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Article

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

Judit Cachero-Rodríguez[1], Álvaro Menéndez-Aller[2], Mei R Fu[3], Ana Llaneza-Folgueras[4], María del Mar Fernández-Alvarez[1,2], and Rubén Martín-Payo[1,2]

[1] Equipo de Investigación PRECAM, [2] Universidad de Oviedo/ISPA, [3] Rutgers, The State University of New Jersey, and [4] Hospital Universitario Central de Asturias

Abstract

Background: Lymphedema is a common late and chronic adverse effect of breast cancer treatment. This study aimed to translate and evaluate the psychometric properties of the BCLE-SEI Spanish version with Spanish-speaking breast cancer patients. **Method:** 286 patients were recruited (2018 to 2020), from the Hospital Universitario Central de Asturias. Data analysis included descriptive statistics; internal consistency and test-retest reliability; principal component analysis and exploratory factor analysis; average variance extracted; and receiver operating characteristic curves. **Results:** No semantic modifications to items were needed. The scores of the instrument demonstrated excellent internal consistency (Cronbach's alpha = .95-.97; McDonald's omega = .96-.98) and test-retest reliability (r = .78-.87, n = 29). A significant difference was observed between the lymphedema group and non-lymphedema group ($p < .001$) in terms of total scale, symptom occurrence ($p < .001$), symptom distress in the physical-functional ($p < .001$), and psychosocial dimension ($p < .001$). Principal component analysis for symptom occurrence revealed a unidimensional factor and two factors were identified for symptom distress via exploratory factor analysis, the two of which explained 45.71% and 54.77% of the total sample variance, respectively. **Conclusions:** This study provided initial evidence to support the psychometric properties of the BCLE-SEI Spanish version.

Keywords: Breast cancer, lymphoedema, quality of life, reliability, validity.

Resumen

Propiedades Psicométricas de la Versión Española del Breast Cancer and Lymphedema Symptom Experience Index. **Antecedentes:** el linfedema es una complicación tras el cáncer de mama. El objetivo fue evaluar las propiedades psicométricas de la versión española BCLE-SEI en mujeres diagnosticadas de cáncer de mama que hablaban español. **Método:** participaron 286 pacientes (2018 a 2020) del Hospital Universitario Central de Asturias. El análisis de datos incluyó estadísticos descriptivos; consistencia interna y fiabilidad test-retest, análisis de componentes principales y análisis factorial exploratorio; varianza media extraída; y curvas de características operativas del receptor. **Resultados:** no se necesitaron modificaciones semánticas en los ítems. El instrumento demostró excelente consistencia interna (alfa de Cronbach = 0,95-0,97; omega de McDonald = .96-.98) y fiabilidad test-retest (r = 0,78-0,87; n = 29). Se observaron diferencias significativas entre grupos linfedema y sin linfedema ($p < .001$) en las escalas total, de síntomas ($p < .001$), físico-funcional ($p < .001$) y psicosocial ($p < .001$). El análisis de componentes principales para la "aparición de síntomas" reveló un factor unidimensional y se identificaron dos factores para la "angustia por síntomas" a través del análisis factorial exploratorio, explicando el 45,71% y el 54,77% de la varianza total de la muestra, respectivamente. **Conclusiones:** la versión española de BCLE-SEI mostró adecuadas propiedades psicométricas.

Palabras clave: cáncer de mama, linfedema, calidad de vida, fiabilidad, validez.

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 of breast cancer treatment is lymphedema (Nguyen et al., 2017; Ribeiro Pereira et al., 2017). The obstruction or disruption of the 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 (Chaput et al., 2020; Fu et al., 2015; Rupp et al., 2019) and these symptoms also negatively impact patients' quality of life (Fu et al., 2013; Rupp et al., 2019) Lymphedema symptoms are patient-centred health outcomes as they reflect the 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, Conley et al., 2016; 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

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Corresponding author: María del Mar Fernández-Alvarez
Equipo de Investigación PRECAM
Universidad de Oviedo
33006 Oviedo (Spain)
e-mail: fernandezmar@uniovi.es

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, Conley et al., 2016). Therefore, to prevent the progression of lymphedema, it is important to promote patient self-care in terms of the awareness and identification of lymphedema symptoms (Arndt et al., 2019; Paramanandam et al., 2021). The original English version of the Breast Cancer and Lymphedema Symptom Experience Index (BCLE-SEI) a two-part, research-based instrument, has been used to assess lymphedema symptom occurrence and symptom distress (Fu et al., 2007; Fu et al., 2015; Fu, Axelrod et al., 2016; Shi et al., 2016). The original version demonstrated reasonable internal consistency (Cronbach's alpha ≥ 0.84) and reliability (r ≥ 0.92) (Fu et al., 2007). 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 evidence of validity, the internal consistency of the scores, and the 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, Axelrod et al., 2016), as well as in a Chinese adaptation (Shi et al., 2016).

Our assumption is that breast cancer survivors with a diagnosis of lymphedema would report significantly more symptoms and severer symptom distress in comparison with survivors without a diagnosis of lymphedema. Given that no other tools in Spanish share similar characteristics to the BCLE-SEI, 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 among Spanish-speaking women diagnosed with breast cancer.

Method

Participants

A purposive sampling was used to recruit breast cancer patients. The inclusion criteria of the study were: (a) had a diagnosis of stage I–III breast cancer; (b) had surgery for breast cancer and completed radiation and/or chemotherapy; (c) self-report of no cognitive impairments; (d) able to independently read and make decisions. The exclusion criteria were: presence of serious mental disorder; occurrence of tumor metastasis; lymphedema prior to breast cancer diagnosis. We recruited patients from the Hospital Universitario Central de Asturias (HUCA) in Oviedo, Spain. Data were collected between October 2018 and June 2020. Among the 286 women who consented to the study, 10% (n = 29) were randomly selected to complete a retest within a two-week interval.

Instruments

Sociodemographic and Medical Data. We used a structured self-report and data collection tool (Fu, Axelrod et al., 2016; Shi et al., 2016) to collect sociodemographic and medical information. The sociodemographic data included age, level of education, employment status, and marital status. Medical data included breast cancer and lymphedema diagnosis, stage of diseases, cancer and lymphedema location, receipt of types of surgery, and receipt of chemotherapy and radiotherapy.

Status of Breast Cancer-Related Lymphedema (BCRL). Two criteria were used to define breast cancer-related lymphedema: patients self-reporting of being diagnosed with and treated for lymphedema; 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. 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 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 and psychological, and self-perception. The symptom occurrence score and symptom distress score were added together to make a total score of symptom experience.

We used an integrative translation method that has been used successfully in previous cross-culture/cross country research studies (Ryu et al., 2013; Li et al., 2016; Shi et al., 2016). This method is based on the back translation and cross translation process in which evidence of content validity is ensured by the experts' consensus. The translation was as follows: two bilingual experts translated the original instruments from English into the Spanish language independently, then the Spanish language version was achieved through comparison of the two independently-translated versions; 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; 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; finally, the 6 experts who were involved in the translation process resolved any discrepancies through discussion and revision until a unanimous agreement was achieved on each translated item and a consensus was reached that the Spanish version was consistent semantically with the English version. In addition, no major revisions were needed for the Spanish version based on the patients' feedback during 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., 2016).

Procedure

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 the breast clinic at the HUCA. 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 detail, 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 for 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 the patients' medical information was verified by reviewing electronic medical records. The test-retest reliability of the scores was estimated using 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, 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.

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.

Data Analysis

Descriptive statistics were computed to summarize the demographic and medical characteristics of the participants. Cronbach's alpha and McDonald's omega was calculated to estimate the internal consistency of the scores for both the total scale and each subscale of the BCLE-SEI-Es. Kolmogorov-Smirnov test was performed to evaluate the normal 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, 2016). Data from 29 participants were used to estimate test-retest reliability at two-week interval using spearman's correlation coefficient (rs).

To study the dimensionality of symptom occurrence, a robust principal component analysis (PCA) was performed. Similarly, an exploratory factor analysis (EFA) was carried out to explore the factorial structure of symptom distress. This distinct approach to dimensionality is due to the different nature of both parts, as the first part deals with symptoms and, therefore, a reduction in information is favourable, while the second part refers to a latent variable akin to psychological distress.

In both analyses, a Pearson correlation matrix and a promin rotation were performed. Additionally, a robust least unweighted squares method was used for the EFA (Lloret-Segura et al., 2014). The number of factors in each instance was determined using an optimal implementation of Parallel Analysis (PA) (Calderón et al., 2019).

The suitability of each analysis was evaluated using the Kaiser-Meyer-Olkin (KMO) test with an acceptable value greater than 0.5 and Bartlett's test of sphericity for determining whether the correlation matrix was an identity matrix ($p < .05$). Factor loadings that exceeded the criterion of 0.30 were considered significant. The goodness of fit for the PCA was evaluated using the 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 (Hoyle, 2011). In the case of the EFA, the indices used were RMSEA (with values below .05) and CFI (with values higher than .95) as two different indices are considered enough to assess a good fit of the data (Kline, 2011). Correlation between factors was calculated using Spearman's rho.

Evidence of discriminant validity was obtained by nonparametric tests between breast cancer patients with lymphedema and non-lymphedema. The Average Mean Extraction (AVE) of each subscale was carried out following Fornell and Larcker (1981) method, with values higher than .05 acting as evidence of convergent validity between the scales. 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 et al., 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).

Data were analysed using IBM's SPSS (version 24) software and Factor (version 10.10.02). The significance level was set at .05 with 95% confidence interval (95% CI) for all statistical estimates.

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 = .005) radiotherapy (83.1% versus 68.1%, p = .190), and chemotherapy (83.3% versus 51.6%, $p < .001$). Compared with patients with non-lymphedema, significantly fewer patients with lymphedema were currently working (31.3% versus 54.6%; p = .001). Table 1 presents more detailed information of the sample.

Reliability

The internal consistency of the total scale (α = .97; ω = .98), as well as the symptom occurrence (α = .95; ω = .98) and symptom distress (α = .96; ω = .96) subscales was excellent. Using spearman's correlation coefficient test, test-retest reliability of the scores was estimated by comparing the total scale and the subscales of symptom occurrence and symptom distress from a second test of 29 participants, which yielded (rs (28) = .78 – .87, $p < .001$) (Table 2).

Table 1
Sociodemographic and Clinical Characteristics (N = 286)

Variables	Total	Lymphedema (n = 67)	Non-Lymphedema (n = 219)	Test statistics		
Continuous variables	**Mean ± SD[1]**	**Mean ± SD**	**Mean ± SD**	**t**	**df[2]**	**p (t test)**
Age	56.97 (8.92)	58.81(9.21)	56.41(8.78)	-1.932	284	.054
Categorical variables	**n (%)**	**n (%)**	**n (%)**	**Pearson χ^2**	**df**	**p (χ^2)**
Level of education						
Elementary school	49 (17.2%)	17 (25.4%)	32 (14.7%)			
Middle school	71 (24.9%)	19 (28.4 %)	52 (23.9%)	5.938	3	.115
High degree	130 (45.6 %)	25 (37.3%)	105 (48.2%)			
Bachelor's degree Vocational training	35 (12.3 %)	6 (9%)	29 (13.3%)			
Marital status						
Married/In relationship	179 (62.8%)	37 (55.2%)	142 (65.1%)			
Single	42 (14.7%)	12 (17.9%)	30 (13.8%)	2.409	2	.492
Separated/divorced	35 (12.3%)	9 (13.4%)	26 (11.9%)			
Widowed	29 (10.2%)	9 (13.4%)	20 (9.2%)			
Currently working						
Yes	140 (49.1%)	21 (31.3%)	119 (54.6%)	11.079	1	.001
No	145 (50.9%)	46 (68.7%)	99 (45.4%)			
Types of Surgery						
Mastectomy	169 (61.2%)	50 (75.8%)	119 (56.7%)	7.710	1	.005
Breast-conserving surgery	107 (38.8%)	16 (24.2%)	91 (43.3%)			
Receipt of radiotherapy						
Yes	201 (71.5%)	54 (83.1%)	147 (68.1%)	5.536	1	.019
No						
Receipt of chemotherapy						
Yes	166 (59.1%)	55 (83.3%)	111 (51.6%)	20.997	1	<.001
No						

Note: [1] *SD*: Standard Deviation; [2] df: degree of freedom

Table 2
BCLE-SEI-Es Test-Retest Reliability of the Scores (n = 29)

	Test #1		Test #2		
	Mean ± SD[1]	**Median**	**Mean ± SD**	**Median**	**Spearman's rho**
Symptom occurrence	12.2 ± 12.8	12	10.3 ± 12.8	8	.78**
Symptom distress	18.9 ± 23.3	10	16.7 ± 20.1	8	.83**
Total scores of symptom occurrence and distress	31.1 ± 32.9	23	27.0 ± 31.1	19	.87**

Note: [1] *SD*: Standard Deviation; ** = $p < .001$

Evidence of 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 both the PCA and the EFA 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, $p < .001$). PA recommended a unidimensional approach for symptom occurrence, while it advised a bidimensional factor structure for symptom distress.

The PCA indicated a good fit to a unidimensional structure, with 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.

Meanwhile, a good fit to a two-dimensional structure was observed in symptom distress, with a RMSEA below 0.05 (RMSEA = 0.013) and a CFI > .95 (CFI = .999), explaining 55.04% of the variance. Table 4 shows the factor loadings of dimensions: physical-functional distress (factor 1) and psychosocial distress (factor 2). Correlations between subscales 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 (rs (285) = .49, $p < .001$).

Discriminant Validity. To find evidence of 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

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

(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 < .001), symptom occurrence (z = 7.002; p < .001), physical-functional distress (z = 4.580; p < .001), and psychosocial distress (z = 3.638; p < .001). Moderate effect sizes were observed for physical-functional distress (d = 0.56), psychosocial distress (d = 0.64), total BCLE-SEi-Es scale (d = 0.651), while large effect size was observed for symptom occurrence subscale (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.

Convergent Validity Between the Scales. The AVE calculated for the physical functional distress and psychosocial distress scales was higher than 0.5, thus acting as evidence of convergent validity between scales. However, in the case of symptom occurrence, the AVE showed a lack of evidence (AVE = 0.45).

Finally, 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 < .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]).

Table 4
Factor Loadings for Symptom Distress (N = 286)

Items	Factor 1 Physical-Functional distress	Factor 2 Psychosocial distress
1. Cooking	0.80	
2. Cutting food with a knife	0.82	
3. Writing/typing	0.87	
4. Cleaning the house	0.72	
5. Vacuuming	0.72	
6. Doing the laundry	0.90	
7. Bathing or showering	0.92	
8. Taking care of children	0.61	
9. Carrying and lifting heavy objects	0.42	
10. Gardening	0.48	
11. Getting dressed	0.89	
12. Driving	0.53	
13. Making bed	0.91	
14. Family activities		0.49
15. Leisure activities	0.39	
16. Frustration		0.80
17. Sadness		1.00
18. Guilt		0.35
19. Concern		0.83
20. Irritability		0.76
21. Fear		0.78
22. Anger		0.64
23. Loneliness		0.89
24. Dependency		0.54
25. Hopelessness		0.84
26. Anxiety		0.90
27. Depression		0.86
28. Self-perception		0.64
29. Sleep disturbance	0.31	
30. Sex life with partner		0.46
31. Emotional relationship with partner		0.44
32. Impact on work outside home		0.36

Table 5
Spearman's Rho Between Subscales (N = 286)

	Physical-functional	Psychosocial	Total scores of symptom occurrence and distress
Symptom occurrence	.63**	.49**	.77**
Physical-functional distress		.69**	.88**
Psychosocial distress			.87**

Note: ** = p < .001

Discussion

As a self-report instrument, BCLE-SEI-Es was acceptable to Spanish breast cancer patients and was able to elicit the patients' report of lymphedema symptoms and distress. The results of the study demonstrated that the Spanish version of the BCLE-SEI is a reliable tool for the assessment of lymphedema symptom occurrence and symptom distress for Spanish breast cancer patients both with and without lymphedema (Hernández et al., 2020). The

Table 6
Mann-Whitney U-test Results, Medians, Interquartile Ranges (IQR), and Size Effect (N = 286)

	z	p	d	Median		IQR	
				Non-lymphedema	Lymphedema	Non-lymphedema	Lymphedema
Symptom Occurrence	7.002	<.001	0.90	4	13	1-11	3-19
Physical-functional Distress	4.580	<.001	0.56	3	9	0-9	5-27
Psychosocial Distress	3.638	<.001	0.44	7	17	2-16	7-26
Total BCLE-SEI-Es	5.651	<.001	0.71	17	43	7-33	19-71

Note: IQR: Interquartile range

findings of the study supported our hypothesis that symptom occurrence and symptom distress for patients with lymphedema were significantly higher than for patients with non-lymphedema. The ability of BCLE-SEI-Es to discriminate breast cancer patients with lymphedema from those without 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) prevent lymphedema from progressing into a chronic and incurable condition and it also 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 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% (AUC = 0.72) (Fu et al., 2015). Findings of our study also support the evidence that the self-reporting of lymphedema symptoms can discriminate breast cancer patients with lymphedema from those with non-lymphedema with a sensitivity of 86% and a specificity of 58% (AUC = 0.78) among Spanish breast cancer patients. These findings supported our hypothesis that symptom occurrence assessed by the 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 the Spanish version, it is possible to program machine learning algorithms in the 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 PCA 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 of BCLE-SEI identified five factors of symptom occurrence that explained 66.1% of the total sample variance (Shi et al., 2016). The differences in the number of factors may be due to differences in the occurrence of each symptom among Chinese and Spanish breast cancer patients. Nevertheless, symptom occurrence assessed by both Spanish and Chinese versions achieved adequate discriminating power to differentiate patients with lymphedema and those with non-lymphedema,

The findings of our study show that a two-dimensional structure for symptom distress was the most recommendable one; moreover, the two symptom distress factors explained 55.04% of the 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, 2016). 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 the addition of leisure activities and sleep disturbance and those in the Chinese version. The item of leisure activities was conceptualized in the English and Chinese versions as belonging to a social dimension. Perhaps, leisure activities in Spanish breast cancer patients reflect the need for physical-functional ability to enjoy leisure activities. Sleep disturbance was loaded in the physical-functional dimension in our study. This loading can be explained by the fact that the presence of lymphedema symptoms can contribute to sleep disorders (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 the Chinese version were similar to the ones conceptualized in the 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

reflects the limitations and negative impact evoked by symptom occurrence, perhaps, it is parsimonious to categorize symptom distress into physical-functional and psychosocial dimensions.

The AVE values of each subscale indicated a lack of evidence for convergent validity between scales in the case of the symptom occurrence dimension, unlike the two subscales of symptom distress, which both showed an AVE value greater than 0.5. However, as the McDonald's omega coefficient of the symptom occurrence dimension was higher than .6, it could be taken as evidence for convergent validity between scales (Fornell & Larcker, 1981).

Strengths of the study included adequate study design with hypothesis testing. As for the limitations, participant recruitment from only one hospital could restrict the generalizability of this study. Although the data was adequate for factor analysis, supported by Bartlett test and the KMO, further studies should replicate this study with larger samples obtained from different hospitals in Spain. This way, not only would it ensure the generalizability of the results, minimizing the effect of regional factors, but it would also allow to carry out analyses such as the analysis of measurement invariance between patients with and without lymphedema. Given that the comparison between these two types of patients is important, such analysis may prove to be crucial for future research as it may limit the extent to which results are interpreted.

In conclusion, the BCLE-SEI Spanish version demonstrated high internal consistency, test-retest reliability and content and construct validity to assess lymphedema symptoms and distress among Spanish breast cancer survivors.

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