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Concordance and Discordance Between BI-RADS and The IAC Yokohama System for Reporting Breast FNAB Cytopathology for Diagnosis of Palpable Breast Lesions: An Institutional Study

[1]Dr. Neethu G.V. MBBS, MD Pathology, Professor, Department of Pathology, JJM Medical College, Davangere, Karnataka.

[2]Dr. Apurva Shrivastava, MBBS, MD Pathology, Senior Resident, Department of Pathology, Manipal Tata Medical College, Jamshedpur, Jharkhand.

[3]Dr. Vardendra Kulkarni, MBBS, MD Pathology, Professor and HOD, Department of Pathology, JJM Medical College, Davangere, Karnataka.

Corresponding Author: Dr. Apurva Shrivastava, MBBS, MD Pathology, Senior Resident, Department of Pathology, Manipal Tata Medical College, Jamshedpur, Jharkhand.

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Abstract

Background: Breast cancer is one of the most prevalent cancers in women worldwide. Early diagnosis of breast lesions is indispensable, as this significantly decreases morbidity and mortality. Triple assessment (physical examination, radiology, and pathological examination-FNAC/core biopsy) is widely used for accurately diagnosing palpable breast lesions. Radiological discordancy poses challenges in precise pathological reporting and limits clinicians' decision making with regards to pre-operative and post-operative patient management.

Aim: To evaluate concordance & discordance rates between BI-RADS (Breast Imaging-Reporting and Data System) and the IAC Yokohama system for reporting breast FNAB cytopathology for diagnosis of palpable breast lesions.

Methods: This retrospective observational study conducted over a period of 1 year (01/01/2023-31/12/2023); included 116 cases with both BI-RADS and cytopathological diagnosis available. Diagnosis of all cases was confirmed by histopathology. Further concordance and discordance rates were tabulated.

Results: Data retrieved from 116 cases-age wise distribution of cases, mean size, laterality, quadrants involved, number of lumps and presenting complaints with duration. USG features included echogenicity, margins, type of lesion and BI-RADS score. Correlation

of BI-RADS with cytopathology included concordant malignant (83.33%) and benign (98.8%) cases, discordant malignant (16.67%) and benign (1.2%) cases, sensitivity (83.33%), specificity (98.8%), positive predictive value (96.2%), negative predictive value (94.4%), accuracy (94.8%), concordance (94.8%) and discordance rate (5.2%) were tabulated. 6/116 cases were discordant.

Conclusion: Detailed understanding with a robust multidisciplinary approach is required for definitive diagnosis, effective implementation of ameliorative strategies and long-term follow-up of patients. The purpose of FNAC is to confirm the diagnosis preoperatively in conjunct with BI-RADS, as both screening tools have their own limitations; and thus, avoid unnecessary surgery in specific benign conditions.

Keywords: Benign, BI-RADS, Concordance, Discordance, FNAC, Malignant

Introduction

Breast carcinoma is the most common and deadly malignancy of women globally.[1] Breast cancer is rare in women younger than 25 years of age and increases in incidence rapidly after 30 years of age.[1] The most important risk factors include gender (99% of those affected are female), increasing age, germline mutations of high penetrance, strong family history (>1 first-degree relative affected, young age, multiple cancers), personal history of breast cancer and high breast density have a relative risk of >4 times; germline mutations of moderate penetrance, high-dose radiation to chest at young age, and family history (1 first-degree relative affected) have a relative risk of 2.1–4.0 times; early menarche (age <12years), late menopause (age >55years), late first pregnancy (age >35 years), null parity, absence of breastfeeding, exogenous hormone therapy, postmenopausal obesity, physical inactivity, and high alcohol consumption have a relative risk of 1.1–2.0 times.[1] One-quarter-one-third of breast cancers occur due to inheritance of a susceptibility gene/genes.[1] Mutations in BRCA1 and BRCA2 are responsible for 80% to 90% of single gene familial breast cancers and about 3% to 6% of all breast cancers.[1]

The most common breast signs and symptoms reported by women are pain, inflammatory changes, nipple discharge, “lumpiness,” or a palpable mass.[1] Patients presenting with these signs/symptoms are assessed by a combination of clinical examination, radiological imaging and tissue sampling taken for either cytology (FNAC)/ histological analysis (core biopsy). This combined approach is called ‘triple assessment.’ The positive predictive value and diagnostic accuracy of this combination approaches 100%.[2]

Ultrasonography (USG) is the primary imaging modality in young women with dense breast tissue in whom mammograms are difficult to interpret.[2] USG can distinguish cystic from solid lesions.[2] Simple cysts do not require further work-up and follow-up can be avoided. Therapeutic aspiration may be performed for cysts causing pain.[2] A well-circumscribed, mobile, solid mass in a young woman is likely a fibro adenoma and has an extremely low likelihood of malignancy.[2] Such a finding requires reassurance and imaging follow-up. Solid masses with an irregular shape and ill-defined margins (indistinct, angular or spiculated) are suspicious for malignancy and require biopsy.[2] USG of the axilla is performed when cancer is diagnosed, with guided percutaneous tissue biopsy of any suspicious lymph glands.[2]

Prior to implementation of BI-RADS there was a lack of uniformity in radiological reporting and this often

resulted in discrepancies in management strategies. Developed in the 1990s, BI-RADS categorization has been extensively used as a quality assurance tool and as a surrogate to pathological reporting of breast lumps. The fifth edition of the Breast Imaging Report and Data System (BI-RADS) was delivered by the American College of Radiology (ACR) to standardize the risk estimation of breast lesion. It includes the categories 0-6 (0- lesion needs additional imaging or prior examinations, 1- negative, 2- benign, 3- probably benign, 4- suspicious, 5- highly suggestive of malignancy and 6- known biopsy proven malignancy).[3-5] However, BIRADS should be used in conjunction with clinical examination & FNAC/core biopsy (Triple Test) to get a comprehensive perspective prior to surgery and to plan the specific management.

Both fine needle aspiration biopsy (FNAB) and core needle biopsy (CNB) are widely accepted for the diagnosis of breast lesions as a part of triple assessment of breast lesions. The technique and diagnostic interpretation of FNAB cytology of the breast has developed over the past 60 years into an extremely useful, accurate, highly specific, sensitive, and cost-effective test for the diagnosis of benign and malignant breast lesions. FNAB has been readily accepted by patients and clinicians as a minimally invasive, cost-effective, and valuable tool for diagnosis and management.[6,7] The IAC Yokohama System for Reporting Breast FNAB Cytopathology was initiated at the Yokohama International Congress of Cytology Meeting in 2016. Further editing and modifications were made in 2019. It uses 5 clearly defined categories described by specific terms, and each has a specific risk of malignancy. The 5 categories are insufficient/inadequate, benign, atypical, suspicious of malignancy, and malignant.[3,6,7] Each category and its risk of malignancy are linked to management recommendations, which include several options because it is recognized that diagnostic infrastructure, such as the use of core needle biopsy and ultrasound guidance, varies between developed and low- and middle-income countries. The system is intended for global use and is based on cytomorphology and includes key diagnostic cytological criteria for each of the many lesions and tumours found in the breast.[6,7]

This article aims to evaluate the concordance and discordance between BI-RADS and the IAC Yokohama system for reporting breast fine needle aspiration biopsy cytopathology for diagnosis of palpable breast lesions.

Aims and Objectives

To evaluate concordance & discordance rates between BI-RADS and the IAC Yokohama system for reporting breast FNAB (Fine Needle Aspiration Biopsy) cytopathology for diagnosis of palpable breast lesions.

Material and Methods

This retrospective observational study conducted from 01/01/2023-31/12/2023(1year), included 116 cases with both BI-RADS and cytopathological diagnosis available. Informed consent was taken prior to the procedure. Physical examination for all cases was done. FNAC was performed following standard procedure using 5-10 ml disposable syringe with a fine needle (22-25 Gauge) introduced into the lesion and 10-15 rapid passages of the needle are made into and across the lesion utilizing the cutting action of the needle bevel. At least 2 aspirates were collected, and FNA smears were prepared immediately (one slide each-H&E stain, PAP stain and Giemsa stain). Clinical data, BI-RADS score and cytopathology reports were retrospectively obtained

from pathology requisition forms. All cytopathology slides were reported by an experienced pathologist.

BIRADS categorisation was based on the latest ACR 5thedition guidelines and breast cytopathology were reported based on The IAC Yokohama System for Reporting Breast FNAB Cytopathology.

Adequacy of aspirated smears was taken in accordance with the latest IAC Yokohama system: a single fragment of epithelial cells; at least 6 epithelial tissue fragments of 5 or more cells; at least 10 bipolar cells in each of 10 medium power (×200) fields; a minimum of 7 tissue fragments each consisting of more than 20 cells; or any number of appropriately smeared and fixed epithelial cells.[6,7]

Data from 116 cases included age wise distribution of cases, size, laterality, quadrants, number of lumps and presenting complaints with duration. USG features included echogenicity, margins of lesion, BI-RADS score and type of lesion. Correlation of BI-RADS score with cytopathological diagnosis, concordant malignant and benign cases, discordant malignant and benign cases, sensitivity, specificity, positive predictive value, negative predictive value, accuracy, concordance, and discordance rate of BI-RADS with cytopathological diagnosis was done.

All female patients with palpable breast lump or lumps (unilateral/bilateral) and with BI-RADS score and cytopathological examination by FNAC/ guided FNAC report available. Patients who have undergone previous breast surgery/recurrent lumps, lactating & pregnant females, male patients, smear that did not meet adequacy criteria (acellular smears, hemorrhagic and necrotic aspirates) and cases that did not undergo ROSE (rapid on site evaluation) were excluded.

Results

Data from 116 patients who underwent both ultrasonography with BI-RADS categorization and FNAC procedure for diagnosis of breast lumps were included in this study.

In our study, the youngest patient was 15 years old and the oldest patient was 76 years of age. Maximum number of cases were seen between 21–30-year age group (27.6%) and least number of cases were seen between 71-80(0.9%). Mean age of presentation was 34.4 years, standard deviation was 14.8 years and patient age ranged from 15-76 years (Table 1).

Table 1: Age wise distribution of cases

Age Group	Number Of Cases	Percentage (%)
11-20	24	20.7
21-30	32	27.6
31-40	24	20.7
41-50	20	17.2
51-60	8	6.9
61-70	7	6.0
71-80	1	0.9
Total	116	100.0

There was slight preponderance in left breast involvement with 74 cases (63.8%) followed by right breast involvement in 39 cases (33.6%) and bilateral lumps in 3 cases (2.6%). Breast lumps were commonly

seen in upper outer quadrant in 56 cases (48.3%), involving more than 1 quadrant in 16 cases (13.8%), upper inner quadrant in 13 cases (11.2%), lower outer quadrant and all quadrants involved in 8 cases each (6.9%), lower inner quadrant and subareolar region in 7 cases each (6%) and least commonly involved is the axillary tail in only 1 case (0.9%). Most common clinical presentation was painless and mobile breast lump with 78/116 cases (67.3%) (Table2).

Table 2: Presenting complaints with duration

Presenting Complaints	Duration				Total	%
	<1 Month	1-6 Months	6 Months - 1 Year	>1 Year		
Routine check-up	2	2	1	5	10	8.6
Painless lump only	11	34	16	17	78	67.3
Lump with nipple discharge	1	6	0	1	8	6.9
Lump with nipple retraction	0	2	1	0	3	2.6
Lump with pain	4	2	2	0	8	6.9
Lump with ulceration	1	1	0	0	2	1.7
Lump with redness	0	2	1	0	4	3.4
Cyclical mastalgia	1	2	0	0	3	2.6
Total	20	51	21	23	116	100

Mean lump size was 3.26 cm, standard deviation was 1.8 cm and lump size ranged from 1-15cm. 108/116 (93.1%) patients presented with solitary lump, whereas 8/116 (6.9%) cases presented with more than one lump/ multiple lumps.

On BI-RADS categorization 94 cases (81%) appeared hypoechoic, 10 cases (8.6%) appeared hypoechoic with calcifications, 7 cases (6.0%) appeared isoechoic, 4 cases (3.4%) appeared hyperechoic, and no lump was detected on USG in 1 case (0.9%). 62 cases (53.4%) had a lump with well-defined margin, 22 cases (19%) had lobulated margins, 18 cases (15.5%) had irregular margins, 9 cases (7.8) had an ill-defined margin, 4 cases (3.4%) had speculated margins and 1 case (0.9%) did not show any lump on USG. BI-RADS category 0 had 0 cases, BI-RADS 1 had 1 case (0.9%), BI-RADS 2 had 72 cases (62.9%), BI-RADS 3 had 21 cases (17.2%), BI-RADS 4 had 9 cases (7.8%), BI-RADS 5 had 13 cases (11.2%) and BI-RADS 6 had 0 cases.

Most common cytopathological diagnosis was Fibroadenoma in 66 cases–IAC Yokohama category 2(56.9%) followed by infiltrating duct carcinoma in 23 cases–IAC Yokohama category 5(19.8%). Category1 (Insufficient/inadequate) had 0 cases, Category2 (benign) had 74 cases, category3 (atypical) had 12 cases, category4 (suspicious for malignancy) had 1 case and category 5(malignant) had 29 cases.

Concordant malignant cases refer to lesions having malignant features on imaging (BI-RADS category 4 or 5) and confirmed as malignancy on pathological examination. In this scenario appropriate action should be taken without delay. The radiologist should inform the referring physician of the results and the patient should be informed and referred to a surgeon or oncologist for further management. Discordant

malignant cases refer to lesions with benign imaging features (BI-RADS category 2 or 3) but proves to be malignant on pathological examination; management should be done as for a concordant malignancy. Concordant benign cases refer to lesions with benign features on imaging (BI-RADS category 2, 3 or 4a) and shows benign morphology on pathological examination. In this case a follow up ultrasound will be recommended because of delayed false negative results after core biopsy. Discordant benign cases are lesions suspicious for malignancy at imaging (BI-RADS category 4 or 5), but shows benign pathologic results. The findings are discussed with referring physician and pathologist, a repeat biopsy in form of open surgical biopsy should be done. [8]

In our study 25 cases were concordant malignant, 5 cases were discordant malignant, 85 cases were concordant benign and 1 case was discordant benign. Diagnostic value of ultrasound in detecting mammary Malignancy-Sensitivity 83.33%, specificity 98.8%, positive predictive value 96.2%, negative predictive value 94.4%, diagnostic accuracy/ concordance rate 94.8% and discordance rate 5.2% (Table3,4).

Table 3: Concordant/discordant cases and diagnostic utility of ultrasound in detecting mammary malignancy

Concordant And Discordant Cases	Number Of Cases	Percentage
Concordant malignant cases	25	83.33
Discordant malignant cases	5	16.67
Concordant benign cases	85	98.8
Discordant benign cases	1	1.2
Diagnostic Value Of Ultrasound In Detecting Mammary Malignancy		
Parameter		Percentage
Sensitivity		83.33
Specificity		98.8
Positive predictive value		96.2
Negative predictive value		94.4
Diagnostic accuracy/ concordance rate		94.8
Discordance rate		5.2

Table 4: Correlation of Ultrasound BI-RADS score with FNAC results

Ultrasound	FNAC		Total
	Positive for malignancy	Negative for malignancy	
Positive for malignancy	25	1	26
Negative for malignancy	5	85	90
Total	30	86	116

Discussion

Breast imaging-reporting and data system(BI-RADS) categorization was proposed by the American College of Radiology(ACR) in 1986 with the original report released in 1993. Due to exponential increase in mammography with the implementation of yearly screening mammograms and overwhelming variation amongst radiology reports, BI-RADS lexicon was implemented to standardize risk assessment, reduce the inter observer variability, quality control for mammography and provide uniformity in the reports for non-radiologist.[9,10]

FNAC technique and diagnostic interpretation of FNAC of breast has been recognised as an extremely useful, accurate, highly specific, and sensitive, and cost-effective test for the diagnosis of benign and malignant breast lesions. FNAB has been readily accepted by patients and clinicians as a minimally invasive, cost-effective, and valuable tool for diagnosis and management.[6,7]

In the present study, 6/116 cases were discordant. 5/116 cases were discordant malignant. One case categorised as BI-RADS category3 (suppurative granulomatous mastitis) was reported as infiltrating duct carcinoma NOS on cytology (IAC Yokohama category 5– malignant) and histopathology. Such discordant finding can stem from lesion undergoing severe inflammation, oedema of surrounding breast tissue, widespread necrosis, multiple foci of calcification, irregular margins of the lesion and failure of the needle tip to hit the exact site of the neoplastic lesion. Cases categorized as BI-RADS category1 (fibroadenosis), category2 and category3 (fibroadenoma) were signed out as infiltrating duct carcinoma NOS, ductal proliferation with focal atypia and infiltrating duct carcinoma NOS on cytology, respectively (IAC Yokohama category5, 4 and 5 respectively). All 3 cases were diagnosed as infiltrating duct carcinoma NOS on histopathology. Probable reason for such discrepancy could be the small size of malignant foci. Another case categorised as category 3 (atypical fibroadenoma) (Figure 1) was signed out as medullary carcinoma of breast on cytology (IAC Yokohama category 5– malignant). Histopathological diagnosis was infiltrating duct carcinoma with medullary features. This variation could be due to fibroadenoma showing ill-defined margin, irregular appearance, heterogenous internal echo-pattern or posterior shadowing. In this case, on gross examination and extensive sampling it was found that the malignant foci were extremely small, embedded in an extensively desmoplastic stroma.

1/116 (Figure 2) cases showed a discordant benign finding, with a report of BI-RADS 4 (phyllodes tumour). A final diagnosis of fibrocystic disease of breast (IAC Yokohama category 2 – benign) on cytology was signed out. Cytological findings were confirmed on histopathology. However, the lesion showed extensive desmoplastic stroma which could be the probable reason for a higher BI-RADS categorization. Common mimickers of breast malignancy on breast sonography include fat necrosis, lymphocytic mastitis, infectious mastitis, diabetic mastopathy, fibrocystic changes, sclerosing adenosis, ruptured inflammatory cysts, inflammatory abscesses, granulomatous mastitis, stromal fibrosis, fibroadenomas, fibro-adenomatous mastopathy, hamartoma, pseudo-angiomatous hyperplasia(PASH), tubular adenoma, desmoid fibromatosis, granular cell tumour and apocrine metaplasia.[11] 110/116 cases were concordant (Figure 3 and figure 4).

In a study conducted by Rahman MZ et al, overall diagnostic accuracy of BI-RADS score in diagnosis of breast disease showed a sensitivity of 82.76%, specificity of 90.36%, PPV (positive predictive value) of 75%, NPV (negative predictive value) of 93.7% and diagnostic accuracy of 88.39%. In the same study, overall diagnostic accuracy of FNAC in diagnosis of breast disease showed a sensitivity of 97.2%, specificity of 99.46%, PPV of 97.2%, NPV of 93.7% and diagnostic accuracy of 99.9%.[12]

In a study conducted by Pandia A et al, overall diagnostic accuracy of BI-RADS score in diagnosis of breast disease showed a sensitivity of 88.57%, specificity of 82.46%, PPV of 75.61%, NPV of 92.16% and diagnostic accuracy of 84.78%. In the same study, overall diagnostic accuracy of FNAC in diagnosis of breast disease showed a sensitivity of 100%, specificity of 100%, PPV of 100%, NPV of 100% and diagnostic accuracy of 100%.[13]

In a study conducted by Bak et al, overall diagnostic accuracy of BI-RADS score in diagnosis of breast disease showed a sensitivity of 91%, specificity of 88%, PPV of 96%, NPV of 71%.[13]

In a study conducted by Garg et al, overall diagnostic accuracy of BI-RADS score in diagnosis of breast disease showed a sensitivity of 84.37% and specificity of 83.33%.[14]

In a study conducted by Tiwari et al, overall diagnostic accuracy of BI-RADS score in diagnosis of breast disease showed a sensitivity of 77.7%, specificity of 97.72%, PPV of 87.5%, NPV of 95.5%.[15]

In a study by Choi et al, overall diagnostic accuracy of FNAC in diagnosis of breast disease showed a sensitivity of 77.7%, specificity of 99.2%, PPV of 88%, NPV of 98.4% and diagnostic accuracy of 91.1%.[16]

In a study by Panjvani et al, overall diagnostic accuracy of FNAC in diagnosis of breast disease showed a sensitivity of 97.82%, specificity of 100%, PPV of 97.85%, NPV of 100% and diagnostic accuracy of 98.9%.[17]

In a study conducted by Bukhari et al, overall diagnostic accuracy of FNAC in diagnosis of breast disease showed a sensitivity of 98%, specificity of 100%, PPV of 97%, NPV of 100% and diagnostic accuracy of 98%.[18]

In a study by Sankaye et al, overall diagnostic accuracy of FNAC in diagnosis of breast disease showed a sensitivity of 88.37%, specificity of 96.42%, PPV of 84.37%, NPV of 97.43% and diagnostic accuracy of 91.54%.[19]

In the present study, diagnostic value of ultrasound in detecting mammary malignancy showed a sensitivity of 83.33%, specificity of 98.8%, PPV of 96.2%, NPV of 94.4%, concordance rate of 94.8% and discordance rate of 5.2%. All 116 cases were confirmed by histopathological examination (gold standard). In our study, FNAC and histopathology showed 100% concordance.

Limitation of our study is the lack of detailed radiological reports of patients as majority of them were lost to follow up.

Conclusion

Lump in breast causes great anxiety both to the patient and family members.[5,10] The main motive behind the evaluation of such a newly detected palpable lump is basically to rule out malignancy.[5] Evaluation of breast lumps involves the rational use of a detailed history, clinical breast examination, imaging modalities and tissue diagnosis (Triple Assessment). Though the final diagnosis is made by HPE of excised tissue, routine excision of all breast lumps would not be rationale,

because majority of lumps are benign. Breast ultrasound is a non-invasive imaging-based technique and breast FNAC is a tissue based minimally invasive technique. Both these diagnostic tools can complement each other; but should not be used alone.[5] Recent advances in both these techniques like immunocytochemistry, imaging guided FNAC and doppler in sonomammography may increase their accuracy. However histopathological examination should be done, which is the gold standard for tissue diagnosis. In our study, the most common age group in our study was 21-30years. Most common benign breast lesion was fibroadenoma. The concordance and the discordance rate between ACR BI-RADS and The IAC Yokohama System for Reporting Breast FNAB Cytopathology for palpable breast lumps is 94.8 % and 5.2% respectively.

Legends Figures

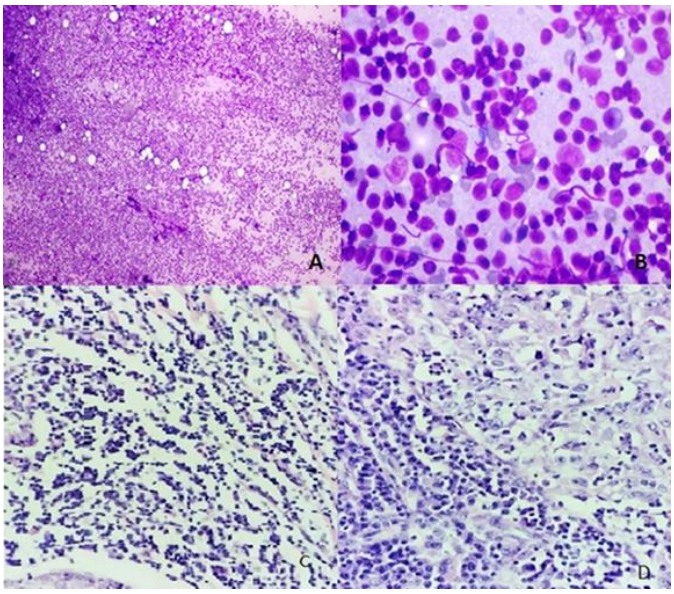

Figure 1: 32-year female with left breast lump (BI-RADS 3-atypical fibroadenoma).

A&B: Cytopathology showed highly cellular smears with large syncytial clusters of epithelial cells having high grade pleomorphism. Background shows dense lymphocytic infiltration, stripped bare tumor nuclei, necrosis, and mitotic figures. Final Diagnosis-Medullary carcinoma of breast. {IAC Yokohama-category5} (Giemsa stain; X4, X40).

C&D: Cytopathological diagnosis was confirmed by histopathology. A final diagnosis of infiltrating duct carcinoma with medullary features was made as the tumor cells had high histologic grade, high grade nuclear features with prominent nucleoli and prominent tumor infiltrating lymphocytes (H&E; X40).

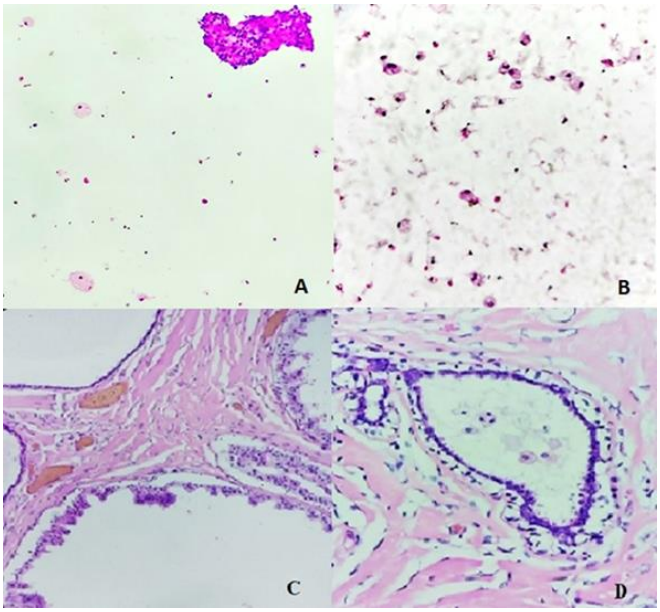

Figure 2: 33-year-old female with right breast lump (BI-RADS 4-phyllodes tumor).

A&B: Cytopathology smears showed occasional clusters, of ductal epithelial cells. Background showed histiocytes, dispersed spindle cells, proteinaceous material, and minimal amount of chronic inflammatory infiltrates. No atypia was seen in smears studied. Final diagnosis-fibrocystic Disease {IAC Yokohama Category 3} (H&E; X40).

C&D: Cytopathological diagnosis was confirmed by histopathology with typical histopathological features of fibrocystic disease with surrounding breast parenchyma showing extensive desmoplasia(H&E; X40).

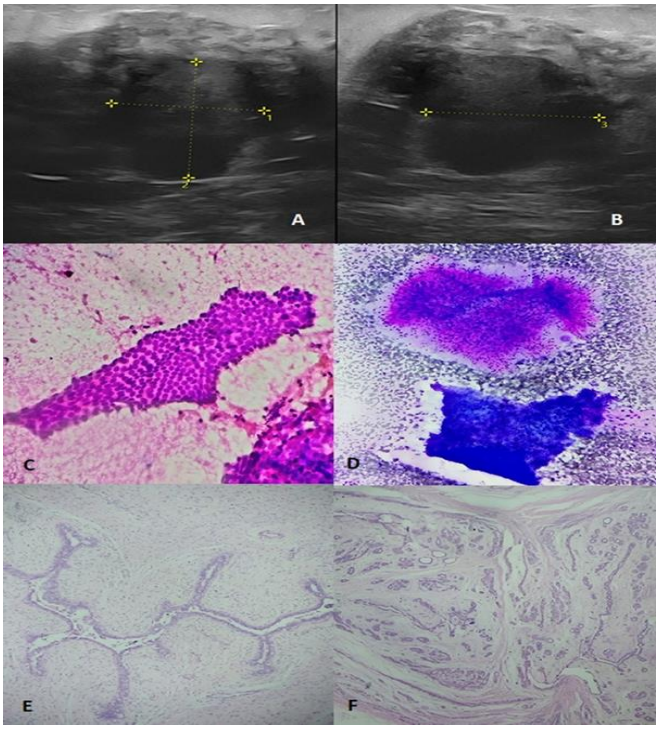

Figure 3: Cytological and histopathologically concordant case of fibroadenoma.

A&B: USG shows a solitary well defined hypoechoic lesion in the right breast of a 56 year old female(BI-RADS 2).

C&D: shows a biphasic neoplasm composed of abundant spindle stromal cells, naked nuclei and epthelial cells arranged in antler horn clusters or fenestrated honeycomb sheets against a fibromyxoid background suggestive of fibroadenoma (IAC Yokohama category 2) (C: H&E stain, 20X; D: Giemsa, 4X).

E&F: HPE shows a well circumscribed biphasic neoplasm composed of bilayered glandular and stromal elements suggestive of fibroadenoma.

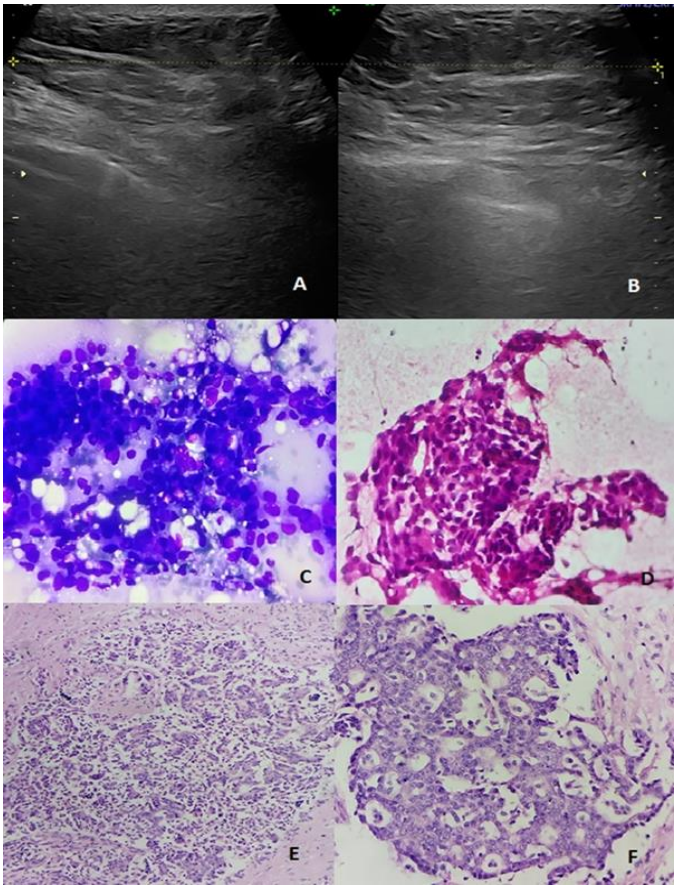

Figure 4: Cytological and histopathologically concordant case of Infiltrating Duct Carcinoma NST.

A&B: USG shows large ill-defined irregular mass lesion with posterior acoustic shadowing, causing distortion of breast architecture and with color doppler showing internal arterial and venous vascularity (BI-RADS 4c-Highly suspicious for malignancy).

C&D: shows cellular pleomorphism, irregular nuclear margin, nucleoli, lack of naked nuclei, cellular dyscohesion Suggestive of Infiltrating Duct Carcinoma NST(IAC Yokohama category 5) (C: H&E stain, 40X; D: Giemsa, 40X).

E&F: HPE show infiltrative nests, cords, trabeculae, and occasional tubules of malignant tumour cells with scant cytoplasm, moderately enlarged nuclei, irregular nuclear borders, coarse clumped chromatin, few showing prominent nucleoli. Background stroma shows

desmoplasia. 3-4 mitotic figures noted/10hpf. No lympho-vascular/ neural invasion was noted(H&E;X40).

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