

## EVALUATION OF HIGH RESOLUTION SONOGRAPHY AND CYTOLOGICAL CORRELATION OF BREAST LESIONS IN A TERTIARY CARE HOSPITAL, U.P., INDIA

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### Abstract

**Background:** The prevalence of breast cancer in India is on the rise, making it the predominant form of cancer among women. Preoperative pathology diagnostics and mammography, using the breast imaging reporting and data system (BI-RADS) score system, are crucial components of the evaluation of breast abnormalities. The aim is to assess the effectiveness of high resolution sonography and its connection with cytological findings in diagnosing breast lesions in a tertiary care hospital in Uttar Pradesh, India. **Materials and Methods:** This retrospective analysis was carried out at the Department of Pathology GSMCH Total number of ultrasound breast was done of 502 patients from 22/05/2019 to 16/09/2023. Out of 502, 100 patients who presented with palpable breast lesions were included in this study. This research comprised female patients of various ages who presented with breast lumps and had undergone breast imaging, including BIRADS assessment, as well as cytological evaluation. **Result:** There were zero patients classified under categories 0, 1, and 6 based on the BIRADS score. There were 24 patients, accounting for 24% of the total, in category 2. Category 3 had 58 patients, representing 58% of the total. Category 4 had 13 patients, making up 13% of the total. Lastly, category 5 had 5 patients, accounting for 5% of the total. Findings were classified as benign if the score was 2 or 3, and as malignant if the score was 4 or 5. The research found that 82% of the patients were benign, whereas 18% were malignant. The majority of patients were located in C2 (67%), with C1 having the second highest proportion (12%), followed by C3 (10%), C4 (7%), and C5 (4%). The majority of patients (34%) had Fibroadenoma, followed by Others (27%), Benign breast diseases (19%), No Opinion Possible (8%), Atypical lesions (5%), Fibrocystic disease (4%), and Ca Breast C5 (3%). There were no patients with suppurative/Breast abscess/Mastitis. **Conclusion:** The current research suggests that the BI-RADS score, due to its non-invasive nature, has the potential to be a valuable diagnostic for assessing breast lump lesions. Nevertheless, the BIRADS score should not be regarded as the definitive standard and hence cannot be used as a substitute for histology in the identification of breast masses.

## INTRODUCTION

Breast cancer is the most common cancer diagnosed in women worldwide accounting for 21% of all cancers diagnosed in women. The prevalence of breast cancer in India is on the rise, making it the predominant form of cancer among women. It has surpassed cervical cancer in major metropolitan cancer registries. Preoperative pathology diagnosis is a crucial component of the evaluation of breast lesions.<sup>[1]</sup> Mammography is the main method used

to test for and diagnose breast cancer. This breast x-ray uses soft tissue imaging to identify the presence of tumours or any other irregularities.<sup>[2]</sup> However, by itself, it does not rule out the possibility of breast cancer and must be conducted as part of the triple examination. The approach has a sensitivity of 90%, meaning that 10% of carcinomas are initially undetected with this method.<sup>[3]</sup> There has been a notable improvement in the quality of X-rays and the documentation of mammographic examinations during the last decade. It has both screening and

diagnostic capabilities. Screening mammography is a radiographic procedure that identifies undetected breast cancer in its early stages in women who do not show any symptoms.<sup>[4]</sup> In India, the use of fine needle aspiration cytology (FNAC) is still prevalent for evaluating breast masses, whether they are detectable by touch or not. This method is favoured due to its ability to quickly, precisely, and economically diagnose the condition. Nevertheless, FNAC has some drawbacks when it comes to evaluating breast abnormalities, resulting in an excessive number of excision biopsies being performed to diagnose breast masses.<sup>[5]</sup> In the majority of Western nations, core biopsy has become the preferred method over fine needle aspiration for diagnosing breast lesions that are causing symptoms or have been found via screening. The incidence of inconclusive or insufficient sample reports is reduced in comparison to FNAC, and it is much less invasive and cost-effective when compared to excision or incision biopsy for diagnostic purposes.<sup>[6]</sup> The American College of Radiology established the Breast Imaging Reporting and Data System (BI-RADS) vocabulary to provide a standardised method for describing and managing abnormalities seen on mammograms. This system aims to enhance communication between radiologists and referring doctors. Utilising predictive words in the standardised assessment of mammographic data allows for the categorization of patient risk, hence enhancing the planning of therapy. The BI-RADS vocabulary categorises morphologic characteristics of microcalcifications into three groups based on their likelihood of being benign or malignant: normally benign, intermediate concern, and increased chance of malignancy.<sup>[7]</sup> The research on interobserver variability of BI-RADS use found that the application of microcalcification descriptors was the most challenging for readers to apply consistently.<sup>[8]</sup> A recent analysis of a comprehensive assessment of biopsies revealed that almost two-thirds of the microcalcifications examined for biopsy were characterised as pleomorphic.<sup>[9]</sup> The fourth edition of BI-RADS included more precise microcalcification descriptors by subdividing the previous pleomorphic descriptor into two categories: coarse heterogeneous and fine pleomorphic. The findings of a research on microcalcifications and categories in the BIRADS fourth edition demonstrated that these improvements aid in accurately predicting the likelihood of cancer for worrisome microcalcifications.<sup>[10]</sup> Stereotactic biopsy and needle-localized open breast biopsy are often used for diagnosing microcalcifications found during mammography. Multiple studies on needle-localized open breast biopsy have examined its diagnostic accuracy, revealing lesion miss rates ranging from 0% to 18% (with an average of 2.6%) and a mean false negative rate (indicating the rate at which cancer is missed) of 2%.<sup>[11-14]</sup>

## MATERIALS AND METHODS

This retrospective analysis was carried out at the Department of Pathology GSMCH Total number of ultrasound breast was done of 502 patients from 22/05/2019 to 16/09/2023. Out of 502, 100 patients who presented with palpable breast lesions were included in this study. This research comprised female patients of various ages who presented with breast lumps and had undergone breast imaging, including BIRADS assessment, as well as cytological evaluation. The research eliminated individuals with recurring masses, a history of previous radiation to the chest or breast, and cystic breast lesions. Additionally, pregnant and breastfeeding women, as well as male patients, were also removed. Statistical analysis was conducted to calculate the sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of sonomammogram in relation to the BIRADS score and FNAC, using histology as the reference standard.

## RESULTS

The research included a cohort of 100 participants who had a breast lump. The highest proportion of instances, 32%, was seen in the age group of 21-30 years. This was followed by the age group below 20 years, which accounted for 26% of the cases. The age group of 31-40 years accounted for 17% of the cases, while the age group of 41-50 years accounted for 11%. The age group of 51-60 years accounted for 9% of the cases, and those beyond 60 years accounted for 5%. [Table 2] indicates that there were zero patients classified under categories 0, 1, and 6 based on the BIRADS score. There were 24 patients, accounting for 24% of the total, in category 2. Category 3 had 58 patients, representing 58% of the total. Category 4 had 13 patients, making up 13% of the total. Lastly, category 5 had 5 patients, accounting for 5% of the total. Findings were classified as benign if the score was 2 or 3, and as malignant if the score was 4 or 5. The research found that 82% of the patients were benign, whereas 18% were malignant.

[Table 3] displays the cytology categorization of the patients. The majority of patients were located in C2 (67%), with C1 having the second highest proportion (12%), followed by C3 (10%), C4 (7%), and C5 (4%).

[Table 4] shows the distribution of diagnoses among the patients. The majority of patients (34%) had Fibroadenoma, followed by Others (27%), Benign breast diseases (19%), No Opinion Possible (8%), Atypical lesions (5%), Fibrocystic disease (4%), and Ca Breast C5 (3%). There were no patients with suppurative/Breast abscess/Mastitis.

[Table 5] indicates that 52 (52%) patients had a right breast lump, 1 (1%) had bilateral breast nodules, 5

(5%) had bilateral breast lumps, and 42 (42%) had a left breast lump.

Our research found that when comparing the results of ultrasound (USG) to cytology as the gold standard, USG had a sensitivity of 84%, specificity of 97%, positive predictive value of 95%, negative

predictive value of 89%, positive likelihood ratio of 34%, and negative likelihood ratio of 18%. Based on the aforementioned data, it can be concluded that cytology exhibits superior sensitivity compared to USG, with almost identical specificity and a higher positive predictive value.

**Table 1: Age of patients**

Age	No. of cases	Percentage
<20 years	26	26
21-30 years	32	32
30-40 years	17	17
41-50 years	11	11
51-60 years	9	9
> 60 years	5	5
Total	100	100

**Table 2: BIRADS Category of the patients**

BIRADS Category	No. of cases	Percentage
BIRADS 2	24	24
BIRADS 3	58	58
BIRADS 4	13	13
BIRADS 5	5	5
Total	100	100

**Table 3: Cytology category of the patients**

Cytology category	No. of cases	Percentage
C1	12	12
C2	67	67
C3	10	10
C4	7	7
C5	4	4
Total	100	100

**Table 4: Diagnosis of the patients**

Diagnosis	No. of cases	Percentage
Fibroadenoma	34	34
Benign breast deceases	19	19
Atypical lesions	5	5
Supputative / Brease abcess/ Mastitie	0	0
No Opinion Possible	8	8
Ca Breast C5	3	3
Fibrocystuc disease	4	4
Others	27	27
Total	100	100

**Table 5: site of the patients**

	Number	Percentage
Rt breast lump	52	52
B/L breast nodules	1	3
B/L breast Lump	5	5
Lt Breast lump	42	42

**Table 6: Sensitivity and specificity of USG**

	USG
Sensitivity	84
Specificity	97
Positive predictive value	95
Negative predictive value	89
Positive likelihood ratio	34
Negative likelihood ratio	18

## DISCUSSION

Among women, breast cancer is the most prevalent form of cancer worldwide. The technique of Fine Needle Aspiration Cytology (FNAC) was first

pioneered by Martin and Ellis in 1930 for the purpose of diagnosing breast masses. Fine needle aspiration cytology (FNAC) has become a widely accepted method for precisely assessing the characteristics of breast tumours. Ultrasound is a valuable tool for assessing breast abnormalities. The

BIRADS score was first created in 1993 to document findings from mammography examinations. Since its inception, several studies have shown its use for clinicians in forecasting the probability of cancer. The use of breast ultrasonography has been widely accepted and several studies have shown that sonomammography may be useful in distinguishing between benign and malignant breast tumours.<sup>[15]</sup> The research included a cohort of 100 participants who presented with a breast lump. The highest proportion of cases, 32%, was seen in the age group of 21-30 years, followed by 26% in the age group below 20 years, 17% in the age group of 31-40 years, 11% in the age group of 41-50 years, 9% in the age group of 51-60 years, and 5% in the age group beyond 60 years. In contrast to Navya et al study, which included a range of age groups. There were also cases in the age groups of 26-35, 36-45, 46-55, and above 56-65 and above 66-75, but these were less common.<sup>[16]</sup> In Mohan et al, 9 patients (36.0%) were aged between 41-50 years, 10 cases (40.0%) were aged between 51-60 years, 5 cases (20.0%) were aged between 61-70 years, and only 1 case (4.0%) was aged between 71-80 years.<sup>[17]</sup> The average age of the participants in this research is 54.58±4.63 years. The research done by Takalkar et al revealed that the patients had a comparable average age of 52.6±10.5 years.<sup>[18]</sup> The research undertaken by Arsalan et al revealed that the average age of the patients was much lower, with a mean of 42.6±7.21 (30-60) years.<sup>[19]</sup> The research done by Soyder et al. found that the average age of the patients was 50±11 years, which was consistent throughout the participants.<sup>[20]</sup> The current research found that 82% of instances had a benign lump, whereas 18% of cases had a malignant lump according to the BIRADS Category. The research undertaken by Navya et al revealed similar results, with 32 cases (64.0%) showing a benign lump and 18 instances (36.0%) showing a malignant lump on histology.<sup>[16]</sup> In the research done by Soyder et al, it was shown that 75.0% of the patients had benign lumps, while only 25.0% had malignant lumps.<sup>[20]</sup> In the research done by Patankar et al, 44 instances (69.8%) were found to have a benign lump, whereas 19 cases (20.2%) were found to have a malignant lump.<sup>[21]</sup> In the research done by Kaira et al, it was noted that 47 instances (40.9%) presented with benign lumps, whereas 68 cases (59.1%) were diagnosed with malignant lumps.<sup>[22]</sup> Based on the BIRADS score, there were zero patients classified in groups 0, 1, and 6. The distribution of patients across different categories is as follows: 24 patients (24%) in category 2, 58 patients (58%) in category 3, 13 patients (13%) in category 4, and 5 patients (5%) in category 5. Findings were classified as benign if the score was 2 or 3, and as malignant if the score was 4 or 5. The study conducted by Arsalan et al found that in the left breast, 2 cases (4.0%) had a BI-RADS score of 0, 19 cases (38.0%) had a BI-RADS score of 1, 8 cases (16.0%) had a BI-RADS score of 2, 1 case

(2.0%) had a BI-RADS score of 3, 5 cases (10.0%) had a BI-RADS score of 4, and 15 cases (30.0%) had a BI-RADS score of 5.<sup>[19]</sup> In the study conducted by Rathi V et al., it was found that out of the cases observed in the right breast, 6.0% had a BIRADS score of 0, 56.0% had a BIRADS score of 1, 12.0% had a BIRADS score of 2, 2.0% had a BIRADS score of 3, 2.0% had a BIRADS score of 4, and 22.0% had a BIRADS score of 5.<sup>[21]</sup> Our research found that the USG had a sensitivity of 84%, specificity of 97%, positive predictive value of 95%, negative predictive value of 89%, positive likelihood ratio of 34%, and negative likelihood ratio of 18% when compared to cytology as the gold standard. Based on the aforementioned data, it can be concluded that cytology exhibits superior sensitivity compared to USG, with almost identical specificity and a higher positive predictive value. In the research done by Navya et al, 28 instances were found to be benign according to both the histopathological examination and the BI-RADS score. Additionally, 4 cases were benign on HPE but malignant on the BI-RADS score, while 2 cases were malignant on HPE but benign on the BI-RADS score. Furthermore, 16 cases were found to be malignant according to both the HPE and the BI-RADS score.<sup>[16]</sup> When comparing to HPE as the benchmark, the BI-RADS score has a sensitivity of 88.0% and a specificity of 87.5%. The BI-RADS score had a positive predictive value of 80.0%, a negative predictive value of 93%, and a diagnostic accuracy of 88%, which aligns with these results. The study conducted by Arsalan et al revealed that 41 cases showed positive results on both Biopsy (FNAC/ trucut/ excision) and BI-RADS score. Additionally, 6 cases exhibited positive results on Biopsy (FNAC/ trucut/ excision) but were negative on the BIRADS score. Furthermore, 3 cases showed negative results on both biopsy (FNAC/ trucut/ excision) and BI-RADS score. When compared to the biopsy methods (FNAC/ trucut/ excision) which are considered the most accurate, the BI-RADS score has a sensitivity of 87.2% and a specificity of 100.0%. The positive predictive value, negative predictive value, and diagnostic accuracy of the BI-RADS score in this investigation were 100.0%, 33.3%, and 88%, respectively.<sup>[19]</sup>

## CONCLUSION

The current research suggests that the BI-RADS score, due to its non-invasive nature, has the potential to be a valuable diagnostic for assessing breast lump lesions. Nevertheless, the BIRADS score should not be regarded as the definitive standard and hence cannot be used as a substitute for histology in the identification of breast masses.

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