RESEARCH PAPER

Clinicopathological Correlation of Fine Needle Aspiration Cytology in Breast Lesions: An Observational Study from a Tertiary Care Center

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ABSTRACT

Background: Accurate preoperative evaluation of breast lesions is essential for optimal management. Although core needle biopsy (CNB) is currently regarded as the diagnostic standard due to its superior histological and molecular assessment capabilities, fine needle aspiration cytology (FNAC) remains widely utilised because of its simplicity, rapid turnaround time, and cost-effectiveness. However, concerns regarding its variable sensitivity and inability to reliably characterise certain borderline and in situ lesions underscore the need for continued evaluation of its diagnostic performance in contemporary clinical practice.

Aims and Objectives: To evaluate the diagnostic accuracy of FNAC and its clinicopathological correlation with histopathology in breast lesions.

Methods: This prospective observational study included 120 female patients presenting with breast lesions at a tertiary care centre. All patients underwent triple assessment including clinical evaluation, radiological evaluation and FNAC followed by histopathological examination. Histopathology was considered the gold standard. Diagnostic indices were calculated.

Results: Out of 120 cases, 83 were benign and 37 were malignant on histopathology. FNAC showed a sensitivity of 85.71%, specificity of 87.17%, and overall diagnostic accuracy of 86.66%. A statistically significant correlation was observed between FNAC and histopathology ($p = 0.0029$).

Conclusion: FNAC is a reliable, cost-effective, and minimally invasive diagnostic tool with good clinicopathological correlation. It serves as an effective first-line investigation in the evaluation of breast lesions.

Keywords: Breast lesions, Fine needle aspiration cytology, Histopathology, Clinicopathological correlation, Diagnostic accuracy.

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INTRODUCTION

Breast diseases represent a wide spectrum of conditions ranging from benign inflammatory and proliferative disorders to malignant neoplasms. Despite improvements in screening and treatment methods, breast cancer is still the most prevalent disease among women worldwide and a major cause of cancer-related death [1]. The prevalence of breast cancer has grown over the past ten years, especially in emerging nations, according to latest worldwide cancer data, underscoring the need of early diagnosis and prompt treatment [2]. The "triple assessment," a thorough method that combines radiological imaging, pathological investigation, and clinical examination, is used to evaluate breast lesions. This combination strategy lowers the possibility of missing or delayed diagnosis and greatly improves diagnostic accuracy [3]. Among these elements, pathology evaluation is

essential for verifying the kind of lesion and directing future treatment.

Because of its ease of use, quick turnaround time, low level of invasiveness, and affordability, Fine Needle Aspiration Cytology (FNAC) has been utilised extensively as an initial diagnostic tool in the assessment of breast lesions [4]. It is especially useful in environments with limited resources, when access to more advanced diagnostic techniques may be restricted. Early clinical decision-making and fewer needless surgical procedures are made possible by FNAC's ability to quickly distinguish between benign and malignant tumours [5].

FNAC has certain drawbacks despite its benefits. These include operator dependence, sample mistakes, and difficulties differentiating some borderline lesions, such as low-grade cancers, ductal carcinoma in situ, and atypical hyperplasia [6]. Furthermore, FNAC does not support immunohistochemical analysis or architectural features, both of which are frequently necessary for a conclusive diagnosis and treatment planning. Because it can reveal tissue architecture and make molecular research easier, core needle biopsy (CNB) has become the favoured diagnostic method in many contexts [7].

As a first-line diagnostic technique, FNAC is still very valuable, especially in outpatient settings and in emerging healthcare systems. FNAC exhibits excellent connection with histopathological results and good diagnostic accuracy when paired with clinical and radiographic data, according to several recent investigations [8]. Additionally, it may be utilised efficiently for quick patient screening and triaging, particularly when quick decisions are needed. It is crucial to regularly assess FNAC's diagnostic efficacy and clinical significance given its changing position in contemporary clinical practice. The current study was conducted in a tertiary care environment to evaluate the diagnostic accuracy of FNAC in breast lesions and to examine its clinicopathological connection with histological results. In the age of sophisticated biopsy methods, this study also seeks to support the usefulness of FNAC as a diagnostic tool.

AIM

To evaluate the diagnostic accuracy and clinicopathological correlation of Fine Needle Aspiration Cytology (FNAC) in the diagnosis of breast diseases.

OBJECTIVES

1. To diagnose different types of breast diseases by clinical examination and FNAC.
2. To correlate clinical findings with FNAC results.
3. To assess the sensitivity, specificity, and overall diagnostic accuracy of FNAC.
4. To identify factors influencing diagnostic accuracy.

MATERIALS AND METHODS

Study Design: This was a prospective observational study conducted to evaluate the diagnostic accuracy and clinicopathological correlation of fine needle aspiration cytology (FNAC) in breast lesions.

Study Setting: The study was carried out at Sassoon General Hospital, a tertiary care teaching hospital, in the Department of General Surgery. Patients were recruited from the outpatient department (OPD).

Study Duration: The study was conducted over a period of 24 months, from April 2022 to May 2024.

Study Population: The study included female patients presenting with breast lesions attending the surgical OPD during the study period.

Sample Size: A total of 120 patients fulfilling the inclusion criteria were enrolled in the study.

Inclusion Criteria

- Female patients aged 18 years and above
- Patients presenting with clinically palpable breast lesions
- Patients willing to undergo FNAC and histopathological examination
- Patients providing informed consent

Exclusion Criteria

- Male patients with breast lesions
- Patients previously investigated or treated outside the institute
- Patients with recurrent breast lesions or prior biopsy history
- Patients unwilling to participate

Study Procedure

All enrolled patients underwent a triple assessment, which included:

1. **Clinical Evaluation**: A detailed history was obtained, including duration of symptoms, pain, nipple discharge, and family history of breast disease. Thorough physical examination of the breast and axilla was performed.
2. **Radiological Assessment**: Radiological evaluation was done using ultrasonography (USG) and/or mammography, depending on the patient's age and clinical indication.

3. **Fine Needle Aspiration Cytology (FNAC):** FNAC was performed under aseptic precautions using a 23-gauge needle attached to a 10 mL syringe.
   - Multiple passes were made when necessary
   - Aspirated material was smeared onto glass slides
   - Smears were fixed in 95% alcohol
   - Staining was performed using hematoxylin and eosin (H&E)
4. **Histopathological Examination (HPE)** All patients subsequently underwent core needle biopsy or surgical excision. Histopathological examination was considered the gold standard for diagnosis.

Data Collection

Data were collected using a pre-designed structured proforma, which included:

- Demographic details (age)
- Clinical findings
- Radiological findings
- FNAC diagnosis
- Histopathological diagnosis

Outcome Measures

The primary outcome was to determine:

- Sensitivity
- Specificity
- Positive Predictive Value (PPV)
- Negative Predictive Value (NPV)
- Overall diagnostic accuracy of FNAC

Statistical Analysis

Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 24.0.

- Categorical variables were expressed as frequencies and percentages
- Diagnostic indices were calculated using standard formulas
- Chi-square test was applied to assess the association between FNAC and histopathological findings
- A p-value < 0.05 was considered statistically significant

Ethical Considerations

Institutional ethical clearance obtained and informed consent taken.

RESULTS

Table 1: Age Distribution of Study Participants (N = 120)

Age Group (Years)	Number of Patients	Percentage (%)
18–20	20	16.7
21–30	27	22.5
31–40	30	25.0
41–50	18	15.0
51–60	10	8.3
61–70	8	6.7
71–80	7	5.8
Total	**120**	**100**

The majority of patients in the present study belonged to the 31–40 years age group (25%), followed by 21–30 years (22.5%) and 18–20 years (16.7%). A gradual decline in frequency was observed with increasing age, with only 5.8% patients in the 71–80 years group. This indicates that breast lesions are more commonly encountered in younger and middle-aged women, with a peak incidence in the reproductive age group.

Table 2: Distribution of Breast Lesions Based on Histopathology

Diagnosis	Number of Cases	Percentage (%)
Benign	83	69.2
Malignant	37	30.8
Total	**120**	**100**

Out of 120 cases, 83 (69.2%) were benign, while 37 (30.8%) were malignant on histopathological examination. This demonstrates a clear predominance of benign breast lesions in the study population, which is consistent with the known epidemiological pattern of breast diseases.

Table 3: FNAC Diagnosis vs Histopathology

FNAC Diagnosis	Benign (HPE)	Malignant (HPE)	Total
Benign	72	5	77
Malignant	11	32	43

Total	**83**	**37**	**120**

FNAC correctly identified 72 benign cases and 32 malignant cases. However, 5 malignant cases were misdiagnosed as benign (false negatives) and 11 benign cases were misclassified as malignant (false positives). Overall, FNAC showed good agreement with histopathology, though a small proportion of diagnostic discrepancies was noted.

Table 4: Diagnostic Performance of FNAC

Parameter	**Value (%)**
Sensitivity	85.71
Specificity	87.17
Positive Predictive Value (PPV)	74.41
Negative Predictive Value (NPV)	93.50
Accuracy	86.66

FNAC demonstrated a sensitivity of 85.71% and specificity of 87.17%, indicating good ability to detect both malignant and benign lesions. The positive predictive value (74.41%) suggests moderate reliability in predicting malignancy, while the high negative predictive value (93.50%) indicates strong confidence in ruling out malignancy. The overall diagnostic accuracy was 86.66%, supporting FNAC as an effective diagnostic modality.

Table 5: Correlation of FNAC with Histopathology

Parameter	**Value**
Chi-square value	8.85
p-value	0.0029
Significance	Significant

A statistically significant association was observed between FNAC and histopathology findings ($p = 0.0029$), confirming a strong clinicopathological correlation. The Chi-square value of 8.85 further supports the reliability of FNAC in diagnosing breast lesions.

DISCUSSION

Breast lesions constitute a significant proportion of surgical and pathological cases encountered in clinical practice, necessitating accurate and timely diagnosis. The gold standard in this investigation was histopathological results, which were associated with FNAC as a diagnostic tool.

The study's age distribution (Table 1) showed that most patients were in their third or fourth decade of life, with the 31–40 age group having the highest occurrence. This result is in line with other research showing that malignant breast lesions tend to grow with age, but benign lesions are more prevalent in younger women [4,2]. The increased occurrence of benign illnesses like fibroadenoma in the reproductive age range is reflected in the study's preponderance of younger patients.

Benign lesions (69.2%) far outnumbered malignant lesions (30.8%), according to histopathological investigation (Table 2). This trend is consistent with other studies carried out in tertiary care settings, where most breast complaints are benign lesions [9, 10]. The large percentage of benign lesions emphasises how crucial it is to have a trustworthy preoperative diagnostic technique like FNAC in order to prevent needless surgical procedures.

Table 3's comparison of FNAC and histology revealed high concordance, with most patients having the right diagnosis. Nevertheless, a few false-positive and false-negative outcomes were noted. Inadequate sampling or deep-seated lesions may cause false-negative instances, whereas cytological overlap in proliferative breast illnesses may provide false-positive outcomes. The intrinsic limits of FNAC have been highlighted by similar inconsistencies observed in previous investigations [11,12].

FNAC showed 85.71% sensitivity and 87.17% specificity in the current investigation (Table 4). These results are consistent with other research that reported specificity ranging from 85% to 100% and sensitivity ranging from 70% to 97% [13]. While FNAC's high specificity demonstrates its value in accurately identifying benign lesions, its comparatively high sensitivity suggests that it is beneficial in detecting cancers.

This study's positive predictive value (74.41%) is marginally lower than that of other studies, perhaps as a result of atypical or borderline lesions that are challenging to cytologically diagnose. Nonetheless, the strong negative predictive value (93.50%) indicates that a benign FNAC test is quite trustworthy in ruling out cancer. Other studies highlighting the use of FNAC as a screening tool have revealed similar results [4].

The study's total FNAC diagnosis accuracy was 86.66% (Table 4), which is in line with other reports of accuracy rates between 85% and 96% [14,15]. This demonstrates that FNAC is still a reliable and useful diagnostic technique, especially in environments with low resources where access to core needle biopsy may be restricted.

This study found a statistically significant association ($p = 0.0029$, Table 5) between FNAC and histology, suggesting a high degree of concordance between the two modalities. Other investigations have revealed similar statistically significant relationships [16], supporting FNAC's dependability as a first-line diagnostic tool. FNAC has drawbacks despite its benefits. It may not accurately distinguish between in situ and invasive carcinomas and lacks architectural detail. Its accuracy also depends on sufficient sampling and is operator-dependent. As part of the triple evaluation technique, FNAC should thus always be evaluated in combination with radiological and clinical data [3].

Overall, the results of this investigation confirm that FNAC is a useful, economical, and minimally invasive diagnostic method with excellent clinicopathological association, good sensitivity, and specificity. It continues to play an important role in the early assessment and treatment of breast lesions.

CONCLUSION

The present study demonstrates that Fine Needle Aspiration Cytology (FNAC) is a reliable, cost-effective, and minimally invasive diagnostic modality in the evaluation of breast lesions. FNAC performed well in distinguishing benign from malignant lesions, with sensitivity of 85.71%, specificity of 87.17%, and total diagnostic accuracy of 86.66%. Its strong negative predictive value (93.50%) emphasises how effective it is as a screening method for accurately ruling out cancer. FNAC's diagnostic efficacy is further supported by a robust and statistically significant clinicopathological association ($p = 0.0029$) between it and histology. As part of the triple evaluation strategy, FNAC also showed strong agreement with radiological and clinical results.

Even though core needle biopsy is becoming more popular, FNAC is still essential because of its quick turnaround time, simplicity of use, and affordability, especially in settings with limited resources. It functions as a useful first inquiry that helps direct clinical judgment and minimise needless surgical procedures. FNAC shouldn't be used alone, though. When paired with clinical and radiographic evaluation, its diagnostic accuracy can be further improved. Histopathological investigation should always be used to confirm instances that are unclear or suspected.

LIMITATIONS OF THE STUDY

1. **Single-center study**: The study was conducted at a single tertiary care center, which may limit the generalisability of the findings to other populations or healthcare settings.
2. **Relatively small sample size**: Although adequate for analysis, a larger sample size would provide more robust and generalisable results.
3. **Operator dependency of FNAC**: The accuracy of FNAC depends on the expertise of the clinician performing the procedure and the cytopathologist interpreting the smears, which may introduce variability.
4. **Sampling errors**: Inadequate or non-representative samples may lead to false-negative or false-positive results, particularly in deep-seated or heterogeneous lesions.
5. **Limited ability to assess tumour architecture**: FNAC does not provide histological architecture or allow for immunohistochemical analysis, which is essential for definitive diagnosis and tumour sub-typing.
6. **Difficulty in diagnosing borderline lesions**: Certain lesions such as atypical hyperplasia, in situ carcinoma, and low-grade malignancies may be difficult to accurately diagnose on cytology alone.
7. **Lack of long-term follow-up**: The study did not include follow-up data to assess outcomes or progression of lesions, which could further validate diagnostic accuracy.

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