

Validation of the FSFI Sexual Desire Domain Diagnostic Cut-Point in Predicting HSDD: Independent Replication and Confirmation

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ABSTRACT

Objective The sexual desire (SD) domain of the FSFI provides a potentially sensitive measure for assessing sexual desire levels in women with Hypoactive Sexual Desire Disorder (HSDD). In a previous analysis (see Abstract #88), we developed a diagnostic cut-point of SD ≤ 5 for distinguishing women with and without HSDD. The objective of this study was to validate the diagnostic accuracy and sensitivity of the cut-point in 4 large, independent study samples of women with and without HSDD.

Methods Subjects for the validation study met similar criteria as those in the development samples, including: (i) an independent clinical diagnosis for all women classified as positive cases of HSDD; (ii) documentation of the presence or absence of other sexual dysfunctions; (iii) information on the age and/or menopausal status of the women; and (iv) complete FSFI data on all study subjects. A total of 4 datasets were used for the validation phase, including 454 women with HSDD and 300 non-dysfunctional controls. Datasets were obtained from the sponsor (Boehringer Ingelheim) for this purpose.

Results The sensitivities and specificities observed in the validation samples were as high or higher than those obtained in the development sample when using a SD cut-point ≤ 5 . Specifically, all sensitivities were $>80\%$ and specificities were $>90\%$ in each of the validation samples of HSDD women, with or without other dysfunction, compared to control subjects included in the analysis.

Conclusions These analyses confirm and validate the diagnostic accuracy of the SD domain of the FSFI scale and use of a specific cut-point (SD ≤ 5) for differentiating women with HSDD from healthy controls.

INTRODUCTION

- The Female Sexual Function Index (FSFI)¹⁻⁴ is a 19-item, self-report measure of sexual function developed and validated for use in clinical trials and epidemiological studies of sexual dysfunction in women. The measure has been widely adopted as a “gold standard” measure of female sexual function.
- The sexual desire (SD) domain of the FSFI consists of two items assessing the frequency and intensity of sexual desire, and provides a potentially sensitive measure for assessing sexual desire levels in women with Hypoactive Sexual Desire Disorder (HSDD).
- A diagnostic cut-point of SD ≤ 5 was recently established for distinguishing women with and without HSDD, based on pooled analyses of multiple datasets from several independent investigators.

OBJECTIVE

- The objective of this study was to validate and replicate the diagnostic accuracy and sensitivity of the cut-point in 4 large, independent study samples of women with and without HSDD.

METHODS AND RESULTS

- For the first phase of the analyses, NERI obtained multiple datasets from independent clinical investigators, including Dr. Cindy Meston (University of Texas at Austin), Dr. Lori Brotto (University of British Columbia), and Dr. Markus Wiegel (Behavioral Medicine Institute of Atlanta). A total of 8 datasets, including 159 women with HSDD and 254 non-dysfunctional controls were included in the first phase of the analyses.
- Receiver operating curves were constructed based on these combined datasets, and sensitivity and specificity analyses were performed on potential cut-points for each of the scale scores. Based on these analyses, the discriminant validity of the SD domain was demonstrated and a diagnostic cut-point (SD ≤ 5) for distinguishing women with and without HSDD was established.
- This diagnostic criterion was then replicated and validated in a large, independent pooled dataset of women with and without HSDD who participated in 4 separate validation studies conducted by the sponsor.
- These datasets comprised a total of 454 women with HSDD and 300 non-dysfunctional controls (Table 1).
- Women in each of these studies met the same criteria as those in the original samples, including: (i) an independent clinical diagnosis for all women classified as positive cases of HSDD; (ii) documentation of the presence or absence of other sexual dysfunctions; (iii) information on the age and/or menopausal status of the women; and (iv) complete FSFI data on all study subjects.

Table 1: Sample Characteristics

	Validation datasets				
	Study 72	Study 73	Study 85	Study 106	Overall
Total sample size	90	248	258	296	892
Diagnosis					
Non-dysfunctional controls	35	62	124	79	300
HSDD only	31	112	118	145	406
HSDD + other dysfunction	0	9	12	27	48
Other (eg, sexual pain disorder)	24	47	1	23	95
Missing	0	18	3	22	43
Age, years					
Mean \pm SD	33.3 \pm 12.0	46.2 \pm 11.1	45.3 \pm 11.7	36.3 \pm 9.2	41.3 \pm 11.9
Range	18 - 61	18 - 64	20 - 68	18 - 53	18 - 68
Menopausal status					
Premenopausal	0	92	128	214	434
Perimenopausal	0	53	18	38	109
Postmenopausal	0	90	110	27	227
Missing	90	13	2	17	122

Table 2: Sensitivity and specificity of SD ≤ 5 for HSDD cut-point in development and replication datasets

	N			Specificity (95% CI)	Sensitivity (95% CI)	
	Controls	HSDD only	HSDD with or without other sexual dysfunction		HSDD only	HSDD with or without other sexual dysfunction
Development sample	254	49	159	83.5%	75.5%	74.8%
				(78.3%, 87.8%)	(61.1%, 86.7%)	(67.4%, 81.4%)
Replication samples						
Study 72	35	31	31	97.1%	96.8%	96.8%
				(85.1%, 99.9%)	(83.3%, 99.9%)	(83.3%, 99.9%)
Study 73	62	112	121	90.3%	92.0%	90.1%
				(80.1%, 96.4%)	(85.3%, 96.3%)	(83.3%, 94.8%)
Study 85	124	118	130	91.1%	87.3%	87.7%
				(84.7%, 95.5%)	(79.9%, 92.7%)	(80.8%, 92.8%)
Study 106	79	145	172	93.7%	95.2%	94.8%
				(85.8%, 97.9%)	(90.3%, 98.0%)	(90.3%, 97.6%)
Studies 72, 73, 85 & 106	300	406	454	92.3%	92.1%	91.6%
				(88.7%, 95.1%)	(89.1%, 94.5%)	(88.7%, 94.0%)

CONCLUSIONS

- Based on the analyses presented in this and the accompanying poster, the SD domain of the FSFI scale was found to have diagnostic accuracy in identifying women with an independent clinical diagnosis of HSDD.
- A cut-point of 5 or less on the 10-point scale was found to have adequate sensitivity and specificity in several datasets provided by independent academic investigators.
- This cut-point was replicated in the current study in several large combined datasets of women with and without clinically diagnosed HSDD provided by the sponsor (Boehringer Ingelheim).
- Taken together, these analyses support the diagnostic accuracy and treatment sensitivity of the SD domain of the FSFI scale for use in future clinical trials of HSDD. These results are also consistent with a large number of published reports indicating the validity, reliability and utility of the FSFI scale in both observational studies and clinical trials of Female Sexual Dysfunction.

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