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ORIGINAL ARTICLE

The performance and role of BI-RADS classification in predicting malignancy in non-palpable breast lesions

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Abstract

Introduction: Breast cancer continues to be a substantial global health concern, constituting a substantial proportion of new cancers diagnosed. Breast Imaging Reporting and Data System (BI-RADS) is a standardised instrument that facilitates the appraisal of lesions in mammographic reporting. A hook wire localisation biopsy (HWLB) is frequently employed to diagnose suspicious microcalcifications or non-palpable lesions. The study aims to ascertain the probability of detecting malignancies in non-palpable breast lesions by examining the malignancy rate detected by BI-RADS classification and HWLB results. *Materials and Methods:* This retrospective study utilised data from patients who underwent HWLB at a tertiary hospital from January 2016 to December 2021. *Results:* Among the 65 patients analysed, 21.5% exhibited malignant lesions, predominantly detected through routine mammogram screening. There was a statistically significant association (p=0.007) between BI-RADS classification and the malignancy status. Using BI-RADS 4A as the threshold ensures 100% sensitivity but leads to a low specificity of 13.73%, Positive Predictive Value (PPV) of 24.1% and Positive Likelihood Ratio (LR+) of 1.2. While increasing the threshold to BI-RADS 4B improves specificity to 80.4%, reducing false positives. This suggests that many BI-RADS 4A cases are actually mostly benign. *Conclusion:* BI-RADS 4A notably exhibited a high false-positive rate, possibly due to benign lesions mimicking cancer radiologically and the operator-dependent nature of radiology. Despite these constraints, findings affirm the crucial role of hook wire localisation biopsy and BI-RADS classification in evaluating non-palpable breast lesions.

Keywords: *Breast Cancer, BI-RADS Classification, Hook Wire Localisation Biopsy, Non-palpable Breast Lesions, Malignancy Detection*

INTRODUCTION

The worldwide burden of cancer incidence and mortality, including female breast cancer, continues to rise, primarily due to population growth, ageing demographics, and the adoption of Western lifestyle behaviours that are associated with elevated cancer risk.[1] The incidence of breast cancer also has been steadily rising over the years, attributed to various factors including lifestyle changes, increasing life expectancy, improved cancer detection and reporting mechanisms. Data indicate a rising trend in breast cancer incidence in Malaysia, particularly among younger women. This trend may be influenced by shifting demographics, changes in reproductive patterns, and lifestyle factors such as obesity, lack of physical activity, and dietary habits.[2]

Breast cancer is the most frequently diagnosed cancer in women, with an expected 2.3 million new cases identified globally in 2020 alone.[3] Breast cancer remains the leading cause of cancer-related deaths among women worldwide, despite advances in detection and treatment. Mortality trends vary by region, influenced by access to healthcare, screening, and treatment. Early detection is key to prevention.[4]

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Mammography is a screening technique that is particularly useful since it uses low-energy X-rays to produce high-resolution images of the breast. There is no need to utilise any contrast-enhancing medications, and the complete diagnostic procedure usually takes less time.[5] Magnetic resonance imaging (MRI) is another often used test for breast cancer screening. It is superior to mammography in terms of sensitivity, especially for women who are at high risk, and it is quite reliable at identifying invasive ductal carcinoma.[6] MRI has advantages over mammography in the identification of occult primary breast cancer, axillary nodal metastases, residual tumours following neoadjuvant chemotherapy, and other tiny cancers since it is not affected by breast density.[6]

The American College of Radiology (ACR) introduced the Breast Imaging Reporting and Data System (BI-RADS) in 1993 with the goals of standardising mammographic reporting, improving communication, lowering uncertainty about results, assisting research endeavors, and making outcomes tracking easier. The latest version in 2013 includes a total of 6 classifications. An incomplete evaluation (category 0) and completed assessments (categories 1 through 6) make up the BI-RADS classifications. BI-RADS 1 (negative) and 2 (benign) have an essentially 0% likelihood of malignancy, while BI-RADS 3 (probably benign) has a very low risk and requires short-term follow-ups or additional imaging. Suspicious categories, BI-RADS 4 and 5, indicate a higher malignancy risk (>2% to >95%) and need tissue diagnosis, while BI-RADS 6 represents biopsy-proven malignancy requiring surgical intervention.[7]

Many screening-detected abnormalities are non-palpable lesions, so methods are required to mark their position prior to surgery. Non-palpable breast lesions have commonly been localised using hook wires, placed either under ultrasound or stereotactic guidance.[8]

Hook wire localisation biopsy (HWLB) plays a crucial role in the management of non-palpable breast lesions by providing accurate localisation guidance for surgeons. In cases where lesions are not palpable during physical examination, precise localisation is essential to ensure complete surgical excision with optimal cosmetics and minimal morbidity. HWLB enables radiologists to precisely mark the target area within the breast tissue, facilitating the identification and removal of the lesion during surgery.[9]

A breast biopsy yields useful prognostic data that guides long-term care and patient counselling. Tumour size, histological grade, lymphovascular invasion, and the existence of lymph node metastases are examples of histopathological criteria that are prognostic indicators that affect the course of the disease and the effectiveness of treatment. Furthermore, biomarkers like the Ki-67 proliferation index and genetic changes (such BRCA1/2 mutations) can be used to further classify individuals into risk groups and inform individualised treatment plans.[10]

This study aims to assess the association between BIRADS classification and the final histopathological examination (HPE) in non-palpable breast lesions for early malignancy detection.

MATERIALS AND METHOD

Study design

This retrospective study was carried out at a tertiary hospital, Hospital Tuanku Jaafar, Seremban, Negeri Sembilan involving archived histopathological examination biopsy reports from patients who had undergone HWLB from January 2016 to December 2021.

Sampling Technique and Data Collection

Collected data include demographic details (age and ethnicity, clinical information (indications and presenting symptoms)) and radiology (mammography and/or ultrasound) imaging reports with their respective BI-RADS classification. This study used a purposive sampling method. Sample list was obtained through search of archived HWLB reports through Laboratory Information System (LIS) and HPE registration book. Out of 109 cases, 44 were excluded due to incomplete clinical information, leaving 65 cases for inclusion in the study.

Data Analysis

IBM SPSS Statistics for Windows, Version 29.0 (IBM Corp., Armonk, NY, USA). Standard computation of sensitivity, specificity, positive likelihood ratio and accuracy were used. When a radiologically suspicious lesion (BI-RADS 4 and 5) is confirmed to be malignant, it is classified as a true positive result. Conversely, if the biopsy is benign despite this, it is considered a false positive result. On the other hand, if a lesion is radiologically deemed probably benign (BI-RADS 2 and 3) but is later found to

be malignant, it is labelled as a false negative result. Finally, if the lesion is both radiologically and pathologically confirmed to be benign, it is categorised as a true negative result. Fisher's exact test was used to determine the correlation between histopathological examination obtained by HWLB and radiological classification (BI-RADS). A probability value (p-value) of less than 0.05 was regarded as statistically significant. The study was conducted in full accordance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline.

Ethical Approval

An ethical approval was obtained from the Medical Research and Ethics Committee of the Malaysian Ministry of Health (MREC) before the commencement of the study (Ref.No.: NMRR ID-22-02773-S94 (IIR)).

RESULT

Clinicopathological Parameters and Histological Features

There was a total of 65 patients with non-palpable breast lesions that underwent HWLB at Hospital Tuanku Jaafar Seremban from January 2016 until December 2021, that meet the study criteria. Most of the patients with non-palpable breast lesions were detected through a routine Malaysian mammogram screening programme (49.2%). While others were presented as mastalgia (20%), nipple discharge (10.8%), breast engorgement (10.8%) and as surveillance for contralateral breast cancer (9.2%) (Fig 1).

Forty-nine localisation biopsies were performed under ultrasound guidance, while 16 localisation biopsies were performed using the mammogram-guided technique. The non-palpable lesions included in this study range from BI-RADS 2 to 5. There are no BI-RADS 1 or 6 lesions in this study. Table 1 summarises the frequency of diagnoses obtained from the studied HWLB samples and their malignancy status. The commonest non-palpable malignant diagnosis was ductal carcinoma in situ (DCIS), accounting for 57.1%, followed by invasive carcinoma of no special type (NST) of 28.6%. Other malignant cases were solid papillary carcinoma (1.7%) and encapsulated carcinoma (1.7%). Fibrocystic change was the most common benign non-palpable breast diagnosis (29.4%). The second most frequently encountered non-palpable breast lesions were atypical ductal hyperplasia (21.6 %) followed by fibroadenoma (13.7%). Other lesions in this category were intraductal papilloma, sclerosing adenosis and microglandular adenosis, of 13.7%, 7.8% and 3.9%, respectively.

Association of Malignancy Status with Radiological Classification and it's Demographic Parameters

Table 2 shows the BI-RADS classification of non-palpable breast lesions: 78.4% of cases have varying levels of malignancy concern (60% BI-RADS 4A, 9.2% BI-RADS 4B, 9.2% BI-RADS 4C, 10.8% BI-RADS 5), while 10.8% are benign or probably benign (6.2% BI-RADS 2, 4.6% BI-RADS 3).

Benign cases were more common in ages 40-59, while malignancies were more frequent in older groups. Malays and Indians had more benign cases, while Chinese participants had an equal distribution, but these differences were not significant. The p-values for age (0.184) and ethnicity (0.314) indicate no significant differences between benign and malignant cases. Similarly, BI-RADS classification by age and

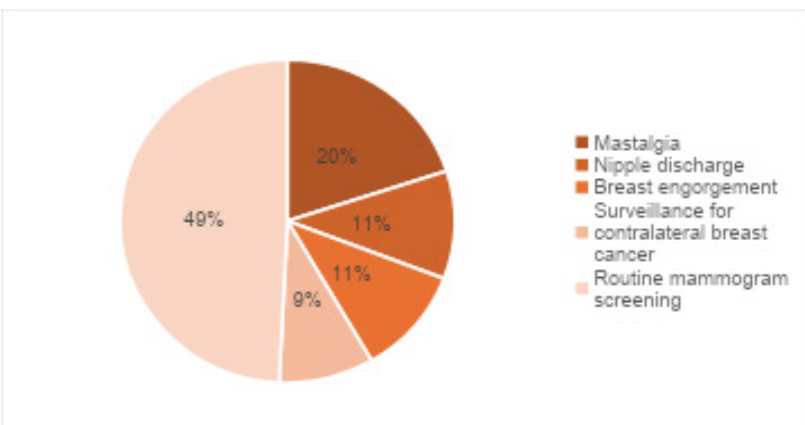

FIG 1. Presenting symptoms and detection of non-palpable breast lesions.

TABLE 1: Malignancy status and diagnosis of hook wire localisation biopsy (HWLB) samples from non-palpable breast lesions

Diagnosis	Benign n (%)	Malignant n (%)
Fibrocystic change	15 (29.4)	
Atypical ductal hyperplasia (ADH)	11 (21.6)	
Fibroadenoma	7 (13.7)	
Intraductal papilloma	5 (9.8)	
Sclerosing adenosis	4 (7.8)	
Usual ductal hyperplasia (UDH)	4 (7.8)	
Micro glandular adenosis	2 (3.9)	
Atypical lobular hyperplasia (ALH)	1 (2.0)	
Adenosis with microcalcification	1 (2.0)	
Lymphocytic mastopathy	1 (2.0)	
Ductal carcinoma in situ (DCIS)		8 (57.1)
Invasive carcinoma (no special type)		4 (28.6)
Encapsulated papillary carcinoma		1 (7.1)
Solid papillary carcinoma		1 (7.1)
Total	51 (100)	14 (100)

ethnicity showed no significant differences (p = 0.368 and p = 0.350), as shown in Table 3.

The distribution of benign and malignant cases across BI-RADS categories was analysed (Table 4). BI-RADS 2 and 3 had only benign cases, while malignancy rates were 12.8% in 4A, 16.7% in 4B, 50.0% in 4C, and 71.4% in 5, with an overall malignancy rate of 21.5%. The p-value of 0.007 indicates a significant difference, showing that malignancy risk increases with higher BI-RADS categories.

TABLE 2: The BI-RADS categories of patients with non-palpable breast lesions who underwent hook wire localisation biopsy (HWLB)

BI-RAD Categories	N = 65, n (%)
2	4 (6.2)
3	3 (4.6)
4A	39 (60)
4B	6 (9.2)
4C	6 (9.2)
5	7 (10.8)

Diagnostic Performance of Radiological Classification in Detecting Malignancy

Table 5 summarises the diagnostic performance of different BI-RADS thresholds for detecting malignancy in non-palpable breast lesions. When BI-RADS 4A is used as the threshold, the test has high sensitivity, meaning it successfully identifies almost all cases of malignancy. However, the specificity is low (13.73%), which means that many benign lesions are incorrectly flagged as suspicious, resulting in a high rate of false positives. As a result, the Positive Predictive Value (PPV) is only 24.1%, indicating that, even with a positive result, there's only a 1 in 4 chance that the lesion is malignant. The Positive Likelihood Ratio (LR+) is 1.2, which is relatively low, meaning a positive result only slightly increases the likelihood of malignancy, suggesting that further testing is required to confirm cancer.

As the threshold is raised to BI-RADS 4B and above, specificity improves, meaning there are fewer false positives, and PPV increases to 47.3%, meaning nearly half of the positive results are cancerous. The LR+ of 3.3 indicates that a positive result increases the likelihood of malignancy by about 3 times, making further diagnostic steps more important.

TABLE 3: The association between age and ethnicity with BI-RADS Classification in the non-palpable breast lesions

	BI-RADS Classification n (%)							
	2	**3**	**4A**	**4B**	**4C**	**5**	**Total**	**p value**
Age								
30-39			4 (100)				4 (100)	
40-49	2 (8.7)	3 (13.0)	13 (56.5)	1 (4.3)	2 (8.7)	2 (8.7)	23 (100)	
50-59	2 (8.7)		11 (47.8)	5 (21.7)	3 (13.0)	2 (8.7)	23 (100)	0.368
60-69			11 (78.6)		1 (7.1)	2 (14.3)	14 (100)	
70-79								
80-89						1 (100)	1 (100)	
Ethnicity								
Malay	3 (7.5)	2 (5.0)	21 (52.5)	6 (15)	5 (12.5)	3 (7.5)	40 (100)	
Indian	1 (5.3)	1 (5.3)	13 (68.4)			4 (21.1)	19 (100)	0.350
Chinese			5 (83.3)		1 (16.7)		6 (100)	

When the threshold is set to BI-RADS 4C and 5, specificity continues to improve, reducing false positives even further, but sensitivity drops, meaning some cancers may be missed. The PPV increases to 61.5%, suggesting a stronger likelihood of malignancy, and the LR+ of 5.8 shows a significant increase in the likelihood of cancer, indicating that biopsy is necessary.

Finally, for BI-RADS 5, the PPV is 71.4%, meaning most positive results will be malignant, and the LR+ of 9.1 strongly supports malignancy, making biopsy essential for confirmation. Clinicians can use these combined measures to prioritize which lesions to biopsy, ensuring that cancerous lesions are promptly identified while minimising unnecessary procedures for benign lesions.

DISCUSSION

In this group of patients, HWLB revealed a positive malignancy rate of 21.54% among 65 cases, aligning closely with the 18.1–32% range observed in existing literature.[9,11,12] Masroor *et al*.[11] studied 151 patients with non-palpable breast lesions and reported a malignancy rate of 25.16%. Another study with 83 patients found a

TABLE 4: The distribution of benign and malignant cases across BI-RADS categories

		Malignancy status			
		Benign n (%)	**Malignant n (%)**	**Total n (%)**	***p value***
BI-RAD Categories	2	4 (100)		4 (100)	
	3	3 (100)		3 (100)	
	4A	34 (87.2)	5 (12.8)	39 (100)	
					0.007
	4B	5 (83.3)	1 (16.7)	6 (100)	
	4C	3 (50.0)	3 (50.0)	6 (100)	
	5	2 (28.6)	5 (71.4)	7 (100)	
Total		51 (78.5)	14 (21.5)	65 (100)	

TABLE 5: Sensitivity, specificity, Positive Predictive Value (PPV) and Positive Likelihood Ratio (LR+) of BI-RADS categories for detecting malignancy in hook wire localisation biopsy (HWLB)

BI-RAD Categories	Sensitivity (%)	Specificity (%)	PPV	LR+
4A and above (4A, 4B, 4C, 5)	100	13.7	24.1	1.2
4B and above (4B, 4C, 5)	62.5	80.4	47.3	3.3
4C and above (4C, 5)	57.1	90.2	61.5	5.8
5	35.7	96.1	71.4	9.1

rate of 18.1%.[9] This falls between the 19% and 32.2% reported by Schwartz *et al*.[12] and Denning *et al*.[13], respectively. The association between BI-RADS classification and malignancy status in this study was statistically significant (p = 0.007), indicating that the risk of malignancy increases with higher BI-RADS scores. A higher BI-RADS score indicates a greater likelihood of malignancy on histopathological examination. This is especially evident in categories 4C and 5, where malignant cases are more prevalent, while categories 2 and 3 are entirely benign. These findings highlight the need for vigilant monitoring in higher BI-RADS categories due to their stronger association with cancer.

Even with the widespread implementation of the BI-RADS category in the reporting of ultrasound and mammograms across healthcare institutions in Malaysia, there is a notable scarcity of studies assessing the performance achieved in the country.[14] When using BIRADS 4A as the threshold for suspicious lesions, as recommended by the ACR, it achieves a sensitivity of 100%, effectively identifying all cancer cases in non-palpable breast lesions. However, its specificity is low at 13.73%, leading to frequent false positives. While the BIRADS 4A category serves as a useful screening tool, its PPV is 24.1%, highlighting the critical need for biopsy confirmation.

Alternatively, if BIRADS 4B were considered the threshold for suspicious lesions, the specificity would notably increase to 80.4% from 13.73%. This implies that a significant portion of cases categorised in BIRADS 4A are benign, resulting in a considerable number of false positives. One possible reason is that benign breast lesions can sometimes mimic cancer radiologically, posing challenges in accurate diagnosis. Various benign conditions share imaging features with malignant tumours, making it important to carefully evaluate and differentiate between them. For example, both benign and malignant lesions can exhibit microcalcifications on mammograms. Benign conditions like fibroadenomas or calcifications related to inflammation may resemble those associated with cancer. Another example, certain benign conditions, like radial scars or complex sclerosing lesions, can cause architectural distortion on mammograms, mimicking the distortion seen in some malignant cases.[15] In our study, there are 39 cases within 4A categories. Only 5 from it are malignant cases, whereas 34 cases showed benign results. The benign cases include mostly fibrocystic changes (35.9%), followed by ADH (12.8%), fibroadenoma (10.3), intraductal papilloma (10.3), sclerosing adenosis (7.7%) ALH (2.6%), adenosis with microcalcification (2.6%) and microglandular adenosis (2.6%). The malignant cases were DCIS (7.7%) and invasive carcinoma (5.1%)

Radiological findings remain operator-dependent, with the interpretation of images being influenced by the skills and expertise of the radiologist. In our study, fibrocystic change (FCC) is the most common cause of false positives for malignancy. Mammography face challenges in providing a reliable diagnosis for FCC due to its diverse imaging presentations. When FCC manifests as a discrete mass or density, it can closely mimic breast cancer on mammograms.

ADH emerges as the second most identified benign entity. ADH carries an increased risk of breast cancer, albeit not a precursor lesion. The key distinction lies in the fact that the heightened risk of breast cancer associated with ADH can manifest anywhere in the breasts, rather than being confined to the area of the ADH itself.[16] Radiologically, ADH typically presents as clusters of microcalcifications. Sonographically, ADH bears resemblance DCIS, featuring a microlobulated mass with mild hypoechogenicity and lacking acoustic enhancement or shadowing.[17]

Another commonly diagnosed benign pathology in non-palpable breast lesion is fibroadenoma. Although fibroadenoma is commonly presented as palpable breast lesion, 25% of fibroadenoma are non-palpable and can be detected with mammogram and ultrasound.[18] Namazi *et al*.[19] conducted a cross-sectional study on female patients with a confirmed histologic diagnosis of fibroadenoma. Ultrasound examinations were performed to identify common sonographic patterns in these lesions. Among 92 patients (mean age 40.4 ± 9.2 years), all were classified as BI-RADS stage 4.[19] The study found that the most frequent features of fibroadenomas included a hypoechoic mass with a circumscribed border. However, complex presentations that overlapped with malignant masses were also detectable, such as non-circumscribed margins, lobulation, presence of a posterior shadow, heterogeneity, and microcalcifications.[19]

Two benign cases were categorised as BIRADS 5 and were reported as atypical ductal hyperplasia with microcalcification and diabetic mastopathy. Guirguis *et al*.[15] have categorised conditions that mimic breast cancer radiologically into three categories: inflammatory breast disorders, proliferative breast conditions, and benign breast tumours. Granulomatous mastitis, diabetic mastopathy, infectious mastitis and breast abscess are examples of benign inflammatory breast diseases that can mimic cancer. Less often occurring inflammatory illnesses involving the breast include sarcoidosis, amyloidosis, granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis), Churg-Strauss syndrome, and other connective tissue disorders. Proliferative breast disorders such as sclerosing adenosis, stromal fibrosis, and fat necrosis can also mimic cancer. Granular cell tumour, desmoid fibromatosis, hamartoma, pseudoangiomatous hyperplasia, and tubular adenoma are other examples of benign tumours that mimic malignancy.[20] This highlights the need for careful histopathological evaluation and differentiation of these conditions, even with a high BI-RADS category, to prevent misclassification and ensure proper patient management.

CONCLUSION

HWLB remains a critical procedure for the early diagnosis of malignancy in non-palpable breast lesions. A malignancy rate of 21.54% found in this study aligned with existing literature. This underscores the critical need for imaging and biopsy to identify malignancies that might otherwise be missed. Vigilant assessment, particularly of lesions classified as BI-RADS 4B or higher, is essential, as higher BI-RADS categories are strongly associated with malignancy. Combining imaging with targeted biopsy enhances diagnostic accuracy and facilitates earlier cancer detection. In this study, the malignancy rate detected among those who underwent routine mammogram screening alone is 33.3% (8 out of 24 patients) which reflects the effectiveness of this routine mammography programme in identifying malignancies among asymptomatic individuals with non-palpable lesions. It also underscores the prevalence of benign findings in such screenings, which is common in asymptomatic patients. Early detection through mammography enables timely interventions and improves patient outcomes, especially for tumours that might otherwise remain undetected during physical examination. The variability in radiologists' interpretations also highlights the potential role of AI and machine learning in radiological image analysis. These technologies can improve consistency, minimise human error, and assist in complex cases, such as those involving fibrocystic changes or atypical ductal hyperplasia. Despite the challenges posed by benign conditions that can mimic malignancy, a multidisciplinary approach involving radiologists, pathologists, surgeons, and oncologists is crucial. Collaborative efforts ensure accurate diagnoses, timely interventions, and optimal patient outcomes. Effective communication among team members streamlines care and enhances management of non-palpable breast lesions.

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Informed consent Statement: Informed consent was waived due to the retrospective nature of the study, which utilized archived histopathological examination biopsy reports and anonymised clinical data.

Author(s) contribution: Conceptualization; formal analysis; writing; review and editing; supervision; final approval of the manuscript. All

authors have read and agreed to the published version of the manuscript.

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