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The Effect of Legislation Requiring Notification of Patients with Mammographically Dense Breasts

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Abstract

Background: Mammographic breast density has been identified as an independent risk factor for breast cancer, and legislation has been introduced that mandates disclosure of density on mammography.

Methods: Retrospective review of adult women who were identified as having dense breasts on an otherwise normal mammogram during the years 2014 (pre-legislation) and 2016 (post-legislation) survey study of the 2016 cohort.

Results: Of 121 survey respondents, only 47.1% (n=57) reported that they understood that dense breasts are a risk factor for breast cancer while 90.9% (n=110) reported that they understood dense breasts could be normal. In total, 18.2% (n=22) reported they experienced anxiety or stress because of the notification of dense breasts but only 53.7% (n=65) of respondents discussed these findings with a physician. Ultimately, 93.3% (n=113) stated they believed that women should be notified of breast density. Patients were older in the 2014 group (mean 61.4 years=11.4) than 2016 (mean 57.0 years=10.7, p<0.0005). Conversely, more breasts were classified as dense in 2014 than 2016 (38.4% *vs.* 28.5%, p=0.012). Having an additional ultrasound following mammogram finding of dense breasts was also higher in 2014 (3.3% *vs.* 1.0% in 2016, p=0.089).

Conclusion: Our study was limited by small sample size but suggests that women can experience stress or anxiety related to the disclosure of breast density and may not fully understand the ramifications. Further research is needed in the effect of this legislation and recommendations for the management of these patients.

Keywords: Breast cancer; Mammography; Anxiety; Screening; Cancer

Background

It is well known that breast cancer is one of the most common cancers and the second leading cause of death in American women. There is much research regarding risk factors and appropriate screening for breast cancer, but mammography remains the gold standard for screening [1]. Unfortunately, mammogram is not perfect. There are some populations in which mammogram is less sensitive and has been found to be highly variable [2,3].

One particularly important population for which mammogram is less effective is women with dense breast tissue. Density makes interpretation of mammogram more difficult, and sensitivity for detection of cancer decreases from 98% in women with fatty breast parenchyma to 36% in women with dense breasts [2,3]. Mammographic breast density has also been identified as an independent risk factor for the development of breast cancer [4,5]. Breast density is inversely related to age and BMI [6-8]. Density on mammography is determined based on a standardized classification system using the American College of Radiology's Breast Imaging Report and Data System (BI-RADS). The categories include, "almost entirely fat (class A)," "scattered fibroglandular densities (class B)," "heterogeneously dense (class C)," and "extremely dense (class D)" [9].

Given the large population affected and the wealth of research and financial support for breast cancer, numerous laws have been enacted focusing on prevention. The Mammography Quality Standards Act (MQSA) was passed and amended over a decade ago; and was created to ensure that mammography facilities meet quality standards and that patients are provided with a written report of the findings in language the patient can understand [10]. In the last decade, multiple states have also introduced legislation that requires addition disclosure of mammography findings: density of breast tissue. In the state of Michigan, this was signed into law on January 10, 2015 and became effective on June 1, 2015. The law requires the following information to be provided to the patient: disclosure of dense breast tissue and its increased risk for breast cancer, information that dense breast tissue may obscure mammography findings and that woman should talk to their physicians regarding this information and the potential for further screening. This applies to women from class C ("heterogeneously dense") or class D ("extremely dense") by previously described BI-RADS classification. As of 2018, there are over 30 states that have mandatory notification laws and additional states with legislation pending [11].

There are multiple issues regarding the disclosure of this information to patients. The prevalence of heterogeneously dense or extremely dense breast tissue in American women is approximately 43.3%, inversely related to age and BMI [12]. This means that almost half of women undergoing a screening mammography will receive the

density notification. There is no research reviewing the effect of this new legislation on patients and limited research on change in practice after this finding. Breast density reporting can be misleading due to high inter-radiologist variability and lack of concordance between BI-RADS class reported and actual measured percent density of the breast [13]. Studies suggest that the percentage of mammograms reports as dense slightly decreases after enactment of these laws, but ultimately returns to pre-legislation percentages within 10 months [14].

Of particular importance to the healthcare provider, there is currently no consensus regarding the need for supplemental imaging and what imaging modality to use for women with dense breast tissue [10]. Potential supplemental modalities include Digital Breast Tomosynthesis (DBT), Contrast-Enhanced Digital Mammography (CE-DM), Hand-Held Ultrasound (HHUS) or Automated US (ABUS), Molecular Breast Imaging (MBI), Magnetic Resonance Imaging (MRI), and abbreviated-MRI. Certain studies have argued that molecular breast imaging (using 99mTc-sestamibi) would be the ideal supplement to mammography in dense breasts [15-17]. Others present arguments for three-dimensional automated breast US [18]. However, some of the large studies are funded by companies supporting the imaging modality [18]. Other literature argues that supplemental imaging in this population increases the detection of cancer, but also significantly increases the false positive rate [19,20]. Others indicate increased cost and benign biopsy rates with supplemental imaging, but increased cancer detection rate and lower cost per cancer detection [16].

We undertook a two-part research project assessing the impact of this legislation in our community. First, we completed a survey study evaluating patient perceptions after receiving notification of dense breasts on screening mammography. Subjects included in the survey included women had an otherwise normal mammogram in 2016, but because of legislation were notified that they have heterogeneously or extremely dense breast tissue. To evaluate a change in practice following this legislation, we retrospectively reviewed charts of two cohorts (random samples from 2014 versus 2016) to identify rates of supplemental imaging or intervention performed. We hypothesized that the notification of dense breast tissue in women following normal screening mammography can be distressing to this population and would result in increased rates of additional imaging and intervention.

Materials and Methods

Saint Joseph Mercy Oakland (SJMO) hospital is a 443-bed community teaching hospital located in Pontiac, Michigan. There are approximately 18,500 screening mammography performed each year at our institution, of which approximately 40% will be reported to have dense breasts [12]. This results in a potential sample size during one year of 7,400 subjects, so we chose a random sample of the population in order to make this study more feasible. We used a standard Krejcie and Morgan table for determining sample size of a known population created in 1970 (for a population of almost 8,000 the random sample would be 367 women).

Research plan is shown in Figure 1. Survey study included an informed consent and simple survey of 2016 sample of adult women (≥ 18 years of age) who had a normal mammogram during at Saint Joseph Mercy Oakland hospital, and were identified as having heterogeneously or extremely dense breast tissue. The survey was pre-tested on a sample size of >5 volunteers from similar demographics to target population, and adjustments were made. The final survey was sent *via* email or traditional mail to the subjects (Figure 1).

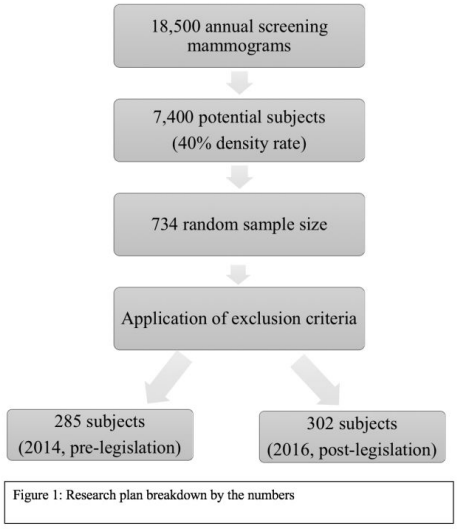

Figure 1: Research plan breakdown by the numbers.

We completed a retrospective review of women with dense breasts identified on mammogram in the year 2014 compared to the year 2016. Data collected from electronic medical records included age, race, mammogram findings, additional imaging ordered following mammography, any biopsy or additional surgical intervention following mammography, and complications. After 367 women with dense breasts were identified, exclusion criteria were applied to the population. Exclusion criteria included: women <18 years of age, women with a known abnormality or newly diagnosed abnormality on mammogram, and women with a history of breast cancer or known genetic mutation predisposing them to breast cancer. These criteria were selected to identify women with any increased risk of breast cancer or more likely to experience stress or distress given the notification of these findings.

Data was collected from electronic medical records or survey study and descriptive statistics were calculated. Associations between categorical variables were made with Chi-square. Differences between groups on continuous variables were examined using the student's t-test. P-values <0.05 were considered statistically significant. Analyses were conducted using SPSS version 22 software.

Results

There were 131 survey respondents, average age 56.5 years (Figure 2). Of respondents, 83.2% (n=109) stated their mammogram results were clearly written and understandable, 11.4% (n=15) were unsure or neutral, and 4.6% of respondents disagreed (n=6). The majority of respondents (91.6%, n=120) understood that dense breast tissue can be a normal finding and 91.6% (n=120) understood that dense breasts can make mammogram more difficult to interpret. However, only 47.3% (n=62) of respondents understood that dense breast is a risk factor for breast cancer (despite this information being a part of the notification received on mammogram due to this legislation). In addition, 38 respondents (or 29%) reported that she did not understand that dense breasts were a risk for breast cancer, and 31 respondents (23.7%) were unsure.

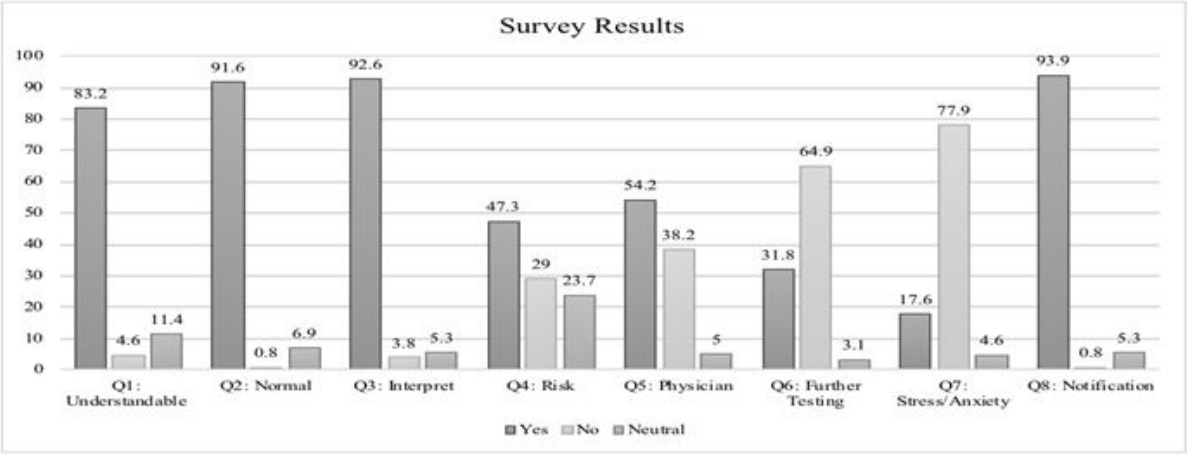

Figure 2: Survey respondent results, reported in percentage (%) of total sample size. Q1: The written report of my mammogram findings was clearly written in terms that I could understand. Q2: I understand that having dense breast tissue can be a normal finding. Q3: I understand that having dense breast tissue can make interpretation of mammogram more difficult. Q4: I understand that having dense breast tissue is a risk factor for breast cancer. Q5: I discussed my breast density results with my physician. Q6: I had further imaging or testing because of my mammogram findings. Q7: The notification of my breast density caused me stress and/or anxiety. Q8: I believe that women should be notified of their breast density.

Only 54.2% (n=71) of respondents discussed these mammogram results and density notification with a physician (38.2% or 50% responded no, while 7.6% or 10% responded unsure or not applicable). In terms of supplemental imaging or intervention, 31.8% (n=42) of respondents stated they had further testing because of mammogram results. Of note, 17.6% (n=23) of respondents stated that notification of breast density caused stress and/or anxiety; however, the vast majority of respondents (93.9%, n=123) stated that they believed women should be notified of their breast density. Only one respondent (0.8%) stated that women should not be notified of their breast density; seven respondents (5.3%) were unsure.

On retrospective review, there were 597 total subjects after inclusion and exclusion criteria application (Table 1). There were 302 subjects in 2014 cohort, and 295 subjects in the 2016 cohort. Patients were older in the 2014 group (mean 61.4 years=11.4) than 2016 (57.0 years=10.7, p<0.0005). There were more Caucasians in 2014 (75.5%) than in 2016 (26.8%, p=0.019). Associations between year and other races were not significant (p>0.05). Additionally, there was no statistically significant difference in the incidence of obesity between the two cohorts (38.4% n=94 *vs.* 41.4% n=99, p=0.5).

Variables	2014	2016	p-value
Sample Size	n=302 subjects	n=295 subjects	
Average Age	61.4 +/-11.4 (years)	57.0 +/- 10.7 (years)	<0.0005
Race			
White	75.5% (n=228)	66.8% (n=197)	0.02
Black	20.2% (n=62)	25.4% (n=75)	0.1
Hispanic	1.0% (n=3)	1.0% (n=3)	1
Asian	1.7% (n=5)	4.1% (n=12)	0.09
Other/Unknown	2.0% (n=6)	4.7% (n=14)	0.07
Obesity	38.4% (n=94)	41.4% (n=99)	0.5

Table 1: Demonstrates the sample size for each cohort and assesses variation in baseline characteristics.

More breasts were classified as dense in 2014 than 2016 (38.4% *vs.* 28.5%, Chi-square, p=0.012). Having an additional ultrasound following mammogram finding of dense breasts was statistically higher in 2014 (3.3% *vs.* 1.0% in 2016, Chi square, p=0.089). There was no statistically significant difference in rates of additional MRI performed between the two years, 2.3% in 2014 versus 0.7% in 2016 (n=7 and n=2

respectively, p=0.177). Finally, when reviewing additional "intervention" (defined as any biopsy or surgical procedure), there was no difference between 2014 and 2016 (0.3% *vs.* 0.3%, 1 subject in each group, p=1.0). There was a single patient identified with DCIS in the 2014 cohort, and no patients identified with an occult in situ lesion or invasive carcinoma (Table 2).

Variables	2014	2016	p-value
Dense Breasts	38.4% (n=116)	28.5% (n=84)	0.01
*High risk	22.80%	15.90%	0.03
Additional US	3.3% (n=7)	1% (n=3)	0.09
Other testing	2.3% (n=7)	0.7% (n=2)	0.2
Additional intervention	0.3% (n=1)	0.3% (n=1)	1

Table 2: Comparison pre-legislation (2014) versus post-legislation (2016).

Thus, there was no statistically significant difference in any of these findings between the two cohorts (p>0.05). Of note, there was a significant disparity between the survey findings and the retrospective review, with 31.8% of women in the survey stated they had additional testing after the finding of breast density.

Discussion

The survey findings highlight the potential risk of misunderstanding in patients that are informed of breast density after mammogram. It demonstrates that there is a lack of understanding on the part of patients regarding the risk of mammographically dense breast tissue. Though it is impossible to assess the full ramifications of these findings given the retrospective and survey nature of the study, they are still important to address. There is also an apparent lack of communication between patient and physician regarding these findings, and a lack of clarity in the management of these patients. As mentioned, further research regarding supplemental imaging will be necessary for this issue.

In regard to the disparity noted between the retrospective chart review and the survey results, multiple factors likely contributed. For example, the survey question did not designate either "imaging or testing" and so may represent a reporting error. Additionally, there may have been differences in the subject populations, given the potential bias inherent in survey respondents (for example, respondents may have a skewed "memory" of experience or respondents who had additional intervention may have been more likely to respond). Finally, there is potential for loss to follow up in the retrospective review, as patients may have had additional supplemental imaging at outside facilities, which would not have been retrievable on retrospective review of SJMO electronic medical records.

The survey demonstrates that some women do experience stress and/or anxiety related to the disclosure of dense breasts. Again, the full ramifications of these results are impossible to assess in this study. It may include distress regarding interactions with healthcare providers, increased breast cancer risk, additional intervention (or lack thereof), etc. Physicians and other healthcare providers who are unfamiliar with this legislation and/or the risks associated with breast density may also experience distress given the unclear management of these patients (this factor is not assessed in this study). Additionally, a wide variety of individuals from multiple disciplines will likely be impacted by the distress of these patients (not just the patients themselves), from increased referrals to breast surgeons for management to increased volume at imaging centers for supplemental imaging.

On retrospective review, there was actually a decrease in the rate of women identified as having dense breasts on mammogram after the passing of legislation requiring disclosure of breast density on mammogram. This is contrary to the finding that women were older in the 2014 group (one would expect lower rates of dense breasts in an older population 6-7). Though there were decreased rates of additional ultrasound from 2014 to 2016, we would argue there were no major or statistically significant changes in practice following this legislation at our community hospital. Similar trends have been supported in some literature, showing no major change in the percentage of breasts categorized as dense after similar legislation [14]. Regardless of the affect legislation, there remains significant inter-radiologist variability in reading mammographic density at baseline [13].

Again, there is a growing variety of research on alternatives to mammography being developed and recommended as supplemental screening in women with dense breasts. This can be overwhelming for providers, which may include primary care physicians and breast surgeons alike. Unfortunately, there remains no standard for the recommended alternative imaging in this patient population. Some disadvantages to these supplemental methods include operator dependence gadolinium exposure (MRI), cost (MRI, molecular breast imaging, tomosynthesis), (US), lack of standardization (US), lack of biopsy capability in the newer technologies (HHUS), etc.

Mammography remains the gold standard imaging modality in the screening of breast cancer, and these discussed supplemental methods do not replace mammography. Though not the main focus of this discussion, we would be remiss not to examine the cost associated issues with this topic. Many of the suggested alternatives to mammography are more expensive than mammography, and so creating guidelines to stratify women into higher risk groups for screening with these alternative methods is paramount. Additionally, the risk of false positive findings on more specific imaging modalities can result in unnecessary interventions and loss of work time in patients. As such, further research is needed to justify additional cost, patient stress, provider visits, etc. by demonstrating a positive impact including (but not limited to) decreased interval cancer rates and decrease in the diagnoses of node-positive or stage II-IV cancers.

There are several limitations to this study including a single institution study, sample size, sampling error and survey generalizability. Unique characteristics of the patient population, institutional standards regarding mammography referral, and provider differences in decision-making and treatment may not make these single institution findings generalizable to other organizations. The small sample size may alter the statistical significance and results may be different with a larger sample.

This is a retrospective study and results are subject to confounding or missing data in chart review or database collection. Random sampling in retrospective data collection may have resulted in inadvertent skewing of data that could have altered the demographics or results. There is also difficulty assessing causal and temporal relationships. All of these limitations may impact the interpretation or the generalizability of the results. Nonetheless, the data gathered from this busy community teaching hospital helps confirm that further

information is needed to address the management of this patient population.

Additionally, there are inherent limitations to a survey study. There is obvious risk of bias in respondents, restrictions in the accuracy of retrospective subject reports, and bias due to ease/accessibility of respondents. These limitations may affect the generalizability of the survey. Although pre-testing was completed, the survey was not further strengthened by pilot or other testing to establish validity or reliability.

Conclusion

This study represents a unique but limited perspective on an evolving topic in women's health that will affect providers and patients alike. Clearly, further research is needed regarding the implications of this legislation, management of women with dense breasts on otherwise normal mammogram, and the impact on the female community. There a wide variety of options for supplemental imaging, and decision making will ultimately depend on individual patient risk stratification, surgeon experience, and hospital or regional resources. Overall the repercussions of the legislation are still unfolding.

Ethical Approval

This work has been approved by the Institutional Review Board at Saint Joseph Mercy Oakalnd hospital.

Contributors

Monica Zipple MD, Shahrzad Abbassi Rahbar MD, and Amy Kirby MD provided substantial contributions to conception and design, acquisition of data, and analysis and interpretation of data; drafted the article and revised it critically for important intellectual content; and gave the final approval of the version of the article to be published. Medical students: Tanya Costa BS, Stephanie Demaso BS, Rushal Patel BS, and Raul Chavarria BS were involved in chart review. Thanks to Karen Hagglund, MS for her help with statistical planning and analysis.

Conflict of Interest

The authors have no financial or personal Conflict of Interest to declare, including employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, grants, or other funding.

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References

1. Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, et al. (2009) Screening for breast cancer: An update for the U.S. preventive services task Force. Ann Intern Med 151: 727-737.
2. Kolb TM, Lichy J, Newhouse JH (2002) Comparison of the performance of screening mammography, physical examination, and breast US and evaluation of factors that influence them: an analysis of 27,825 patient evaluations. Radiology 225: 165-175.
3. Mendelson G, Aronow WS (1998) Underutilization of measurement of serum low-density lipoprotein cholesterol levels and of lipid-lowering therapy in older patients with manifest atherosclerotic disease. J Am Geriatr Soc 46:1128-1131.
4. Boyd NF, Guo H, Martin LJ, Sun L, Stone J, et al. (2007) Mammographic density and the risk and detection of breast cancer. N Engl J Med 356: 227-236.
5. Tice JA, Cummings SR, Bindman RS, Ichikawa L, Barlow WE, et al. (2008) Using clinical factors and mammographic breast density to estimate breast cancer risk: Development and validation of a new predictive model. Ann Intern Med 148: 337-347.
6. Brisson J, Morrison AS, Kopans DB, Sadowsky NL, Kalisher L, et al. (1984) Height and weight, mammographic features of breast tissue, and breast cancer risk. Am J Epidemiol 119: 371-381.
7. Boyd NF, Lockwood GA, Byng JW, Little LE, Yaffe MJ, et al. (1998) The relationship of anthropometric measures to radiological features of the breast in premenopausal women. Br J Cancer 78: 1233-1238.
8. Vachon CM, Kuni CC, Anderson K, Anderson VE, Sellers TA (2000) Association of mammographically defined percent breast density with epidemiologic risk factors for breast cancer (United States). Cancer Causes Control 11: 653-662.
9. Breast imaging reporting and data system (2003) BI-RADS®-Mammography (4th Edtn.) Breast Imaging Atlas. American College of Radiology, Virginia, USA.
10. Ho JM, Jafferjee N, Covarrubias GM, Ghesani M, Handler B, et al. (2014) Dense breasts: A review of reporting legislation and available supplemental screening options. Am J Roentgenol 203: 449-456.
11. Durning MV (2017) Breast density notification laws by state- interactive map. Diagnostic Imaging.
12. Sprague BL, Gangnon RE, Burt V, Dietz AT, Hampton JM, et al. (2014) Prevalence of mammographically dense breasts in the United States. J Natl Cancer Inst 106: dju255.
13. Gard CC, Bowles A, Miglioretti DL, Taplin SH, Rutter CM (2015) Misclassification of breast imaging report and data system (BI-RADS) mammographic density and implications for breast density reporting legislation. Breast J 21: 481-489.
14. Bahl M, Baker JA, Chatfield MB, Brandt EK, Ghate SV (2016) Impact of breast density notification legislation on radiologists' practices of reporting breast density: A multi-state study. Radiology 280: 701-706.
15. Shermis RB, Wilson KD, Doyle MT, Martin TS, Merryman D, et al. (2016) Supplemental breast cancer screening with molecular breast imaging for women with dense breast tissue. Am J Roentgenol 207: 450-457.
16. Hruska CB, Conners AL, Jones KN, O'Connor MK, Moriarty JP, et al. (2015) Diagnostic workup and costs of a single supplemental molecular breast imaging screen of mammographically dense breasts. Am J Roentgenol 204: 1345-1353.
17. Holbrook A, Newel MS (2015) Alternative screening for women with dense breasts: breast-specific gamma imaging (molecular breast imaging). Am J Roentgenol 204: 252-256.
18. Brem RF, Tabar L, Duffy SW, Inciardi MF, Guingrich JA (2015) Assessing improvement in Detection of breast cancer with three-dimensional automated breast US in women with dense breast tissue: The SomoInsight Study. Radiology 274: 663-673.
19. Berg WA, Blume JD, Cormack JB, Mendelson EB, Lehrer D, et al. (2008) Combined screening with ultrasound and mammography vs. mammography alone in women at elevated risk of breast cancer. JAMA 299: 2151-2163.
20. Hooley RJ, Greenberg KL, Stackhouse RM, Geisel JL, Butler RS, et al. (2012) Screening US in patients with mammographically dense breasts: Initial experience with Connecticut Public Act 09-41. Radiology 265: 59-69.