Understanding BI-RADS Category 3

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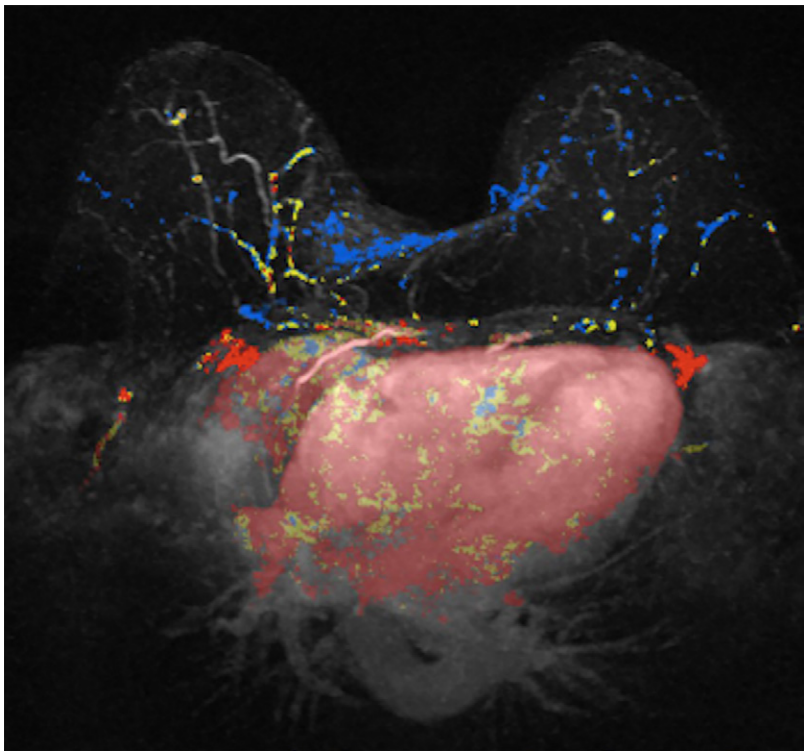
See the invited commentary by Cohen and Leung.



The Breast Imaging Reporting and Data System (BI-RADS) category 3 assessment is used for breast imaging findings considered "probably benign," with less than a 2% likelihood of malignancy. It is used to increase specificity by decreasing the number of breast biopsies. It has been validated for mammography, breast US, and emerging indications for use in contrast-enhanced breast MRI. Despite the long-term use of category 3 and numerous published studies that evaluate characteristic imaging findings appropriate for this category, there is still misuse and confusion regarding its accurate use. Imaging findings classified as category 3 require short-term follow-up to assess stability and identify changes that may warrant a biopsy for early diagnosis of breast cancer. Category 3 should not be used in a screening study without a comprehensive diagnostic evaluation that may reveal suspicious features or downgrade a finding to benign. In mammography, category 3 findings are validated for grouped round calcifications, oval circumscribed masses, and nonpalpable asymmetries. In US, category 3 can be applied to oval circumscribed parallel solid masses and complicated cysts. Category 3 can be assigned to clustered microcysts when they are very small or deep in the breast. Recent studies have yielded characteristic findings appropriate for MRI category 3 that are expected to be included in the sixth edition of the BI-RADS atlas. These include oval circumscribed masses with associated T2-hyperintense signal, focal non-mass enhancement, and foci of enhancement with associated T2-hyperintense signal. Surveillance with short-interval imaging enables radiologists to monitor findings and act early when a change is detected.

Introduction

The American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) lexicon defines the category 3 assessment as "probably benign," with a "≤2% likelihood of malignancy, but greater than the essentially 0% likelihood of malignancy of a characteristically benign finding" (1). Category 3 originated in the late 1980s with Homer's study of benign and probable benign breast findings (2), followed by Sickles' seminal article on periodic surveillance of nonpalpable and probably benign findings (3). Validated findings for category 3 assessment exist for mammography and US and recent advances in breast MRI finding categorization.

The primary aim of category 3 is to reduce false-positive results and unnecessary biopsies while maintaining high sensitivity for early-stage breast cancer detection. However, persistent misuse of category 3 remains a concern. Any suspicious feature should prompt a category 4 or 5 assessment with a biopsy recommendation, and characteristically benign findings should not be assessed as category 3. Radiologists must also consider patient anxiety and compliance with required short-interval follow-up examinations.

While the sixth edition of BI-RADS is pending publication, category 3 is expected to be included for breast MRI, while mammography and US will remain consistent with the fifth edition. This article defines and illustrates category 3 findings for each imaging modality, provides management guidance, and addresses inappropriate use and cost considerations.

Surveillance Algorithm

After diagnostic evaluation, surveillance of category 3 findings entails sequential assessments at 6, 12, and 24 months. Bilateral evaluations at 12 and 24 months align with

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Abbreviations: BI-RADS = Breast Imaging and Reporting Data System, BPE = background parenchymal enhancement, DBT = digital breast tomosynthesis, MIP = maximum intensity projection, NME = non-mass enhancement

TEACHING POINTS

- The American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) lexicon defines the category 3 assessment as "probably benign," with a "≤2% likelihood of malignancy, but greater than the essentially 0% likelihood of malignancy of a characteristically benign finding."
- Assigning category 3 to a finding identified at screening mammography is inappropriate. A comprehensive diagnostic workup, including magnification views for calcifications and US of masses and asymmetries, may downgrade the finding as benign or prompt a biopsy recommendation if suspicious features are identified.
- Regardless of the imaging modality used, radiologists should consider certain patient-related factors when assigning category 3, such as the indication for the examination and the patient's risk for breast cancer, age, possible anxiety from uncertainty and required follow-up examinations, and likelihood of compliance with surveillance imaging.
- Validated category 3 findings on baseline mammograms include *(a)* a noncalcified circumscribed solid mass, *(b)* a solitary group of round calcifications, and *(c)* focal asymmetry without associated suspicious findings.
- Per the BI-RADS US atlas, a solid oval mass with parallel orientation and circumscribed margins can be classified as category 3, representing a benign mass that is often a fibroadenoma.

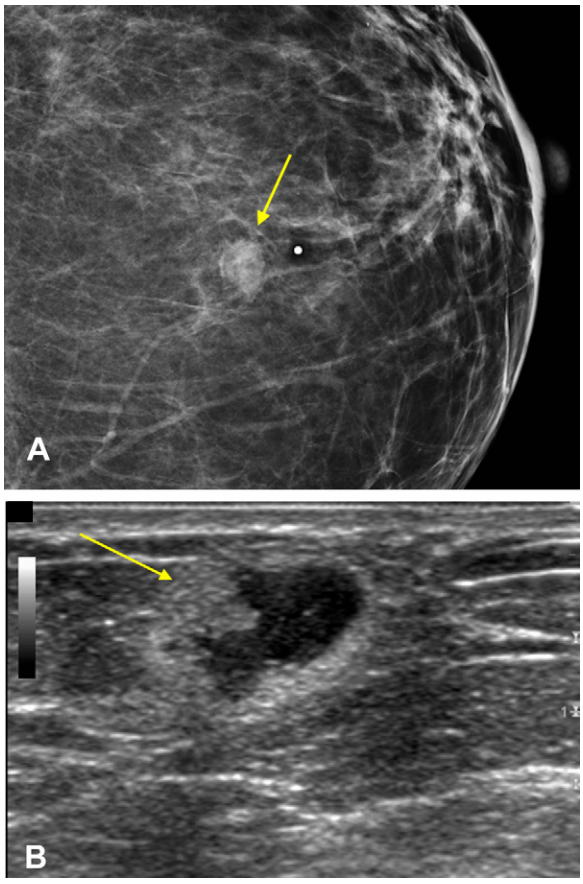


Figure 1. Palpable mass in a 73-year-old woman who was taking blood thinners and did not recall trauma. Category 3 findings can be analyzed at different intervals depending on the clinical presentation. **(A)** Craniocaudal mammogram shows a focal asymmetry (arrow) at the site of the palpable abnormality. **(B)** US image shows a mass with an echogenic rind (arrow). A 3-week follow-up (not shown) was recommended, and findings showed a significant decrease in the size of the suspected hematoma. The finding was downgraded to category 2 benign.

screening intervals on the nonaffected side. Some practices opt for an 18-month interval, while others extend diagnostic follow-up to 36 months. Compliance with short-interval follow-up was 29% during the Digital Mammographic Imaging Screening Trial (4). Chung et al (5) found that cancers diagnosed from category 3 findings were identified at 6 or 12 months, with only 54.8% compliance at 18 months. Berg et al (6) evaluated the use of category 3 in the National Mammography Database and reported 72.5% compliance with the 6-month follow-up, with 57.8% of cancers diagnosed at or before the 6-month evaluation.

Depending on the clinical presentation, not related to screening, alternative follow-up intervals may be considered. For instance, in suspected hematoma cases, a 4-week follow-up can document size reduction and downgrade to benign. Figure 1 exemplifies a patient undergoing anticoagulant therapy with a palpable finding and no trauma recall, illustrating potential downgrades to benign or negative if the finding decreases or disappears. Figure S1 shows a hematoma and follow-up findings after it is resolved. The interpreting radiologist may adjust follow-up intervals based on clinical judgment, while any increase in size or conspicuity warrants an upgrade to category 4 or 5, prompting a biopsy recommendation.

Cost Considerations

Ong et al (7) found that in average-risk women, the imaging follow-up of probably benign findings was more cost-effective than immediate biopsy for mammography, US, and MRI, except for MRI-guided interventions without a postbiopsy follow-up in an average-risk patient not expected to have annual breast MRI. The 2-year mammographic follow-up cost was $484, while the immediate biopsy cost was $1055. For US, the costs were $615 for follow-up and $1173 for biopsy. Two years of follow-up for breast MRI in average-risk patients would cost $1510 compared with $1235 for an MRI-guided biopsy. If post–benign biopsy MRI follow-up is performed, then the cost is $1785. Therefore, from an economic standpoint, category 3 assessment offers cost savings for mammography, US, and MRI (including benign postbiopsy MRI follow-up). However, for MRI biopsy without benign follow-up, the cost is less expensive than category 3 follow-up imaging.

Use of Category 3

Inappropriate Use

Assigning category 3 to a finding identified at screening mammography is inappropriate. A comprehensive diagnostic workup, including magnification views for calcifications and

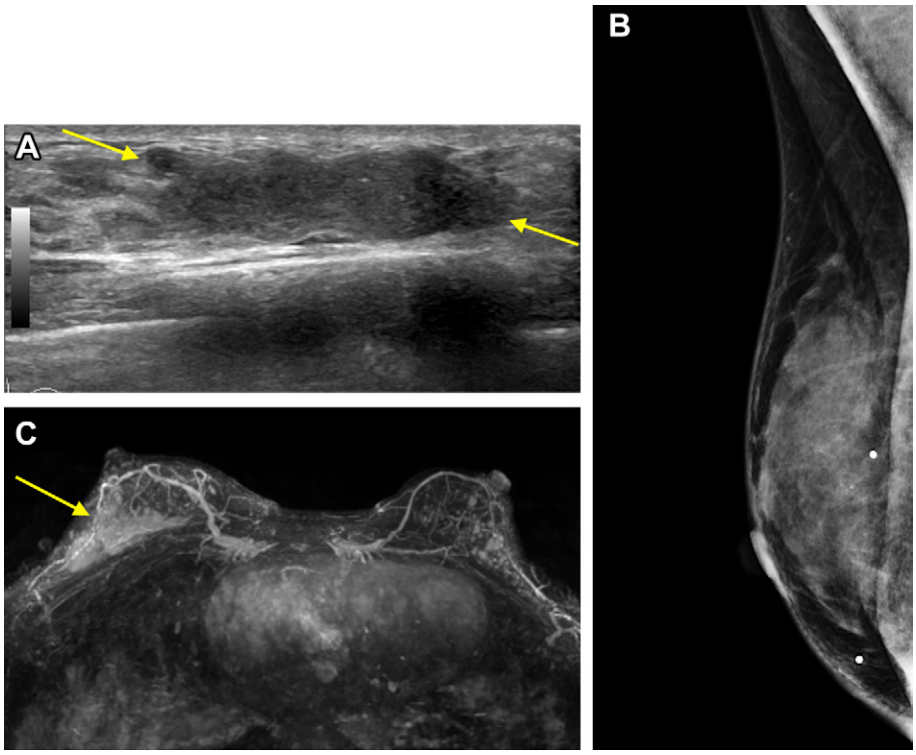


Figure 2. Breast mass in a 43-year-old woman who presented for diagnostic evaluation of a palpable finding. Palpable findings or patients who present with clinical concerns should not be coded as category 3. **(A)** US image shows an irregular mass (between arrows) that was assessed as focal fibrous tissue. **(B)** Mediolateral oblique mammogram shows that the area of clinical concern is not mammographically evident above the extremely dense breast tissue. The patient was recommended to return for a short-interval 6-month follow-up but was not seen again until 2 years later. **(C)** Maximum intensity projection (MIP) breast MR image at the time of follow-up shows skin ulceration, an increase in the size of the palpable mass, extensive non-mass enhancement (NME) (arrow), and liver metastasis. The patient is undergoing maintenance chemotherapy but is not considered curable.

US of masses and asymmetries, may downgrade the finding as benign or prompt a biopsy recommendation if suspicious features are identified. The radiologist should never use category 3 when deciding between benign (category 2) or suspicious (category 4). New or changing findings that are not characteristically benign should be considered suspicious, warranting histopathologic confirmation via biopsy. Findings with any suspicious feature should not be classified as category 3. Palpable findings or those arising from clinical concerns are unsuitable for category 3 assessment (Fig 2).

Exercise caution when assessing findings as category 3 in high-risk patients, particularly those with *BRCA1* or *BRCA2* breast cancer gene mutations (Figs 3, S2). In patients older than age 60, especially those with a personal history of breast cancer, biopsy should be considered instead of a category 3 assessment (8,9). A review of the National Mammography Database suggests an increased cancer yield with age, with a notable 4.6% yield in individuals aged 80–89 (9). In addition, the same review noted that findings in women with a prior comparison had higher cancer yield than in those without a prior comparison (9). Additionally, be wary of cystlike findings that enlarge, which potentially indicates triple-negative breast cancer (Fig 4).

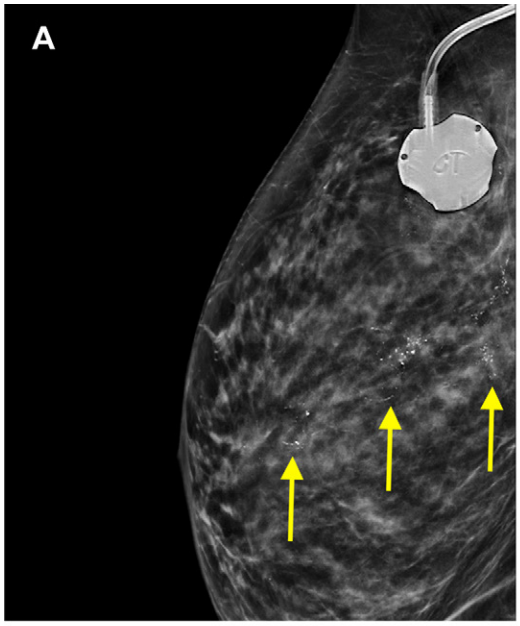
Exercise caution with pregnant or nursing patients due to the aggressive nature of pregnancy-associated breast cancers (10). Preoperative patients, for cancer treatment or cosmetic surgery, and transplant patients should proceed to biopsy rather than short-interval follow-up. Finally, male patients with clinical concerns and nonbenign findings at imaging should undergo a biopsy rather than receive a category 3 assessment. Men present at later stages of breast cancer with a larger tumor size and lymph node metastasis, have a lower volume of breast tissue leading to skin and chest wall invasion, and have lower overall survival rates compared with those in women with breast cancer (1). For all of these reasons and because men present at breast evaluation with clinical findings, the standard practice is not to assign category 3.

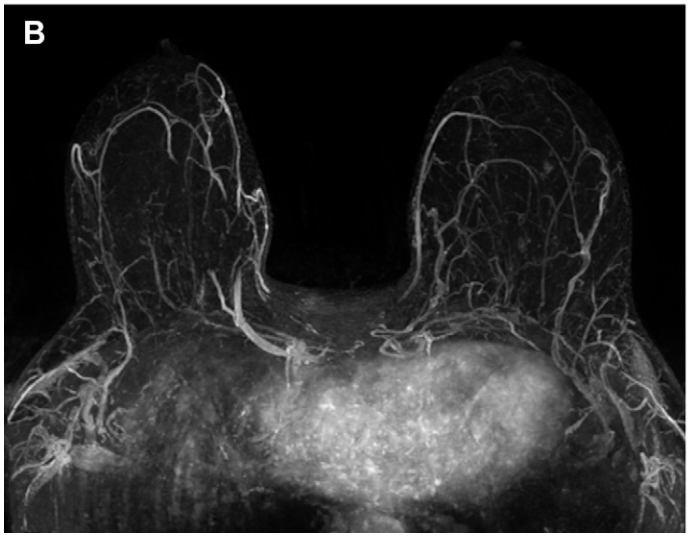
In some patients, a category 3 assessment induces significant anxiety. A biopsy is an alternative to short-interval follow-up (Fig S3). It is inappropriate to provide a category 4 assessment for a probably benign finding. The fifth edition of the BI-RADS manual (1) allows the decoupling of the category code from the recommendation, enabling the radiologist to recommend a biopsy for a probably benign mass based on the patient's preference or clinician's unease, with a short explanation that the biopsy is recommended based on the patient's preference. A shared decision-making approach ensures that the patient and clinician are comfortable with the management strategy.

Appropriate Use

Appropriate use of category 3 mandates a comprehensive diagnostic imaging evaluation and strict adherence to the American College of Radiology BI-RADS atlas criteria. The percentage of cases assessed as category 3 varies from 1.2% to 9.8% (4) but is as high as 14% (1). Conducting medical audits of category 3 findings and reviewing cases that progress to breast cancer diagnosis enhance proficiency category 3 utilization. The Table summarizes the validated and other uses of category 3.

Regardless of the imaging modality used, radiologists should consider certain patient-related factors when assigning category 3, such as the indication for the examination and the patient's risk for breast cancer, age, possible anxiety from uncertainty and required follow-up examinations, and likelihood of compliance with surveillance imaging.





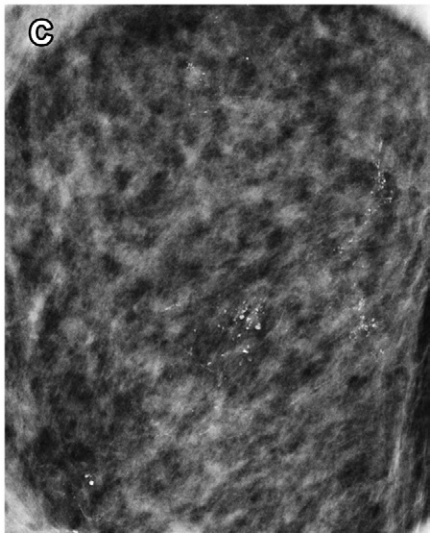


Figure 3. Ovarian cancer and *BRCA1* gene mutation in a 41-year-old woman who presented for baseline mammographic diagnostic evaluation. Caution should be used in assigning category 3 based on the patient's clinical history and risk factors. **(A)** Lateral mammogram shows segmental distribution of calcifications (arrows), and the interpreting radiologist coded the mammogram as category 3 and recommended MRI evaluation without obtaining magnification views. **(B, C)** MIP breast MR image **(B)** does not show an imaging correlate. However, the interpreting radiologist recommended a magnification view **(C)** and stereotactic biopsy of the calcifications. Pathologic findings confirmed high-grade ductal carcinoma in situ that was estrogen receptor positive, progesterone receptor positive, and human epidermal growth factor receptor-2 equivocal.

Mammography

Definition and Characteristics of Category 3 at Mammography

Validated category 3 findings on baseline mammograms include *(a)* a noncalcified circumscribed solid mass, *(b)* a solitary group of round calcifications, and *(c)* focal asymmetry without associated suspicious findings (1). Based on the radiologist's experience and comfort level, other mammographic findings can be coded as category 3.

Noncalcified Circumscribed Mass on Baseline Mammogram.—A mass is visible on two mammographic views and is considered circumscribed if at least 75% of the margin is visualized (Fig 5). To meet category 3 criteria, the mass must be nonpalpable, solid, and devoid of calcifications. Spot compression or magnification views, alongside US, should be part of the diagnostic evaluation. Margin obscurity due to overlapping fibroglandular tissue can be mitigated by digital breast tomosynthesis (DBT). Crucially, there should be no associated suspicious findings with the mass.

Round Calcifications on Baseline Mammogram.—This finding is characterized by a solitary group of round calcifications that comprise a lower limit of five or more calcifications which are clustered within 1 cm or a larger group that measures up to 2 cm in the longest dimension. Individual calcifications may vary in size and density from 1 mm to smaller, less than 0.5-mm, calcifications, termed *punctate*. Category 3 classification is contingent on obtaining magnification and a 90° lateral view (Fig 6). New or increasing calcifications and those with a linear or segmental distribution are considered suspicious and excluded from category 3.

Focal Asymmetry on Baseline Mammogram.—Focal asymmetry is a nonpalpable finding that shows a similar shape in two mammographic views while occupying less than a single quadrant of the breast (Fig 7). Numerous clinical studies have documented a 0.5%–1% likelihood of malignancy for a screening-detected focal asymmetry with no associated architectural distortion, microcalcifications, or a mass found after a complete diagnostic evaluation (3,12–15). A biopsy

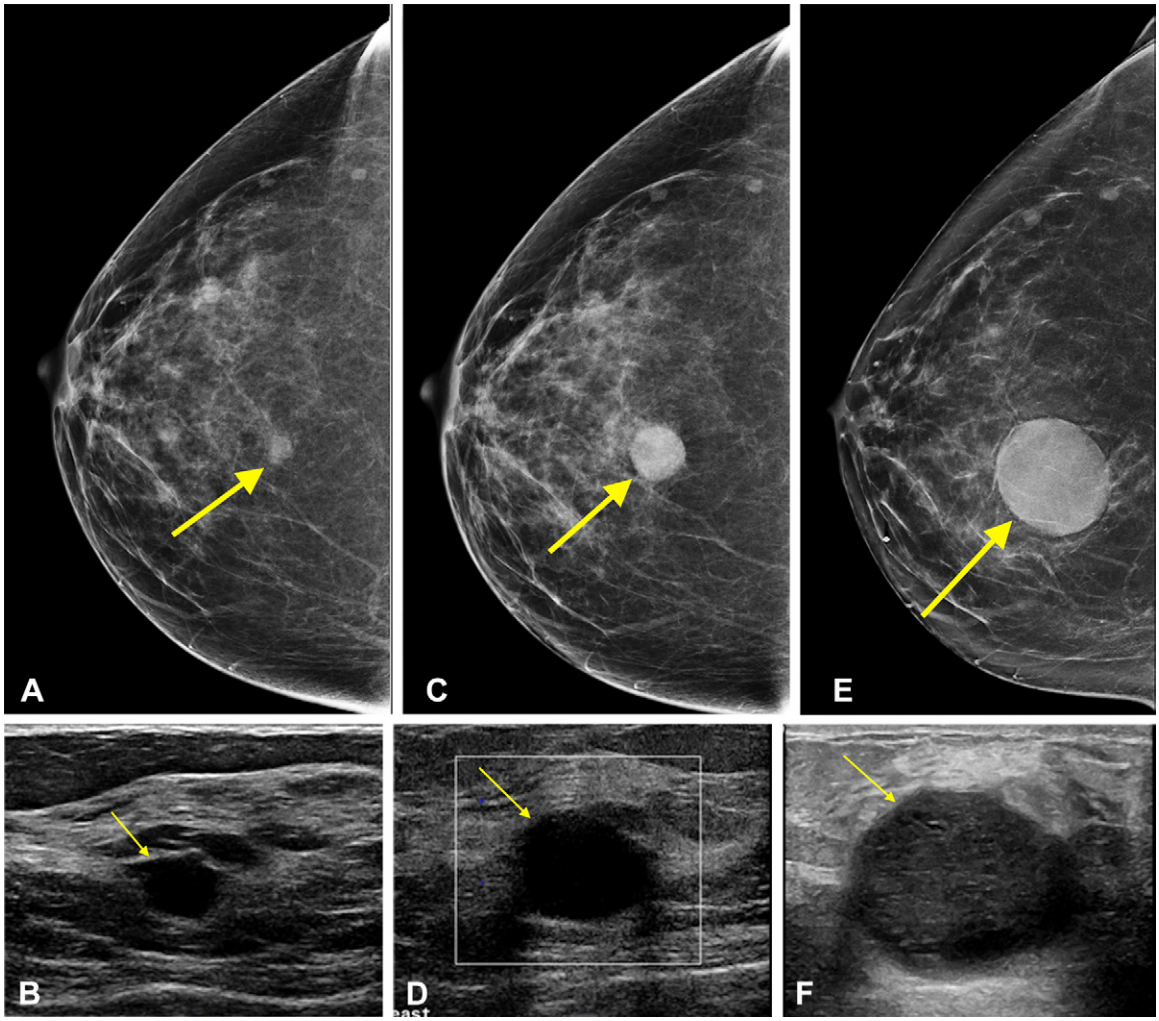


Figure 4. Breast mass in a 51-year-old woman. A change in mass size at follow-up should trigger a change in management. **(A, B)** Craniocaudal mammogram **(A)** shows a subcentimeter oval mass (arrow in **A**) with circumscribed margins, with a sonographic correlate (arrow in **B**) interpreted as a complicated cyst and coded as category 3. **(C, D)** Follow-up craniocaudal mammogram **(C)** and US image **(D)** show interval growth (arrow), at which time an additional 6-month follow-up was recommended. The patient presented for a second opinion before the subsequent follow-up was due. **(E, F)** At that time, a craniocaudal mammogram **(E)** and US image **(F)** were obtained and show interval development of a palpable finding and an increase in the mass size (arrow). A biopsy was performed, which confirmed triple-negative breast cancer.

Summary of Lesions Appropriate for BI-RADS Category 3 Based on Imaging Modality

Modality	Lesion Types	Other Indications
Mammography	Noncalcified circumscribed oval mass Solitary group of round calcifications Focal asymmetry	Developing vascular calcifications, fat necrosis, hematoma, lymph nodes
US	Solid oval mass with circumscribed margins Isolated complicated cyst Cluster microcysts that are too small or deep	Fat necrosis, hematoma, architectural distortion after surgery, adenopathy after vaccination
MRI	NME Oval circumscribed mass with associated T2 hyperintensity Foci with T2 hyperintensity	Category 3 remains intuitive per BI-RADS fifth edition, and other lesions may be appropriate based on the radiologist's level of experience; this is expected to change in the next edition

Source.—Reference 22.
Note.—Based on the radiologist's experience, additional indications may be suitable for category 3 assessment and are included in this table. NME = non-mass enhancement.

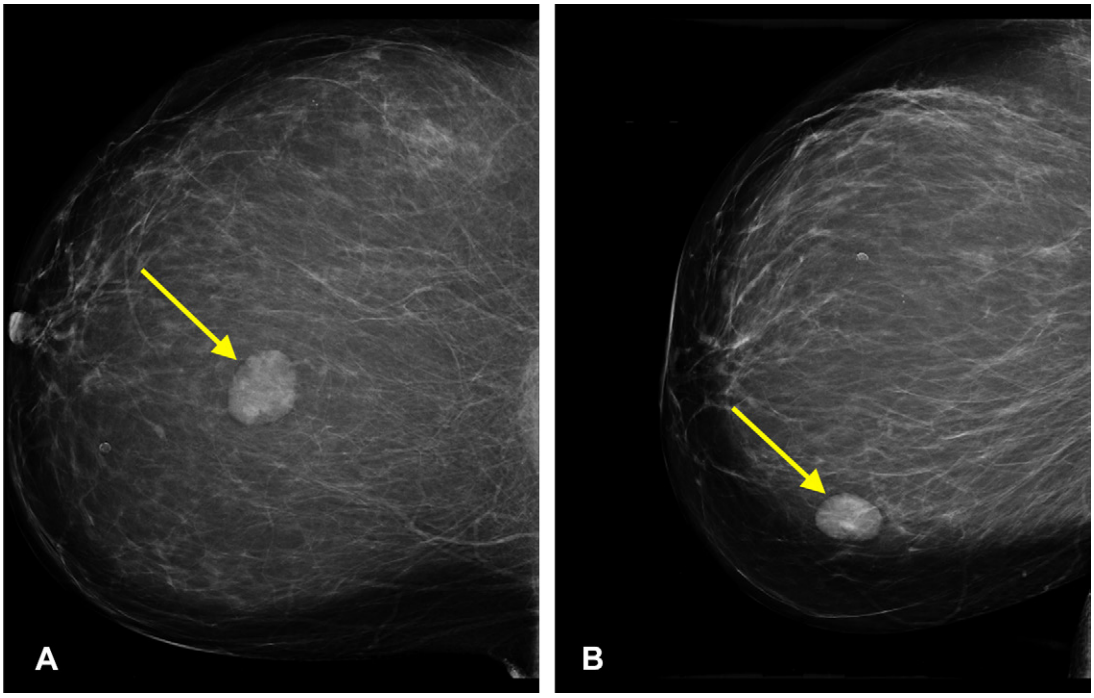


Figure 5. An oval circumscribed nonpalpable mass at baseline mammography is appropriate for category 3. Mediolateral oblique **(A)** and craniocaudal **(B)** mammograms in a 60-year-old woman who presented for screening show a nonpalpable oval circumscribed mass (arrow). There were no suspicious findings, and the appearance of a benign mass was seen at US evaluation (not shown).

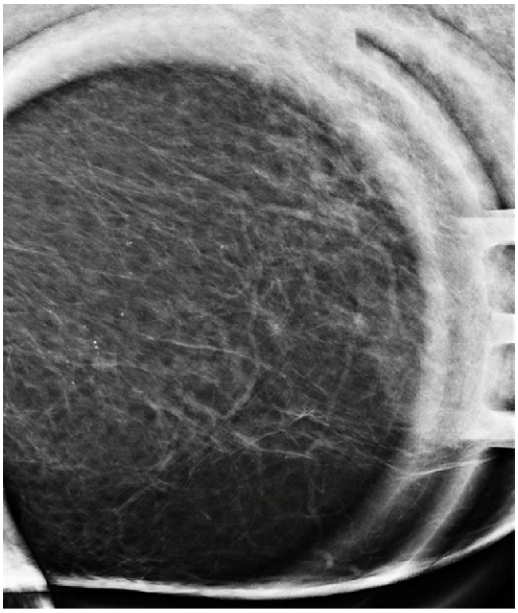


Figure 6. A solitary group of round calcifications at baseline mammographic screening is appropriate for category 3 after complete diagnostic evaluation, including a full lateral view and magnification views in orthogonal projections.

may be indicated if a potential correlate is seen on US images.

Diagnostic Challenges

Single-View Asymmetry.—Single-view asymmetry often results from a summation artifact. To resolve the findings, additional images should be obtained, such as images with rolled and oblique views. DBT can also be beneficial in the evaluation.

Technical Differences or Inadequate Assessment.—Establishing the stability between examinations may be challenging due to technical differences, such as transitioning from full-field digital mammography to DBT (16). In such cases, it may be reasonable to designate a category 3 assessment.

Inadequate Assessment.—Failure to evaluate calcifications with magnification views or the lack of spot compression images for masses or focal asymmetries during prior examinations can compromise assessment accuracy (17). Follow-up imaging should encompass similar views for effective comparison with the identified abnormality.

Other Indications for Category 3

According to the BI-RADS fifth edition, radiologists may code additional findings as category 3 based on their experience level and comfort. In a review published in *RadioGraphics* by Michaels et al (18), the authors suggest that developing vascular calcifications, fat necrosis (Fig 8), hematoma, and intramammary and low-lying axillary nodes could potentially be coded as category 3, although not explicitly validated in the BI-RADS manual. In cases of hematoma, a short-interval follow-up of 4–6 weeks is typically adequate to assess for downgrading to a benign finding.

Impact of DBT in Category 3 Assessment

DBT has demonstrated an overall enhancement in breast screening metrics, with relative reductions ranging from 14% to 30% fewer category 3 assessments compared with those of digital mammography alone (19–21). A notable portion of this improvement stems from decreased callbacks for asymmetries, with reductions that range from 2.4 to 10.3 per 1000 women (19–21). This reduction potentially carries significant implications for alleviating patient anxiety and minimizing the expense associated with follow-up examinations.

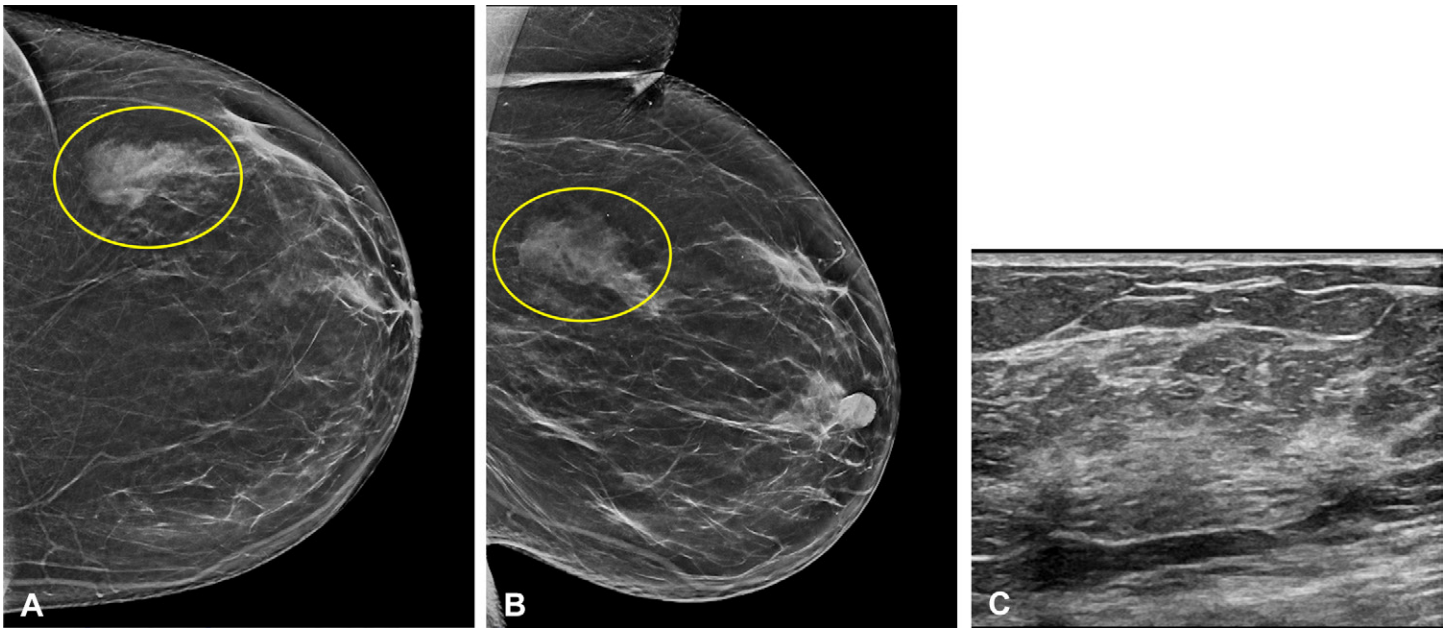


Figure 7. Focal asymmetry is appropriate for category 3. Baseline craniocaudal **(A)** and mediolateral oblique **(B)** mammograms in a 44-year-old woman show focal asymmetry in the upper outer quadrant (circle). The finding persisted on spot compression views (not shown). US image **(C)** shows no mass or shadowing. Focal asymmetry is a validated finding appropriate for category 3 after a complete diagnostic evaluation.

Raghu et al (19) observed a decrease in category 3 assessments from 33.3% to 16.4%, while category 4 or 5 assessments remained unchanged.

Ultrasonography

Solid Masses with Circumscribed Margins

Per the BI-RADS US atlas, a solid oval mass with parallel orientation and circumscribed margins can be classified as category 3, representing a benign mass that is often a fibroadenoma (1) (Fig 9). There is sufficient evidence in the literature to support this classification, with the likelihood of malignancy less than or equal to 2% (22) and with the stage distribution of the few cancers found at follow-up not worse than that in patients undergoing immediate biopsy (23).

In a study by Chae et al (24), the overall malignancy rate of category 3 masses identified at screening US was 0.7%. However, the malignancy rate was 0.4% in patients with a negative mammogram and 2.2% in patients with an abnormal mammogram. Caution must be exercised in patients with an abnormal mammogram and in older women. A retrospective review of category 3 masses found that while the overall malignancy rate of category 3 masses was 1.6%, when stratified by age, the malignancy rate exceeds 2% in patients 60 years or older, 2.1% for women aged 60–69 years, 3.4% for women aged 70–79 years, and 5.1% for women aged 80–89 years (8,23). Greater caution is warranted for masses in women over 60 or with new findings from mammography (23) (Fig 10).

In patients with a concurrent cancer diagnosis (23), Lee et al (25) demonstrated a malignancy rate of 9.6% and a high-risk benign rate of 18.3% in probably benign masses that are synchronous with breast cancer. A biopsy or surgical excision of such masses should be considered, particularly in patients with the following risk factors: large mass size (T3, >5 cm), high progesterone receptor expression, and human epidermal growth factor receptor-2 positivity.

Similar to assessment at mammography, bilateral circumscribed masses with at least one mass in each breast can be classified as category 2 (12,26). At real-time sonographic evaluation, attention should be paid to ensure that margins are completely circumscribed. Any suspicious features warrant classification as category 4.

The category 3 assessment can be applied to patients with palpable benign-appearing masses (27–29). In one study, 97 women aged 34 years or younger demonstrated 151 category 3 findings, most of which were palpable (30). Twenty-five (16%) patients had up-front benign biopsy or surgery. Nine cases were classified as category 4A during the 6-month follow-up due to a more than 20% diameter increase, five fibroadenomas, and four phyllodes tumors. No malignancy was identified, and it was suggested that findings with stability in young women without suspicious imaging features at the 6-month follow-up should not require additional follow-up (30). Harvey et al (29) showed that the prevalence of breast cancer among palpable findings with benign characteristics was low at 0.3% (one of 375), with 81% found to represent fibroadenomas (304 of 375). Similarly, Park et al (27) demonstrated a high negative predictive value of 99.4% among benign-appearing masses, with only two malignancies identified among 310 findings (0.6%).

Isolated Complicated Cyst

The BI-RADS atlas defines complicated cysts as cysts with uniform low-level echoes or debris (1). The echoes may change location as the patient moves without a solid component (1) (Movie 1). Power Doppler US can help detect and demonstrate the movement of the debris (22) (Movie 2). Complicated cysts are often asymptomatic. Symptoms can

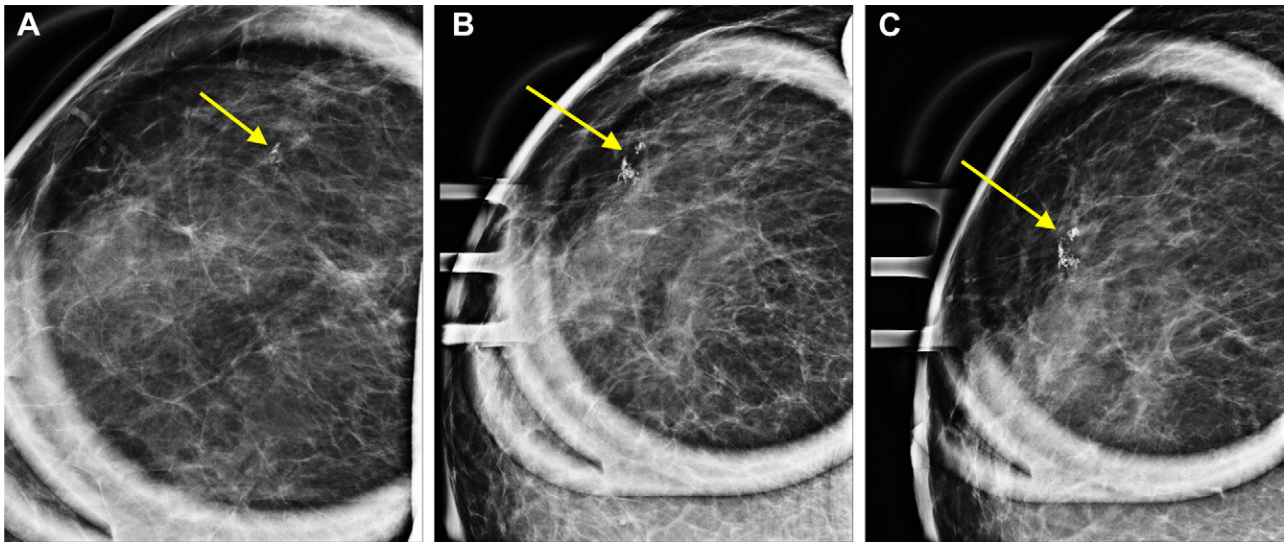


Figure 8. Developing calcifications in a 79-year-old woman who presented for routine follow-up after undergoing right lumpectomy. Radiologists may categorize additional findings, such as suspected fat necrosis, as category 3 based on their experience level and comfort. **(A)** Magnification mammogram shows new calcifications near the lumpectomy site (arrow). **(B, C)** Magnification mammogram at the 6-month follow-up **(B)** shows that the calcifications had progressed to a rim distribution (arrow in **B**), and at 12-month follow-up **(C)** the calcifications were characteristic of fat necrosis (arrow in **C**).

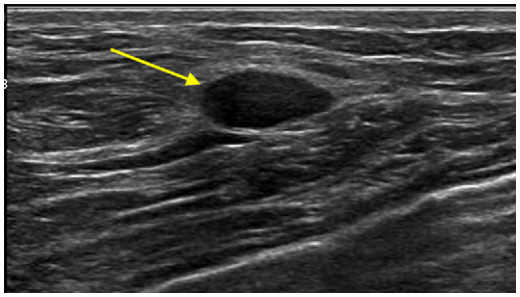


Figure 9. A solid oval mass with parallel orientation and circumscribed margins can be classified as category 3 and most often represents a benign mass. Gray-scale US image shows a hypoechoic oval mass (arrow) with parallel orientation and circumscribed margins characteristic of a fibroadenoma. There are no suspicious findings. A short-interval follow-up with US was recommended.

be attributed to infection, hematoma, fat necrosis, or galactoceles (31). The American College of Radiology Imaging Network (ACRIN) 6666 study identified complicated cysts in 14.1% of participants (376 of 2662) (22). Although a minority of these findings are solid masses, with the minority proving to be malignant (1), the overall likelihood of malignancy remains low, ranging from 0% to 0.5% (22,32,33). Therefore, a category 3 classification remains appropriate.

Mobile debris or fluid-debris levels identified within a complicated cyst should be classified as category 2 if the patient is asymptomatic (23). Complicated cysts in the setting of multiple bilateral cysts should also be coded as category 2 (22,23,34). Kim et al (35) implemented downgrading criteria to reduce the number of false-positive results in screening US. Among 3171 women, complicated cysts and oval circumscribed masses that measure 5 mm or less were classified as category 2, with no difference in cancer detection yield or interval cancers. Similarly, Hooley et al (34) showed a decrease in category 3 classification from 20% to 10% when nonsimple cysts (complicated cysts and clustered microcysts) and nonsimple cysts measuring less than 5 mm were reclassified as category 2 in the setting of multiple cysts. On the other hand, an isolated complicated cyst that is uncertain in nature should be classified as category 3, especially in cases of deep findings or when the debris is uniform and has low echogenicity, making it hard to differentiate it from a solid mass (22,23) (Fig 11).

Clustered Microcysts

Clustered microcysts are defined by the BI-RADS atlas as clusters of anechoic masses, each 2–3 mm in size and separated by a very thin separation that measures up to 0.5 mm (36) (Fig 12). Clustered microcysts reflect the presence of cystic dilatation in the individual acini of the terminal duct lobular unit or a part of it (37). They are characterized by their thin walls and lack of a solid component, with margins that can be microlobulated but not indistinct. The microcyst can contain varying degrees of fluid-debris levels or low-level internal echoes, which can be challenging to differentiate from a solid component (1). The BI-RADS atlas recommends that oval or microlobulated masses consisting of simple clustered microcysts be coded as benign and category 2. However, category 3 is appropriate when smaller or deeper clustered microcysts are evaluated, for which there is decreased diagnostic certainty (1).

Clustered microcysts are common among postmenopausal women and at screening US examinations, with an incidence ranging from 1.5% to 5.6% (38,39). In 76% of cases, the mammographic correlation is often an oval mass (36). About 50% of clustered microcysts maintain their size after one year, 20% vanish, 20% get smaller, and 10% grow larger after 2 years (39). The likelihood of malignancy is low, ranging from 0% to 2.6% (36,40). Several studies have consistently reported a 0% risk of

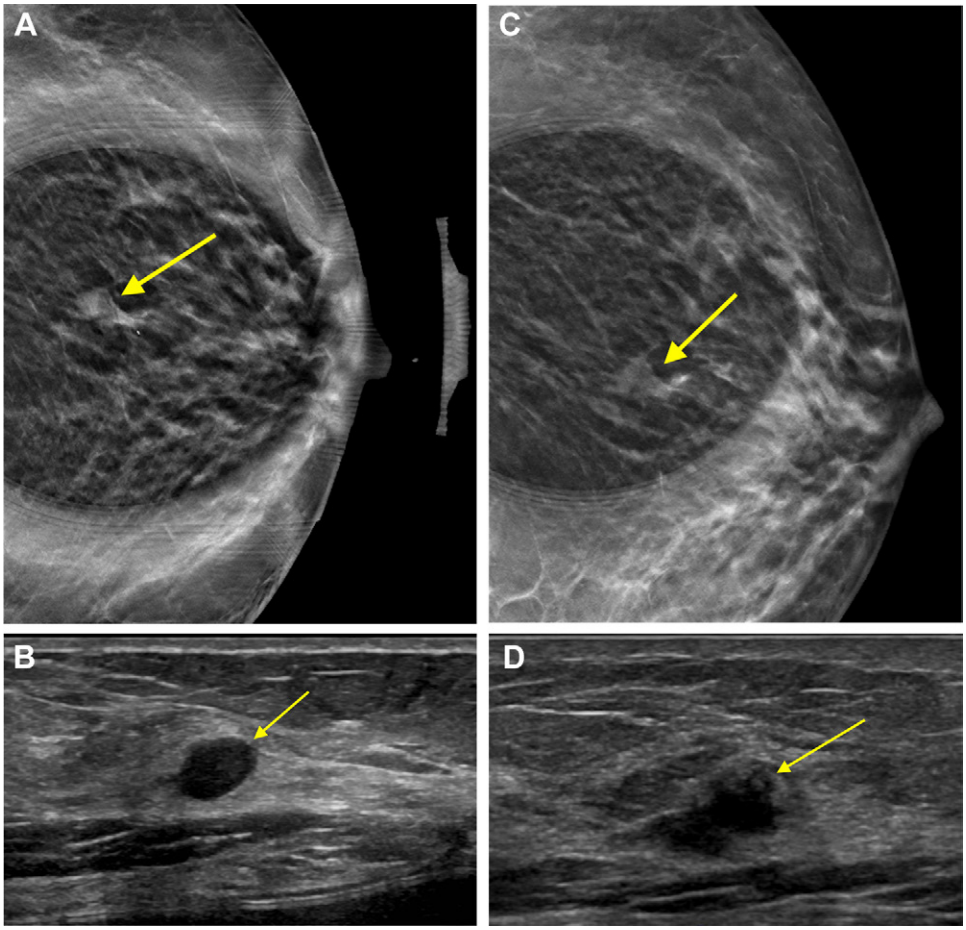


Figure 10. Oval breast mass in a 74-year-old woman with a history of contralateral breast cancer. Not all oval or round masses with circumscribed margins are "probably benign." **(A)** Craniocaudal DBT image shows an oval circumscribed mass (arrow). **(B)** US image shows a corresponding oval hypoechoic mass with circumscribed margins and uniform low-level echoes (arrow), which were thought to represent a complicated cyst. Follow-up mammography and US performed 8 months later demonstrated an interval change in morphology and increase in size. **(C)** Craniocaudal DBT image shows an irregular mass (arrow) with indistinct margins. **(D)** US image shows an irregular hypoechoic mass (arrow) with angular margins. Pathologic findings confirmed triple-negative invasive ductal carcinoma.

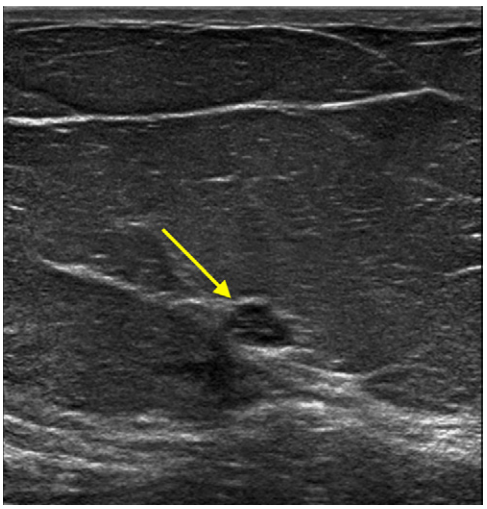


Figure 11. Isolated asymptomatic complicated cysts are unlikely to be malignant. Screening US image in a 64-year-old woman with dense breasts show a deeply located isolated complicated cyst (arrow). Given the cyst's deep location, a category 3 classification was given. Follow-up US demonstrated stability.

malignancy for clustered microcysts (31–33,36,38,39). Therefore, for a finding that exhibits the typical characteristics of clustered microcysts, a category 2 classification is appropriate.

A category 3 classification is appropriate in findings located deep within the breast (>3 cm from the skin) or those seen in a postmenopausal woman. Nevertheless, the radiologist must thoroughly examine the cluster of microcysts to exclude any characteristic that would result in a category 4 assessment (Fig 13), such as the presence of a solid component, indistinct margins, fast growth in a postmenopausal woman, or the presence of vascularity or thick septa (≥0.5 cm) (36,38,40). Suspicious calcifications or architectural distortion at mammography further increase the suspicion of malignancy (41).

Follow-up Imaging of US Findings

Similar to mammographic findings, short-interval follow-up in 6 months is recommended for category 3 US findings (1). If the finding is stable, subsequent follow-up examinations are performed at 12 and 24 months with the option of extending the surveillance period to 36 months (1,23). The finding can then be downgraded to a category 2. The finding can be downgraded to category 2 sooner if there is an interval decrease in size or to category 1 if the finding resolves (23). If, at follow-up, any suspicious change in morphologic features or an interval increase in size by more than 20% is observed, the finding should be upgraded to category 4, prompting a biopsy (42). Figure 14 shows a case of a growing mass that was eventually biopsy-proven fibroadenoma.

Recent studies have demonstrated that the risk of malignancy remains low in probably benign masses even if they

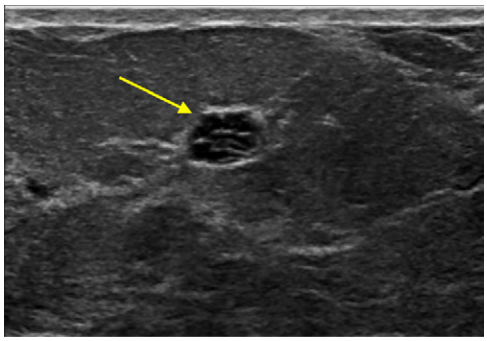


Figure 12. Screening breast US image shows benign clustered microcysts (arrow) in a 57-year-old woman. However, when clustered microcysts are too small or deep in the breast, category 3 is appropriate.

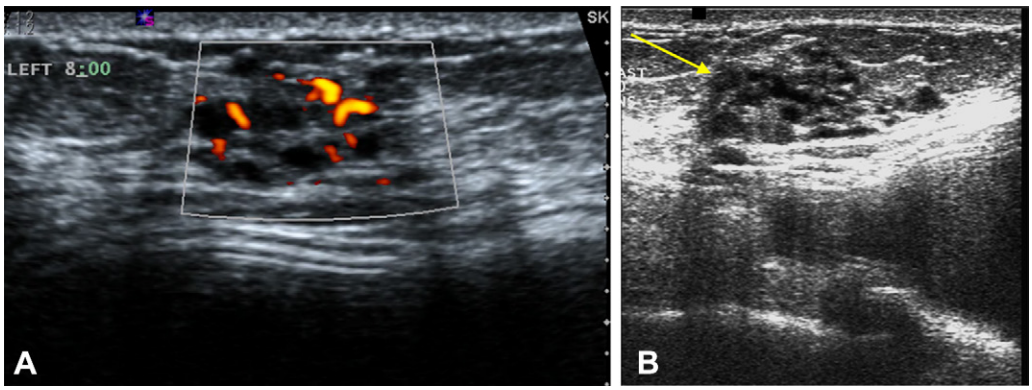


Figure 13. Intraductal carcinoma in a 38-year-old woman with dense breast tissue, a breast implant, and a family history of breast cancer was noted to have what initially was thought to be a clustered microcyst. Increased vascularity was identified, and the finding was misclassified as clustered microcysts. Any solid component, indistinct margin, or increase in size will make a clustered microcyst suspicious. **(A)** US image at 6-month follow-up shows interval growth. **(B)** Findings at US-guided core-needle biopsy confirmed intraductal carcinoma in situ (arrow).

have shown interval increase in size. Ha et al (43) showed that the malignancy rate of increasing category 3 findings was 4.9% and was higher in findings with a more than 50% increase in the anterior-posterior dimension than in those with a less than 50% increase. In 20.3% of the findings, morphologic changes were observed in addition to the size increase. The malignancy rate of findings with morphologic changes and size increase was 16.8%. Conversely, masses that demonstrate an increase in size without a morphologic change or suspicious mammographic or sonographic findings had a malignancy rate of 1.9% (43). Moon et al (44) showed similar findings with a higher rate of malignancy (38.5%) for category 3 findings associated with developing suspicious features and a lower rate (4%) for increasing category 3 findings without suspicious features.

Examples of Expert Opinions on US BI-RADS Category 3 Findings

In addition to the validated findings, the BI-RADS atlas recommends using category 3 based on expert opinion in several additional situations. These include sonographic findings of hematoma, fat necrosis, and architectural distortion associated with a postsurgical scar (1). Lymphadenopathy attributed to COVID-19 vaccination or other vaccines is another distinctive scenario for which a category 3 assessment may be appropriate, as indicated by recent Society of Breast Imaging guidelines (45).

Fat Necrosis and Hematoma.—US findings of fat necrosis include a hyperechoic mass with central hypoechoic or anechoic components and surrounding edema (Fig 15). According to the BI-RADS atlas, while these US findings suggest fat necrosis, they are not diagnostic due to limited data that support the likelihood of malignancy in these cases. Therefore, the use of the category 3 assessment should rely on expert opinion (1). A history of surgery, trauma, fat grafting, or anticoagulant therapy may aid in diagnosis, along with correlation with mammographic findings that display characteristically benign features of fat necrosis, such as oil cysts and rim calcifications. A shorter-interval follow-up of 4–12 weeks may be suggested, as some of these findings are expected to decrease in size or resolve with time (17,23).

Architectural Distortion.—Architectural distortion is classified as category 3 only if it is thought to be caused by a postsurgical scar. Correlation with the patient's history and mammogram is required (1).

Axillary Adenopathy Related to COVID-19 Vaccine.—Axillary lymphadenopathy caused by immunization was a rare finding in breast imaging before the widespread COVID-19 vaccination campaign (Fig 16). Based on the fifth edition of BI-RADS, isolated unilateral axillary adenopathy should be given a category 4 assessment if there is no known infection or inflammation.

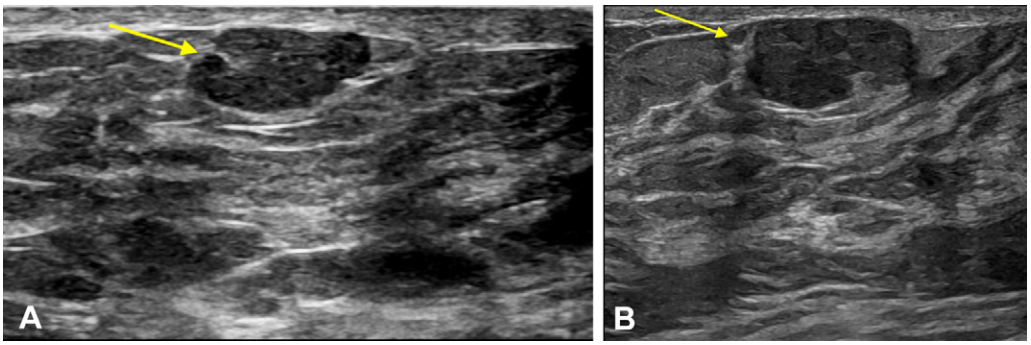


Figure 14. Breast mass in a 21-year-old woman. **(A)** US image shows an oval mass (arrow) with circumscribed margins that measures 1.1 cm at baseline. **(B)** US image at follow-up 6 months later shows that the mass has nearly doubled to 2.1 cm (arrow). A biopsy confirmed fibroadenoma. If the mass size increases by more than 20% at follow-up, category 3 is upgraded to 4, and biopsy is recommended.

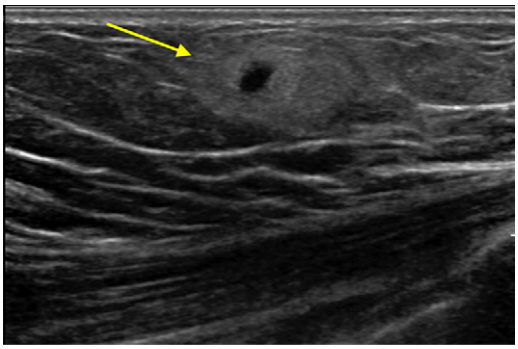


Figure 15. Predominantly hyperechoic mass in a 58-year-old woman with a history of recent trauma who presented with a palpable lump in the upper inner quadrant of the breast. US image shows a hyperechoic mass with a central hypoechoic component (arrow), which suggests fat necrosis or hematoma. The mass was outside the field of view of mammography. In this case, with a clinical history of trauma, the finding is compatible with a hematoma, and very short-interval follow-up in 4–6 weeks will show either a decrease or resolution of the finding.

Unilateral axillary adenopathy might indicate occult breast carcinoma or, less commonly, lymphoma, metastatic melanoma, ovarian cancer, or other metastatic cancer. Therefore, a thorough evaluation of the ipsilateral breast images is imperative. After immunization (COVID-19, influenza, shingles, etc), unilateral axillary lymphadenopathy poses a diagnostic challenge due to frequent lymphadenopathy in breast imaging studies. Of 1217 patients who received the COVID-19 vaccination and underwent breast imaging, 537 (44%) had lymphadenopathy on at least one imaging examination (46). Lymphadenopathy onset was observed within 24 hours after the initial dose and up to 71 days after the second dose.

The Society of Breast Imaging (45) and the European Society of Breast Imaging (47) introduced guidelines based on a risk-based approach. For average-risk patients with unilateral axillary adenopathy detected on screening mammograms and no other abnormal mammographic findings, a classification of category 2 is appropriate. If short-interval imaging follow-up is advised, the lymphadenopathy often persists for over 6 weeks. Hence, US should be performed after 12 weeks to allow the lymphadenopathy to decrease or normalize (48). However, the authors (48) note that lymphadenopathy persisted in over half of the patients for up to 16 weeks. Wolfson et al (46) documented persistent axillary adenopathy for up to 43 weeks after vaccination. Patients who have a personal history of breast cancer and a low risk of metastasis are suitable candidates for a cautious management strategy that does not require mandatory follow-up imaging. For patients with a higher risk of metastasis, short-term follow-up US is recommended after 12 weeks, and those with the highest risk of metastasis should undergo a biopsy (47).

Dynamic Contrast-enhanced Breast MRI

Contrast-enhanced breast MRI utilization has increased over the past 2 decades due to its high sensitivity (94%–100%) for breast cancer detection (49). Unlike mammography and US, MRI lacks standardized criteria for category 3 probably benign assessments. The BI-RADS fifth edition does not define specific MRI features of category 3 breast findings (1). It states that the "use of category 3 assessment at MRI remains intuitive for radiologists who lack extensive personal experience with any given specific type of lesion." The next edition of BI-RADS is expected to use the emerging evidence to validate MRI findings appropriate for the category 3 assessment.

Recent studies have aimed to address appropriate use and follow-up intervals for category 3 MRI assessments. Reported cancer rates for category 3 findings vary widely from 0.6% to 10%, with half of the studies reporting cancer rates that exceed the 2% threshold for probably benign findings (51). Since the publication of the BI-RADS fifth edition, malignancy rates for the probably benign findings at MRI have narrowed to between 0.8% and 6.0%, yet consistency with a threshold of 2% or less remains elusive. Prior studies have shown considerable variation in MRI category 3 use, which has been applied to 6.6%–25% of examinations (51). This wide variability in reported cancer yields in the literature highlights the importance of establishing evidence-based criteria for MRI category 3 findings (50).

Considerations When Assigning Category 3

Radiologists should consider the indication for MRI, high-risk screening, or new diagnosis of breast cancer when assigning

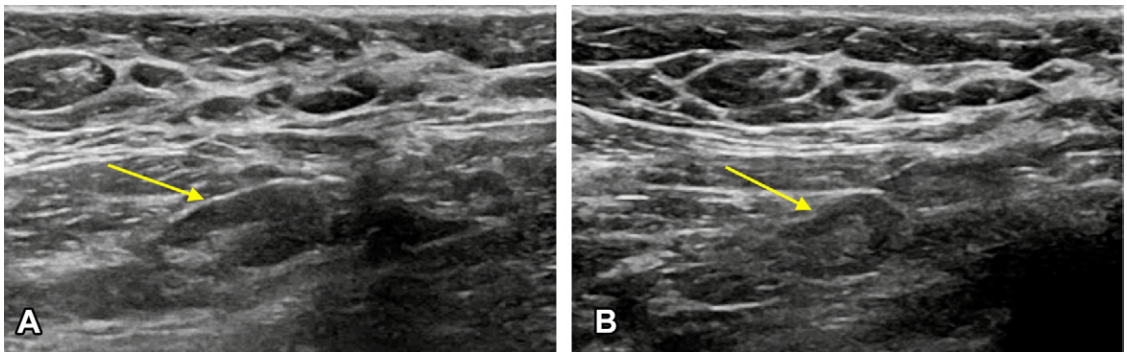


Figure 16. Axillary lymphadenopathy in a patient with a history of recent COVID-19 vaccination in the ipsilateral arm. **(A)** Gray-scale US image shows a mildly prominent axillary lymph node with mild diffuse concentric cortical thickening (arrow) and maintained fatty hilum. **(B)** Follow-up US image shows the resolution of these reactive changes, with interval cortex thinning and a normalized appearance (arrow) of the previously inflamed lymph node. The Society of Breast Imaging and the European Society of Breast Imaging have established risk-based guidelines for the follow-up of unilateral axillary adenopathy.

category 3. For example, interpreting radiologists may have a lower threshold for suspicious findings when evaluating the extent of known cancer or in the setting of a known pathogenic gene mutation. Breast MRI findings should be interpreted alongside mammography and US findings. For example, if a patient's prior mammograms or US show a correlation for a probably benign mass detected on a baseline breast MR image and confirm its long-term stability, an unnecessary 6-month follow-up MRI can be avoided (52).

BI-RADS Category 3 Findings at MRI

Non-mass Enhancement with Benign Features.—Non-mass enhancement (NME) with benign features is defined as an enhancement distinct from the patient's background parenchymal enhancement (BPE) that is not a focus or a mass (53). BPE is the normal enhancement of fibroglandular tissue after contrast agent administration, as shown in Figure 17. Some studies have suggested that assigning category 3 to an area of NME may be appropriate if the distribution is focal or regional, the internal enhancement pattern is homogeneous, and the kinetics are less suspicious (persistent enhancement) (54). Current data, however, are insufficient to support the use of category 3 for NME, with most studies on category 3 NME showing malignancy rates higher than the expected 2% threshold (54,55).

NMEs with heterogeneous or clumped internal enhancement and washout kinetics are more likely malignant and should never be assigned category 3. For NMEs with benign features, any interval changes in size or morphologic features and changes in kinetics during follow-up should raise suspicion for malignancy and warrant a biopsy (54).

The fifth edition of the BI-RADS atlas suggests that a category 3 assessment may be suitable when tissue enhancement is presumed to be linked to the patient's hormonal status and the timing of the MRI examination (Fig 18). In these cases, a very short 2–3-month follow-up that is timed between days 7 and 14 of the menstrual cycle would be appropriate. However, recent literature challenges this approach, proposing that any tissue enhancement not definitively identified as BPE may be better evaluated as NME (55). In such cases, distribution, internal enhancement, and kinetics determine the appropriate BI-RADS category assessment (55).

Mass with Benign Features.—Extrapolated data from mammography and US indicate that any solid enhancing mass that is new or increasing in size warrants a biopsy and should not be assigned category 3 (55). Figure 19 shows an example of a benign mass. An established use of the category 3 assessment at breast MRI is for an incidental oval, T2-hyperintense, circumscribed, and progressively enhancing mass with nonenhancing internal septa on a baseline MR image, which suggests a fibroadenoma (52).

Data from mammography and US findings should be extrapolated to determine if any solid enhancing mass that is new or increasing in size warrants a biopsy and should not be assigned category 3 (53,56). In addition, the use of category 3 is best avoided at MRI performed for the extent of the disease, as patients with known breast cancer have a higher incidence of additional sites of cancer (55,57). There is also a reported higher malignancy rate for round masses than for oval masses (58,59), suggesting caution in using category 3 for round masses.

It is important to note that although homogeneous internal enhancement and T2-hyperintense signal suggest benignity, there are insufficient data on reported outcomes for category 3 masses based on these features. Thus, internal enhancement and T2-hyperintense signal should not be the sole deciding factors for a category 3 assessment of masses (55). The malignant differential considerations for T2-hyperintense oval or round circumscribed masses include triple-negative breast cancer (60) or papillary, mucinous, and medullary cancer, which include the so-called "terrible peanut M&M" findings. Other findings associated with a T2-hyperintense signal include phyllodes tumors and papilloma. Figure 20 shows a T2-hyperintense round invasive mucinous carcinoma. Figure 21 shows a case-assigned category 3 based on T2 hyperintensity and an oval shape, but at follow-up examination, the interpreting radiologist was uncomfortable and recommended a biopsy.

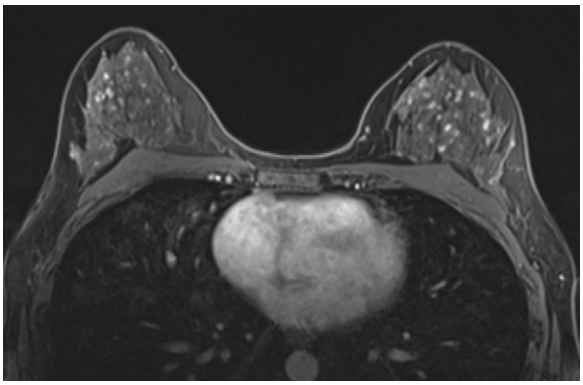


Figure 17. Normal BPE in a 48-year-old woman who underwent high-risk breast screening. Axial postcontrast fat-saturated T1-weighted screening MR image shows moderate BPE. BPE is the normal enhancement of the fibroglandular tissue after contrast agent administration and may vary depending on the menstrual cycle.

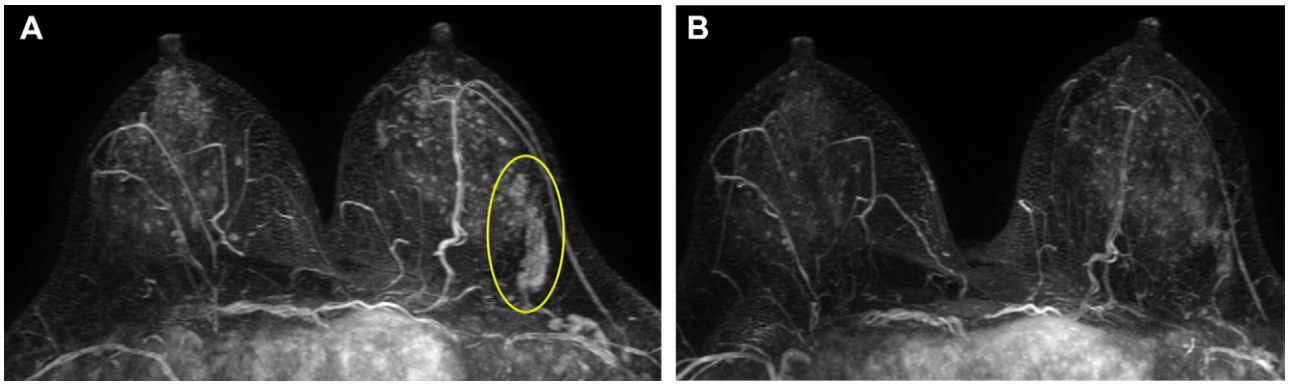


Figure 18. NME is a finding that is distinct from BPE. Focal NME occupies less than a quadrant of the breast. **(A)** MIP MR image shows that a focal area of NME is asymmetric to the contralateral side and above the BPE (oval). The finding was coded as category 3. **(B)** MIP MR image at follow-up shows that the finding had resolved at a different part of the menstrual cycle.

Foci.—The fifth edition BI-RADS atlas lexicon defines a *focus* as a punctate dot of enhancement that does not represent a space-occupying finding or mass and is unique from the surrounding BPE (53). The sixth edition of BI-RADS is expected to eliminate *focus* or *foci* from the lexicon, and previous findings described as foci will likely be considered a small mass or focal NME.

Despite their small size, foci reportedly have a malignancy rate as high as 23% (61). Foci that are T2 hypointense and are new or increased in size have the highest positive predictive value for malignancy (20%–30%) and warrant biopsy rather than short-term follow-up (61) (Fig 22). However, assigning a category 3 assessment to any focus that is T2 hypointense but seen on a baseline high-risk screening breast MRI is likely appropriate (55). Any focus that is not distinct from the BPE or is T2 hyperintense at baseline high-risk MRI can appropriately be given a category 2 assessment (62). Kinetic analysis is not specific to malignancy and should not be used solely to guide the management of an enhancing focus (55). The algorithm used to determine whether or not to follow a unique focus of enhancement is adapted from the Society of Breast MRI (63) and is shown in Figure 23.

Follow-up Imaging.—Optimal follow-up intervals for category 3 MRI findings require further investigation. In the interim, short-term follow-up MRI at 6, 12, and 24 months remains a robust interval for the detection of suspicious findings (55). MRI protocols are considerably more costly and may pose challenges for patients, including the need for intravenous line placement, prone positioning, long examination durations, and potential claustrophobia. In cases where MRI masses are likely to be visualized at US, MRI-directed US should be conducted. If a sonographic correlate is identified and the finding continues to meet category 3 assessment criteria for US, subsequent follow-up should be performed with US (55).

It is important to note that MRI should not replace short-term interval follow-up for category 3 findings detected at mammography or US, nor should it be relied on to rule out malignancy in category 3 calcifications (64–66).

Emerging Research

Utilizing Risk Assessments

Risk stratification may assist in decreasing the number of category 3 assignments. Benndorf et al (67) analyzed 4941 patients with category 3 findings, accounting for age, personal and family history of breast cancer, and breast density. Personal history of breast cancer and older age were found to be significant independent risk factors for malignancy, and patients with these factors had a more than 2% risk, suggesting that a category 4 assessment and biopsy may be warranted in this population.

Elastography

US with elastography can decrease the number of findings coded as category 3. The guiding principle of the technique is

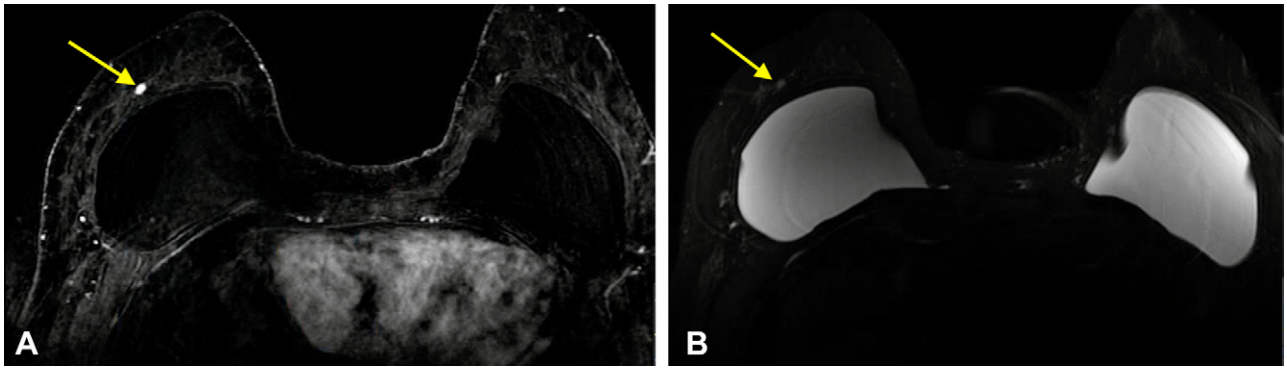


Figure 19. Breast mass in a female patient with a family history of breast cancer and breast implants. **(A)** Axial subtraction baseline T1-weighted breast MR image shows an enhancing oval circumscribed mass (arrow) adjacent to the implant. **(B)** Axial fat-saturated T2-weighted MR image shows that the mass is likely volume averaged but still demonstrates T2 signal hyperintensity (arrow). Based on recent literature, assigning category 3 to oval circumscribed masses with persistent kinetics is likely appropriate.

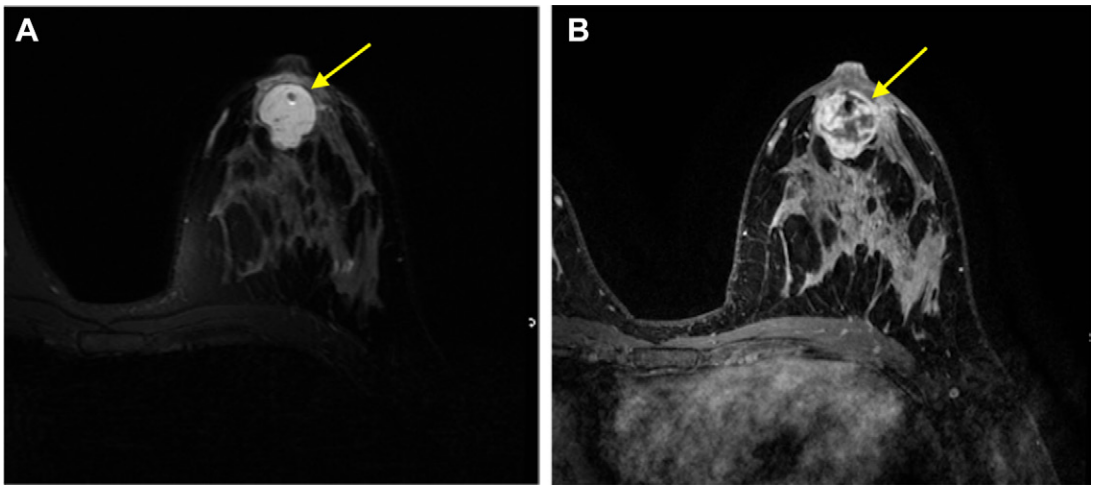


Figure 20. Breast mass in a 30-year-old woman with a previous history of benign fibroadenomas. The patient was hesitant to undergo a biopsy of a new palpable mass. T2-hyperintense masses can be benign or malignant. The mass was biopsied under US guidance (not shown) and proved to be an invasive mucinous carcinoma. **(A)** Axial fat-saturated preoperative T2-weighted breast MR image shows a homogeneously T2-hyperintense mass (arrow). **(B)** Axial postcontrast fat-saturated T1-weighted MR image shows heterogeneous internal enhancement (arrow) after contrast agent administration. Breast MRI should not be used to downgrade a finding from category 4 to 3, for example, because there is an overlap between malignant and benign lesions in terms of signal intensity and enhancement characteristics.

that breast cancer is more likely to be firm, and compression of malignant tissue produces less strain than benign tissue. Cho et al (68) evaluated 276 nonpalpable category 3 findings with elastography and core biopsy and found a negative predictive value of 99.3% in findings with a negative elasticity score (score of 1).

Diffusion-weighted Imaging

Diffusion-weighted imaging is often lauded for its potential to improve specificity in breast finding diagnosis, yet there are no reported studies on category 3 findings. Maltez de Almeida (69) evaluated apparent diffusion coefficients in 92 category 4 findings and noted significantly lower apparent diffusion coefficient values in biopsy-proven malignancy. These results can be extrapolated to category 3 findings, particularly for mass findings. However, the use of diffusion-weighted imaging is more challenging in nonmass findings and may be less effective with current techniques.

Conclusion

BI-RADS category 3 has been a long-standing and occasionally improperly used code that predates the inception of the BI-RADS manual itself. Its judicious application aids in decreasing false-positive biopsies and, by performing short-interval follow-up examinations, ensuring timely detection of potential malignancies. With established validated uses in mammograms and US and emerging evidence supporting its application in MRI, category 3 continues to evolve as an essential component of breast imaging practice. Success in utilizing category 3 hinges on radiologists' continued education, adherence to validated findings, and commitment to performing a medical audit to evaluate the outcomes of category 3 findings.

Figure 21. Mass associated with T2 signal hyperintensity in a 60-year-old woman who presented for high-risk screening based on a family history of breast cancer. **(A)** Axial fat-saturated T2-weighted MR subtraction image shows T2 hyperintensity (arrow). **(B)** Axial postcontrast fat-saturated T1-weighted MR image shows focal asymmetry (arrow) that was coded as category 3. **(C)** MIP projection image best shows the finding (arrow). On follow-up images (not shown), there was a questionable increase in size and a corresponding upgrade to category 4. A biopsy showed a papilloma without atypia.

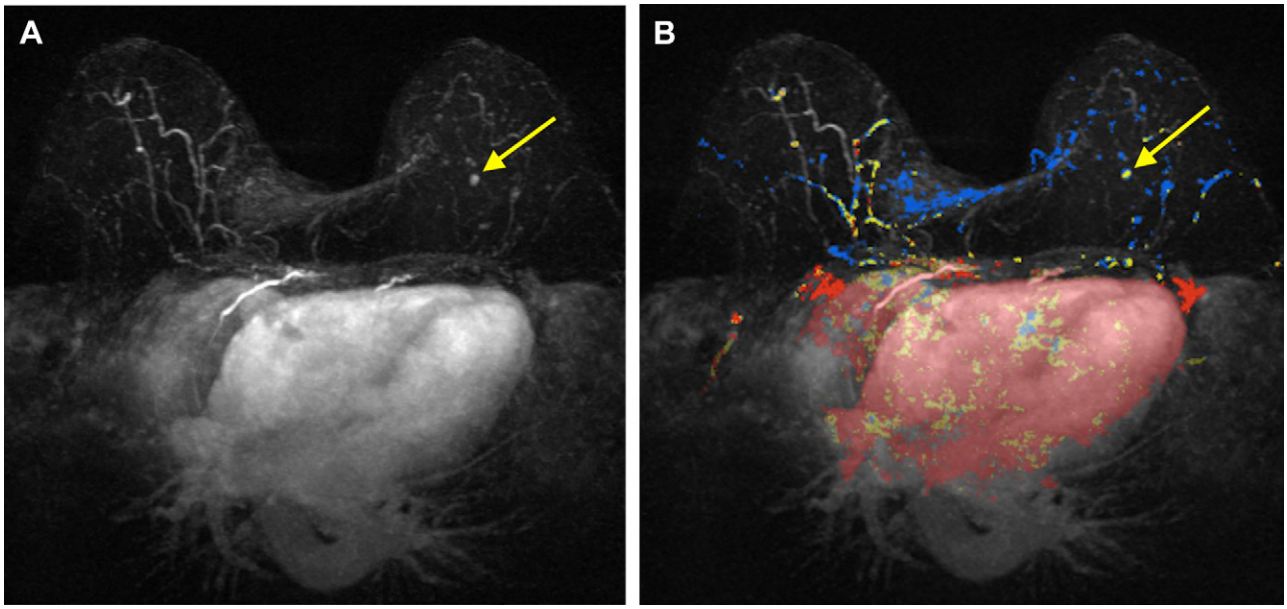


Figure 22. Focal pain in the left breast in a 56-year-old woman of Ashkenazi Jewish descent. A focus is a small area of enhancement that cannot be characterized and is distinct from BPE. **(A)** MIP image shows a focus of enhancement (arrow) that was assigned category 3. **(B)** MIP image with color overlay was reinterpreted when the patient requested a second opinion. Based on the clinical symptoms, high-risk factors, and kinetic assessment that showed plateau enhancement (arrow), the finding was upgraded to suspicious. Biopsy findings confirmed intermediate-grade ductal carcinoma in situ.

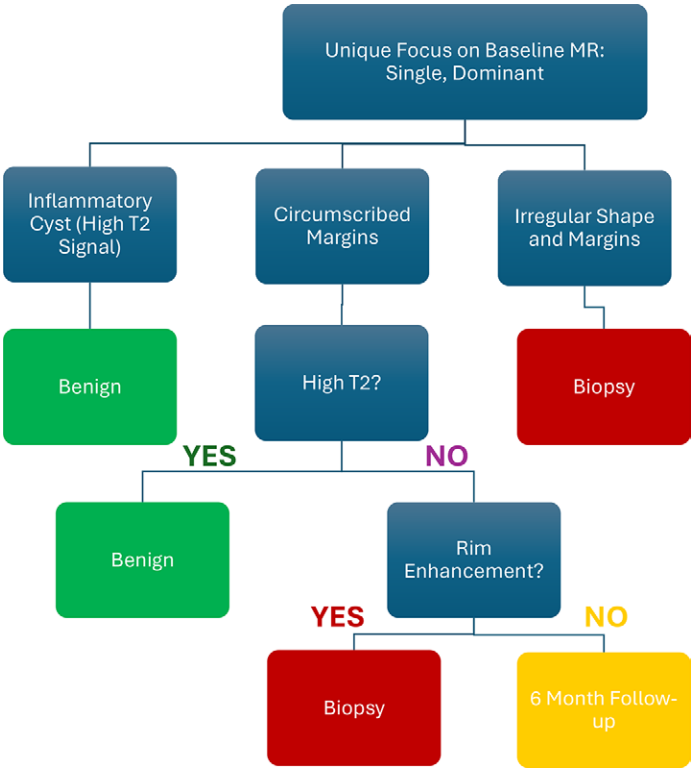


Figure 23. As part of the training material for the American College of Radiology Imaging Network EA1141 clinical trial, an algorithm was developed to manage a unique focus of enhancement seen at baseline breast MRI. The algorithm classifies a T2-high-signal-intensity finding as benign, a T2-hyperintense focus without rim enhancement as probably benign, and a focus with irregular margins or with rim enhancement as suspicious. The algorithm has been adapted from http://www.societyofbreastmri.org/Training.html.

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