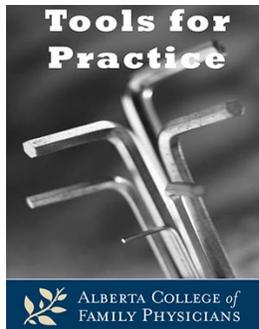


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Flibanserin: Feeling frisky or falling over?

Clinical Question: Does flibanserin improve sexual desire and the number of satisfying sexual episodes for women?

Bottom-line: Flibanserin results in ~7% improvement in desire and 0.4-1 additional “satisfying” sexual event per month. However, it is also associated with adverse events like dizziness or somnolence for one in 10-15 women. Concerns regarding hypotension, syncope, and interactions with commonly used drugs (particularly alcohol) are worrisome and require further research.

Evidence:

- Four double-blind randomized controlled trials of 1,581,¹ 880,² and 1,087³ premenopausal women and 949⁴ postmenopausal women with Hypoactive Sexual Desire Disorder. Flibanserin (versus placebo) demonstrated:
 - Statistically significant increase in “satisfying” sexual events: 0.4-1/28 days.^{3,4}
 - No increase daily sexual desire.^{1,2}
 - Increase in Female Sexual Function Index-Desire domain:
 - 0.3-0.4 on scale of 1.2-6.0.¹⁻⁴
 - Number Needed to Harm (NNH) for any investigator defined adverse event =5, dizziness =10-15, somnolence =10-14, nausea =13-25, fatigue =29-42.³
 - US Food and Drug Administration (FDA) review (including unpublished data)⁵ reports NNH for any serious adverse event =250, syncope =500.
 - Study limitations:
 - Strict exclusion criteria (example no benzodiazepines, sleep aids, narcotics, antidepressants).¹⁻⁴
 - Change in primary outcome to find statistical significance.^{3,4}
 - Poor adverse events and drug interactions reporting.^{1,2}

Context:

- FDA assessed phase 1-3 studies with 6,439 women reports safety concerns regarding hypotension, syncope, and somnolence, worsened with alcohol, oral contraceptives, and antifungals (among others).⁶
- Among 25 patients (23 male) given both alcohol (0.4g/kg) and flibanserin, 17% developed hypotension and/or syncope requiring intervention.⁶

- Following the second FDA rejection, an advocacy campaign entitled “Even the Score” (sponsored in part by flibanserin manufacturers) claimed the FDA was exhibiting gender bias by rejecting flibanserin.^{7,8}
- FDA approved flibanserin for Hypoactive Sexual Desire Disorder on its third application, with a risk mitigation strategy including alcohol contraindication and further research.^{6,8,9}
- Flibanserin has not yet been approved for use in Canada.

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Disclosure:

Authors do not have any conflicts to disclose.

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Tools for Practice is a biweekly article summarizing medical evidence with a focus on topical issues and practice modifying information. It is coordinated by G. Michael Allan, MD, CCFP and the content is written by practicing family physicians who are joined occasionally by a health professional from another medical specialty or health discipline. Each article is peer-reviewed, ensuring it maintains a high standard of quality, accuracy, and academic integrity.

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