Arch Sex Behav
DOI 10.1007/s10508-010-9706-0

LETTER TO THE EDITOR

Should Sexual Desire and Arousal Disorders in Women Be Merged? A Response to DeRogatis, Clayton, Rosen, Sand, and Pyke (2010)

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We are grateful for the opportunity to reply to the Letter to the Editor entitled "Should Sexual Desire and Arousal Disorders in Women Be Merged?" by DeRogatis, Clayton, Rosen, Sand, and Pyke (2010). Considerable debate has emerged since the publication of our proposed revisions for Hypoactive Sexual Desire Disorder (HSDD) and Female Sexual Arousal Disorder (FSAD) for the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) (Brotto, 2010; Graham, 2010). Published commentaries and our response (Binik, Brotto, Graham, & Segraves, 2010) appeared in a recent issue of the *Journal of Sexual Medicine*.

At the outset, we wish to respond to a statement made by DeRogatis et al. regarding the basis for our proposed revisions. DeRogatis et al. argued that fundamental changes to psychiatric nomenclature "…should be based on confirmed data—preferably from multiple clinical trials or observational studies—rather than on theoretical speculations or expert opinion, as in the current proposal." The published guidelines for making changes to DSM-5 (Kendler, Kupfer, Narrow, Phillips, & Fawcett, 2009) clearly state that recommendations should be guided by research evidence but that, unlike DSM-IV, "there will be no a priori constraints on the degree of change between DSM-IV and DSM-V." There is simply no justification for asserting that the proposal for Sexual Interest/Arousal Disorder was based on "theoretical speculations or expert opinion." Comprehensive and critical reviews of the empirical literature were undertaken (Brotto, 2010; Graham, 2010) and these formed the basis for the proposals. It should also be noted that the DSM-IV-TR diagnoses of HSDD and FSAD were not based on any systematically collected body of data. The diagnosis of HSDD was the result of the expert opinion of Helen Singer Kaplan and Harold Lief: FSAD appears to have initially resulted from the early theorizing concerning the human sexual response cycle by Masters and Johnson and was probably saved from extinction by the hope that PDE-5 inhibitors would be effective for women.

In their letter, DeRogatis et al. reported on data from two non-treatment studies funded by Boehringer Ingelheim (BI). In one study, women with primary HSDD and primary FSAD ($n = 143$) differed significantly from each other in terms of symptom profile. The women with HSDD had better sexual functioning, as measured by the Female Sexual Function Index (FSFI), compared to women with FSAD (total mean FSFI scores of 23.7 and 20.2, respectively). On the basis of these two groups showing "different symptom profiles," DeRogatis et al. argued that the diagnostic categories of HSDD and FSAD should not be merged in DSM-5.

We believe that DeRogatis et al.'s findings of distinct symptom patterns among women with HSDD and those with FSAD are due to how the samples were recruited. As women were diagnosed using DSM-IV criteria (which separate deficient or absent desire for sex [HSDD] from impaired lubrication [FSAD], one would expect different symptom profiles in

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Published online: 17 December 2010

these two groups. Furthermore, while this finding indicates that the measure they used was reliable, it does not provide evidence for the validity of the constructs of HSDD and FSAD. In the second study, involving women with HSDD without concomitant FSAD, DeRogatis et al. noted that the mean FSFI Arousal and Lubrication scores were 2.96 and 4.15, respectively, and commented "Thus, these women were unlikely to meet criterion A6 for the proposed Sexual Interest/Arousal Disorder (absent/reduced genital and/or non-genital physical changes during sexual activity on >75% of sexual encounters)." Again, because their sample was recruited on the basis of having HSDD and not having concomitant FSAD, it is not surprising that lubrication scores were in the normal range. In our view, this does not support their position to retain desire and arousal as separate diagnostic categories.

We have some concerns about how representative these samples were of women with low desire who seek treatment. First, the FSFI total score for the sample of women with HSDD was 23.7, which is higher than the mean FSFI total score for women with HSDD reported by other investigators (see Table 1). Because women in these trials had better overall sexual functioning, this suggests that their scores in the non-HSDD domains were high/normal (since the total score is calculated by summing each of the domain scores). In other words, their sample of women likely reported sexual difficulties only in the desire domain, and not in arousal, lubrication, orgasm, pain, or satisfaction. Our clinical experience, as well as studies of clinical samples (Bancroft, Graham, & McCord, 2001; Basson et al., 2000), suggests that women with low desire often present with difficulties in most or all areas of their sexual functioning. Basing conclusions about whether desire and arousal should be merged using findings from this non-representative sample is, in our view, problematic.

Further concerns about the representativeness of these BI samples arise when considering the frequency of sexual activity reported by the women with HSDD. According to DeRogatis et al., "women with HSDD had significantly fewer sexual events (defined as sexual intercourse, oral sex, partner-initiated or self masturbation) per month than those with FSAD (4.45 in the HSDD group vs. 7.73 in the FSAD group). The fact that the mean number of sexual events reported by the HSDD group was 4.45 per month (approximately once a week) raises questions about the inclusion criteria used to recruit women with HSDD. It is not uncommon in clinical situations for women seeking treatment for HSDD to have only a few sexual episodes per year, and achieving 4.45 per month would typically be considered an excellent treatment outcome. Because DeRogatis et al. cited only a conference presentation, and not a peer-reviewed article, details about the recruitment strategy and inclusion criteria for this trial are unavailable.

An additional concern about their sample relates to the HSDD group reporting that 73% of sexual events in the previous 4 weeks had been "satisfying." If 73% of sexual events experienced by these women were satisfying, we are unsure how they would have met criteria for HSDD, given that DSM-IV-TR criteria require the presence of marked distress or interpersonal difficulty. Similarly, in DeRogatis et al.'s analysis of baseline data from three BI-funded clinical trials of flibanserin

Table 1 FSFI total scores from recent studies of women with low desire

Study	FSFI total scores for women diagnosed with HSDD
Meston (2003)	19.70 ($SD = 4.25$); ($n = 44$)
Clayton et al. (2006)	21.3 ($SD = 4.2$); ($n = 31$)
McCall and Meston (2007)	Pre-menopausal "low sexual desire" women ($n = 30$): FSFI total: 19.41 (4.81)[a]
	Post-menopausal "low sexual desire"* women ($n = 39$): FSFI total: 16.55 (7.64)
Brotto, Basson, and Luria (2008)	17.2 (at pre-treatment before a mindfulness-based cognitive behavioral intervention); ($n = 26$)
Carter et al. (2010)	FSFI total for women with cervical cancer prior to radical hysterectomy: 15.72 (2.3); ($n = 26$) and prior to radical trachelectomy: 17.43 (1.79); ($n = 43$)
Clayton et al. (2010)	21.6 ± 6.5; ($n = 113$): In North American Study
	20.4 ± 7.4; ($n = 126$): In European Study
Nappi et al. (2010)	Women in various stages of menopausal transition:
	Early perimenopause (>7 days different from normal, $n = 33$): 26.4
	Late perimenopause (≥60 days interval of amenorrhea) LMT, $n = 40$: 21.9
	Late peri/early post-(amenorrhea for at least 12 months and ≤4 years, $n = 65$): 22.8
Yaylali, Tekekoglu, and Akin (2010)	FSFI Total: 22.1 ± 4.3 (n = 45)
	Women were recruited on the basis of being overweight/obese, not on the basis of having a sexual difficulty

[a] These women did not have a diagnosis of HSDD. Women were assigned to the "low desire" group if their score on the Sexual Desire (SD) domain of the FSFI was within the range of women with HSDD (of the SD) as established by Rosen et al. (2000). McCall and Meston cited this reference as indicating a score of <3 indicated low sexual desire

Table 2 Correlations between FSFI Desire and FSFI Arousal domains

Study	*r*
Rosen et al. (2000)	0.76
Wiegel, Meston, and Rosen (2005)	Women with sexual dysfunction: 0.75 Sexually functional women: 0.65
Nobre, Pinto-Gouveia, and Gomes (2006)	0.69
Ter Kuile, Brauer, and Laan (2006)	0.73
Sidi, Abdullah, Puteh, and Midin (2007)	0.85
Brauer, Lakeman, van Lunsen, and Laan (2010).	0.64
Laan, Termeer, van Lunsen, Zimmerman, and Coelingh Bennink (2010)	0.52

for women with HSDD and no FSAD, they noted that 68% of sexual encounters during a 4-week baseline period were satisfying. Again, we question the representativeness of this sample, given that most of the HSDD group's sexual encounters were non-problematic.

Another important issue concerns the correlation between FSFI desire and arousal domains reported in these BI samples ($r = 0.30$ for women with HSDD and $r = 0.57$ for women with FSAD. These correlations are substantially lower than those reported in a number of previous studies that have used the FSFI (Table 2). In addition to studies using the FSFI, high correlations between desire and arousal have also been reported in studies employing other questionnaire measures. For example, in the large-scale WISHeS study, Leiblum, Koochaki, Rodenberg, Barton, and Rosen (2006) used the Profile of Female Sexual Function to measure desire in pre- and post-menopausal women. Low sexual desire was correlated with low levels of arousal, orgasm, and pleasure; correlations between desire and arousal ranged from 0.74 (for pre-menopausal women) to 0.84 (for surgically postmenopausal women).

In the original FSFI validation study, Rosen et al. (2000) commented on the high correlation between FSFI desire and arousal domains (0.76), noting "This relationship demonstrates a considerable overlap between the dimensions of desire and arousal in women, consistent with clinical observation and contrasting with findings in studies of sexual dysfunction in men" (p. 202). As Table 2 indicates, in the last decade, several studies have reported high correlations between FSFI desire and arousal domains (all reported correlations above .50). We are, therefore, uncertain what to make of the finding of a much lower correlation between desire and arousal in these BI samples. This may reflect the fact that there are different manifestations of desire disorder, with some women showing low and others normal levels of sexual arousal. This type of variability supports our recommendation that a polythetic approach be used to make a diagnosis of Sexual Interest/Arousal Disorder, where not all possible symptoms need to be present in order to meet criteria. In common with a number of other DSM diagnoses, a diagnosis would be given if X of Y symptoms are met.

DeRogatis et al. expressed concern that "…reducing the number of criteria required for a diagnosis to be given would increase the number of women who received the diagnosis…. Indeed, if only three criteria need to be met for a diagnosis of Sexual Interest/Arousal Disorder to be given, women who had symptoms of low desire…but no arousal problems would qualify for a diagnosis of the combined condition." As a fundamental rationale underlying our proposed revised criteria is that desire and arousal cannot be reliably distinguished, women who do not endorse the "arousal" symptoms in our criteria would indeed be said to have difficulties in desire/arousal if the required number of other symptoms were present. That women themselves fail to distinguish desire from arousal (Brotto, Heiman, & Tolman, 2009; Graham, Sanders, Milhausen, & McBride, 2004) supports this position. There is now much empirical evidence to support the notion that desire and arousal emerge from the same process and that both are responses to a sexually relevant stimulus; as Laan and Both (2008) concluded, "there is no good reason to assume that feelings of desire and arousal are two fundamentally different things" (p. 510).

Finally, DeRogatis et al. were also concerned that changes in diagnostic criteria would have implications for treatment: "If women with HSDD according to DSM-IV-TR criteria would not qualify for a diagnosis of Sexual Interest/Arousal Disorder according to the proposed new classification, it raises the question of whether these women would receive any diagnosis at all, and thus whether they would be excluded from consideration for treatment." In fact, in our proposals, we were deliberately trying to "raise the bar" for what qualifies as a disorder, given the extremely high rates of dysfunction reported in many epidemiological studies (e.g., Laumann, Paik, & Rosen, 1999). DeRogatis et al. further argued that "The lumping of diagnostic categories as a strategy for revision carries with it significant risks that the merged category will exclude many women who do not meet criteria for the new disorder, thereby compromising our ability to provide diagnosis and treatment for women with sexual disorders." We think it is likely that DeRogatis et al.'s concern is focused more on the impact that revised diagnostic criteria would have on the development and approval of *pharmaceutical* treatment for women with HSDD (although even here we do not understand the nature of the "significant risks"). In our view, maintaining "continuity in research and clinical practice" should not take precedence over empirical evidence that supports alternative proposals to the DSM-IV categories of discrete "desire" and "arousal" (Mitchell & Graham, 2008).

Unfortunately, DeRogatis et al. could not comment on whether women recruited to their clinical trials met criterion

A5 for Sexual Interest/Arousal Disorder: "desire is not triggered by any sexual/erotic stimulus (e.g., written, verbal, visual, etc.)." At present, there are no validated instruments that assess this symptom, so it is understandable that DeRogatis et al. would find this difficult to assess. Nonetheless, we consider this a key symptom in our proposed diagnostic criteria and one which reflects a key tenet of the Incentive Motivation Model, i.e., that an inability to become sexually excited in response to "effective" or "competent" stimuli denotes a problem.

The basic pre-requisites for any clinical category include demonstrations of diagnostic reliability and construct validity. In fact, there are no published reliability studies for either HSDD or FSAD. We doubt that either diagnosis could withstand a serious reliability check. Considering that both of these diagnoses were created on the basis of expert opinion, have no efficacious treatments, and cannot be differentiated by current psychometrics suggests lack of validity. Other than habit, the motivation to preserve unreliable and invalid diagnostic categories escapes us. On the other hand, there is significant empirical evidence and theory, which we have reviewed, suggesting the overlap between current conceptualizations of desire and arousal. This evidence and theory has motivated our new diagnostic proposal to merge HSDD and FSAD. We hope that the clearly specified criteria for SIAD will motivate definitive studies to address this important diagnostic issue.

Acknowledgments Drs. Brotto, Binik, Graham, and Segraves are members of the DSM-5 Sexual Dysfunctions subworkgroup (Chair, Dr. Segraves) and Dr. Zucker is the Chair of the Sexual and Gender Identity Disorders Workgroup. We wish to also thank Dr. Ellen Laan for her very useful feedback on this Letter.

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