Original Article

Study of Breast Cytology Smears Using the International Academy of Cytology Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology

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Abstract

Background: Breast cancer is a major global health burden, especially in low- and middle-income regions where fine-needle aspiration cytology (FNAC/FINE NEEDLE ASPIRATION CYTOLOGY) remains a widely used diagnostic tool. The International Academy of Cytology (IAC) Yokohama System provides a standardized, evidence-based framework to improve diagnostic consistency in breast cytology.

Objective: To evaluate the diagnostic utility, accuracy, and risk of malignancy (ROM) of the IAC Yokohama System in categorizing breast FNAC/FINE NEEDLE ASPIRATION CYTOLOGY samples in a tertiary care setting.

Methods: A prospective study of 128 FNAC/FINE NEEDLE ASPIRATION CYTOLOGY samples from 120 patients was conducted and categorized according to the IAC Yokohama System. Cyto-histopathological correlation was available for 26 cases. Diagnostic performance indices were calculated using MedCalc.

Results: The distribution of cases was: Category 2 (Benign), 78.1%; Category 3 (Atypical), 3.3%; Category 4 (Suspicious), 3.3%; and Category 5 (Malignant), 15.6%. No Category 1 cases were recorded. Fibroadenoma was the most common benign lesion (38.2%). Overall cyto-histopathological concordance was 84.6%. ROM was 0% (Category 2), 66.7% (Category 3), and 100% for Categories 4 and 5. Diagnostic performance showed sensitivity 40.0%, specificity 95.2%, positive predictive value 66.7%, negative predictive value 87.0%, and overall accuracy 84.6%.

Conclusion: The IAC Yokohama System enhances the diagnostic reliability of FNAC/FINE NEEDLE ASPIRATION CYTOLOGY for distinguishing benign and malignant breast lesions. However, indeterminate categories (3 and 4) continue to require histopathological confirmation. The system offers significant value in resource-constrained settings, though larger multicentric studies are warranted to refine ROM estimates and strengthen generalizability.

Keywords: IAC Yokohama System; Breast cytopathology; FNAC/FINE NEEDLE ASPIRATION CYTOLOGY; Risk of malignancy; Breast cancer

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Introduction

Breast cancer remains the most common malignancy among women worldwide and is a significant contributor to cancer-related morbidity and mortality[1]. According to GLOBOCAN 2022, female breast cancer accounts for 11.6% of all cancers globally, with approximately 2.3 million new cases annually. In India, breast cancer is the leading cancer among women, with 216,108 new cases and 98,337 deaths reported in 2022. Early and accurate diagnosis is therefore crucial, particularly in low- and middle-income countries where resource limitations may restrict access to advanced diagnostic modalities.[2]

Fine-needle aspiration cytology (FNAC/FINE NEEDLE ASPIRATION CYTOLOGY) continues to play a central role in the evaluation of palpable breast lesions due to its minimally invasive nature, low cost, rapid turnaround time, and high patient acceptability. However, diagnostic variability arising from subjective interpretation has historically been a challenge, potentially leading to inconsistent reporting and suboptimal clinical decision-making.[3]

To address this, the International Academy of Cytology (IAC) introduced the Yokohama System in 2019, a standardized reporting framework that categorizes breast cytology into five diagnostic groups: Category 1 (Insufficient), Category 2 (Benign), Category 3 (Atypical), Category 4 (Suspicious for Malignancy), and Category 5 (Malignant). This structured system aims to improve diagnostic reproducibility, enhance communication between clinicians and cytopathologists, and facilitate evidence-based patient management.[4]

Given the high burden of breast disease in India and the reliance on FNAC/FINE NEEDLE ASPIRATION CYTOLOGY as a frontline diagnostic tool, applying a standardized system such as the IAC Yokohama System becomes particularly relevant. The present study was conducted to evaluate the diagnostic utility, accuracy, and risk of malignancy associated with each category of the Yokohama System in a tertiary care setting.[5]

Materials and Methods

Study Design and Setting

This hospital-based prospective observational study was conducted in the Department of Pathology, Muzaffarnagar Medical College, Uttar Pradesh, over a period of 18 months. A total of 128 fine-needle aspiration cytology (FNAC/FINE NEEDLE ASPIRATION CYTOLOGY) samples were obtained from 120 patients presenting with palpable breast lumps. Bilateral breast involvement was noted in eight patients.

Inclusion and Exclusion Criteria

Inclusion criteria:

- Patients presenting with palpable breast swellings.
- Patients undergoing ultrasound- or CT-guided FNAC/FINE NEEDLE ASPIRATION CYTOLOGY for non-palpable lesions.

Exclusion criteria:

- Uncooperative patients.
- Patients with bleeding disorders or contraindications to FNAC/FINE NEEDLE ASPIRATION CYTOLOGY.

Procedure

FNAC/FINE NEEDLE ASPIRATION CYTOLOGY was performed using a 21G or 23G needleattached to a 10 mL syringe under strict aseptic precautions. Aspirated material was smeared onto clean glass slides and stained using:

- May–Grünwald–Giemsa (MGG) stain
- Papanicolaou stain

Cytological smears were categorized according to the International Academy of Cytology (IAC) Yokohama System for Reporting Breast FNAC/ FINE NEEDLE ASPIRATION CYTOLOGY, which classifies cases into:

1. **Category 1 – Insufficient / Inadequate:** scant cellularity, poor preservation, or non-representative material
2. **Category 2 – Benign:**cytomorphology consistent with non-neoplastic benign lesions
3. **Category 3 – Atypical:** cytological features more than benign but insufficient for malignancy
4. **Category 4 – Suspicious for malignancy:** significant atypia but not fully diagnostic
5. **Category 5 – Malignant:** definitive cytological evidence of malignancy

Biopsy specimens were available for 26 patients and were processed routinely. Formalin-fixed tissue was embedded in paraffin, sectioned, and stained with hematoxylin and eosin (H&E) for histopathological correlation.[6]

Statistical Analysis

Data analysis was performed using MedCalc software (version 22.020). Diagnostic performance parameters were calculated for FNAC/FINE NEEDLE ASPIRATION CYTOLOGY:

- Sensitivity
- Specificity
- Positive predictive value (PPV)
- Negative predictive value (NPV)
- Diagnostic accuracy

Risk of malignancy (ROM) was calculated for each Yokohama category using corresponding histopathological outcomes.[7]

Results

This prospective study analyzed 128 fine needle aspiration cytology (FNAC) samples from 120 patients presenting with palpable breast lumps at Muzaffarnagar Medical College and Hospital over a period of 18 months. The cytological findings were systematically categorized according to the International Academy of Cytology (IAC) Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology. The study aimed to assess the spectrum of breast lesions, their distribution across these categories, and their cytohistopathological correlation.

The study examined the clinical characteristics of breast lumps, several key findings were observed. Laterality analysis revealed a predominance of right-sided breast lumps, accounting for 54.1% (n=69) of cases, followed by left-sided lumps at 39.1% (n=50), and bilateral involvement in 6.6% (n=8).

The majority of breast lumps (92.1%) measured between 2 and 5 cm, with a mean size of 2.94 cm and a range spanning from 1.5 to 5.5 cm. Larger lumps exceeding 5 cm constituted 5.4% of the cases. In terms of mobility and consistency, 81.6% of the breast lumps were mobile, while 18.3% were fixed. Specifically, within Category 2 lesions, 75% were mobile, whereas in Category 5, 12.5% were fixed. Hard consistency was observed in 17.8% of cases.

The age distribution of patients ranged from 11 to 80 years, with a mean age of 31 years. More than half (52.5%) presented in their third and fourth decades of life, and 91.6% were under the age of 50. Non-lactating females comprised 96.6% of the cases, while lactating females accounted for 3.3%, primarily presenting with lactational changes or mastitis.

These findings underscore the importance of laterality, size, mobility, consistency, age, and lactational status in the clinical evaluation of breast lumps, as they can provide valuable insights into the nature of the lesion and guide appropriate management strategies.

Of the 128 FNAC samples the distribution across the International Academy of Cytology (IAC) Yokohama System categories was as follows: Category 1 (Insufficient/Inadequate) had no reported cases (0%), which can be attributed to the use of repeat or image-guided FNAC for initially inadequate samples, ensuring sufficient cellular material for diagnosis. Category 2 (Benign) was the most prevalent, comprising 100 cases (78.1%), reflecting the predominance of non-malignant breast conditions in the study population. Category 3 (Atypical) included four cases (3.3%) that exhibited cytological features suggestive of neoplasia but did not fulfill the criteria for malignancy. Similarly, four cases (3.3%) were categorized as Category 4 (Suspicious for Malignancy), where the cytological features strongly indicated malignancy but lacked definitive diagnostic criteria of malignancy. Lastly, Category 5 (Malignant) encompassed twenty cases (15.6%) that were diagnosed as malignant, confirming the presence of breast carcinoma based on definitive cytomorphological findings.

Table 1: Distribution of cases as per various types of cytological categories of breast lumps (As per The International Academy of Cytology Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology) (N=128)

CATEGORY	NO. OF CASES	PERCENTAGE (%)
2 (Benign)	100	78.1
3 Atypical)	4	3.2
4 (Suspicious for malignancy)	4	3.2
5 (Malignant)	20	15.5
Total	128	100

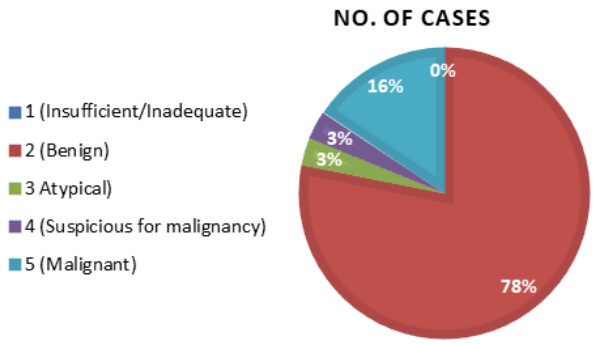

Figure 1: Pie diagram showing category wise distribution of breast lesions on FNAC (N=128)

The predominance of Category 2 cases aligns with global trends, where benign breast lesions are more common, particularly in younger populations. The malignant cases (Category 5) constituted a significant proportion, underscoring the burden of breast cancer in the study setting.

The spectrum of breast lesions identified in this study revealed a predominance of benign lesions among the 100 cases classified under Category 2 of the IAC Yokohama System. Within this category, benign neoplastic lesions comprised 53% (38.2% of total cases). Among these, fibroadenoma was the most frequent, accounting for 92.4% of benign neoplasms (49 cases, 38.2% of total), typically presenting as well-circumscribed, mobile masses in younger women and showing large, cohesive epithelial fragments, stromal fragments, and numerous bare bipolar nuclei on cytology. Benign phyllodestumors represented 5.6% (3 cases) of this subgroup, with hypercellular smears, bonsai-like epithelial clusters, and distinct stromal cellularity. One benign lipomatous lesion (1.8%) was identified, characterized by smears with mature adipocytes and scant stroma. Inflammatory lesions made up 18% of Category 2 cases, including 12 cases (66.6%) of mastitis with neutrophil-rich smears and necrotic debris, and 6 cases (33.3%) of granulomatous mastitis, which displayed granulomas with epithelioid histiocytes and multinucleated giant cells. Cystic lesions accounted for 15% of Category 2 cases, primarily fibrocystic change (14 cases, 93.3%) showing foamy histiocytes, apocrine cells, and proteinaceous background, while one benign cystic lesion (6.6%) lacked apocrine epithelium. Epithelial hyperplasia was seen in 8% of Category 2 cases, with smears demonstrating large ductal epithelial fragments, myoepithelial cells, and mild nuclear enlargement. Lactational changes were observed in 3 cases (3%), characterized by vacuolated epithelial cells and neutrophils. Additionally, galactocele was identified in 2 cases (2%) by milky aspirates and benign epithelial cells, and fat necrosis was noted in 1 case (1%), presenting with adipocytes, inflammation, and necrotic debris.

Among the 20 malignant cases (Category 5), invasive carcinoma of no special type (NST) was the most common, diagnosed in 18 cases (14% of total), featuring discohesive cells, marked nuclear atypia, irregular chromatin, and prominent nucleoli. One case of bilateral lobular carcinoma was also identified, distinguished by small, uniform cells with intracytoplasmic lumina and minimal pleomorphism. In the atypical (Category 3) and suspicious (Category 4) categories, each comprised four cases. Category 3 lesions showed mild nuclear enlargement and pleomorphism, not typical of benign processes, necessitating further assessment. Category 4 cases displayed increased cellularity and nuclear atypia, highly suggestive of malignancy but without definitive diagnostic criteria.

Cytohistopathological correlation was available for 26 cases. All 20 Category 2 cases with follow-up showed 100% concordance, confirming the diagnostic accuracy of FNAC for benign lesions. In Category 3, histopathological follow-up was available for three cases, of which two were confirmed malignant (ductal carcinoma in situ and invasive carcinoma NST), underscoring the intermediate risk associated with this category. The single Category 4 case with histopathology was confirmed malignant, reflecting the high-risk nature of this category. Both malignant cases with histopathological correlation, including the bilateral lobular carcinoma, showed complete agreement, validating FNAC's reliability in diagnosing malignancy. Overall, 22 out of 26 cases (84.6%) showed concordance between cytological and histopathological findings, while 4 cases (15.4%) were discordant, mainly within Categories 3 and 4.

The types of histopathological procedures included excisional biopsy (18 cases), core needle biopsy (5 cases), and modified radical mastectomy (3 cases, including 2 bilateral cases).

Table 2: Cyto-histopathological correlation of available biopsies.

S.no	Cyto Category (IAC)	No. Of Cases	Cyto Diagnosis	Histopathological Diagnosis	No of cases (n)
1	**2** (n=20)	13	Fibroadenoma	Fibroadenoma	9
				Fibrocystic disease	1
				Breast hamartoma	2
				Tubular adenoma	1
		2	Acute Mastitis	Fibroadenoma	1
				Lobular Mastitis	1
		2	Epithelial Hyperplasia	Fibroadenoma	2
		1	Idiopathic Gran. Mastitis	Neutrophilic gran mastitis	1
		1	Tubercular Mastitis	Tubercular Mastitis	1
		1	Fibrocystic change with collagenous spherulosis	Fibrocystic Change with collagenous spherulosis	1
2	**3** (n=3)	3	Atypical	Fibroadenoma	1
				Invasive ductal carcinoma	1
				Invasive ductal carcinoma	1
3	**4** (n=1)	1	Suspicious of malignancy	Invasive ductal carcinoma	1
4	**5** (n=2)	2	Lobular carcinoma	Lobular carcinoma	2

The Risk of Malignancy (ROM) was assessed based on histopathological confirmation. In Category 1, classified as insufficient, there were no cases, rendering the ROM inapplicable. For Category 2, (Benign), the ROM was 0%, as none of the 20 cases with histopathological follow-up were found to be malignant. In Category 3, (Atypical), 3 out of 4 cytology cases had follow-up, with 2 confirmed as malignant, resulting in a ROM of 66.7%. Category 4, (Suspicious for malignancy), included 4 cytology cases as well, with 1 case undergoing follow-up and confirmed as malignant, leading to a ROM of 100%. Finally, in Category 5, (Malignant), among the 20 cytology cases, 1 case with a bilateral presentation had follow-up, which was confirmed malignant, also yielding a ROM of 100%.

Statistical Parameters, the diagnostic performance of fine needle aspiration cytology (FNAC) was assessed using several statistical parameters. The sensitivity was found to be 40%, suggesting a moderate capacity to detect malignant cases, which may be attributed to the limited number of histopathological correlations available. In contrast, the specificity was notably high at 95.2%, showcasing FNAC's strong accuracy in identifying benign cases. The positive predictive value (PPV) stood at 66.6%, indicating that a significant proportion of positive cytology results were confirmed as malignant. Additionally, the negative predictive value (NPV) recorded at 86.9% highlighted the reliability of negative cytology results in effectively ruling out malignancy. Overall, the diagnostic accuracy of FNAC was recorded at 84.6%, reflecting its general effectiveness in correctly classifying breast lesions.

Table 3: Cytohistological correlation (N=26)

Cytology		Histopathology	
IAC Category	No. of cases	Consistent	Inconsistent
2	20	20	0
3	3	0	3
4	1	0	1
5	2	2	0
Total	26	22	4

* One case each in category 2 and category 5 was bilateral.

Discussion

This prospective study reinforces the continued value of fine-needle aspiration cytology (FNAC/ FINE NEEDLE ASPIRATION CYTOLOGY) as a rapid, minimally invasive, and cost-effective diagnostic modality for evaluating breast lesions, especially in resource-limited settings where advanced imaging and core biopsies may not be readily accessible. Breast cancer remains the most common malignancy among women in India, and therefore early, reliable diagnostic triage is crucial for improving outcomes.[8]

Application of the IAC Yokohama System provided a structured and evidence-based framework for FNAC/FINE NEEDLE ASPIRATION CYTOLOGY reporting, reducing subjectivity and improving communication between cytopathologists and clinicians. The predominance of benign cases (78.1%), especially fibroadenomas in younger women, parallels global findings. Similar proportions have been reported by Montezuma et al. [9] (73.3%) and Apuroopa et al.[10], although institutional and demographic differences may account for slight variation.

The proportion of malignant cases (15.6%), predominantly invasive carcinoma of no special type (NST), is consistent with studies by Agrawal et al.[11]and Ahuja et al.[12] , supporting the reproducibility of the Yokohama System across diverse patient populations. The system's utility is particularly evident in Category 5, which showed a risk of malignancy (ROM) of 100% with complete concordance on histopathology. This underscores the system's reliability in guiding immediate and definitive management.

The higher ROM observed in Category 3 (66.7%) compared with prior studies, such as Ahuja et al.[12] (17.4%) and Kamatar et al.[13] (16%), suggests institutional variation, sampling differences, and borderline cytological features contributing to atypical cases. Category 4 (Suspicious) also demonstrated a ROM of 100%, consistent with its inherently high-risk nature. These findings highlight the need for mandatory histopathological evaluation of Categories 3 and 4, as recommended by the Yokohama guidelines.

The absence of insufficient samples (Category 1) reflects effective sampling techniques, including the selective use of repeat aspiration and image-guided FNAC/FINE NEEDLE ASPIRATION CYTOLOGY. Such practices align with evidence from Wong et al.[14], who emphasized the role of rapid on-site evaluation (ROSE) in minimizing inadequate samples.

Diagnostic performance showed high specificity (95.2%) and overall accuracy (84.6%), comparable to earlier studies by De Rosa et al.[15] and Oosthuizen et al.[16] However, the sensitivity (40%) was lower, likely due to the limited number of cases with available histopathology (n=26), than Kamatar et al. [13] (97%) or Verma et al.[17] (100%). This limitation affects the stability of sensitivity estimates and signifies the need for larger cohorts to achieve more robust diagnostic indices.

Clinical characteristics, such as right-sided predominance (54.16%) and mobility (81.6%), align with Sigmani et al. [18] and Bal et al.[19], reinforcing typical presentations of benign lesions. The mean lump size (2.94 cm) and hard consistency (17.8%) in malignant cases provide valuable clinical correlates for diagnosis.

Limitations include the small histopathological cohort, potentially skewing ROM and sensitivity estimates, and the single-institution setting, which may limit generalizability. Future studies should incorporate larger, multicenter cohorts and standardized ROSE protocols to further validate the Yokohama System's utility.

In conclusion, FNAC, guided by the IAC Yokohama System, is a reliable preoperative diagnostic tool for breast lesions, with high concordance for benign and malignant categories.[20] Its challenges in atypical and suspicious categories highlight the complementary role of histopathology, ensuring optimal patient management in breast cancer carcinoma.

Limitations

The main limitations of this study include:

1. Small number of cases with histopathological follow-up, limiting sensitivity estimates and ROM precision.
2. Single-center design, which may restrict generalizability.

Implications for Future Research

To strengthen the evidence supporting the Yokohama System, larger multicentric studies with standardized sampling practices and increased histopathological correlation are recommended. Such studies will help refine ROM estimates, improve diagnostic confidence, and enhance the system's applicability in diverse clinical environments.

Conclusion

The International Academy of Cytology (IAC) Yokohama System provides a clear, structured, and reliable framework for reporting breast FNAC/FINE NEEDLE ASPIRATION CYTOLOGY, significantly enhancing diagnostic consistency and clinical communication. In this study, FNAC/FINE NEEDLE ASPIRATION CYTOLOGY demonstrated high accuracy and specificity for distinguishing benign from malignant breast lesions, with complete concordance in clearly benign (Category 2) and malignant (Category 5) categories. Indeterminate categories (3 and 4), however, continue to require histopathological confirmation due to their higher risk of malignancy.

Given its simplicity, low cost, and strong diagnostic performance, the Yokohama System is particularly valuable in resource-limited settings where FNAC/FINE NEEDLE ASPIRATION CYTOLOGY remains a frontline diagnostic tool. Nevertheless, the limited number of histopathological correlations in this study highlights the need for larger, multicentric investigations to refine the risk of malignancy estimates and further validate the system's applicability across diverse populations.

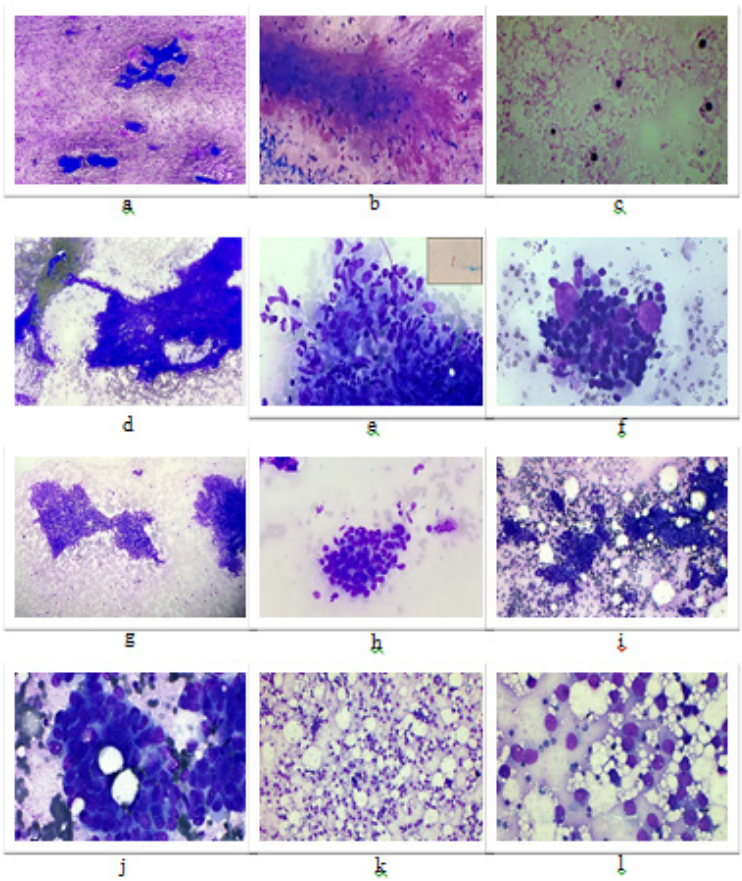

Figure 2: (a) Fibroadenoma (b) Benign phyllodes tumor (c) Galactocele (d) Epithelial hyperplasia (e) Tb mastitis (f) Fibrocystic change with collagenous spherulosis (g) Category 3 : Atypical (h) Category 3 : Atypical (i) Malignant : Invasive Carcinoma NST (j) Malignant : Invasive Carcinoma NST (k,l) Invasive lobular carcinoma.

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