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LYMPH-Q translation, cultural adaptation and validation in Italian language: A prospective PROMs-based study on breast cancer-related arm lymphedema for patients' education

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Abstract *Background:* Upper Extremity Lymphedema following oncological breast surgery affects not only the patient's physique, but also the patient's psychological sphere. One of the best known PROMs-based questionnaires for investigating the condition is the LYMPH-Q. The study aimed to perform the Italian translation and cultural adaptation of the LYMPH-Q and to assess if, independently from disease evolution, arm sleeve improves QoL in these patients.
Materials and methods: Translation included 4 steps: Forward translation, Back translation, Back translation review and Patient interviews. The questionnaire was administered to 50 female patients older than 18 years of age with UEL who received a prescription for daily use of a compression sheath. A second administration took place 30 days after. Forty-four patients completed the study (Group 1: 26 patients with indication to use compression sleeve who wore it;

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Group 2:18 patients who despite the prescription did not want to wear it. A descriptive statistical analysis was performed with Prism 9 software.
Results: T-tests showed statistical significance for changes in "Symptoms," "Function," "Appearance" and "Psychological" scales. There were no statistically significant changes for "Information scale" in Group 1 and for all scales in Group 2.
Conclusion: Data from this observational study show that HR-QOL analyzed from the patients' perspective also tends to improve in terms of symptoms, function, appearance, and psychological sphere in patients with BCRL when using a compression sheath. The Lymph-Q has proven to be a valuable ally of the physician attempting to improve treatment approaches for BCRL based not only on scientific evidence but also on PROMs.

More than one in five women who have survived breast cancer will develop Upper Extremity Lymphedema (UEL) with an incidence of about 5.6% following sentinel lymph node biopsy and from 13.5% to 28.2% after axillary lymphadenectomy.[1,2]

Manual lymph drainage, intermittent pneumatic compression, daily compression bandaging, skin care, surgical methods including vascularized lymph node transfer, lymphatico-venous anastomosis, lymphatico-lymphatic bypass and circumferential suction-assisted lipectomy, kinesio taping, low-level laser therapy and shock waves therapy are described as possible treatments to reduce UEL symptoms.[3-7] No definitive cure for UEL exists, but patient education, symptomatic and prophylactic approaches are the current winning strategies.[8] The condition seems to affect not only the patient's physique by impeding her movements and making daily life more difficult, but also the patient's psychological sphere by negatively impacting her health-related quality of life (HR-QOL).[9,10] Lymphedema's treatment remains challenging both for the patient and for the sanitary operator; and, due to its negative impact on patient life, it is extremely necessary to study and experiment all the possible treatments for this condition.[11]

PROMs (Patient Reported Outcome Measures) associated with Evidence Based Medicine are valid tools that allow us in daily practice to assess the impact of different treatments on patient QoL by objectively analyzing subjective parameters that are difficult to measure.[12-14] Among the PROMs-based questionnaires, one of the best known for investigating UEL following breast cancer, is the LYMPH-Q.[15] The main endpoint of this research was to perform the Italian translation and cultural adaptation of the LYMPH-Q. The secondary aim of the study was to assess if, independently from disease evolution, arm sleeve improves QoL in patients with breast cancer-related arm lymphedema. This research was conducted for patient education.

Materials and methods

Lymph-Q Upper Extremity module: Italian translation and cultural adaptation

The Lymph-Q is a validated multidimensional self-report questionnaire developed using Rasch measurement theory.[15] It permits to study the health-related quality of life (HR-QOL) of patients with breast cancer-related arm lymphedema (BCRL) by patient-reported outcome measures (PROMs).[16] The questionnaire consists of 7 independently functioning scales with four response options. It reports a patient's health status directly from her point of view without others' interpretations. The test investigates 3 domains: "Health-related Quality of Life" (Arm Appearance, Arm Function, Arm Symptoms, Psychology), "Experience of Care" (Information) and "Treatment" (Arm Sleeve). Once the total score for each scale has been calculated, a conversion table should be used to convert values to a Rasch scale score ranging from 0 (worst) to 100 (best). Higher scores reflect better outcomes.

As there was not yet a translated and validated Italian version, authors decided to translate and validate the Lymph-Q in Italian language. Permission for the translation process was sought from the Q-portfolio team. The authors followed the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) best-practice guidelines for the translation and cultural adaptation of patient-reported outcome measures (PROMs).[17] The ISPOR translation steps are described in detail below.[18] The translation process involved three independent translators informed about the entire process of validation and cultural adaptation of the questionnaire. The involved translators were all expert translators at university level and had to report if they worked for a company and eventually which company. Each translator performed his own translation completely independent from the others. Regarding the "Symptoms" scale, 3 instruction notes, 4 response options and 15 items have been translated; while for the "Function" scale the instruction notes, response options and items were respectively 3, 4 and 12; for the "Appearance" scale 3, 4 and 10; for the "Psychological" scale 2, 4 and 12; for the "Information" scale 2, 4 and 9 and finally, for the "Arm sleeve" scale 2, 4 and 10.

The process includes 4 steps (Figure 1):

1) "Forward translation" (two independent Italian translations of the questionnaire by two Italian mother tongue fluent in English were created). Translators were instructed to conduct a conceptual rather than a literal translation of the phrases. The two independent translations derived by this step were similar; major

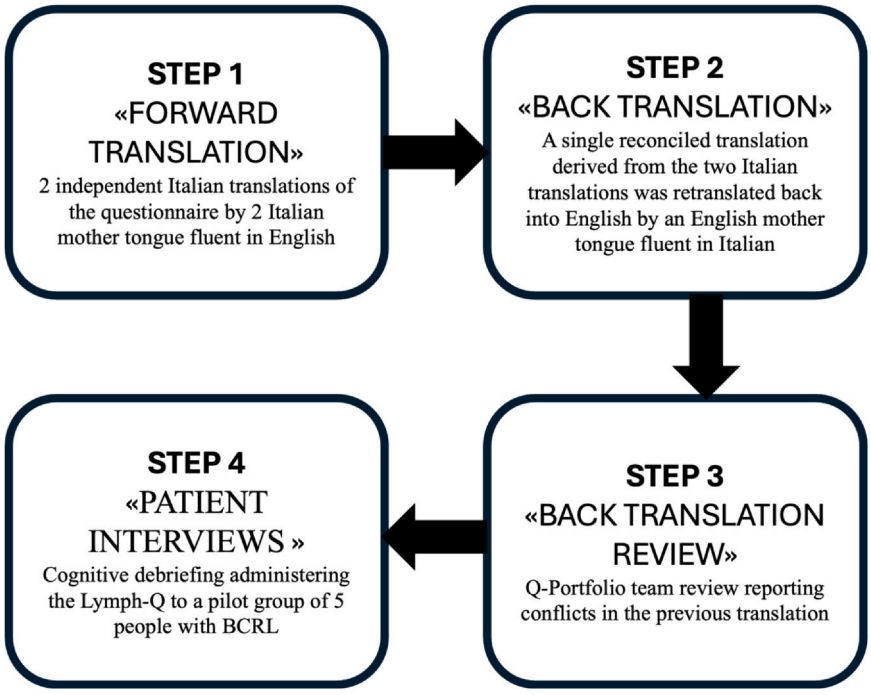

Figure 1 Main steps of the LYMPH-Q translation, validation and cultural adaptation process in Italian language.

differences regarded synonyms. A thorough comparison was then needed for the next step. In an Excel worksheet, the English version of the questionnaire was listed in the first column, the first Italian translation in the second, and the second translation in another. In a further column translators could report words that were difficult to translate.

2) "Back translation" (a single reconciled translation derived from the two Italian translations was retranslated back into English by an English mother tongue fluent in Italian, who did not participate in the first step).
3) "Back translation review" (this process consists of an interactive "discussion" with the Q-Portfolio team who provided the approval for the previous step without reporting conflicts in the "back translation").
4) "Patient interviews"[1,19–21]

A cognitive debriefing was then performed by administering the Lymph-Q to a pilot group of at least 5 people with different ages, genders, and context of use (diagnosis or treatment) to confirm full understanding of the Italian version. We administrated the questionnaire to a group of 7 females; in 5 times the test was used in a diagnosis context, while in other 2 cases in a treatment context. Mean age was 45 years old with a range from 25 to 65. No further language corrections were needed as no linguistic conflicts were noted. The final version of the Lymph-Q was sent back to the Q-Portfolio team.

This approved the Italian translation of the Lymph-Q and gave permission to use the test for this clinical study.

Example of the whole process:

- Step 1/Forward translation: "How does your arm feel (symptoms)?"/English version; "Come senti il tuo braccio (sintomi)?"/First Italian translation; "Come senti il tuo braccio (sintomi)?"/Second Italian translation; No words were difficult to translate.
- Steps 2/Back translation: "Come senti il tuo braccio (sintomi)?"/Reconciled translation; "How does your arm feel (symptoms)?/Back translation.
- Step 3/Back translation review: "OK."
- Step 4/Patient interviews: "No difficulties of participants were reported."

Study design and questionnaire administration

From June to December 2022 all the consecutive patients with UEL following breast cancer surgery were enrolled in the study. All the 50 patients were treated in the authors' Department of Physical Medicine and Rehabilitation. The inclusion criteria of this prospective study were: female patient older than 18 years of age with UEL following breast cancer surgery who had never been under treatment. We excluded: patients not mentally competent, patients with uncompensated diseases, patients who needed further oncological surgical treatment and patients who did not complete both paper tests administered. At time 0, each patient was examined by a physician. A thorough medical history was conducted, sociodemographic characteristics were reported, a compression sheath (mediven esprit®) for daily use for lymphedema treatment prescription was made and a first administration of the Italian version of Lymph-Q in a calm environment in paper form occurred. All patients were instructed to wear the arm sleeve h24 with a different compression scale (CCl 1, CCl 2 or CCl 3) depending on the UEL degree. A second administration took place at time 30 during a second visit (30 days after the first visit). If the lymphedema affected both arms, the patient had to respond by thinking of the arm that is most troublesome, as directed by

PARAMETERS	GROUP 1	GROUP 2	P value
	44 patients		
	26 patients	18 patients	
AVERAGE AGE (y)	61±12	54±11	P>0.05
BMI	24.64±3.92	27.37±6.04	P>0.05
LNSB	10	2	P>0.05
LYMPHADENECTOMY	16	16	
CHEMOTHERAPY	18	11	P>0.05
RADIOTHERAPY	20	13	P>0.05
IMMUNOTHERAPY	6	0	P>0.05
HORMON THERAPY	14	14	P>0.05
DEGREE 1	10	11	P>0.05
DEGREE 2	11	4	
DEGREE 3	5	3	

Figure 2 Mean medical data of the study sample.

the authors of Lymph-Q. Anonymity of the test was ensured. Each patient signed a written consent and was aware of this clinical investigation. Six patients were excluded because they did not complete the second administration of the questionnaire. A total of 44 patients divided into two groups completed the study: "Group 1" composed of 26 patients with indication to use compression sleeve who wore it for 1 month and "Group 2" composed of 18 patients who despite indication to use compression sleeve did not want to wear it (Figure 2). A descriptive statistical analysis was performed with Prism 9 software. The study was conducted in accordance with local regulations, international standards of "Good Clinical Practice" of the European Community, and the principles of the Declaration of Helsinki.

Results

Preliminarily, statistical uniformity of the two groups was verified. In detail, authors performed an analysis on distribution of patients according to sociodemographic and clinical characteristics such as: age, BMI, degree of lymphedema, marital status, education, LNSB or lymphadenectomy, chemotherapy, radiation therapy, immunotherapy and hormone-therapy. Normalization of values was investigated with the Shapiro-Wilk test. To detect a possible significant difference between dichotomous variables of the two groups (marital status, education, LNSB or lymphadenectomy, chemotherapy, radiation therapy, immunotherapy and hormone therapy), unpaired nonparametric Mann-Whitney tests were performed. The unpaired parametric t-test with Welch's correction was used for quantitative variables such as BMI and age, since the distribution was Gaussian. For lymphedema grade, it was necessary to use the unpaired nonparametric Mann-Whitney test because the values did not follow Gaussian distribution. To evaluate each total scale score, data were collected in a Microsoft Excel 2007 spreadsheet database. Then they were exported to statistical software (Prism 9) for descriptive analyses. A value of $p < 0.05$ was considered to be significant. The domain "Arm Sleeve" was specifically related to exclusive use of the compression dressing, so only patients in group 1 had to answer. The sum of mean scores obtained at time 0 and at time 30 was evaluated for each scale separately for the two groups to assess their variation over time and then between the two groups to investigate any statistically significant variation between the deltas of each scale. The normal distribution of the sample was evaluated with the Shapiro-Wilk test and then paired or unpaired t-tests, with or without Welch's correction, or Mann-Whitney's test, were performed as needed to assess the statistical significance of the changes.

The mean age of patients was 61 $\pm$ 12 years in Group 1, and 54 $\pm$ 11 in Group 2. The mean BMI value was 24.64 $\pm$ 3.92 and 27.37 $\pm$ 6.04 for Groups 1 and 2, respectively (Figure 2).

Table 1 LYMPH-Q average values stratified by the group for each scale administrated.

Scales	Group 1 average value 1° administration	Group 1 average value 2° administration	Paired t-test $p < 0.05$?	Group 2 average value 1° administration	Group 2 average value 2° administration	Paired t-test $p < 0.05$?
Symptoms	57.46 ± 17.85	69.73 ± 16.07	$p < 0.05$	67.06 ± 15.76	65.89 ± 18.14	No
Function	52.42 ± 17.05	71.15 ± 15.15	$p < 0.05$	62.67 ± 26.31	56.17 ± 25.93	No
Appearance	52.12 ± 27.01	68.27 ± 15.82	$p < 0.05$	58.39 ± 33.54	55.17 ± 35.60	No
Psychological	57.19 ± 21.97	69.77 ± 15.64	$p < 0.05$	70.06 ± 14.59	57.72 ± 23.81	No
Information	61.77 ± 22.43	68.65 ± 20.68	No	68.94 ± 17.69	61.83 ± 20.03	No
Arm sleeve	-	50.58 ± 15.78	-	-	-	-

Ten patients were classified as lymphedema grade 1 in Group 1, 11 in Group 2; 11 as grade 2 in Group 1 while 4 in Group 2; finally, 5 patients as grade 3 in Group 1 and 3 in Group 2.[22] Ten patients in Group 1 had performed only LNSB, the others had undergone lymphadenectomy. In Group 2, 16 out of 18 patients had performed lymphadenectomy while only 2 had LNSB. Almost all patients in both groups had high school degree or above and they were appaired. The patients who had performed chemotherapy in group 1 were 18, radiotherapy 20, immunotherapy 6 and hormone therapy 14. In Group 2 there were 11 chemotherapy, 13 radiotherapy, none immunotherapy and 14 hormone therapy, respectively. No significant differences were found between the distribution of dichotomous variables (LNSB-lymphadenectomy, high schooling or not, single or appaired, chemotherapy, radiotherapy, immunotherapy and hormone therapy) with the Mann Whitney test. No significant differences were found between the two groups in age, BMI and degree of lymphedema by unpaired t-test with Welch's correction. Normalization of the distribution of values was evaluated by the Shapiro-Wilk test.

LYMPH-Q mean values are shown in the Table 1.

The "Arm sleeve" scale represents a patient's assessment of the arm sleeve applied on the arm with lymphedema. Only group 1, who wore the sleeve, had to answer the questions on this scale during the second administration. The mean value obtained by summing the individual scores and then converted to Rasch scales (0 to 100) is 50.58 ± 15.78. This measure represents an overall assessment of the patient's experience with arm sleeve.

For each scale, a paired t-test was performed between the scores for each individual group to assess the statistical significance of the changes observed 1 month later. Statistical significance was demonstrated for the "Symptoms," "Function," "Appearance" and "Psychological" scales for group 1 only. Deltas between first and second administration were then calculated for both groups (Figures 3-7). A normalization of the values was assessed with the Shapiro-Wilk test.

Depending on Gaussian distribution or not, unpaired t-tests with Welch's correction for different standard deviation or Mann-Whitney tests were then performed to assess whether there were significant differences between changes over time between two groups.

The t-tests were significant for "Function scale," "Psychological scale" and "Information scale." Mann-Whitney test shows significant difference in "Symptom

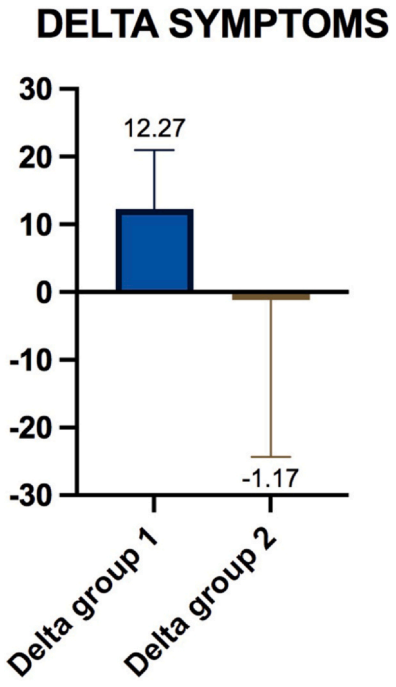

Figure 3 Delta (pre-post) data deriving from LYMPH-Q SYMPTOMS scale for each group.

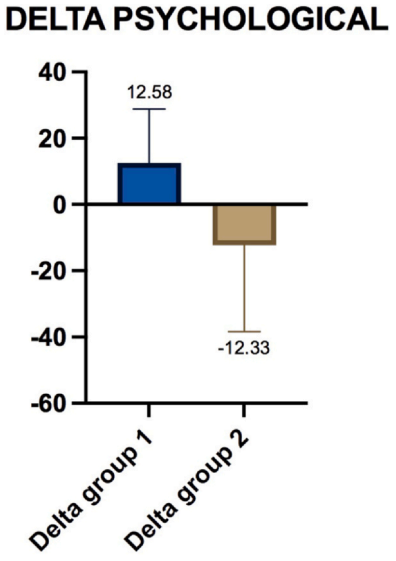

Figure 4 Delta (pre-post) data deriving from LYMPH-Q PSYCHOLOGICAL scale for each group.

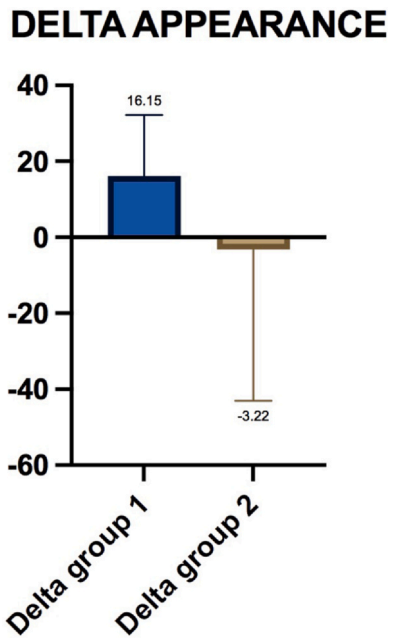

Figure 5 Delta (pre-post) data deriving from LYMPH-Q APPEARANCE scale for each group.

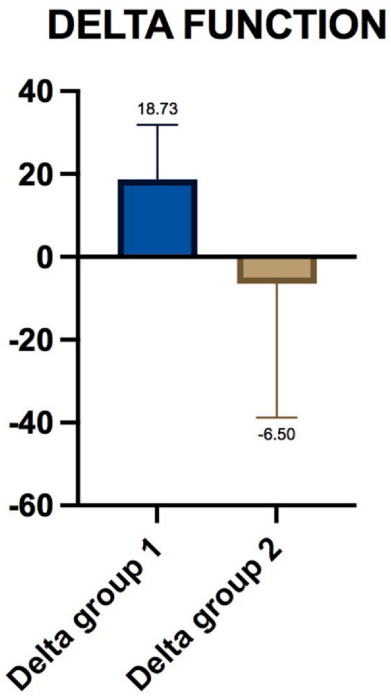

Figure 6 Delta (pre-post) data deriving from LYMPH-Q FUNCTION scale for each group.

scale." No significant difference was found between the deltas of the two groups for the "Appearance" scale.

Discussion

Lymphedema represents one of the side-effects of breast cancer treatment characterized by fluid and protein

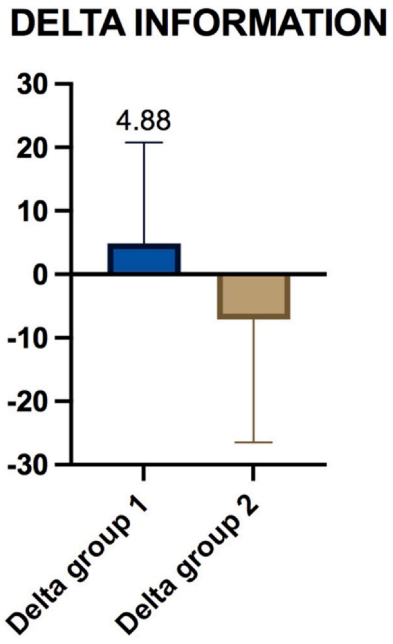

Figure 7 Delta (pre-post) data deriving from LYMPH-Q INFORMATION scale for each group.

accumulation in the tissues. To date, there is no universal specific treatment for BCRL to remove the condition, but essentially palliative care is aimed at improving symptoms.

As previously introduced, this condition is extremely invalidating for the women affected; so, the introduction of new tools able to investigate and objectivate subjective feelings of the patients is mandatory in modern medicine. The PROMs represent data that should always be associated with Evidence Based Medicine/clinical data for continuous improvements in daily practice. They not only allow to better understand QoL of the patients, but also may represent medical tools useful to evaluate the impact of the different treatments on the same patient. In conditions that, as UEL following breast cancer surgery, are chronic and severely affecting QoL, questionnaires as LYMPH-Q may be the key for a better challenge with the pathology as no definitive cure exists yet in most of the cases. This concept remarks the idea of the necessity to have the validation and cultural adaptation of these questionnaire in as much languages as possible. Only this scientific process will lead to a better comparison of these PROMs not only for clinical practice, but also for patient's education. This is the reason why we decided, following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) best-practice guidelines, to translate and adapt in Italian language one of the most known PROMs-based questionnaire aimed to investigate UEL, the LYMPH-Q. The process of translation and culture adaptation was not linear and straightforward, but involved an exchange of different translations and included a multidisciplinary team designed to enable a final translation that was easily understood by the patient but at the same time reflected the value of the initial questionnaire. After obtaining the final form and authorization for patient administration, our study, that was aimed at patient's education, started with the inclusion of a definitive sample composed of 44 patients. Focusing on

the data obtained by the administration of the different scale of the LYMPH-Q to the sample of study, we can confirm that all mean values of the first 5 Lymph-Q scales administered tend to increase after 1 month in group 1. As previously introduced, t-tests showed statistical significance ($p < 0.05$) only for changes in 4 scales for group 1: "Symptoms," "Function," "Appearance" and "Psychological." On the other hand, there were no statistically significant changes for the mean values of "Information scale" for group 1 and for all scales for group 2. The higher the scores, the better the outcomes. This shows that on average, lymphedema-related symptoms such as pain, aching feeling, numbness, pressure, heaviness etc. tend to improve 1 month after arm sleeve daily and constant application. From the data extrapolated from the questionnaires, it seems that patient's rate having better function in daily actions after using the sleeve tends to be higher. The assessment of the appearance of the arm with lymphedema also tends to improve after 1 month of arm sleeve application. We explain these data by thinking that since the sleeve is compressive, the arm lymph is redistributed, and the arm volume tends to decrease. In this way the diseased arm turns out to be similar to the healthy one, when present, in terms of size. The patient will feel more self-confident so she will also have the feeling that people notice his arm less. This mechanism also makes people feel better psychologically. On average, all those negative feelings such as hopelessness, hopelessness, anxiety, fear, irritation and frustration tend to decrease. In the social age, physical appearance is increasingly related to people's psychological sphere. By improving appearance, this improves how a person feels and sees himself or herself. The same things cannot be said for group 2, which represents a control group. This is because lymphedema if left untreated tends not to improve. Most patients with a mild degree of lymphedema, if they do not perform adequate therapy, based not only on arm sleeve but also on lymphatic drainage massage and physiotherapy, tend to worsen reaching a higher degree of severity. This fits with what the data showed. After only 1 month the mean values tend to decrease so the outcomes are on average worse. The mean values reported on the "Information scale" although they increase after 1 month for group 1 are not supported by statistically significant changes. For the same scale the values tend to decrease over time for group 2. We believe that the trend of these data would change and become more similar between the two groups if the number of the study sample was increased. The "Arm sleeve scale" represents an overall assessment of the patient's experience with arm sleeve. The mean value is 50.58 ± 15.78 on a Rasch scale ranging from 0 as the lowest score to 100 as the highest score. Analyzing the changes between the deltas of the two groups between the first and second administration served us to assess whether the significant changes observed in group 1 are valid when compared with a control group with the same pathology, which had the same therapeutic indication but did not want to use the prescribed sheath. The limitations of this prospective study include the number of patients enrolled, the follow-up time and the single-center setting, which can make the questionnaire results less generalizable since geographical, cultural and local aesthetic trends may have influenced the patients' opinion.

Conclusion

The validity of using arm sleeves in lymphedema treatment has already been described in scientific literature. The translation and cultural adaption process led to the development of a conceptually equivalent Italian version of the LYMPH-Q. Data from this observational study show that HR-QOL analyzed from the patients' perspective tends to improve in terms of symptoms, function, appearance, and psychological sphere in patients with BCRL when starting to use a compression sheath in just 1 month. The Lymph-Q has proven to be a valuable ally of the physician attempting to improve treatment approaches for BCRL based not only on scientific evidence but also on PROMs.

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Conflicts of interest

The authors declare that they have no conflicts of interest to disclose.

Statement of human rights

The study was conducted in accordance with local regulations, international standards of "Good Clinical Practice" in the European Community and the principles of the Declaration of Helsinki.

Disclosures

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