

## RESEARCH ARTICLE

Editorial Process: Submission:31/10/2025 Acceptance:05/10/2026 Published:24/10/2026

# Beyond the Guidelines: Evaluating BI-RADS 3 Lesions in a High-Suspicion Breast Cancer Population: Outcomes and Clinical Implications

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### Abstract

**Objective:** BI-RADS category 3 lesions are typically benign (<2% malignancy risk), managed with follow-up imaging, but their upgrade to BI-RADS 4 may indicate malignancy, particularly in high-risk patients. This study evaluates malignancy risk and predictors among BI-RADS 3 lesions upgraded to BI-RADS 4 in a cohort with a high prevalence of breast cancer history. **Methods:** We retrospectively analyzed 352 patients undergoing breast ultrasound from June 2021 to June 2023, with 123 categorized as BI-RADS 3. Of these, 17 patients (18 lesions) were upgraded to BI-RADS 4 and biopsied. Data included age, prior breast cancer history (100/123, 81.3%), lesion characteristics (size, number, morphology), and histopathology. Descriptive statistics, binomial tests, Fisher's exact tests, and logistic regression were used to assess upgrade rates, malignancy rates, and predictors, with significance at  $p=0.05$ . **Result:** The upgrade rate was 13.8% (17/123; 95% CI: 8.5–21.0%), significantly exceeding the ACR's <2% benchmark ( $p=0.05$ ). Among upgraded lesions, 11.1% (2/18; 95% CI: 1.4–34.7%) were malignant (recurrent breast cancer, lymphomatous lymph node), also surpassing the <2% benchmark ( $p=0.05$ ). Benign outcomes mainly included stromal fibrosis (38.9%) followed by benign lymphadenopathy (27.8%), and fibroadenoma (22.2%). Lesion size (OR=1.15 per mm,  $p=0.05$ ) and multiple lesions (OR=3.2,  $p=0.05$ ) predicted malignancy, while age, cancer history, and morphology were not significant ( $p>0.05$ ). **Conclusion:** The high upgrade and malignancy rates in this high-risk cohort suggest that BI-RADS 3 lesions with larger size or multiple foci, particularly in breast cancer survivors, may warrant earlier biopsy to detect malignancy, thereby emphasizing the need for refined surveillance criteria.

**Keywords:** Breast cancer, BIRADS, stromal fibrosis, fat necrosis, recurrence

*Asian Pac J Cancer Prev*, 27 (10), 3637-3643

### Introduction

Breast Imaging Reporting and Data System (BI-RADS) is a globally accepted method of standardizing breast imaging findings to facilitate clear communications and uniform management [1]. BI-RADS 3 denotes lesions as “probably benign,” with less than 2% risk of being malignant [2]. These lesions, such as simple cysts, fibroadenomas, focal asymmetries, and post-treatment changes, e.g. fat necrosis, typically merit short-term follow-up as opposed to immediate biopsy; it is anticipated that they will either resolve or remain stable [3, 4].

The appropriateness of BIRADS 3 guidelines in high-risk populations, including breast cancer survivors, is unclear. In oncologic patients, post-treatment imaging frequently demonstrates several post-operative changes, radiation-induced fibrosis, or fat necrosis, which might

simulate or disguise a malignancy [5]. This may lower the threshold for upgrading BI-RADS 3 lesions to BI-RADS 4, prompting biopsies due to heightened clinical suspicion. Such variations could result in higher upgrade rates and more benign biopsies, raising questions about the appropriateness of standard follow-up protocols [6].

With the increasing reliance on ultrasound for breast cancer screening [7], especially in women with dense breast tissue, the detection of BI-RADS 3 lesions has become more common. In screening cohorts, BI-RADS 3 lesions may constitute roughly 15% of findings; one large cohort study found a 14.6% detection rate among over 12,000 women undergoing supplemental ultrasound following mammography [8]. Additionally, expert guidance highlights that women with dense breasts which makes them up to 45% of the female population, have lower mammographic sensitivity, leading to more

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ultrasound-detected lesions in this subgroup [9-11]. While most BI-RADS 3 lesions remain stable or regress, a subset shows interval growth, warranting further evaluation [12]. These findings raise important questions about the optimal management of BI-RADS 3 lesions, particularly in high-risk populations.

Research has shown that even in lesions initially categorized as probably benign, certain imaging features such as morphological change or size increment may be associated with a higher likelihood of malignancy [13, 14]. In one large-scale study evaluating over 12,000 BI-RADS 3 lesions, the malignancy rate was 4.9% among lesions that demonstrated growth, and notably higher (16.8%) in those showing morphological changes during follow-up [15]. This suggests that current classification thresholds may underestimate malignancy risk in selected subgroups such as cancer survivors where the threshold for suspicion is inherently lower [16].

Furthermore, RSNA-based read-out indicates potential difficulties of classifying BI-RADS 3 categories in oncologic patients [17]. Factors such as post-treatment alteration, fat necrosis [18] and developing calcifications need to be cautiously interpreted. In these instances, the use of clinical judgment in combination with BI-RADS descriptors to help in decision making is recommended by radiologists. The fifth edition of the BI-RADS lexicon permits use of BI-RADS 3 in atypical situations if the radiologist's experience supports short-term follow-up rather than biopsy, particularly in the presence of prior surgery or treatment-related changes [19]. Thus, understanding lesion behavior in high-risk cohorts is essential to prevent both missed cancers and unnecessary interventions.

The American College of Radiology (ACR) expects an upgrade rate of less than 2% for BI-RADS 3 lesions [1], a benchmark derived from general population studies. In a post-treatment setting at a dedicated cancer hospital, upgrade rates may be higher due to clinical caution, imaging complexities, and patient history. Aim of this study was to evaluate the compliance of BI-RADS 3 lesion classification with ACR guidelines at our institution and assess whether current follow-up recommendations suit a population with elevated malignancy risk [20].

## Materials and Methods

This was a retrospective observational study conducted at the Department of Radiology, Karachi Diagnostic Centre, a branch of Shaikat Khanum Memorial Cancer Hospital & Research Centre. Participants included all cases that were classified as BI-RADS category 3 on ultrasound and followed between Jun 1, 2021, and Jun 30, 2023, with two follow-ups in accordance with ACR BI-RADS lexicon (2013). Aplio 300 (Canon Toshiba) system was used for the US examination by one of the two reporting radiologists, one with 22 years of experience, and another with seven years of experience.

### Study Population

Of 352 breast ultrasound examinations, 123 patients were assigned BI-RADS 3 and followed for two years.

Among these, 100 patients had a history of breast cancer and were on surveillance imaging, while 23 were non-cancerous, presenting with breast lumps or mastalgia (Figure 1). One patient with Hodgkin lymphoma was under follow-up. Patients lost to follow-up (n=18) were excluded.

### Data Collection

Data were extracted from the Hospital Information System (HIS) and Radiology Information System (RIS) after Institutional Review Board (IRB) approval. Recorded parameters included demographic details (age, cancer history), BI-RADS 3 lesion characteristics (size, morphology, location), follow-up outcomes (downgrade to BI-RADS 2, persistence as BI-RADS 3, or upgrade to BI-RADS 4), and histopathological findings for biopsied cases.

### Statistical Analysis

Descriptive statistics (means, standard deviations, frequencies, 95% CIs) summarized characteristics. Univariate tests included t-tests (age, lesion size) and Fisher's exact test (categorical variables) to compare malignant and benign lesions. A binomial test compared the malignancy rate to the ACR's <2% benchmark. Logistic regression modeled malignancy using lesion size and number of lesions, selected based on univariate significance, to avoid overfitting (n=18). Significance was set at  $p < 0.05$ .

## Results

A total of 352 breast ultrasounds were performed from June 1, 2021, to June 30, 2023. 123 patients were classified as BI-RADS 3 and followed for two years. The average age was  $47.1 \pm 10.7$  years. These patients were divided into Group A and B. Group A had 100 (81.3%) patients with positive history of breast cancer and group B had 23 (18.7%) patients without any other malignant disease (Figure 1).

A BI-RADS 4-upgrade due to enlargement of size, lymphadenopathy, or new inhomogeneous areas or masses occurred in 17 patients (13.8%; 95% CI: 8.2 n- 21.3%). The binomial test showed that this rate of upgrade was significantly higher than the ACR <2% cut-off for lesions BI-RADS 3 ( $p < 0.001$ ), as expected for a high-risk case. Among patients from group-A (n=15 patients, 15 lesions among the upgraded group), 1 lesion (6.7%) was malignant, compared to 1 lesion (33.3%) in the group B patients (n=2 patients, 3 lesions). (Figure 2) Fisher's exact

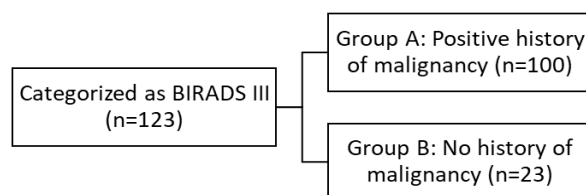


Figure 1. Categorization of BIRADS III Lesions: With and without history of malignancy (n=123).

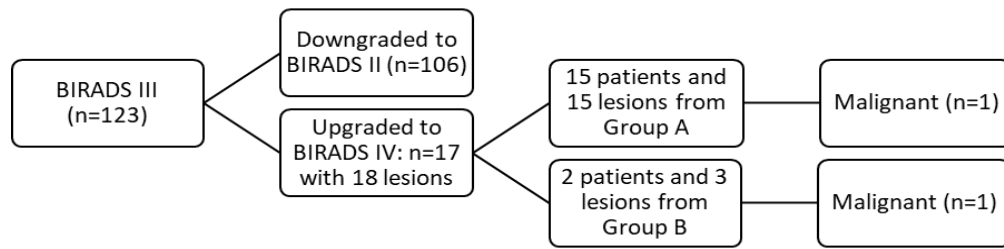


Figure 2: BIRADS III Lesion Reclassification and Malignancy Outcomes: Downgrade to BIRADS II vs Upgrade to BIRADS IV.

test showed no significant difference in malignancy rates between groups ( $p \approx 0.33$ ), suggesting that prior cancer history may not be the primary driver of malignancy in upgraded lesions.

The outcomes of 18 biopsied lesions that were upgraded showed stromal fibrosis in 38.9%, benign lymphadenopathy in 27.8%, fibroadenomas in 22.2%, recurrent breast cancer in 5.6%, and lymphomatous lymph node in 5.6%. Out of total 123 BI-RADS 3 patients, 106 lesions were downgraded to BI-RADS 2. One of the cases from such lesions in Figure 3 shows an area of architectural distortion with dystrophic calcifications

in the left breast at the site of surgery on mammogram (Figure 3a). On ultrasound, it appears to be an ill-defined soft tissue which progressed in size within 2 months (Figure 3b&c). MRI was performed with suspicion of recurrence showing fat signal intensity lesion (Figure 3d-g) and report was finalized with diagnosis of fat necrosis.

Figure 4 shows case of a patient who after 2 years of breast conservation surgery (BCS) developed increased parenchymal density with architectural distortion on follow up mammogram in upper outer quadrant of left breast at the surgical site (Figure 4a&b). On ultrasound showed an ill-defined hypoechoic lesion at 2:00

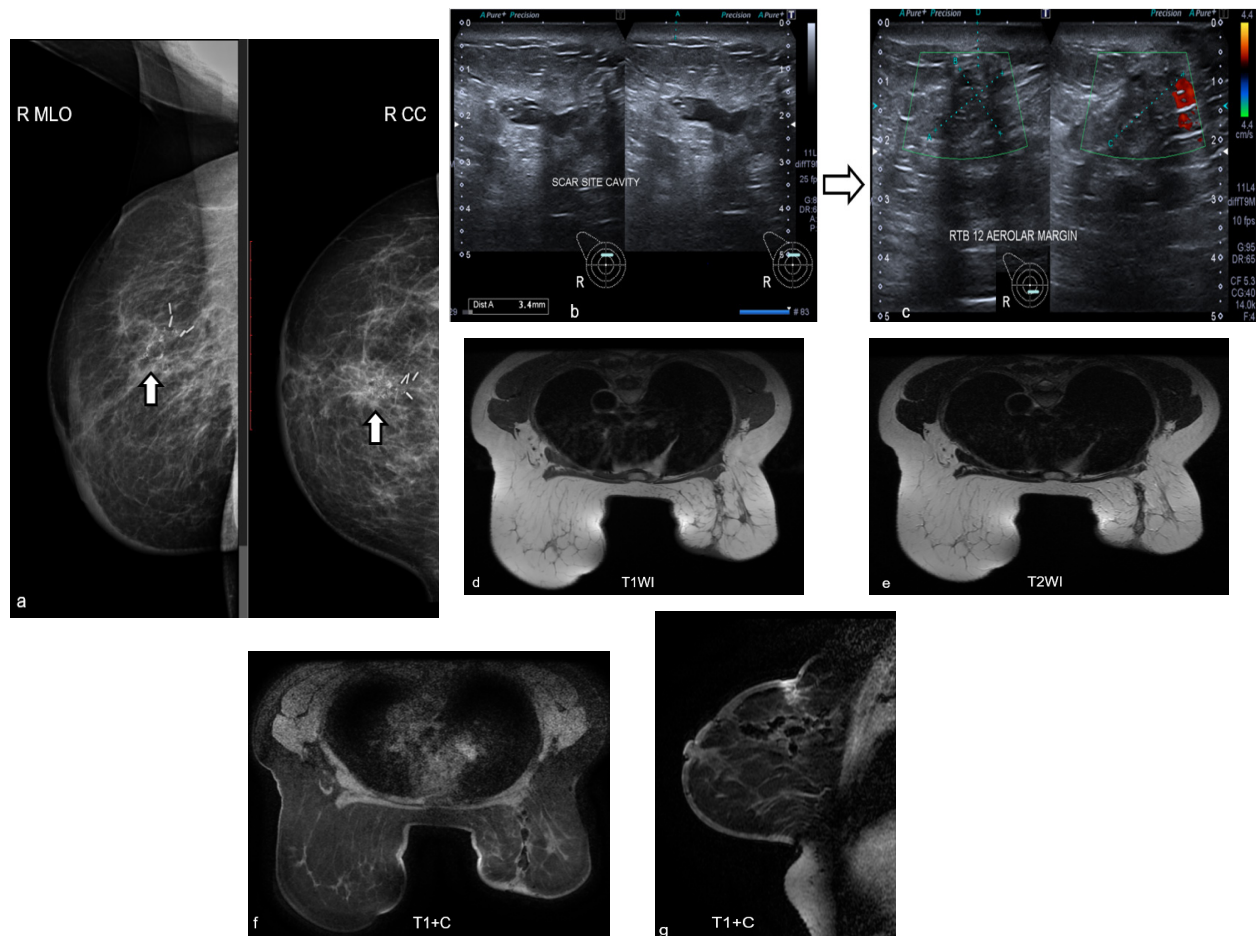


Figure 3. Right Breast MRI and Ultrasound (Gray Scale and Doppler) Image Showing Fat Necrosis. a-g: A patient with left breast conservation surgery shows an area of architectural distortion with dystrophic calcifications on mammogram at the site of surgery (a, white arrow). On ultrasound, an ill-defined hypoechoic soft tissue with cystic foci without definite vascularity increased in size in span of 2 months (b&c). On MRI, T1 and T2 weighted images demonstrate hyperintense lesion along the scar site (d&e) showing fat suppression without enhancement of T1 fat sat post contrast sequences (f&g).

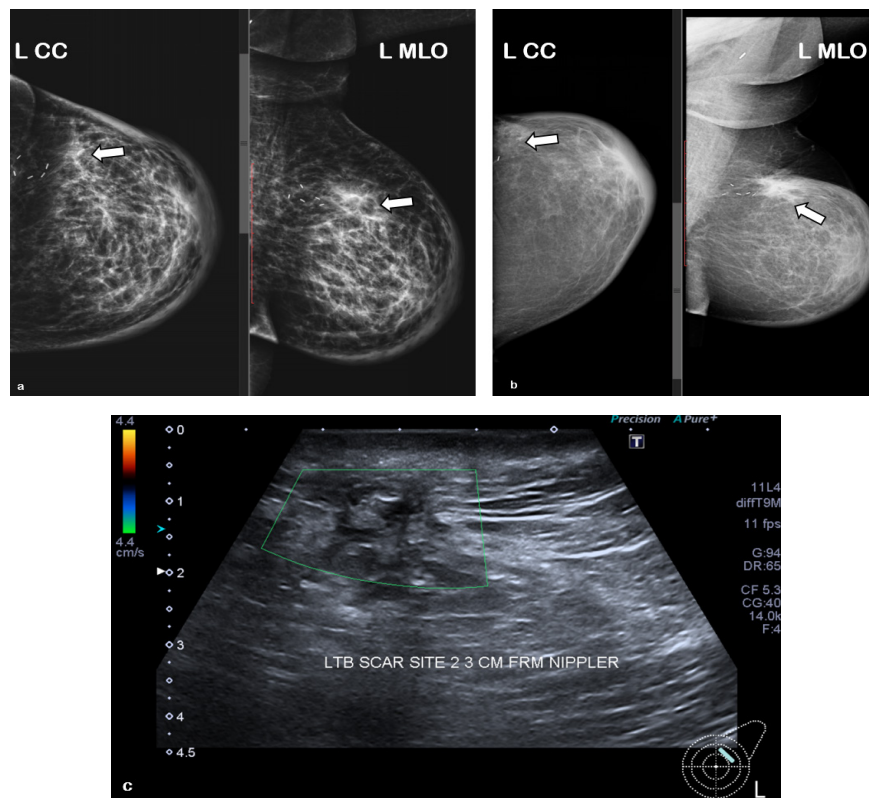


Figure 4. Left Breast Mammogram and Ultrasound Showing a Lesion with Stromal Fibrosis. Left mammogram CC and MLO views (a&b) of a 45-year-old female, followed by BCS, shows increased parenchymal density with architectural distortion in its upper outer quadrant underneath the prior lumpectomy (malignant) scar 2 years post radiotherapy (white arrow). On grey scale and Doppler ultrasound (c), a hypoechoic lesion with ill-defined margins at 2:00, 3 cm from nipple without internal vascularity. She was upgraded to BIRADS IV-a and underwent biopsy which turned out to be stromal fibrosis.

(Figure 4c) which turned out to be stromal fibrosis on histopathology, a benign entity.

Another patient after 1 year of left mastectomy developed enlarged lymph nodes in the right axilla which persisted on 6 months follow-up and subsequently upgraded for biopsy which showed benign reactive

lymphoid tissue (Figure 5).

The only case of recurrence in group A patients is demonstrated in Figure 6 showing a mass like area on mammogram mainly in upper outer quadrant (Figure 6 a) and heterogeneous lesion on ultrasound (Figure 6b) after a year of surgery which progressed in size and came out to be recurrence after its upgrade.

The malignancy rate among upgraded lesions (11.1%; 95% CI: 1.4–34.7%) was significantly higher than the ACR's <2% benchmark (Fisher's exact test,  $p < 0.001$ ).

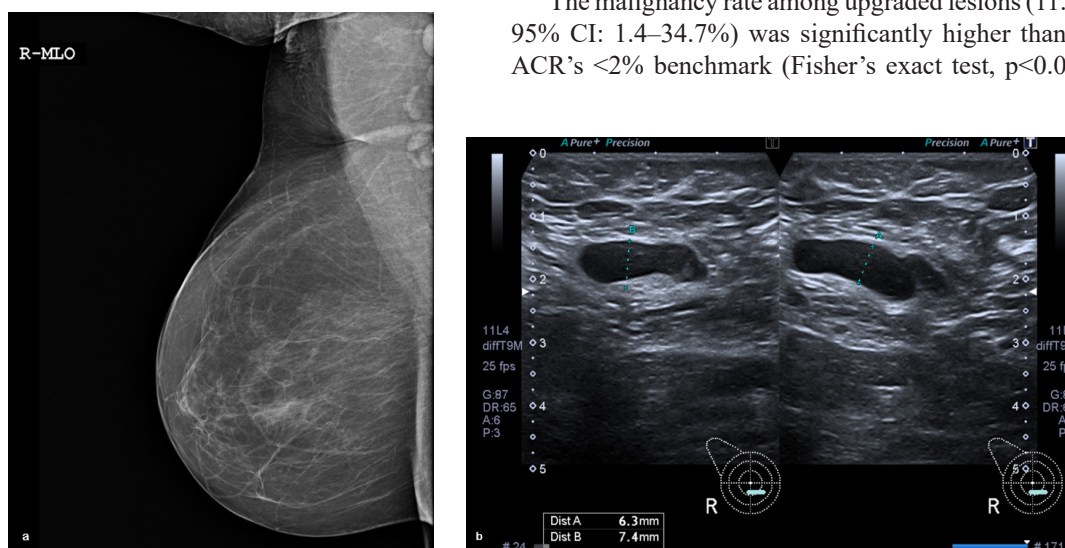


Figure 5. Right Breast Mammogram and Ultrasound Showing benign Reactive Nodes. a&b show partly visualized enlarged right axillary lymph nodes in patient with left mastectomy. These persisted on followup. Histopathology revealed benign reactive lymph nodes.

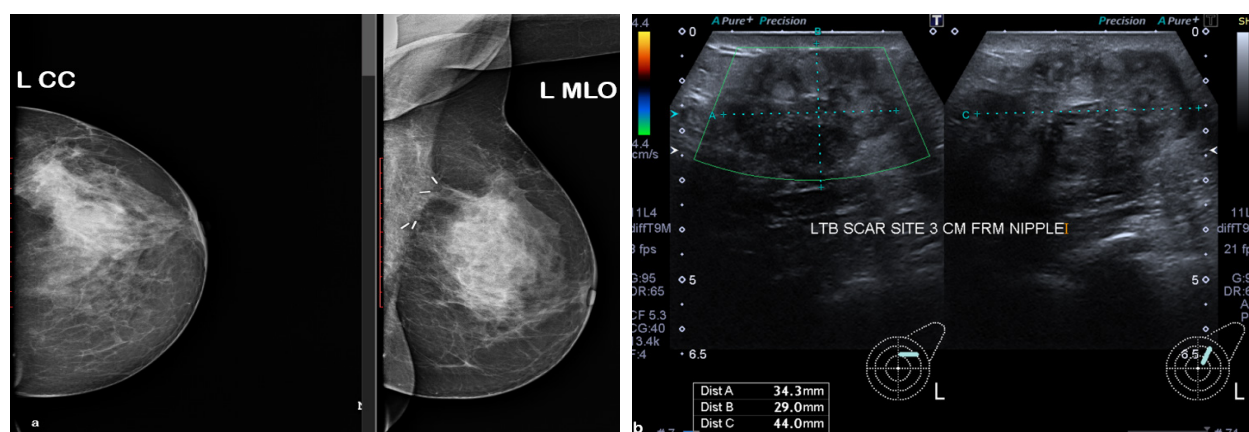


Figure 6. Left Breast Mammogram and Ultrasound Showing Recurrent Lesion. a&b: demonstrate interval development of mass like density on mammogram in its upper outer quadrant at the site of prior surgery and heterogeneous lesion without any significant vascularity on ultrasound. The size progressed on follow up and therefore advised biopsy. This was recurrence on histopathology.

Logistic regression identified lesion size as a significant predictor of malignancy (odds ratio [OR]=1.17 per mm increase, 95% CI: 1.02–1.34,  $p \approx 0.03$ ), while multiple lesions were also significant (OR=3.10, 95% CI: 1.02–9.40,  $p \approx 0.04$ ). Age (OR=0.92, 95% CI: 0.82–1.03,  $p \approx 0.15$ ), prior cancer history (OR=0.14, 95% CI: 0.01–2.50,  $p \approx 0.19$ ), and morphology (e.g., post-surgical site vs. well circumscribed,  $p \approx 0.35$ ) were not significantly associated with malignancy, possibly due to the small sample size.

The high proportion of benign findings (88.9%) among upgraded BI-RADS 4 lesions suggests a need to redefine surveillance criteria to reduce unnecessary biopsies as well as ensuring early detection of malignancies.

## Discussion

The 13.8% upgrade rate from BI-RADS 3 to BI-RADS 4 in our cohort of 123 patients significantly exceeds the ACR's <2% expectation, and the 11.1% malignancy rate among the 18 upgraded lesions surpasses Ha et al.'s 4.9% for growing ultrasound-detected BI-RADS 3 lesions [15], though it aligns with the 10%–56% range reported by Michaels et al. for progressing mammographic lesions [17]. The high upgrade and malignancy rates likely reflect the cohort's elevated risk, with 81.3% having prior breast cancer, increasing baseline malignancy probability. Lesion size (OR=1.17 per mm) and multiple lesions (OR=3.10) predicted malignancy among upgraded lesions, consistent with Ha et al.'s finding that growth (>50% anteroposterior increase) elevates risk (9.2% malignancy) [15]. Our study quantifies size as a continuous predictor, suggesting lesions >10 mm, particularly those 20–30 mm (malignant cases: 13 mm, 34 mm), warrant biopsy.

Unlike Ha et al., where morphological changes (e.g., irregular margins) predicted malignancy (16.8%) [15], morphology was not significant in our study, possibly due to heterogeneous categories (e.g., post-surgical site) and small sample ( $n=18$ ). This contrasts with Michaels et al., who emphasize suspicious morphology (e.g., pleomorphic calcifications) as a biopsy trigger [17]. Our malignant lesions' morphologies (post-surgical site, axillary lymph

node) suggest atypical features in high-risk patients may signal malignancy, necessitating further investigation.

Michaels et al. advocate biopsy for interval changes like growth, aligning with our findings, but warn of misclassification without full workup (ultrasound, mammography) [2]. Our use of both modalities supports this approach, potentially reducing errors noted by Michaels et al. (e.g., incomplete asymmetrical evaluation). Ha et al. [15] highlight combined ultrasound-mammography for suspicious lesions (23.5% malignancy), and our rigorous imaging likely aided malignancy detection. The 88.9% benign rate among upgrades underscores the challenge of balancing early diagnosis with avoiding unnecessary biopsies, particularly in high-risk cohorts.

Clinically, our findings suggest BI-RADS 3 lesions in breast cancer survivors with larger or multiple lesions should prompt earlier biopsy, aligning with Ha et al.'s BI-RADS 4 re-classifications for growth [15]. Overclassification risks patient burden, while under classification delays diagnosis, as Michaels et al. caution [17]. A risk-stratified approach using size and lesion multiplicity could optimize management. Limitations include the small, upgraded sample ( $n=18$ ), selection bias (biopsied lesions only), and missing data (e.g., one lesion size, follow-up losses). The variability among different radiologists in assessing morphology and postoperative changes can influence the results. Future studies should validate these predictors in larger study groups, standardize morphology, and explore biomarkers (e.g., elastography) to refine risk stratification. Longitudinal follow-up could optimize surveillance intervals for high-risk patients.

Our study emphasizes the importance of vigilant monitoring of BI-RADS 3 lesions in high-risk patients, with larger or multiple lesions indicating a higher risk of malignancy, supported by integrated imaging.

In conclusion, in our study, there was a 13.8% upgrade rate from BI-RADS 3 to BI-RADS 4 and an 11.1% malignancy rate of the upgraded lesions, which is significantly higher than the ACR's <2% threshold, possibly due to the high prevalence of breast cancer history in the entire population (81.3%). The size of the lesion and presence of multiple lesions were key factors

predicting malignancy, implying their importance in risk stratification. These results imply that in high-risk patients, especially in those with larger number of lesions, an earlier biopsy rather than a prolonged follow-up is indicated for detecting malignancy in a timely fashion in an otherwise benign-appearing BI-RADS 3 lesion. The high proportion of benign biopsy outcomes (88.9%) underscores the need for refined criteria to minimize unnecessary procedures while maintaining diagnostic accuracy. Future research should validate these predictors in larger cohorts, standardize morphology assessments, and explore imaging biomarkers to optimize management of BI-RADS 3 lesions in high-risk populations.

#### *Implications and Future Directions*

The findings of this study raise important questions about the applicability of standard BI-RADS 3 guidelines in patients who have undergone breast-conserving therapy (BCT). In clinical practice, post-treatment changes such as fat necrosis, scarring, or fibrosis often complicate image interpretation and may mimic malignancy. This makes the conventional “probably benign” label more challenging to apply with confidence.

Our data suggests a need to reconsider whether current follow-up protocols truly suit this higher-risk population. It may be time to think about developing modified or supplementary BI-RADS criteria specifically tailored to post-treatment breasts, particularly in cancer survivors where the threshold for clinical concern is naturally lower.

Another consideration is the value of more personalized, risk-adapted follow-up plans. Not all BI-RADS 3 lesions behave the same, and not all patients carry the same risk. Incorporating factors such as prior treatment type, imaging features, and even clinical context could help determine whether a short-term follow-up or an earlier biopsy is more appropriate.

Radiologist expertise remains a cornerstone in navigating these complexities. In ambiguous cases, multidisciplinary discussions or second reads may offer additional perspective and lead to more balanced decision-making. Similarly, advanced imaging tools like contrast-enhanced mammography, elastography, or breast MRI could provide further clarity, especially when standard ultrasound findings are equivocal.

Importantly, these challenges also highlight the role of effective communication with patients. Shared decision-making where patients are informed about the rationale behind follow-up versus biopsy can reduce anxiety and foster trust in the care process.

Finally, oncology-focused imaging centers may benefit from implementing audit systems to track BI-RADS 3 outcomes. Local data on upgrade and malignancy rates could provide valuable feedback and help refine practice guidelines. Larger, prospective studies will also be essential to validate these observations and move toward evidence-based changes in how BI-RADS 3 is applied in the post-treatment setting.

#### **Author Contribution Statement**

Dr. Mahreen analysed the need for bringing this topic

into discussion while dealing with real time patients and performed an audit after data collection and further made the suggestions. Dr. Attka, Dr. Saman and Dr. Kashif did the data analysis. Dr. Attka, Dr. Mahreen and Dr. Farwa wrote the manuscript. Dr. Farwa gathered the relevant images and did the final editing.

#### **Acknowledgements**

I would like to express my gratitude to Shaukat Khanum Memorial Cancer Hospital and Research Centre for granting access to the PACs system which supported this research.

#### *Approval*

The study was conducted after Institutional Review Board (IRB) approval.

Ethical Declaration: Institutional Review Board (IRB)

#### *Conflict of Interest*

No conflict of interest to declare

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