

Development and Testing of a Reliable and Valid Patient-Needs Questionnaire for Breast Cancer Inpatients in China

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ABSTRACT

Introduction: Breast cancer patients are demanding more active roles in their care, especially in the initial diagnosis and treatment stages. At present, there is no suitable patient questionnaire that appropriately incorporates Chinese language, habits, and cultural differences.

Aim: To develop and validate a patient-needs questionnaire for female breast cancer inpatients in China.

Materials and Methods: The questionnaire structure was based on Maslow's model and a modern medical model. In the first step, a focus group was used to design 125 questions, of which 64 constituted the initial questionnaire for item screening with a group of 115 hospitalized patients with breast cancer. Items were included or excluded based on the evaluation of

eight statistical analysis. Ultimately, 38 items were selected and validated. The reliability and validity of the 38-item questionnaire were determined in a cohort of 323 patients.

Results: The scale was set up with the 38 selected items. The four primary areas were disease knowledge, medical environment, psychosocial parameters and sexual attitudes. Cronbach's coefficient was 0.959. The split-half reliability value was 0.935. Principal component factor analysis extracted four common factors.

Conclusion: Our new questionnaire, designed to assess the care needs of Chinese inpatients with breast cancer is reliable, sensitive, effective, independent and representative. It can be used in medical practice as a tool for a more complete assessment of patients' needs.

Keywords: Bio-psychosocial model, Chinese questionnaire, Demand, Health education, Instrument, Reliability, Validity

INTRODUCTION

Breast cancer patients now-a-days are demanding more active roles in their care [1], especially in the initial diagnosis and treatment stages. They are seeking more information on their disease, treatment options (including at-home treatments), psychosocial support and impacts on quality of life [2]. This information is also of critical importance for family members who are involved in the care of their loved ones. However, although breast cancer incidence has been increasing rapidly and is now a major health risk for Chinese women, there are currently no effective tools for assessing patient needs in China.

Since the 1970s, the demand for patient-based questionnaires has been increasing [3-6]. Numerous reliable and valid tools have been developed specifically for the assessment of patients with breast cancer. For example, Galloway et al., developed the Toronto Informational Needs Questionnaire–Breast Cancer (TINQ-BC) [7], Erci and Karabulut adapted an English version of the Self-Assessed Support Needs questionnaire for use in Turkey [8], and Fielding and Lam developed a Social Life Adjustment Scale in Cantonese at the University of Hong Kong [9].

However, differences between Chinese and Western languages, traditions and cultures require the development of a needs assessment questionnaire specifically for Chinese patients. At present, there is no suitable patient questionnaire that appropriately incorporates Chinese language, habits and cultural differences. Translating foreign instruments directly to Chinese is not an appropriate solution, as there are important differences in the ways that Chinese and non-Chinese doctors approach disease information, death and health education [10].

Aim of this study was to develop a patient-needs questionnaire for breast cancer inpatients in China and to test the reliability and validity of the questionnaire by using established models.

MATERIALS AND METHODS

Eligible patients were enrolled from two hospitals in Changsha (Hunan province) between July 2009 and December 2010. These hospitals are two of the largest medical centers in central China, each with more than 100 beds in their Breast Diseases Departments. Patients with breast cancer were chosen randomly and provided written informed consent. The design was reviewed and adopted by the ethics committee of each institution. Before being enrolled in the study, each patient was informed of the purpose of the investigation, the expectations of participation and the general precautions of the study. After being informed, each patient signed an informed consent agreement prior to completing the study questionnaire.

Questionnaire Development

As deemed important by the World Health Organization (WHO) [11] and described by the Maslow Hierarchy of Needs model [12], an effective health questionnaire needs to inquire not only about the patient's perceived quality-of-life, but also about special characteristics related to breast cancer and patient satisfaction. The four primary areas of inquiry we focused on were: disease knowledge (i.e., knowledge of diagnosis, treatments and side effects), the medical environment (i.e., wards, equipment and food/sleep details), psychosocial parameters (i.e., emotional and physiological functions, activities and interpersonal needs), and sexual attitudes (i.e., sexual attitudes of patients and their families). The structure of scale was guided by the bio-psychosocial medical model.

Question Development

Questions were primarily based on programmed decision. Two groups were assembled to develop the questions: a focus group and a key work group. The focus group had 52 members who were

breast cancer patients, breast surgery specialists, nurses, family members of patients, psychologists and statistical researchers. The key work group had seven people who were primarily responsible for handling research-based questions. In first step, the focus group designed 125 questions, based on patient interviews, the translation of foreign questionnaires, and expert suggestions.

In the second step, the key group discussed all 125 original questions and selected 95 final questions, eliminating or rewriting questions that were difficult to understand. The third step was to test the questions for language acceptance rate and importance. To do this, 26 patients and 26 experts were chosen to examine every question. At the completion of these efforts, the final test version of the questionnaire contained 64 questions.

Scale Evaluation

The Test-retest Reliability

To determine the survey's repeatability, 30 randomly selected patients were asked to complete an identical questionnaire 1–2 weeks after completing their initial survey. We then computed their scores and calculated the Pearson correlation coefficient between each patient's section and total scores [13,14].

Cronbach's Coefficient and Split-half Reliability

Cronbach's coefficient was calculated for each section score and total survey score. Additionally, the split-half reliability was assessed by dividing each section into two halves and calculating the Pearson correlation coefficient [15,16].

Principal Component Factor Analysis

The principal component factor analysis was used and four common factors were extracted using a theoretical model.

STATISTICAL ANALYSIS

SPSS17.0 statistical analysis software package was used to establish a database. To perform screening of questions, eight subjective or objective methods were used. The tests included:

- 1) Importance Score: Two 26-person groups, comprised of medical experts and patients, discussed the survey content and assessed how well it was represented and understood. Poorly understood or irrelevant questions were eliminated [1].
- 2) Response Rate: If any question had a response rate <90%, it was eliminated [17].
- 3) Correlation Coefficient: If any question had a Pearson correlation coefficient (calculated between each question and its section) of less than 0.4, it was eliminated [18].
- 4) Reaction Analysis: If any question had more than three options that were chosen by patients for <10%, combined, or any one option with a chosen rate of >50%, it was eliminated [19].
- 5) Stepwise Regression Analysis: The overall survey score was the dependent variable Y, while the scores of questions were the independent variables. A multiple linear regression analysis was used to select the impact of specific questions in a step-by-step fashion ($\alpha = 0.10$, $\beta = 0.05$). Questions that were included in the regression equation were eliminated [19].
- 6) Cronbach's Coefficient: Cronbach's coefficient was calculated with and without each question. If a question altered the Cronbach's coefficient by >50%, it was eliminated [2].
- 7) Factor Analysis 1: The principal component method was used to extract component values more than 1. Any questions that had factors <0.4 or had two factors that were similar were eliminated [2].
- 8) Factor Analysis 2: The principal component factor analysis was used and four common factors were extracted using a theoretical model. The questions with a score that fell in the lower 50% were removed from the questionnaire.

Quality Control

Investigators used standardized methods of assessment and chose patients with the same diagnostic criteria. Investigators were required to quickly scan the questionnaire when collecting to make sure the questionnaires were complete. In terms of study analysis, two copies of all data were entered into a database by two separate researchers. These data were assessed for digital input and logical errors, both automatically and by hand. If more than 20% of items were not answered, then the questionnaire was not used for statistical analysis, or the missing values of the item were replaced with the mean values.

RESULTS

The Patient Cohort

One hundred and fifteen breast cancer patients completed the test survey. Their average age was 46.0 ± 10.9 years (range: 20–72 years). In total, 323 breast cancer patients completed the first screening, with an age range of 20 to 72 years and an average age of 44.4 ± 9.2 years ($t = 1.321$, $p = 0.188$).

Entry Screening Results

After receiving the completed questionnaires, we evaluated questions using the eight screening tests, or methods, described in the Materials and Methods section. If a question "passed" six or more methods, it was retained. If it passed five methods, it was discussed. If it passed four or less methods, it was eliminated [Table/Fig-1]. Of the 64 original questions, 26 were eliminated and 38 remained, including A1, A3, A8, A10, A14, A19, B20, B21, B22, B23, B28, B29, B30, B32, B33, B34, B36, C37, D41, D43, D44, Model D49, D59, D60, D62, and D63. In total we retained 12 questions from the knowledge section, seven questions from the environmental section, 16 questions from the psychosocial section and three questions from the sexual knowledge section [Table/Fig-1,2].

Structure and Score

The questionnaire was divided into four parts: 1) questions on the patient's general knowledge of her disease; 2) questions inquiring about the patient's inpatient environment; 3) questions concerning the patient's understanding of how the disease may impact her sexual life; and 4) questions to assess psychosocial factors. The 5-point Likert scale method was used to score questions from 1 to 5. Scores of questions in each section were added together to generate a final score for the section. Scores of the four sections were then summed to generate a final questionnaire score.

Questionnaire Assessment

1. The Test-retest Reliability

A test-retest reliability assessment was performed on each section of the survey. The corresponding values for each section were 0.791 in knowledge, 0.815 in environment, 0.753 in psychosocial demand, and 0.632 in sexual knowledge. The score for the entire survey corresponded to 0.781.

2. Cronbach's Coefficient and Split-half Reliability

As seen in [Table/Fig-3], the Cronbach's coefficients for each of the four sections fell in a range from 0.879 to 0.936. The coefficient for the whole survey was 0.959. The split-half reliability rates ranged from 0.837 to 0.918 for the four sections and were 0.935 for the whole survey.

FACTOR ANALYSIS

A principal component analysis was used to assess the partial correlations among the 38 retained questions. The Kaiser-Meyer-Olkin (KMO) measure of sampling was 0.945 and the Bartlett test approximate chi-square distribution was 7755.518 ($p < 0.001$). According to the test results and experiences, the larger the value for KMO, the more suitable the tool is for factor analysis.

Section	Item	Assessment
Knowledge	A4	Knowledge of successful treatments.
	A5	Purpose, meaning, results, and precautions of examinations.
	A6	Different treatment options and cost.
	A7	Side effects and counter measures of chemo or radiotherapy.
	A9	Notice before or after surgery.
	A11	How to resolve the pain from surgery quickly?
	A12	How to prevent hair loss and adjust to wearing wigs?
	A13	Having a guidebook for disease treatment?
	A15	Knowing of prostheses or reconstruction surgery.
	A16	Understanding referrals and post-discharge instructions.
	A17	Understanding recurrence or metastasis.
	A18	Knowing how to perform a breast self examination.
	Environment	B19
B24		To what degree the ward is quiet, clean, and appealing.
B25		The timeliness of medical staff visits.
B26		The presence of security for the protection of property.
B27		Having a skilled medical team.
B31		How to reduce the number of hospital days?
B35		Knowing the price and efficacy of various drugs.
Sexual knowledge	C38	How much the family influences patient's sexual activity?
	C39	Understanding how the disease may impact sexual life.
	C40	How to give families mental health education?
Psychosocial needs	D42	Knowing where to get disease/rehabilitation information for families.
	D45	The presence of curtains between hospital beds.
	D46	The effect of a family's spiritual support.
	D47	Having help from the medical staff to sleep or visit the restroom.
	D48	How much respect the staff has for patient privacy?
	D50	How much respect the staff has for the patient's emotional needs?
	D51	How much help the patient receives eating, getting medication, etc.?
	D52	To what extent the patient interacts with and is able to have good relationships with other patients?
	D53	The presence of organizations to aid in rehabilitation.
	D54	How much the patient is involved in community activities?
	D55	How involved the patient was in his/her treatment choice?
	D56	How much patient participates in recreational or rehabilitation-related community activities?
	D57	How much encouragement the patient receives from medical staff?
	D58	How much concern/encouragement the patient receives from friends, colleagues, and relatives?
	D61	To what degree nurses help the patient cough, stand, get out of bed, and become mobile?
	D64	How the patient's family views disease?

[Table/Fig-1]: Survey questions retained after screening.

Therefore, we proceeded with combining a theoretical model and a plot together and chose four factors (knowledge, environment, sexual knowledge, and emotional considerations) to test. The contribution rate for each section was 16.3%, 15.5%, 7.9%, and 18.9%, respectively and the total variance was 58.6%. The four components were distributed evenly using the theoretical model.

Correlation Coefficient

The correlation coefficient among the items and various sections ranged from 0.213 to 0.564. The correlation coefficient between the sections and the total score ranged from 0.499 to 0.778. All correlation coefficients were statistically significant [Table/Fig-4].

Item	Assessment	EE	RR	CC	RA	SRA	CrC	FA1	FA2
A1	Information in diagnosis and treatment				F		F	F	
A3	Possibility of cure					F		F	F
A8	Side effect of treatment					F	F	F	
A10	Purpose of operation					F	F	F	
A14	Skin care in surgery area	F				F	F		F
A19	Limb rehabilitation and exercise					F	F		F
B20	Caterers and food at reasonable prices	F		F			F	F	F
B21	Cooking equipment available 24 hrs	F		F		F			F
B22	Admission in basic equipment	F				F			F
B23	Entertainment (e.g., TV, newspapers) in ward	F		F		F			F
B28	Learn to call staff emergency					F	F	F	
B29	Inform daily progress in treatment			F			F		F
B30	Limited visit			F	F				F
B32	Get the list of costs			F		F		F	
B33	Economic support from friends/family	F		F					F
B34	Economic support from community	F		F				F	F
B36	Advertised Medicare reimbursement					F	F		F
C37	Guide to contraception and pregnancy		F	F	F				
C38	Guidance on family sexual education	F		F	F		F	F	
C39	Impact on sexual life			F		F	F	F	
D41	Accompanied by family during hospital			F		F			F
D43	Discuss with medical staff			F			F		F
D44	Help nurses and other patients	F				F	F		
D49	Equal treatment			F		F			F
D59	Discuss with family at any time	F				F	F		
D60	Discuss the disease with strangers	F		F		F			F
D62	Support in mental with family					F	F		F
D63	Let strangers know disease condition	F		F	F				

[Table/Fig-2]: Questions eliminated after screening and which tests they failed. Abbrev: EE, expert's evaluation; RR, response rate; CC, correlation coefficient; RA, reaction analysis; SRA, step-wise regression analysis; CrC, Cronbach's coefficient; FA1, Factors Analysis 1; FA2, Factors Analysis 2; F, failed (test did not meet standards).

Section	No. questions	Cronbach's coefficient	Split-half reliability
Total Scale	38	0.959	0.935
Knowledge	12	0.914	0.876
Environmental	7	0.889	0.837
Sexual knowledge	3	0.879	0.918
Psychosocial	16	0.936	0.903

[Table/Fig-3]: Cronbach's coefficient and split-half reliability analysis, divided by survey section.

DISCUSSION

In general, the desired total number of questions on an effective health survey should range from 20 to 139, with most surveys having 30 to 50 questions [20]. Typically, personal interviews take approximately 15–30 minutes, whereas after 30 minutes, the qualities of the survey responses decrease [21]. Our final product

Section	Knowledge	Environmental	Psychosocial	Sexual knowledge	Total
Knowledge	1.000	0.549	0.518	0.231	0.715
Environmental	0.549	1.000	0.564	0.219	0.678
Psychosocial	0.518	0.564	1.000	0.427	0.778
Sexual knowledge	0.231	0.219	0.427	1.000	0.499
Total	0.715	0.678	0.778	0.499	1.000

[Table/Fig-4]: Correlation coefficient calculations between survey sections and survey as a whole.

contained 38 questions, which is reasonable and sensitive, and patients spent no more than 30 minutes completing the questionnaire.

Sexual knowledge has not been widely spread in China [22]. However, treatment of breast cancer can often elicit hormonal changes and subsequently affect sexual life, so it is important to include an assessment of this area on a survey for breast cancer patients. The questions in our sexual knowledge section were focused on the disease's effects on sexual life and clearly showed independence.

We included a panel of experts (i.e., doctors, nurses, and health researchers) and patients in this study during the interview process and scored the items of the potential importance. Patients were chosen after participating in an interview, so that we could better understand the needs and concerns of this cohort. We also included patients in the testing process to ensure questions and terminology that might be misunderstood by patients could be identified.

We selected questions through a subjective expert interview as well as objective assessments, which included: response rate, correlation analysis, variation of reaction, factor analysis and a stepwise regression analysis. The correlation coefficient and factor analysis were used to screen the questionnaire structure for the production of correlated data. The t-test variation and stepwise regression analysis were used to assess the variation of the structure of the data. Finally, a multiple regression analysis was used to find multiple indicators. While the comprehensive evaluation is the most commonly used method, the advantages and disadvantages of each method were considered and compared with other methods. Item selection was a key step in questionnaire development. We used the importance score, response rate, correlation coefficient, reaction analysis, stepwise regression analysis, Cronbach's coefficient, and factor analysis in item selection. Several complementary methods were used to maximize the information derived from the survey data. We also paid attention to each question's importance, sensitivity, independence, proper representation, and uncertainty and have, consequently, developed a practicable and acceptable series of questions.

According to accepted standards, a questionnaire is considered to be reliable if the test-retest reliability value of the survey is more than 0.7 and the Cronbach's coefficient is more than 0.8. Also, the split-half reliability should reach 0.8 or higher [23]. In this study, all of these indicators were acceptable, indicating that our survey is stable and reliable.

In addition, we calculated the Pearson correlation between questions, between each question and the corresponding section, between sections, and between each section and the total survey. For assessments between items and sections, a correlation coefficient between 0.1 and 0.6 is generally acceptable [24], while the correlation between the sections and the total survey should be from 0.3 to 0.8 [25]. In our case, coefficient between an item and its dimension was larger than the coefficient between an item and other dimensions and the coefficient values between item and its dimension exceeded 0.4.

A validity evaluation was used to test the distribution of each sample in a theoretical model, as the relationship between questions and factors is unknown. Estimated results were determined based on here the data was obtained from, and on a combination of experience and imaging. A four-factor analysis yielded a good professional interpretation, while results from the varimax rotation were consistent with the theoretical model. Because there are fewer standard Chinese questionnaires, standard validity was not tested. It should be noted that though this survey was tested in southern China, we plan to use it throughout China, if possible.

The presently described instrument is the first Chinese-language questionnaire designed to assess breast cancer patient needs. It was crafted through interactions with patients, clinicians, nurses, and social workers and we incorporated many of their suggestions to maximize its acceptability by patients. Guided by the bio-psycho-social medical model, the structure of the questionnaire encompassed four dimensions: disease knowledge; medical environment; psychosocial parameters; and sexual attitude. Each of the dimensions is graded independently, yielding four section scores, which sum to produce to total assessment score. In addition to the sexual attitude dimension being assessed as an independent section, we also asked patients to be attentive to their sexual health.

The present questionnaire development has noteworthy strengths. Notably, we used a team-based, collaborative approach to questionnaire development to enable us to develop a highly comprehensive and realistic instrument. Additionally, to produce a maximally objective instrument, we used several statistical methods to select the final questionnaire items. Conversely, this study has some limitations.

LIMITATION

Firstly, this tool is intended for patients who are being treated in the hospital and undergoing surgery, chemotherapy and radiation; it was not designed for patients after they have been treated or for end-stage patients. Secondly, because the questionnaire was produced in Mandarin Chinese in a single province, it needs to be tested broadly throughout mainland China.

CONCLUSION

We developed and tested a new questionnaire for providing a more thorough and comprehensive assessment of Chinese patients with breast cancer. All of the survey's reliability indicators met standard requirements, demonstrating its accuracy and stability. We anticipate the use of this survey in medical practice as a tool for a more complete assessment of patients' needs.

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