

Original Article



Construction and Validation of Breast Cancer Awareness Scale in Iranian Women

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Abstract

Introduction: Application of a single valid and reliable questionnaire in future studies in the area of Iranian women's awareness of breast cancer provides the health policymakers with a comprehensive view over the issue. In designing the current questionnaires in Iran, the prior researchers neither explained about the design procedure, nor calculated the validity and reliability of the questionnaire completely. In this regard, researchers decided to design a standard questionnaire to examine women's awareness about the symptoms and risk factors of the breast cancer.

Methods: This methodological study was conducted on 250 women in Yazd. Data were collected by a researcher-made questionnaire. The reliability was determined using the Cronbach's alpha and test-retest method. Factor analysis was used to determine the construct validity in SPSS version 21.

Results: The face validity of the questionnaire was evaluated by the target population. The results of the impact score indicated that all questions had a score equal or greater than 1.5. The qualitative content validity of the questionnaire was evaluated by the expert panel. Content validity ratio (CVR) and content validity index (CVI) obtained close to one for questionnaire. Construct validity was confirmed by performing factor analysis and dimensions of the questionnaire were determined. Cronbach's alpha coefficient for all dimensions was higher than 0.8. Also, intraclass correlation coefficient (ICC) for all dimensions was close to one and was between 0.84-0.95.

Conclusion: Validity and reliability of designed questionnaire in this study for Iranian women are acceptable and suitable.

Introduction

Increasing the incidence of breast cancer in developing countries has become a worrying issue. It was estimated that more than half the incidence of breast cancer in women were occurring in less developed countries.^{1,2} In Iran, breast cancer has been identified as the most common cancer among women and is also the fifth common cause of death among Iranian women.³ Cancer detection in advanced stages can be due to a low level of women's awareness of risk factors as well as signs and symptoms of breast cancer. In Iran, the contributing factors in the incidence of cancer are very diverse and widespread. Family history of breast cancer, old age, exposure to radiation, Menopause after age 55, menstruation before age 12, inactivity and obesity are risk factors for breast cancer.⁴ In the study of Roohparvarzade et al., the most important risk factors for breast cancer were drug addiction, incorrect lifestyle, high-fat diet, lack

of some micronutrients, and environmental risk factors such as air pollution, occupational exposure.⁵ In the study of Lee et al., the age of the first pregnancy was the main risk factor for breast cancer.⁶ In the study of Brady and Graham, first live birth after age 30 years was the main risk factor for breast cancer, which increased the incidence of breast cancer by 30%.⁷ In the study of Romieu et al., the risk of breast cancer is reduced by increasing lactation duration. Accordingly, a 99% reduction in breast cancer was observed for every 10 months of lactation.⁸ The main signs and symptoms of breast cancer include painless and palpable breast lump, painless mass under the armpit, bleeding or discharge from the nipple, abrupt changes in the shape or size of the breast, wound around the nipple, pulling of the nipple inward, nipple rash, redness of the breast skin (erythema).⁹

Women's awareness of the signs and symptoms of breast cancer can be effective in the early detection of this cancer.

The first step in measuring women's awareness about breast cancer is application a good questionnaire. If we have a valid questionnaire, we can correctly measure the impact of educational interventions. Some questionnaire have been developed for the Western countries such as Stubbings et al.,¹⁰ Linsell et al.,¹¹ Özalp et al.,¹² and Pud.¹³ However, the use of the questionnaires designed for the Western countries is not valid for Iranian women.

Some of the questionnaires were also not fully validated such as Norlaili et al.,¹⁴ Ranasinghe et al.,¹⁵ Liu et al.¹⁶, Sathian et al.,¹⁷ Mazloomi Mahmoodabad and Khodayarian¹ and Roohparvarzade et al.⁵ A survey of existing questionnaires in this regard showed that Breast-CAM designed by Linsell et al., for women in the UK was fully validated. But this questionnaire has a number of limitations. For example, in their study, only the age was evaluated among the risk factors and in the field of the timing of diagnostic tests, there is only one question about the time of checking breast. In addition, the design of this questionnaire was based on British mammographic screening program. This questionnaire also was designed for Western women who are different from Asian women.¹¹

Considering the several researcher-made questionnaires designed to measure women's awareness of the signs and risk factors of breast cancer and regarding the discrepancies about the results of these studies, researchers decided to design a standard questionnaire for investigating women's awareness of the symptoms and risk factors of breast cancer; so that other researchers can conduct studies with a standard tool and compare the results of studies together.

Material and Methods

This methodological study was conducted in Yazd. The target populations in this study were women living in Yazd aged over 20 years who were willing to participate in the study. Exclusion criteria included pregnant, breastfeeding and illiterate women, having a history of breast cancer and those who did not want to participate in the study.

The sample size was calculated as 240 women which was increased to 250 women to account for potential missing cases based on CI = 95%, SD = 5.56 based on a similar study¹ and error estimation of the mean of 0.7. Yazd's health centers were divided into 10 clusters; 25 families from each cluster were randomly selected.

Data was collected using a questionnaire. Initially, researchers searched articles in databases including PubMed, Scopus, Science Direct, Medline, EMBASE and Scientific Information Database (SID) and Iran Medex. All studies about awareness of breast cancer were collected. Main keywords used for searching including breast cancer, awareness, knowledge, questionnaire, women, and Iran. Then, to design the questionnaire, a series of studies related to breast cancer awareness was reviewed. Researchers also studied the questionnaires about women's knowledge of breast cancer. Eventually, a set of questions was gathered.

The initial design of the questionnaire was carried out with a pattern of studies and questionnaires obtained. The initial questionnaire consisted of 32 questions in 3 dimensions including knowledge of risk factors, knowledge of signs and symptoms and knowledge of best time to do diagnostic tests.

For the questions related to risk factors and signs and symptoms, three Likert-type scaling was used (1=no, 2=no comment, 3=yes). The scoring for questions in the dimension of the knowledge of best time to do diagnostic tests was as follows: correct had a score of one (1) and an answer designated as 'wrong' was marked zero (0).

Face validity was evaluated both using qualitative and quantitative methods. The qualitative face validity was evaluated by the target group (10 women). They examined the questionnaire in terms of relevancy, ambiguous and difficulty. For quantitative face validity, the questionnaire was distributed to 10 women. They were also asked to give a score to each question (strongly importance =5, quite a lot importance=4, moderate importance=3, slightly importance=2, not at all=1). Then impact score was calculated based on the following formula: (Impact Score= frequency (%) × importance).¹⁸

Content validity was evaluated both using qualitative and quantitative methods. In order to assess the qualitative content validity, the questionnaire was distributed to 10 experts composed of related specialties included gynecologist, oncologist, gynecological surgery, health education, nutritionist, statistics specialist, midwife and prominent researchers in the field of questionnaire design. They were asked to comment on the appearance, grammar, wording, item allocation, scaling, writing style of questions and putting the proper words in the sentence. The changes were made in the questionnaire according to their opinions.

Content validity ratio (CVR) and content validity index (CVI) were used to evaluate quantitatively content validity. For this purpose, the questionnaire was provided to 10 relevant experts and asked them to choose an option for each question included: "Essential", "Useful, but not essential" and "No necessary". Then CVR was calculated for each question based on Lawshe formula.¹⁹

The CVI was calculated for each question based on Waltz and Basel Index.¹⁸ Therefore, the questionnaire was provided to 10 relevant experts and asked them to evaluate three criteria (simplicity, relevancy and specificity, clarity) based on the 4-point Likert-type scaling (for example irrelevant, somewhat related, related, quite relevant). CVI is measured by the total number of agree score with grade 3 and 4 for each item divided by the total number of responses. The CVI, score more than 0.79 is acceptable.²⁰ Construct validity was confirmed by performing factor analysis and dimensions of the questionnaire were determined.

Cronbach's alpha coefficient and test re-test were used to assess the reliability of the questionnaire. Intraclass

correlation coefficient (ICC) was used for test-retest in this study. According to this method, the questionnaire was completed by 40 people and after 4 weeks the questionnaire was completed again by the same people. Then, ICC was calculated for all dimensions of the questionnaire. If ICC is close to one, it shows that the questionnaire has high stability. Cronbach's alpha coefficient was used to measure internal consistency. If Cronbach's alpha is close to one, it shows that the internal consistency between questions is high.

The researchers referred to the health centers for completing the questionnaires. The starting point of households covered by each health center was randomly selected. The participants were met in their homes by researchers. Then, the next house was selected with a distance of 5 households. Researchers explained the purpose of the study for women, and then questionnaires were completed by women. If women were asked a question while completing the questionnaire, the interviewers helped them through face-to-face interviews.

The SPSS version 21 was used for statistical analyses. Descriptive statistics, *t* test, ANOVA and Pearson's correlation were used for determining the relationship between socio-demographic variables and knowledge. Also, factor analysis was used to determine the construct validity of the questionnaire. The reliability of the questionnaire was determined using the Cronbach alpha coefficient and the test retest method.

Researchers before completing the questionnaire explained the aim of the study to participants. Participation in the study was also voluntary.

Results

The results showed that most of the women were married (88.7%), with diploma education (37.1%), housewife (78.2%), with body mass index (BMI) of 25-29.9 (39.9%), and in the age group of 26-35 years (48%). In addition, the mean of age was 34.13(9.9) years.

Initially, the researchers designed questions (32 items) using existing questionnaires and studies. Then, the face validity of the questionnaire was evaluated by the target population. Then, required changes made in the questionnaire after reviewing the suggestions and comments. The results of the impact score indicated that all questions had a score equal or greater than 1.5. Therefore, they were included in the questionnaire.

The results of content validity indicated that all questions except question 11 had CVI higher than 0.79. Therefore; they were included in the questionnaire. Question 11 had CVI between 0.7-0.79 that needed to be modified and revised. This question was also entered into the questionnaire after the change. The results of CVR showed that all experts chose the "necessary" option for all questions. Therefore, CVR was obtained as one for all questions. At this stage, 32 items were included in the questionnaire.

Construct validity was confirmed by performing factor analysis and the dimensions of the questionnaire were determined. In this study, the Kaiser-Meyer-Olkin statistic was 0.889. This means that the data are suitable for performing factor analysis. The results of the Bartlett test were also significant. This means that the opposite assumption was confirmed and there was a significant correlation between variables ($P < 0.001$). The results showed that most extraction rates were higher than 50%. This indicated the ability of the determined factors to explain the variance of the studied variables. There were also differences in the amount of extraction. The extraction rates were between 0.54-0.93.

Table 1 shows the results of factor analysis, dimensions of questionnaire and questions of each dimension. According to the results of the factor analysis using principal components analysis, 3 dimensions were extracted with an eigenvalue greater than one that determined 75.92% of the variance of knowledge. If the obtained factors were rotated with varimax rotation, the first, second and third factors determined 32.26%, 28.06% and 15.6% of the variance of knowledge, respectively. Dimensions based on Eigenvalue included: 1- Knowledge of risk factors (18 questions), 2- Knowledge of signs and symptoms (8 questions), 3- Knowledge of best time to do diagnostic tests (5 questions). After performing factor analysis, 1 question was deleted from the questionnaire. At this stage, 31 items were included in the questionnaire.

A 3-point Likert-type range was used for scaling of knowledge of risk factors and knowledge of signs and symptoms (1= no, 2= no comment, 3= yes). The responses of knowledge of best time to do diagnostic tests were coded as either 0= incorrect answer and 1 = correct answer. The risk factors knowledge score of 18-30, 30.1-43, and 43.1-54 were considered as poor, moderate and good, respectively. The signs and symptoms knowledge score of 8-13, 13.1-18, and 18.1-24 were considered as poor, moderate and good, respectively.

The results of reliability indicated that Cronbach's alpha coefficient for all dimensions was higher than 0.8 (Table 2). The dimension of the knowledge of signs and symptoms had the highest Cronbach's alpha (0.93). The results also showed that ICC for all dimensions was close to one and was between 0.84-0.95. The dimension of the knowledge of signs and symptoms had the highest ICC (0.95).

Table 3 showed the mean and standard deviation for dimensions of the questionnaire. The results showed that women's knowledge about all dimensions was low. The results also showed that 37.9% of women had poor knowledge of signs and symptoms, 28.9% moderate and 33.2% good. Also, the awareness of 35.5% of women about breast cancer risk factors was poor, 48% moderate and 16.4% good. The current study found that the awareness of 46.5% of women about the best time to do diagnostic tests was poor, 45.7% moderate and 7.8% good.

According to the results, approximately half of women

Table 1. Factor analysis using principal component

Dimensions	Factor loading	Eigen values	% Of variance	Cumulative %
Factor 1(Knowledge of risk factors)		7.21	32.26	32.26
1. History of breast cancer in first-degree relative	0.5			
2. Use oral contraceptive pills more than 5 years	0.66			
3. Hormone therapy after menopause	0.73			
4. Started menstruating before age 12	0.56			
5. Late menopause (after age 55)	0.6			
6. Giving birth for the first time after age 30	0.53			
7. Not having a childbirth experience	0.59			
8. Low physical activity	0.61			
9. Overweight and obesity	0.53			
10. Age over 40 years	0.53			
11. High radiation to the chest or breast in childhood or adolescence (radiation therapy)	0.72			
12. Lack of breastfeeding	0.54			
13. Smoking or alcohol consumption in the past or present	0.72			
14. Stress	0.59			
15. High consumption of red meat	0.55			
16. Low consumption of vegetables and fruits	0.57			
17. High consumption of fatty foods	0.73			
18. History of benign breast disease	0.72			
Factor 2(Knowledge of signs and symptoms)		5.6	28.06	60.32
19. Painless and palpable breast lump	0.78			
20. Painless mass under armpit	0.74			
21. Bleeding or discharge from the nipple	0.83			
22. pulling of the nipple inward	0.83			
23. Wound around the nipple	0.76			
24. Redness of the breast skin	0.78			
25. Abrupt changes in the size of the breast	0.79			
26. Abrupt changes in the shape of the breast	0.86			
Factor 3(Knowledge of best time to do diagnostic tests)		1.7	15.6	75.92
27. When is the best time to start the breast exam by the doctor or midwife?	0.49			
28. When is the best time to start mammography?	0.75			
29. When is the best time to start self-breast exam?	0.61			
30. When is the best time to do monthly self-breast exam in menstrual cycle?	0.83			

Table 2. Reliability coefficients of questionnaire

Dimensions	Cronbach's alpha	ICC	P value
Knowledge of risk factors	0.9	0.9	<0.001
Knowledge of signs and symptoms	0.93	0.95	<0.001
Knowledge of best time to do diagnostic tests	0.87	0.84	<0.001

Table 3. Mean score of dimensions of questionnaire

Dimensions	Mean (SD)	Range
Knowledge of risk factors	34.27(9.7)	18-54
Knowledge of signs and symptoms	15.3(5.7)	8-24
Knowledge of best time to do diagnostic tests	1.69(0.2)	0-5

reported that stress, overweight, obesity, and history of breast cancer in the first-degree relative were risk factors for breast cancer. However, the level of awareness of other risk factors was less than 50%. The results of ANOVA test showed that staffs and students had the highest mean of knowledge in the dimension of signs and symptoms; housewives had the lowest mean than others ($P= 0.016$). The results showed that the mean of knowledge of signs and symptoms increased with the increase in educational level ($P= 0.006$). There was no significant difference between the mean of the dimensions of breast cancer knowledge with marital status, age and BMI.

Discussion

In this study, researchers tried to design a comprehensive tool for women's awareness of breast cancer. The face and content validity of the questionnaire was examined and verified by relevant experts. The results showed that CVR got one for all questions. This means that all questions could be used in the questionnaire. According to the results of this index, the essential and important questions are in this questionnaire. Given that, CVI score more than 0.79 is acceptable, the questions in this questionnaire are best designed to measure the content.

The results showed that 3 dimensions were identified and confirmed with varimax rotation; dimensions based on eigenvalue included: Knowledge of risk factors, knowledge of signs and symptoms, Knowledge of best time to do diagnostic tests. Also, factor loading for all questions was higher than 0.4 that was an acceptable value. Some dimensions of this questionnaire were consistent with previous studies included awareness of signs and symptoms and awareness of risk factors for breast cancer.^{17, 21-24}

Although the reliability test of the questionnaire is not a sufficient method, it is necessary.²⁵ Cronbach's alpha coefficient is one of the common methods for determining the consistency of the questionnaire. If the Cronbach Alpha is close to one, it indicates the internal consistency between questions.²⁶ The results of this study showed that Cronbach's alpha was close to one. This indicated that consistency of the questionnaire was appropriate. One method for measuring reliability is using test retests. This is a suitable method for determining the consistency of the questionnaire over a period of time. If the results of the distribution of the questionnaire in two periods were significantly correlated, it indicated high repeatability for the questionnaire.²⁶ The result of this study indicated that ICC for all dimensions was close to one. So if this questionnaire is used at different times on the same people, the same results will be achieved. Therefore, stability of the questionnaire was appropriate.

The review of studies conducted to measure women's awareness of breast cancer showed that questionnaires used in most of these studies have been self-made. Most of the questionnaires did not include all symptoms or risk

factors. Some researchers not only assess the awareness of women in this regard but also verify the reliability and validity of the questionnaire in a very simple way.

Most instruments were not thoroughly validated or had limitations on statistical methods. Mazloomi Mahmoodabad and Khodayarian, Roohparvarzade et al., examined only qualitative face and content validity and reliability by Cronbach's alpha.^{1,5} Some studies have not mentioned the validity and reliability of their questionnaire.^{3,27,28} Some studies have also used questionnaires designed for other countries.²⁹ While using tools designed for other countries may not be valid for Iranian women.

Some scales were also designed based on health education models such as theory of planned behavior and health belief model.^{30,31} The standard questionnaire in this study was designed for the general population of women, which is the advantage of this questionnaire. While some questionnaires were designed for a specific population, such as questionnaire designed by developed by Cancer Research UK, King's College London and University College London (Breast - CAM scale) that examined the awareness of older women. The questionnaire designed by them also has 3 dimensions: awareness of signs, awareness of risk factors and reported frequency of screening for breast cancer.¹¹

One of the weak points of their study is that among the risk factors, only the age was evaluated by one questionnaire. In addition, in the field of timing of diagnostic tests, there is only one question about the time of checking breast. But their questions about the symptoms were complete and like our study.

Some questionnaires were also designed to examine certain behaviors such as breast self-examination or breast cancer screening.^{23,32,33} Also, outside of Iran; researchers designed questionnaires for assessing women's awareness of breast cancer and examined their validity and reliability, such as a questionnaire designed for women in Pakistan and Egypt.^{34,35}

The revised Chinese version of Breast-Cancer Awareness Measure (Chinese Breast - CAM scale) had 27 questions in 5 dimensions. The validity of this questionnaire was evaluated by 6 experts. The CVI was approved with a value of 0.93. In addition, retest reliability was 0.763 which found within the acceptable range.³⁶

Rakkapao et al., designed a questionnaire for assessing women's awareness (B-CAS) in Thailand. Their questionnaire had five dimensions (awareness of risk factors, awareness of signs and symptoms, attitudes towards cancer prevention, barriers of breast cancer screening, and health behavior related to knowledge of breast cancer). The researchers used exploratory factor analysis to investigate construct validity, and Cronbach's alpha method to confirm the reliability of the questionnaire. Reliability of the questionnaire was confirmed with alpha higher than 0.7.³⁷ One of the weak

points of their study is that the title of the questionnaire is awareness measurement but attitudes and barriers are the dimensions of the questionnaire.

Solikhah et al., developed B-CAS for Indonesian people. Construct validity of the questionnaire in their study was verified using confirmatory factor analysis. The questionnaire designed by them had 5 dimensions. The reliability of the modified version for the Indonesian population was better than the previous version ($\alpha=0.79$).³⁸ A questionnaire was designed for the Ajman (United Arab Emirates) population with three dimensions (awareness of risk factors, knowledge of signs and symptoms, and early detection methods for breast cancer). The number of questions in their questionnaire was limited. The reliability of the questionnaire was confirmed by Cronbach's alpha ($\alpha = 0.85$).³⁹

The results of this study showed that the knowledge of women about breast cancer was poor and moderate. In this study, only 33.2% of women had good knowledge. This result is consistent with Ramezani et al., study.⁴⁰ In general, the highest awareness of risk factors was related to lifestyle risk factors such as obesity, stress, type of diet, lack of exercise, etc. that are consistent with the other studies.^{3,5} Some studies have shown that the incidence of breast cancer increases with increasing age, smoking, obesity, low physical activity, exposure to radiation, alcohol consumption and high-fat diet.⁴¹ Morimoto et al., showed that late menopause is one of the main risk factors for breast cancer,⁴² but in the present study, late menopause has the lowest level of awareness among breast cancer risk factors. Ramezani et al., also indicated a strong impact of first live birth after age 30 years as a main risk factor for breast cancer,⁴⁰ but unfortunately, the level of awareness of this risk factor was also low in this study, which is consistent with the same study.

Comparison of this questionnaire with the similar questionnaires in Iran showed that existing research tools had some weaknesses that were resolved in this questionnaire. The face validity of this questionnaire has been evaluated by the target population. It leads to questionnaire has more acceptance among women and high response rates. While in some studies, for determining face validity, the questionnaire was not evaluated by the target population and the samples were not used in the evaluation of the questionnaire.^{1,5}

A survey of existing questionnaires in this regard in Iran showed that none of the studies fully explained about design their questionnaire, standards and the methods used to determine validity and reliability. It's the first research instrument in regard to breast cancer awareness that its evaluation process and validity is evaluated completely. In terms of statistics, this questionnaire had excellent stability and internal consistency. The appropriate statistical evaluation shows that this questionnaire is a complete tool.

An important advantage of this questionnaire in

comparison with existing tools is that it measures awareness in three dimensions of risk factors, symptoms and best timing of diagnosis tests, while the other questionnaires were not comprehensive. In addition, researchers tried to exclude questions that were in the limit of a hypothesis. Therefore, the questions have a logical comprehensiveness. In most studies, the target population was women who referred to health centers or hospitalized patients, but there are not representative of the community. Therefore, these questionnaires may not be able to extract correct information. One of the benefits of this questionnaire is that it is designed for the general population of women. The limitations of this study are lack of qualitative study before designing the questionnaire and lack of standard timeframe for completing the questionnaire. It is suggested that future studies measure women's awareness of breast cancer based on urban and rural areas.

Conclusion

The designed questionnaire in this study is a questionnaire with high reliability and validity, which is self-report and complete easily and without much time and money. If this standard questionnaire is used in all parts of Iran to examine women's awareness of breast cancer, due to the uniformity of the tool, a comprehensive understanding of Iranian women's awareness of breast cancer is created for researchers, health providers, policymakers, health planners and doctors.

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Ethical Issues

This article has a license from the research ethics committees of Shahid Sadoughi University of Medical Sciences, code IR.SSU.SPH.REC.1395.80.

Conflict of Interest

The authors declare no conflict of interest in this study.

Author's Contributions

Conception and design: MM; Acquisition of data: MM; Analysis

Research Highlights

What is the current knowledge?

Lack of a comprehensive and standardized questionnaire whose validity and reliability have been thoroughly investigated to assess women's awareness of the symptoms and risk factors for breast cancer in Iranian population.

What is new here?

The questionnaire designed in this study is a comprehensive and standard questionnaire with high validity and reliability to assess women's awareness of the symptoms and risk factors for breast cancer in Iranian population.

and interpretation of data: MM, HF; Drafting the article: MM, HF; Review of article and find approval: MM, HF.

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