No significant differences in recurrence rates among women with DCIS taking anastrozole or tamoxifen

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Postmenopausal women with ductal carcinoma in situ (DCIS) had similar outcomes with disease recurrence whether they took tamoxifen or the aromatase inhibitor anastrozole for five years after surgery, but women in the two groups had different side effects, according to results from the phase III IBIS-II DCIS clinical trial presented at the 2015 San Antonio Breast Cancer Symposium, held Dec. 8-12.

This study is being published simultaneously in *The Lancet.*

"The IBIS-II DCIS study followed on from the ATAC and other aromatase inhibitor trials that showed aromatase inhibitors were more effective than tamoxifen in preventing recurrence of hormone receptor-positive invasive breast cancer in postmenopausal women," said Jack Cuzick, PhD, professor and director of Wolfson Institute of Preventive Medicine, Queen Mary University of London. "Given the paucity of data on the effect of aromatase inhibitors on DCIS, it was a natural step to explore them for women with DCIS.

"In this trial, we found that the women in both the anastrozole and tamoxifen groups had similar overall efficacy, with slightly better outcomes for those who took anastrozole. The side-effect profiles were very different for the two drugs; however, the patients had identical compliance and balancing side effects," Cuzick added.

"Anastrozole offers another choice for treating patients with estrogen receptor-positive DCIS. Choice may depend more on tolerability and existing conditions related to side effects than efficacy," he said.

In this multicenter, randomized, placebo-controlled trial, 2,980 postmenopausal women with locally excised hormone receptor-positive DCIS were enrolled; 1,471 were randomly assigned 1mg/day anastrozole and 1,509 were randomly assigned 20 mg/day tamoxifen. All women also received a placebo that looked like the test drug they did not receive in order to ensure that the side-effect profile assessments were reliable, Cuzick explained. The primary endpoint of the study was to assess breast cancer recurrence.

After a median follow-up of 7.2 years, 144 participants developed breast cancer, and 69 died, of which four were due to breast cancer. Women who took anastrozole had an 11 percent lower rate of recurrence of DCIS or invasive cancer than those who took tamoxifen, but this difference was not significant. There were no significant differences across subgroups except for invasive cancer recurrences: Women taking anastrozole were less likely to have HER2-negative invasive cancer recurrences, whereas women taking tamoxifen were less likely to have HER2-positive invasive cancer recurrences.

Side effects from the two drugs

Women who took anastrozole experienced fewer endometrial and ovarian cancers and skin cancers compared with those who took tamoxifen. However, more strokes were seen among those receiving anastrozole. Data were not sufficiently mature to assess differences in death rates.

Women who took tamoxifen had more major thromboembolic events and gynecological issues, including hot flashes, vaginal hemorrhage, and

discharge, compared with those who took anastrozole. On the other hand, women who took anastrozole had more fractures, musculoskeletal issues, and vaginal dryness.

"We are continuing to follow up the patients in this trial," said Cuzick. "Analysis of molecular characteristics of the baseline cancers and those that develop on treatment is underway."

More information: Abstract: S6-03, Title: Anastrozole versus tamoxifen for the prevention of loco-regional and contralateral breast cancer in postmenopausal women with locally excised Ductal Carcinoma In-Situ (IBIS-II DCIS)

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