Current Science International
Volume: 13 | Issue: 01| Jan. - March| 2024

EISSN:2706-7920 ISSN: 2077-4435
DOI: 10.36632/csi/2024.13.1.13
Journal homepage: www.curresweb.com
Pages: 164-178

The Diagnostic Efficacy of Digital Breast Tomosynthesis Comparing with Full-Field Digital Mammography in screening in Women with Dense Breast Using BI-RADS Scoring

Sarah G. Elsayed, Hanan A. N. M. Saleh, Maha H. Helal and Mohammad H. R. Elshafey

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

Received: 05 Feb. 2024 **Accepted: 07** Mar. 2024 **Published: 14** Mar. 2024

ABSTRACT

Background: Mammography stands as the predominant breast screening method, having demonstrated efficacy in lowering mortality associated with breast cancer. However recent research has uncovered the constraints of mammography, particularly in women with breast tissue characterized by high density. Digital Breast Tomosynthesis (DBT) involves reconstructing tomographic images from various projections captured at different angles. This method enables the creation of 3D data, minimizing tissue overlap and enhancing the assessment of masses, architectural distortion, and asymmetries when compared to conventional two-dimensional mammographic images. **Objective:** is to evaluate the diagnostic efficacy of 3D digital breast tomosynthesis in screening of breast cancer. **Patients and methods:** Prospective study for 50 women with dense breast who presented to radiodiagnosis and medical imaging department at the National Cancer Institute for screening purposes between march 2019 to march 2021 with mean age 43.5 ± 5.4. Mammography and Digital breast tomosynthesis were done for all patients. Lesions were evaluated on DM; DBT alone then combined DBT & DM. Comparison of results according to changes in BIRADS, diagnostic performance using histopathology as gold standard. **Results:** 50 women with dense breast underwent conventional mammography that detected (12 asymmetry, 26 masses, 4 micro calcifications), Tomosynthesis reduced the BIRADS 3 count by 39%, upgraded the count of BIRADS 4 lesions by 27.2% with consequent improvement of sensitivity and specificity, PPV, NPV and accuracy to 97%, 90%, 97%,90%, and 96%. **Conclusion:** DBT improved the diagnostic performance and proper BIRADS categorization in evaluation of the lesions in dense breast.

Keywords: Mammography, predominant breast, breast cancer, Digital Breast Tomosynthesis (DBT)

1. Introduction

Breast cancer in women is a major public health problem throughout the world. It is the most common cancer among women in both developed and developing countries (Zeeneldin *et al.,* 2013). Efforts to promote early diagnosis are a necessary prerequisite to population-based screening, as early diagnosis will improve outcomes for all breast cancer patients (Greenwood *et al.,* 2018).

Film-screening mammography was the gold standard in breast cancer imaging (Boyd *et al.,* 2007). It was responsible for a reduction in mortality among the age group of 40 years or older (Tabar *et al.,* 2011). Initially, screen-film mammography was done, but today, the most common two-view examination (mediolateral oblique and craniocaudal) using full-field digital mammography (FFDM) used, searching for any mass, architectural distortion, or calcification, and then giving BIRADS score (Lewin and Niklason, 2007).

Full-field digital mammography (FFDM) has limited sensitivity for breast cancer detection in denser breasts (Nazari and Mukherjee, 2018). Studies have demonstrated low breast cancer detection rates in women who screened with digital mammography, especially those with extremely dense parenchyma (Phi *et al.,* 2018; Iranmakani *et al.,* 2020). Dense breasts women have a higher risk of developing breast cancer (Thigpen *et al.,* 2018)

Corresponding Author: Sarah Gamal Elsayed, Department of Radiodiagnosis, Faculty of Medicine, Tanta University, Egypt.

Advances in full-field digital mammography (FFDM) led to the development of digital breast tomosynthesis which is a three-dimensional breast examination. The multi-view information from the multiple low-dose images used to generate thin slices (at 1-mm spacing) that viewed sequentially as a stack in orientation, e.g., craniocaudal, mediolateral oblique with the potential to improve accuracy by improving differentiation between malignant and non-malignant lesions with the potential to improve accuracy by improving differentiation between malignant and non-malignant lesions (Chong *et al.,* 2019). The additional information obtained from the tomosynthesis acquisition decreases the confounding effect of overlapping tissue, allowing for improved lesion detection, characterization, and localization (Basha *et al.,* 2020).

The study aims to evaluate the impact of digital breast tomosynthesis (DBT) in comparison to full-field digital mammography in improving the detection and characterization of different breast lesions and interpretations of BIRADS scoring in the dense breasts at different age groups.

2. Patients and Methods

This prospective study was conducted on a selected group of 50 females referred to radiodiagnosis and medical imaging department at the National Cancer Institute for breast cancer screening during the period from march 2019 to march 2021.

2.1. Inclusion criteria

1. Females above the age of 40 years who are legible for screening mammography.
2. Females below 35 years with family history of breast cancer.
3. Females who have mammographic ACR C or D.

Exclusion criteria:

1. Contraindication to mammography e.g.: pregnant women
2. Patients already diagnosed to have breast cancer.
3. Females who have mammographic ACR A or B.

2.2. Methodology

All the subjects were submitted to the following: Personal history: patient's name, age, marital status and number of offspring, lactating history, residency and phone number. Past history of any breast complains, previous breast lesions or operations and review of any previous radiological or laboratory examination. Family history of breast cancer.

2.3. Imaging

Mammographic examination was performed using Senographe Essential, GE healthcare Full Field Digital Mammography machine that was upgraded to provide 3D Digital Tomosynthesis.

2.4. Technique of Full Field Digital Mammography:

Patient prepared and was positioned in mammography unit. The breast placed on a platform and was compressed gradually by paddle. This process was repeated for the other breast. A stationery x-ray tube captures an image from the side and an image from above the compressed breast that recorded on detector. Standard views (mediolateral oblique and craniocaudal) views were taken.

2.5. Technique of 3D Tomosynthesis:

In breast tomosynthesis, the x-ray tube moves in an arc over the breast, capturing multiple images from different angles. Two views (MLO and CC) are obtained. Three Dimensional DBT involved the acquisition of twelve to fifteen 2D projection exposures by a digital detector from a mammographic x-ray source which moves over a limited arc angle. The 3D volume of compressed breast was reconstructed from the 2D projections in the form of series of images (slices) through the entire breast. Images were assessed on the workstation.

2.6. Image analysis and interpretation of Mammography and 3D Digital Tomosynthesis:

Two experienced readers independently viewed and interpreted FFDM, synthetic 2D, and DBT. Breast density was assessed bilaterally for each patient. Each breast was evaluated about the presence of lesion or not. Each lesion was evaluated regarding site, type (mass, focal asymmetry ± calcifications). Lesions were classified as benign or malignant according to the mammography BI-RADS lexicon morphology descriptors:

- Mass lesions: shape, margin, density.
- Asymmetry: simple, focal, global or developing.
- Calcifications: morphology and distribution.

We determined the BI-RADS category (table 1) of the lesions in each of the 2 imaging modalities individually according to the BI-RADS lexicon 2013 classification, guided by the results of mammographic findings but blind to final histopathology results. Any detected lesions were compared with available histopathology.

Table 1: BIRADS assessment categories according to BIRADS atlas 2013 (Bernardi *et al.,* 2014).

Category	Assessment
BI-RADS 0	Incomplete – Need additional imaging evaluation and/or prior mammograms for comparison
BI-RADS 1	Negative
BI-RADS 2	Benign
BI-RADS 3	Probably benign
	Suspicious
BI-RADS 4	4A: Low suspicion for malignancy
	4B: Moderate suspicion for malignancy
	4C: High suspicion for malignancy
BI-RADS 5	Highly Suggestive of malignancy
BI-RADS 6	Known biopsy-proven malignancy

2.7. Statistical Analysis

The collected data were coded, computed and analyzed using the SPSS (Statistical Package for Social Sciences) version 25 for Windows® (IBM SPSS Inc, Chicago, IL, USA).

Descriptive statistics

Qualitative data: were presented by frequency tables (Number and percentages).
Quantitative variables: the normality of data was first tested with kolmogorov smirnov test and presented data by central indices and dispersion:
Mean ± Standard deviation (SD) for normally distributed variables.
Median (minimum – mximum) for non-normally distributed variables.

Analytical statistics:

Chi-square test was used to test association between categorical variables. It was replaced by Fisher Exact Test when the expected cell count was less than 5 in four-cells tables, while was replaced by Monte Carlo test when the expected cell count was less than 5 in more than four-cells tables.

Independent samples t-test (student t- test) was used to test association between normally distributed continuous variables in 2 independent groups.

The diagnostic ability of quantitative variable in prediction of categorical outcome was calculated.

Level of significance:

For all above mentioned statistical tests, the results were considered significant if P-value <0.05.

3. Results

This prospective study included 50 female subjects legible for screening mammography. Their ages ranged from 35 - 65 years with a mean age of 43.5 ± 5.4 (mean ± SD). The majority of them (31 females; 62%) were at the age group from 40 years to 50 years.

By fisher extract test, there was no significant correlation between final outcome of the studied females and their ages or breast density (table 2) and (table 3).

Table 2: Age distribution of the studied females (n=50).

Age (years)	N. (%)
>30 –40	14(28%)
>40 – 50	31(62%)
>50 – 60	3 (6%)
>60	1 (2%)
Mean ± SD	43.5 ± 5.4
Min.-Max.	35 – 64

Table 3: Association between final outcome and breast density of the studied females (n=50).

	Non-malignant (n= 41)	Malignant (n= 9)	Test of significance
ACR- C	33 (80.5%)	8 (88.9%)	FET
ACR- D	8 (19.5%)	1 (11.1%)	P= 0.68

Data expressed as number (%). FET: Fisher's Exact Test. P: p-value, not significant: if p > 0. 05

All the studied females were subjected to full field digital mammography and 3D tomosynthesis followed sonographic examination or histopathological correlation or combination of both which were accepted as a standard reference and revealed 41 females with non-malignant (25 females revealed benign findings and the other 16 females revealed no abnormal findings) and 9 females had malignant lesions.

Density of the breast was evaluated and reported according to breast imaging reporting and data system 2013. Nine females (18%) were reported as ACR D and 41 females (82%) were reported as ACR C (Fig. 1).

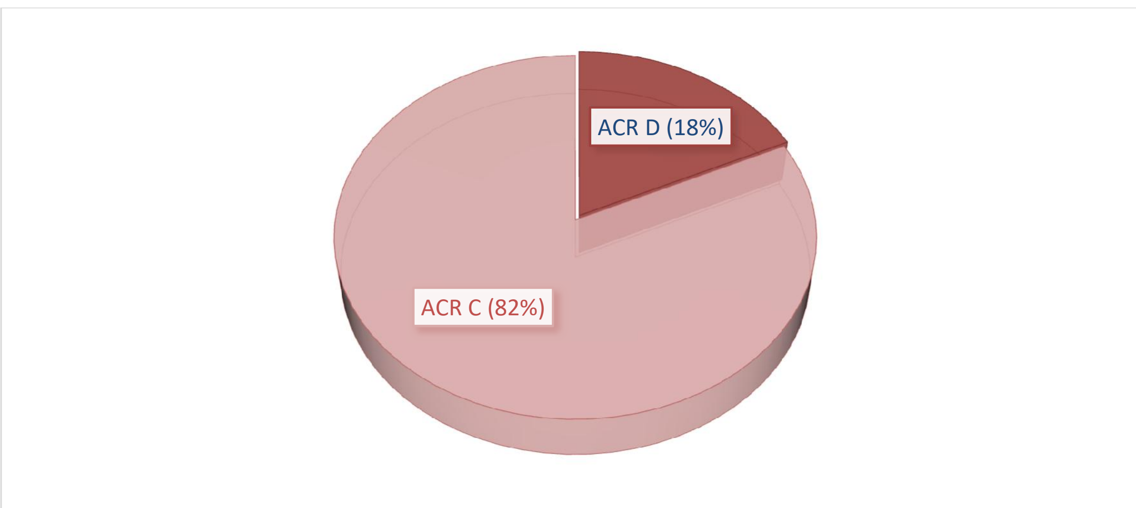

Fig. 1: Breast density of the studied females (n=50).

Regarding 2D mammography, no abnormal findings were detected in 6 females (16%) while abnormal mammographic findings were detected in 44 females (88%) including: mass lesion (26/50; 52%), asymmetry (12/50; 24%), and calcification (12/50; 24%). While by 3D tomosynthesis, no abnormal findings were detected in 10 females (20%) while abnormal finding were detected in 40 females (80%) including: mass lesion (38/50; 76%), asymmetry (0/50; 0%) [(5/50; 10%) cases were proved to be simple overlap while the other (7/50; 14%) cases were proved to be mass lesions], calcifications 13/50 (26%) (Fig. 2).

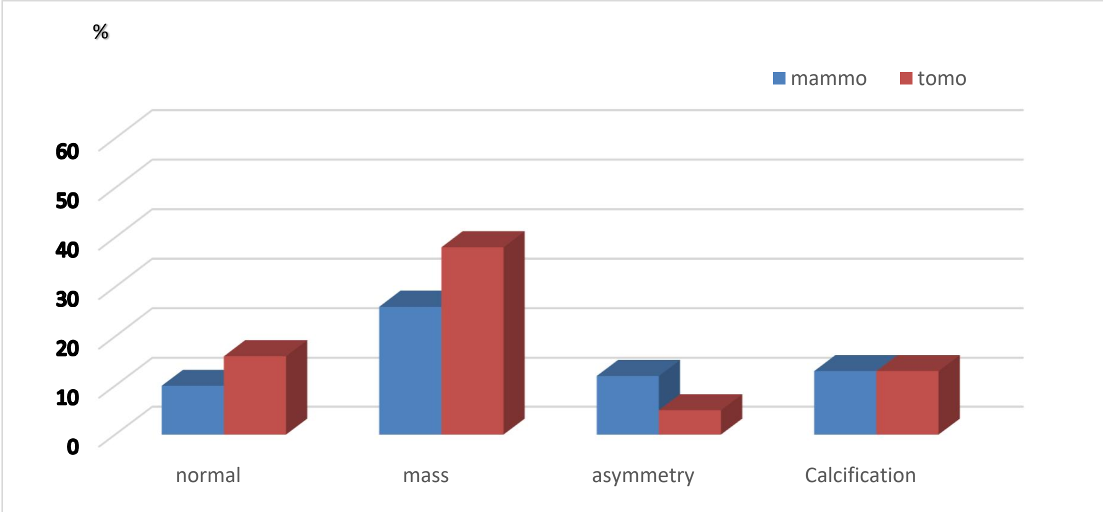

Fig. 2: 2D mammographic and 3D tomosynthesis findings in the studied females (n=50).

Regarding the criteria of masses detected by 2D mammography, the margins of the masses were circumscribed in 7 females (14 %), obscured in 15 females (30%), speculated in 2 females (4%) and indistinct in 2 females (4%). While in tomosynthesis, the margins were circumscribed in 27 females (54%), obscured in 1 female (2%), speculated in 6 females (12%), indistinct in 3 females (6%) and microlobulated in 1 female (2%) (table 4) and (Fig. 3).

Table 4: Mass margin characterization by 2D mammography and 3D tomosynthesis in the studied females (n=50).

Mass margin	Mammography	Tomosynthesis	Test of significance
Circumscribed	7 (14%)	27 (54%)	MC= 33.2 P= 0.001*
Obscured	15 (30%)	1 (2%)	
Indistinct	2 (4%)	3 (6%)	
Micro-lobulated	0 (0%)	1 (2%)	
spiculated	2 (4%)	6 (12%)	

Data expressed as number (%). MC: Monte Carlo test. P: p-vlaue *: significant if p ≤ 0.05.

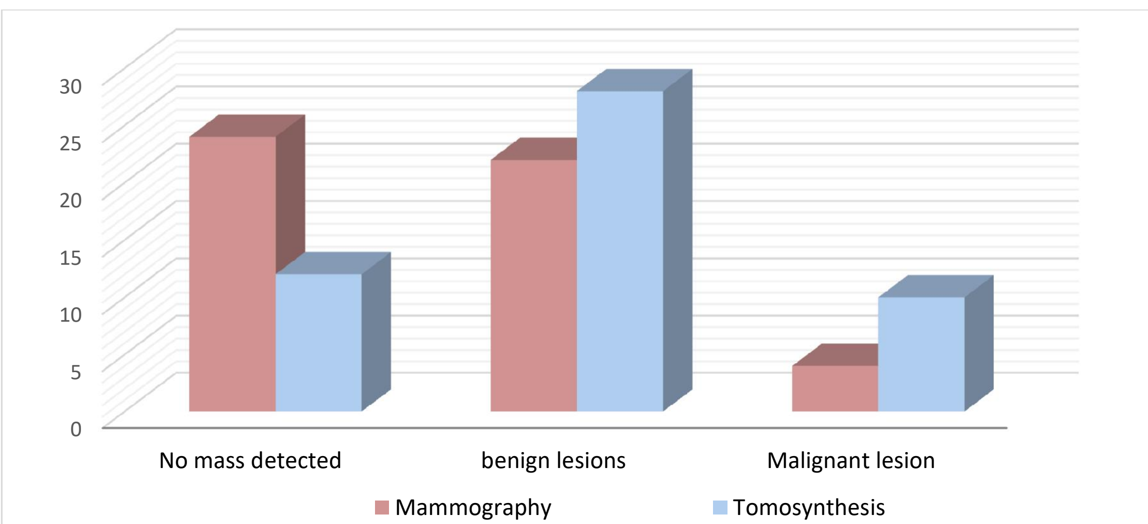

Fig. 3: Mass margin characterization by 2D mammography and 3D tomosynthesis in the studied females (n=50).

The shape of the masses, as detected by 2D mammography, was either rounded in 11 females (22%), oval in 10 females (20%), multiple ovals in in 1 female (2%) and irregular in 4 females (8%). While by 3Dtomosynthesis, it was round in 11 females (22%), oval in 16 females (32%), multiple ovals in 4 females (8%) and irregular in 7 females (14%) (table 5) and (Fig. 4).

Table 5: Mass shape characterization by 2D mammography and 3D tomosynthesis in the studied females (n=50).

Mass shape	Mammography	Tomosynthesis	Test of significance
Oval	10 (20%)	16 (32%)	
Multi oval	1 (2%)	4 (8%)	MC=44.1
rounded	11 (22%)	11 (22%)	P ≤ 0.001*
irregular	4 (8%)	7 (14 %)	

Data expressed as number (%). P: p-value *: significant: p ≤ 0.05. MC: Monte Carlo.

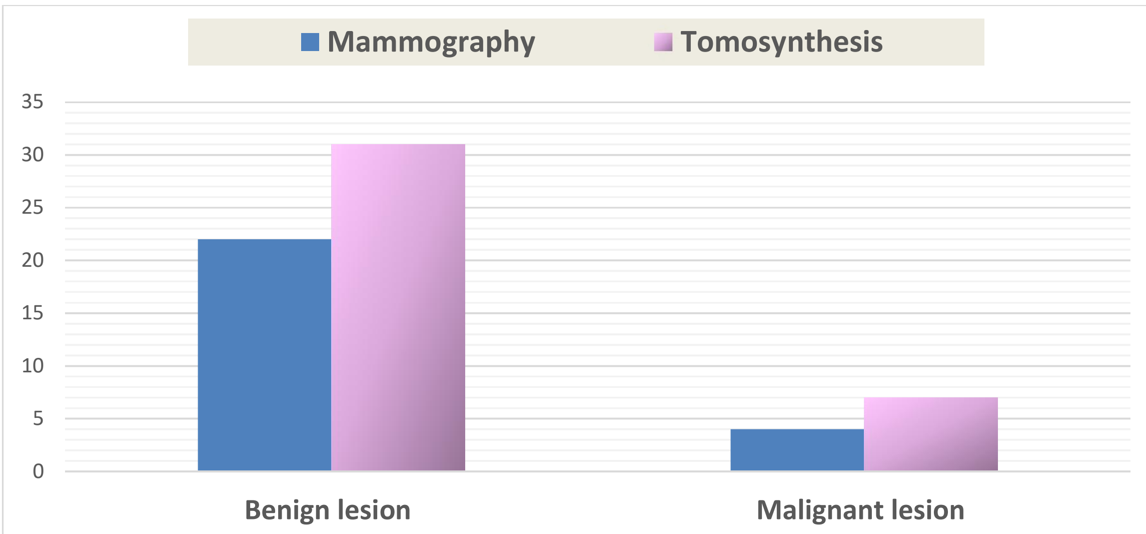

Fig. 4: Difference between mass shape characterization by 2D mammography and by 3D tomosynthesis in the studied group.

Calcification was detected in 12 of the studied females in both 2D mammography and 3D tomosynthesis. It was fine pleomorphic calcification suggesting malignancy in 2 females (4%), punctate calcification in 6 females (12%), round calcification in 3 females (6%), and popcorn calcification in 4 females (8%) (table 6).

Table 6: Calcification according to 2D mammography and 3D tomosynthesis in the studied females (n=50).

Calcification morphology	Mammography	Tomosynthesis
Punctate	6 (12%)	6 (12%)
Popcorn	4 (8%)	4 (8%)
Round	3 (6%)	3 (6%)
Fine pleomorphic	2 (4%)	2 (4%)

Depending on the described 2D mammographic findings, the studied females were categorized according to BIRADS category into BIRADS 0 in 5 females (10%), BIRADS I in 7 females (14%), BIRADS II in 2 females (4%), BIRADS III in 23 females (46%), BIRADS IV in 11 females (14%) and BIRADS V in 2 females (4%). There was no significant correlation between breast density and 2D mammographic BIRADS as illustrated at (table 7), and significant association between 2D mammographic BIRADS and final outcome of the studies females as (table 8).

Table 7: Association between breast density and 2D mammographic BIRADS in the studied females (n=50).

BIRADS	N (%)	ACR-C (n=41)	ACR-D(n=9)	Test of significance
BIRADS 0	5 (10%)	2 (4%)	3 (33.3%)	
BIRADS I	7 (14%)	6 (14%)	1 (11.1%)	
BIRADS II	2 (4%)	2 (4%)	0	MC= 6.5
BIRADS III	23 (46%)	19 (46%)	4 (44.4%)	P= 0.22
BIRADS IV	11 (14%)	10 (24%)	1 (11.1%)	
BIRADS V	2 (4%)	2 (4 %)	0	

Data expressed as number (%). P: p-value not significant: p > 0.05. MC: Monte Carlo test.

Table 8: Association between final outcome and 2D mammography BIRADS in the studied females (n=50).

BIRADS	Non-malignant (n=41)	Malignant (n=9)	Test of significance
BIRADS 0	5 (12%)	0(0%)	
BIRADS I	7 (17%)	0	
BIRADS II	2 (4%)	0	MC= 13.4
BIRADS III	22 (55%)	1 (11.1%)	P= 0.02*
BIRADS IV	8 (19.5%)	3 (33.3%)	
BIRADS V	1(2%)	1 (2%)	

Data expressed as number (%). *: significant: p ≤ 0.05. MC: Monte Carlo test.

According to 3D tomosynthesis findings and BIRADS category; 10 females were BIRADS I, 27 females were BIRADS II, 3 females were BIRADS III, 5 females were BIRADS IV and 5 females were BIRADS V. There was no significant correlation between breast density and 3D tomosynthesis as illustrated at table (9), and strong significant correlation between 3D tomosynthesis BIRADS and final outcome as (table 10).

Table 9: Association between breast density and 3D tomosynthesis BIRADS in the studied females (n=50).

BIRADS by tomosynthesis	N (%)	ACR-C (n=41)	ACR-D(n=9)	Test of significance
BIRADS I	11 20%)	4 (9%)	1 (11.1%)	
BIRADS II	27 54%)	21 (51.2%)	6 (66.7%)	MC= 2.3
BIRADS III	2 (4%)	2 (4%)	1 (11.1%)	P= 0.77
BIRADS IV	2 (4%)	2 (4%)	0	
BIRADS V	8 (16%)	7 (17%)	1 (11.1%)	

Data expressed as number (%). P: p-value not significant: p > 0.05. MC: Monte Carlo test.

Table 10: Association between final outcome and 3D tomosynthesis BIRADS in the studied females (n=50).

BIRADS by tomosynthesis	Non-malignant (n=41)	Malignant (n=9)	Test of significance
BIRADS I	10 (24.4%)	0	
BIRADS II	27 (65.9%)	0	MC= 44.6
BIRADS III	3 (7.3%)	0	P= 0.001*
BIRADS IV	1 (2.4%)	4 (44.4%)	
BIRADS V	0	8 (88%)	

According to these findings, the difference between BIRADS categorization of the studied females depending on 2D tomography and 3D tomosynthesis findings (table 11).

Table 11: Difference between BIRADS by 2D mammography and by 3D tomosynthesis in the studied group (n=50).

BIRADS	Mammography	Tomosynthesis	Test of significance
BIRADS 0	5 (10%)	0	
BIRADS I	7 (14%)	11 (20%)	
BIRADS II	2 (4%)	27 (54%)	MC= 51.9
BIRADS III	23 (46%)	2 (4%)	P ≤ 0.001*
BIRADS IV	11 (22%)	2 (4%)	
BIRADS V	2 (4%)	8 (16%)	

Data expressed as number (%). MC: Monte Carlo test. P: p-value *: significant: p ≤ 0. 05.

The diagnostic accuracy of the 2D mammography and 3D tomosynthesis for the study based statistical analysis is shown at (table 12).

Table 12: Diagnostic indices of 2D mammography versus 3D tomosynthesis in the studied females (n=50).

	Mammography	**Tomosynthesis**
PPV %	83.3%	97.4%
NPV %	30%	90.9%
Sensitivity %	64.1%	97.4%
Specificity %	54.5%	90.9%
Accuracy %	62%	96%

Case Presentation

Case 1:

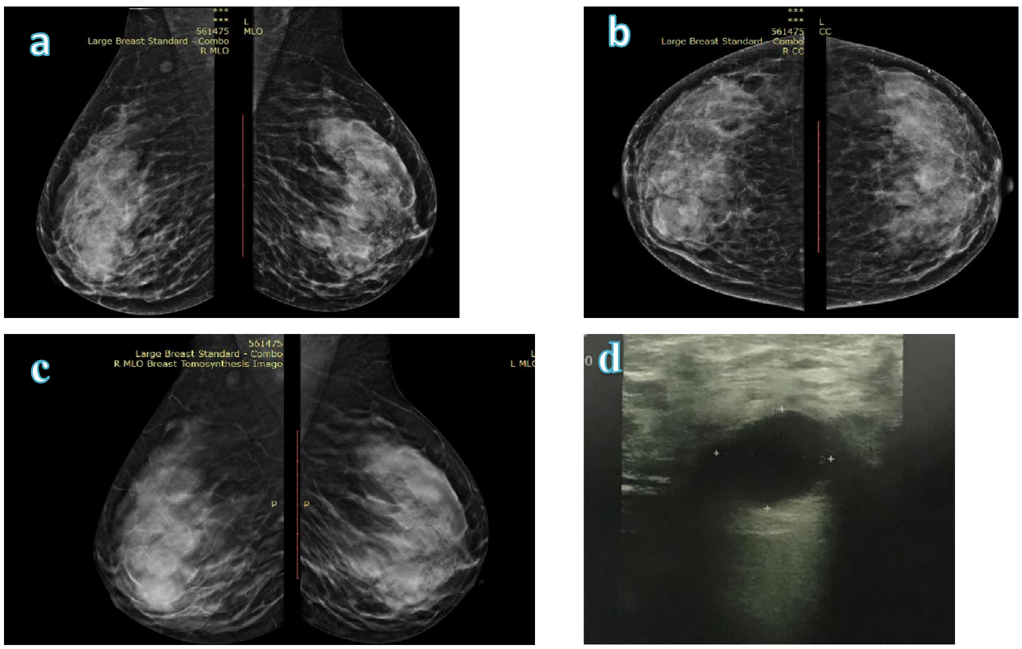

Fig. 5: (a) Craniocaudal, (b) mediolateral oblique DM images of both breasts revealed bilateral heterogenous dense parenchyma (ACR C) and bilateral diffuse nodular increased density with obscured margin (BIRADS III). (c) Thin cuts tomosynthesis revealed bilateral multiple well circumscribed oval and rounded lesions surrounded by a radiolucent halo confirming the benign nature (BIRADS II). (d) Ultrasound showed a well-defined anechoic simple cyst.

Case 2:

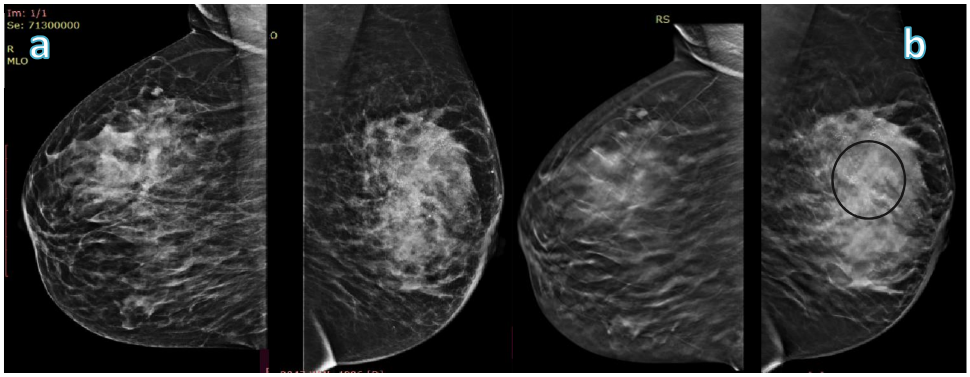

Fig. 6: (a) bilateral mammography MLO views revealed bilateral heterogenous dense parenchyma (ACR C) and left central asymmetry (yellow circle) with bilateral fine calcification (BIRADS IV). (b) bilateral tomosynthesis MLO views revealed central irregular dense mass lesion with fine calcification (BIRADS V). US guided core biopsy was performed and revealed infiltrating ductal carcinoma

Case 3:

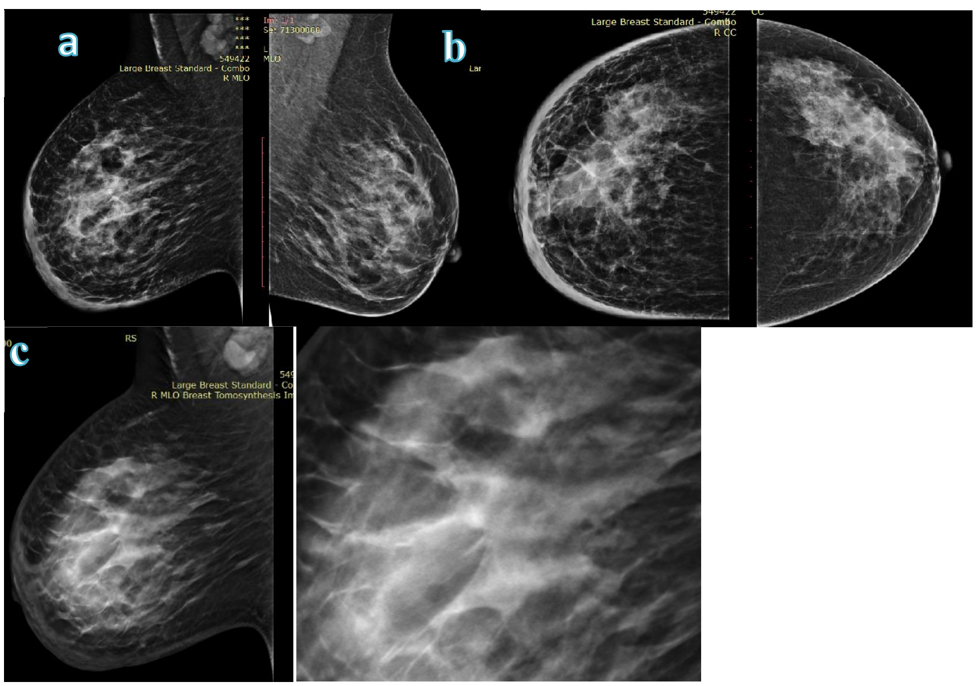

Fig. 7: (a) MLO views and (b) Craniocaudal views revealed bilateral heterogenous dense parenchyma (ACR C) and right breast revealed generalized increase in skin thickness, edema pattern and asymmetry (BIRADS IV), (c) tomosynthesis MLO view revealed right side central irregular spiculated dense lesion with better determining for mass size (BIRADS V) US guided biopsy was performed and revealed invasive ductal carcinoma.

4. Discussion

Breast cancer screening is used to identify women with asymptomatic cancer with the goal of enabling women to undergo less invasive treatments that lead to better outcomes, ideally at earlier stages and before the cancer progresses (Autier and Boniol, 2018).

Mammography remains the method of choice for breast imaging. In the field of Mammography too, significant technical improvements were realized, mainly owing to the introduction of Digital

Mammography. Even though the diagnostic accuracy of Full Field Digital Mammography (FFDM) is good, it depends heavily on breast density (Nazari and Mukherjee, 2018).

Women with extensive breast density are doubly disadvantaged as they are both at higher risk of developing breast cancer and at greater risk that cancer will not be detected because of masking of the radiological signs of cancer by increased density. While almost all cancers are visible in fatty breasts on mammogram, only half may be visualized in dense breasts. Diagnosis of breast carcinoma can therefore be complex and requires multiple imaging modalities (Mann *et al.,* 2022).

Digital Breast tomosynthesis mammography (DBT) is one technology being developed to improve detection and characterization of breast lesions especially in women with non-fatty breasts. DBT is expected to overcome the inherent limitations of mammography caused by overlapping of normal and pathological tissues during the standard two-dimensional (2D) projections, Thus, DBT can provide better tissue visualization through the provision of 3D non-overlapped tissue information (Gao *et al.,* 2021).

The potential benefits of DBT include improvement in screening sensitivity, improvement in lesion size at detection, improvement in characterization, and decrease in recall rates. DBT may be useful in both the screening and diagnostic evaluation (Oeffinger *et al.,* 2015).

The aim of the study was to study the role of 3D Digital tomosynthesis in the screening for early detection of breast cancer.

This study included 50 females, *the* age of them ranged from 35 - 65 years with a mean age of 43.5 ± 5.4. According to American society of cancer; women aged 40 to 44 years have the option to start screening with a mammogram every year, the risks of screening as well as the potential benefits should be considered, women aged 45 to 49 years should be screened with mammography annually, women aged 50 to 54 should get mammograms every year. For women aged 55 years and older, can switch to a mammogram every other year, or they can choose to continue yearly mammograms. Screening should continue as long as a woman is in good health and is expected to live at least 10 more years (Lee *et al.,* 2017).

Different screening guidelines may be suggested for women who have risk factors such as a BRCA1 or BRCA2 mutation, who are an untested family member of someone who has a BRCA1 or BRCA2 mutation, who have a history of mantle or chest radiation which occurred before age 30 years, or who have a lifetime breast cancer risk of 20% or greater based on their family history (Lee *et al.,* 2017).

In this study, 41/50 females (82%) were reported as heterogeneously dense (ACR C) and 9/50 females (18%) were reported as extremely dense breast (ACR D).

According to American cancer society, breast density is important for two main reasons: women who have dense breast tissue have a higher risk of breast cancer compared to women with less dense breast tissue. Also, dense breast tissue makes it harder for radiologists to see cancer on mammograms (Østerås *et al.,* 2019). Many researchers had selected females with dense breasts for their studies as Østerås *et al.,* 2019; Babkina, *et al.,* 2020, and Lee *et al.,* 2015 to detect the role of tomosynthesis in diagnosing breast lesions in dense breasts.

Tomosynthesis showed that the elimination of superimposed breast tissue improves the detection of lesions hidden by dense breast parenchyma. The ability of DBT to reduce or eliminate the interpretation problems caused by overlapping breast tissue was valuable in women with dense breasts (Skaane *et al.,* 2019).

Regarding mammography findings in this study, 26/50 females (52%) presented with mass lesions; 4/26 lesions (47%) were malignant and 13/26 lesions (53%) were benign, 12/50 females (24%) presented with asymmetries, 13/50 females (24%) lesions presented with calcifications and 8/50(16%) were assigned normal.

Regarding tomosynthesis findings; 38/50 females (76%) presented with masses; 10/38 lesions (59%) were malignant and 28/38 lesions (41%) were benign, 13/50 females (26%) presented with calcifications, 5/50 females (10%) presented with asymmetries and 10/50(20%) females were assigned normal.

In a prospective study by Skaane *et al.* (2019), 24,301 women (mean age: 59.1 years) were included with 281 cancers, of which 51 were interval cancers, mammography revealed 16 (10.5%) circumscribed mass 63 (41.4%) spiculated masses, 11 (7.2%) asymmetries, 40 (36.3%) calcifications.

While Additional true-positive females identified with the addition of DBT; 15 (7.6%) circumscribed masses, 91(46%) speculated masses, 8 (4%) asymmetries, 40 (20.6%) calcifications.

Also, in a retrospective study by Mohindra *et al.* (2018) that included 164 patients with 170 pathologically proven lesions, the lesions were evaluated by using first DM alone and thereafter with addition of DBT to DM. On DM, 149 lesions were characterized mass with or without calcifications, 18 asymmetries with or without calcifications, 2 as architectural distortion, and 1 as microcalcification alone. Adjunct DBT helped in better morphological characterization of 17 lesions, with revelation of underlying masses in 16 asymmetries and one architectural distortion. Adjunct DBT was perceived to be slightly better than DM alone in 44.7% lesions, and definitely better in 22.9% lesions. Lesions showing improvement were significantly higher in heterogeneously and extremely dense breasts ($P < 0.001$).

In the current study, tomosynthesis is better in margin and shape characterization as there is no tissue overlap which will help in deciding whether the lesion shows benign or malignant morphology. Regarding the shape of the 26/50 mass lesions detected by Mammography, 22/26 were oval and rounded while 4/26 were irregular. Tomosynthesis detected 38/50 mass lesions. Thirty one out of 38 lesions showed benign shape morphology while 7/38 lesions were described as irregular three of them were missed in mammography by breast density.

Regarding the margin of the 26/50 mass lesions detected by Mammography, 22/26 masses showed benign margin morphology and 4/26 masses had malignant margin morphology. Tomosynthesis identified benign margin in 28/38 mass lesions. 10/38 showed malignant margin morphology. Three lesions showed benign margin in mammography and proved to be malignant.

Babkina *et al.* (2020) stated in a study that included 347 asymptomatic and symptomatic patients with dense breasts who underwent full-field digital mammography, digital breast tomosynthesis and hand-held full breast ultrasound that the use of tomosynthesis significantly helped in better margin evaluation and lesions characterization, consequently verified benign or malignant impression of the identified masses.

Skaane *et al.* (2019) in their prospective study that included 24,301 women, verified that the idea of using DBT is that the shape and margins of breast masses may be more clearly delineated by reducing or eliminating overlapping tissue, and the ability to distinguish superimposed tissue from breast lesions would be improved. Thus, they suggested that this new technology may improve the specificity as compared with conventional mammography.

Tomosynthesis may improve the detection of architectural distortion especially in women with heterogeneous dense breasts. Theoretically, the very thin speculations seen in architectural distortion would be expected to be more easily identified on 1mm thin slices as compared with a conventional projection mammogram Mohindra *et al.,* (2018). In this study, tomosynthesis overcame the tissue overlap in focal asymmetries and could verify if there is an underlying mass or is it only overlapped fibro-glandular tissue; mammography detected 12/50 (19%) asymmetry, 5/12 were confirmed by tomosynthesis to be only areas of overlapped fibro-glandular tissue while 7/12 females proved to have underlying mass lesion.

Skaane *et al.* (2019) in a study about the added value of tomosynthesis, suggested that digital breast mammography detect 11(7.2%) asymmetries of 281 cancers while adding 2 views tomosynthesis detect 8(4%) asymmetries.

The retrospective by Waheed *et al.* (2020) included 185 patients who underwent diagnostic mammography and tomosynthesis. A significant difference was observed with the chi-square test among BIRADS categories assigned by an additional view and digital breast tomosynthesis with a p-value of < 0.001. There was, however, a substantial agreement among additional views and tomosynthesis with a kappa value of 0.767. This suggested that tomosynthesis may be equivalent to, if not more equivalent to, additional imaging in the assessment of mammographically-detected asymmetric densities, thus improving BI-RADS classification and patient management.

Identification of increased density overlapping with calcifications using DBT is able to differentiate between benign and malignant calcifications. DBT improves the ability to differentiate between benign and malignant calcifications (Kuwabara *et al.,* 2020).

In the present study, tomosynthesis confirmed all other calcification detected by mammography. Kuwabara *et al.* (2020) in a retrospective study of 256 subjects, the presence or absence of increased density over-lapping with calcifications was evaluated in three ways: (1) assessment using FFDM alone, (2) assessment using DBT alone, and (3) assessment using both FFDM and DBT. All assessment methods revealed that malignant calcifications were significantly associated with increased density overlapping with calcifications. The highest odds ratio was achieved when evaluated using DBT alone. For segmental calcifications, they found a significant difference for malignant calcifications when evaluated using DBT alone.

Also, in the study by Juntao *et al.* (2018) stated that 305 women were underwent FFDM and DBT imaging of both breasts. Of all 305 patients with 312 calcification clusters, 226 breasts were classified as dense (ACR3–4) and the remaining 86 as non-dense (ACR1–2). The diagnostic accuracy of DBT in dense breast females was notably higher than that of FFDM (89.4% *vs* 81.9%, $\chi 2 = 4.600$, $p = .0320$). In non-dense breast females, the diagnostic accuracy of DBT was slightly higher than that of FFDM, but the difference was not statistically significant (89.5% *vs* 84.9%, $\chi 2 = 0.469$, $p = .4934$).

In this study, 3D Digital Breast tomosynthesis showed better lesion BIRADS classification and diagnosis; mammography classified 5/50(10%) females as (BIRADS 0) for further investigations, 11/50(16%) females were assigned normal (BIRADS I), 27/50 females had benign lesions (BIRADS II), 4/50 (8%) females had an indeterminate lesion (BIRADS III & IV) and 8/50(16%) were had malignant lesions (BIRADS V).

Tomosynthesis changed the identified BIRADS category in 39/50 lesions. It upgraded BIRADS IV in 7/50 lesions and downgraded BIRADS III in 14/50 lesions. Also, the 5/50 females assigned as BIRADS 0 for further assessment turned out to be either normal (BIRADS I) in 3/25 females or showed benign lesions (BIRADS II) in 3/5.

Raghu *et al.* (2016) indicated that in a retrospective study to evaluate the effect of tomosynthesis in diagnostic mammography on the Breast Imaging Reporting and Data System (BI-RADS) final assessment categories over time, found that there was an increase in the percentage of females reported as negative or benign (BI-RADS category 1 or 2) with tomosynthesis (58.7% with 2D mammography vs 75.8% with tomosynthesis at year 3, $P < .0001$). A reduction in the percentage of probably benign (BI-RADS category 3) final assessments also occurred (33.3% with 2D mammography vs 16.4% with tomosynthesis at year 3, $P < .0001$). Although the rates of BI-RADS 4 or 5 assessments did not change significantly with tomosynthesis (8.0% with 2D mammography vs 7.8% with tomosynthesis at year 3, $P = .2$).

We found in this study that tomosynthesis separates overlapping tissue in dense breast by acquisition of multiple images over limited angular range. tomosynthesis showed higher sensitivity and specificity and diagnostic accuracy than Mammography as it allows better detection of breast cancer, characterization of lesions, better margin assessment of masses and decrease false positive recall rate and superior resolution has paved way for making an accurate diagnosis.

A BIRADS category was given for each lesion according to the BIRADS lexicon, 2013; on mammography after revising the pathology results and close follow up, mammography had a sensitivity of 64.1% a specificity of 54.5%, a positive predictive value of 83.3%, a negative predictive value of 30% and diagnostic accuracy of 62%.

While on tomosynthesis and after revising the pathology results and close follow up , tomosynthesis had a sensitivity of 97.4% a specificity of 90.9%, a positive predictive value of 97.4%, a negative predictive value of 90.9% and diagnostic accuracy of 96%.

Skaane *et al.* (2019) reported the final results of their prospective population-based Oslo Tomosynthesis Screening Trial; sensitivity improved significantly when DBT was added to the screening examination from 54.1% (152 of 281) to 70.5% (198 of 281). Specificity also improved with DBT, from 94.2% (22 632 of 24 020) to 95.0% (22 811 of 24 020) for the single-reader mode. The predictive value of positive scores improved with the addition of DBT, from 9.9% (152 of 1540) to 14.1% (198 of 1407), while the predictive value of a negative score improved from 99.4% (22 632 of 22 761) to 99.6% (22 811 of 22 894).

Babkina *et al.* (2020) reported in their study, two-view DBT was compared with two-view FFDM for the detection of BC represented by mass in women with dense breasts. Analysis of the results showed that sensitivity of FFDM was 61.3% while the sensitivity of DBT was 77.4% and the Specificity of FFDM was 92.7% while the specificity of DBT was 94.9%. This showed superior sensitivity and specificity of DBT compared to FFDM, therefor, breast cancer detection in women with dense breasts can be improved by routine use of DBT.

So, the ability to scroll through the three-dimensional data set for a particular view helps in eliminating the overlap of tissues seen in two-dimensional images and better resolution of the internal contents leading to better diagnostic capabilities (Ali and Adel, 2019).

The main limitation in our study was that it was performed at a single-institution, and difficulty in follow of the patients.

4. Conclusion

Breast cancer is one of the leading causes of death in women over the age of 40 years. Breast cancer screening is used to identify women with asymptomatic cancer with the goal of enabling women to undergo less invasive treatments that lead to better outcomes, ideally at earlier stages and before the cancer progresses.

Breast imaging is currently undergoing a major change with the wide spread implementation of Full Field Digital Mammography equipment. Mammography is the best-studied breast cancer screening modality and the only recommended imaging tool for screening the general population of women.

Dense fibroglandular tissue is the most important inherent limitation of mammography due to its masking effect. FFDM is accused of having a low sensitivity because the overlapping breast tissue may hide an abnormality and this increases the number of false negative results. On the other hand, it is accused of having a low specificity because the overlapping tissues may give the impression of a false abnormality which is responsible for a large number of false positive results.

So, our study aimed at evaluating the role 3D Digital Tomosynthesis in screening and diagnosis of cancer breast in women with dense breast.

Fifty females were included in this study; their ages ranged from 35 to 65 years. They were subjected to full history taking and were evaluated by 2D Mammography (cranio-caudal and mediolateral oblique views) and 3D Digital Breast Tomosynthesis individually. Each breast was assessed for its density and for presence of any lesions.

Each lesion was assessed for its site, type (mass, focal asymmetry ± calcifications), and was assigned an independent BIRADS score for each modality. The results were studied and compared to each other and to the final outcome of the studied females according to the standard reference (histopathology, ultrasound or combination) that detected 25 females with no abnormal findings, 16 females with benign lesions, and 9 females with malignant lesions.

3D Digital Tomosynthesis resolved the problem of tissue overlap in FFDM. It enhanced the detection and diagnostic ability of FFDM.

By 2D mammography, no abnormal findings were detected in 8 females (16%), and abnormal mammographic findings were detected in 44 females (88%). While by 3D tomosynthesis, no abnormal findings were detected in 10 females (20%), and abnormal finding were detected in 40 females (80%).

According to BIRADS category, 2D mammography categorized lesions into BIRADS 0 in 25 females (50%), BIRADS I in 8 females (16%), BIRADS II in 3 females (6%), BIRADS III in 10 females (20%), BIRADS IV in 2 females (4%) and BIRADS V in 2 females (4%) with no significant correlation between breast density and 2D mammographic BIRADS, while 3D tomosynthesis detected 10 females with BIRADS I, 27 females with BIRADS II, 3 females with BIRADS III, 5 females with BIRADS IV and 5 females with BIRADS V with no significant correlation between breast density and 3D tomosynthesis.

3D Tomosynthesis in this study showed better screening performance compared to mammography with a sensitivity of tomosynthesis of 97.4%, a specificity of 90.9%, positive predictive value of 97.4%, negative predictive value of 90.9% and a diagnostic accuracy was 96% versus 2D mammography sensitivity of 64.1%, specificity of 54.5%, positive predictive value of 83.3%, negative predictive value of 30%, and diagnostic accuracy of 62%.

From these results, we concluded that Tomosynthesis enables better depiction of masses and asymmetries. It can separate overlapping tissue in dense breast by acquisition of multiple images over limited angular range.

Tomosynthesis is very useful in the screening setting due to better lesion detection and accurate description of its margins, shape and effects on surrounding structures, as well as the presence or absence of microcalcifications which can be of value in confirming or excluding the potential for malignancy of a certain lesion. Therefore, it can detect more cancers and can reduce the number of biopsies from a questionable finding seen on mammography.

Tomosynthesis has higher sensitivity, specificity and diagnostic accuracy than mammography as it allows better detection of breast cancer, decreasing false positive recall rate and superior resolution for making an accurate diagnosis.

So, we recommend using tomosynthesis as a routine investigation in the field of screening for breast cancer and also in evaluation of female patients with suspicious breast lesions for accurate diagnosis.

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