Positive Predictive Value of Breast Imaging Reporting and Data Systems Category 5 in Breast Cancer Diagnosis

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Abstract

- **Objective:** To determine the positive predictive value (PPV) of breast imaging reporting and data systems (BI-RADS) category 5 in the diagnosis of breast cancer.
- Materials and methods: A retrospective study of consecutive women who underwent mammogram and ultrasound at the Diagnostic Breast Cancer Center, Vajira Hospital from January 1, 2015 to December 31, 2019 was performed. Women who were categorized as BI-RADS category 5 (BI-RADS 5) and had pathological diagnosis were enrolled. Clinical information, mammographic and ultrasonographic findings, method of tissue diagnosis, and pathological results were retrospectively reviewed. The PPV of BI-RADS 5 was analyzed.
- **Results:** Of 14,427 women who underwent mammography in the institution during the study period, 208 categorized as BI-RADS 5 and had pathological diagnosis were included. Mean age was 58.9 years (range 34–91 years). Mass was the most common imaging finding in 49% of the 208 women. Breast cancer was found in 202 women (97.1%) and benign pathology in 6 (2.9%). Invasive ductal carcinoma was the most common malignant pathology (85.6%), whereas fibroadenoma was the most common benign pathology (33.3%). The PPV of breast cancer in BI-RADS 5 was 97.1%.
- **Conclusion:** The PPV of breast cancer in BI-RADS 5 was 97.1%. Although the probability of malignancy is very high, preoperative tissue diagnosis before definite treatment is still recommended.

Keywords: predictive value, BI-RADS category 5, breast cancer

ค่าพยากรณ์บวกของมะเร็งเต้านมในรอยโรคกลุ่ม BI-RADS 5

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บทคัดย่อ

้ วัตถุประสงค์: เพื่อศึกษาค่าพยากรณ์บวกของมะเร็งเต้านมในรอยโรคกลุ่ม BI-RADS 5

- **วิธีดำเนินการวิจัย:** เป็นการศึกษาเซิงพรรณาแบบย้อนหลังในสตรีที่ได้รับการตรวจแมมโมแกรมที่ศูนย์วินิจฉัย มะเร็งเต้านมภาควิชารังสีวิทยาระหว่าง 1 มกราคม 2558 ถึง 31 ธันวาคม 2562 เกณฑ์การคัดเข้าคือ สตรีที่ได้รับการรายงานผลตรวจจัดอยู่ในกลุ่ม BI-RADS 5 และมีผลวินิจฉัยทางพยาธิวิทยา ทำการทบทวน ข้อมูลทางคลินิก ลักษณะรอยโรคที่พบจากการตรวจแมมโมแกรม คลื่นเสียงความถี่สูง การพิสูจน์ชิ้นเนื้อ และผลทางพยาธิวิทยา ประเมินค่าพยากรณ์บวกของรอยโรคกลุ่ม BI-RADS 5
- **ผลการวิจัย:** สตรีทั้งหมด 14,427 รายที่ได้มารับการตรวจแมมโมแกรมในช่วงที่ทำการศึกษา พบว่ามีสตรีที่ได้รับ การรายงานผลตรวจจัดอยู่ในกลุ่ม BI-RADS 5 และมีผลวินิจฉัยทางพยาธิวิทยาทั้งหมด 208 ราย อายุเฉลี่ย เท่ากับ 58.9 ปี (พิสัย 34-91 ปี) ลักษณะภาพทางรังสีที่พบมากที่สุดคือ ก้อน เท่ากับร้อยละ 49 ผลพยาธิวิทยา เป็นมะเร็งเต้านมจำนวน 202 ราย (ร้อยละ 97.1) และผลพยาธิวิทยาไม่ใช่มะเร็งจำนวน 6 ราย (ร้อยละ 2.9) มะเร็งเต้านมชนิดที่พบมากที่สุดคือ invasive ductal carcinoma (ร้อยละ 85.6) โดยกลุ่มที่ไม่ใช่มะเร็ง ผลพยาธิวิทยาเป็น fibroadenoma มากที่สุด (ร้อยละ 33.3) ค่าพยากรณ์บวกของมะเร็งเต้านมในรอยโรค กลุ่ม BI-RADS 5 เท่ากับร้อยละ 97.1
- **สรุป:** ค่าพยากรณ์บวกของมะเร็งเต้านมในรอยโรคกลุ่ม BI-RADS 5 ในการศึกษานี้เท่ากับร้อยละ 97.1 ถึงแม้โอกาส เป็นมะเร็งจะสูงแต่ยังคงแนะนำให้ทำการตรวจชิ้นเนื้อก่อนวางแผนการรักษา

คำสำคัญ: ค่าพยากรณ์, กลุ่ม BI-RADS 5, มะเร็งเต้านม

Introduction

Breast cancer is the most common cancer in woman worldwide¹. In Thailand, breast cancer is the most common cancer among women and remains a major public health problem²⁻³. Mammogram is an available and effective tool for screening and diagnosing breast cancer. Mammography is the gold standard for early detection of breast cancer⁴.

The Breast Imaging Reporting and Data System (BI-RADS) was proposed by the American College of Radiology (ACR) and has been used for standard terminology and reporting mammographic findings. ACR BI-RADS atlas 5th edition suggested multimodality evaluation of breast lesion through high-resolution ultrasound (US) or magnetic resonance imaging⁵. BI-RADS category aims to improve the quality of radiology communication, standardize the assessment of imaging findings, communicate with the referring physicians, and to recommend appropriate management in accordance with the level of suspicion malignancy. This reporting system has been used in the radiology report of mammography in Diagnostic Breast Cancer Center Vajira Hospital since 2009. Details of concordance between BI-RADS assessment categories, management recommendations, and the chance of malignancy are described as follows⁵:

Category 0: Incomplete, Need additional imaging evaluation.

Category 1: Negative, Routine screening, Essentially 0% likelihood of malignancy.

Category 2: Benign, Routine screening, Essentially 0% likelihood of malignancy

Category 3: Probably benign, Short interval follow up, >0% but <2% likelihood of malignancy.

Category 4: Suspicious, Tissue diagnosis, >2% but <95% likelihood of malignancy.

Category5: Highly suggestive of malignancy, \geq 95% likelihood of malignancy.

Category 6: Known biopsy proven malignancy, Surgical excision when clinically appropriate.

BI-RADS category is useful in estimating the risk of malignancy, thereby guiding management decisions. BI-RADS category 5 (BI-RADS 5) is highly suggestive of malignancy, i.e., at least 95% chance of malignancy.

The present study aimed to determine the positive predictive value (PPV) of BI-RADS 5 in breast cancer diagnosis. The clinical, mammographic and ultrasonographic findings, method of tissue diagnosis, and pathological results were also determined.

Methods

Approval was obtained from the Ethics Committee of the institution prior to the study. Between January 1, 2015 and December 31, 2019, 14,427 women underwent screening and diagnostic mammography at Diagnostic Breast Cancer Center Vajira Hospital. During this period, 222 women were categorized as BI-RADS 5. Of these 222 women, 14 had no pathological diagnosis and thus were excluded from this study. Therefore, 208 women who had pathological diagnosis were enrolled into this study.

During this period, mammography was performed using full-field digital mammographic equipment (Siemens Mammomat Novation DR, Germany). The institution generally follows the standard practice. Two standard views images, mediolateral obligue and craniocaudal, were obtained with additional views as necessary. Complementary ultrasonography was performed in almost all patients by using 5–14 MHz linear array transducers (GE logiq 9, WI, USA). Mammographic and ultrasonographic studies were interpreted by one of the radiologists in the institution based on the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS).

Patient's age, clinical findings, imaging findings, and pathologic reports were retrospectively reviewed. Data were analyzed using SPSS statistical software, version 26.0. Continuous variable data were summarized as mean with standard deviation or median with range as appropriate. Categorical data were summarized as number and percentage. PPV was calculated and reported as percentage. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM SPSS

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Statistics for Windows, Version 26.0. Armonk, NY, USA: IBM Corp.).

Results

Total of 14,427 women underwent mammography at Diagnostic Breast Cancer Center Vajira Hospital. Exactly 222 women were categorized as BI-RADS 5. Of these 222 women, 208 had pathological diagnosis and were enrolled into this study. The mean age of 208 women who were included in this study was 58.9 years (range 34–91 years). Among indication for mammography, 8 women (3.8%) had screening mammography and 200 women (96.2%) had diagnostic mammography. The most common indication for diagnostic mammography was palpable mass (94.0%). Details of mammographic indications are shown in Table 1.

For the side and position of abnormal breast imaging, this study found that 43.7% had abnormal breast imaging on the right, 53.4% on the left, and 2.9% were bilateral. The most common position was the upper outer quadrant of the breast (58.7%). Among abnormal imaging findings, the most common finding was mass lesion (49.0%), followed by mass with microcalcifications (46.6%). Other findings were axillary lymphadenopathy, skin thickening, nipple retraction, architectural distortion, inflammatory reaction, microcalcifications, and asymmetrical density. Abnormal imaging findings are detailed in Table 2.

Table 1:

Indication for women who had mammography and subsequent pathological result (N=208)IndicationNumber (%)Screening8 (3.8)Diagnostic200 (96.2)Palpable mass188 (94.0)Breast pain6 (3.0)Nipple discharge4 (2.0)Inflammatory breast2(1.0)

Table 2:

Imaging findings of lesions categorized in BI-RADS 5 (N=208)

Finding	Number of patients (%)
Mass	102 (49.0)
Mass with microcalcification	97 (46.6)
Axillary lymphadenopathy	70 (33.7)
Skin thickening	36 (17.3)
Nipple retraction	34 (16.3)
Architectural distortion	34 (16.3)
Inflammatory reaction	7 (3.4)
Microcalcifications	6 (2.9)
Asymmetrical density	1 (0.5)
Note: One subject may have more than one imaging finding. Percentage of imaging finding was obtained from 208 women.	

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Of the 208 women, 202 (97.1%) had malignant pathology and 6 (2.9%) had benign pathology. The most common malignant type was invasive ductal carcinoma (85.6%), followed by invasive lobular carcinoma (5.3%). Among benign pathology, fibroadenoma was the most common benign type, which was found in 2 of 6 women (33.3%). The other benign pathologies were phyllodes tumor, abscess, fibrocystic change, and benign breast tissue with microcalcifications. All pathological results are illustrated in Table 3. Core needle biopsy was the most common method of tissue diagnosis (98.5%), followed by excisional biopsy (1.0%) and fine needle aspiration (0.5%).

In this study, 202 of 208 women with BI-RADS 5 were malignant. The PPV of BI-RADS 5 was 97.1%. Examples of malignant and benign cases in this study are shown in Figures 1 and 2, respectively.

Table 3:

Pathological results found in lesions categorized as BI-RADS 5 (N=208)

Pathology	Number of patients (%)
Malignancy	202 (97.1)
Invasive ductal carcinoma	178 (85.6)
Invasive lobular carcinoma	11 (5.3)
Ductal carcinoma in situ (DCIS)	10 (4.8)
Mucinous carcinoma	1 (0.5)
Poorly differentiated carcinoma	1 (0.5)
Lymphoma involvement	1 (0.5)
Benign	6 (2.9)
Fibroadenoma	2 (1.0)
Phyllodes tumor	1 (0.5)
Abscess	1 (0.5)
Fibrocystic change	1 (0.5)
Benign breast tissue with microcalcification	1 (0.5)



Figure 1: A 57-year-old woman had a palpable mass in the left breast. Mammogram (Figure 1A, B) demonstrated spiculated hyperdense mass with pleomorphic microcalcifications (arrow). This mass appears on US as an irregular solid mass with indistinct border (Figure 1C, D). Note calcifications within the mass (arrowhead). Pathological diagnosis was invasive ductal carcinoma.



Figure 2: A 44-year-old woman presented with a palpable mass in the right breast. Mammogram (Figure 2A, B) demonstrated a large lobulated hyperdense mass occupying almost entirely the right breast with associated pleomorphic microcalcifications at the center of the mass. This mass appears on US as an inhomogeneous solid mass with partially ill-defined border (Figure 2C, D). Pathological diagnosis was benign phyllodes tumor.

Discussion

BI-RADS categorization is useful for predicting breast cancer in female population, and BI-RADS 5 was determined with a high risk of malignancy. Example of mammographic findings placed in BI-RADS 5 was an irregular, spiculated, high-density mass with associated microcalcifications and new fine linear and branching calcifications in segmental distribution.

In this study, the most common presentation of women who were sent to diagnostic mammography was palpable breast mass. The most common imaging finding was mass lesion (49.0%), followed by mass with microcalcifications (46.6%). The imaging findings were similar to those reported in previous studies. Wiratkapun et al.⁶, Muttarak et al.⁷, and Sirikunakorn et al.⁸ also reported mass as the most common finding, being identified in 48.5%, 56.7%, and 62.3%, respectively. Mass with calcifications was identified in 46.6%, which is not significantly different from the 39.2% in the study by Wiratkapun⁶ but higher than the 21.5% and 26.2% in the studies by Muttarak⁷ and Sirikunakorn⁸, respectively. The differences may be explained by the fact that the present study included only breast lesions categorized as BI-RADS 5, which generally have mass and microcalcifications features.

The most common type of malignancy was invasive ductal carcinoma. Invasive ductal carcinoma was found in 85.6% of the subjects, which is not significantly different from the 89.5% in the study by Wiratkapun⁶, 79.2% in the study by Muttarak⁷, and 86.6% in the study by Sirikunakorn⁸. Regarding benign lesions, fibroadenoma was the most common benign lesion (approximately 33.3% or 2 of 6 patients) found in this study. The other benign pathologies were phyllodes tumor, abscess, fibrocystic change, and benign breast tissue with microcalcifications. The benign pathological results were similar to those in previous studies⁶⁻⁹.

The PPV of BI-RADS 5 in diagnosing breast cancer in the present study was very high (97.1%). In fact, it is higher than those in previous studies (81%–97%)⁶⁻¹³. The PPV in this study is compatible with the PPV advocated by the ACR, which proposed a PPV of at least 95% and in the range of previous studies. Although the probability of malignancy was very high, a small number of patients had benign pathologies. This study found that 6 patients (2.9%) presented with lesion initially categorized as BI-RADS 5 and proven benign pathologies on subsequent biopsy. Fibroadenoma was the most common benign pathology encountered in the present study. A false positive case (Figure 2) had

a large lobulated hyperdense mass occupying almost entirely the right breast with associated pleomorphic microcalcifications; thus, this case was categorized as BI-RADS 5. Preoperative biopsy for tissue diagnosis was performed, and pathology result suggested benign phyllodes tumor. Then, this patient underwent right mastectomy, and pathological report indicated that the tumor mass shows features definite for diagnosis of phyllodes tumor. The phyllodes tumors may have large lobulated mass with homogenous or heterogenous echogenicity, which is difficult to differentiate as benign or malignant on the basis of mammographic or ultrasonographic features¹⁴. Although BI-RADS 5 lesions have a high probability of malignancy, a small number of patients had benign pathologies on subsequent biopsy. Preoperative pathologic diagnosis, particularly using percutaneous core needle biopsy, should be performed before definite surgery because of overlapping malignant and benign lesions in some radiological appearances.

In a study on Vajira Hospital, Sirikunakorn⁸ previously reported a 94.8% PPV of BI-RADS 5 in breast cancer diagnosis. A limitation of this previous study was the small number of subjects categorized as BI-RADS 5 (75 women). By contrast, the present study included a larger number of subjects categorized as BI-RADS 5, which could be increase the accuracy of PPV calculation. The PPV in this study was 97.1%, which is compatible with the PPV advocated by the ACR, which proposed a PPV of at least 95%. The PPV of the present study indicated that radiologists can accurately predict breast cancer in a highly suspicious lesion. However, a limitation of the present study was that only one radiologist interpreted the mammographic and ultrasonographic findings. Therefore, the results might be subjected to personal experience and attitude to make a definite diagnosis of BI-RADS 5. Nevertheless, the results of this study might guide radiologists and clinicians to be aware on overlapping in radiological appearances of benign and malignant lesions and help them in their management decisions.

Conclusion

BI-RADS category is useful in predicting breast cancer. The PPV of BI-RADS 5 in this study was 97.1%, which is compatible with the PPV advocated by the ACR and in the range of previous studies. Although the probability of malignancy was very high, a small number of patients had benign pathologies. Preoperative pathological diagnosis is necessary before definite treatment.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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