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To interview Andrea De Censi, contact Julia Gunther at julia.gunther@aacr.org or 770-403-7690. For a photo of De Censi, click [here](#).

Low-Dose Tamoxifen Was Safe and Effective at Reducing Recurrence and New Breast Disease for Patients With DCIS, LCIS, and ADH

SAN ANTONIO — Treatment with a low dose of tamoxifen (5 mg per day) halved the risk of disease recurrence and new disease for women who had been treated with surgery following a diagnosis of breast intraepithelial neoplasia compared with placebo, and it did not cause more serious adverse events, according to data from the randomized, phase III [TAM-01](#) clinical trial presented at the 2018 [San Antonio Breast Cancer Symposium](#), held Dec. 4–8.

“Breast intraepithelial neoplasia is a term for a group of noninvasive conditions in which abnormal cells are found in the breast, including ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), and atypical ductal hyperplasia (ADH),” said Andrea De Censi, MD, director of the medical oncology unit at the National Hospital E.O. Ospedali Galliera – S.C. Oncologia Medica in Genoa, Italy. “These conditions significantly increase a woman’s risk for invasive breast cancer. Because they are often driven by the hormone estrogen, treatment commonly includes five years of tamoxifen, given at 20 mg per day, after surgery and, if needed, radiotherapy.

“Unfortunately, tamoxifen is associated with an increased risk of endometrial cancer and of venous thromboembolism, and can cause menopausal symptoms that lead to treatment discontinuation,” continued De Censi. “Our data show that in a randomized trial, low-dose tamoxifen was effective at reducing the risk of breast cancer development and recurrence for women with DCIS, LCIS, and ADH, and it did not cause significant serious adverse events or any increase in menopausal symptoms. Therefore, we strongly believe that these data are practice-changing.”

De Censi and colleagues randomized 500 women with DCIS, LCIS, and ADH who had been treated with surgery and, if needed, radiotherapy to either low-dose tamoxifen or placebo. Treatment continued for three years and patients were seen by the research team every six months and had a mammogram annually.

After a median follow-up of 5.1 years, 14 of the 253 (5.5 percent) patients in the low-dose tamoxifen arm and 28 of the 247 (11.3 percent) patients in the placebo arm had disease

recurrence or new disease. These data led the researchers to calculate that low-dose tamoxifen reduced the risk of recurrence or new disease by 52 percent.

Among the patients who had a recurrence or new disease in the opposite breast, three of the 14 in the low-dose tamoxifen arm had invasive breast cancer and 11 had breast intraepithelial neoplasia. In the placebo arm, 10 had invasive breast cancer and 18 had breast intraepithelial neoplasia.

There were 12 serious adverse events among the patients in the low-dose tamoxifen arm and 16 among those in the placebo arm. There was one case of endometrial cancer among the patients in the low-dose tamoxifen arm and none among those in the placebo arm. There was one venous thromboembolism in the tamoxifen arm and one pulmonary embolism in the placebo arm.

There were no significant differences between the two arms in reporting of menopausal symptoms such as hot flashes, vaginal dryness, and pain during intercourse.

“When we compare our low-dose tamoxifen data with results from the [NSABP B-24](#) and [NSABP-P1](#) trials of tamoxifen given at 20 mg per day, we see comparable risk reduction and significantly reduced serious adverse events, respectively,” said De Censi. “We would have liked to do a trial comparing the two doses of tamoxifen, but the cost of such a trial was prohibitive given that we had a limited budget because our funding was from nonprofits and the government.”

According to De Censi, the main limitation of the study is that treatment adherence was only 64.8 percent and 60.7 percent in the tamoxifen and placebo arms, respectively. He also said that if compliance to treatment had been higher, he would have expected to see a greater benefit of tamoxifen. De Censi also mentioned that currently, tamoxifen is only available in 10 mg tablets but that prior studies conducted by the researchers have shown that 10 mg every other day are as effective as 5 mg per day at reducing recurrence.

This study was supported by the Italian Ministry of Health, the Italian Association for Cancer Research, and the Italian League Against Cancer. De Censi declares institutional funding from Indena SpA, Roche, Pfizer, Janssen, Novartis, Sanofi Aventis, Quintiles, Gilead, and MacroGenics.

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