# Histopathological Correlation of Breast Carcinoma with Breast Imaging-Reporting and Data System (BIRAD)-King Fahad Medical City-Riyadh City.

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## Abstract

**Background**: In Saudi Arabia, breast cancer (BC) affects women more than any other type of cancer. Breast lesions are evaluated from three different perspectives (clinical, radiographic, and histopathological) in a process called "triple assessment." The purpose of this study was to determine the accuracy of the Breast Imaging-Reporting and Data System (BI-RADS) Classification by correlation the histopathology results of patients brought to King Fahad Medical City, Riyadh City، Saudi Arabia, for screening or complaining of any breast manifestation like: breast lump, breast pain, or nipple discharge with the BI-RADS System.

**Materials and Methods**: This was a retrospective study done at single facility in 2021 among 360 women underwent radiological examination with BI-RADS categories 3, 4 and 5 followed by histopathological examination.

**Results**: Brest malignancy was significantly higher among women above 50 years, those who had a family history of breast cancer and those who were at menopause ($p<0.05$). The most common malignant breast lesion was invasive ductal carcinoma (70.4%). The PPV for BI-RADS category five lesions malignant was 92.7%, whereas the NPV of BI-RADS Category 3 lesions for malignancy was 78.4%. The sensitivity and specificity for the BIRDS system were found to be 80.25% and 88.03%, respectively.

**Conclusion**: Based on the results of this research, it can be concluded that BIRAD System is an extremely valuable tool, particularly because of its noninvasive nature, which results in less invasive and faster reporting. However, the histopathological study of tissue samples remains the gold standard and should always be re-established prior to any surgical intervention.

**Introduction:**

The prevalence of breast cancer (BC) has been steadily rising, and it is now the most common cancer-related cause of death among women globally [1]. In Saudi Arabia, 17.7% of all cancer cases and 30.9% of cases in females of reproductive age were breast cancer [2]. There were 2463 additional cases of BC reported in Saudi Arabia between January and December of 2017 [3]. Early diagnosis, achieved through a careful clinical examination, staging of the disease based on findings by radiography, and histological investigation at the time of disease presentation, all play a crucial role in determining the type of surgery that will be performed and ensuring a fair prognosis for these patients. histopathological subtyping of breast cancer is necessary for determining prognosis, tailoring therapy, and avoiding unnecessary side effects [4]. Women aged 40–49 have the greatest reported BC incidence rate, with 23% of reported cases occurring in younger age groups [5]. Early detection and staging of the disease before surgery are critical in treatment planning due to the high incidence of advanced BC in the young age group [6].



Currently, most breast cancer cases can be detected with biopsy. However, some reasonable exceptions exist for which surgical excision is necessary because it is either feasible or required [7]. Additionally, due to cultural considerations, an excisional biopsy of the breast lump is the initial biopsy option for apparent breast malignancies in many centers [8]. Mammography and ultrasound imaging, both of which are non-invasive radiological investigations, are two essential tools in early detection, appropriate treatment, and favorable outcome, all of which contribute to an increased survival rate in younger females

[9,10]. The mortality rate from BC was lowered by 22% in women over 50 when ultrasound examination was paired with mammography and by 15% in women aged 49–40 when these two screening methods were used together. It is essential to keep in mind that the sensitivity of mammography is greatly influenced by breast density and that one encounters denser breasts in early and young females [11]. Additionally, the sensitivity of mammography decreases as a result of increased breast density with increasing age, which ranges from 30% to 48% [12]. With an ever-increasing number of newly diagnosed cases in breast imaging, radiologists and pathologists must work together to evaluate the congruence of radiologic and pathological results so that the best possible course of action can be taken. In this context, the American College of Radiology created the Breast Imaging-Reporting and Data System (BI-RADS) as a standardized structure and vocabulary. The BI-RADS score is the most vital piece of information in an imaging report. Under this system, the first thing that each report should do is provide a summary of the breast's overall density [13]. The BI-RADS system has seven different classifications, ranging from 0 to 6, with the higher numbers indicating a greater likelihood of malignancy [13,14].



Mammography and ultrasonography, as well as their respective BI-RADS classifications, have not been the subject of a significant amount of research in terms of their accuracy in distinguishing between cancerous and benign breast masses, particularly in our region. Despite widespread use of the BI-RADS category for ultrasound and mammography reporting by hospitals across the country, there has been a dearth of research assessing its success in Saudi Arabia. In the current research, we compared the findings of our institution's radiological assessment (BI-RADS classifications) to the definitive diagnosis reached through histopathological analysis. We also calculated the examination's sensitivity, specificity, and accuracy. Overall, the purpose of this research is to show that the BI-RADS categories have a high predictive value.

**Materials and Methods**:

After receiving validation from our Institutional Research Ethics Committee, we proceeded with this retrospective investigation that was done at King Fahad Medical City (KFMC), Riyadh city. Patients who completed the radiological examination, either ultrasonography or mammography, with a BIRADS grading system 3,4,5 witch followed by histopathological examination. A sample of 360 during the year 2021 who fulfilled the inclusion criteria were included.



Patients with BI-RADS categories 3,4 and5 were evaluated. Malignancy was assumed for BI-RADS categories 4 and 5, whereas malignancy likelihood was less than 2% for BI-RADS category 3. Patients without simultaneous radiological and histological investigation, those with insufficient clinical data or medical records, and those who belonged to BI-RADS categories 0–2 and 6 were excluded from our analysis. Age, symptoms at presentation, menopausal state, family history and histopathological reports were all reviewed. Depending on the lesion and extent, a mastectomy, a large local excision, stereotactic vacuum biopsy or core breast biopsy was used to diagnose the tissue.

A benign breast lesion may have its histological roots in the epithelium, the stroma, or any other type of mammary tissue. Phyllodes tumors were classified as noncancerous or potentially benign for this investigation because there is very small number consider malignant. In addition, lobular carcinoma in situ (LCIS) and ductal carcinoma in situ (DCIS) is consider precursor lesions of breast cancer, as described in the 8th edition of the AJCC Cancer Staging Manual.

SPSS version 25 was used to analyze the data. Descriptive statistics (mean, median, and standard deviation) and the chi-squared test were used to compare and assess the quantitative data. In addition, standard computations of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), with their confidence intervals at 95%, were carried out.



**Results:**

This analysis included 360 patient specimens of breast biopsies during 2021. The mean age of the patients was found to be 50.5 ± 9.9 years. About 179 (49.7%) had a palpable breast lump, and 147 (40.9%) were incidental findings during screening. Breast pain and nipple discharge were less commonly found. The baseline characteristics showed that 207 (57.5%) were in menopause, and 265 (73.5%) had children. The BI-RADS scoring showed that 209 (58.1%) were Category 5, 140 (38.9%) were Category 4, and only 11 (3.1%) were Category 3. When categorized according to either benign or malignant cases after biopsy, 243 (67.5%) were found to be malignant, and 117 (32.5%) were benign.

| Table 1: Baseline characteristics of the patient |
|---|

| | | Frequency | Percent |
|---|---|---|---|
| Age | Less than 50 | 180 | 50 |
| | 50 and more | 180 | 50 |
| Menopausal status | Pre-menopause | 153 | 42.5 |
| | Menopause | 207 | 57.5 |
| Children | No | 95 | 26.4 |
| | Yes | 265 | 73.6 |
| Mammographic and ultrasound BI-RADS scoring | Category 3 | 11 | 3.1 |
| | Category 4 | 140 | 38.9 |
| | Category 5 | 209 | 58.1 |
| Biopsy | Benign | 117 | 32.5 |
| | Malignant | 243 | 67.5 |



When the benign and malignant cases were distributed based on the age of the patients, it was observed that patients above 50 years had significantly higher malignant cases (74.7%) compared to those less than 50 years old (60.6%),p=0.005. Malignant cases were significantly higher in patients who had a positive family history of BC (79.8%) compared to those who didn't have a family history (63.5%), p=0.004. Patients who were in menopause had significantly higher proportions of malignant cases (74.9%) compared to those in pre-menopause (57.5%), p<0.001. Malignant cases were observed in patients who had children (71.7%), significantly higher others those who didn't have children (56.8%), p=0.005 [Table 2] and that likely because the numpers of women with children more than who don’t have children.

Table 2: Distribution of lesion (histopathology) based on sociodemographic characteristics

| | | | Histopathological report | | P value |
|---|---|---|---|---|---|
| | | | Non cancerous | Cancerous | |
| Age | Less than 50 | N | 71 | 109 | 0.005 |
| | | % | 39.4% | 60.6% | |
| | 50 and more | N | 46 | 134 | |

| | | | | | |
|---|---|---|---|---|---|
| | | % | 25.6% | 74.4% | |
| Family History of BC | No | N | 99 | 172 | 0.004 |
| | | % | 36.5% | 63.5% | |
| | Yes | N | 18 | 71 | |
| | | % | 20.2% | 79.8% | |
| Menopausal status | Pre-menopause | N | 65 | 88 | 0.001 |
| | | % | 42.5% | 57.5% | |
| | Menopause | N | 52 | 155 | |
| | | % | 25.1% | 74.9% | |
| Children | No | N | 42 | 53 | 0.005 |
| | | % | 44.2% | 55.8% | |
| | Yes | N | 75 | 190 | |
| | | % | 28.3% | 71.7% | |



When the benign and malignant cases were categorized based on Mammographic and ultrasound BI-RADS scoring, about 93.3% of the cases of Category 5 and only 32.9% of Category 4 cases were found to be malignant cases and about 72.7% of the Category 3 cases were distributed as benign cases, which showed a statistically significant association (p<0.001). It was observed that two cases, which were BI-RADS Category 3, were found to be malignant cases in histopathological examination. Out of two cases, one case was ductal carcinoma in situ, and one was Invasive ductal carcinoma (IDC). About 14 cases that were benign in the histopathological examination were found to be Category 5 in the BI-RADS classification [Table 3]. They are three benign breast tissue (0.83%), three cases of invasive ductal papilloma (0.83%), three cases of sclerosing adenosis (0.83%), and one case (0.27%) each of benign apocrine metaplasia fibroepithelial lesion , phylloid, radical scar and spindle cell neoplasm (PASH).

Table 3: Categorization of histopathological examination based on BI-RADS classification

| | Histopathological report | | P value |
|---|---|---|---|
| | Non cancerous | Cancerous | |

| | | | | | |
|---|---|---|---|---|---|
| Mammographic and ultrasound BI-RADS scoring | Category 3 | N | 9 | 2 | <0.001 |
| | | % | 81.8% | 18.2% | |
| | Category 4 | N | 94 | 46 | |
| | | % | 67.1% | 32.9% | |
| | Category 5 | N | 14 | 195 | |
| | | % | 6.7% | 93.3% | |

The PPV for BI-RADS category five lesions for malignancy was 92.7%, whereas the NPV of BI-RADS Category 3 lesions for malignancy was 78.4%. Overall, the breast lesion tested by BI-RADS classification has a sensitivity of 80.25%, specificity of 88.03%, PPV of 93.3%, and NPP of 68.2%. The most common malignant breast lesion was invasive ductal carcinoma (70.4%), followed by invasive lobular carcinoma (14.4%) and ductal carcinoma in situ (11.5%). The most common benign breast tissue was fibroepithelial lesion (22.0%), followed by fibroadenoma (19.5%), benign breast tissue (16.9%), and sclerosing adenosis (8.5%).



**Discussion**

According to the BIRADS® system, the malignancy estimate found that 3.1% were Category 3 and 58.1% were Category 5. All BIRADS® reports explaining breast density according to glandular and fatty tissue percentages [15,16]. Any description found during the research are discussed in the report's main body. The mass or lesion are all included ,size, location, consistency, calcifications, and structural changes of a mass or lesion also included. Findings from the study were consistent with those from the literature and provided support for behaviors already implemented in clinical practice. It is more likely that the nodule is benign and can be monitored with just one follow-up if it has ultrasound characteristics like regular borders, defined limits, and no posterior acoustic shadow. But in cases of breast lesions with unfavorable ultrasound characteristics, which indicate a higher probability of diagnosing BC—a more active propaedeutic is required for more effective treatment [17]. Before the BI-RADS scoring system was implemented, clinicians were often confused by the wide range of terms used during radiological reporting [18]. There has been a lot of misinterpretation and discrepancies in further evaluation. The BI-RADS scoring system was developed to standardize radiology reports when analyzing breast imaging, with the primary goal of distinguishing benign from malignant lesions and providing recommendations for subsequent treatment [16].



The BIRADS® Category 5's PPV has been shown to reach 100% in specific studies [19,20]. According to the current study's findings, category 5 and the radiolopathological result agreed with one another studies perfectly [19,20]. Correlating the results of the biopsy with those of a mammogram using the BIRADS® system, a sensitivity of 93.5% and a specificity of 100% were reported by Onur et al. [22].

Since its introduction, numerous studies have proven that the BI-RADS system can assist doctors in predicting whether or not a patient has BC [23,24]. Chest wall lesions and muscular and pleural lesions are some of the other non-breast lesions that may manifest with a palpable breast mass [25]. Duct ectasia and fat necrosis are just two examples of the many inflammatory breast lesions that manifest as palpable masses and lead to diagnostic uncertainty [26]. Especially in younger women with dense breast tissue, a significant number of patients with breast carcinoma may be missed by diagnostic mammography [27]. Ultrasound appears to be more effective than mammography in younger women and those with dense breast tissue [28]. Ultrasound is more reliable in evaluating dense breast tissue and can be used to guide FNA or biopsies [29,30]. FNA will always produce some false negative results [31], which are usually caused by inaccuracies in sampling and interpretation [32]. Cancer risk is not increased by inflammatory breast disease or non-proliferative breast disease [33]. Our findings are consistent with those from a previous study [35] that found the highest incidence of malignant breast lesions in women aged 30–50 years. Due to the additional expense, longer recovery time, and increased risk of complications during wound healing associated with open biopsy of mammary lesions, true biopsy is generally preferred [35].



Breast lesion treatment should take the age of the patient into account. It's important to remember that breast cancer risk rises with age. Non-palpable BIRADS-4 and BIRADS-5 lesions in patients older than 50 years have been recommended for mandatory biopsies [36,37]. Our research found that 63.9% of malignant cases occurred at menopause, while 36.2% occurred before menopause. Patients older than 50 years old had a significantly higher risk of developing malignancy. According to these results, age may be an important factor in BI-RADS classification. In many cases of malignancy, the use of a wire marker for the removal of non-palpable lesions appears to be a useful strategy for early diagnosis.

Limitations of the study

- Data sampling may will give more accurate result if they were larger than we collected.
- Some patients who undergo under the including criteria but they did not come for biopsy.

**Conclusion**

The study confirms the good positive predictive value and negative predictive value for BI-RADS 5 lesions in our institution. The BIRADS system is an excellent malignancy predictor when operated by trained professionals. However, imaging should not be employed independently. it is essential to perform imaging in addition to the standard clinical examination and biopsy.

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