Breast Tomosynthesis May Reduce Recall Rates

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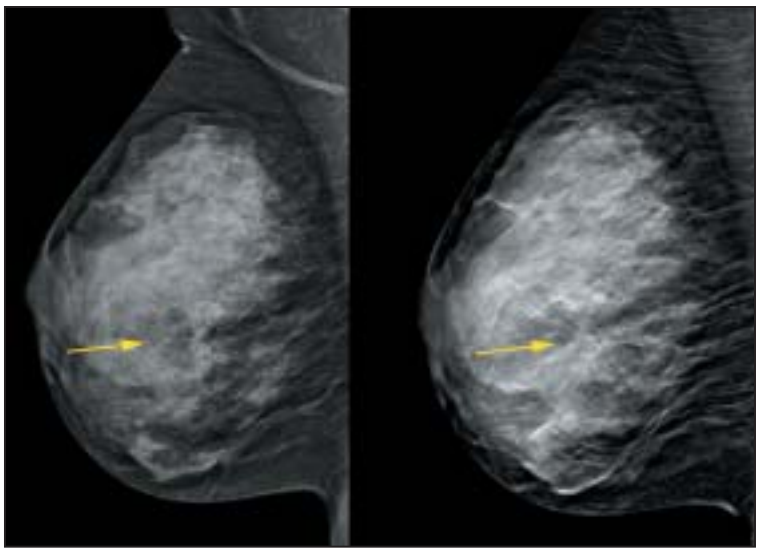
CHICAGO — The addition of digital breast tomosynthesis to digital mammography at screening could improve diagnostic accuracy and reduce recall rates by about 40%, according to results of a multicenter study.

Tomosynthesis creates a single three-dimensional image of the breast by combining data from 11 projection two-dimensional radiographs acquired during a single sweep of the x-ray tube around the patient.

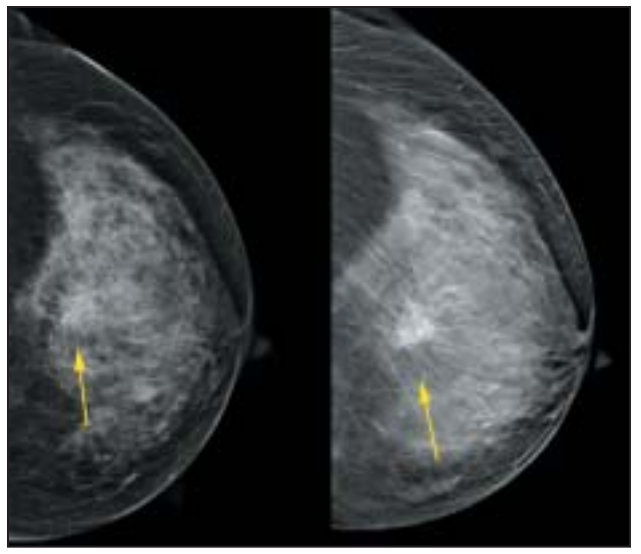
The technique improves breast visualization by reducing the overlap of normal breast structures, Dr. Elizabeth Rafferty reported during a late-breaking session at the annual meeting of the Radiological Society of North America.

As an additional benefit, the total radiation dose of 1.5 mGy is about half that of a single mammographic exposure, she said.

The technique is neither clinically available nor Food and Drug Administration approved, but based on findings from a data set of 316 women, Hologic Inc. (Bedford, Mass.) has petitioned the U.S. Food and Drug Administration for approval of the combined modality of tomosynthesis and digital mammography.



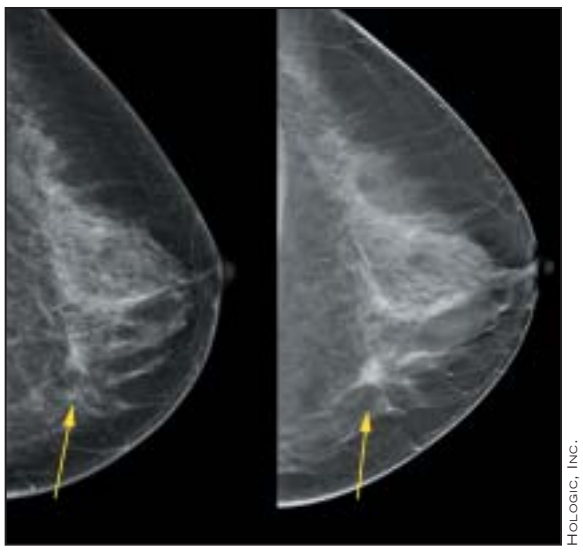
Architectural distortion and microcalcifications are clearer in tomosynthesis slices (right) than on digital mammography (left).



A spiculated cancer is better seen in the tomosynthesis slice (right) than on digital mammography (left).

"Mammography is a proven winner, and this will only make mammography better," Dr. Rafferty of the radiology department at Harvard University Medical School in Boston, said in an interview. "Tomosynthesis is really the first new thing in breast imaging in decades, and I believe it will impact mortality rates."

The data set was derived from a study in which 1,083 women, age 18 years or more, underwent two-view, full-field digital mammogram (FFDM) and digital tomosynthesis exams at five U.S. centers. The 316 women in the study included 100 women who presented for diagnostic examinations and 216 women who presented for screening exams, of which 141 were recalled by the site radiologist for additional imaging and 75 had normal exams. In all, 96 women underwent biopsy; 48 benign and 48 malignant lesions were identified.



HOLOGIC, INC.

A spiculated cancer with microcalcifications is more apparent in the tomosynthesis slice (right) than on digital mammography image (left).

Twelve board-certified radiologists trained on 200 tomosynthesis imaging cases were asked to score the digital mammography images as Breast Imaging Reporting and Data System (BIRADS) 0, 1, and 2. For those cases scored as a BIRADS 0, the radiologists were asked to give a forced BIRADS score of 1-5 indicating the likelihood of disease in that patient, and to assign a probability of malignancy score rating from 1 to 100.

The combination of FFDM and tomosynthesis resulted in highly significant improvements in the radiologist's performance, as demonstrated by receiver-operator curve analyses, said Dr. Rafferty, who has received research support from Hologic, which sponsored the study. The performance benefits were seen primarily in the analysis of masses, architectural distortion, and focal asymmetries.

A receiver-operator analysis showed that for all 12 readers, the combined modality of tomosynthesis and FFDM was superior to FFDM alone when using the forced BIRADS score and the probability of malignancy scale.

Using multicase and multireader analyses, the diagnostic accuracy (area under the curve) improved significantly for the forced BIRADS score from 0.83 with FFDM alone to 0.90 with FFDM plus tomosynthesis, with 0.5 representing a worthless diagnostic test and 1 representing a perfect test. The area under the curve for the probability of malignancy scale also significantly improved from 0.82 to 0.89 with the combined modality.

The investigators hypothesized that tomosynthesis would provide little gain in the assessment of clustered breast calcifications because calcifications are well seen on traditional mammography and aren't typically obscured by surrounding tissue. The data bore out this hypothesis, with only a slight, nonsignificant improvement from 0.80 to 0.84 observed in the area under the curve.

In noncalcified cases, the difference in the area under the curve for FFDM versus the combined modality was highly significant (0.82 vs. 0.92), representing good versus excellent dignostic accuracy, Dr. Rafferty said.

When a forced BIRADS score of 4 or 5 was considered positive for breast cancer and a BIRADS of 1-3 was considered negative, sensitivity improved from 65.5% for FFDM alone to 76% for FFDM plus tomosynthesis, and specificity improved from 84% to 89%, she said.

The mean recall rate for all 12 radiologists was 51.5% for FFDM alone and 12.9% for FFDM plus tomosynthesis, resulting in a reduction of 38.6%. Dr. Rafferty observed that the recall rate for digital mammography alone was very high, but said the data set was highly selected for recall and biopsy patients. ■