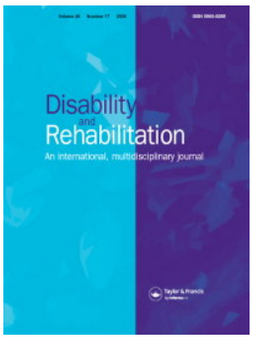

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Cross-cultural validation and responsiveness of the French version of the lymphedema functioning, disability and health questionnaire for lower limb lymphedema (Lymph-ICF-LL)

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ASSESSMENT PROCEDURES

Cross-cultural validation and responsiveness of the French version of the lymphedema functioning, disability and health questionnaire for lower limb lymphedema (Lymph-ICF-LL)

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ABSTRACT

Purpose: To investigate reliability, validity and responsiveness of the French Lymph-ICF-LL questionnaire for lower limb lymphedema (LLL).

Materials and methods: In this observational study, patients with stable LLL completed the Lymph-ICF-LL twice with an interval of 1–2 days. Test-retest reliability was determined with Intraclass Correlation Coefficients (ICC), standard error of measurement and smallest real difference. Internal consistency was analyzed with Cronbach's alpha (α). To assess construct validity, Spearman rank correlation coefficients between the Lymph-ICF-LL and SF-36 were calculated. For responsiveness, the Global Perceived Effect scale (GPE) and Lymph-ICF-LL were completed after 2 months. Other patients completed the Lymph-ICF-LL at start of an intensive treatment and 1 month later together with the GPE. Wilcoxon signed rank test, Standardized Response Mean, Minimal Clinically Important Difference and correlations between the change on Lymph-ICF and GPE were determined. (NCT07075549)

Results: For the total score, excellent reliability (ICC = .94) and good internal consistency (α = .86) were found. Convergent validity was confirmed with significant moderate correlations with SF-36 (r = -0.48–-0.72; p<.001). A significant change in total score was found after intensive treatment (p=.017). Significant correlations between change scores and GPE were obtained (p < .05).

Conclusions: The French Lymph-ICF-LL is a reliable, valid and responsive questionnaire to evaluate lymphedema-specific quality of life in patients with LLL.

➤ IMPLICATIONS FOR REHABILITATION

- The French Lymphedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphedema (Lymph-ICF-LL) is a reliable and valid questionnaire to evaluate lymphedema-specific quality of life in patients with lymphedema at the leg and/or foot.
- The French Lymph-ICF-LL can be used to determine improvement in the lymphedema-specific quality of life after treatment in patients with lower limb lymphedema (LLL).
- A decrease of 14 points on the total score equals a real minimal clinically important improvement in lymphedema-specific quality of life.

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Introduction

Patients with lymphedema experience impairments in body structure and function, activity limitations and participation restrictions [1,2]. An impairment in body structure that is especially reported by patients with lymphedema is the change in shape of the affected body part [1,3,4]. This change in shape is caused by swelling, which is an accumulation of extracellular protein-rich fluid due to insufficiency of the lymphatic system and transport issues [5]. The cause of the insufficiency and transport issues of the lymphatic system can be congenital (primary lymphedema) or acquired after events, especially cancer treatment (lymph node excision, radiotherapy) and/or repeated infections (secondary lymphedema) [5].

To reduce the increased volume caused by the swelling and to prevent infections, patients are treated in an intensive phase with multicomponent bandages, exercises and skin care [6]. Afterwards, in the maintenance phase, the multicomponent bandages are replaced by compression garments to stabilize the volume and self-management becomes more important [6]. This treatment consisting of an intensive and maintenance phase is called Complex Decongestive Therapy (CDT) [5]. The effect of CDT on body structures is evaluated with volume measurements and assessments of tissue and fluid changes [5,6]. However, these measurements do not include the evaluation of activity limitations and participation restrictions and how the patients perceive the consequences of lymphedema. Furthermore, the relationship between volume (reduction) and different aspects of health-related quality of life remains unclear [7–11]. Therefore, an additional evaluation of the health-related quality of life with patient reported outcome measures (PROMs) in research and daily clinical practice is essential [12].

Disease-specific PROMs are developed to evaluate the symptoms and impact of a specific condition and are considered as having a better face validity [13]. The Lymphedema Functioning, Disability and Health Questionnaire for Lower Limb (Lymph-ICF-LL) is a questionnaire developed to evaluate the lymphedema-specific quality of life in patients with lower limb lymphedema (LLL) [14]. This questionnaire is developed based on literature search, patient interviews and the International Classification of Functioning, Disability and Health (ICF) terminology [14]. The ICF-model is a framework of the World Health Organization which provides a universal language for the assessment of disability and functioning [15]. The problems in functioning due to lymphedema are evaluated in the Lymph-ICF-LL questionnaire according to two components described in the ICF-model, i.e., the Body Functions & Structures and Activities & Participation [14]. The reliability and validity of this questionnaire are already investigated and confirmed in different languages, i.e., Dutch, Portuguese, Portuguese Brazil, Turkish, German and Chinese [14,16–20]. Although French is the sixth most spoken language in the world [21], a validated French version of the Lymph-ICF-LL or another lymphedema-specific quality of life questionnaire for LLL does not yet exist. By contrast, the Lymph-ICF version for upper limb lymphedema was already cross-validated in French [22] and is the recommended questionnaire for the evaluation of the lymphedema-specific quality of life in breast cancer-related lymphedema according to the systematic review of Paramanandam et al. 2021 [23]. Therefore, the aims of this study were to obtain a French translation of the Lymph-ICF-LL and to investigate its reliability, validity and responsiveness.

Methods

This multicenter observational study was approved by the ethical committees of all participating centers, i.e., the central ethical committee of University Hospital Leuven (s67308), the ethical committee of the hospital CHU-UCL Namur (site Godinne) and the Comité de Protection des Personnes Nord-Ouest III (N°2023-A01087-38). The study was conducted in agreement with the Declaration of Helsinki. Results are reported according to the guidelines for Strengthening the reporting of observational studies in epidemiology (STROBE) [24] and the reporting guidelines of the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) [25]. The study was registered at ClinicalTrials.gov in July 2025 (NCT07075549).

Participants

A minimum of 44 patients with stable LLL needed to be included for the primary outcome about the test-retest reliability. This sample size calculation was based on the estimation approach with an

anticipated true Intraclass Correlation Coefficient (ICC) of .90, a desired total width of the confidence interval (CI) of maximum .15, a probability of 80% and the presence of two measurement repeats [26]. Additionally, a drop-out of 10% was incorporated.

Recruitment for all outcomes was performed during one year (February 2024–February 2025) in the center for lymphedema of the University Hospitals Leuven (campus Pellenberg, Belgium), the center for lymphedema at the hospital CHU-UCL Namur (campus Godinne, Belgium) and the Reference center for lymphedema at the hospital Cognacq-Jay (Paris, France). These three participating centers are specialized in the evaluation and treatment of patients with lymphedema.

Native French-speaking patients could participate in the study if they had an objective diagnosis of unilateral or bilateral and primary or secondary LLL. Diagnosis had to be either confirmed by a lymphoscintigraphy, by the presence of dermal backflow on near infrared fluorescent imaging or by a volume difference of at least 5% between the two legs. Furthermore, lymphedema had to be present for more than three months and radio- and chemotherapy had to be finished for more than three months, if applicable. Patients could not participate if they were pregnant, less than 18 years or if the lymphedema stage was less than stage 1 according to classification of the International Society of Lymphology [27].

Additionally, two types of patients were recruited for this study, that is, an intensive and stable group. For the intensive group, patients were recruited during the intensive treatment of 1–4 weeks in the hospital. This intensive treatment consisted of daily application of multicomponent low-stretch bandages, skin care, exercises, education and individual guidance by psychologist or dietician if needed. For the stable group, patients were recruited during the follow-up consultations at the hospital. These patients had to be in the maintenance phase of the treatment with compression garments and the start of CDT had to be more than 6 months ago. If an intensive treatment was required, these patients were excluded for the stable group. Patients could only participate after the informed consent form was signed.

Data collection and assessments

Study data were collected and managed with REDCap electronic data capture tools in Belgium [28,29] and Datacapt (Lyon) in France.

Translation process

The development of the original Dutch Lymph-ICF-LL is described in an earlier study [14]. A French version of the Lymph-ICF-LL questionnaire was obtained by a forward-backward translation [30]. First the original Dutch version was translated to French by two independent bilingual persons. There are some differences between the French language spoken in Belgium and France [31]. Therefore, to obtain a version applicable in both countries, one person was from the Walloon region of Belgium, while the other person was French. Furthermore, the first person was specialized in lymphedema treatment, while the other person was not familiar with lymphedema, as recommended in the forward translation [30]. These two translations were discussed during an online meeting with the multidisciplinary research group until a consensus was achieved to obtain one French version. This multidisciplinary research group consisted of one vascular surgeon and three physiotherapists. Two of them were native French-speaking caregivers, while the other two were native Dutch-speaking physiotherapists [30]. One of the present native French-speaking caregivers was one of the forward translators. The obtained French version was again translated by two other independent bilingual persons (blind backward translation) [30]. These two translators were both not familiar with lymphedema. Discrepancies with the original Dutch version were discussed to obtain a last final French version. This version was completed by three French-speaking patients with LLL in Belgium. These patients were asked if everything was clear as a final check before the start of recruitment.

The Lymph-ICF-LL questionnaire evaluates the lymphedema-specific quality of life and consists of 28 questions divided over 5 domains. These domains are the “physical function”, “mental function”, “general tasks/household”, “mobility” and “life domains/social life”. All the questions have to be answered on an 11-point Likert scale from 0 to 10. For some questions, the option “not applicable” is also available. Total score and domain scores can be obtained by the sum of each score divided by the number of answered

questions. If this result is multiplied by 10, a score between 0 and 100 is obtained in which a score of 0 equals a better lymphedema-specific quality of life, while a higher score is equivalent to a worse lymphedema-specific quality of life.

Reliability

Figure 1 shows the overview of the data collection of reliability. To evaluate reliability, only patients of the stable group were included and asked to fill out the Lymph-ICF-LL questionnaire two times with an interval of 1–2 days in between for the test-retest reliability. Patients could choose to complete the questionnaire online or on paper. For determining the internal consistency, the first completion was selected.

Validity

An overview of the data collection of the validity can be found in Figure 1.

The relation between volume (reduction) and (improvement in) quality of life, is unsure [9–11]. Therefore, to investigate construct validity, another quality of life-questionnaire was chosen instead. Patients of the stable group completed the 36-item Short-Form Health survey (SF-36) together with the first Lymph-ICF-LL questionnaire. The SF-36 is a reliable and valid questionnaire which evaluates health status by 36 questions divided over 8 health dimensions [32]. Every dimension and the total questionnaire receive a transformed score from 0 (worst health) to 100 (best health) [33]. Although this questionnaire is not lymphedema-specific, the SF-36 was the most recommended questionnaire for LLL among the health-related quality of life questionnaires [34]. Hypotheses were formulated for significant correlations between domains of the Lymph-ICF-LL and SF-36 which were expected to evaluate similar concepts. This reflects convergent validity. Similarly, other hypotheses were made for non-significant correlations between domains which were expected to evaluate different concepts to evaluate the divergent validity. An overview of these hypotheses can be found in Table 1.

To evaluate face and content validity, a questionnaire was given about the clarity and completeness of the Lymph-ICF-LL after completion of the first Lymph-ICF-LL. This questionnaire consisted of following 4 questions: "Was each question of the Lymph-ICF-LL understandable? (yes/no)", "Was the scoring system clear? (yes/no)", "Were all complaints related to your lymphedema mentioned in the questionnaire?

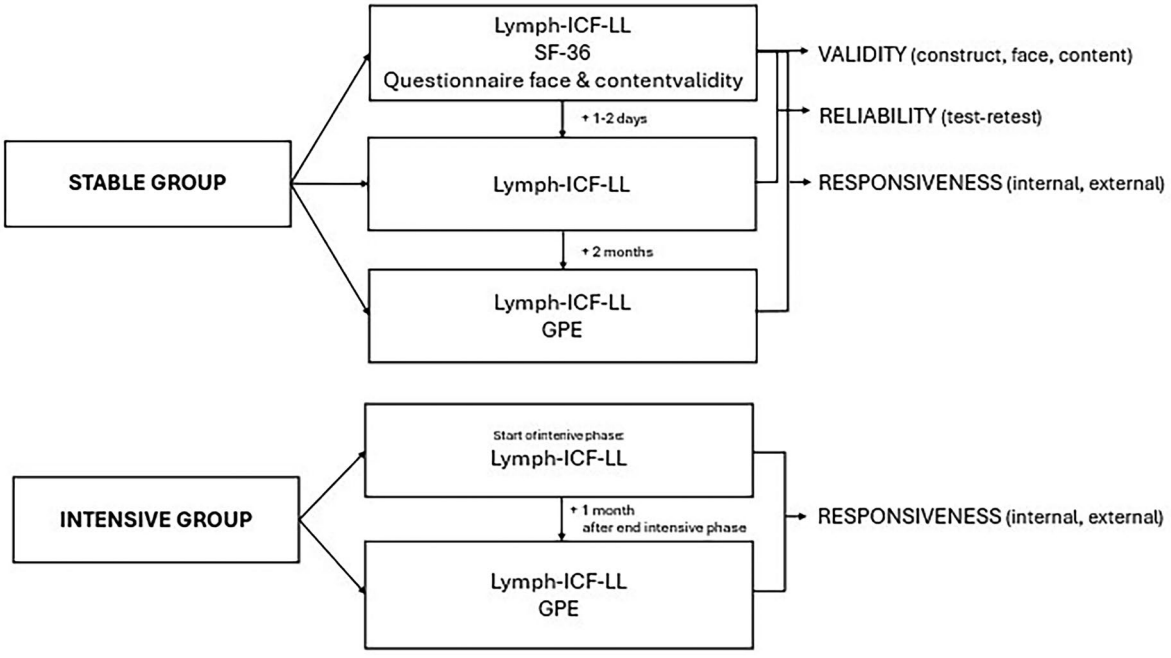

Figure 1. Overview of data collection in stable and intensive groups for investigating reliability, validity and responsiveness of Lymph-ICF-LL.

Table 1. Construct validity: pre-specified hypotheses and Spearman rank correlation coefficients for convergent (**bold**) and divergent *(italics)* validity between domains of the SF-36 and Lymph-ICF-LL ($n = 86$).

		Domains Lymph-ICF-LL				
		Physical function	Mental function	General tasks/ household	Mobility	Life domains/social life
Domains SF-36	Physical functioning	NA	*−0.40 (p<.001)*	**−0.72 (p<.001)**[a]	**−0.74 (p<.001)**[a]	**−0.67 (p<.001)**[a]
	Role limitations due to physical health problems	NA	NA	**−0.59 (p<.001)**[a]	NA	NA
	Bodily pain	**−0.58 (p<.001)**[a]	NA	NA	NA	NA
	Social functioning	NA	NA	NA	NA	**−0.56 (p<.001)**[a]
	Role limitations due to personal or emotional problems	*−0.47 (p<.001)*	**−0.48 (p<.001)**	NA	NA	NA
	Mental health	*−0.43 (p<.001)*	**−0.52 (p<.001)**[a]	*−0.38 (p<.001)*	*−0.38 (p<.001)*	*−0.40 (p<.001)*

Domains between which significant moderate to high correlations (>.50) were expected for convergent validity are indicated in bold. Domains between which no significant correlation or low correlation (<.25) are expected for divergent validity are indicated in italics. Domains of the SF-36 for which there was no prespecified hypothesis, are deleted from the table.
[a]= accepted hypotheses; NA = not applicable, no pre-specified hypothesis of the correlations between domains.

(yes/no)" and "Where there any questions of which you thought they were not relevant for lymphedema? (yes/no)". If patients answered 'no', they could clarify their answer in an open field.

There is no gold standard tool to evaluate lymphedema-specific quality of life. By consequence, criterion validity could not be evaluated.

Responsiveness

Figure 1 shows the data collection of the responsiveness. Two types of responsiveness were assessed, that is, the internal and external responsiveness [35].

The internal responsiveness reflects if a questionnaire is able to show a difference in the measured outcome over time [35]. This implicates that the internal responsiveness is dependent on the provided treatment between two completions of the questionnaire and the impact of this treatment on the outcome of interest of the questionnaire [35]. Since previous research has shown that the intensive phase has an impact on the quality of life, patients in the intensive phase were also included for this purpose [9,36,37]. These patients of the intensive group were asked to fill out the questionnaire at the start of the intensive phase and one month after the end of the intensive phase with a window of 2 weeks. To further assess internal responsiveness among patients for whom significant changes in lymphedema-specific quality of life were not anticipated, individuals from the stable group were also included. Patients of the stable group were asked to complete the questionnaire two times with an interval of 2 months (±2 weeks) in between. The first completion for the investigation of the internal responsiveness was equal to the first completion for the investigation of the reliability.

For the external responsiveness, the relation between the change in the outcome of the Lymph-ICF-LL questionnaire and the change according an external reference measurement of the health status was evaluated [35]. The external reference measurement was the Global Perceived Effect scale (GPE) [38]. This type of scale is developed to evaluate if there is an improvement or deterioration over time according to the patient and can be made condition- and time-specific [38]. The patients of the intensive phase had to complete the following six questions of the GPE online or on paper together with the second Lymph-ICF-LL one month after the end of the intensive phase: "1. To what extent did you recover from your lymphedema-related symptoms and complaints since the beginning of the last intensive treatment?". Thereafter they had to complete five questions related to the different Lymph-ICF-LL domains: "To what extent did you recover from your lymphedema-related symptoms and complaints since the beginning of the treatment related to: 2. your physical symptoms, 3. your mental function, 4. your general tasks and household, 5. your mobility and 6. your life domains and social life?". Every question had to be answered on an ordinal 7-point Likert scale[39]: 1 = completely recovered, 2 = much better, 3 = a little better, 4 = unchanged, 5 = a little worse, 6 = much worse, 7 = worse than ever. The patients of the stable group had to complete the same 6 questions. However, the timeframe in the question was

adapted for this group, i.e., "To what extent have your lymphedema-related symptoms and complaints (what you feel, can perform, etc.) changed compared to the previous evaluation moment within this study?". Patients who gave score 1 or 2 were labeled as positive responders, patients with score 3,4,5 as non-responders and patients with score 6 and 7 as negative responders. Patients with score 2 and 6 were selected for determining minimal clinically important difference (MCID).

Data analysis

Data analysis was performed with IBM SPSS version 29.0 2.0. The normal or not normal distributed continuous data were represented by the mean and standard deviation (SD) or the median and interquartile range (IQR), respectively. Numbers and frequencies were described for the categorical characteristics. Complete case-analysis was performed.

Reliability

The relative reliability was analyzed by the test-retest reliability with the Intraclass Correlation Coefficient (ICC) model 2, form 1 with the 95% confidence interval (CI) [40,41]. An ICC above .90 was interpreted as excellent relative reliability, an ICC between .75 and .90 as good, an ICC between .50 and .75 as moderate and an ICC below .50 as poor relative reliability. For determining the absolute reliability, the standard error of measurement (SEM) was estimated by the square root of mean square error determined by ANOVA [40]. Additionally, the smallest real difference (SRD) was calculated with the formula $1.96*SEM*\sqrt{2}$ [40]. To investigate if there were systematic changes between the scores at the two time point, the Wilcoxon signed rank test was performed. For the internal consistency, Cronbach's alpha was determined to investigate how the different items fit their domain and how the domains fit the overall questionnaire [40]. A Cronbach's alpha between .70 and .90 was considered as a good internal consistency[40,42] Additionally, the Cronbach's alpha was calculated if a domain was deleted and if an item of a same domain was deleted.

Validity

For the convergent and divergent validity, Spearman rank correlation coefficient were used to verify the correlation between domains of the Lymph-ICF-LL and SF-36. A correlation coefficient below .25 represented no to a little relationship, a value between .25 and .50 indicated a low to fair relationship, a value between .50 and .75 was interpreted as a moderate to good relationship and a value above or equal to .75 as a strong relationship [40]. There was good convergent and divergent validity if ≥75% of the predefined hypotheses listed in Table 1 were confirmed [42].

Face and content validity of the Lymph-ICF were evaluated by reporting and discussing the answers on the questionnaires with descriptive statistics.

Floor and ceiling effects were presented by numbers and percentages of participants with a total score of 0 and 100, respectively, and were considered important if this exceeded 15% of the participants [40].

Responsiveness

For the evaluation of the internal responsiveness, the Wilcoxon signed rank test was applied to investigate if there was a significant difference ($p<.05$) in the total and domain scores between the first and second completion in the stable and intensive group, separately [35]. Additionally, the standardized response mean (SRM) was calculated for the total and domain scores by dividing the difference between the mean scores of the second and first completion by the standard deviation of the change between the scores at the two time points in the intensive group [40]. A value below .20 was suggested to represent low responsiveness, a value between .50 and .80 was suggested to show moderate responsiveness, while a value of .80 or higher was suggested to reflect large responsiveness [35]. Concerning the

external responsiveness, the Wilcoxon signed rank test was applied to investigate if there was a statistically significant difference between the first and second total and domain scores of the Lymph-ICF in the positive (score 1 or 2 on GPE) and negative (score 6 or 7 on GPE) responder group ($p<.05$) and not a statistically significant difference in the non-responder group (score 3,4 or 5 on GPE) ($p\geq.05$). The correlations between the change in total and domain scores of the Lymph-ICF with the general and domain scores on GPE, respectively, were analyzed with Spearman Rank correlation coefficient [35]. The same criteria as for the correlation for the construct validity were applied. Lastly, MCID was determined with the anchor-based method [40]. The mean and SD or median and IQR of the change in total and domain scores were calculated for the positive (if score 2 on GPE: much better) and negative responders (if score 6 on GPE = much worse), separately. Missing data were excluded for every analysis.

Results

Translation

The final obtained French version of the Lymph-ICF-LL after the translation process can be found in the Appendix 1.

Compared to the original Dutch version, two items were more clarified after the discussion of the forward-translations. For item 4 about infections, the specification was added that it only involves bacterial infections such as erysipelas. For item 24 about the ability to practice sports, some examples of sport activities were added. Additionally, in the explanation of the questionnaire and in the first example, the location of the presence of pain was specified, i.e., at the lower limbs. For item 18, (the question about the possibility to kneel due to lymphedema), the option 'not applicable' was added, since patients/health care providers indicated that the inability to kneel is often caused by other conditions than lymphedema.

After backward translations, some differences with the original questionnaire were related to the complexity of words, like edema instead of swelling or pathology instead of disease, but were not changed since it was clear for the French patients. Furthermore, in the backward translations, the word "patient" was used, while in the original Dutch version the word "person" was chosen. For the final French version, the French word for "person" was selected (like in the original Dutch version) instead of "patient" to avoid stigmatization. Regarding the second example in the explanation of the questionnaire, "more difficulties" was replaced by "difficulties" after the backward translation. For the final French version, "more difficulties" was chosen to avoid difference in connotation. In the explanation of the scoring system, the original Dutch version verified the meaning of the extreme anchors 0 and 10 of the 11-point Likert scale, while the backward translated versions verified that the whole right part of the scale agreed with having difficulties without explaining the meaning of the extreme scores. Since this is not a problem for the cultural or linguistic differences, the French version was adapted to the explanation of the anchors to maintain agreement with the Dutch version. Other discrepancies were associated with ICF-related terminology. The official ICF terminology was maintained for each language separately. Lastly, there was a disagreement between legs and feet in Dutch and the term lower limbs in French. Since it was clear in French that lower limbs involved both the legs and feet, this term was maintained in the final French version.

Finally, three native French-speaking patients of the Walloon region of Belgium completed the final version as a final check and had no remarks.

Reliability

In total, 99 patients with LLL signed the informed consent form to participate in the stable group. Two patients were excluded. One patient because an intensive phase was required and another patient because of the absence of the diagnosis of LLL. Of the 97 patients in the stable group, 10 patients were excluded from the analyses as both Lymph-ICF-LL questionnaires were missing. From the remaining 87 patients, 56, 87, 86 and 85 were included for the test-retest reliability, internal consistency, construct validity and content/face validity, respectively. Reasons for these numbers of inclusion are explained in

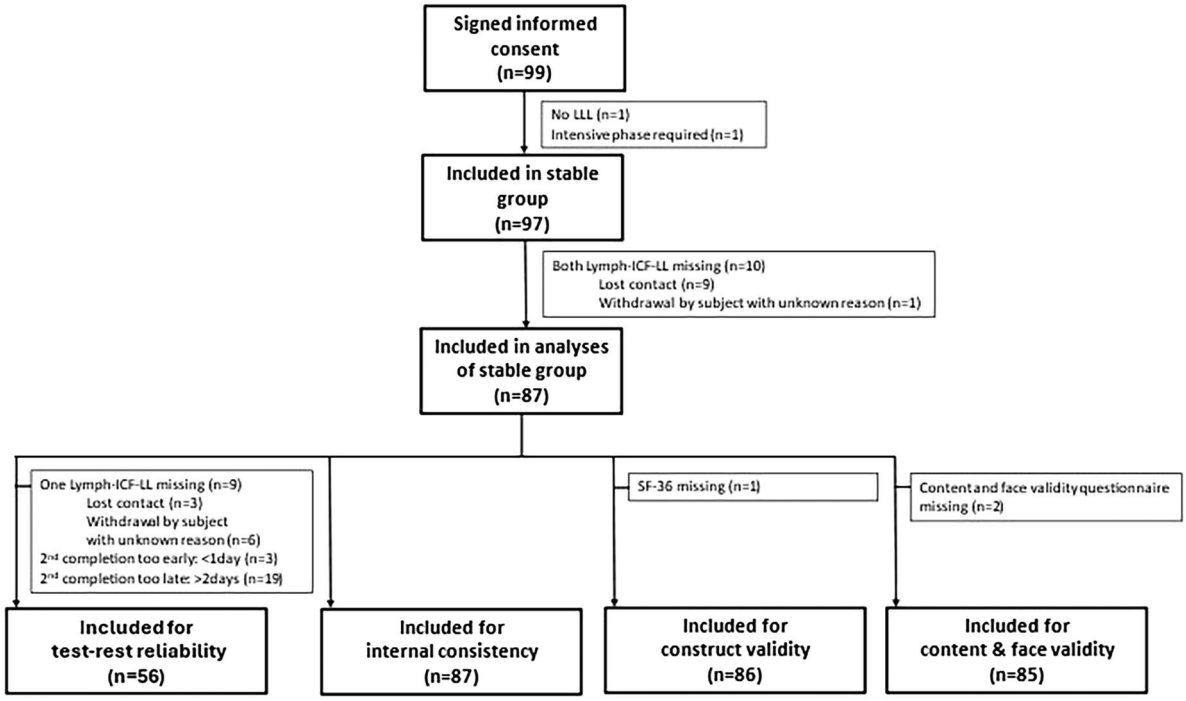

Figure 2. Overview of eligibility and inclusions for each analysis of reliability and validity.

Figure 2. Table 2 presents the characteristics of the included patients for each analysis. The characteristics of patients not included in the analyses were similar. Only for the median age, there was a difference of 10 years between the included and not included patients for the analysis of the responsiveness of the stable group. Lymphedema duration was also different. While patients from the stable group were younger, patients from the intensive group were older compared to the patients not included in the analyses.

Table 3 shows a detailed overview of the results of the reliability. The relative reliability of the total score of the Lymph-ICF-LL was excellent with an ICC of .94. The relative reliability of the domain scores was good to excellent with an ICC between .81 and .96. The absolute reliability represented by SEM was 5 for the total score and ranged from 6 to 10 for the domain scores. The calculated SRD for the total score was 14 and between 18 and 28 for the domain scores. There were no systematic changes between the total and domain scores at the two time points. The internal consistency of the total score of the Lymph-ICF was good with a Cronbach's alpha of .86. Cronbach's alpha varied between .78 and .92 for the different domains. Additionally, Table 3 gives information about the Cronbach's alpha of the total score if a domain was deleted and of the domain scores if an item of the domain was deleted.

Validity

For the construct validity, Table 1 shows the Spearman rank correlation coefficients between the Lymph-ICF-LL and SF-36. Seven from the eight hypotheses (87.5%) of convergent validity were confirmed by significant correlations ($p<.001$). These correlations ranged from −0.48 to −0.74. The negative correlations can be explained by the inverse representation of score 0 and 100 in the Lymph-ICF-LL and SF-36. While score 0 equals a better lymphedema-specific quality of life in the Lymph-ICF-LL, a lower score in the SF-36 equals a worse quality of life. For divergent construct validity, the 6 hypotheses were not confirmed as these showed significant correlations above .25. These spearman rank correlation coefficients were lower than for the convergent validity and varied between −0.38 and −0.47.

Only 1% and 0% of the patients had a minimum and maximum total score, respectively. For the 3 domains "physical function", "mental function" and "mobility", the minimum score was given by 4.6% of the participants. For the domain "general tasks/household", 47.1% had a minimum score. For the domain

Table 2. Demographics included participants for reliability, validity and responsiveness.

	Patients of stable group included in reliability/validity analysis ($n=87$)	Patients of stable group included in responsiveness analysis ($n=60$)	Patients of intensive group included in responsiveness analysis ($n=97$)
General characteristics			
Age (years) mean (SD)	53 (17)*	56 (15)	55 (15)
BMI (kg/m^2) *median (IQR)*	*25.0 (8.0)***	*25.0 (7.2)**	*30.0 [13.0]***
Gender (number [%])			
Male	16 (18.4%)	13 (21.7%)	22 (22.7%)
Female	70 (80.5%)	47 (78.3%)	72 (74.2%)
Unknown	1 (1.1%)	0 (0.0%)	3 (3.1%)
Lymphedema-specific characteristics			
Lymphedema duration (months) *median (IQR)*	*138 (174)**	*144 [191]*	*180 [330]*
Lymphedema type (number (%))			
Unknown	1 (1.1%)	0 (0.0%)	2 (2.1%)
Primary	62 (71.3%)	42 (70.0%)	79 (81.4%)
Secondary	24 (27.6%)	18 (30.0%)	16 (16.5%)
Not cancer-related	5 (5.7%)	4 (6.7%)	2 (2.1%)
Cancer-related	19 (21.8%)	14 (23.3%)	14 (14.4%)
Gynecological	12 (13.8%)	10 (16.7%)	5 (5.2%)
Prostate	2 (2.3%)	2 (3.3%)	3 (3.1%)
Melanoma	2 (2.3%)	1 (1.7%)	3 (3.1%)
Other	3 (3.4%)	1 (1.7%)	2 (2.1%)
Sarcoma	2 (2.2%)	0 (0.0%)	1 (1.0%)
Testicular	1 (1.1%)	1 (1.7%)	0 (0.0%)
Lymphoma	0 (0.0%)	0 (0.0%)	1 (1.0%)
Unknown	0 (0.0%)	0 (0.0%)	1 (1.0%)
Lymphedema stage[a] (number (%))			
Unknown	1 (1.1%)	0 (0.0%)	0 (0.0%)
1	3 (3.4%)	2 (3.3%)	0 (0.0%)
2a	30 (34.5%)	23 (38.3%)	35 (36.1%)
2b	48 (55.2%)	32 (53.3%)	56 (57.7%)
3	5 (5.7%)	3 (5.0%)	6 (6.2%)
Unilateral/bilateral LLL (number (%)) Unknown	1 (1.1%)	0 (0.0%)	1 (1.0%)
Unilateral	57 (65.5%)	40 (66.7%)	31 (32.0%)
Bilateral	29 (33.3%)	20 (33.3%)	65 (67.0%)
Location of lymphedema (number (%))			
Unknown	1 (1.%)	0 (0.0%)	0 (0.0%)
Midline	14 (16.1%)	11 (18.3%)	13 (13.4%)
Upper leg	41 (47.1%)	30 (50.0%)	82 (84.5%)
Lower leg	77 (88.5%)	54 (90.0%)	94 (96.9%)
Foot	70 (80.5%)	49 (81.7%)	84 (86.6%)

*unknown continuous variable for 1 participant.
**unknown for 2 participants.
[a]Lymphedema stage according to the classification of the International Society of Lymphology.
IQR = interquartile range; LLL = lower limb lymphedema; n = number of included participants; SD = standard deviation.

"life domains/social life", 9.2% had the minimum score. The percentage of patients which gave the maximum score for the domains varied between 0% and 1.1%.

From the 85 patients, which completed the questionnaire concerning face and content validity, 79 patients (92.9%) understood all the questions and only six patients (7.1%) answered that not all questionnaire were clear. For one patient, it was not clear if the midline region was also included. One patient mentioned that only one question was not clear without further specifications, another patient found the last questions about going on holiday unclear and two patients just mentioned that it was (sometimes) unclear without mentioning which questions specifically. Lastly, one patient mentioned it was difficult to understand around two or three times when a question was asked in the opposite direction. However, this patient additionally wrote down that it was still clear. Although score 0 always represents the positive side on the questioned item, sometimes score 0 has the label 'not at all' and sometimes 'very well'. Only two patients (2.4%) did not find the scoring system clear, while 83 (97.6%) patients did. No further specifications were given about the reason why it was not clear for the two patients. The Lymph-ICF-LL did contain questions about all the lymphedema-related symptoms for 73 of the 85 patients (85.9%). Twelve patients (14,1%) reported to miss questions, which are detailed in Table 4. Similar questions were only reported by 1–2 patients as missing. According to 77 (90.6%) patients there were no irrelevant questions. This means only 8 patients (9.4%) indicated that there were some irrelevant

Table 3. Absolute reliability ($n = 56$), relative reliability ($n = 56$), internal consistency ($n = 87$) and floor & ceiling effects ($n = 86$) of the total and domain scores of the Lymph-ICF-LL.

			Reliability				Internal consistency				Floor & ceiling effects	
									Items resulting in higher Cronbach's Alpha if deleted			
	Score 1st completion Median [IQR]	Score 2nd completion Median [IQR]	ICC (95%CI)	SEM	SRD	Wilcoxon signed rank test	Cronbach's alpha of total score or domain	Cronbach's alpha of total score if domain was deleted	Item which lowered Cronbach's Alpha	New Cronbach's Alpha if item was deleted	%min score	% max score
Total	22 [33]	23 [35]	.94 (.901;.97)	5.2	14.3	.572	.86	/	/	/	1.0	0
Physical function	24 [32]	25 [31]	.92 (.87;.96)	6.4	17.8	.089	.84	.82	Infections	.87	4.6	0
Mental function	17 [50]	17 [56]	.96 (.93;.97)	6.3	17.5	.115	.92	.86	Disappointment in medical care	.93	4.6	1.1
General tasks/ household	5 [28]	2 [27]	.83 (.73;.90)	9.4	26.1	.769	.90	.83	None	/	47.1	1.1
Mobility	27 [45]	27 [40]	.85 (.76;.91)	9.8	27.1	.683	.84	.83	Driving a car	.85	4.6	1.1
Life domains/ social life	16 [27]	18 [37]	.81 (.70;.88)	10.1	28.0	.107	.78	.83	Wearing clothes and shoes you want to wear	.84	9.2	0

ICC = Intraclass Correlation Coefficient; IQR = Interquartile range; max = maximum; min = minimum; SEM = standard error of measurement; SRD = smallest real difference.

Table 4. Missing and irrelevant questions reported by patients.

	Missing Questions		Irrelevant Questions	
Domain/Theme	Missing question	n	Irrelevant question	n
Physical function	Feeling of heaviness	1	/	/
Mental function	Psychological aspects without further specifications	1	Questions about mental problems were irrelevant	1
	Moral consequences for young people with lymphedema	1		
	The mental burden linked to the precautions you have to take according to the disease	1		
General tasks & household activities	The impact on daily routine because of daily/weekly care	2	/	/
Mobility	Mobility of the limbs	1	Going up the stairs was difficult concerning the question about taking stairs	1
Life domains/ social life	Difficulties with swimming	1	Patients only wearing/choosing clothes could cause problems and not shoes dependent on the presence of foot swelling. Therefore, this patients suggested to split up the question about clothes and shoes.	1
	The impact on choosing clothes	1	Social activities should be more specified concerning timing. For example, it is possible to go out but not that long	1
	The impact on choosing shoes	2	Some hobbies/physical activities are possible, but others are not	2
	/	/	Learned to deal with it and tried to live a normal life as much as possible	1
Environmental-related: Compression-related	Difficulties with bearing compression	1	/	/
	Feeling of numbness or not feeling your toes due to compression	1		
	The impact on sleep because of the constant pressure on the leg and feet	1		
Other environmental related aspects	Arthrosis	1	The relevance is dependent on the severity of lymphedema and that questions will be answered differently by many patients	1
	Difficulties with activities because of high temperatures	1	Many questions were not relevant, because lymphedema did not cause many problems for this participant	1
	The impact on the way that others look at you and how you adapt accordingly	1	/	/
	One person just mentioned it was short	1		
	The impact on sleep because of the feeling of heat	2		
	The impact of costs	1		

n = number of times the remark was reported.

questions/items. These are listed in Table 5. No questions/items were reported as irrelevant by more than two different patients.

Responsiveness

Figure 3 provides more information about the inclusions for each analysis of the responsiveness, while Table 2 presents the characteristics of the included patients. For the responsiveness, 98 and 121 patients signed informed consent to participate in the stable and intensive group, respectively. As for the reliability and validity, two patients of the stable group were excluded after screening because of the

Table 5. Internal responsiveness of the total and domain scores.

		n	First Completion Median [IQR]	Second completion Median [IQR]	P-value Wilcoxon Signed rank test	SRM (intensive group)
Total score	Stable group	60	22 [30]	28 [29]	.476	/
	Intensive group	98	38 [29]	33 [33]	.017*	−0.25
Physical function	Stable group	60	25 [30]	30 [31]	.750	/
	Intensive group	98	35 [31]	27 [33]	<.001*	−0.53
Mental function	Stable group	60	18 [52]	30 [46]	.565	/
	Intensive group	98	39 [51]	32 [56]	.114	−0.17
General tasks/ household	Stable group	60	2 [16]	3 [28]	.242	/
	Intensive group	98	23 [44]	20 [50]	.408	.07
Mobility	Stable group	60	26 [33]	28 [33]	.592	/
	Intensive group	98	43 [30]	37 [35]	.901	−0.13
Life domains/social life	Stable group	60	17 [20]	21 [29]	.118	/
	Intensive group	98	35 [35]	32 [33]	.420	−0.06

IQR = interquartile range; n = number of included participants; SRM: standardized response mean; SD = standard deviation; *= significant difference: $p<.05$.

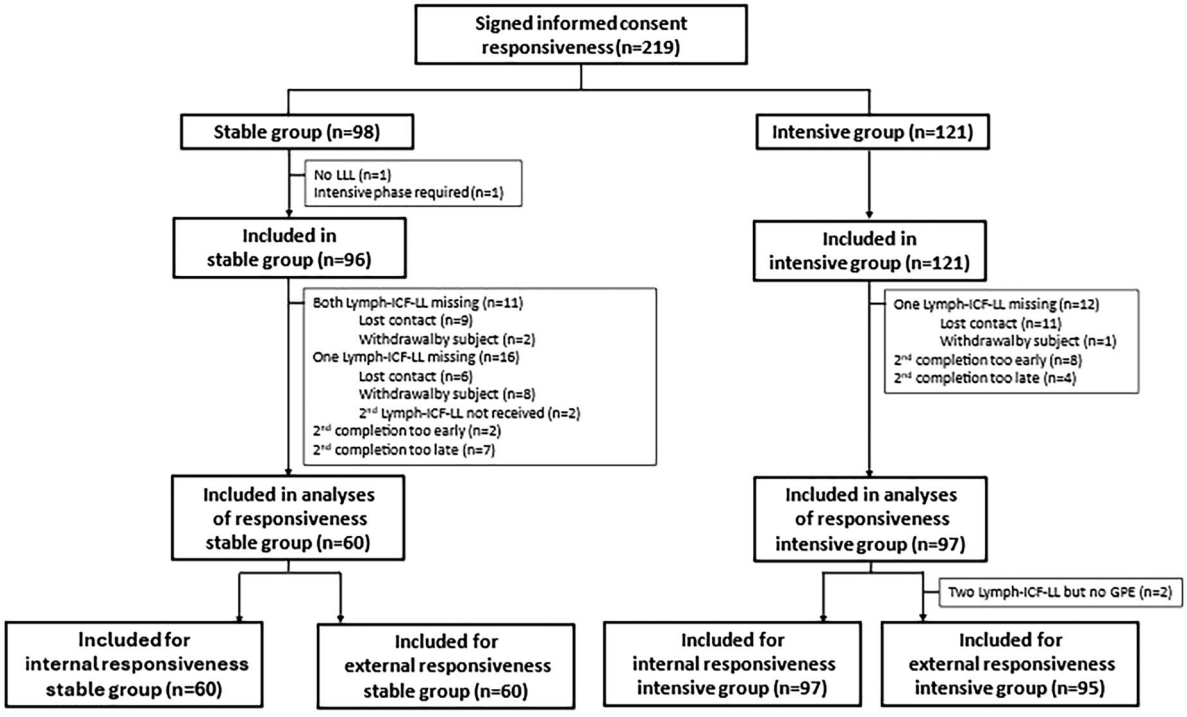

Figure 3. Overview of eligibility and inclusions for the analyses of responsiveness.

requirement of an intensive phase and the absence of LLL. For the analysis of the internal responsiveness, 157 patients were included (60 from the stable group and 97 from the intensive group). To investigate the external responsiveness, data from 155 patients were analyzed (60 from the stable group and 95 from the intensive group).

Concerning internal responsiveness, detailed results are shown in Table 5. There was a significant difference before and after the intensive treatment phase for the total score on the Lymph-ICF-LL and for the 'physical function' domain score. In the stable group, these differences were not statistically significant. For the other domains no within-group significant differences were found between the two completions of the Lymph-ICF-LL. The SRM of the total score was −0.25 and varied between −0.53 and .07 for the different domains.

The results regarding external responsiveness are shown in more detail in Table 6. A significant decrease was found between the first and follow-up completion of the lymph-ICF questionnaire for the total score, "physical function" and "mental function" score in the positive responder group. The differences in the non-responder group were not statistically significant. The sample size of the negative

Table 6. External responsiveness: the difference between the first and second completion in the different type of responders, the minimal clinically important difference and spearman rank correlation between change in Lymph-ICF-LL scores and GPE score.

		Positive responder GPE score = 1,2	Negative responder GPE score = 6,7	Non-responder GPE score = 3-5	MCID GPE score = 2 n (mean(SD))	Correlation between change score and GPE n Spearman rank correlation coefficient p-value
Total score	n	32	2	119	*n* = 31 5 (11)	*n* = 153
	Median[IQR] 1st completion	32 [35]	65 [NC]	34 [32]		r=-0.30
	Median[IQR] 2nd completion	26 [20]	66 [NC]	33 [31]		*p*<.001*
	P-value within responder group	.007*	.655	.783		
Physical function score	n	32	2	121	*n* = 32	*n* = 155
	Median[IQR] 1st completion	32 [32]	66 [NC]	33 [32]	12 (13)	r=-0.39
	Median[IQR] 2nd completion	13 [20]	63 [NC]	30 [29]		*p*<.001*
	P-value within responder group	<.001*	.655	.294		
Mental function score	n	31	3	121	*n* = 24	*n* = 155
	Median[IQR] 1st completion	18 [55]	35 [NC]	38 [58]	7 (15)	r=-0.20
	Median[IQR] 2nd completion	12 [37]	62 [NC]	42 [57]		*p*=.013*
	P-value within responder group	.025*	.109	.737		
General tasks/ household score	n	23	0	132	*n* = 22	*n* = 155
	Median[IQR] 1st completion	7 [17]	NC	13 [49]	2 (9)	r=-0.14
	Median[IQR] 2nd completion	3 [17]	NC	20 [50]		*p*=.091
	P-value within responder group	.328	NC	.128		
Mobility score	n	23	1	131	*n* = 23	*n* = 155
	Median[IQR] 1st completion	36 [30]	45 [NC]	36 [39]	4 (15)	r=-0.17
	Median[IQR] 2nd completion	29 [23]	58 [NC]	34 [37]		*p*=.036*
	P-value within responder group	.082	NC	.742		
Life domains/social life score	n	20	1	134	*n* = 14	*n* = 155
	Median[IQR] 1st completion	29 [27]	73 [NC]	27 [35]	5 (22)	r=-0.17
	Median[IQR] 2nd completion	25 [31]	95 [NC]	28 [33]		*p*=.033*
	P-value within responder group	.538	NC	.269		

IQR: interquartile range; MCID: minimal clinically important difference = mean(SD) of change scores of group with GPE = 2; n = number of patients in the different groups; NC = not calculated because of too small sample size; r = spearman rank correlation coefficient; SD = standard deviation; *= significant: $p<.05$.

responder group was too small ($n<3$) to investigate significant differences. For this reason, the MCID was also only calculated for improvement in the lymphedema-specific quality of life. A significant correlation was found between the GPE score and the change in Lymph-ICF-LL total score and domain scores, except for the domain "general tasks/household". The correlations varied between −0.17 and −0.30.

Discussion

This is the first study that developed and cross-validated the French version of the Lymph-ICF-LL questionnaire. To our knowledge, this is the first validated French version of a lymphedema-specific patient-reported outcome measure in patients with LLL.

Reliability

The French Lymph-ICF-LL showed excellent test-retest reliability for the total score and good to excellent test-retest reliability for the domain scores. A detailed comparison between the studies of the different languages of the Lymph-ICF-LL questionnaire is added in Appendix 2. These results of the reliability of the French version are confirmed for total score and domain scores of the Lymph-ICF-LL versions in Dutch, Brazilian, Turkish and Chinese [14,17–19]. Only the 'mental function' domain showed lower test-retest reliability in the Chinese [18] and German [20] version of the Lymph-ICF-LL. Both studies indicate the possible influence of only including cancer-related LLL with possible more emotional fluctuations [18] or by including LLL with an unclear cause or less primary LLL [20]. The present study did not separately investigate the reliability in patients with secondary LLL to confirm this. However, the time between the two completions is also an important difference between the present study and the Chinese and German version. The time interval was longer for the study of the Chinese (2 weeks) and German version (5 days), compared to this study of the French version (1–2 days) [18,20]. Some might argue the timing between the completion for the test-retest reliability was too short in the present study and might cause recall bias. A previous study about the effect of different intervals in test-retest reliability studies of health-related quality of life instruments did not find a significant difference between an interval of 2 days or 2 weeks [43]. Furthermore, it is important to avoid real clinical change in the outcome measure. One patient in the study about the reliability of the original Dutch Lymph-ICF-LL already stated to find it difficult to complete the questionnaire because problems in functioning were different from day to day [14].

The 'mental function' domain was also the only domain for which the items in the French Lymph-ICF-LL showed a Cronbach's alpha higher than .90. It further increased if the item disappointed in medical care would have been deleted, although the difference was minimal (α=.92 vs. 93). This item might indeed be the odd one out as disappointment in medical care might reflect more a patient experience measurement [44]. However, this item was one of the most frequent reported problems when the original questionnaire was constructed and fits most in the mental function part of the ICF model [14]. Therefore, this item is kept in the final questionnaire underneath the 'mental function' domain. The Cronbach's alpha of the total score and the other domains had a Cronbach's alpha reflecting good internal consistency. Deleting certain items only resulted in a minimal change of Cronbach's alpha not exceeding a value of .90. The internal consistency of the Lymph-ICF-LL in other languages showed similar results, except for the German domains 'general tasks/household' and 'life domains/social life' due to missing answers [14,17–20]. Therefore, no items were deleted from the French questionnaire.

Validity

Seven from the eight hypotheses concerning convergent validity were confirmed by the significant fair to good correlations coefficients between domains of the SF-36 and the Lymph-ICF-LL. These correlations for convergent validity are situated between the results found in the other languages which also used the SF-36 [14,17,19,20]. A detailed comparison with these other languages can be found in appendix 2. The negative correlation can be explained by the inverse meaning of a low score for the Lymph-ICF-LL and SF-36. Correlations between domains reflecting divergent validity were lower than the correlations for convergent validity, representing a low to fair relationship, but were still significant for the French Lymph-ICF-LL. Although the aim is to evaluate different constructs, a relationship between physical functions and mental functions can be expected [45]. Therefore, the construct validity was not considered jeopardized. This was also seen in other studies. Little to moderate significant correlations between the different domains of the Turkish quality of Life Measure for Limb Lymphedema-Leg and the different domains of the SF-36 were found in the study of Borman et al. [46] The study of Klernäs et al. 2015 also compared the SF-36 with another lymphedema-specific quality of life questionnaire [47]. They found a significant low correlation between the 'mental health' domain of SF-36 and the 'physical function' domain of the Lymphedema quality of Life Inventory in patients with lymphedema [47]. This is comparable to the low correlation between the domain 'physical function' of the French Lymph-ICF-LL and 'mental health' of SF-36 in the present study. Also the 'mood/emotions' domain of the Dutch quality of Life

Measure for Limb Lymphedema-Leg showed moderate correlation with the 'physical component scale' of the SF-36 [48].

Concerning floor and ceiling effects, only the domain 'general tasks/household' showed a frequency higher than 15% of the minimum score (47.1%). This is also reflected in the low median score in this domain in the stable group (2[6]). The median score in the intensive group is higher (23[44]). It could be that this domain is more relevant to evaluate for patients in the intensive group. However, patients of the stable group did not mention questions of this domain to be irrelevant.

Regarding content validity, only 7.1% did not understand all questions. This is similar to the opinion of patients included in the study of the original Dutch Lymph-ICF-LL (93%) [14]. Experts of the study of the Chinese Lymph-ICF-LL also found a content validity index between .90 and 1.00 [18]. One of the 14 participants with midline lymphedema was not sure if the midline region was included in the questionnaire. The Lymph-ICF-LL is mainly focused and validated in patients with lymphedema at the legs and feet. By consequence, no firm conclusions could be drawn for the validity in patients with genital lymphedema. The scoring system was clear for 97.6% of the participants. The same frequency was found for the Brazilian Lymph-ICF-LL [19]. One patient mentioned that for some questions it was difficult to understand when a question seemed to be asked in the opposite direction. Similarly, 2 patients mentioned to be confused by the changing anchors in the Dutch version [14]. However, this was deliberately chosen so that a score closer to zero and ten always means a better or worse lymphedema specific quality of life on that item, respectively. Therefore, the labels of the anchors do have to change depending on if a negative consequence is questioned (for example, for pain score 10 equals 'a lot') or not (for example, for the ability to kneel score 10 equals 'not at all'). According 9.4% there were some irrelevant questions and 14.1% indicated that some questions were missing. However, no irrelevant or missing questions were mentioned more than two times. Furthermore, most reported missing questions were related to environmental-related aspects, like high temperatures, costs, how other people look at you and compression [49]. Compression was also mentioned by a participant in the study about the original Dutch Lymph-ICF-LL [14]. Because compression was seen as an external factor, this was not included in the questionnaire [14]. It was suggested to consider a separate questionnaire to evaluate compression-related effects [14]. For this purpose, the ICC compression questionnaire was developed [50]. The other reported missing items were considered to be already included in the domains of the Lymph-ICF-LL questionnaire. A common item both mentioned as missing and irrelevant was the question about choosing clothes and shoes. The common remark was that it would be helpful to split up the question into two parts as patients without swelling at the foot only experience difficulties with clothes and not with shoes. This could be considered.

Responsiveness

The total score and domain score of "physical function" of the Lymph-ICF-LL showed significant differences over time in the intensive group and positive responder group ($p<.05$), an SRM of −0.25 and −0.53 and significant correlations with GPE of −0.30 and −0.39, respectively. The negative SRM and correlations are explained by the scoring system of the Lymph-ICF-LL and GPE. In the Lymph-ICF-LL a lower total or domain score means a better lymphedema-specific quality of life, while for the GPE a higher score equals deterioration of the symptoms. The correlations between the change of scores on Lymph-ICF-LL and GPE were significant (except for the domain "general tasks/household"). However, these correlations showed low to moderate responsiveness. Global rating of change scales is often used to demonstrate responsiveness [38]. However, these scales, like the GPE, also depend on the ability of patients to recall a previous state [38]. It is debated that patients' perception on change is influenced by what happens between the evaluation moments, by the change in how they perceive the context and by the current status [38,51,52]. By consequence, there are studies showing higher correlation between the score on global rating of change scales and the score on the questionnaire of interest at that same time point, rather than high correlation between global rating of change scales with the change in measurement score of interest over time [53,54]. Nevertheless, since there is no clear relationship between volume reductions and quality of life [9–11], the GPE was a better alternative. Furthermore, the high percentage of patients scoring 0 at baseline on the domain "general tasks/household" did not give room for improvement. The mental

function domain did not show significant differences after the intensive treatment. However, there was a significant difference in the positive responder group, indicating that patients who perceived their mental symptoms as improved, were also detected by a significant change in the Lymph-ICF-LL score on mental function. For the domains "mobility" and "life domains/social life", there was trend toward a lower score in the positive responder group, although this was not statistically significant. The study of Keeley et al. also investigated if there was a significant difference in score on quality of Life Measure for Limb Lymphedema-Leg after treatment during one week and one month [11]. Although there was a significant improvement in overall quality of life after one week and in the domain "appearance" after one week and one month, there was no significant improvement in the overall quality of life and the other domains after one month [11]. Even though the small sample size was highlighted, it might also raise the question if one to two months follow-up used in these studies is the best timeframe to detect change in all domains of lymphedema-specific quality of life. Lastly, for some scores, the obtained MCID was smaller than the SRD. This means that a score higher than the MCID is not necessarily a real difference if it is smaller than the SRD. This implies that at least a change higher than the SRD should be obtained to speak of a real and minimal clinically important improvement. For example, for the total score the MCID was 5 and SRD was 14. A change score between 5 and 14 is clinically important but might also not be a real difference because of measurement error. A change score above 14 is needed to speak of a real and minimal clinically important difference. A limited number of participants could be labeled as negative responders ($n = 0–3$). Therefore, no conclusion could be drawn for a minimal clinically important deterioration based on these results.

Strengths and limitations

The present study had several strengths. First of all, it as multicentric study which was performed in two different countries. Secondly, the French forward-backward translation in the different countries accounted for possible differences in the French language resulting in a broadly applicable French questionnaire. Thirdly, patients with various causes of LLL were included in the study, making the results representative for different types of patients with primary and secondary LLL. Fourthly, important psychometric characteristics were investigated to assess the suitability of the questionnaire in research and clinical practice. The reliability and validity results confirmed that the lymphedema-specific quality of life can be assessed at any time point. Additionally, the responsiveness showed that it can be used to investigate the evolution over time or the effect of a treatment on the lymphedema-specific QoL. Fifthly, the study did not only consider measurement errors, but also minimal clinically important improvement for patients. Lastly, the present study included both the digital and paper form, reflecting the application in daily clinical practice.

Our study had some limitations as well. No minimal clinically important deterioration could be determined since a limited number of patients could be labeled as negative responders. The inclusion of negative responders will remain challenging for future research. This could also be explained by the lack of patients with stage 3 LLL and no second completions of patients who withdrew or lost contacts. The missing completions reduced the sample size and these missing patients might had given additional remarks concerning face and content validity. The rate of missing completions might be due to the digital option to complete the questionnaire. Previous research has shown that the response rate was lower for a digital questionnaire, but had less missing values [55]. The influence of the medium (paper form or digitally) was not investigated. However, this allowed every patient to choose their preferred medium. The design of the paper form and digital form was the same and a meta-analytic review showed that electronic and paper based PROs are equivalent [56]. Another limitation was that only a limited number of patients with lymphedema at the midline/genital region were included. Therefore, the results cannot be translated with confidence to patients with lymphedema at the midline region. A separate study or extension of the questionnaire would be required for this population as well as in children with LLL. A last limitation of this study is that the final version was only tested in three French-speaking patients of the Walloon region of Belgium. Guidelines mention a pilot test in around 10 patients [30].

Conclusion

The French Lymph-ICF-LL is a reliable and valid questionnaire to evaluate the lymphedema-specific quality of life and determine improvement over time in patients with limb lymphedema at the leg and/or foot.

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Author contributions

CRediT: **An-Kathleen Heroes**: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing; **Caroline Fourgeaud**: Conceptualization, Data curation, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – review & editing; **Inge Fourneau**: Conceptualization, Methodology, Supervision, Validation, Visualization, Writing – review & editing; **Tessa De Vrieze**: Conceptualization, Formal analysis, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing – review & editing; **Jacqueline Frippiat**: Conceptualization, Data curation, Investigation, Methodology, Project administration, Resources, Validation, Writing – review & editing; **Thierry Deltombe**: Validation, Writing – review & editing; **Sarah Thomis**: Validation, Writing – review & editing; **Sarah Abba**: Validation, Writing – review & editing; **Stéphane Vignes**: Visualization, Writing – review & editing; **Nele Devoogdt**: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing – review & editing.

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There is no conflict of interest to declare concerning the research, authorship and publication of the results.

Data availability and deposition

Data will be available on reasonable request.

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