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Assessment of symptomatic BI-RADS 4 in tertiary care hospitals of Bangladesh

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Introduction

Breast carcinoma is the most prevalent cancer in women globally and the second-leading cause of death from cancer. [1] According to the most recent estimates of the cancer burden worldwide, almost 2.26 million incident breast cancer cases are reported in 2020. The age-standardized incidence rate is expected to be 48/100,000 females worldwide, with sub-Saharan Africa having an incidence rate under 30/100,000 and Western Europe and North America having an incidence rate of 70/100,000 females.[2] The two most prevalent risk factors are advancing age and female gender. Around 10% of breast cancers are caused by genetic abnormalities of BRCA-1 and BRCA-2.[3] Such carriers have a 3% higher chance of developing breast cancer before age 30, and their lifetime risk rises to 50–80% by the time they are 70 years old.[4] A history of ductal carcinoma *in situ*, obesity, a first child at a young age or nulliparity, early menarche, late menopause, and the use of postmenopausal hormone treatment are additional risk factors that have been reported. Palpable breast mass (in around 30% of patients), dimpling, an orange-peel appearance, blistering, excoriations, sanguineous nipple discharge, and nipple retraction are significant clinical signs of breast cancer.[3]

Early detection of breast cancer improves patient survival and decreases treatment costs. The American College of Radiology (ACR) first suggested the BI-RADS categorization system in 1986; the first report was published in 1993.[5] Breast Imaging Reporting and Data System (BI-RADS) is a standardized system of reporting breast disease found during breast imaging (mammography, ultrasound, and MRI), which is divided into seven categories, from category 0 to category 6.[6] "A diagnosis that is incomplete and requires additional imaging or examinations is referred to as BI-RADS 0. No lesions or unfavorable results are in BI-RADS 1, BI-RADS 2 is characterized as a benign tumor without alarming features. BI-RADS 3 is described as potentially benign with a less than 2% risk of being cancerous. BI-RADS 4 is a suspicious lesion with a 2% to 95% likelihood of being malignant and warrants biopsy. BI-RADS 5 is characterized as having a greater than 95% likelihood of being malignant. BI-RADS 6 is a pathologically confirmed malignant lesion.[7] In addition, there are three subcategories of BI-RADS 4: 4a with low suspicion of malignancy (>2 to ≤10%), 4b with moderate suspicion (>10 to ≤50%), and 4c with strong suspicion (>50 to <95%). To confirm the diagnosis, a range of histopathological correlations are often evaluated using the BI-RADS 4.[8] A relatively small number of studies in the scientific literature have assessed the positive predictive values and pathological consequences of the 4a, 4b, and 4c subcategories.[6] According to one study, most BI-RADS 4 lesions revealed fibrocystic modification on histological evaluation followed by ductal carcinoma *in situ*.[8] To our best knowledge, very few studies about the diagnostic evaluation of BI-RADS 4 lesions exist. Therefore, we aimed to conduct a retrospective cohort study to assess the symptomatic BI-RADS 4 lesion in the tertiary care center of Bangladesh.

Methodology

This is a multicentric retrospective study. The data were collected from Bangabandhu Sheikh Mujib Medical University (BSMMU), Bangladesh Institute of Research and Rehabilitation for Diabetes, Endocrine and Metabolic Disorder (BIRDEM), and Dhaka Medical College and Hospital (DMCH) from March 2015 to June 2019.

Inclusion Criteria: All female patients who were categorized as BI-RADS 4 underwent intervention and had concomitant histopathological results from March 2015 to June 2019. Agreement of BI-RADS 4 lesions was performed by three independent different radiologists each from three centers. Histopathology was either done by ultrasound-guided fine needle aspiration (FNA), core needle biopsy (CNB), or surgical excision as per the hospital and patient-physician agreement protocol.

Exclusion criteria: Those patients who have lost follow-up, BI-RADS categorization disagreement among radiologists, those patients who have received prior treatment, poor image quality, or no true lesion were excluded from the study. (Figure 1)

All female patients who had symptomatic breast mass on self-breast examination (SBE) initially presented to a primary care physician. After relevant clinical examination followed by a radiological examination (mammogram and/or ultrasound) was performed for all the patients as per the national women's health guidelines. The findings on mammograms and/or ultrasound were correlated by three independent radiologists each from one center for unanimous agreement on BI-RADS 4. As per hospital guidelines, FNA was performed for those patients with lesion size <2.0 cm, and core needle

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biopsies were performed for mass lesion size ≥2.0cm. Excisional biopsy was performed for ≥1.0 cm depending on the patient-physician agreement.

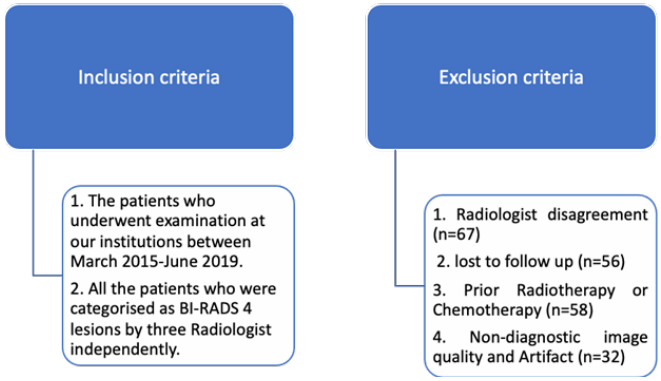


Figure 1 Inclusion and exclusion criteria for BI-RADS 4 lesions.

Data collection and analysis: A total of 764 data was collected. Out of these only 551 data meeting the inclusion criteria for BI-RADS 4 were included in this study. The demographic information like the patient's age, laterality of palpable mass, size, and position of mass from the nipple were collected in Microsoft Excel. The imaging methods used were either mammograms and/or ultrasound. Histopathological findings were followed up. Collected data was entered and analyzed through SPSS version 21.

Result

Out of 764 female patients, 551 patients were included in this study as true BI-RADS 4. 213 were excluded from the study due to radiologist disagreement (67 patients), loss to follow-up visit (56 patients), prior treatment either radiotherapy or chemotherapy (58 patients), non-diagnostic image quality and/ or artifact (32 patients). Of the total 551 included patients, malignant cases 39% (215 patients) were found to be malignant and 61% (336 patients) revealed nonmalignant findings which includes benign, inflammatory, or granulomatous lesions. (Figure 2) (Graph 1) (Table 1)

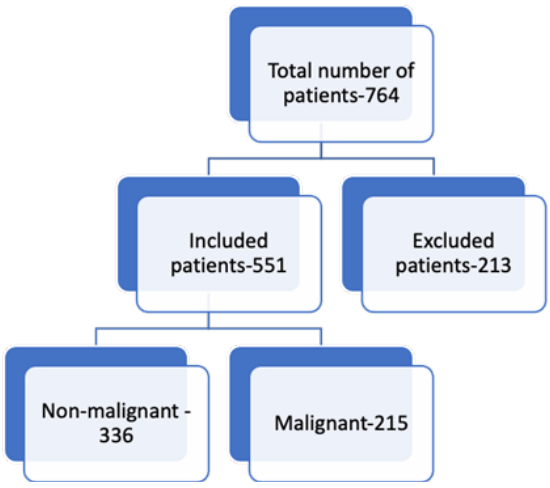
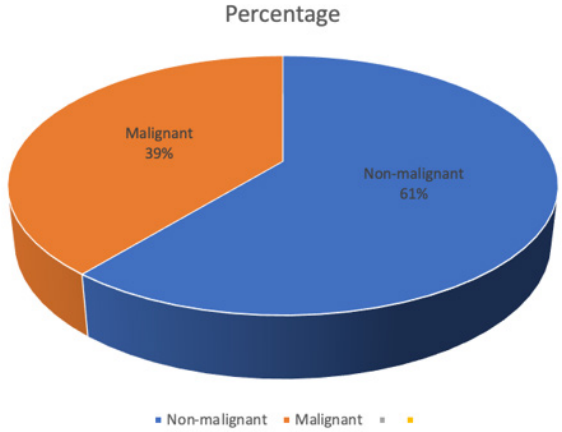


Figure 2 Inclusion and exclusion number for BI-RADS 4 lesions.

According to the table shown above the most common non-malignant lesion was fibroadenoma seen in 103 cases (18.7%), followed by a fibrocystic change in 89 cases (16.2%), ductal hyperplasia in 57 cases (10.3%), Intraductal papilloma in 22 cases (3.9%), Granulation tissue in 12 cases (2.2%), Sclerosing adenosis in 10 cases (1.8%), and least number was fat necrosis in 8 cases (1.5%). Similarly, the most common malignant lesions were Ductal carcinoma *in situ* in 125 cases (22.7%) followed by invasive carcinoma in 45 cases (8.2%), lobular carcinoma in 16 cases (2.9%), tubular carcinoma in 14 cases (2.5%), medullary carcinoma in 7 cases (1.3%), invasive mixed carcinoma in 6 cases (1.1%) and metastasis in 2 cases (0.3%). (Table 2)



Graph 1 Pie chart for BI-RADS 4 lesions showing malignant vs non-malignant.

Table 1 Histopathology results of BI-RADS 4 lesions

Non-malignant lesions	Number of cases	Percentage (%)
Fibroadenoma	103	18.7
Fibrocystic change	89	16.2
Ductal hyperplasia	57	10.3
Intraductal papilloma	22	3.9
Granulation tissue	12	2.2
Sclerosing adenosis	10	1.8
Fat necrosis	8	1.5
Unclassified	35	6.4
Total	336	61%

Malignant lesions	Number of cases	Percentage (%)
Ductal carcinoma *in situ*	125	22.7
Invasive ductal carcinoma	45	8.2
Lobular carcinoma	16	2.9
Tubular carcinoma	14	2.5
Medullary carcinoma	7	1.3
Invasive mixed carcinoma	6	1.1
Metastasis	2	0.3
Total	215	39%

Table 2 Laterality for BI-RADS 4 lesions

Laterality of breast	Number of cases	Percentage (%)
Left side	408	74.1
Right side	120	21.8
Bilateral	23	4.1
Total	551	100.0

As per data, palpable breast mass was predominant on the upper outer quadrant of either breast or predominantly lateralized to the left. Of the 551 patients who presented with palpable breast mass, left-side breast mass was found in 408 patients (74.1%), Right side breast mass in 120 patients (21.8%), and bilateral breast mass in 22 patients (4.1%).

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Discussion

This is a multicentric retrospective study performed from the data collected from three different institutions- Bangabandhu Sheikh Mujib Medical University (BSMMU), Bangladesh Institute of Research and Rehabilitation for Diabetes, Endocrine and Metabolic Disorder (BIRDEM), and Dhaka Medical College and Hospital between March 2015- June 2019 in the age group of women ranging from 30-60 years. The main aim of our study was to access the symptomatic BI-RADS 4 lesion in the tertiary care center in Bangladesh. The BI-RADS 4 includes all the reports that fall within Category 3 (>2% risk of malignancy) and Category 5 (95% risk of malignancy) required for tissue diagnosis either by biopsy or fine needle aspiration.[9] One of the studies stated that BI-RDAS Category 4 lesions are yet considered for biopsy even though the lesion does not fulfill the criteria of malignancy.[10] However, most of the lesions are non-malignant.[11]

Our study resonates with this. Out of 551 included cases, 336 patients were found to be nonmalignant comprising 61%, fibroadenoma being the most common in 103 cases (18.7%), followed by fibrocystic change in 89 cases (16.2%), and the least common was fat necrosis in 8 cases (1.5%). 215 patients were found to be malignant comprising 39%. The most common malignant lesion was Ductal carcinoma *in situ* in 125 cases (22.7%) followed by invasive carcinoma in 45 cases (8.2%), and the least common was metastasis in 2 cases (0.3%).

The palpable breast mass was more predominant on the upper outer quadrant of either breast than on the left breast (74.1%) in comparison to the right side (21.8%). There have been many hypothesized causes, like more substantial trauma to the left breast, nursing habits (most women are right-handed and typically breastfeed on the right side), and larger size and density of the left breast. Moreover, it is assumed that it is easier to investigate and find tumors on the left breast for a right-handed person.[13] It has been also proposed that this might be due to the outcome of increased cell-mediated immunological activity on the left side of the body. A Lebanese study conducted in 2019 stated that left-sided breast tumors are more likely to have HER2 overexpression, estrogen, and progesterone positive.[14] However, the relative increase in the incidence of left breast tumors compared to the right side is still unclear.[13] Some non-malignant lesions like granular cell tumors, sclerosing adenosis, post-surgical scar, fat necrosis, mastitis, and sarcoidosis having spiculated margin might resemble malignant imaging. Nearly 4.0 to 30.9 % of the lesions on ultrasound-guided biopsy are found to be cancerous following exploratory surgical excision.[6] The incidence of breast cancer has increased globally due to early screening, advanced technology, and patient awareness. Consequently, this might result in patient anxiety and high medical expenses. Therefore, a non-invasive diagnostic method should be implemented to reduce the number of biopsies.[12]

Merits and Limitations

The main strength of our study is that this is a multicentric study with three independent radiologist agreements on BI-RADS 4 lesions, one from each center. The sample size was moderately adequate. A few limitations of this study include patients aged between 30-60 years. The duration of the study was limited to 4 years. Despite this limitation, our study has contributed an essential role in expanding knowledge about the symptomatic assessment of BI-RADS 4 lesions. This is somehow a limited study for BIRDS 4 lesions in multicenter tertiary hospitals in a country. Further subcategorization into 4a, 4b, and 4c was not done radiologically. Therefore, more extensive research should be conducted regarding this including multinational scenarios and with further sub-categorization.

Acknowledgments

None.

Conflicts of interest

The authors declare no competing interests.

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