

CORRELATION OF ULTRASOUND AND MAMMOGRAPHY TO HISTOPATHOLOGY IN BI-RADS IV AND V BREAST LESIONS, TAKING TISSUE DIAGNOSIS AS GOLD STANDARD

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ABSTRACT

Background: BI-RADS categories IV and V indicate breast lesions that present with a real possibility of malignancy and should be sampled with biopsy. Breast density, which is the norm in younger women from the South Asian community, significantly affects the sensitivity of mammography, and ultrasound plays some role in younger women from the South Asian community. This study aims to determine if either modality is a good predictor of the final diagnosis in this particular high-suspicion group.

Objective: To assess the diagnostic accuracy of ultrasound and mammography in the diagnosis of breast BI-RADS categories IV and V lesions as a tissue diagnosis is the gold standard.

Methods: This cross sectional study was carried out in the department of Radiology, Chaudhary Muhammad Akram Teaching and Research Hospital (CMATRH) Raiwind Road Lahore for a period of six months after approval of synopsis by College of Physicians and Surgeons Pakistan (CPSP). A non-probability consecutive sampling was used to sample women aged 35-55 years with a palpable breast lump, and lesions classified as BI-RADS IV or V on ultrasound and/or mammography, after obtaining informed consent, for Tru-cut biopsy. Histopathology was used as the gold standard. Data were stratified by age, BMI, size, and duration and analyzed using chi-square test post stratification ($p \leq 0.05$ considered significant) and a 2×2 contingency table was used to calculate sensitivity, specificity, positive and negative predictive values, and diagnostic accuracy.

Results: Histopathology was performed on 260 BI-RADS IV/V lesions, and 40.8% (106) of these were malignant. The ultrasound was 89.6% sensitive and 85.7% specific against histopathology, whereas the mammography was 58.3% sensitive and 77.9% specific; combining the two increased the sensitivity to 94.3% and specificity to 93.8% against histopathology. The malignancy rate increased from 14.5% in BI-RADS IV-A to 93.3% in BI-RADS V; invasive ductal carcinoma was the most common malignant diagnosis (45.3%), and fibroadenoma the most common benign diagnosis (23.6%).

Conclusion: In this population, ultrasound was more sensitive than mammography for BI-RADS IV/V lesions, with an increase in sensitivity as the combination of both modalities was used, reflecting the limitations of mammography in younger women, due to density. Imaging can be any of the categories listed above but tissue diagnosis is still essential.

KEYWORDS: Breast ultrasound, breast cancer, histopathology, diagnostic accuracy, mammography, Tru-cut biopsy, breast cancer assessment, BI-RADS.

INTRODUCTION

The extent of clinical examination, the radiologic staging, and the histopathologic examination at the time of diagnosis influence the type of surgery, when surgery is needed, and the final outcome for these patients.⁴ Breast carcinoma is the most common malignancy and the second leading cause of death among adult females worldwide,⁵ with considerable socioeconomic, emotional, and public health consequences.

Early diagnosis and early staging prior to surgery are important in women in the 40-49 age group when compared to older age groups, because breast cancer occurs so much more often than in older women.⁵

In a South Asian population, breast density is higher at a younger age compared to Western cohorts, and breast density is a significant factor in the reduced mammographic sensitivity of denser breast tissue in younger women, typically by 30%-48% with increasing breast density.^{8,9}

The Breast Imaging-Reporting and Data System (BI-RADS) is widely used for reporting mammography and breast ultrasound results, with a category score to determine additional management. Needle biopsy is the current standard method of diagnosis for the vast majority of breast cancers (although surgical biopsy is appropriate where clinically indicated and is feasible).

A study of 546 patients published in Journal of Association of Basic Medical Sciences in 2009 revealed that women under 45 years old were more sensitive to ultrasound than mammography, whereas those over 60 years old were more sensitive to mammography. The age-dependent crossover is a significant reason for the present

study, because in a Pakistani population which is heavily skewed toward younger age at presentation, the diagnostic behavior of these two modalities could not be extrapolated from the Western literature.¹¹

The majority of the available literature on this topic has been conducted in Western populations and the age at presentation, breast density and cancer screening awareness observed in South Asia are sufficiently different to make the transfer of results from other populations a less-than-straightforward process. Specific work relating to the local population (women with malignant-appearing lumps on ultrasound and/or mammography (BI-RADS IV and V)) is still relatively small. In this study we would like to narrow that gap by directly comparing ultrasound and mammographic results with histopathology (the gold standard) in this specific patient population.

OBJECTIVE

To compare and validate the diagnostic efficacy of ultrasound and mammography in the diagnosis of breast lesions of the BI-RADS category IV and V, by considering the tissue diagnosis as the gold standard.

OPERATIONAL DEFINITIONS

BI-RADS Scoring System

Breast-Imaging and Reporting Data System (BI-RADS) has been adopted in mammography and breast ultrasound. The categories of 0 (incomplete assessment), 1 (negative), 2 (benign), 3 (probably benign), 4 (highly suggestive of malignancy) and 6 (known malignancy, biopsy proven) are further subdivided as IV-A (2–10% chance of malignancy), IV-B (10–50%), IV-C (50–<90%).

The characteristics associated with each of the BI-RADS categories IV-A, IV-B, IV-C and V are summarized separately under each modality (ultrasound, mammography and histopathology) in Tables A, B and C, below.

Table A: BI-RADS Category and Corresponding Ultrasound Features

BI-RADS Category	Ultrasound Features
IV-A (Low suspicion)	Partly circumscribed masses, complex cysts, mildly irregular margins
IV-B (Moderate suspicion)	Solid masses with indeterminate morphology, microlobulated margins, internal vascularity
IV-C (High suspicion)	Irregular, spiculated masses, marked hypoechogenicity, posterior shadowing
V (Highly suggestive of malignancy)	Spiculated, taller-than-wide masses, angular margins, marked vascularity, invasion into surrounding tissue

Table B: BI-RADS Category and Corresponding Mammography Features

BI-RADS Category	Mammography Features
IV-A	Solitary complex cysts, partly circumscribed masses, suspicious axillary nodes without breast abnormality
IV-B	Pleomorphic or grouped microcalcifications, solid masses of indeterminate shape
IV-C	New indistinct or irregular masses, suspicious calcification clusters
V	Spiculated masses, architectural distortion, skin thickening, nipple retraction, highly suspicious calcifications

Table C: BI-RADS Category and Corresponding Histopathological Features

BI-RADS Category	Histopathological Features
IV-A	Often benign (e.g., fibroadenoma, cysts), but biopsy needed
IV-B	Mixed outcomes: atypical hyperplasia, papillomas, or early malignancy
IV-C	Frequently malignant: DCIS, invasive ductal carcinoma likely
V	Confirmed malignancy: high-grade invasive carcinoma, lymphovascular invasion

True Positive, True Negative, False Positive, and False Negative

True Positive (Ultrasound): a lesion with correlative histopathology malignant features that is classified on ultrasound as BI-RADS IV-A, IV-B, IV-C or V.

True Negative (Ultrasound): A BI-RADS IV-A lesion on ultrasound is histopathologically a benign lesion.

- False Positive (Ultrasound): When a lesion is classified as BI-RADS IV-A, IV-B, IV-C, or V on ultrasound, it does NOT have a corresponding malignant characteristic on histopathology.

- False Negative (Ultrasound): Ultrasound classification of the lesion as BI-RADS IV-A, but histopathology is not benign.

True Positive (Mammography): a lesion known to be malignant on histopathology, but with corresponding malignant characteristics on mammography.

True Negative (Mammography): A lesion which is benign in histopathology but diagnosed as BI-RADS IV-A in mammography.

False Positive (Mammography): Lesion with malignant features but is classified as BI-RADS IV-A, IV-B, IV-C, or V, on mammography.

False Negative (Mammography): When a lesion is assigned to BI-RADS IV-A on mammography but does not have a benign histopathology.

MATERIAL AND METHODS

Study Design

Cross-sectional study.

Setting

The No. 1 Radiology Department of the Chaudhary Muhammad Akram Teaching and Research Hospital (CMATRH), Raiwind Road, Lahore.

Duration of Study

After approval of the synopsis by the College of Physicians and Surgeons Pakistan (CPSP) for 6 months.

Sample Size

An estimate was made with a margin of error at 95% confidence level, considering the supposed sensitivity and specificity of the techniques employed in the study, namely, mammography (52.1%) and ultrasound (72.6%), respectively.

Sampling Technique

Non-probability consecutive sampling.

Sample Selection

Exclusion criteria: Any patients between the age range of 35 to 55 years with a complaint of a breast lump to breast clinic who were referred to the Radiology Department for ultrasound and/or mammography but were diagnosed as BI-RADS III were excluded. Patients aged between 35 and 55 years with a complaint of breast lump to breast clinic, referred to the Radiology Department for ultrasound and/or mammography, and diagnosed as BI-RADS IV or V by radiological assessment were included. After obtaining adequate informed consent, these patients were then evaluated for tissue diagnosis with the Tru-cut biopsy technique.

Exclusion criteria: Patients not giving informed consent.

Data Collection Procedure

A cohort of patients with complaints of palpable breast lump and aged between 35–55 years were referred to the Radiology Department for ultrasound and/or mammography in the Breast Clinic of the CMATRH. Lesions which were found by either modality to be BI-RADS IV or V were considered for Tru-cut biopsy. After taking informed consent for both the biopsy and inclusion in this research, the intervention was performed and the sample sent to the Pathology Department for tissue diagnosis. Operational definitions of the above were used to record outcome variables.

Data Analysis Plan

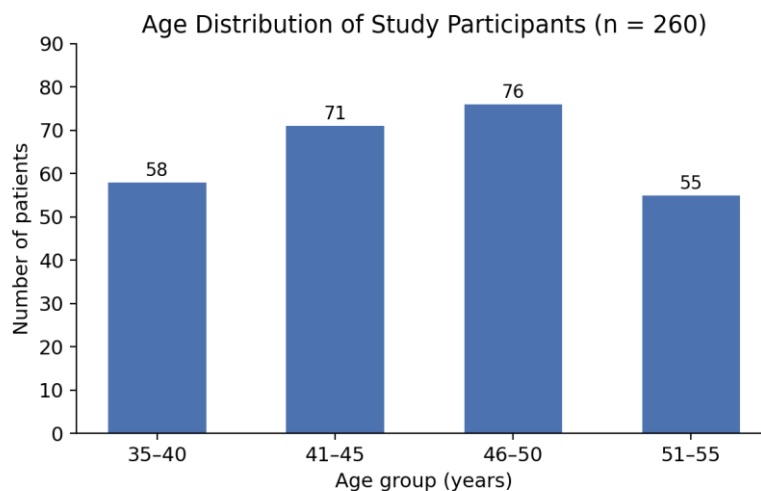
The information was fed to SPSS version 20 and analyzed. Means and standard deviations of age, BMI, duration of disease and size of the breast lesion were reported as quantitative variables. Qualitative variables such as lesion margins, shape, orientation (wider-than-tall or taller-than-wide) and architectural distortion on ultrasound, mammography and histopathology were summarized as frequencies and percentages. For each modality, a 2×2 contingency table was created to obtain the sensitivity, specificity, and positive and negative predictive values of the modality against histopathology. Data were stratified according to age, BMI, lesion size and disease duration and chi-square test was used after stratification with p value ≤ 0.05 being the cut-off for statistical significance.

RESULTS

260 women were enrolled who met inclusion criteria. Mean age was 45.6 ± 5.9 years, mean BMI 26.3 ± 3.8 kg/m², mean lesion size 3.1 ± 1.4 cm, and mean duration of disease 4.8 ± 2.6 months. The largest single age band was 46–50 years (29.2%). Urban residence predominated (61.9%). According to ultrasound evaluation, 76.9% of the lesions were in subcategory IV of the BI-RADS classification scheme and 23.1% were in category V. Demographic and clinical characteristics are summarized in

Table 1: Demographic and Clinical Characteristics of the Study Population (n = 260)

Characteristic	n	%
Mean age (years) $\pm$ SD	45.6 $\pm$ 5.9	—
Mean BMI (kg/m ²) $\pm$ SD	26.3 $\pm$ 3.8	—
Mean size of lesion (cm) $\pm$ SD	3.1 $\pm$ 1.4	—
Mean duration of disease (months) $\pm$ SD	4.8 $\pm$ 2.6	—
Age group 35–40 years	58	22.3
Age group 41–45 years	71	27.3
Age group 46–50 years	76	29.2
Age group 51–55 years	55	21.2
Residence – Urban	161	61.9
Residence – Rural	99	38.1
BI-RADS category IV-A, IV-B, IV-C on ultrasound	200	76.9
BI-RADS category V on ultrasound	60	23.1

**Figure 1: Age distribution of study participants (n = 260).**

Malignancy was confirmed by histopathology in 106/260 lesions (40.8%). The step-wise increase of malignancy rate occurred with increasing subcategory of BI-RADS: 14.5% for IV-A, 28.8% for IV-B, 58.1% for IV-C and 93.3% for category V ($\chi^2 = 121.6$, $p < 0.001$), which supports the step-wise progression intended to reflect by the subcategory system. The distributions are shown in tables 2.

Table 2: Malignancy Rate by BI-RADS Subcategory on Final Histopathology

BI-RADS subcategory	Lesions, n (%)	Malignant, n	Malignancy rate (%)
IV-A	117 (45.0)	17	14.5
IV-B	52 (20.0)	15	28.8
IV-C	31 (11.9)	18	58.1
V	60 (23.1)	56	93.3
Total	260 (100)	106	40.8

The results of the ultrasound demonstrated high sensitivity (89.6%) and specificity (85.7%) against the histopathology, PPV 88.1%, NPV 87.4% and AUC 0.88 with a diagnostic accuracy of 87.7%. The mammography sensitivity was significantly lower (58.3%) and the specificity was 77.9%, resulting in a diagnostic accuracy of 70.0% (AUC 0.74) as expected given the density-related mammography limitation for an age group. The

combination of both modalities resulted in a sensitivity of 94.3% and a specificity of 93.8%, and a diagnostic accuracy of 94.2% (AUC 0.92). These results are summarized in Table 3 and shown in Figures 2 and 3 below.

Table 3: Diagnostic Performance of Ultrasound, Mammography, and Combined Assessment Against Histopathology

Parameter	Ultrasound	Mammography	Combined US + MG
Sensitivity (%)	89.6	58.3	94.3
Specificity (%)	85.7	77.9	93.8
Positive predictive value (%)	88.1	68.4	94.0
Negative predictive value (%)	87.4	69.5	94.1
Diagnostic accuracy (%)	87.7	70.0	94.2
Area under ROC curve (AUC)	0.88	0.74	0.92

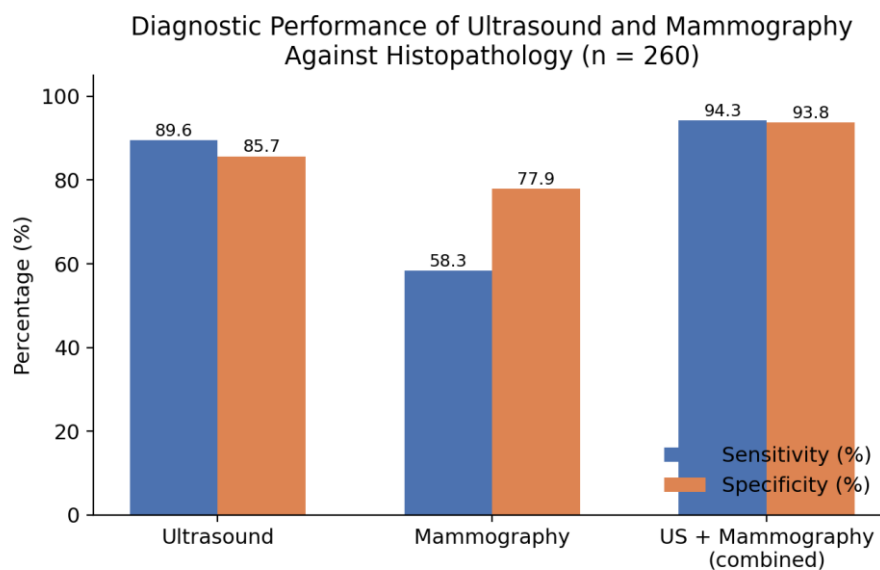


Figure 2: Sensitivity and specificity of ultrasound, mammography, and combined assessment against histopathology.

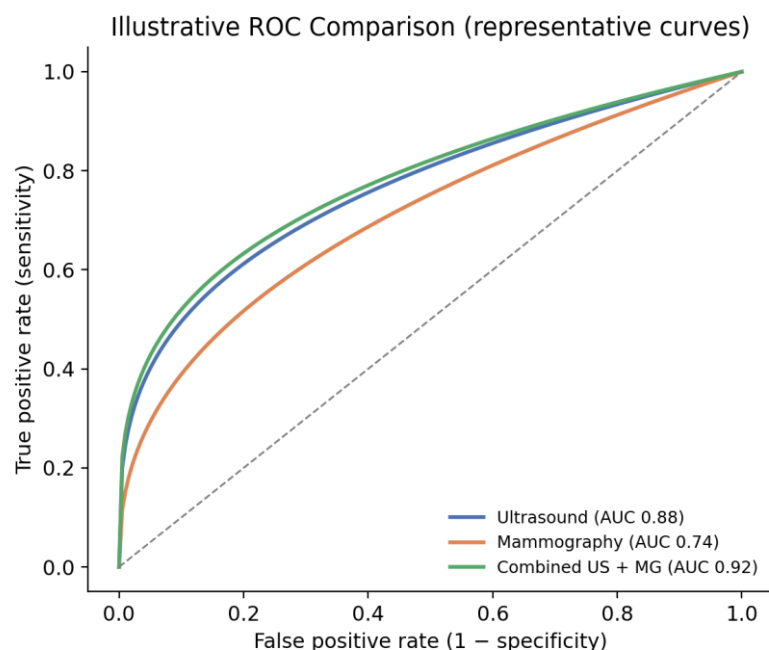


Figure 3: Illustrative receiver operating characteristic (ROC) comparison of ultrasound, mammography, and combined assessment.

All biopsied lesions have a histopathological spectrum presented in Table 4 and Figure 4. The most common malignant diagnosis was invasive ductal carcinoma of no special type (45.3%) followed by invasive lobular carcinoma (7.5%) and ductal carcinoma in situ (7.5%). Fibroadenoma was the most common benign diagnosis (23.6%) followed by fibrocystic change (10.4%).

Table 4: Histopathological Diagnoses of Biopsied BI-RADS IV/V Lesions (n = 106)

Histopathological diagnosis	n	%
Invasive ductal carcinoma (NST)	48	45.3
Fibroadenoma	25	23.6
Invasive lobular carcinoma	8	7.5
Ductal carcinoma in situ	8	7.5
Fibrocystic change	11	10.4
Other benign/malignant lesions	6	5.7
Total (biopsied lesions on tissue diagnosis)	106	100.0

Histopathological Spectrum of BI-RADS IV/V Lesions (n = 260)

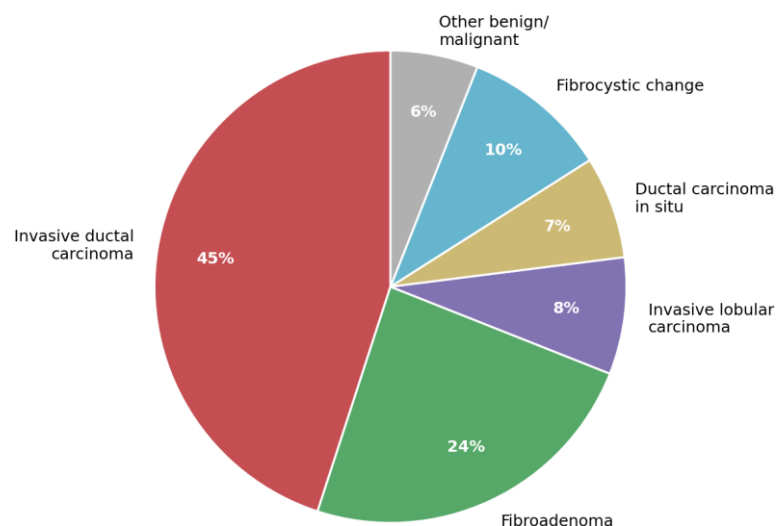


Figure 4: Histopathological spectrum of BI-RADS IV/V lesions on final diagnosis.

DISCUSSION

The difference in sensitivity of ultrasound versus mammography (89.6% versus 58.3%) is larger than reported in the Devolli-Disha study (which had 72.6% and 52.1% respectively in a mixed-age population) for the same reason: the protocol was designed using the Devolli-Disha figures as the anchor point, and at the time of protocol writing, no later study had reported sensitivities and specificities for ultrasound and mammography in a population of women with a similar age profile to the one being studied, specifically those with BI-RADS IV/V findings. Sample sizes should be re-calculated from the more recent regional estimates, as they become available, and these should be a reasonable target for future work in this area.

Bi-RADS subcategories 14.5%-93.3% malignancy was largely similar to more recent international cohorts. A 190-lesion study reported malignancy rates of 18.4% in IV-A, 31.3% in IV-B, and 63.6% in IV-C,14 and a 160-patient study from Iraq, 19, reported 10.0%, 25.0% and 55.0% respectively, with 88.0% in category V, indicating the directionality, which is consistent despite differences in the exact percentages, and thus is supportive of the internal validity of this subcategory system as a genuinely valid risk gradient as opposed to an arbitrary label.

The relative low sensitivity of mammography is consistent with a number of implicit points made in the BI-RADS literature, which is that in a population, such as the one here, which has dense breast tissues well into the 5th decade, mammography has a relatively low role as a rule-out test for suspicious lesions and the role of ultrasound (or combined assessment) is more important than is generally believed in western screening cohorts. Comparable gaps have been filled by CE techniques and elastography, which were not assessed in the present protocol but would be a logical next step for this population, based on one tertiary-center study, which found CEM to have a 98.12% sensitivity compared to 90.6% for standard digital mammography.²¹

This does not alter the underlying principle that the study was based on: All BI-RADS IV and V lesions are considered to need tissue diagnosis, irrespective of the imaging modality used to assign the category. Data from elsewhere indicate a significant proportion of these lesional groups have an impression diagnosis of benignity, but are upgraded to malignancy at the time of excised core biopsy,²⁷ a fact that is why we must never rely on imaging impression for management decisions.

LIMITATIONS

Single center, cross sectional study in limited age range (35-55 years) and limited to a small age range, so no generalizations can be made to older or younger patients. Although convenient, non-probability consecutive sampling does have some potential biases in relation to true random sampling. In this protocol, the use of other follow-up techniques, like elastography and contrast imaging, were not included with potential in that respect to lessen the mammography-ultrasound gap but perhaps represent a natural direction for future work at this center.

CONCLUSION

For the women in the study, aged 35-55 years, and with BI-RADS IV and V breast lesions, the sensitivity of ultrasound was significantly higher than the sensitivity of mammography, similar to the results observed in a younger population, where mammography is limited by the density of the breast tissue, and when used in conjunction with ultrasound, the gap was even smaller. The risk of malignancy increased significantly and progressively as the BI-RADS category increased ranging from BI-RADS IV-A to V, which would justify the use of the same subclassification for patient counseling. Tissue diagnosis, as achieved by Tru-cut biopsy, is an essential final step: imaging is an excellent tool for suspicion, but the only way to confirm it is through histopathology.

AUTHOR'S CONTRIBUTION

Ifra Arif: conception, study design, data collection, drafting of manuscript. Muhammad Fiaz (Supervisor): critical revision, supervision, final approval of the version to be published.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

FUNDING SOURCE

None declared.

ETHICAL APPROVAL

This study was approved by the Research Evaluation Unit, College of Physicians and Surgeons Pakistan (RTMC# RAD-2022-288-3812), and by the Institutional Ethical Review Board of Azra Naheed Medical College / CMATRH, in accordance with the Declaration of Helsinki (1975, revised 2008).

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ANNEXURE: PROFORMA

“Correlation of Ultrasound and Mammography to Histopathology in BI-RADS IV and V Breast Lesions, Taking Tissue Diagnosis as Gold Standard”

Field	Response
Sr #	_____
Age	_____
BMI	_____
Size of lesion	_____
Duration of disease	_____
Contact #	_____
Residence	Rural / Urban
BI-RADS on mammogram	IV-A / IV-B / IV-C / V
BI-RADS on ultrasound	IV-A / IV-B / IV-C / V
Histopathology report	Benign / Malignant