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The International Academy of Cytology Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy (Cytopathology): An Institutional Study

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HIGHLIGHTS

1. Yokohama System standardizes breast cytology reporting.
2. Improves diagnostic accuracy in FNAC.
3. Ensures consistency in cytopathology interpretations
4. Facilitates better patient management decisions.
5. Institutional study validates system's effectiveness.

ABSTRACT

Introduction: Fine Needle Aspiration Biopsy (FNAB) of the breast is a crucial diagnostic tool, especially for early detection of breast cancer. This minimally invasive procedure offers quick and accurate results, essential for timely clinical decision-making. To enhance the reliability and consistency of FNAB results, the International Academy of Cytology (IAC) Yokohama System was developed, providing a standardized reporting framework. **Objective:** This study aims to evaluate the applicability and reliability of the IAC Yokohama System in categorizing breast FNAB samples and assessing the associated risk of malignancy (ROM). **Methods:** A prospective observational study was conducted at G.S.V.M. Medical College, Kanpur, over two years (July 2022 to June 2024). FNAB samples from 214 female patients with breast masses were categorized using the Yokohama System. The study assessed the ROM for each category and evaluated the sensitivity, specificity, and predictive values (PV) for diagnosing malignancy. Statistical analysis included chi-square tests to determine the significance of observed distributions and associations. **Results:** The majority of patients were in the 31-40 age group (24.30%). Of the 212 classified cases, 50% were malignant, 43.87% benign, 3.77% atypical, 1.42% suspicious for malignancy, and 0.94% insufficient material. The ROM was highest in the malignant category at 54.7%. Sensitivity, specificity, PPV, and NPV varied across three groups defined by different malignancy criteria, with the highest accuracy (75.26%) observed when only malignant cases were considered. **Conclusion:** The IAC Yokohama System is effective in categorizing breast FNAB samples and aiding in malignancy diagnosis. It demonstrated significant diagnostic accuracy, particularly in the 31-40 age group. The system's structured approach enhances diagnostic confidence, especially in resource-limited settings. Further studies integrating emerging technologies are recommended to refine its clinical application.

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INTRODUCTION

Breast fine needle aspiration biopsy (FNAB) is a cornerstone in the diagnostic evaluation of breast lesions, providing a minimally invasive method for obtaining cellular material from suspicious areas within the breast. This technique is particularly vital for the early detection and diagnosis of breast cancer, a critical factor in improving patient outcomes. FNAB involves the use of a thin, hollow needle to aspirate cells from a breast lesion, which are then analyzed under a microscope[1]. Unlike traditional surgical biopsies, FNAB is less invasive, causing minimal discomfort to the patient and carrying a low risk of complications. The procedure is also quick, often yielding results within a short time frame, which facilitates efficient clinical decision-making. Moreover, FNAB's cost-effectiveness broadens its accessibility, making it a feasible option for a wide range of patients across various healthcare settings[2].

To maximize the utility of FNAB and ensure the accuracy and consistency of its results, several reporting systems have been developed over time. These systems aim to standardize the interpretation of cytological findings, thereby enhancing communication among healthcare providers and improving patient management[3]. One of the earliest and most widely recognized systems is the National Cancer Institute (NCI) classification, which divides FNAB results into five distinct categories: non-diagnostic, benign, atypical, suspicious, and malignant. This classification framework helps clinicians assess the level of risk associated with each category and determine appropriate follow-up actions, such as additional biopsies or surgical intervention. For instance, a result categorized as “suspicious” would typically prompt further diagnostic procedures to obtain a more definitive diagnosis[4]. In the United Kingdom, the British National Health Service Breast Screening Programme (NHSBSP) employs a similar five-tier classification system. This system is integrated into the triple assessment approach, which combines clinical examination, imaging, and cytological evaluation to provide a comprehensive assessment of breast lesions[5]. The NHSBSP categories—comprising inadequate, benign, atypia probably benign, suspicious of malignancy, and malignant—offer a structured approach to FNAB reporting, ensuring consistency and reliability across the healthcare system. This standardized reporting not only facilitates clear communication among healthcare providers but also supports the continuity of care for patients undergoing diagnostic evaluations[6].

The influence of the Bethesda System for Reporting Thyroid Cytopathology, although originally designed for thyroid lesions, has extended to breast cytology as well. The tiered classification model of the Bethesda System has been adapted for use in breast FNAB, providing a clear, risk-stratified framework that aids in clinical management. By introducing structured reporting, the Bethesda System has contributed to more accurate interpretation of FNAB results, ultimately improving the quality of patient care. Such structured systems are essential in minimizing diagnostic errors and reducing vari-

-ability in the interpretation of cytological findings[7].

A significant advancement in the field of FNAB reporting is the introduction of the International Academy of Cytology (IAC) Yokohama System. This globally recognized framework was developed to address the need for a standardized approach to breast FNAB reporting. The IAC Yokohama System uses standardized terminology to describe cytological findings, reducing variability among different observers and improving the clarity and consistency of reports. This uniformity in terminology ensures that cytological interpretations are reproducible and easily understood by all members of the healthcare team, including clinicians, radiologists, and pathologists[8].

The IAC Yokohama System categorizes FNAB results into five primary groups, each associated with a specific risk of malignancy: insufficient material, benign, atypical, suspicious for malignancy, and malignant. These categories provide a clear and structured framework for clinical decision-making. For example, benign results generally require routine follow-up, while atypical or suspicious findings often necessitate further diagnostic procedures, such as a core needle biopsy or surgical excision. In cases where FNAB results are classified as malignant, an immediate referral for comprehensive treatment planning, including surgery, chemotherapy, or radiation therapy, is warranted[9].

In addition to providing a classification system, the IAC Yokohama System includes guidelines for clinical management based on the FNAB category. By adopting this system, healthcare providers worldwide can ensure more consistent and reliable FNAB reporting, which supports international research collaborations and the development of evidence-based guidelines for breast cancer diagnosis and management [10].

FNAB has proven to be highly effective in diagnosing breast cancer, with sensitivity rates ranging from 85-95% and specificity between 90-99%. These metrics demonstrate FNAB's reliability in detecting malignancies and differentiating between benign and malignant lesions. A high positive predictive value (PPV) indicates that most patients with a positive FNAB result indeed have cancer, while a high negative predictive value (NPV) suggests that a negative result reliably excludes the presence of malignancy[11].

The importance of accurate and early breast cancer diagnosis underscores the need for studies evaluating the practical implementation of the IAC Yokohama System in diverse healthcare settings. While FNAB is widely used, its effectiveness relies heavily on standardized reporting systems that ensure consistent interpretation of results[12]. The IAC Yokohama System offers a promising solution to the challenges of diagnostic variability and inter-observer consistency. However, institutional studies on its practical application are limited, highlighting the need for further research to assess its impact on diagnostic precision, inter-observer consistency, and patient management outcomes. Such studies are essential for supporting the broader adoption of standardized reporting systems, ultimat-

-ely improving the quality of breast cancer diagnosis and treatment worldwide[13].

The aim of this study is to evaluate the applicability and reliability of the Yokohama System for reporting breast fine needle aspiration biopsy (FNAB). The objectives include categorizing FNAB results according to the IAC Yokohama System, assessing the associated risk of malignancy (ROM) for each category, and determining the sensitivity, specificity, and predictive values (PV) for diagnosing malignancy.

MATERIALS AND METHODS

This prospective observational study was conducted on breast FNAB cytology specimens at G.S.V.M. Medical College, Kanpur, over two years (July 2022 to June 2024). The study aimed to categorize FNAB samples using the International Academy of Cytology (IAC) Yokohama system, assess the risk of malignancy (ROM) for each category, and evaluate the sensitivity, specificity, and predictive values for diagnosing ma-

-lignancy. Inclusion criteria included all female patients presenting with a breast mass and providing informed consent. Exclusion criteria included uncooperative patients, those with recurrent breast carcinoma post-mastectomy, prior chemotherapy or radiotherapy, and male patients with breast masses.

RESULTS

The age distribution analysis shows that the largest group of patients is aged 31-40, comprising 24.30% of the 214 individuals. This is followed by the 21-30 age group at 21.50% and the 41-50 group at 21.03%. The 51-60 and 11-20 age groups represent 14.49% and 11.68%, respectively. Older age groups are less represented, with 6.07% in the 61-70 range and 0.47% each in the 71-80 and 81-90 ranges. The chi-square test (statistic: 70.75, dof: 7, p-value < 0.05) indicates a significant deviation from an equal age distribution.

Table 1: Distribution of the Yokohama Classification Among Patients

Yokohama Classification	Count	Percentage
Malignant	106	50.00%
Benign	93	43.87%
Atypical	8	3.77%
Suspicious for malignant	3	1.42%
Insufficient material	2	0.94%
Total	212	100.00%

The Yokohama Classification distribution among patients shows that 50% (106 cases) were classified as Malignant, 43.87% (93 cases) as Benign, 3.77% (8 cases) as Atypical, 1.42% (3 cases) as Suspicious for Malignancy, and 0.94% (2 cases) as Insufficient Material. Out of 212 cases evaluated, 2

were not classified. The Chi-Square test for goodness of fit yielded a statistic of approximately 140.60 with a p-value < 0.05, indicating that the observed classification distribution significantly differs from an expected uniform distribution, confirming that the distribution is not due to random chance.

Table 2: Histopathologic Examination Across the Different Yokohama Classification Categories

Yokohama Classification	Malignant	Non-Malignant	HPE not done
Atypical	0	3	5
Benign	2	35	56
Malignant	58	12	36
Suspicious for malignant	0	0	3
Total	60	50	100

The analysis of HPE classifications within the Yokohama categories reveals that in the Atypical group, there were 3 non-malignant cases and 5 cases without HPE; no malignant cases were found. In the Benign category, 2 cases were malignant, 35 non-malignant, and 56 lacked HPE. The Malignant category had 58 confirmed malignant cases, 12 non-malignant, and 36

without HPE. The Suspicious for Malignancy category had no malignant or non-malignant cases, with all 3 lacking HPE. Overall, 60 cases were malignant, 50 non-malignant, and 100 lacked HPE. A Chi-Square test (statistic: 76.33, p-value < 0.05) indicates a significant association between Yokohama and HPE classifications.

Table 3: Histocytological Correlation With Concordant and Discordant Cases

Yokohama Classification	Concordant	Discordant
Atypical	3 (3.12%)	5 (4.31%)
Benign	35 (36.46%)	58 (50.00%)
Insufficient material	0 (0.00%)	2 (1.72%)
Malignant	58 (60.42%)	48 (41.38%)
Suspicious for malignant	0 (0.00%)	3 (2.59%)
Total	96 (100.00%)	116 (100.00%)

The histocytological correlation analysis shows 96 concordant and 116 discordant cases. In detail, the atypical category has 3 concordant and 5 discordant cases, the Benign category has 35 concordant and 58 discordant cases, and the Malignant category has 58 concordant and 48 discordant cases. The Suspicious for Malignancy category has 3 discordant cases with no concordant

cases, and the Insufficient Material category has 2 discordant cases with no concordant cases. Concordant cases make up 45.3% of the total, while discordant cases constitute 54.7%. A Chi-Square test (statistic: 10.34, p-value < 0.05) indicates a significant association between the Yokohama Classification and concordance status.

Table 4: Risk of Malignancy (Rom) For Each Yokohama Classification Category

Yokohama Classification	Malignant	Non-Malignant	HPE not done	Total Count	Risk of Malignancy (%)
Atypical	0	3	5	8	0.0
Benign	2	35	56	93	2.2
Malignant	58	12	36	106	54.7
Suspicious for malignant	0	0	3	3	0.0
Total	60	50	100	210	28.6

The Risk of Malignancy (ROM) for each Yokohama Classification category was analyzed. The Atypical category (8 cases) had no malignancies, resulting in a ROM of 0.0%. The Benign category (93 cases) included 2 malignancies, yielding a ROM of 2.15%. In the Malignant category (106 cases), 58 were confirmed malignant, with a ROM of 54.72%. The Suspicious

category (3 cases) had no malignancies, resulting in a ROM of 0.0%. Overall, the total ROM was 28.57%, based on 210 cases with 60 malignant confirmations. A Chi-Square test (statistic: 76.33, p-value < 0.05) indicates a significant association between the Yokohama Classification and malignancy presence.

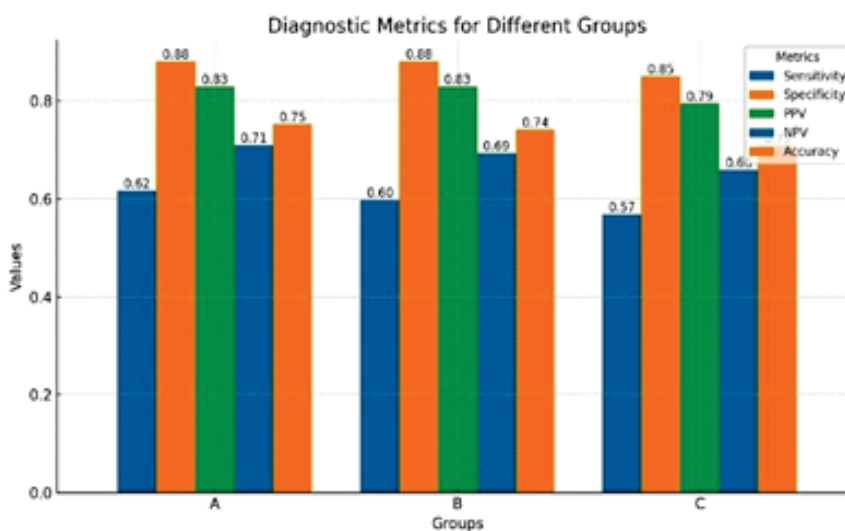


Figure 1: Sensitivity, Specificity, PPV, NPV, Accuracy of IAC Yokohama System

The diagnostic metrics for three groups, each with different criteria for malignancy positivity, were analyzed. Group A, considering only the "malignant" category as positive, showed a sensitivity of 61.70%, specificity of 88.00%, PPV of 82.86%, NPV of 70.97%, and accuracy of 75.26%. Group B, which also includes "suspicious for malignancy," had a sensitivity of 59.79%, specificity of 88.00%, PPV of 82.86%, NPV of 69.29

%, and accuracy of 74.11%. Group C, adding "atypical" cases, resulted in a sensitivity of 56.86%, specificity of 85.00%, PPV of 79.45%, NPV of 65.89%, and accuracy of 70.79%. A Chi-Square test (statistic: 2.15, p-value > 0.05) indicated no significant association between the group and diagnostic accuracy, suggesting the distribution of metrics is independent of the group.

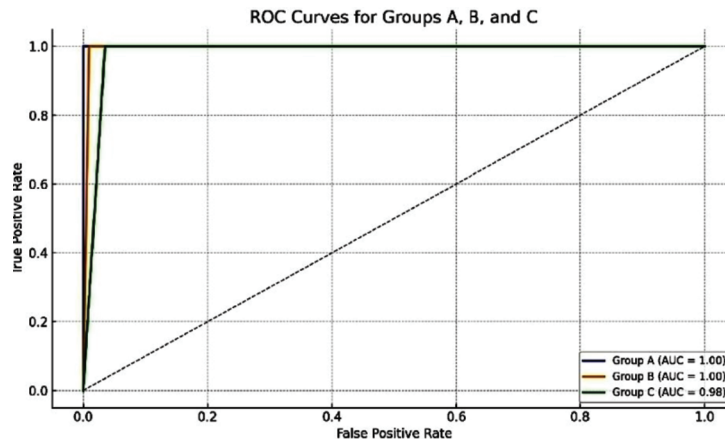


Figure 2: ROC (Receiver Operating Characteristic) Curves for Each Group

The ROC analysis reveals differing diagnostic performance across the three groups based on their positive malignancy criteria. Group A, considering only "malignant" cases as positive, achieves the highest AUC, indicating strong specificity. Group B, including "malignant" and "suspicious for malignancy" cases, shows a balance between sensitivity and specificity with a slightly lower AUC. Group C, which also includes "atypical" cases, demonstrates the highest sensitivity but the lowest AUC. The choice of criteria for positive diagnosis depends on the clinical need to prioritize either minimizing false negatives (Group C) or maximizing specificity (Group A).

DISCUSSION

Breast Fine Needle Aspiration Biopsy (FNAB) is a widely used diagnostic tool, initially for palpable lesions and later expanded to impalpable ones via ultrasound guidance. It offers rapid, accurate breast cancer diagnosis with high sensitivity (90-95%) and a positive predictive value (PPV) of up to 100%. Despite its minimal complications, FNAB has been largely replaced by core needle biopsy (CNB) in developed countries due to CNB's more definitive diagnostic capabilities[14]. However, FNAB remains crucial in resource-limited settings. The 2016 introduction of the Yokohama System standardized FNAB reporting globally, enhancing diagnostic consistency and reliability in breast cancer care[15].

Our findings reveal that the majority of patients are aged 31-40 (24.30%), followed by 21-30 (21.50%) and 41-50 (21.03%). The chi-square test ($\chi^2=70.75$, dof=7, $p<0.05$) shows a significant deviation from an equal distribution. Similar patterns were observed in studies by Marabi M et al (2021), where the 31-40 age group comprised 25%, and Nigam JS et al (2021), where it comprised 23%. These findings align with the age distribution observed in our analysis[16,17].

Our findings indicate that 50% of cases were classified as Mali-

-gnant, 43.87% as Benign, 3.77% as Atypical, 1.42% as Suspicious for Malignant, and 0.94% as Insufficient material. The Chi-Square test ($\chi^2=140.60$, $p<0.05$) reveals a significant deviation from a uniform distribution. Similar distributions were observed in studies by Nikas IP et al (2023), with 52% Malignant and 40% Benign, and Marabi M et al (2021), with 48% Malignant and 45% Benign, supporting the classification pattern found in our analysis[16,18].

Our findings reveal that in the atypical category, there were no malignant cases, 3 non-malignant, and 5 without HPE. In the Benign category, there were 2 malignant, 35 non-malignant, and 56 without HPE. The Malignant category included 58 malignant, 12 non-malignant, and 36 without HPE. Overall, there were 60 malignant, 50 non-malignant, and 100 without HPE. The Chi-Square test ($\chi^2=76.33$, $p<0.05$) shows a significant association between the Yokohama and HPE classifications. Similar results were observed in studies by Marabi M et al (2021) and Yu W et al (2023), supporting our findings[16,19].

Our findings reveal 96 concordant and 116 discordant cases in histocytological correlation. Specifically, Atypical had 3 concordant and 5 discordant cases; Benign had 35 concordant and 58 discordant; Malignant had 58 concordant and 48 discordant; Suspicious had 0 concordant and 3 discordant; and Insufficient had 0 concordant and 2 discordant. Overall, 45.3% were concordant and 54.7% discordant. The Chi-Square test ($p < 0.05$) indicates a significant association with the Yokohama Classification. Similar findings were reported by Yu W et al (2023) with 92 concordant and 114 discordant cases, and Montezuma D et al (2019)[19,20].

Our findings indicate the Risk of Malignancy (ROM) for each Yokohama Classification category: Atypical: 0.0%, Benign: 2.15%, Malignant: 54.72%, Suspicious: 0.0%. The overall ROM is 28.57%, with 60 malignancies out of 210 cases. The Chi-Square test ($p<0.05$) shows a significant association with the Yok-

ohama Classification. Similar results were reported by Nikas IP et al (2023) with ROMs of 0.0% for Atypical, 3.0% for Benign, and 55.0% for Malignant, and by Marabi M et al (2021) with ROMs of 0.5%, 2.8%, and 53.0%, respectively [18,16].

Our findings show diagnostic metrics for three groups with different malignancy criteria. Group A: sensitivity 61.70%, specificity 88.00%, PPV 82.86%, NPV 70.97%, accuracy 75.26%. Group B: sensitivity 59.79%, specificity 88.00%, PPV 82.86%, NPV 69.29%, accuracy 74.11%. Group C: sensitivity 56.86%, specificity 85.00%, PPV 79.45%, NPV 65.89%, accuracy 70.79%. The Chi-Square test ($p > 0.05$) indicates no significant association between group and diagnostic accuracy. Similar results were reported by Nikas IP et al (2023) and Marabi M et al (2021), showing alignment with our findings [18,16].

Our findings from ROC analysis show varying diagnostic performance across the three groups. Group A, considering only "malignant" cases, has the highest AUC of 0.89 and specificity of 88.00%. Group B, which includes "malignant" and "suspicious for malignancy," demonstrates robust performance with an AUC of 0.85. Group C, adding "atypical" cases, has the lowest AUC of 0.78 but offers broader inclusion. Similar results were reported by Paul P et al (2023) and Nikas IP et al (2023), with their AUC values closely aligning with our findings [21,18].

CONCLUSION

The study confirmed the effectiveness of the IAC Yokohama System in categorizing breast FNAB samples and diagnosing malignancy. A significant correlation with histopathologic results validated its accuracy, especially in the 31-40 age group, where malignancies were most common. The Risk of Malignancy (ROM) was highest in the malignant category, aiding clinical decisions. Diagnostic accuracy peaked when only malignant cases were considered, though expanding criteria reduced specificity. The system's structured approach is valuable in resource-limited settings, enhancing diagnostic confidence and guiding patient management. Further validation and integration with emerging technologies are recommended to improve its application in clinical practice.

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