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PSYCHOMETRICS

Psychometric Properties of the Sexual Event Diary in a Sample of Dutch Women With Female Sexual Interest/Arousal Disorder

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ABSTRACT

Background: Efficacy of on-demand drugs for women with hypoactive sexual desire disorder 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, because this type of assessment is more proximate to an on-demand drug's efficacy compared to instruments that assess sexual function over longer periods of time.

Aim: The aim of this study was to assess the psychometric properties of the Dutch translation of the previously validated 11-item Sexual Event Diary (SED) for measuring sexual satisfaction and sexual functioning during discrete sexual events.

Methods: Psychometric assessment was performed on data of 1,840 SEDs from 139 women with hypoactive sexual desire disorder/FSIAD, collected during a randomized clinical cross-over trial conducted in the Netherlands.

Outcomes: Item scores of the SED at the event level, and at subject level, summarized item scores during the placebo run-in period (PRI) and active treatment period, and score changes from PRI to active treatment period.

Results: Reliability and convergent validity were confirmed. All item scores showed the ability to discriminate between known groups. Larger mean score changes from PRI were observed in groups with known benefit from the medication, as compared to those with no benefit. Guyatt effect sizes ranged from 0.51−1.02, thereby demonstrating ability to detect change.

Clinical Translation: The Dutch version of the SED is an excellent instrument for assessing female sexual functioning and sexual satisfaction during discrete sexual events and for assessing these concepts over longer periods of time.

Conclusions: Data were collected in a randomized, well-controlled trial. The large number of data points gave high statistical power, and the results confirmed previous findings. However, care is needed when generalizing the SED's validity to other areas of research, eg, recreational drug use and sexual risky behaviors, since the current validation study has not used such data. Consistent with the US-English version, the Dutch version of the SED is a reliable, valid, and responsive instrument, and suitable for use in evaluating effects of on-demand drugs in women with FSIAD. **van Nes Y, Bloemers J, Kessels R, et al. Psychometric Properties of the Sexual Event Diary in a Sample of Dutch Women With Female Sexual Interest/Arousal Disorder. J Sex Med 2018;15:722−731.**

Key Words: Sexual Event Diary; Dutch; Patient-Reported Outcome; Psychometric Properties; Satisfactory Sexual Event; Sexual Function; Female Sexual Interest/Arousal Disorder; Hypoactive Sexual Desire Disorder

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INTRODUCTION

Low sexual desire and/or low sexual arousal can lead to sexual dissatisfaction, and in turn, lead to severe personal distress.[1] In women, distressing low desire is classified as hypoactive sexual desire disorder (HSDD) and distressing low arousal as female sexual arousal disorder in *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision*.[1,2] These 2 disorders have been merged in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* into female sexual interest/arousal disorder (FSIAD).[3] There are currently only few pharmacotherapeutic options for these women but the large number of off-label testosterone prescriptions for female sexual dysfunction (over 4 million annually) shows there is a clear need.[4] For a pharmacological therapy to receive US marketing authorization by the U.S. Food and Drug Administration (FDA), efficacy must be established through 1 or more patient-reported outcomes. In their regulatory guidance[5] the FDA formulates 4 possible (co) primary end points for pivotal phase III trials in HSDD/FSIAD: change from baseline in the level of sexual interest or desire, change from baseline in the level of sexual arousal, change from baseline in the level of distress, and change from baseline in the number of satisfying sexual events. These end points reflect different perspectives that can be taken when investigating a drug's efficacy in HSDD/FSIAD, focusing on the primary symptom (eg, level of desire), the distress that this symptom generates, or the quality of the sexual event itself. The preferred perspective, and thus end point, is partly based on the drug's characteristics.

Several therapies that are in late stages of clinical development[6–8] are on-demand therapies, ie, they are taken only when a woman with HSDD/FSIAD *wants to want* to have sex. These medications only increase sexual desire prior to and during sexual activity, instead of increasing it continuously as do drugs that are dosed daily (eg, flibanserin and transdermal testosterone applications). This different mode of action should be taken into account when testing on-demand medication in randomized clinical trials.

The efficacy of an on-demand drug for HSDD/FSIAD is best determined by assessing the quality of each discrete sexual event during which the drug was taken, in a given period. Assessing sexual functioning retrospectively over a longer period of time (eg, 4 weeks), as does the Female Sexual Function Index (FSFI),[9] gives a more distal estimation of an on-demand drug's efficacy. With this type of questionnaire, patients report on different aspects of their sexual functioning "on a whole," thus encompassing significant periods of time over which there is no on-demand drug effect. Such a method of assessment is adequate for continuous dosing regimes because these regimens assume continuous effect, but it needlessly introduces noise in the assessment of on-demand dosing regimens.

The Sexual Event Diary (SED) is a patient-reported outcome instrument that has been developed for assessing sexual satisfaction and sexual functioning during a discrete sexual event.[10] The SED is an 11-item questionnaire that is filled out by the subject within 24 hours of a sexual event. 3 Items assess the type and timing of sexual event and if medication was used, 2 binary items assess if the sexual event was satisfactory and if the subject reached orgasm, and six 5-point Likert scale items assess desire, mental arousal/excitement, physical arousal/excitement, presence and strength of distracting thoughts, the ability to let go, and experienced pleasure. The development and validation of the SED is described in Van Nes et al.[10] Content validity was established in 2 sets of cognitive debriefing interviews in women with HSDD aged between 21 and 70 years and psychometric assessment was carried out on data of nearly 11,000 SEDs. These data were collected during 3 double-blind, randomized, placebo-controlled, dose-finding phase II trials, investigating the efficacy and safety of on-demand drug therapies in over 400 women with HSDD, aged between 21 and 70 years.[11] Results of the psychometric assessment showed a 1-factor solution should be retained, based on exploratory factor analysis. This 1-factor solution substantiated the summing of all Likert scale items into a sexual function score. Reliability of the SED was confirmed based on Cronbach alpha coefficient, inter-item and item-rest correlations. Convergent validity was confirmed using Pearson correlation coefficients of the total score and domain scores of the validated FSFI[6] with SED sexual function score and the separate item scores. Construct validity was confirmed by comparing the mean SED scores between responders and non-responders based on the SED items "satisfaction" and "orgasm" and based on the binary single-item Subjective Evaluation of Gain questionnaire assessing benefit from the medication. Ability to detect change (responsiveness) was proven based on the Guyatt effect sizes and based on the comparison of the mean SED score changes from baseline to active treatment period (ATP) between those women reporting benefit from the medication as compared to those reporting no benefit.

The SED proved to be an excellent instrument for determining the effect of on-demand therapies on sexual function and satisfaction during discrete sexual events, in women with HSDD or FSIAD. Moreover, the SED was shown to be a suitable instrument for determining an on-demand drug's efficacy over a longer period of time (ie, over a per-patient variable number of multiple sexual events in a given period), using 1 of the FDA preferred primary end points for the indication HSDD/FSIAD "change in the number of satisfying sexual events from baseline." This end point proved not only to be an excellent and comprehensive measure, but it also correlated strongly with all aspects of sexual functioning and it had an excellent ability to discriminate between drug responders and drug non-responders.[10] For a double-blind, randomized, placebo-controlled, cross-over phase II trial investigating the efficacy of an on-demand drug therapy for HSDD/FSIAD in a Dutch sample, the validated US-English SED version was translated to Dutch. Phase III trials necessitate the use of fully validated instruments that are used to collect the primary end point. As both the English