon-signed-rank tests were performed. To interpret the magnitude of the within-subject variation of the two scores, the standard error of measurement (SEM) and corresponding 95% confidence interval (CI) was calculated [20]. To evaluate clinically important changes, we calculated the smallest real difference (SRD) and corresponding 95% CI [20]. To obtain a reference range for the mean difference of the scores between the two test occasions, we calculated 95% SRD as the mean difference between the two test occasions ± SRD.

Validity

Face validity was examined by asking participants whether the scoring system was obvious and whether the questions in the French Lymph-ICF-UL were understandable. Content validity was examined by analyzing and discussing the answers given by participants to the question about the comprehensiveness of the questionnaire.

To investigate construct (convergent, divergent) validity of the French 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 were non-normally 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 formulated in the Dutch validation study [6]. 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 hypotheses for determining convergent and divergent validity and the rationale for the hypotheses. Correlation coefficients were interpreted as follows: <0.4 was weak, 0.4–0.74 was moderate, 0.75–0.9 was strong and >0.9 was very strong [22]. 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, as good if between 75% and 90% of the hypotheses were confirmed, and as moderate if between 40% and 74% of the hypotheses were confirmed.

For full details regarding psychometric methodology and statistical analyses, we refer to the validation study of the Dutch Lymph-ICF-UL [6].

Results

Translation

Before examining the psychometric properties, the questionnaire was tested on three bilingual patients to clarify any ambiguities or difficulties. One patient proposed a few grammatical reconsiderations, which resulted in the final version after unanimous agreement of all translators.

Validation French version Lymph-ICF-UL

Fifty native French-speaking subjects participated in this study. Mean age was 64 (±11) years and mean body mass index was 27 (±5) kg/m^2. All participants had undergone breast surgery with axillary dissection. For more details about the participant characteristics, see Table 2.

Reliability

Table 3 provides an overview of the ICCs, Cronbach's alpha coefficients, SEMs and SRDs for the total score on the French version Lymph-ICF-UL and for the scores on each domain separately. The table also includes data from previous research conducted on the Dutch [6], Turkish [5] and Danish [7] versions of the questionnaire in order to facilitate comparison of results. Test–retest reliability of the total score of the French Lymph-ICF-UL, physical function and mental function scores were very strong (ICC $>$ 0.90). The household and mobility activities score was found strong (ICC $>$ 0.75), while the life and social activities score was moderate (ICC $=$ 0.66). Test–retest reliability of the scores on 22 questions (90%) were strong to very strong (data not shown). Reliability of scores on the remaining 7 questions (about feelings of heaviness and swelling, the abilities to lift or carry heavy objects, to go on vacation, to perform hobbies, to practice sports and to do social activities) were moderate (ICC $=$ 0.62–0.73).

Internal consistency of the French Lymph-ICF-UL also ranged between strong and very strong. The Cronbach's alpha coefficient for all questions was 0.95 and ranged for the different domains between 0.77 and 0.89.

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

The total score on the French Lymph-ICF-UL had a variation from one test occasion to the other of 5.5. A decrease or an increase in the total score of 11 or more is considered (with 95% certainty) as a statistically significant change. Furthermore, a decrease or increase in the total score of 15.4 or more is considered as a clinically relevant change.

Validity

The questionnaire regarding face and content validity of the French Lymph-ICF-UL was completed by all participants. Each one of them (100%) found the scoring system clear and all participants (100%) mentioned that the questions were understandable. Thirty-nine participants (78%) mentioned that all complaints were addressed in the questionnaire. Complaints not covered in the questionnaire are shown in Table 4. After discussion with a team of experts (ND, TDV), only three missing complaints mentioned by two participants were considered to be relevant of which two were incorporated in the questionnaire afterwards.

Table 5 provides an overview of the Spearman rank correlation coefficients between the different domains of the Lymph-ICF-UL

Table 1. Fourteen hypotheses and rationale for hypotheses for assessing construct validity.

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 weeks? During the past 4 weeks, 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 weeks 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 weeks, 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 weeks, 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 weeks, 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 weeks 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 weeks, 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 weeks, 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 weeks 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 weeks, 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 weeks 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?

and the SF-36. The table also includes data from previous research conducted on the Dutch [6] and Turkish [5] versions of the questionnaire in order to facilitate comparison of the results. All participants completed both questionnaires. Concerning convergent validity, 3 out of 5 domains of the French Lymph-ICF-UL correlated at least moderate with the expected corresponding domains of the SF-36, and were accepted. Correlation coefficients of these 3 ranged from −0.40 to −0.70 (moderate correlations). Concerning divergent validity, 6 out of 9 domains of the French Lymph-ICF-UL showed a weak correlation with the expected corresponding domains of the SF-36. The correlation coefficients of these 6 ranged from −0.14 to −0.39 (no to weak correlation). Consequently, 9 out of 14 hypotheses for assessing construct validity were accepted, resulting in an overall moderate construct validity of the French Lymph-ICF-UL (64%).

Table 2. Characteristics of the included subjects ($n = 50$).

Variable	Outcome
Age (y)	64 (11)
Body mass index (kg/m^2)	27 (5)
Lymphedema volume arm (absolute difference) (mL)	734 (374)
Duration lymphedema (mo)*	78 (30, 177 [147])
BCRL stages	
I, *n*(%)	0 (0%)
IIa, *n*(%)	19 (38%)
IIb, *n*(%)	31 (62%)
Breast surgery	
Mastectomy, *n*(%)	28 (56%)
Breast-conserving surgery, *n*(%)	22 (44%)
Surgery on the dominant side, *n*(%)	23 (46%)
Radiotherapy[b], *n*(%)	48 (96%)
Chemotherapy[b], *n*(%)	39 (78%)
Endocrine therapy[b], *n*(%)	30 (60%)
Target therapy (Herceptin)[b], *n*(%)	9 (18%)

y: years, kg: kilogram, m^2: square meters, mL: milliliter, mo: months, BCRL 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.

Discussion

This study showed that the French version of the questionnaire is appropriate for use in clinical practice and research, showing very good (reliability) to satisfactory (validity) psychometric properties.

Reliability of the French 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 comparable ICC values than those obtained in the Dutch, Turkish and Danish versions of the Lymph-ICF [5,7]. Only the life and social activities score was lower in the present study, representing moderate test–retest reliability (Table 3).

As compared to the Dutch, Turkish and Danish versions, internal consistency determined with Cronbach's alpha coefficients were very strong and similar for the total score but were slightly less for the physical function, the household activities and the life and social activities domains [5–7].

Face and content validity of the French Lymph-ICF-UL were very good. All participants (100%) found the scoring system clear, which was similar to the results regarding the Dutch version with revised scoring system [6], as well as the Danish version [7]. Likewise, all questions were understandable for all participants. Only two participants (4%) reported missing one or two complaints in the French Lymph-ICF-UL which were considered relevant (three in total). The first one was the complaint "number of episodes of erysipelas". However, it is not part of the questionnaire as this item should be additionally queried by the therapist during the clinical assessment. Next, a participant suggested that the question regarding the ability to go on vacation (*question 24*) should make a distinction between different kind of holidays (e.g., city trip versus long-distance destinations), and secondly, that the question regarding the ability to practice sports (*question 26*) should include a distinction between different kinds of sports. Therefore, our team of experts advised to add an extra line below questions 24 and 26 in the questionnaire on which the type(s) of vacation(s) and the type(s) of sport(s) being practiced,

Table 3. Reliability on the total score of the Lymph-ICF-UL and the scores on the 5 domains in relation to the results of the original Dutch questionnaire [6], the Turkish version [5] and the Danish version [7].

			Mean			Test–retest		Internal	Variability		Clinically important changes	
Score		*N*	X1	X2	*p*-value	ICC	95% CI	consistency[a]	SEM	95% CI	SRD	95% CI
Lymph-ICF-UL total score	French version	50	36.26	36.36	0.57	0.91	0.85 to 0.95	0.95	5.54	−10.95 to 10.75	15.35	−15.45 to 15.25
	Dutch version	56	27.50	27.45	0.98	0.95	0.91 to 0.97	0.98	4.89	−9.57 to 9.61	13.56	−13.54 to 13.58
	Turkish version	30	46.53	46.90		0.90		0.99				
	Danish version	50	33.00	34.00	0.26	0.95	0.92 to 0.97	0.98	4.51		12.50	
Physical function score	French version	50	37.31	36.14	0.43	0.90	0.83 to 0.94	0.78	6.28	−11.14 to 13.48	17.40	−16.23 to 18.57
	Dutch version	56	24.30	22.76	0.26	0.90	0.83 to 0.94	0.92	6.76	−11.70 to 14.78	18.73	−17.19 to 20.27
	Turkish version	30	43.33	43.53		0.99		0.99				
	Danish version	50	44.00	42.00	0.20	0.93	0.88 to 0.96	0.97	6.40		17.60	
Mental function score	French version	50	34.60	34.15	0.90	0.95	0.91 to 0.97	0.89	6.34	−11.97 to 12.87	17.56	−17.11 to 18.01
	Dutch version	56	18.97	19.69	0.67	0.93	0.88 to 0.96	0.98	6.31	−13.09 to 11.65	17.49	−18.21 to 16.77
	Turkish version	30	41.90	42.73		0.99		0.99				
	Danish version	50	23.00	22.00	0.59	0.88	0.79 to 0.93	0.93	9.12		25.30	
Household activities score	French version	50	38.91	40.94	0.35	0.88	0.80 to 0.93	0.79	9.19	−20.04 to 15.98	25.47	−27.50 to 23.44
	Dutch version	56	33.02	34.60	0.71	0.79	0.66 to 0.87	0.89	12.31	−25.71 to 22.55	34.13	−35.71 to 32.55
	Turkish version	30	54.13	52.00		0.80		0.89				
	Danish version	50	30.00	34.00	0.04	0.84	0.73 to 0.90	0.92	10.21		28.30	
Mobility activities score	French version	50	38.12	39.19	0.13	0.88	0.80 to 0.93	0.88	8.49	−17.70 to 15.56	23.52	−24.59 to 22.45
	Dutch version	56	30.68	31.03	0.84	0.91	0.85 to 0.95	0.89	7.63	−15.31 to 14.61	21.16	−21.51 to 20.81
	Turkish version	30	57.16	53.46		0.85		0.92				
	Danish version	50	31.00	33.00	0.09	0.94	0.89 to 0.96	0.97	5.69		15.80	
Life and social activities score	French version	50	33.30	32.18	0.50	0.66	0.46 to 0.79	0.77	12.60	−23.57 to 25.81	34.91	−33.79 to 36.03
	Dutch version	56	28.30	30.65	0.22	0.88	0.80 to 0.93	0.92	8.28	−18.58 to 13.88	22.96	−25.31 to 20.61
	Turkish version	30	47.13	48.53		0.98	0.99					
	Danish version	50	30.00	33.00	0.11	0.92	0.87 to 0.96	0.96	7.09		19.60	

X1: mean at time point 1, X2: mean at time point 2, *p*-value is resulting out of Wilcoxon-signed-rank analyses, CI: confidence interval.
[a]Cronbach's alpha coefficient.

Table 4. Overview of mentioned missing complaints ($n = 12$) and reasons why they are not included in the French version Lymph-ICF-UL.

Lymph-ICF-UL domain	Complaint	Argumentation
Physical function domain	Tingling fingers	A (Question 5)
	Feeling of imbalance in body posture	A (Question 1)
	Number of episodes of erysipelas	*
Mental function domain	Feeling annoyed/embarrassed about wearing compression garment	A (Questions 9, 10 or 11)
	Feeling of incomprehension of others	A (Question 9)
Mobility activities domain	Ability to carry the groceries	A (Question 17)
	Ability to carry a purse	A (Question 17)
	Ability to write readable ($n = 2$), to sew, to fold	A (Question 19)
	Ability to ride a bike	A (Question 23)
Life and social activities domain	Ability to function in the heat	A (Question 24, or Question 20 "Mobility activities domain")
	Ability to play with grandchildren	A (Question 25)
One participant found that a question about the age of the patient should be included in the questionnaire		B
One participant found that the question regarding the ability to go on vacation should make a distinction between different kind of holidays* (e.g., city trip versus long-distance destinations), and that the question regarding the ability to sport should include a distinction between different kind of sports*		

A: Can be scored with corresponding questions of the questionnaire. The patient has to give the mean score on his/her problems in functioning during the past two weeks, as reported in the introduction of the questionnaire.
B: Patient's age is an item that is collected separately from the lymph-ICF-UL during the clinical evaluation.

*After discussion, only three complaints mentioned by two participants were considered relevant. For two mentioned complaints, adjustments were made in the questionnaire (i.e., questions 24 and 26).

respectively, can be specified (see Supplementary File S1). Patients should complete the questionnaire by themselves and average their problems in functioning or participation over the past two weeks, and therapists or assessors should instruct patients who repeatedly fill in the Lymph-ICF-UL to score the same type(s) of vacation(s) and sport(s) each time.

Construct validity was tested in terms of convergent and divergent validity and gave acceptable results. Concerning convergent validity, 3 out 5 domains (60%) of the French Lymph-ICF-UL correlated at least moderately with the expected corresponding domains of the SF-36 (r between −0.40 and −0.70). In the Dutch validation study, 4 out of 5 hypotheses concerning convergent validity were accepted [6]. In the current study, the physical function domain of the French Lymph-ICF-UL did not show a moderate or strong correlation with the expected domain bodily pain of the SF-36 ($r = -0.32$). In the Turkish study, this correlation between both domains was weak as well ($r = 0.27$) [5] (Table 5). A possible explanation might be retrieved in the fact that the physical function domain of the Lymph-ICF-UL comprises six questions regarding six different symptoms, in which pain is one out of six. On the other hand, the bodily pain domain of the SF-36 is a domain comprising only two questions exclusively based on pain.

Surprisingly, there was also a weak correlation between the life and social activities domain of the Lymph-ICF-UL and the social functioning domain of the SF-36 ($r = 0.16$) in the present study, despite its moderate correlation in the Dutch validation study ($r = -0.61$) [6]. In these domains, patients tended to score more negatively on the SF-36 (comprises two questions) compared to the Lymph-ICF-UL (comprises six questions). However, also in the Turkish study this correlation appeared to be weak ($r = -0.26$) [5] (Table 5). Nevertheless, in the current study, the hypothesis regarding convergent validity between the household activities domain of the Lymph-ICF-UL and the physical functioning domain of the SF-36 ($r = -0.40$) could be accepted, although this was not the case in the Dutch validation study ($r = -0.24$) [6], nor in the Turkish study ($r = -0.03$) [5].

Concerning divergent validity, 6 out of 9 hypotheses (67%) were accepted in the current study, whereas 7 out of 9 hypotheses (78%) were accepted in the Dutch validation study [6]. Unexpectedly, the mental function domain of the Lymph-ICF-UL showed a moderate correlation with the physical functioning domain of the SF-36 ($r = -0.48$), in contrast with the Dutch version where this correlation was weak ($r = -0.31$). Similarly, a moderate correlation was present between the household activities domain of the French Lymph-ICF-UL and the role-emotional domain of the SF-36 ($r = -0.50$), whereas this correlation was weak in the Dutch version ($r = -0.31$), as we would expect. Nevertheless, in the current study, the hypotheses between the mental function domain of the Lymph-ICF-UL and the role-physical domain of the SF-36 ($r = -0.23$) as well as between the life and social activities domain of the Lymph-ICF-UL and the physical functioning domain of the SF-36 ($r = -0.14$) could be accepted, albeit this was not the case in the Dutch version ($r = -0.53$ and -0.43, respectively) [6] (Table 5).

Strengths and study limitations

The current study consisted of several strengths. First, the translation of the questionnaire comprised sequential stages in which a forward–backward translation process was incorporated, as recommended [14]. Second, different aspects of reliability and validity of the French Lymph-ICF-UL were investigated. Third, the sample size of this study consisted of 50 participants. As stated by Shrout and Fleiss, researchers should try to obtain at least 30 heterogeneous subjects for reliability studies [22]. The sample of our study is heterogeneous since participants with BCRL stages IIa or IIb, with a broad range of duration in months and lymphedema volume were enrolled to accommodate this.

A first limitation of our study is that testing of face and content validity occurred with an author-developed questionnaire. However, we are unaware of an available valid questionnaire to investigate these psychometric properties. Second, the forward-–backward translation was not performed by professional translators as recommended by the ISPOR Task Force [23], however, a meticulous translation was carried out by bilingual speakers with an extensive knowledge of both languages.

This questionnaire can be used for research but also in clinical practice. It provides patient information in the different domains of the ICF, which facilitates evaluating the impact of BCRL. This is an important step in promoting a patient's goal-centered approach in BCRL management. Further research establishing its responsiveness is warranted.

Table 5. Correlation between the SF-36 and the French version Lymph-ICF-UL to determine convergent and divergent validity (Spearman rank correlation coefficient; $n = 50$) in relation to the results of the original Dutch questionnaire [6] and the Turkish version [5].

		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 Correlation Coefficient (Sign.)
Physical functioning	French version	-0.275 (.053)	-0.476 (≤.001)	**-0.399 (.005)**	**-0.472 (.001)**	**-0.144 (.317)**
	Dutch version	-0.249	-0.311	-0.244	-0.415	-0.426
	Turkish version	-0.498	-0.075	0.026	-0.136	-0.088
Role-physical	French version	-0.190 (.186)	**-0.229 (0.109)**	-0.376 (.008)	-0.189 (.188)	-0.260 (.068)
	Dutch version	-0.266	-0.526**	-0.400	-0.428	-0.495
	Turkish version	-0.139	0.071	0.056	0.182	0.337
Bodily pain	French version	-0.321 (.023)	-0.399 (.004)	-0.308 (.033)	-0.335 (.017)	-0.232 (.104)
	Dutch version	-0.440**	-0.292	-0.454	-0.437	-0.586
	Turkish version	-0.266	-0.076	0.066	-0.223	-0.393
General health	French version	-0.240 (.093)	-0.387 (.006)	-0.413 (.004)	-0.270 (.058)	-0.263 (.065)
	Dutch version	-0.390**	-0.388**	-0.511**	-0.471**	-0.541**
	Turkish version	-0.185	-0.349	-0.357	-0.416*	-0.323
Vitality	French version	-0.249 (.082)	-0.432 (.002)	-0.322 (.026)	-0.246 (.086)	-0.230 (.108)
	Dutch version	-0.265*	-0.542**	-0.375**	-0.384**	-0.558**
	Turkish version	-0.150	-0.355	-0.184	-0.287	-0.203
Social functioning	French version	-0.175 (.223)	-0.368 (.008)	-0.158 (.285)	-0.145 (.315)	-0.156 (.278)
	Dutch version	-0.399**	-0.599**	-0.522**	-0.534**	-0.607**
	Turkish version	-0.463	-0.087	-0.030	-0.208	-0.262
Role-emotional	French version	-0.451 (.001)	-0.629 (≤.001)	-0.499 (≤.001)	**-0.350 (.013)**	-0.319 (.024)
	Dutch version	-0.191	-0.488**	-0.306*	-0.369**	-0.419**
	Turkish version	-0.274	0.056	0.077	0.071	-0.156
Mental health	French version	**-0.392 (.005)**	**-0.704 (≤.001)**	**-0.340 (.018)**	**-0.227 (.113)**	-0.153 (.289)
	Dutch version	-0.195	-0.661**	-0.234	**-0.341***	-0.431**
	Turkish version	-0.030	-0.215	-0.133	-0.171	-0.371

Values with bold frame: hypotheses for expected moderate correlations assessing convergent validity; Values with double frame: hypotheses for expected weak correlations assessing divergent validity; Bold values: accepted hypotheses regarding convergent validity (correlation coefficient $\geq$0.4) or regarding divergent validity (correlation coefficient $<$0.4).
*$p < 0.05$, **$p < 0.01$.

Conclusion

In conclusion, the French version of the Lymph-ICF-UL is a reliable and valid questionnaire for assessing problems in functioning of patients with BCRL of the arm and/or hand, enabling a better understanding of the functional status and related experiences of a patient. Based on the outcomes of the Lymph-ICF-UL, treatment goals can be set. Thereafter, the questionnaire may be used to monitor long-term results of this treatment and self-care.

Acknowledgements

The authors are very grateful to the hospitals collaborating in this study. The authors also extend very grateful thanks to the study participants, and to Kevin Dusart and Lore Vos for measuring and handing over the questionnaires to the study participants. All authors critically revised the manuscript for important intellectual content and approved the final manuscript.

Disclosure statement

The authors have no conflicts of interest to declare.

Clinical trial registration number

The cross-cultural validation study makes part of a double-blind, multi-center, randomized controlled trial (EFforT-BCRL trial), which is registered in clinicaltrials.gov (NCT02609724). CME reference S58689, EudraCT Number 2015-004822-33.

Funding

This study is financed by the Agency for Innovation by Science and Technology, applied Biomedical Research (IWT 150178). In order to arrange such financing, a separate collaboration agreement has been signed by the KU Leuven and the beneficiaries.

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