ORIGINAL RESEARCH—OUTCOMES ASSESSMENT

A Methodology Study to Develop and Validate a Screener for Hypoactive Sexual Desire Disorder in Postmenopausal Women

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ABSTRACT

Introduction. Current methods for diagnosing hypoactive sexual desire disorder (HSDD) can be complicated and time-consuming. A previous study reported validity and reliability of a structured diagnostic method created for clinical trials that can be performed in approximately 1 hour.

Methods. A more succinct tool is needed for incorporation into busy physician practices. Therefore, a brief HSDD screening tool was developed consisting of four self-report questions with an interpretable cut-score and concise confirmatory physician interview.

Main Outcome Measures. Accuracy of the HSDD screener cut-score alone, and in combination with physician interview, was then separately evaluated when compared with in-depth interview diagnosis.

Results. The results showed good agreement between the two diagnoses (kappa of 0.669 and 0.562 for cut-score alone and cut-score in combination with physician interview, respectively).

Conclusions. The HSDD screener can reliably detect the likely presence of HSDD in postmenopausal women. **Leiblum S, Symonds T, Moore J, Soni P, Steinberg S, and Sisson M. A methodology study to develop and validate a screener for hypoactive sexual desire disorder (HSDD) in postmenopausal women. J Sex Med 2006;3:455–464.**

Key Words. Hypoactive Sexual Desire Disorder; Diagnostic Testing; History; Physical Examination

Introduction

Few systematic epidemiological data on the prevalence of various subtypes of female sexual dysfunction (FSD) are available and these data show wide variability (25–50%) because of differences in assessment methodology, characteristics of sampled populations, and definitions used [1–3]. The four major subtypes based on the *Diagnostic and Statistical Manual of Mental Disorders* [4] classification of FSD with modifications made in 2000 by the American Foundation for Urologic Disease are described in the following list. Research has highlighted the fact that these disorders overlap and frequently coexist [3,5]. All of the definitions include the consideration and assessment of personal distress when making a diagnosis. The most prevalent of these subtypes is hypoactive sexual desire disorder (HSDD).

1. HSDD: Persistent or recurrent deficiency (or absence) of sexual fantasies/thoughts and/or desire for or receptivity to sexual activity, which causes marked distress or interpersonal difficulty.
2. Female sexual arousal disorder (FSAD): Persistent or recurrent inability to attain or maintain sufficient excitement, causing personal distress, which may be expressed as a lack of subjective excitement, or genital (lubrication/swelling) or other somatic responses.

3. Female orgasmic disorder (FOD): Persistent or recurrent difficulty, delay in, or absence of attaining orgasm following sufficient sexual stimulation and arousal, which causes personal distress.
4. Sexual pain disorder (dyspareunia, vaginismus): Recurrent or persistent genital pain associated with sexual intercourse or the recurrent or persistent involuntary spasm of the musculature of the outer third of the vagina that interferes with vaginal penetration, which causes personal distress.

Currently, there is no standardized test or questionnaire for diagnosing women with HSDD in a primary care setting. Recently, a validated structured diagnostic method (SDM), which can diagnose all the main FSD subtypes, was developed. It showed almost perfect agreement with expert clinician diagnosis for presence or absence of FSD (91.7% agreement; kappa statistic of 0.83) and good agreement with these experts in determining primary diagnosis of FSAD or HSDD (70% agreement; kappa statistic of 0.56). Also, intrarater reliability was excellent with a kappa statistic of 0.97, i.e., almost perfect agreement. However, its primary application is for the selection of women for FSD clinical trials, and it is very time-consuming and complex for use in a primary care setting [6]. Therefore, the objective of this study was to develop (Part A) and validate (Part B) a simple tool for screening the most prevalent type of FSD—HSDD.

Part A

Methods: Development of the HSDD Screener

Item Generation

Because the aim was to develop a simple, self-report screening tool, a panel of internationally recognized experts in female sexuality consisting of sex therapists and physicians, with specialties in psychiatry and general practice, was convened to develop initial specific items and a format for a brief tool to be used by primary care physicians to identify FSD. Due to complexities around developing and validating a comprehensive FSD tool, it was decided to focus effort on developing a simpler tool for the most prevalent FSD—HSDD. Three self-report questions that are specific to sexual desire difficulty were agreed upon, as well as a fourth question related to the extent to which the patient was worried or concerned about any of the changes, as the degree of personal distress is an integral part of all the FSD diagnoses. To simplify scoring, the response options were limited to yes/no. Additionally, to determine the psychological, interpersonal, and contextual precipitating or maintaining factors of the desire problem, a series of prescribed questions were also generated for use by the physician (see Appendix 1 "Other questions you may want to ask" section).

The tool was then optimized based on feedback from focus groups consisting of physicians and patients in the European Union (Italy, the Netherlands, United Kingdom) and the United States. Prior to study initiation, Institutional Review Board (IRB) approval was obtained in each country. Each of the four patient focus groups included seven participants over the age of 50 years, who were recruited through general advertising. During a standardized screening process, women self-reported sexual difficulties or their absence. The four primary care physician focus groups consisted of five participants each. To ensure that the wording of the questions was understandable and captured the concepts being measured (sexual desire/interest), the respondents were asked to carefully consider the language used in each question. As a result of respondent feedback, some changes were made in the interest of clarity and comprehension. For example, a change from the word "responsive" to the word "receptive" was made because the focus group participants felt that "responsive" referred primarily to verbal communication. The term "distress" was replaced by "concerned or worried" because most of the women felt "distress" was too extreme, especially those women who had milder symptoms. The compromise that worked for the women was the use of the terms "concerned/worried." Furthermore, some women preferred the term "interest" rather than "desire," therefore both terms were used to address this concept of desire. Women in the focus groups also felt that the yes/no response option was too restrictive, so it was replaced by a five-point Likert scale. The content of the final screener can be found in Appendix 1. A total score can be derived from the individual five-point Likert scale responses, ranging from 0 (no difficulty and no concern) to 16 (a very great deal of difficulty and concern). Therefore, a scoring system (i.e., cut-score) indicating likely presence or absence of HSDD was required.

Establishment of Cut-Score

Subjects. The study planned to enroll 1,500 women. It was anticipated that this number would provide a sufficient number of subjects with HSDD