The Positive Predictive Value of BI-RADS Microcalcification Descriptors and Final Assessment Categories

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OBJECTIVE. The purpose of this article is to retrospectively assess the likelihood of malignancy of microcalcifications according to the BI-RADS descriptors in a digital mammography environment.

MATERIALS AND METHODS. The study included 146 women with calcifications who underwent imaging-guided biopsy between April 2005 and July 2006. Digital mammograms procured before biopsy were analyzed independently by two breast imaging subspecialists blinded to biopsy results. Lesions described discordantly were settled by consensus. One of the radiologists provided a BI-RADS final assessment score.

RESULTS. The overall positive predictive value of biopsies was 28.8%. The individual morphologic descriptors predicted the risk of malignancy as follows: fine linear/branching, 16 (70%) of 23 cases; fine pleomorphic, 14 (28%) of 50 cases; coarse heterogeneous, two (20%) of 10 cases; amorphous, 10 (20%) of 51 cases; and typically benign, zero (0%) of 12 cases. Fisher-Freeman-Halton exact testing showed statistical significance among morphology descriptors ($p < 0.001$) and distribution descriptors ($p < 0.001$). The positive predictive value for malignancy according to BI-RADS assessment categories were as follows: category 2, 0%; category 3, 0%; category 4A, 13%; category 4B, 36%; category 4C, 79%; and category 5, 100%.

CONCLUSION. BI-RADS morphology and distribution descriptors can aid in assessing the risk of malignancy of microcalcifications detected on full-field digital mammography. The positive predictive value increased in successive BI-RADS categories (4A, 4B, and 4C), verifying that subdivision provides an improved assessment of suspicious microcalcifications in terms of likelihood of malignancy.

Keywords: BI-RADS, digital mammography, microcalcification distribution, microcalcification morphology, microcalcifications of the breast

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Mammographically visible microcalcifications are present in approximately 55% of nonpalpable breast malignancies [1] and are responsible for the detection of 85–95% of cases of ductal carcinoma in situ (DCIS) by screening mammography [2]. The American College of Radiology BI-RADS includes descriptors of the morphology and distribution of microcalcifications [3]. Each morphology descriptor places the described lesion into a category that helps predict the malignant potential of the lesion. These categories include typically benign, intermediate concern, and higher probability of malignancy [3]. For example, amorphous (Fig. 1) calcifications have been reported to represent malignancy in 13–25% of biopsies [4–7]. They are therefore currently placed into the intermediate concern group. Calcifications in the higher probability of malignancy group described as fine linear/branching (Fig. 2) or fine pleomorphic (Fig. 3) have rates of malignancy as high as 92% and 67%, respectively [7].

However, the early studies that led to the establishment of BI-RADS occurred primarily before the advent of digital mammography. In studies comparing full-field digital mammography and screen-film mammography, the attributes of full-field digital mammography have been shown to allow both increased visualization and characterization of microcalcifications. A study of 1,147 breasts examined by both mammographic techniques showed that radiologists identified calcifications in 45% of digital mammograms, compared with 36% of screen-film mammograms [8]. A study by Kim et al. [9] was performed using 37 benign and three malignant cases of calcifications seen on both film and soft-copy digital images. The images were presented prospectively to three radiologists. Digital image quality, calcification quantity, and calcification conspicuity were rated higher 85%,

80%, and 53% of the time, respectively. The studies that assessed and stratified the risk of malignancy for various BI-RADS descriptors were performed before the approval and widespread use of full-field digital mammography. The goal of this study was to assess the predictive value of the likelihood of malignancy for BI-RADS microcalcification descriptors and final assessment categories in the full-field digital mammography environment.

Materials and Methods

Study Cohort

This study was performed in compliance with HIPAA and with the approval of the institutional review board, which waived informed consent. This retrospective study included 146 biopsies from women who underwent imaging-guided biopsy for suspicious microcalcifications at an academic medical center between April 2005 and July 2006. Microcalcifications present within or associated with masses were not included. The women were 34–84 years old at the time of biopsy (mean age [± SD], 54.6 ± 12.7 years). Pathologic analysis results from wire-localized excision or stereotactic core needle biopsies of the suspicious lesions were used to determine the presence or absence of malignancy. All stereotactic biopsies were performed using an 11-gauge vacuum-assisted device, and at least 10 samples were obtained for each biopsy. The exclusion criteria were as follows: patients with a benign finding on histopathologic analysis who did not have a minimum of 12 months of mammographic follow-up after biopsy (to rule out false-negative results), patients whose digital images were unavailable, and patients whose microcalcifications were not identified in the biopsy specimens. Of the 164 consecutive biopsies performed during the study period, a total of 18 were excluded. Images were unavailable for two patients, and there were insufficient follow-up data for 16 patients. The final cohort included 146 lesions.

Imaging Equipment and Evaluation

Digital mammographic examinations were performed with either a Senographe 2000D (GE Healthcare) or a LORAD Selenia (Hologic) full-field digital mammography unit. For all patients included in the study, diagnostic evaluation included lateral and magnification views. All digital images were interpreted with soft-copy technique at a high-resolution workstation. Final histologic diagnoses were withheld from the mammographers until completion of the study.

The digital mammograms acquired before biopsy were analyzed independently in a blinded fashion by two radiologists, each with over 20 years of experience specializing in breast imaging, who recorded BI-RADS descriptors on a worksheet. If descriptor interpretation of the lesion differed between the radiologists, consensus was reached by discussion. This was done to improve the accuracy of the interpretation because interobserver reliability is relatively poor when describing microcalcification morphology ($\kappa = 0.31–0.36$) and distribution ($\kappa = 0.29–0.50$) [10–12]. In this study, if more than one BI-RADS descriptor was assigned to a lesion, the most suspicious descriptor was used for analysis. BI-RADS final assessment categorization (categories 2, 3, 4A, 4B, 4C, and 5) of each lesion was performed by one of the interpreting radiologists. Final assessment categories were scored using lexicon definitions as follows: BI-RADS category 2 for lesions classified as benign; category 3 for lesions classified as probably benign (< 2% risk of malignancy), for which a 6-month follow-up would usually be recommended; category 4A for lesions with a low likelihood of malignancy (2–10%); category 4B for lesions with an intermediate likelihood of malignancy (11–50%); category 4C for lesions with a moderate likelihood of malignancy (51–95%); and category 5 for lesions highly suggestive of malignancy (> 95%) [3].

Tests for statistical significance were performed using the Fisher-Freeman-Halton Exact Test and

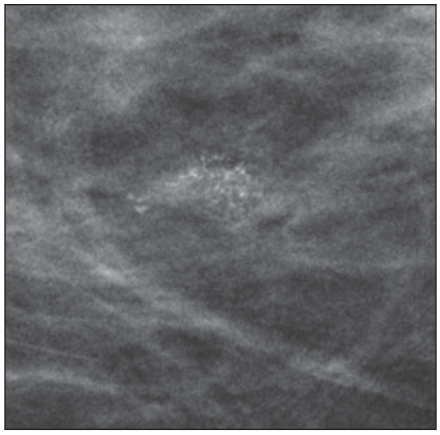

Fig. 1—Left breast of 44-year-old woman. Magnified craniocaudal mammogram shows cluster of amorphous calcifications. Pathologic diagnosis on stereotactic core needle biopsy revealed columnar cell changes and columnar cell hyperplasia without atypia.

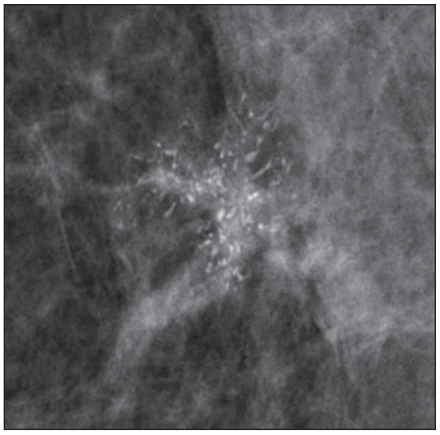

Fig. 2—Right breast of 50-year-old woman. Magnified mediolateral mammogram shows fine linear/branching calcifications in linear ductal distribution. Pathologic diagnosis at stereotactic core needle biopsy and subsequent lumpectomy revealed well-differentiated invasive ductal carcinoma with intermediate nuclear-grade and high-grade comedo type ductal carcinoma in situ with central necrosis.

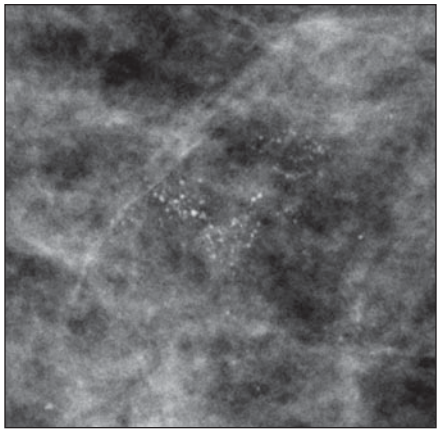

Fig. 3—Right breast of 67-year-old woman. Magnified craniocaudal mammogram shows cluster of fine pleomorphic calcifications. Pathologic diagnosis at stereotactic core needle biopsy and subsequent lumpectomy revealed atypical ductal hyperplasia and columnar cell hyperplasia.

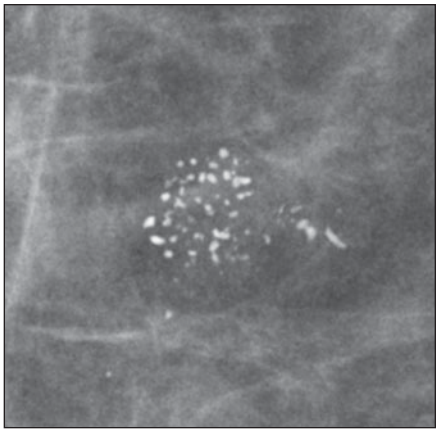

Fig. 4—Right breast of 59-year-old woman. Magnified craniocaudal mammogram shows cluster of coarse heterogeneous calcifications. Pathologic findings at stereotactic core needle biopsy and subsequent excision biopsy showed carcinoma in situ of indeterminate type with central necrosis and histochemical features most consistent with lobular carcinoma in situ. Lesion was considered benign for statistical analysis.

the linear association chi-square test (Stata statistical software, release 9; StataCorp). Statistical significance was defined as $p \leq 0.05$. For results found to be statistically significant, odds ratios and 95% CIs were used in a pairwise fashion to assess differences. Odds ratios were considered to indicate statistical significance if the CI excluded 1.0.

Follow-Up

For patients with microcalcifications identified as benign on biopsy, follow-up was accomplished by subsequent mammography at least 12 months after biopsy to ascertain whether a patient had carcinoma. Follow-up at 1 year after biopsy has been shown to be a sufficient minimum interval to detect false-negative biopsy results [3]. Mammographic follow-up was performed for 104 lesions 1–3.1 years after biopsy (mean ± SD, 1.7 ± 0.5 years). For microcalcifications identified as malignant on biopsy, histologic diagnosis at definitive surgery was used as the end point. In this study, malignancy was defined as a pathologic diagnosis of invasive carcinoma or DCIS. Any lesion with an invasive component was categorized as an invasive carcinoma. High-risk lesions, including atypical ductal hyperplasia, atypical lobular hyperplasia, and lobular carcinoma in situ, were considered benign for statistical analysis. All patients found to have atypical ductal hyperplasia, lobular neoplasia, or columnar cell lesions with atypia (flat epithelial cell atypia) or patients with discordant pathologic analysis results on core needle biopsy were recommended for surgical excision. Pathologic analysis of both the initial core needle biopsy and follow-up excisional biopsy were considered, with the excisional biopsy results being the reference standard.

TABLE 1: Frequency of Malignancy in 146 Lesions by Morphologic Descriptors

Descriptor	No. (%) of Invasive Cancers	No. (%) of Ductal Carcinoma In Situ	Total No. (%) of Malignancies	Total No. of Lesions
Typically benign	0 (0)	0 (0)	0 (0)	12
Coarse heterogeneous	0 (0)	2 (20)	2 (20)	10
Amorphous	5 (10)	5 (10)	10 (20)	51
Fine pleomorphic	6 (12)	8 (16)	14 (28)	50
Fine Linear/branching	5 (22)	11 (48)	16 (70)	23
Total	16 (11)	26 (18)	42 (29)	146

Note—Percentages were calculated by dividing the number of invasive carcinomas and ductal carcinoma in situ malignancies by the total number of lesions for each descriptor. Percentages are rounded to the nearest whole number.

TABLE 2: Risk of Malignancy by Descriptor Pairs

Category, Descriptor Pair	Odds Ratio (95% CI) for Malignancy
Morphology	
Typically benign vs fine linear/branching[a]	0 (0–0.16)
Amorphous vs fine linear/branching[a]	0.11 (0.029–0.37)
Coarse heterogeneous vs fine linear/branching[a]	0.11 (0.010–0.80)
Fine pleomorphic vs fine linear/branching[a]	0.17 (0.049–0.56)
Amorphous vs fine pleomorphic	0.63 (0.22–1.74)
Coarse heterogeneous vs fine pleomorphic	0.64 (0.060–3.84)
Amorphous vs coarse heterogeneous distribution	0.98 (0.16–10.83)
Distribution	
Regional vs clustered[a]	0 (0–0.94)
Segmental vs clustered[a]	4.53 (1.29–16.16)
Linear ductal vs clustered[a]	3.53 (1.30–9.50)
Segmental vs linear ductal	1.29 (0.32–5.31)
Regional vs linear ductal[a]	0 (0–0.28)
Regional vs segmental[a]	0 (0–0.23)

[a]Finding is considered statistically significant because the 95% CI excludes 1.0.

Results

Overall Biopsy Results

Of the 146 microcalcification lesions biopsied, 104 were benign and 42 were malignant, representing an overall positive predictive value for biopsies of 28.8%. The 42 malignant lesions consisted of 26 cases of DCIS and 16 cases of invasive carcinoma. Concordance for the single most suspicious morphology descriptor was reported by the radiologists in 109 (75%) of 146 cases; 37 (25%) of 146 cases required discussion to reach consensus. For distribution, concordance was reached for the most suspicious descriptor in 126 (86%) of 146 cases, and 20 (14%) of 146 cases were settled by discussion.

Morphology

The morphology descriptors predicted malignancy as follows: typically benign, zero (0%) of 12 cases; amorphous, 10 (20%) of 51; coarse heterogeneous, two (20%) of 10; fine pleomorphic, 14 (28%) of 50 cases; and fine linear/branching, 16 (70%) of 23 cases. The results are summarized in Table 1. Of the 12 cases of typically benign calcification, these were described as milk of calcium ($n = 2$), punctate ($n = 7$), milk of calcium/punctate ($n = 2$), and round ($n = 1$). Typically benign calcifications were treated as a unit for statistical purposes. Fisher-Freeman-Halton exact testing showed a statistically significant difference among descriptors ($p < 0.001$). Odds ratios for malignancy by descriptor pair are summarized in Table 2. Because the 95% CI of the odds ratios excludes 1.0 when comparing typically benign, amorphous, coarse heterogeneous (Fig. 4), and fine pleomorphic versus fine linear/branching, this suggests a significantly increased risk of malignancy for fine linear/branching.

For the BI-RADS general categories of morphologic descriptors, 30 (41%) of 73 higher probability of malignancy calcifications were malignant, 12 (20%) of 61 were classified as intermediate concern, and zero (0%) of 12 typically benign calcifications were malignant. The difference in malignancy risk among these categories was significant ($p = 0.001$). The odds ratio of malignancy comparing higher probability of malignancy versus intermediate concern calcifications was 2.85 (95% CI, 1.22–6.86), suggesting significantly increased risk for the former.

Distribution and Combined Descriptors

Similarly, distribution descriptors were predictive of malignancy (Table 3). None of diffuse/scattered ($n = 1$) or regional ($n = 15$) calcifications represented malignancy. Nineteen (22%) of 86 of clustered, nine (56%) of 16 of segmental, and 14 (50%) of 28 of linear ductal calcifications represented malignancy. The

difference among these descriptors was statistically significant ($p < 0.001$). The odds ratios for malignancy by distribution descriptor are summarized in Table 2 and are graphically displayed in Figure 5. The 95% CIs for both segmental versus clustered and linear ductal versus clustered microcalcifications exclude 1.0, indicating statistically significantly increased risk of malignancy for those descriptors compared with clustered. Although the rate of malignancy was determined as a function of both morphology and distribution (Table 3), the number of cases in our study was too limited to allow bivariate statistical analysis.

BI-RADS Categorization

The retrospective assignment of BI-RADS risk assessment scores for each lesion is represented in Table 4. By linear association chi-square testing, the differences among categories ($p < 0.001$) and subcategories ($p < 0.001$) were statistically significant. The retrospectively assigned BI-RADS final assessment scores were also compared with scores reported by the original interpreting radiologist before biopsy was performed. BI-RADS final score agreement occurred in 131 of 146, or 90%, lesions.

Discussion

Taken broadly, our results are consistent with those of other groups. Our data showed that the overall positive predictive value for biopsy was 28.8%, which is consistent with the overall positive predictive value for biopsy found in previous studies of 21–42% [5–7, 13]. Of the malignancies found, 62% represented DCIS, whereas the remaining 38% represented invasive carcinoma. The frequency of these histopathologic results is similar to previously reported findings [6, 7].

In this study, morphology descriptors progressively stratified the risk of malignancy as follows: amorphous, coarse heterogeneous, fine pleomorphic, and fine linear/branching. Overall, this progressively increasing risk of malignancy supports the current categorization of microcalcification descriptors into intermediate concern and higher probability of malignancy categories, because the latter showed a statistically significant increased risk of malignancy with an odds ratio of 2.85 (95% CI, 1.22–6.86) versus the former.

However, although the categorization of malignancy risk into intermediate concern and higher probability of malignancy is supported by our data, the specific placement of descriptors in each category in the current BI-RADS lexicon was not fully consistent with our results. Microcalcifications of fine linear/branching morphology in our study represented a statistically significant increased risk of malignancy, compared with all other morphologies. However, when we compared fine pleomorphic calcifications with amorphous or coarse heterogeneous calcifications, the increased risk of malignancy shown by the fine pleomorphic calcifications was not statistically significant. This finding suggests that these calcifications should occupy the same category. However, in the current lexicon, the first is categorized higher probability of malignancy, whereas the latter two are of intermediate concern. Further studies with increased case numbers and higher statistical power may show a need to reevaluate these groupings.

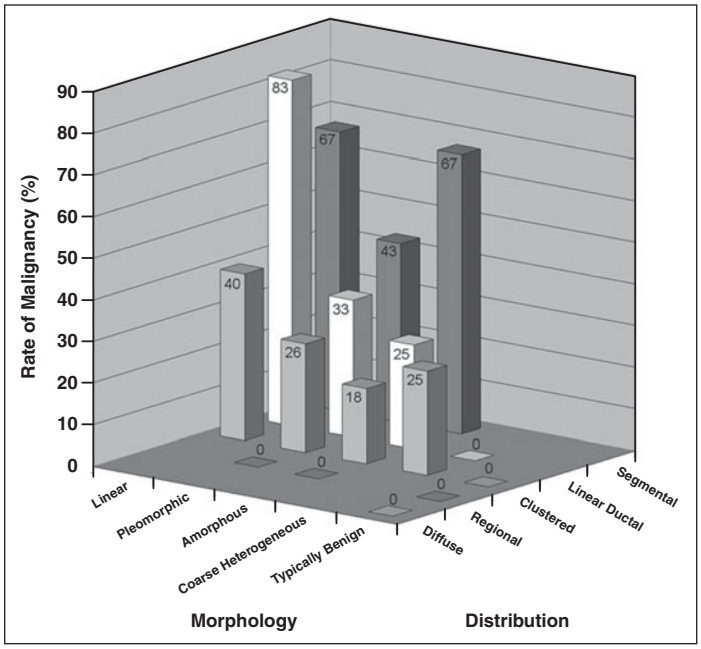

Fig. 5—Probability of malignancy as function of both morphologic and distribution descriptors.

This lack of statistical difference, though, may primarily be due to an abnormally low percentage of fine pleomorphic calcifications resulting in malignancy. The positive predictive value for fine pleomorphic lesions in our study was lower (28%) than, but not inconsistent with, previously reported values of 29–67% [5–7]. Furthermore, the positive predictive values of amorphous and coarse heterogeneous calcifications in our study were 20% and 20%, respectively. Previously published data show that the rate of malignancy of amorphous calcifications is 13–26% [4–7], which is consistent with our findings. Because the coarse heterogeneous descriptor was introduced in 2003 [3], relatively few studies have been performed analyzing its predictive

TABLE 3: Frequency of Malignancy as a Function of Both Morphology and Distribution

Morphology Descriptor	Distribution Descriptor, No. (%) of Lesions					Total No. (%) of Lesions
	Diffuse	Regional	Clustered	Segmental	Linear Ductal	
Typically benign	0/1 (0)	0/6 (0)	0/5 (0)	NA	NA	0/12 (0)
Amorphous	NA	0/6 (0)	6/34 (18)	2/3 (67)	2/8 (25)	10/51 (20)
Coarse heterogeneous	NA	NA	2/8 (25)	NA	0/2 (0)	2/10 (20)
Fine pleomorphic	NA	0/3 (0)	9/34 (26)	3/7 (43)	2/6 (33)	14/50 (28)
Linear/branching	NA	NA	2/5 (40)	4/6 (67)	10/12 (83)	16/23 (70)
Total	0/1 (0)	0/15 (0)	19/86 (22)	9/16 (56)	14/28 (50)	42/146 (29)

Note—Percentages were calculated by dividing the number of invasive carcinomas and ductal carcinoma in situ malignancies by the total number of lesions for each descriptor. Percentages are rounded to the nearest whole number. NA = no cases available.

TABLE 4: Frequency of Malignancy by Assigned BI-RADS Final Assessment Score

BI-RADS Score, Subcategory	No. of Malignant Calcifications	No. of Benign Calcifications	Total No. of Lesions (% of Malignant Calcifications)
2	0	2	2 (0)
3	0	6	6 (0)
4	40	96	136 (29)
4A	9	58	67 (13)
4B	20	35	55 (36)
4C	11	3	14 (79)
5	2	0	2 (100)

Note—Percentages were calculated by dividing the number of invasive carcinomas and ductal carcinoma in situ malignancies by the total number of lesions for each final assessment category. Percentages are rounded to the nearest whole number. BI-RADS final assessment scores were assigned retrospectively by a radiologist blinded to the histopathologic results of biopsies.

power. Compared with the 7% positive predictive value reported by Burnside et al. [5], the risk of malignancy in our population for coarse heterogeneous calcifications was higher. Taken together with the relatively small sample population, these factors may explain our lack of statistical difference among fine pleomorphic, amorphous, and coarse heterogeneous calcifications as an aberration, rather than a broad-scale occurrence.

Although the BI-RADS lexicon does not divide microcalcification distribution descriptors into risk categories, we found that the descriptors were helpful in predicting the risk of malignancy. Linear and segmental calcifications were statistically more likely to represent malignancy than other distribution descriptors. Such calcifications represented malignancy 50% and 56% of the time, respectively. These values are consistent with those in the literature [5–7, 13]. By comparison, clustered calcifications represented an intermediate risk for malignancy (22%), similar to published values of 13–36% [5–7, 13]. Regional microcalcifications showed a very low likelihood of malignancy (0%). These results reinforce those of previous studies indicating that a risk classification system based on distribution descriptors, similar to that currently in use for morphology descriptors, may further increase the usefulness of the BI-RADS system [5, 6].

Although BI-RADS stratifies morphologies and provides a lexicon for describing morphology and distribution, it does not provide guidance on how to categorize microcalcifications into distinct BI-RADS final assessment scores. In practice, it is these final assessments that determine whether a patient is returned to annual screening, referred for short-interval follow-up, or recommended for biopsy. An unfortunate consequence of this scoring system is that most (80–83%) calcifications sent to biopsy arise from lesions scored as category 4, "suspicious for malignancy" [6, 13]. In our study, 136 (93%) of 146 calcifications were given this score. By having such a large percentage of biopsies generated by one scoring interval, meaningful information regarding the radiologist's impression of malignancy potential is lost. To enhance the assessment of category four lesions and improve radiology–pathology correlation, BI-RADS implemented optional subdivisions to signify increasing risk of malignancy [3].

In the present study, the risk of malignancy for each BI-RADS final assessment score and subdivision progressively increased from 2 through 5 (Table 4). The differences among categories ($p < 0.001$) and subcategories ($p < 0.001$) were statistically significant, showing that radiologists can successfully stratify lesions by malignant potential using BI-RADS risk assessment categories and subcategories. The BI-RADS authors did not set out specific guidelines regarding what the risk of malignancy for each of the subcategories should represent. However, we think that, for category 4A, low suspicion of malignancy, the guidance range of malignancy likelihood should be 2–10%. Category 4B, intermediate suspicion, should be 11–50%. Category 4C would be reserved for lesions with a moderate to substantial likelihood of malignancy, or 51–95%. Our results for category 4A were slightly higher (13%), but the results for categories 4B (36%) and 4C (79%) were in the expected ranges. We think that these results reinforce previous studies and support incorporation of these subdivisions into the BI-RADS system to further refine category 4 and provide greater information to pathologists and clinicians [11].

On the basis of the results of this study and its concordance with previously published research, we propose the following assignments for suspicious microcalcifications that will undergo biopsy. Fine linear/branching calcifications in a linear ductal or segmental distribution should be categorized as 4C. Fine linear/branching calcifications in a clustered distribution should be categorized as at least 4B. Fine pleomorphic calcifications in a clustered, linear ductal, or segmental distribution should be classified as 4B. Amorphous or coarse heterogeneous calcifications in a clustered, linear ductal, or segmental distribution should be classified as 4B. Although they are considered typically benign, punctate calcifications are commonly identified within DCIS [14]. Because of the strong association of certain distribution descriptors (segmental and linear ductal) with malignancy, punctate calcifications present in such distributions may warrant a score of 4A and biopsy evaluation.

The results and recommendations of this study, however, should be viewed in light of its limitations. First, the population studied was relatively small (146) and localized to one academic hospital system. As a result, some descriptor subgroups were poorly populated. Additional investigation with larger populations is necessary to further assess the positive predictive value of morphology and distribution descriptors simultaneously. Second, interobserver variability is a well-known problem when characterizing microcalcifications. To control for this variation and ensure the proper usage of BI-RADS descriptors, two experienced breast imaging subspecialists independently reviewed the cases and settled discrepancies by consensus. The fact that more than 25% of our cases went to consensus shows its importance. Finally, our study population sampled only patients recommended for biopsy of suspicious microcalcifications. Because not all microcalcifications result in such recommendation, some patients who would otherwise have qualified may have been excluded because they were not originally referred for biopsy. This case-selection bias may limit the generalizability of our results.

In conclusion, our research supplies additional clinical data regarding the risk of malignancy for microcalcification descriptors in the fourth edition of BI-RADS [3], as well as radiologists' ability to convey that information to other providers via the expanded BI-RADS final assessment scores. Our data contribute

evidence supporting the use of BI-RADS microcalcification descriptors, as well as category 4 subdivisions to stratify the risk of malignancy in patients referred for biopsy, reinforcing the use of BI-RADS as a clinical reporting tool.

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