

Do We Need Breast Magnetic Resonance Imaging or Biopsy for Breast Imaging and Reporting Data System Category 3 Lesions on Ultrasound?

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Abstract

Objective: Breast Imaging and Reporting Data System category 3 was established for lesions that were thought to be probably benign, and its aim was to limit the number of biopsies performed. Breast Imaging and Reporting Data System category 3 lesions are common, but they remain controversial due to high interobserver variability. Our aim is to examine how many cases with a sonographically identified Breast Imaging and Reporting Data System category 3 lesion were performed on breast magnetic resonance imaging and/or biopsy and whether the Breast Imaging and Reporting Data System category changes with the breast magnetic resonance imaging.

Methods: This retrospective study included 498 patients who underwent breast ultrasonography between November 1, 2022, and June 30, 2023, and who had Breast Imaging and Reporting Data System category 3 lesion(s). Among these patients, those who underwent breast magnetic resonance imaging and/or biopsy within 3 months were found. Magnetic resonance images were evaluated for sonographically identified Breast Imaging and Reporting Data System category 3 lesion(s). Tru-cut biopsy results were also evaluated.

Results: Of 498 patients who had Breast Imaging and Reporting Data System category 3 lesion(s) on ultrasonography, 66 (13.3%) underwent breast magnetic resonance imaging subsequently. With the magnetic resonance imaging, there were 17 patients (25.7%) whose Breast Imaging and Reporting Data System category downgraded, 12 (18.1%) whose category upgraded, and 37 (56.1%) whose category remained unchanged. The mean age of those who had a biopsy was found to be lower than those who did not have a biopsy ($P = .028$).

Conclusion: The aim of Breast Imaging and Reporting Data System category 3 was to limit the number of breast biopsies performed. Magnetic resonance imaging can be used as a problem solver for Breast Imaging and Reporting Data System category 3 lesions and can also update the Breast Imaging and Reporting Data System category. Biopsy of Breast Imaging and Reporting Data System category 3 lesions may not be cost effective due to the low probability of malignancy.

Keywords: BIRADS 3, breast US, breast MRI

INTRODUCTION

Breast cancer is the most common solid-organ malignancy in women in developed countries.¹ Since the introduction of breast screening modalities, both malignant and benign lesions have been more easily identified.² The most commonly used screening modalities of breast are mammography and ultrasonography (US). Magnetic resonance imaging (MRI) is most commonly used as a problem solver. It is known that the sensitivity of mammography decreases with increasing breast density.³

The Breast Imaging and Reporting Data System (BIRADS) has been published by the American College of Radiology in order to provide a standardized categorization of breast lesions on mammography, ultrasound, and MRI.⁴ Breast Imaging and Reporting Data System category 3 was initially established for mammographic lesions that were thought to be probably benign and to carry an estimated cancer risk of 2% or less. The aim was to limit the number of breast biopsies performed for findings that cannot be definitively characterized as benign on mammograms but ultimately have benign pathologic results.⁵

Ultrasonography is a commonly used screening modality for breast and especially indicated for young, lactating, or pregnant women. It is also used as a supplement to mammography screening in women with heterogeneous or dense breasts.⁶ It has a high dependence on the operator; therefore, the sensitivity and specificity of US vary between studies. Previous studies reported 81%-98% sensitivity, 33%-89% specificity, 13%-68% positive predictive value, and 92%-100% negative predictive value (NPV) for US.⁷

Findings in ultrasound for BIRADS 3 lesions are as follows: oval circumscribed solid mass, probable isolated complicated cyst, probable clustered microcysts, hyperechoic mass with a central hypoechoic or anechoic component suggestive of fat necrosis, posterior shadowing without the presence of a mass, and architectural distortion thought to be a postsurgical scar.⁸ According to the recent studies, the vast majority of clustered microcysts can now be assessed as benign findings from BIRADS 2.⁹

The current recommended management for BIRADS 3 lesions is imaging surveillance with diagnostic mammography or diagnostic ultrasound at 6, 12, and 24 months.¹⁰ Once 2 years of stability has been obtained, the lesion has decreased in size or has been biopsied with benign results. The lesion can then be recategorized as benign.⁸ Growth in diameter >20% in 6 months should prompt a biopsy.⁹

Breast Imaging and Reporting Data System category 3 lesions are common, but they remain controversial due to high interobserver variability and low compliance with the standard imaging surveillance protocol. In their study, Nam et al reviewed and reclassified lesions seen on US and identified BIRADS 3 lesions in 41.5% of women. In their study, 745 BIRADS 3 lesions were found, and 124 (16.6%) underwent US-guided biopsy due to patient preference and/or risk factors. Benign pathology results were found in 119 lesions, and 5 of them were found to be malignant.⁹ Also recently, Berg et al (2020) assessed the malignancy rate of BIRADS 3 lesions to be 1.86%.⁸⁻¹⁰

Breast MRI is the most sensitive imaging modality for detecting breast cancer.¹¹ The American Cancer Society and American College of Radiology recommend MRI as an adjunct to mammography for women with a high hereditary risk for breast cancer.⁵ For the detection of breast lesions, the sensitivity and specificity of dynamic contrast enhanced MRI are reported as 94%-100% and as 37%-97%, respectively. The NPV of MRI is higher than any imaging modality (over 90%), and a negative breast MRI rules out malignancy.¹¹ Some studies have suggested that MRI may help the clinician manage BIRADS 3 and 4A lesions and limit unnecessary biopsies.⁶

Lesions are classified as BIRADS 3 in MRI when they have an oval or round shape with a circumscribed margin, homogeneous internal enhancement, and type 1 or type 2 kinetic enhancement curve.¹²

MAIN POINTS

- Breast Imaging and Reporting Data System category 3 (BIRADS 3) lesions are common, but they are controversial due to high interobserver variability and low compliance with the standard imaging surveillance protocol.
- With magnetic resonance imaging (MRI), 17 patients' (25.7%) BIRADS category downgraded, 12 patients' (18.1%) category upgraded, and 37 patients' (56.1%) category remained BIRADS 3.
- The rate of biopsy was found to be significantly higher in patients who had breast MRI.
- There was a tendency for younger people to have more biopsies irrespective of whether there is an upgrade in the BIRADS category on MRI or not.
- Magnetic resonance imaging can be used as a problem solver for lesions that are probably benign but difficult to manage, such as BIRADS category 3 lesions, and can update the BIRADS category of lesions.

In this study, our aim is to examine how many of the cases, which were reported as BIRADS 3 on US of the breast, underwent breast MRI for any reason and to investigate whether the BIRADS category changes with the breast MRI performed. In addition, our aim is to investigate the results of biopsies performed after MRI or without MRI in cases with BIRADS 3 lesion(s) on US.

METHODS

The study was carried out at Erzincan Binali Yıldırım University Mengucek Gazi Hospital. Our institutional review board approved this retrospective study (Date: February 23, 2022-KAEK-2023-4/21) with waiver of the requirement for informed consent.

Patient Selection and Radiological Evaluation

Patients who underwent breast US for any reason (including palpable mass) between dates 01/11/2022 and 30/06/2023 and who had at least 1 BIRADS 3 lesion according to sonographic criteria were included in our study (n=513). Care was taken to ensure that mammography was not performed within 3 months before or after sonography in the included patients. Among the patients who had BIRADS 3 lesion(s) sonographically, those who underwent breast MRI and/or biopsy within 3 months of sonography were found in the hospital database. Magnetic resonance imaging images in Picture archiving communication systems (PACS) and reports in the hospital database were evaluated for BIRADS 3 lesion(s) previously identified by sonography. In addition, biopsy results for BIRADS 3 lesions with or without prior MRI were evaluated. Those with poor MR image quality (due to artifacts and inadequate patient cooperation) and those who underwent surgical biopsy or Fine needle aspiration biopsy (FNAB) were excluded from the study. Also among the patients who underwent Tru-cut biopsy, those whose histopathological results showed insufficient material were excluded from the study. The final analysis included 498 patients.

The ultrasound examination was performed with the Samsung RS85 Prestige ultrasound system (Samsung Medison Co. Ltd., Hongcheon, Korea) and a high-resolution linear LM4-15B (15 MHz) transducer. Magnetic resonance images were obtained in the axial plane with a slice thickness of 2 mm at 1.5 T with a dedicated breast coil. The protocol involved an unenhanced nonfat-suppressed T1-weighted sequence and an unenhanced, fat-suppressed T2-weighted sequence. Also, an unenhanced fat-suppressed gradient-echo T1-weighted sequence was performed, followed by 2 to 4 dynamic contrast-enhanced T1-weighted gradient-echo series with fat suppression after IV administration of a gadolinium-based contrast agent. Post processing included sagittal and coronal reconstructions, subtracted contrast-enhanced images, and maximum-intensity projection images. Examinations were interpreted by an experienced breast radiologist using the terminology of the BIRADS atlas.

Tru-cut biopsies were performed by the Interventional Radiologist of our clinic with 16-Gauge tru-cut biopsy needles without any complications. Histopathological evaluations were made by the pathologists of our institution.

It was not investigated why mammography was not performed before or after US in these patients. In addition, the reason for the biopsy or MRI was not investigated in our study.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences version 27.0 for Windows 20 software (IBM SPSS Corp., Armonk,

NY, USA). The normal distribution of the data was evaluated using the Kolmogorov-Smirnov test. Numerical variables with a normal distribution are shown as minimum-maximum values. Categorical variables are shown as percentages. Differences in normally distributed variables between groups were evaluated using the Student's *t*-test and 1-way analysis of variance. Categorical variables were evaluated by the chi-square test between groups. A 2-tailed *P*-value <.05 was considered statistically significant.

RESULTS

The mean age of 498 patients included in the final analysis was 40.2 (maximum: 96, minimum: 13). In the study, 66 (13.3%) of 498 patients who had BIRADS 3 lesions sonographically underwent dynamic contrast-enhanced breast MRI within 3 months.

The mean age of those who had breast MRI was 40.56 and that of those who did not have it was 40.23, and there was no statistically significant difference in age between these groups.

According to the MRI results, there were 17 patients (25.7%) whose BIRADS category decreased, 12 patients (18.1%) whose BIRADS category increased, and 37 patients (56.1%) whose BIRADS category remained BIRADS 3. Representative MR images of one of the patients who had participated in the study are shown in Figures 1 and 2.

The mean age of the patients whose BIRADS category increased with breast MRI was 36.92 years, those whose BIRADS category did not change was 42.19 years, and those whose BIRADS category decreased was 39.59 years, and there was no statistically significant age difference between these groups ($P = .297$).

The BIRADS category of 37 out of 66 patients who underwent MRI remained unchanged (BIRADS 3). Magnetic resonance imaging of the patients with the unchanged category costs \$682.46.

Of those who underwent MRI, biopsy was performed in 12 patients (18.2%); histopathological examination was not performed in 54 patients (81.8%). Among those who did not have an MRI, biopsy was performed in 19 patients (4.4%) and histopathological examination was not performed in 413 patients (95.6%). The rate of biopsy was found to be significantly higher in patients who had breast MRI ($P = .001$).

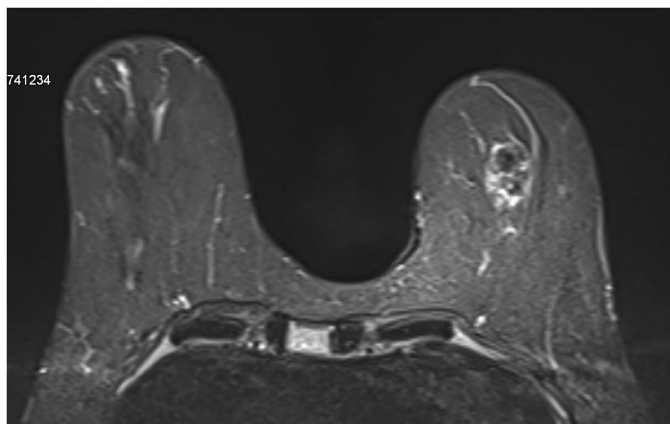


Figure 1. A patient who had a BIRADS 3 solid lesion sonographically underwent MRI, and on postcontrast dynamic fat-saturated images, there is an oval-shaped solid lesion with circumscribed margins. BIRADS, Breast Imaging and Reporting Data System; MRI, magnetic resonance imaging.

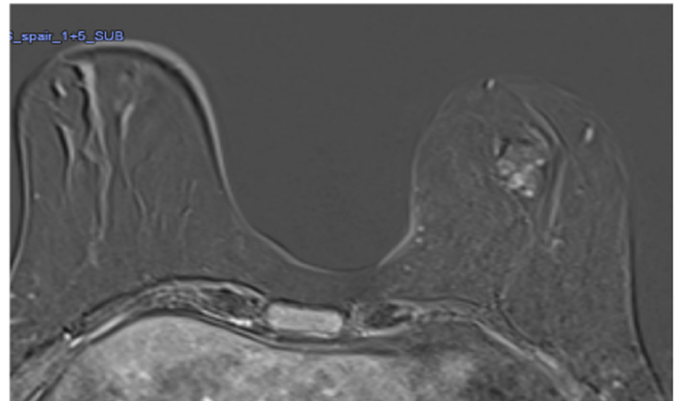


Figure 2. A dynamic kinetic curve was obtained in the same patient. The lesion demonstrated type 1 kinetic enhancement curve. This lesion was reported as BIRADS 3 on MRI. BIRADS, Breast Imaging and Reporting Data System; MRI, magnetic resonance imaging.

Histopathological examination was performed in 31 (6.2%) of the 498 patients in the study. Malignant histopathological results were found in only 1 patient out of a total of 31 biopsied patients (poorly differentiated malignant epithelial tumor). This patient was 33 years old, and biopsy was performed without prior breast MRI. A representative US image of the BIRADS 3 lesion and the image of the US-guided tru-cut biopsy procedure of one of the patients who had participated in the study are shown in Figures 3 and 4, respectively. Histopathologic results of the patients' who underwent biopsy are shown in Table 1.

The mean age of those who had a biopsy was 35.77; the mean age of those who did not have a biopsy was 40.57 years old. The mean age of those who had a biopsy was found to be lower than that of those who did not ($P = .028$).

Biopsy was performed in 1 patient (5.4%) in the group whose BIRADS category decreased as a result of MRI, in 5 patients (13.5%) in the group with an unchanged BIRADS category, and in 6 patients (50%) in the group with an increased BIRADS category. The reason

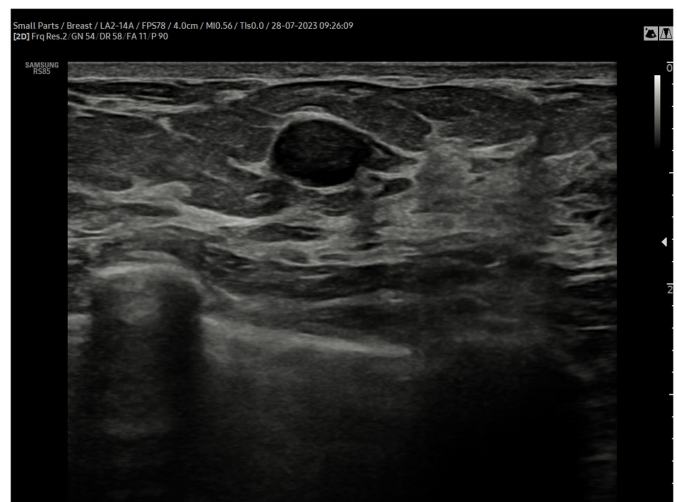


Figure 3. A representative US image of the BIRADS 3 lesion of one of the patients who had participated in the study. BIRADS, Breast Imaging and Reporting Data System; US, ultrasonography.

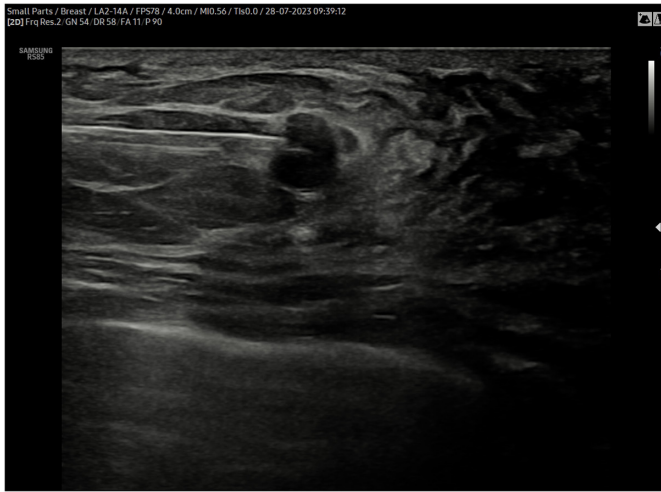


Figure 4. Image of the US-guided tru-cut biopsy procedure of one of the patients who had participated in the study. US, ultrasonography.

Table 1. Histopathologic Results of the Patients Who Underwent Biopsy are Shown with Numbers and Percentages

Histopathology	N	%
Benign	30	96.7
Fibrosis	6	19.3
Mesenchymal tissue	1	3.2
Nonneoplastic ductal and glandular structures	2	6.4
Fibroadenoma	15	48.3
Fibrocystic disease	2	6.4
Usual ductal hyperplasia	1	3.2
Adenosis	1	3.2
Fibroadenolipoma	1	3.2
Malignant	1	3.2
Poorly differentiated malignant epithelial tumor	1	3.2

why the rest of the patients whose BIRADS category increased after MRI (BIRADS 4) were not biopsied was that either these patients did not accept the biopsy or the patients were not followed up at our center. Biopsy rates were found to be higher in the group with increased BIRADS category than in the groups with unchanged and decreased BIRADS categories. The lowest biopsy rate was found in the decreased BIRADS category group ($P=.005$). There was a tendency for younger people to have more biopsies with or without an increase in BIRADS on MRI.

DISCUSSION

The aim of the BIRADS 3 category was to limit the number of breast biopsies performed. Magnetic resonance imaging can be used as a problem solver for BIRADS 3 lesions and can also update the BIRADS category. Biopsy of BIRADS 3 lesions may not be cost effective due to the low probability of malignancy. In this study, with MRI, 17 patients' (25.7%) BIRADS category downgraded, 12 patients' (18.1%) category upgraded, and 37 patients' (56.1%) category remained BIRADS 3.

Breast cancer is the most common solid-organ malignancy in women in developed countries.¹ The imaging modalities of breast are US, mammography(MG), and MRI.³ The BIRADS is a widely accepted lexicon that has been published in order to provide a standardized

categorization of breast lesions on modalities.⁴ Breast Imaging and Reporting Data System category 3 was initially established for lesions that were likely to be benign. The aim of this category was to limit the number of breast biopsies performed.

Ultrasonography is a commonly used screening method for breast, especially in young women who have dense breasts.⁶ The recommended management for BIRADS 3 lesions is imaging surveillance with MG or US at 6, 12, and 24 months.¹⁰

Magnetic resonance imaging is the most sensitive imaging modality for breast lesions.¹¹ It is most commonly used as a problem solver in equivocal lesions and is also used for women with a high hereditary risk for breast cancer.⁵ Due to the high NPV, a negative breast MRI rules out the malignancy.¹¹ Some studies have suggested that MRI may help the clinician manage BIRADS 3 and 4A lesions and limit unnecessary biopsies.⁶ However, it is not uncommon for lesions identified as BIRADS 3 sonographically to form a type 2 kinetic curve on dynamic contrast-enhanced MRI. Especially in lesions such as sclerosing adenosis, a type 2 kinetic curve can be seen on MRI, and subsequently biopsy may be performed.¹³

In their study which investigate the outcomes of imaging and biopsy of BIRADS 3 lesions, Polat et al found that patients younger than 40 years were more likely to undergo biopsy compared with patients older than 40 years. In their study, the mean age of the biopsied patients was 38.2 years compared with 47 years for patients that were not biopsied.⁸ Similarly, in our study, the mean age of those who had a biopsy was found to be lower than that of those who did not have a biopsy. In our study, the mean age of those who had a biopsy was 35.77; the mean age of those who did not have a biopsy was 40.57 years old. In their study, 5 out of 173 biopsied lesions were found to be malignant (2.9%). However, in their study, there were also biopsies performed due to size increase and morphology changes during imaging follow-ups. In our study, there were no other imaging or histopathological results related to the breast before and after. In our study, only 1 of 31 people who underwent biopsy had a malignant result (3.2%). In our series, the rate of biopsy for sonographic BIRADS category 3 lesions was 6.2%. Polat et al found this rate to be 7.5% in their study.⁸ In another study, Turk et al² found that 9 out of 84 (10.9%) biopsied lesions which were identified by MG and/or US were found out to be malignant. Pistolesi et al¹⁴ found a malignancy rate of 4.9% in sonographically detected BIRADS 3 lesions.

In our study, the reason for the biopsy decision was not investigated. However, the difficulties in compliance with the 2-year follow-up, patient anxiety, or the clinician's thought of needing a biopsy in the breast examination may be among the reasons.

In this study, 66 of these patients who had BIRADS 3 lesion(s) sonographically underwent MRI, and there were 17 patients (25.7%) whose BIRADS category downgraded, 12 patients (18.1%) whose BIRADS category upgraded, and 37 patients (56.1%) whose BIRADS category remained the same. However, these findings contradict the findings of Arian et al's study, which investigated the contribution of MR in sonographically detected BIRADS 3 lesions. In their study, they found that BIRADS remained the same in 87%, BIRADS downgraded in 9.8%, and BIRADS upgraded in 3.3% after MRI.¹² Also in their study, which investigated sonographically BIRADS 4 lesions on MRI, Ertekin et al found that 61.2% of the lesions were downgraded and 10.7% of the lesions were upgraded. Their BIRADS category upgrade ratios were

also lower when compared to our study.⁷ Additionally, Hernandez et al's study which investigated the use of MRI in indeterminate lesions found a 90% downgrade ratio in sonographically identified BIRADS 3 lesions.⁶ As seen in these studies, downgrading and upgrading with MRI differ substantially. In our study, biopsy rates were higher in the group that had upgraded the BIRADS category after MRI.

Also in their study, Hernández et al found that breast MRI avoided 22 unnecessary biopsies and 64 short-term follow-ups, allowing the exclusion of malignancy in 81.9% of the patients.⁶ This reflects the potential of breast MRI to avoid unnecessary biopsies and short-term follow-ups for indeterminate lesions.

In our study, 37 of 66 patients from the BIRADS category with MRI remained unchanged; The cost of the MR is \$682.46. The use of MRI is forestalled by the high cost of the examination. There are some literature data which show that for patients at high risk for breast cancer, MRI screening is cost effective. However, for women at lower risks, most studies show that breast MRI is likely not cost effective.¹⁵

Our study has some limitations. First of all, this is a retrospective study; therefore, extensive data review and a detailed history were not possible. Second, our relatively small sample size limits the statistical analysis and decreases the power of our results. Thirdly, the reason why the biopsies were performed could not be investigated.

In conclusion, MRI can be used as a problem solver for lesions that are probably benign but difficult to manage and require patient compliance, such as BIRADS category 3, and can update the BIRADS category of lesions. Biopsy of BIRADS 3 lesions may not be cost effective due to the low probability of malignancy, according to our results and also the results in the literature. Therefore, in BIRADS 3 lesions, it may be useful to re-evaluate the lesion(s) with MRI. However, in the literature, the results differ in terms of recategorization in MRI examinations for BIRADS category 3 lesions. This may be due to the fact that US and MRI evaluations are made by different radiologists or may be due to subjectivity of the interpretations. Our study provides direction for future research on the appropriate usage of MRI for the sonographically detected BIRADS 3 lesions.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Erzincan Binali Yıldırım University (Date: February 23, 2022, Number: EBYU -KA EK-2023-4/21).

Informed Consent: Due to the retrospective design of the study, informed consent was waived.

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