

ORIGINAL RESEARCH

Efficacy and Safety of Flibanserin in Women with Hypoactive Sexual Desire Disorder: A Systematic Review and Meta-Analysis

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ABSTRACT

Introduction. Flibanserin, is a postsynaptic agonist of serotonin receptor 1A and an antagonist of serotonin receptor 2A, has been shown to increase sexual desire and reduce distress in women with hypoactive sexual desire disorder (HSDD).

Aim. We carried out a systematic review and meta-analysis to assess the efficacy and safety of the drug in women with HSDD.

Methods. A literature review was performed to identify all published randomized double-blind, placebo-controlled trials of flibanserin for the treatment of HSDD. The search included the following databases: MEDLINE, EMBASE, and the Cochrane Controlled Trials Register. The reference lists of the retrieved studies were also investigated.

Main Outcome Measures. Four publications involving a total of 3,414 patients were used in the analysis, including four randomized controlled trials that compared flibanserin with placebo.

Results. For the comparison of flibanserin with placebo, primary efficacy endpoints: satisfying sexual events (the standardized mean difference [SMD] = 0.59, 95% confidence interval [CI] = 0.37–0.80, $P < 0.00001$); sexual desire score (the SMD = 1.91, 95% CI = 0.21 to 3.60, $P = 0.03$) and Female Sexual Function Index (FSFI) desire domain score (the SMD = 0.32, 95% CI = 0.19–0.46, $P < 0.00001$) and key secondary efficacy endpoints: FSFI total score, Female Sexual Distress Scale-Revised (FSDS-R) total score, FSDS-R Item 13 score, Patient's Global Impression of Improvement score and Patient Benefit Evaluation indicated that flibanserin was more effective than the placebo. Safety assessments included the proportion of women who experienced an adverse event (odds ratio = 1.54, 95% CI = 1.34 to 1.76, $P < 0.00001$), nervous system disorders and fatigue indicated that flibanserin was well tolerated.

Conclusions. This meta-analysis indicates that flibanserin to be an effective and safe treatment for HSDD in women. **Gao Z, Yang D, Yu L, and Cui Y. The efficacy and safety of flibanserin in women with hypoactive sexual desire disorder: A systematic review and meta-analysis. J Sex Med 2015;12:2095–2104.**

Key Words. Flibanserin; Hypoactive Sexual Desire Disorder; Meta-Analysis; Randomized Controlled Trial

Introduction

Hypoactive sexual desire disorder (HSDD) is defined by the American Psychiatric Association as a persistent or recurrent deficiency or absence of sexual fantasies and desire for sexual

activity that causes marked distress or interpersonal difficulty. For a diagnosis of HSDD to be given, the dysfunction should not be better accounted for by another psychiatric disorder (except another sexual dysfunction) and must not be due exclusively to the physiological effects of a substance or a general medical condition [1]. Consequently, diagnosis of HSDD requires a thorough clinical evaluation [2]. A large US population-

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based survey conducted in 2006 found that about 10% of premenopausal women reported low sexual desire with associated distress, which may indicate HSDD [3]. The prevalence of low sexual desire associated with distress among naturally postmenopausal women was 6.6% in a US survey of 541 naturally postmenopausal women conducted in 2004–2005 and 9.3% in a US survey of 10,429 women conducted in 2006 [3,4].

The etiology of HSDD may involve a multitude of biologic and psychosocial factors [5]. Norepinephrine, dopamine, and testosterone seem to play roles in the stimulation of sexual desire, whereas serotonin inhibits sexual desire [6,7]. Treatment with testosterone has been shown to improve sexual desire in women with HSDD [8–10]. However, that women with HSDD are deficient in testosterone has not been established in general [11]. Flibanserin is a postsynaptic agonist of serotonin receptor 1A and an antagonist of serotonin receptor 2A [12]. When investigated as a treatment for major depressive disorder, flibanserin was observed to increase sexual desire in women with major depressive disorder who had decreased sexual desire at baseline [13]. This provided a rationale for investigating flibanserin as a treatment for HSDD in women.

The goal of the present study was to perform a meta-analysis to evaluate the efficacy and safety of flibanserin in women with HSDD, which may

resolve some of the current controversies over use of this drug.

Materials and Methods

Search Strategy

Medline (1966 to May 2015), Embase (1974 to May 2015), and Cochrane Controlled Trials Register databases were searched to identify randomized controlled trials (RCTs) that referred to the impact of flibanserin in treating HSDD; we also searched the reference lists of the retrieved studies. The following search terms were used: *flibanserin*, *HSDD*, and *randomized controlled trial*.

Inclusion Criteria and Trial Selection

RCTs that met the following criteria were included: (1) The study design included treatment with flibanserin; (2) the study provided accurate data that could be analyzed, including the total number of subjects and the values of each index; and (3) the full text of the study could be accessed. When the same study was published in various journals or in different years, the most recent publication was used for the meta-analysis. If the same group of researchers studied a group of subjects with multiple experiments, then each study was included. A flow diagram of the study selection process is presented in Figure 1.

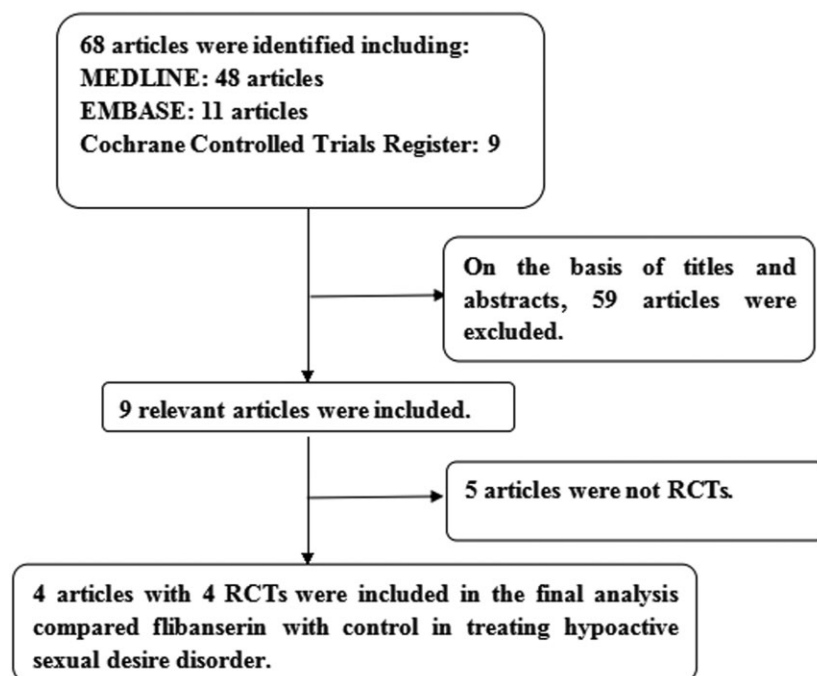


Figure 1 A flow diagram of the study selection process. RCT = randomized controlled trial.

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