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Cross-Cultural Adaptation and Preliminary Validation of Upper Limb Lymphedema Quality of Life Questionnaire (ULL-27) in Italian Female Patients with Breast Cancer-Related Lymphedema

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Upper Limb Lymphedema quality of life questionnaire

Abstract

Purpose: Lymphedema is one of the most recurrent problems reported by breast cancer survivors, which negatively affects quality of life (QoL). The Upper Limb Lymphedema Quality of Life Questionnaire (ULL-27) is a tool that assesses the QoL in patients with breast cancer-related lymphedema. At present, an Italian adaptation does not exist. The aim of this study is to perform a preliminary cross-cultural validation of the Italian version of the ULL-27.

Materials and Methods: A forward–backward translation and cross-cultural adaptation have been performed. One hundred twenty women with lymphedema were evaluated using the Italian version of the ULL-27. The mean age was 60.25 (±11.88) years, and mean body–mass index was 26.35 (5.13) kg/m^2. The Functional Assessment of Cancer Therapy–Breast (FACT-B) was analyzed using Pearson's correlation analysis with the ULL-27 to indicate convergent and external construct validity. Cronbach's alpha and factor analysis were used to assess the questionnaire's structure.

Results: The internal consistency for the total score of the Italian ULL-27 was high (0.90). Content validity was good because items were understandable for all participants. The alpha coefficients for subscale scores were high. External construct validity was confirmed by expected correlations with comparator scales. However, the factor structure of ULL-27 does not seem to completely reflect the original scale.

Conclusions: The Italian version of ULL-27 has good internal consistency and validity. It is a reliable tool for evaluating the QoL of these patients, but additional data should be collected to clarify the factorial structure and test–retest reliability of the scale.

Introduction

The improved breast cancer treatment techniques have allowed more and more people to survive cancer. As a matter of fact, survival rates have significantly increased in the last 20 years and have allowed clinicians and researchers to focus on improving the outcomes and survivors' quality of life (QoL) in the long term through targeted rehabilitation.[1,2] Secondary upper limb lymphedema (ULL) is a long-term chronic condition that can immediately evolve after breast cancer surgery with time not only in 12 to <24 months but also 5, 10, and even 20 years later.[3–6]

ULL is a consequence of the necessary surgery and radiotherapy procedures that are used to treat cancer, but that lead to, as a possible undesired effect, significant reduction of lymphatic fluid transport function.

The level of damage to the lymphatic system can vary in degrees and depends on the type of surgery and dose of radiotherapy.[1] As a result, interstitial fluid can accumulate in the tissues, leading to an increase in arm volume, soft tissue changes (i.e., adipogenesis and fibrosis), limb deformity, and infectious complications.[7]

There is some evidence that supports the importance of a specific rehabilitation intervention in management of lymphedema. In reality, therapeutic management is more likely to be effective if the lymphedema is detected in advance.[8] Physiotherapy interventions, which are summarized in an international consensus document, include skin care, manual lymphatic drainage, muscle pumping exercises, compression with multilayered bandage wrapping, and a low-stretch elastic sleeve, but it is necessary to specify that this issue is, in most cases, a chronic condition.[9,10]

Estimation of the prevalence and incidence of ULL and the related functional impairment has become increasingly complicated due to the rapid changes in breast cancer treatment over the last 20 years. These technological innovations have not only made these therapies tailored to the individual breast cancer status but have also made the group of women treated for breast cancer a very heterogeneous group, so it may be cumbersome to study the health-related information of these patients.[11]

A systematic review by Lee et al. established that patients who have received radiotherapy had a pooled odds ratio of 1.46 (95% confidence interval [CI]: 1.16–1.84; 8 studies) to develop lymphedema compared with those who have not received radiotherapy. Moreover, ULL was more than 11 times more likely (95% CI: 1.45–93.65; 3 studies) in full axillary lymph node dissection compared with sentinel lymph node biopsy.[2] ULL prevalence associated with axillary lymph node dissection was estimated at 43.3% and 22.2% in case of sentinel lymph node biopsy.[12]

However, in a 5-year prospective study of 936 women who underwent axillary lymph node dissection, the ULL cumulative incidence was 16%.[13] Therefore, it has to be taken into account that estimates on ULL occurrence vary greatly. A rigorous review and meta-analysis by DiSipio et al. suggested that of the 1.38 million women worldwide diagnosed with breast cancer every year, 21% will develop ULL in their lifetime.

Additionally, the incidence of ULL seemed to increase up to 2 years after diagnosis/surgery of breast cancer and was about four times higher in women who had an axillary lymph node dissection compared with those who underwent sentinel node biopsy. ULL risk factors with a strong level of evidence were axillary lymph node dissection, a greater number of lymph nodes dissected, mastectomy, and being overweight or obese.[3]

Concerning the health-related QoL of people who suffer from ULL, the literature suggests that physical disability significantly increases as a result of decrements in physical capabilities and functioning. As a consequence, this causes progressive functional impairment, significantly limiting domestic and work-related activities.[7] The involved limb may in fact become dysfunctional because of increased volume and weight as well as recurrent pain and the decreased range of motion.[14–17]

Psychological distress contributes to worse QoL in these patients. Their psychological and social functioning, already threatened by the cancer diagnosis and treatment, is further compromised by ULL. Women with ULL are at greater risk for adaptation disorder and mood disorders than both breast cancer survivors without ULL and the general population.[18] Almost half of the women who survive breast cancer experience body image-related discomfort with their body appearance as well as some degree of psychological, social, and physical functioning impairment.[19–21]

Body image-related distress is also frequent in people who develop ULL; this condition is associated with significantly increased psychopathology, such as depression and anxiety, and with significant impairment in professional and social and relationship functioning.[18,22,23]

Despite the heavy burden experienced by cancer survivors with ULL, currently, not many tools are available to specifically assess their QoL. The ULL-27, created and validated in French by Launois et al., is a promising tool that is useful in this context. ULL-27 is an easy-to-use self-administered scale that evaluates physical, psychological, and social issues experienced by patients with ULL.

However, the ULL-27 is currently validated in very few countries. Considering the long-term management of this chronic condition, limitations in everyday life for patients who develop ULL, the risk of a decreased long-term health-related QoL, and the psychopathology that they may develop,[25] our aim was to perform a cross-cultural validation and reliability study of the Italian version of the ULL-27.

Materials and Methods

Participants

The following data refer to a sample of 120 women who developed ULL after breast cancer treatment and who were considered eligible for the study after being informed about the purpose and the procedures of the present study. All patients were consecutively included, to minimize selection bias, and were referred to the Istituto Dermopatico dell'Immacolata (IDI-IRCCS), Department of Medical Oncology—Day Hospital in Rome, Italy, between September 2019 and May 2021.

All procedures performed within the studies involving human participants were in accordance with the Helsinki Declaration. The study protocol was approved by the IDI-IRCSS Ethics Committee with the practice number, n°589/1. Written informed consent was obtained from all individual participants involved in the study.

The inclusion criteria were (1) eighteen years old and over; (2) no local and systemic treatment (colorectal surgery, chemotherapy, and radiotherapy) in the last 6 months; (3) ability to read, write, and understand Italian; (4) mild–moderate–severe degree of lymphedema due to breast cancer treatment; and (5) will and ability to attend the study. The exclusion criteria were (1) the presence of malignant lymphedema; (2) current infection in the arms; (3) cancer therapy currently underway; (4) diagnosed psychopathology or cognitive impairment; and (5) diagnosis of muscle or severe joint issues.

Physiotherapy and clinical assessment

An electronic health record has been used for data collection. The following information was collected:

- demographic information such as age, education level, and marital and job status;
- oncological history such as type and date of surgery, number of lymph nodes removed, number of metastatic lymph nodes, oncological treatments performed (radiotherapy, chemotherapy, immunotherapy, and hormone therapy), postsurgical complications (seroma, axillary web syndrome, scars, radiodermatitis, functional limitations, and peripheral neuropathy, etc.), and oncological follow-up information;
- lymphedema assessment such as staging (stage I–III according to the International Society of Lymphology); affected side; date and type of onset (early or late onset); progression (proximal–distal progression, or vice versa) and distribution; involvement of the hand (specifying if dominant or not); presence of a positive pitting test; pain and functional limitations; presence of vascular complications such as thoracic outlet syndrome or axillary vein syndrome; and any previous episodes of bacterial infection (sporadic or relapsing); and
- information about the type (flat knit or circular knit), frequency of use (daily or occasional), and compression class of elastic compression garments.

Circumferential measurement

The lymphedema assessment has been conducted by a single licensed physiotherapist with >30 years of experience in lymphedema management and circumference measurements. Participants were positioned supine, still on the same physiotherapy bed, with the limb abducted at 30°. Both limbs' circumferences were assessed in a standardized technique at predefined heights, starting from the first wrist crease, proceeding every 5 cm in the proximal direction to the extremity of the limb. The hand circumference was calculated using the figure-of-eight method.

All patients were assessed using the same standard dynamometric tape measure that has been used with the aim of carrying out a more precise measurement of body circumference. Subsequently, the volume of both limbs was calculated using the truncated cone formula (excluding the hand). For each patient, the clinical grading of edema was assessed according to criteria established by the International Society of Lymphology.

The grading was assessed by comparing the volumetry of the two limbs. The grade of severity ranged from minimal (volumetric difference between 5% and 20%) to moderate (20%–40%) and to severe (≥40%).

QoL assessment

The participants were administered the Italian adaptation of the following questionnaires: the Functional Assessment of Cancer Therapy–Breast (FACT-B), 4th version,[26] and the ULL-27.

The FACT-B is a self-administered specific questionnaire designed to assess psychosocial, emotional, and physical well-being (PWB) of breast cancer patients.[37] The FACT-B consists of the FACT-General (FACT-G) plus the Breast Cancer Subscale, which complements the general scale with items specific to the QoL of breast cancer patients.

The questionnaire consists of 36 items that are subdivided into 4 primary QoL domains: PWB, N. 7 items (score ranging from 0 to 28); Social/Family Well-Being (SFWB), N.7 items (score ranging from 0 to 28); Emotional Well-Being (EWB), N. 6 items (score ranging from 0 to 24); and Functional Well-Being (FWB), N.7 items (score ranging from 0 to 28); and contains 9 additional items concerning breast cancer (score ranging from 0 to 36).[27]

These specific scales can provide adequate information about breast cancer issues (i.e., feelings of femininity and self-consciousness about clothes) and the current state of patients living with long-term consequences of breast cancer.[28] Each item can range from 0 (not at all) to 4 (very much). When single questions are omitted, their missing score is imputed as the average of the other answers in the same scale.[29] Final scores (FACT-B-Total) of all subscales range from 0 to 148, and higher scores are indicative of better QoL.[30]

The Upper Limb Lymphedema Quality of Life Questionnaire (ULL-27) is a self-administered tool developed and validated by Launois et al.[24] This tool specifically evaluates the QoL of subjects with ULL, considering three dimensions (physical functioning and social and psychological dimensions). Each of the 27 items can be scored on a 5-point Likert scoring scale (1 = strongly disagree and 5 = strongly agree).

In the original scoring form, the first 15 items evaluate the physical dimension (max 75 points), questions between 16 and 22 measure the psychological dimension (max 35 points), and questions between 23 and 27 assess the social dimension (max 25 points). The global score is made up of all 27 items. The lowest obtainable score is 27 points and the highest is 135. Higher scores reflect a worse QoL.[24]

Translation and cross-cultural adaptation

The aim of the translation process and the cross-cultural adaptation was to establish a tool that was conceptually equivalent to the original, but that was specific for the Italian population. For this reason, the instrument has to be acceptable to patients and should perform in the same way.

The focus was on cross-cultural and conceptual equivalence rather than on a linguistic/literal one. For this reason, the authors have performed this step according to the Beaton and World Health Organization guidelines[31–33] for the Italian adaptation of the ULL-27 (the steps of the translation and cultural adaptation are summarized in Table 1).

Table 1. Process of Translation and Adaptation of Instruments

(1) Forward translation	One translator, a health professional, familiar with the terminology of the area covered by the tool and with interview skills, took part in the project. The translator was knowledgeable about the French-speaking culture, but his mother tongue was Italian. He used the conceptual equivalent of a word or phrase, not a literal translation, and strived to be simple, clear, and concise. He used the most common language, considering the typical respondent, and avoided issues about jargon and colloquialism or offensive terms.
(2) Expert panel back translation	Using the same approach used in first step, the instrument will then be translated back to French by an independent translator. A single problematic phrase of a single item does not completely capture the concept. The issue was solved with the solution: "feel self-confident."
(3) Pretesting and cognitive interviewing	A provisional version of the Italian ULL-27 was pretested on 20 patients during their follow-up clinic visit. Patients accepted to complete the questionnaire after they were interviewed by the clinical psychologists. Subjects were asked about the degree of difficulty encountered when answering the questionnaire and to comment on the comprehensiveness and clarity of items in the ULL-27.
1. 4. Final version	The final version of the Italian adaptation of ULL-27 was the result of all the iterations described above.

ULL-27, Upper Limb Lymphedema Quality of Life Questionnaire.

Study design

This work is a cross-sectional study that aims to assess the questionnaire's reliability, internal consistency (measured with Cronbach's α), and factor structure of the Italian version of ULL-27. To indicate the convergent validity, Pearson's correlation analysis was performed between items and subscales of the FACT-B and compared with the ULL-27 items and subscales.

FACT-B[27,28] is a questionnaire widely used to measure the QoL in different patient populations and its adaptations in the Italian language are broadly used.[34–36] Each participant was evaluated by the same researchers for the QoL assessment and by the same physiotherapist for the physiotherapy assessment. All measurements were carried out in a single session and face to face with the participants. All evaluations lasted ∼45–60 minutes.

Statistical analyses

All statistical analyses have been performed with the Statistical Package for the Social Sciences (SPSS), version 25. All clinical and sociodemographic variables have been calculated in terms of frequencies and percentages or means and standard deviations. Cronbach's alpha coefficients were calculated to measure the internal consistency. The acceptable level of reliability was determined to be above 0.70.

The test-retest reliability of the scale was assessed by computing intraclass correlation coefficients between ULL-27 scores on the first administration and ULL-27 scores on the second administration. This procedure was applied to the last 12 patients at a 2-week interval. Convergent validity of ULL-27 was assessed with FACT-B by examining the correlation between patients' scores in ULL-27 and FACT-B subscales.

Both instruments measure constructs such as physical, psychological, and social functioning, but only the ULL-27 contains specific items related to lymphedema. Both questionnaires included a total health-related QoL general subscale, so we hypothesized that the ULL-27 and FACT-B would be highly correlated, but not overlapping, in their general QoL subscale measurement (r = 0.40–59).

However, ULL-27 measures the QoL of people with lymphedema after breast cancer treatment, while FACT-B measures the QoL of people who currently have cancer. The social reactions of the caregivers to the disease may be very different, so it is expected that correlation among the social subscales of these measures would be low (r < 0.30). Finally, we studied the factor structure of ULL-27 to identify latent dimensions of the Italian adaptation of the scale.

We used the principal axis method of factor extraction with the quartimax rotation technique. Spearman's correlation coefficient was used to assess the association between the ULL-27 and FACT-B global and specific dimensions.

Results

All participants reported that they understood the meaning of the items included in the ULL-27. In general, adherence to the study procedures was good. The mean age of the sample was 60.25 (±11.88) years. More than 20% of the sample reported a body–mass index ≥30 kg/m^2. Overall, 97.5% of the study population had undergone oncology surgery, and 46.7% of the participants had undergone radical lymphadenectomy. The average time taken to complete the questionnaire was 0:08:58 (DS: 0:04:46). Complete demographic and clinical data are reported in Table 2.

Table 2. Clinical and Sociodemographic Features of the Sample

Variables	*N* = 120	% | M (SD)
Age, M (SD) in years		60.52 (11.88)
BMI, M (SD) kg/m^2		26.35 (5.13)
	BMI <18.5	3.3%
	BMI 18.5 to 24.9	40.8%
	BMI 25 to 29.9	21.7%
	BMI 30+	32.4%
Marital status		
	Single	10.8%
	Married	73.3%
	Divorced	5.8%
	Widow	10.0%
School attainment		
	Primary school	10.8
	Secondary school	17.5
	High school	44.2
	Degree or higher	27.5
Job status		
	Active	55.5
	Retired	44.5
Oncological breast surgery		
	Yes	97.5
	No	2.5
Radiotherapy		
	Yes	83.2
	No	16.8
Lymphadenectomy		
	None	25.0
	Partial	28.3
	Radical	46.7
Lymphedema of the dominant arm		54.6
Lymphedema onset		
	Immediate	(N 54) 62.5%
	Gradual	(N 50) 37.5%
Volume of the arm with lymphedema		19.01 (1.06) mL
% Discrepancy between arms		1.12 (2.03) mL
Stadiation		
	I	6.7%
	II	89.9%
	III	3.4%
Grading		
	I	45.8%
	II	29.7%
	III	24.6%
Fovea of the hand		
	None	44.2%
	I	20.0%
	II	32.5%
	III	3.3%
Time to complete the ULL-27		0:08:58 (0:04:46)

BMI, body–mass index; SD, standard deviation.

Reliability and convergent validity of the ULL-27

The internal consistency, reliability, and item scores were investigated in terms of correlation and invariance, with satisfactory results. ULL-27 internal consistency (reliability) was assessed using Cronbach's alpha, which was 0.87 for the physical subscale, 0.73 for the psychological subscale, 0.81 for the social subscale, and 0.90 for the ULL-27 global score (Table 3). An appreciable level of reliability has been achieved also for every item of the ULL-21 (Table 4). Convergent validity assumes that scales intended to measure similar constructs should be highly intercorrelated.

Table 3. Upper Limb Lymphedema Quality of Life Questionnaire Subscale and Global Measure Reliability

	Cronbach's alpha	No. of items
Physical subscale	0.87	15
Psychological subscale	0.73	7
Social subscale	0.81	5
Global score	0.90	27

Table 4. Reliability of Each Question in the Upper Limb Lymphedema Quality of Life Questionnaire

	Mean	SD	α	r
Ull-1	2.43	1.46	0.90	0.39
Ull-2	2.27	1.46	0.89	0.55
Ull-3	2.33	1.44	0.90	48
Ull-4	2.03	1.30	0.90	0.48
Ull-5	2.79	1.56	0.89	0.55
Ull-6	2.54	1.57	0.90	0.46
Ull-7	1.87	1.32	0.90	0.40
Ull-8	2.67	1.52	0.90	0.54
Ul-l9	2.91	1.48	0.90	0.45
Ull-10	2.46	1.49	0.89	0.58
Ull-11	2.39	1.60	0.89	0.60
Ull-12	2.95	1.48	0.89	0.56
Ull-13	2.91	1.48	0.90	0.46
Ull-14	3.23	1.47	0.89	0.55
Ull-15	3.09	1.41	0.90	0.51
Ul-l16	2.53	1.37	0.90	0.44
Ull-17	2.89	1.40	0.89	0.62
Ull-18	3.25	1.53	0.89	0.55
Ull-19	2.70	1.42	0.90	0.44
Ull-20	2.61	1.39	0.90	0.18
Ull-21	2.86	1.53	0.90	0.40
Ull-22	3.09	1.44	0.90	0.30
Ull-23	2.44	1.44	0.90	0.43
Ull-24	1.87	1.40	0.90	0.51
Ull-25	1.86	1.44	0.90	0.44
Ull-26	1.89	1.39	0.90	0.35
Ull-27	2.28	1.54	0.89	0.57

The scores of FACT-B and ULL-27 subscales (i.e., ULL Global score; FACT Global score; ULL Physical subscale; ULL Psychological subscale; ULL Social subscale; PWB FACT subscale; and EWB FACT subscale) are very similar and they are all significantly related to each other (all comparisons: p < 0.001) except for the FACT Social Well-Being subscale (FACT-SWB): FACT SWB × ULL Global score p = 0.13; FACT SWB × ULL Physical subscale p = 0.71; FACT SWB × ULL Psychological subscale p = 0.07; and FACT SWB × PWB FACT subscale p = 0.08. Results for each subscale are described in Table 5.

Table 5. Spearman's Correlation Between the Upper Limb Lymphedema Quality of Life Questionnaire and Functional Assessment of Cancer Therapy Subscales and Global Indexes

	FACT Global score	ULL Physical subscale	ULL Psychological subscale	ULL Social subscale	FACT PWB	FACT EWB	FACT SWB
ULL Global score	−0.530**	0.925**	0.759**	0.678**	−0.550**	−0.407**	−0.14
FACT Global score		−0.396**	−0.546**	−0.474**	0.623**	0.742**	0.573
ULL Physical subscale			0.558**	0.482**	−0.521**	−0.243**	−0.03
ULL Psychological subscale				0.505**	−0.415**	−0.577**	−0.16
ULL Social subscale					−0.288**	−0.368**	−0.26
PWB FACT subscale						0.276**	0.16
EWB FACT subscale							0.298

Results in the table assume that in ULL-27, a higher score indicates poorer QoL; in FACT-B, the higher score indicates a better QoL; for this reason, negative scores are reported. **p < 0.001.

ULL-27, Upper Limb Lymphedema Quality of Life Questionnaire; FACT-B, Functional Assessment of Cancer Therapy–Breast; FACT EWB, FACT Emotional Well-Being subscale; FACT PWB, FACT Physical Well-Being subscale; FACT SWB, FACT Social Well-Being subscale; QoL, quality of life.

Validity of the ULL-27

The factor structure of the ULL-27 was studied with the principal axis method of factor extraction. To prefer clarity in explanations, the rotational technique used was quartimax with Kaiser normalization, which minimizes the number of factors needed to explain each variable. The three factors accounted for 41.42% of the total variance (factor I: 23.31%; factor II: 10.20%, and factor III: 7.91%).

In this model (as close as possible to the proposed structure of the original scale), the first factor corresponded to the physical subscale, the second factor corresponded to the psychological subscale, and the third factor corresponded to the social subscale. With the commonly used cutoff for size of loading to be interpreted of 0.32,[38] a fairly simple pattern of factor loadings emerged, as illustrated in Table 6, where loadings under 0.32 are replaced by blank spaces.

Table 6. Factor Structure of the Italian Adaptation of the Upper Limb Lymphedema Quality of Life Questionnaire

	I	II	III
ULL-1	0.563		
ULL-2	0.629		
ULL-3	0.575		
ULL-4	0.644		
ULL-5	0.539		
ULL-6	0.584		
ULL-7	0.572		
ULL-8	0.555		
ULL-9	0.664		
ULL-10	0.658		
ULL-11	0.475		0.367
ULL-12	0.673		
ULL-13	0.493		
ULL-14	0.666		
ULL-15	0.656		
ULL-16		0.570	
ULL-17		0.762	
ULL-18		0.656	
ULL-19		0.644	
ULL-20			0.392
ULL-21		0.524	
ULL-22			
ULL-23			0.370
ULL-24	0.427		0.640
ULL-25			0.689
ULL-26			0.348
ULL-27	0.373		0.625

Item 22, which had already been the focus of discussion at the translation stage, did not load sufficiently on any factor.

Discussion

This study provides a preliminary validation of ULL-27 in an Italian adaptation. People who survive breast cancer face many problems and have to adapt to a new lifestyle. Lymphedema is one of the possible postcancer treatment-related problems. It is a chronic condition and has a negative impact on the QoL of breast cancer survivors. For this reason, it is important to have QoL measures tailored for this condition.

In this study, a preliminary validation of the Italian version of ULL-27 has been performed. This measure was found to be a reliable measure in Italian female patients who suffered from lymphedema due to breast cancer. Previous studies stated that limb lymphedema affects patients' lives in functional, psychological, and social dimensions.[39]

In recent years, the questionnaire proposed by Launois et al.[24] has been adapted in languages other than French, that is, in Turkish and Dutch.[40,41] Both versions detected the presence of three subscales corresponding to three factors underlying the questionnaire, as in the original version. This structure was detected in our study also.

FACT-B[26] is a widely used assessment tool for this specific population, therefore this measure and ULL-27 were the main assessment scales chosen for this study. FACT-B has been used as a comparator tool in this study differently from Viehoff et al.,[41] who used the RAND 36-item, and from Kayali Vatansever et al.,[40] who used the Health Survey and European Organization for Research and Treatment of Cancer (EORTC) 30-item Quality of Life Questionnaire and Quality of Life Questionnaire-Breast Cancer 23 (QLQ-BR23).

FACT-B was chosen as a comparator for this study because of its widespread use in QoL assessment in breast cancer survivors[42] and because it is a specific measure that involves not only specific questions about arm symptoms but also all breast cancer symptoms. However, its manual scoring mode is not immediate and could be time-consuming, unlike the ULL-27 that specifically assesses limb lymphedema symptoms and has an easier scoring system.

Cronbach's alpha values for the ULL-27 physical, psychological, and social scores were calculated by Launois et al.,[24] and this procedure was exactly replicated in our study. Similarly, Kayali Vatansever et al. used this method in the Turkish adaptation. In our study, the observed Cronbach alpha values for the global score, as well as for specific subdimensions, were relatively high and similar to those reported in previous studies.[24,40,41] The ULL-27 and FACT-B subscales were found to be highly correlated, but did not overlap.

However, the factor structure of the Italian version of the ULL-27 does not seem to completely reflect the structure of the original scale. For example, in our study, one item in the first factor (#11: "difficulty in washing") was found to be related to the first and third factors in the physical and social subscales. A possible theoretical explanation can be related to the fact that difficulties in daily hygiene can interfere with social life. In addition, a second item (20#: "have confidence in the future") was found to be related to the third factor in our study, instead of the second, as in the original scale.

It is possible that hope for a better future could be related to patients' social boundaries. In fact, a well-established social support is a protective factor against hopelessness.[43] Item #24, "difficulties in social life (restaurant, cinema, and theater)," loads on the third and first factors. A possible explanation could be that a worse physical condition and a large arm circumference widely interfere with social life, so these two physical and social dimensions could actually be associated. However, when presenting the questionnaire to patients, they should be warned to pay particular attention to these items.

In conclusion, the preliminary data from our Italian adaptation of the ULL-27 indicate that in our settings and cultural environment, this self-administered tool seems to be a reliable and valid scale for assessing the QoL in ULL patients

environment, this self-administered tool seems to be a reliable and valid scale for assessing the QoL in ULL patients. Furthermore, given that it is easy for patients to complete and quite manageable in routine clinical settings, it should be used not only for clinical but also for research purposes.

Conclusions and Limitations

This study aimed to assess the convergent validity, internal consistency, reliability, and factor structure in clinical use of the ULL-27. Further research is needed to better establish the factor structure of the questionnaire and to test the results and intraclass correlation in a larger sample.

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Note of the Authors

The original French version of ULL-27 was developed by Professor Robert Launois with an educational grant from REES France. Any person who wishes to use the questionnaire should contact Professor Robert Launois (reesfrance@wanadoo.fr).

Authors' Contributions

R.B. and V.A. conceived of the presented idea. D.A. and T.S. developed the study design and obtained the approval of the ethics committee. R.B., E.S.P., T.S., and C.Q. enrolled patients. R.B. performed physiotherapy treatments. T.S. performed the statistical analysis. All authors discussed the results and contributed to the final manuscript.

Author Disclosure Statement

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