

The Subjective Sexual Arousal Scale for Men (SSASM): Preliminary Development and Psychometric Validation of a Multidimensional Measure of Subjective Male Sexual Arousal

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ABSTRACT

Introduction. Sexual arousal is a multifaceted process that involves both mental and physical components. No instrument has been developed and validated to assess subjective aspects of male sexual arousal.

Aim. To develop and psychometrically validate a self-administered scale for assessing subjective male sexual arousal.

Methods. Using recommendations of the Food and Drug Administration (FDA) guidance on patient-reported outcome instruments, important aspects of male sexual arousal were identified via qualitative research (focus groups and interviews) of U.S. men with erectile dysfunction (ED) and healthy controls. After a preliminary questionnaire was developed by a panel of experts, a quantitative study of men with ED and controls was conducted to psychometrically validate the Subjective Sexual Arousal Scale for Men (SSASM).

Main Outcome Measures. To develop a male sexual arousal scale and determine its factor structure, reliability, and construct validity.

Results. Five aspects of male sexual arousal were identified from the qualitative focus groups and cognitive interviews. Men's preferred language for describing sexual arousal and preferred response formats were incorporated into the questions. Factor analysis of data from the quantitative study of 304 men aged 21 to 70 years identified five domains with eigenvalues >1: sexual performance (six items), mental satisfaction (five items), sexual assertiveness (three items), partner communication (three items), and partner relationship (three items). The five domains had a high degree of internal consistency (Cronbach's alpha values 0.88–0.94). Test–retest reliability over a 2- to 4-week period was high–moderately high (r values 0.75–0.88) for the five domain scores. Correlations between SSASM domain scores and standardized scale scores for social desirability, general health, life satisfaction, and sexual function demonstrated the construct validity of the scale.

Conclusions. Preliminary validation data suggest that the 20-item SSASM scale may be useful as a multidimensional, reliable, self-administered instrument for assessing subjective sexual arousal in men of different ages. **Althof SE, Perelman MA, and Rosen RC. The Subjective Sexual Arousal Scale for Men (SSASM): Preliminary development and psychometric validation of a multidimensional measure of subjective male sexual arousal. J Sex Med 2011;8:2255–2268.**

Key Words. Patient-Reported Outcomes; Psychological Assessment of Sexual Dysfunction; Questionnaire; Sexual Arousal

Introduction

Erectile dysfunction (ED), a highly prevalent age-related disorder in men, has a significant impact on quality of life, self-esteem, and interpersonal well-being [1–5]. Clinical interest in sexual

pharmacology was greatly increased with the discovery and approval in 1998 of sildenafil citrate, the first phosphodiesterase type 5 (PDE5) inhibitor approved for the treatment of ED [6]. Two other PDE5 inhibitors, vardenafil and tadalafil, were subsequently approved in 2003 for the

treatment of ED [7,8]. The availability of effective and well-tolerated oral therapies for ED, particularly PDE5 inhibitors, has led to a dramatic increase in the number of men seeking treatment [9,10]. It is estimated that 40 million men worldwide are taking PDE5 inhibitors for the treatment of ED [11], and that an additional 50 million men are potential candidates for treatment [10,12–14].

Research that led to the development of PDE5 inhibitors for the treatment of ED was primarily focused on the physiological/mechanical aspects of male sexual function (i.e., penile erection), without due consideration of the role of mental/subjective components, including subjective sexual arousal. More recently, studies of female sexual function and dysfunction have provided important insights on the importance of subjective sexual arousal in sexual function [15,16]. The human sexual response has been traditionally described with a linear sequence model of desire, arousal, orgasm, and resolution [17,18]. However, updated models suggest that the sexual response of mind as well as body has a more complex and variable pattern [19], with subjective arousal sometimes preceding sexual desire [20].

Male sexual arousal has been historically described as a central physiological state, with penile erection in a sexual context as its most valid objective measure [21]. Bancroft defines sexual arousal as a state that is motivated toward experiencing sexual pleasure and possibly orgasm, which involves the processing of relevant stimuli, general arousal, incentive motivation, and genital response [22]. A multifaceted process of male sexual arousal is supported by functional magnetic resonance imaging data indicating different patterns of brain stimulation during sexual arousal, penile tumescence, and penile erection in healthy male volunteers [23]. Furthermore, studies in men without sexual dysfunction have demonstrated that penile erection is not always highly associated with subjective mental aspects of sexual arousal [24,25]. Based on these findings, a lack of subjective sexual arousal may explain why some men with ED fail to respond to treatment with PDE5 inhibitors despite having the physiological ability to achieve and maintain an erection.

Major advances have been made in our understanding of the neurophysiology and endocrinology of sexual arousal [26,27] and the effects of various pharmacological agents on centrally mediated aspects of sexual arousal in men and women [28–30]. Although clinical and basic research has focused on the physiological effects of peripherally

acting agents, such as PDE5 inhibitors, increased interest has developed in the psychological and subjective effects of agents that act on the central nervous system, particularly dopamine agonists and α -melanocortin agonists [31–33], which appear to influence subjective and genital aspects of sexual arousal. Medications that can improve both the subjective/mental and physiological/mechanical aspects of male sexual function may provide a more complete and effective approach to the treatment of ED.

Various validated instruments are available for assessing erectile function, including the widely used International Index of Erectile Function (IIEF) [34]. However, the IIEF focuses on the physiological aspects of erectile function, with only a limited assessment of the mental, psychological, and partner-related aspects of sexual function [35]. We believe that both the physiological and subjective components of male sexual function should be assessed. A scale that assesses subjective aspects of male sexual arousal could be a valuable tool in research designed to assess sexual arousal in healthy men and investigate the therapeutic effects of agents that act on the central nervous system in men with ED and other types of sexual dysfunction.

Aim

The aim of this study was to develop and psychometrically validate a self-administered measure of subjective male sexual arousal using qualitative and quantitative research criteria recommended in the guidance from the FDA on patient-reported outcome instruments [36].

Methods

Two studies were conducted to develop and psychometrically validate the Subjective Sexual Arousal Scale for Men (SSASM). A qualitative study was designed to identify important aspects of male sexual arousal, to reduce the number of items in a preliminary scale, and to evaluate men's comprehension of the items and preferred language and response formats. A quantitative validation study evaluated the factor structure, reliability, and convergent and divergent validity of a shortened questionnaire developed by a panel of experts based on the findings from the qualitative study. Both studies were approved by the Institutional Review Board of the New England Research Institutes, Inc. (Watertown, MA, USA) and conducted in accordance with Good Clinical Practice guidelines.

Table 1 Main inclusion and exclusion criteria of qualitative and quantitative studies

Study	Inclusion criteria	Exclusion criteria
<i>Qualitative Study</i>		
	Men aged 21–70 years who provided informed consent	Any medical condition with an impact on sexual function or severe impact on daily life
	Heterosexual and in a relationship with a woman with sex occurring ≥ 2 times in previous month, including vaginal intercourse ≥ 1 time	Psychiatric condition or use of psychotropic drugs or androgens
	Control (no ED) Group: No lack of sexual desire, difficulty achieving or maintaining an erection, or premature ejaculation during past 2 years IIEF-5 score ≥ 22 Never taken any ED therapy	Current alcohol or drug abuse
	PDE5 Inhibitor Group: Difficulty achieving or maintaining an erection during past 2 years IIEF-5 score ≥ 22 with PDE5 inhibitor treatment	Present or previous employment in fields of advertising, media, healthcare, pharmaceuticals, or market research
	Bremelanotide Group: IIEF-5 score ≥ 22 at end of clinical trial and a ≥ 5 -point improvement in IIEF-5 score during bremelanotide treatment	
<i>Quantitative Study</i>		
	Men aged 21–70 years in good general health (hypertension and/or diabetes allowed) who provided informed consent	Major medical condition that severely impacts physical/mental functioning or hospitalization during past 30 days
	In an ongoing sexual relationship with a female partner for ≥ 6 months and living with or spending time with partner on ≥ 2 occasions per week	History of prostate cancer, prostatectomy, condition requiring pelvic surgery or radiation, or penile implant/prosthesis
	Age-Matched Control (no ED) Group: No ED within 6 months Never taken ED therapy IIEF-5 score ≥ 22 Successful sexual activity on ≥ 2 occasions during past 4 weeks	Use of nitrates, psychotropic drugs, or hormonal therapy for ≤ 6 months prior to study
	ED Group: Difficulty achieving or maintaining erection for ≥ 6 months IIEF-5 score < 22 ~50% of men previously received ED therapy, but not within 3 months of study ~50% of men had not previously received any ED therapy	4 alcoholic drinks per day for ≥ 5 days per week during the past 6 months or a history of alcohol or drug abuse for ≥ 2 years prior to study

ED = erectile dysfunction; IIEF-5 = 5-item International Index of Erectile Function; PDE5 inhibitor = phosphodiesterase type 5 inhibitor.

Qualitative Study

Participants were informed during recruitment that the purpose of this study was research and that the information that they provided would be kept confidential. Men who met eligibility criteria provided written informed consent.

Phase I

From May through August 2006, 10 focus groups and 20 in-depth individual interviews of men who had taken the melanocortin-4 agonist bremelanotide in clinical trials, men taking a PDE5 inhibitor for the treatment of ED, and men with no sexual function problems were held at facilities in four U.S. cities (Edison, NJ; Hollywood, FL; Torrance, CA; and San Antonio, TX, USA). Of the four focus groups of men with no sexual function problems, two were conducted with men aged 21 years to 45 years, and two were conducted with men aged 46 years to 70 years. Among men who

had taken bremelanotide in clinical trials, four additional in-depth interviews were held in New York, NY, USA, and Newport Beach, CA, USA, and 10 additional in-depth interviews were conducted by telephone. Subjects were recruited and screened for eligibility by The Henne Group (San Francisco, CA, USA). During the telephone screening process, men aged 21 years to 70 years who met the prespecified inclusion and exclusion criteria were identified (Table 1). Participants discussed eight preliminary aspects of male sexual arousal (i.e., desire, vitality-energy-youth-well-being, self-concept, sexual arousal, mood, sexual attractiveness, mental satisfaction-orgasm, and intensity) that had been identified based on anecdotal input from men enrolled in bremelanotide clinical trials and the advice of an expert panel¹ in

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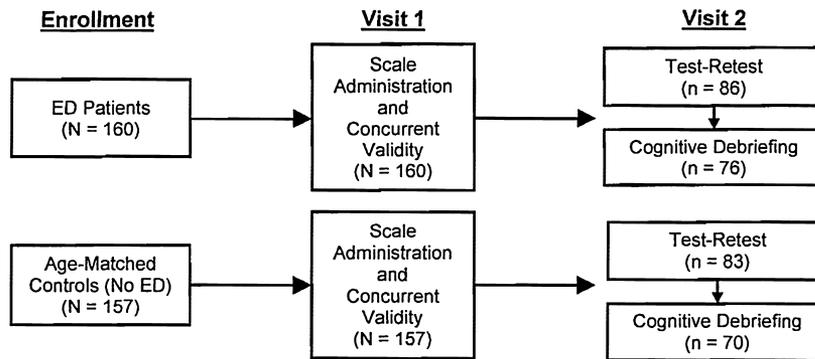


Figure 1 Design of the Quantitative Validation Study.

the field of male sexual function. In phase 1, participants also discussed some questions on each of these topics from a preliminary questionnaire, including their impressions of the types of questions, word choices, and response formats, and any questions missing from the scale.

Phase 2

In September 2006, 25 in-depth interviews of men who had taken bremelanotide in clinical trials (N = 15 via telephone), men taking the PDE5 inhibitor tadalafil for the treatment of ED (N = 5 at a focus group facility in New York, NY), and men with no sexual function problems (N = 5 at a focus group facility in New York, NY) were conducted. Men taking tadalafil were selected for the in-depth interviews based on reports that this long-acting PDE5 inhibitor had a greater effect on psychological aspects (i.e., self-confidence, spontaneity) of ED than sildenafil [37–39]. Six of the 15 interviews of men in the bremelanotide group were among men who had been interviewed during phase 1. Subjects were recruited and screened via telephone by The Henne Group, using the same eligibility criteria used in phase 1 (Table 1).

Based on phase 1 findings, the eight preliminary aspects of male sexual arousal were reduced to the following five domains: sexual desire and arousal, sexual self-concept, mood-feelings, mental satisfaction with sexual experience, and communication-overall relationship. The three groups of men then completed different preliminary questionnaires, with the questionnaires completed by the bremelanotide users and the tadalafil users containing specific wording to describe each agent (e.g., “while using the nasal spray” or “while using tadalafil”). Participants were compensated for their participation in the study. The findings from the focus groups and interviews were coded and qualitatively analyzed using grounded theory [40], a methodology that uses observational data to generate a

reverse-engineered hypothesis. Guided by the data (e.g., clarity vs. confusion of each question and response set), the panel of experts developed a shortened SSASM for psychometric validation.

Quantitative Validation Study

The design of the quantitative validation study of heterosexual men is shown in Figure 1. The protocol included two visits and was based on the administration of a preliminary SSASM and other validated questionnaires to men with or without ED in two age groups (i.e., 21 to 50 years and 51 to 70 years). Telephone screening of men from 15 geographically diverse U.S. cities (Philadelphia, Phoenix, Boston, Chicago, Dallas, Los Angeles, Edison, New York, San Francisco, Atlanta, Orlando, Cincinnati, Seattle, St Louis, and Miami) was conducted by The Henne Group. During the screening process, respondents were informed that the research addressed sexual health issues and that participation in the study would involve attending a 60-minute study visit and that a group of men would be randomly selected to participate in a second visit.

Subjects provided verbal consent for telephone screening. For respondents who agreed to participate in the screening interview, further demographic and medical information was requested. The main inclusion and exclusion criteria for enrollment in the study are listed in Table 1. All eligible subjects provided written informed consent for participation in the study. A unique identification number was provided to each eligible subject. Subject numbers contained information assigning the number of visits, the recall version (7 days or 30 days) of the SSASM to be filled out first at Visit 2, the version of the cognitive debriefing interview that would be administered, the subject’s age group, and whether the subject was a control or a patient with ED. Equal groups of eligible men with ED and with normal

sexual function were invited to attend Visit 1. At Visit 1, all subjects completed a questionnaire booklet in a private setting, including a preliminary SSASM, the 15-item IIEF (a validated self-report measure of male sexual function that focuses on erection ability and maintenance) [34], a five-item measure of social desirability (SDRS-5; a validated measure of an individual's tendency to provide socially responsible responses) [41], the SF-12 health survey, and the Life Satisfaction Scale (LSS; a validated, eight-domain, self-report measure of social indicators of an individual's well-being and satisfaction) [42], which took approximately 60 minutes to complete. A site coordinator reviewed each booklet and asked participants to complete any unanswered questions.

The second portion of the visit included a telephone debriefing interview at one of the sites, with subjects given simple written instructions regarding the interview, which took place by telephone in a private office. Subjects had their questionnaire booklet to use as a reference during this interview; however, the site coordinator removed any pencils or pens from the room so that subjects could not alter any responses. Subjects were informed that the telephone interview would be audio recorded and transcribed, but that their names would not be linked to their comments in the written transcript. The cognitive debriefing interviews, which lasted approximately 30 minutes, were designed to assess the men's reactions to questions on the preliminary SSASM questionnaire. The interview questions used the 30-day recall version of the SSASM and included two questions on the men's reactions to the 30-day and 7-day recall time frames. Following the telephone interview, the men returned the questionnaire booklets to the site coordinator, who confirmed the visit date and time for those subjects selected to participate in Visit 2.

At Visit 2, subjects completed two SSASM questionnaires with alternate recall periods (30 days and 7 days administered in a randomized, counterbalanced order) to obtain test-retest reliability data. At the end of Visit 2, a telephone-based, cognitive debriefing interview of each of the men ($N = 169$) was conducted. The objectives of the cognitive debriefing interviews were: (i) to confirm the content validity of the scale via questions on participants' comprehension, rating choice, and thoughts on the response categories for the items of the preliminary scale; (ii) to assess how well the items reflected the participants' experiences; (iii) to identify any missing topics; (iv) to

assess the validity of the time frame mentioned in the items; and (v) to determine the participants' general comfort with answering the items. Participants were compensated for their participation in the study.

A principal components analysis, using the maximum likelihood method with varimax rotation, via the FACTOR procedure of SAS software version 9.1 (SAS Institute, Inc., Cary, NC, USA), was performed on the ordinal items of the preliminary SSASM questionnaire for men with complete data for all items, after eliminating items that demonstrated a high degree of redundancy (inter-item correlation coefficient of >0.75) or items that did not discriminate between the men with ED and the age-matched controls (i.e., insignificant difference in item scores using analysis of variance). The factor analysis was performed iteratively, such that items that did not load highly on any factor were removed at each stage of the analysis.

The reliability of the SSASM was evaluated by computing Cronbach's alpha values [43] (internal consistency) and Pearson product-moment correlation coefficients (test-retest reliability of Visit 1 and Visit 2 scores) for each domain. The construct (convergent and divergent) validity of the scale was assessed by calculating the Pearson product-moment correlation coefficients for domain scores with scores for the SDRS-5, SF-12, IIEF domains, and LSS domains. As the gold standard for assessing erectile function, the IIEF would be expected to be positively associated with some domains of the SSASM (convergent validity). Both instruments assess components of male sexual function, with the IIEF focusing on the penile response and the SSASM focusing on mental/subjective arousal. In contrast, the SDRS-5, SF-12, and LSS, which primarily assess conceptually independent variables, would not be expected to correlate highly with the SSASM (divergent validity).

Main Outcome Measures

To develop and psychometrically validate a new, self-administered instrument for assessing subjective male sexual arousal, qualitative and quantitative studies were conducted to identify important aspects and domains of subjective male sexual arousal among men who reported normal sexual function and those with ED, to select questions and responses for inclusion in the SSASM, and to evaluate the factor structure, reliability, and construct validity of the scale.

Table 2 Characteristics of 304 men with complete data in quantitative validation study

Characteristic	21–50 years		51–70 years		All men
	Controls N = 78	ED patients N = 79	Controls N = 72	ED patients N = 75	N = 304
Age, years					
Mean (SD)	37.2 (8.1)	38.9 (8.4)	57.1 (4.7)	57.8 (5.4)	47.5 (11.9)
Range	22–50	21–50	51–69	51–70	21–70
Comorbidities					
1 condition	14 (17.9)	13 (16.5)	19 (26.4)	12 (16.0)	58 (19.1)
≥2 conditions	2 (2.6) 1(0)	2 (2.6)	4 (5.6)	7 (9.35.3)	15 (5.0)
Premature Ejaculation	4 (5.1)	46 (59.0)	1 (1.4)	23 (30.7)	74 (24.4)
Lost sexual desire In last 2 years	0 (0)	44 (55.7)	0 (0)	44 (58.7)	88 (28.9)
IIEF-5 score					
Mean (SD)	24.4 (0.9)	16.0 (3.3)	24.3 (0.9)	15.3 (3.8)	20.0 (5.1)
Range	22–25	9–20	22–25	5–20	5–25
Race/ethnicity, N (%)					
White/Anglo	53 (68)	40 (51)	54 (75)	51 (68)	198 (65)
African American	12 (15)	29 (37)	12 (17)	13 (17)	66 (22)
Hispanic/Latino	11 (14)	8 (10)	5 (7)	7 (9)	31 (10)
Asian	1 (1)	2 (3)	1 (1)	2 (3)	6 (2)
Other	3 (1)	0	0	2 (3)	3 (1)
Marital status, N (%)					
Married	41 (53)	38 (48)	59 (82)	49 (65)	187 (62)
Divorced	6 (8)	5 (6)	3 (4)	5 (7)	19 (6)
Separated	1 (1)	1 (1)	0	3 (4)	5 (2)
Widowed	0	0	1 (1)	0	1 (<1)
Single	30 (38)	35 (44)	9 (13)	18 (24)	92 (30)
Education, N (%)					
<High school	1 (1)	0	1 (1)	0	2 (1)
High school grad	7 (9)	12 (15)	5 (7)	6 (8)	30 (10)
Trade school	0	1 (1)	2 (3)	2 (3)	5 (2)
Some college	20 (26)	26 (33)	14 (19)	23 (31)	83 (27)
AA degree	4 (5)	7 (9)	3 (4)	5 (7)	19 (6)
College grad	39 (50)	28 (35)	22 (31)	26 (35)	115 (38)
>College	7 (9)	5 (6)	25 (35)	13 (17)	50 (16)

Percentages may not total 100% due to rounding. IIEF-5 = 5-item International Index of Erectile Function.

Results

Subjects

The baseline characteristics of the 304 men with complete data in the quantitative validation study are summarized in Table 2. The men were a diverse group recruited from 15 sites across the continental United States. The subjects had a mean age of 47 years and a mean IIEF-5 score of 20. Overall, the men were relatively healthy, with only 24% reporting other existing medical conditions. The majority of the men reported only one comorbid condition. Diabetes was the most frequently reported comorbid medical condition, which was more common in patients than in controls. The men in the patient groups also reported a greater incidence of lost desire during the past 2 years and premature ejaculation than the control men. The majority of the men were married (62%), had at least a college degree (54%), and reported an annual income of >\$60,000.

Qualitative Study

A total of 317 men met participation criteria and completed all aspects of Visit 1. Of 205 men invited to attend Visit 2, which was held 2 to 4 weeks after Visit 1, 169 completed all aspects of Visit 2. Five preliminary domains of male subjective sexual arousal were identified by the analysis of the findings from the focus groups and in-depth interviews of phase 1 of the qualitative study: (i) sexual desire and arousal; (ii) sexual self-concept; (iii) mood-feelings; (iv) mental satisfaction with sexual experience; and (v) communication-overall relationship. In phase 2, all of the questions were interpreted in the same manner by men who had taken bremelanotide in clinical trials, men taking tadalafil for the treatment of ED, and men with no sexual function problems. In general, the men preferred a seven-point response scale, often misunderstood questions written from a negative perspective, and failed to notice a difference

Table 3 Factor analysis of 20-item subjective sexual arousal scale for men (SSASM)

Item (item number)	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
EASE OF MAINTAINING ERECTION (11)	0.817	0.259	0.252	0.174	0.157
EASE OF GETTING ERECTION (1)	0.759	0.312	0.248	0.154	0.157
HARDNESS SATISFACTION (14)	0.766	0.232	0.273	0.240	0.123
CONTROL OF SEXUAL PERFORMANCE (3)	0.699	0.361	0.337	0.218	0.156
EASE OF REACHING ORGASM (12)	0.634	0.372	0.213	0.184	0.177
START ERECTION WITHOUT TOUCH (2)	0.549	0.225	0.294	0.186	0.081
SATISFIED AFTER SEX (9)	0.411	0.663	0.292	0.145	0.288
CONTENTED AFTER SEX (10)	0.416	0.659	0.264	0.164	0.272
HAPPY DURING SEX (7)	0.388	0.646	0.239	0.252	0.167
PLEASURE DURING ORGASM (13)	0.474	0.554	0.296	0.260	0.163
SATISFACTION WITH TENSION RELEASE AFTER SEX (15)	0.354	0.572	0.213	0.183	0.234
FELT SEXUALLY VIGOROUS (5)	0.413	0.253	0.820	0.154	0.109
FELT READY FOR SEX (4)	0.433	0.225	0.738	0.109	0.173
CONFIDENT INITIATING SEX (6)	0.296	0.301	0.696	0.255	0.132
COMFORTABLE TALKING WITH PARTNER (19)	0.210	0.171	0.146	0.843	0.238
COMFORTABLE ASKING PARTNER (18)	0.207	0.204	0.142	0.788	0.261
SATISFACTION WITH COMMUNICATION ABOUT SEX WITH PARTNER (20)	0.303	0.187	0.207	0.603	0.391
FELT CLOSE TO PARTNER (16)	0.170	0.188	0.146	0.228	0.923
ENJOYED TIME WITH PARTNER (17)	0.106	0.207	0.079	0.350	0.750
FELT CLOSE TO PARTNER AFTER SEX (8)	0.208	0.470	0.150	0.234	0.525
Eigenvalue	122.47	31.72	6.77	5.14	2.59

Items with the highest loadings for each domain are boldfaced.

between responses using a disagree-to-agree and dissatisfied-to-satisfied format. Interestingly, interviews of men taking the peripherally acting tadalafil seemed to suggest that they had increased confidence in their ability to perform sexually that resulted in increased sexual desire, whereas interviews of men who had taken the centrally acting melanocortin-4 agonist bremelanotide suggested that they had an increase in confidence in conjunction with or after an increase in sexual desire. Using a convergence method, 73 ordinal items for assessing subjective male sexual arousal were identified based on findings from phase 2 of the qualitative study and expert panel opinion.

Quantitative Validation (Study 2)

Factor Analysis

A principle components analysis with varimax rotation investigated the factor structure of the 73-item preliminary SSASM questionnaire, using data from 304 subjects who completed all of the items. Seven items that did not discriminate between the men with ED and the age-matched controls were not included in the factor analysis. The factor analysis was performed iteratively, such that items that did not load highly on any factor or were redundant with other items in the analysis were removed at each stage of the analysis. Overall, 53 items were removed from the scale. For the remaining 20 items, five factors with eigenvalues ranging from 122.47 to 2.59 were identified (Table 3). The final 20 items of the

SSASM comprised five domains: (i) sexual performance domain (six items); (ii) mental satisfaction domain (five items); (iii) sexual assertiveness domain (three items); (iv) partner communication domain (three items); and (v) partner relationship domain (three items).

No significant cross-loading of items on multiple factors was observed, with the exception that items in the mental satisfaction domain also exhibited moderately high loading on the sexual performance domain. The cross-loading of these domains was not unexpected, given the role that sexual performance plays in mental satisfaction. Overall, the factor solution revealed three important constructs: physical sex (domains i and iii); emotional sex (domain ii); and interpersonal sex (domains iv and v), thereby illustrating the multifaceted nature of subjective male sexual arousal.

Separate factor analyses of data from men with ED and age-matched controls indicated eigenvalues ranging from 37.19 to 2.15 for men with ED and from 54.10 to 2.16 for controls. The eigenvalues were generally lower in each of the subgroups than for the entire sample, but the solution fit well for both subgroups of men.

Domain scores were calculated by summing the scores of the individual items in each domain (Table 4), with higher scores representing greater sexual arousal. The highest positive correlation was between the sexual performance domain and the mental satisfaction domain (Table 5). Unlike

Table 4 Domain scoring in quantitative validation study*

	Number of items	Item score range	Domain score range	Mean (SD) score N = 304
SPD	6	1–7	6–42	29.81 (9.74)
MSD	5	1–7	5–35	26.87 (7.09)
SAD	3	1–7	3–21	13.74 (4.63)
PCD	3	1–7	3–21	15.51 (4.63)
PRD	3	1–7	3–21	16.79 (4.17)

*Higher domain scores indicate better subjective aspects of sexual desire and arousal.

SPD = sexual performance domain; MSD = mental satisfaction domain; SAD = sexual assertiveness domain; PCD = partner communication domain; PRD = partner relationship domain.

other sexuality scales, no total score is summed over the five domains.

Scale Reliability

The Cronbach's α values observed for the entire sample demonstrated adequate internal consistency, with the lowest Cronbach's α value (0.88 for the partner relationship domain) above the 0.80 cutoff value indicative of good internal consistency (Table 6). A high degree of internal consistency also was found for men with ED and age-matched controls, with Cronbach's α values ranging from 0.87 to 0.91 for men with ED and 0.85 to 0.90 for the controls. Similar results were observed among men aged 21 to 50 years and those aged 50 to 70 years.

Table 5 Domain intercorrelations

Domain	SPD	MSD	SAD	PCD	PRD
SPD	1.00				
MSD	0.80	1.00			
SAD	0.73	0.70	1.00		
PCD	0.57	0.59	0.51	1.00	
PRD	0.50	0.64	0.45	0.64	1.00

SPD = sexual performance domain (6 items); MSD = mental satisfaction domain (5 items); SAD = sexual assertiveness domain (3 items); PCD = partner communication domain (3 items); PRD = partner relationship domain (3 items).

Table 6 Domain characteristics: reliability

Domain	Internal consistency*			Test-retest reliability†					
	All men N = 304	ED patients N = 154	Controls N = 150	All men N = 155		ED patients N = 84		Controls N = 69	
				7-day N = 155	30-day N = 156	7-day N = 84	30-day N = 87	7-day N = 71	30-day N = 69
SPD	0.94	0.87	0.85	0.86	0.88	0.72	0.77	0.77	0.78
MSD	0.92	0.90	0.85	0.82	0.84	0.73	0.75	0.76	0.80
SAD	0.93	0.91	0.90	0.68	0.77	0.52	0.64	0.67	0.77
PCD	0.90	0.90	0.89	0.78	0.77	0.74	0.69	0.77	0.84
PRD	0.88	0.87	0.86	0.75	0.76	0.70	0.72	0.70	0.69

*Cronbach's alpha.

†Pearson product-moment correlation coefficient for 7-day or 30-day recall period.

All five domains scores demonstrate good test-retest reliability (Table 6), with a correlation of at least 0.76 between the scores at the two visits among all subjects completing the 30-day recall period questionnaire. The test-retest correlations for the domains among all subjects were comparable for the 7-day and the 30-day recall periods, with the exception of the sexual assertiveness domain ($r = 0.77$ for 30-day recall vs. $r = 0.68$ for 7-day recall). The men with ED had slightly more variable responses over time than those of the age-matched controls, with the exception of the partner relationship domain. Younger men had slightly lower test-retest correlations than older men, with the exception of the partner relationship domain.

Convergent and Divergent Validity

Correlation coefficients between SDRS-5 scores and domain scores of the SSASM ranged from 0.15 to 0.30, indicating that the scale items were not responded to in a socially desirable manner and demonstrating the divergent validity of the scale (Table 7). Likewise, the SF-12 scores for physical and mental health did not correlate strongly with any of the SSASM domain scores. Scores for the eight domains of the LSS also had a low degree of correlation with the SSASM domain scores, with the exception of the sexual life domain (r values 0.60 to 0.76). The relationship domain score of the LSS was only moderately correlated with the scores for the two partner-related SSASM domains, indicating that the scales are not redundant. With the exception of the sexual desire domain, scores for the domains of the IIEF demonstrated moderate-to-high correlation with scores for the SSASM domains. As expected, some redundancy between the SSASM sexual performance domain and the IIEF erectile function domain was indicated ($r = 0.82$). The correlations between the SSASM domain scores and scores for

Table 7 Domain characteristics: convergent and divergent validity*

Scale	SSASM domain				
	SPD	MSD	SAD	PCD	PRD
SDRS-5 (N = 304)	0.15	0.25	0.19	0.21	0.3
SF-12 (N = 147)					
Physical	0.38	0.29	0.36	0.21	0.23
Mental	-0.39	-0.37	-0.35	-0.36	-0.36
IIEF Domains (N = 157)					
Erectile function	0.82	0.75	0.64	0.51	0.48
Orgasmic function	0.6	0.65	0.51	0.43	0.38
Sexual desire	0.38	0.4	0.51	0.27	0.23
Intercourse satisfaction	0.64	0.68	0.63	0.49	0.51
Overall satisfaction	0.75	0.72	0.62	0.67	0.6
LSS (N = 157)					
Whole life	0.37	0.38	0.33	0.36	0.38
Sexual life	0.76	0.76	0.66	0.67	0.6
Relationship	0.37	0.4	0.29	0.56	0.7
Family life	0.21	0.23	0.16	0.34	0.4
Contacts	0.16	0.21	0.14	0.24	0.22
Leisure	0.24	0.24	0.26	0.3	0.26
Vocational	0.18	0.18	0.2	0.16	0.26
Financial	0.2	0.14	0.09	0.17	0.14

*Values represent Pearson-product-moment correlation coefficients. SPD = sexual performance domain (6 items); MSD = mental satisfaction domain (5 items); SAD = sexual assertiveness domain (3 items); PCD = partner communication domain (3 items); PRD = partner relationship domain (3 items). IIEF = International Index of Erectile Function; LSS = Life Satisfaction Scale; SDRS-5 = 5-item measure of social desirability; SF-12 = 12-item subset of the SF-36 Health Survey.

the SDRS-5, SF-12, and the LSS were generally lower for men with ED than for age-matched controls or the entire sample. Overall, these analyses demonstrated the high degree of construct validity of the SSASM.

Cognitive Debriefing

The results of the qualitative cognitive debriefing interviews suggested that the participants interpreted the majority of the questions as they were intended (79%), had no difficulty rating the individual questions ($\geq 75\%$), were comfortable answering the questions asked regarding the questionnaire (70%), and had no difficulty with the seven-point response scales (95%). Regarding the recall time frame, 42% indicated no preference between the 7-day and 30-day recall period, 41% preferred the 7-day recall, and 17% preferred the 30-day recall.

Discussion

A 20-item, multidimensional, self-administered SSASM was developed and validated for assessing subjective male sexual arousal. This instrument was developed in stages, as described in the FDA guidance [36], using both qualitative and quantitative research studies of men with ED and age-

matched controls, together with the input of a panel of experts on male sexual function. After collecting data on important aspects of subjective male sexual arousal and the preferred language and response formats for individual items from men who had been treated with bremelanotide (a centrally acting agent affecting sexual arousal), men taking tadalafil for the treatment of ED, and men with no sexual function problems, preliminary domains of subjective male sexual arousal were identified. Based on this qualitative data, an expert panel developed a 73-item preliminary scale for psychometric testing. From these 73 items, factor analysis using a varimax rotation yielded 20 items that loaded on five factors or domains: sexual performance domain, mental satisfaction domain, sexual assertiveness domain; partner communication domain, and partner relationship domain. The varimax rotation allowed us to “force” items into the hypothesized factors and to test for homogeneity of items within factors. No assumptions were made regarding inter-domain correlations for this initial factor analysis. Further psychometric validation of the final 20-item SSASM demonstrated its strong internal consistency, test-retest reliability, and construct validity. The variability observed in test-retest reliability of the sexual assertiveness domain for men with ED appeared to be related to the recall period and possibly the ED severity category of the group. Men with mild or moderate ED would be expected to report some variability in their sexual assertiveness. Validated self-administered questionnaires for assessing sexual function, which can help physicians evaluate patients with ED and other types of sexual dysfunction, are standardized and generally easy for patients to complete without embarrassment. However, the results of self-administered questionnaires should be used in conjunction with a detailed medical and sexual history, physical examination, and supportive patient-physician communication [44].

The SSASM represents the first validated instrument that specifically focuses on assessing subjective male sexual arousal. In humans, sexual arousal is a multifaceted process that is dependent on neural, hormonal, genetic, cultural, and psychological factors [26,45]. Currently available medical treatments for ED, including oral PDE5 inhibitors, were developed based on their ability to facilitate achieving and maintaining an erection sufficient for satisfactory sexual performance. Likewise, various validated instruments used in the assessment of ED, including the gold standard

IEEF, focus on the physical aspects of male sexual arousal and do not capture important subjective aspects of sexual function. This focus on physical male sexual arousal without assessing important mental and psychological aspects may explain, in part, the high rate of discontinuation of current treatments by men with ED [46]. Therefore, assessments of partner communication and the partner relationship, which can play an important role in sexual function [47–49], together with other subjective aspects of male sexual arousal, should contribute to a broader understanding of sexual function. With increased understanding of the peripheral and central mechanisms involved in male sexual arousal, desire, and penile erection, new treatment options and combination therapies may play a role in the treatment of ED [50]. The current preliminary results suggest that the SSASM may be a valuable new tool for assessing men with ED in clinical trials and clinical practice settings, as it provides a unique measure of subjective aspects of male sexual arousal.

Other self-report instruments have been developed that include assessments of subjective sexual arousal (e.g., the Sexual Arousal and Desire Inventory [51] and the Multiple Indicators of Subjective Sexual Arousal [52]), but none specifically focuses on sexual arousal in men of different ages and socioeconomic backgrounds and none was developed based on input from healthy men and men with ED. Therefore, use of the SSASM in conjunction with instruments measuring erectile function should provide a more complete assessment of sexual arousal and function in healthy men and men with ED.

Some limitations of the SSASM should also be discussed. The studies described were conducted using a convenience sample of heterosexual men that may not be representative of the general population. A confirmatory factor analysis is needed to test the fit of the model suggested by the results of the initial factor analysis. The instrument was designed to assess subjective male sexual arousal in heterosexual men with ED and healthy controls. Therefore, additional studies are needed to evaluate its validity in other populations of men, including homosexual men and men with hypoactive sexual desire or ejaculatory dysfunction. Furthermore, the SSASM has been psychometrically validated only in U.S. English-speaking men, so additional studies are needed to assess its linguistic and cultural validation in men from other countries. Further studies also would be needed to determine if the qualitative difference observed

between a peripherally acting PDE5 inhibitor and a centrally acting α -melanocortin agonist with respect to the temporal relationship of sexual desire and sexual confidence can be confirmed.

Conclusions

The 20-item SSASM represents the first validated instrument with a focus on assessing subjective male sexual arousal in men with ED in a clinical trial setting. Preliminary validation data suggest that the SSASM is a brief, self-administered, multidimensional, reliable instrument that may be useful for measuring subjective sexual arousal in men of various ages and socioeconomic backgrounds.

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Appendix

Individual items of the 20-item Subjective Sexual Arousal Scale for Men (SSASM) and response options

Please circle the number that best describes how much you agree or disagree with the following statements about your sexual arousal. As indicated, answer each question by thinking about the past 30 days.
 If you were not sexually active during the last 30 days, answer the questions for the most recent 7 day period during which you were sexually active.

1. It was easy for me to get an erection during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

2. I was able to start to become erect without me or my partner touching me during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

Please circle the number that best describes how much you agree or disagree with the following statements about the way you felt about your sexuality. Answer each question thinking about the past 30 days.

3. I felt in control of my sexual performance during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

4. I felt ready and energized for sex during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

5. I felt sexually vigorous during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

6. I felt like I was able to initiate sex with confidence during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

Please circle the number that best describes how much you agree or disagree with the following statements about the feelings you experienced before, during, or after sex. Answer each question thinking about the past 30 days.

7. I felt happy while having sex during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

8. I felt close to my partner after sex during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

9. I felt satisfied after sex during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

10. I felt contented after sex during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

Please circle the number that best describes your mental satisfaction or dissatisfied satisfaction with the following. Answer each question thinking about the past 30 days.

11. Ease of maintaining an erection long enough to perform sexually during the past 30 days.

1	2	3	4	5	6	7
Extremely Dissatisfied			Neither Satisfied Nor Dissatisfied			Extremely Satisfied

12. Ease of reaching an orgasm during the past 30 days.

1	2	3	4	5	6	7
Extremely Dissatisfied			Neither Satisfied Nor Dissatisfied			Extremely Satisfied

13. Pleasure during orgasm during the past 30 days.

1	2	3	4	5	6	7
Extremely Dissatisfied			Neither Satisfied Nor Dissatisfied			Extremely Satisfied

14. The hardness of your penis during the past 30 days.

1	2	3	4	5	6	7
Extremely Dissatisfied			Neither Satisfied Nor Dissatisfied			Extremely Satisfied

15. Release of your physical tension after sex during the past 30 days.

1	2	3	4	5	6	7
Extremely Dissatisfied			Neither Satisfied Nor Dissatisfied			Extremely Satisfied

Please circle the number that best describes how much you agree or disagree with the following statements about overall relationship and communication with your partner. Answer each question thinking about the past 30 days.

16. I felt close to my partner during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

17. I enjoyed spending time with my partner during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

18. I felt comfortable asking my partner for things I wanted sexually during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

19. I felt comfortable talking about sex with my partner during the past 30 days.

1	2	3	4	5	6	7
Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree

20. Considering everything, how satisfied have you been with the communication that you and your partner have had about sex during the past 30 days?

1	2	3	4	5	6	7
Completely Dissatisfied			Neither Satisfied Nor Dissatisfied			Completely Satisfied

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