## Title

Man Versus Machine: Does Automated Computer Density Measurement Add Value?



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# Man Versus Machine: Does Automated Computer Density Measurement Add Value?

Among the many known risk factors for breast cancer (1), only breast density is known to decrease the accuracy of screening mammography. Breast density may obscure tumors, hampering a radiologist's ability to detect them. The risk for missed breast cancer is greatest in women with extremely dense breasts, and the rate of "interval cancer" detected in the year after a screening examination is higher in this setting. Density also is associated with increased rates of false-positive readings, leading to anxiety and additional testing (2). Laws in more than half of the United States now require that women be informed of their breast density, and some states also mandate that supplemental imaging with magnetic resonance or ultrasonography be recommended.

Radiologists classify breast density on the basis of a subjective assessment. They visually estimate the percentage of the breast that is "dense" and categorize it into 4 Breast Imaging Reporting and Data System (BI-RADS) classes: (a) almost entirely fatty, (b) scattered fibroglandular densities, (c) heterogeneously dense, and (d) extremely dense. As a consequence, these density assessments are affected by both intra- and interobserver variation (3). On second examination, radiologists assign a different subjective density class approximately 20% of the time. This discrepancy may be attributable to normal physiologic changes over time (such as slight decreases in breast density due to aging) but also to human nature and the challenges inherent in subjective judgment. Similar patterns of variability have been noted for radiologists' overall interpretation of mammograms (for example, benign vs. cancer) and in many other, unrelated medical practices (4, 5).

Given the inconsistency in radiologists' subjective assessment of density, should machine measurements be introduced? Kerlikowske and colleagues (6) evaluated this question by using data from 2 case–control studies to compare the predictive ability of subjective density assessment by radiologists with that of ratings derived from fully automated grading. Automatic grading measurements assess not only areas of dense tissue, but also its volume and distribution relative to breast size on a 3-dimensional image. The authors compared subjective assessments with automated density measurements on the basis of their ability to predict 2 outcomes: the risk for a future breast cancer diagnosis and the risk for a future interval invasive cancer diagnosis. They concluded that "either automated or clinical BI-RADS measures could be used to inform women of their breast density."

The study had several methodological strengths. It was designed to include an outcome period of 12 months, which is shorter and more relevant than the time frames used in other studies. In addition, by excluding ductal carcinoma in situ from the outcome variable, the authors reduced the uncertain effect of its overdiagnosis as well as the inconsistency among pathologists in its diagnosis (7). Of interest, the association of BI-RADS density ratings (by either a radiologist or an automated measure) with these breast cancer outcomes is noted on mammograms up to 5 years earlier.

Although this study offers several methodological advantages, the authors emphasize comparisons that are not used in clinical practice. Women in the United States are advised that their breast tissue is dense if it is categorized as BI-RADS (c) or (d). The authors, however, focused on comparing category (d) with category (b). Because 3 times more women receive a BI-RADS density assessment of (c) than (d), the study's focus may have limited the generalizability of its conclusions.

Automated measurement technology is new, but is it "improved"? That remains to be determined. In the meantime, the breast imaging community's experience with the parallel technology of computer-aided detection (CAD) may be a cautionary tale. Computer-aided detection is a program that highlights areas on a mammogram that may be abnormal. In the 20 years since the U.S. Food and Drug Administration approved CAD and its implementation became widespread—at a cost exceeding $400 million each year (8)—its value has been questioned. A 2007 study published in *The New England Journal of Medicine* raised early concern by reporting an increased rate of breast biopsy with the use of CAD, with no associated improvement in detection of invasive breast cancer (9). A follow-up publication in 2015 likewise reported that CAD was associated with lower accuracy (8). Despite these reports, widespread use and Medicare coverage continue.

Like CAD, automated density measurement has the potential to improve reproducibility and workflow efficiency. However, we are in an era of "choosing wisely" and seeking value in health care. Therefore, we must be cautious before implementing and paying for medical technology.

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