Probably Benign (BI-RADS-3) Lesions in Mammography: Is the 18-Month Follow-Up Exam Necessary?

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Purpose

The American College of Radiology (ACR) developed the BI-RADS atlas to standardize the reporting system for mammography and to eliminate ambiguity in mammogram reports\(^1\text{-}^4\). The BI-RADS 3 classification is one of the seven established categories and represents the category for a probably benign finding\(^5\text{-}^7\). The BI-RADS 3 category is used to reduce both the number and the cost of unnecessary biopsies in a patient population and to describe a lesion with a low probability of malignancy\(^1\text{-}^{10}\). BI-RADS 3 lesions should have less than a 2\% estimated chance of malignancy\(^5\text{-}^{10}\). Yet, there are no standardized follow up protocols for these probably benign BI-RADS 3 lesions. In general, BI-RADS 3 lesions are followed up for 2-3 years, with 6 months interval exams. Some institutions utilize a 6, 12, 18 and 24 month follow-up paradigm, while other institutions follow a 6, 12 and 24 (up to 36) month protocol (\textit{Figure 1})\(^1\text{-}^4\text{-}^{11}\). While there is variation in the recommended follow-up surveillance for these BI-RADS 3 patients varies, generally all of these institutions utilize a initial short-interval 6-month exam and followed by 6-12 months interval exams for a duration of at least 2-years\(^8\text{-}^{13}\).

The purpose of our study was to assess the value of the 18-month follow-up mammogram for evaluation of BI-RADS-3 lesions.

Images for this section:

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<th>Study</th>
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\textbf{Fig. 1:} Schematic demonstrating follow-up protocols for BI-RADS 3 lesions as described in the literature. Our 6-month short interval follow-up protocol for a total duration of 2 years is depicted by red 'X's.
Methods and Materials

This study was institutional review board approved and HIPAA compliant. 121,862 diagnostic mammograms were performed between February 2002 and May 2009. Out of these 121,862 diagnostic mammograms, 8,403 lesions were identified and given a BI-RADS 3 classification. At our institution, BI-RADS 3 lesions are followed at 6-month intervals for a total duration of 24-months.

A total of 714 patients were excluded from this study as they were lost to follow-up. The remaining 7,662 patients constituted our study population. Of the 7,662 patients, 254 patients were subsequently upgraded and/or biopsied from a BI-RADS 3 to a BI-RADS 4 or 5 over a 2-year follow-up course, however, 15 of these 254 patients which were upgraded from a BI-RADS 3 were lost to follow-up. The remaining 239 lesions were upgraded and/or biopsied. The reports of these mammograms were retrospectively reviewed and evaluated for changes in classification, time, and reason for changing the BI-RADS classification if applicable. The corresponding electronic medical records for these 8,403 patients were retrospectively reviewed for physical exam findings, histopathologic correlation, and changes in clinical presentation.

Results

Of the 7,662 patients included in this study, 239 patients were subsequently upgraded from a BI-RADS 3 and/or biopsied (3.1%). Of these 239 lesions, 37 were positive for malignancy (15.5%), with an overall prevalence rate of 0.5%, given our study population of 7,662 patients. When we retrospectively reviewed the reports of these 37 cases of biopsy-proven malignancy, 15 of these lesions did not demonstrate an objective change in the reported findings as characterized by a change in size or morphology of the lesion prior to biopsy (40.5%) (Figure 2).

Out of these 37 cases of biopsy proven malignancy, 34 lesions (91.2%) were upgraded from a BI-RADS 3 by a radiologist. Three out of those 37 lesions went immediately to biopsy after the first diagnostic mammogram without radiologic upgrade (8.1%). These lesions were biopsied at the patient's or surgeon's request. The most common reasons for biopsy instead of imaging follow-up included patient preference for biopsy and/or breast pain associated with the lesion. The histopathology of these 3 malignant lesions included one case of DCIS and two cases of invasive ductal carcinoma. At the 6-month follow-up mammogram 25 of the 37 biopsy-proven malignancies (68%) were upgraded from their original classification as a BI-RADS 3 lesion to a BI-RADS 4 or 5. At the 12-month follow-up mammogram five out of 37 biopsy-proven malignancies (14%) were
upgraded. At the 18-month diagnostic mammogram follow-up three out of 37 biopsy-proven malignant lesions (8.1%) were upgraded, and lastly at the final 24-month follow-up diagnostic mammogram one out of 37 biopsy-proven malignant lesions (2.6%) were upgraded to BI-RADS 4 or 5 (Figures 3 and 4).

Images for this section:

![Chart showing the percentage of objective changes in reported findings for upgraded and/or biopsied BI-RADS 3 lesions.](image)

Fig. 2: Chart showing the percentage of objective changes in reported findings for upgraded and/or biopsied BI-RADS 3 lesions.
**Fig. 3:** Schematic outlining malignant lesion detection in lesions originally classified as a BI-RADS 3 in a study conducted by Sickles et al. (left) compared to our institution (right).
**Fig. 4:** Percentage of biopsy-proven malignant lesions at 6, 12, 18, and 24-month follow-up exams. Note that the majority of upgraded BI-RADS 3 lesions occurred at the 6-month follow-up exam.
Conclusion

BI-RADS 3 is used for the classification of probably benign lesions; however, there are no clear guidelines for the follow-up these BI-RADS 3 lesions. This results in wide variation in follow-up protocols for these BI-RADS 3 lesions between institutions. Follow-up imaging surveillance for these lesions with a low rate of malignancy (< 2%) should ensure the goal of earliest possible cancer detection while avoiding excessive follow-up studies, unnecessary radiation exposure and healthcare cost burden\textsuperscript{12-16}.

Prior studies have investigated the efficacy and utility of different follow-up recommendations for patients with BI-RADS 3 lesions\textsuperscript{14-19}. Most of these studies recommend short-interval imaging follow-up at a 6-month interval and follow lesions for at least two years, however, some studies advocate lesion follow-up for 36-months\textsuperscript{5,14-19}.

In this study, the vast majority of malignant lesions were detected at the first 6 and 12-month interval follow-up exams comprising 81.2% of the detected malignancies. Only three lesions originally classified as a BI-RADS 3 lesion out of 239 lesions were upgraded at the 18-month interval were found to be malignant (1.2%). Given the low rate of malignant lesions detected in BI-RADS 3 lesions at the 18-month follow-up exam, we propose that based on the results of this study to eliminate the 18-month follow: A 6-month, 12-month, and 24-month follow-up protocol (for BI-RADS-3 lesions may be sufficient and reasonable. (Figure 5).

Images for this section:

![Proposed BI-RADS 3 Protocol](image)

**Fig. 5:** Proposed follow-up protocol of BI-RADS 3 lesions conducted at 6-month, 12-month, and 24-month intervals with the omission of the 18-month and 36-month follow-up exams.
References


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