

# Tamoxifen chemoprevention tied to early detection of breast cancer

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The drug tamoxifen does not prevent or treat estrogen receptor (ER) negative breast cancer, but it can make the disease easier to find, researchers report in the Oct. 1 *Journal of the National Cancer Institute*.

Women at high-risk for breast cancer who took tamoxifen as a preventive measure in a clinical trial and later developed ER-negative breast cancer had a median time to first diagnosis of 24 months, compared with 36 months for those who received placebo, according to a retrospective statistical analysis.

While long-term survival has not yet been observed for the trial, that one-year advanced diagnosis is an unexpected and significant finding, said study lead author Yu Shen, Ph.D., professor in The University of Texas M. D. Anderson Department of Biostatistics. "Based on our basic understanding of breast cancer, survival rate is higher when cancer is detected at an earlier stage. Our findings open up a new area of research."

"It's a good example of how innovative application of statistical analysis can make a great contribution to better understanding the biological mechanisms of cancer," Shen said.

Tamoxifen is an anti-hormonal therapy known to be effective against ER-positive breast cancer, which is driven by the hormone estrogen. In the Breast Cancer Prevention Trial, conducted at 300 centers, 13,388 women at high risk for breast cancer were randomized to either

tamoxifen or placebo. Of those, 174 were diagnosed with ER-positive tumors and 69 with ER-negative tumors. This study found that the drug prevents the incidence of ER-positive breast cancer.

Shen and colleagues requested access to the trial data to illustrate a new statistical methodology and examine tamoxifen's effect on time to diagnosis of disease, which was not determined in the original trial. The more flexible statistical model allowed the team to separately estimate time to diagnosis among diseased cases and the incidence of disease among study participants in both the placebo and tamoxifen arms of the study.

They found that taking tamoxifen made no difference in the time to diagnosis of ER-positive breast cancer and reduced the incidence of ER-positive cancer. Tamoxifen had no effect on the incidence of ER-negative disease, while reducing the median time to diagnosis of ER-negative disease by a year.

The researchers discovered a few hints as to why tamoxifen treatment might make ER-negative cancers more detectable, but Shen cautions that pinpointing the biological factors behind the finding will require additional research. "As statisticians, we uncover the phenomenon, but we cannot explain why it happened," she said.

Other research has indicated that ER-negative breast cancer is less likely to be detected by mammography. In this study, mammography detected 77.4 percent of ER-negative tumors in the placebo group, compared with 94.7 percent in the tamoxifen group, however this finding fell short of statistical significance.

Taking tamoxifen alters breast density, which appears to be a major factor in the sensitivity of mammography screening, the authors note. By altering the density of normal tissue, tamoxifen may modify the contrast

between normal tissue and tumors, which might increase the ability of mammography to detect disease. The BCPT trial did not collect breast density data, so this risk factor could not be evaluated.

Source: University of Texas M. D. Anderson Cancer Center

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