

SPECIAL FEATURE

A decade after the Women's Health Initiative—the experts do agree

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This year marks the 10th anniversary of the 2002 presentation of the results of the Women's Health Initiative hormone trials. Amidst the debate that ensued, the one consistent theme was that “even the experts don't agree.” Much has been learned and is still being unraveled regarding the safety and efficacy of hormone therapy from previous and ongoing studies. In response to the many women and clinicians seeking answers, our goal is to reassure both symptomatic women and their providers that experts do indeed agree on key points regarding the safety and role of hormone therapy in menopause management based on the scientific evidence of the last 10 years. We believe that women deserve to know the facts that can inform their decision to use or not to use hormone therapy.

OVERVIEW

Systemic hormone therapy is an acceptable option for relatively young (up to age 59 or within 10 years of menopause)

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and healthy women who are bothered by moderate to severe menopausal symptoms. Individualization is key in the decision to use hormone therapy. Consideration should be given to the woman's quality-of-life priorities as well as her personal risk factors such as age, time since menopause, and her risk of blood clots, heart disease, stroke, and breast cancer.

SYMPTOM RELIEF BENEFITS

Systemic hormone therapy is the most effective treatment for most menopausal symptoms, including vasomotor symptoms and vaginal atrophy. Estrogen therapy as a single agent is sufficient in women who have undergone hysterectomy.

Progestogen therapy is required to prevent endometrial cancer when estrogen is used systemically in women with a uterus.

Local estrogen therapy is effective and preferred for women whose symptoms are limited to vaginal dryness or discomfort with intercourse; low-dose vaginal estrogen therapy is recommended in this setting.

HORMONE THERAPY RISKS

Vascular risks

Both estrogen therapy and estrogen with progestogen therapy increase the risk of venous thromboembolic events—deep vein thrombosis and pulmonary emboli. Although the risks of venous thromboembolic events and ischemic stroke increase with either estrogen therapy or estrogen and progestogen therapy, the risk is rare in the 50- to 59-year-old age group.

Breast cancer

An increased risk of breast cancer is seen with 5 years or more of continuous estrogen with progestogen therapy, possibly earlier with continuous use since menopause. The risk is real but not great, and the risk decreases after hormone therapy is discontinued. Use of estrogen alone for a mean of 7 years in the Women's Health Initiative did not increase the risk of breast cancer.

DURATION OF THERAPY

The lowest dose of hormone therapy should be used for the shortest amount of time to manage menopausal symptoms. Although fewer than 5 years is recommended for estrogen with progestogen therapy, duration should be individualized.

For estrogen therapy alone, more flexibility in duration of therapy may be possible. There are reports of increased risk of breast cancer after 10 to 15 years of use in large observational studies with estrogen alone.

ADDITIONAL INFORMATION

In observational studies, both transdermal estrogen therapy and low-dose oral estrogen therapy have been associated with lower risks of venous thromboembolic events and stroke than standard doses of oral estrogen, but comparison randomized clinical trials are not yet available.

Many options for Food and Drug Administration–approved bioidentical hormone therapy (estradiol and progesterone) are available. Evidence is lacking that custom compounded bio-identical hormone therapy is safe or effective. Many medical organizations and societies agree in recommending against the use of custom compounded hormone therapy for menopause management, particularly given concerns regarding content, purity, and labeling. There is a lack of safety data supporting the use of estrogen or estrogen with progestogen therapy in breast cancer survivors. Nonhormonal therapies should be the

first approach in managing menopausal symptoms in breast cancer survivors.

CONCLUSION

Leading medical societies devoted to the care of menopausal women agree that the decision to initiate hormone therapy should be for the indication of treatment of menopause-related symptoms. Although research is ongoing and these recommendations may be modified over time, there is no question that hormone therapy has an important role in managing symptoms for women during the menopausal transition and in early menopause.

Endorsed by: This statement has been endorsed by the Academy of Women's Health, the American Academy of Family Physicians, the American Academy of Physician Assistants, the American Association of Clinical Endocrinologists, the American Medical Women's Association, the Asociación Mexicana para el Estudio del Climaterio, the Association of Reproductive Health Professionals, the National Association of Nurse Practitioners in Women's Health, the National Osteoporosis Foundation, the SIGMA Canadian Menopause Society, the Society for the Study of Reproduction, and the Society of Obstetricians & Gynaecologists of Canada.