The Sexual Event Diary (SED): Development and Validation of a Standardized Questionnaire for Assessing Female Sexual Functioning During Discrete Sexual Events

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ABSTRACT

Background: The efficacy of on-demand drugs for hypoactive sexual desire disorder (HSDD) or female sexual interest/arousal disorder (FSIAD) should be assessed using a validated instrument that assesses the discrete sexual events during which the on-demand drug is taken.

Aim: To develop and validate an event log for measuring sexual satisfaction and sexual functioning of discrete sexual events.

Methods: Psychometric assessment was carried out on data of 10,959 Sexual Event Diaries (SEDs) collected during three clinical trials in a total of 421 women with HSDD. Cognitive debriefing interviews were held with 16 women with HSDD.

Outcomes: Item scores of the SED at the event level and at the subject level, summarized item scores of women during the baseline establishment and active treatment periods, and score changes in women from baseline establishment to active treatment.

Results: Several items of the initial 16-item SED items showed weak validity. The 16-item SED was refined to the 11-item SED. The reliability, content, and convergent validity of the 11-item SED were confirmed. For most 11-item SED item scores, the ability to discriminate between known groups was confirmed. Larger mean score changes from the baseline establishment period were found in those with than in those without known benefit from the medication, and Guyatt effect sizes ranged from 0.73 to 1.58, thereby demonstrating the ability to detect change.

Clinical Translation: The SED is a good tool for assessing sexual function during a discrete sexual event and for assessing the sexual function of women over longer periods.

Strengths and Limitations: The validation of the SED was performed on data from nearly 11,000 sexual events, gathered as part of a drug development program for HSDD and FSIAD. This amount of data provides very robust results when related to drug use for HSDD and FSIAD, but caution is advised when generalizing the validity of the SED directly to other areas of research (eg, recreational drug use and sexual risky behaviors), because such data were not used in this validation.


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Key Words: Patient Reported Outcome; Questionnaire; Validation; Reliability; Satisfactory Sexual Event; Sexual function; Female Sexual Interest/Arousal Disorder; Female Sexual Dysfunction; Hypoactive Sexual Desire Disorder
INTRODUCTION

Low sexual desire and arousal are the most common sexual complaints among women and commonly cause sexual dissatisfaction and personal distress. These conditions were classified in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) as hypoactive sexual desire disorder (HSDD) and female sexual arousal disorder, respectively, but have been merged in the fifth edition of the DSM as female sexual interest/arousal disorder (FSIAD).

The pharmacotherapeutic options for HSDD and FSIAD are limited, with only one approved drug on the market in the United States. This drug, ibanserin, is taken daily to increase overall sexual desire. There are other therapies in the late stages of clinical development that are not taken daily but instead are taken on demand (ie, when a woman with HSDD or FSIAD wants to have sex). These medications are not intended to increase sexual desire continuously, but only before and during sexual activity. Measuring the efficacy of such an on-demand drug necessitates a different approach.

The efficacy of ibanserin was assessed using the Female Sexual Function Index (FSFI). The FSFI assesses different dimensions of female sexual functioning during the preceding 4 weeks. The efficacy of an on-demand drug for HSDD and FSIAD is best determined by assessing the quality of a sexual event during which the drug was taken. Assessing sexual functioning retrospectively over a longer period, for example, during 4 weeks as in the FSFI, yields a more distal estimation of an on-demand drug’s influence on sexual functioning than assessing sexual functioning during the actual events during which the drug was taken. However, to determine an on-demand drug’s efficacy, an estimation of long-term effects is necessary. This can be operationalized by evaluating the change in the number of satisfactory sexual events from a baseline establishment period (BLE) to an active treatment period (ATP) during which the on-demand therapy was used. The primary end point in such trials is the difference between active treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms in the change in the number of satisfactory sexual events from baseline to the end of treatment and placebo treatment arms.

A principal components analysis was performed to determine the factors underlying the SED. Correlations of the items with global sexual satisfaction and Cronbach α coefficients were calculated to assess internal consistency (reliability).

The goal was to develop a comprehensive and compact questionnaire that could adequately assess the quality of a sexual event without burdening the subject. Based on the gathered qualitative and psychometric assessments, the 58-item SED was reduced to a 16-item version. This 16-item version was subsequently translated into US English by a certified medical translation office in the Netherlands. Two female interviewers with experience in women’s sexual medicine (RTI Health Solutions, Research Triangle Park, NC, USA) performed cognitive debriefing interviews with 5 native US English-speaking women to test the adequacy of the translated version.

All participants of the focus groups, debriefing interviews, and observational study described earlier provided written informed consent.

The first versions of the SED were called the Satisfaction of an Event Questionnaire, but it was later renamed to the SED because this name covered the content of the questionnaire more adequately. In the present article, only the name SED is used (and to refer to prior versions) for clarity.

METHODS

Questionnaire Development

The first version of the SED included 58 items, which were selected based on literature review, expert opinion, and information from more than 250 clinical interviews that were conducted at our laboratory with women having sexual problems. The items that were included were selected to provide a comprehensive representation of sexual functioning and sexual satisfaction of a sexual event. 3 focus groups, 2 with 5 premenopausal women and 1 with 5 postmenopausal women, with (predominantly) sexual problems were formed to discuss what constituted sexual satisfaction and whether the 58-item SED adequately measured satisfaction and all other relevant aspects of sexual functioning.

The Dutch pilot version of the 58-item SED was tested in 156 women with (n = 89) and without (n = 67) sexual problems. These data were used for the initial validation and item reduction. Aside from completing the SED at their most recent sexual event, subjects were asked to select those 15 SED items that were most relevant to them in capturing sexual satisfaction and sexual functioning during an event. Principal components analysis was performed to determine the factors underlying the SED. Correlations of the items with global sexual satisfaction and Cronbach α coefficients were calculated to assess internal consistency (reliability).

The reliability, validity, and responsiveness of the 16-item US version of the SED were assessed using data collected during two clinical studies.

Clinical Studies

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