The impact of false positive breast cancer screening mammograms on screening retention: A retrospective population cohort study in Alberta, Canada

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ABSTRACT

OBJECTIVES: The impact of false positives on breast cancer screening retention is inconsistent across international studies. We investigate factors associated with screening retention, including false positive screening results, invasiveness of diagnostic procedures, and geographic variation in Alberta, Canada.

METHODS: A total of 213 867 women aged 50–67 years who had an index screen mammogram between July 2006 and June 2008 were evaluated at 30 months post index screen to determine the screening retention rate. The association of screening retention with invasiveness of the diagnostic procedure, time to diagnostic resolution, and region of residence were investigated using multivariable log binomial regression, adjusting for women's age.

RESULTS: Women with false positive screening results were less likely to return for their next recommended screening than those with a true negative result (62.0% vs. 68.7%). Compared to women with normal screening results, the adjusted risk ratios of fail-to-rescreen for women with imaging-only follow-up, needle sampling, and open biopsy were 1.08 (95% CI: 1.05–1.12), 1.72 (95% CI: 1.44–2.07) and 2.29 (95% CI: 2.09–2.50) respectively. Screening retention rates were slightly higher for rural residents than urban residents. Time to diagnostic resolution was not associated with screening retention. Screening retention peaked at one year from the index date of the previous screening.

CONCLUSION: Higher awareness of the strong negative impact that biopsies in the case of a false positive screening have on screening retention is needed. Such awareness can inform intervention strategies to mitigate the impact and improve screening retention rate.

KEY WORDS: Breast cancer; screening; retention; false positive

La traduction du résumé se trouve à la fin de l'article.

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Biennial or triennial breast cancer screening mammography, as an effective public health strategy to reduce breast cancer mortality, has been recommended to women aged 50–74 in the United States, Canada and most European countries.[1–3] The survival benefits of breast cancer screening are deemed to outweigh the harms from over-diagnosis, over-treatment, false positive screening results, and benign biopsies.[4,5] The latter two have been shown to be associated with depression and long-term anxiety in women and possibly reduce the likelihood of future screening.[6,7] False positives account for about 9% of all screening mammograms and make up approximately 93% of abnormal calls in Canada and the US.[8,9] It is therefore important to understand the magnitude of the impact of false positives on screening retention in order to mitigate it.

The impact of false positives on screening retention rates, however, is conflicting across studies. In a systematic review, false positive screening mammograms were not associated with retention rate in European countries, but were associated with an increased retention rate in the US.[10] A recent study in the United Kingdom showed that while the retention rate was not affected by false positives, it was reduced in women who underwent biopsies.[6] Two studies in Canada, both published over a decade ago, found that false positive screening results reduced the likelihood of screening retention.[11,12] There are important differences in the organization and delivery of screening programs and in the characteristics of the populations screened across different countries. Furthermore, practice has changed with respect to follow-up procedures in the past decade; for instance, core biopsy is now used broadly.[13] Efforts have also been made to improve organized screening performance, which could affect retention rates as well as the impact of false positives on them. It is therefore unknown whether and which of the findings from previous studies are applicable today.

The primary objective of this study was to investigate the impact of false positives on breast cancer screening retention and to determine whether invasiveness of the follow-up procedure and time to diagnostic resolution have independent effects on screening retention. A secondary objective was to investigate the extent of geographical variation in retention rates. Implications of these associations are discussed and recommendations are made to improve screening programs and to benefit screen-eligible women.

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Conflict of Interest: None to declare.

METHODS

Overview of breast cancer screening program in Alberta

The population-based Alberta Breast Cancer Screening Program (ABCSP) was established in 2004 through the collaboration of two organizations: Screen Test (ST), which utilizes radiologists employed by Alberta Health Services, and the Alberta Society of Radiologists (ASR), a non-profit professional organization representing 92% of the fee-for-service radiologists and radiology residents in Alberta.[14] The ABCSP ensures an organized approach for screen-eligible women to access screening mammography. Prior to the launch of the provincial-wide ABCSP, ST represented the much smaller organized "screening program" available in the province, while screening by ASR radiologists represented "opportunistic screening". Breast cancer screening and diagnostic procedures performed in Alberta, including procedure type, date, results and follow-up recommendations, were captured by complementary ASR and ST databases. Breast cancer screening and diagnostic procedures include imaging (screening and diagnostic mammography, ultrasound, MRI) and biopsies (aspiration, stereotactic core, closed, surgical/open). Breast Imaging Reporting and Data System (BI-RADS) scores[15] are captured for imaging procedures. BI-RADS classifies lesions into seven categories: 0 for incomplete and further imaging is required, 1 for negative findings, 2 for benign findings, 3 for probably benign, 4 for suspicious abnormality, 5 for a mammographic appearance, and 6 for known malignancy.

ST provides mammography services in clinics in two metropolitan cities (Edmonton and Calgary); mobile units visit rural and remote communities throughout the province once a year.[16] Additionally, ASR-member radiologists provide mammography services in community radiology clinics throughout the province.

Study design and data linkage

The Canadian province of Alberta has a single-payer publicly funded health care system under which standard medical care, including breast cancer screening services, are free. The Alberta clinical guideline recommended breast cancer screening at least every two years for women between 50 and 69 years of age during the study period.[17] In order to satisfy the age eligibility at screening retention, 67 years of age was chosen as the upper limit for inclusion in this study.

All women aged 50–67 years who had at least one screening mammogram between July 1, 2006 and June 30, 2008 were identified from the combined ASR and ST database. Women with screen-detected breast cancer or who developed breast cancer prior to their scheduled subsequent screening mammogram were excluded. Breast cancers were identified from the Alberta Cancer Registry (the third edition of International Classification of Disease for Oncology (ICD-O-3) code C50 behaviors 2 and 3).[18]

This study was approved by the ethics board at the University of Alberta. Databases were linked using the unique provincial health care identification number that was anonymized for data analysis. Quality assurance and cross checks were performed to ensure accuracy and completeness.

Index screening

A woman's first screening mammogram during the study period was referred to as her index screen. The index screen test was classified into either normal screening result group (BI-RADS score 1 or 2) or abnormal group. At least two of the following three criteria were required for the index screen to be classified into the abnormal group: 1) from test result: a BI-RADS* score 0, 3, 4 or 5 for the index screen; 2) from radiologist's recommendation: an immediate, 3-month or 6-month follow-up recommendation; and 3) from follow-up test: at least one breast-related diagnostic procedure within 30 days of index mammogram. Data for which criterion 1) and criterion 2) were not consistent were assumed to have a data entry error and the test was classified according to criterion 3). For example, a screening mammogram record of a BI-RADS* score 5 with a recommendation for a follow-up in two years would not occur in practice and is evidence of a data error. To determine whether the BI-RADS* score or the recommendation was incorrect, we used criterion 3) which reflects what actually occurred. If a follow-up breast-related diagnosis procedure was not identified within 30 days of the screening mammogram, the screening mammogram was deemed normal. Since women diagnosed with breast cancer during the study period were excluded from the study, the abnormal group only consists of false positives.

Breast cancer diagnostic follow-up procedures conducted in response to a false positive were categorized as follows (in order of decreasing invasiveness): open biopsy, needle sampling (fine needle aspiration, core needle biopsy, and closed biopsy), imaging-only follow-up (typically diagnostic mammography and/or ultrasound), and no follow-up procedure. There were two possible explanations for the "no follow-up procedure": 1) The follow-up test data were missing: this could occur if the breast-related diagnostic tests were performed by radiologists who are outside ASR (approximately 8% of radiologists in Alberta), resulting in test data not being captured in the ASR database; and 2) those women did not comply with the recommendation.

Diagnostic resolution

The most invasive procedure within six months of an abnormal index screen was deemed the diagnostic resolution procedure, based on an adaptation of a previously validated algorithm.[19] The corresponding procedure date was used to calculate time to diagnostic resolution and served as the index date for the screening retention period for women with false positives. For women with no follow-up procedures, the index date for the screening retention period was six months after the initial screen, to account for possible missing follow-up test dates. For women in the normal screening group, the date of the index screen was used as the index date of the screening retention period.

Screening retention

Screening retention was defined as the receipt of a subsequent screening mammogram between 9 and 30 months from the index date (see Figure 1), as 30-month is consistent with the definition for calculating retention rate in Canada.[20]

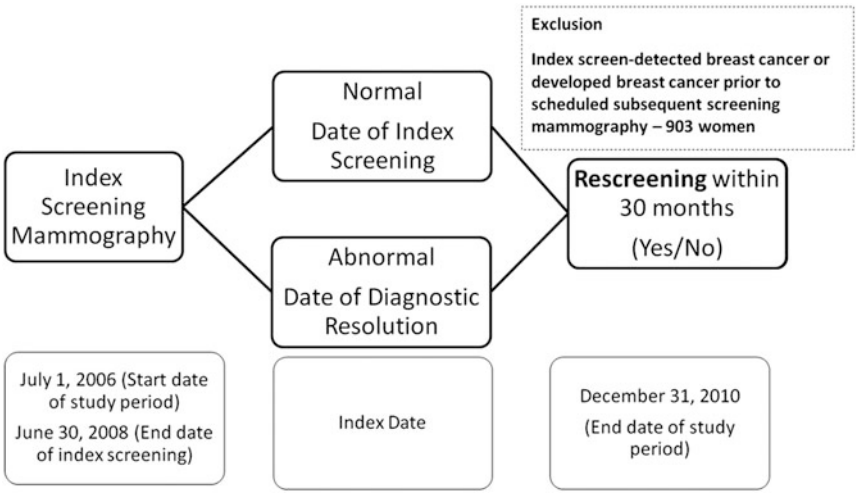

Figure 1. Diagram of outcome definition

Statistical analysis

Screening retention rate was tabulated by the index screen result and diagnostic follow-up procedure category, region of residence, and time to diagnostic resolution. Region of residence was categorized into the following three groups based on the Regional Health Authorities (RHA) that existed at the beginning of the study period: the RHAs that included Edmonton and Calgary are classified as the metropolitan region; central and southern Alberta are classified as small cities/rural region; northern Alberta is classified as the remote region, where access to health care is most limited (Figure 2). A histogram showing time from index screen to rescreen in the study population is shown in Figure 3. A multivariable log-binomial regression model was used to estimate the risk ratios of fail-to-rescreen associated with invasiveness of diagnostic procedure, region of residence, and time to diagnostic resolution, adjusted for women's age. SAS® 9.4 (SAS Institute, Cary, NC) was used for data management and analyses.

RESULTS

A total of 213 867 women were eligible and included in the study. The index screen results for 20 105 (9.4%) was a false positive: the most invasive follow-up procedures performed were imaging studies for 16 695 (83.0%), needle biopsy for 243 (1.2%) and open biopsy for 1499 (7.5%) of those with a false positive. The benign biopsy rate is 8.1 per 1000 screen.

Retention rate

Table 1 shows the retention rates for normal and abnormal index screen and each follow-up procedure type, stratified by region, time to diagnostic resolution, and age group. The retention rates were 62.2% and 68.7% for the false positive and normal index screen groups respectively. The unadjusted risk ratio was 0.9 (95% CI: 0.90–0.92). As the invasiveness of procedure increased, the retention rate decreased. The retention rates were 64.0%, 57.6%, and 39.8% for imaging-only follow-up, needle sampling and open biopsy respectively. For women with no follow-up procedure after an abnormal result, the retention rate was 65.0%.

The retention rate varied considerably across regions by invasiveness of procedure. For women who resided in metropolitan regions, the retention rate for those with an index false positive result decreased with increasing invasiveness of procedure (63.9% for imaging only follow-up, 53.1% for needle sample and 37.2% for open biopsy). This trend did not exist for residents outside the metropolitan areas, however, retention rate was lowest for residents of the small cities/rural region who received an open biopsy. Women with false positives had lower retention rate than those with normal results across all regions. The retention rate increased with increasing rurality (67.9% for metropolitan region, 68.7% for small cities/rural region and 70.5% for remote region). A longer time to diagnostic resolution was also associated with a lower retention rate for those who received open biopsy: 48% same day, 41% within 1 month, and 36% within 6 months, but not for those who received imaging only (63%, 65% and 65% respectively).

Women aged 50–59 and 60–67 have similar rescreen rates by invasiveness of procedure (Table 1).

Time from index to rescreen

The provincial screening guideline recommended women aged 50–69 receive screening for breast cancer at least every two years during the study period. The screening retention peaked close to one year (12 months) from the index date (Figure 3). A second peak of screening retention occurred close to two years from the index date, but the number of women at the second peak was much lower than the number at the first peak. Among women who rescreened within 30 months, approximately 50% had their rescreening mammograms within 15 months of their index screen.

Log-binomial regression analysis of fail-to-rescreen

Figure 4 illustrates the adjusted risk ratio estimates of factors associated with fail-to-rescreen. Age is adjusted in the model using a cubic spline. Compared with women who had a normal index screen result, the adjusted risk ratios of fail-to-rescreen were 1.08 (95% CI: 1.05–1.12) in women who had imaging-only

Figure 2. Region division. Metropolitan region: Regions of Edmonton and Calgary, i.e., R6 and R3. Small cities/rural region: R1, R2, R4, R5 and R7. Remote region: R8 and R9

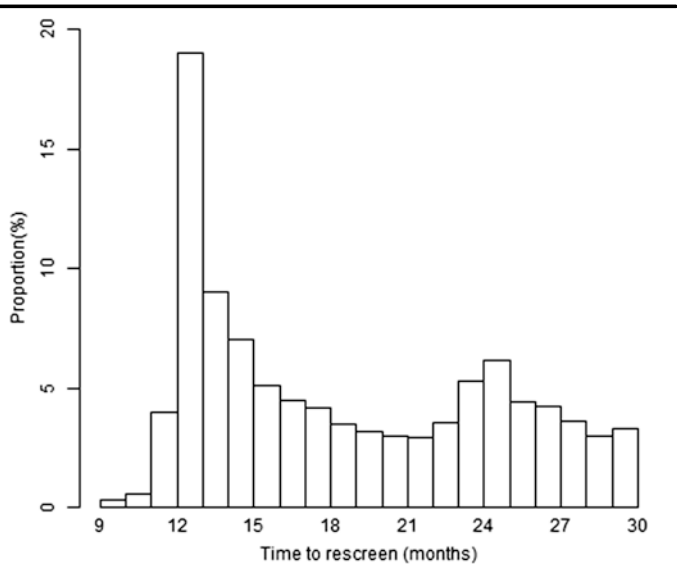

Figure 3. Proportion of rescreening mammograms performed each month of the total conducted between 9 and 30 months of the index screen

follow-up, 1.72 (95% CI: 1.44–2.07) in women who had needle sampling and 2.29 (95% CI: 2.09–2.50) among women who had open biopsy.

Screening retention rates varied to a smaller extent across regions after adjusting for other factors. In small cities/rural and remote regions, the risk ratios are 0.99 (95% CI: 0.98–1.00; $p = 0.193$) and 0.96 (95% CI: 0.94–1.00; $p = 0.026$) respectively, compared to the metropolitan region. Time to diagnostic resolution was not significantly associated with the fail-to-rescreen in the multivariable regression analysis.

DISCUSSION

The factor most strongly related to screening retention after a false positive screening result was the procedure used for diagnostic resolution: screening retention decreased with increasing invasiveness of the diagnostic resolution procedure. Women who had an open biopsy were 2.3 times less likely to be rescreened within 30 months after their diagnostic resolution compared to those who had a normal index screen. The negative effect of false positives on screening retention is consistent with the findings from two-decade-old Canadian studies[11,21] and a more recent study conducted in Spain, where breast cancer screening is also free and is recommended biennially.[22] Retention rates were higher in the Spanish study than in ours: retention rates for women with false positive vs. normal results were 78.3% vs. 81.9%, compared to ours which were 68.1% vs. 68.7% respectively. Both studies found significantly lower retention rates, 66.5% (Spain) and 45.8% (Alberta) for those who underwent invasive procedures, including aspiration, closed biopsy and/or open biopsy.[22] Invasive follow-up tests have been shown to create psychological distress in the context of false positive breast cancer screens,[23] which can last for up to three years;[7,24] it is likely that psychological distress plays an important role in screening retention.

We did not find a statistical association between time to diagnostic resolution and retention rate in our study. This is consistent with a study conducted in The Netherlands.[25] Women residing in remote regions were more likely to rescreen compared to the women residing in metropolitan regions. This may reflect that the availability of care is valued and acted upon in remote regions where the health care resources are limited.

Fifty percent of the women in our study were rescreened within 15 months in spite of provincial guidelines at the time for biennial screening. This is of concern as more frequent screening results in higher cumulative false positive findings,[26] which in turn increases the risk of invasive procedures and, based on our study and others,[6] lowers screening retention. In addition, modeling studies show that biennial screening does not lead to higher prevalence of late-stage breast cancer than annual screening.[27] More frequent screening mammography also increases women's exposure to X-ray and cost to the publicly funded health system. Combined, these facts suggest that annual breast cancer screening is unnecessary, and may even be harmful, for average-risk women. Currently, the Canadian guidelines recommend breast cancer screening for women aged 50–74 every 2–3 years, although these guidelines have not been embraced in all provinces.[1]

Although invasive procedures appear to reduce breast cancer screening retention rates, sometimes invasive tests are necessary to

Table 1. Frequency of procedure and retention rate (% screened within 30 months of index date) by invasiveness of procedure, stratified by region and time to diagnostic resolution

	Normal index screen	False positive index screening				Total
		Imaging-only follow-up	Needle sampling	Open biopsy	No follow-up procedure within 6 months	Total	
	n (retention rate)	*n* (retention rate)	*n* (retention rate)	*n* (retention rate)	*n* (retention rate)	*n* (retention rate)	*n* (retention rate)
Overall	193 762 (68.7)	16 695 (64.0)	243 (57.6)	1499 (39.8)	1668 (65.0)	20 105 (62.2)	213 867 (68.1)
Region*							
Metropolitan	145 860 (68.5)	13 838 (63.9)	162 (53.1)	1201 (37.2)	1247 (65.0)	16 448 (61.9)	162 308 (67.9)
Small city/rural	42 119 (69.1)	2584 (65.1)	62 (66.1)	254 (46.9)	202 (57.4)	3102 (63.1)	45 221 (68.7)
Remote	5783 (70.9)	273 (61.5)	19 (68.4)	44 (68.2)	219 (71.7)	555 (66.3)	6338 (70.5)
Time to diagnostic resolution							
Same day	193 762 (68.7)	8959 (63.2)	47 (63.8)	110 (48.2)	NA	9116 (63.0)	202 878 (68.4)
Within 1 month	0	6825 (65.0)	40 (35.0)	778 (41.4)	NA	7643 (62.4)	7643 (51.9)
Within 6 months	0	911 (65.2)	156 (61.5)	611 (36.2)	NA	1678 (54.3)	1678 (46.6)
No follow-up procedure within 6 months	0	NA	NA	NA	1668 (65.0)	1668 (65.0)	1668 (65.0)
Age (years)							
50–59	131 006 (68.6)	11 444 (63.6)	176 (59.1)	980 (40.4)	1114 (64.9)	13 714 (62.0)	144 720 (68.0)
60–67	62 756 (69.0)	5251 (64.9)	67 (53.7)	519 (38.5)	554 (65.2)	6391 (62.7)	69 147 (68.4)

Note: Women with breast cancer during study period were excluded.
* Region: region division can be found in Figure 2.
NA = not applicable.

determine whether a tumour is present. Identifying and implementing factors that positively contribute to screening behaviours is therefore important as they may overcome the negative impact of invasive follow-up procedures. Tailored invitation letters as well as motivational telephone calls have been shown to positively impact breast cancer screening behaviour.[28,29] The combination of a tailored letter and motivational phone calls may improve screening retention among those with false positive screening mammograms, particularly those who have invasive follow-up tests.

Our study is the first population-based study to assess breast cancer screening retention and factors related to it in Alberta, and the most recent one in more than a decade in Canada. It provides an updated and detailed picture of the screening retention in Alberta, which is useful to screening programs in Canada and elsewhere. A strength of the study was our use of population-based data from the screening program, however, there are a few notable limitations to our analyses, largely based on the data available for the dataset. First, we were not able to determine and adjust for whether the index screen in our study was the initial screen for a particular woman. One study reported that initial screening had higher false positive results (12% vs. 6%) and lower retention rate (70% vs. 81%).[8] A recent report from the Canadian Partnership Against Cancer (CPAC) also found that women with initial screening had lower retention rates compared to those with subsequent screening. Screening participation rates in Alberta have been relatively stable, however – between 55% and 60% in the last 10 years[13,30,31] – so we expect that our adjustment for age in the multivariable regression analysis mitigates the confounding effect of the index screen status.

The second limitation is that we did not have access to detailed demographic data; some factors have been found to be associated with screening rates.[23,32] The third limitation is that about 8% of the biopsy data are estimated to be missing from the ASR database. This could lead to a slight underestimation of the odds of fail-to-rescreen for women who had benign biopsies, which means the reported effect size is likely to be conservative. In contrast, the fourth limitation – limiting the definition of rescreen to 30 months – may overestimate the effect size. It is possible that a higher proportion of women who had false positive results at their index screen were rescreened more than 30 months after their index screen than those with a true negative. Thirty months, however, has been used consistently in studies[8,13] to define rescreen rates, so our analysis is comparable to previous reported rates. Furthermore, it is unlikely that even if the rescreen definition were extended to include screens within 36 months, the more than 10% difference in retention rates for those women who had needle sampling or open biopsy would be eliminated. Last, the follow-up time for 105 women who had an abnormal index screen was slightly less than 30 months (the median follow-up time was 28 months) and they were categorized as "fail-to-rescreen"; as this group only accounted for 0.5% of all women with an abnormal index screen, the expected bias introduced is negligible.

In order to maximize the benefits of breast cancer screening in populations and individuals, greater efforts are needed to minimize both the risk of false positives as well as their burden on women, which affect likelihood of rescreening. Suggested tactics include screening average-risk women no more than

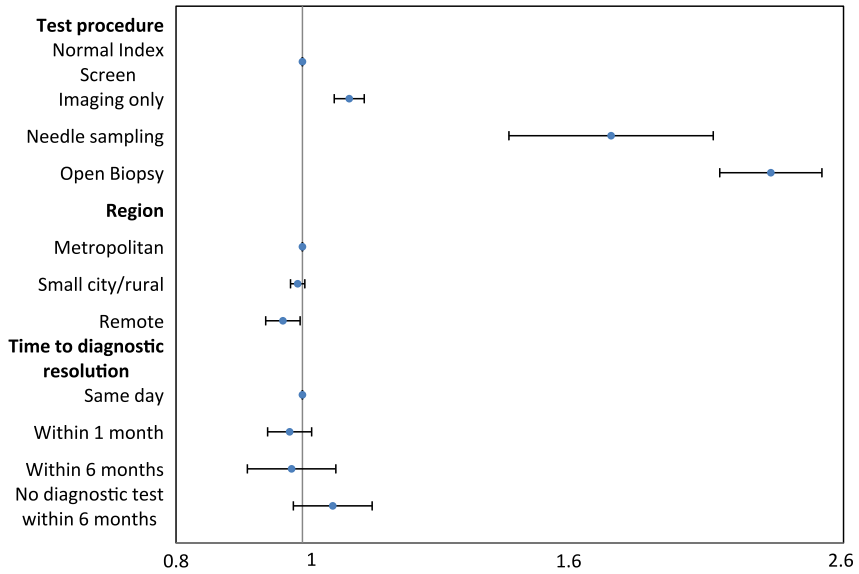

Figure 4. Adjusted risk ratios of fail-to-rescreen. Log binomial regression model includes test procedure, region, time to diagnostic resolution, and age (adjusted as a cubic spline)

biennially, minimizing invasive testing and providing targeted communication with those with a previous false positive screen. Further improvements in technology are also needed to decrease false positive rates and reduce the need for invasive follow-up tests.

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RÉSUMÉ

OBJECTIFS : L'incidence des faux positifs sur la fidélisation au dépistage du cancer du sein varie dans les études internationales. Nous étudions les facteurs associés à la fidélisation au dépistage en Alberta, au Canada, dont les résultats faux positifs au dépistage, le caractère invasif de la méthode diagnostique et la variation spatiale.

MÉTHODE : En tout, 213 867 femmes de 50 à 67 ans ayant subi une mammographie de dépistage indicielle entre juillet 2006 et juin 2008 ont été évaluées 30 mois après pour déterminer le taux de fidélisation au dépistage. Les associations entre la fidélisation au dépistage et le caractère invasif de la méthode diagnostique, le délai de résolution du diagnostic et la région de résidence ont été étudiées par régression log-binomiale multivariée avec ajustement en fonction de l'âge des femmes.

RÉSULTATS : Les femmes ayant obtenu des résultats faux positifs au dépistage étaient moins susceptibles de retourner subir leur prochain dépistage recommandé que celles ayant obtenu des résultats vrais négatifs (62,0 % c. 68,7 %). Comparativement aux femmes ayant obtenu des résultats normaux au dépistage, les risques relatifs ajustés des femmes n'ayant pas subi un dépistage ultérieur étaient de 1,08 (IC de 95 % : 1,05–1,12) pour le suivi avec imagerie seulement, de 1,72 (IC de 95 % : 1,44–2,07) pour le prélèvement à l'aide d'une aiguille et de 2,29 (IC de 95 % : 2,09–2,50) pour la biopsie ouverte. Les taux de fidélisation au dépistage étaient légèrement plus élevés chez les résidentes des zones rurales que chez celles des zones urbaines. Le délai de résolution du diagnostic n'était pas associé à la fidélisation au dépistage. La fidélisation au dépistage a culminé un an après la date indicielle du dépistage précédent.

CONCLUSION : Il est nécessaire d'être plus sensibilisé à l'effet très nuisible des biopsies sur la fidélisation au dépistage en cas de résultats faux positifs. Une telle sensibilisation peut éclairer les stratégies d'intervention pour atténuer cet effet et améliorer les taux de fidélisation au dépistage.

MOTS CLÉS : cancer du sein; dépistage; fidélisation; faux positifs