

Adding ultrasound screening to mammography brings benefits, risks

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Adding a screening ultrasound examination to routine mammography reveals more breast cancers than mammography alone, according to results of a major new clinical trial. The trial, however, also found that adding an ultrasound exam also increases the rate of false positive findings and unnecessary biopsies.

Results of the clinical trial, conducted by the American College of Radiology Imaging Network (ACRIN) and analyzed by Brown University statisticians, appear in the May 14, 2008 issue of the *Journal of the American Medical Association*.

“The trial uncovered a significant trade-off with ultrasound screening,” said Jeffrey Blume, an associate professor in the Department of Community Health and the deputy director of the ACRIN Biostatistics and Data Management Center at Brown. “While supplemental ultrasound screening uncovers more breast cancers, it also substantially increases the risk of a false positive cancer finding and unnecessary biopsy.”

“The medical community may well decide that the screening benefit is offset by the increase in risk to women from a false positive finding,” Blume said. “However this study also shows that supplemental ultrasound may be beneficial in women at high risk of breast cancer who could not, or would not, otherwise undergo a magnetic resonance imaging scan. Women should consult their doctor for more information.”

A biostatistician and trial methodologist, Blume oversaw the statistical design of the ACRIN trial and led the analysis of the study, which enrolled 2,809 women in 21 clinical sites in the United States, Canada and Argentina. Participants were women at increased risk for breast cancer – women 25 years or older, women with dense breasts, women with a family history of breast cancer, and women who'd already had a breast biopsy.

The goal of the study was to determine whether the addition of a screening ultrasound to the current screening practice of mammography would reveal more cancers than mammography alone. Ultrasound screening uses high frequency sound waves to depict and detect tumors, while mammography – the current gold standard for breast cancer screening – uses low-dose X-ray.

During the first year of screening, mammography alone revealed breast cancers at a rate of 8 for every 1,000 women screened and resulted in 25 women for every 1,000 screened having an unnecessary biopsy due to a false positive exam. The combination of mammography and ultra-sound revealed breast cancers at a rate of 12 for every 1,000 women screened and resulted in 93 women for every 1,000 screened having an unnecessary biopsy due to a false positive exam.

So the ultrasound exam caught cancer in four additional women. But the exam also caused false positive findings in 68 additional women for every 1,000 screened – a four-fold increase.

“This false positive rate is significant,” Blume said. “And the combination of screening exams, both mammography and ultrasound, still missed one out of every five cancers. So the trial shows that ultrasound is not a silver bullet for breast cancer screening.”

Source: Brown University

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