The Role of Inter-Reader Variability of Radiologists in the Assessment of Mammographic Probably Benign (BI-RADS-3) Lesions

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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\(^1\)\(^-\)\(^4\). The BI-RADS 3 classification is one of the seven established categories in the BI-RADS atlas and represents the category for a probably benign mammographic finding\(^5\)\(^-\)\(^7\). The BI-RADS 3 category is used to reduce the number of biopsies in a patient population with a low probability of having a malignant lesion\(^1\)\(^-\)\(^5\). BI-RADS 3 lesions should have less than a 2% chance of malignancy\(^5\)\(^-\)\(^7\). During the course of a study investigating the value of the 18 months follow up exam for BI-RADS 3 lesions, we found that in our institution actually 41% of the up or down graded BI-RADS 3 lesion over a 2 year surveillance period, did not show any objective change. This raised the question whether the experience and training of the reader plays a role in the assessment of BI-RADS 3 lesions. At our institution (between 2002- 2009), mammograms were read by dedicated mammographers as well as general radiologists.

The purpose of this study was to evaluate how the level of experience in mammography influences the interpretation of BI-RADS 3 lesions and to evaluate the inter-reader variability in the interpretation of BI-RADS 3 lesions.
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 mammogram reports of these BI-RADS 3 lesions were retrospectively reviewed and evaluated for changes in classification, time, and reason for changing the BI-RADS classification if applicable. The reports were also reviewed for the type of radiologist (dedicated breast imager versus a general radiologist) interpreting the examination. 22 radiologists read mammograms in this period at our institution. Those radiologists were dichotomized into two groups: 1) dedicated mammographers with more than 5 years experience as a full-time breast imager and/or breast fellowship training and 2) general radiologists with less than 5 years experience.

Statistical analysis was performed using a Fisher’s exact test. P values less than 0.05 were considered statistically significant.
Results

Of the 22 radiologists included in this study, five completed either a dedicated breast imaging fellowship or have worked as full-time breast imagers for more than 5 years and were subsequently classified as a "dedicated" mammographer. The remaining 17 radiologists who did not meet these criteria were classified as "general" radiologists.

There were a total of 121,862 mammograms performed between February 2002 and May 2009 out of which 8,403 mammograms were classified having a BI-RADS 3 lesion (7%). A total of 714 patients were lost to follow-up with the remaining 7,662 patients comprising our study population (91.2%). Of the 7,662 patients, 239 patients were subsequently upgraded from a BI-RADS 3 to a BI-RADS 4 or 5 over a 2-year follow-up course and/or underwent biopsy (3.1%). Of the 239 patients that were upgraded and biopsied, 37 were positive for malignancy (15.5%). Of these 37 cases of biopsy-proven malignancy, 15 of these lesions did not demonstrate an objective change in the reported findings characterized by a change in size or morphology of the lesion prior to biopsy (40.5%) (Figure 1). Of these 15 upgraded and biopsy-proven malignant lesions, seven were initially read by general radiologists and upgraded by a mammographer (46.7%; false negative). Two of these 15 lesions were upgraded by the same mammographer (13.3% intra-reader variability). Five of these 15 lesions were upgraded by different general radiologists (33.3%). One of these lesions was upgraded by two different dedicated mammographers (6.7%). No dedicated mammographers had malignant lesions upgraded by general radiologists (0%; false negative) (Figure 2).

Of the 239 lesions originally classified as BI-RADS 3 and upgraded or subsequently biopsied, 202 lesions demonstrated benign histopathology at biopsy (84.5% false positive). Of these 202 benign biopsy-proven lesions, 57 patients were biopsied without an upgrade from BI-RADS 3 (28.2%). Of 145 benign lesions, 97 were upgraded by a general radiologist (67%, false positive). Of the 145 benign lesions, 48 were upgraded by a dedicated mammographer (32.7%, false positive), (Figure 3).

Out of 37 cases of biopsy proven malignancy, 34 (91.2%) were upgraded from a BI-RADS 3 by a radiologist. Three lesions went immediately to biopsy after the first diagnostic mammogram and were never upgraded from a BI-RADS 3 lesion (8.1%). These lesions were biopsied at the patient’s or surgeon’s request. The most common reasons for biopsy over continued imaging follow-up included patient preference for biopsy and breast pain associated with the lesion. The histopathology of these three malignant lesions included one case of DCIS and two cases of invasive ductal carcinoma.
25 of the 37 biopsy-proven malignancies (68%) were upgraded at the 6-month follow-up, 5/37 at the 12-month follow (14%), 3/37 at the 18-month follow-up (8.1%), and one out of 37 (2.6%) at the final 24-month follow up exam. (Figure 4).
**Fig. 1:** Chart showing the percentage of objective changes in reported findings for upgraded and/or biopsied BI-RADS 3 lesions.

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**Fig. 2:** Percentage of BI-RADS 3 lesions which were upgraded. G to M = general radiologist upgraded by mammographer, M1 to M1 = lesion upgraded by the same mammographer, G1 to G2 = lesions upgraded by different general radiologists, M1 to M2 = lesions upgraded by different mammographers, and M to G = mammographer upgraded by general radiologist. Note, no lesions originally classified as a BI-RADS 3 lesion were upgraded by a general radiologist.

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**Fig. 3:** Chart showing the percentage of upgraded BI-RADS 3 lesions which were benign.

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**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.

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Conclusion

Several prior studies have attempted to quantify the number of mammograms needed for a radiologist to qualify as an experienced mammographer and to achieve high accuracy in interpretation\textsuperscript{1-9}. Linver et al. demonstrated that dedicated training in mammography improves the performance of the radiologists by both increasing the sensitivity for cancer detection and decreasing the size of lesions detected without a loss in specificity\textsuperscript{10}. Nodine et al. demonstrated that improved performance and accuracy for mammographic interpretation occurs in readers after the interpretation of 10,000 mammograms\textsuperscript{11}. Ciatto et al. evaluated 117 Italian radiologists and noted an increase in mammographic accuracy and proficiency directly correlated with number of years in practice and total number of mammograms reviewed\textsuperscript{12}. In a study performed by Kan et al., improved reader performance was observed after the interpretation of a minimum of 2,500 mammograms per year\textsuperscript{13}. Additionally, several European countries have adopted qualification standards requiring the annual interpretation of 5,000 mammograms per year to qualify for as a screening mammographer\textsuperscript{14}.

Our study confirms the findings of prior studies that the experience of mammographers plays an important role in inter-reader variability: Less experienced readers have both a significantly higher false positive rate (P = 0.003) as well as a significantly higher false negative rate (P = 0.005) compared to dedicated mammographers, resulting in a delay of diagnosis and treatment of breast cancer (\textit{Figure 5}). Furthermore, our results show, that the majority of upgrades of BI-RADS 3 lesions occurred at the first 6-month follow up exam (67.7%).

Based on the findings of this study, fellowship trained or dedicated mammographers should be involved in the initial assessment of BI-RADS 3 lesions. We suggest second readers at the initial and first 6-month follow-up examination.
Summary:

41% of upgraded malignant BI-RADS 3 lesions were reader dependent without objective mammographic interval change.

80% of the false negatives of BI-RADS 3 lesions were initially classified by a general radiologist.

0% of the upgraded BI-RADS 3 lesions were initially classified by a dedicated mammographer.

68% of upgrades from a BI-RADS 3 were given at the first 6-month follow up.

Fig. 5: Overall summary of our study results.
References


