

Screening Ultrasound for Women with Dense Breasts in the Age of Patient-centered Care

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ABSTRACT

As the field of medicine moves toward practicing patient-centered care, radiologists in breast imaging must continue to look for ways to increase the value of their practice in the eyes of patients. Providing adjunct screening of women with dense breasts provides such an opportunity. The presence of dense breast tissue is not only an independent risk factor for breast cancer but also a risk factor for the delayed diagnosis of breast cancer as dense tissue reduces the efficacy of screening mammograms due to the tissue masking effect. As legislation for notifying women of their breast density becomes commonplace, both women and referring physicians need to understand the risks of dense breast tissue as well as the benefits of additional screening affords. Breast radiologists can become integral to their patients' care team by offering education to both referring providers and patients on the topic of dense breasts and supplemental screening solutions, such as screening breast ultrasound, which has been shown to have benefit in overcoming mammography's shortcomings in this demographic of women.

Keywords: Dense breasts, Patient-centered care, Screening breast ultrasound, Supplemental screening

INTRODUCTION

In recent years, radiology has made a concentrated effort to embrace patient-centered and value-based care. This has become less of an option and more of a requirement as the newest Medicaid repayment plan, Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), involve the Quality Payment Program, which decides how practices will be reimbursed based on the value they present to their patients compared to other practices. These payment practices have required physicians to incorporate changes to their practice

that will add value that will benefit patients, in a way that will be most visible and acceptable to patients. For radiologists, this can be a particularly difficult scenario, as many never meet the patients whose images they are interpreting. To assist in solving this limitation, major radiology organizations have created initiatives to help guide radiologists to have more personal connections with patients, as well as greater communication with all members of the patient's care team. Examples of these initiatives include ACR Imaging 3.0 and RSNA radiology cares campaigns, which both offer resources to guide radiologists into a more visible and active role as a clinical physician. Radiologists specializing in the field of breast imaging are well positioned to lead this change. Many breast imaging physicians already report having a more clinical relationship with patients than other branches of radiology; personally communicating results of pathology and additional testing to their patients and having hands-on interaction through clinical exams, ultrasounds, and biopsies. ^[1] Further increasing communication with patients is a solid first step to adding value to a radiology practice, but for many

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breast imagers, the question turns into what next, what more can I do, and how?

A current hot topic in breast imaging is related to the evaluation of women with dense breasts and the most optimal way to advise additional screening for these women. Supplemental screening modalities are being investigated, due to the inherent limitations of mammography technology in evaluating women with dense breast tissue.

SCREENING WOMEN WITH DENSE BREASTS

Mammography has been documented to have reduced sensitivity (47.8–64.4%) in women with dense breast tissue. Several large-scale studies have suggested that, for women in the highest density categories, up to 50% of cancers are not detected by mammography and are approximately 6-fold more likely of being diagnosed with an interval cancer compared to those in the lowest two BI-RADS categories.^[2,3] Supplemental screening modalities have been suggested to aid in screening this population of women, which makes up almost half of the general screening population.^[4] Screening ultrasound is one modality that has been adopted widely throughout the country, after the incorporation of density notification legislation. Beginning in Connecticut in 2009, dense breast notification (DBN) legislation has since been adopted by 35 states, with 7 states having an insurance mandate. Although these 7 states have an insurance law, this does not mean that all patients are completely covered. Patients are encouraged to contact their insurance providers to verify if there is coverage for the screening ultrasound, regardless of insurance mandates. Due to state-mandated legislation, more women are receiving their density information; however, it does not mean that this information is being understood or acted upon.

Many women, as well as their primary care physicians, are unaware of what the implications are behind having dense tissue, and how supplemental screening modalities, such as screening breast ultrasound, can best be utilized. Breast imagers can help to clear the confusion surrounding this complicated issue by educating both referring providers and patients about the risks of dense breasts and the benefits and limitations of adding supplemental screening ultrasound to a woman's annual screening. As part of the referring provider and patient education, radiologists will need to clearly explain the benefits and limitations of mammography and discuss the benefits and drawbacks of supplemental screening. This need for education creates a venue for breast imagers to play a vital role in the patient care team and provide guidance and support to patients.

PATIENT UNDERSTANDING OF BREAST DENSITY

Although women are being given breast density information, they do not truly understand the implications of dense breasts. A 2013 telephone survey conducted by Guterbock *et al.* in Virginia, 1 year after the enactment of the state's Breast Density notification law, showed this to be true. Women between the ages of 35 and 70 were contacted at random by telephone and asked questions designed to gauge their awareness and knowledge of breast density. Of the women interviewed, only 39% of respondents answered that their health-care provider had informed them of their breast density. 50% of women who had a mammogram within the prior year recalled being told of their density. However, only 25% of the women interviewed answered correctly when asked if breast density was a risk factor for cancer, and only 20% answered correctly when asked if breast density caused their mammogram to be more difficult to interpret.^[5] A survey by Gunn *et al.* invited 202 women with dense breasts who received a DBN to participate; 58 women were fully screened, of whom 18 (19%) did not remember receiving a DBN and thus were ineligible. Forty (81%) were found to be fully eligible by recalling receiving a DBN, and of those, 30 women completed the whole interview. Those that participated were asked about their recollection of four main points that the presence of dense breast tissue increases cancer risk (10% recalled), a recommendation to speak with their physician (34%), masking bias (28%), and the possible need for supplemental screening (31%). Only one participant remembered all four main points in the letter. Many women described feeling confused due to vague wording. In addition to answering the questions, the women voluntarily expressed a desire for this information to be communicated by a doctor and to be put into more straightforward, layman terms.^[6]

The issue of not understanding the terminology, nor the topic, of dense breasts is not confined to one state or one demographic of women. To investigate the level at which these notifications are distributed, Kressin *et al.* reviewed the laws requiring DBNs for the 23 states with legislation effective as of January 1, 2016, to compare the content, readability, and understandability of the varying legislation across the states. The researchers measured readability using the Flesch–Kincaid reading grade level and the Dale–Chall readability grade score. Understandability was assessed using the Patient Education Materials Assessment Tool. The study authors found wide variation in the 23 states' DBN content, with most having readability at the high school level or above, poor understandability, and discontinuity with states' average literacy.^[7] These findings support the notion that patients have a difficult time understanding the legislation, ultimately affecting the patients' ability to act on density notification, and

seeking additional screening services. The study authors conclude that efforts should focus on creating more understandable DBNs so that all women have a clear and accurate understanding of their density and its effect on their breast cancer risk, as well as the risks and benefits of supplemental screening.

REFERRING PHYSICIAN UNDERSTANDING OF BREAST DENSITY

Anticipating some women would have follow-up questions to notification legislation, and some states include a statement suggesting the patient speak further about the topic of dense breasts with a primary care provider. However, studies have shown that there is confusion even among general practitioners about the proper way to advise screening for women in this patient population.

In Massachusetts, a survey was administered to 145 primary care physicians at two urban hospitals to explore PCP attitudes, knowledge, and impact of the Massachusetts DBN legislation on how they counseled women in the year following enactment of the law.^[8] Of the 80 completed surveys, 64 (80%) responded that they had some familiarity with the law. Survey results revealed that 49% of respondents did not feel comfortable fielding questions about breast density or how to handle it the information with patients. None of the respondents correctly identified all eight components of the mandated notification.

In a multisite survey administered through e-mail to all Mayo Clinic Staff Physicians, residents, fellows, nurse practitioners, and physician assistants in the departments of internal medicine, family medicine, and obstetrics and gynecology, researchers surveyed providers to gauge awareness of and familiarity with dense breast legislation and supplemental screening.^[9] Of the 246 providers surveyed, 32% were unaware of the existence of breast notification legislation. In addition, 50% of the respondents answered that they felt “slightly comfortable” or “not comfortable at all” discussing breast density and its implications. Furthermore, 62% of the providers responded that their practice had never had a formal discussion about the best ways to handle supplemental screening policies. Having providers with this level of unfamiliarity and discomfort with the laws, in combination with the fact that there lacks consensus of how to handle supplemental screening within practices, show that there is a great need for guidance and education for referring providers.

SCREENING ULTRASOUND AS A SUPPLEMENTAL TOOL

Identifying women with dense breasts is of utmost importance to provide them with ideal screening outcomes. As it has

been previously revealed that these women with dense breast tissue result in poor mammographic sensitivity at screening, ultrasound has been shown to be an effective supplemental screening tool, detecting cancers that are mammographically occult due to dense breast tissue. Multiple studies have demonstrated cancer detection rates in the range of 2.1–3.8/1000. ACRIN 6666 evaluated an elevated-risk population, which was enriched with dense breasts, and reported a sensitivity of mammography of 50%; mammography plus ultrasound increased sensitivity to 77.5%. The ACRIN Trial found adding screening ultrasound to mammography will identify an additional 4.3 cancers per 1,000 women screened.^[10-13] A large 4-year trial in Japan (J-START trial) enrolled 72,998 women, dividing the groups into an intervention group to undergo supplemental screening ultrasound and a control group who only underwent screening mammography. Although specificity was found to be lower in the intervention group, sensitivity was found to be significantly higher. In addition, it was found that the intervention group had an increased number of cancers detected that were more frequently stage 0 or 1 compared to the mammography alone group.^[14] Further, cancers detected by screening ultrasound have been shown to be smaller and node-negative, indicating early stage breast cancer.^[15] The ability to detect cancers at an earlier stage can help spare women the more rigorous, physically, and mentally challenging treatments that accompany later stage cancer diagnoses. Looking at this benefit in a more pragmatic light, sparing women from treatments that accompany later stage cancers will also spare the financial costs that are associated with longer, more demanding treatments. There has been opposition to adding supplemental screening ultrasound due to the increased financial burden and it would place on individual women and insurance companies;^[16] however, the benefits of screening with ultrasound cannot be ignored. By screening with ultrasound and finding cancer at an earlier stage, it is possible to avoid the financial burden of later treatments in addition to the mental and physical burden women are faced with.

UTILIZATION OF SCREENING US POST-LEGISLATION

Since legislation has become mandated in many states, screening breast ultrasound has seen an increase in demand, suggesting that ultrasound is a supplemental screening service that patients want.

Sanders *et al.* performed a retrospective chart review at one of the New Jersey’s largest ACR-accredited breast centers over an 18-month period before the implementation of the state’s notification legislation (November 1, 2012, to April 30, 2014), compared to an 18-month period after passage of the law.^[17] Utilization of screening ultrasound increased significantly after implementation of the notification law,

from 1,530 in the 18 months prior to 11,486 in the 18 months following. The state of New York has had breast density notification legislation since 2013. Since this time our outpatient breast care center has reported a large increase in demand for screening breast ultrasound, with the numbers continuing to increase in large intervals every year. The numbers began at 691 screening ultrasounds performed for dense tissue in 2013, to approximately 9,339 in 2017, and 2018 looks to surpass this number again.^[15]

Horný *et al.* investigated whether DBN legislation affected the probability of screening mammography follow-up by ultrasound.^[18] The study authors found that implementation of DBN legislation was associated with a statistically significant increase in the probability of downstream breast imaging. Specifically, an increased probability of breast ultrasound within 30 days of screening mammography was seen, suggesting that women desire the opportunity to have additional testing that may increase the efficacy of screening given their breast density. Sobotka and Hinrichs studied the use of breast ultrasound within several months after screening mammography and found an increase in follow-up rates from 17.6% pre-legislation to approximately 42.2% post-legislation at a medical center in New Jersey. The authors of this study noted that, due to the large demand for ultrasound screening, they had to purchase an additional ultrasound unit and hire a full-time technologist.^[19] Practices will have to evaluate the demand for screening ultrasound in their area and make adjustments to staffing and scheduling as needed, to meet the needs of the patients.

Taking the question of DBN and its effect on utilization of supplemental ultrasound, a step further, Aripoli *et al.* explored the utilization of supplemental screening automated ultrasound after three different methods of DBN notification. Three different notifications with increasing levels of information and communication were distributed evenly among women identified with dense breasts and asymptomatic mammograms. The first letter recommended a screening mammogram in 1 year, the next letter added a statement informing the patient of their breast density and that they may benefit from supplemental screening, and the third notification method was the same letter as in the second group, with a follow-up phone call saying the same thing. What was found was that, at each increasing level of notification, significantly higher numbers of women were found to return for screening ultrasound.^[20] This illustrates how implementing a higher level of patient education and direct communication helps to increase utilization of a supplemental screening that adds value in the eyes of the patient. Aside from hiring dedicated ultrasonography staff, automated breast ultrasound is an option, which utilizes an ultrasound system which automatically scans a woman's breast, independently of a radiologist or sonographer. This automation can cut down on personnel costs and save time for radiologists, as well as create reproducible scans as opposed

to the variability with handheld ultrasound. Studies have shown that ABUS produces the results in cancer detection rates, specificity, and sensitivity that are equal to that of handheld ultrasound.

In a high-volume breast mammography screening center, FFDM alone was compared to ABUS plus FFDM in relation to cancer detection and recall rates in asymptomatic women with heterogeneously and extremely dense breasts.^[21] The addition of ABUS was found to increase recall rates, from 13.8/1000 for FFDM alone to 22.8/1000. This was found to be an acceptable recall rate when compared to the increase in cancer detection, which increased from 4.2/1,000 (FFDM alone) to 6.6/1,000 (FFDM plus ABUS), resulting in a statistically significant difference of 2.4/1,000. In a multireader, multicase reader study, 17 radiologists interpreted the images from 185 examinations of FFDM alone and FFDM with ABUS, with results showing ABUS+FFDM significantly improved readers' breast cancer detection.^[22] Sensitivity was shown to increase significantly in cases of mammography negative cancers, by 23.9%. Specificity was shown to be similar as well; 78.1% for FFDM and 76.1% for FFDM+ABUS, the difference in which did not reach statistical significance. In a 2016 study by Vourtsis and Kachulis, the performance of ABUS in comparison to HHUS in the visualization and BIRADS characterization of breast lesions was evaluated.^[23] The results showed a 99.8% level of agreement between ABUS and HHUS. ABUS successfully identified five additional carcinomas which were not found with mammography. The benefits of the addition of ABUS to a practice are demonstrated by studies such as these providing evidence to facilities looking to implement the technology to provide supplemental screening to patients with dense breasts.

AN OPPORTUNITY FOR BREAST IMAGING RADIOLOGISTS

Currently, no organization has strong recommendations that promote screening ultrasound for women with no risk factors other than dense breasts. Rather, some organizations state supplemental screening ultrasound as an option that should be a personalized decision based on the individual patient.^[24-26] This ambiguity has led referring providers to feel uncertain regarding how to best handle referrals for patients with this tissue type, creating an opportunity for radiologists to step in and educate referring providers. Providing balanced information to referrers, and patients, necessitates a discussion of both the benefits and drawbacks of supplemental screening. A primary reason screening ultrasound does not have widespread endorsement from medical organizations which is the high rate of false-positive findings that lead to unnecessary procedures and anxiety for patients. This has led many providers to not recommend ultrasound screening for their patients. However, several studies have proven that

the patient anxiety related to false-positive results is short term, decreasing once the negative result was confirmed, and sharply decreasing by the 6-month follow-up point.^[27] Anxiety has been found to resurface concerning future appointments but has not been found to deter women from attending their routine screening mammography appointments.^[28] Instead, women felt more convinced to continue regular screenings because of a heightened awareness of breast cancer.^[29]

Although receiving a false-positive result is an anxiety-producing event, women generally find it an acceptable event for saving lives. Regardless, in an effort to put the decision in the hands of the patient, it is important to provide a well-rounded view to patients and ultimately allow the woman to have the choice of how they would like to manage their care. As breast imagers, we can further educate both the physicians and women directly in our care. Discussion of the possibility of false positives in advance of ultrasound screening may allow the opportunity to mitigate some of the anxiety the patient may feel. In addition, once the woman is aware of the false-positive possibility, she will be able to make a fully informed decision for herself based on her level of tolerance. Providing patient-centered care puts a large emphasis on meeting the needs of the patient; having these conversations allows the physician to understand what the patient wants, rather than be solely based on an organization or individual doctor's beliefs.

CONCLUSION

Patient-centered care is a term that radiologists are becoming more familiar with, as practices seek the best way to improve their patients experience. Ensuring that there are direct communication and education to both the patient and other members of her care team, such as her referring provider is one method to do so. The need for education regarding dense breast tissue and supplemental screening with breast ultrasound is an optimal place for radiologists to expand their role in patient care, increasing communication with both the referring provider as well as the patient. Radiologists can provide patients with information needed to make an informed decision, ultimately enhancing the patients care by providing the option for a population of patients that can benefit from valuable additional screening. As the ultimate goal of screening is to detect cancers as early as possible to avoid more invasive treatments, screening ultrasound is an important supplemental tool to discuss with both the patient and referring providers, ultimately aiding in the empowerment of patients to make the best health-care choices.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest.

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