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Diagnostic accuracy of contrast-enhanced breast mri in suspicious breast lesions: A prospective observational study with histopathological correlation.

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Abstract
Background
Accurate characterization of suspicious breast lesions is central to early diagnosis and optimal management of breast cancer. While mammography and ultrasonography are frontline tools, their diagnostic performance may be limited in dense breasts and complex lesions.

Objective
To assess the diagnostic performance of contrast-enhanced breast MRI in differentiating benign from malignant breast lesions, using histopathology as the reference standard.

Materials and Methods
This prospective observational study included 100 female patients presenting with suspicious breast lesions categorized as BI-RADS 4 or 5 on mammography or ultrasonography. All participants underwent contrast-enhanced breast MRI followed by histopathological confirmation through core needle biopsy or surgical excision. MRI evaluation focused on lesion morphology, internal architecture, enhancement characteristics, and kinetic curve patterns. Diagnostic indices, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy, were calculated by comparing MRI findings with histopathological results.

Results
Histopathology confirmed 65 malignant and 35 benign lesions. Breast MRI correctly identified 60 malignant and 25 benign lesions. The sensitivity was 92.3%, specificity 71.4%, positive predictive value 85.7%, negative predictive value 83.3%, and overall diagnostic accuracy 85%. Overall agreement between MRI and histopathology was 85%, demonstrating strong concordance.

Conclusion
Contrast-enhanced breast MRI is a highly sensitive and dependable modality for evaluating suspicious breast lesions. It serves as an effective adjunct to conventional imaging, improves lesion characterization, and supports accurate clinical decision-making.

Recommendations:
Contrast-enhanced breast MRI should be routinely considered in patients with BI-RADS 4–5 lesions, equivocal findings on conventional imaging, or dense breast parenchyma. Integration of advanced functional techniques, such as diffusion-weighted imaging and quantitative kinetic analysis, may enhance specificity and reduce unnecessary biopsies.

Keywords: *Breast magnetic resonance imaging; Contrast-enhanced magnetic resonance imaging; Breast cancer; Suspicious breast lesions; Diagnostic accuracy; Histopathology*
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Introduction

Breast cancer is one of the most prevalent malignancies affecting women worldwide and remains a major public health concern. Early and accurate differentiation between benign and malignant breast lesions is essential for improving prognosis, reducing disease-related mortality, and guiding timely therapeutic interventions. Mammography and ultrasonography are routinely employed as first-line imaging modalities; however, their diagnostic performance may be limited in women with dense breast tissue, complex lesion morphology, or equivocal imaging findings, often resulting in diagnostic ambiguity [1].

Dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) has emerged as an important adjunct in breast imaging. By providing high-resolution anatomical visualization along with functional assessment of tumor vascularity and contrast kinetics, DCE-MRI offers enhanced lesion characterization compared to conventional modalities [2,3]. Interpretation of DCE-MRI relies on detailed analysis of lesion morphology, internal enhancement patterns, and time–intensity kinetic curves, which are standardized through the BI-RADS MRI lexicon to estimate the likelihood of malignancy [4–6].

Multiple studies have demonstrated that DCE-MRI exhibits higher sensitivity for the detection of invasive breast cancer than mammography or ultrasound. However, specificity remains variable because certain benign lesions may show enhancement patterns similar to malignant tumors [7]. Histopathological examination, therefore, continues to serve as the definitive diagnostic gold standard and is indispensable for confirming imaging-based diagnoses [8].

Correlation between DCE-MRI findings and histopathological results is critical for evaluating diagnostic accuracy, refining imaging criteria, guiding biopsy and surgical planning, and reducing unnecessary invasive procedures. The present study aimed to assess the diagnostic accuracy of contrast-enhanced breast MRI in the characterization of suspicious breast lesions and to determine its correlation with histopathological findings as the reference standard, thereby optimizing imaging-based clinical decision-making and patient management.

Materials and Methods

Study design and setting

This study was designed as a prospective, hospital-based diagnostic accuracy study conducted in the Department of Radiology in collaboration with the Department of Surgery at Konaseema Institute of Medical Sciences, Amalapuram, Andhra Pradesh, India. The institute is a tertiary care teaching hospital that caters to patients from Amalapuram and the surrounding coastal districts and provides integrated diagnostic, surgical, and histopathological services. The availability of mammography, ultrasonography, contrast-enhanced magnetic resonance imaging, image-guided biopsy, surgical excision, and pathology reporting made the center suitable for a diagnostic correlation study using histopathology as the reference standard. The study was carried out over 14 months from November 2024 to December 2025. All eligible women presenting during the study period with suspicious breast lesions categorized as BI-RADS 4 or 5 on conventional imaging were screened for inclusion

Study Size

The sample size of 100 female patients was determined by consecutive recruitment of all eligible participants presenting during the study period and was considered adequate for estimation of the primary diagnostic accuracy measures of contrast-enhanced breast MRI in this single-center prospective study. The final sample represented the total number of patients who met the eligibility criteria and completed both MRI and histopathological assessment within the defined recruitment period.

Study Population

A total of 100 female patients with suspicious breast lesions detected on mammography and/or ultrasonography were consecutively enrolled.

Inclusion criteria

- Age ≥18 years
- Presence of a BI-RADS category 4 or 5 lesion on conventional imaging
- Willingness to undergo contrast-enhanced breast MRI and histopathological evaluation

Exclusion criteria

- Contraindications to MRI (such as pacemakers or non-compatible metallic implants)
- Known hypersensitivity to gadolinium-based contrast agents
- Pregnancy or lactation
- History of prior surgery, radiotherapy, or chemotherapy involving the same breast

MRI Protocol

All patients underwent contrast-enhanced breast MRI using a 1.5 Tesla or 3 Tesla MRI scanner with a dedicated breast coil. Imaging was performed in the prone position. The protocol included pre-contrast T1-weighted and T2-weighted sequences, followed by dynamic contrast-enhanced imaging after intravenous administration of a

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gadolinium-based contrast agent at a dose of 0.1 mmol/kg body weight.

Image Analysis

MRI images were independently reviewed by two experienced radiologists who were blinded to histopathological results. Lesions were evaluated for morphological characteristics (shape, margins, internal architecture), enhancement patterns (homogeneous, heterogeneous, rim enhancement), and kinetic curve behavior (wash-in, wash-out, plateau). Lesions were categorized according to the BI-RADS MRI lexicon. Any disagreement between observers was resolved by consensus.

Histopathological Correlation

All patients subsequently underwent ultrasound-guided core needle biopsy or surgical excision of the lesion. Histopathological examination was performed by an experienced pathologist blinded to MRI findings, and the results were considered the reference standard.

Bias

Several measures were undertaken to minimize potential sources of bias. Selection bias was reduced by consecutively enrolling eligible patients who met the predefined inclusion and exclusion criteria during the study period. Information and observer bias were addressed by using a standardized MRI protocol and interpreting lesions according to the BI-RADS MRI lexicon. MRI images were reviewed independently by two experienced radiologists who were blinded to histopathological findings, and disagreements were resolved by consensus. Diagnostic review bias was further reduced because histopathological examination was performed by a pathologist blinded to MRI interpretation. Verification bias was minimized by ensuring that all enrolled patients underwent histopathological confirmation through core needle biopsy or surgical excision, which served as the uniform reference standard. In addition, patients with prior surgery, chemotherapy, or radiotherapy to the same breast were excluded to reduce distortion of imaging appearance and misclassification.

Data Collection and Statistical Analysis

Clinical and demographic details, imaging characteristics, and histopathological findings were systematically recorded. Diagnostic performance parameters of MRI, including sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy, were calculated using 2×2 contingency tables. Agreement between MRI findings and histopathology was assessed using Cohen's kappa statistic. Statistical analysis was performed using SPSS version 26 (IBM Corp., Armonk, NY), and a p-value <0.05 was considered statistically significant.

Ethical Approval

The study protocol was reviewed and approved by the Institutional Ethics Committee of Konaseema Institute of Medical Sciences, Amalapuram. The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment, and patient confidentiality was strictly maintained throughout the study.

Results

Participant flow

During the study period, female patients with suspicious breast lesions categorized as BI-RADS 4 or 5 on mammography and/or ultrasonography were assessed for eligibility. A total of 100 eligible patients were enrolled in the study. All 100 enrolled patients underwent contrast-enhanced breast magnetic resonance imaging, followed by histopathological confirmation by core needle biopsy or surgical excision. Complete imaging and histopathological data were available for all participants, and all 100 patients were included in the final analysis. No patient was excluded after enrollment, and no loss to follow-up occurred between MRI evaluation and histopathological diagnosis.

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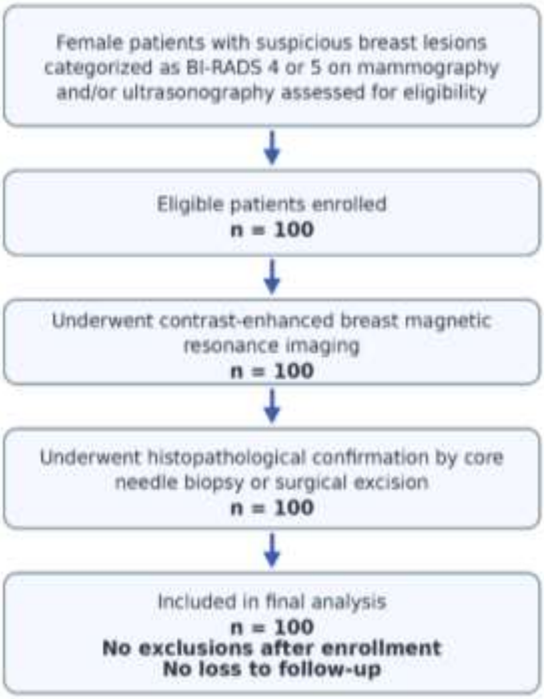

Figure 1: Participant Flow Diagram

Patient Demographics

A total of 100 female patients with suspicious breast lesions were included in the present study. The mean age of the study population was 47.6 ± 10.2 years, with an age range of 25 to 70 years. The majority of patients (60%) belonged to the 40–59-year age group, followed by 25% in the 20–39-year group and 15% aged 60 years or above. A positive family history of breast cancer was noted in 20% of patients. Lesions were slightly more common in the right breast (55%) compared to the left breast (45%) (Table 1).

Table 1: Demographic Characteristics of Study Population (n = 100)

Variable	Number (%)
Age (years)	
20–39	25 (25%)
40–59	60 (60%)
≥60	15 (15%)
Family history of breast cancer	20 (20%)
Lesion side	
Right breast	55 (55%)
Left breast	45 (45%)

MRI Findings

On contrast-enhanced breast MRI, lesion size was ≤2 cm in 40% of cases, between 2.1 and 5 cm in 45%, and greater than 5 cm in 15%. Morphologically, mass lesions were the predominant presentation, observed in 70% of patients, while non-mass enhancement patterns were seen in 30%. With respect to enhancement characteristics, heterogeneous enhancement was the most frequent pattern (45%), followed by homogeneous enhancement (35%) and rim enhancement (20%). Based on BI-RADS MRI assessment, 55% of lesions were categorized as BI-RADS 4 and 45% as BI-RADS 5, indicating a high level of suspicion for malignancy (Table 2).

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Table 2: MRI Characteristics of Lesions (n = 100)

MRI Feature	Number (%)
Lesion size	
≤2 cm	40 (40%)
2.1–5 cm	45 (45%)
>5 cm	15 (15%)
Morphology	
Mass	70 (70%)
Non-mass enhancement	30 (30%)
Enhancement pattern	
Homogeneous	35 (35%)
Heterogeneous	45 (45%)
Rim enhancement	20 (20%)
BI-RADS MRI category	
4	55 (55%)
5	45 (45%)

Histopathological Diagnosis

Histopathological examination following biopsy or surgical excision served as the reference standard. Malignancy was confirmed in 65% of cases, while 35% were benign. Among malignant lesions, invasive ductal carcinoma was the most common histological type (50%), followed by invasive lobular carcinoma (10%) and ductal carcinoma in situ (5%). Benign lesions predominantly comprised fibroadenomas (20%) and fibrocystic changes (10%), with other benign entities accounting for 5% (Table 3).

Table 3: Histopathological Findings (n = 100)

Histopathology	Number (%)
Malignant	65 (65%)
Invasive ductal carcinoma	50 (50%)
Invasive lobular carcinoma	10 (10%)
DCIS	5 (5%)
Benign	35 (35%)
Fibroadenoma	20 (20%)
Fibrocystic change	10 (10%)
Other benign lesions	5 (5%)

Diagnostic Accuracy of Contrast-Enhanced Breast MRI

Comparison of MRI findings with histopathology revealed 60 true-positive, 25 true-negative, 10 false-positive, and 5 false-negative cases. Contrast-enhanced breast MRI demonstrated a sensitivity of 92.3% and a specificity of 71.4%. The positive predictive value was 85.7%, and the negative predictive value was 83.3%. The overall diagnostic accuracy of MRI in differentiating malignant from benign breast lesions was 85%. These findings indicate that contrast-enhanced breast MRI is highly sensitive with good overall accuracy, although moderate false-positive rates contributed to lower specificity (Table 4).

Table 4: Diagnostic Performance of Contrast-Enhanced Breast MRI (n = 100)

Parameter	Value (%)
True positive	60
False positive	10

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True negative	25
False negative	5
Sensitivity	92.3%
Specificity	71.4%
Positive predictive value (PPV)	85.7%
Negative predictive value (NPV)	83.3%
Overall accuracy	85%

Correlation with histopathological findings

When MRI findings were compared with histopathological diagnosis, 60 lesions were true positive, 25 were true negative, 10 were false positive, and 5 were false negative. Thus, MRI findings were concordant with histopathology in 85 of 100 cases, yielding an overall agreement of 85%. The observed agreement between contrast-enhanced breast MRI and histopathology corresponded to a Cohen's kappa value of 0.66, indicating substantial agreement. These findings demonstrate a strong association between MRI-based lesion characterization and the final histopathological diagnosis, supporting the reliability of breast MRI as a diagnostic adjunct in suspicious breast lesions (Table 5).

Table 5. Correlation of breast MRI findings with histopathological diagnosis

MRI diagnosis	Histopathology malignant	Histopathology benign	Total
Malignant	60	10	70
Benign	5	25	30
Total	65	35	100

Discussion

In this prospective study of 100 patients with suspicious breast lesions, contrast-enhanced breast MRI showed strong overall diagnostic performance, with high sensitivity [92.3%] and moderate specificity [71.4%]. These findings indicate that breast MRI is highly effective in identifying malignant lesions and has substantial value as an adjunctive imaging tool in the evaluation of indeterminate breast abnormalities. From a clinical perspective, the high sensitivity suggests that MRI is particularly useful when the primary goal is to minimize missed cancers and improve diagnostic confidence before biopsy or treatment planning [9].

The excellent sensitivity observed in the present study is in agreement with earlier reports demonstrating the superior cancer detection capability of dynamic contrast-enhanced MRI, especially in women with dense breasts and in those with inconclusive findings on mammography or ultrasonography [10,11]. This high sensitivity can be explained by the ability of MRI to depict both morphologic and functional tumor features. In addition to lesion shape and margins, MRI captures vascular behavior, contrast uptake, and enhancement kinetics, which reflect the neoangiogenesis and altered perfusion typically associated with malignant transformation. These features likely contributed to the high true-positive rate observed in our cohort and support the role of MRI in early lesion characterization.

However, although MRI performed well in detecting malignancy, its specificity was comparatively lower. This pattern suggests that while MRI is highly reliable for ruling in suspicious disease, some benign lesions may still mimic malignant enhancement characteristics, resulting in false-positive interpretations [12]. In the present study, benign entities such as fibroadenomas and fibrocystic changes likely contributed to this reduction in specificity because they can also exhibit heterogeneous or rapid contrast enhancement. This finding has practical importance, as it indicates that MRI findings should always be interpreted in conjunction with clinical assessment, conventional imaging, and tissue diagnosis rather than being used in isolation.

The moderate specificity observed in this study also highlights an important area for refinement in breast MRI protocols. Previous studies have shown that the incorporation of diffusion-weighted imaging into dynamic contrast-enhanced MRI can improve lesion characterization by providing information on tissue cellularity and water diffusivity, thereby helping distinguish benign from malignant lesions with greater precision [13]. In this context, the present findings support the concept that multiparametric MRI may reduce unnecessary biopsies and strengthen diagnostic confidence, particularly in borderline or equivocal cases.

Compared with other breast imaging modalities, contrast-enhanced MRI continues to offer distinct clinical advantages. Although contrast-enhanced mammography has emerged as a useful alternative in selected situations, MRI remains particularly valuable for evaluating multifocal or multicentric disease, defining the true extent

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of tumor involvement, and assessing the contralateral breast [14,15]. These strengths are highly relevant in preoperative assessment, where accurate delineation of disease burden directly influences surgical planning and overall management strategy.

Histopathological examination remained the definitive reference standard in the present study, and the observed concordance between MRI and histopathology further supports the reliability of MRI in suspicious breast lesions. The high level of agreement indicates that MRI can serve as a dependable non-invasive problem-solving tool in patients with BI-RADS 4 and 5 lesions, dense breast parenchyma, or elevated clinical risk. Thus, the findings of this study reinforce the role of contrast-enhanced breast MRI not only in lesion detection, but also in biopsy targeting, preoperative decision-making, and individualized patient management [16-18].

Generalizability:

The generalizability of the present findings may be influenced by the single-center design, limited sample size, and potential referral bias inherent to a tertiary care setting. Nevertheless, the results apply to similar clinical environments where MRI is used as a problem-solving tool for suspicious breast lesions. Larger, multicenter studies incorporating standardized MRI protocols, multiparametric imaging, and emerging artificial intelligence–based analysis are warranted to validate these findings across diverse populations and to further enhance diagnostic accuracy while minimizing false-positive rates.

Conclusion

Contrast-enhanced breast MRI proved to be a highly sensitive and clinically reliable modality for the assessment of suspicious breast lesions in this prospective study of 100 patients. The strong correlation between MRI findings and histopathological diagnosis underscores its value as a non-invasive adjunct to conventional imaging. MRI was particularly beneficial in patients with BI-RADS 4–5 lesions, dense breast parenchyma, and high-risk clinical profiles, where accurate lesion characterization is crucial for guiding biopsy decisions and surgical planning. Incorporation of functional techniques such as diffusion-weighted imaging, along with adherence to standardized MRI interpretation protocols, may further improve specificity, minimize false-positive results, and optimize individualized patient management strategies.

Limitations

This study has certain limitations that should be considered while interpreting the results. It was conducted at a single tertiary care center, which may introduce referral bias and limit wider applicability. The sample size, though adequate for diagnostic accuracy assessment, was relatively small. Inter-observer variability, despite consensus reading, cannot be completely excluded. Advanced MRI parameters such as quantitative diffusion metrics were not systematically analyzed. Long-term clinical outcomes were also not evaluated, which could further clarify the prognostic relevance of MRI findings.

Recommendations

Contrast-enhanced breast MRI should be routinely considered for patients with BI-RADS 4 and 5 lesions, dense breast tissue, or inconclusive findings on mammography and ultrasound. Incorporation of multiparametric MRI, including diffusion-weighted imaging and quantitative kinetic analysis, is recommended to improve specificity and reduce false-positive results. Standardization of imaging protocols and reporting using the BI-RADS MRI lexicon should be encouraged. Future multicenter studies with larger cohorts and integration of artificial intelligence–based tools may further refine diagnostic accuracy, reduce unnecessary biopsies, and optimize personalized breast cancer management strategies.

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Abbreviations

MRI – Magnetic Resonance Imaging;
DCE-MRI – Dynamic Contrast-Enhanced Magnetic Resonance Imaging;
BI-RADS – Breast Imaging Reporting and Data System;
DWI – Diffusion-Weighted Imaging;
PPV – Positive Predictive Value;
NPV – Negative Predictive Value;
DCIS – Ductal Carcinoma In Situ;
SPSS – Statistical Package for the Social Sciences

Source of funding

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Conflict of interest

The authors declare no conflict of interest.

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Author contributions

PSN-Concept and design of the study, results interpretation, review of literature, and preparation of the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript. **RD-** Concept and design of the study, results interpretation, review of literature, preparing the first draft of the manuscript, and revision of the manuscript. **BK-** Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation.**AA-** Concept and design of the study, results interpretation, review of literature, and preparation of the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript

Data availability

Data available on request

Author Biography

Dr. Puppala Sirisha Naidu is an Assistant Professor in the Department of Radiology at Konaseema Institute of Medical Sciences, Amalapuram, Andhra Pradesh, India. Her academic interests include cardiovascular imaging, cross-sectional imaging, and advanced MRI applications. She is actively involved in undergraduate and postgraduate teaching and has contributed to clinical research focused on the diagnostic and prognostic role of imaging modalities.

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Dr. Anand Acharya, MBBS, MD (Pharmacology), currently serves as Dean and Professor, Department of Pharmacology, at the Konaseema Institute of Medical Sciences & Research Foundation (KIMS&RF), Amalapuram, Andhra Pradesh, India. A distinguished academician, researcher, and medical education leader, he has been pivotal in transforming KIMS&RF from its formative phase into a premier medical institution with over 200 undergraduate and 100 postgraduate seats.

With more than 18 years of teaching and administrative experience, Dr. Acharya has held several leadership positions, including Vice Principal, Principal, Chief Warden, Member Secretary of Institutional Ethics and Animal Ethics Committees, and is an approved PhD Guide under Dr. NTR University of Health Sciences, Vijayawada. His visionary leadership has significantly enhanced the institution's academic quality, clinical exposure, research infrastructure, and postgraduate training standards.

He has completed prestigious national faculty development programs such as the Revised Basic Course Workshop (rBCW), Advanced Course in Medical Education (ACME), and National Teacher Training Course (NTTC, JIPMER, Puducherry). He also serves as Coordinator for Pharmacovigilance and Materiovigilance Programs under IPC–PvPI and MoHFW, Government of India, contributing actively to national drug safety and regulatory initiatives.

A prolific academician, Dr. Acharya has authored and co-authored more than 100 scientific publications in reputed national and international indexed journals. His wide-ranging research covers toxicology, pharmacovigilance, antimicrobial resistance, endocrinology, neuropharmacology, and clinical pharmacology. His recent studies include long-term analyses of pyrethroid, paraquat, and chlorpyrifos poisoning, investigations into antimicrobial resistance trends, and predictive models for treatment outcomes in dermatological and toxicological emergencies.

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