Potential Use of American College of Radiology BI-RADS Mammography Atlas for Reporting and Assessing Lesions Detected on Dedicated Breast CT Imaging: Preliminary Study

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Rationale and Objectives: Dedicated breast computed tomography (DBCT) is an emerging and promising modality for breast lesions. The objective of this study was to evaluate the potential use of applying the BI-RADS Mammography Atlas 5th Edition for reporting and assessing breast lesions on DBCT. Currently, no atlas exists for DBCT.

Materials and Methods: Four radiologists trained in breast imaging were recruited in this institutional review board-approved, Health Insurance Portability and Accountability Act-compliant study. The enrolled radiologists, who were blinded to mammographic and histopathologic findings, individually reviewed 30 randomized DBCT cases that contained marked lesions. Thirty-four lesions were included in this study: 24 (70.6%) masses, 7 (20.6%) calcifications, and 3 (8.8%) architectural distortions. Eight (23.5%) lesions were malignant and 26 (76.5%) were benign. The reader was asked to specify according to the BI-RADS Mammography Atlas for each marked DBCT lesion: primary findings, features, breast density, and final assessment. We calculated readers' diagnostic performances for differentiating between benign and malignant lesions and interobserver variability for reporting and assessing lesions using a generalized estimating equation and the Fleiss kappa (κ) statistic.

Results: The estimated overall sensitivity of the readers was 0.969, and the specificity was 0.529. There were no significant differences in the sensitivity and the specificity between lesion types. For reporting the presence of a primary finding, the overall substantial agreement ($\kappa = 0.70$) was seen. In assigning the breast density and the final assessment, the overall agreement was moderate ($\kappa = 0.53$) and fair ($\kappa = 0.30$).

Conclusion: The use of the BI-RADS Mammography Atlas 5th Edition for DBCT showed high performance and good agreement among readers.

Key Words: Breast neoplasm; breast CT; BI-RADS; mammography.

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INTRODUCTION

Breast Imaging Reporting and Data System (BI-RADS), established by the American College of Radiology, was begun in the late 1980s to address a lack of standardization and uniformity in mammography practice and reporting (1), and the BI-RADS lexicon has provided a valuable and reliable guide for reporting breast lesions on mammography, ultrasound, and magnetic resonance imaging (MRI), and has been familiar to most radiologists specializing in breast imaging. The descriptors in the BI-RADS lexicon have been selected on the basis of their ability to discriminate between benignity and malignancy as clear and standardized terms (2,3). BI-RADS has also recommended that a final impression be summarized by choosing only one among several standardized final assessment categories at the end of a report, each of which included a matched, standardized management recommendation (4,5). The BI-RADS atlas is intended to be a "living" document that changes as new data are acquired and more sophisticated patterns of breast care emerge (4). With continued evolvement of lesion characterization and assessment for malignancy, the BI-RADS Mammography Atlas is now in its fifth edition (6).

In addition to the updates in mammography, the fifth edition contains standardized breast lesion lexicons and assessment language for breast ultrasound and MRI. With advancements in breast imaging technologies, such as dedicated computed tomography of the breast, the BI-RADS Mammography Atlas can serve as the standard terminology upon which lexicons in other areas of radiology and research can be modeled.

Mammography is the current gold standard for detecting breast cancer in asymptomatic women and has been proven to decrease mortality (7–9). However, this technology does have some limitations because of the superimposition of anatomic structures. In women with dense breasts, mammography has not been proven as sensitive as in the population of women with nondense breasts (10,11). In reaction to this problem, dedicated breast computed tomography (DBCT), which provides three-dimensional data that can be reconstructed into multiple imaging planes, similar to breast MRI, has emerged as a new imaging modality in some researchers (12–31). DBCT is performed without breast compression and is not as limited as full-field digital mammography or digital breast tomosynthesis by breast density or breast implants (14,15,17). The radiation dose level is similar to the dose of a conventional two-view digital mammogram (23,24,26,28). Since the initial clinical experience of DBCT was begun by Lindfors in 2008 (23), DBCT has showed promising results for the diagnostic evaluation of breast lesions, particularly for breast masses (12,20,25–29,31). Published articles have shown that DBCT has shown a significant improvement in the characterization or differentiation of breast lesions using BI-RADS descriptor and category terminology compared to digital mammography (20,31). However, to our knowledge, there is no published study about the reproducibility of readers for reporting and assessing breast lesions on DBCT with the use of BI-RADS. Determining the reproducibility of BI-RADS is important because it can offer standardized guidance in reporting and assessing breast lesions with DBCT. Currently, no atlas exists for DBCT.

The purpose of the present study was to evaluate the diagnostic performance and the variability of multireaders for the use of the BI-RADS Mammography Atlas 5th Edition in reporting and assessing breast lesions on DBCT.

MATERIALS AND METHODS

Institutional review board approval was obtained for this radiologist reader study. Informed verbal and written consent was obtained from all of the readers involved in the present study. The deidentified DBCT cases that were used in the current study were from a DBCT image database of collected cases from two other institutional review board-approved, Health Insurance Portability and Accountability Act-compliant DBCT clinical trials. A total of 34 lesions in 30 subjects were identified in the database and are included in our study. All the lesions in the database had been assessed as BI-RADS 4 or 5 lesions with standard of care imaging, which consisted of full-field digital mammography and their pathologic diagnoses based on image-guided percutaneous core needle biopsy or surgical excision. All lesions were mammographically evident on standard of care diagnostic evaluation. Pathologic results for all lesions were evaluated with image-guided percutaneous core biopsy. In cases referred for excisional biopsy after needle core biopsy because of the finding of atypia, malignancy, or radiology-pathology discordance, final surgical pathologic analysis was used for correlation with imaging findings. At our institution, our protocol for breast lesions that result in a diagnosis of atypia on needle core biopsy was to perform surgical excision to exclude histologic underestimation.

Before the reader study, each lesion for each case was electronically marked and numbered on the images by the principle investigator, who was familiar with the clinical, mammographic, and pathologic information of each case in the study.

Readers

Eligible radiologists were identified by research staff review of their credentials from academic practice centers. A total of four fellowship trained breast imaging radiologists were recruited and enrolled in the present study. The readers had 1–13 years (mean of 7 years) of clinical experience and use of the BI-RADS Mammography Atlas. According to self-reports of the radiologists, they interpreted at least 140 mammography examinations (80–180) per week on average. The readers had no experience of DBCT imaging as part of their daily practice. To minimize reader bias, these breast imaging radiologists possessed no conflicts of interest in the research study or with the use of the device.

Data Description

Table 1 shows the cross-tabulation for the mammographic lesion types and pathology of the 34 lesions. The 34 lesions

TABLE 1. Cross-Tabulation of Lesion Type and Pathology

Type		Mass	Calcification	AD	Total
Pathology	Benign, *n* (%)	19 (56)	5 (15)	2 (6)	26 (76)
	Malignant, *n* (%)	5 (15)	2 (6)	1 (3)	8 (24)
	Total, *N* (%)	24 (71)	7 (21)	3 (9)	34 (100)

AD, architectural distortion.

comprised of 24 (71%) masses, 7 (21%) calcifications, and 3 (9%) architectural distortions. Pathologic diagnosis was available for all lesions. Eight (24%) lesions were malignant and 26 (76%) were benign. Four subjects had bilateral lesions. Twelve of the 34 lesions (35.3%) were associated with symptoms of palpable mass ($n = 10$) and focal pain ($n = 2$). The remaining 22 lesions in 22 subjects were asymptomatic. For the subsequent analysis, we combined the lesion types of mass and architectural distortion into one lesion group.

Image Interpretation

The readers underwent dedicated training with five pilot cases that were pathologically proven on a dedicated workstation in our Breast Imaging Research Lab before starting the reader study. For each case, the readers were allowed to roam and zoom, adjust the contrast, and display the images in coronal, sagittal, and axial planes. The readers then individually reviewed a total of 34 randomized, deidentified DBCT cases. The readers were blinded to the clinical, mammographic, and pathologic results. The readers were given a mandatory 15-minute break after each hour in the reader study.

Each reader was asked for each case and for each lesion to evaluate the breast density, the lesion type, the lesion location, the lesion size in the longest dimension, the lesion characteristics, and the BI-RADS assessment score using the BI-RADS Mammography Atlas 5th Edition (6). All readers were given paper data recording sheets to mark their answers. Breast density was recorded as almost entirely fatty, scattered areas of fibroglandular density, heterogeneously dense, or extremely dense. Lesion type was classified as a mass, calcifications, architectural distortion, or asymmetry. Table 2 lists the BI-RADS terminology used in the present study. Figures 1 and 2 are an example of mass and calcification lesion cases, respectively. Final assessment was assigned based on lesion characterization according to the BI-RADS lexicon as previously mentioned, and was classified into five categories (1 = negative, 2 = benign, 3 = probably benign, 4 = suspicious, and 5 = highly suggestive of malignancy).

TABLE 2. BI-RADS Atlas 5th Edition

Description	Characteristic
Masses	
Shape	Oval
	Round
	Irregular
Margin	Circumscribed
	Obscured
	Microlobulated
	Indistinct
	Spiculated
Density	High density
	Equal density
	Low density
	Fat-containing
Calcifications	
Typically benign	Skin
	Vascular
	Coarse or "popcorn-like"
	Large rodlike
	Round
	Dystrophic
	Milk of calcium
	Suture
Suspicious morphology	Amorphous
	Coarse heterogenous
	Fine pleomorphic
	Fine linear or fine-linear branching
Distribution	Diffuse
	Regional
	Grouped
	Linear
	Segmental
Architectural distortion	
	Yes
	No
Asymmetry	
	Asymmetry
	Global asymmetry
	Focal asymmetry
	Developing asymmetry

Data Analysis and Statistics

All data for each reader in both reading conditions were entered into a database and analyzed. We estimated the sensitivity and specificity of DBCT according to mammographic lesion types from the four readers, where BI-RADS categories 4 and 5 were diagnosed as malignancy. A generalized estimating equation was used to produce such estimates, and a compound symmetry working covariance was used. Normal distributions were used to construct 95% confidence intervals (CIs). The Fleiss *k* statistic was calculated to assess interobserver agreement for reporting a primary finding,

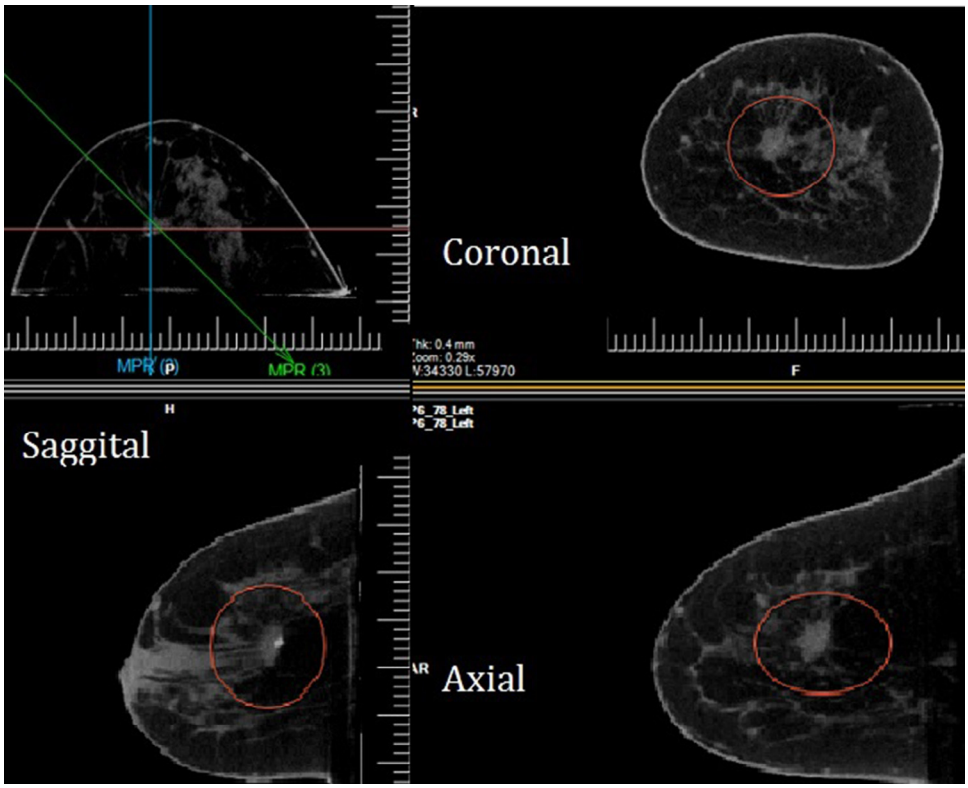

Figure 1. Breast computed tomography images of a 44-year-old woman with a palpable mass in the upper central left breast diagnosed with invasive ductal cancer, grade I. Dedicated breast computed tomography displays the three-dimensional image data set (coronal, sagittal, and axial planes) and demonstrates a 1.5-cm irregular mass with a spiculated margin containing a calcification (*circle*).

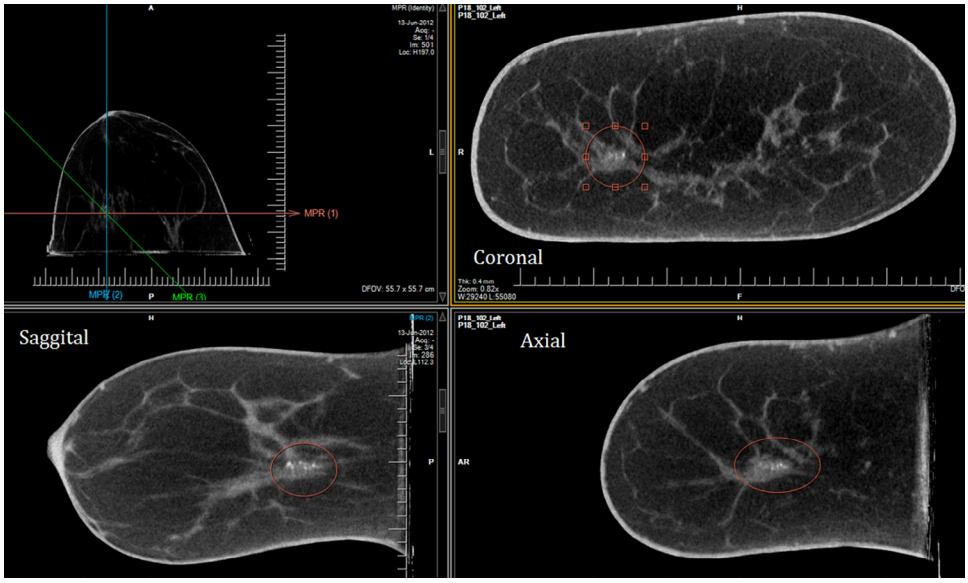

Figure 2. Breast computed tomography images of a 48-year-old woman with asymptomatic calcifications in the medial left breast diagnosed as ductal carcinoma in situ. Dedicated breast computed tomography displays the three-dimensional image data set (coronal, sagittal, and axial planes) and demonstrates a 1.2-cm, grouped, heterogeneous calcifications (*circle*).

lesion features, breast density, and final assessment among the four readers. The guidelines of Landis and Koch were followed in interpreting k values: a k value of equal to or less than 0.20 means slight agreement; 0.21–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, substantial agreement; and 0.81–1.00, almost perfect agreement. The lesion types of mass and architectural distortion were combined in the statistical analysis.

TABLE 3. Sensitivities and Specificities of Readers for Different Lesion Types

	Mass and AD		Calcification		Overall	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Reader 1	1.000	0.762	1.000	0.200	1.000	0.654
Reader 2	1.000	0.762	1.000	0.600	1.000	0.731
Reader 3	0.833	0.476	1.000	0.400	0.875	0.462
Reader 4	1.000	0.286	1.000	0.200	1.000	0.269

AD, architectural distortion.

Statistical analysis was performed using the SPSS version 20.0 software package (SPSS, Chicago, IL) and MedCalc version 14.10.2 (MedCalc Software, Mariakerke, Belgium).

RESULTS

Performances

The total reading time for all 34 cases was from 2 hours, 24 minutes, to 4 hours (mean of 3 hours, 27 minutes) in the four readers. We examined the sensitivities and specificities of DBCT according to mammographic lesion types from the four readers. The results are shown in Table 3. The estimated overall sensitivity was 0.969 (95% CI: 0.946–0.990), and the specificity was 0.529 (95% CI: 0.456–0.601). For lesion types, the *P* values comparing the sensitivity and specificity between the two types of groups were 0.5896 and 0.2916, respectively. There were no significant differences in the sensitivity and the specificity between the lesion types.

Interobserver Variability

Nineteen of 24 mass-type lesions (79.2%) were detected as mass by all of the four readers. The presence of all of the three architectural distortions and three of seven calcification-type lesions (42.9%) were noted by all four readers. For reporting the presence of a primary finding, the overall agreement was substantial ($\kappa = 0.70$). The agreement for the presence of 24 mass-type and 3 architectural distortion-type lesions ($\kappa = 0.78$) was higher than that for the 7 calcification-type lesions ($\kappa = 0.52$). Meanwhile, in assigning the final assessment, the agreement was higher in calcification-type lesions ($\kappa = 0.56$) than in mass- and architectural distortion-type lesions ($\kappa = 0.22$). The results are shown in Table 3. In describing mass features, the overall agreement for shape was fair ($\kappa = 0.39$); for margin, moderate ($\kappa = 0.455$); and for density, slight ($\kappa = 0.17$). Statistical analysis was not possible for agreement for assessing calcification features because only three cases were visualized by all four readers. The results are shown in Table 4.

TABLE 4. Interobserver Variability in Description of Mammographic Lesions

BI-RADS Descriptor	Kappa Value
Presence of primary finding	
Overall	0.70
Mass and architectural distortion	0.78
Calcification	0.52
Breast density	
Overall	0.53
Final assessment	
Overall	0.30
Mass and architectural distortion	0.22
Calcification	0.56

BI-RADS, Breast Imaging Reporting and Data System.

DISCUSSION

We used the BI-RADS mammography atlas in reporting and assigning the assessment for DBCT breast lesions, and its diagnostic performance and interobserver variability were analyzed. We found that having radiologists use BI-RADS for DBCT lesions resulted in overall high performance and good agreement among readers.

According to Zhao et al. (31), in the receiver operating characteristic curve analysis, the area under the curve of DBCT was larger than that of two-view mammography (0.911 vs 0.827) for differentiating breast masses with BI-RADS. Our results were similar to those of Zhao et al. study, and the overall performance for assessing DBCT lesions with BI-RADS was relatively high with a sensitivity of 0.969 and a specificity of 0.529.

For lesion types, there were no significant differences in estimated performances between mass- and architectural distortion-type lesions and calcification-type lesions (sensitivity, 0.958 vs 1.000; specificity 0.572 vs 0.350; $P = 0.5869$ and $P = 0.2916$, respectively). The performance of each radiologist can be affected by work experience duration in breast imaging. In our study, three of the four readers had 10 or more years of experience in breast imaging, and one reader only had 1 year of experience. However, we found that the number of years of the experience in breast imaging had no influence on the performance and the agreement of reporting a primary finding and assigning the BI-RADS final assessment and breast density. The reason might be that all the readers had no experience of DBCT imaging as part of their daily practice.

Lindfors et al. studied the clinical experience of DBCT and reported that DBCT was equal to mammography for the visualization of breast masses, but mammography outperformed

CT for the visualization of microcalcifications (23). In the most recent study by Kuzmiak et al. (20), reader visualization confidence of mass characterization using BI-RADS mammography descriptors was significantly improved with DBCT compared to digital mammography, but reduced for calcifications. Currently, DBCT is regarded as inferior to mammography in the visualization of calcifications because of its lower spatial resolution, even though DCIS visualization on contrast-enhanced DBCT was equal to mammography in a recent study (32). The shape of a microcalcification group and the spatial distribution of an individual microcalcification within it are important indicators of malignancy; however, the resolution of DBCT was too low to resolve the three-dimensional shape of calcifications in our study. Among the seven calcification cases in the present study, only three cases were visualized by all of the four readers. In two of the calcification cases, only two of the four readers visualized them. The remaining two calcification cases were interpreted as mass or architectural distortion by the readers. Therefore, our study also suggested that the agreement for reporting the presence of calcification-type lesions among the readers was lower than that for mass- and architectural distortion-type lesions ($\kappa = 0.52$ vs $\kappa = 0.78$), but moderate agreement was obtained for calcification-type lesions. Meanwhile, in assigning the final assessment, the agreement was higher for calcification-type lesions ($\kappa = 0.56$) than for mass- and architectural distortion-type lesions ($\kappa = 0.22$). We noted that the overall agreement on the final assessment was not high ($\kappa = 0.30$) in the present study but was similar to the result ($\kappa = 0.28$) of a prior study on interobserver variability for mammography using the BI-RADS 4th Edition (33). Moreover, the agreement for mass descriptors was also comparable to the prior results (33).

In this preliminary study, these results are encouraging in lesion evaluation, especially in women with dense breasts where the phenomenon of masking of lesions by normal breast tissue is encountered.

Our study has several limitations. The first limitation is the small cohort size, especially with regard to patients with malignant lesions. The small number of these cases may have statistical bias. The second was that each lesion was marked on the images for each study for the reader. This may result in bias for the lesion perception of the readers. Third, we combined the lesion type of mass and architectural distortion in our data analysis. Consequently, this may result in data analysis error in the mass lesion type. Future studies with larger numbers of lesions and different lesions types are needed.

In conclusion, the use of the BI-RADS Mammography Atlas 5th Edition for DBCT showed high performance and good agreement among readers. As with our current breast imaging modalities, when new breast imaging tools emerge, a standard terminology needs to be developed and updated for radiologists to practice wisely and to provide outstanding patient care. The BI-RADS Mammography Atlas 5th Edition can be a potential starting point in breast lesion characterization and assessment category with breast lesions detected on DBCT.

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