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Comparative study between digital breast tomosynthesis plus digital mammography and digital mammography alone in symptomatic women using BI-RADS score

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ABSTRACT

Background: Digital mammography (DM) is the only screening modality that has been proven to reduce mortality from breast cancer through early detection. However, to reduce false positive results and improve the sensitivity of DM, we undertook a study to compare the impact of digital breast tomosynthesis (DBT) to DM in the evaluation of symptomatic women using the breast imaging reporting and data system (BIRADS) score. **Aims and Objectives:** The aim of the study was to compare the impact of DBT to DM in the evaluation of symptomatic women using BIRADS score. **Materials and Methods:** This cross-sectional study of 100 symptomatic patients in the age group of 35–85 years who underwent DM and DBT was included in the study and was analyzed using the American College of Radiology-BIRADS score. Patients with a palpable breast lump, pain, nipple discharge, skin dimpling, or skin changes over breast and nipple inversion or other nipple abnormalities were included in the study. **Results:** Comparison based on the diagnostic accuracy of mammography alone and mammography plus DBT based on BIRADS score revealed DM had a sensitivity of 96%, specificity of 40.6%, a positive predictive value (PPV) of 72.9% and negative predictive value (NPV) of 86.7% with an accuracy of 75.3% while DM plus DBT had a sensitivity of 98.1%, specificity of 46.9%, the PPV of 75.4%, and NPV of 78.8%. There was no significant increase in sensitivity (P = 1.000), specificity (P = 0.614), PPV (0.734), and accuracy (0.584). **Conclusion:** DM plus DBT does not change the BIRADS scoring but its addition increases the diagnostic confidence while there is no significant increase in sensitivity/specificity/PPV/NPV or diagnostic accuracy using DM plus DBT.

Key words: Breast cancer; Digital mammography; Digital breast tomosynthesis; Breast imaging reporting and data system score

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INTRODUCTION

Breast cancer is one of the leading cancers in females worldwide and is the most frequent cause of cancer-related death in women in the less developed region and the second most common cause in more developed region.[1] In India, breast cancer is ranked as the number one cancer among females (25.8/100,000) with a mortality of 12.7/100, 000 women.[2] The low survival rate due to breast cancer in less developed countries is mainly due to a lack of early detection programs resulting in a high proportion of women presenting with a late-stage disease as well as by lack of adequate diagnosis and treatment facilities.[3] Present-day full-field digital mammography (FFDM) is the only screening modality that has been proven to reduce mortality from breast cancer through early detection.[4] The sensitivity of mammography in the detection of breast cancers in the screening set-up

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ranges from 83% to 95%.[5] However, it decreases to as low as 30–48% in patients with radiographically dense and glandular breasts.[6] Advances in FFDM have led to the development of digital breast tomosynthesis (DBT) which is a pseudo-3D mammography imaging system that produces a series of thin slice images with multiple very low dose X-ray projections to reveal the inner architecture of the breast after eliminating interference from overlapping breast tissue.[7] At present, DBT is advanced enough to supplement but not supplant conventional FFDM and has the potential to reduce false-positive results while offering improved sensitivity for detecting breast cancer.[8] Hence, we undertook a study to compare the impact of DBT to DM in the evaluation of symptomatic women using the breast imaging reporting and data system (BIRADS) score.

Aims and objectives

The aim of the study was to compare the impact of DBT to DM in the evaluation of symptomatic women using BIRADS score.

MATERIALS AND METHODS

This cross-sectional study was done in the Department of Radiodiagnosis and Imaging, Government Medical College, Srinagar, over a period of 1 ½ years. A total of 100 symptomatic patients who underwent DM and DBT were included in the study after approval from the Institutional Ethical Committee and informed written consent from patients. Patients with a palpable breast lump, pain, nipple discharge, skin dimpling or skin changes over the breast, nipple inversion, or other nipple abnormalities were included in our study while pregnant and lactating women, patients with open wounds over the breast, females with age <18 years and patients with breast implants were excluded from the study.

An adequate history was elicited with special attention to breast symptoms followed by a clinical examination and relevant laboratory investigations before DM and DBT being done. DM and DBT were done in all patients on Selenia Dimensions Hologic machine (Figure 1). Participants underwent DM and DBT imaging of both breasts in the mediolateral oblique (MLO) and craniocaudal position (CC). For DBT, the technologist applied breast compression similar to that for DM. The reconstructed tomosynthesis imaging was viewed as one slice at a time or in a cine loop. Other relevant imaging (USG Breast, Galactography, MRI Breast, and USG/Mammography-guided Biopsy) was done if clinically indicated. The histopathology reports were obtained in patients once the biopsy was done. The DM and DBT of each patient were interpreted by a senior radiologist. Another senior radiologist interpreted the DBT images only and he was blinded to the DM findings.[9]

The DM and DBT were examined according to American College of Radiology (ACR) guidelines edition 2013, BIRADS-IV classes 9 for Lesion visibility, Radiographic pattern of the lesion (Mass and Calcification), and Conspicuity of the Lesion. A final assessment into seven categories according to ACR-BIRADS score was done to define a normal breast, benign, or malignant lesion.

Statistical software SPSS (version 20.0) and Microsoft Excel were used to carry out the statistical analysis of data. Continuous variables were expressed as Mean±SD and categorical variables were summarized as percentages. Graphically, the data were presented by bar and pie diagrams. Diagnostic accuracy (sensitivity, specificity, positive predicted value, and negative predicted value) of mammography alone and mammography plus DBT was obtained for the detection of various breast lesions, taking histopathology as the gold standard. The Chi-square test or Fisher's exact test, whichever is appropriate, was employed for the comparison of diagnostic accuracy between the two techniques. $P<0.05$ was considered statistically significant.

RESULTS

The mean age in our study was 48.9 years (35–85) with a standard deviation of 11.21. The maximum number of patients was in the age group of 35–55 years (74%). We had slightly more premenopausal women (53% premenopausal vs. 47% postmenopausal) with predominantly more of the rural population in our study (61%) and most of our study population consisted of unemployed females (74%). Chief complaint at presentation was breast lump in 67%, pain in 15%, nipple discharge in 13%, and vague discomfort in 5%. On examination, 70% of patients in our study population had a palpable lump, 5% had erythema and nipple retraction in 5%, whereas about 20% had an unremarkable examination. As per the location of breast lesions, most of the lesions were located in the outer upper quadrant (47.4%), while retroareolar (16.5%), upper inner (12.4%), lower outer (14.4%), and lower inner (9.3%) were less common. As per the laterality of lesions, they were more common on the right side (56.7%). Regarding size, most of the lesions (57.7%) were between 2 and 5 cm in size while 35.1% of lesions were <2 cm and only 7.2% of lesions were more than 5 cm. As per the type of composition on DM, most of the patients (61%) had Type B breast composition, 27% had Type A, while Type C and Type D were found in 9% and 3%, respectively. Regarding the shape of lesions on DM, the majority of breast lesions were irregular (45.8%) while oval (26%), lobular (21%), and round (6%) were less

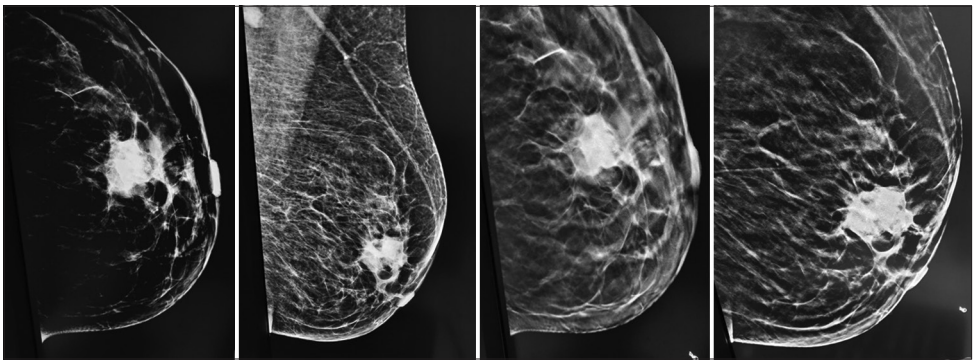

Figure 1: (a) MLO and CC views of the left breast, (b) MLO and CC views of the left breast on DM plus DBT

common. Margins of breast lesions on DM were speculated (29%), indistinct (30%), circumscribed (22.9%), obscured margins (8.3%), and microlobulated (7.3%). Regarding the density of lesions on DM, high-density lesions were found in 77%, with equal density lesions in 19.8% while low-density lesions in 2.1% and fat-containing lesions in 2.1%.

Mammography characteristics of breast lesions showed microcalcification in 29%, architectural distortion in 46%; skin thickening in 14%; nipple retraction in 28%; and satellite nodules in 13%. Axillary lymphadenopathy was found in 70% of patients on DM. As per the final BIRADS score on mammography as depicted in Table 1, the majority (47%) of patients had a score of IV, 23% had a score of V; 19% had a score of III, 8% had a score of II, and only 3% had BIRADS I.

Now combining mammography with DBT, the majority of patients (63%) had Type B breast density/composition while Type A, C, and D was found in 24, 10, and 3%, respectively.

Regarding the shape of lesion on mammography plus DBT, the majority were irregularly shaped (57.7%); while it was oval in 26.8%; round shape in 9.3%, and lobular in 6.2%. Margins of lesions on mammography plus DBT were spiculated in 40.2%, indistinct in 20.6%; circumscribed in 28.6%; microlobulated in 10.3%, and obscured in 3.1%. The density of lesions on mammography plus DBT showed high-density lesions in 68%, equal-density lesions in 30%, and low density in 1%. Characteristics of breast lesions using mammography plus DBT showed microcalcifications in 37%, architectural distortion in 45%, skin thickening in 16%, nipple retraction in 17%, and satellite nodules in 16%. Combining mammography plus DBT, axillary lymphadenopathy was found present in 76%. As per the final BIRADS score on mammography plus DBT, 37% of patients had a score of IV, 32% of patients had a score of V, 37% of patients had a score of IV, while score I and II was found in 6% and 1%, respectively (Table 1).

Table 1: BIRADS score on mammography and mammography plus DBT

BIRADS score	No. of patients	Percentage
BIRADS score on mammography		
I	3	3
II	8	8
III	19	19
IV	47	47
V	23	23
BIRADS score on mammography plus DBT		
I	1	1
II	6	6
III	24	24
IV	37	37
V	32	32

Diagnostic accuracy of mammography on the basis of the shape of the lesion revealed that irregular (n=30) and lobular lesions (n=17) were mostly malignant, whereas the majority of the oval (n=11) and round lesions (n=4) were benign. Regarding margins of the lesion, lesions with spiculated (n=23) and indistinct margins (n=20) were predominantly malignant whereas the majority of circumscribed lesions were benign (n=12). Most of the obscured lesions proved to be malignant (n=6) while lesions with microlobulated margins proved to be both benign (n=3) and malignant (n=3). Diagnostic accuracy of mammography on the basis of the density of the lesion showed that most breast malignancy lesions were high-density lesions (n=47). As per the diagnostic accuracy of mammography on the basis of microcalcifications, the majority (n=22) were malignant while only a few (n=4) were benign. Diagnostic accuracy of mammography on the basis of BIRADS score revealed that most patients with BIRADS scores IV (n=31) and V (n=20) were malignant while the majority of patients with BIRADS score of III (n=10) were benign (Table 2).

Now taking into consideration the diagnostic accuracy of mammography plus DBT on the basis of the shape of the lesion, the majority of breast lesions with irregular shape were malignant (n=43) while the majority of the

Table 2: Diagnostic accuracy of mammography and mammography plus DBT on the basis of BIRADS score (n=85)

BIRADS score	Malignant	Benign
BIRADS score on mammography		
I	1	1
II	0	2
III	1	10
IV	31	16
V	20	3
Total	53	32
Parameter	**Estimate**	**95% CI**
Sensitivity	96.2	87.3–98.9
Specificity	40.6	25.5–57.7
PPV	72.9	61.5–81.9
NPV	86.7	62.1–96.3
Accuracy	75.3	65.2–83.2
BIRADS score on mammography plus DBT		
I	0	0
II	0	1
III	1	14
IV	24	13
V	28	4
Total	53	32
Parameter	**Estimate**	**95% CI**
Sensitivity	98.1	90.1–99.7
Specificity	46.9	30.8–63.6
PPV	75.4	64.1–84.0
NPV	93.8	71.7–98.9
Accuracy	78.8	68.9–86.2

oval (n=10) and round shape lesions (n=6) were benign. On the basis of the margins of the lesion, diagnostic accuracy of mammography plus DBT showed that the majority of lesions with indistinct (n=14) and spiculated (n=30) margins were malignant, whereas the majority of circumscribed lesions (n=14) were benign. While some of the lesions (n=5) with microlobulations were malignant and some (n=5) were benign and only n=2 lesions with obscured margins were malignant. Diagnostic accuracy of mammography plus DBT on the basis of density of lesion depicted that most of the breast malignancy lesions were high-density lesions (n=48) and only n=12 were benign while breast lesions with equal density were mostly benign, n=18 and only n=5 were malignant. Further regarding the diagnostic accuracy of mammography plus DBT on the basis of microcalcifications depicted that n=34 had microcalcifications, out of which n=29 were malignant and only, n=5 were benign. As per diagnostic accuracy of mammography plus DBT on the basis of BIRADS score, most of the patients with BIRADS score IV, n= 24 and V, n=28 were malignant whereas most of the patients with BIRADS score III were benign, n=14 (Table 2).

Comparison based on the diagnostic accuracy of mammography alone and mammography plus DBT on the basis of BIRADS score shown in (Table 2) revealed that DM has a sensitivity of 96%, specificity of 40.6%, a positive predictive value (PPV) of 72.9%, and negative predictive value (NPV) of 86.7% with an accuracy of 75.3% while DM plus DBT has a sensitivity of 98.1%, specificity of 46.9%, the PPV of 75.4% and NPV of 78.8%. There was no significant increase in sensitivity (P=1.000), specificity (P=0.614), PPV (0.734), and accuracy (0.584). BIRADS distribution of cases in which calcification was detected in both DBT+DM and DM alone showed that the majority of malignant microcalcifications were seen in BIRADS IV and V.

It was observed that in most cases of the case, DBT plus DM did not change the BI-RADS scoring (Figures 1a and b, 2a and b) but its addition increases the diagnostic confidence. Architectural distortion, if present on DBT plus DM, needs careful assessment of the lesion given its strong association with malignancy (Figure 3a and b).

Case no. 1

MLO and CC views shows an irregular radio-dense mass lesion with spiculation located in superolateral quadrant of left breast. No evidence of any microcalcification in the lesion shown in DM and DM plus DBT (BI-RADS 5). Histology proven invasive ductal carcinoma as shown in Figure 4a.

Case no. 2

- On DM, and DM plus DBT: An irregular spiculated high density lesion with architectural distortion located in inferomedial quadrant of the right breast seen – BIRADS 5
- HPE proven ductal carcinoma *in situ* (DCIS) as depicted in Figure 4b.

Case no 3

- In Figure 3a ON DM, a round microlobulated high density lesion located in inferiomedial quadrant of the right breast BIRADS 4. In Figure 3b, On DM plus DBT speculation and architectural distortion is depicted. BIRADS was upgraded to V
- HPE proven medullary carcinoma as shown in Figure 4c.

DISCUSSION

The main purpose of this study was to evaluate the potential impact of adding breast tomosynthesis to FFDM for the detection and diagnosis of breast lesions which were finally compared with histopathological diagnosis, which was considered the gold standard.

Almost 74% of our patients were in the age group of 35–55 years which is comparable to studies like of Tagliafico et al.,[10] who reported a median age of 51 years with an interquartile range of 44–78 years, McCavert et al.,[11] reported a median age of 57 years and Shen et

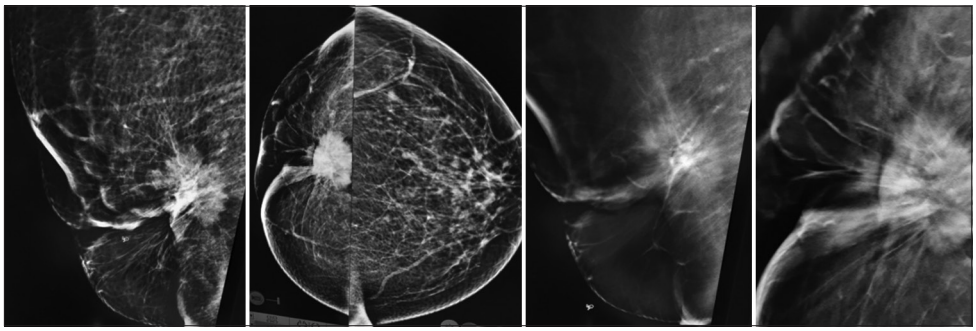

Figure 2: (a) MLO and CC views of DM of the right breast, (b) MLO and CC views of DM plus DBT of the right breast

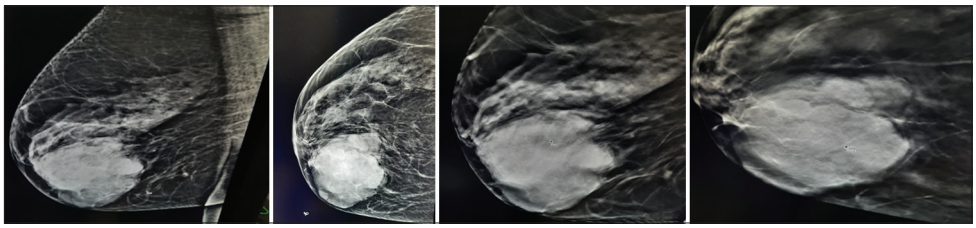

Figure 3: (a) MLO and CC views of DM of the right breast, (b) MLO and CC views of DM plus DBT of the right breast

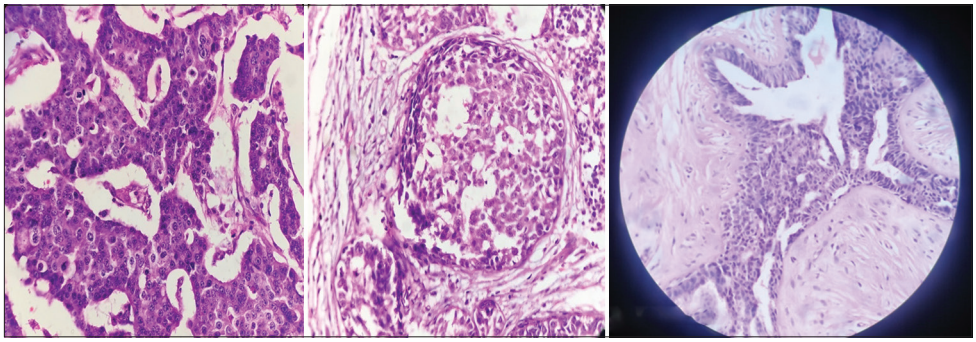

Figure 4: (a) ×40 - histopathology image corresponding to case 1 showing features of invasive ductal cell carcinoma in the lesion depicted above, (b) ×40 - histopathology image of case 2 showing features of ductal carcinoma *in situ* in the lesion depicted above, (c) Histopathology of image of case 3 proven Medullary carcinoma

al.,[12] reported a median age of 44 years (range 13–92). Regarding the chief complaint, 67% of patients presented with a breast lump, pain was found in 15%, nipple discharge in 13%, and vague discomfort in 5%. This is consistent with studies of Bland et al.,[13] Inglehart and Kaelin[14] in which breast lump or space-occupying lesion was reported as the most common presenting symptom. About 70% of our study population had a palpable lump on examination, 20% had an unremarkable examination, remaining patients had erythema (5%) and nipple retraction (5%). Shen et al.,[12] reported the accuracy of physical examination in the detection of breast masses was 84.4% which is comparable to our study. Thus, significant proportion will be non-palpable and hence will be missed by physical examination alone, thus emphasizing the need for further investigations/imaging. Most of the patients in our study had breast lesions located in the upper outer quadrant (47.4%), thus higher chances of malignancy in the same quadrant as also reported by Lee.[15] The high incidence of the mass lesion may be explained by the increased amount of glandular tissue in this region. While the mean size of breast lesions in our study was 26.8mm, which is almost comparable to the study done by Luparia et al.,[16] who had a mean size of 22.3 mm. Houssami et al.,[17] reported the cross-over age between dense to fatty breasts to occur in the range of 48–62 years. Most of our study population corresponded to this age range with a higher number of non-dense breasts which can be explained by the fact that we included only women above 35 years of age and a wide age range with the oldest participant being 85 years of age. Mariscotti et al.,[18] also reported a higher percentage of non-dense breasts in their study. As per the shape of lesions, the majority of our malignant lesions were irregular in shape. Kim et al.,[19] also reported irregular shape in 69.7% of malignant lesions on DBT. Mansour et al.,[20] reported that using tomosynthesis significantly helped in better lesion characterization and consequently verified benign or malignant impressions of the identified

masses. Mansour et al.,[20] found that on tomosynthesis images tumor margins were better assessed. Teertstra et al.,[21] also reported that the delineation of benign lesions on DBT was better than that of malignant lesions. Kim et al.,[19] found spiculated margins in most of the malignant breast lesions in their study which matches our study. Most of the breast malignancies were of high-density lesions on both modalities which were also found by Woods et al., (2011).[24] Rafferty et al.,[22] reported a non-significant increase in diagnostic accuracy for calcification using DM plus tomosynthesis, as was reported by our study.

Singla et al.,[23] found that in most cases (47) DBT did not change BIRADS scoring but its addition increased the diagnostic confidence. Almost similar results were reported by our study where BIRADS was upgraded in only 3 cases and downgraded in only one case with the addition of DBT to FFDM. The difference in sensitivity between DM plus DBT and DM only was not statistically significant in our study which was comparable to the results of Gilbert et al.,[24] in which there was only marginal improvement in sensitivity when DBT was used in conjunction with DM compared with DM alone. Barry-Brookes et al.,[25] reported that there was no significant difference in the biopsy PPV or cancer detection rates per thousand patients screened in the pre-tomosynthesis group versus the post-tomosynthesis group. PPV for DM was 72% and for DM plus DBT was 75.4% with an insignificant P-value. Specificity and NPV also revealed a non-significant P-value. A non-significant increase in cancer detection ranging from 4.3% to 4.9% has been reported in our study which was largely attributed to sampling size limitations. However, our results differ from Singla et al.,[23] who reported the addition of DBT to FFDM resulted in a significant increase in the sensitivity, specificity, and PPV. Our results also differ from a prospective screening trial, by Skaane et al.,[26] in which significant gains in sensitivity and specificity were found in the addition of DBT to DM.

Limitatios of the study

There were a few limitations of our study that could explain the above differences. Although the sample size was adequate but was not large enough. More so, it was a hospital-based study done on symptomatic patients for diagnostic purposes. Furthermore, as our data set comprised primarily cases that had a mammographic abnormality identified by 2D imaging. Thus, we may have underestimated the contribution of DBT, since these cases had already been detected by 2D mammography. Similarly, the lack of significant improvement in sensitivity and specificity is that the addition of DBT had minimal impact on the performance of experienced, high-volume film readers.

CONCLUSION

DM plus DBT does not change the BI-RADS scoring but its addition increases the diagnostic confidence while there is no significant increase in sensitivity/specificity/PPV/NPV or diagnostic accuracy using DM plus DBT.

Architectural distortion, if present on DBT, warrants careful assessment of the lesion given its strong association with malignancy while margins of the lesion are better assessed on DBT plus DM than DM only. We also conclude that the majority of high-density lesions proved to be malignant on both DM and DM plus DBT.

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Nil.

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Authors Contribution:
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