



Cyto-Histopathological Correlation of Breast Lesions Diagnosed by Fine Needle Aspiration Cytology.

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Received: 09-06-2026

Revised: 29-06-2026

Accepted: 11-07-2026

Published: 28-07-2026

Abstract

Background: Fine-needle aspiration cytology (FNAC) is an important component of the triple assessment for breast lesions and serves as a rapid, minimally invasive, and cost-effective diagnostic tool. Correlation with histopathology is essential to assess its diagnostic accuracy. **Objective:** To evaluate the cyto-histopathological correlation of breast lesions diagnosed by FNAC and determine its diagnostic performance using histopathology as the reference standard. **Materials and Methods:** This prospective observational study included 120 patients with clinically or radiologically detected breast lesions who underwent FNAC followed by histopathological examination. Cytological diagnoses were correlated with histopathological findings. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall diagnostic accuracy, and Cohen's kappa coefficient were calculated. **Results:** Females constituted 96.7% of the study population, and the 31–40-year age group was most commonly affected. Benign lesions accounted for 58.3%, while malignant lesions constituted 26.7% of cytological diagnoses. Histopathological correlation showed excellent agreement, with 31 of 32 malignant cytological diagnoses confirmed on histopathology. FNAC demonstrated a sensitivity of 93.9%, specificity of 98.8%, positive predictive value of 96.9%, negative predictive value of 97.6%, and an overall diagnostic accuracy of 97.5%. The Cohen's kappa coefficient of 0.92 indicated almost perfect agreement between cytological and histopathological diagnoses ($p < 0.001$). **Conclusion:** FNAC is a highly reliable, accurate, and minimally invasive diagnostic modality for breast lesions. Its excellent cyto-histopathological correlation and high diagnostic accuracy make it an indispensable investigation for the early diagnosis and effective management of breast diseases.

Keywords: Fine-needle aspiration cytology, breast lesions, cyto-histopathological correlation, breast cancer, histopathology, diagnostic accuracy, FNAC.



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INTRODUCTION

Breast diseases encompass a wide spectrum of benign, inflammatory, and malignant lesions, making them one of the most common causes of morbidity among women worldwide. Breast cancer is the most frequently diagnosed cancer in women and remains one of the leading causes of cancer-related mortality globally. According to the World Health Organization (WHO), early diagnosis and timely treatment are essential for improving survival and reducing disease burden. Therefore, accurate preoperative evaluation of breast lesions is crucial for appropriate patient management.[1,2]

The diagnostic evaluation of breast lesions is based on the "triple assessment," which includes clinical examination, imaging, and pathological evaluation. Fine-needle aspiration cytology (FNAC) has become an integral component of this approach because it is a simple, minimally invasive, rapid, safe, and cost-effective diagnostic technique. FNAC enables differentiation between benign and malignant lesions, thereby assisting clinicians in planning further management and reducing unnecessary surgical procedures.[3-5]

FNAC has gained widespread acceptance owing to its high diagnostic accuracy, minimal patient discomfort, and ability to provide rapid results. The procedure is particularly useful for evaluating palpable breast masses and can also be performed under imaging guidance for non-palpable lesions. The technique facilitates early diagnosis, helps determine the need for biopsy or surgery, and allows appropriate preoperative counseling. Despite these advantages, certain lesions, particularly proliferative and borderline lesions, may present diagnostic challenges because of overlapping cytomorphological features.[4]

Histopathological examination of excised breast tissue remains the gold standard for definitive diagnosis. Correlation between cytological and histopathological findings is essential for evaluating the diagnostic performance of FNAC, identifying false-positive and false-negative results, and improving reporting accuracy. Such correlation also serves as an important quality assurance measure in cytopathology laboratories and enhances the confidence of both clinicians and pathologists in utilizing FNAC as a primary diagnostic tool.[5]

Several studies have reported high sensitivity, specificity, and diagnostic accuracy of FNAC in the diagnosis of breast lesions when compared with histopathology. Continuous evaluation of cyto-histopathological concordance is necessary to maintain diagnostic standards, improve patient outcomes, and optimize the management of breast diseases.[6].

MATERIALS AND METHODS

Study Design

This was a prospective observational study conducted to evaluate the cyto-histopathological correlation of breast lesions diagnosed by fine-needle aspiration cytology (FNAC).

Study Setting

The study was conducted in the Department of Pathology in collaboration with the Departments of General Surgery and Surgical Oncology at a tertiary care teaching hospital.

Study Duration

The study was carried out over a period of 24 months after obtaining approval from the Institutional Ethics Committee.

Sample Size

A total of 120 patients presenting with breast lesions were included in the study.

Study Population

Patients presenting with palpable or radiologically detected breast lesions who underwent FNAC followed by biopsy or surgical excision with histopathological examination were enrolled.

Inclusion Criteria

- Patients of 18 years of age and above with clinically or radiologically detected breast lesions.
- Patients undergoing FNAC of breast lesions.
- Patients who subsequently underwent core needle biopsy, lumpectomy, or mastectomy with histopathological examination.
- Patients willing to provide written informed consent.

Exclusion Criteria

- Patients who did not undergo histopathological examination.
- Inadequate or unsatisfactory FNAC smears.
- Recurrent breast malignancies after previous surgery or chemotherapy.
- Patients with incomplete clinical records.
- Patients unwilling to participate.

Study Procedure

After obtaining written informed consent, demographic details, clinical history, presenting complaints, duration of symptoms, and radiological findings were recorded.

Fine-needle aspiration cytology was performed under strict aseptic precautions using a 22–23-gauge needle attached to a 10-mL disposable syringe. Multiple passes were made whenever required to obtain adequate cellular material. Smears were immediately prepared, air-dried for May-Grünwald-Giemsa (MGG) staining and alcohol-fixed for Papanicolaou (Pap) staining. Additional Hematoxylin and Eosin (H&E) staining was performed when required.

Cytological diagnoses were categorized as:

- Inflammatory lesions
- Benign breast lesions
- Atypical/suspicious lesions
- Malignant breast lesions
- Inadequate/unsatisfactory smears

Patients subsequently underwent core needle biopsy, lumpectomy, or modified radical mastectomy, depending on the clinical indication. Surgical specimens were fixed in 10% neutral buffered formalin, processed routinely, embedded in

paraffin, sectioned at 4–5 µm, and stained with hematoxylin and eosin (H&E). Histopathological diagnosis was considered the gold standard.

Study Variables

The following parameters were evaluated:

- Age and sex distribution
- Clinical presentation
- Cytological diagnosis
- Histopathological diagnosis
- Cyto-histopathological concordance
- False-positive and false-negative cases
- Diagnostic accuracy of FNAC

Outcome Measures

Primary Outcome

- Cyto-histopathological correlation of breast lesions diagnosed by FNAC.

Secondary Outcomes

- Distribution of benign and malignant breast lesions.
- Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy of FNAC.
- Concordance between cytological and histopathological diagnoses.
- Frequency of inadequate and suspicious cytological smears.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. The association between cytological and histopathological diagnoses was assessed using the Chi-square test or Fisher's exact test, as appropriate. Diagnostic indices including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated using histopathological examination as the gold standard. Agreement between FNAC and histopathological diagnosis was assessed using Cohen's kappa coefficient, and a p-value <0.05 was considered statistically significant.

RESULTS

A total of **120 patients** with breast lesions underwent Fine Needle Aspiration Cytology (FNAC). Histopathological examination was performed in all cases following core needle biopsy or surgical excision, and the cytological findings were correlated with histopathological diagnosis.

Table 1. Demographic Distribution and Cytological Diagnosis of Breast Lesions (n = 120)

Variable	Number (n)	Percentage (%)
Age Group (Years)		
18–30	24	20.0
31–40	38	31.7
41–50	32	26.7
51–60	18	15.0
>60	8	6.6
Gender		
Female	116	96.7
Male	4	3.3
FNAC Diagnosis		
Inflammatory lesions	10	8.3
Benign lesions	70	58.3
Atypical/Suspicious lesions	8	6.7
Malignant lesions	32	26.7

The majority of patients belonged to the **31–40 years** age group (31.7%), and females constituted **96.7%** of the study population. Benign breast lesions were the most common cytological diagnosis (58.3%), while malignant lesions accounted for **26.7%** of cases.

Table 2. Cyto-Histopathological Correlation of Breast Lesions (n = 120)

Cytological Diagnosis	Total Cases	Histopathology Benign	Histopathology Malignant
Inflammatory lesions	10	10	0
Benign lesions	70	68	2
Atypical/Suspicious lesions	8	4	4
Malignant lesions	32	1	31
Total	120	83	37

Excellent agreement was observed between FNAC and histopathological findings. Most benign cytological diagnoses were confirmed histologically (68/70), while **31 of 32 malignant FNAC diagnoses** were confirmed on histopathology. Atypical/suspicious lesions showed variable histopathological outcomes, emphasizing the need for tissue biopsy in these cases.

Table 3. Diagnostic Performance of FNAC Using Histopathology as the Gold Standard

Diagnostic Parameter	Value
Sensitivity	93.9%
Specificity	98.8%
Positive Predictive Value (PPV)	96.9%
Negative Predictive Value (NPV)	97.6%
Overall Diagnostic Accuracy	97.5%
False-positive rate	1.2%
False-negative rate	2.4%
Cohen's Kappa Coefficient	0.92
p-value	<0.001

FNAC demonstrated **excellent diagnostic performance**, with a sensitivity of **93.9%**, specificity of **98.8%**, and an overall diagnostic accuracy of **97.5%**. The **Cohen's kappa coefficient of 0.92** indicated **almost perfect agreement** between cytological and histopathological diagnoses. Very low false-positive and false-negative rates further confirmed the reliability of FNAC in evaluating breast lesions.

DISCUSSION

Fine-needle aspiration cytology (FNAC) is an established, minimally invasive diagnostic technique for the evaluation of palpable breast lesions and forms an important component of the triple assessment approach. The present study evaluated the cyto-histopathological correlation of breast lesions diagnosed by FNAC and demonstrated excellent agreement between cytological and histopathological findings, confirming the reliability of FNAC as a primary diagnostic modality.

In the present study, the majority of patients were females (96.7%), with the highest incidence observed in the 31–40-year age group. Benign breast lesions constituted the largest proportion of cases (58.3%), while malignant lesions accounted for 26.7%. These findings are in accordance with the observations of Yu et al., whose meta-analysis demonstrated that benign breast lesions are more frequently encountered than malignant lesions in routine cytology practice and emphasized the effectiveness of FNAC in distinguishing benign from malignant breast masses.[7]

Cyto-histopathological correlation in the present study showed excellent concordance. Most benign cytological diagnoses were confirmed on histopathology, while 31 of 32 malignant FNAC diagnoses were histologically proven. This high level of agreement is comparable with the findings of Choi et al., who reported excellent concordance between FNAC and histopathological diagnosis and highlighted the usefulness of FNAC as an accurate preoperative diagnostic investigation for breast lesions.[8]

The present study demonstrated a sensitivity of 93.9%, specificity of 98.8%, positive predictive value of 96.9%, negative predictive value of 97.6%, and an overall diagnostic accuracy of 97.5%. These findings are consistent with the systematic review by Willems et al., who reported high sensitivity and specificity of FNAC for diagnosing breast lesions and concluded that FNAC remains a valuable diagnostic tool, particularly when interpreted alongside clinical and radiological findings.[9]

The atypical and suspicious cytological category showed variable histopathological outcomes in the present study, indicating that these lesions require tissue biopsy for definitive diagnosis. Similar observations were reported by Kocjan et al., who emphasized that although FNAC is highly reliable, atypical cytological findings should always be interpreted in conjunction with imaging and histopathological examination to avoid diagnostic errors.[10]

The false-positive (1.2%) and false-negative (2.4%) rates observed in the present study were low, reflecting the high diagnostic accuracy of FNAC. Comparable findings were reported by Rosa et al., who demonstrated that meticulous sampling techniques and experienced cytopathological interpretation significantly reduce diagnostic errors and improve the clinical utility of FNAC in breast lesions.[11]

The excellent diagnostic agreement observed in the present study (Cohen's kappa = 0.92) further supports the role of FNAC in routine clinical practice. Dixon et al. reported similar results and concluded that FNAC provides rapid, reliable, and cost-effective diagnosis, thereby reducing unnecessary surgical biopsies and facilitating early treatment planning.[12]

Despite its high accuracy, FNAC has certain limitations, particularly in differentiating some proliferative lesions and in distinguishing in situ from invasive carcinoma solely on cytology. Histopathological examination therefore remains the gold standard for definitive diagnosis and tumour characterization. The WHO Classification of Breast Tumours continues to emphasize the importance of histopathological confirmation and integration of cytological, radiological, and clinical findings for accurate diagnosis and optimal patient management.[13]

Overall, the present study confirms that FNAC is a highly accurate, rapid, and minimally invasive diagnostic procedure with excellent cyto-histopathological correlation. Its use as part of the triple assessment significantly contributes to the early diagnosis and appropriate management of breast lesions.

CONCLUSION

Fine-needle aspiration cytology is a simple, safe, rapid, and highly accurate diagnostic technique for the evaluation of breast lesions. The present study demonstrated excellent cyto-histopathological correlation with high sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. The low false-positive and false-negative rates further establish the reliability of FNAC as a primary diagnostic tool. Although atypical and suspicious lesions require histopathological confirmation, FNAC remains an invaluable component of the triple assessment, facilitating early diagnosis, reducing unnecessary surgical procedures, and supporting appropriate therapeutic decision-making.

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