

Comparative Study between Ultrasonography and Fine Needle Aspiration Cytology in Diagnosing Palpable Breast Lesions

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ABSTRACT

Background: Breast lesions are among the most common clinical presentations in women, ranging from benign conditions to malignant neoplasms. Early and accurate diagnosis using a combination of imaging and cytological evaluation is essential for appropriate management and improved patient outcomes.

Methods: A comparative analytical study was conducted over one year in a tertiary care teaching hospital in Central Maharashtra involving 50 female patients with palpable breast lumps. All patients underwent clinical examination, ultrasonography (USG), fine needle aspiration cytology (FNAC), and histopathological examination, with histopathology considered the gold standard. The diagnostic performance of USG and FNAC was evaluated using sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy.

Results: Among the 50 cases, 66% were benign and 34% were malignant, with fibroadenoma (50%) being the most common benign lesion and invasive ductal carcinoma (32%) the most common malignant lesion, predominantly occurring in women above 45 years of age. Larger breast lumps showed a significant association with malignancy ($p=0.029$). FNAC demonstrated excellent concordance with histopathology, with only one false-negative case. Ultrasonography showed a sensitivity of 94.44%, specificity of 100%, positive predictive value of 100%, negative predictive value of 96.97%, and an overall diagnostic accuracy of 98%.

Conclusion: The combined use of clinical examination, ultrasonography, and FNAC provides a reliable and effective approach for the evaluation of palpable breast lesions, while histopathology remains the definitive diagnostic standard. Early integrated assessment facilitates timely diagnosis, appropriate treatment, and improved patient outcomes.

Key-words: Palpable Breast lesions; Ultrasonography; Fine needle aspiration cytology; Histopathology; Breast carcinoma

INTRODUCTION

Breast cancer has emerged as one of the most significant public health concerns affecting women worldwide, and its burden is steadily increasing in developing countries such as India. ^[1,2]

In recent decades, changing lifestyles, increasing life expectancy, urbanization, delayed childbearing, reduced breastfeeding practices, and dietary changes have contributed to the rising incidence of breast cancer. Early detection and timely diagnosis play a crucial role in improving survival rates and reducing mortality associated with the disease. In India, where awareness, screening facilities, and access to healthcare services vary widely across regions, the challenge of early detection remains substantial. ^[3-5] Breast cancer is the most common cancer among women in India and accounts for approximately 27% of all cancers diagnosed

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in women. According to GLOBOCAN 2012 data, a total of 1,44,937 new cases of breast cancer were registered in the country, with 70,218 deaths attributed to the disease. [6] These figures highlight the significant morbidity and mortality associated with breast cancer in India. Despite advances in diagnostic and therapeutic modalities, a large proportion of patients in India continue to present at advanced stages of the disease, primarily due to lack of awareness, inadequate screening programs, and socio-cultural barriers that delay medical consultation. [4,7]

The age distribution of breast cancer in India shows a distinctive pattern compared to Western countries. The incidence rates in India begin to rise in women during their early thirties and reach a peak between the ages of 50 and 64 years. This trend indicates that Indian women tend to develop breast cancer at a relatively younger age. The earlier onset of the disease has significant implications for screening strategies and emphasizes the need for increased vigilance among clinicians and healthcare providers when evaluating breast-related symptoms in younger women. [7,8]

Epidemiological data also demonstrate a marked difference in the risk of breast cancer between urban and rural populations. Overall, it is estimated that approximately 1 in 28 women in India is likely to develop breast cancer during her lifetime. However, the risk is considerably higher in urban areas, where approximately 1 in 22 women develop breast cancer during their lifetime. In contrast, the lifetime risk in rural areas is estimated to be around 1 in 60 women. These variations may be attributed to differences in lifestyle factors, reproductive behavior, dietary habits, and levels of healthcare access between urban and rural populations. [9]

The increasing burden of breast cancer in India underscores the importance of effective diagnostic approaches that can facilitate early detection and accurate characterization of breast lesions. Among the commonly used diagnostic modalities, ultrasonography and FNAC play important roles in the evaluation of breast masses. Ultrasonography is a non-invasive imaging technique that helps in differentiating cystic from solid lesions and provides valuable information regarding the morphological characteristics of breast masses. On the other hand, FNAC is a minimally invasive cytological technique that allows direct microscopic

evaluation of cellular material obtained from breast lesions, thereby aiding in the confirmation of malignancy. [10,11]

Accurate and timely diagnosis of malignant breast lesions is essential for guiding appropriate management and improving patient outcomes. Therefore, comparative evaluation of diagnostic modalities such as ultrasonography and fine needle aspiration cytology is important to determine their effectiveness, reliability, and role in the early detection of breast cancer. Understanding the strengths and limitations of these techniques can help clinicians select the most appropriate diagnostic strategy for patients presenting with breast lesions. [12]

MATERIALS AND METHODS

Study Design and Setting- This comparative analytical study was conducted over a period of one year (January 2025 to December 2025) at a tertiary care teaching hospital in Central Maharashtra. The study included patients attending the Departments of Radiology, Surgery, and Pathology of the institute.

Sample Size- A total of 50 cases clinically suspected to have breast lesions and subsequently diagnosed as benign breast lesion or carcinoma breast were included in the study. Convenience sampling technique was used for selecting the cases.

Inclusion Criteria

- ✓ Female patients presenting with palpable breast lump.
- ✓ Patients who underwent both USG of the breast and FNAC.
- ✓ Patients with histopathological confirmation of the breast lesion following biopsy or surgery.
- ✓ Patients willing to participate in the study and providing informed consent.

Exclusion Criteria

- ✓ Patients with previously diagnosed or treated carcinoma breast.
- ✓ Patients with recurrent breast malignancy.
- ✓ Patients who did not undergo both ultrasonography and FNAC evaluation.
- ✓ Patients with incomplete clinical or diagnostic records.
- ✓ Patients unwilling to participate in the study.

Data Collection Procedure- All patients presenting with breast lumps during the study period were clinically evaluated in the Surgical Outpatient Department. A detailed history, including age, duration of the lump, and associated symptoms such as pain, nipple discharge, and skin changes, was recorded. A thorough clinical examination of the breasts and regional lymph nodes was performed.

Patients with suspected breast lesions were referred to the Department of Radiology for ultrasonographic examination. Breast ultrasonography was performed using a high-frequency linear transducer. Lesions were evaluated based on sonographic characteristics, including size, shape, margins, echogenicity, posterior acoustic features, and the presence of axillary lymphadenopathy. Based on standard radiological criteria, lesions were categorized as benign or suspicious/malignant.

Following ultrasonographic evaluation, FNAC was performed under aseptic precautions using a sterile disposable needle and syringe. The aspirated material was smeared onto clean glass slides, fixed, and stained using standard cytological stains, including Hematoxylin and Eosin (H&E) and May–Grünwald–Giemsa (MGG). The cytological smears were examined by experienced pathologists and categorized as benign, suspicious, or malignant.

The final diagnosis was confirmed by histopathological examination (HPE) of the biopsy or surgical specimen, which served as the gold standard. The findings of ultrasonography and FNAC were compared with histopathological results to assess their diagnostic accuracy in detecting malignant breast lesions. Relevant clinical, radiological, cytological, and histopathological data were recorded in a structured proforma and entered for statistical analysis.

Statistical Analysis- Data collected were entered into Microsoft Excel and analyzed using SPSS software version 21. Descriptive statistics such as frequencies and percentages were used to represent categorical variables. Quantitative variables were expressed as mean and standard deviation. Data were presented using tables, charts, and graphs. Appropriate statistical tests were applied to compare the diagnostic accuracy of ultrasonography and fine needle aspiration cytology in detecting malignant breast lesions. Sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy were calculated wherever applicable.

RESULTS

We evaluated a total of 50 cases of Breast lesions reporting to our hospital. In the present study, the majority of patients belonged to the 36–45 years age group (24%), followed by the 26–35 years and 46–55 years age groups (22% each). Patients aged ≥ 56 years accounted for 20%, while the 18–25 years age group constituted the smallest proportion (12%). Breast lumps were almost equally distributed between the right breast (24 cases) and left breast (26 cases), with the upper outer quadrant being the most common site (44%), followed by the upper inner quadrant (22%) and subareolar region (16%). There was no statistically significant association between the side/location of the lump and disease pattern ($p = 0.79$). Regarding lump size, malignant lesions were significantly associated with larger tumor size, with most malignant lumps measuring 3–4 cm (24%) and >4 cm (22%), whereas benign lesions were more common in smaller-sized lumps. This association between lump size and pathology was statistically significant ($p = 0.029$) (Table 1).

Table 1: Sociodemographic profile of the cases

Age	Age in year	Number of patients			
Age Groups	18-25 year	6 (12%)			
	26-35 year	11 (22%)			
	36-45 year	12 (24%)			
	46-55 year	11 (22%)			
	≥ 56 year	10 (20%)			
Side and Location of Lump	Quadrant	Number of breast lump			p-value
		Right	Left	Total	
	Upper-outer	10	12	22	0.79, NS
	Lower-outer	4	2	6	

	Sub areolar	3	5	8	
	Upper-inner	6	5	11	
	Lower-inner	1	2	3	
	Total	24	26	50	
Size of Lump	Max dimension in cm	Number of breast lump			p-value
		Benign	Malignant	Total	*0.029, S
	≤1cm	2	0	2	
	1-2cm	5	2	7	
	2-3cm	5	7	12	
	3-4cm	4	12	16	
	>4cm	2	11	13	

* $p < 0.05$, Significant

In the present study, fibroadenoma was the most common histopathological diagnosis, accounting for 25 (50%) cases, and was predominantly observed in patients aged ≤45 years (20 cases). Invasive ductal carcinoma was the most frequent malignant lesion, comprising 16 (32%) cases, with the majority occurring in patients aged >45 years (10 cases). Other benign lesions included adenosis

(6%), ductal hyperplasia (4%), and papilloma (4%), while diffuse large cell non-Hodgkin lymphoma and ductal carcinoma in situ were each identified in 1 (2%) case. Overall, benign breast lesions were more common in younger women (≤45 years), whereas malignant lesions were relatively more frequent in patients older than 45 years (Table 2).

Table 2: Histopathological findings of the specimens

HPE Result	≤45 years	>45 years	Total
Fibroadenoma	20	5	25
Adenosis	1	2	3
Ductal hyperplasia	1	1	2
Papilloma	1	1	2
Lymphoma (Diffuse large cell Non-Hodgkin Lymphoma)	0	1	1
Ductal carcinoma in situ	0	1	1
Invasive ductal carcinoma	6	10	16
Total	29	21	50

In the present study, histopathological examination confirmed 17 (34%) malignant and 33 (66%) benign breast lesions. FNAC diagnosed 16 cases as malignant, all of which were confirmed malignant on histopathology, with no false-positive results. Among the 34 cases reported as benign on FNAC, 33 were confirmed benign,

while one case was found to be malignant on histopathology, representing a false-negative result. These findings demonstrate a high level of agreement between FNAC and histopathological examination in the diagnosis of breast lesions (Table 3).

Table 3: Comparison of FNAC and Histopath findings

FNAC Result	Malignant (HPE)	Benign (HPE)	Total
Malignant on FNAC	16	0	16
Benign on FNAC	1	33	34
Total	17	33	50

In the present study, USG identified 17 cases as malignant, all of which were confirmed as malignant on histopathological examination, with no false-positive results. Among the 33 cases reported as benign on USG, 32 were confirmed benign, while one case was malignant on histopathology, representing a false-negative result. In patients aged ≤ 45 years, USG correctly identified all 6 malignant and 23 benign lesions, demonstrating

complete agreement with histopathology. In patients aged >45 years, USG diagnosed 11 malignant lesions, all confirmed on histopathology, while one malignant lesion was misclassified as benign. Overall, USG showed excellent concordance with histopathological findings across both age groups, with slightly better diagnostic performance in patients aged ≤ 45 years (Table 4).

Table 4: Comparison of Histopathology and USG findings

USG Result	Age Group	Malignant (HPE)	Benign (HPE)	Total
In all 50 cases	Malignant	17	0	17
	Benign	1	32	33
	Total	18	32	50
≤ 45 years	Malignant	6	0	6
	Benign	0	23	23
	Total	6	23	29
>45 years	Malignant	11	0	11
	Benign	1	9	10
	Total	12	9	21

In the present study, USG demonstrated high diagnostic accuracy in differentiating benign from malignant breast lesions when compared with histopathological examination. The sensitivity of USG was 94.44%, indicating its high ability to correctly identify malignant lesions, while the specificity was 100%, showing that all benign lesions were accurately diagnosed without any false-positive results. The positive predictive value (PPV)

was 100%, indicating that every lesion reported as malignant on USG was confirmed as malignant on histopathology. The negative predictive value (NPV) was 96.97%, reflecting a high probability that lesions diagnosed as benign on USG were truly benign. The overall diagnostic accuracy of USG was 98.00%, demonstrating excellent agreement with histopathological findings (Table 5).

Table 5: Diagnostic parameters of USG as compared to Histopathology

Diagnostic Parameter	Value (%)
Sensitivity	94.44
Specificity	100
Positive Predictive Value (PPV)	100
Negative Predictive Value (NPV)	96.97
Diagnostic Accuracy	98

DISCUSSION

The evaluation of breast lesions requires a multidisciplinary approach combining clinical examination, imaging, cytology, and histopathological confirmation. Histopathology remains the gold standard for diagnosis, while USG and FNAC serve as important preoperative diagnostic tools. Early and accurate differentiation between benign and malignant breast lesions is essential for selecting appropriate treatment

strategies and avoiding unnecessary surgical procedures. The present study assessed the clinicopathological profile of breast lesions and evaluated the diagnostic performance of USG and FNAC in comparison with histopathological findings. Similar studies by Takhellambam *et al.* ^[13], Mandal *et al.* ^[14], Kanumuri *et al.* ^[15], and Schmidt *et al.* ^[16] have also emphasized the complementary role of imaging and cytological evaluation in the diagnosis of breast lesions.

In the present study, the highest proportion of patients belonged to the 36–45 years age group (24%), followed by the 26–35 years and 46–55 years age groups (22% each). Patients aged ≥ 56 years constituted 20% of the study population, while only 12% were aged 18–25 years. Similarly, Kanumuri *et al.* reported that the majority of patients with palpable breast masses were in the 30–39-year age group, whereas Mandal *et al.* [14] observed that malignant lesions were predominantly encountered in the 51–60-year age group. These findings suggest that benign breast lesions are more frequently encountered in younger women, whereas the incidence of malignancy increases with advancing age.

The breast lumps in our study were almost equally distributed between the right breast (48%) and the left breast (52%), and the upper outer quadrant was the most common site (44%), followed by the upper inner quadrant (22%). No significant association was observed between the side or location of the lump and pathological diagnosis ($p=0.79$). Kanumuri *et al.* [15] similarly reported right-sided lesions in 22 patients and left-sided lesions in 26 patients among 50 cases, demonstrating a comparable distribution between the two breasts. The predominance of lesions in the upper outer quadrant is consistent with the larger volume of glandular tissue present in this region and has been reported consistently in previous literature.

Tumor size showed a statistically significant association with histopathological diagnosis in our study ($p=0.029$). Most malignant lesions measured 3–4 cm (24%) or >4 cm (22%), whereas benign lesions were more frequently observed in smaller tumors measuring ≤ 3 cm. Larger tumor size is a well-recognized indicator of malignant disease and reflects delayed presentation and disease progression. Similar observations have been reported by Schmidt *et al.* [16], who demonstrated that imaging techniques accurately estimated tumor size and emphasized the importance of lesion size in treatment planning.

Histopathological examination revealed fibroadenoma as the commonest lesion, accounting for 25 (50%) cases, predominantly in women aged ≤ 45 years. Invasive ductal carcinoma constituted 16 (32%) cases and occurred more frequently in women aged >45 years. Other lesions included adenosis (6%), ductal hyperplasia (4%), papilloma (4%), ductal carcinoma in situ (2%), and diffuse large cell non-Hodgkin lymphoma (2%). Mandal *et al.*

similarly reported benign lesions in 76.88% of patients and malignant lesions in 23.11%, with invasive ductal carcinoma accounting for 91.83% of all malignant tumors. Takhellambam *et al.* [13] also found fibroadenoma to be the commonest benign lesion and invasive ductal carcinoma to be the predominant malignant lesion. These findings reaffirm that fibroadenoma is the most frequent benign breast lesion, whereas invasive ductal carcinoma remains the most common breast malignancy. The present study demonstrated excellent agreement between FNAC and histopathological examination. Histopathology confirmed 17 malignant and 33 benign lesions. FNAC correctly diagnosed 16 of the 17 malignant lesions with no false-positive cases and only one false-negative diagnosis. Takhellambam *et al.* [13] similarly reported that FNAC showed excellent specificity, with malignant cytological findings being highly reliable for guiding clinical management. They emphasized that indeterminate cytology should prompt tissue biopsy rather than be considered a diagnostic error. These findings support the role of FNAC as an accurate, minimally invasive, and cost-effective diagnostic modality for the evaluation of palpable breast lumps.

Ultrasonography also demonstrated excellent diagnostic performance in our study. USG correctly identified 17 malignant lesions without any false-positive diagnosis, while only one malignant lesion was missed. Among patients aged ≤ 45 years, USG achieved complete agreement with histopathology, correctly identifying all six malignant lesions. In patients aged >45 years, only one malignant lesion was misclassified as benign. Takhellambam *et al.* [13] reported comparable findings and concluded that USG and FNAC should be regarded as complementary diagnostic techniques, particularly because imaging characteristics vary with patient age and breast density. Schmidt *et al.* also reported that breast sonography could evaluate 99.5% of tumors following neoadjuvant chemotherapy, highlighting its excellent applicability in breast imaging.

The diagnostic parameters observed in the present study further validate the usefulness of ultrasonography. USG demonstrated a sensitivity of 94.44%, specificity of 100%, positive predictive value of 100%, negative predictive value of 96.97%, and overall diagnostic accuracy of 98%. These values compare favorably with those reported by Mandal *et al.*, who observed a sensitivity of 85.71%, specificity of 90.18%, positive

predictive value of 72.41%, and negative predictive value of 95.45% for high-resolution ultrasonography. Similarly, Takhellambam *et al.* [13] reported a specificity of 100% for USG in diagnosing malignant breast lesions, while Kanumuri *et al.* [15] demonstrated that combining ultrasonography with mammography improved sensitivity to 95.7% and positive predictive value to 100%. The comparatively higher diagnostic accuracy observed in the present study may be attributed to careful patient selection, improved imaging quality, and correlation with histopathological findings.

Overall, the findings of the present study are in agreement with previously published literature, confirming that ultrasonography and FNAC are highly reliable preoperative diagnostic modalities for evaluating breast lesions. Although histopathological examination remains the definitive diagnostic method, the combined use of clinical examination, USG, and FNAC can accurately differentiate benign from malignant lesions, facilitate early diagnosis, reduce unnecessary biopsies, and improve patient management.

CONCLUSIONS

The present study highlights that the majority of breast lesions are benign, with fibroadenoma being the most common diagnosis, while invasive ductal carcinoma remains the predominant malignant lesion, particularly among women above 45 years of age. Larger breast lumps were found to have a greater likelihood of malignancy, emphasizing the importance of early clinical evaluation and prompt investigation. Ultrasonography demonstrated excellent diagnostic performance, with an overall accuracy of 98%, making it a highly dependable imaging modality for the initial assessment of breast lesions. Fine needle aspiration cytology also showed a strong correlation with histopathological findings and proved to be an effective, minimally invasive diagnostic tool. The findings support the combined use of clinical examination, ultrasonography, and FNAC for the evaluation of palpable breast lumps, while histopathology continues to remain the definitive method for diagnosis. An integrated diagnostic approach can facilitate early detection, guide appropriate treatment, reduce unnecessary surgical procedures, and ultimately improve patient outcomes.

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