Zagazig University Medical Journal
www.zumj.journals.ekb.eg
https://doi.org/10.21608/zumj.2025.406397.4069 Volume 31, Issue 10 October. 2025
Manuscript ID:ZUMJ-2507-4069
DOI:10.21608/zumj.2025.406397.4069

ORIGINAL ARTICLE

Role of Digital Tomosynthesis in Changing the BIRADS Categorization of Mammographically Detected Breast Lesions

Norhan Magdy Salah Moustafa Amer *, Engy Fathy Tantawy, Awad Abdel-Elaziz Besar, Ahmed Gamil Ibrahim

Radiodiagnosis Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt

***Corresponding author:**

Norhan Magdy Salah Moustafa Amer
MBBCH, Faculty of Medicine, Zagazig University, Zagazig, Egypt

Email address:
Norhanmagdyy@icloud.com

Submit Date: 22-07-2025
Revise Date: 29-08- 2025
Accept Date: 06-09-2025

ABSTRACT

Background: Breast cancer remains the most common cancer among women globally and is a leading cause of cancer-related deaths. Although digital mammography (DM) is the current gold standard for breast cancer screening, it has limitations, particularly in dense breast tissue. The present work aimed to evaluate the additive role of digital breast tomosynthesis to mammography in changing the BIRADS classification of breast lesions.

Methods: A total of 30 women who were eligible to undergo full-field digital mammography, 3D DBT and ultrasound. Lesions were categorized independently by each modality using BI-RADS 2013 criteria. Histopathology or follow-up imaging was used as reference standards.

Results: DBT detected more lesions than DM. DM identified 42 lesions, with 29 (69%) as BI-RADS 3, 4 (9.5%) as BI-RADS 5, 3 (7.1%) as BI-RADS 0, 3 (7.1%) as BI-RADS 4A, 2 (4.8%) as BI-RADS 4C, and 1 (2.4%) as BI-RADS 2. DBT detected 54 lesions, including 23 (42.6%) as BI-RADS 3, 12 (22.2%) as BI-RADS 5, 8 (14.8%) as BI-RADS 2, 5 (9.3%) as BI-RADS 4A, 5 (9.3%) as BI-RADS 4C, and 1 (1.9%) as BI-RADS 4B. The diagnostic accuracy of BI-RADS with DBT for predicting breast cancer, with BI-RADS 5 indicating malignancy, showed a sensitivity of 90.9%, specificity of 91.1%, and accuracy of 92.4%. In comparison, BI-RADS with DM had a sensitivity of 89%, specificity of 88.3%, and accuracy of 81%. The combined use of DM and DBT yielded excellent results, with a sensitivity of 91%, specificity of 100%, and overall diagnostic accuracy of 93.5%.

Conclusions: DBT significantly enhances lesion detection and characterization compared to DM, particularly in dense breasts. It improves diagnostic confidence, refines BI-RADS categorization, and may reduce unnecessary biopsies. The findings support integrating DBT as a frontline tool in breast cancer screening and diagnostic workflows.

Keywords: Digital tomosynthesis; BIRADS categorization; Mammography; Breast lesions.

INTRODUCTION

Breast cancer is considered the most frequently diagnosed cancer among women globally, representing approximately 22.9% of all female malignancies. In Egypt, it accounts for around 37.7% of newly diagnosed cancers among women, highlighting its significant public health burden [1]. Advances in the treatment modalities and widespread adoption of screening techniques, principally mammography, have contributed to a notable increase in the five-year survival rate among breast cancer patients over recent decades [2]. Mammography continues to be the cornerstone of breast cancer screening as well as diagnostic imaging, offering a reliable, non-invasive means of estimating tumor size in addition to evaluation of the breast tissue [3]. However, this technique could be limited by two major drawbacks. First, its sensitivity significantly

decreases in dense breast tissue due to the masking effect, where overlapping fibroglandular tissue may obscure lesions. Second, the specificity can be compromised by the superimposition of normal anatomical structures, which may mimic pathology [4]. Also, mammographic screening is usually advised against in women younger than 40 years of age because of cumulative radiation exposure and the high density of breast tissue prevalent at this age, which can lower sensitivities to about 45% [5]. Digital Breast Tomosynthesis (DBT) has come into existence as an innovative solution to many of the limitations inherent to conventional methods. The 3D imaging technique has rapidly become accepted as an adjunct or a replacement for compromised digital mammography because of its enhanced diagnostic performance [6,7]. Tomosynthesis takes multiple low-dose projections of the breast from a slight arc in standard craniocaudal and mediolateral oblique views. This technique minimizes tissue overlapping to improve lesion conspicuity, especially in dense breasts.

DBT has also been shown to increase sensitivity to architectural distortion detection and is superior in cases where in detection relies on this architectural distortion, such as in the detection of invasive lobular carcinoma, which is often very subtle on conventional imaging [8]. The Breast Imaging Reporting and Data System (BI-RADS) was established by the American College of Radiology to ensure uniform terminology and reporting for breast imaging, thereby enhancing the consistency of diagnosis and contributing to decision-making in clinical management. There are seven categories to classify breast lesions, according to shape, margin, and density. These categories range from Category 0, in which extra imaging is needed, to Category 6, which refers to a biopsy-proven malignancy. In between, the categories include negative findings, benign lesions, and suspicious abnormalities with recommendations for follow-up or biopsy, depending on the level of concern [9,10]. Despite the proven advantages of digital breast tomosynthesis, more clinical evidence is still needed to evaluate its influence on BI-RADS classification in real-world diagnostic settings, especially among populations with dense breast tissue. Limited studies have specifically compared how DBT alters lesion categorization compared to digital mammography alone, especially in resource-constrained or regional healthcare environments. So, the present work aimed to assess the additive role of digital breast tomosynthesis to mammography in changing the BIRADS classification of breast lesions.

METHODS

We carried out this observational cross-sectional study at the Radiology Department, Faculty of Medicine, at our institute, from October 2023 to October 2024, after obtaining approval from the Institutional Review Board (IRB#10858/6-6-2023). The research was conducted under the World Medical Association's Code of Ethics (Helsinki Declaration) for humans. The inclusion criteria for the study were women referred for diagnostic breast imaging either due to screening program or positive findings during routine screening or because of breast-related symptoms such as palpable lumps, pain, discomfort, or nipple discharge. A total of 30 female patients were included in the study, with mean age 45.88 ± 13 years. The exclusion criteria included pregnant women and women who had refused to participate.

Clinical and Imaging Assessment

All participants underwent a comprehensive assessment, including collection of demographic and clinical data (age, marital status, number of offspring, lactation history, residence, chief complaints, and family history of breast cancer).

Imaging Modalities

All patients underwent Full-Field Digital Mammography (FFDM) and Wide-Angle 3D Digital Breast Tomosynthesis using the Senographe Pristina by GE Healthcare. Breast ultrasound was performed in all cases as a complementary modality, using the GE LOGIQ F8 Expert linear probe (7–12 MHz, breast

preset), to provide additional lesion characterization and correlation with mammographic and DBT findings. All imaging studies were completed during a single visit.

Technique and Acquisition

Mammography was performed in standard craniocaudal (CC) and mediolateral oblique (MLO) projections. 3D tomosynthesis was performed using the same CC and MLO views as mammography. During DBT, the X-ray tube moves in an arc to capture multiple low-dose images from different angles, which are reconstructed into sequential slices. This reduces tissue overlaps and improves lesion visibility, particularly in dense breasts. After imaging, data such as age, breast density, and the imaging modality used were recorded. Each patient's digital mammography (DM) was reviewed first, followed by digital breast tomosynthesis (DBT) in a separate, blinded session to prevent bias. Radiological abnormalities were identified independently for each modality, with findings cross-referenced with ultrasound data when applicable. BI-RADS classifications were assigned separately for each modality, using the 2013 BI-RADS Atlas descriptors. Final diagnoses were made based on histopathological correlation for BI-RADS 4 and 5 lesions and routine follow-up for BI-RADS 3 cases. Lesions were categorized based on several characteristics: mass features such as shape (round, oval, or irregular); margin (well-defined or ill-defined) and density (fat-containing density, hypodense, dense, or hyperdense), asymmetry (focal, global, or developing), parenchymal distortion (architectural changes without a distinct mass), and calcifications (whether benign or malignant in appearance).To reduce diagnostic bias, radiologists were blinded to histopathological results and ultrasound findings during the interpretation of mammography and DBT. All BI-RADS 4 and 5 lesions were subjected to core needle biopsy for histopathological confirmation. BI-RADS 3 lesions were managed with short-term (6-month) imaging follow-up, with biopsy indicated only upon documented progression. According to established guidelines, BI-RADS 1 and 2 lesions were considered negative and not biopsied. The BI-RADS categories and follow-up protocol are designed to standardize the classification and management of breast lesions. BI-RADS 0 indicates incomplete findings that require additional imaging. BI-RADS 1 represents negative results, meaning no abnormal findings were observed. BI-RADS 2 is assigned to benign findings, indicating no cause for concern. BI-RADS 3 suggests the findings are probably benign, but a short-interval follow-up is recommended for further monitoring. BI-RADS 4 indicates any suspicious abnormality, with a biopsy that should also be considered for confirming the diagnosis. BI-RADS 5 means it is highly suggestive of malignancy, needing immediate further investigation. Finally, BI-RADS 6 means that it is a known biopsy-proven malignancy. The follow-up actions varied based on the BI-RADS category. For BI-RADS 1 or 2, no additional follow-up was arranged beyond the patient’s routine screening schedule, except in high-risk patients, who were advised to return annually. For BI-RADS 3, follow-up imaging every 6 months was recommended to confirm whether the lesion remained stable. For BI-RADS 4 or 5, patients have been referred for histopathological evaluation to determine whether the lesion was malignant.

Statistical analysis

Statistical data analysis involved coding, entry, sorting, and various statistical manipulations. The collected data were summarized and presented using appropriate tables. Continuous variables that followed a normal distribution were expressed as mean and standard deviation, while categorical variables were presented as numbers and percentages. A receiver operating characteristic (ROC) curve analysis was used to evaluate the diagnostic performance and determine the areas under the curve (AUCs). A p-value of ≤ 0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 22.

RESULTS

Table 1 shows that the average age of the 30 studied females was 45.88 years (SD=13), with most patients (26.7%) in the 31–40-year range. Table 2 indicates that the majority (53.3%) had a negative family history, while 47% had a positive one. Regarding the ACR classification, 46.7% of patients were in class C, and 33.3% were in class D. Most patients (73.4%) had complaints, including 33.3% with a palpable mass, 20% with pain and a palpable mass, 16.6% with pain only, and 3.3% with a nipple discharge. Among the detected lesions, 55.6% were in the left breast, 29.6% in the right breast, and 14.8% in both breasts. The final diagnosis, confirmed by a gold standard test, revealed that majority (72.2%) of lesions were benign, with 41% being simple cysts. Table 2 shows that DM detected 42 lesions, while DBT detected 54. Most lesions were in the left breast (52.4% by DM, 55.6% by DBT). The majority were masses (80.9% by DM, 92.6% by DBT), with well-defined margins at 64.7% (DM) and 66% (DBT), while spiculated margins were detected at 17.6% (DM) and 18% (DBT). Table 3 shows that based on DM, 42 lesions were graded as follows: 29 (69%) as BI-RADS 3, 4 (9.5%) as BI-RADS 5, 3 (7.1%) as BI-RADS 0, 3 (7.1%) as BI-RADS 4A, 2 (4.8%) as BI-RADS 4C, and 1 (2.4%) as BI-RADS 2. DBT graded 54 lesions : 23 (42.6%) as BI-RADS 3, 12 (22.2%) as BI-RADS 5, 8 (14.8%) as BI-RADS 2, 5 (9.3%) as BI-RADS 4A, 5 (9.3%) as BI-RADS 4C, and 1 (1.9%) BI-RADS 4B. BI-RADS categories of the breast lesions detected on DM and DBT about the final diagnosis: DM, 30 (71.4%) of the BI-RADS graded lesions were benign and 12 (28.6%) were malignant. For DBT, 40 (74.1%) were benign and 14 (25.9%) were malignant. Table 4 shows that DBT upgraded lesions graded as BI-RADS 0 by DM to BI-RADS 2, 3, and 4C (1, 1.9% each). BI-RADS 3 lesions by DM were upgraded to BI-RADS 4A, 4C, and 5 (5.6%, 5.6%, and 9.3%), while 5 (9.3%) were downgraded to BI-RADS 2, and 13 (24.1%) remained unchanged. One BI-RADS 4A lesion remained unchanged, and two BI-RADS 4C lesions were upgraded to BI-RADS 5 (3.7%). One BI-RADS 5 lesions remained unchanged, while two were downgraded to BI-RADS 3 (3.7%) and one to BI-RADS 4C. Table 5 demonstrates that BI-RADS with DM had a sensitivity of 89%, specificity of 88.3%, and accuracy of 81%; BI-RADS with DBT achieved a sensitivity of 90.9%, specificity of 91.1%, and accuracy of 92.4%; and the combined BI-RADS with DM and DBT resulted in a sensitivity of 91%, perfect specificity of 100%, and an accuracy of 93.5%. Mammography of a 48-year-old woman with left breast pain and a palpable lump showed heterogeneously dense tissue (ACR D) with a retro areolar, partially obscured lesion (BIRADS 3). Tomosynthesis further revealed two well-defined dense lesions with surrounding halo (BIRADS 3) and a small spiculated lesion in the upper outer quadrant (BIRADS 4) not seen on standard views. Histopathology confirmed invasive ductal carcinoma in the spiculated lesion, fibroadenoma and a complicated cyst in the remaining lesions, highlighting the incremental value of tomosynthesis in detecting malignancy in dense breasts (Fig. 1). Mammography performed on a 35-year-old woman with a positive family history and a palpable left breast lump demonstrated scattered fibroglandular density (ACR B). They revealed two well-defined, macro lobulated lesions in the upper outer quadrant (BIRADS 3) and an enlarged lymph node in the left axilla. Tomosynthesis confirmed all these findings, which further detected a spiculated lesion with grouped microcalcifications in the upper outer quadrant (BIRADS 5, arrowhead). Histopathology confirmed invasive ductal carcinoma in the spiculated lesion. This finding therefore supports tomosynthesis as being superior in detecting suspicious features that were not visible on standard mammography (Fig. 2).

Table 1: Basic data of patients, patients' lesion, and final diagnosis of breast lesions (N=54).

Variable	Value
Age (Yrs) (Mean± SD)	45.88±13
Family history	
Positive	14 (46.7%)
Negative	16 (53.3%)
ACR	
A	1 (3.3%)
B	5 (16.7%)
C	14 (46.7%)
D	10 (33.3%)
Total	30 (100%)

Complaint of patients	No.	%
Palpable mass only	10	33.3%
Pain/Discomfort only	5	16.6%
Pain & palpable mass	6	20%
Nipple discharges	1	3.3%
No complaint (screening)	8	26.6%
Total	30	100%

Site of lesion	
Variable	**Value**
Site of lesion	
Right Breast	16 (29.6%)
Left Breast	30 (55.6%)
Both Breast	8 (14.8%)
Total	54 (100%)
Final diagnosis	
Benign	39 (72.2%)
Simple Cyst	16 (41%)
Fibroadenoma	9 (23.1%)
Complicated cyst	6 (15.4%)
IMLN (Intramammary Lymph Node)	3 (7.7%)
Fibroadenosis	2 (5.1%)
Abscess	1 (2.6%)
Fat necrosis	2 (5.1%)
Malignant	15 (27.8%)
Invasive lobular carcinoma	7 (46.7%)
Invasive ductal carcinoma	6 (40%)
Lobular carcinoma in-situ	2 (13.3%)
Total	54(100%)

Table 2: Lesions' findings based upon digital mammography (DM) and digital breast tomosynthesis (DBT) and margins of the detected masses.

	DM	**DBT**
	Frequency (%)	**Frequency (%)**
Number of lesions	42	54
Site of lesion		
Right breast	16 (38.1%)	16 (29.6%)
Left breast	22 (52.4%)	30 (55.6%)
Both breasts	4 (9.5%)	8 (14.8%)
Type of lesion		
Mass	34	50
Distortion	4	0
Asymmetry	9	8
Calcifications	6	7
Detected Mass Margins	**Total (n=34)**	**Total (n=50)**
Mass margin	**DM**	**DBT**
	Frequency (%)	**Frequency (%)**
Well defined	22 (64.7%)	33 (66%)
Obscured	5 (14.7%)	3 (6%)
Lobulated	1 (2.9%)	5 (10%)
Spiculated	6 (17.6%)	9 (18%)
Total	34 (100%)	50 (100%)

Table 3: BI-RADS categories of breast lesions detected on DM and DBT in relation to the final diagnosis.

DM BI-RADS categories in relation to final diagnosis				**DBT BI-RADS categories in relation to final diagnosis**			
	Benign	**Malignant**	**Total**		**Benign**	**Malignant**	**Total**
BI-RADS 0	3 (7.1%)	0 (0%)	3 (7.1%)	**BI-RADS 0**	0(0%)	0(0%)	0(0%)
BI-RADS 1	0 (0%)	0 (0%)	0 (0%)	**BI-RADS 1**	0(0%)	0(0%)	0(0%)
BI-RADS 2	1 (2.4%)	0 (0%)	1 (2.4%)	**BI-RADS 2**	8(14.8%)	0(0%)	8(14.8%)
BI-RADS 3	24(57.1%)	5 (11.9%)	29 (69%)	**BI-RADS 3**	22(40.7%)	1(1.9%)	23(42.6%)
BI-RADS 4A	1 (2.4%)	2 (4.7%)	3 (7.1%)	**BI-RADS 4A**	3(5.6%)	2(3.7%)	5(9.3%)
BI-RADS 4B	0 (0%)	0 (0%)	0 (0%)	**BI-RADS 4B**	0(0%)	1(1.9%)	1(1.9%)
BI-RADS 4C	0 (0%)	2 (4.7%)	2 (4.7%)	**BI-RADS 4C**	0(0%)	5(9.3%)	5(9.3%)
BI-RADS 5	1 (2.4%)	3 (7.1%)	4 (9.5%)	**BI-RADS 5**	7(13%)	5(9.3%)	12(22.2%)
Total	30(71.4%)	12(28.6%)	42 (100%)	**Total**	40(74.1%)	14(25.9%)	54(100%)

Table 4: Change in the grading of individual breast lesion by DBT, compared to DM.

DBT / DM	BI-RADS 0	BI-RADS 1	BI-RADS 2	BI-RADS 3	BI-RADS 4A	BI-RADS 4B	BI-RADS 4C	BI-RADS 5	Total
Not detected			**1 (1.9%)**	**7 (12.9%)**	**1 (1.9%)**	**1 (1.9%)**		**2 (3.7%)**	12 (22.2%)
BI-RADS 0			**1(1.9%)**	**1(1.9%)**			**1(1.9%)**		3 (5.6%)
BI-RADS 1									0 (0%)
BI-RADS 2			**1(1.9%)**						1(1.9%)
BI-RADS 3			**5 (9.3%)**	**13 (24.1%)**	**3 (5.6%)**		**3 (5.6%)**	**5 (9.3%)**	29 (53.7%)
BI-RADS 4A					**1(1.9%)**			**2(3.7%)**	3 (5.6%)
BI-RADS 4B									0 (0%)
BI-RADS 4C								**2(3.7%)**	2 (3.7%)
BI-RADS 5				**2(3.7%)**			**1(1.9%)**	**1(1.9%)**	4 (7.4%)
			8 (14.8%)	23 (42.6%)	5 (9.3%)	1 (1.9%)	5 (9.3%)	12 (22.2%)	54 (100%)

The different colors indicate whether DBT upgraded (Purple), downgraded (blue), or kept the grade the same(green) as DM.

Table 5: BI-RADS with digital mammography (DM), digital breast tomosynthesis (DBT), and combined as predictors of breast cancer diagnosis considering BI-RADS 5 as a predictive of malignancy.

	Sensitivity	**Specificity**	**AUC**	**Accuracy**	**95%CI**		**P-value**	**PVP**	**PVN**
					Lower end	Upper end			
DM	89%	88.3%	0.925	81%	.826	1.000	**.000***	88.9%	80%
	Sensitivity	**Specificity**	**AUC**	**Accuracy**	**95%CI**		**P-value**	**PVP**	**PVN**
DBT					Lower end	Upper end			
	90.9%	91.1%	0.944	92.4%	0.882	1.000	**.000***	94%	91.8%
	Sensitivity	**Specificity**	**AUC**	**Accuracy**	**95%CI**		**P-value**	**PVP**	**PVN**
Combined DM & DBT					Lower end	Upper end			
	91%	100%	0.963	93.5%	.882	1.000	.000*	100%	81.4%

AUC=Area under curve, CI=Confidence Interval * Statistically significant p-value <0.05.

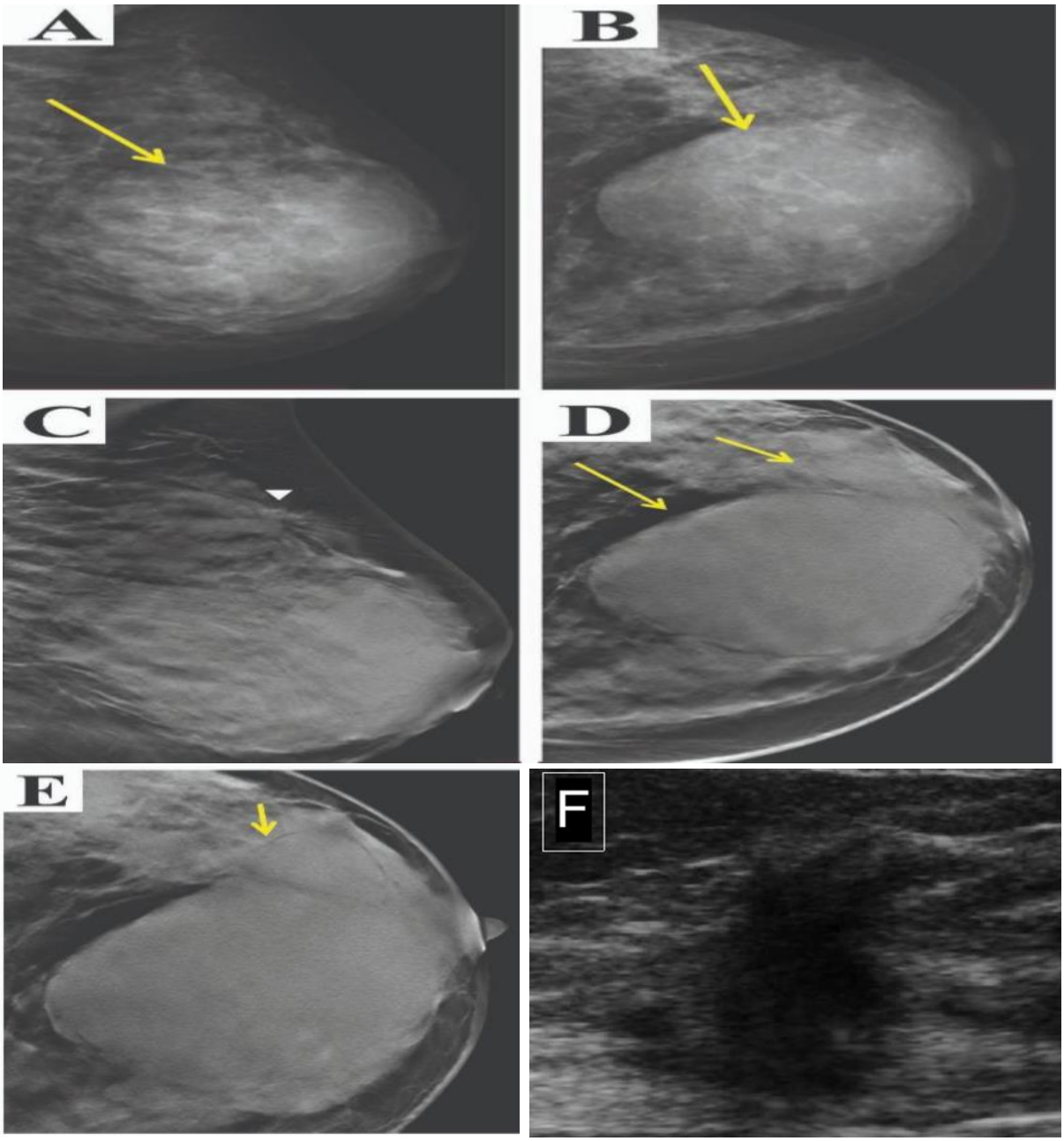

Fig1: A 48-year-old female patient with a positive family history of breast cancer presented with left breast pain and a lump sensation. (A) mediolateral oblique and (B) craniocaudal mammography images of the left breast demonstrate heterogeneously dense parenchyma (ACR D), which may obscure small lesions. A retro areolar, partially obscured dense lesion is identified (BI-RADS 3, yellow arrow). (C) mediolateral oblique and (D, E) craniocaudal tomosynthesis images reveal two well-defined dense lesions with surrounding halo (BI-RADS 3, yellow arrow). In addition, tomosynthesis detected a small dense lesion with spiculated margins in the upper outer quadrant (BI-RADS 4, arrowhead). (F) ultrasound image of the left breast showing an irregular spiculated hypo-echoic lesion at 2 o'clock with no calcifications. Histopathological examination revealed invasive ductal carcinoma, fibroadenoma, and multiple cysts, one of them is a complicated cyst.

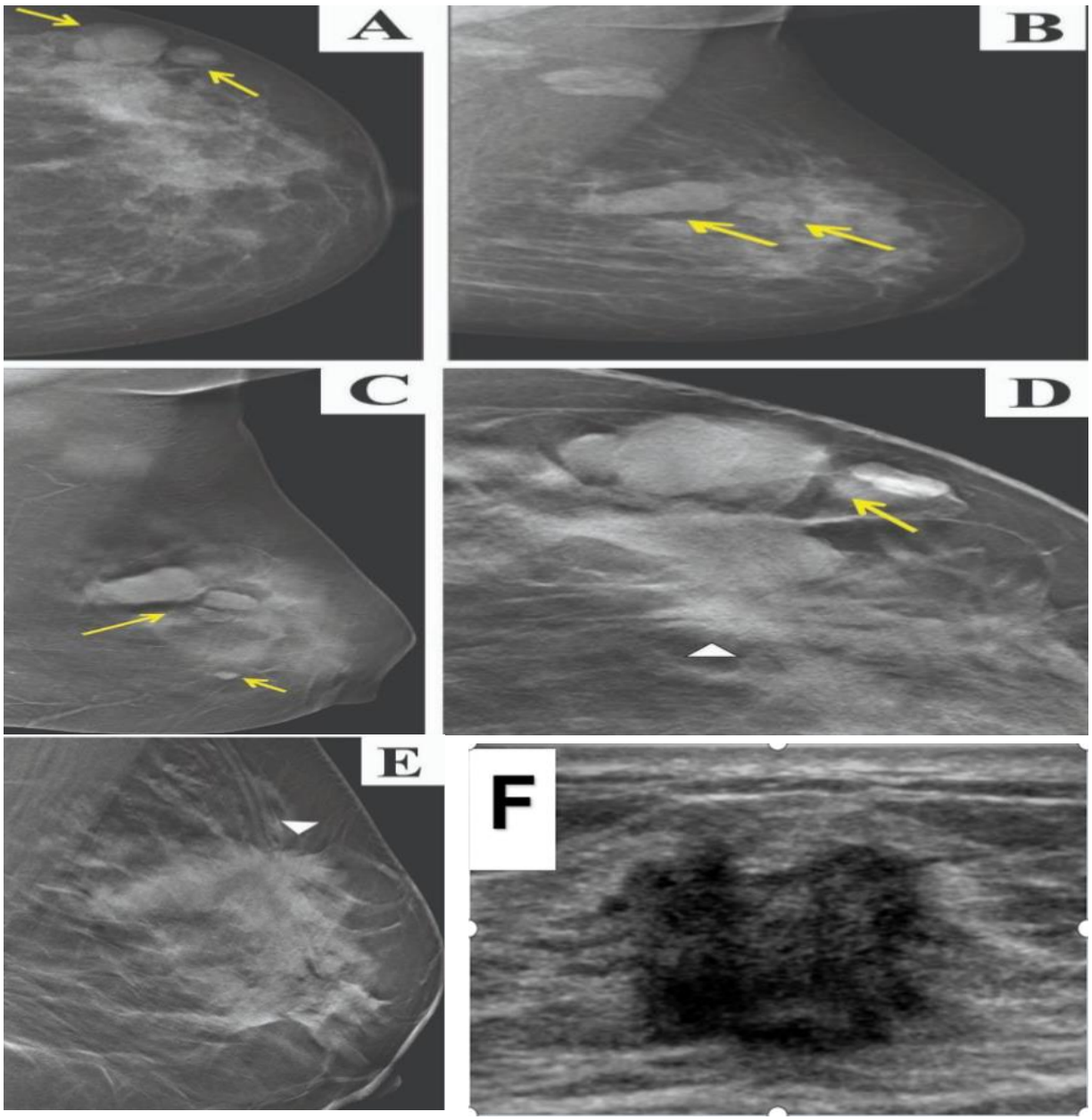

Fig. 2: A 35-year-old female patient with a positive family history of breast cancer presented with a left breast lump. (A) craniocaudal and (B) mediolateral oblique mammography images of the left breast show scattered fibroglandular density (ACR B). Two well-defined, macro lobulated lesions are identified in the upper outer quadrant (UOQ), both categorized as BI-RADS 3 (yellow arrow). Also, an area of architectural distortion is noted in the UOQ, as well as an enlarged left axillary lymph node. (C) mediolateral oblique and (D, E) craniocaudal tomosynthesis images of the left breast demonstrate two well-defined dense lesions and two additional macro lobulated dense lesions in the UOQ (BI-RADS 3, yellow arrow). Tomosynthesis also reveals a lesion with spiculated margins and grouped microcalcifications in the UOQ (BI-RADS 5, arrowhead). (F) ultrasound image of hypoechoic lesion with irregular spiculated margins in the left breast at 3 o'clock. Histopathological examination revealed invasive ductal carcinoma, fibroadenoma, and multiple cysts.

DISCUSSION

Breast cancer remains a leading cause of female deaths worldwide, showcasing the need for improvement in early detection and diagnostic precision. Conventional mammography has long been recognized to screen breast abnormalities and categorize lesions under the BI-RADS system. However, its diagnostic performance is notably reduced in women aged 40 to 49, particularly those with dense breast tissue. The decreased sensitivity in such cases is primarily due to the "masking effect," where dense fibroglandular tissue can obscure underlying malignancies, leading to potential diagnostic delays [2, 11]. Having evolved to overcome mammography's limitations, DBT is one of the newest modalities complementing breast imaging. Due to the extreme overlapping of tissues that impair a typical mammogram, the 3D imaging system enhances lesion visualization. The high sensitivity of DBT toward detecting architectural distortions and subtle lesions, especially with dense breasts, improves diagnostic accuracy [12]. The current research aimed to assess the influence of DBT on the BI-RADS categorization of breast lesions, with its potential to guide decisions regarding biopsy, surveillance, or treatment. As BI-RADS classification plays a central role in clinical management, optimizing the accuracy of lesion characterization through adjunctive DBT could meaningfully improve diagnostic outcomes [13]. In our study of 30 women, the mean age was 45.88 years (±13), Our results are consistent with previous research supporting the clinical utility of DBT. Basha et al. [13] demonstrated that DBT enhances lesion visibility, particularly in indeterminate cases, and frequently leads to changes in BI-RADS classification compared to conventional mammography. Their findings reinforce that DBT provides more detailed lesion morphology, aiding in more accurate categorization. Palpable breast lumps remain the most common presenting symptom of breast cancer and are highly associated with malignancy. Public health efforts frequently focus on awareness of this symptom to promote early evaluation [14]. In our study, most patients presented with complaints: 33.3% had a palpable mass, 20% reported both pain and a palpable mass, 16.6% had pain alone, 3.3% experienced nipple discharge, and only 6.6% were asymptomatic. The anatomical distribution of lesions revealed a predominance in the left breast (55.6%), followed by the right (29.6%) and bilateral involvement in 14.8% of cases. This distribution agrees with the findings of Babkina et al. [12], who also noted a left-sided predominance in breast lesion detection using DBT versus full-field digital mammography (FFDM). However, they did not quantify this trend. On the other hand, Mariscotti et al. [15] observed that lesion laterality did not significantly impact BI-RADS categorization, suggesting that location is relevant epidemiologically. Still, it may not influence interpretative categorization outcomes. In our study, ultrasound was used as a diagnostic adjunct in all 54 detected lesions (100%), while histopathological confirmation was obtained in 24 lesions (44.4%). This reflects standard clinical practice, where not all BI-RADS 3 lesions undergo biopsy. Regarding final diagnosis outcomes, our data revealed that 72.2% (39 lesions) were benign, with simple cysts accounting for 41% of those benign findings. These diagnoses were confirmed by ultrasound and pathology for BI-RADS categories 4, 5and some BI-RADS 3 cases, or by ultrasound alone for BI-RADS 2 and the remaining BI-RADS 3 lesions. These results reflect real-world diagnostic stratification where not all indeterminate lesions warrant immediate histopathological evaluation. Our findings are consistent with the results reported by Basha et al. [13], who noted that fibrocystic changes (41.1%) and fibroadenomas (30.4%) were the most frequently encountered benign breast lesions in their study cohort. In terms of lesion detection, digital mammography (DM) identified 42 lesions, while digital breast tomosynthesis (DBT) detected 54 lesions, indicating the superior sensitivity of DBT.

Among these, most lesions were located in the left breast, 52.4% by DM and 55.6% by DBT. Furthermore, most lesions were characterized as masses, with 80.9% seen on DM and 92.6% on DBT. DBT also enhanced the visibility of lesion morphology; well-defined margins were observed in 64.7% of masses using DM, compared to 66% with DBT. These observations align with those of Romeih et al. [16], who reported that DBT improves lesion detection and enhances morphological characterization, contributing to more precise BI-RADS categorization. Similarly, Nakashima et al. [8] highlighted DBT's advantage in evaluating lesion borders, which are vital in distinguishing between benign and malignant findings. As seen in our study, enhanced margin clarity may reduce false-positive assessments and help to avoid unnecessary biopsies. Significant shifts in BI-RADS classification were observed between DM and DBT. DM categorized the majority of lesions as BI-RADS 3 (69%), followed by BI-RADS 5 (9.5%) and BI-RADS 0 (7.1%). In contrast, DBT assigned fewer lesions to BI-RADS 3 (42.6%) and a greater number to BI-RADS 5 (22.2%) and BI-RADS 2 (14.8%). This suggests that DBT tends to reclassify lesions into higher BI-RADS categories, particularly BI-RADS 4A and 5, reflecting enhanced detection of suspicious features. These findings are supported by McDonald et al. [17], who noted that incorporating DBT resulted in increased lesions being classified into higher BI-RADS categories, improving diagnostic clarity and follow-up decision-making. Basha et al. [13] also confirmed that DBT is beneficial in refining BI-RADS assignments in indeterminate lesions. When comparing benign versus malignant categorization, DM identified 71.4% of lesions as benign and 28.6% as malignant. In contrast, DBT classified 74.1% of lesions as benign and 25.9% as malignant. These results suggest that while both modalities are comparable in identifying malignant lesions, DBT offers slight improvements in lesion discrimination, likely due to enhanced resolution and 3D imaging depth. Naeim et al. [18] also found DBT was effective in differentiating benign from malignant lesions with greater visual detail. However, Ezeana et al. [19] reported that DBT, while more sensitive to malignancies, might detect fewer benign lesions than conventional mammography, depending on lesion characteristics and patient-specific variables. Finally, substantial BI-RADS category changes were observed when comparing DM and DBT. Lesions initially were graded as BI-RADS 0 by DM and were upgraded by DBT to BI-RADS 2 (1.9%), 3 (1.9%), or 4C (1.9%). Among BI-RADS 3 lesions on DM, several were reclassified to BI-RADS 4A (5.6%), 4C (5.6%), or 5 (9.3%) on DBT. A few BI-RADS 3 lesions (9.3%) were also downgraded to BI-RADS 2. DBT left 24.1% of lesions unchanged but also upgraded two BI-RADS 4C lesions to BI-RADS 5 (3.7%) and downgraded two BI-RADS 5 lesions to BI-RADS 3 and 4C (3.7% each). This shift pattern closely resembles findings from Basha et al. [13], who demonstrated that DBT could lead to both upward and downward reclassification of BI-RADS categories, reflecting improved lesion evaluation. Likewise, Hassan et al. [20] found that DBT enhanced classification accuracy, especially for BI-RADS 4 lesions, allowing more appropriate clinical follow-up or intervention. Our results are consistent with several prior investigations that examined the impact of digital breast tomosynthesis (DBT) on BI-RADS classification. Basha et al. [13] demonstrated that DBT could both upgrade and downgrade BI-RADS categories, noting that some lesions initially assessed as BI-RADS 3 or 4 on digital mammography were reclassified to BI-RADS 5 or downgraded to BI-RADS 1 when re-evaluated with DBT. These observations align with our findings, where several BI-RADS 3 lesions were upgraded to BI-RADS 5, reinforcing the improved lesion visibility and characterization offered by DBT. Similarly, Hassan et al. [20] reported that DBT frequently altered BI-RADS assessments in both directions, particularly within category 4 lesions. Their findings indicated that DBT's enhanced tissue resolution enabled more

precise evaluation of lesion morphology, resulting in reclassification of cases originally interpreted as BI-RADS 4C on DM to BI-RADS 5, consistent with our study's outcomes. However, it is noteworthy that not all literature supports the same degree of impact. For example, Mariscotti et al. [15] found that although DBT improved lesion detectability, the change in BI-RADS categorization was less pronounced, especially for lesions initially categorized as BI-RADS 4A. This contrasts with our data, where many lesions underwent categorization changes following DBT assessment, suggesting that DBT may provide more diagnostic clarity in ambiguous cases. Regarding diagnostic performance, our study found that BI-RADS category 5, when assigned via DBT, was highly predictive of malignancy, yielding a sensitivity of 90.9%, specificity of 91.1%, and an overall diagnostic accuracy of 92.4%. These findings strongly support DBT as an effective modality for differentiating between benign and malignant breast lesions. Our results are consistent with those of Alabousi et al. [21], who conducted a comprehensive systematic review and meta-analysis on DBT's diagnostic performance. They reported high sensitivity and specificity for breast cancer detection, confirming that DBT enhances diagnostic accuracy and supports integration into routine clinical practice. Similarly, Naeim et al. [18] evaluated the use of BI-RADS scoring with DBT and FFDM and found comparable diagnostic indices, reinforcing the reliability of DBT in lesion stratification. Furthermore, our study's combined use of digital mammography (DM) and DBT yielded even stronger diagnostic performance: a sensitivity of 91%, a specificity of 100%, and an overall accuracy of 93.5%. These results suggest a synergistic benefit when the two imaging modalities are applied together, maximizing diagnostic yield while minimizing false positives. These observations align with those reported by Alabousi et al. [21], who found that combining DBT with DM significantly increased sensitivity and specificity compared to DM alone, making it a superior approach in clinical screening and diagnostic workflows. Similarly, Naeim et al. [18] demonstrated that combined imaging approaches enhanced lesion detection and improved confidence in BI-RADS classification, which mirrors the improved accuracy demonstrated in our findings. In a study by Safwat et al. [22], the addition of DBT to conventional mammography for BIRADS III–IV lesions significantly enhanced diagnostic performance, with sensitivity, specificity, PPV, NPV, and accuracy improving from around 60% with digital mammography alone to over 90% with DBT. These findings closely parallel to ours, as DBT in our study achieved a sensitivity of 90.9%, specificity of 91.1%, and diagnostic accuracy of 92.4%. Future research should be done to validate these findings in larger, multi-center cohorts to enhance generalizability and minimize selection bias. Additionally, studies integrating DBT with emerging imaging modalities and artificial intelligence-assisted interpretation may improve diagnostic accuracy and workflow efficiency. It is also important to note that the study does not recommend the use of mammography or digital breast tomosynthesis (DBT) for patients in their twenties, as it is not aligned with current screening guidelines and may not be appropriate for this age group.

CONCLUSIONS

Tomosynthesis improves the detection and assessment of masses, asymmetries, and micro-calcifications, enhancing lesion characterization and malignancy assessment. Its use in screening reduces biopsy rates and enables earlier cancer detection. The findings of this study advocate for the use of DBT as a primary modality for breast cancer screening.

Limitations:

The relatively small sample size of 30 patients may limit the generalizability of the findings. Additionally, being a single-center study conducted within a university hospital setting may introduce selection bias, particularly since some patients in their late twenties were included after being referred for diagnosis, even though screening by mammogram or

tomosynthesis at that age is not typically recommended.

Availability of Data:

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request. Author Contribution: N.M.S.M.A. was responsible for the study's conception and design, data collection, image interpretation, and drafting the initial manuscript. E.F.T. supervised the research process, contributed to the study design and interpretation of results, and provided critical revisions to the manuscript. A.A.B. assisted in supervision, methodology guidance, and manuscript review, ensuring the integrity of the imaging analysis. A.G.I. supported data analysis, conducted the literature review, contributed to editing, and provided expertise in radiological assessment.

Conflict of interest

None

Financial disclosure

None

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Table S1: Age of studied patients (N=54).

Variable	Value	
Age (Yrs) (Mean±SD)	45.88±13	
Age groups	**Frequency**	**Percentage**
20-<=30	6	20
31-<=40	8	26.7
41-<=50	7	23.3
51-<=60	6	20
61-<=70	3	10
Total	30	100

Citation

Amer, N., Tantawy, E., Besar, A., Ibrahim, A. Role of Digital Tomosynthesis in Changing the BIRADS Categorization of Mammographically Detected Breast Lesions. *Zagazig University Medical Journal*, 2025; (5090-5103): -. doi: 10.21608/zumj.2025.406397.4069