



Stereotactic 9-gauge vacuum-assisted breast biopsy, how many specimens are needed?*



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ABSTRACT

Purpose: To determine the minimum number of stereotactic 9-gauge vacuum-assisted biopsy specimens required to establish a final histopathological biopsy diagnosis of mammographically suspicious breast lesions.

Methods: This prospective single-center observational cohort study included 120 women referred for stereotactic vacuum-assisted biopsy of 129 mammographically suspicious lesions between December 2017 and October 2018. Stereotactic 9-gauge vacuum-assisted biopsy was performed, acquiring twelve specimens per lesion. Calcification retrieval was assessed with individual specimen radiography. Each specimen was histologically analyzed in chronological order and findings were compared with the final histopathological result after assessment of all twelve specimens and with results of surgical excision. Cumulative diagnostic yield per specimen was calculated.

Results: In total, 131 biopsy procedures were performed in 120 women (mean age 59 years). In 95% (95%CI 90%–98%) of the procedures a final histopathological diagnosis was reached after six specimens. After nine specimens the final biopsy diagnosis was established in all 131 cases. In the subgroup of 41 patients with a DCIS or invasive diagnosis at biopsy there were eight procedures (20%) where calcifications were retrieved before the diagnostic specimen was obtained. Underestimation of subsequent resection diagnosis occurred in six out of 30 excised lesions classified as DCIS (20%) and in one out of four excised high-risk lesions.

Conclusions: With six stereotactic 9-gauge vacuum-assisted biopsy specimens a final histopathological biopsy diagnosis could be established in 95% (95%CI 90%–98%) of the biopsy procedures. Taking nine 9-gauge specimens seems to be optimal. Ending the stereotactic vacuum-assisted breast biopsy procedure as soon as calcifications are retrieved may cause false negative results.

1. Introduction

The detection of non-palpable breast lesions has greatly increased since the introduction of screening mammography. Suspicious breast lesions require pathological evaluation, preferably in a timely, non-operative way. Breast biopsy under stereotactic guidance provides a reliable and cost-effective diagnostic procedure for lesions that are visible on mammography only [1–4]. Vacuum-assisted breast biopsy (VABB) devices enable to obtain multiple larger specimens under vacuum suction using a single insertion. VABB is superior to large core breast biopsy, harvesting specimens of larger volume which results in

increased calcification retrieval, decreased cancer underestimation rates [5–7] and reduced sampling error [8,9]. Thus, accuracy of this method depends, besides accurate positioning and quality assurance of the whole process, on the number and volume (and thereby needle thickness) of specimens taken. In currently available VABB systems, needle size varies from 7 gauge to 14 gauge. For stereotactic 11-gauge VABB, the reported sensitivity and specificity in the literature ranges from 85 to 100% and 98–100%, respectively [10–18]. According to EUSOBI consensus guidelines a minimum of twelve 11-gauge cores should be obtained [19]. The literature on stereotactic 9-gauge VABB is limited. Pfeleiderer et al. evaluated the performance of a self-contained

Abbreviations: VABB, vacuum-assisted breast biopsy; BI-RADS, breast imaging reporting and data system; DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ; ADH, atypical ductal hyperplasia; UDH, usual ductal hyperplasia; IQR, interquartile range

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9-gauge VABB system and found excellent sensitivity (97.7%) and specificity (100%) after obtaining a median of 12 specimens per procedure [20].

Venkataraman et al. compared an 11-gauge with an 8-gauge biopsy device, obtaining at least 1000 mg of total tissue for pathological analysis corresponding to ten to twelve 11-gauge specimens and four 8-gauge specimens, respectively [21]. The 8-gauge biopsy procedure outperformed the 11-gauge in obtaining the correct diagnosis. This suggests that with increasing needle size the number of obtained specimens can be reduced without compromising diagnostic performance. Not taking more specimens than necessary is essential to prevent complications, maintain cost-effectiveness and to keep patient burden to a minimum. Complications of VABB include significant bleeding (1–3.9%), infection (0–0.1%) and pain [20,22,23]. Scar formation following VABB has been described in up to 16.1% of the procedures [24]. Schaefer et al. found that using larger needle-sizes increase the rate of interventional bleedings and post-interventional hematomas [24].

To our knowledge, no study has been published that evaluates the diagnostic value of each consecutive specimen to determine the minimum number of stereotactic 9-gauge VABB specimens required to establish a final histopathological diagnosis of mammographically suspicious breast lesions, which was the aim of the present study.

2. Materials and methods

This prospective single-center observational cohort study was approved by the Institutional Review Board of the UMC Utrecht. Between December 2017 and October 2018, 157 women were referred for stereotactic VABB (Fig. 1). 135 women of age ≥ 18 years with mammographically detected breast lesions were considered eligible for VABB aiming at twelve biopsy specimens. Written informed consent was obtained from 129 patients. Seven patients were excluded because the chronological order of the specimens was lost during the procedure. Two patients were excluded because the biopsy procedure failed, in one

case due to loss of vacuum during biopsy of a very superficially located lesion and in one case insufficient material was obtained for the inking procedure (see below). Thus, 120 patients were included in the analysis. There were nine patients with two lesions and in two patients there was a large (> 50 mm) calcifications only lesion that was biopsied at two locations consecutively to confirm the extent of disease and to reduce the chance of sampling error. As a result, a total of 131 biopsy procedures for 129 lesions were evaluated.

Lesions were detected with mammography or tomosynthesis, depending on the available imaging modalities in each hospital. Mammographic findings were categorized according to the standardized Breast Imaging Reporting and Data System (BI-RADS). Lesions were categorized either as mass, mass with calcifications, calcifications only, asymmetry or architectural distortion. Maximum lesion diameter was recorded.

2.1. Stereotactic biopsy procedure

Biopsy procedures were performed by one of four radiologists specialized in breast imaging, with at least five years of experience in performing breast biopsy. All biopsies were performed under tomoguidance with a 9-gauge vacuum-assisted biopsy device (Brevera® Breast Biopsy System, Hologic) in prone position on a dedicated table (Affirm® Prone Breast Biopsy System, Hologic). Biopsy was performed at one skin entry site after infiltration of a local anesthetic (10 mL lidocaine 10 mg/mL or 10 mL lidocaine with adrenalin), similar to VABB procedures described elsewhere in the literature [23]. For mass lesions and calcifications, the needle was targeted at the center of the lesion. For larger areas of calcifications the needle was targeted at the region with the highest suspicion of being cancerous. Correct position of the needle was confirmed with routine prefire stereotactic views. The tissue-harvesting protocol was prospectively designed to obtain twelve specimens in every lesion in a standardized way. The probe was always inserted with the aperture of the sampling chamber at the 12 o'clock

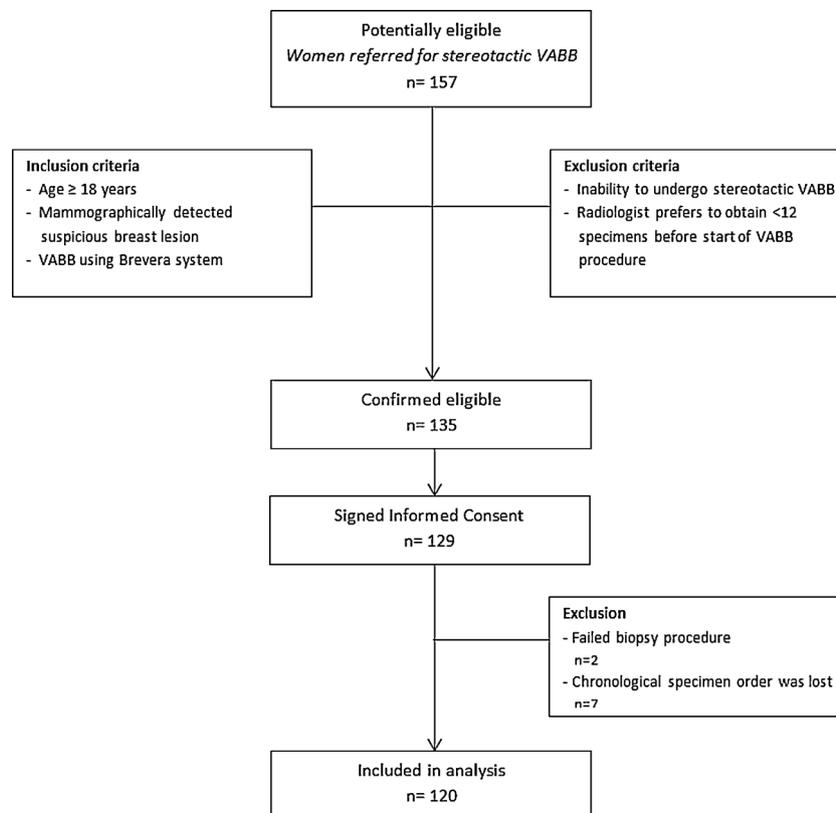


Fig. 1. Flowchart of selection of study participants.

position. The sampling chamber was moved with 2-h (60°) increments, from the 12- to 2- to 4 o'clock position, in order to obtain six specimens per needle rotation. Each specimen was stored in a separate, chronologically numbered chamber of a carousel and radiography of the specimen was performed within the biopsy system (Supplemental materials Fig. 1). For each specimen the presence of calcifications on radiography was recorded. Complete retrieval of calcifications was assessed on post-biopsy imaging.

2.2. Histopathology

At the pathology department the VABB specimens were embedded in four cassettes with three specimens each. Black, blue and yellow ink was applied to distinguish the subsequent specimens (Supplemental materials Fig. 2). Histopathological analysis was performed retrospectively by one dedicated breast pathologist. The histologic findings for the consecutive specimens were evaluated and compared to the final diagnosis, which was determined after assessment of all specimens. The minimum number of the specimen required for final histopathological diagnosis was recorded. The number of the specimen with the first calcification at histopathological assessment was recorded.

For the patients that underwent surgery, histopathological results of the resection were collected from PALGA, the Dutch nationwide histopathology registry.

2.3. Statistical analysis

All data was analyzed using SPSS (IBM® SPSS Statistics® version 25) and RStudio (R version 3.5.1). Descriptive statistical analysis included the calculation of means, medians, and interquartile range (IQR) of the obtained data. Diagnostic yield per specimen was calculated using cumulative percentages with 95% confidence intervals. Differences between means were analyzed statistically using the Wilcoxon rank sum test. A p-value ≤ 0.05 was considered statistically significant.

3. Results

A total of 131 stereotactic vacuum-assisted biopsy procedures were performed for 129 lesions in 120 women (mean age 59 years, range 29–84 years).

3.1. Imaging lesion characteristics

Of all 129 lesions, 88 (68%) were detected on mammography and 41 (32%) on tomosynthesis. There were two (2%) BI-RADS 3 lesions, 125 (97%) BI-RADS 4 lesions and two (2%) BI-RADS 5 lesions. Of all 129 lesions, 114 lesions (88%) appeared as calcifications only, eleven lesions (9%) as a mass, two (2%) as a mass with calcifications and two (2%) as architectural distortion. Lesion size ranged from 2 to 91 mm (median 10 mm, IQR 16.5 mm) (Table 1).

3.2. Number of specimens obtained and calcification retrieval

Twelve specimens per lesion were obtained in 126 out of 131 procedures (96%) in two 360° probe rotations at one skin entry site. One procedure was aborted after seven specimens because of patient's complaints of pain. In four procedures, concerning calcification only lesions, the radiologist decided to take more than twelve specimens because no calcifications were visualized with radiography of the first twelve specimens. In these cases 15, 17, 18 and 36 specimens were obtained, respectively.

Calcifications were retrieved in the first specimen in 51 out of 118 biopsy procedures (43%, 95%CI 34%–53%) in lesions with calcifications. Acquisition of two, three, four, five, and six specimens resulted in calcification retrieval in 77 (65%, 95%CI 56%–74%), 87 (74%, 95%CI 65%–81%), 101 (86%, 95%CI 78%–91%), 107 (91%, 95%CI

Table 1

Lesion characteristics of 129 lesions targeted with 9-gauge VABB.

Mammographic features	
Total number of lesions	129
BI-RADS classification	
BI-RADS 3	2 (2%)
BI-RADS 4	125 (97%)
BI-RADS 5	2 (2%)
Lesion type	
Calcifications only	114 (88%)
Mass	11 (9%)
Mass with calcifications	2 (2%)
Architectural distortion	2 (2%)
Lesion size	
Median lesion size in mm (IQR)	10 (16.5)
1-10 mm	67 (52%)
11-20mm	27 (21%)
21-50 mm	29 (22%)
> 50 mm	8 (6%)

VABB: vacuum-assisted breast biopsy, IQR: interquartile range.

84%–95%), and 110 (93%, 95%CI 87%–97%) procedures, respectively (Supplemental materials Figure 3). Of the 116 lesions that contained calcifications, there was complete retrieval of all calcifications in 40 (34%, size range 2–12 mm). Lesions in which complete retrieval of calcifications was achieved were significantly smaller than lesions in which calcifications were partially retrieved (mean lesion size 7 mm vs. 25 mm, p-value < 0.001).

3.3. Histopathological results of VABB specimens

Histopathological analysis of 9-gauge VABB specimens of 129 lesions revealed invasive malignancy in twelve lesions (9%), DCIS in 31 lesions (24%), high-risk lesions in 21 (16%) and benign pathology in 63 (49%) (Table 2). In two lesions (2%) histopathology showed no abnormalities. Radiological-histological correlation was assessed during multidisciplinary meetings. In one case of no abnormalities at VABB, concerning an oval, dense mass of 5 mm on tomosynthesis (BI-RADS 4),

Table 2

Histopathological diagnosis at 9-gauge vacuum-assisted biopsy of 129 mammographically suspicious breast lesions.

Histopathological diagnoses at 9-gauge VABB	n 129
Total number of lesions	
Malignant lesions	43
Invasive ductal carcinoma	9
Invasive ductolobular carcinoma	2
Invasive lobular carcinoma	1
DCIS	31
High risk lesions	21
ADH	10
Complex sclerosing lesion	1
Intraductal papilloma	2
LCIS	8
Benign lesions	63
Adenosis	5
Apocrine cyst	1
Apocrine metaplasia	13
Columnar cell changes	6
Dystrophic calcifications	7
Fibroadenoma	15
Fibrosis	4
Fibrocystic changes	1
Mucocele-like lesion	1
Reactive changes	1
UDH	9
No abnormalities	2

VABB: vacuum-assisted breast biopsy, DCIS: ductal carcinoma in situ, ADH: atypical ductal hyperplasia, LCIS: lobular carcinoma in situ, UDH: usual ductal hyperplasia.

* In 1 case of no abnormalities a repeat VABB yielded invasive malignancy.

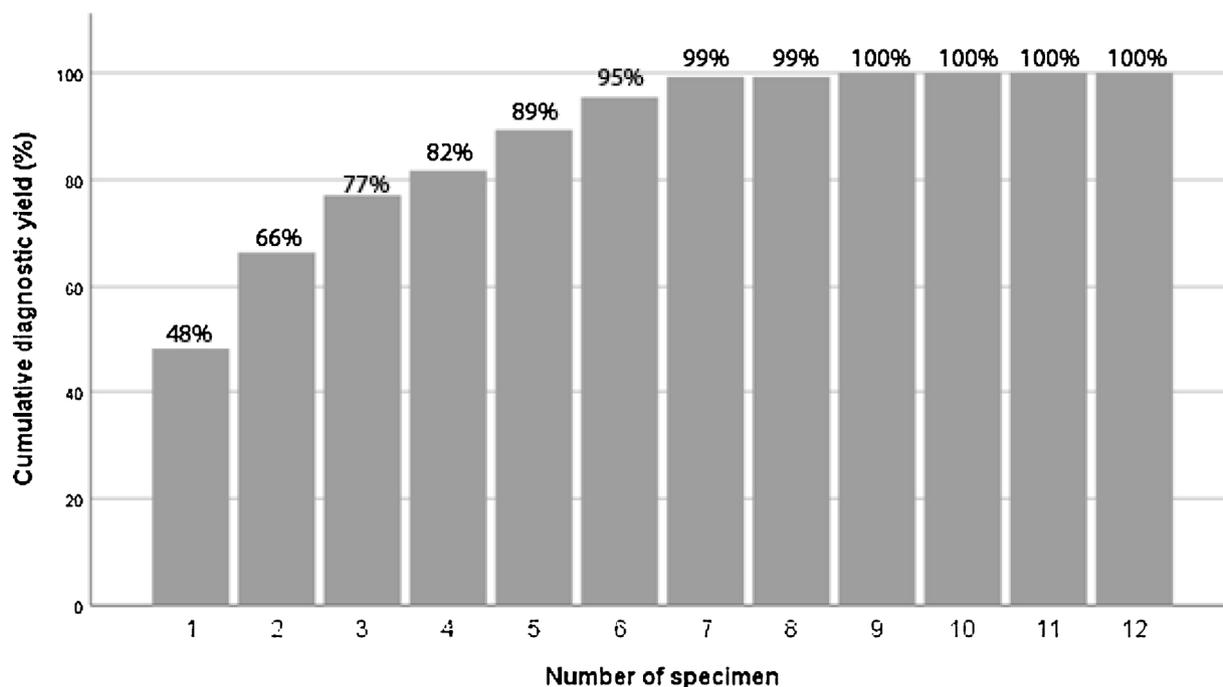


Fig. 2. Cumulative diagnostic yield of sequential biopsy specimens of 131 vacuum-assisted breast biopsy procedures.

a repeat biopsy procedure was performed because of discordance between imaging and pathologic findings, yielding invasive carcinoma.

3.4. Diagnostic yield of consecutive specimens

Of all 131 biopsy procedures the first specimen yielded the final histopathological biopsy diagnosis in 63 (48%, 95%CI 39%–57%) procedures. Acquisition of two, three, four, five, and six specimens yielded the final VABB diagnosis in 87 (66%, 95%CI 58%–74%), 101 (77%, 95%CI 69%–84%), 107 (82%, 95%CI 74%–88%), 117 (89%, 95%CI 82%–94%), and 125 (95%, 95%CI 90%–98%) procedures, respectively (Fig. 2). In all 131 biopsy procedures the final biopsy diagnosis was reached after nine specimens.

There were six calcifications only lesions (5%) in which the final biopsy diagnosis was reached after the sixth specimen. Two lesions were benign, one showed atypical ductal hyperplasia (ADH) in specimen 7, one LCIS in specimen 7, one DCIS (grade 3) in specimen 9 and one invasive ductal carcinoma in specimen 7. During the biopsy procedures of the DCIS and IDC lesions, calcifications were obtained in specimens 2 and 1, respectively. The correlation of the diagnostic yield of sequential biopsy specimens with lesion size and lesion type is shown in Table 3.

Table 3

Correlation of the diagnostic yield of sequential 9-gauge VABB specimens with lesion size and type of lesion.

	Diagnostic yield per number of specimen in 131 VABB procedures (n, cumulative %)									
	n	1	2	3	4	5	6	7	8	9
Total	131	63 (48%)	87 (66%)	101 (77%)	107 (82%)	117 (89%)	125 (95%)	130 (99%)	–	131 (100%)
Lesion size										
1-10 mm	67	28 (42%)	12 (60%)	7 (70%)	3 (75%)	8 (87%)	5 (94%)	4 (100%)	–	–
11-20mm	27	12 (44%)	10 (81%)	3 (93%)	1 (96%)	1 (100%)	–	–	–	–
> 20mm	37	23 (62%)	2 (68%)	4 (78%)	2 (84%)	2 (89%)	2 (95%)	1 (97%)	–	1 (100%)
Lesion type										
Mass	11	6 (55%)	2 (73%)	2 (91%)	–	–	1 (100%)	–	–	–
Mass with calcifications	2	2 (100%)	–	–	–	–	–	–	–	–
Calcifications only	116	53 (46%)	22 (65%)	12 (75%)	6 (80%)	10 (89%)	7 (95%)	5 (99%)	–	1 (100%)
Architectural distortion	2	2 (100%)	–	–	–	–	–	–	–	–

VABB: vacuum-assisted breast biopsy.

In four biopsy procedures of calcifications only lesions, the radiologist decided to obtain more than twelve specimens: 15, 17, 18 and 36 specimens, respectively. These procedures were extended because no calcifications were visualized with radiography of the first twelve specimens. In these cases, the first calcifications were detected in specimens 13, 14, 13 and 21, respectively. At histopathological assessment, however, calcifications were already visible in specimens 1, 6, 2 and 1, respectively. The number of the specimen required to arrive at the final diagnosis was 1 (atypical ductal hyperplasia), 5 (mucocele-like lesion), 3 (usual ductal hyperplasia) and 1 (usual ductal hyperplasia), respectively.

3.5. Diagnostic value of specimens containing calcifications

In lesions with calcifications, the diagnostic specimen was not necessarily the first specimen with calcification retrieval as seen on the specimen radiogram. In all 118 procedures of 116 lesions with calcifications the first specimen that contained calcifications at the specimen radiogram was diagnostic in 56 procedures (47%). In 31 procedures (26%) the diagnosis was established in a specimen prior to the first specimen with calcification retrieval. On the other hand, in 31 procedures (26%), the diagnosis was established in a specimen after the first

specimen with calcification retrieval.

For lesions with calcifications that yielded DCIS or invasive malignancy at biopsy, the specimen with the first calcification retrieval was diagnostic in 20 out of 41 procedures (50%). There were eight procedures (20%) in which the final diagnosis was established in a specimen after the first specimen with calcification retrieval.

Calcifications that were detected on the specimen mammogram were not always found at histopathological assessment. We found that in 33 of 118 procedures for lesions with calcifications, the first specimen with calcification retrieval at specimen radiography did not show calcifications at histopathological analysis. Vice versa, calcifications detected by the pathologist were not always observed by the radiologist. In 26 of 118 procedures for lesions with calcifications, the pathologist noted calcifications in a specimen prior to the specimen in which the radiologist had seen the first calcification retrieval. In addition, there were three lesions with the mammographic appearance of a mass, which contained calcifications at histopathological assessment.

3.6. Histopathological results of surgical specimens and underestimation

Following the VABB procedure a total of 45 patients with 47 lesions underwent surgical excision. Correlation of histopathological results at VABB with histopathological results at surgery is summarized in Table 4. Surgery was performed in 41 out of 43 patients with DCIS/invasive carcinoma, one patient with an invasive malignancy did not undergo surgery because of bone metastases and one 76-year-old patient with DCIS grade 1 refrained from surgery. Surgery was also performed in three patients with a total of four high-risk lesions and in one patient with a benign VABB result but a second ipsilateral lesion that was proven malignant.

In 8/47 lesions (17%), 9-gauge VABB did not yield the correct diagnosis. Underestimation of diagnosis occurred in seven of these; six out of 30 excised lesions classified as DCIS (20%) with VABB showed infiltrating cancer at surgical excision. Of the four high-risk lesions that underwent surgical excision, one diagnosed as LCIS showed invasive lobular carcinoma. Lesions in which underestimation occurred were significantly larger than lesions without underestimation (mean lesion size 52 mm vs. 18 mm, p-value 0.001). All seven cases of underestimation occurred in lesions that were partially removed at VABB, underestimation did not occur in the seven lesions that were completely removed at VABB.

As mentioned earlier, one diagnosis of cancer was initially missed at VABB. A repeat VABB was performed because of discordance between imaging and histologic findings which yielded invasive malignancy, while the subsequent resection did not show residual malignancy. This case of an initially missed diagnosis of cancer underlines the importance of correlating imaging and histopathology findings.

Table 4
Correlation of histopathological results at stereotactic 9-gauge VABB with histopathological results at surgery for all 47 lesions that underwent surgical excision.

VABB	Surgery					Total
	No abnormalities	Benign	High risk	DCIS	Invasive malignancy	
No abnormalities	1**	0	0	0	0	1
Benign	0	1	0	0	0	1
High risk	0	0	3	0	1*	4
DCIS	2	4	0	18	6*	30
Invasive malignancy	0	0	0	4	7	11
Total	3	5	3	22	14	47

* Note: there was a total of seven underestimated diagnoses.
 ** Note: there was one case of no abnormalities in which a repeat VABB yielded invasive malignancy, the following resection did not show remaining malignancy. The first VABB procedure was a case of a missed diagnosis of cancer.

4. Discussion

The results of this prospective study show that with six stereotactic 9-gauge vacuum-assisted biopsy specimens a final histopathological biopsy diagnosis could be established in 95% (95%CI 90%–98%) of VABB procedures. After nine specimens the final biopsy diagnosis was established in all 131 procedures, and further specimens did not provide relevant diagnostic information. In all 41 VABB procedures for lesions with calcifications that yielded DCIS or invasive malignancy at biopsy there were eight (20%) where calcification retrieval was established in a specimen prior to the diagnostic specimen. This is a very important finding, as calcification retrieval might suggest that sufficient and representative tissue has been sampled from the targeted lesion. Recently introduced new biopsy equipment enables direct specimen radiography during the procedure. If radiologists decide to end the procedure as soon as calcifications are retrieved, a false negative result may thus arise.

Several authors have reported the diagnostic accuracy of stereotactic breast biopsy in relation to the number of specimens. However, there was wide variation in needle sizes, biopsy techniques and equipment used and a highly variable number of specimens obtained. Lomoschitz et al. [15] found that the highest diagnostic yield was achieved with twelve specimens per lesion using 11-gauge VABB, independent of the mammographic appearance of the lesion. Even with standardized retrieval of twenty specimens per lesion they found that underestimation of disease still occurs. Lomoschitz et al. performed a pooled histopathological assessment of specimens 7–12 and 13–20. In contrast, we did a separate analysis for each specimen obtained. This enables a more precise evaluation of the added value of each consecutive specimen. Furthermore, we used a 9-gauge probe, yielding specimens with approximately 1.5 times the volume of a specimen obtained with 11-gauge VABB [25]. The larger volume per specimen increases the likelihood that the final histopathological diagnosis is established in an earlier specimen.

The visualization of calcifications on specimen radiography provides proof that the targeted lesion was successfully sampled. In our study we noted that the presence of calcifications at specimen radiography was not always in accordance with calcifications seen at histopathological analysis. A possible explanation might be that during the processing of the tissue not all calcium specks end up in the few slides that are assessed by the pathologist for each tissue block. Benign calcifications tend to be on average smaller, and partly concern calcium oxalate (usually requiring birefringence to see them well), which are therefore more difficult to catch in slides and are less easy visible to the pathologist. Vice versa, in some cases the pathologist noted calcifications in a specimen prior to the specimen in which the radiologist had seen the first calcification retrieval. The pathologist can visualize small calcifications of 5–100 µm, for which we propose the term nanocalcifications, whereas for the radiologist only larger calcifications ≥

150 µm are visible at mammography. Zagouri et al. [26] studied the diagnostic value of specimens with and without calcifications and found that VABB cores with microcalcifications are superior in DCIS/ADH diagnosis but cores without microcalcifications may be valuable for the diagnosis of the invasive component. Liberman et al. reported that retrieval of all calcifications resulted in significantly lower frequencies of underestimation of the diagnosis of ADH and DCIS using 11-gauge VABB [27].

These results lead to the question; the more tissue, the more calcifications, the better? Some investigators have reported benefits of complete lesion removal rather than sampling. Complete excision of the targeted lesion was associated with a significantly lower frequency of imaging-histologic discordance and a trend toward lower frequency of DCIS underestimation [28]. However, the extent of the lesion may be underestimated at mammography and complete removal of the mammographic target does not eliminate the possibility of underestimation. The underestimation rate of DCIS in our study was 20% (6/30) at 9-gauge VABB. This rate is comparable to the reported underestimation rates of DCIS in the literature ranging from 5% up to 22.7% for 11-gauge VABB [27,29,30]. A recent systematic review on the use of a breast lesion excision system (BLES), designed to excise entire lesions in one intact specimen, reported complete excision rates for IDC and DCIS of 5.3–76.5% and underestimation rates of ADH and DCIS of 0–14.3% and 0–22.2%, respectively [31]. Underestimation seems to be a problem difficult to tackle. When the aim is to obtain a definitive, non-operative diagnosis of all potential breast abnormalities in a cost-effective and timely way with minimal patient burden, more tissue is not always better.

There are some limitations in the presented study. First, the pathologist who analyzed the specimens in our study was not blinded to the study design, nor to the histopathological conclusion from clinical assessment. Another limitation of our study is the standardized pattern of acquisition of twelve specimens per lesion in two probe rotations at one skin entry site. Starting the biopsy procedure with the aperture facing the lesion and acquiring more samples from this location might reduce the number of specimens required to yield a diagnosis [32]. Besides this, the same biopsy protocol was followed irrespective of the size of the lesion. However, we chose to use a prospectively designed biopsy protocol in order to accurately describe the results of procedures performed by different radiologists.

In conclusion, with six stereotactic 9-gauge vacuum-assisted biopsy specimens a final histopathological biopsy diagnosis could be established in 95% (95%CI 90%–98%) of the biopsy procedures. Taking nine 9-gauge specimens seems to be optimal for establishing a diagnosis of mammographically suspicious breast lesions. Ending the stereotactic vacuum-assisted breast biopsy procedure as soon as calcifications are retrieved may cause false negative results.

Declaration of Competing Interest

This study was funded by Hologic. Hologic was not involved in the design of the study; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the

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