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Original Research Article

Utility of Yokohama system for classification of breast FNA

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ABSTRACT

Background: Breast carcinoma is the most common malignancy among women globally. FNA is used as an important diagnostic tool as a part of triple assessment. The application of the IAC Yokohama system in breast cytology standardises reporting and also allows the calculation of risk of malignancy (ROM).
Objectives: To categorize all FNAC specimens according to the newly proposed IAC Yokohama reporting system for breast cytology. The ROM was determined for each category, sensitivity, specificity, negative and positive predictive values were evaluated to estimate the diagnostic accuracy of each category and inter-observer variability.
Materials and Methods: 105 cases of breast FNACs were classified according to the IAC Yokohama system. The study was conducted over a period of 4 years and 9 months retrospectively from August 2018 to May2023. All FNACs were correlated with corresponding histology, but in most studies correlation of FNACs with histopathology was not possible in all cases because many were lost to follow-up. ROM for each category, Specificity, sensitivity, diagnostic accuracy, negative predictive value, positive predictive value and interobserver variability of FNAC were calculated. p-value was also calculated.
Results: Out of 105 breast FNACs, the category wise distribution from category 1 to 5, were category 1:4(3.8%), category2: 20(19.1%), category3: 16(15.2%), category4:5(4.8%) and category 5: 60(57.1%) respectively. The sensitivity, specificity, positive and negative predictive value and diagnostic accuracy was 90.3%, 100%, 100%, 82.5% and 93.3% respectively.
Conclusion: The Yokohama system has standardized, broadly used, and well-understood diagnostic categories, with clear criteria for inclusion in a category and appears to be reproducible by most cytopathologists.

1. Introduction

Breast carcinoma is the most common malignancy among women globally.[1] It has now surpassed lung cancer as the leading cause of global cancer incidence in 2020 with an estimated 2.3 million new cases, representing 11.7% of all cancer cases. From being fourth in the list of most common cancers in India during the 1990s, it has now become the first.[1] The estimated number of incident cases in India in 2016 was 118000, 98.1% of which were females, and the prevalent cases were 526000.[1] Early diagnosis plays a major role in decreasing the mortality and morbidity in breast malignancy.[1] Triple assessment has proven essential to the diagnosis and treatment of breast cancer.[2] Mammography has proven to be an excellent technique for screening women over 40 years with a sensitivity of 97.0%, a specificity of 64.5%, a positive predictive value of 89.0%, and a negative predictive value of 90.9%, with a diagnostic accuracy of 89.3%.[2]

Triple assessment, includes three modalities, physical examination, imaging (mammography and/or ultrasound),

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and FNAC and core needle biopsy (CNB). To determine whether a breast mass is benign or malignant, a cytological or pathological diagnosis is typically required. Triple assessment has an essential role in the assessment and management of breast carcinoma.[3]

FNAC was first introduced in the 1930.[4] It is a simple, reasonably painless, less expensive, outpatient procedure which gives immediate results.[5] Breast FNAC has a sensitivity of 90-99%, a positive predictive value (PPV) of malignancy approaching 100 and a high degree of diagnostic accuracy that is up to 96.2%.[6] FNAC preferred over biopsy in specific clinical situations like confirmation and drainage of simple and complex cysts, diagnosis of infections/abscesses and to procure material for microbiological studies, patients taking anti-coagulants or with a history of bleeding diatheses and axillary staging of invasive breast cancer.[7] Successful breast FNA cytology service depends crucially on performance of the FNA technique as best as possible and the subsequent making of direct smears.[8] Poor technique is the major source of suboptimal quality.[8] Generally, cytopathologists were responsible for performing FNAC on palpable lesions however with improvement in radiology screening, radiologists and their trainees are increasingly doing both palpable and non-palpable lesions, especially in well developed countries.[9] Because they report on the slides pathologists are aware of their sampling practices, the same cannot be said for the radiologists who often have minimal contact with the pathologists.[9]

Due to the high inadequacy rates, fewer FNACs are being performed in certain wealthy countries, which has reduced the opportunity for radiologists and pathologists to receive proper training.[9] This presents a difficulty since FNAC necessitates continuous experience, solid training, and close monitoring of the diagnostic output and adequacy rates. When non-palpable lesions are present, the accuracy of FNAC is substantially lower.[9] The application of ultrasound-guided fine needle aspiration can compensate for this drawback.[10]

2. Materials and Methods

The present study is a retrospective study, in which a total of 105 cases of breast FNACs were evaluated. Period of study was for 4 years and 9 months, from August 2018 to May 2023.

All female and male patients who presented without a previous diagnosis of a breast mass during the study period were included in study. Cases with no corresponding histology were excluded from the study.

FNAC slides were stained by Giemsa and Papanicolaou stain, Haematoxylin & Eosin slides of the corresponding biopsies were retrieved from our archives. Two observers independently reviewed each slide and were blinded for the original diagnosis, clinical history, and image findings. The observers each assigned cases to 1 of the 5 diagnostic categories of the newly proposed IAC Yokohama system using the published criteria, where category 1 is insufficient, category 2 is benign, category 3 is atypical, category 4 is suspicious of malignancy, category 5 is malignant.

These were correlated with corresponding histopathology which were considered as the gold standard.

For each category was the risk of malignancy (ROM) calculated. Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy were evaluated.

The inter-observer agreement was then established by statistical methods.

3. Results

In this study total 105 Fnac cases were included and all these cases were categorized according to the IAC Yokohama system by 2 observers.

In present study the average age of cases was 52.33 years with a standard deviation of 14.44 years. There was a predominance of females with 95.24% cases (n=100), as opposed to 4.7% cases (n=5) seen in males 96.19% of lesions were unilateral as compared to bilateral lesions which are only 3.81%.

Out of a total 105 FNAC cases the category wise distribution from category 1 to category 5 as follows:

1. Category 1: 4 cases (3.8%), (Figure 1 A&B)
2. Category 2: 20 cases (19.1%), (Figure 2 A&B)
3. Category 3: 16 cases (15.2%), (Figure 3 A&B)
4. Category 4: 5 cases (4.8%), (Figure 4A&B)
5. Category 5: 60 cases (57.1%).(Figure 5 A&B)

After the Yokohama system categorization, correlation with histology was done in all 105 cases. Out of 105 cases, 68.6% (n=72) were malignant and 31.4% (n=33) were benign. Most of the cases in our study were malignant. 93.3% cases were concordant, and 6.7% cases were discordant when compared with histopathology. (Table 2)

The risk of malignancy (ROM) was calculated category-wise. The Category 1 had ROM of 75% with 3 out of 4 patients reported to have malignancy. Category 4 and 5 had 100% ROM, category 2 had 0% ROM, and category 3 had 25% ROM.

In our study for a total of 105 cases, the Yokohama category-based malignancy assessment had an accuracy of 93.3% on comparing with the histology. Predictive values were calculated. The sensitivity was 90.3% and specificity was 100%. The PPV was 100% and NPV was 82.5%. The p-value for the present study is 0.0001, it is statistically very significant.

Inter observer variability was assessed in our study. There were 2 observers in this study who were blinded for original diagnosis, and they assigned the cases into one of the 5 diagnostic categories of the Yokohama system. It was

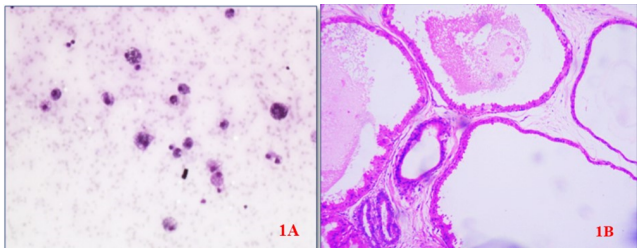

Figure 1: A): Insufficient category (C1); Giemsa 40x, showing only cyst macrophages, **B**): H&E 10x, corresponding histology showing fibrocystic disease

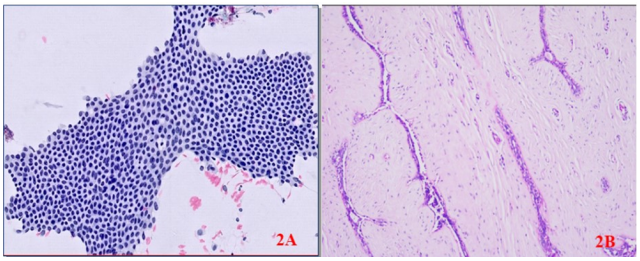

Figure 2: A): Benign category (C2); Pap 20x, benign ductal epithelial cells in sheets, **B**): H&E 20x, corresponding histology showing fibroadenoma

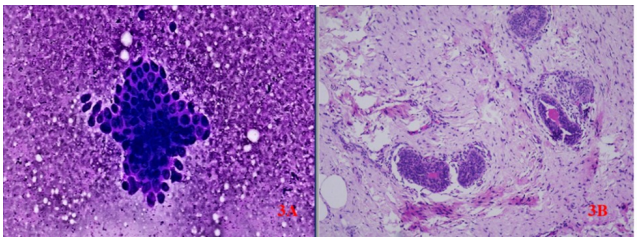

Figure 3: A): Atypical category (C3); Giemsa 40x, ductal epithelial clusters with nuclear crowding and atypia, **B**): Corresponding histology showing gynaecomastia

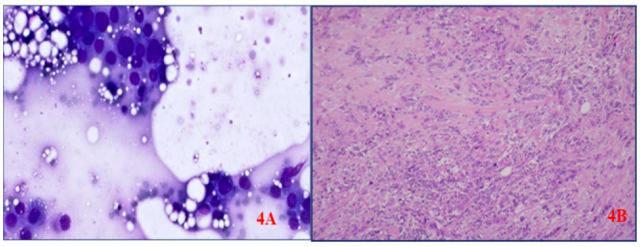

Figure 4: A): Suspicious of malignancy category (C4), Giemsa 40 Sparsely cellular smear with atypical cells showing anisonucleosis, **B**): H&E 20x, Corresponding histology showing duct carcinoma

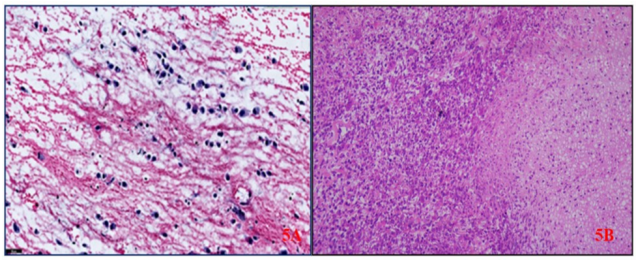

Figure 5: A): Malignancy category (C5), Papanicolaou stain 20x, malignant neoplastic cells in abundant stromal background; **B**): H&E 20x, corresponding histology showing malignant phyllodes

then compared with the histopathology. There was a very good interobserver agreement in the study for the Yokohama category assessment. It was seen that the inter observer 2 concordance was 73.33%. The Kappa value, which is concordance measure of agreement between the two data sets, was suggestive of moderate to good agreement with a k value of 0.616. (Table 1)

4. Discussion

The most common cancer among the women worldwide is carcinoma of the breast. In India, it is the most common cancer among women in metropolitan areas, making up about 30% of all cancers, while cervical cancer is more prevalent in t rural areas.[11] Over the past half-century, India has had a considerable increase in the age-standardized incidence rate of carcinoma breast. From 1990 to 2016, this rate rose by 39.1%, and regional reports of the same trend indicate that this pattern has been consistent.[11]

According to data from the Indian Council of Medical Research (ICMR), the age-adjusted risk of breast cancer was between 7.0 and 48.0 per lakh people in different parts of India, whereas the crude rate was from 4.5 to 39.0 per lakh people.[11] According to Globocan statistics from 2020, breast carcinoma was responsible for 10.6% (90408) of all cancer deaths in India as well as 13.5% of all cancers (178361).[11]

According to reports, the 5-year overall survival rate for patients in stages I, II, and III is 95%, 92%, 70%, and 21%, respectively.[12] In India, patients with breast cancer have a lower survival rate than in Western nations because to factors such as early beginning of the disease, late stage of the disease upon presentation, delayed start of definitive care, and insufficient or fragmented treatment.[12] The World Cancer Report of 2020 states that early detection and prompt treatment are the most effective interventions for controlling breast cancer.[12]

Triple assessment includes three modalities, physical examination, imaging (mammography and/or ultrasound), FNAC and core needle biopsy (CNB).[13] Cytological or pathological diagnosis is usually needed to ensure that a

Table 1: Interobserver variability (n=105)

IO variability		**Observer 1** Reported categories					
		Category 1	**Category 2**	**Category 3**	**Category 4**	**Category 5**	**Grand Total**
Observer 2 Reported Categories	Category 1	4		3			7
	Category 2		19	5			24
	Category 3		1	8	2	1	12
	Category 4				3	16	19
	Category 5					43	43
	Grand Total	4	20	16	5	60	105

Table 2: Predictive values comparison with other studies in literature

	Sensitivity	**Specificity**	**Positive predictive value**	**Negative predictive Value**	**Diagnostic accuracy**
Wong et al	94.2%	99.3%	98.0%	98.0%	99.7%
Oosthuizen et al	63%	100%	100%	84.6%	-
Nargund et al	86.7%	97.3%	99.2%	66.1%	88.9%
Hoda RS et al	96.3%	98.8%	98.7%	95.3%	-
Poornima et al	94.6%	98.9%	98.6%	95.7%	97.0%
Tejeswini et al	89.6%,	100%,	100%,	90.2%,	94.7%,
Sunitha et al	100%,	93.54%	100%	89.19%	95.78%
Cunha et al	94.4%	100%	100%	91.6%	96.5%
Our study	90.3%	100%	100%	82.6%	93.3%

breast mass is malignant or benign.[13] In the assessment of breast lesions, both core biopsy and fine needle aspiration cytology (FNAC) are useful techniques.[13]

A breast FNAC or CNB is indicated in several clinical scenarios that have mainly diagnostic values With the exception of some therapeutic applications for FNAC, such as when a benign cyst is present and can be evacuated during FNAC.[13]

FNAC is a reasonably safe procedure with a low rate of procedure-related problems that can be used for both palpable and nonpalpable breast lesions. However, hematoma development is rarely caused by FNAC.[13] The primary drawback of FNAC is its incapacity to identify and differentiate between some benign or borderline breast lesions and malignant lesions.[13]

The clear benefits of CNB include its high sensitivity and specificity, high negative and positive predictive value, low inadequacy rate, and advantage in the diagnosis of breast lesions in the grey zone, such as in-situ carcinomas and atypical ductal hyperplasia.[13]

Due to its quick diagnosis time, high level of acceptance, cost-effectiveness, high sensitivity and specificity, and ability to sample both the primary site and metastatic sites, FNAC is preferred over CNB.[13]

FNAC is considered a better procedure and has the great potential, especially in resource-limited settings since CNB is more expensive and requires a setup that is not possible in all areas, especially in developing countries with low socioeconomic status.[13]

Breast FNAC has a high degree of diagnostic accuracy (DA) of up to 96.2%, a positive predictive value (PPV) of malignancy reaching 100%, and a sensitivity of 90-99%.[14] Nonetheless, the technique used during the FNA and the smear-making process are critical to the success of breast FNA cytology. Issues with quality assurance are primarily caused by inadequate technique.[14]

Due to the overlap of cytomorphological features of both benign and malignant breast lesions to a significant extent, differentiation in all cases is not possible.[8] A standardised reporting system is necessary to address these areas of uncertainty that are in the grey area and to bring some uniformity to the reporting system. It is also necessary to standardise and enhance the reporting of breast cytology, establish best practice guidelines, enhance training in the performance and interpretation of breast cytology, and facilitate clear communication between cytopathologists and breast clinicians.[15]

The reproducibility of the results across institutions and nations is made possible by a standardised reporting system.[8] It enhances diagnostic consistency across various practice settings and not only helps the pathologists and treating surgeons or oncologists communicate more effectively.[8]

A Breast Group was formed by the International Academy of Cytology (IAC) in 2016 with the goal of creating thorough and uniform rules for reporting breast FNA cytology.[6] In 2019, the IAC Yokohama System for Reporting Breast Cytopathology was established. It includes FNAC methodology, smear preparation and handling, reproducible standardised reporting, use of ancillary diagnostic and prognostic tests, correlation with clinical work-up algorithms, and reasons for breast FNA

cytology.[16]

The Yokohama System for Reporting Breast Cytopathology comprises 5 categories that can be stratified by their risk of malignancy (ROM):[6]

1. Category 1: Insufficient/inadequate
2. Category 2: Benign
3. Category 3: Atypical
4. Category 4: Suspicious of malignancy
5. Category 5: Malignant

Many studies have been conducted over the past few years that categorized the FNAC cases according to the Yokohama system. Such studies are required to standardize and validate the Yokohama system.

The present study is a retrospective study done over 4 years and 9 months from August 2018 to May 2023. In this study, 105 cases were included all with histologic correlation, and they were classified according to the IAC Yokohama system.

In present study it was seen that the average age of patients was 52.33 years with a standard deviation of 14.44 years. Most of the patients were in the age group of 40-60 years.

A study done by Sigamani et al. had a median age group of 30 to 40 years.[17]

Present study population comprised 95.2% were females and 4.8% of males**.** This study is comparable to studies done by Nargund et al[18] and Wong et al,[19] in which there is a female predominance.

48.6% cases had lesions of left breast with 47.6% in the right breast. Bilateral cases were only 3.8%.

In this study, out of a total of 105 cases, 60(57.1%) cases were in Category 5 constituting the malignancy. This was followed by Category 2, 20 cases (19.5%), then Category 3,16 cases (15.2%), category 4 and category 1 which were 5 cases (4.8%) and 4 cases (3.8%) respectively.

This study was comparable with studies of Montezuma et al,[20] Wong et al,[19] Chauhan et al[21] and De Rosa et al.[22] Our study had highest number of cases were in category 5, possibly, since this is a tertiary care center.

98 cases that is 93.3% were concordant with histology and 6.7% (n=7) cases were discordant. According to Chauhan et al[21] and Joshee et al[23] had concordance of 98.4%, 97.5% in their studies respectively**.**

However, in most studies correlation of FNACs with histopathology was not possible in all cases because many were lost to follow-up. In this study we correlated all FNACs with corresponding histopathology

The risk of malignancy (ROM) for the category 1 was 75%, the category 2 was 0%, the category 3 was 25%, category 4 and category 5 had 100% ROM. We compared ROM of each category with studies like Andrew S Field et al,[6] Nikas et al,[24] Niaz et al,[25] Sunder et al[26] and Oosthuizen et al.[27]

In this study the ROM was 75% in insufficient category (category 1). However, the pitfall was that our study had a smaller number of cases in this category (C1). The low sample size was one of the reasons for the high ROM. Inadequate specimens can be caused by a variety of factors, such as bloody aspiration, smearing, and staining errors. The high insufficient rates in our study highlight problems in sampling method of FNA and usefulness of a rapid on-site evaluation. A low proficiency in sampling and smearing techniques of palpable breast lesions by the radiologists may also be a reason for the high insufficient results. ROSE technique helps decrease the rate of insufficiency.

This study has a sensitivity, specificity, positive predictive value and negative predictive values of 90.3%, 100%, 100% and 82.6% respectively. Which was statistically significant with a p value of 0.0001 and consistent with the various studies in literature (Table 2)

Moreover, all the cases had corresponding histopathology for comparison with diagnostic accuracy of 93.3%. In literature most studies did not have a histological correlation in all cases.

Another important aspect was a comparison of interobserver variability between two observers. Observer 1 was a senior pathologist, observer 2 was a junior pathologist. Both were blinded for the original diagnosis. There was a high degree of interobserver agreement between the two observers. The accuracy of categorization observer 2 as compared to Observer 1 was 73.3%. The Kappa value, which is a measure of agreement between two data sets was suggestive of good agreement with a k value of 0.616. The Kendall tau values of >0.8 and contingency coefficient of >0.8 were also suggestive of high inter observer agreement with low variability.

Layfield et al. conducted a study in 2020 on interobserver agreements for the Yokohama System. In this study, cases are evaluated by 4 pathologists, almost 70% of cases, were in agreement between the 4 observers, with a K value of 0.70,[28] similar to the results in this series.

Boler A K et al did a study in 2022 to assess the reproducibility of the Yokohama system.[29] Three cytopathologists independently reviewed each slide. Among them, 1 had approximately 20 years of experience and the other 2 had 12 years and 8 years of experience, respectively. Inter-observer agreement among the observers was 70.5% and k value was 0.63.[29]

The majority of the discrepancies were seen between category 4 and category 5. This could be due to a lack of definite objective criteria between category 4 and category 5 of the IAC Yokohama system[74], and possible inexperience of the junior pathologist.

5. Conclusion

FNAC is a good alternative to CNB for diagnosing breast lesions in resource limited settings. Triple assessment, with

judicious use of FNAC is preferable over CNB, especially in palpable lesions of the breast and in screening programs. The Yokohama system has standardized, broadly used, and well-understood diagnostic categories, with clear criteria for inclusion in a category, hence appears to be reproducible by most cytopathologists.

Yokohama system helps to identify inefficiencies such as inadequate specimens. Rapid onset evaluation (ROSE) if available could circumvent difficulty and this decreases the number of insufficient samples.

The risk of malignancy (ROM) can be used by all clinicians alike as some form of guidance in the clinical management of patients. This system appears to provide greater agreement among observers and this has a high reproducibility. The structured reporting also enhances the reproducibility of reports by those with short training and experience as junior pathologists. Accurate and consistent communication between the cytopathologist and the treating clinician is the key to appropriate treatment and follow-up based on cytopathological classification.

Our study recommends the usage of FNA for the evaluation of breast lumps and further categorization based on the Yokohama system for appropriate patient management, especially in resource limited countries.

6. Source of Funding

None.

7. Conflict of Interest

Authors declare no conflict of interest.

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