

Diagnostic Correlation of Imaging and Histopathology in Giant Breast Masses: A Prospective Observational Study

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Abstract: Giant breast masses, defined as lesions over 5 cm, present diagnostic challenges due to their size and varied pathology. This prospective study evaluated 50 women with palpable giant breast lumps using mammography, ultrasonography, and image-guided biopsy. Imaging findings were compared with histopathology to assess diagnostic agreement. Infiltrative carcinoma was the most common malignancy, while benign phyllodes tumours were the largest benign group. A strong correlation was observed between higher BI-RADS categories and malignancy. These findings highlight the usefulness of a combined clinical, imaging, and biopsy approach for accurate diagnosis and informed treatment of large breast masses.

Keywords: Breast masses, BI-RADS, ultrasonography, histopathology, phyllodes tumour

1. Introduction

Breast disease poses a major public health issue, with more than 25% of women experiencing a breast-related disorder during their lifetime. Breast masses are a common clinical presentation and include a wide spectrum of benign and malignant conditions, often causing considerable patient anxiety and necessitating accurate diagnostic evaluation [1].

Giant breast masses, defined as lesions measuring more than 5 cm in maximum dimension, are relatively uncommon and arise from diverse pathologies such as lipoma, hamartoma, cysts, fibroadenoma, phyllodes tumour, hematoma, abscess, and carcinoma [2]. Because of their size and delayed detection, such masses often cause visible disfigurement, emotional strain, and difficult treatments, underscoring the importance of early and accurate diagnosis.

The triple assessment approach—clinical examination, imaging, and cytological or histopathological evaluation—remains the standard for the assessment of breast lumps. Studies have shown that combining mammography and ultrasonography with clinical evaluation improves diagnostic accuracy compared with any single modality [3]. Mammography demonstrates an approximate sensitivity of 75%, while ultrasonography is particularly useful for lesion characterisation. Magnetic resonance imaging offers high sensitivity but is limited by reduced specificity, higher cost, and restricted availability [4]. Although radiologic evaluation is effective in distinguishing benign from malignant breast

lesions, the diagnostic reliability of Breast Imaging Reporting and Data System categorisation in giant breast masses has not been well established, representing a clinically relevant gap in current knowledge.

This study aimed to evaluate giant breast masses using mammography and ultrasonography and to correlate radiological findings with histopathological results in order to assess diagnostic concordance and support informed clinical decision-making.

This study fills a gap in current literature by examining diagnostic reliability in giant breast lesions, where standard BI-RADS stratification may not always apply due to size-related imaging challenges.

2. Materials and Methods

Study Design and Setting

This prospective observational study was conducted in the Departments of Radiology and Pathology at a tertiary care hospital, where patients with palpable breast masses are routinely referred for diagnostic imaging and tissue diagnosis.

Study Population and Sampling

Fifty female patients aged 15–75 years presenting with clinically palpable giant breast masses (defined as lesions >5 cm in the longest dimension) were enrolled over 18 months. Purposive non-probability sampling was used; all consecutive eligible patients during the study period were included until

the target sample size was reached. No randomisation or blinding was applied.

Inclusion and Exclusion Criteria

Patients aged ≥ 15 years with a palpable breast mass > 5 cm on clinical examination, referred for mammography and ultrasonography, and willing to provide written informed consent for imaging and core needle biopsy were included. Patients < 15 years, those refusing consent, breast masses related to trauma, and purely inflammatory or post-traumatic swellings were excluded.

Imaging and Biopsy Protocols

Mammography was performed using a digital mammography system (Fujifilm FDR M53500) with standard craniocaudal and mediolateral oblique views; tomosynthesis was included when indicated. Ultrasonography was carried out on Samsung Madison H60 and Mindray DC-80 units with high-frequency linear transducers. Lesions were categorised according to the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS), documenting size, shape, margins, internal echotexture, lymphadenopathy, and skin involvement. All imaging examinations were interpreted by a single experienced breast radiologist. The radiologist was blinded to the histopathological findings at the time of image interpretation to minimise observer bias.

All patients underwent ultrasound-guided core needle biopsy using a 14-gauge needle. Tissue specimens were fixed in formalin and processed for histopathological examination by experienced pathologists. The pathologists were blinded to the radiological BI-RADS categorisation. Histopathological results acted as the final diagnostic benchmark for diagnostic correlation.

Statistical Analysis

Data were entered, verified, and cleaned before analysis. Continuous variables were expressed as mean \pm standard deviation; categorical variables were described using frequencies and percentages. Associations between BI-RADS categories and histopathology were examined with chi-square tests. Pearson correlation was used for age and lesion size associations. Diagnostic agreement between radiologic assessment and histopathological results was evaluated using the McNemar test. Analyses were performed using JAMOVI and R software, with $p < 0.05$ considered statistically significant.

Ethical Considerations

Ethical clearance was granted, and all participants gave written consent. Patient confidentiality was maintained, and imaging/biopsy procedures were conducted according to standard clinical practice.

3. Results

A total of 50 female patients with clinically palpable giant breast masses were included in the study. No patients meeting the inclusion criteria were excluded after enrollment, and no dropouts occurred during the study period.

The mean age of the study population was 49.6 ± 14.7 years. All lesions fulfilled the criteria for giant breast masses, with a

mean maximum dimension exceeding 6 cm in all measured planes (Table 1).

Table 1: Descriptive statistics of age and lesion size

Variable	Mean	Standard Deviation
Age (years)	49.6	14.7
AP diameter (mm)	66.5	26.7
CC diameter (mm)	63.8	28.5
TR diameter (mm)	63.1	23.7

According to the American College of Radiology breast density classification, density types A and C were most frequently observed, each accounting for 34.7% of cases, followed by type B (28.6%). Extremely dense breasts (type D) were uncommon, observed in only one patient (Table 2).

Table 2: Distribution of breast density

Breast Density	Count (n)	Percentage (%)
A	17	34.7
B	14	28.6
C	17	34.7
D	1	2
Total	50	100

Imaging assessment demonstrated a predominance of higher Breast Imaging Reporting and Data System categories. BI-RADS category 5 was assigned most frequently (42%), followed by BI-RADS 4C (18%), 4B (16%), and 4A (16%). Only a small proportion of lesions were categorised as BI-RADS 3 (8%) (Table 3).

Table 3: Frequency of BI-RADS categories

BI-RADS Categories	Count (n)	Percentage (%)
3	4	8
4A	8	16
4B	8	16
4C	9	18
5	21	42
Total	50	100

Histopathological examination revealed malignancy in the majority of cases. Infiltrative breast carcinoma was the most common diagnosis, accounting for 64% of lesions. Benign phyllodes tumours constituted the largest benign subgroup (12%), while malignant phyllodes tumours and giant fibroadenomas each accounted for 6% of cases. Other malignant subtypes, including lobular, mucinous, clear cell, and spindle cell carcinomas, were less frequent (Table 4).

Table 4: Histopathological diagnoses

Diagnosis	Count (n)	Percentage (%)
Infiltrative breast carcinoma	32	64
Lobular carcinoma	2	4
Benign phyllodes	6	12
Malignant phyllodes	3	6
Giant fibroadenoma	3	6
Clear cell carcinoma	1	2
Mixed mucinous carcinoma	1	2
Spindle cell carcinoma	1	2
Breast Abscess	1	2
Total	50	100

There was a strong agreement between imaging and histopathology. Most infiltrative carcinomas were categorised

as BI-RADS 5, whereas benign phyllodes tumours and giant fibroadenomas were predominantly assigned lower-risk categories (BI-RADS 3 and 4A). Malignant phyllodes

tumours were mainly classified as BI-RADS 4B and 4C (Table 5). Higher BI-RADS categories showed a clear association with malignant histopathology.

Table 5: Correlation of BI-RADS with histopathology

Histopathology	BI-RADS 3	BI-RADS 4A	BI-RADS 4B	BI-RADS 4C	BI-RADS 5	Total
Infiltrative breast carcinoma	0	2	4	6	20	32
Lobular carcinoma	0	0	1	1	0	2
Benign phyllodes	2	3	1	0	0	6
Malignant phyllodes	0	0	2	1	0	3
Giant fibroadenoma	2	1	0	0	0	3
Other carcinomas*	0	1	1	1	2	7
Breast abscess	0	1	0	0	0	1

*Other carcinomas included rare subtypes (clear cell, mucinous, and spindle cell).

4. Discussion

Giant breast masses are defined as lesions exceeding 5 cm in maximum dimension and may present as solitary or multiple palpable lumps with a wide pathological spectrum. As described by A. F. I. Moustafa et al., these lesions commonly include giant fibroadenomas, phyllodes tumours, and malignant neoplasms, with imaging forming the cornerstone of initial evaluation followed by histopathological confirmation [2].

The present study evaluated radiological and histopathological characteristics of giant breast masses in 50 women, focusing on the correlation between BI-RADS categorisation, mammographic breast density, and final histopathological diagnosis. A strong radiologic–pathologic concordance was observed, with malignancy constituting the predominant pathology.

The mean age of patients was 49.6 years, with the highest incidence in the third and fourth decades, consistent with findings by Thiriveedi R.S.N. Lakshmi et al. [5]. The large mean lesion size reflects delayed clinical presentation, particularly in malignant cases.

Breast density significantly influences mammographic sensitivity. In this study, ACR density categories A and C were most frequently encountered. Dense breast parenchyma can obscure lesions and reduce mammographic sensitivity, emphasising the importance of adjunct ultrasonography, especially in heterogeneously dense breasts [4].

Most cases were classified as BI-RADS 5 category, indicating high suspicion for malignancy. This finding correlates well with studies by Vinod Kumar et al. and Poornima V. Kamatar et al., which demonstrated strong agreement between higher BI-RADS categories and malignant histopathology [6,7].

These results reaffirm the reliability of BI-RADS as a standardised risk stratification system, even in large breast lesions.

Benign lesions comprised a smaller proportion of cases. Giant fibroadenomas accounted for 6% of cases and were predominantly seen in younger patients. Fibroadenomas are the most common benign breast tumours in young women, and giant variants are defined by size exceeding 5 cm or weight over 500 g. Imaging typically demonstrates well-circumscribed, homogeneous hypochoic masses, occasionally with coarse calcifications. However, significant overlap with phyllodes tumours makes imaging differentiation challenging [8–10].

Phyllodes tumours accounted for 18% of cases. These rapidly growing fibroepithelial tumours may be benign or malignant, with approximately 20% showing malignant behaviour. Imaging features alone are insufficient for reliable differentiation, although larger tumour size and older age increase the likelihood of malignancy, consistent with previous reports [9–11]. In the present study, benign phyllodes tumours (figure 1) were assigned lower BI-RADS categories, while malignant tumours (figure 2) were more frequently categorised as BI-RADS 4B and 4C, necessitating histopathological confirmation.

Infiltrative breast carcinoma was the most common diagnosis, accounting for 64% of cases. Typical imaging features included irregular margins, architectural distortion, and suspicious calcifications. Ultrasound findings such as hypoechogenicity, spiculated or angulated margins, and posterior acoustic shadowing were consistent with established malignant descriptors [12] (figure 3). Approximately 25% of invasive breast cancers (figure 4) exhibit specific histological subtypes, including lobular, tubular, mucinous, and neuroendocrine variants [13].

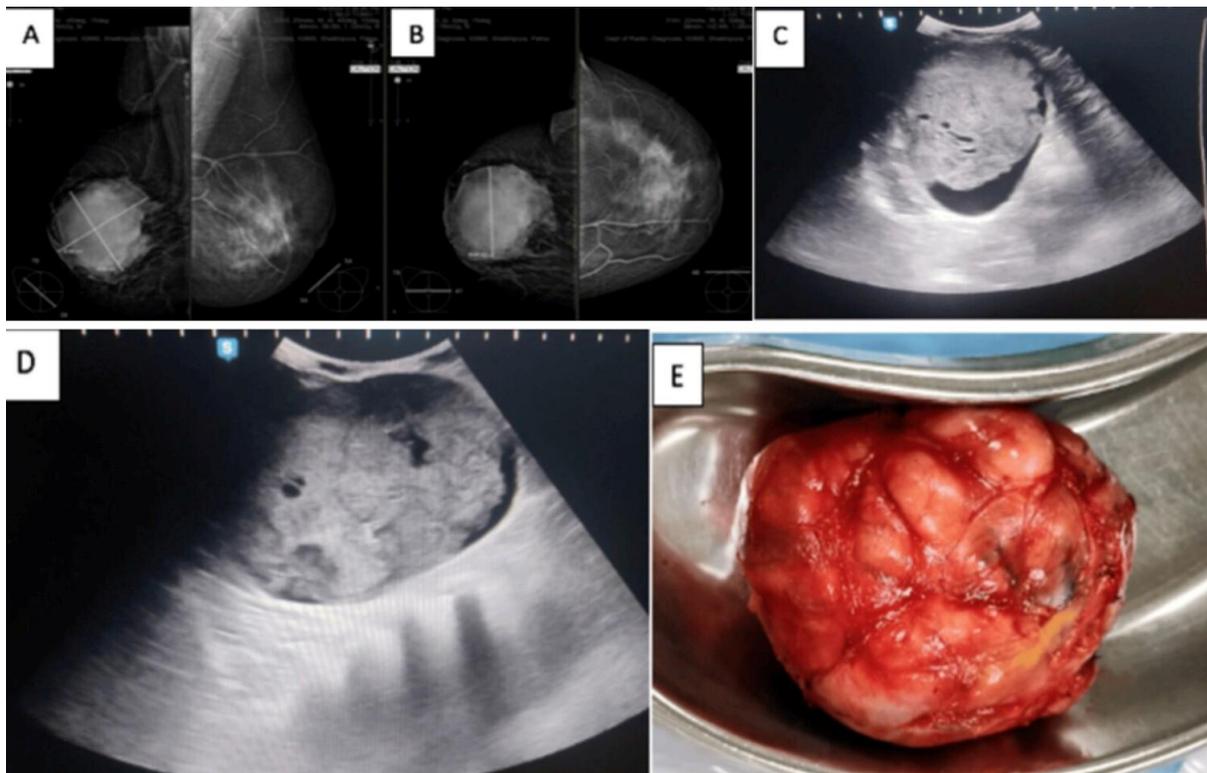


Figure 1: Benign Phyllodes- MLO view (A) and CC view (B) mammography – Type B breast density shows a large, well-circumscribed, round, high-density lesion with perilesional isodensity in the central quadrant of the right breast, behind the nipple areola complex. No evidence of any suspicious calcification. USG right breast (C & D) shows a large echogenic solid appearing mass with a surrounding cleft-like cystic space and showing posterior acoustic enhancement- BIRADS 4A. On histopathology, benign phyllodes. Postoperative gross specimen (E) shows bosselated and congested external surface with a few focal areas of haemorrhage and necrosis.

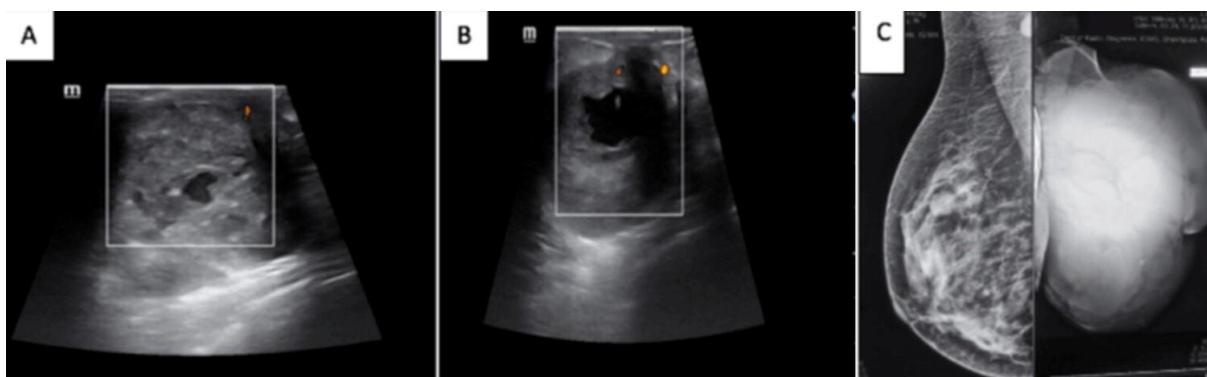


Figure 2: Malignant Phyllodes - USG Left breast (A and B) shows a large, irregularly shaped, inhomogeneous, solid lesion with mild peripheral vascularity and cystic component within the left breast, nearly involving the whole of the breast parenchyma. The margins are not well circumscribed. Mammography RMLO view (C), type C breast density shows high density lesion involving the whole of the left breast with a mild peri-lesional halo. There is involvement of the overlying skin. BIRADS 4 (B) – On histopathology- Phyllodes of malignant variety.

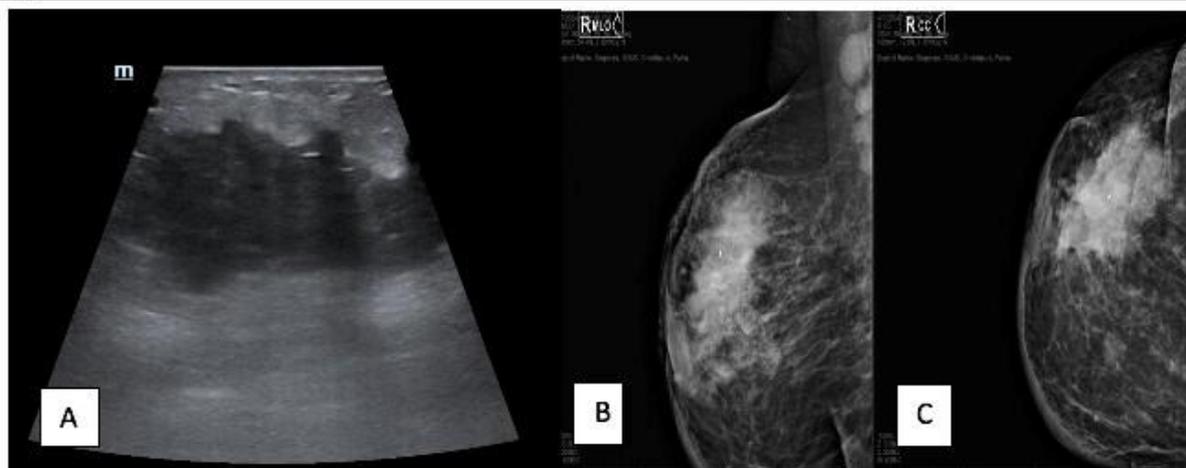


Figure 3: Infiltrative breast carcinoma USG right breast (A) shows a large, oval, parallel hypoechoic lesion with microlobulated margins. RMLO view (B) and R CC view (C) mammography- Breast density B with scattered area of fibroglandular tissue shows an irregularly shaped high-density lesion with partially indistinct and partially speculated margins in the upper and lower outer quadrants. There is a focus of coarse heterogeneous calcification within. There is associated skin and trabecular thickening, BIRADS – 4C. On histopathology, Infiltrative breast carcinoma was the diagnosis.

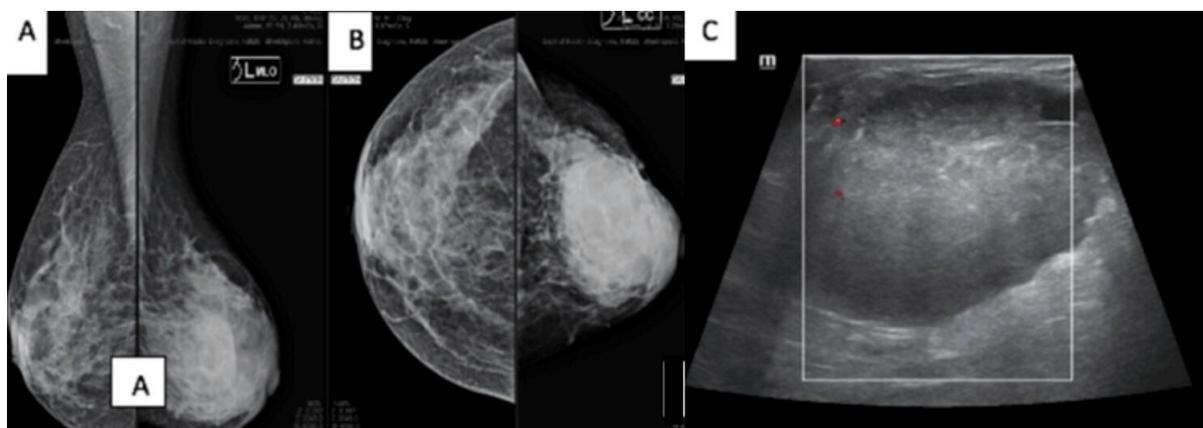


Figure 4: Invasive Breast Carcinoma MLO view (A) and CC view (B) mammography- Type C breast shows a large irregular high-density lesion with partly circumscribed and partly indistinct margins involving all quadrants of the left breast, predominantly the outer quadrants. Skin infiltration and trabeculation thickening were also noted. USG left breast (C) shows a large irregular-shaped heteroechoic solid lesion with internal echogenic foci. Skin infiltration with a partly indistinct margin was noted. BIRADS – 4 (C). On histopathology – Invasive Breast Carcinoma

Cases with a ductal carcinoma in situ component demonstrated characteristic calcification patterns. Fine pleomorphic, amorphous, and linear calcifications are well-recognised imaging hallmarks of DCIS (figure 5), with linear morphology reported in up to 80% of cases [14].

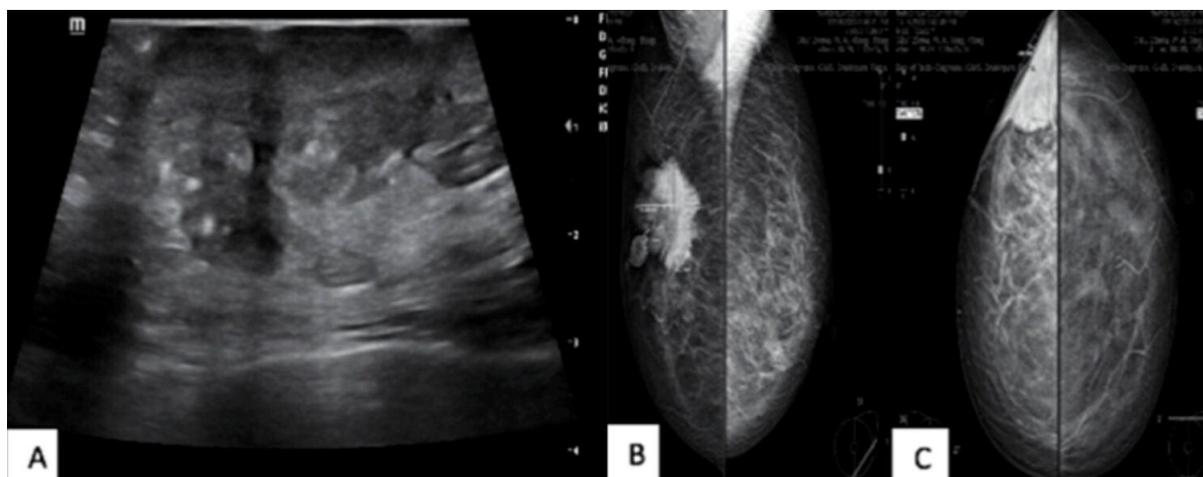


Figure 5: Invasive Breast Carcinoma with ductal carcinoma in situ. USG right breast (A) shows a large ill-defined heteroechoic mass with hyperechoic angular margins and posterior acoustic shadowing. MLO view (B) and CC view (C) –

Mammography with breast density C shows an irregular high-density lesion with speculated margins in the upper outer quadrant of the right breast, involving the surrounding skin. A few foci of calcification were also noted. BIRADS –5 – on histopathology – Invasive breast carcinoma with ductal carcinoma in situ.

Microcalcifications, architectural distortion, and spiculated margins showed a strong association with malignancy, in agreement with Muttarak et al. [9]. However, several invasive carcinomas lacked these classical features, indicating that their absence does not exclude malignancy.

Other entities, including lobular carcinoma, clear cell carcinoma, spindle cell carcinoma, mixed mucinous

carcinoma, and breast abscess, highlighted the diverse pathology of giant breast masses. Invasive lobular carcinoma, in particular, demonstrated subtle and variable imaging features (Figure 6), supporting the recommendation for biopsy in cases of asymmetry or architectural distortion even without a discrete mass [15].

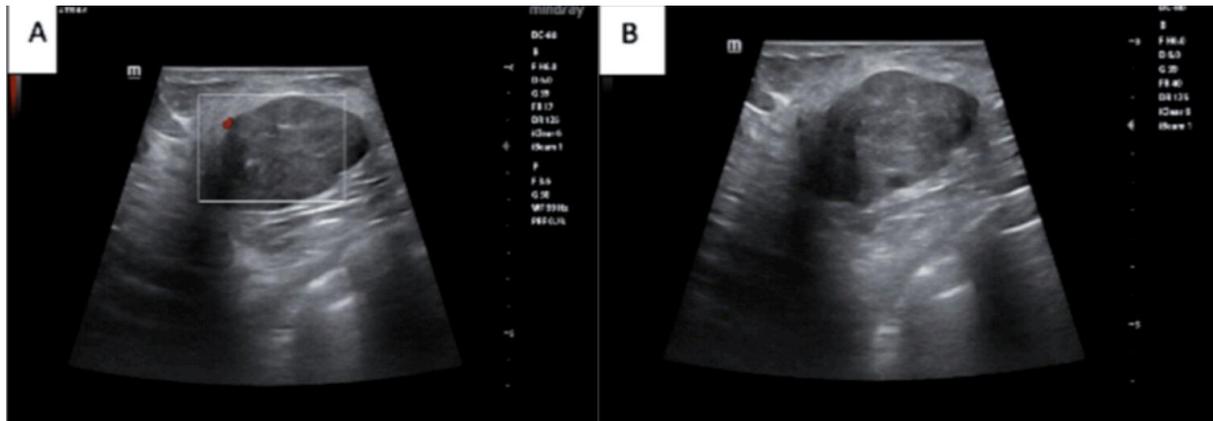


Figure 6: Lobular Carcinoma USG right Breast (A & B) – shows a large oval heteroechoic solid lesion with lobulated margins and mild vascularity at the periphery. Posterior acoustic enhancement was noted without any skin infiltration. BIRADS – 4 B – on histopathology- Lobular carcinoma.

Overall, BI-RADS categorisation showed good concordance with histopathology. Higher BI-RADS categories were strongly predictive of malignancy, whereas BI-RADS 4A lesions were benign in most cases, with few malignant exceptions. This supports using multiple imaging methods while emphasising the necessity of histopathological confirmation for definitive diagnosis.

5. Conclusion

This study confirms that giant breast masses are predominantly malignant, with infiltrative breast carcinoma representing the most frequent histopathological diagnosis, thereby addressing the objective of defining their radiologic–pathologic spectrum. Ultrasonography proved to be an essential adjunct to mammography, particularly in heterogeneously dense breasts where mammographic assessment was limited, supporting the role of multimodality imaging in lesion evaluation. Breast Imaging Reporting and Data System categorisation demonstrated strong concordance with histopathology in differentiating benign from malignant giant breast masses, validating its use as a reliable risk stratification tool. However, imaging findings alone were insufficient for accurate histological subtyping, especially among fibroepithelial lesions such as phyllodes tumours and giant fibroadenomas. Therefore, image-guided core needle biopsy remains necessary for definitive diagnosis. Based on these findings, a prompt combined clinical, imaging, and tissue-based assessment is recommended for all large palpable breast masses to ensure appropriate and timely management.

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