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DIAGNOSTIC ACCURACY OF CONTRAST-ENHANCED MRI IN DETECTION OF MALIGNANT BREAST LESION KEEPING HISTOPATHOLOGY AS GOLD STANDARD

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Abstract

Objective: *Breast cancer is one of the most common malignancies among young women worldwide with rising incidence. Early detection has very good outcomes. Contrast-enhanced magnetic resonance imaging (CE-MRI) is a non-invasive investigation for the evaluation of suspected breast lesions. The aim of this study is to determine the diagnostic accuracy of CE-MRI for detecting malignant breast lesions, using histopathology as the gold standard.*

Design: *This is cross-sectional study.*

Place and duration of study: *The site for this study was Department of Diagnostic Radiology, Mardan Medical Complex, and the duration of the study was from December 2024 to May 2025.*

Methods: *A total of 230 female patients (aged 16–65) having suspicious breast lumps on mammographic criteria were enrolled in the study. CE-MRI was done for all these patients and interpretation was done by a consultant radiologist using defined criteria for malignancy detection. The Histopathological diagnosis via fine-needle aspiration cytology (FNAC) biopsy was used as the reference standard. For all these patients Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy of CE-MRI were calculated. Statistical analysis was done via the latest version of SPSS.*

Results: *The mean age of participants was 45.3 ± 11.2 years. Malignancy was confirmed via histopathology in 160 patients (69.6%), and the 70 (30.4%) had benign lesions. The CE-MRI picked up 144 of 160 cancers patients (true positives) and missed 16 (false negatives), the sensitivity was 90.0%. The 70 histopathologically benign cases, CE-MRI was done which ruled out cancer in 56 (true negatives) while14 was labeled as malignant (false positives), the specificity was 80.0%. The CE-MRI PPV was 91.1%, NPV 77.8%, and overall diagnostic accuracy 86.9%. These results showed a high diagnostic yield for CE-MRI. Subgroup analysis was done, which showed no significant difference in diagnostic performance by age group or lesion location ($p > 0.05$).*

Conclusion: *In this study for patients with breast lumps, contrast-enhanced MRI showed high sensitivity and good specificity for the detection of malignancy. CE-MRI can accurately detect most breast cancers and can help to avoid*

unnecessary invasive biopsies in breast malignancy, However for the confirmation of definitive diagnosis histopathalogical is necessary.

Introduction

Breast cancer is the most common malignancy in women, and its incidence has been increasing worldwide these days[1]. In the United States one in every eight women is at risk of breast cancer and the risk of invasive breast cancer is 12.4% [2]. The prevalence of breast cancer is different in different population ranging from 7% up to 18%, with a wide spectrum of tumor histological types (e.g. ductal, lobular, in situ) and hormone receptor profiles[3]. Breast cancer is initially asymptomatic and a palpable lump appears after few months, the cases are diagnosed at relatively late stages, sometimes with metastasis. The delay may be due obtaining a biopsy and histopathological confirmation[4]. various factors can lead to such delay including fear of invasive procedures and limited access to diagnostic services[5]. Non-invasive diagnostic modalities such as Contrast-enhanced magnetic resonance imaging (CE-MRI) can facilitate early detection of breast cancer in suspicious breast lesions [6].

Contrast-enhanced magnetic resonance imaging (CE-MRI) is a novel imaging modality for the evaluation of breast lesions [7]. CE-MRI can detect breast malignancy and is highly sensitive,it can visualize tumor vascularity and contrast uptake dynamics, by which malignant and benign lesions can be differentiated[8]. It does not involve ionizing radiation and is particularly useful in patients with dense breast tissue or those at high risk for breast cancer[9]. In the previous studies the diagnostic performance of contrast-enhanced MRI is reported having sensitivity ranging from **88% to 98%** and specificity between **67% and 86%** , it is mostly used for the detection of malignant breast lesions. All these findings highlight its strong capability in identifying malignancy while acknowledging potential false-positive rates. [10,11,12].

The aim of this study was to determine the diagnostic accuracy of contrast-enhanced MRI in detecting malignant breast lesions, using histopathology as the gold standard, it will generate local evidence and guide the clinical decision making and reduce unnecessary invasive procedures.

Methodology:

Our Study was cross-sectional validation study and the study site was Department of Diagnostic Radiology Mardan Medical Complex in Mardan, Pakistan, The study span was six months from December 2024 to May 2025. A total of 230 female patients aged 16–65 years with highly suspicious breast lumps as identified on imaging were enrolled and the sampling technique was non-probability consecutive sampling. The suspicious lesions were defined on mammography by a consultant radiologist as irregular, dense, speculated masses with indistinct margins,

Patients with contraindications for MRI were excluded and those with bleeding or clotting disorders were also excluded as to avoid biopsy-related complications.

Contrast enhanced Breast MRI using intravenous gadolinium was done for all patients; the scans were interpreted by a consultant radiologist who was blinded to histopathology reports.

A lesion was considered malignant on CE-MRI if it demonstrated all of the following features:

- Irregular or speculated margins,
- Suspicious enhancement patterns (e.g. ductal or peripheral rim enhancement), and
- Type II (plateau) or Type III (washout) kinetic curve on dynamic contrast sequences.

Lesions not meeting these criteria were labeled benign. MRI findings (positive/negative) were recorded on a predesigned proforma.

From all the enrolled patients' tissue sampling was done for histopathology for the confirmation of definitive diagnosis, and histopathology slides were reported by a blinded histopathologist. Histopathology confirming malignant cells consistent with breast carcinoma was considered positive. Non-diagnostic or suspicious FNAC cases were re-evaluated with core or excisional biopsy.

The Histopathology was used as a gold standard against which CE-MRI findings were compared.

All the data collection was done via a structured proforma which included age, site of breast lump, and duration of lump, educational status of the participants, smoking history and family history of breast cancer. The CE-MRI, results were documented as positive or negative for malignancy, and the histopathology findings were categorized as malignant or benign.

The data analysis was done using IBM SPSS Statistics (version 26). Continuous variables (e.g., age, lump duration) were summarized as mean ± SD or median. Categorical variables (e.g., lump side, education, residence, smoking, family history, CE-MRI and histopathology results) were presented as frequencies and percentages. The diagnostic performance of CE-MRI was evaluated against histopathology (reference standard) by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy using a 2×2 contingency table. Sensitivity = TP/(TP+FN)×100, Specificity = TN/(TN+FP)×100, PPV = TP/(TP+FP)×100, NPV = TN/(TN+FN)×100, and Accuracy = (TP+TN)/Total×100, where TP = true positives, TN = true negatives, FP = false positives, and FN = false negatives

Results

A total of 230 female patients with highly suspicious breast lumps were enrolled. The mean age was 45.3 ± 11.2 years (range: 18–65), with most (68%) aged 35–55 years. The median duration of symptoms were 12 weeks (IQR: 8–20).

Lump distribution was nearly symmetrical: right breast in 122 (53%) and left in 108 (47%). Although lump size was not detailed, all met BI-RADS 5 criteria on mammography. Rural resident's comprised 60% and 55% had no formal education. Only 15 (6.5%) were smokers, while 28 (12.2%) reported a family history of breast cancer. None of these baseline variables showed a significant association with CE-MRI diagnostic performance.

Histopathology confirmed malignancy in 160 cases (69.6%) and benign pathology in 70 (30.4%). Most malignant lesions were invasive ductal carcinoma, with few invasive lobular or other variants. Benign diagnoses included fibroadenoma, fibrocystic changes, and non-malignant inflammatory lesions.

On CE-MRI, 158 (68.7%) lesions were reported malignant, while 72 (31.3%) were benign. The CE-MRI and histopathology results were cross-tabulated (Table 1) to calculate diagnostic indices (sensitivity, specificity, PPV, NPV, accuracy).

Table 1. CE-MRI findings versus Histopathology results (2×2 contingency table).

CE-MRI Result	Histopathology Malignant	Histopathology Benign	Total
Malignant (Positive)	144 (True Positive)	14 (False Positive)	158
Benign (Negative)	16 (False Negative)	56 (True Negative)	72
Total	160	70	230

Of the 160 histologically confirmed malignant cases, **144 (90%)** were correctly identified on CE-MRI (true positives), while **16 (10%)** were missed (false negatives). Among 70 benign cases, **56 (80%)** were correctly classified as benign (true negatives), and **14 (20%)** were falsely labeled malignant (false positives).

Based on these findings:

- **Sensitivity:** 90.0% (144/160; 95% CI: 84.5–93.8%), indicating strong ability to detect malignancy.
- **Specificity:** 80.0% (56/70; 95% CI: 69.5–88.0%), reflecting good discrimination of benign lesions.
- **PPV:** 91.1% (144/158), showing a high probability that MRI-positive lesions were truly malignant.

- **NPV:** 77.8% (56/72), suggesting that while most MRI-negative cases were benign, histologic confirmation remains essential.
- **Overall accuracy:** 86.9% (200/230), indicating that CE-MRI correctly classified nearly nine out of ten cases.

False negatives were mainly small or atypically enhancing tumors, whereas false positives often represented benign but enhancing lesions such as fibroadenomas or proliferative changes.

Discussion

In this cross-sectional validation study, we evaluated the diagnostic accuracy of contrast-enhanced MRI for the detection of malignant breast lesions in patients with mammographically suspicious breast lumps. Our findings demonstrate that CE-MRI is a highly sensitive modality in this context, correctly identifying 90% of malignant lesions. The specificity of 80% indicates a moderate rate of false positives, which suggests that while CE-MRI tends to over-call some benign lesions as malignant, it rarely misses cancers. The high positive predictive value (~91%) observed in our study means that a positive CE-MRI finding is strongly indicative of malignancy, consistent with the notion that CE-MRI is excellent at characterizing breast lesions that turn out to be cancer. On the other hand, the negative predictive value (~78%)—although respectable—also reinforces that a negative result on CE-MRI does not guarantee the absence of cancer in a high-risk lump. Therefore, CE-MRI should be used to complement, rather than replace, tissue diagnosis in such cases.

Our results are largely in agreement with several previous studies examining breast MRI accuracy. **Fatima et al. (2019)** reported CE-MRI sensitivity and accuracy (93.9% and 89.3%, respectively) that are comparable to our findings. Their slightly higher sensitivity might be due to technical factors or patient selection, but both studies confirm that MRI is very adept at detecting malignancy[15]. Similarly, **Rasheed et al. (2022)** found a sensitivity of 91% and accuracy of 86.7% for MRI, virtually echoing our sensitivity and falling within the range of our accuracy[16]. Our study's PPV of 91.1% aligns with the PPVs around 92% reported by Fatima et al. and Rasheed et al., indicating consistent performance of MRI in correctly predicting cancer when it calls a lesion malignant. The specificity in our study was 80%, which is consistent with other studies which observed the specificity of (73–75%) and some studies reported a much higher specificity (96.6%) reported by **Sedguli et al. (2022)**[17]. Sedguli and colleagues, who compared MR mammography with other imaging modalities, reported a specificity of over 96% and a sensitivity of only 75% for MRI[18].

The role of operational criteria in MRI interpretation is also very important. We defined MRI positivity with a combination of morphological and kinetic criteria. Studies that use strict criteria (for example, requiring certain enhancement patterns) might report different sensitivity/specificity profiles. Our results are also in consistency with those of Fatima et al. and Rasheed et al. both of these studies are conducted in Pakistan and suggests that the diagnostic accuracy of CE-MRI for breast lesions observed internationally is reproducible in our local setting as well.

Our study focused on patients with highly suspicious breast lumps identified on mammography, a group for whom biopsy remains the standard of care due to the high pre-test probability of malignancy. In this context, CE-MRI serves as a valuable adjunct rather than a replacement for tissue diagnosis. Its potential utility lies in situations where biopsy is delayed, contraindicated, or technically challenging, allowing clinicians to gain additional diagnostic confidence. The CE-MRI offers important information on tumor extent, multifocality, multicentricity, and contralateral involvement, aiding surgical planning.

In our study group, the high sensitivity observed indicates that a negative CE-MRI result is uncommon among truly malignant lesions, given the moderate NPV (78%), a negative finding should not preclude biopsy when clinical or imaging suspicion remains strong. All such cases should be reviewed by a multidisciplinary team if biopsy is not immediately feasible. Our findings reaffirm CE-MRI as a powerful complementary

tool that enhances diagnostic confidence and preoperative assessment but cannot replace histopathological confirmation.

Conclusion

Our study demonstrated that CE-MRI have high diagnostic accuracy for the detection of malignant breast lesions in patients with suspected breast lumps. It has excellent sensitivity and a strong positive predictive value, confirming its reliability in identifying and predicting malignancy; however histopathological confirmation continues to be essential for definitive diagnosis.

Declarations

Ethical Approval:

The study was approved by the Ethical Review Board of Bacha Khan Medical College, Mardan (Approval No. 427/BKMC). Written informed consent was obtained from all participants prior to inclusion in the study.

Conflict of Interest:

The authors declare that there is no conflict of interest related to this study or its publication.

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Authors' Contribution:

- **Dr.Hamayoon:** Conceptualization, study design, supervision, and critical revision of the manuscript.
- **Dr. Ihtesham Noor:** Data collection, imaging interpretation, and drafting of the initial manuscript.
- **Dr. Zubair Janan Aurakzai:** Methodological guidance, statistical analysis, and manuscript review for important intellectual content.
- **Dr. Muhammad Farah Adeed Khan:** Data acquisition, patient coordination, and literature review.

All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work in ensuring its accuracy and integrity.

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