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Review Article

The use of patient–reported outcome measures in assessing the prevalence and tolerance of SSRI–related sexual dysfunction: a systematic review

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Abstract

Introduction: **Selective serotonin reuptake inhibitors (SSRIs) are associated with sexual dysfunction (SD) which can impact patient wellbeing and treatment compliance. Patient–reported outcome measures (PROMs) can be valuable in ensuring sexual functioning is robustly assessed in clinical practice and research. The current review aims to synthesize and evaluate the evidence base regarding the use of PROMs in assessing SSRI-related SD.**

Methods: **A systematic literature review was conducted using EMBASE, MEDLINE Ultimate, PsycINFO, CINAHL Ultimate, and OpenDissertations to identify which sexual functioning PROMs have been used to assess SSRI-related SD, and what the results indicate regarding the prevalence and tolerance of SD.**

Results: **Twenty seven articles were eligible for inclusion, and the results were evaluated and summarized using a narrative and visual synthesis. Ten PROMs were identified, varying significantly in their comprehensiveness in assessing possible sexual concerns. SSRI-associated SD is prevalent across studies, though tolerance of SD was only reported in 8 studies.**

Discussion: **Existing PROMs are a feasible method for collecting patient-reported data on sexual functioning at baseline and post-treatment in clinical trials of SSRIs. Tolerance of sexual side effects should be carefully considered when assessing patient outcomes, and caution is advised when interpreting outcomes for patients with SD at baseline.**

Keywords selective serotonin reuptake inhibitors; SSRIs; sexual dysfunction; patient reported outcome measures; PROMs.

Introduction

Antidepressants are widely prescribed around the world, with prescription rates continuing to increase in many countries.[1] Patient perspectives indicate that whilst antidepressants can provide significant therapeutic benefit, adverse events can be worrisome.[2] Selective serotonin reuptake inhibitors (SSRIs), a commonly prescribed type of antidepressant, are particularly associated with sexual dysfunction (SD).[3] Whilst side effects may be temporary, SD can be bothersome and may impact medication compliance, with patients often citing side effects, including SD, as a factor in decisions around adherence to treatment.[4,5]

Despite the potential impact of SD on wellbeing and quality of life, patients with sexual difficulties can be reluctant to discuss these concerns with a clinician. Moreover, even when concerns are reported, they may not be adequately documented. In a survey at 13 general practices (GP), Nazareth et al[6] found that whilst almost 1 in 3 participants reported seeking sexual advice from their doctors, entries regarding sexual problems were found in only 3%-4% of participants' GP records. Sexual side effects of antidepressant medication are similarly underestimated; in a study where patients were interviewed by telephone 75-105 days after receiving an SSRI and explicitly asked about adverse reactions, SD was among the most commonly cited side effects.[7] Importantly, however, clinicians who were surveyed as part of this study had significantly underestimated both the prevalence of side effects and how impactful they may be for patients.

The use of patient–reported outcome measures (PROMs), which are instruments used to measure an aspect of patient health without requiring clinician interpretation,[8] provide a valuable opportunity to improve quality of care by promoting patient involvement and taking action based on feedback.[9] In mental health settings, for example, PROMs can highlight any discrepancies between clinician and patient perspectives in the outcomes/impact of care being provided.[10] Given that the majority of patients with antidepressant-related SD may not

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Table 1 Search terms utilized across EBSCOHost and OVID.

Term one	**"Patient–reported outcome measure*" OR "PROMS" OR "Questionnaire*" OR "Measure*" OR "Screening" OR "Scale"**
AND	
Term two	"Sexual dysfunction" OR "Sexual side effects" OR "Sexual difficulties" OR "Sex* problems" OR "Erectile dysfunction" OR "Anorgasmia" OR "Genital numb*" OR "Loss of libido" OR "Low libido"
AND	
Term three	"Selective serotonin reuptake inhibitor*" OR "SSRI*"

Table 2 PICO Framework detailing paper selection criteria.

Population	**Psychotropic drug-naïve participants**
Intervention	Medications listed as SSRIs in the British National Formulary excluding Dapoxetine (Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Paroxetine or Sertraline)
Comparison	Baseline, placebo or other medication
Outcome	Sexual functioning as measured by a validated sexual functioning PROM, results for both pre- and post-SSRI are reported

spontaneously report these side effects to their clinicians,[11] the use of PROMs would allow a standardized measurement of sexual functioning before and after treatment to ensure that patient concerns can be taken into account when considering treatment options.

Research question

Despite the significant association between SSRIs and sexual side effects, and the potential value of PROMs in providing a robust measurement, the extent to which PROMs have been used in clinical trials of SSRIs has not been, to our knowledge, previously described. This systematic review aims to synthesize existing research on SSRI-related SD that has utilized sexual functioning PROMs, equipping clinicians, services, researchers, and patients with an understanding of what PROMs have been used in clinical trials, and what the results indicate regarding the prevalence and tolerance of SD as assessed by validated patient–completed questionnaires.

Methods

This systematic review was conducted according to the Preferred Reporting Guidelines for Systematic Reviews and Meta-Analyses guidelines.[12] This review's protocol was previously registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 21st July 2025 (CRD420251043649).

Search strategy

A systematic search of the literature was conducted on November 21, 2025 using the following electronic databases: EMBASE (via OVID) and MEDLINE Ultimate, CINAHL Ultimate, OpenDissertations, and PsycINFO (via EBSCOHost). A supplementary search was also completed using Google Scholar. Search terms related to PROMs, SD, and medication were selected for their relevance to the research question (see Table 1).

Eligibility criteria

The PICO (Population, Intervention, Comparison and Outcome) Framework[13] was used to develop the review's selection criteria (see Table 2). English-language quantitative peer–reviewed studies in human participants of any design were considered eligible for inclusion if they met the criteria. Studies were excluded if participants were being treated for organic SD, or if non-SSRI medications, herbal remedies, psychological/psychosocial interventions, or drug holidays were also prescribed in conjunction with SSRIs. Literature reviews and pooled analyses were excluded to avoid duplication of findings.

Screening and selection

Following the removal of duplicates, titles and abstracts of all search results were screened by the lead author to determine if an article should proceed to full-text screening. A second reviewer (E.B.), blind to the lead author's decisions, independently screened 20% of results at both stages. Any disagreements were discussed and resolved with consideration of the eligibility criteria.

Quality assessment

Risk of bias assessments were conducted using the Joanna Briggs Institute (JBI) quality appraisal tools. Clinical trials in which participants were randomized to one of at least two intervention arms were classified as randomized controlled trials (RCTs) and appraised using the 13-item checklist for RCTs.[14] Single arm trials and studies where randomization did not occur were appraised using the 9-item checklist for quasi-experimental studies.[15] Checklist items are answered with a nominal response of "Yes", "No", "Unclear", or "Not applicable". The checklists do not provide an overall rating but instead facilitate careful critical evaluation of a study's strengths and weaknesses. All papers were initially appraised by the lead author, with a 20% random sample independently appraised by a second reviewer (E.B.). Checklist items were then jointly discussed, and a consensus was reached in all instances.

Data extraction

Data extraction was completed by the lead author with the second reviewer verifying the extracted information for 20% of the studies. Details regarding the studied population, the utilized SD PROMs, the timepoints at which said PROMs were administered, and their findings (including prevalence of treatment-emergent SD if reported) were extracted. Additionally, details regarding the authors, year of publication, study design, country, SSRI administered, controls/comparators, sample size, mean age, and gender split were also extracted.

Data synthesis

Due to anticipated heterogeneity in the literature including how SD is defined and assessed, a narrative synthesis in line with guidance established by Popay et al[16] is used to present and evaluate findings. Elements of a comprehensive narrative synthesis include organizing relevant findings from selected studies, consideration of relationships within and between studies, and assessing the robustness of the synthesis. Information regarding utilized PROMs is presented in tabular and narrative format. In synthesizing the evidence regarding the prevalence and impact of SD, studies are grouped by utilized PROM in tabular format and narratively discussed to evaluate patterns and relationships in the data. Additionally, a harvest plot[17] was created using R Software[18] to synthesize results of studies reporting inferential analyses, highlighting patterns of methodological heterogeneity and variation in outcomes of SD by SSRI and gender.

Results

Search results

The search strategy yielded 825 results after the removal of duplicates, and three additional relevant articles were identified and retrieved via Google Scholar. Retrieved articles were exported into Rayyan,[19] a reference management platform, and screening was completed manually. Following title and abstract screening, 112 articles proceeded to full-text screening, of which 27 articles were considered to meet all eligibility criteria. The inter-rater agreement coefficient for both title/abstract (Gwet's $AC_1 = 0.88$) and full-text screening (Gwet's $AC_1 = 0.84$) indicated excellent agreement. See Figure 1 for study selection procedure and reasons for exclusion.

Study characteristics

The majority of studies ($n = 21$) utilized an RCT design, with all other studies ($n = 6$) utilizing a quasi-experimental design. Studies were conducted in the United States ($n = 12$), India ($n = 4$), Canada ($n = 3$), the United Kingdom ($n = 3$), Germany ($n = 2$), France ($n = 2$), Iran ($n = 2$), Ireland ($n = 2$), Austria ($n = 1$), Belgium ($n = 1$), Denmark ($n = 1$), Italy ($n = 1$), Lithuania ($n = 1$), the Netherlands ($n = 1$), Spain ($n = 1$), and South Africa ($n = 1$), with some studies spanning multiple locations. Most studies ($n = 19$) were conducted in clinical populations recruiting participants with a primary diagnosis of depression ($n = 15$), women with vasomotor symptoms ($n = 2$), participants with a diagnosis of a depressive or anxiety disorder ($n = 1$), or participants with a primary diagnosis of generalized social anxiety disorder ($n = 1$). SSRIs were often compared with non-SSRI treatment ($n = 16$), placebo ($n = 14$), or both ($n = 10$). Individual study characteristics are reported in Table 3.

Quality assessment

Most RCTs (14/21) were clearly double-blinded, and all 10 RCTs reporting on their randomization procedure appeared to use true randomization for treatment allocation. Inclusion and exclusion criteria were generally well defined, however confounding variables (including baseline sexual functioning) were rarely controlled for, particularly in studies of clinical populations. Several studies (5/27) reported no inferential analyses. PROMs were generally administered reliably across participant groups. Only 1 study reported concurrent validity between a utilized PROM and an investigator-rated measure, and just 2 studies utilized multiple full-length PROMs of SD. Many studies, including RCTs, utilized small sample sizes, likely affecting statistical power (see Table 3). Individual responses to critical appraisal checklist items per study are presented in Supplementary Details S1. The inter-rater agreement coefficient for quality appraisal checklist items (Gwet's $AC_1 = 0.67$) indicated substantial agreement.

PROMs assessing SD

Ten standardized PROMs were utilized across studies to assess treatment-emergent SD.

PROMs vary widely in length, domains covered, and items related to tolerance of SD (if any). See Table 4 for details regarding utilized PROMs.

Gender-inclusive PROMs

The Arizona Sexual Experiences Scale (ASEX) was developed as a quick, easy-to-administer tool for use in clinical settings[47] and is widely used in the identified papers ($n = 7$). The ASEX contains 5 items including 1 question which is divided into a sub-item on erections and a sub-item on vaginal lubrication, with individuals only answering the relevant sub-item. Whilst there are no items on sexual distress or overall sexual satisfaction, the final item pertains specifically to satisfaction with orgasms. Internal consistency was assessed by 1 study,[39] with the ASEX demonstrating good internal consistency in this cohort (Cronbach's Coefficient $\alpha = 0.88$).

The Sexual Functioning Questionnaire (SFQ)[48] was initially developed for use in unmedicated depressed individuals, comprising of items (10 for males and 8 for females) for which the individual can indicate whether a problem has been occurring less, the same, or more often than usual. The Sex Effects (SexFx) Scale[34] is a further refinement of the SFQ by the same research team, transforming it into a 13-item tool with more detailed options regarding the frequency of certain sexual experiences. Both the SFQ and the SexFx Scale were utilized by the same number of studies ($n = 2$ each) and contain some items applicable only to males or females. Unlike the SFQ, the SexFx Scale contains 2 items on satisfaction (assessing overall sexual satisfaction and enjoyment with sexual romantic life). In their cohort, Kennedy et al[34] also assessed the concurrent validity of the SexFx Scale with the Investigator-Rated Sexual Desire and Functioning Scale (IRSD-F).[49] The researchers found that SexFx scores correlated significantly with IRSD-F scores at all timepoints.

The Massachusetts General Hospital Sexual Functioning Questionnaire (MGH-SFQ),[50] partly derived from the ASEX, is a similarly brief 5-item questionnaire developed primarily for use in psychiatric outpatients[51] and is utilized by 1 study. The questionnaire includes 1 item targeted at male responders, querying erectile functioning, with no alternative question for female respondents. Whereas the final item on the ASEX pertains to orgasmic satisfaction specifically, the final item on the MGH-SFQ asks responders to rate their overall sexual satisfaction.

Only 1 questionnaire, the Psychotropic-Related Sexual Dysfunction Questionnaire (PRSexDQ),[52] is validated specifically for the measurement of SD secondary to psychotropic treatment and was utilized by 3 studies. In addition to 2 screening items asking

Table 3 Study characteristics.

Authors	Year	Study design	Country	Participant group	SSRI medication and dosage (participants)	Non-SSRI comparators (participants)	Mean age (SD)	Gender split
Abbasinazari et al[20]	2018	RCT	Iran	Depressed females with "no history of SD"	Citalopram 20 mg (11) and Fluoxetine 20 mg (12)	-	Flu 30.4 (7.6), Cit 27.8 (7.3)	F
Abler et al[21]	2011	RCT (crossover trial)	Germany	Healthy males	Paroxetine 20 mg (23)	Bupropion and placebo (crossover trial)	25.4 (2.9)	M
Baldwin et al[22]	2006	RCT	Europe (multi-site)	Depressed adults	Escitalopram 10-20 mg (166) and Paroxetine 20-40 mg (159)	-	Par 45.1 (13.2), Esc 44.9 (14.7)	F on Esc = 121, F on Par = 119
Bathla & Anjum[23]	2020	RCT	India	Depressed married adults	Sertraline 50-200 mg (30)	Vilazodone (30)	37.27 (4.25)	F = 15
Bathla et al[24]	2018	RCT	India	Depressed married adults	Escitalopram 10-20 mg (30)	Vilazodone (30)	37.27 (5.09)	F = 18
Clayton et al[25]	2007	RCT	US	Depressed adults	Escitalopram 10 mg (274)	Duloxetine (273) and placebo (137)	43.3 (13)	F = 186
Clayton et al[26]	2015	RCT	US	Depressed adults	Citalopram 40 mg (257)	Placebo (264) and Vilazodone (526)	42.9 (12.5)	F = "57.6%"
Clayton et al[27]	2017	RCT	US	Healthy adults	Paroxetine 20 mg (49)	Placebo (51) and Vilazodone (100)	31.3 (7.7)	F = 30
Detke et al[28]	2004	RCT	US	Depressed adults	Paroxetine 20 mg (86)	Duloxetine (188) and placebo (93)	42 (10.6)	F = 58
Dunn et al[29]	2007	RCT	US	Healthy males	Paroxetine 20 mg (33)	CP-448187 (33) and placebo (33)	Total sample 31 (SD unreported)	M
Espinola et al[30]	2022	Quasi-experiment	Canada	Depressed adults	Escitalopram 10-20 mg (208)	-	35.1 (12.5)	F = "63%"
Fabre et al[31]	2012	RCT	US	Depressed males	Fluoxetine 20-40 mg (unclear, total sample 181)	Gepirone-ER and placebo	Total sample 38.6 (11.2)	M
Jacobsen et al[32]	2019	RCT	US	Healthy adults	Paroxetine 20 mg (85)	Placebo (92) and Vortioxetine (184)	28.9 (5.96)	F = 42
Kennedy et al[33]	2000	Quasi-experiment	Canada	Depressed adults	Paroxetine 10-80 mg (30) and Sertraline 50-200 mg (26)	Moclobemide (15) and Venlafaxine (36)	F on Par 36.9 (12.1) and Ser 37.7 (12.6), M on Par 36.6 (9.1) and Ser 38.5 (12.6)	F on Par = 10, F on Ser = 22
Kennedy et al[34]	2006	RCT	Canada	Depressed adults "reporting sexual interest"	Paroxetine 20 mg-40 mg (68)	Bupropion (65)	Total sample 37.8 (10.5)	F = 34
Khazaie et al[35]	2015	RCT	Iran	Depressed adults	Fluoxetine 20-40 mg (67) and Sertraline 200 mg (64)	Trazodone (64)	Flu 37 (11), Ser 38 (11)	Total F = 93
Madeo et al[36]	2008	RCT	Italy	Healthy males	Citalopram 40 mg (16) and Fluoxetine 20 mg (16)	Placebo (16)	Cit 31.1 (4.9), Flu 29.2 (4.7)	M
Montejo et al[37]	2010	RCT	Spain	Healthy males	Paroxetine 20 mg (23)	Agomelatine (46) and placebo (23)	24.7 (2.3)	M
Montejo et al[38]	2015	RCT	UK	Healthy adults	Escitalopram 20 mg (36)	Agomelatine (65) and placebo (32)	24.1 (4.1)	Unreported

(continued)

Table 3 Continued.

Authors	Year	Study design	Country	Participant group	SSRI medication and dosage (participants)	Non-SSRI comparators (participants)	Mean age (SD)	Gender split
Piazza et al[39]	1997	RCT	US	Depressed adults	Paroxetine (14) and Sertraline (11) (mean dose 25 mg and 60 mg for F, 20 mg and 66.7 mg for M)	-	F total sample 40.6 (10.3), M total sample 49.3 (9.7)	F on Par = 9, F on Ser = 5
Portman et al[40]	2014	RCT	US	Postmenopausal females with vasomotor symptoms	Paroxetine 7.5 mg (585)	Placebo (589)	Mean and SD not reported, median = 54	F
Preeti et al[41]	2018	Quasi-experiment	India	Adults with a depressive or anxiety disorder	Escitalopram (47), Fluoxetine (41) and Sertraline (56) (dosage unspecified)	Desvenlafaxine (37) and Mirtazapine (28)	Total sample 36.5 (12.7)	Total F = 123
Reed et al[42]	2012	RCT	US	Perimenopausal or postmenopausal females with vasomotor symptoms	Escitalopram 10-20 mg (101)	Placebo (99)	53.3 (4.2)	F
Shah et al[43]	2024	Quasi-experiment	India	Depression adults free of SD	Unspecified (100)	-	30.9 (8.14)	F = 47
Tanrikut et al[44]	2010	Quasi-experiment	US	Healthy males	Paroxetine 10-30 mg (35)	-	33.9 (11.1)	M
Weber et al[45]	2023	Quasi-experiment	Denmark	Depressed adults	Escitalopram 5-20 mg (92)	Health controls database (cross-sectional, baseline) (73)	26.8 (7.5)	F = 66
Westernberg et al[46]	2004	RCT	South Africa, Europe (multi-site), US	Adults with generalized social anxiety disorder	Fluvoxamine controlled-release 100-300 mg (149)	Placebo (151)	38.6 (SD unreported, standard error = 0.9)	F = 81

Note. "Cit" = Citalopram, "Esc" = Escitalopram, "F" = Females, "Flu" = Fluoxetine, "M" = Males, "Par" = Paroxetine, "Pla" = Placebo, "RCT" = Randomized controlled trial, "Ser" = Sertraline, "SD" = Standard deviation.

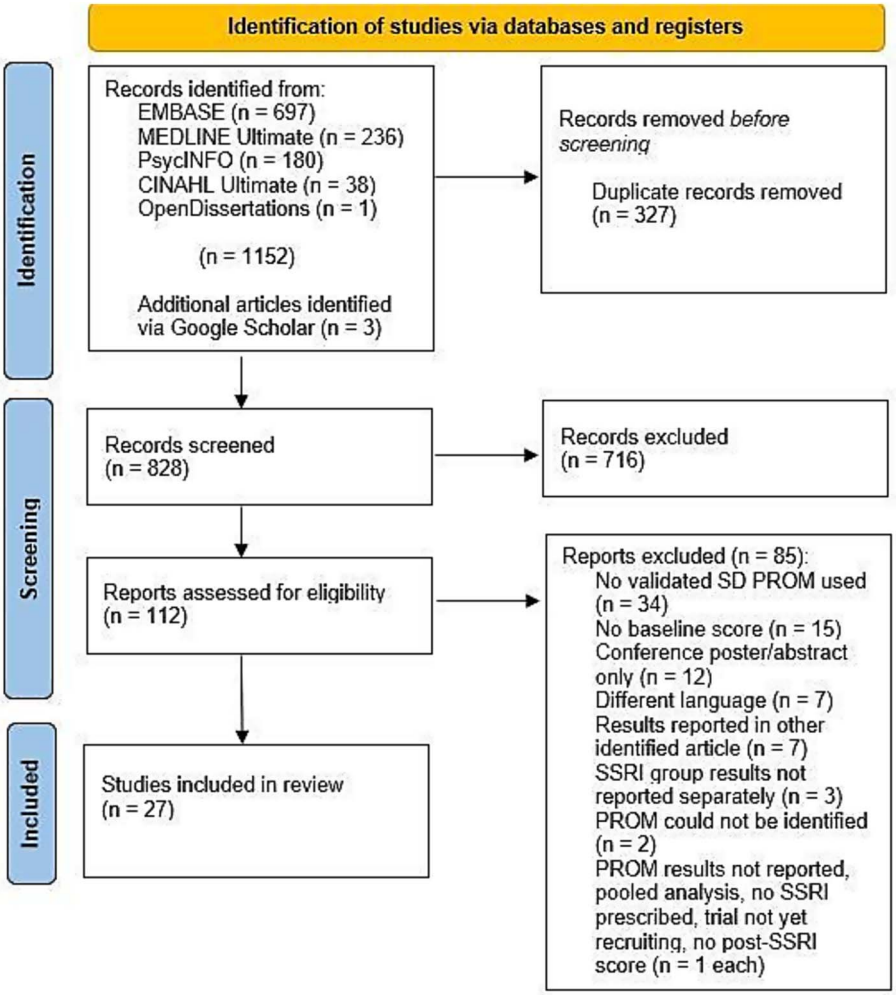

Figure 1 Flowchart of the study identification, screening and inclusion/exclusion process. Adapted from Page et al.[12]

if participants have observed any change in sexual functioning and whether any changes were spontaneously reported, the questionnaire contains 5 further items which are primarily designed to assess changes in sexual functioning relative to a baseline (eg, if the responder has observed any "decrease in [their] sexual desire"), and as such may be more suited to use in cross-sectional designs. The final item assesses responders' tolerance to changes in sexual functioning, providing options to indicate if the changes have interfered with the person's relationship.

Gender-specific PROMs

In addition to the aforementioned questionnaires, several PROMs have been developed specifically for men or women, or entail separate male and female versions. The most widely used of these questionnaires is the Changes in Sexual Functioning Questionnaire (CSFQ)[53] ($n = 8$), developed for the measurement of SD secondary to illness or medication. The CSFQ includes 2 versions (male and female) which are each 14 items in its short form,[54] the version utilized by identified studies in the current review. Aside from an item related to enjoyment in sex, neither the male nor female version of the CFSQ contains any items pertaining to sexual distress, satisfaction, or impact of SD.

Two questionnaires designed for use in male populations, the International Index of Erectile Function (IIEF)[55] and the Brief Sexual Function Inventory (BSFI),[56] were utilized by studies ($n = 2$ and $n = 1$ respectively). The IIEF is a 15-item questionnaire developed to measure treatment-emergent male SD and is designed for use in clinical and non-clinical populations. It contains 4 items related to sexual satisfaction (2 items specific to intercourse satisfaction, and 2 items pertaining to overall satisfaction). The BSFI, an 11-item questionnaire encompassing similar domains, is also developed for similar purposes.[56] It contains 4 items related to the tolerance of SD, querying whether individuals perceive any issues related to sex drive, erections or ejaculation as being a "problem" (3 items), and overall sexual satisfaction (1 item).

One questionnaire designed for use in female populations, the Female Sexual Function Index (FSFI),[57] was utilized by most female-only studies ($n = 2$). The FSFI is a 19-item questionnaire developed for a comprehensive assessment of various aspects of female sexual functioning in clinical and non-clinical populations. The PROM contains 3 items related to the impact of SD, assessing individuals' emotional closeness during sex, satisfaction with their sexual relationship, and overall satisfaction with their sex life.

PROMs for sexual satisfaction and distress

Only 1 satisfaction questionnaire, the Golombok-Rust Inventory of Sexual Satisfaction (GRISS),[58] was utilized in the retrieved literature ($n = 1$). The GRISS entails separate male and female versions (both 28 items) and was developed to evaluate sexual difficulties in heterosexual relationships. The questionnaire

Table 4 Patient-reported outcome measures utilized by retrieved studies.

PROM	Usage in retrieved literature	Domains covered (as described by the PROM)	Number of items	Score range	Items related to tolerance (including satisfaction)
Changes in Sexual Functioning Questionnaire (CSFQ)	8/27	Pleasure, desire/frequency, desire/interest, arousal/excitement (F) or arousal/erection (M), orgasm/completion (F) or orgasm/ejaculation (M)	14 (Short Form)	14-70 (lower score being poorer sexual functioning)	-
Arizona Sexual Experience Scale (ASEX)	7/27	Sex drive, arousal, lubrication/erection, orgasm, orgasmic satisfaction	5	5-30 (higher being poorer sexual functioning)	1 item on orgasmic satisfaction
Psychotropic-Related Sexual Dysfunction Questionnaire (PRSexDQ)	3/27	Desire (libido), orgasm/ejaculation, erectile function/lubrication, tolerance of changes	2 screening items +5 items	0-15 (higher being poorer sexual functioning)	1 item regarding tolerance of SD
Sex Effects Scale (SexFX)	2/27	Desire, arousal, orgasm, satisfaction. Some separate items for M and F responders	13	0-44 main scale (lower being poorer sexual functioning), 2 additional items scored 0-10	1 item on sexual satisfaction, 1 item on enjoyment of sexual romantic life
Sexual Function Questionnaire (SFQ)	2/27	Drive/desire, arousal/orgasm, sexual activity. Some separate items for M and F responders	10 for males, 8 for females	Each item in drive/desire and arousal/orgasm rated on 3-point scale, prevalence considered per item	-
Female Sexual Function Index (FSFI)	2/27	Female sexual functioning: Desire, arousal, lubrication, orgasm, satisfaction, pain	19	Range 2-36 (lower being poorer sexual functioning)	1 item on emotional closeness during sex, 1 item on satisfaction with sexual relationship, 1 item on overall sexual satisfaction
International Index of Erectile Dysfunction (IIEF)	2/27	Male sexual functioning: Erectile functioning, orgasmic functioning, sexual desire, intercourse satisfaction, overall satisfaction	15	6-75 (lower being poorer sexual functioning)	2 items on intercourse satisfaction, 2 items on overall sexual satisfaction
Massachusetts General Hospital-Sexual Functioning Questionnaire (MGH-SFQ)	1/27	Interest, arousal, orgasm, erection (M only item - no F equivalent), overall satisfaction	5	4-30 (higher being poorer sexual functioning)	1 item on sexual satisfaction
Brief Sexual Function Inventory (BSFI)	1/27	Male sexual functioning: Sexual drive, erections, ejaculation, problem assessment, overall satisfaction	11	0-44 (lower being poorer sexual functioning)	3 items on whether SD is a "problem", 1 item on overall sexual satisfaction
Golombok Rust Inventory of Sexual Satisfaction (GRISS)	1/27	Non-communication, infrequency, avoidance, non-sensuality, dissatisfaction, anorgasmia (F), vaginismus (F), impotence (M), PE (M)	28	Answers transformed into score of 1-9 per domain (higher being poorer sexual functioning)	Various items across domains

Note. "F" = Females, "M" = Males, "PE" = Premature ejaculation.

contains a combination of items pertaining to the presence and severity of any difficulties, as well as the impact of said difficulties (particularly in a relational context). In addition to the GRISS, 1 single item from the Female Sexual Distress Scale,[59] pertaining to distress caused by the individual's sex life, was utilized by a separate study.[42] Furthermore, another study[38] utilized a Visual Analogue Scale for Sexual Functioning Satisfaction (VAS-SFS),[60] allowing individuals to mark their overall sexual satisfaction on a vertical line.

Prevalence of SD

Individual study findings related to SD, grouped by utilized PROM, are presented in Supplementary Details S2. SSRIs were associated

with significantly higher PROM-assessed SD relative to baseline and/or comparators in most studies. With regard to estimating the prevalence of new treatment-emergent SD, Detke et al[28] reported that 62.8% of participants on Paroxetine experienced sexual side effects (as measured by the ASEX) compared to 40.5% of participants on placebo. Similarly, Montejo et al[37] reported that 85.7% of participants on Paroxetine experienced treatment-emergent SD (as measured by the PRSexDQ) at the 8-week mark. In contrast, Clayton et al[27] reported the prevalence of treatment-emergent SD (as measured by the CSFQ) at end of treatment (EOT) for participants with detectable plasma levels of Paroxetine to be 23.1% for men and 0% for women in their cohort. However, in addition to excluding participants with no detectable levels of the drug, the latter study was also briefer, with EOT figures representing the 5-week mark.

For Escitalopram, Clayton et al[25] reported that 48.7% and 43.6% of participants experienced treatment-emergent SD (as measured by the CSFQ) at the 8-week and 8-month mark, respectively. Similarly, Montejo et al[38] reported that 50% of participants on Escitalopram reported SD (as measured by the PRSexDQ) by EOT (approximately 8-week mark), however it is unclear how many participants in this group, albeit a minority, indicated they experienced sexual problems at baseline. In a study of participants on unspecified SSRIs and utilizing the CSFQ, Shah et al[43] reported that 41% of participants experienced treatment-emergent SD by EOT (12-week mark). Prevalence rates were similar for both men (39.6%) and women (42.6%). Importantly, most studies estimating the prevalence of treatment-emergent SD had small sample sizes, with only Shah et al[43] recruiting at least 100 participants. Moreover, given the various PROMs utilized across studies, it is possible that the variance in prevalence rates may be at least partially explained by the selected PROM and its criteria.

SD by gender

Studies in which analyses are reported by sex highlight that men may be more likely to report worsening SD, as measured by PROMs, than women. Six studies included only male participants; all 5 studies in nonclinical populations reported a significant worsening of sexual functioning for men following SSRI use. One study on depressed males,[31] however, found no change in SD scores among both SSRI responders and non-responders. For women, 3 studies included only female participants; whilst Abbasinazari et al[20] reported a decrease in FSFI scores following Citalopram and Fluoxetine use, no inferential analysis were reported. Portman et al[40] and Reed et al[42] found no significant impact for Paroxetine and Escitalopram respectively on sexual functioning. However, both studies reported mean PROM scores at baseline which indicated a high presence of SD in their female cohorts. Moreover, the dosage of Paroxetine in 1 study[40] (7.5 mg) is below the usual starting dose of 20 mg seen in most other studies.

When inferential analyses regarding outcomes were reported, studies most frequently reported an effect of SSRIs on sexual functioning in male participants or an overall effect across the whole cohort (see Figure 2). It is important to be mindful, however, that there are twice as many male-only studies in the retrieved literature compared to female-only studies. Moreover, several studies ($n = 4$) found that women reported significantly poorer sexual functioning at baseline than men, whereas no study reported poorer sexual functioning at baseline in men. This makes it difficult for some studies to ascertain whether men are more likely to experience treatment-emergent SD, or whether higher baseline levels of SD in women make it less likely that PROMs could detect further treatment-related deterioration in sexual functioning.

SD by medication

SSRIs varied widely in the number of studies assessing their outcomes: Paroxetine ($n = 12$), Escitalopram ($n = 8$), Fluoxetine ($n = 5$), Sertraline ($n = 5$), Citalopram ($n = 3$), and Fluvoxamine ($n = 1$) (see Table 3 for medications utilized by each study). One further study[43] did not specify which SSRI(s) was administered to participants. Among studies reporting inferential analyses, the majority of studies on Paroxetine ($n = 8$) and Sertraline ($n = 4$) reported significantly poorer sexual functioning for at least 1 participant group (eg, males, females, or both) relative to baseline and/or control, including 1 study[39], which analysed outcomes for the Paroxetine and Sertraline groups together. Half of the studies on Escitalopram ($n = 4$) reported significantly poorer sexual functioning in at least 1 group. Citalopram was associated with significantly poorer sexual functioning in 1 study.[36] The only retrieved study on Fluvoxamine[46] did not find a significant link between the SSRI and change in SD scores. Several other studies reported outcomes indicating potentially higher SD in the SSRI group(s) but did not report inferential analyses (see Supplementary Details S2). Moreover, results regarding medication outcomes are strongly confounded by participant gender (see Figure 2).

Tolerance of SD

Only a minority of studies ($n = 8$) reported any findings regarding the tolerance of SSRI-related SD or its impact on any aspect of participant wellbeing, including satisfaction with overall sex life. Six studies reported findings related to satisfaction items on their utilized PROMs, and 2 studies administered separate items (1 question each) regarding sexual distress or satisfaction. Whilst 1 study[36] also reports administering a sexual satisfaction questionnaire, the results of this are not reported. Unsurprisingly, in studies where there was no significant association between SSRI use and SD, there was no change in orgasm satisfaction[40] or sexual distress scores.[42] One further study[21] also reported no changes in sexual satisfaction despite a significant increase in SD; however, participants completed SD measures after just 1 week of medication, meaning that any changes to sexual functioning had only occurred very recently.

Using the PRSexDQ, Preeti et al[41] reported that 40.7% of men and 14.6% of women with SD in their cohort reported their tolerance as "poor" following SSRI use. Alternatively, Montejo et al[38] found that all participants experiencing SD in their cohort reported their tolerance as "well" (42.3% of whole sample) or "fair" (7.7% of whole sample). It should be noted, however, that the answer "fair" on the PRSexDQ indicates the SD "interferes with the couple's relationship". Moreover, whilst no inferential analysis was reported, the researchers note that scores on the VAS-SFS decreased (indicating poorer sexual satisfaction) after SSRI use.

Three studies reported a significant change in participants' satisfaction with their sex lives; Espinola et al[30] found that only SSRI responders and remitters had higher satisfaction scores after treatment, whilst Kennedy et al[34] found that men on Paroxetine who had reported sexual interest at baseline scored

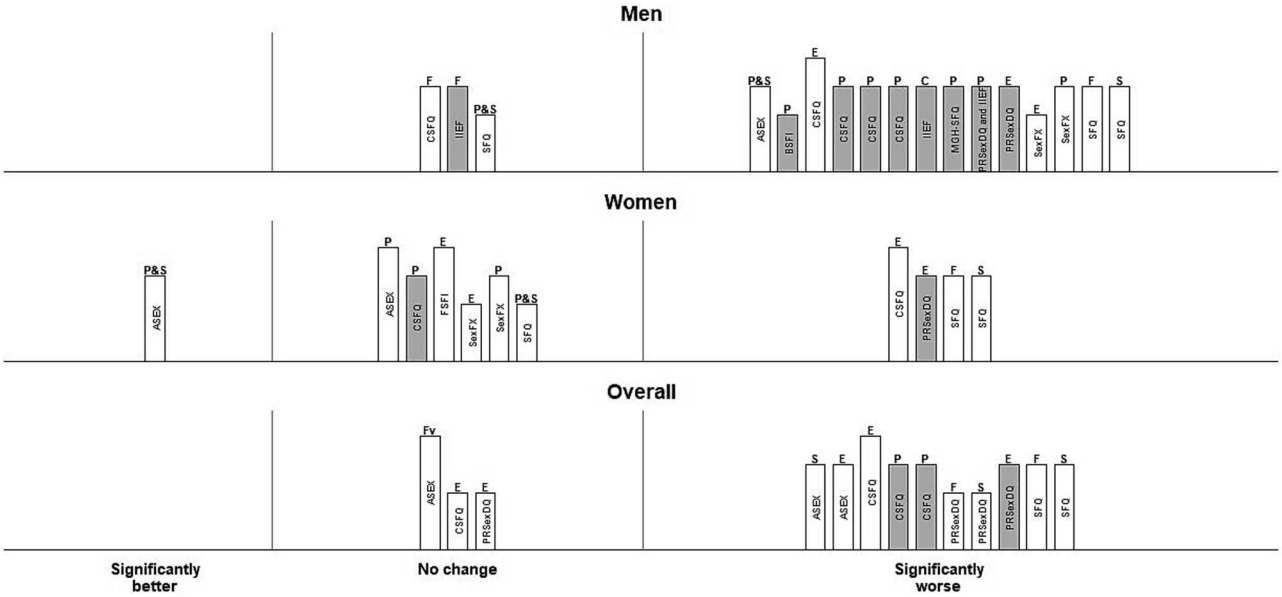

Figure 2 Harvest plot depicting outcomes for sexual functioning following SSRI use for studies reporting inferential analyses. Note. Harvest plot generated using R Software,[18] coding script generated using Claude Sonnet 4.6.[61] Each bar represents a separate study (for studies analyzing multiple SSRIs separately, separate analyses are represented by different bars). White bars = clinical populations, gray bars = nonclinical populations. Tallest bars = RCTs of ≥100 participants in SSRI arm, medium bars = RCTs of <100 participants in SSRI arm, shortest bars = non-RCTs. PROM listed inside bar. Letter above bar = SSRI ("C" = Citalopram, "E" = Escitalopram, "F" = Fluoxetine, "Fv" = Fluvoxamine, "P" = Paroxetine, "S" = Sertraline.

significantly lower on satisfaction items after treatment. Similarly, Madeo et al[36] found that healthy males on Citalopram reported significantly poorer satisfaction (both with intercourse and overall satisfaction with their sex lives) after treatment.

Discussion

Overview

This systematic review describes the use of standardized, validated PROMs to assess sexual functioning in individuals taking SSRI medication. Various PROMs have been used in the literature to assess the prevalence of treatment-emergent SD, demonstrating acceptability of said measures in identifying medication–related sexual side effects. SSRIs are associated with a significant increase in SD scores, with prevalence rates of sexual side effects in studies of at least 8 weeks duration ranging from 41% to 85.7%. Whilst some PROMs contained items related to the impact of SD on the individual's sexual satisfaction or relationship, results for these items were seldom described separately. Where reported, it is evident that treatment-emergent SD can have a significant impact on individual's sexual satisfaction and, possibly, relationship quality. Most PROMs have been validated for the assessment of secondary SD, however only one PROM, the PRSexDQ, has been developed specifically for the assessment of psychotropic-related SD.

Importantly, PROMs can vary significantly in how SD is defined or which stages of sexual functioning are assessed, making it difficult to make direct comparisons between studies utilizing different measures. For example, while SD is determined by total score on the CSFQ, it is generally determined by responses to individual items on the PRSexDQ. Whilst all PROMs described in this review have been validated, previous research has established that estimated prevalence of SD can vary substantially depending on the utilized instrument,[62] and as such, clinicians and researchers should carefully consider which PROM may be most appropriate for use depending on the context and need. For example, of the three most widely used PROMs in the SSRI literature (the CSFQ, ASEX, and PRSexDQ), a systematic review of SD measurement in patients using antipsychotics[63] noted that only the CSFQ and PRSexDQ covered all stages of sexual functioning. Moreover, the authors note that direct comparisons of psychometric properties between the measures were lacking in the existing literature.

The findings of studies described in this systematic review are consistent with the wider literature which has frequently highlighted the prevalence of SD following SSRI use.[64] Importantly, whilst baseline SD was often present in clinical populations, placebo-controlled studies in nonclinical populations with normal baseline sexual functioning support a causal association between SSRI treatment and worsening sexual functioning. Whilst prevalence rates were rarely reported, the findings indicate that Paroxetine may be more associated with SD than other SSRIs, a characteristic of Paroxetine that has previously been demonstrated in other clinical studies.[65,66] The frequency with which SSRIs cause SD is an important relevant factor when considering therapeutic adherence, given the impact of side effects on medication compliance.[4,5]

When examining gender differences in SD, findings highlight that male participants may be more likely to report sexual side effects compared to baseline and/or control. This is in contrast with cross-sectional research which report similar rates of SD in men and women who have been taking SSRIs or antidepressant medication.[11,67,68] However, as participants in these studies have no pre-SSRI baseline scores, there is a risk of attributing pre-existing sexual difficulties to treatment. A recent systematic review[69] of SD prevalence in patients with major depressive disorder found that 82.75% of women experience SD, as measured

by sexual function PROMs, compared to 63.26% of men. This is consistent with several studies described in the current systematic review who reported higher SD scores at baseline for women. Thus, whilst women were less likely in some studies to report poorer sexual functioning after SSRI treatment, in some instances this may be at least partially explained by the presence of SD before medication.

The interaction between gender and sexual functioning is therefore an important consideration for any study assessing SSRI-related SD. Historically, female sexual functioning has often been assessed using male-centered paradigms.[70] Basson's model of female sexual functioning highlights the dangers of diagnosing SD based on the usage of said paradigms which may fail to accurately reflect the female sexual response.[71] Moreover, various social, psychological, and biological factors which closely interact with gender roles and inequality—such as female genital mutilation, access to sex education, gynecological care, and safety within relationships—have been shown to be predictive of the comparatively high rates of SD in women globally.[72] Utilizing robust assessment tools that are well-designed to reflect the female sexual experience (which can be at least partly considered by evaluating the items or criteria included in the tool), and that also form part of a wider holistic assessment which considers the various relevant factors, is thus essential to accurately capturing SD outcomes for women taking SSRIs.

Further evidence that SSRI use may impact sexual functioning differently across genders was reported by Lee et al,[73] who found that in a cohort of depressed individuals divided into those unmedicated and those medicated with antidepressants, only unmedicated women and medicated men scored significantly lower on the CSFQ (signifying higher SD) than healthy controls. Studies of medication-related SD without an assessment of baseline sexual functioning should therefore be interpreted with caution. Moreover, even in studies where pre-medication data has been obtained, the sensitivity of the utilized PROMs in detecting treatment-related change in sexual functioning for individuals with baseline SD—particularly in women—is unclear. This is perhaps best illustrated by Shah et al's[43] study, who reported similar rates of treatment-emergent SD for men and women with normal sexual functioning at baseline.

An under-explored consideration is the difference in SSRI-related SD among treatment responders and non-responders, or indeed how sexual side effects may interact with response to treatment. In addition to studies which highlight the impact of SD on sexual satisfaction,[30,34,36] antidepressant-related SD has been shown to impact overall quality of life.[67] Furthermore, in a cross-sectional survey, Jacobsen et al[74] reported that SD was correlated with depression severity and lower self-esteem in individuals taking antidepressants. Hence, whilst a reduction in SD following SSRI use may sometimes occur as a result of improved mental health, it is important to consider whether an apparent lack of response to SSRI treatment in some individuals may be at least partially explained by emerging or worsening sexual functioning.

Strengths and limitations

To our knowledge, we describe the first systematic review on the use of PROMs to assess the prevalence and tolerance of SSRI-related SD. The findings demonstrate the feasibility of using SD PROMs in clinical trials of psychotropic medication, whilst also highlighting issues to consider when relying on PROMs to detect further SSRI-related changes in sexual functioning. In selecting only studies with baseline sexual functioning scores, this review synthesizes the existing evidence base for a causal link between SSRIs and patient-rated SD, including in individuals with normal sexual functioning at baseline. The findings also contribute to our understanding of the interaction between SSRIs, baseline SD, and gender, demonstrating the importance of considering these factors when assessing SSRI-related sexual side effects and their impact on individuals.

There are several limitations to this review. Due to the selection criteria (eg, the exclusion of non-English articles), and the use of specific terms related to SSRIs and PROMs, it is possible that some relevant clinical trials may have fallen outside the scope of the review's search. Moreover, due to heterogeneity in the literature, there is considerable uncertainty regarding the prevalence of SD for different SSRIs in different populations. Additionally, as the primary focus of this review was to identify and appraise the use of PROMs in SSRI research, no studies were excluded due to methodological quality. Whilst this decision allows for a comprehensive assessment of the literature, it is unclear how many clinical trials were adequately powered to detect SD. Finally, whilst all utilized PROMs have been evaluated in the literature, this review did not consider their psychometric properties, or which PROMs may be most appropriate for use.

Clinical implications

This review has several implications for clinicians prescribing and treating SSRI-medicated individuals. The use of validated PROMs before, during and after treatment would facilitate a patient-led assessment of sexual functioning which can inform discussions around possible side effects, particularly for individuals who may be reluctant to spontaneously report difficulties. Assessing sexual functioning in this intentional manner would allow for the early identification of patient concerns regarding their sexual health, barriers to treatment adherence, and possible treatment strategies for SSRI-related SD. Given the potential impact of SD on overall sexual satisfaction, assessing patients' tolerance and management of sexual side effects may also be an important consideration when evaluating treatment response and overall wellbeing. Various strategies to manage SSRI-related SD have been described,[75] and the use of PROMs could allow for prompt identification of any side effects as well as a robust method of measuring the effectiveness of any used strategies or interventions.

Recommendations for future research

Given the prevalence of SD seen in studies of people with depression, further research examining the sensitivity of existing PROMs—or the development of suitable PROMs—in detecting SSRI–related sexual side effects for individuals with baseline SD would be beneficial. Additionally, whilst some PROMs are comprehensive in covering various domains of sexual functioning, further work, including qualitative studies, should be conducted to consider whether existing PROMs capture aspects that are relevant and important to medicated patients. Importantly, given that gender and baseline SD may be significant confounding variables in being able to detect further treatment-related SD,

strategies to address this factor should be carefully considered; for example, researchers may consider recruiting a sufficient number of participants of both sexes who are free of SD at baseline screening, and incorporating multiple measures of sexual functioning to ensure a holistic assessment. Finally, research on the psychological impact of sexual side effects is limited, and its potential to confound treatment response has not been widely considered. Future research should thus explore the impact of SSRI-related SD on wellbeing, quality of life, relationships, and treatment response.

Conclusion

To summarize, we identified 10 validated PROMs that have been used in the literature to evaluate the prevalence and tolerance of SSRI-related SD. PROMs are an acceptable and feasible method of collecting patient-reported data on sexual side effects, and the results highlight a clear causal relationship between SSRIs and SD. However, factors such as gender, baseline SD, and sensitivity of the PROM in capturing further treatment-related decline in sexual functioning should be carefully considered; PROMs should thus form part of a wider assessment and conversation with patients. Additionally, whilst PROMs could be used to assess the impact of SSRI-related SD, this outcome was rarely reported in identified studies. Carefully assessing patient tolerance of emergent side effects would support the development of patient-centered approaches to managing any concerns, improving outcomes. Given the relatively low rates of spontaneous reporting of SD, standardized measures provide a valuable opportunity to reflect on changes in sexual functioning that could have a significant impact on patient wellbeing and compliance with treatment.

Disclosure of AI

The lead author used Claude Sonnet 4.6[61] to assist with producing the R coding script required for the harvest plot. After using this tool, the author carefully reviewed, verified and edited the content as needed and takes full responsibility for the content of the publication.

Author contributions

S.B.: Conceptualization-Lead, Formal analysis-Lead, Investigation-Lead, Methodology-Lead, Visualization-Lead, Writing—original draft-Lead, Writing—review & editing-Lead. E.B.: Investigation-Supporting, Validation-Lead, Writing—review & editing-Supporting. B.B.: Conceptualization-Equal, Methodology-Equal, Supervision-Equal, Writing—review & editing-Equal, S.F.: Conceptualization-Equal, Methodology-Equal, Supervision-Equal, Writing—review & editing-Equal.

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Conflicts of interest

The authors report there are no competing interests to declare.

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