SEXUAL MEDICINE

What Sexual Behaviors Relate to Decreased Sexual Desire in Women? A Review and Proposal for End Points in Treatment Trials for Hypoactive Sexual Desire Disorder

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ABSTRACT

Introduction: Counts of satisfying sexual events (SSEs) per month have been criticized as an end point in treatment trials of women with hypoactive sexual desire disorder (HSDD) but grounding improvement in sexual desire by assessing changes in sexual behavior remains of some importance.

Methods: We conducted a literature review to find validated measurements that are specific sexual behavioral correlates of low sexual desire. We compared expert-proposed criteria for dysfunctional desire, expert-developed sets of scale items, and self-rated scales developed before issuance of, or in accordance with, the Food and Drug Administration's guidance on developing patient-reported outcomes. Behavioral measurements of HSDD were isolated from these sets of criteria or scales.

Main Outcome Measures: We outline a plan to evaluate such behavioral measurements of HSDD with reference to SSEs.

Results: Eleven rating scales, four expert-originated and seven self-rated scales mainly derived from patient input were identified as well validated and relevant to HSDD. Three recent sets of diagnostic criteria for conditions such as HSDD were compared with the scales. Twenty-four different symptoms were found in the scales. Content found relevant to HSDD during development of the rating scales varied highly among measurements, including the self-rated scales developed in conformity with current recommendations for patient-reported outcome measurements. The only item on all sets was desire for sexual activity. Four other items were in approximately at least half the sets: sexual thoughts or fantasies, frequency of sexual activity, receptivity, and initiations. Sexual thoughts or fantasies were in every expert-derived set but in only three of the seven patient-derived sets. Receptivity was in five of the seven expert-derived sets vs two of the seven patient-derived sets. Frequency of sexual activity was in one of the seven expert-derived sets but in five of the patient-derived sets. Initiation was in approximately half the two sets. All other items were on one to three sets each. We identified three sexual behaviors of validated specificity for female HSDD: frequency of sexual activity, receptivity, and initiations. Six or seven items are relevant and informative. The item on frequency of sexual activity in the Changes in Sexual Functioning—Female scale is the only item that covers frequency of dyadic and solitary sexual activity. An item in the Female Sexual Desire Questionnaire (FSDQ) covers the intuitively relevant topic of frequency of sexual activity motivated by the woman's desire. Three FSDQ items on initiations and two items on receptivity reflect expert opinion on the sexual behaviors of most relevance to HSDD, but the FSDQ has not been validated in women with HSDD.

Conclusions: SSEs have been discredited as the primary measurement in clinical trials of women with HSDD, but it would be meaningful to include at least one sexual behavioral symptom specific to HSDD as an end point. Expert-recommended sexual behaviors specifically related to HSDD are irregularly represented in self-rating scales whether developed as in the Food and Drug Administration guidance on patient-reported outcomes or not. Six or seven items on sexual behavior in self-rated scales can be recommended for relevance to women with HSDD in clinical trials. Items on female sexual behavior should be tested in comparison with SSEs in women with HSDD for relevance and for treatment sensitivity, and responder and functional and dysfunctional cutoffs should be determined before incorporation into large-scale clinical trials.

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INTRODUCTION

To prove efficacy for female sexual dysfunction (FSD) and for hypoactive sexual desire disorder (HSDD) specifically, the US Food and Drug Administration (FDA) division of bone, reproductive, and urologic products has long recommended[1] as the primary end point a monthly count of satisfying sexual events (SSEs), although for HSDD it also has come to accept a validated measurement of sexual desire as a second, co-primary, end point.[2] SSEs have long been a stumbling block to showing efficacy because of large, right-skewed variance,[3] poor reflection of severity,[4] lack of a well-defined change score for improvement,[5,6] and poorly identified value as a measurement to patients and clinicians alike.[7,8]

The regulatory primacy of SSEs might be wavering. Experts convened by the FDA to address measurement issues in trials of women with HSDD have recommended demoting SSEs to a secondary end point.[9]

For HSDD, if the objective of treatment is to restore sexual desire and obviate distress about loss of desire, and thereby help a woman regain the sexual aspects of her primary relationship, then the evaluation of treatment needs to assess change in the quality and quantity of the sexual behavior that was affected by her loss of desire.

Measuring improvement in a particular form of sexual dysfunction (eg, HSDD) by measuring specific aspects of sexual behavior that relate closely to the dysfunction seems a basic requirement. However, this has been minimally explored apart from research into the male sexual disorders of erectile dysfunction and premature ejaculation.

In women with sexual dysfunctions, SSEs reflect a non-specific impairment. SSEs are as infrequent in those with female sexual arousal disorder (FSAD) as in those with HSDD.[10,11] Data on SSEs in women with orgasmic disorder are scarce, but a large clinical trial sample[12] showed rates similar to those in trials of women with HSDD.[3,13]

This review attempted to determine the closest sexual behavioral correlates of female HSDD by a review of the literature and to propose which are sufficiently validated to be incorporated into clinical trials.

METHODS

We conducted a Medline search from 2010 to March 2016 for all published reviews of well-validated rating scales relevant to assessment of low sexual desire in women. This disclosed two reviews.[14,15] We supplemented the search with a compendium of sex-related measurements published in 2011.[16] We updated the search for relevant measurements by conducting Medline searches for *scales of sexual desire* and *measures of sexual desire* for 2010 through March 2016. We reviewed the scales for items that are specific behavioral correlates of low sexual desire and can be used to measure such behavior in studies of FSD. The measurements of sexual desire had to apply to adult women in general, not only women with a specific disease. This eliminated sexual scales on depression,[17] breast cancer,[18] pelvic problems[19] or incontinence,[20] or validated only for postmenopausal women[21–23] or for postpartum women.[24]

Validation had to include discriminant validity between women diagnosed with low sexual desire and sexually functional women. This eliminated three otherwise extremely detailed and well-characterized scales, the Sexual Arousal and Desire Inventory (SADI),[25] a partner-specific scale of the Sexual Wanting and Liking Scale,[26] and the Sexual Interaction System Scale.[27]

Several measurements were rejected for this review because, although much of their coverage was similar to that for measurements relevant to low sexual desire in women, the aim of the measurement was different (eg, the Sexual Activity Questionnaire to measure partners' initiation of sexual activities but not to measure desire per se[28]; the Sexual Awareness Questionnaire covers items similar to desire scales but its thrust is to measure sexual consciousness, preoccupation, monitoring, and assertiveness, not desire per se).[29] Other measurements were rejected because published discriminant validation was lacking[30,31] or because the validation was limited to accuracy in use of the instrument to diagnose rather than measure low desire (Decreased Sexual Desire Screener,[32] Women's Sexual Interest Diagnostic,[33] the Sexual Complaints Screener for Women,[34] and a structured diagnostic method to enable diagnosis of FSD in postmenopausal women).[21] Other measurements were rejected because they covered sexual desire only in a single, generic item (the Arizona Sexual Experiences Scale,[35] the Massachusetts General Hospital Sexual Function Questionnaire,[36] and an unnamed measurement).[37] In addition, the measurement had to be available in English to be included in this review.

RESULTS

General Findings

Seven sets of items generated by expert clinicians were found: three criteria sets of symptoms required for disorders of low sexual desire and four rating scales. Seven well-validated scales generated from patient input were found. All desire-related items that were found in expert-recommended rating scales or patient-generated scales are presented in and Table 1 and Appendix A.

Clinician-Developed Sets of Criteria or Items

The three sets of criteria developed in this century for disorders of low sexual desire include the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (DSM-IV-TR) of 2000[38]; the International Consensus Criteria of 2003[39]; and the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) criteria of 2013 for the newly defined disorder that subsumes HSDD (ie, female sexual interest-arousal disorder [FSIAD]).[40] The only symptoms in the DSM-IV-TR set are low desire, low sexual thoughts or fantasies,

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