Rx

A Nonhormonal Treatment for Moderate to Severe Vasomotor Symptoms of Menopause

HEIDI COLLINS FANTASIA

Editor's note: *The Rx column is intended to objectively inform and report on developments in pharmacologic treatments and medical devices. Because in many cases the products being reported on have not been on the market for an extended period or are being used for a new indication, the literature cited is likely to include trials sponsored by the pharmaceutical manufacturer(s).*

Menopause is the permanent cessation of menses caused by loss of ovarian follicular activity. For women in the United States, the average age of menopause is 51 years, although the transition to menopause begins in the previous decade (Kaunitz & Manson, 2015). It is

Abstract It is estimated that up to 80% of women experience symptoms related to declining estrogen levels that occur with menopause. The most common bothersome symptoms reported by women during and after this transition are vasomotor symptoms, which can include hot flashes, flushing, night sweats, and sleep disturbances. These symptoms are the most common reason women seek care during menopause. Until recently, the mainstay of treatment and symptom relief has been estrogen supplementation. In 2013, the U.S. Food and Drug Administration approved paroxetine, a low-dose selective serotonin reuptake inhibitor, as the first nonhormonal treatment for moderate to severe vasomotor symptoms of menopause. This article provides an overview of the use of paroxetine to treat vasomotor symptoms of menopause, including potential adverse reactions, special considerations for use, and implications for nursing practice.
http://dx.doi.org/10.1016/j.nwh.2016.08.007

Keywords hot flash | menopause | paroxetine | vasomotor symptoms

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estimated that up to 80% of women experience symptoms related to loss of ovarian function and declining estrogen levels that occur with menopause (Alexander & Moore, 2007). The most common bothersome symptoms reported by women during and after this transition are vasomotor symptoms, which can include hot flashes, flushing, night sweats, and sleep disturbances (Handley & Williams, 2015). For some women these symptoms can persist for more than 7 years (Avis et al., 2015). Vasomotor symptoms are the most common reason women seek health care during menopause.

Vasomotor symptoms that occur with menopause are not harmful but can have a significant negative impact on a woman's quality of life. Women have reported a disruption in daily activities because of flushing and perspiration, poor sleep quality, irritability, labile moods, and anxiety (Alexander & Moore, 2007; Handley & Williams, 2015). The mainstay of treatment and symptom relief has been estrogen supplementation, which had previously been the only treatment approved by the U.S. Food and Drug Administration for treatment for vasomotor symptoms of menopause (Orleans et al., 2014). This has limited treatment options, especially for women who are not candidates for estrogen therapy or for women who are concerned about adverse effects.

In 2013, the FDA approved paroxetine as the first nonhormonal treatment for vasomotor symptoms of menopause (FDA, 2013). This column provides an overview of paroxetine, possible adverse reactions, contraindications, and implications for nurses who work with women during the transition into menopause.

Overview of Paroxetine

Paroxetine (Brisdelle, Noven Therapeutics, Miami, FL) is a selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of moderate to severe vasomotor symptoms of menopause. There is no estrogen component to paroxetine. The mechanism of action in reducing vasomotor symptoms is unclear and complex, and it differs from the mechanisms involved in treating psychiatric disorders with SSRIs (Noven Therapeutics, 2014; Simon et al., 2013). It is hypothesized that the decreasing estrogen levels associated with menopause affect the hypothalamus and change both serotonin and norepinephrine levels. This can alter the thermoregulatory set point in the hypothalamus and trigger temperature instability (Simon et al., 2013). Paroxetine may reduce vasomotor symptoms through activation of serotonin receptors in the hypothalamus.

Effectiveness of paroxetine for the treatment of vasomotor symptoms of menopause has been documented in a large randomized controlled trial. Simon et al. (2013) evaluated the effectiveness of paroxetine compared with placebo in more than 1,000 postmenopausal women with moderate to severe vasomotor symptoms of menopause. By Study Week 4 there were statistically significant decreases in vasomotor symptoms among women taking paroxetine compared with placebo. These effects were still seen at 24 weeks of treatment (Simon et al., 2013).

Dosage and Administration

Paroxetine is available in a single strength of 7.5 mg that is taken orally every day. Because of the potential for cognitive impairment, fatigue, and impaired motor skills, paroxetine should be taken at bedtime (Noven Therapeutics, 2014). It may be taken with or without food. Although paroxetine is an SSRI, the dosage approved for relief of vasomotor symptoms of menopause is lower than what would be therapeutic for the treatment of psychiatric conditions. A missed dose should be taken as soon as the woman remembers but should not be doubled (Noven Therapeutics, 2014).

Potential Adverse Effects

The most significant potential adverse effect is a change in mood. Antidepressants, including SSRIs such as paroxetine, have been linked to an increased risk of suicidal thoughts and behaviors, especially in adolescents and young adults. These medications are required to carry a black box warning for use in individuals through the age of 24 years (Reeves & Ladner, 2010). Paroxetine for vasomotor symptoms of menopause is not given in this age group and is prescribed at a lower dosage than for depression and other psychiatric conditions, but it carries the black box warning for mood changes. Monitoring for adverse mood changes should occur, especially at the beginning of treatment (Noven Therapeutics, 2014). In Phase 3 clinical trials to monitor effectiveness and adverse effects, no paroxetine-related suicidal behaviors were reported (Simon et al., 2013).

Heidi Collins Fantasia, PhD, RN, WHNP-BC, is an assistant professor in the College of Health Sciences, School of Nursing at the University of Massachusetts Lowell in Lowell, MA, and a nurse practitioner at Health Quarters in Beverly, MA. The author reports no conflicts of interest or relevant financial relationships. Address correspondence to: heidi_fantasia@uml.edu.