DBT in Screening and Diagnosis

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Breast Cancer Incidence and Screening

- US female invasive breast cancer cases estimated to reach 281,550 in 2021
  - Estimated 44,130 deaths from the disease

- Death rate has decreased by 37% since mid 1980s, largely attributable to screening
  - Falling on average 1.8% each year (2006-2015)

American Cancer Society. Cancer Facts & Figures 2021. Atlanta: American Cancer Society; 2021 https://seer.cancer.gov/statfacts/html/breast.html

Benefits of Screening- Dr Tabár

- Investigated the question: If a woman chooses to participate in regular mammography screening, then how much will this choice improve her chances of avoiding a death from breast cancer compared with women who choose not to participate?
- For women aged 40 to 69 years participating in screening:
  - Incidence of fatal breast cancers within 10 years of diagnosis per 100,000 women during the screening period was 60% lower
  - Significant 45% reduction in the risk of dying from breast cancer within 20 years of diagnosis in screening participation group

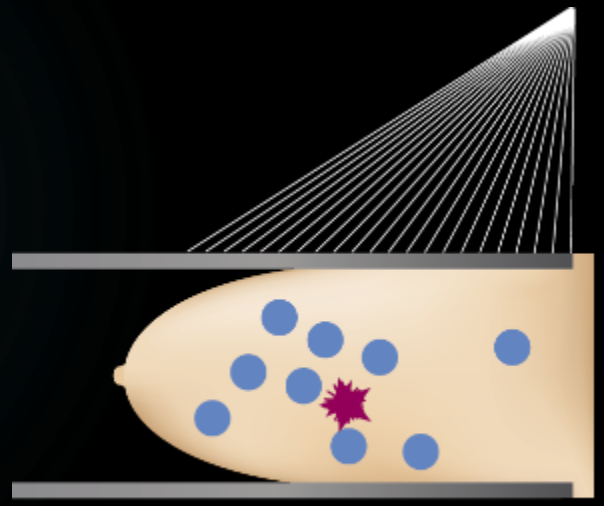
Tabár, L., et al. "The incidence of fatal breast cancer measures the increased effectiveness of therapy in women participating in mammography screening." *Cancer* 125.4 (2019): 515-523.

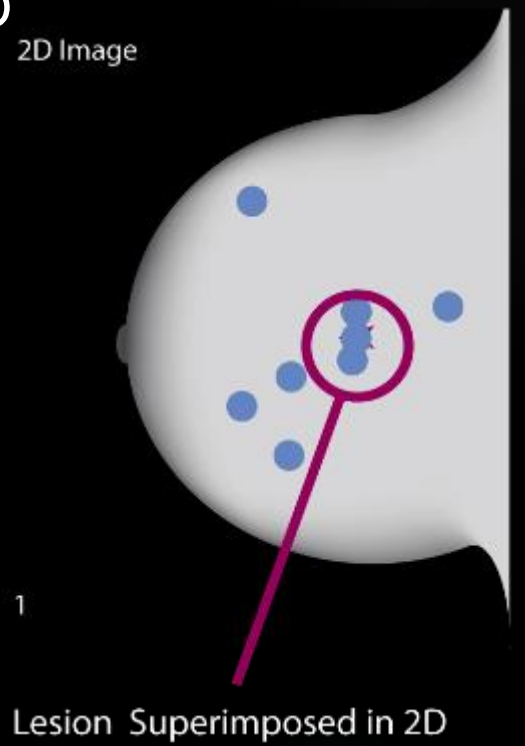
Digital Breast Tomosynthesis (DBT)

- Decreases recall rates (15-37%)
- Improved cancer detection (up to 53%)
  - Increase in invasive cancer detection, without change in detection of DCIS
- Potential to decrease interval cancer rates
- Benefits seen in a variety of patient populations

Why DBT?

- Tissue superimposition hides pathologies in 2D
- Tissue superimposition mimics pathologies in 2D





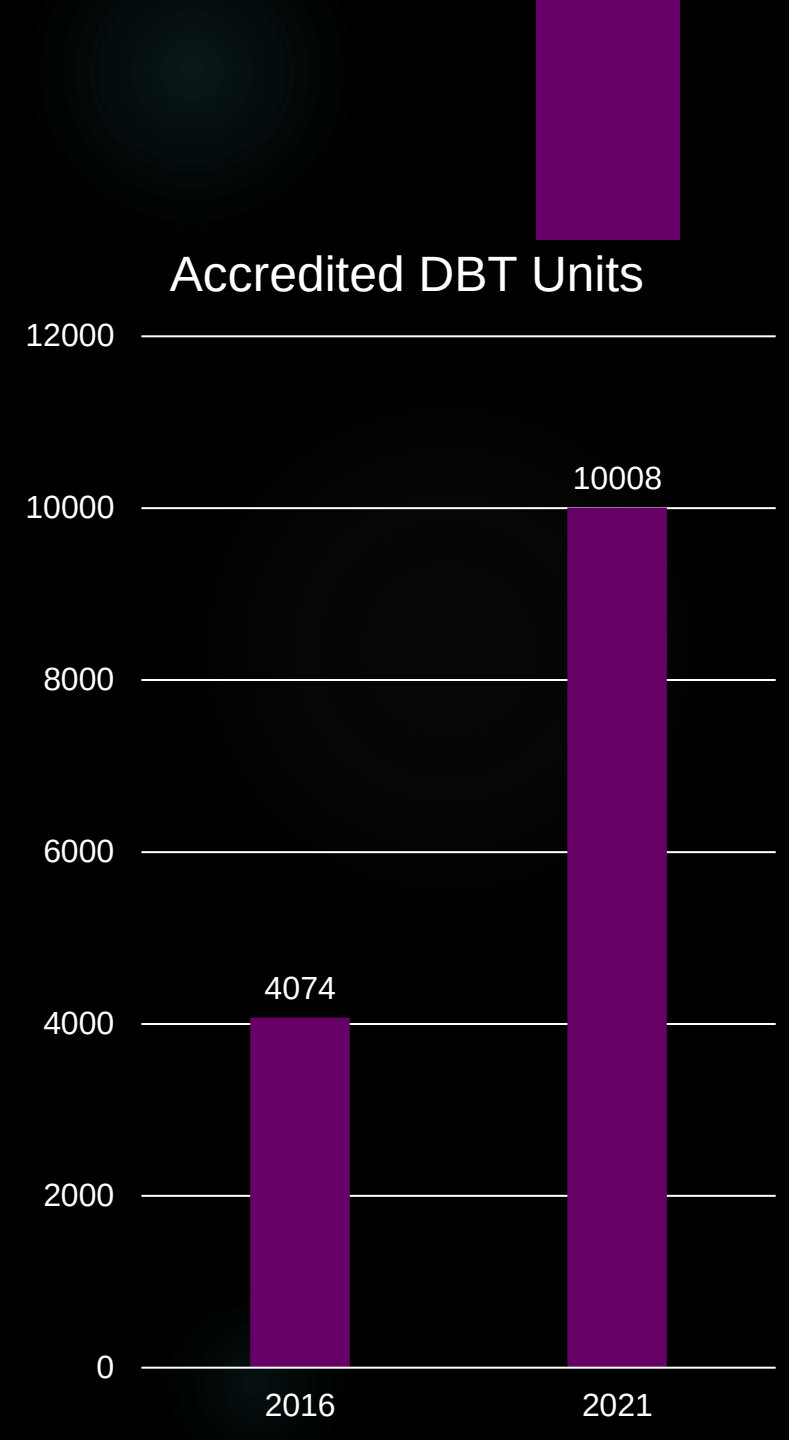
Courtesy of Hologic, Inc.

DBT Use in Practice

- Varieties of ways DBT is applied in clinical practice
  - Some facilities utilize combination imaging, still obtaining a traditional FFDM 2D image with the DBT
  - Some facilities have transitioned completely away from FFDM, utilizing the synthesized mammogram with DBT

DBT in the US Today

	December 2016	June 2021
Total certified facilities	8,747	8,705
Total accredited units	16,959	23,070
Certified facilities with FFDM	8,574	8,694
Accredited FFDM units	12,660	13,055
Certified facilities with DBT	2,948	6,734
Accredited DBT units	4,074	10,008



FDA-approved DBT Systems

Table 3: FDA-approved DBT Systems in the United States

Vendor	Tube Motion	Detector Angular Range	Scan Angle (degrees)	No. of Projections	Scan Time (sec)	Detector	Pixel Size (μm)	SM
Hologic	Continuous	Rotating (± 2.1°)	15	15	4	aSe	140 (reg)/ 70 (HR)	C-view
GE	Step and shoot	Stationary	25	9	10	CsI-aSi	100	V-preview
Siemens	Continuous	Stationary	50	25	22	aSe	85	Insight-2D
Fuji	Continuous	Stationary	15 (reg)/ 40 (HR)	15	4	aSe	150 (reg)/ 100 (HR)	None

Note.—aSe = amorphous selenium, CsI/aSi = cesium iodide/amorphous silicon, HR = high resolution, reg = regular.

Gao Y et al. Digital Breast Tomosynthesis: Update on Technology, Evidence, and Clinical Practice. RadioGraphics 2021; 41:321-337.

Current Scope – Gao et al

- DBT gained rapid acceptance early on, however long-term outcomes data is lacking, which precludes full endorsement of DBT as standard of care in some clinical guidelines
- Worldwide adoption of DBT has been relatively slow, often with cost-effectiveness as a primary concern, particularly in parts of the world where resources are limited
- Variation in adoption highlights the question of whether an upgrade from FFDM to DBT is worthwhile and will save more lives

Gao Y et al. Digital Breast Tomosynthesis: Update on Technology, Evidence, and Clinical Practice. RadioGraphics 2021; 41:321-337.

Early DBT Screening Studies

Table 1: Screening Outcomes with Combined DBT and DM Compared with DM Alone in Representative Retrospective Studies Published in 2013–2016

	No. of Examinations		Cancer Detection Rate			Recall Rate		
Study and Year	DBT/DM	DM	DBT/DM*	DM*	*P* Value	DBT/DM†	DM†	*P* Value
Rose, 2013 (9)	9499	13856	5.4	4.0	.07	5.5	8.7	<.001
Haas, 2013 (10)	6100	7058	5.7	5.2	.7	8.4	12	<.01
Greenberg, 2014 (11)	23149	54684	6.3	4.9	.0056	13.6	16.2	<.0001
McCarthy, 2014 (12)	15571	10728	5.5	4.6	.02	8.8	10.4	<.001
Friedewald, 2014 (13)	173663	281187	5.4	4.2	<.001	9.1	10.7	<.001
Durand, 2015 (14)	8591	9364	5.9	5.7	.88	7.8	12.3	<.0001
Lourenco, 2015 (15)	12921	12577	5.4	4.6	.44	6.4	9.3	<.0001
McDonald, 2015 (16)	15571	10728	5.4	4.6	.41	8.8	10.4	<.001
Sharpe, 2016 (17)	5703	80149	5.4	3.4	.0001	6.1	7.5	<.018
Conant, 2016 (18)	559998	142883	5.9	4.4	.0026	8.7	10.4	<.0001
All	830766	623214	. . .	. . .	. . .	. . .	. . .	. . .

Note.—Numbers in parentheses are reference numbers. Study populations may overlap in studies from the same institution.

*Number per 1000 examinations.

†Numbers are percentages.

Gao Y et al. Digital Breast Tomosynthesis: Update on Technology, Evidence, and Clinical Practice. RadioGraphics 2021; 41:321-337.

Consecutive DBT Screening: Conant 2020

- Retrospective analysis: One year DM, 5 years DBT screening; 67,350 exams in 29,310 women
  - Recall rates significantly lower for DBT vs DM (8.0% vs. 10.4%)
  - CDR higher with DBT vs. DM (6.0/1000 vs. 5.1/1000)
  - FNs lower with DBT vs. DM (0.6/1000 vs. 0.8/1000)
  - Higher proportion of cancers detected with DBT were invasive vs. DM, and had poor prognostic characteristics
  - Findings sustainable over multiple years and screening rounds

Conant EF, et al. Five Consecutive Years of Screening with Digital Breast Tomosynthesis: Outcomes by Screening Year and Round. Radiology 2020; 295:285-293.

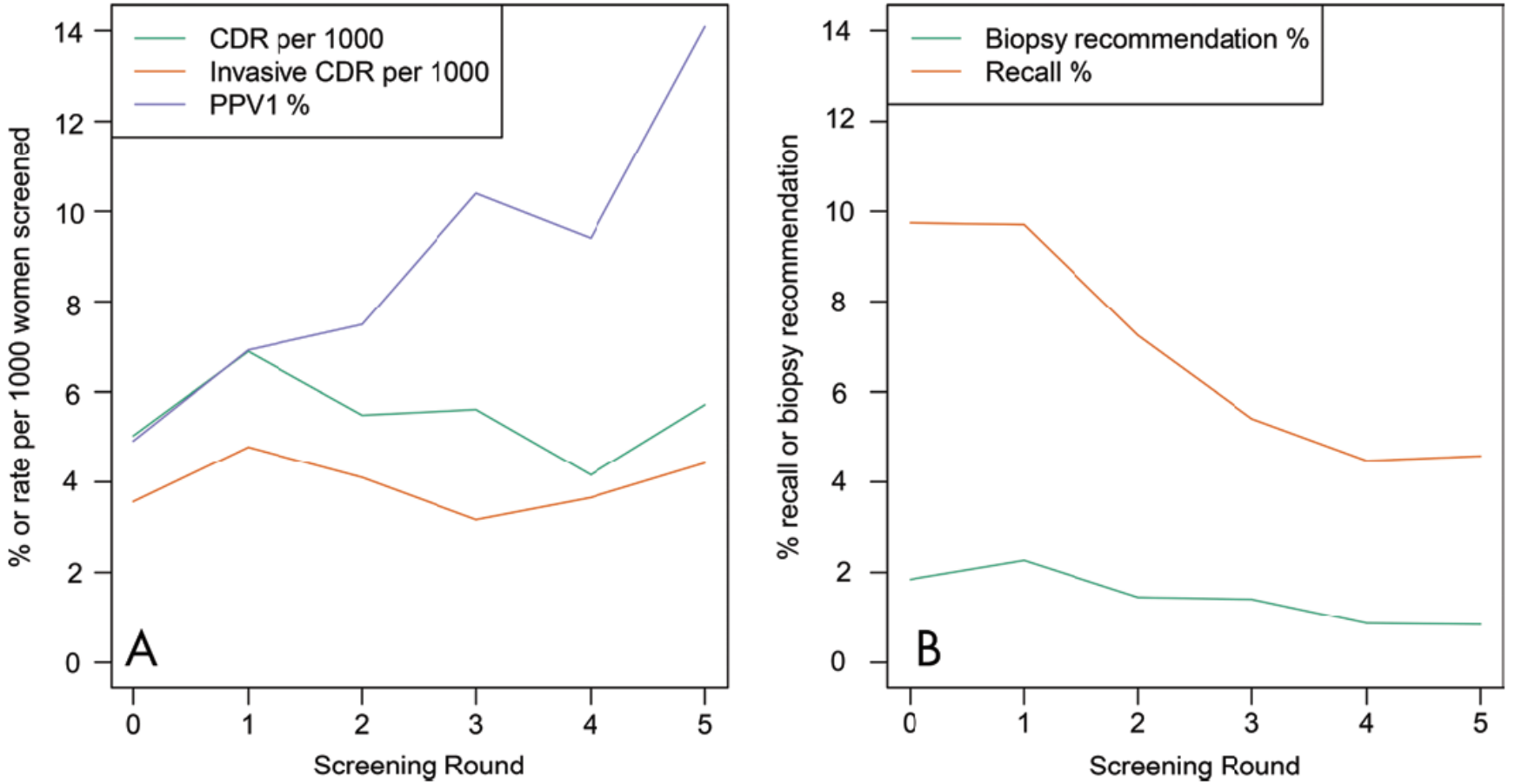


Figure 1: *A*, Graph shows patient-level variation in cancer detection rate (CDR), invasive CDR, and positive predictive value of recall (PPV1) across rounds of digital breast tomosynthesis (DBT) screening (rounds 1–5) compared with digital mammography (DM) (round 0) adjusted for age, race, breast density, and whether the mammogram was a baseline or subsequent screening. *B*, Graph shows patient-level variation in biopsy recommendation and recall across rounds of DBT screening (rounds 1–5) compared with DM (round 0) adjusted for age, race, breast density, reader, and whether the mammogram was a baseline or subsequent screening. CDR and invasive CDR are reported per 1000 women screened. PPV1, biopsy recommendation rate, and recall rate are reported as percentages.

From Conant Radiology 2020

Sustainability of DBT Benefits over Time: Bahl 2020

- Study to determine whether improved screening performance metrics with DBT are sustained over time at the population level and after the first screening round at the individual level

- Retrospective review of screening mammograms that were obtained before DBT implementation (March 2008 to February 2011, DM group) and for 5 years after implementation (January 2013 to December 2017, DBT1–DBT5 groups, respectively)

Bahl M, et al. Breast Cancer Screening with Digital Breast Tomosynthesis: Are Initial Benefits Sustained? Radiology 2020; 529-539.

Table 3: Comparison of Screening Performance Metrics with DM versus DBT (with DM as Referent)

Performance Metric	DBT1 vs DM	*P* Value	DBT2 vs DM	*P* Value	DBT3 vs DM	*P* Value	DBT4 vs DM	*P* Value	DBT5 vs DM	*P* Value
CDR	1.05 (0.88, 1.25)	.60	0.99 (0.83, 1.20)	.95	1.18 (0.98, 1.41)	.08	1.16 (0.94, 1.43)	.16	1.23 (0.98, 1.55)	.08
AIR	0.85 (0.81, 0.89)	<.001	0.85 (0.81, 0.89)	<.001	0.88 (0.84, 0.93)	<.001	0.97 (0.92, 1.03)	.31	0.93 (0.87, 0.99)	.02
PPV1	1.14 (0.95, 1.38)	.16	1.11 (0.91, 1.34)	.31	1.28 (1.06, 1.55)	.01	1.11 (0.89, 1.39)	.35	1.21 (0.96, 1.53)	.11
PPV2	1.02 (0.80, 1.30)	.87	1.04 (0.81, 1.33)	.78	1.25 (0.98, 1.60)	.08	0.99 (0.75, 1.31)	.95	1.07 (0.79, 1.45)	.66
PPV3	1.08 (0.85, 1.38)	.54	1.05 (0.81, 1.35)	.72	1.22 (0.95, 1.57)	.12	1.03 (0.77, 1.37)	.84	1.15 (0.84, 1.56)	.38
Sensitivity	1.55 (0.92, 2.60)	.10	0.96 (0.59, 1.57)	.87	1.37 (0.81, 2.34)	.24	1.32 (0.76, 2.28)	.32	1.05 (0.58, 1.93)	.86
Specificity	1.20 (1.14, 1.26)	<.001	1.19 (1.13, 1.25)	<.001	1.16 (1.10, 1.22)	<.001	1.04 (0.98, 1.10)	.18	1.10 (1.03, 1.17)	.004
False-positive rate	0.84 (0.80, 0.88)	<.001	0.84 (0.80, 0.89)	<.001	0.86 (0.82, 0.91)	<.001	0.96 (0.91, 1.02)	.17	0.91 (0.86, 0.97)	.004
True-negative rate	1.18 (1.12, 1.24)	<.001	1.18 (1.12, 1.24)	<.001	1.14 (1.08, 1.20)	<.001	1.03 (0.98, 1.09)	.27	1.08 (1.01, 1.15)	.02
False-negative rate	0.74 (0.46, 1.19)	.21	1.04 (0.66, 1.62)	.88	0.73 (0.45, 1.18)	.20	0.83 (0.51, 1.34)	.45	0.98 (0.59, 1.63)	.94

From Bahl Radiology 2020

Bahl Results

- Benefits of reduced abnormal interpretation rate and improved specificity with DBT were sustained beyond the first screening round
  - Study did not find increased CDR after DBT implementation but did observe a preferential ratio of invasive relative to in situ cancers in the 2nd, 3rd, and 5th years after implementation
  - The highest CDR was observed with a woman's first DBT examination
- DBT led to a small increase in specificity

Bahl M, et al. Breast Cancer Screening with Digital Breast Tomosynthesis: Are Initial Benefits Sustained? Radiology 2020; 529-539.

DBT Screening Performance in Community Practice: Lowry 2020

- Compared DM vs DBT performance by age, baseline vs subsequent screening round, and breast density category
  - Assessed 1,584,079 screening examinations of women aged 40 - 79 years without prior history of breast cancer, mastectomy, or breast augmentation undergoing screening mammography at 46 participating Breast Cancer Surveillance Consortium facilities from January 2010 to April 2018
- Study found that recall and CDR rates showed greatest improvements on baseline exam; benefits varied on subsequent mammograms based on age and breast density
  - Extremely dense breasts did not show as much improvement in recall or CDR

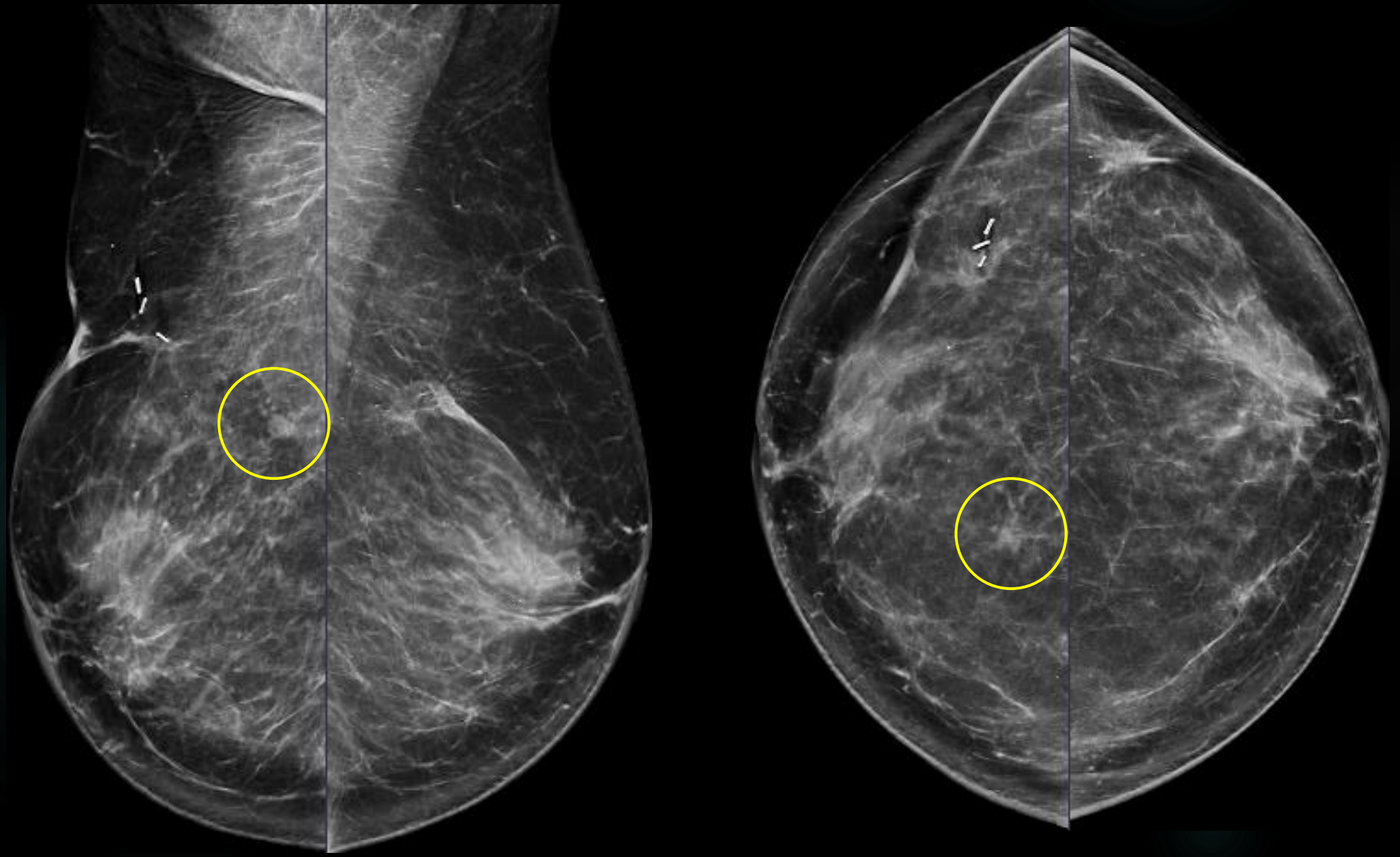
Lowry KP, et al. Screening Performance of Digital Breast Tomosynthesis vs Digital Mammography in Community Practice by Patient Age, Screening Round, and Breast Density. JAMA Network Open 2020; 3(7):e2011792.

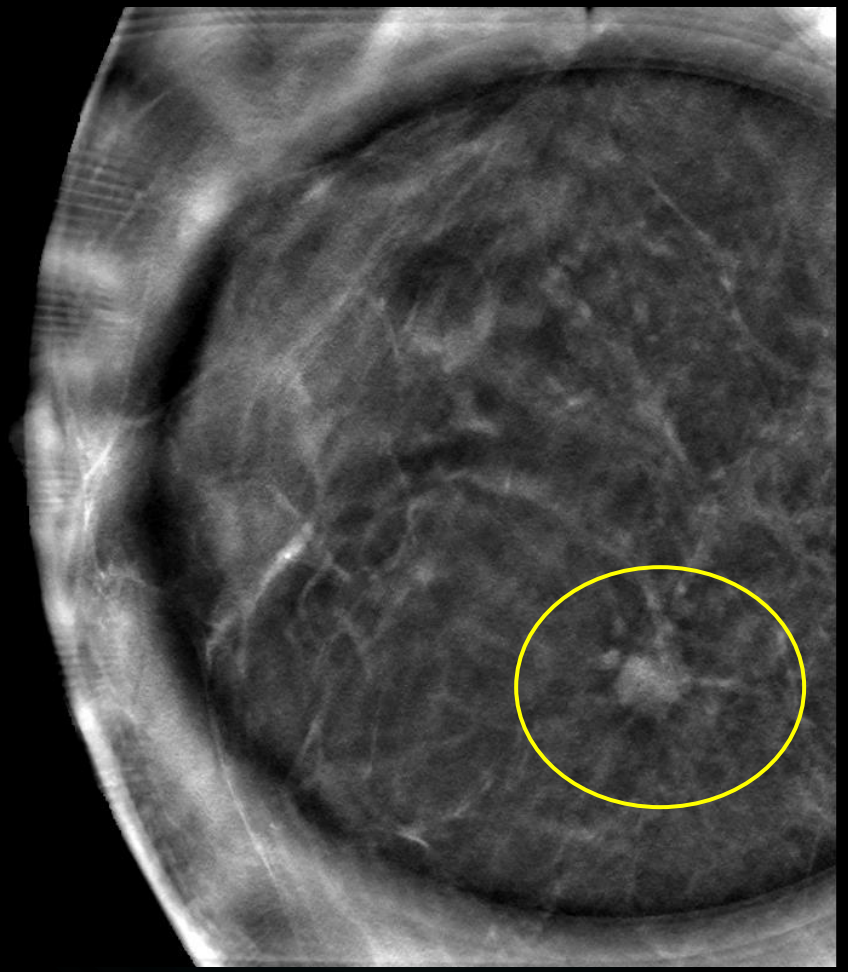
Table 4. Adjusted Ratios of Screening Recalls per Cancers Detected and Biopsies per Cancers Detected[a]

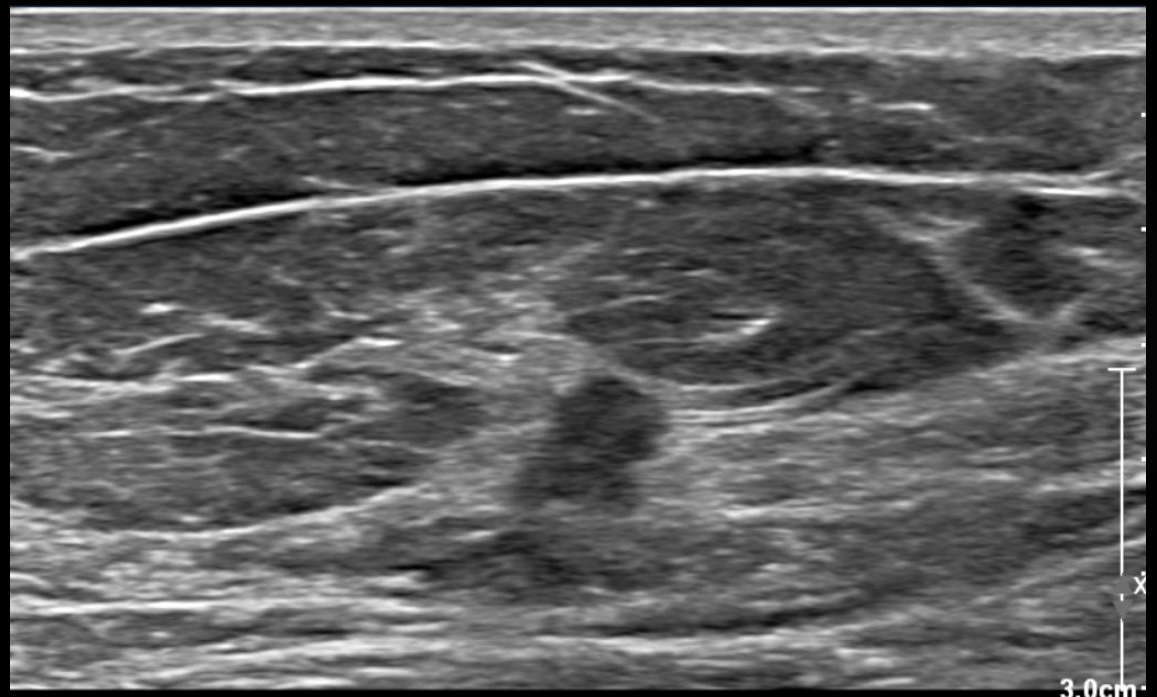
	Adjusted ratio (95% CI)			
	Recalls per cancer detected		Biopsies per cancer detected	
BI-RADS density	DM	DBT	DM	DBT
Baseline screening				
All women aged 40-49 y	75.0 (61.7-92.3)	48.9 (37.1-64.1)	11.0 (8.6-14.0)	10.6 (7.9-13.9)
All women aged 50-59 y	40.8 (32.8-50.3)	23.2 (16.3-32.4)	7.0 (5.3-8.9)	6.2 (4.3-8.6)
All women aged 60-79 y	20.3 (16.5-24.5)	11.8 (8.7-15.6)	3.7 (3.0-4.6)	3.3 (2.5-4.3)
Subsequent screening				
Aged 40-49 y				
Almost entirely fat	36.2 (28.9-42.7)	30.6 (23.1-43.7)	6.9 (5.5-8.4)	6.6 (4.6-10.7)
Scattered fibroglandular density	46.8 (42.1-52.7)	33.3 (26.7-42.7)	6.2 (5.5-7.1)	5.8 (4.5-7.5)
Heterogeneously dense	52.8 (47.9-60.1)	38.4 (30.1-47.5)	6.8 (6.1-8.0)	6.6 (5.0-8.6)
Extremely dense	44.8 (37.9-52.7)	45.2 (34.2-62.7)	7.2 (6.0-8.5)	7.3 (5.6-10.1)
Aged 50-59 y				
Almost entirely fat	21.9 (18.3-26.1)	17.0 (12.0-24.9)	4.8 (3.9-5.8)	4.4 (3.0-6.7)
Scattered fibroglandular density	24.8 (22.7-27.6)	17.2 (14.4-20.7)	3.9 (3.6-4.4)	3.5 (3.0-4.1)
Heterogeneously dense	27.6 (24.7-30.6)	17.5 (15.2-20.4)	4.4 (3.8-5.0)	3.8 (3.3-4.5)
Extremely dense	24.6 (21.1-27.7)	21.1 (14.6-29.6)	4.5 (3.7-5.3)	4.3 (3.0-6.1)
Aged 60-79 y				
Almost entirely fat	13.4 (11.2-16.3)	10.0 (7.3-14.0)	2.8 (2.4-3.5)	2.7 (1.8-4.0)
Scattered fibroglandular density	13.5 (12.3-14.9)	9.4 (8.0-11.0)	2.5 (2.3-2.7)	2.1 (1.9-2.5)
Heterogeneously dense	14.3 (12.9-15.8)	9.1 (8.0-10.4)	2.7 (2.5-3.0)	2.4 (2.1-2.7)
Extremely dense	10.8 (9.2-12.8)	9.0 (6.6-12.1)	2.9 (2.4-3.3)	2.7 (2.0-3.6)

From JAMA Network Open 2020

Patient presents for screening mammogram – status post bilat lumpectomies

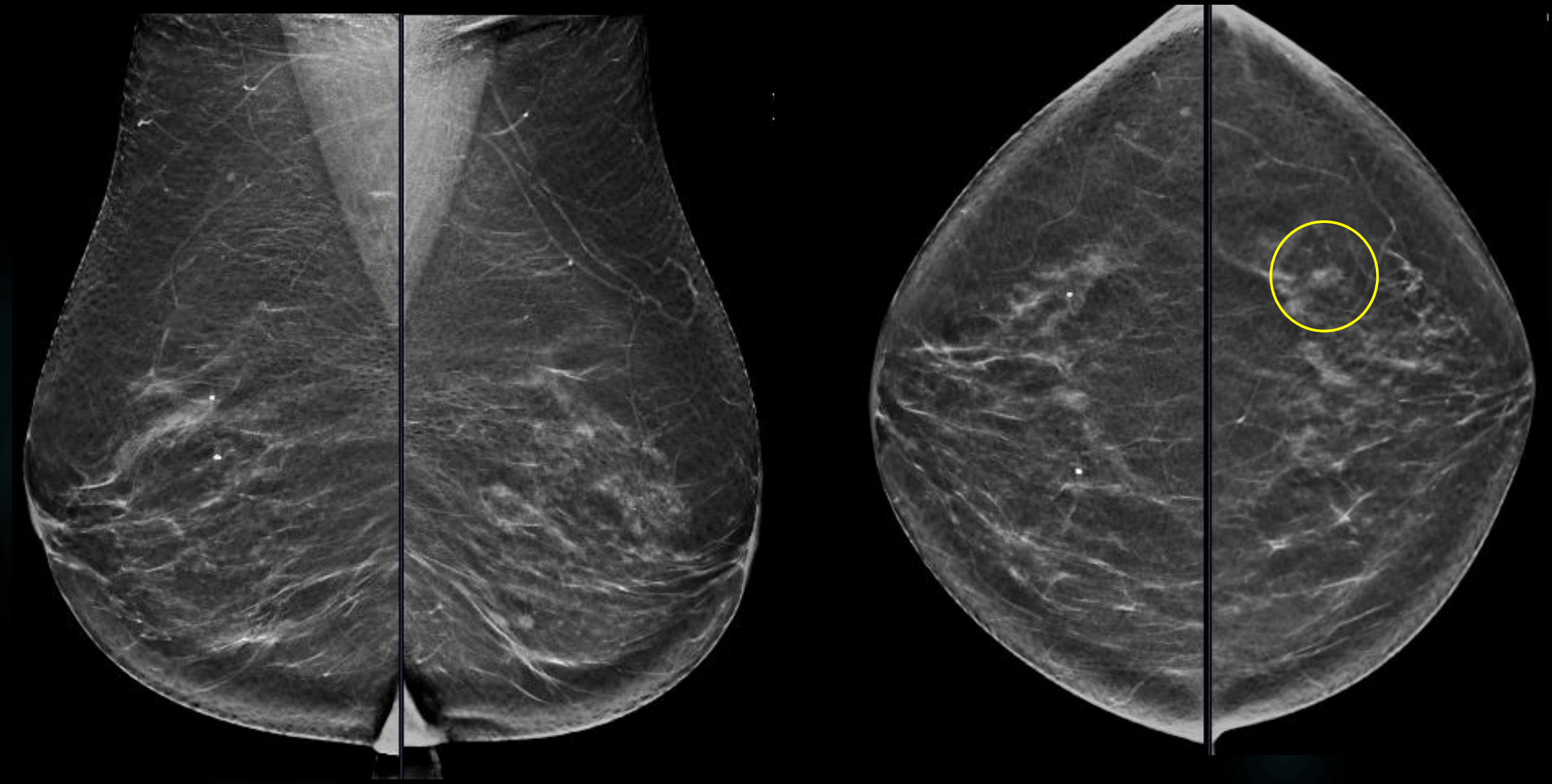


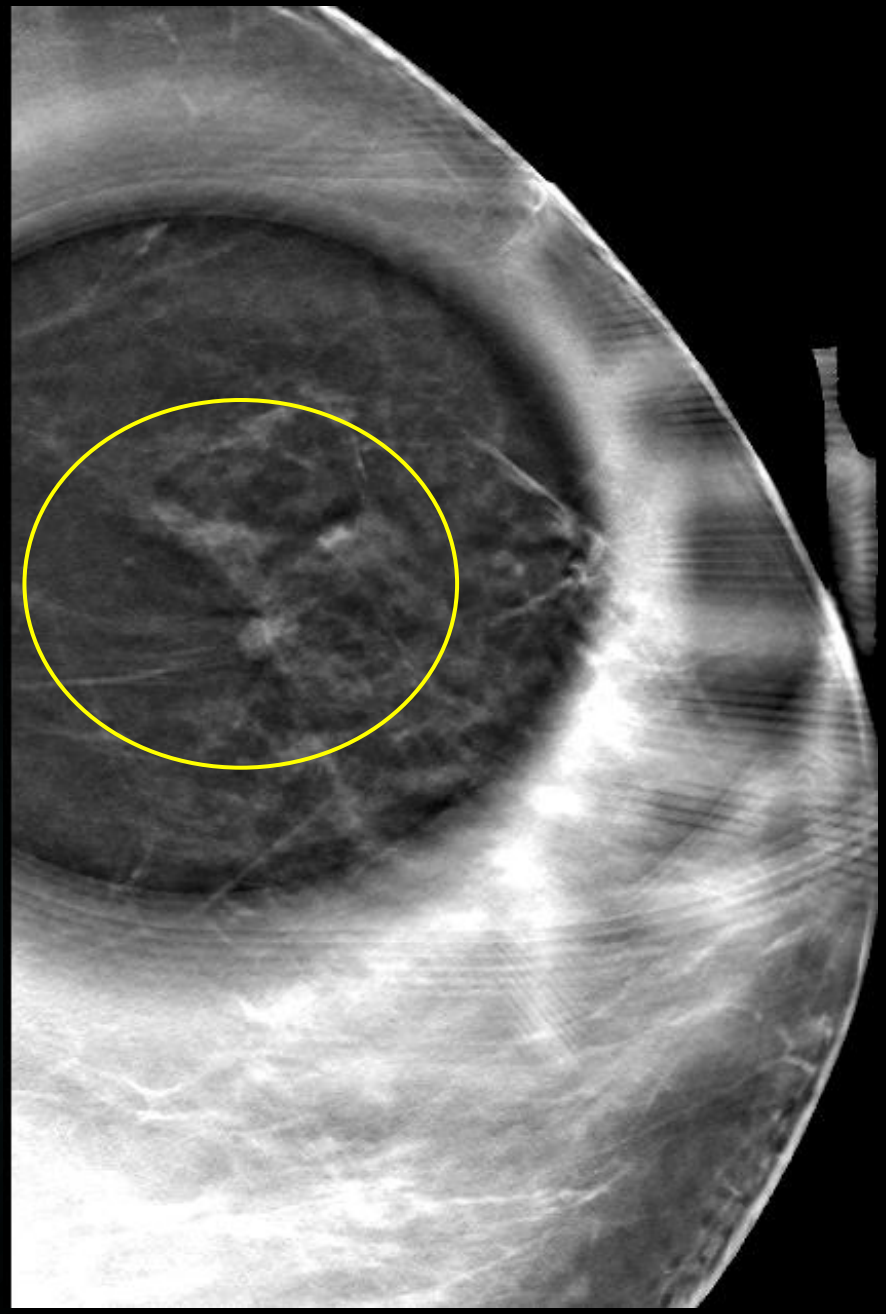




Right 1:00 – Invasive ductal carcinoma w/ apocrine feat., grade 1

Patient presents for screening mammogram





Invasive ductal carcinoma gr 2, ER Positive, PR Positive, Her2 Negative

Screening DBT by Age and Density: Conant 2019

- Retrospective analysis of 96,269 women 40-74 years old who underwent screening using Digital Mammography (DM) and DBT from the Population-based Research Optimizing Screening Through Personalized Regimens (PROSPR) consortium

- Investigated whether DBT screening detects breast cancers that are associated with an improved prognosis and compared detection rates by age and breast density

Conant EF, et al. Association of Digital Breast Tomosynthesis vs Digital Mammography With Cancer Detection and Recall Rates by Age and Breast Density. *JAMA Oncol.* 2019; 5(5):635–642.

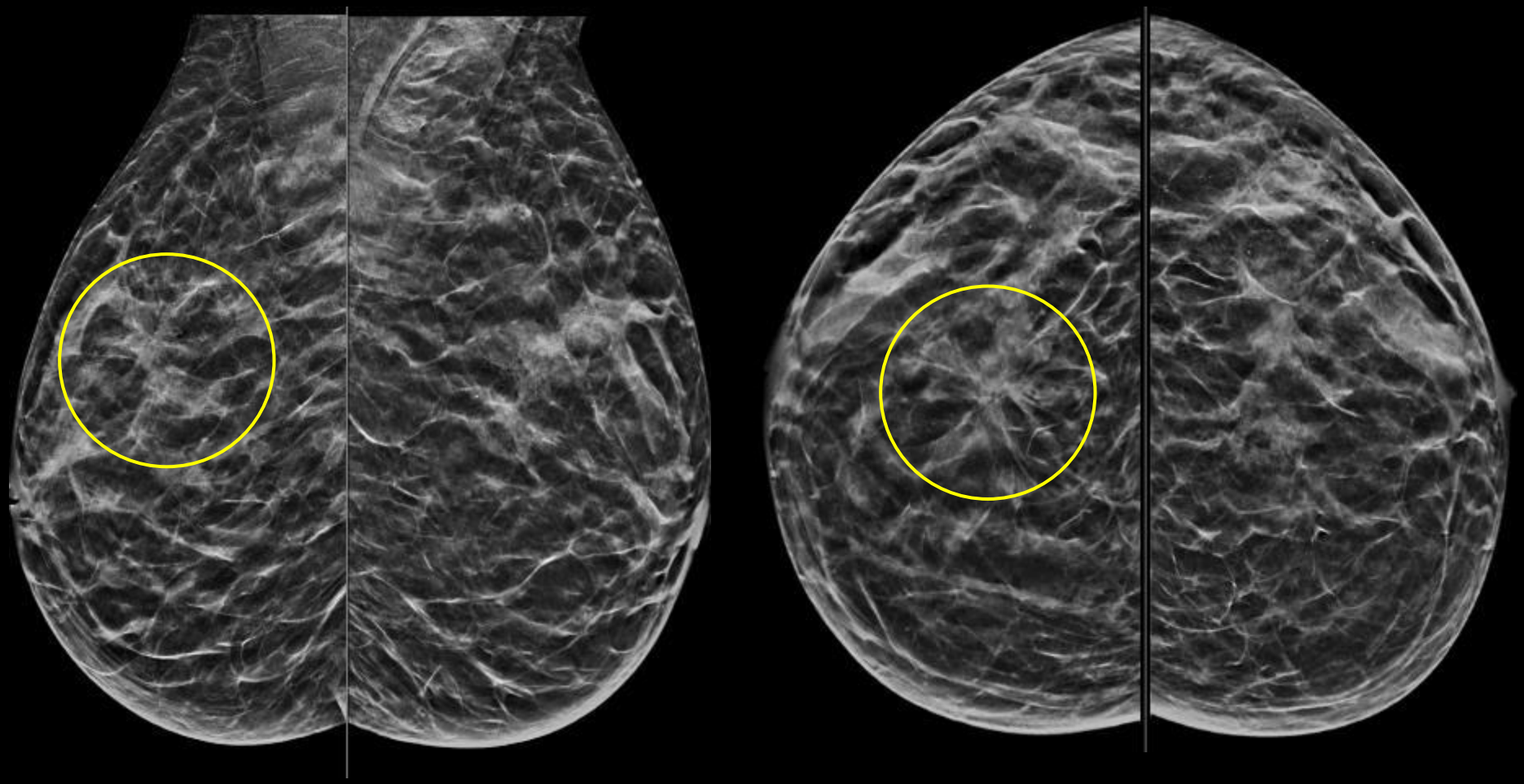
DBT by Age and Density

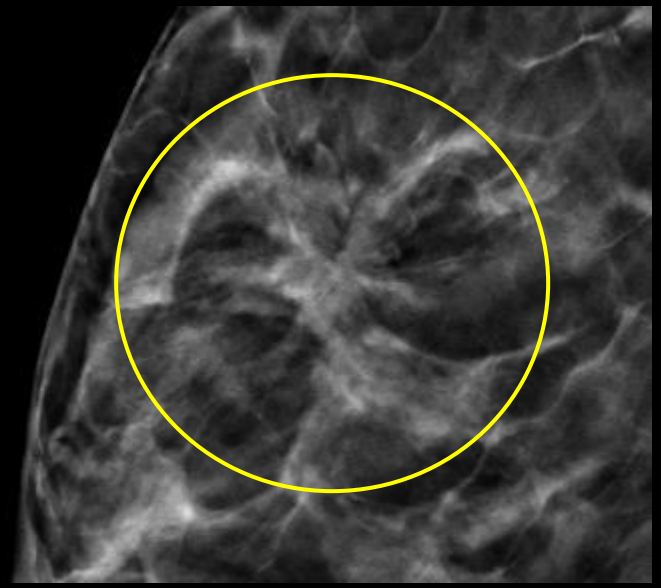
	Recall	CDR	PPV1	Node-Negative
DM	11.2%	4.42	3.85	81%
DBT	8.7%	5.82	6.29	88.8%

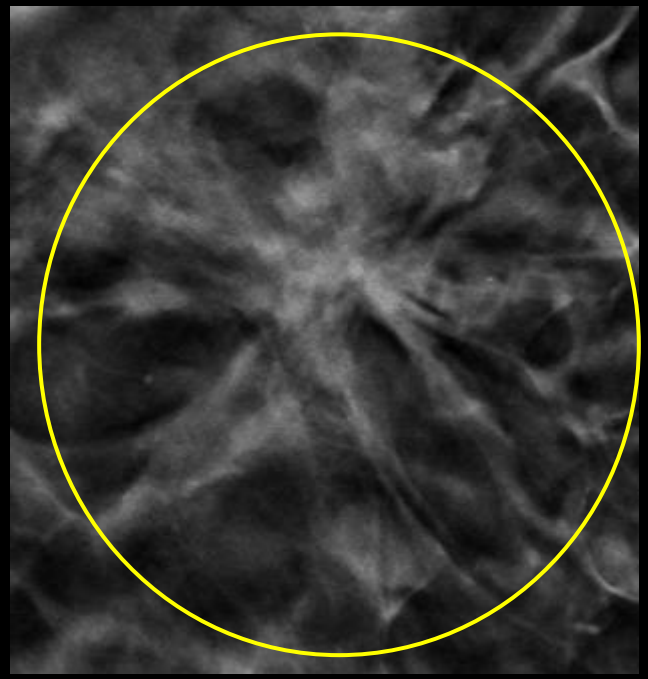
- DBT showed the greatest significance in women 40-49
  - For women with nondense breasts: CDR for DBT was 1.70/1000 women higher than DM
  - For women with dense breasts: CDR was 2.27/1000 higher than DM
  - 25.0% of DBT-detected cancers were categorized as advanced cancers vs. 40.4% of DM-detected cancers (not statistically significant)
    - Routine DBT screening may have a favorable risk-benefit ratio in this age group

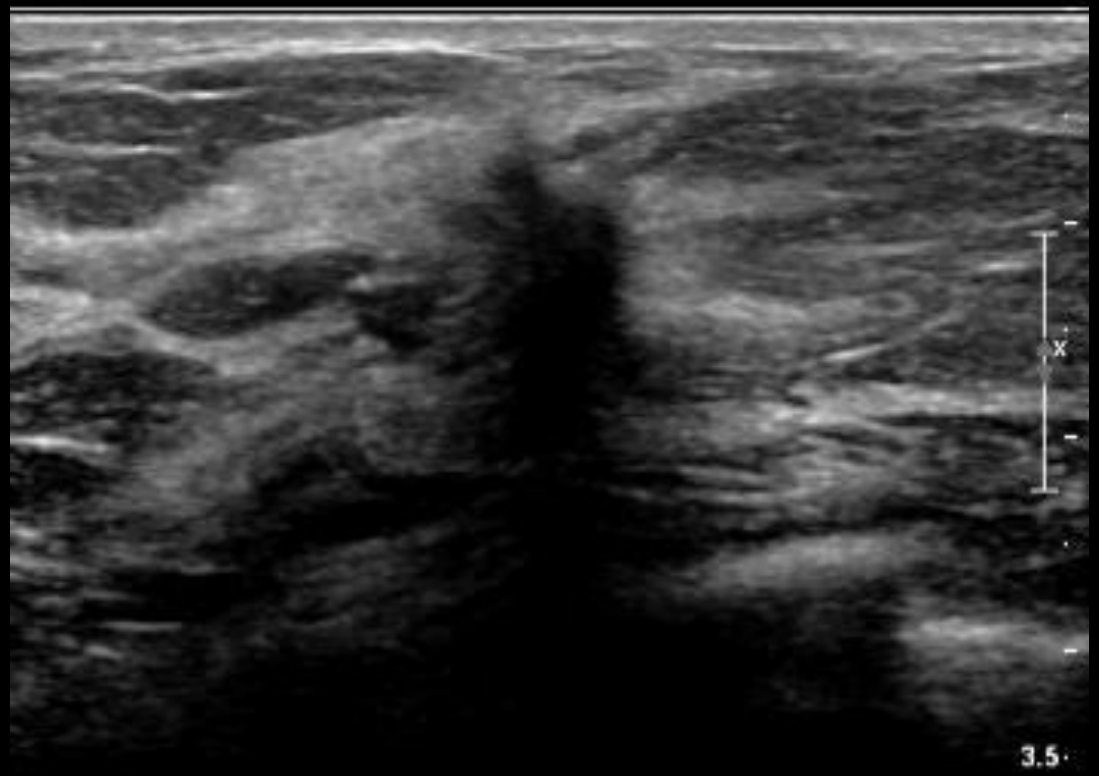
Conant EF, et al. Association of Digital Breast Tomosynthesis vs Digital Mammography With Cancer Detection and Recall Rates by Age and Breast Density. *JAMA Oncol.* 2019; 5(5):635–642.

49-year-old presents for baseline screening mammography









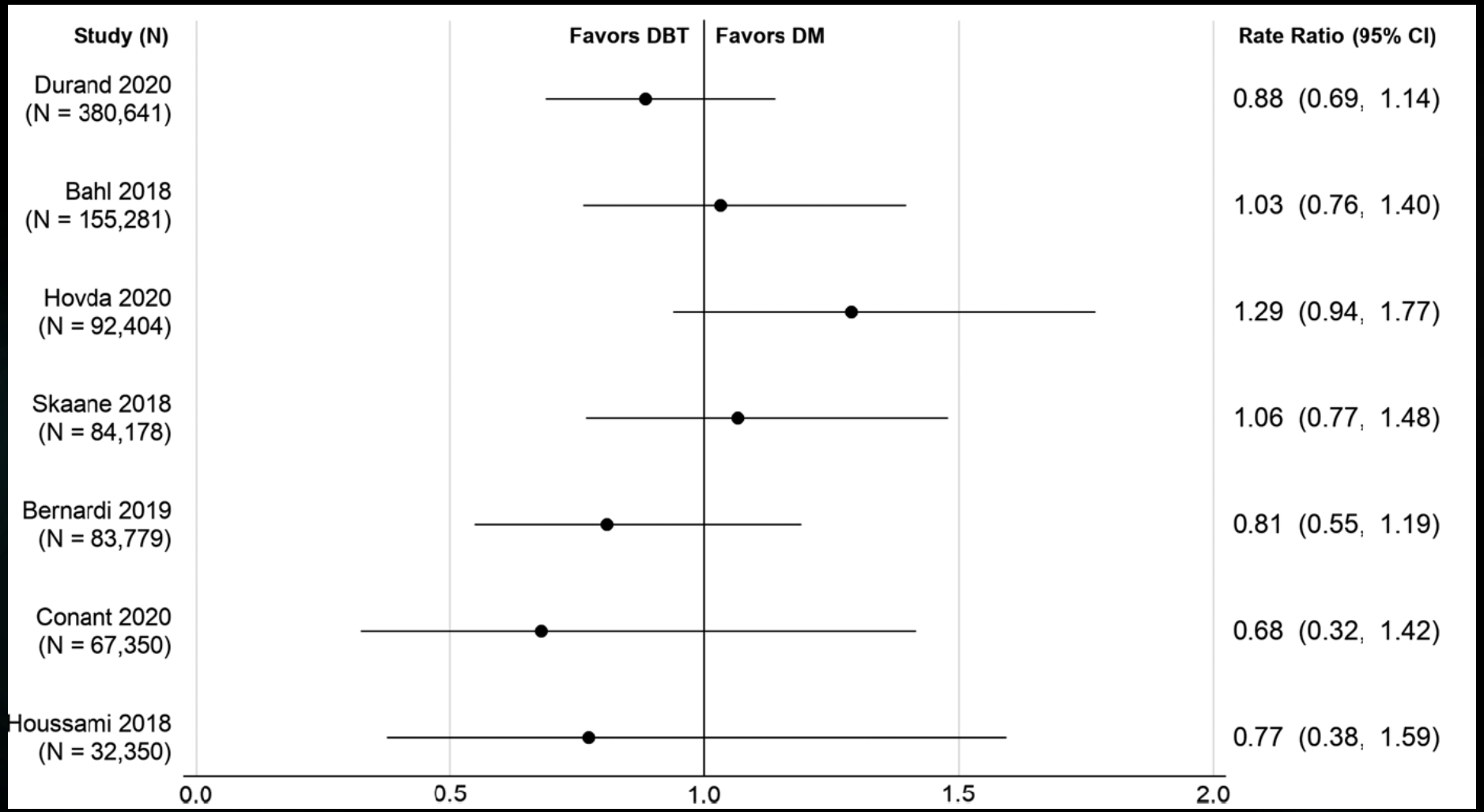
Invasive lobular carcinoma

DBT and False Negative Rates: Durand 2021

- Determined if screening with DBT is associated with lower FN rates, detection of cancers with more favorable prognoses, and improved performance outcomes versus DM
- Retrospective study involved 10 academic and community practices
  - 380,641 exams
    - 183,989 DBT, 196,652 DM

Durand MA, et al. False-Negative Rates of Breast cancer Screening with and without Digital Breast Tomosynthesis. Radiology 2021; 298: 296-305.

FN Rates as Reported in the Literature



From Durand Radiology 2021

Durand Results

Table 3: False-Negative Counts, Rates, and Proportions: Digital Mammography versus Digital Breast Tomosynthesis

Parameter	Overall	DM	DBT	Difference*	*P* Value*
No. of screenings	380 641	196 652	183 989	…	…
False-negative cancers†	243 (0.6)	133 (0.7)	110 (0.6)	−0.1 (−0.3, 0.1)	.20
Symptomatic false-negative cancers‡	167 (0.4)	93 (0.5)	74 (0.4)	−0.1 (−0.2, 0.0)	.21
Symptomatic invasive false-negative cancers	148 (0.4)	81 (0.4)	67 (0.4)	−0.1 (−0.2, 0.1)	.37
Symptomatic DCIS false-negative cancers	19 (0.05)	12 (0.06)	7 (0.04)	−0.02 (−0.07, 0.02)	.31
Asymptomatic false-negative cancers‡	58 (0.2)	23 (0.1)	35 (0.2)	0.05 (−0.03, 0.14)	.21
Asymptomatic invasive false-negative cancers	36 (0.1)	16 (0.1)	20 (0.1)	0.02 (−0.04, 0.08)	.54
Asymptomatic DCIS false-negative cancers	22 (0.06)	7 (0.04)	15 (0.08)	0.04 (−0.01, 0.09)	.11
Detected by means of other modalities or Breast Imaging Reporting and Data System category 3					
Detected with other modalities§	22 (37.9)	8 (34.8)	14 (40.0)	0.13 (−0.04, 0.30)	.12
Screening US‖	9 (40.9)	4 (50.0)	5 (35.7)	−0.1 (−0.5, 0.3)	.54
Screening MRI‖	11 (50.0)	4 (50.0)	7 (50.0)	0.005 (−0.394, 0.403)	.98
Other (PET, surgery)‖	2 (9.1)	0 (0.0)	2 (14.3)	0.1 (−0.1, 0.4)	.29
Breast Imaging Reporting and Data System category 3§	36 (62.1)	15 (65.2)	21 (60.0)	−0.13 (−0.30, 0.04)	.12

From Durand Radiology 2021

Durand Results Summary

- FN rates trended lower with DBT
  - Symptomatic FN exams
- Asymptomatic FN rates higher in women with dense breasts (DBT 0.14/1000 vs. 0.07/1000 DM)
- DBT resulted in improved sensitivity and specificity
- Cancers identified with DBT were more often invasive, with fewer positive lymph nodes and distant metastases, & lower odds of a FN finding of advanced cancer

Benefit of DBT – Types of Cancers Detected

- In order to show benefit, it is important for a new technology to demonstrate the ability to find the invasive cancers over in situ
  - Thus far many studies have supported the DBT does preferentially detect invasive cancers
  - Data has supported DBT-detected cancers are often smaller, of lower histologic grade, and less likely to be node positive

Tumor Characteristics of Breast Cancers Diagnosed with DBT Screening: Dang 2020

- Purpose to compare the CDRs, tumor types, and characteristics between screening DBT and screening DM

TABLE 1: Comparison of Overall Cancer Detection Rates of DBT and FFDM

	Cancer Detection Rates			
			With FFDM as Reference	
Cancer Type	FFDM Examinations (n = 14,180)[a]	DBT Examinations (n = 9817)[a]	Rate Ratio (95% CI)	p[b]
Total cancers	1.8 (25)	3.7 (36)	2.1 (1.3–3.5)	**0.01**
DCIS	0.5 (7)	0.9 (9)	1.9 (0.7–5.0)	0.22
Invasive	1.3 (18)	2.8 (27)	2.2 (1.2–3.9)	**0.01**
Minimal cancer	1.2 (17)	2.4 (24)	2.0 (1.1–3.8)	**0.03**
Nonminimal cancer	0.6 (8)	1.2 (12)	2.2 (0.9–5.3)	0.09

Note—DBT = digital breast tomosynthesis, FFDM = full-field digital mammography, DCIS = ductal carcinoma in situ.
[a]Values are rate per 1000 with number of examinations in parentheses.
[b]Values in bold are statistically significant.

Dang PA, et al. Comparing Tumor Characteristics and Rates of Breast Cancers Detected by Screening Digital Breast Tomosynthesis and Full-Field Digital Mammography. AJR 2020; 214: 701-706.

TABLE 2: Cancer Detection Rates for Invasive Cancers on DBT and FFDM Stratified by Tumor Characteristics

Tumor Characteristic	Cancer Detection Rates			
	FFDM Examinations (n = 14,180)[a]	DBT Examinations (n = 9817)[a]	With FFDM as Reference	
			Rate Ratio (95% CI)	p[b]
Overall cancers	1.3 (18)	2.8 (27)	2.2 (1.2–3.9)	**0.01**
Size				
≤ 1 cm	0.7 (10)	1.5 (15)	2.2 (1.0–4.8)	0.06
> 1 cm	0.6 (8)	1.2 (12)	2.2 (0.9–5.3)	0.09
Grade				
Well-differentiated	0.4 (5)	1.0 (10)	2.9 (1.0–8.5)	**0.05**
Poorly or moderately differentiated	0.9 (13)	1.7 (17)	1.9 (0.9–3.9)	0.08
ER status				
Positive	1.1 (15)	2.6 (25)	2.4 (1.3–4.6)	**0.01**
Negative	0.2 (3)	0.2 (2)	1.0 (0.2–5.8)	0.97
Node involvement				
Negative	1.1 (15)	2.3 (23)	2.2 (1.2–4.2)	**0.02**
Positive	0.2 (3)	0.4 (4)	1.9 (0.4–8.6)	0.39

From Dang AJR 2020

Dang Results Summary

- Overall detection rates for screen-detected cancers were ***higher for DBT*** than for FFDM irrespective of tumor type, size, or grade of cancer
- Higher CDRs were noted for all invasive, in situ, minimal, and nonminimal cancers; however, these differences were statistically significant only for invasive cancers and minimal cancers
  - Among invasives, DBT detected more cancers of all sizes, grades, and hormone receptor statuses, with or without node involvement
    - Statistically significant for node-negative, well-differentiated and ER-positive tumors

Interval Cancer Rates at DBT

Table 2: Interval Cancer Rates at DBT and DM Screening in Studies Published in 2018–2020

	Screening Interval		Rate of Interval Cancer (No.)*		
Study and Year	No. of Rounds	Frequency	DBT	DM	*P* Value
Skaane, 2018 (39)	2	Biennial	2.1	2.0	.73
Houssami, 2018 (40)	2	Biennial	1.23	1.6	NA
Bahl, 2018 (25)	3	Annual	1.1	1.1	.84
Hovda, 2020 (2)	2	Biennial	2	1.5	.12
Conant, 2020 (8)	5	Annual	0.6	0.9	.30
Bernardi, 2020 (33)	1	Biennial	1.1	1.36	NA

Note.—Numbers in parentheses are reference numbers. NA = not available.
*Per 1000 examinations.

From Gao Y RadioGraphics 2021

Interval Cancers and Tumor Characteristics – Malmö: Johnson 2021

Table 2: Histopathologic Characteristics of Interval and Screen-detected Cancers in the Malmö Breast Tomosynthesis Screening Trial and in the Age-matched Control Group

Parameter	Women with Interval Cancers in the MBTST	Women with Interval Cancers in the Control Group	Screen-detected Cancers in the Control Group	Screen-detected Cancers in the MBTST*
No. of cancers	21 (100)	76 (100)	176 (100)	139 (100)
Total invasive cancers	19 (90)	72 (95)	154 (87.5)	118 (84.9)
Total in situ cancers	2 (10)	4 (5)	22 (12.5)	21 (15.1)
Mean age at diagnosis (y)	61 ± 11	58 ± 10	61 ± 9	61 ± 9
Invasive cancers				
Histologic type				
Invasive ductal carcinoma	17 (90)	58 (80)	122 (79.2)	75 (63.6)
Invasive lobular carcinoma	2 (11)	13 (18)	21 (13.6)	25 (21.2)
Other invasive carcinoma	0 (0)	0 (0)	11 (7.1)	17 (14.4)
Missing	0 (0)	1 (2)	0 (0)	1 (0.8)
Mean tumor size at pathologic analysis (mm)	15 ± 7	20 ± 10	16 ± 9	14 (± 10)
pT1a-b ≤10 mm	3 (16)	9 (13)	42 (27.3)	41 (34.7)
pT1c >10–20 mm	11 (58)	29 (40)	66 (42.9)	58 (49.2)
pT2 >20–50 mm	2 (11)	23 (32)	35 (22.7)	16 (13.6)
pT3 >50 mm	0 (0)	1 (1)	1 (0.6)	1 (0.8)
Neoadjuvant treatment†	3 (16)	7 (10)	9 (5.8)	0 (0)
Missing	0 (0)	3 (4)	1 (0.6)	2 (1.7)
Mean tumor size at imaging, neoadjuvant treatment (mm)	21 ± 4	32 ± 10	43 ± 25	NA
Node status				
Positive	7 (37)	32 (44)	50 (32.4)	30 (25.4)
Negative	11 (58)	38 (53)	100 (64.9)	86 (72.9)
Missing	1 (5)	2 (3)	4 (2.6)	2 (1.7)
Histologic grade				
1	2 (10)	7 (10)	36 (23.4)	47 (39.8)
2	10 (50)	30 (42)	77 (50.0)	52 (44.1)
3	4 (20)	32 (44)	35 (22.7)	17 (14.4)
Missing†	3 (20)	3 (4)	6 (3.9)	2 (1.7)
In situ cancers				
Mean size (mm)	30 ± 10	8 ± 8	21 ± 18	17 ± 14
Nuclear grade				
1	0 (0)	2 (50)	1 (5)	2 (10)
2	1 (50)	0 (0)	10 (46)	8 (38)
3	0 (0)	2 (50)	11 (50)	11 (52)
Missing	1 (50)	0 (0)	0 (0)	0 (0)

- Compared interval cancer rates and tumor characteristics in DBT screening to those in a contemporary population screened with DM
  - Malmö trial compares one-view DBT and two-view DM
- IC rate 1.6/1000 vs. 2.8/1000 in control group
- Invasive ICs showed high Ki-67, low proportion of luminal A subtype

Johnson K, et al. Interval Breast Cancer Rates and Tumor Characteristics in the Prospective Population-based Malmö Breast Tomosynthesis Screening Trial. Radiology 2021; 299:559-567.

Diagnostic DBT

- Replacement for traditional diagnostic views
- Diagnostic examinations with DBT are more expedient, more accurate, and lower in radiation dose when compared with DM, which both benefits the patient and improves clinical outcomes and workflow - Gao

- Peppard et al. noted that in their initial use of DBT, they obtained both FFDM spot compression and DBT images to evaluate noncalcified findings, as well as single view findings
  - Found 2-view DBT was sufficient in most cases, which allowed for the number of diagnostic FFDM views to decrease

Peppard, H. R., et al. (2015). Digital breast tomosynthesis in the diagnostic setting: indications and clinical applications. Radiographics, 35(4), 975-990.

Replacing Additional Mammographic Views

- 2017 study examined equivalence of single-view DBT to standard assessment by additional views in 311 lesions from 285 patients [Heywang-Köbrunner, Breast Care]
  - Found additional views unnecessary in 88.8% of lesions
  - Concluded DBT proved at least equivalent to additional views in assessing screen-detected abnormalities

- Another 2017 study found DBT caused spot compression to be unnecessary in the evaluation of 340/341 non-calcified lesions, concluding spot compressions could become obsolete [Ni Mhuircheartaigh, The Breast Journal]

Heywang-Köbrunner, S., et al (2017). Value of digital breast tomosynthesis versus additional views for the assessment of screen-detected abnormalities-a first analysis. *Breast Care*, *12*(2), 91-96.
Ni Mhuircheartaigh, N., et al. (2017). With the advent of tomosynthesis in the workup of mammographic abnormality, is spot compression mammography now obsolete? An initial clinical experience. The breast journal, 23(5), 509-518.

DBT in the Diagnostic Setting (Østerås Radiology 2019)

- Utilized prospectively collected screenings from the Oslo trial to compare true-positive (TP) and false-positive (FP) interpretations in DM versus DBT according to volumetric density, age, and mammographic findings

	TP DM	TP DBT	FP DM	FP DBT
Fatty	15	17	197	152
Scattered	79	105	1224	972
Heterogeneously Dense	64	83	815	721
Extremely Dense	18	23	229	234

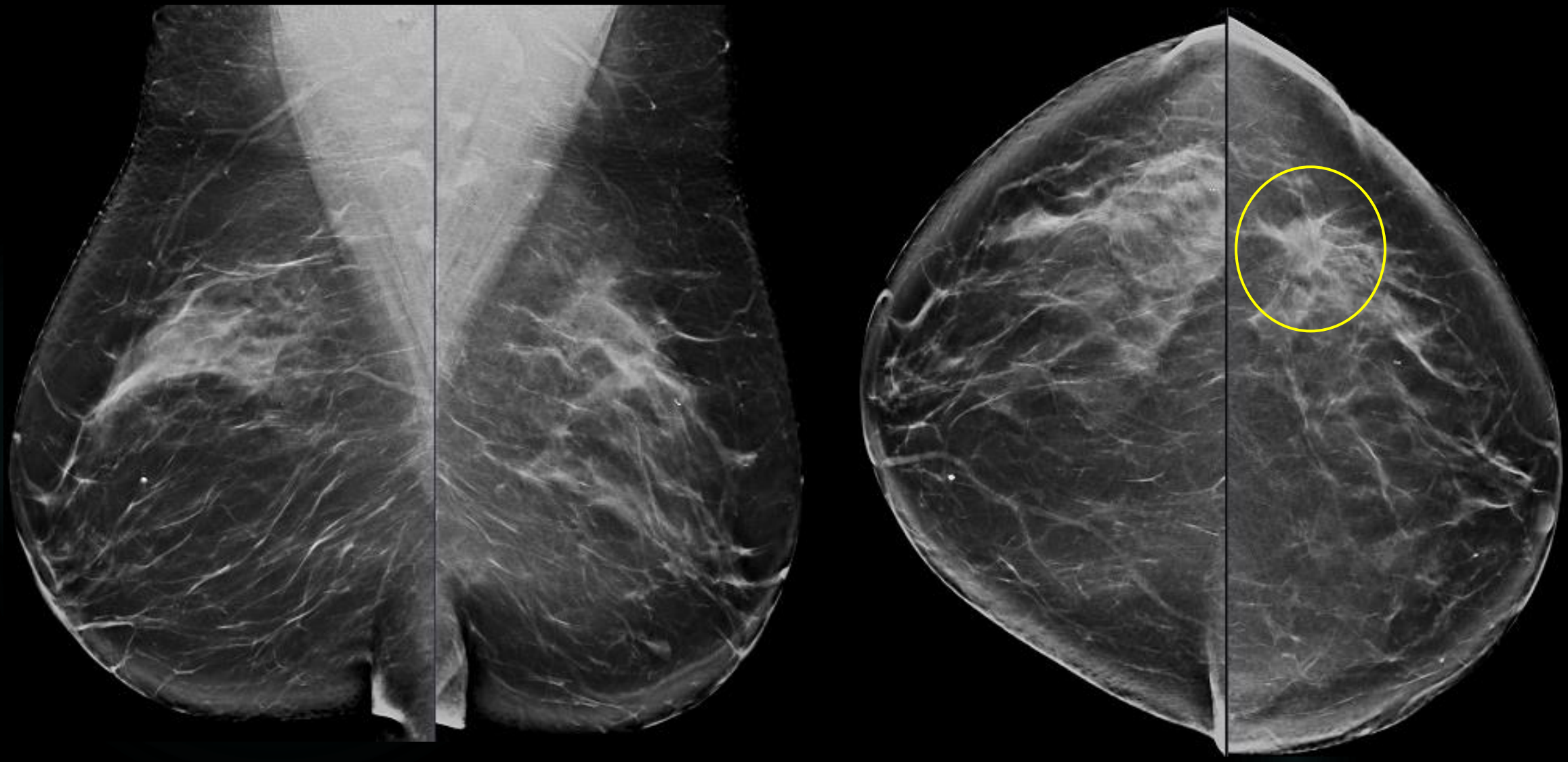
Østerås, BH et al. Digital mammography versus breast tomosynthesis: impact of breast density on diagnostic performance in population-based screening. Radiology 2019; 293(1), 60-68.

DBT in the Diagnostic Setting

Age Group	TP DM	TP DBT	FP DM	FP DBT
50-54	44	52	901	800
55-59	48	57	619	542
60-64	46	61	521	388
65-69	39	60	425	351

- The true-positive rate with DBT was higher than DM in all volumetric density and all age groups
- The false-positive rate with DBT was lower than DM in all age groups and volumetric density groups except extremely dense breasts
- DBT depicted more cancers in all density and age groups compared with DM due to higher number of spiculated masses and architectural distortions

61-year-old presents with nontender left breast lump

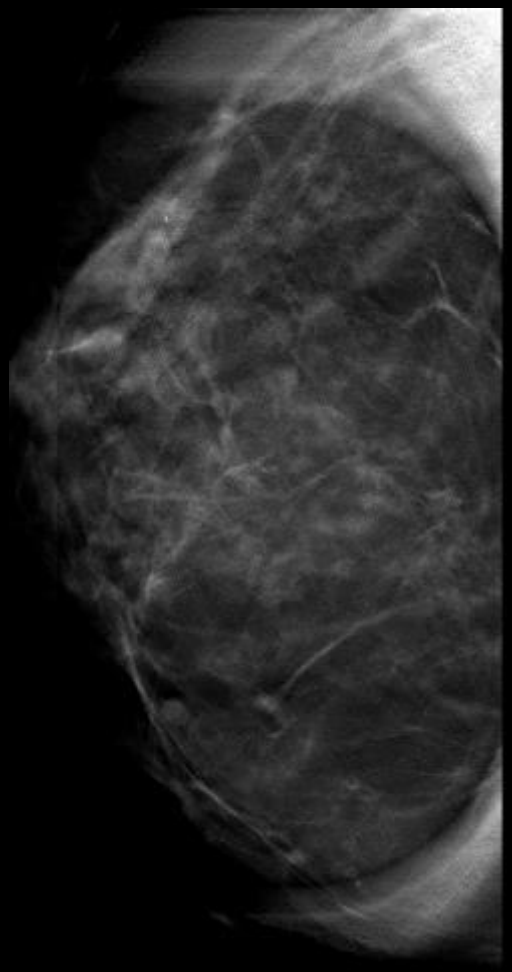


Left 1:00- Infiltrating ductal carcinoma grade 2
ER negative, PR negative, Her2 negative

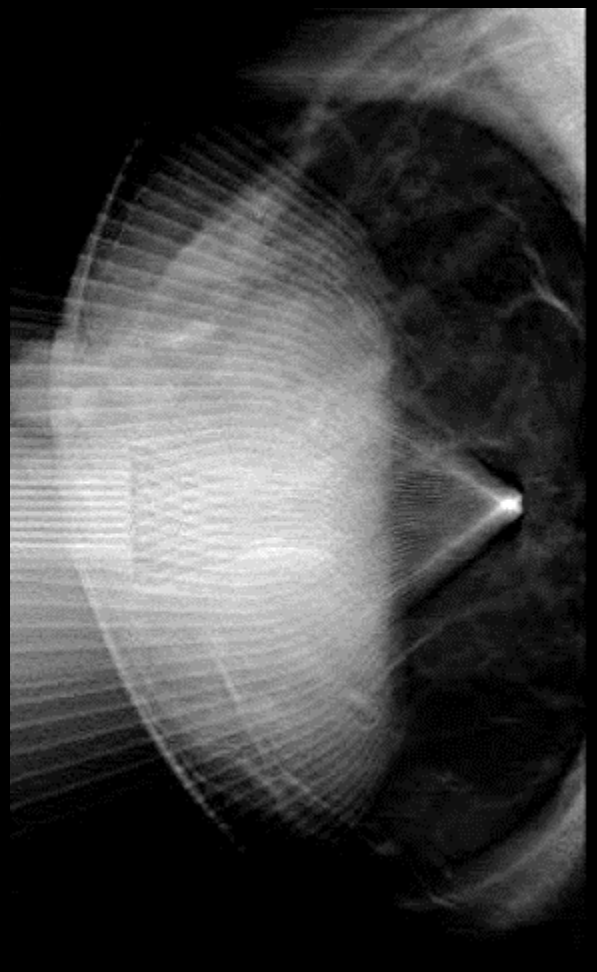
DBT-Guided Biopsy

- Investigations with DBT-guided biopsy have proven the procedure is safe and effective

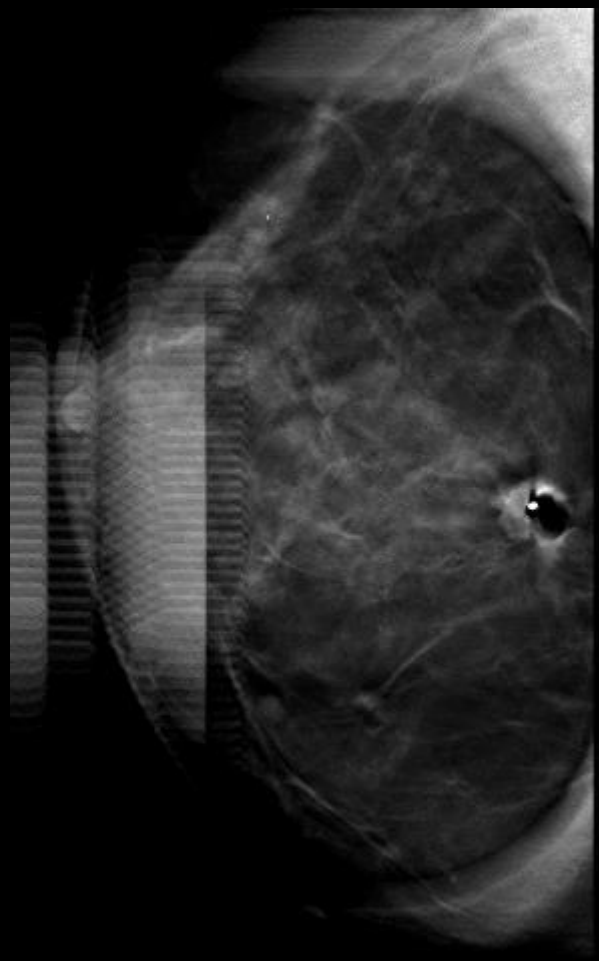
	Technical Success Rate DBT (%)	Technical Success Rate PS (%)	Procedure Time DBT (min)	Procedure Time PS (min)
Bahl 2019	99.3	95.1	12	27
Ariaratnam 2018	100	NA	15	NA
Waldherr 2016	100	95	15.4	23
Schrading 2015	100	93	13	29



Tomo scout slice

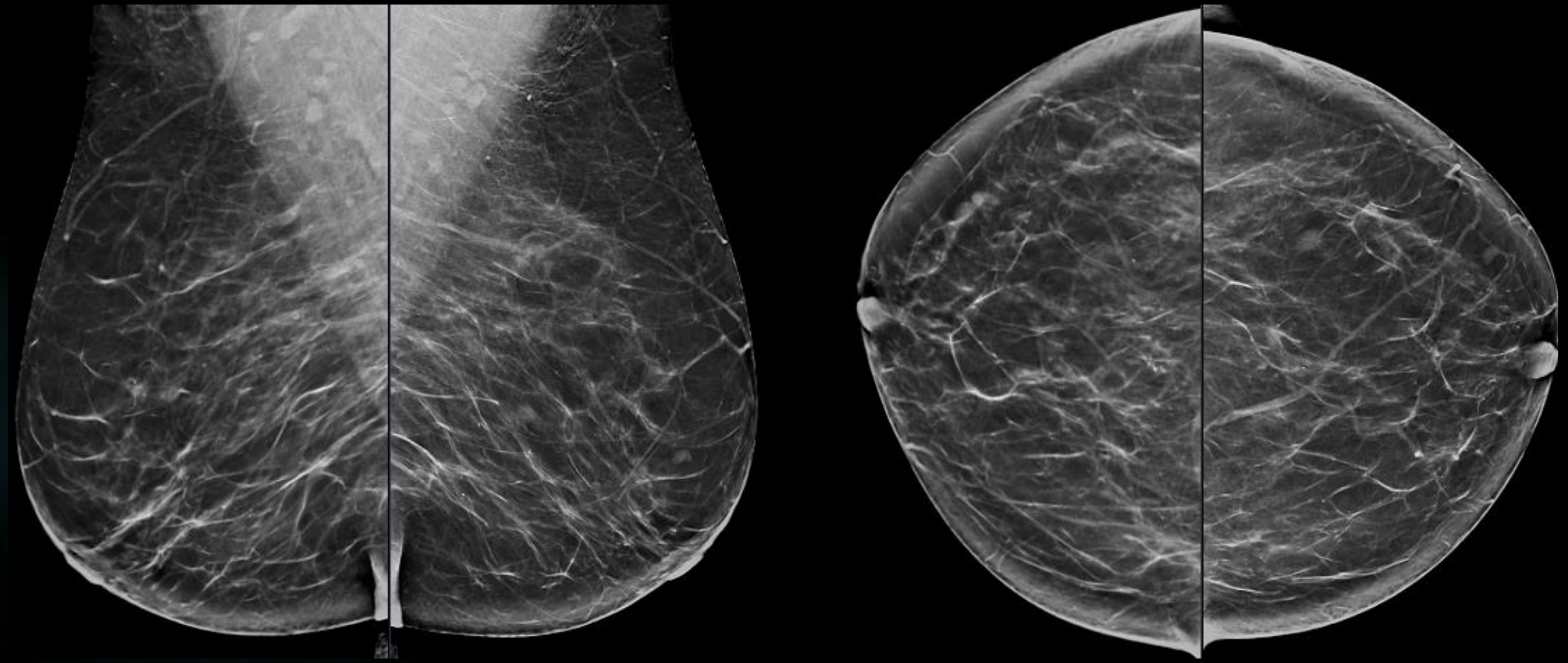


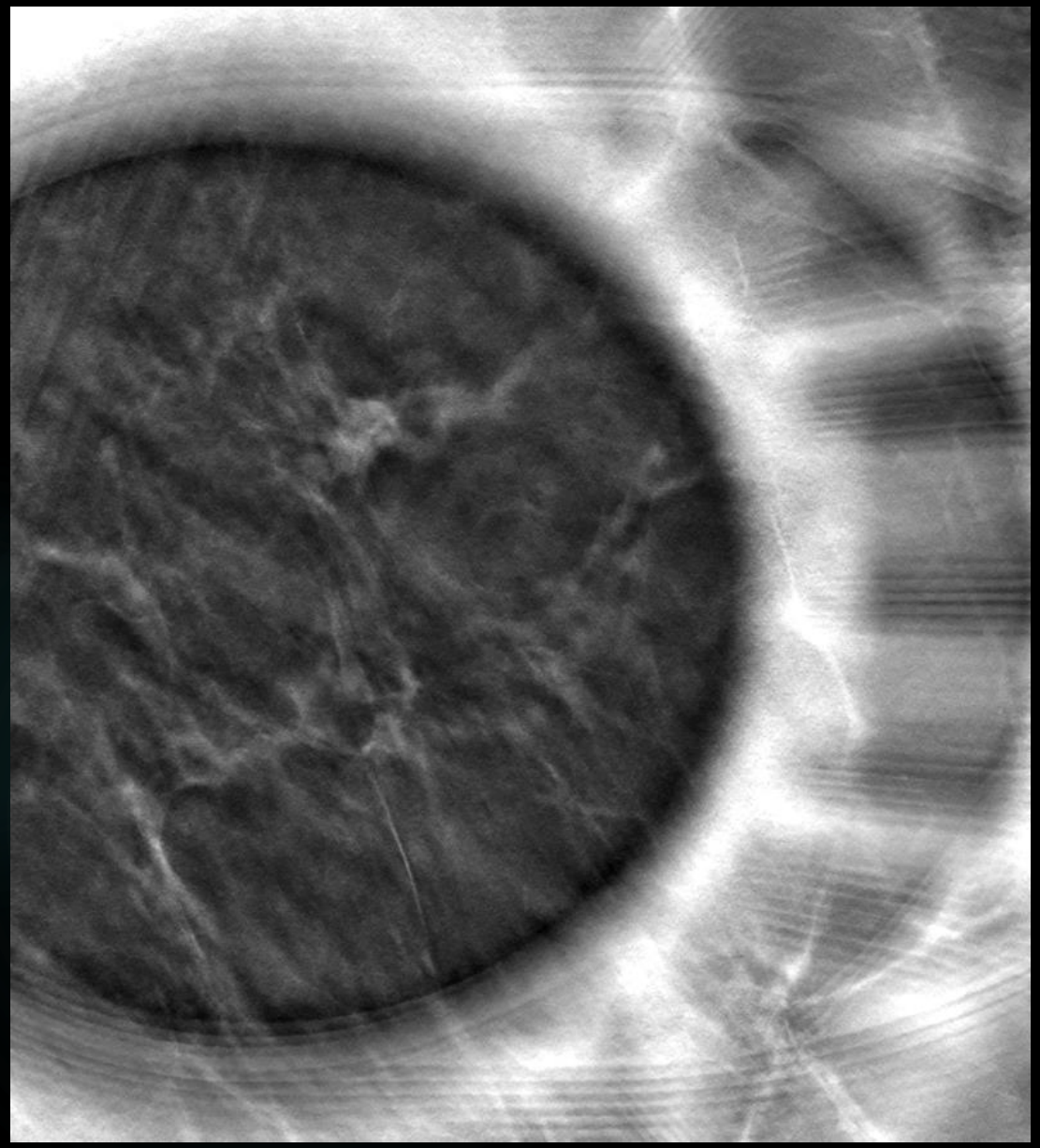
Tomo pre-fire slice



Tomo clip slice

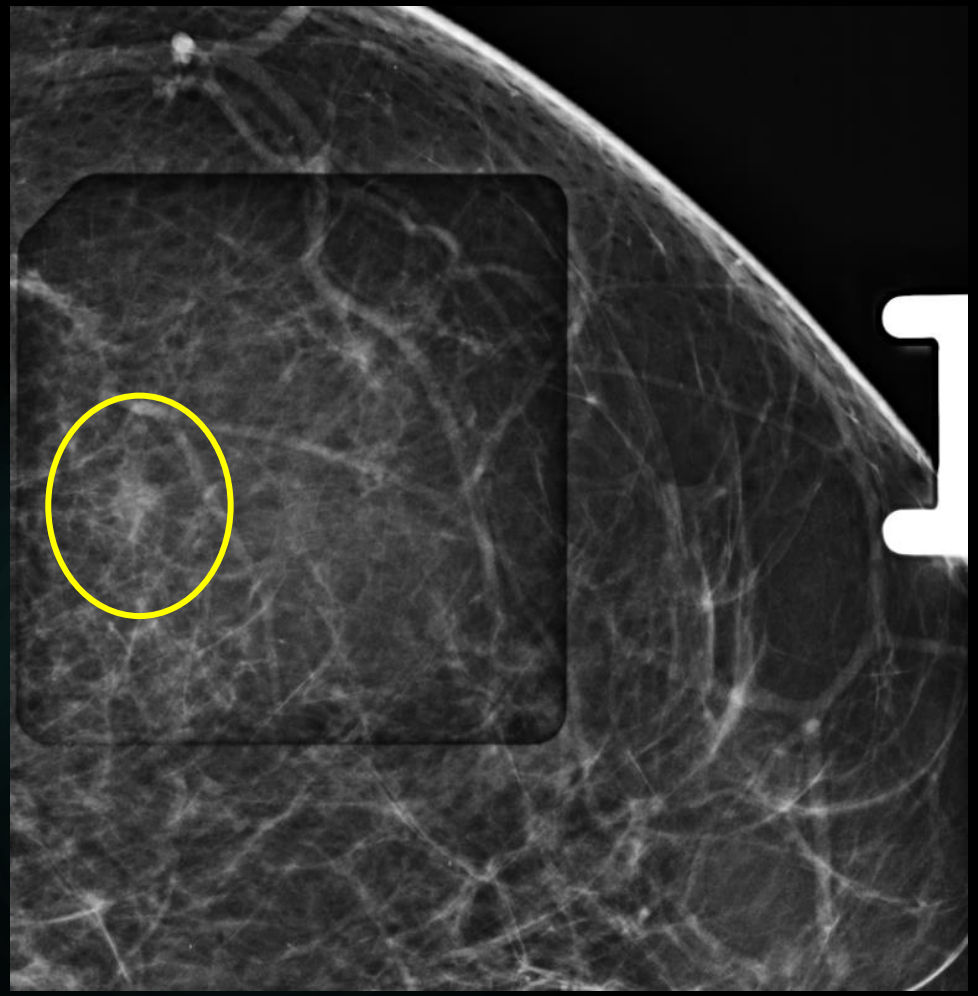
BRCA1 positive patient presents for screening mammogram

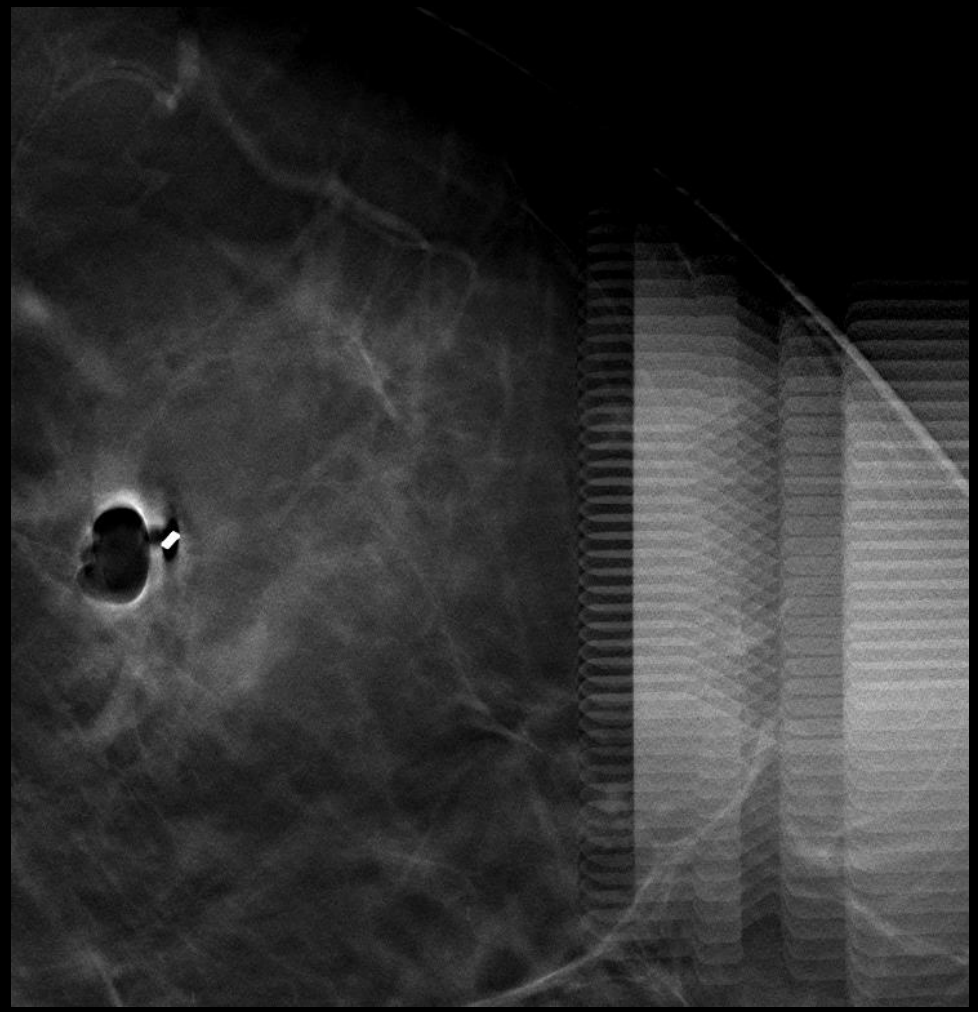




No correlate on ultrasound

DBT guided biopsy – clip placement

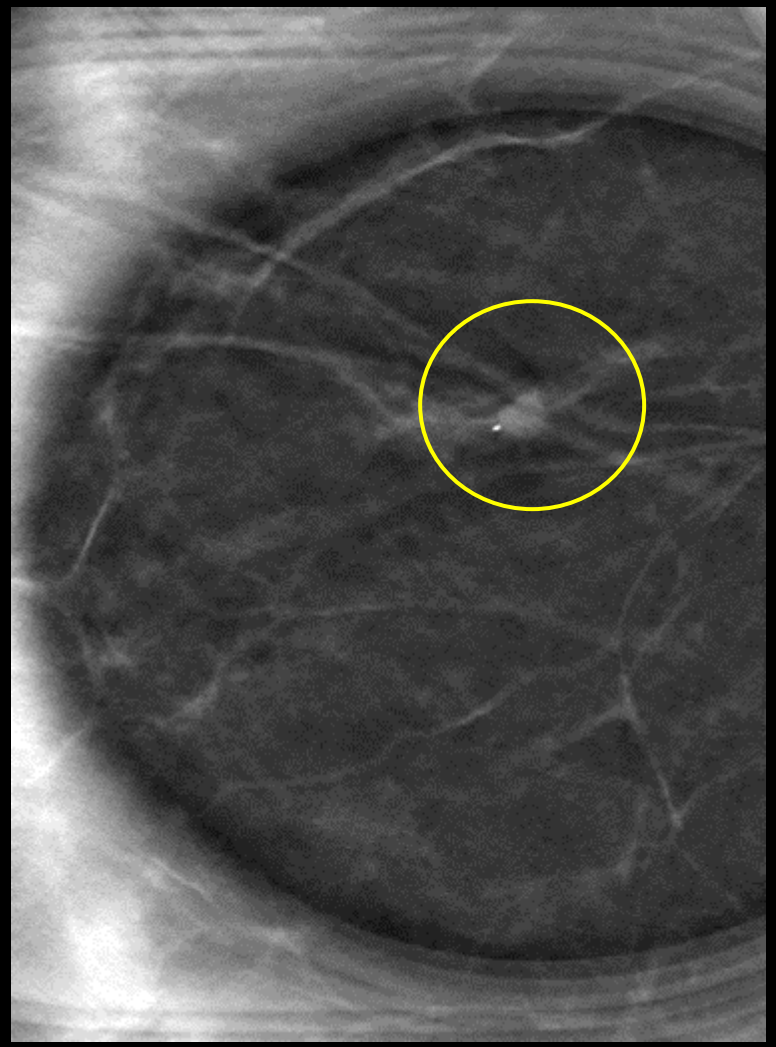


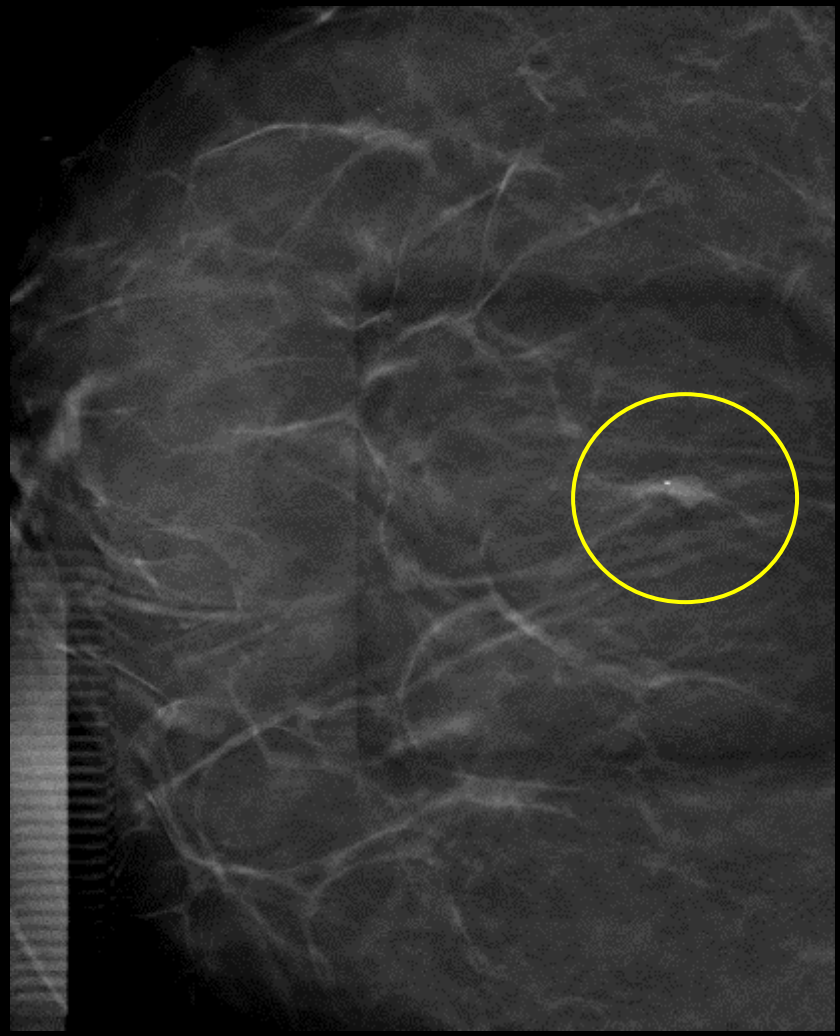


Grade 1 Invasive ductal carcinoma
ER+/PR+/Her2-

Patient presents for screening mammogram

Tomo scout





Grade 3 invasive ductal carcinoma, triple negative

Summary

- The better mammogram for screening and diagnostic evaluation
  - Reducing recall rates
  - Increasing cancer detection rates
  - Useful for diagnostic imaging and for screening
  - Benefits are sustainable over time
- Improved efficiency with DBT can be seen in both screening and diagnostic arenas and could have an impact on the cost-effectiveness of breast imaging
- Long-term data still needed on impact on mortality rate and improved patient outcomes

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“Mammography has been shown in randomized, controlled trials to reduce the death rate from breast cancer, DBT is a better mammogram. It simply makes sense to find more cancers early while decreasing the recall rate.”- Dr. Kopans

Thank You for listening
and thank you to my Research administrator
Andrea Arieno

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