

Breast density change linked to cancer development in WHI hormone replacement study

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An increase in breast density appears to be the culprit behind an increase of breast cancer found in women participating in the estrogen and progestin therapy study, a part of the Women's Health Initiative (WHI). That is the finding of a new WHI analysis led by Celia Byrne, PhD, assistant professor at Georgetown Lombardi Comprehensive Cancer Center, and presented during the AACR 101st Annual Meeting 2010 in Washington, DC.

The WHI was launched in 1991 and consisted of a set of clinical trials and an observational study, which together involved 161,808 generally healthy [postmenopausal women](#). One of the clinical trials examined the health effects of [estrogen](#) plus progestin therapy (EPT). The study was stopped early in 2002 because of an increased cancer risk found in those taking EPT. In the current analysis, researchers set out to determine if a change in mammographic density for EPT users could explain the increased [breast cancer](#) risk.

"In fact, that's exactly what we found," says Byrne. She adds that mammographic density is one of the strongest predictors of breast cancer risk suggesting that it might be a useful intermediate marker of change in breast cancer risk.

For the analysis, researchers obtained mammograms from study participants taken before they were randomized to the EPT or placebo

arm of the WHI study. They also obtained mammograms from 97 women in the EPT arm who later developed invasive breast cancer. The mammograms (of the contralateral breast) were taken a year after they were randomized. In addition, the researchers collected mammograms from 77 women, also taken a year after they were randomized to the placebo arm. Finally, mammograms from a "random side" were collected for 733 health controls. The mammograms were digitized. Four experienced readers blinded to treatment and outcome assessed mammographic density, the proportion of the breast area appearing dense on the mammogram. The risk associated with both baseline mammographic density and change in mammographic was evaluated. The four readers' results were highly correlated.

A decline in mammographic density was seen in more than half (57 percent) of the women in the placebo group compared with a 16 percent decrease in the EPT arm. Eight-four percent of women in the EPT arm had increased mammographic density compared to 47 percent of the women in the placebo group.

In the EPT arm, both the baseline and change in mammographic density were significantly associated with breast cancer risk. Using these mammograms, researchers could "predict" those who would go on to develop breast cancer. Among the 20 percent of women with the greatest increase in mammographic density in the EPT arm of the study, breast cancer risk was more than tripled (3.6-fold) compared to the 20 percent increased risk in the group with the lowest increase or decrease in density.

"The overall result within this sub-study for the effect of EPT on breast cancer risk compared to placebo was similar to that of the WHI findings," says Byrne. The researchers reported an overall 24 percent increased breast cancer risk for those in the EPT arm.

"For women using hormone replacement therapy with estrogen and progestin, [breast density](#) is a factor that a physician should consider when tracking their breast health," concludes Byrne. "For general screening, breast density might one day be used to help determine [mammograms](#) that demonstrate uncertainty about a visual anomaly."

Provided by Georgetown University Medical Center

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