Intended or Unintended Consequences? The Likely Implications of Raising the Bar for Sexual Dysfunction Diagnosis in the Proposed DSM-V Revisions: 2. For Women with Loss of Subjective Sexual Arousal

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ABSTRACT

Introduction. Brotto proposes to combine female sexual desire and arousal disorders in the Diagnostic and Statistical Manual of Mental Disorders, fifth edition.

Aim. We provide evidence that the proposed criteria could potentially exclude from diagnosis or treatment a large number of women with distressing dysfunction in sexual arousal.

Methods. Rating scale data from nontreatment validation studies of patient-reported outcome measures including almost 500 women in North America and Europe, including 49 women diagnosed with arousal disorder only, were compared with the proposed criteria.

Main Outcome Measures. The main measures were an early version of the eDiary (an electronic diary on sexual activity) and four previously validated measures of female sexual dysfunction (FSD), the clinician-rated Sexual Interest and Desire Inventory—Female and the self-rated Female Sexual Function Index, Changes in Sexual Functioning Questionnaire, and Female Sexual Distress Scale.

Results. The women with female sexual arousal disorder (FSAD) scored as manifestly sexually dysfunctional and significantly sexually distressed. They had fewer satisfying sexual events (SSEs) vs. women with no FSD, with a lower proportion of SSEs, and significantly fewer orgasms.

Conclusion. Despite evidence presented that women with FSAD have clinically disordered sexual function, our data also suggest that the majority of these women with FSAD would meet none of the six proposed "A" criteria for Sexual Interest/Arousal Disorder, raising new validity and utility concerns for the proposed diagnostic classification. Suggestions are made to modify the proposed new criteria so as to include such distressed women. **Clayton AH, DeRogatis LR, Rosen RC, and Pyke R. Intended or unintended consequences? The likely implications of raising the bar for sexual dysfunction diagnosis in the proposed DSM-V revisions: 2. for women with loss of subjective sexual arousal. J Sex Med 2012;9:2040–2046.**

Key Words. Sexual Dysfunction; HSDD; FSAD

Introduction

Brotto [1] has critiqued the existing *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition, text revision (DSM-IV-TR) [2] criteria for hypoactive sexual desire disorder (HSDD) and recommended that female sexual desire and arousal disorders be combined into one taxonomic category in the forthcoming revision (DSM, fifth edition [DSM-V]). In a previous letter [3] and a companion article [4], we provided evidence that premenopausal women with HSDD and women with female sexual arousal disorder (FSAD) according to DSM-IV-TR criteria have distinct symptom patterns and that the majority of premenopausal women with HSDD are unlikely to

meet the proposed new criteria for Sexual Interest/Arousal Disorder (SI/AD), though equally distressed by their disorder (based on Female Sexual Distress Scale [FSDS]-Revised scores).

Here, we provide additional data to suggest that the new criteria proposed by Brotto would potentially exclude large numbers of women from diagnosis or treatment if they have FSAD.

Basson et al. criticized the DSM-IV diagnosis of FSAD—requiring absent or impaired genital congestion and lubrication—because "women diagnosed with sexual arousal disorder usually show a normal vasocongestive response in the genitalia in response to erotic sexual stimulation, when tested in a controlled laboratory environment. Thus, it is this women's lack of subjective arousal that is key to their distress rather than failure of genital congestion." [5] Criticism of the diagnosis of FSAD has also focused on the artificiality of diagnosing arousal disorder on the basis of genital changes alone when subjective sensations of arousal are usually also impaired [6,7]. Proposed criterion *A6*, *Absent/reduced frequency or intensity of genital and/or nongenital sensations during sexual activity* would require such impairment in "all or almost all" (approximately 75%) of sexual encounters. Thus, we investigated subjective feelings of arousal in our sample of women with FSAD, comparing the Female Sexual Function Index (FSFI) arousal domain to the FSFI lubrication domain.

Methods

Study Design, Subjects

Both studies were 4-week prospective multicenter trials designed to assess the reliability and validity of the Sexual Interest and Desire Inventory—Female (SIDI-F) in assessing the severity of HSDD symptoms, as previously described [4,8].

Assessments

Four measures of sexual dysfunction were utilized. One was the 13-item clinician-rated SIDI-F, a scale created to measure each of the dimensions of female HSDD found most relevant by experienced clinicians, using a 1-month recall [9]. The other three measures of sexual dysfunction were self-rated and had been extensively validated previously: the FSFI [10], the Changes in Sexual Functioning Questionnaire—Female (CSFQ-F [11]), and the FSDS [12].

Of the 13-item clinician-rated SIDI-F, six items were used to investigate the applicability of the first five proposed "A" criteria of Brotto. *A1*, *Absent/reduced frequency or intensity of interest in sexual activity:* "Desire—frequency" asks frequency and intensity of desire for sexual activity; *A2*, *Absent/reduced frequency or intensity of sexual/erotic thoughts or fantasies:* "Thoughts—Positive" asks how often a woman has thought about sex; *A3*, *Absence or reduced frequency of initiation of sexual activity and is typically unreceptive to a partner's attempts to initiate:* "Initiations" asks whether a woman did anything to initiate sexual activity with her partner over the prior month; "Receptivity" asks how often and with what level of interest she responded; *A4*, *Absent/reduced frequency or intensity of sexual excitement/pleasure during sexual activity on all or almost all (approximately 75% of sexual encounters):* "Arousal—Frequency" asks frequency of sexual excitement during sexual activity over the prior month, to be answered (0) not at all, (1) infrequent (<1/2 the time), (2) often (half the time or more), or (3) always; *A5*, *Sexual interest/arousal is absent or infrequently elicited by any sexual/erotic cues (written, verbal, visual, etc.):* "Erotica" asks "Over the past month, how did you react to sexually suggestive material (e.g., love scenes in movies and on television, erotic pictures/stories in magazines/books)?"

The relevant items of the self-rating scales (FSFI, CSFQ-F, and FSDS) were also used to investigate the applicability of the proposed "A" criteria, regarding proposed criterion A4 about sexual pleasure. The CSFQ Pleasure item asks intensity of pleasure, "How enjoyable or pleasurable is your sex life right now?," to be answered (1) no, (2) little, (3) some, (4) much, and (5) great enjoyment or pleasure. RE proposed criterion *A6*, *Absent/reduced frequency or intensity of genital and/or nongenital sensations during sexual activity on all or almost all (approximately 75% of sexual encounters)*; "genital and/or nongenital sensations during sexual activity" appears to overlap with criterion A4's focus on "sexual excitement." Thus, to investigate the applicability of this criterion as a differentiable construct, *genital* changes during sexual activity were evaluated using the FSFI lubrication domain. Its four items, on frequency and difficulty of becoming lubricated, and frequency of and difficulty of lubrication maintenance, follow four items explicitly reflective of genital sexual excitement and are thus sharply contrasted. (The SIDI has no directly applicable items; the CSFQ's only applicable item asks only how often vaginal lubrication was "adequate.") To test the applicability of proposed criterion A6 and to focus on whether

diagnosing arousal disorder on the basis of genital changes alone is artificial because subjective sensations of arousal are usually also impaired [6,7], we investigated subjective feelings of arousal in our sample of women with FSAD by comparing the FSFI arousal domain to the FSFI lubrication domain.

Statistical Analysis

All results are based on prespecified analyses; no post hoc analyses were performed for this article. The sample size calculations and statistical methods are outlined elsewhere [4,8].

Results

Study Subjects

The demographics of the volunteers are set forth elsewhere [8]. In the North American sample, 49 women were diagnosed with FSAD only and 61 with no female sexual dysfunction (FSD). Close similarity was found between the two groups in race, age, marital/relational status, and menopausal status [8]. As the companion article's table 1 [4] shows, we found that women with primary FSAD (by DSM-IV-TR criteria), compared at baseline with women volunteers with no sexual complaints, were manifestly sexually dysfunctional as assessed by the FSFI total score (means 19.7 vs. 31.4, respectively) and the CSFQ-F total score (means 41.8 vs. 55.5, respectively) and were significantly distressed by their sexual complaint as assessed by the FSDS score (means 25.0 vs. 4.7, respectively; foregoing P values < 0.0001; all P values cited for rating scale comparisons were from analysis of covariance (ANCOVA) using age group and center as covariates).

Collection of sexual event information by electronic diary for 28 days following baseline assessment showed using the Wilcoxon rank-sum test stratified by age group and center that the women with FSAD were also impaired regarding their sexual behavior, with fewer satisfying sexual events (SSEs) (median 3.6 vs. 7.2 for women with no FSD, $P < 0.0001$). Though women with FSAD did not have fewer sexual events overall, their proportion of *satisfying* events was lower, means 58.2% vs. 92.2%, respectively (difference not tested statistically). Their reported number of orgasms was also lower, medians 3.3 vs. 4.8, respectively ($P = 0.0004$).

Few volunteers screened were excluded (10.1%), and mean (standard deviation [SD]) baseline scores for the FSAD group, 26.7 (8.4) on the SIDI-F, fell below the cutoff of 33, values above which indicate no sexual dysfunction [13] and were well below those for the control women with no FSD, 42.1 (5.2) (significant at $P < 0.0001$). These data show that the women with FSAD had not been artificially selected for pure arousal problems.

However, we find from our North American study that women with FSAD are unlikely to meet any of the proposed new criteria for SI/AD (Table 1). *A1, Absent/reduced frequency or intensity of interest in sexual activity.* On the SIDI-F Desire—Frequency item, women with FSAD scored significantly lower ($P < 0.0001$) than women with no FSD, but their lower quartile (Q1), median, and upper quartile (Q3) scores showed that at least half of the women with FSAD would not separate from at least 25% of women with no FSD (Figure 1). Moreover, the median score of 3 for FSAD women corresponds to moderate desire for sex at least three to four times per month, suggesting only a modest deficiency, if any, in interest in sexual activity.

A2, Absent/reduced frequency or intensity of sexual/erotic thoughts or fantasies. On the SIDI-F Thoughts—Positive item, women with FSAD scored significantly lower ($P = 0.002$) than women with no FSD, but their Q1, median, and Q3 scores revealed that at least half of the group of women with FSAD would not separate from at least 25% of women in the study with no FSD (Figure 1). Moreover, the median score of 3 for FSAD women corresponds to "moderately positive thoughts about sex" at least three to four times per month, suggesting only a modest deficiency, if any, in interest in sexual activity.

A3, Absence or reduced frequency of initiation of sexual activity and is typically unreceptive to a partner's attempts to initiate. On the SIDI Initiation item, women with FSAD scored significantly lower than women with no FSD ($P < 0.0001$), although their Q1, median, and Q3 scores indicated that at least half of the women with FSAD would not separate from a quarter or more of the women with no FSD (Figure 1). The median score of 1 for FSAD women corresponds to subtle, indirect encouragement of partnered sexual activity one to two times per month. The median for women with no FSD (2) corresponds to similar encouragement three to four times a month or active initiation one to two times per month. This at least on the surface appears to show that initiation of partnered sexual activity is relatively subtle and infrequent even in women with no sexual complaints or sexual disorder, thus militating against its use as an explicit criterion for SI/AD.

Table 1 Baseline rating scale scores relevant to Proposed DSM-V Sexual Interest/Arousal Disorder in women with DSM-IV-TR FSAD or no sexual dysfunction in the North American study.

Proposed criteria, set A (condensed)	Measure	Range		FSAD (N = 49)	No FSD (N = 61)	*P* value, FSAD vs. no FSD	95% CI
1. Absent/reduced interest in sexual activity	SIDI-F Desire—Frequency item	0–5	Mean	2.8	3.9	<0.0001	−1.5, −0.6
			Std.Dev.	1.4	1.0		
			Q1	2	3		
			Median	3	4		
			Q3	4	4		
2. Absent/reduced sexual/erotic thoughts or fantasies	SIDI-F Thoughts—Positive item		Mean	3.2	3.9	0.002	−1.1, −0.3
			Std.Dev.	1.2	0.8		
			Q1	3	3		
			Median	3	4		
			Q3	4	4		
3. Absent/reduced frequency of initiation of sexual activity and is typically unreceptive to a partner's attempts to initiate	SIDI-F Initiation item	0–5	Mean	1.1	1.8	<0.0001	−1.1, −0.4
			Std.Dev.	1.1	1.0		
			Q1	0	1		
			Median	1	2		
			Q3	2	3		
	SIDI-F Receptivity item	0–5	Mean	2.5	4.1	<0.0001	−2.1, −1.1
			Std.Dev.	1.6	1.0		
			Q1	1	4		
			Median	2	4		
			Q3	3	5		
4. Absent/reduced sexual excitement/pleasure during sexual activity (≥75% of sexual encounters)	SIDI-F Arousal—Frequency item	0–3	Mean	1.3	2.7	<0.0001	−1.6, −1.0
			Std.Dev.	0.8	0.5		
			Q1	1	2		
			Median	1	3		
			Q3	2	3		
	CSFQ-F Pleasure subscale	1–5	Mean	2.6	4.1	<0.0001	−1.8, −1.2
			Std.Dev.	1.0	0.8		
5. Interest/arousal is absent/infrequently elicited by any sexual/erotic cues*	SIDI-F Erotica item	0–4	Mean	1.4	1.8	0.0966	−0.7, 0.1
			Std.Dev.	0.9	1.1		
			Q1	1	1		
			Median	2	2		
			Q3	2	3		
6. Absent/reduced genital and/or nongenital sensations during sexual activity (≥75% of sexual encounters)	FSFI Lubrication domain	0–6	Mean	3.0	5.4	<0.0001	−2.9, −1.7
			Std.Dev.	1.6	1.0		
	FSFI Arousal domain	0–6	Mean	2.8	5.2	<0.0001	−2.8, −1.8
			Std.Dev.	1.3	0.8		

*For the 113 women with HSDD, on the Erotica item the mean (SD) was 0.8 (0.9), and the Q1, median, and Q3 scores were 0, 1, and 1, respectively.
CI = confidence interval; CSFQ-F = Changes in Sexual Functioning Questionnaire—Female; DSM-IV-TR = Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision; DSM-V = Diagnostic and Statistical Manual of Mental Disorders, fifth edition; FSAD = female sexual arousal disorder; FSD = female sexual dysfunction; FSFI = Female Sexual Function Index; HSDD = hypoactive sexual desire disorder; SIDI-F = Sexual Interest and Desire Inventory—Female; Std.Dev. = standard deviation

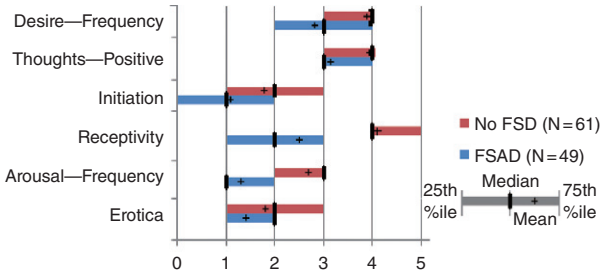

Figure 1 Baseline SIDI-F scores relevant to Proposed DSM-V Sexual Interest/Arousal Disorder in women with DSM-IV-TR FSAD or no sexual dysfunction in a nontreatment study. DSM-IV-TR = Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision; DSM-V = Diagnostic and Statistical Manual of Mental Disorders, fifth edition; FSAD = female sexual arousal disorder; FSD = female sexual dysfunction; SIDI-F = Sexual Interest and Desire Inventory—Female

The women with FSAD were, however, deficient in receptivity. The SIDI Receptivity item showed that women with FSAD were much less receptive than women without FSD ($P < 0.0001$), and the Q1, median, and Q3 scores did not overlap with their no FSD counterparts (Figure 1). If the proposed criterion required only deficient receptivity, these women with FSAD would qualify, but not if the criteria continue to require deficient receptivity *and* initiations. Thus, a criterion based on receptivity seems reasonable, at least for North American women, whereas one based on initiations does not.

A4, Absent/reduced frequency or intensity of sexual excitement/pleasure during sexual activity (≥75% of sexual encounters). On the SIDI-F Arousal—Frequency item and the CSFQ Pleasure item, women with FSAD, compared with women with no FSD, had markedly lower scores ($P < 0.0001$ for each). However, as noted above, 58% of sexual encounters were rated as satisfying; thus, most women with FSAD in this study would not qualify for this criterion in terms of the proportion of SSEs. If the diagnosis of SI/AD required instead an Arousal—Frequency score of "infrequent (<1/2 the time)" or "not at all," over half of these FSAD patients might qualify, i.e., their lowest quartile score was 1, their median score was 1, and their third quartile score was 2 (Figure 1). For women with no FSD, Q1, median, and Q3 scores were 2, 3, and 3, respectively.

A5, Sexual interest/arousal is absent or infrequently elicited by any internal or external sexual/erotic cues. On the SIDI-F Erotica item, women with FSAD scored similarly to women with no FSD (Table 1 and Figure 1). Thus, the women with FSAD would not qualify for this proposed criterion, even if the SIDI-F item does not predict response to all sexual/erotic stimuli, because the criterion requires nonresponse to *any* sexual/erotic cues.

The sensitivity of these SIDI items to identify women with dysfunction reflected in each of the above-mentioned factors, e.g., disinterest in erotica, was verified by comparing the study's sample of 113 women with HSDD to those with no FSD. Not only was each difference highly significant ($P < 0.0001$), but the overlap of the Q1–Q3 distributions between women with HSDD and with no FSD on each item was nil or minimal. For example, for Erotica, comparing women with HSDD to women with no FSD, means (SD) were 0.8 (0.9) vs. 1.8 (1.1), and Q1/median/Q3 values were 0/1/1 (i.e., at least 75% of the women with HSDD either "actively avoided" or were "uninterested" in the sexually suggestive material they saw on TV and in movies, magazines, etc.) vs. 1/2/3.

A6, Absent/reduced frequency or intensity of genital and/or nongenital sensations during sexual activity (≥75% of sexual encounters). On the FSFI lubrication domain, women with FSAD scored significantly lower than women with no FSD ($P < 0.00001$). Their mean score of 3.0 corresponds to rating oneself at 3 on two items and at 2 on the other two items (becoming lubricated about half the time or almost never, finding it "difficult" or "very difficult" to become lubricated, maintaining lubrication about half the time or almost never, and finding it "difficult" "or very difficult" to maintain lubrication). Thus, most of the study subjects with FSAD might qualify for this proposed criterion, perhaps if it were simplified to cover genital changes only, although the criterion would also need to be modified to require difficulties about half the time instead of at least 75% of the time or on all or almost all sexual encounters.

Impairment in women with FSAD on the FSFI arousal domain was similar to that in the lubrication domain (Table 1), verifying that impairment of genital lubrication and subjective arousal interrelate closely in women with FSAD. Such impairments are specific to FSAD in comparison with women with HSDD [3]. This information appears to have some relevance to proposed criterion A4, Absent/reduced sexual excitement/pleasure during sexual activity (≥75% of sexual encounters), but, as for the SIDI-F item on Arousal—Frequency (see above), no answer option is available that corresponds to 75% of sexual encounters. However, if a criterion required impairment about half the time or almost never, they would have met it.

Discussion

The women with FSAD in our sample were manifestly sexually dysfunctional as assessed by the FSFI total score and the CSFQ-F total score and were significantly distressed by their sexual complaint as assessed by the FSDS score. They reported significantly fewer SSEs vs. women with no FSD, a lower proportion of SSEs, and significantly fewer orgasms. These findings provide consistent and compelling evidence that women with FSAD have clinically disordered sexual function.

Yet our data also indicate that the majority of these women with FSAD would meet none of the six proposed "A" criteria for SI/AD, though they showed evidence of impairment relative to normal controls in each proposed criterion.

These results raise validity and utility concerns for the proposed diagnostic classification, which may result inadvertently in a lack of access to care for a potentially large group of women. In PRESIDE, the largest U.S. epidemiologic study of sexual problems in women to date, over 5% of women age 18–64 had a loss of arousal associated with significant distress [14]. To deny women in this group the current diagnosis is a potential step backwards from the perspective of access to care for women with sexual dysfunction generally and sexual arousal disorder in particular.

The proposed new criteria could be modified to include such distressed women. Criteria A1, A2, and A5 appear, both logically and by our study results, not to apply to most women with FSAD alone. However, criterion A3, if limited to lack of receptivity alone, would apply to the majority of our subjects with DSM-IV FSAD. Criterion A4, if modified to require sexual excitement less than half the time instead of being absent or reduced at least three quarters of the time, would also apply. Criterion A6, if limited to genital sexual sensations only and required absent/reduced genital sensations at least half of the time instead of three quarters of the time, would also apply.

The number of criteria proposed to qualify for the diagnosis was recently reduced from four to three [15]. This would be necessary to be applicable to our subjects with FSAD, and other potential shortcomings would need to be addressed. For example, reducing the number of required criteria to three would reduce the specificity of the diagnosis: if a woman's problem is lack of arousal only or (as we showed previously) lack of desire only, then research conducted on such women in aggregate would lack sufficient focus for heuristics or development of new therapies.

Brotto et al. [16] suggested that our findings are unrepresentative of the close relationship they find between desire and arousal. We had cited relatively low correlations between FSFI desire and arousal domains ($r = 0.30$ for women with HSDD and $r = 0.57$ for women with FSAD). They cited r-values between 0.5 and 0.76 in other publications. Taken at face value, these values seem sufficiently large to suggest a close relation between desire and arousal problems in these women; possibly that low desire in some cases may lead to arousal difficulties, or vice versa, or that some common diathesis may produce both, but they certainly are not high enough to suggest identity, i.e., that arousal and desire problems are one and the same. This is particularly the case when one considers the fact that the percentage of shared variation between the two is given by the squares of their correlation coefficients: i.e., 25% and 58%, respectively. Moderate correlations such as these do not imply identity of the underlying constructs. This is a key element of our rejoinder based on results of multiple studies including those cited above.

As we noted in our prior letter, caution should always be exercised when considering fundamental changes to medical or psychiatric nomenclatures. Any such changes should be based on confirmed data—preferably from multiple clinical trials or large observational studies. We recommend that the proposed questionnaire set to be studied in diagnostic field trials in preparation for DSM-V, and add the modifications suggested here, because they appear relevant to provide clear-cut evidence that will be applicable to real-world patients and thus determine whether diagnostic criteria should be changed.

In summary, regarding the applicability of the diagnosis of FSAD, we contend that there is compelling evidence of syndrome specificity in affected women, yet the proposed criteria for SI/AD would potentially exclude such women from diagnosis or treatment. Such an omission appears as problematic as the exclusion of significant numbers of women who currently meet criteria for HSDD, as treatments for FSAD are Food and Drug Administration approved and available in the United States (estrogen, Eros® device, etc.).

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