Development of The Psychosocial Adaptation Questionnaire Among Breast Cancer Women With Adjuvant Endocrine Therapy in China

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Abstract

Background

The adjuvant endocrine therapy (AET) of breast cancer often impacts women on physiological, psychological, and social facets, which requires them to adjust to achieve psycho-social adaptation (PSA). As a standardized evaluation tool was lacking, we developed a PSA questionnaire of breast cancer women with AET.

Methods

Item development and extraction based on literature, qualitative interviews (n = 16) and assessment of content validity in phase I. Phase II: 300 participants were used to perform item analysis, internal consistency reliability, and exploratory factor analysis by cross-sectional studies. Phase III: Test–retest, criterion validity, and confirmatory factor analysis of the questionnaire were performed with 96 respondents.

Results

In Phase I, the initial questionnaire was formed. In Phase II, exploratory factor analysis demonstrated 4 factors: emotional dimension (6 items), self-cognitive (5 items), self-image (3 items), and social dimension (2 items), the cumulative contribution of the factors was 65.057%. The Cronbach's alpha coefficient of the questionnaire was 0.876. The correlation coefficient between the questionnaire and General Self-Efficacy Scale (GSES) was 0.565 ($p < 0.01$). In Phase III, the 16-item questionnaire and its factorial structure was confirmed.

Conclusions

The 16-item questionnaire has been confirmed by good reliability and validity. In conclusion, it could be a useful tool to assess the PSA among breast cancer women with AET and provide a basis for further research.

Key Message

This paper develops new instrument for assessing the status of PSA among breast cancer women with AET.

Introduction

Breast cancer (BC) is the most diagnosed cancer globally, with 2.3 million new cases expected, accounting for 11.7% of all cancer cases in 2020 [1]. BC accounts for 1 in 4 cancer cases and 1 in 6 cancer deaths among women, with the highest incidence in most countries (159 out of 185 countries). Approximately two-thirds of BC women test positive for the estrogen receptor (ER) and/or progesterone receptor (PR) [2]. Due to early diagnosis and aggressive adjuvant therapy, the 5-year survival rate for cancer is more than 91.2%, higher than for other cancers [3, 4]. Updated clinical practice guidelines recommend extending the use of adjuvant endocrine therapy (AET) from 5 to 10 years [2, 5].

With the Higher survival rates, breast cancer has gradually become a chronic disease. While physical functioning in quality of life improved over time after completion of aggressive cancer treatment, emotional and social functioning as well as some breast cancer-specific symptoms significantly worsened, with all symptoms of distress (except pain) higher than in the general population [6]. Breast cancer survivors (BCS) need to coexist with cancer for a long time and face the problem of disease adaptation [7]. Compared with the general population, after oncology treatment, such as surgery, chemotherapy, and AET, BCS experience physical symptoms and emotional issues as they enter remission [8, 9]. In addition, BCS suffers from a variety of psychosocial distress due to self-blame (negative perceptions of cancer) and social stigma. Adaptation on a multidimensional level, such as social and sexual, while tolerating the symptoms of diagnosis and treatment is called psychosocial adaptation [10]. Psycho-social adaptation (PSA) in BCS is an important part of BCS evaluation [11].

Londono & McMillan used literature analysis to form the intermediate domain theory of the concept of PSA, showing its multidisciplinary characteristics and properties of variability, process, persistence, interactivity, and individuality [12–13]. PSA involves the integration of illness or disability into an individual's life, identity, self-concept, and self-image [14]. Based on the perspective of positive psychology, PSA refers to the process of the disabled person's transition from a disabled state to an enabling state, which is characterized by the transition from negative to positive happiness [15]. After an extensive literature review, no effective questionnaire was found that reveals the PSA of BC women undergoing AET, among the few studies available regarding the psycho-social adjustment of breast cancer patients. For instance, the Self-Reported version of the Psycho-social Adjustment to Illness Scale (PAIS-SR) is designed by Derogatis [16] in 1986 to measure psycho-social adjustment in heterogeneous cancer and their close family members, Cronbach's alpha coefficients > 0.62 in Greek breast cancer patients [17]. Leung Mei Yuet reported the internal consistency coefficient was 0.93 in the study of Chinese patients with COPD. When we used the Chinese version of PAIS-SR to measure the psycho-social adaptation of breast cancer women with AET, patients felt that many contents of the questionnaire were not applicable, and the internal consistency coefficient was only 0.129. Based on the perspective of positive psychology, PSA is defined as the process by which an individual with a disability transitions from a state of disability to an enabling state, characterized by a transition from a negative to a positive health state [13]. Based on a clinical perspective, short questionnaires can be quickly answered and easily managed in a busy clinical practice. There are currently no measures to evaluate PSA in breast cancer women with AET.

To measure the psycho-social adaptation of BC patients more accurately and better provide targeted intervention measures, our team constructed a questionnaire that evaluate the level of PSA among BC women with AET, test the questionnaire and subscales in breast cancer women with AET, and examine the reliability and validity of the new assessment tool.

Methods

Based on the preliminary concept, the development of the questionnaire includes item development, questionnaire development and evaluation [18, 19]. This mixed research was performed during the period from March to June 2021 in China. According to the inclusion and exclusion criteria, the participants were identified and then included them on a voluntary basis.

Inclusion criteria: diagnosed with BC; positive ER and/or PR; receive AET for more than 1 month; women over the age of 18 with breast cancer; and volunteer to participate in the study.

Exclusion criteria: women with other critical diseases (such as severe infection, malignant tumors, malignant hypertension, myocardial infarction, severe cerebrovascular accident, heart failure, etc.).

Item development

The related literature of PSA in breast cancer women with AET were reviewed. This qualitative study was conducted by interviews and participatory observation [20]. The qualitative study data and literature of participants (n=16) provided abundant data for the development of the item pool and initial questionnaire. Psycho-social adaptation of breast cancer women with AET was closely related to emotional response, self-cognitive, and social situation.

Questionnaire development

5 experts (2 breast cancer specialists, 2 psychologists, and 1 nursing specialist) assessed the content validity of questionnaire by 2 rounds of consultation. In preparation for the formal survey, participants meeting the criteria were chosen prior to the survey, and the difficulty, suitability, and complexity of the item was assessed.

Investigation

The questionnaire was divided into two steps. 300 participants were used to perform item analysis, internal consistency reliability, and exploratory factor analysis. Test-retest, criterion validity, and confirmatory factor analysis of the questionnaire were performed with 96 respondents. The cases included in each subsample meet the requirement of 5-10 times the sample size. The survey instruments were as follows.

Sociodemographic characteristics include population and disease-related variables. A PSA questionnaire among BC women with AET was developed. The answers were scored on a 5-point Likert scale: all the time, often, sometimes, rarely, and never. The higher the score, the better the PSA. The 10-items General Self-Efficacy Scale (GSES) developed by Schwarzer in 1981 was widely used to measure the self-efficacy, which has been shown to have good reliability and validity.

The items were analyzed by CR value, DI, and ITC. And the items below the standard value are deleted. The construct validity was assessed by exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). The internal consistency of a questionnaire was evaluated by Cronbach's alpha coefficient. Test-retest reflects the stability and consistency of the test in time. After 10-18 days, 31 patients answered the questionnaire again, and the correlation coefficients of the two measures were used to assess the reliability of the retest. Spearman correlation coefficient test was used to reflect the validity of the scale stability. GSES was used to assess criterion validity [21].

Statistical analysis

If an item is not answered, the score is replaced by an average. If two or more questions are not answered, the questionnaire will be excluded from the analysis. In the qualitative phase, all data was managed and analyzed

using Nvivo 11.0. In the quantitative stage, IBM SPSS Statistics 25.0 and AMOS 23.0 were used for statistical analysis.

Results

Subject characteristics

A total of 409 breast cancer women with adjuvant endocrine therapy were selected from May to June 2021; 396 patients agreed to participate (response rate = 96.82%). The socio-demographic and clinical characteristics of the participants are shown in Table 1.

Table 1
Socio-demographic and clinical characteristics of the participants (n = 396)

Characteristics		n(%) / Mean $\pm$ SD
Age(year)		50.628 $\pm$ 9.024
BMI		24.112 $\pm$ 2.903
Education level	Junior high school or below	108(27.272)
	High school/College	190(47.980)
	Undergraduate college or above	98(24.748)
Marital status	Married	339(85.606)
	Unmarried	9(2.273)
	Divorced	31(7.828)
	widowed	17(4.293)
Professional	Retired	166(41.920)
	Did not work	99(25.000)
	Temporary worked	13(3.283)
	Work as usual	118(29.798)
Years taking endocrine medications		3.333 $\pm$ 2.152

Development And Analysis Of Items

Item pool

An initial questionnaire included items for literature, qualitative research, and group discussion. The content validity was evaluated by 5 specialists (3 breast specialists and 2 psychologists) through 2 rounds of consultations. The content validity index (CVI) range of 76 questionnaires ranged from 0.769 to 0.893, and the average of the first round was 0.832. The content validity after the deletion of 19 items was 0.930. A pre-questionnaire survey was conducted on 37 breast cancer women receiving adjuvant endocrine therapy to test the reliability of the questionnaire contents, and 31 questionnaires were effective (the effective rate was 83.78%). Whether women with BC receiving AET judged the content of the questionnaire as appropriate and accurate. Cronbach's alpha coefficient of the questionnaire was 0.934 ($P < 0.05$).

Item analysis

After independent sample t -test, item 2 that did not achieve significance was deleted. Items with DI and ITC < 0.3 were deleted at the same time, a total of 17 items were deleted.

Exploratory factor analysis

23 items were deleted by 21 rounds of EFA. From the perspective of factor load and content, the first subscale was emotional dimension, consisting of 6 items. The second subscale was self-cognition dimension, consisting of 5 items. The third subscale was self-image dimension, consisting of 3 items (Table 2). The Kaiser-Meyer-Olkin index of the 16-item questionnaires was 0.880, and the result of Bartlett's spherical test was 2129.914 ($P = 0.000$), which was suitable for factor analysis. When the eigenvalue was > 1.0 (Fig. 1), 4 factors were extracted through principal factor analysis and varimax rotation, and the cumulative contribution rate of factors was 65.057%.

Table 2
Results of reliability and validity analysis for the PSA questionnaire among BC women with AET

Factor	Item	Factor loading	Eigenvalue	Explanatory variation (%)	Cumulative explanatory variation(%)	Cronbach's alpha coefficient	Correlation coefficient
1	Q1. I am worried about metastasis or recurrence	0.845	5.920	36.997	36.997	0.899	0.857**
	Q2. Breast problems make me feel nervous	0.802					
	Q3. I am worried that breast disease will get worse	0.800					
	Q4. Breast problems make me feel scared	0.795					
	Q5. I am worried about the side effects of the drug	0.705					
	Q6. Breast problems make me very depressed	0.670					
2	#Q7. I still think of myself as an attractive person	0.784	1.954	12.211	49.208	0.790	0.685**
	#Q8. Overall, I am satisfied with myself	0.761					
	#Q9. I think I am still a valuable person	0.738					
**. At level 0.01 (double tail), the correlation is significant. # is the reverse scoring item.							

Factor	Item	Factor loading	Eigenvalue	Explanatory variation (%)	Cumulative explanatory variation(%)	Cronbach's alpha coefficient	Correlation coefficient
	#Q10. I can share happiness and sadness with friends and colleagues	0.660					
	#Q11. I am still interested in things I was interested in before	0.649					
	Q12. Breast problems affect my couples sex life	0.795	1.468	9.174	58.382	0.664	0.698**
	Q13. I can not face the weight gain	0.681					
	Q14. Disease affects my appearance and makes me unhappy	0.638					
3	Q15. I am not willing to discuss breast problems with others	0.861	1.068	6.675	65.057	0.730	0.573**
	Q16. I do not like others asking about my condition	0.839					
**. At level 0.01 (double tail), the correlation is significant. # is the reverse scoring item.							

Confirmatory factor analysis

CFA was used to further evaluate the construct validity, and the results were shown in Fig. 2. Except for item 10, the load coefficient of standardized factor obtained is > 0.50. The path coefficients of the three subscales are highly correlated ($p < 0.001$, Table 3). The discrimination degree of the questionnaire and the common fitting indexes of the CFA model are shown in Table 4.

Table 3
Confirmatory factor analysis of PSA in BC women with AET

ITEMS			Estimate	S.E.	Z	P	Estimate	CR	AVE
Q1	<—	F1	1				0.781	0.887	0.577
Q2	<—	F1	1.076	0.109	9.869	***	0.908		
Q3	<—	F1	1	0.12	8.309	***	0.79		
Q4	<—	F1	1.088	0.118	9.243	***	0.86		
Q5	<—	F1	0.575	0.131	4.392	***	0.452		
Q6	<—	F1	0.806	0.117	6.904	***	0.678		
Q7	<—	F2	1				0.779	0.803	0.461
Q8	<—	F2	0.781	0.126	6.216	***	0.669		
Q9	<—	F2	0.91	0.123	7.42	***	0.819		
Q10	<—	F2	0.494	0.13	3.791	***	0.416		
Q11	<—	F2	0.78	0.132	5.921	***	0.639		
Q12	<—	F3	1				0.371	0.632	0.390
Q13	<—	F3	0.973	0.329	2.953	0.003	0.542		
Q14	<—	F3	1.891	0.598	3.164	0.002	0.86		
Q15	<—	F4	1				0.727	0.747	0.596
Q16	<—	F4	1.308	0.378	3.463	***	0.815		
☒: ***p<0.01									

Table 4
Discrimination and model fit of confirmatory factor analysis for the questionnaire

ITEMS	AVE	F1	F2	F3	F4	CMIN/DF	RMB	GFI	AGFI	PGFI
F1	0.577	0.760				1.366*	0.070	0.857	0.802	0.618
F2	0.461	0.290	0.679							
F3	0.390	0.655	0.478	0.625						
F4	0.596	0.399	0.165	0.405	0.772					
⊠: * $p < 0.01$										

Psychometric Properties

Internal consistency

The Cronbach's alpha coefficient of the psycho-social adaptation questionnaire among breast cancer women with AET and the four subscales were 0.876, 0.899, 0.790, 0.664, and 0.730 (Table 2). The correlation analysis showed that the correlation coefficients between each dimension and the total questionnaire ranged from 0.573 to 0.857 ($p < 0.01$; Table 2). After 10–18 days, 30 patients answered the questionnaire again, with a correlation coefficient of 0.846 for the two measures ($p < 0.01$).

Convergent validity

The correlation coefficient between the psycho-social adaptation questionnaire among breast cancer women with AET and GSES was 0.565 ($p < 0.01$).

Discussion

Based on Roy's adaptation theory and the PSA defined by Londono & McMillan, literature review found that PSA is associated with psychological, social, and other factors [12, 22]. Qualitative analysis found that the self-cognitive of breast cancer women with AET played a crucial role in the process of PSA. Based on this, a questionnaire for breast cancer women with AET was developed, which consisted of 16 items and 4 subscales (emotional, self-cognitive, self-image, and social dimension) was developed. According to the indicators of CFA value, the questionnaire was considered to have good compatibility from three aspects of goodness of fit index (GFI), adjusted goodness of fit index (AGFI) and contracted goodness of fit index (PGFI) [23].

The item pool is derived from review, qualitative research, and expert consultation. The DI and ITC among 16 items of the psycho-social adaptation questionnaire among breast cancer women with AET were > 0.30 , which confirms that the entries are sufficiently differentiated and relevant [24, 25].

In practice, the 4-factor structure can display the connotation of PSA in breast cancer patients with AET more finely and intuitively. In short, these statistical correlations and structural relationships can be reasonably

explained by logical relationships [26]. The KMO of the 16 questionnaires was 0.880, which was considered suitable for factor analysis [27]. 4 subscales were extracted, and the factor load of each item of the questionnaire was > 0.6 [28].

The correlation coefficient between each subscale is smaller than that between each subscale and the overall questionnaire, indicating that the correlation coefficient between each subscale and each subscale and the overall questionnaire is significant [29].

Standard correlation validity reflects the level of consistency between research tools and other measurement criteria. The 16-item questionnaire was positively correlated with GSES [30], indicating that the lower the PSA level of psychosocial breast cancer patients assisted by endocrine therapy, the lower the self-efficacy. The correlation coefficient of standard correlation validity was $0.4 \sim 0.8$, indicating a good level of correlation [31, 32]. The correlation coefficient between the 16-item questionnaire and GSES met this.

By convention, an alpha of 0.60 or higher is needed to keep an item on a "sufficient" scale [33, 34]. Therefore, the 16-item questionnaire was considered to have a good internal consistency. Retest reliability could reflect the stability of the questionnaire, which is used to test the consistency of the same tool, and the same subjects are evaluated twice or more [34]. The retest reliability of 16 questionnaires is high [33]. To sum up, this questionnaire has good reliability.

Clinical Implications

From a clinical perspective, the 16-item questionnaire can be answered quickly and would be easy to administer in a busy breast cancer practice. Breast cancer women with AET will be completed directly on Appendix A, and their PSA will be assessed by their health care provider based on the scoring method listed below. The questionnaire can be used as a comprehensive and cost-effective clinical assessment tool and can also be used to further study the mood, self-perception, self-image, social dimension, and overall PSA level of breast cancer patients with AET.

Limitations

The use of self-reports may influence answers that show more "morally acceptable" intentions. The external validity needs further evaluation. Therefore, we encourage action to acculturate, translate and validate the psycho-social adjustment questionnaire for women with breast cancer receiving adjuvant endocrine therapy, and to refine the normative component by adding descriptive and ethical norms [35].

Conclusions

The reliability and validity of 16-item questionnaire were verified in this study, which can be used as a tool for clinical evaluation and further study. This will help health care providers to evaluate PSA in women with AET for breast cancer and provide appropriate basis for women with AET to adapt to AET and improve their quality of life.

Abbreviations

Adjuvant endocrine therapy, AET; Psycho-social adaptation, PSA; Breast cancer, BC; Breast cancer survivors, BCS; Estrogen receptor, ER; Progesterone receptor, PR; Psycho-social Adjustment to Illness Scale, PAIS-SR; General Self-Efficacy Scale, GSES; Exploratory factor analysis, EFA; Confirmatory factor analysis, CFA; Content validity index, CVI.

Declarations

Statement of Ethics to Ethics approval and Consent participate.

All methods were carried out in accordance with relevant guidelines and regulations. This study was approved by the ethics committee at First Affiliated Hospital of China Medical University (Project No.2016-5-2).

Participants have adequate information about the purpose, methods, and processes of the study. Participants had the right to choose freely and could choose to participate or withdraw from the study. All participants signed the informed consent.

Consent for publication

All authors have read and approved the manuscript to be published.

Availability of data and material

The datasets used and analysed during the current study available from the corresponding author on reasonable request.

Conflict of Interest Statement to Competing Interest.

The authors have no conflicts of interest to disclose.

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None.

Authors' contributions

Study conceptualization: HR, XJ and F; Data Curation: HR, Y and H; Investigation: HR, Y, XJ and H; Formal analysis: HR, XJ, Y, H and F; Supervision: HR and F; Writing – review & editing: HR, and F. All authors have read and approved the manuscript.

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Figures

Figure 1

Scree plot

Figure 2

The standardized estimate of each coefficient in the confirmatory factor analysis model

Supplementary Files

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