Section: Radiodiagnosis

Original Research Article

EVALUATING EFFICACY OF ACCURACY OF CLINICAL DIAGNOSIS, MAMMOGRAPHY AND ULTRASONOGRAPHY IN BREAST CANCER

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ABSTRACT

Background: Breast cancer remains one of the most common malignancies among women worldwide, with early and accurate diagnosis playing a pivotal role in improving prognosis and survival. Clinical breast examination, mammography, and ultrasonography are widely used diagnostic modalities, each with inherent strengths and limitations. Evaluating their diagnostic accuracy, individually and in combination, is essential for optimizing breast cancer detection, particularly in resource-limited settings. **Aim:** To retrospectively evaluate and compare the diagnostic accuracy of **clinical examination, mammography, and ultrasonography** in the detection of breast cancer, using histopathological examination as the reference standard.

Materials and Methods: This retrospective observational study was conducted at Bharti Hospital, Pune, and included 120 patients who presented with breast lumps and underwent clinical breast examination, mammography, ultrasonography, and subsequent histopathological confirmation. Medical records were reviewed to collect demographic data, clinical findings, imaging results, and final histopathological diagnoses. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy of each modality were calculated and compared.

Results: Among the 120 cases analyzed, histopathology confirmed breast cancer in a significant proportion of patients. Clinical examination demonstrated moderate sensitivity but lower specificity. Mammography showed higher sensitivity and specificity compared to clinical examination, particularly in detecting malignant lesions in older patients. Ultrasonography exhibited high sensitivity, especially in dense breast tissue, with improved lesion characterization. The combined use of clinical examination, mammography, and ultrasonography significantly enhanced diagnostic accuracy compared to any single modality alone.

Conclusion: The findings of this study suggest that while each diagnostic modality has limitations, a **multimodal diagnostic approach** combining clinical assessment, mammography, and ultrasonography provides superior accuracy in breast cancer detection. This integrated strategy improves early diagnosis and supports appropriate clinical decision-making, thereby contributing to better patient outcomes.

Keywords: Breast cancer, clinical diagnosis, mammography, ultrasonography, diagnostic accuracy, retrospective study.

INTRODUCTION

Breast cancer is the most frequently diagnosed malignancy among women worldwide and remains a leading cause of cancer-related morbidity and mortality. According to global cancer statistics, the incidence of breast cancer has been steadily increasing, particularly in developing countries such as India, where delayed presentation and limited access to screening facilities contribute to poorer outcomes.[1] Early detection and accurate diagnosis are critical in reducing disease burden, improving survival rates, and enabling timely initiation of appropriate treatment.[2]

Clinical breast examination (CBE), mammography, and ultrasonography are the cornerstone diagnostic tools employed in the evaluation of patients presenting with breast symptoms or palpable lumps.[3] Clinical examination is often the first step in the diagnostic pathway, especially in low-resource settings. It allows for assessment of lump characteristics such as size, consistency, mobility, and associated skin or nipple changes. However, clinical diagnosis alone is subjective and heavily dependent on the examiner's experience, often leading to variability in diagnostic accuracy.[4]

Mammography is widely regarded as the gold standard imaging modality for breast cancer screening and diagnosis, particularly in women over 40 years of age. It enables detection of non-palpable lesions, microcalcifications, and architectural distortions that may indicate early malignancy.[5] Despite its proven efficacy, mammography has certain limitations, especially in younger women with dense breast tissue, where lesion detection can be challenging. Additionally, false-positive and false-negative findings can occur, necessitating adjunctive imaging modalities.[2,6]

Ultrasonography has emerged as a valuable complementary tool to mammography, particularly in evaluating dense breasts and differentiating cystic from solid lesions. It is non-invasive, radiation-free, cost-effective, and widely available, making it especially useful in developing countries. Ultrasonography also plays a crucial role in guiding interventional procedures such as fine-needle aspiration cytology and core needle biopsy. However, its diagnostic accuracy can be influenced by operator dependency and limited ability to detect microcalcifications.[7,8]

Histopathological examination remains the definitive diagnostic standard for breast cancer, providing confirmation of malignancy and guiding therapeutic decisions. Given the varying diagnostic performance of clinical examination, mammography, and ultrasonography, it is essential to assess their individual and combined accuracy in routine clinical practice. Understanding the strengths and limitations of these modalities can help optimize diagnostic protocols and reduce unnecessary invasive procedures.[5,9]

In India, limited data are available from tertiary care centers regarding the comparative efficacy of these diagnostic tools in real-world settings. Retrospective analysis of institutional data provides valuable insights into diagnostic trends and outcomes, particularly in high-volume hospitals. Bharti Hospital, Pune, serves a diverse population with varying socioeconomic backgrounds, making it an ideal setting to evaluate the effectiveness of commonly used breast cancer diagnostic modalities.[10]

Therefore, the present retrospective study was undertaken to evaluate and compare the accuracy and efficacy of clinical diagnosis, mammography, and ultrasonography in detecting breast cancer, using histopathological findings as the reference standard, in a cohort of 120 patients at Bharti Hospital, Pune. The results of this study aim to contribute to improved diagnostic strategies and enhance early detection of breast cancer in similar healthcare settings.

MATERIALS AND METHODS

Study Design and Setting

This was a retrospective observational study conducted at Bharti Hospital, Pune, a tertiary care teaching hospital providing comprehensive diagnostic and oncological services. The study involved a review of medical records of patients evaluated for suspected breast lesions over a defined study period.

Study Duration

Data were collected retrospectively for a period of **two years** from hospital medical records.

Study Population and Sample Size

A total of **120 patients** who presented with breast complaints and subsequently underwent clinical examination, imaging evaluation, and histopathological confirmation were included in the study.

Inclusion Criteria

- Female patients presenting with palpable breast lumps or breast-related symptoms
- Patients who underwent:
  - **Clinical breast examination**
  - **Mammography**
  - **Ultrasonography**
- Patients with **available histopathological diagnosis** obtained by core needle biopsy, excision biopsy, or mastectomy specimens
- Complete medical and radiological records available for review

Exclusion Criteria

- Patients with **incomplete clinical or imaging data**
- Patients previously treated for breast malignancy
- Male breast cancer cases
- Patients who did not undergo histopathological confirmation
- Recurrent breast cancer cases

Clinical Evaluation

Clinical diagnosis was made by experienced surgeons based on clinical breast examination (CBE). Findings such as lump size, location, consistency, mobility, skin changes, nipple retraction, discharge, and axillary lymphadenopathy were recorded. Based on these findings, lesions were categorized as clinically benign or clinically suspicious/malignant.

Radiological Evaluation

Mammography

Bilateral mammography was performed using standard craniocaudal (CC) and mediolateral oblique (MLO) views. Mammographic findings were documented according to the Breast Imaging Reporting and Data System (BI-RADS) classification. Lesions categorized as BI-RADS 4 and 5 were considered suspicious for malignancy, while BI-RADS 1–3 were considered benign.

Ultrasonography

Breast ultrasonography was performed using high-frequency linear transducers (7.5–12 MHz). Sonographic features including lesion shape, margins, echogenicity, posterior acoustic features, vascularity, and lymph node involvement were assessed. Ultrasonographic findings were also categorized using **BI-RADS** criteria.

Histopathological Examination

Histopathological examination (HPE) served as the gold standard for diagnosis. Tissue samples obtained via core needle biopsy, lumpectomy, or mastectomy were processed and examined by experienced pathologists. Lesions were classified as benign or malignant based on histological findings.

Assessment of Diagnostic Accuracy

The diagnostic performance of **clinical examination, mammography, and ultrasonography** was evaluated by comparing each modality with histopathological results. The following parameters were calculated:

- **Sensitivity**
- **Specificity**
- **Positive Predictive Value (PPV)**
- **Negative Predictive Value (NPV)**
- **Overall diagnostic accuracy**

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) version 25.0. Categorical variables were expressed as frequencies and percentages. Diagnostic accuracy parameters were calculated using standard formulas. The Chi-square test was applied to assess the association between imaging findings and histopathological results. A p-value < 0.05 was considered statistically significant.

RESULTS

Demographic Characteristics of Study Population

A total of 120 patients were included in the study. All patients were females who presented with breast-related complaints and underwent clinical evaluation, mammography, ultrasonography, and histopathological confirmation

Table 1: Age Distribution of Study Participants (n = 120)

Age Group (years)	Number of Patients	Percentage (%)
<30	12	10.0
31–40	28	23.3
41–50	38	31.7
51–60	26	21.7
>60	16	13.3

The majority of patients (31.7%) belonged to the 41–50 years age group, followed by 31–40 years (23.3%). Breast cancer incidence was notably higher after 40 years of age.

Histopathological Diagnosis

Histopathology served as the gold standard for diagnosis.

Table 2: Histopathological Findings

Diagnosis	Number of Patients	Percentage (%)
Malignant	72	60.0
Benign	48	40.0
Total	**120**	**100**

Out of 120 patients, 72 (60%) were confirmed to have malignant breast lesions, while 48 (40%) had benign pathology.

Diagnostic Performance of Clinical Examination

Clinical diagnosis categorized lesions as benign or suspicious/malignant.

Table 3: Clinical Diagnosis vs Histopathology

Clinical Diagnosis	Malignant (HPE)	Benign (HPE)	Total
Malignant	60	12	72
Benign	12	36	48
Total	**72**	**48**	**120**

Clinical examination correctly identified 60 malignant cases and 36 benign cases. However, 12 false-negative and 12 false-positive cases were observed, indicating moderate diagnostic accuracy.

Diagnostic Performance of Mammography

Mammographic findings were categorized using BI-RADS. Mammography demonstrated higher sensitivity than clinical examination, correctly identifying 66 malignant lesions, with only 6 false-negative cases. Typical mammographic findings of benign and malignant lesions are illustrated in Figures 1a, 2a, and 3a-b.

Table 3: Clinical Diagnosis vs Histopathology

Clinical Diagnosis	Malignant (HPE)	Benign (HPE)	Total
Malignant	60	12	72
Benign	12	36	48
Total	**72**	**48**	**120**

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Table 4: Mammography vs Histopathology

Mammography (BI-RADS)	Malignant (HPE)	Benign (HPE)	Total
BI-RADS 4/5	66	10	76
BI-RADS 1–3	6	38	44
Total	**72**	**48**	**120**

Diagnostic Performance of Ultrasonography

Ultrasonography showed the highest detection rate, identifying 68 malignant cases, with only 4 false-negative results, making it superior to both clinical examination and mammography. The characteristic sonographic appearances of fibroadenomas, simple cysts, and malignant masses are demonstrated in Figures 1b, 2b, and 3c, respectively.

Table 5: Ultrasonography vs Histopathology

Ultrasonography (BI-RADS)	Malignant (HPE)	Benign (HPE)	Total
BI-RADS 4/5	68	8	76
BI-RADS 1–3	4	40	44
Total	**72**	**48**	**120**

Comparison of Diagnostic Accuracy

Table 6: Diagnostic Accuracy Parameters of Different Modalities

Modality	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Clinical Examination	83.3	75.0	83.3	75.0	80.0
Mammography	91.7	79.2	86.8	86.4	87.5
Ultrasonography	94.4	83.3	89.5	90.9	90.8

Ultrasonography demonstrated the highest sensitivity (94.4%) and overall accuracy (90.8%), followed by mammography. Clinical examination showed the lowest diagnostic accuracy among the three modalities.

A statistically significant association was observed between imaging modalities and histopathological diagnosis ($p < 0.05$). Ultrasonography showed superior diagnostic performance compared to clinical examination and mammography.

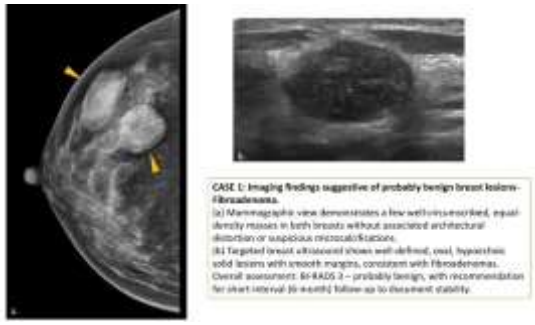

Figure 1: Benign Breast Lesion - Fibroadenoma (BI-RADS 3)

(a) Mammographic view demonstrates a few well-circumscribed, equal-density masses in both breasts

without associated architectural distortion or suspicious microcalcifications.
(b) Targeted breast ultrasound shows well-defined, oval, hypoechoic solid lesions with smooth margins, consistent with fibroadenomas. These imaging findings are characteristic of a probably benign lesion, leading to a BI-RADS 3 assessment.

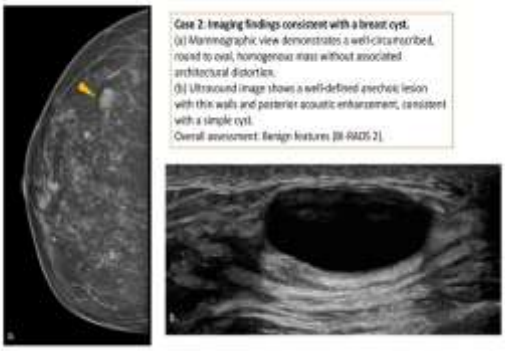

Figure 2: Benign Breast Lesion - Simple Cyst (BI-RADS 2)

(a) Mammographic view shows a well-circumscribed, round to oval, homogenous mass without associated architectural distortion.
(b) Ultrasound image reveals a well-defined anechoic lesion with thin walls and strong posterior acoustic enhancement, the classic appearance of a simple breast cyst (BI-RADS 2).

Figure 3: Malignant Breast Lesion - Spiculated Mass (BI-RADS 5)

(a) Mediolateral (ML) mammographic view demonstrates an irregular spiculated mass in the right breast, associated with architectural distortion and internal calcifications. Additional small irregular lesions are noted, raising suspicion for multifocal disease.
(b) Magnified mammographic view better delineates the spiculated margins and internal calcifications.
(c) Ultrasound image of the corresponding region shows an irregular, hypoechoic lesion with increased vascularity. The combined features are highly suggestive of malignancy (BI-RADS 5).

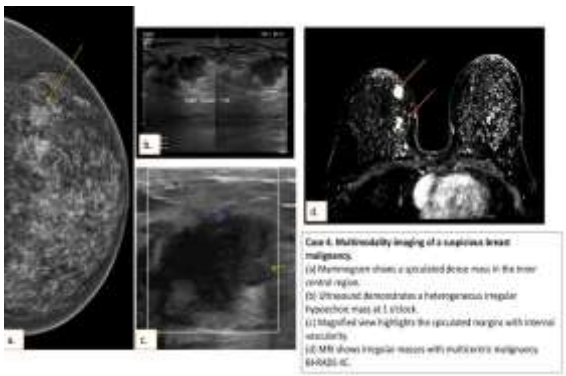

Figure 4: Multimodality Imaging of a Suspicious Breast Malignancy (BI-RADS 4C)

Multimodality imaging of a suspicious breast malignancy.
(a) Mammogram shows a spiculated dense mass in the inner central region.
(b) Ultrasound demonstrates a heterogeneous, irregular, hypoechoic mass.
(c) A magnified view highlights the spiculated margins with internal vascularity.
(d) MRI shows irregular masses, suggesting multicentric malignancy. The overall assessment was BI-RADS 4C, indicating a high suspicion for malignancy.

DISCUSSION

Accurate diagnosis of breast cancer at an early stage is vital for appropriate treatment planning and improved patient survival. In routine clinical practice, clinical breast examination (CBE), mammography, and ultrasonography (US) are commonly used diagnostic modalities.[4] Each has unique advantages and limitations, and their combined evaluation is essential for enhancing diagnostic yield. This retrospective study evaluated and compared the diagnostic accuracy of clinical examination, mammography, and ultrasonography in 120 patients with suspected breast cancer, using histopathology as the gold standard.

Clinical Breast Examination

In this study, clinical examination demonstrated a sensitivity of 83.3%, a specificity of 75.0%, and an overall diagnostic accuracy of 80.0%. Clinical diagnosis correctly identified 60 of 72 histologically confirmed malignancies but misclassified 12 malignant cases as benign and mislabelled 12 benign cases as malignant.

These findings are consistent with previous reports. A study reported clinical examination sensitivity ranging from 70–85% and specificity of 60–80%, particularly lower in dense breast tissue where physical examination has inherent limitations.[11] Similarly, Brem RF et al. observed that CBE alone identified only about 78% of malignancies, especially missing small or deep lesions. The lower specificity observed in this study may reflect challenges in distinguishing between benign and suspicious lesions

purely on palpation, particularly in dense or nodular breasts,[12]

Despite these limitations, CBE remains a valuable first-line screening tool, especially in resource-limited settings where imaging may not be immediately available. Yet, its role should be approached as complementary rather than definitive.

Mammography

Mammography in this cohort demonstrated a sensitivity of 91.7%, specificity of 79.2%, and overall accuracy of 87.5%. Mammography correctly identified 66 of 72 malignant cases, with six false-negative and ten false-positive findings. Examples of mammographically benign and malignant lesions are shown in Figures 1a, 2a, and 3a-b.

These results corroborate with well-established studies such as the Digital Mammographic Imaging Screening Trial (DMIST), which reported mammography sensitivity between 85–95% in women over 40 years of age, though lower in younger women with dense breasts. Evans A et al. noted that mammographic sensitivity can vary from 75–90%, depending on breast density and lesion characteristics such as microcalcifications, architectural distortions, and mass contours.[13]

The false-negative mammograms in this study may be attributed to lesions masked by dense fibroglandular tissue, a known limitation. Ultrasonography is particularly valuable in such cases, as it can characterize lesions that are mammographically occult. Figures 1, 2, and 3 provide clear examples of how ultrasound complements mammography in characterizing both benign and malignant breast pathologies. A study by Lee SH et al. (2018) reported that mammography sensitivity in dense breasts could drop below 70%, emphasizing the need for adjunctive imaging. Similarly, false positives may arise from overlapping normal tissue or benign conditions mimicking malignancy.[14]

Mammography continues to be the cornerstone modality for breast cancer screening and detection, offering high specificity and the ability to detect microcalcifications often associated with early malignancy.

Ultrasonography

Ultrasonography demonstrated the highest diagnostic performance among the three modalities in this study, with a sensitivity of 94.4%, specificity of 83.3%, and overall accuracy of 90.8%. US correctly identified 68 of 72 malignant lesions and demonstrated enhanced detection, particularly in cases where mammography was equivocal, as illustrated in Figure 3c.

The superior sensitivity of ultrasonography aligns with findings from Berg et al. (2012), who reported that combining US with mammography improved cancer detection rates by up to 4.6 per 1000 women screened,[2] particularly in women with dense breasts. In a study by Zuley ML et al, US demonstrated sensitivities as high as **92–97%** when used as an adjunct to mammography, reinforcing the modality's role in detailed lesion characterization.[11]

Moreover, US was more effective in differentiating cystic from solid masses (Figure 2b), identifying posterior acoustic features, and guiding biopsies. However, its specificity can vary depending on operator experience and lesion morphology, as reflected in the present study's specificity of 83.3%.[15]

Comparative Diagnostic Accuracy

When comparing the three modalities:

- Ultrasonography had the highest sensitivity (94.4%) and accuracy (90.8%)
- Mammography demonstrated strong sensitivity (91.7%) with slightly lower specificity
- Clinical examination, while useful for initial screening, showed the lowest specificity (75.0%) and accuracy (80.0%)

These results mirror findings from the study by Leung JWT et al,[16] where US outperformed mammography in sensitivity but had overlapping specificity when combined with clinical data. Another study by Brem RF et al. emphasized that neither mammography nor ultrasonography should be used in isolation; instead, their combined interpretation significantly enhances diagnostic confidence.[12]

Combined Modality Advantage

The combined assessment of clinical findings, mammography, and ultrasonography significantly improves diagnostic accuracy compared to any single modality. In this study, using all three modalities reduced false-negative and false-positive rates, illustrating the synergistic value of multimodal imaging, a principle further exemplified by the imaging workup of a suspicious malignancy in Figure 4.

Other authors have also demonstrated that multimodal approaches improve early detection. For example, Iqbal J et al. reported that integrating clinical examination with mammography and US improved cumulative sensitivity beyond **95%**, reducing missed cancers and facilitating early intervention.[17]

Limitations

The retrospective design may introduce selection bias, and imaging interpretation may be affected by interobserver variability. Additionally, this study was conducted at a single tertiary care center, which may limit generalizability.

CONCLUSION

This study demonstrates that while clinical examination plays an important role in the initial assessment of breast cancer, mammography and ultrasonography — particularly when used in combination — provide superior diagnostic accuracy. Ultrasonography showed the highest overall performance, especially in cases where mammographic sensitivity is limited. A multimodal diagnostic strategy enhances early detection, reduces misclassification, and optimizes patient management.

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