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Commentary

Understanding Breast Density Reporting: Implications for Family Medicine Clinicians

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Abstract

The Food and Drug Administration (FDA) mandated that beginning September 10, 2024, every screening mammogram report include an assessment of Breast Density (BD), which must be communicated to the patient [1]. As the ordering clinician, Family Medicine clinicians will be responsible for advising patients about the implications of identifying patients' breasts as dense and for providing recommendations about whether additional imaging should be considered based on the reported BD. Here, we briefly discuss BD and offer guidance for providers as they discuss this important topic with their patients.

INTRODUCTION

Breast cancer will be diagnosed in one in eight women in their lifetime and is the second most common cause of U.S. cancer deaths for women annually [2]. The World Health Organization states "Early detection in order to improve breast cancer outcome and survival remains the cornerstone of breast cancer control" and mammography is the standard-of-care screening tool [3]. Forty to fifty percent of U.S. women have mammographically dense breasts and younger age particularly correlates strongly with increased BD, as does weight, hormonal status, and other factors [4-13]. Because the United States Preventive Services Task Force (USPSTF) lowered beginning screening for average risk women to age 40, increased BD is likely to be found more commonly [14]. The new FDA regulations mandate that mammogram reports in all 50 states describe whether and to what extent BD is seen, but neither the FDA nor the USPSTF recommend management strategies to ensure that reporting BD has clinical utility, which is commonly defined as meaning that patient outcomes are improved by the recommended measure [15]. However, clinical utility will only be possible if ordering clinicians are aware of what options their patients might reasonably pursue when increased BD is detected.

Increased Breast Density is Associated with Decreased Sensitivity of Mammograms

BD is associated with decreased sensitivity of mammography for detecting breast cancer [16]. For example, the likelihood of detecting cancer is roughly only 40% in those with heterogeneous dense or extremely dense breasts [17]. Increasing BD correlates inversely with mammographic sensitivity for BC detection [18]. Finally, although there is evidence that the current preferred screening mammography, Digital Breast Tomography (DBT), provides higher sensitivity compared to older mammographic methods [19], Black women have reduced access to DBT, and therefore the limited sensitivity of mammography also underscores an important equity issue [4,5].

Increased Breast Density is Associated with Increased Risk of Developing Breast Cancer

BD is a risk factor for developing breast cancer. Women with mammograms with the highest density have an estimated 1.5 to 4.7 fold increased risk of developing breast cancer [20]. Another study showed absolute 5-year breast cancer risks in 45 year-olds with average BD and extremely dense breasts were 0.7% and 1.3%, respectively [21].

THE FDA MANDATE AND FAMILY MEDICINE CAREGIVERS

Family Medicine clinicians play a major role in advising patients about screening mammograms. Women rely on their expertise for understanding whether to undergo additional screening measures should their mammogram show increased BD. Yet most literature addressing the appropriate management of women with mammograms displaying increased BD is published in radiology or other non-primary care or family medicine journals. Without improved guidance, clinicians might even consider not ordering screening mammograms or patients might decline mammograms if they sense considerable uncertainty regarding what would be a reasonable approach to management when increased BD is seen.

In 2015, Gunn et al reported, from a study of 145 primary care providers practicing general internal medicine in Massachusetts-where reporting density had been required for some time-49% "did not feel prepared to respond to patient

questions about dense breasts" and 85% indicated interest in further training [22]. Nickel et al reported on six studies that involved U.S. primary care practitioners in states that required reporting BD. The authors concluded that "Findings consistently demonstrated PCPs overall lack of knowledge about BD, low level of comfort managing patients in relation to dense breasts, and limited consensus on the most appropriate approach for managing women with dense breasts, particularly in relation to supplemental screening [23]. These studies highlight the need to better educate providers about the significance of and the options that should be discussed when BD is reported.

Scoring Breast Density

How Breast Density is Scored

BI-RADS is the most common scoring method used by mammographers to describe BD [24]:

BI-RADS BD classification:

A. Almost entirely fatty.

B. Scattered areas of fibroglandular density.

C. Heterogeneously dense, which may obscure small masses.

D. Extremely dense, which lowers the mammographic sensitivity for detecting apparent malignancy.

Providers should recognize the possibility of discordant assessment of breast density. From one study the authors noted "among women with consecutive mammograms interpreted by different radiologists, 17.2% (5,909 of 34,271) had discordant assessments of dense versus nondense status" [25]. There is emerging evidence that inter and intra-radiologist differences can be mitigated by applying Artificial Intelligence to BD interpretation on mammograms [26-28].

OPTIONS FOR SUPPLEMENTAL SCREENING

Supplemental imaging is recommended for certain high-risk populations, but supplemental imaging based solely on BD remains controversial [29]. For example, Scheel, et al concluded that one potential supplemental tool, ultrasound, should not be used routinely [30]. On the other hand, the authors of a New England Journal of Medicine report concluded, from a study of over 40,000 women, that "the use of supplemental MRI screening in women with extremely dense breast tissue and normal results on mammography resulted in the diagnosis of significantly fewer interval cancers than mammography alone during a 2-year screening period" [33]. Because roughly forty to fifty percent of women have heterogeneously or extremely dense breasts, and due to the risk of false-positive results associated with supplemental screening, some experts have suggested that supplemental screening related to BD only be limited to that 10% of patients with extremely dense breasts (BI-RADS category D) [19].

Also, because payers often will not cover the costs of supplemental testing when BD is the only risk factor, when a provider and patient decide to pursue supplemental imaging, only patients who can afford to pay out-of-pocket might have the opportunity to be tested. Thus, the gap in who will be screened among those who wish supplemental imaging, based solely on BD, will potentially be widened between socioeconomic groups, for example, once more patients discuss supplemental imaging with their PCC providers after the FDA mandate is adopted.

Whole Breast Ultrasound (WBUS)

Supplemental screening modalities include WBUS screening with either handheld or automated breast ultrasound [32]. One large study found that for patients with heterogeneously dense breasts and one additional risk factor, supplemental WBUS screening identified an additional 4.3 cancers per 1000 women, but also resulted in significant false positives results (i.e., the positive predictive value of mammography alone was reduced from 22.6 to 11.2 when mammography was supplanted with WBUS) [33]. In a meta-analysis involving women with dense breasts, sensitivity increased from 74% with mammograms alone to 96% with supplemental ultrasound, but specificity decreased from 93% to 87% with supplemental ultrasound screening [34].

Breast Magnetic Resonance Imaging (MRI)

MRI contrast-enhanced supplemental imaging for women with only dense breasts as a risk factor has not been studied extensively. MRI's are recommended for those who are estimated to carry a >20% lifetime BC risk (e.g., BRCA carriers). In a European study of women with extremely dense breasts (DENSE trial), women screened with mammography and supplemental MRIs were diagnosed with 2.5 BCs/1000 screenings versus 5.0 BCs/1000 screenings, respectively, over a two-year study period [31]. In a recent review, Mann et al noted that the sensitivity of contrast enhanced MRI reportedly ranges between 81% and 100% and abbreviated MRI protocols may lead to the more widespread use of breast MRI for screening [35]. In a study of 1400 women with dense breasts, screening involving dense breast tissue with or without abbreviated MRIs increased BC detection (11.8 versus 4.8 cancers per 1000 patients), although specificity for breast cancer detection was lower for abbreviated MRI compared with DBT, 39. 1 versus 95.7% percent, respectively [36]. The European Society of Breast Imaging (EUSOBI) suggested that "in light of the available evidence, in women aged 50-70 years with extremely dense breasts, the EUSOBI now recommends offering screening breast MRI every 2 to 4 years [37].

BREAST CANCER RISK STRATIFICATION

Risk stratification tools that rely on family history of breast, ovarian, or other cancers, prior breast biopsies, current age, age of menarche/menopause, age of first pregnancy, diagnosis of carrying a BRCA1 or other pathogenic germline variant that is known to be breast cancer-predisposing and other factors can be used stratify patients into "High risk" (> 20 percent lifetime breast cancer risk), "Intermediate risk" (15-20 percent lifetime breast cancer risk) and "Average or Low risk" (< 15 percent

lifetime breast cancer risk) groups. Stratifying patients into these groups takes little time and can help with supplemental imaging decision-making. Three commonly used tools for classifying risk are the NCI Breast Cancer Risk Assessment Tool or Gail Model (www.cancer.gov/bcrisktool/Default.aspx), the Breast Cancer Surveillance Consortium calculator, (https://tools.bcsc-scc.org/BC5yearRisk/) and the Tyrer-Cuzick tool (www.ems-trials.org/risk/evaluator/). In addition to stratifying women in a risk category (High, Intermediate, Average/Low risk), these tools also provide stratified guidance on use of supplemental screening.

a. High Risk: Routine supplemental breast MRI is recommended for this group. Contrast enhanced mammography or molecular breast imaging are also considered when patients in this group are either allergic to gadolinium or the patient declines MRI for other reasons. The American College of Radiology (ACR) recommends screening USN for women in this group who are unable to undergo MRI screening [38].

b. Intermediate Risk: The ACR does not offer definitive recommendations for MRIs in women with dense breasts and at an intermediate risk for breast cancer [38].

c. Average or low risk: As mentioned, the ACR guidelines state that for women with dense breasts as their sole risk factor "the addition of ultrasound to screening mammography may be used for incremental cancer detection" but also that a thorough conversation that includes the potential for "harms" related to supplemental USNs (e.g., testing reproducibility, low positive predictive value) should be part of the discussion [38].

DISCUSSIONS WITH PATIENTS ABOUT SUPPLEMENTAL SCREENING

The FDA mandated reporting of BD does not go into effect until September 2024 and does not recommend supplemental screening based on BD alone. BD reporting is largely aimed to encourage more women to discuss their other risk factors with their providers, as other risk factors might suggest an indication for supplemental screening.

There has been considerable attention in the popular media as a result of the FDA's decision to require reporting BD in all fifty states. For example, on March 9, 2023, Dr. Christoph Lee, a mammographer at the Fred Hutchinson Cancer Center in Seattle, was quoted in the New York Times as saying: "The big question is: What do women do with the information? " and "If a woman is told her breasts are "dense," what does that mean? Many women have heard - repeatedly-that if they have "dense" breasts, they need more frequent screening or extra screening with ultrasound or an MRI" and "The FDA's hope is that the information - dense or not dense - will lead to a formal assessment by a doctor that can actually advise women if they are at overall higher risk and the new regulations "are a step toward informing women, but it is not clear where that will lead" [39].

Unfortunately, from one study in states where BD reporting is required, the authors concluded that the language used exceeded 8th grade readability levels and was poorly understood by the patients [40]. During their visits, virtual meetings, or electronic interactions with patients, time constraints make a thorough discussion of the implications of BD often terribly difficult. Although contacting the mammographer for guidance seems reasonable, mammographers often lack the key information regarding the patient's other risk factors and seldom is it realistic to believe that mammographers can substitute for the primary care or family medicine providers for truly informed shared-decision making. Although challenging, the brief conversation in which the harms (e.g., a false positive supplemental imaging result) and benefits (e.g., diagnosis of a true invasive cancer on supplemental imaging not seen on mammography) is warranted in order to provide truly personalized guidance that is consistent with each patient's individualized goals and values.

It is reasonable that patients are advised that none of the major current standard-of-care guidelines suggest that increased BD alone should be considered an indication to recommend supplemental imaging. The ACR states that, for women with BD as their only risk factor for developing breast cancer, "the addition of USN [ultrasound] to screening mammography may be useful for incremental cancer detection", but also the ACR qualifies that recommendation by stressing important considerations such as reproducibility, high false-positive rates, operator dependency, and low positive predictive value that must be discussed with the patient [38]. Discussion of breast tissues density results seen on the mammogram should be seen as an opportunity for providers to have personalized decision-making discussions of other risk factors and the harms to benefits ratio of pursuing supplemental testing.

CONCLUSIONS

All mammography facilities will be required to report BD to patients beginning September 10, 2024. The sensitivity for detecting breast cancer is reduced in women with dense breasts noted on mammograms and dense breasts are also a risk factor for developing breast cancer. As with all shared-decision making in healthcare, there is not a "one size fits all" approach to discussing a mammographic finding of dense breasts with patients, particularly because, as described above, BD results are not binary, but rather BD is typically classified into one of four categories. Also, according to their personal values and preferences, one patient might understandably wish to pursue options that another patient, with the same degree of BD on their mammogram, would choose to not pursue. None of the major organizations currently clearly recommend supplemental imaging with either WBUS or MRI when dense breasts are the sole identified risk factor for developing breast cancer. Still, it is hoped that reporting breast density will prompt discussions and stratification of patients into breast cancer risk groups that are a basis for guideline-informed supplemental screening recommendations, preventive therapy recommendations, and

more precise calculations of risks that, together with breast density, might lead appropriate patients to consider supplemental imaging for breast cancer screening.

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