RESEARCH PAPER

Diagnostic accuracy of FNAC, BIRADS, in Palpable breast lesions: A Prospective Correlation with Histopathology and Immunohistochemistry

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ABSTRACT

Introduction

Breast cancer remains a major health burden and the leading cause of cancer in women worldwide. In India, the incidence is rapidly increasing due to urbanization and lifestyle changes. Fine needle aspiration cytology (FNAC) is a rapid, cost-effective diagnostic tool, while radiological scoring through Breast Imaging Reporting and Data System (BIRADS) guides further management.

Combining FNAC with BIRADS improves diagnostic precision. The UK National Health Service Breast Screening Programme (NHS BSP) scoring system provides standardized cytological grading, which helps correlate cytology with imaging and histopathology.

This study aims to evaluate the concordance between BIRADS and FNAC and validate cytological findings with histopathology/IHC

Objectives

To correlate radiological (BIRADS) scores with cytological diagnosis (FNAC) and confirmatory histopathology/IHC findings.

Methodology

A prospective observational study was conducted on 81 patients presenting with breast lumps. Each underwent imaging evaluation (BIRADS classification), FNAC (with UK NHS BSP score), and subsequent histopathology where available.

Results

A total of 81 female patients with palpable breast lumps were included in the study, with a mean age of 46.07 ± 13.28 years. The majority of patients belonged to the 41–60-year age group (47%). Histopathological examination confirmed malignancy in 37 cases (45.7%) and benign lesions in 44 cases (54.3%). Cytological evaluation categorized 48 cases as positive (C4/C5) and 33 as negative (C1–C3). A significant concordance was observed between FNAC, BIRADS assessment, and histopathological findings.

Conclusion

Integrating radiological and cytological data enhances diagnostic accuracy and assists in triaging patients for appropriate management

Keywords: *Breast Lesions, FNAC, BIRADS, cytology, histopathology, breast cancer.*

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INTRODUCTION

Breast Carcinoma (BC) is considered as a critical illness. Detection of the breast carcinoma is a major challenge for medical professionals even though, various scanning modalities such as mammography, ultrasound, Magnetic Resonance Imaging (MRI) and clinical procedures such as, Fine Needle Aspiration Cytology (FNAC), Biopsy and Positron Emission Tomography (PET) scan are already reported in existing medical research literature. Hence, embedding Ultrasound and FNAC based screening of breast nodules or breast lumps either as benign or malignant will be a great support to the medical professionals as well as to the public.

Kulothungan, V et al reported that projected rate of disability-adjusted life years (DALYs) for Breast Cancer cases significantly increases from 2012 to 2025 [4]. World Health Organization (WHO) mentioned that 6,70,000 deaths happened during 2022 due to breast cancer. The primary goal of WHO Global Breast Cancer Initiative (GBCI) is to reduce global breast cancer mortality to 2.5 % per year which helps to reduce the deaths due to breast cancer drastically[5]. As per the American Cancer Society, approximately 42,000 deaths will happen from 3 lakh breast cancer cases in United States during 2024 [6]. László Tabár et al (2000) conducted a randomised study with 77,080 women who were subjected to mammographic screening of breast carcinoma. During this trial, 2468 breast carcinoma cases were diagnosed. This study concluded that breast carcinoma is progressive and its detection in early stages can arrest the development of the disease [7].

AIMS & OBJECTIVES

1. To assess the diagnostic value of FNAC in breast lesions.
2. To correlate cytological findings with radiological BIRADS scores.
3. To validate cytological diagnosis with histopathological and immunohistochemical (IHC) findings.

MATERIALS AND METHODS

Study Design:
Prospective observational study.

Study Period:
January 2024 to May 2025.

Sample Size:
81 female patients presenting with palpable breast lumps.

Inclusion Criteria:

- Patients of all ages presenting with palpable breast masses.
- Those who underwent imaging (BIRADS), FNAC, and follow-up histopathology/IHC.

Exclusion Criteria:

- Cystic lesions not yielding cellular material.
- Inflammatory lesions without follow-up histopathology.

Procedure:

- Radiological evaluation was performed using ultrasound and/or mammography, and each lesion was assigned a BIRADS category (1–5).
- FNAC was done using a 22–23G needle, and smears were stained with May-Grünwald Giemsa (MGG) and Papanicolaou stain.
- Cytological grading was based on the UK NHS BSP C1–C5 system.
- Histopathological correlation was done wherever tissue was available post-surgery or biopsy. Immunohistochemistry (IHC) was performed in cases of malignancy for receptor status (ER, PR, HER2).

ULTRASOUND FEATURES

Tissue Composition: Tissue composition may be fat, fibroglandular or heterogeneous background echotexture.

Masses: Mass feature includes shape, orientation, margin, echo pattern and posterior features.

Calcification: Calcification may be seen internal / external to a mass or its also present as intraductal calcifications.

Breast ultrasound also helps to extract and examine other features such as architectural distortion, duct changes, skin changes, edema, vascularity, elasticity, cyst, lymph nodes, vascular abnormalities, and fat necrosis [8].

Breast Imaging Reporting and Data Assessment (BI–RADS)

BI-RADS is a tool developed by American College of Radiology for categorizing breast images into seven classes. BI-RADS 0 represent "incomplete" which means additional imaging is required. BI-RADS 1 to BI-RADS 6 represent the class as shown in following table [8].

Table 1: BI-RADS Scoring system for BC

BI-RADS Score	Meaning
BI-RADS - 1	Negative
BI-RADS - 2	Benign
BI-RADS - 3	Probably benign (<2% probability for malignancy)
BI-RADS - 4	Suspicious for malignancy (2 to 95 % probability for malignancy) BI-RADS 4A: low suspicion for malignancy (2-9%) BI-RADS 4B: moderate suspicion for malignancy (10-49%)

	BI-RADS 4C: high suspicion for malignancy (50-94%)
BI-RADS - 5	Highly suggestive of malignancy (>95% probability for malignancy)
BI-RADS - 6	Confirmed malignancy

United Kingdom National Health Service Breast Screening Program (UK NHS BSP)

The main objective of this system is to detect the malignancies at an early stage. The result is best achieved when 3 screening modalities are used together (mammography or ultrasound , image guided FNAC and clinical examination) [9]. According to NHS BSP, the FNAC features of breast are classified into 5 categories [10]. :

C1 – Insufficient,

C2 – Benign,

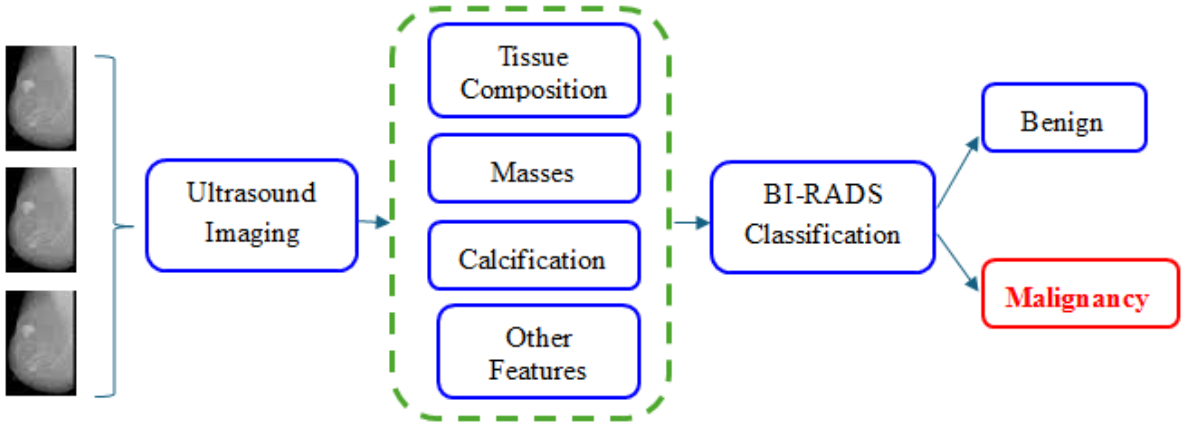
C3 – Intermediate,

C4 – Suspicious and

C5 – Malignant This proposed project consists of two phases.

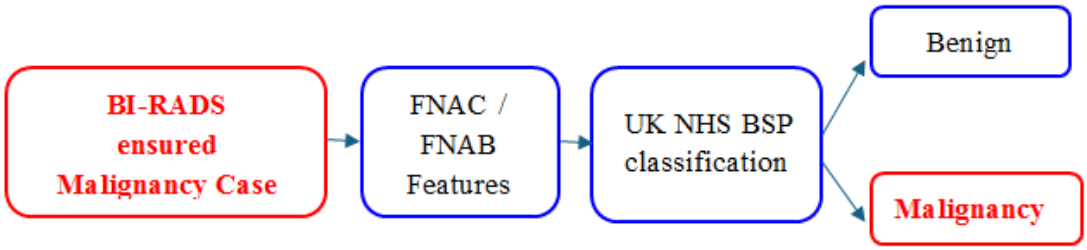
PHASE - I

In the first phase, breast ultrasound images will be acquired from benign and malignancy patients. Various possible features from these images will be extracted. The images will be classified using BI-RADS method based on ultrasound features as shown below.



PHASE - II

In the second phase, BI-RADS based malignancy cases will be considered for further confirmation through cytological procedure. FNAC features will be collected from those malignancy cases and UK NHS BSP classification is applied to ensure whether its benign or malignant tumours as a second confirmative method as shown.



As Phase – III

Following the FNAC procedure and scoring, the patients with malignant or suspicious FNAC results, histopathological correlation was done. The cases that proceeded to surgical intervention, **tissue specimens** were processed for **histopathological examination (HPE)** using routine hematoxylin and eosin staining.

Table 2. Analysis between FNAC & BIRADS

Variable		FNAC		Total
		Positive	**Negative**	
BIRADS	Positive	38	12	50
	Negative	10	21	31
Total		48	33	81

Immunohistochemistry (IHC) was performed in malignant cases to assess **estrogen receptor (ER), progesterone receptor (PR), and HER2/neu** expression. HER2 equivocal cases on IHC (score 2+) were further

evaluated using **In Situ Hybridization (ISH)** to confirm HER2 gene amplification. **A total of 4 cases** underwent ISH testing for definitive molecular classification.

Statistical Analysis

- Data were entered in Microsoft Excel and analysed using descriptive statistics.
- Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of FNAC were calculated using histopathology as the gold standard.
- Concordance between BIRADS and cytology was analysed.

RESULTS

A total of 81 female patients presenting with palpable breast lumps were included in the study. The age ranged from 20 to 85 years, with a mean age of 46.07 ± 13.28 years. The majority of patients belonged to the 41–60 year age group (38 cases, 47%), followed by 20–40 years (32 cases, 39.5%) and 61–85 years (11 cases, 13.5%).

On histopathological examination (HPE), 37 cases (45.7%) were confirmed malignant, while 44 cases (54.3%) were benign.

A total of 48 cases were categorized as cytologically positive (C4/C5) and 33 as negative (C1–C3).

- Sensitivity- 79.17%
- Specificity- 63.64%
- PPV- 76%
- NPV- 67.74%
- Diagnostic accuracy- 72.84%

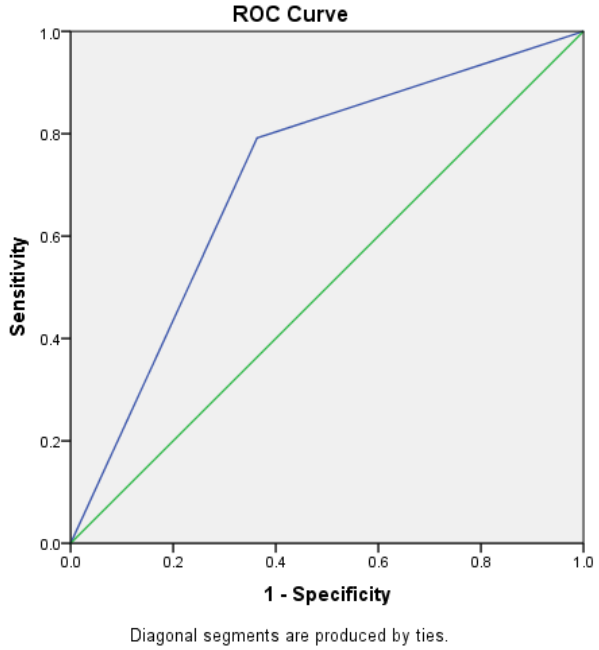
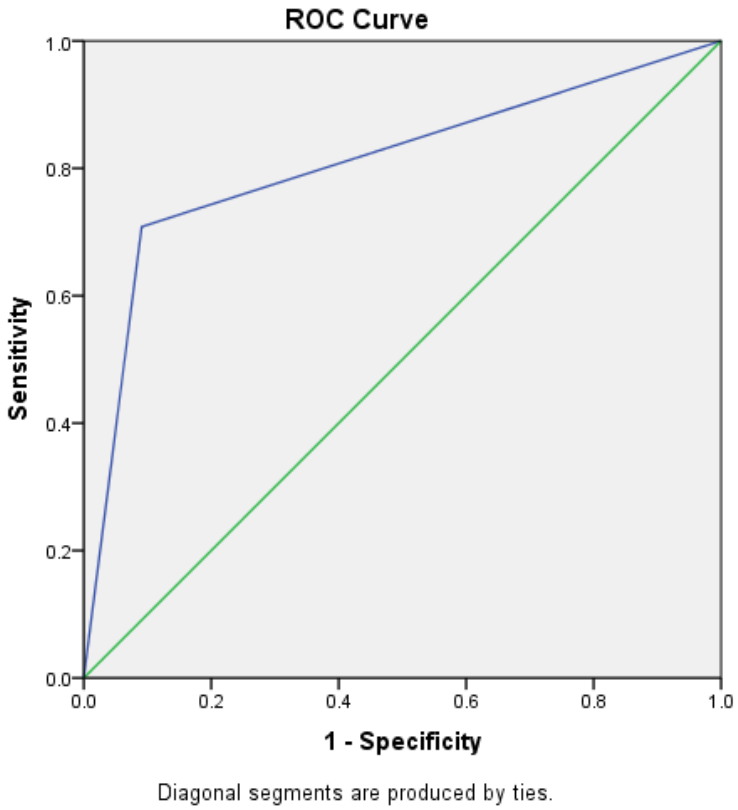


Table 3. Analysis between FNAC & HPE

Variable		FNAC		Total
		Positive	Negative	
HPE	Positive	34	3	37
	Negative	14	30	44
Total		48	33	81

- Sensitivity- 70.83%
- Specificity- 90.91%
- PPV- 91.89%
- NPV- 68.18%
- Diagnostic accuracy- 79.01%



Total malignant cases out of 81 cases, 37 (45.7%) were confirmed malignant on HPE, while 44 (54.3%) benign.

When correlated with histopathology:

- True positives – 34 cases
- False negatives – 3 cases
- False positives – 14 cases
- True negatives – 30 cases

Table.4 Age distribution

Age	Number	Percentage
20 to 40	32	39.5
41 to 60	38	47
61 to 85	11	13.5

Mean age: 46.07±13.28

Mean age: 46.07±13.28

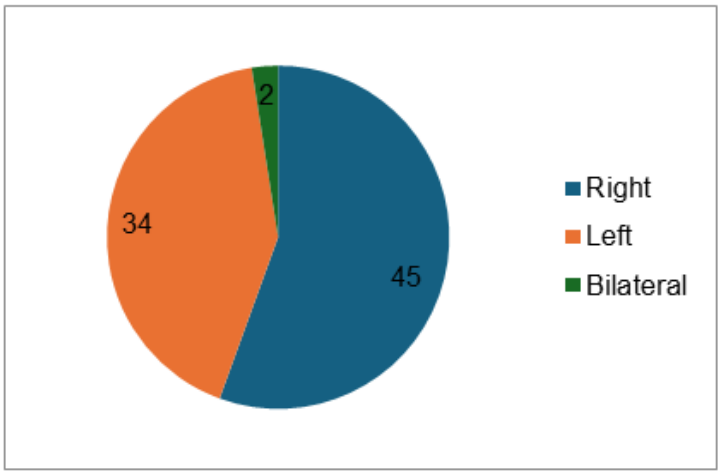


Fig.1 Location of tumour

DISCUSSION

Breast cancer continues to be the most commonly diagnosed malignancy among women globally. Early and accurate diagnosis plays a pivotal role in determining prognosis and optimizing management. In this context, Fine Needle Aspiration Cytology (FNAC) has emerged as a valuable frontline diagnostic modality, particularly in resource-limited settings, due to its rapid turnaround time, minimal invasiveness, and cost-effectiveness.

Age Distribution

In the present study, the majority of patients belonged to the 41–60-year age group (47%), with a mean age of 46.07 ± 13.28 years. This finding is consistent with several Indian studies reporting a peak incidence of breast lesions in the perimenopausal age group. The relatively younger mean age compared to Western populations reflects regional demographic and epidemiological differences and underscores the importance of early diagnostic strategies in this age group.

FNAC Performance and Initial Findings

In our study of 81 patients presenting with palpable breast lesions, FNAC demonstrated high diagnostic efficacy, with 34 cases diagnosed as malignant (C5) and an additional 8 cases reported as suspicious (C3/C4) subsequently confirmed as malignant on histopathology. These findings are in line with Kocjan et al., who reported over 95% diagnostic accuracy for breast FNAC when performed with optimal technique and interpretation [1].

Benign lesions such as fibroadenomas and fibrocystic changes were also effectively identified through FNAC, especially among cases categorized radiologically as BIRADS 2 and 3. This aligns with the findings of Choi et al., who emphasized FNAC's role in reducing unnecessary biopsies for low-risk breast lesions [5].

Correlation between FNAC and BIRADS Categories

Radiological classification using the BI-RADS (Breast Imaging Reporting and Data System) is a cornerstone in breast lesion risk stratification and management. In our cohort, a high degree of concordance was observed between FNAC results and BIRADS scoring, particularly in BIRADS 4 and 5 lesions, where FNAC was highly sensitive in detecting malignancy. However, a significant observation was that several patients categorized under BIRADS 2 and 3—typically considered low risk—were diagnosed as malignant by FNAC and subsequently confirmed by histopathology.

BIRADS demonstrated a sensitivity of 79.17% and a specificity of 63.64% when correlated with FNAC findings. The high sensitivity indicates that BIRADS is effective in identifying lesions suspicious for malignancy, making it a valuable screening and risk-stratification tool. However, the moderate specificity and false-positive rate emphasize that BIRADS alone cannot reliably distinguish benign from malignant lesions.

The diagnostic accuracy of 72.84% suggests acceptable concordance between imaging and cytology. These findings reinforce the established role of BIRADS as an adjunctive modality, guiding further evaluation rather than serving as a definitive diagnostic method. The AUC derived from ROC analysis further supports the moderate discriminative ability of BIRADS in predicting cytological outcomes.

These findings are supported by Abdullah et al. and Singh et al., who emphasized the increased diagnostic yield when BIRADS is interpreted in conjunction with FNAC [2,3].

Correlation between FNAC and Histopathology

When FNAC findings were compared with histopathology, FNAC demonstrated a sensitivity of 70.83% and a specificity of 90.91%, with a high positive predictive value of 91.89%. This highlights FNAC's strong reliability in confirming malignant lesions. The high specificity indicates that a positive FNAC result is highly predictive of malignancy and can significantly aid in preoperative decision-making.

The relatively lower sensitivity can be attributed to factors such as sampling error, low cellularity, cystic changes, and overlapping cytomorphological features in borderline or well-differentiated tumors. Despite these limitations, the overall diagnostic accuracy of 79.01% and favorable AUC values confirm good agreement between FNAC and histopathology.

Triple Assessment and the Role of Histopathology (Phase 3)

The concept of triple assessment, involving clinical examination, imaging, and cytology or histopathology, remains the most reliable strategy for breast lesion evaluation. In our series, concordant results across all three modalities significantly enhanced diagnostic confidence. However, in discordant cases—particularly those with C3/C4 cytology—histopathology (HPE) was crucial in achieving definitive diagnosis. Our findings reinforce those of Noreen et al., who demonstrated near-perfect diagnostic reliability when triple assessment modalities are aligned [6].

Immunohistochemistry and Molecular Subtyping

Histopathological evaluation in Phase 3 revealed that most malignant cases corresponded to invasive ductal carcinoma (IDC). These tumors were further characterized using immunohistochemistry (IHC), assessing hormone receptor (ER/PR) and HER2 status. Most tumors exhibited ER and/or PR positivity, while HER2 expression was variable. This molecular profiling is essential for therapeutic decision-making, particularly for hormone receptor-positive tumors eligible for endocrine therapy, consistent with the molecular subtypes and clinical utility outlined by Rakha et al. and NCCN guidelines [4,7].

HER2 Equivocal Cases and the Use of In Situ Hybridization (ISH)

In four cases with equivocal HER2 IHC (2+), in situ hybridization (ISH) was employed to determine HER2 gene amplification. ISH provided definitive clarification in these borderline cases, allowing accurate classification into HER2-enriched or HER2-negative subtypes. This step proved vital in guiding eligibility for HER2-targeted

therapies and demonstrated the added value of incorporating molecular techniques into diagnostic workflows.

Clinical Relevance and Diagnostic Integration

Our findings emphasize that while BIRADS offers a standardized and valuable imaging-based risk stratification tool, FNAC acts as a crucial adjunct—particularly in ambiguous or discordant imaging cases. FNAC's ability to triage patients for surgery or conservative management is further enhanced when complemented by histology and molecular assays. This is especially relevant in younger women with dense breasts, where imaging can underestimate malignancy.

Several cases initially classified as BIRADS 3 were upgraded based on FNAC and later confirmed malignant by histopathology and IHC. These observations suggest that a lower threshold for FNAC should be maintained in clinically suspicious cases, even when imaging appears benign.

Limitations of FNAC and Ancillary Techniques

Despite its advantages, FNAC showed limitations in evaluating fibroepithelial and cystic lesions, where interpretative challenges or sampling issues can lead to inconclusive or misleading results. In such cases, cell block preparation, IHC, or core needle biopsy provided additional diagnostic clarity and should be considered when cytology findings are inconclusive.

Also, the study is limited by a relatively small sample size and the inherent limitations of FNAC, including sampling variability and subjective interpretation. Additionally, not all cases underwent histopathological confirmation, which may have influenced sensitivity estimates.

CONCLUSION

In summary, BIRADS demonstrates high sensitivity but moderate specificity, making it suitable as a screening modality, whereas FNAC exhibits high specificity and positive predictive value, confirming its role as a reliable diagnostic tool. The combined application of BIRADS and FNAC enhances diagnostic accuracy and remains an effective, minimally invasive strategy for the evaluation of breast lesions, particularly in resource-limited settings FNAC, when interpreted in conjunction with BI-RADS and supported by histopathology and IHC, remains a robust and cost-effective strategy for diagnosing breast lesions. The inclusion of advanced molecular techniques such as ISH, even in a limited subset, reflects the growing importance of precision diagnostics in breast cancer. As access to molecular pathology continues to expand, this integrated approach will become increasingly relevant, particularly in India and other low-to-middle-income countries where early detection has a profound impact on outcomes.

Future studies with larger cohorts and longer follow-up are warranted to further validate the diagnostic utility of combining cytology, radiology, and molecular profiling in routine clinical practice.

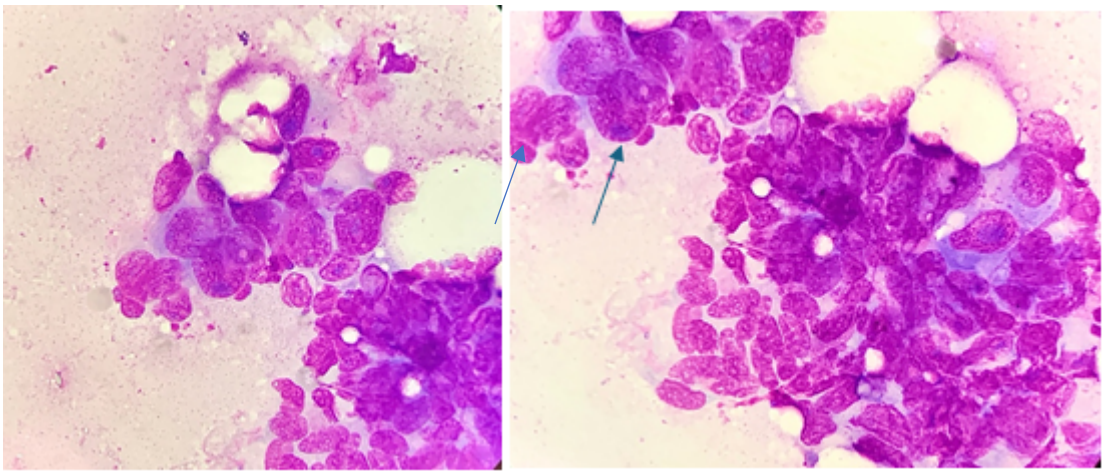


Figure 2: Pleomorphic tumour cells from breast swelling (arrow mark) (Leishman stain, 40x)

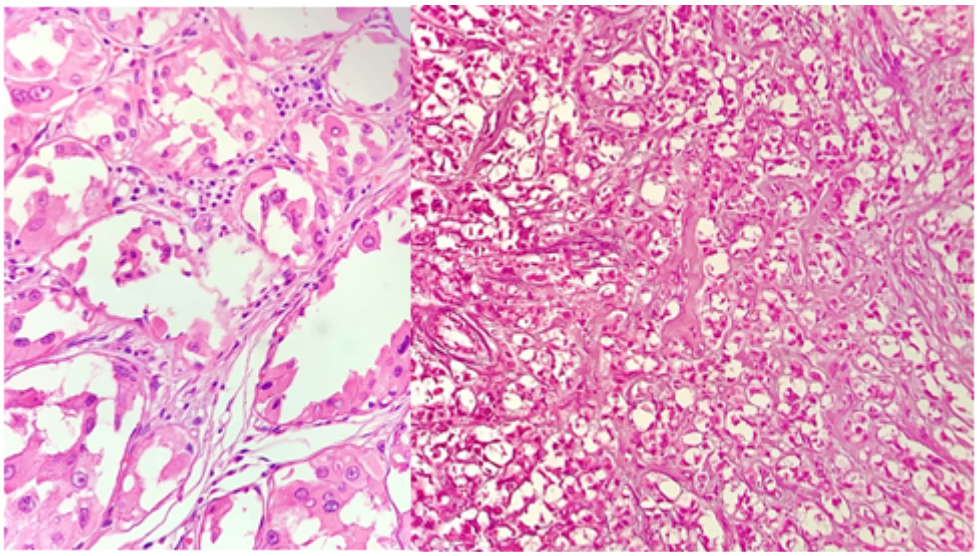


Figure 3: Microscopic image showing Pleomorphic tumour cells showing bizarre cells and tumour necrosis of mastectomy specimen. (H&E staining, 40x & 20x magnification)

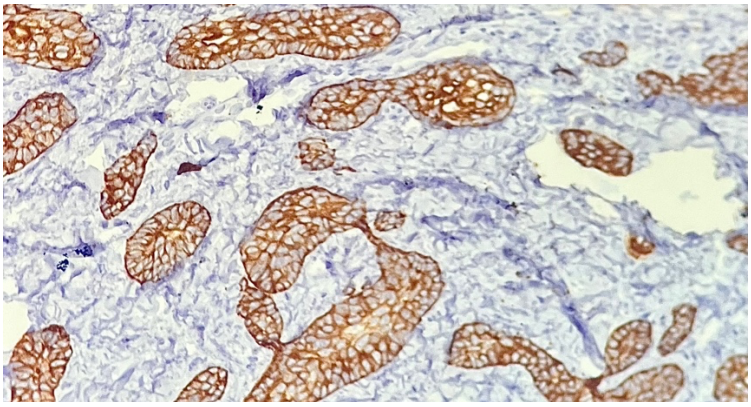


Figure 4: Membranous strong positivity of immunohistochemical marker HER2μ (20x)

CONTRIBUTIONS

Dr Pooja E Moorthy - Concept and design of study, analysis and interpretation of data; supervising the performance of the experimental methods involved in this study, drafting the article, revising it critically for important intellectual content; and final approval of the version to be published.

Dr Jane - Concept and design of study, analysis and interpretation of data; supervising the performance of the experimental methods involved in this study, drafting the article, revising it critically for important intellectual content; and final approval of the version to be published.

Dr Vindu Srivastava - Supervising the performance of the experimental methods involved in this study, drafting the article, revising it critically for important intellectual content; and final approval of the version to be published.

Dr Vimal Manickam - Concept and design of study, analysis and interpretation of data; supervising the performance of the experimental methods involved in this study, drafting the article, revising it critically for important intellectual content; and final approval of the version to be published.

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