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ULTRASOUND FINDINGS OF BREAST MASSES WITH HISTOPATHOLOGICAL CORRELATION: A PROSPECTIVE STUDY.

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ABSTRACT

Background

Breast carcinoma is the most frequent cancer and cause of death in women worldwide and in India. Early breast cancer diagnosis and therapy reduce mortality. Breast lesions are first imaged using ultrasound due of its availability, radiation-free nature, and good cost-benefit ratio. Ultrasound is preferred over mammography for diagnosing breast lesions in thick breasts and during pregnancy and lactation.

Aim

To differentiate breast lesions into benign and malignant lesions. Correlate benign and malignant lesions with histopathological findings.

Methodology

This was a prospective study. 100 patients were evaluated by ultrasound and lesions were categorized according to the Breast Imaging Reporting and Data System, Sonographic findings were correlated with histopathological findings, and statistical analysis was done.

Results

The age distribution of the patients ranged from 15 to 75 years, with a mean age of approximately 45 years. The study found that 68% of the patients had benign lesions and 32% had malignant lesions according to ultrasound. Histopathological examination confirmed that 63 patients had benign lesions, while 37 had malignant lesions. There were 2 false-positive cases (radial scars) and 5 false-negative cases (malignant phyllodes, metastatic lesions, and papillary carcinoma). The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of ultrasound in diagnosing breast lesions were found to be 85.7%, 96.9%, 93.7%, 92.6%, and 93%, respectively. The most common benign lesions were fibroadenomas, followed by fibrocystic disease. Among malignant lesions, infiltrative ductal carcinoma was the most common.

Conclusions

Results demonstrated a positive correlation between the sonographic findings and histopathological diagnoses of the breast masses.

Recommendation

Ultrasound should be utilized as a primary imaging modality for evaluating breast lesions, particularly in resource-limited settings and for patients with dense breast tissue, to facilitate early and accurate differentiation between benign and malignant lesions, thereby improving patient management and outcomes.

***Keywords**: Breast Carcinoma, Ultrasound, BI-RADS, Histopathology*
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INTRODUCTION

Breast cancer is one of the most commonly diagnosed cancers in women globally and also in India. It is presented as a breast lump associated with either a benign or malignant lesion. The advent of population growth, lifestyle change, and migration from rural to urban areas lead to an increase in breast cancer in developing countries. In India, a

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statistically significant increase in the trends of incidence of breast carcinoma is noticed. Mortality rates associated with breast cancer have also increased during the last two decades. It has now surpassed lung cancer as the leading cause of global cancer incidence in 2020, with an estimated 2.3 million new cases, representing 11.7% of all cancer cases (1).

The mortality rate of breast cancer in India is on the rise due to late diagnosis, lack of awareness, and financial constrain in some regions.

Detection of breast lesions in the early stage is the ultimate goal of breast cancer control. Early detection of breast cancer through screening leads to detection of cancer in the early stage resulting in reduced morbidity and mortality. Mammography has been accepted as a gold standard diagnostic tool for screening and early detection of breast carcinoma. Still, it is unavailable everywhere in limited resource countries due to high cost. However, one of the limitations of mammography is the obscuration of lesions in dense breasts. Sono mammography (Ultrasound of the breast) is a widely accepted and cost-effective diagnostic tool for the evaluation of breast lesions especially in young age (< 30 years) patients, in pregnant and lactating patients. The lesion which is not visualized on mammography due to dense breast, is visualized in USG breast. USG plays an important role in differentiating solid and cystic lesions and differentiating benign and malignant lesions among solid lesions.

Histology of breast masses has been identified as the confirmatory test and the gold standard for diagnosis, however large no. of biopsy is performed in benign breast lesions without undergoing imaging leads to mental trauma in women undergoing biopsy and unnecessary cost of biopsy procedure. Therefore, ideally, radiological imaging is followed by pathological imaging either FNAC or biopsy. USG also helps to reduce the no. of negative biopsies. Improvements in USG equipment improve the visualization and characterization of lesions, especially in nonpalpable lesions.

Breast surgery, either breast-conserving surgery in the early stage or modified radical mastectomy in the late stage associated with either neoadjuvant chemotherapy or chemotherapy after surgery is the most common treatment method.

The purpose of the study is to correlate USG findings of breast lesions with histopathological findings.

Objective

- To characterize the breast lesions into benign and malignant.
- To correlate benign and malignant lesions with histopathological findings (taking histology as a gold standard).

MATERIAL AND METHOD

Study design

This was a prospective observational study.

Study setting

Data collected from patients referred to the Department of Radiodiagnosis, Indira Gandhi Institute of Medical Science (IGIMS), Patna, Bihar, India, from March 2021 to November 2023.

Participants

The study included 100 female patients with age between 15 – 75 years.

Inclusion criteria

All patients with solid breast lesions on USG with age between 15 – 75 years.

Exclusion criteria

- Simple cystic lesions.
- breast abscess.
- Cases treated with neoadjuvant chemotherapy.
- Post-treatment recurrence of breast carcinoma.

Bias

There was a chance that bias would arise when the study first started, but it was avoided by giving all participants identical information and hiding the group allocation from the nurses who collected the data.

The technique of Ultrasonography (Sono mammography)

All USG examinations in this study were performed with a 05 to 13MHz High Frequency Linear array probe, of Samsung Machine with Model H-60.

All patients were scanned after taking detailed clinical history and clinical examination. Patients were scanned in a supine position with their hands extended overhead. Impressions were provided according to BIRADS.

USG Guided Intervention Procedures

At first consent was taken from patients. Biopsy was performed under the guidance of USG using an automatic firing gun of 14G, 10cm length, with 22mmm throw or a semi-automatic gun with 10mm and 20mm throw depending upon the size of the lesion after full aseptic and antiseptic precaution. 12 cores of sample were taken, and samples were sent in Neutral Buffered Formalin fixation solution.

USG (Sonomammographic) observations

The following observations were made and impressions were given according to BIRADS –

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- Shape: round, oval, lobulated, and irregular.
- Margin: circumscribed, irregular, angular, ill-defined, microlubated.
- Internal echotexture: homogenous hypoechoic, heterogeneous, echogenic
- Posterior echoes: posterior acoustic enhancement, posterior shadowing, not affected.
- Parallel to skin or not.
- Lesions are taller than wider.
- Lateral shadowing.
- Duct extension.
- Presence of calcification.

Statistical analysis

The study used sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy to evaluate the diagnostic performance of ultrasound in differentiating between benign and malignant breast lesions. These metrics were calculated based on the true positive, true negative, false positive, and false negative results obtained from correlating ultrasound findings with histopathological diagnoses.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULTS

In the present study 100 patients were evaluated clinically and ultrasound. These patients underwent biopsy under USG guidance and results of HPE examinations were correlated with findings with USG. The age of patients ranges from 15 to 75.

On USG out of 100 patients,68 had benign beast lesions and 32 had malignant breast lesions. On HPE 63 patients had benign lesions and 37patients had malignant lesions. On USG (02) cases were misdiagnosed (false positive) as carcinoma were found to have radial scar on histopathological examination. 05 cases of malignancy were missed (false negative) on USG were found to have malignant phyllodes (02), metastatic lesions (02) and papillary carcinoma on histopathological examinations (01). Frequency of benign lesions on USG were given in table no. 02, showing fibroadenoma were most common benign breast disease followed by fibrocystic diseases of breast.

Among malignant lesions of breast, infiltrative duct carcinoma was the most common carcinoma.

On USG (Sonomammogram), most common feature of malignant lesions was irregular shape with speculated margin and hypoechoic echotexture. Common features of benign lesions were oval shape, circumscribed margin, hypoechoic echotexture with posterior acoustic enhancement and parallel orientation along chest wall.

Table 1: Breast ultrasound versus histopathology in differentiating malignant and benign breast lesions.

USG diagnosis		Histopathological diagnosis	
USG BREAST	Malignant lesion	Malignant lesion	Benign lesion
	32	30	02
	Benign lesion		
	68	05	63

Sensitivity = True positive /true positive +false negative = 85.7%

Specificity = True negative/ True negative +false positive = 96.9%

Positive predictive value = true positive /true positive +false positive = 93.7%

Negative predictive value = true negative /true negative+false negative =92.6%

Accuracy = true positive + true negative / true positive +false positive + true negative + false negative = 93.0%

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Table 2: Histopathological diagnosis of benign breast lesion. Total no. of benign diseases was 63.

Fibroadenoma	22
Fibrocystic diseases	12
Granulomatous disease of breast	07
Giant Fibroadenoma	05
Intraductal Papilloma	04
Phyllodes	03
Fat necrosis	02
Hamartoma	02
Lipoma	02
Lactating adenoma	02
Radial Scar	02
Total	63

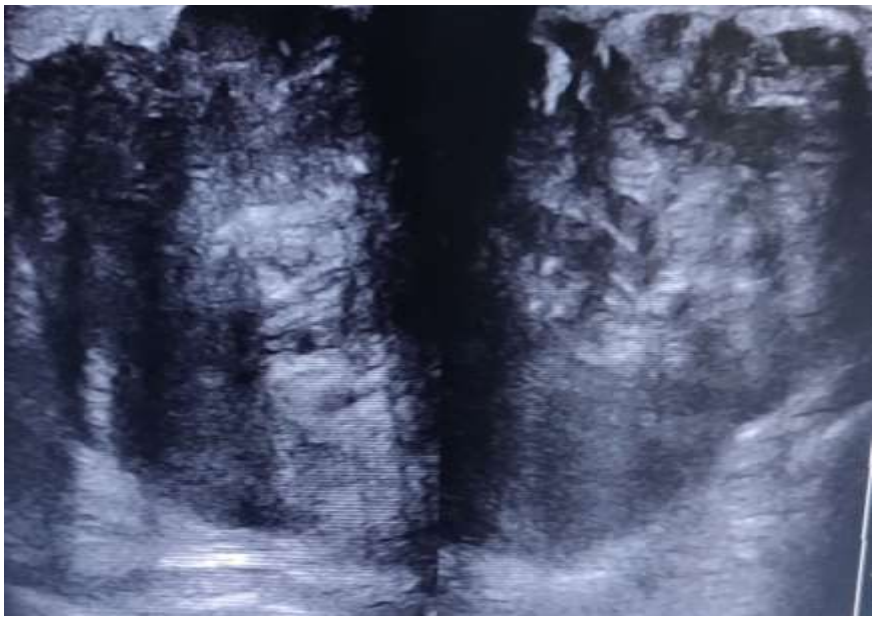

Image -1. (Giant Fibroadenoma). A large oval shaped soft tissue lesion with gentle lobulated margin and posterior accaustic enhancement.

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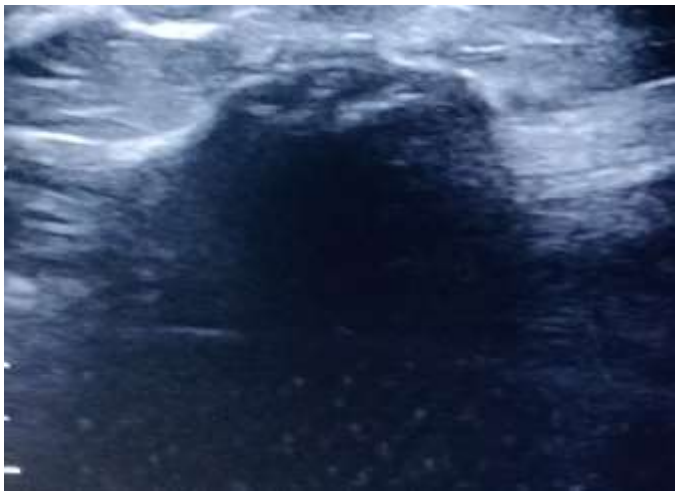

Image -2. (Post lumpectomy Fat Necrosis). A hypoechois lesion with irregular shape and margin with posterior accaustic shadowing along with dotted echogenic foci of the suture in the anterior part of the lesion.

Table 3: Histopathological diagnosis of malignant lesions of the breast. The total no. of malignant diseases was 37.

Infiltrative ductal carcinoma	20
Ductal carcinoma insitu	06
Lobular carcinoma	04
Mucinous carcinoma	03
Phyllodes carcinoma	02
Metastatic lesion	02
Intracystic papillary carcinoma	01
Total	38

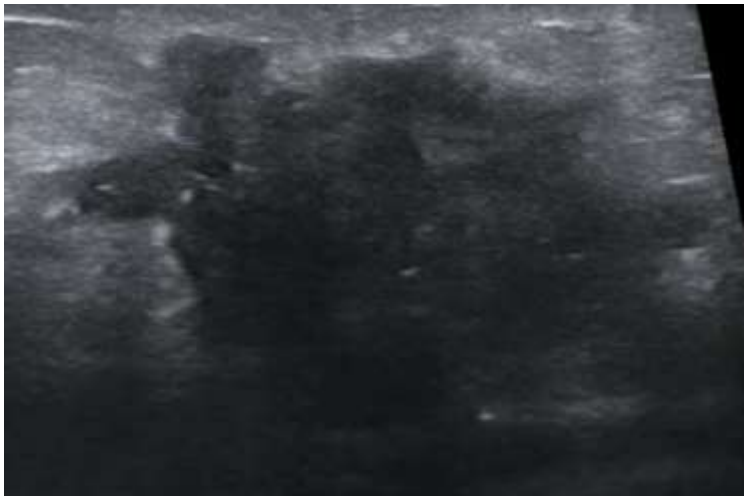

Image -3. (Invasive Ductal Carcinoma). Irregular shaped hypoechoic soft tissue lesion with irregular margin with posterior accaustic shadowing.

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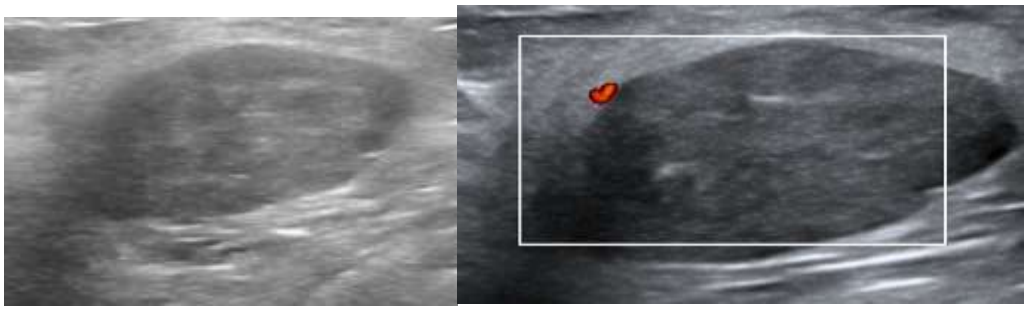

Image – 4. (Lobular carcinoma). Oval shaped hypoechoic soft tissue lesion with well circumscribed and lateral indistinct margin with mild peripheral vascularity.

Table 4: Frequency of USG morphology description of malignant lesions of breast.

Morphology description	Frequency (n=37)	percentage
SHAPE		
irregular	24	65.0%
round	08	21.65
oval	05	13.5
MARGIN		
spiculated	20	54.0%
microlobulated/irregular	08	21.6%
angular	05	13.5%
circumscribed	04	10.8%
ECHOGENICITY		
hypoechoic	21	65.7%
heterogeneous	10	27.0%
complex	06	16.2%
CALCIFICATION		
Calcification present in lesion	20	54.0%
Calcifications absent in lesion	17	25.9%s
POSTERIOR ACCOUTIC FEATURE		
shadow	20	54.0%
enhancement	08	21.6%
Combined (shadow +enhancement)	07	18.9%
No posterior feature	02	5.4%
ORIENTATION		
Not parallel to skin	22	59.4%
Parallel to skin	15	40.5%
ASSOCIATED FEATURE		
DUCT EXTENSION		
duct extension present	11	29.7%
Duct extension not present	16	43.7%
VASCULARITY		
vascularity present	34	91.8%
LYMPH ADENOPATHY		
present	27	72.9%
Not present	10	27.0%
SKIN CHANGES		
present	14	37.8%
Not present	23	62.1%

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Table 5: Frequency of USG morphology description of benign lesions of breast.

Morphology description	Frequencys (n=68)	Ratio
SHAPE		
oval	47	69.1%
round	17	25.0%
irregular	04	05.8%
MARGIN		
circumscribed	44	64.7%
Non-Circumscribed		
Indistinct	10	14.7%
Microlobulated/irregular	08	11.7%
ECHOTEXURE		
hypoechoic	47	69.1%
heterogeneous	10	14.7
isoechoic	04	05.9%
complex	04	05.9%
echogenic	03	04.4%
POSTERIOT ACCOUSTIC FEATURES		
enhancement	48	70.5%
shadowing	05	07.4%
Mix (shadow & enhancement)	08	11.7%
ORIENTATION		
parallel to skin	49	72.0%
not parallel to skin	19	27.9%
CACIFICATIN		
no suspicious calcification seen.		
DUCT EXTENSION		
duct extension not present	26	93.15
duct extension present	06	06.9%
LYMPH ADENOPATHY		
lymph adenopathy absent	56	89.7%
lymph adenopathy present	06	10.3%
SKIN CHANGES		
skin changes not present		96.6%
Skin changes present		03.4%

Table 6: BIRADS assessment of USG findings of breast lesion.

BIRADS	percentage
2	68%
3	04%
4	13%
5	15%

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DISCUSSION

In this study, 100 patients aged 15 to 75 years were evaluated both clinically and through ultrasound (USG). The findings from the ultrasound were then correlated with histopathological examination (HPE) results obtained through USG-guided biopsy. Of the 100 patients, an ultrasound diagnosed 68 patients with benign breast lesions and 32 with malignant breast lesions. However, histopathological examination revealed 63 benign cases and 37 malignant cases. There were 2 false positives where radial scars were misdiagnosed as carcinoma on ultrasound and 5 false negatives where malignant conditions such as malignant phyllodes, metastatic lesions, and papillary carcinoma were missed on ultrasound.

The diagnostic performance of ultrasound in this study was high, with a sensitivity of 85.7%, specificity of 96.9%, positive predictive value of 93.7%, negative predictive value of 92.6%, and an overall accuracy of 93.0%. These metrics indicate that ultrasound is a reliable diagnostic tool for distinguishing between benign and malignant breast lesions. Among the benign lesions, fibroadenoma was the most common, followed by fibrocystic disease. Among the malignant lesions, infiltrative duct carcinoma was the most frequently identified.

Morphological features observed on ultrasound also provided significant diagnostic insights. Malignant lesions most commonly appeared with an irregular shape (65%), spiculated margins (54%), and hypoechoic echotexture (65.7%). Additionally, 54% of malignant lesions exhibited calcifications and shadowing as a posterior acoustic feature. In contrast, benign lesions typically had an oval shape (69.1%), circumscribed margins (64.7%), and hypoechoic echotexture (69.1%). Posterior acoustic enhancement was observed in 70.5% of benign lesions. Orientation and additional features such as duct extension, vascularity, lymphadenopathy, and skin changes were also noted, with malignant lesions showing more irregular and concerning patterns.

The BIRADS assessment categorized the lesions into various levels of concern, with 68% of the cases falling into category 2 (benign), 4% into category 3 (probably benign), 13% into category 4 (suspicious abnormality), and 15% into category 5 (highly suggestive of malignancy). This distribution highlights the effectiveness of ultrasound in identifying and categorizing breast lesions accurately.

These results are consistent with other studies in the literature, where ultrasound sensitivity and specificity for breast cancer detection typically range from 72.2% to 86.3% and 79.8% to 93.6%, respectively. The study supports the use of ultrasound as a first-line diagnostic tool, especially in settings where mammography is not available or in populations with dense breast tissue. The high specificity and positive predictive value can reduce unnecessary biopsies, although the moderate sensitivity underscores the need for follow-up and additional diagnostic modalities when necessary.

In Western countries, the peak age of breast cancer is 60–70 years, but in Asian countries, it is 40–50 years. In India, breast cancer incidence peaks among women at a younger age as compared to women from Western countries. Research studies conducted earlier in the country have observed age at diagnosis of breast carcinoma between 45 and 50 years (2). In developing countries like India, patients present in late-stage with the locally advanced disease of the breast at diagnosis, USG is the first imaging modality in these countries as USG is well tolerated in these patients.

Female breast cancer incidence rates have been slowly increasing by about 0.5% per year since the mid-2000s, attributed at least in part to continued declines in the fertility rate and increases in excess body weight. (2)

Ultrasound is the examination of choice in the young and for dense breasts as it is safe, dynamic, well tolerated, and does not use ionizing radiation. In comparison with Western women, Asian women have small and dense breasts and USG is an appropriate tool for early detection of cancer in these women. Early identification of malignant features by high-frequency ultrasound reduces morbidity and improves overall management. The ACR formulated the BI-RADS to standardize breast imaging reporting to avoid ambiguity in communication and interpretation (3).

In recent decades technical advances in ultrasound machines including High Frequency Linear Array Transducers with excellent near-field resolution along with compound imaging and harmonics have made USG a primary imaging modality, especially in young women with dense breasts and it led to improved characterization of lesions in the form of shape, margin and internal echotexture. The feature of USG is to show images and lesions of the breast without overlapping breast tissue to overcome problems of overlapping additional Mammographic views and the new technique of breast Tomosynthesis is being used.

In the present study nature of breast lesions was determined by USG and final assessments were made according to BIRADS and then correlated with histopathological findings for maximizing the accuracy of USG (Sonomammography) and minimizing false positive and false positive findings.

Screening USG in women with dense breasts and negative mammograms can yield an incremental increase in the cancer detection rate of 3.7 to 4.2 more cancers identified per 1000 women screened (4).

In the present study, sensitivity, specificity, positive predictive value, negative predictive, and accuracy of USG for the diagnosis of benign and malignant lesions are 85.7%, 96.9%, 93.7%, 92.6%, and 93.0%. These results correlate with studies in systemic review and meta-analysis and found overall pooled sensitivity and specificity of 72.2% to 86.3% and 79.8% to 93.6% (6).

Numerous studies report high sensitivity and negative predictive value up to 100% when USG is used for cancer detection at the site of focal breast symptoms. As a detection modality, USG has a particular potential to affect early detection rates in areas that lack access to Mammography. In developing countries / low-income countries, where patients present with locally advanced breast disease and at younger ages, ultrasound is the first imaging modality.

Breast Health Global Initiatives advocates for the introduction of diagnostic USG at a resource-limited level, given that it is more widely available than Mammography in these countries and is extremely useful in women with palpable lesions. (5,6). Higher sensitivity was noted in studies that involved women with breast symptoms (7).

Generalizability: The study findings, with high specificity (96.9%) and accuracy (93.0%) of ultrasound in differentiating benign and malignant breast lesions, suggest that ultrasound can be a reliable, first-line diagnostic tool for breast cancer screening in larger populations, particularly in resource-limited settings or among those with dense breast tissue. This can lead to early detection, reduced unnecessary biopsies, and improved patient management on a broader scale.

CONCLUSION

This study found a positive correlation between USG findings and HPE correlation in the diagnosis of breast lesions. USG showed high specificity and predictive value in differentiating between benign and malignant lesions of breast lesions. USG is the first imaging modality where mammography is not available and in locally advanced diseases of the breast.

Limitations: The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

Recommendation: Ultrasound should be utilized as a primary imaging modality for evaluating breast lesions, particularly in resource-limited settings and for patients with dense breast tissue, to facilitate early and accurate differentiation between benign and malignant lesions, thereby improving patient management and outcomes.

Acknowledgment: We are thankful to the patients; without them, the study could not have been done. We are thankful to the supporting staff of our hospital who were involved in the patient care of the study group.

LIST OF ABBREVIATIONS

ACR: American College of Radiology
BIRADS: Breast Imaging Reporting and Data System
FNAC: Fine Needle Aspiration Cytology
HPE: Histopathological Examination
IGIMS: Indira Gandhi Institute of Medical Sciences
PPV: Positive Predictive Value
NPV: Negative Predictive Value
USG: Ultrasonography / Ultrasound
US: Ultrasound
MRI: Magnetic Resonance Imaging
NBF: Neutral Buffered Formalin
IDC: Infiltrative Ductal Carcinoma
DCIS: Ductal Carcinoma in Situ
H&E: Hematoxylin and Eosin
WHO: World Health Organization
CI: Confidence Interval
SD: Standard Deviation
N/A: Not Applicable
US-FNAC: Ultrasound-guided Fine Needle Aspiration Cytology

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CONFLICT OF INTEREST

The authors have no competing interests to declare.

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