# Dense Breast Notification Laws: Study Shows Pros and Cons

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September 27, 2012 — Technologist-performed handheld ultrasound screening in women with dense breasts yields a detection rate of 3.2 additional cancers per 1000 women screened, but has a high false-positive rate, according to a study published in the October issue of *Radiology*.

The screening, offered to women in the general population with dense breasts, "can aid detection of small mammographically occult breast cancers...although the overall PPV [positive predictive value] is low," write lead author Regina Hooley, MD, and colleagues from the Department of Diagnostic Radiology at Yale University School of Medicine in New Haven, Connecticut.

The retrospective study involved all women with dense breast tissue who underwent screening ultrasound at the Yale University School of Medicine from October 1, 2009 to September 30, 2010 — the first year in which Connecticut required radiologists to communicate dense breast information to patients undergoing mammography (Connecticut Public Act 09-41).

A separate preexisting law mandates that Connecticut insurance companies pay for physician-recommended breast ultrasound, the authors note.

This study is especially important given legislative trends on screening ultrasound in the United States, said an expert not involved in the study.

**There is much to learn from the Connecticut experience.**

"Now that Texas, Virginia, New York, and most recently...California have passed similar legislation requiring patient notification of breast density (but not including a requirement for insurance reimbursement for supplemental screening), there is much to learn from the Connecticut experience," Wendie A. Berg, MD, PhD, told *Medscape Medical News* in an email. Dr. Berg is professor of radiology at the University of Pittsburgh School of Medicine in Pennsylvania.

Another expert was less equivocal about the study's importance.

These findings expose many of the weaknesses of current breast ultrasound research and highlight the prematurity of breast density notification laws, said Carl D'Orsi, MD, emeritus director of the division of breast imaging, director of breast imaging research at Emory University in Atlanta, Georgia, and spokesperson for the Society of Breast Imaging. He and Edward Sickles, MD, from the University of California, San Francisco, coauthored an accompanying editorial.

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"What happens now is this study becomes a piece of data that people use to justify screening breast ultrasound...[and its] cost effectiveness," he said in an interview with *Medscape Medical News*. "I'm not saying [the data] should never be used; I'm just saying it's a little early to make a law out of it."

**Positive Predictive Value Is "Low"**

The study involved 935 women (mean age, 52 years) who underwent handheld whole-breast ultrasound screening after a mammographic finding of dense breast tissue.

The ultrasounds were performed by mammography technologists trained in breast ultrasound, and women received their ultrasound within 1 year (mean, 60.8 days) of a screening mammogram (n = 753) or a diagnostic mammogram (n = 182).

The majority of women (65.7%) were considered to be at low risk for breast cancer, 15.9% were considered to be at intermediate risk, and 9.3% were considered to be at high risk. Risk factors were unknown in 9.0%.

If cysts or solid masses were detected, their location and size were recorded and recommendations for follow-up interval, biopsy, and aspiration were made.

When screening ultrasound results were classified using the Breast Imaging Reporting and Data System (BI-RADS), 75% were category 1 or 2, 20% were category 3, and 5% were category 4.

Biopsy or aspiration was recommended for 54 BI-RADS 4 lesions (46 women) and 9 BI-RADS 3 lesions (7 women). Of these, there were 60 negative results in 50 women and a total of 3 cancers detected.

All 3 cancers were in postmenopausal women and BI-RADS 4 lesions (1 from each of the low-, intermediate-, and high-risk groups) and "were found in women with negative results (BI-RADS 1) on a screening mammography obtained within 1 to 2 months of the screening [ultrasound], and none of the cancers were retrospectively visualized on the mammogram," the authors report.

The overall PPV for all biopsies performed on BI-RADS 4 lesions was 5.6%; for all patients with suspicious BI-RADS 4 lesions, the PPV was 6.5%. When recommended biopsies from BI-RADS 3 lesions were included in the analysis, the PPV dropped to 4.8%.

**Our screening ultrasound examinations were performed by a technologist.**

"As expected, the PPV of suspicious lesions detected at screening ultrasound in women who underwent biopsy or aspiration was low," the authors note. "However, unlike in most of the prior studies, our screening ultrasound examinations were performed by a technologist, and not a radiologist, and included patients at average risk for breast cancer," they explain.

Dr. Berg, who is the lead author of the American College of Radiology Imaging Network (ACRIN) 6666 screening trial of mammography compared with ultrasound (*JAMA*. 2012;307:1394-1404), said that although "many studies, including ACRIN 6666, have shown that physician-performed whole-breast ultrasound will depict another 3 to 4 cancers per 1000 women screened, the Yale experience is only the second study to show that mammographic technologists trained in breast ultrasound can produce similar results" (the first was *Radiology*. 2001;221:641-649).

She explained that the study's high false-positive rate is "comparable to results in the ACRIN 6666 protocol, and higher than [that seen in previous studies] averaging 3% of women screened with ultrasound."

Dr. Berg also put the low PPV in context. "In the Yale experience, overall, 5.0% of women screened with ultrasound were recommended to have a biopsy (6.8% ultimately did), and only 3 of 54 (5.6%)

lesions biopsied because of the ultrasound showed cancer, which is lower than the literature average of 11%, although even 11% is low compared with mammography, where about 35% of biopsies show cancer," she noted.

In an email to *Medscape Medical News*, Dr. Hooley predicted that as technologists gain experience with whole-breast ultrasound and there is an improved categorization of high-risk lesions, PPV will increase.

"Our study shows that many lesions classified as BI-RADS 3/probably benign could, in fact, be classified as BI-RADS 2," she said. "I believe that further research will show that many solid masses detected on whole-breast ultrasound that do not have a mammographic correlate will also not require biopsy (i.e., it is likely that many solid lesions will be classified as BI-RADS 3 instead of BI-RADS 4).... Round, well-circumscribed, oval, homogeneous solid masses have a benign appearance on ultrasound and probably do not require biopsy. All 3 cancers in our study had suspicious features," she added.

**More Criticism and Concerns**

Dr. D'Orsi said this study has skewed results and "a falsely elevated cancer detection rate" because there are currently so many questions about the categorization of lesions on ultrasound and the definition of a false-positive finding, and because the study included a mixed population comprised of both screening and diagnostic mammogram patients."

In their editorial, Drs. D'Orsi and Sickles write that the study flaws have "considerable relevance as a potential indicator of future benchmark performance.... These data may be used to affect the decisions of lawmakers who are considering similar legislation in other states. In our opinion, such government mandates are premature."

"Undoubtedly, it is beneficial to more fully inform women about their breast health; the pertinent question is how to do this," they add.

Dr. Berg emphasized that "mammography is still the only test proven to reduce deaths due to breast cancer.... Women are increasingly aware of their breast density and now have choices to make. It is imperative that we provide women with details of both potential improved cancer detection and the risks from any testing they might consider."

She also called for more research. "With many new technologies now in clinical validation for breast cancer screening...comparative-effectiveness studies are urgently needed."

*The study authors and Dr. Sickles have disclosed no relevant financial relationships. Dr. Berg reports being a consultant for Naviscan; being on the speakers bureau for SuperSonic Imagine; receiving equipment support from Gamma Medica; receiving a research grant from Hologic; and being on the medical advisory board of Philips. Dr. D'Orsi reports being a paid consultant for Fuji and Philips; owning stock or stock options in Hologic; and that his institution received grants from Fuji.*

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