

Diagnostic Accuracy of Fine-Needle Aspiration Cytology in Detectable Breast Lesions: A Retrospective Cyto-histopathological Correlation Study

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Received: 12-04-2026 / Revised: 20-05-2026 / Accepted: 24-06-2026

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Conflict of interest: Nil

Abstract:

Background: Fine-needle aspiration cytology (FNAC) is a rapid, minimally invasive, and cost-effective technique widely used for the preoperative evaluation of palpable breast lesions. Although FNAC demonstrates high diagnostic performance, histopathological examination remains the gold standard for definitive diagnosis. This study evaluated the diagnostic accuracy of FNAC by correlating cytological findings with subsequent histopathological diagnoses in patients with detectable breast lesions.

Aim: To assess the diagnostic accuracy of FNAC in palpable breast lesions through retrospective cyto-histopathological correlation.

Methodology: A retrospective observational study was conducted in the Department of Pathology, Madhubani Medical College & Hospital, Bihar, from January 2025 to December 2025. Ninety-three patients underwent FNAC for clinically detectable breast lumps, of whom 47 with corresponding histopathological reports were included for analysis. Histopathology served as the reference standard. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy of FNAC were calculated.

Results: Most patients belonged to the 21–30 years age group. Fibroadenoma was the most common benign lesion, while invasive ductal carcinoma was the predominant malignant lesion. Cyto-histopathological correlation showed 9 true-positive, 36 true-negative, 1 false-positive, and 1 false-negative case. FNAC demonstrated a sensitivity of 90.0%, specificity of 97.3%, PPV of 90.0%, NPV of 97.3%, and an overall diagnostic accuracy of 95.7%, indicating excellent agreement with histopathological findings.

Conclusion: FNAC is a highly reliable, accurate, and minimally invasive first-line diagnostic modality for the evaluation of palpable breast lesions. Its excellent diagnostic performance supports its routine use in clinical practice, while histopathological confirmation remains essential for suspicious or discordant cases to ensure accurate diagnosis and appropriate patient management.

Keywords: Fine-Needle Aspiration Cytology, FNAC, Breast Lesions, Breast Lump, Histopathology, Cyto-Histopathological Correlation, Diagnostic Accuracy, Fibroadenoma, Breast Carcinoma.

DOI: 10.25258/IJPQA.17.6.68

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Introduction

Breast diseases are a significant public health issue globally, and a variety of benign, inflammatory and malignant breast diseases exist. Breast lumps are one of the most frequently seen clinical presentations in surgery and pathology practice, especially in women of reproductive and postmenopausal age. While most palpable breast lumps are not cancer, it is important to recognize cancer in the earliest stages as prompt diagnosis is important to boost treatment success and survival. Although screening, imaging and therapeutic advances have been made in breast cancer, it is still the most commonly diagnosed cancer among women worldwide and is a primary source of cancer-related death. Breast cancer has emerged as the most prevalent form of cancer in urban areas and is steadily gaining popularity in rural

areas in India, including Bihar, owing to changing lifestyles, longer life expectancy, late marriage, and late pregnancy which have led to better access to healthcare and awareness. Hence, it is crucial to have accurate diagnostic methods with low cost to analyze breast lesions in a resource-limited healthcare system [1].

A breast lump is an abnormal growth or mass of tissue that develops in part of the breast, whether caused by some kind of developmental, inflammatory, benign or malignant process. Palpable breast masses are more likely to be benign in younger women (fibroadenoma, fibrocystic disease, breast abscess and duct ectasia), while in older women the likelihood of malignancy increases. The most com-

mon types of malignant breast lesions are invasive ductal carcinoma, invasive lobular carcinoma and rare histological variants. A systematic diagnostic approach is necessary for an accurate diagnosis and a suitable treatment plan since clinical examination alone is not reliable in distinguishing benign from malignant lesions [2].

Traditionally the breast lesions are assessed using the well-established "triple assessment" or "triple test" which consists of clinical examination, radiological imaging (mammography and/or ultrasonography) and pathological examination (either FNAC or core needle biopsy). If all three components are concordant, the diagnostic accuracy is greater than 95% and clinicians can manage patients more confidently. Of these, FNAC has been a valuable first-line diagnostic technique, is simple to perform, quick, minimally invasive, inexpensive, and can be performed without anesthesia in an outpatient setting. Furthermore, FNAC allows for early diagnosis by cytology and thus timely therapy decisions and decrease patient anxiety.

Fine-needle aspiration cytology is a technique whereby cells are aspirated from a palpable lesion in the breast with a fine needle for cytomorphological analysis of stained smears. Since its application in the routine clinical practice, FNAC has been widely accepted in the preoperative evaluation of breast masses. This provides many benefits such as minimal patient discomfort, lack of significant complications, rapid reporting, repeatability and a reduction in healthcare costs. The technique is especially useful in regions like Bihar, where access to advanced diagnostic facilities can be scarce and an affordable diagnostic pathway is critical in developing areas. Further, FNAC can be used to establish the diagnosis of malignancy prior to definitive surgery, thus enabling appropriate surgical planning, patient counselling, and consideration of neoadjuvant therapies if indicated. On the other hand, patients with benign lesions could avoid unnecessary open surgical biopsy, thus decreasing the morbidity of the procedure and the cost of the health care [3].

FNAC has some inherent limitations. The success of the procedure largely depends on adequate sampling, proper smear preparation, lesion characteristics and experience of the aspirating clinician and reporting cytopathologist for diagnostic accuracy. False negative results can occur when the samples are inadequate, when the sample is cystic, when extensive fibrosis is present, and/or when the carcinoma is well differentiated; and false positive results can occur when the benign sample is proliferative with atypia. In addition, FNAC is not able to reliably evaluate the tissue architecture, stromal invasion, tumor grading, receptor status, or some special histological variants. Therefore, pathological analysis of specimens obtained from a biopsy or an excision re-

mains the standard for precise diagnosis and is still essential for treatment planning [4].

The cyto-histopathological correlation is an important quality control tool for assessing the diagnostic accuracy of FNAC. Cytological results can be correlated with the subsequent histopathological diagnosis for the assessment of sensitivity, specificity, positive predictive value, negative predictive value, overall diagnostic accuracy and reasons for discordant results [5]. Many studies have shown that FNAC has high sensitivity and specificity in the diagnosis of palpable breast lesions when performed by experienced hands, with the diagnostic accuracy of FNAC generally being greater than 90%. However, differences in patient population, spectrum of disease, institutional expertise and health care infrastructure warrant periodic reassessment of FNAC performance in various settings. These audits help in ongoing quality improvement and increase trust in the cytological diagnosis [6,7].

In Bihar breast disease is one of the major causes of referral to tertiary care hospitals and there is not much literature available on the assessment of the diagnostic accuracy of FNAC by cyto-histopathological correlation. Variation in access to health services, socioeconomic factors, awareness and presentation of the disease at regional level may impact on diagnosis and the need for region-specific evidence. The retrospective comparison of the FNAC results with the histopathological diagnosis can be useful to understand the overall effectiveness of FNAC in day-to-day practice and pinpoint the areas that need improvement in sampling or reporting. This evidence can be relevant to the tertiary healthcare institutions that have a large population from both urban and rural areas.

The present retrospective cyto-histopathological correlation study was thus executed to evaluate the diagnostic utility of FNAC in cases of palpable breast lump in a tertiary care center in Bihar. The study compares the FNAC diagnosis with the subsequent histopathological diagnosis, in order to determine the sensitivity, specificity, positive predictive value, negative predictive value and overall diagnostic accuracy of FNAC. The results are anticipated to confirm FNAC as a useful, inexpensive, minimally invasive diagnostic tool for the pre-operative assessment of breast lesions and highlight the need for continued use of the histopathological confirmation of FNAC in the appropriate cases.

Materials and Methods

Study Design: This retrospective observational cyto-histopathological correlation study was conducted to evaluate the diagnostic accuracy of fine-needle aspiration cytology (FNAC) in patients presenting with clinically detectable breast lesions. The study assessed the concordance between FNAC findings and the corresponding histopathological di-

agnosis, which was considered the gold standard for definitive diagnosis.

Study Area: The study was carried out in the Department of Pathology, Madhubani Medical College & Hospital, Madhubani, Bihar, India.

Study Duration: The study was conducted over a period of one year, from January 2025 to December 2025.

Sample Size and Study Population: A total of 93 patients with clinically detectable breast lumps underwent fine-needle aspiration cytology (FNAC) during the study period. Among these, 47 patients subsequently underwent surgical excision or biopsy, and their specimens were subjected to histopathological examination. These 47 cases, for whom both FNAC and histopathological reports were available, constituted the final study population for cyto-histopathological correlation and diagnostic accuracy analysis.

Data Collection: Data were collected retrospectively from the medical records maintained in the Department of Pathology and the hospital medical record section. Information extracted included patient demographic characteristics (age and sex), clinical presentation, site of the breast lesion, FNAC findings, histopathological diagnosis, and relevant operative details where available. Cytological diagnoses were retrieved from archived FNAC reports, while histopathological diagnoses were obtained from corresponding biopsy or surgical specimen reports. Histopathology was considered the reference standard against which the diagnostic performance of FNAC was evaluated. All collected information was anonymized before analysis to maintain patient confidentiality.

Inclusion Criteria

The study included patients who fulfilled the following criteria:

- Patients presenting with clinically detectable (palpable) breast lesions who underwent FNAC during the study period.
- Patients whose FNAC smears were adequate for cytological interpretation.
- Patients who subsequently underwent surgical biopsy, lumpectomy, or mastectomy with available histopathological examination reports.
- Patients with complete clinical, cytological, and histopathological records.

Exclusion Criteria

The following cases were excluded from the study:

- Patients who underwent FNAC but did not undergo subsequent histopathological examination.
- Cases with inadequate or unsatisfactory FNAC smears.

- Patients with incomplete medical records or missing cytological or histopathological reports.
- Recurrent breast lesions or previously treated breast malignancies lacking complete diagnostic documentation.

Procedure: Patients presenting with palpable breast lumps underwent clinical evaluation followed by fine-needle aspiration cytology (FNAC) using standard aseptic techniques. FNAC was performed using a 22–23-gauge disposable needle attached to a 10-mL syringe. Aspirated material was expelled onto clean glass slides, immediately smeared, and fixed appropriately. Air-dried smears were stained with May–Grünwald–Giemsa (MGG) stain, while alcohol-fixed smears were stained using the Papanicolaou (Pap) stain. Additional hematoxylin and eosin (H&E) staining was performed whenever required.

Cytological diagnoses were categorized as benign, suspicious, or malignant according to established cytomorphological criteria. Patients requiring definitive surgical management subsequently underwent excisional biopsy, lumpectomy, or mastectomy based on clinical indications. Surgical specimens were fixed in 10% neutral buffered formalin, processed routinely, embedded in paraffin, sectioned at approximately 4–5 μm , and stained with hematoxylin and eosin (H&E) for histopathological examination. Histopathological diagnosis served as the gold standard for comparison.

The cytological findings were compared with the corresponding histopathological diagnoses to determine cyto-histopathological concordance. Diagnostic indices including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall diagnostic accuracy, and cyto-histopathological concordance rate were calculated.

Statistical Analysis: Data were entered into Microsoft Excel 2021 and analyzed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation (SD) or median with interquartile range (IQR) depending on data distribution, whereas categorical variables were summarized as frequency and percentage.

Histopathological diagnosis was considered the gold standard for evaluating the diagnostic performance of FNAC. Diagnostic parameters including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated with corresponding 95% confidence intervals (CIs). The agreement between FNAC and histopathological diagnosis was assessed using Cohen's kappa (κ) statistic, with interpretation according to standard guidelines. Associations between categorical variables were evaluated using the

Chi-square test or Fisher's exact test, as appropriate. A two-tailed p-value <0.05 was considered statistically significant."

Result

Table 1 shows the age distribution of the 47 patients included in the study. The majority of patients belonged to the 21–30 years age group (15 patients, 31.9%), followed by those aged 31–40 years (13 patients, 27.7%). Patients aged 41–50 years accounted

for 8 cases (17.0%), while 5 patients (10.6%) were in the 51–60 years age group. Younger patients aged ≤20 years constituted 4 cases (8.5%), whereas the >60 years age group represented the smallest proportion with 2 patients (4.3%). Overall, the findings indicate that palpable breast lesions were most frequently observed among young and middle-aged adults, with nearly two-thirds of the study population falling within the 21–40 years age group.

Table 1: Age distribution of patients (N=47)

Age group (years)	Number	Percentage (%)
≤20	4	8.5
21–30	15	31.9
31–40	13	27.7
41–50	8	17
51–60	5	10.6
>60	2	4.3
Total	47	100

Table 2 presents the distribution of breast lesions diagnosed by fine-needle aspiration cytology (FNAC) and confirmed by histopathological examination among 47 patients. Fibroadenoma was the most common lesion identified by both FNAC (21 cases, 44.7%) and histopathology (20 cases, 42.6%). Fibrocystic disease was observed in 5 cases (10.6%) on both modalities, while fibroadenosis was diagnosed in 6 cases (12.8%) by FNAC and 5 cases (10.6%) on histopathology. Breast abscess and granulomatous mastitis showed complete concordance between the two methods, accounting for 3 cases (6.4%) and 2 cases (4.3%), respectively. Histopathology additionally identified one case (2.1%) each of benign phyllodes tumour and intraductal

papilloma, which were not specifically diagnosed on FNAC. Cytologically, 2 cases (4.3%) were categorized as suspicious for malignancy, while histopathological examination confirmed 8 cases (17.0%) of invasive ductal carcinoma and 2 cases (4.3%) of invasive lobular carcinoma. FNAC identified 6 cases (12.8%) of invasive ductal carcinoma and 2 cases (4.3%) of invasive lobular carcinoma as malignant. Overall, the findings demonstrate that benign breast lesions, particularly fibroadenoma, predominated in the study population, while histopathological examination detected a slightly higher number of malignant lesions and certain specific benign entities, emphasizing its role as the definitive diagnostic standard.

Table 2: Distribution of breast lesions on FNAC and histopathology (N=47)

Diagnosis	FNAC n (%)	Histopathology n (%)
Fibroadenoma	21 (44.7)	20 (42.6)
Fibrocystic disease	5 (10.6)	5 (10.6)
Fibroadenosis	6 (12.8)	5 (10.6)
Breast abscess	3 (6.4)	3 (6.4)
Granulomatous mastitis	2 (4.3)	2 (4.3)
Benign phyllodes tumour	—	1 (2.1)
Intraductal papilloma	—	1 (2.1)
Suspicious for malignancy	2 (4.3)	—
Invasive ductal carcinoma	6 (12.8)*	8 (17.0)
Invasive lobular carcinoma	2 (4.3)*	2 (4.3)
Total	47 (100)	47 (100)

*Malignant lesions diagnosed cytologically.

Table 3 shows the distribution of breast lesions diagnosed by fine-needle aspiration cytology (FNAC) and confirmed by histopathological examination among 47 patients. On FNAC, 39 lesions (83.0%) were reported as benign, 2 lesions (4.3%) were categorized as suspicious, and 6 lesions (12.7%) were diagnosed as malignant. Histopathological examina-

tion, considered the gold standard, identified 37 lesions (78.7%) as benign and 10 lesions (21.3%) as malignant. The higher proportion of malignant lesions detected on histopathology compared with FNAC reflects the reclassification of some suspicious or benign cytological findings after definitive tissue diagnosis. Overall, the findings indicate that while benign lesions constituted the majority of

breast masses in the study population, histopathological examination identified a greater number of malignant lesions than FNAC, underscoring the im-

portance of histopathological confirmation in cases with suspicious or inconclusive cytological findings.

Table 3: Distribution of benign and malignant lesions

Diagnosis	FNAC n (%)	Histopathology n (%)
Benign	39 (83.0)	37 (78.7)
Suspicious	2 (4.3)	—
Malignant	6 (12.7)	10 (21.3)
Total	47 (100)	47 (100)

Table 4 presents the cyto-histopathological correlation between fine-needle aspiration cytology (FNAC) and histopathological examination, which served as the gold standard, among 47 patients with palpable breast lesions. FNAC identified 10 lesions as positive (malignant or suspicious), of which 9 were confirmed as malignant on histopathology, while 1 case was found to be benign, representing a false-positive result. Among the 37 lesions reported as benign on FNAC, 36 were confirmed as benign

on histopathological examination, whereas 1 lesion was subsequently diagnosed as malignant, representing a false-negative case. Thus, the study yielded 9 true-positive, 36 true-negative, 1 false-positive, and 1 false-negative cases. Overall, the findings demonstrate a high degree of concordance between FNAC and histopathological diagnosis, indicating that FNAC is a reliable and accurate pre-operative diagnostic modality for differentiating benign from malignant palpable breast lesions.

Table 4: Cyto-histopathological correlation (Gold standard = Histopathology)

FNAC	Histopathology Malignant	Histopathology Benign	Total
Positive (Malignant + Suspicious)	9	1	10
Negative (Benign)	1	36	37
Total	10	37	47

Table 5 summarizes the diagnostic performance of fine-needle aspiration cytology (FNAC) in detecting palpable breast lesions using histopathology as the reference standard. FNAC demonstrated a sensitivity of 90.0%, indicating its high ability to correctly identify malignant breast lesions, while the specificity was 97.3%, reflecting excellent accuracy in correctly classifying benign lesions. The positive predictive value (PPV) was 90.0%, suggesting that nine out of ten lesions diagnosed as malignant by FNAC were confirmed on histopathological examination.

Similarly, the negative predictive value (NPV) was 97.3%, indicating a very high probability that lesions reported as benign on FNAC were truly benign. The overall diagnostic accuracy of FNAC was 95.7%, demonstrating excellent concordance with histopathological findings. Overall, these results highlight that FNAC is a highly reliable, sensitive, and specific diagnostic modality for the preoperative evaluation of palpable breast lesions, supporting its role as an effective first-line investigation.

Table 5: Diagnostic accuracy of FNAC

Parameter	Formula	Value
Sensitivity	$TP/(TP+FN)$	90.00%
Specificity	$TN/(TN+FP)$	97.30%
Positive Predictive Value	$TP/(TP+FP)$	90.00%
Negative Predictive Value	$TN/(TN+FN)$	97.30%
Overall Accuracy	$(TP+TN)/47$	95.70%

Discussion

Fine-needle aspiration cytology (FNAC) is one of the most popular primary diagnostic tests available for the evaluation of palpable breast lesions as it is quick, have minimal complications, is affordable and can give a good separation between benign and malignant breast diseases. The overall diagnostic accuracy of the present study was found to be 95.70%, while the sensitivity was 90.00%, specificity was 97.30%, positive predictive value was 90.00% and negative predictive value was 97.30% which was

excellent. These results further highlight the value of FNAC as a valuable tool in the initial assessment, especially in resource-limited areas where prompt diagnosis and management is increasingly important”.

Age distribution in the present study showed that most of the patients (59.6%) were in the age group of 21-40 years with the maximum in 21-30 years (31.9%) and 31-40 years (27.7%). Tiwari (2007) [8] reported similar findings that most of the benign breast lesions were found in 2nd and 3rd decades of

life, and fibroadenoma constituted 39.5% of the total breast lesions. Similarly, Yalavarthi et al (2014) [9] reported that about 45% of the benign breast lesions were found in the third decade of life while malignant breast lesions were largely found in the fifth decade of life. The age-related trend of breast pathology was confirmed by the predominance of benign lesions in younger women and more malignant lesions in women older than 40 years in our study.

Fibroadenoma was the most frequently encountered lesion in the present study, representing 44.7% of the lesions in FNAC and 42.6% in histopathology. This finding is in line with Pinto and Singh (2004) [10] who found fibroadenoma as the most common benign breast lesion diagnosed by FNAC and confirmed by histopathology. Likewise, Tiwari (2007) [8] reported fibroadenoma in 39.5% of the cases and highlighted that fibroadenoma is the most common benign breast tumour in young females. The slightly higher frequency seen in our study might be explained by the relatively younger sample and the high proportion of women in reproductive age. Moreover, fibrocystic disease accounted for 10.6 % of the lesions in both types of analyses (cytology and histopathology) in our series and showed very good agreement in diagnosing common benign breast conditions.

Histopathological evaluation revealed that 17.0% of the sample cases were IDC and 4.3% were ILC, while FNAC revealed 12.8% IDC and 4.3% ILC, thus a small percentage of malignant lesions were underestimated cytologically. Yalavarthi et al. (2014) [9] have reported similar findings with malignant breast lesions being more common in the fifth decade with the most common histological type being invasive ductal carcinoma. Similarly, Tiwari (2007) [8] found that all the malignant lesions diagnosed with FNAC were confirmed at histopathology except one inflammatory lesion on FNAC which was subsequently confirmed as carcinoma in biopsy. In the present study one false-negative case and one false-positive case were encountered; thus, FNAC has excellent diagnostic performance, but histopathology is always the standard and should be performed in doubtful and suspicious lesions.

When lesions were broadly classified, 83.0% were categorized as benign by FNAC compared with 78.7% by histopathology, while malignant lesions increased from 12.7% on FNAC to 21.3% after histological confirmation. The value of the complementary role of tissue diagnosis is highlighted by the presence of two cases with cytologically suspicious features that were subsequently confirmed by histology. Ishita and Singh (2003) [11] suggested that the FNAC of breast be classified in the following categories as: Benign, Malignant, Suspicious and Inadequate, in order to increase the accuracy of the diagnosis and to better inform clinical decisions. This same reporting method was used in the current

study, with suspicious lesions being subjected to additional pathological reassessment, and reducing risk of missed malignancies.

In the present study, there were a total of 47 cases, of which FNAC correctly classified 45 cases (95.7%) with the help of cyto-histopathological correlation. Similar results were obtained by López-Ferrer et al. (1999) [12] who reviewed 405 fibroadenoma cases and found an overall cyto-histological agreement of 79.3%. Their correlation rate was less than that in the present study, but this may be due to the fact that they included cases of fibroadenoma only and that they dealt with a larger number. However, both studies suggest good reliability of FNAC for diagnosis of common benign breast lesions and with an understanding that it can occasionally be incorrect because of sampling error or similarity of cytological features.

The diagnostic indices observed in our study compare favourably with previously published literature. The present results of sensitivity (90.0%), specificity (97.3%) and diagnostic accuracy (>95.7%) are very similar to those reported by Waghmare et al. (2016) [13] FNAC sensitivity of approximately 92.6%, specificity of 100%, and diagnostic accuracy of more than 95%. Similarly, Rubin et al. (1997) [14] showed that FNAC was not only very accurate but also cost effective in solid breast lesions, thus it is still advisable to use it as a primary investigation prior to biopsy. Our negative predictive value (97.3%) was also high, suggesting that when a lesion is cytologically benign, it is very likely that it is actually benign, thus decreasing unnecessary surgery.

FNAC has some inherent limitations, although it is an excellent diagnostic tool. In this study, one benign cytological diagnosis was later found to be malignant on histopathology, while one suspicious cytological diagnosis was found to be benign. However, similar false-negative results have been reported by Hamed et al. (1989) [15] stating that cystic and inflammatory breast disease sometimes can mask underlying malignancy and careful clinical follow-up, and pathological assessment are required in cases of persisting radiological or clinical suspicion. These differences are typically due to limited sampling, tumor heterogeneity, or similar cytomorphological characteristics and not to a lack of technique.

Overall, the findings of the present study demonstrate excellent agreement between FNAC and histopathology and are consistent with previously published literature. Our results are found to have high sensitivity, specificity, PPV, and diagnostic accuracy, which further sustains the use of FNAC as reliable, rapid, less invasive, and cost-effective first line diagnostic test for palpable breast lesions. But the histopathological examination is still essential for definitive diagnosis, especially in suspicious

cases, discordant cases or cases with high clinical risk.

Conclusion

The present retrospective cyto-histopathological correlation study has shown that FNAC is an effective, quick and less invasive diagnostic technique for the primary evaluation of palpable breast lesions. Benign breast conditions were most common, and the most frequent diagnosis was fibroadenoma and the most frequent malignancy was invasive ductal carcinoma. Excellent agreement between FNAC and HPE suggests a high diagnostic efficiency of FNAC in distinguishing benign from malignant breast lesion. However, a few cases with discordance and suspicious features have been reported and this highlights the importance of pathological examinations in cases with inconclusive cytological results or those with discrepancy in clinical and radiological features. FNAC overall is an effective first-line investigation to allow timely diagnosis, clinical decision making and optimum patient management whilst limiting unnecessary surgical interventions.

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