Combining One View Digital Breast Tomosynthesis to One View Digital Mammography versus Standard Two Views Digital Mammography for Lesion Detection and Characterization

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ABSTRACT

Background: Breast cancer in women is considered a major public health problem throughout the world. Despite advances in digital mammography (DM), at least one in four malignant tumors remains undetected. Digital breast tomosynthesis (DBT) is a screening and diagnostic modality that acquires images of a breast at multiple angles. **Objective:** to evaluate the clinical value of combining one-view DM (cranio-caudal, DMcc) with the complementary view DBT (mediolateral-oblique, DBTMLO) in terms of both lesion detection and characterization. **Methods:** longitudinal cohort study included 475 female patients with total 950 breasts attending to Helwan university hospital. Bilateral two-view digital mammography and additional single-view DBTMLO of both breasts using a 3D digital mammography system were done in the same setting with complementary breast and axillary ultrasound. **Results:** Combined technique DM\CC and DBT\MLO was superior in detection of mass lesions and architectural distortion and superior in confirming the focal asymmetry as a true asymmetry not a tissue superimposition, the two modalities were equal in detection and characterization of calcification. **Conclusion**: Combining one view DMcc with one view DBTmlo decrease the need to additional mammographic views and has a better value in breast lesion detection and lesion characterization especially in dense breasts more than fatty breasts, with accepted radiation dose.

Keywords: Breast cancer; Digital Mammography ; Digital Breast Tomosynthesis

Introduction

Breast cancer is the most common cancer among women both in developed and developing countries, accounting for 22.9% of all female cancers. In Egypt, breast cancer accounts for 37.7% of the total new cancer cases. It is the leading cause of cancer related mortality accounting for 29.1% of the cancer related deaths **(1)**. Conventional digital mammography (DM) is the standard breast cancer screening technique, as it is the only technique that has been shown to decrease mortality in large studies **(2)**. However, it has limitations, such as false negatives (20-30 %) and a high recall rate, of about 11%, most of which are false positive **(3)**. DM has low sensitivity and specificity in women with radiographically dense breast due to decrease contrast between a possible tumor and surrounding breast tissue and summation of tissues may obscure lesions **(4)**.

Digital breast tomosynthesis (DBT) improves breast cancer detection and diagnosis compared to DM. Instead of resulting in a two-dimensional (2D) image of the compressed breast as in DM, DBT acquires several low-dose 2D projections over a limited angular range, which are then used to reconstruct a pseudo-3D image of the breast **(5)**. Better visualization of lesions' margin by DBT, particularly in dense breasts, has improved the sensitivity and specificity of lesion detection and allows for better categorization of suspicious and benign breast lesions **(6)**. Early studies comparing screening with DBT combined with DM to screening with DM alone have shown reductions in recall from 15 to 37 % and increases in cancer detection from 10 to 35 % **(7)**.

Although several papers have demonstrated the multiple potential benefits of DBT, several questions remain regarding its clinical application, particularly whether it should be used in screening, diagnosis, or both; and whether DBT should be used alone, replacing 2D mammography, or in combination with 2D mammography **(6)**. DBT in combination with DM increases radiation dose to above that of DM alone, roughly by a factor of two **(4)**. Therefore, methods to decrease the amount of radiation exposure to the patient are critical to the advancement and widespread acceptance of this technology **(8)**.

DBT is a 3D technique, and, as such, could allow full coverage of breast tissue with a single view. This is why some earlier studies of DBT compared medio-lateral oblique (MLO)-only DBT views with two-view mammography. Another reason was the desire to keep DBT radiation doses at levels delivered by standard two-view mammography **(5)**. several studies comparing breast tomosynthesis alone to mammography alone showed that tomosynthesis alone did not outperform digital mammography, especially using a one-view tomosynthesis acquisition **(8-10)**. One possible explanation is that mammography is slightly more sensitive than breast tomosynthesis to detect calcification, while tomosynthesis seems to improve visualization of masses and architectural distortions **(11)**.

Thus, this study aimed to evaluate the clinical value of combining one-view DM (cranio-caudal, DMcc) with the complementary view DBT (mediolateral-oblique, DBTMLO) in terms of both lesion detection and characterization.

Patients and Methods

The longitudinal cohort study included 475 female patients with total 950 breasts attending either Helwan university hospital or El Nasr insurance hospital outpatient clinic complaining of breast lesion found either clinically or by mammography and /or ultrasound during the period from July 2021 to Mars 2023.

Inclusion criteria

Women with clinically diagnosed breast lesion, age > 40 years, and women who diagnosed with breast lesion either by mammography and/or ultrasound. Women recalled from screening (suspicion of lesions or architectural distortion).

Exclusion criteria

Women with prior breast surgery or mastectomy,and women with breast size exceeding the digital detector size. Women with breast implants, women with known breast cancer (BI-RADS 6), and pregnant women were excluded.

Ethical approval:

After approval from Helwan faculty of medicine Ethical Committee with serial number (31-2021), informed written consent was obtained from each patient after a full explanation of the study to the patient. Privacy of all patient`s data is guaranteed and there was a code number for every patient file that includes demographic data and all investigations.

All patients were submitted to the following:

1. Complete personal, medical history and full clinical examination.
2. Imaging procedure as following: Bilateral two-view digital mammography "DM-CC\MLO" and additional single-view digital breast tomosynthesis –mediolateral oblique "DBT\MLO" of both breasts using a 3D digital mammography system were done in the same setting.
3. Complementary breast and axillary ultrasound were done for all patients.

- **Equipment:**

1-Mammographic examination was performed using (FUJIFILM Amulet Innovality 2019)
2- Complementary breast and axillary ultrasound (US) evaluation using (Seimens acusonX300 2018) with a high frequency (12.5 MHz) linear transducer.

- **Technique:**

A dedicated DM unit, (FUJIFILM Amulet Innovality), was used for imaging. The system supported both DM and DBT imaging by acquiring cranio-caudal and medio-lateral oblique projections during the same breast compression (25–30 kV, 100 mA,). DBT images were acquired with X-ray tube rotation through the angular range of 25° with fifteen low dose projections with the breast in standard compression in medio-lateral oblique projection. Image acquisition was performed with a step-and-shoot method, with an acquisition time of <10 s for one breast. Image reconstruction was performed immediately after image acquisition with slice thickness of 1 mm and time of reconstruction of <15 s. Exposure was controlled by manual selection of technique factors based on compressed breast thickness, such that the total radiation dose for DBT\MLO, was approximately equal to the dose delivered in one view mammography DM \MLO as manufacturers optimize tomosynthesis data acquisition.

- **Image analysis and interpretation:**

1-Two views of DM images, and also "one view DM cranio-caudal "DM\CC combined with one view "DBT\MLO"images, were analyzed by two breast radiologists.
2-All cases were anonymised and images were reviewed by two radiologists independently and were blinded to the findings of other modalities, to the clinical report, patient history, histology and clinical follow up.
3-The reporting and grading of the BI-RADS score was determined as per American College of Radiology (ACR) BI-RADS 5th edition,2013 **(12)**. Mammogram lexicon and the assessment criteria (table 1) included:
- Breast density was assessed for each patient. According to ACR system: (A,B,C,D)
- Each lesion detected was evaluated as mass,calcifications, asymmetric density, architectural distortion and other associated features like nipple retraction,skin thickening and pathological lymph nodes.

- Lesions were classified according to the mammography BI-RADS lexicon morphology descriptors:

A-Mass lesions: A 'Mass' is a space occupying lesion seen in two different projections (12).

The mass is described according to the shape, margins and density: Shape (oval, round or irregular) ; Margins (circumscribed, obscured, microlobulated or speculated) ; and Density: low, equal, high or fat-containing projections.

B-Asymmetry: A fibroglandular parenchyma region that can only be visible on a single mammography projection and is mostly brought on by the superimposition of normal parenchyma of the breast which may be a single view, focal, global or developing."

- Focal asymmetry is visible on two projections, concerning it as a real finding rather than superimposition
- Global asymmetry consisting of an asymmetry over at least one quarter of the breast and is usualy a normal variant
- Developing asymmetry new is larger and conspicuous than on a previous examination.

C-Calcifications: either benign or suspicious according their morphology and distribution.

D- Architectural distortion: means that continuity of normal architecture is distorted with no visible mass

-Each lesion examined by ultrasound was evaluated according to (echogenicity, shape, margin, Doppler signal, skin thickening and interstitial edema).

We determined the BI-RADS category of the lesions in each of the 2 imaging modalities individually according to the BI-RADS lexicon 2013 classification **(Table1) D'orsi et al. (12)** guided by the results of mammographic findings but blind to final histopathology results and complementary ultrasound. Women diagnosed as BI-RADS 4 or 5 and some cases of BIRADS 3 were subjected to histopathological examination which was the gold standard reference for cancer detection. Women with un-biopsied findings BI-RADS 3 were evaluated with ultrasound and subjected to follow-up three times every 6 months. Ultrasound was the golden standard for BIRADS 1, 2 cases.

Table (1): BIRADS assessment categories according to BIRADS atlas 2013" (12).

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
BI-RADS 4	Suspicious
BI-RADS 5	Highly Suggestive of malignancy
BI-RADS 6	Known biopsy-proven malignancy

Statistical Methods

All data were analyzed by the statistical package SPSS (Statistical Package for the Social Sciences) version 22 (IBM Corp., Armonk, NY, USA). Categorical data were represented as numbers and percentages. A Chi-Square test was applied to investigate the association between the categorical variables. For continuous data, they were tested for normality by the Shapiro-Wilk test. Normally distributed data were expressed as mean±

standard deviation. Furthermore, the distribution of the breast lesions characterization according to breast densities was performed for the studied techniques.

RESULTS

Our study included 475 female patients with different complaint on at least one breast; the other breast is routinely screened, with total 950 examined breasts. Patients' age ranges from 40 y to 80 y with mean age ± SD of 52.7±10.0 **(Table 2)**. With total 950 breasts Patients have a complaint of 483 breasts with percent of 51 % and 467 breasts were routinely screened as "the other breast" with percent of 49 % **(Table 3)**.

The breast denisty was decided by ACR classification as follow "16.4%" of breasts were given ACR A, "47.2%" were classified as ACR B, "25.9%" classifed as ACR C and "10.5%"were ACR D **(Table 4)**.

Table (2): Age distribution of the studied women

Age, years	Minimum- Maximum		40.0-80.0
	Mean± SD		52.7±10.0
Age groups	40-<50	N	468
		%	49.3%
	50-<60	N	200
		%	21.1%
	60-<70	N	210
		%	22.1%
	70-80	N	72
		%	7.6%

Table (3): Complaint of the studied women

	N	%
Routine screening	467	49.2%
Breast lump	289	30.4%
Mastalgia	56	5.9%
Palpable thickening	45	4.7%
Rapidly growing lump	22	2.3%
Nippel discharge	21	2.2%
Palpable lump	14	1.5%
Painless soft lump	8	0.8%
Nipple retraction+ lump	7	0.7%
Nipple discharge	7	0.7%
Mastalgia+lump	7	0.7%
lump after trauma	7	0.7%

Table (4): ACR distribution according to the age groups of the studied women

	Age groups				Total
	40-<50	50-<60	60-<70	70-80	

		N	%	N	%	N	%	N	%	N	%
ACR	A	0	0.0%	0	0.0%	98	46.7%	58	80.6%	156	16.4%
	B	156	33.3%	166	83.0%	112	53.3%	14	19.4%	448	47.2%
	C	212	45.3%	34	17.0%	0	0.0%	0	0.0%	246	25.9%
	D	100	21.4%	0	0.0%	0	0.0%	0	0.0%	100	10.5%

Mammographic findings was presented in **Table (5)**. The DM-CC\MLO defined 394 lesions as a mass with 48 % with unclear margin(ill-defined,obscuredand partially obscured) and 52 % with clear margin (circumscribed, spiculated,and lobulated) while DM\CC with DBT\MLO defined 624 lesions as a mass with 100% clear margin **(Table 5)**.

Breasts lesions detected were assesed using BI-RADS mammography lexicon, shows distribution of BIRADS score of studied breast lesion in DM-CC\MLO and DM\CC with DBT\MLO **(Figure 1)**.

DM\CC with DBT\MLO show Changes were observed mainly in ACR: C&D. Of 246 breasts ACR C there are 109 upgraded thier BIRADS ,73 downgraded and 64 breast shows no changes in BIRADS, of 100 breasts ACR D there are 44 upgraded,28 downgraded and 28 shows no changes in BIRADS **(Table 6)**.

DM-CC\MLO revealed “26.5%”of breasts classified as normal with BIRADS 1. And “41%” of breasts with benign lesions classified as BIRADS 2,3. And “32.5%”of breasts with malignant lesions classified as BIRADS 4,5. DM\CC with DBT\MLO revealed “15%” of breasts as normal with BIRADS 1, “46,5%”of breasts with benign lesion as BIRADS 2,3. “38.5%”of breasts with malignant lesions classified as BIRADS 4,5. Both modalities were compared to the golden standard which was the histopathology results for BIRADS 4,5 lesions,and follow up for BIRADS 3 lesions,and ultrasound examination results for BIRADS 1,2 lesions. The final diagnosis by golden standards revealed “14.8%”normal breasts and “49.4%” breasts with benign lesions,“35.8%” breasts with malignant lesions **(Table 7)**.

Table (5): Description of the breast lesions according to DM-CC\MLO

Mammography		N	%
Mass Shape	Yes	394	41.4%
	Oval	169	17.8%
	Rounded	120	12.6%
	Irregular	77	8.1%
	Linear branching densities	21	2.2%
	Multiple rounded	7	0.7%
Mass Margine	Yes	394	41.4%
	Partially obscured	163	17.2%
	Circumscribed	105	11.1%
	Spiculated	77	8.1%
	Well defined	21	2.2%
	Obscured	14	1.5%
	Macro lobulated	7	0.7%
	Ill-defined	7	0.7%
Breast Calcification	Yes	189	80.1%
	suspicious looking	105	11.1%

	benign looking	84	8.8%
Breast Architectural distortion	Yes	21	2.2%
Assymetry	Yes	221	76.7%
	Focal asymmetry	193	20.3%
	(singel view assymetry)	14	1.5%
	(global)	7	0.7%
	(developing)	7	0.7%
Skin thickening	Yes	49	5.2%
Nipple retraction	Yes	21	2.2%

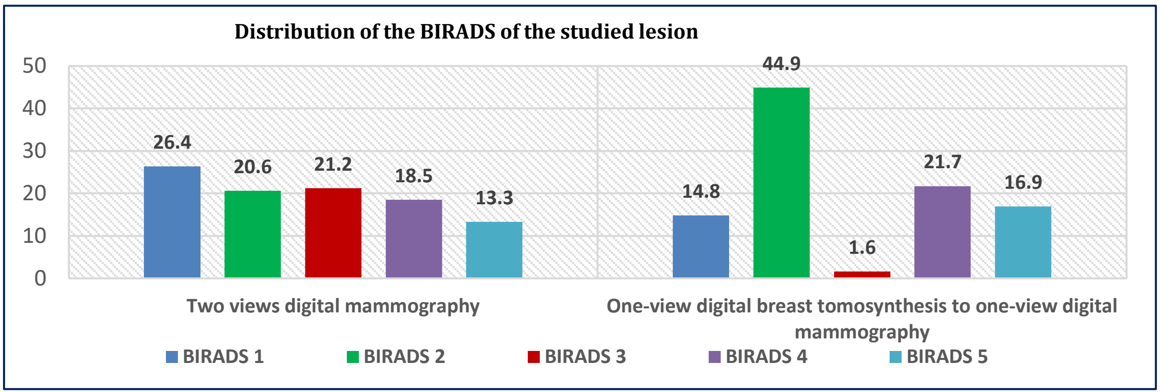

Fig. (1): Distribution of the BIRADS of the studied lesion.

Table (6): Changes in BIRAD scoring by using DM\CC with DBT\MLO technique in comparison to the standard DM-CC\MLO technique

	ACR categories							
	A N=156 (16.4%)		B N=448 (47.2%)		C N=246 (25.9%)		D N=100 (10.5%)	
	N	%	N	%	N	%	N	%
Upgrading	0	0.0%	63	14.1%	109	44.3%	44	44.0%
Downgrading	0	0.0%	35	7.8%	73	29.7%	28	28.0%
No change	156	100.0%	350	78.1%	64	26.0%	28	28.0%

Table (7): Detection and diagnosis by the investigated and the standard techniques

			N=950	%
DM-CC\MLO	Detection	Negative	251	26.4%
		Positive	699	73.6%
	BIRADS	1	251	26.4%
		2	196	20.6%
		3	201	21.2%
		4	176	18.5%
		5	126	13.3%
	Diagnosis	Normal	251	26.4%
		Benign	397	41.8%
		Malignant	302	31.8%
DM\CC with DBT\MLO	Detection	Negative	141	14.8%
		Positive	809	85.2%
	BIRADS	1	141	14.8%
		2	427	44.9%

		3	15	1.6%
		4	206	21.7%
		5	161	16.9%
	Diagnosis	Normal	141	14.8%
		Benign	442	46.5%
		Malignant	367	38.6%
Standard diagnosis	Detection	Negative	141	14.8%
		Positive	809	85.2%
	Diagnosis	Normal	141	14.8%
		Benign	469	49.4%
		Malignant	340	35.8%

Discussion:

Breast cancer is the most common malignancy affecting women worldwide and main cause of morbidity and mortality among women, early diagnosis and proper treatment plan markedly affect the course and prognosis of the affected women **(3)**. Imaging of the breast was known to be the first line for early detection and diagnosis for breast cancer **(6)**. Standard digital mammography was the imaging technique approved worldwide for screening and diagnosis of breast lesion in women over 40 years **(13)**.

Yet, many studies shows the high false positive cases detected in digital mammography with consequent high recall rate, additional tests, patient anxiety, and cost, these was due to the effect of overlapping normal tissue in the two -dimensional image acquired in the DM **(14,15)**.

So many studies suggest the use of digital breast tomosynthesis (DBT), which is a newly developed three-dimensional (3D) imaging technique that reduces overlapping shadows from breast tissue **(16,17)**.

Despite proven higher sensitivity of DBT alone in lesion detection compared to DM,DBT show far less sensitivity in calcification detection than DM so Combined use of DBT with 2D mammography is suggested in many studied and researches **(18)**.

At the other hand there are many drawbacks of adding “two views DBT” to standard “two views DM”, firstly the increased acquisition time and doubling reading time as stated in Oslo Tomosynthesis Screening Trial (OTST) that shows a mean interpretation time for 2D plus 3D of about 90 s compared with about 45 s for conventional 2D screen-reading which affects its implementation in screening programs. secondly the problem of increased radiation dose delivered to the patients **(19,20)**.

The concept of use of one view DBT was discussed in many recent researches, **Chae et al. (21)** showed that use of one-view DBT has beneficial effect on the detection and characterization of breast lesions when compared with two-view FFDM in a selective diagnostic population. Improvements were more evident in females with dense breasts. In this study, using selective diagnostic study cases, one-view DBT offered improved reader performance compared with two-view FFDM for detection and characterization of breast cancers **(22)**.

The Malmö Breast Tomosynthesis Screening Trial (MBTST) shows that breast cancer screening by use of one-view DBT has a higher sensitivity and a slightly lower specificity for breast cancer detection compared with two-view digital mammography and has the potential to reduce the radiation dose and screen-reading burden required by two-view digital mammography **(23)**.

As several studies have suggested that cancers are more conspicuous on the craniocaudal view compared with the mediolateral oblique view **(24,25)**. Our study suggest use of cranio-caudal view of DM with medio-lateral oblique view of DBT may offer beneficial diagnostic performance without increasing the time of acquisition and interpretation time with also comparable average glandular radiation dose.

Conclusion:

Combining one view DMcc with one view DBTMLO decrease the need to additional mammographic views and has a better value in breast lesion detection and lesion characterization especially in dense breasts more than fatty breasts, with accepted radiation dose.

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