Screening Breast Ultrasound as a Supplement to Mammography: Yield of Annual Screening in ACRIN* 6666 *American College of Radiology Imaging Network with support from The Avon Foundation and National Cancer Institute (CA079778, CA80098)

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PURPOSE

To compare the cancer detection rate (yield) of combined mammography plus ultrasound to mammography alone in incidence screens of ACRIN 6666.

METHOD AND MATERIALS

2809 women at elevated risk for breast cancer with nonfatty breasts were recruited from 4/04 to 2/06 from 21 IRB-approved sites to undergo mammography (M) or physician-performed ultrasound (US) exams, randomized in order, masked, and interpreted by different physicians prior to integrated interpretation, with screening at time 0 (year 1), 12 (year 2), and 24 months (year 3). Reference standard is based on biopsy and/or 12-month follow-up for each screen. Results from screens in years 2 and 3 were compared to those in year 1.

RESULTS

2648 eligible women had reference standard for the first screen [mean age 55.2 yr, range 25-91], and were at elevated risk due to: personal history of breast cancer (53%); familial high-risk by Gail or Claus models (43%); prior ADH/ALH/LCIS/atypical papilloma (3%); BRCA-1 or -2 mutation (1%).

In year 1, of 2648 screened, cancer was found in 36 (1.4%) women: 8 on both M and US; 12 M alone; 12 US alone; 4 neither. In year 2, of 2487 screened, 28 (1.1%) had cancer: 7 on both M and US; 6 on M alone; 9 on US alone; 6 neither. In year 3, of 1921 screened, 46 (2.4%) had cancer: 7 on M and US; 14 on M alone; 9 on US alone; 16 neither (with 8 seen only on MRI).

Supplemental yield of US was 4.2/1000 in year 1 (95% CI 1.1 to 7.2); 4.0/1000 in year 2 (95% CI 1.1 to 6.9); and 4.7/1000 in year 3 (95% CI 0.8 to 8.6). 110 participants were diagnosed with cancer, including 23 (21%) DCIS and 87 invasive, with 12/66 (18%) node positive among those staged. Of participants with cancer seen only on US, 28/30 (93%) were invasive, with median size of 10 mm (range 2 to 40), and 1/24 (4.2%) was node positive among those staged. Of 26 participants with cancer not depicted by M or US, only 8 presented clinically in the interval between screens, for an interval cancer rate of 7.3%. There was no difference in supplemental yield of US among the 41.3% of exams performed with digital vs. film-screen mammography.
CONCLUSION

The supplemental yield of screening US after mammography is constant, averaging 4.3 per 1000 annual screens [95% CI 2.7 to 6.0] among women at elevated risk of breast cancer.

CLINICAL RELEVANCE/APPLICATION

Detection of mammographically-occult node-negative invasive breast cancer is improved by supplemental annual screening with US.