Identifying Women at High Risk for Breast Cancer Using Data From the Electronic Health Record Compared With Self-Report

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PURPOSE A barrier to chemoprevention uptake among high-risk women is the lack of routine breast cancer risk assessment in the primary care setting. We calculated breast cancer risk using the Breast Cancer Surveillance Consortium (BCSC) model, accounting for age, race/ethnicity, first-degree family history of breast cancer, benign breast disease, and mammographic density, using data collected from the electronic health records (EHRs) and self-reports.

PATIENTS AND METHODS Among women undergoing screening mammography, we enrolled those age 35 to 74 years without a prior history of breast cancer. Data on demographics, first-degree family history, breast radiology, and pathology reports were extracted from the EHR. We assessed agreement between the EHR and self-report on information about breast cancer risk.

RESULTS Among 9,514 women with known race/ethnicity, 1,443 women (15.2%) met high-risk criteria based upon a 5-year invasive breast cancer risk of 1.67% or greater according to the BCSC model. Among 1,495 women with both self-report and EHR data, more women with a first-degree family history of breast cancer (14.6% v 4.4%) and previous breast biopsies (21.3% v 11.3%) were identified by self-report versus EHR, respectively. However, more women with atypia and lobular carcinoma in situ were identified from the EHR. There was moderate agreement in identification of high-risk women between EHR and self-report data (κ , 0.48; 95% CI, 0.42-0.54).

CONCLUSION By using EHR data, we determined that 15% of women undergoing screening mammography had a high risk for breast cancer according to the BCSC model. There was moderate agreement between information on breast cancer risk derived from the EHR and self-report. Examining EHR data may serve as an initial screen for identifying women eligible for breast cancer chemoprevention.

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INTRODUCTION

Breast cancer is the most common malignancy among women in the United States, leading to more than 40,000 deaths in 2017.¹ Therefore, the primary prevention of breast cancer is a major public health issue. Breast cancer risk assessment and available interventions for prevention, such as chemoprevention with selective estrogen receptor modulators and aromatase inhibitors, are underused in the United States despite several randomized controlled trials demonstrating a relative risk reduction in breast cancer incidence of up to 50% to 65% among women at high risk.²⁻⁶ Approximately 15% of women between the ages of 35 and 79 years in the United States meet high-risk criteria and are eligible for breast cancer chemoprevention, but only a small fraction of women agree to take the necessary medications.^{7,8} Reasons for low uptake of chemoprevention include concerns about adverse effects, inadequate time for counseling,

and lack of a survival benefit demonstrated in clinical trials.^{7,9} In addition, a large proportion of women may be unaware of their high-risk status because of a lack of routine breast cancer risk assessment in primary care.¹⁰

Known breast cancer risk factors include age, family history of breast cancer, and mammographic density.^{11,12} In addition, women with benign breast disease such as atypical hyperplasia and lobular carcinoma in situ (LCIS) are four to ten times more likely to develop breast cancer compared with women with nonproliferative breast disease.¹³ The Breast Cancer Surveillance Consortium (BCSC) risk calculator estimates a woman's 5-year and 10-year risk of invasive breast cancer and has been well validated at the population level.^{14,15} The model was developed in a community-based, ethnically and geographically diverse sample that broadly represents the population in the United States. The BCSC model accounts for

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age, race/ethnicity, first-degree family history of breast cancer, previous benign breast biopsy (including non-proliferative lesions, proliferative changes with or without atypia, and LCIS), and mammographic density. Women with a 5-year invasive breast cancer risk of 1.67% or greater are defined as high risk and may be eligible for chemoprevention.

For this study, our objective was to use clinical data extracted from the electronic health record (EHR) to calculate breast cancer risk according to the BCSC model and to compare this with self-reported data on breast cancer risk factors. We hypothesized that we can accurately identify women at high risk for breast cancer using data from EHRs.

PATIENTS AND METHODS

Study Population and Selection Criteria

We gathered breast cancer risk factor information among women who underwent screening mammography at Columbia University Irving Medical Center (CUIMC) in New York, NY, from 2014 through 2016. Eligibility criteria for the study included the following: female sex, age 35 to 74 years, no prior history of invasive breast cancer or ductal carcinoma in situ (DCIS), no previous breast augmentation, and no previous mastectomy. We excluded those with missing data for race/ethnicity. We obtained written informed consent from a subset of English- or Spanish-speaking women to complete a self-administered survey on breast cancer risk factors and to access their medical records. This study was approved by the Institutional Review Board at CUIMC.

Data Collection From the EHR

Information on age, race/ethnicity, first-degree family history of breast cancer, breast pathology, and mammogram reports was extracted from the EHR. At CUIMC, we have a standards-based clinical data warehouse, which contains more than 25 years' worth of comprehensive, longitudinal EHRs for more than 4.5 million racially, ethnically, and socioeconomically diverse patients. Structured family history of breast cancer (yes/no) in the patient's mother, sister(s), or daughter(s) was extracted from the outpatient clinic notes from primary care providers (internists, family medicine practitioners, or gynecologists) or was categorized as unknown if there was no documentation in the EHR. Breast pathology reports were manually classified as nonproliferative lesion (ie, fibroadenoma, cysts, duct ectasia, apocrine metaplasia, fibrosis), proliferative changes without atypia (ie, intraductal papilloma, radial scar, sclerosing adenosis, epithelial hyperplasia without atypia) or with atypia (ie, atypical ductal or lobular hyperplasia), LCIS, or prior biopsy with unknown diagnosis, based upon the most advanced lesion for each woman if she had multiple breast biopsies.¹³ No documentation of a prior breast biopsy in the EHR was classified as "none." The most recent mammogram report for each woman was

scanned for the following key terms to determine breast density: "almost entirely fatty," "scattered fibroglandular densities," "heterogeneously dense," or "extremely dense."¹⁶ Since 2013, reporting of breast density has been mandatory in New York State.¹⁷

Diagnostic codes (International Classification of Diseases, Ninth Revision [ICD-9] or ICD-10) were used to exclude women with a prior history of breast cancer. In addition, mammogram reports were scanned for any references to breast implants to exclude women with prior breast augmentation from the analysis.

Data Collection From Self-Reported Questionnaires

We enrolled women undergoing screening mammography in the Know Your Risk: Assessment at Screening (KYRAS) survey study.¹⁸ After providing informed consent, all participants completed a baseline self-administered questionnaire in English or Spanish. We collected information on demographics and breast cancer risk factors. Race was reported as white, black, Native American, Asian, or other. Those who listed multiple races were classified as "other/multiple races." Ethnicity was either Hispanic or non-Hispanic. Participants were asked about first-degree family history of breast cancer: "How many of your direct relatives—mother, sisters, and/or daughters—have had breast cancer?" with responses of 0, 1, more than 1, or don't know. They were also asked about prior breast biopsies: "Have you ever had a biopsy of your breast?" with follow-up questions such as "Have you had at least one breast biopsy with atypia or atypical hyperplasia?" and "Have you had at least one breast biopsy with lobular carcinoma in situ?" with responses of yes, no, or don't know.

Breast Cancer Risk Assessment

Five-year and 10-year risk of invasive breast cancer was calculated using the BCSC risk calculator. The tool takes into account current age (35 to 74 years), race/ethnicity (white, black, Hispanic, Asian, Native American, other/multiple races, unknown), first-degree family history of breast cancer (yes, no, unknown), prior benign breast biopsy (none, prior biopsy with unknown diagnosis, non-proliferative lesion, proliferative changes with or without atypia, and LCIS), and mammographic density (almost entirely fatty, scattered fibroglandular densities, heterogeneously dense, and extremely dense). Classification of benign breast disease was based upon a manual review of pathology reports by a trained physician (J.E.M.), and classification of mammographic density was assessed by a key word search of mammography reports. Women with a 5-year invasive breast cancer risk of 1.67% or greater were defined as high risk and may be eligible for chemoprevention. Of note, the BCSC model excluded women with a prior history of invasive breast cancer or DCIS, as well as those with breast augmentation or a prior mastectomy which has an impact on the interpretation of mammographic density.

Statistical Analysis

Patients were stratified according to breast cancer risk, and descriptive statistics of sociodemographic and clinical characteristics were generated. Descriptive analysis was also used to compare the distribution of breast cancer risk factors between EHR data and self-report data. Inter-rater agreement analysis was conducted to compare risk information from the EHR and self-reported questionnaire data for the subset of participants enrolled in the KYRAS survey study. Raw agreement (percentage of EHR information that resulted in correct self-reported risk group classification) was calculated. The weighted Cohen's κ statistic and 95% CIs were then used to measure agreement between self-report and EHR data on breast cancer risk status (low to average risk v high risk). We also estimated the simple correlation coefficient to determine how the results of EHR data agreed with self-report data in terms of continuous 5-year invasive breast cancer risk according to the BCSC model. Data were analyzed using SAS, version 9.4 (SAS Institute, Cary, NC).

RESULTS

A total of 15,836 women underwent screening mammograms during the study period from 2014 to 2016 (Fig 1). Of the 6,322 patients (39.9%) excluded from the analysis, 1,444 (9.1%) were not within the age range of 35 to 74 years, 4,250 (26.8%) had missing information for race/

ethnicity, 336 (2.1%) had a previous diagnosis of invasive breast cancer, 37 (0.2%) had DCIS, 281 (1.8%) had prior breast augmentation, and 1 had a previous mastectomy. Among eligible women ($n = 9,514$) with EHR data for BCSC risk calculation, 1,443 women (15.2%) met high-risk criteria, based upon a 5-year invasive breast cancer risk of 1.67% or greater. When we conducted a sensitivity analysis that included those with missing race/ethnicity data as "unknown", 19.7% of women ($n = 2,719$) met high-risk criteria according to the BCSC model. A subset of 1,495 patients (15.7%) had breast cancer risk factor data available from both the EHR and a self-administered questionnaire.

Table 1 summarizes demographic and breast cancer risk factors for eligible women with EHR data ($n = 9,514$), stratified by breast cancer risk status (low to average risk v high risk according to the BCSC model). The median age was 57 years (range, 35 to 74 years). More than 60% were Hispanic, 4.2% had a first-degree family history of breast cancer documented as structured data in the EHR (87.2% had missing data on family history of breast cancer), 35.3% had high breast density (heterogeneously or extremely dense), and 10.6% had a prior benign breast biopsy.

Table 2 describes the demographic characteristics and breast cancer risk factors of the subset of women ($n = 1,495$) with both EHR data and data from a self-administered questionnaire. Comparing patient-reported

FIG 1. Patient inclusion/exclusion diagram. (*) Some participants met multiple exclusion criteria. (†) Five-year invasive breast cancer risk according to the Breast Cancer Surveillance Consortium model.

TABLE 1. Demographic Characteristics Associated With Breast Cancer Assessment Among Women Undergoing Screening Mammography at the Columbia University Medical Center (New York, NY; 2014-2016)

Characteristic	Low to Average Risk for Breast Cancer* (n = 8,071 [84.8%])		High Risk for Breast Cancer† (n = 1,443 [15.2%])		Total (n = 9,514 [100%])	
	No.	%	No.	%	No.	%
Age (years)						
35-39	31	0.4	0	0.0	31	0.3
40-44	933	11.6	7	0.5	940	9.9
45-49	1,306	16.2	25	1.3	1,331	14.0
50-54	1,502	18.6	109	7.6	1,611	16.9
55-59	1,332	16.5	240	16.6	1,572	16.5
60-64	1,322	16.4	339	23.5	1,661	17.5
65-69	988	12.2	396	27.4	1,384	14.6
70-74	657	8.1	327	22.7	984	10.3
Race/ethnicity						
Hispanic	5,421	67.2	368	25.5	5,789	60.9
Non-Hispanic white	964	11.9	675	46.8	1,639	17.2
Non-Hispanic black	906	11.2	196	13.6	1,102	11.6
Asian	294	3.6	18	1.3	312	3.3
Native American	5	0.1	1	< 0.1	6	< 0.1
Other	481	6.0	185	12.8	666	7.0
First-degree family history of breast cancer						
Yes	192	2.4	204	14.2	396	4.2
No	756	9.4	63	4.4	819	8.6
Unknown	7,123	88.3	1,176	82.0	8,299	87.2
Mammographic density						
Almost entirely fatty	679	8.4	11	0.8	690	7.3
Scattered fibroglandular density	4,815	60.0	652	45.2	5,467	57.5
Heterogeneously dense	2,487	30.8	730	50.6	3,217	33.8
Extremely dense	90	1.1	50	3.5	140	1.5
Breast pathology						
No prior biopsy	7,670	95.0	839	58.1	8,509	89.4
Prior biopsy	398	4.9	429	29.7	827	8.7
Proliferative changes with atypia	3	< 0.1	142	9.8	145	1.5
Lobular carcinoma in situ	0		33	2.3	33	0.4

*Low to average risk, women with a 5-year invasive breast cancer risk of less than 1.67% according to the Breast Cancer Surveillance Consortium (BCSC) model.

†High risk, women with a 5-year invasive breast cancer risk of 1.67% or greater according to the BCSC model.

versus EHR data, more women with a first-degree family history of breast cancer (14.6% v 4.4%) and benign breast biopsies (21.3% v 11.3%) were identified with patient-reported data. Of note, fewer women with atypia or LCIS were identified from self-report versus EHR data (1.1% v 2.3%). However, the proportions of high-risk women identified with self-report compared with EHR data were comparable (15.0% v 14.6%).

Table 3 summarizes the agreement in breast cancer risk status (high risk v low to average risk) between self-reported

data compared with EHR data. Raw agreement (precision) was 86.9%. Weighted κ for group classification was 0.48 (95% CI, 0.42-0.54), demonstrating moderate agreement between EHR and self-reported data. If self-reported data are considered the gold standard, then sensitivity for identifying high-risk women with EHR data was 55%, specificity was 93%, positive predictive value was 56%, and negative predictive value was 92%. We conducted simple correlations to determine whether 5-year invasive breast cancer risk according to the BCSC model using EHR

TABLE 2. Breast Cancer Risk Status Based Upon Risk Factors Derived From Patient Reports and Electronic Health Records for Women Undergoing Screening Mammography at the Columbia University Medical Center (New York, NY; 2014 to 2016; N = 1,495)

Characteristic	Patient-Reported				Electronic Health Record			
	Low to Average Risk* (n = 1,271 [85.0%])		High Risk† (n = 224 [15.0%])		Low to Average Risk* (n = 1,277 [85.4%])		High Risk† (n = 218 [14.6%])	
	No.	%	No.	%	No.	%	No.	%
Age, years								
35-39	9	0.7	0	0.0	7	0.6	0	
40-44	152	12.0	0	0.0	126	9.9	0	
45-49	187	14.7	4	1.8	173	13.6	4	1.8
50-54	243	19.1	15	6.7	238	18.6	15	6.9
55-59	219	17.2	44	19.6	217	17.0	35	16.1
60-64	198	15.6	44	19.6	208	16.3	54	24.8
65-69	185	14.6	74	33.0	194	15.2	61	28.0
70-74	78	6.1	43	19.2	114	8.9	49	22.5
Race/ethnicity								
Hispanic	1,023	80.5	120	53.6	948	74.2	66	30.3
Non-Hispanic white	104	8.2	63	28.1	105	8.2	88	40.3
Non-Hispanic black	97	7.6	29	13.0	115	9.0	34	15.6
Asian	26	2.1	4	1.8	28	2.2	2	0.9
Other	21	1.7	8	3.6	81	6.3	28	12.8
First-degree family history of breast cancer								
Yes	119	9.4	99	44.2	36	2.8	30	13.8
No	1,113	87.6	116	51.8	152	11.9	11	5.1
Unknown	39	3.1	9	4.0	1,089	85.3	177	81.2
Mammographic density								
Almost entirely fatty	NA		NA		124	9.7	2	0.9
Scattered fibroglandular density	NA		NA		779	61.0	107	49.1
Heterogeneously dense	NA		NA		368	28.8	101	46.3
Extremely dense	NA		NA		6	0.5	8	3.7
Breast pathology								
No prior biopsy	1,104	86.9	72	32.1	1,210	94.8	116	53.2
Prior biopsy	165	13.0	138	61.6	67	5.2	67	30.7
Proliferative changes with atypia	2	0.2	13	5.8	0	0.0	31	14.2
Lobular carcinoma in situ	0		1	0.5	0	0.0	4	1.8

Abbreviation: NA, not applicable.

*Low to average risk: women with a 5-year invasive breast cancer risk of less than 1.67% according to the Breast Cancer Surveillance Consortium (BCSC) model.

†High risk: women with a 5-year invasive breast cancer risk of 1.67% or greater according to the BCSC model.

data correlated with patient-reported data (Fig 2). The risk scores were positively associated with a correlation of 0.67.

DISCUSSION

We were able to extract data from EHRs for women age 35 to 74 years undergoing screening mammography to calculate breast cancer risk according to the BCSC model. Among those with known race/ethnicity, we determined

that approximately 15% of women met high-risk criteria for breast cancer. The EHR had missing data on race/ethnicity for 26.8% of women and on structured first-degree family history of breast cancer for 87.2%. Among the subset of women with both self-reported and EHR data on breast cancer risk factors, the self-reported data identified more women with a first-degree family history (14.6% v 4.4%) and prior breast biopsies (21.3% v 11.3%), but fewer

TABLE 3. Agreement in Breast Cancer Risk Status From Data Derived From the Electronic Health Record and a Self-Administered Survey (Cohen's inter-rater agreement κ , 0.48)

Self-Reported Data	Electronic Health Record Data		Total
	High Risk*	Low to Average Risk†	
High risk*	123	101	224
Low to average risk†	95	1,176	1,271
Total	218	1,277	1,495

*High risk: women with a 5-year invasive breast cancer risk of 1.67% or greater according to the Breast Cancer Surveillance Consortium (BCSC) model.

†Low to average risk: women with a 5-year invasive breast cancer risk of less than 1.67% according to the BCSC model.

women with atypia or LCIS (1.1% v 2.3%). However, the proportion of high-risk women identified was similar (15.0% v 14.6%), with moderate agreement (κ , 0.48) in breast cancer risk status from the two data sources.

The Gail model or Breast Cancer Risk Assessment Tool is the most widely used risk calculator for estimating 5-year and lifetime invasive breast cancer risk among women age 35 years or older.¹⁹ This tool was used to determine eligibility for breast cancer chemoprevention trials conducted in North America.^{2,4,6} The Gail model incorporates age, race/ethnicity, number of first-degree relatives with breast cancer (0, 1, more than 1), number of breast biopsies (0, 1, more than 1), presence of atypical hyperplasia (yes, no, unknown), and reproductive factors, such as age of menarche (7-11, 12-13, 14 years or older, unknown), and age of first live birth (younger than 20, 20-24, 25-29, 30 years or older, no births, unknown). Given the limited data on age of menarche and first live birth available in the EHR, we opted to use the BCSC model for breast cancer risk assessment, which uses mammographic density in place of reproductive factors. Although the Gail model has been well validated at the population level with updates for more sensitive risk estimates in African American and Asian American women,^{20,21} few studies have used this model in predominantly Hispanic populations.^{22,23} Given that our study population consisted of more than 60% Hispanic women, we used the BCSC model which has been well validated at the population level in multiethnic women undergoing screening mammography from geographically diverse populations throughout the United States.^{14,15} Of note, we excluded those with missing information on race/ethnicity, because the majority of our study sample was Hispanic and the default for unknown race/ethnicity is non-Hispanic white for the BCSC model, which may overestimate breast cancer risk in our study population.

On the basis of data extracted from the EHRs, we determined that 15% of women met high-risk criteria for breast cancer according to a 5-year invasive breast cancer risk of 1.67% or greater, which is consistent with prior studies.^{8,24} An estimated 10 million women age 35 to 79 years in the United States may be eligible for breast

FIG 2. Correlation of Breast Cancer Surveillance Consortium (BCSC) 5-year breast cancer risk (percentage) derived from self-reported and electronic health record data.

cancer chemoprevention; however, fewer than 5% of high-risk women offered selective estrogen receptor modulators or aromatase inhibitors for reducing breast cancer risk agreed to take these medications.⁷ Contributing to the underuse of chemoprevention is the fact that many women may be unaware of their high-risk status because of the lack of routine breast cancer risk assessment in the primary care setting. Despite under-reporting of first-degree family history of breast cancer and breast biopsies in the EHRs, the proportion of high-risk women identified from EHR and self-report data in our study was comparable. Although the Gail model is more commonly used to identify high-risk women who are eligible for chemoprevention, using EHR data to calculate breast cancer risk according to the BCSC model may serve as an initial screen for risk stratification. In general, younger women with a higher absolute risk of breast cancer derive a greater benefit from chemoprevention with a lower risk of adverse effects.²⁵ We are currently approaching high-risk women identified in this study to participate in a randomized controlled trial (NCT03069742; Study of Web-based Decision Aids for Increasing Breast Cancer Chemoprevention in the Primary Care Setting) for high-risk women and primary care providers to increase breast cancer chemoprevention.

Approximately 85% of women in our study sample were found to be at low to average risk for breast cancer according to the BCSC model, and the specificity and negative predictive values for identifying high-risk women with EHR data were greater than 90%. The U.S. Preventive Services Task Force revised their breast cancer screening recommendations in 2009 from annual mammograms starting at age 40 to biennial mammograms at age 50 to 74 years for average-risk women.²⁶ Similarly, in 2015, the

American Cancer Society recommended a more individualized approach to breast cancer screening.²⁷ However, these updated guidelines have not had a significant impact on changing mammography screening practices.^{18,28} A recent publication found that risk-stratified breast cancer screening was cost-effective with a favorable benefit-to-harm ratio using a life-table model, and there are ongoing prospective studies in the United States testing this hypothesis.²⁹ If systematic breast cancer risk assessment can be incorporated into clinic workflow and included in the patient's medical record (ie, incorporated into the mammography report), this may help identify women with low to average risk who may benefit from less frequent routine screening and women with high risk who may be eligible for more intensive supplemental screening (ie, breast ultrasound or magnetic resonance imaging). Although the Gail and BCSC models have poor discriminatory ability at the individual patient level, they are well validated at the population level³⁰ and may be used to better risk-stratify breast cancer screening practices.

Our study had several strengths, including the relatively large sample size, the racially and ethnically diverse study population, and the systematic collection of breast cancer risk information from the EHR paired with patient-reported data. We were able to collect structured data on mammographic density and first-degree family history of breast cancer from the EHR. Limitations of our study included the large amount of data missing from the EHR on race/ethnicity and family history of breast cancer. Our study was conducted at a single urban academic institution; therefore, our results may not be generalizable to other geographic and clinical settings. However, the proportion of high-risk women identified in our study population (15%)

was comparable to that in the published literature.^{8,24} We relied on manual review of pathology reports to classify benign breast disease. However, all other breast cancer risk information involved structured data elements or key word searches, which would be amenable to automated clinical data extraction. Future studies may use ICD-9 or ICD-10 diagnostic codes for atypical hyperplasia or LCIS or use natural language processing of breast pathology reports to classify benign breast lesions. Developing more automated methods for breast cancer risk assessment using EHR data may improve efficiency during the clinical encounter.

To our knowledge, this is the first study to extract clinical data from EHRs for breast cancer risk assessment, which showed moderate agreement with self-reported data. Incorporating formal breast cancer risk assessment at the time of screening mammography may represent a teachable moment for communicating risk information to patients. During the mammography screening visit, EHR data on mammographic density and breast pathology (ie, atypical hyperplasia, LCIS) may be complemented with self-reported data on race/ethnicity and first-degree family history to facilitate breast cancer risk assessment. For example, software may be developed to extract breast cancer risk information from the medical record, which prepopulates a breast cancer risk calculator in the EHR and may be updated with self-reported data collected by ancillary staff such as medical assistants or radiology technicians. If individual breast cancer risk profiles can appear in an EHR dashboard or be incorporated into the mammogram report, this would facilitate a more risk-stratified approach to breast cancer screening and prevention strategies, including chemoprevention.

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