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Reliability and Validity of the Malay BREAST-Q in Women Undergoing Breast Cancer Surgery in Malaysia

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Abstract

This study aims to translate the BREAST-Q into Malay and validate it in breast cancer patients undergoing surgery. The English BREAST-Q was translated to Malay using the back-translation method. A total of 144 newly diagnosed breast cancer patients were sampled conveniently between December 2015 and November 2016. Test-retest was done after two to three weeks. Data were analyzed using SPSS and AMOS software. Content experts agreed the items in the Malay BREAST-Q were measuring the constructs appropriately. Internal consistencies were good for all items in each subscale (Cronbach's alpha = 0.83-0.95). The highest inter-item correlation for each item with at least one other item in the construct ranged from 0.47 to 0.90. The lowest corrected item-total correlation values ranged from 0.47 to 0.72. The test-retest analysis showed good reproducibility (intraclass correlation coefficient = 0.71-0.98). In exploratory factor analysis, the Kaiser-Meyer-Olkin values were excellent in all four subscales (0.76, 0.92, 0.91, and 0.86). For all subscales, the number of factors extracted cumulatively explained more than 50% of the variance. The Malay BREAST-Q demonstrated good reliability, face validity, content validity, and construct validity.

Keywords

BREAST-Q, breast cancer surgery, back-translation, cross-cultural adaptation, reliability, validity

What We Already Know

- Patient satisfaction and health-related quality of life are considered important endpoints in cancer care and have been associated with treatment compliance.
- The BREAST-Q was developed in 2009 to measure patient satisfaction and quality of life before and after breast cancer surgery.
- BREAST-Q is a validated patient-reported outcome measure which has been translated into 30 languages to date.

What This Article Adds

- The rigorous translation process of the original English BREAST-Q to Malay language using the back-translation method.
- The cross-cultural adaptation, reliability, face, content, and construct validity of BREAST-Q in breast cancer patients undergoing surgery.

Introduction

Breast cancer has been one of the five most common types of cancer afflicting women in Malaysia.[1]

In Malaysia, a total of 21 634 cases of female breast cancer were diagnosed for the period of 2012 to 2016, an increase from 18 206 cases as reported in the 2007-to-2011 report. The age-standardized rate increased from 31.1 per

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100 000 populations to 34.1 in the recent report. The incidence was highest among Chinese, followed by Indians, and Malays ethnicities. Staging was reported for 13 485 cases (62.3%), and of these, 47.9% were detected at late stage (III and IV).[1]

Patient satisfaction is an important indicator of quality health care and has been associated with acceptance, compliance with treatment, and better post-treatment quality of life (QOL).[2-4] Measuring patient satisfaction is important, particularly in cancer which requires long-term continuous care.[5] Previous studies have examined factors associated with patient satisfaction and they can be categorized into patient factors (such as age, gender, and type of cancer) and patient care factors (such as information provision, doctor-patient relationship, and continuity of care). Patient care factors, particularly information provision,[6,7] and a patient-centered consultation style[8-10] were found to be important predictors of patient satisfaction. Unresolved physical symptom distress[11] and psychological distress[12] have shown to lower patient satisfaction.

Health-related quality of life (HRQOL) is considered an important endpoint in cancer care, and studies on this have made a considerable contribution in improving breast cancer care.[13] Breast cancer patients experience physical symptoms and psychosocial distress that adversely affect their QOL. QOL is found to be lower in dissatisfied patients than in satisfied patients.[14] QOL generally consists of a number of domains including physical functioning, psychological well-being (such as levels of anxiety and depression), and social support.[3] Breast cancer has received most attention among the HRQOL studies in cancer patients due to the increasing incidence and prevalence of breast cancer survivors from higher survivability[13] as early detection and better treatments have improved the survival rates.[3]

BREAST-Q was originally developed in 2006 by Pusic et al.[15] This patient-reported outcome measure (PROM) was developed to measure the QOL and satisfaction among patients undergoing breast surgery. Currently, the BREAST-Q has already been translated into 30 languages and is being psychometrically validated being used around the world. Since the BREAST-Q was developed in English in the United States (US) and was tested in the US and Canada, the validity and reliability properties cannot be generalized to the Malaysian population due to the differences in the patients' values, cultural beliefs, health care systems[16] and also because theoretically, psychometric properties of an instrument cannot be transferred to its translations.[17] While developing a new instrument for use in Malaysia might be laborious, time-consuming, and costly,[16] translation and contextual adaptation of the BREAST-Q saves time, effort, and resources.

Currently, there are limited data available on patient satisfaction and QOL among breast cancer patients in Malaysia. Although a wide range of instruments measuring different aspects of breast cancer care from different perspectives exist, only a small number had undergone rigorous psychometric testing. In selecting a measurement tool, not only the contextual appropriateness and clinical meaningfulness but also a strong development process and evidence of strong psychometric properties are required.[18] Hence, this study aims to translate the original English BREAST-Q into Malay language and validate it in breast cancer patients undergoing surgery.

Methods

Back-translation of Malay BREAST-Q

Permission to translate the English BREAST-Q into Malay language was obtained from MAPI Research Trust and the original author.[15] The Malay tanslation was done based on a linguistic validation protocol provided by the MAPI Research Trust.[19] First, the original English BREAST-Q was translated to Malay independently by two professional translators who are native Malay speakers. The two Malay translations were synthesized into one common version. Consensus was reached through discussion between the translators and a project manager. The Malay translation was back-translated into English by a professional translator who is also a native Malay speaker. The translator was blinded from the original English BREAST-Q. The back-translated English BREAST-Q was sent to the original authors for review and comparison with the original English BREAST-Q (conceptual equivalence testing). The Malay translation was then approved to be equivalent to the original English BREAST-Q and could be further validated.

Content Validity

Four content experts comprising breast surgeons and breast care nurses assessed the Malay BREAST-Q using the Content Validity Index (CVI), calculated at item-level (I-CVI).[20] The acceptable values of I-CVI indicated that each item measures the patient's QOL and satisfaction before and after the breast cancer surgery. This revealed that the Malay BREAST-Q is appropriate for further testing without any modification to the words, terms, or phrases.

Pilot Testing and Face Validity

The Malay BREAST-Q was pilot tested on 12 breast cancer patients selected conveniently from the breast clinic where the main sample was drawn. They were assessed on their understanding of the questionnaire, interpretations, and time consumption. All of them agreed that the Malay BREAST-Q could be easily understood and not time-consuming to be completed (mean time taken to complete: 15.3 minutes). No major modifications were proposed, and overall, the Malay BREAST-Q exhibited good face validity.

Study Design

Data were collected from the breast clinic in the University Malaya Medical Center between December 2015 and November 2016.

Women aged 18 years or older, diagnosed with breast cancer, and planned for breast cancer surgery were included in this study. Patients who already had a surgery or with psychological problem and deemed unfit for consent were excluded. Hair et al[21] recommended a sample size of minimum 100 respondents and more to generate better results. The convenience sampling technique was used to recruit the patients.[22]

Emotionally stable patients were approached following their consultations. The patient information sheet was given, the study was briefly explained to the patients, and they were given the opportunities to inquire about the study and their participation. Patients who have agreed to participate were screened for eligibility and written consent was obtained from them. They were given a socio-demographic questionnaire and the Malay BREAST-Q to be self-administrated. All data were collected by the same researcher in a separate room where the treating doctors were not present. Test-retest was done after two to three weeks with the same version of BREAST-Q.

Research Instrument

Three breast cancer modules of BREAST-Q were used in this study: mastectomy, breast conserving surgery, and breast reconstruction surgery. Each module comprised two domains: HRQOL and patient satisfaction. Four subscales were used from these two domains: three from the QOL domain (psychosocial well-being, physical well-being, and sexual well-being) and one from the patient satisfaction (satisfaction with breasts) domain. Following are the number of items and response scale for each subscale: psychosocial well-being (10 items with five-point Likert scale), physical well-being (16 items with five-point Likert scale), sexual well-being (six items with six-point Likert scale), and satisfaction with breasts (four items with four-point Likert scale). The raw scores for each independent scale will be converted to a score between 0 and 100, with a higher score indicating greater satisfaction or better QOL.[3]

Statistical Analysis

Data were analyzed using the SPSS-version 20 software for the reliability testing and exploratory factor analysis (EFA) and AMOS software for the construct validity. Four measures were used for reliability testing of the Malay BREAST-Q: Cronbach's alpha, inter-item correlation, and corrected item-total correlation, and test-retest reliability. Four measures were used to perform EFA: Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy, average variance extracted (AVE), number of factors, and factor loading.

The model fit of the Malay BREAST-Q was tested using the chi-square/df ratio, Goodness of Fit Index, Adjusted Goodness of Fit Index, Comparative Fit Index, Tucker-Lewis Index, and the root mean square error of approximation.

Results

Malay Translation of the BREAST-Q

We found discrepancies in the forward translations of item 2f and 4a. In 2f (feminine in your clothes), "*berunsur kewanitaan dari segi pakaian anda*" and "*bersifat kewanitaan semasa berpakaian*" were then revised to "*anda kelihatan bersifat kewanitaan semasa berpakaian*." Since many medical terms are not commonly used in Malay, they were translated into a more conventional Malay version. because some of the words could not be found even in the Malay dictionary. In 4a (sexually attractive in your clothes), between "*kelihatan menarik dari seksual dengan pakaian anda*" and "*menarik dari segi seksual semasa berpakaian*," the latter was considered accepted to be more accurate. Discrepancies were also found in items 3m and 3n in the back-translation. In 3m (sharp pain in your breast area), "*sakit yang mencucuk*" was back-translated as "pricking pain," but it was revised to "*rasa sakit yang kuat (untuk sekejap)*" after deliberating on the meaning of "sharp pains," which means "quick and strong pain." In 3n (shooting pain in your breast area), "*rasa sakit mendadak*" was revised to "*sakit yang kuat dan mendadak*" after deliberating on the meaning of "shooting pain," which means "sudden and severe pain."

Sample Characteristics

A total of 144 patients have completed the Malay BREAST-Q. Background characteristics of the participants are described in Table 1. The age of a majority (81.3%) of the participants was between 30 and 60 years. Most of the participants (77.1%) were from stages 2 and 3.

Reliability

A total of 74 patients completed the test-retest after two to three weeks with the same version of BREAST-Q. The Cronbach's alpha ranging from 0.85 to 0.94 indicated good internal consistency and that the instrument had reached acceptable reliability. All items in the Malay BREAST-Q correlated well together (r = above 0.3) and with the instrument (r = above 0.3). At retest, the Intraclass Correlation Coefficient ranged from 0.584 to 0.902, indicating moderate to good correlation. Table 2 shows the detailed results.

Construct Validity

In each subscale, the KMO values were high and unidimensional, with AVE above 50.0%. Factor loadings were within the recommended value except for item three in the

Table 1. Characteristics of the participants.

Characteristics (n = 144)	n (%)
Age (Years)	
21-30	1 (0.7%)
31-40	26 (18.1%)
41-50	44 (30.6%)
51-60	47 (32.6%)
More than 60	26 (18.0%)
Education level	
No formal education	6 (4.1%)
Primary school	42 (29.2%)
Secondary school	58 (40.3%)
University/college	38 (26.4%)
Race	
Malay	64 (44.5%)
Chinese	47 (32.6%)
Indian	28 (19.4%)
Others	5 (3.5%)
Marital status	
Single	18 (12.5%)
Married	126 (87.5%)
Type of surgery	
Mastectomy	97 (67.4%)
Breast conserving surgery	29 (20.1%)
Mastectomy with reconstruction	18 (12.5%)
Cancer stage	
Stage 1	30 (20.8%)
Stage 2	59 (41.0%)
Stage 3	52 (36.1%)
Stage 4	3 (2.1%)

"satisfaction with breast" subscale, and items 1 to 5, 7 to 9, 11, and 12 in the "physical pain" subscale loaded lower than 0.70.

When the original four-factor model with 36 items reported to have good reliability and validity was used as the hypothesized null model and tested independently against data from this study, the model fit (S1, S2, S3, S4) was not acceptable (Table 2). The suggested modification indices were used to adjust the model fit. Modifications were made until the recommended ideal values for a good model fit (S1M, S2M, S3M, S4M) were achieved (see Table 2).

Discussion

All the three original English Breast-Q instrument were translated into Malay preserving the meaning and securing cultural adaptation. Internal consistencies were good for all items in each subscale with the value of Cronbach's alpha in the range of 0.83 to 0.95. The highest interitem correlation for each item with at least one other item in the construct ranged from 0.47 to 0.90. The lowest corrected item-total correlation values ranged from 0.47 to 0.72. The test-retest analysis showed good reproducibility (intraclass correlation coefficient = 0.71-0.98). In EFA, the KMO values were excellent in all four subscales (0.76, 0.92, 0.91, and 0.86). For three subscales, single factors were extracted that explained more than 50% of the variance. In one subscale, "physical well-being," three factors were extracted (breast pain, general pain, and discomfort) that cumulatively explained more than 50% of the variance.

The stepwise linguistic validation protocol provided by MAPI Research Thrust revealed the difficulties in the unavailable literal translation as patient satisfaction and HRQOL are relatively new concepts in Malaysian patient care and local research.

Translating the 16 items (in the "physical pain" subscale) on different types of pain in the breast area proved to be a challenging exercise as compared to the other items. As pain is a subjective description or expression that is steeped in culture, pain language may be an expression or description of the pain.[23] Hence, it was a very challenging section to translate. Based on the results, we found the factor loadings for k and l were very low. Further examination revealed some inaccuracy in the contextual meaning of the word "tenderness" in item l (tenderness in the breast area/*"rasa lembut" dibahagian payudara*). Tenderness in English means sensitive to pain or soreness in the breast area. However, in the English language, the word "*lembut*" means softness and "*rasa*" is feel. Thus, contextually, this is not correct. It was unfortunate that it was not picked up earlier despite going through the translation process. Hence, we are not surprised that the factor loading was low. Thus, we recommend that the Malay translation for item l is changed to "*rasa berbisa di bahagian payudara*" as "*rasa berbisa*" which means feeling of soreness.

As for item k (nagging feeling in the breast/*selalu tidak selesa di bahagian payudara*), nagging in the English term means a persistent ache in the breast, and the translated Malay term was fairly close as "*selalu*" which means persistent and "*tidak selesa*" which meant an uncomfortable feeling. Other Malay words that can be used here are "*sakit merenyai-renyai*" or "*sakit sengal-sengal*," but given that these words are less used in everyday life, we will recommend the same translation to be used.[24] However, considering the good reliability and construct validity properties found in our study, coherence with previous studies, and experts' opinions, we recommend to use this version that was used in our translation despite lower factor loadings in items with translational issues.

The Malay translation of the BREAST-Q had adhered to a rigorous procedure as recommended in the MAPI Research Trust's guidelines. The back-translation ensured the accuracy and quality of the Malay BREAST-Q produced in this study.

The confirmatory factor analysis (CFA) had used the data set used for EFA because the total number of eligible participants made it challenging to recruit enough sample within

Table 2. Key Findings of the Reliability and Validity Analyses of the Malay BREAST-Q.

		Malay BREAST-Q				
		Patient satisfaction	Health-related quality of life			
Analyses	Ideal values	S1	S2	S3	S4	Interpretations
Reliability						
Cronbach's alpha	$\alpha > 0.7$	0.83	0.94	0.92	0.95	High internal consistency indicated by the high α score shows the Malay BREAST-Q is reliable
Inter-item correlation	$r = 0.3$-0.9	0.46-0.72	0.52-0.75	0.19[a]-0.77	0.60-0.90	All items in each domain correlated well together except for items 1, 7, 9, and 13 in S3
Corrected item-total correlation	$r > 0.3$	0.57-0.74	0.72-0.83	0.47-0.74	0.69-0.88	All items correlated well with the overall BREAST-Q score
Cronbach's alpha if item deleted	Increase in α	—	—	—	—	No item was considered for deletion because there was no substantial increase in α with deletion of any item
Test-retest reliability	$r = 0.3$-0.9	0.80-0.89	0.87-0.94	0.74-0.90	0.90-0.94	The Malay BREAST-Q is reproducible
Exploratory factor analysis						
Kaiser-Meyer-Olkin (KMO)	>0.8	0.76	0.92	0.91	0.86	Good KMO values show that the sampling was adequate to run factor analysis
Number of factor	1	1	1	1	1	One-factorial structure extracted in each subscale revealed that all items in each subscale are measuring a single construct (unidimensionality)
Average variance extracted (AVE)	>50.0%	56.3%	62.7%	56.0%	75.4%	More than 50% AVE indicated that amount of variance captured by the construct is more than that of the measurement errors.
Factor loading	$L > 0.7$	0.62[a]-0.86	0.74-0.86	0.48[a]-0.80	0.71-0.92	All items loaded adequately indicated the factor extracted sufficient variance from them (means the factor strongly influences the items), except for item 3 in S1; items 1, 5, 7, 8, 9, and 12 in S3, which loaded slightly below 0.7 but still above 0.5

		Confirmatory factor analysis								
Indices for model fit	Ideal values	S1	S1M	S2	S2M	S3	S3M	S4	S4M	Interpretations
Chi-square/df ratio	<3	5.80[a]	0.03	5.72[a]	1.18	4.43[a]	1.34	9.60[a]	0.96	S1, S2, S3, S4 = original model as validated in the English BREAST-Q
Goodness of Fit Index	>0.9	0.97	1.00	0.82[a]	0.97	0.73[a]	0.94	0.88	0.99	S1M = modified model to fit the subscale 1 data
Adjusted Goodness of Fit Index	>0.9	0.87	1.00	0.71[a]	0.93	0.65[a]	0.89	0.71[a]	0.97	S2M = modified model to fit the Subscale 2 data S3M = Modified model to fit the subscale 3 data
Comparative Fit Index	>0.9	0.97	1.00	0.89	1.00	0.78[a]	0.98	0.94	1.00	S4M = modified model to fit the subscale 4 data
Tuker-Lewis Index	>0.9	0.91	1.00	0.85	0.99	0.75[a]	0.98	0.91	1.00	When the original model tested: no subscales had attained the recommended ideal values (poor model fit)
Root mean square error of approximation	<0.08	0.16[a]	0.00	0.16[a]	0.03	0.14[a]	0.04	0.22[a]	0.00	

[a]The value exceeded the recommended ideal value.

the stipulated time to run CFA independently. Exploratory factor analysis yielded acceptable results with more than 50.0% AVE and good KMO values. Although a few items loaded slightly below 0.7, most items reported acceptable factor loadings. No items were proposed for deletion or modifications, enabling CFA to be run on the same data. Convergent validity was not established in this study because there is no other comparable validated instrument in Malaysia assessing a similar construct.

Conclusion

The Malay BREAST-Q demonstrated good reliability, face validity, content validity, and construct validity. This establishes an evidence-based approach to providing a standardized PROM instrument for breast surgery patients in Malaysia. Hence, we propose the use of the Malay BREAST-Q to measure patient satisfaction and HRQOL in breast cancer patients undergoing breast cancer surgery in Malaysia.

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Declaration of Conflicting Interests

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Ethical Approval

The study protocol was reviewed and approved by the Medical Ethics Committee, University Malaya Medical Center (20153-1184).

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