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Translation and Validation of the Breast Cancer and Lymphedema Symptom Experience Index (BCLE-SEI) in Marathi

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ABSTRACT

Background: A common side effect of breast cancer treatment is breast cancer-related lymphedema (BCRL), which is associated with many symptoms, such as swelling, heaviness, tightness, pain, discomfort and poor quality of life. The breast cancer and lymphedema symptom experience index (BCLE-SEI) captures the presence of BCRL-related symptoms and distress. However, the BCLE-SEI is not available in Marathi, one of the most commonly spoken Indian languages. The purpose of this study was to translate and validate the BCLE-SEI in Marathi.

Methodology: The BCLE-SEI was forward- and backward-translated, and the consolidated back translation was checked for equivalence following established guidelines. The BCLE-SEI-Marathi was then validated among 169 Marathi-speaking women with or at risk of developing BCRL. Content validity, structural validity, internal consistency, test-retest reliability, construct validity (through hypothesis testing) and known group validity were tested. Three different thresholds were used when testing known group validity.

Results: Content validity of the BCLE-SEI-Marathi was confirmed by 98% of the participants. Exploratory factor analysis identified two factors in the symptom occurrence subscale and three factors in the symptom distress subscale, which explained 49% and 53.8% of the total sample variance, respectively. Internal consistency of dimensions (factors) ranged from $\alpha = 0.82$ to 0.94 . Construct validity was established through hypothesis testing. The test-retest reliability was strong (Spearman's rho of 0.88 ($p < 0.01$, 95% CI: $0.8-0.9$)). The BCLE-SEI total score was able to distinguish the participants with BCRL from those at risk for BCRL.

Conclusion: This study demonstrated that the BCLE-SEI-Marathi questionnaire is a valid and reliable tool to assess the occurrence and distress of symptoms in Marathi-speaking women with or at risk of BCRL.

Trial Registration: Clinical Trials Registry India: CTRI/2017/11/010326

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1 | Introduction

Breast cancer is the most commonly diagnosed cancer among women worldwide, including in India [1]. One of the most persistent and debilitating complications of breast cancer treatment is breast cancer-related lymphedema (BCRL), which significantly impacts long-term survivorship [2, 3]. Risk factors for BCRL include both treatment-related variables, such as advanced cancer stage, axillary lymph node dissection (ALND), number of lymph nodes removed, mastectomy, radiotherapy to lymph nodes and certain chemotherapy drugs, and potentially modifiable lifestyle factors like body mass index (BMI) and skin trauma [4, 5].

Over 20% of patients undergoing ALND develop BCRL [3]. Despite a global decline in ALND because of early cancer detection and advanced treatment [6, 7], ALND remains prevalent in India, mainly due to delayed cancer diagnoses [8–10]. BCRL manifests through a range of symptoms, including swelling, firmness, tightness, numbness, pain and weakness that can severely impair quality of life [11, 12]. The subjective nature of BCRL symptoms necessitates the use of patient-reported outcome measures (PROMs) to capture individual experiences accurately [11, 13]. These measures inform clinical decision-making, guide treatment planning and support personalized care strategies [11, 14]. Additionally, incorporating PROMs into routine practice enhances treatment effectiveness, improves patient satisfaction and contributes to comprehensive cancer survivorship care [11, 15]. Furthermore, systematic assessment and monitoring of BCRL symptoms are essential for early detection of lymphedema and delivering timely intervention [16, 17].

Two PROMs have been specifically developed to assess BCRL symptoms: the breast cancer and lymphedema symptom experience index (BCLE-SEI) and the Lymphedema Symptom Intensity and Distress Survey–Arm (LSIDS-A) [18, 19]. However, these tools are not yet available in Marathi, one of the most commonly spoken Indian languages [20]. Existing validated PROMs in the Marathi language, such as the EORTC QLQ-C30 and BR23, include only limited items on arm symptoms and lack a detailed assessment of BCRL-specific symptom severity [21, 22].

The BCLE-SEI offers several advantages over other PROMs, including its ability to detect BCRL through symptom counts, support machine learning-based prediction and monitor treatment outcomes [23, 24]. Initially developed in English, the BCLE-SEI has been translated and validated in Chinese, Spanish and Bengali [25–27]. Its psychometric properties, including structural validity, internal consistency, test–retest reliability and construct validity, have been well established [25–27]. This study aimed to translate and validate the BCLE-SEI into Marathi and to evaluate its psychometric properties for use in assessing BCRL symptom experiences among Marathi-speaking breast cancer survivors.

2 | Method

2.1 | Design

This two-stage study used a cross-sectional and test–retest design. Stage 1 focused on translating the BCLE-SEI from English to

Marathi, while Stage 2 focused on validating the BCLE-SEI–Marathi questionnaire among Marathi-speaking women with or at risk of BCRL. Translation and validation of the BCLE-SEI questionnaire from English to Marathi were undertaken in accordance with the established standards [28, 29]. Permission for this study was obtained from the author of the English version of the BCLE-SEI questionnaire [18].

2.2 | Stage 1: Translation of BCLE-SEI From English to Marathi

Two bilingual (English and Marathi) translators independently translated the English version of the BCLE-SEI to Marathi. A consensus meeting was led by a bilingual coordinator and the two translators to consolidate the two Marathi versions of the BCLE-SEI [28]. Subsequently, two additional bilingual translators translated the consolidated Marathi version of the BCLE-SEI back into English. These two English versions of the BCLE-SEI were consolidated through a consensus process. The back-translated and consolidated BCLE-SEI English version was evaluated for conceptual equivalence to the original English questionnaire by an expert panel comprising lymphedema therapists, physiotherapists and psychologists with more than 5 years of experience working in breast cancer.

2.3 | Stage 2: The Validation Study

2.3.1 | Participants

Women who have undergone unilateral breast cancer surgery, with or without a BCRL, were recruited from the Tata Memorial Hospital, Mumbai, Maharashtra, India, between 2018 and 2020. Women were initially introduced to the study by the physiotherapists who were not part of the research team at the outpatient oncology departments. If interested and with permission, the physiotherapists would share the contact information of the potential participants with them, and they would then be sent to the research team. Then, the researchers would contact the potential participants to confirm their interests and eligibility. Participants aged ≥ 18 years, without any self-reported significant cognitive impairment and able to read and write in Marathi independently were included in this study. All participants provided informed consent.

2.3.2 | Data Collection

Data collection was conducted in the following order at the physiotherapy outpatient department.

2.3.3 | Demographic and Clinical Information

Demographic and clinical information was collected through structured interviews and electronic medical records. These data included the participants' age, hand dominance, menopausal status, cancer stage, cancer treatment information and BCRL status.

2.3.4 | Physical Measurement

Participants' height, weight, hip and waist circumference, arm circumference measurement and bioimpedance for arm fluid level were measured following established standards. The participants' heights were measured using a wall-mounted stadiometer (Libra, India) to the nearest 0.5 cm, and their weights

were measured using a digital weighing scale (Sknol, model number 7281) to the nearest 0.1 kg. The bioimpedance measurements were performed using the SFB7 (ImpediMed Ltd., Brisbane) bioimpedance spectroscopy device according to the manufacturer's instructions. Bilateral arm circumference measurements were taken starting at the ulnar styloid and at 10 cm intervals proximally up to 40 cm using an inelastic tape measure to the nearest 1.0 mm.

2.3.5 | Status of BCRL

The status of the BCRL was determined using clinical diagnosis, interarm impedance ratio and relative arm volume difference (RAVD), separately [30]. To determine the presence of lymphedema using clinical diagnosis, a certified lymphedema therapist examined the participants and determined lymphedema based on the clinical history, symptoms and physical signs. To determine the presence of lymphedema using the bioimpedance (BIS) ratio, the interarm impedance ratio (unaffected arm: affected arm) was calculated from the SFB7 impedance device. The interarm ratio more than the normative mean and three standard deviations (SDs) ($\geq \text{mean} + 3\text{SD}$) was used as the threshold for the determination of BCRL [30]. Finally, to determine the presence of lymphedema using the RAVD, each arm's volume was calculated from the arm circumference measures using the truncated cone formula. RAVD between the at-risk and unaffected arms was then calculated [31], and a threshold of RAVD $\geq 10\%$ was used to determine the presence of BCRL.

2.3.6 | Self-Reported Questionnaires

Participants completed the Marathi versions of the BCLE-SEI and the EORTC QLQ-C30 and BR23 by themselves. The time taken to complete the BCLE-SEI-Marathi was recorded. Additionally, patients were interviewed with six questions regarding the contents of the BCLE-SEI-Marathi to evaluate its relevance, comprehensibility (clarity) and comprehensiveness (all relevant items are present) to their experience with BCRL.

2.3.7 | The BCLE-SEI Questionnaire

The BCLE-SEI questionnaire comprises 34 items divided into two subscales: (1) symptom occurrence, which includes severity, and (2) symptom distress [18]. The symptom occurrence subscale evaluates 24 symptoms using 27 items, with the first four items considered as a single unit. Symptom presence or absence is assessed categorically through a "yes" or "no" response for each item or analysed continuously by summing the total number of "yes" responses. Symptom severity is rated on a five-point Likert scale, yielding a total score ranging from 0 to 96, with higher scores indicating greater symptom severity and more severe symptom experiences. The symptom distress subscale measures the negative impact of symptoms associated with BCRL. Distress is also assessed using a five-point Likert scale, with total scores ranging from 0 to 128, in which higher scores denote greater symptom-related distress. This subscale encompasses six dimensions: functional, social, sleep disturbance, sexuality, emotional and attributive [18, 25].

2.3.8 | EORTC QLQ-C30 BR23

The EORTC QLQ-C30 BR23 is a commonly used and most frequently cross-culturally adapted breast cancer-specific QOL

questionnaire [32, 33]. EORTC QLQ-C30 BR23 is a modular questionnaire comprising a core module, QLQ-C30 and a supplementary module, BR23. The core module consists of 30 QOL items related to the broader range of cancer populations, and the supplementary module consists of 23 QOL items specific to the breast cancer population. The core module includes physical, role, cognitive, emotional and social multi-item functional scales; fatigue, pain and emesis multi-item symptom scales; six single symptom items and financial burden; and a global QOL item [22, 34]. The supplementary breast-specific module includes body image, future perspective and sexuality multi-item scales and four symptom scales, including arm symptoms, breast symptoms, hair loss and the side effects of the treatment [22, 35].

The EORTC QLQ-C30 BR23 has good psychometric properties [34–36]. This questionnaire has been cross-culturally adapted and validated in Indian languages, including Marathi [22]. Cronbach's alpha for the internal consistency for the English and Indian language versions ranged from 0.61 to 0.96; the item scale correlation ranged from 0.63 to 0.93. However, Cronbach's alpha for the internal consistency of the Marathi version was not reported separately. The known group validity and responsiveness of this questionnaire have also been documented [22].

2.3.9 | Test-Retest Data Collection

Seventy-one participants who volunteered for a follow-up visit 1 week later underwent physical measurements and completed the PROMs to assess the test-retest reliability of the BCLE-SEI-Marathi.

2.3.10 | Ethical Considerations

Ethical approval was obtained from the Tata Memorial Hospital Institutional Ethics Committee-I (IEC/1017/1946/002).

3 | Data Analysis

Descriptive statistics were used to present means and SDs, or frequencies and proportions of the demographic, clinical and treatment-related variables. The evaluation of content validity was conducted by calculating the proportion of participants who agreed on the relevance, comprehensiveness, and comprehensibility of each item on the questionnaire. Specifically, items were considered valid if 85% or more of participants rated them as relevant to the symptoms of BCRL, comprehensive in terms of coverage of relevant aspects, and comprehensible [37]. To enhance the rigour of this evaluation, qualitative responses to the items were reviewed by at least two authors, ensuring that subjective interpretations were minimized and that a consensus on item quality was reached. The structural validity of the BCLE-SEI-Marathi questionnaire was assessed through exploratory factor analysis (EFA). The adequacy of the sample for EFA was determined using the Kaiser-Meyer-Olkin (KMO) test, with a threshold of > 0.5 considered acceptable for factor analysis. Additionally, Bartlett's test of sphericity was conducted to confirm that the correlation matrix was not an identity matrix, which would suggest that the variables are related and suitable for factor analysis.

Subsequently, a Pearson correlation matrix was computed to explore relationships among the items, and factors were extracted from the 27-item symptom occurrence and the 32-item

symptom distress subscales of the BCLE-SEI questionnaire. To address any missing data, hot-deck multiple imputation was utilized [38]. The number of factors to be extracted was estimated using a parallel analysis method, which is a recommended technique for determining the appropriate number of factors based on the data. The robust unweighted least squares (RULS) method was used to extract the factors. For improved interpretability, Robust Promin oblique rotation was applied, allowing for the correlation between factors. Items with loadings lower than 0.30 were excluded from the rotation matrix. Internal consistency of the total scale, subscales and dimensions was evaluated using the Cronbach's alpha test. The test-retest reliability of the scale was assessed using Spearman's rho. The Mann-Whitney *U* test was used to determine the difference in the total and the subscale scores between the women who had BCRL and those who were at risk of BCRL to evaluate the known-group discriminant validity. Hypothesis testing was used to assess the construct validity of the questionnaire. To test the hypothesis, correlations between the dimension scores of the BCLE-SEI-Marathi questionnaire and the various scales' scores of the EORTC-QLQ-C30 and BR23 questionnaire were examined using Spearman's correlation coefficient. This correlation matrix was also used to test the following generic hypotheses developed based on the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines: (1) all the dimension scores of the BCLE-SEI-Marathi are negative, higher scores are either severe symptoms or higher distress; (2) in EORTC QLQ-C30 BR23 PROM, the functional scales are positive, whereas the symptom scales are negative, therefore higher functional scores mean better outcome and higher symptom scores means worst outcome; (3) the dimensions of the BCLE-SEI-Marathi are, therefore, expected to have a negative correlation with EORTC QLQ-C30 BR23-functional scales and a positive correlation with the EORTC QLQ-C30 BR23-symptom scales; (4) correlations with instruments measuring similar constructs should be ≥ 0.50 ; (5) correlations with instruments measuring related, but dissimilar, constructs should be lower, i.e., ≥ 0.30 and < 0.50 ; and (6) correlations with instruments measuring unrelated constructs should be < 0.30 . It was determined that the construct validity of the questionnaire would have been met if at least 50 percent of the correlations met the criteria mentioned above. The factor analysis was performed using the Factor program (release 12.04.05 64-bit). All other analyses were performed using SPSS (version 30.0.0.0 (172)).

4 | Results

4.1 | Participants

A total of 169 women who had undergone breast cancer surgery participated in this study, with a mean age of 52.8 years ($SD = 10.3$) (Table 1). Among the participants, 79 had clinical signs and symptoms of BCRL, and 90 did not have BCRL. Nine participants who previously had a clinical diagnosis of BCRL did not show any signs or symptoms of lymphedema during recruitment. Women with BCRL, as expected, had a higher mean interarm impedance ratio (1.38 vs. 1, $p < 0.001$) and RAVD (24.1% vs. 1.6%, $p < 0.001$) than the women at risk of BCRL. Additionally, participants with BCRL had a higher waist-hip ratio (0.9 vs. 0.88, $p = 0.04$) and a greater number of node removals (16.6 vs. 14, $p = 0.03$) than participants at risk of BCRL. Other participants' and treatment-related characteristics are presented in Table 1.

4.2 | Content Validity

A high proportion of participants ($> 90\%$) agreed that the items and the scoring system of the BCLE-SEI-Marathi were relevant, comprehensive and understandable (Figure 1). A higher proportion of women at risk of BCRL, compared to those with BCRL, reported that the items and the scoring system of the BCLE-SEI-Marathi were clear to understand (98% vs. 93%). A similar proportion of women at risk or with BCRL reported that the items and the instructions of the BCLE-SEI-Marathi were relevant (93% vs. 92%) and comprehensive (96% vs. 97%). Two participants mentioned that the items related to physical intimacy could be avoided when the participants were asked whether they wanted to modify or delete any of the items in the BCLE-SEI-Marathi questionnaire. Two participants suggested adding items related to exercises, changes following radiation, and sleep disturbance when asked, "do you want any other items to be added to this questionnaire?" However, in response to the detailed considerations, the authors of this study decided that no items needed to be added or deleted due to the infrequent nature of the suggested changes and the limited proportion of participants who requested changes. This study showed that the BCLE-SEI has sufficient content validity.

4.3 | Structural Validity

The Pearson correlation matrix showed that all variables had at least one correlation coefficient greater than 0.30 in symptom occurrence and symptom distress subscales. The overall KMO measures of the symptom occurrence and symptom distress subscales were 0.85 and 0.79, respectively. The individual KMO measures all were greater than 0.7, with the classifications of "middling" to "meritorious" [39], indicating sampling adequacy for the EFA. Bartlett's test of sphericity was statistically significant ($p < 0.00001$), demonstrating that the data were likely factorable.

Seven factors, each in the occurrence and distress subscales, had eigenvalues greater than one in RULS, which explained 69.2% of the variance in the occurrence scale and 71.8% of the variance in the distress scale. However, the parallel analysis based on minimum rank factor analysis recommended two factors for the occurrence and three factors for the distress subscales, respectively [40]. Although the rotated solutions were conceptually meaningful, they did not produce a simple structure. Some items were cross-loading in more than one factor.

On inspection of the two-factor rotated matrix of the symptom occurrence subscale, it was noted that five items did not load adequately (< 0.3). These five items ("soreness," "redness in the affected limb," "blistering in the affected limb," "burning in the affected limb," and "pocket of fluid developed") had low normed Measure of Sampling Adequacy (MSA) and low communality. These items were removed randomly one by one and in different combinations, and factor extractions were performed to check whether this would lead to a simple factor structure. After removing all five low-loading items, a simple two-factor structure was obtained; however, the authors decided against the deletion of the "soreness" because pain, soreness, and aching are important symptoms of lymphedema and scored together as one item. The final two-factor solution consisted of (1) lymphatic symptoms and (2) impaired movement symptoms (Table 2). The two-factor

TABLE 1 | Participant and breast cancer treatment characteristics.

Characteristics	All (n = 169)	BCRL (n = 79)	At risk (n = 90)	p-value
Age, years, mean (SD)	52.8 (10.3)	52.8 (10.2)	52.8 (10.4)	0.97 [†]
Hand dominance, right, n (%)	163 (96.4)	78 (98.7)	85 (94.4)	0.13*
BMI, kg/m ² , mean (SD)	28.1 (4)	28.6 (3.8)	27.7 (4.1)	0.17 [†]
WHR, mean (SD)	0.89 (0.1)	0.9 (0.1)	0.88 (0.1)	0.04 [†]
<i>Affected side</i>				
Right, n (%)	83 (49.1)	41 (51.9)	42 (46.7)	0.53*
<i>Pathology grading</i>				
2, n (%)	18 (10.7)	6 (7.6)	12 (13.3)	0.37*
3, n (%)	139 (82.2)	66 (83.5)	73 (81.1)	0.37*
<i>Hormone receptor status</i>				
Oestrogen positive, n (%)	95 (56.2)	36 (49.94)	59 (65.6)	0.20*
Progesterone positive, n (%)	83 (49.1)	38 (44.7)	51 (56.7)	0.58*
HER2 positive, n (%)	77 (45.6)	40 (50.6)	37 (41.1)	0.25*
<i>Neoadjuvant chemotherapy</i>				
NACT, n (%)	61 (36.1)	33 (41.8)	28 (31.1)	0.15*
<i>Arm measurements</i>				
Inter-arm impedance ratio, ohm, mean (SD)	1.2 (0.3)	1.4 (0.3)	1 (0.2)	< 0.001 [†]
Relative arm	12.1 (19.6)			
Volume difference, mean (SD)		24.1 (21.9)	1.6 (8.4)	< 0.001 [†]
<i>Breast surgical procedures</i>				
BCS, n (%)	71 (42)	29 (36.7)	42 (46.7)	0.19*
Mastectomy, n (%)	87 (51.5)	61 (77.2)	42 (46.7)	0.18*
<i>Axillary surgery</i>				
Number of nodes removed, mean (SD)	15.2 (7.5)	16.6 (8.2)	14 (6.7)	0.03 [†]
Number of nodes involved, mean (SD)	2 (3.6)	2.2 (4)	1.9 (3)	0.62 [†]
<i>Adjuvant chemotherapy</i>				
Chemotherapy, n (%)	61 (36.1)	65 (76.5)	75 (83.3)	0.32*
<i>Hormone therapy, n (%)</i>				
	100 (59.2)	41 (51.9)	59 (65.6)	0.72*
<i>Radiotherapy, n (%)</i>				
	145 (85.8)	63 (79.7)	82 (91.1)	0.04 *
Breast, n (%)	95 (56.2)	39 (49.4)	56 (62.2)	0.09*
Chest wall, n (%)	42 (24.9)	17 (21.5)	25 (27.8)	0.35*
Axilla, n (%)	1 (0.6)	1 (1.3)	0 (0)	0.47*
Supraclavicular, n (%)	102 (60.4)	44 (55.7)	58 (64.4)	0.25*

Note: Bold, statistically different; NACT, neoadjuvant chemotherapy; HER2, Human Epidermal Growth Factor Receptor 2.

Abbreviations: BCRL, Breast Cancer-Related Lymphedema; BCS, breast conservation surgery; BMI, body mass index; n, number; SD, standard deviation; WHR, waist to hip ratio.

[†]t-test.

*X²/exact test.

solution for the occurrence subscale explained 49% of the total variance.

Regarding the three-factor rotated matrix of the symptom distress subscale, it was noted that two items did not load adequately (< 0.3). Items “taking care of children” and “driving” did not load adequately for any of the factors. The items were, therefore, dropped one by one, and the EFA was repeated. Removing both items led to a simple three-factor solution: (1) physical-functional distress, (2) psychological distress, and (3) social distress. The three-factor solution for the distress subscale explained 53.8% of the total variance (Table 2).

4.4 | Internal Consistency

The internal consistency of the BCLE-SEI-Marathi symptom occurrence and symptom distress subscales was excellent ($\alpha > 0.90$). The internal consistency of the dimensions ranged from high to excellent ($\alpha = 0.82$ to 0.94, Table 3).

4.5 | Reliability

The BCLE-SEI-Marathi's test-retest reliability was evaluated using Spearman's rank correlation coefficient across two visits with a sample size of 71 participants. The Spearman's rho for the

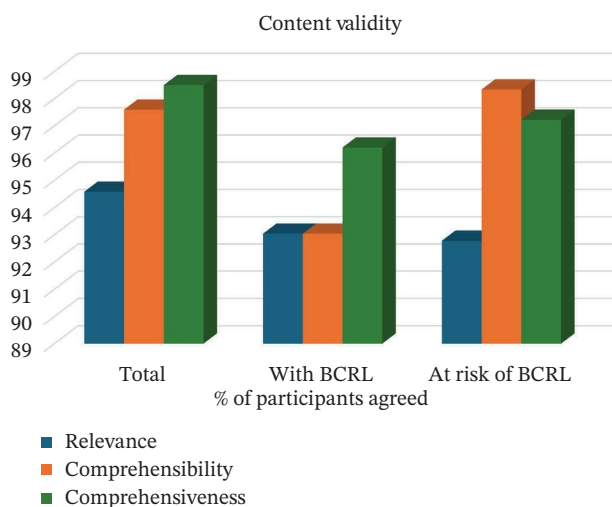


FIGURE 1 | Content validity of the BCLE-SEI-Marathi.

symptom occurrence and the symptom distress subscales were 0.84 ($p < 0.01$, 95% CI: 0.7–0.9) and 0.82 (95% CI: 0.7 to 0.9, $p < 0.01$), respectively, indicating a strong correlation between the two visits among the subscales. Likewise, the total score exhibited high reliability, with a Spearman's rho of 0.88 (95% CI: 0.8 to 0.9, $p < 0.01$). Overall, the BCLE-SEI-Marathi demonstrates excellent test–retest reliability in the Marathi-speaking population (Table 4).

4.6 | Hypothesis Testing

Hypothesis testing was performed by testing the Spearman's correlations between the dimensions of the BCLE-SEI-Marathi and scales of the EORTC-C30 BR23 and testing against the generic hypothesis set a priori. In total, 115 correlations were tested against the generic hypotheses, with 81 (70%) of them meeting the criteria (Table 5), confirming the construct validity of the BCLE-SEI-Marathi.

4.7 | Known Group Validity (Discriminant Validity)

The BCLE-SEI overall score and its subscale scores differed between the participants with or at risk of BCRL when they were determined to have lymphedema based on the clinical and the BIS-based thresholds (Table 6). Additionally, the symptom occurrence subscale scores consistently differed between the participants with or at risk of BCRL, irrespective of whether they were found to have BCRL through clinical diagnosis, BIS ratio, or RAVD-based thresholds. However, the median symptom distress score or the total scores between the participants with or at risk of BCRL did not differ significantly when using the RAVD $\geq 10\%$ as the threshold to determine participants with or at risk of BCRL.

5 | Discussion

This study translated and validated the BCLE-SEI questionnaire into the Marathi language. The results established that the BCLE-SEI-Marathi questionnaire demonstrates good content validity, structural validity, internal consistency, test–retest validity, construct validity and known group validity among Marathi-speaking women with or at risk of BCRL. According to the

COSMIN guidelines, sufficient content validity, structural validity and internal consistency are the minimum measurement properties for a PROM to be recommended [41]. The BCLE-SEI-Marathi, therefore, can be used in the Marathi-speaking population.

This study found that the BCLE-SEI-Marathi questionnaire has good content validity in Marathi-speaking women. A large proportion of the participants reported that the items, responses, and instructions of the BCLE-SEI questionnaire were relevant to their symptom experience, easy to understand, and comprehensive. Translation and validation of the BCLE-SEI into Chinese, Spanish, and Bengali also showed good content validity in Chinese-, Spanish-, and Bengali-speaking women, respectively [25–27]. Although a few changes were recommended by participants to the BCLE-SEI-Marathi questionnaire, these suggestions were made by only a few participants. As suggestions for changes were infrequent, it was determined that those changes were not required to capture the experience of having BCRL.

Two and three conceptually meaningful factors were extracted for the symptom occurrence and the distress subscales, respectively, in the BCLE-SEI-Marathi questionnaire. This factor structure was different from the proposed factor structure of the BCLE-SEI-English and the factor structures of the BCLE-SEI-Chinese and BCLE-SEI-Spanish [18, 25, 27]. Although the BCLE-SEI-Marathi's factor structure was similar to the BCLE-SEI-Bengali, it was not identical. The factor structure of the symptom occurrence scale was identical, but the factor structure of the symptom distress scales differed marginally. The symptom distress scale of the BCLE-SEI-Bengali had two factors, physical distress and psychosocial distress [26]. In contrast, BCLE-SEI-Marathi showed three factors, physical distress, psychological distress, and social distress. This could be due to the cultural differences between these language groups. Given that previous language versions' factor structures have been found to differ, EFA was performed instead of confirmatory factor analysis in this study, contrary to the COSMIN recommendations. Unlike previous studies that used only conceptual analysis [18], principal component analysis [27], or a combination of principal component analysis and the RULS method, this study employed RULS with a robust Promin rotation to extract the factors. Additionally, the parallel analysis based on minimum rank factor analysis [40] was used to estimate the number of factors instead of using only the eigenvalue or scree plot to follow the best practices of the EFA [42, 43].

Five items from the symptom occurrence and the two items from the symptom distress subscales were initially removed to achieve the simple structures in both subscales of the BCLE-SEI-Marathi. These items failed to regress to any of the factors (< 0.30). This may be due to semantic differences in Marathi and English, as well as cultural differences between the Marathi- and English-speaking populations. An example of a semantic issue is the symptom “soreness,” which does not have an equivalent word in Marathi, as the word soreness could mean either pain or aching in Marathi. However, the authors decided against the deletion of the “soreness” because pain, soreness, and aching are essential symptoms of lymphedema and were scored together as one item. An example of a cultural issue is an item in this subscale, “driving”. Despite the rapidly changing gender-based roles in the urban areas of India, very few women drive regularly, and rarely

TABLE 2 | Factor loadings for BCL-E-SEI-Marathi.

Occurrence items	Symptom occurrence subscale			Symptom distress subscale		
	Lymphatic symptoms	Impaired movement symptoms	Distress items	Physical-functional distress		Psychological distress
				Social distress	distress	
Pain	0.253	0.557	Cooking	0.08	0.77	0.019
Soreness	0.148	0.268	Using a knife to cut food	0.073	0.71	0.04
Aching	0.097	0.572	Writing or typing	0.109	0.682	0.008
Tenderness	0.048	0.623	Cleaning house	0.046	0.813	0.06
Arm or hand swelling	0.089	0.505	Vacuuming	0.117	0.848	0.056
Breast swelling	−0.307	0.704	Doing laundry	0.128	0.669	0.146
Chest wall swelling	−0.247	0.519	Bathing self	0.071	0.775	0.022
Firmness in the affected limb	0.001	0.695	Carrying or lifting heavy objects	0.083	0.413	0.201
Tightness in the affected limb	0.044	0.689	Yard work or gardening	0.016	0.565	0.145
Heaviness in the affected limb	0.059	0.755	Dressing self	0.098	0.674	0.078
Thickness of skin in the affected limb	0.155	0.588	Making bed	0.021	0.714	0.243
Stiffness in the affected limb	0.04	0.778	Family activities	0.232	0.03	0.489
Hotness in the affected limb	−0.134	0.521	Leisure activities	0.007	0.003	0.558
Numbness in the affected limb	0.001	0.575	Frustration	0.025	0.062	0.845
Stabbing in the affected limb	−0.11	0.746	Sad	0.079	0.038	0.776
Tingling in the affected limb	0.029	0.704	Guilty/self-blame	0.127	0.042	0.631
Fatigue in the affected limb	0.224	0.479	Worried	0.131	0.084	0.752
Weakness in the affected limb	0.4	0.271	Irritable	0.087	0.069	0.715
Shoulder restriction	0.675	−0.056	Fear	0.053	0.173	0.523
Elbow restriction	0.758	−0.196	Angry	0.151	0.03	0.751
Wrist restriction	0.862	−0.123	Lonely	0.076	0.084	0.843
Fingers restriction	0.802	0.075	Helpless	0.209	0.019	0.657
Arm restriction	0.924	−0.025	Hopeless	0.013	0.061	0.796
			Anxious	0.056	0.018	0.76
			Depressed	0.027	0.132	0.842
			Self-perception	0.025	0.108	0.485
			Sleep disturbance	0.052	0.03	0.38
			Sex life with partner	0.912	0.013	0.057
			Emotional relationship with partner	0.918	0.037	0.026
			Impact on work outside home	0.708	0.023	0.109
						0.109

Note: O, items from the occurrence subscale; D, items from the distress subscale; bold values, items loaded above 0.30.

TABLE 3 | Internal consistency of the domain BCLEI-SEI-Marathi.

Subscale	Cronbach's alpha	N	Number of items	Mean (SD)
BCLE-SEI-Marathi	0.942	123	53	19.66 (19.2)
Symptom occurrence	0.916	138	23	10.27 (10.5)
Symptom distress	0.926	138	30	10.14 (11.8)
Lymphatic symptoms	0.906	142	18	8.58 (8.8)
Impaired movement symptoms	0.891	165	5	1.32 (2.5)
Physical and functional	0.898	149	11	3.50 (5.6)
Emotional and psychological	0.937	153	16	6.63 (8.5)
Social	0.821	157	3	0.56 (3.3)

Abbreviations: N, number of participants; SD, standard deviation.

any women drive in the rural areas. Dropping these items led to a simple factor solution that was conceptually meaningful in the BCLE-SEI-Marathi questionnaire. Since the BCLE-SEI questionnaire has been translated into Marathi for the first time, it is advisable to confirm the factor structure in another sample of Marathi women with or at risk of BCRL using confirmatory factor analysis [25]. However, the internal consistency of identified dimensions of the symptom occurrence and symptom distress subscales in this study ranged from high to excellent, similar to BCLE-SEI-Chinese, -Spanish, and -Bengali [25–27]. The internal structure of the BCLE-SEI-Marathi questionnaire is valid to be used to capture the symptom experience in Marathi-speaking women who have or are at risk of BCRL.

The BCLE-SEI-Marathi PROM's construct validity was acceptable. A high proportion of the a priori set hypotheses was met. The dimensions of the BCLE-SEI-Marathi correlated as expected with the scales of the EORTC-QLQ-C30 and BR23 Marathi versions. Many symptom occurrences and distress dimensions were negatively correlated with the functional scales and positively correlated with the symptom scales of the EORTC-QLQ-C30 and BR23 Marathi questionnaires. This finding was similar to the BCLE-SEI-Chinese [27] and BCLE-SEI-Bengali [26], although the Chinese version was compared with SF-36, a generic QOL questionnaire.

The test–retest reliability of the BCLE-SEI-Marathi was confirmed. The overall PROMs and their subscale scores exhibited a high Spearman's correlation between the two visits with a 1-week interval. This result was similar to that of the English and Spanish versions of the BCLE-SEI questionnaire [18, 25]. However, the test–retest reliability of the Bengali version, in contrast to the current study, was inconclusive due to an inadequate test–retest sample size in that study [26]. The interval time between the two visits in this study was similar to the Chinese version [27] but shorter than the Spanish version

[25]. A 2-week interval is generally considered suitable for preventing participants' ability to recall their responses from the first visit [44]. As the questionnaire is relatively long, 34 items (59 items including 25 subitems), this will likely limit the participants' ability to recall their previous responses. Additionally, as these participants were recruited from the outpatient clinic of a tertiary cancer centre, where they came from distant places for their follow-up visits, it was not practical for them to revisit the hospital again in 2 weeks only for this study.

The BCLE-SEI overall score and its subscale scores differed between participants with or at risk of BCRL, as determined by both clinical and BIS-based thresholds. The Chinese and Spanish versions of the BCLE-SEI demonstrated good discriminant validity in symptom occurrence, symptom distress, and overall scores using the clinical diagnosis as the criterion [25, 27], which was similar to the current study. However, when the RAVD-based threshold was used, only the symptom occurrence scale discriminated between women with or at risk of BCRL. Therefore, it is essential to use the symptom occurrence, as recommended by the authors of the BCLE-SEI-English, to differentiate individuals with lymphedema from those at risk of lymphedema [18].

6 | Strengths and Limitations of the Study

This cross-cultural adaptation of the BCLE-SEI-Marathi was performed following established guidelines. The translation, back translation, and consolidation processes of the BCLE-SEI questionnaire were performed following established protocols [29, 45]. The questionnaire validation was conducted in close collaboration with the COSMIN recommendations for the evaluation of psychometric properties. A sample size of 170 was considered adequate for the validation study based on five participants per item (5 * 34) in the BCLE-SEI-Marathi PROM

TABLE 4 | The test–retest reliability of BCLE-SEI-Marathi (n = 71).

Items	First visit Median (range)	Second visit Median (range)	Spearman's rho (95% CI ^{a,b} , p)
Symptom occurrence	6 (46)	5 (32)	0.84 (0.7–0.9, < 0.01)
Symptom distress	5 (57)	5 (50)	0.82 (0.7–0.9, < 0.01)
BCLE-SEI-Marathi	16 (83)	13 (73)	0.88 (0.8–0.9, < 0.01)

Abbreviations: CI, confidence interval; SD, standard deviation.

^aEstimation is based on Fisher's r-to-z transformation.

^bEstimation of the standard error is based on the formula proposed by Fieller, Hartley, and Pearson.

TABLE 5 | Spearman's correlation coefficient between the BCLE-SEI-Marathi and the EORTC-QLQ-C30-BR23.

Subscales of EORTC-QLQ-C30-BR23	BCLE-SEI domains						
	Lymphatic symptoms	Impaired movement symptoms	Physical distress	Psychological distress	Social distress	BCLE-SEI subscales	
						Symptom occurrence	Symptom distress
Global health status	-0.39**	-0.37**	-0.34**	-0.47**	-0.44**	-0.43**	-0.50**
Physical functioning	-0.57**	-0.33**	-0.39**	-0.55**	-0.38**	-0.59**	-0.62**
Role functioning	-0.34**	-0.24**	-0.23**	-0.43**	-0.55**	-0.37**	-0.44**
Emotional functioning	-0.54**	-0.25**	-0.37**	-0.77**	-0.4**	-0.55**	-0.71**
Cognitive functioning	-0.36**	-0.24**	-0.4**	-0.49**	-0.4**	-0.37**	-0.48**
Social functioning	-0.41**	-0.1	-0.38**	-0.50**	-0.46**	-0.41**	-0.51**
Fatigue	0.57**	0.21**	0.37**	0.59**	0.4**	0.57**	0.64**
Nausea and vomiting	0.41**	0.16*	0.35**	0.42**	0.44**	0.4**	0.45**
Pain	0.57**	0.32**	0.32**	0.54**	0.43**	0.58**	0.60**
Dyspnoea	0.24**	0.04	0.19*	0.29**	0.26**	0.22**	0.26**
Insomnia	0.46**	0.19*	0.18*	0.43**	0.32**	0.44**	0.46**
Appetite loss	0.32**	0.13	0.27**	0.26**	0.33**	0.31**	0.32**
Constipation	0.2*	0.11	0.13	0.23**	0.16*	0.21**	0.24**
Diarrhoea	0.20*	0.08	0.07	0.11	0.16*	0.2*	0.19*
Financial difficulties	0.30**	0.08	0.29**	0.40**	0.33**	0.29**	0.4**
Body image	-0.52**	-0.27**	-0.42**	-0.6**	-0.35**	-0.54**	-0.61**
Sexual functioning	-0.12	0.0	0.03	0.04	-0.05	-0.1	-0.04
Sexual enjoyment	-0.03	0.06	0.13	0.11	0.06	0.02	0.07
Future perspective	-0.47**	-0.22**	-0.29**	-0.54**	-0.33**	-0.49**	-0.56**
Systemic therapy side effects	0.39**	0.15	0.29**	0.46**	0.38**	0.4**	0.5**
Breast symptoms	0.56**	0.21**	0.32**	0.39**	0.35**	0.54**	0.53**
Arm symptoms	0.66**	0.43**	0.28**	0.48**	0.2**	0.69**	0.68**
Upset by hair loss	0.39**	0.21*	0.24*	0.48**	0.42**	0.4**	0.47**

Note: Bold and/or italics, met hypothesis; bold and italic, similar and related constructs; bold, related but dissimilar constructs; plain and italics, not related and dissimilar constructs.

***Correlation is significant at the 0.001 level (2-tailed).

*Correlation is significant at the 0.05 level (2-tailed).

TABLE 6 | Known group validity.

Threshold	BCLE-SEI	LE status (n)	Median (range)	Median difference (95% CI, <i>p</i> -value)*
BIS	Symptom	LE (60)	11 (50)	4 (2 to 7, < 0.001)
	Occurrence	At-risk (93)	6 (56)	
	Symptom	LE (60)	18 (82)	5 (1 to 10, 0.011)
	Distress	At-risk (93)	12 (65)	
	Total	LE (60)	28.5 (132)	10 (3 to 17, 0.004)
		At-risk (93)	18 (121)	
Volume				
RAVD ≥ 10%	Symptom	actLE (61)	10.5 (48)	3 (0.0 to 6, 0.02)
	Occurrence	At-risk (104)	6 (57)	
	Symptom	LE (61)	8 (49)	3 (−1 to 8, 0.104)
	Distress	At-risk (104)	7 (59)	
	Total	LE (61)	20 (94)	6 (0–14, 0.057)
		At-risk (104)	15 (78)	
Clinical Diagnosis				
	Symptom	LE (78)	11 (56)	4 (2 to 6, < 0.001)
	Occurrence	At-risk (89)	6 (35)	
	Symptom	LE (78)	15.5 (82)	4 (4 to 0.0, 0.030)
	Distress	At-risk (89)	12 (63)	
	Total	LE (78)	26.5 (132)	8 (2 to 15, 0.009)
		At-risk (89)	21 (83)	

Note: Bold values, significantly different; n, sample size; BIS, bioimpedance spectroscopy; LE, lymphedema. Abbreviations: CI, confidence interval; M, mean; RAVD, relative arm volume difference; SD, standard deviation. *Mann–Whitney *U* test.

[46]. However, a larger sample size would be ideal for the psychometric evaluation of PROMs, particularly for the factor analysis. Since this current study was a cross-sectional study with a test–retest design, the responsiveness of the BCLE-SEI-Marathi PROM was not tested in this study. Participants were recruited from Tata Memorial Hospital, the largest cancer centre in India, which provides care for breast cancer patients from across India and serves a range of socioeconomic groups. Yet this is a single-centre study, caution is warranted regarding its generalizability. Despite these minor shortcomings, this study established that the BCLE-SEI-Marathi questionnaire has good content validity, structural validity, internal consistency, and construct validity.

7 | Conclusion

The results of this study showed that the BCLE-SEI-Marathi questionnaire could be used to assess the occurrence and distress of the symptoms in Marathi-speaking women with or at risk of BCRL. The BCLE-SEI-Marathi questionnaire was found to have good content validity, structural validity, internal consistency, test–retest, construct validity, and known group validity. The results also showed that the responsiveness of the BCLE-SEI-Marathi questionnaire needed further evaluation.

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Disclosure

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Ethics Statement

Ethical approval was obtained from the Institutional Ethics Committee-I (IEC/1017/1946/002), Tata Memorial Hospital.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The datasets from the current study are available from Dr Vincent Singh Paramanandam (vincentsingh.paramanandam@mq.edu.au) on reasonable request.

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