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Original Article

Association of Yokohama System for Reporting Breast Lesions with BI-RADS

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ABSTRACT

Introduction: The newly developed International Academy of Cytology Yokohama System standardizes reporting system, fostering uniformity in reporting practices. The study aimed to assess the diagnostic utility of the International Academy of Cytology Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology and comparison with Breast Imaging-Reporting and Data System.

Materials and Methods: A prospective cross-sectional observational study was conducted, spanning a one-year period. The study focused on patients with breast lesions who were undergoing Fine Needle Aspiration Cytology and had ultrasonography. The association of Yokohama system and Breast Imaging-Reporting and Data System with calculation of statistical measures; sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy was done.

Results: The study included 109 patients with breast lesions, comprising 101 females (92.7%) and 8 males (7.3%). Results showed a strong association between Yokohama categories and Breast Imaging-Reporting and Data System, with high sensitivity (94.44%), specificity (97.70%), positive predictive value (89.47%), negative predictive value (98.83%), and overall accuracy (97.14%). The p value calculated was <0.05 and was statistically significant.

Conclusions: This study successfully implemented a standardized reporting system for all breast Fine Needle Aspiration Cytology cases, utilizing The International Academy of Cytology Yokohama System for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology at Patan Academy of Health Sciences. The findings of the study demonstrated consistency with Ultrasonography Breast Imaging-Reporting and Data System, thereby contributing valuable insights for patient management.

Keyword: BI-RADS; Fine Needle Aspiration Cytology; Yokohama

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INTRODUCTION

Breast cancer stands out as a significant global health challenge, in the year 2020, a staggering 2,261,419 cases of breast cancer were diagnosed globally, resulting in 684,996 deaths.[1] The incidence of breast cancer in South-Eastern Asia is notably high, reaching 41.2% per 100,000 female populations.[2] In the context of Nepal, the Population-Based Cancer Registry report of 2019, which encompassed a study of 12,336 cancer cases, revealed 224 cases (11.1%) of breast cancer.[3] The increasing incidence of breast cancer underscores the critical need for novel approaches in early detection and improved survival outcomes.

The reporting system of breast Fine Needle Aspiration Cytology (FNAC) is not uniform at many centers.[4] Breast ultrasound (USG) and/or mammography serve as straight forward methods for the initial risk assessment of breast lesions.[5] The radiological investigations for breast mass follows Breast imaging-reporting and data system (BI-RADS).[6] The development of the cytopathology reporting system began at the International congress of cytology in Yokohama, in May 2016. The International academy of cytology (IAC) Yokohama system for reporting breast FNAC uses five clearly defined categories (insufficient/ inadequate, benign, atypical, suspicious of malignancy, and malignant), each with a clear definition, description, specified risk of malignancy (ROM) and a suggested management algorithm.[7] Currently most institutions outside Nepal are using this system for uniformity of reporting.[7-8] Studies have been done to evaluate the association of cytopathology using the IAC Yokohama system with histopathology and radiological BI-RADS.[8]

The application of IAC Yokohama system for reporting breast cytopathology standardizes reporting system, brings uniformity in reporting, clarifies communication between pathologist and clinicians, empowers the quality and reproducibility of reports, and assists patient management.

MATERIALS AND METHODS

The overarching aim of this study is to evaluation of fine needle aspiration cytology of breast lesions by application of International Academy of Cytology Yokohama System. In pursuit of this objective, specific goals have been outlined. Firstly, to categorize breast lesions according to the IAC Yokohama System, providing a structured framework for reporting FNAC results. Additionally, the investigation aims to establish an association between the Yokohama system categories and the BI-RADS. Furthermore, the study intends to quantify the performance of the Yokohama system by calculating key metrics such as sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy concerning BI-RADS.

This was a prospective cross-sectional study conducted at the Department of Pathology, Patan Hospital, Lagankhel, Nepal over a one-year period from May 23, 2022, to May 22, 2023. The study was commenced only after ethical approval from the Institutional Review Committee (IRC) of PAHS with reference number: PML2205221623. Informed consent was obtained from all the participants willing to participate in the research after explaining in detail about the purpose of the study. Confidentiality was strictly maintained. All the data collected were only relevant to study, stored safely in password protected computer of department of pathology and was disseminated only for study purpose. There was no additional financial burden to participants for the study population.

In estimating the sample size for this study, the approach involves referencing a previous study conducted by Pudasaini et al.[9] which reported a 9.4% prevalence rate of breast FNAC over a year period. To ensure a 95% confidence level and a 5% absolute error or precision (d), the Daniel formula (1999) for prevalence is applied: n=Z2 P(1-P)/d2. Here, Z is 1.96 for a 95% confidence interval, P is 9.4%, and d is 5%. Plugging in these values, the calculation yields 85.56≈86. Nevertheless, data analysis involved 109 cases that met the inclusion criteria during the study period.

The study included all patients with breast lesions undergoing FNAC at the Department of Pathology and the Department of Interventional Radiology. Exclusion criteria comprised patients without an ultrasonography report, those with an ultrasonography report lacking BI-RADS category, and patients with mammography BI-RADS category. Standard procedure of FNAC was done for breast lesions and the aspirate was obtained in at least 4 glass slides. Routine staining of slides with giemsa stain for air dried samples and papanicolaou stain for alcohol fixed sample was done.[10] The prepared slides were screened in low power 100X followed by evaluation under high power 400X using light microscope (Olympus CH20i). The results are analyzed by the consultant pathologists and myself. The findings were categorized according to IAC Yokohama System.[7]

All data was collected on preformed proforma and entered in excel sheet. The data was analyzed using EPI INFO version 7.2.2.2 and EZR version 1.36. The categorical data comprises of sex, age groups, side, procedure, Yokohama category and BI-RADS. Independent variable of the study includes Yokohama category and dependent variable includes BI-RADS.

In the primary statistical analysis, the categorization of lesions was based on their malignancy potential, and the approach considered specific types as either malignant or benign. All the invasive carcinomas, lesion suspicious for malignancy and atypical were considered as malignant. All other lesions (including fibroadenoma, benign breast lesion, benign cystic lesion, benign fibroepithelial lesion, epidermal cyst, fibroadenoma with fibrocystic changes, galactocele, granulomatous mastitis, gynaecomastia, proliferative breast disease, subareolar abscess and lipoma) were considered as benign. Inadequate category was not included in comparison.

Likewise, BI-RADS 4A, BI-RADS 4B, BI-RADS 4C and BI-RADS 5 were considered malignant and BI-RADS 1, BI-RADS 2, BI-RADS 3 were considered as benign. However, there was no FNAC data on BI-RADS 0, BI-RADS 1 and BI-RADS 6 and was not included in analysis.

RESULTS

During the period from May 23, 2022, to May 22, 2023, a total of 109 patients FNAC and USG for breast lesions. Among these

participants, the majority were females, constituting 101(92.7%) individuals, while males represented 8(7.3%) individuals. The highest prevalence of breast lesions was observed in the age group of 20-30. The age distribution in the study population revealed a mean age of 34.50 years, with participants ranging from 14 to 83 years old. In terms of laterality, among the 109 cases, 50 had right-sided breast lesions, 54 had left-sided breast lesions, and 5 presented with bilateral breast lesions. The majority of cases, comprising 90 instances, underwent blind FNAC, while a smaller number, specifically 19 cases, opted for USG-guided FNAC.

As per IAC Yokohama system for reporting fine needle aspiration cytology there are 5 categories which includes inadequate, benign, atypical, suspicious of malignancy and Malignant. The frequency of each category is depicted into Table 1. A case of breast lesion categorized as Malignant with cytomorpholgical features are shown in Figure 1.

Table 1: Classification of breast lesion as per IAC Yokohama system for reporting fineaspiration cytology

Yokohama category	Frequency	Percent (%)
Inadequate	4	3.7
Benign	86	78.9
Atypical	1	0.9
Suspicious of malignancy	5	4.6
Malignant	13	11.9
Total	**109**	**100**

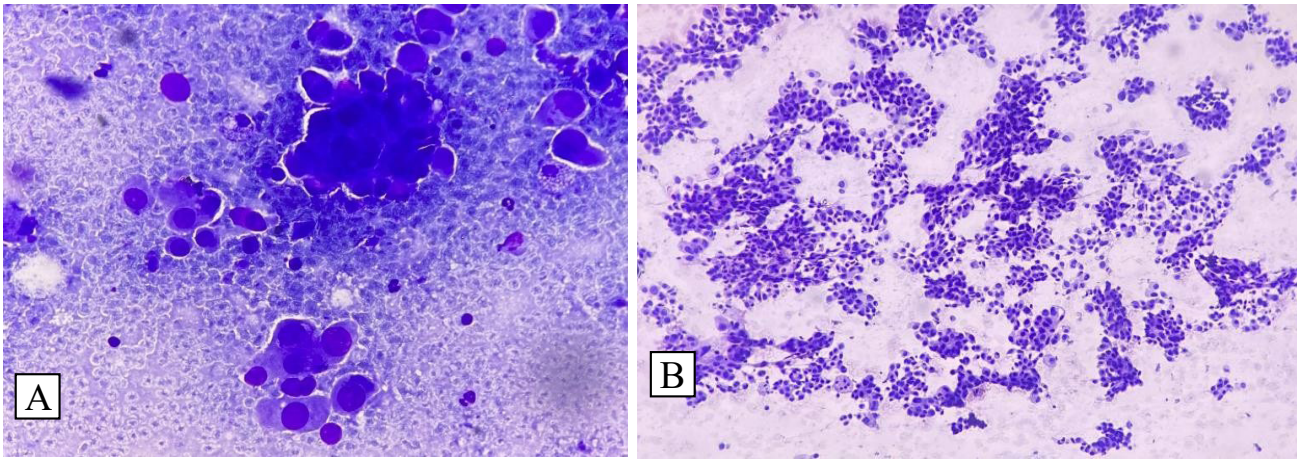

Figure 1. A case of breast lesion categorized as Malignant. (A) Tumor cells with marked *pleomorphism, large nucleus giving rise to high N:C ratio (Giemsa stain, X40). (B) Cellular smear composed of tumor cells arranged into clusters and singly scattered form with individual tumor cells with large nucleus, irregular nuclear rim, granular to clumped chromatin and prominent nucleoli (PAP stain, X10).*

The BI-RADS category includes BI-RADS 2, BI-RADS 3, BI-RADS 4A, BI-RADS 4B, BI-RADS4C

and BI-RADS 5. There was prevalence of BI-RADS 2 category 82 cases (75.2%) in benign condition and BI-RADS 5 category have 12 cases (11%) among malignant category. There were no observed cases in BI-RADS categories 0, 1, and 6, as illustrated in Table 2.

Table 2: Classification of breast lesion as BI-RADS

BI-RADS category	Frequency	Percent (%)
2	82	75.2
3	9	8.3
4A	2	1.8
4B	1	0.9
4C	3	2.8
5	12	11.0
Total	**109**	**100**

The specific diagnosis includes both benign and malignant disease of breast. The benign diagnosis includes; fibroadenoma, benign breast lesion, benign cystic lesion, benign fibroepithelial lesion, epidermal cyst, fibroadenoma with fibrocystic changes, galactocele, granulomatous mastitis, gynaecomastia, proliferative breast disease, subareolar abscess and lipoma. The malignant diagnosis includes; malignant ductal carcinoma and lesion suspicious for malignancy. The diagnostic entity "suspicious for malignancy" and includes 7 (6.5%) cases. The suspicious of malignancy as diagnosis were given for the lesions with the presence of some cytomorphological features which are usually found in malignant lesions, but with insufficient malignant features, either in number or quality, to make a definite type of malignancy diagnosis. Benign breast lesions were classified based on cytomorphological features indicative of a benign nature. However, a definitive diagnosis was challenging due to insufficient cytomorphological features for a precise characterization within the benign category.[11] There was prevalence of fibroadenoma 53(48.6%) to most as benign disease, the cytomorphology. Similarly, malignant ductal carcinoma 13(11.9%) to most as in malignancy. These findings are tabulated in Table 3.

Table 3: Specific diagnosis of fine needle aspiration

Specific diagnosis		Frequency	Percent (%)
Benign	Fibroadenoma	53	48.6
	Benign breast lesion	5	4.6
	Fibroadenoma with fibrocystic changes	4	3.6
	Lipoma	4	3.7
	Gynaecomastia	4	3.7
	Galactocele	3	2.8
	Granulomatous mastitis	3	2.8
	Benign cystic lesion	2	1.8
	Epidermal cyst	2	1.8
	Proliferative breast disease	2	1.8
	Subareolar abscess	2	1.8
	Benign fibroepithelial lesion	1	0.9
Malignant	Malignant ductal carcinoma	13	11.9
Suspicious	Suspicious for malignancy	7	6.5
Inadequate	Inadequate	4	3.7
	Total	**109**	**100.0**

The distribution of breast lesion cases across BI-RADS categories, indicating varied diagnoses as per IAC Yokohama categories are summarized in Table 4.

Table 4: Comparison of IAC Yokohama system categories with radiology BI-RADS

Yokohama category	BI-RADS						
	2	**3**	**4A**	**4B**	**4C**	**5**	**Total**
Inadequate	3	1	0	0	0	0	4
Benign	79	6	1	0	0	0	86
Atypical	0	0	0	0	0	1	1
Suspicious for malignancy	0	2	1	0	0	2	5
Malignant	0	0	0	1	3	9	13
Total	**82**	**9**	**2**	**1**	**3**	**12**	**109**

A comparative analysis between the IAC Yokohama classification and BI-RADS cases was conducted. All the malignant, suspicious and atypical of IAC Yokohama and BI- RADS 4A, BI-RADS 4B, BI-RADS 4C and BI-RADS 5 are considered as malignant. Similarly, benign category of IAC Yokohama and BI-RADS 2 and BI-RADS 3 are considered as benign. The cross tabulation of same is done in Table 5.

Table 5: Cross tabulation of benign and malignant lesions on Yokohama category andradiology BI-RADS

Yokohama Category	Radiological findings			Chi-square (p-value)
	BI-RADS 4A, 4B, 4C and 5	**BI-RADS 2 and 3**	**Total**	
Malignant/Suspicious/ Atypical	17	2	19	<0.05
Benign	1	85	86	
Total	18	87	105	

The calculation of sensitivity, specificity, positive predictive value, negative predictive value and accuracy of radiology BI-RADS comparing with IAC Yokohama system for reporting breast cytopathology was 94.44%, 97.70%, 89.47%, 98.83% and 97.14% respectively. The Chi- square test was used to find an association between the BI-RADS and IAC Yokohama system. The p value calculated was <0.05 and was statistically significant. These values provide an assessment of the effectiveness of both systems in diagnosing breast cytopathology and indicate the reliability of their predictions.

DISCUSSION

The study emphasizes the advantages of breast FNAC as a diagnostic test, highlighting its low cost, rapid reporting, well-defined diagnostic categories, and comparability with radiological BI-RADS. The confirmation of the malignant disease aids suitability of FNAC as a first-line diagnostic test. The study also emphasizes the accuracy of radiological BI-RADS, especially in diagnosing breast lesions in correlation with breast FNAC as per IAC Yokohma system ultimately adding values to clinical assessment. The implementation of the IAC Yokohama System for reporting breast FNAC is highlighted for its role in clearly identifying different diagnostic categories with increasing ROM.[12] Pathologists using this system contribute to the diagnosis, classification, and management recommendations, ensuring uniformity in reporting. Clinicians can easily comprehend the disease condition and proceed with the management of breast lesions, ultimately leading to early diagnosis and treatment, benefiting the patients.

The study had included 109 cases with breast lesion. These cases had undergone clinical examination and had undergone USG where the lesion was reported according to BI-RADS. The FNAC was performed and includes the cases of both blind and USG guided FNAC. The Out of 109, 101(92.7%) were females and 8(7.3%) were males. The mean age of study population was 34.50 years, minimum and maximum age being 14 and 83 years respectively. The laterality of breast lesion among the study population includes 50 cases (45.9%) with lesion at right side of breast, 54 cases (49.5%) with lesion at left side of breast and 5 cases (4.6%) with bilateral breast lesion. Among 109 cases; 90 cases (82.6%) had undergone blind FNAC procedure and rest 19 cases (17.4%) had undergone USG guided FNAC. This demographic overview provides key insights into the composition of the study population, including gender distribution, age prevalence, and the laterality of breast

lesions, along with the preferred method of FNAC. The breast lesion was categorized as per The IAC Yokohama system for reporting breast FNAC includes 4 cases (3.7%) of inadequate, 86 cases (78.9%) of benign, 1 case (0.9%) of atypical, 5 cases (4.6%) of suspicious of malignancy and 13 cases (11.9%) of Malignant.

The finding of present study is comparable to the studies done across the globe representing the high burden of breast disease were category benign followed by malignant even in developing countries like Nepal similar to other part of world. The study conducted by Montezuma D et al in Portugal in 2021, out of 3625 cases, 209 (5.77%) were categorized as inadequate, 2660 (73.38%) as benign, 499 (13.74%) as atypical, 57 (1.57%) as suspicious for malignancy, and 200 (5.54%) as malignant[13] Similarly, Marabi et al in the Philippines in 2021 analyzed 1080 cases, reporting 126 (11.7%) cases as inadequate, 611 (56.6%) as benign, 217 (20.1%) as atypical, 66 (6.1%) as suspicious for malignancy, and 60 (5.6%) as malignant.[14] In India, Sundar et al, in 2021, studied 663 cases, finding 62 (9.4%) cases inadequate, 436 (65.7%) benign, 41 (6.2%) atypical, 26 (3.9%) suspicious for malignancy, and 98 (14.8%) malignant.[15] Dixit N et al, also in India in 2021, examined 512 cases, identifying 38 (7.4%) cases as inadequate, 379 (74%) as benign, 29 (5.7%) as atypical, 7 (1.4%) as suspicious for malignancy, and 59 (11.5%) as malignant.[16] Nigam et al in 2021 studied 123 cases, reporting 4 (3.25%) cases as inadequate, 57 (46.34%) as benign, 15 (12.2%) as atypical, 6 (4.88%) as suspicious for malignancy, and 41 (33.33%) as malignant.[17]

The specific diagnosis on basis of cytomorphology includes both benign and malignant disease of breast. The benign diagnosis includes; benign breast lesion (4.6%), benign cystic lesion (1.8%), benign fibroepithelial lesion (0.9%), epidermal cyst (1.8%), fibroadenoma (48.6%), fibroadenoma with fibrocystic changes (3.6%), galactocele (2.8%), granulomatous mastitis (2.8%), gynecomastia (3.7%), lipoma (3.7%), proliferative breast disease (1.8%) and subareolar abscess (1.8%). The malignant diagnosis includes; malignant ductal carcinoma (11.9%) and lesion suspicious for malignancy (6.5%). Inadequate category and atypical category have 3.7%. There was highest prevalence of fibroadenoma 53(48.6%) among all the diagnostic category and in females. The malignant ductal carcinoma has prevalence of 12 (11.9%) in malignancy category which had included both male and female gender. This was comparable with study by Marabi et al. which have most prevalence of fibroadenoma 134 (26.2%).[14] The diagnostic entity "suspicious for malignancy" and includes 7 (6.5%) cases. The suspicious of malignancy as diagnosis were given for the lesions with the presence of some cytomorphological features which are usually found in malignant lesions, but with insufficient malignant features, either in number or quality, to make a definite type of malignancy diagnosis. There were total 8 males in our study and was diagnosed as; 4 (3.7%) cases of gynecomastia, 2 (1.8%) cases malignant ductal carcinoma, 1 (0.9%) case of epidermal cyst and 1 (0.9%) case of suspicious for malignancy.

The BI-RADS category includes BI-RADS 2, BI-RADS 3, BI-RADS 4A, BI-RADS 4B, BI-RADS4C and BI-RADS 5. There was prevalence of BI-RADS 2 category 82 cases (75.2%) in benign condition and BI-RADS 5 category have 12 cases (11%) among malignant category. There were no cases of BI-RADS 0, 1 and 6. Categorization of breast lesion with Yokohama and BI-RADS was done. IAC Yokohama inadequate category includes 3 cases of BI-RADS 2 and 1 case of BI-RADS 3. Benign category includes 79 cases of BI-RADS 2, 6 cases of BI-RADS 3, 1 case of BI-RADS 4A. Atypical category include 1 case of BI-RADS 5. Suspicious for malignancy includes 2 cases of BI-RADS 3, 1 case of BI-RADS 4A and 2 cases of BI-RADS 5. Malignant category includes 1 case of BI-RADS 4B, 3 cases of BI-RADS 4C and 9 cases of BI-RADS 5.

A study done by Patro S et al. in year 2021 in India out of 100 cases, 1 (1%) case of BI-RAD 1, 55 (55%) cases of BI-RADS 2, 22 (22%) cases of BI-RADS 3, 15 (15%) cases of BI-RADS 4 and 7 (7%) cases of BI-RADS 5.[18] In 2017, Mahtab Y conducted a study in India involving 66 cases. The findings revealed that 38 cases (57.58%) were classified as BI-RADS 2, 15 cases (22.73%) as BI-RADS 3, 5 cases (7.57%) as BI-RADS 4, and 8 cases (12.2%) as BI-RADS 5.[19] As per IAC Yokohama classification and BR-RADS cases comparison was made between benign and malignant was made. All the malignant, suspicious and atypical of IAC Yokohama and BI- RADS 4A, BI-RADS 4B, BI-RADS 4C and BI-RADS 5 are considered as malignant. Similarly, benign category of IAC Yokohama and BI-RADS 2 and BI-RADS 3 are considered as benign. Inadequate category which consists of 4 cases was not included as there was no diagnosis made in these cases. The cross tabulation of same was done with independent variable as Yokohama category and dependent variable as BI-RADS. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of radiology BI-RADS on comparison with IAC Yokohama system for reporting breast cytopathology was 94.44%, 97.70%, 89.47%, 98.83% and 97.14% respectively. The p value calculated was <0.05 and was statistically significant.

In a study conducted by Patro S et al. there was sensitivity, specificity, positive predictive value and negative predictive value of 88.8%, 96.1%, 85.7% and 94.8% respectively.[18] The study have comparable specificity with our study. Similarly, comparison with study conducted by Mahtab Y shows sensitivity of 86.75%, specificity of 95.45%, positive predictive value of 97.09% and negative predictive value of 2.91% among malignant diagnosis. The sensitivity and specificity among benign diagnosis was 95.45% and 86% respectively with similar PPV and NPV as malignant diagnosis.[19]This study have comparable sensitivity with our study. According to the study conducted by Nandan Kumar et al. the sensitivity, specificity, positive predictive value, negative predictive value and accuracy was 89.45%, 90.31%, 91.44%, 85% and 88.17% respectively.[20] The study had compared BI-RADS with histopathology and FNAC which ever available as diagnostic modality available for that case. In a study conducted by Bn N et al. the study had compared the BI-RADS and FNAC with gold standard test histopathology with sensitivity, specificity, positive predictive value, negative predictive value and accuracy was 88%, 87.5%, 80%, 93% and 88% respectively for BI-RADS and 100% for all the parameters on FNAC.[21] However, our study lacks comparison with histopathology due to limitation of sample.

The core-needle biopsies are recommended for a confirmatory diagnosis of breast cancer; we believe that FNAC still should play an important role in the diagnosis of breast lesions. Core-needle biopsies provide the ability to document invasion and conveniently provide tissue for assessment of estrogen receptor, Progesterone receptor, and HER2 positivity in the invasive component in malignant lesions. The FNAC provides an

advantages when assessing benign lesions. FNAC is less costly and has a lower turnaround time. The proper correlation with clinical and radiological assessment, FNAC rapidly reassures patients at a fraction of the cost of core-needle biopsies.

The acknowledgment that the study was conducted at a single center for one-year duration and that the sample size was limited are important considerations for interpreting the results. The reliance on histopathology as the gold standard is a strength, as it provides a definitive diagnosis. However, the impact of a limited histopathology sample on the precision of correlations with BI-RADS and IAC Yokohama system results is duly noted.

In conclusion, this study re-confirms the excellent accuracy of radiological BI-RADS and breast FNAC using the IAC Yokohama system in diagnosing breast lesions. Breast FNAC should retain its relevance in situations where cost and time are limited resources.

CONCLUSIONS

In conclusion, this study conducted at the Patan Academy of Health Sciences has made significant strides in standardizing the reporting system for breast FNAC. By adopting the International Academy of Cytology Yokohama system for Reporting Breast Fine Needle Aspiration Biopsy Cytopathology, the study has established a consistent and structured framework for reporting practices. The research findings demonstrated a noteworthy concordance with USG BI-RADS assessments, indicating a harmonious integration between cytological and radiological evaluations. The implementation of the IAC Yokohama system not only aided in the effective management of patients but also introduced uniformity in reporting procedures. This standardization has resulted in clearer communication between pathologists and clinicians, facilitating a more collaborative and informed approach to patient care. The study has played a pivotal role in empowering the quality and reproducibility of reports, ensuring a reliable and standardized diagnostic process for breast lesions. Ultimately, the successful application of the IAC Yokohama system at the Patan Academy of Health Sciences has not only improved the overall quality of reporting but has also contributed to enhanced patient management strategies. This study serves as a foundation for continued advancements in breast healthcare practices, emphasizing the importance of standardized reporting systems for optimal patient outcomes.

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