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Quantitative analysis of radiation dosage and image quality between digital breast tomosynthesis (DBT) with two-dimensional synthetic mammography and full-field digital mammography (FFDM)☆

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ABSTRACT

Purpose: Currently in diagnostic setting for breast cancer, FFDM and DBT are performed conjunctively. However, performing two imaging modalities may increase radiation exposure by double. Two-dimensional reconstructed images created from DBT with 2DSM, has a potential to replace conventional FFDM in concerning both radiation dosage and image quality. With increasing concerns for individual radiation exposure, studies analyzing radiation dosage in breast imaging modalities are needed. This study compared radiation dosage and image quality between DBT + 2DSM versus FFDM.

Methods and materials: 374 patients (mean age 52 years) who underwent both DBT and FFDM were retrospectively reviewed. Radiation dosage data were obtained by radiation dosage scoring and monitoring program Radimetrics (Bayer HealthCare, Whippany, NJ). Entrance dose and mean glandular doses in each breast were obtained for both modalities. To compare image quality of DBT + 2DSM and FFDM, a 5-point scoring system for lesion clarity was assessed. The parameters of radiation dosage (entrance dose, mean glandular dose) and image quality (lesion clarity scoring) were compared.

Results: For entrance dose, DBT had lower mean dosage (14.8 mGy) compared with FFDM (21.8 mGy, p-value $<$ 0.0001). Mean glandular doses for both breasts were lower in DBT (Left 1.74, Right 2.1) compared with FFDM (Left 2.85, Right 2.74, p-value $<$ 0.0001). Lesion clarity score was higher in DBT with 2DSM (mean score 4.03) compared with FFDM (3.82, p-value $<$ 0.0001).

Conclusion: DBT showed lower radiation entrance dose and mean glandular doses to both breasts compared with FFDM. DBT + 2DSM had better image quality than FFDM, suggesting that DBT with 2DSM has potential as an alternative to FFDM.

1. Introduction

Full-field digital mammography (FFDM) is currently the gold standard for screening and effectively detecting early-stage breast cancer. It is used as the primary diagnostic method, but has major limitations in creating false positives and negatives due to overlapping breast tissue. Therefore, the emerging imaging modality of digital breast tomosynthesis (DBT) has been used adjunctively to improve cancer detection rates. DBT has been found to be superior to FFDM in both screening and diagnostic settings for early detection and improved diagnosis of breast cancer [1–5]. It is approved by the U.S. Food and Drug Administration (FDA) to be used in combination with FFDM [1].

DBT obtains multiple low radiation dose mammograms at various angles as the X-ray source moves in an arc above the breast. The obtained multiple images are reconstructed by eliminating overlapping structures and allowing for three-dimensional localization. The addition of DBT to FFDM offers significantly increased diagnostic accuracy and reduced recall rates [1–6].

However, limitations of the combined procedures have been recognized, including increasing radiation dose roughly by a factor of two by acquiring both DBT and FFDM [1]. To lower radiation exposure, multiple vendors have suggested making the 3D data obtained from DBT into two-dimensional synthesized mammography (2DSM) images. The reconstructed 2DSM data has promising image quality, not inferior to FFDM.

Radiation dosage applied to the patient has been of increasing

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concern but has been difficult to quantitatively compare between different modalities. Studies have compared image quality between the two modalities (FFDM and DBT) but rarely compared radiation dosage. A new software called Radimetrics allows for direct, easy comparison and monitoring of radiation dosage data. With the help of this program, this study compared radiation doses and image quality between DBT and FFDM.

2. Materials and methods

2.1. Case selection

This was an IRB-approved retrospective study with all patients enrolled in accordance with IRB protocols and waived informed consent. At our institution, DBT is used as an adjunct to regular FFDM and can be performed on both symptomatic and asymptomatic women. After detecting an abnormal finding in screening FFDM, patient is recalled to take additional DBT with 2DSM images for further diagnostic accuracy. A total of 374 patients underwent DBT between June 2015 and February 2017 in a single tertiary institution, Korea University Guro Hospital. To allow direct comparison of radiation doses between DBT and FFDM, patients who had undergone only one exam or who did not have radiation dosage data available were excluded. The excluded patients were referred to our institution from other hospitals for further evaluation and already had FFDM images with them. A total of 208 patients who had undergone both DBT with 2DSM and FFDM studies, total of 416 studies, were included and retrospectively reviewed. The included group performed DBT with 2DSM within two weeks after they were recalled for abnormal finding on screening FFDM.

2.2. Image acquisition

Both DBT and FFDM were acquired by Selenia Dimensions mammography system (Hologic, Marlborough, MA). FFDM acquired both conventional CC (craniocaudal) and MLO (mediolateral oblique) views. DBTs were obtained by 15 low dose projection images along 15 degrees of arc and reconstructed using the 2D synthesized image reconstruction system (C-view 2D, Hologic) for each set. The 2D synthesized image processing software used in this study was cleared for clinical use by the FDA in 2013 [7]. The image was acquired using standard compression methods by qualified radiological technicians. DBT with 2DSM recreated the conventional CC and MLO views to compare with FFDM.

2.3. Radiation parameters

For this study, radiation dosimetry parameters including entrance dose and mean glandular dose were used. Entrance dose is the entrance surface or skin exposure where the X-ray beam first interacts with the patient's skin, and the mean glandular dose (MGD) is the summation of absorbed doses in fibroglandular tissues of breast from multiple projection images. The radiation dose exposed to the breast is expressed as MGD since only the dose absorbed in glandular breast tissues is associated with risk of cancer induction [8].

Previously, mean glandular dose has been calculated using a model described by Dance [9]: AGD = KgcsT where K is incident air kerma at the upper surface of the breast, g, c, s, and T are respective conversion factors for the incident air kerma to glandular dose, the actual breast composition of the homogenous mixture of glandular and adipose tissue in the central region excluding the surrounding adipose region, the X-ray spectrum used, and a correction for series of exposures in DBT acquisition [9].

However, a more resourceful way of obtaining the radiation dosimetry data has been introduced by a single manufacturer. The radiation data for this study were obtained using a radiation dosage scoring and monitoring program named Radimetrics (Bayer HealthCare, Whippany, NJ). This system provides radiation dosage data such as entrance dose and the mean glandular dose per patient and per exam which allows for direct comparison of the amount of exposure between different imaging modalities or between different study protocols. This allows for the development of more radiation-reduced protocols and tracking and control of individual patient exposure risks.

This system provides many variables including entrance dose and mean glandular doses for each patient and the data were obtained from both imaging modalities. The specific software programming behind the presented data was not exposed, but is believed to be calculated through the traditional equation mentioned above and with the Monte Carlo simulation. This has a tremendous advantage of being provided the data without difficulty.

2.4. Image analysis

Image analysis took part in two different sessions by two different specialized breast radiologists (OH Woo, HS Shin). The two radiologists were experienced readers who routinely interpreted DBT with 2DSM and FFDM images in clinical practice for both screening and diagnostic settings.

The database included deidentified DBT with 2DSM and FFDM images and the readers were blinded to the clinical history, location of the lesion, imaging modality, imaging reports and pathological reports if biopsy or surgery was performed. The readers were acknowledged with instructions beforehand, including how to rate certain parameters and how to individually evaluate specific characteristics.

In the first session, the readers evaluated image quality, contrast, and noise of randomly presented images of DBT with 2DSM and FFDM and rated the quality in a 5-point scoring scale of lesion clarity (1, very indistinct; 2, indistinct; 3, fair; 4, clear; 5, very clear) and were unaware of the image modality that was presented. In the second session, the readers evaluated different detailed characteristics such as mass, calcifications, and asymmetries, and then were asked to pick a number representing which image modality was superior (0, FFDM; 1, Equal; 2, DBT with 2DSM) for each of the categories. In this session, deidentified FFDM and 2DSM images were presented as a set, side by side, and the readers chose which of the two images had better depiction of individual lesion characteristics. The readers were aware that there was a lesion in the image, however they were to find the lesion and rate the score for corresponding category based on conspicuity. In case of discrepancy among the readers, a consensus was made through discussion. Detailed lesion characterization categories were determined according to BI-RADS 2013.

2.5. Statistics

The parameters of radiation dosages (entrance dose, mean glandular dose) for the two modalities were compared using the Wilcoxon signed rank test. Similarity in between inter-observer performances was obtained using kappa values. The diagnostic accuracy of DBT with 2DSM and FFDM were assessed by McNemar's test of sensitivity and specificity. Comparison of scores in image quality, contrast, and noise was through the Mann-Whitney *U* test. In selecting the better modality, the chi-squared test was used to figure out which modality was significantly chosen for specific characteristics. Statistical analysis was performed using SPSS and MedCalc, with p-value 0.05.

3. Results

All patients were females between the ages of 26 to 84 years (mean age of 52 years). Among the 208 patients who underwent both DBT and FFDM, 199 patients were confirmed with malignant breast lesions through biopsy or surgery, and the remaining 9 patients were pathologically confirmed benign. The benign lesions had ductal hyperplasia or nonspecific fibrocystic changes. Of the 208 patients, the lesions consisted of 149 masses, 76 calcifications and 18 asymmetries with

Table 1
Radiation dosage parameters.

Parameters		DBT	FFDM	p-Value
Entrance dose		14.8	21.8	< 0.0001
Mean glandular dose (mGy, n = 208)	Left	1.74	2.85	< 0.0001
	Right	2.10	2.74	< 0.0001

Table 2
Average score of lesion clarity for assessing each variables.

Variable	DBT with 2DSM	FFDM	p-Value
Image quality	3.938	3.842	0.009
Contrast	4.215	3.98	0.00
Noise	3.949	3.638	0.00
Overall	4.03	3.82	0.00

some overlapping characteristics in a single lesion. 31 lesions were shown as mass with calcifications, 3 were asymmetry with calcifications and 3 lesions contained all three characteristics of mass with calcification and asymmetry.

The diagnostic sensitivity and specificity for malignancy in DBT with 2DSM was 95.5%, 78.8% respectively, and in FFDM was 80.4% and 78.8%. The positive and negative predictive values for DBT with 2DSM were 96.4 and 18.2, whereas for FFDM they were 95.8 and 4.9. As the study population included patients that undergone both DBT with 2DSM and FFDM, there were higher possibility of malignancy in the population.

DBT with 2DSM showed statistically significant lower entrance dose and mean glandular doses for both breasts compared to FFDM (Table 1). For entrance dose, DBT had lower mean dosage (14.8 mGy) compared with FFDM (21.8 mGy, p-value < 0.0001). Mean glandular doses for each breast had lower values in DBT (Left 1.74, Right 2.1 mGy) compared with FFDM (Left 2.85, Right 2.74 mGy), (p-value < 0.0001).

Inter-observer agreement was evaluated for the given lesion clarity score (1–5) and for the chosen number for better modality (0, FFDM; 1, Equal; 2, DBT with 2DSM). The kappa-value for inter-observer agreement was 0.825, demonstrating very good inter-observer agreement. DBT with 2DSM scored higher in the 5-point lesion clarity scales of all three categories: image quality, contrast, and noise. Overall lesion clarity score was higher in DBT with 2DSM (mean score 4.03) compared with FFDM (3.82, p-value < 0.0001). For each category, the average scores are shown in Table 2.

In choosing the better modality for assessing detailed characteristics such as mass, calcification, and asymmetry, DBT with 2DSM was chosen to be equal to or better than FFDM. The percentages of the number assigned by the readers for each category are shown in Table 3.

4. Discussion

FFDM has been known as the gold standard in breast cancer screening due to its low cost, fast speed, and noninvasive technique. However, its weakness of tissue superimposition has led to growing attention for DBT which provides three-dimensional localization of lesions in the breast. Evidence on clinical performance of DBT is growing as it is known to reduce recall rates in screening and improve detection of abnormalities in women with dense breast tissue, improve diagnosis of benign findings, and thereby reduce the number of negative biopsies and assess therapeutic efficacy [10,11].

However, as DBT obtains multiple images at multiple angles, there has been concern about radiation exposure. Moreover, as DBT is being performed in combination with FFDM, the nearly double radiation dosage is worrisome. Although the combined dose for DBT and FFDM is two times that of FFDM alone, it is still less than the U.S. FDA limit for a single mammogram [12]. Nevertheless, reducing radiation dosage is important since individual exposure doses are of increasing concern. Both FFDM and DBT use X-ray beams which are associated with increasing risk of breast cancer [13]. Although the risk of radiation-induced breast cancer from these two imaging modalities is quite small, monitoring and regulating individual radiation exposure dosage are important.

As the female breast is a radiosensitive organ, the radiation absorbed dose to the breast has been of special concern [11]. Diagnostic Reference Levels (DRLs) were introduced by the International Commission on Radiological Protection (ICRP) as guideline for management of patient doses [11]. In North America, FDA standards are outlined in the Mammography Quality Standard Act (MQSA), which set a breast dose restriction of 3 mGy per acquisition [11].

Furthermore, in an attempt to lower radiation exposures, multiple vendors have suggested turning the 3D data obtained from DBT into two-dimensional synthesized mammography images. It is known that DBT with 2DSM provides clearer depiction and increased sensitivity and specificity in diagnostic imaging. With 2DSM, it is possible to reconstruct 2D images with lower radiation exposure compared with conventional FFDM, and the quality of synthesized reconstruction has been clearly demonstrated as it was approved by FDA in 2011 [1].

With the increasing concern of individual radiation exposure doses, there was increasing need for studies to compare different breast imaging modalities, to enable reduced radiation exposure and higher image quality.

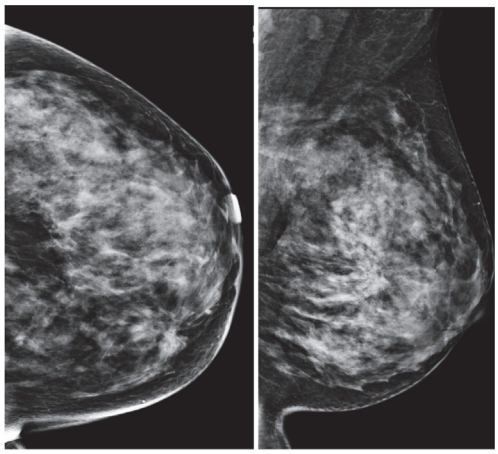
A previous study showed DBT having similar radiation dosage exposed to the breast as FFDM and, in combination, the dosage levels were about two times that of FFDM alone [11]. Our study was founded on the thought that if DBT with 2DSM is not inferior to FFDM in diagnostic accuracy and image quality while providing lower radiation exposures, there might be a possibility of DBT replacing FFDM instead of being used in conjunction.

When comparing the two modalities, DBT with 2DSM showed statistically significant lower entrance dose and lower mean glandular dose for both breasts, providing lower individual radiation exposures. DBT with 2DSM showed lower radiation dosage compared to FFDM itself, which implies that performing DBT with 2DSM alone would much decrease radiation exposure compared with current diagnostic protocol of performing DBT plus FFDM. Previous studies have published dosimetric patient data for DBT ranging from 1.49 mGy to 2.56 mGy [8]. Our data has a range of 1.74 to 2.85 mGy which is slightly higher compared with previous publications, but it is known

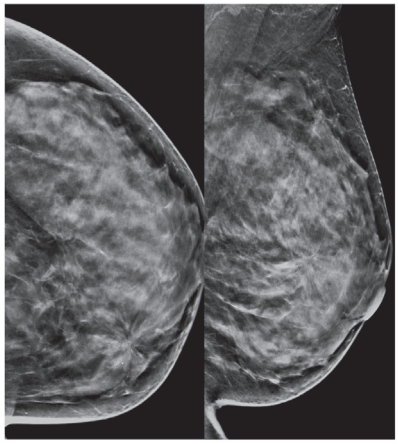
Table 3
Better modality in between FFDM and DBT with 2DSM for each characteristic.

Characteristics	0 (FFDM > DBT + 2DSM)	1 (FFDM = DBT + 2DSM)	2 (FFDM < DBT + 2DSM)	p-Value
Mass (n = 149)	8.1%	76.7%	15.2%	p < 0.0001
Calcification (n = 76)	0%	38.2%	61.8%	p < 0.0001
Asymmetries (n = 18)	2.9%	80%	17.1%	p < 0.0001

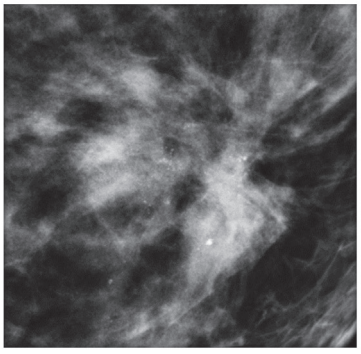
(a) CC and MLO view of FFDM



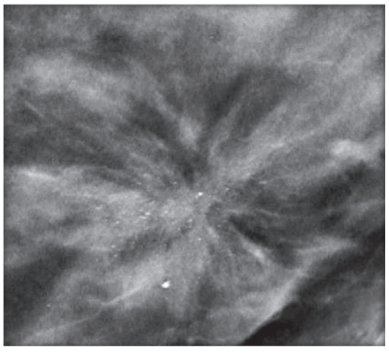
(b) CC and MLO view of DBT with 2DSM



(c) Magnification of FFDM showing irregular mass with calcification at upper inner area



(d) Magnification of DBT with 2DSM showing higher resolution of the speculated margin and internal calcifications



(caption on next page)

Fig. 1. Patient with pathologically proven malignancy at left breast upper inner portion.
(a) CC and MLO view of FFDM.
(b) CC and MLO view of DBT with 2DSM.
(c) Magnification of FFDM showing irregular mass with calcification at upper inner area.
(d) Magnification of DBT with 2DSM showing higher resolution of the speculated margin and internal calcifications.

that mean MGD values depend mainly on vendor-specific technical implementations to achieve the optimum between image quality and radiation dose [8], which may differ across institutions.

In diagnostic accuracy, DBT and FFDM both had high specificity values and low sensitivity values, which may be due to the clinical indication of DBT with 2DSM at our institution. Currently, there are no established clinical indications for the use of DBT. Our institution performs DBT with 2DSM for patients who are suspected of malignancy or have indeterminate findings from previously performed FFDM or US studies, thus increasing the possibility of the DBT with 2DSM population to be largely composed of patients with malignancy. The process of selecting the patient group who had undergone both DBT and FFDM is why the sensitivity values were very low. Despite the characteristics of the study population, DBT with 2DSM had significantly higher values of specificity compared with FFDM, presenting higher diagnostic accuracy.

DBT with 2DSM showed higher scores for lesion clarity and was chosen as better modality for distinguishing mass, calcifications, and asymmetries, which suggests that DBT with 2DSM is not only superior, but also provides better results. For lesion clarity, DBT with 2DSM scored higher for all three categories (image quality, contrast, noise) with statistical significance. The highest score was noted for image contrast (4.215 out of 5). For choosing the better modality, the readers evaluated DBT with 2DSM as equal as or better than FFDM. For mass and asymmetries, the highest percentage was given a score of 1, which implies that the two modalities had similar qualities in distinguishing the characteristics. In comparing the percentage of scores of 0 (FFDM more superior) and 2 (DBT with 2DSM more superior), 2 was more common, implying that DBT with 2DSM was chosen with a minor superiority. In case of calcifications, the readers selected DBT with 2DSM as incomparable to FFDM. The highest percentage was given to score 2 (61.8%) and the remainder was given to score 1. This result is inconsistent with previous studies that suggested DBT with 2DSM has challenges in detecting calcifications even though this has conflicts [3–5]. Our study suggests that DBT with 2DSM has higher conspicuity for not only the features previously known in publications (mass, asymmetries), but also in clearly depicting calcifications. This somewhat correlated with our data having the highest lesion clarity score in contrast and having a slightly higher radiation dose compared with other studies. It can be presumed that DBT images at our institution acquire images with more contrast, leading to clearer depiction of calcifications but with more exposure. An example of DBT with 2DSM showing superiority in clear depiction of calcifications is shown in Fig. 1.

Our study is consistent with similar previous studies that compared DBT with 2DSM versus DBT with FFDM [14–16], thus supporting that DBT with 2DSM is noninferior in cancer detection [14–16] and radiation exposure [14]. However, as these previous studies have compared recall rates and biopsy rates, our study focused on comparing the detail characteristics of lesions in between the two modalities. Also, when comparing the radiation exposure, our study introduced a novel quantification program “Radimetrics” differentiated from conventional manual calculations [14]. Even though DBT with 2DSM has concern in detecting calcifications [3–5,16] and has assumptions that it might not as good as the ‘real’ 2D images [16], our study presents satisfactory results of the modality in characterizing breast lesions and lowering radiation doses.

4.1. Limitations

This study has a few limitations. First, data were collected in a retrospective manner and the patients were not randomized. The study population of patients who underwent FFDM and DBT has the tendency to be highly proportionate with respect to malignant lesions and the reviewers were aware of the indications for DBT which may increase the possibility of bias. However, this study group allows for more direct comparison of radiation dosage and image quality by eliminating patient specific variabilities. Second, all scans were performed in a single institution with a single vendor machine. The 2DSM images were from a single version of the software from the same manufacturer. Third, there is a difference in the study dates of DBT and FFDM, which could lead to differences in physiological status or compression state of the breast. Lastly, mean glandular dose has the potential to be overestimated compared to actual exposed dose and the radiation exposure may also be affected by the breast density which was not included in this study. Despite the potential to be overestimated, it provides a method to compare dosimetry consequences of different imaging technologies, acquisition techniques, or protocols.

5. Conclusion

This study suggests the possibility of quantitative comparison of radiation dosage data between different imaging studies using Radimetrics. Moreover, image acquisition with DBT plus 2DSM can be accomplished with lower absorbed radiation doses and achieve higher image quality compared to FFDM alone and also compared to the current standard of FFDM plus DBT. Therefore, this study suggests that DBT with 2DSM has potential as an alternative to conventional FFDM.

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