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FULL PAPER

Detection and characterization of breast lesions in a selective diagnostic population: diagnostic accuracy study for comparison between one-view digital breast tomosynthesis and two-view full-field digital mammography

EUN YOUNG CHAE, MD, HAK HEE KIM, MD, JOO HEE CHA, MD, HEE JUNG SHIN, MD and WOO JUNG CHOI, MD

Department of Radiology and Research Institute of Radiology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea

Address correspondence to: Dr Hak Hee Kim
E-mail: *hhkim@amc.seoul.kr*

Objective: To compare the performance of one-view digital breast tomosynthesis (DBT) and two-view full-field digital mammography (FFDM) in the detection and characterization of breast lesions in a selective diagnostic population.
Methods: A total of 598 breasts of 319 diagnostic patients were prospectively enrolled. Participants underwent bilateral one-view, mediolateral oblique (MLO) DBT and two-view, craniocaudal and MLO FFDM. The sensitivity and specificity of these methods and their classification into correct Breast Imaging-Reporting and Data System (BI-RADS) categories were compared. These methods were also compared in patients subgrouped by mammographic parenchymal density. Receiver operating characteristic (ROC) curve analysis was performed using the probability of cancer scores.
Results: DBT had higher overall sensitivity than FFDM (88.7% *vs* 80.7%, $p = 0.001$). Subgroup analyses showed that DBT had significantly higher sensitivity in assessing dense breasts and invasive cancers than FFDM. The BI-RADS category assessment was significantly better for DBT than for FFDM. The differences between the two modalities in specificity (94.1% and 93.2% for FFDM and DBT) were not significant ($p = 0.664$). The area under the ROC curves using the probability of cancer scores were 0.93 [95% confidence interval (CI), 0.91–0.95] for FFDM and 0.96 (95% CI, 0.94–0.97) for DBT ($p = 0.005$). ROC curve analysis indicated that most of the increased performance of DBT was due to dense breasts.
Conclusion: A beneficial effect on the detection and characterization of breast lesions was found for one-view DBT compared with two-view FFDM in a selective diagnostic population. Improvements were especially enhanced in females with dense breasts. These results need to be examined in studies using large-scale consecutive sampling of a diagnostic population.
Advances in knowledge: In this study, using selective diagnostic study cases, one-view DBT offered improved reader performance compared with two-view FFDM for detection and characterization of breast cancers.

INTRODUCTION

To date, mammography has been the only screening test that reduces mortality rates due to breast cancer.[1,2] Despite these benefits, however, full-field digital mammography (FFDM) yields two-dimensional images; thus overlapping tissue can obscure masses and other important features of malignancy and mask the conspicuity of some breast lesions.[3–5] This limits the sensitivity of mammography, which has been shown to be as low as 30–48% in females with dense breast tissue.[6–8]

Digital breast tomosynthesis (DBT) has been shown to be a promising imaging technique for breast cancer detection and was recently introduced into daily clinical practice. Because DBT involves a series of images in different planes acquired over a limited angular range, which are reconstructed into a quasi-three-dimensional breast volume rather than with a single projection, as in FFDM, the effects of tissue overlap are reduced, potentially making its results easier to interpret. Previous investigations of DBT report its potential benefits, including increased cancer detection rates and decreased rates of recall,[9–13] mostly when performed in two views adjunct to FFDM. Results for one-view DBT are diverging, ranging from a comparable performance (slightly better/worse)[14–17] to that of FFDM to a superior performance.[18,19]

The utility of DBT in the screening and/or diagnosis of breast tissue is still under investigation. There have only been relatively limited number of studies that have compared one-view DBT with two-view FFDM in diagnostic patients.[14,18,19] To extend these findings, this study compared one-view [mediolateral oblique (MLO) view] DBT with two-view [craniocaudal (CC) and MLO view] FFDM in the detection and characterization of breast lesions in a diagnostic population.

METHODS AND MATERIALS

Study population

The institutional review board of our institution approved this prospective study, and written informed consent was obtained from all participants. The study plan and data collection were planned before the test because of the prospective design of this study. From January 2010 to April 2011, study participation was offered to females with suspected breast cancer, *i.e.* scores on the Breast Imaging-Reporting and Data System (BI-RADS) of 4 or 5, and those newly diagnosed with pathology-proven breast cancer at other hospitals (BI-RADS 6). Both symptomatic and asymptomatic females were eligible for the study. Patients aged less than 30 years were excluded due to additional exposure to ionizing radiation from DBT. And those who had undergone prior excisional biopsy or mammotome excision for the diagnosis of breast cancer and females with breast implants were also excluded. We did not consider the history of hormone replacement therapy. The study population consisted of 319 diagnostic patients (Figure 1) with findings in at least 1 breast, as diagnosed by mammography and/or ultrasound (age range, 30–75 years; mean age, 49 years).

Participants in the study underwent one-view (MLO) DBT of both breasts in addition to standard bilateral two-view (CC + MLO) FFDM. If the patient had already undergone FFDM prior to the study enrolment, additional one-view (MLO) DBT of both breasts were acquired. If the patient did not undergo FFDM prior to the study participation, both FFDM and DBT were acquired. 93 patients underwent FFDM after the point of selection. The reference standard was established using a combination of fine-needle aspiration cytology or histology of core needle or surgical biopsy samples, and clinical follow-up at least 1 year later for unbiopsied findings and normal breasts.

Image acquisition: FFDM and DBT

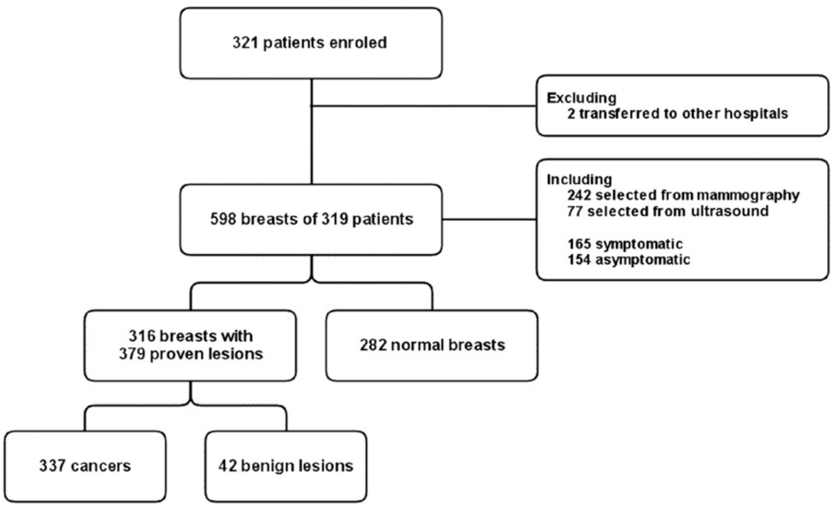
Standard bilateral FFDM images were obtained using a Senographe™ DS (GE Healthcare, Buc, France). Two standard image planes, the MLO and CC views, were acquired for each breast.

Single-view (MLO) DBT examinations were performed using an investigational prototype device (GE Healthcare, Chalfont St Giles, UK) added onto a Senographe DS platform. The DBT images were acquired using tube voltages and target/filter combinations (Mo/Mo, Mo/Rh or Rh/Rh) similar to those used for the FFDM images, with the latter determined by the automatic exposure control of the FFDM unit. For DBT, each breast was compressed in the MLO position. The X-ray gantry was adapted to allow independent rotation of the X-ray tube to acquire 15 projection images in a step-and-shoot mode over an angular range of 40° (from −20° to +20° around the MLO position). The DBT projection images were acquired with a spatial resolution of 0.1 mm per pixel and 14-bit grey level. Following DBT acquisition, a custom algebraic iterative reconstruction technique was used to reconstruct images at 5 line pairs mm^{-1} in-plane resolution and 12-bit grey level, with 1-mm tomographic section spacing. Using the prototype device, three-dimensional DBT images for both breasts were reconstructed within 3 min. The radiation dose of DBT was adjusted to the equivalent level of FFDM.

Image interpretation

Images were interpreted by three dedicated breast radiologists with 8–18 years' experience in breast imaging. All had undergone training in the interpretation of DBT images and had participated in prior studies involving the interpretation of DBT

Figure 1. Flow of study participants.



results.[20,21] One of the three readers was randomly assigned to independently review images acquired using DBT and FFDM at an Advantage workstation 4.4 (GE Healthcare, Chalfont St Giles, UK). Each reader reviewed one-third of the cases in both the FFDM and DBT conditions and the one-third contained matched pairs of FFDM and DBT. All used the same workstation and monitors, and ambient lights had the same. 1-cm-thick slabs were reconstructed from sets of adjacent planes to allow fast volume scroll and were available for the readers. Each reader was blinded to the other imaging results, all clinical information and pathological data as well as other the findings of the other readers. The reading sessions were spaced at least 1 month apart to minimize any possible bias resulting from reader memory. FFDM images were read previously for clinical purposes irrespective of this study, and all of the FFDM and DBT reads were part of a retrospective analysis. Among the total 661 cases, including 337 cancers and 324 non-cancers (282 normal and 42 benign), each reader read 111 cancers and 115 non-cancers for Reader 1; 112 cancers and 103 non-cancers for Reader 2; and 114 cancers and 106 non-cancers for Reader 3, respectively.

Images were interpreted per breast not per patient. The contralateral breast without any lesions was considered as the normal case. Abnormalities were assessed according to the BI-RADS of the American College of Radiology.[19] BI-RADS categories included: 1, negative; 2, benign; 3, probably benign; 4, suspicious abnormality; and 5, highly suggestive of malignancy. BI-RADS 6-cases fell into the BI-RADS 5 category. These scores were used to calculate diagnostic sensitivity, specificity and accuracy. Each reader recorded a probability of cancer score for each lesion, categorized as: 1, definitely not cancer; 2, almost certainly not cancer; 3, probably not cancer; 4, possibly cancer; 5, probably cancer; 6, almost certainly cancer; and 7, definitely cancer. For the normal/lesion-free images, a probability of cancer score was recorded as score "1".

The readers were also asked to record mammographic breast density on FFDM for subgroup analysis according to the BI-RADS protocol.[22] For this study, "almost entirely fat" and "scattered fibroglandular densities" were classified as "fatty", and "heterogeneously dense" and "extremely dense" breast tissue were classified as "dense".

Pathological data were reviewed, including histological tumour type and the longest diameter of each lesion. Pathological size could not be determined for 34 lesions, either because patients underwent neoadjuvant chemotherapy before surgery ($n = 20$) or only biopsy results were available ($n = 14$).

Statistical analysis

The data of the three readers were added together and analyzed as one reader, yielding one accumulated operating point. The McNemar test was used to compare diagnostic sensitivity and correct BI-RADS categories, with BI-RADS 4 and 5 considered positive and BI-RADS 1, 2 and 3 considered negative. Patients were also subgrouped by mammographic parenchymal density (fatty *vs* dense), pathological tumour invasiveness (non-invasive *vs* invasive), lesion size (<2 *vs* ≥ 2 cm), and the sensitivities of DBT and FFDM were compared.

The probability of cancer scores in 337 breast cancers was compared using the Wilcoxon signed rank test. Receiver operating characteristic (ROC) curve analysis was performed to evaluate the diagnostic performance of each technique, and the areas under the ROC curves compared. In ROC curve analysis, we used R software v. 2.15.3 (http://www.r-project.org) with pROC package. The 95% confidence intervals (CIs) were computed with 2000 stratified bootstrap replicates.

All statistical analyses were performed using SPSS® v. 14.0 (IBM Corp., New York, NY; formerly SPSS Inc., Chicago, IL). A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 598 breasts of 319 patients that were selected from BI-RADS 4 ($n = 23$, 7.2%), BI-RADS 5 ($n = 67$, 21.0%) or BI-RADS 6 ($n = 229$, 71.8%) were analysed, including 316 breasts with 1–3 lesions each, and 282 breasts without any lesions (Figure 1).

The 316 breasts with lesions included 337 cancers and 42 benign lesions, yielding a total of 379 proven lesions. The 337 breast cancers included 262 invasive ductal carcinomas, 30 ductal carcinomas *in situ*, 19 invasive lobular carcinomas, 15 microinvasive ductal carcinomas, 4 mucinous carcinomas, 4 metaplastic carcinomas and 3 invasive tubular carcinomas.

Table 1 summarizes the sensitivity analyses of two-view FFDM and one-view DBT. In evaluating the 337 breast cancers, DBT had a significantly higher overall sensitivity than FFDM (88.7% *vs* 80.7%, $p = 0.001$; Figures 2 and 3). Subgroup analysis according to breast density showed that DBT had higher sensitivity than FFDM for fatty breasts (89.5% *vs* 88.4%) and significantly higher sensitivity for dense breasts (88.4% *vs* 77.7%, $p = 0.001$). Subgroup analysis by tumour invasiveness showed that DBT had significantly higher sensitivity than FFDM for invasive cancers ($p = 0.004$) but not for non-invasive cancers ($p = 0.227$). In addition, DBT had significantly higher sensitivity than FFDM for both tumour size categories, <2 cm ($p = 0.008$) and ≥ 2 cm ($p = 0.011$).

The final BI-RADS assessment of the 337 cancerous lesions, the 42 benign lesions and the 282 normal breasts (total, 661) were assessed. Overall, DBT and FFDM correctly assessed BI-RADS categories in 601 (90.9%) and 577 (87.3%), respectively, of the 661 cases, showing that the accuracy of DBT was significantly greater ($p = 0.013$). DBT was also significantly more accurate than FFDM in assessing BI-RADS categories of the cancerous lesions ($p = 0.001$) but not significant in the benign lesions and normal breasts ($p = 0.664$).

Table 1 also shows the specificity and false-positive rate of two-view FFDM and one-view DBT. Overall specificity values were 94.1% and 93.2% for FFDM and DBT ($p = 0.664$), respectively. The differences were not significant in both fatty ($p > 0.999$) and dense breasts ($p = 0.607$). The false-positive rate, defined as the percentage of cases without a diagnosis of cancer after positive test results (BI-RADS categories 4 and 5), was 6.5% for FFDM and 6.9% for DBT ($p = 0.873$). When evaluated as a function of breast density, the false-positive rates for both fatty and dense

Table 1. Sensitivity and specificity analyses of two-view full-field digital mammography (FFDM) and one-view digital breast tomosynthesis (DBT)

Variables	FFDM	DBT	*p*-value
Sensitivity			
All cancers ($n = 337$)	80.7 (272/337)	88.7 (299/337)	0.001
Breast density			
Fatty ($n = 95$)	88.4 (84/95)	89.5 (85/95)	>0.999
Dense ($n = 242$)	77.7 (188/242)	88.4 (214/242)	0.001
Tumour invasiveness			
Non-invasive ($n = 30$)	53.3 (16/30)	70.0 (21/30)	0.227
Invasive ($n = 307$)	83.4 (256/307)	90.6 (278/307)	0.004
Size[a]			
<2 cm ($n = 157$)	73.9 (116/157)	84.7 (133/157)	0.008
≥2 cm ($n = 146$)	85.6 (125/146)	94.5 (138/146)	0.011
Specificity			
All non-cancers ($n = 324$)	94.1 (305/324)	93.2 (302/324)	0.664
Breast density			
Fatty ($n = 94$)	93.6 (88/94)	93.6 (88/94)	>0.999
Dense ($n = 230$)	94.3 (217/230)	93.0 (214/230)	0.607

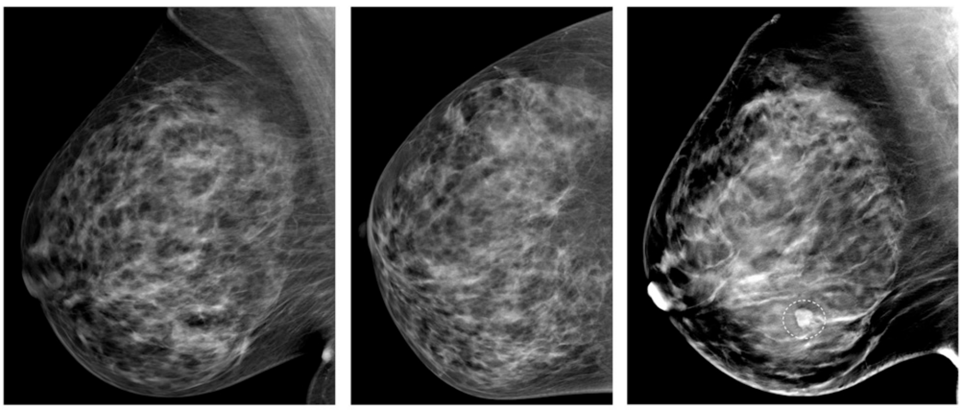
Data indicate percentages.
Among the total 661 cases, including 337 cancers and 324 non-cancers, each reader read 111 cancers and 115 non-cancers for Reader 1; 112 cancers and 103 non-cancers for Reader 2; 114 cancers and 106 non-cancers for Reader 3, respectively.
[a]Subgroup analysis by tumour size involved 303 malignant lesions of known size.

breasts did not differ significantly ($p = 0.984$ for fatty breast; $p = 0.840$ for dense breast). The mean probability score for cancer for the 337 cancerous lesions was significantly higher for DBT than for FFDM (5.64 ± 1.735 *vs* 5.11 ± 1.973, $p < 0.001$; Table 2). ROC analysis based on the discrimination between 337 cancers and 42 benign/282 normal cases indicated that the overall areas under the ROC curve values estimated using the probability of cancer scores were 0.93 (95% CI, 0.91–0.95) for FFDM and 0.96 (95% CI, 0.94–0.97) for DBT ($p = 0.005$) (Figure 4). When diagnostic performance was evaluated by breast density, the gain of reader performance was mainly attributable to dense breasts (Figure 5), with a significant gain in diagnostic performance for dense ($p = 0.006$), but not for fatty ($p = 0.412$) breasts.

DISCUSSION

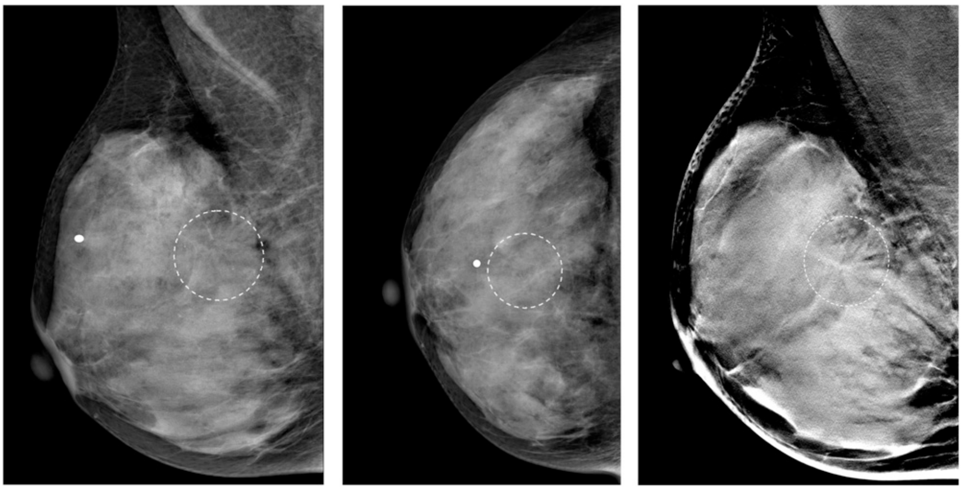
This study showed that one-view DBT had a significantly higher average diagnostic sensitivity than two-view FFDM in a diagnostic

Figure 2. A 48-year-old female with invasive ductal carcinoma. (a, b) Full-field digital mammograms showing heterogeneously dense breasts without definite focal abnormality. (c) Mediolateral oblique digital breast tomosynthesis showing a mass (dashed circle) in the lower portion of the right breast.



(a) (b) (c)

Figure 3. A 53-year-old female with invasive lobular carcinoma. (a, b) Craniocaudal and mediolateral oblique (MLO) full-field digital mammograms showing subtle architectural distortion (dashed circles) in the upper portion of the right breast. (c) MLO digital breast tomosynthesis showing improved visibility of spiculate margins (dashed circle), findings highly suggestive of malignancy.



population using selective study materials. When diagnostic performance was evaluated in relation to breast density, the gain of reader performance was mainly attributable to dense breasts.

The clinical role of DBT has been investigated in both screening and diagnostic settings. A large, multicentre study of patients being screened for breast cancer found that the addition of two-view DBT to FFDM was associated with an increase in cancer detection rate and a decrease in recall rate.[12] A study comparing mass characterization by DBT and mammographic spot views found that mass visibility ratings and reader performance were similar.[23] In addition, tomosynthesis was found to show significantly improved diagnostic accuracy for non-calcified lesions when compared with supplemental mammographic views.[24] The results reported here are consistent with these earlier findings, in that DBT showed significantly higher average sensitivity as well as significantly higher correct BI-RADS assessment than FFDM.

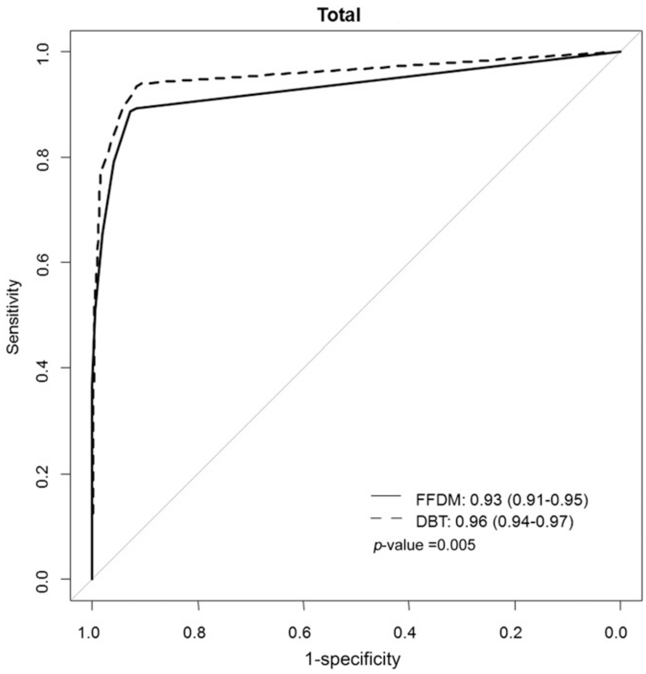
The addition of DBT to conventional FFDM was expected to improve the sensitivity and specificity of the latter because tissue overlap is the major problem with FFDM.[3] This study found that one-view DBT had a significantly higher sensitivity than two-view FFDM in detecting breast lesions, based on their BI-RADS classification. Subgroup analysis by breast density found that the greater sensitivity of DBT reached statistical significance only when assessing dense breasts. In analysing fatty breasts, DBT tended to show greater sensitivity, but the difference was not statistically significant. When diagnostic performance was analysed based on the probability of cancer scores, most of the gain in reader performance for DBT was due to dense breasts. This was consistent with earlier findings, showing that the addition of MLO tomosynthesis had significant benefits only in females with dense breast tissue.[25] Thus, DBT may be of particular value in females with dense breasts. One interesting thing is that the patients' age included in this

Table 2. Full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) determinations of cancer probability in 337 breast cancers

Probability of cancer	FFDM ($n = 337$)	DBT ($n = 337$)
1	36 (10.7)	20 (5.9)
2	2 (0.6)	2 (0.6)
3	32 (9.5)	15 (4.5)
4	46 (13.6)	42 (12.5)
5	49 (14.5)	53 (15.7)
6	48 (14.2)	37 (11.0)
7	124 (36.8)	168 (49.9)
Mean ± standard deviation	5.11 ± 1.973	5.64 ± 1.735
p-value	<0.001	

Data indicate numbers of cases.
Data in parentheses indicate percentages.

Figure 4. Receiver operating characteristic curves for full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) using probability of malignancy scores.



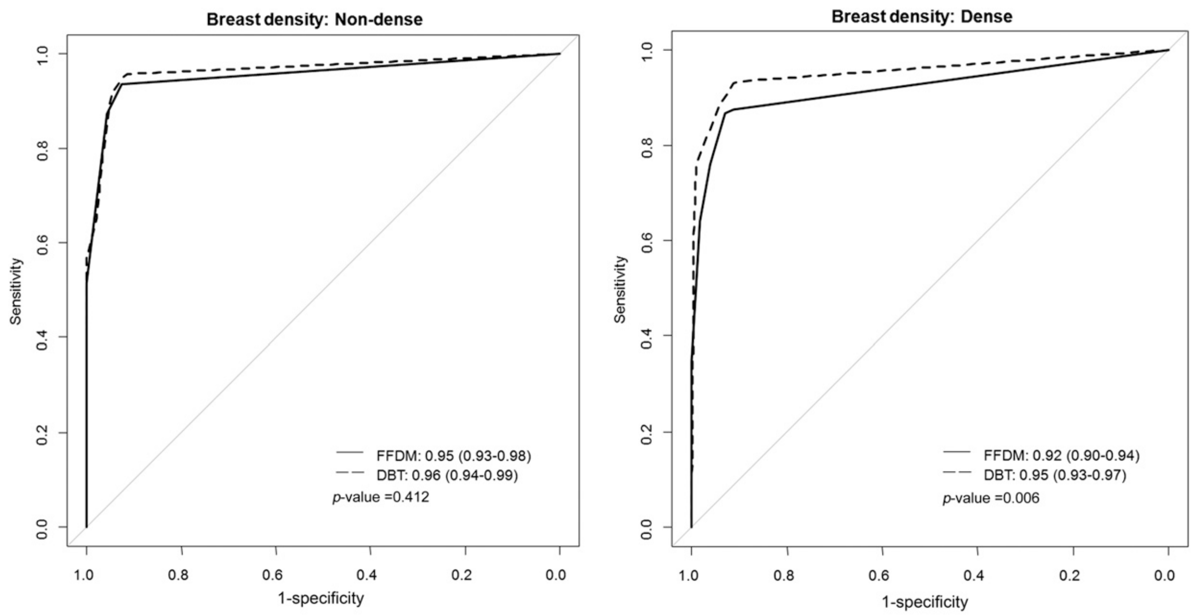
study (mean age, 49 years), despite excluding patients less than 30 years, was lower than in most studies.[12–14,26] It is known that the incidence of dense breast tissue is increased with decreasing age. DBT is more useful in dense breast tissue, and similar results were obtained from this study including even more young females.

In contrast to this study, which compared one-view DBT with two-view FFDM, previous studies have mostly compared two-view DBT plus FFDM with FFDM alone.[12–14] The combination of digital mammography and tomosynthesis has advantages in that standard digital mammograms provide an overview of distributional features, particularly calcifications and allow comparisons with previous mammograms. However, additional radiation exposure should be considered in the addition of DBT to the standard FFDM. Our study found that one-view DBT showed improved diagnostic performance than that with two-view FFDM for the detection and characterization of breast lesions in the diagnostic population. Recent advances in synthesised mammograms reconstructed from projection images may solve the problems caused by additional radiation exposure.[26]

Benefits have also been found by performing DBT in two views compared with only one-view, in adjunct to FFDM.[22] Potential additional benefits of using a second view may be present, as it provides more diagnostic information. However, one-view DBT might still be sufficient because one-view tomosynthesis alone offers improved reader performance compared with FFDM[18,19] and less incremental radiation dose than a two-view tomosynthesis. It requires further research on which method is most beneficial to the patients, considering these trade-off.

This study had several limitations. First, potential selection bias is present since we considered the contralateral breast without any lesions as the normal case, the sampling of abnormal and normal/benign cases were exclusively from the same patients. As there are correlations between breasts (right and left), the results of this study may not be generalized to other patients in the diagnostic setting. In addition, we included the same images (FFDM) in the study, from which the selection was made rather

Figure 5. Receiver operating characteristic curves for full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) in fatty (a) and dense (b) breasts.



(a) (b)

than acquiring a new set. And we included females with suspected or known breast cancer, and who agreed to participate, rather than consecutive sampling. Although readers assessed patients randomly, with time gaps between reading sessions, certain biases by the three readers could not be ruled out. Furthermore, each reader had far more experience with FFDM than with DBT. However, all readers had participated in prior reader studies with DBT.[20,21] Next, all three readers did not read all cases in both the FFDM and DBT conditions, and the interobserver agreement and results for individual radiologists could not be evaluated. Because the reader variability is one of the largest sources of variability in medical imaging, it is a relevant limitation of this study. Finally, all types of lesions were included, including masses, calcifications and architectural distortions, during patient enrolment, and these lesions were not subclassified for analyses. Several studies report that DBT is less than ideal in the detection and evaluation of calcifications.[27,28] Further studies are needed to assess the role of DBT relative to each type of lesion.

In conclusion, a beneficial effect on the detection and characterization of breast lesions was found for one-view DBT than FFDM in a diagnostic population. These improvements vary, depending on parenchymal density, but are especially enhanced in females with dense breasts. Specificity of one-view DBT *vs* two-view FFDM did not show significant differences in this population. Since the limited sampling of this study (extracting both abnormal and normal cases from the same patients, including images from the selective modality, *e.g.* FFDM), further studies are necessary to validate and generalize the findings of the current study to the overall diagnostic population.

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