Determinants of false positive recall in an Australian mammographic screening program

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Abstract

We conducted a case-control study (n=30 128) to assess the importance of clinical (eg family history, age, HRT use and duration) and service-related characteristics (eg time since introduction of Kodak MINR2000 film, year of screen) for false positive (FP) recall at BreastScreen Victoria, Australia.

There was an age-adjusted upward trend in FP recall rates with year of screen at first (Odds Ratio 1.11, 95% CI 1.08-1.13) and subsequent rounds (Odds Ratio 1.04, 95% CI 1.01-1.06). In the multivariate analysis, the upward trend only remained for first round and age and family history also remained statistically significant at first round. At subsequent rounds the time since introduction of MINR2000, age, strong family history of breast cancer, use of HRT, recall at previous screen and previous screen at more than 27 months were all important predictors of false positive recall.

The rise in FP rates with year of screen at first round screening is of concern and may require further training of radiologists to improve confidence when viewing films when there are no films for comparison.

Introduction

High rates of recall have been associated with significant social and emotional costs for women ¹⁻⁶ although many of the studies have not used appropriate instruments to assess psychological consequences and the evidence regarding long-term psychological sequelae is weak ⁷. High recall rates will also translate into a high cumulative risk of women being recalled over a period of regular attendance at a screening program ^{8,9} although they do not seem to result in lower rates of subsequent attendance at screening ^{5,10,11}. Previous research suggests that sensitivity does not increase once recall rates reach around 5% ¹².

A false positive screen is generally defined as one which results in a recall for assessment for a woman who is found not to have breast cancer. False positive rates vary by age ¹³, symptomatic status ¹⁴, use of hormone replacement therapy ^{8,15-19}, family history of breast cancer ^{8,13,20} and whether or not previous mammograms are available for comparison ⁸. In addition at least one study has found that radiologists differ in the frequency with which they identify abnormalities on a mammogram ²¹ and increasing time since screen has also been associated with higher recall rates ⁸.

At BreastScreen Victoria (BSV) recall rates increased between 1994 and 1999. ²²⁻²⁷ for unknown reasons. Using data collected from this large population-based screening program, we measure the association between selected clinical and service-related attributes and subsequent time trends in false positive recall rates. We examine the impact of individual characteristics

including HRT use and duration of use, family history and age on false positive recall at first and subsequent round screening, and time since screen and previous false positive mammogram on false positive recall rates at subsequent round screening. In addition we test the impact of the introduction of new mammographic film on false positive recall. Since early 1997, most Screening and Assessment Services (of which there are eight at BSV) have introduced a new film screen combination with improved performance: higher speed, reduced noise, and improved resolution and contrast — Kodak Min-R 2000 or Kodak Min-R2190 screens with Kodak Min-R 2000 film. This higher speed system reduces patient dose due to reduced radiation. Reduced exposure should reduce image blur due to patient movement.^{28 29} Reduction in film noise should theoretically improve detection and visualisation of small microcalcifications (Personal Communication, Dr Ken Gifkins, Health Imaging Division, Marketing Manager, Kodak Australia and New Zealand). Using the large, detailed data set we have available, we have the capacity to investigate multiple determinants of false positive recall and to control for potential confounding.

Methods

BreastScreen Australia was introduced in the early 1990s and offers free biennial mammographic screening to women aged 40 years and older, although women aged 50 to 69 years are the target age group. In Victoria mammographic screening is offered through 8 screening and assessment services (SAS) including 4 urban and 4 rural sites. These services provide screening and assessment services and regional program coordination in

eight catchment areas in Victoria. Each SAS has from 1 to 8 associated screening centres that conduct screening mammography. One of the requirements for the accreditation of these services through the national program is that their recall rates are not greater than 10% for first round screens and 5% for subsequent round screens³⁰.

The study population consisted of all episodes of screening for women who attended BSV for screening mammography between January 1 1994 and December 31 1999. Women could attend for more than one episode during this time. Episodes were excluded if women were diagnosed with breast cancer (invasive or ductal carcinoma in situ) or if they reported symptoms that automatically result in call back for further investigation, irrespective of the mammographic findings. At BSV women who report a breast lump for less than 12 months that has not previously been evaluated by a doctor or women with a current watery or blood-stained nipple discharge are recalled for further assessment. Women with these call-back symptoms were excluded from this analysis.

Details of the program

Details for the program have been described previously³¹. Briefly, BSV offers free biennial, two-view mammography through an organised screening program to women aged 40 and older. Women aged 50 to 69 are the target group, and those who are listed on the electoral roll (voting is compulsory in Australia) and who have never attended for screening are sent an invitation. Women aged 50 to 74 receive a reminder for rescreening 23 months after

their previous screen if they have not made a further appointment. Although screening is biennial, women may attend for rescreening from 21 months after their previous screen. In 2000 the participation rate was 59% for women aged 50 to 69 years ²⁷.

The films are read independently by two radiologists. In the case of discordant reads, either the films are reviewed by the two radiologists and a consensus reached, or a third reader makes the decision. Women are then recommended for routine rescreen or are referred for assessment.

Assessment may include clinical examination, further x-rays, ultrasound, or biopsy. After assessment women may have a cancer diagnosed, be recommended for routine rescreening or be recommended for further assessment at a later date, usually 6 to 12 months hence (early review).

Classification of false positive recall

A woman was classified as having a false positive or true negative episode. A false positive episode is defined as an episode where the woman was recalled for assessment but did not have cancer diagnosed at that episode. All other women were classified as true negatives. (Women with interval cancers were not excluded but they make a very small proportion (0.2%) of all women and hence will not affect the results ³¹.

Explanatory variables

Data on explanatory variables was collected from the questionnaire women fill out at the time they attend for each screening episode and data from

screening services. The questionnaire collects details of family history of breast cancer, date of birth, use of hormone replacement therapy at the time of screening (yes/no) and duration of use, and symptomatic status. For family history, women are asked if their mother, a daughter or sister had breast cancer and the age at diagnosis. Strong family history is defined as having a first degree relative with breast cancer before the age of 50. Any other family history is recorded as 'other family history'. Age was divided into five categories: 40-49, 50-59, 60-69, 70-79, 80+ years. Use of HRT was modelled in the following categories: non-user, up to 2 years, 3-5 years, 6 to 10 years, greater than 10 years and user of unknown duration. During the time period of the study, seven of the eight SASs introduced a new Kodak film called Min-R2000. We collected the date of introduction of the MINR2000 films from the SASs and created a variable to test whether 'time since MINR2000 introduction (not introduced, 0.01 to 3 months, 3.01 to 6 months, 12.01 to 24 months, 24.01 to 48 months) influenced the risk of false positive recall. To test for trend in the effect of time since introduction on MINR2000 we coded these categories as 1 to 6 and fitted this term along with a dichotomous term for introduction of MINR2000 (yes/no). For analysis of recall rates at subsequent screens we created a variable 'time since previous screen' (0-<21 months, 21-<24 months, 24-<27 months, >=27 months). In the case of subsequent rounds we also examined whether a false positive finding at previous round (yes/no) was associated false positive recall at current round. To control for the fact that the readers varied in terms of experience and could be a potential confounder we created a variable 'cumulative reads' (0-30,000, 30,001-60,000, 60,001-80,000, >80000).

Statistical analysis

We describe rates of false positive recall over the six years of the study by age group and round (first and subsequent). The numerator is the number of women who have a screening episode that resulted in a false positive recall divided by the total number of screens.

A case-control study was conducted to examine predictors of false positive recall in this large data set. Cases were false positive cases and controls were true negative episodes. Separate case control sets were selected for each round (ie rounds 1, 2, 3 and 4) with differing proportions of cases and controls in each set to maximise efficiency (round 1: 20% of cases and 2% of controls; round 2: 50% of cases and 3% of controls; round 3: 60% of cases and 3% of controls; round 4: 100% of cases and 20% of controls). We then combined the case control sets for rounds 2, 3 and 4 as similar results were obtained. We present the results as first and subsequent round (rounds 2, 3 and 4) analyses. In subsequent round analyses all analyses are adjusted for round to take into account the different sampling strategies.

Unconditional logistic regression was used to examine the impact of predictor variables (age-group, duration of HRT use, family history, time since introduction of MINR2000, cumulative reads and, in addition for subsequent round screening time since previous screen, history of false positive previous screen and screening round) on the odds of false positive recall. Both unadjusted analyses for each of the predictor variables and a multivariate

analysis where all predictors were examined simultaneously are presented.

The analysis was conducted in Stata 7.

Results

At first round there were 395,399 women screens and subsequent rounds there were 488,563 screens. Figure 1 shows the increase in recall rates over time. For first round screening the recall rate increased from 6.24% in 1994 to 9.44% in 1999. A smaller rise from 3.49% in 1994 to 4.57% in 1999 was observed for subsequent round screening. (see figure 1)

See Figure 1

Figure 2 shows the crude cancer detection rates by screening round and year of screen. These appear to be stable over the study period apart from an unexpected low at subsequent round screening in 1995.

See Figure 2

Figure 2 shows small cancer detection rates by screening round and year of screen. At subsequent round screening small cancer detection rates appear to improve from 1997. The trend for first round screening is less clear however there are fewer cancer cases reducing the precision of the estimates.

See Figure 3

For the first round analysis there were 5357 cases and 7310 controls and for the subsequent round analyses there 10151 cases and 17420 controls. Table 1 shows the results of the unadjusted logistic regression analyses. Important predictors of false positive recall for both first and subsequent round screening were age, a strong family history of breast cancer, the number of cumulative reads, and the time since introduction of the new MINR2000 film. Year of screen was an important predictor of false positive recall for first round screening and HRT use, time since screen, false positive recall at previous screen and screening round were important predictors of false positive recall at subsequent round screening.

When adjusting for time since introduction of MINR2000, use of MINR2000 was associated with increased odds of false positive recall at first round (Odds Ratio 1.58, 95%CI 1.27-1.97) and subsequent round screening (Odds Ratio 1.35, 95% CI 1.21-1.51). There was downward trend in the effect in time since introduction of MINR2000 at subsequent round screening (Odds Ratio 0.96, 95% CI 0.93-0.99, P for trend=0.01) but no effect was found for first round screening (Odds Ratio 0.98, 0.92-1.05, P for trend=0.61).

See Table 1

There was a significant age-adjusted upward trend in recall rates with year of screen at first (Odds Ratio 1.11, 95% CI 1.08-1.13) and subsequent round screening (Odds Ratio 1.04, 95% CI 1.01-1.06).

Table 2 shows the multi-variate analysis when we adjusted for all variables simultaneously. We were unable to fit specific terms for year of screen in the subsequent round analysis due to problems of collinearity with time since introduction of MINR2000 (see below). Therefore we simply present the screening year as a continuous term at both rounds. At first round there is still a significant time trend with year of screen (OR 1.06, 95% CI 1.02-1.11) even after adjusting for other variables. In the multivariate analysis only strong family history and age at screening remain statistically significant predictors of false positive recall at first round screening.

At subsequent round screening there is no longer a significant time trend with year of screen after adjusting for other variables (OR 0.96, 95% CI 0.93-1.00) but age, time since introduction of MINR2000, strong family history of breast cancer, use of HRT, recall at previous screen and previous screen at more than 27 months are all important predictors of false positive recall. At subsequent round screening, the effect of year of screen is attenuated when time since introduction of MINR2000 and time since previous screen are entered into the model. Time since introduction of MINR2000 is highly correlated with year of screen ($r=0.72$). At subsequent round screening there was a downward trend in false positive recall rates with time since introduction of MINR2000 (OR 0.92, 95% CI 0.89-0.95, P for trend<0.001) and a non-significant downward trend at first round screening (OR 0.95, 95% CI 0.88-1.01, P for trend=0.10).

See Table 2

Discussion

This study confirms the results of previous research that younger age and family history are important predictors of false positive recall^{8 13 20}. Use of HRT was a significant predictor of false positive recall at subsequent round screening an effect that was evident for both short and long term use. This effect is consistent with other studies that have found higher false positive rates with HRT use although many of the studies have not distinguished first and subsequent screening rounds^{8 15-19}. At subsequent round screening, the introduction of the new MINR2000 film, a screening interval of 27 months or more and a false positive recall at previous screen were also significant. The attenuation of the effect of MINR2000 with time since introduction of this new film is observed for both first and subsequent round screening but the strong correlation with year of screen makes it difficult to separate these two effects.

The upward trend in recall rates with year of screen is not attenuated by controlling for potential confounders at first round screen (Odds Ratio 1.11). This effect is completely attenuated at subsequent round screening (Odds Ratio 0.96) although year of screen is highly correlated with time since introduction of MINR2000 as most services introduced MINR2000 in 1997 (68%), a smaller proportion in 1998 or 1999 (19%) and 10 services (13%) did not introduce the film at all. The proportion of women attending BSV for first round screens dropped from 77% in 1994 to 6% in 1999²⁷. This means that radiologists who began reading after the mid 1990s are less experienced at reading first round screening mammograms where previous mammograms

are not usually available for comparison. While it would be expected that these readers may also have higher recall rates this does not appear to be the case. Using a variable that measured the combined experience of the two readers we found that the higher number of reads was associated with increased recall rates, particularly at first round screening. However, the readers in the program changed over the course of the study, so it is possible the experienced readers earlier in the study period may read differently than readers later in the study period.

Younger age ³², use of HRT ³³⁻³⁶, and family history of breast cancer ³⁷ have all been associated with increases in mammographic density. These breast tissue changes may explain the higher false positive recall rates. We cannot explain why the effect of HRT is not found at both first and subsequent round screening. A strong family history is marked on readers' sheets and previous research has shown that radiologists' knowledge of family history increases diagnostic suspicion and recall rates without a corresponding increase in diagnostic accuracy ²⁰.

The increase in false positive recall associated with the introduction of MINR2000 film is probably due to improved resolution resulting in increased call-back of non-malignant lesions. However, this effect becomes non-significant after 24 months so it is possible that with more experience with use of this film recall rates will continue to fall. Given that this film leads to improved resolution it is also possible that it is associated with higher small cancer detection rates. While this study did not set out to specifically address

this question, there does not appear to be evidence for this at first round screening however at subsequent round screening there is some evidence for a rise in small cancer detection between 1997 and 1999 (see figure 3). We suggest that in future services might consider introducing new film on a trial basis and then evaluating the effect of the introduction on recall rates before implementing changes in film on a wider scale.

The increased risk of recall associated with a previous mammogram conducted more than 27 months ago may be due to the fact that with a greater interval elapsed since previous screen there is a higher probability of development of a non-malignant lesion than women screened at an earlier interval. The increase in rate of recall in women who had a false positive mammogram at previous screen may be due to the fact that these women tend to have inherently more difficult breasts to assess and the presence of previous work-up films may draw radiologists attention to possible lesions and/or that presence of a previous abnormality on mammogram alerts radiologists to the possibility of current abnormalities.

Some of the risk factors for false positive recall are potentially modifiable while others such as age, family history, and HRT use, are not. Of the unmodifiable risk factors, the higher rate of recall among women younger than 50 years is of concern, particularly as mammographic screening has not been shown to be as effective in this age-group. While family history increases the likelihood of recall it is not known whether the lower specificity is associated with improved sensitivity of mammography in women with a family history. It is

important that this is further evaluated because if sensitivity is not improved with knowledge of family history then it is not cost-effective to continue recording family history on reader sheets. Among the potentially modifiable risk factors is the effect of introducing new film, an effect that should continue to be monitored. Introduction of new film should be fully evaluated and it may be important to include training for radiologists making the transition to using new film with reputedly higher resolution. The fact that recall rates for first round screening are continuing to rise is of concern. It may be important to train readers to feel more confident about clearing first round screens when no previous films are available.

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Figure 1: Time trends in recall rates by first and subsequent rounds

Figure 2: Time trends in cancer detection rates by first and subsequent round screening

Figure 3: Time trends in small cancer detection rates by first and subsequent round

Table 1 Frequencies and unadjusted odds ratios for false positive recall at first and subsequent round screening

	First Round			Subsequent Round ^a		
	Controls	Cases	Crude Odds Ratio	Controls	Cases	Crude Odds Ratio
Screening date by year						
1994	2,036	1,182	1.0	228	139	1.0
1995	2,058	1,406	1.18	1,018	489	1.14
1996	1,201	793	1.14	3,114	1,444	0.85
1997	759	730	1.66	3,370	2,054	0.97
1998	680	697	1.77	4,039	2,917	1.00
1999	576	549	1.64	5,651	3,108	0.85
Age Group						
40-49yrs	1,502	1,345	1.15	694	709	1.49
50-59yrs	3,183	2,481	1.0	7,223	4,754	1.0
60-69yrs	1,913	1,097	0.74	6,734	3,415	0.83
70-79yrs	651	385	0.76	2,717	1,242	0.75
80yrs plus	61	49	1.03	52	31	0.89
Family History of Breast Cancer						
strong family history	238	213	1.26	568	499	1.61
other family history	903	706	1.10	2,213	1,348	1.07
no family history	6,125	4,345	1.0	14,542	8,227	1.0
unknown	44	93	2.98	97	77	1.41
Hormone Replacement Therapy						
never on HRT	5,536	4,041	1.0	12,974	6,453	1.0
1 to 2 years on HRT	675	494	1.00	956	784	1.57
3 to 5 years on HRT	377	270	0.98	886	759	1.65
6 to 10 years on HRT	300	241	1.10	1,429	1,204	1.72
more than 10 years on HRT	301	215	0.98	991	783	1.58
yes, on HRT but unknown time	107	83	1.06	148	151	1.96
unknown	14	13	1.27	36	17	1.07
Time since MINR2000						
not introduced	6,137	4,164	1.0	8,548	4,601	1.0
0.01 to 3 months	193	205	1.57	866	642	1.30
3.01 to 6 months	136	136	1.47	701	544	1.33
6.01 to 12 months	264	274	1.53	2,154	1,287	1.12
12.01 to 24months	447	447	1.47	3,836	2,373	1.19
24.01 to 48 months	133	131	1.45	1,315	704	1.08
Abnormality at previous screen						
No				15258	8705	1.0
Yes				669	619	1.51
Time since previous screen						
0-<21 months				373	199	1.24
21-<24 months				11915	6552	1.0
24-<27 months				2185	1317	1.08
>=27 months				1454	1256	1.47
Cumulative reads						
0-30,000	4,496	2,844	1.0	3,321	1,852	1.0
30,001-60,000	1,647	1,389	1.33	6,321	3,685	1.05
60,001-80,000	438	388	1.40	3,060	1,672	1.05
>80,000	621	673	1.71	4,681	2,927	1.22

a. Adjusted for screening round

Table 2 Multivariate analysis of false positive recall at first and subsequent round screening

		First Round			Subsequent Round		
		Adjusted Odds ratio	95% Confidence interval		Adjusted Odds ratio	95% Confidence interval	
Screening date							
	years	1.06	1.02	1.11	0.96	0.93	1.00
Age Group							
	40-49yrs	1.11	1.01	1.22	1.38	1.22	1.57
	50-59yrs	1.0			1.0		
	60-69yrs	0.79	0.72	0.87	0.90	0.85	0.96
	70-79yrs	0.80	0.70	0.92	0.87	0.80	0.94
	80 + years	1.08	0.73	1.58	0.86	0.53	1.38
Family History of Breast Cancer							
	strong family history	1.24	1.03	1.51	1.65	1.44	1.88
	other family history	1.07	0.96	1.19	1.06	0.98	1.15
	no family history	1.0			1.0		
	unknown	3.12	2.16	4.49	1.35	0.97	1.88
Hormone Replacement Therapy							
	never on HRT	1.0			1.0		
	1 to 2 years on HRT	0.97	0.86	1.10	1.54	1.39	1.72
	3 to 5 years on HRT	0.99	0.84	1.16	1.67	1.49	1.86
	6 to 10 years on HRT	1.14	0.96	1.36	1.73	1.59	1.90
	more than 10 years on HRT	1.01	0.84	1.21	1.61	1.45	1.79
	yes, on HRT but unknown time	1.29	0.91	1.84	2.04	1.58	2.63
	unknown	1.06	0.48	2.31	0.87	0.44	1.74
Time since MINR2000							
	not introduced	1.0			1.0		
	0.01 to 3 months	1.17	0.94	1.45	1.26	1.12	1.41
	3.01 to 6 months	1.09	0.84	1.41	1.29	1.13	1.46
	6.01 to 12 months	1.10	0.90	1.35	1.09	0.99	1.20
	12.01 to 24 months	0.99	0.82	1.18	1.15	1.05	1.26
	24.01 to 48 months	0.93	0.70	1.24	1.04	0.91	1.19
Abnormality at previous screen							
	No				1.0		
	Yes				1.48	1.32	1.66
Time since previous screen							
	0-<21 months				1.15	0.96	1.39
	21-<24 months				1.00		
	24-<27 months				1.05	0.98	1.14
	>=27 months				1.40	1.28	1.53
Cumulative reads							
	0-30,000	1.0			1.0		
	30,001-60,000	1.16	1.05	1.29	1.03	0.95	1.12
	60,001-80,000	1.14	0.96	1.34	1.03	0.94	1.14
	>80,000	1.30	1.11	1.53	1.15	1.05	1.26

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