



Three-Dimensional Digital Breast Tomosynthesis versus Two-Dimensional Mammography in Detection and Characterization of Breast Lesions Keeping Biopsy as the Gold Standard

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ABSTRACT

Background: Breast cancer is a major cause of cancer death in women throughout the world. Accurate detection at an early stage is extremely important to improve outcomes. Digital breast tomosynthesis (DBT) has potential advantages over conventional digital mammography (DM) due to reduction of tissue superimposition. This study is being conducted with the aim to compare the diagnostic performance of the three-dimensional digital breast tomosynthesis and two-dimensional digital mammography in the detection and characterization of the breast lesions, using histopathology as the gold standard. **Methods:** This cross-sectional validation study was conducted in the radiology department of a Combined Military Hospital, Gujranwala from 31 January 2025 to 31 May 2025. Female patients aged 25-70 years who underwent both the digital mammography and digital breast tomosynthesis and had a breast lesions categorized as BI-RADS categories three to five were included. All participants afterwards underwent histopathological evaluation through the biopsy or surgical excision. Imaging findings were interpreted independently by the experienced radiologists who were blinded to the histopathological results. Sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy were measured for both imaging modalities. **Results:** The mean age of participants was found to be 48.32±12.96 years. DBT was shown to have improved diagnostic performance over DM, having higher sensitivity (92.3% vs. 84.6%), specificity (79.4% vs. 76.5%), PPV (77.4% vs. 73.3%), NPV (93.1% vs. 86.7%) and overall accuracy (85.0% vs. 80.0%). **Conclusion:** 3-D digital breast tomosynthesis is a superior modality to conventional mammography for the detection and characterization of breast lesions in terms of sensitivity, specificity, and negative predictive value. Its superior performance in diverse patient subgroups supports the role of this modality as a preferred modality of imaging, especially in symptomatic patients and patients of challenging breast compositions.

INTRODUCTION

Breast cancer is a significant cause of all female cancers and deaths worldwide. According to the global cancer statistics, it is responsible for about 2.3 million new cases and almost 685,000 deaths every year, which is a major public health concern in both developed and developing countries [1]. Increased incidence of breast cancer is attributed to demographic transition, delayed presentation, lifestyle changes, genetic predisposition and enhanced detection strategies [2]. Early detection and proper diagnosis is extremely important in minimizing mortality and aiding the survival rate. Two-dimensional digital mammography (2D-DM) has long been established as the established screening modality for early breast cancer screening because it is accessible, cost-effective and has been shown to reduce mortality [3]. It enables

visualization of microcalcifications, masses, architectural distortions that are suggestive of early cancer. Conventional mammography is associated with considerable limitations that are mostly attributed to tissue superimposition. Overlapping fibroglandular tissue can conceal lesions resulting in false negative results or mimic abnormalities resulting in false positives and unwarranted biopsy. These difficulties are greater among women with dense breasts, in which mammographic sensitivity can decrease from about 85% fatty breasts to nearly 60% extremely dense tissue [4,5]. Three-dimensional digital breast tomosynthesis (DBT) has been developed to overcome these shortcomings. By obtaining several low-dose projections from varying angles and reconstructing them into thin slices, DBT minimizes tissue overlap and improves lesion detection, characterization

and localization [6,7]. Clinical studies, such as the Oslo Tomosynthesis Screening Trial, have shown that the use of DBT in addition to conventional mammography increases cancer detection rates whereas recall rates are reduced [8,9]. Research has shown that DBT is more effective in detecting invasive cancer and other lesions that are covered by dense tissue, as well as radiation exposure for the 2D pictures that are produced is significantly less according to meta-analyses. Accurate characterization of the lesion is crucial to proper management and this is typically standardized using the Breast Imaging Reporting and Data System (BI-RADS). Histopathological examination is the gold standard for definite diagnosis, as it allows distinction between benign and malignant lesions, and is a critical source of prognostic information [10,11]. Therefore, correlation of imaging results with histopathology is basic for validation of diagnostic accuracy.

In developing countries such as Pakistan, late-stage presentation is still common because of low screening programs and awareness. Comparative evaluation of DBT and conventional mammography in local populations is therefore of essential importance.

METHODOLOGY

This study was designed as a cross-sectional validation and conducted in the radiology department of a Combined Military Hospital, Gujranwala from 31 January 2025 to 31 May 2025. The study population consisted of the female patients presenting for the breast imaging due to the screening purposes, clinical breast symptoms, or suspicious findings on the preliminary imaging following detection of lump in the breast on self-physical examination. A non-probability consecutive sampling technique was also employed to include all the desirable participants. The sample size was calculated as 60 patients based on the expected sensitivity values reported in the prior study by Abdelattef SAA et al. [12] comparing digital breast tomosynthesis and the digital mammography, and found the sensitivity, specificity and prevalence as 100%, 90.5% and 37% respectively while confidence level kept as 95% and described precision kept as 10%. The female patients aged 25-70 years who underwent both the digital mammography and digital breast tomosynthesis and had breast lesions categorized as the BI-RADS 3, 4, or 5 were included in this study. Only patients who subsequently underwent histopathological evaluation through biopsy or the surgical excision were considered eligible. Patients with a history of the previous breast cancer treatment, pregnancy, incomplete imaging or histopathological records, or the poor-quality imaging studies that prevented adequate to the evaluation were excluded from the study.

The standard digital mammographic examinations were also performed using the craniocaudal and mediolateral oblique projections with the calibrated equipment under the standardized exposure protocols. The experienced radiologists independently interpreted the mammographic images. Digital breast tomosynthesis was performed using the specialized equipment capable of acquiring a multiple low-dose projection images from very different angles, which were reconstructed into the thin

slices to allow a detailed evaluation of the breast tissue. The radiologists interpreted the tomosynthesis images independently and were blinded to the histopathological results. Histopathological analysis was carried out following core needle biopsy, fine needle aspiration cytology, or the surgical excision. The tissue specimens were processed using routine histological techniques and stained with the hematoxylin and eosin. The histopathological findings served as the gold standard for the confirmation of the lesion characteristics.

The demographic data including the patient age, clinical presentation, and imaging findings were recorded. The imaging results were classified according to the BI-RADS classification system, and lesion characteristics such as shape, margins and density were also registered. The primary outcome measures included the sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. These parameters were calculated separately for the digital mammography and digital breast tomosynthesis using histopathology as the reference standard. The statistical analysis was also performed using appropriate statistical software. The continuous variables were expressed as mean and the standard deviation, whereas categorical variables were presented as frequencies and the percentages. Diagnostic accuracy parameters were measured using the standard formulas, and the comparative analysis between the two imaging modalities was conducted using appropriate statistical tests, with a significance level set at the p-value <0.05. The study protocol received approval from the institutional ethical review committee, and patient confidentiality was very strictly preserved. All imaging and histopathological procedures were performed in accordance with the standard clinical guidelines.

RESULTS

The mean age of all the 60 enrolled subjects was 48.32 ± 12.96 years, mean duration of the breast lesion was 24.47 ± 15.59 weeks while, mean BMI was 26.01 ± 5.16 kg/m². Patients were further categorized into different groups on the basis of age, BMI and duration of lesion which are graphically illustrated in figure 1, figure 2 and figure 3. Patients were also distributed in different groups on the basis of mammographic feature of breast lesions and we found that 63.3% were presented with regular margins, 51.7% well-defined margins and were iso-dense (table 1).

Figure 1

Distribution of Patient in Different Age Categories (n=60)

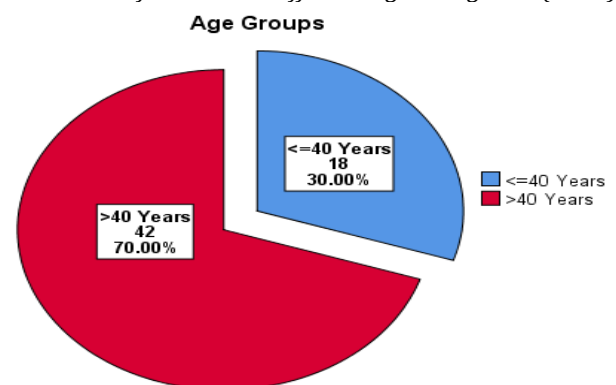


Figure 2
Distribution of Patient in Different Subgroups on the Basis of Duration of Lesion (n=60)

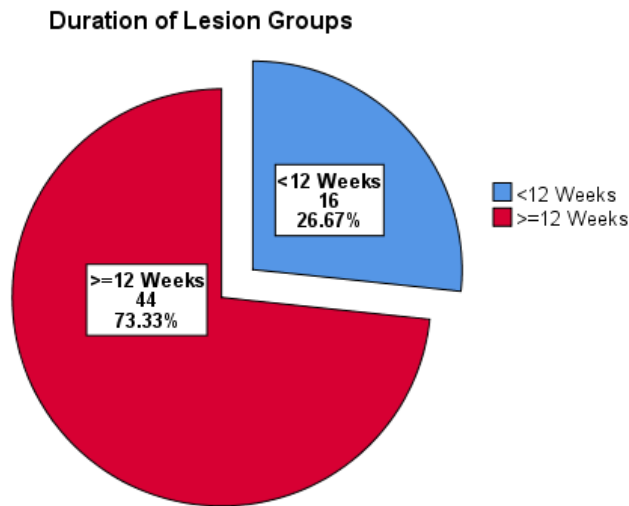


Figure 1
Distribution of Patient in Different BMI Categories (n=60)

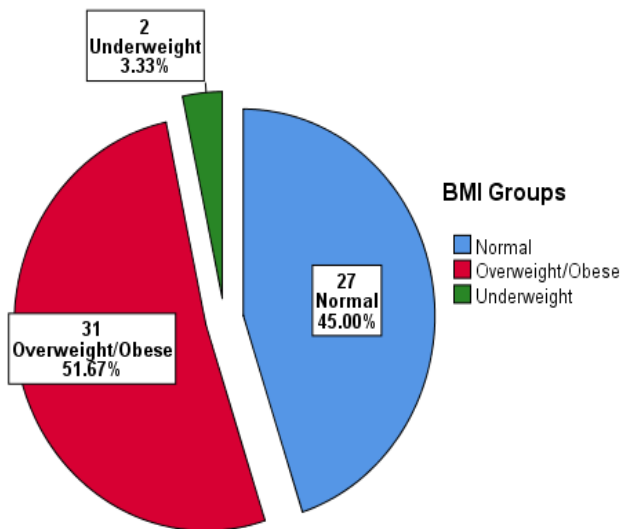


Table 1
Distribution of Study Patients on the basis of various mammographic features

Mammographic Features	Category	Frequency (n)	Percent (%)
Shape	Irregular	22	36.7
	Regular	38	63.3
Margin	Spiculated	29	48.3
	Well-defined	31	51.7
Density	Hyperdense	29	48.3
	Isodense/Fat-density	31	51.7

Mammographic screening showed that 50% (n=30) patients were positive for mammography while tomosynthesis showed 51.7% (n=31) of positive results. On the other hand, the gold standard histopathology showed 43.3% (n=26) of cases positive for malignancy (table 2).

Table 2
Overall Findings of Mammography, Tomosynthesis and Histopathology

Diagnostic Modality	Category	Frequency (n)	Percent (%)
Mammography Result	Negative	30	50.0
	Positive	30	50.0
Tomosynthesis Result	Negative	29	48.3
	Positive	31	51.7
Histopathology Result	Negative	34	56.7
	Positive	26	43.3

Cross tabulation analysis of mammography and tomosynthesis reflected that both the modalities have a stronger diagnostic capability for accurate detection of breast lesion while 3D-tomosynthesis showed little bit superior diagnostic performance in comparison with tomography, as its sensitivity was 92.3% while mammography showed 84.6% of sensitivity. Similarly, specificity was also higher for 3D-tomosynthesis (79.4% vs. 76.5%) showing better identification. Detailed analysis of diagnostic accuracy parameters is presented in table 3, table 4 and table 5.

Table 3
Cross-Tabulation of Mammography vs Histopathology (Gold Standard)

Mammography	Histopathology Negative	Histopathology Positive	Total
Negative	26 (True Negative)	4 (False Negative)	30
Positive	8 (False Positive)	22 (True Positive)	30
Total	34	26	60

Table 4
Cross-Tabulation of 3-D Tomosynthesis vs Histopathology (Gold Standard)

3D-Tomosynthesis	Histopathology Negative	Histopathology Positive	Total
Negative	27 (True Negative)	2 (False Negative)	29
Positive	7 (False Positive)	24 (True Positive)	31
Total	34	26	60

Table 5
Comparative Evaluation of Diagnostic Accuracy Parameters among Mammography and Tomosynthesis

Modality	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Mammography (2D)	84.6	76.5	73.3	86.7	80.0
Tomosynthesis (3D)	92.3	79.4	77.4	93.1	85.0

Stratification analysis showed a consistent better performance of Tomosynthesis than mammography in all subgroups with higher overall accuracy (85.0% vs. 80.0%). Optimal diagnostic performance for both modalities was seen in overweight / obese patients, regular-shaped lesions, spiculated margins and isodense / fat density lesions. Mammography had lower sensitivity in patients who were older than 40 years (77.8%) and had shorter duration of symptoms (66.7%), whereas the sensitivity of tomosynthesis was excellent (>88%) in all groups. Diagnostic challenges were greatest for

hyperdense lesions, irregular shape and well-defined margins, where the specificity and PPV were significantly

lower. Detailed stratification analysis findings are tabulated in table 6 and table 7.

Table 6
Stratified Diagnostic Accuracy of Mammography by Variable

Variable		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Age Group	≤40 Years	100% (8/8)	70.0% (7/10)	72.7% (8/11)	100% (7/7)	83.3% (15/18)
	>40 Years	77.8% (14/18)	79.2% (19/24)	73.7% (14/19)	82.6% (19/23)	78.6% (33/42)
Duration Group	<12 Weeks	66.7% (4/6)	80.0% (8/10)	66.7% (4/6)	80.0% (8/10)	75.0% (12/16)
	≥12 Weeks	90.0% (18/20)	75.0% (18/24)	75.0% (18/24)	90.0% (18/20)	81.8% (36/44)
BMI Group	Normal	90.9% (10/11)	62.5% (10/16)	62.5% (10/16)	90.9% (10/11)	74.1% (20/27)
	Overweight/Obese	85.7% (12/14)	88.2% (15/17)	85.7% (12/14)	88.2% (15/17)	87.1% (27/31)
	Underweight*	100% (1/1)	100% (1/1)	100% (1/1)	100% (1/1)	100% (2/2)
Shape	Irregular	77.8% (7/9)	61.5% (8/13)	58.3% (7/12)	80.0% (8/10)	68.2% (15/22)
	Regular	88.2% (15/17)	85.7% (18/21)	83.3% (15/18)	90.0% (18/20)	86.8% (33/38)
Margin	Spiculated	92.9% (13/14)	80.0% (12/15)	81.3% (13/16)	92.3% (12/13)	86.2% (25/29)
	Well-defined	75.0% (9/12)	73.7% (14/19)	64.3% (9/14)	82.4% (14/17)	74.2% (23/31)
Density	Hyperdense	72.7% (8/11)	66.7% (12/18)	57.1% (8/14)	80.0% (12/15)	69.0% (20/29)
	Isodense/Fat-density	93.3% (14/15)	87.5% (14/16)	87.5% (14/16)	93.3% (14/15)	90.3% (28/31)

Table 7
Stratified Diagnostic Accuracy of Tomosynthesis by Variable

Variable	Category	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Age Group	≤40 Years	100% (8/8)	80.0% (8/10)	80.0% (8/10)	100% (8/8)	88.9% (16/18)
	>40 Years	88.9% (16/18)	79.2% (19/24)	76.2% (16/21)	90.5% (19/21)	83.3% (35/42)
Duration Group	<12 Weeks	100% (6/6)	80.0% (8/10)	75.0% (6/8)	100% (8/8)	87.5% (14/16)
	≥12 Weeks	90.0% (18/20)	79.2% (19/24)	78.3% (18/23)	90.5% (19/21)	84.1% (37/44)
BMI Group	Normal	90.9% (10/11)	68.8% (11/16)	66.7% (10/15)	91.7% (11/12)	77.8% (21/27)
	Overweight/Obese	92.9% (13/14)	88.2% (15/17)	86.7% (13/15)	93.8% (15/16)	90.3% (28/31)
	Underweight*	100% (1/1)	100% (1/1)	100% (1/1)	100% (1/1)	100% (2/2)
Shape	Irregular	88.9% (8/9)	61.5% (8/13)	61.5% (8/13)	88.9% (8/9)	72.7% (16/22)
	Regular	94.1% (16/17)	90.5% (19/21)	88.9% (16/18)	95.0% (19/20)	92.1% (35/38)
Margin	Spiculated	100% (14/14)	80.0% (12/15)	82.4% (14/17)	100% (12/12)	89.7% (26/29)
	Well-defined	83.3% (10/12)	78.9% (15/19)	71.4% (10/14)	88.2% (15/17)	80.6% (25/31)
Density	Hyperdense	90.9% (10/11)	66.7% (12/18)	62.5% (10/16)	92.3% (12/13)	75.9% (22/29)
	Isodense/Fat-density	93.3% (14/15)	93.8% (15/16)	93.3% (14/15)	93.8% (15/16)	93.5% (29/31)

DISCUSSION

This study shows that digital breast tomosynthesis (DBT) offers better diagnostic accuracy than conventional digital mammography (DM) for detecting and characterizing breast lesions (higher sensitivity 92.3% vs 84.6% in DBT and higher specificity 79.4% vs 76.5% in DBT and higher overall accuracy 85.0% vs 80.0% in DBT). These findings are in line with established evidence that shows the diagnostic benefits of DBT over conventional mammography. The superior performance of DBT is due to its quasi-three-dimensional imaging capability, which minimizes tissue superimposition and increases visualization of masses and architectural distortions and spiculations. Our stratified analysis also found that DBT had excellent sensitivity (>88%) regardless of subgroup, but DM had a lower sensitivity in patients >40 years (77.8%) and patients with shorter symptom duration (66.7%). Notably, optimal diagnostic performance for both modalities was determined for overweight/obese patients, regular shaped lesions, spiculated margins, and isodense/fat density lesions, with diagnostic challenges for hyperdense lesions, irregular shapes, and well defined margins.

Our findings support previous evidence of the diagnostic superiority of DBT over conventional mammography. The higher negative predictive value (NPV) of DBT in our study (93.1% vs. 86.7%) is consistent with the meta-analysis performed by Friedewald et al. [13], which demonstrated significant improvement in cancer detection rates with the reduction of recall rate over DM alone in a large multicenter study of 454,850 exams. Similarly, Skaane et al. [14] showed in a population-based screening program that DBT plus DM resulted in a higher rate of cancer detection (27% higher incidence than DM alone) with a greater improvement in detecting invasive cancers. The enhanced characterization of the lesions using DBT, especially spiculated margins in which we found 100% sensitivity and NPV, is in line with the results of Michell et al. [15] in which they found that use of DBT allows a more accurate characterization of lesion margins and minimizes the diagnostic ambiguity. Furthermore, our result that DBT was superior to DM in the overweight/obese subgroup (90.3% vs. 87.1% accuracy) is echoed by the work of Destounis et al. [16] who showed that DBT continues to perform better in women with higher body mass index where tissue overlap is likely to impair

conventional mammography.

The clinical implications of our study findings are high, as the higher NPV of DBT means more reassurance in ruling out malignancy, which could result in fewer unnecessary biopsies and follow-up examinations in patients with no imaging findings. This is of particular value in resource limited settings where the reduction of invasive procedures is desirable. Second, the superior ability of DBT to describe features of lesions (especially spiculated margins and regular shapes) can improve the accuracy of BI-RADS categorization and support more appropriate clinical management decisions. Michell et al. [15] stressed that better characterization of lesions using DBT makes it easier to distinguish benign from malignant lesions, and may result in less unnecessary benign biopsies. Third, our finding that DBT shows excellent sensitivity across all age groups and symptom duration suggests that DBT may be of particular value to evaluate symptomatic patients as well as those with shorter symptom duration, in which case, DM showed low sensitivity. The European Society of Breast Imaging recommends DBT as a first line modality in symptomatic patients especially those with dense breasts based on its superior diagnostic performance [17]. Additionally, the work of Bernardi et al. [18] showed that DBT significantly reduces recall rates without compromising cancer detection, supporting the use of DBT in a broader clinical setting in both screening and diagnostic settings.

This study has several strengths including the use of histopathology as the gold standard as a reference for all cases, stratified analysis in multiple demographic and imaging characteristics, and direct head-to-head comparison of both modalities in the same patient

population. However, there are a number of limitations to be recognized. The single center design and relatively small sample size (n=60) may preclude generalizability to larger populations. The non-probability sampling method is prone to selection bias, and the interobserver variability was not formally evaluated. Additionally, as mentioned by McDonald et al. [19], although DBT has superior demonstration metrics, it stands to reason that its implementation needs to consider factors such as cost, radiation dose, and interpretation time. For validation of these results as well as guide evidence-based screening recommendations, future multicenter studies with bigger cohorts and standardized reporting procedures are necessary especially in developing nations where the incidence of breast cancer is still on the rise and delayed presentation is still a major problem.

CONCLUSION

Digital breast tomosynthesis has shown better diagnostic accuracy than conventional mammography for the detection and characterization of breast lesions with higher sensitivity (92.3% vs. 84.6%), specificity (79.4% vs. 76.5%) and negative predictive value (93.1% vs. 86.7%). DBT had excellent performance in all patient subgroups, while mammography had a decreased sensitivity in older patients and patients with shorter duration of symptoms. The increased NPV of DBT is more reassuring in the exclusion of malignancy and may lead to less unnecessary biopsies. These findings support DBT as an imaging modality of choice for detecting breast lesion, especially in patients with symptoms and in difficult diagnostic circumstances.

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