Section: Miscellaneous

Original Research Article

ASSESSMENT OF RISK OF MALIGNANCY AND DIAGNOSTIC ACCURACY BY CATEGORIZATION OF BREAST FINE NEEDLE ASPIRATES USING THE INTERNATIONAL ACADEMY OF CYTOLOGY YOKOHAMA SYSTEM IN A NEWLY ESTABLISHED MEDICAL COLLEGE IN REMOTE AREA OF J&K, INDIA

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ABSTRACT

Background: Breast fine needle aspiration cytology (FNAC) remains a vital diagnostic tool in resource-constrained settings. The International Academy of Cytology (IAC) Yokohama System offers a standardized five-tier classification to improve communication and clinical management. This study aimed to categorize breast FNAs using the IAC Yokohama System and assess the risk of malignancy (ROM) and diagnostic accuracy in a tertiary care centre.

Materials and Methods: A total of 173 breast FNAC cases were retrospectively categorized into five IAC Yokohama categories: Inadequate (Category 1), Benign (Category 2), Atypical (Category 3), Suspicious of Malignancy (Category 4), and Malignant (Category 5). Histopathological correlation was available for 160 cases. ROM was calculated for each category. Diagnostic metrics, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy, were assessed using three diagnostic thresholds.

Results: Of the 173 cases, 160 had histological correlation. ROM for Categories 1 to 5 were 0%, 0%, 11%, 75%, and 100%, respectively. Diagnostic accuracy was highest when Categories 4 and 5 were considered positive, with sensitivity of 84.6%, specificity of 99.3%, PPV of 91.7%, NPV of 98.7%, and overall accuracy of 97.9%.

Conclusion: The IAC Yokohama System provides a reproducible and effective framework for categorizing breast FNAs. The system shows high diagnostic accuracy and stratified ROMs, supporting its clinical utility in triaging breast lesions and guiding patient management.

Keywords: Breast Carcinoma, IAC Yokohama System, Breast FNAC.

INTRODUCTION

Breast cancer is the most common cancer and one of the leading causes of death among women worldwide.[1] According to WHO, about 1 lakh new patients with breast cancer are diagnosed annually in India, and an estimated 70,218 Indian women die due to breast cancer every year.[2] Most breast cancers present as palpable lumps, inflammatory lesions, nipple secretions, or mammographic abnormalities. Preoperative pathology diagnosis constitutes an essential part of the workup of breast lesions wherein radiology and cytology play a crucial role.[3] Several preoperative diagnostic

modalities are used to diagnose breast cancer adequately and preferably on time. Out of which Fine Needle Aspiration Cytology (FNAC) is most used rapid, sensitive, cost effective and less traumatic diagnostic method of breast lesions[4,5]

The International Academy of Cytology (IAC) Yokohama System for Reporting Breast Fine-Needle Aspiration Cytology (FNAC). Cytology was developed by a group of expert cytopathologists and clinicians in the breast field.[6,7] The work started following a meeting at the Yokohama International Congress of cytology in 2016. The goals of the system are to standardize the reporting of breast cytology, improve communication between cytopathologists and clinicians, and facilitate optimal patient care. Breast FNAC is a simple, fast, and cost-effective procedure that can provide a rapid and accurate diagnosis with minimal complications. In developing countries, it is widely used, representing one of the most performed FNAC procedures.[4] The reported sensitivity is 91–92% and the specificity is approximately 98% in two meta-analyses.[8,9] The studies selected in those meta-analyses were based on a set of rules including an assessment of the risk of bias; most of the studies were retrospective while a few were prospective.[10-17] For the diagnosis of breast carcinoma, the positive predictive value (PPV) is particularly high, in the range of 99–100%.5 In developed countries, where medical resources are more readily available, as a component of the "triple test" (the other two are clinical information and imaging information), FNAC has a PPV close to 100%.[18] However, FNAC has intrinsic limitations in that it is unable to assess invasion status (i.e., in situ vs. invasive carcinoma) and intact histologic architecture. Although in many institutions, Core needle biopsy (CNB) has been gradually replacing FNAC, CNB should be used as a complementary rather than a replacement procedure.[19]

The present study aims at classifying the breast FNAs according to the IAC Yokohama system and evaluating the risk of malignancy and diagnostic accuracy of different categories in a newly established medical college hospital. The sensitivity, specificity, PPV, and NPV were also assessed.

MATERIALS AND METHODS

Study was performed in a newly established medical college hospital, Doda, J&K, India. It was a retrospective study in which all the breast fine needle aspirates done from April 2020 to March 2025 (173 FNAs were performed). Informed consent was taken from all patients before FNAC. At least two passes were done from each breast lump, and the adequacy of smears was assessed using rapid onsite evaluation (ROSE) with Diff-quik stain. For breast lesions that were radiologically nonfibrotic and solid, adequacy criteria of at least seven cellular fragments with at least 20 cells in each fragment was suggested, provided no atypical/suspicious or malignant cells were identified. The final reporting was done on smears stained with May Grunwald Giemsa and Papanicolaou stains.

The clinical details were also retrieved, and all cases were categorized according to the IAC Yokohama reporting system into five categories –

C1. Insufficient
C2. Benign
C3. Atypical
C4. Suspicious of Malignancy
C5. Malignant.

Histological diagnosis, which is considered the gold standard, was available in 160 cases (92.48%).

Statistical analysis: The risk of malignancy (ROM) was calculated for each category as the number of malignant cases confirmed histologically/total number of cases in the diagnostic category. The cases in the insufficient category were excluded from further statistical analysis, as they could not be included in either negative or positive for malignancy. Using the histological diagnosis as the gold standard, the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated.

Sensitivity = True positive/ (True positive + False negative)

Specificity = True negative/ (True negative + False positive)

PPV = True positive/ (True positive + False positive)

NPV = True negative/ (True negative + False negative)

Diagnostic accuracy = (True positive + True negative)/All analysed cases

The above ratios were calculated for the following groups–

- Group A- Only the "malignant" category was regarded as a positive report.
- Group B- All cases in the "malignant" and "suspicious of malignancy" category was regarded as positive for malignancy.
- Group C- All cases in the "malignant," "suspicious of malignancy," and "atypical" categories were regarded as positive for malignancy.

RESULTS

A total of 173 patients underwent breast fine needle aspirates in the period from April 2020 to March 2025. The age group of patients ranged from 15 years to 74 years with most cases belonging to the 2nd and 3rd decades.

The breast FNAs were categorized according to the IAC Yokohama System as follows:

C1. Insufficient- 10 cases (6.25%)
C2. Benign- 120 cases (75%)
C3. Atypical- 18 cases (11.25%)
C4. Suspicious of malignancy- 4 cases (2.5%)
C5. Malignant- 8 cases (5%).

Histopathological correlation was available in 160 cases (92.48%). The histopathological diagnoses for the breast lesions in different cytological categories were evaluated and are summarized with cyto-histological correlation in [Table 1].

The ROM for insufficient, benign, atypical, suspicious, and malignant categories were 0%, 0%, 11%, 75%, and 100%, respectively. The sensitivity, specificity, PPV, NPV, and diagnostic accuracy of the three groups are summarized in [Table 2].

Maximum diagnostic accuracy is achieved (97.9%) when malignant and suspicious of malignancy are considered positive, whereas highest sensitivity is achieved (100%) when malignant, suspicious, and atypical are considered positive for malignancy.

Among the suspicious and malignant categories, invasive ductal carcinoma was the most common histological diagnosis, whereas in the benign category, fibroadenoma was the most common. In the atypical category, the majority (88.89%) of the histological diagnoses were benign (cellular fibroadenomas and benign phyllodes).

Table 1- Distribution of IAC Yokohama System categories with cyto- histological correlation and Risk of malignancy

	Insufficient	Benign	Atypical	Suspicious of Malignancy	Malignant
Histological Benign diagnosis	10(Fibrocystic disease-7 Inflammatory lesion-3	120(Fibroadenoma-70 Abscess- 8 Galactocele- 4 Granulomatous mastitis-10, Fibrocystic disease-6 Fat necrosis- 12, Gynecomastia-8 EIC 2)	16 (Benign phyllodes- 11, papilloma- 2, Fibroadenoma with usual ductal hyperplasia- 3)	1 (Cellular FA-1)	0
Histological Malignant diagnosis	0	0	2 DCIS	3(Invasive ductal carcinoma)	8 (Invasive ductal carcinoma)
Risk of Malignancy	0%	0.00%	11.00%	75.00%	100%

Table - 2. Sensitivity, specificity, PPV, NPV, accuracy of IAC Yokohama System

	Group A (Category Malignant considered positive)	Group B (Category Malignant and Suspicious considered positive)	Group C (Category Malignant, Suspicious, and Atypical considered positive)
Sensitivity	61.8%	84.6%	100%
Specificity	100%	99.3%	88.4%
PPV	100%	91.7%	43.3%
NPV	96.7%	98.7%	100%
Accuracy	97.3%	97.9%	91.2%

Table - 3. Distribution of breast lesions according to IAC Yokohama System in various published studies

Study	Insufficient	Benign	Atypical	Suspicious of Malignancy	Malignant
De Rosa et al.[11] (n=4624)	19.20%	36.90%	10.80%	4.70%	28.40%
Mc Hugh et al.[20] (n=695)	9%	47%	7%	11%	26%
Wong et al.[14] (n=2696)	11.20%	72%	4.30%	2.20%	10.30%
Montezuma et al.[13] (n=3625)	5.77%	73.38%	13.74%	1.57%	5.54%
Agarwal et al.[16] (n=1205)	19%	50.20%	6.60%	3.80%	20.40%
Sana Ahuja et al.[22] (n=554)	3.60%	69.50%	6.30%	2.30%	18.20%
Present Study (n=160)	6.25%	75.00%	11.25%	2.50%	5.00%

Table - 4. Risk of malignancy of different categories of IAC Yokohama System in various published studies

	Insufficient	Benign	Atypical	Suspicious of Malignancy	Malignant
De Rosa et al.[11]	49.60%	4.90%	20.70%	78.70%	98.80%
Mc Hugh et al.[20]	0%	12%	25%	46%	91%
Wong et al.[14]	2.60%	1.70%	15.70%	84.60%	99.50%
Montezuma et al.[13]	4.80%	1.40%	13%	97.10%	100%
Agarwal et al.[16]	60.90%	8.30%	17.20%	77.80%	100%
Sana Ahuja et al.[22]	5%	1.50%	17.40%	81.80%	100%
Present Study	0%	0%	11%	75%	100%

Table – 5. Comparison of diagnostic accuracy of breast FNAC in diagnosis of malignancy using Yokohama system in various studies

Category included		De Rosa et al.[11]	McHugh et al.[20]	Wong et al.[14]	Montezuma et al.[13]	Agarwal et al.[16]	Sana Ahuja et al [22]	Present Study
	No. of cases	1616	199	536	755	299	224	160
Only malignant category taken as positive	Sensitivity	82.20%	65.40%	75.40%	68.70%	86.70%	79.20%	61.8
	Specificity	97.80%	95.90%	100%	100%	100%	100%	100
	PPV	98.80%	91.10%	100%	100%	100%	100%	100
	NPV	71.00%	81.10%	80.70%	87.70%	71.20%	90.90%	96.7
	Accuracy	87.00%	83.90%	87.90%	90.30%	90.00%	93.20%	97.3
Suspicious of malignancy and malignant taken as positive	Sensitivity	93.70%	79.50%	92.0%'	83.30%	96.00%	91.70%	84.6
	Specificity	90.80%	85.10%	97.80%	99.80%	91.90%	98.70%	99.3
	PPV	95.80%	77.50%	97.60%	99.50%	97.30%	97.10%	91.7
	NPV	86.60%	86.60%	92.70%	93.00%	88.30%	96.10%	98.7
	Accuracy	92.80%	82.90%	95.00%	94.70%	95.00%	96.40%	97.9
Atypical, suspicious and malignant category taken as positive	Sensitivity	98.90%	84.60%	98.90%	98.30%	98.20%	97.20%	100
	Specificity	46.30%	75.20%	62.10%	54.80%	59.50%	86.00%	88.4
	PPV	80.50%	68.80%	71.70%	49.20%	88.00%	77.00%	43.3
	NPV	95.10%	88.30%	98.30%	98.60%	91.70%	98.50%	100
	Accuracy	82.70%	78.90%	80.20%	68.20%	88.60%	89.60%	91.2

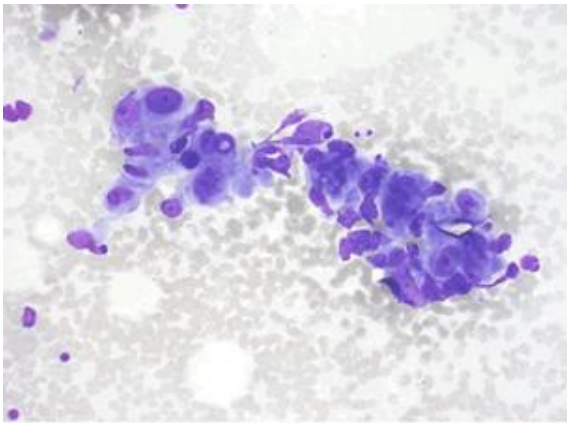

Figure 1: Photomicrograph showing pleomorphic neoplastic ductal cells in loosely cohesive clusters. Stromal and myoepithelial cells are scant.

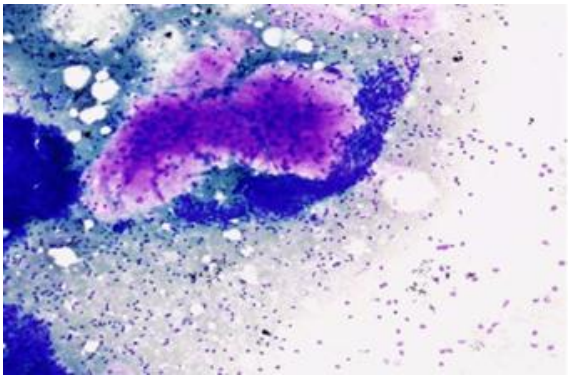

Figure 2: FNAC Slide: Photomicrograph showing dense cohesive clusters of benign ductal epithelial cells, stromal tissue and many naked oval bipolar nuclei in the background. (Fibroadenoma

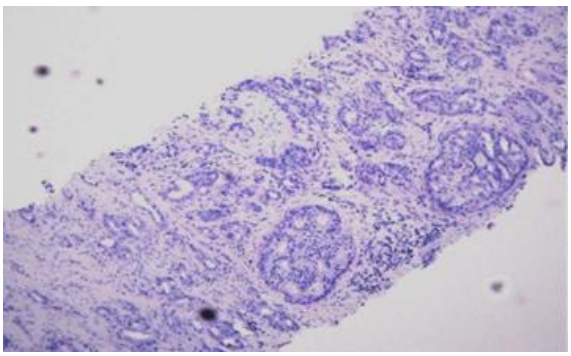

Figure 3: HPE Slide: Photomicrograph showing Intra-ductal Carcinoma

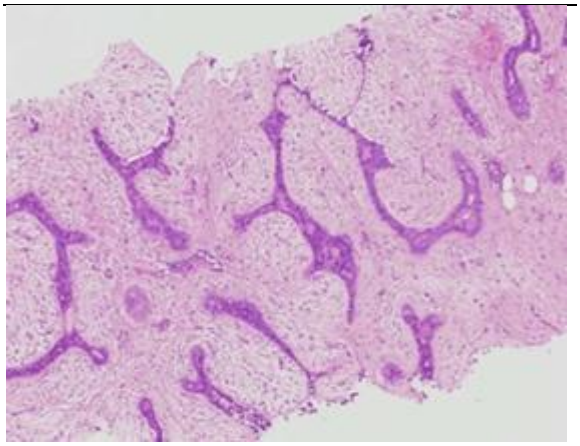

Figure 4: HPE Slide: Photomicrograph showing Fibroadenoma.

DISCUSSION

The current study aimed to evaluate the diagnostic utility of the International Academy of Cytology (IAC) Yokohama System for Reporting Breast Fine Needle Aspiration (FNA) Cytology, focusing on the categorization of breast lesions and correlation with histopathological outcomes. A total of 173 cases were assessed over five years, with histological correlation available for 160 cases (92.48%), making it possible to determine the risk of malignancy (ROM) across the five diagnostic categories.

The largest proportion of cases (75%) fell into the benign (C2) category, in line with findings from Montezuma et al., where benign lesions comprised 65–75% of all FNAs.[13] This high representation reflects the prevalence of non-neoplastic lesions and fibroadenomas, which were the most common histological correlate in our series (120 benign cases). Similarly, our study recorded 10 (6.25%) insufficient (C1) cases, comparable to the rates reported by Wong et al. (5–10%).[14] [Table 3]

The atypical (C3) category accounted for 11% of cases. This category includes lesions that exhibit mild nuclear atypia or architectural distortion but do not fulfil the criteria for suspicious or malignant classification. Histological evaluation revealed that 88.89% (16/18) of these cases were benign, with benign phyllodes tumours and cellular fibroadenomas being predominant. Only two cases (11%) were diagnosed as ductal carcinoma in situ (DCIS), yielding a ROM of 11%. While our ROM is slightly lower than some reports, it reinforces the need for cautious follow-up and further diagnostic work-up in C3 lesions.[11,20]

The suspicious of malignancy (C4) category made up 2.5% of cases, with a ROM of 75%. This is consistent with literature values, where ROMs for C4 range between 70–85%.[11,14,21] Out of four C4 cases, three were confirmed to be invasive ductal carcinoma, with one turning out to be a cellular fibroadenoma. These findings underscore the interpretative difficulty that arises when high cellularity and atypia overlap in cytology.

All eight cases classified as malignant (C5) were confirmed as invasive ductal carcinoma on histology, resulting in a ROM of 100%. This finding supports the extremely high predictive value of the malignant category, as described in prior validation studies.[21,13] The specificity and PPV for this category remain consistent with other major studies using the IAC system. [Table 4]

When assessing diagnostic performance based on different groupings for positivity:

- Group A (only C5 considered positive) showed high specificity (100%) and PPV (100%), but relatively lower sensitivity (61.8%), indicating its conservative nature. This means fewer false positives, but a risk of missing malignancies.
- Group B (C4 and C5 considered positive) achieved the highest diagnostic accuracy at 97.9%, with improved sensitivity (84.6%) while maintaining high specificity (99.3%). This grouping strikes an effective balance between identifying malignancies and avoiding overtreatment of benign cases. Similar performance has been reported by Hoda et al. affirming this strategy's clinical utility.[18]
- Group C (C3 to C5 considered positive) maximized sensitivity (100%) and NPV (100%), minimizing the chance of false negatives. However, this came at the cost of a significant drop in specificity (88.4%) and PPV (43.3%). While useful in screening contexts where missing a malignancy is unacceptable, it could potentially lead to unnecessary interventions. [Table 5]

These results highlight the versatility of the IAC Yokohama system in allowing clinicians to adjust diagnostic thresholds based on clinical context—whether prioritizing certainty (as in surgery planning) or maximizing detection (as in early screening).

From a clinical standpoint, the adoption of this system enables standardized reporting and clearer communication between cytopathologists, radiologists, and surgeons. It offers a reproducible framework that not only predicts malignancy risk accurately but also aligns with triple assessment strategies for breast lesion evaluation.

Despite its strengths, the study had limitations. It was retrospective in design, and inter-observer variability in assigning categories, especially C3 and

C4, was not formally evaluated. Moreover, radiological findings were not always available for correlation, which could have further refined diagnostic stratification.

Nevertheless, our findings agree with major studies validating the IAC Yokohama system and confirm its robustness in everyday diagnostic cytopathology. We recommend its continued use and integration with imaging and clinical findings for optimal patient care.

CONCLUSION

The application of the International Academy of Cytology Yokohama System for categorizing breast fine needle aspirates has demonstrated high diagnostic accuracy and a reliable stratification of malignancy risk. The findings affirm the system's value in routine cytological evaluation, especially in resource-limited settings. The structured five-tiered approach enhances diagnostic clarity, facilitates clinical decision-making, and ensures better patient care by guiding appropriate management pathways for each category. The study highlights the significance of adopting standardized reporting systems in improving diagnostic consistency and communication between pathologists and clinicians.

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