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Mammographic Breast Density as a Risk Factor for Breast Cancer: Awareness in a Recently-Screened Clinical Sample

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Abstract

Background—Breast density is an established, independent risk factor for breast cancer. Despite this, density has not been included in standard risk models or routinely disclosed to patients. However, this is changing in the face of legal mandates and advocacy efforts. Little information

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exists regarding women's awareness of density as a risk factor, their personal risk, and risk management options.

Methods—We assessed awareness of density as a risk factor and whether sociodemographic variables, breast cancer risk factors and perceived breast cancer risk were associated with awareness in 344 women with a recent screening mammogram at a tertiary care center.

Findings—62% of women had heard about density as a risk factor and 33% had spoken to a provider about breast density. 18% of the sample reported that their provider indicated that they had high breast density. Awareness of density as a risk factor was greater among White women and those with other breast cancer risk factors.

Conclusion—Our results suggest that while a growing number of women are aware of breast density as a risk factor, this awareness varies. Growing mandates for disclosure suggest the need for patient education interventions for women at increased risk for the disease and to ensure all women are equally aware of their risks.

INTRODUCTION

In 2013, an estimated 232,340 women in the US were diagnosed with invasive breast cancer (American Cancer Society, 2013). Many of these women were unaware of disease risk factors, their own personal risk, and risk management strategies (Cummings et al., 2009). Several models use prevalent risk factors to estimate breast cancer risk, with the Gail model being most widely used (Chlebowski et al., 2007; Costantino et al., 1999; Gail et al., 1989; Gail et al., 2007). Several risk factors are not included in the Gail model, most notably mammographic breast density (noted as breast density from here forward). Breast density is a strong, independent breast cancer risk factor (Boyd et al., 2010; Tamimi, Byrne, Colditz, & Hankinson, 2007; Vachon et al., 2007). Women with extremely dense breasts have at least a four-fold greater breast cancer risk than women with the least density (Cummings et al., 2009; McCormack & dos Santos Silva, 2006). High breast density also decreases the sensitivity of mammography (van Gils, Otten, Verbeek, & Hendriks, 1998). The Breast Cancer Surveillance Consortium's (BCSC) validated model incorporates density as it is typically measured clinically (BI-RADS) (Tice et al., 2008). A recent systematic review argued that the combination of standard risk factors with density is the best approach for estimating risk while also acknowledging challenges in wide implementation within clinical settings (Cummings et al., 2009).

Despite this known risk, density has not been routinely communicated to patients (Colin & Schott, 2011; Vachon et al., 2007). This is due to insufficient discriminatory power and lack of independent validation (Barlow et al., 2006; Chen et al., 2006; Tice et al., 2008). Despite these concerns, rates of disclosure likely are increasing due to legal mandates in several states requiring women to be informed of their density status (Brower, 2013; Hall, 2013). These laws are heterogeneous regarding the level of detail communicated to patients and whether further discussion with a provider is suggested (Hall, 2013). Discussions with a provider, or another means of patient education, could place this health information in the context of a woman's overall breast health. For instance, a woman with high breast density, but no other risk factors, would not face substantially elevated breast cancer risks (Chen et

al. 2006). In contrast, women with extremely dense breasts and other risk factors, such as an affected first degree relative and history of previous biopsy, would be at clinically elevated risk that would suggest consideration of risk management strategies. Therefore, this information could be incorporated into decisions about screening and risk reduction (National Comprehensive Cancer Network, 2013; U.S. Preventive Services Task Force, 2002; Visvanathan et al., 2013). Currently, we do not know rates of women's awareness of breast density and whether awareness varies by sociodemographics, breast cancer risk factors or women's perceived risk of the disease. To our knowledge, only one previous study has assessed awareness of breast density (Manning et al., 2013). This study was conducted within the context of a larger study of the use of a novel ultrasound technology for women returning for additional screening following a diagnostic mammogram. As a result, study results might not reflect women having routine screening mammography.

We assessed awareness of breast density as a risk factor and awareness of personal risk in a large, diverse sample of women who received a recent screening mammogram with benign results. We determined how this awareness varied by sociodemographics, breast cancer risk factors, and perceived risk for breast cancer.

METHODS

Participants

Female participants were recruited from 2011–2013 following a normal mammogram examination (BI-RADS Category 1) at the Ourisman Center for Breast Health at Georgetown University Medical Center. Eligibility criteria included being aged 35–50, English-speaking, with no history of previous cancer or abnormality, including ductal or lobular carcinoma in situ or atypical ductal hyperplasia. While population guidelines do not recommend routine screening until aged 40 (Saslow et al., 2007) or 50 (USPSTF, 2009), we approached younger women in an effort to recruit women who might be receiving screening mammography at this age due to heightened breast cancer risk. With that said, we did not know the a priori risk of the sample or whether they were being screened as a result of risk factors known to them, such as a strong family history. The study was approved by the Institutional Review Board of Georgetown University. All participants provided written informed consent.

Eligible women received a mailed survey, written consent and HIPAA documents, a letter of invitation from the study PI (SCO) and the medical director of Ourisman (SCW), and a self-addressed stamped envelope to return study documents. We also included a self-addressed stamped postcard by which participants could decline the study. A total of 822 packets were sent to eligible patients. Of these, 453 (55%) refused participation (113 active, 340 passive refusals). 25 women were determined ineligible upon return of their survey. Our final sample of 344 women who completed questionnaires and consents represents 43% of the eligible sample. Our respondents did not differ from non-respondents on age (45.7 vs. 45.2, $t=1.84$, $p=.07$). We did not assess differences by race as chart data are known to be less reliable for this variable than patient self-report (West, Geiger et al., JNCI, 2005; Maizlish & Herrera, 2006; Gomez & Glaser, 2006). Participants received a \$20 gift card to thank them for their time.

Measures

Sociodemographic and medical variables—We assessed age, race, ethnicity, marital status, education, income, as well as known breast cancer risk factors, such as number of affected first-degree relatives and number of breast biopsies.

Breast Density Classification—We used the American College of Radiology BI-RADS to classify density. BI-RADS classification consists of four categories: 1) almost entirely fat; 2) scattered fibroglandular densities; 3) heterogeneously dense; and 4) extremely dense. The most recent mammogram available in the electronic medical record maintained by MedStar Health, the health system to which the Ourisman Center and GUMC belong, was used. Two board-certified radiologists (E.M. and E.P.) independently classified each participant. Consensus was met in an iterative fashion, continuing independent ratings to full consensus.

Risk Classification—We used Gail and BCSC risk models to calculate 5-year breast cancer risk estimates and Gail model lifetime risk (Breast Cancer Surveillance Consortium, 2013; National Cancer Institute, 2011).

Perceived breast cancer risk—We assessed perceived lifetime risk for developing a breast cancer by asking participants to rate their risk from 0 (no chance) to 100 (definitely will) (Graves et al., 2012; Schwartz et al., 2012). We assess comparative risk with the item, “Compared to the average women your age, would you say that you are more likely to get breast cancer, less likely or about as likely?” (Orom et al., 2013).

Outcomes: Awareness of breast density—Following a description of density as provided on the National Cancer Institute website (National Cancer Institute, 2012), we asked the following questions to assess awareness: if the participants had heard of breast density as a risk factor, if their health providers had spoken to them about breast density, and whether they were informed that they had extremely dense breasts.

Data analyses—We generated descriptive statistics to characterize the sample. We conducted a series of point-biserial correlations to determine whether sociodemographic variables, breast cancer risk factors or breast cancer perceived risk were associated with our awareness outcomes. We then conducted separate multivariate logistic regression analyses for meeting each of our awareness outcomes, including variables identified as statistically significant at $p < .10$ in bivariate analyses. We analyzed data with two-tailed statistical tests with a critical alpha of .05 in SPSS 22.

RESULTS

Sample characteristics

The sample was predominantly White (68%; 24% African American, 4% Asian American, 2% Native American/Pacific Islander, 2% self-identified as more than one race), college-educated (53%), and married (64%). Seven percent of the sample identified as Latina. The mean age was 46 years ($SD = 3.5$ years; range 35–50 years). 14% had a first-degree relative with breast cancer and 16% had at least one previous breast biopsy. With regards to breast

density, 19% of participants were categorized as extremely dense, 35% as heterogeneously dense, 29% as having scattered fibroglandular densities and 17% as having almost entirely fatty tissue. Eight percent of the sample had a 1.66% 5-year risk of breast cancer using the Gail model and 11% of the sample had a 1.66% 5-year risk of breast cancer using the BCSC model. 3% of women were at 20% lifetime risk according to the Gail model. The BCSC model does not provide a validated algorithm for lifetime risk.

All participants had received a recent mammogram, as this was a condition for eligibility. 91% reported having had a clinical breast exam in the previous year. 34% reported ever having had a breast ultrasound and 8.2% reported ever having had breast MRI.

Awareness of density

Sixty-two percent of the sample (N = 213) had heard of breast density as a risk factor prior to our survey. Of these, 112 had discussed breast density with their healthcare provider. Of the 112 who had spoken to their provider about breast density, 63 had been told they had dense breasts. Bivariate associations between these awareness outcomes and sociodemographic variables, breast cancer risk factors and perceived risk are presented in Table 2.

Results of the multivariate logistic regression analyses are presented in Table 3. Awareness of density as a risk factor was higher among White women (OR=2.22, $p<.05$), as women aged (OR=1.07, $p<.10$) and among those with an affected first-degree relative (OR=4.048, $p<.05$). Women with a prior biopsy (OR=2.436, $p<.05$) were more likely to have spoken to their provider about breast density. Non-White women (OR=0.28, $p<.05$), women with higher incomes (OR=3.70, $p<.10$), and those with lower perceived lifetime risks were more likely to report that they had been told they had dense breasts.

DISCUSSION

In our sample of women recently screened at a tertiary care facility, awareness of breast density as a risk factor was consistently greater among women with other breast cancer risk factors, such as an affected first-degree relative, a previous biopsy, or a combination of risk factors that placed them at elevated risk. It is unclear how they became aware of breast density as a risk factor for breast cancer. It is possible that women at increased risk were more aware due to media coverage of recent legislation mandating disclosure of density status in Virginia, which shares a media market with Washington, DC (Vozzella, 2012). These women could have brought this topic to their provider as a point of discussion to further inform their risk. In contrast, providers may be more likely to educate their patients who are at increased risk due to other clinical risk factors in the context of risk counseling.

White women also were more aware of breast density as a risk factor. These findings are similar to a previous study of women's breast density knowledge (Manning et al., 2013). In contrast, among women who had spoken to their provider, non-White women were more likely to have been told they had dense breasts. We did not have an adequate sample to allow us to perform additional analyses to determine whether these results varied by race or ethnicity, such as whether there were differences in reporting between African American

and Asian American women (24% vs. 4% of the overall sample, respectively). Some studies show that mean percent density is higher among women of Asian descent than women of other races (Nie et al., 2010). Racial and ethnic variation in the clinical communication of breast density deserves further attention in research moving forward.

Differences in general awareness of density does raise concerns regarding continued health disparities. A substantial literature points to disparities in breast cancer knowledge among African American women when compared to women of other races or ethnicities (Taioli et al., 2013; Paskett et al., 2004; Cyrus-David, 2010). Further, many studies have found that African American women experience inadequate communication about breast health (Jones et al., 2007; Perez-Stable et al., 2013). These findings serve as a reminder to continue to ensure that all women are equally aware and that cancer risk disparities are not exacerbated. Importantly, disclosure is not required by law in Washington, DC. Therefore, discussions occurred outside of these mandates.

Finally, women with lower perceived lifetime breast cancer risk and higher household incomes were more likely to have spoken to a provider about density. Given our cross-sectional data, we cannot comment on whether these variables are related to a greater likelihood to broach the topic of breast density with their provider, or whether risk factors prompted their providers to raise the topic. Given that several risk factors were accounted for in our model, our results suggest that these patient-related variables could potentially play a role in how women will interact with breast density information moving forward.

Implications for Practice and/or Policy

Breast density legislation has fueled significant controversy (Brower, 2013; Hall, 2013) and has direct implications for patient care and health care costs (Hall, 2013). As noted recently by Fajardo (2013), while advocates assert that patients will benefit from this legislation through increased awareness, there are several reasons that density has not been communicated to date that should be acknowledged as these mandates continue. These include the subjective nature of density assessment, incomplete data regarding the nature of density as an independent breast cancer risk factor, and costs related to supplemental screening that might not be covered by insurance. Also, there are no evidence-based clinical guidelines regarding how to manage women with heterogeneously or extremely dense breasts. Providers and systems required to disclose density status to patients should not ignore these caveats in their efforts to comply with these laws in order to fully inform patients regarding the nature of this health information.

Density legislation has implications for health care delivery as well. For instance, in California, more than 2 million women each year will receive a notification letter that they fall into the heterogeneously or extremely dense categories (Price et al., 2013). As noted by the California Breast Density Information Group (Price et al., 2013), risk assessment for this population as a whole would place an inordinate demand on providers. Clinical systems that trigger the presence of additional risk factors, such as a positive family history or history of atypia at a previous biopsy, would allow for the limited resource of clinician time to be focused on risk counseling for women most at risk. In contrast, women who have high breast density but few other risk factors could receive patient education outside of the clinical

encounter in order to place their high breast density in context, perhaps allaying unnecessary concern. In sum, these processes could facilitate more open communication between the clinical and advocacy communities that would assist the most effective implementation of these laws (Lee, Bassett, & Lehman, 2012).

Our study is limited by our cross-sectional data. We cannot speak to awareness in the general population, as women who have had a recent mammogram are likely more aware of breast health issues as compared to women in general. We were limited by our relatively low rate of recruitment, though this is not atypical for a mailed survey. While non-responders did not differ from our participants on age, we do not know if they differed in other important ways, such as race, ethnicity, education, or level of risk. Our recruitment of younger patients from one institution in an urban area, where patients are mostly well-educated and White or African-American, limits generalizability. Despite these limitations, our findings suggest that many young women receiving screening mammography are aware of breast density as a risk factor, but not their personal risk. Awareness varies by race as well as by breast cancer risk factors. Additional research is needed as legal mandates require disclosure to women in order to support effective understanding and use of this information. Specifically, this research should focus on ensuring the reduction in disparities in awareness, both of breast density in general and one's personal risk specifically, as well as on ensuring that women understand the effect of high density as a risk factor in the context of their overall risk. This would include placing density status in context for women who are at otherwise average risk so as not to cause undue distress, and for those at clinically elevated risk, receipt of risk counseling and interventions, such as chemoprevention, to address this risk.

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Table 1

Sociodemographic and risk factor characteristics (N = 344)

	N (%)	M (SD)
Sociodemographics		
Age		45.71 (3.54)
Education		
< College Degree	71 (19)	
College Degree	99 (29)	
Graduate/Professional Training	174 (52)	
Race		
White	235 (68)	
African American	84 (24)	
Asian American	14 (4)	
Native American or Pacific Islander	6 (2)	
Identified as more than one race	5 (2)	
Ethnicity		
Latina	29 (7)	
Non-Latina	316 (93)	
Marital Status		
Married/Partner	221 (64)	
Single/Widow/Divorced	123 (36)	
Annual Household Income		
< \$50,000	29 (9)	
\$50,000–100,000	65 (20)	
> \$100,000	201 (60)	
Refused/missing	49 (11)	
Breast cancer risk factors		
Breast Density		
Fatty	58 (17)	
Scattered densities	100 (29)	
Heterogeneously dense	121 (35)	
Extremely dense	65 (19)	
Age at menarche		
7–11	52 (16)	
12–13	194 (58)	
<14	98 (26)	
Age at first live birth		
Nulliparous	30 (9)	
<20	35 (10)	
20–24	28 (8)	
25–29	28 (8)	
30	223 (65)	

	N (%)	M (SD)
Affected first degree relative		
No	296 (86)	
Yes	48 (14)	
Breast biopsies		
0	291 (85)	
1	43 (13)	
>1	10 (3)	
Perceived breast cancer risk		
Perceived lifetime risk		28.29 (21.46)
Comparative risk		
Less likely	136 (39)	
About as likely	144 (42)	
More likely	64 (19)	

Table 2

Bivariate Associations Between Sociodemographic and Risk Variables and Awareness of Breast Density as a Risk Factor

	Awareness (N=344) r	Talked to Provider (N=213) r	Told high density (N=112) r
Sociodemographics			
Age	.14*	.13*	-.13
Education	.05	-.01	-.11
Race	.23***	.05	-.23*
Partnered/Not Partnered	.13*	.10	-.19 ⁺
Annual Household Income	.14**	.07	.01
Breast cancer risk factors			
Breast density	.01	.00	-.04
Age at menarche	.03	.02	.03
Age at first live birth	.08	.09	.03
Affected first degree relative	.24***	.18***	-.19 ⁺
Previous biopsy	.13*	.16**	-.19 ⁺
BCSC 5-year risk	.09 ⁺	.13*	-.20*
Gail 5-year risk	.16**	.09	-.17 ⁺
Gail lifetime risk	.13*	.08	-.09
Perceived risk			
Perceived lifetime risk	.10	.04	-.29**
Comparative perceived risk	.20***	.17**	-.10

⁺ $P < .10$;

* $P < .01$,

** $P < .001$.

Table 3

Multivariate Regression Analysis of Relationship Between Sociodemographic and Risk Variables and Awareness of Breast Density as a Risk Factor

	Awareness OR (CI)	Talked to Provider OR (CI)	Told high density OR (CI)
Race (White vs. Other)	2.22 (1.15–4.30)*	0.95 (0.48–1.86)	0.26 (0.08–0.93)*
Partnered/not Partnered	0.68 (0.58–2.27)	1.40 (0.70–2.81)	0.61 (0.14–2.66)
Income	1.25 (0.66–2.35)	1.25 (0.66–2.35)	3.70 (0.86–15.90) ⁺
Age	1.07 (0.99–1.16) ⁺	1.05 (0.97–1.14)	0.95 (0.82–1.11)
First-degree affected relative	4.04 (1.26–12.99)*	1.56 (0.68–3.54)	0.76 (0.17–3.42)
Prior breast biopsy	2.29 (0.96–5.45) ⁺	2.43 (1.21–4.88)*	0.36 (0.10–1.30)
Perceived lifetime risk	1.00 (0.99–1.02)	0.99 (0.98–1.01)	0.96 (0.93–0.99)*
Comparative risk	1.19 (0.74–1.91)	1.31 (0.84–2.06)	1.79 (0.69–4.66)

⁺ $P < .10$;

* $P < .05$;

** $P < .01$;

*** $P < .001$.