Development and Validation of a Cardiotoxicity Risk Assessment Scale for Breast Cancer Chemotherapy Patients: A Post-Print

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Abstract

Background Cardiotoxicity in breast cancer chemotherapy patients represents a major cause of mortality among breast cancer survivors and patients, and early risk assessment and detection of cardiotoxicity holds significant importance for clinical prevention and treatment of cardiotoxicity; however, there is currently a lack of recognized risk assessment tools for cardiotoxicity in breast cancer chemotherapy patients in China.

Objective To develop a cardiotoxicity risk assessment scale for breast cancer chemotherapy patients and examine its reliability and validity.

Methods An item pool was constructed through review of relevant domestic and international literature. Using purposive sampling, healthcare professionals were selected for semi-structured interviews at Jiangsu Cancer Hospital from September to October 2022 to preliminarily establish an item pool for the cardiotoxicity risk assessment scale for breast cancer chemotherapy patients. Breast cancer chemotherapy patients treated at Jiangsu Cancer Hospital were selected for pilot survey and reliability and validity testing of the scale. All cardiotoxicity risk scores of breast cancer chemotherapy patients were ranked, with the lowest 27% designated as the low-score group and the highest 27% as the high-score group. Cronbach's α coefficient was employed to evaluate internal consistency of the scale. Item-level content validity index (I-CVI) and scale-level content validity index (S-CVI) were utilized for validity testing. Exploratory factor analysis was applied to assess structural validity of the scale. Receiver operating characteristic curve (ROC curve) was plotted, and area under the ROC curve (AUC) was calculated to determine predictive validity.

Results Semi-structured interviews included 20 healthcare professional experts. Following two rounds of expert consultation, a 19-item cardiotoxicity risk assessment scale for breast cancer chemotherapy patients was developed. This study comprised 79 patients in the low-score group and 83 patients in the high-score group. Comparison of critical ratios between the two groups revealed no statistically significant differences in endocrine therapy history and immunotherapy history ($P>0.05$). Correlation analysis results indicated that smoking history and immunotherapy history showed no correlation with total score ($P>0.05$). Ultimately, three items– "smoking history," "endocrine therapy history," and "immunotherapy history" –were deleted, resulting in a 16-item scale. The scale' s Cronbach' s α coefficient was 0.739; test-retest reliability was 0.983; inter-rater reliability was 0.984. Content validity results demonstrated: I-CVI ranged from 0.83 to 1.00; S-CVI was 0.98. Predictive validity results showed: scale AUC was 0.887 (95%CI=0.827~0.947, $P<0.001$), cutoff value was 32.50 points, Youden index was 0.649, specificity was 89.1%, and sensitivity was 75.9%. Exploratory factor analysis results revealed: KMO value was 0.700, Bartlett' s test of sphericity 2 value was 1,037.898 (df=120, $P<0.001$). This study extracted five common factors with a cumulative variance contribution rate of 61.991%. Risk stratification results indicated: scores of 32~38 represented low risk, 39~56 represented medium risk, and \$ \$57 represented high risk.

Conclusion The cardiotoxicity risk assessment scale for breast cancer chemotherapy patients exhibits good reliability and validity, can effectively predict high-risk populations for cardiotoxicity, and may provide an effective assessment tool for clinicians and nurses to identify high-risk groups for cardiotoxicity among breast cancer chemotherapy patients.

Full Text

Development and Reliability and Validity Testing of a Cardiotoxicity Risk Assessment Scale for Breast Cancer Patients Undergoing Chemotherapy

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Abstract

Background: Cardiotoxicity is a leading cause of morbidity and mortality among breast cancer survivors and patients, making early risk assessment vital for clinical prevention and treatment. However, China currently lacks a recognized assessment tool for cardiotoxicity risk in breast cancer patients undergoing chemotherapy.

Objective: To develop a cardiotoxicity risk assessment scale for breast cancer patients undergoing chemotherapy and to test its reliability and validity.

Methods: An item pool was constructed through systematic literature review. Using purposive sampling, semi-structured interviews were conducted with medical staff at Jiangsu Cancer Hospital from September to October 2022 to initially formulate the item pool. Breast cancer patients undergoing chemotherapy at Jiangsu Cancer Hospital were then selected for pilot testing and reliability and validity testing. All patient risk scores were ranked, with the lowest 27% designated as the low-risk group and the highest 27% as the high-risk group. Internal consistency was evaluated using Cronbach' s α coefficient. Content validity was assessed using the item-level content validity index (I-CVI) and scale-level content validity index (S-CVI). Construct validity was evaluated through exploratory factor analysis. Predictive validity was determined by receiver operating characteristic (ROC) curve analysis and calculation of the area under the curve (AUC).

Results: Twenty medical experts participated in the semi-structured interviews. After two rounds of expert consultation, a 19-item cardiotoxicity risk assessment scale was developed. The study included 79 patients in the low-score group and 83 in the high-score group. Comparisons between groups showed no statistically significant differences in endocrine therapy history or immunotherapy history ($P>0.05$). Correlation analysis revealed that smoking history and immunotherapy history were not significantly correlated with total scores ($P>0.05$). Three items– "smoking history," "endocrine therapy history," and "immunotherapy history" –were subsequently deleted, resulting in a 16-item scale. The scale demonstrated a Cronbach' s α coefficient of 0.739, test-retest reliability of 0.983, and inter-rater reliability of 0.984. Content validity results showed I-CVI ranging from 0.83 to 1.00 and S-CVI of 0.98. For predictive validity, the scale' s AUC was 0.887 (95%CI=0.827-0.947, $P<0.001$), with a cutoff value of 32.50 points, Youden' s index of 0.649, specificity of 89.1%, and sensitivity of 75.9%. Exploratory factor analysis yielded a Kaiser-Meyer-Olkin (KMO) value of 0.700 and Bartlett' s test of sphericity ^{2} value of 1,037.898 (df=120, $P<0.001$). Five common factors were extracted with a cumulative variance contribution rate of 61.991%. Risk stratification identified scores of 32–38 as low risk, 39–56 as medium risk, and $ $57 as high risk.

Conclusion: The cardiotoxicity risk assessment scale for breast cancer patients undergoing chemotherapy demonstrates good reliability and validity, effectively predicting high-risk populations and providing clinicians and nurses with an

effective tool for identifying patients at high risk of cardiotoxicity.

Keywords: Breast neoplasms; Chemotherapy side effects; Cardiotoxicity; Qualitative research; Reliability and validity testing

1. Methods

1.1 Scale Development

1.1.1 Literature Review A systematic literature search was conducted to construct the initial item pool. Eight databases were searched: PubMed, CINAHL, Cochrane Library, Web of Science, Chinese Biomedical Literature Database, CNKI, VIP, and Wanfang Database. All published studies on risk factors for cardiotoxicity in breast cancer patients undergoing chemotherapy were retrieved, with secondary literature tracked. The specific databases and search terms are shown in . Inclusion criteria were: (1) female breast cancer patients undergoing chemotherapy, aged >18 years; (2) publications in English or Chinese. Exclusion criteria were irrelevant studies and duplicate publications.

1.1.2 Qualitative Interviews Using purposive sampling, semi-structured interviews were conducted with medical staff at Jiangsu Cancer Hospital from September to October 2022. Inclusion criteria were: (1) bachelor' s degree or higher; (2) associate senior professional title or above with >10 years of experience in breast cancer care. Sample size was determined based on saturation principle in qualitative research—when no new codes emerged during analysis. To ensure credibility, two additional participants were interviewed after saturation was reached. A preliminary interview outline was developed based on literature review and research objectives . With informed consent, data were collected through face-to-face, semi-structured interviews in convenient, undisturbed locations (such as demonstration rooms or lounges). Interviews were audio-recorded with field notes, each lasting $ $30 minutes. The interviewer was professionally trained and conducted all interviews, observing participants' expressions, speech rate, and tone while clarifying and confirming responses. Any uncertainties during transcription were verified with participants to ensure accuracy and objectivity. Content analysis was performed, with interview data transcribed verbatim and read repeatedly.

1.1.3 Research Group Discussion The research group comprised five members: one professor, two associate professors, and two graduate students. Based on literature analysis and qualitative interview findings, the group discussed the scale framework, providing opinions and suggestions on the importance, applicability, and rationality of each item to revise the item pool and initially formulate the cardiotoxicity risk assessment items.

1.1.4 Expert Consultation Expert selection criteria were: (1) clinical physicians or specialist nurses in breast cancer; (2) research experience in relevant fields; (3) master's degree or above for physicians, bachelor's degree or above for nurses. Twenty experts were invited to participate. The consultation package included an expert letter, initial scale, and expert demographic survey . Items were rated using a 5-point Likert scale (1=not important to 5=very important). Questionnaires were distributed via face-to-face or email. After the first round, expert feedback was analyzed and discussed by the research team to develop the second-round questionnaire. Two rounds were conducted, retaining items with mean importance scores >3.5. Expert reliability was analyzed using: (1) response rate as the expert active coefficient; (2) expert authority coefficient (Cr), calculated as (Ca+Cs)/2, where Ca is the judgment coefficient and Cs is the familiarity coefficient (range 0–1, higher scores indicating greater authority); (3) Kendall' s coefficient of concordance (W) with ^{2} test (P<0.01 indicating good consistency). Retrieved data were analyzed to calculate mean ($\bar{x}$) and standard deviation (S) for each item, then coefficient of variation (CV=S/$\bar{x}$). Items with mean score <3.5 or CV>0.25 were considered for modification, deletion, or supplementation based on expert opinions and focus group discussions to ensure scale coherence.

1.2 Pilot Survey and Item Analysis

1.2.1 Participants Using purposive sampling, breast cancer patients undergoing chemotherapy at Jiangsu Cancer Hospital were selected for pilot testing. Inclusion criteria were: (1) female patients aged $ $18 years with pathologically confirmed breast cancer; (2) receiving chemotherapy; (3) primary school education or above; (4) adequate comprehension and clear thinking; (5) informed consent. Exclusion criteria were: (1) psychiatric or severe cognitive disorders; (2) patients unaware of their diagnosis; (3) those already experiencing cardiotoxicity. Sample size was 5-10 times the number of items for item analysis and 5 times (minimum 100) for exploratory factor analysis, with 10–20% allowance for invalid responses. With 19 initial items, 230 patients were enrolled [10].

1.2.2 Item Analysis The critical ratio method was used, with risk scores ranked and the lowest 27% designated as the low-score group and highest 27% as the high-score group [11]. Items showing no significant between-group differences on nonparametric tests were considered for deletion. Correlation analysis examined item-total correlations, with nonsignificant items flagged for removal.

1.2.3 Weight Determination and Scoring Criteria After item analysis, exploratory factor analysis was used to calculate item weights, extracting eigenvalues, factor loadings, and variance percentages. Composite coefficients were calculated and normalized to obtain average weight values. Items were scored as: weight 0–<0.02=1 point, 0.02–<0.04=2 points, 0.04–<0.06=3 points, 0.06–<0.08=4 points, 0.08–<0.10=5 points, and 0.10–0.12=6 points .

1.3 Formal Survey and Psychometric Testing

1.3.1 Participants Using purposive sampling, breast cancer patients undergoing chemotherapy at Jiangsu Cancer Hospital were selected, with the same inclusion/exclusion criteria as the pilot survey. A total of 203 patients were ultimately enrolled.

1.3.2 Reliability Testing **(1) Internal Consistency:** Cronbach' s α coefficient was used, with α>0.7 indicating good internal consistency.
(2) Test-Retest Reliability: The retest sample comprised 10–15% of the total, with minimum 20 participants.
(3) Inter-Rater Reliability: Pearson correlation coefficient was used to analyze total score correlations.

1.3.3 Validity Testing **(1) Content Validity:** Measured appropriateness and relevance using I-CVI and S-CVI.
(2) Construct Validity: Evaluated through exploratory factor analysis. During scale development, this method determined item weights, with cumulative contribution rate \$ \$50% indicating good construct validity.
(3) Predictive Validity: ROC curve analysis was performed, with maximum Youden' s index determining the cutoff value, expressed as AUC, sensitivity, and specificity.

1.3.4 Sensitivity, Specificity, and High-Risk Threshold **(1) Diagnostic Threshold Determination:** Larger AUC indicates better diagnostic efficacy. AUC \$ 0.5 = *nodiagnosticvalue*; 0.5 < *AUC* 0.7 = *lowdiagnosticvalue*; 0.7 < *AUC* \$0.9=moderate accuracy; AUC>0.9=high accuracy.
(2) Risk Stratification: Quartile method was used: scores <25th percentile=low risk, 25th–75th percentile=medium risk, >75th percentile=high risk.

1.4 Statistical Analysis

SPSS 26.0 and Excel were used for data analysis. Categorical data were expressed as [n (%)]. Normally distributed continuous data were presented as ($\bar{x}\pm s$), while non-normally distributed data as $M(P_{25},P_{75})$. Between-group comparisons used rank-sum tests. Item screening employed critical ratio and correlation coefficient methods. Content validity was assessed via I-CVI and S-CVI. Construct validity used exploratory factor analysis. ROC curves were plotted to determine diagnostic thresholds.

2. Results

2.1 Expert Consultation Results

Twenty experts from 10 provinces and 3 municipalities (Jiangsu, Zhejiang, Shanghai, Harbin, Hunan, Yunnan, Chongqing, Shaanxi, Fujian, Liaoning, Guangdong, Gansu, Tianjin) specializing in breast cancer research were enrolled, including 4 males and 16 females, aged 34–62 years (mean 46.8$±$6.0). Ten held senior professional titles, nine associate senior titles, and one intermediate title . In the first round, 20 questionnaires were distributed and all returned (100% response rate), with 10 experts providing modification suggestions. In the second round, all 20 questionnaires were again returned (100% response rate), with 3 experts providing suggestions. Both rounds exceeded the 70% threshold, indicating good expert engagement.

First round results: Ca=0.965, Cs=0.810, Cr=0.887, Kendall' s W=0.337 (^{2}=105.470, P<0.001). Based on expert feedback and group discussion, items were added: "Liver function normal," "Kidney function normal," "Planned treatment includes anthracyclines," and "Planned treatment includes trastuzumab." Item "Age" was modified to categories "18–49 years," "50–65 years," and "<18 or >65 years." "BMI" was revised to "<18.5 kg/m^{2}," "18.5–<25.0 kg/m^{2}," "25.0–<30.0 kg/m^{2}," and "$ 30.0kg/m^{2}$." The term "previous" was removed from medical history items. "Planned treatment includes cardioprotective drugs" was re-categorized as "Yes (dexrazoxane)," "Yes (other cardioprotective drugs)," and "No."

Second round results: Ca=0.970, Cs=0.870, Cr=0.920, Kendall' s W=0.471 (^{2}=169.592, P<0.001). Based on feedback, "Tumor stage" was modified to categories " ," " ," " ," " ," and "Cardiovascular disease" was changed to "Cardiac disease history." After two rounds, a 19-item scale was finalized.

2.2 Item Analysis Results

The study included 79 patients in the low-score group and 83 in the high-score group. Critical ratio comparisons showed no significant differences in endocrine therapy history or immunotherapy history between groups (P>0.05) . Correlation analysis revealed that smoking history and immunotherapy history were not significantly correlated with total scores (P>0.05) . Following group discussion, three items ("smoking history," "endocrine therapy history," and "immunotherapy history") were deleted. After exploratory factor analysis, factor matrices were used to determine component weights, resulting in a 16-item scale with a maximum score of 99 points.

2.3 Reliability Analysis Results

The scale demonstrated a Cronbach's α coefficient of 0.739, test-retest reliability of 0.983, and inter-rater reliability of 0.984.

2.4 Validity Analysis Results

Content validity showed I-CVI ranging from 0.83 to 1.00 and S-CVI of 0.98. Predictive validity results indicated an AUC of 0.887 (95%CI=0.827-0.947, P<0.001), cutoff value of 32.50 points, Youden' s index of 0.649, specificity of 89.1%, and sensitivity of 75.9% [Figure 1: see original paper]. Exploratory factor analysis yielded a KMO value of 0.700 and Bartlett' s test ^{2}=1,037.898 (df=120, P<0.001), confirming suitability for factor analysis. Five common factors were extracted with a cumulative variance contribution rate of 61.991%.

2.5 Risk Stratification

Using the integer cutoff value of 32 points from the ROC curve, 22 true-positive patients were identified. Quartile analysis of their scores stratified risk as: 32–38 points=low risk, 39–56 points=medium risk, and $ $57 points=high risk.

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3. Discussion

3.1 Scientific Rigor in Scale Development

This study strictly adhered to scale development principles and protocols, demonstrating strong scientific rigor. First, systematic literature analysis and qualitative interviews with medical staff identified relevant risk factors. A research group then analyzed, integrated, and screened these factors to form the initial item pool. Second, during Delphi consultation, strict selection criteria were applied to revise the preliminary scale. The 20 selected experts were all specialists with substantial research experience (mean 21.25 years). The second-round response rate was 100%, indicating high expert engagement. Authority coefficients were 0.887 and 0.920, reflecting high expertise. Kendall' s W values of 0.337 and 0.471 (P<0.001) showed good expert consensus [12]. Item analysis using critical ratio and correlation methods deleted three items, ensuring homogeneity and finalizing the 16-item scale.

3.2 Adequate Reliability and Validity

A robust measurement tool requires sufficient psychometric properties. This scale showed a Cronbach' s α of 0.739, test-retest reliability of 0.983, and inter-rater reliability of 0.984, indicating good reliability [13]. Content validity indices were excellent (S-CVI=0.98, I-CVI=0.83-1.00). The KMO value of 0.700 and Bartlett' s test (^{2}=1,037.898, df=120, P<0.001) supported factor analysis [14]. All item loadings on their respective factors were >0.4 without cross-loadings, demonstrating stable structure [15]. The cumulative variance contribution rate of 61.991% indicated comprehensive coverage of cardiotoxicity risk information [16]. Predictive validity reflects screening accuracy. The AUC of 0.887 at a cutoff of 32 points yielded 75.9% sensitivity and 89.1% specificity (Youden' s index=0.649). Among 203 patients, 29 developed cardiotoxicity, with 22 scoring

$ $32 points, demonstrating good positive predictive value for identifying high-risk individuals.

3.3 High Clinical Applicability

Chemotherapy-induced cardiotoxicity (CIC) remains a major concern affecting quality of life and overall survival in breast cancer patients [17]. However, clinical monitoring lacks early indicators, and preventive strategies lack specificity [18]. Therefore, risk assessment is crucial for prognosis and quality of life [19]. CLARK et al. [20] developed a combined questionnaire for cardiotoxicity and cardiovascular disease risk assessment in breast cancer patients receiving chemoradiotherapy. However, this joint questionnaire has low specificity for breast cancer, contains nearly 200 items, and requires lengthy completion, limiting clinical utility.

Our 16-item scale covers general and treatment-related factors with three risk levels, enabling nurses to early identify cardiotoxicity risk. The scale uses clear, accessible language with explicit evaluation criteria, facilitating clinical completion and demonstrating high practical value.

This cardiotoxicity risk assessment scale shows good reliability and validity, serving as an effective tool for evaluating cardiotoxicity risk in breast cancer patients undergoing chemotherapy. Future preventive interventions should use this scale for risk assessment to develop personalized cardioprotective strategies, enabling early prevention and treatment. However, this study' s limitation is its single-center sample, requiring further validation of representativeness and generalizability.

Author Contributions: YAO Shanshan conceptualized and designed the study, implemented the research, and drafted the manuscript. YAO Shanshan, MA Zhuyue, SHI Yanyan, and WU Yuqing collected and analyzed data, performed statistical analysis, and created figures and tables. ZHANG Liuliu, CHEN Mingxia, WU Bing, and CHENG Fang revised the manuscript. CHENG Fang supervised quality control and was accountable for the overall work.

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Note: Figure translations are in progress. See original paper for figures.