Research Paper

Diagnostic Efficacy of Digital Breast Tomosynthesis with Digital Mammography in BI-RADS IV and V Breast Lesions

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ABSTRACT:

BACKGROUND:

Breast cancer is comments type of cancer in women, and the second leading cause of death worldwide. Mammography had been the cornerstone for breast cancer diagnosis throughout the years. Digital breast tomosynthesis had been developed as an advanced method for early diagnosing a breast lesion and found to have promising results in both screening and diagnostic measures more importantly in dense and previously treated breasts.

OBJECTIVE:

To evaluate digital breast tomosynthesis (DBT) compared to digital mammography for the detection of different breast lesions and interpretations of BIRADS IV and V scoring in different breast densities.

PATIENTS AND METHODS:

A prospective cohort conducted at Oncology teaching hospital in Medical City teaching complex in Baghdad for the period of 8 months from March 2021 to November 2021, included 101 suspicious breast lesions (BIRADS IV and V) was undergone Digital mammography and Digital Breast tomosynthesis, and diagnosis confirmed with FNA cytology and/or US guided core needle biopsy.

Statistical analysis was done using IBM SPSS software version 25, statistical comparisons were performed using the Chi-square test or fisher's exact test. Significance was defined as a P value less than 0.05.

RESULTS:

The results obtained from the study regarding the diagnostic performance of each modality showed that higher sensitivity for DBT 100% in comparison to DM 69.2%, however the specificity for DBT was not measured because of absence of true negative cases as the result of the selection criteria, the accuracy of DBT was higher for ACR a (100% vs 72.7%) and c (54.5 vs 45.4%) than mammography, However, they were the same for ACR b, for ACR d we have only 2 cases.

Additionally, we found that change in BI-RADS scoring with BDT was 12/24 (50%) in dense breast categories (ACR c and d) while in fatty and scattered fibroglandular breasts (ACR a and b), it was 44/77 (57%).

CONCLUSION:

These findings indicate that tomosynthesis is superior to mammography in terms of sensitivity at all breast densities, but notably at greater densities. It is advantageous because, unlike mammography, which produces two-dimensional images, it eliminates obscuring breast tissue and provides a higher resolution of the internal breast structures. And this will result in a decrease in false positive results, recalls, and special mammographic views, as well as a decrease in radiation exposure and costs.

KEYWORDS: Breast Cancer, Mammography, Digital Breast Tomosynthesis.

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INTRODUCTION:

Breast cancer is the commonest cancer in women in the world, accounting for about 12% of all new cancers and 27% of all female cancers (1,2), in females below 50 years of age Breast cancer incidence had increased by 20%.

The pursuit of accurate and cost-effective methods to detect breast cancer early remains admirable (3).

However, full-field digital mammography (FFDM) has some limitations, such as a reduced sensitivity by as much as 50% in dense breast tissue compared to fatty breast tissue resulting from fibroglandular density, which can mask suspicious findings [4,5], and increased false positive rates due to superimposition of overlapping tissues, which can obscure masses or other important features of malignancy [6], As many as 20–30% of breast cancers can be undetected on FFDM (7). Digital breast tomosynthesis (DBT) is a three-dimensional imaging technique that has demonstrated promise for breast cancer detection. An X-ray tube moves through a limited arc angle and reconstructs the tissue based on thin slices to minimize the influence of overlapping breast structures. DBT is expected to improve mammographic sensitivity for breast cancer detection.

PATIENTS AND METHODS:

This is a prospective cohort study that was conducted at Oncology Teaching Hospital in Medical city teaching complex during a period of 8 months between March 2021 until November 2021.

The study included 99 female patients with 101 breast lesions, 2 patients with bilateral breast lesions. Those patients were referred due to breast Lumps, follow up of diagnosed breast cancer cases or diagnostic purposes. All suspicious (BIRADS IV–V) detected on either digital mammography or digital breast tomosynthesis underwent U/S guided Fine Needle Aspiration cytology or core needle biopsy with a 16 - 18G needle.

Inclusion Criteria

Female patients referred either for screening or diagnosis and categorized as BIRADS IV, V, on either DBT or DM.

Exclusion Criteria

Pregnant and Lactating women, those having breast surgeries, and female patients with obvious BIRAD I, II and III on both modalities.

Data Collection

A questionnaire was applied to all enrolled individuals to highlighten the following information:

- Menstrual and childbearing history.
- Personal and family history of breast carcinoma.
- Breast surgical history.

3D Tomosynthesis

Device used was Senoghraph Pristine manufactured by General Electrics which operates since 2020.

The breast is compressed between the breastplates, the x-ray tube was hinged in an arc range from -15° to +15° aligned in the plane of the chest wall permitting 9 low-dose projection planes (2D) for the tomosynthesis images. And as in mammography, tomosynthesis images were taken in the standard projections (mediolateral oblique and craniocaudal).

Data from the low-dose 2D images were used to reconstruct 1mm sections thickness and separated by 1mm space to form the 3D images in a fashion of series of images throughout the breast. Then the DBT is read by an experienced Radiologist.

Digital Mammography

During acquisition, the breasts compressed by breastplates for taking the standard views, which are the craniocaudal and the medio-lateral oblique views for all the participants.

The mammography taken at the time of DBT by reconstructing a 2D image (Synthetic 2D), to decrease the radiation dose to the patient, this can be found in DBT software.

Then, the findings in DM are to be reported by another specialist radiologist to prevent Bias by being affected by the Tomosynthesis reading.

Image analysis and interpretation

One experienced radiologist interpreted DM and another experienced radiologist interpreted DBT images in both CC and MLO views, each breast was examined and evaluated for the following:

- Breast densities using ACR classification.
- Lesion site.
- Type (mass, focal asymmetry, and architectural distortion).
- Margin definition.
- Presence of calcification.

The 2D mammographic images of each patient were assessed and the findings were categorized according to BIRADS, then 3D DBT images were assessed and analyzed and given BIRADS scoring. When the BIRADS are IV or V on either DBT or DM then the patient was included in the study.

When the BIRADS scoring was clearly I, II or III on these studies the patient then was excluded as mentioned in our inclusion and exclusion criteria.

All the patients then underwent complementary U/S and FNA or Biopsy were performed, and the results were registered and compared. For the 2 patients with bilateral breast lesions biopsy was done for each lesion.

And lastly, the BIRADS category were assigned to everyone according to the imaging modalities

according to the BIRADS lexicon 2013 classification.
True positive, true negative, and false positive values were obtained by further work-up including histopathological examination or follow-up.

Histopathological Examination

The final diagnosis was obtained by histopathological examination, for the lesions categorized as BIRADS IV-VI.

Statistical Analysis

The Statistical Package for Social Sciences (IBM SPSS) software version 25 was used for all statistical analyses. Observational data was presented in the form of frequencies and percentages. According to the data distribution, continuous variables were expressed as mean, standard deviation (SD), and range.
To assess the proportions of nominal/ ordinal variables in different groups, statistical comparisons were performed using the Chi-square test or Fisher's exact tests, as appropriate. Statistical significance was defined as a P value less than 0.05.
Sensitivity was measured as the proportion of malignancies that were correctly identified.

Specificity was measured as the proportion of benign diseases that were correctly identified as such. The positive predictive value (PPV) measured as the proportion of positive for malignancy tests that were true positive. Negative predictive value (NPV) was measured as the proportion of negative for malignancy tests that were true negative. The overall test accuracy was measured as the proportion of all results that were true as shown in the following formulas:
Sensitivity =True positive/ (True positive + False negative).
Specificity =True negative/ (True negative + False positive).
PPV=True positive/ (True positive +False positive).
NPV=True negative/ (True negative + False).
Accuracy= (True positive + True negative)/grand total.

RESULTS:

PATIENT'S DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

The patients' age ranged between 27-85 years with a mean of 53.33 years and a stander deviation of ±10.79 year. Most of the patients (43.4%) were in the age category of (50-59) year (Table 3-1). The vast majority were married and only 8.1% were nulliparous. History of hormone consumption was reported by 35.4%.

Breast composition and radiological diagnosis.

ACR b density was the dominant composition in patients between 50 and 59 years old, whereas ACR c was seen more in patients younger than 40 years, as shown in (Figure 1).

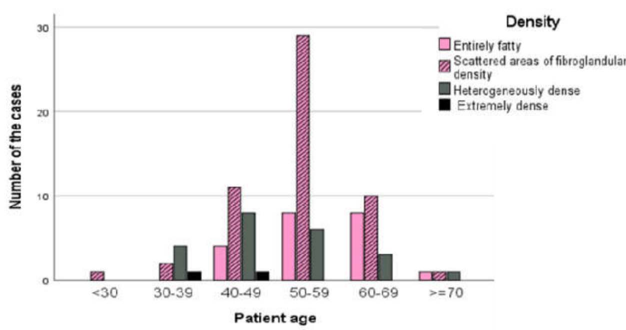

Figure 1: The distribution of breast density among age groups.

When the diagnostic BIRADS categories of DM and DBT compared for each ACR density group, three out of 22 patients with ACR a were upgraded from BIRIDS III by DM to BIRDAS IV by DBT and one patient was downgraded from BIRADS (DM) V to BIRADS (DBT) IV. In patients with ACR b, all BIRADS II (4/55) and III (23/55) in DM were upgraded to BIRADS IV, five (21.7%) of those in BIRDAS III were given IVc in the DBT. There was also 8 (38.1%) of BIRADS IV cases which were upgraded by DBT to BIRADS V and one downgraded to BIRADS III. In ACR c density, all cases in BIARSD II and III (DM) were upgraded to BIRADS IV by DBT, 50% of which as IVa but there was also 2 cases in BIRADS V (DM) were downgraded to BIRADS IV and one in BIRADS IV downgrade to III by DBT.

In ACR d, the two cases in BIRADS II and III (DM) were upgraded to BIRADS IVa by DBT as shown in (Table 1).

Table 1: Comparison between lesions categorization by DM and DBT in different breast density.

Density	DM				DBT			Total
	II No (%)	III No (%)	IV No (%)	V No (%)	III No (%)	IV No (%)	V No (%)	
A	0	3 (13.6)	8 (36.4)	11 (50)	0	12 (54.5)	10 (45.5)	22
B	4 (7.3)	23 (41.8)	21 (38.2)	7 (12.7)	1 (1.8)	39 (70.9)	15 (27.3)	55
C	1 (4.5)	8 (36.4)	8 (36.4)	5 (22.7)	1 (4.5)	18 (81.8)	3 (13.6)	22
D	1 (50)	1 (50)	0	0	0	2 (100)	0	2
Total	6	35	37	23	2	71	28	

Diagnostic performance of DM and DBT

As (Table 2) depicts, the true positive cases diagnosed by DM were 45 out of 65 malignant cases with a sensitivity of 69.2% compared to 100% sensitivity of DBT and a PPV of 75% and 65.7% respectively. There were 21 true negative cases diagnosed by DM as BIRADS II and III out of 36 benign cases giving the test a specificity of 58.3%. Although all the lesions categorized as BIRADS III by DBT were benign the number was very small due to the inclusion criteria, and hence the specificity of DBT was only 5.9%. The NPPV of DM and BDT were 51.2% and 100% respectively. The accuracy of both modalities was comparable. When the diagnostic performance of each modality was evaluated for different breast densities, the accuracy of DBT was higher for ACR a (100% vs. 72.7%) and c (54.5 vs 45.4%) than DM as shown in (Table 3-6). However, they were the same for ACR b. No malignant cases were diagnosed in ACR d, hence validation values cannot be generated. (Table 3)

Table 2: Diagnostic performances and indices for FFM and DBT.

		Cytological diagnosis	
		Malignant No (%)	Benign No (%)
Digital mammography	BI-RAD IV& V	45 (69.2%)	15 (41.7%)
	BI-RADS II & III	20 (30.8%)	21 (58.3%)
	Total	65	36
	Sensitivity Specificity PPV NPV Accuracy	69.2% 58.3% 75% 51.2% 65.3%	
Digital breast tomosynthesis	BIRAD IV& V	65 (100%)	34 (94.4%)
	BIRADS II & III	0	2 (5.6%)
	Total	65	36
	Sensitivity Specificity PPV NPV Accuracy	100% 5.6% 65.7% 100% 66.3%	

Table 3: Diagnostic performance of DM and DBT in ACR density groups.

	Sensitivity (%)		Specificity (%)		PPV (%)		NPV (%)		Accuracy (%)	
	DM	DBT	DM	DBT	DM	DBT	DM	DBT	DM	DBT
ACR a (n=22)	88.2	100	20	100	78.9	77.3	33.3	22.7	72.7	100
ACR b (n=55)	64.9	100	77.8	5.6	85.7	68.5	51.9	100	69	69
ACR c (n=22)	54.5	100	36.4	9.1	54.5	52.4	44.4	100	45.4	54.5
ACR d (n=2)	-	-	-	-	-	-	-	-	-	-

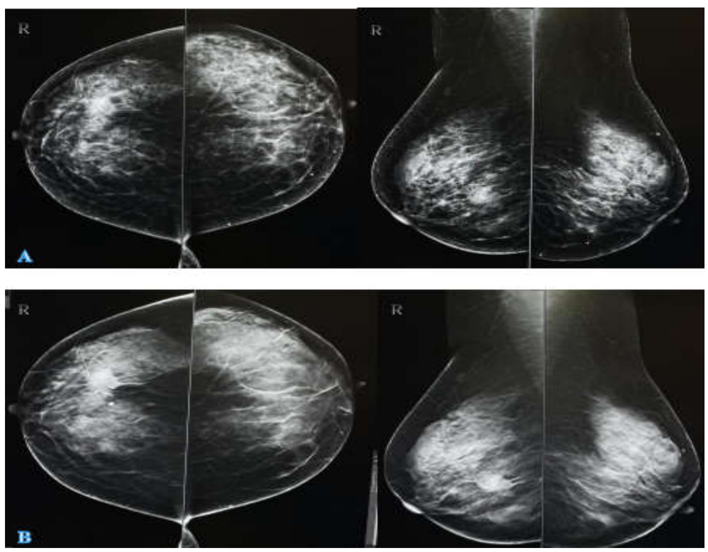

Figure 2: Patient 62 years old presented with a palpable Rt breast mass. (A) 2D DM shows scattered fibroglandular tissue ACR b, shows ill-defined equal density mass at the outer central aspect 9 o'clock with architectural distortion BIRAD IV. (B) DBT shows an irregular radiodense mass with spiculated outline and architectural distortion (Suspicious mass) BIRAD IV b. FNA was done under US guide cytology revealed Mammary CA.

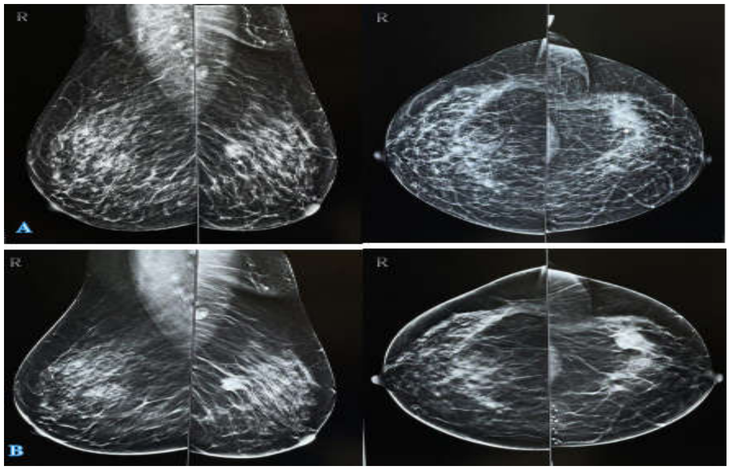

Figure 3: 54 years old patient with Lt breast Lump. (A) DM show ill-defined equal density mass in the UOQ partially obscured by adjacent glandular tissue, BIRADS IV. (B) DBT showing most of the mass appear well defined and very small part obscured margin IV-A. FNA cytology mammary CA

DISCUSSION:

In this study, we compared the diagnostic performance of the DBT with that of mammography, specifically in BI-RADS IV and V, and found that DBT was superior to mammography in diagnosing and characterization of breast lesions in all ACR density categories with a perfect overall sensitivity of 100% as compared to that of mammography (69.2%). Numerous research, including systematic reviews and meta-analyses, has demonstrated that DBT has a higher sensitivity in cancer detection (8). This was consistent with other recent studies (Table 4). [9-12]

Table 4: Summary table for studies comparing the diagnostic performance of digital mammography and digital breast tomosynthesis.

Author	Year	Modality	Study groups	Sensitivity (%)	Specificity (%)
Naeim *et al.* (10)	2021	FFDM	Total 90	64.44	97.77
		DBT		100	77.87
Singla *et al.* (11)	2018	FFDM	Ca 49 Benign 37	83.6	38.7
		DBT		100	87.88
Whelehan *et al.* (13)	2021	FFDM	Ca 152 Benign 148	86.6	81.4
		DBT		89.1	84.6
Skaane *et al.* (12)	2018	FFDM	Total 24,301	76	96.4
		FFDM + DBT	Total 59,877	80.8	97.5

In the current study, the rate of malignancy in patients younger than 40 years was 27%. Previous local studies reported comparable rates 15-30% in younger patients [14,16]. A trend of increasing breast cancer detection in younger age group has been observed all over the world. SEER estimates that 5.6 percent of all invasive breast cancers occur in adolescents and young adults, 15-39 years old [17]. This flags up the need of robust early detection in this age group who has characteristic breast composition. Breast density represents the composition of the breast tissue and is strongly connected with the risk of breast cancer [18]. A significant inverse association between the radiologists' ACR breast density rating and the patient's age has been reported in many studies [19]. In agreement with that, we found that ACR c and d were the highest in age groups 40-49 (36%), (50%) respectively and reversed to low density ACR a and b after 60s.

When the diagnostic performance of each modality was evaluated for various breast densities, the DBT accuracy was higher for ACR a (100% vs 72.7%) and c (54.5 vs 45.4%) than mammography; however, they were the same for ACR b. Out of two cases in ACR d, no malignant cases were diagnosed; hence validation values could not be generated. High breast density has been linked to reduced accuracy of screening mammography [10]. Chiu and colleagues reported earlier that mammography sensitivity reduced to 62.8% in dense breasts compared to 82% in non-dense breasts, and specificity was 89.6% compared to 96.5% in non-dense breasts [20]. Naeim and colleagues [10] found that FFDM sensitivity in (ACR c and d) was 76.7%, compared to 84.5% in non-dense breasts (ACR a and b), while DBT sensitivity was 100% for both groups. A relatively recent meta-analysis of sixteen studies concluded that in the diagnosing setting, DBT+/-DM improved sensitivity but not specificity [21].

In a multi-institution study of approximately 452,320 women, DBT increased cancer detection rates and PPV for recall in dense and non-dense breasts. The benefit, however, was greatest in moderately dense breasts and non-significant in dense breasts. DBT may miss some breast tumors in dense breasts, especially those without architectural deformation or microcalcifications [22]. It is worth noting that the low specificity in our results does not reflect the actual specificity of DBT because the study was designed to include BIRADS IV and V, and specificity calculation requires true negative cases.

When the cancer detection rate of each modality was evaluated for BI-RADS categories, it was 16.6% and 54.3% in BI-RADS II and III respectively, when DM was used. We observed that BI-RADS scoring of 58.4% (59/101) was changed between DBT and mammography. This is comparable to Singla et al results [11], who found that adding DBT to mammography 53% changed their BI-RADS scoring.

Similarly, Naeim and colleagues [10], showed that there was a 57.7% change BI-RADS scoring between the two modalities. This is because the identification of lesions was easier with DBT, which depicted the margins more precisely and eliminated the overlying breast tissue [23,24]. Many studies also highlighted the ability of DBT to resolve asymmetries/ focal asymmetries [25]. Additionally, we observed the change in BI-RADS scoring with BDT was 12/24 (50%) in dense breast categories (ACR c and d) while in fatty and fibroglandular breasts (ACR a and b), it was 44/77 (57%). Naeim and colleagues [10], reported a change of 61% for ACR c and d, compared to only 45% for ACR a and b. The discrepancy between the results was mainly due to the limited number of cases in ACR d we had in our cohort.

Taken together, these findings indicate that tomosynthesis is superior to mammography in terms of sensitivity and specificity at all breast densities, but notably at greater densities. It is advantageous because, unlike mammography, which produces two-dimensional images, it eliminates obscuring breast tissue and provides a higher resolution of the internal breast structures. And this will result in a decrease in false positive results, recalls, and special mammographic views, as well as a decrease in radiation exposure and costs.

The study's limitation was the small patients' number with true negative lesions, hence lowering the specificity value. While the risk of malignancy is minimal in BI-RADS Iva lesions and the majority of the patients are scheduled for follow-up, lesions in this subcategory remain suspicious and cannot be considered negative. Additionally we lacked information on whether the test was diagnostic or screening, given the fact that tomosynthesis has been recommended as a potent screening technique with a low recall rate.

CONCLUSION:

Digital breast tomosynthesis is the modality that provides improved detection of different breast lesions, and it performs better in dense breast where the conventional mammography proved to be of less value.

Recommendations:

According to the results we recommend DBT as a first step tool for diagnosis, especially in those with proposed dense breasts such as those on hormonal therapy and young females, with favorable benefit to accurately characterize and evaluate the breast lesion and support the final radiological outcome and approximate it to the histopathological results. The precise specificity of tomosynthesis can be determined by a study including whole spectrum of breast lesions from benign to malignant lesions. The screening benefit of tomosynthesis and its cost-effectiveness can be further addressed, and the DBT and DM can be readed together to increase the diagnostic accuracy.

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