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

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Abstract

This study was designed to adapt the Breast Cancer and Lymphedema Symptoms Experience Index (BCLE-SEI) to the Spanish language (BCLE-SEI-Es) and to assess its psychometric properties in Spanish-speaking women diagnosed with breast cancer. 286 breast cancer survivors were recruited. Study measured demographic and medical data and the BCLE-SEI. Reliability was measured using Cronbach's alpha and test-retest reliability ($n = 29$) after an interval of two weeks. A robust principal components analysis was conducted to explore the dimensions of each BCLE-SEI-Es subtest. Discriminant power of the BCLE-SEI was assessed through a non-parametric test evaluating score differences between non-lymphedema and lymphedema patients. A cut-off point was established via a ROC curve. Cronbach's alpha: all scales had a value above 0.9. Test-retest reliability: Correlations between questionnaire administrations were above 0.7. The first and second subtests showed a good fit to a unidimensional and two-factor structure, respectively. Lymphedema patients score significantly higher in all BCLE-SEI scales ($p < 0.001$). A cut-off point was established to predict a possible lymphedema case. The BCLE-SEI-Es is a valid, reliable tool for assessing and identifying the presence of lymphedema among breast cancer survivors and assessing its impact on the physical, functional, psychological and emotional aspects.

Introduction

Breast cancer is the most frequently diagnosed cancer among women worldwide (1). 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 an affected limb or upper body, and its prevalence ranging from 9–45% (2,3). The obstruction or disruption of lymphatic system associated with breast cancer treatment (e.g., removal of lymph nodes, radiation therapy) is recognized as the major cause of lymphedema (2, 4–6) while obesity or higher body mass index is known to increase the risk of lymphedema among breast cancer survivors (2,6). Patient-Centered Outcomes Research Institute (7) emphasizes that symptoms and health-related quality of life (QOL) are patient-centered outcomes that reflect patient's experience in disease management and are critical markers for healthcare providers to make ongoing treatment and care decisions (7,8). Lymphedema can result in women experiencing a range of symptoms in the arm and/or hand on the side where they received treatment, such as pain, swelling, heaviness, firmness, tightness, burning, stabbing, numbness, stiffness, tingling, loss of sensation, or impaired limb mobility (9,10). In addition, lymphedema has been associated with impairments in physical, psychological, and social functions (9,11).

Lymphedema can appear soon after treatment or months or even years after cancer diagnosis (9,12). It may also be present for some time before it manifests itself with the onset of symptoms indicative of lymphedema (13). Therefore, in order to be able to prevent it or avoid its progression, it is important to promote self-care, i.e. the awareness and identification of lymphedema-related symptoms (14,15). To this end, 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) (10,16,17). 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 (10,16), as well as in a Chinese adaptation (17,18). Given that no tools with similar characteristics to the BCLE-SEI have been found 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 tool to the Spanish language (BCLE-SEI-Es) and to assess its psychometric properties in Spanish-speaking women diagnosed with breast cancer at the Asturias Central University Hospital (HUCA).

The study was designed to answer the following research questions and test the research hypotheses: (1). Is the Spanish version acceptable to the Spanish population? (2) Is the Spanish version able to collect adequate data regarding lymphedema symptom occurrence and symptom distress among Spanish population? (3) Is the Spanish version able to differentiate breast cancer survivors with a diagnosis of lymphedema from survivors without a diagnosis of lymphedema? (4) Is the Spanish version able to establish a cut-off point to allow clinicians and practitioners to discriminate between healthy or at-risk cancer survivors? The study hypotheses were: (1) 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; (2) It's possible to establish a cut-off point in order to differentiate between healthy and at-risk cancer survivors.

Methods

Study Design

A 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

A purposive sampling method was used to recruit breast cancer survivors. The inclusion criteria of the study were: (a) 21 years or older; (b) had a diagnosis of stage I–III breast cancer; (c) had surgery for breast cancer and completed radiation and/or chemotherapy; (d) self-report of no cognitive impairments; (e) able to independently read and make decisions. The exclusion criteria were: (a) the presence of serious mental disorder; (b) the occurrence of tumor metastasis; (c) lymphedema prior to breast cancer diagnosis. We recruited participants from the Asturias Central University Hospital (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 test-retest at two-week interval.

Translation and content validity

We used an integrative translation method that has been used successfully in previous cross-culture/cross country research studies (17, 19). 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) 2 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 (17).

Instruments

Sociodemographic and medical data

We used a structured self-report and data collection tool (4,17) to collect sociodemographic and medical information. The sociodemographic data included age, level of education, employment status, marital status, alcohol and tobacco consumption. 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. 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, blistering, 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 survivors by the physicians and nurses who worked at breast clinic at the Asturias Central University Hospital. If any potential breast cancer survivors 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. 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. All the participants in the study received 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.

Statistics

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 normally 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* (20). Data from 29 participants were used to evaluate the test-retest reliability at two-week interval using spearman's correlation coefficient (*rs*). The discriminant validity of the scale was obtained by

nonparametric tests between breast cancer survivors with and without lymphedema. Clinical variables between the lymphedema and non-lymphedema groups were compared using chi square.

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 exceed 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 (21,22). Correlations between principal components were calculated using Spearman's rho.

A receptor operating characteristic curve (ROC) was calculated to establish the cut-off point to for lymphedema detection using the diagnosis of lymphedema as the standard criterion. The total 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 (23). The best possible cut-off point was chosen according to the Youden index, which ranges from 0 to 1 (24). Higher values of the Youden index indicate a more powerful cut-off point, that is, a more optimal sum of sensitivity and specificity (24).

Results

Characteristics of the sample

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. Table 1 provides a more detailed description of the sociodemographic and clinical characteristics of the sample. Significant differences were observed in currently working, tobacco and/or alcohol consumption, type of surgery undergone (mastectomy/breast-conserving surgery) and treatment received (radiotherapy/chemotherapy) between patients with and without lymphedema (Table 1).

Validity

Dimensionality

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 ($p<0.001$). A correct fit to a unidimensional structure was observed in symptom occurrence (Appendix 1), with an RMSR below 0.1 ($RMSR=0.0881$) and 45.71% of the variance explained. Factor loadings ranged from 0.37 to 0.79.

A good fit to a two-dimensional structure was observed in symptom distress, with an RMSR below 0.08 ($RMSR=0.0533$) and 54.77% of the variance explained. The correlation between the factors was 0.68.

Table 3 shows the factor loadings of both dimensions: physical-functional (factor 1) and psychosocial (factor 2).

Correlations between principal components are shown in Table 4. All correlations are positive, with moderate values, the weakest being the correlation between the psychosocial factor and the symptom occurrence factor ($r_s=0.49$).

Discriminating power of the test

Table 5 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. There were significant differences in each scale, and all the effect sizes are moderate, with the exception of the symptom occurrence subscale, whose effect size is large ($d=0.90$).

Reliability

Table 2 shows the test-retest correlations and alpha coefficients for the total BCLE-SEI-Es scale and for each of its subscales, with the symptom occurrence subscale having the lowest score ($r_s = 0.78$). In both cases, the scales had good or excellent reliability.

Specificity and Sensitivity

The analysis of the ROC curve for the symptom occurrence subscale total score as a screening variable for discriminating between the lymphedema group and the healthy group showed an AUC close to 1 (AUC= 0.78; $p < 0.001$; 95% CI: 0.72 - 0.84). According to Youden's index, a score of 6 in the symptom occurrence subscale is the best cut-off point (Youden's index= 0.45), with a sensitivity of .86 and a specificity of 0.58.

Discussion

The results of our study are partly consistent with the findings of previous studies indicating that the BCLE-SEI has acceptable psychometric properties. Overall, the Spanish version of BCLE-SEI (BCLE-SEI-Es) demonstrated adequate construct validity and reliability. In addition, an adequate sensitivity and specificity in the detection of the risk of lymphedema is also demonstrated. These results confirm that the BCLE-SEI-Es can be used as an assessment tool in populations of Spanish women with breast cancer.

Given that the survival rate for breast cancer is improving due to increased life expectancy and technological advances, the likelihood of developing lymphedema as a result of treatment and/or surgery could become greater. The risk of developing lymphedema is present even years after being treated for breast cancer (9,12) and its after-effects cause tremendous physical (25) and psychological impairment to the women who suffer from it (9,26). In addition, Bowman et al. (27) show that individuals with lymphedema sometimes visit multiple specialists about their lymphedema symptoms without receiving an official diagnosis, suggesting the existence of diagnostic disparities. This may lead to a delayed

diagnosis and, as a result, a delay in treatment. For this reason, it is extremely important to develop reliable, clinically valid tools for the early identification of lymphedema among breast cancer survivors (10,16,17). There is evidence to suggest that early intervention and detection of subclinical lymphedema reduces the incidence of lymphedema and improves treatment efficacy (28), which would allow women to participate in lymphedema self-management programmes to prevent breast cancer-related lymphedema (29).

Regarding sociodemographic characteristics, in line with other studies (10,17), no differences were found in relation to age, level of education, or marital status, with similar results across groups. However, unlike the Chinese version of the BCLE-SEI (17), statistically significant differences were found for the currently working variable, as the percentage of unemployed women was higher among those diagnosed with lymphedema. Returning to work after being diagnosed with cancer is rarely a problem (14), but studies indicate that the presence of complications, such as lymphedema symptoms, is associated with a lower return to work (30). Differences have also been identified with regard to tobacco use, alcohol consumption, and the treatment received; however, the literature reviewed suggests that these behaviours are not associated with the development of lymphedema, but with the type of treatment received (6,9,12), excess weight, and breast density, among others (26, 31).

Regarding the first part of the BCLE-SEI-Es, symptom occurrence subscale, the principal components extraction analysis showed that the data fitted correctly to a unidimensional structure with an RMSR below 0.1 (RMSR = 0.0881), which explained 45.71% of the variance. This is in contrast to the Chinese version of the BCLE-SEI, whose results conformed to 5 factors (17). Appendix 1 shows the different items assessed, which are all lymphedema-related symptoms (9,10) and, consequently, their greater or lesser presence is directly related to the occurrence of lymphedema.

In the second part of the BCLE-SEI-Es, symptom distress, our results differ from the original scale (16) and the Chinese version (17). The principal components extraction analysis showed that the data fitted correctly to a two-dimensional structure, with an RMSR below 0.08 (RMSR = 0.0533) and 54.77% of the variance explained. The first dimension, the physical-functional factor, includes items 1–13, 15, and 29 (Appendix 2), i.e. all aspects relating to a physical or functional impairment when it comes to housework, leisure activities, or sleep problems resulting from the presence of lymphedema-related symptoms. While sleep problems are not a physical or functional sign, its presence within this dimension can be attributed to the fact that the presence of symptoms directly influences the presence of disordered sleep (32). The second dimension (the psychosocial factor) includes items 14, 16–28, and 30–32 (Appendix 2), i.e. items assessing the emotional and psychological impact of the presence of lymphedema-related symptoms.

Statistically significant differences were observed in BCLE-SEI-Es total scores and subscales, which were higher in the presence of lymphedema, with a moderate or high effect size (20). This suggests that the BCLE-SEI-Es has a strong discriminating power and, as such, is valid for distinguishing between the presence and absence of lymphedema among female breast cancer survivors. Women diagnosed with

lymphedema experience continuous distress due to their symptoms and negatively influencing different aspects of their lives.

One of the hypotheses of the study was to check whether the Spanish version of the BCLE-SEI was valid to establish a cut-off point from which to detect those women who were breast cancer survivors who were at risk of developing lymphedema. The data obtained show that, in accordance with the Youden index (24), from a score of 6 in the first part of the BCLE-SEI-Es (symptom occurrence subscale), the tool can discriminate with a sensitivity of the 86% and a specificity of 58% to women without lymphedema who are at risk of suffering from it, which is similar to the results of the English version (10). These data are added to the previous ones to enhance the value of the test and that, by identifying the symptoms related to lymphedema, it is possible to detect those women who may have it in a latent phase even when it is not yet visible.

This tool can therefore be used in clinical settings in Spanish-speaking women to detect lymphedema after being diagnosed with breast cancer even when the presence of symptoms is mild or virtually unnoticeable to the woman herself.

One limitation of our study is that data collection was not mandatory for all the sociodemographic, clinical, and questionnaire items, with the result that some of the participants' answers were left blank. Due to the longer life expectancy of women diagnosed with breast cancer, some of the participants in the study were over 70 years of age. This was initially a slight limitation when answering the questionnaire using the tablet because they were less proficient with digital devices. Regarding alcohol consumption results, at least one box had a count of less than 5, which should be interpreted with great caution and tested using a larger sample.

Conclusion

Our results show that the BCLE-SEI-Es is a reliable, valid tool for assessing and identifying the presence of lymphedema among breast cancer survivors based on the occurrence of lymphedema-related symptoms and their impact on physical, functional, psychological, and/or emotional aspects of life. Given that lymphedema is a life-long after-effect faced by breast cancer survivors, it is all the more important to develop instruments such as the BCLE-SEI-Es that are useful in clinical practice for preventing the onset of lymphedema or avoiding its progression.

Declarations

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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.

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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

Due to technical limitations, table 1-5 is only available as a download in the Supplemental Files section.

Appendices

Appendices 1 and 2 are not available in this version of the manuscript.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

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