Original Article

BI-RADS 4 and 5 lesions on mammography and ultrasonography: Positive predictive values and analysis of discordant cases

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Abstract

Background: Breast cancer is the leading cause of morbidity and mortality among women worldwide, including Thailand. Early detection and treatment significantly decrease mortality. The accuracy and effectiveness of mammograms are important in early breast cancer detection. In the present study, the positive predictive values of BI-RADS categories were compared against the suggested values and the histopathological results for the purposes of auditing, quality assurance, and benchmarking.

Objective: To determine the positive predictive values of different BI-RADS categories and compare the values against the suggested values based on the BI-RADS 2013 Standard, and to describe the discordant cases (cases with a mismatch between imaging and BI-RADS categorization) to determine how the misdiagnoses might happen.

Materials and Methods: This retrospective diagnostic study was conducted at Srinagarind Hospital, Thailand, between 1 January 2017 and 31 December 2021. It included 1,666 breast lesions in BIRADS 4 and 5 that had undergone image-guided biopsy (ultrasound or tomosynthesis-guided biopsy) to assess the positive rates of breast cancer among these lesions.

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Results: The 1,666 breast lesions were in the BI-RADS subtype categories 4A (n=899), 4B (n=492), 4C (n=149), and 5 (n=126), with positive rates for breast cancer of 5.01%, 19.51%, 57.05%, and 89.68%, respectively, with category 5 showing a lower positive rate than the standard. The discordant cases were mostly overdiagnoses of benign morphologies.

Conclusions: The positive rates of lesions in the BI-RADS 4 subcategories were within the expected ranges, whereas the positive rate of lesions in the BI-RADS 5 category was lower than expected, indicating overcategorization.

Keywords: Breast cancer, BI-RADS, Positive predictive value.

Introduction

On a global scale, breast cancer remains a primary driver of oncological morbidity and mortality. In 2022, approximately 2.3 million women were newly diagnosed with the disease, resulting in over 670,000 fatalities [1]. Within Thailand, the incidence of breast cancer has risen consistently over the past twenty years, surpassing cervical and colorectal cancers to become the most prevalent malignancy among Thai women [2].

Given that early-stage breast cancer is frequently asymptomatic, the implementation of robust screening programs and early detection initiatives is critical. Substantial evidence from large-scale studies confirms that mammography significantly reduces breast cancer mortality [3-5]. While mammography and ultrasonography serve as the primary non-invasive modalities for evaluating breast abnormalities, a definitive diagnosis necessitates histopathological assessment—typically achieved through image-guided core needle biopsy, tomosynthesis-guided biopsy, or minimally invasive surgical procedures.

To ensure standardized reporting of breast lesions, the American College of Radiology (ACR) developed the Breast Imaging Reporting and Data System (BI-RADS) [6]. This classification framework enhances the accuracy and consistency of imaging interpretation and serves as a vital instrument for predicting malignancy.

Under current guidelines, lesions categorized as BI-RADS 4 or 5 warrant tissue sampling for histopathological verification. However, the positive predictive values (PPVs) for these categories exhibit significant variability across different institutions and popu-

lations [7-13]. Consequently, institutional audits comparing radiological findings with pathological outcomes are recommended to maintain quality assurance and benchmark performance against established BI-RADS standards.

The diagnostic efficacy and detection rates of breast cancer are fundamentally dependent on the accuracy of mammographic interpretation. While existing literature has documented the PPVs of BI-RADS categories, this study aims to evaluate the PPVs specifically for BI-RADS 4 and 5 lesions and to elucidate the factors contributing to discrepancies between radiographic categorization and histopathological results.

Materials and methods

Study design and setting

The present study was a retrospective diagnostic accuracy study conducted at Srinagarind Hospital. This Hospital is a university hospital located in Khon Kaen. The study protocol was approved by the Center for Ethics in Human Research of Khon Kaen University. The study code was HE661158. Patient confidentiality was maintained by using study identification codes, and identifiable information was kept separately in secure files with restricted access.

Study patients

Inclusion Criteria:

Patients who underwent ultrasound-guided or tomosynthesis-guided breast biopsy with BI-RADS assessment of categories 4A, 4B, 4C, or category 5 at the study site during the period from January 2017 to December 2021

Exclusion criteria:

(1) Patients who did not receive histopathological results within 60 days of breast imaging at the study site.
(2) Patients whose histopathological results were unavailable or who had their biopsies performed elsewhere; or patients who had previously been diagnosed with breast cancer at the same site

Procedure

Breast imaging was performed using digital mammography and high-resolution ultrasound. All cases were serviced by one of seven board-certified radiologists at the institution, each possessing over five years of experience. The diagnostic team included three fellowship-trained breast radiologists and one breast imaging fellow. Prior imaging and clinical history were available should a radiologist request them.

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Each lesion was assigned a BI-RADS category (4A, 4B, 4C, or 5) based on morphological features, margins, calcification patterns, and other suspicious findings. In instances where a BI-RADS subcategory was not initially documented, a fellowship-trained radiologist performed a secondary review to assign the specific 4A, 4B, or 4C classification. All imaging interpretations were completely blinded to the histopathology results.

Histopathological sampling of breast tissue was performed by core-needle biopsy under ultrasonography-guided or tomosynthesis-guided biopsy, chosen based on the modality that provided the best lesion visibility. All ultrasonography-guided and tomosynthesis-guided biopsies were performed by the three radiologists who had been fellowship-trained. Possible pathological diagnoses are listed in Table 1.

Table 1. *Possible pathological diagnoses.*

Negative (Benign)	o Fibroadenoma o Benign phyllodes tumor o Proliferative disease without atypia o Negative for malignancy o Benign papillary neoplasm papillary lesion without atypia

Positive (Malignant)	o Proliferative disease with atypia
	o Atypical lobular hyperplasia (ALH)
	o Atypical ductal hyperplasia (ADH)
	o Non-invasive breast carcinoma
	  o Lobular carcinoma in situ (LCIS)
	  o Ductal carcinoma in situ (DCIS)
	o Invasive breast carcinoma
	  o Invasive ductal carcinoma
	  o Invasive lobular carcinoma
	  o Carcinoma with medullary features
	  o Mucinous carcinoma
	  o Tubular carcinoma

Statistical analysis

Diagnostic accuracy metrics included the positive predictive value (PPV) for BI-RADS 4 (overall and subcategories) and BIRADS 5, while using histological results as the gold standard. Exact 95% confidence intervals were calculated using the Clopper-Pearson method. All statistical analyses were conducted using STATA version 17.

Results

We enrolled the records of 1,666 patients who met the study criteria. The patients' ages ranged from 12 to 84 years old. There were 1,665 female patients and one male patient. The most common age group was 40-59 years old, encompassing 1,089 individuals, which accounted for approximately 65% of the patients in the present study.

Table 2. *Distribution of enrolled patients by age.*

Age range (years)	Patient (n)
< 19	7
20-29	82
30-39	205
40-49	554
50-59	538
60-69	219
70-79	55
> 80	6

Of the 1,666 breast lesions, 899 were in Category 4A, 492 in Category 4B, 149 in Category 4C, and 126 in Category 5. To evaluate the diagnostic accuracy of mammography at our institution in detecting breast cancer, Table 2 presents the PPV for each BI-RADS category and subcategories along with 95% confidence intervals (CI).

PPV increased with the severity of the BI-RADS category. The positive rate for PPV for BI-RADS 5 was 89.7%, whereas BI-RADS 4A had the lowest positive rate (PPV= 5.0%). The positive rates increased in a stepwise order from BI-RADS 4A to BI-RADS 5.

Table 3. describes the details of the PPVs of the present study's population, while Table 4. compares the observed positive rates of breast cancer in the present study with the expected likelihood according to BI-RADS 2013 guidelines. The observed positive rates for BI-RADS 4A (5.0%), 4B (19.5%), and 4C (57.0%) fell within the expected ranges outlined by the 2013 guidelines, indicating that the mammography assessments for these subcategories at our institution were consistent with the standard classification. However, the observed positive rate for BI-RADS 5 was 89.7%, which is slightly lower than the ≥ 95% likelihood suggested by BI-RADS 2013.

Table 3. *Agreement between BI-RADS categories and histopathological results.*

BI-RADS	# patients, n	Pathology result		Positive predictive value, (95% CI)
		Negative (n, %)	Positive (n, %)	
5	126	13 (10.3)	113 (89.7)	89.7% (83.0 – 94.4)
4C	149	64 (42.9)	85 (57.0)	57.0% (48.7 – 65.1)
4B	492	396 (80.4)	96 (19.5)	19.5% (16.1 – 23.3)
4A	899	854 (94.9)	45 (5.0)	5.0% (3.7 – 6.6)

Table 4. *Positive rates of breast cancer by BI-RADS category according to BI-RADS 2013.*

BI-RADS	BI-RADS 2013 likelihood of cancer	Observed positive rate (%)	Agreement between the observed rate and the expected likelihood
4A	Low suspicious for malignancy (>2% to <=10%)	5.0	Within the expected range
4B	Moderate suspicious for malignancy (>10% to <=50%)	19.5	Within the expected range
4C	High suspicious for malignancy (>50% to <=95%)	57.0	Within the expected range
5	Highly suggestive of malignancy (>=95%)	89.7	Lower than the expected likelihood

Table 5. summarizes the cases in which the histopathological findings were discordant with the imaging assessment for lesions categorized as BI-RADS 5. We focused on BI-RADS 5 because the observed positive rate was lower than the expected likelihood, thus highlighting this category as an area for improvement. For each case, patient demographics and clinical presentation, mammographic or ultrasound findings, and histopathological results are presented. The table also provides the reasons for the discordant diagnoses.

In the reported cases, discordance was primarily due to misinterpretation of imaging findings. Out of the twelve misinterpreted cases, ten were over-categorized as BI-RADS 5, when the imaging findings were more consistent with BI-RADS 4. These included cases with benign lesions such as fibroadenoma, fibrocystic changes, phyllodes tumors, and benign fibroepithelial lesions, in which certain clinical factors such as patient age, palpability, or interval change contributed to misinterpretation.

The last two misinterpreted cases were classified as BI-RADS 5 despite benign pathological results (angiolipoma with stromal fibrosis and lymphocytic mastitis with fibrotic stroma). Diagnosing these cases was challenging because benign conditions could mimic malignancy radiologically. The imaging findings of these two cases showed irregular spiculated margins, hyperdense masses, and suspicious axillary lymph nodes, which justified the BI-RADS 5 categorization. This misclassification to BI-RADS 5 of benign lesions was considered acceptable because fibrotic lesions are among the usual causes of false positives in BI-RADS 5.

Table 5. describes these twelve cases in the order presented above: nine cases of overcategorization of benign lesions, two cases of acceptable false positives from benign lesions, and one case of overcategorization but with a positive histopathological result.

Table 5. *Descriptions of cases with discordant diagnoses in BI-RADS category 5.*

Case No.	Demographics and Clinical presentation	Mammographic or ultrasound findings	Histopathological findings	Reasons for discordant findings
1	63-year-old female undergoing a workup for multiple organ metastases from a primary tumor	-Mammography: Suspicious segmental/linear calcifications at the 4 to 7 o'clock position of the right breast - Ultrasonography: An irregular-shaped, non-circumscribed margin, hypoechoic mass corresponding to the area of abnormal calcifications on mammography.	US-CNB: Dense fibrotic tissue without terminal ductal lobular unit. No malignancy.	The observed segmental/linear calcifications demonstrate suspicious morphology and distribution and should have been categorized as BI-RADS 4C.
2	58-year-old female with undifferentiated right breast cancer, post modified radical mastectomy, with detection of a new palpable irregular mass at the 2 o'clock position of the left breast	- Mammography: A group of amorphous calcifications suspected at the upper outer quadrant of the left breast. - Ultrasonography: A new irregular-shaped, lobulated margin hypoechoic mass corresponding to the area of abnormal calcifications on mammography.	US-CNB: Fibrotic breast tissue with unremarkable terminal ductal lobular units, no malignancy. Non-lactating effect tissue contained a group of suspicious calcification. Surgical excision: Foci of sclerosing adenosis with extensive intraluminal calcification. No malignancy.	The observed abnormal group of amorphous calcifications demonstrated suspicious morphology and distribution and should have been categorized as BI-RADS 4B.
3	43-year-old female with a known history of fibrocystic breast disease	- Mammography: No suspicious abnormalities detected. - Ultrasonography: A new irregular-shaped hypoechoic mass at the 2 o'clock position of the left breast.	US-CNB: Focal adenosis with apocrine metaplasia and increased fibro collagenous stroma with an area of fibrocystic change, no definite malignancy identified.	An irregularly shaped mass without calcifications should be classified as BI-RADS 4B.

Case No.	Demographics and Clinical presentation	Mammographic or ultrasound findings	Histopathological findings	Reasons for discordant findings
4	42-year-old female with a palpable mass located at the 10 o'clock position of the right breast	- Mammography: No suspicious abnormalities detected. - Ultrasonography: Interval growth of a macrolobulated mass with peripheral vascularity at the corresponding location, now 3.2 x 1.6 cm (previously 2.4 x 1.5 cm).	US-CNB: Fibroepithelial lesion, suggestive of fibroadenoma.	- The sonographic findings of a solid, hypoechoic mass with a macrolobulated margin correspond with BI-RADS 4A-B. - Prior ultrasounds showed variability in the reported size of the right mass at the corresponding site. These fluctuations most likely represented measurement variability rather than a true change and could have contributed to the overcategorization.
5	67-year-old female with a palpable mass located at the 12 o'clock position of the right breast	- Mammography: A 3.6 cm isodense mass with popcorn-like macrocalcifications, corresponding to the palpable area. - Ultrasonography: An oval-shaped, hypoechoic mass with internal macrocalcifications at the same location	US-CNB: Initially revealed benign breast tissue, negative for malignancy, with equivocal findings of microcalcifications. A repeated biopsy confirmed benign breast tissue, with stromal microcalcifications.	Benign morphology involving fibroadenoma (typically BI-RADS 2) could justifiably be upgraded to BI-RADS 4A based on age and clinical factors and the lack of prior imaging to confirm stability, but should not have been upgraded to BI-RADS 5.
6	64-year-old female with a palpable mass located at the 12 o'clock position of the right breast	- Mammography: Typical popcorn-like calcification without an associated soft tissue mass at the corresponding position. - Ultrasonography: An oval-shaped, heterogeneous echoic mass with internal macrocalcifications at the same site.	US-CNB: Sclerotic fibroadenoma with stromal calcification, no malignancy.	Benign morphology involving fibroadenoma (BI-RADS 2) was graded as BI-RADS 4A based on age and clinical factors, and the lack of prior imaging to confirm stability. This justified an upgrade to a low-suspicion category.
7	47-year-old female with enlarging palpable mass in the right breast at the 6 o'clock position	- Mammography: A large, well-circumscribed, and hyperdense mass corresponding to the palpable area. - Ultrasonography: A large heterogeneous echogenic mass with internal cystic changes at the same site	US-CNB: Fibroepithelial lesion Excisional biopsy: A benign phyllodes tumor, measuring about 11cm.	A growing, palpable, and large, well-circumscribed, and hyperdense mass with complex cystic features should be categorized as BI-RADS 4B or 4C due to the absence of frank malignant features.

Case No.	Demographics and Clinical presentation	Mammographic or ultrasound findings	Histopathological findings	Reasons for discordant findings
9	54-year-old female with a palpable mass at the 12 o'clock position of the left breast	- Mammography: A focal asymmetry at the palpable area without associated calcification. - Ultrasonography: An indistinct margin, isoechoic mass without posterior acoustic features or abnormal vascular flow at the same site.	US-CNB: Fibrocystic change, no malignancy	An indistinct margin, isoechoic mass corresponding to a palpable focal density on mammography. The mass showed no posterior features or abnormal vascularity. These findings warrant a BI-RADS 4B categorization.
10	64-year-old female with a palpable mass located at the 9 o'clock position of the right breast	- Mammography: A new circumscribed hyperdense mass identified at the corresponding site. - Ultrasonography: A hypoechoic mass with angular margins identified in the corresponding location.	US-CNB: Invasive ductal carcinoma, not otherwise specified	The sonographic findings of a solid, hypoechoic mass with angular margins corresponded with the palpability and mammographic abnormality. These findings should have been categorized as BI-RADS 4C.
11	61-year-old female with a history of left breast cancer, post left modified radical mastectomy, undergoing screening mammography of the right breast	- Mammography: A new irregularly shaped, hyperdense mass with spiculated margin, but without internal calcification at the 12 o'clock position of the right breast. - Ultrasonography: An irregularly shaped, heterogeneous echogenic mass measuring about 1.1 cm at the same site.	US-CNB: Benign breast tissue with increased fibrotic stroma. Excisional biopsy: Angiolipoma with stromal fibrosis.	- An irregularly shaped, hyperdense mass with a spiculated margin is highly suspicious for malignancy. - Benign fibrotic lesions can mimic malignancy and are among the benign lesions that warrant BI-RADS 5 categorization.
12	72-year-old female with a palpable mass at the axillary tail of the right breast	- Mammography: Two irregularly shaped, hyperdense masses with spiculated margins but without internal calcification at the upper outer quadrant of the right breast. - Ultrasonography: Two contiguous, irregularly shaped, and heterogeneously echogenic masses at the same site, corresponding to the findings on mammography, with associated enlarged right axillary lymph nodes.	US-CNB: Fibroadipose tissue with chronic inflammation. Wide excisional biopsy: Focal lymphoid infiltration with fibrotic stroma, suggestive of lymphocytic mastitis.	- Irregularly shaped hyperdense masses with spiculated margins and associated lymphadenopathy are highly suspicious for malignancy and warrant a BI-RADS 5. - Benign inflammation lesions with fibrosis can mimic malignancy and are among the benign lesions that warrant BI-RADS 5 categorization.

US-CNB: Ultrasound-guided core needle biopsy technique.

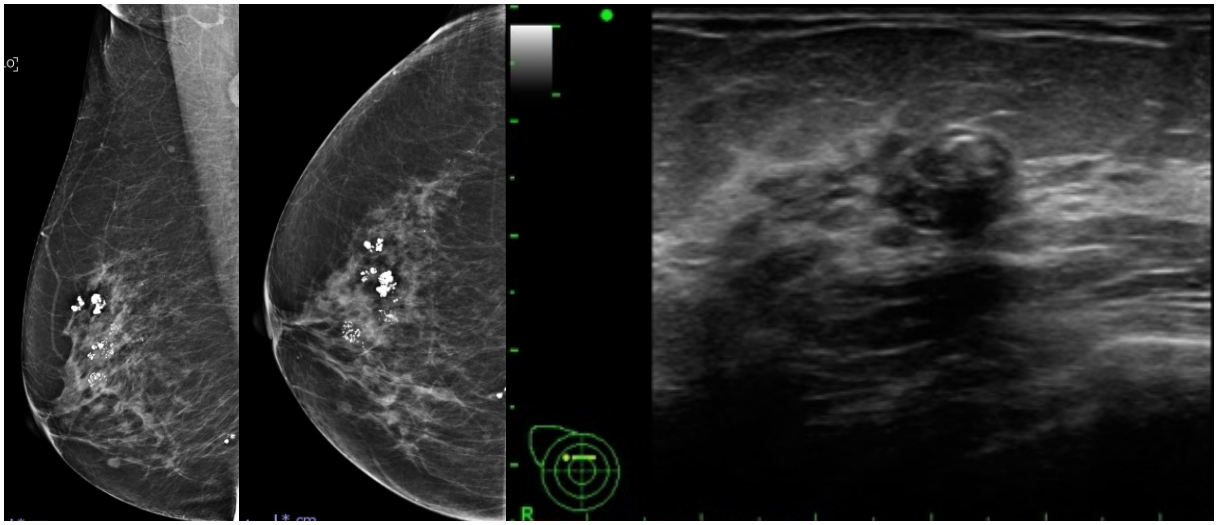

Figure 1. *Images from case no. 6 show an overcategorization to BI-RADS 5 of a calcified lesion which should have been at most BI-RADS 4A.*

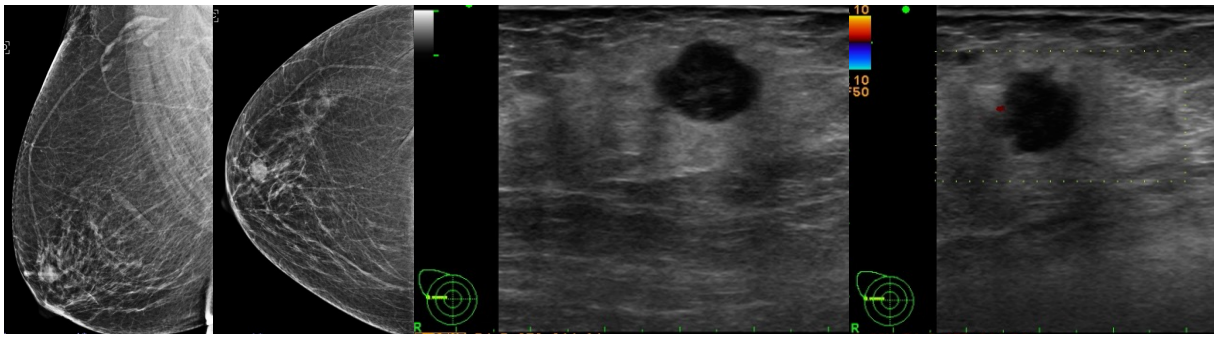

Figure 2. *Images from case no. 10 show an overcategorization to BI-RADS 5 of a non-calcified lesion which should have been at most BI-RADS 4A.*

Figure 3. *Images from case no. 11 show a benign fibrotic mass with malignant features, which correctly warranted a BI-RADS 5 categorization.*

Discussion

The present study found that the observed positive rates were mostly in agreement with the BI-RADS 2013 recommendation, except for the BI-RADS 5 category, which showed overcategorization. This overcategorization happened due to 1) benign masses with associated calcification, 2) inadequacies in lesion measurement or technical limitations, 3) fibrosis changes mimicking malignancy, and 4) overcalling a benign-looking mass that turned out to be cancerous.

Similar to some previous studies in Thailand [8-10], the present study highlighted the risk of overcategorization and its clinical consequences. Enhanced radiologic-pathologic correlation, cautious use of BI-RADS 5, and adherence to standardized criteria may help optimize diagnostic accuracy and reduce unnecessary interventions.

On the other hand, the recognition that a small proportion of BI-RADS 5 lesions may yield benign pathology is inevitable. The present study describes two cases of acceptable false positive BI-RADS 5 categorizations. Thus, the awareness that some BI-RADS 5 patients do not have malignancy is crucial to avoid repeated investigations.

Another possible explanation for the low observed positive rate in BI-RADS 5 cases was that we only included patients who underwent biopsies by radiologists, whereas patients with frank, palpable masses and thus higher likelihoods of cancer had been biopsied by surgeons.

Various studies have similarly shown overcategorization [8-11] while some others have shown under-categorization [12, 13]. This shows that there is still a need for continuous quality improvement and breast imaging practice and training, with awareness and considerations for local factors that contribute to the discordance.

The strengths of the present study include a detailed evaluation of BI-RADS 4 subcategories and an exploration of causes of overdiagnosis in BI-RADS 5 lesions. Limitations include the exclusion of biopsies performed by surgeons and the retrospective nature of the study. Future research should focus on refining imaging criteria to improve specificity and further evaluating challenging entities such as masses with calcifications or lesions with inadequate measurement. The addition of other imaging modalities and their effects on diagnostic accuracy can prove to be a fruitful direction for future research as well.

Conclusion

In the present study, the PPVs for BI-RADS 4 lesions were within the expected range, whereas for BI-RADS 5 lesions, the PPV was 89%, which is slightly lower than the expected likelihood. Overcategorization was responsible for most of the discordant cases. Continuous auditing and updating of mammographic accuracy remain essential to enhance early detection and reduce breast cancer mortality.

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