

# Psychometric Properties of the Spanish Version of Breast Cancer and Lymphedema Symptom Experience Index.

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## Research Article

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# Abstract

**Aim:** to translate and evaluate psychometric properties of the BCLE SEI Spanish version among Spanish-speaking breast cancer patients in Spain.

**Methods:** cross-sectional, known-group comparison, and test-retest study design. To ensure the semantic equivalence and content validity, an integrative translation method was employed to translate the English version into Spanish. 286 patients were recruited, from 2018 to 2020, from the Asturias Central University Hospital, Spain. Data analysis included descriptive statistics, Cronbach's alpha and test-retest reliability, and factor analysis, and the receiver operating characteristic (ROC) curves.

**Results:** No semantic modifications to items were needed. The Spanish version of the instrument demonstrated excellent reliability (Cronbach's alpha= 0.93–0.97) and test-retest reliability ( $r = 0.78 - 0.87$ ,  $n = 29$ ). A significant difference was observed between the lymphedema group and non-lymphedema group ( $p < 0.001$ ) in terms of total scale, symptom occurrence ( $p < 0.001$ ), symptom distress of physical-functional ( $p < 0.001$ ), and psychosocial dimension ( $p < 0.001$ ). Factor analysis for symptom occurrence revealed a unidimensional factor and two factors were identified in symptom distress factor, which explained 45.71% and 54.77% of the total sample variance, respectively.

**Conclusions:** This study provided initial evidence to support the psychometric properties and patient acceptance of the BCLE SEI Spanish version.

## Summary Statement

What is already known about this topic?

- The likelihood of developing lymphedema for breast cancer patients is lifelong and its incurability causes tremendous physical and psychological impairments to patients treated for breast cancer.
- A variety of symptoms occur due to abnormal lymph fluid accumulation or lymphedema and these symptoms negatively impact patients' quality of life.
- The original English version of the Breast Cancer and Lymphedema Symptom Experience Index (BCLE-SEI) is a reliable and valid instrument developed in the USA to assess multiple lymphedema symptoms and distress for populations who speak English in the USA; the Chinese version is also reliable and valid for populations who speak Chinese.
- Lymphedema symptoms are cardinal signs of early stage lymphedema as they often precede changes in limb size or girth or a lymphedema diagnosis.
- Machine learning using lymphedema symptom occurrence by English version has been developed with over 90% of accuracy, sensitivity, and specificity to detect lymphedema.
- There is a need for a Spanish language instrument assessing lymphedema symptom occurrence and distress.

What this paper adds?

- The Spanish version demonstrated high internal consistency, test–retest reliability and content validity.
- Construct validity was supported by factor analysis and significant differences of symptom occurrence and distress scores between breast cancer patients with lymphedema and non-lymphedema.

- Evidence of patients' acceptance and the psychometric properties of the Spanish version supports its application in assessing lymphedema symptom occurrence and distress among Spanish-speaking patients.

The implications of this paper:

- It is important for health-care professionals to recognize the importance of systematically assessing lymphedema symptom occurrence and distress to ensure early detection and intervention of lymphedema.
- It should be noted the consistent findings from studies in the USA, China and Spain provided initial evidence for the universal attribute of lymphedema symptom occurrence and distress.
- It is feasible to use the Spanish version to establish machine learning algorithms in Spanish language to facilitate lymphedema detection among Spanish breast cancer patients.

## Introduction

Breast cancer is the most frequently diagnosed cancer among women worldwide (International Agency for Research on Cancer, 2020). One of the most common late and chronic adverse effects from breast cancer treatment is lymphedema defined as an accumulation of lymph fluid within the interstitial space that leads to the swelling of the affected limb or upper body (Nguyen, Hoskin, Habermann, Cheville, & Boughey, 2017; Ribeiro Pereira, Koifman, & Bergmann, 2017). The obstruction or disruption of lymphatic system associated with breast cancer treatment (e.g., removal of lymph nodes, radiation therapy) is the major cause of lymphedema (Asdourian et al. 2017; Fu, 2014; Gillespie et al. 2018; Nguyen et al., 2017). A variety of symptoms occur due to abnormal lymph fluid accumulation or lymphedema, including pain, swelling, heaviness, firmness, tightness, burning, stabbing, numbness, stiffness, tingling, numbness, or impaired limb mobility (Fu et al., 2015; Rupp et al., 2019) and these symptoms also negatively impact patients' QOL (Fu et al., 2013; Rupp et al., 2019) Lymphedema symptoms are patient-centered health outcomes as they reflect patient's experience in disease management and are critical markers for healthcare providers to make ongoing treatment and care decisions (Burns et al., 2020; Fu et al., 2015; Fu et al., 2016a; Washington et al., 2011).

The likelihood of developing lymphedema for breast cancer patients is lifelong and its incurability causes tremendous physical and psychological impairments to patients treated for breast cancer (Armer et al., 2019; Fu et al., 2013; Rupp et al., 2019). Lymphedema symptoms are cardinal signs of early stage lymphedema as they often precede changes in limb size or girth or a lymphedema diagnosis (Fu et al., 2015; Fu et al., 2016a). Therefore, to prevent lymphedema from its progression, it is important to promote patient self-care in terms of the awareness and identification of lymphedema symptoms (Arndt et al., 2019; Paramanandam, Lee, Kilbreath, & Dylke, 2021). The original English version of the Breast Cancer and Lymphedema Symptom Experience Index (BCLE-SEI), a two-part reliable, valid, and research-based instrument, has been used to assess lymphedema symptom occurrence and symptom distress (i.e., the negative impact and suffering evoked by an individual's experience of symptoms related to lymph fluid accumulation or lymphedema) (Fu et al., 2015; Fu et al., 2016b; Shi et al., 2017). The BCLE-SEI has also been used in machine learning for lymphedema diagnosis (Fu et al., 2018) and clinical trials (Fu et al., 2021; Liu et al., 2021). Its validity, internal consistency, and ability to differentiate between breast cancer survivors with and without lymphedema based on the presence of symptoms have been demonstrated in English (Fu et al., 2015; Fu et al., 2016b), as well as in a Chinese adaptation (Shi et al., 2017). Given that no tools sharing similar characteristics of the BCLE-SEI in Spanish, this cross-culture/cross-nation study was designed to provide an accurate and effective instrument for measuring lymphedema symptoms and distress among Spanish breast

cancer survivors. The purpose of the study was to adapt the BCLE-SEI to the Spanish language (BCLE-SEI-Es) and to assess its psychometric properties in Spanish-speaking women diagnosed with breast cancer.

The study was designed to answer the following research questions and test the research hypotheses. Research questions included: (1) Is the Spanish version acceptable to the Spanish breast cancer patients? (2) Is the Spanish version able to collect adequate data regarding lymphedema symptom occurrence and symptom distress among Spanish breast cancer patients? (3) Is the Spanish version able to differentiate breast cancer patients with lymphedema defined as having a medical diagnosis of lymphedema from those with non-lymphedema defined as having no medical diagnosis of lymphedema? The study hypotheses were: (1) Breast cancer patients with a diagnosis of lymphedema would report significantly more symptoms and severer symptom distress in comparison with patients without a diagnosis of lymphedema; (2) It's possible to establish a cut-off point for count of symptom occurrence to discriminate patients with lymphedema from those with non-lymphedema.

## **Methods**

### **Study Design**

A cross-sectional, known-group comparison, and test-retest study design was used to evaluate the psychometric properties of the Spanish version of BCLE-SEI.

### **Participants and Settings**

#### **Translation and content validity**

We used an integrative translation method that has been used successfully in previous cross-culture/cross country research studies (Ryu et al., 2013; Li, Fu, Zhao, & Chen, 2016; Shi et al., 2017). This method is based on the back translation and cross translation process in which content validity is ensured by the experts' consensus. The following steps were accomplished to ensure translation and content validity: (a) two bilingual experts translated the original instruments (BCLE-SEI) from English into Spanish language independently, then the Spanish language version was achieved through comparison of the two independently-translated versions; (b) two bilingual native Spanish-speaking experts translated the Spanish version into English to ensure that the Spanish version had the same implications as the English version; (c) two bilingual native Spanish-speaking healthcare experts compared the original English version with the Spanish version to assure that each item has the same implication as the English version and each item is culturally relevant; (d) finally, the 6 experts who were involved in the translation process resolved any discrepancies through discussion and revision until an unanimous agreement was achieved on each translated item and a consensus was reached that the Spanish version was consistent semantically with English version. In addition, no major revisions were needed for the Spanish version based on patients' feedback of the in the study. This translation method was used successfully in a cross-culture/cross-nation study that tested the psychometric properties of the Chinese version of the BCLE-SEI (Shi et al., 2017).

### **Variables and Measures**

*Sociodemographic and medical data.* We used a structured self-report and data collection tool (Fu et al., 2016b; Shi et al., 2017) to collect sociodemographic and medical information. The sociodemographic data included age, level of education, employment status, marital status. Medical data included breast cancer and lymphedema diagnosis,

stage of diseases, cancer and lymphedema location, receipt of types of surgery, receipt of chemotherapy and radiotherapy.

*Status of Breast Cancer-Related Lymphedema (BCRL)*. Two criteria were used to define breast cancer-related lymphedema: (a) Patients self-reported of being diagnosed with and treated for lymphedema; (b) medical record review to confirm that patients had an existing medical diagnosis of and treatment for lymphedema following breast cancer treatment.

*The Spanish Version of The Breast Cancer and Lymphedema Symptoms Experience Index (BCLE-SEI-Es)*. The Spanish version of BCLE-SEI-Es is a two-part, 5-point, Likert-type self-report instrument. Like the English version, Part I assesses lymphedema symptoms, including impaired limb mobility, arm swelling, breast swelling, chest wall swelling, heaviness, firmness, tightness, stiffness, numbness, tenderness, pain/aching/soreness, stiffness, redness, cording, burning, stabbing, and tingling (pain and needles). Each item is rated on a Likert-type scale from 0 (no presence of a given symptom) to 4 (greatest severity of a given symptom). Total symptom occurrence score is the summation of each symptom occurrence item score. Higher scores indicate more severe symptom occurrence.

Part II of the instrument assesses the symptom distress, that is, the negative impact and suffering evoked by an individual's experience of lymphedema symptoms. Total symptom distress score is the summation of each symptom distress item. A higher score reflects more severe symptom distress. Symptom distress is conceptually defined into 6 dimensions: activities of daily living, social interaction, sleep disturbance, sexuality, emotional & psychological, and self-perception. The symptom occurrence score and symptom distress score were added together to make a total score of symptom experience.

## **Study Procedures and Data collection**

Researchers were trained for data collection. After obtaining the approval of the study, study invitations were distributed to breast cancer patients by the physicians and nurses who worked at breast clinic at the Asturias Central University Hospital. If any potential patients expressed their interest in the study and met the eligibility for the study, researchers would meet the potential participants in person to further explain the study in details, including the information concerning the BCLE-SEI-Es questionnaire, the need for a Spanish version and the researchers' contact information for the study, procedures and ethical implications. All participants received the information about their rights to withdraw at any time without any changes in their care. The potential participants were provided enough time to read the consent form, and any questions about the study and consent were answered by the researchers. All the participants signed the written consent form to the study.

During a face-to-face research visit, participants completed the self-report Instruments (i.e., demographic information, BCLE-SEI-Es) using a touch-screen electronic tablet specific for the study. Data regarding patients' medical information was verified through reviewing from electronic medical records. The test-retest reliability assessment was conducted with 29 randomly selected participants. A time lapse of two weeks after the first administration was used to administer the retest. Given the dynamic attributes of the symptom experience for breast cancer survivors (16). The time lapse of two weeks was appropriate to avoid events exerting influence on participants' symptom experience and preventing participants from recalling their previous response.

## **Statistical Analysis**

Data were analysed using IBM's SPSS (version 24) software and Factor (version 10.10.02). The significance level was set at 0.05 with 95% confidence interval (95% CI) for all statistical estimates. Descriptive statistics were computed to summarize the demographic and medical characteristics of the participants. Cronbach's alpha was calculated to evaluate the internal consistency and reliability of the total scale and each subscale of the BCLE-SEI-Es. Kolmogorov-Smirnov test was performed to evaluate the normality distribution of the total scale and subscale scores. Due to the non-normal distribution of the data, nonparametric methods (Mann Whitney test) were used. Effect sizes were calculated via Cohen's *d* (Lenhard & Lenhard). Data from 29 participants were used to evaluate the test-retest reliability at two-week interval using Spearman's correlation coefficient (*r<sub>s</sub>*).

A robust principal component extraction analysis (PCA) was performed using a Pearson correlation matrix and a promax rotation to examine the construct of the BCLE-SEI-Es. Suitability of PCA analysis was evaluated using the Kaiser-Meyer-Olkin (KMO) test for model validity with an acceptable value greater than 0.5 and Bartlett's test of sphericity for determining whether the correlation matrix was an identity matrix ( $\alpha < 0.05$ ). Factor loading that exceeded the criterion of 0.40 were considered as significant. Goodness of fit of models was evaluated using percentage of variance explained and the RMSR indicator, where values below 0.08 are considered good, although values lower than 0.1 are also acceptable (Kline, 2012; Hoyle, 2011). Correlations between principal components were calculated using Spearman's  $\rho$ .

The discriminant validity of the scale was obtained by nonparametric tests between breast cancer patients with lymphedema and non-lymphedema. A receiver operating characteristic curve (ROC) was calculated to establish the cut-off point for lymphedema detection using the diagnosis of lymphedema as the standard criterion. The score of the symptom occurrence subscale was used to calculate sensitivity and specificity. Sensitivity represents the rate of true positive cases, while specificity represents true negative cases. The area under the curve (AUC) was calculated with a 95% CI. An AUC of 1.0 represents perfect sensitivity and specificity, while an AUC of 0.5 represents a test with weak sensitivity and specificity (Smoot, Wong, & Dodd, 2011). The best possible cut-off point was chosen according to the Youden index, which ranges from 0 to 1 (Youden, 1950). Higher values of the Youden index indicate a more powerful cut-off point, that is, a more optimal sum of sensitivity and specificity (Youden, 1950).

## **Ethical Considerations**

The study was approved by the Principality of Asturias Research Ethics Committee, Spain (ref. 190/18). All the women who participated in the study did so voluntarily, signed an informed consent form, and were informed about the study objectives.

# **Results**

## **Participants' Characteristics**

A total of 286 women, with a mean age of 56.97 years ( $SD=8.92$ ), participated in the study. Among the 286 patients, 23.4% ( $n=67$ ) were diagnosed with lymphedema. In terms of clinical characteristics, compared with patients with non-lymphedema, significantly more patients with lymphedema underwent mastectomy (75.8% versus 56.7%,  $p=0.005$ ) radiotherapy (83.1% versus 68.1%,  $p=0.19$ ), and Chemotherapy (83.3% versus 51.6%,  $p<0.001$ ). Compared with patients with non-lymphedema, significantly fewer patients with lymphedema were working currently (31.3% versus 54.6%;  $p=0.001$ ). Table 1 presents more detailed information of the sample.

## **Reliability**

Cronbach's alpha was 0.97 for the total scale and 0.95 for symptom occurrence and

0.94 for symptom distress, indicating high internal consistency. Using Spearman's correlation coefficient test, test-retest reliability was examined by comparing the total scale and the subscales of symptom occurrence and symptom distress from a second test of 29 participants, which yielded  $r_s = 0.78 - 0.87$  (Table 2).

## **Validity**

### *Content validity*

The integrative translation method was utilized to ensure the accuracy of the translation. The 6 experts who were involved in the translation process unanimously agreed that each translated item and the Spanish version was consistent semantically with the English version.

### *Construct validity*

The suitability of the data for a principal components' extraction analysis was confirmed using the KMO test for sampling adequacy ( $KMO=0.93$ ) and Bartlett's test of sphericity (Approx. Chi-Square = 3049.0,  $df = 1653$ ,  $p < 0.001$ ). As the concepts of symptom occurrence and symptom distress measured by the BCLE-SEI denote different conceptual connotations, the exploratory factor analyses to determine their construct validity were conducted separately. A good fit to a unidimensional structure was observed in symptom occurrence, with an eigenvalue greater than 1.0, RMSR below 0.1 ( $RMSR=0.0881$ ) and 45.71% of the variance explained. Factor loadings ranged from 0.37 to 0.79. Table 3 presents the factor loadings for symptom occurrence.

A good fit to a two-dimensional structure was observed in symptom distress, with eigenvalues greater than 1.0, RMSR below 0.08 ( $RMSR=0.0533$ ) and 54.77% of the variance explained. The correlation between the factors was 0.68. Table 4 shows the factor loadings of dimensions: physical-functional distress (factor 1) and psychosocial distress (factor 2). Correlations between principal components are shown in Table 5. All correlations are positive, with moderate values, the weakest being the correlation between the psychosocial factor and the symptom occurrence factor ( $r_s=0.49$ ).

### *Discriminant validity*

To evaluate the discriminant validity of BCLE-SEI-Es, the participants were divided into 2 groups by lymphedema status, that is patients with a diagnosis of lymphedema (lymphedema group) and those without lymphedema diagnosis (non-lymphedema group) to compare the total scale between the two groups as well as symptom occurrence, symptom distress of physical-functional and psychosocial. Significant differences between lymphedema and non-lymphedema group were observed for total BCLE-SEI-Es scale ( $z = 5.651$ ,  $p < 0.001$ ), symptom occurrence ( $z = 7.002$ ,  $p < 0.001$ ), physical-functional distress ( $z = 4.580$ ,  $p < 0.001$ ), and psychosocial distress ( $z = 3.638$ ,  $p < 0.001$ ). Moderate effect sizes were observed for physical-functional distress (Cohen's  $d = 0.56$ ), psychosocial distress (Cohen's  $d = 0.3638$ ), total BCLE-SEI-Es scale (Cohen's  $d = 0.5651$ ), while large effect size was observed for symptom occurrence subscale (Cohen's  $d = 0.90$ ). Table 6 displays the results of the Mann-Whitney U-test, along with the medians and interquartile ranges for each group, as well as the effect sizes of the analyses performed.

Analysis of the ROC curve for the count of lymphedema symptom occurrence as a continuous screening variable for discriminating between the lymphedema patients and the non-lymphedema patients yielded an AUC of 0.78

(AUC= 0.78;  $p < 0.001$ ; 95% CI: 0.72 - 0.84). To discriminate lymphedema patients from non-lymphedema, the best screening cut-off point was six symptom occurrences (Youden's index= 0.45), with a sensitivity of 0.86 (95% CI: 0.76 - 0.93) and a specificity of 0.58 (95% CI: 0.51 - 0.65).

## Discussion

As a self-report instrument, the Spanish BCLE-SEI (BCLE-SEI-Es) was acceptable to Spanish breast cancer patients and was able to elicit patients' report of lymphedema symptoms and distress. The results of the study demonstrated that the Spanish version (BCLE-SEI-Es) is a valid and reliable tool to assessment lymphedema symptom occurrence and symptom distress for the Spanish breast cancer patients with lymphedema and non-lymphedema. Findings of the study supported our hypothesis that symptom occurrence and symptom distress for patients with lymphedema were significantly higher than patients with non-lymphedema, supporting the discriminant validity of the BCLE-SEI-Es. The ability of BCLE-SEI-Es to discriminate breast cancer patients with lymphedema and non-lymphedema provides strong foundation for clinical use of this instrument among Spanish breast cancer patients.

Lymphedema symptoms are patient-centered health outcomes that are critical for monitoring the risk of and treating cancer-related lymphedema as well as patients' quality of survival. The likelihood of developing lymphedema for breast cancer patients is lifelong (Armer et al., 2019; Rupp et al., 2019) and its incurability causes tremendous physical (Viehoff et al., 2015) and psychological impairment to the women who suffer from it (Rupp et al., 2019; Sayegh et al., 2016). Early detection and intervention of subclinical lymphedema (i.e., defined as the presence of lymphedema symptoms without changes in limb size or girth or having a lymphedema diagnosis) prevents lymphedema from progressing into chronic and incurable condition as well as improves lymphedema treatment efficacy (Soran et al., 2014; Temur & Kapucu, 2019). Bowman et al. (2021) reported that breast cancer patients sometimes had to visit multiple specialists about their lymphedema symptoms without receiving an official diagnosis of lymphedema, leading to the to a delayed diagnosis and treatment. A study in the USA using the English version of BCLE-SEI found a diagnostic cutoff of nine symptoms discriminated breast cancer patients with lymphedema from those with non-lymphedema with a sensitivity of 64% and a specificity of 80% (area under the curve =0.72) (Fu et al., 2015). Findings of our study also support the evidence that self-report of lymphedema symptoms has the ability to discriminate breast cancer patients with lymphedema from those with non-lymphedema with sensitivity of 86%and specificity of 58% (area under the curve = 0.78) among Spanish breast cancer patients. These findings supported our hypothesis that symptom occurrence assessed by Spanish version of the BCLE-SEI was able to establish a cut-off point to detect patients with lymphedema. In the absence of objective measurements capable of detecting subclinical lymphedema, count of symptom occurrence may be a cost-effective initial screening tool for detecting lymphedema. Furthermore, machine learning using lymphedema symptom occurrence by English version BCLE-SEI has been developed with over 90% of accuracy, sensitivity, and specificity to detect subclinical (mild), moderate, and severe lymphedema (Fu et al., 2018). With the validation of Spanish version, it is possible to program machine learning algorithms in Spanish language to facilitate lymphedema detection among Spanish breast cancer patients.

Like the English version, Part I of the Spanish version BCLE-SEI-Es assesses symptom occurrence. The English version of BCLE-SEI conceptualizes lymphedema symptoms to have a single conceptual structure, that is, all the symptoms are related to lymph fluid accumulation. In our study, the principal components extraction analysis showed that the data fitted correctly to a unidimensional structure, which explained 45.71% of the variance. In contrast, the study on the Chinese version BCLE-SEI identified five factors of symptom occurrence that explained

66.1% of the total sample variance (Shi et al, 2017). The differences in factor analysis may due to differences in presence of each symptom occurrence among Chinese and Spanish breast cancer patients. Nevertheless, symptom occurrence assessed by both Spanish and Chinese version achieved adequate discriminating power to differentiate patients with lymphedema and those with non-lymphedema,

Findings of our study show that two dimensions of symptom distress were identified using the principal components extraction analysis; the two symptom distress factors explained 54.77% of the total sample variance. The English version of BCLE-SEI conceptually defines symptom distress as 6 dimensions: physical function of activities of daily living, social interaction, sleep disturbance, sexuality, emotional/psychological, and self-perception. Using exploratory factor analysis, the Chinese version identified five symptom distress factors (Shi et al, 2017). The items in first symptom distress factor identified in our study are consistent with the items in conceptually defined physical-functional dimension of activities of daily living in the English version with addition of leisure activities and sleep disturbance and those in the Chinese version. The item of leisure activities was conceptualized in the English version and factor analysis in Chinese version as social dimension. Perhaps, leisure activities in Spanish breast cancer patients reflect the needs for physical-functional ability to enjoy leisure activities. Sleep disturbance was loaded in physical-functional dimension in our study. This loading can be explained by the fact that the presence of lymphedema symptoms can contribute to sleep disorder (Roux et al., 2020). The items in the second symptom distress factor identified in our study included all the items in conceptually defined dimensions of social interaction, sleep disturbance, sexuality, emotional/psychological, and self-perception. Psychosocial symptom distress factors identified in Chinese version were similar as conceptualized in English version to include emotional-psychological, social interaction, and sexuality. The six conceptualized dimensions of symptom distress can be broadly categorised as physical-functional distress (i.e., negative impact on activities of daily living) and psychosocial distress (i.e., negative impact on emotional/psychological, self-perception, social interaction, sleep disturbance, and sexuality). Symptom distress reflect limitations and negative impact evoked by symptom occurrence, perhaps, it is parsimonious to categorize symptom distress into physical-functional and psychosocial dimensions.

### **Strengths and limitations of the study**

Strengths of the study included adequate study design with hypothesis testing. Participant recruitment from only hospital could restrict generalizability of this study. Although the data was adequate for factor analysis, supported by Bartlett test and the KMO, further studies using larger samples from different hospitals in Spain are warranted to ensure that regional factors are considered in testing the Spanish version.

## **Conclusion**

Breast cancer patients face life-time challenge of developing lymphedema. Monitoring lymphedema symptoms is essential in early detecting and early intervention to ensure lymphedema can be effectively prevented and controlled. The Spanish version demonstrated high internal consistency, test–retest reliability and content and construct validity. Patients' acceptance of the Spanish version and its ability to collect adequate data among Spanish population provided evidence for using this version among Spanish-speaking patients to help to systematically report lymphedema symptoms and distress. Lymphedema and lymphedema symptoms are still under-recognized and underassessed in clinical practice in Spain, the Spanish version of BCLE-SEI-Es can be used as a screening tool in the clinical settings to encourage symptom reporting and to ensure communication between patients and healthcare professionals so that timely interventions can be provided.

# Declarations

## Acknowledgements

The authors are grateful to all the women who participated in the study.

## Authorship contribution

**JCR:** Methodology, Writing-original draft, Formal analysis, Data curation, Data collection, Data analysis, Writing-review & editing. **AMA:** Formal analysis, Data curation, Writing- review & editing. **MMFA:** Conceptualization, Methodology, Writing-original draft, Writing- review & editing. **ALIF:** Methodology, Data collection. **MF:** Conceptualization, Methodology, Writing- review & editing. **RMP:** Conceptualization, Methodology, Writing-original draft, Resources, Writing- review & editing

## Availability of data and material

Data can be shared with other researchers upon justified request.

## Conflict of Interest

The authors declare that they have no conflict of interest.

## Funding

This research received no external funding.

## Ethical consideration and consent process

The study was approved by the Principality of Asturias Research Ethics Committee, Spain (ref. 190/18). The research was performed in accordance with relevant guidelines and regulations, specifically each participant was informed of their voluntary participation and confidentiality. All the participants in the study signed the written informed consent form.

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## Tables

**Table 1.** Sociodemographic and clinical characteristics (n=286).

| Variables                      | TOTAL                | Lymphedema<br>(n=67) | Non-<br>Lymphedema<br>(n=219) | Test Statistics   |                 |                          |
|--------------------------------|----------------------|----------------------|-------------------------------|-------------------|-----------------|--------------------------|
| <b>Continuous Variables</b>    | Mean SD <sup>1</sup> | MeanSD               | MeanSD                        | t                 | df <sup>1</sup> | p (t-<br>test)           |
| <b>Age</b>                     | 56.97<br>(8.92)      | 58.81(9.21)          | 56.41(8.78)                   | -1.932            | 284             | .054                     |
| <b>Categorical Variables</b>   | n (%)                | n (%)                | n (%)                         | <b>Pearson c2</b> | <b>df</b>       | <b>P (c<sup>2</sup>)</b> |
| <b>Level of education</b>      |                      |                      |                               | 5.938             | 3               | 0.115                    |
| Elementary School              | 49 (17.2%)           | 17 (25.4%)           | 32 (14.7%)                    |                   |                 |                          |
| Middle School                  | 71 (24.9%)           | 19 (28.4 %)          | 52 (23.9%)                    |                   |                 |                          |
| High Degree                    | 130 (45.6<br>%)      | 25 (37.3%)           | 105 (48.2%)                   |                   |                 |                          |
| Bachelor's Degree              |                      | 6 (9%)               | 29 (13.3%)                    |                   |                 |                          |
| Vocational training            | 35 (12.3<br>%)       |                      |                               |                   |                 |                          |
| <b>Marital status</b>          |                      |                      |                               |                   | 2               | 0.492                    |
| Married/In relationship        | 179<br>(62.8%)       | 37 (55.2%)           | 142 (65.1%)                   | 2.409             |                 |                          |
| Single                         | 42 (14.7%)           | 12 (17.9%)           | 30 (13.8%)                    |                   |                 |                          |
| Separated/divorced             | 35<br>(12.3%)        | 9 (13.4%)            | 26 (11.9%)                    |                   |                 |                          |
| Widowed                        | 29<br>(10.2%)        | 9 (13.4%)            | 20 (9.2%)                     |                   |                 |                          |
| <b>Currently working</b>       |                      |                      |                               | 11.079            | 1               | 0.001                    |
| Yes                            | 140<br>(49.1%)       | 21 (31.3%)           | 119 (54.6%)                   |                   |                 |                          |
| No                             | 145<br>(50.9%)       | 46 (68.7%)           | 99 (45.4%)                    |                   |                 |                          |
| <b>Types of Surgery</b>        |                      |                      |                               | 7.710             | 1               |                          |
| Mastectomy                     | 169<br>(61.2%)       | 50 (75.8%)           | 119 (56.7%)                   |                   |                 | 0.005                    |
| Breast-conserving surgery      | 107<br>(38.8%)       | 16 (24.2%)           | 91 (43.3%)                    |                   |                 |                          |
| <b>Receipt of Radiotherapy</b> | 201<br>(71.5%)       | 54 (83.1%)           | 147 (68.1%)                   | 5.536             | 1               | 0.019                    |
| Yes                            |                      |                      |                               |                   |                 |                          |
| No                             |                      |                      |                               |                   |                 |                          |
| <b>Receipt of Chemotherapy</b> | 166<br>(59.1%)       | 55 (83.3%)           | 111 (51.6%)                   | 20.997            | 1               | <0.001                   |
| Yes                            |                      |                      |                               |                   |                 |                          |
| No                             |                      |                      |                               |                   |                 |                          |

<sup>1</sup> SD: Standard Deviation; df: degree of freedom

|   | Test #1                    |        | Test #2         |        | Spearman's rho |
|---|----------------------------|--------|-----------------|--------|----------------|
|   | Mean $\pm$ SD <sup>1</sup> | Median | Mean $\pm$ SD   | Median |                |
| Symptom occurrence                              | 12.2 $\pm$ 12.8            | 12     | 10.3 $\pm$ 12.8 | 8      | 0.78           |
| Symptom distress                                | 18.9 $\pm$ 23.3            | 10     | 16.7 $\pm$ 20.1 | 8      | 0.83           |
| Total Scores of Symptom Occurrence and Distress | 31.1 $\pm$ 32.9            | 23     | 27.0 $\pm$ 31.1 | 19     | 0.87           |

<sup>1</sup> SD: Standard Deviation

**Table 3.** Factor loadings for symptom occurrence (n=286).

| Items   | Factor Loading |
|---|----------------|
| 1. Pain/aching/soreness   | 0.73           |
| 2. Tenderness   | 0.70           |
| 3. Arm/hand swelling  | 0.70           |
| 4. Breast swelling  | 0.37           |
| 5. Chest wall swelling  | 0.43           |
| 6. Firmness in the affected limb  | 0.78           |
| 7. Tightness in the affected limb   | 0.72           |
| 8. Heaviness in the affected limb   | 0.79           |
| 9. Fibrosis (thickness of the skin) in the affected limb  | 0.66           |
| 10. Stiffness in the affected limb  | 0.68           |
| 11. Hotness in the affected limb  | 0.78           |
| 12. Redness in the affected limb  | 0.65           |
| 13. Burning sensation in the affected limb  | 0.78           |
| 14. Numbness in the affected limb   | 0.63           |
| 15. Stabbing in the affected limb   | 0.642          |
| 16. Tingling in the affected limb   | 0.78           |
| 17. Weakness in the affected limb   | 0.78           |
| 18. Seroma (pocket of fluid)  | 0.59           |
| 19. Cording (Palpable and even observable, that go from the armpit, down the inside of the arm, accompanied by axillary pain and limitation of shoulder movement) | 0.67           |
| 20. Limited movement in shoulder  | 0.55           |
| 21. Limited movement in elbow   | 0.68           |
| 22. Limited movement in wrist   | 0.75           |
| 23. Limited movement in arm   | 0.70           |
| 24. Limited movement in fingers   | 0.72           |

**Table 4.** Factor loadings symptom distress (n=286).

| Items                                 | Factor 1                     | Factor 2              |
|---------------------------------------|------------------------------|-----------------------|
|                                       | Physical-Functional Distress | Psychosocial Distress |
| 1. Cooking                            | 0.83                         |                       |
| 2. Cutting food with a knife          | 0.84                         |                       |
| 3. Writing/typing                     | 0.88                         |                       |
| 4. Cleaning the house                 | 0.71                         |                       |
| 5. Vacuuming                          | 0.73                         |                       |
| 6. Doing the laundry                  | 0.90                         |                       |
| 7. Bathing or showering               | 0.93                         |                       |
| 8. Taking care of children            | 0.67                         |                       |
| 9. Carrying and lifting heavy objects | 0.44                         |                       |
| 10. Gardening                         | 0.54                         |                       |
| 11. Getting dressed                   | 0.91                         |                       |
| 12. Driving                           | 0.58                         |                       |
| 13. Making bed                        | 0.92                         |                       |
| 14. Family activities                 |                              | 0.51                  |
| 15. Leisure activities                | 0.41                         |                       |
| 16. Frustration                       |                              | 0.80                  |
| 17. Sadness                           |                              | 0.97                  |
| 18. Guilt                             |                              | 0.36                  |
| 19. Concern                           |                              | 0.85                  |
| 20. Irritability                      |                              | 0.76                  |
| 21. Fear                              |                              | 0.81                  |
| 22. Anger                             |                              | 0.57                  |
| 23. Loneliness                        |                              | 0.90                  |
| 24. Dependency                        |                              | 0.55                  |
| 25. Hopelessness                      |                              | 0.83                  |
| 26. Anxiety                           |                              | 0.90                  |
| 27. Depression                        |                              | 0.88                  |
| 28. Self-perception                   |                              | 0.68                  |
| 29. Sleep disturbance                 | 0.31                         |                       |
| 30. Sex life with partner             |                              | 0.54                  |

|   |      |
|---|------|
| 31. Emotional relationship with partner | 0.53 |
| 32. Impact on work outside home         | 0.43 |

**Table 5.** Spearman’s rho between principal components (n=286).

|                              | Physical-functional | Psychosocial | Total Scores of Symptom Occurrence and Distress |
|------------------------------|---------------------|--------------|---|
| Symptom Occurrence           | 0.63                | 0.49         | 0.77  |
| Physical-functional Distress |                     | 0.69         | 0.88  |
| Psychosocial Distress        |                     |              | 0.87  |

**Table 6.** Mann-Whitney *U*-test results, medians, interquartile ranges (IQR), and Cohen’s *d* (n=286).

|                              | z     | p Value | Cohen’s <i>d</i> | Median         |            | IQR            |            |
|------------------------------|-------|---------|------------------|----------------|------------|----------------|------------|
|                              |       |         |                  | Non-lymphedema | Lymphedema | Non-lymphedema | Lymphedema |
| Symptom Occurrence           | 7.002 | <0.001  | 0.90             | 4              | 13         | 1-11           | 3-19       |
| Physical-functional Distress | 4.580 | <0.001  | 0.56             | 3              | 9          | 0-9            | 5-27       |
| Psychosocial Distress        | 3.638 | <0.001  | 0.44             | 7              | 17         | 2-16           | 7-26       |
| Total BCLE-SEI-Es            | 5.651 | <0.001  | 0.71             | 17             | 43         | 7-33           | 19-71      |

Note. IQR: Interquartile range