ORIGINAL ARTICLE

# Assessment of Diagnostic Accuracy of Digital Breast Tomosynthesis in Distinguishing Malignant and Benign Breast Lesions

Kanza Afzal[1], Nadia Gul[1*], Khalid Mehmood[2], Sobia Jawwad[1], Bushra Iqbal[1]


## ABSTRACT

**Objective:** The study aims to determine the diagnostic accuracy of digital breast tomosynthesis in diagnosing malignant and benign lesions, keeping histopathology as the gold standard.

**Study Design:** Cross-sectional study.

**Place and Duration of Study:** The study was carried out at the Department of Diagnostic Radiology, POF Hospital, Wah Cantt, Pakistan over a period of six months from 11th July 2021 to 11th January 2022.

**Methods:** A total of 200 women presenting with suspicion of breast malignancy were selected consecutively from the outpatient department, and Digital Breast Tomosynthesis (DBT) was performed, followed by a biopsy of the specimen to confirm the findings on histopathology.

**Results:** The average age of the sample was 48.3 + 7.1 years, ranging between 35 and 60 years. Palpable breast lump was recorded in 44.5%, pain in 33%, and nipple discharge in 35.5%. Family history of breast Ca was present in 25.5. On Digital Breast Tomosynthesis (DBT), 58.5% of lesions were labeled as malignant, while 53.5% were labeled as malignant on follow-up histopathology. On applying the formulae for calculation, the sensitivity of DBT was found to be 86% and specificity 73.1%. The positive predictive value of the DBT is 78.6%, and the negative predictive value is 81.9%.

**Conclusion:** In conclusion, Digital Breast Tomosynthesis is a significantly sensitive and specific tool for detecting malignant breast lesions in women suspected of breast carcinoma.


**Keywords:** *Architectural Distortion, Breast Carcinoma, Digital Breast Tomosynthesis.*

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## Introduction

Breast cancer is the most common cancer in women worldwide and is a significant public health concern due to its high incidence and impact on morbidity and mortality.[1] If not detected and treated early, breast cancer can metastasize to distant body parts and become lethal. The five-year survival of metastatic breast cancer is 10%. However, earlier detection and treatment can improve five-year survival to 85%.[2]

The Food and Drug Administration (FDA) first approved Digital Breast Tomosynthesis (DBT) in 2011, and multiple studies have shown that DBT is effective in screening and diagnostic settings.[3] Digital breast tomosynthesis (DBT) is a new technique added to digital mammography that decreases the masking effect of overlapping tissue in improved characterization of breast tissue and providing good-quality images. DBT allows the creation of pseudo-3D imaging of the breast and can detect breast carcinoma in an earlier stage, resulting in good prognosis, improved breast cancer detection and diagnostic accuracy with fewer false positives, and increased patient comfort and survival rate.[2]

Breast tomosynthesis takes images of a breast at various angles during a short scan. These multiple images are then reconstructed into a series of 1mm thin slices that can be displayed individually or in cine

[1]*Department of Radiology*
*POF Hospital, Wah Cantt, Pakistan*
[2]*Department of Neurosurgery*
*Combined Military Hospital (CMH) Kharian, Pakistan*
*Correspondence:*
*Dr. Nadia Gul*
*Associate Professor, Radiology*
*POF Hospital, Wah Cantt, Pakistan*
*E-mail: mrsnadiagul@gmail.com*

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mode. Thus, radiologists see breast tissue more clearly.[3] The standard DBT craniocaudal and mediolateral oblique views can depict mass shapes and margins with fine details, revealing a suspicious irregular shape, indistinct or spiculated margins, or both.[3]

DBT can potentially eliminate the confounding information caused by structural noise and improve the visibility of masses. DBT accurately detects masses and architectural distortion, thus significantly reducing false negatives and false positives due to overlapping.[4]

DBT is evaluated according to the American College of Radiology Breast Imaging Reporting and Data System (ACR-BIRADS) from BIRADS I to V. BIRADS 0, which indicates the need for further imaging. BIRADS I indicates negative, and II indicates benign screening mammogram. BIRADS III is classified as probably benign and should have a short-term follow-up (Figure 1).

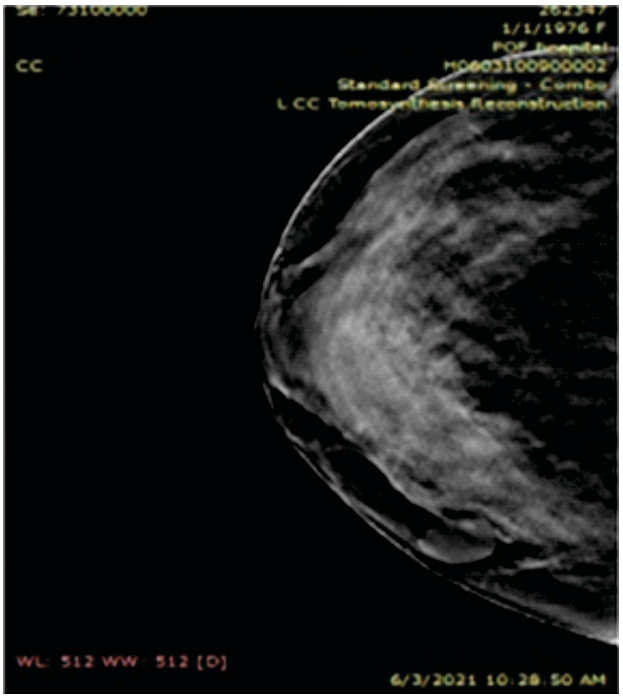


**Fig 1: A well-defined ovoid low-density mass is noted in the inner lower quadrant. No associated architectural distortion or skin thickening noted likely fibroadenoma - BIRADS III**

BIRADS IV and V indicate suspicious malignancy and highly suggestive malignancy (Figure 2), respectively.[5]

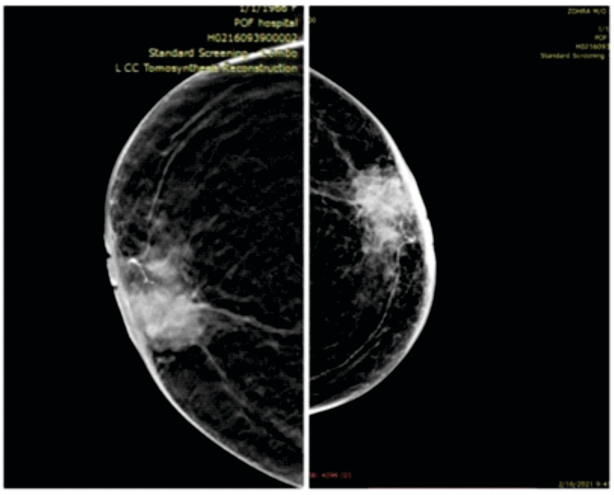


**Fig 2: Large irregular high-density soft tissue mass with indistinct margins are seen in the retroareolar region predominantly in the upper outer quadrant. Associated architectural distortion, skin thickening, and pleomorphic microcalcification was noted, -BIRADS V**

Even though breast cancer is common in Pakistan, only limited literature is available from Pakistan, according to which Digital Breast Tomosynthesis is the best diagnostic and screening tool for benign and malignant breast lesions. The study aims to evaluate the diagnostic accuracy of Digital Breast Tomosynthesis in the assessment of malignant and benign lesions which will guide the clinician to make a reasonably sure diagnosis before invasive procedure and improve patient comfort.

## Methods

It is a cross-sectional validation study held in the Department of Diagnostic Radiology, POF Hospital, Wah Cantt, Pakistan over a period of six months from 11th July 2021 to 11th January 2022 after taking permission from the ethics committee of the hospital held on 3rd July 2021 vide letter no: WMC/IRB/21. A sample size of 200 cases is calculated from the WHO calculator with a confidence level of 95%, taking the prevalence of breast cancer as 50%. The sensitivity of DBT is 97% with a precision of 10%, and the specificity of DBT is 64.5% with a precision of 10% and taking histopathology as the gold standard.[2] The sampling technique is nonprobability consecutive sampling. Patients aged between 35-65 years with suspected breast lumps based on clinical presentation are included in our study. Pregnant, lactating females or

females with breast implants are excluded from the study.

**Data collection procedure**

The study was carried out after institutional ethical committee approval. Consent was taken, the procedure was explained to patients. History was taken regarding patient signs and symptoms, especially family history of breast cancer in first-degree relatives from patients. Patients fulfilling inclusion criteria were included in the study. Patients underwent DBT imaging of bilateral breasts in the craniocaudal and mediolateral oblique positions using a standard DBT system (Selenia Dimensions 500). This machine's specifications are as follows: detector pixel size 3328 x 4096; resolution 7.1 lp/mm; pixel pitch 70 µm. The average glandular radiation doses for DBT in a single view are approximately 1.65 mGy. For DBT, the Breast is compressed once, and a machine takes multiple, low-dose images of the breast; x-ray tube moves in an arc of -7.5 to +7.5 across the breast. These images were used to produce a series of 1mm thick images (from 60 to 90 slices, according to the breast sizes) that can be reconstructed to a three-dimensional image of the breast using the filtered back projection technique. All the results were analyzed by a consultant radiologist. To minimize the learning and memory bias, they evaluated the DBT images and assigned the BI-RADS category. All patients a breast lump biopsy in the concerned ward, and the specimen was sent for histopathology in the institutional laboratory, where the histopathology report was interpreted by a pathologist. DBT results were correlated with histopathology reports.

**Data analysis**

Data were entered and analyzed using SPSS version 23. Descriptive statistics were calculated for both qualitative and quantitative variables. For qualitative variables (mass composition and contour, benign or malignant, calcification, architectural distortion, skin thickening, and nipple retraction), frequency and percentage were calculated. For quantitative variables (age, size of breast mass), mean and standard deviation was calculated. Effect modifiers like age and size of breast mass were controlled through stratification. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) or Digital Breast Tomosynthesis were calculated by 2x2 table, taking histopathology as the gold standard. The receiver operator curve was formed. All results were presented as tables and graphs.

## Results

The study was conducted on 200 women presenting with suspicion of breast malignancy. The mean age of the sample was 48.3 $\pm$ 7.1 years. The minimum age of 35 years, and maximum age is 35 years, and the maximum age is 60 years. Palpable breast lump was recorded in 44.5%, pain in 33%, and nipple discharge in 35.5%. Family history of breast Ca was present in 25.5%. On DBT, 58.5% of lesions were labeled as malignant, while on follow-up histopathology, 53.5% were labeled as malignant. On applying the formulae for calculation, the sensitivity of DBT was found to be 86% and specificity 73.1%. The positive predictive value of the DBT is 78.6%, and the negative predictive value is 81.9% (Table 1).

## Discussion

Mammography serves as the main imaging technique for detecting breast cancer in women over the age of 40. When digital breast tomosynthesis (DBT) is used in conjunction with digital mammography (DM), it proves valuable in enhancing sensitivity and refining BIRADS (Breast Imaging Reporting and Data System) characterization by mitigating the issue of overlapping tissue. Moreover, when ultrasonography (US) is added to this

**Table 1: DBT and histopathology 2x2 (n = 200)**

| Malignancy on DBT | Malignancy on Histopathology | | Total |
|---|---|---|---|
| | Yes | No | |
| Yes | 92 | 25 | 117 |
| No | 15 | 68 | 83 |
| Total | 107 | 93 | 200 |

*Sensitivity of DBT: TP/TP + FN = 86%*
*Specificity of DBT: TN/TN + FP = 73.1%*
*Positive Predictive Value DBT: TP/TP + FP = 78.6%*
*Negative Predictive Value DBT: TN/TN + FN = 81.9%*
*Accuracy: TP + TN / n = 80%*

combination, it further elevates sensitivity and enhances diagnostic confidence in detecting breast cancer.[6]

Women who present with palpable breast lumps have a higher likelihood of having cancer compared to all women undergoing breast imaging.[7] Mammography employs X-rays to evaluate the breast's internal structures based on the differential attenuation properties of its tissues. Different tissues in the breast, such as fat, glandular tissue, and tumors, absorb X-rays to varying degrees. This differential attenuation allows mammography to create detailed images of the breast, helping detect abnormalities such as breast cancer or other breast-related conditions. Superimposition of breast tissue structures is a significant challenge in mammography, as it can obscure small masses or abnormalities, making it difficult to detect breast cancer at an early stage. Screening mammograms are typically performed from at least two standard views: the craniocaudal view (CC) and the mediolateral oblique (MLO) view to address this issue. This comparison helps identify and differentiate structures that might be obscured or superimposed in one view but visible in the other. In cases where there is uncertainty or if a suspicious area needs further evaluation, additional diagnostic views, like spot compression and mediolateral (ML) views, may be employed to get different vantage points and aid in the diagnostic process. Tomosynthesis overcomes this limitation by capturing multiple images of the breast from different angles, allowing the creation of thin "slices" of breast tissue.[8]

Digital mammography (DM) has two limitations. The first one is a masking effect in dense breasts. This effect arises due to the overlying of normal parenchyma, which may simulate a lesion, leading to decreased sensitivity. The second one is its low specificity, which arises due to the summation of normal breast parenchyma that mimics a lesion.[9]

DBT is an advanced imaging technology that produces three-dimensional volumetric images of the breast, unlike traditional 2D mammography. DBT images are obtained by taking each breast's X-ray projections in the mediolateral oblique (MLO) and craniocaudal (CC) views. The X-ray tube moves in a positive and negative arc over compressed breast tissue, typically ranging from 15 to 50 degrees, depending on the thickness of the breast tissue. The acquisition time varies, usually 10 to 25 seconds for each projection. The result is a series of 11 to 19 images reconstructed into 1 mm-thick slices. Radiologists review DBT images by scrolling through individual or multiple sections, enabling a thorough evaluation of the breast tissue. The ability to generate 3D images with reduced tissue overlap has improved cancer detection rates, leading to better patient outcomes. Artifacts have the potential to mask the lesion and decrease the sensitivity or specificity of the modality.[10,11]

DBT cannot replace digital mammography but is used in combination with digital mammography to provide a more comprehensive evaluation of breast tissue, thus improving diagnostic confidence. However, it is not a replacement of histopathology, which remains the gold standard, but combining DBT with digital mammography enhances diagnostic yield.[12]

Numerous previous studies have underscored the advantages of integrating DBT into screening studies, reducing recall rates and improving sensitivity. Similar mammographic sensitivity and specificity improvements will probably be observed in the diagnostic setting. However, this aspect necessitates further investigation.[13]

In our study, DBT shows 86% sensitivity, 73,1% specificity, 78,6% PPV, and 81.9 %NPV with a diagnostic accuracy of 80%. Our study's results align with those of Nakashima et al., who demonstrated better overall visibility of circumscribed masses on DBT images compared to digital mammograms in 59 cases.[14] These findings line also align with the results reported by Chan et al., indicating significantly greater conspicuity of lesions on DBT compared to DM.[15] The enhanced visibility of lesions on DBT was attributed to the substantial reduction of overlapping tissue in DM. As a result, lesion characteristics such as shape and margin became more discernible, leading to improved conspicuity and better characterization of margins. These enhancements contributed to an improved assessment of the degrees of suspicion.

Our study results are also similar to the findings of Naeim et al. and Ko et al., in their studies, found

higher pooled sensitivity with DM in combination with DBT as compared to DM alone.[16,17] Another study conducted by Osman et al. compares the recall rate and the cancer detection rate of combined full-field and digital breast tomosynthesis to those of full-field digital mammography alone in breast cancer survivors.[18] Their result showed a significant decrease in patient recall rate and improved cancer detection rate with combined DBT and DM than alone DM. Asbeutah et al. showed that the sensitivity of DM and DBT was 73.5 and 100%, respectively, while the specificity was 67.7 and 94%, respectively.[19] However, an OSLO trial conducted by Skaane et al. and a study by Ohashi et al. reported relatively higher sensitivities with the addition of DBT to digital mammography.[9,20] It could be explained by the fact that POF Hospital Wah Cantt is a tertiary care cancer hospital where most women are presented with BIRADS IV and V category lesions in contrast with the OSLO trial, which was a screening trial. As most suspicious masses can easily be detected on digital mammography alone, limiting the value of digital breast tomosynthesis. In addition, the studies studies are having large sample sizes as compared to our study, so this could be the reason for affecting the results.

## Conclusion

DBT is a significantly sensitive and specific tool for detecting malignant breast lesions in women suspected of breast carcinoma and thus should be routinely added to digital mammography.

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**Authors Contribution**

**KA:** Data collection, data analysis, manuscript writing and proof reading

**NG:** Idea conception, study designing, data collection, data analysis, results and interpretation, manuscript writing and proof reading

**KM:** Data analysis, results and interpretation, manuscript writing and proof reading

**SJ:** Data collection, data analysis, results and interpretation, manuscript writing and proof reading

**BI:** Manuscript writing and proof reading