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Original Research Article

RISK OF MALIGNANCY AND DIAGNOSTIC PERFORMANCE OF THE IAC YOKOHAMA SYSTEM IN BREAST CYTOPATHOLOGY

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ABSTRACT

Background: FNAC is the common method adopted for the diagnosis of breast lesions. The IAC Yokohama System was introduced to standardize reporting of breast cytology and provide category-specific risk of malignancy (ROM) for clinical management. **Purpose:** To assess the utility of the IAC Yokohama System of reporting breast cytopathology, calculate the ROM for each category and to evaluate the diagnostic accuracy of FNAC with histopathology as the gold standard.

Materials and Methods: The present hospital-based observational study was conducted on 89 patients presenting with palpable breast lesions and undergoing FNAC. Cytological smears were categorized as per the IAC Yokohama System. Histopathological correlation was available in 37 cases. For each category, ROM was computed and diagnostic performance parameters were calculated.

Results: The most affected age group was the 41–50-year (25.8%). Major cytological category was Category II (Benign) which accounted for 52.8% of cases followed by Category V (Malignant) which accounted for 30.3% of cases. The most common benign and malignant lesion was fibroadenoma and ductal carcinoma, respectively. Histopathological correlation showed invasive ductal carcinoma (NST) as the most common diagnosis (59.4%). ROM was 75% in category I, 11.1% in category II, 0% in category III, and 100% in categories IV and V. The sensitivity of the IAC Yokohama System was 100%, specificity 100%, positive predictive value 100%, negative predictive value 90.9% and diagnostic accuracy 92.5%.

Conclusion: IAC Yokohama System found to be an appropriate system for breast cytopathology that can help in the accurate stratification of ROM. This will help in the accurate diagnosis of patients with breast cancer.

Keywords: Breast lesions; FNAC; IAC Yokohama System; Risk of malignancy; Breast cytopathology.

INTRODUCTION

Breast cancer ranks second after lung cancer worldwide. Around 2.3 million new cases were reported worldwide, accounting for 11.7% of all cancer cases. It surpassed lung cancer to become the most commonly diagnosed cancer globally in 2020. Epidemiological estimates suggest that breast cancer cases will continue to rise worldwide. In 2016, India recorded around 118,000 new cases of the disease. Based on GLOBOCAN 2020 statistics, breast cancer represented 13.5% of total cancer cases and contributed to 10.6% of cancer deaths in India[1]. It constitutes 14% of all cancers among Indian women, with peak incidence between 50–64 years of age and a rising trend beginning in the early 30s[2]. Increasing urbanization has also been associated with a growing burden of breast cancer, which has overtaken cervical cancer as the most

common cancer among women in several metropolitan regions[3].

Himachal Pradesh, a northern Himalayan state with a relatively higher life expectancy, has also witnessed an increasing incidence of breast cancer. Studies on breast cancer are important in this region even though many Indian women do not show the classical risk factors reported in Western populations. The hospital-based prevalence rate of breast cancer in Himachal Pradesh is reported to be 1.24 per 1 million female population[4].

Early detection is essential for improving prognosis, especially in low-income countries like India where most cases are diagnosed in advanced stages. Breast masses are usually evaluated by clinical examination, radiological imaging, and breast cytopathology, with or without core needle biopsy (CNB)[5,6]. These modalities combined form the "triple test" that is widely used in screening as well as symptomatic patients[5,6]. The main goal is to achieve an accurate preoperative diagnosis that allows appropriate treatment while avoiding unnecessary invasive procedures and patient anxiety.

Fine needle aspiration biopsy (FNAB) and CNB serve complementary roles in the evaluation of breast lesions. However, the diagnostic accuracy of FNAB depends on several factors, including operator expertise, localization techniques, pathologist experience, and lesion characteristics[7]. FNAB is a minimally invasive technique that provides an initial evaluation of breast lesions[8,6]. Although cytological features are useful in differentiating benign from malignant lesions, overlapping features may occasionally limit a definitive diagnosis.

In the past, reporting of breast FNAB at our centre used various descriptive diagnostic categories, such as benign inflammatory lesions, proliferative lesions, suspicious lesions, and malignancies. However, this traditional system has several drawbacks, including heterogeneous diagnostic categories, descriptive reports, poor standardized communication between pathologists and clinicians, and the inability to uniformly assess the risk of malignancy (ROM). These limitations emphasize the need for a standardized reporting system.

To address these limitations, the Breast Group of the International Academy of Cytology (IAC) developed the Yokohama System, which was introduced at the Yokohama International Congress of Cytology in 2016. Based on recommendations from cytopathologists, radiologists, surgeons, and oncologists, a standardized five-tier reporting system for breast FNAB was established: Category I (Insufficient/Inadequate), Category II (Benign), Category III (Atypical), Category IV (Suspicious for malignancy), and Category V (Malignant)[6,9,10]. Beyond standardizing reporting, the system also provides category-specific ROM and management recommendations, thereby improving communication, reducing unnecessary surgeries, and facilitating effective patient management[11,12].

Despite these advantages, the diagnostic performance, reliability, and reproducibility of the IAC Yokohama System require further validation. Therefore, the present prospective study was undertaken at our tertiary care hospital to evaluate the utility of the IAC Yokohama System for reporting breast cytopathology, determine the ROM for each category, and assess the diagnostic accuracy of FNAB using this standardized reporting system.

MATERIALS AND METHODS

Study Design and Eligibility Criteria: This hospital-based observational study that was carried out over a period of seven months from October 2023 to April 2024. The study included patients of either sex who were presented with palpable breast lump(s). Patients who underwent FNAC and those with corresponding histopathological specimens received were included. Patients with recurrent breast cancer following mastectomy, and patients who had received chemotherapy or radiotherapy prior to mastectomy were excluded.

Source of Data: The study data were obtained from breast FNAB samples, including true-cut biopsies and mastectomy specimens, obtained from cytologically proven breast lesions. Histopathological findings, wherever available, were used for cyto-histological correlation.

Fine Needle Aspiration Cytology Procedure: FNAC was done under standard aseptic precautions. The skin over the lesion was cleaned with alcohol and the swelling was stabilized between the thumb and index finger. A 22–23-gauge needle connected to a disposable 20 mL syringe in a Franzen's syringe holder was inserted into the lesion. Suction was applied and the needle was moved back and forth in different directions within the lesion while suction was maintained. When enough material had been collected, the negative pressure was relieved before the needle was withdrawn. The aspirated material was spread on glass slides and smears were prepared. Two to three smears were air-dried and the others were fixed immediately in methanol or 95% ethanol for subsequent staining.

Cytology Staining and Reporting: Air dried smears were stained with May-Grunwald Giemsa (MGG) staining technique. The smears were stained with freshly prepared diluted Giemsa stain in buffered water (pH 7.2) for 20–30 minutes, washed in buffered water and air dried. More smears were stained with Hematoxylin and Eosin (H&E) technique. Ethanol-fixed smears were rehydrated, stained with hematoxylin, acid alcohol differentiated, blued, counterstained with eosin, dehydrated through graded alcohols, cleared in xylene and mounted in DPX. Cytological smears were classified as per IAC Yokohama System into

five categories i.e. C1 (Insufficient/Inadequate), C2 (Benign), C3 (Atypical), C4 (Suspicious of Malignancy), and C5 (Malignant).

Histopathological Processing and Study: Specimens were fixed in 10% neutral buffered formalin for 24 to 72 hr, grossly examined, and representative tissues sampled. Tissues were processed by a fully automated vacuum tissue processor (Leica ASP6025). The specimens were dehydrated in increasing grades of alcohol, cleared in xylene and impregnated with molten paraffin wax. The tissues were embedded in paraffin blocks and 2–3 µm thick sections were cut using a semi-automated microtome (Leica RM2125RTS). Sections were stained with Hematoxylin and Eosin using a Tissue-Tek DRS™ 2000 multiple slide stainer (Sections were deparaffinized, hydrated, stained with hematoxylin, differentiated, blued, counterstained with eosin, dehydrated, cleared and mounted with DPX for microscopic examination. The gold standard for definitive diagnosis was the histopathological diagnosis.

Outcome Measures and Cyto-Histological Correlation: Cyto-histological correlation was done in all those cases where histopathology specimens were available. The ROM per IAC Yokohama category was calculated. The diagnostic parameters of IAC Yokohama System including sensitivity, specificity, positive predictive value, negative predictive value and overall diagnostic accuracy were determined by taking histopathological diagnosis as the reference standard.

Statistical analysis: Statistical analysis was conducted using SPSS software version 27.0. Quantitative variables are expressed as percentages and proportions. The sample size was calculated with 95% confidence, an expected sensitivity of 96% for the IAC Yokohama reporting system in diagnosing malignant breast lesions, an absolute margin of error of 5% and a prevalence of malignant lesions among suspicious breast lesions of 75% (Wong *et al*., 2021). The sample size calculated was 78. Considering the loss to follow up of 10%, the final sample size was calculated to be 86 patients.

RESULTS

The age of the patients was between 12 and 92 years. The most common age group affected was 41-50 years (25.8%), followed by 31-40 years (19.1%) and 21-30 years (16.9%). The left breast showed more breast lesions in 53 cases (59.6%) as compared to 35 cases (39.3%) in the right breast. Bilateral involvement was seen in only 1 case (1.1%). Upper outer quadrant was the commonest site of involvement (47.2%) followed by lower outer quadrant (20.2%), lower inner quadrant (15.7%) and upper inner quadrant (13.5%). Retroareolar lesions 3 (3.4%) were the least common lesions. [Table 1]

Table 1: Demographic and Clinical Characteristics of Study Participants (n = 89)

Variable	Category	n (%)
Age Group (years)	11–20	6 (6.7)
	21–30	15 (16.9)
	31–40	17 (19.1)
	41–50	23 (25.8)
	51–60	14 (15.7)
	61–70	10 (11.2)
	71–80	3 (3.4)
	>80	1 (1.1)
Laterality	Left breast	53 (59.6)
	Right breast	35 (39.3)
	Bilateral	1 (1.1)
Quadrant Involved	Upper outer quadrant	42 (47.2)
	Upper inner quadrant	12 (13.5)
	Lower outer quadrant	18 (20.2)
	Lower inner quadrant	14 (15.7)
	Retroareolar	3 (3.4)

The most common category was found to be Category II (Benign) with 47 cases (52.8%) followed by Category V (Malignant) with 27 cases (30.3%) using IAC Yokohama System. Fibroadenoma was the most common cytological diagnosis seen in 37 cases (41.5%) whereas ductal carcinoma was the most common malignant lesion seen in 26 cases (29.2%). 9 cases (10.1%) were in Category I (Insufficient), 3 cases (3.3%) in Category III (Atypical) and 3 cases (3.3%) in Category IV (Suspicious for malignancy). Benign breast lesions were more prevalent overall in the study population. [Table 2]

Table 2: Cytological Spectrum of Breast Lesions According to the IAC Yokohama System (n = 89)

IAC Category	Diagnosis	n (%)
C1	Insufficient	9 (10.1)
C2	Fibroadenoma	37 (41.5)
	Granulomatous mastitis	3 (3.4)
	Fibrocystic change	3 (3.4)
	Proliferative breast disease without atypia	3 (3.4)

	Phyllodes tumour	1 (1.1)
	Total Benign (C2)	**47 (52.8)**
C3	Atypical ductal hyperplasia	3 (3.3)
C4	Suspicious for malignancy	3 (3.3)
C5	Ductal carcinoma	26 (29.2)
	Mucinous carcinoma	1 (1.1)
	Total Malignant (C5)	**27 (30.3)**
Total		**89 (100)**

Category V (Malignant) was the most common category, comprising 22 cases (59.4%) followed by Category II (Benign) with 9 cases (24.3%) of the 37 cases with histopathological correlation. Category I (Insufficient) was 4 cases (11.0%) and Category III (Atypical) and Category IV (Suspicious for malignancy) were 1 case (2.7%) respectively. Most of the cases subjected to histopathological evaluation were malignant lesions. [Table 3]

Table 3: Distribution of Cases with Histopathological Correlation (n = 37)

IAC Yokohama Category	n (%)
C1 (Insufficient)	4 (11.0)
C2 (Benign)	9 (24.3)
C3 (Atypical)	1 (2.7)
C4 (Suspicious for malignancy)	1 (2.7)
C5 (Malignant)	22 (59.4)

Histopathology of 37 cases revealed that invasive ductal carcinoma (NST) was the most common diagnosis, with 22 cases (59.4%). Fibroadenoma was the most common benign lesion reported in 10.8% of cases, followed by chronic nonspecific mastitis which was found in 8.1% cases. Fibrocystic disease, benign breast disease, atypical ductal hyperplasia, ductal carcinoma in situ, intraductal carcinoma, secretory carcinoma, invasive papillary carcinoma, and mucinous carcinoma were each observed in 2.7% of cases. Malignant lesions were present in 72.9% cases and benign lesions in 27.1% cases. [Table 4]

Table 4: Distribution of Cases with Histopathological Spectrum (n = 37)

Histopathological Diagnosis	n (%)
Fibroadenoma	4 (10.8)
Chronic nonspecific mastitis	3 (8.1)
Fibrocystic disease	1 (2.7)
Benign breast disease	1 (2.7)
Atypical ductal hyperplasia	1 (2.7)
Ductal carcinoma in situ	1 (2.7)
Intraductal carcinoma	1 (2.7)
Invasive ductal carcinoma (NST)	22 (59.4)
Secretory carcinoma	1 (2.7)
Invasive papillary carcinoma	1 (2.7)
Mucinous carcinoma	1 (2.7)

In 37 cases with histopathological correlation, most common category was Category V (Malignant) with 22 cases (59.5%) followed by Category II (Benign) with 9 cases (24.3%). The ROM was highest in Category IV and V (100% each), followed by Category I (75.0%) and Category II (11.1%), while Category III showed no malignancy (0%). Histopathological examination revealed 27 cases (73.0%) to be malignant and 10 cases (27.0%) benign. [Table 5]

Table 5: Cyto-Histological Correlation and Risk of Malignancy According to IAC Yokohama Categories (n = 37)

IAC Category	Total Cases n (%)	Benign n (%)	Malignant n (%)	ROM (%)
C1 Insufficient	4 (10.8)	1 (25.0)	3 (75.0)	75.0
C2 Benign	9 (24.3)	8 (88.9)	1 (11.1)	11.1
C3 Atypical	1 (2.7)	1 (100)	0 (0)	0
C4 Suspicious for malignancy	1 (2.7)	0 (0)	1 (100)	100
C5 Malignant	22 (59.5)	0 (0)	22 (100)	100
Total	**37 (100)**	**10 (27.0)**	**27 (73.0)**	—

The IAC Yokohama System showed a sensitivity of 100%, specificity of 100%, positive predictive value of 100%, negative predictive value of 90.9%, and an overall diagnostic accuracy of 92.5%. Cyto-histological concordance was observed in 35 cases (94.6%), while discordance was noted in 2 cases (5.4%). No false-positive diagnoses were recorded, whereas 2 false-negative diagnoses were identified. [Table 6]

Table 6: Diagnostic Performance of the IAC Yokohama System (n = 37)

Parameter	Value
Sensitivity	100%
Specificity	100%
Positive Predictive Value	100%
Negative Predictive Value	90.9%
Diagnostic Accuracy	92.5%
Concordance	35/37 (94.6%)
Discordance	2/37 (5.4%)
False Positive Diagnoses	0
False Negative Diagnoses	2

DISCUSSION

Breast cancer is the leading cancer imposing a significant public health burden globally. The situation is more challenging in low- and middle-income countries, where late presentation and delayed diagnosis are common. FNAC is a simple and minimally invasive method for assessing breast lesions. The adoption of the IAC Yokohama System has improved breast cytology reporting by introducing the risk of malignancy (ROM), thereby facilitating more informed clinical decision-making and patient management.[6,9,11]

In the present study, the age of patients ranged from 12 to 92 years, with the highest proportion of cases occurring in the 41–50 years age group (25.8%). Similar findings have been reported in previous studies, which also observed a predominance of breast lesions in middle-aged women.[2,4] The increasing incidence in this age group may be related to hormonal, reproductive, and lifestyle factors. The predominance of left-sided breast lesions observed in the present study is consistent with previous reports.[2,13] The upper outer quadrant was the most common site of involvement, a finding that has also been documented in earlier studies.[2]

The application of the IAC Yokohama System showed the largest proportion of cases in Category II (Benign) (52.8%), followed by Category V (Malignant) (30.3%). Fibroadenoma was the most common benign lesion, whereas ductal carcinoma was the most common malignant lesion. Similar observations have been reported in previous studies.[14,3,2] The high frequency of benign lesions in breast FNAC studies further supports the role of cytology in avoiding unnecessary surgical procedures.

Malignant lesions constituted the majority of cases (72.9%) among the 37 patients with histopathological correlation. No Special Type (NST) carcinoma was the most common histopathological diagnosis (59.4% of correlated cases). Similar findings have been reported previously, where invasive ductal carcinoma was the predominant histopathological subtype.[15-17] These observations further confirm the consistent predominance of invasive ductal carcinoma across different populations.

A major strength of the IAC Yokohama System is the availability of category-specific ROM. In the present study, the ROM was 75% for Category I, 11.1% for Category II, 0% for Category III, and 100% for Categories IV and V. Comparable ROM values for Categories IV and V have been documented in previous studies.[18,19] The relatively higher ROM observed in Categories I and II may be attributed to the limited number of cases with histopathological follow-up. The progressive increase in ROM across the diagnostic categories supports the validity of the Yokohama classification and its usefulness in guiding clinical decision-making.

The present study demonstrated excellent diagnostic performance of the IAC Yokohama System, with a sensitivity, specificity, and positive predictive value of 100%, a negative predictive value of 90.9%, and an overall diagnostic accuracy of 92.5%. Cyto-histological correlation was achieved in 94.6% of cases. Comparable diagnostic performance has been reported in previous validation studies of the IAC Yokohama System.[18,19-21] The absence of false-positive diagnoses and the presence of only two false-negative cases further highlight the reliability of FNAC when interpreted using a standardized reporting system.

In conclusion, the findings of the present study support the utility of the IAC Yokohama System as a standardized and effective reporting system for breast cytopathology. The system provides reliable risk stratification, excellent diagnostic performance and improved communication between clinicians and cytopathologists resulting in appropriate patient management and avoidance of unnecessary procedures.

CONCLUSION

This study confirms that application of the IAC Yokohama System enhances the diagnostic utility of FNAC, making it a reliable tool for breast lesion assessment. The majority of the lesions were benign, the most common benign lesion being fibroadenoma and the most common malignant lesion being invasive ductal carcinoma. The system successfully stratified risks with category-specific ROM and exhibited excellent diagnostic performance with high sensitivity, specificity, PPV, NPV and diagnostic accuracy. Adoption of the IAC Yokohama System facilitate the appropriate management of breast lesions.

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