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Racial Differences in False-Positive Mammogram Rates: Results from the ACRIN Digital Mammographic Imaging Screening Trial (DMIST)

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Abstract

Background—Mammography screening reduces breast cancer mortality, but false-positive tests are common. Few studies have assessed racial differences in false-positive rates.

Objectives—We compared false-positive mammography rates for black and white women, and the effect of patient and facility characteristics on false-positives.

Research Design and Subjects—Prospective cohort study. From a sample of the American College of Radiology Imaging Network (ACRIN) Digital Mammographic Imaging Screening Trial (DMIST), we identified black/African American (N=3176) or white (N=26,446) women with no prior breast surgery or breast cancer.

Measures—Race, demographics, and breast cancer risk factors were self-reported. Results of initial digital **and film** mammograms were assessed. False-positives were defined as a positive mammogram (Breast Imaging Reporting and Data System [BIRADS] category 0, 4, 5) with no cancer diagnosis within 15 months.

Results—The false-positive rate for digital mammograms was 9.2% for black women compared to 7.8% for white women ($p=0.009$). After adjusting for age, black women had 17% increased odds of false-positive digital mammogram compared to whites (OR=1.17, 95% CI **1.01-1.35**, **$p=0.033$**). This association was attenuated after adjusting for patient factors, prior films and study site (OR=1.04, 95% CI 0.91-1.20, $p=0.561$). There was no difference in the occurrence of false-positives by race for film mammography.

Conclusion—Black women had higher frequency of false-positive digital mammograms explained by lack of prior films and study site. The variation in the disparity between the established technique (film) and the new technology (digital) raises the possibility that racial differences in screening quality may be greatest for new technologies.

Keywords

mammography; false-positive; race; black; African American

Introduction

Mammography screening reduces breast cancer mortality by 15%.(1) However, mammography results in a significant number of false-positive tests. A large prospective study estimated that women who are screened starting at age 40 years experienced a 61% chance of receiving a false positive result over a 10-year screening period.(2) False-positive risks include increased anxiety and stress (3), financial burdens for patient and institutions (4) as well as unnecessary procedures to confirm or refute a diagnosis which may result in increased radiation exposure from additional imaging. Concern about the rate of false positives contributed to the 2009 US Preventative Services Task Force recommendation to individualize screening decisions among women in their 40s.(5)

Racial disparities in health care are well described in many settings (6, 7) but surprisingly little is known about racial differences in screening outcomes. Breast cancer risk factors such as age, menopause status, and breast density affect the false-positive rate (2, 8, 9), and are known to differ across racial/ethnic groups. In addition, mammographic accuracy varies by institution and radiologist characteristics, and a few studies have shown poorer mammography performance at facilities that treat predominantly minority and low-income women (2, 10, 11). Lack of availability of prior images is also associated with higher false-positive rates (2, 12) and may be more common among populations with more difficulty accessing care. The effect of new technologies on potential disparities in screening outcomes is also unknown, with some studies suggesting minorities may be less likely to have access to new health care technologies (13-18) and potentially even have worse outcomes when they do have access.(19) Understanding potential racial differences in mammography outcomes is particularly important given the substantially higher breast cancer mortality among African American than white women, particularly among women under the age of 50.(20)

Given potential racial differences in patient risk factors for false-positive screens and the data suggesting that African-Americans may receive care from lower quality facilities in the US (21-24), we examined whether patient and site factors explained racial differences in false positive rates using digital and film screening mammography data from the American College of Radiology Imaging Network (ACRIN) Digital Mammographic Imaging Screening Trial (DMIST). (25-29)

Methods

Study Population

ACRIN DMIST compared the diagnostic accuracy of digital mammography to film screen mammography, and the methods and results have been published previously (30, 31) and the study protocol is available on the ACRIN website. In brief, DMIST enrolled 49,528 asymptomatic women with no history of breast cancer treated with lumpectomy from 2001-2003 who were undergoing screening at 33 sites in the U.S. and Canada. Participants received both digital and film mammogram at entry to the study and were followed through cancer diagnosis or subsequent follow-up mammogram performed 10-15 months after initial

screening mammogram. Digital and film mammograms were independently evaluated. Informed consent was obtained from all participants and the DMIST protocol was approved by the institutional review boards (IRB) at all study sites. Because de-identified data was used for the current analysis, our study was exempt from IRB review at the University of Pennsylvania. Per ACRIN policy, we were provided with data from a random sample of 75% of the trial participants (N=32,069), and our study population included women who reported no prior breast surgery, mastectomy, or malignant biopsy and who identified their race as white (N=26,446) or black (N=3,176).

Outcome Measures

Both film and digital mammograms were performed at study entry and interpreted independently by two radiologists. For both film and digital mammography, a negative screen was defined as a mammogram with Breast Imaging Reporting and Data System (BIRADS) category 1 (Negative) 2 (Benign), or 3 (Probably Benign) assessment. A positive screen was defined as a mammogram with BIRADS 0 (Incomplete), 4 (Suspicious Abnormality), or 5 (Highly Suggestive of Malignancy). These definitions were used in the original DMIST study (31). As in the DMIST study, cancer status was ascertained within 15 months of screening mammogram. Cancer status was based on biopsy pathology reports when biopsy was performed, or based on the follow-up mammogram at 11-15 months. If a participant did not return for follow-up mammography during this interval, breast cancer status was ascertained through other information such as medical records, report of the participant, family member or physician, etc.(30) Therefore, a false-positive screen was defined as a positive mammogram screen (BIRADS 0, 4, 5) with no subsequent diagnosis of cancer within the 15 month follow-up period.

Statistical Analysis

Outcomes of mammography were compared for white and black women using Chi square tests separately for digital and film mammography. For each of the 33 participating sites, the percent of black participants and the percent of false-positive mammograms were calculated, and the Pearson's correlation between percent black patients and percent false-positive screens was assessed. Multivariate logistic regression was used to estimate the odds of false-positive mammograms by race. Models were fit sequentially adjusting for age (<50, 50 yrs), patient factors (menopause status, breast density, age at menarche, birth control use, estrogen replacement therapy use, age at first birth, breastfeeding, prior biopsy, first or second degree family history of breast cancer), and availability of prior mammography films at the time of screening mammogram interpretation. **Standard errors were adjusted for clustering within site.** In addition we used generalized linear mixed modeling (PROC GLIMMIX) to account for the effect of study site. Study site was included in the model as a G-side random effect. The interactions of race with age, menopause status, breast density, and prior films were assessed since these factors are known to be associated with false-positive mammograms. Sequential models were estimated first for results of digital mammography and then for results film mammography. All statistical tests were two-sided with an alpha of 0.05. Analyses were performed using **STATA version 13 (College Station, TX) and SAS version 9.3 software (Cary, NC).**

Results

The baseline characteristics of the study population are shown in Table 1. Black participants were younger than white participants, had a different distribution of most reproductive risk factors, and were less likely to report a family history of breast cancer. Black participants were less likely to have used birth control or estrogen replacement therapy. In addition, black participants were more likely to lack prior films at the time of screening interpretation than whites (13.2% vs. 8.7%). Black women were less likely to have dense breasts than white women ($p<0.001$).

Among digital screening mammograms, black participants were significantly more likely to have a positive screen compared to white participants (Table 2, 9.5% vs. 8.4% $p=0.027$). Nearly all (99%) of the positive screens were initially coded BIRADS 0. There was no difference in cancer detection by race, though the number of cancers diagnosed among black women was small ($N=25$ vs $N=252$ among whites, $p=.359$). The false-positive rate was 9.2% for black women compared to 7.8% for white women ($p=0.009$). For film mammography, there were no racial differences in initial screening result, cancer diagnosis, or screening outcomes (Table 2).

Figure 1 plots the total percent of false-positive exams for digital mammography by the percent black patients enrolled for each study site. There was a moderate positive correlation between the percent of black participants at a study site and the site's digital mammography false-positive rate that was of borderline statistical significance (Figure 1 $r=0.34$, $p=0.050$). **The** correlation was slightly attenuated to $r=0.26$ ($p=0.164$) after removing the three sites with the highest proportion of black patients.

The results of logistic regression estimating the odds of false-positive **digital mammography** are shown in Table 3. **For digital mammography**, after adjusting for age, black women had 17% increased odds of false-positive mammograms compared to whites (Table 3, Model 1, OR=1.17, **95% CI 1.01-1.33, $p=0.033$**). As expected, younger age and higher breast density were associated with increased odds of false-positive mammography; however, the odds ratio for the association between race and false positive screen was similar after adjusting for additional patient factors (Model 2, OR=1.15, **95% CI 0.97-1.35, $p=0.100$**). Women lacking prior films were three times more likely to have a false positive mammogram than those with comparison films available (Model 3, OR=3.02, **95% CI 2.54-3.60, $p<0.001$**) and the odds ratio for race was attenuated and no longer statistically significant after adjusting for prior films. (Model 3, OR=1.09, **95% CI 0.94-1.27, $p=0.245$**). Finally, there was significant variation in false-positives across study sites (Model 4, covariance parameter=0.151, SE=0.044, $p<0.001$), and the odds ratio for race was further attenuated when the effect of study site was included (Model 4, OR=1.04, 95% CI 0.91-1.20, p -value=0.561). There were no significant interactions between race and age, breast density, or prior films with respect to false-positives. Regression analysis was repeated for film mammography, and there was no racial difference in false-positives for blacks compared to white women in any of the models (Table 4).

Discussion

Black participants in the ACRIN DMIST trial had 17% greater odds of having a false-positive digital mammogram compared to white participants after adjusting for age. The absence of prior films and study site **were** stronger determinants of the disparity in false-positives than patient factors **such as age, menopause status, or breast density**. This difference was unique to the new technology of digital mammography in DMIST, as no racial difference in false-positives was seen with film mammography, the established screening technique.

Studies in multiple areas of health services have highlighted the connection between slower diffusion of new technology and racial and socioeconomic disparities in health outcomes. (13-18) However, this has usually been due to minorities not having access to the new and improved technology. Our results may suggest that even when black women had access to digital mammography, they received less benefit and more harms in terms of false-positives than their white counterparts because they were less likely to have comparison films and because they were screened at study sites with higher overall false-positive rates. Studies have documented a learning curve for digital mammography in which recall rates increased after implementation of digital mammography and decreased over time.(32, 33) The effect of the learning curve appears to have been magnified in black women since they were less likely to have comparison films available at the time of digital mammography evaluation. Our results with DMIST participants may reflect a transient racial difference in digital mammography accuracy during implementation of a new screening technology, but additional data tracking the false-positive rate over time after digital mammography implementation would be needed to test this hypothesis.

Only a few prior studies have examined racial differences in false-positive mammography rates. Unlike our results, among women undergoing mammography from 1994-2000 in the Carolina Mammography Registry, sensitivity and specificity of screening mammography were similar for black and white women.(34) However, among the same population the specificity of diagnostic mammography, that is, mammograms performed after an abnormal screening exam or symptoms, was 25% lower for black women compared to whites.(35) Similarly, a study of the Breast Cancer Surveillance Consortium found overall callback rates for blacks and whites were comparable, but there was a higher probability of false-positive biopsy recommendations for blacks compared to whites.(36) Of note, the vast majority of screening exams in both of these cohorts were film rather than digital mammograms, and these studies controlled for first mammogram, but not use of comparison films at interpretation.

Our finding of higher false-positive rates among facilities treating a greater proportion of black participants is consistent with several prior studies showing differences in mammography quality for sites treating predominantly minority and low-income women. (22, 23, 37) Facility level variation in false-positive rates may reflect quality of mammography screening and be a result of practice patterns, radiologist factors, and facility resources. Radiologists with greater training and experience reading mammograms tend to have lower false-positive rates. (11, 38, 39) A study of 40 mammography facilities in

Chicago found that black women were less likely to have mammograms at academic facilities or facilities where breast imaging specialists exclusively read mammograms. (24) We did not have data on such facility characteristics in the current study. We observed a significant effect of study site on false-positive rates despite the fact that the study was performed in the context of a clinical trial with a defined protocol for screening and follow-up. Our data may therefore underestimate the true effect of mammography facility on racial differences in false-positives.

The absence of prior mammogram films was a very strong predictor of false-positives, which is consistent with several studies noting higher specificity when comparison mammograms are available (40-44). The greater proportion of black women who lacked prior films may reflect patient or facility level effects. Lack of prior films may be associated with underutilization of screening mammography, as women who were never screened would not have prior films, and women with a longer screening interval may be less likely to have readily available films. DMIST study participants were asked to report the year of their first baseline mammogram. If year of first mammogram was the same as the study year, we assumed the study mammogram was the first mammogram, unless prior films were available. Using this definition, 3% of study participants were first time screeners, and black women were more likely to be having their first screening mammogram than whites (4.2% vs. 2.8% $p<0.001$). However, when baseline mammograms were excluded, black women still had higher occurrence of false-positive digital screens than whites (8.7% vs. 7.6%, $p=0.037$) and the results of logistic regression models were similar when first mammograms were excluded. In addition to frequency of screening, lack of prior films could also reflect greater movement of patients across facilities from one screening to the next, as well as facility level differences in procedures to obtain and share prior films. Increasing use of electronic medical records may facilitate access to digital mammography images, and steps to streamline transfer of images across institutions could result in lower false-positive recalls.

The absolute difference in the digital mammography false-positive rate was 1.4% higher for blacks than whites. Though this absolute difference may seem relatively small at first glance, the higher burden of false-positives for black women would be substantial given the large numbers of women who undergo screening mammography in the U.S. While much attention has rightfully been paid to screening utilization as a determinant of breast cancer disparities, disparities in screening quality are less well studied. False-positive mammograms can be burdensome for patients, causing anxiety and leading to additional unnecessary healthcare utilization. (2, 4, 45-47) While the ACA mandates coverage of screening mammograms, diagnostic mammograms may not be covered by insurers, and therefore higher false-positive rates may translate to increased financial burden for black patients. Additional imaging of false-positive screens also increases radiation exposure, though the radiation dose of mammography screening is low. (48, 49)

The current study has several limitations. The study population was women enrolled in a clinical trial of digital mammography effectiveness, and this enrolled population and the participating mammography screening sites may not be representative of mammography screening across the U.S. In addition, women in the study were imaged with both digital and

film mammography at baseline, which is not reflective of clinical practice. However digital and film mammograms were evaluated independently and we defined false-positives separately for digital and film mammography. As of June 2014, 95% of accredited mammography machines in the U.S. are full-field digital. (50) (50) Data on participants' BMI and characteristics of screening facilities were unavailable, so we could not evaluate their effect on false-positives. In addition, we lacked data on radiologist characteristics, such as training and interpretive volume, which have been shown to influence false-positive rates (11, 38, 39).

Despite these limitations, our study is unique in its ability to compare screening outcomes for a large sample of black and white women with data on breast cancer risk factors. Furthermore, the setting of a clinical trial increases the consistency of methods across study sites, and intensive follow-up procedures were followed across sites. Our results demonstrate a difference in the frequency of false-positive mammograms between black and white women with the newly implemented screening tool, digital mammography, which was mediated by access to prior screens and study site. Given the difference in outcomes of the new screening technology by race, more attention should be paid to ensuring equity and quality in the early adoption of new cancer screening technologies.

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Figure 1. Correlation of Percent False-positives with Percent Black Patients

Table 1
Baseline Characteristics of ACRIN DMIST Trial Participants (N=29,622)

	White N=26,446		Black N=3,176		p-value
	N	%	N	%	
Age at enrollment					<0.001
<45	4443	16.8	621	19.6	
45-50	4359	16.5	596	18.8	
50-54	4937	18.7	614	19.3	
55-59	4400	16.6	485	15.3	
60-64	3356	12.7	330	10.4	
65	4951	18.7	530	16.7	
Menopause status					<0.001
Pre/Perimenopausal	9859	37.3	1132	35.6	
Postmenopausal	16048	60.7	1940	61.1	
Age at menarche					<0.001
<12	5153	19.5	790	24.9	
12 or 13	15380	58.2	1563	49.2	
>=14	5763	21.8	776	24.4	
Birth Control use					<0.001
No	8579	32.4	1198	37.7	
Yes	17867	67.6	1978	62.3	
Estrogen Replacement use					<0.001
No	13760	52	2043	64.3	
Yes	12686	48.0	1133	35.7	
Age at first full term pregnancy					<0.001
Nulliparous	7089	26.8	707	22.3	
<20	2284	8.6	935	29.4	
20-24	6661	25.2	763	24.0	
25-29	5771	21.8	437	13.8	

	White N=26,446		Black N=3,176		p-value
	N	%	N	%	
30+	4498	17.0	280	8.8	
Breastfeeding					<0.001
No	14024	53.0	2124	66.9	
Yes	12422	47.0	1052	33.1	
Prior Breast biopsy					0.540
No	20673	78.2	2502	78.8	
Yes	5773	21.8	674	21.2	
Family History of Breast Cancer					
No	16209	61.3	2244	70.7	<0.001
Yes (First or Second Degree)	10237	38.7	932	29.3	
Prior films					<0.001
Present with interpretation	24154	91.3	2758	86.8	
Not present with interpretation/No prior films	2292	8.7	418	13.2	
BIRADS Breast Density					<0.001
Almost entirely fat	2969	11.2	497	15.6	
Scattered fibroglandular densities	11003	41.6	1468	46.2	
Heterogeneously dense	10707	40.5	1069	33.7	
Extremely dense	1767	6.7	142	4.5	

Table 2

Screening Mammography Results

		White N=26,446		Black N=3,176	
Digital Mammography		N	%	N	%
Initial Screening Result					
Negative (BIRADS 1, 2, 3)		24229	91.6	2873	90.5
Positive (BIRADS 0, 4, 5)		2217	8.4	303	9.5
Cancer Diagnosis		252	1.0	25	0.8
Screening outcome					
True Positive		145	0.5	12	0.4
False Positive		2072	7.8	291	9.2
True Negative		24122	91.2	2860	90.1
False Negative		107	0.4	13	0.4

Film Mammography		N	%	N	%
Initial Screening Result					
Negative (BIRADS 1, 2, 3)		24159	91.4	2887	90.9
Positive (BIRADS 0, 4, 5)		2287	8.7	289	9.1
Cancer Diagnosis		252	1.0	25	0.8
Screening outcome					
True Positive		132	0.5	16	0.5
False Positive		2155	8.2	273	8.6
True Negative		24039	90.9	2878	90.6
False Negative		120	0.5	9	0.3

Table 3
Logistic Regression of the Odds of False-Positive Digital Mammogram

	Model 1: Age Adjusted				Model 2: Patient Factors*				Model 3: Patient Factors, Prior Films*				Model 4: Site as Random Effect*			
	OR	95% CI	p-value		OR	95% CI	p-value		OR	95% CI	p-value		OR	95% CI	p-value	
Digital Mammography																
Black vs. White	1.17	1.01-1.35	0.033		1.15	0.97-1.35	0.100		1.09	0.94-1.27	0.245		1.04	0.91-1.20	0.561	
Age <50 vs 50 yrs	1.33	1.19-1.48	<0.001		1.26	1.10-1.45	0.001		1.12	0.98-1.29	0.102		1.12	0.99-1.27	0.081	
Menopause																
Pre/Peri vs Post					1.11	0.97-1.28	0.142		1.05	0.91-1.22	0.489		1.10	1.00-1.21	0.163	
Breast Density																
Almost Entirely Fat					1.00	Reference			1.00	Reference			1.00	Reference		
Scattered fibroglandular					1.83	1.47-2.29	<0.001		1.87	1.48-2.38	<0.001		1.86	1.56-2.23	<0.001	
Hetero dense					2.16	1.74-2.69	<0.001		2.24	1.78-2.82	<0.001		2.25	1.88-2.70	<0.001	
Extremely dense					1.72	1.32-2.23	<0.001		1.75	1.33-2.30	<0.001		1.84	1.44-2.35	<0.001	
Prior Films																
None/Not present vs. present with interpretation									3.02	2.54-3.60	<0.001		3.27	2.90-3.68	<0.001	
Site covariance parameter																
Standard error														0.151		<0.001
														0.044		

* Patient factors additionally include: age menarche, birth control, ERT, Age first birth, breastfeeding, prior biopsy, family history. Models are sequential.

Table 4
Logistic Regression of the Odds of False-Positive Film Mammogram

Film Mammography	Model 1: Age Adjusted			Model 2: Patient Factors *			Model 3: Patient Factors, Prior Films *			Model 4: Site as Random Effect *		
	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
Black vs. White	1.04	0.90-1.21	0.528	1.02	0.88-1.18	0.797	0.96	0.82-1.12	0.594	0.93	0.80-1.08	0.327
Age <50 vs 50 yrs	1.36	1.23-1.50	<0.001	1.23	1.09-1.39	0.001	1.08	0.96-1.23	0.197	1.09	0.96-1.24	0.174
Menopause												
Pre/Peri vs Post				1.22	1.08-1.37	0.001	1.16	1.03-1.31	0.015	1.20	1.05-1.37	0.008
Breast Density												
Almost Entirely Fat				1.00	Reference		1.00	Reference		1.00	Reference	
Scattered fibroglandular				2.13	1.73-2.61	<0.001	2.17	1.77-2.67	<0.001	2.16	1.77-2.64	<0.001
Hetero dense				2.86	2.25-3.64	<0.001	2.98	2.34-3.77	<0.001	2.93	2.40-3.59	<0.001
Extremely dense				2.12	1.53-2.91	<0.001	2.14	1.56-2.92	<0.001	2.07	1.61-2.66	<0.001
Prior Films												
None/Not present vs. present with interpretation							3.18	2.66-3.81	<0.001	3.37	3.00-3.79	<0.001
Site covariance parameter												
Standard error											0.228	<0.001
											0.065	

* Patient factors additionally include: age menarche, birth control, ERT, Age first birth, breastfeeding, prior biopsy, family history. Models are sequential.