TITLE: The Female Sexual Function Index: reliability and validity in Spanish postmenopausal women.

RUNNING TITLE: Validation of the Spanish FSFI.

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ABSTRACT

Objective: To examine the reliability and validity of the Spanish version of the Female Sexual Function Index (FSFI) and its ability to discriminate between women with and without female sexual dysfunction (FSD) among Spanish postmenopausal women.

Methods: A total of 152 postmenopausal women completed the Spanish version of FSFI. Internal consistency, test-retest reliability, and construct validity (exploratory factor analysis) were analyzed. Concurrent and divergent validity were assessed using a visual analogue scale for overall satisfaction with sexual life and the Hospital Anxiety and Depression Scale, respectively. To determine the ability and the accuracy of the FSFI total score in discriminating between women with and without FSD, a receiver operating characteristic (ROC) curve analysis was performed.

Results: Factor analysis suggested a three-factor structure (explained variance 77.77%). The Spanish FSFI showed substantial-to-excellent test-retest reliability, with good internal consistency in the FSFI total score (Cronbach's alpha=0.964) as well as in its three dimensions. The FSFI total and domains scores showed strong ($r>0.50$) and significant correlations ($p<0.01$) with overall satisfaction with sexual life (concurrent validity), and low correlations with anxiety and depression (divergent validity). The Spanish FSFI total score and dimensions were significantly able to discriminate between women with and without FSD ($p<0.05$), with an optimal cut-off point of <24.95 for the FSFI total score (64.15% sensitivity and 75.76% specificity).

Conclusions: The Spanish FSFI is a valid and reliable instrument for assessing and discriminating for FSD among Spanish postmenopausal women.

Keywords: Female sexual function; Postmenopausal; Psychometric; Reliability; Validity.

INTRODUCTION

Female sexual dysfunction (FSD) is a multi-causal and a multi–dimensional medical problem that adversely affects self-esteem and quality of life, causing emotional distress and relationship problems.[1] The International Consensus Development Conference on Female Sexual Dysfunction recommends the inclusion of personal distress and interpersonal difficulties as an integral part of FSD[2] . Female Sexual Dysfunction has a major impact on women's quality of life, with effects that reach the social, physical, psychological, domestic, and occupational spheres of life. Epidemiological surveys report a variable prevalence of FSD, ranging from 19% to 45%,[3] with 15% of the population reporting a sexual problem that causes significant personal distress.[4]

With increased longevity, women spend about one third of their life in the postmenopausal period,[5] and sexual dysfunction is one of the primary health concerns of postmenopausal women.[6] The frequency of these sexual problems increases as menopause approaches, and then reaches a peak in the postmenopausal years.[7] The Women's International Study of Health and Sexuality (WISHeS) of 2006 estimated a prevalence of low sexual desire among postmenopausal women of 9%–26%.[8] Hormonal changes associated with estrogen may also alter a patient's sexual activity and interest. The menopause-related decline of estrogen levels, together with other sex steroids, is linked to the development of the genitourinary syndrome of menopause.[9] The main signs and symptoms of the vulvovaginal and lower-urinary tract associated with this

1 condition have a considerable impact on sexual health and quality of life, significantly
2 contributing to sexual dysfunction in postmenopausal women.[10]
3 Having access to valid and reliable assessment tools for FSD is important for both
4 research and clinical practice.[11] Several methods can be used to evaluate FSD (i.e.
5 photoplethysmography, Doppler velocimetry, or magnetic resonance imaging), but self-
6 reported questionnaires are considered to be the gold standard for measuring FSD in
7 outcome and diagnostic studies of FSD that evaluate sexual function in women. This
8 tool has a level 1 of evidence and a grade A recommendation.[12]
9 The Female Sexual Function Index (FSFI) is a universal and widely used
10 multidimensional questionnaire that evaluates the key dimensions of sexual function in
11 women.[13] The FSFI consists of 19 items which refer to the past 4 weeks. These items
12 are summarized into 6 domains or subscales: sexual desire (items 1 and 2), arousal
13 (items 3, 4, 5, 6), lubrication (items 7, 8, 9, 10), orgasm (items 11, 12, 13), satisfaction
14 (items 14, 15, 16), and pain (items 17, 18, 19). Subscales range from 0 (or 1) to 5, and
15 the sum of scores for these six subscales yields one global score of female sexual
16 function (with higher scores indicating better sexual function).
17 The FSFI has been validated for several languages and populations,[14-18] and its
18 applicability has been confirmed at various life stages.[19-21] However, and to the extent
19 of our knowledge, no validation of the FSFI psychometric properties has been carried
20 out for a Spanish postmenopausal population. Thus, the objective of the present study
21 was to evaluate the psychometric properties of the Spanish version of the FSFI in
22 Spanish postmenopausal women by assessing its internal consistency and test-retest
23 reliability, as well as its construct, concurrent, and divergent validity. In addition, we set
24 out to assess the ability of the Spanish version of the FSFI to discriminate between
25 women with and without FSD among a population of Spanish postmenopausal women.
26

27 METHODS

28 Participants

29 Out of 323 postmenopausal women who were initially contacted, 152 (ages 49-81
30 years) participated in this study, which took place from July 2018 to October 2018. A
31 flow chart of participants is presented in Figure 1. Participants were recruited by
32 contacting the staff of several associations of postmenopausal women in the Eastern
33 Andalusian region. The sample size of this study was considered appropriate according
34 to psychometric recommendations described by Kline (at least 100 participants).[22]
35 Before filling out the questionnaires, all women were interviewed to collect certain
36 demographic data such as age, years since menopause onset, occupational, educational
37 and marital status, and smoking habits.
38 This study was approved by the Ethical Committee of the University of Jaén, Spain. All
39 participants gave their written informed consent to participate in this study, which was
40 conducted in accordance with the Declaration of Helsinki, good clinical practices, and
41 all applicable laws and regulations. Inclusion criteria were: having experienced at least
42 twelve months of amenorrhea, being sexually active in the previous four weeks, capable
43 of completing the questionnaire, and willing to provide their written informed consent
44 to participate in the study. Participants were excluded if they suffered from a chronic
45 and/or severe medical disease, or from any neuropsychiatric disorder that could
46 influence their responses to the questionnaire.
47

48 Questionnaires

49 Following the guidelines recommended by the International Quality of Life Assessment
50 project for cross-cultural translation,[23] the original version of the FSFI was

independently translated into Spanish by two bilingual experts working together with clinical professionals who were familiar with both the topic and the research concept. Then, the translators and researchers reached a consensus for a preliminary forward translation and the Spanish version of the FSFI was then completed by 20 participants in order to verify that they were able to understand the instructions, questions, and answering options. The time required to complete the questionnaire was 15-20 minutes. Finally, two bilingual experts translated the Spanish version back into English. A comparison between the initial English and the final English versions showed semantic and linguistic equivalence.

To evaluate test-retest reliability, the Spanish FSFI was again completed by 50 randomly chosen women two weeks later. The test-retest time interval was long enough for participants to forget how they had previously responded, but sufficiently short that their sexual function outcomes were unlikely to have changed.

In order to assess concurrent validity of the Spanish FSFI we employed a visual analogue scale (VAS) to measure overall satisfaction with sexual life (concurrent validity). It consisted of 100-mm lines with descriptors at both ends representing extremes of satisfaction (from not-at-all-satisfied to very-satisfied).[24] The Hospital Anxiety and Depression Scale (HADS)[25] was used to evaluate discriminant validity. This is a self-administered questionnaire widely used for detecting anxiety and depressive disorders. It comprises 14 items, 7 of which relate to anxiety symptoms and 7 to depressive symptoms. The total scores range from 0 to 21 for both depression and anxiety. In this study we used the Spanish version of HADS.[26] Two researchers assessed, via a structured clinical interview, the presence of FSD based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria,[25] which include the presence of personal distress or interpersonal difficulties.

Statistical analysis

Data management and analysis were performed using the SPSS 20.0 statistical package (SPSS Inc., Chicago, IL, USA). Data were described using mean and standard deviation (SD) for the continuous variables, and frequencies and percentages for the categorical variables. The level of statistical significance was set at $p<0.05$. Test-retest reliability was determined using Intraclass Correlation Coefficients ($ICC_{2,1}$) by Shrout and Fleiss. Reliability was considered poor when the ICC was <0.40, moderate between 0.40 and 0.75, substantial between 0.75 and 0.90, and excellent when ICC >0.90.[28]

Cronbach's α coefficient was used to assess the internal consistency of the instrument. Values ≥0.70 were considered acceptable for general research purposes.[29] Given that different factor structures have been showed in prior validations[14,18], and due to the characteristics of the sample population of this study (postmenopausal women), an exploratory factor analysis using principal component analysis was performed to test construct validity. A varimax rotation of factors was used, and the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was obtained. A KMO value ≥0.60 was considered to be acceptable.[30] Pearson's correlation coefficient (r) was employed to analyze concurrent validity of the Spanish FSFI with overall satisfaction with sexual life (VAS), as well as divergent validity with anxiety and depression (HADS). Correlation coefficients >0.50 were considered to be strong, and those between 0.30 and 0.50 were considered to be moderate.[31]

Discriminant validity was assessed by comparing the mean scores of the FSD and non-FSD groups using Student's *t* test. The accuracy of the Spanish FSFI total score in discriminating between participants with and without FSD was evaluated using receiver operating characteristic (ROC) curve analysis. Participants were first diagnosed with

FSD according to DSM-5 criteria, and then a total cut-off point was calculated for the FSFI total score, together with its respective predictive values. In a ROC curve, the true-positive rate (sensitivity) is plotted in the function of the false-positive rate for different cut-off points. Each point on the ROC curve represents a sensitivity/specificity pair corresponding to a particular decision threshold.[32] The area under the ROC curve (AUC) was also calculated as a measure of how well a parameter is able to distinguish between two groups (with and without FSD). AUC was considered statistically significant when the 95% CI did not include the 0.5 value. The method of Hanley and McNeil[33] and the binomial exact test were used to calculate the standard error of AUC and the CI for the AUC, respectively.

RESULTS

A total of 152 women completed all the questionnaires included in this study. Their descriptive characteristics are shown in Table 1.

The mean age of participants was 63.91±6.99 years. Most of them were non smokers (92.10%), 71.71% were married or living with their partner, 57.24% had either no formal education at all or only primary education, and 63.16% came from urban areas. The mean FSFI total score of the participants was 22.78±7.07.

The exploratory factor analysis of the Spanish FSFI (using the principal components option) suggested a three-factor structure (Table 2), in which all items corresponding to original subscales Desire, Arousal and Orgasm, together with items 7 and 9 of Lubrication, were included in one single factor (dimension 1). Items 14, 15 y 16, (original satisfaction subscale) were loaded in another factor (dimension 2), together with items 8 (difficulty in becoming lubricated) and 10 (difficulty in maintaining lubrication), and finally Items corresponding to pain were loaded in a third different factor (dimension 3). The total variance explained by this model was 77.77%, and sampling adequacy was measured as KMO = 0.921 ($p<0.001$). For this reason the sample can be considered adequate for the purposes of this analysis.

As for reproducibility, the test-retest data of the Spanish version of FSFI show excellent reliability for the total score, dimensions 1 and 2, and items 3, 4, 14, 15, and 16. The rest of the items of the Spanish FSFI show substantial reliability (Table 3). Internal consistency reached good values, with a Cronbach's alpha value of 0.964 for the FSFI total score and 0.964, 0.916, and 0.899 for dimensions 1, 2, and 3, respectively.

Domain intercorrelations of the Spanish FSFI were significantly high (all $p<0.01$) for all dimensions (Table 4). FSFI total score was highly correlated with all dimensions, with Pearson's correlation coefficients of 0.961, 0.911, and 0.679 for dimensions 1, 2, and 3, respectively. To measure concurrent validity (Table 5), the correlations of the Spanish FSFI total score and dimensions with overall satisfaction with sexual life (VAS) were calculated using Pearson's coefficient. Our analysis showed strong ($r>0.50$) and significant correlations ($p<0.01$) for all dimensions and also for the total FSFI score. As for divergent validity, we only found low degrees of correlation of the FSFI total score and its domains with anxiety and depression as assessed by the HADS.

To evaluate discriminant validity, scores for the FSFI and its dimensions were compared between participants with and without FSD. Statistically significant differences between the two groups were observed for the FSFI total score and for all domains (Table 6). When analyzing the degree of accuracy in discriminating between participants with and without FSD, our results show that total score and all dimensions had a statistically significant AUC (Table 7). For the total score of FSFI, a cut-off point of <24.95 had a 64.15% sensitivity and a 75.76% specificity for detecting FSD (Figure 2).

1

DISCUSSION

In the present study we assessed the psychometric properties of the Spanish FSFI in postmenopausal women. The FSFI has been found to be a valid and reliable instrument for assessing female sexual function among this population, and to be able to discriminate between women with and without sexual disorders.

In our analysis, the mean±SD score for the FSFI total score was 22.78±7.07, which is comparable to the score (22.0) described by Carranza-Lira et al.[34] in a cross-sectional study performed in postmenopausal women in Mexico (55-59 years). Nevertheless, in other studies such as the one performed in Iranian women (52.8±3.7 years) the mean FSFI total score was higher (24.11±6.04).[35] These differences may be due to the fact that the mean age of participants in our study was higher. Physical, mental, and emotional changes associated with the aging process have been described to affect sexual function, and their effects add up to those of menopause.[35] The time required to complete the Spanish FSFI was between 15 and 20 minutes, while in other validations it was 10-20 minutes (Portuguese),[37] or 15 minutes (Chinese).[38] Given that there are other factors apart from the questionnaire that may influence the probability of a particular response,[39] such as the specific characteristics of persons to whom it is administered, these differences may be linked to the fact that in the present study 57.24% of the participants had primary school education or less, while in other validations 88.4% had secondary education or more (Chinese),[38] and 89% had medium-level education or more (Portuguese).[37]

Exploratory factor analysis by principal components yielded a three-factor structure, with a total explained variance of 77.77% and a KMO value of 0.921. This is larger than 0.60,[30] the minimum recommended value considered as adequate for the analysis. The items of the Lubrication domain referring to frequency were integrated with the items of the original domains Desire, Arousal, and Orgasm (dimension 1). In the Polish validation, Nowosielski, et al.[40] showed that Desire and Arousal were loading in the same factor, as did Ghassamia et al.[18] Moreover, our results revealed that items concerning pain loaded in one single factor (dimension 3), which is in accordance to previous research.[14,41] Finally, the items of the original Lubrication subscale referring to difficulty were included in the same factor, together with items of the original Satisfaction subscale (dimension 2). This could be related to the characteristics of the participants, the physical and psychological importance linked to lubrication problems, and their association with sexual dysfunction among postmenopausal women.[42] Our results may be interpreted as an example of how the different domains of female sexual function overlap, and illustrate the multifactorial nature of female sexual dysfunction.[43]

In order to assess test-retest reliability, the questionnaire was administered again two weeks later to a randomly selected subset of the population, a time period that has been employed before in other FSFI validations.[44,45] In the original version, overall test-retest reliability coefficients were high for every individual domain.[13] The ICC values of the Spanish FSFI were substantial-to-excellent for the FSFI total score, with ICC values ranging between 0.884 and 0.972, which are comparable to those described by Takahashi et al.[14] in the analysis of the Japanese version of FSFI.

In the original validation, Rosen et al.[13] described a high degree of internal consistency, with Cronbach's alpha values of 0.89 and higher, and 0.97 for the FSFI total score. A recent validation of the Persian version (53.63±7.8 years) reported a Cronbach's alpha larger than 0.80 for the entire scale and its dimensions.[46] Our analysis showed good reliability values for all the dimensions of the Spanish version (0.899-0.964), higher than those described in the Colombian validation[16] (0.84-0.89) or in the Iranian version

of FSFI (0.72-0.90).[41] Meanwhile, our Cronbach's alpha for the FSFI total score was 0.964, which is in agreement with the reliability values reported in studies performed in different population sets such as healthy women from Poland aged 17-55 years[40] or Swedish women with hypoactive sexual desire disorder.[44]

The analysis of the intercorrelations between the FSFI total and individual dimensions scores revealed that the weakest intercorrelations were observed for dimension 3 (pain items), which is in agreement with previous validations,[13,40,47] while the strongest correlations appeared between dimensions 1 and 2 and between FSFI total score and both dimensions 1 and 2. Similar results were described in other studies where the highest correlations appeared between the original domains Desire and Arousal,[40] (both included in domain 1 of the Spanish FSFI) or between Desire with Arousal, and Orgasm with Arousal and Satisfaction (which is included in domain 2).[48]

As regards concurrent validity, we employed a VAS to assess respondents' overall satisfaction with their sex life, which has been previously used in other validations.[14,40,41] Our results revealed a strong significant correlation ($p<0.001$) between all the dimensions and the total score of the Spanish FSFI, which indicates a sufficient degree of concurrent validity. These results are in agreement with those reported in the validations of the Japanese,[14] Polish,[40] and Iranian[41] FSFI versions. As for divergent validity (low association with a test that measures a different domain or entity), the Spanish FSFI total score and dimensions showed very low and non-significant correlations with depression and anxiety as assessed with HADS, in accordance with the findings reported in the Swedish validation (which employed the anxiety and depression subscales of the Symptom Checklist-90-Revised).[44]

Finally, in our study 65.13% of the participants had FSD, a similar proportion to the one recently reported by Nazarpour et al.[35] (61%, also among postmenopausal women). As for discriminant validity, our results indicate that all the scores yielded significant values in discriminating between participants with and without FSD, with an AUC of 0.721 for the Spanish FSFI total score, and with dimension 3 (pain) showing the largest AUCs (0.807). Based on the AUC analysis, we established a cut-off for the Spanish FSFI total score of <24.95 to discriminate between Spanish postmenopausal women with and without FSD. Higher cut-off points have been proposed in the Polish (27.5)[40] and Greek (26.0)[47] validations of FSFI, and Wiegel et al.[43] described an optimal cut-off score of 26.55 in a study performed in several samples of women with mixed sexual dysfunctions (18-74 years). These differences may be associated with the fact that the participants in our study are, on average, older in age, postmenopausal, and present a lower educational level, factors that have been associated with worsened sexual function and therefore with a lower FSFI total score.[36,49]

Some limitations of the present study should be considered. It was conducted on a convenience sample of participants, and thus the generalizability of its results to the Spanish female population or to other subpopulations might be limited. Also, 36.84% of the participants were from rural areas, 13.82% had university education, and 28.95% had secondary education. Our results are only applicable to the Spanish population, which is why this adaptation should be used with caution in other Spanish-speaking countries. Another limitation of the study is the lack of assessment of partner variables, of the use of hormone replacement therapy (HRT), and of other medications that may affect sexual function (e.g. antidepressants). Future studies should be conducted among a more general population, including women with different health conditions, with a heterogeneous educational level, and from a variety of geographical regions. In addition, future studies should take into account partner variables, as well as usage of HRT and of any medication with the potential to affect sexual function.

CONCLUSIONS

The results of the present study reveal that the Spanish version of the FSFI shows good internal consistency and test-retest reliability, as well as good construct, concurrent, and divergent validity for a population of postmenopausal women. Moreover, the Spanish version of FSFI shows satisfactory general psychometric properties, and is able to discriminate between women with and without sexual dysfunctions among a population of Spanish postmenopausal women.

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Figure 1. Flow diagram of the study participants.

1 Figure 2. The ROC curve of the FSFI total score for discriminating among women with
2 and without FSD. ROC: receiver-operating characteristic. FSFI: female sexual function
3 index. FSD: female sexual dysfunctions.
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