Failure of stereotactic core needle biopsy in women recalled for suspicious calcifications at screening mammography: frequency, causes, and final outcome in a multi-institutional, observational follow-up study

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Abstract
Objectives We determined the failure rate of stereotactic core needle biopsy (SCNB) and its causes and final outcome in women recalled for calcifications at screening mammography.

Methods We included a consecutive series of 624,039 screens obtained in a Dutch screening region between January 2009 and July 2019. Radiology reports and pathology results were obtained of all recalled women during 2-year follow-up.

Results A total of 3495 women (19.6% of 17,809 recalls) were recalled for suspicious calcifications. SCNB was indicated in 2818 women, of whom 12 had incomplete follow-up and another 12 women refused biopsy. DCIS or invasive cancer was diagnosed in 880 of the remaining 2794 women (31.5%). SCNB failed in 62 women (2.2%, 36/2794). These failures were mainly due to a too posterior (n = 30) or too superficial location (n = 17) of the calcifications or calcifications too faint for biopsy (n = 13). Of these 62 women, 10 underwent surgical biopsy, yielding one DCIS (intermediate grade) and two invasive cancers (one intermediate grade and one high grade) and another two women were diagnosed with DCIS (both high grade) at follow-up. Thus, the malignancy rate after SCNB failure was 8.1% (5/62). Calcifications were depicted neither at SCNB specimen radiography nor at pathology in 16 women after (repeated) SCNB (0.6%, 31/2732). None of them proved to have breast cancer at 2-year follow-up.

Conclusions The failure rate of SCNB for suspicious calcifications is low but close surveillance is warranted, as breast cancer may be present in up to 8% of these women.

Key Points
• The failure rate of stereotactic core needle biopsy (SCNB) for calcifications recalled at screening mammography was 2.2%.
• Failures were mainly due to calcifications that could not be reached by SCNB or calcifications too faint for biopsy.
• The management after failed SCNB was various. At least, close surveillance with a low threshold for surgical biopsy is recommended as breast cancer may be present in up to 8% of women with SCNB failure.

Keywords Breast cancer • Core needle biopsy • Screening mammography

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Introduction

Many countries have implemented regional or nationwide screening mammography programs [1]. These programs aim to detect breast cancer at an early stage, and significant improvements in breast cancer morbidity and mortality have been achieved through this early detection and improved breast cancer treatment [2, 3]. The Netherlands has a long history of screening mammography; a nationwide screening program, offering free biennial screening mammography to women aged 50–75 years, was fully implemented in 1998.

Calcifications at mammography may be a sign of the presence of ductal carcinoma in situ (DCIS) or invasive breast cancer and comprise a substantial proportion of recalls at screening mammography [4]. Digital mammography has a higher sensitivity for the detection of suspicious calcifications than screen-film mammography [5]. Screen-film mammography was replaced by full-field digital screening mammography in the Dutch screening program in 2009 and 2010 and this transition came along with higher calcification recall rates and higher DCIS detection rates [6]. The standard of reference for pathological analysis of suspicious calcification is surgical biopsy. However, this type of biopsy is costly and invasive and it may have a negative impact on cosmetic outcome. Percutaneous, minimally invasive vacuum-assisted biopsy has been proven to be a reliable alternative to surgical biopsy and it has largely replaced surgical biopsy for the assessment of suspicious calcifications seen at mammography [7, 8].

The reported technical success rate and the sensitivity for the detection of malignant breast abnormalities of vacuum-assisted biopsy are high [7]. There are, however, very sparse data on the policy to follow in case of a failure to obtain a representative vacuum-assisted biopsy of calcifications and the probability of breast malignancy in these women. In a multi-institutional observational follow-up study, we therefore determined the failure rate of stereotactic core needle biopsy and the causes of these failures in women recalled for suspicious calcifications at screening mammography, as well as the further management and the risk of breast malignancy in these women.

Materials and methods

Study population and design of the screening mammography program

All women who underwent biennial screening mammography in a southern screening region of the Netherlands between January 1, 2009, and July 1, 2019, were eligible for inclusion. Prior to participation, women gave informed consent that their data may be used for quality assurance of the screening program and for scientific purposes. An opt-out construction enables the women to refrain from this consent. Only three recalled women used this opt-out and they were excluded from analysis. Ethical approval was not required for the current study, according to the Dutch Central Committee on Research involving Human Subjects (CCMO).

Women aged 50–75 years were offered free biennial screening mammography. A transition from screen-film to full-field digital mammography took place in 2009 and 2010. The screening mammograms were obtained at four screening units (one fixed unit and three mobile units) by trained mammography radiographers. The examinations were then double read by a team of certified screening radiologists, each reading more than 6000 screening mammograms yearly. Suspicious mammographic abnormalities were categorized as follows: (1) mass; (2) calcifications; (3) mass with calcifications; (4) asymmetry; (5) architectural distortion; or (6) other. Women without mammographic abnormalities (BI-RADS 1) or benign mammographic lesions (BI-RADS 2) were not recalled, whereas BI-RADS 0 lesions (low probability of malignancy), BI-RADS 4 lesions (intermediate probability of malignancy), and BI-RADS 5 lesions (high probability of malignancy) were recalled for further analysis [9, 10].

Assessment after recall and follow-up

Recalled women underwent further assessment of their mammographic abnormality at a specialized breast unit of a surgical department, mostly at one of the regional hospitals. The majority of these recalls was performed in six hospitals (97.7%, 3412/3494 recalls). From 2017, BI-RADS 0 recalls were initially evaluated at a radiology department and, if indicated, by surgical oncologists as well. The clinical radiologists classified all breast imaging examinations according to BI-RADS. The diagnostic results of recalled women and their consequences were discussed at multidisciplinary meetings. The screening organization routinely received the initial follow-up data from the hospitals where the women were analyzed after recall. To complete the 2-year follow-up (until the next biennial screen), one of the radiologists (L.D.) and several radiology residents collected additional reports on radiological, surgical, and biopsy procedures that were not received by the screening organization through visits at these
departments. All data were then entered into a database, created for quality control of the screening program and scientific purposes, by the radiologist.

**Stereotactic core needle biopsy of calcifications**

In the six hospitals that handled the majority of recalls, the vacuum-assisted stereotactic core needle biopsy of calcifications was done using 9-Gauge or 10-Gauge needles (Table 1). Prone stereotactic biopsy was performed in all hospitals, whereas two hospitals could also use a supine biopsy approach. The number of biopsies taken was at the discretion of the radiologist (usually 6–12 biopsy specimen). Specimen radiography of the biopsies was routinely obtained to assess the presence of calcifications in the specimens and a marking clip was placed at the biopsy site at the end of the procedure. Additional mammographic images were acquired to confirm that the target lesion was sampled and the marking clip was in an appropriate position. Both radiologists and pathologists routinely mentioned in their reports whether or not calcifications were present in the biopsy specimen. Vacuum biopsies were processed after 6 to 24 h of formalin fixation. Biopsies with calcifications at specimen radiography were separated from those without calcifications. Hematoxylin and eosin (HE) stained slides were made from all biopsies and examined at three levels. If no calcifications were seen in the HE sections, deeper levels were examined by the pathologist. Care was taken not to miss birefringent calcium oxalate crystals.

**Data analysis**

All data were entered into an automated spreadsheet (Excel; Microsoft). The analyses were conducted using statistical software (IBM SPSS Statistics for Windows, Version 24.0). The differences between hospitals in the proportion of SCNB failures and differences between BI-RADS 4 and BI-RADS 3 calcifications in the proportion undergoing wire-guided surgical biopsy were tested using the χ² test or the Fisher exact test, when appropriate. All tests were two sided and the significance level was set at 5%.

**Results**

**Overall screening outcome**

We included a consecutive series of 624,039 screens (67,960 initial screens and 556,079 subsequent screens), of which 17,809 were recalled (recall rate: 2.9%). Breast cancer was diagnosed in 4172 recalled women (875 DCIS and 3297 invasive cancers), yielding a cancer detection rate of 6.69 per 1000 screens and a positive predictive value of recall of 23.4% (4172/17,809).

**Target population**

Recall for suspicious calcifications at screening mammography occurred in 3495 women (19.6% of all recalls, Fig. 1). Stereotactic core needle biopsy (SCNB) for further analysis of the calcifications was indicated in 2818 women. Follow-up was incomplete in 12 of these women and another 12 women refused SCNB, leaving 2794 women for final analysis. A unilateral, single SCNB procedure was indicated in 2582 women. Another 157 women were scheduled for two or more ipsilateral SCNB procedures and 55 women for bilateral SCNB, totaling 3020 stereotactic biopsies indicated in the 2794 women available for final analysis. After 2 years of follow-up, DCIS (668 women, low grade: 113; intermediate grade: 246; high grade: 309) or invasive breast cancer (211 women, Bloom & Richardson grade I: 89; grade II: 89; grade III: 25; grade unknown: 8) was diagnosed in 879 women (31.5%, 879/2794).

SCNB was not considered necessary in 677 of the women recalled for suspicious calcifications. A total of 301 women were assigned BI-RADS 1 or BI-RADS 2 after additional breast imaging and they were advised to re-attend the biennial screening program (Fig. 2). Another 164 women were categorized BI-RADS 3, of whom 126 received mammographic surveillance and 38 underwent ultrasound-guided percutaneous biopsy (yielding two DCIS and four invasive cancers). The remaining 212 women underwent US-guided biopsy for a BI-RADS 4 or BI-RADS 5 lesion, yielding 49 DCIS and 101 invasive cancers.

**Failed stereotactic biopsy procedures**

SCNB was initially unsuccessful in 65 women. In three of these cases, SCNB was performed successfully at the second instance in another hospital where an upright approach was used rather than the prone position, leaving 62 final SCNB failures in 62 women (2.2%, 62/2794; Fig. 3). Respectively, 24 and 38 of the calcification lesions were categorized as BI-RADS 3 (38.7%) or 4 (61.3%). The SCNB failure ranged from 1.2% (3/249) to 8.0% (6/75) among the six hospitals that performed the majority of recalls, with hospital F showing a significantly higher failure percentage than hospitals A–D (Table 1). The most frequently encountered reasons for technical failure were non-visualization of the calcifications at SCNB due to a too deep location of the calcifications (48.4%, 30/62), followed by a too superficial location of the calcifications hampering the creation of vacuum (27.4%, 17/62), and calcifications of a too low density to allow a proper localization (21.0%, 13/62). The remaining two failures were patient related and included severe Bechterew disease (1 woman) and immobility (1 woman). Wire-guided surgical biopsy was performed in 10 women (16.1%, 10/62) and this was done as frequently for BI-RADS 4 calcifications as for BI-RADS 3.
| Hospital | Start vacuum-assisted SCNB (year) | Radiologists performing SCNB during study period, no. | SCNB equipment | SCNB needles | Patient position | SCNB procedures, no. | SCNB failures, no. (%) | p value, % failures (vs. hospital F) |
|----------|----------------------------------|------------------------------------------------------|----------------|--------------|-----------------|----------------------|------------------------|-------------------------------|
| A        | 2001                             | 8                                                    | Multicare Platinum (Hologic Inc, Bedford, MA, USA) + Suros ATEC Pearl Biopsy Unit U-1354 (Hologic) | Eviva, 9 Gauge (20 mm or 12 mm length; Hologic Inc) | Prone | 747 | 18 (2.4) | 0.016 |
| B        | 2001                             | 5                                                    | Multicare Platinum + Suros ATEC Pearl Biopsy Unit U-1354 | Eviva, 9 Gauge (20 mm or 12 mm length; Hologic Inc) | Prone | 734 | 11 (1.5) | 0.001 |
| C        | 2000                             | 7                                                    | Multicare Platinum + Suros ATEC Pearl Biopsy Unit U-1354 | Eviva, 9 Gauge (20 mm or 12 mm length; Hologic Inc) | Prone | 669 | 14 (2.1) | 0.009 |
| D        | 2000                             | 4                                                    | Multicare Platinum + Suros ATEC Pearl Biopsy Unit U-1354 | Eviva, 9 Gauge (20 mm or 12 mm length; Hologic Inc) | Prone | 249 | 3 (1.2) | 0.006 |
| E        | 2004                             | 6                                                    | Multicare Platinum + Suros ATEC Pearl Biopsy Unit U-1354 Affirm breast biopsy guidance system (Hologic) + Suros ATEC Pearl Biopsy Unit U-1354 | Eviva, 9 Gauge (20 mm or 12 mm length; Hologic Inc) | Prone Supine, sitting | 268 | 8 (3.0) | 0.10 |
| F        | 2003                             | 6                                                    | Multicare Platinum + Suros ATEC Pearl Biopsy Unit U-1354 Affirm breast biopsy guidance system + Suros ATEC Pearl Biopsy Unit U-1354 | Vacora, 10 Gauge (Bard, Covington, GA, USA) | Prone Supine, sitting | 75 | 6 (8.0) | Not applicable |
| Other*   | N/A                              | N/A                                                  | N/A | N/A | N/A | 52 | 2 (3.8) | 0.56 |

SCNB, stereotactic core needle biopsy; N/A, not available

*Remaining 12 hospitals
RADS 3 calcifications (18.4% (7/38) versus 12.5% (3/24), \( p = 0.79 \)). Surgical biopsy yielded one DCIS (intermediate grade) and two invasive cancers (one intermediate grade and one high grade). Two women underwent ultrasound-guided, vacuum-assisted biopsy after stereotactic placement of a marking clip at the calcifications, with benign pathology outcome (Fig. 4 (1) and (2)). Another 34 women underwent mammographic surveillance of their calcifications. This surveillance consisted of ipsilateral 2-view mammography after 6 months, bilateral 2-view mammography after 12 months, and a final bilateral 2-view mammogram at 24 months. Mammographic surveillance was terminated if follow-up mammography showed a regression of the calcifications. On the other hand, progression of the calcifications at follow-up prompted another attempt of percutaneous biopsy or surgical biopsy. In total, two high-grade DCIS (35 mm and 15 mm, respectively) were diagnosed at this follow-up. Two women did not comply with the recommended mammographic follow-up and 14 other women received breast MRI, followed by mammographic surveillance. Breast cancer was not diagnosed in any of these 16 women within 2 years after their SCNB failure. Thus, the overall malignancy rate was 8.1% (5/62) among women who experienced a failure of their SCNB procedure.

**Absence of calcifications at pathology**

In 29 women (1.1%, 29/2732), of whom two underwent a repeated SCNB procedure, no calcifications could be identified in the SCNB specimen at pathology. In 13 of them, calcifications were present at specimen radiography and pathological analysis of the core biopsies revealed three cases of DCIS (of which two intermediate grade and one high grade). No breast cancer was diagnosed in the other 10 women (of whom three underwent additional surgical biopsy, three received follow-up mammography, and four returned to the screening program without further examinations after their SCNB). In 16 women, no calcifications could be identified, neither at specimen radiography of
the biopsies nor at pathology (0.6%, 16/2732). None of these women was diagnosed with breast cancer during the 2-year follow-up period (three women underwent surgical biopsy, nine received mammographic surveillance of the calcifications, one did not adhere to mammographic follow-up, and three returned to the screening program without additional examinations following SCNB).

**Discussion**

In this multi-institutional study, we found that 2.2% of women experienced a technical failure of their SCNB procedure. The most frequent reasons for failures were a too posterior or a too superficial location of the calcifications and calcifications too faint for biopsy. The approach after failed stereotactic biopsy was various and included surgical biopsy, ultrasound-guided vacuum-assisted biopsy after stereotactic placement of a marking clip, breast MRI, or mammographic follow-up. At histology (second attempt) or after 2-year follow-up, the eventual malignancy rate among women with an initially unsuccessful stereotactic biopsy was 8.1% (5/62).

Several studies have reported on retrieval failure of calcifications during stereotactic biopsy, despite a good visibility of the calcifications and a proper needle localization, but very few data are available on other causes of SCNB failure. In a
single-center study from the USA that included 99 SCNB failures for calcification lesions out of a series of 1874 stereotactic biopsies for various mammographic lesions, Brennan et al report that three-quarters of these cancellations were due to calcified foci that were too faint for visualization during biopsy [11]. This percentage is much higher than we observed, which may partly be explained by differences in the study populations. Brennan et al only included women with calcifications seen at digital mammography, whereas our study population also comprised screen-film mammograms. Moreover, our series was limited to screened women, whereas the US study also included younger women with denser breasts. Many studies have shown that full-field digital mammography is superior to screen-film mammography for the detection of small calcifications [5, 12]. This improved detection by digital mammography likely increases the probability of SCNB failures as the system that provides the diagnostic images may be superior to the one used for stereotactic biopsy. In another single-center study that included 439 prone SCNB procedures, Bahl et al reported a failure rate of 4.9%, with a majority of these failures caused by calcifications that could not be targeted [13]. In only 0.5%, two out of 439 failures, SNCB was unsuccessful due to a very low density of the calcifications.

We encountered different approaches in case of a cancelled SCNB procedure for suspicious calcifications. One would assume that surgical biopsy may be performed more frequently for BI-RADS 4 than for BI-RADS 3 calcifications, but this was not the case in our series. Although women with BI-RADS 4 lesions more frequently underwent surgery (18.4% versus 12.5%), the overall low number of surgical biopsy procedures may likely be the reason for not reaching a statistically significant difference. It may be worthwhile to repeat the biopsy procedure using an upright digital breast tomosynthesis-guided approach when the calcifications cannot be targeted with the patient in prone position, as was done successfully in three women in our series. The upright biopsy technique has a higher technical success rate than prone stereotactic biopsy as posterior lesions are more easily accessible and some patients are not able to tolerate a prone position [13]. A disadvantage of the upright approach, however, is a higher probability of fainting. One out of six women in our series underwent surgical biopsy after SCNB failure, yielding three malignancies in the 10 diagnostic, surgical biopsies (30%).
Fig. 4 Ultrasound-guided vacuum-assisted biopsy of suspicious calcifications not accessible by stereotactic core needle biopsy (SCNB). 1: Two-view screening mammogram (A, right medio-lateral-oblique; B, left medio-lateral-oblique; C, right cranio-caudal; D, left cranio-caudal) shows grouped, amorphous calcifications in the left breast (magnification E and F, arrows). 2: The calcifications were located too superficially for SCNB, but a marker could be placed under stereotactic guidance (G and H, needle tip near the calcifications (arrows)). The subsequently obtained medio-lateral (I) and cranio-caudal (J) views show the marker at the site of the calcifications (arrows). Both the calcifications (K, arrow) and the marker (L, arrow) were retrieved at ultrasound-guided, 9-Gauge vacuum-assisted biopsy. Pathology yielded columnar cell changes with atypia.
Sometimes a marking clip can be placed at the site of the calcifications under stereotactic guidance when stereotactic biopsy itself is not possible. In two women, the calcifications could successfully be biopsied through ultrasound-guided localization of the clip, followed by vacuum-assisted biopsy. Other women underwent mammographic follow-up of their calcifications or received breast MRI. Biopsy is mandatory when progress of the calcifications is seen at mammographic surveillance. The rationale to perform MRI is the ability of this imaging technique to improve DCIS detection, especially DCIS with high nuclear grade [14].

Literature on the probability of malignancy after SCNB failure is very sparse. In a small series of 20 surgical biopsy procedures in 19 women with suspicious calcifications that were too faint for stereotactic core biopsy, Jeffries et al reported five malignancies, including two DCIS [15]. These findings are in line with another study reporting a malignancy rate of 17% in women with such calcifications [11]. Our 8.1% malignancy rate in women who experienced a failure of their stereotactic biopsy of calcifications for a variety of reasons, including too faint calcifications, implies that the threshold for surgical biopsy should be low. On the other hand, since only one of the surgical biopsies showed a high-grade invasive cancer, one may either opt for close surveillance or surgical biopsy through shared decision between the patient and clinician.

The number of biopsies taken at SCNB may vary according to the radiologist’s discretion. One study, reporting on the use of 11G needles, found that the highest diagnostic yield was achieved with 12 specimens [16]. Fewer specimens were usually obtained in our series (routinely 6 to 12 specimens). On the other hand, most hospitals used a 9G needle that yields more tissue than the smaller 11G needle. SCNB may fail to retrieve calcifications in the biopsy specimen, as we found in just more than 1% of the women undergoing SCNB, and this percentage is in line with the 1–5% retrieval failure rates reported in two studies that used 11G needles [17, 18]. Although none of the 16 women in our series, whose SCNB yielded no calcifications at specimen radiography nor at pathology, was ultimately diagnosed with breast cancer, a repeated SCNB procedure or at least strict radiological follow-up should be performed as cores without calcifications may fail to show malignant lesions [19].

One hospital showed a significantly higher SCNB failure rate. Although this specific hospital had the lowest number of SCNB procedures, one cannot automatically conclude from this observation that lower SCNB volumes are related to worse success rates as the hospital in question may have performed SCNB procedures in women that were recalled from a neighboring screening region and thus not included in our series. Nevertheless, as any hospital in the Netherlands may perform the workup of recalled women, we feel that an introduction of quality assurance and assessment sessions will have a beneficial effect on diagnostic and therapeutic outcome after recall.

Our study has several strengths and limitations. Strengths are the large size of the study population, the multi-institutional design and the virtually complete follow-up. To our knowledge, this study is the first that reports on the overall failure rate of stereotactic biopsy for suspicious calcifications and its final outcome. A limitation is the likely presence of different levels of experience among different radiologists performing SCNB. The latter, on the other hand, reflects routine clinical practice. Since follow-up was limited to the next screening mammography (2 years), malignancies appearing afterwards were not included, resulting in a possible underestimation of the risk. Finally, we considered a thorough analysis on factors associated with SCNB failure not to be feasible as our series comprises a low number of these failures per hospital and many radiologists performed the SCNB procedures.

In summary, we conclude that the failure rate of SCNB for calcifications is very low, but a close surveillance with a low threshold for surgical biopsy is recommended as breast cancer may be present in a substantial number of these women. There are several options to choose from when one encounters SCNB failure urging for a well-informed shared decision making process. The development of evidence-based guidelines, supported by large studies, may help clinicians and patients alike to decide which further steps to take in these cases.

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Declarations

Guarantor The scientific guarantor of this publication is Lucien EM Duijm, MD, PhD.

Conflict of interest Lucien EM Duijm is Associate Editor for the “Breast section” of European Radiology. He has not taken part in the review or selection process of this article. The authors do not opt for preprint-sharing.

Statistics and biometry One of the authors has significant statistical expertise.

Informed consent Prior to participation, women gave informed consent that their data may be used for quality assurance of the screening program and for scientific purposes. An opt-out construction enables the women to refrain from this consent. Only three recalled women used this opt-out and they were excluded from analysis.

Ethical approval Ethical approval was not required for the current study, according to the Dutch Central Committee on Research involving Human Subjects (CCMO).

Methodology

• prospective
• observational
• multicenter study
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