

The Relevance of IAC Yokohama System for Standardized Reporting of Breast FNAC in Peripheral Regions of Jharkhand and Its Histopathological Correlation

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Abstract:

Background: Fine-needle cytology (FNAC) is a crucial, low-cost diagnostic tool for breast lesion in resource-limited areas. This study evaluates the diagnostic utility of the **International Academy of Cytology (IAC) Yokohama System** in peripheral Jharkhand by correlating its standardized categories with histological outcomes.

Materials and Methods: A cross-sectional study evaluated **113 patients** presenting with palpable breast lumps. Cytology smears were categorized from **C1 (Inadequate)** to 113 patients Histopathological examination (HPE) correlation was available for 75 cases. Diagnostic metrics were analyzed across **three interpretation thresholds** (Scenario 1: C3-C5 malignant; Scenario 2: C4-C5 malignant; Scenario 3: C5 malignant).

Results: The cohort included 109 females and 4 males. The risk of malignancy (ROM) was 0% for C2 (Benign), 55.5% for C3 (Atypical), and 100% for C1, C4 (Suspicious), and C5.

- **Scenario 1** showed the highest sensitivity (100%).

- **Scenario 2** provided the most balanced profile with 93.15% accuracy, 87.50% sensitivity and 86.84% specificity.

- **Scenario 3** yields 100% specificity and PPV, but low sensitivity (40.47%).

Conclusion: The IAC Yokohama system successfully standardizes breast cytology reporting and ensures high diagnostic accuracy. Including atypical (C3) and suspicious (C4) categories under positive interpretations significantly improves sensitivity, making it a reliable framework for early breast cancer screening in low-resource settings.

Key Words: FNAC, IAC, Yokohama system, Breast lumps, Atypical, Suspicious

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I. Introduction

One of the most common invasive malignancies is breast cancer. Recent data indicates that 30% of new cancer cases in women in the US are caused by this illness as well as breast cancer has surpassed cervical cancer as the most prevalent disease in India^{1,2}. Male breast cancer is a rare disease and accounts for ~1% of all cancers in men and 0.5% of all malignancies in men. Men often present in an advanced stage (Stage III / IV) of the disease³.

The national health planning sector is now focused on finding the finest diagnostic techniques for early-stage cancer diagnosis as a result of this emerging new trend. By a majority consensus, fine-needle aspiration cytology (FNAC) was identified as one such ideal technique.

FNAC is a simple, rapid, minimally invasive, and economical diagnostic procedure that has been in widespread use for both palpable and non-palpable breast lesion evaluation and is recognized as first-line technique for the first assessment of breast abnormalities. Its usefulness stems from its capacity to offer prompt and precise cytological evaluation, which is essential for directing suitable clinical care and enhancing patient outcomes⁴. Access to cutting-edge diagnostic services is still difficult in peripheral areas of Jharkhand. Because of the low cost, convenience of use, and high diagnostic yield, FNAC is still a crucial technique for the early detection of breast lesions in these situations. It offers a high degree of diagnostic accuracy when paired with clinical examination and imaging forming the "triple assessment" approach^{5,6,7}. In the era of core needle biopsy (CNB), FNAC is still essential, particularly in certain situations like pregnancy or when mammography is not practical. FNAC guided by ultrasound is especially useful for improving sampling accuracy. Its diagnostic potential is further increased by including rapid on-site evaluation (ROSE) by increasing the detection rates of both benign and malignant lesions and decreasing the occurrence of insufficient or ambiguous samples⁸.

The International Academy of Cytology (IAC) has formulated a process to ensure a standardized and comprehensive approach to FNAC reporting. Accordingly, they have categorized breast lesions into five categories, C1–C5 (C-code): Code 1 – Insufficient material; Code 2 – Benign; Code 3 – Atypical, probably benign; Code 4 – Suspicious, probably in situ or invasive carcinoma; and Code 5 – Malignant. For FNAC of breast lesions, the IAC has developed a checklist that allows cytopathologists to apply an analytical method based on cytological diagnostic criteria and pattern recognition for producing reports⁹.

As of right now, image analysis of FNAC samples is thought to be the least intrusive preoperative screening method for determining whether breast lesions are malignant. However, some breast diseases make it more difficult to clinically characterize malignant cells' morphology. Fibroepithelial lesions, fibrocystic disease, papillary lesions, sclerosing adenosis and radial scars, flat epithelial atypia, borderline proliferative lesions, low-grade cancer, etc. are examples of these¹⁰. The insufficiency of aspirated samples, which leads to incorrect diagnosis, is also influenced by the type of lesions¹¹. Researchers have recently been adopting combinational approaches to rule out these limitations, including AI-based techniques. Ara, S. et al. developed several machine learning-based algorithms to detect breast cancer from nuclear features of FNAC samples¹².

The objective of this research was to evaluate the diagnostic performance of breast FNAC using the IAC Yokohama reporting categories, with histopathology correlation wherever available. This study is conducted under the umbrella of a broader digital health initiative named, **'The National Cyto-surveillance Project'**, managed through a collaborative partnership between **'ICMR-NIRDH' (Indian Council of Medical Research, New Delhi and National Institute for Research in Digital Health)** and our institution. The foundational data for this project originates from an ongoing multi-centeric study, titled, **"Clinical and Reproductive Risk Factors Associated with Suspicious or Malignant Breast Findings: A Multicenteric Study Of 4,777 Participants in India"**—are currently being processed for formal publication on the **Springer Nature** platform. As an active contributor to this framework, our medical center utilizes these shared findings, aiming to develop local best practice guidelines, strengthen training in breast cytology interpretation, and ultimately improve patient care in low-resource settings.

II. Materials and Methods

The current cross- sectional study was undertaken in the Department of Pathology at Mahatma Gandhi Memorial Medical College and Hospital in Jamshedpur city in the state of Jharkhand, after receiving the required ethical approval from the Institutional Review Committee, under the number "IEC/52/2024". This study is a part of **'ICMR- NIRDH' national project under the guidance of Dr. Garima Jain (MD, Scientist D & PI, NIP, ICMR)**. A total of 113 patients who underwent an FNAC procedure for palpable breast lumps between April 1, 2025, and March 31, 2026, were included in the study. Any cases subjected to neo-adjuvant chemotherapy were excluded. Patients who were unwilling to participate and who did not consent to the study were not included. Written informed consent was obtained from the participants.

The FNAC technique was performed using 10-cc syringes with a 22-gauge needle under aseptic conditions. No local anaesthesia was administered during the procedure. The aspirated material was evaluated on-site for adequacy. Following FNAC, two smears, made by gently pressing one clean slide over the slide with the specimen material, were air-dried and stained with Giemsa stain. Another two smears were immediately fixed with Papanicolaou stain. Light microscopy technique was used to examine the specimens. Breast lesions on cytopathology (FNAC) were categorized as per the International Academy of Cytology (IAC) Yokohama System, which classifies breast FNAC into five diagnostic categories:

- **C1 – Inadequate/Insufficient**
- **C2 – Benign**
- **C3 – Atypical, probably benign**
- **C4 – Suspicious for Malignancy**
- **C5 – Malignant**

When available, the FNAC results were compared with corresponding histological diagnoses and diagnostic performance was evaluated by calculating:

- **Sensitivity**
- **Specificity**
- **Positive Predictive Value (PPV)**
- **Negative Predictive Value (NPV)**
- **Risk of Malignancy (ROM) for each category**

The mastectomy specimens of breast lesions, received in the histopathology department, were fixed in 10% formalin. These specimens were grossly and aptly sampled after adequate fixation. The tissue samples were processed, and slides were prepared. Staining was performed using hematoxylin and eosin stain.

Diagnostic Scenarios for Accuracy Calculation

FNAC performance was assessed under three diagnostic thresholds:

1. **Scenario 1:** C2 considered benign; C3, C4, and C5 as malignant.
2. **Scenario 2:** C2 and C3 considered benign; C4 and C5 as malignant.
3. **Scenario 3:** C1 to C4 considered non-malignant; only C5 considered malignant.

A thorough history, a clinical examination, and a review of the cytological results from FNAC procedures were all included in the data gathering process. This comprehensive approach facilitated a robust analysis of the participants' cytomorphological patterns of breast lesions.

Statistical analysis

The diagnostic performance of FNAC was assessed in cases where histopathological confirmation through biopsy was available. Key metrics – including sensitivity, specificity, PPV and NPV– 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.

III. Results

In the present study, 113 patients aged 16– 80 years underwent FNAC for breast masses with a strong female predominance (109 females, 4 males). The age distribution in relation to sex is shown in Table 1. According to the IAC standardized reporting, 113 cases were graded with a code (C1–C5) as shown in Table 2. Follow-up data on histopathological reports were available for 75 of the cases, among which 33 were benign and 42 were malignant (Table 2).

Table 1: Age and sex distribution

Age (Years)	≤ 20	21- 40	41- 60	61- 80	Total
Male	0	1	3	0	4
Female	7	39	45	18	109
Total	7	40	48	18	113

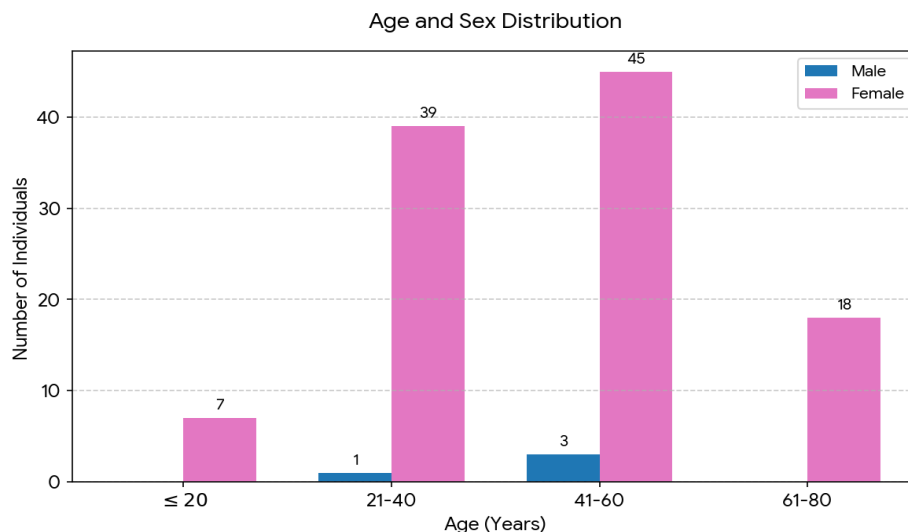
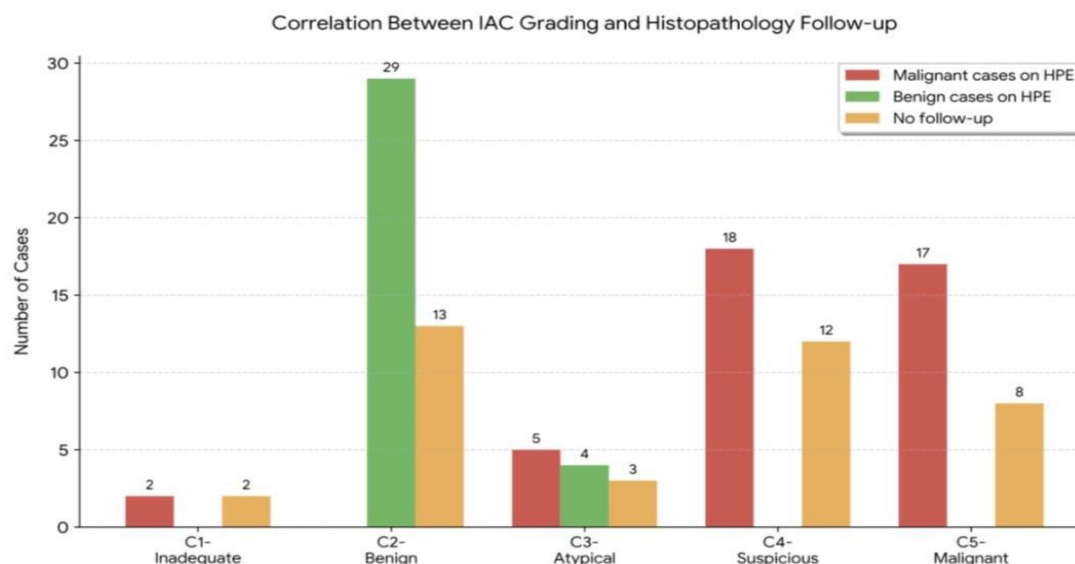


Table 2: Correlation between IAC grading and histopathology follow-up

IAC grading cytology	Number of cases in cytology	Number of cases where surgical specimen was received	Malignant cases on HPE	Benign cases on HPE	Risk Of Malignancy ROM (%)	No follow-up
C1- Inadequate/Insufficient	4	2	2	0	100	2
C2- Benign	42	29	0	29	0	13
C3- Atypical, probably benign	12	9	5	4	55.5	3
C4- Suspicious for malignancy	30	18	18	0	100	12

C5-Malignant	25	17	17	0	100	8
Total	113	75	42	33	-	38



Category 1: Inadequate/ Insufficient material

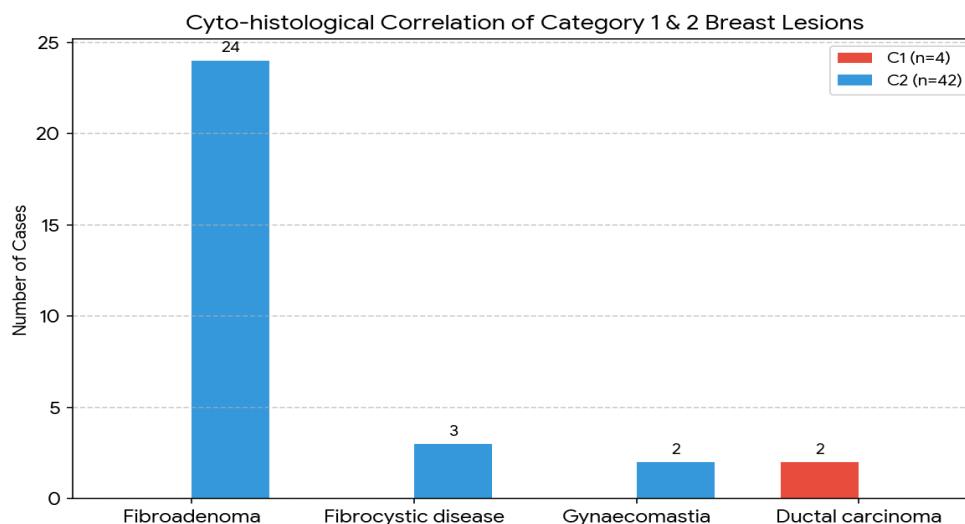
Smears that do not show epithelial cells are labelled as insufficient or inadequate collections. According to the MD Anderson Cancer Centre Group's proposal, the presence of 4–6 well-visualized groups ≥ 10 cells or flat sheets is considered adequate¹³. In the current study, the C1 category comprised four cases (3.53%), two of which were later diagnosed as malignant on HPE (Table 2, 3).

Category 2: Benign

Category 2 comprised lesions showing benign epithelial clusters with no atypical or malignant features. High cellularity is rare in these cases, and cells present a low nucleocytoplasmic ratio, fine chromatin, no pleomorphism, and a smooth nuclear membrane. Fatty fragments are common, along with bare nuclei. In the present study, most lesions belonged to the C2 category (42 cases, 37.16%). Among these 42 lesions, 36 (85.71%) were fibroadenomas, 4 (9.52%) were fibrocystic diseases and 2 (4.76%) were gynecomastia. In the C2 category, follow-up data on HPE were available for 29 cases (Table 3), including 24 cases of fibroadenomas, 3 cases of fibrocystic diseases and 2 cases of gynecomastia.

Table 3: Cyto- histological correlation of category 1 and 2 breast lesions

Histopathology	IAC GRADING				
	C1(n=4)	C2(n=42)			
		Fibroadenoma	Fibrocystic disease	Gynaecomastia	Ductal carcinoma
Fibroadenoma	-	24	-	-	-
Fibrocystic disease	-	-	3	-	-
Gynaecomastia	-	-	-	2	-
Ductal carcinoma	2	-	-	-	-



Category 3: Atypical, probably benign

Findings of category 3 lesions are similar to those in the benign category but with slight crowding, greater cellularity, pleomorphism, three-dimensional grouping, and nuclear enlargement. C3 lesions in our study were present in 12 cases (10.61%), all diagnosed as fibroadenoma with atypia (Fig. 2). Follow-up data were available for 9 C3 cases, including 4 cases of fibroadenoma and 5 cases of malignancy (Table 2).

Category 4: Suspicious, probably in situ or invasive carcinoma

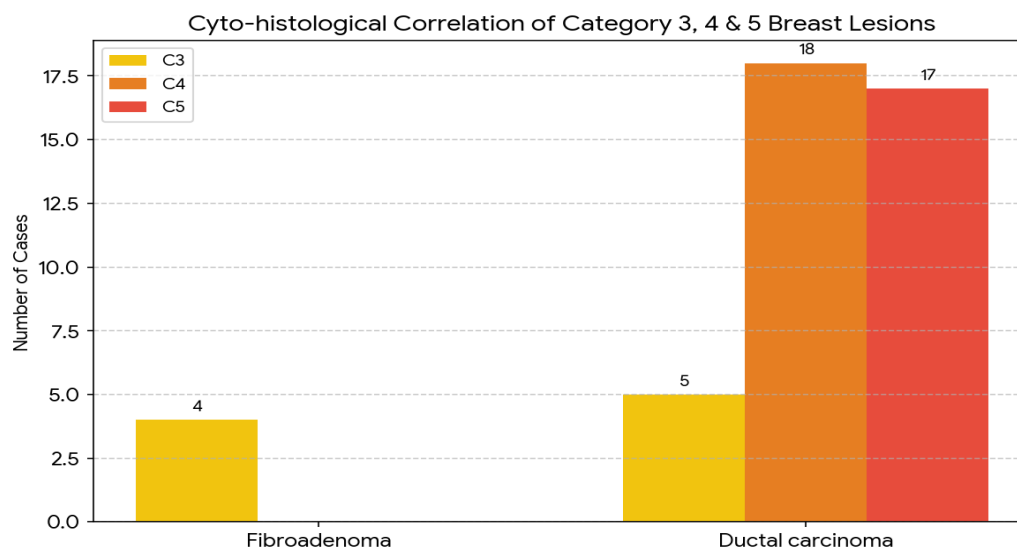
Category 4 lesions exhibit highly atypical findings that remain insufficient to label them as malignant. Cases in this category include those with poorly preserved or hypocellular smears, those with focally atypical cells in a benign background, and those with an insufficient degree of atypia to classify C5 but where the atypia is greater than that of C3. In the present study, C4 lesions were the second most common entity, found in 30 cases (26.54%). On follow-up, 18 cases were confirmed to be ductal carcinoma (Table 2).

Category 5: Malignant

These lesions show high cellularity. Cells are seen in singles or loose clusters, and malignant features such as hyperchromasia, high nucleocytoplasmic ratio, irregular nuclear contour, and conspicuous nucleoli are noted. Some cases show necrotic debris in the background. Follow-up was available for only 17 cases out of total 25 C5 cases, which were all confirmed to be ductal carcinoma (Table 2, Fig. 3).

Table 4: Cyto- histological correlation of category 3, 4 and 5 breast lesions

Histopathology	IAC GRADING			
	C3(n=12)	C4(n=30)	C5(n=25)	Total
	Fibroadenoma with atypia	Suggestive of ductal carcinoma	Ductal carcinoma	
Fibroadenoma	4	-	-	4
Ductal carcinoma	5	18	17	40
Total	9	18	17	44



The Risk of malignancy (ROM) was calculated as 100% for category I, IV and V, 55.5% for category III and 00% for category II.

The diagnostic accuracy of FNAC was assessed using three different interpretation thresholds:

1. Scenario 1: C2 considered benign; C3, C4, and C5 as malignant.
2. Scenario 2: C2 and C3 considered benign; C4 and C5 as malignant.
3. Scenario 3: C1 to C4 considered non-malignant; only C5 considered malignant.

Table 5: Statistical Results for Diagnostic Scenarios (n = 113)

Metric	Scenario 1	Scenario 2	Scenario 3
Sensitivity	100	87.50	40.47
Specificity	87.87	86.84	100
Positive predictive value	90.90	100	100
Negative predictive value	100	86.84	56.89
Accuracy	84.52	93.15	66.66

Interpretation:

- Scenario 1, where C3, C4, and C5 are considered malignant, shows the highest sensitivity but slightly lower specificity.
- Scenario 2 offers a balanced profile, with high values across all parameters.
- Scenario 3, where only C5 is labelled malignant, gives perfect specificity and PPV, but lower sensitivity due to exclusion of borderline categories.

This demonstrates the importance of incorporating suspicious and atypical categories (C3 and C4) for improved diagnostic coverage in clinical settings. The IAC Yokohama system showed excellent sensitivity, specificity, and accuracy in every situation; performance improved when atypical and suspicious categories (C3 and C4) were added as positive interpretations. This demonstrates the system's dependability in diagnosing breast FNAC.

IV. Discussion

The International Academy of Cytology's (IAC) diagnostic performance is assessed in this study through fine-needle aspiration cytology (FNAC) and by incorporating histopathological correlation in 75 out of 113 cases. Diagnosing breast cancers at an early stage is imperative for suitable treatment outcomes, but cases often go undiagnosed for socio-economic reasons. Hence, it is of paramount importance that an easy, cost-effective, and reliable investigation like FNAC be performed in such circumstances¹⁴. The results confirm the importance of uniform cytological classification, particularly in regions with low resources where FNAC is still the main diagnostic technique.

In this study, the 41–60 age group emerged as the most affected, and 21- 40 age group as the second most affected, highlighting a predominance of breast pathology in younger women as well in the reproductive age group. This aligns with prior findings by Mrudula et al., Yoga lakshmi et al., Bhavani et al., and Yerakly et al.,

emphasizing the need for early screening and cytological assessment in this demographic to enable timely diagnosis and intervention¹⁵. 3 males in the former age group and one from the later age group were included in this study.

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 build appropriate clinical management strategies.

Category 1: Inadequate smears

In our study, 4 cases were coded as C1 due to inadequate cytological samples, characterized by low cellularity and haemorrhagic backgrounds from small, ill-defined swellings. These findings bring to light the critical role of operator skill and interpretive expertise in ensuring FNAC adequacy and diagnostic reliability. As shown in Table 6, our study documented a C1 prevalence of 2.9%, which was almost similar to that reported by Nigam JS et al¹⁶.

Category 2: Benign

Cases in the C2 category are considered benign and include instances of fibroadenoma, fat necrosis, abscess, granulomatous mastitis, and other benign entities such as intra-mammary lymph nodes. Cytology smears in these cases will demonstrate a regular ductal epithelium, cysts, or fibrofatty fragments depending on the etiology. Most of the cases in our study were C2 cases (37.16%), concurring with rates in De rosa et al. (Table 6) Among the C2 cases, fibroadenomas were most common (85.71%), as reported by Modi et al²³.

Category 3: Atypical, probably benign

Cases in the C3 category are atypical but probably benign and include papillary lesions. Cytology smears in such instances may show pleomorphism, increased cellularity, and loss of cohesion. No definitive surgery is recommended for cases in this category. The prevalence of C3 cases was 10.61% in the present study, similar to reports by both Nigam et al¹⁶ and De rosa et al et al¹⁸. Meanwhile, Kamatar et al²⁰ encountered a much lower frequency of C3 lesions (Table 6)

Category 4: Suspicious, probably in situ or invasive carcinoma

Category 4 cases are suspicious for malignancy. Cytology findings may show scant/ poor preservation of cells, along with occasional malignant cells or some features of malignancy. However, no definitive surgery is recommended for this category. Kamatar et al.¹⁷ and Montezuma et al¹⁹ reported very few cases of C4 lesions, opposite to the observations in our study. C4 lesions were the second most common lesions after C2 lesions in our, which indicates a rising trend in the frequency of suspicious breast cancer cases. In the present study, 30 cases (26.54%) were reported as C4 and 18 cases were histologically confirmed as ductal carcinoma.

Category 5: Malignant

Cytology smears will show overt malignant features like a high nucleocytoplasmic ratio, hyperchromasia, irregular nuclear contours, and conspicuous nucleoli. The risk for malignancy is 100%. In the present study, malignant cases (C5) were accurately identified by FNAC as later confirmed by histopathology. This was also true in Panwar et al²⁴. However, 8 cases (C5) were lost to follow-up in our study (Table 2)

Table 6: Comparison of various studies that used International Academy of Cytology Grading

	C1	C2	C3	C4	C5
Nigam JS et al ^[16]	3.2	46.34	12.2	4.88	33.33
Kamatar et al ^[17]	59	71	1	2	21
De Rosa et al ^[18]	19.2	36.9	10.8	4.7	28.4
Montezuma et al ^[19]	5.77	73.38	13.74	1.57	5.54
Dogra et al ^[20]	7.8	64.39	7.31	7.80	12.68
Agarwal et al ^[21]	19	50.2	6.6	3.8	20.4
Present study	3.53	37.16	10.61	26.54	22.12

Table 7: Correlation of ROM of IAC Yokohama system (present study) with other studies

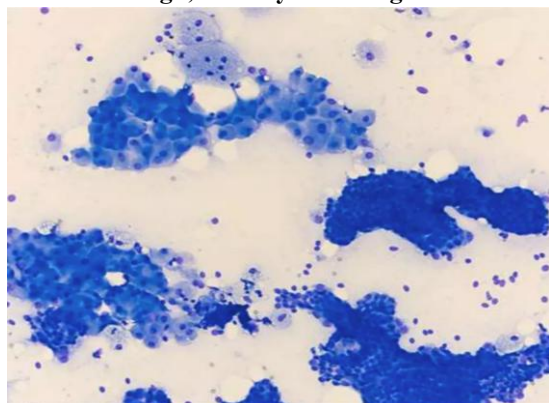
	C1	C2	C3	C4	C5
Nigam JS et al ^[16]	50	7.27	40	83.33	97.5
Kamatar et al ^[17]	0	4	66	83	99
De Rosa et al ^[18]	49.6	4.9	20.7	78.7	98.8

Montezuma et al ^[19]	4.8	1.4	13	97.1	100
Dogra et al ^[20]	100	0	55.5	100	100
Agarwal et al ^[21]	60.9	8.3	17.2	77.8	100
Present study	100	00	55.5	100	100

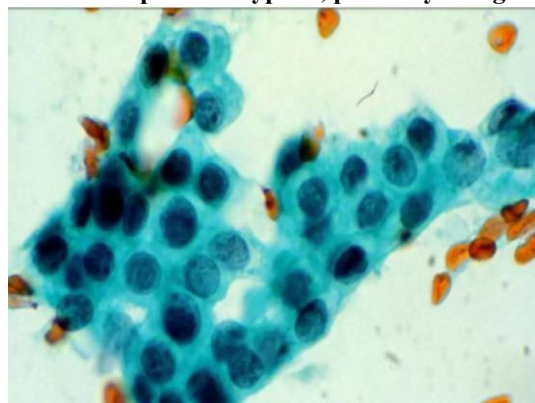
Table 8: Correlation of statistical parameters of present study with several other studies

	Sensitivity	Specificity	PPV	NPV	Diagnostic accuracy
Nigam JS et al ^[16]	73.58	98.46	97.5	82.05	87.29
Kamatar et al ^[17]	97	94	91	98	95
Malvina D and Reshma G ^[22]	95.12	100	100	91.66	96.82
Montezuma et al ^[19]	97.56	100	100	98.62	99.11
Dogra et al ^[20]	74.07	100	100	86	90

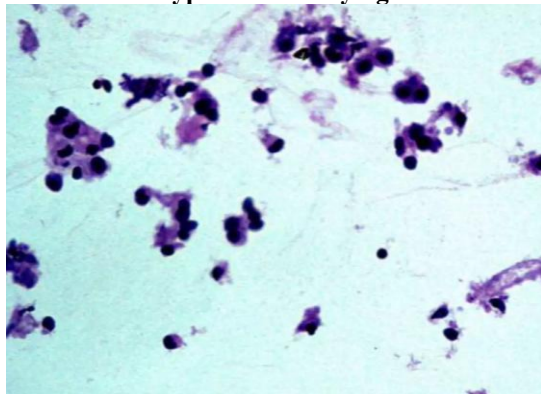
C2: Benign, Fibrocystic change



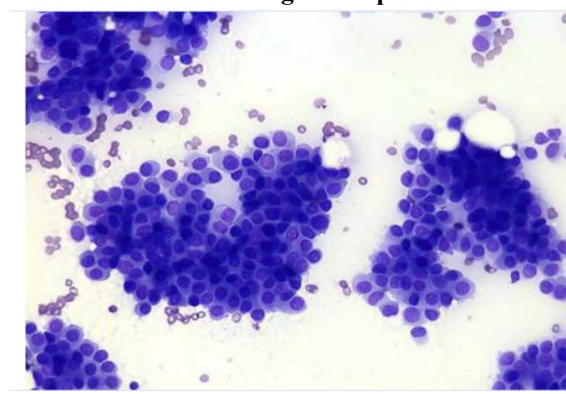
C3 Aspirate: Atypical, probably benign



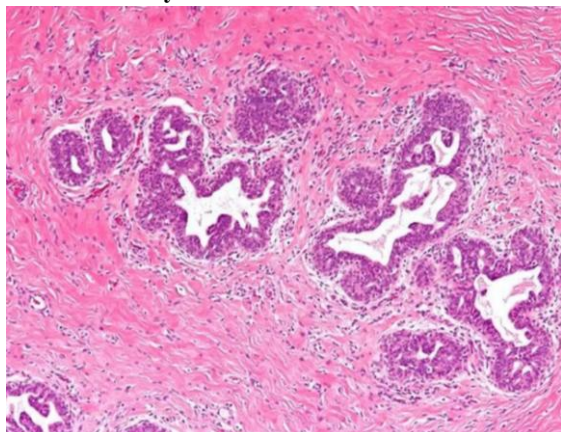
Atypia: due to drying artifact



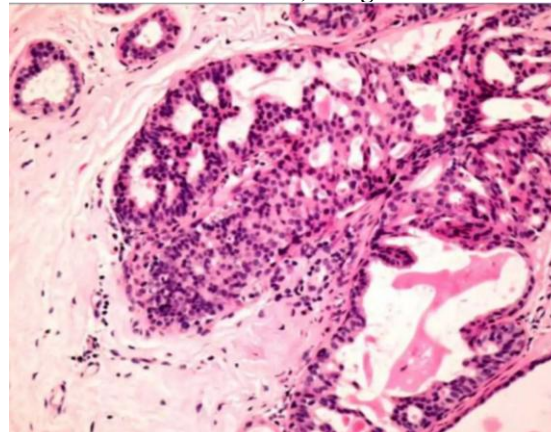
C5: Malignant aspirate



Gynaecomastia: Male breast tissue



Ductal Carcinoma, low grade



V. Limitation of the Study

1. Single-center design: Because the study was conducted at a single institution, the findings might not be as applicable to other regions or groups.
2. Relatively small sample size (n=113): More statistical power and more reliable subgroup analysis would be possible with a larger sample.
3. Operator-dependent variability: The cytopathologist's and performing clinician's experience, which was not consistent across instances, may have an impact on FNAC outcomes.
4. Limited follow-up data: Long-term patient outcomes and recurrence in instances with inconsistent Cyto-histology results were not evaluated in this investigation.
5. Absence of radiological correlation data: The triple assessment approach is great; however this analysis did not formally incorporate radiological findings.

VI. Conclusion

With a strong connection with histopathology, our results validate the IAC Yokohama System's usefulness in standardizing breast cytology reporting. The clinical relevance of the C3 and C4 categories is reinforced by their inclusion in malignant interpretation, which improves diagnostic sensitivity and accuracy. Frequent use of the system may enhance early diagnosis, lower inter-observer variability, and increase clinician-pathologist communication.

The field of cytological diagnostics is changing as a result of the continuous integration of cutting-edge technologies like LBC, molecular testing employing FNAC samples, and digital pathology assisted by WSI and AI. Even in the current era of breast pathology, FNAC is a useful and relevant tool because of these advancements, which enable more accurate molecular profiling, better sample preservation, and improved diagnostic accuracy. FNAC's importance may grow as these technologies advance, offering a less intrusive, efficient, and cost-effective option for diagnosing breast cancer, especially in multidisciplinary settings where prompt, accurate diagnoses are essential for treatment planning.

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Availability of Data and Material

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

Conflicts of Interest

The authors declare that they have no potential conflicts of interest.

Funding Statement

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