Psychometric Properties of the Fertility Intention Scale among Patients with Breast Cancer of Childbearing Age in Mainland China

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ABSTRACT

Objective: There are no valid assessment instruments assessing fertility intention among breast cancer survivors in mainland China. Therefore, this study aims to examine the psychometric properties of the Taiwanese version of the Fertility Intention Scale (FIS) among female patients with breast cancer of childbearing age in mainland China.

Methods: Two hundred and sixty-four female patients with breast cancer of childbearing age were recruited from two tertiary hospitals in Tianjin and Baoding, of which 32 patients completed the survey twice. Confirmatory factor analysis was adopted to assess construct validity. Correlations between the Reproductive Concerns After Cancer scale and FIS scores were calculated using Spearman correlation for convergent validity. The known-group validity of the FIS was verified using Mann-Whitney U test to compare the FIS scores between patients with or without the intention to conceive. Moreover, reliabilities were examined using Cronbach's alpha and intra-class correlation coefficient.

Results: Confirmatory factor analysis showed a good model fit to previous factor structures ($\chi^2/df = 3.19$, root mean square error of approximation = 0.091, comparative fitting index = 0.980, Tucker-Lewis index = 0.975), and no FIS item was dropped. The FIS scores were weak negatively correlated with the Reproductive Concerns After Cancer scale scores ($r = -0.172, P < 0.01$). The convergent validity of FIS was not satisfactory. Differences were noted between patients with or without the intention to conceive ($50.62 \pm 6.35$ vs. $45.98 \pm 7.19$, $P < 0.01$). The FIS showed acceptable known-group validity. The internal consistency (Cronbach's $\alpha = 0.824$) and the test-retest reliability ($r = 0.863$, $P < 0.01$) of the FIS were also acceptable.

Conclusions: Overall, the FIS provides a comprehensive evaluation of the fertility intention among patients with breast cancer of childbearing age in mainland China. However, the convergent validity was not satisfactory; thus, further revision and validation may be required in the future.

Introduction

Globally, the incidence of breast cancer is the highest among all cancers in women and is increasing among young women gradually. Conventional treatment for breast cancer includes surgery, radiotherapy, chemotherapy, and endocrine therapy. Anti-tumor therapy can improve the survival rate of patients with breast cancer; however, it can negatively affect fertility. A study showed that 57% of female patients with cancer had fertility intentions. However, only 3% of patients with breast cancer became pregnant after treatment. Due to treatment-related fertility impairment, insufficient fertility-related knowledge, and reproductive concerns, patients may reconsider their fertility plans. Studies have reported that patients who abandoned their fertility plans had an increased likelihood of experiencing decision-making regret, anxiety, depression, and decreased quality of life.

Fertility intention refers to a type of psychological motivation or desire for fertility among individuals to achieve pregnancy. In contrast to healthy individuals, the risk of disease and treatment among patients with cancer of reproductive age creates complexity in terms of...
their fertility intentions. A comprehensive evaluation of the fertility intention of patients with breast cancer can facilitate personalized fertility-related care for patients to eliminate reproductive concerns. Furthermore, healthcare providers can assist patients in making informed fertility decisions, thus providing patients with targeted fertility preservation measures.

Fertility intention is determined by an individual's values, which are related to an individual's circumstances, perceptions of fertility risks, interests, and expectations. Previously, most studies focused on the attitude, motivation, and decision-making preference toward fertility among patients with cancer, with limited studies focusing on fertility intention. Several qualitative studies have explored the perception of fertility intention among patients with cancer. Furthermore, studies have underscored concerns among patients that pregnancy could negatively affect both personal and child health, perhaps even causing tumor recurrence, thus reducing the fertility intention of patients. Additional reproductive concerns are related to decreased fertility intention among patients. Furthermore, fertility-related information, social support, and symptom burden also affect patients' fertility intention.

There are limited instruments that assess fertility intention among patients with cancer. To investigate the fertility intention among cancer survivors, Mancini et al. asked the following question, ie. “Do you plan to have a child or more children?”. Although this method is simple and direct, it lacks guidance for clinical intervention because of the limited information provided. Quinn et al. developed a 10-Item Reproductive Concerns Assessment to evaluate future fertility intention and the reproductive concerns among adolescent girls with cancer. However, the scale mainly measured the reproductive concerns and reported only the validity. Gorman et al. developed the Reproductive Concerns After Cancer (RCAC) scale in 2014 which demonstrated good reliability and validity to assess the reproductive concerns of patients with cancer. Although the reproductive concern is an important predictor of fertility intention, the scale failed to express the influence of social support, culture, and other factors on fertility intention. As a result, Newton et al. developed the Fertility Problem Inventory in 1999. Currently, it is used mainly to assess the perspective on marriage, sexual life, fertility, social interaction, and childless lifestyle among infertile patients. While the Fertility Problem Inventory demonstrates good reliability and validity; it focuses merely on the negative impact of infertility on daily life patients.

Li et al. developed the Taiwanese Fertility Intention Scale (FIS) in 2018, which had acceptable reliability and validity. The FIS can evaluate the fertility intention among patients with breast cancer of childbearing age in Taiwan from multiple dimensions. Furthermore, the FIS can be used to understand the reasons for the low fertility intention among patients with breast cancer to guide further intervention.

Despite the common cultural backgrounds and languages between mainland China and Taiwan, several differences in language expression habits and family values still exist. Furthermore, the applicability of the Taiwanese version of the FIS in mainland China is still unclear. Therefore, the study aimed to validate the Taiwanese version of the FIS among patients with breast cancer of childbearing age in mainland China.

Methods

Sample and data collection

This was a descriptive study with a methodological design that used convenience sampling to recruit participants from a tertiary general hospital in Baoding and a tertiary cancer hospital in Tianjin from July 2 to October 26, 2021. The inclusion criteria included the following: (1) diagnosed with primary breast cancer; (2) age ranging from 18 to 40 years old; (3) awareness the diagnosis. The exclusion criteria included the following: (1) had severe cognitive impairment; (2) diagnosed with infertility before the diagnosis of breast cancer; (3) had a family history of breast cancer; (4) had severe diseases or malignant tumors. According to Ferguson and Cox, the sample size should be 5–10 times as many as the number of items for psychometric validation in the measurement instrument. FIS has 15 items in total. The sample size in this study used 10 times the number of items. Furthermore, at least 150 cases were required. When performing the factor analysis, the sample size should exceed 200 cases. A total of 264 patients were included in the study.

All paper questionnaires were distributed and collected in person by trained researchers. The self-report questionnaires were completed by all the consenting participants. Medical history and additional information were obtained from electronic medical records. Furthermore, 32 participants completed the second FIS survey after three weeks of test-retest reliability testing.

Instruments

Sociodemographic and clinical information questionnaire

The questionnaire comprised the following: (1) sociodemographic characteristics: age, marital status, education, number of children, and employment situation; (2) disease and treatment information: diagnosis time, cancer stage, surgery type, and adjuvant treatment; (3) access to fertility-related services: fertility information, fertility consultation, and fertility preservation; (4) whether to have a pregnancy desire or not.

FIS

The FIS was used to measure the fertility intention level of female patients with breast cancer in Taiwan. It contains 15 items that are divided into four dimensions, namely, six items for pregnancy risk (perceptions about the burden and safety of pregnancy), four items for disease control (perceptions of the threat of illness and treatment), three items for social support (perceived potential assistance from others for raising children), and two items for happiness (the feeling of being able to create the next generation). A five-point Likert scale (1 = strongly disagree to 5 = strongly agree) was used to assess each item. The score of FIS is 15–75. A higher score indicates stronger fertility intention. The FIS scored 0.88 of the content validity index and 0.61 on the test-retest reliability. The Cronbach’s alpha of FIS was 0.88.

RCAC scale

The RCAC was used to assess the reproductive concerns and related issues among young female patients with cancer. It contains 18 items, which are divided into six dimensions, namely, fertility potential, partner disclosure of fertility status, children’s health, personal health, acceptance, and becoming pregnant. Each item was evaluated on a 5-point Likert type response (1 = strongly disagree to 5 = strongly agree). A higher RCAC score indicates an increased level of reproductive concern. The Cronbach’s alpha of RCAC was 0.82. The RCAC also demonstrated good validity. And the reliability and validity of the Chinese version of RCAC are acceptable.

Data analysis

SPSS for Windows version 26.0 and Mplus version 7.0 were used to analyze the data. Categorical variables were expressed as counts and percentages. A normal distribution test was performed using the Shapiro–Wilk test. Normally distributed data were expressed as mean and standard deviation (SD), and non-normally distributed data were expressed as the interquartile range. Parametric tests (e.g. Pearson correlation and t-test) were used to analyze normal distribution data, and non-parametric tests (e.g. Spearman correlation and Mann–Whitney U test) were used to analyze non-normal distribution data. When P < 0.05, the differences in all statistical tests were statistically significant (two-sided).

Item analysis was performed using item-total correlation and critical ratio value. There was careful consideration to remove items with a correlation coefficient below 0.3. The critical ratio value was used to assess the discrimination of each item. According to the
descending order of the total scores of the FIS for all participants, the high score group was in the top 27th percentiles, and the low score group was in the lowest 27th percentiles. The difference between the two groups was analyzed using the t-test \( (P < 0.05) \). Similarly, there was careful consideration to remove items below the \( P > 0.05 \) or \( t < 3 \). Confirmatory factor analysis (CFA) was used to analyze the construct validity, and the estimator for modeling adopted weighted least squares-mean and variance adjusted. Furthermore, Chi-square degree of freedom, root mean square error of approximation (RMSEA), Tucker–Lewis index (TLI), and comparative fitting index (CFI) were performed to assess the CFA model. Cut-off values required for the acceptable model fit were recommended according to \( \chi^2/df < 5 \), \( \text{RMSEA} < 0.1 \), \( CFI > 0.95 \), and \( TLI > 0.95 \). Based on previous research, this study hypothesized that fertility intention negatively correlated with reproductive concerns. Spearman correlation between the FIS scores and the RCAC scores was to verify the convergent validity of FIS. The correlation was divided into three levels: namely, weak correlation (0.00–0.30), moderate correlation (0.40–0.60), and strong correlation (0.70–1.00). The participants were divided into two groups based on whether they had the desires to conceive or not. The rank-sum test (Mann–Whitney U test) was adopted to evaluate the FIS scores of the two groups in order to verify the known-group validity of FIS. This study also hypothesized that participants who wished to have another child had higher FIS scores than those who did not. The internal consistency of the FIS was evaluated using Cronbach’s alpha coefficient. Alpha values between 0.70 and 0.95 were considered satisfactory for internal consistency. An intra-class correlation coefficient was adopted to compare FIS scores of the 32 patients for both surveys to calculate the test-retest reliability of the scale. Intra-class correlation coefficient exceeding 0.70 was considered sufficient, while scores between 0.30 and 0.70 were considered acceptable.

| Characteristic                  | n  | %   |
|---------------------------------|----|-----|
| Education                       |    |     |
| Junior high school or lower     | 56 | 21.2|
| Senior high school or technical school | 38 | 14.4|
| Associate degree                | 67 | 25.4|
| Bachelor's degree or above      | 103| 39.0|
| Marital status                  |    |     |
| Married                         | 238| 90.2|
| Single                          | 22 | 8.3 |
| Others                          | 4  | 1.5 |
| Number of children              |    |     |
| 0                               | 33 | 12.5|
| 1                               | 145| 54.9|
| 2                               | 79 | 29.9|
| >2                              | 7  | 2.7 |
| Employment status               |    |     |
| Employed                        | 151| 57.2|
| Unemployed                      | 113| 42.8|
| Cancer stage                    |    |     |
| I                               | 6  | 2.3 |
| II                              | 143| 54.2|
| III                             | 115| 43.6|
| Surgical approach               |    |     |
| No                              | 57 | 21.6|
| Breast-conserving surgery        | 45 | 17.0|
| Modified radical resection      | 29 | 11.0|
| Total mastectomy                | 133| 50.4|
| Adjuvant therapy                |    |     |
| Radiotherapy                    | 70 | 26.5|
| Chemotherapy                    | 213| 80.7|
| Endocrine therapy               | 81 | 30.7|
| Fertility intention             |    |     |
| Yes                             | 29 | 11.0|
| No                              | 235| 89.0|

Table 2
FIS Item analysis.

| PR 1 | PR 2 | PR 3 | PR 4 | PR 5 | PR 6 | PR 7 | PR 8 | PR 9 | PR 10 | SS 11 | SS 12 | SS 13 | Ha 14 | Ha 15 |
|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|-------|
| 0.575** | 0.683** | 0.506** | 0.636** | 0.590** | 0.623** | 0.358** | 0.445** | 0.358** | 0.354** | 0.499** | 0.511** | 0.311** | 0.636** | 0.636** |

| Fertility intention | 0.275** | 0.563** | 0.250** | 0.461** | 0.223** | 0.838** | 0.245** | 0.354** | 0.238** | 0.645** | 0.354** | 0.495** | 0.645** | 0.645** |

** \( P < 0.01 \).
Ethical considerations

The Research Ethics Review Committee of the Affiliated Hospital of Hebei University where the study was based approved the ethical approval (Approval No. HDFY-LL-2021-142). The study complied with the guidelines of the Declaration of Helsinki. All the potential participants were informed about the purpose and content of the study, voluntary participation, and personal information confidentiality. All participants provided both verbal and written informed consent.

Results

Patient characteristics

The mean age of the 264 participants was 35.83 ± 3.78 (median: 37.0; range: 19–40) years. The mean time since diagnosis was 10.03 ± 12.59 (median: 7.0; range: 2–90) months. Furthermore, 33 (12.5%) participants did not have any children, and 29 (11%) participants had the intention of having another child. Moreover, 91 (34.5%) participants received fertility-related information from oncologists, while 230 (87.1%) patients did not know about assisted reproductive technology, and only 38 (14.4%) participants had consulted with medical staff regarding fertility-related issues. Additional participants’ characteristics are displayed in Table 1.

Item description and analysis

The mean and SD of the total score of the FIS scale were 46.49 ± 7.24. The mean and SD of the four dimension scores (ie. pregnancy risk, disease control, social support, happiness) were 16.46 ± 4.05, 15.75 ± 2.24, 8.78 ± 2.10, and 5.50 ± 1.93, respectively. For item analysis, the item–total correlations of all items are shown in Table 2, and all the item–total correlations were > 0.30. The results of the critical ratio value showed that the differences among all the items in the two groups were statistically significant, and t > 3 indicated that the scale items had good discrimination.

Validity analysis

Construct validity

The CFA model showed that the original FIS four-factor structure was acceptable with χ²/df = 3.19 (χ² = 268.228, df = 84, P < 0.01) and RMSEA = 0.091, TLI = 0.975 and CFI = 0.980. The standardized loadings of each item are presented in Fig. 1.

Convergent validity

The relationship between fertility intention and reproductive concerns is shown in Table 3. The total score of fertility intention was weak negatively correlated with the total score of reproductive concerns

Fig. 1. Confirmatory factor analysis model for the Chinese version of the Fertility Intention Scale (FIS).
Happiness had a test-retest reliability of 0.841, 0.650, 0.793, and 0.762, respectively. Moreover, pregnancy risk, disease control, social support, and happiness were respectively 0.796, 0.818, 0.598, and 0.930, respectively. Furthermore, there were significant differences among the dimensions of pregnancy risk, social support, and happiness, except for the dimension of disease control. Table 4 shows the differences between the two groups. The FIS had acceptable known-group validity.

**Known-group validity**

For the known-group validity, the participants were divided into two groups according to whether they had a pregnancy desire or not. The scores of the participants who intended to have children were higher than the participants who did not (50.62 ± 6.35 vs. 45.98 ± 7.19, P < 0.01). Furthermore, there were significant differences among the dimensions of pregnancy risk, social support, and happiness, except for the dimension of disease control.

**Reliability**

The Cronbach’s alpha was 0.824 for FIS and the Cronbach’s alphas for pregnancy risk, disease control, social support, and happiness were 0.796, 0.818, 0.598, and 0.930, respectively. Furthermore, 32 patients completed the FIS twice and the test-retest reliability of the FIS was 0.863. Moreover, pregnancy risk, disease control, social support, and happiness had a test-retest reliability of 0.841, 0.650, 0.793, and 0.762, respectively (P < 0.01).

**Discussion**

This study verified that the FIS is an effective instrument for assessing the fertility intention among female patients with breast cancer of childbearing age in mainland China. The CFA was performed to test whether the original structure of the FIS was aligned with patients with breast cancer in mainland China. The CFA model showed that the original FIS structure was acceptable, except for item 13, “I feel I have received enough information for my pregnancy.” While factor loadings of the items were greater than 0.40, item 13 had a factor loading of 0.356, and should be removed according to statistical principles. However, since that fertility-related knowledge is pertinent to fertility intention, item 13 was retained. Limited fertility-related knowledge may lead to cognitive bias in patients with breast cancer and cause unnecessary reproductive concerns. Furthermore, patients could even miss the best implementation time of assisted reproductive technologies. In this study, only 38 (14.4%) patients consulted with their oncologists about fertility-related issues. The low factor loading for item 13 could be attributed to inadequate fertility counseling and lack of fertility knowledge among patients with breast cancer. Thus, the research results showed that the original structure of FIS was reasonable.

For the convergent validity, the results demonstrated that FIS scores were weak correlated negatively with RCAC scores (r = -0.172, P < 0.01), consistent with the previous studies. The FIS scores only correlated negatively with the subscales for child’s health and personal health (Table 3). The family planning policy in China had been in place for several years, hence the consensus to have one or two children. In contrast to Taiwan and Western countries, the majority of the participants in this study already had children and were no longer concerned about the impact of fertility or infertility on their family relationships. This may explain the weak correlations between the FIS scores and certain subscales of the RCAC. Patients with breast cancer and with fertility intention might have considered the personal risk-benefit of pregnancy based on the assessment of their situation and condition. Furthermore, patients might prioritize their health first and feel that taking care of them is more pertinent. Moreover, patients with fertility intention worry that becoming pregnant might cause physical discomfort and negatively affect their health through the recurrence of cancer or that they could not spend time with their children due to the heavy disease burden. The genetic risk factor of cancer was also a concern among patients with breast cancer as the disease and treatment would not only affect their health but also the health of their children. Therefore,
patients with reproductive concerns had a weaker fertility intention. Overall, the convergent validity of the FIS is not satisfactory and further revision and validation are required in the future.

For the known-group validity, patients with breast cancer were divided into two groups according to whether they wanted to have children or not. The results of this study revealed that the participants had significantly higher scores than those without intention of having children (Table 4), which was consistent with the study by Li et al.14 Furthermore, there was no difference in the dimension of disease control between the two groups. One possible explanation was that patients would worry about their disease status whether they wanted to have children or not. In general, the FIS could effectively differentiate between patients with high and low fertility intention and had acceptable known-group validity.

The internal consistency of the FIS was evaluated by calculating Cronbach's alpha coefficient. The reliability coefficients of the total FIS and four subscales ranged between 0.598 and 0.930. Notably, only the reliability coefficient of the social support subscale (0.598) was below 0.70. The social support subscale contains both instrumental support and information support. Furthermore, only a few patients obtained fertility information support and there were a low number of the items in the social support subscale, which might have influenced the medium internal consistency reliability of the social support subscale. Moreover, the test-retest reliability results demonstrated acceptable stability of this scale. Thus, the FIS was an acceptable and applicable instrument to assess fertility intention among patients with breast cancer accurately, provide individualized fertility consultation for patients, and eliminate their unnecessary reproductive concerns.

Limitations

This study has several limitations. First, convenience sampling was used, thus representativeness is limited to a certain extent. Second, most participants already had at least one child, which may have affected their fertility intentions. The FIS is an instrument assessing the level of fertility intention among breast cancer patients already had at least one child, which may have affected their fertility intentions. The FIS is an instrument assessing the level of fertility intention among breast cancer patients with reproductive concerns had a weaker fertility intention. Overall, the convergent validity of the FIS is not satisfactory and further revision and validation are required in the future.

For the known-group validity, patients with breast cancer were divided into two groups according to whether they wanted to have children or not. The results of this study revealed that the participants had significantly higher scores than those without intention of having children (Table 4), which was consistent with the study by Li et al.14 Furthermore, there was no difference in the dimension of disease control between the two groups. One possible explanation was that patients would worry about their disease status whether they wanted to have children or not. In general, the FIS could effectively differentiate between patients with high and low fertility intention and had acceptable known-group validity.

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Conclusions

Overall, this study confirms that the FIS can provide a comprehensive assessment of the fertility intention among breast cancer of childbearing age in mainland China. However, the convergent validity was not satisfactory, which may require further revision and validation. Upon further refinement of the FIS, healthcare providers could use this instrument to evaluate the fertility intention among patients with breast cancer in clinical practice, and develop effective fertility preservation measures, thus enhancing the development of oncofertility care.

Table 4
Comparison of the FIS scores between breast cancer patients with or without pregnancy desires (n = 264).

| Fertility intention | n (%) | Total fertility intention<sup>a</sup> | Pregnancy risk<sup>b</sup> | Disease control<sup>b</sup> | Social support<sup>b</sup> | Happiness<sup>b</sup> |
|---------------------|-------|---------------------------------------|---------------------------|---------------------------|-------------------------|------------------------|
| No                  | 235 (66.3) | 45.98 ± 7.19** | 16.00* (4.12) | 16.00 (2.23) | 9.00** (2.07) | 5.00** (1.87) |
| Yes                 | 29 (2.7) | 50.62 ± 6.35** | 18.00* (3.11) | 15.00 (2.38) | 10.00** (2.07) | 7.00** (1.39) |
| Z                   | –     | 3.32 | 2.45 | –0.72 | 2.93 | 5.28 |
| P                   | –     | 0.001 | 0.470 | 0.003 | <0.001 |

<sup>a</sup> Mean ± Standard deviation; <sup>b</sup> Median (Interquartile range); *P < 0.05, **P < 0.01.
FIS, Fertility Intention Scale.

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Authors' contributions

Conceptualization: Qian Lu, Chunlei Liu, Fei Zhu. Methodology: Qian Lu, Chunlei Liu, Fei Zhu, Lisha Pang. Data collection: Fei Zhu, Juan Qi, Ying Bian. Statistical analysis: Fei Zhu, Qian Lu and Chunlei Liu, Lisha Pang, Juan Qi, Ying Bian. Writing - Original Draft: Fei Zhu, Chunlei Liu, Lisha Pang. Writing - Review & Editing: Qian Lu, Chunlei Liu, Fei Zhu.

Declaration of competing interest

None declared.

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Ethics statement

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