



## Validation of a newly developed questionnaire regarding clinical history in patients with breast and colorectal cancers

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### Original Article

#### Abstract

**BACKGROUND:** Understanding the close interaction between the specialties of cardiology and oncology is necessary for early detection of cardiovascular disease (CVD) events in cancer patients. For the risk assessment of CVD in Breast and Colorectal Cancers (CIBC) study, in the current study we aimed to validate a questionnaire for the assessment of clinical history in patients with breast cancer and colorectal cancer (CRC).

**METHODS:** We determined the content validity of the questionnaire using the 2 indexes of content validity ratio (CVR) and content validity index (CVI) to examine the specificity, simplicity, clarity, and transparency of the items. Content validity assessment was performed through a panel of experts including 2 oncologists, 5 cardiologists, 2 general practitioners, and 1 epidemiologist. The reliability of the questionnaire was estimated using Cronbach's alpha coefficient in 50 patients. Intraclass correlation coefficient (ICC) was used to examine the reproducibility of the questionnaire during 1 week.

**RESULTS:** The CRC and breast cancer questionnaire were designed with 16 and 32 questions, respectively. To obtain acceptable CVR, 5 and 11 questions were removed from the CRC and breast cancer questionnaires, respectively. Cronbach's alpha was 0.70 in the breast cancer questionnaire and 0.94 in the CRC questionnaire. All questions had a CVI of higher than 80%. The ICC in the breast cancer questionnaire ranged between 0.71 and 0.96 and in CRC questionnaire ranged between 0.78 and 0.98.

**CONCLUSION:** The validity and reliability of our newly developed questionnaire was desirable. The reliability of the breast cancer questions was acceptable and that of the CRC questions was excellent. Thus, this questionnaire can be used in this group of patients regardless of whether the goal is cardiac care or not.

**Keywords:** Breast Cancer; Colorectal Cancer; Cardiovascular Disease; Questionnaire; Validity; Reliability

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## Introduction

Cancers is the third leading cause of death after heart disease and accidents.<sup>1</sup> Breast cancer is one of the most common malignancies among women worldwide and the second leading cause of death in American women, and during a woman's lifetime the chance of having invasive breast cancer is approximately 1 in 8.<sup>2</sup> In Iran, breast cancer is recognized as the most common type of cancer, and according to studies, it accounts for 16% of all cancers.<sup>3</sup> Colorectal cancer (CRC) is also 1 of the 4 most common cancers worldwide. According to the annual report of the Iranian Ministry of Health, CRC has been the second most common cancer in women and the fourth in men, the incidence of which has increased over the last 25 years.<sup>4,5</sup>

Cancer treatments include a combination of treatments such as surgery, chemotherapy, hormone replacement therapy, targeted therapy, and radiotherapy, which are usually used to improve overall survival. Some of these treatments, such as chemotherapy, left-handed radiotherapy, and targeted therapy are associated with cardiac toxicity, and women who have survived breast cancer are at greater risk of developing cardiovascular diseases (CVDs) than women without breast cancer.<sup>6-8</sup> Cardiotoxicity is a common complication of many drugs prescribed for the treatment of cancer and poses a serious threat to the safety and prognosis of patients. Cardiac manifestations of anticancer drugs include hypotension, ischemia, heart failure, QT prolongation, arrhythmia, and thromboembolism.<sup>9</sup>

Close interaction between these 2 specialties is needed for the early detection of cardiac injury and the optimal care of many cancer patients.<sup>10</sup>

Due to the importance of CVD events and their impact on mortality and morbidity in cancer patients, we decided to perform a cohort study to evaluate a cardiovascular risk assessment model that can predict the occurrence of CVD events in patients with breast cancer and CRC (CIBC study). To the best of our knowledge, there were few questionnaires regarding cancer history in Iran. Thus, this study aimed to validate the questionnaire

used for patients with either breast cancer or CRCs, which are the most common cancers in our country.

## Materials and Methods

**Questionnaire development:** To develop the initial questionnaire, we searched different databases including PubMed, Scopus, ISI, and Google Scholar and extracted the basic questions on breast cancer and CRC. We drew the flow chart and designed the initial questionnaire after reviewing and approving of 3 oncologists.

**Face validity:** The face validity, reasonableness, appropriateness, attractiveness, and logical sequence of items of the questionnaire were evaluated by 5 oncologists and cardiologists.

**Content Validity:** Content validity ratio (CVR) and content validity index (CVI) were used to evaluate the content validity of the questionnaire. The content validity was evaluated by an expert panel. The panel members included 2 oncologists, 5 cardiologists, 2 general practitioners, and 1 epidemiologist.

To calculate CVR, we asked experts to specify whether an item was necessary. Then, each item was scored on a 3-point scale ranging between 1 and 3 (not necessary, useful but not essential, and essential).

Subsequently, CVR was calculated based on Lawshe's CVR,<sup>11</sup>  $CVR = (N_e - N/2)/(N/2)$ , where  $N_e$  is the number of panelists indicating "essential" and  $N$  is the total number of panelists. In validating the questionnaire, CVR value was computed for each item using the following formula:

$$CVR = \frac{n_e - n/2}{n/2}$$

The numeric value of CVR is determined using Lawshe's table.<sup>11</sup> In this table the minimum acceptable CVR for each item is determined based on the number of experts who evaluated the questions. Questions for which the calculated CVR value is less than the number specified in tables 1 and 2 were excluded from the questionnaire. Based on the number of experts ( $n = 10$ ) in this study, the acceptable value is 0.62.<sup>11</sup>

To examine the CVI, panel members rated each of the questions for their specificity, simplicity, clarity, or transparency based on a 4-point Likert scale ranging from 1 to 4 (I disagree, I have no opinion, I agree, and I agree very much). Finally, it was calculated using the following formula:

$$CVI = \frac{n_i}{n}$$

where  $n_i$  is the number of experts who have given a score of 3 and 4 and  $n$  is the total number of panel members. The minimum acceptable CVI is 79%, and if the index was lower than 79%, the item was deleted.<sup>1</sup>

**Reliability:** Cronbach's alpha coefficient was applied to assess the questionnaire's internal consistency (the level of relationship between the different items in the scale) in 50 patients. To evaluate reproducibility over time, the questionnaires were completed by 50 patients twice within 1 week. Then, intraclass correlation coefficient (ICC) was measured.

## Results

The study participants included 50 patients with breast cancer and CRC who were referred to the cardio-oncology clinic of Isfahan Cardiovascular Research Center, Iran, for cardiac evaluation.

The CRC and breast cancer questionnaires were designed with 16 and 32 questions, respectively. After CVR calculation, questions with an index value of less than 0.62 were considered as unacceptable and were removed. In the CRC questionnaire, 5 questions were deleted, (Table 1) and in the breast cancer questionnaire, 11 questions were deleted (Table 2).

In terms of specificity, simplicity, clarity, and transparency in the CVI, the index level of all questions in all areas was above 80% (Tables 1 and 2).

Cronbach's alpha of the breast cancer and CRC questionnaires was 0.70 and 0.94, respectively.

The ICC of the breast cancer questionnaire ranged between 0.71 (95% CI: 0.39-0.86) and 0.96 (95% CI: 0.92-0.98), and the ICC of the CRC questionnaire ranged between 0.78 (95% CI: 0.44-0.91) and 0.98 (95% CI: 0.94-0.99).

## Discussion

We can conclude that the validity and reliability of the questionnaire developed in the present study for the purpose of conducting the CIBC study were desirable. The CVR value for 30 questions (62.5%) was above 90% and 46 questions (95.8%) had a CVI of above 90%. The reliability of the breast cancer questions was acceptable, and that of the CRC questions was excellent.

In a study by Danesh et al., for determining the status of knowledge, attitude, and practice of women employed by the board of education in the field of breast self-examination in Shahrekord, Iran, a demographic characteristics questionnaire as well as a knowledge, attitude, and practice in breast self-

examination questionnaire were prepared, and the reliability of the questionnaire was determined to be 85% ( $n = 84$ ) using Cronbach's alpha.<sup>12</sup>

In another study by Naghibi et al., the theoretical face validity of the questionnaire was created.<sup>13</sup> This was done by identifying factors associated with breast cancer screening based on the PEN-3 model (one of the models for examining and studying behavior in health education and promotion factors that influence an individual's behavior) among teachers in the city of Kermanshah, Iran, using the content validity method, followed by consultation with 10 experts and specialists. The reliability of the questionnaire was determined by the Cronbach's alpha of each of the sections of the questionnaire, which included screening performance ( $\alpha = 0.80$ ), perceptual factors ( $\alpha = 0.81$ ), enabling factors ( $\alpha = 0.78$ ), and reinforcing factors ( $\alpha = 0.77$ ).<sup>13</sup>

The value of Cronbach's alpha in the studies by Naghibi et al.<sup>13</sup> was higher than that of our breast cancer questionnaire. Perhaps this is due to the larger sample size in those studies. In a questionnaire of another study that assessed the motivation theory among Iranian women regarding participation in breast cancer preventive behaviors, the reliability of the questionnaire was assessed using internal consistency and Cronbach's alpha coefficient, and values equal to or higher than 0.7 were considered as acceptable.<sup>14</sup> The Cronbach's alpha of their questionnaire was similar to that of our study.<sup>14</sup> In a study by Shouri Bidgoli et al. on the knowledge, attitude, and practice of people over 50 years of age regarding CRC screening, the content validity of the questionnaire was confirmed by experts with a Cronbach's alpha of 78% in 30 individuals.<sup>15</sup> In another study on physical activity in patients with CRC, the content validity of the questionnaire was confirmed based on the opinion of 10 experts and Cronbach's alpha of 0.7.<sup>16</sup> The Cronbach's alpha obtained in our study was higher than that in the studies by Shouri Bidgoli et al.<sup>15</sup> and Mahmoodi et al.<sup>16</sup>

In other similar studies, the value of Cronbach's alpha ranged between 0.61% and 0.094%, which was in line with the results of our study.<sup>17-20</sup>

In the studies by Heidari and Feizi<sup>18</sup> and Ashton-Prolla et al.,<sup>21</sup> the ICC of the questionnaire was 0.84, which was similar to that obtained in our study.<sup>18,21</sup>

In the studies by Grarup et al.<sup>22</sup> and Momayyezi and Fallahzadeh,<sup>23</sup> ICC values ranged between 0.84 and 0.95. This is also in line with our study findings.

**Table 1.** The content validity of the colorectal cancer questionnaire

Number	Colorectal cancer Questions	CVR	CVI specificity	CVI simplicity and fluency	CVI clarity and transparency	Status
1	Have you ever had colitis or Crohn's disease? 1-Yes 2-No	0.4	1	1	1	Rejected
2	Have you ever had familial colon polyps? 1-Yes 2- No	0.8	1	1	1	Accepted
3	Have you ever had a history of other cancers? 1- Yes 2- No	1	1	1	1	Accepted
4	If yes, the type? Do you have a history of cancer treatment? 1-Yes 2-No If yes, the type?	1	1	1	1	Accepted
5	Have you had weight loss in the last six months? 1-yes 2-No If yes, how many kilograms?	0.8	0.9	1	1	Accepted
6	Have you recently had chronic diarrhea? 1-yes 2-No If yes, your period of diarrhea: 1- Less than 2 weeks (acute) 2- 24 weeks (subacute) 3- More than 4 weeks (chronic)	1	0.8	1	0.9	Accepted
7	Has any of your relatives had a colorectal tumor? 1-Yes 2-No If yes, who? 1-1 <sup>st</sup> degree (father, mother, sister, brother, child) 2-2 <sup>nd</sup> degree (aunt, uncle) 3-3 <sup>rd</sup> degree (offspring of an aunt or uncle or uncle or aunt)	0.8	1	1	1	Accepted
8	Have you had a long history of taking painkillers other than acetaminophen? 1-Yes 2-No	-0.2	0.9	0.9	0.9	Rejected
9	Do you have a history of stomach disease? 1) Yes 2- No If yes, which case? 1- gastric ulcer 2- reflux 3- gastritis 4- gastric tumor	0.4	0.9	0.9	0.9	Rejected

**Table 1.** The content validity of the colorectal cancer questionnaire (continue)

Number	Colorectal cancer Questions	CVR	CVI specificity	CVI simplicity and fluency	CVI clarity and transparency	Status
10	Have you ever done a stool-screening test? 1- Yes                      2- No	1	0.9	0.9	0.9	Accepted
11	If yes, stool test results: 1- Abnormal 2- Normal 3- I do not know	1	0.9	1	1	Accepted
12	Have you ever undergone gastric endoscopy? 1- Yes                      2- No If yes, how long ago?	0.4	1	1	1	Accepted
13	If yes, present the document Endoscopy result:    1- Normal 2- Wound and inflammation 3- Tumor 4- I do not know	0.4	1	1	1	Rejected
14	Have you ever had gastrointestinal bleeding? 1-Yes                      2-No If yes, how was it? 1) Light color bleeding 2) excretion of dark stool	0.8	1	1	1	Accepted
15	Have you ever had a colonoscopy? 1- Yes                      2- No	1	1	1	1	Accepted
16	If yes, colonoscopy results: 1- Normal 2-Inflammation 3-Polyp 4- Tumors 5- I do not know	1	1	1	1	Accepted

**Table 2.** The content validity of the breast cancer questionnaire

Number	Breast cancer Questions	CVR	CVI specificity	CVI simplicity and fluency	CVI clarity and transparency	Status
1	When was your menstruation?	1	0.9	1	1	Accepted
2	Currently, are you pregnant? 1-Yes 2- No	0.8	0.9	1	1	Accepted
3	At what age was your first pregnancy?	1	0.9	1	1	Accepted
4	How old were you at your first live birth or full pregnancy?	1	0.9	1	1	Accepted
5	How old were you in your last pregnancy?	1	0.9	0.9	0.9	Accepted
6	How long ago was your last pregnancy?	0.63	0.9	1	1	Accepted
7	To date, how many pregnancies have you had (including: live birth, stillbirth, abortion, ectopic)?	0.63	0.9	1	1	Accepted
8	How many years were your pregnancy intervals?	0.4	0.9	0.9	1	Rejected
9	Lowest interval: ..... years	0.4	0.9	0.9	0.9	Rejected
10	Highest interval: ..... years	0.4	0.9	0.9	1	Rejected
11	How many live births have you had?	-0.2	0.9	0.9	0.9	Rejected
12	How many miscarriages and stillbirths have you had?	0	0.9	0.9	0.9	Rejected
13	Have you breastfed your babies? 1- Yes 2- No	0.8	0.9	1	1	Accepted
14	How many months was the lactation? Have you ever taken birth control pills? 1-Yes 2- No	1	1	1	1	Accepted
15	If yes, at what age did you start taking the pill? How many months have you been taking the pill? Have you taken birth control pills? 1. I am taking contraceptives right now. 2. I have not been taking contraceptives for less than a year. 3. I have not been taking contraceptives for 1-4 years. 4. I have not been taking contraceptives for more than 4 years.	1	1	1	1	Accepted
16	Has your period permanently stopped? 1) Yes 2) No	0.8	1	1	1	Accepted
17	Do you know at what age your menstrual cycle stopped? 1) yes 2) no If yes, at what age? What was the cause? 1) Normal menopause 2) Hysterectomy 3) Hysterectomy + removal of an ovary 4) Hysterectomy + removal of both ovaries 5) I do not know	0.4	1	1	1	Rejected

**Table 2.** The content validity of the breast cancer questionnaire (continue)

Number	Breast cancer Questions	CVR	CVI specificity	CVI simplicity and fluency	CVI clarity and transparency	Status
18	Have you ever taken hormone replacement after menstruation cessation? 1) Yes 2) No 3) I do not know	1	1	1	0.9	Accepted
19	Are you currently taking an alternative hormone medication after menstruation cessation? 1) Yes 2) No 3) I do not know	1	1	1	0.9	Accepted
20	If yes, how long have you been taking the hormone replacement: Month: Year: Have you been treated for infertility? 1) Yes 2 No If yes, the name of the medicine?	1	1	1	1	Accepted
21	How long are your menstrual intervals? 1) Less than 21 days 2) Between 21 and 35 days 3) More than 35 days 4) Irregular	0.4	1	1	1	Rejected
22	Have any of your relatives been diagnosed with breast cancer? 1-Yes 2-No If yes, who? -1 <sup>st</sup> degree (father, mother, sister, brother, child) -2 <sup>nd</sup> degree (aunt, uncle) -3 <sup>rd</sup> degree (offspring of an aunt or uncle or uncle or aunt)	1	1	1	1	Accepted
23	Do you have a history of surgery on the uterus? 1-Yes 2-No If yes, at what age? Type of diagnosis:	0.2	1	1	1	Rejected
24	Do you have a history of ovarian resection surgery? 1-Yes 2-No If yes, at what age?..... Type of diagnosis?	0.8	1	1	1	Accepted
25	Have you done regular monthly or non-monthly examinations of your breasts? 1-Yes 2-No	1	1	1	1	Accepted

**Table 2.** The content validity of the breast cancer questionnaire (continue)

Number	Breast cancer Questions	CVR	CVI specificity	CVI simplicity and fluency	CVI clarity and transparency	Status
26	Have you ever had a mammogram? 1-Yes 2-No If yes, how many times? How long ago?	1		1	1	Accepted
27	After how many mammograms, did suspicion arise for tumors? When was the last mammogram diagnosed with a tumor? 1-Less than 6 months ago 2- 6 months to 1 year ago 3-1 to 2 years ago 4- over 2 years ago	0.8		1	1	Accepted
28	Do you have a history of benign breast disease that has led to a breast biopsy? 1-Yes 2-No If yes, how many times?	1		1	0.9	Accepted
29	How many biopsies have led to the diagnosis? Do you have a history of specific birth defects in your family or relatives? 1-Yes 2-No	0.2		0.9	0.9	Rejected
30	If yes, who: -1 <sup>st</sup> degree (father, mother, sister, brother, child) -2 <sup>nd</sup> degree (aunt, uncle) -3 <sup>rd</sup> degree (offspring of an aunt or uncle or uncle or aunt)	0.2		0.9	0.9	Rejected
31	Who has diagnosed your illness? 1-myself 2-general practitioner 3-midwife 4-specialist physician	0		0.8	0.8	Rejected
32	Which of your breasts was involved? 1-Right 2-Left 3- Both	0.8		1	0.9	Accepted

### Conclusion

This questionnaire has good validity and reliability and can be used in breast cancer and CRC patients. Of the 48 questions designed for this questionnaire, 18 questions with a CVR of less than 0.62 were deleted from the questionnaire. Our goal was to make a tool for collecting data on a patient's clinical history in breast cancer and CRC patients.

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### Authors' Contribution

NS, NM, SH, and FA formulated the concept, designed the research, ZV, JN, MS, SM, AD, MK, FA, MS and MHE collected the data, ZV analyzed and interpreted the obtained data and wrote the text of the article, and NM and NS critically revised the article. All authors approved the final manuscript.

### Conflict of Interests

Authors have no conflict of interests.

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