Original Investigation

Characterization of Breast Masses in Digital Breast Tomosynthesis and Digital Mammograms: An Observer Performance Study

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Abbreviations

AUC Area under the receiver operating characteristic curve

BI-RADS Breast Imaging Reporting and Data System

CI confidence interval

CC craniocaudal

DBT digital breast tomosynthesis

DM digital mammogram

ICC intraclass correlation coefficient

MLO mediolateral oblique

MQSA Mammography Quality Standards Act

MRMC multi-case multi-reader

ROC receiver operating characteristic

Rationale and Objectives: This study aimed to compare Breast Imaging Reporting and Data System (BI-RADS) assessment of lesions in two-view digital mammogram (DM) to two-view wide-angle digital breast tomosynthesis (DBT) without DM.

Materials and Methods: With Institutional Review Board approval and written informed consent, two-view DBTs were acquired from 134 subjects and the corresponding DMs were collected retrospectively. The study included 125 subjects with 61 malignant (size: 3.9–36.9 mm, median: 13.4 mm) and 81 benign lesions (size: 4.8–43.8 mm, median: 12.0 mm), and 9 normal subjects. The cases in the two modalities were read independently by six experienced Mammography Quality Standards Act radiologists in a fully crossed counterbalanced manner. The readers were blinded to the prevalence of malignant, benign, or normal cases and were asked to assess the lesions based on the BI-RADS lexicon. The ratings were analyzed by the receiver operating characteristic methodology.

Results: Lesion conspicuity was significantly higher ($P << .0001$) and fewer lesion margins were considered obscured in DBT. The mean area under the receiver operating characteristic curve for the six readers increased significantly ($P = .0001$) from 0.783 (range: 0.723–0.886) for DM to 0.911 (range: 0.884–0.936) for DBT. Of the 366 ratings for malignant lesions, 343 on DBT and 278 on DM were rated as BI-RADS 4a and above. Of the 486 ratings for benign lesions, 220 on DBT and 206 on DM were rated as BI-RADS 4a and above. On average, 17.8% (65 of 366) more malignant lesions and 2.9% (14 of 486) more benign lesions would be recommended for biopsy using DBT. The inter-radiologist variability was reduced significantly.

Conclusion: With DBT alone, the BI-RADS assessment of breast lesions and inter-radiologist reliability were significantly improved compared to DM.

Key Words: Digital breast tomosynthesis; BI-RADS assessment; ROC observer study.

INTRODUCTION

Digital breast tomosynthesis (DBT) is increasingly being used in breast imaging clinics. Three commercial DBT systems have been approved by the Food and Drug Administration for screening and diagnostic workup, and more systems are available outside the United States. The three systems have different designs of scan parameters ranging from 15° to 50°. The screening protocols for the systems also differ;

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one system was approved for a combination mode (combo mode) that includes two-view DBT in combination with two-view digital mammograms (DMs), the second system was approved for a craniocaudal (CC) view DM with a mediolateral oblique (MLO) view DBT, and the third system was approved for a stand-alone two-view DBT. A number of prospective or observational studies of clinical performance before and after implementation of DBT have been conducted to compare the combo mode with DM alone (1–10) in screening settings. All these studies found significant improvement in cancer detection rate and a reduction in the overall recall rate or a reduction in the recall rate per cancer detected. Other investigators have conducted retrospective reader studies as reviewed in References 11 and 12; most of these studies also revealed the potential of the combo mode, yielding higher cancer detection rate and lower recall rate compared to DM alone.

The vast majority of the studies to date evaluated DBT as an adjunct to DM using DBT systems with a scan angle of 15°. A few studies evaluated DBT systems with larger scan angles (40°–50°) (13–18), in which an MLO-view DBT replaced the MLO-view DM or both views of DM. The results from the studies using different modes other than the combo mode are more varied. The DM in the combo mode is also being replaced with a mammogram-like image synthesized from DBT to reduce dose, and the adequacy of such approach is being investigated. DBT is still an evolving technology, and its capability and limitations have not been fully explored, especially its performance for scan angles other than 15° and as a stand-alone modality. Continued development and studies of the impact of DBT acquisition geometry (scan angle, number of projections) and other factors on the performance of DBT are crucial to further improve its efficacy in both screening and diagnostic applications.

The purpose of our current study is to evaluate two-view DBT acquired with a prototype wide-angle (60°) DBT system as a stand-alone modality in the characterization of soft-tissue lesions compared to two-view DM in a retrospective observer study using receiver operating characteristic (ROC) methodology. The characteristics of lesions in terms of Breast Imaging Reporting and Data System (BI-RADS) descriptors were also compared.

MATERIALS AND METHODS

Data Set

With approval of the Institutional Review Board and written informed consent, we collected DBT of human subjects with a General Electric (GE) prototype GEN2 DBT system (GE Global Research, Niskayuna, NY). The system acquired 21 projections in 3° increments, with a total tomographic angle of 60°. To our knowledge, this is the only system that can acquire such wide-angle DBT for human subjects to date. The subjects were recruited from patients who had undergone diagnostic workup for a suspicious finding by screening or clinical findings. Two-view (CC and MLO) DBTs of the breast with the lesion were acquired. For each subject, the corresponding DMs were collected retrospectively from the patient archive. The time interval between the DM and the DBT ranged from 0 to 84 days (median: 13 days). Cases with microcalcifications as the only finding or cases without DM were excluded. A data set of 134 cases (age range of subjects: 29–88 years, median: 46 years) was formed, of which 125 cases contained a total of 142 lesions and 9 cases were normal.

TABLE 1. Pathology of the Malignant or Benign Lesions Included in the Study

Lesion Type	Pathology	Number
Benign	Fibroadenoma	43
	Fibrocystic change	8
	Fat necrosis	2
	Lymph node	2
	Usual intraductal hyperplasia	4
	Atypical ductal hyperplasia and atypical lobular hyperplasia	1
	Pseudoangiomatous stromal hyperplasia	1
	Cyst	11
	Hematoma	2
	Benign tissue	7
Malignant	Invasive ductal carcinoma	31*
	Invasive lobular carcinoma	12*
	Invasive carcinoma with ductal and lobular features	14*
	Adenocarcinoma	1
	Invasive tubular carcinoma	1
	Mucosa-associated lymphoid tissue (MALT) lymphoma	2

* Twenty-eight of the invasive ductal or lobular carcinomas also had ductal carcinoma in situ or lobular carcinoma in situ.

An experienced Mammography Quality Standards Act (MQSA)-qualified breast radiologist (MH) marked the corresponding lesions on the DM and in the DBT volume based on all available clinical information, including images and pathology reports. The radiologist also provided description of the appearance of the 142 lesions on DM, resulting in 96 masses, 14 architectural distortions, and 32 asymmetries. The data set was highly enriched with malignant cases. The pathology of 61 malignant and 74 benign lesions were proven by biopsy or fine-needle aspiration; 7 lesions were determined to be cysts by ultrasound and remained normal after a 2-year follow-up. Table 1 listed the pathology of the lesions. This radiologist did not participate in the observer study.

All DBT were reconstructed with the simultaneous algebraic reconstruction technique at 0.1 mm × 0.1 mm in-plane pixel size and 1 mm slice spacing.

Observer Study

The observer study was conducted with a multi-case multi-reader (MRMC) ROC methodology (19) in a fully crossed