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Original article

Our experience using synthesized mammography vs full field digital mammography in population-based screening

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ABSTRACT

Background: Synthesized Mammogram (SM) from Digital Breast Tomosynthesis (DBT) images is introduced to replace the routine Full Field Digital Mammography (FFDM) to reduce radiation dose.
Purpose: to compare the conspicuity of cancer related findings between SM and FFDM and combination of these methods with DBT
Methods: The study was conducted in a tertiary breast imaging center, where 200 women referred for screening were enrolled in the study sequentially. Patients underwent FFDM and DBT simultaneously and a two-year follow-up was done. Data was evaluated for Breast Imaging Reporting and Data System (BI-RADS) score, breast density, mass lesions, calcification, and focal asymmetry by two expert breast radiologists. Comparison between different methods was made by Cohen Kappa test.
Results: 22 patients with likely malignant findings went under biopsy. Taking histopathologic findings and two-year follow up as reference, the overall sensitivity and specificity for FFDM+DBT (86.1 and 88.9 respectively) and SM+DBT (86.1 and 88.2) didn't show a meaningful difference. Comparing SM and FFDM, calcification in 20 subjects were overlooked on SM, but later detected when combined with DBT. Considering breast composition and BI-RADS categorization, an excellent agreement existed between the readers.
Conclusion: Screening with SM+DBT shows comparable results with FFDM+DBT considering BI-RADS categorization of the patients. Although SM showed slightly inferior sensitivity compared to FFDM, after combining DBT with SM no malignant appearing calcification or mass lesion was missed.

1. Background

Mammographic screening is demonstrated to cause significant reduction in breast cancer related mortality [1–5]. Digital mammography (FFDM) is also suggested to increase diagnostic accuracy. Despite the benefits, mammography has a sensitivity about 70–80 % detecting

List of abbreviations: SM, Synthesized Mammograms; DBT, Digital Breast Tomosynthesis; FFDM, Digital Mammography; BI-RADS, Breast Imaging Reporting and Data System; ICC, Intra Class Correlations; CC, Cranio-Caudal; MLO, Medio Lateral Oblique; PPV, Positive Predictive Value; NPV, Negative Predictive Value; AWS, Acquisition Workstation; TUMS, Tehran University of Medical Sciences.

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cancers, still missing a significant number of malignancies [6]. This might result from summation of breast tissue, which can either obscure an underlying lesion or mimic a malignant mass. Hence, digital breast tomosynthesis (DBT) was introduced as a solution to overlapping densities with acquiring multiple thin section images from the breast tissue. DBT and FFDM obtained in craniocaudal (CC), and mediolateral-oblique (MLO) views is shown to increase cancer detection rates and to decrease in recall rates [7–10]. However, adding DBT to screening program means an excess radiation dose [10,11]. Therefore, synthesized mammogram (SM) from the 3D DBT is suggested as a substitution to FFDM. Multiple studies are conducted to compare FFDM and SM [11–14]. Systematic review by Zeng B, concluded that FFDM can be omitted from the screening after implementing SM+DBT [15]. But not many similar studies are conducted in Middle East, which is suggested to have higher breast densities in normal population in comparison with Western communities[16,17]. Thus, we decided to design a similar study in our institute, considering differences in ethnicity might show different results.

2. Methods

2.1. Study design and patient population

The project was approved by the ethical committee of the institute, and written informed consent was obtained from all the patients included in the study. Retrospectively 200 eligible patients, who underwent both FFDM and DBT in a tertiary center for breast cancer management, since April 2018 to February 2019, were included. All the women were in the screening setting and referred by the related clinicians, and no further imaging studies were applied for the purposes of research. All subjects were between ages 40–75, except two; a 35-year-old female with history of ovarian cancer who refused to have genetic tests, advised for annual screening by MRI and mammography, and an 80-year-old female referred due to patient's concerns. The patients with previous breast surgery, pathologically proven breast cancer, unwilling to participate, or the ones who didn't refer for follow up were excluded from the study. Tissue diagnosis was obtained in 22 patients.

2.2. Image acquisition

All patients underwent FFDM and tomosynthesis using Fujifilm AMULET Innovality device with automatic sensor automatic exposure control (AEC) mode. In breast tomosynthesis, standard mode (acquisition angle: $\pm$ 7.5° and pixel size: 100/150 m) was employed. The X-ray tube moves through an arc while acquiring a series of low-dose X-ray images with 1 mm thickness and 1 mm intervals. Tungsten anode tube with aluminum filter was used for tomosynthesis acquisition.SM was obtained for each one of the subjects, combining multiple slice images, without exposing the patients to any excess radiation. Therefor three sets of data were available for each patient, including, FFDM, DBT and SM.

2.3. Reader assessment

Dedicated mammography acquisition workstation (AWS) of Fujifilm was used to interpret images. Two board certified breast radiologists assessed the data independently. They were not provided by the patient's previous images or clinical history. The readers interpreted FFDM and SM images retrospectively in a separate seating, filling data collection sheets. Next, they were provided by the tomosynthesis, and then all the data were reviewed together. Items included during the assessment were Breast Imaging-Reporting and Data System (BI-RADS), mass, calcification, and focal asymmetry.

Radiologists scored BI-RADS category 0–5 according to American College of Radiology (ACR) BI-RADS atlas fifth edition [18]. BI-RADS 6 category (known breast cancer) were excluded from the study.

Patients with calcifications were further classified based on shape and distribution. The mass lesions were classified by shape and margin. Focal asymmetries were classified as present or absent.

2.4. Statistical analysis

All statistical analyses were done using SPSS 22(IBM SPSS Statistical software), and p value less than 0.05 was considered significant in all the statistical tests applied. Biopsy for 22 subjects and a 2-year follow up for all the subjects was done.

For evaluation of the BI-RADS category, it was further classified into two groups of likely benign (BI-RADS 1,2 and 3) and likely malignant (BI-RADS 4 and 5) and then the ratios in FFDM+DBT were compared to SM+DBT.BI-RADS 0 items were excluded from this part of the analysis. The subjects categorized as likely benign with stable findings after a two-year follow up were considered true negative in later statistical analyses.

First, the items including focal asymmetry, calcifications and mass lesions were compared between FFDM+ DBT and SM+DBT groups separately between the two readers using Cohen Kappa test. Inter-reader correlation coefficient was analyzed in different categories to ascertain the agreement between the two readers.

Later the data obtained from the two readers were merged into one, and the senior reader was asked to re-evaluate the images in cases of discrepancy between the readers. Taking histopathologic findings and two-year follow-up results, the sensitivity and specificity of two methods were calculated.

3. Results

In this study 200 female patients between ages 35–80 years were studied. Mean of their age was 48.08 $\pm$ 8.38 years and majority of them (53.6 %) were aged in the range of 41–50 years. Two breast radiologists reported their findings as mentioned above. Initial characteristics are featured below (Table 1).

According to both radiologists most patients had breast density in category C and D (70% and 71% respectively for reader number 1(R1) and reader number 2(R2)).

22 patients in our study had tissue biopsies after the same screening and 12 (54.4%) of them were malignant. We used histopathologic findings as gold standard for detecting malignancy in our patients (n = 22) and estimated PPV of two combined modalities SM+DBT and FFDM+DBT between two readers (R1: 57.1 %−60 % vs R2: 54.5 %−54.5 % respectively). There was an excellent agreement between FFDM+DBT and SM+DBT among two readers for BI-RADS categorization with K value: 0.973 and 0.979 for R1 and R2 respectively (P-value<0.05). There was a high level of agreement between two readers in BI-RADS category for SM+DBT with ICC: 0.878 (95 % CI: 0.839–0.908, P-value<0.05). Similarly, an excellent level of agreement was noted between two readers for BI-RADS categorization via FFDM+DBT with ICC: 0.903 (95 % CI 0.872–0.926, P-value<0.05).

3.1. Mass

According to the readers most detected masses were benign appearing (R1: 61.2 %-R2: 68.5 %) with equal density (R1: 65.3 %-R2: 64 %) and oval shape (R1:54.1 %-R2:73.3 %) (Figs. 1,2). We used Cohen's Kappa test with two-way mixed model of inter class correlation co-efficient to assess agreement between readers for breast mass detection. There was a high level of agreement between two readers about discovering masses via FFDM+DBT with ICC: 0.806 (95 % CI 0.744–0.853, P-value<0.05) and adequate level of agreement between two readers about detecting masses via SM+DBT with ICC: 0.799 (95 % CI 0.735–0.848, P-value<0.05). As for breast composition there was an excellent agreement between two readers with ICC: 0.962 (95 % CI 0.950–0.972, P-value<0.05). Our two radiologists used BI-RADS

Table 1
Initial characteristic findings of both readers.

Findings		Mass N: 200 - (100 %)		Focal asymmetry N: 200 - (100 %)		Calcification N: 200 - (100 %)	
	modality	absent	present	absent	present	absent	present
Reader 1	FFDM	145 (72.5 %)	55 (27.5 %)	145 (72.5 %)	55 (27.5 %)	66 (33 %)	134 (67 %)
	DBT	126 (63 %)	74 (37 %)	177 (88.5 %)	23 (11.5 %)	78 (39 %)	122 (61 %)
	SM	151 (75.5 %)	49 (24.5 %)	141 (70.5 %)	59 (29.5 %)	89 (44.5 %)	111 (55.5 %)
	FFDM+DBT	106 (53 %)	94 (47 %)	137 (68.5 %)	63 (31.5 %)	66 (33 %)	134 (67 %)
	SM+DBT	125 (62.5 %)	75 (37.5 %)	139 (69.5 %)	61 (30.5 %)	78 (39 %)	122 (61 %)
Reader 2	FFDM	110 (55 %)	90 (45 %)	162 (81 %)	38 (19 %)	63 (31.5 %)	137 (68.5 %)
	DBT	89 (44.5 %)	111 (55.5 %)	177 (88.5 %)	23 (11.5 %)	72 (36 %)	128 (64 %)
	SM	125 (62.5 %)	75 (37.5 %)	157 (78.5 %)	43 (21.5 %)	83 (41.5 %)	117 (58.5 %)
	FFDM+DBT	68 (34 %)	132 (66 %)	152 (76 %)	48 (24%)	61 (30.5 %)	139 (69.5 %)
	SM+DBT	88 (44 %)	112 (56 %)	153 (76.5 %)	47 (23.5 %)	69 (34.5 %)	131 (65.5 %)

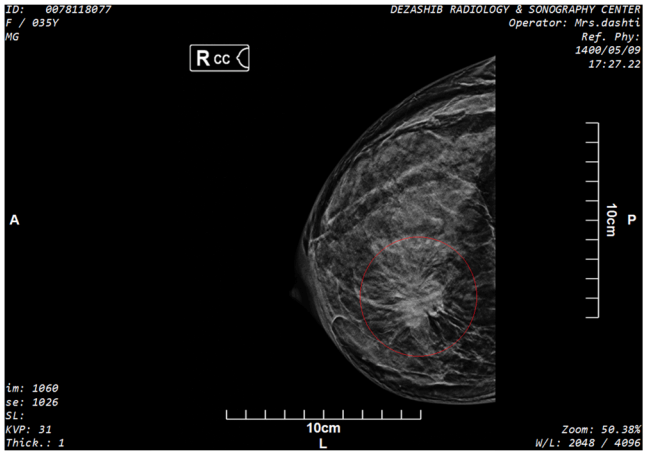

Fig. 1. *irregular mass in DBT.*

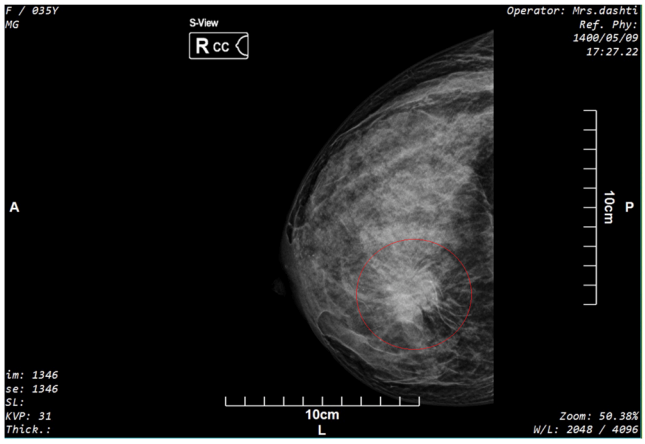

Fig. 2. *irregular mass in S-view.*

categorization to describe these masses. We regrouped the BI-RADS categories of 0–5 into 3 groups as discussed before (Table 2).

3.2. Calcification

Our two readers detected calcification in more than half of the patients (R1: 67 %-R2: 69.5 %) but majority of them were benign appearing (R1:65.7 %-R2:65 %), scattered (R1:55.9 %-R2:55.6 %) and round-punctate (R1: 76.9 %-R2:75.9 %) (Figs. 3, 4). Both readers missed calcifications in exact 20 subject on SM, compared to FFDM.

3.3. Focal asymmetry

There was a moderate level of agreement between two radiologists for detecting focal asymmetry via FFDM with ICC: 0.638(95 % CI 0.522–0.726, P-value<0.05) and SM with ICC: 0.678 (95 % CI 0.574–0.756, P-value<0.05). Afterwards the level of agreement between two readers was studied for combined modalities. Similarly, there was a moderate level of agreement between two radiologists for detecting focal asymmetry via FFDM+DBT with ICC: 0.666 (95 % CI 0.559–0.747, P-value<0.05) and SM+DBT with ICC: 0.668(95 % CI 0.562–0.749, P-value<0.05).

After 2 years we excluded the initial inconclusive BI-RADS reports (BI-RADS: 0) and investigated the remaining patients to determine the outcome of initial screening. We used the outcome of two-year follow-up (benign/malignant) as the gold standard to estimate the sensitivity, specificity, PPV and NPV of SM+DBT and FFDM+DBT to detect malignancy (Table 3).

During the two-year follow up 29 patients were diagnosed with cancer, either in next screening (11 subjects) or in diagnostic setting due to mass palpation/suspicious nipple discharge (18 subjects). The mean time for cancer diagnosis after first screening was 15.97 months (standard deviation 4.54, minimum 6 months and maximum 24 months).

4. Discussion

Replacing FFDM with SM obtained from the DBT images, with purpose of decreasing radiation dose, has been a subject to numerous studies. Study by Jeffrey S. Nelson et al., has concluded that SM better depicts certain objects, but it has poorer overall resolution and noise properties [19]. David Gur et al., found that SM+DBT had comparable specificity, but slightly lower sensitivity compared with FFDM+DBT

Table 2
BI-RADS reclassification.

		Reader 1		Reader 2	
		FFDM+DBT	SM+DBT	FFDM+DBT	SM+DBT
BI-RADS	Inconclusive (0)	45(22.5 %)	45(22.5 %)	37(18.5 %)	38(19 %)
	Benign (1–2–3)	117(58.5 %)	117(58.5 %)	117(58.5 %)	117(58.5 %)
	malignant (4–5)	38(19 %)	38(19 %)	46(23 %)	45(22.5 %)

Fig. 3. *microcalcifications in FFDM.*

Fig. 4. microcalcifications in S-view.

Table 3
comparing two combined modalities in cancer detection.

		Sensitivity	specificity	PPV	NPV
Combined modalities	**SM+DBT**	**86.1 %**	**88.9 %**	**68.9 %**	**95.7 %**
	FFDM+DBT	**86.1 %**	**88.2 %**	**67.4 %**	**95.7 %**

[20,21]. Conducted numerous clinical studies afterwards suggested comparable results between using SM+DBT and FFDM+DBT [10–15].

Our study population was representative of the women referring to our institute. There was an excellent agreement between the two readers considering breast density, mass and calcification detection. About 70 % of the study population had dense breasts (breast composition C and D). SM had lower sensitivity detecting calcifications in our study; reader one missing 23 and reader 2 missing 20 cases of calcification in SM compared to FFDM, taking FFDM and DBT as reference. Missed calcifications occurred in the exact same 20 patients by two readers in SM images, suggesting possible loss of conspicuity of the lesions during the image reconstruction. All missed calcifications were benign appearing and rounded-punctate micro-calcifications except for two cases: one single group of amorphous micro-calcification and one intra-mass amorphous calcification, both later diagnosed when adding DBT to SM. Our findings are consistent with TOMMY trial results, suggesting SM has lower sensitivity detecting calcifications [20]. Although there are other studies offering similar sensitivity between the two modalities considering micro-calcification detection [9,22,23]. In contradiction to our results, N. Ab Muminet et al., has shown that more micro-calcifications were seen in SM images compared to FFDM in their study, all of them being benign [24].

Since SM is meant to be interpreted alongside DBT, we also intended to compare FFDM+DBT and SM+DBT. There was excellent agreement between the readers in BI-RADS category. We found high level of agreement between the SM+DBT and FFDM+DBT in each of the readers which is consistent with the results of systematic review conducted by Baoqi zeng et al. suggesting SM+DBT could replace FFDM+DBT for breast cancer screening [15].

Regarding focal asymmetries, there was only moderate level of agreement between the two readers (ICC: 0.638 and 0.678 for FFDM and SM respectively). Taking FFDM+DBT as reference, DBT alone had less sensitivity than FFDM or SM alone and R2 with more experience had higher sensitivity in diagnosing asymmetries in DBT alone (AUC 0.702 and 0.774 for readers one and two respectively). Unlikely SM+DBT was comparable with FFDM+DBT diagnosing asymmetries.

We must also touch the point that after adding DBT to FFDM images the number of BI-RADS 0 categorized studies and hence recalls were reduced 36 and 25 subjects in R1 and R2 respectively. Two patients were recategorized as benign appearing after combining DBT to FFDM and therefore reducing need for invasive assessment, which was in contradiction with the results of the study by Fransesca Caumo et al., proposing that SM+DBT increases recall rates and need for invasive assessment [25].

Finally, the overall sensitivity and specificity of the two combines modalities including SM+DBT and FFDM+DBT didn't have a meaningful difference.

5. Limitations

DBT is not widely available in our country and number of patients referred for screening with this new modality is limited, therefore we couldn't run a multicentric study in larger populations.

6. Conclusion

Screening with SM+DBT shows comparable results with FFDM+DBT considering BI-RADS categorization and overall sensitivity and specificity in detecting malignancies. Although SM showed slightly inferior sensitivity compared to FFDM, after combining DBT with SM no

malignant appearing calcification or mass lesion was missed.

Ethical approval statement

This study was conducted with the ethicalcode:ID:IR.TUMS.IKHC.REC.1400.308 under the supervision of TUMS ethical committee. Written informed consent was obtained from all the patients included in the study.

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CRediT authorship contribution statement

Seyedeh Nooshin Miratashi Yazdi:(corresponding author) Conceptualization, Methodology, Writing - Review & EditingVisualization, Resources **Nasrin Ahmadinejad**:(first author) Conceptualization, Methodology, Supervision, Investigation, Resources **Seyedehsahel Rasoulighasemlouei**: Conceptualization, Methodology, Software, Formal analysis, Writing - Original Draft, Data Curation **Negin Rostamzadeh**: Software, Formal analysis, Writing - Original Draft **Arvin Arian**: Validation, Investigation, Resources **Amirhassan Mohajeri**: Resources, Data Curation.

Author contributions

NA designed the study, participated in recruiting the patients, performed the image studying, supervised the study and revised the final manuscript. SNM designed the study, participated in recruiting the patients, performed the image studying and revised the final manuscript. SR participated in designing the study, analyzed the data, wrote and finalized the manuscript.NR analyzed the data, wrote and finalized the document.MM and AM participated in recruiting the patients and revised the final manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The datasets used during the current study are available from the corresponding author on reasonable request.

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