Breast Cancer Preventive Effects of Anastrozole Persist Long After Stopping Treatment

The researchers found that women assigned to anastrozole were 50 percent less likely to have developed breast cancer compared with women assigned to the placebo.

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Breast cancer incidence among postmenopausal women at high risk for developing the disease continued to be significantly reduced 5.9 years after stopping five years of the aromatase inhibitor anastrozole, according to data from the International Breast Cancer Intervention Study II (IBIS-II) Prevention trial presented at the 2019 San Antonio Breast Cancer Symposium, held Dec. 10–14. The study is being simultaneously published in the The Lancet.

“IBIS-II Prevention was designed to investigate whether five years of anastrozole can safely and effectively prevent breast cancer in postmenopausal women who are at high risk for the disease,” said Jack Cuzick, PhD, cochairman of the International Breast Cancer Intervention Studies. “In 2013, we reported that in the first seven years of follow-up, anastrozole significantly reduced breast cancer incidence compared with placebo and that it did so with very few side effects.

“Our new data show that after a median of 10.9 years of follow-up there continues to be a significant reduction in breast cancer incidence,” continued Cuzick, who is also director of the Wolfson Institute of Preventive Medicine, head of the Centre for Cancer Prevention, and the John Snow Professor of Epidemiology at Queen Mary University of London. “It is exciting to see that anastrozole has a continued impact on breast cancer incidence even after stopping treatment, as this strengthens the case for its use as a breast cancer prevention therapy.”

Cuzick and colleagues enrolled 3,864 postmenopausal women at increased risk for developing breast cancer in the IBIS-II Prevention study from 2003 to 2012. Women were considered to be at high risk for breast cancer if they fulfilled any one of a number of criteria, including having two or more blood relatives with breast cancer, having a mother or sister who developed breast cancer before the age of 50, and having a mother or sister who had breast cancer in both breasts. Among the participants, 1,920 were randomly assigned to anastrozole for five years and 1,944 to placebo. Five-year adherence to treatment was 74.6 percent for anastrozole and 77.0 percent for placebo, which is not significantly different.

After a median follow-up of 10.9 years, the researchers found that women assigned to anastrozole were 50 percent less likely to have developed breast cancer compared with women assigned to the placebo.

Cuzick explained that there were no new adverse side effects to add to those reported in 2013, which were mostly small increases in muscle aches and pains, and hot flashes. “No excess of fractures or other serious side effects were seen with anastrozole,” he said.

“The 50 percent reduction in likelihood of breast cancer incidence after 10.9 years of follow-up is slightly less than the 53 percent reduction we reported after the first seven years of follow-up, but it is still a significant effect and larger than that seen for tamoxifen,” said Cuzick. “Another way to consider the data is that it translates into an estimated 29 women needing to be treated with anastrozole for five years to prevent one breast cancer during treatment and in the next five years.

“This is far fewer women than the estimated 49 women that need to be treated with tamoxifen for five years to prevent one breast cancer in the same time period,” added Cuzick. “Therefore, our new results strongly suggest that anastrozole should be the preferred therapy for breast cancer prevention in postmenopausal women at increased risk for the disease, with tamoxifen used for women who experience severe side effects from anastrozole.”

Cuzick cautioned that the preventive benefits of anastrozole are seen for estrogen receptor–positive breast cancer and for ductal carcinoma in situ but not for estrogen receptor–negative breast cancer. This is to be expected, he says, because anastrozole targets the estrogen pathway.

At the time of analysis, 129 deaths had been reported, with no significant difference in all-cause mortality between the anastrozole and placebo groups. There had been only five deaths from breast cancer, two among those assigned anastrozole and three among those assigned placebo.

“This is too few breast cancer deaths to determine if anastrozole reduces breast cancer mortality, so we are planning to follow the IBIS-II Prevention participants for longer to investigate this,” Cuzick concluded.

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