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Detection rates for benign and malignant diagnoses on breast cancer screening with digital breast tomosynthesis in a statewide mammography registry study

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Abstract

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CONFLICT OF INTEREST: The authors report that they have no conflict of interest relationships to disclose.

CONFERENCE PRESENTATION: Preliminary results from this study were presented as a poster at the annual meeting of the American Society of Preventive Oncology in Seattle, WA, March 11-14, 2017.

HUMAN SUBJECTS: This study was approved by the University of Vermont Institutional Review Board with a waiver of consent and all study procedures were compliant with the Health Insurance Portability and Accountability Act.

Purpose: To determine whether detection rates of specific benign and malignant diagnoses differ for breast cancer screening with digital breast tomosynthesis (DBT) versus full-field digital mammography (FFDM) alone.

Subjects and Methods: We analyzed observational data from the Vermont Breast Cancer Surveillance System, including 86,349 DBT screening exams and 97,378 FFDM screening exams performed at 8 radiology facilities in Vermont that adopted DBT screening during 2012-2016. We determined the most severe diagnosis made within six months following positive screening exams. Multivariable-adjusted logistic regression was used to compare detection rates for specific diagnoses on DBT versus FFDM.

Results: Compared to FFDM, DBT had a lower recall rate (adjusted odds ratio [OR] 0.81; 95% confidence interval [CI]: 0.77-0.85) but comparable biopsy rate (OR=1.05; 95% CI:0.93-1.17), benign biopsy rate (OR=1.12; 95% CI:0.97-1.29), and cancer detection rate (OR=0.94; 95% CI: 0.78-1.14). Among benign diagnoses, DBT and FFDM had comparable detection rates for non-proliferative lesions (OR=1.19; 95% CI:0.92-1.53), fibroepithelial proliferations (OR=1.24; 95% CI:0.85-1.81), proliferative lesions without atypia (OR=1.13; 95% CI:0.90-1.42), atypical lesions (OR=0.77; 95% CI:0.43-1.38), and lobular carcinoma in situ (OR=0.92; 95% CI:0.53-1.61). Among malignant diagnoses DBT and FFDM had comparable detection rates for ductal carcinoma in situ (OR=1.05; 95% CI:0.70-1.57) and invasive breast cancer (OR=0.92; 95% CI:0.74-1.13), with no statistically significant differences in detection of invasive ductal (OR=0.83; 95% CI: 0.66-1.06), invasive lobular (OR=1.11; 95% CI:0.59-2.07), or invasive mixed ductal-lobular carcinoma (OR=1.49; 95% CI:0.65-3.39).

Conclusions: Compared to FFDM, breast cancer screening with DBT has a lower recall rate while detecting a similar distribution of benign and malignant diagnoses.

INTRODUCTION

Digital breast tomosynthesis (DBT) has emerged as a new breast cancer screening modality that could substantially improve the benefit-to-harm ratio for screening [1]. Observational studies in the United States suggest that DBT decreases recall rates and increases invasive cancer detection rates when added to conventional FFDM [2–9]. While early data are promising, the United States Preventive Services Task Force concluded in early 2016 that there is insufficient evidence to evaluate the benefits and harms of DBT for screening [10]. One particular area of uncertainty is the effect DBT has on the detection and diagnosis of specific benign and malignant lesions.

The use of DBT results in the improved depiction of architectural distortion, which on 2D images often appears due to overlapping fibroglandular tissue [11]. Previous studies have reported that DBT increases the rate of recall for architectural distortion and masses [8, 12] while reducing recall for asymmetries [12, 13]. These various types of mammographic findings are associated with different types of benign and malignant diagnosis, and thus these properties could influence the type of benign and malignant lesions detected on screening.

Benign diagnoses are typically perceived as an undesired outcome of screening, representing scenarios where cancer was suspected but is found not to be present. At least one study has

suggested that use of DBT may be associated with increased benign biopsy rates [2], though this has not been consistently observed [14]. To our knowledge no prior studies have described the rate of specific benign diagnoses identified via screening with DBT compared with FFDM alone.

The purpose of this study was to determine whether detection rates of specific benign and malignant diagnoses differ for breast cancer screening with DBT versus FFDM alone. We used data from the Vermont Breast Cancer Surveillance System, which includes a statewide registry of all breast cancer screening mammography performed in Vermont, linked to patient risk factor data and pathology records for benign and malignant diagnoses.

SUBJECTS AND METHODS

Design

We conducted an analysis of observational data from the Vermont Breast Cancer Surveillance System (VBCSS) [15]. The VBCSS has collected statewide mammography data in Vermont since 1994 and is a member of the Breast Cancer Surveillance Consortium [16]. The VBCSS includes a registry of all breast imaging (mammography, ultrasound, and MRI) performed at radiology facilities in Vermont, linked to statewide breast pathology reports and records from the Vermont Cancer Registry. This study was approved by the University of Vermont Institutional Review Board with a waiver of consent and all study procedures were compliant with the Health Insurance Portability and Accountability Act. However, women attending breast imaging exams at radiology facilities in Vermont are given the option to “opt-out” of participation in research via the health questionnaire they complete at each visit. This study was limited to women who did not opt out of participation in research (90% of women). A prior publication reporting basic screening performance statistics for DBT and FFDM from the consortium for Population-based Research Optimizing Screening Through Personalized Regimens included data on 18,983 DBT and 43,198 FFDM exams that are also included in this manuscript [14]. The current study includes a larger number of exams from the VBCSS and evaluates detection rates for specific benign and malignant diagnoses.

Study setting and population

The analyses for this study were restricted to 8 radiology facilities in Vermont that adopted DBT for breast cancer screening during 2012-2016. All facilities used DBT mammography systems manufactured by Hologic (Bedford, MA). The DBT adoption date and implementation method varied by facility. At facilities that gradually transitioned from FFDM to DBT screening, DBT screening was not explicitly targeted to certain patient populations. Rather, screening modality (FFDM vs. DBT) was generally assigned based on room availability, though women were given the option to decline DBT screening if they preferred FFDM alone. All facilities used DBT combined with 2D FFDM views at the start of the study period. Six facilities replaced FFDM views with synthetic 2D views reconstructed from the DBT views during the course of the study period. Among DBT exams included in the analyses, 67% did not include synthetic 2D views; 13% included

synthetic 2D views but also obtained conventional 2D FFDM views; and 20% obtained synthetic 2D views without conventional 2D FFDM views.

FFDM and DBT screening exams from January 2012 through December 2016 were identified for women who had not opted out of participation in research (N=201,523 screening exams among 70,276 women). Screening exams among women with a prior history of breast cancer (N=15,679 exams) or breast implants (N=2,117 exams) were excluded since screening performance metrics differ markedly among women in these populations compared to the general screening population [17, 18]. A total of 86,349 DBT and 97,378 FFDM exams among 66,003 women and interpreted by 49 radiologists met the final eligibility criteria.

Data Collection

Patient demographic and risk factor data (including age, race/ethnicity, and family history of breast cancer) were obtained from standardized questionnaires completed by subjects at each breast imaging exam.

Radiologic information including date of exam, modality (FFDM vs. DBT), indication for exam (i.e., screening vs. diagnostic), assessment category, and breast density category was provided by the radiology facility. Assessments and breast density were categorized as per standard clinical practice according to the Breast Imaging Reporting and Data System (BI-RADS) [19].

The VBCSS obtains copies of pathology reports for all breast specimens evaluated at pathology facilities in the state of Vermont. Malignant and benign diagnoses were abstracted from pathology reports by a trained abstractor. The VBCSS also obtains consolidated breast cancer diagnosis data, including date of diagnosis, histological subtype, and stage at diagnosis, via linkage to the statewide Vermont Cancer Registry.

Measures and definitions

A positive screening exam was defined as those with an initial BI-RADS assessment of 0, 3, 4 or 5 [19]. The recall (abnormal interpretation) rate was defined as the number of positive screening exams divided by the total number of screening exams. The biopsy rate was determined as the proportion of positive screening exams followed by a biopsy within 6 months. Screen-detected lesions were defined as those that were diagnosed within 6 months of a positive screening exam. Positive predictive value of recall (PPV-1) was defined as the proportion of positive screening exams that resulted in a screen-detected cancer (DCIS or invasive). Positive predictive value of biopsy (PPV-3) was defined as the proportion of positive exams with biopsy that resulted in a screen-detected cancer.

Each breast pathology diagnosis occurring within 6 months of a positive screening exam was categorized as non-proliferative benign changes (fibrosis, cysts, adenosis, and apocrine metaplasia), fibroepithelial proliferations (fibroadenoma, adenomyoepithelioma, and phyllodes tumor), proliferative lesions without atypia (intraductal papilloma without atypia, usual ductal hyperplasia, columnar cell change, columnar cell hyperplasia, sclerosing adenosis, and complex sclerosing lesion), atypical lesions (atypical ductal hyperplasia,

atypical lobular hyperplasia, flat epithelial atypia, columnar cell change or hyperplasia with atypia, and atypical papilloma), lobular carcinoma in situ (LCIS), DCIS, and invasive breast cancer. For women with multiple screen-detected diagnoses after a single screening exam, the most severe diagnosis was determined according to the following hierarchy: non-proliferative benign changes, fibroepithelial proliferations, proliferative lesions without atypia, atypical lesions, LCIS, DCIS, and invasive breast cancer. Invasive breast cancer diagnoses were further subdivided by histologic subtype into ductal, lobular, mixed ductal-lobular and other/unknown (metaplastic, invasive NOS).

Statistical Analysis

We compared screening performance metrics and rates of specific types of screen-detected benign and malignant lesions for DBT versus FFDM exams. Since screening modality was not randomly assigned, we controlled for potential differences in the risk profiles of women undergoing DBT versus FFDM using multivariable logistic regression. We selected potential confounding factors *a priori* for inclusion in the model based on their known association with screening performance metrics. Logistic regression models were adjusted for exam year, age group, breast density, family history of breast cancer, and facility. Odds ratios (ORs) and 95% confidence intervals (CIs) were used to describe the strength of the associations and evaluate statistical significance. The use of 95% CIs helps to avoid the limitations of reliance on p-values, by quantifying the precision of the odds ratio point estimates and indicating the range of possible associations that are reasonably compatible with the observed data [20, 21]. We conducted stratified analyses to examine whether the cancer detection results varied according to academic vs. non-academic affiliation, and tested for a statistical interaction using cross-product terms in the regression model. To evaluate the potential influence of a learning curve on DBT diagnoses, we conducted a sensitivity analysis in which the first year of DBT screening data at each facility was excluded from the analyses. SAS Version 9.4 (SAS Institute Inc., Cary, NC) were used for all analyses.

RESULTS

Use of DBT for breast cancer screening at the 8 included facilities increased steadily throughout the study period, with 92% of screening exams using DBT views by 2016 (Figure 1). Approximately half of exams (54%) were conducted at facilities associated with an academic medical center and the remainder were conducted at community hospitals. Average annual facility volumes ranged from 1,378 exams per year to 12,307 exams per year (Figure 2). Patient characteristics were very similar between FFDM and DBT screening groups (Table 1). The mean age was 59.1 years in the FFDM group and 58.3 in the DBT group.

Screening with DBT had a lower recall rate than screening with FFDM alone (7.9% vs 10.9%; adjusted OR=0.81, 95% CI: 0.77-0.85; Table 2). The biopsy rate was very similar on DBT and FFDM screening (OR=1.05; 95% CI: 0.93-1.17). A total of 1,694 benign diagnoses and 984 malignant diagnoses were screen-detected (Table 3). The benign biopsy rate and cancer detection rate on DBT were effectively equivalent to FFDM after statistical

adjustment for covariates. Similarly, there were no statistically significant differences in PPV-1 or PPV-3 after statistical adjustment. In stratified analyses, we found that the cancer detection rates were similar for DBT vs. FFDM among both academic (OR=1.04; 95% CI: 0.83-1.32) and non-academic (OR=0.85; 95% CI: 0.61-1.19) facilities (P=0.74 for interaction).

Compared to FFDM, DBT had slightly elevated rates after covariate adjustment of screen-detected non-proliferative lesions (OR=1.19; 95% CI: 0.92-1.53), fibroepithelial proliferations (OR=1.24; 95% CI: 0.85-1.81), and proliferative lesions without atypia (OR=1.13; 95% CI: 0.90-1.42), and a lower rate of atypical lesions (OR=0.77; 95% CI: 0.43-1.38), but none of these differences were statistically significant. DBT and FFDM had comparable detection rates for lobular carcinoma in situ (OR=0.92; 95% CI: 0.53-1.61).

Detection rates for DCIS and invasive breast cancer were similar on DBT and FFDM (Table 3). Among invasive cancers, there was a slight decrease in detection of invasive ductal cancer on DBT compared to FFDM (OR=0.83; 95% CI: 0.66-1.06) but it was not statistically significant. There was no evidence that detection rates for lobular or mixed ductal-lobular invasive cancers were different on DBT vs. FFDM, though the confidence intervals were wide.

In sensitivity analyses in which the first year of DBT screening data at each facility was excluded, there were a total of 561 benign diagnoses and 336 malignant diagnoses made on 66,940 DBT screens. The results remained essentially the same. There was a similar reduction in recall rate on DBT (OR=0.82; 95% CI: 0.77-0.87), and very little change in the other screening performance metrics. Similarly, there was little change in OR estimates for any of the categories of benign and malignant diagnoses and there remained no statistically significant differences between DBT and FFDM.

DISCUSSION

In this study, the adoption of DBT for breast cancer screening was associated with reduced recall rate but did not appear to substantially change the distribution of specific screen-detected benign and malignant diagnoses in this sample of 8 academic and community-practice Vermont facilities. Our study provides the first evidence regarding detection rates for specific types of benign diagnoses on DBT, and the comparable benign diagnosis detection rates for DBT and FFDM suggest that longstanding evidence on detection rates for specific benign diagnoses for breast cancer screening with full-field digital mammography can likely be expected to apply to screening with DBT.

Similar to previous studies reported in the literature [3], we observed that DBT screening was associated with a reduced recall rate compared to FFDM alone. Prior studies have reported elevated biopsy rates on DBT screening [2, 7], yet others have reported no difference [5, 6]. We observed no difference in overall or benign biopsy rates on DBT vs. FFDM screening. A majority of prior studies have observed elevated cancer detection rates with DBT compared to FFDM alone [2, 5–7, 14, 22], though other studies have provided exceptions [8, 13, 23]. It is unclear why increased cancer detection was not experienced in

Vermont. One potential contributing factor is the relatively high cancer detection rate on FFDM screening exams in this study (5.6 per 1000 exams). Studies reporting increased cancer detection with DBT in the United States have had comparison FFDM cancer detection rates under 5 per 1000 exams [2, 5–7, 14]. Our findings suggest that it may be difficult for DBT to increase cancer detection rates among providers who are already achieving high cancer detection rates with FFDM. Our results are consistent with the recent study by Bahl et al. [23], which also reported a relatively high cancer detection rate on FFDM (5.0 per 1000 exams) that was not improved by DBT. However, randomized trials in European settings have achieved elevated cancer detection rates on DBT in settings with high FFDM cancer detection rates [24, 25]. Our included low volume community hospitals with relatively limited experience with DBT. However, stratified analyses revealed no increase in cancer detection with DBT at both the academic and non-academic facilities. Further research is needed to identify facility, radiologist, and patient factors associated with differences in the impact of DBT on cancer detection rates and other screening performance metrics, including the potential for a “learning curve” effect with increasing experience in DBT interpretation.

We are aware of only two prior studies reporting on DBT detection of specific categories of benign disease. Lourenco et al. [8] noted that 19.6% of screen-detected diagnoses with DBT were high-risk benign lesions, compared to 11.7% for FFDM screening. Lamb et al. [26] described the distribution of high-risk benign lesions detected after FFDM and DBT screening, reporting that atypical hyperplasia constituted a lower proportion of all high risk lesions in the DBT group, while radial scar, papilloma, and atypical lobular hyperplasia made up a higher percentage. Absolute detection rates for benign and high-risk benign lesions were not reported in either study. We found no evidence in our study that detection rates of high risk benign lesions (i.e., atypical lesions or LCIS) were elevated on DBT. There was a small decrease in detection of atypical lesions on DBT, but the confidence interval was wide and not statistically significant. Confidence intervals for other benign diagnoses were more narrow, though we could not exclude small increases in the detection of non-proliferative changes, fibroepithelial proliferations, and proliferative lesions without atypia.

As an observational study, the results of our study must be interpreted with caution and the potential influence of selection bias must be considered. Half of the facilities included in the study transitioned gradually from FFDM to DBT screening. While DBT was not targeted based on patient characteristics at any facility, patients were permitted to undergo screening with FFDM alone if they preferred. We used statistical adjustment to control for the modest differences in measured patient factors, and additionally controlled for secular trends and variation by facility by including calendar year and facility ID in the regression models. Although there is little racial/ethnic diversity in Vermont (96% of women in the study were white), socioeconomic diversity is prevalent – with particularly high representation of rural women. Additional studies will be needed to confirm our findings in other populations, and examine potential differences in racial and ethnic subgroups. Finally, all the facilities in our study used Hologic mammography systems and thus our results may not be generalizable to other mammography systems.

In this statewide registry-based observational study, breast cancer screening with digital breast tomosynthesis was associated with reduced recall rate and did not substantially change the distribution of specific benign and malignant diagnoses compared to screening with full-field digital mammography alone. Our results provide the first evidence to our knowledge regarding detection of specific types of benign diagnoses on DBT vs. FFDM screening, and suggest that the introduction of DBT improves screening performance by reducing recall rates but has little influence the benefits or harms of breast cancer screening through an impact on benign diagnoses. Our finding of no elevated cancer detection on DBT screening provides motivation for further research on factors associated with variability in the impact of DBT on cancer detection and other performance metrics.

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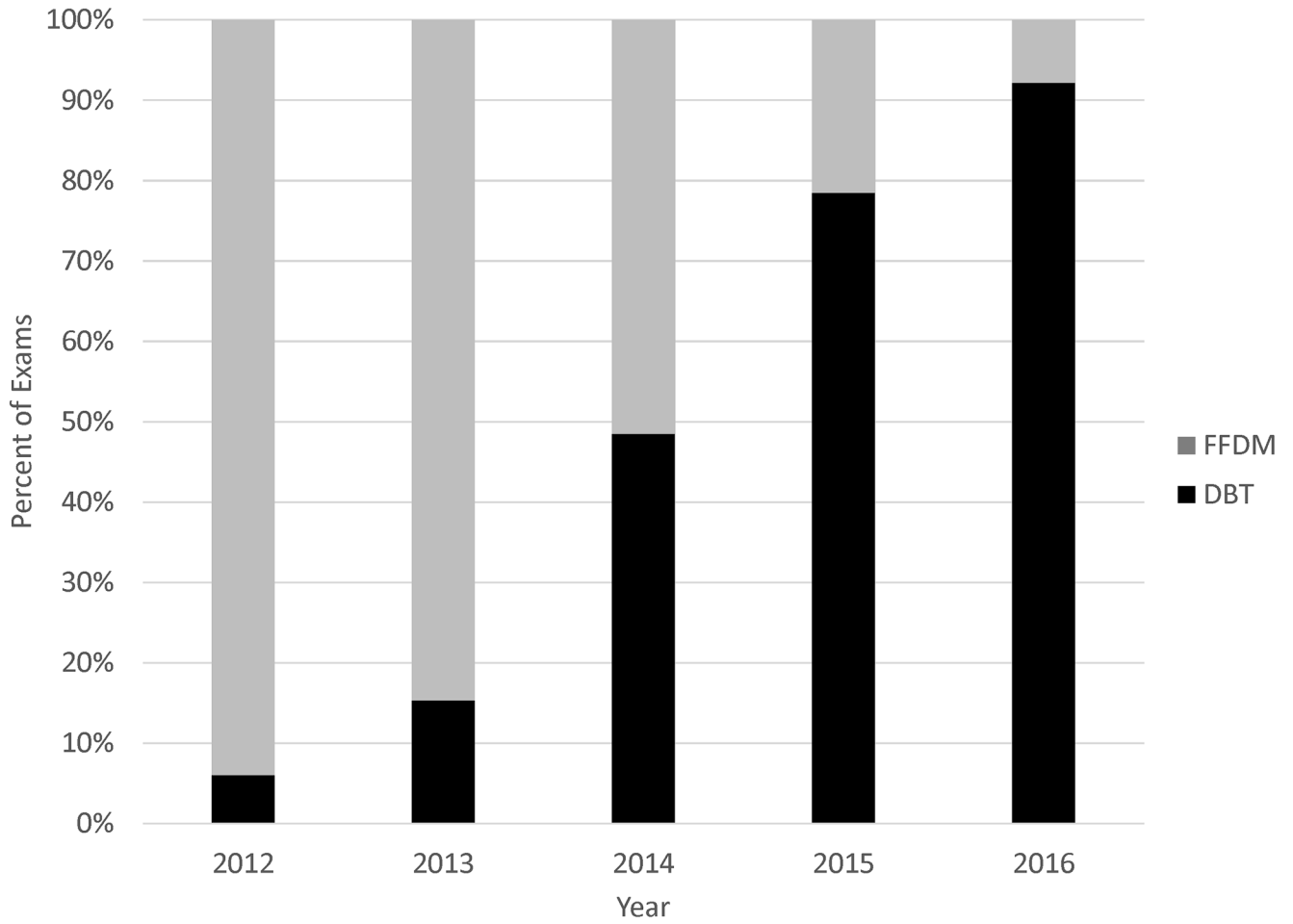


Fig 1 – Adoption of digital breast tomosynthesis for breast cancer screening at 8 radiology facilities in Vermont, Vermont Breast Cancer Surveillance System, 2012-2016. FFDM, full-field digital mammography. DBT, digital breast tomosynthesis.

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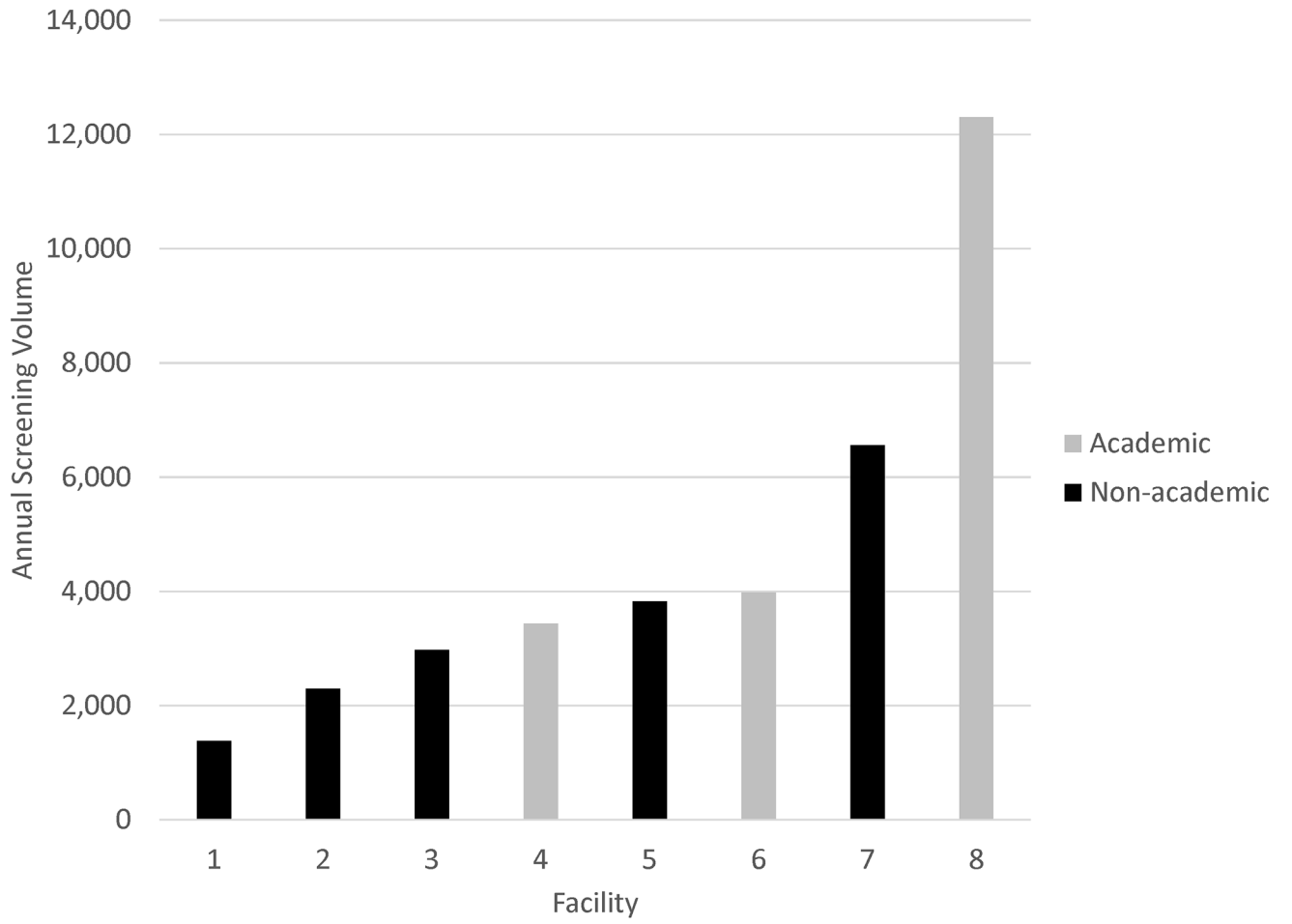


Fig 2 –. Annual screening volume by facility and academic affiliation at 8 radiology facilities in Vermont, Vermont Breast Cancer Surveillance System, 2012-2016.

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Table 1.

Characteristics of the study population undergoing breast cancer screening at 8 radiology facilities in Vermont, Vermont Breast Cancer Surveillance System, 2012-2016.

	FFDM (N=97,378)		DBT (N=86,349)	
	n	%	n	%
Age at mammogram (years):				
<40	988	1.0	805	0.9
40-49	21,368	21.9	20,133	23.3
50-59	31,684	32.5	28,639	33.2
60-69	26,654	27.4	24,162	28.0
70+	16,684	17.1	12,610	14.6
Breast density				
Almost entirely fat	16,782	17.5	12,115	14.1
Scattered fibroglandular density	48,759	50.8	45,550	52.9
Heterogeneously dense	26,478	27.6	24,565	28.5
Extremely dense	4,028	4.2	3,932	4.6
Unknown	1,331		187	
Family history of breast cancer				
No first-degree history	71,344	80.7	61,232	78.3
First-degree relative	17,057	19.3	16,922	21.7
Unknown	8,977		8,195	

FFDM: full-field digital mammography alone; DBT: digital breast tomosynthesis.

Screening performance metrics for full-field digital mammography and digital breast tomosynthesis at 8 radiology facilities in Vermont, Vermont Breast Cancer Surveillance System, 2012–2016.

Table 2.

Diagnosis on pathology	FFDM (N=97,378)		DBT (N=86,349)		Unadjusted		Adjusted*	
	N	rate	N	rate	OR	95% CI	OR	95% CI
Abnormal interpretation rate (recall), %	10,608	10.9%	6,798	7.9%	0.70	0.68-0.72	0.81	0.77-0.85
Biopsy rate, per 1000 exams	1,477	15.2	1,201	13.9	0.92	0.85-0.99	1.05	0.93-1.17
Cancer detection rate, per 1000 exams	548	5.6	436	5.0	0.90	0.79-1.02	0.94	0.78-1.14
Benign disease detection rate, per 1000 exams	929	9.5	765	8.9	0.93	0.84-1.02	1.12	0.97-1.29
PPV-1 (cancer/recall), %	548	5.2%	436	6.4%	1.26	1.11-1.43	1.12	0.92-1.36
PPV-3 (cancer/biopsy), %	548	37.1%	436	36.3%	0.97	0.83-1.14	0.84	0.65-1.08

FFDM: full-field digital mammography alone; DBT: digital breast tomosynthesis; OR, odds ratio; CI, confidence interval; PPV: positive predictive value.

* Adjusted for exam year, age group, breast density, family history of breast cancer, and facility.

Table 3.

Benign and malignant diagnoses detected via screening with full-field digital mammography alone vs. digital breast tomosynthesis at 8 radiology facilities in Vermont, Vermont Breast Cancer Surveillance System, 2012-2016.

Most severe diagnosis*	FFDM (N=97,378 exams)			DBT (N=86,349 exams)			Unadjusted			Adjusted [†]		
	N	rate		N	rate		OR	95% CI	OR	95% CI	OR	95% CI
Benign												
Non-proliferative lesions	325	3.3		232	2.7		0.81	0.68-0.95	1.19	0.92-1.53		
Fibroepithelial proliferations	112	1.2		120	1.4		1.21	0.93-1.56	1.24	0.85-1.81		
Proliferative lesions without atypia	379	3.9		329	3.8		0.98	0.84-1.14	1.13	0.90-1.42		
Atypical lesions	55	0.6		42	0.5		0.86	0.58-1.29	0.77	0.43-1.38		
Lobular carcinoma in situ	15	0.2		9	0.1		0.72	0.49-1.05	0.92	0.53-1.61		
Benign, other/NOS	43	0.4		33	0.4		0.87	0.55-1.36	0.80	0.40-1.59		
Malignant												
Ductal carcinoma in situ	117	1.2		91	1.1		0.88	0.67-1.15	1.05	0.70-1.57		
Invasive breast cancer	431	4.4		345	4.0		0.90	0.78-1.04	0.92	0.74-1.13		
Ductal carcinoma	335	3.4		265	3.1		0.89	0.76-1.05	0.83	0.66-1.06		
Lobular carcinoma	42	0.4		42	0.5		1.13	0.74-1.73	1.11	0.59-2.07		
Mixed ductal-lobular carcinoma	30	0.3		26	0.3		0.98	0.58-1.65	1.49	0.65-3.39		
Invasive, other/NOS	24	0.2		12	0.1		0.56	0.28-1.13	1.47	0.53-4.02		

FFDM: full-field digital mammography alone; DBT: digital breast tomosynthesis; OR, odds ratio; CI, confidence interval; NOS, not otherwise specified.

[†] Adjusted for exam year, age group, breast density, family history, and facility.