Efficacy and Safety of Flibanserin for the Treatment of Hypoactive Sexual Desire Disorder in Women

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In August 2015, the US Food and Drug Administration (FDA) approved flibanserin as a treatment for hypoactive sexual desire disorder (HSDD) in premenopausal women, despite concern about suboptimal risk-benefit trade-offs.
Objective

» To conduct a systematic review and meta-analysis of randomized clinical trials assessing efficacy and safety of flibanserin for the treatment of HSDD in women.
Data sources

» Medical databases (among others, Embase, Medline, Psycinfo) and trial registries were searched from inception to June 17, 2015.

» Reference lists of retrieved studies were searched for additional publications.
Study selection

» Randomized clinical trials assessing treatment effects of flibanserin in premenopausal and postmenopausal women were eligible.

» No age, language, or date restrictions were applied.

» Abstract and full-text selection was done by 2 independent reviewers.
Data extraction and synthesis

» Data were extracted by one reviewer and checked by a second reviewer.

» Results were pooled using 2 approaches depending on the blinding risk of bias.
Main outcomes and measures

» **Primary efficacy outcomes** included number of satisfying sexual events (SSEs), eDiary sexual desire, and Female Sexual Function Index (FSFI) desire.

» **Safety outcomes** included, among others, 4 common adverse events (AEs)
  » dizziness
  » somnolence
  » nausea
  » fatigue.
Results (1)

» Five published and 3 unpublished studies including 5914 women were included.

» Pooled mean differences for SSE change from baseline were 0.49 (95% CI, 0.32-0.67) between 100-mg flibanserin and placebo, 1.63 (95% CI, 0.45-2.82) for eDiary desire, and 0.27 (95% CI, 0.17-0.38) for FSFI desire.

» The risk ratio for study discontinuation due to AEs was 2.19 (95% CI, 1.50-3.20).
Results (2)

- The risk ratio for dizziness was 4.00 (95% CI, 2.56-6.27) in flibanserin vs placebo, 3.97 (95% CI, 3.01-5.24) for somnolence, 2.35 (95% CI, 1.85-2.98) for nausea, and 1.64 (95% CI, 1.27-2.13) for fatigue.

- Women’s mean global impression of improvement scores indicated minimal improvement to no change.
Conclusions and relevance (1)

» Treatment with flibanserin, on average, resulted in one-half additional SSE per month while statistically and clinically significantly increasing the risk of dizziness, somnolence, nausea, and fatigue.

» Overall, the quality of the evidence was graded as very low.
Conclusions and relevance (2)

Before flibanserin can be recommended in guidelines and clinical practice, future studies should include women from diverse populations, particularly women with comorbidities, medication use, and surgical menopause.
Loes Jaspers, MD; Frederik Feys, MSc, PhD; Wichor M. Bramer, BSc; Oscar H. Franco, MD, PhD; Peter Leusink, MD; Ellen T. M. Laan, PhD. Efficacy and Safety of Flibanserin for the Treatment of Hypoactive Sexual Desire Disorder in Women A Systematic Review and Meta-Analysis. JAMA Intern Med. February 29, 2016.

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