Published in final edited form as:

Clin Radiol. 2017 July ; 72(7): 573–579. doi:10.1016/j.crad.2017.02.013.

Assessment of disease extent on contrast-enhanced MRI in breast cancer detected at digital breast tomosynthesis versus digital mammography alone*

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*A portion of this research was presented at RSNA 2014.

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Declaration of Interests:

- Our work has been supported by a U54 grant from NIH/NCI's Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) Network (U54CA163313).
- All authors of this research paper have directly participated in the planning, execution, or analysis of the study. Please see below for contact details for each author.
- All authors of this paper have read and approved the final version submitted.
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- All directly related manuscripts or abstracts, published or unpublished, by one or more authors of this paper have been included with the manuscript submission.
- Dr. Conant is on the Scientific Advisory Board of Hologic, Inc., and both Drs. Conant and Weinstein are Consultants to Siemens Healthcare.

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Abstract

AIM—To compare the utility of breast magnetic resonance imaging (MRI) in determining the extent of disease in patients with newly diagnosed breast cancer detected on combination digital breast tomosynthesis (DBT) versus digital screening mammography (DM).

MATERIALS AND METHODS—Review of 24,563 DBT-screened patients and 10,751 DM-screened patients was performed. Two hundred and thirty-five DBT patients underwent subsequent MRI examinations; 82 to determine extent of disease after newly diagnosed breast cancer. Eighty-three DM patients underwent subsequent MRI examinations; 23 to determine extent of disease. MRI examinations performed to assess disease extent were considered true positives if additional disease was discovered in the contralateral breast or >2 cm away from the index malignancy. Differences in cancer subtypes and MRI outcomes between the DM and DBT cohorts were compared using chi-squared tests and post-hoc Bonferroni-adjusted tests for equal proportions.

RESULTS—No differences in cancer subtype findings were observed between the two cohorts; however, MRI outcomes were found to differ between the DBT and DM cohorts ($p=0.024$). Specifically, the DBT cohort had significantly ($p=0.013$) fewer true-positive findings (7/82, 8.5%) than did the DM cohort (7/23; 30%), whereas the false-positive rate was similar between the cohorts (not statistically significant). When stratifying by breast density, this difference in true-positive rates was primarily observed when evaluating women with non-dense breasts ($p=0.001$).

CONCLUSION—In both the DM- and DBT-screened populations with new cancer diagnoses, MRI is able to detect additional cancer; however, in those patients who have DBT screen-detected cancers the positive impact of preoperative MRI is diminished, particularly in those women with non-dense breasts.

INTRODUCTION

The role of magnetic resonance imaging (MRI) in determining the extent of disease in women with newly diagnosed breast cancer remains controversial. Digital breast tomosynthesis (DBT) is rapidly being adopted as standard of care for breast cancer screening based on studies demonstrating improved cancer detection coupled with reductions in recall compared to screening with digital mammography (DM) alone [1–10]. This mammographic technique uses low-dose X-rays obtained from multiple angles that are reconstructed into a series of “sections” and displayed in a “quasi-three-dimensional (3D)” format. The ability to scroll through the layers of the breast allows better localisation of structures and minimises the impact of overlapping breast tissue associated with two-dimensional (2D) imaging. The combination of DBT combined with DM screening also increases cancer detection, demonstrating improved sensitivity and specificity over DM alone [2, 3, 6, 8–10]. This raises a new clinical question: if DBT screening detects additional cancer, is MRI for the evaluation of extent of disease needed in women with DBT screen-detected cancer? Further, could DBT screening help prevent false-positive preoperative breast MRI examinations by allowing confident identification of normal versus abnormal tissue? Although preoperative MRI has been shown to detect additional disease in the ipsi-

and contralateral breast, lasting morbidity or mortality benefit has not yet been definitively shown. The goal of preoperative MRI is to locally stage the extent of disease within the breast and guide appropriate surgical management. One meta-analysis of 19 studies ($n=2610$) determined that breast MRI-detected additional disease in 16% of women with newly diagnosed breast cancer [11]. Additional analysis of 13 studies with information on preoperative MRI and breast cancer surgical management demonstrated 11.3% (95% CI: 6.8–18.3) conversion to more extensive surgery for true-positive MRI examinations and 5.5% (95% CI: 3.1–9.5) conversion to more extensive surgery for false-positive MRI examinations [11]. Another meta-analysis of four studies ($n=3169$) found no difference between 8-year local or distant recurrence in patients with preoperative MRI compared to patients without preoperative MRI [12]. The implementation of DBT in screening and diagnostic breast imaging may further challenge the use of MRI for breast cancer evaluation.

To the authors' knowledge, this is the first retrospective analysis of a natural outcomes study evaluating the role of MRI specifically in the context of DBT-screen-detected breast cancers. Mariscotti *et al.*¹³ evaluated MRI for disease extent in women who underwent DBT for specific reasons: symptomatic women, asymptomatic with dense breasts, asymptomatic between 40 and 49 years, or a previous mammogram classified as Breast Imaging-Reporting and Data System (BI-RADS) 3, 4 or 5. They found no statistically significant difference in sensitivity or accuracy of preoperative assessment of breast cancer with the addition of MRI to combination DM-DBT and ultrasound [13]. Mercier *et al.*¹⁴ evaluated the detection and staging of breast cancer using DBT compared to DM, ultrasound, and MRI in 75 patients with BI-RADS 4–5 classified lesions. They found that the additional extent of disease detected by MRI altered the treatment plan in 17% of cases; additional disease detected by DBT altered the treatment plan in 10% of cases [14]. These studies suggest diminished impact of preoperative MRI in specific patient populations evaluated by DBT. The purpose of the present study was to compare the utility of breast MRI in two cohorts of screen-detected breast cancer: a population screened with DM alone versus a population screened with combination DM-DBT.

MATERIALS AND METHODS

Study population

DBT screening was implemented for all screening patients on 19 September 2011 using two-view DBT and two-view DM of each breast (Dimension, Hologic, Bedford, MA, USA). Screening was performed in asymptomatic patients without a prior history of breast cancer. The institutional review board approved analysis of 24,563 patients screened with DBT from 1 October 2011 to 20 November 2013, and 10,751 patients screened with DM from 1 September 2010 to 30 August 2011. The baseline characteristics of these cohorts have been previously described [6]. In these two cohorts, 83 of the DM-screened patients underwent subsequent MRI (utilisation rate of 0.77%) of which 26 were obtained for evaluating newly diagnosed breast cancer. Three examinations were excluded as the final disposition could not be determined leaving 23 examinations. Patients in the DM cohort were not evaluated by DBT as part of their diagnostic work-up. Two hundred and thirty-five of the DBT-screened patients underwent subsequent MRI (utilisation rate of 0.88%) of which 83 were obtained

for evaluating newly diagnosed breast cancer. One study was excluded as it was not completed due to patient shortness of breath. Another was excluded as the final disposition could not be determined leaving 81 examinations. These two groups constituted the study population.

Data collection

A retrospective database query of the radiology information system (RIS; GE Centricity, Milwaukee, WI, USA) retrieved MRI examination information as well as breast density and other clinical information. MRI examination indications were reported at the time of examination dictation and tracked in the institutional database. The cohorts were categorised by the types of histopathology-proven breast cancer: invasive (invasive ductal and lobular) and non-invasive (ductal carcinoma *in situ* [DCIS]) cancers. The breast density was extracted from the clinical screening report that used the BI-RADS [15] categories (1=almost entirely fat, 2=scattered fibroglandular densities, 3=heterogeneously dense, 4=extremely dense), and divided into two categories, non-dense (categories 1 and 2) and dense (categories 3 and 4).

The MRI examinations were reviewed and separated into three separate categories: true-positive, false-positive, or no additional disease. A true-positive was defined as additional disease detected at MRI in either the contralateral breast or in the ipsilateral breast >2 cm away from the index malignancy. A false-positive was defined as an MRI-suspicious lesion that was subsequently histologically proven to be a benign finding. A third category was defined as no additional clinically significant lesions in either breast detected at MRI. Findings related to lymph nodes were not included in the analysis. The true-positive and false-positive cases were reviewed by three fellowship-trained breast imagers (E.C., E.M., S.W.) with mean practice experience of 20 years and median 23 years.

Statistical analysis

Differences in the proportions of cancer subtypes (i.e., invasive ductal, invasive lobular, and DCIS) between the DBT and DM screened cohorts, as well as outcomes in detecting additional disease from MRI (i.e., true-positive, false-positive, and no additional disease) before and after stratification by breast density in the two cohorts, were compared using chi-squared tests at the standard $\alpha=0.05$ significance level. When overall significance was observed for a given comparison, post-hoc Bonferroni-corrected ($\alpha=0.017$; i.e., $\alpha=0.05/3$, for three pair-wise comparisons in a given analysis) two-sample tests of equal proportions were performed to identify which categories were significantly different between the two screening cohorts. All statistical tests were two-sided and performed using Stata 14.2 (StataCorp LP, College Station, TX, USA).

RESULTS

The DBT-screened cohort included 81 cancers (73% invasive) and the DM cohort included 23 cancers (70% invasive; Figs. 1–2). There was no significant difference in cancer subtypes between the two cohorts (chi-squared test $p=0.714$). There was no difference in total number

of true-positive examinations in dense versus non-dense breasts, when the DBT and DM cohorts were combined ($p=0.578$).

The impact of MRI on detection of additional disease was found to be statistically different between the DM and DBT cohorts (chi-squared test $p=0.024$). Specifically, post-hoc testing found that DBT cohort had significantly ($p=0.013$) fewer true-positive findings (7/82, 8.5%) than did the DM cohort (7/23; 30%). In contrast, there were no significant differences in the proportion of false-positive MRI outcomes ($p=0.627$) between the two cohorts (Table 1).

When outcomes were stratified by breast density, significant differences in MRI outcomes between the DM and DBT cohorts were observed in women with non-dense breasts ($p=0.004$) but not in those with dense breasts ($p=1.0$; Table 2). Specifically, in the women with non-dense breasts, there were less true-positives ($p=0.004$) and more patients with no additional disease ($p=0.016$) in the DBT cohort relative to the DM cohort, but no difference in the false-positive rates ($p=0.67$). More information about the additional disease detected after DBT screening is provided in Table 3.

DISCUSSION

Breast MRI has an established role in breast imaging for evaluation of axillary malignancy with unknown primary, silicone implant rupture, residual disease after lumpectomy, high-risk screening, and as an additional diagnostic tool after inconclusive diagnostic mammography and/or ultrasound [16]. Although preoperative MRI is an accepted indication for evaluation of an occult primary tumour and for staging invasive lobular carcinoma [17, 18], the utility in preventing re-excision and recurrence is controversial. Although there is a prospective randomised clinical trial in preparation addressing this question (ACRIN 6694) at the time of writing, the role of breast MRI in the evaluation of extent of disease is largely based on retrospective studies and single-institution prospective studies.

Controversies regarding preoperative MRI continue while DBT continues to gain rapid clinical acceptance with studies reporting improved cancer detection over screening with DM alone; thus potentially further diminishing the impact of MRI in the evaluation of the extent of disease in newly diagnosed breast cancer. In the present study, although MRI detected a similar number of cancers in dense versus less dense breasts when both modalities were combined, the number of additional cancers detected after women with less dense breasts were screened with DBT was small and significantly less than when women with less dense breasts were screened with DM. Thus, this suggests that women with non-dense breasts screened with DBT may benefit less from preoperative MRI than women with more dense breasts. The main difference in additional MRI-detected disease was observed in those women with fatty and the scattered breast density categories.

The present results suggest that preoperative MRI for the evaluation of disease extent may be more beneficial in women with non-dense breast tissue after DM screening; however, the number of patients in the present study is small, limiting firm conclusions and more data are needed to corroborate the present results. The present study found no statistically significant difference in the incidence of MRI detected false-positives in the DM and DBT cohorts,

indicating that the false-positive detection remains fairly constant irrespective of the initial screening study. Given the lower additional cancer yield on MRI in women with non-dense breasts screened with DBT, and the continued high potential for false-positives, careful consideration should be given before requesting preoperative MRI studies in this population. Alternatively, contrast-enhanced spectral mammography (CESM) may serve as an alternative vascular-based study to MRI, with high specificity and promising results in early studies [19–23], including a specific study evaluating women with dense breasts [24].

There are limitations to the present study. First, it was a retrospective, single-institution analysis. Although the number of total screeners in each group was considerable, the study populations were small. The population size also limits the interpretation of the results of the outcomes based on breast density, particularly in the dense breast cohorts. At the University of Pennsylvania Perelman School of Medicine, the use of preoperative breast MRI is surgeon dependent. Not every patient with cancer is scheduled for an MRI, and the possibility of a selection bias must be considered. Another limitation is that follow-up data are not yet available to evaluate for false negatives. Furthermore, the study was not designed to address clinical outcomes such as alterations in treatment plans or re-excision rates.

Despite these limitations, these early results suggest that the utility of preoperative MRI to determine extent of disease in newly diagnosed breast cancer may be diminished when DBT screening is available, particularly in women with non-dense breasts. The role of MRI in newly diagnosed breast cancer remains controversial and the increasing use of DBT adds another degree of complexity to the ongoing debate. Additional research and longer follow-up are needed.

Acknowledgments

This work was supported by a U54 grant from the National Cancer Institute at the National Institutes of Health: Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) Network (U54CA163313). E.S.M. is an American Roentgen Ray Society/Philips Healthcare Scholar.

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Highlight

- Utility of preoperative breast MRI in DBT versus DM screen detected breast cancers
- MRI detects additional disease in both screen detected DBT and DM cancers
- MRI detects less additional disease in DBT compared to DM screen detected cancers
- Role of preoperative MRI may be diminished when DBT screening is available

Figure 1.

A 62-year-old woman with new diagnosis of breast cancer detected at screening DBT with no additional disease detected at MRI. (a) Mediolateral oblique (MLO) mammogram shows no suspicious findings. (b) MLO DBT and (c) magnification view of MLO DBT shows architectural distortion in upper breast, middle third depth (arrows). (d) Ultrasound shows a corresponding spiculate hypoechoic mass with posterior shadowing. Subsequent biopsy yielded invasive lobular carcinoma. (e) Sagittal minimum intensity projection (MIP) post-contrast MRI demonstrates a corresponding spiculate enhancing mass consistent with biopsy-proven malignancy without additional suspicious disease (arrow).

Figure 2.

A 49-year-old woman with DBT-detected cancer, with additional disease detected at MRI. (a) MLO mammogram shows no suspicious findings. (b) MLO DBT and (c) magnification view of MLO DBT shows a spiculate equal density mass in the upper breast (arrows). (d) Ultrasound shows corresponding irregular hypoechoic mass with indistinct margins and posterior shadowing. Subsequent biopsy yielded invasive carcinoma with signet features. (e) Sagittal MIP post-contrast MRI demonstrates a corresponding spiculate enhancing mass consistent with biopsy-proven malignancy (arrow). Additional distant enhancing foci were seen (arrowheads) consistent with multicentric disease.

Table 1

Cancer subtypes and outcomes of magnetic resonance imaging (MRI) performed for extent of disease in DBT- and DM-screened patients.

	True positive (%)	False positive (%)	No additional disease (%)	Total (%)
DBT	7 (9)	11 (14)	63 (78)	81
IDC	4 (5)	7 (9)	40 (49)	51 (63)
ILC	2 (2)	1 (1)	5 (6)	8 (10)
DCIS	1 (1)	3 (4)	19 (23)	23 (28)
DM	7 (30)	3 (13)	13 (57)	23
IDC	7 (30)	0 (0)	8 (35)	15 (65)
ILC	0 (0)	0 (0)	1 (4)	1 (4)
DCIS	0 (0)	3 (13)	4 (17)	7 (30)
	DBT versus DM true positive $p=0.013$	DBT versus DM false positive $p=0.627$	DBT versus DM no additional disease $p=0.061$	

IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; DCIS, ductal carcinoma *in situ*; DBT, digital breast tomosynthesis; DM, digital mammography.

Table 2

Magnetic resonance imaging outcomes in women with non-dense breasts (i.e., BI-RADS 1 and 2 breast density) and in women with dense breasts (i.e., BI-RADS 3 and 4 breast density).

	Total	True positives (%)	False positives (%)	No additional disease (%)
Women with non-dense breasts ^a				
DBT	45	3 (7)	5 (11)	37 (82)
DM	14	6 (43)	1 (7)	7 (50)
Non-dense DBT versus DM		$p=0.004$	$p=0.67$	$p=0.016$
Women with dense breasts ^b				
DBT	36	4 (11)	6 (17)	27 (75)
DM	9	1 (11)	2 (22)	6 (67)
Dense DBT versus DM		$p=1.0$	$p=0.645$	$p=0.698$

^aNon-dense is defined as BI-RADS density categories 1 and 2.

^bDense is defined as BI-RADS density categories 3 and 4.

DBT, digital breast tomosynthesis; DM, digital mammography.

Table 3

Characteristics of additional disease detected by magnetic resonance imaging (MRI) in digital breast tomosynthesis (DBT) cohort

Age	Density	Original diagnosis	Side/multifocal or multicentric	Additional disease type detected at MRI	Size of additional disease (cm)	Distance from primary tumour (cm)	Additional malignancy
65	Dense	DCIS	Ipsilateral/Multicentric	Mass	1.6	7.2	IDC
60	Non-dense	ILC	Ipsilateral/Multicentric	Mass	1.0	8.6	ILC
77	Non-dense	IDC	Ipsilateral/Multicentric	NME	1.6	3.8	ILC
56	Non-dense	DCIS	Ipsilateral/Multicentric	Foci	1.7	4.0	DCIS
49	Dense	IDC	Contralateral	Mass	1.4	N/A	DCIS
51	Dense	DCIS	Ipsilateral/Multifocal	NME	4.2	4.2	DCIS
66	Non-dense	IDC	Ipsilateral/Multicentric	NME	7.0	7.0	DCIS

IDC, invasive ductal carcinoma; ILC, invasive lobular carcinoma; DCIS, ductal carcinoma *in situ*; NME,