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Nonpalpable BI-RADS 4 breast lesions: sonographic findings and pathology correlation

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PURPOSE
We aimed to evaluate ultrasonography (US) findings for Breast Imaging Reporting and Data System (BI-RADS) category 4 lesions using BI-RADS US lexicon and determine the positive and negative predictive values (PPV and NPV) of US with respect to biopsy results.

METHODS
Sonograms of 186 BI-RADS 4 nonpalpable breast lesions with a known diagnosis were reviewed retrospectively. The morphologic features of all lesions were described using BI-RADS lexicon and the lesions were subcategorized into 4A, 4B, and 4C on the basis of the physician's level of suspicion. Lesion descriptors and biopsy results were correlated. Pathologic results were compared with US features. PPVs of BI-RADS subcategories 4A, 4B, and 4C were calculated.

RESULTS
Of 186 lesions, 38.7% were malignant and 61.2% were benign. PPVs according to subcategories 4A, 4B, and 4C were 19.5%, 41.5%, and 74.3%, respectively. Microlobulated, indistinct, and angular margins, posterior acoustic features, and echo pattern were nonspecific signs for nonpalpable BI-RADS 4 lesions. Typical signs of malignancy were irregular shape (PPV, 66%), spiculated margin (PPV, 80%) and nonparallel orientation (PPV, 58.9%). Typical signs of benign lesions were oval shape (NPV, 77.1%), circumscribed margin (NPV, 67.5%), parallel orientation (NPV, 70%), and abrupt interface (NPV, 67.6%).

CONCLUSION
BI-RADS criteria are not sufficient for discriminating between malignant and benign lesions, and biopsy is required. Subcategories 4A, 4B, and 4C are useful in predicting the likelihood of malignancy. However, objective and clear subclassification rules are needed.

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Advancements in ultrasonography (US) equipment has significantly increased the value of US in breast imaging (1). Especially in women under the age of 50, detection of mammographically occult masses by US has increased up to 27% (1, 2). With the increasing use of US in routine breast imaging, in 2003 the American College of Radiology developed the first version of Breast Imaging Reporting and Data System (BI-RADS) US lexicon in order to standardize breast lesion characterization with US, as with mammography (3). In 2013, the second version of BI-RADS US lexicon was published in the fifth edition of BI-RADS atlas (4). The first version of BI-RADS US lexicon included shape, orientation, margins, lesion boundary, echo pattern, posterior acoustic features, and surrounding tissue alterations as descriptors (1–3, 5–8). The changes were minimal in the second version of BI-RADS US lexicon, with no changes in shape, orientation, margin, and feature descriptors; however, lesion boundary was removed. There were some differences in the nomenclature such as "posterior features" instead of "posterior acoustic features," and "associated features" instead of "surrounding tissue alterations." In the second version, "elasticity assessment" was added among the associated features and heterogeneous term was added to its echo pattern. Macrocalcification was removed from calcifications terminology, but intraductal was added (4).

On the basis of these descriptors, each lesion is assigned to a final assessment category. The evaluation categories use the same model that is used in mammography. BI-RADS classification consists of seven categories, from 0 to 6 (3). BI-RADS 4 is reserved for findings that do not have the classic appearance of malignancy, but are sufficiently suspicious to justify a recommendation for biopsy. Category 3 assessment represents a 2% likelihood of malignancy, while category 5 assessment represents a 95% likelihood of malignancy; thus, category 4 covers a wide range of likelihood of malignancy in between (4). To improve internal audits, communication with clinicians, pathologists, and image-directed research, many facilities subdivide category 4 into 4A, 4B, and 4C.

There are very few studies in the literature evaluating the pathological results of 4A, 4B, and 4C subcategories and their positive predictive values (PPVs) (9, 10). The aim of this study was to calculate the PPV of BI-RADS 4 and subcategories 4A, 4B, 4C for breast cancer and to evaluate the correlation between the descriptors of the BI-RADS US lexicon and the pathology results.

Methods

Institutional review board approval was obtained for this retrospective study, and informed consent was not required (Approval number, 2012-390).

Patient population

The study group was recruited from those subjects recommended for biopsy. Lesions with sonographic images recorded before the biopsy were included. Between January 2007 and January 2011, 240 female patients with 265 nonpalpable lesions underwent sonographically-guided wire localization and surgical biopsy at our facility. All 265 lesion images were evaluated using BI-RADS lexicon. In total, 62 lesions were classified as BI-RADS 3 or 5; thus, 203 BI-RADS 4 lesions were included in the study. Of these, 17 lesions were excluded because of missing pathology results. The remaining 186 lesions in 179 women constituted the study population. The mean age of the patients was 48.1±9.6 years (range, 23–77 years).

Imaging and interpretation

Sonography was performed using an ultrasound system (General Electric Medical Systems; Logiq 7) with a linear 12 MHz (10–14 MHz) probe. For each case static images were recorded in at least two representative orthogonal planes. Images were evaluated by two radiologists with six and 14 years of experience in breast imaging and intervention. Mammographic images and medical history were not provided to eliminate the possibility of introducing bias into the description and assessment of the sonographic images. The morphologic features of all lesions were described using BI-RADS lexicon.

Lesions with benign features such as oval shape, parallel orientation, circumscribed margin, abrupt interface, posterior acoustic enhancement, and absence of surrounding tissue alterations were accepted as BI-RADS 3. All lesions exhibiting a combination of at least three signs suggestive of malignancy were assigned to BI-RADS 5 (irregular shape, antiparallel orientation, noncircumscribed margin, echogenic halo, posterior acoustic shadowing, and abnormalities of the surrounding tissue) (5). Lesions that could not be classified as BI-RADS 3 or 5, were evaluated as BI-RADS 4. Individual lesion morphology was reviewed and the lesions were subcategorized as 4A, 4B, and 4C, in consensus, on the basis of the physicians' level of suspicion.

Table 1. Distribution of lesions according to BI-RADS 4 subcategories A, B, and C

BI-RADS 4 lesions	Benign	Malignant	Total
A	66 (70.9)	16 (19.5)	82 (44)
B	38 (62.2)	27 (41.5)	65 (34.9)
C	10 (31.2)	29 (74.3)	39 (20.9)
Total	114 (61.2)	72 (38.7)	186 (100)

Data are given as n (%).

Each patient's age, lesion location and dimensions, BI-RADS classification according to the imaging findings, and pathological report were retrospectively evaluated. Pathology results were grouped as benign and malignant. A definitive diagnosis of atypical ductal hyperplasia and columnar cell lesion with atypia was classified as a high risk lesion. High risk lesions were added to the malignant group for the purpose of PPV calculation.

Statistical analysis

Data analysis was carried out using statistical software (IBM Corp). Categorical data were summarized as number and percentage. Groups were compared using chi-square or Fisher's exact test. Multiple logistic regression analysis was used to determine the independent risk factors of malignancy (variables with $P < 0.20$ in the univariate analysis were included in the model). Coefficients of risk were determined for significant variables. Statistical significance was defined as $P < 0.05$. PPV and negative predictive value (NPV) were calculated for each sonographic descriptor. PPV was defined as the number of malignant lesions per sonographic feature, while NPV was defined as the number of benign lesions per sonographic feature.

Results

Overall, 186 nonpalpable breast lesions in 179 patients were categorized as BI-RADS 4. Mean diameter of the lesions was 9.86±4.43 mm horizontally and 6.2±2.82 mm vertically; the mean diameter of the malignant lesions was 10.9±5.57 mm horizontally and 7.2±4.04 mm vertically.

The lesions were classified as category 4A in 82 (44%), 4B in 65 (34.9%) and 4C in 39 (20.9%). The distribution of lesions as benign or malignant according to BI-RADS 4 subcategories is presented on Table 1.

Most common malignant lesion was infiltrative ductal carcinoma present in 20 of 32 malignant patients (62.5%), followed by ductal carcinoma in situ (DCIS) seen in six patients (18.7%). The most common benign pathology was fibrocystic change (FCC), followed by fibroadenoma. Pathology results and the detection rate of lesions are presented on Table 2.

Rates of benign and malignant BI-RADS 4 lesions in terms of US descriptors of BI-RADS lexicon are presented in Table 3. Lesion shape was significantly different between benign and malignant lesions ($P < 0.05$).

Lesion margins were circumscribed in 37 cases (19.8%), indistinct in 46 (24.7%), microlobulated in 79 (42.4%), angular in 14 (7.5%) and spiculated in 10 (5.3%) (Table 3). Of 10 patients with spiculated lesions, eight were malignant and two were benign. The pathology results of two patients with benign spiculated lesions were reported as sclerosing adenosis and ductal hyperplasia. According to lesion margin features, there was no significant difference between the benign and malignant lesions ($P > 0.05$).

The majority of lesions were hypoechoic (124 of 186, 66.7%) with no statistically significant difference between the echo patterns of benign and malignant lesions. Parallel orientation, seen in 130 lesions (69.8%), was found to be significantly in favor of benign findings. Lesion boundary was described as abrupt interface in 139 lesions (74.4%) compared with echogenic halo in 47 (25.2%). The presence of an abrupt interface was statistically significant for benign lesions ($P < 0.001$).

In multivariate regression analysis, shape was defined as an independent

Table 2. Pathology results of BI-RADS 4 lesions

Pathology result	Number of lesions (%)
Malignant lesions	32 (17.2)
Invasive ductal carcinoma	20 (62.5)
Ductal carcinoma in situ	6 (18.7)
Medullary carcinoma	1 (3.1)
Tubular carcinoma	2 (6.2)
Cribriform carcinoma	1 (3.1)
Invasive mix carcinoma	1 (3.1)
Metastasis	1 (3.1)
Benign lesions	114 (61.2)
Fibrocystic change	25 (21.9)
Fibroadenoma-fibroadenomatoid malformation	22 (19.2)
Columnar cell lesions	20 (18.1)
Ductal hyperplasia	21 (18.4)
Papilloma	9 (7.8)
Sclerosing adenosis	4 (3.5)
Fat necrosis	4 (3.5)
Others*	9 (7.8)
High risk lesions	40 (21.5)
Columnar cell lesions with atypia	26 (65)
Atypical ductal hyperplasia	14 (35)
Total	186

*Other benign lesions were radial scar, abscess, granulomatous mastitis, lobular neoplasia, pseudoangiomatous stromal hyperplasia, foreign body reaction, and collagenous spherulosis.

variable. Irregular shape had an odds ratio (OR) of 6.56 (range, 3.16–13.59; $P = 0.016$), while round shape had an OR of 2.92 (range, 1.22–6.99; $P < 0.01$) for malignancy. However, no significant differences were found when shape, orientation, margin, boundary, echo pattern, and posterior features were compared with the pathological results. Table 4 presents the distribution of lesion shapes according to pathology, orientation, margin, and boundary.

An analysis of lesions by shape and orientation showed significant difference in pathology of parallel lesions ($P = 0.002$), but no difference in nonparallel ones ($P = 0.034$). Benign lesions constituted 76.9% of parallel and oval lesions and 44% of parallel and irregular lesions (Table 4). On the other hand, 75% of nonparallel and irregular-shaped lesions were malignant. An analysis of lesions by shape and margin showed that 66.7% of lesions with oval shape and circumscribed margins were benign, while 80% of lesions with irregular shape and spiculated margins were malignant (Table 4). Benign lesions constituted 86% of lesions with oval shape and microlobulated margins, 83.3% of lesions with oval shape and angular margins, and 73.9% of lesions with oval shape and indistinct margins. Malignant lesions constituted 61.5% of lesions with irregular shape and indistinct margins, 57.1% of lesions with irregular shape and angular margins, 65.2% of lesions with irregular shape and microlobulated margins, and 80% of lesions with irregular shape and spiculated margins.

When shape, margin, and orientation variables were evaluated together, of eight lesions having an irregular shape, microlobulated margins, and nonparallel orientation, six were identified as malignant (75%); similarly, of nine lesions having an irregular shape, indistinct margins, and nonparallel orientation, five were malignant (55%); and all three lesions with irregular shape, angular margins, and nonparallel orientation were malignant (100%). Among five lesions with irregular shape, spiculated margins, and nonparallel orientation, four were malignant and one was benign. The pathology of the benign lesion was reported as granulomatous mastitis.

In total, 21 of 24 lesions having an oval shape, circumscribed margins, and parallel orientation were benign (87%); similarly, 61 of 72 lesions having an oval shape, microlobulated margins, and parallel orientation were benign (84%). However, these combined mass characteristics were not statistically significant in terms of benign-malignant differentiation.

Associated features such as architectural distortion, duct changes, skin changes, and edema were not seen in our lesions.

Discussion

Our results suggests that some sonographic signs, such as microlobulated, indistinct, and angular margins, posterior acoustic features, and echo pattern are nonspecific signs for category 4 lesions. Many oval-shaped and parallel-oriented lesions were benign, despite having microlobulated contours. In this study, 84% of lesions with microlobulated margins, oval shape, and parallel orientation were determined to be benign; similarly, 87% of lesions with oval shape, parallel orientation, and circumscribed margin were benign. Irregular shape, nonparallel orientation, and spiculated margin were determined as important positive predictive signs for malignancy. The probability of malignancy was fairly high (100%–80%) in lesions with irregular shape, nonparallel orientation, and angular or spiculated margins. These criteria were nonetheless insufficient for discriminating between malignant and benign lesions, and biopsy was required.

There are many studies evaluating the PPV and accuracy of BI-RADS lexicon (2, 6, 8). In previous studies, the PPV of BI-RADS 4 ranged from 3% to 94% (7, 9). However, there are very few studies evaluating the PPV of BI-RADS 4 subcategories and sonographic descriptors (9, 11). The PPVs of BI-RADS

Table 3. Rates of benign and malignant BI-RADS 4 lesions in terms of US lexicon descriptors

Descriptor	Benign	Malignant	Total	P*
Shape				<0.001
Oval	81 (77.1)	24 (22.9)	105 (56.4)	
Round	15 (53.6)	13 (46.4)	28 (15)	
Irregular	18 (34)	35 (6)	53 (28.5)	
Margin				0.077
Circumscribed	25 (67.5)	12 (32.4)	37(19.8)	
Indistinct	28 (60.9)	18 (39.1)	46 (24.7)	
Microlobulated	47 (59.4)	32 (40.5)	79 (42.4)	
Angular	8 (57.1)	6 (42.9)	14 (7.5)	
Spiculated	2 (20)	8 (80)	10 (5.3)	
Orientation				<0.001
Parallel	91 (70)	39(30)	130 (69.8)	
Not parallel	23 (41.1)	33(58.9)	56 (30.1)	
Posterior acoustic features			0.416	
Enhancement	10 (52.6)	9 (47.4)	19 (10.2)	
No posterior acoustic features	76 (64.4)	42 (35.6)	118 (63.4)	
Shadowing	28 (58.3)	20 (41.7)	48 (25.8)	
Combined pattern	0	1 (100)	1 (0.5)	
Lesion boundary				<0.002
Abrupt interface	94 (67.6)	45 (32.4)	139 (74.7)	
Echogenic halo	20 (42.6)	27 (57.4)	47 (25.2)	
Echo pattern				0.694
Hyperechoic	1 (100)	0	1 (0.5)	
Isoechoic	18 (66.7)	9 (33.3)	27 (14.5)	
Hypoechoic	76 (61.3)	48 (38.7)	124 (66.6)	
Complex	18 (54.5)	15 (45.5)	33 (17.7)	
Anechoic	1 (100)	0	1 (0.5)	
Total	114 (61.2)	40 (21.5)	186	

Data are given as n (%).
*Chi-square or Fisher's exact test was used as appropriate.

4 calculated in our study and previous studies (9, 11, 12) are presented on Table 5.

The PPVs calculated in different studies vary over a wide range, probably as a result of differences in the prevalence of breast cancer and the patient selection criteria. In the present study, only nonpalpable lesions were included and overall PPV for BI-RADS 4 was 38.7%. The rate of high risk lesions in our study (21.4%) was considerably higher compared to other studies (8, 9). In Wiratkapun et al. (9), the most common high-risk and benign lesions were atypical ductal hyperplasia and fibroadenoma, respectively. In our study, the most common high-risk lesion was columnar cell lesion with atypia and the most common benign lesion was FCC. Columnar cell lesion with atypia is a high-risk lesion for breast cancer and should be treated like DCIS (13). According to a study (14), in women with atypical hyperplasic lesions, the OR of breast cancer was 8.17 on the same breast, and 5.98 on the opposite breast.

Shape is the most important criteria for differentiating malignant breast lesions from benign lesions. In our study, lesion shape was significantly different between benign and malignant lesions ($P < 0.05$). The rates of benign and malignant BI-RADS 4 lesions according to shape determined in this study and in previous studies are presented in Table 6. In these studies, oval-shaped lesions are more often benign, while irregular-shaped lesions are more often malignant. In terms of round lesions, our results are comparable with Costantini et al. (15), where 64% of round lesions were benign and 36% were malignant. However, in Hong et al. (1), none of the round lesions were benign.

The rates of benign and malignant lesions determined in previous studies according to the margin of BI-RADS 4 lesions are presented on Table 7. Circumscribed margin was mostly associated with benign lesions. Costantini et al. (15) found that lesions with microlobulated and spiculated margins were 100% malignant, differently than our findings. The malignancy rates established in our study for lesions with microlobulated, indistinct, and angular margins are comparable with Hong et al. (1), which included only nonpalpable lesions as our study. Our results and the results of Hong et al. (1) suggest that microlobulated, indistinct, and angular margin descriptors cannot be accepted as significant malignancy criteria for nonpalpable BI-RADS 4 lesions. Small lesion dimensions may be the reason for this. The differentiation of microlobulated, indistinct, and angular margin can be difficult in small lesions.

In this study, combinations of oval shape with microlobulated, indistinct, or angular margins yielded benign lesions in 86%, 73.9%, and 83.3% of cases, respectively (Table 4). The rate of benign lesions among oval and circumscribed lesions was 66.7%, which is lower than expected. In lesions with irregular shape and spiculated margins the rate of malignancy was 80%, which is again lower than expected. The reasons of this could be the smaller size of the lesions and evaluation of only nonpalpable lesions.

In nonpalpable BI-RADS 4 lesions, orientation and morphology are the most reliable features for differentiating benign from malignant lesions.

Table 4. Rate of benign and malignant BI-RADS 4 lesions according to shape and other US descriptors

Shape	Pathology	Orientation: Parallel	Orientation: Not parallel	Margin: Circumscribed	Margin: Indistinct	Margin: Angular	Margin: Microlobulated	Margin: Spiculated	Boundary: Abrupt interface	Boundary: Echogenic halo	Total
Oval	Benign	80 (76.9)	1 (100)	22 (66.7)	17(73.9)	5 (83.3)	37 (86.0)	0	72 (77.4)	9 (75)	81
	Malignant	24 (23.1)	0	11 (33.3)	6 (26.1)	1 (16.7)	6 (14.0)	0	21 (22.6)	3 (25)	24
Round	Benign	0	15 (55.6)	1 (25.0)	6 (60.0)	0	8 (61.5)	0	11 (61.1)	4 (26.7)	15
	Malignant	1 (100)	12 (44.4)	3 (75.0)	4 (40.0)	1 (100)	5 (38.5)	0	7 (38.9)	6 (60.0)	13
Irregular	Benign	11 (44)	7 (25)	0	5 (38.5)	3 (42.9)	8 (34.8)	2 (20.0)	11 (39.3)	7 (28.0)	18
	Malignant	14 (56)	21 (75)	0	8 (61.5)	4 (57.1)	15 (65.2)	8 (80.0)	17 (60.7)	18 (72.0)	35
Total		130	56	37	46	14	79	10	139	47	186

Data are given as n (%).

Table 5. PPV of BI-RADS category 4 in this study and previous studies

Study	Lesions	Imaging method	Category 4 PPV (%)	Category 4A PPV (%)	Category 4B PPV (%)	Category 4C PPV (%)
Wiratkapun et al. (9)	Palpable and nonpalpable	MG, US	21	9	21	57
Lazarus et al. (11)	Palpable and nonpalpable	MG, US	23	6	15	53
Lee et al. (12)	Palpable and nonpalpable	US	51	26	83	91
Present study	Nonpalpable	US	38.7	19.5	41.5	74.3

PPV, positive predictive value; MG, mammography; US, ultrasonography.

Table 6. Rate of benign and malignant BI-RADS 4 lesions according to shape in this study and previous studies

Shape	Oval (%)		Round (%)		Irregular (%)	
Pathology	B	M	B	M	B	M
Costantini et al. (15)	58.6	41.4	64	36	28.6	71.4
Hong et al. (1)	88	12	0	100	42	58
Present study	72.1	22.9	53.6	46.4	34	66.1

B, benign; M, malignant.

A careful analysis of the sonographic descriptors associated with BI-RADS 4 demonstrated that malignant lesions were frequently associated with irregular shape (PPV, 66%), spiculated margin (PPV, 80%) and nonparallel orientation (PPV, 58.9%). Oval shape (NPV, 77.1%), circumscribed margin (NPV, 67.5%), parallel orientation (NPV, 70%), and abrupt interface (NPV, 67.6%) were the most predictive descriptors for benign lesions.

In this study, shape was determined as an independent risk factor. Irregular shape suggested a 6.56-fold increase in risk of malignancy, while round shape suggested a 2.92-fold increase. On the other hand, oval-shaped lesions with indistinct, angular, and microlobulated margins were highly likely to be benign. Oval shape and parallel orientation were the most important criteria for predicting benign lesions. Moreover, the presence of abrupt interface was statistically significant for benign lesions ($P < 0.001$). When shape was not taken into consideration, 67.6% of lesions with abrupt interface were benign, while 77.4% of lesions with oval shape and abrupt interface were benign. However, in the second version of sonographic BI-RADS, which was published in BI-RADS 5th edition, lesion boundary was eliminated from the descriptors. Since the absence of an echogenic rim is quite common and is now considered to be of no diagnostic significance, the descriptor "abrupt interface" is no longer deemed necessary. An echogenic rim may be seen with malignancies and abscesses, and its presence should be noted (4). In the present study, 72% of lesions with echogenic halo and irregular shape were malignant, however, posterior acoustic feature findings and echo pattern were not specific for differentiating the lesion pathology.

There are some limitations to our study. First, only nonpalpable lesions were included. Second, radiologists evaluated only static images of the lesions. However, in routine exam real-time US evaluation is performed, allowing collection of more detail. Lesions are better evaluated with real-time US, especially in the presence of calcification and associated features. Third, since our study was retrospective, the vascularity of the lesions could not be evaluated and elasticity assessment which was mentioned in the second version of US lexicon could not be performed.

In conclusion, subcategorizing BI-RADS 4 lesions is useful in determining the risk of malignancy, but no definitive diagnostic criteria could be established for subcategorization. BI-RADS 4 subcategorization is based solely on the radiologist's level of suspicion of

Table 7. Rate of benign and malignant BI-RADS 4 lesions according to margins, in this study and previous studies

Margin	Circumscribed (%)		Angular (%)		Indistinct (%)		Microlobulated (%)		Spiculated (%)	
Pathology	B	M	B	M	B	M	B	M	B	M
Costantini et al. (15)	70.6	29.4	18.2	81.8	55.8	44.2	0	100	0	100
Hong et al. (1)	89	11	51	49	58	42	67	33	12	88
Present study	67.5	32.4	57.1	42.8	60.9	39.1	59.4	40.5	20	80

B, benign; M, malignant.

malignancy. This is highly dependent on the experience of a radiologist. Moreover, subcategorization is more difficult for smaller lesions. Thus, objective and clear subclassification rules are needed.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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