

Original Research Article

DIAGNOSTIC ACCURACY OF FINE-NEEDLE ASPIRATION CYTOLOGY IN PALPABLE BREAST LESIONS: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Palpable breast lesions include a broad spectrum of benign and malignant conditions. Fine-needle aspiration cytology is a rapid, minimally invasive, and cost-effective diagnostic technique used for initial evaluation of breast lumps. This study evaluated the diagnostic accuracy of fine-needle aspiration cytology in palpable breast lesions using histopathological examination as the reference standard.

Materials and Methods: This prospective observational study was conducted in the Departments of General Surgery and Pathology at Rama Medical College Hospital and Research Centre, Hapur, Uttar Pradesh, from March 2024 to December 2025. Sixty female patients with clinically palpable breast lumps were included. Fine-needle aspiration cytology was performed in all cases, followed by histopathological examination of the same lesion after biopsy or surgical excision. Sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy were calculated.

Results: The age of patients ranged from 18 to 70 years, with 36 patients (60.0%) in the 31–50-year age group. The most common presentation was breast lump only, observed in 48 patients (80.0%). Fine-needle aspiration cytology categorized 35 lesions (58.3%) as benign, 3 (5.0%) as suspicious/atypical, and 22 (36.7%) as malignant. Histopathology diagnosed 34 lesions (56.7%) as benign and 26 (43.3%) as malignant. Diagnostic outcome analysis showed 22 true-positive, 33 true-negative, 4 false-negative, and 1 false-positive result. Fine-needle aspiration cytology showed a sensitivity of 84.6%, specificity of 97.1%, positive predictive value of 95.6%, negative predictive value of 89.18%, and overall diagnostic accuracy of 91.6%.

Conclusion: Fine-needle aspiration cytology showed high diagnostic accuracy for the evaluation of palpable breast lesions. It is useful as a first-line diagnostic modality for distinguishing benign from malignant breast lesions; however, suspicious, atypical, false-negative, and clinically discordant cases require histopathological confirmation.

Keywords: Fine-needle aspiration cytology; FNAC; Breast lump; Breast lesions; Histopathology; Diagnostic accuracy.

INTRODUCTION

Breast disease includes a wide range of benign and malignant lesions, including fibroadenoma, fibrocystic change, mastitis, ductal carcinoma, and lobular carcinoma.^[1] Palpable breast lumps are among the most common presentations in surgical

outpatient practice and require accurate evaluation to differentiate benign conditions from malignancy.

Breast cancer remains one of the leading malignancies affecting women worldwide, with substantial morbidity and mortality.^[2,3] In India, breast cancer has emerged as a major public health concern, with patients often presenting at a relatively younger age compared with Western populations.^[4,5]

Early and accurate diagnosis is therefore essential for timely treatment planning, avoidance of unnecessary surgery in benign disease, and prompt management of malignant lesions.

Fine-needle aspiration cytology is widely used for initial assessment of palpable breast lesions because it is simple, rapid, minimally invasive, cost-effective, and suitable for outpatient practice.^[6,7] It provides cytological information that helps classify lesions as benign, atypical, suspicious, or malignant. However, fine-needle aspiration cytology has limitations because it does not assess tissue architecture and may yield false-negative results in low-cellularity, fibrotic, or atypical lesions.^[8]

The International Academy of Cytology Yokohama System has improved standardization of breast fine-needle aspiration cytology reporting by categorizing cytological findings into defined diagnostic categories with associated risk of malignancy.^[9] Despite these advances, histopathological examination remains the reference standard for definitive diagnosis. This study aimed to evaluate the diagnostic accuracy of fine-needle aspiration cytology in palpable breast lesions by correlating cytological findings with histopathological examination.

MATERIALS AND METHODS

Study design and setting: This was a prospective observational study conducted in the Departments of General Surgery and Pathology at Rama Medical College Hospital and Research Centre, Hapur, Uttar Pradesh, India. Female patients presenting with clinically palpable breast lumps were evaluated clinically and investigated by fine-needle aspiration cytology followed by histopathological examination of the same lesion.

Study duration: The study was conducted from March 2024 to December 2025 over a duration of 22 months.

Participants: The study population included female patients presenting to outpatient or inpatient services with clinically palpable breast lumps. All enrolled patients underwent clinical evaluation, fine-needle aspiration cytology, and subsequent histopathological examination after biopsy or surgical excision.

Inclusion criteria

Patients of any age presenting with a clinically palpable breast lump were included. Patients were eligible if fine-needle aspiration cytology and histopathological examination were performed on the same lesion. Written informed consent was obtained from participants before enrollment.

Exclusion criteria

Patients with incomplete clinical, cytological, or histopathological records were excluded. Inadequate or unsatisfactory fine-needle aspiration cytology samples were excluded. Patients who did not provide

informed consent were excluded. Male patients were excluded.

Sample size: The final sample size was 60 patients. The sample size was calculated using an anticipated sensitivity of 0.95, α value of 0.05, Z value of 1.96 for 95% confidence level, and allowable error of 5.5%.

Sampling method: Consecutive sampling was used. Eligible patients presenting during the study period were enrolled sequentially until the required sample size was achieved.

Data collection and variables: Data were collected regarding age, presenting symptoms, duration of symptoms, side of breast involvement, fine-needle aspiration cytology diagnosis, Yokohama category, histopathological diagnosis, and diagnostic outcome classification. Fine-needle aspiration cytology was performed under aseptic precautions using a 22–25 gauge needle with a 10 mL syringe. Aspirated material was spread on glass slides and stained using May-Grünwald Giemsa, haematoxylin and eosin, and Papanicolaou stains. Cytological smears were classified using standard cytological criteria and Yokohama categories. Histopathological examination was performed on excision biopsy, lumpectomy, or mastectomy specimens fixed in 10% formalin and processed using routine haematoxylin and eosin staining.

Outcome measures: The primary outcome measure was diagnostic accuracy of fine-needle aspiration cytology in comparison with histopathological examination. Diagnostic indices included sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. Secondary outcome measures included distribution of age, symptoms, duration of symptoms, laterality, cytological categories, Yokohama categories, and histopathological diagnoses.

Statistical analysis: Data were entered into Microsoft Excel and analyzed using SPSS version 22. Descriptive statistics were used to present frequencies and percentages. Diagnostic performance parameters, including sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy, were calculated using histopathological examination as the reference standard.

Ethical considerations: The study was conducted after approval from the Institutional Ethics Committee of Rama Medical College Hospital and Research Centre, Hapur, Uttar Pradesh. Written informed consent was obtained from all participants. Patient confidentiality was maintained throughout the study.

RESULTS

Demographic and clinical profile: A total of 60 female patients with clinically palpable breast lumps were included. The age range was 18–70 years. The largest proportion of patients belonged to the 31–40

years and 41–50 years age groups, with 18 patients (30.0%) in each group. Overall, 36 patients (60.0%) were in the 31–50-year age group. Left-sided breast

involvement was observed in 34 patients (56.7%), while right-sided involvement was observed in 26 patients (43.3%).

Table 1: Baseline demographic and clinical characteristics of the study population

Characteristic	Category	Number of patients	Percentage (%)
Age group	<20 years	4	6.7
	21–30 years	10	16.6
	31–40 years	18	30.0
	41–50 years	18	30.0
	>50 years	10	16.6
Sex	Female	60	100.0
Side of breast involved	Left	34	56.7
	Right	26	43.3

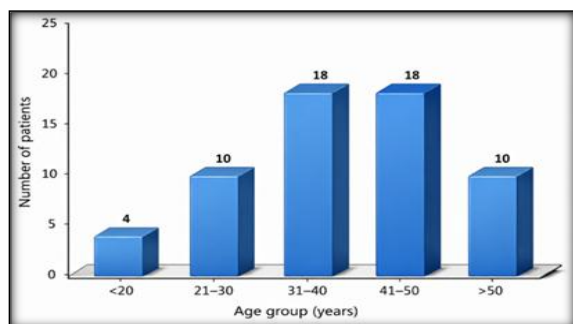


Figure 1: Age distribution of patients with palpable breast lumps

The most common clinical presentation was breast lump only, seen in 48 patients (80.0%). Lump with pain was present in 6 patients (10.0%), lump with nipple discharge in 4 patients (6.7%), and lump with

nipple retraction in 2 patients (3.3%). The most frequent symptom duration was 7–12 months, observed in 18 patients (30.0%), followed by more than 12 months in 16 patients (26.7%).

Cytological and histopathological findings: Fine-needle aspiration cytology categorized 35 lesions (58.3%) as benign, 3 lesions (5.0%) as suspicious/atypical, and 22 lesions (36.7%) as malignant. Using the Yokohama system, 35 cases (58.3%) were Category 2, 3 cases (5.0%) were Category 3, and 22 cases (36.7%) were Category 5. No cases were categorized as insufficient/inadequate or suspicious for malignancy. Histopathological examination diagnosed 34 lesions (56.7%) as benign and 26 lesions (43.3%) as malignant. Fibroadenoma was the most common benign lesion, while invasive ductal carcinoma was the predominant malignant lesion.

Table 2: Clinical presentation and duration of symptoms among study participants

Variable	Category	Number of patients	Percentage (%)
Clinical presentation	Breast lump only	48	80.0
	Lump with pain	6	10.0
	Lump with nipple discharge	4	6.7
	Lump with nipple retraction	2	3.3
Duration of symptoms	≤3 months	12	20.0
	4–6 months	14	23.3
	7–12 months	18	30.0
	>12 months	16	26.7

Table 3. Cytological and histopathological categorization of breast lesions

Assessment	Category	Number of cases	Percentage (%)
Fine-needle aspiration cytology	Benign	35	58.3
	Suspicious/Atypical	3	5.0
	Malignant	22	36.7
Yokohama category	Category 1: Insufficient/Inadequate	0	0.0
	Category 2: Benign	35	58.3
	Category 3: Atypical	3	5.0
	Category 4: Suspicious for malignancy	0	0.0
	Category 5: Malignant	22	36.7
Histopathological examination	Benign lesions	34	56.7
	Malignant lesions	26	43.3

FNAC and histopathological outcome correlation

For diagnostic accuracy analysis, FNAC outcomes were evaluated against histopathological examination using a binary diagnostic outcome table.

Histopathological examination identified 34 benign and 26 malignant lesions. FNAC outcome analysis showed 33 true-negative, 22 true-positive, 4 false-negative, and 1 false-positive result.

Table 4: Binary diagnostic outcome correlation of fine-needle aspiration cytology with histopathological examination

FNAC outcome	Benign on HPE	Malignant on HPE	Total
Negative/benign outcome	33	4	37
Positive/malignant outcome	1	22	23
Total	34	26	60

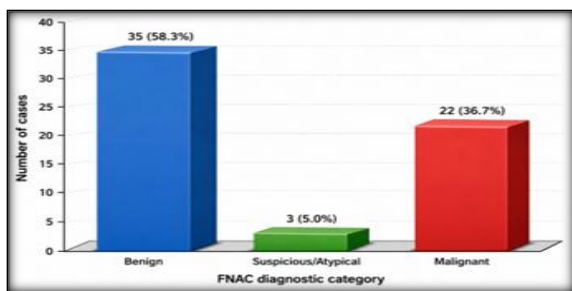


Figure 2: Distribution of fine-needle aspiration cytology diagnostic categories

Table 5: Diagnostic performance of fine-needle aspiration cytology

Diagnostic parameter	Value
Sensitivity	84.6%
Specificity	97.1%
Positive predictive value	95.6%
Negative predictive value	89.18%
Overall diagnostic accuracy	91.6%

DISCUSSION

This prospective observational study evaluated the diagnostic accuracy of fine-needle aspiration cytology in 60 female patients with palpable breast lesions. Fine-needle aspiration cytology showed a sensitivity of 84.6%, specificity of 97.1%, positive predictive value of 95.6%, negative predictive value of 89.18%, and overall diagnostic accuracy of 91.6%. These findings support its role as a useful first-line diagnostic modality for palpable breast lesions.

Most patients were aged 31–50 years, and the most common presentation was breast lump only. Benign lesions formed the largest cytological category, while histopathology confirmed benign disease in 56.7% and malignant disease in 43.3% of cases. Fibroadenoma was the most common benign diagnosis, and invasive ductal carcinoma was the predominant malignant diagnosis.

The diagnostic performance observed in this study is comparable to published evidence on fine-needle aspiration cytology in breast lesions. A meta-analysis by Yu et al. reported substantial diagnostic value of fine-needle aspiration biopsy for breast masses.^[10] Rubin et al. reported that fine-needle aspiration for solid breast lesions was accurate and cost-effective, supporting its role in early diagnostic triage.^[11] Ishikawa et al. highlighted the value of combined clinical, imaging, and cytological assessment in palpable breast masses.^[12]

Indian studies have similarly reported the usefulness of fine-needle aspiration cytology as a rapid and reliable diagnostic method for breast lesions. Jan et al. reported its role in institutional breast lesion evaluation, while Verma et al. reported high diagnostic accuracy when cytological findings were correlated with histopathology.^[13,14] These findings are consistent with previous reports, particularly regarding high specificity and overall diagnostic accuracy.

The high specificity and positive predictive value observed in this study indicate that malignant

Diagnostic performance of fine-needle aspiration cytology: Diagnostic performance was calculated using histopathological examination as the reference standard. Fine-needle aspiration cytology showed 22 true-positive results (36.7%), 33 true-negative results (55.0%), 4 false-negative results (6.7%), and 1 false-positive result (1.6%). The sensitivity was 84.6%, specificity was 97.1%, positive predictive value was 95.6%, negative predictive value was 89.18%, and overall diagnostic accuracy was 91.6%.

cytology was strongly associated with histopathological malignancy. This supports its clinical utility in early diagnostic triage of patients with malignant cytology. The negative predictive value of 89.18% indicates that benign cytology provides useful diagnostic reassurance, although it should be interpreted along with clinical and imaging findings.

False-negative results were observed in 4 cases (6.7%). False-negative cytology is a recognized limitation of fine-needle aspiration cytology and may occur due to low cellularity, sampling error, fibrotic lesions, or cytologically subtle malignancies.^[15] Suspicious, atypical, and clinically discordant cytology results require histopathological confirmation to reduce the risk of missed malignancy.

Strengths and limitations: The strengths of this study include its prospective design, inclusion of histopathological examination as the reference standard, and evaluation of key diagnostic indices including sensitivity, specificity, predictive values, and overall accuracy. The study also used standardized cytological categorization through Yokohama categories.

The limitations include a sample size of 60 patients and single-institution design. Fine-needle aspiration cytology does not assess tissue architecture and cannot reliably differentiate in situ from invasive carcinoma. Receptor status assessment, including estrogen receptor, progesterone receptor, and HER2/neu evaluation, was not included. Long-term follow-up outcomes were not assessed.

CONCLUSION

Fine-needle aspiration cytology is a rapid, safe, minimally invasive, and accurate diagnostic modality for evaluating palpable breast lesions. In this study, it showed high specificity, positive predictive value, and overall diagnostic accuracy when compared with histopathological examination. It is useful as a first-

line diagnostic tool for breast lumps; however, suspicious, atypical, false-negative, false-positive, and clinically discordant cases require histopathological confirmation.

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