Translation in Bahasa Indonesia and Linguistic Validation of Mastectomy Module of BREAST-Q: A Description of The Process

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ABSTRACT

Background: Breast-related Symptom Questionnaire (BREAST-Q) has been globally used and validated to measure the outcomes among women undergoing various breast surgery. There was a lack of tools to evaluate patient's quality of life and satisfaction after mastectomy in Indonesia. In addition, most patients in Indonesia may feel reluctant to express their honest opinions regarding the post-operative outcome openly. Prior to this issue, this study aims to translate and validate the BREAST-Q Mastectomy Module into Bahasa Indonesia, which can be applied to the Indonesian population

Method: Primarily based on the guidelines from the International Society for Pharmacoeconomics and Outcome Research (ISPOR), the process includes preparation, forward translation, back translation, panel discussion, cognitive debriefing interview with 57 respondents, statistic evaluation of validity and reliability, and final consensus.

Results: Two translators worked on two different forward translation, while a third translator handled the back translation. The translations were then discussed and reviewed to reach an agreement on the finalized version. Statistic evaluation showed Pearson's r value > 0.26 in all items, with Cronbach's alpha range 0.72–0.92 (> 0.70). Bland-Altman plots comparison showed that the direction of the mean difference between score 1 and score 2 is close to zero. At the same time, the limits of agreements exceed the minimally detectable change for both scales, indicating all items are valid, reliable, and reflect the concepts of the BREAST-Q Mastectomy Module. The final version of the Bahasa Indonesia Translation is then approved by the Q-Portfolio team.

Conclusion: The translation of BREAST-Q questionnaire Mastectomy Module in Bahasa Indonesia is valid and reliable. It is a suitable instrument to assess the quality of life of patients who underwent mastectomy in the Indonesian population.

INTRODUCTION

Breast cancer is the most prevalent cancer affecting women globally. According to the 2020 Global Cancer Statistics (GLOBOCAN) from the International Agency for Research, breast cancer accounts for 16% of all new cancer cases in Indonesia, totaling 68,858 out of 396,914 cases. The estimated mortality rate is approximately 22,000 cases per year [1].

Surgery has been a mainstay of breast cancer treatment for several decades. Breast surgery encompasses aesthetic, oncological, and reconstructive procedures, including both breast-conserving surgery and mastectomy. The primary goal of reconstructive breast surgery is to improve the quality of life of the patient, which is necessary to be assessed [2–4]. However, patients may perceive their preoperative condition and postoperative outcomes differently from the surgeon's perspective.

Evaluating the outcomes of breast surgery, especially following a mastectomy, can benefit greatly from using patient-reported outcome measurement (PROM), which provides valuable insights for both the surgeon and

the patient. To accurately capture these patient-reported outcomes, the assessment tool must be capable of detecting specific changes that occur after surgery, ensuring a more precise reflection of the patient's experience and satisfaction [5]. One specific PROM that has been globally used and validated is the Breast-related Symptom Questionnaire (BREAST-Q) Mastectomy Module. It measures the quality of life and satisfaction in mastectomy patients, covering aspects such as psychosocial, physical functioning, and sexual well-being [6].

There was a lack of specific and official PROM to evaluate patients' quality of life and satisfaction after mastectomy in Indonesia. In addition, most of the patients in the Indonesian population might find it challenging to openly share their genuine opinions regarding the post-operative result and may feel uneasy discussing sensitive topics like their sexual well-being in detail with their doctor. Moreover, meaningful linguistic and cultural divergences also might be present. Given these considerations, this study aims to translate and validate the Mastectomy BREAST-Q module into Bahasa Indonesia, making it suitable for use among the Indonesian population.

METHODS

First, we engaged with the QPortfolio team, which includes BREAST-Q developers, to gain access to the questionnaire and obtain authorization for its translation and validation into Bahasa Indonesia. The translation and validation process was carefully structured according to the recommended steps provided by the QPortfolio team. These guidelines are primarily adopted from the International Society for Pharmacoeconomics and Outcome Research (ISPOR) steps for linguistic validation and cultural adaption of patient-reported outcome tools [7]. The translation process was carried out in several steps:

Preparation

Access to the instrument was obtained by authors and official authorization was subsequently granted to proceed with its translation and linguistic validation process. The team involved, including the recruited translator, designed a comprehensive plan for the process along with an established timeline.

Forward translation

Two independent translations of the BREAST-Q Mastectomy module questionnaire from English to Bahasa Indonesia were completed by two separate translators. Both translators were professional medical translators and native speakers of Bahasa Indonesia. In this process, we prioritize translation to be conceptually and culturally equivalent over pure literal translation.

The two translators discussed the translation and agreed on a reconciliation version. The discussion between the two translators led to an agreement on the most appropriate and accurate translation.

Back translation

A back-translation of the questionnaire from Bahasa Indonesia to English was carried out by a professional medical translator whose native language is English. The authors of the original BREAST-Q questionnaire then reviewed the back-translation and compared it with the original version.

Panel discussion

A panel consisting of a surgical oncologist, a coordinator, and three translators convened to thoroughly discuss and review each of the materials produced. The results of the review are then readjusted until a reconciliation version is agreed upon. This version is sent back to the Q-portfolio team for approval to proceed to the cognitive debriefing interview stage.

Cognitive debriefing interview

This process is carried out by instructing the patient to answer the BREAST-Q Mastectomy Module questionnaire in the Bahasa Indonesia version systematically and stating whether there are items that are difficult to understand. The eligible criteria for patient recruitment is a breast cancer patient who underwent mastectomy surgery and radiation, and whose mother language is Bahasa Indonesia. The exclusion criteria included the inability to provide informed consent and inadequate proficiency in Bahasa Indonesia. 57 patients met the criteria and was conducted at Kariadi General Hospital, Central Java, Indonesia. They were also requested to assess the relevance of each item and propose additional items they deemed necessary if something was perceived as lacking. All encountered difficulties and suggested solutions were registered. Two weeks later, all 57 patients were sent a second questionnaire to facilitate analysis and assess t-retest reliability.

Statistic evaluation

Validity and reliability tests were conducted. Construct validity was described by calculating Pearson's r value. The value of Pearson's *r* table must be > 0.2609. The authors evaluated reliability using internal consistency and test-retest reliability.

Internal consistency measures assess the degree to which the different questions (items) are correlated, determining whether they evaluate the same concept (construct) and whether it is justifiable to combine the scores into a single overall score. Internal consistency is calculated using coefficient alpha or Cronbach's alpha, with a coefficient greater than 0.70 (> 0.70) indicating adequate internal consistency [8]. A low Cronbach's

alpha (< 0.70) suggests a lack of correlation between the items on the scale, indicating that combining them into a total score is therefore unjustified. Conversely, a very high Cronbach's alpha (> 0.90) may signal redundancy among the items in the scale [9].

Test-retest reliability reflects the extent to which repeated measurements in stable patients yield consistent scores [9]. Often referred to as longitudinal reproducibility, test-retest reliability was assessed by inviting all participants to complete the questionnaire on two separate occasions, two weeks apart. Bland-Altman plots were generated to assess the agreement between the measurements. The mean difference should ideally be close to zero, and the limits of agreements should be smaller than the minimally detectable change [10]. The data were collected and then analyzed by using IBM SPSS Version 27.

Final consensus

The resulting final version of the questionnaire was achieved by conducting proofreading.

RESULTS

Translation

During the discussion to produce a version that is conceptually equivalent to the original questionnaire, the issue was the translation of the word "pain" and "aching", both in Bahasa Indonesia means "nyeri", but then the group decided to translate "pain" as "nyeri tajam" and "aching" as "nyeri tumpul". It was decided because it was way more idiomatic in Bahasa Indonesia.

None of the participants who completed the questionnaire encountered difficulty in understanding and interpreting the questions correctly. Additionally, none of them proposed alternative solutions, and all the women found the items to be acceptable. Consequently, face validity was deemed acceptable, and no modifications were made to the questionnaire. However, several patients noted that it was challenging to answer questions regarding the satisfaction with office staff due to time constraints and the high volume of patients in healthcare settings.

Validity

All questions showed a value of r > 0.26 means all items are valid and reflected the concepts of the BREAST-Q Mastectomy Module (**Table 1**).

Internal consistency

Internal consistency was considered to be acceptable and adequate across all categories, with Cronbach's alpha ranging from 0.72 to 0.92 (> 0.70), indicating that all items exhibited satisfactory internal consistency (**Table 2**).

Test-retest reliability

According to the Bland-Altman plots (**Figures 1** and **Figures 2**), the overall comparison of score 1 and score 2 reveals that the direction of the mean difference is close to zero, while the limits of agreements exceed the minimally detectable change for both scales. This indicates that all items demonstrated reliable measurements.

DISCUSSION

Breast cancer is a serious, stressful, and life-threatening disease that presents unique and complex emotional dimensions different from all other malignancies. Its impact on the psychological well-being and quality of life of patients is undeniable, largely because of the significance of the female breast in relation to self-identity, body image, and confidence [11]. In light of the rising incidence of breast cancer and the advancements in breast surgery, there has been a growing interest in examining the health-related quality of life outcomes resulting from breast surgical interventions, particularly mastectomy procedures [12].

The choice of surgical method should be considered taking into account the expected survival outcomes and the impact on quality of life as well as available resources and patient references. Breasts are a symbol of femininity for a woman. Breast surgery can result in deformities, quality of life, and post-operative patient satisfaction. These are very important factors for evaluating the result of operations. Adequate information about the advantages and disadvantages of several modalities should be well discussed preoperatively by surgeons and patients to plan suitable breast cancer surgery and achieve better results in quality of life. Several studies have shown that women who undergo mastectomy often experience disturbances related to body image, self-esteem, and decreased quality of life scores [13].

BREAST-Q is increasingly utilized in both clinical practice and research studies related to breast surgery. Its use plays a crucial role in providing valuable insights into patient-reported outcome measures (PROM) following breast surgery, with the potential to support an evidence-based approach to assist both patients and surgeons in making decisions and optimizing the standard of care provided [12]. BREAST-Q Mastectomy Module has 11 sections consisting of psychosocial well-being, sexual well-being, cancer worry, fatigue, impact on work, physical well-being – chest, satisfaction with breasts, adverse effects of radiation, satisfaction with the surgeon, satisfaction with the medical team, and satisfaction with office staff.

As anticipated, the forward translations tended to be more literal rather than conceptual wording differences, similar to the backward translation when compared to the original version. The discussion with the expert panel led to the development of a harmonized version in accordance with ISPOR guidelines.

Table 1. Validity evaluation with Pearson's r value

No.	Category	r	Sig	Interpretation
1.	Psychosocial Well-Being	a. 0.57		VALID
		b. 0.50		VALID
		c. 0.93		VALID
		d. 0.38		VALID
		e. 0.76	> 0.26	VALID
		f. 0.86		VALID
		g. 0.74		VALID
		h. 0.77		VALID
		i. 0.33		VALID
		j. 0.65		VALID
2.	Sexual Well-Being	a. 0.71		VALID
		b. 0.83		VALID
		c. 0.92	> 0.26	VALID
		d. 0.76		VALID
		e. 0.70		VALID
		f. 0.64		VALID
3.	Cancer Worry	a. 0.27		VALID
		b. 0.33		VALID
		c. 0.69		VALID
		d. 0.69		VALID
		e. 0.32	> 0.26	VALID
		f. 0.51		VALID
		g. 0.46		VALID
		h. 0.46		VALID
		i. 0.63		VALID
		j. 0.56		VALID
4.	Fatigue	a. 0.79		VALID
		b. 0.77		VALID
		c. 0.45		VALID
		d. 0.46		VALID
		e. 0.79	> 0.26	VALID
		f. 0.71		VALID
		g. 0.69		VALID
		h. 0.77		VALID
		i. 0.76		VALID
		j. 0.87		VALID
5.	Impact on Work	a. 0.53		VALID
		b. 0.64		VALID
		c. 0.73		VALID
		d. 0.44	> 0.26	VALID
		e. 0.45		VALID
		f. 0.76		VALID
		g. 0.74		VALID
		h. 0.87		VALID

No.	Category	r	Sig	Interpretation
6.	Physical Well-Being: Chest	a. 0.62		VALID
		b. 0.73		VALID
		c. 0.62		VALID
		d. 0.59		VALID
		e. 0.84		VALID
		f. 0.45	> 0.26	VALID
		g. 0.84		VALID
		h. 0.71		VALID
		i. 0.31		VALID
		j. 0.76		VALID
		k. 0.54		VALID
7.	Satisfaction with Breasts	a. 0.47		VALID
		b. 0.63	> 0.26	VALID
		c. 0.48		VALID
		d. 0.56		VALID
8.	Adverse Effects of Radiation	a. 0.43		VALID
		b. 0.78		VALID
		c. 0.65	> 0.26	VALID
		d. 0.81		VALID
		e. 0.66		VALID
9.	Surgeon	a. 0.67		VALID
		b. 0.45		VALID
		c. 0.32		VALID
		d. 0.54		VALID
		e. 0.55		VALID
		f. 0.56	> 0.26	VALID
		g. 0.76		VALID
		h. 0.87		VALID
		i. 0.98		VALID
		j. 0.87		VALID
		k. 0.76		VALID
		l. 0.65		VALID
10.	Medical Team	a. 0.54		VALID
		b. 0.66		VALID
		c. 0.43		VALID
		d. 0.64	> 0.26	VALID
		e. 0.54		VALID
		f. 0.62		VALID
		g. 0.34		VALID
11.	Office Staff	a. 0.44		VALID
		b. 0.59		VALID
		c. 0.62		VALID
		d. 0.43	> 0.26	VALID
		e. 0.32		VALID
		f. 0.65		VALID
		g. 0.55		VALID

Table 2. Cronbach's alpha value

No.	Item	Cronbach's alpha
1	Psychosocial Well-Being	0.80
2	Sexual Well-Being	0.84
3	Cancer Worry	0.74
4	Fatigue	0.89
5	Impact on Work	0.81

No.	Item	Cronbach's alpha
6	Physical Well-Being: Chest	0.80
7	Satisfaction with Breasts	0.79
8	Adverse Effects of Radiation	0.82
9	Surgeon	0.72
10	Medical Team	0.92
11	Office Staff	0.80
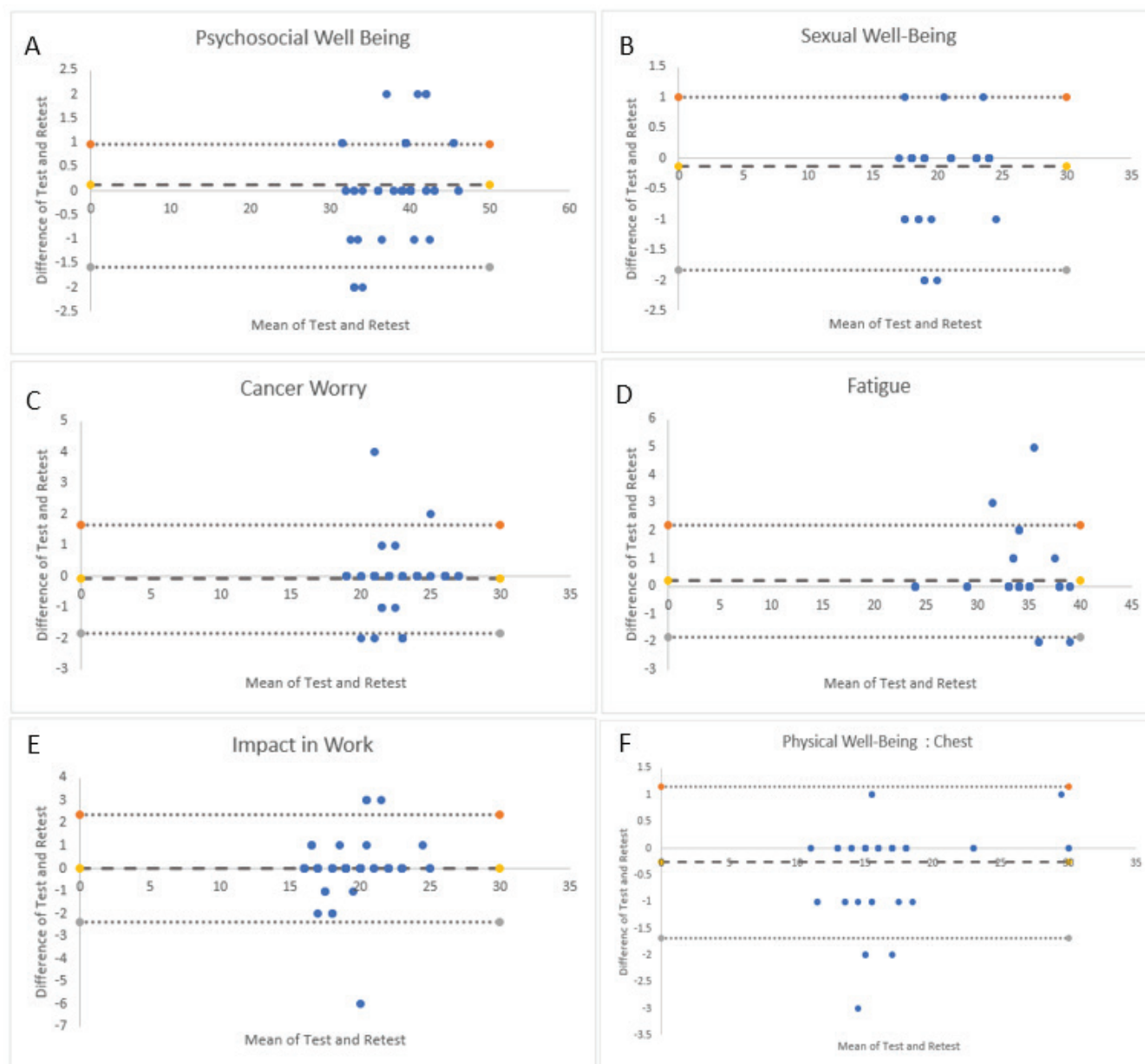
Figure 1. (A) Bland-Altman plot for psychosocial well-being, the mean difference between scores 1 and 2 was 0.12 (SD 0.86) and limits of agreement 0.95 and -1.57; (B) Bland-Altman plot for sexual well-being, the mean difference between scores 1 and 2 was -0.15 (SD 0.59) and limits of agreement 1.01 and -1.82; (C) Bland-Altman plot for cancer worry, the mean difference between scores 1 and 2 was -0.08 (SD 0.89) and limits of agreement 1.66 and -1.83; (D) Bland-Altman plot for fatigue, the mean difference between scores 1 and 2 was 0.19 (SD 1.02) and limits of agreement 2.20 and -1.81; (E) Bland-Altman plot for impact on work, the mean difference between scores 1 and 2 was -0.01 (SD 1.21) and limits of agreement 2.36 and -2.40; (F) Bland-Altman plot for physical well-being: chest, the mean difference between scores 1 and 2 was -0.26 (SD 0.72) and limits of agreement 1.14 and -1.67.
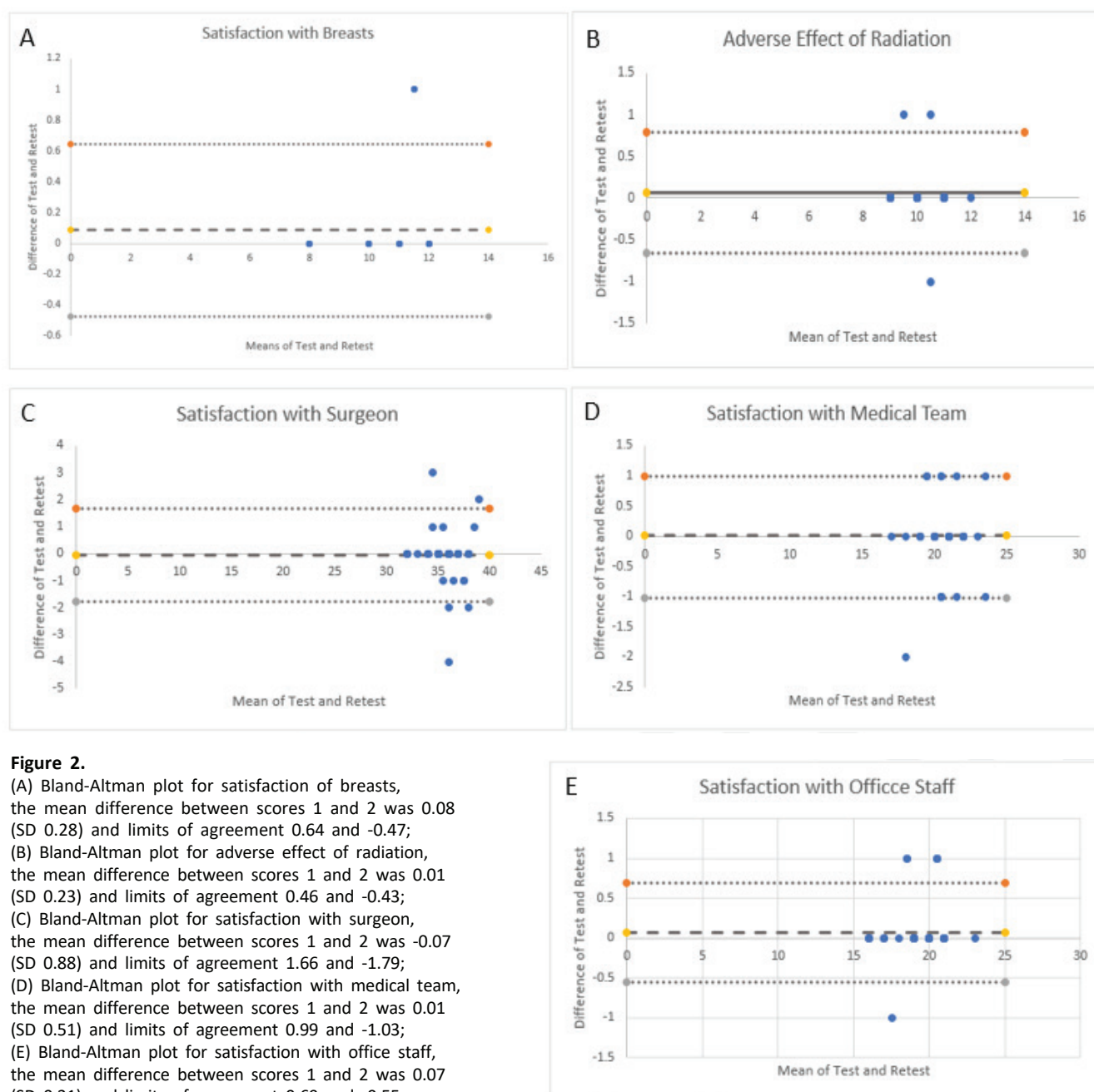
Figure 2.
(A) Bland-Altman plot for satisfaction of breasts,
the mean difference between scores 1 and 2 was 0.08
(SD 0.28) and limits of agreement 0.64 and -0.47;
(B) Bland-Altman plot for adverse effect of radiation,
the mean difference between scores 1 and 2 was 0.01
(SD 0.23) and limits of agreement 0.46 and -0.43;
(C) Bland-Altman plot for satisfaction with surgeon,
the mean difference between scores 1 and 2 was -0.07
(SD 0.88) and limits of agreement 1.66 and -1.79;
(D) Bland-Altman plot for satisfaction with medical team,
the mean difference between scores 1 and 2 was 0.01
(SD 0.51) and limits of agreement 0.99 and -1.03;
(E) Bland-Altman plot for satisfaction with office staff,
the mean difference between scores 1 and 2 was 0.07
(SD 0.31) and limits of agreement 0.69 and -0.55.

Discrepancies were identified and resolved, with changes duly documented, resulting in a final consensual translation that was equivalent to the original version.

The construct validity of the questionnaire translation was evaluated by calculating the Pearson's correlation coefficient r of the score of patients' responses to an item with their total scores. The value of Pearson's r table must be > 0.2609. The results showed the value of r in all questions > 0.26, despite some questions having a lower value than the others. The lowest value is shown in the Cancer Worry section which is associated with the mental health domain. The explanation related to this low value might be that the respondents had a hard time translating what they felt into words [14].

Overall, all items are valid and reflect the concepts of BREAST-Q Mastectomy Module.

Internal consistency was acceptable and adequate for all categories, with Cronbach's alpha range 0.72–0.92 (> 0.70), indicating all items had satisfying internal consistency. One section, "Satisfaction with Medical Team", had a Cronbach's alpha value > 0.9, which may suggest redundancy among the questions. However, a certain degree of redundancy is deemed preferable over the items, as that would complicate comparisons of outcomes across different countries [15].

According to the Bland-Altman plots (**Figures 1** and **Figures 2**), the overall comparison of score 1 and score 2 reveals that the direction of the mean difference is

close to zero. At the same time, the limits of agreements exceed the minimally detectable change for both scales. However, some plots indicated that the difference between the first and second measurements occasionally exceeded the predefined Minimally Detectable Change (MDCs) for the scale. Furthermore, the observed changes between score 1 and score 2 could reflect both a true clinical change between the two measurements and a measurement error. Theoretically, a patient's evaluation of physical well-being of chest satisfaction should remain relatively stable over two weeks, particularly in patients who underwent surgery several years ago. Nevertheless, satisfaction with appearance is a highly subjective measure that may fluctuate, which could account for these differences [15,16].

The limitations of this study include the absence of evaluations for convergent and discrimination validity, known group validity, and also factor analysis.

CONCLUSIONS

The translation of BREAST-Q questionnaire Mastectomy Module in Bahasa Indonesia is valid and reliable. It is a suitable instrument to assess the quality of life of patients who underwent mastectomy in the Indonesian population.

DECLARATIONS

REFERENCES

1. WHO. International Agency for Research on Cancer Globocan 2020 [Internet]. Available from: https:// gco.iarc.fr/today/data/factsheets/populations/360-indonesia-fact-sheets.pdf.

2. Pusic AL, Chen CM, Cano S, et al. Measuring quality of life in cosmetic and reconstructive breast surgery: a systematic review of patient-reported outcomes instruments. Plast Reconstr Surg. 2007;120(4):823–37.

3. Pusic AL, Klassen AF, Scott AM, et al. Development of a new patient-reported outcome measure for breast surgery: the BREAST-Q. Plast Reconstr Surg. 2009;124(2):345–53.

4. Han J, Grothuesmann D, Neises M, et al. Quality of life and satisfaction after breast cancer operation. Arch Gynecol Obstet. 2010;282(1):75–82.

5. Cano SJ, Klassen A, Pusic AL. The science behind quality-of-life measurement: a primer for plastic surgeons. Plast Reconstr Surg. 2009;123(3):98e–106e.

6. Cano SJ, Klassen AF, Scott AM, Pusic AL. A closer look at the BREAST-Q((c)). Clin Plast Surg. 2013;40(2):287–96.

7. Wild D, Grove A, Martin M, et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health. 2005;8(2):94–104.

8. Osburn HG. Coefficient alpha and related internal consistency reliability coefficients. Psychol Methods. 2000;5(3):343–55.

9. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34–42.

10. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1(8476):307–10.

11. Pittermann A, Radtke C. Psychological Aspects of Breast Reconstruction after Breast Cancer. Breast Care (Basel). 2019;14(5):298–301.

12. Tevis SE, James TA, Kuerer HM, et al. Patient-Reported Outcomes for Breast Cancer. Ann Surg Oncol. 2018;25(10):2839–45.

13. Perry S, Kowalski TL, Chang CH. Quality of life assessment in women with breast cancer: benefits, acceptability and utilization. Health Qual Life Outcomes. 2007;5:24.

14. Ramadhanty Z, Yarsa KY, Probandari A. Construct Validity and Reliability of Indonesian Version of RAND SF-36 Quality of Life Questionnaire in Breast Cancer Patients Indonesian Journal of Cancer. 2019;13(2), 55–58.

15. Kamya L, Hansson E, Weick L, Hansson E. Validation and reliability testing of the Breast-Q latissimus dorsi questionnaire: cross-cultural adaptation and psychometric properties in a Swedish population. Health Qual Life Outcomes. 2021;19(1):174.

16. Haimovitz D, Lansky LM, O'Reilly P. Fluctuations in body satisfaction across situations. Int J Eat Disord. 1993;13(1):77–84.