

Development, Validation, and Implementation of a Short Breast Health Questionnaire

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Abstract

Background

Health status and perception can be assessed by general or disease-specific questionnaires, the latter are more sensitive. Considering the importance of breast health in women's lives and the lack of any pertinent questionnaire, we performed this study to develop a valid and reliable short BH questionnaire (BHQ); and then use it for the assessment of participants.

Methods

We first designed and developed the instrument, followed by measurement of inter-rater agreement IRA, content validity including content validity index (I-CVI) and scale content validity index (S-CVI), and reliability (through internal consistency and test-retest). We then included eligible women with normal breasts and benign breast disorders who attended our breast clinic.

Results

The IRA index (78.6%) showed optimal relevance and clarity of the questionnaire. The content validity was acceptable; with an S-CVI of 87.35 and 84.42 for clarity and relevance, respectively. One question was eliminated (I-CVI < 70%). The internal reliability was high (Cronbach's alpha = 0.93). For external consistency, three questions were eliminated (intraclass correlation coefficient < 0.7), the rest of the questions showed good and excellent reliability. In the next step, BH in the 350 eligible participants showed an overall score of 55.86 ± 11.57 . Among different variables, age was the only one that showed a significant direct relationship with BH. A history of breast surgery for benign lesions and a family history of breast cancer did not affect BH.

Conclusion

This study introduces a valid reliable 11-item BHQ. We propose its use in various conditions throughout breast cancer screening, diagnosis, and treatment; and in the assessment of BH in various physiologic and reproductive situations.

Background

Cancer is the second leading cause of death worldwide, and breast cancer is the most common cause of cancer-related mortality [1]. The breast is a distinctive feature of women and an emotional symbol of femininity and motherhood, and any threat to the breast can be devastating to the feminine identity of women [2]. Diagnosis of breast cancer can be destructive and induce various negative reactions in most women [3]. In addition, the loss of a breast can result in low self-esteem, false self-perception, social

isolation, and communication problem with others [4, 5], while the psychological healthiness of the operated woman can diminish along with poor health outcomes [6, 7]. Thinking about the possibility of developing breast cancer itself can cause intense mental stress, which leads to different emotional disorders such as anxiety, distress, and depression [2, 8].

Breast cancer screening can facilitate early detection of malignancy, improve patient quality of life and reduce cancer-related mortality [9]. However, being called for further investigation after primary screening is a stressful experience for many women [10], and false-negative, false-positive, and overdiagnosis can affect the decision for participating in the screening program [11]. In addition, psychological reactions such as anxiety and depression during detection, diagnosis, and treatment of cancer are common [12].

Other than the stress regarding getting cancer, these issues can affect the perception of health a woman has about her breasts. Health perception, regardless of the real health status, is important enough to affect the quality of life (QOL) and the life satisfaction of people [13, 14]. This is why the health status of the body and mind and the perception of health are assessed in various conditions. This assessment takes place via questionnaires that have been designed for this purpose [15]. Overall, general health feelings are important aspects of medical care and can be assessed by general or disease-specific questionnaires. The general health questionnaire, with a frequently used short version which consists of 12 questions and has been translated and validated in different languages and countries, is the best-known one in this regard [16]. However, site or disease-specific questionnaires are more sensitive to detect and quantify small changes related to the patients [17]. Numerous valuable specialized questionnaires which focus on an important body organ or a specific disease and measure the health status, health perception, or quality of life of people in relation to that matter, have been developed and validated. In 2014, Oldridge et al validated a questionnaire that was specifically aimed at patients with ischemic heart disease. It comprised 14 items including physical and emotional subscales and a global score, and the Cronbach's alpha index for consistency was > 0.8 [18]. Another study conducted in the Netherland for validation of QOL after pulmonary embolism reported an adequate internal consistency with a Cronbach's alpha of 0.62–0.94 and a reliability (ICC) of 0.78–0.94 [17]. A few other examples among a large number include peripheral artery [19], cystic fibrosis [20], leiomyomata [21], sleep apnea [22], and onychomycosis [23] questionnaires.

Despite the importance of the breast in a woman's life, a questionnaire that targets breast health (BH) and the health perception of women toward this body part is not available. Although questionnaires for assessing breast cancer fear (the Champion Breast Cancer Fear Scale) [24] and patient-stated outcome after breast reduction, augmentation, and reconstruction have been validated (the Breast-Q) [25] but no BH questionnaires have been introduced until now.

So while the threat of cancer and its burden can be destructive and result in depression and anxiety in women, many other issues like harboring a premalignant lesion in the breast, benign breast disorders, various types of breast surgery, mild and moderate breast symptoms like mastalgia or benign nipple discharge, and even physiologic reproductive conditions such as pregnancy, lactation, or menstrual

fluctuations of the breast, can impact the self-perception of BH. The development of a questionnaire with acceptable validity and reliability can be used in different situations to evaluate the feeling of women about their BH in all these or other circumstances. Therefore, we carried out a study to develop a valid and reliable short BH questionnaire (BHQ), and then use it for the assessment of this variable in women with normal breast and benign breast disorders who attended our breast clinic.

Method And Materials

This study has been approved by the Research Deputy of Tehran University of Medical Sciences, approval code 99-1-259-48164. Also, the study has been approved by the Ethics Committee of Tehran University of Medical Sciences, ethics code: IR.TUMS.IKHC.REC.1399.112. All the participants consented to take part in the study by written consent.

1.1 Questionnaire Design

To design a BHQ, after an extensive literature review and several discussion panels with 7 general surgeons, breast surgeons, and gynecologists, 14 questions were designed based on the Likert scale, including always (almost always), usually, sometimes, rarely, and never as answer options; to assess the women's perception toward their BH.

1.2 Validity Assessment

1.2.1 Face Validity

Face validity is used to assess whether a questionnaire is appropriate for the measurement of what is expected to be measured in general [26]. To do this, the approved questions were given to 10 experts to examine their form, comprehensibility, sequence, and fluency.

1.2.2 Content Validity

To conduct content validity [27], the designed questionnaire was given to 5 health experts experienced in the field of breast diseases and 5 knowledgeable participants; and each question was scored in terms of relevancy, clarity, and simplicity. Responses were categorized into four groups including not relevant, somewhat relevant, quite relevant, and highly relevant.

1.3 Inter-Rater Agreement

The Inter-Rater Agreement (IRA) is used to examine the observed agreement between experts participating in the study in terms of relevancy or clarity of questions [27]. The assessment of IRA is performed in two different ways, conservative and less conservative. For the conservative approach, the number of items that all experts rated as "quite appropriate" or "appropriate" was divided by the total number of items. For the less-conservative approach, the number of items that the majority of experts (80%) rated as "quite

appropriate” or “appropriate” was divided by the total number of items. The acceptable level of agreement was presented as 70%-80% [28].

1.4 Item Content Validity Index

This index rates the relevancy, clarity, and simplicity of each item [27, 26]. To obtain this index, the number of experts judging each item as relevant or clear (rated as quite relevant or highly relevant) was divided by the total number of experts. Returned values range from zero to one; when the item content validity index (I-CVI) is more than 0.79 the item is relevant, when it is between 0.70 and 0.79 it needs revision, and if the value is below 0.70, the item is eliminated.

1.5 Scale Content Validity Index

There are two methods used to assess the relevancy and clarity of the instrument: total agreement and mean approach. In the mean approach, for estimation of the relevancy (or clarity), first not relevant and quite relevant items were combined to make up a “not relevant” option, and relevant and totally relevant items were combined to form a “relevant” option. Then relevancy was calculated by dividing the number of experts that opted for relevance by the total number of experts. In different references, the minimum acceptable scale content validity index (S-CVI) for a new instrument is considered 80% [27].

1.6 Comprehensiveness

The last step of measuring the content validity is comprehensiveness which is the ability of the instrument in covering all dimensions of the subject and evaluates whether the instrument items and their dimensions are complete samples of the intended content or not [29]. It includes four items, incomplete, somewhat comprehensive, comprehensive, and totally comprehensive. The overall comprehensiveness of the instrument was calculated by dividing the number of experts who identified the instrument comprehensiveness as favorable to the total number of experts. A comprehensiveness score of more than 70% is acceptable.

1.7 Reliability

Reliability is the degree to which the research method produces stable and consistent results under the same method and circumstance over time [29]. We used Cronbach’s alpha to determine the internal consistency, and the Test-Retest method for reliability. Since in this study, all items (questions) were related to one area, then only one Cronbach’s Alpha index was estimated for the instrument. In internal consistency evaluation, the desired value for Cronbach’s Alpha is 0.7 or higher. To evaluate the reliability of the instrument, questions were given to a group of 36 people at two different times with 2 to 3 weeks intervals under the same circumstance, and obtained scores were used to measure the reliability by using the intraclass correlation coefficient (ICC). Reliability above 0.7 is desirable.

1.8 Study Design

After designing a valid and reliable questionnaire, a descriptive-analytical and cross-sectional study was carried out on women who attended the Breast Clinic of Arash Women's Hospital from August 1st to October 31st, 2020. The inclusion criteria of the study were: age 18 years or above, willingness to participate, no suspicious breast lesion in clinical breast exam, no suspicious breast lesion in breast ultrasound when needed, and breast ultrasound when this imaging modality was needed for the assessment of the breast of the woman, and the absence of any suspicious lesion in mammography during the past year in women over 40 years of age. Exclusion criteria consisted of a history of breast cancer, diagnosis of a benign breast lesion except for fibrocystic changes or small (less than 1 centimeter) fibroadenomas, history of cosmetic breast surgery, a new change in the breast exam or imaging in the recent last exam, history of psychological disease, or use of psychotropic medications. After providing written informed consent from the eligible women, 350 women were entered into the study. Sampling was done in a full-census manner and all eligible participants were selected to fill out the questionnaire. Each question (item) included five-choice options; always (almost always), usually, sometimes, rarely, and never; which were given one to five scores, respectively. The overall calculated raw score for each participant was between 14 and 70.

1.9 Statistical Analysis

Statistical analyses were conducted using SPSS V.26. The calculated mean score of BH was considered as a dependent variable and age, parity, lactation, menopausal status, miscarriage, history of benign breast disease in oneself or family members, and history of benign breast surgery were independent variables. Descriptive statistics (mean, standard deviation, frequency, and percent) were used to assess the status of variables. To evaluate the effect of independent variables on the mean BH, Student T-Test (Man-Whitney for non-parametric), correlation (Spearman) and regression were conducted.

Results

A total of 350 women were included in the study. The mean age of the participants was 42.7 ± 10.29 years. The youngest participant was 18 and the oldest was 83 years old. According to the descriptive results, the average duration of breastfeeding in participants who had a history of lactation was 22.46 (SD 22.7) months.

Content Validity

Five knowledgeable participants and five experts who specialize in breast cancer participated in the assessment of content validity. I-CVI and S-CVI were used to assess the content validity. I-CVI values for relevancy and clarity were between 58.8 and 100, and S-CVI was 87.35 and 84.42, respectively. The calculated IRA for the BHQ was 78.6. (Table 1)

Table 1

Items content validity index (I-CVI), scale content validity scale (S-CVI) and IRA for clarity and relevancy

Question	Clarity				Relevancy			
	S-CVI (Mean approach)	IRA	I-CVI	Number of agreements among 17 observed	S-CVI (Mean approach)	IRA	I- CVI	Number of agreements among 17 observed
Q.1	87.35	78.6	82.3%	14	84.42	78.6	100	17
Q.2			82.3%	14			82.3	14
Q.3			64.7%	11			58.8	10
Q.4			70.5%	12			70.5	12
Q.5			94.1%	16			94.1	16
Q.6			94.1%	16			94.1	16
Q.7			100%	17			94.1	16
Q.8			94.1%	16			82.3	14
Q.9			100%	17			94.1	16
Q.10			76.5%	13			82.3	14
Q.11			100%	17			88.2	15
Q.12			88.2%	15			82.3	14
Q.13			88.2%	15			88.3	15
Q.14			88.2%	15			70.5	12

I-CVI: Item Content Validity Index, S-CVI: Scale Content Validity Index (with mean approach), IRA: Inter Rater Agreement

Reliability

To assess the internal consistency based on the Likert scale (Q1 to Q14), we used Cronbach's Alpha. According to the results, the internal consistency of the BHQ was excellent (Cronbach's Alpha = 0.93). Also, the reliability of the instrument was measured by the ICC and for each question by comparing the total score of the questionnaire filled by people at two different times (with 2 to 3-week intervals).

The calculated ICC index for qualitative variables showed that the internal consistency of most of the questions was acceptable; questions with ICC < 0.7 were removed from the questionnaire.

Table 2
Test-retest reliability

Question	Intraclass correlation Coefficient (ICC)
Q.1	0.81
Q.2	0.89
Q.3	0.73
Q.4	0.71
Q.5*	0.50
Q.6	0.71
Q.7	0.80
Q.8	0.74
Q.9*	0.34
Q.10	0.81
Q.11	0.76
Q.12	0.71
Q.13	0.75
Q.14*	0.43
*Excluded questions	

The minimum and maximum overall scores for the questionnaire were 14 and 70, respectively. The overall mean score of BH was 55.86 ± 11.57 . The result of the analysis revealed that among different variables, age was the only variable, which had a significant relationship with BH, and older women had a higher score of BH. The results are shown in Table 3.

Table 3
Sociodemographic characteristics of all patients and their association with breast health

Variable	Mean \pm standard deviation		P-value
Age	42.69 \pm 10.29		0.019
Lactation	22.46 \pm 22.7		0.759
Parity	1.87 \pm 1.49		0.807
Variable	Yes, N (%)	No, N (%)	P-value
Miscarriage	72 (21.2%)	258 (75.9%)	0.434
Menopause	70 (20.6)	259 (76.2%)	0.335
Family history of breast cancer	52 (15.3%)	284 (83.5%)	0.41
History of benign breast surgery	40 (11.8)	296 (87.1%)	0.161

Discussion

This study aimed to develop a new questionnaire for measuring BH in women, assess the validity and reliability of the instrument, and evaluate the status of BH in a group of women who did not have breast cancer and were not at an immediate risk for the disease according to imaging and physical examination. Results of the study provided evidence that the designed tool yielded a reliable and valid 11-item BHQ for evaluating BH. The process started with designing and developing the instrument, followed by measurement of IRA, content validity study including I-CVI and S-CVI, and finally reliability (through internal consistency and test-retest).

Based on the results, the IRA index obtained for the instrument (78.6%) indicates optimal relevance and clarity of the questionnaire. Also, the content validity of the final BHQ is acceptable: the S-CVI, which is one of the most important indices in designing an instrument [27], is acceptable (87.35 and 84.42 for clarity and relevance, respectively); and one question was disqualified and eliminated based on I-CVI less than 70%. Reliability is a term that is used to describe the consistency of a measure. Essentially, if findings can be replicated consistently, they are considered to be reliable [30]. In our study, the internal reliability of the BHQ was found to be high with a Cronbach's alpha of 0.93, which shows the excellent consistency of the questionnaire. For external consistency, three of the questions showed an ICC less than 0.7 and were removed from the questionnaire; the rest of the questions showed good and excellent reliability. Thus, a valid reliable 11-item BHQ was developed.

In the second part of the study, measurement of BH in the eligible women who attended the Breast Clinic of Arash Women's Hospital showed an overall score of 55.86 ± 11.57 . According to the findings, among different variables, which could affect BH, age was the only one that showed a significant relationship with BH; older women showed a higher BH score. It might be assumed that this is because understanding

and correctly answering questions of a survey are more difficult for elder people and the results are biased. However, it has been shown that short questionnaires usually do not induce such a bias, contrary to lengthy ones [31]. Also, it has been mentioned that life satisfaction usually does not decrease with increasing age [32], and even living with a disease beyond a certain time leads to increased levels of wellbeing [33]. Actually, this finding in our study might be attributed to the fact that older women had lived a longer time without any important breast lesion, and were somehow reassured about their BH.

Our study showed that the history of breast surgery for benign lesions does not affect BH. A study conducted by Klassen et al revealed that cosmetic and reconstructive breast surgery affect the psychological well-being of women [34], and higher satisfaction and psychological well-being were detected after breast reconstruction in the study of NG et al [35]. However, these types of surgery aim to resolve a defect or compensate for a subject of dissatisfaction of the patients and expectedly yield positive feelings. However, the BH perception of these patients has not been evaluated in these or other studies; our questionnaire can be used for this purpose in the future.

Having a family history of breast cancer was evaluated as a potential feature that could affect BH, but according to the results, there was no significant difference between women with a positive or negative family history. This finding is consistent with a previous study conducted by Al-Naggar et al., which reported that a family history of cancer does not influence the QOL [36]. However, Abu-Helaleh et al reported positive family history of breast cancer as an important predictor of low QOL [37].

Other factors, which were considered and evaluated as a potential predictor of BH, were menopause, lactation, parity, and miscarriage; none of them showed any significant relationship with BH.

Our study had some limitations. We did not differentiate women with healthy breasts from those with mild benign disorders (fibrocystic changes and small fibroadenomas). Also, we did not include women who had undergone previous cosmetic breast surgery and only evaluated surgery for a benign lesion. In addition, we did not evaluate the BH status of patients with previous breast cancer. The BHQ is now in Farsi, the English translation and validation should be performed in the next step to make it usable for a wide population.

Conclusion

This study introduces an 11-item BHQ that can be used in various situations for the assessment of BH. We propose its use in breast cancer survivors at different stages of diagnosis, treatment, survivorship, and follow-up, in women at high risk for the cancer, and in various conditions throughout breast cancer screening.

List Of Abbreviations

BH= breast health, BHQ= breast health questionnaire, I-CVI= content validity index, S-CVI= scale content validity index , ICC= intraclass correlation coefficient

Declarations

Ethics approval and consent to participate: This study has been approved in the Ethics Committee of Tehran University of Medical Sciences, Ethics code: IR.TUMS.IKHC.REC.1399.112. All the participants consented to take part in the study by informed written consent. All methods were performed in accordance with the relevant guidelines and regulations.

Consent for publication: Not applicable

Availability of data and materials: Not applicable

Competing interests: Not applicable

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Authors' contributions: SA: conception and design of the project, interpretation of data, substantial revision of the manuscript, approval of the submitted manuscript; HR: analysis of data, drafting the manuscript, approval of the submitted manuscript; KM: analysis and interpretation of data, drafting the manuscript, approval of the submitted manuscript; MO: design of the project, acquisition of data, approval of the submitted manuscript; YE: conception of the project, acquisition of data, revision of the manuscript, approval of the submitted manuscript

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