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The use of estrogen plus progestin in postmenopausal women has once again been linked to an increased risk for breast cancer, according to the results from a Women’s Health Initiative observational cohort study. The study was published in the Journal of the National Cancer Institute.

In 2002, results from the Women’s Health Initiative (WHI) randomized trial showed that the use of estrogen plus progestin increased breast cancer incidence and mortality; however, this result differed from many of the observational studies looking at estrogen and progestin use, which showed similar links to incidence but not outcome.

In this study, researchers led by Rowan T. Chlebowski, MD, PhD, Los Angeles Biomedical Research Institute (LA BioMed), enrolled 41,449 postmenopausal women with characteristics similar to those in the WHI clinical trial. Women had no prior hysterectomy and were mammogram negative within 2 years. Women were either not hormone users (n = 25,328) or were estrogen and progestin users (n = 16,121).

Researchers followed the women for an average of 11.3 years. During that time, 2,236 breast cancers occurred. Incidence was higher in hormone users (0.60%) compared with non-users (0.42%; P < .001).

This incidence was especially increased among women who initiated hormone therapy closer to menopause. Women who started therapy at menopause had a hazard ratio of 1.68 (95% CI, 1.52–1.86) for breast cancer incidence. “This study shows that women who begin the hormonal therapy of estrogen plus progestin closer to menopause are at greater risk of breast cancer than those who started the therapy earlier,” Chlebowski said in a press release. “Because menopause usually is the reason for women to undergo hormonal therapy, this is a very significant finding.”

No difference in survival after breast cancer diagnosis was found between estrogen plus progestin users and non-users. However, on a population basis, more deaths from breast cancer (hazard ratio [HR] = 1.32; 95% CI, 0.90–1.93) and more all-cause mortality (HR = 1.65; 95% CI, 1.29–2.12) were seen among women on hormone therapy than those who were not.

In an accompanying editorial, Catherine Schairer, PhD, and Louise A. Brinton, PhD, both of the National Cancer Institute, wrote that “lingering questions” remain about whether the data analyzed from the WHI observational study resolves the differences in tumor prognosis and tumor characteristics when compared to the WHI randomized trial. Specifically, Schairer and Brinton...
pointed out that neither WHI study “addressed the issues of currency and duration of hormone use at time of diagnosis with regard to tumor characteristics and prognosis.”

“In general, tumors in estrogen plus progestin users in the WHI Observational Study were not significantly different from those in non-hormone users with regard to number of positive lymph nodes or tumor size, but were more likely to be well differentiated and positive for hormone receptors, findings which are similar to other observational studies,” they wrote.

This, however, did not translate into a survival benefit. They recommended further analyses in this and other datasets of currency and duration of hormone use in relationship to tumor development to fully resolve the issue of tumor characteristics associated with estrogen plus progestin therapy.

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