Original Research Paper

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Radio-Diagnosis

"BEYOND THE PIXEL: CAN SYNTHETIC 2D MAMMOGRAPHY DELIVER WHAT DIGITAL CAN'T"

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ABSTRACT **Objective:** This study aimed to compare two-dimensional (2D) synthetic mammography (SM) and conventional 2D full-field digital mammography (FFDM) in the evaluation of breast lesions. We aim to determine whether SM, when combined with digital breast tomosynthesis (DBT), can serve as a new standard suitable for clinical adoption. This potential shift could impact existing screening protocols, offering benefits such as improved patient outcomes, maintained diagnostic accuracy, and workflow efficiency. Implementing SM+DBT may reduce radiation exposure, streamline image acquisition, and maintain diagnostic detail. This protocol could also increase patient throughput by minimizing image capture time and may enable more frequent, guideline-aligned screenings, ultimately supporting healthcare delivery efficiency from a clinical perspective. **Material And Method:** Mammograms from 100 patients with suspected breast pathologies were obtained using the Hologic Selenia Dimensions System in COMBO HD mode, generating FFDM, DBT, and SM images. FFDM and SM images were independently assessed using the 5th edition ACR Breast Imaging Reporting and Data System (5th edition BI-RADS) lexicon and compared. Institutional review board approval and patient consent were obtained. **Result:** Spiculated margins and fine pleomorphic calcifications were more distinctly visualised on SM images. FFDM images provided a more precise visualisation of nipple retraction and skin thickening. There was no significant difference in average glandular dose between FFDM and SM images ($p = 0.12$). BI-RADS categorisation showed complete agreement across both methods in all cases. **Conclusion:** FFDM and SM images provided equivalent diagnostic performance for breast lesion evaluation. Combining DBT with SM reduced patient radiation dose without compromising diagnostic accuracy. **Advances In Knowledge:** Synthetic mammography may be considered a viable alternative to full-field digital mammography when combined with digital breast tomosynthesis.

KEYWORDS : Mammography, Synthetic mammography, Full-field digital mammography, Digital breast tomosynthesis, Spiculated margin.

INTRODUCTION

Breast screening using mammography remains the standard for detecting early breast cancer.[1] The U.S. Food and Drug Administration (FDA) approved full-field digital mammography (FFDM) for clinical use in January 2000. FFDM effectively identifies early-stage cancer. However, overlapping fibroglandular tissue can obscure malignancies or mimic cancerous lesions. Digital breast tomosynthesis (DBT) provides a three-dimensional perspective by capturing images from multiple angles, which are displayed as sequential slices. DBT reduces tissue overlap, enhancing the detection of lesions and distinguishing abnormalities from normal tissue.[2]

Current evidence supports the use of DBT (digital breast tomosynthesis, a 3D imaging technique) as a standalone imaging modality. However, some anatomical details may remain suboptimally visualised with DBT alone. Consequently, DBT acquisitions are typically accompanied by FFDM (full-field digital mammography), resulting in two exposures per view and a corresponding increase in radiation dose.

Synthetic mammography (SM) consists of 2D images reconstructed from DBT data and the view is referred to as C-view[3]. This method eliminates additional radiation exposure from separate 2D acquisitions. The US FDA approved synthesised 2D mammography in May 2013 as an alternative for DBT screening. SM simplifies image acquisition, minimises motion artefact, and reduces breast compression time—factors contributing to patient comfort and imaging efficiency in routine clinical settings[4].

This study compared the diagnostic performance of synthetic mammography (SM) with digital breast tomosynthesis (DBT) to that of full-field digital mammography (FFDM) alone.

MATERIAL AND METHODS

A comparative cross-sectional study was conducted on 100 patients with suspected breast pathologies between January 2020 and May 2021 at the Department of Radiodiagnosis, Maulana Azad Medical College and associated Lok Nayak Hospital, New Delhi, using the Hologic Selenia Dimensions system for mammography and tomosynthesis.

Inclusion Criteria:

Eligible Study Subjects Included:

- All patients who underwent screening/ diagnostic mammography and presented with suspicious breast pathologies.

Exclusion Criteria:

- Severe inflammation/ulceration of the breast.

Methodology:

This prospective study received approval from the institutional review board, and written informed consent was obtained from all participants.

All images were acquired using the Selenia Dimensions System (Hologic Inc.) in COMBO HD mode, generating full-field digital mammography (FFDM), digital breast tomosynthesis (DBT), and synthesized mammography (SM) images from the DBT dataset. During DBT acquisition, the X-ray tube sweeps from +7.5° to -7.5°; for mediolateral oblique (MLO) views, with initial position at ±45°. After breast compression, sequential images are captured and reconstructed into 1-mm slices. These datasets are further processed on a clinical workstation to generate synthesised C-view images.

The Following Views Were Obtained:

- Cranio-caudal (CC)
- Mediolateral oblique (MLO)

Two radiologists with experience of 1-5 years in breast imaging independently interpreted FFDM and SM images at a high-resolution workstation using the 5th edition ACR Breast Imaging Reporting and Data System (BI-RADS 5th edition)[5] lexicon to assess breast composition, masses, asymmetry, calcifications, associated features, and glandular dose. After image review, each breast received a final BI-RADS assessment for both modalities. All detected lesions underwent ultrasound, with histopathological correlation when required.

Statistical Analysis:
The collected data were transformed into variables, coded, and entered into Microsoft Excel. Analysis was done with SPSS PC 25. Quantitative data were expressed as mean ± standard deviation or median with interquartile range. Differences between groups were tested by Student's t-test (unpaired) or Mann-Whitney 'U' test. Qualitative data were expressed in percentages. Statistical differences between proportions were tested by the chi-square test or Fisher's exact test. Kappa agreement was calculated to assess agreement between 2D FFDM and SM images. A p-value less than 0.05 was statistically significant. The statistical power of the study was evaluated to reinforce confidence in the findings, especially for non-significant results. Effect size thresholds were calculated to determine the study's ability to detect meaningful differences between the imaging methods. This addresses potential concerns about sample size and robustness.

RESULTS

The study included 100 females aged 30 to 83 years. Most patients (42%) were in the 41–50 year age group. The mean age was 47.25±10.08 years.

Breast Composition- Type A was seen in 10%, type B in 53%, type C in 29% and type D in 8% of the cases (Figure 1&2). There was complete concurrence between FFDM and SM in all the cases.

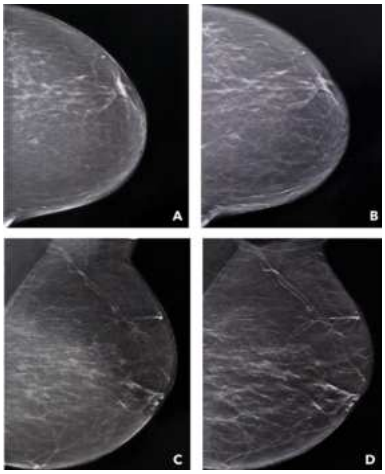


Figure1 (A-D): FFDM (A&C) and SM (B&D) images in CC and MLO views show Type A breast composition in both FFDM and SM images.

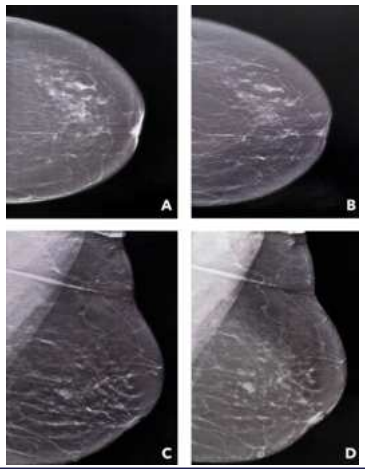


Figure 2 (A-D): FFDM (A&C) and SM (B&D) images in CC and MLO views show Type B breast composition in both FFDM and SM images.

Breast Lump - Shape of Mass: Of the 100 patients, 80 had lesions. Irregular and oval shapes were observed in 49% of masses, while 2% were round. FFDM and SM results were concordant in all cases.

Margin Of Mass: Out of the 100 patients, 80 had lesions. Well-circumscribed margins were most frequent, present in 50% of lesions (see Table 1). FFDM and SM were equally effective in visualising circumscribed margins. Spiculated margins, present in 30%, were more sharply defined on SM images than on FFDM images (Figure 3). The p-value was <0.001, indicating a significant difference in spiculated margin visualisation. This suggests SM may help earlier detection and intervention for specific lesions.

Table 1: Margin Of Mass (n=80)

MARGIN	FFDM	SM	BETTER SEEN ON	p value
Circumscribed	40(50%)	40(50%)	-	-
Indistinct	11(14%)	11(14%)	9(11% SM)	<0.001
Microlobulated	1(1%)	1(1%)	-	-
Obscured	4(5%)	4(5%)	-	-
Spiculated	24(30%)	24(30%)	24(30% SM)	<0.001

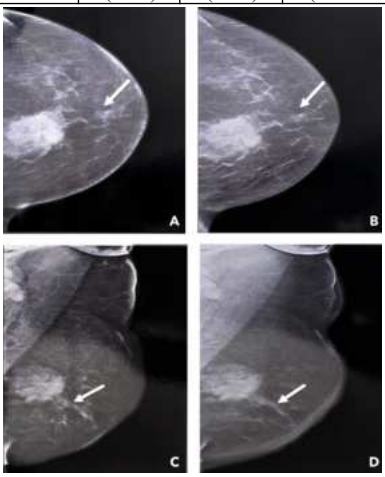


Figure 3(A-D): Infiltrating ductal carcinoma patient FFDM (A&C) and SM (B&D) images in CC and MLO views show an irregular shaped high density mass lesion in inner quadrant in posterior third of left breast with spiculated margins. Nipple traction is better visualized on FFDM (A&C) as compared to SM (B&D) image.

Density Of Mass: Equal density was observed in 30%, high density in 61%, and low density in 9% of the lesions. Both FFDM and SM showed similar density of the lesion in all the cases and were concordant.

Asymmetry was seen in 2 cases. Both FFDM and SM images were comparable in visualising asymmetry.

Architectural distortion was present in 12% of cases and appeared more pronounced on SM images. The p-value was <0.001, signifying a significant difference in the depiction of this feature between FFDM and SM.

Calcification: Morphology - The most common morphology of calcification observed was fine pleomorphic calcification, which was present in 40% of the lesions (Table 2). In all these cases, fine pleomorphic calcifications were more clearly appreciated on SM images compared to FFDM images (Figure 4).

Table 2 : Morphology Of Calcifications (n=75)*

MORPHOLOGY	FFDM	SM	SM	BETTER SEEN ON	BETTER SEEN ON	p value
Coarse	9(12%)	9(12%)	9(12%)	-	-	-
Dermal	14(18%)	14(18%)	14(18%)	18% (SM)	18% (SM)	<0.001

Round	19(25%)	19(25%)	19(25%)	25% (SM)	25% (SM)	<0.001
Fine Pleomorphic	30(40%)	30(40%)	30(40%)	40% (SM)	40% (SM)	<0.001
Vascular	11(15%)	11(15%)	11(15%)	4% (SM)	4% (SM)	0.09
Rim	2(2%)	2(2%)	2(2%)	2(2%)	2% (SM)	0.49

* In few patients, more than one morphology of calcification was found.

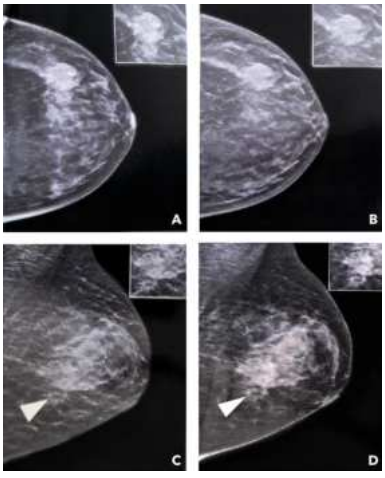


Figure 4 (A-D): Breast metastasis patient FFDM (A&C) and SM (B&D) images in CC and MLO views show an irregular high density mass lesion with indistinct margins in upper outer quadrant of left breast, showing grouped fine pleomorphic calcification within and surrounding architectural distortion (shown by arrowhead). Margins of the lesion calcification and architectural distortion are better appreciated on SM (B&D) image.

Distribution Of Calcifications: The most common distribution of calcification found was grouped, seen in 59% of the lesions. Diffuse was seen in 28%, linear in 9% and regional in 4% of the lesions. Both FFDM and SM were comparable in visualising the distribution of calcifications in all cases.

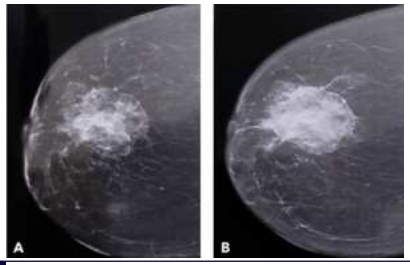
Other Findings

Nipple retraction was seen in 9 cases. In all these cases, nipple retraction was more clearly visible on FFDM images compared to SM images.

Skin thickening was noted in 22 cases, with FFDM images consistently providing superior visualisation compared to SM images ($p < 0.001$). This significant difference indicates that FFDM is more effective for detecting skin thickening.

Axillary lymphadenopathy was found in 64% of cases. FFDM images better visualised lymphadenopathy in 64% of cases, whereas SM was better in 43%. The difference in visualisation between FFDM and SM was statistically significant ($p < 0.001$).

Artefacts in synthetic mammography included bright bands or subcutaneous tissue blurring across all images, loss of skin resolution/burned skin artefact (Figure 4) in 58%, decreased axillary contrast resolution (Figure 5) in 43%, shadowing in 22%, and a single case of foreign body artefact. Although these artefacts did not hinder interpretation, radiologists should remain vigilant for their presence. Careful evaluation of tomosynthesis slices, and, when necessary, reassessment with FFDM can help mitigate the effects. This method supports diagnostic safety and clinician confidence in imaging results.



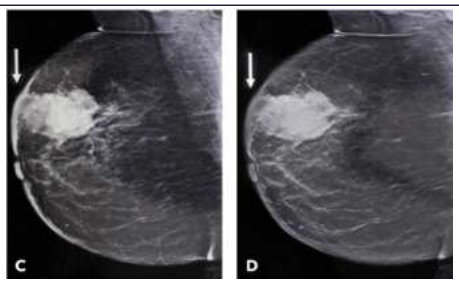


Figure 4 (A-D): Loss of skin resolution. CC(A) and MLO(C) FFDM image show better visualization of the skin (shown by arrow) CC (B) and MLO (D) SM image show loss of visualization of the skin.

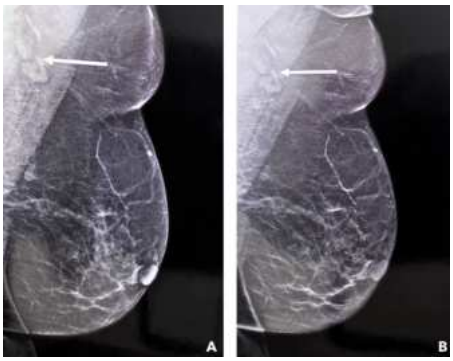


Figure 5 (A-B): Decreased axillary contrast resolution artifact. MLO SM image (B) shows decrease resolution in the axilla (marked by arrow) as compared with that of MLO FFDM image (A).

Average glandular dose (AGD) was compared for FFDM and SM. The mean AGD for FFDM was 2.46±1.30 mGy, and for SM, 2.50±0.78 mGy. There was no significant difference between the two modalities ($p = 0.12$).

Table 3 : Average Glandular Dose Comparison Between Ffdm And Synthetic 2 Dmammography (n=100)

Average glandular dose (mGy)	FFDM	DBT/SM
<1	5(5%)	0
1-1.99	29(29%)	26(26%)
2-2.99	48(48%)	54(54%)
3-3.99	12(12%)	17(17%)
4-4.99	2(2%)	1(1%)
≥5	4(4%)	2(2%)

BIRADS Category Comparison Between FFDM And SM (n=100)

Out of 100 cases, 1 case was reported as BIRADS I, 28 as BIRADS II, 23 as BIRADS III, 13 as BIRADS IVa, 11 as BIRADS IVb, and 16 cases as BIRADS V category. 8 out of 100 cases were histopathologically proven cases of breast malignancy, hence categorised as BIRADS VI.

The Kappa agreement between SM and the final diagnosis was 1.0, and between FFDM and the final diagnosis was also 1.0, indicating complete concordance in BI-RADS categorization for both methods.

DISCUSSION

Digital breast tomosynthesis (DBT) delivers a three-dimensional assessment of breast tissue. Traditionally, DBT image sets are paired with a 2D image to provide comprehensive diagnostic information. This study evaluates whether 2D synthetic mammography (SM) images can reliably replace 2D full-field digital mammography (FFDM) images.

Limitation: This study had several limitations. First, the sample size was limited to 100 patients, which might affect the generalizability of the findings. Second, the study utilised imaging equipment from a single vendor, which may not account for variations in image quality or performance across different manufacturers. Finally, various artefacts, such as bright bands and blurring of subcutaneous tissue, were noted in synthetic mammography images. While these artefacts did not hinder interpretation, their presence should be considered in the context of clinical application. Acknowledging these limitations can inform future research and help refine synthetic mammography techniques.

Breast Composition: FFDM and SM were fully concordant in visualising breast composition, mass shape, and density, consistent with study by Davis et al[6] which comprised of 385 cases and the most common breast composition in their study was also Type B.

Spiculated margin was better visualised on 2D SM as compared to 2D FFDM images. An indistinct margin was found in 11 out of 80 lesions. Out of these 11 lesions, in 9 lesions, the indistinct margin was better seen on SM images as compared to FFDM images. Both FFDM and SM images were comparable in the visualisation of circumscribed, obscured, and micro lobulated margins. Our findings were in concordance with a study by Choi et al.[7], who found that 2D SM was comparable to 2D FFDM in the detection of circumscribed, obscured, microlobulated, and indistinct margins, but was superior in the detection of spiculated margins (p value < 0.001).

Asymmetry was seen in only 2 cases. Both FFDM and SM images were comparable in visualising asymmetry.

Architectural distortion was observed in 12% of the cases and was more clearly visualised on 2D SM images. Our findings were similar to a study by Giess et al.[8], who also found that architectural distortion was more conspicuous on SM compared to FFDM.

Fine pleomorphic calcifications were more conspicuous on SM images. Dermal, round, vascular, and rim calcifications also appeared clearer on SM than FFDM images. Coarse calcifications were similar on both modalities. The p-value for calcifications was <0.05, indicating a statistically significant difference in calcification visualisation between FFDM and SM. These findings were consistent with previous reports, including Chikarmane et al.[9], who observed higher calcification conspicuity on SM. Both FFDM and SM were fully concordant in depicting the distribution of calcification.

In our study, **nipple retraction** was seen in 9% of the lesions. In these cases, nipple retraction was better visualised on FFDM images.

Skin thickening was found in 22% of the lesions. In all these cases, skin thickening was better appreciated on 2D FFDM images. There was a statistically significant difference in the visualisation of skin thickening on FFDM and SM images.

Axillary lymphadenopathy was seen in 64% of the cases. In 43% of cases, axillary lymph nodes were better visualised on 2D FFDM images compared to SM images. There was a statistically significant difference in the visualisation of axillary lymph nodes on FFDM and SM images.

Artefacts in synthetic mammography: The most common artefact was a bright band or blurring of subcutaneous tissue, observed in all cases. Loss of skin resolution (burned skin artefact) was seen in 58% of cases. Decreased axillary contrast resolution occurred in 43%, shadowing or a slinky artefact in 22%, and a foreign body artefact appeared in one case. These artefacts did not interfere with lesion assessment because tomosynthesis slices provided adequate information.

In our study, the mean average glandular dose for FFDM was 2.46 ± 1.30 mGy, and for SM, it was 2.50 ± 0.78 mGy. The p-value for the mean average glandular dose was 0.12 (>0.05), indicating no significant difference between FFDM and SM images for average glandular dose. International dose-limit guidelines suggest that a mean glandular dose below 3 mGy per view is generally considered acceptable for mammographic examinations, making the doses observed in this study clinically negligible. Our findings were concordant with a study by Choi et al.[10], who found similar radiation dose levels in their patients for FFDM and DBT (mean AGD: 1.70 mGy for single-view DBT and 1.73 mGy for single-view FFDM). Our findings were in variance with a study by Gennaro et al.[11], who found a 38% increase in radiation dose per view with DBT compared to FFDM.

Both FFDM and SM were fully concordant in BIRADS categorisation for all cases.

CONCLUSION:

FFDM and SM images provided comparable diagnostic outcomes. SM is an effective alternative to FFDM when used with DBT, with no significant difference in average glandular dose. SM improved visualisation of spiculated margins and fine pleomorphic calcifications, while FFDM was superior for skin thickening and nipple retraction. Using SM with DBT reduces radiation exposure without compromising diagnostic information, making FFDM unnecessary for patients undergoing DBT. Radiology departments should consider piloting the implementation of SM with DBT in their protocols to optimize patient care and reduce radiation exposure.

Key Messages:

- Synthetic Mammography is an effective alternative to FFDM when used with DBT.
- SM + DBT reduces radiation exposure to the patient in comparison to FFDM + DBT.
- Spiculated margins and fine pleomorphic calcifications are better visualised on 2D SM images as compared to 2D FFDM images.
- Skin thickening and nipple retraction are better visualised on 2D FFDM images as compared to 2D SM images.
- While SM may lead to the loss of some detail in skin imaging, this should be weighed against the benefits of reduced radiation exposure and the maintenance of diagnostic accuracy in the context of overall breast assessment.

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