Original Article

Cumulative risk of a false-positive screening result: A retrospective cohort study using empirical data from 10 biennial screening rounds in BreastScreen Norway

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BACKGROUND: False-positive screening results are an inevitable and commonly recognized disadvantage of mammographic screening. This study estimated the cumulative probability of experiencing a first false-positive screening result in women attending 10 biennial screening rounds in BreastScreen Norway, which targets women aged 50 to 69 years. **METHODS:** This retrospective cohort study analyzed screening outcomes from 421,545 women who underwent 1,894,523 screening examinations during 1995-2019. Empirical data were used to calculate the cumulative risk of experiencing a first false-positive screening result and a first false-positive screening result that involved an invasive procedure over 10 screening rounds. Logistic regression was used to evaluate the effect of adjusting for irregular attendance, age at screening, and number of screens attended. **RESULTS:** The cumulative risk of experiencing a first false-positive screening result was 18.04% (95% confidence interval [CI], 18.00%-18.07%). It was 5.01% (95% CI, 5.01%-5.02%) for experiencing a false-positive screening result that involved an invasive procedure. Adjusting for irregular attendance or age at screening did not appreciably affect these estimates. After adjustments for the number of screens attended, the cumulative risk of a first false-positive screening result was 18.28% (95% CI, 18.24%-18.32%), and the risk of a false-positive screening result including an invasive procedure was 5.11% (95% CI, 5.11%-5.22%). This suggested that there was minimal bias from dependent censoring. **CONCLUSIONS:** Nearly 1 in 5 women will experience a false-positive screening result if they attend 10 biennial screening rounds in BreastScreen Norway. One in 20 will experience a false-positive screening result with an invasive procedure. ***Cancer* 2021;0:1-8**.

LAY SUMMARY:

- A false-positive screening result occurs when a woman attending mammographic screening is called back for further assessment because of suspicious findings, but the assessment does not detect breast cancer.
- Further assessment includes additional imaging. Usually, it involves ultrasound, and sometimes, it involves a biopsy.
- This study has evaluated the chance of experiencing a false-positive screening result among women attending 10 screening examinations over 20 years in BreastScreen Norway.
- Nearly 1 in 5 women will experience a false-positive screening result over 10 screening rounds. One in 20 women will experience a false-positive screening result involving a biopsy.

KEYWORDS: breast neoplasms, false-positive reactions, mammography, mass screening.

INTRODUCTION

A false-positive screening result is an inevitable and commonly recognized disadvantage associated with mammographic screening. This occurs when a woman is recalled for a diagnostic assessment because of suspicious findings on her screening mammogram, but the outcome is negative for breast cancer. This assessment involves additional imaging, which can include ultrasound, and it can also involve invasive procedures such as fine-needle aspiration cytology (FNAC), core-needle biopsy, and open biopsy. Although negative results from additional workup can reassure women that they do not have breast cancer, false-positive screening results can cause temporary uncertainty, stress, anxiety, and fear.[1,2] Population-based mammographic screening targets healthy women. It is important to recall women who have suspicious findings that require additional follow-up to rule out or confirm malignancy while minimizing further assessment among women with a very low suspicion for breast cancer.[3]

Recall rates due to abnormal screening mammograms are higher in the United States than Europe.[4-6] In the United States, data from the Breast Cancer Surveillance Consortium indicate that the risk of a false-positive screening result

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(recall) is 21.4% for prevalently screened women aged 50 to 54 years and 8.7% for subsequently screened women.[7] In Norway, the corresponding estimates for women who initiate biennial screening at the ages of 50 to 51 years are 4.4% to 6.0% and 1.6% to 2.5%.[8,9] The risk of experiencing an invasive procedure with a benign outcome is roughly 3.5% for prevalent screens and 1.0% for subsequent screens in the United States; the corresponding values are 1.3% to 1.7% and 0.3% to 0.6% in Norway.[7-9]

Biennial screening is recommended for women aged 50 to 69 years in Europe; this increases the risk of experiencing the benefits and harms of screening during one's lifetime.[10] Describing the cumulative risk of a false-positive screening result is, therefore, important for women and screening program administrators. The cumulative risk of a false-positive screening result associated with initiating biennial screening around the age of 50 years is more than 40% after 10 years for women in the United States but approximately 20% after roughly 20 years in Europe.[7,9,11-13] The cumulative risk of experiencing a false-positive screening result that includes an invasive procedure among women who initiate biennial screening at the age of 50 years in the United States is 6% after 10 years and 14% after 25 years.[7,14] In Europe, the risk is roughly 2% to 5% after 20 years.[9,13]

To the best of our knowledge, no studies have used exclusively empirical data to describe the cumulative risks of experiencing a false-positive screening result in Europe because of the need for very long follow-up and complete data registration. This study aimed to use complete, population-based data from BreastScreen Norway to generate empirical evidence about the probability of experiencing a false-positive screening result. Our objective was to describe the cumulative risk of experiencing a first false-positive screening result at any time among women attending 10 consecutive screening rounds in BreastScreen Norway. We also aimed to describe the cumulative risk of experiencing a first false-positive screening result that involved an invasive procedure.

MATERIALS AND METHODS

This study is part of the Quality Assurance and Improvement in BreastScreen Norway project and was reviewed by the privacy ombudsman at the Oslo University Hospital (PVO 20/12601).

Study Setting

BreastScreen Norway is a population-based screening program that invites roughly 650,000 women aged 50 to 69 years to 10 rounds of biennial mammographic screening. BreastScreen Norway began in 1 region in late 1995 and was nationwide by 2005.[15] In 2019, women in 6 of 16 screening regions had been invited to 10 screening rounds. Invitations with a suggested appointment for screening are sent to women on the basis of birth cohorts. Some women may receive an invitation to start screening slightly before or after the age of 50 years because of regional differences in the startup of the program. Screen-film mammography was used exclusively until the early 2000s, and the transition to full-field digital mammography was competed in 2011.[15]

Two radiologists independently read each screening mammogram and assign each breast a score of 1 (no abnormalities), 2 (probably benign), 3 (intermediate suspicion), 4 (probably malignant), or 5 (high suspicion of malignancy). Women's mammograms are discussed at a consensus or arbitration meeting if either radiologist assigns either breast a score ≥ 2, and a decision is made whether to recall the woman for further assessment. This follow-up assessment involves diagnostic imaging (eg, mammography and ultrasound), and approximately 40% of women also experience an invasive procedure (FNAC, core-needle biopsy, or open biopsy).[15]

Study Sample

This retrospective cohort study included women who attended BreastScreen Norway between November 1, 1995, and December 31, 2019. We included only women who could potentially attend 10 screening rounds on the basis of their age when they first attended the program and who did not opt out of their data being used for research purposes (>98% of invited women).[15] This meant that, for example, we did not include women aged 60 years when they first attended screening because they could not attend 10 screening rounds before aging out of BreastScreen Norway. We did include women aged 50 years when they first attended screening because they would have the opportunity to attend 10 screening rounds before aging out of the program. Women were included if they had already had the opportunity to attend 10 screening rounds (eg, first screened at the age of 50 years in 1996) or would have this opportunity in the future (eg, first screened at the age of 50 years in 2016).

We excluded women who had a history of ductal carcinoma in situ (DCIS) or invasive breast cancer before attending the program or who participated in studies investigating different screening ages or techniques within BreastScreen Norway.[16-21] We also excluded women who ever self-referred to screening, were recalled because clinical symptoms of breast cancer were reported at their

screening appointment, had technically unsatisfactory screening mammograms, or declined follow-up after a positive screening result.

Data Source

Data were obtained from the Cancer Registry of Norway, which administers BreastScreen Norway. The registry's databases contain information about women's screening invitations, attendance, and results as well as information about DCIS and invasive breast cancer diagnoses for all women of all ages. The latter is nearly complete and morphologically verified in more than 99% of cases.[22]

Outcome Variables

The primary outcomes in this study were 1) a first false-positive screening result and 2) a first false-positive screening result that involved an invasive procedure. Women were classified as having experienced a false-positive screening result if they were recalled for further assessment because of abnormal mammographic findings and were not diagnosed with DCIS or invasive breast cancer within 180 days (approximately 6 months) of the screening examination associated with the recall.[23] Women were classified as having experienced a false-positive screening result that involved an invasive procedure if they had a false-positive screening result and underwent FNAC, core-needle biopsy, or open biopsy as part of their diagnostic workup. These women were a subgroup of the women who experienced a false-positive screening result.

Statistical Analyses

We described the study sample by using means and ranges for continuous variables and frequencies and proportions for categorical variables. These descriptive statistics included the observed proportion of women who experienced a false-positive screening result during the study period.

The cumulative risk was defined as the probability that a woman experienced the outcome of interest over the course of attending 10 screening rounds in BreastScreen Norway. We calculated this by adding the products of the probability of experiencing a first false-positive screening result (or a first false-positive screening result that involved an invasive procedure) at each screening round and the probability of not experiencing the outcome of interest at any previous round. Women's follow-up information was censored if they were diagnosed with DCIS or invasive breast cancer, aged out of the screening program, died, emigrated, or reached the end of the study period. The 95% confidence intervals (CIs) for cumulative risks were calculated with standard errors derived from the Greenwood approximation.[24]

To supplement the empirical analyses, we also estimated these risks with discrete-time survival models.[25] We fitted logistic regression models where the outcome was either a first false-positive screening result or a first false-positive screening result that involved an invasive procedure (separate models). As described by Singer and Willett, the screening rounds acted as multiple intercepts.[25] We used these models to evaluate the effects of the screening technique (screen-film or full-field digital mammography), screening year, age at screening, screening center, and total number of screening rounds attended. The last provided information about the potential impact of dependent censoring.[26]

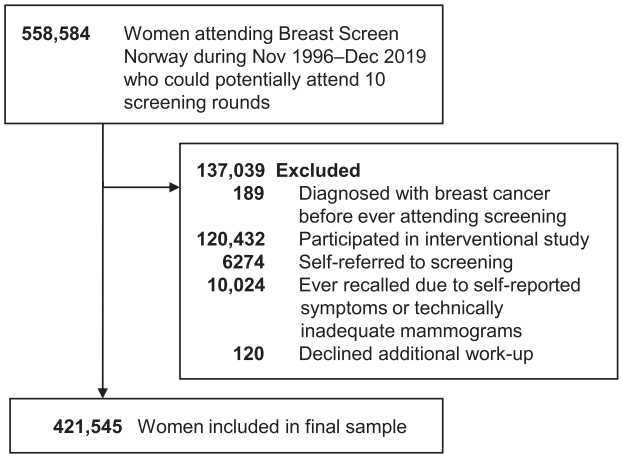

Figure 1. Number of women included and excluded in this study. Women were excluded sequentially according to the given criteria.

RESULTS

During the study period, 558,584 women who could potentially attend 10 screening rounds in BreastScreen Norway attended the program. We excluded 137,039 women, and this left 421,545 women (1,894,523 screening examinations) in the final sample (Fig. 1). The mean age at prevalent (first) attendance was 50.7 years (range, 48-53 years; Table 1). By December 20, 2019, 18,203 women had attended a tenth screening round with a mean age of 68.5 years (range, 66-71 years). Digital mammography was offered to 57.0% of women attending their prevalent screening examination and to 100% of women attending their tenth screening examination.

TABLE 1. Characteristics of 421,545 Women Attending BreastScreen Norway From November 1995 to December 2019

	Screening Round									
	1	2	3	4	5	6	7	8	9	10
Attendees	421,545	342,318	278,519	231,250	190,802	153,257	118,830	86,561	53,238	18,203
Age at screening, mean (range), y	50.7 (48-53)	53.0 (49-70)	55.2 (50-70)	57.3 (52-70)	59.3 (54-71)	61.3 (56-70)	63.3 (59-71)	65.3 (61-71)	67.1 (63-71)	68.5 (66-71)
Irregular attendance pattern[a]	33,813 (8.0%)	28,718 (8.4%)	18,416 (6.6%)	12,743 (5.5%)	8427 (4.4%)	5532 (3.6%)	3093 (2.6%)	1405 (1.6%)	412 (0.8%)	0 (0.0%)
Digital screens	240,366 (57.0%)	206,124 (60.2%)	181,754 (65.3%)	168,613 (72.9%)	160,483 (84.1%)	140,375 (91.6%)	117,613 (99.0%)	86,009 (99.4%)	53,235 (100.0%)	18,203 (100.0%)
False-positive screening result	24,998 (5.9%)	7981 (2.3%)	5367 (1.9%)	3847 (1.7%)	3076 (1.6%)	2338 (1.5%)	1759 (1.5%)	1262 (1.5%)	759 (1.4%)	251 (1.4%)
Negative additional imaging[b]	16,654 (4.0%)	6130 (1.8%)	4045 (1.5%)	2956 (1.3%)	2315 (1.2%)	1778 (1.2%)	1386 (1.2%)	974 (1.1%)	569 (1.1%)	187 (1.0%)
Invasive procedure[b,c]	8005 (1.9%)	1743 (0.5%)	1264 (0.5%)	860 (0.4%)	731 (0.4%)	536 (0.3%)	362 (0.3%)	281 (0.3%)	189 (0.4%)	62 (0.3%)
Information not available	339	108	58	31	30	24	11	7	1	2

Cell values represent frequencies unless otherwise indicated.

[a]Did not attend prior invitation to screening.

[b]Proportions calculated as the percentage of the total number of attendees.

[c]Fine-needle aspiration cytology, core-needle biopsy, or open biopsy.

In our sample, 4% of women attended 10 screening examinations, and most women (88.7%) never experienced a false-positive screening result; 10.5% of women experienced 1 false-positive screening result, and 0.8% of women experienced 2 or more (Fig. 2A). Similarly, most women (96.7%) never experienced a false-positive screening result that involved an invasive procedure. Roughly 3.1% of women experienced 1 invasive procedure, and 0.1% of women experienced 2 or more (Fig. 2B).

The proportion of women who experienced a false-positive screening result was higher for prevalent screens than subsequent screens (5.9% for prevalent screens vs 2.3% for second screens; Fig. 3A). This risk decreased until women attended 7 screening rounds, from which point it was 1.3% per round. The cumulative risk of a first false-positive screening result after 10 screening rounds was 18.04% (95% CI, 18.00%-18.07%; Fig. 3A).

The proportion of women experiencing a false-positive screening result that involved an invasive procedure was also higher for prevalent screens than subsequent screens (1.9% for prevalent screens vs 0.5% for second screens; Fig. 3B). This risk was relatively constant afterwards (0.3%-0.4% per round). The cumulative risk of experiencing a first false-positive screening result that involved an invasive procedure was 5.01% (95% CI, 5.01%-5.02%) after 10 screening rounds (Fig. 3B).

Results from the regression analyses indicated that both cumulative risks were relatively consistent whether adjustments were made for the screening technique (screen-film or full-field digital mammography), screening year, age at screening, screening center, or total number of screening examinations attended (Table 2). Adjusting for the last allowed us to evaluate the potential for dependent censoring (see the supporting information). The effect of this adjustment was modest: we observed a cumulative risk of 18.28% (95% CI, 18.24%-18.32%) for experiencing a false-positive screening result and a cumulative risk of 5.11% (95% CI, 5.11%-5.22%) for experiencing a false-positive screening result that involved an invasive procedure. We concluded that dependent censoring was unlikely to have had a substantial effect on our results. The fully adjusted models, which did not include the screening year because of its collinearity with age at screening, indicated that the cumulative risk was 17.94% (95% CI, 17.90%-17.97%) for experiencing a false-positive screening result and 5.05% (95% CI, 5.05%-5.06%) for experiencing a false-positive screening result that involved an invasive procedure (Table 2).

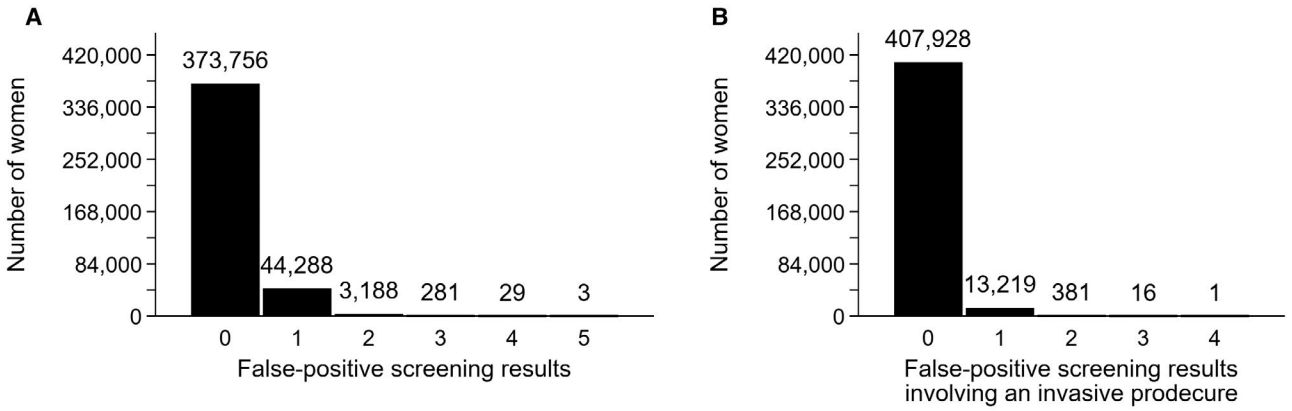

Figure 2. Number of (A) false-positive screening results and (B) false-positive screening results involving an invasive procedure experienced by 421,545 women attending BreastScreen Norway from November 1995 to December 2019.

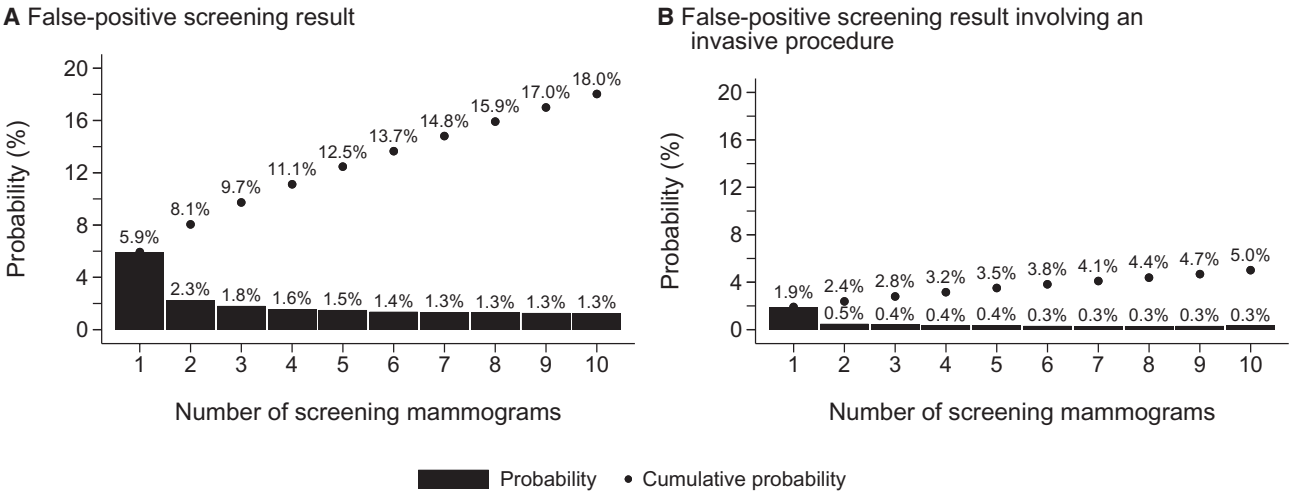

Figure 3. Observed risk of experiencing (A) a false-positive screening result and (B) a false-positive screening result involving an invasive procedure among 421,545 women attending BreastScreen Norway from November 1995 to December 2019.

DISCUSSION

This study used empirical data to describe the probability of experiencing a first false-positive screening result associated with attending 10 biennial screening rounds in BreastScreen Norway. The cumulative risk of experiencing a first false-positive screening result was 18.04%, and the cumulative risk of experiencing a first false-positive screening result that involved an invasive procedure was 5.01%.

Similar to the Kaplan-Meier approach to calculating survival, our empirical approach to calculating the cumulative risk assumed that the risk of experiencing the outcome of interest did not change for women with censored follow-up time. This assumption facilitated the inclusion of screening data from as recently as 2019. As a result, many women's follow-up was censored at the end of the study period before they had attended 10 screening rounds. We observed that 11.3% of the women in our sample experienced at least 1 false-positive screening result during the study period, and 3.3% experienced at least 1 false-positive screening result that involved an invasive procedure. These proportions underestimate the cumulative risks because not all women had attended 10 screening rounds. The proportion of observed false-positive screening results equals the cumulative risk in a scenario where all women have complete follow-up.

In addition to the empirical approach, our study also used a discrete-time survival models to estimate cumulative risks with logistic regression. This method produces

TABLE 2. Adjusted Cumulative Risks (%) of Experiencing a False-Positive Screening Result or a False-Positive Screening Result Involving an Invasive Procedure Among 421,545 Women Attending BreastScreen Norway From November 1995 to December 2019

	Screening Round									
Adjusted for	1	2	3	4	5	6	7	8	9	10
False-positive screening result										
Screening technique[a]	5.97	8.11	9.78	11.18	12.51	13.70	14.83	15.93	16.99	18.01
Irregular attendance pattern	5.91	8.03	9.70	11.10	12.44	13.65	14.80	15.92	17.01	18.05
Screening year	6.03	8.18	9.86	11.25	12.57	13.75	14.87	15.94	16.97	17.97
Age at screening	5.60	7.90	9.83	11.44	12.89	14.06	15.05	15.89	16.61	17.25
Screening center	5.76	7.87	9.56	10.98	12.34	13.56	14.73	15.88	17.00	18.09
Number of screens attended	5.59	7.66	9.33	10.76	12.15	13.43	14.67	15.90	17.10	18.28
All variables[b]	4.73	6.81	8.69	10.38	12.01	13.43	14.71	15.88	16.95	17.94
False-positive screening result involving an invasive procedure										
Screening technique[a]	1.94	2.44	2.86	3.21	3.56	3.86	4.13	4.41	4.70	5.01
Irregular attendance pattern	1.89	2.37	2.79	3.14	3.50	3.80	4.09	4.39	4.69	5.02
Screening year	1.96	2.46	2.89	3.23	3.58	3.88	4.15	4.42	4.70	5.00
Age at screening	2.29	2.83	3.27	3.61	3.94	4.20	4.43	4.65	4.87	5.09
Screening center	1.83	2.31	2.73	3.09	3.45	3.77	4.06	4.36	4.66	4.98
Number of screens attended	1.69	2.14	2.56	2.92	3.30	3.65	3.98	4.32	4.70	5.11
All variables[b]	1.68	2.14	2.56	2.92	3.31	3.65	3.98	4.32	4.68	5.05

[a]Analogue or full-field digital mammography.
[b]The screening year variable was omitted because of its collinearity with the age at screening.

biased results if experiencing the outcome of interest affects women's screening attendance (dependent censoring).[26] To evaluate the potential for dependent censoring, we adjusted our models for the total number of screening rounds that women attended. The effect of this adjustment was modest, and we concluded that dependent censoring was unlikely to have had a substantial effect on our results.

As with other European studies, our results also differed notably from US studies, which largely use data from the Breast Cancer Surveillance Consortium. The latter have indicated that, for women who initiate biennial screening at the age of 50 years, the cumulative risk after 10 years is 42% for experiencing at least 1 false-positive screening result and 6.4% for experiencing at least 1 false-positive screening result involving an invasive procedure.[7] Other US-based studies evaluating different age groups, screening intervals, or follow-up have observed cumulative risks of 42.0% to 59.3% for false-positive screening results and 6.2% to 18.6% for false-positive screening results that involve invasive procedures.[7,11,26-28]

Organizational factors can play a significant role in the risk of a false-positive screening result and likely contribute to the large differences in false-positive rates between United States and BreastScreen Norway.[13] For example, the European guidelines recommend that breast radiologists read 3500 to 11,000 mammograms annually, whereas 960 every 2 years are required by the US Mammography Quality Standards Act.[29,30] This likely results in a lower risk of a false positive in Europe compared with the United States.[31,32] Moreover, cumulative risks increase with shorter screening intervals (eg, annual vs biennial screening) and a longer screening duration (eg, ages of 40-74 vs 50-69 years), both of which are common in the United States.[7,28] Additionally, the risk of a false-positive screening result increases when prior mammograms are not available for comparison.[7,28] Prior screening examinations are readily available in Norway, where the screening program is administered nationally, but this is not always the case in the United States.[28]

Our results are consistent with previous Norwegian estimates for experiencing a first false-positive screening result (20.8% and 20.0%, respectively) and an invasive procedure with a benign outcome (3.9% and 4.1%, respectively).[8,9] The similarly in results across studies suggests that the cumulative risk of experiencing a false-positive screening result in BreastScreen Norway is not very sensitive to small differences in the age at which women initiate screening.

A strength of our study is the inclusion of data from more than 1.8 million screening examinations performed during 1995-2019, including those for 18,203 women who attended 10 biennial screening rounds in BreastScreen Norway. In previous Norwegian studies, women had yet to be invited to 10 screening rounds, and the risk of a false-positive screening result or invasive procedure with a benign outcome in later screening rounds was extrapolated.[8,9] The results of our study confirm that

the methodological approach used in these previous studies was robust.

Following data privacy protocols, we did not include women who requested that their data pertaining to negative screening results not be used for research. Because this limited the number of women included in the denominator, we could have overestimated the proportion of women experiencing a false-positive screening result. However, this is unlikely to have had a major impact on our results because <2% of women attending BreastScreen Norway have made this request.[15]

Women who experience a false-positive screening result have a higher risk of breast cancer than those with negative screening results.[33,34] This risk is further increased among women whose false-positive result involves an invasive procedure.[33] More than 50% of the women invited to BreastScreen Norway attend 10 consecutive screening rounds, and this suggests that the cumulative risk of a false-positive screening result is relevant to women in the program's target group.[35] As informed choice becomes increasingly important in organized breast cancer screening, it is essential to provide women with accurate information about the cumulative risks associated with attending repeated screening and the increased breast cancer risk associated with false-positive screening results.

In conclusion, the risk of experiencing a false-positive screening result or a false-positive screening result involving an invasive procedure in any given screening round was low. However, our study found that less than 1 in 5 women would experience a false-positive screening result if they attended 10 screening rounds with BreastScreen Norway. One in 20 women would experience a false-positive screening result that involved an invasive procedure. These cumulative risks are important to communicate with women targeted for repeated mammographic screening.

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CONFLICT OF INTEREST DISCLOSURES

Solveig Hofvind is the head of BreastScreen Norway. The other authors made no disclosures.

AUTHOR CONTRIBUTIONS

Kaitlyn M. Tsuruda: Study conceptualization, data curation, formal analyses, funding acquisition, investigation and methodology, validation, visualization, and writing (original draft preparation, review, and editing). **Marthe Larsen:** Study conceptualization, formal analyses, investigation and methodology, validation, visualization, and writing (review and editing). **Marta Román:** Study conceptualization, formal analyses, investigation and methodology, supervision, validation, visualization, and writing (review and editing). **Solveig Hofvind:** Study conceptualization, data curation, formal analyses, funding acquisition, investigation and methodology, project administration, resources, supervision, validation, visualization, and writing (review and editing).

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