Sexual Desire and the Female Sexual Function Index (FSFI): A Sexual Desire Cutpoint for Clinical Interpretation of the FSFI in Women with and without Hypoactive Sexual Desire Disorder

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ABSTRACT

Introduction. A validated cutpoint for the total Female Sexual Function Index scale score exists to classify women with and without sexual dysfunction. However, there is no sexual desire (SD) domain-specific cutpoint for assessing the presence of diminished desire in women with or without a sexual desire problem.

Aims. This article defines and validates a specific cutpoint on the SD domain for differentiating women with and without hypoactive sexual desire disorder (HSDD).

Methods. Eight datasets (618 women) were included in the development dataset. Four independent datasets (892 women) were used in the validation portion of the study.

Main Outcome Measures. Diagnosis of HSDD was clinician-derived. Receiver-operator characteristic (ROC) curves were used to develop the cutpoint, which was confirmed in the validation dataset.

Results. The use of a diagnostic cutpoint for classifying women with SD scores of 5 or less on the SD domain as having HSDD and those with SD scores of 6 or more as not having HSDD maximized diagnostic sensitivity and specificity. In the development sample, the sensitivity and specificity for predicting HSDD (with or without other conditions) were 75% and 84%, respectively, and the corresponding sensitivity and specificity in the validation sample were 92% and 89%, respectively.

Conclusions. These analyses support the diagnostic accuracy of the SD domain for use in future observational studies and clinical trials of HSDD. **Gerstenberger EP, Rosen RC, Brewer JV, Meston CM, Brotto LA, Wiegel M, and Sand M. Sexual desire and the female sexual function index (FSFI): A sexual desire cutpoint for clinical interpretation of the FSFI in women with and without hypoactive sexual desire disorder. J Sex Med 2010;7:3096–3103.**

Key Words. Sexual Desire; Cutpoint; Hypoactive Sexual Desire Disorder; Female Sexual Function Index

Introduction

The Female Sexual Function Index (FSFI) [1–3] is a 19-item, self-report measure of sexual function developed for use in clinical trials and epidemiological studies of sexual dysfunction in women. The FSFI was designed as a multidimensional questionnaire measure, with subscales to assess the major components of sexual function in women, including sexual desire, arousal, orgasm, pain, and satisfaction. Development of the questionnaire included both qualitative and quantitative studies, with individual items based on qualitative interviews in women with and without sexual dysfunction [1]. Separate validation studies have been reported by a number of authors using independent samples of women [2,3]. The FSFI has been translated into multiple languages and has been widely used to assess female sexual function in a variety of clinical and nonclinical settings

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[4–7]. The FSFI is a well-characterized instrument and its psychometric properties have been previously described [2,3,8].

Based on early validation studies, a cutpoint for the total FSFI scale score (26.5) was proposed by Wiegel et al. [3] in order to classify women with and without sexual dysfunction. Despite the use of the total score cutpoint in differentiating women with or without sexual dysfunction, it does not provide a domain-specific cutpoint for assessing the presence of diminished desire in women [8–10]. Sexual desire (SD) is a complex, multifaceted component of sexual response in men and women, which requires independent assessment by means of a validated self-report scale.

There are two important reasons for considering the need for a domain-specific cutpoint. First, diminished desire can be assessed in women who are not currently sexually active, whereas other domains and the total sexual function score are predicated on sexual activity with or without a partner [12]. Second, since hypoactive sexual desire disorder (HSDD) is the most frequently diagnosed sexual problem in women and frequently occurs concurrently with other sexual disorders in women [13,14], a validated diagnostic cutpoint for the SD domain would be valuable for use in future clinical and research studies, particularly in assessing desire-related outcomes of treatment.

Methods

Development Sample

To establish a diagnostic cutpoint for the SD domain of the FSFI, datasets were obtained from independent clinical investigators at geographically diverse sites in the United States and Canada. In order to be included in this analysis, a dataset had to meet several criteria, including: (i) an independent clinical assessment plus diagnosis for all women classified as positive cases of HSDD; (ii) documentation of the presence or absence of other sexual dysfunctions; (iii) information on age or menopausal status of the women; and (iv) complete FSFI data on all study participants. Eight datasets (four datasets each from Dr. Lori Brotto and Dr. Markus Wiegel), totaling 618 women, met these criteria and were considered for inclusion in the analysis. Diagnosis of HSDD was made by an independent clinician assessment using the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) criteria, which defines HSDD as "persistent or recurrent deficiency (or absence) of sexual fantasies and desire for sexual activity, which causes marked distress or interpersonal difficulty, and which is not better accounted for by a medical, substance-related, psychiatric, or other sexual condition." [15] The FSFI questionnaire was administered in paper and pencil form using standard instructions and scoring procedures [1–3]. The diagnostic interview by clinicians was not controlled across studies in this retrospective analysis.

Validation Sample

An independent sample of participants was used to confirm and validate the cutpoint identified. Four separate studies (not published) conducted by Boehringer Ingelheim (the sponsor) were used, resulting in a total sample size of 892 participants. In these studies, the diagnosis of HSDD was made using a structured in-depth clinical interview conducted by a trained clinician according to the text revision of the DSM IV criteria. The FSFI questionnaire was administered in the standardized (i.e., paper and pencil) form [1].

Human Subjects Protection

The studies used in this analysis were approved by the appropriate local institutional review boards, and subjects signed study-specific informed consent forms. Each study was conducted in accordance with the standards of the Helsinki Declaration of 1975, as revised in 1983.

Statistical Methods

Internal consistency for the two items comprising the SD domain of the FSFI was assessed using Cronbach's alpha [16]. Receiver-operator characteristic (ROC) curves [17] were constructed using logistic regression to assess the sensitivity and specificity of each cutpoint on the scale as compared with the independent clinician-derived diagnosis of HSDD. A series of analyses were performed in which the presence or absence of an HSDD diagnosis in women without any concomitant sexual dysfunction was regressed on the SD domain score, which was dichotomized at each of the possible values of the scale. The ROC curve was created by plotting sensitivity against 1—specificity, where sensitivity is the proportion of participants correctly identified as having HSDD and specificity is the proportion of participants correctly identified as not having HSDD. The curve was used to identify the cutpoint in the SD scale that simultaneously optimized sensitivity and specificity. These analyses were repeated com-

paring women without an HSDD diagnosis with women with an HSDD diagnosis and possible concomitant sexual dysfunctions, overall and within premenopausal and postmenopausal women. The area under the curve is reported as a measure of diagnostic accuracy.

The sensitivity and specificity of the proposed cutpoint, along with 95% exact binomial confidence intervals, were subsequently confirmed in the validation sample.

All analyses were carried out using SAS version 9.1.3 (SAS Institute, Cary, NC, USA), except for the exact 95% binomial confidence intervals, which were calculated using Stata version 7 (StataCorp LP, College Station, TX, USA).

Results

Development of a Diagnostic Cutpoint

Since each dataset contained a relatively small number of participants and a limited number of women with HSDD (either alone or in combination with another sexual disorder), the eight datasets were combined for this analysis. Characteristics of the eight datasets, separately and combined, are given in Table 1.

The age range of women in the pooled sample was 18–74, with an average age of 37.8 years (standard deviation of 13.5 years). Approximately 72.5% were premenopausal, 14.4% perimenopausal, and the remaining 13.1% were postmenopausal. Menopausal status was collected for 248 (40.1%) women, and the remaining women were categorized as follows: women aged 45 or younger were considered premenopausal, women between the ages of 46 and 59 were considered perimenopausal, and women aged 60 or older were considered postmenopausal. Of the 618 participants, 159 participants had an HSDD diagnosis and 254 participants were sexually healthy controls; the remaining participants were diagnosed with sexual disorders other than HSDD.

The SD domain of the FSFI consists of two Likert-type items, one item on frequency and another item on intensity of sexual desire. The internal consistency of the SD domain was assessed and found to have a Cronbach's alpha of 0.92. This high value implies that the SD scale is one-dimensional, and the single cutpoint arising from a Classification and Regression Trees (CART) analysis with a unidimensional scale would have yielded results similar to those obtained by using a conventional ROC analysis.

Figure 1A shows an ROC curve predicting HSDD as a function of SD domain scores comparing women without sexual dysfunction (controls, $n = 254$) with women with HSDD only ($n = 49$). Classifying women with SD scores of 5 or less as positive cases (i.e., having the condition) and women with SD scores of 6 or above as negative cases (i.e., not having the condition) simultaneously maximizes sensitivity (75.5%, 37 out of 49 women with HSDD were correctly classified) and specificity (83.5%, 212 of the 254 women without sexual dysfunction were correctly classified). Figure 1B shows an ROC curve predicting HSDD as a function of SD domain scores comparing women without sexual dysfunction (controls, $n = 254$) with HSDD women with or without other sexual dysfunctions ($n = 159$). A similar classification scheme maximized sensitivity (74.8%, 119 out of 159 women with HSDD were correctly classified) and specificity (83.5%, 212 of 254 women without sexual dysfunction were correctly classified as not having HSDD).

Separate ROC curves (Figure 1C, D) that compared women with and without sexual dysfunction and by menopausal status were constructed. Classifying women with SD scores of 5 or less as positive cases and women with SD scores of 6 or above as negative cases, simultaneously maximized sensitivity (premenopausal: 70.0%, 70 out of 100 women with HSDD were correctly classified; postmenopausal: 82.4%, 14 out of 17 women with HSDD were correctly classified) and specificity (premenopausal: 87.6%, 177 of the 202 women without HSDD were correctly classified; postmenopausal: 62.1%, 18 of the 29 women without HSDD were correctly classified) in both subsets of women.

All four ROC curves provided similar results. Specifically, the use of a diagnostic cutpoint to classify women with SD scores of 5 or less on the SD domain as having HSDD and those with SD scores of 6 or more as not having HSDD maximized diagnostic sensitivity and specificity.

Validation of the Diagnostic Cutpoint

The cutpoint was validated in four separate studies and in a fifth analysis that combined all four studies. The age range was 18–68, with an average age of 41.3 years (standard deviation of 11.9 years). Approximately 59.1% were premenopausal, 15.0% perimenopausal, and the remaining 25.8% were postmenopausal. Menopause status was collected for 770 (86.3%) women, and the remaining women were categorized in the manner described above for the development sample. Of the 892

Table 1 Selected characteristics of women included in the sexual desire cutpoint development datasets

	Wiegel datasets				Brotto datasets				
	Study 1	Study 2	Study 3	Study 4	Study 1	Study 2	Study 3	Study 4	Total
Sample size in analysis dataset (*n*)	185	34	41	259	26	24	27	22	618
Diagnosis									
Sexually healthy controls (*n*)	86	17	16	131	2	0	2	0	254
HSDD only (*n*)	8	0	6	0	9	13	4	9	49
HSDD + other dysfunction (*n*)	49	4	7	0	12	10	15	13	110
Other (e.g., sexual pain disorder) (*n*)	42	13	12	128	3	1	6	0	205
Key variables									
Age									
Mean ± std. deviation	28.5 ± 8.7	30.8 ± 9.1	52.2 ± 10.2	40.1 ± 13.0	37.0 ± 9.8	55.0 ± 7.8	42.3 ± 12.2	49.4 ± 11.0	37.8 ± 13.5
Range	18–53	18–53	26–74	21–69	24–55	31–64	25–65	23–68	18–74
Menopausal status*									
Premenopausal (*n*)	170	30	25	174	19	4	18	8	448
Perimenopausal (*n*)	15	4	0	33	7	12	8	10	89
Postmenopausal (*n*)	0	0	16	52	0	8	1	4	81
FSFI sexual desire domain score (scaled, range 1.2–6)									Overall
(mean ± std. deviation)	4.08 ± 1.16	4.13 ± 1.19	2.85 ± 1.20	3.50 ± 1.37	2.15 ± 0.93	1.65 ± 0.85	2.00 ± 1.03	2.40 ± 0.89	3.43 ± 1.41
Sexually healthy controls (mean ± std. deviation)	4.63 ± 0.90	4.69 ± 0.74	3.15 ± 1.49	4.14 ± 1.13	2.10 ± 0.42	—	1.80 ± 0.85	—	4.24 ± 1.15
HSDD Only (mean ± std. deviation)	3.38 ± 0.71	—	2.60 ± 0.98	—	2.07 ± 1.28	1.80 ± 1.07	1.95 ± 0.57	2.67 ± 0.91	2.38 ± 1.10
HSDD + other dysfunction (mean ± std. deviation)	3.16 ± 0.98	4.35 ± 1.14	1.97 ± 0.75	—	2.10 ± 0.65	1.50 ± 0.51	2.00 ± 1.06	2.22 ± 0.86	2.59 ± 1.12
Other (mean ± std. deviation)	4.14 ± 1.21	3.32 ± 1.29	3.10 ± 0.84	2.83 ± 1.27	2.60 ± 1.25	1.20	2.10 ± 1.41	—	3.12 ± 1.35

*For datasets without information on menopausal status, women 45 or younger were assumed to be premenopausal, women aged 46–59 were assumed to be perimenopausal, and women 60 or older were assumed to be postmenopausal.
HSDD = hypoactive sexual desire disorder; FSFI = Female Sexual Function Index.

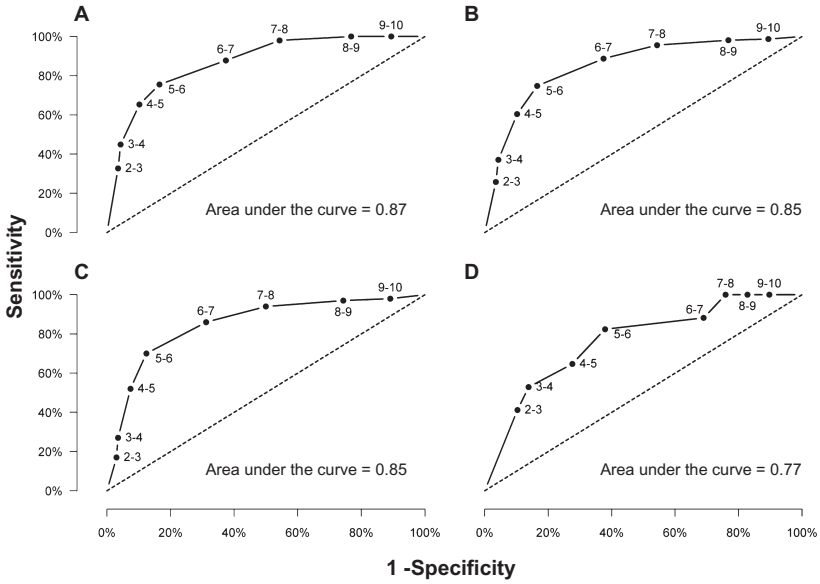

Figure 1 Receiver-operator characteristic (ROC) curves predicting hypoactive sexual desire disorder (HSDD) as a function of sexual desire (SD) domain scores (range: 2–10) comparing (A) women without sexual dysfunction (controls, $n = 254$) to women with HSDD only ($n = 49$), (B) women without sexual dysfunction (controls, $n = 254$) to HSDD women with or without other sexual dysfunctions ($n = 159$), (C) premenopausal women without sexual dysfunction (controls, $n = 202$) to premenopausal women with HSDD or HSDD and concomitant sexual dysfunction ($n = 100$), and (D) postmenopausal women without sexual dysfunction (controls, $n = 29$) to postmenopausal women with HSDD or HSDD and concomitant sexual dysfunction ($n = 17$). Each point in the figure is labeled by its corresponding cutpoint (for example, "5–6" means that women with a SD domain score of 5 or less was predicted to have HSDD and women with a SD domain score of 6 or greater was predicted to not have HSDD) and shows the sensitivity and 1-specificity of the cutpoint used to predict HSDD. A cutpoint between 5 and 6 (women with SD scores of 5 or less are considered to be positive cases, while women with SD scores of 6 or above are considered to be negative cases) simultaneously maximizes sensitivity and specificity in all four cases. The area under each curve has been calculated as a measure of accuracy.

participants, 454 participants had an HSDD diagnosis and 300 participants were sexually healthy controls; the remaining participants were diagnosed with sexual disorders other than HSDD. Characteristics of the four validation datasets, separately and combined, are given in Table 2.

The range of specificity across the five analyses was 90.3–97.1% (Table 3). The sensitivity range

Table 2 Selected characteristics of women included in the sexual desire cutpoint validation datasets

	Validation datasets				
	Study A	Study B	Study C	Study D	Overall
Total sample size (*n*)	90	248	258	296	892
Diagnosis					
Sexually healthy controls (*n*)	35	62	124	79	300
HSDD only (*n*)	31	112	118	145	406
HSDD + other dysfunction (*n*)	0	9	12	27	48
Other (e.g., sexual pain disorder) (*n*)	24	47	1	23	95
Missing (*n*)	0	18	3	22	43
Key variables					
Age					
Mean ± std. deviation	33.3 ± 12.0	46.2 ± 11.1	45.3 ± 11.7	36.3 ± 9.2	41.3 ± 11.9
Range	18–61	18–64	20–68	18–53	18–68
Menopausal status*					
Premenopausal (*n*)	75	98	129	226	528
Perimenopausal (*n*)	12	60	19	43	134
Postmenopausal (*n*)	3	90	110	27	230

*For datasets without information on menopausal status, women 45 or younger were assumed to be premenopausal, women aged 46–59 were assumed to be perimenopausal, and women 60 or older were assumed to be postmenopausal.
HSDD = hypoactive sexual desire disorder.

Table 3 Specificity and sensitivity of the SD domain cutpoint: development and validation samples

	N			Specificity (95% CI)	Sensitivity (95% CI)	
	Sexually healthy controls	HSDD only	HSDD with or without other sexual disorders	(%)	HSDD only (%)	HSDD with or without a concomitant condition (%)
Development sample	254	49	159	83.5 (78.3, 87.8)	75.5 (61.1, 86.7)	74.8 (67.4, 81.4)
Validation samples						
Study A	35	31	31	97.1 (85.1, 99.9)	96.8 (83.3, 99.9)	96.8 (83.3, 99.9)
Study B	62	112	121	90.3 (80.1, 96.4)	92.0 (85.3, 96.3)	90.1 (83.3, 94.8)
Study C	124	118	130	91.1 (84.7, 95.5)	87.3 (79.9, 92.7)	87.7 (80.8, 92.8)
Study D	79	145	172	93.7 (85.8, 97.9)	95.2 (90.3, 98.0)	94.8 (90.3, 97.6)
Studies A, B, C, and D	300	406	454	92.3 (88.7, 95.1)	92.1 (89.1, 94.5)	91.6 (88.7, 94.0)

HSDD = hypoactive sexual desire disorder; SD = sexual desire; CI = confidence interval.

for women with HSDD alone was 87.3–96.8%. The sensitivity range for women with HSDD and a concomitant condition related to sexual function was 87.7–96.8%. In all analyses, the specificity and sensitivity ratios were higher than in the development samples.

Discussion

Despite use of the FSFI in observational studies and clinical trials [9–11], and the recent recommendation for an abbreviated version of the FSFI [18], a diagnostic cutpoint has not previously been reported for differentiating SD differences between women with and without HSDD. Accordingly, we performed a series of analyses to develop and validate a diagnostic cutpoint for the SD domain to differentiate women with and without HSDD, as diagnosed by an independent clinician assessment. Since the SD domain consists of two items (the wording of the two questions and the response items, with their raw or unscaled scores, are contained in Table 4), one of which assesses frequency and the other intensity of desire, different combinations of scores are possible. Future applications of the cutpoint might include screening women for clinical trials, determining population estimates in representative samples of women, and assessing outcomes in clinical trials. Importantly, we have followed key methods and statistical procedures to validate this new psychometric tool [19].

In contrast to the FSFI total score, neither of the items in the SD domain are dependent on sexual intercourse or other forms of sexual activity for scoring. Thus, the SD domain cutpoint can be effectively used to assess low SD in women who are not currently sexually active. Since women with HSDD often report little or extremely infrequent sexual activity, and some report no sexual activity at all, these women are often excluded from randomized clinical trials, but may be included in other (e.g., sex therapy) studies, patients registries, or other large-scale observational studies. The ability to use the SD domain prospectively to assess SD in women who may not

Table 4 Sexual desire domain questions and response options

Over the past 4 weeks . . .	Response				
	1	2	3	4	5
Item 1. How often do you feel sexual desire or interest?	Almost never or never	A few times (less than half the time)	Sometimes (about half the time)	Most times (more than half the time)	Almost always or always
Item 2. How would you rate your level (degree) of sexual desire or interest?	Very low or none at all	Low	Moderate	High	Very high

be sexually active will be a useful addition in future studies generally.

It should be noted that we included women diagnosed with lifelong and acquired HSDD, some of whom had other sexual complaints or difficulties. In part, this is due to the fact that women with other sexual complaints frequently have lower SD scores than age-matched controls. For this reason, it would be important to identify a cutpoint within that distinguishes reliably between women whose sexual problems impacts their SD from women with sexual problems that do not impact their SD. This would be relevant information for the clinician who might be managing the symptoms, and who would be aware of concomitant SD problems in other groups of women. For clinical or research purposes, we strongly recommend that a measure of distress (e.g., Female Sexual Distress Scale [20]) be included in the clinical assessment of HSDD. This is an important limitation of the cutpoint. Another limitation involves the variability in desire within individual women and across women over time. Thus, as personal distress associated with low desire decreases markedly with age [21], an adjustment for age in the cutpoint scores might be necessary in some studies, depending on the specific design of the study.

To broaden the generalizability of our results, there was no age restriction on the samples studied, which included both pre- and postmenopausal women. We did not identify a separate perimenopausal group for analysis because of lack of reliable information across samples regarding presence or absence of menstrual periods, in addition to marked variability in sexual function generally within and across women during the menopausal transition [22,23]. The sample was also diverse in regard to the presence or absence of other sexual dysfunctions in the HSDD group. We did not include samples of women with other sexual dysfunctions alone because of small sample sizes, a lack of specific diagnostic information on some women in this group, and high variability across dysfunctions. This is another limitation of the study. Further studies are needed to assess the validity of the proposed new diagnostic cutpoint in women with a primary diagnosis of sexual arousal, pain, or orgasmic disorders.

While the use of multiple independent datasets from different investigators and the use of a large, well-characterized validation sample are strengths of this study, there are a number of potential limitations including the small sample size of women with only HSDD in the validation studies, lack of control for phase of the menstrual cycle, and different methodologies used in each study (time periods, subject populations, menopause status information). The lack of standardization of diagnostic interviews across centers is an important limitation of the study. The investigators reported having independent clinical assessments according to DSM-IV criteria, although the specific questions used and clinical decision-making process was not standardized from one center to another. Nonetheless, the data presented in this report provide strong evidence for the cutpoint selection and its stated purpose, viz., to differentiate women with and without HSDD, as its diagnostic accuracy was confirmed in the independent validation studies.

Conclusions

These analyses support the diagnostic accuracy of the SD domain for use in future observational studies and clinical trials of HSDD. A score of 5 or less on the combination of items comprising the SD domain is predictive of decreased SD in women regardless of menopausal status.

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