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Original Research Article

Ultrasonographic Breast Imaging-Reporting and Data System (BI-RADS): Radiologic-Pathological Correlation

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Abstract

Background: Breast cancer is the leading cause of cancer deaths among women worldwide. Breast cancer clinically presents as breast lump. Biopsy/Fine needle aspiration cytology (FNAC) and breast ultrasound is pivotal in characterization of a breast lump as benign and malignant lesion. Despite advances in modern investigations, accurate diagnosis is challenge. Delay in diagnosis may leads to Morbidity and mortality. Early diagnosis of breast lump reducing health care costs and also morbidity and mortality of patients. BI-RADS (Breast Imaging-Reporting and Data System) are a risk assessment and quality assurance tool developed by American College of Radiology that provides a widely accepted lexicon and reporting schema for imaging of the breast.

Aim: To assess the accuracy of categorization of breast ultrasound findings based on scoring for malignancy using the Sonographic Breast Imaging-Reporting and Data System (BI-RADS) and its correlation with Pathological finding. To assess the prevalence of common breast lesions in general population.

Materials and Methods: This prospective study was conducted on all patients who presented to the department of Surgery, Radiodiagnosis and Pathology of Government Medical College and Bangur Hospital, Pali (Rajasthan) for ultrasonography breast from November 2021 to October 2022 with breast lump and willing to undergo ultrasonography biopsy of the breast lesions. The various features of breast lesions were noted.

Results: Most commonly affected age group was 42±11.69 yrs. In our study out of 560, 180 breasts were classified as BI-RADS 3-5. Calcification was present 42.22% breasts. BI-RADS 4A showed the highest sensitivity (72.8%). BI-RADS 3 and 5 showed 100% positive predictive value (PPV) and BI-RADS 5 had highest accuracy 84.5 among these categories.

Conclusion: High accuracy can be achieved when evaluating breast ultrasound findings for malignancy using the BI-RADS breast ultrasound criteria.

Keywords: BI-RADS, Ultrasound, Breast Lump, Biopsy, Breast cancer.

Introduction

Globally, breast cancer (BC) is the most prevalent cancer that affects women. With an anticipated 2.3 million new cases, or 11.7% of all cancer cases, it will now surpass lung cancer as the most common type of cancer worldwide in 2020 [1]. The most common cancer in the globe as of the end of 2020 was breast cancer, which had been diagnosed in 7.8 million women in the previous five years. Greater than any other type of cancer, breast cancer causes more lost disability-adjusted life years (DALYs) for women worldwide. According to Melina Arnold *et al*., the number of new instances of breast cancer will reach more than 3 million annually by 2040, up by 40%, and the number of fatalities will reach more than 1 million annually, up by 50%. 13.5% of cancer cases and 10.6% of all fatalities from cancer in India were due to breast cancer [2].

In India, patients with breast cancer have a worse chance of survival compared to Western nations because of early age at onset, advanced illness at presentation, a delay in the start of decisive management, and insufficient or fragmented care [3]. Early detection and prompt treatment are the most effective interventions for BC management, according to the World Cancer Report 2020 [4].

A collaboration between radiologists and pathologists seems important in the assessment of the consistency of radiologic and pathological data, in order that the right and appropriate approach is taken into account, given the rising rate of newly diagnosed cases in breast imaging. In this context, the American College of Radiology created the breast imaging reporting and data system (BI-RADS), which uses a uniform structure and nomenclature. The most crucial section of an imaging report is the BI-RADS. In this system, every report must begin with an explanation of the breast's general make-up. The greater number is in support of malignancy among the seven BI-RADS categories, which range from 0 to 6 [5,6].

Recent research have suggested that the BI-RADS method may be helpful in differentiating between malignant and benign breast tumours. Its accuracy rate is still up for debate, and additional data is required to establish it with certainty. Particularly, several researchers have examined the BI-RADS accuracy between ultrasonography and mammography, and some studies have hinted at the same accuracy between these two techniques [7,8].

The purpose of this study was to evaluate the reliability of the classification of breast ultrasound findings based on the Sonographic Breast Imaging-Reporting and Data System (BI-RADS) scoring for malignancy and its correlation with pathological findings.

Materials and Methods

This prospective study was conducted on all female patients who presented to the department of Surgery, Radiodiagnosis and Pathology of Government Medical College and Bangur Hospital, Pali (Rajasthan) for ultrasonography breast from November 2021 to October 2022 with breast lump and willing to undergo ultrasonography and FNAC/biopsy of the breast lesions. Patients less than 10 years old, pregnant women, hemodynamic instable, inability to understand the information about the protocol and/or refusal to consent, with inadequate biopsy material, cases where only biopsy was done without preceding ultrasonography were excluded from study.

USG was performed in all patients with breast lumps using linear and convex probe. Color doppler mode was used to see internal vascularity. The various features including size, shape, echotexture, internal calcification and margin etc. of breast lesions were noted. Patients whose BI-RADS was 3, 4, or 5 underwent CNB. BI-RADS score 3,4 and 5 was defined as follows [9].

1. BI-RADS 3 (probably benign): ≤ 2% malignancy risk
2. BI-RADS 4A (low suspicion): >2% to ≤10% malignancy risk
3. BI-RADS 4B (moderate suspicion): >10% to ≤50% malignancy risk
4. BI-RADS 4C (high suspicion): > 50% to < 95% malignancy risk
5. BI-RADS 5 (probably malignant): ≥ 95% malignancy risk

Standardized data collection forms were used throughout the study and will be filled-in by investigator. It contained three parts. First part was filled at the time of clinical presentation to surgery department by surgeon. Second part was filled by radiologist at the time of ultrasonography and third part was filled by pathologist at time of histo-cytological evaluation. After collecting the data, they were analyzed using SPSS software. The descriptive statistics were used for the data analysis.

Result

In this study total 560 breasts of female patients were examined in one year. On examination out of 560, 180 breasts were classified as BI-RADS 3-5. The age range of the patients was 20–90 years, with a mean age of 42±11.69 years. The range of tumour sizes was 1 to 7cm, with a mean of 2.94 ±1.74 cm. Clinico-pathologic data and sonographic features of female patients are showed in table 1.

Table 1: Clinico-pathologic data and sonographic features of female patients

		No. (n=180)	Percentage %
Echogenicity	Isoechoic	34	18.89
	Heterogeneous	22	12.22
	Hypoechoic	124	68.89
Shape	Oval	32	17.78
	Rounded	66	36.67
	Irregular	82	45.55
Margin	Angular	18	10
	Spiculated	84	46.67
	Circumscribed	22	12.22
	Lobulated	56	31.11
Boundary	Abrupt interface	82	45.56
	Echogenic halo	98	54.44
Calcification	Present	76	42.22
	Absent	104	57.78

In this study all patients agreed for biopsy. The BI-RADS 3 classification was given to 24 of the investigated masses, the BI-RADS 4A to 86, the BI-RADS 4B to 5, the BI-RADS 4C to 14, and the BI-RADS 5 to 51. For each BI-RADS classification, Table 2 shows the computed sensitivity, specificity, accuracy, positive predictive value, and negative predictive value. As was already mentioned, BI-RADS 4A showed the highest sensitivity (72.8%) out of all the BI-RADS

categories. Out of all the BI-RADS categories, the 3 and 5 categories have the highest specificity (100%). Additionally, the highest accuracy was achieved by BI-RADS 5 (84.5%).(Table 2)

Table 2: Diagnostic value of Breast Imaging-Reporting and Data System (BI-RADS) classification.

BI-RADS	Sensitivity (%, 95% CI)	Specificity (%, 95% CI)	Positive predictive value (%, 95% CI)	Negative predictive value (%, 95% CI)	Accuracy (%, 95% CI)
3	27.9	100	100	62.1	72.1
4A	72.8	28.1	28.1	39.1	36.7
4B	24.8	99.4	78	54.8	55.5
4C	34.2	98.2	85.1	56.4	57.4
5	64.6	100	100	75.6	84.5

Conclusion

For the purpose of reporting mammography, the BI-RADS score was initially created in 1993. Since its creation, numerous research have discovered that it can be useful in estimating the likelihood of cancer [10-12]. Breast sonography is now well-established as a useful imaging technique, despite some dispute around its utility in assessing solid breast masses for the likelihood of malignancy, even if mammography is still the most effective way to screen for breast cancer [13,14]. Sonographic appearance may help distinguish between malignant and benign solid breast tumours, according to a number of studies [15-17].

With a sensitivity of 98.4% and an NPV for malignancy of 99.5%, Stavros *et al*. created a categorization system for solid breast tumours [15].

Despite the lexicon's allegedly excellent sensitivity and NPV, Baker *et al*. discovered that interobserver agreement for six of the seven sonographic features was at most modest [18]. The ACR released a sonography lexicon in 2003 in response to the growing use of sonography in clinical settings. The sonographic BI-RADS vocabulary, like its mammographic equivalent, was created with the goal of providing a common language for sonographic reporting and research as well as eliminating ambiguity in sonographic interpretation communication and instruction [19,20].

The sensitivity and specificity of ultrasonography was compared with mammography findings and clinical examination in a study by Shafiee *et al*. According to that study, the sensitivity and specificity of ultrasonography were higher than mammography examination (25.8% and 71.9% vs. 5% and 7.1%). Therefore, mammography was not a reliable diagnostic test in diagnosis of breast cancer [21]. So in this study we evaluated the reliability of the classification of breast ultrasound findings based on the Sonographic Breast Imaging-Reporting and Data System (BI-RADS) scoring for malignancy and its correlation with pathological findings.

According to previous studies BI-RADS 3 referred to masses with regular margin, asymmetric parenchymal densities, and round micro-calcifications. The malignancy risk of BI-RADS 3 is less than 2%, and therefore, most of the specialists recommended a six-month follow-up diagnostic mammography. Regarding BI-RADS 4, the lesions were not classically malignant, however, they were suspicious enough for biopsy. With respect to BI-RADS 5, the lesions had a high malignancy risk and should undergo biopsy. Spiculated masses

and clusters of pleomorphic calcifications were classified in this category [5,22,23].

In our study BI-RADS 3, 4B, 4C and 5 showed high PPV between 78 to 100% but in BI-RADS 4A it was 28.1% which was lower. Specificity was also near to 100% in all BI-RADS category except BI-RADS 4A. Naser Ghaemian *et al* also showed high rates of PPV for BI-RADS 3-5 categories [24].

According to Hong *et al*., the sonographic BI-RADS lexicon features have high positive and negative predictive values for assessing solid masses [25] In this study accuracy of BI-RADS was highest (84.5) in BI-RADS 5 category. In another study it was 80.3 in BI-RADS 5 category [24].

The diagnostic precision of imaging techniques can be influenced by a number of circumstances. Age, breast surgery history, lesion characteristics, menstrual/menopausal status, and patient and technician collaboration during the imaging process are some factors that are related to the patients. Other factors that are related to the health system are hardware (such as the presence of a new, standardised imaging device, like vacuum-assisted breast biopsy technology), as well as human resources (such as the presence of an experienced radiologist) [26-28]. The variations in the outcomes between the numerous research can be attributed to these reasons.

Conclusion

Ultrasonography is a tool that can screen for, diagnose, and track breast disorders before and after treatment. It can also help detect breast cancer at an incredibly early stage when it has not yet been officially identified. The classification BI-RADS using ultrasound demonstrated a respectable positive predictive value. The use of non-invasive diagnostic tools can help in breast lesion diagnosis overall because they are accessible, affordable, and easy to use.

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