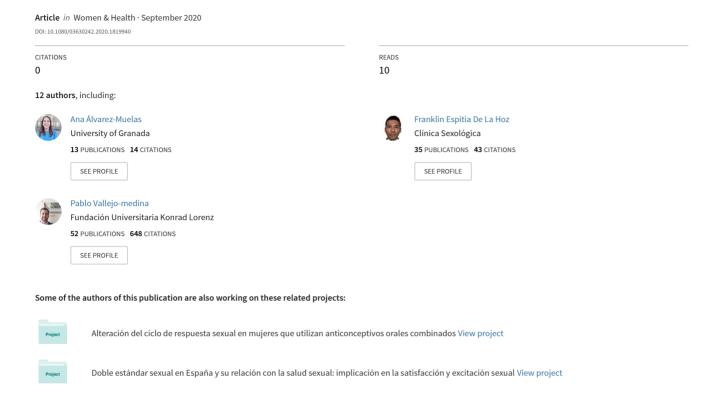
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## Temporal stability and clinical validation of the Spanish version of the female sexual function inventory (FSFI)

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#### **ABSTRACT**

The Female Sexual Function Index is one of the most common instruments used to evaluate the female sexual function. The present study aimed to analyze the test-retest reliability, internal consistency, and discriminant validity of the index in clinical samples and to determine a specific and sensitive cutoff point for the Spanish version of the Female Sexual Function Index. For that purpose, a sample consisting of 117 Colombian women was recruited to evaluate test-retest reliability, and a second sample, consisting of 185 women, was divided into diagnosis and no-diagnosis groups based on DSM-5 criteria. Results showed adequate test-retest reliability after four weeks, and satisfactory evidence of internal consistency was obtained for subscale and overall scores. The inventory was found to have an adequate criterion validity, and it confirmed the differences between diagnosis and nodiagnosis groups. The instrument's cutoff point was determined to be 26 points, with a specificity of 73.9%, a sensitivity of 87.7%, and an area under the curve of 85.9 (CI = 80.0-91.7). These results confirm that the Spanish version of the FSFI is an adequate tool for evaluating female sexual dysfunction based on DSM-5 criteria.

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#### **KEYWORDS**

Colombia; DSM-5; female orgasmic disorder; FSFI; sexual dysfunction; Spanish; women

Sexual dysfunctions are a set of heterogeneous sexual disorders that affect sexual pleasure or sexual response capacity (APA 2013). The prevalence of sexual dysfunctions among women is high, ranging from 22% to 70% (Biddle et al. 2009; Jaafarpour et al. 2013; Kingsberg and Rezaee 2013; Laumann, Paik, and Rosen 1999; McCabe et al. 2015). However, in comparison with male sexual dysfunction, research on female sexual dysfunction is still scarce (Rosen et al. 2000). According to different studies, the prevalence of sexual dysfunction among Latin American women ranges from 21 to 94.5% (Blümel et al. 2009; Monterrosa-Castro, Márquez-Vega, and Arteta-Acosta 2014). In the specific case of Colombia, the figure ranges from 20 to 83% (Ceballos, De la Rosa, and León 2008; Espitia-De La Hoz 2016; García, Aponte, and Moreno 2005; Monterrosa-Castro, Márquez-Vega, and Arteta-Acosta 2014; Raigosa-Londoño and Echeverri-Ramírez 2012). In terms of percentages, individual disorders affecting Colombian women were 32.9% in the case of sexual desire disorder, 21.5% in the case of absence or low frequency of orgasm, 16.7% in the case of sexual arousal disorder, and 8.4% in the case of dyspareunia (Espitia-De La Hoz 2016; Raigosa-Londoño and Echeverri-Ramírez 2012). The prevalence of these disorders is higher in women over 40 years of age,

who presented some type of sexual dysfunction in 79.41% of cases; the prevalence decreases to 21.08% for women under 40 years of age in some reports. Sexual desire disorder is the most prevalent issue, with percentages of 38.4 among women over 40 years of age and 23.7 among women under 40 years of age (Espitia-De La Hoz, 2018). Low sexual desire has been associated with a decrease in other aspects of the sexual response, such as arousal, in addition to orgasm issues and an overall reduction of sexual pleasure (Basson 2001, 2002). Incidentally, the population of Afro-Colombian women was found to have the lowest prevalence (38.4%) of sexual dysfunctions (Monterrosa-Castro, Márquez-Vega, and Arteta-Acosta 2014).

In women, sexual dysfunction has been associated with a significant decrease in general health status. It presents comorbidity with disorders such as depression and anxiety (Dennerstein et al. 2008; Dunn, Croft, and Hackett 1999). As a result of the difficulties in forming and maintaining intimate relationships due to the sexual dysfunction, which often decreases satisfaction for both members of the couple, these disorders are negatively associated with relationship stability (Heiman 2013). Research has also found increased emotional distress as a result of sexual dysfunction, as well as a deteriorating effect on family relationships (Leiblum et al. 2006). Additionally, people suffering from sexual dysfunction are at a higher risk of presenting suicidal ideation, which is associated with lower levels of arousal and sexual satisfaction (Blais, Monteith, and Kugler 2017).

The Female Sexual Function Index (Rosen et al. 2000) is one of the most common instruments used to assess the female sexual function (Neijenhuijs et al. 2019). The original clinical version, published by Rosen et al. (2000) and Wiegel, Meston, and Rosen (2005), consists of 19 Likert-type items scored on a scale from 1 to 5 where 0 indicates an absence of sexual activity. The items are grouped into six dimensions: desire (items 1 and 2), arousal (items 3 to 6), lubrication (items 7 to 10), orgasm (items 11 to 13), satisfaction (items 14 to 16), and pain (items 17 to 19). A score of 26 or lower indicates the presence of sexual dysfunction. The internal consistency indicators of the inventory were found to be adequate in all dimensions, both for the general population and subsamples of patients with a diagnosed sexual dysfunction disorder. The Spanish adaptation of the FSFI to the Colombian population, published by Vallejo-Medina, Pérez-Durán, and Saavedra-Roa (2018), presents the same six-factor structure resulting from the 19 Likert-type items in the original scale by Rosen et al. (2000); it also presents good internal consistency.

Although the U.S. Food and Drug Administration (2016) recommends the FSFI as the primary method for assessing women's sexual functioning, it can still be improved. Not inclusion of a measure of sexual distress and inadequate coding for sexually inactive people are its two major weaknesses (Meston et al. 2020). A systematic review found satisfactory evidence of the internal consistency and validity of the FSFI (Neijenhuijs et al. 2019). Concerning the cutoff point of the inventory, the value ranges from scores as low as 23.45 (Ma et al. 2014) and 24.75 (Fakhri et al. 2012) to intermediate values between 26 (Zachariou, Filiponi, and Kirana 2017) and 26.55 (Wiegel, Meston, and Rosen 2005), and the highest values are 27.5 (Nowosielski et al. 2013), 28.1 (Anis et al. 2011) and 31.37 (Ryding and Blom 2015). Therefore, its central value is close to 26 points: the cutoff point of the original version. Current Spanish validations (Pérez-Herrezuelo et al. 2019; Sánchez-Sánchez et al. 2020; Vallejo-Medina et al. 2018) have failed to include clinical interviews. Therefore, to date, it is not known whether the Spanish versions identify significant differences between populations of women with and without sexual dysfunctions or if the 26-point threshold is valid in Spanish-speaking countries.

Rosen et al.'s (2000) original FSFI allows for the differentiation of sexual dysfunction types based on criteria established by the DSM IV-TR (APA 2000); however, the current standard is the DSM-5 (APA 2013). The latter has introduced certain changes, such as the merger of arousal and desire issues into a single disorder. Therefore, the cutoff points of the FSFI use criteria no longer in use (Wiegel, Meston, and Rosen 2005), and the discriminative capacity of the FSFI with respect to the new DSM-5 criteria is still to be tested.



The present study aimed to analyze the test-retest reliability, internal consistency, and discriminant validity of the index using clinical samples and to determine a specific and sensitive cutoff point for the Spanish version of the FSFI (Vallejo-Medina, Pérez-Durán, and Saavedra-Roa 2018).

#### Method

#### **Participants**

The present study used two different samples. The first sample included 117 women, and it was used for the test-retest reliability analysis. This n allow us to have a statistical power of .99 given our minimal r observed with an apha of .05 (Zou 2012). Inclusion criteria were being of legal age and having engaged in sexual activity during the month prior to the study. The age range of the sample was 18 to 32 years (M = 21.28; SD = 2.58). A total of 98 participants (81%) self-reported being exclusively heterosexual, 4 (3.3%) being exclusively homosexual, and 19 (15.80%) reported different degrees of bisexuality. Seventy-five women (62%) reported having a stable relationship (longer than six months). The mode was 1 or 2 events of sexual activity per week. All participants were university students from Konrad Lorenz University.

The second sample included 185 women who responded to the FSFI. The age range of the sample was 18 to 52 years (M = 28.71; SD = 7.91). Of these participants, 127 (68.6%) were included in the Non-diagnosis group, that is, women not meeting the DSM-5 criteria for any of the three sexual disorders. Concerning the presence of disorders, 27 women (14.6%) met diagnostic criteria for a single disorder (female sexual interest/arousal disorder, 37.04%; female orgasmic disorder, 33.33%; genital/pelvic pain disorder, 29.63%). Twenty-three women (12.4%) presented comorbidity between two disorders, and the remaining eight (4.32%) met the criteria for all three disorders. Thus, according to parameters published by Wiegel, Meston, and Rosen (2005), all women who met the criteria for at least one disorder were grouped in the group labeled as Diagnosis (n = 58). The statistic power associated with this sample sizes and the given AUC is 1. Mean age was 32.57 (SD = 8.51) for the diagnosis group, and 26.90 (SD = 6.94) for the no diagnosis group; the difference was statistically significant t(180) = 4.76; p < .01; d = 0.73. Exclusion criteria for this subsample were being a victim of sexual abuse, being unable to read or write, failing to provide consent to participate in the study, not completing the questionnaire, and being underage. Table A1 presents descriptive variables for both groups.

#### Instruments

Sociodemographic questionnaire. This instrument was composed of 15 items, and its purpose was to collect data on sex, age, nationality, educational level, medical and psychological treatments, religiosity, and sexual orientation, among other information.

Semi-structured interview using DSM-5 criteria for female sexual dysfunction. This semistructured interview used the DSM-5 diagnostic criteria for each of the three types of female sexual dysfunction (female orgasmic disorder, female sexual interest/arousal disorder, and genito-pelvic pain/penetration disorder).

Female Sexual Function Index (FSFI; Rosen et al. 2000; Vallejo-Medina, Pérez-Durán, and Saavedra-Roa 2018). This instrument is a self-report measure consisting of 19 items grouped into six domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. Each question has five or six response options, which are given a score from 0 to 5. The score for each domain is multiplied by a homogenization factor, and the final result is the sum of all domains. Validity tests for the original inventory (Rosen et al. 2000) showed high test-retest reliability coefficients for each of the domains (r 0.79 to 0.86), and a high degree of internal consistency was observed (Cronbach's alpha values of .82 and above).

#### **Procedure**

Test-retest was carried out with female students in the final semesters of undergraduate programs at Konrad Lorenz University. The interval between the first and second tests was four weeks. The study used the convenience sampling method.

Women in the diagnosis group were surveyed in different clinics in Colombia, specifically, in the cities of Armenia, Barranquilla, Bogotá, and Villavicencio. Thus, a total of five clinics or hospitals participated in the present study. Different physicians and psychologists administered the battery, which included a semi-structured interview on DSM-5 criteria, the FSFI, and the sociodemographic battery. All evaluators, men and women over 30 years of age, were trained in this procedure. On the other hand, participants in the no diagnosis group were given the tests in facilities of universities, libraries, associations, and different companies. As with the previous sample, these two subsamples were obtained using convenience sampling.

#### **Ethical statement**

The anonymity of participants and the confidentiality of data to be used in the study were guaranteed, as well as the possibility of accessing the results of the study. All participants signed an informed consent form, and treatment was provided to all participants who were diagnosed with a sexual disorder. This study was approved and endorsed by an independent ethics committee from one of the participating institutions. The authors declare no conflict of interest.

#### Data analysis

Data were analyzed using the R software (Version 3.6.0; R Core Team 2017) and the RStudio interface (Version 1.1.463; RStudio Team 2016). Cor curves were obtained using the pROC package (R package, Version 1.15.3; Robin et al. 2011), which was also used to calculate confidence intervals (95% CI) with 2000 stratified bootstrap replicates. Finally, the ggplot2 package (R package, Version 3.1.1; Wickham 2009) was used to create plots.

#### Results

#### **Test-retest reliability**

The main purpose of the present study was to evaluate the reliability of the FSFI. As can be observed in Figure A1, both the total scale and its subscales showed temporal stability four weeks after the evaluation. The subdimension of desire seemed to be the most unstable; however, intraclass correlation (ICC) was still high.

#### **Internal consistency**

Cronbach's alpha values for the non-diagnosis group were as follows: desire = .89, arousal = .93, lubrication = .94, orgasm = .91, satisfaction = .82, pain = .97, and total FSFI = .94. In the case of the diagnosis group, the values were: desire = .88, arousal = .94, lubrication = .95, orgasm = .95, satisfaction = .64, pain = .97, and total FSFI = .91.

#### **Criterion validity**

The criterion validity of the inventory was tested. Figure A2 shows that the FSFI measured statistically significant differences between diagnosis and non-diagnosis groups for all subdimensions and total score. Moreover, except for one exception (pain), all observed effect sizes were high.



#### **Cutoff point**

Finally, the cutoff point of the inventory was tested by using ROC curves. Figure A3 shows the obtained function. The cutoff point that best discriminated was 26.5, that is, any woman with a score lower than 26.5 was considered to be dysfunctional. This value represents a specificity of 73.9% and a sensitivity of 87.7%; the area under the curve (AUC) was found to be 85.9 (CI = 80.0-91.7).

#### Discussion

Female sexual dysfunction is a public health problem (Fuentealba-Torres et al. 2018) affecting the quality of life of women who suffer from sexual dysfunction and their partners' (García, Aponte, and Moreno 2005). The FSFI is the preferred and recommended self-report measure for assessing sexual function in women (Meston et al. 2020). To that end, and to follow up on a previous Spanish validation of the FSFI for Colombian population (Vallejo-Medina et al. 2018), the present study sought to validate its test-retest reliability and adequate internal consistency and to determine a cutoff point capable of discriminating the presence of sexual dysfunction in Colombian women per DSM-5 criteria.

Test-retest reliability was found to be adequate for individual dimensions and overall score; the interval beteen tests was four weeks. Despite its high intraclass correlation, the dimension of desire was more unstable than the rest of the dimensions. Hormonal (Caruso et al. 2014), relational (Basson 2005), and social factors (Bodenmann et al. 2006) have been found to have effects on sexual desire. Regardless of these factors, sexual desire fluctuates visibly over a given month, and considerable fluctuations take place over short periods (Vowels et al. 2018). These fluctuations could explain the variability of the levels of sexual desire observed in the present study.

On the other hand, the Spanish version presents adequate evidence of internal consistency; the results found in the present study were between .64 and .97 in the diagnosis and the non-diagnosis group, respectively. These values are similar to those found in the original study by Rosen et al. (2000), whose sample consisted of women in the general population and, as in the present study, used two subgroups: one composed of women diagnosed suffering from a sexual dysfunction disorder and the other of women without such diagnosis; a score lower than 26.5 was found to indicate the possible presence of sexual dysfunction. This cutoff score matches the values reported by Wiegel, Meston, and Rosen (2005) and Zachariou, Filiponi, and Kirana (2017), and is close to the average cutoff point reported by Anis et al. (2011), Fakhri et al. (2012), Ma et al. (2014), Nowosielski et al. (2013), and Ryding and Blom (2015). Therefore, the Spanish version allows for the differentiation of different sexual dysfunction disorders as described by the DSM-5. The discrimination capacity of the inventory is compatible with current diagnostic criteria, at least in this Spanishspeaking sample.

The assessment of female sexuality must be more decisively addressed by research, and adequate and reliable evaluation tools must be available for the allocation of intervention resources (Muñoz & Camacho 2016). In this regard, validating these tools for specific populations is the recommended practice; in the case of the FSFI, it should reliably determine significant differences between diagnostic and non-diagnostic groups (Meston et al. 2020). In view of these recommendations and the evidence found during the present study, we conclude that the FSFI provides a valid measure to determine such difference, and the obtained cutoff point can discriminate the possible presence of sexual dysfunction according to DSM-5 criteria. Therefore, the Spanish version of FSFI can be used during the evaluation and treatment of female sexual dysfunction in the clinical and research contexts. However, the inventory fails to provide information on the etiology or prognosis of the problem; therefore, one of its limitations is that it must be used in combination with other instruments. Furthermore, despite that the Spanish version of the FSFI was found to be compatible with DSM-5 criteria, the inventory lacks a distress measure and its test-retest interval was only four weeks, whereas, the DSM-5 includes



a distress criterion and recommends a six-month interval. Finally, in this study, the sample consisted of Colombian participants only, most of them heterosexual. For this reason, it should be used with caution in other Spanish-speaking populations, and other sexual orientations should be studied separately.

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#### **Disclosure statement**

No potential conflict of interest was reported by the authors.

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#### Appendix A

**Table A1.** Description of sample variables for diagnosis and non-diagnosis groups.

	Diagnosis (n)	Non-Diagnosis (n)	Contrast
Sample	58	124	
Orientación sexual*			$\chi 2 (3) = 7.58; p = .055$
Completely heterosexual	54	104	
2	2	13	
3	2	1	
4	0	3	
5	0	1	
6	0	0	
Completely homosexual	0	3	
Couple relationship			$\chi 2 (1) = 4.95; p = .02; \eta^2 = 0.20$
Yes	54	104	K 17 71
No	3	22	
Marital status			$\chi 2 (3) = 13.50; p < .01; \eta^2 = 0.27$
Married	26	26	, , , , , , , , , , , , , , , , , , , ,
Single	18	71	
Separated	3	6	
Common law marriage	11	22	
Disease			$\chi 2 (1) = 3.01; p = .83$
Thyroid	8	8	K
High/low blood pressure	1	6	
Heart problems	1	6	
Psychiatric diagnosis	4	16	
Anxiety	6	15	
Alcohol abuse	2	3	
Drug abuse	1	2	
Diabetes	1	0	
Cancer	1	1	
Blood problems	1	4	
Depression	2	9	
STIs	1	3	

(Continued)

Table A1. (Continued).

	Diagnosis (n)	Non-Diagnosis (n)	Contrast
Ovarian excision	1	0	
Medications			$\chi 2 (6) = 2.15; p = .90$
Antihypertensive	0	1	
Antidepressant	0	1	
Tranquilizer/anxiolytic	1	1	
Somnifer/hypnotic	1	3	
Hormone replacement	4	5	

Sexual orientation. 2 = predominantly heterosexual, only incidentally homosexual; 3 = predominantly heterosexual, but more than incidentally homosexual; 4 = equally heterosexual and homosexual; 5 = predominantly homosexual, but more than incidentally heterosexual; 6 = predominantly homosexual, only incidentally heterosexual.

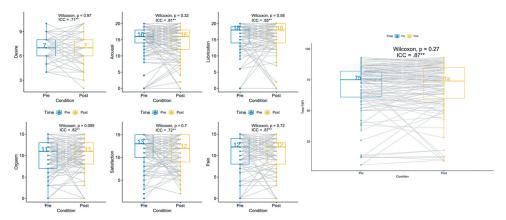


Figure A1. Test-retest reliability of total FSFI score and subscales.

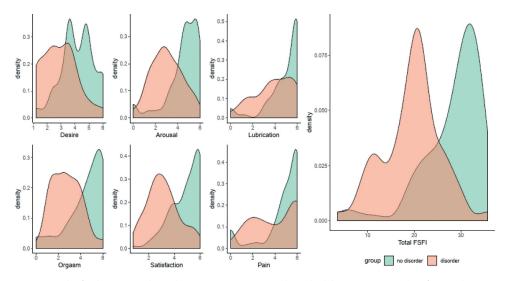


Figure A2. Density plot for diagnosis and non-diagnosis groups. Mean and standard deviation M (SD) values for non-diagnosis group: Desire = 4.17(1.15), arousal = 4.54(1.46), lubrication = 4.92(1.50), orgasm = 4.51(1.64), satisfaction = 4.90(1.14), pain = 4.73(1.76), total FSFI = 28.3(6.30). Mean and standard deviation M (SD) values for diagnosis group: Desire = 2.88(1.26), arousal = 3(1.39), lubrication = 3.88(1.70), orgasm = 2.74(1.31), satisfaction = 3.14(1.24), pain = 3.94(1.97), and total FSFI = 19.6(6.12). All contrasts are significant (p < .01).

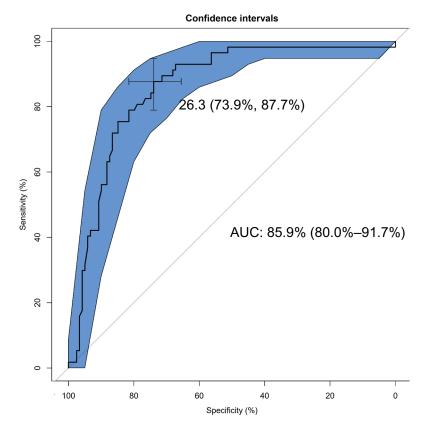


Figure A3. ROC curves, total FSFI scale.