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Supplemental breast imaging utilization following breast density legislation in North Carolina

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Abstract

Objective: Breast density notification laws are increasingly common, but little is known of how they affect supplemental screening use. We investigated supplemental screening before and after density notification in North Carolina, where notification has been required since 2014.

Methods: We evaluated breast screening data from Carolina Mammography Registry participants aged 40-79 years with no personal history of breast cancer or breast implants. Supplemental screening was defined as a non-diagnostic digital breast tomosynthesis (DBT), whole breast ultrasound, or breast magnetic resonance imaging examination performed within three months of a negative or benign screening mammogram (2-D or DBT). Supplemental screening before (2012-2013) and after (2014-2016) the notification law was compared using logistic regression.

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Results: During the study period, 78,967 women received 145,279 index screening mammograms. Supplemental screening use was similar before and after the notification law, regardless of breast density (dense breasts, adjusted odds ratio [aOR] 1.01, 95% confidence interval [CI] 0.58, 1.75; non-dense breasts, aOR 0.63, 95% CI 0.38, 1.04). Though there was no change in supplemental screening, new use of any screening DBT in 2014-2016 was greater for women with dense breasts (vs. non-dense breasts, aOR 1.15, 95% CI 1.08, 1.23).

Discussion: Data suggest that supplemental screening use in North Carolina did not change after enactment of a breast density notification law, though the increase in new use of any screening DBT was greater for women with dense breasts. The short-term lack of change in supplemental screening should be considered as additional notification laws are developed.

Summary sentence:

Our data suggest that in North Carolina, where pre-existing supplemental screening use was low and insurance coverage for supplemental screening was not part of the legislation, supplemental screening trends did not change after enactment of the breast density notification law.

Keywords

breast density; mammography; digital breast tomosynthesis; screening

Introduction

Mammographic breast density, a measure of the ratio of fibroglandular to fatty tissues in the breast, is both an independent predictor of breast cancer risk and a determinant of mammography accuracy [1]. In the US, there are increasing efforts to inform women of their breast density, based on the rationale that knowledge of breast density may assist in determining the appropriateness of an individual woman's breast cancer screening regimen [2]. As of March 2019, 36 states have passed some form of breast density notification legislation, and a federal bill requiring the direct reporting of breast density to patients in a lay letter was passed into law in February 2019 [3, 4]. The exact notification terms for the federal law have yet to be determined by the US Food and Drug Administration. Most existing state laws require that a woman be informed of her breast density. Many also require the inclusion of language suggesting that women with dense breasts discuss their breast cancer risk and alternative screening methods, such as supplemental screening, with their physician.

The rationale for supplemental screening, or additional breast cancer screening that occurs after a screening mammogram with no abnormal findings, is that use of additional imaging has the potential to increase screening sensitivity. This could be particularly advantageous for women with dense breasts, for whom the sensitivity of mammography is known to be lower than mammography sensitivity among women with non-dense breasts [5,6]. Currently, seven states require that supplemental screening be covered by insurance for women with dense breasts [3]. However, most professional societies, policy organizations, and systematic reviews of the literature do not support the use of supplemental screening among women with dense breasts who are not otherwise "high risk," due to concerns about increased recall

rates, biopsy rates, and a lack of evidence that supplemental screening detects clinically meaningful cancers [7-12]. Furthermore, it is unclear how breast density notification affects patterns of supplemental screening given the increasing prevalence of notification requirements and lack of evidence to support the contention that notification is beneficial.

In North Carolina, a state law went into effect on January 1, 2014 requiring that women undergoing screening mammography be notified of their breast density. Furthermore, the law states that women with heterogeneously dense or extremely dense breasts should be advised to talk with their physician about breast density and other breast cancer risk factors to "...decide which screening options are right for [them]" [13]. The extent to which the law has impacted the use of supplemental breast screening in North Carolina is unknown. To address this question, we examined the use of breast cancer supplemental screening in North Carolina before and after the implementation of the breast density notification law.

Methods

Population

This observational study used data from the Carolina Mammography Registry, a prospective, community-based breast imaging registry that collects patient- and radiologist-reported data on breast imaging procedures and outcomes among women in North Carolina [14]. We evaluated breast imaging examinations among women aged 40-79 years who received at least one mammogram between January 2012 and April 2016 with an indication of routine screening and a Breast Imaging Reporting and Data System (BI-RADS) assessment of negative (BI-RADS 1) or benign (BI-RADS 2). Women may have received multiple imaging examinations during this time period. Women were excluded from the study if they had a personal history of breast cancer. Women with breast implants were also excluded, as implant placement can distort and/or obscure the appearance of breast tissue on an x-ray, which may influence the assessment of breast density.

Breast Imaging Examinations

We defined the index examination as a screening mammogram, performed as either two-dimensional (2-D) full-field digital mammography or digital breast tomosynthesis (DBT), with a negative or benign BI-RADS assessment (Fig. 1). Additionally, the index examination must have been acquired at an imaging facility that performed screening DBT, ultrasound, or magnetic resonance imaging (MRI), or was affiliated with another facility that provided those imaging services. Index examinations were excluded from analysis if women reported breast symptoms, if the examination was part of a diagnostic work-up or intended to evaluate a breast problem, if there was a mammogram within the preceding 270 days, or if breast density was not recorded.

A supplemental screening examination was defined as a whole breast ultrasound or breast MRI examination that was not part of a diagnostic work-up or intended to evaluate symptoms or a breast problem and was performed up to 3 months after the index screening mammogram. For example, if a woman received a 2-D screening mammogram that had a negative or benign assessment followed by a screening ultrasound or MRI within 3 months,

this would be considered supplemental screening. A woman who received a screening DBT with a negative or benign assessment followed by a screening ultrasound or MRI within 3 months would also be considered a recipient of supplemental screening.

Covariates

Information on demographics, breast cancer risk factors, and screening history were self-reported at the time of the index imaging examination. The BI-RADS mammography assessment and BI-RADS breast density were determined by the interpreting radiologist. For this analysis, breast density was classified as dense (heterogeneously dense or extremely dense) or non-dense (almost entirely fatty or areas of scattered fibroglandular density). Five-year predicted risk of breast cancer was calculated using a validated model [15, 16].

Statistical Analysis

We compared the frequency of supplemental screening occurring between January 2012 and December 2013 (prior to the North Carolina notification law) with the frequency of supplemental screening occurring between January 2014 and April 2016 (after the notification law) using logistic regression models, stratified by whether breasts were classified as dense or non-dense at the time of the index screening mammogram. We used random effects logistic regression to account for correlated observations among women who had multiple index screening examinations during the study period, and to account for correlations between women who used the same imaging facility [17]. To evaluate the potential for confounding, we estimated regression models that adjusted for covariates for which distributions differed between the 2012-2013 and 2014-2016 time periods. Observations with missing covariate data were excluded from adjusted models. As a sensitivity analysis, we re-evaluated the frequency of supplemental screening after extending the time interval for the supplemental examination to 6 or 9 months after the index screening mammogram. Index exams were excluded from the sensitivity analyses if there were less than 6 or 9 months, respectively, of follow-up time during which a supplemental screening exam could have been obtained.

We also conducted analyses to gauge the effect of the notification law on the overall use of alternatives to 2-D mammography for any screening (*i.e.*, primary screening method or supplemental screening). Among the subset of women who used 2-D screening mammography exclusively in the pre-law period and had a screening examination of any type in the post-law period (Fig. 1), we used logistic regression to evaluate whether women with dense breasts were more likely than women with non-dense breasts to become new users of screening DBT in the post-notification law period. There were too few screening ultrasound or screening MRI examinations to evaluate new use in the post-notification law period.

To evaluate the potential effects of excluding examinations with missing breast density information, we repeated the main analyses after imputing missing breast density data using the non-missing density value closest in time to the examination with the missing value.

Analyses were performed using SAS v9.4 (SAS Institute, Inc., Cary, NC). All statistical tests and confidence intervals were two-sided. This study was approved by our institution's

Institutional Review Board and was Health Insurance Portability and Accountability Act compliant. Research was conducted under a waiver of informed consent granted by the Institutional Review Board.

Results

Between January 2012 and April 2016, there were a total of 145,279 eligible index screening mammograms among 78,967 Carolina Mammography Registry participants examined at 16 participating imaging facilities (Fig. 1) — 88% were 2-D mammograms and 12% were DBT. The mean age at the time of the index screening mammogram was 59.8 years (standard deviation 10.1 years). As shown in Table 1, index examination characteristics were similar before and after the notification law, with the following exceptions: a higher proportion of screening examinations were acquired among pre-menopausal and peri-menopausal women in 2014-2016 (41%, vs. 35% in 2012-2013); the proportion of DBT index screening exams increased by more than 600%, comparing 2014-2016 with 2012-2013 (20% vs. 3%); and a lower proportion of screening mammograms resulted in a negative (BI-RADS 1) (vs. benign [BI-RADS 2]) assessment in 2014-2016 (49%, vs. 53% in 2012-2013). The proportion of exams where breast composition was interpreted as ‘dense’ and five-year predicted breast cancer risk at the time of the index screening examination were similar in the pre- and post-breast density notification time periods (Table 1).

During the study period, 172 women received 181 supplemental screening examinations within 3 months of an index screening mammogram, the majority of which were supplemental ultrasound examinations (Fig. 2). There was no evidence that use of supplemental screening within 3 months of an index mammogram differed before vs. after the notification requirement in either breast density category (non-dense breasts, adjusted odds ratio [aOR] 0.63, 95% confidence interval [CI] 0.38, 1.04; dense breasts, aOR 1.01, 95% CI 0.58, 1.75; Table 2). Results were similar when the supplemental screening window was extended to 6 or 9 months after the index mammogram (Table 2) and when we imputed missing breast density data (Supplementary Table S1).

Given the large increase in the use of DBT as the primary screening method (Table 1), we further examined how the enactment of the breast density notification law was associated with new use of DBT among women with dense and non-dense breasts. Among the 30,850 women who used 2-D screening mammography exclusively in 2012-2013, had negative or benign assessments, and returned for a screening exam (of any type) in 2014-2016, 39% became new users of screening DBT after the notification law went into effect. Women with dense breasts were slightly more likely to become new DBT users than women with non-dense breasts (aOR=1.15, 95% CI: 1.08, 1.23) (Table 3). These findings were robust to whether we adjusted for factors assessed during the pre-notification or post-notification time period and the imputation of missing breast density data (Supplementary Table S2).

Discussion

The rationale behind breast density notification is that individual knowledge of breast density may provide additional useful information to screening participants regarding the

appropriateness of their recommended screening regimen, given that breast density is a known breast cancer risk factor and also independently affects mammogram interpretation accuracy. Spurred by a grassroots effort that began in Connecticut, breast density notification is now law in more than 35 US states. The first state law was passed in 2010, but many others are more recent. Given the newness of these density notification laws, there is a paucity of real-world data to assess how they may affect screening habits.

In this study, we examined supplemental screening in a community-based population of women undergoing routine screening mammography in North Carolina. North Carolina's breast density notification law contains language suggesting that women with dense breasts discuss supplemental screening with their physician, but does not require insurance coverage for such screening. We found that the use of supplemental screening in the Carolina Mammography Registry was low and did not change after the implementation of breast density notification requirements, even among women with dense breasts. However, women with dense breasts were more likely than women with non-dense breasts to have started using DBT as a screening method (including as the primary or supplemental screening method) after the notification law was in effect.

Our finding that supplemental screening use did not increase among Carolina Mammography Registry participants differs from what has been reported from populations in other states. In California, screening MRI rates increased significantly after notification legislation, particularly among women with dense breasts and women with the highest incomes [18, 19]. In New Jersey, screening ultrasound increased by 651% after the implementation of a notification law that also mandated insurance coverage for supplemental screening [20]. Specific to supplemental ultrasound, one facility experienced a 260% increase in a three month period after notification went into effect [21]. Data from a single academic medical center in Texas showed a 23-fold increase in screening MRI use for the evaluation of dense breasts after enactment of breast density notification (from 2 per year to 46 per year) [22]. Reports from other states also suggest that notification requirements may shift how radiologists choose to classify density status, with fewer mammograms classified as heterogeneously dense and more mammograms classified as scattered fibroglandular density [23, 24]; however, a similar trend was not observed in North Carolina.

There are likely multiple reasons why supplemental screening rates North Carolina did not show increases similar to those observed in California, New Jersey, and Texas. One possible reason is that the North Carolina law does not require insurance coverage for supplemental screening. As a result, women without insurance coverage, with limited coverage, or with high-deductible plans may forgo supplemental screening which they otherwise might have received in the absence of economic barriers. We did not have information on the type of health insurance plans held by Carolina Mammography Registry participants, the deductible levels associated with those plans, or their out-of-pocket costs, which limits our capacity to understand how the ability to pay for care may have affected our results. Another explanation may be the low rates of supplemental screening use before the density notification law was passed, which may be due in part to availability. There are only 41 accredited MRI facilities in the state compared with 259 mammography facilities, and of the 16 facilities included in this study, only 4 offered screening MRI services. None of the

facilities included in this study offered automated whole-breast screening ultrasound, which may be more amenable to breast screening than the current approach of conducting examinations using a hand-held probe.

Furthermore, this study addressed changes in supplemental screening patterns that occurred within two years of the breast density notification law being enacted in North Carolina. It is possible that changes in supplemental screening patterns will become more evident when a longer period of time is considered, particularly given that breast cancer screening for average-risk women typically occurs on an annual or bi-annual basis. Multiple factors may contribute to why a woman may not get a supplemental examination within 3, 6, or 9 months of a negative mammogram. These include a sense of reassurance after receiving a negative mammogram assessment; provider reluctance to recommend an additional test soon after a negative result; and real and perceived barriers to obtaining the supplemental examination (e.g., additional costs and time spent obtaining the examination). For example, a woman who receives a breast density notification letter that includes language about supplemental screening may be told, "Your exam is negative this year, but you may want to consider a supplemental exam for next year when it can be done all in one visit."

Our data showed a notable increase in the use of screening DBT, with use increasing by more than 600% over the course of the study period. The increase in DBT prevalence in this study was consistent with a reported 496% increase in screening DBT use in New Jersey after density notification was enacted [20], as well as other reported trends in DBT use in the southern US. Only 18% of practices reported using DBT in a 2012 survey, whereas 77% reported using DBT approximately three years later [25, 26]. The increase also mirrors the increase in the availability of DBT at imaging facilities included in this study, with a greater number of facilities offering DBT in 2014-2016 than in 2012-2013. As a result, it is unclear how much of the increase in use is due to increased awareness, increased access, and/or increased patient and provider demand. Research addressing patient, physician, and imaging facility attitudes toward different screening modalities is needed to clarify these findings. It is also unclear the extent to which the increased use of DBT inhibited greater uptake of supplemental ultrasound or supplemental MRI in the post-notification law period.

There are several limitations to this analysis that may affect the interpretation of our results. We only studied screening patterns in North Carolina and our results may not be generalizable to other states, particularly the small subset of states where insurance coverage for supplemental screening among women with dense breasts is required by law. Another limitation is that facility participation in the Carolina Mammography Registry is voluntary. Therefore, our data are a sub-sample of North Carolina imaging practices, with 7% of imaging facilities across the state currently contributing data. We do not receive records pertaining to breast imaging received at facilities that do not participate in the Carolina Mammography Registry, which could lead to potential under-ascertainment of supplemental screening examinations. It is possible that a woman might have obtained screening mammography at a participating facility and then sought supplemental screening at a non-participating facility. However, this analysis only included facilities where supplemental screening modalities were available onsite to reduce the likelihood of this type of under-ascertainment. Additionally, our data do not contain information regarding whether a

synthetic 2-D image, a digital re-construction created from images obtained during a 3-D DBT scan, was evaluated in conjunction with a DBT examination. It is unclear how this practice affects the acquisition of supplemental screening examinations as defined in this study.

Despite these limitations, our study also has several notable strengths. We included data from 16 community-based breast imaging facilities that are representative of where the majority of North Carolina women receive their breast screening examinations. The imaging examinations were from a racially-diverse population. We stratified our analyses according to whether women had dense or non-dense breasts at the time of the imaging examination. This is important, owing to the fact that density notification language recommending consideration of supplemental screening is targeted towards women with dense breasts. Our sensitivity analyses demonstrated that our results were not biased by missing data for density assessment. Finally, the language used in North Carolina's notification is similar to notification laws enacted in a majority of other states, increasing the likelihood that our results will be generalizable to other states that also do not require insurance coverage for supplemental screening. The degree of generalizability will likely also depend on the rate of supplemental screening use before the notification law, potential for insurance reimbursement, availability of supplemental screening at imaging facilities, and other factors.

It is essential that the questions regarding the risks and benefits of breast density legislation are answered in a timely manner. State notification laws have been implemented at a rapid pace and terms of the recently-passed national notification law are currently being determined. Additionally, some state notification laws were instituted with an expiration date: Utah's notification requirement expired in 2017 and California's is due to expire in 2019. If allowed to expire, reporting laws may be difficult to reinstate, which may prove important if breast density notification is shown to have beneficial effects.

Our data suggest that in North Carolina, where pre-existing supplemental screening use was low and insurance coverage for supplemental screening was not part of the legislation, supplemental screening trends did not change after enactment of the breast density notification law. However, a trend towards the replacement of screening 2-D mammography with screening DBT was observed. These results reflect the Carolina Mammography Registry experience up to two and a half years after the notification law was passed. Continued monitoring is needed to understand the potential long-term effects of breast density notification on breast cancer screening trends.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Take-Home Points

- Despite increased availability of alternative screening modalities, supplemental screening use remained low among women with dense and non-dense breasts after the implementation of breast density notification requirements.
- Women with dense breasts were slightly more likely than women with non-dense breasts to start using DBT as a standalone screening method after the notification law went into effect.
- Our findings reflect the Carolina Mammography Registry experience up to two and a half years after the notification law was passed; screening patterns may change after notification has been in place for a longer period of time.

Fig 1. Inclusion and exclusion of study examinations and participants.

The criteria for participants included in the analysis of supplemental screening use before and after breast density notification are shown above the dotted line. Screening examinations were the unit of observation for that analysis, and a total of 145,279 screening mammograms were evaluated. Criteria for the analysis of new use of screening DBT in the breast density notification period is shown below the dotted line. These data were a subset of that included in the analysis of supplemental screening use. Screening participants were the unit of analysis; data from 32,012 women were evaluated.

Fig 2. Types of supplemental screening examinations at 3, 6, and 9 months after the index mammogram.

Some women had more than one supplemental screening exam after the index mammogram. At 3 months, there were 175 supplemental screening exams associated with 171 index mammograms. At 6 months, there were 331 supplemental screening exams associated with 322 index mammograms. At 9 months, there were 502 supplemental screening exams associated with 481 index mammograms.

Table 1.

Characteristics of 145,279 screening mammograms* received by Carolina Mammography Registry participants between 2012 and 2016.

Characteristic	Year of mammogram			
	2012-2013 N=70,348		2014-2016 N=74,931	
	N	%	N	%
Age at mammogram, years				
40-49	13397	19	13162	18
50-59	20796	30	22451	30
60-69	22382	32	24803	33
70-79	13773	20	14515	19
Race				
White	45724	71	46982	68
Black	16900	26	20211	29
Other	1376	2	1491	2
Missing	6348		6247	
Menopausal Status				
Pre/Peri-menopausal	16123	35	22320	41
Postmenopausal	30289	65	32530	59
Missing	23936		20081	
Family history of breast cancer				
No	58473	83	48946	80
Yes	11812	17	11890	20
Missing	63		14095	
Personal history of breast biopsy				
No	58905	85	60320	83
Yes	10460	15	12053	17
Missing	983		2558	
Mammogram type				
Two-dimensional	68258	97	59924	80
Digital breast tomosynthesis	2090	3	15007	20
Examination BI-RADS assessment				
Negative	37085	53	36428	49
Benign	33268	47	38503	51
Breast density				
Non-dense [†]	48314	69	52323	70
Dense [‡]	22034	31	22608	30
Five-year predicted breast cancer risk				
Overall	16068	27	17048	26
Low (0 to <1%)	25741	43	27263	42
Average (1% to 1.66%)	12358	21	13931	21

Characteristic	Year of mammogram			
	2012-2013 N=70,348		2014-2016 N=74,931	
	N	%	N	%
Intermediate (1.67% to 2.49%)	4893	8	5906	9
High (2.5% to 3.99%)	577	1	772	1
Very high (>3.99%)	10711		10011	
<i>Missing</i>				
<i>Non-dense Breasts</i>				
Low (0 to <1%)	13135	32	14308	32
Average (1% to 1.66%)	19894	49	21438	48
Intermediate (1.67% to 2.49%)	5664	14	6850	15
High (2.5% to 3.99%)	1679	4	2103	5
Very high (>3.99%)	106	<1	153	<1
<i>Missing</i>	7836		7471	
<i>Dense Breasts</i>				
Low (0 to <1%)	2933	15	2740	14
Average (1% to 1.66%)	5847	31	5825	29
Intermediate (1.67% to 2.49%)	6694	35	7081	35
High (2.5% to 3.99%)	3214	17	3803	19
Very high (>3.99%)	471	2	619	3
<i>Missing</i>	2875		2540	

Abbreviations: BI-RADS - Breast Imaging Reporting and Data System; N - number

* Index screening examinations, as defined in the Methods

[†] Almost entirely fatty or scattered areas of fibroglandular density

[‡] Heterogeneously dense or extremely dense

Use of supplemental breast screening in the Carolina Mammography Registry before and after implementation of the North Carolina breast density notification law (effective January 1, 2014).

Table 2.

2012-2013		2014-2016		Rate per 1,000	Unadjusted OR* (95% CI)	Adjusted OR*† (95% CI)
Use of Supplemental Screening	N	N	N			
Within 3 months of index exam						
Non-Dense Breasts‡						
Total index exams	48260		52280			
Supplemental imaging exams	54	1.12	43	0.82	0.87 (0.59, 1.28)	0.63 (0.38, 1.04)
Dense Breasts§						
Total index exams	21997		22571			
Supplemental imaging exams	37	1.68	37	1.64	1.23 (0.79, 1.93)	1.01 (0.58, 1.75)
Within 6 months of index exam						
Non-Dense Breasts‡						
Total index exams	48210		47283			
Supplemental imaging exams	104	2.15	71	1.50	0.84 (0.63, 1.12)	0.65 (0.45, 0.95)
Dense Breasts§						
Total index exams	21948		20608			
Supplemental imaging exams	86	3.90	61	2.95	1.00 (0.71, 1.39)	0.83 (0.55, 1.25)
Within 9 months of index exam						
Non-Dense Breasts‡						
Total index exams	48146		42441			
Supplemental imaging exams	168	3.48	110	2.59	0.90 (0.72, 1.14)	0.83 (0.62, 1.11)
Dense Breasts§						
Total index exams	21903		18495			
Supplemental imaging exams	131	5.95	72	3.88	0.81 (0.60, 1.08)	0.79 (0.55, 1.13)

Abbreviations: CI – confidence interval, N-number, OR – odds ratio

*Comparing receipt of supplemental screening in pre-law (2012-2013) versus post-law (2014-2016) time periods

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Adjusted for BI-RADS exam assessment, menopausal status, and type of index mammogram
* Almost entirely fatty or scattered areas of fibroglandular density
* Heterogeneously dense or extremely dense

New use of digital breast tomosynthesis after the enactment of a breast density notification law, among Carolina Mammography Registry participants who used only two-dimensional screening mammography between 2012 and 2014.

Table 3.

	Non-dense breasts [*]		Dense breasts [†]		Unadjusted OR (95% CI)	Adjusted [‡] OR (95% CI)	Adjusted [§] OR (95% CI)
	N	%	N	%			
Total number of women	21485		9365				
Screening digital breast tomosynthesis between 2014 and 2016	8213	38	3697	39	1.05 (1.00, 1.11)	1.15 (1.08, 1.23)	1.11 (1.04, 1.18)

Abbreviations: CI – confidence interval, N=number, OR – odds ratio

^{*} Predominantly fatty or scattered fibroglandular densities

[†] Heterogeneously dense or extremely dense

[‡] Adjusted for race, age, menopausal status, and biopsy history, at the time of the 2012-2013 examination

[§] Adjusted for race, age, menopausal status, and biopsy history, at the time of the 2014-2016 examination