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Validity and Reliability Analysis of the Body Image After Breast Cancer Questionnaire in the Turkish Population

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Abstract

Objective: The aim of this study is to evaluate the perception of body image in female patients with breast cancer using the Turkish version of the Body Image After Breast Cancer Questionnaire (tBIBCQ), to test its validity and reliability, and to determine the psychiatric features of patients.

Methods: The study group consisted of 80 patients aged 18-75 years with breast cancer. The control group comprised 80 patients of the same age with no history of cancer who were visiting an internal medicine specialist. A sociodemographic data form, the tBIBCQ, Beck Depression Inventory (BDI), and Beck Anxiety Inventory (BAI) were used as tools.

Results: The Cronbach's alpha value for tBIBCQ was 0.761. The Spearman–Brown correlation coefficient was found as 0.609. Eight factors for type 1 and 7 factors for type 2 described 73.4% and 70.2% of the total variance, respectively. The mean scores of vulnerability, body stigma (BS), limitations (L), body concerns (BC), transparency, and BAI subscales were higher in the study group. A positive correlation was found separately between the BAI and BDI with each BIBCQ subscale. Arm concerns (AC), BS, L, BAI, and BDI variables were higher in those who underwent surgery. Higher scores were obtained in patients with mastectomy compared with patients with lumpectomy in terms of BS, BC, AC, and BDI.

Conclusion: The tBIBCQ form is reliable and valid for detecting the effect of breast cancer on the body image of Turkish women.

Keywords: Breast cancer, body image, mastectomy

Introduction

Breast cancer is the most common with a frequency of 24.7% among all cancers in all age groups in women in Turkey.[1] Breast cancer treatment includes isolated or combined treatment options such as chemotherapy, radiotherapy, and hormone therapy other than surgery. Apart from surgery, treatments also have negative effects on body image. With chemotherapy treatment, hair loss, color and structure changes in the skin and nails, weight change, hot flashes, and sweating with effects such as negative body image. In the body parts where radiotherapy is applied, long-term neurological changes are observed with skin reactions. Hormone therapy can negatively affect body image by triggering weight gain and hot flashes.[2] When surgery is required, the loss of a breast, an organ that is visible from the outside, and a change in body image cause important problems for patients. Mastectomy has a negative and severe effect on women, and it creates a feeling equivalent to deficiency and disability.[3] Body image with breast surgery may be negatively affected by conditions such as: partial or complete loss of one or both breasts; breast asymmetry, scars and shape changes in the breast and/or nipple area, loss of breast sensation, need for breast prosthesis, limitation of limb movements and development of lymphedema.[2,4,5] In most societies, the female breast is seen as a symbol of aesthetic appearance, sexuality, motherhood, and breastfeeding.[6] Thus, mastectomy negatively affects women's sexuality and affects their personal appearance.[7-9]

General Surgeon Nancy Baxter developed this scale for application in breast cancer patients from Vamos' 1998 study. In a study he conducted in 1993, Vamos showed 4 dimensions of body image in individuals with chronic diseases that are affected by the disease. These dimensions are defined as comfort, competence, appearance, and predictability. The first dimension, comfort, is defined as the personal experience of the alteration in sensations because of disease or treatment, including items such as pain, tiredness, and nausea. Competence is defined as the evaluation of changes in functional ability because of illness or treatment and includes items such as cognitive ability, mobility, and sexual functioning. Appearance is defined as the change in outward appearance due to disease or related treatment and the obviousness of the disorder and includes self and other evaluated aspects of appearance. The final dimension, predictability, is defined as the stability of illness over time and includes the degree of variability, sudden change, age appropriateness of disability, fear of recurrence, and feelings of control over body functions.[10-12]

There are various scales adapted to Turkish that evaluate body image. The difference of the Body Image After Breast Cancer Questionnaire (BIBCQ) scale is that it is a scale that allows physical disease to measure body image, specifically in people who have loss of an organ or a limb in the body. The scale has been accepted as the only specific tool to assess body image, especially in people who have had or have had breast cancer. It is superior to other scales because it is specifically unique to this subgroup of patients.

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In this study, it was aimed to evaluate the perception of body image in female patients with breast cancer by using the Turkish version of the BIBCQ (tBIBCQ), to test the validity and reliability of the form and to determine the psychiatric features of the patients. According to our hypothesis, body image is more negatively affected, and comorbid psychiatric conditions are more common in female patients with breast cancer compared with patients without cancer.

Methods

Participants

The study was conducted with 79 people from 400 breast cancer patients who applied to the Medical Oncology Polyclinic of our hospital between November 23, 2019 and December 23, 2019. Other patients were excluded from the study.

Except for not wanting to participate in the research, the exclusion criteria from the research are as follows:

1. Having cancer other than breast cancer
2. Receiving active treatments such as chemoradiotherapy,
3. Having brain metastases
4. Having a psychiatric and neurological comorbid disease
5. Having diseases that affect reasoning
6. Illiteracy
7. Being under 18 years of age or over 75 years of age
8. It was determined that she had a physical disability not related to breast cancer.

Every condition affecting body image and reasoning was included in the exclusion criteria. Having cancer other than breast cancer was included in the exclusion criteria as receiving chemoradiotherapy would affect body image. Female patients who had breast cancer diagnosis at least 3 months ago and had no conditions that could affect their discernment constituted the study group. The control group consisted of those who applied to the internal medicine outpatient clinic of our hospital for the first time. patients were selected from female patients who did not have any history of cancer and who did not have physical disabilities, who had reading comprehension, who had reasoning, and who were over 18 years of age or under 75 years of age. The control group consisted of 80 patients. Adhering to the ethical principles for medical research on human body of the World Medical Association's Declaration of Helsinki, informed consent was taken from all participants. The forms and scales given were stored in places where only the researchers could reach them. Participants were always informed that they had the right to withdraw from the study. We obtained permission for the study from the local ethics committee with document number IDR 2019 – 939 on November 22, 2019.

Procedure

The patients of the 2 groups between November 2019 and December 2019 were asked to complete the sociodemographic data form, BDI, BAI, and tBIBCQ. The cultural adaptation of the BIBCQ and its adaptation to Turkish were performed by an English translator by translating it from English to Turkish and then by a local translator by retranslating it from Turkish to English. Then, the translators, a psychiatrist, and medical oncology specialist team agreed on a mutual Turkish form. This form was first performed in a small pilot group. There was no difficulty in performing it on the pilot group; therefore, it was used in the study and control groups in the validity and reliability study.

Tools

The sociodemographic features of the groups were compared using a sociodemographic data form. The Beck Depression Inventory (BDI) and the Beck Anxiety Inventory (BAI) were used to detect psychiatric disorders.[13-15] The BIBCQ, which is used to evaluate the body image of patients after breast cancer, was administered to the groups.

Sociodemographic Data Form

The participants were asked about marital status, their duration of marriage if married, satisfaction from marriage, education status, whether they had children, the city where they lived, profession, income status, working status, history of psychiatric disease, whether they had/required psychological support, the presence of negative past situations, stress status in the last year, history and type of surgery, the presence of other diseases, social support, and substance or alcohol addiction. These data were recorded in the sociodemographic data form.

Beck Depression Inventory

The BDI is a 21-item tool that measures somatic, emotional, cognitive, and impulsive symptoms of depression, which is answered by the patients themselves.[13] Each item is scored between 0 and 3 points, and 0-63 points can be achieved from the inventory. High scores indicate an elevation in depressive symptoms. This scale does not aim to diagnose, but calculates the symptoms into an objective number.[16] Scores between 10 and 16 indicate low depressive symptoms, 17 and 29 show moderate depressive symptoms, and 30-63 indicate severe depressive symptoms. Internal consistency for the BDI ranges from 0.73 to 0.92, with a mean of 0.86.[17] This inventory was adapted to Turkish, and its validity and reliability test was performed by Hisli et al.[14]

Beck Anxiety Inventory

The BAI is a 21-item tool that lists the symptoms of anxiety and is completed by patients themselves. The responder is asked to rate how much each symptom has affected them in the last week. The symptoms are scored between "not at all" (0) and "severely" (3) in 4 -point scales. The BAI has excellent internal consistency (Cronbach's alpha = 0.92) and high test-retest reliability (r = 0.75).[15]

Body Image After Breast Cancer Questionnaire

The BIBCQ was established by Baxter et al.[12] It consists of 6 scales: (1) the vulnerability (V) scale, (2) the body stigma (BS) scale, (3) the limitations (L) scale, (4) the body concerns (BC) scale, (5) the transparency (T) scale, and (6) the arm concerns (AC) scale. In the original BIBCQ validity and reliability study, the AC subscale was not used in the control group, and we also did not use it.

Statistical Analysis

Descriptive statistics were used to define continuous variables. Frequencies (n) and percentages (%) were used to define categorical variables. Descriptive factor analysis (DFA) was performed to examine the validity of the questionnaire. As a preliminary test of DFA, the Bartlett's test of sphericity and the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy were used. The Cronbach's alpha coefficient was used to evaluate internal consistency. The split-half method Spearman–Brown correlation coefficient was used to assess the consistency between classes. Descriptive statistics were used to define continuous variables. The Student's t-test, the Mann–Whitney U-test, and the chi-square test (or Fisher's exact test) were used for the statistical analysis of other data.

Statistical significance level was determined as .05. Analyses were performed using the MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2013)

Results

The Validity and Reliability Analysis of the Turkish Version of the Body Image After Breast Cancer Questionnaire

Internal Consistency

The Cronbach's alpha for the tBIBCQ was 0.761; ≥0.70 is known as an acceptable indicator of reliability. Whole alpha values of the subscales are shown in Table 1.

Consistency Between Classes

The consistency was 0.609. Values above 0.6 indicate strong correlation.

Validity/Factor Analysis

The questions on the BIBCQ scale are divided into type 1 and type 2. In order not to affect factor analysis, the validity of these 2 sections was calculated separately because of quintet answers to Likert-type questions.

- Type 1 – Type 2

In this study, the KMO criterion was 0.717 for type 1 and 0.753 for type 2; this indicated that the sample size was suitable for factor analysis. The diagonal values of the anti-image correlation matrix ranged from 0.526 to 0.856 for type1 and 0.375 to 0.864 for type 2. In this study, 8 factors explained 73.4% for type 1 and 7 factors explained 70.2% for type 2 of the total variance. The removal of the 1st, 2nd, 15th, and 18th instructions with low-power factors increases the validity of the type 1 test. The removal of the 37th, 41st, 45th, and 51st instructions with low-power factors increases the validity of the type 2 test. In our study, the "breast satisfaction" and "normality" subscales were determined as additional subscales, different from Baxter et al's[12] study in factor analysis. Eight subscales were determined in the type 1 test, and the first subscale appeared to represent the breast satisfaction subscale, the second subscale the V subscale, the third and fourth subscales the BC subscale, and the sixth and seventh subscales the BS subscale. However, the eighth subscale appeared to be the normality subscale. Also 7 subscales were determined in the type 2 test and the first subscale appeared to represent the T subscale, the second subscale the V subscale, the fifth subscale the AC subscale, and the seventh subscale the BS subscale. However, the fourth subscale seemed to be appropriate for the breast satisfaction subscale in our study. The sixth subscale seemed to fit the normality subscale. As a result, the normality subscale comprised the 2nd, 16th, 37th, 43rd, and 49th. The instructions and the breast satisfaction subscale consisted of the 24th, 25th, 26th, 27th, 28th, 51st, 52nd, and 53rd instructions. It seemed that the normal should be explained or be structured in comparison with the former situation in order to increase the clarity of the instructions of the normality subscale in the Turkish population. As a subtype of the BS subscale, the subscale Retention and Avoidance was found to be factorially

Table 1. Alpha Values of Subscales of the Turkish Version of the Body Image After Breast Cancer Questionnaire

Subscales	Cronbach's Alpha Value
Vulnerability	0.870
Body stigma	0.810
Limitation	0.829
Body concerns	0.795
Transparency	0.856
Arm concerns	0.856

Table 2. Characteristics of the Participants in the Study

		Control		Patient	
		n	%	n	%
Marital status	**Single**	15	18.8	4	5.1
	Married	51	63.8	57	72.2
	Living together	5	6.3	0	0.0
	Divorced	4	5.0	9	11.4
	Widow	5	6.3	9	11.4
Education status	**Literate**	0	0.0	5	6.3
	Primary school	14	17.5	23	29.1
	Secondary school	9	11.3	5	6.3
	High school	22	27.5	32	40.5
	Graduate	20	25.0	12	15.2
	Postgraduate	15	18.8	2	2.5
Occupation	**Housewife**	37	46.3	48	60.8
	Civil servant	29	36.3	14	17.7
	Public worker	4	5.0	1	1.3
	Private worker	5	6.3	10	12.7
	Free	0	0.0	6	7.6
	Student	5	6.3	0	0.0
History of psychiatric disease	**No**	61	76.3	61	77.2
	Yes	19	23.8	18	22.8
Surgery	**No**	80	100.0	33	41.8
	Yes	0	0.0	46	58.2
Type of surgery	**Mastectomy**	0	0.0	28	60.9
	Lumpectomy	0	0.0	17	37.0
	Lymph node dissection	0	0.0	1	2.2
BAI	**<17**	73	91.3	54	68.4
	>17	7	8.8	25	31.6
BDI	<17	72	90.0	57	72.2
	>17	8	10.0	22	27.8

BAI, Beck Anxiety Inventory; BDI, Beck Depression Inventory.

Table 3. The Turkish Version of the Body Image After Breast Cancer Questionnaire Subscale Scores, Beck Anxiety Inventory, Beck Depression Inventory Scores, and the Mean Age of the Study and Control Groups

	Control, n = 80	Patient, n = 79	
	Mean ± SD Median (Minimum–Maximum)	Mean ± SD Median (Minimum–Maximum)	*P*
Age	46 ± 1347 (24-71)	49 ± 1149 (27-74)	.152
V	18 ± 418 (11-27)	29 ± 927 (13-50)	**<.001**
BS	14 ± 314 (10-20)	28 ± 826 (15-54)	**<.001**
L	14 ± 214 (10-19)	19 ± 618 (8-38)	**<.001**
BC	9 ± 29 (6-13)	14 ± 413 (6-25)	**<.001**
T	7 ± 16 (5-9)	9 ± 48 (5-25)	**<.001**
AC	No administration	11 ± 311 (4-16)	–
BAI	8 ± 67 (1-28)	15 ± 1211 (0-59)	**<.001**
BDI	9 ± 67 (0-28)	11 ± 99 (0-37)	.173

AC, arm concerns; BAI, Beck Anxiety Inventory; BC, body concerns; BDI, Beck Depression Inventory; BS, body stigma; L, limitations; T, transparency; V, vulnerability.

differentiated. In particular, the 18th, 21st, 30th, 32nd, and 40th instructions determined the body's retention and even the avoidance of contact, and it was considered that it could differentiate as a separate subscale rather than a subscale of body stigma in the Turkish form.

Table 4. Correlations Between the Turkish Version of the Body Image After Breast Cancer Questionnaire Subscales and Beck Anxiety Inventory and Beck Depression Inventory Scores

		BAI	BDI
V	*r*	0.453	0.343
	P	**<.001**	**<.001**
BS	*r*	0.361	0.268
	P	**<.001**	**.001**
L	*r*	0.466	0.492
	P	**<.001**	**<.001**
BC	*r*	0.284	0.234
	P	**<.001**	**.003**
T	*r*	0.200	0.224
	P	**.012**	**.005**
AC	*r*	0.337	0.405
	P	**.002**	**<.001**

AC, arm concerns; BAI, Beck Anxiety Inventory; BC, body concerns; BDI, Beck Depression Inventory; BS, body stigma; L, limitations; T, transparency; V, vulnerability.
The bold values states that they are statistically significant.

Statistical Analysis Results of Other Data

The characteristics of the participants in both groups are shown in Table 2. The mean age of the study group was 49 years. While 5.1% of the study group was single and 72.2% was married, 18.8% of the control group was single and 63.8% was married. In the study group, 40.5% of them were high school graduates, and 29.1% of them were primary school graduates. The control group had 27.5% high school graduates and 17.5% primary school graduates. Although the majority of the participants were housewives, this number was higher in the study group (60.8%). Civil servants were found to be more common in the control group (36.3%). When screened for psychiatric disorder history, no statistically significant difference was found between the groups. When evaluated according to the history of surgery, it was observed that no one in the control group had it. In the study group, the frequency of surgery was found to be 58.2%. There were statistically significant differences between the groups in terms of V, BS, L, BC, T, and BAI means ($P < .05$); they were all higher in the study group, which are shown in Table 3. A positive correlation was found separately between the BAI and BDI with each BIBCQ subscale. It is stated in Table 4. Body stigma, L, AC, BAI, and BDI subscale scores were higher in patients who underwent surgery, as shown in Table 5. Body stigma, BC, AC, and BDI scores were higher in the mastectomy group. It is shown in Table 6.

Table 5. The Turkish Version of the Body Image After Breast Cancer Questionnaire Subscale Scores and Beck Anxiety Inventory and Beck Depression Inventory Scores in Patients Who Did and Did Not Undergo Surgery

	Surgery (–)	Surgery (+)	
	Mean ± SD Median (Minimum–Maximum)	Mean ± SD Median (Minimum–Maximum)	*P*
V	28.1 ± 7.2 27 (16-40)	30 ± 9.9 28.5 (13-50)	.329*
BS	25.1 ± 5.5 24 (15-36)	30 ± 8.6 28.5 (16-54)	**.003***
L	16.9 ± 5.0 5 (8-29)	20.1 ± 7 19.5 (9-38)	**.029***
BC	13.9 ± 3.7 13 (7-23)	14.3 ± 4.7 13 (6-25)	.904†
T	8.3 ± 2.9 8 (5-16)	10.2 ± 5.0 9 (5-25)	.212†
AC	9.5 ± 31 9 (5-16)	11.3 ± 3.4 12 (4-16)	**.014‡**
BAI	10.5 ± 8.8 8 (1-35)	17.7 ± 12.4 14 (0-59)	**.003‡**
BDI	7.3 ± 6.0 5 (0-21)	14.0 ± 9.5 12.5 (1-37)	**.001†**

AC, arm concerns; BAI, Beck Anxiety Inventory; BC, body concerns; BDI, Beck Depression Inventory; BS, body stigma; L, limitations; T, transparency; V, vulnerability.
*Student's *t*-test.
†Mann–Whitney *U*-test. Statistically, the standard deviation is subtracted from the mean value and added.
‡Chi-square test.
The bold values state that they are statistically significant. p<0.05

Table 6. The Turkish Version of the Body Image After Breast Cancer Questionnaire Subscale Scores and Beck Anxiety Inventory and Beck Depression Inventory Scores in Patients Who Underwent Mastectomy and Those Who Underwent Lumpectomy

	Mastectomy n = 28	Lumpectomy n = 17	Lymph Node Dissection n = 1	
	Mean ± SD Median (Minimum–Maximum)	Mean ± SD Median (Minimum–Maximum)	Mean ± SD Median (Minimum–Maximum)	*P*
V	31.6 ± 10.8 30.5 (13-50)	27.7 ± 8 26 (17-44)	23 23 (23-23)	.200[a]
BS	32.3 ± 9.6 33.5 (16-54)	26.1 ± 5.4 25 (19-37)	25 25 (25-25)	**.008**[a]
L	21.5 ± 7.4 23 (10-38)	18.2 ± 5.8 19 (9-28)	14 14 (14-14)	.121[a]
BC	15.7 ± 4.8 14.5 (7-25)	12.4 ± 3.4 12 (6-20)	8 8 (8-8)	**.010**[a]
T	10.9 ± 5.8 9.5 (5-25)	9.4 ± 2.8 9 (5-14)	5 5 (5-5)	.724[b]
AC	12.1 ± 3.3 13 (4-16)	10.3 ± 3.3 11 (4-16)	7 7 (7-7)	**.042**[b]
BAI	19 ± 12.4 14.5 (3-59)	16.3 ± 12.4 11 (0-39)	14 14 (14-14)	.419[b]
BDI	16.1 ± 9.6 16 (3-37)	10.1 ± 7.9 9 (1-24)	23 23 (23-23)	**.034**[b]

AC, arm concerns; BAI, Beck Anxiety Inventory; BC, body concerns; BDI, Beck Depression Inventory; BS, body stigma; L, limitations; T, transparency; V, vulnerability.

[a]Student's *t*-test.
[b]Mann–Whitney *U*-test.
Bold characters are written this way to indicate statistical significance.

Discussion

This study aimed to evaluate the perception of body image in female patients with breast cancer by using the tBIBCQ, to test the validity and reliability of the form, and to determine the psychiatric features of the patients. According to our hypothesis, body image is more negatively affected and comorbid psychiatric conditions are more common in female patients with breast cancer compared with patients without cancer. We obtained the Cronbach's alpha for the tBIBCQ as 0.761; ≥0.70 is known as an acceptable indicator of reliability. The consistency was 0.609. There were statistically significant differences between the groups in terms of V, BS, L, BC, T, and BAI means ($P < .05$); they were all higher in the study group. A positive correlation was found separately between the BAI and BDI with each BIBCQ subscale.

As a result of the study, the tBIBCQ has been proven to be a valid and reliable tool for evaluating body image in women with breast cancer. Results consistent with validity and reliability studies of the BIBCQ in the literature were observed in the Turkish population. The Cronbach's alpha values of all scales and subscales were similar to those of other studies in the literature.[12,18-20] In tBIBCQ, unlike the study of Baxter et al,[12] 2 extra subscales, including breast satisfaction and normality subscales, were found appropriate in factor analysis. In addition, a subscale that determines the body's retention/avoidance of contact may be differentiated in the tBIBCQ. In contrast to the Canadian population, the factor analysis was more similar to the Polish population.[19]

The higher V, BS, L, BC and T subscale scores in the study group are especially important because these scales measure limitations of the body due to disease and question body image. In Baxter et al's[12] study, only the V subscale was found to be statistically significantly higher in the study group.[12]

In our study, there was a positive correlation between all subscales and BAI and BDI scores. Other studies indicated that the subscales of BIBCQ were significantly correlated with symptoms of anxiety and depression.[12,19,21] In this study, there were statistically significant differences between patients who did and did not undergo surgery in terms of BS, L, AC, BAI, and BDI scores; all were higher in patients who underwent surgery. As shown in other studies in the literature, the increased BS score might be explained by negative changes in body image after surgery, and physical limitations due to surgery might explain the increased L subscale score.[18,21] In a study conducted on women with breast cancer, it was found that cancer led to an increase in feelings of sadness, shame, and disappointment in women. It has been shown that there are participants who report conditions such as not being able to get used to breast loss or not being able to look at themselves in the mirror.[22] In the Brazilian population, there were statistically significant differences between the group of patients who underwent reconstruction mastectomy in the BS, L, and BC subscales, who did not undergo surgery, or who underwent only lumpectomy, and who underwent mastectomy without reconstruction.[18] The social stigma associated with cancer inevitably affects mood and social relationships, but it also reduces the quality of life by changing body image perception. The Persian BIBCQ's third subscale was determined as body-related shame, which shows the level of frustration and negative emotion caused by being aware that one's own body does not meet global standards.[23] Also, pain and swelling in the arms after surgery caused increased AC subscale scores in patients who underwent surgery.

Body image was more affected in patients who underwent mastectomy than in patients who underwent lumpectomy. BS, T, and AC subscale scores, in particular, were increased. Similarly, Baxter et al[12] found an increase in BS, T, and AC scores. The higher scores in BS compared with other subscales indicated that body image was more affected.[21]

Cancer causes depression, and when pain is added, the BDI score increases more.[24] In addition to a meta-analysis investigating the relationship between cancer and depression, many studies like our study have found a positive correlation between anxiety and depression levels in patients with breast cancer. It has been shown that the main anxiety symptoms in chronic diseases can also cause depressive symptoms later on.[25]

In general, there is a negative relationship between depression and body image; therefore, depressed individuals tend to have a more negative body image.[11,12] Mastectomy was associated with an increase in depressive symptoms and in BDI scores. These results, which were consistent with previous studies, indicate that women with mastectomy are more anxious and depressed because their body images are affected.[2,12,19,21,26]

There are some limitations to our study. Although this was the first study of the BIBCQ in Turkey, the study was performed in a private hospital with a smaller sample size, which means that the results are not fully representative of the entire Turkish population. In addition, the combination of chemoradiotherapy and surgical treatments prevented the determination of reliability in the study group using the retest method.

Conclusion

This study showed that the tBIBCQ is reliable and valid in detecting the effect of breast cancer on the body image of Turkish women.

Ethics Committee Approval: Ethical committee approval was received from the Şişli Florence Nightingale Hospital Local Authority Comittee (Approval no: IDR2020-226, Date: November 22, 2019).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

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