Original Article
Male sexual health and dysfunction

pISSN: 2287-4208 / eISSN: 2287-4690
World J Mens Health 2022 Apr 40(2): 257-263
https://doi.org/10.5534/wjmh.210155

The World Journal of MEN's HEALTH

Selective Serotonin Re-Uptake Inhibitors for Premature Ejaculation in Adult Men: A Cochrane Systematic Review

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Purpose: Selective serotonin re-uptake inhibitors (SSRIs) are frequently used to treat premature ejaculation (PE) in men. We performed a Cochrane review to assess the efficacy of SSRI treatment for PE.

Materials and Methods: We extensively searched a range of databases up to May 2020 and only included randomized controlled trials.

Results: A total of 31 studies with 8,254 men were included in this analysis. We found that SSRI treatment probably improves self-perceived PE symptoms (defined as a rating of 'better' or 'much better'; risk ratio [RR], 1.92; 95% confidence interval [CI], 1.66–2.23; moderate-certainty evidence) and satisfaction with intercourse (defined as a rating of 'good' or 'very good'; RR, 1.63; 95% CI, 1.42–1.87; moderate-certainty evidence) compared to placebo. Furthermore, SSRI treatment likely improve participants' self-perceived control over ejaculation (defined as rating of 'good' or 'very good'; RR, 2.29; 95% CI, 1.72–3.05; moderate-certainty evidence) and probably lessens distress (defined as rating of 'a little bit' or 'not at all') about PE (RR, 1.54; 95% CI, 1.26–1.88; moderate-certainty evidence). SSRI treatment may increase IELT compared to placebo (mean difference, 3.09 minutes higher; 95% CI, 1.94 higher to 4.25 higher; low-certainty evidence). However, SSRIs may increase treatment cessations due to adverse events compared to placebo (RR, 3.80; 95% CI, 2.61–5.51; low-certainty evidence).

Conclusions: SSRI treatment for PE appears to substantially improve a number of outcomes of direct patient importance such as symptom improvement, satisfaction with intercourse and perceived control over ejaculation when compared to placebo.

Keywords: Meta-analysis; Premature ejaculation; Serotonin and noradrenaline reuptake inhibitors; Systematic review

INTRODUCTION

Premature ejaculation (PE) is reported to effect a significant proportion of men with an estimated prevalence of 5% to 30% [1-3] and can have a significant negative impact on quality of life. In a community-based observation study, Rowland et al [4] reported that men with PE and their partners reported lower levels of

Received: Aug 16, 2021 **Accepted:** Aug 23, 2021 **Published online** Jan 2, 2022
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sexual functioning and satisfaction, and higher levels of personal distress and interpersonal difficulty. PE can foster feelings of inadequacy, disappointment and anxiety [5]. In addition to adverse impacts on sexual function and relationships, the consequences of PE can permeate to other domains and negatively affect overall quality of life [6].

There are a range of treatments that have been recommended as treatments for PE [7]. Selective serotonin re-uptake inhibitors (SSRIs), which is mainly used as a treatment for depression, have been prescribed off-label to men experiencing PE. There have been several reviews already conducted examining the effectiveness of SSRI medication for the treatment of PE but none have been performed in a rigorous manner and are relatively outdated [8-10].

Therefore, we aimed to conduct a systematic review and meta-analysis in accordance with Cochrane guidelines to assess the effects of SSRIs in the treatment of PE in adult men.

MATERIALS AND METHODS

The full protocol of this review was published a priori in the Cochrane Database of Systematic Reviews [11].

We extensively searched a number of databases including PUBMED Medline, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Latin American and Caribbean Health Sciences Literature (LILACS), Cumulative Index of Nursing and Allied Health Literature (CINAHL) and World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) up to May 2020. We also searched the grey literature and the abstracts of major urological meetings.

We included studies of men aged ≥18 years with lifelong PE only (from first sexual experience). We excluded men with PE secondary to other known conditions such as prostatitis or PE as a medication side effect (acquired PE). We only included RCTs in which participants were allocated to receive either SSRI or placebo/no treatment. We also included cross-over clinical trials. We did not include agents classified as serotonin-norepinephrine re-uptake inhibitors such as duloxetine.

The primary outcomes were:

- Participant perception of change with treatment: assessed using the Clinical Global Impression of Change (CGIC) questionnaire, we recorded the number of participants describing the change as 'better' or 'much better' after treatment in a dichotomous manner.
- Participant satisfaction with intercourse: we recorded the number of participants describing their satisfaction as 'good' or 'very good' before and after treatment (for satisfaction and control) using the CGIC.
- Study withdrawal due to adverse events.

The secondary outcomes were:

- Perceived control over ejaculation: using the PEP questionnaire, the recorded the number of participants describing their satisfaction as 'good' or 'very good' before and after treatment (for satisfaction and control).
- Participant distress about PE: we recorded the number of participants describing their distress as 'a little bit' or 'not at all' using the PEP questionnaire.
- Relationship difficulties: we recorded the number of participants describing their difficulties as 'a little bit' or 'not at all' using the PEP questionnaire.
- Adverse events
- Intravaginal ejaculatory latency time (IELT)
- Depression

We expected the following characteristics to introduce clinical heterogeneity, and carried out the following subgroup analyses including investigation of interactions.

- Long-acting SSRIs (*e.g.*, paroxetine, fluoxetine, sertraline, citalopram and fluvoxamine) *versus* short-acting (on-demand type) SSRIs (*e.g.*, dapoxetine). We compared the long- *versus* short-acting SSRIs.
- Among the long-acting SSRIs, comparison of individual agents (*e.g.*, paroxetine *versus* fluoxetine *versus* sertraline *versus* citalopram *versus* fluvoxamine).
- If applicable, different dose levels (*e.g.*, dapoxetine 30 mg *versus* 60 mg).

Statistical analysis

Statistical analysis was conducted in accordance with the Cochrane Handbook for Systematic Reviews. Random effects models were used for all analyses.

RESULTS

Our search retrieved 1,218 references from which 31 studies were included in this analysis after abstract

screening and full-text review [12-48] (Supplement Fig. 1). We included 8,049 randomized participants (SSRI 4,990, placebo 2,928, other drug 131). The included studies tested a range of SSRIs including fluoxetine, duloxetine, citalopram, sertraline, dapoxetine, paroxetine, escitalopram, and fluvoxamine. The characteristics of included studies can be found in Supplement Table 1. The risk of bias assessment is shown in Fig. 1.

The GRADE summary of findings is outlined in Table 1. A detailed description of the results of this review including the subgroup analyses is available in the original review [49].

1. Primary outcomes

SSRI treatment probably results in an improvement in PE-related symptoms defined as a rating of 'better' or 'much better' using the CGIC questionnaire compared to placebo (risk ratio [RR], 1.92; 95% confidence interval [CI], 1.66–2.23; I^2=24%; studies=6, participants=3,260; moderate certainty of evidence).

SSRI treatment probably improves satisfaction with intercourse defined as a rating of 'good' or 'very good' using the CGIC questionnaire compared to placebo (RR, 1.63; 95% CI, 1.42–1.87; I^2=53%; studies=3, participants=4,273; moderate certainty of evidence).

However, SSRI treatment may result in an increase in the number of treatment cessations due to adverse events compared to placebo (RR, 3.80; 95% CI, 2.61–5.51; I^2=0%; studies=20, participants=7,367; low certainty of evidence).

2. Secondary outcomes

SSRI treatment probably improves participants' control over ejaculation defined as a rating of 'good' or 'very good' based on the PEP questionnaire compared to placebo (RR, 2.29; 95% CI, 1.72–3.05; I^2=75%; studies=3, participants=4,273; moderate certainty of evidence).

Furthermore, SSRI treatment probably decreases PE-related distress defined as 'a little bit' or 'not at all' distressing based on the PEP questionnaire compared to placebo (RR, 1.54; 95% CI, 1.26–1.88; studies=1, participants=652; moderate certainty of evidence).

Treatment with SSRIs may reduce relationship difficulties to only 'a little bit' or 'not at all' based on the PEP questionnaire compared to placebo (RR, 1.20; 95% CI, 1.07–1.34; studies=1, participants=652; low certainty of evidence).

Additionally, SSRI treatment may increase IELT

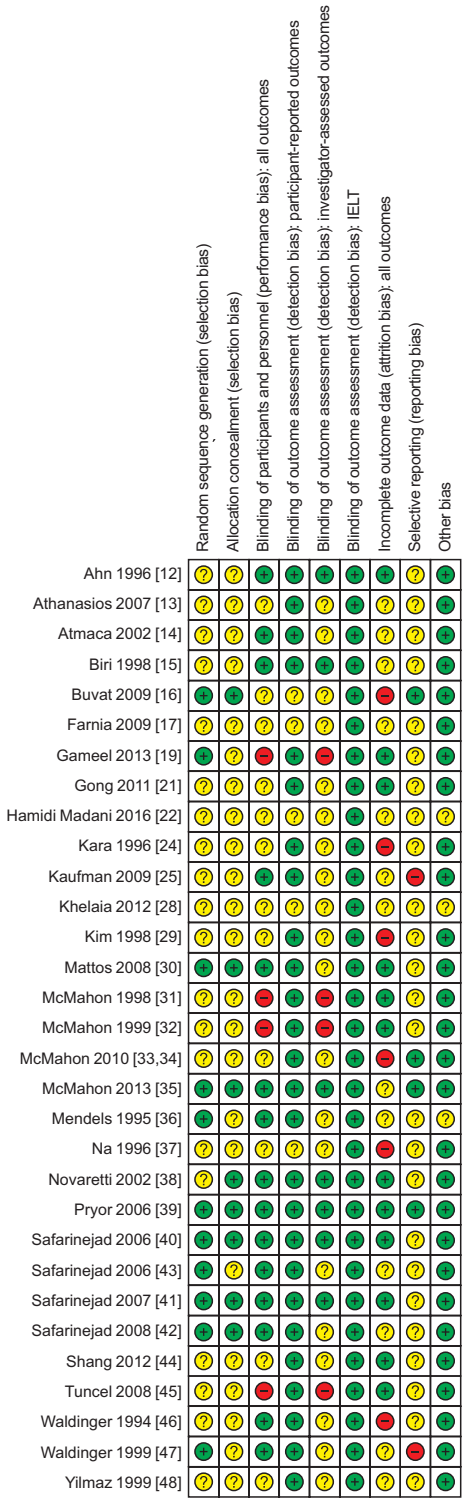

Fig. 1. Risk of bias assessment.

compared to placebo (mean difference 3.09 minutes higher; 95% CI, 1.94 higher to 4.25 higher; I^2=99%; studies=20, participants=5,872; low certainty of evidence).

SSRI treatment probably increases adverse events substantially compared to placebo (RR, 1.71; 95% CI,

https://doi.org/10.5534/wjmh.210155

Table 1. SSRI compared to placebo for premature ejaculation in adult men

Outcomes	No. of participants (studies)	Certainty of the evidence (GRADE[a])	Relative effect (95% CI)	Anticipated absolute effects[b] (95% CI)		What happens
				Risk with placebo	Risk difference with SSRI	
Participant perception of change with treatment assessed with: Clinical Global Impression of Change questionnaire (event is good as it represents improvement in symptoms)	3,260 (6 RCTs)	⊕⊕⊕⊖ Moderate[c]	RR 1.92 (1.66–2.23)	Study population 220 per 1,000	202 more per 1,000 (145 more to 270 more)	SSRI probably results in perceived improvement compared to placebo.
Participant satisfaction with intercourse assessed with: Premature Ejaculation Profile questionnaire (event is good as it represents increased satisfaction)	4,273 (3 RCTs)	⊕⊕⊕⊖ Moderate[c,d]	RR 1.63 (1.42–1.87)	Study population 278 per 1,000	175 more per 1,000 (117 more to 242 more)	SSRI probably results in improved satisfaction with intercourse compared to placebo.
Study withdrawal due to adverse events	7,367 (20 RCTs)	⊕⊕⊖⊖ Low[c,e]	RR 3.80 (2.61–5.51)	Study population 11 per 1,000	30 more per 1,000 (17 more to 49 more)	SSRI may result in more withdrawals due to adverse events compared to placebo.
Perceived control over ejaculation assessed with: Premature Ejaculation Profile questionnaire (event is good as it represents increased control over ejaculation)	4,273 (3 RCTs)	⊕⊕⊕⊖ Moderate[c]	RR 2.29 (1.72–3.05)	Study population 132 per 1,000	170 more per 1,000 (95 more to 270 more)	SSRI probably results in improved perceived control over ejaculation compared to placebo.
Participant distress about PE assessed with: Premature Ejaculation Profile questionnaire (event is good as it represents less distress)	652 (1 RCT)	⊕⊕⊕⊖ Moderate[c]	RR 1.54 (1.26–1.88)	Study population 353 per 1,000	191 more per 1,000 (92 more to 311 more)	SSRI probably results in increased numbers of men not distressed about PE compared to placebo.
Adverse events	4,624 (17 RCTs)	⊕⊕⊕⊖ Moderate[c]	RR 1.71 (1.48–1.99)	Study population 243 per 1,000	173 more per 1,000 (117 more to 241 more)	SSRI probably results in increased adverse events compared to placebo.
IELT	5,872 (20 RCTs)	⊕⊕⊖⊖ Low[c,f]	-	The mean IELT was 1.41 minutes	MD 3.09 minutes higher (1.94 higher to 4.25 higher)	SSRI probably results in extended IELT compared to placebo.

Patient or population: adult men with premature ejaculation. Setting: outpatient. Intervention: SSRI. Comparison: placebo.

CI: confidence interval, RCT: randomized controlled trial, RR: risk ratio, SSRI: selective serotonin re-uptake inhibitor, PE: premature ejaculation, IELT: intravaginal ejaculatory latency time, MD: mean difference.

[a]GRADE Working Group grades of evidence: (1) High certainty: we are very confident that the true effect lies close to that of the estimate of the effect. (2) Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. (3) Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. (4) Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[b]The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[c]Downgraded one level for study limitations: most studies had an unclear or high risk of selection, performance and detection bias.

[d]Not downgraded for high I2 statistic since observed inconsistency did not appear clinically relevant.

[e]Downgraded one level due to serious concerns regarding attrition bias.

[f]Downgraded one level for serious inconsistency.

1.48–1.99; I^2=41%; studies=17, participants=4,624; moderate certainty of evidence).

We are very uncertain whether SSRI treatment compared to placebo increases depression (RR, 2.00; 95% CI, 0.23–17.34; studies=1, participants=14; vert low certainty of evidence).

DISCUSSION

This comprehensive systematic review and meta-analysis included 31 studies with 8,254 participants and found that compared to placebo, SSRI treatment for PE probably improves perception of change with treatment, satisfaction with intercourse, perceived control over ejaculation, participant distress about PE, relationship difficulties, and IELT. However, the administration of SSRIs may increase study withdrawals due to adverse events and probably increases adverse events. These findings are consistent with other published reviews on the topic [8,10,50].

We consistently downgraded the certainty of evidence by one or two steps to moderate or low. Our confidence in the estimates of effect were primarily limited by study limitations and heterogeneity. Most studies were classified at unclear or high risk of bias for multiple domains and, therefore, the potential biases in those studies introduced a degree of uncertainty in the calculated summary estimates.

CONCLUSIONS

Compared to placebo, the administration of SSRIs for PE may improve perception of change with treatment and satisfaction with intercourse. SSRIs may also improve perceived control over ejaculation and reduce both distress about PE and relationship difficulties. These potential benefits need to be weighed up against the possible increase in adverse events with SSRIs.

Conflict of Interest

The authors have nothing to disclose.

Funding

None.

Acknowledgements

This article is based on a Cochrane Review published in the Cochrane Database of Systematic Reviews (CDSR) 2021, Issue 6, DOI: 10.1002/14651858.CD012799.pub2. (see cochranelibrary.com for information). Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and the CDSR should be consulted for the most recent version of the review.

We thank Cochrane Urology for its support. We are grateful to Dr Yu Xie for translating articles. We are also appreciative of the feedback provided by Dr Josip Vukina, MD, MPH (University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA) and Dr Ege Can Serefoglu, MD, FECSM (Professor of Urology, Biruni University School of Medicine, Istanbul, Turkey; Editor-in-Chief, International Journal of Impotence Research, London, UK) who served as peer referees.

Author Contribution

Conceptualization: NJS, RM, ECH, JAB, SS, PD. Data curation: NJS, ECH, JAL, RM, AS. Formal analysis: NJS, ECH. Investigation: JAB, SS, PD. Methodology: NJS, JAL, ECH, RM, JAB, SS, PD. Supervision: JAB, PD. Writing – original draft: NJS, ECH, JAL, PD. Writing – review & editing: RM, JAB, AS, SS.

Supplementary Materials

Supplementary materials can be found *via* https://doi.org/10.5534/wjmh.210155.

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