

# Diagnostic Accuracy of Sonographic Breast Imaging Reporting and Data System Classification in Distinguishing Benign From Malignant Masses

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## Abstract

**Objective:** To establish diagnostic accuracy of sonographic Breast Imaging Reporting and Data System classification in distinguishing benign from malignant lesions keeping histopathology as gold standard. **Study Design:** Cross sectional study. **Place and Duration of Study:** Department of Radiology, Combined Military Hospital Lahore over a period of six months from 12<sup>th</sup> February 2009 to 11<sup>th</sup> August 2009. **Material and Methods:** We analyzed 150 patients presenting in OPD with breast lump. All the patients underwent ultrasound evaluation and histopathological assessment via FNAC or biopsy. Sensitivity, specificity, PPV and NPV of ultrasound findings and

histopathological results were calculated keeping histopathology as gold standard. **Results:** The Sonographic BI-RADS Lexicon is based on six categories. Categories 2, 3, 4 and 5 were included in this study. Out of 150 patients using BI-RADS system 82 were category 2, 38 patients were category 3, 18 patients were category 4 and 12 patients were category 5. Sonographic BI-RADS Lexicon showed sensitivity of 82%, specificity of 99 %, PPV of 96 % and NPV of 95 %. **Conclusion:** Sonographic BI-RADS Lexicon is an accurate and cost effective system for characterization of breast lesions. **Key words:** BI-RADS, Ultrasonography, Breast masses, Diagnosis.

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## INTRODUCTION

Ultrasonography as an adjuvant to clinical examination and mammography is at present considered as the most effective tool for diagnosing breast lesions.<sup>1,2</sup> So much so that ultrasound is the investigation of choice in dense breasts with suspicious lesions<sup>3</sup>. The BI-RADS lexicon was first developed for use in mammograph reporting. Several studies have shown that mammographic BI-RADS terminology

is helpful in predicting likelihood of malignancy. Now that sonography has evolved as an indispensable technique for evaluation of breast lesions, studies have proved that sonographic appearance can also be useful in differentiating benign from malignant solid breast masses.<sup>4</sup> Because of frequent overlap of radiologic signs breast lesions have to be biopsied to prove their malignancy or benignity. With the introduction of BI-RADS classification radiologist can define sonographic features and define final assessment category associated with the most appropriate management of the case. If these reliable criteria of sonographic BI-RADS classification are strictly followed the number of biopsies for benign

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lesions can be decreased.<sup>5,6</sup> In the sonographic BI-RADS lexicon lesions are described on the basis of shape, orientation, margin, echogenicity, echotexture, posterior acoustic transmission, lesion boundary and surrounding tissue alterations. The lesions are put into final assessment categories ranging from category 0 to category 6.<sup>7</sup>

## MATERIAL AND METHODS

### Patient Selection

A total of 150 adult female patients ranging from age 18 years to 65 years, coming to Combined Military Hospital Lahore with symptom of breast lump and referred from OPD were included in our study. Patients who had undergone biopsy before acquisition of sonographic images, patients with negative sonographic findings and incomplete prior assessment were excluded from the study.

### METHODOLOGY

Breast Ultrasound was done on TOSHIBA NEMIO and LOGIC 200 using high frequency linear probe with frequency of 7.5 MHz Scanning was done in supine position with ipsilateral arm raised above the head and supine oblique position for lateral lesions. Images were taken in both radial and anti radial projections. The position of lesion was described by clock face localization. All lesions were carefully described using the sonographic BI-RADS lexicon. And put into final assessment categories ranging from category 0: additional imaging evaluation required, category 1: negative finding, category 2: benign finding, category 3: probably benign, category 4: suggestive abnormality, category 5: highly suggestive of malignancy and category 6: known biopsy proved malignancy. Lesions with definitely benign characteristics e.g. cysts were placed in category 2. All lesions with round or oval shape, parallel orientation, circumscribed margins, well-defined interface, hyper echoic or isoechoic nature, posterior acoustic enhancement or no posterior acoustic alteration and absence of alterations in

adjacent tissue were assigned to class 3. Lesions having at least three of the following signs were assigned to BI-RADS class 5 i.e. irregular shape, antiparallel orientation, noncircumscribed margins, abrupt interface, posterior acoustic shadowing and presence of hyper echoic halo. Class 4 included indeterminate lesions i.e. not having three signs of malignancy. We included categories 2 & 3 (benign lesions) and categories 4 and 5 (malignant lesions). All lesions were correlated with either FNAC or biopsy.

## RESULTS

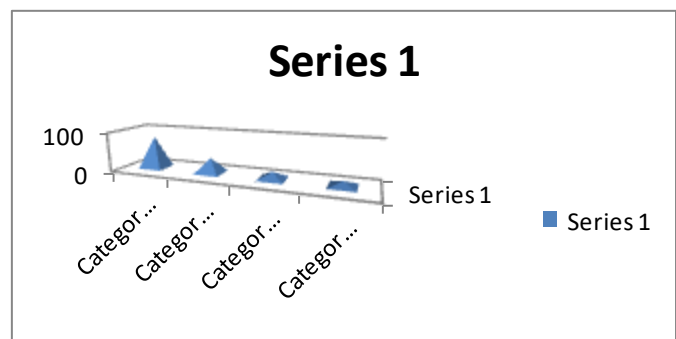
### PATIENT CHARACTERISTICS

A total of 150 patients were included in this study over a period of six months. Ultrasound of the presenting lesion was done by the same sonologist in all cases. All lesions were carefully described using the sonographic BI-RADS lexicon which describes the lesions for shape, orientation, margins, lesion boundary, interface, echo pattern, posterior acoustic features and surrounding tissue alterations.

### SONOGRAPHIC FINDINGS

Out of 150 patients using BIRADS system 82(54.6%) were category 2, 38(25.3%) patients were category 3. 18(12%) patients were category 4 and 12(8%) patients were category 5. Category 2 and 3 were taken as benign and category 4 and 5 as malignant.

**Figure-1**  
**Distribution of Sonological Findings**



## HISTOPATHOLOGICAL RESULTS

In 150 patients who underwent ultrasound were worked up with FNAC/biopsy by the same histopathologist. In these 150 patients 35 patients were found to have malignant lesion and 115 had benign disease. The details are shown table

## PATIENT OUTCOME

Patients in this study were explained in detail about their disease and were treated according to WHO protocols.

## STATISTICAL SIGNIFICANCE

SPSS version 11.0 was used to analyze the data. Diagnostic accuracy was determined by

- **True Positive:** implies that ultrasonography correctly diagnosed breast disease.
- **False Positive:** implies that ultrasonography erroneously diagnosed breast disease
- **False Negative:** implies that ultrasonography failed to diagnose breast disease.
- **True Negative:** implies that ultrasonography correctly excluded breast disease

**Table-1**

**Cross Tabulation of Ultrasound Findings VS Histology of Lesion**  
Count

		Histology of Lesion		Total
		Benign	Malignant	
Ultrasound	Benign	114	6	120
Findings	Malignant	1	29	30
Total		115	35	150

- Sensitivity was  $TP/(TP + FN) = 82\%$
- Specificity was  $TN/(TN + FP) = 99\%$
- Positive predictive value was  $TP/(TP + FP) = 96\%$
- Negative predictive value was  $TN/(TN + FN) = 95\%$

**Table-2**

**Descriptive statistics of age**

### DESCRIPTIVE STATISTICS

	N	Minimum	Maximum	Mean	Std. Deviation
Age of Patient	150	18	65	32.87	10.81
valid (listwise)	150				

**Table-3**

**Frequency of shape**

### SHAPE OF LESION

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Round	82	54.7	54.7	54.7
Oval	36	24.0	24.0	78.7
Irregular	32	21.3	21.3	100.0
Total	150	100.0	100.0	

**Table-4**

**Frequency of Orientation**

### ORIENTATION OF LESION

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Parallel	114	76.0	76.0	76.0
Anti Parallel	36	24.0	24.0	100
Total	150	100.0	100.0	

**Table-5**

**Frequency of Echo pattern**

### ECHO PATTERN

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Hypoechoic	143	95.3	95.3	95.3
Isoechoic	2	1.3	1.3	96.7
Hyderechoic	1	.7	.7	97.3
Complex	4	2.7	2.7	100.0
Total	150	100.0	100.0	

**Table-6**  
**Frequency of Different Interfaces**

	SHAPE OF LESION			
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Abrupt	120	80.0	80.0	80.0
Echogenic Halo	30	20.0	20.0	100.0
Total	150	100.0	100.0	

**Table-7**  
**Frequency of Lesional Boudnary**

	ECHO PATTERN			
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Circumscribed	87	58.0	58.0	58.0
Indistinct	23	15.0	15.0	73.3
Angular	6	4.0	4.0	77.3
Microlobullated	14	9.3	9.3	86.7
Speculated	20	13.3	13.3	100.0
Total	150	100.0	100.0	

**Table-8**  
**Frequency of Tissue Alterations**

	Marginal Distribution and Lesion Boundary			
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Circumscribed	87	58.0	58.0	58.0
Indistinct	23	15.0	15.0	73.3
Angular	6	4.0	4.0	77.3
Microlobullated	14	9.3	9.3	86.7
Speculated	20	13.3	13.3	100.0
Total	150	100.0	100.0	

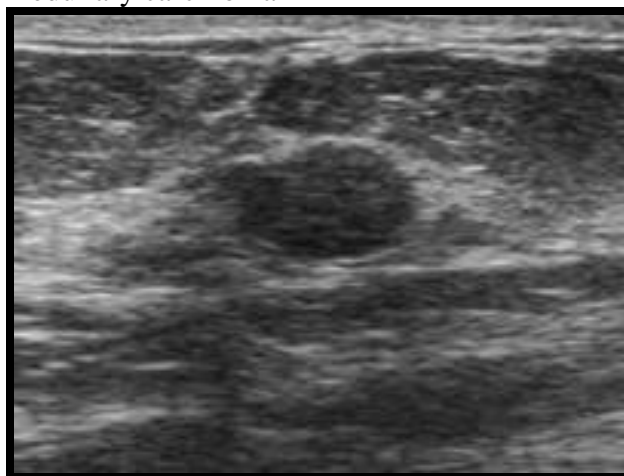
**Table-9**  
**Frequency of Posterior Acoustic Feature**

	Posterior Acoustic Feature			
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Enhancement	105	70.0	70.0	70.0
No Enhancement	16	10.7	10.7	80.7
Shadowing	29	19.3	19.3	100.0
Total	150	100.0	100.0	

**Figure-2**  
**Age VS Histology of Lesion**

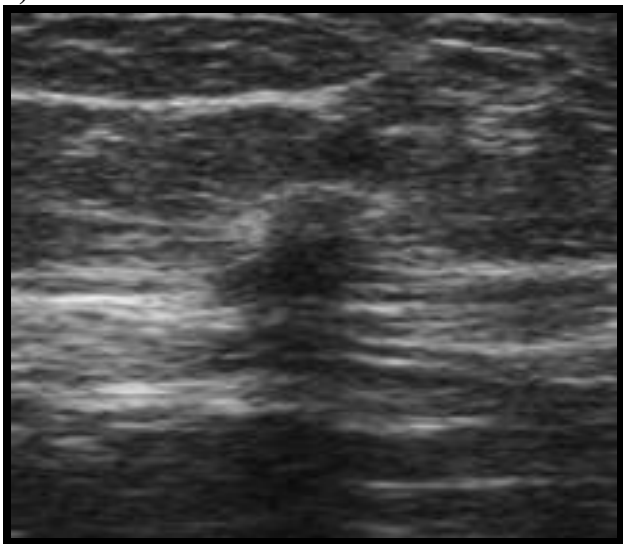


**Figure-3**  
Oval hypoechoic mass with angular margins, an abrupt interface, and no posterior acoustic features (BI-RADS class 4). The definitive diagnosis was medullary carcinoma



**Figure-4**

**Irregular antiparallel hypoechoic mass with spiculated margins, an echogenic halo, and posterior acoustic shadowing (BI-RADS class 5).**



#### **DISCUSSION**

In 1993 Breast Imaging Reporting and Data system (BI- RADS) was developed to standardize mammographic interpretations and to facilitate communication between radiologists and clinicians. As breast sonography is a well established and widely used imaging modality, American College of .Radiology (ACR) developed a standardized lexicon for breast sonography in 2003.<sup>4</sup>

Breast sonography has evolved as an indispensable tool in evaluation of breast lesions.<sup>8</sup> Because of the frequent overlap of radiologic signs, suspected malignant breast lesions detected on sonography have to be examined with biopsy. The large number of biopsies performed for benign abnormalities because of patient's fear, physician uncertainty, or standard protocols is always recognized as an additional problem. Excessive biopsies have adverse effects on society, increasing the costs of screening projects and health care.<sup>5,6,9</sup>

Improvements have been achieved in sonographic diagnosis by the ACR (American college of

Radiology) with the introduction of the BI-RADS classification, which helps the radiologist in describing sonographic features of the lesion and defining the final category. If these reliable criteria are strictly applied starting from the initial radiologic report, the number of biopsies for benign lesions could be decreased.<sup>10</sup>

The aim of our study was to prove whether ultrasound can correctly diagnose benign and malignant lesions so as to avoid unnecessary biopsies keeping sonographic BI-RADS descriptors as standard .We conducted this study with a total of 150 patients. The mean overall age of the patients was 32.87 (18- 65) years. Among these 150 patients 115(80%) had benign lesions and 35 (16.6 %) had malignant lesions proved histologically. Our study confirmed a reliable sensitivity (identification of malignant lesions in patients with breast cancer (82%), high specificity (99%), high PPV (96%) and high NPV (95%). Exhaustive review of literature revealed some interesting findings which are quoted as under.

Mean overall age of our patients (32.87 yrs) was relatively less as compared to other studies. This was because our study dealt with palpable breast lesions only. It is noted in a study conducted by Kim et al. that age of the women with palpable lesions was significantly younger than for non-palpable lesions.<sup>6</sup> The mean age in the above mentioned study for palpable lesions was 40.2 years which is relatively comparable to the mean age of our study group.

In a retrospective study conducted by Costantini et al, the sonographic BI-RADS lexicon showed 71.3% accuracy, 98.1% sensitivity, 32.9% specificity, 67.8% PPV and 92.3% NPV<sup>3</sup>. Our results showed relatively lesser sensitivity (82.8% vs 98.1%) because of higher number of false negative cases (6 cases). However the specificity of our results was higher (99% vs 32.9%) because of less number of false positive cases in our study (1 case).Note that NPV of my results was comparable to the above mentioned study (95% vs 92.3%).<sup>7</sup>

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Stavros et al in a randomized control trial studied a large series of patients and reported 98.4% sensitivity, 67.8% specificity, 38% PPV, 99.5% NPV, and 72.9% accuracy. These results differ from my study due to the fact that patients were from the same ethnic background with a more than 500 individuals and different prevalence of breast cancer.<sup>11</sup>

In a study done on a group of 160 patients to assess the reliability of modified Triple Test by Kwak et al, lesions were interpreted on sonography according to BI- RADS sonographic final assessment. In this study 90.9% sensitivity, 82.7 % specificity, 57.7 % PPV and 97.2% NPV was reported. Note that NPV of our study (95%) is comparable to this study (97.2 %).<sup>12</sup>

Another prospective study carried out by Paulinelli et al showed sensitivity of 96.1%, specificity of 60.2%, PPV of 45.9% NPV of 97.7%. Note that the sensitivity quoted in this study is higher than my study (96.1% vs 82.8%) because of less false negative cases in this study. However my results showed higher specificity (99% vs 60.2%) and PPV (96% vs 45.9%). The NPV of 97.7% is very much comparable to my results i.e. NPV of 95%. Note that in the objective of not missing malignancy sensitivity and NPV are most important. In our study sensitivity of 82.8 % and NPV of 95 % indicated the reliability of sonographic BI-RADS lexicon in distinguishing benign from malignant lesions.<sup>12</sup>

In our study descriptors e.g. irregular shape (31/32, 96.8%), speculated margins (20/20,100%) antiparallel orientation (33/36, 91.6) were highly predictive of malignancy whereas descriptors e.g. oval shape (34/36, 94.4%), circumscribed margins (87/87,100%) and parallel orientation (112/114, 98.2%) were highly predictive of benignity. These results were very much comparable to the results of study conducted by Hong et al.<sup>4</sup>

There were several limitations to our study. As the sample size was very small and included a filtered group of patients, further investigations with a larger data set including other social strata are also

needed. Furthermore follow up was not included in my study due to short study period. True application of sonographic BI-RADS includes follow up particularly for probably benign lesions i.e. category 3. Also majority of lesions (n=82) were allocated to category 2 i.e. definitely benign. Many international studies e.g. Costantini et al. have excluded category 2 i.e. (benign cysts) and this led to difference in our results as compared to theirs.<sup>7</sup>

## CONCLUSION

Ultrasound is a time tested and cost effective technique to study breast lesions. The ACR BI-RADS lexicon provides standardized terminology to facilitate accurate and consistent breast sonography and mammography reporting. This study shows that features from the standardized sonographic lexicon can be helpful in distinguishing benign from malignant masses. It is important to determine whether our results are reproducible when applied to practices with different ultrasound equipment, operator experience,

Interpreting physicians and patient populations. It is also very important to establish interobserver variability in the assessment of sonographic features.

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Submitted for Publication:	04-09-2011
Accepted for Publication:	15-12-2013
After minor revisions	