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Accuracy of the Bi-Rads Classification on Ultrasonography in Predicting Malignancy of Breast Lesions Based on Histopathology: A Literature Review

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Abstract

Breast cancer remains a major health concern, and early detection is essential for improving treatment outcomes. Ultrasonography combined with the Breast Imaging Reporting and Data System (BI-RADS) is widely used to assess breast lesions and estimate their risk of malignancy. This literature review aimed to analyze the accuracy of BI-RADS classification on breast ultrasonography in predicting malignancy based on histopathological examination as the gold standard. A narrative literature review was conducted using articles retrieved from PubMed/NCBI, Google Scholar, ScienceDirect, SpringerLink, the Cochrane Library, and other relevant scientific sources. Articles published within the last five years were selected based on predefined inclusion and exclusion criteria. A total of 20 relevant articles were included and narratively synthesized. The findings showed that BI-RADS ultrasonography generally demonstrated high sensitivity, ranging from 83% to 98.4%, whereas specificity varied from 25.0% to 93.8%. The likelihood of histopathologically confirmed malignancy increased progressively with higher BI-RADS categories. BI-RADS 3 was predominantly associated with benign lesions, BI-RADS 4 showed heterogeneous malignancy risks requiring subdivision into categories 4A, 4B, and 4C, and BI-RADS 5 was strongly associated with malignancy. Variations in diagnostic performance were influenced by the BI-RADS cutoff, lesion characteristics, breast density, operator experience, equipment quality, population characteristics, and study design. In conclusion, BI-RADS ultrasonography is an effective tool for breast lesion risk stratification, particularly because of its high sensitivity. However, it cannot replace histopathological examination, which remains necessary for definitive diagnosis, especially for BI-RADS 4 and 5 lesions.

Introduction

Breast cancer is a major health problem in Indonesia. According to national data, there were approximately 65,858 cases of breast cancer out of a total of 396,914 cancer cases, accounting for approximately 16.6% of all diagnosed cancer cases (Aprilia, 2024). This figure indicates that breast cancer is the most common type of cancer in Indonesia and a leading cause of cancer morbidity and mortality. Epidemiologically, breast cancer ranks among the most prevalent cancers, along with cervical, liver, colorectal, and lung cancers (Gautama, 2022).

Globally, data from the Global Cancer Observatory (GLOBOCAN) in 2024 reported approximately 2,296,840 cases of breast cancer out of a total of 19,976,499 cancer cases worldwide. This number equates to approximately 11.5% of all cancer cases, placing breast cancer among the most prevalent cancers globally. The high prevalence of breast cancer makes this disease a significant focus in prevention, early detection, and treatment efforts in various countries (Bray et al., 2024; Ferlay et al., 2021).

In Indonesia, many breast cancer patients do not recognize symptoms in the early stages, so the diagnosis is often made at an advanced stage. Delays in detection and treatment contribute

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to the high mortality rate from this disease. It is estimated that approximately 70% of the 22,000 breast cancer deaths occur because patients receive appropriate therapy too late. However, if breast cancer is detected and treated at an early stage, the chances of successful treatment and patient survival rates can significantly increase.

Early detection is a crucial strategy for increasing treatment success rates and improving patient prognosis. Various imaging methods have been used to detect breast abnormalities, one of which is ultrasound (USG). Breast ultrasound has several advantages, including the absence of ionizing radiation, relatively affordable cost, ease of performance, and high sensitivity, especially in women with dense breast tissue (Pangaribuan, 2024).

To improve the consistency of imaging results interpretation, the American College of Radiology developed the Breast Imaging Reporting and Data System (BI-RADS). This system categorizes breast lesions based on the level of suspicion for malignancy, assisting clinicians in determining appropriate diagnostic and therapeutic steps. A higher BI-RADS category indicates a greater risk of malignancy and is generally an indication for biopsy (Arian et al., 2022). Although ultrasound examination has good diagnostic value, a definitive diagnosis of breast cancer still requires anatomic histopathology. Histopathology is the gold standard used to determine the type of lesion, the degree of malignancy, and the biological characteristics of the tumor (Haezer et al., 2026).

The BI-RADS lexicon categorizes breast findings into seven categories ranging from 0 to 6. Category 0 is labeled inconclusive and requires additional imaging, category 1 as normal, category 2 as benign, category 3 as likely benign, category 4 as likely malignant, category 5 as malignant, and category 6 as biopsy-proven malignant. Each category directs the physician to a different management plan and the accurate implementation of available treatment options. Category 0 requires additional imaging, and categories 1 and 2 require routine annual screening. For category 3 lesions, a 6-month follow-up assessment is recommended, category 4 and 5 lesions require biopsy and histopathologic evaluation, and category 6 lesions require surgical excision when clinically appropriate (Turk et al., 2023).

Therefore, it is crucial to study the accuracy of the BI-RADS classification on ultrasound in predicting breast lesion malignancy based on histopathology. Several studies have reported the diagnostic value of the BI-RADS classification on ultrasound in relation to histopathology, but the results vary between studies. Based on this description, this literature review aims to summarize and analyze the current scientific evidence regarding the accuracy of the BI-RADS classification on ultrasound in predicting breast lesion malignancy based on histopathology as the gold standard.

Method

Type of Research

This study is a literature review with a narrative review design. The aim of this study was to identify, examine, and summarize various scientific literature discussing the accuracy of the Breast Imaging Reporting and Data System (BI-RADS) classification of breast ultrasound examinations in predicting breast lesion malignancy based on histopathology as the gold standard. This literature review utilized secondary data obtained from research articles, review articles, systematic reviews, meta-analyses, clinical guidelines, and other scientific sources relevant to the research topic. The study was conducted by examining the results of previous studies on the diagnostic value of BI-RADS ultrasonography, particularly its sensitivity, specificity, positive predictive value, negative predictive value, and accuracy in differentiating benign and malignant breast lesions.

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Reference Criteria

The type of data used in this study is secondary data obtained from scientific publications in the form of original research articles, systematic reviews, meta-analyses, review articles, clinical guidelines, and textbooks discussing breast ultrasonography, the BI-RADS classification, breast lesions, breast cancer, and histopathology. The literature used was prioritized from nationally and internationally indexed scientific journals. Databases used in the literature search included PubMed/NCBI, Google Scholar, ScienceDirect, SpringerLink, the Cochrane Library, and other relevant scientific sources accessible online. References used were published within the last 5 years to maintain the relevance of scientific evidence.

Literature Search Strategy

The literature search was conducted using keywords in Indonesian and English relevant to the research topic. The keywords used included: “BI-RADS ultrasound breast lesion", "BI-RADS ultrasonography histopathology", "diagnostic accuracy of BI-RADS ultrasound", "breast ultrasound BI-RADS sensitivity specificity", "ultrasound BI-RADS classification breast cancer", "BI-RADS 3 4 5 histopathology", "breast lesion ultrasonography and histopathology", "accuracy of BI-RADS ultrasonography breast", "BI-RADS ultrasound breast histopathology", "benign malignant breast lesion ultrasonography". The search was conducted by combining keywords using Boolean operators such as AND and OR. Examples of keyword combinations used are "BI-RADS" AND "breast ultrasound" AND "histopathology," "diagnostic accuracy" AND "BI-RADS ultrasound" AND "breast lesion," and "BI-RADS ultrasound" AND "sensitivity" AND "specificity." Articles obtained from the search results were then selected based on the suitability of the title, abstract, full-text availability, topic suitability, and established inclusion and exclusion criteria.

Literature Selection Criteria

The inclusion criteria for this literature review included scientific articles discussing the BI-RADS classification of breast ultrasound examinations and assessing the accuracy of BI-RADS ultrasound in predicting breast lesion malignancy. Selected articles should compare BI-RADS ultrasound results with histopathology as the gold standard and report at least one diagnostic parameter, such as sensitivity, specificity, positive predictive value, negative predictive value, accuracy, or malignancy grade based on the BI-RADS category. Articles should also discuss the BI-RADS categories, particularly BI-RADS 3, BI-RADS 4, and BI-RADS 5, in relation to histopathology results. Article types that could be included include original research, cross-sectional studies, retrospective studies, prospective studies, diagnostic tests, systematic reviews, meta-analyses, or relevant review articles. Furthermore, articles should be available in full text, published in Indonesian or English, and published within the last five years.

Exclusion criteria for this literature review included articles that solely discussed other imaging modalities, such as mammography or MRI, without specific analysis of BI-RADS ultrasound. Articles that assessed breast ultrasound without using the BI-RADS classification as the basis for lesion grading were also excluded. Furthermore, articles that used a gold standard other than histopathology, such as based solely on clinical follow-up or imaging without tissue confirmation, and did not present sufficient data to assess the relationship between the BI-RADS ultrasound category and histopathology results, were excluded. Articles that focused on additional methods, such as elastography, Doppler, contrast-enhanced ultrasound, or artificial intelligence, without separately presenting conventional BI-RADS ultrasound data were also excluded. Other exclusion criteria included studies with populations inappropriate for the review's purpose, such as animal studies, phantom studies, or nonclinical experimental studies;

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case reports; case series with very small sample sizes; editorials; opinion pieces; letters to the editor; conference abstracts without complete data; and publications that were not peer-reviewed. Duplicate articles from different databases were excluded, and if publications with identical data were available, only the article with the most complete data was used. Articles with inadequate methodological quality, such as not clearly describing the ultrasound method, BI-RADS criteria, histopathology examination method, or study population characteristics, were also excluded.

Data Synthesis

Data from articles meeting the inclusion criteria were extracted and compiled into a synthesis table. Collected data included author names, year of publication, article title, study design, sample size, population characteristics, BI-RADS categories assessed, histopathology results, and reported diagnostic accuracy parameters. Diagnostic accuracy parameters analyzed included sensitivity, specificity, positive predictive value, negative predictive value, and accuracy. When available, additional data such as likelihood ratio, area under the curve, or malignancy grade for each BI-RADS category were also recorded as supporting information. The results of various studies were analyzed narratively, comparing the diagnostic value of BI-RADS ultrasonography in predicting the malignancy of breast lesions based on histopathology. Differences in results between studies were discussed, considering factors that may influence accuracy, such as population characteristics, lesion size, lesion type, breast density, ultrasound equipment quality, examiner experience, and variations in BI-RADS interpretation.

Research Flow

The research flow in this literature review was conducted through several stages, as follows: (1) Determining the topic and problem formulation regarding the accuracy of BI-RADS classification in breast ultrasonography in predicting breast lesion malignancy based on histopathological examination; (2) Developing literature search keywords in Indonesian and English; (3) Conducting a literature search through relevant scientific databases; (4) Conducting an initial selection based on article titles and abstracts; (5) Assessing the eligibility of articles based on inclusion and exclusion criteria; (6) Reading the selected articles in their entirety or full text; (7) Extracting important data from each article that met the criteria; (8) Compiling a synthesis table based on the research results obtained; (9) Analyzing and comparing results across the literature narratively; (10) Compiling results, discussion, conclusions, and recommendations based on the literature synthesis.

Result and Discussion

Based on a literature search through the PubMed/NCBI database, Google Scholar, ScienceDirect, SpringerLink, the Cochrane Library, open-access journals, and other relevant scientific online sources, we obtained articles discussing the accuracy of the Breast Imaging Reporting and Data System (BI-RADS) classification of breast ultrasound in predicting breast lesion malignancy. The search was conducted using the keywords "BI-RADS ultrasound breast lesion," "BI-RADS ultrasonography histopathology," "diagnostic accuracy of BI-RADS ultrasound," "breast ultrasound BI-RADS sensitivity specificity," "BI-RADS 3 4 5 histopathology," and Indonesian keywords such as "accurasi BI-RADS ultrasonografi payudara" and "BI-RADS USG payudara histopatologi."

The selected articles were open-access publications published within the last five years and met the inclusion criteria in Chapter III, which discussed breast ultrasound, BI-RADS classification, malignancy prediction, and/or comparing imaging results with histopathology as the gold standard. Articles that solely discussed mammography, MRI, artificial intelligence,

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or elastography without a direct connection to BI-RADS ultrasonography and histopathology were not included as primary articles, but were used in limited support to explain factors influencing accuracy.

From the literature search and screening results, 20 of the most relevant articles were selected for analysis. These articles included diagnostic studies, cross-sectional studies, retrospective studies, radiology-pathology correlation studies, and articles assessing the relationship between BI-RADS categories and histopathology results. In general, the analyzed literature showed that BI-RADS ultrasonography has a relatively high sensitivity in detecting malignant lesions, while its specificity varies significantly between studies. This variation is primarily influenced by differences in BI-RADS category cutoff points, the proportion of malignant lesions, breast density, lesion characteristics, operator experience, ultrasound equipment quality, and the consistent use of BI-RADS subcategories 4A, 4B, and 4C.

Literature Screening Process

The article screening process is carried out in stages, starting with identifying articles based on keywords, eliminating duplicate articles, screening titles and abstracts, assessing full-text eligibility, and selecting final articles that align with the research focus:

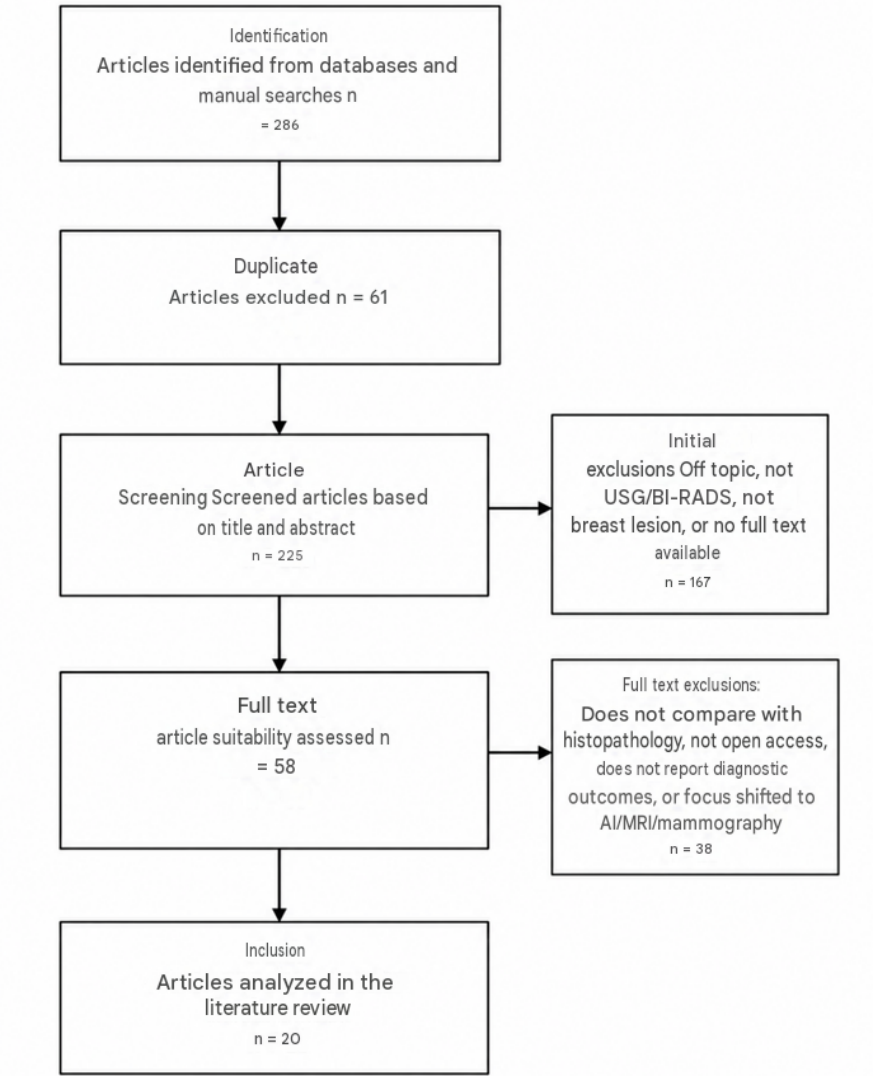

Figure 1. Literature Screening Process Flow

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The number of articles in the diagram above illustrates the search results used in compiling this Chapter IV. If the search were repeated at a different time or with a broader database, the initial number of articles may change. However, the final criteria remained focused on articles that best align with the research objective, which is to assess the accuracy of BI-RADS ultrasonography relative to histopathology.

Characteristics of the Analyzed Literature

Most of the studies analyzed used histopathology as the reference standard, either through core needle biopsy, excisional biopsy, or postoperative tissue examination. The most frequently analyzed BI-RADS categories were BI-RADS 3, 4, and 5, according to the focus of the study. BI-RADS 3 is used for lesions that are likely benign, BI-RADS 4 for lesions suspicious for malignancy, and BI-RADS 5 for lesions that are highly suggestive of malignancy.

Table 1. Presents a Summary of The Analyzed Literature

No	Author, Year	Title	Methods/Sample	Key Results
1	Jaber et al., 2025	Predictive value of ultrasound BI-RADS in conjunction with cytological and histopathological outcomes in breast disease management	Diagnostic studies; BI-RADS USG + FNAC/histopathology	At a BI-RADS cutoff of ≥4A, sensitivity was 98.4% and specificity was 40.6%. Increasing the cutoff to ≥4C increased specificity but decreased sensitivity.43
2	Ciurescu et al., 2025	Stratifying Breast Lesion Risk Using BI-RADS: A Comprehensive Analysis of Histopathological Correlation and Tumor Markers	Retrospective; correlation of BI-RADS, histopathology, and tumor markers	Accuracy 89.4%, sensitivity 93.8%, specificity 80.0%. BI-RADS 5 is very strong in predicting malignancy.44
3	Vardhan et al., 2026	A Retrospective Study of Breast Imaging Reporting and Data System and Histopathological Correlation in Breast Lumps	Retrospective; 215 patients with breast lumps	Sensitivity 96.3%, specificity 38.3%, PPV 61.2%, NPV 91.1%, and accuracy 67.4%. The risk of malignancy increases progressively from BI-RADS 3 to BI-RADS 5.45
4	Aziz et al., 2022	Histopathological Correlation of Breast Carcinoma with Breast Imaging-Reporting and Data System	Radiology-histopathology correlation study	Sensitivity was 94.48%, specificity was 43.14%, PPV was 63.9%, and NPV was 88%. BI-RADS 5 had a high PPV for malignancy.46
5	Khan et al., 2023	Sonographic Characteristics and Pathology Correlation of BI-RADS Category 4 Lesions	Cross-sectional; 227 lesi BI-RADS 4	The PPV for BI-RADS 4 was 44.49%. This result confirms that BI-RADS 4 is a heterogeneous category and requires subcategories 4A, 4B, and 4C.47
6	Nisar et al., 2022	Diagnostic Accuracy of Ultrasound BI-RADS in Diagnosing Breast Lesions Utilizing the Core Needle Biopsy	Cross-sectional; 51 patients; core needle biopsy as confirmation	Accuracy 90.19%, sensitivity 96.77%, specificity 80.00%, PPV 88.23%, and NPV 94.11%.48

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		Keeping Histopathology as a Gold Standard		
7	Quratulain et al., 2024	The Diagnostic Accuracy of Conventional Breast Ultrasound in Diagnosing Malignant Breast Lesions Taking Histopathology as Gold Standard	Cross-sectional; 185 patients	Sensitivity 91.07%, specificity 83.57%, PPV 89.47%, NPV 85.92%, and accuracy 88.11%.49
8	Begum et al., 2024	Correlation of Diagnostic Accuracy of BI-RADS Scoring with FNAC and Histopathology in Palpable Breast Lumps	Correlation study; 103 patients	BI-RADS has a sensitivity of 83%, specificity of 75%, PPV of 58%, NPV of 91%, and accuracy of 78%.50
9	Chukwuegbo et al., 2024	Diagnostic Accuracy of Ultrasonographic BI-RADS Scoring Compared with Histopathologic Features of Breast Lumps in Nigerian Adult Females	Diagnostic study; Nigerian adult female with breast lump	US BI-RADS 2–5 can be used to differentiate benign and malignant lesions and supports the application of BI-RADS in African populations.51
10	Sharma et al., 2024	Correlation Between Radiological Imaging and Histopathological Findings in Patients with Breast Lump	Correlation study; 100 patients	BI-RADS has a sensitivity of 88.9%, specificity of 89.5%, PPV of 97.3%, NPV of 65.4%, and accuracy of 81%.52
11	Haezer et al., 2026	Accuracy of Mammography and Ultrasonography in Differentiating Benign and Malignant Breast Lesions Based on Histopathology at MRCCC Siloam Semanggi Hospital	Diagnostic accuracy study; Indonesia	USG demonstrated high sensitivity but lower specificity. This study is relevant to the Indonesian clinical context because it used histopathology as a comparator.8
12	Alotaibi et al., 2025	Evaluation of the Diagnostic Accuracy of Mammography and Ultrasound Compared with Histopathology in the Detection of Breast Carcinoma	Comparative study; mammography and ultrasound compared with histopathology	Ultrasound shows significant diagnostic value and is comparable to histopathology. It is used as supporting literature because it also discusses mammography.53
13	Rehman et al., 2025	Comparison of Diagnostic Accuracy of Ultrasound and Mammography in Detecting Breast Cancer in Radiographically Dense Breasts	Diagnostic studies; dense breasts	Ultrasound has a sensitivity of 85.3%, a specificity of 88.4%, a NPV of 93.8%, and an accuracy of 87.1%. Ultrasound is superior in high-density breasts.54
14	Khalid et al., 2025	High-Resolution Ultrasound in Breast Cancer Diagnosis:	High-resolution ultrasound studies	BI-RADS 5 has very high PPV and specificity. BI-RADS 4 remains the most challenging

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		Sensitivity, Specificity, and Clinical Implications		category due to the wide variation in malignancy risk.55
15	Adebiyi et al., 2025	Comparison of Sonographic and Histological Findings Among Women with Breast Masses in Owo	Retrospective; 123 patients with breast masses	BI-RADS USG has a sensitivity of 96.5%, specificity of 93.8%, PPV of 93.3%, NPV of 96.8%, and accuracy of 95.1%.56
16	Mohan et al., 2024	Correlation of Histopathology and Radiological Findings in Breast Lesions	Radiology-histopathology correlation study	Imaging modalities show high sensitivity in detecting breast lesions, but histopathology is still required for confirmation of the diagnosis.57
17	Akinnibosun-Raji et al., 2022	Correlation of Sonographic Findings and Histopathological Diagnoses in Breast Masses	Breast mass correlation study	There is a significant positive correlation between sonographic findings and histopathological results in breast masses.58
18	Bello et al., 2023	The Correlation of Sonographic and Histopathologic Findings in the Diagnosis of Palpable Breast Masses in Zaria	Correlation study of palpable breast masses	There is a significant correlation between ultrasound findings and histopathology in differentiating benign and malignant breast masses.59
19	Sultan et al., 2024	Diagnostic Accuracy of Combined Mammography and Ultrasound in the Detection of Malignant Breast Lesions Using BI-RADS Classification Taking Histopathology as the Gold Standard	Retrospective; combination of mammography and ultrasound	Sensitivity was 98.3%, specificity was 25.0%, PPV was 90.9%, NPV was 66.6%, and accuracy was 89.9%. High sensitivity, but also high false positives.60
20	Kuntjoro et al., 2026	Modified BI-RADS Model for Stratifying Borderline Breast Lesions Based on BI-RADS: A Cross-Sectional Study	Cross-sectional; Indonesia	The modified BI-RADS model helps stratify borderline lesions without changing the standard BI-RADS system.30

Discussion

The following discussion is based on an analysis of 20 articles that met the inclusion criteria. To maintain alignment with the research objectives, the discussion is grouped into five main sections: (1) the general accuracy of BI-RADS ultrasonography in predicting breast lesion malignancy; (2) the relationship between BI-RADS categories 3, 4, and 5 and histopathology results; (3) comparison of diagnostic value between studies; (4) factors influencing accuracy; and (5) the role of histopathology as the gold standard.

Accuracy of BI-RADS Ultrasonography in Predicting Breast Lesions Malignancy

Most studies have shown that the BI-RADS classification of breast ultrasonography has high sensitivity in detecting malignant lesions. This is evident in the study by Jaber et al., which reported a sensitivity of 98.4% at a BI-RADS cutoff of ≥4A. Similar findings were demonstrated by Nisar et al. with a sensitivity of 96.77%, Adebiyi et al. with 96.5%, and Vardhan et al. 96.3%, Ciurescu et al. 93.8%, Aziz et al. 94.48%, and Quratulain et al. 91.07%.

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These data indicate that BI-RADS ultrasonography is quite robust as an initial stratification tool for identifying lesions requiring further tissue evaluation (Jaber et al., 2025; Ciurescu et al., 2025; Vardhan et al. 2026; Aziz et al., 2022; Khan et al., 2023; Nisar et al., 2022).

Although sensitivity tends to be high, specificity varies significantly between studies. In the studies by Adebiyi et al. and Sharma et al., specificity was reported to be high, at 93.8% and 89.5%, respectively. In contrast, Jaber et al. reported a specificity of only 40.6% at a BI-RADS cutoff of ≥4A, Vardhan et al. 38.3%, and Aziz et al. 43.14%. These differences indicate that BI-RADS ultrasonography is more consistent in detecting malignant lesions than in confirming benign lesions. In other words, the BI-RADS system tends to prioritize sensitivity to reduce the likelihood of missed cancers, although this results in increased false positives and biopsies that do not always result in malignancy (Sharma et al., 2024).

These findings align with the nature of BI-RADS as a risk assessment system. In clinical practice, suspicious BI-RADS categories, particularly categories 4 and 5, are typically directed toward biopsy or histopathological confirmation. Therefore, the inconsistent specificity cannot be considered an absolute weakness, as the primary goal of this system is to identify potentially malignant lesions early (Diaz-Cano, 2012). However, low specificity remains important to discuss because it is associated with patient anxiety, examination costs, and the possibility of unnecessary biopsies (Kuntjoro et al., 2026; Abdulloh & Ni'mah, 2023; Jaber et al., 2025).

Relationship of BI-RADS Categories 3, 4, and 5 with Histopathology Results

The relationship between BI-RADS categories and histopathology results is the core of this literature review. Theoretically, BI-RADS 3 carries a low risk of malignancy, BI-RADS 4 carries a broad risk of malignancy, and BI-RADS 5 strongly suggests malignancy. The literature review shows a consistent pattern: the higher the BI-RADS category, the greater the likelihood of a lesion being proven malignant on histopathology.

In the study by Jaber et al., the malignancy rate increased from BI-RADS 3 at 2.5%, BI-RADS 4A at 10%, BI-RADS 4B at 25%, BI-RADS 4C at 55%, to BI-RADS 5 at 88%. A similar progressive pattern was reported by Vardhan et al., with malignancy rates for BI-RADS 3 of 8.9%, BI-RADS 4A 32.7%, BI-RADS 4B 46.3%, BI-RADS 4C 82.1%, and BI-RADS 5 91.8%. These findings demonstrate the importance of the BI-RADS 4A-4C subcategories, as BI-RADS 4 is not a homogeneous group (Jaber et al., 2025; Vardhan et al., 2026).

BI-RADS 5 consistently demonstrates a high predictive value for malignancy. Aziz et al. reported a PPV of 93.3% for BI-RADS 5, while Ciurescu et al. reported that BI-RADS 5 is highly predictive of malignancy and strongly correlates with histopathology results. Khalid et al. also demonstrated that BI-RADS 5 has very high specificity and PPV on high-resolution ultrasonography. This supports the recommendation that BI-RADS 5 should be promptly confirmed by biopsy and prepared for definitive management (Ciurescu et al., 2025; Aziz et al., 2022; Khalid et al., 2025).

In contrast to BI-RADS 5, BI-RADS 4 is the most challenging category. Khan et al. specifically assessed BI-RADS 4 lesions and obtained a PPV of 44.49%. This value indicates that most BI-RADS 4 lesions are not necessarily malignant, but still raise sufficient suspicion to warrant biopsy. Therefore, dividing BI-RADS 4 into 4A, 4B, and 4C is crucial for more accurate estimation of the probability of malignancy and reducing overtreatment of low-risk lesions.

Comparison of Diagnostic Values Between Studies

Comparison of diagnostic values between studies shows that the performance of BI-RADS ultrasound is not entirely uniform. Sensitivity is generally in the high range, while specificity

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varies more. These differences may occur due to variations in study design, sample size, population characteristics, proportion of malignant lesions, and how researchers determine the BI-RADS positive cutoff.

Table 2. Results of the BI-RADS Classification Diagnostic Test on Ultrasonography in Predicting Breast Lesions Malignancy

Researchers	Sensitivity	Specificity	PPV	NPV	Accuracy
Jaber et al., 2025	98,4%	40,6%	52,5%	97,5%	Not reported
Ciurescu et al., 2025	93,8%	80,0%	Not reported	Not reported	89,4%
Vardhan et al., 2026	96,3%	38,3%	61,2%	91,1%	67,4%
Aziz et al., 2022	94,48%	43,14%	63,9%	88,0%	Not reported
Nisar et al., 2022	96,77%	80,00%	88,23%	94,11%	90,19%
Quratulain et al., 2024	91,07%	83,57%	89,47%	85,92%	88,11%
Begum et al., 2024	83%	75%	58%	91%	78%
Sharma et al., 2024	88,9%	89,5%	97,3%	65,4%	81%
Rehman et al., 2025	85,3%	88,4%	Not reported	93,8%	87,1%
Adebiyi et al., 2025	96,5%	93,8%	93,3%	96,8%	95,1%
Sultan et al., 2024	98,3%	25,0%	90,9%	66,6%	89,9%

Table 2 shows that the highest sensitivity was reported by Jaber et al. and Sultan et al., at 98.4% and 98.3%, respectively. However, both studies had low specificities, at 40.6% and 25.0%. This suggests that using a more sensitive cutoff increases the ability to detect malignant lesions, but at the expense of the ability to exclude benign lesions. Therefore, the high sensitivity values in these studies should be interpreted with a greater risk of false positives.

The highest specificity was found by Adebiyi et al. at 93.8%, followed by Sharma et al. at 89.5% and Rehman et al. at 88.4%. Studies with high specificity generally demonstrate better ability to differentiate benign from malignant lesions. However, differences in population, patient referral patterns, and the proportion of malignant cases can influence these values. In tertiary referral populations with a higher proportion of suspicious lesions, specificity tends to be lower because more benign lesions have sonographic characteristics that mimic malignancy.

The sensitivity range in the analyzed studies ranged from 83% to 98.4%, while the specificity ranged from 25.0% to 93.8%. This range indicates that BI-RADS ultrasonography is relatively consistent as a detection tool, but not always consistent as an exclusion tool. Therefore, interpretation of BI-RADS results should take into account the clinical context, particularly the patient's age, breast density, family history, mass characteristics, and the availability of histopathology.

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Factors Affecting BI-RADS Ultrasonography Accuracy

The first factor affecting accuracy is the BI-RADS cutoff used. If BI-RADS ≥4A is considered positive, sensitivity will increase because more suspicious lesions are included in the positive group. However, specificity will decrease because some 4A lesions are found to be benign on histopathology. Jaber et al. showed that increasing the cutoff from ≥4A to ≥4C resulted in increased specificity but decreased sensitivity. Thus, the choice of cutoff reflects a balance between the goal of early detection and efforts to reduce unnecessary biopsies.

The second factor is the heterogeneity of BI-RADS 4. BI-RADS 4 has a wide range of malignancy risks, making the subcategories 4A, 4B, and 4C crucial. Khan et al. showed a PPV of 44.49% for BI-RADS 4, while Vardhan et al. showed an increase in malignancy rates from 4A to 4C. This demonstrates that BI-RADS 4 should not be treated as a single group in accuracy analyses.

The third factor is breast density. In women with dense breasts, mammography can experience decreased sensitivity because the mass can be obscured by fibroglandular tissue. Rehman et al. demonstrated that ultrasonography retains good sensitivity in dense breasts, making ultrasound an important modality in this population. This aligns with the theoretical basis that ultrasound is useful in dense breast tissue because it does not rely on radiographic density differences like mammography.

The fourth factor is lesion size and characteristics. Small lesions, non-mass lesions, lesions with indistinct margins, or benign lesions with inflammatory changes can present interpretation difficulties. Sonographic features such as irregular shape, ill-defined margins, taller-than-wide orientation, posterior acoustic shadowing, and tissue distortion tend to raise suspicion for malignancy. However, some benign lesions may also exhibit suspicious features, thus decreasing specificity. This finding explains why the sensitivity of BI-RADS ultrasound tends to be high but its specificity is more fluctuating (Khalid et al., 2025; Mohan et al., 2024).

The fifth factor is operator experience and the quality of the ultrasound equipment. Ultrasonography is a highly operator-dependent examination. The radiologist's experience in applying the BI-RADS lexicon, transducer quality, instrument resolution, and consistency of the examination protocol can influence the final BI-RADS category. In studies with experienced readers and standardized protocols, interpretation variation may be smaller. Conversely, in facilities with limited equipment or varying examiner experience, the risk of misclassification may increase (Abdulloh & Ni’mah, 2023).

The sixth factor is population characteristics and study design. Studies from tertiary referral centers often have a higher proportion of malignant lesions than general population-based studies. A high proportion of malignancies may increase PPV but may decrease generalizability to the general screening population. Furthermore, retrospective studies are more susceptible to selection bias because only patients with complete data and histopathology results are included in the analysis. This situation may explain why accuracy values differ between studies even though they use the same BI-RADS system.

The Role of Histopathology as the Gold Standard

All major studies in this literature review place histopathology as the primary comparator or gold standard. This is important because BI-RADS ultrasonography only predicts the risk of malignancy based on morphological features, whereas histopathology determines the definitive diagnosis of benign or malignant lesions. Histopathology can also determine tumor type, such

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as fibroadenoma, invasive ductal carcinoma, invasive lobular carcinoma, or other specific types.

The role of histopathology is clearly demonstrated in the study by Begum et al., which compared BI-RADS and FNAC with histopathology. The results showed that BI-RADS had a high NPV, but a lower PPV than FNAC. This suggests that BI-RADS is useful as a risk stratification tool, but confirmation with tissue examination is still needed, especially for BI-RADS 4 and 5 (Sultan et al., 2024).

Thus, BI-RADS ultrasonography and histopathology have complementary roles. BI-RADS helps determine the probability of malignancy and the need for biopsy, while histopathology provides the final diagnosis. In a clinical context, a high BI-RADS result should not be considered a definitive diagnosis of cancer until histopathological confirmation is obtained. Conversely, a low BI-RADS result should still be considered alongside clinical factors if there is a discrepancy between symptoms, physical examination, and imaging findings.

Synthesis and Discussion

Overall, the literature review indicates that the BI-RADS classification of breast ultrasonography has good diagnostic value in predicting the malignancy of breast lesions, particularly in terms of sensitivity. BI-RADS 4 and 5 are generally associated with an increased risk of malignancy, while BI-RADS 3 is more often associated with benign lesions. However, the variation in malignancy rates for BI-RADS 3 and 4 across studies suggests that interpretation of these categories should be done cautiously and not rely solely on a single sonographic parameter.

Comparison results between studies also indicate that the accuracy of BI-RADS ultrasonography is influenced by many factors. The use of a low cutoff increases sensitivity but decreases specificity, while a higher cutoff increases specificity but risks decreasing sensitivity. Breast density, lesion size, population variation, examiner experience, equipment quality, and the use of BI-RADS 4A-4C subcategories are important factors to consider in interpreting results.

Based on this synthesis, BI-RADS ultrasonography can be used as an effective tool for risk stratification of breast malignancy. However, this examination does not replace histopathology as the gold standard. In BI-RADS 4 and 5 lesions, tissue confirmation is still necessary. In BI-RADS 3 lesions, short-term follow-up may be considered, but clinical decisions must be tailored to patient characteristics and the concordance between clinical and imaging findings.

Conclusion

Based on a review of 20 open access articles from the past five years, it can be concluded that the BI-RADS classification of breast ultrasound has good diagnostic accuracy in predicting breast lesion malignancy when compared with histopathology, the gold standard. The sensitivity of BI-RADS ultrasound in most studies is in the high range, around 83% to 98.4%, making this system useful for detecting potentially malignant lesions and determining biopsy indications. The specificity of BI-RADS ultrasound varies more than the sensitivity, ranging from 25.0% to 93.8%. This variation indicates that BI-RADS ultrasound has good detection ability, but its ability to differentiate benign from malignant lesions can be influenced by lesion characteristics, BI-RADS category cutoffs, and the context of the study population. Low specificity in some studies suggests the possibility of false positives, particularly in BI-RADS 4A lesions or benign lesions with suspicious sonographic findings. BI-RADS categories have a clear correlation with histopathology results. BI-RADS 3 is generally associated with a low

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risk of malignancy and more often indicates benign histopathology. BI-RADS 4 indicates a variable risk of malignancy and is the most heterogeneous category, making subcategories 4A, 4B, and 4C crucial for more accurate risk stratification. BI-RADS 5 consistently indicates a high likelihood of malignancy and generally requires immediate histopathological confirmation. Factors that influence the accuracy of BI-RADS ultrasound include the BI-RADS cutoff used, breast density, lesion size and characteristics, operator experience, ultrasound equipment quality, population composition, and study design. Therefore, BI-RADS interpretation should be performed comprehensively, taking into account clinical findings, patient risk factors, and the concordance between imaging and tissue examination results. Therefore, BI-RADS ultrasound serves as an effective risk stratification tool in aiding the prediction of breast lesion malignancy, but it cannot replace histopathology. Histopathological examination remains the gold standard for establishing a definitive diagnosis, especially in lesions categorized as BI-RADS 4 and BI-RADS 5.

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