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SEXUAL FUNCTION

Development and validation of a new screening tool for hypoactive sexual desire disorder: The Brief Profile of Female Sexual Function© (B-PFSF©)

JOHN RUST[1], LEONARD DEROGATIS[2], CYNTHIA RODENBERG[3], PATRICIA KOOCHAKI[3], SONJA SCHMITT[3], & SUSAN GOLOMBOK[4]

[1]*The Psychometrics Centre, University of Cambridge, Cambridge, UK,* [2]*Center for Sexual Medicine at Sheppard Pratt, Baltimore, Maryland, USA,* [3]*Procter & Gamble Pharmaceuticals, Cincinnati, Ohio, USA and Petit-Lancy, Switzerland, and* [4]*Centre for Family Research, Faculty of Social and Political Sciences, University of Cambridge, Cambridge, UK*

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Abstract

Aim. To develop a screening tool to allow a postmenopausal woman to determine whether to seek evaluation for hypoactive sexual desire disorder (HSDD).

Methods. The Brief Profile of Female Sexual Function© (B-PFSF©) was developed using items from the Profile of Female Sexual Function© (PFSF©) and the Personal Distress Scale© (PDS©). Logistic regression analysis was used to select items best able to discriminate between women with HSDD ($n = 743$) and controls ($n = 226$) and a screening cut-off score was identified. Cross-validation analyses were conducted using PFSF and PDS responses from an independent group of 147 HSDD women and 104 controls. Forty cognitive interviews were additionally conducted to assess validity of the final tool.

Results. A seven-item instrument was found to provide good discrimination between postmenopausal women with HSDD and controls and to be a reliable and valid tool. Ninety-six percent of women with HSDD and 97% of control women in the independent validation were classified correctly using the identified cut-off score. In the cognitive interviews, all women stated that the questionnaire was easy to complete and covered relevant aspects of sexual function.

Conclusion. The Brief Profile of Female Sexual Function (B-PFSF) is psychometrically valid and appropriate for use as a self-administered screening tool.

Keywords: *Female sexual function, hypoactive sexual desire disorder, postmenopausal women, psychometric instrument*

Introduction

Menopause is a time of physical, emotional and psychological change for women and some of these changes may affect sexual functioning. Studies have reported decreases in sexual desire and responsiveness in naturally menopausal women [1,2] and in women after hysterectomy with bilateral oophorectomy [3,4], while other studies have found that sexual function may improve after hysterectomy [5,6]. Hypoactive sexual desire disorder (HSDD) is defined as the persistent or recurrent deficiency of sexual fantasies or thoughts or decreased desire for or receptivity to sexual activity that causes personal distress [7]. Estimates of the percentage of postmenopausal women who experience decreased sexual desire and are distressed by this decrease vary widely across studies. Recent large surveys in the USA [8] and Europe [9] estimate that between 9 and 26% of postmenopausal women experience low sexual desire that is distressing, with the highest prevalence of the condition occurring among younger (<50 years), bilaterally oophorectomized and hysterectomized (surgically menopausal) women.

Previous research has shown that both female patients and health professionals often find it difficult to discuss existing sexual problems and the awareness of female sexual dysfunction (FSD), especially HSDD, is very low among women and health professionals [10–13]. Simple tools that promote

Correspondence: J. Rust, The Psychometrics Centre, Cambridge Assessment, 1 Regent Street, Cambridge CB2 1GG, UK. Tel: 44 1223 553371. Fax: 44 1223 552590. E-mail: Rust.J@cambridgeassessment.org.uk

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communication between women and physicians should aid in the appropriate diagnosis and management of sexual complaints.

The Profile of Female Sexual Function© (PFSF©) and the Personal Distress Scale© (PDS©) were developed to measure clinical efficacy of therapies for HSDD [14–16] in women after menopause. The PFSF is a 37-item questionnaire with seven domains that women identified as important in sexual functioning and the PDS is a seven-item scale designed to assess distress or concerns due to low sexual desire. We have developed a new, brief form of these instruments, the Brief Profile of Female Sexual Function© (B-PFSF©), for use as a screening tool. The purpose of the B-PFSF is to provide postmenopausal women with an assessment tool to help them determine whether they may benefit from a clinical evaluation of HSDD. The screening tool was developed to provide good discrimination between women who have HSDD and those who do not, and to reflect the diagnostic criteria for HSDD. It was also important that the tool be easy to use, accepted by the women complaining of low sexual desire, and appropriate to capture aspects of the condition relevant to them.

Methods

Development of the B-PFSF

Subjects. Three hundred and forty-nine surgically menopausal women with HSDD and 261 age-matched control women (women who considered themselves to have good and satisfying sex lives and were not concerned or bothered by their current levels of sexual desire or activity) were enrolled in three validation studies for the development and validation of the PFSF and PDS. In addition, 524 surgically menopausal women with HSDD were enrolled in two double-blind, placebo-controlled clinical trials investigating the efficacy and safety of transdermal testosterone. These trials have been described previously [14,16–18].

Item selection. The development of the PFSF and PDS has been previously described [14–16]. These instruments are self-administered, multi-lingual, patient-based questionnaires that assess loss of sexual desire and associated symptoms, including distress, in menopausal women. They have been shown to have robust psychometric properties as established in multiple geographic regions and languages, and have been used to measure efficacy of transdermal testosterone treatment in HSDD clinical trials [17–22]. In order to develop a practical screening tool, we used a stepwise logistic regression analysis along with clinical considerations to identify the set of items of the PFSF and PDS that best predicted the presence of HSDD. Responses corresponding to the initial visit in the three validation studies and the baseline visit for the two phase-II studies were used in the analysis [14,17,18]. Of the 873 surgically menopausal women with HSDD and 261 control women, 743 menopausal women with HSDD and 226 control women responded to all 44 PFSF and PDS items and were included in the analysis. An α level of 0.05 was used to determine which items were entered into the logistic regression model and whether they were retained after entry of subsequent items. The final screening tool consisted of seven items (Table I). Each item was scored on a 6-point Likert scale ('always' to 'never') and item scores were transformed so that lower scores were indicative of poorer sexual function and higher distress. A total score for the B-PFSF is obtained by summing the scores for each item, resulting in a total score ranging from 0 to 35.

Choice of cut-off score. The distribution of total scores on the B-PFSF was examined for postmenopausal women with HSDD ($n = 813$) and control women ($n = 247$) who had completed the responses to all seven of the selected items. Misclassification rates were computed for each potential cut-off score. A woman was classified as having HSDD if her B-PFSF score was less than or equal to the potential cut-off score. A cut-off value for the total score was

Table I. Final items and ability to distinguish menopausal women with hypoactive sexual desire disorder (HSDD) ($n = 743$) from control women without HSDD ($n = 226$).

B-PFSF item	Original domain*	p Value†
1. I felt like having sex	Sexual desire	0.01
2. I was unhappy about my lack of interest in sex	PDS	0.002
3. Getting aroused took forever	Sexual arousal	0.08
4. I felt sexually numb	Sexual concerns	0.04
5. I felt disappointed by my lack of interest in sex	PDS	0.001
6. I lacked sexual desire	Sexual desire	0.003
7. I reached orgasm easily	Orgasm	0.05

B-PFSF, Brief Profile of Female Sexual Function©; *original domain of the PFSF (Profile of Female Sexual Function©) or the PDS (Personal Distress Scale©) scale; †p value is based on a logistic regression analysis run on items in the final model.

chosen to provide low false-positive (i.e. a low proportion of control women classified as HSDD) and false-negative (i.e. a low proportion of HSDD women classified as not having HSDD) rates.

Validation of the B-PFSF

Initial validation. Confirmatory validation of the PFSF and PDS in surgically and naturally menopausal women with HSDD was shown in a final validation study [15,16]. This study included 59 surgically menopausal women with HSDD, 88 naturally menopausal women with HSDD, and 104 control women. A subset of 47 women of the 104 control women were naturally menopausal and served as the age-matched controls for the 88 naturally menopausal women with HSDD.

Cross-validation analyses of the B-PFSF were conducted using the initial responses to the PFSF and PDS for subjects who had completed all seven items of the B-PFSF. A receiver-operating characteristic (ROC) curve analysis was conducted to assess the overall ability of the B-PFSF to discriminate between both surgically and naturally menopausal women with HSDD and their respective age-matched control groups. Correct classification rates, corresponding to the cut-off score identified in the previous development analyses, were estimated. Convergent validity (positive correlation with an instrument measuring a similar construct) was assessed by correlating the B-PFSF with domains of the DISF-SR© (the Derogatis Interview for Sexual Functioning – Self-Report©) [23] and the FSDS© (Female Sexual Distress Scale©) (inventories measuring sexual functioning and associated distress) [24]. Test–retest (retest corresponds to follow-up responses to PFSF and PDS at week 4) and internal consistency reliability were evaluated for both women with HSDD and the control group.

Final validation. Cognitive interviews were conducted to validate the algorithm for HSDD classification, patient understanding, and ease of use for the final B-PFSF. Research to validate the screening tool was conducted in four cities (Birmingham, UK; Rome, Italy; Frankfurt, Germany; and Columbus, Ohio, USA). A mix of 19 naturally and 20 surgically menopausal women (one unclassified) with normal sexual desire (19 women) and HSDD (21 women) were recruited; all women were required to be in a sexual relationship for at least the last 6 months. Women were classified as having HSDD if they reported that they had a good and satisfying sex life prior to menopause, experienced a meaningful loss of desire after menopause, and were very or extremely bothered by a decreased interest in sex. Women were classified as having normal libido if they had a good and satisfying sex life prior to menopause, and no meaningful loss of sexual desire following menopause. The women were asked to complete the B-PFSF and then were interviewed. The interview was designed to assess comprehension, ease of completing and scoring the B-PFSF, whether the items adequately addressed the issues with sexual function that women with HSDD experience, whether the final score the woman received agreed with her own perception of her level of sexual desire and associated distress, and whether she felt such a tool would be useful in starting a discussion with her physician about any sexual problems or complaints.

Results

Development of the B-PFSF

Item selection. Seven hundred and forty-three menopausal women with HSDD (mean age, 48.9 years) and 226 control women (mean age, 44.9 years) who responded to all 44 PFSF and PDS items were included in the analysis. Based upon the statistical analyses and clinical input, the items shown in Table I were chosen for the final screening tool. These items reflected aspects of the disorder consistent with criteria for the diagnosis of HSDD found in the 4th edition of the *Diagnostic and Statistical Classification Manual for Mental Disorders* (DSM-IV) [7]; deficiency of sexual desire (items 1 and 6), leading to personal distress (items 2, 4 and 5), problems of arousability (item 3) and orgasmic difficulties (item 7).

Values of p corresponding to a logistic regression analysis on the final set of items are provided in Table I. Item 3 ('Getting aroused took forever') had been removed from the model after item 7 ('I reached orgasm easily') entered. Because both these items are part of the DSM-IV criteria, it was determined that both should be retained for cognitive testing. The relevance of both these items was later confirmed in the cognitive interviews.

Choice of cut-off. The distribution of B-PFSF responses for subjects with HSDD was significantly lower than the scores for the control women (data not shown). Figure 1 displays the misclassification rates corresponding to potential cut-off scores. A B-PFSF score ≤ 20 minimized simultaneously misclassification of HSDD women and control women (8% of HSDD and 9% of normal libido women were misclassified).

Validation of the B-PFSF

Ability of the B-PFSF to discriminate between women with hypoactive sexual desire disorder and controls. The ability of the B-PFSF to discriminate between surgically and naturally menopausal women with HSDD and age-matched controls is shown in Figure 2.

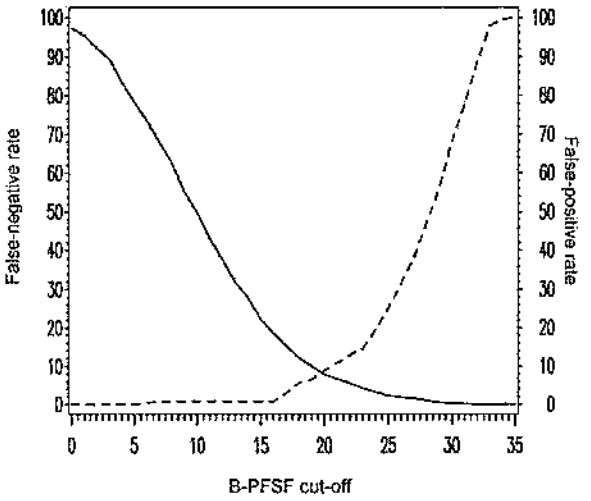

Figure 1. Misclassification rates (——, false-negative rate; – – –, false-positive rate) for potential cut-off scores of the B-PFSF (Brief Profile of Female Sexual Function®).

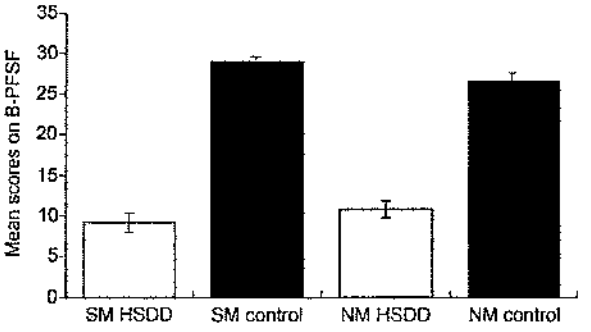

Figure 2. Mean scores on the B-PFSF (Brief Profile of Female Sexual Function®) for surgically menopausal (SM) and naturally menopausal (NM) women with hypoactive sexual desire disorder (HSDD) and age-matched controls. Error bars indicate the standard error.

The mean score for surgically menopausal women with HSDD (mean ± standard error of the mean (SEM): 9.2 ± 0.8) was similar to naturally menopausal women with HSDD (mean ± SEM: 10.8 ± 0.6; $p = 0.12$), illustrating the similarity in scores regardless of etiology, and both were significantly lower than their age-matched controls ($p < 0.0001$ for both).

Figure 3 displays the individual ROC curve for each HSDD group vs. its appropriate control group. Similar curves are seen for each HSDD group illustrating again the similarity in B-PFSF scores, regardless of etiology. Sensitivity and specificity estimates (proportion of correct classification for HSDD women and controls, respectively) and the area under the curve corresponding to the combined surgically and naturally menopausal women with HSDD vs. control women are given in Table II. Excellent discrimination capability and ability to correctly classify subjects was observed in this independent group of women.

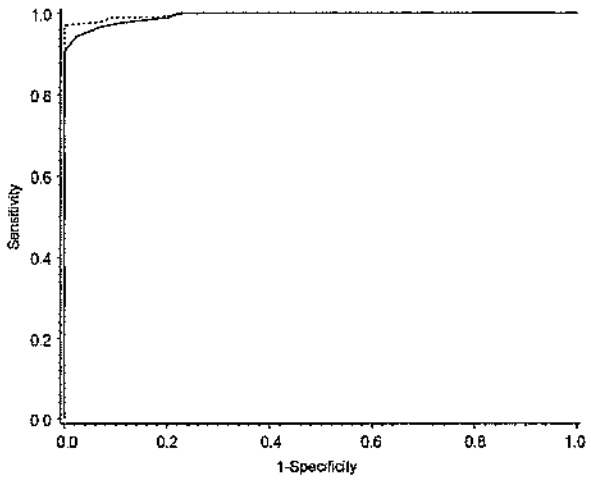

Figure 3. Receiver-operating characteristic curves (area under the curve = 0.99) for discriminating between surgically menopausal (- - - -) and naturally menopausal (—) women with hypoactive sexual desire disorder and age-matched controls.

Convergent validity. The total score on the B-PFSF was highly correlated with domains of the DISF-SR inventory (Pearson correlation coefficients: sexual cognition/fantasy, 0.5; sexual arousal, 0.7; sexual behavior/experiences, 0.6; orgasm, 0.8; drive and relationship, 0.8) and the FSDS (−0.8).

Test–retest and internal consistency reliabilities are given in Table II. The B-PFSF was shown to have a good intraclass correlation coefficient, indicating good temporal stability. Cronbach's α was slightly lower than was seen in the original domains of the PFSF; this is not unexpected as items reflect the underlying but slightly distinct aspects of HSDD, but still represents good internal consistency.

Cut-off validity, patient understanding, and ease of use. A total of 40 postmenopausal women were interviewed in the four cities. Of these, 20 (50%) were naturally menopausal, 19 (48%) were surgically menopausal, and one (2%) did not know. Twenty-one of 40 (52%) women reported during the screening interview that they had normal levels of sexual desire, while the remaining 19 women (48%) reported they had low levels of sexual desire. All the women interviewed agreed that the instructions for completing the instrument were clear and understandable. Consistent feedback indicated that a recall period of 2–3 months was more appropriate in order for them to adequately assess their status. Hence the recall period was rephrased to refer to the last 2–3 months rather than a 30-day recall, as in the original PFSF and PDS instruments. All women were able to

Table II. Discrimination and reliability of the B-PFSF total score.

Group	*n**	Correct classification†	AUC‡	ICC (95% CI)§	Cronbach's α
HSDD	142	137 (96%)	0.99	0.7 (0.6, 0.8)	0.8
Control	100	97 (97%)		0.7 (0.6, 0.8)	0.8

B-PFSF, Brief Profile of Female Sexual Function©; AUC, area under the curve; ICC, intraclass correlation coefficient; CI, confidence interval; HSDD, hypoactive sexual desire disorder; *number of patients with no missing responses on the seven items at initial visit; †correct classification corresponds to B-PFSF score ≤20 for HSDD women and B-PFSF score >20 for controls; ‡AUC corresponds to the overall discriminative capability of the B-PFSF; §ICC based on initial visit and follow-up visit at week 4.

correctly calculate the total score and identify the classification indicated by that score (score ≤20, possible HSDD; score >20, unlikely to have HSDD). One woman with cataracts required assistance to complete the questionnaire.

Most women, irrespective of considering themselves as having HSDD or not, indicated that they thought a questionnaire like this would make it easier to start a conversation with their physician. Two of the women who did not feel it would be useful felt so because they had normal libido and hence saw no need to discuss sexual problems with their physician, while a third woman felt that the form could be more technical and that her physician would not be receptive to her bringing in 'a form'.

When respondents' classifications by B-PFSF scores were compared with the classifications based on screening criteria, 34 of 40 respondents (85%) received identical classifications. Five of the six women who did not have matching classifications were women who were considered normal at screening but who received a score of <20 on the B-PFSF. Four of these women were borderline (scores of 16 and 19, respectively), one of whom was the woman with cataracts, and two women specifically stated that they would probably not talk to their doctors because they really didn't feel they had a problem, demonstrating that they were able to apply their own judgment when interpreting the scores to decide an appropriate course of action. One woman who scored an 11, although she agreed with the item descriptions regarding her level of desire and concern, considered herself normal for someone her age. One woman scored 22 on the B-PFSF who was classified as having low desire by the screening criteria and hence could also be considered borderline. Although based on original screening criteria 15% of women were misclassified, of the 38 women who responded to the question, 36 (95%) indicated that the total score accurately reflected how they saw themselves with regard to their level of sexual desire and concern.

Discussion

Low sexual desire is the most commonly reported sexual complaint in menopausal women in both Europe and the USA [25–27]. Irrespective of the high prevalence, many women appear to have difficulties in bringing the topic of sexual health complaints up when visiting their gynecologist [26,28]. Therefore easy-to-use screening questionnaires that enable women to articulate their sexual complaints will help to establish a common platform for better patient management for these problems.

Currently few standardized tests exist for diagnosing women with HSDD. A Structured Diagnostic Method has been developed to diagnose FSD subtypes, including HSDD. However, this method is time-consuming, up to 1 hour, and requires a physician trained in the methodology to assess the patient [29,30]. Additionally, Quirk and colleagues have developed cut-off scores, based on the Sexual Function Questionnaire (SFQ), for identifying the specific components of FSD [31]. Because the SFQ is an overall sexual function questionnaire it is considerably longer (34 items) than the B-PFSF (seven items) and has not been designed for patient self-assessment.

A recently published brief screening tool for HSDD [32] consists of two sections: a four-item questionnaire completed by the patient, followed by a physician's section to facilitate the interpretation of the assessment results. This tool is mainly targeted for use at physician practices. The items and their format were chosen by a panel of sexual therapists and physicians and then refined based on focus group interviews with patients from the USA and Europe. Additionally, development of the cut-off score was based only on US patients and hence, as noted by the authors, further research is needed to validate this cut-score for use in other countries.

In contrast, the B-PFSF was developed as a self-assessment tool for use by women who are experiencing low sexual desire that is concerning to them to help them decide whether or not to consult a physician. Items for the B-PFSF were derived from previously validated instruments for the measurement of treatment response in women with HSDD. These items reflect the language that women with HSDD use themselves to describe their symptoms and underwent rigorous qualitative validation to ensure linguistic validity across numerous cultures and languages [14–16].

We have created a brief, easy-to-complete, self-administered screening tool to identify postmenopausal women who may benefit from clinical assessment to determine whether they have HSDD. The final seven-item instrument was cross-validated

in an independent set of women and shows good overall discrimination and specificity and sensitivity. The B-PFSF is consistent with the criteria set forth by the DSM-IV for the diagnosis of HSDD [7], in that it includes assessment of decreases in sexual desire, distress associated with low sexual desire, and difficulties in arousal and orgasm. High correlation coefficients between the B-PFSF score and domains of the DISF-SR and the FSDS, previously validated instruments, provide additional evidence of validity. It is interesting to note that the highest correlation coefficients were seen for the drive and relationship domain and the orgasm domain of the DISF-SR and for the FSDS, a distress measure; negative changes in these aspects of sexuality are described in the DSM-IV definition of HSDD [7].

Although the initial cross-validation of the B-PFSF was conducted using responses to the full PFSF and PDS instruments obtained in previous work rather than with the screening tool itself, additional validation of the final screening tool was provided by the cognitive interviews. It has been evaluated in cognitive interviews with women in four countries and was shown to be easy to understand and use. A cut-off of 20 was found to be clinically relevant in categorizing women as possibly having HSDD or not, as this categorization was found to be consistent with the women's own perceptions of their sexual function. Many women categorized as possibly having HSDD reported that use of the screening tool would cause them to consider discussing their sexual complaints with a physician.

Although using a dichotomous classification based upon a cut-off score categorizes women with a range of scores in the same way, the results of cognitive interviews indicated that women were able to use their own judgment and make appropriate decisions concerning whether they should discuss the results with a physician. Women who felt that their responses were normal, regardless of score, did not feel a need to take further action. The brevity of the screening tool (seven items) limits the amount of detail that it can provide on a patient's sexual problems, but brevity also makes the tool easy to use and score, which is desirable for a screening instrument. Importantly, the B-PFSF is capable of identifying women who may benefit from further assessment and the majority of women agreed that such a tool facilitated discussion with their physician on this topic.

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