

# Likelihood of cancer in breast cancer imaging according to BI-RADS

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## Ethics Committee Approval

Ethics committee approval was obtained from Adiyaman University Medical School (Approval code: 2021/05-15).

All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

## Conflict of Interest

No conflict of interest was declared by the authors.

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## Abstract

**Background/Aim:** Breast cancer is the most common type of cancer among women and one of the most common causes of cancer-related death. Breast Imaging-Reporting and Data System (BI-RADS) is widely used in breast imaging and aims to provide effective communication between physicians. This study aimed to investigate the positive predictive values (PPVs) of BI-RADS categories as assessed by different imaging modalities in reference to Tru-Cut biopsy results.

**Methods:** This retrospective cross-sectional observational study included 415 lesions obtained by Tru-Cut biopsy between March 2018 and December 2020. The lesions were examined by ultrasound (US), mammography, and magnetic resonance imaging (MRI) and categorized as BI-RADS 3, 4, or 5. In this system, every category has its own likelihood of cancer ratio.

**Results:** The most common malign and benign lesions were invasive ductal carcinoma and fibroepithelial lesion, respectively. The PPVs of US BI-RADS category 3, 4, and 5 lesions were 2.15%, 47.44%, and 95.19%, respectively, those of mammographic BI-RADS 3, 4, and 5 lesions were 3.79%, 53.45%, and 94.2%, respectively, and those of MRI BI-RADS 3, 4, and 5 lesions were 0%, 57.89%, and 88.1%, respectively.

**Conclusion:** Predicting the probability of cancer in breast imaging is of significance for patient management and effective communication between the radiologist and other physicians. We demonstrated the compatibility of our experience with the literature with this study, in which we demonstrated the possibility of imaging modalities to predict cancer according to BIRADS categories.

**Keywords:** Breast, Ultrasonography, Mammography, Magnetic resonance imaging, BI-RADS

## Introduction

Breast cancer, the most common cancer among women, constitutes 35% of female cancers in Turkey and 23% of all cancers affecting women worldwide [1, 2]. It is also one of the most common causes of cancer-related deaths [3]. Widespread screening programs and advances in imaging technologies allowed the early diagnosis of breast cancer and drastically reduced breast cancer-related deaths [4, 5]. The most common and easy-to-use breast imaging method is ultrasonography (US). Mammography is another frequently used imaging method, particularly for detecting early breast cancer and as a screening tool. Magnetic resonance imaging (MRI) is an advanced imaging method used particularly as a problem-solving tool and for the screening of high-risk patient groups, albeit less commonly. The American College of Radiology (ACR) developed a lexicon named the Breast Imaging-Reporting and Data System (BI-RADS) to standardize reporting between radiologists and facilitate communication with other clinicians in 1992 [6]. Most recently, the ACR published the revised and modified 5<sup>th</sup> edition of BI-RADS in 2013 [7]. Breast lesions are assigned BI-RADS categories based on US, mammography, and MRI findings.

The diagnosis of breast lesions often includes a multidisciplinary approach involving radiology, pathology, and general surgery specialists. After categorization, imaging-guided Tru-Cut biopsy is routinely used to confirm the diagnosis. Tru-Cut biopsy has been used to diagnose solid lesions since 1930 [8]. With this study, we aimed to evaluate the agreement between Tru-Cut biopsy results and BI-RADS classifications and compare our results with the literature.

## Materials and methods

This retrospective cross-sectional observational study was approved by Adiyaman University Non-Interventional Ethics Committee (approval code: 2021/05-15).

### Patient selection

We analyzed 415 lesions obtained by Tru-Cut biopsy in our interventional radiology clinic between March 2018 and December 2020. To prevent potential bias, Tru-Cut biopsies performed by defining BIRADS in our center were included in the study. Fine-needle biopsies and BIRADS definitions performed in an external center were excluded from the study. All participants were informed about the study verbally and in writing and signed informed consent forms.

### Radiologic assessment

Patients' US, mammography, and MRI findings were evaluated. Breast lesions were assigned BI-RADS categories based on US, mammography, and MRI findings according to the last (5<sup>th</sup>) edition of the ACR BI-RADS lexicon [9] (Figure 1, 2, 3). Patients who were assessed only by US were assigned US BI-RADS categories. In patients who underwent US and mammography, the lesions were classified using only mammography findings. MRI BI-RADS was separately evaluated in patients who underwent MRI. Biopsy specimens were obtained from all patients with BI-RADS 4 or 5 lesions, and from patients with BI-RADS 3 lesions who were at high risk for breast cancer, whose lesions had grown in size on follow-up, or at the request of the physician and/or the patient. Lesion sizes

and locations were recorded. Mammography was performed for all patients over 40 years of age and for patients under 40 years of age if recommended by a radiologist. Breast MRI was decided by a radiologist according to the indications specified by the Turkish Society of Radiology [10].

Figure 1: The patient was diagnosed with intraductal papilloma by Tru-Cut biopsy. A) Mammography screen, evaluated as mammography-BIRADS 3, shows an increase in periareolar density (white circle). B) US image shows that tru-cut biopsy needle and US-BIRADS 3 lesion (white arrow). C) Contrast-enhanced MR image shows MR-BIRADS 3 lesion (white circle).

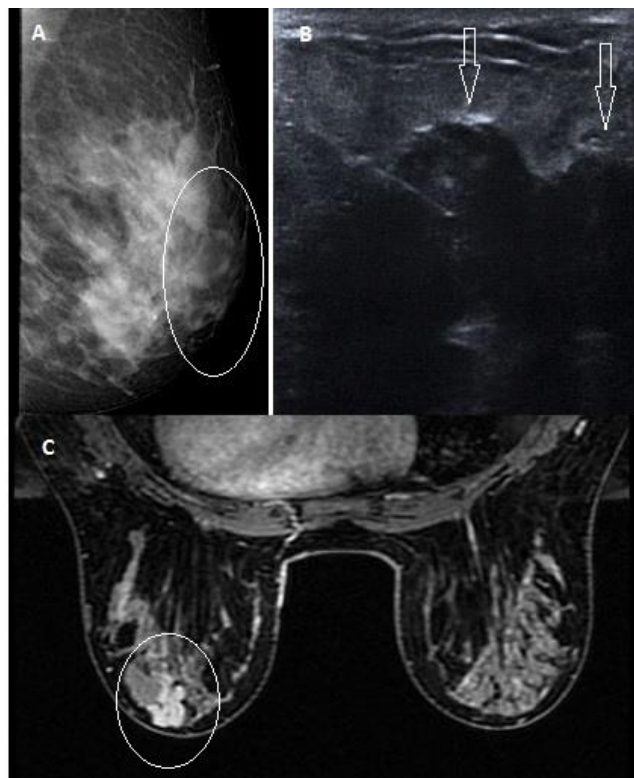


Figure 2: The patient was diagnosed with granulomatous mastitis by Tru-Cut biopsy. A) Mammography screen shows mammography-BIRADS 4 lesion (white circle). B) US image shows US-BIRADS 4 lesion (white circle). C) Contrast-enhanced MR image shows BIRADS 4 lesion (white circle).

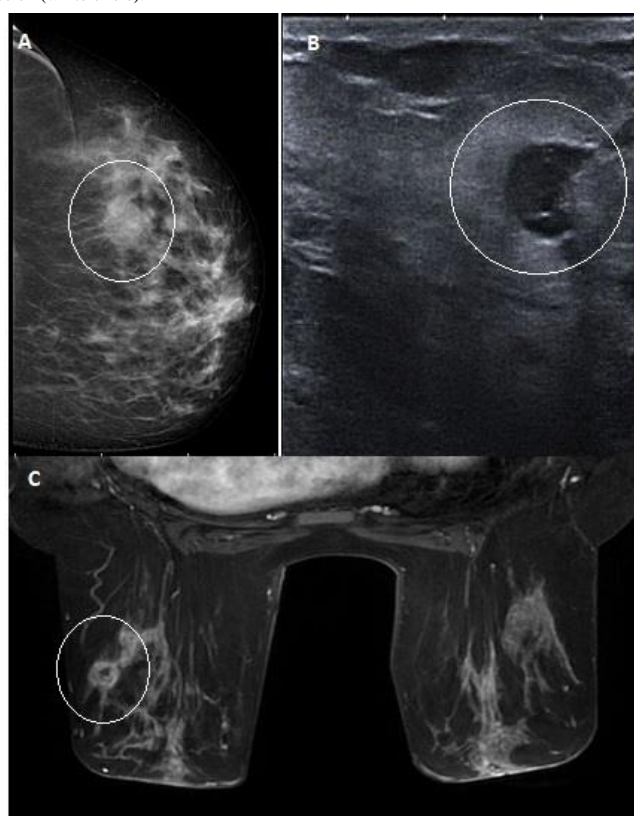
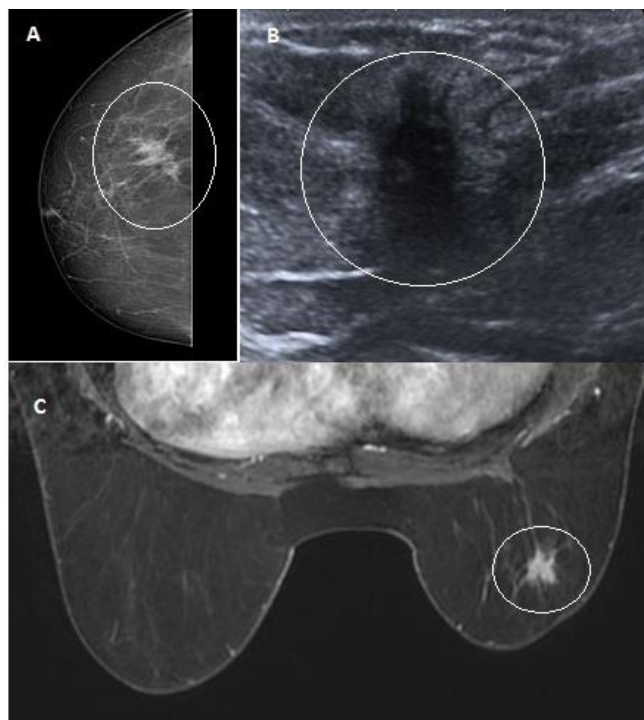


Figure 3: The patient was diagnosed with invasive ductal carcinoma by Tru-Cut biopsy. A) Mammography screen shows mammography-BIRADS 5 lesion (white circle). B) US image shows US-BIRADS 5 lesion (white circle). C) Contrast-enhanced MR image shows MR-BIRADS 5 lesion (white circle).



**Biopsy procedure**

All biopsy procedures were performed under ultrasound guidance using a Toshiba Aplio 300 ultrasound device (Toshiba Medical System, Tokyo, Japan) and a 7-MHz linear-array transducer. After the patient was positioned, the biopsy site was wiped with an antiseptic. Local anesthesia was administered (Citanest %2, 2-3 mL; AstraZeneca, Kırklareli, Turkey). A small incision was made with a scalpel, allowing the biopsy needle to pass through the skin. Targeted biopsy was performed with a 16-gauge coaxial semi-automatic biopsy needle (Geotek Healthcare Products, Ankara, Turkey). Samples were obtained from different sites of the lesions. Sampling was repeated at least three times until a sufficient amount of specimen was obtained from each lesion. The specimens were placed in formaldehyde and sent for pathological examination. The patients were kept under observation for 30 minutes for possible complications. They were not given antibiotic prophylaxis before the procedure. Coagulation tests and complete blood count were not assessed for patients without known coagulopathies and who were not on any medication.

**Statistical analysis**

The subjects were divided into two groups: Those aged ≤40 and >40 years. Statistical analysis was performed with SPSS 25.0 (IBM Corp., Armonk, NY, USA). The chi-square ( $\chi^2$ ) test was used to compare radiological classification and histopathological results. Pearson’s correlation analysis was used to test the correlation between age and malignancy. A *P*-value of <0.05 was considered statistically significant.

**Results**

A total of 579 patients were included in the evaluation. Forty-one patients who underwent fine-needle biopsy, 91 patients who visited our center for biopsy after the definition of BIRADS in another center, and 32 patients who underwent a biopsy without using BIRADS lexicon were excluded from the

study, leaving 415 patients to be included (Figure 4). The mean age was 44.13 (12.60) years (range: 13-82). All participants were female. The biopsy results indicated that 274 lesions (66%) were benign, and 141 lesions (34%) were malignant. While 156 biopsies (115 benign, 41 malignant) were obtained from women younger than 40 years of age, 259 biopsies (159 benign, 100 malignant) were from women older than 40 years. The incidence of malignancy significantly differed according to age (*P*=0.01) (Table 1). The most common malignant and benign lesions were invasive ductal carcinoma and fibroepithelial lesions, respectively (Table 2). There were no complications associated with the biopsy procedure.

Figure 4: Flow-diagram of patient selection

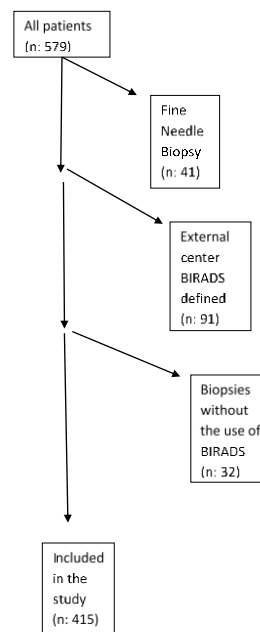


Table 1: The relationship between demographic characteristics and biopsy results \*

	<40 (n=156)	≥40 (n=259)	All Patients (n=415)	<i>P</i> -value
Age(years)	32.07 (6.65) (13-39)	53.50 (13.35) (40-82)	44.13 (12.60) (13-82)	
Pathology				0.01
Benign, n(%)	115(73.7%)	159(61.3%)	274(66%)	
Malignant, n(%)	41(26.2%)	100(38.6%)	141(34%)	

\* Expressed as mean (SD) or n (%)

Table 2: Distribution of pathologies \*

Benign, n(%)	274 (100%)	Malignant, n(%)	141(100%)
Fibroepithelial Lesion	144(52.5%)	Invasive Ductal Carcinoma	127(90%)
Fibrocystic Change	12(4.3%)	Invasive Lobular Carcinoma	11(7.8%)
Adenosis	17(6.2%)	Neuroendocrine Carcinoma	1(0.7%)
Mastitis	69(25.1%)	Papillary Carcinoma	1(0.7%)
Ductal Hyperplasia	8(2.9%)	Chondroid Carcinoma	1(0.7%)
Fat Necrosis	7(2.5%)		
Intraductal Papilloma	5(1.8%)		
Stromal Fibrosis	5(1.8%)		
Radial Scar	4(1.4%)		
Breast Tissue	3(1%)		

\* Expressed as n (%)

All patients (100%) underwent US, 259 patients (62.4%) underwent mammography, and 64 (15.4%) underwent MRI. US examinations were most commonly (n=305, 73.4%) performed due to pain and swelling in the breast, mammography was mostly (n=203, 78.3%) performed for breast cancer screening, and MRI examinations, mostly (n=51, 79.6%) at the recommendation of the radiologist.

Among patients who underwent US, 233 cases were classified as BI-RADS 3, 78 as BI-RADS 4, and 104 as BI-RADS 5. Among these, 5 (2.1%) BI-RADS 3, 37 (47.4%) BI-RADS 4, and 99 (95.1%) BI-RADS 5 lesions were malignant. A higher US BI-RADS category was associated with malignancy

( $P < 0.01$ ). The positive predictive values (PPVs) of US BI-RADS category 3, 4, and 5 lesions were 2.15%, 47.44%, and 95.19%, respectively (Table 3).

Table 3: Radiologic assessment and pathology results \*

	Benign (n)	Malignant (n)	%Sensitivity (%)	%Specificity (%)	%PPV (%)	%NPV (%)
US BI-RADS 3	228	5	3.5	16.7	2.1	25.2
US BI-RADS 4	41	37	26.2	85	47.4	69.1
US BI-RADS 5	5	99	70.2	98.1	95.1	86.5
Mammographic BI-RADS 3	127	5	4.9	19.6	3.7	24.4
Mammographic BI-RADS 4	27	31	30.6	82.9	53.4	65.1
Mammographic BI-RADS 5	4	65	64.3	97.4	94.2	81
MRI BI-RADS 3	3	0	0	81.2	0	21.3
MRI BI-RADS 4	8	11	22.9	50	57.8	17.7
MRI BI-RADS 5	5	37	77	68	88.1	50

\* Expressed as n and %, %To detect malignancy

Among the patients who underwent mammography, 132 cases were classified as BI-RADS 3, 58 as BI-RADS 4, and 69 as BI-RADS 5. Among these, 5 (3.7%) BI-RADS 3, 31 (53.4%) BI-RADS 4, and 65 (94.2%) BI-RADS 5 lesions were malignant. A higher mammographic BI-RADS category was associated with malignancy ( $P < 0.01$ ). The PPVs of mammographic BI-RADS category 3, 4, and 5 lesions were 3.79%, 53.45%, and 94.2% respectively (Table 3).

Among those who underwent MRI, 3 cases were classified as BI-RADS 3, 19 as BI-RADS 4, and 42 as BI-RADS 5. Among these, 0 (0%) BI-RADS 3, 11 (57.8%) BI-RADS 4, and 37 (88%) BI-RADS 5 lesions were malignant. A higher MRI BI-RADS category was associated with malignancy ( $P=0.015$ ). The PPVs of MRI BI-RADS category 3, 4, and 5 lesions were 0%, 57.89%, and 88.1%, respectively (Table 3).

## Discussion

We designed this study to correlate breast lesion biopsy results with BI-RADS assessment categories as determined by US, mammography, and MRI, the mostly used breast imaging modalities in daily practice. We then calculated the PPV of BI-RADS categories 3, 4, and 5 for each imaging modality. Due to the lack of similar studies and the relatively large sample size of the present work, we believe that our study contributes valuable information to the literature.

Our study revealed that benign pathologies were more common in patients under 40 years of age, whereas malignant pathologies were more common in those aged  $>40$  years. This finding is consistent with the literature and data from Turkey [2, 11]. We showed that the diagnostic accuracy of Tru-Cut biopsies was 100%, in line with the literature [12]. Due to its low complication rates, high diagnostic accuracy, and easy application, Tru-Cut biopsy should be used for breast lesions.

The PPVs of US BI-RADS category 3, 4, and 5 lesions were 2.15%, 47.44%, and 95.19%, respectively. İmamoğlu et al. reported the PPVs of US BI-RADS category 3, 4, and 5 lesions as 0%, 29.8%, and 100%, respectively [13]. In our study, there were several malignant cases classified as BI-RADS category 3, as well as benign lesions classified as BI-RADS category 5. In this regard, our study conflicts with the data presented by İmamoğlu et al., who highlighted the lack of malignant BI-RADS 3 and benign BI-RADS 5 lesions as a limitation of their study. We also found a higher PPV for BI-RADS 4 lesions.

In our clinic, mammography examinations are mostly performed for women aged over 40 years for screening purposes. Our study included patients who were diagnosed with breast

lesions by mammography who subsequently underwent biopsy. In our clinic, mammography is routinely performed in combination with US. However, since our study aimed to establish the PPV of mammographic BI-RADS, to prevent bias, we did not include US findings while determining mammographic BI-RADS categories. The PPVs of mammographic BI-RADS category 3, 4, and 5 lesions were 3.79%, 53.45%, and 94.2%, respectively. Ağaçlı et al. correlated mammographic and sonographic BI-RADS categories with pathology results and calculated the PPVs of BI-RADS categories 3, 4, and 5 as 3.8%, 40.6%, and 100% for malignancy, respectively [14]. The literature reports similar PPVs for mammography findings [15-18].

In our study, 64 (15.4%) breast lesions were assessed by MRI. All MRIs were obtained at the request of a radiologist and, to prevent bias, US and mammography findings were not utilized while determining MRI BI-RADS categories. MRI BI-RADS categories were determined by evaluating morphological characteristics and enhancement patterns. MRI enhancement kinetics were not considered. The PPVs of MRI BI-RADS category 3, 4, and 5 lesions were 0%, 57.89%, and 88.1%, respectively. In their study, Mahoney et al. investigated the positive predictive value of BI-RADS MRI and reported PPVs for BI-RADS categories 3, 4, and 5 as 0.9%, 20.5%, and 71.4%, respectively [19]. There is a prominent difference between the PPVs of BI-RADS category 4 as reported by Mahoney et al. and our results. This difference may be ascribed to differences in methodology, as Mahoney et al. evaluated lesion morphology as well as lesion kinetics and included more benign lesions in BI-RADS category 4 [19]. Breast MRI is increasingly used in recent years and it is quite sensitive in detecting breast cancer. Sensitivity rates ranging from 94% to 100% have been reported in the literature [20, 21]. That said, breast MRI has a relatively low specificity due to overlapping of malignant and benign lesions [22, 23].

The ACR states that the likelihood of malignancy is  $< 2\%$  for BI-RADS3,  $\geq 2\%$  and  $\leq 95\%$  for BI-RADS 4, and  $>95\%$  for BI-RADS 5 [24]. Our PPVs for malignancy for BI-RADS categories 3, 4, and 5 as assessed by US, mammography, and MRI are consistent with those reported by the ACR, demonstrating our success in evaluating breast lesions.

## Limitations

Its retrospective and single-centered design are some of the major limitations of our study. All biopsies were obtained under US guidance; mammography-guided biopsy and MRI-guided biopsy were not considered as they were not available at the time. Moreover, we did not evaluate the subcategories of BI-RADS category 4. Premalignant lesions such as lobular and ductal carcinoma in situ were excluded from the study; therefore, they were not assessed according to BI-RADS. Finally, our study did not include elastography, a more recent imaging modality.

## Conclusion

We conclude that BI-RADS categories as assessed by US, mammography, and MRI are highly correlated with pathology results. Our study showed that the BI-RADS lexicon can yield successful results that are consistent with the literature when used correctly. Predicting the probability of cancer in breast imaging is of great importance for patient management



and effective communication between the radiologist and other physicians. We recommend that all physicians dealing with breast diseases have knowledge of the BIRADS classification.

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