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RESEARCH ARTICLE

A Pre-Test—Post-Test Trial of a Breast Cancer Risk Report for Women in Their 40s

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Introduction: Guidelines recommend individualized breast cancer screening and prevention interventions for women in their 40s. Yet, few primary care clinicians assess breast cancer risk.

Study design: Pretest-Posttest trial.

Setting/participants: Women aged 40—49 years were recruited from one large Boston-based academic primary care practice between July 2017 and April 2019.

Intervention: Participants completed a pretest, received a personalized breast cancer risk report, saw their primary care clinician, and completed a posttest.

Main outcome measures: Using mixed effects models, changes in screening intentions (0—100 scale [0=*will not screen* to 100=*will screen*]), mammography knowledge, decisional conflict, and receipt of screening were examined. Analyses were conducted from June 2019 to February 2020.

Results: Patient (n=337) mean age was 44.1 (SD=2.9) years, 61.4% were non-Hispanic white, and 76.6% were college graduates; 306 (90.5%) completed follow-up (203 with 5—year breast cancer risk <1.1%). Screening intentions declined from pre- to post-visit (79.3 to 68.0, p<0.0001), especially for women with 5-year risk <1.1% (77.2 to 63.3, p<0.0001), but still favored screening. In the 2 years prior, 37.6% had screening mammography compared with 41.8% over a mean 16 months follow-up (p=0.17). Mammography knowledge increased and decisional conflict declined. Eleven (3.3%) women met criteria for breast cancer prevention medications (ten discussed medications with their clinicians), 22 (6.5%) for MRI (19 discussed MRI with their clinician), and 67 (19.8%) for genetic counseling (47 discussed with the clinician).

Conclusions: Receipt of a personalized breast cancer report was associated with women in their 40s making more-informed and less-conflicted mammography screening decisions and with high-risk women discussing breast cancer prevention interventions with clinicians.

Trial registration: This study is registered at www.clinicaltrials.gov NCT03180086.

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INTRODUCTION

As the ratio of benefits to risks of mammography screening for women in their 40s depends on their breast cancer risk and preferences, guidelines increasingly recommend that mammography use for women in this age group be individualized.[1−4] Mammography screening is associated with a 15% reduction in breast cancer mortality among women in their 40s.[5] However, approximately half of women screened regularly for 10 years will experience a false positive,[6] and some may experience overdiagnosis at a younger age (detection of a tumor that would not have become clinically evident without screening; 1%−35% of screen-detected tumors are estimated to be overdiagnosed).[5,7] Women in their 40s must weigh these benefits and risks when making screening decisions.

Similar to women in other age groups, for women in their 40s, the American Cancer Society (ACS) recommends breast magnetic resonance imaging (MRI) screening for women with approximately 20%−25% or greater lifetime breast cancer risk,[8] and the U.S. Preventive Services Task Force (USPSTF) and American Society of Clinical Oncology recommend that women at high risk be offered breast cancer prevention medications (BCPMs).[9−13] Guidelines further recommend genetic counseling for women at high risk for a *BRCA* gene mutation.[14,15]

Despite this, breast cancer risk assessment in primary care tends to be ad hoc, and few primary care clinicians (PCCs) discuss BCPMs or genetic testing with patients.[16−20] Many report barriers including lack of time, poor reimbursement, and lack of training.[16,18,19,21,22] Interventions are needed to standardize breast cancer risk assessment, risk communication, and risk-based management in primary care, especially for women in their 40s for whom guidelines recommend individualized screening decisions in addition to other breast cancer prevention interventions. This study aims to test the effect of providing women in their 40s and their PCCs (physicians/nurse practitioners) with a 2-page personalized breast cancer risk report before a primary care visit in a pre-test−post-test trial. Investigators hypothesize that patients' intentions to undergo mammography screening would be more closely associated with their 5-year breast cancer risk after the intervention.

METHODS

This study tested the effects of providing women in their 40s and their PCCs a 2-page breast cancer risk report (examples in Appendix, available online) before a visit in a pre-test−post-test trial. Beth Israel Deaconess Medical Center's IRB approved this study.

An interdisciplinary team, which included internists, a breast imager, an oncologist, an administrator, and patient advocates, drafted a prototype risk report on the basis of the USPSTF's 2016 breast cancer screening and 2013 BCPM guidelines, the ACS's 2007 breast MRI guidelines, the 2017 and 2018 National Comprehensive Cancer Network's (NCCN's) criteria for genetic counseling (detailed in Appendix Table 1, available online), and the team's experience in developing decision aids.[2,8,23−26] The report was designed for women to receive it immediately before a visit and for patients and PCCs to use it together during the visit. The report's first page informed women of their 5-year breast cancer risk compared with the average woman their age using words, frequencies, and a pictograph. Using patient survey responses supplemented by medical record data when necessary (e.g., to obtain breast density), 5-year risk was estimated using the Breast Cancer Risk Assessment Tool (BCRAT) and the Breast Cancer Surveillance Consortium (BCSC) model (when breast density was available); the report presented the higher-risk estimate.[27,28] These risk calculators were chosen to estimate women's 5-year breast cancer risk because BCRAT is the most commonly used breast cancer risk calculator in primary care and BCSC works similarly but also considers breast density.[18,29,30] In addition, previous studies calculated the ratio of benefits to risks of BCPMs using BCRAT's 5-year risk estimates.[31] Then, the report told women that having a mammogram is a personal decision and to consider the benefits and risks (listed in 4 bullet points); users were also referred to an online mammography screening decision aid for women in their 40s for more information.[32,33] On the basis of the USPSTF's 2013 guidelines, the report then informed postmenopausal women with 5-year risk ≥3.0% that they should consider taking BCPMs.[12,13] For premenopausal women, the report told women with a 5-year risk ≥1.7% to consider BCPMs on the basis of the American Society of Clinical Oncology's 2013 guidelines. Although the USPSTF states that evidence on adjunctive screening with breast MRI is insufficient, ACS recommends breast MRI screening for women with >20%−25% lifetime breast cancer risk (using risk models that consider detailed family history [such as Tyrer−Cuzick]). On the basis of PCC feedback and concerns about the conflicting guidelines, the report conservatively recommended breast MRI screening to women with ≥25% lifetime risk using Tyrer−Cuzick.[8,34] Women at high risk for a *BRCA* mutation were recommended genetic counseling.[35] At the bottom of the page was a short checklist of recommendations. The report's second page included details about risk calculators and the supporting guidelines. Before study initiation, the risk report was revised on the basis of feedback from practice-based PCCs. During the study, minor revisions were made to the risk report on the basis of participant feedback (detailed in Appendix Table 1, available online).

Study Sample

English-speaking, cognitively and emotionally intact women (as determined by PCCs) were eligible if they were aged 40−49 years; had a routine PCC visit between July 2017 and April 2019 at Beth Israel Deaconess Medical Center's large, diverse, academic practice (includes 5 suites on 2 floors); and received a risk report. To identify women more likely to be contemplative about breast cancer screening and prevention interventions, women were excluded if they had a history of invasive breast cancer, ductal carcinoma in situ, or atypia (ductal/lobular hyperplasia), had a mammogram within 6 months or an abnormal mammogram within 24 months; had breast complaints; had received BCPMs, breast MRI, or genetic counseling; were seen in a high-risk clinic; had BRCA testing; or had a breast reduction or enlargement.

With IRB approval, data managers sent a research assistant a monthly list of women aged 40−49 years scheduled to see their PCC in 3−10 weeks. The research assistant reviewed patient records to confirm eligibility. After obtaining PCC approval, the research assistant sent patients a study informational letter and a number to call to opt out of contact. Research assistants contacted patients who did not opt out to confirm eligibility and willingness to participate. Patients could complete the previsit questionnaire by a secure web link or by telephone (on the basis of preference).

Measures

All study questionnaires are provided in the Appendix, available online). The previsit questionnaire, completed on a median of 19 days before a visit (IQR=8−36 days), assessed women's breast cancer risk factors to compute their BCRAT, BCSC, and Tyrer−Cuzick breast cancer risk estimates and to identify women who met NCCN criteria for genetic counseling.[26] It also assessed women's screening intentions for the next year,[36] decisional conflict,[37] knowledge of mammography's benefits and risks,[38−41] health characteristics, and sociodemographics (each scale is described in Appendix Table 2, available online). PCCs were e-mailed a copy of the risk report, and a copy was uploaded to the online medical record. In addition, a macro (Appendix, available online) was made available in the online medical record and mailed to PCCs when relevant to help PCCs discuss and document discussion of BCPMs. In addition, medical assistants were asked to deliver the reports before visits. Because delivery by medical assistants was inconsistent, 3 months into the study, patients received a secure copy of the report by e-mail (if the patient approved). After the visit, patients were called or e-mailed (depending on preference) to complete a postvisit questionnaire. PCC visit notes were reviewed to determine whether discussion about breast cancer risk was documented.

Each outcome and when it was assessed are described briefly here and in detail in Appendix Table 2 (available online). The postvisit questionnaire was completed on a median of 9 days after the visit (IQR=1−23 days). The primary outcome was mean change in screening intentions (100-point scale [0=*will not* to 100=*will get screened*]) from previsit to postvisit overall and by 5-year risk <1.1% or ≥1.1%. The average 5-year breast cancer risk for women aged 50−54 years is 1.1%, and all guidelines recommend mammography screening for women in this age group. Therefore, outcomes were examined by this risk threshold. In sensitivity analyses, outcomes were also examined by a 5-year risk of 1.7% as several guidelines define high risk by this threshold.[1] Secondary outcomes included change in decisional conflict (including 5 subscales) and knowledge overall and by 5-year risk.[37] The postvisit questionnaire also asked about acceptability (e.g., helpfulness) of the report and suggestions for improvement.[42] Using claims data supplemented by chart review, mammography screening use from 2 years before the study visit through October 2019 (this time frame allowed at least 6 months of follow-up for all participants) by 5-year breast cancer risk were examined. PCCs whose patients participated were sent a web-based questionnaire asking their feedback on the risk report.

For patients for whom the report recommended discussion of BCPMs, breast MRI, or genetic counseling, medical records were reviewed at 2 months to ascertain whether this care was discussed or received. If not, PCCs were e-mailed to ensure they were aware of the recommendation(s); patients' records were rereviewed at 6 months to determine the care received.

Statistical Analysis

Mixed-effect models with fixed effects for time were used to compare previsit and postvisit information. The Bonferroni correction was used to examine the effects of secondary outcomes. Effect modification by educational attainment and race/ethnicity was also assessed. The study aimed to recruit 445 women because it was estimated that 9% would meet the risk threshold for additional breast cancer prevention interventions (besides mammography), and investigators aimed to describe the intervention's effects in at least 40 of such women.[43] Using qualitative content analysis, 2 investigators (MAS and MK) independently reviewed participants' open-ended comments to identify themes; code discrepancies were resolved by consensus.[44] Analyses were completed from June 2019 to February 2020.

RESULTS

Of the 2,632 patient records that were reviewed, 891 were ineligible, 865 were not reached, 25 opted out of initial telephone contact, 213 refused participation, and 638 agreed to participate. Of these 638 women, 417 completed the baseline questionnaire in which 337 saw 1 of 69 different PCCs and received a risk report (Figure 1 shows study recruitment). Refusers were similar in age to participants but were less likely to be white, non-Hispanic or college educated. Mean age of the 337 participants was 44.1 (SD=2.9) years, 61.4% were white, non-Hispanic, and 76.6% were college graduates. A total of 78 (23.1%) met the criteria for at least 1 breast cancer prevention intervention besides mammography (11 [3.3%] for BCPMs, 22 [6.5%] for breast MRI, and 67 [19.8%] for genetic counseling) (Appendix Figure 1, available online provides a Venn diagram of the overlap). Overall, 306 (90.8%) of 337 participants completed the postvisit questionnaire (88.2% online), of which 203 (66.3%) had a 5-year breast cancer risk <1.1%, and 12 (3.9%) had a 5-year risk ≥1.7%. Patients who did not complete follow-up were less likely to be white, non-Hispanic, college educated, or married (Appendix Table 3, available online). Table 1 shows the patient characteristics, and Appendix Table 4 (available online) shows characteristics for women who were recommended additional interventions. Appendix Table 5 (available online) shows characteristics for the 51 PCCs who completed a questionnaire.

Table 2 shows the study outcomes. Intentions to be screened declined significantly from previsit to postvisit (79.3−68.0 postvisit, $p<0.0001$), especially among women with a 5-year risk <1.1% (77.2−63.3, $p<0.0001$), but still favored screening (i.e., >50). Screening intentions increased among women with a 5-year risk ≥1.7% but

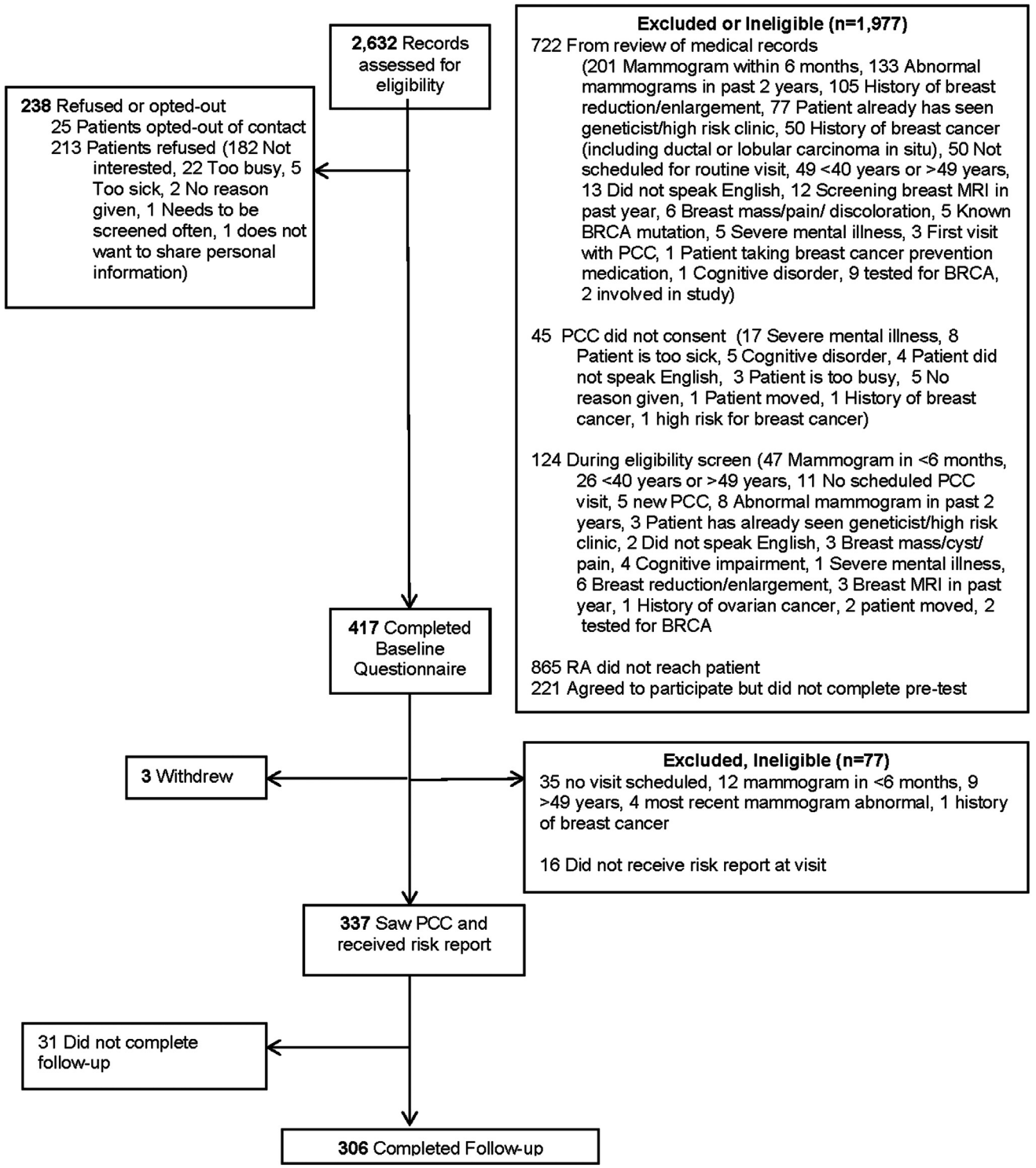

Figure 1. Participant study flow diagram. MRI, magnetic resonance imaging; PCC, primary care clinician; RA, research assistant.

not significantly (Appendix Table 6, available online). Patients' decisional conflict declined, and women with a 5-year risk ≥1.1% were especially likely to feel clearer in their values (Appendix Table 7, available online). Knowledge of mammography's benefits and risks increased significantly, especially regarding screening harms (Appendix Table 8, available online). Compared with screening within 2 years before the study visit (37.6%), screening tended to increase afterward (41.8%, p=0.17, 16.1 months [SD=5.4] mean follow-up); 39 of

Table 1. Participant Characteristics

Characteristic	Study sample overall (*n*=337)	Patients who completed follow-up (*n*=306)	Completed follow-up <1.1% 5-year risk (*n*=203)	Completed follow-up ≥1.1% 5-year risk (*n*=103)	*p*-value for <1.1 vs 1.1% 5-year risk
Age, years, mean (SD)	44.1 (2.9)	44.1 (2.9)	43.1 (2.6)	46.0 (2.3)	**<0.0001**
Race, *n* (%)					**<0.0001**
White, non-Hispanic	207 (61.4)	196 (64.1)	110 (54.2)	86 (83.5)	
Black, non-Hispanic	60 (17.8)	51 (16.7)	46 (22.7)	5 (4.9)	
Hispanic	31 (9.2)	24 (7.8)	21 (10.3)	3 (2.9)	
Asian	24 (7.1)	22 (7.2)	18 (8.9)	4 (3.9)	
Other	15 (4.4)	13 (4.3)	8 (3.9)	5 (4.9)	
Ashkenazi Jewish	41 (12.2)	40 (13.1)	25 (12.3)	15 (14.6)	0.56
Missing	4 (1.2)	4 (1.3)	2 (1.0)	2 (1.9)	
Education, *n* (%)					**0.02**
Less than high school	3 (0.9)	1 (0.3)	1 (0.5)	0	
High school	12 (3.6)	8 (2.6)	4 (2.0)	4 (3.9)	
Some college	61 (18.1)	54 (17.7)	44 (21.7)	10 (9.7)	
College degree or beyond	258 (76.6)	241 (78.8)	153 (75.4)	88 (85.4)	
Missing	3 (0.9)	2 (0.6)	1 (0.5)	1 (1.0)	
Income, $					**0.003**
≤35,999	38 (11.3)	32 (10.5)	27 (13.3)	5 (4.8)	
36,000–65,999	54 (16.0)	46 (15.0)	38 (18.7)	8 (7.8)	
≥66,000	228 (67.7)	214 (69.9)	128 (63.1)	86 (83.5)	
Declined to answer	17 (5.0)	14 (4.6)	10 (4.9)	4 (3.9)	
Currently married, *n* (%)	202 (59.9)	189 (61.8)	114 (56.2)	75 (72.8)	**0.003**
Missing	1 (0.3)	1 (0.3)	0	1 (1.0)	
Somewhat to not at all confident (3–5) filling out medical forms by yourself,[a] *n* (%)	16 (4.8)	13 (4.3)	11 (5.4)	2 (1.9)	0.23
Missing	1 (0.3)	1 (0.3)	0	1 (1.0)	
Problems paying for medical bills in the past 12 months, *n* (%)	47 (14.0)	39 (12.8)	31 (15.3)	8 (7.8)	0.07
Missing	1 (0.3)	1 (0.3)	0	1 (1.0)	
Had mammogram ever, *n* (%)	234 (69.4)	218 (71.2)	126 (62.1)	92 (89.3)	**<0.0001**
Perceived risk, *n* (%)					**0.0002**
Higher than average	52 (15.4)	50 (16.3)	22 (10.8)	28 (27.2)	
Average	97 (28.8)	92 (30.1)	58 (28.6)	34 (33.0)	
Below average	184 (54.6)	161 (52.6)	121 (59.6)	40 (38.8)	
Missing	4 (1.2)	3 (1.0)	2 (1.0)	1 (1.0)	
Smoking history, *n* (%)					0.72
Never smoked	245 (72.7)	221 (72.2)	144 (70.9)	77 (74.8)	
Former smoker	72 (21.4)	65 (21.2)	45 (22.2)	20 (19.4)	
Current smoker	18 (5.3)	18 (5.9)	13 (6.4)	5 (4.8)	
Missing	2 (0.6)	2 (0.6)	1 (0.5)	1 (1.0)	
Postmenopausal, *n* (%)	29 (8.6)	23 (7.5)	12 (5.9)	11 (10.7)	0.13
Missing	5 (1.5)	5 (1.6)	3 (1.5)	2 (1.9)	
BMI, *n* (%)					0.49
<25	119 (35.3)	106 (34.6)	66 (32.5)	40 (38.8)	
25 to <30	99 (29.4)	96 (31.4)	67 (33.0)	29 (28.2)	
≥30	118 (35.0)	103 (33.7)	69 (34.0)	34 (33.0)	
Missing	1 (0.3)	1 (0.3)	1 (0.5)	0	

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Table 1. Participant Characteristics (*continued*)

Characteristic	Study sample overall (*n*=337)	Patients who completed follow-up (*n*=306)	Completed follow-up <1.1% 5-year risk (*n*=203)	Completed follow-up ≥1.1% 5-year risk (*n*=103)	*p*-value for <1.1 vs 1.1% 5-year risk
Lifetime risk					—
≤20% lifetime risk Tyrer–Cuzick	284 (84.2)	253 (82.7)			
≥20%–24% lifetime risk Tyrer–Cuzick	31 (9.2)	31 (10.1)			
≥25% lifetime risk Tyrer–Cuzick	22 (6.5)	21 (6.9)			

Note: Boldface indicates statistical significance ($p<0.05$).
[a]Lack of confidence completing medical forms is a validated measure of low health literacy.[45]

Table 2. Effects of the Breast Cancer Risk Report

Outcomes	Baseline (*n*=306)	Follow-up (*n*=306)	Estimated mean difference/RR (95% CI)	*p*-value
Change in intentions to be screened, mean (SD)[a]				Interaction $p=0.03$
Overall	79.3 (27.5)	68.0 (40.0)	−10.3 (−14.3, −6.3)	**<0.0001**
5-year risk <1.1%	77.2 (28.5)	63.3 (40.8)	−13.4 (−18.4, −8.5)	**<0.0001**
5-year risk ≥1.1%	83.4 (25.1)	77.0 (36.9)	−4.3 (−11.2, 2.6)	0.22
Missing, *n* (%)	22 (7.2)	8 (2.6)		
Knowledge, mean correct (SD)[b]	5.8 (1.30)	6.2 (1.2)	0.40 (0.25, 0.54)	**<0.0001**
5-year risk <1.1%	5.6 (1.3)	6.1 (1.2)	0.42 (0.24, 0.60)	**<0.0001**
5-year risk ≥1.1%	6.0 (1.2)	6.3 (1.2)	0.35 (0.10, 0.61)	**0.007**
Missing, *n* (%)	1 (0.3)	0		
Decisional conflict scale total, mean (SD)[b,c]	24.0 (15.04)	16.8 (12.5)	−7.2 (−8.6, −5.8)	**<0.0001**
5-year risk <1.1%	25.11 (14.87)	18.09 (12.43)	−7.0 (−8.70, −5.34)	**<0.0001**
5-year risk ≥1.1%	21.71 (15.19)	14.19 (12.34)	−7.6 (−9.91, −5.18)	**<0.0001**
Missing, *n* (%)	1 (0.3)	0		
Decisional conflict subscales, mean (SD)				
Informed subscale[d]	18.7 (15.4)	9.3 (12.1)	−9.4 (−11.1, −7.7)	**<0.0001**
Missing, *n* (%)	1 (0.3)	0		
Values clarity subscale[e]	30.7 (18.2)	22.1 (16.1)	−8.6 (−10.5, −6.6)	**<0.0001**
Missing, *n* (%)	1 (0.3)	0		
Support subscale[f]	21.6 (18.3)	15.6 (15.2)	−6.0 (−7.8, −4.1)	**<0.0001**
Missing, *n* (%)	1 (0.3)	0		
Uncertainty subscale[g]	27.3 (21.5)	21.4 (19.0)	−5.9 (−8.0, −3.7)	**<0.0001**
Missing, *n* (%)	1 (0.3)	0		
Effective decision subscale[h]	22.2 (18.4)	15.7 (15.4)	−6.5 (−8.4, −4.6)	**<0.0001**
Missing, *n* (%)	1 (0.3)	0		
Talked to PCC about having a mammogram (*n*=306), *n* (%)	X	273 (89.2)	—	—
Missing, *n* (%)	X	1 (0.3)	—	—
Talked to PCC about benefits of mammogram (*n*=273), *n* (%)	X	235 (86.1)	—	—
Talked to PCC about downsides of mammogram (*n*=273), *n* (%)	X	184 (67.4)	—	—
Talked to PCC about risk report, *n* (%)	X	208 (68.0)	—	—
Missing, *n* (%)	X	19 (6.2)	—	—

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Table 2. Effects of the Breast Cancer Risk Report (*continued*)

Outcomes	Baseline (*n*=306)	Follow-up (*n*=306)	Estimated mean difference/RR (95% CI)	*p*-value
Patient plans to review an online decision aid on mammography screening for women in their 40s	X	130 (42.4)	—	—
Missing, *n* (%)	X	26 (8.5)	—	—
Breast examination at visit, *n* (%)	X	166 (54.2)	—	—
Missing, *n* (%)	X	2 (0.7)	—	—
PCC documented discussion of mammography's benefits and risks, *n* (%)	X	164 (53.6)	—	—
PCC documented discussion of breast cancer risk, *n* (%)	X	118 (38.6)	—	—
Had mammogram[i]	In 2 years prior	In follow-up		Interaction 0.38
Overall, *n* (%)	115 (37.6)	128 (41.8)	1.12 (0.95, 1.33)	0.17
5-year risk <1.1%	62 (30.5)	65 (32.0)	1.05 (0.82, 1.33)	0.70
5-year risk ≥1.1%	53 (51.5)	63 (62.2)	1.22 (0.97, 1.53)	0.10

Note: Boldface indicates statistical significance ($p<0.05$) for the effect of the intervention on women's screening intentions and ($p<0.01$) for secondary outcomes.
[a]Intentions to be screened—from 0 (will not have a mammogram in the next year) to 100 (will have a mammogram in the next year).[29]
[b]Knowledge—8 True/False questions about the benefits and risks of screening mammography.
[c]Decisional conflict scale— measures uncertainty in a decision, feeling informed in a decision, clear about personal values, supported, and whether one feels that decision making is effective and likely to be implemented (scores range from 0 [no decisional conflict] to 100 [extremely high decisional conflict]). There are 5 subscales detailed below.[28,38]
[d]Informed subscale—scores range from 0 (feels extremely certain about best choice) to 100 (feels extremely uncertain about best choice).
[e]Values clarity subscale—scores range from 0 (feels extremely clear about personal values) to 100 (feels extremely unclear about personal values).
[f]Support subscale—scores range from 0 (feels extremely supported in decision making) to 100 (feels extremely unsupported in decision making).
[g]Uncertainty subscale—scores range from 0 (feels extremely certain about best choice) to 100 (feels extremely uncertain about best choice).
[h]Effective decision subscale—scores range from 0 (good decision) to 100 (bad decision).
[i]Receipt of mammography screening was assessed from 2 years before participating through October 2019 using billing claims (mean follow-up was 16.1 months [SD=5.4 months]). If there were no claims for mammography screening, then the patient's medical record was reviewed to ensure there was no receipt of mammography screening documented.[39] Receipt of screening from the 306 sample is presented (those who completed the postvisit questionnaire); however, results were similar among women who did not complete the postvisit questionnaire.
PCC, primary care clinician; X, questions only asked posttest, no pretest data.

306 women turned age 50 years during follow-up. There was no significant effect modification by patients' race/ethnicity or educational attainment.

Of the 11 women who met the criteria for BCPMs, 10 (91%) discussed BCPMs with their PCCs, 4 (36%) were referred to a high-risk clinic, and 1 (9%) started tamoxifen. Of the 22 women who met the criteria for breast MRI, 19 (86%) discussed breast MRI with their PCCs, 11 (50%) were referred to a high-risk clinic, and 3 (14%) underwent breast MRI. Of the 67 women who met the criteria for genetic counseling, 47 (70%) discussed their risk with their PCCs, 29 (43%) were referred, and 4 (6%) went (Appendix Table 9, available online, shows the number of women who met each NCCN criterion). In open-ended comments, patients gave several reasons (detailed in Appendix Table 10, available online) for not pursuing these interventions, such as wanting more time to consider, not wanting to know, doubts about the accuracy of their family history, the family member who had cancer tested *BRCA*-negative, and questions about insurance coverage.

Patients found the report helpful (95.0%), clear (89.4%), and its length just right (86.0%); 69.8% said it did not make them nervous (Table 3). Most (74.3%) would prefer to receive the risk report by mail/e-mail before a visit to have time to review it. A total of 43 of 51 PCCs (84.3%) reported that risk assessment was their responsibility, and most found the report helpful (96.0%), user-friendly (92.0%), and time-saving (72.6%) (Table 3).

In open-ended comments, most patients reported that the risk report was helpful, "this should be standard practice." PCCs also described the risk report as helpful, but some questioned its use in low-literacy patients. Appendix Table 8 (available online) presents themes in participants' open-ended comments.

DISCUSSION

Receipt of a short personalized breast cancer risk report before a visit was found to be helpful to patients and PCCs and was associated with patients having more knowledge of mammography's benefits and harms and

Table 3. Patient and PCC Thoughts on the Acceptability of the Risk Report

Variable	*n* (%) (*n*=306)
Patients	
Length of the risk report	
Too short	22 (7.2)
Just right	258 (84.3)
Too long	20 (6.5)
Missing	6 (2.0)
Amount of information in the risk report	
Too much	16 (5.3)
Just right	240 (78.4)
Too little	42 (13.7)
Missing	8 (2.6)
Clarity of the risk report	
All or most of the information was clear	269 (87.9)
Some or less of the information was clear	32 (10.5)
Missing	5 (1.6)
Understandable	
Understood all or most of the information	282 (92.2)
Some or less was understandable	16 (5.2)
Missing	8 (2.6)
Anxiety provoking	
Made me very or extremely anxious	5 (1.6)
A little anxious	85 (27.8)
Not at all	208 (68.0)
Missing	8 (2.6)
Helpfulness of the risk report	
It was at least a little helpful	288 (94.1)
Not helpful	9 (2.9)
Missing	9 (2.9)
Preferred way to receive the risk report	
In mail before visit	53 (17.3)
E-mailed before visit	155 (50.6)
In waiting room before visit	32 (10.5)
No preference	33 (10.8)
Other	4 (1.3)
Don't know	3 (1.0)
Missing	26 (8.5)
PCCs	*n*=51
Breast cancer risk assessment is a PCC's responsibility	
Strongly agree or agree	43 (84.3)
Neutral	8 (15.7)
Length of the risk report	
Too short	0
Just right	32 (62.8)
Too long	19 (37.2)
Missing	0
Amount of information in the risk report	
Too much	15 (29.4)
Just right	33 (64.7)
Too little	2 (3.9)
Missing	1 (2.0)
Clarity	
All or most of the information was clear	48 (94.1)
Some or less was clear	3 (5.9)
Missing	0
Would recommend the risk report to colleagues	
Would recommend	44 (86.3)
Would not recommend	6 (11.8)
Missing	1 (2.0)
Most PCCs would learn to use the risk report quickly	
Agree	49 (96.1)
Neutral	2 (3.9)
Missing	0
It was easy to use	
Agree	46 (90.2)
Neutral	3 (5.9)
Disagree	1 (2.0)
Missing	1 (2.0)
It helped me identify women at high risk	
Agree	43 (84.3)
Neutral	7 (13.7)
Disagree	1 (2.0)
Missing	0
It saves me time	
Agree	37 (72.6)
Neutral	10 (19.6)
Disagree	4 (7.8)
Missing	0
It complements my usual approach	
Agree	47 (92.2)
Neutral	2 (3.9)
Disagree	2 (3.9)
Missing	0
The risk report is helpful	
Agree	48 (94.1)
Neutral	2 (3.9)
Disagree	0
Missing	1 (2.0)

PCC, primary care clinician.

with lower decisional conflict about screening. Although screening intentions decreased after receiving the report, especially for women at lower breast cancer risk, they remained in favor of screening. The use of mammography screening tended to increase over time.[46] Overall, 23% (78) of patients met guideline criteria for other breast cancer prevention interventions, and the majority discussed these interventions with their PCC; however, few patients

(8) chose to enact the intervention. Of note, PCCs believed that the use of the risk report saved them time.

Previous studies that have developed decision support for breast cancer screening and prevention have tended to focus on 1 aspect of screening/prevention (e.g., mammography alone,[47−49] BCPMs only[50−52]) or on screening and prevention for women at high risk.[53,54] Few comprehensive decision tools exist, and none exists for quick use during a visit.[54−56] Kaplan et al.,[57] in an RCT of 1,235 women aged 40−74 years, screened patients for their risk of a *BRCA* mutation and provided patients and PCCs with patients' estimated 5-year breast cancer risk before a visit. Similar to this study, their intervention led to more discussions about breast cancer risk and more high-risk clinic referrals. However, that study did not incorporate educational support for patients or PCCs and did not examine the intervention's effect on decision-making outcomes. PCCs increasingly are asked to estimate their patient's breast cancer risk and discuss multiple breast cancer screening and prevention interventions during a visit. This study was designed to help PCCs assess which breast cancer screening/prevention interventions applied to their patients and to help patients better understand their breast cancer risk to engage in shared decision making.

Most patients offered positive comments about the risk report; however, some believed it was too long and others thought more information would be useful. Although most PCCs thought that the risk report was easy to use, some questioned its use in low-literacy patients. The report was designed as a conversation aid. Conversation aids are designed to be brief, require minimal training for use, and fit into clinical workflow.[58,59] They are not meant to be exhaustive but to support patient−PCC communication. To increase adoption, as a next step, investigators will focus on developing a web-based conversation aid that would present basic information on risk and breast cancer screening and prevention recommendations first with links to more information for interested users (e.g., information of lifestyle modifications to lower breast cancer risk).

Similar to previous recommendations, in 2019, the USPSTF recommended clinicians who use 1 of 6 screening tools to identify women at high risk for a *BRCA* mutation.[15] The research team considered using these tools in this study; however, they have not been updated. Beth Israel Deaconess Medical Center genetic counselors who follow NCCN criteria did not want women who would likely not be recommended counseling to be referred or for women for whom counseling would be appropriate to be missed. Despite this, some patients recommended for genetic counseling did not feel that their cancer family history was concerning enough to warrant testing. In addition, as guidelines conflict regarding screening breast MRI in high-risk women, the risk report conservatively recommended breast MRI for women with ≥25% lifetime risk rather than for women with ≥20% lifetime risk using Tyrer−Cuzick. More data on outcomes of breast MRI in high-risk women are needed to inform the broad implementation of breast MRI screening in primary care.

This study was designed to be pragmatic, in that methods of providing patients their risk report were studied in addition to its effects. The study was designed initially so that patients would receive the risk report immediately before a visit, given the investigators' concerns that patients would be anxious if they received the report earlier. However, patient participants wanted more time to review the report. Thus, the next generation of this risk report should allow for flexibility in the timing of completing risk assessments.

Limitations

This study has important limitations. Generalizability is limited because it was a single-site study. However, this allowed the research team to upload risk reports into the health system's online medical record and to follow referrals. Many participants were highly educated; however, there was no effect modification by educational attainment. The study design was quasi-experimental; therefore, changes in outcomes could be due to secular changes. Knowledge may have improved because the post-test was the second exposure to the test. The effects of the risk report cannot be separated from the effects of the PCC; however, the report was designed to support shared decision making.

CONCLUSIONS

Informing women in their 40s of their breast cancer risk before a primary care visit using a brief personalized risk report was associated with more women making more-informed and less-conflicted decisions about mammography and with many at high risk discussing additional screening and prevention interventions with their PCCs. This study is timely because there have been multiple calls for tools to support breast cancer risk assessment and communication in primary care, especially for women in their 40s.[60,61] On the basis of these findings, investigators plan to develop a user-friendly, web-based risk report for women in their 40s and their PCCs to support shared decision making during a visit.

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MAS takes full responsibility for the integrity of the work as a whole from inception to publication. She conceived of the study and acquired, analyzed, and interpreted the data. SS acquired, analyzed, and interpreted the data for this study. AP analyzed and interpreted the data for this study. ARJ, GMA, and MK acquired data for this study. MC, TA, NMT, JLC, TSM, and RBD conceived of the study and analyzed and interpreted the data. All authors drafted the work or revised it critically for important intellectual content and gave final approval of this manuscript. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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SUPPLEMENTAL MATERIAL

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