Original Article

Diagnostic Accuracy of Ultrasound Bi-RADS Classification Among Females Having Breast Lumps, by Taking Histopathology as Gold Standard

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Abstract

Objective: To determine the diagnostic accuracy of ultrasound BI-RADS classification in patients presented with breast lump by cytology as histopathology as "a benchmark".

Methodology: This cross-sectional study was conducted at department of Radiology at Islamabad Diagnostic Center, F-8, Markaz, Islamabad from February 2018 to July 2018. All the patients who presented with breast lumps were included and underwent mammograms (Digital Mammogram DRE by GE USA). Mammogram reports were categorized 0-VI according to Breast Imaging-Reporting and Data System (BI-RADS) scores 0-VI. Patients having BI-RADS score 0-III were considered as negative and BI-RADS score IV-V were considered as positive Patients further underwent fine needle aspiration of breast lump for cytology. Data was collected via self-made performa and analyzed by using SPSS version 20.

Results: Total 72 females presented with breast lump were studied; their mean age was 40.27+4.48 years. 22 patients had breast cancer according to BI-RADS classification, and out of these 16 patients were conformed on histopathology. Sensitivity and specificity of BI-RADS classifications were 75% and 82% respectively, while diagnostic accuracy was 80% by taking histopathology as gold standard. There was a significant positive correlation between BI-RADS classification and lump size on ultrasound r-value 0.279 and p-value 0.001.

Conclusion: Ultrasound BI-RADS classification is the effective reliable modality with sensitivity was 75% and specificity 82% in the diagnosis of breast lump in order to decrease the burden of unnecessary biopsies.

Keywords: Benign lump, BI-RADS, histopathology

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Introduction

Benign breast conditions are the lesions with multiple etiologies that occur in mammary epithelial cells or further mammary tissues as well as associated with traumatic , inflammatory or vascular diseases.[1] This is a major challenge for wellbeing and a major factor of female morbidity as well as mortality worldwide, both in developed and the developing nations including Pakistan.[2-4] Pakistan bears the greatest breast cancer rate in Asia. Young females also develop breast cancer that impacts negatively on prognosis.[5] The yearly Age-Standardized Prevalence Rate for breast cancerous conditions in 2012 stood at: 43.3/100,000 women worldwide and in Pakistan at 50.3/100,000.[6,7] The ultimate target of breast screening is to identify breast cancer. When successful percutaneous biopsy procedures are increasingly being used, an eventual aim

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in controlling the breast tumor is detailed pre-treatment strategy for a specific definitive surgery of lymph node testing when needed.[8,9] Presently, total resection including breast preservation and radiotherapy of any carcinoma is a norm to achieve clear resection thresholds to minimize local relapse.[8,9] Several examinations, such as an ultrasound, mammogram, biopsy, and MRI, may detect breast cancer. All through breast palpation, medical professionals have long practiced the hypothesis that malignant and benign breast lesions possess intrinsically different strength; lesions with tougher and less mobility are deemed as malignant.[10] Many specific imaging techniques were established to assess the comparative strength of lesions than the underlying tissue, particularly ultrasonographic strain scanning (also recognized as ultrasound elastography).[10,11] Ultrasound elastography, based on variances in stiffness, can enable the distinction of malignant from benign solid masses. There is a high specificity and sensitivity of breast MRI. When a lesion on MRI seems to be abnormal however invisible or noticeable on mammogram, a biopsy should be undertaken.[12,9] Even though ultrasound can direct the MRI detected lesion.

MRI-based biopsy, however, is not readily accessible and is expensive due to the equipment application time as well as hours of involved professionals. Conversely, ultrasound-based biopsy is affordable and widespread, and this scenario could be subject to ultrasound-based localization.[9] Whereas breast ultrasound is commonly practiced, it has prominent disadvantages including operator reliance and shortage of reproducibility and standardization.[13,14] American College of Radiology established a Data and Reporting System regarding Breast Imaging (BI-RADS) ultrasound lexicon during 2003. The ACR published a revised version of ultrasound lexicon following a long period of clinical practices with the introduction of terminology improvements and new sections during 2013,[11,15] along with low inter observer agreement particularly in case of malignant & small masses and BI-RADS 4 (suspected malignancy).[16] Literature showed controversial findings and due limited local data this study assessed the diagnostic accuracy of ultrasound BI-RADS classification in patients presented with breast lump by considering histopathology as “a benchmark” at IMS, SZABMU, and Islamabad.

Methodology

This cross-sectional study was performed at department of Radiology at Islamabad Diagnostic Center, F-8, Markaz, Islamabad. All the patients presented with breast lumps were included and underwent ultrasound of breast were included. Patients who already known with breast cancer (BI-RADS score 6) and those were not agreeing to participation in the study were excluded.

Breast ultrasound was done of each patient by senior radiologist having experience >5 years. In line with Breast Imaging-Reporting and Data System (BI-RADS), ultrasound reports were categorized (scale: 0-6) as: BI-RADS: (0= incomplete, I=Negative, 2= benign, 3=Probably benign, 4= suspected for malignancy, 4a= lowly suspected malignancy, 4b= Partially suspected malignancy, 4c=Fully suspected for malignancy, 5= malignancy and BI-RADS 6= proven malignancy. Patients those having BI-RADS score 0-3 were considered as negative and BI-RADS score 4-5 were considered as positive. All the patients were further undergoing fine needle aspiration biopsy for taken specimens for histopathology by senior surgeons having experience more than 5 years. All the data was collected via self-made proforma.

Data analysis calculation was obtained by SPSS version 20. Mean and standard deviation will be estimated for quantitative variables like age. Simple frequency and percentage will be calculated for categorical variables. 2X2 tables were used to represent the calculations of the specificity (SP) “negative predictive value (NPV) and positive predictive value (PPV) and Sensitivity (SE) of “BI-RADS classification” by taking histopathology as gold standard.

Results

Total 72 females presented with breast lump were studied; their mean age was 40.27$\pm$4.48 years with range of minimum 21 years and maximum 60 years. (Table I)

In this study ultrasound BI-RADS classification showed sensitivity, specificity, PPV, NPV and diagnostic accuracy as 75%, 82%, 92%, 54% and 80% respectively. (Table II)

There was a significant positive association between BI-RADS classification and lump size on ultrasound r-value 0.279 and p-value 0.001

Table I: Mean age of patients. (n=72)	
Mean	40.27 years
Std. Deviation	4.48 years
Minimum	21 years
Maximum	60 years

Table II: Patients distribution according to Diagnostic accuracy. (n=72)

BI-RADS classification	Histological		Total
	Positive	Negative	
4-5 (positive)	12	10	22
0-3 (negative)	4	46	50
Total	16	56	72

Sensitivity: TP/(TP+FN) x100 = 75%
Specificity: TN/FP+TNx100 = 82%
PPV: TP/TP+FPx100 = 92%
NPV: TN/FN+TNx100 =54%
ACC: TP+TN/TP+TN+FP+FNx100 =80%

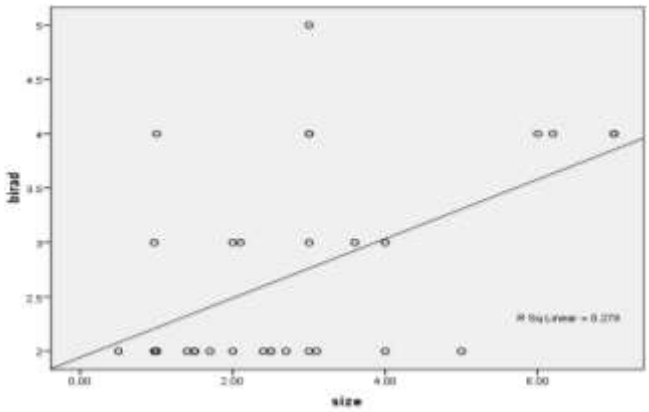

Figure 1. Correlation between BI-RADS classification and lump size on ultrasound.

Discussion

The accuracy of breast ultrasonography and clinical diagnosis in the preoperative evaluation of breast malignancy is essential for early diagnosis.[16] In this study BI-RADS classification showed sensitivity 75%, specificity 82%, PPV 92%, NPV 54% and diagnostic accuracy of 80%. Breast ultrasound is routinely used to differentiate breast cancer and benign tumor with a great value. Evans et al.[16] found that the sensitivity of the ultrasound BI-RADS score to identify benign and malignant breast tumors was 0.95 and the specificity was 0. 69. In the favor of this study Tan Y et al[17] reported that sensitivity of the ultrasound breast Imaging Reporting and Data System (BI-RADS) classification was 87.75 %, specificity 90.89 % and accuracy was 91.04 %. Another study of Gao Y et al[18] showed sensitivity (0.817) and specificity (0.898) of ultrasound BI-RADS. Hille H et al[19] also found similar findings as analyzing sensitivity and specificity of BIRADS, are 0.92, 0.85, and accuracy was 0.87. Timmers JM et al[20] breast malignancy was diagnosed in 485 women and observed that the BI-RADS, showed sensitivity of 66 % and specificity of 99 %. On other hand Gao Y et al[21] reported that there was 73% sensitivity and 91% specificity of breast ultrasound BI-RADS classification were seen.

In present study, patients' mean age was 40.27±4.48 years, which was similar to the study of Quershi SA et al[16] where patients mean age was 41.4± 6.92 years. Tan Y et al[17] reported that patients' mean age was 55.72±10.85 years.

In this study, there was a significant positive association between BI-RADS classification and lump size on ultrasound r-value 0.279 and p-value 0.001. Similarly, a study stated that on correlating ultrasound findings with the findings of MRI, the operator who performs handheld scanning must correlate the location and size of lesions and match the arrangement and type of tissues that surround the lesion for reducing the chances of mis-enrollment. Tumor size remains among the most vital factors when determination of cause-specific and disease-free survival rates are intended for invasive breast cancer, mainly in case of node-negative breast malignancies, where tumor size is highly significant in deciding extent and type of succeeding oncological and surgical management. Mennella et al[22] described that the margins, histology and size of tumors really have an effect and yet there extent of influence and also the other factors that result in inconsistency in tumor-size evaluation, remain a subject of argument. The study of Onesti, reports that pathology of tumor size and MRI were positively associated (R=.650).[23]

Conclusion

It was concluded that ultrasound is a first-line imaging technique, which can sufficiently discriminate malignant and benign findings in terms of BI-RADS categories with sensitivity of 75% and specificity 82% in the diagnosis of breast lump to decrease the burden of preventable biopsies. Further studies are required to identify this diagnostic tool.

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