Radiology

Reported Mammographic Density: Film-Screen versus Digital Acquisition[1]

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Purpose: To test the hypothesis that American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) categories for breast density reported by radiologists are lower when digital mammography is used than those reported when film-screen (FS) mammography is used.

Materials and Methods: This study was institutional review board approved and HIPAA compliant. Demographic data, risk factors, and BI-RADS breast density categories were collected from five mammography registries that were part of the Breast Cancer Surveillance Consortium. Active, passive, or waiver of consent was obtained for all participants. Women aged 40 years and older who underwent at least two screening mammographic examinations less than 36 months apart between January 1, 2000, and December 31, 2009, were included. Women with prior breast cancer, augmentation, or use of agents known to affect density were excluded. The main sample included 89 639 women with both FS and digital mammograms. The comparison group included 259 046 women with two FS mammograms and 87 066 women with two digital mammograms. BI-RADS density was cross-tabulated according to the order in which the two types of mammogram were acquired and by the first versus second interpretation.

Results: Regardless of acquisition method, the percentage of women with a change in density from one reading to the next was similar. Breast density was lower in 19.8% of the women who underwent FS before digital mammography and 17.1% of those who underwent digital before FS mammography. Similarly, lower density classifications were reported on the basis of the second mammographic examination regardless of acquisition method (15.8%–19.8%). The percentage of agreement between density readings was similar regardless of mammographic types paired (67.3%–71.0%).

Conclusion: The study results showed no difference in reported BI-RADS breast density categories according to acquisition method. Reported BI-RADS density categories may be useful in the development of breast cancer risk models in which FS, digital, or both acquisition methods are used.

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Mammographic breast density is a moderately strong risk factor for breast cancer (1–4). Women with extremely dense breast tissue are approximately four times more likely to be diagnosed with breast cancer than are women with fatty breasts (4). Only prior biopsy showing lobular carcinoma in situ or atypical ductal hyperplasia and genetic mutations are associated with a higher breast cancer risk.

Breast cancer risk models used in clinical practice (Gail, BRCAPro, Claus, Tyrer-Cuzick) do not include analysis of breast density (5,6). These models do not predict risk well; the accuracy (area under the receiver operating characteristic curve) ranges from 50% to 80% (5). Inclusion of breast density in cancer risk models may improve accuracy. A few breast cancer risk models have incorporated breast density (7–9). In particular, two models that include the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS) (10) density categories have shown improved breast cancer risk prediction (8,9). Radiologists typically interpret and record BI-RADS density as a part of clinical practice, making these models potentially more clinically relevant than models with continuous breast density.

The association of breast density and breast cancer risk is largely based on studies of film-screen (FS) mammography (4). The U.S. Food and Drug Administration approved digital mammography for use in 2003. Digital mammography is increasingly being used instead of FS acquisition; 82% of Food and Drug Administration–certified mammography units were digital as of November 1, 2011 (*http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandards-ActandProgram/FacilityScorecard/ucm113858.htm*). The appearance of a digital mammogram is inherently different than that of an FS mammogram. Digital mammography, although similar in spatial resolution to FS, is higher in contrast resolution (11–13). Electronic processing of the digital mammogram results in improved visualization of the skin and subcutaneous fat, which are often not readily apparent on FS mammograms. The perceived density may therefore be lower on digital than on FS mammograms.

Computer-assisted quantitative measurements of breast density have been shown to be lower for digital than for FS mammography (14). In a study of 60 consecutive women with mammograms obtained by using both acquisition methods, the mean percentage of breast density was significantly lower for digital (32.2%) than for FS mammography (40.3%) ($P < .01$) (14).

Because of the higher contrast resolution and improved visualization of the total breast area on digital versus FS mammograms, we hypothesized that BI-RADS breast density categories would also be lower when digital mammography is used than when FS mammography is used. If the hypothesis was valid, then the BI-RADS breast density categories in breast cancer risk models would have to be adjusted for mammographic acquisition method.

Advances in Knowledge

- The percentage of agreement between American College of Radiology's Breast Imaging Reporting and Data System breast density readings is similar (range, 67.3%–71.0%) whether digital or film-screen mammography is used.
- Reported Breast Imaging Reporting and Data System breast density categories may be incorporated in breast cancer risk assessment models regardless of acquisition method.

Implications for Patient Care

- Breast density reporting by radiologists is consistent whether mammograms are obtained by means of film-screen or digital acquisition.
- The development of breast cancer risk models that include breast density can make use of reported BI-RADS breast density categories because they do no not vary by acquisition method.

Materials and Methods

Study Population

Data were collected from five mammography registries that are in the the National Cancer Institute–funded Breast Cancer Surveillance Consortium (15) (*http://breastscreening.cancer.gov*), which is funded by: the Carolina Mammography Registry, the New Hampshire Mammography Network, the San Francisco Mammography Registry, the Vermont Breast Cancer Surveillance System, and the Group Health Cooperative in western Washington. These registries are collections of demographic, risk factor, and clinical information on screening and diagnostic mammographic examinations performed in their defined catchment areas. Data were pooled at a central statistical coordinating center for analysis. Each registry and the statistical coordinating center received institutional review board approval for either active or passive consent processes or a waiver

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Abbreviations:
BI-RADS = Breast Imaging Reporting and Data System
FS = film screen

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Conflicts of interest are listed at the end of this article.

of consent to enroll participants, link data, and perform analytic studies. All procedures were Health Insurance Portability and Accountability Act compliant.

We included women aged 40 years and older who underwent at least two screening mammographic examinations less than 36 months apart between January 1, 2000, and December 31, 2009. A screening examination was defined by radiologists or technicians as a routine screening and consisted of bilateral routine views (16). To avoid misclassification of diagnostic mammographic examinations as screening examinations, we excluded mammograms of women who had undergone a breast imaging examination within the previous 9 months. Both examinations were required to include a BI-RADS measurement of breast density that was assigned in clinical practice by a radiologist at the time of screening.

Because cancer therapies may affect breast density, we excluded mammograms of women with a history of breast cancer. We also excluded mammograms of women with a history of breast augmentation and those who reported using oral contraceptives, hormone therapy, tamoxifen, or raloxifene at the time of the examination or during the previous year because these agents could affect breast density.

Data Collection and Definitions

Demographic and risk-factor information, including birth date, race, ethnicity, menopausal status, hormone therapy use, and oral contraceptive use were collected by means of a questionnaire administered at each mammographic examination. Mammographic breast density was described by using the BI-RADS four-category terminology. In the third edition of the BI-RADS manual (17), density categories were defined as almost entirely fat (category 1), scattered fibroglandular densities (category 2), heterogeneously dense (category 3), and extremely dense (category 4). In the fourth edition of the BI-RADS manual (10), which was released in 2003, the density definition was changed to include the percentage of glandular material in each category: less than 25% glandular (category 1), 25%–50% glandular (category 2), 51%–75% glandular (category 3), and greater than 75% glandular (category 4). Our study included density interpretations from both the third and fourth edition definitions.

After applying the exclusion criteria, we paired mammograms for each woman. We removed any pairs for which there was an intervening report of use of oral contraceptives, hormone therapy, tamoxifen, or raloxifene. Because breast density may decline considerably during menopause (18), we limited the study participants to women who were either premenopausal at both examinations or postmenopausal at both examinations. Women were considered to be premenopausal if they reported having had a period in the previous 180 days. Women were considered to be postmenopausal if they reported having undergone natural menopause or removal of both ovaries or if they were aged 55 years or older (19).

In creating the main sample, we limited inclusion to pairs for which one mammogram was FS and one mammogram was digital. We included pairs for which the FS mammogram was acquired before the digital mammogram (FS-digital) and pairs for which the digital mammogram was acquired first (digital-FS). For women with more than one FS-digital or digital-FS pair, we used the most recent pair. The comparison group included pairs for which both mammograms were FS (FS-FS) and pairs for which both mammograms were digital (digital-digital). Mammograms from the same woman could appear in both the main sample and the comparison group.

Statistical Analysis

We performed cross-tabulations of measurements of BI-RADS density on FS versus those on digital mammograms for women in the main sample. We stratified the pairs of mammograms by the order of the acquisitions, whether FS or digital mammography came first. For women in the comparison group, we performed cross-tabulations of measurements of BI-RADS density at first interpretation (ie, in the earlier of the pair of mammograms for each woman) versus BI-RADS density measurement at the second interpretation for FS-FS and digital-digital pairs. We calculated the percentage of women who were categorized as having BI-RADS density 1–3 at the first interpretation and had higher density measurements at the second interpretation, and the percentage of women with a BI-RADS density category of 2–4 at first interpretation and had lower density measurement at second interpretation. From first to second interpretation, BI-RADS density changed by more than one category for 1289 of 89639 (1.4%) women in the main sample. BI-RADS density changed by more than one category for 4056 of 259046 (1.6%) women with an FS-FS pair and for 1016 of 87066 (1.2%) women with a digital-digital pair.

We used percentage of agreement and the κ statistic to estimate agreement in BI-RADS density for FS-digital and digital-FS pairs and compared this to agreement for FS-FS and digital-digital pairs. We used a bootstrap approach (14) to construct confidence intervals for estimates of agreement.

We performed several sensitivity analyses to assess the potential effect of changes in breast density due to factors other than acquisition method on our results. To minimize the effect of changes in density due to aging, we repeated the analysis, limiting the sample to women whose mammograms were obtained 9–18 months apart. We restricted the analysis to women who were postmenopausal at both examinations because their density measurements were thought to be the most stable and to women who were premenopausal at both examinations. To eliminate differences due to intraradiologist variability, we repeated the analysis, limiting the sample to women for whom the same radiologist interpreted both examinations. To test for possible effects of changes in the BI-RADS breast density lexicon in the fourth edition, we repeated the analysis, limiting the sample to density assessments made after May 1, 2004. Analyses were performed by using SAS 9.2 (SAS Institute, Cary, NC).

Results

The inclusion and exclusion criteria were met by 435 751 women in the study (Table 1). The main sample included 89 639 women who underwent both FS and digital mammography. For the comparison group, 259 046 women underwent two FS mammographic examinations and 87 066 women underwent two digital mammographic examinations during the study period. The study groups were not exclusive. Of the 871 502 mammograms included in the study, 831 795 were included in only one study set. Of these, 585 549 were FS and 246 246 were digital. Women who underwent two digital examinations tended to be younger (mean ± standard deviation, 57.7 years ± 11.4; range, 40–89 years or older) than women who underwent one FS mammographic examination and one digital mammographic examination (mean age, 59.5 years ± 11.5; range 40–89 years or older) ($P < .001$), and women who had two FS mammograms (mean age, 59.3 years ± 11.5; range, 40–89 years or older) ($P < .001$). There was no difference in race between women in the main sample and women in the comparison group.

Table 1

Characteristics of Women Included in the Study

Characteristic	FS-Digital or Digital-FS	FS-FS	Digital-Digital
No. of women	89 639	259 046	87 066
Age at first mammographic examination (y)			
40–49	21 130 (23.6)	67 758 (26.2)	24 724 (28.4)
50–59	24 509 (27.3)	70 410 (27.2)	26 807 (30.8)
60–69	24 895 (27.8)	61 618 (23.8)	21 013 (24.1)
70–79	14 973 (16.7)	44 434 (17.2)	10 853 (12.5)
≥ 80	4132 (4.6)	14 826 (5.7)	3669 (4.2)
Race			
White, non-Hispanic	71 657 (79.9)	200 680 (77.5)	66 420 (76.3)
Black, non-Hispanic	4685 (5.2)	22 719 (8.8)	2836 (3.3)
Hispanic	2964 (3.3)	7826 (3.0)	3624 (4.2)
Asian, Native Hawaiian, or Pacific Islander	6784 (7.6)	11 343 (4.4)	10 767 (12.4)
American Indian or Alaska Native	212 (0.2)	842 (0.3)	139 (0.2)
Other or Mixed	1318 (1.5)	3730 (1.4)	1574 (1.8)
Unknown	2019 (2.3)	11 906 (4.6)	1706 (2.0)
Which came first			
Digital first	2623 (2.9)	. . .	. . .
FS first	87 016 (97.1)	. . .	. . .
Time between first and second mammographic examination			
9–18 months	61 158 (68.2)	195 286 (75.4)	78 157 (89.8)
19–30 months	23 602 (26.3)	56 134 (21.7)	7665 (8.8)
31–36 months	4879 (5.4)	7626 (2.9)	1244 (1.4)
First and second mammographic examination interpreted by same radiologist	20 079 (22.4)	67 916 (26.2)	17 256 (19.8)
Digital first	218 (8.3)	. . .	. . .
FS first	19 861 (22.8)	. . .	. . .

Note.—Data are number of patients, with percentage in parentheses.

For women who underwent both FS and digital mammography, nearly all (97.1%) underwent FS mammography first (Table 1); only 2.9% of women underwent digital mammography first. Most women (68.2%) underwent FS and digital mammography within 18 months of each other. Only 5.4% of women had more than 30 months between the two mammographic examinations. Time between first and second mammographic examinations was significantly longer for women with an FS-digital or digital-FS pair (530 days ± 196; range, 276–1110) than for women with an FS-FS pair (483 days ± 171; range, 276–1110) ($P < .001$) and women with a digital-digital pair (429 days ± 127; range, 276–1110) ($P < .001$). The time interval between mammographic examinations was shortest for women with two digital mammograms.

Of all women in the main sample and comparison groups, 24.2% had their two mammographic examinations interpreted by the same radiologist (Table 1). This percentage was higher for women with two FS mammographic examinations (26.2%) than for women with an FS and a digital examination (22.4%; $P < .001$) or two digital examinations (19.8%; $P < .001$).

Regardless of the types of mammographic examinations prepared, the percentage of women with a change in density from one reading to the next was similar (Table 2). Breast density was reported as lower on the basis of the digital mammogram for 17.1% of women with a digital-FS pair and 19.8% of women with a FS-digital pair. The breast density measurement was reported as lower on the basis of the FS mammogram for 15.1% of women with a digital-FS pair and 16.0% of women with a FS-digital pair. A similar percentage of women had lower density on the second examination regardless of mammographic type, varying from 15.8% to 19.8%. Breast density decreased from first to second interpretation for 19.8% of women with an FS-digital pair versus 18.1% of women with an FS-FS pair. Breast density increased for 16.2% of women with a digital-FS pair versus 14.7% of women with a digital-digital pair. Agreement between density readings was similar regardless of the mammographic type; the percentage of agreement varied from 67.3%–71.0%, and κ statistic varied from 0.49 to 0.56 (Table 2).

Variability between readings was evaluated at the category level (Table 3). The most variability was seen in women who were initially assigned to the extremely dense category. For women with extremely dense breast tissue on

Table 2

BI-RADS Density Readings by Mammographic Acquisition Method and Reader Agreement

Acquisition Method Pairs	Digital < FS*	FS < Digital†	Second > First Interpretation‡	Second < First Interpretation§	Agreement (%)	κ Value
FS-digital or digital-FS	19.8 (15922/80580)	16.0 (13323/83326)	16.0 (13356/83364)	19.7 (15889/80562)	67.4	0.49 (0.45, 0.56)
Digital first	17.1 (397/2324)	15.1 (364/2411)	16.2 (397/2449)	15.8 (364/2306)	71.0	0.56 (0.48, 0.65)
FS first	19.8 (15525/78256)	16.0 12959/80915)	16.0 (12959/80915)	19.8 (15525/78256)	67.3	0.49 (0.44, 0.55)
FS-FS	. . .	. . .	16.9 (40598/239903)	18.1 42873/237385)	67.8	0.49 (0.47, 0.57)
Digital-digital	. . .	. . .	14.7 (11728/79961)	18.9 (14567/76894)	69.8	0.54 (0.50, 0.62)

Note.—Excpet for κ values, data are percentages, with numerators and denominators in parentheses. For κ values, 95% confidence intervals (CIs) are in parentheses.

* Among BI-RADS density categories 2–4 on FS mammograms.

† Among BI-RADS density categories 1–3 on FS mammograms.

‡ Among BI-RADS density categories 1–3 at first interpretation.

§ Among BI-RADS density categories 2–4 at first interpretation.

Table 3

Variability in BI-RADS Density Categories between First and Second Reads

	Second Read Categories				
Pairs and First Read Categories	1	2	3	4	Total
FS first, digital second					
1	5348 (61.1)	3111 (35.5)	280 (3.2)	21 (0.2)	8760
2	4575 (11.5)	27427 (69.1)	7489 (18.9)	191 (0.5)	39682
3	426 (1.3)	7540 (23.2)	22640 (69.7)	1867 (5.7)	32473
4	19 (0.3)	315 (5.2)	2650 (43.4)	3117 (51.1)	6101
Digital first, FS second					
1	203 (64.0)	97 (30.6)	17 (5.4)	0 (0.0)	317
2	85 (7.9)	794 (73.6)	193 (17.9)	7 (0.6)	1079
3	11 (1.0)	216 (20.5)	743 (70.6)	83 (7.9)	1053
4	0 (0.0)	2 (1.1)	50 (28.7)	122 (70.1)	174
FS-FS					
1	11946 (55.1)	8732 (40.3)	51 (4.3)	52 (0.2)	21661
2	9326 (7.8)	86706 (72.3)	22992 (19.2)	964 (0.8)	119988
3	977 (1.0)	24346 (24.8)	66004 (67.2)	6927 (7.1)	98254
4	51 (0.3)	1081 (5.6)	7092 (37.0)	10919 (57.0)	19143
Digital-digital					
1	7123 (70.0)	2807 (27.6)	230 (2.3)	12 (0.1)	10172
2	4188 (11.5)	25941 (71.4)	5928 (16.3)	259 (0.7)	36316
3	311 (0.9)	7387 (22.1)	23283 (69.6)	2492 (7.4)	33473
4	16 (0.2)	188 (2.6)	2477 (34.9)	4424 (62.3)	7105

Note.—Data are number of patients, with percentages in parentheses.

the initial FS mammogram, only 51.1% and 57.0% were reassigned to this category when the second mammographic examination was digital or FS, respectively. The assignment of "extremely dense" was more consistent for women with an initial digital mammogram; 70.1% and 62.3% remained in this category on the basis of the second FS or digital mammogram, respectively.

We obtained comparable results when limiting analyses to women whose mammographic examinations were 9–18 months apart, to women who were postmenopausal at both examinations, and to women who were premenopausal at both examinations. Results were also similar after we restricted the sample to mammographic pairs that were obtained after May 1, 2004, which was six months after the release of the fourth edition of the BI-RADS lexicon (Table E1 [online]). Agreement was slightly higher for women for whom the same radiologist interpreted both examinations, with a κ of 0.61–0.64, but the percentage of women with a change in density was similar, regardless of mammographic pair, as it was for the main analysis.

Discussion

FS and digital mammograms can have very different appearances because of film and image processing and manufacturer-specific display protocols. Digital mammograms are higher in contrast resolution than FS mammograms are. Although the visual appearance is different, our study results suggest that there was no difference in how radiologists assigned BI-RADS breast density categories on the basis of acquisition with FS or digital mammography. The implications of this study are important if reported BI-RADS density categories are to be included in breast cancer risk models and for studies that combine visual breast density measurements from FS and digital mammograms.

Breast density is a strong independent risk factor for breast cancer (1–4). Incorporation of breast density into breast cancer risk assessment models improves accuracy (7–9). The commonly used version of the Gail model, which is available on the National Cancer Institute website (20), does not include breast density. Inclusion of breast density in the model results in a modest improvement in accuracy (7). Two recent models have included BI-RADS breast density with similar improvements in accuracy of breast cancer risk prediction (8,9). The inclusion of this risk factor improves accuracy; however, there are several barriers to doing so.

A reproducible automated method of measuring breast density would be optimal for inclusion in a breast cancer risk assessment model. Breast density can be measured by using area-based or volumetric methods, where the percentage of the breast occupied by fibroglandular tissue is calculated. Theoretically, volumetric methods are expected to have a stronger association with breast cancer risk than are area-based methods. Unfortunately, volumetric methods have shown mixed results for association with breast cancer risk in comparison with area-based methods (21,22). Volumetric methods to determine breast density must incorporate an accurate measurement of compressed thickness by using the Digital Imaging and Communications in Medicine header or a phantom, or by using an internal reference to normalize fat density (23,24). In a comparison of volumetric and area-based methods, at least 6% of patients showed a large difference between the measurements (24). Until automated methods become more reliable and demonstrate at least a moderate association with breast cancer risk, use of the readily available BI-RADS density categories is a reasonable, temporary proxy in breast cancer risk models.

The association of breast density and breast cancer risk is well validated for FS but much less so for digital mammography. Results of one recent study showed the association of breast cancer by using BI-RADS density categories for FS and digital acquisitions to be similar (25). The measurement of breast density differs between FS and digital mammography when computer-based methods are used. When breast density is measured by using quantitative methods, the percentage of density is lower for digital than for FS mammography (14). Quantitative methods determine the percentage of breast density by defining the area of breast tissue, which is then divided by the total area of the breast by using one mammographic view (26). Digital mammography involves image processing algorithms that improve visualization of the skin line and subcutaneous tissues. This increases the measured total area of the breast on digital mammograms. The changes are most apparent for women with at least 20% breast density (14) compared with women who have fatty-replaced breasts. The incorporation of quantitative measures of breast density into breast cancer risk models would therefore require adjustment based on mammographic acquisition method because of the lower percentage of density for digital than for FS mammography.

Although we hypothesized that reported BI-RADS density categories would also be lower for digital than those for FS mammography, we found no differences in our study. It appears that radiologists may be making adjustments in the application of density categories to accommodate for the acquisition method. There is moderate to substantial intra- and interreader agreement in assignment of BI-RADS density categories (27–30). The variability in reporting of BI-RADS breast density categories will have some effect on the estimation of risk if used in breast cancer risk models. Reproducible automated measures of breast density that have at least a similar association with breast cancer risk are needed to eliminate observer variability. There are obstacles to automation including accurate accounting of compressed breast thickness and exposure calibration by machine and detector type (24). Reported BI-RADS density categories may therefore be a good intermediary estimate of breast density for use in breast cancer risk models until automated measures for digital mammography are better validated for association with breast cancer risk.

Results of a previous study also from the Breast Cancer Surveillance Consortium (31) showed that changes in breast density occurred over time, and that these changes may influence breast cancer risk. In that study (31), mammographic pairs were purposely chosen at longer intervals (the latest and earliest mammograms available for each patient). Only 28%–32% of women included in each study group had an interval between mammographic examination pairs of less than 2 years (31); the mean interval was 3.2 years. In our study, the closest interval mammographic pair was selected to minimize the effects of age-related breast involution; 68%–90% of women in each study group had an interval of less than 18 months. Despite the shorter interval between mammographic examinations, we also found an overall decline in breast density between these two consecutive mammographic examinations (although changes occurred in both directions) to be consistent with results of the prior study (31). We found these changes were independent of acquisition method.

A limitation of our study is that we included density interpretations that were determined on the basis of both the third and fourth editions of the BI-RADS lexicon. In the third edition, breast density categories were descriptive. In the fourth edition, quantitative criteria by quartile of percentage of density were provided. Because we selected mammographic pairs that were obtained at relatively close time frame, it is not likely that the changes in definition influenced the outcome of our study, and the results were similar when limited to BI-RADS density assessments made more than 6 months after the fourth edition was released (Table E1 [online]).

In summary, our study results showed no difference in reported BI-RADS breast density categories based on acquisition method of FS or digital mammography. Because our study showed that reported BI-RADS breast density categories do not differ on the basis of acquisition method, these reported density categories may be used in the development of breast cancer

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risk models in which both FS and digital mammography are used.

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