# ROLE OF BREAST ULTRASOUND IN EVALUATION OF BIRADS 3 AND BIRADS 4 BREAST MASSES

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**ABSTRACT**

**BACKGROUND**

Breast Ultrasound (US) is widely used as a diagnostic tool in evaluating mammographically detected masses,(1) palpable lumps,(2,3) nipple discharge(4) and in guiding percutaneous biopsy.(5) Breast ultrasound is a primary diagnostic tool along with mammography for the evaluation of breast masses.

Aim- To determine the accuracy of Breast Ultrasound in evaluating BI-RADS 3 and 4 breast masses with pathologic diagnosis as reference gold standard.

**MATERIALS AND METHODS**

Study was conducted in the period, December 2015 to December 2016. A total of 756 patients who presented to the Surgery outpatient department with complaints of breast lump, pain or nipple discharge were subjected to breast imaging. From 756 patients, 143 patients who had BIRADS 3 and 4 mass were selected for the study. Patients with masses that fulfilled the BI-RADS 3 and 4 were enrolled in the study. Breast ultrasound with and without Doppler performed in these patients with GE Voluson S6 (Linear Array 4 - 12 MHz, Curved Array 2 - 8 MHz). Informed written consent for the ultrasound-guided biopsy procedures was obtained from each patient.

**RESULTS**

All the 143 breast masses were evaluated and categorised according to the BI-RADS classification on B mode US. A total of 51 masses were categorised into BI-RADS 3 and 92 masses into BI-RADS 4. Among the 51 BI-RADS category 3 masses, only 4 (7.8%) were malignant. Of the 92 masses of category 4, 75 (81.5%) were malignant on histopathology. Thus, the B mode US had a sensitivity of 94.9% and specificity of 73.4%, positive predictive value of 81.5% and negative predictive value of 92.2%; (P value < 0.001) in detecting malignancy.

**CONCLUSION**

Breast ultrasonography is an appropriate tool in the detection of cancer and should be included in the workup of symptomatic breast disease. Breast ultrasound has a very high sensitivity in detecting malignancies and guiding further management of the suspicious lesions. But the occurrence of false positive diagnosis in the clinical settings like that of inflammatory breast disease should also be considered and the management be decided after correlation with the clinical data and the biopsy results.

**KEYWORDS**

Contents of Appendix, Ultrasonography, Predominant Contents.

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## BACKGROUND

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### Aims and Objectives

AIM- To determine the accuracy of Breast Ultrasound in evaluating BI-RADS 3 and 4 breast masses with pathologic diagnosis as reference gold standard.

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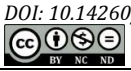

## MATERIALS AND METHODS

### Study Type

### Observational Diagnostic Study

Study was conducted in the period, December 2015 to December 2016. A total of 756 patients who presented to the Surgery Outpatient Department with complaints of breast lump, pain or nipple discharge were subjected to breast imaging. From 756 patients, 143 patients who had BIRADS 3 and 4 mass were selected for the study. Patients with masses that fulfilled the BI-RADS 3 and 4 were enrolled in the study. Breast ultrasound with and without Doppler performed in these patients with GE Voluson S6 (Linear Array 4 - 12 MHz, Curved Array 2 - 8 MHz). Informed written consent for the ultrasound-guided biopsy procedures was obtained from each patient.

Patients who were unwilling to provide informed consent, Patients with breast implants and Patients with previous breast conserving surgery on the breast of interest were excluded from the study.

**Ultrasound Examination**

The breast ultrasound examinations were performed using GE Voluson S6 (Linear Array 4 - 12 MHz, Curved Array 2 - 8 MHz) With patient in supine position and ipsilateral arm above the head, the affected breast was systematically examined with overlapping scans in transverse and radial planes from the nipple to the periphery to ensure complete coverage of all breast tissue. A minimum of two orthogonal B-mode images and one power or colour Doppler image was acquired. Maximum lesion diameter was measured on B mode images. The size, shape, margins, echotexture, posterior acoustic shadowing/enhancement, calcification and internal vascularity were evaluated in each of the cases as follows.[6,7]

- **Border of the Lesion-** A well-defined smooth, lobulated (Benign), ill-defined, irregular (Malignant).
- **Orientation-** Unique to US-imaging and defined as parallel (benign) or not parallel (Suspicious finding) to the skin.
- **Echo Pattern-** Anechoic, hypoechoic, complex cystic and solid, isoechoic, hyperechoic and heterogeneous. Echogenicity can contribute to the assessment of a lesion, together with other feature categories. Alone, it has little specificity.
- **Posterior Features-** Enhancement, shadowing. Posterior features represent the attenuation characteristics of a mass with respect to its acoustic transmission, also of additional value. Alone, it has little specificity.
- **Calcifications-** On US poorly characterised compared with mammography, but can be recognised as echogenic foci, particularly when in a mass.
- **Associated Features-** Architectural distortion, duct changes, skin changes, oedema and increased vascularity favours malignant lesion.

**Reference Standard**

The final diagnosis for each lesion was derived from histopathologic results after core biopsy. Positive reference standard was defined as malignant histopathologic (any invasive malignancy or ductal carcinoma in situ) result. The sensitivity, specificity and positive predictive value and negative predictive value of Ultrasound in predicting benign and malignancy were calculated.

All the data were analysed using Test statistics (Screening method)- Specificity. Sensitivity, Positive predictive value, negative predictive value and probability calculation.

**RESULTS**

A hundred and forty three patients with a single breast mass, each were included in the study. The mean age of our study population was 45.3 years ± 13.6 years; (range 22 - 65 years). Seven patients were asymptomatic at first presentation, while the rest (136/143, 95.1%) presented with symptoms such as a palpable mass (109/143, 76.2%), breast pain (46/143, 32.1%), bloody nipple discharge (9/143, 6.3%), skin changes (15/143; 12.6%) and nipple retraction (7/143; 5.8%). The mean duration of symptoms was 6.5 ± 5 months (range, 1 - 36 months). The mean size of the breast mass in these patients was 2.3±1.4 cm (range, 0.5 - 9.4 cm).

All the 143 masses were subjected to ultrasound-guided core biopsy and histopathological diagnosis was considered as the gold standard. Sixty four masses were benign, while seventy nine masses were malignant on histopathology. On comparison of the profile of patients with benign and malignant masses, the mean age of patients with benign masses was relatively less as compared to the ones with malignant disease (35.2 ± 11.7 years vs 48.8 ± 11.9 years respectively, $p < 0.001$). Significant differences were seen in symptoms and their duration in the two groups of patients. Palpable breast lump (96.7% vs 75.4%), skin changes (21% vs 3.5%) and nipple retraction (11.3% vs 0%) were more common in patients with malignant masses, while pain was a common feature with patients with benign masses (31.6% vs 14.5%, p= 0.02). Mean duration of the symptoms was more in benign masses (7.2 ± 6.4 months) in comparison to malignant masses (4 ± 2.3 months, p= 0.001). The malignant masses had a larger mean size compared with those of the benign masses (2.9 ± 1.3 cm vs 2.5 ± 1.5 cm, respectively, p= 0.03).

All the 143 breast masses were evaluated and categorised according to the BI-RADS classification on B mode US. A total of 51 masses were categorised into BI-RADS 3 and 92 masses into BI-RADS 4. Among the 51 BI-RADS category 3 masses, only 4 (7.8%) were malignant. Of the 92 masses of category 4, 75 (81.5%) were malignant on histopathology. Thus, the B mode US had a sensitivity of 94.9% and specificity of 73.4%, positive predictive value of 81.5% and negative predictive value of 92.2%. (P value < 0.001) in detecting malignancy.

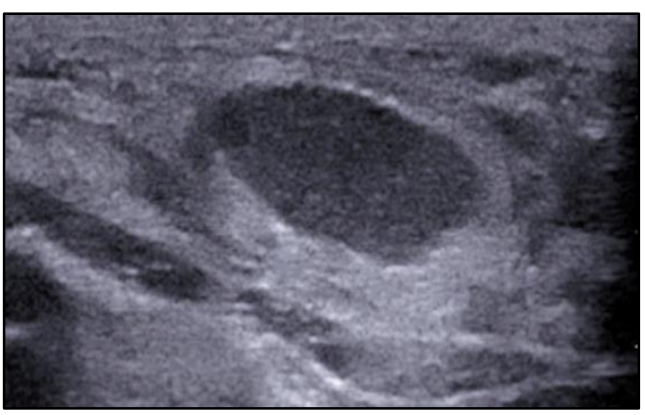

***Figure 1. BI-RADS 3 Mass. Breast Ultrasound Images showing a Well Circumscribed Hypoechoic Mass with Smooth Margins with Posterior Acoustic Enhancement***

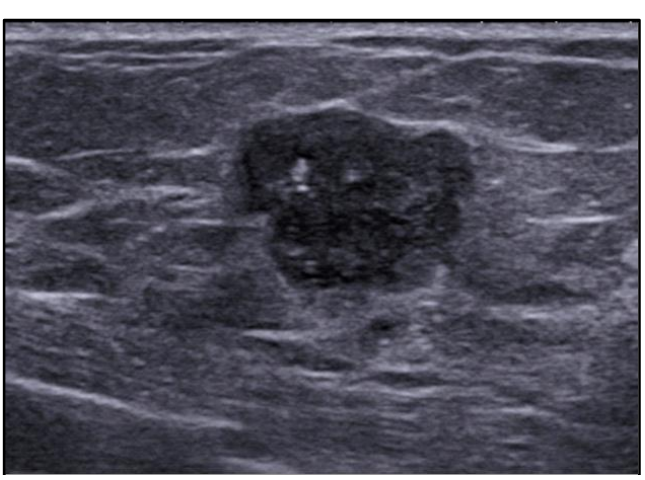

***Figure 2. BIRADS 4 Mass- Breast Ultrasound Images showing a Hypoechoic Mass with Multiple Lobulations and Small Calcific Foci within It***

| USG Findings | Biopsy Findings | | No. of Patients |
|---|---|---|---|
| | Malignant | Benign | |
| BIRADS 4 | 75 | 17 | 92 |
| BIRADS 3 | 4 | 47 | 51 |
| **Total** | **79** | **64** | **143** |

***Table 1. Correlation of USG and Biopsy Findings***

## DISCUSSION

B mode US is the most widely used and invariably the first imaging modality for breast masses with a reported sensitivity of 69.6% to 100% and specificity of 14.3% to 94.8%([8,9,10,11,12,13,14]) for the characterisation of these masses.

Our study population of 143 patients comprised of a mean age of 42.3 ± 13.6 years, predominantly females and the vast majority were symptomatic, the commonest of which was the presence of a breast lump seen in 76.5% followed by breast pain (32.6%), skin changes (10.6%), bloody nipple discharge (6.4%) and nipple retraction (5.8%). The mean size of the malignant breast masses was larger than that of the benign (2.4 ± 1.3 vs 1.5 ± 1.1 cm, respectively). These presenting features reflect presence of chronic, longstanding disease of advanced nature at the outset.

In our study using the BI-RADS classification and considering BI-RADS 3 as benign and BI-RADS 4 as malignant, ultrasound had a high sensitivity of 94.9% and moderate specificity of 73.4% in detecting malignancy. The sensitivity of B mode ultrasound in detecting malignancy in our study (94.9%) was consistent with most of the studies (Berg et al- 97.2%, Lee et al- 94.3%, Evans et al- 95%).[10,11,13] On the other hand, the specificity of breast ultrasound was highly variable among different studies from 14.3% to 94.8%. Our study showed a moderate specificity of 73.4%, quite similar to the ones reported by Berg et al, Evans et al and Chang et al.[10,11,12] This variability could be attributed to the differences in the study population, prevalence of disease (pretest probability) and in the thresholds adopted for diagnosing malignancy on breast ultrasound. Due to lack of facility of the screening programs, all our patients were symptomatic and 76.2% had palpable breast lumps. A study conducted on similar population has yielded comparable results.[14]

We analysed the malignancy rates in our patient population according to the BI-RADS classification on B Mode US. The malignancy rate was 7.8% for BI-RADS 3 lesions and 81.5% for BI-RADS 4 masses.

### Limitations of the Study

Diagnosis of breast masses in our study were based on ultrasound-guided core-needle biopsy. Although, 14-gauge ultrasound-guided core-needle biopsy has been proven to be a safe and accurate diagnostic method, false-negative rates of ultrasound-guided core-needle biopsy have been reported to range from 2.4% to 3.7%.[15,16] There were limited spectrum of pathologies in our study. Studies involving larger number of patients with different histopathological diagnosis could help better assessment of the role of ultrasound.

## CONCLUSION

Breast ultrasonography is an appropriate tool in the detection of cancer and should be included in the workup of symptomatic breast disease. Breast ultrasound has a very high sensitivity in detecting malignancies and guiding further management of the suspicious lesions. But the occurrence of false positive diagnosis in the clinical settings like that of inflammatory breast disease should also be considered and the management be decided after correlation with the clinical data and the biopsy results.

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