

Hormone therapy use by postmenopausal women may increase incidence of more advanced breast cancer

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Follow-up of about 11 years of participants in the Women's Health Initiative finds that among postmenopausal women, use of estrogen plus progestin is associated with an increased incidence of breast cancers that are more advanced, and with a higher risk of deaths attributable to breast cancer, according to a study in the October 20 issue of *JAMA*.

In the Women's Health Initiative (WHI) randomized, placebo-controlled trial of [estrogen](#) plus [progestin](#), after an average intervention time of 5.6 years and an average follow-up of 7.9 years, [breast cancer](#) incidence was increased among women who received combined hormone therapy. "questions of clinical relevance remain, including the cumulative, long-term effect of estrogen plus progestin on breast cancer incidence and whether breast cancer mortality is increased by combined hormone therapy use," the authors write.

Rowan T. Chlebowski, M.D., Ph.D., of the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Torrance, Calif., and colleagues analyzed data and report updated information on breast cancer incidence and, for the first time, information on breast cancer mortality related to combined hormone therapy use in the WHI trial. A total of 16,608 [postmenopausal women](#) ages 50 to 79 years with no prior hysterectomy from 40 U.S. clinical centers were randomly assigned to receive combined conjugated equine estrogens, 0.625 mg/d, plus medroxyprogesterone acetate, 2.5 mg/d, or placebo pill. After the original trial completion date (March 31, 2005), re-consent was required for continued follow-up for breast cancer incidence and was obtained from 12,788 (83 percent) of the surviving participants.

The researchers found that in intention-to-treat analyses including all randomized participants and censoring those not consenting to additional follow-up, estrogen plus progestin compared with placebo increased the incidence of invasive breast cancer (385 cases [0.42 percent per year] vs. 293 cases [0.34 percent per year], respectively). A significantly larger fraction of women in the combined hormone therapy group had breast cancers with positive lymph nodes compared with women in the placebo group (81 [23.7 percent] vs. 43 [16.2 percent], respectively).

"More women died of breast cancer in the combined hormone therapy group compared with the placebo group (25 deaths [0.03 percent per year] vs. 12 deaths [0.01 percent per year]), representing 2.6 vs. 1.3 deaths per 10,000 women per year, respectively," the authors write. "Consideration of all-cause mortality after breast cancer diagnosis provided similar results; among women in the combined hormone therapy group, there were 51 deaths (0.05 percent per year) compared with 31 deaths (0.03 percent per year) among women in the placebo group, representing 5.3 vs. 3.4 deaths per 10,000 women per year, respectively."

"With some exceptions, the preponderance of observational studies have associated combined hormone therapy use with an increase in breast cancers that have favorable characteristics, lower stage, and longer survival compared with breast cancers diagnosed in nonusers of hormone therapy. However, in the WHI randomized trial, combined hormone therapy increased breast cancer risk and interfered with breast cancer detection, leading to cancers being diagnosed at more advanced stages. Now, with longer follow-up results available, there remains a cumulative, statistically significant increase in breast cancers in

the combined hormone therapy group, and the cancers more commonly had lymph node involvement. The observed adverse influence on breast cancer mortality of combined hormone therapy can reasonably be explained by the influence on breast cancer incidence and stage."

"Following the initial report of results from the WHI trial, a substantial decrease in breast cancer incidence occurred in the United States, which was attributed to the marked decrease in postmenopausal [hormone therapy](#) use that occurred after publication of the trial results. The adverse influence of estrogen plus progestin on breast cancer mortality suggests that a future reduction in breast cancer mortality in the United States may be anticipated as well," the researchers note.

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