POSITIVE PREDICTIVE VALUE OF BIRADS (BREAST IMAGING REPORTING AND DATA SYSTEM) IV LESIONS IN DETECTION OF CARCINOMA BREAST, USING HISTOPATHOLOGY AS A GOLD STANDARD.

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ABSTRACT…Objective: To determine the Positive Predictive Value of BIRADS IV lesions in detection of carcinoma breast, using histopathology as a gold standard. **Study Design:** A Cross-Sectional study. **Setting:** Department of Radiology Allied Hospital Faisalabad. **Period:** From 01-09-2015 to 01-03-2016. **Material & Methods:** 93 female patients referred to radiology department were included after taking consent. Data were collected on structured proforma. The final diagnosis of the BIRASDS IV lesion seen on mammography has made by consultant. Then patients were sent for biopsy. Mammographic diagnose was then compared with the histopathological diagnose by consultant. The primary performance outcomes of diagnostic mammography like sensitivity, specificity and accuracy were evaluated. **Results:** The mean age of patients was 45.96±7.85years. There were 19 females had subcategory A, 22 had subcategory B and 52 females had subcategory C. The mean size of lump was 3.23±0.69cm. The mean duration of symptoms was 3.97±3.43months. On BIRADS IV, malignant lesion detected in 71 (76.3%) females while 22 (23.7%) females had benign lesion. On histopathology, malignant lesions detected in 50 (53.8%) females while 43 (46.2%) females had benign lesion. Findings of BIRADS IV were compared with histopathology and the PPV was 43.7% and NPV was 13.6%. **Conclusion:** Through findings of this study, we concluded that in comparison to histopathology, BIRADS IV had PPV of 43.7% and NPV of 13.6%. In some cases, we can rely on BIRADS-IV and skip interventional method including biopsy for diagnosis of breast lesion.

Key words: Breast Lumps, Breast Cancer, BIRADS IV, Histopathology, Mammography.

INTRODUCTION

Breast diseases are common misery of the females. About one-fourth of women suffer from breast disease in their life span after adolescence. At least 90% patients attending a breast clinic will have a benign breast status.[1] Carcinoma of Breast among women is the most typical malignancy and stands second as the culprit for related deaths.[2]

Among US women more than 180,000 new cases of breast cancer are diagnosed each year and more than 40,000 women die from its fatality.[3] More recently there has been increase in incidence of breast cancer in developing countries.[4] In Pakistan breast cancer epidemiology is troublesome to portray due to inadequacy of tumor registry system 4 but it is most often listed malignancy , computing for one third of all cancers occurring in females.[5]

Mammographic reporting, evaluation of the disease and perceptions are based on The Breast Imaging Reporting and Data System (BIRADS) developed by the American College of Radiology. Concerns of diagnostic mammography along with sonographic findings are incorporated in the same report with final judgment division ranging from 1 to 6 according to the degree of lesion suspicion.[6]

The Fourth edition of BI-RADS was published in 2003 Comprising category of sonomammogram and magnetic Resonance imaging as well as sub-categorizing category 4 lesion into (4A, 4B and 4C) 3 subdivisions. Suspicious looking lesions falling in BIRAD IV are stratified and they

require interventional procedures. 4A category of BIRADS IV (needing intervention but low suspicion for malignancy), category 4B (lesions with intermediate suspicion for malignancy) and category 4C (moderate concern but not classic for malignancy). Clinicians are better communicated by the extent of disease process and about the level of involvement for carcinoma.[7] This subdivision also revitalize pathologists to conscious of benign subcategory 4C lesions.7 Subcategorizing BI-RADS category 4 lesions are helpful to update the level of concern for carcinoma. Literature review showed positive predictive value of 8.8% for subcategory 4A, for subcategory 4B it was 18.9%, and 58.3% was for subcategory 4C.[8]

While screening mammography is highly tricky for the apprehension of clinically veiled breast cancer, most mammographically identified suspicious lesions for which biopsy is recommended will prove to be benign. Other involvements are psychological impact and probable complexity of radiographic interpretation of future mammograms. A latter report in the New York Times portray the high rate of breast biopsies as diagnostic overkill, drastic and valuable.[9] Fibrocystic disease of the breast stands second to ductal carcinoma in situ(DCIS) according to a study conducted in 2010.[10]

Although Mammogram owns moderate sensitivity (approximately 80%) and specificity (approximately 85 %), especially for dense breasts (sensitivity of approximately 60 %) and less than 1 cm lesios, et is considered to be the gold standard [1-5].[11]

Though carries overall limited sensitivity and specificity mammography is capable for early detection of breast cancer and therefore results in decreased mortality.[12]

Although mammographic lesions classified as BI-RADS 4 are considered suspicious for carcinoma - by definition - and biopsy (bx) is therefore always recommended, only 20-30% of such lesions ultimately yield malignancy at biopsy.[13]

BI-RADS classification helps in detection of breast parenchymal changes and its risk of malignancy. It also guided whether biopsy of that change is indicated or not. Histopathological verification is necessary in BI-RADS 4 (A, B, C), which yields an appropriate indicator of BI-RADS classification accuracy. Therefore, the purpose of this study was to categorize mammographic finding into BI-RADS 4 (A, B, C) and correlation with histopathological finding of a breast change.[14]

RATIONALE
The rationale of this study emphasizes on evaluating the authenticity of BI-RADS category 4 lesions and their malignant outcome using histopathology as a gold standard. On careful literature search very limited data available in our part of society, as breast cancer is leading cause of death my study will be aid in seeking a more reliable guideline and to minimize unnecessary interventions for breast cancer detection.

MATERIAL AND METHODS

Inclusion Criteria
Diagnosed case of BIRADS-IV lesions in mammography as described in operational definition irrespective of category were included in the study. Only adult female patients (30-60 years) having family history or palpable Breast lump of size (1-5 cm) were selected.

Exclusion Criteria
Unwilling patients, patients with diagnosed breast carcinoma and benign diseases, patients with residual cancer after surgery, chemotherapy and radiotherapy, patients with metastatic deposits in the breast and male patients were excluded from the study.

Data Collection
All female patients refer to radiology department and fulfilled the inclusion criteria were included in this study. Verbal informed consent was taken for procedure and enrolment for this study. Data was collected on a structured proforma (attached at the end of this synopsis). Detailed history was taken and breast examination was done by consultant radiologist. Mammography

was performed with Planned Sophie Classic RFH 40822 by mammographic consultant. Standard mediolateral oblique and craniocaudal projections were obtain, additional projections such as coned down compression, magnification, axillary and true lateral views were taken if needed. The mammograms were reported by radiologist experienced more than five years in breast mammography for evaluation of abnormalities like mass with its peculiar characteristics, calcification pattern, asymmetric density, architectural distortion, abnormal axillary nodes. The final diagnosis of BIRADS IV lesion irrespective of category seen on mammography was made by consultant. Then patients were followed till biopsy. Mammographic diagnosis was compared with the histopathological report by consultant. Histopathological report was accessed and findings were noted down along with age and subcategories o BIRADS-IV lesion (A,B,C).

Data Analysis Procedure
SPSS software package (version 16.0, SPSS) was used for statistical analysis. Continuous variables seen as age, size of lump, and duration of symptoms were presented as mean & SD. Frequency of qualitative variables seen as BIRADS IV histopathological diagnosis. To assess the diagnostic assessments of as BIRADS IV lesion category positive predictive value and negative predictive value test were calculated. Effect modifier were controlled through stratification of age, duration of symptoms, size of the breast lump and subcategories of BIRADS IV.

RESULTS
The mean age of patients was 45.96±7.85years. The minimum age of females was 35 years while maximum age of females was 60 years. (Table-I)

There were 31 (33.3%) females were of age 30-40 years, 38 (40.9%) females were of age 40-50 years, 24 (25.8%) were of age 50-60 years. (Table-II)

There were 19 females had subcategory A, 22 had subcategory B and 52 females had subcategory C. (Figure-1)

The mean size of lump was 3.23±0.69cm. The minimum and maximum size of lump were 2.0 and 5.0cm. (Table-III)

In this study, 2 (2.2%) females had lump size 1-2cm, 44 (47.3%) had size 2-3cm, 37 (39.8%) had 3-4cm lump size while 10 (10.8%) females had 4-5cm lump size. (Table-IV)

The mean duration of symptoms was 3.97±3.43months. The minimum duration was 1month while maximum duration was 14months. (Table-V)

In this study, 56 (60.2%) females had duration of symptoms of 1-3months, 21 (22.6%) females had duration of symptoms of 3-6months, 3 (3.2%) females had duration of symptoms of 6-9months, 10 (10.8%) females had duration of symptoms of 9-12months and 3 (3.2%) females had duration of symptoms of 12-16months. (Table-VI)

In this study, 42 females had lesion in right breast while 51 females had lesion in left side. (Figure-2)

On BIRADS IV, malignant lesion detected in 71 (76.3%) females while 22 (23.7%) females had benign lesion. (Table-VII)

On histopathology, malignant lesions detected in 50 (53.8%) females while 43 (46.2%) females had benign lesion. (Table-VIII)

Findings of BIRADS IV were compared with histopathology and the PPV was 43.7% and NPV was 13.6%. (Table-IX)

Data was stratified for age and it was noticed that the PPV and NPV of BIRADS IV were 38.5% and 40% in age 30-40years, 36% and 7.7% in age group 40-50 years and 60% and 0% in age 50-60 years, respectively. (Table-X)

Data was stratified for subcategory and it was noticed that the PPV and NPV of BIRADS IV were 18.2% and 0% for subcategory A, 26.3% and 66.7% for subcategory B, and 58.5% and 9.1% for subcategory C. (Table-XI)

Data was stratified for duration of symptoms and it was noticed that the PPV and NPV of BIRADS IV were 43.2% and 16.7% for 1-3months duration, 42.1% and 0% for 3-6months, 100% and 0% for 6-9months, 50% and 0% for 9-12months and 0% and 50% for 12-16 months duration. (Table-XII)

Data was stratified for size of lesion and it was noticed that the PPV and NPV of BIRADS IV were 0% for 1-2mm size, 47.2% and 0% for 2-3mm size, 44.8% and 25% for 3-4mm size and 20% and 20% for 4-5mm size of lesion. (Table-XIII)

	n	Mean	SD	Minimum	Maximum
Age (years)	93	45.96	7.85	35	60

Table-I. Descriptive statistics of age of patients.

Age (yrs)	Frequency	Percent
30-40	31	33.3%
40-50	38	40.9%
50-60	24	25.8%
Total	93	100%

Table-II. Distribution of patients in different age groups.
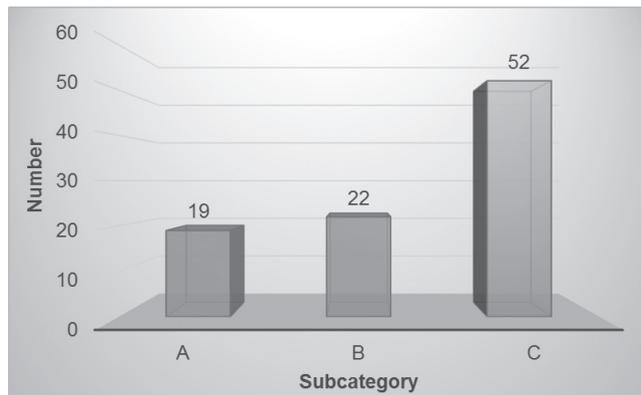
Figure-1. Distribution of subcategory.

Size of lump	93	3.23	0.69	2.0	5.0

Table-III. Descriptive statistics of size of lump.

Size		Frequency	Percent
Size	1-2	2	2.2
	2-3	44	47.3
	3-4	37	39.8
	4-5	10	10.8
	Total	93	100.0

Table-IV. Distribution of size of lesion (in categories).

	n	Mean	SD	Minimum	Maximum
Duration (in month)	93	3.97	3.43	1	14

Table-V. Descriptive statistics of duration of lesion.

Duration		Frequency	Percent
Duration	1-3 months	56	60.2%
	3-6 months	21	22.6%
	6-9 months	3	3.2%
	9-12months	10	10.8%
	12-16 months	3	3.2%
	Total	93	100.%

Table-VI. Descriptive statistics of duration of symptoms.
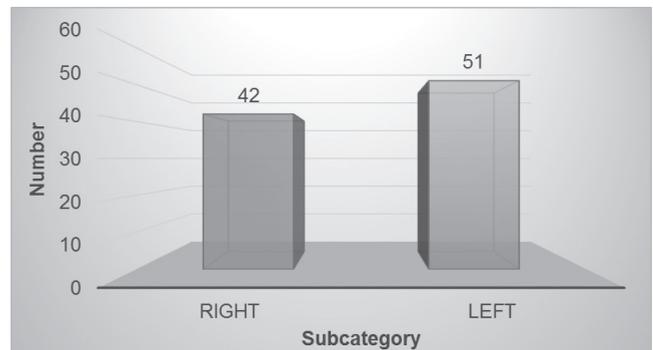
Figure-2. Distribution of side of lesion.

BIRADS IV	Frequency	Percent
Malignant	71	76.3%
Benign	22	23.7%
Total	93	100%

Table-VII. Distribution of findings of BIRADS IV.

		Frequency	Percent
Histopathology	Malignant	50	53.8%
	Benign	43	46.2%
	Total	93	100%

Table-VIII. Distribution of findings of histopathology.

BIRADS IV	Histopathology		Total
	Malignant	Benign	
Malignant	31	40	71
Benign	19	3	22
Total	50	43	93

Table-IX. Comparison of BIRADS IV and histopathology.

PPV = 43.7%
NPV = 13.6%

Age	BIRADS IV	Histopathology		Total	PPV	NPV
		Malignant	Benign			
30-40	Malignant	10	16	26		
	Benign	3	2	5	38.5	40
	Total	13	18	31		
40-50	Malignant	9	16	25		
	Benign	12	1	13	36	7.7
	Total	21	17	38		
50-60	Malignant	12	8	20		
	Benign	4	0	4	60	0
	Total	16	8	24		

Table-X. Comparison of BIRADS IV and histopathology stratified for age.

Subcategory	BIRADS IV	Histopathology		Total	PPV	NPV
		Malignant	Benign			
A	Malignant	2	9	11		
	Benign	8	0	8	18.2	0
	Total	10	9	19		
B	Malignant	5	14	19		
	Benign	1	2	3	26.3	66.7
	Total	6	16	22		
C	Malignant	24	17	41		
	Benign	10	1	11	58.5	9.1
	Total	34	18	52		

Table-XI. Comparison of BIRADS IV and histopathology stratified for subcategory.

Duration of Symptoms	BIRDS IV	Histopathology		Total	PPV	NPV
		Malignant	Benign			
1-3 months	Malignant	19	25	44	43.2	16.7
	Benign	10	2	12		
3-6 months	Malignant	8	11	19	42.1	0
	Benign	2	0	2		
6-9 months	Malignant	1	0	1	100	0
	Benign	2	0	2		
9-12months	Malignant	3	3	6	50	0
	Benign	4	0	4		
12-16 months	Malignant	0	1	1	0	50
	Benign	1	1	2		

Table-XII. Comparison of BIRADS IV and histopathology stratified for duration of symptoms.

Size	Birds IV	Histopathology		Total	PPV	NPV
		Malignant	Benign			
1-2cm	Malignant	0	1	1		
	Benign	1	0	1	0	0
	Total	1	1	2		
2-3cm	Malignant	17	19	36		
	Benign	8	0	8	47.2	0
	Total	25	19	44		
3-4cm	Malignant	13	16	29		
	Benign	6	2	8	44.8	25
	Total	19	18	37		
4-5cm	Malignant	1	4	5		
	Benign	4	1	5	20	20
	Total	5	5	10		

Table-XIII. Comparison of BIRADS IV and histopathology stratified for size of lump.

DISCUSSION

Improvement in sonographic equipment quality has proved a major role in breast imaging and lesions detection.[15]

Detection of mammographically occult masses in women of less than 50 years age has increased by the use of sonomammoram up to 27%.[15,16] In 2003 the American College of Radiology developed the first version of BI-RADS US lexicon on account of this increasing use of US, in order to better characterize breast lesions and for their standardized characterization with US, as with mammography.[17] It was also explained that BI-RADS criteria are insufficient for distinguishing between malignant and benign lesions, and biopsy is mandatory in such cases.[18]

Thus we conducted this study non 93 female with suspicion of breast lesions. The mean age of patients was 45.96±7.85years. In our study, mostly females were of age 40-50 years (40.9%). The mean size of lump was 3.23±0.69cm. The mean duration of symptoms was 3.97±3.43months. In this study, 42 females had lesion in right breast while 51 females had lesion in left side.

In our study, we found that there were 19 females had subcategory A, 22 had subcategory B and 52 females had subcategory C. In one study conducted by Sanders, et al., 94 of 191 (49%) were 4A, 73 (38%) were 4B, and 24 (13%) were 4C.[10]

In our study, on BIRADS IV, 71 (76.3%) females had malignant lesion while 22 (23.7%) females had benign lesion. On histopathology, 50 (53.8%) females malignant lesions while 43 (46.2%) females had benign lesion. Findings of BIRADS IV were compared with histopathology and the PPV was 43.7% and NPV was 13.6%.

In a Brazilian study, it was reported that in a comparison of the different imaging modalities with BI-RADS categories in a Brazilian study showed, increased PPV among the modalities for the category 5 (100% for mammography, and 92.85% for MRI). Category 3 lesions are MR negative with NPV approaching (100%), while intermediate PPV exhibited by mammography and sonomammogram (respectively 69.23% and 70.58%). And all the three modalities exhibited intermediate PPV for category 4: ultrasound, 50%; mammography, 63%; and MRI, 65.96%.[19]

In our study, for subcategory, the PPV and NPV of BIRADS IV were 18.2% and 0% for subcategory A, 26.3% and 66.7% for subcategory B, and 58.5% and 9.1% for subcategory C. Prado et al., reported that PPV for categories 3, 4 and 5 were, respectively, 7.14%, 16.96% and 82.61%.[20] In the USA, this value ranges between 15% and 40%.[21-23] Met analysis of the studies have shown gradually increased PPV, for BIARDS category 3 between 0% & 3%, while for category 4 it is between 15% and 40%, and for category 5, it ranges between 81% and 97%.[23-28]

Wiratkapun et al., reported 21% overall PPV for BIRADS IV and PPVs for subcategories 4A, 4B and 4C, were 9%, 21% and 57%, respectively.[29]

Another study conducted in South Africa, demonstrated a PPV of 20.9% for category 4. And results of this study correlated well with international studies for BIRADS 4 and 5 lesions. Among all the malignancies DCIS accounted for 21.4% and the current literature agrees with it. Thus it was finalized that inspite of limited sources, outcomes were comparable with those of BIRADS. Considering general categorization of the breast lesions, it should be emphasized that BIRADS permits better assimilation of data, compiling, consistency and clarity in reporting system, as well as accurate data comparison among centers facing limitations similar to this study.[30]

Elverici et al., had reported the PPV of BIRADS 4 lesions in determination of typical signs of malignancy, that were irregular shape (PPV, 66%), speculated margin (PPV, 80%) and nonparallel orientation (PPV, 58.9%). Signs exhibited by benign lesions were oval shape (NPV, 77.1%), ell defined circumscribed margins (NPV, 67.5%), parallel orientation (NPV, 70%), and abrupt interface (NPV, 67.6%).75

Constantine et al., found that lesions which showed speculated margins and microlobulation were 100% malignant, same as our findings.[31]

CONCLUSION

Through findings of this study, we concluded that in comparison to histopathology, BIRADS IV had PPV of 43.7% and NPV of 13.6%. In some cases, we can rely on BIRADS-IV and skip interventional method including biopsy for diagnosis of breast lesion.

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