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FULL PAPER

Masses in the era of screening tomosynthesis: Is diagnostic ultrasound sufficient?

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Objectives: The purpose of this study is to compare diagnostic outcomes of digital breast tomosynthesis screen-detected masses worked up with mammography first with those evaluated with diagnostic ultrasound initially.

Methods: All masses recalled from screening digital breast tomosynthesis between July 1, 2017 and December 31, 2017 that were sent either to diagnostic mammography or ultrasound were compared. Size, shape, margins, visibility on ultrasound, diagnostic assessment and pathology of all masses along with breast density were evaluated.

Results: 102/212 digital breast tomosynthesis screen-detected masses were worked up with diagnostic mammography initially and 110/212 were worked up

with ultrasound directly. There was no significant difference in ultrasound visibility of masses sent to diagnostic mammography first with those sent to ultrasound first ($p = 0.42$). 4 (4%) masses sent to mammogram first and 2 (2%) masses sent to ultrasound first were not visualized. There was a significant difference in size between masses that were visualized under ultrasound versus those that were not ($p = 0.01$), when masses in both groups were assessed cumulatively.

Conclusions: 98% of digital breast tomosynthesis screen-detected masses sent to ultrasound directly were adequately assessed without diagnostic mammography.

Advances in knowledge: There is potential for avoiding a diagnostic mammogram for evaluation of majority of digital breast tomosynthesis screen-detected masses.

INTRODUCTION

In the era of digital breast tomosynthesis (DBT), the need for diagnostic mammography (MG) before a diagnostic ultrasound for masses recalled from screening tomosynthesis has been questioned.^{1–3} Historically, most masses recalled from two-dimensional (2D) screening mammography underwent diagnostic mammography prior to ultrasound.^{4,5} In this setting, diagnostic mammography views have been shown to increase the specificity of mammography by improving margin assessment, determining lesion location, and confirming persistence of the screen-detected mass.^{5,6} In comparison to 2D imaging, DBT allows better differentiation of true findings from superimposition of fibroglandular tissue, increases mass margin visibility, and improves location assessment.^{7–9} In addition, studies have shown that DBT has similar accuracy as routine diagnostic mammography for non-calcified findings,¹⁰ is comparable to spot compression mammography for characterizing masses as benign or malignant,¹ and is equivalent or better than spot compression mammography for evaluating findings recalled from 2D screening mammography.^{2,3,11}

Currently, institutions and practitioners vary in how the work-up of masses recalled from screening tomosynthesis is performed, with some opting for ultrasound first and others performing diagnostic mammography before ultrasound. There are no clear American College of Radiology practice guidelines for work-up of DBT-detected masses. The purpose of this study is to compare outcomes of masses recalled from screening DBT worked-up initially with diagnostic mammography with those first evaluated with diagnostic ultrasound.

METHODS AND MATERIALS

Study subjects, imaging technique, and interpretation

Our Institutional Review Board approved this retrospective Health Insurance Portability and Accountability Act-compliant study. Informed consent was waived.

We performed a retrospective review of our mammography reporting system for all screen-detected masses from July 1, 2017, from the time of our conversion to

all three-dimensional screening, to December 31, 2017. All non-calcified masses without associated features of architectural distortion or skin thickening and with follow-up at Mayo Clinic Rochester, MN were included in this study. A mass was defined, according to the fifth edition of the Breast Imaging-Reporting and Data System (BI-RADS), as a three-dimensional lesion seen on two views with complete or partial convex border.¹² Lesions that did not fit the BI-RADS definition of a mass were excluded.

Mammographic screening and diagnostic DBT examinations were performed using Hologic Selenia Dimensions digital breast tomosynthesis (Hologic, Bedford, MA) with synthesized 2D (C-View™) images. Screening exams included bilateral DBT mediolateral oblique (MLO) and craniocaudal (CC) views with C-View, and diagnostic exams included CC and MLO DBT spot compression views with C-View of the mass and a 2D full-field digital MG ML view of the breast. Ultrasound exams were performed by breast imaging specialized sonographers and/or breast imaging radiologists using GE Logiq E9 (General Electric Healthcare, Milwaukee, WI).

All exams were prospectively interpreted by 1 of 18 breast imaging radiologists with 1–5 years of tomosynthesis experience and 1–29 years of practice in a tertiary academic setting. Recalled masses were either worked-up with diagnostic MG first or sent directly to diagnostic ultrasound at the discretion of the screening radiologist as specified on the screening mammogram report. The diagnostic work-up was completed in one visit by any 1 of the 18 breast imaging radiologists and resulted in a final BI-RADS assessment. Masses sent to diagnostic MG first were either given a final assessment based on the MG or, if directed by the diagnostic radiologist, were further evaluated with diagnostic ultrasound before a final combined assessment was established. Masses sent directly to diagnostic ultrasound were either given a final assessment based on the ultrasound or were further worked-up with diagnostic MG after the ultrasound before a final combined assessment was determined. Patients given BI-RADS, one or two were returned to routine screening mammography. Patients with BI-RADS three were recommended to have a 6 month follow-up imaging exam, and patients with BI-RADS four or five masses were recommended to have core needle biopsies. The final diagnostic BI-RADS assessment was recorded for each mass. Pathology was recorded from core needle biopsies of masses that underwent sampling. The BI-RADS density assessment from the screening study was also recorded for each patient as dense, comprising the BI-RADS categories of heterogeneously dense and extremely dense, and non-dense, comprising the BI-RADS categories of almost entirely fatty and scattered areas of fibroglandular density.

Data collection and statistical analysis

Two breast imaging radiologists, not blinded to the final outcomes, reviewed the screening DBT to determine if the recalled mass met the BI-RADS definition used in this study. In addition, each radiologist assessed and recorded the shape, size, margins, and density of each mass seen on the screening DBT exam. χ^2 or Fisher's exact tests were used to compare categorical characteristics by MG or ultrasound first, and *t*-tests were used to

compare mass size by MG or ultrasound first. Descriptive statistics are provided as frequencies (N) and percent (%) or mean and standard deviations (SDs). Statistical analyses were conducted using SAS (v. 9.4; Cary, NC).

RESULTS

2072/16,916 patients were recalled during our study period, which included 214 patients with 226 masses. Of these 226 masses, 14 masses were excluded on retrospective review since they did not fit the BI-RADS definition of a mass. 102/212 (48%) masses were sent to diagnostic MG first whereas 110/212 (52%) masses were sent to ultrasound initially. There was no significant difference in the size of the masses ($p = 0.31$) or density of the breasts ($p = 0.74$) in the two groups (Table 1). There was a significant difference in the shape of masses in these two groups ($p < 0.0001$) (Table 1) with 65 (64%) oval, 21 (21%) round, and 16 (16%) irregular masses in the MG first group in comparison to 96 (87%) oval, 12 (11%) round, and 2 (2%) irregular masses in the ultrasound first group. Similarly, there was a significant difference in the margins of masses in these two groups ($p < 0.0001$) with 66 (65%) circumscribed, 12 (12%) indistinct, 12 (12%) obscured, and 12 (12%) spiculated masses in the MG first group in comparison to 97 (88%) circumscribed, 8 (7%) indistinct, and 5 (5%) obscured masses in the ultrasound first group. There was also a significant difference in the density ($p = 0.039$) of masses, BI-RADS assessments ($p = 0.0002$), and pathology of masses ($p = 0.011$) in the two groups (Table 1). There were 55 (54%) BI-RADS 1 and 2, 11 (11%) BI-RADS 3, and 36 (35%) BI-RADS 4 and 5 masses in the MG first group compared to 85 (77%) BI-RADS 1 and 2, 7 (6%) BI-RADS 3, and 18 (16%) BI-RADS 4 and 5 masses in the US first group ($p = 0.0002$). There were 22 (61%) benign and 14 (39%) malignant lesions in the MG first group compared to 14 (94%) benign and 1 (6%) malignant lesions in the ultrasound first group ($p = 0.011$). Cysts were the most common benign lesion in both groups, 39/80 (49%) and 74/104 (71%) in the MG and ultrasound first groups respectively. Invasive ductal carcinoma (IDC) was the most common malignant pathology in the MG first group with 8/14 (57%) malignant masses representing IDC. The only malignant mass in the ultrasound first group was also IDC. Positive-predictive values from screening mammography (PPV1) were 14 and 0.9% for MG and US first groups respectively and from biopsy recommendation (PPV2)/from biopsy performed (PPV3) were 39 and 6% for MG and US first groups respectively.

94/102 (92%) masses sent to MG first were subsequently worked up with ultrasound and no ultrasound was performed for the remaining eight masses (Figure 1). Of these eight masses that did not undergo ultrasound evaluation, three were felt to be stable benign lymph nodes, three were mammographically stable masses, and two were thought to represent overlapping tissue by the radiologist interpreting the diagnostic mammogram. Of the 94 masses sent to subsequent ultrasound in this group, 90 (96%) had a sonographic correlate, and 4 (4%) were not visualized with ultrasound (Table 2). 3/4 masses that were not visualized by ultrasound were round, 1/4 was oval, 3/4 had circumscribed margins and 1/4 had obscured margins on the screening DBT. All 4 (100%) occurred in females with non-dense breasts. In

Table 1. Characteristics of masses worked up with diagnostic MG versus diagnostic ultrasound first

	Category	MG first	Ultrasound first	<i>p</i> -value
		<i>n</i> = 102	<i>n</i> = 110	
		<i>n</i> (%) or mean $\pm$ SD	<i>n</i> (%) or mean $\pm$ SD	
Breast density	Non-dense	87 (87.9)	95 (86.4)	0.74
	Dense	12 (12.1)	15 (13.6)	
Size (cm) ^a		0.9 $\pm$ 0.5	1.0 $\pm$ 0.6	0.31
Shape ^a	Irregular	16 (15.7)	2 (1.8)	<0.0001
	Oval	65 (63.7)	96 (87.3)	
	Round	21 (20.6)	12 (10.9)	
Margins ^a	Circumscribed	66 (64.7)	97 (88.2)	<0.0001
	Indistinct	12 (11.8)	8 (7.3)	
	Obscured	12 (11.8)	5 (4.6)	
	Spiculated	12 (11.8)	0 (0)	
Mass density ^a	High density	17 (16.7)	7 (6.4)	0.039
	Equal density	79 (77.5)	90 (81.8)	
	Low density	3 (2.9)	10 (9.9)	
	Fat-containing	3 (2.9)	3 (2.7)	
Final BI-RADS	1/2	55 (53.9)	85 (77.3)	0.0002
	3	11 (10.8)	7 (6.4)	
	4/5	36 (35.3)	18 (16.4)	
Pathology ^b	Benign	22 (61.1)	17 (94.4)	0.011
	Malignant	14 (38.9)	1 (5.6)	

MG, mammography; SD, standard deviation.

^aMass characteristics are based on findings on screening digital breast tomosynthesis (DBT)

^bPathology is for masses that underwent core needle biopsy

the final assessment, 3/4 of these recalled “masses” were felt to represent overlapping fibroglandular tissue. These lesions looked like masses on the screening exam but did not definitely persist on diagnostic MG and an ultrasound was done for confirming the absence of a true lesion. 1/4 of the masses persisted on diagnostic mammography and was not seen under subsequent diagnostic US so a stereotactic biopsy was performed with resulting pathology of apocrine cysts with stromal fibrosis, which was considered concordant with the imaging findings.

108/110 (98%) of masses sent to US first had a sonographic correlate, and 2/110 (2%) did not (Figures 1–3). The two masses not seen on US were subsequently sent to a diagnostic mammogram. Both of these masses were oval in shape, one had circumscribed and one had obscured margins on the screening DBT (Table 2). Both masses occurred in females with non-dense breasts. The mass with the obscured margins effaced on subsequent diagnostic mammography and was thought to represent overlapping fibroglandular tissue. The mass with circumscribed margins persisted on subsequent diagnostic MG so a stereotactic core biopsy was performed with pathology revealing fibrocystic changes, which was considered concordant with imaging findings.

Overall, 198/204 (97%) of DBT-screen detected masses were found to have a sonographic correlate in our study. There was no significant difference in the US visibility of masses sent to MG first compared to those sent initially to US ($p = 0.42$). There was a significant difference in the mean size between masses that were seen on US (0.9 ± 0.5 cm) versus those that were not seen (0.5 ± 0.4 cm) ($p = 0.01$), when assessing the US visibility of masses in the MG first and US first groups cumulatively.

DISCUSSION

Our study shows that diagnostic mammography can be eliminated for working up majority of DBT screen-detected masses, defined as two-view lesions with complete or partial convex borders. 92% of masses sent to MG first were further evaluated with a diagnostic US after the MG, and 96% of these masses were successfully visualized by US. In comparison, 98% of masses sent to US first were satisfactorily assessed with US alone and 2% were further evaluated with a diagnostic mammogram after the US.

Studies have shown that DBT screening increases cancer detection rate,^{13–17} reduces recall rate,^{14,15,18,19} and improves diagnostic accuracy.^{18,20} DBT also has advantages in the diagnostic setting. Several studies have shown that diagnostic DBT is

Figure 1. Flow chart demonstrating the diagnostic pathways of masses recalled from screening digital breast tomosynthesis in our study. DBT, digital breast tomosynthesis; MG, mammography.

comparable to spot compression mammography.^{1-3,10,11} Our study is one of the first to evaluate the impact of screening DBT on the subsequent diagnostic work-up of recalled findings. Since DBT improves differentiation of true findings from superimposition of fibroglandular tissue, mass margin visibility, and location assessment⁷⁻⁹ and is equivalent to routine mammography in the diagnostic setting,^{1-3,10,11} it is not surprising that most DBT screen-detected masses in the US first group in our study did not require a diagnostic mammogram. Additionally, the US visibility

of masses in the MG first and the US first groups did not vary significantly ($p = 0.42$).

In our study, we found no significant differences in the size of the masses or the density of the breasts in our MG first and US first groups. However, there was a difference in the shape, margins, and pathology of the masses between the two groups. Masses sent to US first were more likely to be oval (87.3% vs 63.7%), circumscribed (88.2% vs 64.7%), and benign (94.6% vs

Table 2. Characteristics of masses visible and not visible on ultrasound in the diagnostic MG and diagnostic ultrasound first groups

		MG first		Ultrasound first	
		Not visible on ultrasound	Visible on ultrasound	Not visible on ultrasound	Visible on ultrasound
		<i>n</i> = 4	<i>n</i> = 90	<i>n</i> = 2	<i>n</i> = 108
	Category	<i>n</i> (%) or mean $\pm$ SD		<i>n</i> (%) or mean $\pm$ SD	
Breast density	Non-dense	4 (100)	75 (86.2)	2 (100)	93 (86.1)
	Dense		12 (13.8)		15 (13.9)
Size (cm) ^a		0.4 $\pm$ 0.1	0.9 $\pm$ 0.5	0.9 $\pm$ 0.6	1.0 $\pm$ 0.6
Shape ^a	Irregular		16 (17.8)		2 (1.9)
	Oval	1 (25)	57 (63.3)	2 (100)	94 (87.0)
	Round	3 (75)	17 (18.9)		12 (11.1)
Margins ^a	Circumscribed	3 (75)	58 (64.4)	1 (50)	96 (88.9)
	Indistinct		10 (11.1)		8 (7.4)
	Obscured	1 (25)	10 (11.1)	1 (50)	4 (3.7)
	Spiculated		12 (13.3)		
Mass density ^a	High density	1 (25)	16 (17.8)		7 (6.5)
	Equal density	3 (75)	69 (76.7)		90 (83.3)
	Low density		3 (33.3)	2 (100)	8 (7.4)
	Fat-containing		2 (2.2)		3 (2.8)
Final BI-RADS	1/2	3 (75)	44 (48.9)	1 (50)	84 (77.8)
	3		11 (12.2)		7 (6.5)
	4/5	1 (25)	35 (38.9)	1 (50)	17 (15.7)
Pathology ^b	Benign	1 (100)	21 (60)	1 (100)	16 (94.1)
	Malignant		14 (40)		1 (5.9)

MG, mammography; SD, standard deviation.

^aMass characteristics are based on findings on screening digital breast tomosynthesis (DBT).

^bPathology is for masses that underwent core needle biopsy.

79.2%) than masses sent to MG first. Cysts were more common among the benign lesions in the US first group than the MG first group (71% vs 49%). This suggests that radiologists reading the screening DBT exam were more inclined to send benign-appearing masses to ultrasound first. We conjecture that this may have been because the benign appearing masses were likely to be cysts which are typically seen well and definitively assessed by US. For the more suspicious appearing masses, it is likely that the radiologists wished to assess margins and confirm the finding, as has been done historically, with diagnostic MG. However, studies have shown that margin assessment with ultrasound alone can accurately predict the benign or malignant nature of a mass,^{21,22} and diagnostic MG before US may not be necessary for margin assessment. It should be noted that the majority of the masses in our study that were eventually not seen by US in both groups had benign features (3/4 round, 1/4 oval, and 3/4 circumscribed in the MG first group versus 2/2 oval and 1/2 circumscribed in the US first group). This suggests that mammographic shape and margins may not significantly affect US visibility. However, size may be a factor as the masses not seen by US were significantly smaller (mean size of 0.5 $\pm$ 0.4 cm) than those seen under US

(mean size of 0.9 $\pm$ 0.5 cm), when assessing the US visibility of masses in the MG first and US first groups cumulatively. Additionally, all masses that were not visible by US in both groups occurred in non-dense breasts. Hence, size and breast density may impact the US visibility of masses, but our conclusions are limited because only six masses in both groups combined were not visible under US, and some did not persist as masses on diagnostic mammography.

In our study, eight masses sent to the MG first group were not further worked up with US. Of these eight masses, three were felt to be lymph nodes present on prior exams, three were other mammographically stable masses, and two were thought to represent overlapping tissue. On retrospective review by the study radiologists, the three lymph nodes and three masses were mammographically stable, and some radiologists might not have recalled these masses on the initial screening exam. If these had gone to US first, they would likely have been seen, but correlation with the current and prior screening mammograms would have been needed to establish their stability and arrive at the final benign assessments for these lesions. Therefore, it is critical

Figure 2. A 64-year-old female recalled from screening DBT for an oval, circumscribed mass in the right breast (circles) and sent to ultrasound directly. (A, B) MLO (A) and CC (B) synthesized 2D (C-View™) screening mammographic views. (C, D) enlarged MLO (C) and CC (D) DBT images. (E) Ultrasound demonstrates an oval, anechoic mass with posterior acoustic enhancement, consistent with a cyst. CC, cranio caudal; DBT, digital breast tomosynthesis; MLO, medio lateral oblique.

Figure 3. A 45-year-old female recalled from screening DBT for an oval, circumscribed mass in the right breast (circles) and sent to ultrasound first. (A, B) MLO (A) and CC (B) 2D screening mammographic views. (C,D) magnified MLO (C) and CC (D) DBT images. (E) Ultrasound does not show an abnormality to correspond to the mammographic finding. A diagnostic mammogram was subsequently performed and the finding persisted. A stereotactic biopsy was recommended and revealed fibrocystic changes. 2D, two-dimensional; CC, cranio caudal; DBT, digital breast tomosynthesis; MLO, medio lateral oblique.

to note that a DBT screen-detected mass sent directly to diagnostic US cannot be interpreted alone and correlation with other studies, particularly prior mammograms, is critical as in the rest of diagnostic breast imaging.

Additionally, if the two masses representing overlapping tissue in this MG first group went to US first, no US findings would have been detected and a subsequent diagnostic mammogram with spot compression views would have been needed to establish a final assessment. This was the case for one mass in our US first group. Hence, if a mass sent to US directly from DBT screening is not seen, a diagnostic mammogram should be subsequently performed as the mass may represent superimposition of normal tissue. However, this was rare in our study with only 2/110 (2%) of the masses in our US first group not being visualized and needing diagnostic MG after US.

Our study has a few limitations. It is a retrospective, single-institution study. We had 18 readers who read the screening DBT, and there was likely variability in a finding being defined as a mass versus a focal asymmetry by the reader. We did not respectively review findings called focal asymmetries to see if they qualified

as masses. There was a selection bias in which masses went to MG or ultrasound first as the decision was at the discretion of the screening radiologist. We did not account for the years of training or expertise of the interpreting radiologist. The two study radiologists were not completely blinded to the final outcomes of the patients. We are currently in an early stage of DBT screening, which may explain the low positive predictive value of biopsies in this study, and these findings may not be generalizable to practices with multiple years of DBT screening experience. In addition, our practice is a tertiary academic center, and our findings may not be generalizable to other practice settings. Most of our diagnostic ultrasounds are performed initially by breast imaging specialized sonographers with subsequent scanning by the breast imaging radiologist. This practice pattern is not universal and could impact the success rate of mass visibility. Also, due to our recent conversion to universal DBT screening, 2 year follow-up was not obtained in this study. Lastly, we only evaluated masses and did not assess asymmetries and focal asymmetries in this

study. Studies evaluating all types of lesions recalled from screening DBT are needed to further establish optimal diagnostic pathways in the era of increasing DBT utilization.

In summary, our study indicates that the majority (98%) of masses, as defined by the BI-RADS, recalled from screening DBT can be adequately assessed with a diagnostic ultrasound alone. When a recalled mass is not seen by ultrasound, a diagnostic mammogram should be subsequently performed to provide a final assessment. This indicates a possibility to forego diagnostic mammography for work-up of majority of DBT screen-detected masses. Eliminating diagnostic MG can decrease cost and radiation to patients and increase the diagnostic workflow efficiency for radiology practices.

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