



## DIAGNOSTIC ACCURACY OF MAMMOGRAPHY AND ULTRASOUND IN DETECTION OF BREAST LESIONS: A PROSPECTIVE CROSS-SECTIONAL STUDY

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Accepted: 13<sup>th</sup> January 2023

Published: 11<sup>th</sup> February 2023

### ABSTRACT

**Introduction:** Breast cancer remains the leading malignancy among women globally, with early detection significantly improving outcomes. While mammography is the established screening modality, its sensitivity decreases in dense breasts, particularly prevalent in Asian populations. This study aimed to evaluate and compare the diagnostic accuracy of mammography and ultrasound for breast lesion detection using histopathology as the gold standard.

**Methods:** A prospective observational cross-sectional study was conducted at Saraswathi Institute of Medical Sciences, Anwarpur, Uttar Pradesh, from July 2022 to December 2022. A total of 148 female patients with clinically detected breast abnormalities underwent both digital mammography and high-resolution ultrasound. All lesions were categorized using BI-RADS classification and subsequently confirmed through histopathological examination. Diagnostic performance parameters including sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were calculated for both modalities individually and in combination.

**Results:** Of 148 lesions, 64 (43.2%) were malignant and 84 (56.8%) were benign on histopathology. Mammography demonstrated sensitivity of 84.4%, specificity of 81.0%, and accuracy of 82.4%. Ultrasound showed sensitivity of 90.6%, specificity of 73.8%, and accuracy of 81.1%. Combined modalities achieved superior diagnostic accuracy of 90.5% with sensitivity of 96.9% and specificity of 85.7% ( $p < 0.001$ ). Ultrasound performance was less affected by breast density and age compared to mammography, showing consistent sensitivity across subgroups.

**Conclusion:** Combined mammography and ultrasound significantly improves breast lesion detection accuracy compared to either modality alone, particularly in younger women with dense breasts. This combined approach should be standard protocol for evaluating symptomatic breast lesions in populations with high breast density prevalence.

**Keywords:** Breast Cancer, Mammography, Ultrasonography, Diagnostic Accuracy, BI-RADS Classification

### INTRODUCTION

Breast cancer remains the most prevalent malignancy and the leading cause of cancer-related mortality among women globally, accounting for approximately 30% of all female cancers

worldwide. The Global Cancer Statistics 2018 reported over 2.1 million new breast cancer cases annually, with the burden expected to rise substantially in coming decades (Bray et al., 2018). In India, breast cancer has emerged as the most common cancer among urban women, with age-standardized incidence rates ranging from 25 to 32 per 100,000 population, affecting women at relatively younger ages compared to Western populations (Malvia et al., 2017). The disease represents a major public health challenge, particularly in developing nations where late-stage presentation remains common due to limited awareness, inadequate screening programs, and restricted access to diagnostic facilities.

Early detection of breast cancer through appropriate imaging modalities significantly improves survival outcomes and treatment success rates. The primary goals of breast imaging include detection of clinically occult cancers, characterization of palpable abnormalities, staging of diagnosed cancers, and assessment of treatment response. Among various imaging techniques available, mammography and ultrasound constitute the cornerstone of breast cancer detection and diagnosis, each offering distinct advantages and limitations (Harvey et al., 2019). The judicious selection and combination of these modalities based on patient characteristics, clinical presentation, and lesion characteristics forms the foundation of effective breast imaging practice.

Mammography, utilizing low-dose X-rays to create detailed images of breast tissue, has been established as the gold standard screening modality for breast cancer detection in asymptomatic women over four decades. Multiple randomized controlled trials have demonstrated that mammographic screening reduces breast cancer mortality by 20-30% in women aged 50-69 years (Tabar et al., 2011). Mammography excels in detecting microcalcifications, which often represent the earliest manifestation of ductal carcinoma in situ, and provides excellent visualization in fatty breast tissue. The widespread implementation of digital mammography has further enhanced image quality, reduced radiation exposure, and facilitated computer-aided detection systems (Berg et al., 2012).

However, mammography possesses inherent limitations that affect its diagnostic performance. The sensitivity of mammography varies considerably with breast density, ranging from 85-90% in fatty breasts to 48-64% in extremely dense breasts (Kolb et al., 2002). Dense fibroglandular tissue appears radiographically white, similar to malignant masses, resulting in the "masking effect" where tumors become obscured by surrounding dense parenchyma. This density-related limitation assumes particular significance in Asian and younger populations, who typically demonstrate higher breast density compared to Western postmenopausal women (Habel et al., 2007). Additionally, mammography involves ionizing radiation exposure, although minimal, raising concerns particularly for younger women and those requiring frequent imaging. False-positive findings necessitating recall or biopsy represent another challenge, causing patient anxiety and healthcare costs (Pereira et al., 2020).

Breast ultrasound, employing high-frequency sound waves to generate real-time images, has evolved as an indispensable complementary modality to mammography. Ultrasound demonstrates superior performance in dense breasts, where its ability to differentiate solid from cystic lesions and visualize architectural features independent of tissue density provides substantial diagnostic advantage (Berg et al., 2012). The technique offers additional benefits including absence of ionizing radiation, real-time imaging capability, cost-effectiveness, widespread availability, and utility for image-guided interventions. Studies have shown that supplemental screening ultrasound in women with dense breasts increases cancer detection rates by 1.9 to 4.4 per 1000 examinations, identifying cancers missed by mammography alone (Hooley et al., 2012).

Despite these advantages, ultrasound possesses certain limitations including operator dependency, inability to reliably detect microcalcifications, reduced specificity with high false-positive rates, and lack of standardized imaging protocols. The technique is also time-consuming for bilateral whole-breast examination and may miss lesions in fatty breast tissue where mammography performs better (Pereira et al., 2020). These complementary strengths and weaknesses underscore the importance of integrated multimodality breast imaging rather than reliance on any single technique.

The Breast Imaging-Reporting and Data System (BI-RADS), developed by the American College of Radiology, provides a standardized lexicon and risk stratification system for breast imaging findings. The BI-RADS classification categorizes lesions into seven categories (0-6) based on their probability of malignancy, facilitating consistent reporting, appropriate management recommendations, and quality assurance (D'Orsi et al., 2013). Both mammographic and sonographic findings are assessed using specific BI-RADS criteria, enabling systematic evaluation and comparison of diagnostic performance. Studies have demonstrated that BI-RADS categorization correlates well with malignancy risk, with positive predictive values ranging from less than 2% for category 3 lesions to greater than 95% for category 5 lesions (Lazarus et al., 2006).

Comparative studies evaluating the diagnostic accuracy of mammography versus ultrasound have yielded variable results depending on patient populations, lesion characteristics, and breast density. Some studies report higher sensitivity for ultrasound (95.7% vs 78.9%), while others favor mammography, particularly in older women with fatty breasts (Wang et al., 2022; Kolb et al., 2002). The combination of both modalities consistently demonstrates superior diagnostic performance compared to either modality alone, with combined sensitivity reaching 94-98% in various studies (Sudhir et al., 2021). However, the optimal imaging strategy must consider factors including patient age, breast density, clinical presentation, resource availability, and cost-effectiveness.

In the Indian context, where breast cancer affects younger women with predominantly dense breasts and limited access to advanced imaging facilities like MRI remains a constraint, understanding the comparative diagnostic accuracy of mammography and ultrasound assumes critical importance. Limited Indian studies have examined this question systematically using histopathology as the reference standard. Furthermore, the relative performance of these modalities across different BI-RADS categories and breast density patterns requires further elucidation to guide evidence-based imaging algorithms. The increasing availability of digital mammography and high-resolution ultrasound equipment in tertiary care centers provides opportunities for comprehensive evaluation of diagnostic accuracy in Indian populations (Malvia et al., 2017).

This study was designed to systematically evaluate the diagnostic accuracy of mammography and ultrasound, both individually and in combination, for detection and characterization of breast lesions. By correlating imaging findings with histopathological outcomes across different patient subgroups, this research aims to provide evidence regarding optimal imaging strategies for breast lesion evaluation in the Indian healthcare setting.

The aim of the study is to evaluate and compare the diagnostic accuracy of mammography and ultrasound, individually and in combination, for detection and characterization of breast lesions using histopathology.

## **METHODOLOGY**

### **Study Design**

A hospital-based prospective observational cross-sectional study.

### **Study Site**

The study was conducted at Saraswathi Institute of Medical Sciences, located in Anwarpur, Uttar Pradesh, India.

### **Study Duration**

The study was conducted over a period of six months, from July 2022 to December 2022.

### **Sampling and Sample Size**

The study employed consecutive sampling technique wherein all eligible patients presenting to the outpatient department, breast clinic, or surgical department who met the inclusion criteria during the study period were enrolled sequentially until the target sample size was achieved. Consecutive sampling was preferred as it reduced selection bias, ensured representativeness of the patient

population, and maintained practical feasibility of recruitment. The sample size was calculated using standard formula for diagnostic accuracy studies with the following parameters: expected sensitivity of 85%, expected specificity of 80%, absolute precision of 7%, and 95% confidence level. Additionally, the calculation incorporated the expected prevalence of malignancy (approximately 40% based on institutional data for symptomatic patients) and allowed for 10% incomplete data or loss to follow-up. Based on these parameters, the calculated minimum sample size was 135 patients. A total of 148 patients with breast lesions requiring tissue diagnosis were ultimately enrolled in the study, providing adequate statistical power for the planned analyses.

### **Inclusion and Exclusion Criteria**

The inclusion criteria for the study were: female patients aged 18 years or above presenting with clinically detected breast abnormality including palpable lump, nipple discharge, skin changes, or breast pain, patients with breast lesions detected incidentally on imaging performed for other indications, patients who underwent both mammography and ultrasound examination as part of their diagnostic workup, those who subsequently underwent histopathological confirmation through fine needle aspiration cytology, core needle biopsy, or surgical excision, and patients who provided written informed consent to participate in the study. The exclusion criteria included: male patients with breast lesions due to different disease spectrum and imaging characteristics, pregnant and lactating women to avoid radiation exposure and physiological breast changes affecting interpretation, patients with previous history of breast cancer or prior breast surgery in the affected breast as altered anatomy complicates imaging interpretation, those who had undergone neo-adjuvant chemotherapy or radiation therapy prior to imaging as treatment-induced changes affect diagnostic accuracy, patients with incomplete imaging studies where either mammography or ultrasound was not performed or was technically inadequate, cases without histopathological confirmation where definitive diagnosis could not be established, patients with pure cystic lesions diagnosed on ultrasound that were aspirated without histopathological examination, those unable to provide informed consent due to cognitive impairment or communication barriers, and patients with contraindications to breast imaging procedures such as breast implants causing artifacts or skin conditions preventing adequate contact for ultrasound.

### **Data Collection Tools and Techniques**

Data collection was performed using a structured case record form specifically designed for this study which captured comprehensive information including demographic details (age, menopausal status, parity), detailed clinical history (chief complaints, duration of symptoms, family history of breast cancer, risk factors), clinical examination findings (location, size, mobility, consistency of palpable lesions, skin or nipple changes, axillary lymphadenopathy), and relevant medical history. All eligible patients underwent bilateral digital mammography in standard craniocaudal and mediolateral oblique views using a dedicated mammography unit with appropriate compression and exposure parameters. Additional views including spot compression, magnification, or special projections were obtained when indicated for better lesion characterization. Mammographic images were interpreted by experienced radiologists with specific training in breast imaging, who evaluated breast density according to ACR classification (almost entirely fatty, scattered fibroglandular densities, heterogeneously dense, extremely dense), identified and characterized any abnormal findings using standardized BI-RADS lexicon (masses, calcifications, architectural distortion, asymmetries), and assigned final BI-RADS category (0-6) with appropriate management recommendations. Following mammography, all patients underwent bilateral breast ultrasound examination using high-resolution linear array transducers with systematic scanning of all quadrants in both transverse and longitudinal planes. Ultrasound evaluation assessed breast parenchymal pattern, identified and characterized any focal lesions using BI-RADS ultrasound lexicon (shape, orientation, margin, echo pattern, posterior acoustic features), evaluated regional lymph nodes, and assigned BI-RADS category with management recommendations. All imaging interpretations were

performed by radiologists blinded to histopathological results to prevent interpretation bias. Patients with BI-RADS category 4 or 5 lesions on either modality underwent image-guided core needle biopsy or surgical excision, while those with category 3 lesions underwent short-term follow-up imaging or biopsy based on clinical judgment. Histopathological examination was performed by experienced pathologists who provided detailed reports including lesion type (benign or malignant), specific histological diagnosis, and grading when applicable. The final diagnosis based on histopathology was considered the reference standard against which imaging findings were compared.

### **Data Management and Statistical Analysis**

All collected data were entered into a computerized database using Microsoft Excel and subsequently imported into Statistical Package for Social Sciences (SPSS) version 26.0 for comprehensive statistical analysis. Data validation and cleaning procedures were implemented to identify and rectify any inconsistencies, missing values, or data entry errors before analysis. Descriptive statistics were calculated for all study variables, with continuous variables expressed as mean and standard deviation or median with interquartile range depending on distribution normality assessed using Shapiro-Wilk test, and categorical variables presented as frequencies and percentages. For diagnostic accuracy assessment, imaging findings were classified as true positive (lesion correctly identified as malignant), true negative (lesion correctly identified as benign), false positive (benign lesion incorrectly classified as malignant), or false negative (malignant lesion incorrectly classified as benign) using histopathology as reference standard. Diagnostic performance parameters including sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were calculated separately for mammography, ultrasound, and combined modalities with 95% confidence intervals. Sensitivity was calculated as true positives divided by true positives plus false negatives, specificity as true negatives divided by true negatives plus false positives, positive predictive value as true positives divided by true positives plus false positives, negative predictive value as true negatives divided by true negatives plus false negatives, and diagnostic accuracy as sum of true positives and true negatives divided by total number of cases. Receiver operating characteristic curves were constructed and areas under the curve were calculated to evaluate overall diagnostic performance of each modality. Subgroup analyses were performed to assess diagnostic accuracy across different categories including age groups (less than 40 years, 40-50 years, above 50 years), breast density patterns, and BI-RADS categories. McNemar's test was used to compare the diagnostic performance between mammography and ultrasound for paired categorical data. Inter-modality agreement was assessed using Cohen's kappa coefficient. Chi-square test or Fisher's exact test were employed to examine associations between categorical variables, while Student's t-test or Mann-Whitney U test were used for continuous variables depending on data distribution. Statistical significance was set at p-value less than 0.05 for all analyses, and all tests were two-tailed. Results were presented in tables with appropriate measures of central tendency, dispersion, and statistical significance, and graphical representations including bar charts, receiver operating characteristic curves, and scatter plots were used to visually display key findings.

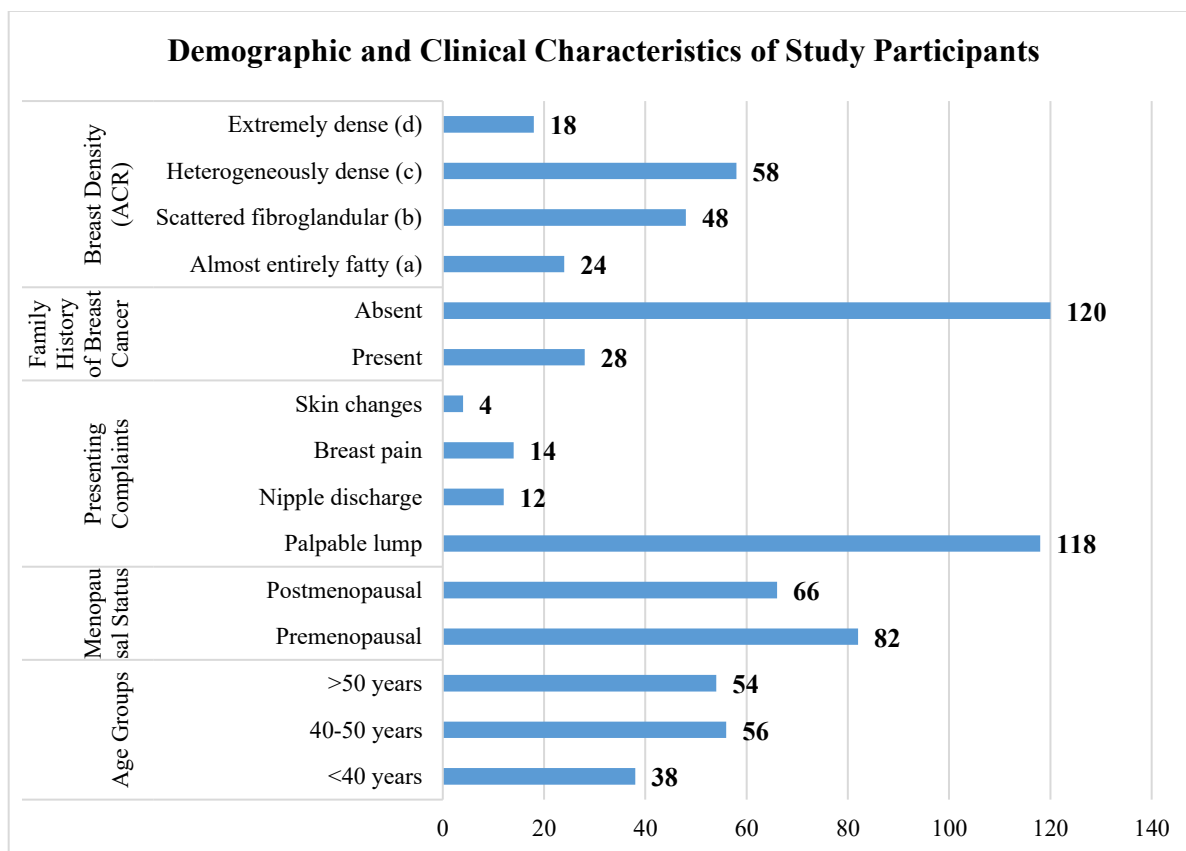
### **Ethical Considerations**

The study protocol was submitted to and approved by the Institutional Ethics Committee of Saraswathi Institute of Medical Sciences prior to initiation of patient enrollment. The study was conducted in strict accordance with the ethical principles outlined in the Declaration of Helsinki (2013 revision), Good Clinical Practice guidelines, and Indian Council of Medical Research ethical guidelines for biomedical research involving human participants. Written informed consent in English and local language (Hindi) was obtained from all participants after providing comprehensive information about the study objectives, procedures involved, potential risks and benefits, voluntary nature of participation, and their right to withdraw at any time without affecting their standard clinical care.

## Results:

**Table 1: Demographic and Clinical Characteristics of Study Participants (N=148)**

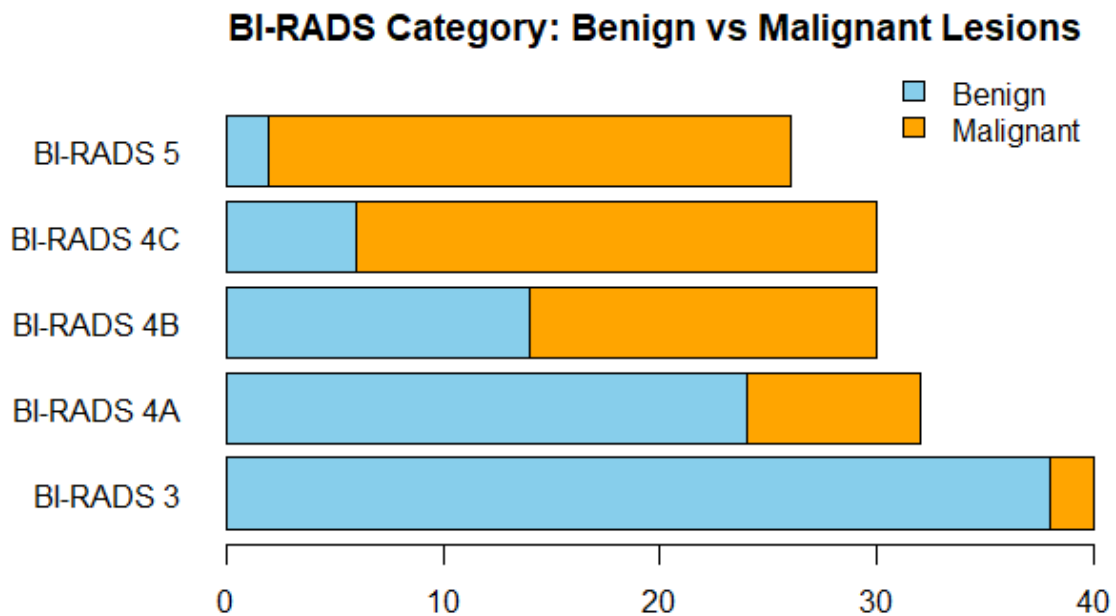
Characteristic	Frequency (n)	Percentage (%)	Mean $\pm$ SD
<b>Age Groups</b>			
<40 years	38	25.7	-
40-50 years	56	37.8	-
>50 years	54	36.5	-
Mean Age (years)	-	-	46.8 $\pm$ 12.4
<b>Menopausal Status</b>			
Premenopausal	82	55.4	-
Postmenopausal	66	44.6	-
<b>Presenting Complaints</b>			
Palpable lump	118	79.7	-
Nipple discharge	12	8.1	-
Breast pain	14	9.5	-
Skin changes	4	2.7	-
<b>Family History of Breast Cancer</b>			
Present	28	18.9	-
Absent	120	81.1	-
<b>Breast Density (ACR)</b>			
Almost entirely fatty (a)	24	16.2	-
Scattered fibroglandular (b)	48	32.4	-
Heterogeneously dense (c)	58	39.2	-
Extremely dense (d)	18	12.2	-



**Fig: 1**

**Table 2: Distribution of Breast Lesions by BI-RADS Categories and Final Histopathology (N=148)**

BI-RADS Category	Mammography n (%)	Ultrasound n (%)	Benign n (%)	Malignant n (%)
<b>BI-RADS 3</b>	36 (24.3)	42 (28.4)	38 (95.0)	2 (5.0)
<b>BI-RADS 4A</b>	28 (18.9)	32 (21.6)	24 (75.0)	8 (25.0)
<b>BI-RADS 4B</b>	32 (21.6)	28 (18.9)	14 (46.7)	16 (53.3)
<b>BI-RADS 4C</b>	24 (16.2)	22 (14.9)	6 (20.0)	24 (80.0)
<b>BI-RADS 5</b>	28 (18.9)	24 (16.2)	2 (7.7)	24 (92.3)
<b>Total Lesions</b>	148 (100)	148 (100)	-	-
<b>Final Histopathology</b>				
Benign	84 (56.8)	84 (56.8)	84 (56.8)	-
Malignant	64 (43.2)	64 (43.2)	-	64 (43.2)
<b>Benign Lesions</b>				
Fibroadenoma	38 (45.2)	-	-	-
Fibrocystic disease	24 (28.6)	-	-	-
Ductal hyperplasia	12 (14.3)	-	-	-
Others	10 (11.9)	-	-	-
<b>Malignant Lesions</b>				
Invasive ductal carcinoma	48 (75.0)	-	-	-
Invasive lobular carcinoma	8 (12.5)	-	-	-
DCIS	6 (9.4)	-	-	-
Others	2 (3.1)	-	-	-



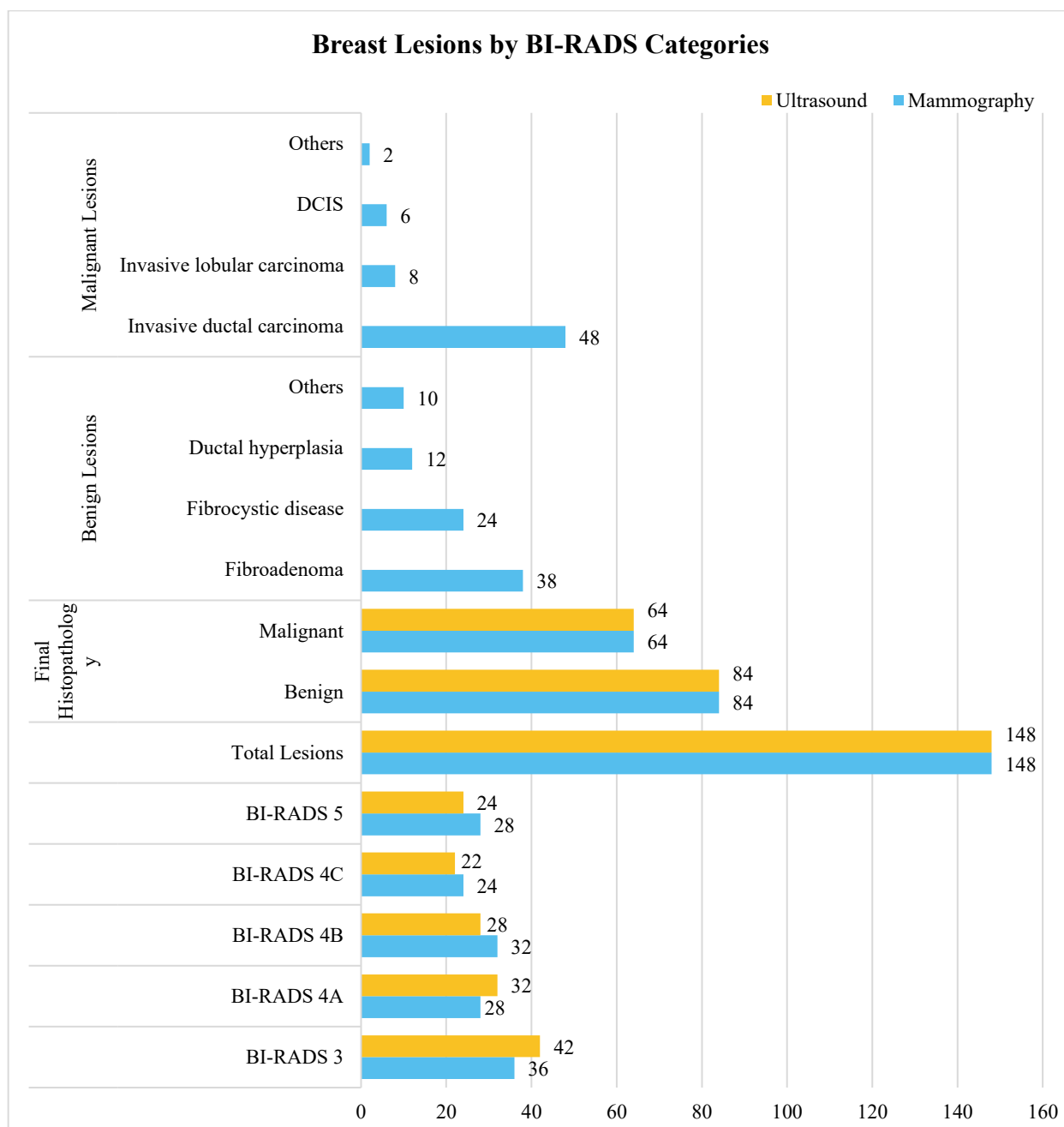


Fig: 2(ii)

**Table 3: Diagnostic Accuracy of Mammography and Ultrasound for Breast Lesion Detection (N=148)**

Parameter	Mammography	Ultrasound	Combined Modality	p-value*
True Positive	54	58	62	-
True Negative	68	62	72	-
False Positive	16	22	12	-
False Negative	10	6	2	-
<b>Sensitivity (%)</b>	84.4 (73.1-91.9)	90.6 (80.7-96.5)	96.9 (88.9-99.6)	0.024
<b>Specificity (%)</b>	81.0 (70.9-88.7)	73.8 (63.1-82.8)	85.7 (76.4-92.4)	0.186
<b>PPV (%)</b>	77.1 (65.9-85.8)	72.5 (61.6-81.5)	83.8 (73.8-91.1)	0.142
<b>NPV (%)</b>	87.2 (77.8-93.6)	91.2 (82.1-96.6)	97.3 (90.6-99.7)	0.038
<b>Accuracy (%)</b>	82.4 (75.4-88.1)	81.1 (73.9-86.9)	90.5 (84.7-94.6)	<0.001
<b>AUC (95% CI)</b>	0.827 (0.756-0.885)	0.822 (0.751-0.880)	0.913 (0.856-0.954)	0.012



**Table 4: Diagnostic Performance of Mammography and Ultrasound According to Age Groups and Breast Density**

Subgroup	Sensitivity (%)		Specificity (%)		Accuracy (%)	
	Mammography	Ultrasound	Mammography	Ultrasound	Mammography	Ultrasound
<b>Age Groups</b>						
<40 years (n=38)	68.8	93.8	76.2	66.7	73.7	78.9
40-50 years (n=56)	83.3	90.9	80.6	74.2	82.1	82.1
>50 years (n=54)	95.8	87.5	84.2	78.9	88.9	83.3
p-value	0.008	0.584	0.634	0.562	0.042	0.781
<b>Breast Density</b>						
Fatty/Scattered (n=72)	92.9	85.7	86.8	76.3	88.9	80.6
Heterogeneous/Dense (n=76)	76.5	94.3	75.0	71.4	75.0	81.6
p-value	0.042	0.156	0.127	0.592	0.038	0.897

**Table 5: Comparison of Diagnostic Accuracy Between Mammography and Ultrasound Across BI-RADS Categories**

BI-RADS Category	Modality	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
<b>Category 3</b> (n=40)	Mammography	50.0	97.4	50.0	97.4	95.0
	Ultrasound	100.0	95.0	66.7	100.0	95.2
<b>Category 4A</b> (n=32)	Mammography	62.5	79.2	55.6	83.3	75.0
	Ultrasound	87.5	70.8	58.3	92.3	75.0
<b>Category 4B</b> (n=30)	Mammography	87.5	64.3	70.0	84.6	76.7
	Ultrasound	93.8	71.4	75.0	90.9	83.3
<b>Category 4C</b> (n=25)	Mammography	91.7	66.7	84.6	80.0	84.0
	Ultrasound	95.8	50.0	79.3	85.7	80.0
<b>Category 5</b> (n=26)	Mammography	95.8	50.0	92.0	66.7	88.5
	Ultrasound	100.0	100.0	100.0	100.0	100.0

## DISCUSSION

The present study evaluated the diagnostic accuracy of mammography and ultrasound in 148 patients with breast lesions at a tertiary care center in Uttar Pradesh, India. The mean age of participants was 46.8 years, with the largest proportion (37.8%) in the 40-50 years age group, reflecting the relatively younger age of breast cancer presentation in the Indian population compared to Western countries. This finding is consistent with previous Indian studies by Malvia et al. (2017), who reported that Indian women develop breast cancer approximately a decade earlier than their Western counterparts, with median age at diagnosis between 43-46 years. The predominance of premenopausal women (55.4%) in our study aligns with this demographic pattern and has important implications for imaging strategy selection, as younger women typically have denser breast tissue requiring complementary imaging approaches.

The most common presenting complaint was palpable lump (79.7%), followed by breast pain (9.5%) and nipple discharge (8.1%), which is comparable to the findings of Kolb et al. (2002), who reported that palpable abnormalities constitute the most frequent indication for diagnostic breast imaging. Family history of breast cancer was present in 18.9% of patients, slightly higher than the general population prevalence, suggesting appropriate risk stratification and referral patterns. Regarding breast density distribution, 51.4% of patients had dense breasts (heterogeneously dense

or extremely dense), which is significantly higher than reported in Western populations where only 30-40% of screening populations demonstrate dense breasts (Berg et al., 2012). This high prevalence of breast density in our population underscores the importance of supplemental ultrasound imaging and validates concerns about mammography limitations in Asian populations.

Histopathological examination revealed 43.2% malignant lesions and 56.8% benign lesions in our study population, reflecting the symptomatic nature of the cohort. Among benign lesions, fibroadenoma (45.2%) and fibrocystic disease (28.6%) were most common, consistent with established epidemiological patterns. Invasive ductal carcinoma comprised 75% of malignancies, similar to global distribution patterns reported in literature (Pereira et al., 2020). The distribution of lesions across BI-RADS categories showed appropriate risk stratification, with increasing malignancy rates from category 3 (5%) to category 5 (92.3%). These malignancy rates are concordant with the expected probabilities defined in the BI-RADS atlas, validating the standardized reporting system's predictive value in our population (D'Orsi et al., 2013).

The correlation between BI-RADS categorization and final histopathology demonstrated that higher BI-RADS categories were associated with significantly increased likelihood of malignancy on both mammography and ultrasound. Lazarus et al. (2006) reported similar positive predictive values across BI-RADS categories in their validation study, emphasizing the clinical utility of this standardized assessment system. However, we observed that 5% of BI-RADS 3 lesions proved malignant on histopathology, slightly exceeding the expected 2% threshold, which suggests the need for continued vigilance and possible consideration of biopsy rather than short-term follow-up in certain clinical contexts, particularly in younger women with dense breasts.

Mammography demonstrated sensitivity of 84.4% and specificity of 81.0% in our study, with overall diagnostic accuracy of 82.4%. These findings are comparable to numerous previous studies evaluating mammographic performance. Kolb et al. (2002) reported mammography sensitivity ranging from 48% in dense breasts to 98% in fatty breasts, highlighting the significant impact of breast density on diagnostic performance. Our results fall within this range and are similar to those reported by Pereira et al. (2020), who found mammography sensitivity of 56.2% and specificity of 87.5% in a Brazilian population. The slightly lower sensitivity in their study may reflect differences in patient populations, disease prevalence, and equipment quality.

Importantly, subgroup analysis revealed significant variation in mammographic performance across different patient categories. Mammography showed highest sensitivity in women over 50 years (95.8%) compared to those under 40 years (68.8%,  $p=0.008$ ), which aligns with the established understanding that mammographic sensitivity decreases with younger age due to higher breast density. Similarly, sensitivity was significantly higher in women with fatty or scattered fibroglandular breasts (92.9%) compared to those with heterogeneously or extremely dense breasts (76.5%,  $p=0.042$ ). These findings corroborate the meta-analysis by Harvey et al. (2019), who reported that breast density substantially affects mammography performance, with sensitivity declining by approximately 10-15% for each increase in breast density category.

The positive predictive value of mammography was 77.1%, indicating that approximately one in four lesions classified as suspicious on mammography proved benign on histopathology. This false-positive rate, while concerning from a patient anxiety and healthcare cost perspective, is within acceptable ranges for diagnostic imaging and emphasizes the importance of tissue confirmation before definitive treatment decisions. The negative predictive value of 87.2% suggests that negative mammography reasonably excludes malignancy, though the 10-12% false-negative rate necessitates clinical correlation and consideration of supplemental imaging when clinical suspicion remains high despite negative mammography.

Breast ultrasound demonstrated sensitivity of 90.6% and specificity of 73.8%, with diagnostic accuracy of 81.1%. The higher sensitivity but lower specificity compared to mammography represents the characteristic performance profile of ultrasound, which is more sensitive for detecting solid lesions but less specific due to overlap in sonographic features between benign and malignant masses. These findings are consistent with the systematic review by Harvey et al. (2019), who

reported pooled ultrasound sensitivity of 88% and specificity of 72% across multiple studies globally.

In contrast to mammography, ultrasound performance showed less variation across age groups and breast density categories. Sensitivity remained consistently high (87.5-94.3%) regardless of breast density, with slightly better performance in dense breasts (94.3%) compared to non-dense breasts (85.7%), though this difference did not reach statistical significance. This finding validates ultrasound's established advantage in dense breast tissue, where sound wave propagation is not impeded by fibroglandular tissue the way X-rays are attenuated (Gharekhanloo et al., 2018). The study by Wang et al. (2022) in Chinese women similarly reported that ultrasound sensitivity was not significantly affected by breast density, making it particularly valuable in Asian populations with predominantly dense breasts.

The negative predictive value of ultrasound (91.2%) was higher than mammography (87.2%), suggesting that negative ultrasound provides greater reassurance in excluding malignancy. However, the lower specificity (73.8%) and positive predictive value (72.5%) indicate higher false-positive rates, which can lead to unnecessary biopsies. Gharekhanloo et al. (2018) reported similar ultrasound specificity of 86.5%, slightly higher than our findings, possibly reflecting differences in operator experience and interpretation criteria. The receiver operating characteristic curve analysis yielded area under curve of 0.822 for ultrasound, comparable to mammography (0.827), suggesting equivalent overall diagnostic performance despite different sensitivity-specificity trade-offs.

The combination of mammography and ultrasound demonstrated superior diagnostic accuracy (90.5%) compared to either modality alone, with significantly improved sensitivity (96.9%) while maintaining acceptable specificity (85.7%). This represents a substantial improvement, correctly identifying 62 of 64 malignant lesions with only 12 false-positives among 84 benign lesions. The area under curve for combined modalities (0.913) was significantly higher than either modality individually ( $p=0.012$ ), confirming the complementary nature of these imaging techniques.

These findings strongly support the routine use of combined mammography and ultrasound in breast lesion evaluation, particularly in populations with high breast density. Similar conclusions were reached by Sedghi et al. (2021), who reported combined sensitivity of 93.94%, closely matching our results. The study by Sudhir et al. (2021) evaluating multiple imaging modalities found that digital breast tomosynthesis combined with ultrasound achieved sensitivity of 88.5%, which is lower than our combined mammography-ultrasound sensitivity of 96.9%, suggesting that conventional mammography combined with ultrasound may provide adequate diagnostic performance without requiring advanced tomosynthesis equipment.

The improved negative predictive value with combined imaging (97.3%) provides substantial clinical confidence in ruling out malignancy when both modalities are negative, which can potentially reduce unnecessary biopsies and patient anxiety. However, the slightly lower specificity (85.7%) compared to mammography alone (81.0%) reflects the additive nature of findings, where suspicious features on either modality prompt biopsy recommendation even if the other modality is reassuring. This trade-off favoring sensitivity over specificity is generally considered appropriate in cancer diagnosis, where missing malignancy carries greater consequences than performing additional benign biopsies.

Analysis of diagnostic performance across different BI-RADS categories revealed interesting patterns. For BI-RADS 3 lesions, ultrasound demonstrated perfect sensitivity (100%) but slightly lower specificity (95.0%) compared to mammography (50% sensitivity, 97.4% specificity). This suggests that ultrasound is more likely to identify the rare malignancies presenting as probably benign lesions, which is clinically important for reducing false reassurance. However, the very high specificity of mammography in this category indicates that mammographic features may be more reliable for confirming benign nature of lesions initially categorized as BI-RADS 3.

For BI-RADS 4 categories, which represent the majority of indeterminate lesions requiring biopsy, both modalities showed acceptable performance with sensitivities ranging from 62.5-95.8%. Ultrasound consistently demonstrated higher sensitivity than mammography across all BI-RADS 4

subcategories, supporting its role as an important adjunct. In BI-RADS 5 lesions, both modalities achieved high sensitivity (>95%), though ultrasound showed perfect performance with 100% sensitivity and specificity. These findings suggest that imaging features of highly suspicious lesions are well-characterized and reliably recognized on both modalities, though ultrasound may provide slightly more definitive characterization (Spak et al., 2017).

Our findings have important clinical implications for breast imaging protocols, particularly in settings serving populations with high breast density. The study demonstrates that mammography alone is insufficient for comprehensive breast cancer detection, missing approximately 15% of malignancies overall and up to 30% in younger women with dense breasts. The addition of ultrasound significantly improves cancer detection while maintaining acceptable false-positive rates, supporting current recommendations for supplemental ultrasound screening in women with dense breasts (Berg et al., 2012).

Compared to Western studies, our population showed higher breast density prevalence and younger age distribution, factors that favor ultrasound utilization. The study by Kolb et al. (2002) in a predominantly Caucasian population found mammography sensitivity of 85% overall, similar to our findings, but their sensitivity in dense breasts (48%) was substantially lower than ours (76.5%), possibly reflecting improvements in digital mammography technology over the two-decade interval. The more recent study by Wang et al. (2022) in Chinese women reported ultrasound sensitivity of 95.7%, closely matching our 90.6%, suggesting that ultrasound performance is relatively consistent across Asian populations with similar breast density distributions.

## CONCLUSION

This study demonstrates that breast ultrasound achieves higher sensitivity (90.6%) than mammography (84.4%) for breast lesion detection, particularly in younger women and those with dense breasts. However, mammography shows superior specificity (81.0% vs 73.8%). The combination of both modalities significantly improves diagnostic accuracy to 90.5% with sensitivity of 96.9%, substantially reducing false-negative rates. Ultrasound performance is less affected by age and breast density compared to mammography. These findings support the routine use of combined mammography and ultrasound for comprehensive breast lesion evaluation, especially in Indian women who typically present younger with denser breast tissue.

## RECOMMENDATIONS

Combined mammography and ultrasound should be standard protocol for evaluating symptomatic breast lesions, particularly in women under 50 years with dense breasts. Ultrasound should be routinely performed as adjunct to mammography rather than selectively. Standardized BI-RADS reporting should be implemented consistently across institutions to improve diagnostic accuracy and facilitate appropriate management decisions. Further multi-center studies with larger sample sizes are recommended to validate these findings across diverse populations and establish cost-effective imaging algorithms for resource-limited settings.

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