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COMPARISON OF BIRADS LEXICON TO BREAST BIOPSY FINDINGS IN LOW RESOURCE COUNTRIES

Shailaja Prabhala, Annapurna Srirambhatla, Sujatha Pasula

Breast cancer is the most common malignancy in women worldwide and early detection is of utmost importance. In developed countries, mandatory mammographic screening programs help in early detection, whereas, in developing countries cancer is often detected at an advanced stage. The BIRADS guidelines permit a standard approach and follow up for breast lesions. Many newer imaging modalities are being available for better diagnosis.

Breast lesions have a varied spectrum and the gold standard for diagnosis of breast cancer is based on histopathological examination of tissue. At times, even on trucut biopsy, it is difficult to categorize the lesion as the tissue studied is limited and some evolving lesions may have overlapping features. As there are limitations to both radiologic and pathologic approaches, the general and accepted way is to combine both modalities to arrive at a diagnosis.

The aim: *The aim of the study was to find out how well the BIRADS radiological findings correlate with histopathological findings on breast biopsies.*

Materials and methods: *A MEDLINE search for articles published in English language, with key words as breast biopsy histopathology and BIRADS was done for the years between 1985 and 2021. In addition, other cross-referenced articles were also searched for relevant data.*

Results: *There is good correlation between BIRADS category 1, 2 and 5 with the findings on core needle biopsy in breast lumps i.e., good correlation is seen at the end of spectrum of breast lesions in totally benign and unequivocally malignant lesions. But this correlation is lacking in the middle of the spectrum i.e., in borderline/intermediate category of BIRADS.*

Conclusion: *The non-suspicious (BIRADS 1/ 2) and highly suspicious (BIRADS 4C/5) compare very well with the histopathologic findings. It is the grey zone i.e., BIRADS 3/4A which has a wide and variable predictive value for breast cancer when compared with histopathology and imaging study alone is insufficient and mandates histopathology in all such cases*

Keywords: *Trucut Biopsy breast, BIRADS, CNB breast, mammography, histopathology breast biopsy, DCIS, atypical ductal hyperplasia, CEUS, FNAC breast, breast cancer*

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1. Introduction

Cancer of the breast is the most common malignancy in women globally. It accounts for 23 % cases of cancer in women in both developed and developing countries [1]. During the past twenty-five years, there has been a substantial increase in breast cancer mortality rate globally, which should be an alarming sign for health policy makers in all countries, especially in the developing countries wherein, marked increase in breast cancer mortality rate has been observed [2].

Worldwide, breast cancer is one of the leading causes of cancer morbidity and mortality. According to GLOBOCAN 2018 report on cancer incidence and mortality, breast cancer was the second most diagnosed malignancy, accounting for more than 11.6 % of all female cancers. It ranked as the fifth commonest cause of cancer deaths [3].

Breast cancer progresses through various stages like stage 0 with excellent prognosis wherein it is a carcinoma in situ; through stage 4 with distant metastasis and poor prognosis. At the time of diagnosis, about 64 % patients have local stage breast cancer, 27 % have regional stage and 6 % have distant/metastatic spread. [4] Hence, it is very essential to diagnose this cancer in its earliest stages, treat adequately and prevent metastasis as far as possible. Here comes the search for better diagnostic modalities which can pick up the cancer in its earliest stages.

2. Materials and methods

A MEDLINE search for articles published in English language, with key words as breast biopsy histopathology and BIRADS was done for the years between 1985 and 2021. In addition, other cross-referenced articles were also searched for relevant data.

3. Results and discussion

Early detection of breast cancer has become easy after the introduction of mammography as a screening tool and especially after the introduction of BIRADS

classification, guidelines for follow-up of patients based on mammographic findings have streamlined the further workup that is required. Many new imaging modalities are available in the present day, but they all have limitations due to various factors such as ease of availability, cost, expertise for interpreting the data, feasibility, duration for reporting, etc. Despite the advances in imaging, it is difficult to predict the nature of borderline category BIRADS breast lesion and requires histopathological examination of the trucut specimen.

Mammography is a screening test used to detect breast cancers/lesions. In 1913, Albert Salomon, a German surgeon, published his monograph about the utility of radiological studies of mastectomy specimens, demonstrating the possibility of correlating radiological, macro and microscopic anatomy of breast diseases with differentiation between benign and malignant entities. [5] In 1965, Charles Gross, from Strasbourg, France, developed the first unit dedicated to mammography [5].

The BIRADS lexicon was introduced in 1993 to standardize the reporting of mammographic findings. The first digital equipment was approved by FDA in 2000. The equipment for direct digital mammographic image acquisition is composed of an x-ray generator like that of the conventional system. The great innovation consists in the introduction of a computerized control unit (with automated quality control) and the replacement of the screen/film system by a highly differentiated electronic detector that is effective in x-ray beam absorption.

Currently, several digital mammography machines, computer-aided diagnosis (CAD) systems and breast tomosynthesis (the latter approved in 2011 by FDA) are available. So, over the last 100 years, mammography and screening for breast cancer have come a long way with contributions from numerous workers [5].

Mammography screening reduces breast-cancer related death and variable relative reductions of 15 to 25 % have been reported in randomized trials [6].

Many countries have breast cancer screening programs aimed at detecting early disease in asymptomatic women. The diagnostic process involves the "Triple test" consisting of clinical examination, mammography and fine needle aspiration cytology (FNAC) or biopsy [7].

As mammography became more acceptable, the incidence rates of DCIS and invasive breast cancer rose rapidly during the 1980s and 1990s particularly among women 50 years of age and older, largely due to increases in the prevalence of mammography screening, which increased from 29 % in 1987 to 70 % in 2000 [8]. For many years mammography was the only breast imaging examination available and it reduced the cancer mortality, with a population-based sensitivity of 75 % to 80 % [9].

Detection of breast cancer by mammography has an overall sensitivity of 75 % to 85 % but when the mammary tissue is dense the sensitivity decreases sharply [10].

In the present day, screen film mammography is almost entirely replaced by full-field mammography (FFDM). The latter has higher imaging quality and higher contrast resolution with faster processing of images and reduced false positive rate thereby increasing the cancer detection rates and increased effectiveness of breast cancer screening programs [11]. The newer modalities like computer-aided detection (CAD) systems specifically search digitized mammographic images for density, mass, calcifications etc, and alert the radiologist for possible presence of cancer [12] Digital Breast Tomosynthesis (DBT) is a three-dimensional mammography. It is advanced form of breast imaging where multiple images of the breast from different angles are captured and reconstructed ("synthesized") into a three-dimensional image set. It is similar to computed tomography (CT) imaging in which a series of thin "slices" are assembled together to create a 3-D reconstruction of the body. The American College of Radiology (ACR) and the National Comprehensive Cancer Network (NCCN) recommend annual screening mammography for women beginning at age 40 and even earlier for those who are at increased risk [13].

Contrast-enhanced magnetic resonance imaging (CE-MRI) is used as a gold standard method for diagnosing breast cancer based on the angiogenesis of the tumor. It is recommended for women at high risk, but it has low specificity, takes more time, is not easily available and costs almost ten times more than mammography [14–16].

Nowadays, contrast-enhanced spectral mammography (CESM) is available which gives information on anatomic and functional features of the lesion similar to MRI [16].

CESM is less costly, easier to perform and has shorter examination time as compared to MRI [17]. CESM is the method of choice in those having contraindications for MRI like pacemakers, aneurysm clips, metal implants or severe claustrophobia [18].

The Breast Imaging Report and Data System (BI-RADS) of the American College of Radiology (ACR) is today largely used in most of the countries where breast cancer screening is implemented. It is a tool defined to reduce variability between radiologists when creating the reports in mammography, ultrasonography or MRI [19].

The BIRADS lexicon was first developed in 1993 for reporting mammography. It is helpful to physicians in predicting the likelihood of cancer. Although mammography is recognized as the best method of screening for breast cancer, breast sonography is now well established as valuable adjunctive imaging technique [20].

BIRADS (**Breast Imaging-Reporting and Data System**) is 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. It applies to mammography, ultrasound, and MRI [21].

BIRADS classification

Breast imaging studies are assigned one of seven assessment categories:

BI-RADS 0: Incomplete. Needs additional imaging evaluation (additional mammographic views or ultrasound) and/or for mammography, obtaining previous images not available at the time of reading

BI-RADS 1: Negative. Symmetrical and no masses, architectural distortion, or suspicious calcifications.

BI-RADS 2: Benign. 0 % probability of malignancy

BI-RADS 3: Probably benign. <2 % probability of malignancy and short interval follow-up suggested (usually of 6 months)

BI-RADS 4: Suspicious for malignancy. 2–94 % probability of malignancy

for mammography and ultrasound, these can be further divided:

BI–RADS 4A: Low suspicion for malignancy (2–9 %)

BI–RADS 4B: Moderate suspicion for malignancy (10–49 %)

BI–RADS 4C: High suspicion for malignancy (50–94 %)

Biopsy should be considered.

BI–RADS 5: Highly suggestive of malignancy. >95 % probability of malignancy and appropriate action should be taken.

BI–RADS 6: Known biopsy–proven malignancy.

When there are multiple findings, the BI-RADS category for the exam is assigned the highest category. Most screening mammograms fall into BI-RADS 1 or 2 or 4. Screening mammograms with suspicious findings should generally be assigned BI-RADS 0 to indicate a call-back for diagnostic evaluation, meaning additional views to confirm and further evaluate the finding.

BI-RADS provides standardized terminology to describe breast imaging findings. If the pathological results do not adequately explain the imaging features, then the two are considered discordant.

Mammography is the baseline imaging method for the detection of breast cancer in women aged > >40 years. Invasive breast cancer is most seen on mammography as an ill-defined or spiculated mass, with or without associated calcifications, but could also present as architectural distortion, focal asymmetric density, or calcifications alone. Ultrasound could be added to improve sensitivity in women with mammographically dense breasts. Ultrasound alone is the method of choice for imaging the breast in women aged < 40 years. Magnetic resonance imaging (MRI) is the most sensitive method for detecting breast cancer, but its use is confined to screening women at very high risk (e.g., carriers of mutations in the *BRCA1* or *BRCA2* genes) and local staging of certain breast cancers.

Further assessment and staging. Imaging should always be used to assess both breasts before any treatment is implemented. Mammography and ultrasound are complementary for the pre-treatment assessment of the size, extent and presence of multifocality of breast cancer. Most breast cancers should be diagnosed without the need for surgical biopsy, and imaging guided / ultrasound guided core biopsy / trucut biopsy is the method of choice. Ultrasound is also used routinely to assess the axilla at the time of presentation, with biopsy of any abnormal lymph nodes. MRI has a low specificity, in patients with high breast density, while mammography has low sensitivity in patients with high breast density, whereas, USG has been proven to be useful in such patients [22].

To classify breast lesions to determine the lesions that have a high relative risk of becoming malignant, Page categorised breast lesions based on morphological features into four categories. The first category included non-proliferative lesions (no increased risk) such as florid adenosis, apocrine change, mild epithelial hyperplasia of usual type and duct ectasia. The second category included epithelial proliferative lesions without atypia (1.5–2 times increased risk) such as moderate/florid hyperplasia of usual type or papillomatosis. The third category consists of atypical hyperplastic lesions (4–5 times increased risk) such as ADH and ALH. Finally, the fourth category is lesions considered to be carcinoma in situ and high-risk lesions (8–10 times increased risk), which include DCIS and LCIS. This criterion is still referred to by pathologists to classify breast lesions based on their histology [23].

Mammography is a well-established screening tool in the detection of early breast cancer, but it has low sensitivity for women with dense breasts. Radiologists usually recommend meticulous, regular screening and follow-up for women with dense breasts as the mammography is inaccurate in dense breasts. The breast density of the Indian population is less when compared to the Western population and hence, mammography may prove to be a good tool for screening the Indian population [24, 25].

For BIRADS 3 category a "wait and see" approach is followed which is cost-effective as compared to an immediate biopsy [26]. BI-RADS assessment category 3 (probably benign finding) is associated with a suggested recommendation for short-interval (<1 year, usually 6 months) follow-up. These lesions have an extremely low (<2 %) probability of being malignant [27]. Short-interval follow-up mammography is supported by literature, and it monitors lesions for changes at a more frequent interval than regular screening and is intended to serve as an alternative to invasive procedures, such as biopsy or fine-needle aspiration [27, 28].

BI-RADS 3 gives rise to a variety of actions and reactions. Even though a biopsy is not recommended for BIRADS 3 lesions, patient anxiety and physician insecurity can prompt a biopsy in BIRADS 3 lesions. BIRADS 3 is usually assigned at diagnostic imaging. Then after six months another diagnostic mammogram is done and if the finding is worrisome then a biopsy is performed. If the lesion is stable, then it is again assigned BI-RADS 3 and a bilateral mammogram in 6 months is performed and reassessed. At 12 months from the screening exam the lesion will be either upgraded to BIRADS 4 or 5 or downgraded to BIRADS 2. If it persists at BIRADS 3 then the follow-up interval is increased to one year. Assuming 24 months of stability, the patient can revert to BI-RADS 2 or one can continue as BI-RADS 3 recommending imaging in 1 year assuming no need for biopsy. The timing of follow-up exams is the same for ultrasound and MRI. Compliance with BI-RADS 3 recommendations is imperfect. Even though a biopsy is not recommended for BIRADS 3 lesions, patient anxiety and physician insecurity can prompt a biopsy in BIRADS 3 lesions. There is room for radiologist's discretion and personal experience to justify the BIRADS assessment. Sometimes technical factors may also affect the assessment like asymmetry, distortion due to post-surgical scars etc. So, in the present day, majority of BIRADS 3 assessments are recommended for short interval follow up, but it varies depending on radiologist discretion and patient factors [27]. On ultrasound too, BI-RADS 3 masses typically undergo a 6, 12, and 24-month follow up to determine the continued benign nature of the lesion [29]. Proper and consistent use of the BI-RADS classifi-

cation is important to determine next step in management options for breast masses detected at mammography or ultrasonography.

A biopsy is recommended for BIRADS 4 mammograms. This category has a wide span of probability for malignancy ranging from 2 % to 94 % and has a high rate of unnecessary biopsies. Therefore, the differential diagnosis of benign and malignant BI-RADS 4 breast lesions has become extremely important. Liu et al in their study investigated the diagnostic value of conventional sonography (US), contrast-enhanced ultrasound (CEUS) and shear wave elastography (SWE) for BI-RADS 4 breast lesions and tried to figure out a multi-mode ultrasonic method. They concluded that using US + CEUS + +SWE and US + SWE could significantly improve the diagnostic efficiency and accuracy of US in the diagnosis of BI-RADS 4 breast lesions [30].

Chaitanya and Prabhala et al [31] in their study observed the positive predictive value for BIRADS 4 lesions for malignancy to be 49 %. They concluded that core biopsy is a reliable method to diagnose breast lesions and has high accuracy compared to ultrasound categorization using BIRADS score. Their study concluded that BIRADS 3 and 5 category have high positive and negative predictive value for malignancy and that the positive predictive value for BIRADS 4 lesions is less due to inclusion of a wide spectrum of lesions including inflammatory lesions, breast abscesses, hyperplasias, etc. Eda Elverci et al in their study reported the PPV for BI-RADS 4 lesions as 38.7 % [32]. In another study by Sarangan et al the PPV for BIRADS 4 lesions was 56.25 % [33]. The PPV of BIRADS 4 lesions can be higher if 4A lesions are excluded and only 4B and 4C are considered for correlation with histopathology. The sub categorization of BIRADS 4 is subjective without any definitive diagnostic criteria established for sub categorization. It is solely based on Radiologist/Physician's level of suspicion of malignancy. Objective and clear sub classification rules are needed for BIRADS 4 category to reach higher accuracy.

It has been shown that ADH and DCIS have very similar characteristics histologically. Often it has been difficult to distinguish between ADH and DCIS especially on smaller tissue samples such as those obtained from fine needle aspiration cytology (FNAC) or core needle biopsy (CNB). [34] The clinical recommendation for the definitive management of ADH still remains as EBB despite the improved CNB techniques as the percentage of underestimation of cancer after an ADH diagnosis can carry a risk of over 10 % [34, 35]. ADH and ALH are radiologically difficult to diagnose as they have features like DCIS and LCIS respectively and thus are best diagnosed and managed by excisional breast biopsy (EBB) [36].

Based on the BIRADS category the recommendations must be followed. Whether these recommendations are followed or not is influenced by many factors. Especially in developing countries and low resource settings one may not be able to go for additional radiologic testing such as diagnostic mammography, 3D mammography, CEUS, SWE, MRI, spectral MRI etc. The resources may not be available and / or the patient may not be able to afford, the patient recall may be poor, and they may get lost to follow-up, and/or both the patient and physician may directly prefer a biopsy. Despite the limitations to screening mammography, BIRADS categorization, and to biopsy interpretation, still screening mammography has led to the early diagnosis and investigation of breast cancer lesions. The early implementation of appropriate management of breast cancer has reduced mortality rates by 30 %. Early detection is of paramount importance for breast cancer prevention [37].

The search for newer screening and diagnostic modalities and guidelines continues to overcome breast cancer.

4. Conclusion

Mammography and the BIRADS system are helpful in early detection of breast cancer. The BIRADS recommendations guide the clinician and patient for subsequent course of action. However, it may not be always possible to follow the established recommendations, especially in developing countries with low resource settings.

BIRADS 4 category has a wide span of probability for malignancy ranging from 2 % to 94 % and hence, higher probability of unnecessary biopsies. Objective and clear sub-classification guidelines are needed for BI-RADS 4 category to reach higher accuracy. With all the advances going on in this field we can hope that very soon the gap between BIRADS and breast biopsy will be bridged.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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Shailaja Prabhala*, Additional Professor**,** Department of Pathology and Lab Medicine**,** All India Institute of Medical Sciences**,** Bibinagar, Hyderabad, India, 508126

Annapurna Srirambhatla, Associate Professor**,** Department of Radiodiagnosis, All India Institute of Medical Sciences, Bibinagar, Hyderabad, India, 508126

Sujatha Pasula, Assistant Professor, Department of Biochemistry, Nilofer Hospital/ Osmania Medical College, Hyderabad, Telangana, India, 500004

***Corresponding author:** Shailaja Prabhala, e-mail: shailajaprabhala@yahoo.co.in*