ORIGINAL RESEARCH—OUTCOMES ASSESSMENT

Validation of the Female Sexual Distress Scale-Revised for Assessing Distress in Women with Hypoactive Sexual Desire Disorder

Leonard DeRogatis, PhD,* Anita Clayton, PhD,† Diane Lewis-D'Agostino, RN,‡ Glen Wunderlich, PhD,§ and Yali Fu, PhD¶

*Johns Hopkins Department of Psychiatry and Behavioral Sciences—Center for Sexual Medicine at Sheppard Pratt, Baltimore, MD, USA; †University of Virginia Health System—Department of Psychiatric Medicine, Charlottesville, VA, USA; ‡Boehringer Ingelheim Pharmaceuticals—Clinical Operations, Ridgefield, CT, USA; §Boehringer Ingelheim Ltd., Burlington, Ontario, Canada; ¶Boehringer Ingelheim Pharmaceuticals—Medical Affairs, Ridgefield, CT, USA

DOI: 10.1111/j.1743-6109.2007.00672.x

ABSTRACT

Introduction. The concept of sexually related personal distress is currently central to the diagnosis of all female sexual dysfunctions (FSD). In the current study, we have focused on validating a slightly revised version of the Female Sexual Distress Scale (FSDS), the FSDS-Revised (FSDS-R), to enhance the sensitivity of the instrument with patients suffering from hypoactive sexual desire disorder (HSDD). In addition, we have attempted to extend the validation generalizability of the scale by demonstrating that both instruments possess reliability and discriminative validity in premenopausal women with HSDD.

Aim. To assess the validity of the revised version of the FSDS, the FSDS-R, for measuring sexual distress in women with HSDD.

Methods. A prospective methodological study carried out at 27 centers in North America enrolled 296 women aged 18–50 years with HSDD, another female sexual dysfunction (FSD), or no FSD. The subjects completed the FSDS-R at baseline, day 7, and day 28, with a 30-day recall at baseline and with a 7-day recall on days 7 and 28.

Main Outcome Measures. Receiver operating characteristic (ROC) analyses of FSDS, FSDS-R, and FSDS-R item 13 were used for the differentiation of HSDD from no FSD, while intraclass correlation coefficient (ICC) was used to estimate test–retest reliability. Cronbach's coefficient alpha was used to measure the internal consistency of the FSDS-R and Pearson's correlation coefficient to assess FSDS, FSDS-R, and FSDS-R item 13 with different recall periods (7 and 30 days).

Results. Mean total FSDS, FSDS-R, and FSDS-R item 13 scores with either recall period were significantly higher ($P < 0.0001$) in women with FSD or HSDD than in women with no FSD, showing both tests had discriminant validity. ROC analysis confirmed these findings, while an ICC of >0.74 showed the test–retest reliability of both scales, including FSDS-R item 13 alone, and Cronbach's coefficient alpha of >0.86 confirmed the internal consistency of both tests.

Conclusions. Consistent with the FSDS, the FSDS-R demonstrated good discriminant validity, high test–retest reliability, and a high degree of internal consistency in measuring sexually related personal distress in women with HSDD. FSDS-R item 13 alone also demonstrated good discriminant validity and test–retest reliability. **DeRogatis L, Clayton A, Lewis-D'Agostino D, Wunderlich G, and Fu Y. Validation of the female sexual distress scale revised for assessing distress in women with hypoactive sexual desire disorder. J Sex Med 2008;5:357–364.**

Key Words. Hypoactive Sexual Desire Disorder; Female Sexual Distress Scale; Nontreatment Study

Introduction

The Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) and most recent revision (DSM-IV-TR) recognize four distinct disorders of female sexual dysfunction (FSD): female orgasmic disorder (FOD), female sexual arousal disorder (FSAD), sexual pain disorders, and sexual desire disorders such as hypoactive sexual desire disorder (HSDD) [1]. HSDD is usually defined as the persistent or recurrent deficiency or absence of sexual fantasies and thoughts, and/or desire for, or receptivity to, sexual activity, which causes personal distress or interpersonal deficiencies and is not caused by a medical condition or drug [1,2].

HSDD, believed to be the most prevalent form of FSD, occurs in both premenopausal and postmenopausal women [3]. As recent surveys have revealed, HSDD is associated with significant levels of emotional and psychologic distress, as well as contributing to lower sexual and relationship satisfaction. In comparison to women with normal levels of sexual desire, less than 10% of whom experienced emotional or psychologic distress "often," "very often," or "always," over 80% of women with HSDD felt concerned, unhappy, or that they were letting their partner down [3,4]. Women with HSDD were 11 times more likely than women with normal desire to feel dissatisfied with their sex lives and 2.5 times more likely to feel dissatisfied with their marriage or partner relationships [4]. Not surprisingly, HSDD can have a detrimental effect on women's physical and mental health.

The presence of personal distress is central to the diagnosis of HSDD. This is recognized in the DSM-IV-TR and other recent diagnostic guidelines for FSD, including those emanating from the 1999 International Consensus Development Conference on FSD, which stated that women with decreased sexual desire can only be diagnosed with HSDD if they have evidence of associated personal distress [2]. The criterion is considered important in differentiating women with HSDD from those who experience decreased sexual desire but are not distressed by the condition and do not perceive it as having a negative impact on their physical or psychologic well-being [5].

Several psychometric instruments have been used to measure sexually related personal distress in women with HSDD, including the Female Sexual Distress Scale (FSDS) [5]. This relatively new 12-item self-rating instrument has been used and tested extensively, and shown to distinguish between sexually dysfunctional women and women with no sexual dysfunction, as well as effectively measure sexually related personal distress in women with HSDD [5].

In this article, we described the results from a methodological, nontreatment study of women with HSDD, in which the FSDS and the FSDS-Revised (FSDS-R), an extended version of the FSDS, were used to collect data on sexually related personal distress. The aim of the study was to assess the validity of the FSDS-R, which differed from the FSDS in that it included one additional question that asked women to rate distress related to low sexual desire, consistent with its use as part of the diagnostic algorithm for HSDD.

Methods

Study Design

This was a 4-week prospective, multicenter, methodological study designed to assess the validity of the FSDS and FSDS-R with 7- and 30-day recall periods for measuring sexually related distress in women with generalized acquired HSDD. No medication or treatment was administered as part of this study.

The enrollment took place at 27 investigative sites in the United States and Canada, all of which received Institutional Review Board approval to carry out the study, which was conducted in accordance with the ethical principles of the current Declaration of Helsinki (1996 version) and the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice. All participants gave a written informed consent before entering the study.

Study Population

Women between the ages of 18 and 50 years, independent of their menopausal status, were eligible to participate if, based on a standard diagnostic interview with a clinician trained in the diagnosis of FSD, they met the DSM-IV-TR criteria for HSDD, or for another FSD (including FSAD or FOD) but not generalized, acquired HSDD. HSDD should have been present for at least 24 weeks before study entry. In addition, a cohort of women with no FSD was included, provided that the subjects had no sexual complaints and did not meet the DSM-IV-TR diagnostic criteria for FSD. All subjects were required to be in a monogamous, heterosexual relationship for at least 12 months and