

# Criterion Validity of the Sexual Desire Domain of the Female Sexual Function Index (FSFI): Identifying a Diagnostic Cut-Point for Differentiating Women With and Without HSDD

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## ABSTRACT

**Objective** The Female Sexual Function Index (FSFI) is a widely used, self-administered questionnaire for assessing sexual function in women.<sup>1</sup> 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). Our objective was to develop a diagnostic cut-point for differentiating women with HSDD based on analysis of pooled datasets from multiple investigators.

**Materials and Methods** To establish a diagnostic cut-point for the SD domain, multiple datasets were obtained from independent clinical investigators at geographically diverse sites in the USA. Criteria for datasets included: (i) 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 age and/or menopausal status of the women; and (iv) complete FSFI data on all study subjects. A total of 8 datasets, including 159 women with HSDD and 254 non-dysfunctional controls, were included in this analysis.

**Results** Receiver operating curves were constructed based on combined datasets, and sensitivity and specificity analyses were performed on potential cut-points for each of the SD scale scores. These analyses yielded a diagnostic cut-point; SD  $\leq 5$  indicates HSDD and SD  $> 5$  indicates no HSDD. This cut-point has moderate sensitivity (74.8%) and high specificity (83.5%) for accurately classifying women with HSDD (with or without other dysfunctions), compared to healthy controls.

**Conclusions** These analyses support the diagnostic accuracy of the SD domain of the FSFI scale and use of a specific cut-point (SD  $\leq 5$ ) for differentiating women with HSDD from healthy controls.

## INTRODUCTION

- The Female Sexual Function Index (FSFI) is a widely used, self-administered questionnaire for assessing sexual function in women. It assesses sexual function in six major domains, including desire, arousal, orgasm, pain, and satisfaction.
- The sexual desire (SD) domain consists of two items assessing frequency and intensity of sexual desire.
- The SD domain provides a potential domain-specific assessment of diminished desire in women with Hypoactive Sexual Desire Disorder (HSDD).
- It can be scored independently of the FSFI total score, and has potential use as a cut-point for diagnostic or treatment outcome assessment.

## OBJECTIVES

- To develop and validate a cut-point for differentiating women with HSDD from non-HSDD controls.
- To differentiate women with HSDD with or without other sexual dysfunctions, based on analyses of pooled datasets from several investigators.

## METHODS

- Multiple datasets were obtained from four independent clinical investigators at geographically diverse sites in the USA (Meston, Brotto, Wiegel, Rosen).
- Criteria for inclusion were: (i) independent clinical diagnosis of HSDD status; (ii) assessment of other sexual dysfunctions; (iii) age and/or menopausal status of the women; and (iv) complete FSFI data.
- A total of 8 datasets, including 159 women with HSDD and 254 non-dysfunctional controls, met these criteria and were included in this analysis.
- A series of analyses were computed in which HSDD status was regressed on the SD domain score dichotomized at each of the possible values of the scale.
- ROC curves were plotted with sensitivity and 1-specificity for each analysis (Figures 1 and 2).

## RESULTS

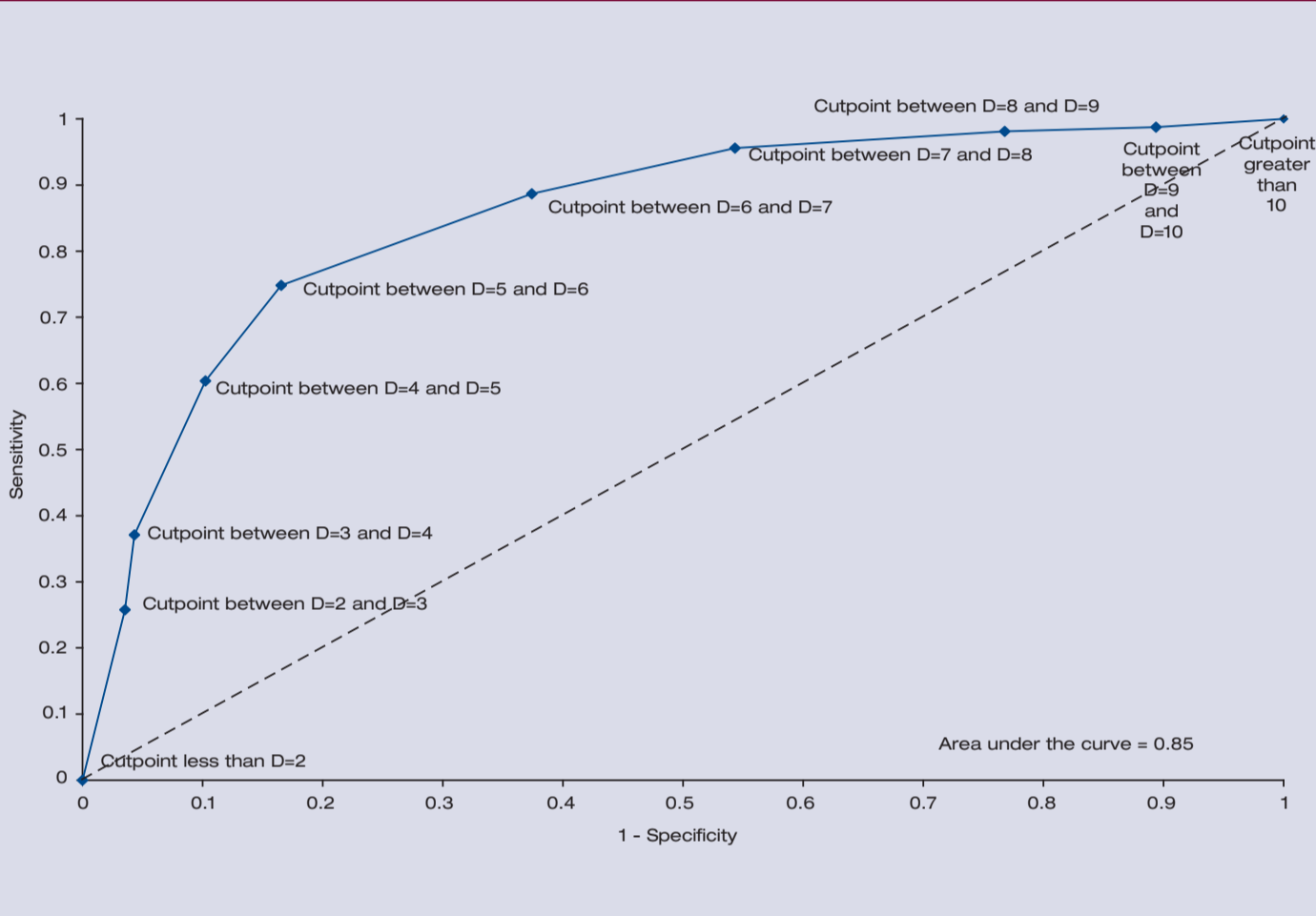
- ROC analyses were conducted separately on (Table 1):
  - Women without a diagnosis of Female Sexual Dysfunction (FSD) (healthy controls; n=254) vs. women with a diagnosis of HSDD and no other sexual dysfunction diagnosis (n=49).
  - Women without a diagnosis of FSD (n=254) vs. women with HSDD with/without a comorbid sexual dysfunction (n=159).
- Selection of a diagnostic cut-point of 5 or less on the SD domain maximized diagnostic sensitivity (i.e., the probability of correctly identifying women with HSDD) and specificity (i.e., the probability of correctly identifying cases without HSDD).
- Comparing women with HSDD to non-FSD controls (Figure 1), a cut-point between 5 and 6 simultaneously maximized sensitivity (74.8%, 119 out of 159 women with HSDD were correctly classified) and specificity (83.5%, 212 of 254 women without FSD were correctly classified as not having HSDD).
- Similarly, pre-menopausal women without sexual dysfunction were compared to age-matched controls with HSDD or HSDD and concomitant sexual dysfunction (n=100). A cut-point between 5 and 6 again simultaneously maximized sensitivity (70.0%, 70 out of 100 women with HSDD were correctly classified) and specificity (87.6%, 177 of the 202 women without FSD were correctly classified (See Figure 2).
- A similar cut-point of between 5 and 6 differentiated between post-menopausal women with and without HSDD (data not shown).
- Results obtained were highly consistent across each of the samples examined.

**Table 1. Diagnostic Accuracy of the Sexual Desire (SD) Domain Score**

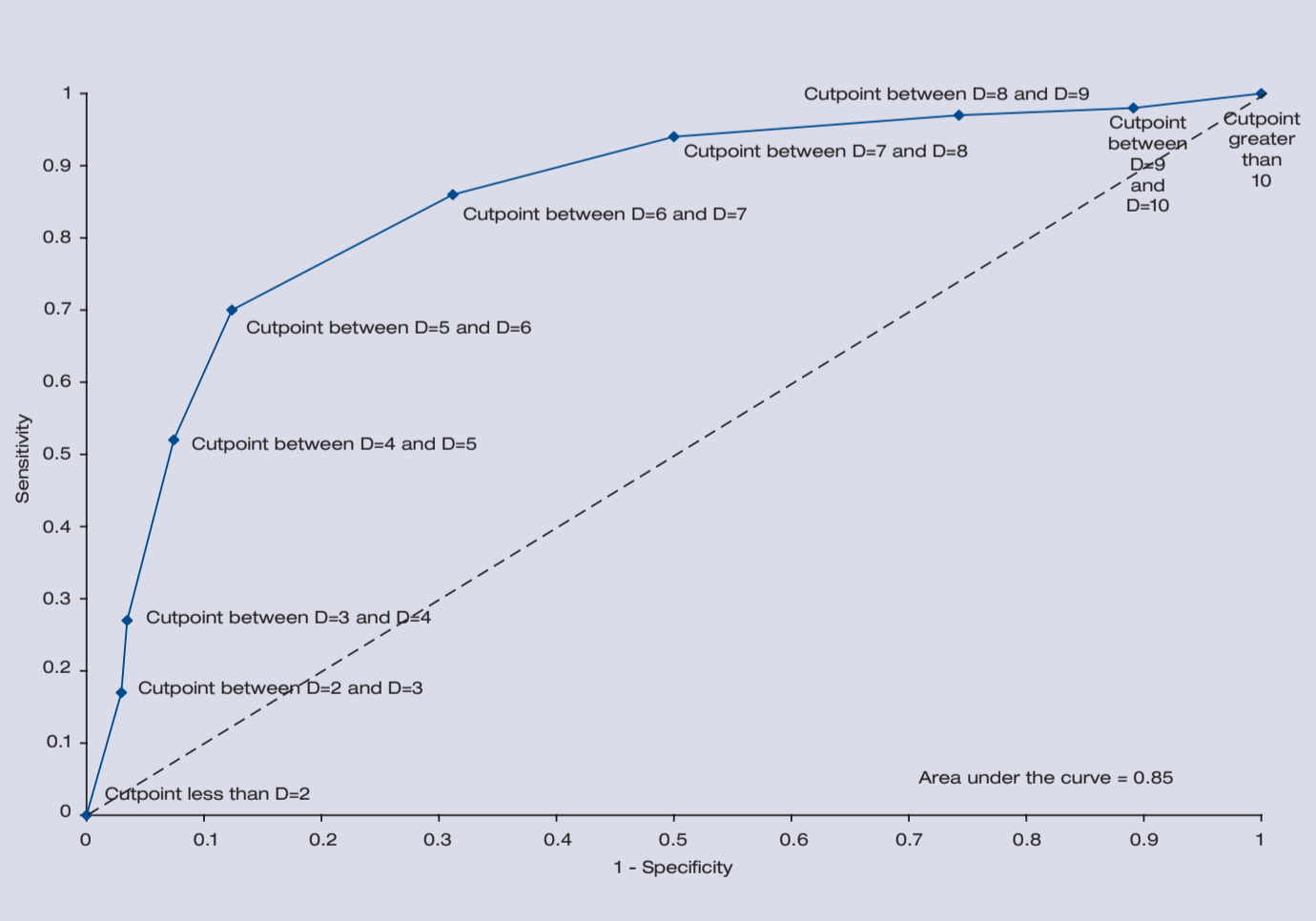
SD domain cut-point	Controls (n=254) vs. women with HSDD without other sexual disorder (n=49)		Controls (n=254) vs. women with HSDD with or without other sexual disorder (n=159)		Pre-menopausal controls (n=202) vs. pre-menopausal women with HSDD with or without other disorders (n=100).	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
$\leq 2$	32.7%	96.5%	25.8%	96.5%	17.0%	97.0%
$\leq 3$	44.9%	95.7%	37.1%	95.7%	27.0%	96.5%
$\leq 4$	65.3%	89.8%	60.4%	89.8%	52.0%	92.6%
$\leq 5$	75.5%	83.5%	74.8%	83.5%	70.0%	87.6%
$\leq 6$	87.8%	62.6%	88.7%	62.6%	86.0%	68.8%
$\leq 7$	98.0%	45.7%	95.6%	45.7%	94.0%	50.0%
$\leq 8$	100.0%	23.2%	98.1%	23.2%	97.0%	25.7%
$\leq 9$	100.0%	10.6%	98.7%	10.6%	98.0%	10.9%
$\leq 10$	100.0%	0.0%	100.0%	0.0%	100.0%	0.0%

Note: Shaded line denotes cut-point. A cut-point of  $\leq 5$  provides optimal sensitivity and specificity across independent samples of pre- or post-menopausal women diagnosed with HSDD, with or without other sexual disorders

**Figure 1. ROC curve predicting HSDD as a function of SD domain scores comparing women without sexual dysfunction (controls, n=254) to HSDD women with or without other sexual dysfunctions (n=159)**



**Figure 2. ROC curve predicting HSDD as a function of SD domain scores comparing pre-menopausal women without sexual dysfunction (controls, n=202) to pre-menopausal women with HSDD or HSDD and concomitant sexual dysfunction (n=100)**



## CONCLUSIONS

- 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.
- Results have been replicated across independent datasets made available by the sponsor.
- 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.

## REFERENCES

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