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The Effect of Digital Breast Tomosynthesis Adoption on Facility-Level Breast Cancer Screening Volume

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Abstract

Objective: To determine whether digital breast tomosynthesis (DBT) adoption was associated with a decrease in screening mammography capacity across Breast Cancer Screening Consortium (BCSC) facilities given concerns about increasing imaging and interpretation times associated with DBT.

Materials and Methods: Facility characteristics and examination volume data were collected prospectively from BCSC facilities that adopted DBT between 2011 and 2014. Interrupted time series analyses using Poisson regression models with facility as a random effect were used to evaluate differences between monthly screening volumes during the 12-month pre-adoption period and 12-month post-adoption period (separated by a 3-month lag period) and to test for changes in month-to-month facility-level screening volume during the pre-adoption and post-adoption periods.

Results: Across five regional breast imaging registries, 15 out of 83 (18.1%) facilities adopted DBT for screening between 2011 and 2014. The majority had no academic affiliation (73.3%, 11/15), were non-profit (80.0%, 12/15), and were general radiology practices (66.7%, 10/15). Facility-level monthly screening volumes were slightly higher during the post- vs. pre- adoption periods (relative risk [RR] = 1.09, 95% confidence interval [CI] 1.06–1.11). Monthly screening volumes remained relatively stable within the pre-adoption period (RR = 1.00 per month, 95% CI 1.00–1.01) and the post-adoption period (1.00, 95% CI 1.00–1.01).

Conclusion: In a cohort of facilities with varied characteristics, monthly screening examination volumes did not decrease after DBT adoption.

Introduction

Over the last decade, the number of imaging facilities offering breast cancer screening in the U.S. has steadily declined (1). Between 2000 and 2010, the number of U.S. Food and Drug Administration (FDA) -certified mammographic facilities declined 10% from 9,434 to 8,469, affecting all geographic regions (2). During the same period, the number of mammography machines declined 10% from 13,100 to 11,762 while the number of machines per 10,000 women aged ≥ 40 years decreased nearly 20%, from 1.77 to 1.42 (2). An Institute of Medicine (IOM) report suggests that decreasing mammography capacity

likely contributes to declines in screening mammography use (3). Furthermore, several reports also suggest that available cancer screening resources are not distributed proportionally to meet the needs of traditionally underserved populations or to meet national screening targets of 81% screened set by *Healthy People 2020* (4–6).

In 2011, concurrent with the decreasing capacity for breast cancer screening, digital breast tomosynthesis (DBT) was approved by the FDA and has since diffused into practice with purported improvements in breast cancer screening outcomes (7–10). This new screening modality is being adopted rapidly by imaging facilities with Medicare reimbursement available starting in 2015; however, it currently is not reimbursed by all major insurance companies (11). As of October 2017, 42% of U.S. screening facilities now offer DBT screening (12). Screening with DBT, in conjunction with 2D digital mammography, has been shown to decrease recall rates by 15% while increasing cancer detection by 29% in a large multicenter retrospective study (13).

As DBT diffuses into clinical practice, it is uncertain whether the already shrinking number of imaging facilities can maintain their screening capacities. DBT requires a longer imaging acquisition time (8–11), especially for vendors that require an add-on device to be loaded on to existing mammography units. In addition, DBT is associated with a doubling in the radiologists' interpretation time (9). Moreover, at facilities that require out-of-pocket payments, access to DBT screening may be dependent on women's willingness to pay (11). In an environment of increasing financial pressures, less reimbursement by insurers, and ongoing consolidation of healthcare services (3, 14, 15), there is concern for worsening of disparities in screening access as DBT replaces 2D digital mammography for breast cancer screening (16).

Understanding facility-level volume changes associated with the adoption of DBT is a critical step in determining if there may be additional barriers to screening access (17). Our main study objective was to determine whether or not facility-level screening volumes were negatively impacted among early adopters of DBT within the Breast Cancer Surveillance Consortium (BCSC) from 2011 to 2014. We analyzed whether facility-level monthly screening examination volumes were maintained after allowing for a 3-month adoption lag period and controlling for multiple confounding factors.

Materials and Methods

Study Population

We prospectively collected data from five geographically diverse National Cancer Institute-funded BCSC breast imaging registries, comprised of facilities in North Carolina, San Francisco, Vermont, Chicago, and New Hampshire. The BCSC population as a whole has been shown to be comparable to the general U.S. population (18). All data were de-identified and pooled at a central Statistical Coordinating Center (SCC). Each regional registry and the SCC obtained institutional review board approval for active or passive consenting processes or a waiver of consent to enroll individual facilities, perform data linkages, and analyze pooled data. All procedures were Health Insurance Portability and Accountability Act (HIPAA) compliant, and each registry and the SCC received federal

certificates of confidentiality and additional protections for the identities of individual breast imaging facilities. To protect the identity of individual facilities, each facility is referred to using a randomly assigned number (#1-#15).

Data Parameters

Facility Inclusion and Characteristics—We included data from all BCSC facilities across five regional registries (total n = 83) that adopted DBT for screening starting in 2011 (the year of FDA approval for DBT) through 2014. To be included in this analysis, facilities needed to have available screening volume data for the one-year pre-DBT adoption period, the three-month peri-adoption period, and one-year post-DBT adoption period (27 months of continuous volume data). The date of adoption of DBT for screening was known for each facility, because BCSC imaging data are collected at the time of imaging, including the date, clinical indication, and imaging modality of the exam.

Facilities self-reported multiple characteristics, including their academic medical center affiliation, for-profit versus not-for-profit status, radiology practice type, and practice location. For practice type, we categorized each as one of the following: a multi-specialty breast center, full diagnostic radiology practice, breast imaging only practice, or a non-radiology practice. A multi-specialty breast center was a facility that was part of an integrated care center with breast-specific specialists (e.g., on-site breast oncologists, breast radiation oncologists, and breast pathologists). A full diagnostic radiology practice was one offering imaging services for multiple body parts beyond the breasts. A breast imaging only practice offered imaging services limited to the breasts. A non-radiology practice was one that was located within and operated by a different specialty (e.g., obstetrics and gynecology). Facility location was specified as hospital-based or office-based.

Outcome Variables—The main outcome of interest was average monthly screening volume at the facility level. Monthly volume was compared during a twelve-month pre-adoption period and twelve-month post-adoption period, separated by a lag period of three months to allow integration of this new modality into a practice's workflow. Our secondary outcome of interest was to determine if diagnostic imaging volume trended inversely with screening volume after DBT adoption. The majority of breast imaging appointments are composed of either screening or diagnostic imaging examinations. With longer imaging acquisition and interpretation times expected with DBT, the length of a screening appointment may be increased. In contrast, since DBT is purported to decrease recall rates, it may be that the number of screening appointments can be expanded in lieu of fewer diagnostic examination appointments during the post-adoption period. Moreover, diagnostic work-ups may be shortened with the additional information offered by DBT. Based on this rationale, we determined diagnostic imaging volumes (both digital mammography and DBT exams) in the pre-adoption and post-adoption periods as secondary outcome measures.

Confounding Variables—Data on multiple potential confounding factors to facility-level screening volume were recorded from BCSC facility surveys and through direct query of registry directors based on relationships with their individual facilities. Potential confounding factors included concurrent temporal changes in the total number of screening

mammography/DBT units at each facility. In addition, we obtained FDA mammography facility-specific data for the study period through a Freedom of Information Act request. These FDA facility files detail every active screening unit in the U.S. We cross-referenced BCSC facility data with FDA facility files to determine if any new screening facilities and/or mammography/DBT units became active within the same zip code of a BCSC facility during the study period that could change facility-level screening demand, and to verify the number of active mammography units at each facility over time (e.g., addition of a new screening unit versus replacement of an existing mammography unit with DBT adoption).

Registry leads were also directly surveyed to identify additional confounding factors for screening volume during the study period (100% response rate). Survey questions included whether individual facilities kept existing mammography units active or replaced them with a new DBT-capable unit, if a competing screening facility opened nearby that would cause an expected decrease in their screening volume during the study period, if a competing screening facility closed nearby that would cause an expected increase in screening volume during the study period, if any facility's times of operation (e.g., evening screening appointments) were lengthened or shortened during the study period, and if radiologist personnel increased or decreased during the study period.

Statistical Analysis—We determined distributions for facility-level characteristics including academic affiliation, for-profit status, practice type, and practice location. We tabulated average monthly screening volumes for each individual facility in the 12-month pre-adoption period, 3-month peri-adoption period, and 12-month post-adoption period, and then calculated the percentage change in average monthly volume pre-adoption versus post-adoption. We also tabulated diagnostic imaging volumes for each facility during the same pre-adoption and post-adoption periods, and calculated percentage changes in average monthly diagnostic volume pre-adoption versus post- adoption.

We fit generalized Poisson regression models to assess the association between DBT technology adoption and the following outcome measures: 1) average monthly screening examination volume change between pre-adoption and post-adoption periods; 2) average monthly screening examination volume within the pre-adoption period; and 3) average monthly screening examination volume within the post-adoption period. We included facility-specific random effects to account for repeated measures correlation within facilities over time and variation between facilities. We fit regression models for the overall study population, as well as for two subgroups: facilities replacing a mammography unit with a DBT unit and facilities adding a DBT unit to existing units.

We controlled for multiple potential confounding variables by including dummy variables for increase/decrease in radiologist personnel from pre- to post-adoption, opening/closing of nearby screening facilities, increase/decrease in facility operating hours pre-to post-adoption, and inclusion of October and November in study periods (higher expected monthly volumes. In our multiple regression models, we addressed these potential confounding variables by creating one combined variable to indicate any change that would be expected to lead to an increase in screening volume and a separate combined variable for any change that would be expected to lead to a decrease in screening volume. We also separately

adjusted for temporal seasonal changes by including an indicator of whether the month was October or November (to account for higher screening volumes during and shortly following breast cancer awareness month). All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Across five BCSC regional breast imaging registries, 15 out of 83 (18.1%) facilities adopted DBT for screening during our study period. Dates of DBT adoption ranged from November 2011 to May 2014. We previously reported characteristics across all BCSC facilities, where 92.4% (97/105) of facilities had no academic affiliation, 72.9% (62/105) were non-profit, and 62.9% (66/105) were general radiology practices (19). Similarly, the majority of early DBT adopter facilities had no academic affiliation (73.3%, 11/15), were non-profit (80.0%, 12/15), and were general radiology practices (66.7%, 10/15) (Table 1). More than half of facilities had single mammography units (53.3%, 8/15), while the remaining facilities had 2–8 mammography units prior to DBT adoption. All fifteen facilities incorporated a single DBT capable mammography unit, rather than multiple units, into their practice at the time of adoption. At the time of DBT adoption, about half (46.7%, 7/15) of facilities replaced an outgoing digital mammography unit with the new DBT capable unit, while the other half (53.3%, 8/15) added a DBT capable unit while keeping their existing digital mammography units active.

During the study period, none of the fifteen DBT-adopting facilities had a change in practice type or profit status. Three of the facilities (facilities 10, 11, and 13) reported that a nearby screening facility had opened during the post-adoption period, but each of these facilities experienced a single digit percentage change in monthly average screening volume from pre- to post-adoption periods (+4.9, +1.6%, and −6.3% change, respectively). None of the fifteen facilities reported a nearby screening facility closure during the post-adoption period. One facility (facility 1) stopped offering evening appointments starting at the ninth month of the 12-month post-adoption period (−0.8% change in monthly screening volume from pre- to post-adoption). One other facility (facility 14) started offering evening appointments during the fourth month of the 12-month post-adoption period (+45.3% change in monthly screening volume from pre- to post-adoption; of note, this facility also kept existing mammography units active after adding a DBT capable unit).

In total, our exam volume analysis included 194,531 digital 2D screening mammograms, 45,554 screening DBT exams, and 56,875 diagnostic exams (both digital 2D mammography and DBT exams). Both pre-adoption and post-adoption total screening average monthly volumes ranged widely across individual facilities (Table 2). Overall, just over half of facilities (53.3%, 8/15) saw ≤ 5% change in total average monthly screening volume in either direction when comparing before and after DBT adoption (Figure 1). No facilities experienced a decrease in monthly screening volume of >10%. Three facilities (20%, 3/15) experienced >20% increase in average monthly screening volume in the post-adoption period, but all of these facilities were ones that kept existing screening mammography units clinically active in addition to adding a new DBT capable unit to their clinical workflow. Overall, there was a 7.2% increase in average monthly screening exam volumes across

facilities between the pre-adoption and post-adoption periods. The average proportion of screening examinations that were DBT also increased steadily over time (Figure 2).

With regards to diagnostic imaging average monthly volume, 60% (9/15) of facilities had pre-adoption average monthly diagnostic imaging volumes >50 exams per month (Table 2). Of these facilities with this minimum level of diagnostic imaging exams, the majority (66.7%, 6/9) experienced decreasing diagnostic imaging volumes from the pre-adoption to the post-adoption periods (range, −23.8% to −2.5%) (Figure 3). One facility experienced >20% increase in monthly average diagnostic imaging volume from pre-adoption to post-adoption, but this facility kept existing mammography units clinically active in addition to adding a new DBT capable unit. Overall, there was an 8.4% decrease in average monthly diagnostic imaging volumes between the pre-adoption and post-adoption periods across the nine facilities performing >50 diagnostic imaging examinations per month in the pre-adoption period.

The results of our multivariable Poisson regression models are summarized in Table 3. In the overall regression model including all DBT adopters, facility-level monthly screening volume increased slightly during the post- vs. pre-adoption periods (relative risk [RR] = 1.09, 95% confidence interval [CI] = 1.06–1.11). This held true among facilities replacing an existing unit with a DBT unit (RR = 1.09; 95% CI = 1.06–1.12) as well as among facilities adding a DBT unit to existing units (RR = 1.06; 95% CI = 1.04–1.08). In the regression models evaluating changes in slope within each of the two time periods, the month-to-month screening volumes within the pre-adoption period and the post-adoption period held stable with very little change noted across all facilities, facilities replacing an existing unit with a DBT unit, and facilities adding a DBT unit to existing unites (RRs for monthly volume change 1.00–1.01).

Discussion

Our study, a longitudinal analysis of facility-level examination volume data across five regional breast imaging registries, demonstrates no evidence of decreased capacity for breast cancer imaging after DBT adoption. With reported increases in image acquisition time and doubling of imaging interpretation time with DBT screening, concerns of decreasing capacity for screening at the facility level has been mentioned as a potential concern. Our results indicate that facility level volume was maintained and slightly improved at least 15 months after DBT adoption, despite concerns of increased image acquisition and interpretation time.

Our interrupted time series analysis provides multiple additional, novel practice-level findings regarding DBT screening adoption. First, month-to-month facility-level screening volume was steady following a short lag period (three months) after DBT adoption. This suggests that facilities were able to adjust their workflow relatively rapidly to ensure that their pre-adoption screening levels were maintained. In contrast to the relatively significant workflow changes needed to transition from screen-film to digital mammography (11), the transition from digital mammography to DBT screening appears to involve lower overall impact to clinical workflow in relation to overall screening capacity. More than 60% of

screening exams were DBT exams across all facilities by end of study period (Figure 2), suggesting that the month-to-month screening volumes were maintained even after a substantial transition to DBT experienced by adopting facilities.

Moreover, the trends for screening and diagnostic volumes associated with DBT adoption are inversely related. While we observed an overall small increase in facility-level screening volumes after DBT adoption, we observed a small overall decrease in average monthly diagnostic imaging volumes in the post- vs. pre-adoption periods. This inverse relationship suggests that the relative mix of screening and diagnostic breast imaging examinations may be changing with DBT adoption, with purported fewer recalls leading to lower diagnostic imaging volumes as well as shorter diagnostic work-up times due to added information from DBT. This, in turn, may allow practices to shift their appointments from time-intensive diagnostic examinations towards shorter screening examinations, potentially leading to the observed incremental increases in facility-level screening volumes after DBT adoption.

Several strengths of our study design support the validity of our results. First, we used interrupted time series analysis with twelve time points (months) for volume data in the pre-adoption and post-adoption periods, separated by a three-month lag period. Interrupted time series analysis is recognized as a robust method of identifying and visualizing patterns in complex systems and is a strong design to evaluate longitudinal effects of new interventions (20, 21). By including monthly data from multiple facilities and with accurate identification of the date of new modality adoption, we were able to control for secular trends in screening mammography utilization (e.g., changes in reimbursement, changes in screening recommendations)(21). Moreover, potential confounding variables are limited to facility-level factors that relate to the outcome of interest and that could change at the time of technology adoption (e.g., expansion of hours of operation at the facility level or the opening of additional facilities in the same geographic area). Second, by focusing on facility-level volume changes, confounding variables were limited to facility-level factors (e.g., substitution or addition of screening units, opening of additional facilities in the same geographic area, number of interpreting radiologists). These potential confounding factors were addressed through cross-referencing with FDA mammography facility files, which contain information on every active mammography unit in the U.S. over time, and through direct queries of registry directors. Third, we obtained volume data from a geographically diverse set of facilities with varying practice types that are part of the BCSC, the largest national research source of breast imaging data linked to outcomes. The use of this study population ensures accurate data collection regarding examination date, examination indication (e.g., screening versus diagnostic), and imaging modality (e.g., digital mammography, DBT).

Our study also had limitations. Facility characteristics were self-reported and not all potential factors related to facility-level screening volume could be captured as potential confounders. For instance, while we were able to capture number of radiologists in the pre- and post-adoption periods for each facility, we could not characterize the change in intensity of their workload. The increased interpretation time and effort required among radiologists with the adoption of DBT were not examined in this study, but are likely significant. Our analysis is also limited to early adopter sites that incrementally adopted DBT, usually

starting with one DBT capable unit replacing a digital mammography unit, and the small increase in volume post-adoption may not hold with larger facilities replacing multiple mammography units with DBT capable units at the same time.

Future studies regarding screening capacity after DBT adoption should address whether the population served at individual facilities differs after DBT adoption. Historically, traditionally underserved populations have been the last to benefit from new health interventions (22, 23). Moreover, while Medicare began reimbursing for DBT in 2015, several major insurance companies still consider the technology as experimental and do not routinely cover the additional costs associated with DBT acquisition and interpretation (approximately $50) (24). Thus, outside of Medicare, additional out-of-pocket expenses may be required in order to obtain combined DBT and digital mammography screening. This differential access to DBT may lead to changes in the population served with regards to their sociodemographic characteristics. Such issues regarding individual access to DBT are beyond the scope of this analysis, which was focused on screening volume changes at the facility level.

In summary, we found that screening volume after DBT adoption did not decline among a geographically diverse cohort of fifteen BCSC facilities. Contrary to concerns regarding increased image acquisition and interpretation time that could theoretically decease screening capacity, monthly screening examination volumes were maintained and slightly increased after a modest adoption lag period, controlling for multiple confounding factors. We also found an inverse trend between screening volume and diagnostic imaging volume after DBT adoption, suggesting that facilities may be shifting more examination appointments towards screening examinations with decreasing need for diagnostic imaging. Finally, the minimal month-to-month slope change in monthly screening volume in the post-adoption phase suggests that facilities are able to transition from digital mammography to DBT relatively rapidly, reaching a steady state in screening volume within a few months of adoption.

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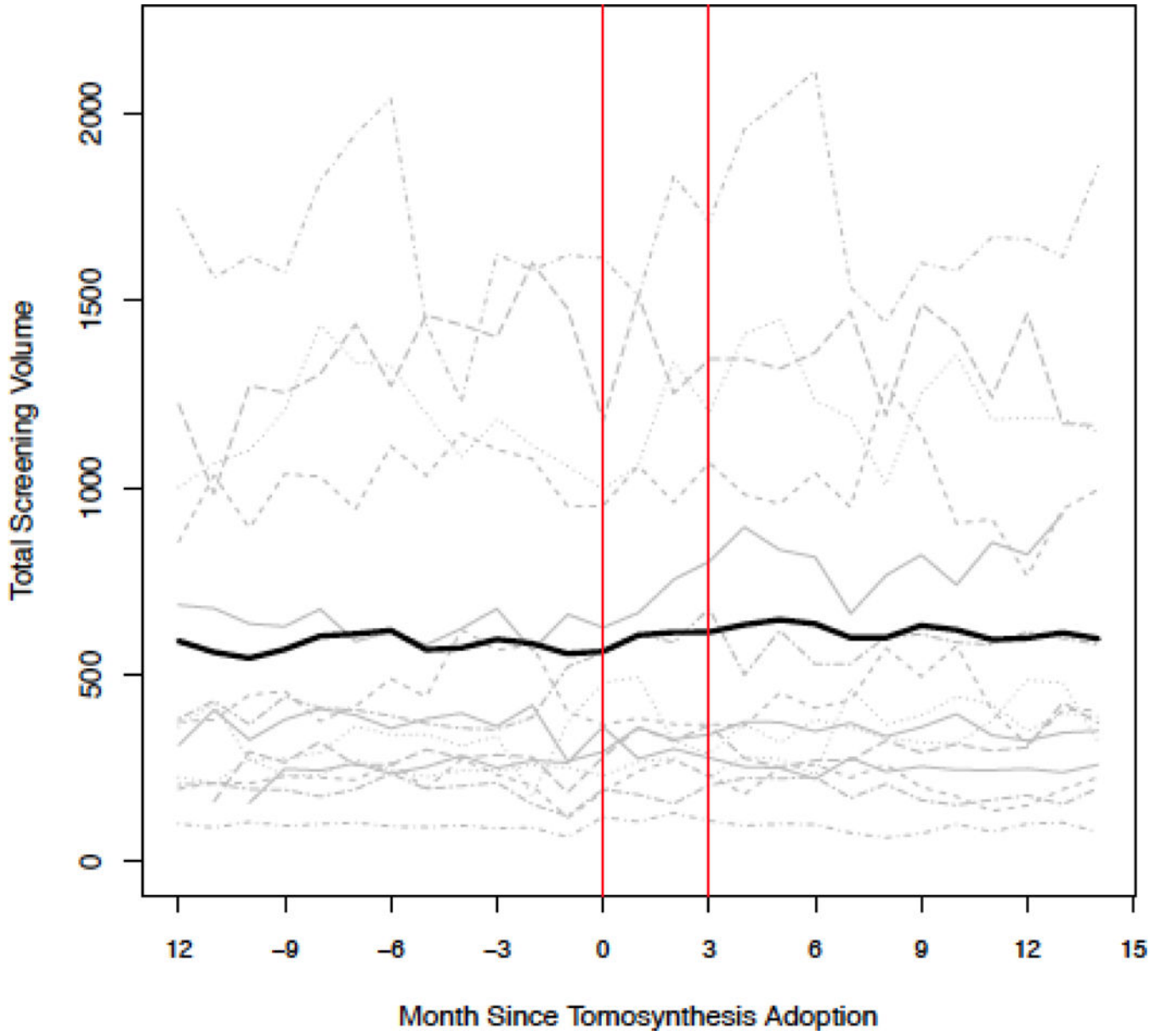

Figure 1. Monthly Screening Volume Trends Pre- and Post-Tomosynthesis Adoption

Monthly screening volumes for each facility are plotted with dashed lines. The overall combined average is demonstrated as a solid black line. The vertical lines represent the adoption (lag) period (three months) for digital breast tomosynthesis.

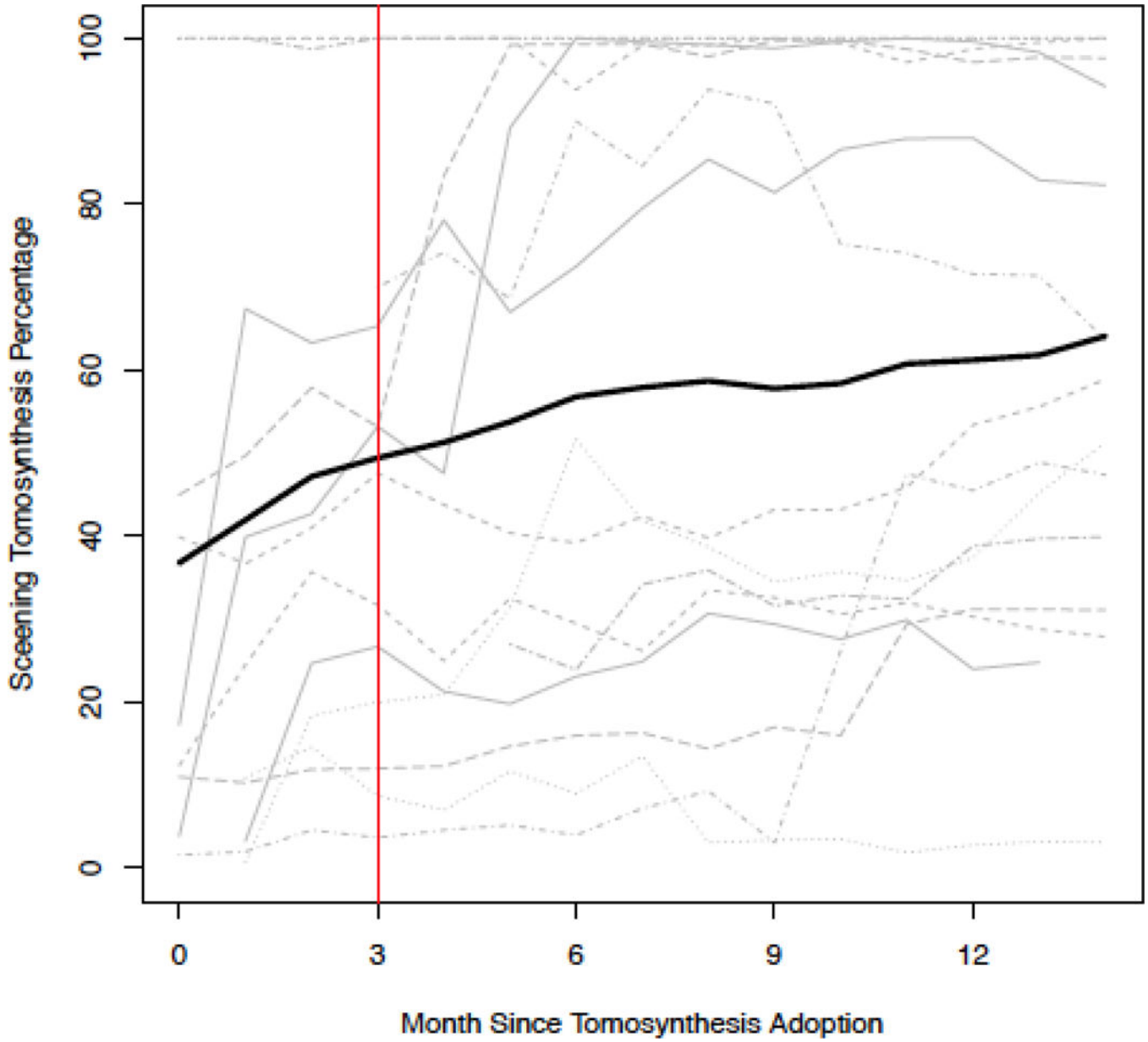

Figure 2. Monthly Facility-Level Screening Tomosynthesis Percentages Post-Adoption

Monthly percentage of screening exams that were digital breast tomosynthesis for each facility are plotted with dashed lines. The overall combined average is demonstrated as a solid black line. The vertical lines represent the end of adoption (lag) period (three months) for digital breast tomosynthesis.

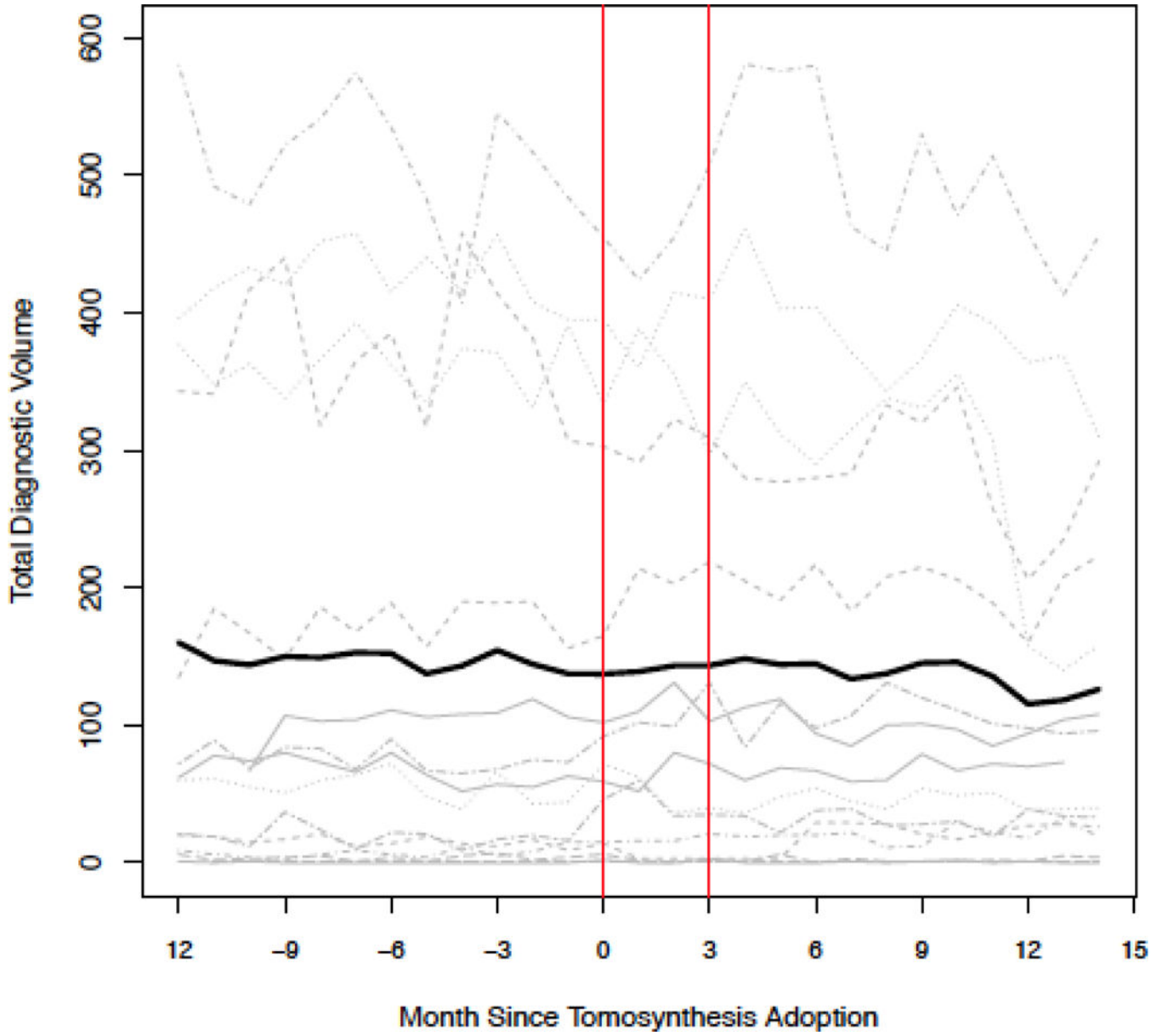

Figure 3. Monthly Diagnostic Volume Trends Pre- and Post-Tomosynthesis Adoption

Monthly diagnostic volumes for each facility are plotted with dashed lines. The overall combined average is demonstrated as a solid black line. The vertical lines represent the adoption (lag) period (three months) for digital breast tomosynthesis.

Table 1.

Characteristics of Facilities Based on Adoption of Digital Breast Tomosynthesis

Facility Characteristic	Adopted DBT Number (%) Total n = 15	Did Not Adopt DBT Number (%) Total n = 68
Academic Medical Center Affiliation		
Academic affiliation	4 (26.7%)	2 (2.9%)
No academic affiliation	11 (73.3%)	63 (92.6%)
Unknown		3 (4.4%)
Profit Status		
For-profit	2 (13.3%)	13 (19.1%)
Non-profit	12 (80.0%)	38 (55.9%)
Unknown	1 (6.7%)	17 (25.0%)
Facility Type		
Multi-specialty breast center	4 (26.7%)	12 (17.6%)
Full diagnostic radiology practice	10 (66.7%)	43 (63.2%)
Breast imaging only	1 (6.7%)	8 (11.8%)
Non-radiology practice		2 (2.9%)
Unknown		3 (4.4%)
Location		
Hospital-based	13 (86.7)	42 (61.8%)
Office-based	2 (13.3)	18 (26.5%)
Other/unknown		8 (11.8%)

Table 2.

Facility Screening and Diagnostic Volumes Pre- and Post-Tomosynthesis Adoption

Facility	Pre-Adoption Average Monthly Screening Volume	Post-Adoption Average Monthly Screening Volume	% Screening Volume Change Pre- to Post-Adoption	Pre-Adoption Average Monthly Diagnostic Volume	Post-Adoption Average Monthly Diagnostic Volume	% Diagnostic Volume Change Pre- to Post-Adoption
Facilities Where DBT Unit Replaced DM Unit						
Facility 1	1342	1331	−0.8	**	**	----
Facility 5	1016	994	−2.2	172	202	17.4
Facility 6	263	314	19.4	**	**	----
Facility 8	191	189	−1	**	**	----
Facility 11	248	252	1.6	104	100	−3.8
Facility 12	322	362	12.4	55	44	−20
Facility 13	462	433	−6.3	374	285	−23.8
Facilities Where DBT Unit Added to Existing Unit(s)						
Facility 2	401	585	45.9	75	107	42.7
Facility 3	634	812	28.1	67	68	1.5
Facility 4	215	208	−3.3	**	**	----
Facility 7	95	91	−4.2	**	**	----
Facility 9	368	354	−3.8	**	**	----
Facility 10	1174	1232	4.9	426	383	−10.1
Facility 14	243	353	45.3	362	279	−22.9
Facility 15	1648	1730	5	513	500	−2.5

** = Average diagnostic volume failed to reach threshold > 50 exams per month

Table 3.

Multivariable Poisson Regression Results on Changes in Screening Volume Post- vs. Pre-Adoption of Digital Breast Tomosynthesis

Model Description	All Facilities Adopting DBT Relative Risk (95% Confidence Interval)	Facilities Where DBT Unit Replaced DM Unit Relative Risk (95% Confidence Interval)	Facilities Where DBT Unit Added to Existing Unit(s) Relative Risk (95% Confidence Interval)
Model 1			
Monthly facility-level screening volume post-adoption versus pre-adoption, adjusting for confounding variables	1.09 (1.06, 1.11)	1.09 (1.06, 1.12)	1.06 (1.04, 1.08)
Model 2			
Pre-adoption month-to-month facility-level screening volume change within the 12-month period, adjusting for confounding variables	1.00 (1.00, 1.01)	1.01 (1.01, 1.01)	1.00 (0.99, 1.00)
Post-adoption month-to-month facility-level screening volume change within the 12-month period, adjusting for confounding variables	1.00 (1.00, 1.01)	1.00 (0.99, 1.00)	1.00 (1.00, 1.00)