ORIGINAL ARTICLE

DIAGNOSTIC ACCURACY OF ULTRASOUND BI-RADS IN DIAGNOSING BREAST LESIONS UTILIZING THE CORE NEEDLE BIOPSY KEEPING HISTOPATHOLOGY AS A GOLD STANDARD

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ABSTRACT

Objective: To determine the diagnostic accuracy of Ultrasound BI-RADS classification in diagnosing breast lesions utilizing the core needle biopsy method keeping histopathology as a gold standard.

Materials and Methods: A cross-sectional study was conducted in the Radiology department of CMH Peshawar incorporating 51 patients having breast lesions as presenting complaints. After performing ultrasonography, lesions were categorized as benign and malignant according to BI-RADS scoring. A core needle Biopsy of lesions was done and histopathology reports were collected. Diagnostic accuracy, Sensitivity, Specificity, Positive predictive and Negative predictive value of "BI-RADS classification were calculated by analyzing data.

Results: The mean age was calculated as 45.63± 16.83 years. According to the BI-RADS score, 17 cases (33.3%) were categorized as benign and 35 cases (66.7%) as malignant while Histopathology reported 20 cases (39.2%) as benign while 31 cases (60.8%) as malignant. Diagnostic accuracy, Sensitivity, Specificity, Positive predictive value Negative predictive value for ultrasound BI-RADS turned out to be 90.19%, 96.77 %, 80.00%, 88.23% and 94.11% respectively.

Conclusion: Ultrasound BI-RADS classification has high diagnostic accuracy in differentiating benign from malignant lesions. Universal application of ultrasound BI-RADS guidelines will help in the early diagnosis of malignant breast lesions while avoiding unnecessary biopsies in benign lesions.

Keywords: Breast imaging, Core needle biopsy, Diagnostic accuracy

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INTRODUCTION

Breast cancer is the second most common malignancy and a significant contributor to the female mortality rate. Annually new 1.6 million cases of breast cancer are diagnosed.[1, 2] The incidence of breast cancer is >80 per 100,000 population in developed countries which is higher than the developing countries accounting for <40 per 100,000 population.[3] In Asia, Pakistan has the greatest prevalence rate of 50.3/100,000 for breast cancer which is higher than the worldwide prevalence of 43.3/100,000.[4] Mostly, females over 40 years of age are affected but cases are now also reported in younger individuals accounting for up to 7 % of all breast cancers in USA.[5,6]

The majority of solid masses of breast are benign, however, due to fear of malignancy, they are unnecessarily biopsied. If the US BI-RADS lexicon is applied, unwanted breast biopsies can be avoided leading to an increased rate of breast conservation.[2] The malignant lesions of the breast can be invasive and non-invasive. The commonest of invasive carcinoma is invasive ductal carcinoma while Ductal carcinoma in situ (DCIS) is the most common among non-invasive carcinomas.[2, 7]

Breast Ultrasound is a cheaper and easily available imaging modality that is non-invasive and accurate in diagnosing breast lesions. It differentiates solid from cystic lesions and can help in the pre-surgical detection of tumors as small as 2mm in size. It is also used for better characterization of palpable masses in dense tissues which are not detected on mammography. Ultrasonography also has an edge on mammography as the sensitivity of mammography is 90% leaving 10% of carcinomas being undetected initially, particularly in a dense breast, which is later on detected by ultrasonography or MRI .[3, 5]

With the increasing rate of newly diagnosed cases, radiological and pathological findings must show consistent agreement for precise diagnosis of breast lesions.[8] In

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2003, a universally accepted data and reporting system named ultrasound lexicon for BI-RADS was developed for uniformity in diagnosing breast lesions among radiologists which was revised in 2013. [9]

Percutaneous breast biopsy under image guidance is a fundamental tool for diagnosing breast pathology. Technological improvements in imaging modalities and core biopsy equipment have led to the broader application of ultrasound-guided biopsy for nearly all breast lesions even non-mass pathologies and micro-calcifications. Image-guided core needle biopsy (CNB) has high diagnostic accuracy in diagnosing breast lesions and has proven as an accurate substitute for surgical excision biopsy.

Sonomammography was first reported in 1975 yet its widespread implication was not utilized until 1993 when Parker et al reported 100% agreement in CNB and surgical excision in diagnosing breast lesions. A false negative rate of 14-gauge ultrasound-guided CNB is low ranging from 0.1% to 3.7% being equivalent to open surgery .[10] BI-RADS is a risk assessment and quality assurance reporting system developed by the American College of Radiology. It applies to mammography, ultrasound, and MRI. Core Needle Biopsy is a diagnostic test that uses a wide-bore needle to remove a piece of tissue from a lesion through a percutaneous approach. The collected sample is then examined under the microscope for histopathology.Literature reveals that most of the work has been done on mammographic findings of breast lesions and where ultrasound findings have been documented, a standard scoring system is not used. This study aims to compare the diagnostic capability of ultrasound BIRADS scoring with histopathological outcomes using the CNB method for optimal differentiation of benign from malignant lesions resulting in early diagnosis and treatment of carcinomas avoiding unnecessary surgical interventions in benign lesions. The rationale of the study is to prove that ultrasound can be effectively used for evaluating breast lesions, particularly in centers where facility of mammography is not available.

MATERIALS AND METHODS

The radiology department of CMH Peshawar conducted a cross-sectional study from September 2020 to September 2021 after taking study approval from Hospital Ethical Committee. Any breast abnormality that presented as a lump, swelling, redness or rash associated with dimpling or nipple discharge was included. Female patients who presented with breast lesions and underwent both Ultrasonography and Core Needle Biopsy for evaluation of these lesions were evaluated. Diagnosed patients with breast cancer who were already categorized as BI-RADS score 6, those who differed to participate in this study, cases with untraceable CNB results, and CNB results reported as inadequate biopsies were excluded.

Fifty-one patients met the inclusion criteria and were included in the study. Non-probability convenient sampling technique was used. Each patient underwent breast ultrasound on Xario 200 ultrasound machine using a linear probe of 5-7Hz frequency. These scans were performed by a consultant radiologist with more than 10-year experience. Ultrasound reports were categorized (scale: 0-6) in accordance with guidelines provided by ACR BI-RADS Atlas 5th Edition.

Breast lesion was assessed on the basis of breast composition, characteristics of the mass, calcifications, associated feature, and special cases. Characteristics of mass were further elaborated as shape, margin, orientation, echo pattern and posterior features. On the basis of these features BI-RADS score was assigned as BIRADS: 0 as incomplete, 1 as Negative, 2 as benign, 3 as Probably benign, 4 as suspicious for malignancy, 4a as low suspicious for malignancy, 4b as moderate suspicious for malignancy, 4c as High suspicious for malignancy, 5 as malignancy and BI-RADS 6 as proven malignancy.[9] Patients with BI-RADS scores 3 and below were characterized as negative and BI-RADS scores 4 and above as positive. The decision for biopsy in patients with BI-RADS 2 and 3 was done based on their request or the physician's decision.

All these patients then underwent core needle biopsy under strict aseptic measures by a consultant radiologist having more than 10-year experience. Bard Monopty Disposable 18G core biopsy needles were used for this purpose. These samples were then sent to the Department of Pathology for Histopathological analysis. CNB reports were traced from the Pathology department and a self-made proforma was used to collect the data.SPSS version 20 was used for analyzing Data calculations. Quantitative variables like age had their Mean and Standard deviation estimated. Calculations of Simple frequency and percentage were done for categorical variables. 2X2 tables were utilized to calculate Diagnostic Accuracy, Sensitivity, Specificity, Positive predictive value(PPV), and Negative predictive value(NPV) of BI-RADS classification keeping histopathology outcomes of core needle biopsy as a gold standard.

RESULTS

The mean age of 51 patients included in this study was calculated as 45.63$\pm$ 16.83 years ranging from a minimum of 20 years to a maximum of 79 years of age. Results of ultrasonography findings in accordance with the BI-RADS score are shown in Table 1. No patients were reported with BI-RADS scores of 0, or 6. BI-RADS score 2 was reported in 06 patients (11.8%) corresponding to benign findings, BI-RADS score 3 was reported in 10 patients (19.6%) corresponding to probably benign findings, BI-RADS 4 was reported in 31 patients (60.8%) corresponding to suspicious abnormality while 04 patients (7.8%) had BI-RADS 5 score suggestive of high suspicion of malig-

nancy. BI-RADS scores 3 and below were considered benign while BI-RADS scores 4 and above were considered malignant. On the basis of the BI-RADS score, 17 (33.3%) cases were categorized as benign while 34 (66.7%) cases as malignant. The mean age of patients diagnosed with malignant and benign lesions was 48.82 $\pm$ 17.25 and 39.29 $\pm$ 14.39 respectively.

The distribution of cases on histopathology reports using CNB is given in Figure 1. Twenty cases (39.2%) turned out to be benign with mastitis (7 cases) being the most common pathology followed by Fibroadenoma (6 cases). Thirty-one cases (60.8%) turned out to be malignant with Infiltrating ductal carcinoma (19 cases)being most common pathology followed by mucinous carcinoma (6 cases). Out of 16 patients categorized as BI-RADS 2 or 3 and considered benign, only one case turned out to be malignant on histopathology, while all the 17 cases categorized as BI-RADS 4c or 5 turned out to be malignant. A comparison of BI-RADS results with core needle biopsy outcomes is shown in Table 3. For ultrasound BI-RADS classification diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value turned out to be 90.19%, 96.77 %, 80.00%, 88.23% and 94.11% respectively.

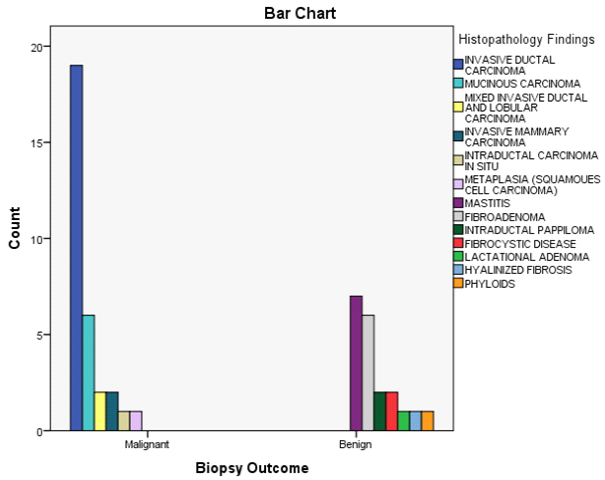

Fig 1: Categorization of Histopathological findings (benign and malignant)

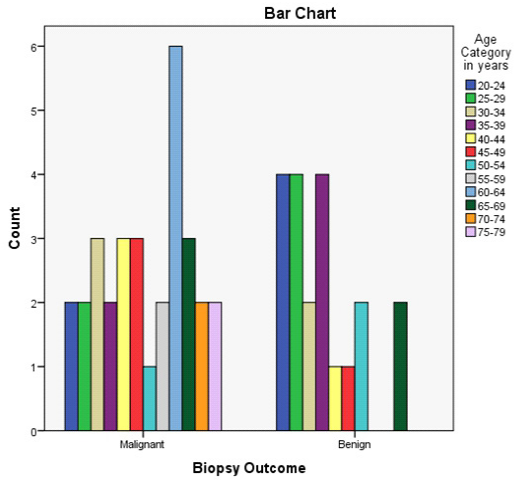

Fig 2: Age-wise distribution of benign and malignant lesions according to histopathology reports

Table 1: Ultrasound BI-RADS score

BI-RADS score	Frequency (n)	Percent (%)
BI-RADS 2	6	11.8
BI-RADS 3	10	19.6
BI-RADS 4a	6	11.8
BI-RADS 4b	12	23.5
BI-RADS 4c	13	25.5
BI-RADS 5	4	7.8
Total	51	100.0

Table 2: Core needle biopsy outcome according to Histopathology categorized as benign or malignant

Core needle Biopsy Outcome	Frequency (n)	Percent (%)
Malignant	31	60.8
Benign	20	39.2
Total	51	100.0

Table 3: Table comparing BI-RADS and Core needle biopsy outcomes categorized as malignant and benign

BI-RADS RESULTS	Biopsy Outcome		Total
	Malignant (Positive)	Benign (Negative)	
Malignant (Positive)	30 (TP)	4 (FP)	34
Benign (Negative)	1(FN)	16 (TN)	17
Total	31	20	51

Key: TP = True positive, FP = False positive, FN = False negative, TN = True Negative

Sensitivity=[TP/(TP+FN)] ×100

Specificity=[TN/(FP+TN)] ×100

Positive predictive value(PPV)=[TP/(TP+FP)] ×100

Negative predictive value(NPV)=[TN/(FN+TN)] ×100.

DISCUSSION

There is a high prevalence of breast pathologies in females accounting for a high mortality rate. In developing nations, inhabitants are oblivious to breast pathologies and also exhibit reluctance to unveil breast abnormalities resulting in the diagnosis of breast pathologies at advanced stages.[11] Jallad et al., reported that breast ultrasound can reliably differentiate benign from malignant lesions and can reduce the rate of unwanted biopsies. Taking this into consideration, breast ultrasound should be routinely used as the first-line technique to distinguish benign and malignant breast lesions avoiding unnecessary biopsies in

younger patients yet identifying suspicious lesions.[2]

Our study estimated Diagnostic accuracy, sensitivity, specificity, PPV, and NPV for BI-RADS classification as 90.19%, 96.77%, 80%, 88.23%, and 94.11% respectively. Broad variability in the sensitivity of sonomammography for breast lesion diagnosis has been reported ranging between 67% and 97%.[3] A study conducted at Islamabad Diagnostic Centre, Islamabad, determined the Sensitivity, Specificity, PPV, and NPV as 80%, 75%, 82%, 92%, and 54% respectively for ultrasound BI-RADS. [4] The specificity and PPV are analogs with our study while sensitivity and NPV of this study are lower than our study. Shrestha M K et al., in Nepal, described the specificity and sensitivity of ultrasound BI-RADS scores as 95% and 78.9 respectively.[12] Our study has sensitivity greater while specificity is lower than this study. Evans et al., estimated the sensitivity and specificity of the ultrasound BI-RADS score as 95% and 69% respectively where specificity is marginally lower than our study.[13] In a study conducted by Tan et al., the sensitivity, specificity, and diagnostic accuracy of the ultrasound BI-RADS classification came out to be 87.75 %, 90.89 %, and 91.04 % respectively .[14] Hille et al., reported analogous findings of sensitivity, specificity and diagnostic accuracy of BIRADS as 92%, 85% and 87% respectively .[15] Conclusions of these two studies are analogous with our study. Timmers et al. described a sensitivity of 66 % and a specificity of 99 % for BI-RADS. [16] Gao et al., described the sensitivity and specificity of breast ultrasound BI-RADS classification as 73% and 91% respectively. [17] These two studies illustrated lower sensitivity while higher specificity compared to our study. Emine et al. reported sensitivity and specificity for sonomammography as 72.6 and 88.5% respectively.[18] The results of this study were lower compared to our findings. Keeping in view the statistics of previous studies, it is evident that integrating BI-RADS guidelines in breast ultrasound technique results in achieving high diagnostic accuracy for diagnosing malignant breast lesions as most of these international studies are in concordance with our study.

In our study, the core needle biopsy method was used to acquire samples for histopathology. Excision biopsy is regarded as a benchmark for diagnosing breast lesions, yet CNB has also shown promising results in precisely diagnosing breast pathologies. Sun et al., reported that CNB has some limitations yet it could be used for the preoperative analysis of breast neoplasm leading to a convenient treatment regimen and an increased number of breast conservations.[19] Homesh et al., and Usami et al. compared CNB & FNAC and found sensitivity ranging from 91–99% and specificity between 96% and 100%, while positive predictive value, and negative predictive value were 100% for CNB correlating to FNAC.[20-21] These findings suggest that core needle biopsy has proved to be an accurate technique in diagnosing breast lesions and should be the preferred technique for diagnostic purposes.In our study, the mean age was reported as 45.63$\pm$ 16.83 which is in line with the findings of Malik et al., (40.27$\pm$4.48 years).[4] Moreover, Tan et al. reported the mean age as 55.72$\pm$ 10.85 years which is higher compared to our findings. [14] The mean age of patients having malignant lesions on ultrasound was 48.82 $\pm$ 17.23 years which is slightly higher than the peak incidence determined by Khemka et al., as 40-44 years.[22]

Our study revealed that among cases confirmed as malignant on histopathology, 29.07% were reported in individuals younger than 40 years. Wong et al. stated that in younger patients' ultrasound is elementary for breast screening and ensuring positive findings.[23] It has been reported that almost 7% of all breast carcinomas in the USA are diagnosed in females less than 40 years of age.[5, 6] This suggests that though breast carcinoma is still more prevalent in females aged 40 and above, younger patients are also at risk of malignancy and an increasing number of cases are now being reported. The strength of our study is that the standardized scoring system BI-RADS was used for the assessment of breast lesions which is accepted globally and the findings of our study are in keeping with previously reported findings. The limitation of the present study was that the CNB results of some patients could not be traced which resulted in their exclusion from this study.

CONCLUSION

Ultrasound is a rapid, convenient, and effective modality for evaluating breast lesions. Ultrasound BI-RADS classification has high diagnostic accuracy for diagnosing breast lesions. CNB is a convenient, less invasive, and effective method for diagnosing breast lesions that are suspicious on ultrasonography. Universal application of ultrasound BI-RADS guidelines will help in the early diagnosis of malignant breast lesions while avoiding unnecessary breast biopsies in benign lesions.

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under

Nisar U:	Concept, proposal writing, and data collection
Anwar J:	Writing and data collection
Ihsan HR:	Data collection and review
Yadain SH:	Writing and data collection
Sultana SM:	Data collection
Khan M:	Writing, review, and statistical analysis

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.