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Original Article

Correlation and Diagnostic Accuracy between Clinical Manifestation and Ultrasound BI-RADS Scoring Finding with Pathological Findings for Breast Disease Among Women in Sulaymaniyah Governorate, Iraq

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Abstract

Background: The Breast Imaging-Reporting and Data System (BI-RADS) is a crucial tool for assessing and categorizing breast lesions, particularly breast lumps.

Objective: To assess the correlation and diagnostic accuracy between clinical manifestation and ultrasound BI-RADS scoring findings with pathological findings for breast disease among women. Furthermore, it also assesses the sensitivity and specificity of clinical and ultrasonographic findings in breast lesions at the Sulaimani Breast Disease Treatment Center.

Materials and Methods:
A cross-sectional study was conducted at the Sulaimani Breast Disease Treatment Center to evaluate 250 female patients with breast lesions from January 2023 to February 2025. In this study, the association between American College of Radiology - Breast Imaging-Reporting and Data System (ACR-BIRADS) results and histopathology reports was evaluated using the chi-square test.

Results: The mean age was calculated as 46.8 $\pm$ 11.6 years. Amongst the total, 104 (41.6%) and 63 (24.9%) of all breast lesions were in the range of BIRADS 3 and 5, respectively. Furthermore, 133 (53.2%) of the breast lesions amongst the total 250 were malignant, with the remaining 117 (46.8%) lesions being benign on histopathology. Diagnostic accuracy, sensitivity, and specificity for ultrasound BI-RADS turned out to be 90.8%, 86.5%, and 95.7%, respectively. The correlation between the ACR-BI-RADS system and histopathology results was found to be highly significant.

Conclusion: High sensitivity and specificity are demonstrated by BI-RADS-guided ultrasound in differentiating benign from malignant breast tumors. While it aids early detection of malignancy and reduces unnecessary biopsies, BI-RADS cannot replace histopathology as the diagnostic gold standard.

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1. Introduction

Breast lumps are a common issue for women seeking medical attention. Although most are often benign lumps, their presence can still result in anxiety due to the potential cancer concerns. Therefore, it is the surgeon's primary aim to provide a comprehensive, effective, and prompt consultation to reduce anxiety, rule out cancer, and provide an accurate diagnosis and suitable treatment plan. Triple evaluation, encompassing clinical examination, imaging, and pathological diagnosis, is a method that can significantly improve the precision of the final diagnosis [1]. If used correctly, triple assessment can yield a sensitivity of 99% [2]. Worldwide, breast cancer (BC) is the most frequent cancer among women and, after lung cancer, the second most common cause of cancer-related death. Globally, differences exist in the incidence of BC, with developed countries having a higher rate (> 80 per 100,000) than developing nations (< 40 per 100,000). Women over the age of 40 are typically affected. Nonetheless, younger women, especially those with a genetic predisposition, can also be impacted [2].

In 1953, Wild and Reid performed the first breast ultrasonography, employing a homemade 15 MHz transducer to detect a 7 mm breast malignancy [3]. Ultrasound enhances mammography by improving lesion detection in dense breasts and distinguishing between cystic and solid masses. It evaluates for lesion size, form, consistency, and echogenicity and detects blood flow parameters and velocity using Doppler ultrasonography. This modality is radiation-free, making it further suitable for women under 30 years old, pregnant, or lactating [4]. The interventional procedure guide includes core needle biopsy, fine needle aspiration, presurgical localization, and axillary lymph node biopsy, with preoperative follow-up details for scheduling operations and neoadjuvant chemotherapy. Although posing many advantages, it is not devoid of drawbacks since microcalcification may be missed during breast ultrasonography reservations, fat and air may obscure the lesion, relatively well-defined malignant masses may be mislabeled as benign isoechoic, and multicentric tumors may veer [5, 6]. In 1993, the American College of Radiology (ACR) announced the Breast Imaging Reporting and Data System (BI-RADS), which aimed at achieving verbal uniformity among radiologists and treating physicians and surgeons to obtain clear, unambiguous, and standard language. BI-RADS's estimation classification ranged from 0 to 6, with 0 indicating the need for additional imaging evaluation, 1 meaning negative, 2 indicating benign findings, and 3 indicating a probably benign finding. The risk of cancer in category 3 is less than 2% with short-interval follow-up. Moreover, class 4 is suspicious of malignancy, wherein in the most recent BIRADS edition, it is further subdivided into subgroups 4a, 4b, and 4c based on the probability of malignancy, with the risks being 2-10%, 11-50%, and 51-95%, respectively. Then, BIRADS 5 is a stage highly suggestive (>95%) of malignancy, this highlights the need for appropriate actions to be taken regarding lesions. BIRADS 3 does not commonly require biopsy, particularly based on clinical requirements, however, for BIRADS 4 and 5, biopsy is needed. Lastly, BI-RADS 6 is known as biopsy-proven malignancy [2, 7].

Sonographic features frequently observed in breast lesions that are benign: smooth and well circumscribed, isoechoic, hyperechoic, or somewhat hypoechoic thin echogenic capsule, ellipsoid shape with the maximum diameter being in the transverse plane, three soft lobulations or less, and lack of any malignant findings [8].

Ultrasound criteria for suspicious breast lesions:

It includes hypoechoic nodular lesions with ill-defined borders, irregular shapes, nonparallel orientation ("taller than broader"), posterior acoustic shadowing, punctate

microcalcifications, and spiculated edges [9].
Breast lesions are diagnosed using triple assessments, with core needle biopsy (CNB) and fine-needle aspiration cytology (FNAC) being the most common methods. In the past, FNAC was preferred due to its lack of pain, cost, availability, and low risk of complications. However, since the 1980s, CNB has gained popularity due to its high accuracy. CNB is a popular tool for obtaining information on pathogenic subtype, grade, and receptor status before starting chemotherapy in patients scheduled for neoadjuvant chemotherapy. It differentiates between benign and malignant tumors and invasive carcinoma and in situ lesions, making it increasingly popular [10].
The aim of this research is to determine the correlation and diagnostic accuracy between clinical manifestation and ultrasound BI-RADS scoring findings with pathological findings in the diagnosis of both benign and malignant breast illnesses.

2. Materials and methods

2.1 Study Design and Setting

This analytical cross-sectional study was conducted at the breast disease treatment center in Sulaimani. It evaluates 250 female patients with breast lesions who were obtained between January 2023 and February 2025. Data collection was carried out over a period of three months, from November 2024 to February 2025. The University of Sulaimani's College of Medicine's Ethical Committee approved the project (Approval Number 331, on the committee’s 24th meeting on 13/10/2024) with consent from the directorates of Health-Sulaimani and the Breast Diseases Treatment Center. Participants gave their informed consent after being fully informed about the study's objectives. Convenience sampling was the sampling technique used in this study. Finally, the authors declare that there was no conflict of interest throughout the embodiment and drafting of this study.

2.2 Sample Size Calculation

The sample size was calculated based on an estimated prevalence of 10%, a 95% confidence level (Z = 1.96), and a 5% margin of error, resulting in a required sample size of approximately 139 participants. After adjusting for a 10% anticipated non-response rate, the final required sample size was increased to 154. A total of 250 patients were included in this study, exceeding the minimum sample requirement and thereby strengthening the study’s power and precision.
Patients were selected consecutively based on the inclusion criteria within the specified timeframe to reduce the risk of selection bias. All eligible female patients who presented during the study period and met the criteria were included, ensuring a comprehensive and unbiased sample.

2.3 Inclusion and Exclusion Criteria

Inclusion criteria for this study were female patients of all ages who had undergone both breast imaging (with documented BI-RADS scores) and pathological examination (FNAC, core needle biopsy, or excisional biopsy) at the Sulaimani Breast Disease Treatment Center, with complete medical records available, including clinical and diagnostic results.
Exclusion criteria included male patients, patients with incomplete or missing data, patients with previous treatments or surgeries affecting current diagnostic outcomes, and cases without documented BI-RADS scores or pathological results.

2.4 Data Acquisition and Variables

The study involved patients referred for sonography after obtaining a complete medical history and examining their breasts for breast lumps. Three skilled sonographers in the radiodiagnosis department performed ultrasound examinations and interventions on the breast using Samsung H60 models and a linear transducer with a 40 mm width and 3-14 MHz frequency. The images were classified as benign or malignant based on the BI-RADS score. The BI-RADS classification followed the standardized criteria outlined in the 5th edition of the American College of Radiology's (ACR) Breast Imaging Reporting and Data System recommendations [11]. By using standard imaging techniques and reporting templates, radiologists made sure that all cases were classified consistently using BI-RADS. The study found that while BI-RADS categories 4, 5, and 6 for ultrasonography were deemed malignant, BI-RADS categories 1, 2, and 3 were deemed benign. Although no systematic inter-observer variability analysis was performed, efforts were made to ensure consistency by using standardized reporting forms and working together to reach consensus on cases that were deemed questionable. Patients were then subjected to FNAC/core needle biopsy, and histopathological findings were correlated with the BI-RADS score. If surgery was performed, the removed specimen was sent for HPE for diagnosis confirmation. Then sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of clinical manifestations and ultrasound BI-RADS score were calculated and assessed against the gold standard of pathology**.** For each diagnostic metric, 95% confidence intervals (CIs) were calculated using binomial exact methods available in SPSS to assess the precision of the estimates.

2.5 Ethical Approval

This study obtained ethical consideration from the ethical committee of the College of Medicine, University of Sulaimani (No: 331, dated 13/10/2024)

2.6 Statistical Analysis

The study used a computer-based program (SPSS version 21) for data entry and statistical analysis, displaying quantitative data as mean and standard deviation and categorical data as numbers and percentages. The findings of the chi-square test were deemed statistically significant at a p-value of ≤0.05, with a p-value of less than 0.001 being considered highly significant.

3. Results

The study included 250 patients presenting with breast lumps. Participants' average age, with standard deviation, was 46.8 ± 11.6 years. Patients between the ages of 45 and 59 years constituted the largest percentage (40.8%). A breast mass was the most common presenting complaint, reported in 160 patients (64.0%), followed by pain in 49 (19.6%), as shown in Table 1.

The correlation between histopathological results and ultrasonography BI-RADS classifications was statistically significant (P < 0.001). According to ACR-BIRADS, 104 cases (41.6%) were classified as ACR-BIRADS category 3, and the next most common category, which included 63 cases (24.9%), was ACR-BIRADS category 5. Based on histopathology, the majority of the breast lesions, 133 (53.2%), were malignant, while 117 (46.8%) were benign (Table 2).

Out of the 117 (46.8%) non-malignant lesions on histopathology, the findings were arranged as follows: granulomatous mastitis 27 (23.1%), fibroadenoma 22 (18.8%), duct ectasia 19 (16.2%), fibrocystic changes 17 (14.5%), intraductal papilloma 7 (6.0%), and others 25 (12.6%). There were 133 (53.2%) cases of malignant lesions on histopathology, with invasive ductal carcinoma accounting for the vast majority of the cases, 111 (83.46%), followed by invasive lobular carcinoma, 14 (10.53%).

The sensitivity, specificity, positive predictive value, and negative predictive value of ultrasound for breast were 86.5%, 95.7%, 95.8%, and 86.2%, respectively, and overall diagnostic accuracy was 90.8%. This indicates that BI-RADS scoring is a dependable technique with good sensitivity and specificity for identifying breast lumps. (Table 3)

There was a statistically significant correlation (p-value < 0.001) between histopathological diagnosis and presenting complaints. Breast mass was the most prevalent complaint among the patients, occurring in 160 cases, of which 69 (43.1%) were benign and 91 (56.9%) were malignant, followed by pain, which was primarily benign (61.2%). A palpable breast mass proved to be the most reliable indicator of cancer, showing the highest sensitivity (68.4%) but the lowest specificity (41.0%). In contrast, axillary mass, skin changes, and nipple retraction all demonstrated excellent specificity (99–100%) and positive predictive value (PPV up to 100%). This shows that although these signs are not common, they are highly diagnostic of malignancy when present, as shown in Table 4.

Table 1. Distribution of clinical presentations among patients with breast lesions.

Clinical presentation			Frequency(n)	%
Complaint	Asymptomatic (screening)		14	5.6
	Pain		49	19.6
	Nipple retraction		6	2.4
	Axillary mass		2	0.8
	Mass		160	64.0
		Unilateral	156	62.4
		Bilateral	4	1.6
	Nipple discharge		14	5.6
		Bloody	8	3.2
		Serous	2	0.8
		Yellow	3	1.2
		Green	1	0.4
	Skin changes		5	2.0
		Dimpling	3	1.2
		Redness	1	0.4
		Ulceration	1	0.4
Total			250	100.0

Table 2. Distribution of histopathological outcomes across ultrasound BI-RADS categories**.**

Ultrasound BI-RADS Category	**Histopathology**			
	Benign n (%)	**Malignant n (%)**	**Total n (%)**	**P value**
Category 2 (benign)	24 (20.5)	2 (1.5)	26 (10.4)	< 0.001
Category 3 (probably benign)	88 (75.2)	16 (12.0)	104 (41.6)	
Category 4 (suspicious)	5 (4.3)	49 (36.8)	54 (21.6)	
Category 5 (highly suspicious)	0 (0)	63 (47.4)	63 (24.9)	
Category 6 (proved malignancy)	0 (0)	3 (2.3)	3 (1.2)	
Total	117 (46.8)	133 (53.2)	250 (100)	

BI-RADS: Breast Imaging Reporting and Data System, n: number of patients, P value: probability value

Table 3. Diagnostic performance metrics of ultrasonography in breast lesion evaluation.

Parameter	**Value (%)**
Sensitivity	86.5
Specificity	95.7
PPV	95.8
NPV	86.2

Accuracy	90.8

PPV: Positive predictive value; NPV: Negative predictive value.

Table 4. Association between clinical presentations and histopathological diagnosis with diagnostic performance in predicting breast malignancy**.**

Clinical Presentation	Benign n(%)	Malignant n (%)	Total n (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)	*P* value
Mass	69 (43.1)	91 (56.9)	160 (100)	68.4	41.0	56.9	53.3	55.6	< 0.001
Pain	30 (61.2)	19 (38.8)	49 (100)	14.3	74.4	38.8	43.3	42.4	
Asymptomatic	5 (35.7)	9 (64.3)	14 (100)	6.8	95.7	64.3	47.5	48.4	
Nipple discharge	12 (85.7)	2 (14.3)	14 (100)	1.5	89.7	14.3	44.5	42.8	
Nipple retraction	0 (0.0)	6 (100.0)	6 (100)	4.5	100.0	100.	48.0	49.2	
Skin changes	1 (20.0)	4 (80.0)	5 (100)	3.0	99.1	80.0	47.3	48.0	
Axillary mass	0 (0.0)	2 (100.0)	2 (100)	1.5	100.0	100.	47.2	47.6	
Total	**117 (46.8)**	**133 (53.2)**	**250 (100)**						

PPV: Positive predictive value; NPV: Negative predictive value; P value: Probability value

4. Discussion

Breast lumps frequently occur in surgery patients, leading to anxiety and apprehension. Timely identification is essential for efficient intervention. The BI-RADS grading system is utilized for the imaging assessment of breast lesions, offering a systematic method to classify results and inform management decisions. Noninvasive, sonographically-based approaches are being explored to minimize the need for invasive biopsies. Breast ultrasonography is believed to have higher sensitivity for identifying breast cancer in high-risk women, women under 50, and those with dense breast tissue. Ultrasound detection frequency varies with patient age and subsequent breast density. Furthermore, it can detect cancers not evident on mammography in 10-40% of cases [12].

The present study assessed the demographic characteristics of 250 women with breast lumps, with a mean age of 46.8 ± 11.6 years. A significant proportion of cases (40.8%) were among those aged 45 to 59. This distribution is consistent with findings from an earlier Iraqi study, which found the highest prevalence of breast lesions in women aged 40 to 60 and a mean age of 47.3 years [13]. These similarities could be due to similar health-seeking habits and demographic characteristics in both groups and shared lifestyle or environmental factors that affect the onset of breast disease in this age group.

Malignant lesions constituted 53.2% of patients in the current study, whereas benign lesions represented 46.8%. This distribution aligned with the findings of Singh et al. (2015) [14] but was inconsistent with earlier studies, which found that more than half of the patients had benign lesions based on BI-RADS scores and histopathology results [2, 15]. This discrepancy is likely multifactorial, reflecting the absence of a structured breast cancer screening program in our community, lack of knowledge about self-breast examination or infrequent breast clinic visits, and the tendency of many patients to present only when malignancies have already become palpable. In contrast to previous studies, our results showed a distinct pattern when analyzing the spectrum of benign pathology. Granulomatous mastitis emerged as the most frequent benign lesion (23.1%), followed by fibroadenoma (18.8%). In contrast, previous studies have more often reported fibroadenoma as the leading benign entity [2, 16]. Granulomatous mastitis is known to clinically and radiologically resemble breast carcinomas [17]. However, in the clinic where this study took place, lesions that normally show up on ultrasonography with benign appearances did not undergo histological examinations, which may have influenced the observed distribution. Among malignant pathologies, invasive ductal carcinoma was the predominant subtype, which accounted for 83.46% of malignant cases. Invasive lobular carcinoma came in second at 10.53%. This distribution supports the dominance of invasive ductal carcinoma as the most prevalent subtype of breast cancer, aligning with patterns consistently reported in both regional and international literature [16, 18].

In this study, BI-RADS category 3 was the most frequently used classification in breast ultrasonography evaluations, accounting for 41.6% of the cases. This predominance aligns with reports from other studies [19, 20], where BI-RADS 3 assessments were also common. Such a high proportion may reflect the interplay between imaging techniques, radiologist interpretation, and research population characteristics. There are more BI-RADS 3 evaluations among groups with a higher density of breast tissue, such as younger women. This is because there is a greater chance of finding probably benign lesions [21]. In line with the American College of Radiology recommendations (2013), BI-RADS 3 findings warrant short-interval follow-up, typically ultrasound after six months to confirm stability [22]. It's significant to note that the study's cross-sectional design limits the capacity to identify causal relationships between histopathological outcomes and BI-RADS categories. While significant relationships were found, the available data do not permit the interpretation of temporal direction or predictive power. Longitudinal studies would be necessary to prove causation or advancement patterns.

When evaluating diagnostic performance, the BI-RADS classification in our study achieved an accuracy of 90.8%, sensitivity of 86.5%, specificity of 95.7%, positive predictive value (PPV) of 95.8%, and negative predictive value (NPV) of 86.2%. These metrics are broadly comparable to those reported in other settings, but with notable differences. For instance, in a study conducted in Pakistan by Nisar et al. (2022), reported higher sensitivity (96.77%) and NPV (94.11%) but lower specificity (80.0%), yielding a similar overall accuracy of 90.2% [23]. In contrast, Ghaemian et al. (2021) documented substantially lower sensitivity (68.9%) and specificity (48.6%) [24]. While Badu-Peprah et al. (2024) and Lin et al. (2022) similarly reported lower specificity in comparison to our results [25, 26].

Meta-analyses further contextualize these results. Azarpey et al. (2023) reported a pooled sensitivity of 87%, closely matching our study, yet a lower specificity of 75% [27]. Similarly, Weber et al. (2025), in a meta-analysis of handheld ultrasonography performance in women with symptoms, found pooled specificity values ranging from 65% to 85% and sensitivities in the high 80s to low 90s, placing our specificity at the higher end of the reported range [28]. Furthermore, according to the findings of another study, the ultrasound's sensitivity and specificity were 60.0% and 96.0%, respectively, with the sensitivity being lower and the specificity being higher than the current study [29], while another found the reverse, with higher sensitivity (89.9%) and lower specificity (66.7%) [30]. Aziz et al. (2022) found markedly higher sensitivity (94.5%) and substantially lower specificity (43.1%) [31].

Taken together, these differences likely reflect variation in imaging quality, radiologist skill, study population differences, BI-RADS categorization criteria, and gold standard differences (core needle biopsy, FNAC, and excisional biopsy). Importantly, the current study found a statistically significant ($p < 0.001$) association between BI-RADS categories and histopathological findings, consistent with previous research [31, 32]. However, due to the cross-sectional nature of the study, these results do not establish causality or fully confirm the predictive value of BI-RADS classification.

In the present study, most women (64.3%) had a palpable breast mass, which was the most common clinical symptom. The majority (62.7%) of these masses were unilateral, consistent with previous studies suggesting that unilateral breast lumps are the most common symptom and often linked to cancer. Conversely, bilateral breast involvement was less common and more often associated with benign conditions [33, 34]. Breast pain was the next most frequent symptom, reported by 19.7% of patients. This aligns with existing evidence that mastalgia is a common but non-specific symptom, more often associated with benign conditions and infrequently indicative of malignancy [35]. Patients who only reported pain were less likely to have cancer than those with palpable tumors. Therefore, breast pain is a poor predictor of cancer, despite its prevalence. Collectively, these findings demonstrated a statistically significant correlation between clinical presentation and histopathology ($p < 0.001$).

When the diagnostic performance of clinical complaints was assessed, palpable breast lumps remained the predominant finding, with a sensitivity of 68.4% and specificity of 41.0%, indicating poor discriminating value due to their common incidence in benign diseases. This pattern somewhat corresponds with the findings of Badu-perah et al. (2018), who documented a comparable specificity (41.2%) but a significantly elevated sensitivity (90.4%) [36]. The lower sensitivity in this study may reflect differences in patient presentation, particularly a greater proportion of early-stage or non-palpable lesions detected through imaging. Moreover, differences in the timing of clinical assessments, diagnostic criteria, and demographic variables may also explain the discrepancies observed.

Conclusion

In conclusion, ultrasonography showed high levels of sensitivity, specificity, and predictive values in identifying benign and malignant breast masses when classified using the BI-RADS system, with a significant association to histological results. Although these findings are encouraging, the cross-sectional design limits causal inference and predictive certainty. The findings suggest that BI-RADS can serve as a reliable guide to stratify patients by risk, prioritize further diagnostic imaging, and determine the urgency of biopsy. In our local context, where resource allocation and timely decision-making are critical, adopting BI-RADS-based assessment can help reduce unnecessary procedures in clearly benign cases while ensuring prompt intervention for suspicious lesions. Consequently, BI-RADS should serve as an adjunctive imaging modality rather than a substitute for histological validation in the diagnosis of breast lesions.

Limitations of the study:

The study was limited by incomplete documentation in some patient files, resulting in some cases not being eligible and hence being excluded. Only patients with both reports were included in the final analysis. This limitation emphasizes the need for better record-keeping and data integration in institutional archives to enhance future research validity. Additionally, the cross-sectional nature of the study limits the ability to establish temporal or causal relationships between clinical symptoms, imaging findings, and pathology results. Future prospective studies are warranted to explore these associations over time.

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