

Psychometric properties of the Malay version of the Breast Module (BR23)

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INTRODUCTION The Breast Module (BR23) is increasingly being used worldwide in breast cancer research. This study evaluates the appropriateness of the translated version (i.e. BR23-Malay version) as a useful tool for the Malaysian population who could understand Malay, and examines the reliability and validity of the BR23-Malay version.

METHODS This was a prospective study involving 68 Malaysian women who could understand Malay very well. They answered the BR23-Malay version at two evaluation points – three and ten weeks following surgery for breast cancer. Internal consistency, test-retest intraclass correlation coefficients (ICC), effect size index, sensitivity and discriminability of the scale were calculated.

RESULTS Internal consistencies were acceptable for the functional domains (0.87 for body image; 0.84 for sexual functioning) and symptomatology domains (0.82 for systemic therapy side effect; 0.82 for breast symptoms; 0.70 for arm symptoms). Test-retest ICC ranged from 0.26 to 1.00. Sensitivity of the scale was observed in all domains except sexual functioning.

CONCLUSION The Malay version of BR23 is a suitable tool to measure the functional and symptomatology domains of women diagnosed with breast cancer.

Keywords: BR23, Cronbach's alpha, intraclass correlation coefficient, Malay version, test-retest reliability and validity
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INTRODUCTION

The Breast Module (BR23) was designed and copyrighted by the Quality of Life Unit, European Organisation for Research and Treatment of Cancer (EORTC), Brussels, Belgium.⁽¹⁾ It has been validated in a larger cross-cultural study involving 12 countries. This module is meant for use among patients varying in disease stages and treatment modalities (i.e. surgery, chemotherapy, radiotherapy and hormonal treatment). Comprising 23 questions, the module can be divided into two areas: (1) Functional scales, consisting of body image (four items), sexual functioning (two items), sexual enjoyment (one item) and future perspective (one item); and (2) Symptomatology scales, consisting of systemic therapy side effects (seven items), breast symptoms (four items), arm symptoms (three items) and 'upset due to hair loss' (one item).

The functional and symptomatology scales of BR23 are rated on a four-point scale, ranging from 'not at all' (1 point) to 'very much' (4 points). Linear transformation is used to standardise the raw score. A high scale score represents a higher response level. Thus, a high score for the functional scale represents a high/healthy level of functioning, and a high score for the symptom scale represents a high level of symptomatology/problems. The reliability of the sub-scales had previously been established with Cronbach's alpha coefficients, at 0.7–0.91 among breast cancer patients in the USA and 0.46–0.94 among those in Spain.⁽²⁾ The validity of the sub-scales had also been established, as indicated

by a known-group comparison where selective scales clearly distinguished the patients according to their disease stages, previous surgery, performance status and treatment modality.⁽²⁾

Thus far, no translation of BR23 into Malay has been undertaken or validated among the Malaysian population. Thus, this study was conducted with the aim to translate the original version into Malay and examine the psychometric properties of this translated version. The specific objective of the study was to determine the reliability and validity of the Malay version of BR23. The research questions regarding the appropriateness of this version as a valid and reliable tool for Malaysians who could understand Malay very well are discussed in the next section.

METHODS

Women who satisfied the inclusion and exclusion criteria of the study were sampled from three main hospitals in Klang Valley, the capital area of Malaysia. The inclusion criteria were new cases of breast cancer, patients who had undergone breast cancer surgery or were scheduled for adjuvant chemotherapy and those with no current major diseases or chronic psychiatric condition. The exclusion criteria were patients who possessed a history of breast cancer surgery and had received neo-adjuvant therapy before the surgery. The three hospitals were the University of Malaya Medical Centre (UMMC), the Kuala Lumpur General Hospital (KLGH) and the Hospital Universiti Kebangsaan Malaysia (HUKM). These hospitals were selected as they are the main hospitals in Klang

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Valley, with large capacity for cancer treatment, e.g. oncology clinic for chemotherapy treatment. Ethical approval was obtained from the Ministry of Health Malaysia and the ethical boards of each of the hospitals.

Permission for using and translating the BR23 was obtained from the Quality of Life Unit, EORTC Data Centre, Brussels, Belgium. Translation of the original scale (English) into Malay was conducted based on the standard protocol of the EORTC.⁽³⁾ This procedure employed two Malay native speakers who were fluent in English for the 'forward translation' from English to Malay. Two other Malay native speakers who were proficient in both spoken and written English carried out the 'backward translation' from Malay to English. The feedback and comments of all the respondents regarding difficulties in understanding or ambiguity in the meaning of certain words or sentences were taken into consideration and improved upon. The backward translation was re-implemented for controversial words or sentences reported. The Malay version of BR23 was then pre-tested and finalised before the commencement of the study. Approval from the EORTC committee was obtained after the validation, and the translated version was then finalised.

A total of 68 women who were approached in the Clinical Oncology Clinics answered the Malay version of BR23. They were selected using purposive sampling, which was based on the inclusion and exclusion criteria of the study. Only women aged > 18 years were selected, as this age was the standard cut-off point for the consent form. However, there was no restriction on the maximum age of the respondent, as long as she had no psychiatric problem, could understand Malay very well and was able to answer the questions herself. The sample size was calculated using the following means formula:⁽⁴⁾

$$n = \frac{2\sigma^2}{\Delta^2} (Z_{\alpha} + Z_{\beta})^2$$

where the significance level of two-tailed test (α) = 0.05; power of the study (β) = 80%; standard deviation of either group (σ) = ± 18 ; expected detectable difference between two groups (Δ) = ± 12 ; value of standard normal distribution cutting off probability α in one tail for one-sided alternative or $\alpha/2$ in each tail for a two-sided alternative (Z_{α}) = 1.96; and value of the standard normal distribution cutting off probability β (Z_{β}) = 0.84.

The standard deviation of either group (σ) and expected detectable difference between two groups (Δ) were referred to in a previous study.⁽⁵⁾ The calculation is as follows:

$$n = 2 \times \frac{18^2}{12^2} (1.96 + 0.84)^2$$

where $n = 35$ women diagnosed with breast cancer. However, the sample size was adjusted upwards in order to allow for non-response of as much as 20%, resulting in the final sample size required for the study to be 42.

The breast surgeon and oncologist provided a list of women who were considered eligible for the study. Before the commencement of the study, informed consent was obtained from all participants. Patient information sheets, which were based on the standard format from the Ethics Committee of

Table I. Demographic and medical characteristics of women with breast cancer (n = 68).

| Demographic | No. (%) |
|---|------------------|
| Mean age \pm SD (yrs) | 46.91 \pm 7.65 |
| Educational level | |
| Primary | 10 (14.7) |
| Lower secondary | 20 (29.4) |
| Upper secondary | 24 (35.3) |
| Form 6/Diploma/Certificate | 13 (19.1) |
| Tertiary | 1 (1.5) |
| Household income (per mth) | |
| < RM1,000 | 17 (25.0) |
| RM1,001–3,000 | 38 (55.9) |
| RM3,001–5,000 | 6 (8.8) |
| > RM5,000 | 7 (10.3) |
| Occupation | |
| Professionals | 7 (10.3) |
| Technicians/associate professionals | 5 (7.4) |
| Clerical workers | 11 (16.2) |
| Service/shop/market sales staff | 4 (5.9) |
| Housewives | 40 (58.8) |
| Pensioners | 1 (1.5) |
| Type of surgery | |
| Mastectomy | 53 (77.9) |
| Lumpectomy | 15 (22.1) |
| Menopausal status | |
| Pre-menopausal | 42 (61.8) |
| Peri-menopausal | 5 (7.4) |
| Post-menopausal | 21 (30.9) |
| Stage of cancer | |
| Stage 1 | 5 (7.4) |
| Stage 2a | 21 (30.9) |
| Stage 2b | 16 (23.5) |
| Stage 3a | 16 (23.5) |
| Stage 3b | 7 (10.3) |
| Stage 3c | 3 (4.4) |
| Mean duration of cancer from diagnosis to participation \pm SD (days) | 52.04 \pm 2.47 |

SD: standard deviation

UMMC, were also attached to the consent form. For the purpose of reliability and validity analyses, by using test-retest method, this study was implemented prospectively with two points of evaluation: approximately 2–3 weeks following surgery (prior to chemotherapy) and approximately ten weeks following surgery (during chemotherapy). All the participants were able to understand, read and write Malay very well; thus, they answered the scale independently in a privacy room provided in the clinic. Sociomedical data of the participants, such as age, ethnicity, education, occupation, monthly income, duration of marriage, type of surgery, time since diagnosis and stage of breast cancer, was also documented.

The Statistical Package for the Social Sciences version 15.0 (SPSS BI, Kuala Lumpur, Malaysia) was used to calculate the various analyses for the justification of reliability and validity of BR23. Cronbach's alpha coefficient was presented to interpret the internal consistency of the Malay version of BR23.⁽⁶⁾ The intraclass correlation coefficient (ICC), which ranges from one

Table II. Internal consistencies and intraclass correlation coefficient (ICC) of BR23-Malay version.

| Domain | Mean \pm SD | | Cronbach's alpha | Test-retest ICC |
|------------------------------|-------------------|-------------------|------------------|-----------------|
| | Phase I* | Phase II† | | |
| Functioning | | | | |
| Body image | 46.69 \pm 24.18 | 63.23 \pm 30.85 | 0.87 | 0.40 |
| Sexual functioning | 60.78 \pm 22.07 | 60.78 \pm 22.07 | 0.84 | 1.00 |
| Sexual enjoyment | 36.31 \pm 15.93 | 63.69 \pm 15.93 | S | @ |
| Future perspective | 48.53 \pm 23.35 | 50.98 \pm 24.07 | S | 0.90 |
| Symptomatology | | | | |
| Systemic therapy side effect | 30.32 \pm 17.55 | 49.10 \pm 17.34 | 0.82 | 0.26 |
| Breast symptoms | 24.63 \pm 19.87 | 23.04 \pm 17.64 | 0.82 | 0.49 |
| Arm symptoms | 42.32 \pm 21.91 | 31.86 \pm 18.70 | 0.70 | 0.41 |
| Upset due to hair loss | 41.67 \pm 33.49 | 54.17 \pm 33.86 | S | 0.58 |

*Two weeks following surgery, †Ten weeks following surgery
SD: standard deviation; S: single question; ICC: intraclass coefficient; @: ICC is not computed due to zero variance

Table III. Sensitivity of BR23-Malay version.

| Domain | Mean \pm SD | | Difference in means | Effect size index | p-value |
|------------------------------|-------------------|-------------------|---------------------|-------------------|-----------|
| | Phase I* | Phase II† | | | |
| Functioning | | | | | |
| Body image | 46.69 \pm 24.18 | 63.23 \pm 30.85 | 16.54 | 0.28 | p < 0.001 |
| Sexual functioning | 60.78 \pm 22.07 | 60.78 \pm 22.07 | 0.00 | 0.00 | NS |
| Sexual enjoyment | 36.31 \pm 15.93 | 63.69 \pm 15.93 | 27.27 | 0.65 | p < 0.001 |
| Future perspective | 48.53 \pm 23.35 | 50.98 \pm 24.07 | 2.49 | 0.05 | NS |
| Symptomatology | | | | | |
| Systemic therapy side effect | 30.32 \pm 17.55 | 49.10 \pm 17.34 | 18.83 | 0.47 | p < 0.001 |
| Breast symptoms | 24.63 \pm 19.87 | 23.04 \pm 17.64 | 2.11 | 0.06 | NS |
| Arm symptoms | 42.32 \pm 21.91 | 31.86 \pm 18.70 | 10.78 | 0.25 | p < 0.001 |
| Upset due to hair loss | 41.67 \pm 33.49 | 54.17 \pm 33.86 | 9.33 | 0.14 | NS |

*Two weeks after surgery, †Ten weeks after surgery
SD: standard deviation; NS: not significant

(perfectly reliable) to zero, was calculated so as to infer the test-retest reliability.⁽⁷⁾ The sensitivity of the scale was assumed by calculating the mean differences between the evaluations undertaken, by means of a paired *t*-test. The effect size index (ESI) of every domain of the Malay version of BR23 was also accounted for.⁽⁷⁾ In order to confirm the validity of the scale, discriminant analysis was performed, which compared women who had undergone mastectomy with those who had undergone lumpectomy.

RESULTS

The detailed sociodemographic and medical data of the participants is presented in Table I. The mean age of the women was 46.91 \pm 7.65 years. 77.9% (n = 53) of the women had previously undergone mastectomy and 22.1% (n = 15) had undergone lumpectomy. Based on their medical records, the majority of the women were reported as having stage 2 breast cancer (54.4%, n = 37), followed by stage 3 (38.2%; n = 26) and stage 1 (7.4%, n = 5). The mean duration between the time of diagnosis and participation in the study was 52.04 \pm 2.47 days. Based on the menstrual cycle symptoms reported, the majority of the women were in the pre-menopausal group (61.8%, n = 42), followed by the post-menopausal (30.9%, n = 21) and peri-menopausal (7.4%, n = 5) groups. The women had at least a secondary education (64.7%, n = 44), with most being unemployed or housewives (58.8%, n = 40). The

household monthly income was reported to be at least RM3,000 or US\$1,000 (80.9%, n = 55).

The results of the analyses of reliability and validity of BR23-Malay version are presented in Tables II–IV. For the functional domains of the Malay version of BR23, the Cronbach's alpha for body image and sexual functioning was 0.87 and 0.84, respectively. For the symptomatology domains, the Cronbach's alpha for systemic therapy side effect, breast symptoms and arm symptoms was 0.82, 0.82 and 0.70, respectively. The value for test-retest ICC was 0.40–1.00 for the functional domains. The symptomatology domains exhibited a range of 0.26 to 0.58 (Table II). Low sensitivity was observed in all domains except sexual functioning. However, significant mean differences were only observed for body image (p < 0.001), sexual enjoyment (p < 0.001), systemic therapy side effect (p < 0.001) and arm symptoms (p < 0.001). For all domains except sexual functioning, the ESI was 0.06–0.65 (Table III). In the validity analysis (i.e. discriminant analysis), no difference between the women who had mastectomy and those who had lumpectomy was found (Table IV).

DISCUSSION

The internal consistency of BR23-Malay version was excellent, as indicated by all the domains. This situation is similar to Sprangers et al's study, in which the Cronbach's alpha coefficients ranged from 0.7 to 0.91 and 0.46 to 0.94 among breast cancer patients

Table IV. Discriminant validity of the BR23-Malay version.

| Domain | Mean \pm SD | | t-value | p-value |
|------------------------------|-------------------|-------------------|---------|---------|
| | Mastectomy | Lumpectomy | | |
| Functioning | | | | |
| Body image | 44.18 \pm 23.72 | 55.56 \pm 24.53 | -1.63 | NS |
| Sexual functioning | 60.06 \pm 21.52 | 63.33 \pm 24.60 | -0.50 | NS |
| Sexual enjoyment | 37.04 \pm 16.24 | 33.33 \pm 14.91 | 0.69 | NS |
| Future perspective | 48.42 \pm 23.17 | 48.89 \pm 24.77 | -0.07 | NS |
| Symptomatology | | | | |
| Systemic therapy side effect | 28.93 \pm 15.17 | 35.24 \pm 24.20 | -1.23 | NS |
| Breast symptoms | 26.10 \pm 21.44 | 19.44 \pm 12.06 | 1.15 | NS |
| Arm symptoms | 43.39 \pm 21.04 | 38.52 \pm 25.15 | 0.76 | NS |
| Upset due to hair loss | 38.33 \pm 29.17 | 50.00 \pm 43.64 | -0.83 | NS |

SD: standard deviation; NS: not significant

in the USA and Spain, respectively.⁽²⁾ The Malay version of BR23 showed a range of effect size, from trivial to moderate (0.00–0.47). This finding interprets the effect of different phases of treatment (prior to and during chemotherapy) on the women's functional and symptomatology domains. The differences among domains could possibly be attributed to the treatment condition measured prior to and during the chemotherapy phases, and not due to low sensitivity of the scale. It was observed that the Malay version of BR23 did not detect differences between groups of women who had undergone mastectomy and those who had undergone lumpectomy. This is acceptable, as the women's functioning and symptomatology may not be affected by the type of surgery (mastectomy or lumpectomy), as was previously proven by other studies.⁽⁸⁻¹¹⁾

Collection of the data at two weeks (baseline) and ten weeks following surgery (follow-up) as well as the effect of the treatment phases itself may be a limitation of the study, as a number of data such as test-retest ICC and sensitivity of the scale revealed very low results. This is conceivably due to the short interval between the baseline and follow-up phases. However, the strength of this study is the population-specific sample selected for the study, i.e. breast cancer patients who were advised six cycles of adjuvant chemotherapy. Thus, the homogeneity of the respondents could be controlled. This study has significant implications, especially for researchers who are actively involved in breast cancer research in Malaysia, as the BR-23 Malay version is very useful for measuring the functional and symptomatology domains of women who have been diagnosed with breast cancer and who can understand Malay very well. For future research, it is recommended that the BR23-Malay version be tested between baseline (two weeks after surgery/prior to chemotherapy) and at six months, in order to make a strong justification for the test-retest ICC and sensitivity of the scale.

In conclusion, the Malay version of BR23 is a reliable tool for Malaysian women with breast cancer, with justification

for the effect of treatment phases on their functioning and symptomatology.

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