



Breast Cancer Risk Assessment and Evaluation of Risk-Based Screening Practices by Primary Care Providers: A Single Institution Experience

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Abstract

Importance: Breast cancer risk assessment is a critical step towards identifying patients who may benefit from risk-based screening and chemoprevention. The utilization of chemoprevention in the US remains very low.

Objective: To determine if primary care providers belonging to different departments in our institution perform breast cancer risk assessment, risk-based screening, and prescribe chemoprevention for high-risk patients.

Design: Retrospective chart review of patients seen for annual preventive care visits at the Texas Tech University Health Sciences Center between Jan 1, 2014 to Dec 31, 2014 in the Internal Medicine (IM, n=1076), Family Medicine (FM, n=80), and Obstetrics and Gynecology (OB-GYN, n=59) was performed.

Setting: Single-institution.

Participants: Charts of women who aged ≥ 35 to ≤ 78 and were seen between Jan 1, 2014 to Dec 31, 2014 for preventive health care visits were eligible for review. A total of 1220 charts were reviewed.

Main Outcomes and Measures: Documentation of breast cancer risk assessment, chemoprevention, and for availability of data to calculate Gail scores were collected. Compliance to screening mammography per recommendations by NCCN, ACS, ACOG, and USPSTF guidelines was assessed by looking at utilization of mammograms in the past 2 years in eligible patients.

Results: No breast risk assessment was done among 1220 charts reviewed. Fraction of charts having complete data to calculate Gail score was 56.9% in OB, 9.4% in FM, and 1.7% in IM, and was statistically different between departments, $\chi^2(2)=131.08$, $p<0.001$. 149 patients (12.2%) were found to have high-risk for breast cancer based on Gail scores. No patients in our study were offered chemoprevention. Rates of compliance to screening mammogram across departments ranged from 45.74% to 81.58%.

Conclusions and Relevance: Breast cancer risk assessment, risk-based screening, and chemoprevention is not adequately practiced by primary care providers in our institution. A significant fraction of women who are at high risk for breast cancer are not offered chemoprevention. OB and FM PCPs' screening mammogram practices are more consistent with NCCN, ACS, and ACOG recommendations, compared to IM PCPs who follow USPSTF recommendations more consistently. Methods to improve education and awareness of breast cancer risk assessment and its implications for prevention and altered screening among high risk women are clearly indicated.

Key Points

Question: Do primary care providers in our institution assess breast cancer risk, practice risk-based screening, and order chemoprevention for breast cancer?

Findings: Out of 1220 charts reviewed, none was found to document breast cancer risk assessment. 140 patients (12.2%) were found to be high-risk based on Gail score. None of the patients were offered chemoprevention. Compliance to screening mammogram based on existing guideline recommendations across departments ranged from 45.74% to 81.58% and differed significantly

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between IM, FM, and OB-GYN providers.

Meaning: Breast cancer risk assessment, risk-based screening, and chemoprevention are not practiced by primary care providers in our institution.

Introduction

Breast cancer is the most common cancer diagnosed in women with an estimated 252,710 new cases in 2017, contributing to 14% of cancer-related deaths [1]. Breast cancer chemoprevention utilizing Selective Estrogen Receptor Modulators (SERMs) or Aromatase Inhibitors (AIs) in high-risk women has been well established in the literature as early as 20 years ago demonstrating reduced risk of developing breast cancer in these patients. Results of the NSABP-1 study showed an impressive 49% reduction in the risk of breast cancer among high risk women randomized to tamoxifen vs placebo [2,3]. In a subset analysis of the NSABP-1 study, women who had history of Atypical Hyperplasia (AH) had an even greater risk reduction of 86% [2]. Studies of other agents i.e. Raloxifene, Anastrozole, and Exemestane have also shown consistent significant reductions in the risk of breast cancer among high-risk patients [4-7]. The efficacy of some of these agents has also been demonstrated in women with more common benign breast tumor types, i.e. usual hyperplasia and aspirated cysts [8]. In 2003, a study by Freedman, et al. [9] estimated that approximately 10.2 million American women aged 35 to 79 years could benefit from tamoxifen chemoprevention. However, despite evidence of efficacy, there is a persistently low prevalence (0.03%) of the use of SERMs and AIs for chemoprevention in eligible patients [10,11].

Several breast cancer risk assessment tools are available and may be used to identify women who are at higher risk for developing breast cancer and are hence eligible for chemoprevention. The Gail model is the first and arguably the most popular tool to identify high-risk women having been validated and used in the early landmark clinical trials i.e. NSABP-1 [2,3] and STAR [4,7]. It has also been updated to approximate breast cancer risk better in women of different races, i.e. African American [12], Asian, and Pacific Islanders [13]. The USPSTF indicates that the Gail model maybe used to determine the 5-year risk of breast cancer in women [14,15]. Other risk assessment tools including Tyrer-Cuzick, BRCAPRO, Claus, BOADICEA, etc., rely on more extensive family histories and genetic information to calculate breast cancer risk and therefore may be less utilized than the Gail model in the primary care setting [16-21]. It is the Primary Care Physicians (PCPs) who are in the most favorable position to use these tools to assess breast cancer risk, discuss chemoprevention, and tailor risk-based breast cancer screening as they are often the first physicians encountered by patients. Despite this, studies evaluating primary care physicians' practices reveal that as many as 60% to 76% of physicians have never calculated Gail scores for their patients [22,23]. The medical community has not been naïve as to the complex reasons for low uptake of chemoprevention including the low rates of breast cancer risk assessment by physicians. Discussions aimed to improve uptake through increased patient and physician awareness, minimizing side effects, improving patient selection, and improving risk assessment remain relevant in present times [24-26].

Screening mammography has been shown to be beneficial in decreasing breast cancer mortality in women starting at age 40 [27]. Recommendations for age of initiation of screening mammography and interval screening for average risk women vary depending on

which guideline is followed. There are several large organizations who have published guidelines on screening mammography, each with variations on when to start screening and frequency of mammograms [27-31]. As part of our retrospective chart review, in addition to evaluating utilization of risk assessment, we sought to determine if appropriate breast cancer screening based on patient risk and existing guidelines by the NCCN, ACOG, ACS, and USPSTF [30,32,33] was being performed by PCPs in Internal Medicine (IM), Family Medicine (FM), and Obstetrics and Gynecology (OB) in our institution.

Methods

Study patients

With the approval of the Institutional Review Board at Texas Tech University Health Sciences Center, we conducted a retrospective chart review of patients seen between Jan 1, 2014 to Dec 31, 2014 in the Internal Medicine (IM, n=1076), Family Medicine (FM, n=80), and Obstetrics and Gynecology (OB-GYN, n=59) clinics for annual preventive care visits. A total of 1220 electronic charts of women aged ≥ 35 to ≤ 78 were reviewed. Data was collected regarding documentation of breast cancer risk assessment, use of and/or counseling regarding chemoprevention, and for availability of documented historical data to calculate Gail scores for breast cancer risk assessment. Data points included age, age at menarche, age at first live birth or null parity, number of breast biopsies and biopsy results, history of atypical ductal or lobular hyperplasia, number or first-degree relatives with breast cancer, race or ethnicity, and history of any breast cancer, Ductal Carcinoma in Situ (DCIS), Lobular Carcinoma in Situ (LCIS), or previous radiation therapy to the chest. Based on available data, Gail scores were calculated using the breast cancer risk assessment tool available online at www.cancer.gov/bcrisktool/, with conservative estimates calculated in those with incomplete data recorded. Screening compliance with annual or biennial mammography per recommendations by NCCN, ACS, ACOG, and USPSTF guidelines was assessed by looking at the frequency and utilization of mammograms in the past 2 years in eligible patients based on their age and breast cancer risk.

Statistical analysis

Data were summarized as mean (standard deviation) or frequency (percentage) as appropriate. Differences between departments in continuous variables where assessed using two-sided one-way ANOVA, and categorical variables were compared using two-sided chi-squared test. Post-hoc Bonferroni-adjusted pair wise comparisons were performed as appropriate. When comparing two risk groups based on Gail score, Student's t test or chi-squared test were used. Significance level was set at 0.05. All statistical analyses were performed using Stata 13.1 (StataCorp., College Station, TX).

Results

Baseline characteristics

Bonferroni-adjusted pair wise comparisons between departments determined that Internal Medicine patients were significantly older than Obstetrics-Gynecology ($p < 0.001$) and Family Medicine ($p < 0.001$) patients. No statistically significant age difference in age was found between Obstetrics-Gynecology and Family Medicine patients. Race/ethnicity was significantly different between departments (Table 1).

Breast cancer risk assessment and modified Gail score

Out of 1220 women in our institution, there was no instance that a breast risk assessment was completed and documented in the chart.

Table 1: Baseline Characteristics.

	Department			p
	Obstetrics-Gynecology	Family Medicine	Internal Medicine	
Age at 2014 exam, mean (SD), years	48.09 (9.01)	48.6 (7.76)	55.93 (10.72)	<0.001
Race/Ethnicity, n (%)				<0.001
African American	36 (3.48)	14 (17.28)	5 (8.93)	
American Indian	2 (0.19)	0 (0)	0 (0)	
Asian	15 (1.45)	4 (4.94)	4 (7.14)	
Hispanic	161 (15.57)	19 (23.46)	3 (5.36)	
Middle Eastern	1 (0.1)	0 (0)	0 (0)	
White	819 (79.21)	44 (54.32)	44 (78.57)	

Table 2: Gail calculation and high risk cutoff.

	Total (n=1220)	High Risk (Gail \geq 1.67)		p-value
		Yes (n=149)	No (n=1071)	
Gail score, mean (SD)	1.01 (0.68)	2.36 (0.86)	0.82 (0.37)	<0.001
Age at 2014 exam, mean (SD), years	48.51 (9.17)	56.74 (7.99)	47.36 (8.73)	<0.001
Age at 1 st mammogram, mean (SD), years	45.13 (7.77)	49.15 (7.69)	44.41 (7.56)	<0.001
Age at menarche, mean (SD), years	12.62 (1.49)	12.36 (1.49)	12.65 (1.48)	0.105
Age at first live birth, mean (SD), years	24.34 (5.85)	26.39 (6.37)	24.06 (5.73)	0
Have children, n (%)	819 (90.2)	98 (89.1)	721 (90.4)	0.677
Number of first degree relatives with history of breast cancer, n (%)				<0.001
0	1036 (84.9)	55 (36.9)	981 (91.6)	
1	143 (11.7)	84 (56.4)	59 (5.5)	
2	9 (0.7)	8 (5.4)	1 (0.1)	
Unknown	32 (2.6)	2 (1.3)	30 (2.8)	
Personal history of Breast Ca/DCIS/LCIS, n (%)				0.403
No	1215 (99.6)	149 (100)	1066 (99.5)	
Unknown	5 (0.4)	0 (0)	5 (0.5)	
History of breast biopsy, n (%)				<0.001
No	1150 (94.3)	128 (85.9)	1022 (95.4)	
Yes	64 (5.3)	21 (14.1)	43 (4)	
Unknown	6 (0.5)	0 (0)	6 (0.6)	
Number of biopsies				0.021
1	57 (89.1)	16 (76.2)	41 (95.4)	
2	7 (10.9)	5 (23.8)	2 (4.7)	
Mutation in either BRCA1 or BRCA2, or genetic syndrome	7 (0.57)	0 (0)	0 (0)	

P value compares two groups based on Gail score cutoff (1.67). Continuous variables were compared using t-test and categorical variables were compared two-sided using chi-squared test.

Even though PCPs are described to be more comfortable with taking a family history [22], many did not have documented reproductive history or history of abnormal breast biopsies, information which comprises 5 out of the 7 data points used to calculate the Gail score.

Utilizing available data and conservative score calculations, comparison of patients based on Gail score high risk criterion (≥ 1.67) showed that predicted high risk patients were older in age at the 2014 exam, had their first mammogram later, and were older at first live birth, but no differences were found in age at menarche and parity (Table 2). The number of first degree relatives with a history of breast cancer was significantly higher among high risk patients. No differences were found in personal cancer history. A larger number of high risk patients had a history of breast biopsy (14% vs. 4%), and the

number of biopsies required was also significantly larger ($p=0.021$). No patients in our study had documented genetic mutations that predispose to breast cancer.

The fraction of patients having complete documented histories to allow accurate calculation of a Gail score was 56.9% among OB patients, 9.4% in FM, and 1.7% in IM, showing statistically significant differences between departments, $\chi^2(2)=131.08$, $p<0.001$ (Table 3), in risk documentation. Age at menarche and parity-related information were the most under documented fields. Age at menarche was not documented in 29.5% of OB patients, 56.5% of FM patients, and 94.5% of IM patients, $\chi^2(2)=123.78$, $p<0.001$. Similarly, age at first live birth or parity was not documented in 17.8%, 85.9%, and 97.7% of OB, FM, and IM patients respectively, $\chi^2(2)=286.89$, $p<0.001$.

Table 3: Availability of information required to calculate Gail score in different departments.

	Department			Total	p-value
	Obstetrics-Gynecology	Family Medicine	Internal Medicine		
Fully documented					<0.001
No	464 (43.1)	77 (90.6)	58 (98.3)	599 (49.1)	
Yes	612 (56.9)	8 (9.4)	1 (1.7)	621 (50.9)	
History of breast cancer					0.715
No	5 (0.5)	0 (0)	0 (0)	5 (0.4)	
Yes	1071 (99.5)	85 (100)	59 (100)	1215 (99.6)	
Genetic mutation					
No	0 (0)	0 (0)	0 (0)	0 (0)	
Yes	1076 (100)	85 (100)	59 (100)	1220 (100)	
Age					
No	0 (0)	0 (0)	0 (0)	0 (0)	
Yes	1076 (100)	85 (100)	59 (100)	1220 (100)	
Age at menarche					<0.001
No	320 (29.7)	48 (56.5)	56 (94.9)	424 (34.8)	
Yes	756 (70.3)	37 (43.5)	3 (5.1)	796 (65.3)	
Children– Age at first live birth					<0.001
No	192 (17.8)	73 (85.9)	47 (79.7)	312 (25.6)	
Yes	884 (82.2)	12 (14.1)	12 (20.3)	908 (74.4)	
First-degree Relatives with history of cancer					0.111
No	32 (3)	0 (0)	0 (0)	32 (2.6)	
Yes	1044 (97)	85 (100)	59 (100)	1188 (97.4)	
Breast biopsy					0.668
No	6 (0.6)	0 (0)	0 (0)	6 (0.5)	
Yes	1070 (99.4)	85 (100)	59 (100)	1214 (99.5)	
Race/ethnicity					0.854
No	42 (3.9)	4 (4.7)	3 (5.1)	49 (4)	
Yes	1034 (96.1)	81 (95.3)	56 (94.9)	1171 (96)	

P values were calculated two-sided chi-squared test and Fisher's exact test.

Calculation of the Gail score, including conservative calculations, yielded a total of 149 patients (12.2%) who are considered high-risk for breast cancer and potentially eligible for CP. No patients in our study were offered CP as part of their care plan.

Breast cancer screening compliance

The age at 1st mammogram differed between departments, with OB and FM patients having mammograms performed at an earlier age, compared to IM patients (44.71 and 45.16 vs 53.33). Overall, Internal Medicine physicians have a higher adherence to the NCCN, ACS, ACOG, and USPSTF guidelines (Table 4). Depending on which guideline are followed rates of compliance to screening mammogram across departments ranged from 45.74% to 81.58%. IM had the best compliance with the USPSTF recommendation of performing biennial screening mammogram on average risk women starting age 50.

Discussion

Based on retrospective chart review, our data indicate that no patients seen by their PCP for preventive care had discussion regarding breast cancer risk or potential use of chemoprevention even among high risk patients. Gynecologists' documentation included a more

complete set of data to accurately calculate the risk of breast cancer by the Gail model. Even after utilizing conservative risk estimates in our patient population, we estimate 12.2% of women (n=149) would be considered high risk and therefore eligible for chemoprevention based on Gail scores. Our data approximates the estimated 15.5% of women calculated to be high risk from the National Health Interview Survey Cancer Control Module [9].

Breast cancer risk assessment and the Gail score

Current guidelines state that average risk women, i.e. without known genetic mutations, history of thoracic radiation prior to age 30, history of LCIS, should undergo breast cancer risk assessment either by the modified Gail or a family history based model [34-36]. As we have noted in our study, this recommended risk assessment is not being performed and appropriate risk assessment histories are not consistently obtained. We have noted that menstrual and obstetric histories are not well documented particularly by FM and IM PCPs. As a result, only 1.7% of IM patients and 9.4% of FM patients, as opposed to 56.9% of gynecology patients had complete data to estimate their breast cancer risk by Gail model. A plausible explanation for this is that as specialists, gynecologist asks about reproductive history more often than FM and IM practitioners.

Table 4: Screening Mammogram adherence based on USPSTF, NCCN, ACOG, and ACS recommendations.

	Department			p
	Obstetrics- Gynecology	Family Medicine	Internal Medicine	
Age at 1st mammogram, mean (SD), years	44.71 (7.52)	45.16 (6.47)	53.33 (9.6)	<0.001
Mammogram last 12 months, n (%)	415 (38.57)	39 (45.88)	31 (52.54)	<0.001
40+ age subgroup	392 (45.74)	39 (52)	31 (55.36)	<0.001
<40	23 (10.5)	0 (0)	0 (0)	0.711
40 to 49	154 (38.6)	18 (45)	6 (33.3)	0.645
50 to 74	234 (51.9)	21 (60)	24 (64.9)	0.225
75 and above	4 (57.1)	0 (0)	1 (100)	1
Mammogram last 24 months, n (%)	560 (52.04)	43 (50.59)	38 (64.41)	<0.001
50+ age subgroup	313 (68.34)	24 (68.57)	31 (81.58)	<0.001
<40	29 (13.2)	0 (0)	0 (0)	0.745
40 to 49	218 (54.6)	19 (47.5)	7 (38.9)	0.312
50 to 74	308 (68.3)	24 (68.6)	30 (81.1)	0.268
75 and above	5 (71.4)	0 (0)	1 (100)	1

Continuous variables were compared using two-sided one-way ANOVA and categorical variables were compared using two-sided chi-squared test

This is consistent with previous reports that gynecology physicians have higher rates of using the Gail model compared to FM and IM physicians (60% vs 33% and 37% respectively) [23].

Despite having a more robust data for risk assessment, this did not translate into higher rates for breast cancer risk assessment in the gynecology department. However, we do acknowledge that we may be underestimating breast cancer risk assessments in all departments due to the cross-sectional design of our study, i.e. physicians may have had performed breast risk assessment and discussed chemoprevention at other clinic encounters. Moreover, physicians may not have fully documented their discussions with patients. Nevertheless, we were able to obtain conservative estimates of breast cancer risk using the Gail model on all our patients and identified a significant number of women who are eligible for chemoprevention and found that no patients underwent risk based screening.

In our data set, the history of breast biopsies was significantly different between those with average and high-risk scores. Not having this data and utilizing a conservative Gail calculation may potentially miss high-risk women underlying the importance of appropriate and complete risk assessment by a knowledgeable physician. Although differences in menarche and age at first live birth were not significantly different between risks groups, the results may be confounded by lack of data in a substantial number of patients. On the other hand, age and family history of breast cancer, both of which increased the risk for breast cancer in our data set, appear to have been well documented in patient charts.

Barriers to breast cancer risk assessment by PCP

In spite of being available for more than 20 years, data suggests that many PCPs have never used the Gail model in their practice (60% to 76%) [22,23]. As high as 82% of physicians who had never used the Gail model in practice cited unfamiliarity with the Gail score as the most influential reason [23]. In our increasingly complex health care system, logistic reasons such as the lack of time as well as the need to address other issues also serve as barriers for risk assessment and counseling [22,23,37]. Many providers are not comfortable with potential discussions about chemoprevention and genetic testing if patients are determined high-risk and thereby may not perform full

risk-assessment altogether [22,38-40]. These practices remarkably go against the strong agreement (96%) between providers that assessing breast cancer risk is the responsibility of primary care physicians [22].

PCPs and their use of chemoprevention for high risk women

As PCPs are often the first encounter for patients regarding their health issues, this provides the greatest opportunity to assess risk and offer risk based intervention with tailored screening. The role of the provider in improving chemoprevention uptake should not be underestimated especially given that patients strongly consider physician recommendations in decision making [26,41-43]. In a survey of 107 providers affiliated with an academic medical center, only 13% have discussed chemoprevention as an option in high-risk women [22]. In another survey of prescribing patterns of 316 primary care physicians, only 13% of internists, family physicians, and gynecologists recommended or prescribed risk reduction therapy to their patients [23]. It is not surprising that use of chemoprevention is higher in clinical trials compared to non-trial settings. A meta-analysis of chemoprevention uptake in 21,423 women showed a 25.2% vs 8.7% uptake in trial vs non-trial setting [26]. The non-existent practice of chemoprevention use in our study (0%) however more closely resembles the already very low prevalence of use of tamoxifen (0.03%) and raloxifene (0.21%) in the U.S. in the early 2000s [10]. A more contemporary dataset in 2012, albeit in a hospitalized and older group of women aged 50-79 years in a single institution, showed a very high prevalence of high risk women at 32.4% and yet the prevalence of chemo prevention was 0%. These studies imply minimal improvement in uptake since the national data has been published and that continued efforts to improve breast risk assessment practice by primary care physicians are still needed [44].

Barriers to chemoprevention by PCPs

The impact of the level of training and physician's knowledge is demonstrated by the higher rates of uptake in patients under specialist care [45]. On the other hand, there are higher odds for PCPs to prescribe Tamoxifen when patients ask for information [46]. Also if patients are not identified by their PCP it is unlikely they will be appropriately referred to specialist for further evaluation and care. Unfortunately, physicians cannot rely on patient demand,

as awareness maybe low even in highly educated women [47]. Even if offered chemoprevention, patients may be reluctant to take these agents despite educational sessions regarding side effects and benefit as data has shown they may perceive the risks to outweigh benefits [48]. Hence, it is apparent that there is a need for better training of physicians not only to properly assess breast cancer risk but to be able to assess risk and benefits of chemoprevention and be able to comfortably select eligible patients.

Screening mammogram practices and adherence to guidelines

Within our study, patients under OB and FM care had an earlier age of first mammogram compared to IM patients. Also the fraction of women aged between 40 and 50 and who had mammograms in the past 12 or 24 months was higher in both OB and FM patients compared to IM. This trend reversed after the age of 50 where IM patients are more likely to have had a mammogram in the past 12 to 24 months. This may be due to differences in practice and which guidelines are followed between the departments. FM and OB PCPs may be more adherent to recommendations by NCCN, ACOG, and ACS and IM to USPSTF on when to initiate screening mammography. At the time the patients were seen, the NCCN, ACOG, and ACS guidelines recommended starting annual screening mammograms at age 40, as opposed to biennial screening starting age 50 as recommended by USPSTF. The ACOG, USPSTF, and ACS have since updated their recommendations [27,29,31]. Notably, the ACS now recommends starting annual mammograms at age 45 and biennially at age 55 and over, and to offer annual screening at age 40 after considering risks and benefits of screening [27]. The ACOG guidelines also recommend the decision when to begin mammography screening should be made through a shared decision-making process, and that screening mammography should be offered as early as age 40, but no later than age 50. Moreover, screening mammogram can be done every 1-2 years [31].

Conclusion

Breast cancer risk assessment, risk-based screening, and use of breast cancer chemoprevention are not adequately practiced by primary care providers in our institution. There remains a significant fraction of women who are at high risk for breast cancer is not offered chemoprevention. OB and FM PCPs' screening mammogram practices are more consistent with NCCN, ACS, and ACOG recommendations, compared to IM PCPs who tended to follow USPSTF recommendations more consistently. Rates of adherence to chemoprevention and mammogram screening recommendations approximated national data. Our study demonstrates that methods to improve education and awareness of breast cancer risk assessment and its implications for prevention and altered screening among high risk women are clearly indicated.

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