Use of BI-RADS 3—Probably Benign Category in the American College of Radiology Imaging Network Digital Mammographic Imaging Screening Trial¹

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Purpose:

To determine (a) how often the Breast Imaging Reporting and Data System (BI-RADS) category 3 was used in the American College of Radiology Imaging Network (ACRIN) Digital Mammographic Imaging Screening Trial (DMIST), either at the time of screening mammography or after work-up, (b) how often subjects actually returned for the recommended follow-up examination, and (c) the rate and stages of any malignancies subsequently found in subjects for whom short-term interval follow-up was recommended.

Materials and Methods:

This study was approved by the Institutional Review Board at all institutions where subjects were enrolled. All subjects participating in DMIST gave informed consent and the study was HIPAA-compliant. A total of 47 599 DMIST-eligible and evaluable subjects, all of whom consented to undergo both digital and screen-film mammography, were included in this analysis. Cases referred for short-term interval follow-up based on digital, screen-film, or both imaging examinations were determined. Compliance with the recommendations and the final outcome (malignancy diagnosis at biopsy or no malignancy confirmed through follow-up) of each evaluable case were determined.

Results:

A total of 1114 of the 47 599 (2.34%) subjects had tumors assigned a BI-RADS 3 category and were recommended to undergo short-interval follow-up. In this study, 791 of 1114 (71%) of the subjects were compliant with the recommendation and returned for short-interval follow-up. Of the women who did not return for short-interval follow-up, 70% (226 of 323) did return for their next annual mammography. Among all subjects whose tumors were assigned a BI-RADS 3 category either at screening mammography or after additional work-up, nine of 1114 (0.81%) were found to have cancer. Of the nine biopsy-proved cancers, six were invasive cancers and three were ductal carcinoma in situ stage Tis-T1c. The invasive cancers were all less than 2 cm in size.

Conclusion:

In DMIST, radiologists used the BI-RADS 3 classification infrequently (2.3% of patients). Tumors assigned a BI-RADS 3 category had a low rate of malignancy. The relatively high rate of noncompliance with short-interval follow-up recommendations (323 of 1114, or 29%) supports prior recommendations that radiologists thoroughly evaluate lesions before placing them in this category.

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The decision to classify some mammographic lesions as Breast Imaging Reporting and Data System (BI-RADS) category 3—probably benign and recommend a short-interval follow-up, usually at 6 months (1), continues to be problematic for many radiologists, patients, and referring physicians. Even if the lesions meet the descriptors in the BI-RADS classification that would indicate that these lesions are probably benign, many of these lesions are instead recommended for biopsy, as described in an article by Pijnappel et al (2), in which the authors depicted this as common practice in England and the Netherlands. Other lesions undergo biopsy because of referring physician or patient concern that there could be a substantial risk of malignancy (3,4). All of these biopsies contribute to the total false-positive rate of mammography. Also, concern exists that if these lesions change at follow-up and ultimately biopsy is performed, they may have progressed to more advanced stages (2).

The percentage of screening mammograms that are placed in BI-RADS category 3 has been variably reported, ranging 1.2%–9.8%, with an average of 5%, in one study (5), and 1.4%–14%, with an average of 7.7%, in another study (6). A later study by Monticciolo et al demonstrated a slight decline in the number of cases (average of 6%) referred for short-term follow-up, with a range of 1.1%–12.2% (7). A retrospective study from the Breast Cancer Surveillance

Consortium from January 1996 through December 1999 demonstrated even lower rates, with 5.2% of first and 1.7% of subsequent screening examinations having a recommendation for short-interval follow-up (8). Many studies, including one by Sickles in 1991 (9), demonstrated that if the BI-RADS descriptors are used appropriately, lesions placed in this category have a rate of malignancy lower than 2%. A number of articles in the 1990s suggested that this recommendation should only be given after a thorough evaluation of the lesion with additional mammographic and/or ultrasonographic imaging and that the chance of malignancy for these probably-benign lesions should be less than 2% (10,11). In a 2004 article, Monticciolo and Caplan proposed that one of the possible reasons for the decline in the number of mammograms assigned a BI-RADS 3 classification was that more patients had undergone diagnostic work-up after a screening examination and prior to the final BI-RADS 3 recommendation (7).

Short-term follow-up recommendations do not work as intended if patients do not return for follow-up imaging. Patient compliance with recommendations for additional imaging and/or follow-up has been shown to be low after initial screening in a mobile setting (12). This compliance has also been shown to decrease with time, from 88% at 4 months to 60% at 2 years (13). This is important because short-interval follow-up typically includes not only the first 6-month follow-up but also annual follow-up for up to 2 years. There are many barriers to follow-up imaging. Factors that reduce compliance are low educational level, low patient concern for cancer, poor general health, and race (14). It is also important for radiologists to involve referring physicians to increase patient compliance for all mammographic recommendations, from annual screening

to immediate additional imaging, short-interval follow-up, or biopsy (15).

The purposes of this retrospective study were to determine (a) how often BI-RADS category 3 was used in the American College of Radiology Imaging Network (ACRIN) Digital Mammographic Imaging Screening Trial (DMIST), either at the time of screening mammography or after work-up, (b) how often subjects actually returned for the recommended follow-up examination, and (c) the rate and stages of any malignancies subsequently found in subjects for whom short-interval follow-up was recommended.

Materials and Methods

This study was approved by the Institutional Review Board at all institutions where subjects were enrolled. All subjects participating in DMIST gave informed consent, and the study was compliant with Health Insurance Portability and Accountability Act. The study was supported by the National Cancer Institute. Some of the digital mammography equipment used in the study was provided by GE Medical Systems (Milwaukee, Wis), Hologic (Bedford, Mass), Fuji

Advances in Knowledge

- Short-term interval follow-up mammography can be used safely in screening as demonstrated through its use by private and academic radiologists who participated in the Digital Mammographic Imaging Screening Trial.
- Among all subjects whose tumors were assigned a Breast Imaging Reporting and Data System category 3 either at screening mammography or after additional work-up, only nine of 1114 (0.81%) were found to have cancer (stage Tis–T1c tumors).

Implication for Patient Care

- Short-interval follow-up can be used safely in the screening setting but patient compliance can be problematic.

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Abbreviations:

ACRIN = American College of Radiology Imaging Network
 ASE = asymptotic standard error
 BI-RADS = Breast Imaging Reporting and Data System
 CI = confidence interval
 DMIST = Digital Mammographic Imaging Screening Trial

Author contributions:

Guarantors of integrity of entire study, J.K.B., E.D.P.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; literature research, J.K.B., E.F.C., E.D.P.; clinical studies, J.K.B., M.C.M., E.F.C., L.W.B., E.D.P.; experimental studies, L.W.B., E.D.P.; statistical analysis, L.G.H., S.A.; and manuscript editing, all authors

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Medical Systems (Tokyo, Japan), and Fischer Imaging (Denver, Colo) at no cost to the participating sites. Control of data and information included in this study were maintained by the study personnel who did not serve as consultants to these corporations

Subjects

Eligible subjects with no protocol violations who enrolled in DMIST between October 29, 2001, and November 14, 2003, were included in this study (16). These asymptomatic women had agreed to undergo both screen-film and digital mammography on the same day (16). The studies were interpreted by two different radiologists at the same institution, and recommendations using the BI-RADS lexicon were made according to institutional protocols and radiologist interpretation, not according to centrally-mandated DMIST rules regarding the use of BI-RADS terms. The mammograms were read by 153 radiologists at 33 institutions. There are several published DMIST articles that include the subset of participants in this study (17–21). We reviewed all mammograms on which tumors were classified as BI-RADS 3—probably benign (short-interval follow-up suggested) on the basis of either initial digital and/or screen-film mammograms or after additional imaging evaluation was recommended on the basis of findings from one or both screening examinations. In this study, short-interval follow-up is defined as follow-up with breast imaging occurring between 3 and 10 months of enrollment in DMIST. Cases with tumors BI-RADS 3 category on one mammogram and a BI-RADS 4 or 5 category on the other mammogram were excluded, since the higher BI-RADS classification generated an immediate work-up or biopsy. There were 24 such cases. To be as inclusive as possible for the population recommended for short-interval follow-up, the population reported on in this article included women for whom definitive follow-up information was not available. The exclusion of women without appropriate follow-up for this analysis was deemed inappropriate since it would cause overestimation of the compli-

ance rate for short-interval follow-up. Compliance with follow-up recommendations was encouraged at all DMIST sites by using standardized protocols of phone calls and/or letters, as described elsewhere (16).

The types of lesions recommended for short-interval follow-up were classified. The results of the short-interval follow-up, including whether to return to annual examination or undergo biopsy, were compiled. The reference standard for our results was the same as that for DMIST, either biopsy or follow-up information (16). The outcomes of the subjects who went to follow-up or biopsy were evaluated and if a cancer was detected, the size and stage of the malignant tumor were determined. A comparison of the rate of use of BI-RADS 3 was made by radiologist practice setting—academic versus private practice.

Data included in this study are those obtained from the interpretations at the DMIST site. Lesion descriptions for cancer cases were based on image review by the principal investigator (E.D.P.), a radiologist with more than 20 years experience in breast imaging.

Statistical Analysis

The statistical analysis was mostly exploratory and involved a descriptive assessment of the use of the BI-RADS 3 category by DMIST radiologists. χ^2 tests were used to compare the rates of return for follow-up between those assigned short-interval follow-up directly from screening versus those who underwent additional imaging for work-up first. All analyses were performed with SAS software (version 9.1.3; SAS, Cary, NC) (22).

Results

The BI-RADS 3—probably benign category was utilized for 1114 (2.34%; asymptotic standard error [ASE], 0.07%; exact 95% confidence interval [CI]: 2.21%, 2.48%) (Table 1) of the 47 599 women enrolled in DMIST and who were included in this analysis. There was no significant difference in the use of this recommendation between screen-film and digital mammographic interpretations ($P = .28$). The demographic charac-

teristics of the DMIST subject population have been published elsewhere (18). The majority of radiologists recommended short-interval follow-up only after additional diagnostic imaging was performed (1002 of 1114 women, or 89.9% [ASE, 0.90%; exact 95% CI: 88.03%, 91.65%]). This approach of calling a patient back for additional diagnostic imaging is suggested in the literature to be the correct way to assign the BI-RADS 3 category (9,10). Although the study was not designed to evaluate whether there was a significant difference in the usage of the category dependent on the practice of the radiologist, either academic or private, there was not a large variation in the use of this category among radiologists. The 45 radiologists in practices not associated with medical schools referred 2.6% of the patients for short-interval follow-up, while the 120 radiologists in academic practices referred 2.3% for short-interval follow-up.

Only 791 of the 1114 (71.0%; ASE, 1.36%; exact 95% CI: 68.24%, 73.66%) women referred for short-interval follow-up returned for the recommended short-interval follow-up, while 1021 (91.7%; ASE, 0.83%; exact 95% CI: 89.87%, 93.21%) subjects had some evaluation of the suspicious lesion during the study period—short-interval follow-up, annual follow-up, or biopsy (Table 2). Thus, 8.35% (93 of 1114; ASE, 0.83%; exact 95% CI: 6.79%, 10.13%) of the women recommended to have short-interval follow-up did not undergo any follow-up imaging or biopsy within the time frame of the study. It should be noted that only 962 of the 1114 (86.4%; ASE, 1.03%; exact 95% CI: 84.20%, 88.32%) women had short-interval follow-up, an annual screening examination, or both within 15 months after their initial entry into the study. In addition, only 552 of the 1114 women (49.6%; ASE, 1.50%; exact 95% CI: 46.57%, 52.53%) recommended for short-interval follow-up had short-interval follow-up and 1-year follow-up. This suggests that for women who had short-interval follow-up on one breast only, almost half did not then receive a mammogram on the other breast at the recommended yearly screening interval.

The return rate for interval follow-up for those subjects who received this recommendation after undergoing only the screening examination was 65.2% (73 of 112; ASE, 4.50%; exact 95% CI: 55.60%, 73.93%), while the return rate for those who received this recommendation after additional imaging was 71.7% (718 of 1002; ASE, 1.42%; exact 95% CI: 68.76%, 74.43%). The difference in these rates of return was not significant ($P = .15$).

It should be noted that the return rate for annual screening examination in the entire DMIST was 89.8% (ASE, 0.14%; exact 95% CI: 89.56%, 90.10%), with 42 760 of the 47 599 evaluable women returning for some follow-up in 15 months (63.5%–97.9% across the 33 sites).

Thirty-two subjects who were recommended for short-interval follow-up underwent biopsy before or instead of short-term interval follow-up (Table 3). Presumably, the woman or her physician opted for the biopsy rather than short-interval follow-up. Of these, two (6.3%; ASE, 4.28%; exact 95% CI: 0.77%, 20.81%) had findings positive for malignancy; one of these, who received a diagnosis of cancer a few weeks after her screening mammogram, also had a positive mammogram at her annual follow-up approximately 1 year later. Eleven (34.4%; ASE, 8.40%; exact 95% CI: 18.57%, 53.19%) of the women who underwent biopsy later had short-interval follow-up, and 21 (65.6%; ASE, 8.40%; exact 95% CI: 46.81%, 81.43%) had annual follow-up, all with findings negative for additional evidence of malignancy.

Among those who returned for short-interval follow-up, 37 (4.7%; ASE, 0.75%; exact 95% CI: 3.31%, 6.39%) were referred for biopsy on the basis of short-interval follow-up mammogram findings and of those, three were diagnosed with cancer, yielding a positive predictive value of 8.1% (three of 37; ASE, 1.70%; exact 95% CI: 1.7%, 21.9%). Another cancer was diagnosed in a subject with a BI-RADS 3 classification at her short-interval follow-up mammography who opted to undergo biopsy without further imaging. A fifth cancer was found in a subject who received a BI-RADS

Table 1

Source of Referral to Short-Interval Follow-up (BI-RADS 3)

Source	Datum*
Not referred to short-interval follow-up	46 485 (97.7)
Referred to short-interval follow-up	1114 (2.3)
Referred directly from screening mammography	112 (10.1)
Both screen-film and digital mammography	6 (0.6)
Screen-film mammography only	47 (4.2)
Digital mammography only	59 (5.3)
Referred after additional imaging	1002 (89.9)
Screen-film mammography and additional work-up	7 (0.6)
Digital mammography and additional work-up	8 (0.7)
Screen-film and digital mammography and additional work-up	987 (88.6)

* Data in parentheses are percentages.

Table 2

Follow-up Completion Rates

Type of Follow-up Completed	No. of Women*
Short-interval follow-up	791 (71.0)
Annual follow-up within 15 months of initial mammogram	723 (64.9)
Annual follow-up later than 15 months after initial mammogram	705 (63.3)
Any follow-up (short-interval follow-up, annual, or >15 months)	1017 (91.3)
Both short-interval follow-up and annual examination anytime during DMIST	552 (49.6)

Note.—Categories are not mutually exclusive.

* Data in parentheses are percentages.

3 classification at short-interval follow-up mammography but was referred for biopsy at subsequent annual mammography. A total of 226 of the 323 (69.7%; ASE, 2.55%; exact 95% CI: 64.65%, 74.92%) subjects who did not return for short-interval follow-up did return after 10 months for their annual follow-up. Biopsy was recommended for 47 of these women (20.8%; ASE, 2.70%; exact 95% CI: 15.70%, 26.68%), and one cancer was found (2.13%; ASE, 2.10%; exact 95% CI: 0.05%, 11.29%). Therefore, among the 1114 subjects recommended to undergo short-interval follow-up, there were nine cancers (0.81%; ASE, 0.27%; exact 95% CI: 0.37%, 1.53%).

All nine cancers found after recommendations for short-term interval follow-up were either invasive tumors 2 cm or smaller in size or ductal carcinoma in situ. The three cases of ductal carcinoma in situ all measured between 11 and 20 mm in size. The six invasive tumors ranged from 3 to 20 mm, with

the largest being an invasive lobular carcinoma. Size was not available for one of the invasive cancers. Thus, of those cancers for which data are available, all were stage Tis or T1 lesions, with only two of these T1c lesions (Table 4). Data were not collected in a way that allowed definitive description of the types of lesions for all lesions for which short-interval follow-up was recommended. The types of lesions that resulted in a positive diagnosis of malignancy, as classified by the study principal investigator, were four masses, three calcifications, and one focal asymmetry, with one unclassified lesion.

Discussion

The most important finding in this study is the high percentage of noncompliance for women who were recommended to undergo short-interval follow-up. Even in the context of this clinical trial, for women interested and concerned enough

Table 3

Order of Events among Cases Referred for Short-Interval Follow-up

	BI-RADS Score*						
Cancer Status and Timing of Biopsy	1	2	3	4	5	No Follow-up Reported	Total
Cancer							
Biopsy performed before any follow-up imaging	0	0	1 [†]	1	0	0	2
Follow-up preceded biopsy, and biopsy was completed	0	0	1 [†]	2	3	0	6
Biopsy performed, but no follow-up imaging was reported	0	0	0	0	0	1	1
Total no. of cancers	0	0	2	3	3	1	9
No cancer							
Biopsy performed before any follow-up imaging	12 [†]	15 [†]	3 [†]	0	0	0	30
Follow-up preceded biopsy and biopsy was completed	0	1 [†]	5 [†]	68	1	0	75
No biopsies reported, but there was some follow-up	114	397	382	11 [†]	0	0	904
Biopsy performed and but no follow-up reported	0	0	0	0	0	3	3
Neither biopsy nor follow-up	0	0	0	0	0	93	93
Total with no cancer reported	126	413	390	79	1	96	1105

Note.—Unless otherwise indicated, data are number of patients.

* Maximum score per case among all follow-up mammograms completed. Mammograms include short-interval follow-up and annual.

[†] Biopsy was performed because of subject or physician preference rather than recommendation based on imaging reported to DMIST.

[‡] Subject was referred to biopsy, but the biopsy was either not performed or not reported to DMIST.

Table 4

Cancers Identified in Subjects Recommended for Short-Interval Follow-up

Type of Cancer	Size (mm)			
	Pathologic Examination	Mammography	T Stage	N Stage
Ductal carcinoma in situ	70	20	Tis	NX
Ductal carcinoma in situ	2	11	Tis	NX
Ductal carcinoma in situ	Not measured	11	Tis	NX
Invasive	15	20	T1c	NO
Invasive	13	3	T1c	N1
Invasive	8	8	T1b	NO
Invasive	7	12	T1b	NX
Invasive	4	Not measured	T1a	NX
Invasive	4	5	T1a	N1

to participate, only 791 of 1114 (71%) returned for their recommended short-term follow-up between 3 and 10 months after screening mammography. Several previous studies have documented low compliance with short-interval follow-up (11). Our results confirm the importance of a complete evaluation of lesions before classifying the lesion as probably benign, given the low rate of compliance with this recommendation. When a woman is called back for additional imaging of a lesion, the radiologist has the opportunity to discuss the finding and the importance of short-

interval follow-up as that recommendation is given. This approach may also improve compliance with the appropriate follow-up (14).

It is important to note that we included all women who participated in DMIST without protocol violations in this report, including those without recorded follow-up information available for the primary DMIST endpoints. It is difficult to determine whether our results underestimate or overestimate the true rate of compliance with short-interval follow-up recommendations in actual community practice. Since DMIST

subjects may have returned to other non-DMIST sites for short-interval follow-up, the results reported here may underestimate the rate of compliance, but since DMIST sites contacted subjects during the follow-up interval to ascertain whether follow-up mammography had occurred at other locations (perhaps more than usually takes place in usual clinical practice) and since subjects were highly motivated participants in a clinical trial to assess digital mammography, the rate of compliance may be overestimated.

Another important finding in this study is the low rate of malignancy (0.81%) when short-interval follow-up was recommended by the diverse group of radiologists who participated as readers in DMIST, a rate well below the proposed 2% rate of malignancy suggested previously for BI-RADS 3 lesions (6–11). Of the cancers found in this context, all were early malignancies, confirming the safety of this management strategy as practiced by the North American radiologists. Of note is the fact that none of the women referred for short-interval follow-up without additional imaging after the screening examination (112 of the 1114 women) were found to have cancer. This suggests that these lesions

were of extremely low suspicion. Perhaps if patients had undergone additional imaging (BI-RADS 0), or if radiologists trusted their judgment and categorized such lesions as BI-RADS 2, short-interval follow-up could have been avoided. Of course, another reason for such a low rate of recommendation for short-interval follow-up in our study could be the two coincident screening mammograms. The second mammogram might have provided information (ie, additional projections) to radiologists that gave them more reassurance than is usually available about the likelihood of malignancy for screening-detected findings and therefore, fewer short-interval follow-ups were recommended. While readers in the primary DMIST study were not permitted to consult the other type of mammogram prior to rendering their screening interpretation, they were permitted to review both mammograms (and whatever additional imaging they obtained) in deciding how to treat the patient after work-up.

Our study confirms prior findings regarding cancers initially categorized as BI-RADS 3, in that all of the tumors found at biopsy at the time of short-interval follow-up or at next annual examination in the subjects initially recommended for short-interval follow-up were early-stage cancers (10). This lends support for the use of BI-RADS category 3—probably benign (short-interval follow-up) and the view that short-interval follow-up does not lead to clinically important delays in diagnosis of breast cancer.

The generalizability of this study is limited in that it is not a population-based evaluation of a screening mammography program. The experimental methodology involved in DMIST may have influenced our results. The subjects and radiologists involved may not have performed as per their usual practices for the use of BI-RADS 3 classification since they were participating in a clinical trial to evaluate digital versus screen-film mammography. In addition, Sickles (9) recommends 2 years of annual follow-up mammography before a patient is considered cancer-free in the lesion that prompted short-interval

follow-up. The DMIST study design did not permit 2 years of follow-up for our subjects. This may have slightly falsely reduced the cancer rate in the short-interval follow-up lesions compared with other studies of this topic.

We believe these results do add to the body of literature (6–11) on BI-RADS 3. The BI-RADS category can be appropriately utilized by breast imaging radiologists without substantial risk to women but it continues to represent a compliance challenge.

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