

# Evaluating the diagnostic accuracy of birads assessment of mammography and ultrasound according to ultrasound-guided core needle biopsy: 9 years-experience in a small town

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## Abstract

**Aim:** To examine the diagnostic accuracy of the BI-RADS (Breast Imaging Reporting and Data System) assessment of ultrasonography and/or mammography according to US-guided core needle biopsy.

**Materials and Methods:** 463 patients who had ultrasonography and/or mammography imaging and subsequent US-guided core needle biopsy between June 2011 and June 2020 in the Radiology Departments of two different centers in our town were studied retrospectively. BI-RADS assessment of ultrasonography and/or mammography were compared with histopathological diagnoses. When both examination existed, the higher score was determined as the final BIRADS category.

The diagnostic efficiency of ultrasonography and/or mammography for determining malignancy were calculated.

**Results:** Of the 463 lesions 222 (47.9%) were malignant and 241(52.1%) were benign. Based on ultrasonographic examination, malignancy was observed in 5 of the 86 (5.8%), 89 of 178 (50%), 4 of 63 (6.3%), 26 of 26 (100%) and 86 of 86 (100%), cases reported as BI-RADS 3, 4, 4A, 4C and 5. Based on mammography results, all of 50 masses (100%) classified as BI-RADS 5 and 38 of 47 masses (80.8%) classified as BI-RADS 4 were malignant. The frequency of malignancy in BI-RADS 3 masses was 5.8% based on ultrasonographic examination and 0.7% with both modalities.

Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy for ultrasonography were 92.2, 61.0, 69.1, 89.2, and 76.2%; for mammography were 96.7, 41.1, 89.8, 70.0, and 88.0%; for combined radiological evaluation were 99.5, 53.5, 66.3, 99.2 and 75.5% respectively.

**Conclusion:** When mammography and ultrasonography were evaluated together, the rate of malignancy in BIRADS 3 lesions decreased from 5.8% (only ultrasonography) to 0.7%. In addition, sensitivity and negative predictive value increased statistically significantly ( $p<0.001$ ). This finding showed the importance of the co-evaluation of mammography and ultrasonography.

**Keywords:** BI-RADS; breast; mammography; ultrasonography; US-guided core needle biopsy

## INTRODUCTION

The most common tumors in women worldwide are breast tumors (1). Radiological examination is routinely applied after physical examination in the evaluation of the breast masses. Mammography (MG), ultrasonography (US), and magnetic resonance imaging in some cases are the most commonly used diagnostic tools for breast masses. The BI-RADS (Breast Imaging Reporting and Data System) classification system has been developed by the American College of Radiology (ACR) to establish a common terminology for the interpretation of the masses in the breast (2). Although this system was developed to identify and interpret the masses in the breast through

mammography in the first years, it was adapted to ultrasonography in 2003 (3,4). When a suspicious mass is detected in the breast clinically and radiologically, the most commonly used histopathological evaluation method is US-guided core needle biopsy (USGCNB) due to its high accuracy (5). Unlike excisional biopsy, less scar develops in USGCNB, and breast parenchyma is not distorted in follow-up mammography. Besides, USGCNB has the advantages of faster recovery of patients and is a cost-effective procedure (6,7). In addition, sentinel lymph node mapping is more effective as the lymphatic system remains intact in patients undergoing USGCNB (8). USGCNB also allows the grading of cancer and facilitates receptor studies when malignancy is detected (9). The

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present study aimed to compare the diagnostic accuracy of US, MG and their combined use in breast lesions of BI-RADS 3, 4, and 5 groups based on ultrasonography US-guided core needle biopsy.

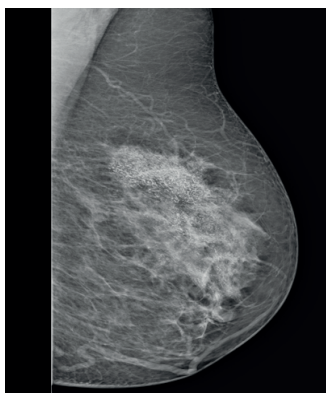
## MATERIALS and METHODS

### Study Population

This study was conducted after approval from the Ethics Board of Clinical Research at Gaziosmanpasa University Faculty of Medicine (20-KAEK-194). A total of 463 patients who had US and/or MG examination followed by USGCNB between June 2011 and June 2020 in Radiology Departments of two different centers in our town were studied retrospectively. All patients underwent US, and 228 of them had MG. Patients with insufficient or suspicious results, patients whose pathology records could not be accessed, and patients who had fine-needle aspiration biopsy were excluded from the study.

### Radiological Evaluation

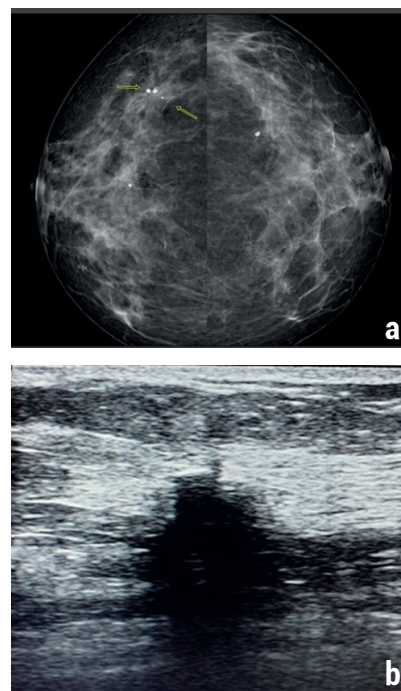
Bilateral MLO and CC images were obtained with a digital MG device. USGCNB procedure was performed by the authors, while the referring radiologists performed MG and US reporting in our institute or different centers. When a patient had both US and MG, the examination with the highest BI-RADS value was considered for the common radiological evaluation (Figure 1, 2).



**Figure 1.** Pleomorphic microcalcifications in a segmental distribution on mammography. US (not shown here) revealed a non-mass, mixed-echoic lesion. Mammographic BIRADS 5, US BIRADS 4C. Final BIRADS according to combined radiological evaluation is category 5. Biopsy result: Ductal carcinoma in situ

Some radiologists used the updated ACR classification in 2013 and reported the examinations as BIRADS 4a 4b 4c, while some radiologists used the old classification and reported the examinations as BIRADS 4. Therefore, both BIRADS 4 and BIRADS 4a 4b 4c subtypes are available in radiological classification.

The demographic data of all patients were recorded. The patients were grouped as 40 years of age and younger, 41-50 years, and 51 years and over. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy (DA) of US, MG, and common radiologic evaluation for determining the malignancy were calculated.



**Figure 2.** (a) Mammography (craniocaudal view) shows architectural distortion with associated calcifications in the right breast (arrow). Mammographic BIRADS 0 (US was recommended for the examination of the distorted area). (b) US revealed an irregular hypoechoic lesion with spiculated borders and associated calcifications. US BIRADS 4C. Core biopsy revealed ductal epithelial hyperplasia with atypia. Diagnosis confirmed by excisional biopsy

### Statistical Analysis

We used Pearson's Chi-square test for statistical evaluation of radiological and pathological results.  $p < 0.05$  was considered statistically significant. Calculations were performed using SPSS Statistics software (ver. 20, IBM, SPSS Inc., IBM Co., Armonk, NY, United States).

## RESULTS

The average age of all patients, the average size of all lesions, gender ratio, localization of the lesions were given in Table 1. The average age of patients with benign diagnosis based on histopathological examination was  $44.2 \pm 12.9$  years (range: 15-81). The mean age of patients who had malignancy based on histopathological examinations was  $56.1 \pm 12.8$  years (range: 26-89). Of the patients with malignancy, 99.6% were female and 0.4% were male.

Table 1. Patient's characteristics (n=463)		
	n ( $\pm$ SD)	%
<b>Gender</b>		
Female	458	98.9
Male	5	1.1
<b>Mean age</b>	49.9 ( $\pm$ 14.1) Range: 15-89	
<b>Lesion side</b>		
Right	239	51.6
Left	224	48.4
<b>Mean lesion size mm</b>	19.9 ( $\pm$ 10.9)	Range: 4-64

Benign masses were more common under 40 years of age, while malignant masses were more frequent in 50 years and over age group. The distribution of histopathological diagnoses in age groups is given in Table 2.

Histopathology	40 years and younger	41-50 years	51 years and over	Total
Benign	100 (41.5%)	70 (29.0%)	71 (29.5%)	241 (52.1%)
Malignant	27 (12.1%)	53 (23.9%)	142 (64.0%)	222 (47.9%)

In terms of BI-RADS categories of the masses evaluated, the highest frequency was observed in BI-RADS 4 category (38.4%). All masses classified as BI-RADS 4C and BI-RADS 5 by US had malignancy diagnoses based on histopathological examination. Of the five masses classified as BI-RADS 3 with US but had malignancy diagnosis based on histopathological examination, two were low- grade ductal carcinoma in situ (DCIS), two were invasive ductal carcinoma and one was mucinous carcinoma. Four masses were reported to be BI-RADS 4A based on US but had malignancy based on histopathological evaluations. They were diagnosed as papillary carcinoma, moderate grade DCIS, invasive lobular carcinoma, and invasive ductal carcinoma. The number of patients reported as BI-RADS 4B based on US examination was two, and lesions in these two patients were benign.

		BI-RADS 3	BI-RADS 4	BI-RADS 4A	BI-RADS 4B	BI-RADS 4C	BI-RADS 5
US	Benign	81	89	59	2	0	0
	Malignant	5	89	4	0	26	86
	Malignancy percentage	5.8%	50%	6.3%	0%	100%	100%
MG	Benign	3	9				0
	Malignant	2	38				50
	Malignancy percentage	40.0%	80.8%				100%
Combined radiologic evaluation	Benign	129	112	0		0	0
	Malignant	1	96	4		1	120
	Malignancy percentage	0.7%	46.1%	100%		100%	100%

US: ultrasonography, MG: mammography

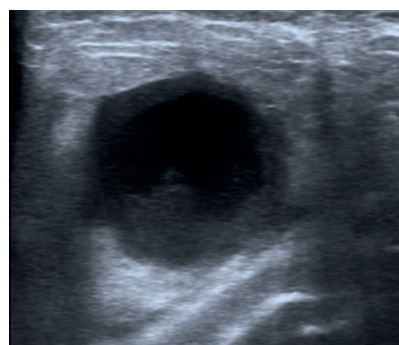


**Figure 3.** US shows a hypoechoic mass lesion with well-defined contours and posterior acoustic enhancement, with parallel orientation in the left breast. Formerly reported as BIRADS 3, determined to be BIRADS 4A, due to an increase in size at the six-month follow-up. Note the biopsy needle in the mass. Biopsy result: fibroadenoma

The diagnosis of the two masses reported to be BI-RADS 3 based on MG but turned out to be malignant in the histopathological examination was moderate stage DCIS. Malignancy counts and ratios of masses classified as BI-RADS 3, 4A, 4B, 4C, and 5 based on US and MG are given in Table 3. Histopathological diagnoses of the two malignant masses detected in male patients were invasive ductal carcinoma and mucinous carcinoma.

Ninety-nine of the histopathologically benign masses (Figure 3, 4), (41.0%) were fibroadenoma, 39 (16.1%) were

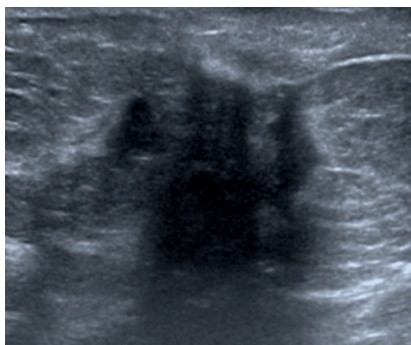
benign breast tissue, and 30 (12.4%) were fibrocystic changes. The distribution of benign masses is given in Table 4. Of all histopathologically malignant masses, 178 (80.1%) were invasive ductal carcinoma, 13 (5.8%) were DCIS and 10 (4.5%) were invasive lobular carcinoma (Figure 5). The distribution of malignant masses is given in Table 5. In determining the malignancy of breast masses, it was found that US and MG had the sensitivity values of 92.2 and 96.7%, respectively, for the highest diagnostic efficiency. Malignant and benign mass numbers, malignancy frequency, and diagnostic efficiency values detected in US and MG are given in Table 6.



**Figure 4.** US shows a cystic lesion with a thick wall and a solid component on the posterior wall. There was no vascular structures on Doppler US. BIRADS 4A. Biopsy result: abscess

**Table 4. Distribution of benign masses based on histopathological examination**

	n	%
Fibroadenoma	99	41.0
Benign breast tissue	39	16.1
Fibrocystic changes	30	12.4
Mastitis	10	4.1
Adenosis	8	3.3
Sclerosing adenosis	8	3.3
Fat necrosis	8	3.3
Granulomatous mastitis	7	2.9
Epithelial hyperplasia without atypia	5	2.0
Abscess	5	2.0
Intraductal papilloma	4	1.6
Complex sclerosing lesion	3	1.2
Papillary lesion	3	1.2
Sclerosing papilloma	3	1.2
Epithelial hyperplasia with atypia	2	0.8
Reactive lymph node	2	0.8
Tubular adenoma	2	0.8
Lipoma	1	0.4
Pseudo-angiomatous sclerosing hyperplasia	1	0.4
Adenomyoepithelioma	1	0.4

**Figure 5.** US shows an irregular hypoechoic mass with ill-defined borders. BI-RADS 4C. Biopsy result: invasive ductal carcinoma**Table 5. Distribution of malignant masses based on histopathologic examination**

	n	%
Invasive ductal carcinoma	178	80.1
Invasive lobular carcinoma	10	4.5
Mucinous carcinoma	9	4.0
Ductal carcinoma in situ moderate grade	6	2.7
Ductal carcinoma in situ low grade	5	2.2
Tubular carcinoma	3	1.3
Papillary carcinoma	3	1.3
Ductal carcinoma in situ high grade	2	0.9
Papillary ductal carcinoma In situ	1	0.4
Metaplastic carcinoma moderate grade	1	0.4
Metaplastic carcinoma low grade	1	0.4
Invasive micropapillary carcinoma	1	0.4
Diffused B celled lymphoma	1	0.4
Medullary carcinoma	1	0.4

**Table 6. Sensitivity, specificity, PPV, NPV, and diagnostic accuracy values in ultrasonography, mammography and common radiologic evaluation**

	Sensitivity	Specificity	PPV	NPV	DA
US	92.2	60.7	69.1	89.2	76.2
MG	96.7	41.1	89.8	70.0	88.0
Common radiologic evaluation	99.5	53.5	66.3	99.2	75.5

PPV: positive predictive value, NPV: negative predictive value, DA: diagnostic accuracy, US: ultrasonography, MG: mammography

## DISCUSSION

The most common malignant tumor in women is breast cancer (1). The frequency of male breast cancer in literature is 0.6% (10, 11), while was 0.4% in the present study. Five of the 249 patients (2%) in the study by Eke et al. (12) and 20 of the 314 patients (6.3%) in the study of Bhavani et al. (13) who underwent USGCNB were male, while the male gender percentage of USGCNB was 1.1% (5/463) in the present study.

According to Bhavani et al. (13), benign breast masses are most commonly seen in the 2<sup>nd</sup> and 3<sup>rd</sup> decades of life while malignant masses are most commonly reported in the 5<sup>th</sup> and 6<sup>th</sup> decades. In the present study, the average age of the patients was  $49.9 \pm 14.1$  years, and benign masses were more frequent under 40 years of age while malignant ones were more frequent over the age of 50 years. The frequency of breast cancer increases with age (14). The age of the youngest patient with breast cancer in the present study was 26, which indicated that breast cancer could be observed at a very young age.

Similar to the previously reported studies, there was no significant difference between the localization of masses in the right or left breast in the present study (15).

USGCNB is the most common method for studying breast lesions today when a suspicious lesion is detected clinically and radiologically in the breast. This method allows for the most suitable preoperative treatment planning. Yeniçeri et al. (15) examined breast tumors using USGCNB, and found that 42% of tumors were BI-RADS 3, 19% BI-RADS 4, and 39% BI-RADS 5. After histopathological examination, 51.4% of these tumors turned out to be benign and 48.6% malignant. In their study, malignancy was not observed in BI-RADS 3 tumors, while a malignancy rate of 50% was calculated for BI-RADS 4 tumors and 100% for BI-RADS 5 tumors. Korpraphong et al. (16) evaluated 144 tumors smaller than 10 mm using US, and found malignancies in 31.9% of them. Rikabi et al. (17) on the other hand, performed the histopathological examination in 275 tumors that underwent USGCNB and observed that 33.5% were malignant and 64.3% were benign while 2.2% of the specimens were not suitable for the diagnosis. In the present study, total malignancy frequency was 47.9% in

tumors examined with USGCNB, which was similar to the findings of Yeniçeri et al. (15) but higher than those reported by Korpraphong et al. (16) and Rikabi et al. (17).

The diagnostic efficiency values of MG and US examinations in distinguishing between benign and malignant tumors varied in the previous studies. Sensitivity, specificity, PPV, NPV, and diagnostic accuracy values of MG in the literature varied in the ranges of 97-49, 89-64.5, 89-53, 90.9-88, and 89.3-81, respectively (18-20). Sensitivity, specificity, and NPV values of US in distinguishing the malignant tumors from the benign ones, on the other hand, varied in the ranges of 98.4-82, 84-65.5, and 99.5-94, respectively, in the previous studies (19-23). In the present study, sensitivity in differentiating benign and malignant tumors was 92.2% in US, 96.7% in MG, and 99.5% in common radiologic evaluation. This finding showed that when MG and US were evaluated together, its sensitivity increased statistically significantly ( $p<0.001$ ). These values were higher than most studies in the literature. In the present study NPV, which is a valuable index for avoiding unnecessary biopsies, increased to 99.2% when US and MG were evaluated together.

According to the BI-RADS Atlas of ACR published in 2013, the frequency of malignancy is less than 2% in BI-RADS 3 masses, between 2-95% in BI-RADS 4 masses, and more than 95% in BI-RADS 5 masses. In terms of different subgroups of BI-RADS 4 masses, the malignancy rate was 2-10% for BI-RADS 4A, 10-50% for BI-RADS 4B, and 50-95% for BI-RADS 4C (2,4). In the present study, the prevalence of no-special type malignancies (invasive ductal carcinoma) among all malignant masses was 80.1%. On the other hand, invasive ductal carcinoma rate was 30% in BI-RADS 3 and BI-RADS 4A masses, which have low malignancy expectancy according to ACR ( $\leq 10\%$ ). This finding suggested that special type carcinomas could be more atypical. In the present study, the frequency of malignancy in BI-RADS 3 masses in US was 5.8%, and this value was somewhat higher than the values mentioned in the literature. This could be due to the atypical appearance of these masses. In combined evaluation based on US and MG, the frequency of malignancy in BI-RADS 3 masses decreased to 0.7%, which was comparable to ACR data. This finding demonstrated the importance of the co-evaluation of US and MG.

## LIMITATIONS

Our study had some limitations. The first was that the study was retrospective. Secondly, although we conducted the biopsies of our patients, their MG and US examinations were carried out by different radiologists. Third, some of our radiologists used the 2013 BI-RADS system and further classified BI-RADS 4 masses in subgroups (A, B, C), while some others reported these masses only as BI-RADS4 using the previous BI-RADS system.

## CONCLUSION

When MG and US were evaluated together, the rate of malignancy in BI-RADS 3 lesions decreased from 5.8% (only

US) to 0.7% and became compatible with the American College of Radiology catalog malignancy rate. In addition, sensitivity and NPV increased statistically significantly ( $p<0.001$ ). This finding showed the importance of the co-evaluation of MG and US. In the present study, the prevalence of no-special type malignancies (invasive ductal carcinoma) among all malignant masses was 80.1%. On the other hand, the invasive ductal carcinoma rate was 30% in BI-RADS 3 and BI-RADS 4A malignancy. This finding may suggest that special type carcinomas could be more atypical.

*Competing Interests: The authors declare that they have no competing interest.*

*Financial Disclosure: There are no financial supports.*

*Ethical Approval: This study was conducted after approval from the Ethics Board of Clinical Research at our institute (20-KAEK-194).*

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