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Fine-needle aspiration cytology of breast lesions using the NCI c1–c5 reporting system: A one-year retrospective observational study in a tertiary care hospital.

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Abstract

Background:
Fine-needle aspiration cytology (FNAC) is widely used for rapid triage of breast lumps, particularly where access to immediate core biopsy is constrained. Standardized category-based reporting improves clarity and supports consistent clinical decision-making.

Objectives:
To describe the spectrum of breast lesions evaluated by FNAC over one year using the National Cancer Institute (NCI) C1–C5 reporting system and to summarize the completeness of basic radiology documentation.

Methods:
A retrospective observational audit was performed over one year in a tertiary care pathology service. Consecutive breast FNAC cases were extracted from routine registers. Age, recorded laterality, and BI-RADS category, NCI category assignment, repeat aspiration events, and final cytological diagnosis were compiled and summarized using descriptive statistics.

Results:
A total of 59 breast FNAC cases were included. The age ranged from 12–70 years (mean 39.44 ± 14.07). Benign category C2 predominated (41 cases), followed by malignant category C5 (15 cases). Atypical category C3 constituted 2 cases, and inadequate smears (C1) constituted 1 case. Fibroadenoma/fibroadenosis spectrum formed the largest diagnostic group (29 cases), while ductal carcinoma spectrum accounted for 15 cases. Repeat aspiration was performed in two cases, yielding a final benign diagnosis in one and a malignant diagnosis in one.

Conclusion:
Over the one-year audit period, breast FNAC was predominantly reported as benign, with fibroadenoma/fibroadenosis constituting the largest diagnostic group. BI-RADS information was incompletely recorded, highlighting the need for standardized requisition proformas and tighter clinicoradiological linkage to reinforce triple assessment, streamline triage, and improve continuity of care.

Recommendations:
Routine capture of laterality and BI-RADS category, preferential use of ultrasound guidance for challenging lesions, and rapid on-site adequacy checks, where feasible, can improve report quality and reduce repeat procedures.

Keywords: *Breast lump; fine-needle aspiration cytology; National Cancer Institute, Breast Imaging Reporting and Data System, fibroadenoma; ductal carcinoma; BI-RADS.*
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Introduction
Breast lumps constitute a frequent cause of outpatient visits and radiological referral, spanning benign developmental lesions, inflammatory conditions, and malignancy. Given the rising incidence of breast cancer, early and accurate categorization of breast lesions remains central to improving

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outcomes. Timely risk stratification is essential because prolonged diagnostic intervals intensify psychological stress and delay definitive care. In many hospitals, especially those serving large catchment populations, a rapid, low-cost diagnostic step remains valuable for triage and prioritization. Fine-needle aspiration cytology (FNAC) offers a minimally invasive procedure that can be performed in the clinic, provides same-day provisional interpretation, and supports decisions for observation, medical therapy, core biopsy, or surgery. Although core-needle biopsy has expanded as the preferred method for tissue diagnosis, FNAC retains practical relevance because it is repeatable, inexpensive, and particularly efficient for cystic lesions and palpable masses, especially when interpreted alongside imaging and clinical assessment [11,14].

Standardized terminology is critical for maximizing the clinical utility of breast cytology. The National Cancer Institute (NCI) approach to breast FNAC introduced a uniform categorical scheme that distinguishes inadequate smears from benign, atypical, suspicious, and malignant interpretations, enabling clinicians to align cytology outcomes with management algorithms and audit performance indicators [1–3]. Category-based reporting also facilitates internal quality assurance, allows monitoring of inadequate rates, and highlights the "grey-zone" categories where cytohistological correlation is most informative. More recently, the International Academy of Cytology (IAC) has proposed the Yokohama system for breast FNAC, which provides standardized definitions, risk-of-malignancy estimates, and management suggestions, reinforcing the role of structured reporting across diverse practice environments [6,7].

Diagnostic performance in breast FNAC depends on a chain of pre-analytical and analytical factors. Sampling technique, lesion size, cystic change, operator experience, smear preparation, and cytomorphological overlap between proliferative benign lesions and low-grade malignancies contribute to interpretive variability [3-5]. Evidence from meta-analysis indicates high overall accuracy for distinguishing benign from malignant disease, yet inadequate smears and equivocal categories remain major drivers of repeat procedures and downstream biopsy decisions [8,9,13]. Equally important, clinicoradiological documentation determines how effectively FNAC results integrate with the triple assessment pathway; when imaging details are missing, the multidisciplinary value of cytology is diluted [4,14].

This study presents a one-year retrospective audit of breast FNAC performed at a tertiary care hospital and categorized using the NCI C1–C5 reporting system. The objectives of the study were to describe the age profile, assess completeness of radiology documentation (laterality and BI-RADS), quantify the distribution of NCI categories, and summarize the spectrum of final cytological diagnoses.

Materials and Methods

Study Design

This study was designed as a retrospective observational cross-sectional study using routinely maintained cytology records. The study evaluated breast fine-needle aspiration cytology cases reported over a defined one-year period and categorized them according to the National Cancer Institute C1–C5 reporting system. As the data were collected from existing departmental records without follow-up intervention, the study design was descriptive and record-based.

Study Setting

The study was conducted in the Department of Pathology, Government Medical College and General Hospital, Bhadradri Kothagudem, Telangana, India. The institution is a tertiary care teaching hospital that provides diagnostic and referral services to patients from Bhadradri Kothagudem district and surrounding rural and semi-urban areas. The pathology department receives cytology samples from outpatient departments, inpatient wards, surgical units, and radiology-assisted procedures. Breast FNAC is routinely performed as part of the diagnostic work-up of palpable and clinically suspected breast lesions, usually in coordination with clinical examination and available radiological assessment.

Study Period

The study included breast FNAC cases reported over one year from January 2025 to December 2025.

Eligibility Criteria

Inclusion criteria

All patients who underwent FNAC for breast lesions during the study period were included, irrespective of age and sex. Cases with a documented final cytological diagnosis and assigned NCI category were considered eligible for analysis. Repeat aspiration cases performed for adequacy or diagnostic clarification were also included, and the final cytology category after reassessment was used for analysis.

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Exclusion criteria

Cases with incomplete records that did not permit final cytological categorization were excluded. Cases without a definitive final FNAC interpretation after repeat assessment, duplicate entries, and non-breast cytology samples incorrectly entered in the breast FNAC register were excluded from quantitative analysis.

FNAC procedure and smear processing

Aspirations were performed under aseptic precautions using standard needles and syringes. Palpable lesions were sampled directly, while selected deep, small, or clinically ambiguous lesions were aspirated under ultrasound guidance according to institutional practice. Material was expressed onto clean slides, and smears were prepared with gentle spreading to minimize crushing artifacts. Air-dried and alcohol-fixed smears were prepared where feasible, and staining was performed using routine departmental protocols. Smears were assessed for adequacy and salient morphological features, including cellularity, epithelial cohesion, nuclear atypia, background necrosis, stromal fragments, and inflammatory elements. When initial smears were inadequate or discordant with clinicoradiological impressions, repeat aspiration was recommended to improve representativeness.

Reporting framework and diagnostic grouping

All cases were categorized using the National Cancer Institute (NCI) breast FNAC reporting scheme: C1 (inadequate/unsatisfactory), C2 (benign), C3 (atypical/probably benign), C4 (suspicious/probably malignant), and C5 (malignant) [1–3]. For interpretive summaries, the final cytological impression was consolidated into clinically meaningful groups: fibroadenoma/fibroadenosis spectrum, benign cystic/fibrocystic lesions, benign breast lesion (not otherwise specified), galactocele, acute mastitis, gynecomastia, atypical ductal hyperplasia (C3), ductal carcinoma spectrum (C5), and inadequate/unsatisfactory (C1). Where the requisition form documented a BI-RADS category, it was recorded verbatim; otherwise, it was coded as not recorded.

Ethical approval and data handling

Ethical approval was obtained from the Institutional Ethics Committee, Government Medical College and General Hospital, Bhadradri Kothagudem, Telangana, India. As this was a retrospective record-based study using routinely generated diagnostic data, patient identifiers were removed before analysis. Confidentiality was maintained throughout the study, and the data were used only for academic and quality-improvement purposes.

Statistical analysis

Data variables included age, recorded laterality, BI-RADS category, NCI category, repeat aspiration status, and final cytology diagnosis. Data were entered and analyzed in a spreadsheet with spot checks for transcription errors. Descriptive statistics were applied: continuous variables are presented as range, mean with standard deviation, and median with interquartile range; categorical variables are summarized as frequencies and percentages. No hypothesis testing was performed because the primary objective was service characterization.

Results

Fifty-nine breast FNAC cases were analyzed over the one year. One case represented gynecomastia on cytology, corresponding to a male patient in the records. The age ranged from 12–70 years with a mean ± SD of 39.44 ± 14.07 and a median (IQR) of 38 (30–48). The highest case concentration was observed in the 30–39-year age group (19 cases, 32.2%), followed by 40–49 years (14 cases, 23.7%). Age distribution details are summarized in Table 1.

Table 1. Age profile of cases (n = 59)

Measure	Value
Age range (years)	12–70
Mean ± SD (years)	39.44 ± 14.07
Median (IQR) (years)	38 (30–48)
Age group (years)	n (%)
<20	5 (8.5)
20–29	8 (13.6)
30–39	19 (32.2)

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40–49	14 (23.7)
50–59	4 (6.8)
≥60	9 (15.3)

Radiology documentation specified laterality in 55 cases (93.2%), with right-sided lesions more frequently recorded (33 cases, 55.9%). BI-RADS category was documented for 18 cases (30.5%), while it was not recorded in 41 cases (69.5%). Among the total cohort, BI-RADS IV or higher impressions constituted 14 cases (23.7%). Radiology documentation details are shown in Table 2.

Table 2. Radiology documentation: laterality and BIRADS (n = 59)

Variable	n (%)
Right-sided	33 (55.9)
Left-sided	22 (37.3)
Unspecified/not recorded	4 (6.8)
BI-RADS not recorded	41 (69.5)
BI-RADS II	3 (5.1)
BI-RADS III	1 (1.7)
BI-RADS IV	12 (20.3)
BI-RADS IV/V	1 (1.7)
BI-RADS V	1 (1.7)

Note: BI-RADS IV, IV/V, and V together comprised 14/59 (23.7%) cases.

Using the final NCI cytology category assignment, most aspirates were reported as benign (C2) (41 cases, 69.5%), followed by malignant (C5) (15 cases, 25.4%). Atypical cytology (C3) accounted for 2 cases (3.4%), and there was one inadequate smear (C1). Repeat aspiration was documented in two cases (3.4%), resulting in final revision of category (one case to C2 and one case to C5). The category distribution is presented in Table 3.

Table 3. Final NCI cytology category distribution (n = 59)

NCI category	**n (%)**
C1	1 (1.7)
C2	41 (69.5)
C3	2 (3.4)
C5	15 (25.4)

On final diagnostic grouping, fibroadenoma/fibroadenosis spectrum was the predominant diagnosis (29 cases, 49.2%), followed by ductal carcinoma spectrum (15 cases, 25.4%). Benign cystic/fibrocystic lesions comprised 8 cases (13.6%). Among malignant cytology reports, invasive or infiltrative descriptors were documented in 8 of 15 cases, and nodal/axillary metastatic deposits were noted in 5 cases based on cytology comments. The overall spectrum is detailed in Table 4.

Table 4. Spectrum of final diagnoses (grouped) (n = 59)

Final diagnosis (grouped)	**n (%)**
Fibroadenoma/fibroadenosis spectrum	29 (49.2)
Benign cystic/fibrocystic lesions	8 (13.6)
Benign breast lesion	1 (1.7)
Galactocele	1 (1.7)
Acute mastitis	1 (1.7)
Gynecomastia	1 (1.7)

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Atypical ductal hyperplasia (C3)	2 (3.4)
Ductal carcinoma spectrum (C5)	15 (25.4)
Inadequate/unsatisfactory (C1)	1 (1.7)

Discussion

This one-year retrospective audit demonstrates that benign breast lesions constituted the predominant FNAC workload, with the fibroadenoma/fibroadenosis spectrum accounting for nearly half of all cases. This distribution aligns with the established epidemiology of benign fibroepithelial lesions and with large cytohistological correlation series where fibroadenoma remains the leading benign diagnosis [12]. In contrast, roughly one-quarter of aspirates were categorized as malignant (C5), emphasizing the triage role of FNAC for prompt referral to tissue confirmation and staging workflows [3,11]. In malignant reports, the frequent use of invasive/infiltrative descriptors reflects routine cytology practice, where high-grade atypia, necrosis, and dissociation patterns guide an interpretation consistent with carcinoma.

The NCI C1–C5 framework provided a simple, clinically interpretable structure for stratifying results, particularly for separating clearly benign (C2) from unequivocally malignant (C5) aspirates [1–3]. Meta-analytic work has reported high sensitivity and specificity of FNAC for palpable breast masses, supporting its continued relevance as an initial diagnostic tool when combined with appropriate downstream confirmation strategies [8]. However, performance is sensitive to adequacy and representativeness. Published literature shows wide variability in inadequate rates and highlights that inadequate smears can conceal malignancy and create delays through repeated procedures and prolonged uncertainty [13]. Within this context, approaches such as ultrasound guidance for difficult lesions and rapid on-site adequacy assessment are operationally attractive, although standardized ROSE guidance remains inconsistent across laboratories [13].

A salient process issue in the present dataset was incomplete imaging documentation. BI-RADS category was absent in a majority of cases, limiting formal clinicoradiological correlation and weakening the interpretive value of cytology within the triple assessment pathway. Evidence from triple-test studies shows that concordant physical examination, imaging, and FNAC results yield very high diagnostic accuracy and can safely reduce open biopsy rates in selected patients, while discordance triggers escalation to core biopsy or excision [14]. In addition, studies comparing core biopsy and FNAC reinforce that both tests provide complementary value, and institutional pathways often balance local expertise, imaging access, and resource constraints [11].

Grey-zone diagnoses deserve particular attention. Although uncommon in this cohort, atypical (C3) cases have meaningful downstream implications because their malignancy probability is higher than C2 and lower than suspicious categories. Histopathological correlation studies support maintaining distinct atypical and suspicious categories to avoid over-treatment of proliferative lesions and under-triage of early malignancy [9,10]. Newer standardized systems, such as the IAC Yokohama classification, build on the same principles by pairing categories with risk-of-malignancy estimates and management suggestions, strengthening communication and enabling inter-laboratory benchmarking [6,7]. Adopting structured requisition and reporting templates, alongside periodic audits, can therefore improve both documentation quality and the clinical actionability of breast cytology.

Generalizability

The findings of this study have external validity for similar tertiary care teaching hospitals and diagnostic pathology services where FNAC continues to be used as an initial triage tool for breast lesions. The predominance of benign cytological diagnoses, especially fibroadenoma and fibroadenosis, is likely applicable to comparable hospital-based populations with a high burden of palpable benign breast lesions. The study also highlights a practical service-level issue—limited documentation of BI-RADS category—which may be relevant to many resource-constrained or high-volume centres where cytology, radiology, and clinical data are not consistently integrated. However, the results should be generalized with caution to cancer referral centres, private oncology units, or settings where core needle biopsy is the primary diagnostic modality, because referral patterns, imaging access, operator expertise, and histopathological follow-up may differ substantially.

Conclusion

This one-year retrospective evaluation of breast FNAC, reported using the NCI C1–C5 system, showed a predominance of benign lesions, with fibroadenoma/fibroadenosis forming the largest diagnostic cluster. Malignant (C5) interpretations constituted about

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one-quarter of cases, supporting FNAC as an efficient triage tool to expedite referral for histopathological confirmation and downstream staging pathways. Repeat aspiration altered the final category in a small subset, reinforcing the value of reassessment when smears are inadequate or clinicoradiological findings are discordant. Although radiology details were available, BI-RADS documentation was incomplete (recorded in 30.5% of cases); standardized requisition templates and consistent clinicoradiological integration can strengthen FNAC utility within triple assessment, improve decision-making, and enable reproducible service audits.

Limitations

This study was limited by its retrospective design and reliance on requisition and register documentation, which restricted assessment of clinical presentation, lesion size, and imaging details beyond recorded laterality and BI-RADS. Histopathological follow-up was not available for all cases, preventing calculation of sensitivity, specificity, and category-wise risks of malignancy. Interobserver variability was not assessed because reporting was drawn from routine service sign-out.

Recommendations

Standardized breast FNAC requisition forms should mandate documentation of laterality, imaging modality, and BI-RADS category, enabling transparent clinicoradiological correlation. Ultrasound guidance should be preferentially used for small, deep, or heterogeneous lesions to improve representative sampling. Where feasible, rapid on-site adequacy assessment can reduce inadequate smears and shorten diagnostic timelines. Adoption of structured reporting templates aligned with NCI or IAC Yokohama categories, with periodic internal audits of category distribution and cytohistological correlation, can improve consistency, training, and quality assurance. Dedicated multidisciplinary review of discordant triple assessment results and periodic competency refreshers for aspirators can further reduce missed malignancy and inappropriate excision.

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Abbreviations

BI-RADS: Breast Imaging Reporting and Data System;
FNAC: Fine-needle aspiration cytology;
FNA: Fine-needle aspiration;
IAC: International Academy of Cytology;
IQR: Interquartile range;
NCI: National Cancer Institute;
ROSE: Rapid on-site evaluation;
SD: Standard deviation;
ROM: Risk of malignancy.

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Conflict of interest

The authors declare no conflict of interest.

Author contributions

CS -Concept and design of the study, results interpretation, review of literature, and preparation of the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript. **SM**- Design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript, and revision of the manuscript.**KRK**- design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of the manuscript

Data availability

Data is Available

Author Biography

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