

COMPARATIVE STUDY OF BIRADS SCORE WITH HISTOPATHOLOGICAL FINDINGS IN CORE NEEDLE BIOPSIES OF BREAST LESIONS IN A TERTIARY CARE HOSPITAL

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Abstract

Background: Breast cancer represents the most common cancer diagnosed in women worldwide, constituting 21% of all cancer cases in women. Mammography and ultrasound are the two non-invasive, affordable, widely available radiological interventions that aid in the diagnosis. The Breast-Imaging and Reporting Data System (BIRADS) has been implemented widely for mammography reporting. Core needle biopsy has replaced fine needle aspiration for diagnosing breast lesions. Present study was planned to assess efficacy of BIRADS over histopathology in evaluation of breast lesions **Materials and Methods:** 145 patients having breast lesions, who had undergone radiological imaging, either ultrasound or mammography, followed by core needle biopsy were enrolled. Mammography reports & Histopathological reports of biopsies of all patients were retrieved from Hospital Information System. All the patients were classified into one of BIRADS categories 2–5. BIRADS category 2-3 was considered most likely benign and BIRADS categories 4–5 was considered as malignant. Breast lesions on histopathology, were classified into benign or malignant, according to WHO classification of tumours, 5th edition, 2022. **Observations and Results:** Majority of the patients were above 50years of age with Category IV being the most common BIRADS category. On histopathology, total benign cases were 63 (43 %) & malignant were 82 (57 %). Amongst benign lesions, maximum were fibroadenoma & amongst malignant, it was Invasive breast carcinoma, No special type. 52% malignant cases were diagnosed on both BIRADS & biopsy whereas 34% were diagnosed as Benign on both BIRADS & biopsy. 5% cases were considered Benign on BIRADS but categorized as malignant on biopsy. Similarly, 9% cases were considered malignant on BIRADS but categorized as benign on biopsy. Sensitivity of BIRADS was found 91.46 % & specificity was 77.78 %. **Conclusion:** To conclude, BIRADS classification had an acceptable sensitivity & positive predictive (PPV) values for diagnosing breast lesions. However, core needle biopsy is a reliable method and still remains gold standard for diagnosing breast lesions. **Keywords:** BIRADS score, Core needle biopsy, BIRADS score and biopsy finding comparison

Introduction

Breast cancer represents the most common cancer diagnosed in women worldwide making upto 21% of all cancers diagnosed in women. Breast cancer incidence in India is increasing and has now become the most common cancer among women, surpassing cervical cancer in all the urban cancer registries¹. The most typical symptom of benign or malignant breast tumours is a breast lump. Thanks to sophisticated imaging studies, breast lesion identification has significantly improved in recent years. The two non-invasive, widely accessible, low-cost radiological procedures that help in diagnosis and are essential for early diagnosis, therapy, and a positive prognosis, improving the survival rates of patients with breast cancer are mammograms and ultrasounds². Breast ultrasonography and mammography reporting have both made extensive use of the Breast-Imaging and Reporting Data System (BIRADS). Reporting is completed by assigning a BIRADS category score and appropriately advising additional management. BIRADS for mammogram and ultrasound included category 0 (incomplete assessment), category 1 (negative), category 2 (benign finding(s)), category 3 (probable benign findings), category 4 (suspicious abnormality), category 5 (highly suggestive of malignancy) and category 6 (known biopsy-proven malignancy)³. BIRADS category 3 has the lowest probability of malignancy (< 2%), BIRADS category 4 is predictive of breast cancer at approximately 30% and BIRADS category 5 has the highest likelihood of malignancy at more than 95%. The BIRADS category 4 is divided into BIRADS 4a, 4b and 4c subcategories to stratify the risk of malignancy. It is advised to have an annual mammography screening programme for those in BIRADS categories 1 and 2. A short interval follow-up within 6 months is recommended for BIRADS category 3 whereas for BIRADS categories 4 and 5, tissue diagnosis is suggested³.

Fine needle aspiration cytology (FNAC) in the assessment of breast masses in both palpable and non-palpable lesions provide a rapid, accurate and cost-effective diagnosis. However, there are many pitfalls with FNAC in the assessment of breast lesions, leading to too many excision biopsies for diagnosis of breast masses⁴. In most western countries, core needle biopsy has taken the position of fine needle aspiration for symptomatic and screen-detected breast lesions. FNAC is more common than excision or incision biopsy for diagnosis, but it is also far less invasive and costly. It also has a reduced rate of nondiagnostic or inadequate sample reports⁵.

With this perspective present study was planned to assess efficacy of BIRADS over histopathology in evaluation of breast lesions.

Aim

To compare BIRADS score with histopathological findings of core needle biopsies in diagnosing breast lesions in patients.

Objectives

1. To study the role of radiology through BIRADS as initial diagnostic tool in breast lesions patients
2. To study histopathological findings of core needle biopsies in breast lesion patients
3. To compare findings in BIRADS categories with histopathological findings

Material and Methods

Present study was a retrospective study conducted between January 2020 to December 2023 in Department of Pathology, MGM MCH, Aurangabad. Institutional ethics committee

approval was obtained prior to start of study. 145 patients with breast lesion fulfilling inclusion and exclusion criteria were enrolled.

Inclusion Criteria

145 patients with breast lesion who had undergone radiological imaging, either ultrasound or mammography, with BIRADS categories 2 to 5 and had core needle biopsy with histopathological examination were included.

Exclusion Criteria

1) Cases lacking radiological evaluation 2) Cases with inadequate biopsy material

Methodology

All the breast biopsy cases were retrieved from department register. Mammography reports of all these patients were retrieved from Hospital Information System. All the cases were categorised as BIRADS categories 2–5. BIRADS categories 2-3 were considered to be most likely benign, and categories 4-5 were considered to be malignant. The biopsy slides were reviewed separately by two pathologists. In case of disagreement in opinion to classify benign versus malignant, assessment of senior pathologist was taken as definitive.

- **Core needle biopsy**

Under local anaesthesia with 2% plain lignocaine, a 14 G automated biopsy gun was used to perform a core needle biopsy. 2-4 cores are taken for each case.

- **Biopsy slides**

After being fixed in 10% formalin, each core was processed. 5 micron thick sections were taken and stained with Haematoxylin and Eosin stain.

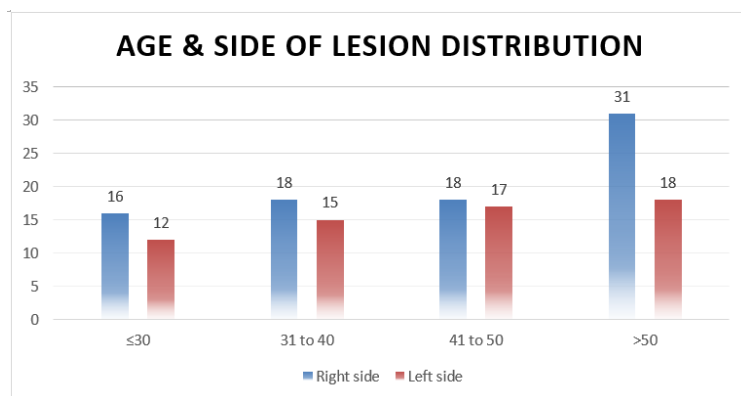
Neoplastic breast lesions were classified into benign and malignant, according to World Health Organisation (WHO) classification of tumours, 5th edition, 2022.

Observation and Result

Table 1: Age distribution

Sr. No	Age group (Years)	Total N (%)
1	≤30	28 (19 %)
2	31 to 40	33 (23 %)
3	41 to 50	35 (24 %)
4	>50	49 (34 %)
Total N (%)		145 (100 %)

As shown in **Table 1**, 28 (19 %) patients were from age group ≤30, 33 (23 %) from 31 to 40, 35 (24 %) from 41 to 50 & majority of patients, 49 (34 %), were >50 years of age.



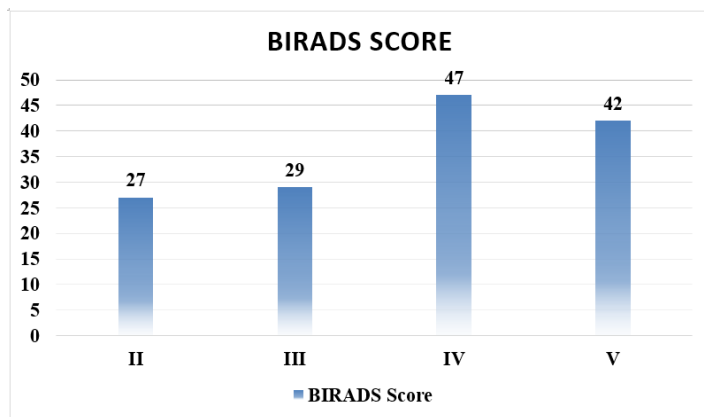
Graph 1: Age & side of lesion distribution

In **Graph 1**, Distribution of age and side of lesion is shown. In ≤ 30 years, 16 patients were having right sided lesion & 12 left sided. In 31 to 40 years, 18 patients were having right sided lesion & 15 left sided. In 41 to 50 years, 18 patients were having right sided lesion & 17 left sided. In > 50 years, 31 patients were having right sided lesion & 18 left sided.

Table 2: BIRADS category

Sr. No	BIRADS Score (Category)	Number of cases N	Percentage (%)
1	II	27	19 %
2	III	29	20 %
3	IV	47	32 %
4	V	42	29 %
Total N (%)		145	100 %

As shown in **Table 2**, in majority patients i.e. 47 (32 %), belong to category IV followed by 42 (29 %) with category V, 29 (20 %) with category III & 27 (19 %) with category II.

**Graph 2: BIRADS category**

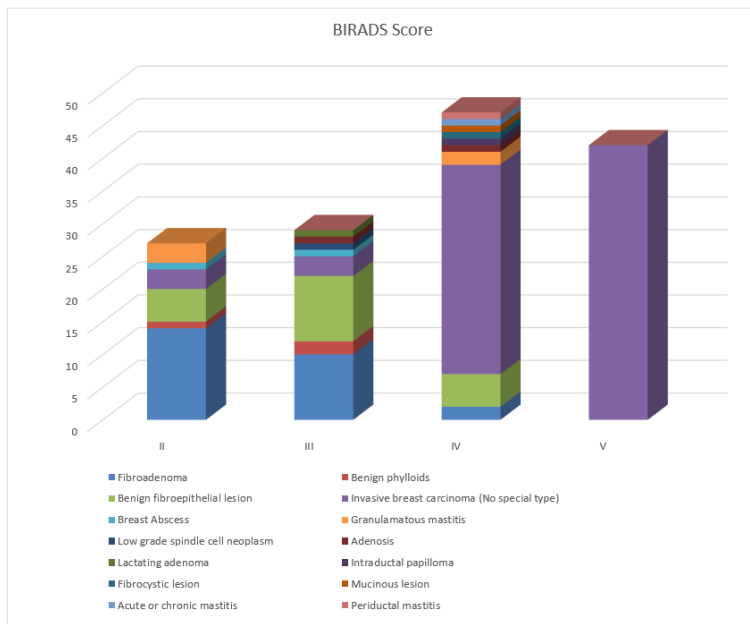
As seen in **Graph 2**, BIRADS II category were found in 27, III category were found in 29, IV category were found in 47 & V category were found in 42.

Table 3: Histopathological diagnosis on Core Needle biopsies

Sr. No	Histopathological type	Number of cases N	Percentage (%)
1	Non-neoplastic	9	5.5%
	a. Granulomatous mastitis	5	2 %
	b. Abscess	2	1.5 %
	c. Acute or chronic mastitis	1	1 %
	d. Periductular mastitis	1	1 %
2	Benign	54	37.5 %
	a. Fibrocystic change	1	1 %
	b. Intraductal papilloma	1	1 %
	c. Benign fibroepithelial Lesion	17	12 %
	d. Lactating Adenoma	1	1%
	e. Adenosis	2	1.5 %
	f. Fibroadenoma	26	18 %
g. Phyllodes tumour	6	3 %	

3	Malignant	82	57 %
	a. Invasive breastcarcinoma	80	55 %
	b. Mucinous lesion	1	1 %
	c. Low grade spindle cell neoplasm	1	1 %
Total N (%)		145	100%

As shown in **Table 3**, total non-neoplastic and benign cases were 63 (43 %) & malignant were 82 (57 %) as diagnosed on histopathology. Amongst benign cases maximum were fibroadenoma found in 26 (18 %) & amongst malignant it was Invasive breast carcinoma found in 80 (55%)



Graph 3: Histopathological distribution of lesions and BIRADS score

As shown in **Graph 3**, amongst category II cases, majority i.e. 14 had fibroadenoma. Amongst category III cases, 10 had fibroadenoma & 10 had benign fibroepithelial lesion. Amongst category IV cases, 32 had invasive carcinoma. Amongst category V cases, all (42) were invasive breast carcinoma.

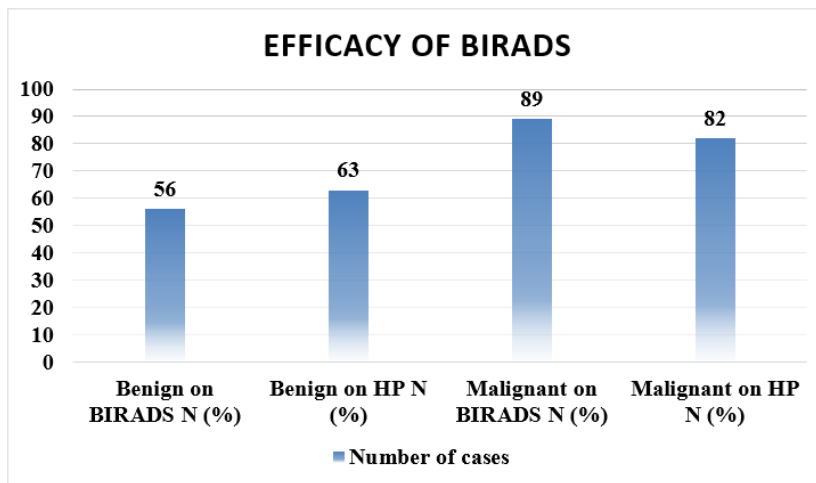
Also, Category IV showed highest variety of cases, diagnosed on biopsy than other categories.

Table 4: Efficacy of BIRADS

Sr. No	BIRADS Diagnosis	Histopathological diagnosis		Total N (%)
		Malignant N (%)	Benign N (%)	
1	Malignant N (%)	75 (52 %)	14 (9 %)	89 (61 %)
2	Benign N (%)	7 (5 %)	49 (34 %)	56 (39 %)
Total N (%)		82 (57 %)	63 (43 %)	145 (100 %)
Sensitivity 91.46 % Specificity 77.78 % PPV 84.27 % NPV 87.50 %				
Diagnostic Accuracy 85.52 %				

As shown in **Table 4**, 75 (52 %) Malignant cases were diagnosed on both BIRADS & biopsy whereas 49 (34 %) were diagnosed as Benign on both BIRADS & biopsy.

7 (5 %) cases were initially found Benign on BIRADS but later found Malignant on biopsy. Similarly, 14 (9 %) cases were initially found malignant on BIRADS but later found benign on HP. Sensitivity of BIRADS was found 91.46 % & specificity was 77.78 %.



Graph4: Efficacy of BIRADS

As found in **Graph 4**, 56 cases were identified as benign on BIRADS while 63 were benign histopathology, whereas 89 cases were diagnosed as malignant on BIRADS while 82 were malignant on histopathology.

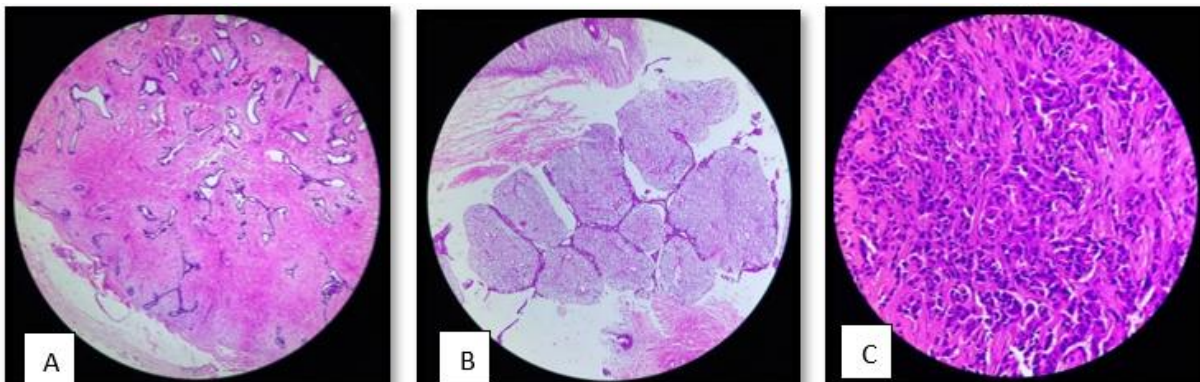


Figure 1: Histopathology on trucut biopsy: A) Fibroadenoma, H & E, 10x; B) Benign Phyllodes Tumour, H & E, 10x; C) Invasive breast carcinoma, No special type, H & E, 40x.

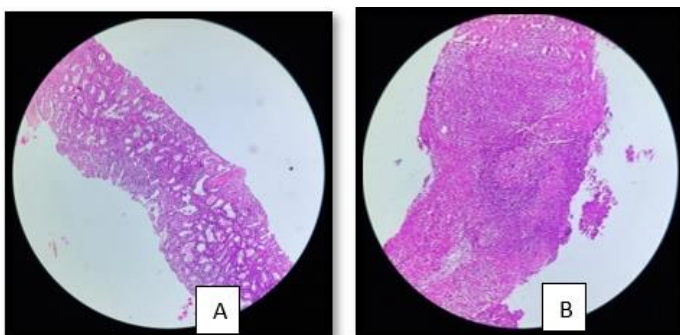


Figure 2: Histopathology on trucut biopsy: A) Lactating adenoma, H & E, 4x; B) Granulomatous mastitis, H & E, 10x;

Discussion

Breast carcinoma remains a major cause of morbidity among affected women. Over 2 million new cases of breast cancer are diagnosed globally each year, and this number is growing. Women who have clinically examined and found to have palpable lumps in their breasts are subjected to imaging evaluations such as mammography and ultrasound. These are the primary non-invasive imaging modalities used to assess breast abnormalities. Breast masses can be screened for and diagnosed by mammography. Lastly, for a definitive diagnosis based on worrisome imaging findings, pathology assessments are required.

In present study 28 (19 %) cases were from age group ≤ 30 , 33 (23 %) from 31 to 40, 35 (24 %) from 41 to 50 & 49 (34 %) from >50 . In similar study by **Aziz S et al. (2022)**⁶ six patients underwent bilateral breast biopsies. Age of the cases ranged from 18 years old to 84 years old (mean = 53 years). **INVLChaitanya et al. (2020)**⁷ in their study found that the most common age group involved was women in the fifth decade. **Chavan SG et al. (2020)**⁸ in their study found that mean age of the study participants was 55.7 ± 8.3 years & of benign cases was 52.1 ± 9.4 years and malignant cases was 57.2 ± 8.9 years. **N, Haji Ghazi Tehrani N et al. (2021)**⁹ in their study found that 207 had single and 3 had two breast masses. Mean age of the patients was 46.91 ± 12.22 years old with a range of 19-92 years.

In present study in majority patients i.e. 47 (32 %), category IV was found followed by 42 (29 %) with category V, 29 (20 %) with category III & 27 (19 %) with category II. In similar study by **Aziz S et al. (2022)**⁶ 75 cases were reported into BIRADS category 3, 166 as BIRADS category 4 and 75 as BIRADS category 5. **INVLChaitanya et al. (2020)**⁷ in their study found that amongst the 100 cases, 55 (55%) cases were categorized as BIRADS 4, 37 (37%) cases were BIRADS 5, 6 (6%) cases as BIRADS 3 and 2 (2%) cases were of BIRADS 2. **Chavan SG et al. (2020)**⁸ in their study found that on BIRADS score, it was observed that 68 (68.0%) cases were having benign lump while 32 (32.0%) cases were having malignant lump. **N, Haji Ghazi Tehrani N et al. (2021)**⁹ in their study found that 28 masses were classified as BIRADS 3, 99 as BIRADS 4A, 4 as BIRADS 4B, 18 as BIRADS 4C, and 64 as BIRADS 5. **Handan Eren et al. (2022)**¹⁰ in their study found that eight biopsies scored as BIRADS 3 or 4. Three cases (2%) were BIRADS 2, 27% (n=34) BIRADS 3, 35% (n=44) BIRADS 4, 25% (n=32) BIRADS 5 and 2% (n=2) was BIRADS 6.

In present study total benign cases were 63 (43 %) & malignant were 82 (57 %) as diagnosed on histopathology. Amongst benign cases maximum were fibroadenoma found in 26 (18 %) & amongst malignant it was Invasive breast carcinoma found in 80 (55%). In similar study by **Aziz S et al. (2022)**⁶, commonest malignant pathology diagnosed was invasive ductal carcinoma of no special type which account for 71.5% of the total malignant cases. Benign breast tissue or fibrotic breast tissue was the most common diagnosis (29.1%). Fibroadenoma accounted for 21.8% of all breast lesions, the second most common kind. In their study, **Chavan SG et al. (2020)**⁸ discovered that, upon histological study, 66 (66.0%) of the cases had benign lumps, while 34 (34.0%) had malignant lumps.

In present study 75 (52 %) Malignant cases were diagnosed on both BIRADS & biopsy whereas 49 (34 %) were diagnosed as Benign on both BIRADS & biopsy. 7 (5 %) cases were initially found Benign on BIRADS but later found Malignant on biopsy. Similarly, 14 (9 %) cases were initially found malignant on BIRADS but later found benign on biopsy. Sensitivity of BIRADS was found 91.46 % & specificity was 77.78 %. In similar study by **Aziz S et al. (2022)**⁶ BIRADS classification had a sensitivity of 94.48%, specificity of 43.14%, a positive predictive value of 63.9% and a NPV of 88%. **N, Haji Ghazi Tehrani N et al. (2021)**⁹ in their study found that BIRADS 4A had the highest sensitivity (70.1%) among BIRADS categories. Among the BIRADS categories, BIRADS 3 and 5 (100%) had the best specificity.

BIRADS 3 refers to masses with regular margin, asymmetric parenchymal densities, and round micro-calcifications having malignancy risk of less than 2%. In this case most of the specialists recommend a six-month follow-up diagnostic mammography. The lesions in BIRADS 4 are sufficiently suggestive for a biopsy even though they are not traditionally malignant. In BIRADS 5, the lesions have a high malignancy risk and should undergo biopsy as spiculated masses and clusters of pleomorphic calcifications are classified in this category^{11,12,13}. Various factors that affect the diagnostic accuracy of BIRADS are age, breast surgery history, lesion characteristics, menstrual/menopausal status, and collaboration between patients and technicians in the imaging process. These factors can explain the differences in the results found in various studies. According to one study, the BIRADS grading system is a useful tool for differentiating between benign and malignant breast tumours without needlessly requiring more biopsies¹⁴.

Table 5: Comparison of current study with other studies

Study	Sensitivity	Specificity	PPV	NPV	Accuracy
Elverici E et al (2015) ¹³	100 %	97 %	100 %	97 %	65 %
Saranganel et al (2017) ¹⁵	95 %	82.92 %	95 %	82.9 %	75.43 %
Kim MJ et al (2012) ¹⁶	100 %	87.5 %	100 %	87.5 %	85 %
Selvi Radha Krishna et al (2013) ¹⁷	93 %	98.5 %	93 %	98.5 %	76 %
Arsalan et al (2010) ¹⁸	100 %	100 %	100 %	82.5 %	88.8 %
INVL Chaitanya et al. (2020) ⁷	97.3 %	100 %	100 %	87.5 %	97.7 %
Present study	91.46 %	77.78 %	84.27 %	87.50 %	85.52 %

Conclusion

To conclude BIRADS classification had an acceptable sensitivity & positive predictive value (PPV). Imaging methods BIRADS classification is a useful but not an alternative to histopathology diagnosis as BIRADS category IV has a wide spectrum of lesions, so its clinico-radio-pathological correlation is utmost importance. Hence, core needle biopsy is a reliable method and still remains gold standard for diagnosing breast lesions.

Conflict of interest: Nil

Acknowledgment:

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