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Mammography screening outcomes for women screened by standard versus high resolution digital breast tomosynthesis

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ABSTRACT

Objective: This study compared breast cancer screening outcomes between high resolution (HR; 70-micron) and standard resolution (SR; 100-micron) digital breast tomosynthesis (DBT) systems in real-world practice.
Methods: This retrospective, observational cohort study included women ages 40–79 screened for breast cancer at a U.S. health system from 2013 to 2023. Cancer detection rate (CDR), recall rate (RR), and positive predictive value of recall (PPV1) were reported. The odds of each outcome following HR versus SR DBT, adjusted for age, race, density, risk status, prior resolution, facility, and radiologist, were estimated using logistic regression. Additional analyses assessed the impact of having prior mammograms on outcome measures.
Results: A total of 184,006 mammograms were included (95,633 SR, 88,373 HR). The CDR was 5.38/1000 (HR) and 4.87/1000 (SR) ($p = 0.1296$). The increase in cancer detection with HR was statistically significant after adjusting for potential confounders (OR = 1.370, 95 % CI:1.117, 1.681). The RR was 9.80 % (HR) and 9.07 % (SR) ($p < 0.0001$), with an adjusted OR of 1.392 (95 % CI:1.327, 1.460). PPV1 was similar: 5.57 % (HR), 5.45 % (SR) ($p = 0.2730$). For exams with a known prior, the CDR was 5.38/1000 (HR) and 4.22/1000 (SR) ($p = 0.0020$), the RR was 9.39 % (HR) and 7.80 % (SR) ($p < 0.0001$), and the PPV1 was 5.74 % (HR) and 5.49 % (SR) ($p = 0.0437$). For HR exams with a known prior, the RR was 10.00 % (SR prior) and 9.14 % (HR prior) ($p = 0.0001$).
Conclusions: This large, real-world study demonstrated that HR DBT is associated with a higher CDR than SR DBT, with a greater increase in CDR for exams with a known prior.

1. Introduction

Breast cancer is the most common cancer among women in the United States (US), and the US has one of the highest age-standardized incidence rates in the world (95.9 per 100,000 in 2022).[1,2] In 2022, breast cancer accounted for 11.5 % of all new cancer diagnoses and 25.0 % of new cancer diagnoses among women in the US.[2] In 2024, it was predicted that 310,720 new cases of invasive breast cancer would be diagnosed in the US.[3]

Due to improvements in screening and treatment, breast cancer mortality has steadily decreased by 44 % between 1989 and 2022 (3). Mammographic imaging is the standard method of screening for breast cancer, and early detection of breast cancer improves patient outcomes.[4] Digital breast tomosynthesis (DBT) received approval from the Food and Drug Administration (FDA) in 2011 and rapidly became the standard of care for breast cancer screening due to its improved sensitivity and specificity.[5–7] As of March 2025, DBT is available at 93 % of certified mammography facilities in the US.[8] By acquiring images at multiple angles to reduce the effects of overlapping structures, DBT improves lesion conspicuity, allowing for improved detection and characterization compared to digital mammography. However, there remains potential for additional advances to further improve patient outcomes.

In 2018, new detector and image processing technology was introduced commercially that increased the image resolution from 100 μm pixel size (standard resolution [SR]) to 70 μm pixel size (high resolution [HR]). This HR mammography imaging technology (Hologic Clarity HD® imaging, Hologic, Inc.) was granted pre-market approval from the FDA.[9] HR tomosynthesis is designed to create clearer delineation of mass

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margins, enhanced visibility of subtle distortions, and improve the visibility of small micro-calcifications. In a randomized, blinded preference study, seven radiologists reviewed 119 cases (833 readings total) using a 5-point Likert Scale to evaluate preference for image quality and lesion conspicuity between Hologic Clarity HD® and standard resolution images. Hologic Clarity HD® imaging was rated as equivalent to or better than standard resolution for 99 % of readings for overall image quality, 98 % for conspicuity of masses, and 99 % for conspicuity of calcifications.[9]

No studies have yet compared common screening metrics between high resolution and standard resolution imaging in a large, real-world setting. Therefore, the primary objective of this study was to evaluate differences in cancer detection rate (CDR) for breast cancer screening performed with high resolution versus standard resolution DBT systems in real-world practice. Secondary objectives evaluated the recall rate (RR) and the positive predictive value of recall (PPV1) between HR and SR DBT screenings.

2. Materials and methods

2.1. Study design and data source

This was a retrospective, observational cohort study of women screened for breast cancer at a large U.S. health system (Sanford Health) between January 2013 and December 2023. This study was conducted in compliance with the Health Insurance Portability and Accountability Act and approved by the institutional review board with a waiver of consent to use a database containing standardized and integrated electronic medical record (EMR), radiology information system, and tumor registry data. All study data elements were collected and derived from information routinely recorded in the EMR or other relevant existing data sources.

Data was collected from all Sanford Health sites, though the analysis was restricted to exams from two facilities within the Sioux Falls, South Dakota metropolitan area that upgraded to high resolution (Hologic Clarity HD® imaging, Hologic, Inc.) shortly after its release. The transition from standard resolution to high resolution was implemented on all mammography units at these two facilities in July 2018 (Facility 1) and March 2019 (Facility 2). High resolution synthetic imaging (Intelligent 2D™ imaging, Hologic, Inc.) was used for all high resolution exams after January 2019. At these facilities, all exams prior to the relevant conversion dates were defined as standard resolution, and all exams following the conversion dates were defined as high resolution. Exams occurring on or within the range of conversion dates were considered of undetermined screening resolution and excluded from the analysis.

Standard four-view screening mammograms were conducted, consisting of left and right craniocaudal and mediolateral oblique images. The imaging protocol remained consistent for HR and SR DBT exams. No artificial intelligence-based detection algorithms were used in the interpretation of the screening mammograms or in the evaluation of outcomes throughout the study.

The date of the screening mammogram was considered the index date. The analyses were conducted at the screening mammogram level, and therefore women may have had multiple index dates. Individuals who met the following criteria were included in the primary analysis: female sex, at least one DBT screening mammography exam between January 2013 and December 2023, and aged 40–79 years at the time of the screening. For inclusion in the analysis of CDR and PPV1, at least six months of follow-up data were required. For inclusion in the analysis of RR, no minimum follow-up data were required. Patients with a history of breast cancer or additional screening mammograms within nine months of the index date were excluded.

The CDR was calculated as the number of screen-detected cancers detected within six months of the screening mammogram divided by the total number of screens, reported per 1000 screens. Only the first detected breast cancer following a positive screen and within six months of the exam date was included in the analysis. RR was defined as the proportion of screening mammograms that received an initial BI-RADS score of 0, 4, or 5, among all screening mammograms. PPV1 was calculated as the proportion of women recalled after a screening mammogram who were subsequently diagnosed with breast cancer (i.e. screen-detected breast cancer) within six months of the screening mammogram.

2.2. Statistical analysis

Demographic and clinical characteristics of patients at the time of screening were summarized overall and by screening resolution (HR, SR). Short-term risk status was determined by the Gail Model, as recorded by the site. Elevated risk was defined as Gail Risk score ≥ 1.66. Mammographic breast density was classified using the 5th edition of the Breast Imaging Reporting and Data Systems (BI-RADS), which categorizes breast composition as fatty (A), scattered fibroglandular (B), heterogeneously dense (C), or extremely dense (D).[10]

Missing data were imputed for breast density and facility ID. When possible, missing breast density values were imputed using a carry-forward/carry-backward method (i.e., breast density recorded at any time during the study period was applied to each screening event with missing breast density). When women had conflicting breast density values, the breast density recorded closest to index date was selected. Missing facility ID was imputed using the carry-forward method (i.e., if facility information was missing for a screen but available for a previous screening exam, the available facility ID was applied to the screen with missing facility data).

CDR, RR, and PPV1 were reported overall and by the resolution of the screening exam. Logistic regression modeling was used to estimate the unadjusted and adjusted odds of CDR, RR, and PPV1 following HR versus SR DBT; the adjusted models included age group, race, breast density, short-term risk status, past mammogram resolution, facility, and radiologist. Odds ratios were reported with 95 % confidence intervals (CI).

Screening outcomes may vary based on whether a patient has previously received a mammogram. In this study, a screen was classified as having a known prior exam if the woman had at least one previous screening exam within the study period (2013−2023). Analyses were conducted to examine the association between having a known prior mammogram and the CDR, RR, and PPV1. Additionally, for HR exams, the impact of the type of known prior (SR or HR) on outcomes was investigated.

All analyses were performed using SAS version 9.2 (SAS Institute, Inc.; Cary, NC).

3. Results

A total of 37,673 women met the inclusion criteria. On average, each woman contributed 4.88 exams to the analysis. The mean age at first screening mammogram during the study period was 54.8 years overall (55.3 years for SR, 51.1 years for HR). Nearly all women were White (97.6 %) and non-Hispanic (98.9 %).

A total of 184,006 screening mammograms were included (95,633 SR, 88,373 HR) (Table 1). Women who received HR screens were slightly older than those who received standard screens (mean age 59.3 $\pm$ 10.1 vs 57.5 $\pm$ 10.1 years; $p < 0.001$), more likely to have heterogeneously or extremely dense breast tissue (42.5 % vs 39.3 %, $p < 0.001$), and more likely to have elevated short-term risk status (38.0 % vs 25.3 %; $p < 0.001$). The characteristics of the population by exam type is reported in Table 1. For exams with at least one known prior, the median number of days between exams was similar for HR and SR screens (393 days for HR screens; 380 days for SR screens).

Table 1
Characteristics of the population at all screening mammograms, by resolution (HR vs. SR).

		Standard resolution *(N = 95,633)*	High resolution *(N = 88,373)*	Total *(N = 184,006)*	*P*-value
Age (continuous)	Mean (s.d.)	57.5 (10.1)	59.3 (10.1)	58.4 (10.1)	<0.001*
	Median (Q1-Q3)	57 (49–65)	60 (51–67)	58 (50–66)	
Age (categorical)	40–44	11,212 (11.7 %)	6984 (7.9 %)	18,196 (9.9 %)	<0.001**
	45–49	13,250 (13.9 %)	11,501 (13.0 %)	24,751 (13.5 %)	
	50–54	14,642 (15.3 %)	12,255 (13.9 %)	26,897 (14.6 %)	
	55–59	15,961 (16.7 %)	13,255 (15.0 %)	29,216 (15.9 %)	
	60–64	14,971 (15.7 %)	14,464 (16.4 %)	29,435 (16.0 %)	
	65–69	12,241 (12.8 %)	13,265 (15.0 %)	25,506 (13.9 %)	
	70–74	8355 (8.7 %)	10,749 (12.2 %)	19,104 (10.4 %)	
	75–79	5001 (5.2 %)	5900 (6.7 %)	10,901 (5.9 %)	
Race	Asian	744 (0.8 %)	732 (0.8 %)	1476 (0.8 %)	0.148**
	Black	441 (0.5 %)	454 (0.5 %)	895 (0.5 %)	
	White	93,881 (98.4 %)	86,642 (98.3 %)	180,523 (98.3 %)	
	Other	379 (0.4 %)	322 (0.4 %)	701 (0.4 %)	
	Unknown	188	223	411	
Ethnicity	Hispanic	641 (0.7 %)	714 (0.8 %)	1355 (0.7 %)	<0.001**
	Non-Hispanic	93,652 (99.3 %)	86,304 (99.2 %)	179,956 (99.3 %)	
	Unknown	1340	1355	2695	
Breast density	Almost entirely fatty (A)	7672 (8.0 %)	6696 (7.6 %)	14,368 (7.8 %)	<0.001**
	Scattered fibroglandular densities (B)	50,165 (52.6 %)	43,454 (49.6 %)	93,619 (51.1 %)	
	Heterogeneously dense (C)	30,140 (31.6 %)	30,863 (35.2 %)	61,003 (33.3 %)	
	Extremely dense (D)	7401 (7.8 %)	6684 (7.6 %)	14,085 (7.7 %)	
	Unknown	255	676	931	
Condensed breast density at exam	Non-dense (almost entirely fatty or scattered fibroglandular densities)	57,837 (60.5 %)	50,150 (56.7 %)	107,987 (58.7 %)	<0.001**
	Dense (heterogeneously dense or extremely dense)	37,541 (39.3 %)	37,547 (42.5 %)	75,088 (40.8 %)	
	Unknown	255 (0.3 %)	676 (0.8 %)	931 (0.5 %)	
Short term risk status	Elevated	23,827 (25.3 %)	32,966 (38.0 %)	56,793 (31.4 %)	<0.001**
	Normal	70,229 (74.7 %)	53,840 (62.0 %)	124,069 (68.6 %)	
	Unknown	1577	1567	3144	
Year of screen	2013	3513 (3.7 %)	0 (0.0 %)	3513 (1.9 %)	<0.001**
	2014	18,418 (19.3 %)	0 (0.0 %)	18,418 (10.0 %)	
	2015	19,156 (20.0 %)	0 (0.0 %)	19,156 (10.4 %)	
	2016	19,249 (20.1 %)	0 (0.0 %)	19,249 (10.5 %)	
	2017	19,532 (20.4 %)	0 (0.0 %)	19,532 (10.6 %)	
	2018	14,287 (14.9 %)	5409 (6.1 %)	19,696 (10.7 %)	
	2019	1478 (1.5 %)	17,500 (19.8 %)	18,978 (10.3 %)	
	2020	0 (0.0 %)	17,505 (19.8 %)	17,505 (9.5 %)	
	2021	0 (0.0 %)	16,912 (19.1 %)	16,912 (9.2 %)	
	2022	0 (0.0 %)	15,629 (17.7 %)	15,629 (8.5 %)	
	2023	0 (0.0 %)	15,418 (17.4 %)	15,418 (8.4 %)	
Resolution of prior exam	Standard Resolution	63,223 (100.0 %)	23,699 (28.1 %)	86,922 (58.9 %)	<0.001**
	High Resolution	0 (0.0 %)	60,621 (71.9 %)	60,621 (41.1 %)	
	Unknown/None	32,410	4053	36,463	
Known prior exams	0	32,405 (33.9 %)	3714 (4.2 %)	36,119 (19.6 %)	<0.001**
	1 or more	63,228 (66.1 %)	84,659 (95.8 %)	147,887 (80.4 %)	
Facility	Facility 1	54,932 (57.4 %)	56,613 (64.1 %)	111,545 (60.6 %)	<0.001**
	Facility 2	40,701 (42.6 %)	31,760 (35.9 %)	72,461 (39.4 %)	

(*continued on next page*)

Table 1 (*continued*)

		Standard resolution (*N = 95,633*)	High resolution (*N = 88,373*)	Total (*N = 184,006*)	*P*-value
Radiologist***	1,001,868	23,365 (24.4 %)	17,755 (20.1 %)	41,120 (22.3 %)	<0.001**
	1,000,757	10,770 (11.3 %)	8560 (9.7 %)	19,330 (10.5 %)	
	1,013,103	1493 (1.6 %)	14,916 (16.9 %)	16,409 (8.9 %)	
	1,005,762	15,326 (16.0 %)	301 (0.3 %)	15,627 (8.5 %)	
	1,004,745	0 (0.0 %)	14,098 (16.0 %)	14,098 (7.7 %)	
	Others	44,679 (46.7 %)	32,743 (37.1 %)	77,422 (42.1 %)	

* Analysis of Variance.
** Chi-Square Test.
*** Only the five radiologists with the highest volume are listed separately.

3.1. CDR

Of 174,059 screens with at least six months of follow-up data available, the overall CDR was 5.11/1000 screens (Table 2). When stratified by screening resolution, the CDR was 5.38/1000 for HR screens and 4.87/1000 for SR screens (absolute difference: 0.51/1000, $p = 0.1296$). The adjusted OR for cancer detection following HR versus SR DBT was 1.370 (95 % CI: 1.117, 1.681). For exams with a known prior exam, the CDR was 4.22/1000 for SR screens and 5.38/1000 for HR screens ($p = 0.0020$); the adjusted OR was 1.504 (95 % CI: 1.204, 1.879). For HR screens with a known prior exam, the CDR was 6.26/1000 if the known prior exam was an SR exam and 5.07/1000 if the known prior exam was an HR exam ($p = 0.0395$).

3.2. RR

The overall RR was 9.42 % among the 184,006 screens with available data (Table 3). When stratified by screening resolution, the RR was 9.80 % for HR screens and 9.07 % for SR screens (absolute difference: 0.73 %, $p < 0.0001$). The adjusted OR for recall following HR versus SR DBT was 1.392 (95 % CI: 1.327, 1.460). For exams with a known prior exam, the RR was 7.80 % for SR screens and 9.39 % for HR screens ($p < 0.0001$); the adjusted OR was 1.302 (95 % CI: 1.233, 1.376). For HR exams with a known prior exam, the RR was 10.00 % if the known prior exam was SR and 9.14 % if the known prior exam was HR ($p = 0.0001$).

3.3. PPV1

The overall PPV1 was 5.51 % (Table 4). When stratified by screening resolution, the PPV1 was 5.57 % for HR screens and 5.45 % for SR screens (absolute difference: 0.12 %, $p = 0.2730$). The adjusted OR for PPV1 following HR versus SR DBT was 1.054 (95 % CI: 0.856, 1.297). For exams with a known prior, the PPV1 was 5.49 % for SR screens and 5.74 % for HR screens ($p = 0.0437$).

4. Discussion

In this real-world study, DBT screening with HR was associated with a higher CDR as compared to DBT screening with SR (5.38/1000 exams vs 4.87/1000 exams). The difference was statistically significant after adjusting for potentially confounding characteristics (age group, race, breast density, short-term risk status, past mammogram resolution, facility, and radiologist). The increase in CDR between HR and SR exams was most pronounced when comparing exams with a known prior (5.38/1000 for HR vs. 4.22/1000 for SR). This increase in cancer detection is notable, as detecting breast cancer at an earlier stage reduces morbidity and improves survival rates.[4]

A slight increase in recall rate was observed with the adoption of HR. This may be expected as the improved resolution enhances the visibility of findings that may otherwise be less detectable. However, our results indicate that the increase in RR after HR adoption may be transient. Recall rates were lower for exams with a known prior exam for both SR and HR screens. Among the subgroup of screens with a known prior HR screen, the RR was lower compared to the entire HR group, suggesting that the RR decreases in subsequent HR screening rounds. A transient increase in recall is consistent with previous advances in mammography. For example, previous studies reported an increase in RR for women receiving their first digital mammogram, while the RR for women receiving subsequent digital mammograms was similar to the RR with film mammography.[11]

PPV1 values were similar for HR and SR exams overall, and PPV1 was greater for HR versus SR exams with a known prior. As the primary goal of breast cancer screening is early detection, a greater CDR with a similar or greater PPV1 suggests that a potential tradeoff between cancer detection and recall may be clinically justified, especially if recall rates decrease when prior HR exams are available.

Previous studies have documented an increase in CDR and a reduction in RR when SR tomosynthesis was compared to two dimensional full-field digital mammography (FFDM).[7,12–14] However, to our knowledge, no previous studies have compared the real-world performance of HR tomosynthesis to SR tomosynthesis. While this study was not designed to compare HR tomosynthesis to FFDM, it is notable that this study reports higher CDR and similar RR with HR tomosynthesis compared to rates reported with 2D FFDM within the same health system in a previous study (CDR: 5.4/1000 vs 4.1/1000, RR: 9.8 % vs 10.1 %).[12]

In March 2022, Sanford Health adopted a technology that utilizes artificial intelligence-driven analytics to produce 6-mm "SmartSlices" from high resolution 1-mm tomosynthesis images (3DQuorum®, Hologic, Inc.). This technology generates smaller files for easier storage and is intended to reduce reading time while maintaining clinical performance.[9] The adoption of this technology towards the end of the study period may introduce confounding for the period after this technology was adopted. However, potential confounding may be limited as screening outcomes in 2023, the first full year after this technology was adopted (CDR = 5.49/1000, RR = 9.49 %, PPV1 = 5.63 %), are similar to those in the overall HR population.

4.1. Limitations

There are limitations inherent to retrospective study designs and in the secondary use of data.

Data used in this study primarily relies on data captured in the EMR during routine medical practice. Information not documented, as well as information captured external to the data source, such as patient encounters at sites outside of the health system, are not available for study use. As this is a retrospective, observational study of real-world breast cancer screening practices, information on radiologist reading time and

Table 2
Cancer detection rates (CDR) stratified by screening resolution (HR vs. SR) and select patient characteristics.

Characteristic	Standard resolution		High resolution		Total		*p*-value*
	n (Screens)	CDR (1/1000)	*n* (Screens)	CDR (1/1000)	*n* (Screens)	CDR (1/1000)	
Total	91,046	4.87	83,013	5.38	174,059	5.11	0.1296
Age (categorical)							0.5249
40–44	10,310	2.33	6024	2.49	16,334	2.39	
45–49	12,283	3.34	10,739	3.26	23,022	3.30	
50–54	13,840	4.70	11,491	5.13	25,331	4.90	
55–59	15,219	4.34	12,474	4.41	27,693	4.37	
60–64	14,401	4.51	13,679	5.56	28,080	5.02	
65–69	11,893	6.98	12,618	6.02	24,511	6.49	
70–74	8178	6.85	10,334	8.90	18,512	7.99	
75–79	4922	8.74	5654	6.90	10,576	7.75	
Race							0.1286
Asian	686	1.46	667	1.50	1353	1.48	
Black	397	7.56	401	0.00	798	3.76	
White	89,442	4.89	81,463	5.47	170,905	5.17	
Other	341	0.00	292	0.00	633	0.00	
Unknown	180	11.11	190	0.00	370	5.41	
Breast density							0.1558
Almost entirely fatty (A)	7381	1.90	6444	2.95	13,825	2.39	
Scattered fibroglandular densities (B)	48,046	4.70	41,159	5.37	89,205	5.01	
Heterogeneously dense (C)	28,598	5.91	29,153	6.00	57,751	5.96	
Extremely dense (D)	7014	4.70	6257	5.11	13,271	4.90	
Unknown	7	142.86	0	0.00	7	142.86	
Condensed breast density at exam							0.1514
Non-dense (breast density A or B)	55,427	4.33	47,603	5.04	103,030	4.66	
Dense (breast density C or D)	35,612	5.67	35,410	5.85	71,022	5.76	
Unknown	7	142.86	0	0.00	7	142.86	
Known prior exams							0.0043
0	30,446	6.14	2383	5.46	32,829	6.09	
1 or more	60,600	4.22	80,630	5.38	141,230	4.89	0.0020
Short term risk status							0.1953
Elevated	23,282	3.74	31,486	6.99	54,768	5.61	
Normal	66,230	5.33	50,010	4.42	116,240	4.94	
Unknown	1534	1.96	1517	3.96	3051	2.95	
Resolution of prior exam							0.0019
Standard resolution	60,595	4.22	22,358	6.26	82,953	4.77	
High resolution	0	0.00	57,949	5.07	57,949	5.07	
Unknown/none	30,451	6.14	2706	4.80	33,157	6.03	
Year of screen							0.3714
2013	3363	4.46	0	0.00	3363	4.46	
2014	17,666	5.21	0	0.00	17,666	5.21	
2015	18,207	5.22	0	0.00	18,207	5.22	
2016	18,180	4.73	0	0.00	18,180	4.73	
2017	18,440	3.96	0	0.00	18,440	3.96	
2018	13,754	5.31	5191	4.05	18,945	4.96	
2019	1436	6.27	16,832	6.36	18,268	6.35	
2020	0	0.00	15,452	6.02	15,452	6.02	
2021	0	0.00	16,700	5.27	16,700	5.27	
2022	0	0.00	15,365	4.17	15,365	4.17	
2023	0	0.00	13,473	5.49	13,473	5.49	
Facility							0.0793
Facility 1	52,216	4.37	53,377	4.95	105,593	4.66	
Facility 2	38,830	5.54	29,636	6.17	68,466	5.81	
Radiologist**							0.3269
1001868	22,229	5.89	16,679	6.48	38,908	6.14	
1000757	10,273	3.60	8194	2.68	18,467	3.19	
1013103	1436	5.57	14,141	5.52	15,577	5.52	
1005762	14,569	5.77	287	6.97	14,856	5.79	
1004745	0	0.00	13,177	6.60	13,177	6.60	
Others	42,539	4.30	30,535	4.91	73,074	4.55	

* All *p*-values are the comparison between SR and HR adjusted for that specific covariate (e.g., age, race, etc...).
** Only the five radiologists with the highest volume are listed separately.

qualitative metrics around use of HR imaging, such as patient comfort or ease of reading images for radiologists, was not available for analysis. Additionally, cancer characteristics (lesion type, size, stage, grade, receptor status) were not evaluated in this analysis. Interval cancers were not analyzed. Given the study methodology, outcomes such as radiologist fatigue or interpretation time could not be evaluated.

Due to the lag in case reporting to registries, some breast cancer cases among the screened cohort may not have been reported in the registries at the time the data were retrieved. Unreported cancers are more likely in the HR cohort as the HR period (2018/19–2023) was more recent than the SR period (2013–2018/19). The analysis was conducted at the exam level, which could lead to underestimated standard errors and overstated significance. Additionally, this study was conducted at a single health system with a relatively homogeneous population (98.3 % White), which may impact the generalizability of the results to other racial groups. Furthermore, the generalizability may be impacted by the fact that the study was conducted at only two sites. Although consistent trends were observed across both locations—specifically, HR

Table 3
Recall rates stratified by screening resolution (HR vs. SR) and select patient characteristics.

Characteristic	Standard resolution		High resolution		Total		*p*-value*
	n (screens)	Recall rate (%)	*n* (screens)	Recall rate (%)	*n* (screens)	Recall rate (%)	
Total	95,633	9.07	88,373	9.80	184,006	9.42	<0.0001
Age (categorical)							<0.0001
40–44	11,212	14.46	6984	14.83	18,196	14.60	
45–49	13,250	11.55	11,501	13.22	24,751	12.33	
50–54	14,642	9.70	12,255	10.97	26,897	10.28	
55–59	15,961	7.73	13,255	8.74	29,216	8.19	
60–64	14,971	7.08	14,464	8.18	29,435	7.62	
65–69	12,241	7.24	13,265	8.04	25,506	7.65	
70–74	8355	6.94	10,749	8.04	19,104	7.56	
75–79	5001	6.80	5900	8.32	10,901	7.62	
Race							<0.0001
Asian	744	9.54	732	11.48	1476	10.50	
Black	441	14.74	454	12.11	895	13.41	
White	93,881	9.04	86,642	9.78	180,523	9.39	
Other	379	7.39	322	8.70	701	7.99	
Unknown	188	11.17	223	10.31	411	10.71	
Breast density							<0.0001
Almost entirely fatty (A)	7672	3.58	6696	5.17	14,368	4.32	
Scattered fibroglandular densities (B)	50,165	7.80	43,454	9.15	93,619	8.43	
Heterogeneously dense (C)	30,140	11.53	30,863	11.58	61,003	11.55	
Extremely dense (D)	7401	13.23	6684	9.90	14,085	11.65	
Unknown	255	12.94	676	15.53	931	14.82	
Condensed breast density at exam							<0.0001
Non-dense (breast density A or B)	57,837	7.24	50,150	8.62	107,987	7.88	
Dense (breast density C or D)	37,541	11.86	37,547	11.28	75,088	11.57	
Unknown	255	12.94	676	15.53	931	14.82	
Known prior exams							<0.0001
0	32,405	11.54	3714	19.20	36,119	12.33	
1 or more	63,228	7.80	84,659	9.39	147,887	8.71	<0.0001
Short term risk status							<0.0001
Elevated	23,827	7.08	32,966	8.52	56,793	7.91	
Normal	70,229	9.70	53,840	10.52	124,069	10.06	
Unknown	1577	11.16	1567	11.93	3144	11.55	
Resolution of prior exam							<0.0001
Standard resolution	63,223	7.80	23,699	10.00	86,922	8.40	
High resolution	0	0.00	60,621	9.14	60,621	9.14	
Unknown	32,410	11.55	4053	18.50	36,463	12.32	
Year of screen							0.0058
2013	3513	8.11	0	0.00	3513	8.11	
2014	18,418	9.45	0	0.00	18,418	9.45	
2015	19,156	8.52	0	0.00	19,156	8.52	
2016	19,249	8.61	0	0.00	19,249	8.61	
2017	19,532	9.56	0	0.00	19,532	9.56	
2018	14,287	9.58	5409	10.39	19,696	9.80	
2019	1478	8.12	17,500	10.18	18,978	10.02	
2020	0	0.00	17,505	10.88	17,505	10.88	
2021	0	0.00	16,912	9.35	16,912	9.35	
2022	0	0.00	15,629	8.67	15,629	8.67	
2023	0	0.00	15,418	9.59	15,418	9.59	
Facility							<0.0001
Facility 1	54,932	9.05	56,613	9.64	111,545	9.35	
Facility 2	40,701	9.10	31,760	10.09	72,461	9.53	
Radiologist**							<0.0001
1001868	23,365	7.28	17,755	7.76	41,120	7.48	
1000757	10,770	8.85	8560	9.33	19,330	9.06	
1013103	1493	9.11	14,916	8.93	16,409	8.95	
1005762	15,326	9.63	301	9.63	15,627	9.63	
1004745	0	0.00	14,098	10.15	14,098	10.15	
Others	44,679	9.87	32,743	11.28	77,422	10.46	

* All p-values are the comparison between SR and HR adjusted for that specific covariate (e.g., age, race, etc).
** Only the five radiologists with the highest volume are listed separately.

tomosynthesis demonstrated increases in CDR and RR—variations in recall rate and PPV1 highlight site-level variation in outcomes.

This study evaluated high resolution imaging of a single vendor (Hologic Clarity HD® imaging, Hologic, Inc.). As image quality is influenced by a number of system design factors, the results of this study may not be applicable to other systems with similar resolution specifications.

5. Conclusion

With the introduction of any new breast screening technology, it is important to evaluate the impact on real world clinical outcomes. This study demonstrated that breast cancer screening with HR DBT, compared to SR DBT, is associated with an increased CDR in a large, real-world cohort. HR DBT showed an initial increase in recall rate, which diminished in subsequent HR DBT screening rounds.

Table 4
PPV1 stratified by screening resolution (HR vs. SR) and select patient characteristics.

Characteristic	Standard resolution		High resolution		Total		*p*-value*
	n (recalls)	PPV1(%)	*n* (recalls)	PPV1(%)	*n* (recalls)	PPV1(%)	
Total	8130	5.45	8018	5.57	16,148	5.51	0.2730
Age (categorical)							<0.0001
40–44	1477	1.62	850	1.76	2327	1.68	
45–49	1390	2.95	1408	2.49	2798	2.72	
50–54	1346	4.83	1262	4.68	2608	4.75	
55–59	1169	5.65	1073	5.13	2242	5.40	
60–64	1002	6.48	1105	6.87	2107	6.68	
65–69	848	9.79	1014	7.49	1862	8.53	
70–74	563	9.95	836	10.98	1399	10.56	
75–79	335	12.84	470	8.30	805	10.19	
Race							<0.0001
Asian	65	1.54	74	1.35	139	1.44	
Black	57	5.26	45	0.00	102	2.94	
White	7962	5.49	7854	5.68	15,816	5.58	
Other	25	0.00	27	0.00	52	0.00	
Unknown	21	9.52	18	0.00	39	5.13	
Breast density							<0.0001
Almost entirely fatty (A)	258	5.43	328	5.79	586	5.63	
Scattered fibroglandular densities (B)	3692	6.12	3723	5.93	7415	6.02	
Heterogeneously dense (C)	3257	5.19	3357	5.21	6614	5.20	
Extremely dense (D)	921	3.58	610	5.25	1531	4.25	
Unknown	2	50.00	0	0.0	2	50.00	
Condensed breast density at exam							<0.0001
Non-dense (breast density A or B)	3950	6.07	4051	5.92	8001	5.99	
Dense (breast density C or D)	4178	4.83	3967	5.22	8145	5.02	
Unknown	2	50.00	0	0.0	2	50.00	
Known prior exams							
0	3464	5.40	459	2.83	3923	5.10	
1 or more	4666	5.49	7559	5.74	12,225	5.64	0.0437
Short term risk status							<0.0001
Elevated	1656	5.25	2689	8.18	4345	7.06	
Normal	6299	5.60	5152	4.29	11,451	5.01	
Unknown	175	1.71	177	3.39	352	2.56	
Resolution of prior exam							<0.0001
Standard resolution	4664	5.49	2212	6.33	6876	5.76	
High resolution	0	0.0	5313	5.53	5313	5.53	
Unknown	3466	5.39	493	2.64	3959	5.05	
Year of screen							<0.0001
2013	268	5.60	0	0.0	268	5.60	
2014	1657	5.55	0	0.0	1657	5.55	
2015	1547	6.14	0	0.0	1547	6.14	
2016	1544	5.57	0	0.0	1544	5.57	
2017	1699	4.30	0	0.0	1699	4.30	
2018	1300	5.61	542	3.87	1842	5.10	
2019	115	7.83	1698	6.30	1813	6.40	
2020	0	0.0	1573	5.91	1573	5.91	
2021	0	0.0	1560	5.63	1560	5.63	
2022	0	0.0	1331	4.80	1331	4.80	
2023	0	0.0	1314	5.63	1314	5.63	
Facility							<0.0001
Facility 1	4646	4.91	5074	5.20	9720	5.06	
Facility 2	3484	6.17	2944	6.21	6428	6.19	
Radiologist**							<0.0001
1001868	1593	8.22	1291	8.35	2884	8.28	
1000757	889	4.16	760	2.89	1649	3.58	
1013103	729	6.25	775	6.35	1504	6.34	
1005762	1395	6.02	29	6.90	1424	6.04	
1004745	128	0.0	1229	6.64	1357	6.64	
Others	3396	4.44	3934	4.41	7330	4.42	

* All p-values are the comparison between SR and HR adjusted for that specific covariate (e.g., age, race, etc).
** Only the five radiologists with the highest volume are listed separately.

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CRediT authorship contribution statement

Melinda Talley: Supervision, Investigation, Data curation, Writing – review & editing. **Kathryn Starzyk:** Supervision, Project administration, Formal analysis, Data curation, Conceptualization, Writing –

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Declaration of competing interest

Julia Olsen and Scott Pohlman are employees of Hologic, Inc. and may hold stock or stock options. Melinda Talley, Kathryn Starzyk, Paul Buzinec, and Jamie Williams have no conflicts of interest to disclose.

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