STOP enforcing a 5-year rule for menopausal hormone therapy

START individualizing therapy to optimize health and quality of life

The 5-year rule originated with the Women's Health Initiative, but a closer look at the data reveal that it may not be appropriate for all HT users

Robert L. Reid, MD

FAST TRACK

Reanalysis of data from the Women's Health Initiative has shown that, when hormone therapy is initiated within 10 years of menopause, the risks are few and generally are outweighed by benefits

EXPERT COMMENTARY

Dr. Reid is Professor of Obstetrics and Gynecology and Chair of the Division of Reproductive Endocrinology and Infertility at Queen's University and Kingston General Hospital in Kingston, Ontario, Canada.

Immediately after the worrisome initial findings of the Women's Health Initiative (WHI) were published in July 2002,[1] leading organizations and experts in menopausal medicine began advising practitioners to prescribe the "lowest dose of hormones for the shortest period of time." News headlines that cited menopausal hormone therapy (HT) as a risk factor for myocardial infarction, venous thromboembolism (VTE), gall bladder disease, stroke, urinary incontinence, dementia, and cancers of the breast and lung fueled fear among the lay public and led to a burgeoning market for alternative therapies to address menopausal symptoms.[2] Companies that marketed alternative therapies, including bioidentical hormones, often exaggerated the reported risks of menopausal HT and implied that their products were safe and effective, although supporting evidence was lacking.[3]

More than a decade later, despite a growing body of data reinforcing the safety and efficacy of HT for recently menopausal women,[4] many medical professionals remain reluctant to prescribe HT—and when they do prescribe it, they push for a 5-year limit.[4,5] This has led to needless suffering and reduced quality of life among thousands of women entering the menopausal transition.[6,7]

The author reports that he is a consultant to Bayer and Pfizer, and serves on the Data and Safety Monitoring Board at Merck Pharmaceuticals.

The importance of targeting HT to the appropriate population

Over the past decade, experts have conducted in-depth analyses of WHI findings and other contemporary data on the benefits and risks of HT. One fact is clear: The original reports and the way the data were portrayed in the media overstated the risks of HT in newly menopausal women.[2,8] Reanalysis has shown that when HT is initiated within 10 years of menopause, the risks are few and generally are outweighed by benefits.[9–11] When HT is initiated by women in their 60s and 70s, however, the reverse may be true.

HT is the best therapy for menopausal vasomotor symptoms and has a secondary benefit of preventing osteoporosis.[12] HT also may offer cardiovascular benefits in younger menopausal women, although no

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appropriately powered randomized, clinical trial has yet confirmed this presumption.[9,13]

HT and breast cancer: Context is critical

The original WHI publication and the news reports that followed emphasized that women using combination estrogen-progestin HT experienced a 24% increase in the incidence of breast cancer, which became apparent in the fifth year of therapy.[1] A closer look at the data reveals that the increased incidence of breast cancer reported in this arm of the WHI involved just 38 breast cancers per 10,000 women using HT per year, compared with 30 breast cancers per 10,000 women using placebo. The absolute risk increased by eight breast cancers per 10,000 women, or 0.08%, for each year of use. In the WHI, the 75% of women who were new users of HT actually had no increased risk of breast cancer (hazard ratio [HR], 1.06; 95% confidence interval [CI], 0.81–1.38).

It is important to put this degree of increased risk into perspective. An increase of 0.08% per year is less than one-tenth of a percentage point and is comparable to the risk of breast cancer that a woman accepts if she drinks alcohol regularly, allows herself to become overweight during perimenopause, or fails to exercise at least three times a week.[14] Cumulative data from a number of observational studies suggest that the effect of estrogen alone (without a progestin) on breast cancer is even lower, and that estrogen can be taken for many years before any effect is seen. Indeed, among women receiving estrogen alone in the WHI, the risk of breast cancer did not increase. In fact, there was a statistically significant *decrease* in breast cancer in this population.

FAST TRACK

The increased incidence of breast cancer observed in the estrogen-progestin arm of the WHI after 5 years represents an increase in the absolute risk of breast cancer of only 0.08% per year

Why a 5-year limit is inappropriate

As I explained above, the increase in the incidence of breast cancer observed in the estrogen-progestin arm of the WHI after 5 years represents an increase in the absolute risk of breast cancer of only 0.08% per year. Although HT carries other small potential risks, most experts agree that they are outweighed by the potential benefits among most perimenopausal women. Because an individual's risks and benefits probably vary according to her personal and family history, clinicians can mitigate the risks, in part, by tailoring the dose, regimen, and route of delivery to the individual's situation. The risk of VTE is greatest during the first year of HT and approaches background rates thereafter. The risk of stroke in newly menopausal women who initiated HT in the WHI was approximately 1/1,000.[13]

Health-care practitioners also can minimize the risks of HT by monitoring outcomes, such as blood pressure, unscheduled bleeding, and so on.[15] It also may be helpful to counsel patients about interventions for other conditions that contribute to risk, including obesity, smoking, inactivity, hypertension, and hyperlipidemia.

Quality of life was largely ignored in the decade after publication of the initial WHI findings because it was thought that the lives saved by avoiding HT would justify some level of distress.[6,7] There also was a presumption—promoted by advocates of natural products and alternative therapies—that interventions such as acupuncture, paced respiration, and herbal remedies were safe and effective at alleviating hot flashes, night sweats, mood swings, and sleep disruption. Complaints of vaginal dryness and dyspareunia from urogenital atrophy often were inadequately addressed because local estrogen was incorrectly thought to increase the risk of hormone-induced breast cancer. Rates of osteoporosis and hip fracture also have risen over the past decade as the protective effect of systemic HT for many women was lost.[16]

Although most postmenopausal women (60%) experience hot flashes for less than 7 years, as many as 15% report that hot flashes persist for 15 years or longer. The symptoms that can accompany hot flashes (including sweating, palpitations, apprehension, and anxiety) contribute to a woman's

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discomfort, inconvenience, and distress, particularly when the hot flashes are frequent, and can be a significant contributor to sleep disturbance. Vasomotor symptoms adversely affect quality of life for 20% to 25% of women, primarily due to the physical discomfort and social embarrassment that they evoke—although night sweats and sleep disturbance also are reported to exert a negative impact.[17–19]

The bottom line

Nothing magical happens after 5 years of HT to increase a woman's risk of breast cancer. Any cumulative effect of combination HT on the risk of breast cancer is gradual and small. It is not appropriate to demand that a patient stop HT after 5 years if it affords dramatic improvement in her quality of life, provided she has been correctly informed about potential risks and chooses to continue with therapy.

Tell Us...

Do you offer hormone therapy to your patients with menopausal symptoms?
Send us your letter!
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