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Introduction of additional double reading of mammograms by radiographers: Effects on a biennial screening programme outcome

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ABSTRACT

Purpose: To determine the effect of introducing radiographer double reading, in addition to standard radiologist double reading, on screening mammography outcome.
Methods: In period A, 66,225 mammograms were read by two screening radiologists. In period B, 78,325 mammograms were read by two radiographers in addition and radiologists were blinded to the referral opinion of the radiographers. Mammograms, for which only radiographers had suggested referral, (i.e. cases that would only be referred by technologists) were re-evaluated by the screening radiologists. Women were referred if at least one radiologist considered this necessary, and diagnostic costs of these additional referrals were estimated.
Results: In period A, 322 cancers were diagnosed after referral of 678 women. During period B, radiologists initially referred 1122 patients and 411 cancers were detected. Radiologists' referral rate was higher in period B than in period A (1.43% versus 1.02%, $p < 0.001$), as well as the cancer detection rate per 1000 women screened (CDR) (5.25 versus 4.86, $p = 0.3$). The positive predictive value of referral (PPV) was 36.6% versus 47.5% ($p < 0.001$). In period B, radiologist review of 544 additional positive radiographer readings led to 102 extra referrals, with 29 additional cancers detected, resulting in an overall referral rate of 1.56% (compared to period A, $p < 0.001$), an overall CDR of 5.62 ($p = 0.048$) and an overall PPV of 35.9% ($p < 0.001$). Workup expenses of the 102 additional referrals were €60,274.
Conclusion: Additional radiographer double reading detected cancers that would have been missed by radiologists. Mean expenses for diagnostic confirmation of these extra cancers was €2078 per cancer.

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1. Introduction

Many countries have introduced breast cancer screening programmes for asymptomatic women aged 50 years and older.[1–3] Breast screening aims at reducing mortality from breast cancer through early detection of breast malignancy. Although screening mammograms may be assessed by a single reader, it has been shown that double reading by two radiologists can increase the cancer detection rate in breast screening by as much as 15%.[4–6] In the case of double reading by consensus or arbitration in particular, the increase in cancer detection rate may be accompanied by a reduction in the rate of women recalled for assessment. In countries like the United Kingdom and the United States, however, radiologist double reading may not always be feasible due to a shortage of trained and experienced radiologists. In the Netherlands, there is no such shortage and independent double reading by radiologists is standard of care.[7] From January 2003, independent double reading of screening mammograms by dedicated screening mammography radiographers, in addition to standard radiologist double reading, was introduced in the southern breast cancer screening region of the Netherlands.[8] The radiographers involved already had much experience in reviewing screening mammograms as part of quality assurance activities.

The aim of the current study was to determine the impact of additional radiographer double reading on screening parameters and screening outcome.

2. Patients and methods

2.1. Study population

We included all 144,550 mammographic screening examinations of women aged 50–75 years that were obtained at two specialised conventional screening units (one fixed and one mobile) in the southern breast cancer screening region of the Netherlands (BOBZ, Bevolkings Onderzoek Borstkanker Zuid) between 1st July 2000 and 1st July 2005. Written informed consent regarding patient identification and exchange of data on screening and clinical follow-up was obtained from all women participating in the breast cancer screening programme. Institutional review board approval was not required for this study. Details of the nation-wide breast cancer screening programme, offering biennial screening mammography for women aged 50–75 years, are described elsewhere.[7,9]

2.2. Readers and referral procedure

2.2.1. Screens performed between 1st July 2000 and 31st December 2002

From 1st July 2000 to 31st December 2002 (period A), all 66,225 screening mammograms were independently read by two certified screening radiologists. At the end of each mammography screening day, all examinations were collected and transported to the reading unit of the screening organisation. The mammograms were mounted on a light box in a room devoid of daylight and two screening radiologists for each case recorded whether additional diagnostic procedures were required. Two of the eight screening radiologists in the southern region independently read 140 screened cases on average within 60–75 min. The experience in screening mammography of the radiologists ranged from 39 to 95 months (mean, 79 months; median, 94 months) and each radiologist reads more than 6000 screening mammograms annually. Prior screening mammograms were always available and mammographic findings of positive cases were divided into five categories of abnormal findings: density, microcalcifications, density in combination with microcalcifications, architectural distortion and asymmetry. If a screening examination showed more than one mammographic abnormality, the mammogram was classified according to the most suspect finding, or according to the largest finding in case of equal suspicion of malignancy.

Radiologists tried to reach consensus in cases where they initially did not agree about referral. Until 1st January 2001, an arbitration panel of three radiologists assessed those screening mammograms for which the two screening radiologists could not reach consensus. Women were referred for further analysis if at least one arbitration panel radiologist considered referral desirable. From January 2001, the panel strategy for arbitration of discordant readings was abandoned: women were always referred if only one of the two screening radiologists persisted that further workup was indicated in case of a discordant reading.

2.2.2. Screens performed between 1st January 2003 and 1st July 2005

All 21 radiographers working at the two screening units participated in the study. They had been trained at the National Expert and Training Centre for Breast cancer screening (NETCB) prior to their employment as a screening radiographer. Mammography technique and positioning, and evaluation of the images for technical quality are central to their training, but radiographers are also instructed in breast anatomy and mammographic features of benign and malignant breast conditions. Radiographers receive further training at the Centre on a regular basis and frequently attend mammography symposia and conferences. From the start of mammography screening in the southern part of the Netherlands in 1995, radiographers have been encouraged to look for mammographic abnormalities. During quality assurance sessions, once every three weeks, radiographers bring mammographic abnormalities that may require additional work-up to the attention of a supervising breast radiologist. Examinations for which the screening radiologists requested additional workup are reviewed at these meetings as well: mammographic abnormalities are compared with pathology outcome. In addition, false-negative cases, that is, interval cancers, are discussed. At the beginning of 2003, radiographer experience in screening mammography ranged from 1 to 124 months (mean, 69 months; median, 74 months). From 1st January 2003 to 1st July 2005 (period B), all 78,325 screening mammograms were independently double read by a pair of radiographers at the screening site, immediately after their completion. The radiographers decided for each case whether additional workup was required. In case of a discrepant reading, they tried to reach consensus. If one radiographer persisted in the opinion that additional workup was indicated, the case was considered positive as well. For each positive case, a form was filled in, indicating the woman's name and date of birth and the date of screening. Similar to radiologist double reading, prior screening mammograms were always available and radiographers used the same five categories for positive cases.

Independent radiologist double reading of all mammograms was then performed at the reading unit of the screening organisation as described previously. After consensus reading, a woman was referred for workup if at least one radiologist considered referral necessary ('primary' referral). Radiologists were blinded to the referral opinion of the radiographers.

During the quality assurance sessions, a supervising breast radiologist discussed all recall decisions made by the screening radiologists with the radiographers. In addition, all cases that only the radiographers would have referred were reviewed by two screening radiologists (preferably those who had performed the original assessment). Only then, radiologists were informed about the mammographic abnormalities detected by the radiographers and a woman was recalled at this stage if at least one of the reviewers considered workup necessary ('secondary' referral).

2.3. Screening follow-up and estimation of diagnostic costs of secondary referrals

Throughout the study period, the screening radiologists amongst themselves discussed breast cancer cases that were detected after secondary referral. In routine sessions with a supervising breast radiologist, radiographers evaluated those breast cancer cases that had been referred by the radiologists only.

During a follow-up period of approximately two years (until the next screening round), we collected data on any radiological procedures, histopathology and TNM-classification of all referred women. To determine a possible difference in breast cancer incidence between the two screening periods, we traced interval cancers in addition to all screen-detected cancers.[8,10]

To estimate the costs of radiological imaging and percutaneous biopsy procedures of secondary referred women, we used 2006 national reimbursement rates.[11] To estimate the expenses of diagnostic lumpectomy and surgical consultation, we applied the mean costs of these procedures charged at the four hospitals that performed the follow-up of secondary referred women. For women with a false-positive screening examination, that is, women with benign findings at follow-up, diagnostic expenses included all tests that were performed until the next screening examination. If breast cancer was diagnosed, assessment of diagnostic expenses ended at the time of preoperative diagnosis through percutaneous biopsy, or at the time of diagnostic lumpectomy if the diagnosis of breast cancer had not been established preoperatively.

2.4. Statistical analysis

The primary outcome measures were referral rate, cancer detection rate (number of cancers detected per 1000 women screened, CDR), positive predictive value of referral (PPV) and tumour stage. All data were entered into a computerised spreadsheet (Excel; Microsoft, Redmond, WA, USA). Statistics were performed using Statistical Package for Social Sciences 13.0.1 (SPSS Inc. Chicago, IL, USA). The χ^2 test or Fisher's Exact test was used to compare proportions between screening periods. The significance level was set at 5%.

3. Results

During period A, a total of 66,225 mammograms were independently read by screening radiologists: 8695 (13.1%) initial (prevalent) screens and 57,530 (86.9%) subsequent (incident) screens (Table 1). Radiologists referred 678 women for further workup, with a referral rate of 1.02% (95%-CI: 0.9–1.1%) (Table 2). Of these 678 women, 462 (68.1%) underwent percutaneous or surgical biopsy in addition to radiological assessment of the mammographic abnormality. Breast cancer was pathologically proven in 322 out of 462 biopsied women (69.7%), resulting in a CDR of 4.86 per 1000 women screened (95%-CI: 4.33 to 5.39).

During period B, all 8950 initial screens (11.4%) and 69,375 subsequent screens (88.6%) were assessed both by radiologists and radiographers (Table 1). As compared with period A, a larger proportion of women were referred by radiologists for further workup (1.43% versus 1.02%; χ^2 test, $p < 0.001$), whereas mammographic abnormalities less often comprised suspicious densities (67.1% versus 77.4%; χ^2 test, $p < 0.001$) and more often suspicious microcalcifications (20.6% versus 13.6%; χ^2 test, $p < 0.001$) (Table 2). Biopsy was performed in 711 out of 1122 referred women (63.4%), revealing breast cancer in 411 cases. The PPV of biopsy for breast cancer in period B was lower than in period A (57.8% versus 69.7%; χ^2 test, $p < 0.001$). CDR had increased from 4.86 to 5.25 ($p = 0.3$), at the expense of a decreased PPV of referral (36.6% versus 47.5%, $p < 0.001$). The proportion of DCIS did not differ significantly between period A (14.9%) and period B (16.1%; Fisher's Exact test, $p = 0.4$). Tumour size distributions of invasive breast cancers did not differ significantly either between the two screening periods (Fisher's Exact test, $p = 0.08$).

In period B, a total of 544 screening examinations had been considered abnormal by radiographers only (368 densities,

Table 1 – Characteristics of the screened population

Screening period	1st July 2000–31st December 2002 (Period A)	1st January 2003–1st July 2005 (Period B)
Mammograms, no	66,225	78,325
Initial screens	8695 (13.1)	8950 (11.4)
Subsequent screens	57,530 (86.9)	69,375 (88.6)
Age distribution, no		
<50	3167 (4.8)	3346 (4.3)
50–54	16,728 (25.3)	18,495 (23.6)
55–59	13,884 (21.0)	18,082 (23.1)
60–64	12,262 (18.5)	14,446 (18.4)
65–69	11,435 (17.3)	12,962 (16.5)
70–74	8607 (13.0)	10,865 (13.9)
>74	142 (0.2)	129 (0.2)

Percentages are given in parentheses.

Table 2 – Screening results at different screening periods and at different screening strategies

Screening period	1st July 2000–31st December 2002		1st January 2003–1st July 2005		1st January 2003–1st July 2005	
Reading strategy	Independent radiologist double reading		Independent radiologist double reading		Independent radiographer double reading followed by independent radiologist double reading	
Mammograms, No	66,225		78,325		78,325	
Referral, No	678 (1.0)		1,122 (1.4)		1224 (1.6)	
Mammographic abnormality, No						
Density	525 (77.4)		753 (67.1)		813 (66.4)	
Microcalcifications	92 (13.6)		231 (20.6)		269 (22.0)	
Density with microcalcifications	42 (6.2)		82 (7.3)		84 (6.9)	
Architectural distortion	12 (1.8)		38 (3.4)		40 (3.3)	
Breast parenchyma asymmetry	7 (1.0)		18 (1.6)		18 (1.5)	
Breast cancers, No	322		411		440	
PPV of referral (%)	47.5		36.6		35.9	
Cancer detection rate[a]	4.86		5.25		5.62	
Type of breast cancer	No	%	No	%	No	%
DCIS	48	14.9	66	16.1	74	16.8
Invasive	274	85.1	345	83.9	366	83.2
T1a/b/c	209	76.3	271	78.6	289	79.0
T2	60	21.9	73	21.2	75	20.5
T3	4	1.5	0	0.0	0	0.0
Unknown	1	0.4	1	0.3	2	0.5
Lymph-node status of invasive cancers						
Positive	77	28.1	91	26.4	94	25.7
Negative	190	69.3	251	72.8	266	72.7
Unknown	7	2.6	3	0.9	6	1.6

Percentages are given in parentheses. PPV = positive predictive value.
a Per 1000 women screened.

67.6%; 142 suspicious microcalcifications, 26.1%; 19 densities with microcalcifications, 3.5%; 10 architectural distortions, 1.8% and 5 breast parenchyma asymmetries, 0.9%). Radiologist review of these positive radiographer readings resulted in 102 secondary referrals. Table 3 shows the diagnostic procedures performed in these women, as well as the workup expenses. Biopsy was performed in 64 of the 102 additionally referred women (62.7%) and 29 cancers were detected. These cancers comprised 8 ductal carcinomas in situ and 21 invasive cancers. The mean diagnostic cost for cancers, detected after secondary referral, was €2078 per cancer. Compared with cancers detected by radiologist double reading only, cancers diagnosed after secondary referral constituted a larger proportion of ductal carcinomas in situ (27.6% versus 16.1%; Fisher's Exact test, $p = 0.08$). Of the 21 additional invasive cancers, 18 were T1-tumours and 3 cancers (1 T1 and 2 T2-tumours) showed axillary lymph node metastasis. In period B, the additional double reading by radiographers led to an overall CDR of 5.62 (compared to period A, $p = 0.048$) and an overall PPV of referral of 35.9% (compared to period A, $p < 0.001$).

Whilst double reading by radiologists alone resulted in 1122 referrals, double reading by radiographers alone would have resulted in 1015 referrals (McNemar's test, $p = 0.002$), corresponding to a referral rate of 1.30%. After two years of follow-up, a total of 352 breast cancers had been diagnosed amongst these 1015 women. These 352 cancers comprised 304 malignancies detected by both radiologists and radiographers, 29 malignancies detected upon radiologist review of radiographer positive readings, 12 interval cancers and seven mammographic abnormalities that proved to be cancers at the subsequent screening examination. Double reading by radiographers alone would have resulted in a cancer detection rate of 4.50 per 1000 women screened (compared with a detection rate of 5.25 at double reading by radiologists alone; McNemar's test, $p < 0.001$) and a PPV of 34.7%. Referral of all positive readings by the radiologists or the radiographers would have resulted in 1666 referrals and 459 screen-detected cancers, corresponding to a referral rate of 2.1%, a PPV of 27.6% and a cancer detection rate of 5.86 cancers per 1000 screened women, respectively.

The age distribution of the screened population had not changed significantly between the two periods (χ^2 test, $p = 1.0$). The breast cancer incidence in the screened population was 7.35 (322 screen-detected cancers and 165 interval cancers in 66,225 screened women) per 1000 screened women in period A and 7.47 (440 screen-detected cancers and 145 interval cancers in 78,325 screened women) in period B (χ^2 test, $p = 0.8$).

4. Discussion

Between 1st July 2000 and 31st December 2002 (period A), independent double reading by radiologists in the southern breast screening region in the Netherlands resulted in a can-

Table 3 – Diagnostic procedures and diagnostic workup expenses in 102 women, referred upon radiologist review of screens considered positive by radiographers only

Diagnostic procedure, type	Diagnostic procedure, No	Unit cost (€)[b]	Total costs (€)
Radiological imaging			
Mammography	182	77.30	14,068.60
Breast US	111	73.10	8114.10
Axillary US	14	73.10	1023.40
Breast MRI	7	203.00	1421.00
Percutaneous biopsy			
Breast FNAC or CB, US-guided	37	149.10	5516.70
Breast FNAC or CB, not image-guided	2	75.20	150.40
Axillary FNAC, US-guided	1	149.10	149.10
Stereotactic core biopsy	36	202.70	7297.20
Lumpectomy			
Image-guided[a]	8	1203.95	9631.60
Not image-guided	1	989.20	989.20
Specimen radiography	8	53.60	428.80
Outpatient surgical consultation	319	36.00	11,484.00
Total			60,274.10

US = ultrasonography; MRI = magnetic resonance imaging; FNAC = fine needle aspiration cytology; CB = core biopsy.
Cost prices of 2006, charged at the four hospitals that performed follow-up of referred women, were used to estimate lumpectomy costs and consultation costs.
a US-guided or stereotactic-guided.
b National reimbursement rates of 2006 were applied for estimation of radiological imaging costs and percutaneous biopsy costs (source: Nederlandse zorgautoriteit, www.ctg.bit-ic.nl/Nzatarieven/top.do).

cer detection rate comparable with that of the standard radiologist double reading nation-wide.[12] With the introduction of additional radiographer double reading in the following 30 months (period B), we saw radiologists increase their referral rate with 40%, from 1.0% to 1.4%. There is no obvious explanation for this increase in referral rate after the introduction of radiographer double reading. A similar trend could be seen in the Dutch breast cancer screening programme nation-wide,[12] though the radiologists' awareness of the study may have influenced their screening behaviour as well. It is not very likely that changes in women characteristics influenced referral rates, as, for example, the proportion of initial screens has been stable for many years. Moreover, the age distribution and breast cancer incidence did not show statistically significant differences between the two screening periods.

A 1.4% referral rate is still very low compared with 6–13% referral rates that are typical in UK and USA breast cancer screening programmes.[13,14] In the Netherlands, however, recall rates exceeding 4% would level off breast cancer detection, with a disproportionate increase of false-positive rates and a less favourable cost-effectiveness outcome.[15,16]

The increased referral rates resulted in a higher cancer detection rate, but also in a drop of positive predictive value of referral. There is a delicate balance between referral rate and cancer detection rate. With reduced referral rates, too many small cancers may be missed. Increased referral rates, on the other hand, will result in extra cancer detection in a limited number of women only, whilst causing anxiety and reducing re-attendance in larger numbers.[17]

Review of radiographer positive readings proved to be a fruitful screening strategy. With a relative increase of the referral rate by 9.1% (from 1.43% to 1.56%), the cancer detection rate increased by 7.0% as compared with radiologist double reading only, and 28.4% of the secondarily referred women (29 of 102) proved to have breast cancer. The mean diagnostic cost of these cancers was a modest €2078 per cancer. Moreover, a majority of the cancers detected after secondary referral showed a favourable tumour stage, such as ductal carcinomas in situ and smaller invasive cancers. Therefore, implementation of radiographer double reading in addition to standard radiologist double reading may provide an effective strategy.

A few studies have assessed the effects of involving radiographers in reading mammograms on breast screening performance indicators. In these studies with small screening populations, radiographers have been employed as pre-readers, single readers or double readers. The radiographers showed higher false-positive rates at referral and similar sensitivity for breast cancer detection as compared with radiologists.[18–22] In our study, radiographers detected fewer cancers than the screening radiologists. The primary aim of our study, however, was not to compare radiographer double reading with radiologist double reading, but to determine the possible benefit of additional radiographer double reading on screening results in a programme which is characterised by standard independent radiologist double reading and a very low referral rate. Compared with selective referral upon radiologist review of radiographer positive readings, referral of all radiographer positive readings would have increased the cancer detection rate by another 4.3% (from 5.62 to 5.86), whereas the referral rate would still be low at 2.1%. Therefore, referral of all radiographer positive readings should be considered.

In the future, digital screening mammography may facilitate screening and reading procedures for radiographers and radiologists. Computer Assisted Detection (CAD) may then be an alternative to additional reading of screening mammograms by radiographers. On the other hand, several studies have demonstrated that independent double reading by radiologists yields better detection performances than CAD-assisted single reading and the use of CAD may be associated with reduced accuracy of interpretation of screening mammograms.[23–25] Finally, clinical breast examination at screening may be another method to improve cancer detection. Feigin and colleagues found that clinical breast examination by nurse practitioners increased the cancer detection rate by 3%; the cost of detecting these additional cancers was estimated to be $122,598 per cancer.[26]

There are several limitations to our study. First, the data in this study were not suited to explore the performance of radiologist-radiographer double reading as each mammogram was independently read (that is, the second reader was not blinded to the reading outcome of the first reader) by two radiographers and, in turn, by two radiologists. Due to a shortage of screening radiologists in other breast cancer screening programmes, such as the UK programme, it would be interesting to assess whether a dedicated radiographer can replace one of the screening radiologists. Second, official implementation of radiographer double reading may imply reimbursement for radiographers and radiologists may want financial compensation for the extra time they spend on review of the radiographers' positive referral recommendations. We did not take into account these potential additional cost factors when calculating the diagnostic cost of cancers detected by additional radiographer double reading.

In summary, CDR increased after the introduction of radiographer double reading in addition to radiologist double reading. This increase was the combined result of improved cancer detection rates achieved by radiologists and additionally detected cancers after secondary referral of radiographer positive readings. The mean diagnostic cost of cancers after secondary referral was €2078 per cancer.

Conflict of interest statement

None declared.

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