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Original Article

Psychometric properties of the Brazilian version of the Female Sexual Function Index in women with breast cancer

Propriedades psicométricas da versão brasileira do Female Sexual Function Index em mulheres com câncer de mama

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ABSTRACT

Objective: to evaluate the measurement properties of the Female Sexual Function Index – Brazilian version in women with breast cancer. **Methods**: this methodological study involved 246 patients treated at two specialized breast cancer outpatient clinics. Data were collected using two instruments: a sociodemographic and clinical characterization questionnaire and the Brazilian version of the FSFI. Construct validity was assessed through confirmatory factor analysis, and reliability was evaluated using composite reliability. **Results**: in the factor analysis, the model achieved satisfactory results with acceptable fit indices (p=0.270; χ^2/df=1.070; Comparative Fit Index=0.999; Tucker-Lewis Index=0.999; Standardized Root Mean Residual=0.061; Root Mean Square Error of Approximation=0.019). Evidence of reliability was also confirmed (composite reliability: 0.980). **Conclusion**: the instrument demonstrated satisfactory validity and reliability for assessing sexual function in women with breast cancer. **Contributions to practice**: this study provides methodological support for using this tool to assist in the nursing diagnosis of "Sexual dysfunction" in women with breast cancer.

Descriptors: Validation Study; Factor Analysis, Statistical; Breast Neoplasms; Sexuality.

RESUMO

Objetivo: avaliar as propriedades de medida do instrumento *Female Sexual Function Index* – versão brasileira em mulheres com câncer de mama. **Métodos**: estudo metodológico, realizado com 246 pacientes atendidas em dois ambulatórios especializados no tratamento do câncer de mama. Os dados foram coletados por meio de dois instrumentos: questionário para caracterização sociodemográfica e clínica e versão brasileira do *Female Sexual Function Index*. A validade de construto foi verificada por meio de uma análise fatorial confirmatória, e a confiabilidade por meio de fidedignidade composta. **Resultados**: na análise fatorial, o modelo convergiu para um resultado satisfatório, com índices de ajuste aceitáveis (p=0,270; χ2/gl=1.070; *Comparative Fit Index*=0,999; *Tucker-Lewis Index*=0,999; *Standardized Root Mean Residual*=0,061; *Root Mean Square Error of Approximation*=0,019). Também foram encontradas evidências satisfatórias de confiabilidade (fidedignidade composta: 0,980). **Conclusão**: o instrumento demonstrou evidências de validade e confiabilidade satisfatórias entre mulheres com câncer de mama. **Contribuições para a prática**: fornece embasamento metodológico para a utilização de uma ferramenta que pode ser empregada para o diagnóstico de enfermagem "Disfunção sexual" em mulheres com câncer de mama.

Descritores: Estudo de Validação; Análise Fatorial; Neoplasias da Mama; Sexualidade.

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Introduction

Sexuality and intimacy are crucial aspects of quality of life and fundamental to individual well-being. However, the sexual side effects of cancer treatment are widespread, especially among women. At least half of the women treated for breast cancer experience sexual dysfunction. Cancer-related changes in sexual function can affect all aspects of the female sexual response cycle[1]. Approximately 60% to 70% of breast cancer survivors report sexual problems resulting from oncological treatment[2], and these issues can persist for long periods, even after treatment completion, affecting their quality of life and relationships[3].

Breast cancer treatments can lead to physical changes that result in sexual dysfunctions. The most prevalent issues include loss of sexual desire, vaginal dryness, dyspareunia, difficulty in arousal and pleasure, and orgasmic problems. Vaginal spasms and dryness may result from the effects of chemotherapy drugs and the lack of sexual arousal in these women. Additionally, the absence of stimulation impedes the secretion of viscous vaginal fluid, leading to painful intercourse[4].

Ovarian failure, which can be temporary or permanent, is often a consequence of systemic therapies such as chemotherapy and hormone therapy. Even when menstruation is maintained or restored, there is an increased risk of long-term premature ovarian failure[5].

The treatment of young breast cancer patients affects their reproductive potential, reducing ovarian reserve. It can lead to reversible or permanent premature menopause, decreased libido, and other symptoms of sex hormone deficiency. Consequently, in addition to oncological treatment, patients require genetic and oncofertility counseling, psychological support, and sexological counseling[6]. Thus, it is essential to recognize the nurse as a key professional capable of diagnosing maladaptive human responses related to sexual dysfunction and applying the entire nursing process[7].

In this process, the development of clinical reasoning is crucial. Clinical reasoning refers to how a nurse analyzes and understands a patient's situation and forms conclusions. In the NANDA International (NANDA-I) nursing diagnosis classification, a multinational practice standard, the nursing diagnosis "Sexual dysfunction" (00059) reflects the human response pattern or state in which an individual experiences a change in sexual function during the phases of desire, arousal, or orgasm, which is perceived as unsatisfactory, unrewarding, or inadequate[8].

Therefore, the FSFI, currently composed of six dimensions—desire, arousal, lubrication, orgasm, satisfaction, and pain—can be used as an instrument to support the nursing diagnosis of "Sexual dysfunction." The FSFI is a robust instrument that is widely used in different populations and contexts[9].

Given the need to better identify changes in female sexual function and support nursing practice with more accurate diagnoses, thereby promoting more effective nursing care that meets individual needs, it is essential to use instruments with appropriate psychometric properties. Consequently, due to the impact of sexual dysfunction on the quality of life, relationships, and well-being of women with breast cancer, and the absence of a reliable and valid instrument for this purpose, the following question arises: Does the Brazilian version of the FSFI demonstrate reliability and construct validity for measuring the sexual function of women with breast cancer? Thus, the objective of this study was to evaluate the measurement properties of the Female Sexual Function Index – Brazilian version in women with breast cancer.

Methods

Study design, period, and location

This methodological study evaluated the con-

struct validity and reliability of the Brazilian version of the FSFI in women with breast cancer. The COSMIN Reporting Guideline for studies on measurement properties of patient-reported outcome measures was used as the framework for the scientific reporting of this study[10]. The research was conducted from February to December 2022 in two outpatient clinics specialized in oncology treatment, located in the municipality of Fortaleza, Ceará, Brazil. These clinics serve patients from the public healthcare system (SUS - *Sistema Único de Saúde*).

Sample definition and inclusion/exclusion criteria

The sample size was determined based on the study's objective of validating the instrument through structural validity analysis. According to the reference[11], a minimum of 10 patients per item is required for confirmatory factor analysis. As the FSFI consists of 19 items, the minimum sample size was 190 patients. Women were selected by convenience sampling. Inclusion criteria were women undergoing oncological treatment for breast cancer at stages I, II, III, or IV and having a sexual partner (regardless of gender).

Exclusion criteria included patients receiving treatment for other types of cancer or with cognitive impairments that would prevent the application of the instrument. Patients were also assessed for auditory acuity using the Whisper Test, in which the evaluator positioned themselves behind the patient, out of their visual range, approximately 33 centimeters away, and whispered a brief and simple question, such as "What is your name?". The evaluator then verified whether the patient could perceive verbal contact and respond appropriately.

Data collection

Data were collected through a hybrid approach by the principal researcher. For remote data collection, one of the institutions provided the patients' phone numbers, through which the participants were contacted, informed about the study's objectives, and invited to participate. After signing the Informed Consent Form, which was sent via email, the instruments were applied. For in-person data collection, patients were approached at the respective outpatient clinics (chemotherapy, radiotherapy, and hormone therapy). The same steps were followed for applying the instruments. Each patient had only one encounter, which took place in a private setting without companions. The research instruments were administered in reserved areas provided by the healthcare facilities where the study was conducted.

The instruments used for data collection were: a sociodemographic and clinical questionnaire, previously developed and applied[12] and the Brazilian version of the FSFI[9].

The sociodemographic and clinical questionnaire included personal information (age, educational level, race, marital status, occupational status, origin, family income, religion, number of children, weight, height, menstrual status, comorbidities, and breast cancer risk factors) and clinical data (time since diagnosis, tumor stage, lymph node involvement, metastasis, prior surgeries, current treatment modality, and any previous treatments received).

Female Sexual Function Index – Brazilian version

The FSFI was originally developed and validated in English through a study conducted in the United States with 259 volunteers who met the clinical diagnostic criteria for female sexual arousal disorder. These women were recruited from five major research centers, and the study achieved satisfactory validation indices: Cronbach's alpha (internal consistency) greater than 0.90, and a high overall test-retest reliability coefficient (intraclass correlation coefficient) for all domains of the scale (r = 0.79 to 0.86)[13].

In another study, the FSFI was translated and

validated for Brazilian Portuguese in a population of 100 women treated at the Urology Service of São Francisco University in São Paulo, achieving a Cronbach's alpha of 0.96. Domain-specific assessments varied from 0.31 to 0.97, and the test-retest reliability coefficient was also considered strong and identical (r = 1.0). The conclusion of this study was that the Brazilian version of the FSFI, translated and culturally adapted, is valid for measuring the sexual response of Brazilian women[14].

The FSFI consists of 19 items distributed across 6 domains or factors that use a Likert scale, ranging from 1 to 5 points for items 1 and 2, and from 0 to 5 for items 3 to 19[9]. The domains are as follows: Desire – two items (1 and 2), Arousal – four items (3 to 6), Lubrication – four items (7 to 10), Orgasm – three items (11 to 13), Satisfaction – three items (14 to 16), and Pain – three items (17 to 19). The instrument includes questions about the patient's sexual experiences in each domain over the past four weeks. Each domain receives an individual score, calculated by summing the scores of its respective items and multiplying by the domain-specific factor (0.6 for desire, 0.3 for arousal, 0.3 for lubrication, 0.4 for orgasm, 0.4 for satisfaction, and 0.4 for pain), resulting in a weighted score. The total score can range from a minimum of 2 to a maximum of 36, with higher scores indicating better sexual function[13].

Data analysis

Data were entered into Microsoft Excel and analyzed using the JASP statistical software, version 0.15 for Mac, developed by the University of Amsterdam. Categorical variables underwent descriptive analysis, with results presented in absolute and relative frequency tables. For numerical variables, measures of central tendency (mean) and dispersion (standard deviation) were calculated. The Kolmogorov-Smirnov test was performed to assess the data distribution, yielding a p-value of 0.731, indicating a normal distribution. Scores for the FSFI dimensions were determined by averaging participants' responses.

To assess the reliability of the instrument, composite reliability was used, which takes into account the factor loadings of the items and does not assume equivalence among them. Cronbach's alpha was not considered as it assumes equal importance for all items, which is not consistent after factor analysis[15].

Composite reliability (CR), also known as McDonald's omega, is considered good when values exceed 0.7[16]. To assess validity, particularly construct validity, a confirmatory factor analysis (CFA) was performed using the Robust Diagonally Weighted Least Squares (RDWLS) estimation method, appropriate for categorical data. This analysis was used to verify the plausibility of the psychometric structure of the Brazilian version of the FSFI, which had already been previously defined.

Model fit was evaluated using the following indices: Chi-square ($\chi 2$), Chi-square to degrees of freedom ratio ($\chi 2/df$), Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), Standardized Root Mean Residual (SRMR), and Root Mean Square Error of Approximation (RMSEA). Model fit was considered adequate when $\chi 2 > 0.05$, $\chi 2/df < 5$, preferably < 3, CFI and TLI > 0.90, preferably > 0.95, SRMR < 0.08, RMSEA < 0.08, preferably < 0.06, with the upper confidence limit < 0.10. Standardized factor loadings should be at least 0.5, ideally 0.7. Values within these ranges indicate good model fit, suggesting that the proposed instrument structure is plausible for the studied group.

The average variance extracted (AVE) for each factor was also calculated, with values above 0.5 indicating satisfactory convergent validity.

Ethical considerations

The research project was approved under opinion number 4.613.609/2021 by the Ethics Committee of the Federal University of Ceará, with Ethical Approval Certificate number 43072721.9.0000.5054.

The study adhered to ethical guidelines in accordance with Resolution 466/2012 of the National Health Council. All participants were informed and agreed to sign the informed consent form.

Results

The sample consisted of 246 women diagnosed with breast cancer, with a mean age of 45.5 years (standard deviation (SD) ±7.4). Most participants were mixed-race (65.7%), lived in rural areas (54.3%), identified as Catholic (55.1%), were married or in a stable union (78.4%), and had children (94.7%), with 57.1% of these children being of school age. The mean duration of the marital relationship was approximately 19.3 years (SD ±10.7), with an average of 4.8 sexual relations per month (SD ±5.4). Regarding education, the women had an average of 12.3 years of schooling (SD ±3.0), and most were unemployed (51.4%). The average family income was R$ 1,948.20 (SD ±1,285.50), and the average number of residents per household was 3.7 (SD ±1.2).

Regarding the participants' health, 38% had entered menopause due to breast cancer treatment, 60.8% had no comorbidities, and 87% had risk factors for breast cancer, with genetic factors being the most common (43.2%), followed by obesity, with 38.8% of the women having a Body Mass Index (BMI) between 30 and 39.9. Tumor staging was classified as T2 in 39.2%, N2 in 48.6%, and M1 in 83.3% of the participants. Most women had not undergone breast cancer surgery (53.9%) or received breast implants (84.8%). At the time of data collection, 76.3% were undergoing chemotherapy treatment, and 74.3% had not received any other previous therapeutic modality. The mean time since diagnosis was 9.1 months (SD ±11.1), with the current treatment lasting an average of 3.4 months (SD ±3.1), previous treatments lasting 8.6 months (SD ±9.3), and surgery being performed on average 4.9 months (SD ±4.5) prior to data collection.

The confirmatory factor analysis applied to the structure of the Brazilian version of the FSFI, composed of 6 factors and 19 items, indicated a satisfactory fit. The chi-square to degrees of freedom ratio was relatively high (χ^2/df = 1.070, with χ^2 = 146.716 and df = 137), but the chi-square value was not significant (p = 0.270). The fit indices, such as the Comparative Fit Index (CFI = 0.999), Tucker-Lewis Index (TLI = 0.999), Standardized Root Mean Residual (SRMR = 0.061), and Root Mean Square Error of Approximation (RMSEA = 0.019), with the upper limit of the confidence interval (90% CI: 0.000 - 0.040), were all within the recommended thresholds.

For the 246 participants, the values for the Average Variance Extracted (AVE) and composite reliability were calculated for each dimension, as shown in Table 1.

Table 1 – Composite reliability and average variance extracted from the dimensions of the Female Sexual Function Index instrument – Brazilian version (n=246). Fortaleza, CE, Brazil, 2022

Dimensions	Composite reliability	Average variance extracted
Desire	0.798	0.664
Arousal	0.953	0.837
Lubrication	0.974	0.904
Orgasm	0.613	0.390
Satisfaction	0.803	0.589
Pain	0.962	0.893

The standardized factor loadings of the items in their respective dimensions and the correlations identified between the domains (factors) are presented in Figure 1.

The factors arousal and orgasm were strongly correlated (0.988), and among the 19 items of the instrument, only three showed low factor loadings (≤ 0.60): items 12 (0.272), 13 (0.521), and 16 (0.586).

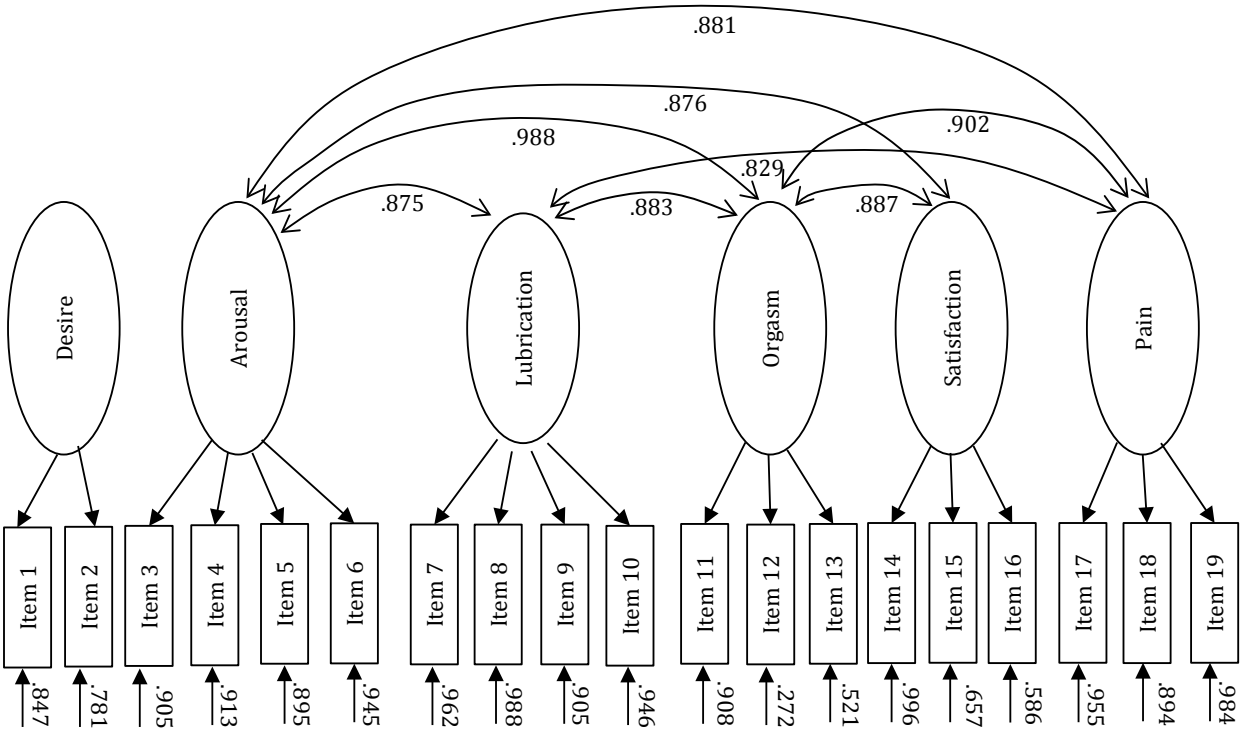

Figure 1 – Standardized factor loadings per item and correlations between domains (factors) (n=246). Fortaleza, CE, Brazil, 2022

Discussion

Many constructs in research are latent and cannot be directly observed. Therefore, researchers often measure them using established scales with multiple indicators. However, these scales may not perform equally well across different populations and samples. Hence, it is crucial to evaluate and report their psychometric properties before examining the relationships between constructs or testing hypotheses.

The properties of an instrument can be assessed through validity, reliability, and responsiveness. As these measures are independent and complementary, it is recommended to use more than one. This recommendation was followed in the present study[10,17]. The validity of an instrument indicates its ability to accurately measure what it is intended to, while reliability refers to its ability to consistently reproduce a result[17-18].

Confirmatory factor analysis (CFA), a structural equation modeling technique, was used to assess construct validity using the Robust Diagonally Weighted Least Squares (RDWLS) estimation method. CFA evaluates the extent to which the structure and parameters of a psychometric instrument remain constant (equivalent) across different groups. This technique has proven to be an important tool in the development, application, evaluation, and improvement of psychometric instruments. However, there are still few publications on this subject in Brazil[18].

Unlike exploratory factor analysis (EFA), in CFA, the researcher must have a predefined factor structure, clearly specifying the number of factors and the items corresponding to each one. Therefore, it is a theory- or evidence-based method[19]. In many cases, EFA and CFA techniques can be used complementarily to evaluate the plausibility of a specific factor structure[20].

In this sample, the Female Sexual Function Index – Brazilian version, demonstrated satisfactory fit

indices in the confirmatory factor analysis, as most of the analyzed parameters reached values within the recommended ranges. The analysis of the AVE revealed that most domains explained more than 58% of the studied construct, sexual function, demonstrating that the results represent an acceptable model[16].

When analyzing the factor loadings of the items, which reflect how important an item is for the construct, it was observed that only three (items 12, 13, and 16) had low factor loadings (<0.60). This reflects the limited relevance of these items in this specific sample. Two of these three items belong to the Orgasm domain, which corroborates the low AVE (<50%) of this domain. Nevertheless, since the instrument showed satisfactory fit indices in this study, there is no indication to modify it by removing these items[15]. However, it is suggested that future research investigate the addition of items to improve the explained variance and representation of the domain in this population.

The results obtained from the reliability analysis cannot be directly compared to the original studies (English and Brazilian versions), as those used Cronbach's alpha. In this research, since a CFA was performed, composite reliability was used as the parameter. Composite reliability is a more robust measure that does not underestimate internal consistency and takes into account the factor loading of the items, recognizing that each item has a different level of importance to the construct[10,21]. This differs from Cronbach's alpha, which operates under the principle of tau-equivalence, assuming that all items have the same importance for the construct[22].

A systematic review of the FSFI's measurement properties was conducted, evaluating 83 published studies based on evidence of measurement properties and the quality of the evidence according to COSMIN guidelines. It was found that reliability was sufficient but of low quality, and construct validity was inconsistent and of moderate quality. The review concluded that the divergence and lack of evidence for some FSFI properties indicate the need for further research on the validity of patient-reported measures. Therefore, confirmatory factor analyses and detailed descriptions of the factor structure identified in the study samples were recommended. Despite these issues, the FSFI has strong criterion validity and is a useful screening tool for female sexual dysfunction[23-24].

The composite reliability for all dimensions of the instrument was above the recommended minimum[15]. Therefore, based on all these analyses, it is evident that the Brazilian version of the FSFI, when applied to women with breast cancer, did not undergo any structural changes when compared to the original version, maintaining the same 19 items distributed across the six dimensions.

Study limitations

One limitation is the specificity of the sample, as it consists of breast cancer patients undergoing active treatment. However, it is important to emphasize the need for studies in diverse populations to evaluate the psychometric properties of the instrument, ensuring its accuracy. Additionally, social desirability bias, where respondents provide answers that do not reflect their true attitudes, values, or behaviors, may have occurred. This bias is commonly observed in surveys that utilize questionnaires. Nevertheless, the hybrid data collection method used in this study is increasingly common in the current epidemiological context, offering potential benefits and helping to minimize the risk of this bias.

Contributions to practice

This research provides a valuable contribution to nursing by offering methodological support for the use of a tool that can be employed in diagnosing the nursing diagnosis of "Sexual dysfunction" in women with breast cancer. It aims to implement more targeted interventions to improve the quality of life

and relationships of these patients, increase nurses' autonomy for safe and interdisciplinary practice, and, consequently, offer higher quality and safer nursing care to women with breast cancer experiencing sexual dysfunction.

Conclusion

The evaluation of the psychometric properties of the Brazilian version of the Female Sexual Function Index demonstrated satisfactory evidence of construct validity and reliability. Therefore, it is considered a suitable instrument for measuring sexual function in women with breast cancer. This study aims to contribute to the development of instruments with better psychometric properties, facilitating the identification of sexual problems in women with breast cancer, in order to reduce or eliminate these issues and improve the sexual well-being of these patients.

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Author contributions

Conceptualization, data analysis and interpretation, and critical review of the intellectual content: Vaz ISF, Fernandes AFC. Interpretation and writing of the manuscript, final approval of the version to be published, and responsibility for all aspects of the manuscript: Vaz ISF, Silva DM, Fernandes AFC, Castro RCMB, Rodrigues AB, Coelho MMF.

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