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EPIDEMIOLOGY

Association of diagnostic work-up with subsequent attendance in a breast cancer screening program for false-positive cases

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Abstract The objective of this study is to determine whether the likelihood of returning for routine breast cancer screening differed for false-positive cases depending on the diagnostic work-up. Using the original data from a French population-based breast cancer screening program, we compared the attendance rates at the subsequent round of screening for 16,946 and 1,127 participants who received negative (i.e., American College of Radiology, ACR, categories 1–2) and false-positive mammograms, respectively. False-positive mammograms were categorized ACR 0 (i.e., warranting additional imaging evaluation), 3 (i.e., warranting clinical and imaging follow-up), and 4–5 (i.e., warranting biopsy). We estimated the odds ratios of attendance at subsequent screening round using logistic regression, adjusting for age and history of previous mammography. The attendance rates at the subsequent screening round were 80.6% for women who received negative mammograms versus 69.6, 74.3, and 70.1% for women who received false-positive mammograms warranting additional imaging evaluation, clinical and imaging follow-up, or biopsy, respectively. In comparison to women who received negative mammograms, the corresponding adjusted odds ratios of returning for routine screening were 0.6 [95% confidence interval (CI) 0.4–0.8], 0.8 (95% CI 0.6–0.9), and 0.6 (95% CI 0.4–0.8). No significant differences were found in odds ratios of attendance across ACR categories among women who received false-positive mammograms. Similar figures were observed for attending at least one of the two subsequent screening rounds. In conclusion, in comparison to women with normal or benign findings on index mammograms, false-positive cases warranting additional imaging evaluation, clinical and imaging follow-up, or biopsy had uniformly decreased odds of attending subsequent routine screening rounds.

Keywords Breast cancer · Mass screening · False positive · Re-attendance

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Introduction

Based on evidence that screening mammography helps save lives by detecting breast cancer in its earlier stages [1], many Western countries have implemented breast cancer screening programs for women aged 50 years or older [2]. Yet, screening mammography also has adverse effects including the consequences of false-positive results [3].

A false-positive mammogram causes short-term anxiety and psychological distress as well as long-term breast cancer-related concerns [4, 5]. Whether or not receiving a false-positive mammogram undermines attendance at subsequent scheduled screening mammography is

controversial. A meta-analysis of 12 studies reported no significant relationship between false-positive mammograms and return for routine screening among European women, a decreased likelihood of re-attendance among Canadian women who received false-positive results, and even an increased likelihood of re-attendance among women who received false-positive results in the United States [4].

Different diagnostic procedures including further imaging evaluation, short-term clinical and radiological follow-up, and surgical biopsy may be proposed to women who received positive mammograms. Few studies focused on the adverse psychological consequences of false-positive mammograms according to the diagnostic procedure used to exclude cancer. As part of the Uppsala County screening program in Sweden [6], no differences in adverse psychological consequences and comparable levels of re-attendance rates were found depending on the diagnostic procedure by which the result was ultimately determined (i.e., imaging evaluation, fine-needle aspiration, or surgical biopsy).

In this study, we compared attendance rates at subsequent routine screening between women who received negative and false-positive mammograms. More specifically, we aimed to determine whether the likelihood of returning for routine breast cancer screening differed depending on the diagnostic work-up as rated by the American College of Radiology (ACR) category assigned to the index mammogram.

Participants and methods

Study design and setting

We analyzed the original data from an ongoing population-based breast cancer screening programme in Isère, a French administrative entity with nearly 1.2 million inhabitants.

Screening procedure and diagnostic work-up

The program, which was coordinated and monitored by the Office De Lutte contre le Cancer, routinely screened women aged 50–74 every 2 years [7]. For both index and subsequent mammograms, eligible women were sent a personal letter inviting them to make an appointment at their convenience. Nonattendees were sent a reminder within 6 months.

Two-view mammography and clinical breast examination were performed for both first and subsequent screens. Mammographies were performed by trained radiographers and were read independently by two board-certified radiologists with specific training in screening mammography and who met standard performance criteria [8].

Each mammogram was categorized using the ACR criteria derived from the Breast Imaging Reporting and Data Systems [9]. Mammograms assigned to ACR category 1 (i.e., negative) or 2 (i.e., benign finding) by the two radiologists were considered negative and did not warrant further work-up. Women with mammograms assigned to ACR category 3 (i.e., lesion with a high probability of being benign) by at least one of the two radiologists were proposed clinical and radiological follow-up usually for a 6-month period. Women with mammograms assigned to ACR category 4 (i.e., suspicious abnormality) or 5 (i.e., highly suggestive of malignancy) were recommended surgical biopsy. Mammograms were assigned to ACR category 0 when the second radiologist proposed additional imaging evaluation.

Study sample

The present analysis focused on participants who received negative or false-positive mammograms between January 2002 and December 2003. Negative mammograms were defined as mammograms categorized ACR 1–2 (i.e., mammograms with normal or benign findings), while false-positive mammograms included mammograms categorized ACR 0 (i.e., warranting additional imaging evaluation), 3 (i.e., warranting clinical and radiological follow-up), or 4–5 (i.e. warranting biopsy) that were ultimately concluded to be negative for malignancy after further diagnostic work-up. Women who did not comply with the diagnostic work-up (6.8%) were considered false-positive cases if they were not recorded by the Isère Cancer Registry. This population-based registry covered the entire resident population of Isère and collected cases from different sources including histopathology laboratories, oncology departments, and computerized hospital discharge databases.

In accordance with previous reports [10, 11], attendance rates at subsequent routine screening rounds were estimated after excluding women who were over the screening age range (i.e., 75 and older), had moved out of Isère, had undergone earlier self- or general practitioner-referred private screening, had developed interval breast cancer, or were deceased. The database of women eligible for routine breast cancer screening was updated every 3 months, using the information provided by the local public health insurance agencies. Additionally, women could explain the reasons for not attending routine screening mammography by completing and returning a questionnaire sent along with the invitation letter. Data on interval breast cancer cases were provided by the Isère Cancer Registry [7]. All cases of interval cancer were validated using a structured chart review.

Data collection

The Office de Lutte contre le Cancer routinely collected information on participant characteristics including age, previous history of routine breast cancer screening, screening mammography findings categorized using the ACR criteria, and the results of the diagnostic work-up.

Study outcomes

Our primary study outcome was attendance at the following routine screening round. The following routine screening round was scheduled 2 years after the index mammogram for women with normal or benign findings. Since false-positive cases were sent a personal invitation letter 2 years after the index mammogram and two reminders 6 and 12 months after the first invitation, we considered that a woman re-attended if she participated up to 1 year after the second reminder, i.e., within 2 years after the first invitation. This strategy prevented us from underestimating attendance rates at subsequent screening rounds because of delays resulting from additional evaluation among false-positive cases. Our secondary outcome was attendance at one or more of the two following routine screening rounds (i.e., scheduled 2 and 4 years after the index mammography, respectively).

Statistical analyses

We compared baseline characteristics depending on ACR category using the Chi-square test. We computed point estimates of attendance rate and their corresponding 95% confidence intervals (CIs) from the binomial distribution for women who received mammograms with normal or benign findings (i.e., ACR 1–2), warranting additional imaging evaluation (i.e., ACR 0), clinical and radiological follow-up (i.e., ACR 3), or biopsy (i.e., ACR 4–5) separately.

We performed multivariable logistic regression to estimate the odds ratios of attendance at subsequent screening rounds for women warranting additional imaging evaluation, clinical and radiological follow-up, or biopsy in comparison to those who received mammograms with normal or benign findings. Odds ratios were adjusted for age (5-year categories) and previous history of routine screening. Because attendance at the following rounds may vary depending on whether women have undergone a previous screening program mammography [12], we tested for significance a first-order interaction term between ACR category and history of previous screening program mammography.

Two-sided P values less than 0.05 were considered statistically significant. Analyses were performed using Stata version 10.0 (Stata Corporation, College Station, TX, USA).

Results

Overall 21,299 women were screened between January 2002 and December 2003, including 19,601 women who received mammograms with normal or benign findings, 1,503 women who received false-positive mammograms, 188 women who were diagnosed with histologically confirmed breast cancer, and 7 women for whom the mammogram was technically inadequate (Fig. 1). Our analytical samples consisted of 18,073 women who were eligible for attending the first subsequent routine screening round (i.e., scheduled 2 years after the index mammography), and 15,139 women who were eligible for attending both the first and second subsequent routine screening rounds (i.e., scheduled 2 and 4 years after the index mammography, respectively).

Of 18,073 women eligible for attending the following routine screening, 16,946 (93.8%) received index mammograms with normal or benign findings and 1,127 (6.2%) received false-positive index mammograms, including 191 (1.1%) mammograms warranting additional imaging evaluation, 789 (4.4%) warranting clinical and radiological follow-up, and 147 (0.8%) warranting biopsy (Table 1). False-positive cases were younger and more likely to have a history of a previous screening program mammography than women who received mammograms with normal or benign findings.

The overall attendance rates at the first subsequent screening were 72.9% (95% CI 70.2–75.5) and 80.6% (95% CI 80.0–81.2) for women who received false-positive and negative mammograms, respectively (odds ratio 0.6, 95% CI 0.6–0.7). Re-attendance rates were lower for false-positive cases with mammograms warranting additional imaging evaluation, clinical and radiological follow-up, or biopsy than for women who received mammograms with normal or benign findings at baseline (Table 2).

After adjusting for age and history of previous screening program mammography, false-positive mammograms warranting additional imaging evaluation, clinical and radiological follow-up, or biopsy remained associated with decreased odds of returning for subsequent routine screening (Table 3). No significant interaction was found between ACR category and history of previous screening mammography.

In order to account for delays in diagnostic work-up, we analyzed participation rates at longer time to follow-up for women who received false-positive mammograms (i.e., 4 years after the index mammogram) in comparison to negative cases (i.e., 3.5 years after the index

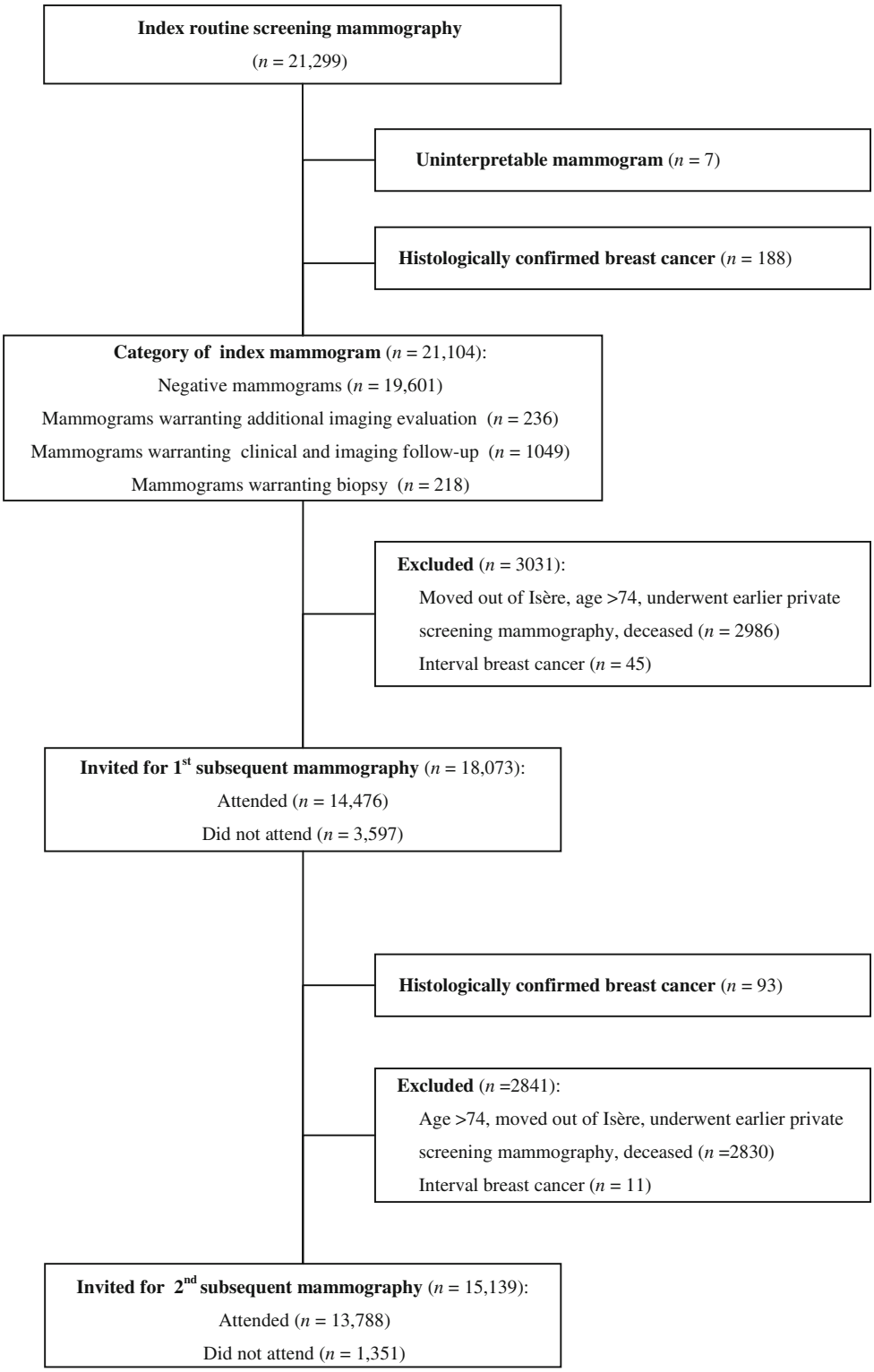

Fig. 1 Flow-chart of women's enrollment

mammogram). These new results neither modify our conclusions with regard to the association of diagnostic work-up with the attendance at the first subsequent screening round nor did it alter the magnitude of its effect.

When restricting the analysis to 15,139 women eligible for the two subsequent routine screening rounds, re-attendance rates were 87.8% (95% CI 85.6–89.9%) and 91.3% (95% CI 90.8–91.7%) for women who received

Table 1 Comparison of characteristics of women eligible for attending the first ($n = 18,073$) and the two ($n = 15,139$) subsequent screening rounds depending on the category of the index mammogram

	Women eligible for the first subsequent screening ($n = 18,073$)					Women eligible for both the first and second subsequent screenings ($n = 15,139$)				
	Mammograms warranting additional imaging evaluation ($n = 191$)	Negative mammograms ($n = 16,946$)	Mammograms warranting clinical and imaging follow-up ($n = 789$)	Mammograms warranting biopsy ($n = 147$)	*P* value	Mammograms warranting additional imaging evaluation ($n = 155$)	Negative mammograms ($n = 14,210$)	Mammograms warranting clinical and imaging follow-up ($n = 653$)	Mammograms warranting biopsy ($n = 121$)	*P* value
Category of index mammogram										
Age [*n* (%)]										
50–54	66 (34.5)	4,909 (29.0)	279 (35.4)	53 (36.0)	0.005	57 (36.8)	4,433 (31.2)	249 (38.1)	46 (38.0)	0.006
55–59	34 (17.8)	3,083 (18.2)	150 (19.0)	25 (17.0)		31 (20.0)	2,766 (19.5)	132 (20.2)	22 (18.2)	
60–64	35 (18.3)	3,729 (22.0)	165 (20.9)	28 (19.1)		31 (20.0)	3,415 (24.0)	149 (22.8)	26 (21.6)	
65–69	31 (16.2)	2,837 (16.7)	104 (13.2)	18 (12.2)		27 (17.4)	2,599 (18.3)	89 (13.6)	16 (13.2)	
70– 74	25 (13.1)	2,388 (14.1)	91 (11.5)	23 (15.6)		9 (5.8)	997 (7.0)	34 (5.2)	11 (9.1)	
History of previous screening, *n* (%)	114 (59.7)	10,439 (61.6)	383 (48.5)	83 (56.5)	0.000	89 (57.4)	8,562 (60.2)	305 (46.7)	66 (54.6)	0.000

false-positive and negative mammograms at baseline, respectively (odds ratio 0.7, 95% CI 0.6–0.8). In comparison to women who received mammograms with normal or benign findings at baseline, re-attendance rates were lower for false-positive cases with index mammograms warranting additional imaging evaluation or biopsy but not for those warranting clinical and radiological follow-up (Table 2). In multivariable analysis, false-positive mammograms warranting additional imaging evaluation or biopsy remained associated with decreased odds of attending at least one of the two subsequent screening rounds relative to mammograms with normal or benign findings (Table 3). Yet, no significant differences were found in odds ratios of attending subsequent screening rounds across ACR categories among false-positive cases.

Discussion

In this population-based study, receiving a false-positive mammogram was associated with a decreased likelihood of returning for subsequent routine breast cancer screening rounds. Unexpectedly, we did not find evidence of statistically significant differences in the adjusted odds of subsequent attendance according to ACR category among women who experienced recalls for ultimately negative findings.

As few as 72.9% of women who received false-positive mammograms returned for subsequent routine breast cancer screening in our study. This finding is at variance with the results of previous surveys, suggesting that a substantial fraction of women actively participating in screening mammography would be willing to be recalled for either a noninvasive or a invasive diagnostic procedure if it resulted in even a small increase in the chance of detecting a cancer [13, 14]. Published estimates of the re-attendance rate after receiving false-positive mammograms range between 27 and 52% in Canada [15, 16], 63 and 87% in the US [10, 17], and 73 and 95% in Europe [6, 18]. As noted by others [4], regional differences in re-attendance rates are likely to reflect variations in baseline participation in routine screening as well as screening interval and procedures. In most European countries, screening programs are implemented at the national level, contributing to higher participation rates than in the US. These regional differences may also reflect heterogeneity in opportunistic screening [19, 20].

Overall, compared to women with negative mammograms, receiving a false-positive mammogram was associated with a 0.6 odds ratio of returning for routine screening in our study. This finding was at variance with the results from a meta-analysis of European studies, which failed to show any relationship between a false-positive

Table 2 Attendance rates depending on baseline characteristics

	Attendance at the first subsequent screening ($n = 18,073$)			Attendance at the first and/or second subsequent screening ($n = 15,139$)		
	Eligible women	Attendance	% (95% CI)	Eligible women	Attendance	% (95% CI)
Category of index mammogram						
Warranting additional imaging evaluation	191	133	69.6 (62.6–76.0)	155	132	85.2 (78.6–90.4)
Negative	16,946	13,654	80.6 (80.0–81.2)	14,210	12,972	91.3 (90.8–91.7)
Warranting clinical and imaging follow-up	789	586	74.3 (71.1–77.3)	653	582	89.1 (86.5–91.4)
Warranting biopsy	147	103	70.1 (62.0–77.3)	121	102	84.3 (76.6–90.3)
Age						
50–54	5,307	4,012	75.6 (74.4–76.7)	4,785	4,260	89.0 (88.1–89.9)
55–59	3,292	2,677	81.3 (79.9–82.6)	2,951	2,699	91.5 (90.4–92.4)
60–64	3,957	3,365	85.0 (83.9–86.1)	3,621	3,369	93.0 (92.2–93.8)
65–69	2,990	2,527	84.5 (83.2–85.8)	2,731	2,534	92.8 (91.8–93.7)
70–74	2,527	1,895	75.0 (73.3–76.7)	1,051	926	88.1 (86.0–90.0)
History of previous screening						
No	7,053	5,165	73.2 (72.2–74.3)	6,117	5,326	87.1 (86.2–87.9)
Yes	11,020	9,311	84.5 (83.8–85.2)	9,022	8,462	93.8 (93.3–94.3)

Table 3 Unadjusted and adjusted odds ratios (95% confidence interval) of attending the first subsequent screening round ($n = 18,073$) and one of the two subsequent screening rounds ($n = 15,139$)

	Attendance at the first subsequent screening round ($n = 18,073$)		Attendance at the first and/or second subsequent screening rounds ($n = 15,139$).	
	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Category of index mammogram				
Negative	1	1	1	1
Warranting additional imaging evaluation	0.5 (0.4–0.8)	0.6 (0.4–0.8)	0.5 (0.4–0.9)	0.5 (0.3–0.9)
Warranting clinical and imaging follow-up	0.7 (0.6–0.8)	0.8 (0.6–0.9)	0.8 (0.6–1.0)	0.9 (0.7–1.1)
Warranting biopsy	0.6 (0.4–0.8)	0.6 (0.4–0.8)	0.5 (0.3–0.8)	0.5 (0.3–0.9)
History of previous screening				
No	1	1	1	1
Yes	2.0 (1.8–2.1)	2.1 (1.9–2.2)	2.2 (2.0–2.5)	2.4 (2.1–2.8)
Age				
50–54	1	1	1	1
55–59	1.4 (1.3–1.6)	1.0 (0.9–1.1)	1.3 (1.1–1.5)	0.9 (0.8–1.1)
60–64	1.8 (1.6–2.0)	1.2 (1.1–1.4)	1.6 (1.4–1.9)	1.0 (0.8–1.2)
65–69	1.8 (1.6–2.0)	1.1 (1.0–1.3)	1.6 (1.3–1.9)	0.9 (0.8–1.1)
70–74	1.0 (0.9–1.1)	0.6 (0.5–0.7)	0.9 (0.7–1.1)	0.5 (0.4–0.6)

mammogram and attendance at subsequent screening [4]. However, most of these studies were conducted in the early or mid-1990s, with different screening intervals and procedures, age range, and baseline participation rates, which may explain these apparently conflicting observations. Additionally, the attitude toward breast cancer screening and behavioral intent might have evolved differently over the last decade among women receiving normal and false-positive mammograms.

The effect of a false-positive result on subsequent screening behavior might depend on the general attitude of women toward screening. Indeed, higher participation rates likely reflect greater confidence in the benefit of routine breast cancer screening. Interestingly, the overall attendance rates in our study were 23.2, 33.0, 41.5 and 44.0% in 2004, 2005, 2006, and 2007, respectively. The increase in participation rates paralleled a nationwide mass media campaign aimed at promoting breast cancer screening. Yet,

participation rates in Isère and in France still fall below the estimates observed in other European countries [6, 11, 21], a finding that might explain the lower odds of returning for breast cancer screening after receiving a false-positive mammogram in our study.

Although a number of studies have investigated both short- and long-term psychological consequences of receiving false-positive mammograms [4], their findings were inconsistent and the relationship between the psychological effects of a false-positive mammogram and subsequent participation remains unproven. However, several authors have speculated that higher levels of anxiety motivate women to participate [22, 23] while lack of confidence in mammography and fear of finding breast cancer or having the breast removed are potential deterrents to subsequent participation [4, 5].

There are several potential explanations for the comparable odds of attending subsequent screening rounds across ACR categories among women who received false-positive mammograms. First, this negative finding may suggest that being recalled because of a false-positive mammogram results in decreased subsequent participation, independent of the diagnostic work-up that ultimately excluded malignancy. Although we did not find evidence supporting this hypothesis, previous studies reported comparable attendance rates at subsequent screening for false-positive cases who underwent additional imaging evaluation, fine-needle aspiration, or surgical biopsy [6, 24]. However, these studies also failed to show any difference in subsequent participation rates between women with false-positive and negative mammograms. Second, imbalances in baseline characteristics across study groups might have confounded our results. This was unlikely to occur since odds ratios were adjusted for age and previous history of screening mammography, which are strong determinants of participation [10]. However, unidentified or unmeasured confounding characteristics cannot be formally excluded. Third, our study might have been underpowered in detecting differences across study groups due to the relatively limited numbers of false-positive cases. Indeed, women who received false-positive mammograms warranting clinical and radiological follow-up had similar odds of attending at least one of the two subsequent screening rounds compared to women who received negative mammograms. However, the odds of subsequent attendance did not significantly differ among ACR categories for false-positive cases, possibly as a consequence of a statistical power issue.

The potential limitations of our study should be acknowledged. First, nonattendance at subsequent screening may be related to death or a change in residence. This was unlikely to affect our estimates as our analytical sample consisted of women who were reinvited. Indeed, the database is updated regularly by local public health insurance agencies. In addition, women or a family member could report the reasons for refusal to participate by returning a postal questionnaire.

Second, opportunistic screening might partly explain the low attendance rates observed in our study. Physician or self-referred screening mammography was partly collected by postal questionnaire and women who declined to participate in the organized screening program because of concurrent opportunistic screening were excluded from our analysis.

Third, it would have been interesting to conduct interviews with false-positive women in order to elucidate the reasons for nonattendance at subsequent screenings. However, this could not be done because of our study design.

Fourth, the participation rates distinguish our study from previous research and our results may not extend to other settings or countries with higher participation rates.

In summary, excluding breast cancer after additional imaging evaluation, clinical and radiological follow-up, or surgical biopsy motivated by abnormal findings on index mammograms results in uniformly decreased subsequent attendance in the routine screening program. Additional research should clarify re-attendance after clinical and radiological follow-up for the two subsequent routine screening rounds, since the number of false-positive cases was relatively limited, suggesting a possible lack of statistical power. Although further qualitative study is needed, specific follow-up should be proposed to women who receive false-positive mammograms in order to increase re-attendance rates. High-quality screening procedures are crucial to maintaining low rates of false-positive mammograms.

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