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The Effect of Tamoxifen on Benign Breast Disease in Women at Increased Risk for Breast Cancer

SAN ANTONIO—Today, researchers from the National Surgical Adjuvant Breast and Bowel Project (NSABP) presented the results of a study that demonstrated tamoxifen's ability to reduce the risk of benign breast disease in women at high risk for developing breast cancer. These findings were presented at the 24th Annual San Antonio Breast Cancer Symposium.

In 1998, the NSABP published the results of the Breast Cancer Prevention Trial (BCPT) in which women at increased risk for developing breast cancer were randomly assigned to receive either tamoxifen or placebo. This study demonstrated that tamoxifen was able to significantly reduce the incidence of invasive and non-invasive breast cancer by almost fifty percent. Because the effect was seen early in the course of the BCPT, a concern was raised that tamoxifen was treating established pre-clinical invasive breast cancer rather than preventing the precursors of breast cancer.

“Based on this data it appears that tamoxifen does more than just treat pre-clinical invasive breast cancer,” said Dr. Elizabeth Tan-Chiu, who presented the data. “The fact that tamoxifen reduced the absolute number of biopsies should not be trivialized,” continued Tan-Chiu, “In an era in which optimum care is countered by the reality of shrinking resources, a decrease in biopsy rate is also likely to translate into decreased imaging and test requirements, to say nothing of lessened anxiety for these women who are at increased risk for breast cancer.”

(more)

Medical histories of the 13,388 women who enrolled in the BCPT were examined. Women who had undergone a breast biopsy and who had a diagnosis of benign breast disease such as adenosis, cyst, duct ectasia, fibrocystic disease, fibroadenoma, fibrosis, hyperplasia, and metaplasia were included in the analysis. The number of biopsies performed for women in both the tamoxifen and placebo groups were also tabulated.

Researchers found that women in the tamoxifen group had their overall risk for developing benign breast disease reduced by twenty-eight percent. Statistically significant reductions in risk were found for lesions such as adenosis, cyst, duct ectasia, fibrocystic disease, hyperplasia, and metaplasia. The risk for fibroadenoma and fibrosis was also reduced but was not statistically significant. Further, women in the tamoxifen group had twenty-two percent fewer biopsies compared to women in the placebo group; this was observed predominantly in premenopausal women.

The next crucial question is whether raloxifene, also being studied for breast cancer prevention, might have the same effect. The proven benefits of tamoxifen are being compared to the promising results of raloxifene in the NSABP's Study of Tamoxifen and Raloxifene (STAR), which is actively recruiting.

In this trial, 22,000 postmenopausal women at increased risk for developing breast cancer will be randomly assigned to either tamoxifen or raloxifene. Raloxifene, approved for the treatment and prevention of osteoporosis, has shown promise in decreasing the incidence of breast cancer. To date, over 11,900 women have enrolled in STAR.

“The design of STAR is similar to that of the BCPT and the same type of medical history is being collected on the women enrolled,” said Tan-Chiu, “It will be interesting to determine the affect that raloxifene has on benign breast disease.”

The NSABP is a nonprofit, clinical trials cooperative group located in the U.S. and Canada. Research conducted by the NSABP is supported primarily by grants from the National Cancer Institute. Information on the NSABP and STAR can be found on the NSABP Web site www.nsabp.pitt.edu. To locate a STAR site, call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).

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