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BREAST IMAGING
ORIGINAL ARTICLE

Vacuum-assisted stereotactic biopsy for isolated BI-RADS 4 microcalcifications: evaluation with histopathology and midterm follow-up results

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PURPOSE
The aim of this study was to evaluate the 10-gauge vacuum-assisted stereotactic biopsy (VASB) of isolated Breast Imaging Reporting and Data System (BI-RADS) 4 microcalcifications, using histology and follow-up results.

METHODS
From January 2011 to June 2013, VASB was performed on 132 lesions, and 66 microcalcification-only lesions of BI-RADS 4 were included into our study. VASB was performed using lateral decubitis stereotaxy for all patients. Pathologic results of VASB and further surgical biopsies were reviewed retrospectively. Patients who were diagnosed to have benign lesions by VASB were referred for follow-up. VASB and surgical histopathology results were compared to determine the underestimation ratios.

RESULTS
Fifteen out of 66 lesions from 63 patients (median age, 47 years; range, 34–88 years) were identified as malignant by VASB. Pathological results after surgery revealed three cases of invasive ductal carcinoma among the 12 VASB-diagnosed ductal carcinoma in situ (DCIS) lesions, for a DCIS underestimation rate of 25%. The atypical ductal hyperplasia underestimation rate was 0% for the three lesions. The follow-up period was at least 10 months, with an average of 22.7 months for all patients and 21.2 months for patients with VASB-diagnosed benign lesions. None of the patients had malignancy during the follow-ups. The false-negative rate was 0% in the follow-up of 48 patients.

CONCLUSION
VASB should be the standard method of choice for BI-RADS 4 microcalcifications. This method obviates the need for a surgical procedure in 73% of BI-RADS 4 microcalcification-only patients.

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Recently, growing concern regarding breast cancer has resulted in increasingly frequent recommendations for screening mammography and more intensive requirements for biopsies of subclinical (impalpable) lesions. Microcalcifications may be the only finding of early stage malignancies, including atypical ductal hyperplasia (ADH) and ductal carcinoma in situ (DCIS). Isolated microcalcifications comprise 55% of the suspicious lesions detected by mammography (1, 2).

Until recently, the most common approach for this type of pathology has been surgical excision of the lesion after wire localization by mammographic guidance. However, studies have shown that surgical excisions result in benign histology in 76%–81% of the cases (3, 4). Understandably, surgical excisions generate anxiety in most patients. Additionally, the cost and morbidity associated with the surgical procedures have prompted many physicians to explore less invasive, alternative procedures (5–7).

For the past two decades, vacuum-assisted stereotactic biopsy (VASB) has been increasingly used for histologic diagnosis of suspicious microcalcifications. The 11-gauge VASB allows radiologists to obtain a sufficiently large specimen with better calcification retrieval (8), a lower re-biopsy rate, and fewer histologic underestimates (9–11), compared with other core-needle biopsy techniques. The false-negative rate of VASB procedure can be as low as 0.6% when performed by experienced radiologists (12). This technique also has some cost advantages compared to needle-localized surgical biopsy (NLSB)(13).

Although numerous studies of VASB under real-time ultrasonography (US) or mammography guidance exist, none have included a sufficient subgroup analysis (2, 14). Core needle biopsy is the cheapest and easiest technique for lesions that can be visualized by US; however, isolated, suspicious microcalcifications can only be sampled by means of stereotaxy. To our knowledge, there is no study that has specifically evaluated isolated Breast Imaging Reporting and Data System (BI-RADS) 4 microcalcifications, even though these constitute the majority of subclinical lesions detected by screening mammography. BI-RADS 3 microcalcifications can be followed confidently, whereas BI-RADS 5 microcalcifications should be subjected to surgical excision in all cases.

BI-RADS 4 microcalcifications are the most critical issue facing radiologists reporting screening mammography. Through the routine use of VASB for BI-RADS 4 microcalcifications, surgical excision can be avoided in most patients (3, 4). It is important to consider the underestimation and false-negative rates, specifically for isolated BI-RADS 4 microcalcifications, before considering more invasive methods (surgical biopsies) as a further step after VASB. The aim of this study was to evaluate the

utility of VASB for isolated BI-RADS 4 microcalcifications by studying their midterm follow-up results.

Methods

From January 2011 to June 2013, 132 VASBs were performed for microcalcifications, architectural distortions, asymmetrical density and mass lesions detected by mammography alone. In total, 96 microcalcification-only lesions were evaluated, and 66 lesions from 63 patients with BI-RADS 4 were included in the present study (Fig. 1). Each patient had an initial breast US assessment that showed no abnormality. All patients were routinely advised to schedule their first follow-up at the 6th month of the biopsy, regardless of the histopathology result. All pathologic results of VASB and further surgical biopsies were routinely scanned into the picture archiving and communication system (PACS) (RamSoft Inc., Toronto, Ontario, Canada). Data were retrospectively reviewed from the PACS. Before each VASB, potential risks and benefits were explained in detail, and informed written consent was obtained from each patient. Additionally, throughout the study, the Principles of the Helsinki Declaration were strictly followed. Institutional review board approval was not obtained, as it is not required for retrospective studies at our institution.

Microcalcification-only lesions were classified by two radiologists, both having more than 10 years of experience (more than 1500 mammograms per year), in consensus. The classification of the microcalcifications was conducted according to the current BI-RADS criteria. Lesions were categorized as most likely benign (BI-RADS 3), suspicious (BI-RADS 4) or highly suggestive of malignancy (BI-RADS 5). Because of the wide range of malignancy risk belonging to the BI-RADS 4 category, this group was subdivided into groups 4A, 4B, and 4C, according to the lesions' morphology, distribution, and localization. Predominantly, the classification of the microcalcifications was performed using the following BI-RADS criteria: the presence of round/punctate microcalcifications alone in a focal area was assessed as BI-RADS 3, whereas fine linear branching (casting) microcalcifications were accepted as BI-RADS 5; both of these groups were excluded from the study. Amorphous/indistinct (4A), pleomorphic, coarse heterogeneous (4B) and fine linear microcalcifications without branching (4C) were accepted as BI-RADS 4. Radiologists could upgrade or downgrade the BI-RADS category according to the localization and distribution of the calcifications. Although typically considered benign, punctate calcifications are commonly identified within the DCIS (15). Because of the strong association of certain distributional descriptors (segmental and linear ductal) with malignancy, punctate calcifications present in such distributions sometimes warranted a score of 4A and biopsy evaluation. Fine linear/branching calcifications in a clustered distribution were categorized at least as 4B. Fine pleomorphic calcifications in a clustered, linear ductal, or segmental distribution were classified as 4B. Fine linear/branching calcifications in a linear ductal or segmental distribution were categorized as 4C (16). In addition, progression was assessed when earlier mammograms were available. Progression was documented when there was a definitive increase in the number of microcalcifications within the last one or two years. For lesions categorized as BI-RADS 3, follow-up was generally recommended. Patients with BI-RADS 5 microcalcifications were either recommended to undergo a surgical biopsy or VASB after being informed that the benign pathologic result of VASB would not obviate surgical excision. However, VASB was performed for all patients with BI-RADS 4 microcalcifications.

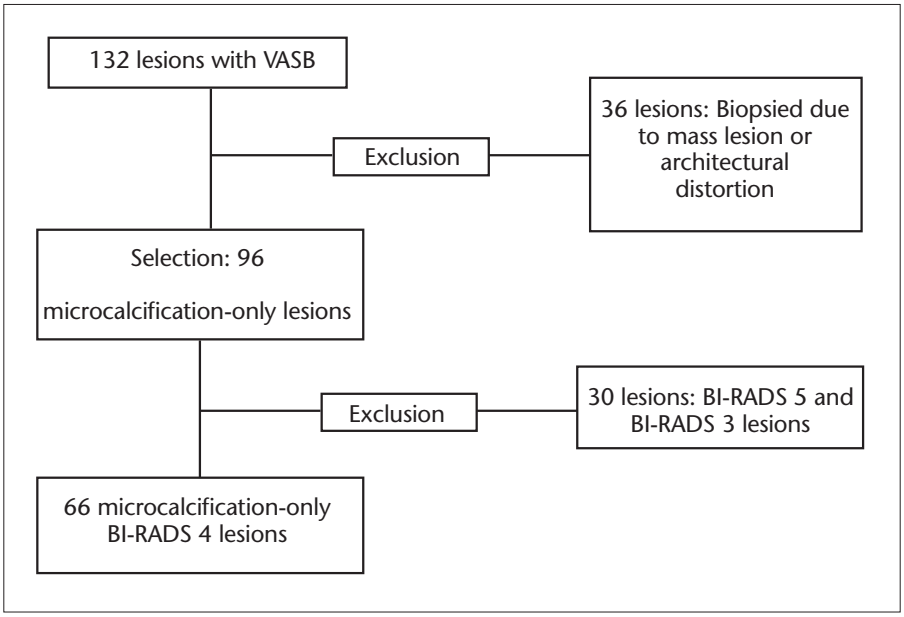

Figure 1. Flow chart showing the formation of the study group. VASB, vacuum-assisted stereotactic biopsy.

Biopsy procedure

All VASB procedures were routinely performed on a lateral decubitus table with a full field digital mammography system (Amulet, Fujifilm, Tokyo, Japan) using a 10-gauge VACORA™ Breast Biopsy System (Bard Biopsy Systems, Tempe, Arizona, USA). Patients were all positioned in the lateral decubitus position, and compression was applied with ML projection, as the 5×5 cm biopsy window is suitable for the localization of the lesion. The target lesion was identified following the scout view and two 15° stereotactic images. Local anesthetic was applied using 5 mL of 2% lidocaine just before the 10-gauge needle was inserted into the center of the lesion. A second set of stereotactic images was taken to confirm the correct position of the needle. When more than one lesion was targeted, the steps were repeated. Routinely, eight core samples were obtained, and the procedure was completed when microcalcifications were identified in these samples. We

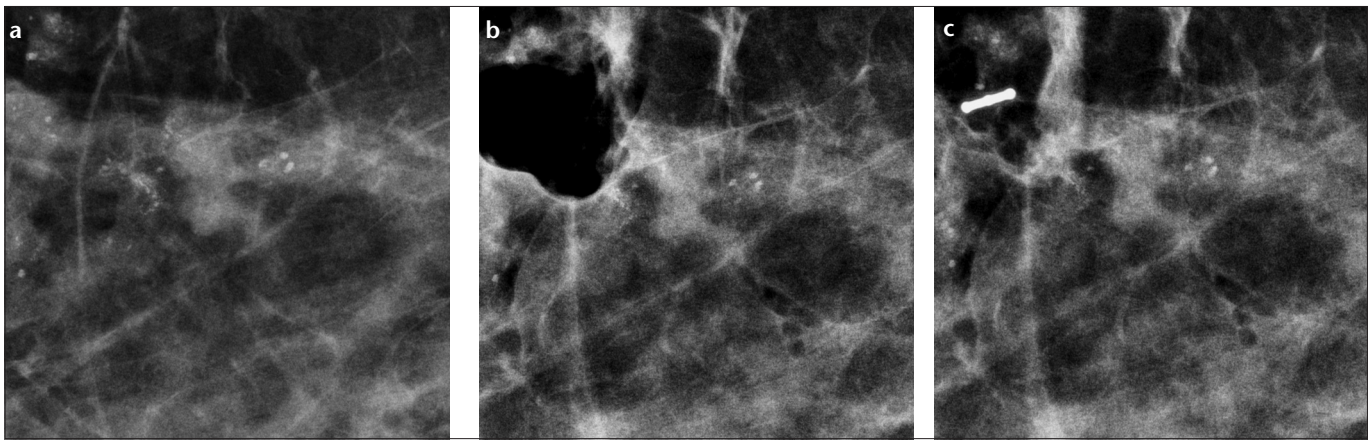

Figure 2. a–c. BI-RADS 4A microcalcifications **(a)** were detected at the right breast of a 46-year-old woman. After VASB procedure with a 10-gauge needle, microcalcifications were removed and air **(b)** is seen at the biopsy site. A radiopaque marking clip **(c)** is released, so that possible subsequent operations can be easily planned if required.

Table 1. Histologic results with VASB according to the BI-RADS categories

		VASB results			
BI-RADS	n	IDC	DCIS	ADH	Benign
4A	46	0	3	2	41
4B	15	1	6	1	7
4C	5	1	4	0	0

VASB, vacuum-assisted stereotactic biopsy; IDC, invasive ductal cancer; DCIS, ductal carcinoma in situ; ADH, atypical ductal hyperplasia.

checked the target breast tissue through the biopsy window before releasing the compression in all patients; if the microcalcifications were not reduced, additional samples were obtained. The procedure was not terminated until the microcalcification sampling was achieved or 12 core samples were obtained. As a result, all patients had microcalcifications on their specimen's radiogram. Before the completion of the procedure, a radiopaque marking clip was released into the biopsy cavity, and a final assessment was performed with a mammogram to confirm the accurate clip placement if all of the calcifications were removed. The tissue samples were then placed in formalin and processed in a pathology laboratory. Core specimens were visualized using the same digital mammography with the exposure factors of 25 kV and 10 mA to confirm the presence of microcalcifications in the specimen's radiography.

Follow-up

In our protocol, patients who had benign histology by VASB from any category (4A, 4B, or 4C) were referred for follow-up. Any patients, with atypical findings that were considered premalignant, were referred for a surgical operation, similar to DCIS and invasive ductal cancer (IDC) patients.

The imaging and pathological findings of the 66 lesions were reviewed, including the results of subsequent excisions and follow-up imaging studies. The rate of histologic underestimation or false-negative result was assessed based on the follow-up data. Histologic underestimation included a VASB-diagnosed ductal carcinoma in situ (DCIS) that was later revealed to be an invasive carcinoma or a VASB-diagnosed ADH that was later revealed to be a DCIS or invasive cancer by surgical operation. The underestimation rate was calculated by dividing the number of underestimated lesions by the total number of lesions with ADH or DCIS, as determined after a VASB. False-negativity was defined as the final diagnosis being malignant after a benign diagnosis by the VASB procedure. The false-negative rate was calculated by dividing the number of lesions with a false-negative result in the final diagnosis by the total number of VASBs performed. The data were entered into a computerized spreadsheet, after which simple descriptive statistics were performed using appropriate software (Excel; Microsoft, Redmond, Washington, USA) for analysis.

Results

A total of 63 patients were included in the analysis (median age, 47 years; range, 34–88 years). All patients were able to cooperate with the procedure.

The BI-RADS category and diagnosis with VASB for each patient are shown in Table 1. We were able to examine the specimens' mammography in all 66 lesions. The mean number of VASB specimens per lesion was 8.4±3.2 (range, 8–12). It was possible to validate the microcalcifications on all specimen radiograms (Fig. 2). As we checked the target breast tissue by mammography before releasing the compression in all patients, none of the patients required a re-biopsy.

Fifteen out of 66 lesions were identified as a breast malignancy by VASB: 13 lesions were identified as DCIS, and two lesions were identified as IDC. Three lesions had atypical findings. The remaining 48 lesions were diagnosed as benign by VASB; these cases fell into either of the BI-RADS 4A or 4B categories (Table 1). None of the patients diagnosed with benign disease by VASB underwent a surgical excision, and there were no malignant changes throughout the follow-ups.

Patients with the malignant and premalignant lesions (18/66, 27%)

Table 2. Comparison of the histologic results of VASB and surgical biopsy

		Surgical biopsy result		
		IDC (n=2)	DCIS (n=9)	ADH (n=3)
VASB result	IDC (n=2)	2	0	0
	DCIS (n=12)	3	9	0
	ADH (n=3)	0	0	3

VASB, vacuum-assisted stereotactic biopsy; IDC, invasive ductal cancer; DCIS, ductal carcinoma in situ; ADH, atypical ductal hyperplasia.

underwent a mastectomy or a breast conservation surgery. The pathological results after surgery revealed the presence of IDC in three lesions previously diagnosed as DCIS by VASB. Nine patients who were diagnosed with a DCIS showed no residual cancer after surgery. The DCIS underestimation rate was 25% (3/12). The underestimation rates for BI-RADS 4C and 4B lesions were 16.6% (2/12) and 8.3% (1/12), respectively. Three patients who were diagnosed with ADH underwent excision for further pathological confirmation. None of the ADH-diagnosed patients showed residual atypia by surgical excision. The ADH underestimation rate was 0% (Table 2). In terms of the positive predictive value (PPV) for breast cancer, a category 4A mammogram was quite low at 6.5%, whereas a category 4B mammogram was moderately high, at approximately 46.6%. Although the number of cases was insufficient to make a reliable comment, the PPV was very high in category 4C microcalcifications (100%), in the present study.

The follow-up period was at least 10 months, with an average of 22.7 months for all the patients. Six-month follow-up data was available for all benign lesions. There were no additional cases of malignancy after an average of 21.2 months of follow-up for the benign lesions. The false-negative rate was 0%, according to the follow-up results. The average underestimation rate of both DCIS and atypical findings was 20% for all patients.

Discussion

The increasing use of mammographic screening has led to the detection of smaller, earlier-stage malignancies that commonly present as microcalcifications (17, 18). The majority of lesions from screening-provoked surgical biopsies were ultimately identified as benign calcifications (19). For decades, the use of the NLSB has been accepted as the standard choice for a biopsy of calcifications detected on mammography (20, 21). However, as the imaging equipment has evolved and biopsy skill levels have improved, the use of image-guided percutaneous VASB has emerged as another alternative. Currently, VASB is a well-known and widely used procedure for the diagnosis of microcalcifications.

By using VASB as a routine procedure for BI-RADS 4 microcalcifications, many patients can avoid unnecessary surgical excisions. There were no false-negative cases in the present study, according to the midterm follow-up results. Additionally, the average underestimation rate for DCIS and atypical findings were acceptable for this subgroup of patients.

The present study showed that VASB can be used as a first-line diagnostic approach for BI-RADS 4 microcalcifications. Patients with benign histopathology, as determined by VASB, can be safely followed. Using this method, 73% of unnecessary surgical excisions could have been avoided in the present study. The false-negative rate for malignancies was reported as 0.6%–3.3%, although this value changes according to the experience of the radiologists (12). The suggested reasons for missed cancers were failure to identify calcium on specimen radiographs, failure to identify calcium at histologic analysis, imaging-histologic discordance, or a combination of these features. In the present study, the false-negative ratio for malignancy was zero; this finding could be due to the extensive experience of our radiologists and/or the presence of microcalcifications on all included specimen radiograms (12, 22). The importance of these two points, the experience of the radiologist and the use of specimens containing microcalcifications, should be underlined when generating guidelines for the VASB procedure.

ADH underestimation rates in the range of 0% to 88% have been reported for stereotactic biopsy techniques (23–26). However, the ADH underestimation rate was zero in the present study, a rate essentially equivalent to open surgical biopsy. Still, the number of included ADH cases was insufficient to make a reliable comment on underdiagnosis. In previous studies, underestimation rates for carcinoma ranged between 18% and 20% (9, 27–31). Our results are comparable with the literature for carcinoma underestimations using DCIS.

Two different clinics (Radiology and General Surgery) should work in concert to optimize the NLSB. Patients and specimens must be transported from one clinic to another. Frequently, the pathologists are also in the operation room. In addition, an excisional biopsy may lead to a decreased chance of sentinel lymph node sampling if the lesion is malignant, whereas the tumor region is intact after VASB, preserving the opportunity to sample sentinel lymph nodes as needed. Sometimes, operations are prolonged when specimen radiograms do not show certain microcalcifications. Uncontrollable movement of the localization needle before or during the operation remains a considerable issue, particularly for fatty breasts. In such cases, a specimen radiograph may either not be taken or give false confirmation of a successful biopsy when the lesion was actually missed, at a miss rate of 4.2% (32). It is clear that, although NLSB is considered the "gold standard," it is imperfect. If VASB can approach a false-negative rate as low as 1%–3%, as observed in the most recent studies (33), this modality should potentially replace NLSB for the first-line histopathological diagnosis of non-palpable mammographic lesions.

VASB can constitute the first step for the evaluation of BI-RADS 4 microcalcifications. Acceptable underes-

timation rates and false-negative rates of this procedure have been reported by experienced radiologists (12). VASB decreases the cost of diagnostic procedures compared with surgical excisional biopsy (13). Additionally, VASB produces better cosmetic results without inducing the structural distortions often caused by surgical procedures, which in turn generate difficulties for radiologists on follow-up, prompting additional imaging requirements, such as magnetic resonance imaging or spot mammograms. VASB can be performed in a very short time, in the same suite as diagnostic mammography, using local anesthesia. For any possible residual lesions, as in ADH- or DCIS-detected cases containing DCIS or IDC, a radiopaque marking clip is released. Using this clip, subsequent operations can be easily planned if necessary. Furthermore, using a lateral decubitis table has some advantages compared to using prone table systems. First of all, microcalcifications can be visualized with the same unit used for diagnostic mammography, delivering high resolution and high contrast images compared to prone table systems. This system also facilitates the identification of an access point for deep lesions and lesions adjacent to the axilla that cannot be reached by a prone table. As far as we know, there is no disadvantage to this system except the patient's discomfort at not seeing the procedure with the prone table systems.

There are some limitations to this study. First, the follow-up period for some lesions was too short; although lesions with less than one year of follow-up were in the minority. As we did not refer VASB-diagnosed benign cases to surgery, we may have missed some underestimated or false-negative cases that would have manifested on the long-term follow-ups. However, many lesions were followed no less than two years. Thus, we believe that any possible false-negative cases after 21.2 months of mean follow-up period for benign lesions do not affect the main conclusions of the present study. Second, the number of underestimated or false-negative cases is insufficient to draw exact conclusions. As such, this report can be accepted as a preliminary study.

In conclusion, 73% of patients with BI-RADS 4 microcalcifications were diagnosed as benign without surgical excision. The false-negative rate was 0%, according to the midterm follow-ups. The average underestimation rate was 20% for ADH and DCIS patients. These findings reflect an accuracy rate comparable to that of surgical excision and validate the 10-gauge VASB as a first-line alternative to mammography-guided wire localization and surgical excision, which are currently performed in many centers throughout the world. This preliminary study must be further supported by larger studies, including more patients, with longer follow-up periods.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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