

No need to fear menopause hormone drugs, finds major women's health study

A landmark women's health study scared women and doctors away from menopause hormone treatments. A 20-year follow-up found that fears were largely overblown.

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By Marlene Cimonis

More than two decades ago, the shocking results of a major women's health study challenged the safety of menopause hormones, and overnight, millions of women and their doctors abandoned the drugs — a reluctance that lingers today.

Now, a long-term follow-up of the Women's Health Initiative (WHI) shows that the reaction was largely overblown. The new research found that for many younger menopausal women — typically those under 60 — the benefits of the drugs probably outweigh the risks for the short-term treatment of menopause symptoms, including hot flashes and night sweats.

The new analysis, published in JAMA, shows that younger women starting menopause and experiencing symptoms can take hormone treatments for several years with a lower likelihood of adverse effects.

“Women in early menopause with bothersome symptoms should not be afraid to take hormone therapy to treat them, and clinicians should not be afraid to prescribe them,” said JoAnn Manson, chief of the division of preventive medicine at Brigham and Women's Hospital and the paper's first author.

A landmark study that scared women and doctors

The importance of the WHI and its impact on women’s health can’t be overstated. The study enrolled more than 160,000 postmenopausal women between the ages of 50 and 79. But in 2002, part of the study’s menopause hormone trial was abruptly stopped after monitoring data suggested that women in the hormone group had an increased risk of cardiovascular disease, stroke, pulmonary embolism and breast cancer.

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(Abbey Lossing for The Washington Post)

The results disrupted medical care for millions of women who had been taking hormones, many of whom had been advised by their doctors that the drugs not only relieved symptoms, but also offered long-term protection against heart attacks, which was widely believed at the time. The sudden about-face also meant that scores of baby boomer and Gen X women were forced to navigate the vexing symptoms of menopause — including hot flashes, night sweats, insomnia and mood disturbances — without the benefit of highly effective hormone treatments.

Later, it became clear that the design of the study, which included large numbers of older women, may have skewed the results. The risks were seen largely among older women, long past menopause, who would not normally need to use the drugs for symptoms. Younger women in the study seemed to fare better.

Long-term follow-up paints a different picture of hormone safety

Now, more than 20 years later, a long-term follow-up of the women in the WHI suggests the drugs are a relatively safe option for the short-term treatment of menopause symptoms in women under 60. Hormones still aren’t recommended for long-term use to prevent heart attack, dementia or other chronic conditions.

“There is still a substantial group of women still not using hormone therapy because they are fearful of its adverse effects,” said Stephanie Faubion, director of the Mayo Clinic’s Center for Women’s Health in Jacksonville, Fla., who was not involved in the paper. “This should be reassuring to women under the age of 60 with bothersome symptoms.”

For women “significantly impacted” by symptoms, especially in the workplace, hormone therapy “is the most effective treatment,” she added.

Here are the findings from the long-term follow-up.

- The researchers found that hormone therapy didn’t increase mortality rates (deaths from all causes) in any age group, when compared with women of similar age taking a placebo.
- There was no statistically significant difference in heart risk between hormone users and nonusers. When the study was stopped in 2002, the organizers reported a 29 percent increase in heart risk among women taking hormone drugs.
- Stroke risk among young hormone users was relatively low — less than one extra case per 1,000 women using estrogen-progestin therapy and no excess risk with estrogen alone.
- The different forms of hormone therapy (combination estrogen-progestin and estrogen alone) had opposite effects on breast cancer risk. Women who used estrogen alone (which is allowed only for those who have had a hysterectomy) saw a 20 percent reduction in breast cancer risk over the follow-up period.
- Breast cancer risk increased with longer use of combination hormone drugs that include estrogen and progestin. (Adding progesterone to estrogen for women with a uterus reduces the risk of developing endometrial cancer.) “Putting the risk into perspective, it’s the equivalent of the excess risk of breast cancer associated with drinking one to two alcoholic beverages daily,” Manson said. “The absolute risk is low, and all choices involve trade-offs. It’s important for women to have the information they need to share in decision-making and also make choices about the duration of treatment.”
- Bone fracture risk among hormone users was 33 percent lower across all age groups compared to placebo.

The paper also stressed that women should not routinely take hormones to prevent heart disease, stroke, dementia or other chronic diseases, and that they don’t need calcium or vitamin D supplements unless they are nutritionally deficient in them.

Finally, the review also recommended a diet low in fat and high in fruits, vegetables and grains, saying it’s linked to a lower risk of breast cancer deaths. Such a diet, however, doesn’t appear to reduce the risk of developing breast or colorectal cancer.

The Women’s Health Initiative is funded by the National Heart, Lung and Blood Institute. During the trials, the active and placebo pills were provided by Wyeth-Ayerst for the hormone study and by GlaxoSmithKline Consumer Healthcare for the calcium and vitamin D supplement trial. Of the 19 authors on the current study, 18 had no financial disclosures to report. One researcher on the study, Rowan T. Chlebowski, chief of medical oncology and hematology at Harbor-UCLA Medical Center, reported receiving fees from Novartis, AstraZeneca, Pfizer and other firms.

A low-risk treatment for women with menopause symptoms

Experts pointed out that today, hormone drugs include a range of options such as lower-dose estrogen, as well as estrogen delivered through the skin as a patch or gel. Non-hormonal treatments are also available to ease the symptoms of menopause.

“I love this review,” said Christine Kistler, associate professor of medicine in the geriatrics division of the University of Pittsburgh, who also was not part of the research. “It nicely demonstrates that HRT is relatively low risk in younger postmenopausal women when menopausal symptoms typically are worse and wane over time, though some women still have hot flashes well into their 60s.”

Hormones began to gain traction in the 1960s as a way to preserve youthfulness and femininity. Later, several observational studies found that women taking hormone therapy had less heart disease and bone fractures and less risk of death from all causes, compared with women who were not taking them.

Before the Women’s Health Initiative, nearly 15 million women were getting annual prescriptions for hormone therapy, including for the prevention of heart disease, despite a lack of controlled research on the topic. Use of the drugs to prevent heart attacks and dementia had become “increasingly common,” Manson said.

“It was important to put the brakes on that,” said Manson, also a professor of medicine at Harvard Medical School. “But it was never intended for women to stop using it for bothersome hot flashes and night sweats. It’s important that women know there is this option.”

Kistler said she generally prescribes HRT only for patients with significant symptoms who are at low risk for stroke, heart disease and breast cancer and usually only after first trying non-hormonal therapies. She limits their use to five or six years and weans patients off the drugs by age 60. “The review notes relatively little harm from HRT until 60,” she said.

Faubion said she’s heard from many women over the years “frustrated because they have read and heard conflicting things about the risk and benefits of hormone therapy and don’t know what to believe.” The review, she said, “reiterates the relative safety of hormone therapy in early menopause.”
