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Evaluating the Efficacy of 6-Month Follow-Ups for BI-RADS 3 Lesions Identified by Screening Ultrasound: A Retrospective Analysis

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ABSTRACT

Background: The Breast Imaging-Reporting and Data System (BI-RADS), developed to standardize mammographic findings, categorizes 'probably benign' lesions as BI-RADS 3, aiming to reduce unnecessary biopsies from false positives, with a cancer likelihood of less than 2%. In some countries, screening programs have been expanded to include ultrasound alongside mammography, particularly in populations with predominantly dense breast tissue, leading to an increased detection of BI-RADS 3 lesions through this additional modality. This study examines the effectiveness of 6-month follow-ups for these ultrasound-identified BI-RADS 3 lesions.

Methods: We retrospectively analyzed 7,577 women who underwent mammography and ultrasound screening from January 2016 to December 2021. Of these, 2,907 were classified as BI-RADS 3 based on ultrasound findings. The study focused on 1,163 patients with normal mammography and assessed BI-RADS 3 from ultrasound findings, who completed a 24-month follow-up. Data analysis included assessing demographic data, breast cancer risk, imaging features, and pathological findings.

Results: Among the 1,163 patients, the cancer detection of the entire cohort was 0.7%, with no cancers detected during the first six months. The cancer found at 6 months and 12-24 months were 0 and 0.17%, respectively (P<0.001). The median time for reassessment from BI-RADS 3 to BI-RADS 4 was 18.4 months. Upon the change of BI-RADS, spiculation and angular margins were the most predictive ultrasound features for malignancy. Lesion size growth alone was found insufficient as a biopsy criterion. A 28% growth cutoff distinguished between benign and malignant lesions better than a 20% cutoff.

Conclusion: A 12-month follow-up interval may be more appropriate than the traditional 6-month interval for average-risk patients with BI-RADS 3 lesions detected by screening ultrasound. Combining suspicious imaging features with size increases enhances diagnostic accuracy, providing a tailored follow-up approach based on individual risk profiles and imaging characteristics.

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INTRODUCTION

The Breast Imaging-Reporting and Data System (BI-RADS), instituted by the American College of Radiology, standardizes the classification of mammographic findings. A particularly challenging category is BI-RADS 3, which identifies lesions as 'probably benign.' This classification emerged and

became widely accepted in the early 1990s, coinciding with an increase in screening mammography. Historically, before the introduction of the 'probably benign' assessment, biopsy rates were considerably high, affecting up to 3% of women undergoing screening mammography.[1] The introduction of the BI-RADS 3 category aimed to mitigate the incidence of unnecessary biopsies due to false-positive results, while maintaining an acceptable rate of early cancer detection.[2] The categorization implies a cancer likelihood of less than 2%, with minimal risk of cancer progression within the recommended follow-up period.[3]

Approximately 1.5% of patients with BI-RADS 3 lesions, identified through screening mammography, were diagnosed with cancer at 6-month, and 1.86% during a 2-year follow-up, validating the importance of short-interval follow-up.[4] In several countries, e.g., Thailand, where the majority of population have dense breasts, screening ultrasound of the breasts was added to the opportunistic screening program along with the mammography.[5]

In contrast to mammography, where BI-RADS category 3 lesions have a higher cancer yield, several studies have reported a low malignancy rate in BI-RADS 3 lesions identified through screening ultrasound.[6-8] This study was designed to specifically evaluate the effectiveness of a short-interval follow-up by assessing the the number of cancers found in BI-RADS 3 lesions detected by ultrasound and to analyze factors that may influence the decision to proceed to early biopsy in these patients.

METHODS

Study population

This retrospective study received approval from the Institutional Review Board (EC 64-132), and the requirement for informed consent was waived due to its retrospective nature.

A comprehensive review was conducted on 7,577 women who underwent breast cancer screening at our institution, involving mammography coupled with ultrasound, from January 2016 to December 2021. The inclusion criteria were undergoing screening for breast cancer, being older than 18 years, and completing 24 months of the follow-up protocol. Of these participants, 2,907 were initially classified as BI-RADS 3 based solely on ultrasound findings. The exclusion criteria included presence of breast symptoms at the screening, being diagnosed with breast cancer, undergoing breast intervention, and BI-RADS 3 categorization being attributed to mammographic findings. Consequently, the study focused on a cohort of 1,163 patients who presented with normal mammographic results but were classified as BI-RADS 3 from ultrasound findings, and who successfully completed a follow-up period of 24 months.

Mammography and ultrasound of the breasts

Mammographic screening was conducted using the General Electric Senographe digital mammography system (GE Healthcare, Milwaukee, WI, USA). Standard craniocaudal and mediolateral oblique views were obtained for each participant, with additional views acquired as deemed necessary. The interpretation of mammograms was carried out by one of the five board-certified radiologists with expertise in breast imaging.

Concurrent with mammography, breast ultrasound screening was usually performed on the same day for each participant. The ultrasounds were conducted by one of the same five radiologists, utilizing either the Aplio 300 or Aplio 500 series ultrasound machines (Canon Medical Systems Corporation, Kawasaki, Japan), which are equipped with linear array transducers featuring a bandwidth of 12-5 MHz. Lesions were assessed as category 3 on ultrasound based on the following features: Circumscribed oval solid masses, parallel orientation to the skin, no or minimal posterior acoustic enhancement, hyperechoic masses with central hypoechogenicity suggesting fat necrosis, complicated cysts, and clustered microcysts. Prior to the ultrasound examination, each patient's mammographic findings and relevant clinical information were reviewed by the radiologist. The ultrasound screening encompassed a thorough examination of both breasts and the axillary regions.

Findings from each imaging modality were evaluated and categorized according to the BI-RADS criteria. A final assessment was assigned based on the highest BI-RADS category identified from the imaging studies.

Follow-up protocol

A structured follow-up protocol was implemented for patients categorized as BI-RADS 3. Initially, a short-term follow-up using ultrasound was scheduled at six months post-screening. In cases where there was no reassessment in the BI-RADS category, further follow-ups were conducted at 12 and 24 months, involving both mammography and ultrasound.

If any suspicious findings emerged, either from mammography or ultrasound, a prompt tissue diagnosis would be performed. This included options of ultrasound-guided percutaneous biopsy, stereotactic biopsy, needle-localized excision, or surgical excision. The choice of procedure was determined based on a collaborative decision-making process, taking into account the clinical judgment of

the healthcare providers and the preferences of the patients.

Data collection

Demographic data of the patients were collected. Breast cancer risk assessment was conducted utilizing the Gail Model. A thorough review of imaging and radiological reports was performed. This included the extraction of initial features pertinent to the categorization of BI-RADS 3, as well as imaging characteristics that contributed to the upgrading of BI-RADS from 3 to 4 during the follow-up. Additionally, pathological findings were documented and analyzed. The rate of cancer found was calculated from the number of breast cancers divided by the number of women undergoing the screening at a particular time point.

The reference standard for our analysis combined both pathological outcomes and clinical follow-up data.

Statistical analysis

Statistical analyses were executed using STATA software (version 18, StataCorp LLC, Texas, USA). For determining statistical significance, a P-value threshold of less than 0.05 was adopted. The sample size was estimated by calculating the power of a two-proportion z-test, given 0.05 as alpha, which yielded 0.807 power. The t-test was employed for comparing the means of normally distributed parametric variables, while the Mann-Whitney U test was utilized for comparing medians of non-normally distributed variables. The diagnostic performance was performed using STATA's Diagt package. To find the diagnostic performance of each ultrasound findings indicating the need for biopsy, the area under the receiver operating characteristic curve (AUROC) analysis was conducted, and the optimal cutoff point was determined using the Liu's method.[9]

RESULTS

Out of the 7,577 women who underwent combined screening mammography and ultrasound, 2,907 were classified as BI-RADS 3. A cohort of 1,163 patients completed the 24-month follow-up. During this period, 57 patients were reassessed to be BI-RADS 4 and underwent tissue diagnosis. Of these, 49 lesions were benign, including 21 fibroadenomas, 9 cases of fibrocystic changes, 7 nonproliferative lesions, 4 fibrosis cases, 3 instances of periductal chronic inflammation, 2 proliferative lesions without atypia, 2 intraductal papillomas, and 1 adenosis. Consequently, 8 patients were confirmed to have malignancies, comprised of 6 cases of invasive ductal carcinoma, and 2 cases of ductal carcinoma in situ, yielding a cancer detection of 0.7% among the followed cohort (Figure 1).

The age of the patients ranged from 19 to 79 years, with a median age of 46. The majority of the population were less than 50 years of age and in premenopausal status. Both life time and 5-year breast cancer rates were at low risk as indicated by the Gail Model (Table 1).

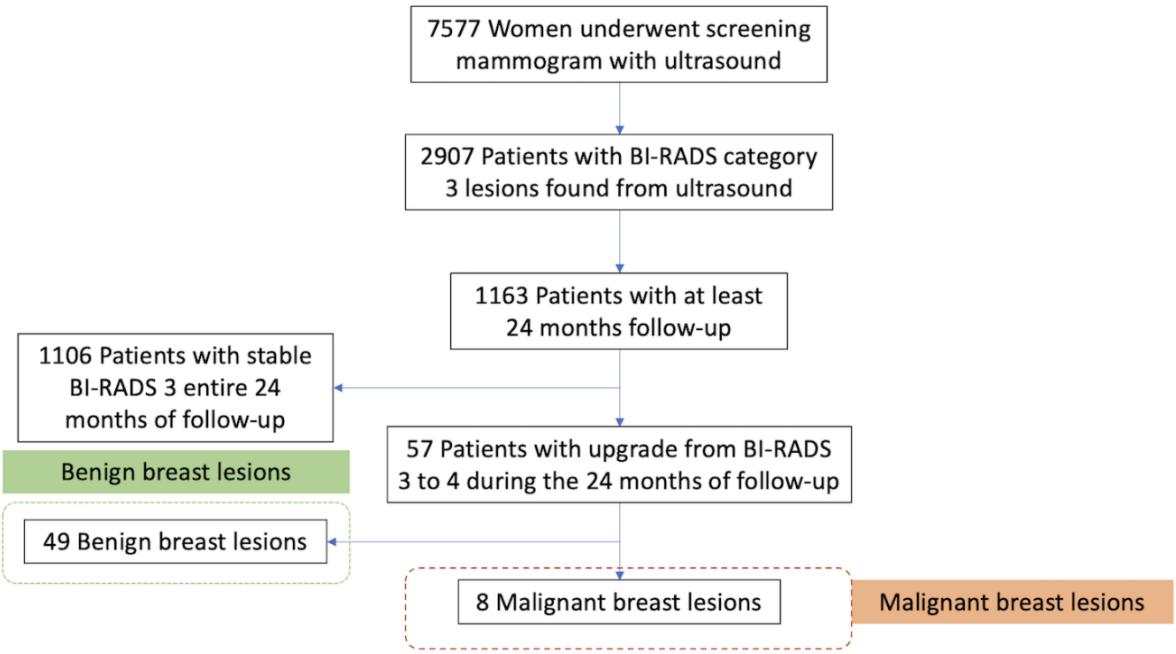

Figure 1. Flowchart of patient population. Among 7757 women who underwent screening mammogram with ultrasound, 2907 women were categorized with BI-RADS 3 with subsequently 1163 (40%) patients had completed follow-up of 24 months.

Table 1. Demographic characteristics and risk factors of patients with Breast Imaging Reporting & Data System (BI-RADS) 3 lesions

Characteristic n=1163	No (%)
Age (Median, years)	46 IQR(40-53)
<=50 years	764 (65.7)
>50 years	399 (34.3)
Menopausal status	
Premenopausal	714 (61.4)
Perimenopausal	368 (31.6)
Postmenopausal	81 (7)
Risk factor	
Median Lift time risk with Gail model	3.6 IQR(3.1-3.9)
Median 5-year risk with Gail model	0.3 IQR(0.2-0.5)
Biopsy	57 (4.9)
Biopsy proven cancer	8 (0.6)
Median follow-up time	47.7 IQR(36.2-61.3)

The median duration for reassessment from BI-RADS 3 to BI-RADS 4 was 18.4 months. Notably, a shorter median time for a lesion to be reassessed as BI-RADS 4 was observed in patients with benign lesions compared to those with malignancies (16.7 months versus 27.0 months, P=0.027). The rate of cancer found at 6-, 12-, and 15-months were 0%, 0.09% (1/1163) at 18-months, and 0.17% (2/1163) at 24-months.

Imaging features such as spiculation, hypoechogenicity, and the presence of new suspicious calcifications were significantly more common in patients who were ultimately diagnosed with cancer. These features were pivotal in the reassessment from BI-RADS 3 to BI-RADS 4 (Table 2). In contrast, microlobulation was significantly more prevalent among patients with benign lesions.

Table 2. Imaging features associated with reassessment Breast Imaging Reporting & Data System (BI-RADS) category 3 to 4

Findings lead to reassessment of BI-RADS	Cancer (n=8)	%	Benign (n=49)	%	P-value
Increased size	4	50	30	61.22	0.702
Median increased size %	40 (28.6-283.3)		25 (4.4-433)		0.161
Percent increased size at standard cutoff point					
<=20%	0	0	14	28.6	
>20%	8	100	35	71.4	0.179
Percent increased size at cutoff point					
<=28%	0	0	18	36.7	
>28%	8	100	31	63.3	0.046
Mass margin					
Microlobulation	0	0	18	36.7	0.046
Hypoechogenicity change	2	25	18	36.7	0.699
Spiculation	4	50%	0	0	<0.001
Angular margin	4	50%	6	12.2	0.025
New suspicious calcificaition	4	50%	0	0	<0.001

The analysis of size increase demonstrated an AUROC of 0.718 for predicting malignancy (Figure 2), yet this was not statistically significant across the groups when using the standard threshold of a 20% increase. However, applying a new cutoff of 28% revealed a significant distinction (P=0.046) between benign and malignant lesions (Table 2).

The diagnostic performance of the 20% size increase cutoff—in terms of sensitivity, specificity, positive predictive value, and negative predictive value, including AUROC (Figure 3)—compared to the new 28% threshold was found to be statistically significant (P=0.039) (Table 3).

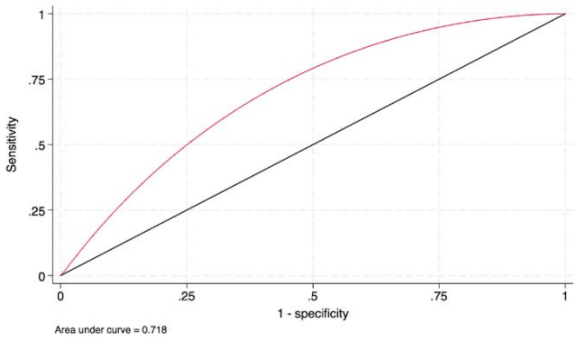

Figure 2. Receiver Operating Characteristic (ROC) curve for the prediction of malignancy based on percent increase in lesion size.

Table 3. Diagnostic performance of imaging features in predicting malignancy

Imaging features	Sensitiviy (95%CI)	Specificity (95%CI)	PPV	NPV	AUROC
Microlobulation	0 (0-36.9)	63.3 (48.3-76.6)	0 (0-18.5)	79.5 (63.5-90.7)	0.32
Hypoechogenicity change	25 (3.2-65.1)	63.3 (48.3-76.6)	10 (1.2-31.7)	83.8 (68-93.8)	0.44
Spiculation	50 (15.7-84.3)	100 (92.7-100)%	100 (39.8-100)	92.5 (81.8-97.9)	0.75
Angular margin	50 (15.7-84.3)	87.8 (75.2-95.4)%	40 (12.2-73.8)	91.5 (79.6-97.6)	0.69
New suspicious calcificaition	50 (15.7-84.3)	100 (92.7-100)%	100 (39.8-100)	92.5 (81.8-97.9)	0.75
Cutoff percent increased size					
at 20%	100 (63.1-100)	28.6 (16.6-43.3)	18.6 (8.4-33.4)	100 (76.8-100)	0.64
at 28%	100 (63.1-100)	36.7 (23.4-51.7)	20.5 (9.3-36.5)	100 (81.5-100)	0.68

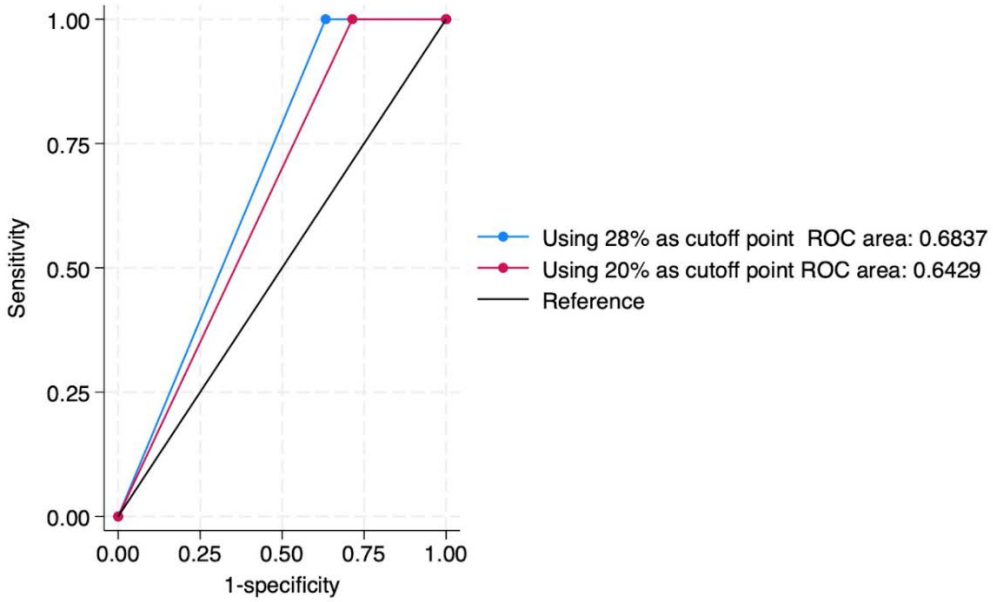

Figure 3. Comparison of Receiver Operating Characteristic (ROC) curves for 20% and 28% increase in lesion size as cutoff points to predict malignancy.

DISCUSSION

BI-RADS 3 lesions represent a significant proportion of findings in screening breast ultrasound, accounting for approximately 38% of women undergoing screening in this study. This prevalence aligns with the broad range reported in the literature, which varies from 14.6%-41.4%.[6,7,10-12] The biopsy observed in our study was 4.9%, which falls within the previously reported range of 0.6-6.2% in the literature.[6,12] Remarkably, 93% of the decision to proceed to biopsy were based on ultrasound features, from which only 7.6% were ultimately confirmed as cancers. This yields a sensitivity of 50% (15.7%-84.3%), a specificity of 0% (0-7.3%), a PPV of 7.5% (2.1%-18.2%), and an NPV of 0% (0-60.2%). These findings suggest that while ultrasound is highly sensitive in detecting a large number of BI-RADS 3 lesion in screening settings, its specificity for malignancy is low.

In contrast, findings from mammograms that prompt biopsies accounted for 7%, with a 100% confirmation of cancer, translating to a sensitivity of 50% (15.7%-84.3%), a specificity of 100% (92.7%-100%), a PPV of 100% (39.8%-100%), and an NPV of 92.5% (81.8%-97.9%).

In discerning the potential malignancy of BI-RADS 3 lesions, certain ultrasound features stand out as pivotal in the decision-making process for biopsies. Specifically, spiculation and angular margins were identified as the most predictive of malignancy in this study (Figure 4) (Table 3), aligning with the findings reported in prior research.[13,14]

However, the variability observed in diagnostic performance metrics may be explained by the moderate interobserver variability that is well-documented in mass margin descriptions.[15] This variability underscores the need for standardized descriptors and reinforces the importance of comprehensive training in ultrasound interpretation to ensure consistency and accuracy in biopsy decisions.

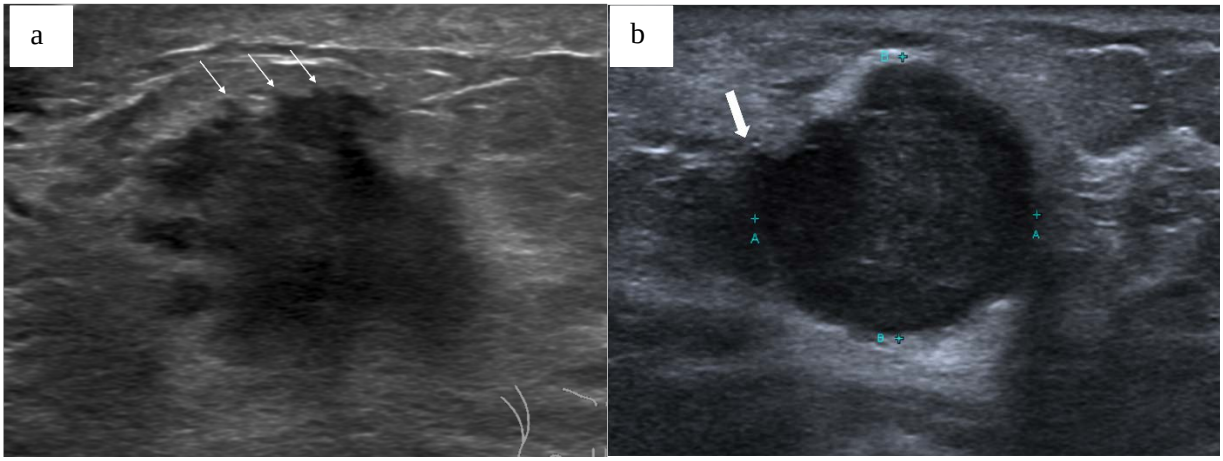

Figure 4. Ultrasound features that were most predictive of malignancy; 4a: Spiculated margin characterized by sharp projecting lines (fine arrows); 4b: Angular margin characterized by a sharp corner that forms acute angle (thick arrow). Both lesions were ultimately diagnosed with invasive ductal carcinomas.

Notably, despite the high diagnostic performance of hypoechogenicity highlighted in prior studies[13], its effectiveness in distinguishing between benign and malignant lesions was limited in our analysis. This discrepancy could be explained by the fair interobserver agreement on this feature, as noted in previous research.[15] Factors such as varying setting adjustment on each ultrasound machines could contribute to this inconsistency (Figure 5).

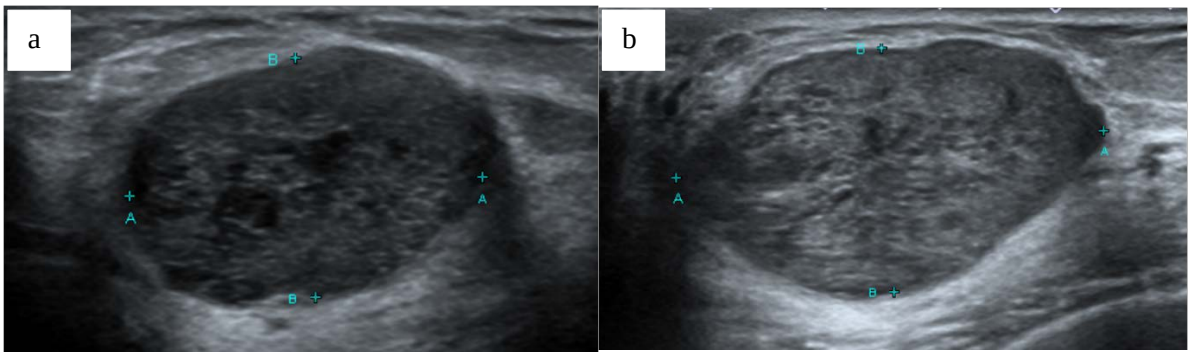

Figure 5. The impact of machine setting on lesion echogenicity; 5a and 5b display the same lesion, using different ultrasound machine settings on the same day.

In this cohort, 2.9% of BI-RADS category 3 lesions demonstrated growth on follow-up, with observed growth ranging from 4.4% to 433.3%. Despite the standard threshold of a 20% mean change for solid masses over a 6-month period being acceptable across all age groups[16], 21% of biopsies were conducted on patients with less than 20% growth and no other suspicious findings, with none resulting in a cancer diagnosis. Contrary to the findings of Moon HJ *et al.*[17], the median increase in size between malignant and benign lesions in our study was not significantly different (P=0.161). Furthermore, using the 20% growth threshold[16] did not effectively differentiate between benign and malignant lesions (P=0.179). The decision to use a 28% growth cutoff, determined via the Liu index, showed improved distinction in our study (P=0.046). However, none of the lesions that exhibited size increase on follow-up, in the absence of other suspicious findings, were found to be cancerous. An increased diagnostic accuracy of 5.1% was observed when adding suspicious findings to the growth cutoff point (P=0.019), suggesting that absolute size growth alone may not be a sufficient criterion for biopsy.

In assessing the overall effectiveness of short-interval follow-up, our study observed a low cumulative cancer rate of 0.7% within the entire cohort. This finding falls within the range reported in similar studies, which have documented yields between 0.7% and 1.3%.[7,8,10] Notably, the cancer rate found during the first six months of the follow-up was 0%. This aligns with findings from several studies that reported no or very low cancer detection (up to 0.1%) in this early follow-up[6,8,10], closely aligning with the observed 0.08% malignancy rate within one year for women with dense breasts classified as BI-RADS 1.[18] The finding at 6 months follow-up was statistically inferior compared to the rate found at 12-24 months follow-up (0 vs 0.17%, P<0.001) (Table 4). Furthermore, all cancers identified in our study

were node-negative at the time of diagnosis. Considering the absence of malignancies during the short interval follow-up in our cohort, the utility of an initial 6-month follow-up for women at average risk with 'probably benign' findings from screening ultrasound appears to be limited. These results suggest that such an early follow-up may not offer substantial benefit in detecting malignancies in this specific group of patients.

Table 4. Comparison of efficacy in detecting cancer between follow-up at 6 months and at 12-24 months

Parameters	At 6 months follow-up	At 12-24 months follow-up	P-value
Biopsy rate	0.001 (2/1163)	0.030 (35/1163)	0.194
Biopsy proven cancer	0	2	0.893
Rate of cancer found	0	0.17% (2/1163)	<0.001

This study has certain limitations that should be considered when interpreting the findings. Primarily, the study population consisted of women who opted for self-paid screening, which might not represent the broader population. The risk assessment was confined to women categorized as average risk, leading to a potential underrepresentation of high-risk individuals, for example, women with breast cancer in a first degree relative, or from inherited mutation (BRCA1, BRCA2). Consequently, the findings and subsequent recommendations may not be directly applicable to women with a higher risk profile. The lack of data on high-risk women suggests the need for further research in this subgroup to ascertain if the observed trends and recommendations hold true in a more diverse and inclusive patient population. The study also is limited due to its retrospective nature. For instance, the follow-up protocol could not be achieved precisely, due to multifactorial causes, e.g., patient's convenience for the schedule, and availability of the schedule.

CONCLUSION

This study's findings suggest that for patients with average risk and BI-RADS 3 lesions identified from breast ultrasound screening, a 12-month follow-up interval may be more appropriate than the conventional 6-month follow-up. Our data indicate a low cumulative cancer rate of 0.7%, with no malignancies detected during the first six months.

The most predictive ultrasound features of malignancy were spiculation and angular margins. Importantly, the study also reveals that the increased size of a lesion alone should not be the sole criterion for biopsy. Incorporating suspicious imaging features alongside size increases could significantly improve diagnostic accuracy.

Overall, these insights advocate revising current follow-up recommendations for BI-RADS 3 lesions detected via ultrasound. A more individualized approach, considering specific risk profiles and imaging characteristics, could optimize resource use, reduce patient anxiety, and maintain compliance without undermining the efficacy of breast cancer screening programs.

ETHICAL CONSIDERATIONS

The research was submitted to the Suranaree University of Technology Institutional Review Board (EC 64-132), and was approved on December 1, 2021.

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None.

CONFLICTS OF INTEREST

None to declare.

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None.

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