Rx

Treatment of Dyspareunia Secondary to Vulvovaginal Atrophy

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In the United States, the average age of menopause is 51 (North American Menopause Society [NAMS], 2012), and women can expect to spend one-third of their lives in the postmenopausal years. The menopause transition is a universal event that signals the end of reproductive capability. While many women transition through menopause without significant symptoms, fluctuating and declining estrogen levels can produce bothersome symptoms for some women. Vasomotor instability, more commonly referred to as hot flashes, is often the most common menopausal symptom that causes women to seek care (Hess et al., 2012).

An additional side effect of the declining estrogen levels in menopause is vulvovaginal atrophy. This refers to changes in the vaginal tissues from the lack of estrogen, and can include

Abstract: Declining estrogen levels associated with menopause can result in vulvovaginal atrophy and some degree of dyspareunia for more than half of all women in menopause. In 2013, the U.S. Food and Drug Administration approved ospemifene, a nonhormonal oral medication for the treatment of dyspareunia in menopause. This article will provide an overview of ospemifene and its indications, side effects and implications for nurses. DOI: 10.1111/1751-486X.12125

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pale, dry vaginal tissues that have decreased elasticity. Additionally, changes associated with vulvovaginal atrophy can include thin, atrophic mucosal surfaces, decreased vaginal secretions and inflamed urogenital tissues (NAMS, 2013; Woods, 2012). Atrophic changes are progressive and do not improve over time (NAMS, 2013). Up to 60 percent of women who have not been treated with estrogen therapy in menopause will experience some degree of vulvovaginal atrophy (Calleja-Agius & Brincat, 2009; Santoro & Komi, 2009) during the postmenopausal years. Despite the prevalence rate for vulvovaginal atrophy, few women seek care for their symptoms or are offered treatment by health care providers (NAMS, 2013).

Dyspareunia is associated with female sexual dysfunction, decreased arousal and decreased interest in sexual activity

Dyspareunia

One of the most significant symptoms of vulvovaginal atrophy is dyspareunia, or painful vaginal intercourse secondary to dry, inflamed and inelastic tissues. Dyspareunia is associated with female sexual dysfunction, decreased arousal and decreased interest in sexual activity (NAMS, 2013). Atrophic changes can result in friable vaginal tissues that are prone to trauma, tearing and bleeding during intercourse. Pain and trauma with intercourse may cause women to avoid sexual activity and place strain on relationships.

The most common treatment for vulvovaginal atrophy and dyspareunia has been hormone therapy with estrogen plus progesterone or estrogen alone. Although very effective in alleviating symptoms, hormone therapy, including topical administration (most common) and systemic formulations, is not utilized to its full extent due to both patient and provider concerns about potential side effects, which include risk for breast cancer and venous thromboembolism (Hersh, Stefanick, & Stafford, 2004; Newton et al., 2010).

Recently, the U.S. Food and Drug Administration (FDA) approved ospemifene, an oral nonhormonal selective estrogen receptor modulator (SERM) as a treatment for vulvovaginal atrophy. SERMs are synthetic, nonhormonal and nonsteroidal agents that possess both estrogen agonist and antagonist properties (Pinkerton & Thomas, 2013). The mechanism by which SERMs exert their unique effects on target tissues is not fully understood.

Overview of Ospemifene

Ospemifene (Osphena™) is an oral estrogen agonist/antagonist that was approved by the FDA in 2013 specifically for the treatment of moderate to severe dyspareunia associated with menopause-related vulvovaginal atrophy (Shionogi Inc., 2013). In clinical trials, ospemifene has demonstrated positive effects on the vaginal epithelium, minimal stimulation of the endometrium and neutral or antiestrogenic properties on breast tissue (Cui, Zong, Yan, Li, & Zhang, 2013; Goldstein, Dicks, Kim, & Hartzell, 2013; Kangas & Unkila, 2013; Simon, Lin, Radovich, & Bachmann, 2013). Although not approved for the treatment or prevention of low bone mass or osteoporosis, ospemifene demonstrated antiresorptive effects on bone in preclinical studies (Kangas & Unkila, 2013).

Dosage and Administration

The dose of ospemifene is 60 mg taken orally each day. It should be taken with food because this will increase the bioavailability of the medication (Shionogi Inc., 2013). Women who begin ospemifene should be evaluated periodically for improvement in symptoms. In clinical trials, decrease in vaginal pH and reversal of atrophic changes was noted 12 weeks after beginning therapy (Cui et al., 2013; Goldstein et al., 2014). There are no current, established guidelines for the recommended length of treatment with ospemifene, nor have there been any clinical trials comparing the effectiveness of ospemifene to treatment with localized estrogen therapy. Women taking this medication should discuss their own treatment with their health care provider.

Adverse Reactions

Although ospemifene does not contain estrogen or any other hormone, it has estrogen-like properties and therefore exerts some of the same side effects as estrogen-containing medications. Ospemifene carries a black box warning (see Box 1) that highlights potential serious

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