Biopsy Rate and Positive Predictive Value for Breast Cancer in BI-RADS Category 4 Breast Lesions

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Objective: *To examine the biopsy rate and positive predictive value (PPV) for breast cancer in lesions categorized as BI-RADS (Breast Imaging reporting and Data System) category 4.*

Material and Method: *The medical records of patients with BIRADS 4 breast lesion diagnosed at the breast diagnostic center, Ramathibodi Hospital between December 1, 2004 and December 31, 2005 were retrospectively reviewed. PPV was calculated for patients who had biopsy performed or had clinical follow-up for at least two years. The radiographic and pathological findings were compared.*

Results: *The biopsy rate of 536 lesions categorized as BI-RADS 4 was 75% (403 of 536). Malignancy was found in 95 of 460 patients; or a PPV of 21%, PPVs for subcategories 4A, 4B and 4C, were 9%, 21% and 57%, respectively. The most common malignancy was invasive ductal carcinoma (67%). Patients with advanced age, having a clinically palpable breast mass of large size, with mammographic findings of architectural distortion and asymmetrical density were significantly associated with a higher risk of breast cancer.*

Conclusion: *PPV for malignancy in the present study was comparable to previous studies. In subcategories 4B and 4C, the malignancy rate was higher than that in subcategory 4A.*

Keywords: *Breast cancer, BI-RADS 4, Mammography, Core needle biopsy*

Breast cancer is the second most common cancer in Thai women. In Ramathibodi Hospital, between 2003 and 2005, breast cancer was the most common malignancy found in female patients. Breast cancer screening has resulted in detection of many early cancer and reduction in mortality from the disease. Mammography is an available and effective tool for screening breast cancer.

The Breast Imaging Reporting and Data System (BI-RADS) lexicon[1] was developed in 1993 by the American College of Radiology (ACR) to standardize the terminology used in reporting mammographic findings[2-5]. The lexicon describes the morphology of breast lesions and defines final assessment categories to describe the level of suspicion of breast cancer. The lexicon has improved communication between radiologists and clinicians

and provides quality of patient care[6,7]. This reporting system is used in the Breast Diagnostic and Imaging Center, Ramathibodi Hospital. Table 1 reveals details of BI-RADS category 4A, 4B, and 4C with examples of findings.

In 2003, the fourth edition of BIRADS provided a major addition by sub-categorizing category 4 lesions into those with a small (category 4A), moderate (category 4B), or substantial (category 4C)[1] likelihood of malignancy. This subcategorization better informs the physician and the patient as to the level of concern regarding the lesion and prepares both the physician and the patient for the likely biopsy findings and the potential need for follow-up.

To the authors' knowledge, only one study[4] has provided the positive predictive value (PPV) of category 4 lesions and those of its sub-categories 4A, 4B and 4C. The present study was undertaken to evaluate the rate of biopsy and the PPV's for breast cancer in BI-RADS category 4 breast lesions and subcategories in Ramathibodi Hospital. A secondary

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Table 1. Details of BI-RADS category 4A, 4B and 4C[(1)]

Category	Description
4A (low suspicion for malignancy)	Malignant pathology report not expected and a 6-month or routine follow-up after a benign biopsy or cytology is appropriate. Examples of findings may be a palpable, partially circumscribed solid mass with ultrasound features suggestive of a fibroadenoma, a palpable complicated cyst or probable abscess.
4B (intermediate suspicion of malignancy)	Follow-up with benign result depends on concordance. A partially circumscribed, partially indistinctly marginated mass yielding fibroadenoma or fat necrosis is acceptable, but a result of papilloma might warrant excisional biopsy.
4C (moderate concern, but not classic for malignancy)	A malignant result is expected. Examples of findings are an ill-defined, irregular solid mass or a new cluster of fine pleomorphic calcifications.

objective was to determine the association between clinical, mammographic and US findings and breast cancer.

Material and Method

Between December 1, 2004 and December 31, 2005, 16,848 women underwent screening and diagnostic mammogram at the Breast Diagnostic Center, Faculty of Medicine, Ramathibodi Hospital. Mammography was performed in craniocaudal (CC) and mediolateral oblique (MLO) views with additional spot compression magnification view to clarify suspected lesions by using two mammography machines (Lorads M-IV; Danbury, CT, USA and Senographe DMR; GE, Milwaukee, WI, USA). An additional ultrasonography (HDI 5000; Philips ultrasound, Bothell, WA, USA) of the breasts was performed in almost all patients immediately after mammography, except for cases with almost entirely fatty breasts.

The BI-RADS assessment category is based on the combined results of both mammography and US breasts. Thirteen radiologists, including three radiologists specializing in breast imaging, interpreted the mammograms and sonograms. Final assessment was based on the guidelines from ACR.

During this period, five hundred and thirty-six (536) imaging (3.1%) were assigned BI-RADS category 4. Both screening and diagnostic examinations were included. The present study included both examinations of patients who underwent two mammograms during the study period, if each examination was followed by an intervention procedure.

Each patient's age, clinical findings, imaging findings with category (4A, 4B, or 4C), size of lesions,

details of intervention procedure, pathological report, clinical and imaging re-evaluation in non-biopsy group were retrospectively reviewed. The size of the mass or complicated cyst was estimated from record of the maximum diameter of the mass as measured by either US or mammogram. Pathology was determined by the most worrisome pathology from any kind of biopsy or surgery.

The biopsy rate was calculated from all of the patients who were categorized in BI-RADS category 4. Then, the patients who did not have a biopsy and were followed up less than 2 years were excluded. After that, the prevalence of malignancy was calculated from the remaining 460 patients. If no intervention procedure were performed during the follow-up period for 2 years, it would be defined as false positive examination.

Continuous data were summarized as mean (SD) or median (range) as appropriate. Categorical data were summarized as counts and percentages. The unit of analysis was generally at the level of the imaging study, as any one patient might have more than one lesion or one imaging study. Because relatively few patients had more than one imaging study, correlations between lesional or imaging findings in a given patient with repeated imaging were ignored. The presented statistics were as if all units of analysis were independent. Multiple logistic regression analysis was used to identify clinical and radiological features significantly associated with malignant lesions. More realistic models with clustering around individual patients to allow for correlation between dependent observations as in a random effects logistic regression model or by calculating robust standard errors of the odds ratio estimates did not substantially change the

estimates or their statistical significance. All statistical analyses were performed using Stats v.9 (Stata Corp, College Station, TX, USA). Statistical significance was defined as a p-value of 0.05 or less.

Results

Between December 2004 and December 2005, 536 breast lesions in 520 patients were categorized in BI-RADS category 4. The mean age of the patients at initial imaging was 50.1 years (standard deviation, 9.1 years). Thirty-eight of 520 patients (7%) had a personal history of breast cancer. Palpable masses were noted in 147 patients (28%). The details of indications for mammography are listed in Table 2.

The lesions were classified as category 4A in 281 imaging studies (52%), 4B in 176 (33%), and 4C in 79 (15%). The example of category 4A lesion is demonstrated in Fig. 1A and 1B. Fig. 2A and 2B show mammographic and US features of BI-RADS category 4B lesion. The example of category 4C is shown in Fig. 3A and 3B. The most frequent mammographic finding was mass lesions, which were found in 178 imaging studies (33%), followed by negative finding in mammography in 148 studies (28%).
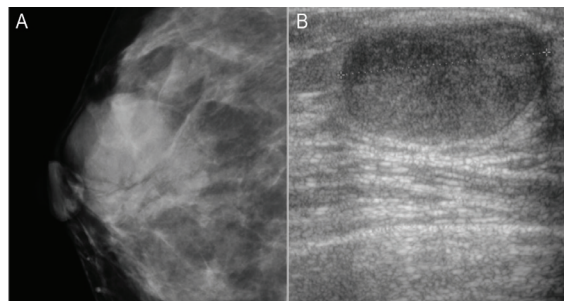
Sonography was able to detect a higher frequency of breast masses both palpable and non-palpable, which were found in 370 studies (69%). The median of size of each mass or complicated cyst from 425 lesions was 1.2 cm (ranged from 0.2 cm to 10.0 cm). Details of mammographic and sonographic findings of BI-RADS category 4 lesions for these lesions are listed in Table 3.

Biopsies were performed in 403 lesions (75%), the mean period from diagnosis and biopsy was 32.9

Fig. 1 The example of category-4A lesion. A 42-year-old female had a palpable mass in the right breast. Mammogram (A) demonstrates a well-defined mass at the right periareolar region. This mass appears on US (B) as a well-defined, heterogeneously hypoechoic mass. Pathology is fibroadenoma with cystic change
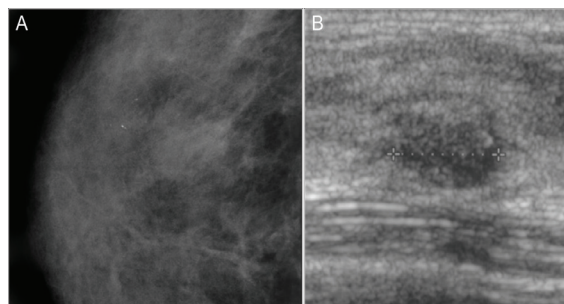
Fig. 2 The example of category-4B lesion. A 37-year-old female had right breast pain. Mammogram (A) demonstrates extremely dense breast with an ill-defined mass containing internal calcifications in the right breast. The additional US (2B) shows a partially indistinct border mass with internal calcifications. Pathology is fibroadenoma
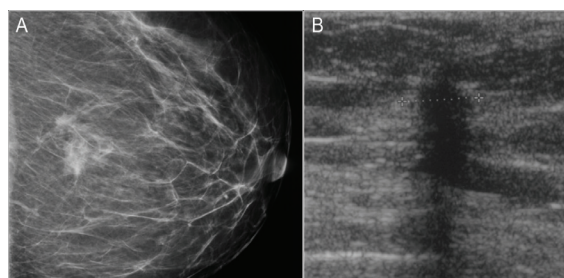
Fig. 3 The example of category-4C lesion. A 62-year-old female had a palpable mass in the left breast. Mammogram (A) demonstrates an ill-defined mass with a tiny spiculated nodule. The US (B) reveals a spiculated hypoechoic nodule with taller-than-wide appearance and posterior acoustic shadowing. Pathology is invasive ductal carcinoma

Table 2. Indications for mammography (n = 521)*

| Indication	Number of imagings (%)
Screening	177 (34%)
Palpable mass	147 (28%)
Follow-up specific lesions	111 (21%)
History of breast cancer	38 (7%)
Breast pain	14 (3%)
Nipple discharge	12 (2%)
Hormonal use	7 (1%)
Skin changes	2 (<1%)
Others (metastatic work up, abscess, to confirm lesion)	13 (3%)

* Indications for mammography did not record in 15 of 536 studies

days (SD 93.6 days, range; 1 to 718 days). Core needle biopsy was done in 63% of the lesions, surgical biopsy in 33%, and fine needle biopsy in 4%.

The most frequent imaging guidance for CNB was ultrasonography, using 87% of lesions, the remaining were biopsied by stereotactic guidance. The median of number of biopsy cores was seven (ranged from 1 core to 8 cores).

There were 95 malignancies of 460 biopsied lesions in the present study (21% PPV for malignancy). Of the 95 lesions 21 (22%) were category 4A, 32 (34%) were 4B, and 42 (44%) were 4C. The PPV according to subcategories 4A, 4B, and 4C were 9%, 21%, and 57%, respectively. The false positive examinations were 73 of 536 lesions (13.6%). The PPV's are summarized in Table 4.

Table 5 shows characteristics of patients with determined cancer status and those with indeterminate status (patients who did not have a biopsy and were followed up less for than 2 years). The median size of the malignant lesions was 1.6 cm (range; 0.6-10 cm). Invasive ductal carcinoma was the most common breast malignancy, found in 64 lesions (67%). Fig. 3A and 3B

Table 3. Mammographic and sonographic findings of lesions categorized in BI-RADS category 4 (n = 536)

Finding	Number of imagings (%)
Mammographic findings	
Mass lesions	178 (33%)
Negative findings	148 (28%)
(detected by US)	
Calcifications	117 (22%)
Asymmetrical density	36 (7%)
Mass with calcification	31 (6%)
Architectural distortion	21 (4%)
Others (trabecular thickening, lymphadenopathy)	5 (1%)
Sonographic findings	
Mass lesions	370 (69%)
Negative findings (detected by mammography)	100 (19%)
Mass & calcifications	21 (4%)
Complicated cyst	21 (4%)
Architectural distortion	7 (1%)
Calcification	4 (1%)
Others (intraductal nodule, lymphadenopathy, thickened and distort duct)	9 (2%)

Table 4. Positive predictive value [malignancy rate] (n = 460)

Category	Number of imagings or lesions (%)
Overall malignancy rate	95 (21%)
Malignancy rate according to BIRADS category	
Category 4A (n = 232)	21 (9%)
Category 4B (n = 154)	32 (21%)
Category 4C (n = 74)	42 (57%)

Table 5. Contrasting characteristics of patients with determined cancer status and those with indeterminate status

Characteristic	Determined status n = 460	Indeterminate n = 76	p-value*
Age (years), mean (SD)	50.0 (9.2)	50.8 (84)	0.498
Indications for mammography; n = 521			
Palpable mass, number (%)	136 (30)	11 (15)	0.005
Other indications, number (%)	310 (70)	64 (85)	
BIRADS category, number (%)			
4A	232 (50)	49 (64)	0.032
4B	154 (34)	22 (29)	
4C	74 (16)	5 (7)	
Mammographic findings, number (%)			
Architectural distortion & asymmetry	50 (11)	7 (9)	0.664
Other findings	410 (89)	69 (91)	
Size of lesion (cm), n = 425			
Mean (SD)	1.59 (1.28)	1.09 (0.56)	
Median (range)	1.2 (0.3 to 10)	1 (0.4 to 2.6)	0.001

* p-values by t-test, Chi-square test and rank test as appropriate

show typical mammographic and US features of BI-RADS category 4C lesion with pathological report of invasive ductal carcinoma. Details of types of malignancies are displayed in Table 6.

In the malignant group, there were mucinous carcinomas in three patients. Mammogram revealed mass, mass with cluster of indeterminated calcification and focal asymmetrical density. The sonographic findings in three lesions were well defined hypoechoic masses, ranging from 0.6 cm to 1.3 cm in size.

Benign pathology was reported in 279 lesions (69%). The most common benign pathology was fibroadenoma, followed by fibrocystic change. Table 7 shows details of benign pathologic results. Twenty-nine high-risk lesions (7%) were found from the pathological report. Twenty-eight (28) lesions or 97% were atypical ductal hyperplasia, and one lesion (3%) was lobular carcinoma in situ (LCIS).

Clinical and radiographic features most strongly associated with the presence of cancer are presented in Tables 8 and 9. Table 8 presents the result of a univariate logistic regression analysis while Table 9 shows a multivariable analysis adjusting for

the effects of all significant features simultaneously. It can be seen from Table 9 that the clinical findings of a palpable breast mass and older age, a higher BIRADS category, larger size of the lesion and the mammographic findings of asymmetrical density and architectural distortion were independently associated with a malignant lesion.

Discussion

The BI-RADS Category 4 classification is associated with a higher risk of malignancy ("suspicious lesion") and a biopsy should be considered. In the present study, 403 of 536 lesions were biopsied, resulting in a 75% biopsy rate. The BIRADS category 4 further divided into subcategories 4A, 4B, and 4C, with an increasing risk of malignancy.

Several studies have assessed accuracy and positive predictive value of the BI-RADS lexicon. A recent study by Zonderland et al[8] revealed a carcinoma in 39 (52.7%) of 74 category 4 lesions. Another study by Orel et al. [9] reports that of 1,312 lesions that underwent mammographically guided biopsy, 449 were cancers. There were 936 (71%) category 4 lesions; the PPV was 30% (279 of 936 lesions). In conclusion, the PPV of BIRADS category 4 lesions in most previous studies [2, 4-6, 8, 9] ranged from 6.2% to 52.7%.

The overall PPV for malignancy in BIRADS category 4 images was 21% (95 of 527 patients), which in the range of previous studies mentioned previously from other institutions and similar to the results of a previous study done in Ramathibodi Hospital in 2001[10]. This is consistent with the PPV's for malignancy in category 3 (2.4%) and category 5 (94%) lesions as previously reported from Ramathibodi Hospital[11, 12].

In the study of Lazarus et al [4], the PPV's of lesions categorized as BI-RADS 4 were as follows: subcategory 4A, six of 102 (6%); sub-category 4B, 17 of 110 (15%); sub-category 4C, 48 of 91(53%).

In the present study, the PPVs according to subcategories 4A, 4B, and 4C were 9%, 21%, and 57%, respectively. The prevalence of malignancy in subcategories 4B and 4C were two and six times higher than that in subcategory 4A (p-value < 0.05). The present study conclusion is that the optional subcategories of 4A, 4B and 4C are useful in stratifying the likelihood of malignancy.

In the group of indeterminate cancer, there is a tendency to have lower probability of breast cancer, which was determined from a lower number of palpable masses, higher proportion of imaging in subcategory

Table 6. Type of malignancies (n = 95)

Type	Number of lesions (%)
Invasive ductal carcinoma (IDC)	64 (67%)
Ductal carcinoma in situ (DCIS)	21 (22%)
Mucinous carcinoma	3 (3%)
Others (malignant phyllodes, malignant lymphoma, invasive lobular carcinoma)	7 (7%)

Table 7. Details of the benign pathology (n = 279)

Type	Number of lesions (%)
Fibroadenoma	86 (31%)
Fibrocystic change	73 (26%)
Adenosis	33 (12%)
Fibrosis	17 (6%)
Benign phyllodes tumor	14 (5%)
Duct papilloma	11 (4%)
Papillomatosis	11 (4%)
Others (inflammation, abscess, TB, focal sclerosis, fibroepithelial, hemorrhagic cyst, hamartoma, capillary hemangioma)	34 (12%)

Table 8. Factors predicting the presence of malignancy in category 4 mammographic lesions (univariable logistic regression)

Factor (n = 460)	Odds ratio	95% CI	p-value
Clinical and imaging characteristics			
Age (per year increase)	1.02	0.99 to 1.05	0.055
Indications for breast imaging (n = 446)			
Screening	1	-	-
Follow-up previously seen lesions	1.22	0.59 to 2.52	0.590
Palpable mass	3.04	1.68 to 5.49	<0.001
Others (see Table 1)	1.59	0.75 to 3.37	0.228
BIRADS category			
4A	1	-	-
4B	2.64	1.46 to 4.77	0.001
4C	13.20	6.49 to 25.1	<0.001
Maximum size of lesion (n = 370)			
Per every log cm. increase	2.09	1.40 to 3.11	<0.001
Mammographic findings			
Negative findings	1	-	-
Mass lesion	3.65	1.69 to 7.89	0.001
Calcifications	2.09	0.86 to 5.07	0.102
Mass and calcifications	7.40	2.69 to 20.4	<0.001
Architectural distortion and asymmetry	8.99	3.77 to 21.4	<0.001
US findings			
Negative findings	1	-	-
Mass lesion	1.88	0.92 to 3.82	0.084
Cysts and complicated cysts	2.23	0.84 to 5.93	0.107
Biopsy and imaging techniques			
Biopsy technique (n = 387)			
Opened biopsy	1	-	-
CNB	0.89	0.54 to 1.42	0.601
FNAB (not estimable; all malignant)	-	-	-
CNB imaging technique (n = 253)			
US-guided	1	-	-
Mammography-guided	0.65	0.26 to 1.67	0.374

Table 9. Factors predicting the presence of malignancy in category 4 mammographic lesions (multivariable logistic regression)

Significant factor (n = 358)	Odds ratio	95% CI	p-value
Palpable mass vs. other indications	2.13	1.10 to 4.14	0.025
Age (per year increase)	1.06	1.02 to 1.10	0.001
BIRADS category (vs. 4A)			
4B	2.58	1.24 to 5.36	0.011
4C	15.60	7.13 to 34.2	<0.001
Size of lesion (per log increase)	1.92	1.11 to 3.31	0.019
Mammographic findings			
Architectural distortion and asymmetry vs. all others	3.54	1.57 to 7.34	0.002

4A and small size of lesion. The authors expected that the PPV's be decreased, if imaging in this group is included.

Independent factors associated with increased probability of breast cancer included age. The older the patient, the greater probability of cancer as would

be expected. A clinically palpable mass had a significantly higher prevalence for malignancy than other clinical findings.

A breast mass was the most common finding on both mammography and sonography. The malignancy rate increased with increased size of mass or complicated cyst on the log scale. A negative finding on mammography was seen in 148 of 521 patients (28%). In this group of patients, ultrasound has a major role in detecting unseen mass lesions. Malignancy was found in 10 from 148 patients (6.7%) in this group from the present study. US has a lower sensitivity for detecting calcifications compared with mammography. Indeed, 89% (89 of 100) of all negative sonographic imaging turned out to have calcifications on mammography. Asymmetrical density and architectural distortion were associated with the highest probability of cancer among all mammographic signs.

The most common type of malignancy was invasive ductal carcinoma. Common benign pathologies included fibroadenoma and fibrocystic change. The most common high-risk lesion was atypical ductal hyperplasia (97%) and lobular carcinoma in situ in the rest. These pathological findings are consistent with previous studies[6-7,11,12].

Core needle biopsy was the preferred biopsy procedure in the present study. With this approach, the patient benefits from less morbidity, improved cosmesis, cost saving and avoiding an unnecessary surgical procedure[11].

Conclusion

PPV for malignancy in the present study was comparable to the previous studies. In subcategory 4B and 4C, malignancy was higher than in subcategory 4A. Architectural distortion and asymmetrical density are statistical significant risk factor of malignant lesion in breast in Ramathibodi Hospital.

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อัตราการเจาะตรวจชิ้นเนื้อและอัตราการเป็นมะเร็งในรอยโรคที่เต้านมที่ได้รับการวินิจฉัยว่าเป็น BI-RADS 4

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วัตถุประสงค์: *เพื่อศึกษาอัตราการเจาะตรวจชิ้นเนื้อ และอัตราการเป็นมะเร็งในรอยโรคที่เต้านมที่ได้รับการวินิจฉัยว่าเป็น BI-RADS 4*

วัสดุและวิธีการ: *ศึกษาข้อมูลผู้ที่ได้รับการวินิจฉัยว่าเป็น BI-RADS 4 ที่ศูนย์วินิจฉัยเต้านม คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี ตั้งแต่ 1 ธันวาคม พ.ศ. 2541 ถึง 31 ธันวาคม พ.ศ. 2542 ได้ทำการศึกษาข้อมูลย้อนหลังด้านคลินิก ลักษณะแมมโมแกรมและอัลตราซาวด์ และผลพยาธิวิทยาหรือติดตามผลการรักษา*

ผลการศึกษา: *มีการเจาะชิ้นเนื้อ 403 จาก 536 รอยโรคที่เป็น BI-RADS 4 พบมะเร็งเต้านม 95 จาก 460 ราย คิดเป็น positive predictive value (PPV) ร้อยละ 21 แยก PPV ตามกลุ่มย่อยได้ดังนี้ ร้อยละ 9 ในกลุ่ม 4A, ร้อยละ 21 ในกลุ่ม 4B และ ร้อยละ 57 ในกลุ่ม 4C มะเร็งชนิดที่พบบ่อยที่สุด คือ invasive ductal carcinoma (ร้อยละ 67) ผู้ป่วยสูงอายุ, คลำได้ก้อนขนาดใหญ่จากการตรวจร่างกาย, มีลักษณะ architectural distortion และ asymmetrical density ในแมมโมแกรม มีความเสี่ยงสูงที่จะเป็นมะเร็งเต้านม*

สรุป: *PPV จากการศึกษานี้สอดคล้องกับการศึกษาอื่น ๆ ที่ผ่านมารอยโรคที่ได้รับการจัดอยู่ใน BI-RADS 4B, 4C มีโอกาสเป็นมะเร็งสูงกว่า 4A กลุ่มที่พบลักษณะ architectural distortion และ asymmetrical density ในแมมโมแกรม มีความเสี่ยงสูงที่จะเป็นมะเร็งเต้านม*