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Adding Breast Ultrasound Screening to Mammography Reveals Cancers not Seen on Mammography Alone in Women at Increased Risk for Breast Cancer

In women at increased risk for breast cancer, adding a screening ultrasound examination to routine mammography revealed 28 percent more cancers than mammography alone. However, the additional ultrasound exam substantially increased the rates of false positive findings and unnecessary biopsies, according to an American College of Radiology Imaging Network (ACRIN) study published in the May 14, 2008 issue of the *Journal of American Medical Association*.

This ACRIN study enrolled 2,809 women at increased risk for breast cancer at 21 sites and 2,637 of these women were eligible for analysis. The criteria used to determine an increased breast cancer risk included: participant age of 25 years or older, dense breasts, prior atypical breast biopsy, personal and/or or moderate family history of breast cancer. The study was made possible through funding from a novel private-public partnership between the Avon Foundation and the National Cancer Institute (NCI), part of the National Institutes of Health (NIH).

Forty women were diagnosed with breast cancer within 12 months of the initial screening. Mammography alone revealed 20 cancers (50 percent of all cancers detected) for a cancer detection rate of 7.6 women per 1,000 women screened, though one cancer was dismissed. The combination of mammography plus screening ultrasound revealed 31 cancers (78 percent of all cancers detected) for a cancer detection rate of 11.8 women per 1,000 women screened. Eight of the 40 cancers were not seen with either mammography or ultrasound at the time of the initial screen, but were discovered later during the twelve month period for a rate of three cancers missed per 1,000 women screened.

The risk of incurring an unnecessary biopsy due to a false positive exam result from the supplemental screening ultrasound was also substantially increased in this study. Mammography alone prompted an unnecessary biopsy for one in 40 women in this study. The combination of mammography and ultrasound screening prompted an unnecessary biopsy for one in 10 women, or four times more women having an unnecessary biopsy.

According to the study's principal investigator, Wendie Berg, M.D., Ph.D., a radiologist specializing in breast imaging with American Radiology Services at Johns Hopkins Green Spring, Lutherville, Md., "The study results confirm that screening ultrasound in combination with mammography detects more cancers than mammography alone in women at increased risk for breast cancer. However, this benefit comes with the added risk of a false positive result. If we are going to offer screening ultrasound, we need to inform women of the substantial risk of receiving an unnecessary biopsy."

The study's statistician, Jeffrey Blume, Ph.D., associate professor and deputy director of the ACRIN Biostatistics and Data Management Center at Brown University in Providence, R.I., emphasized the reliability of these results: "Rigorous, well controlled trials like this one - where participants uniformly undergo both screening exams in a randomized order and investigators interpreting one exam are masked to the results of the

other - yield the highest level of medical evidence. A study as large as this one could not have been completed without the ongoing support and cooperation of NCI and Avon."

The American Cancer Society recently recommended women at very high risk for breast cancer be screened with magnetic resonance imaging (MRI) in addition to mammography, and these results do not change that recommendation. Women who do have screening MRI do not need screening ultrasound. Women who are at increased risk, who are currently undergoing mammographic screening and are not recommended for MRI, or for whom it is not available or not tolerated, may wish to consider adding screening ultrasound. Women should talk with their doctor about their breast cancer risk profile and whether a screening ultrasound exam supplemental to mammography might be beneficial, keeping in mind the potential for a false positive result and an unnecessary biopsy. At present, there is a limited supply of trained personnel and facilities who offer screening ultrasound. Women also should consult their health insurance policy regarding the coverage for breast cancer screening options. An annual mammogram is still recommended: neither MRI nor ultrasound is meant to replace mammography.

The study continues to follow participants to examine the potential benefit of routine annual combination screening of mammography and ultrasound.

For a listing of participating sites, please visit:

http://www.acrin.org/PROTOCOLSUMMARYTABLE/PROTOCOL6666/6666PARTICIPATINGSITES/tabid/169/Default.aspx

To arrange an interview with Dr. Berg, please contact American College Radiology (ACR) Public Relations manager Shawn Farley at 703-648-8936 or sfarley@acr.org.

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The American College of Radiology Imaging Network (ACRIN) is a National Cancer Institute Clinical Trials Cooperative Group with operations headquartered in Philadelphia, PA and the ACRIN Biostatistics Center located at Brown University in Providence, RI. ACRIN is made up of investigators from over 100 academic and community–based medical facilities in North America and several abroad. ACRIN's mission is to conduct clinical trials of medical imaging that will result in: 1) the earlier diagnosis of cancer, 2) allaying the concerns of those who do not have cancer, and 3) extending the length and improving the quality of lives of cancer patients. Further information about ACRIN can be found at **www.acrin.org**.

The American College of Radiology (ACR) is a national professional organization serving more than 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists, with programs focusing on the practice of radiology and the delivery of comprehensive health care services.