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Hormone Therapy for the Management of Menopause Symptoms

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ABSTRACT

Many women will undergo menopause without incident, but others will experience bothersome effects resulting from declining estrogen levels. Vasomotor symptoms, which manifest as intense feelings of warmth, flushing, and perspiration, are the most common symptoms for which women seek treatment. Hormone therapy is indicated for the relief of vasomotor symptoms related to menopause. We review current Food Drug Administration-approved options for hormone therapy and discuss implications for practice and patient education.

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According to the U.S. Census Bureau demographic profile, in 2010 there were almost 23 million women in the United States between the ages of 45 and 54 (U.S. Census Bureau, 2010), and the average age of natural menopause in the United States is 51 (North American Menopause Society [NAMS], 2013). This physiologic transition is a universal event that affects all women and marks the end of reproductive capability. It is influenced by a myriad of factors, including genetics, environment, diet, weight, smoking, and overall health status (NAMS, 2010).

Vasomotor instability that occurs as a result of declining estrogen levels can have a negative impact on the quality of life and is often the main symptom of menopause that causes women to seek treatment (Avis et al., 2009; Burleson, Todd, & Trevathan, 2010; Hess et al., 2012). Hormone therapy is approved by the Food and Drug Administration (FDA) as the most effective treatment for vasomotor symptoms of menopause (NAMS, 2012) but is currently underused due to concerns regarding potential side effects, including risk for breast cancer and venous thromboembolism (Hersh, Stefanick, & Stafford, 2004; Neal-Perry & Pal, 2011; Newton et al., 2010). Patients and health care providers may overestimate the potential for harm and underestimate the potential benefits of hormone therapy (HT) (Rees, 2005). In this article we review current FDA-approved hormonal pharmacologic options for women experiencing symptoms of menopause, discuss the controversy surrounding HT, and discuss clinical implications for nurses who work with women experiencing the transition through menopause.

Diagnosis of Menopause

Menopause can only be diagnosed retrospectively, and menstrual cycle details provided by women represent the most important information to determine menopause status (Harlow et al., 2012). Menopause is defined as occurring after 12 months of amenorrhea that results from the loss of ovarian follicular activity that cannot be attributed to another physiologic or pathologic cause (NAMS, 2010; National Institutes of Health [NIH], 2005; World Health Organization [WHO], 1996). The years preceding the permanent cessation of menses are characterized by endocrine changes that affect menstrual cycle frequency, amount, and duration (NAMS, 2010). Although physiologic signs of hormone fluctuation during menopause may occur, no one specific laboratory or diagnostic test to determine if a patient is menopausal exists. Hormonal biomarker assays, especially for follicle stimulating hormone (FSH), are not reliable due to lack of international standardization and wide variability among women (Harlow et al., 2012; NAMS, 2010). Elevated FSH levels > 30 IU/ml are indicative of increasing ovarian follicular atresia, but laboratory measurements cannot confirm menopause (Harlow et al., 2012; O'Neill & Eden, 2012).

Symptoms of Menopause

Vasomotor Instability

Vasomotor instability (or hot flashes), a primary symptom of menopause, includes a sudden feeling of intense heat accompanied by perspiration and flushing (NIH, 2005) and typically lasts less than 10 minutes. Vasomotor instability may also be associated with symptoms of anxiety, palpitations, and sleep disturbances. Although the prevalence of vasomotor symptoms varies across racial and ethnic backgrounds, more than 50% of women report vasomotor symptoms at some point during menopause (O'Neill & Eden, 2012).

Hypoestrogenic Changes

Declining estrogen levels are associated with urogenital atrophy. Vulvar and vaginal symptoms may include dryness, pruritus, burning, and pain, especially with intercourse (Gorodeski, 2012). Although the natural aging process is a contributing factor to urogenital symptoms, estrogen deficiency has been established as the main etiology of vaginal epithelial thinning and atrophic vaginitis (Gorodeski, 2012; O'Neill & Eden, 2012).

The Women's Health Initiative Hormone Trials

The Women's Health Initiative (WHI) clinical trials were parallel, multicenter, randomized, controlled primary prevention trials designed to investigate the effects of hormone therapy (HT) on major health issues in postmenopausal women such as coronary artery disease (CAD). The primary adverse outcome of the research trials was invasive breast cancer (Rossouw et al., 2002; Anderson et al., 2004). Researchers studied multiple foci and in one arm compared daily estrogen (conjugated equine estrogen [CEE] 0.625 mg) plus progesterone (medroxyprogesterone acetate [MPA] 2.5mg) with a placebo for the primary prevention of cardiovascular disease among postmenopausal women. A total of 16,608 healthy, postmenopausal women with an intact uterus and a baseline age of 50 to 79 were enrolled between 1993 and 1998. In May of 2002 after 5 out of 8 years of anticipated follow-up, the estrogen plus progesterone arm was halted by the study's Data Safety Monitoring Board after unanticipated risks were judged to outweigh potential benefits. Compared to women receiving placebo, women in the estrogen/progesterone group had increased risks of breast cancer, stroke, pulmonary embolism, and myocardial infarction (Rossouw et al., 2002).

The early termination of the estrogen plus progesterone and estrogen only arms of the Women's Health Initiative has shaped the pharmacologic treatment of menopause symptoms.

The estrogen-only arm of the study was also terminated early. In this portion of the WHI, 10,739 postmenopausal women age 50 to 70 who had undergone a hysterectomy were enrolled. These women received daily estrogen (0.625 mg CEE) without added progesterone. Early termination occurred when investigators reported that when compared with placebo, the use of daily estrogen increased the risk of stroke and did not reduce the incidence of CAD (Anderson et al., 2004).

Rethinking WHI Study Results

The early termination of both arms of the WHI has shaped the subsequent pharmacologic treatment of menopause symptoms. Prior to the publication of the WHI results, HT was most commonly prescribed to control the vasomotor symptoms of menopause that are experienced by more than one half of perimenopausal and postmenopausal women (Santen et al., 2010). When the initial research results were published, use of HT declined significantly as a result of patient and provider concerns and fear of potential liability if adverse events were to occur (Hersh et al., 2004; Neal-Perry & Pal, 2011; Newton et al., 2010).

Since the initial publication of the WHI results, the original research conclusions regarding risks of adverse events have been questioned and limitations closely examined (Utian, 2012). Three limitations often cited include the age of the sample, the determination of relative risk, and the formulation of the HT. The age range for inclusion in the WHI trials was 50 to 79, and the mean age was 63 (Rossouw et al., 2002). The age range of almost 20 years was necessary due to the large numbers of participants needed to adequately power the study and achieve statistical significance for the small number of predicted adverse outcomes (Anderson et al., 2004; Rossouw et al., 2002). However, the average age of participants (63) was more than 10 years older than the age at which women would typically be offered HT for symptoms of menopause. As women age their risks for cardiovascular incidents such as myocardial infarction and thromboembolic events increase. Therefore, it is challenging to determine whether the adverse cardiovascular events that

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