

Fine-needle aspiration cytology as a screening tool for palpable breast lesions: Comparative analysis with histopathology



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ABSTRACT

Background: Breast cancer remains a leading malignancy among women worldwide, underscoring the need for timely and accurate pre-operative evaluation of breast lumps. In resource-limited settings, diagnostic challenges persist due to limited access to advanced modalities. Despite the growing preference for core needle biopsy, fine-needle aspiration cytology (FNAC) continues to serve as a vital diagnostic tool due to its simplicity, affordability, and rapid turnaround. **Aims and Objectives:** The present study evaluates the diagnostic utility of FNAC in palpable breast lesions and correlates cytomorphologic findings with histopathological outcomes, to assess its sensitivity, specificity, and overall diagnostic accuracy. **Materials and Methods:** The study was conducted over 21 months (September 2019–June 2021) at the Department of Pathology, Shimoga Institute of Medical Sciences, Shivamogga, which included 100 patients with palpable breast lumps. FNAC was performed following clinical evaluation, and aspirates were categorized using National Health Service Breast Screening Program (NHSBSP) criteria (C1–C5). Histopathological confirmation was obtained post-surgical excision. **Results:** Of the 100 FNAC cases, distribution by NHSBSP criteria was as follows: C1–2, C2–63, C3–7, C4–3, and C5–25. Benign lesions (C2) predominated, with fibroadenoma as the most common diagnosis (n=46). Among malignant cases (C5), infiltrating ductal carcinoma was the leading type (n=24). All cases were histologically confirmed. FNAC showed excellent diagnostic performance with sensitivity 100%, positive predictive value 95.24%, negative predictive value 100%, and overall accuracy 96.59%. **Conclusion:** FNAC remains a highly accurate, minimally invasive, and cost-effective modality for evaluating palpable breast lesions. Its diagnostic reliability reinforces its role in both benign and malignant pathology, especially in settings with limited resources.

Key words: Fine-needle aspiration cytology; Breast lump; National Health Service Breast Screening Program; Fibroadenoma; Infiltrating ductal carcinoma; Sensitivity; Diagnostic accuracy

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INTRODUCTION

Fine-needle aspiration cytology (FNAC) is a routinely employed diagnostic technique for evaluating palpable lesions, including superficial growths of the skin,

subcutaneous tissues, soft-tissue masses, and organs such as the thyroid, breast, salivary glands, and superficial lymph nodes. It is a minimally invasive, cost-effective, and easily repeatable procedure, making it particularly valuable in outpatient settings.¹⁻⁴

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FNAC of the breast is a well-established diagnostic technique applicable to both palpable and non-palpable lesions. As a minimally invasive, cost-effective, and rapid modality, FNAC is widely accepted as a first-line approach in the initial evaluation of breast abnormalities. Its utility lies in its ability to provide early and accurate cytological assessment, which is critical for guiding appropriate clinical management and improving patient outcomes.⁵

The high diagnostic accuracy of FNAC – particularly in distinguishing benign from malignant lesions – facilitates timely and informed decision-making. This enables clinicians to plan surgical or medical interventions more effectively, reducing diagnostic delays and optimizing resource utilization. In settings where access to advanced histopathological services may be limited, FNAC serves as a valuable screening tool that supports triage and prioritization of care. However, despite its utility, interobserver variability and occasional diagnostic discrepancies have been reported in the literature.^{5,6}

FNAC offers several distinct advantages in the evaluation of palpable lesions. It provides a rapid and accurate diagnosis, facilitating timely clinical decision-making. In cystic conditions, FNAC serves both diagnostic and therapeutic purposes by enabling fluid aspiration and cytologic assessment in a single procedure. One of its most significant benefits is its feasibility in outpatient settings, eliminating the need for anesthesia and thereby reducing the cost and logistical burden associated with surgical interventions.

Moreover, FNAC allows for immediate discussion of treatment options – particularly in cases of suspected malignancy – during the same clinical visit, enhancing patient engagement and streamlining management planning.

The diagnostic scope of cytology extends beyond initial lesion detection to include subclassification of both benign and malignant breast lesions. FNAC also plays a role in identifying minimal residual disease, thereby aiding in the formulation of therapeutic protocols and long-term follow-up strategies. As part of the widely accepted “Triple Test” – which integrates clinical breast examination, mammography, and – FNAC serves as a crucial component of pre-operative assessment. This multimodal approach enhances diagnostic accuracy and informs appropriate management decisions.

However, it is essential to acknowledge the limitations of FNAC, particularly its lower diagnostic accuracy in certain conditions such as lobular carcinoma or in differentiating between high-grade ductal carcinoma *in situ* (DCIS)

and invasive carcinoma which may necessitate further histopathological evaluation.⁶⁻⁸

Despite advancements in breast lesion diagnostics, FNAC remains a widely utilized and trusted modality due to its high diagnostic yield, minimal invasiveness, ease of repetition, and rapid turnaround time. In experienced hands, FNAC offers reliable results that support timely clinical decision-making. The overall diagnostic accuracy of FNAC in evaluating breast lesions has been reported to be approximately 97.40%, with a sensitivity of 93.80%, specificity of 98.21%, and a positive predictive value (PPV) of 92.70%.⁹ These metrics underscore its continued relevance as a first-line diagnostic tool, particularly in outpatient and resource-constrained settings.

In the context of breast malignancy, FNAC has demonstrated robust diagnostic performance. Reported metrics include a sensitivity of 94.5%, specificity of 98%, diagnostic accuracy of 97%, PPV of 95.8%, and negative predictive value (NPV) of 97.4%. These figures underscore FNAC’s reliability in distinguishing malignant lesions and support the continued use of FNAC as a frontline diagnostic tool in tertiary care settings, particularly when rapid decision-making is essential.^{9,10}

However, literature also highlights limitations, with false-negative rates ranging from 7.5% to 21.9%, even in cases evaluated by frozen section biopsy, where a 4% false-negative rate has been documented. These findings emphasize the need for cautious interpretation, especially in clinically suspicious cases, and support the integration of FNAC with imaging and histopathology for comprehensive diagnostic assessment.

Aims and objectives

The present study was designed to:

1. Evaluate the diagnostic utility of fine-needle aspiration cytology (FNAC) in palpable breast lesions.
2. Correlate cytomorphological findings with corresponding histopathological outcomes.
3. Determine the sensitivity, specificity, and overall diagnostic accuracy of FNAC.

MATERIALS AND METHODS

A prospective study was conducted on breast aspirates over a period from September 2019 to June 2021 at the Department of Pathology, Shimoga Institute of Medical Sciences, Shivamogga. The study included patients presenting with palpable breast lesions, all of whom underwent FNAC following a detailed clinical evaluation comprising medical history, general physical examination, and focused local assessment.

FNAC procedures were performed under aseptic conditions. The aspirated material was immediately smeared onto glass slides. Smears intended for hematoxylin and eosin staining were promptly fixed in 95% ethyl alcohol, while air-dried smears were prepared for Leishman staining. Ziehl-Neelsen (ZN) staining was performed selectively when tuberculosis or other acid-fast bacilli (AFB) were clinically suspected.

Cytologic interpretation of all breast lesions was classified into five diagnostic categories (C1–C5) according to the National Health Service Breast Screening Program (NHSBSP) criteria¹¹, as shown in Table 1:

Cytological grading of malignant lesions was performed using Robinson's grading system, which evaluates six parameters, as shown in Table 2:

Each parameter was scored on a scale of 1–3, and the cumulative score was used to assign the cytologic grade:

- Grade I: Total score 6–11
- Grade II: Total score 12–14
- Grade III: Total score 15–18.

Lesions confirmed as malignant on histopathology were further graded using the Scarff-Bloom-Richardson (SBR) grading system, which incorporates tubule formation, nuclear pleomorphism, and mitotic count to assess tumor differentiation.

Statistical analysis

The diagnostic performance of FNAC was assessed in cases where histopathological confirmation through biopsy was available. Key metrics – including sensitivity, specificity, PPV, NPV, and overall diagnostic accuracy – were calculated to evaluate the reliability of FNAC in differentiating benign from malignant breast lesions. These parameters were derived using standard statistical formulas based on true-positive, true-negative, false-positive, and false-negative results.

RESULTS

The present study was analyzed 100 breast lesion cases through FNAC over 22 months (September 2019–June 2021), yielding 102 aspirates due to bilateral involvement in two patients. Patient ages ranged from 15 to 80 years, with a strong female predominance (99 females, 1 male). The age distribution in relation to sex is shown in Table 3.

The highest incidence occurred in women aged 21–40 years, followed by those aged 41–60, highlighting increased prevalence during reproductive and perimenopausal periods.

In the present study, the most common presenting symptom was a palpable breast lump, observed in all 100 cases, as shown in Table 4.

In 100 cases, 65 cases had right side lump, 43 cases had left side lump, and two cases presented with bilateral lump, as shown in Table 5.

Most commonly lump was located in 22 cases in lower inner quadrant and 22 cases in upper outer quadrant, as

Table 1: Cytologic diagnostic categories of breast lesions (C1–C5) according to NHSBSP criteria

Category	Interpretation
C1	Inadequate
C2	Benign
C3	Atypia, probably benign
C4	Suspicious of malignancy
C5	Malignant

Table 2: Robinson's cytological grading system for breast carcinoma

Feature	Score 1	Score 2	Score 3
Dissociation	Cells in clusters	Single, with cell clusters	Mostly single cells
Nuclear size	1–2×RBC	3–4×RBC	5×RBC
Cell uniformity	Monomorphic	Mildly pleomorphic	Highly pleomorphic
Nucleoli	Indistinct	Noticeable	Prominent/Abnormal
Nuclear margins	Smooth	Folds	Clefts/Buds
Chromatin	Vesicular	Granular	Clumped and clear

RBC: Red blood cell

Table 3: Age and sex distribution

Age in years	<20	21–40	41–60	61–80	Total
Male	0	0	0	1	1
Female	19	42	28	10	99
Total	19	42	28	11	100

Table 4: Presenting symptoms

Symptoms	Number of cases
Lump in breast	100
Pain associated with the lump	30
Nipple discharge	2
Nipple retraction	4
Ulceration adjacent to the lump	2

Table 5: Anatomical distributions of breast lesions

Laterality	Number of cases
Right-sided lumps	55
Left-sided lumps	43
Bilateral involvement	2

shown in Table 6. Least common was seen in lower outer quadrant in 15 cases.

Out of the 100 FNAC procedures performed, 98 cases were deemed adequate for cytological interpretation, while two cases were classified as inadequate due to the presence of proteinaceous material with scant cellularity, rendering them non-diagnostic. All aspirates were categorized into five diagnostic groups (C1–C5) based on the NHSBSP criteria, as shown in Table 7. The two inadequate cases were assigned to C1, representing the “inadequate” category.

C1-, C2- Benign, C3- Atypia, probably benign, C4- Suspicious of malignancy, C5- Malignant.

C2 category (benign lesions)

Among the 100 FNAC cases analyzed, 63 lesions were classified as benign under the C2 category according to NHSBSP criteria. The most frequently involved quadrants were the lower inner quadrant and the upper outer quadrant, each accounting for a significant proportion of cases, as shown in Table 8.

Fibroadenoma was the most frequent benign lesion, accounting for 46 cases. Inflammatory lesions were noted in three cases, including one of granulomatous mastitis. Distribution of benign lesion is shown in Table 9.

Histopathological correlation was available for most cases, validating FNAC's reliability in diagnosing benign breast lesions. Among 63 benign (C2) cases, fibroadenoma was most common (46 cases), with 40 confirmed histologically as shown in Table 10. Three inflammatory lesions were noted. One fibroadenoma case was later identified as infiltrating ductal carcinoma (IDC), indicating a false-negative FNAC result.

Fibroadenoma smears showed classic cytologic features – cohesive ductal epithelial clusters, bipolar bare nuclei, and stromal fragments. Of 46 excised cases, 40 were histologically confirmed. Two cases suggestive of fibrocystic disease showed foamy histiocytes, apocrine cells, and stromal fragments; one was histologically confirmed.

C3 category (atypia, probably benign)

Seven cases were classified as C3 (atypia, probably benign), including one male, all presenting with ill-defined lumps. Cytology showed atypical ductal and myoepithelial cells. Surgical excision revealed five cases of IDC and one tubular adenoma, emphasizing the diagnostic uncertainty of C3 lesions and the need for histopathologic confirmation.

C4 category (suspicious of malignancy)

Three cases were classified under the C4 category (suspicious for malignancy), with cytological smears demonstrating

Table 6: Quadrant-wise distribution of lesions

Breast quadrant	Number of cases
Lower inner	22
Upper outer	22
Upper inner	21
Central	20
Lower outer	15
Total	100

Table 7: Categorization in cytology of breast lesions

Category	No of cases
C1	2
C2	63
C3	7
C4	3
C5	25

Table 8: Quadrant-wise distribution of lesions with percentage

Quadrant	No of cases	Percentage
Upper outer	14	22.22
Upper inner	12	19.05
Lower outer	10	15.88
Lower inner	16	25.40
Central	11	17.46
Total	63	100

Table 9: Distribution of benign lesion

Benign lesions	No of cases	Percentage
Inflammatory	3	4.76
Simple cyst	1	1.58
Fibroadenoma	46	73.01
Fibrocystic disease	2	3.17
Fibroadenomatoid hyperplasia	5	7.93
Benign breast disease	5	7.93
Proliferative breast disease	1	1.58
Total	63	100

Table 10: FNAC and histopathology correlation

Diseases	FNAC	Histopathology	
	No of cases	Positive	Negative
Fibroadenoma	46	40	6
Fibrocystic disease	2	1	1
Benign breast disease	5	3	2
Fibroadenomatoid hyperplasia	6	1	5
Simple cyst	1	0	1
Inflammatory	3	2	1
Total	63	47	16

FNAC: Fine-needle aspiration cytology

pleomorphic ductal epithelial cells exhibiting marked nuclear atypia. All patients subsequently underwent surgical excision, and histopathological examination confirmed

IDC in each case. These findings underscore the strong predictive value of C4 cytological features and reinforce the necessity of surgical confirmation for definitive diagnosis.

C5 category (malignant)

In this study, 25 cases were cytologically diagnosed as malignant (C5), predominantly affecting the upper breast quadrant and women aged 41–60. FNAC smears showed high cellularity, pleomorphic ductal cells with high N: C ratios, and absent myoepithelial cells. All underwent modified radical mastectomy; histopathology confirmed 24 cases as IDC and one as lobular carcinoma. Cytologic grading (Robinson's criteria) and histologic grading (SBR system) showed concordance in 14 cases, with Grade II being most common, supporting FNAC's reliability in pre-operative malignancy assessment.

Cytological diagnosis was correlated with histopathology in all cases. One hundred fine-needle aspiration (FNA) cases material had a corresponding histological diagnosis. With this confirmation an overall sensitivity, predictive value of a positive result and percentage of false-negative indices were calculated.

Out of 63 benign lesions on FNA, the discrepancies at cytology were as follows: In 46 cases of fibroadenoma on cytology. On histopathology, 40 were reported as fibroadenoma, five cases were reported as benign lesions, and one case turned to be malignant. The sensitivity was 100% and PPV was 86.96%, as shown in Table 11.

Out of 5 cases reported as benign breast disease on cytology. On histopathology, two cases were diagnosed as fibroadenoma, one case as fibrocystic disease, and two cases were diagnosed as malignant. Here, PPV was less with 20%. Out of two cases, fibrocystic disease one case was concordant; one was discordant and was reported as normal breast tissue on histology with PPV of 50%. Out of three inflammatory lesion cases, only one case was concordant and other two cases were discordant with PPV of 33.33%.

Coming to malignant lesions, out of 25 cases as malignant in cytology, all 25 cases were diagnosed as malignant on histopathology. Therefore, the FNAC proved to be 100% sensitive and 89.29% specific in the diagnosis of malignant lesions in our study, as shown in Table 12.

DISCUSSION

In this study of 100 breast lesion cases evaluated through FNAC, the 21–40 age groups emerged as the most affected, highlighting a predominance of breast pathology in younger women. This aligns with prior findings by Mrudula et al., Yogalakshmi et al., Bhavani et al., and Yerakly et al.,

Table 11: Benign lesion correlation

Parameter	Estimate (%)	Lower-Upper 95% confidence intervals	Method
Sensitivity	100	(91.24, 100)	Wilson score
Specificity	0.00	(0.0, 39.03)	Wilson score
Positive predictive value	86.96	(74.33, 93.88)	Wilson score
Diagnostic accuracy	86.96	(74.33, 93.88)	

Table 12: Malignant lesion correlation

Parameter	Estimate (%)	Lower-Upper 95% Confidence intervals	Method
Sensitivity	100	(93.98, 100)	Wilson score
Specificity	89.29	(72.8, 96.29)	Wilson score
Positive predictive value	95.24	(86.91, 98.37)	Wilson score
Negative predictive value	100	(86.68, 100)	Wilson score
Diagnostic accuracy	96.59	(90.45, 98.83)	

emphasizing the need for early screening and cytological assessment in this demographic to enable timely diagnosis and intervention.¹²

Benign breast lesions were more frequently encountered than malignant ones, reflecting a diagnostic trend consistent with previous studies. Similar findings have been reported by Makkar et al., and Bhagat et al., both of whom observed a predominance of benign pathology in breast lesion evaluations. This pattern emphasizes the importance of accurate cytological differentiation to avoid overtreatment and to guide appropriate clinical management strategies.^{12,13}

In our study, the majority of breast lumps were localized to the right breast (55 cases), followed by the left breast (43 cases), with bilateral involvement observed in two cases. This laterality distribution is consistent with the findings reported by Sreedevi et al.,¹⁴ and Gore et al.¹⁵

Quadrant-wise distribution analysis revealed that the upper outer quadrant and lower inner quadrant were the most frequently involved sites, each accounting for 22% of cases in our cohort. This pattern aligns with the findings of Kosthi et al., and Yalavarthi et al.,^{16,17} who similarly noted frequent localization in these regions.

All FNAC samples were classified into five diagnostic categories (C1–C5) based on the NHSBSP reporting criteria, facilitating standardized interpretation and clinical correlation.

C1 category (inadequate smears)

In our study, two cases were categorized as C1 due to inadequate cytological samples, characterized by low cellularity and hemorrhagic backgrounds from small, ill-defined swellings. These findings underscore the critical role of operator skill and interpretive expertise in ensuring FNAC adequacy and diagnostic reliability.

C2 category (benign lesions)

Within the C2 category, representing benign breast lesions, a total of 63 cases were classified as follows, as shown in Table 9.

Fibroadenoma was the most common benign lesion consistent with the observations of Pavithra *et al.*¹⁸ Of 46 cytological diagnoses, 40 were histologically concordant, affirming FNAC's reliability. However, one case misclassified as benign on cytology was later confirmed as IDC, highlighting the potential for false negatives and the inherent limitations of FNAC.

Among the inflammatory lesions, a single case of granulomatous mastitis was identified, showing histiocytes, ductal epithelial clusters, multinucleated giant cells, and epithelioid granulomas. ZN staining was negative for AFB, excluding tuberculosis.¹⁹

The patient subsequently underwent surgical excision and histopathology confirmed suppurative granulomatous inflammation. Granulomatous mastitis, often linked to retained breast secretions, can mimic carcinoma both clinically and radiologically, and epithelial atypia may further obscure diagnosis, highlighting the need for meticulous cytological–histological correlation.

Two C2 cases, in patients aged 25–45 years, were diagnosed as fibrocystic disease, characterized by apocrine cell clusters, cyst macrophages, and ductal epithelial cells; both subsequently underwent surgical excision.

Histopathology confirmed fibrocystic disease in one case, while the other showed no significant pathology, indicating partial concordance and highlighting cytology's limitations. Of five cases diagnosed as benign breast disease, two proved malignant on histology, reflecting possible misclassification. In addition, six cases were identified as fibroadenomatoid hyperplasia on cytology.

Smears from these cases showed monolayered sheets of ductal and myoepithelial cells, with antler horn patterns in two cases, sparse bare nuclei in four cases, and cyst macrophages in four cases. Features overlapped with fibroadenoma and fibrocystic disease, reflecting the spectrum of benign proliferative changes.

These findings are consistent with fibroadenomatoid hyperplasia, a diagnostic challenge where cytology alone may mimic fibroadenoma, necessitating clinical and radiological correlation for accurate classification.²⁰

In the C3 category, representing atypia, probably benign, a total of seven cases were reported, comprising six female patients and one male. The cytological aspirates showed moderately cellular smears with ductal and myoepithelial cells, scattered bare nuclei, and epithelial clusters displaying mild-to-moderate atypia. These features reflect the diagnostic ambiguity of the C3 category, often requiring histopathological correlation for definitive classification.

All cases in the C3 category underwent excision biopsy in accordance with NHSBSP guidelines.²¹ Histopathology revealed malignancy in six cases (including the male patient, all IDC), while one was tubular adenoma. These results highlight the diagnostic challenge of cytologic atypia, where reactive changes may mimic malignancy, underscoring the need for cautious interpretation and histopathological confirmation.²²

In the C4 category, three cases were reported as suspicious for malignancy, showing pleomorphic ductal epithelial clusters with marked atypia. All underwent excision, and histopathology confirmed IDC in each, underscoring the high predictive value of C4 and its role in guiding definitive surgical management.

In the C5 category, 25 cases were diagnosed as malignant, predominantly in the upper breast quadrant. IDC was the most common subtype, consistent with the observations of Yalavarthi *et al.*,¹⁷ and Gardas.²³ All cases were histologically confirmed, yielding 100% cytohistological concordance and reinforcing the high diagnostic accuracy of FNAC in unequivocally malignant lesions as reported by Waghmare *et al.*¹⁹

Complete cytohistological concordance demonstrated 100% diagnostic sensitivity of FNAC for malignant breast lesions, with no false positives or negatives observed in the present study. Malignant aspirates were reliably identified by characteristic cytomorphological features, including cell discohesion, increased nuclear-to-cytoplasmic (N:C) ratio, cellular dissociation, monomorphic cell patterns, and nuclear pleomorphism, reaffirming FNAC as a robust frontline diagnostic tool.¹⁹

Cellular discohesiveness is a hallmark of malignancy, yet distinguishing DCIS from invasive carcinoma on FNAC remains challenging. In this present study, many malignant cases showed cohesive atypical clusters with scattered single cells, and diagnoses relied on overall morphology,

underscoring both the utility and limitations of FNAC in differentiating between *in situ* and invasive disease.

Limitations of the study

The study was conducted at a single institution, which limits external validity and the applicability of findings across different populations, practice settings, and operator experiences.

Future studies should be multicenter and prospective with a larger, more heterogeneous cohort that includes all lesion types and varied clinical scenarios, and should standardize the handling of inadequate and indeterminate categories to produce generalizable, precise performance estimates.

CONCLUSION

FNAC is a simple, cost-effective, and reliable first-line diagnostic tool for evaluating palpable breast lesions. When combined with clinical and imaging data, it offers high sensitivity and specificity, aiding surgical decision-making and accurately identifying malignancies.

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IDK- Definition of intellectual content, Literature survey, Prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation, final editing and submission of article; **SK-** Concept, design, protocol preparation, manuscript preparation, editing, and manuscript revision; **KC-** Concept, design of study, literature study, statistical Analysis and Interpretation, review manuscript.

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