

## CLINICAL CHALLENGES

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### Hormone Replacement Therapy in Postmenopausal Women

#### Case Study

Ms. P is 48 years old, at average risk for breast cancer, and is complaining of menopause-related hot flashes and insomnia. She is 30 pounds overweight, sedentary, and a social smoker. Ms. C is 40 years old and had breast cancer that was treated successfully with radiation nine years ago. She is a non-smoker, an avid exerciser, and at her optimal body weight. She is complaining of severe menopausal symptoms, particularly vaginal dryness that is making sexual activity painful. Both women want to know whether hormone replacement therapy (HRT) is warranted.

#### Clinical Highlights

Several large clinical trials were initiated in the 1990s to obtain scientific data regarding the risks and benefits of HRT. One of the largest trials was conducted by the Women's Health Initiative (WHI). WHI randomly assigned more than 16,000 postmenopausal women 50–79 years of age with an intact uterus to estrogen plus progestin or placebo. The drug arm was halted in 2002 when results revealed that instead of protecting against cardiovascular disease, use of HRT actually increased risks of cardiovascular events, breast cancer, pulmonary emboli, and stroke. However, the study's data and safety monitoring board stopped the trial based on the finding of increased breast cancer risk, supported by the fact that overall health risks exceeded any benefit (Writing Group for the WHI Investigators, 2002).

Specific study findings for the drug arm included a 113% increase in pulmonary emboli, 41% increase in strokes, 29% increase in myocardial infarctions, 22% increase in total cardiovascular events, and 26% increase in breast cancer. A 37% reduction in colorectal cancer and a 24% reduction in fractures also were found. No difference was identified for total mortality. Effects were apparent after an average of five years of follow-up (Grady, 2003; Hays et al., 2003; Monson & Martin, 2001; National Institutes of Health [NIH], 2002; Solomon & Dluhy, 2003; Writing Group for the WHI Investigators, 2002).

Other observational studies have indicated that breast cancer risk may be greater among women using combined estrogen and progestin therapy than estrogen alone (NIH, 2002; O'Meara, Rossing, Daling, & Elmore, 2001). Additional findings have revealed that risk increased with length of use but returned to near-normal levels after therapy was discontinued (NIH; O'Meara et al.; Ross, Paganini-Hill, & Wan, 2000; Schairer et al., 2000). In a study of women diagnosed with breast cancer, prior estrogen users had lower mortality rates than nonusers (Ross et al.). Another study that followed more than 44,000 postmenopausal women who took estrogen for 20 years found that their risk of ovarian cancer was twice as high as nonusers and documented an even higher risk when estrogen was used longer than 20 years (Lacey et al., 2002; Rodriguez, Patel, Callee, Jacob, & Thun, 2001). One study of women with breast cancer who continued estrogen use after their diagnosis reported no increase in recurrence or mortality (O'Meara et al.).

Significant research needs to be conducted to address many unanswered questions. The actual risk increases in the WHI study are small: A 29% increase in the risk of coronary disease and a 26% increase in breast cancer risk actually translate into an additional 4 cases per 1,000 women (Solomon & Dluhy, 2003). Further research will help to clarify the clinical implications of HRT.

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#### Clinical Problem Solving

Responding to this clinical challenge are Karen Kattwinkel, RN, MA, and Marjorie Knowles, RN, BA, both graduate students in the advanced practice nursing track, and Jeanette Sweeney-Calciano, RN, MSN, an assistant professor, all in the School of Nursing at the University of Medicine and Dentistry of New Jersey in Newark.

#### What considerations for HRT would you discuss with Ms. P?

*J. Sweeney-Calciano:* Menopause is a process that occurs as a part of the female life cycle. Consideration of HRT poses many challenges for two million women turning 50 each year (U.S. Department of Health and Human Services, 2001). During initial consultations, postmenopausal patients' symptoms must be reviewed. Assessments should include how severe the symptoms are and the degree to which they are affecting quality of life. Family history of breast cancer is of significance when considering whether to initiate therapy. Educating patients regarding the dynamic nature of symptoms may relieve some associated stress levels and assist patients in coping with their new status as perimenopausal or menopausal women. During patient counseling, patients must be assured that they are a part of the decision-making process. Patients should receive current information about the appropriateness of beginning or continuing HRT.

*K. Kattwinkel:* Weighing the risks and benefits of HRT is key to making the best health-care decision (see Figure 1). Symptoms of menopause can be very disabling. Ms. P has cardiovascular and thromboembolic disease risks, namely being overweight, sedentary, and a smoker. The Writing Group for the WHI Investigators (2002) determined that women taking estrogen plus progestin replacement therapy were at increased risk for myocardial infarction, venous thromboemboli, and stroke. This study documented one serious adverse event in every 100 women

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Digital Object Identifier: 10.1188/03.ONF.747-749