Invited Commentary

BI-RADS Category 3: Guidelines, Challenges, and the Path Forward

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See also the article by Fazeli et al in this issue.

In their article "Understanding BI-RADS 3 Category" in this issue, Fazeli et al (1) provide a clear, in-depth, and clinically useful analysis of the Breast Imaging Reporting and Data System (BI-RADS) category 3 assessment of "probably benign" and emphasize its application across mammography, US, and MRI. The concept of the probably benign lesion was first introduced in mammography decades ago, with the goal of reducing false-positive results and avoiding unnecessary biopsies while preventing the upstaging of disease associated with delayed breast cancer diagnoses (2,3). This concept continues today, and the likelihood of malignancy of a probably benign breast lesion is 2% or less (1–6).

Despite its goal of improving patient care, the BI-RADS category 3 is sometimes misapplied to findings that should instead be classified as category 2 benign or category 4 suspicious, leading to unnecessary follow-up examinations or delays in appropriate tissue sampling (5,6). For instance, National Mammography Database data from 2009 through 2018 revealed that the majority of category 3 findings after screening mammography recall were downgraded to a category 1 negative or category 2 benign assessment before 24 months of total imaging surveillance, indirectly implying overuse of the BI-RADS category 3 assessment for findings that should require only routine (and not short-term) interval imaging surveillance (5). This underscores the importance of strictly adhering to established criteria for this assessment category to ensure optimal outcomes, including cost-effectiveness. At the same time, it also highlights the necessity for continuing education in the use of BI-RADS category 3 to avoid patient anxiety and ensure appropriate care.

An assessment of BI-RADS category 3 should not be made at the time of screening mammography; the probably benign assessment should be rendered only after diagnostic recall imaging (3,4,6). This point is clinically important because a comprehensive diagnostic workup, including magnification mammography for calcifications and US for masses or asymmetries, may downgrade the finding to benign or prompt a biopsy recommendation if suspicious features are identified. Radiologists should not use category 3 as a middle ground when deciding between benign (category 2) and suspicious (category 4) findings. Moreover, any new or changing findings that do not have characteristically benign features should be considered suspicious and warrant histopathologic determination through biopsy. Palpable findings or those arising from clinical concerns might not be appropriately assigned a category 3 assessment. Caution should be used when assigning a BI-RADS category 3 in high-risk patients, especially those with *BRCA1* or *BRCA2* mutations, or in patients older than 60 years (7) for whom a biopsy might be a more appropriate course of action due to the higher cancer yield observed in these populations. Other groups in which short-term follow-up imaging (in lieu of tissue sampling) should be used only after judicious consideration include pregnant patients, those with a personal history of breast cancer, preoperative patients (either surgical oncology or plastic surgery), male patients, and patients with limited access to appropriate follow-up imaging.

Fazeli et al (1) effectively outline criteria for assigning BI-RADS category 3 across different imaging modalities. In mammography, category 3 is appropriate for three findings at baseline imaging or when there are no prior mammograms available for comparison: noncalcified circumscribed masses, solitary groups of round calcifications, and focal asymmetries without suspicious associated features. These findings, validated through extensive research, provide a reliable framework for reducing unnecessary biopsies while maintaining sensitivity for early-stage breast cancer (3). For US, category 3 is appropriately applied to oval, circumscribed, and parallel solid masses, commonly representing fibroadenomas, and isolated complicated cysts. Clustered microcysts typically demonstrate a characteristically benign appearance at US and most of the time may be assessed as a category 2 finding, although a BI-RADS category 3 assessment is acceptable in cases where there is less diagnostic certainty.

The fifth edition of the BI-RADS atlas notes that there are no individual breast MRI findings in which the likelihood of malignancy appropriately falls into the BI-RADS assessment category 3 range of 0%–2% (4). Fazeli et al (1) observe that, in the published literature, the likelihood of malignancy for BI-RADS category 3 MRI findings (0.6%–10%) and the frequency of BI-RADS category 3 use for MRI (6.6%–25%) vary widely. The forthcoming sixth edition of the BI-RADS atlas is expected to provide more guidance for radiologists to use this assessment category more appropriately with breast MRI examinations. Emerging evidence supports the use of BI-RADS category 3 for circumscribed masses with persistent kinetics at baseline high-risk screening breast MRI (8). Importantly, current data are insufficient to support the use of BI-RADS category 3 for non-mass enhancement (8), which remains an issue for active investigation.

Other less well-substantiated imaging findings might also be appropriately assessed as BI-RADS category 3 based on expert opinion. At mammography, these findings include

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Abbreviation: BI-RADS = Breast Imaging Reporting and Data System

developing vascular calcifications, probable fat necrosis, presumed hematomas, and intramammary or low-lying axillary lymph nodes. Probable fat necrosis and presumed hematomas at US may also be assessed similarly, along with presumed postsurgical architectural distortion and vaccine-related axillary adenopathy.

Fazeli et al (1) reinforce the role of short-interval imaging follow-up, typically at 6, 12, and 24 months, to monitor stability and detect any malignancy at an early stage, thus ensuring timely intervention and minimizing the risk of progression to more advanced cancer stages when diagnosed. Follow-up sooner than 6 months may be helpful for findings that are expected to decrease or resolve more quickly, such as a presumed hematoma or vaccine-related axillary adenopathy. Additionally, the use of BI-RADS category 3 for probably benign findings has been shown to be cost-effective compared with immediate biopsy, particularly in average-risk patients. According to Ong et al (9), the imaging follow-up for BI-RADS category 3 findings is significantly less expensive than performing an immediate biopsy, with 2-year mammographic follow-up costing approximately $484 in U.S. dollars compared with $1055 for biopsy. For US, the cost differences are similar, with imaging follow-up costing $615 versus $1173 for biopsy. Even for breast MRI, in which costs are generally higher, follow-up imaging remains economically advantageous at $1510 compared with $1785 when including postbenign biopsy follow-up. This economic benefit, combined with the reduction in patient anxiety and biopsy-associated patient morbidity, underscores the value of appropriately applying BI-RADS category 3 in clinical practice.

One challenge in incorporating these recommendations is ensuring patient compliance with follow-up imaging. Fazeli et al (1) highlight the relatively low compliance rates observed in some studies, which could undermine the effectiveness of category 3 assessments. To address this, imaging centers should prioritize patient education and support by ensuring that patients understand the rationale for follow-up imaging and feel reassured about the low likelihood of malignancy.

In general, the literature suggests that BI-RADS category 3 is being used appropriately with respect to the intended 0%–2% likelihood of malignancy (5,10). However, the frequency of its use requires more study because inappropriate overuse of category 3 for benign findings reduces the calculated likelihood of malignancy for category 3 and can falsely reassure radiologists that they are using this category correctly. This has led the American College of Radiology BI-RADS Committee to develop a new practice for auditing outcomes of BI-RADS category 3 assessments, which will be detailed in the 6th edition of the BI-RADS atlas. A modality-specific audit will be performed, with outcomes separated by screening versus diagnostic indications, allowing more precise evaluation of category 3 usage. The most important performance metrics within the audit will be the frequency of use and the likelihood of malignancy, both of which are expected to be included within the basic clinically relevant audit. When a sufficient number of facilities have conducted and published their results, radiologists will have the opportunity to benchmark their use of category 3 against these data, thereby refining their practice and improving patient outcomes.

The article by Fazeli et al (1) provides a valuable contribution to the field of breast imaging by offering comprehensive and thoughtful guidance on the application of BI-RADS category 3 across different imaging modalities. Future research efforts should focus on refining the criteria for category 3 assessments, particularly in MRI, and publishing BI-RADS assessment category 3 auditing benchmarks. Additionally, further studies are needed to explore the psychologic impact of category 3 assessments on patients, as understanding and mitigating patient anxiety are crucial for improving patient care. As imaging technologies and clinical practices continue to evolve, it will be important to update the BI-RADS atlas to ensure that its recommendations remain relevant and effective. By addressing these areas of concern, the radiology community can enhance the accuracy of diagnoses and the overall patient experience, ultimately leading to better outcomes in breast cancer detection and management.

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