Vacuum-assisted breast biopsy under ultrasonographic guidance: analysis of a 10-year experience

ULTRA SONO GRAPHY

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ORIGINAL ARTICLE

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Purpose: To determine the indications and the diagnostic accuracy of vacuum-assisted breast biopsy (VABB) under ultrasonographic (US) guidance based on a 10-year period of clinical use.
Methods: This was a retrospective analysis of 2,920 breast lesions in 2,477 consecutive patients who underwent US-guided VABB between February 2002 and December 2011. The proportions of each indication for VABB were analyzed as well as the trend of its use over divided time periods. Histopathological diagnosis and the malignancy rate of the lesions with VABB were analyzed. A comparison of the pathological diagnosis of VABB and the gold standard diagnosis revealed the false negative rate, the underestimation rate, and the agreement rate.
Results: Palpable lesions (44.4%), low-suspicion lesions (15.7%), high-risk lesions (12.4%), and calcifications (10.3%) were the most common indications for US-guided VABB. The malignancy rate of lesions submitted to VABB was 5.4%. The false negative rate was only 0.1%, while the underestimation rate of high-risk lesions and ductal carcinoma *in situ* was 3.1% and 13.8%, respectively, with a 98.7% agreement rate. Among 1,512 therapeutic VABB cases, 84.9% showed no residual or recurrent lesions on long term follow-up US for more than a year. Complications occurred in 1% of the patients without need for surgical intervention.
Conclusion: US-guided VABB is an accurate and safe method that can help decision-making in the diagnostic process and can be an alternative for excisional surgery in some therapeutic circumstances.

Keywords: Breast; Image-guided biopsy; Breast neoplasms; Ultrasonography

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Introduction

Vacuum-assisted breast biopsy (VABB) was introduced in the mid-1990s with the advent of large-lumen cannula [1], as a technique enabling the removal of all visible lesions while potentially reducing false negative rates and underestimation rates [2,3]. VABB allows faster acquisition of larger tissue volumes than core needle biopsy (CNB) as it permits retrieval of contiguous tissue specimens by using a single insertion with a larger gauge probe, thereby resulting in a more reliable histological diagnosis [4]. The reliability of histopathological diagnosis after VABB is known to be nearly equivalent to that of open biopsy in some studies [5]. VABB also allows accurate diagnosis and

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complete image-guided removal of presumed benign breast lesions [4,6]. Compared to a 14-gauge CNB, VABB with an 8-gauge needle (for lesions that are 1.3–3.0 cm in the greatest dimension) or an 11-gauge needle (for lesions that are 1.0 cm or less in the greatest dimension) offers greater reliability, fewer complications, and more satisfactory cosmetic outcomes [7–10].

VABB is often used for diagnostic purposes for palpable or non-palpable nodular breast lesions, particularly in cases of mismatch between imaging reports and histological diagnosis after CNB or in breast lesions with radiologically suspicious findings, and in breast lesions that are too small (<5 mm) for a representative biopsy by CNB [4,10,11]. VABB is also therapeutically performed for symptomatic lesions not suspicious for carcinoma, such as fibroadenoma or recurrent cysts, with the aim of complete removal of all visible lesions [4]. There have been attempts to make recommendations for the use of VABB under ultrasonographic (US) guidance [4,12], but it is not yet clear when VABB should be performed or the diagnostic accuracy of its performance. The aim of this study was to determine the indications and diagnostic accuracy of VABB under ultrasonographic guidance, based on 10 years of experience in a single center, so that the appropriate timing and circumstances of US-guided VABB use can be further clarified in clinical practice.

Materials and Methods

Patient Selection

This was a retrospective single-center study. This study was approved by our hospital's Institutional Review Board, and informed consent was waived because of its retrospective design. From February 2002 to December 2011, 2,920 lesions of 2,477 patients who had undergone US-guided VABB in our institution were included in this study.

US-guided VABB

By means of a vacuum-assisted device (Mammotome, Ethicon-Endosurgery, Cincinnati, OH, USA) with an 8-gauge or an 11-gauge probe under the guidance of high-resolution US with 5–10-MHz or 5–12-MHz linear-array transducers (HDI 5000, Philips Advanced Technology Laboratories, Bothell, WA, USA; Logic 9, GE Medical Systems, Milwaukee, WI, USA; or iU22, Philips Medical Systems, Bothell), the VABB procedure was performed as described by Kim et al. [13]. The VABB procedure was performed by one of 24 radiologists with 2–11 years of experience in breast imaging and US-guided biopsy.

Indications for US-guided VABB

Indications for US-guided VABB were retrospectively classified into 9 categories as follows, with 7 indications for diagnostic purposes and 2 indications for therapeutic purposes.

Indications for diagnostic VABB included calcifications, complex and intraductal lesions, discordant benign lesions, growing lesions, high-risk lesions on previous CNB, low-suspicion lesions, and non-mass lesions. Calcifications were mainly microcalcifications delineated by US. Discordant benign lesions were defined as lesions suspicious for malignancies at imaging, but which demonstrated benign pathological results after CNB [14]. High-risk lesions on previous CNB included atypical ductal hyperplasia (ADH), lobular neoplasia (atypical lobular hyperplasia and lobular carcinoma *in situ*), phyllodes tumors including fibroepithelial lesions, papillary lesions, mucocele-like lesions, complex sclerosing lesions, and radial scars [15–19]. Low-suspicion lesions were breast lesions that had findings that presented a low suspicion of malignancy on US imaging, such as hypoechogenicity or ill-defined margins, except for lesions with microcalcifications and complex cystic or intraductal lesions. Non-mass lesions were breast lesions that showed diffuse heterogeneous echogenicity or parenchymal distortion, without a definite focal mass.

Indications for therapeutic VABB included palpable lesions and lesions that the patients wished to have removed. Palpable lesions were those that were removed by VABB with the aim of complete image-guided excision but did not have any of the findings above. Breast lesions that were excised by VABB because of a patient's desire to have the breast lesion removed even if the lesion did not show any of the above features, were classified into the last indication. The proportions of each indication for VABB were analyzed as well as their chronological trend of occurrence.

Histopathological Diagnosis

Histopathological diagnosis and the malignancy rate of the lesions with VABB were analyzed, as well as those of the lesions with previous CNB and excisional surgery afterwards. Histopathological diagnosis of the breast lesions were classified into four categories: benign, high-risk, ductal carcinoma *in situ* (DCIS), and invasive cancer. The diagnostic accuracy of US-guided VABB was assessed using a 4×4 table method introduced by Burbank and Parker [20]. We compared the pathological results of US-guided VABB and the gold standard results, which were obtained from surgical excision or long-term US follow-up. The gold standard results were pathological results of surgical excision in cases that had undergone surgery, and long-term US follow-up showing no interval change or no evidence of recurrence for more than 1 year in the case of benign or high-risk lesions that had not undergone surgery were considered as benign

gold standard result.

Subsequently, we calculated the agreement rate, the high-risk underestimation rate, the DCIS underestimation rate, and the false-negative rate of US-guided VABB. High-risk underestimation was considered when high-risk group lesions diagnosed by VABB were upgraded to DCIS or invasive cancer after subsequent surgery. The underestimation rate was calculated for all high-risk lesions (ADH lesions and non-ADH high-risk lesions). The DCIS underestimation rate was defined as the proportion of lesions diagnosed as DCIS by VABB that were upgraded to invasive carcinoma after surgical excision. The false negative rate was defined as the proportion of all breast cancers (invasive cancer and DCIS) diagnosed by surgery or on follow-up biopsy, after a benign diagnosis on US-guided VABB. The agreement rate was defined as the proportion of lesions that were not classified as DCIS underestimation, high-risk underestimation, or false-negative diagnosis [21].

Post-Biopsy Management and Follow-up

For patients with breast lesions diagnosed as DCIS or invasive cancer, or as the high-risk group, surgical excision was recommended. Otherwise, patients were followed up with breast US at a certain interval. A follow-up US at 6 months after VABB was recommended for every patient in order to evaluate any complications that occurred after the procedure as well as to evaluate residual or recurrent lesions. For the high-risk group patients who did not undergo surgery, a follow-up period of 6 months was recommended for up to 2 years after the initial diagnosis. The complications of the VABB procedure were recorded at the time of the procedure and at follow-up if any were newly discovered.

Results

The average age of the 2,477 patients was 39 years (range, 11 to 81 years), and the average size of the 2,920 lesions was 14.4 mm (range, 3 to 80 mm). The pathological results of US-guided VABB in the 2,920 breast lesions are summarized in Table 1. Out of the 2,920 breast lesions submitted to VABB, the pathological diagnosis was benign in 2,302 lesions (78.84%), high-risk group in 460 lesions (15.75%), DCIS in 122 lesions (4.18%), and invasive cancer in 36 lesions (1.23%).

The overall indications for VABB and the chronological trend over divided intervals are shown in Table 2. Palpable lesions were the most common indication overall and for every time period from 2002 to 2011. Suspicious lesions and high-risk lesions have been common indications for VABB since 2006. Among the 363 high-risk lesions that were diagnosed by previous CNB, 338 lesions were papillary lesions, 9 lesions were ADH, 7 lesions were mucocele-like lesions, 6 lesions were phyllodes tumors, including fibroepithelial lesions, and 3 lesions were radial scars.

Breast lesions were classified according to the US Breast Imaging-Reporting and Data System (BI-RADS) by a US examination conducted before VABB. The BI-RADS category and positive predictive values (PPV) of the breast lesions according to the indications of US-guided VABB are summarized in Table 3. High PPVs of lesions with calcifications, non-mass lesions, and discordant benign lesions are related to the higher BI-RADS category.

Pathological results and the malignancy rate of breast lesions according to the indications of VABB are shown in Table 4. The malignancy rate of all lesions submitted to VABB was 5.4%.

Among the 2,920 lesions of 2,477 patients with histological

Table 1. Pathological results of ultrasonographic-guided vacuum-assisted breast biopsy in 2,920 lesions

Finding	No. of lesions
Benign	2,302
Fibroadenoma	919
Fibrocystic change	558
Fibroadenomatous hyperplasia	379
Adenosis	166
Fibrosis	114
Ductal epithelial hyperplasia	81
Columnar cell change	35
Inflammation	5
Others[a]	45
High-risk	460
Atypical ductal hyperplasia	30
Non-atypical ductal hyperplasia	430
Papillary lesion	355
Phyllodes tumor	53
Mucocele-like lesion	15
Radial scar	7
Malignant	158
Ductal carcinoma *in situ*	122
Invasive cancer	36
Invasive ductal carcinoma	28
Invasive lobular carcinoma	2
Mucinous carcinoma	1
Tubular carcinoma	1
Neuroendocrine carcinoma	1
Leukemia	1
Metastasis to breast	2

[a] Others included inflammation, diabetes mastopathy, epidermal cyst, galactocele, hamartoma, lobular hyperplasia, and xanthogranulomatous mastitis.

diagnosis after VABB, 367 lesions of 309 patients were removed by surgery. The final pathological diagnosis after surgery revealed benign pathology in 128 lesions, high-risk pathology in 84 lesions, DCIS in 106 lesions, and invasive cancer in 49 lesions. 1,784 lesions were breast lesions that underwent US follow-up and showed no interval change or no evidence of recurrence for more than 1 year (i.e., benign diagnosis by the gold standard). Therefore, the gold standard diagnosis revealed benign diagnoses in 1,912 lesions, high-risk pathology in 84 lesions, DCIS in 106 lesions, and invasive cancer in 49 lesions, as shown in Table 5.

The false negative rate of US-guided VABB was 0.1% (2/1,620). False negative results were found for 2 lesions that showed benign pathology at VABB but were finally confirmed as DCIS after surgery. Both cases were initially submitted to VABB due to suspicious microcalcifications, but specimen mammography taken after US-guided VABB showed no or insufficient calcification, and the pathological diagnosis was benign at VABB. VABB results in these patients were considered discordant. Immediate surgical excision for a definite pathological diagnosis was recommended, and surgery confirmed these lesions as DCIS.

The high-risk underestimation rate was 3.1% (12/389), while the ADH underestimation rate was 23.3% (7/30) and the non-ADH high-risk lesion underestimation rate was 1.4% (5/359). The DCIS underestimation rate was 13.8% (15/109). The agreement rate was 98.7% (2,124/2,151).

In two cases of invasive cancer confirmed at VABB, the final pathological diagnosis after surgical excision was DCIS, probably because the VABB procedure removed the entire invasive cancer component. In one case, invasive cancer diagnosed by VABB showed benign pathology without any evidence of carcinoma at

Table 2. Indications for ultrasonographic-guided vacuum-assisted breast biopsy (VABB) by time period

Indication of VABB	Overall	2002–2005	2006–2008	2009–2011
Palpable lesions	1,296 (44.4)	414 (58.8)	446 (42.3)	436 (37.6)
Low-suspicion lesions	458 (15.7)	45 (6.4)	179 (17.0)	234 (20.2)
High-risk lesions	363 (12.4)	43 (6.1)	155 (14.7)	165 (14.2)
Calcifications	302 (10.3)	72 (10.2)	102 (9.7)	128 (11.0)
Patient's desire	216 (7.4)	86 (12.2)	70 (6.6)	60 (5.2)
Complex and intraductal lesions	112 (3.8)	14 (2.0)	37 (3.5)	61 (5.3)
Discordant benign lesions	79 (2.7)	9 (1.3)	40 (3.8)	30 (2.6)
Non-mass lesions	65 (2.2)	20 (2.8)	17 (1.6)	28 (2.4)
Growing lesions	29 (1.0)	1 (0.1)	9 (0.9)	19 (1.6)
Total	2,920	704	1,055	1,161

Values are presented as number (%).

Table 3. BI-RADS category and positive predictive values of breast lesions according to indications of ultrasonographic-guided VABB

Variable	BI-RADS category						PPV (%) [a]
	1, 2	3	4a	4b	4c	5	
Palpable lesions (n=1,296)	6	1,259	27	4	0	0	6.6 (2/31)
Low-suspicion lesions (n=458)	0	0	444	14	0	0	1 (5/458)
High-risk lesions (n=363)	1	100	238	13	9	2	3 (7/262)
Calcifications (n=302)	0	31	164	41	44	22	41 (111/271)
Patient's desire (n=216)	9	207	0	0	0	0	0 (0/0)
Complex and intraductal lesions (n=112)	2	48	57	3	2	0	3 (2/62)
Discordant benign lesions (n=79)	0	0	8	42	16	13	12.7 (10/79)
Non-mass lesions (n=65)	1	19	29	10	3	3	24 (11/45)
Growing lesions (n=29)	0	19	10	0	0	0	0 (0/10)
Total (n=2,920)	19	1,691	1,011	99	73	27	12.2 (148/1,210)

BI-RADS, Breast Imaging-Reporting and Data System; VABB, vacuum-assisted breast biopsy; PPV, positive predictive value.

[a] The number of breast lesions diagnosed as malignant (invasive cancer or ductal carcinoma *in situ*) with VABB divided by the number of lesions belonging to ultrasonographic-BI-RADS categories 4 and 5.

Table 4. Pathological results and malignancy rates of breast lesions according to indications of ultrasonographic-guided vacuum-assisted breast biopsy

Variable	Total	Benign	High-risk group	Ductal carcinoma *in situ*	Invasive cancer	Malignancy rate (%)
Palpable lesions	1,296	1,220	70	3	3	0.5
Suspicious lesions	458	419	34	4	1	1.1
High-risk lesions	363	83	272	7	1	2.2
Calcification	302	163	28	96	15	36.8
Patient's desire	216	206	10	0	0	0
Complex and intraductal lesions	112	80	30	1	1	1.7
Discordant benign lesions	79	60	9	3	7	12.7
Non-mass lesions	65	45	5	8	7	18.5
Growing lesions	29	26	2	0	1	3.4
Total	2,920	2,302	460	122	36	5.4

Table 5. Comparison of pathological results of 2,151 US-guided VABB with gold standard diagnoses confirmed by subsequent surgery or follow-up US for more than 1 year

US-guided VABB	Gold standard			
	Invasive cancer	Ductal carcinoma *in situ*	High-risk lesion	Benign
Invasive cancer	30	2	0	1
Ductal carcinoma *in situ*	15	94	0	0
High-risk lesion	4	8	54	323
Benign	0	2	30	1,588

US, ultrasonography; VABB, vacuum-assisted breast biopsy.

surgery afterwards due to complete remission after neoadjuvant chemotherapy.

Among 1,512 breast lesions that underwent VABB for therapeutic purposes (i.e., indications for VABB being palpable lesions and the patient's desire), 105 lesions underwent surgery and 910 lesions underwent follow-up US for more than a year without surgical excision. Among the 910 lesions that underwent follow-up US for more than a year, 773 lesions (84.9%) showed no residual or recurrent lesions and 116 lesions (12.7%) showed minimal residual lesions without remarkable changes through follow-up. The remaining 21 lesions (2.3%) had recurred lesions that showed probably benign US findings.

Complications after VABB occurred in 28 patients (1%). Hematoma developed in 24 patients after VABB, which were seen as resolved on follow-up US. Post-biopsy bleeding persisted for a while in 3 patients, but the bleeding stopped after manual compression. One patient complained of severe pain after the VABB procedure, but this soon resolved itself.

Discussion

Data collected from a 10-year period at our hospital showed that US-guided VABB is useful for various diagnostic and therapeutic purposes. VABB allows a fast acquisition of a large tissue volume as compared to CNB, resulting in a more reliable histopathological diagnosis after biopsy and complete image-guided removal of breast lesions. Thus far, indications for performing VABB have not been clarified in the literature, irrespective of its proven usefulness. Therefore, we tried to classify indications for VABB, analyze pathological results according to these indications, and suggest a guideline for the VABB procedure.

Over the past 10 years, palpable lesions have been the most common indication, and for every time period as well. A palpable breast lesion is the most common chief complaint in itself for patients visiting breast clinics; therefore, it might have been the most common reason for performing VABB. Low-suspicion lesions, high-risk lesions, and calcifications were the next most common indications for VABB. VABB was performed in these lesions for a definite diagnosis as these lesions were suspicious for malignancy with or without previous CNB results.

High-risk lesions diagnosed after CNB are known to show a significant underestimation rate. In the past, CNB was, therefore, followed by an open diagnostic biopsy, while, in the present, it is being replaced by VABB [4,5]. In papillary lesions diagnosed by CNB,

US-guided large-lumen VABB (8-gauge) has been proven to be an alternative to surgical excision for reliable histological diagnosis with image-guided complete resection [13,22,23]. In our institution, papillary lesions diagnosed by CNB were a particularly common indication for VABB for reliable histological diagnosis with a low underestimation rate of 1.7%. Non-ADH high-risk lesions including papillary lesions, phyllodes tumors, and radial scars showed an acceptable underestimation rate of 1.4%.

On the other hand, thus far, ADH lesions diagnosed by CNB have usually been removed by open surgery because of a lack of sufficient evidence on whether it is suitable for excision by VABB alone [4]. The ADH underestimation rate of VABB, in our study, was 23.3% (7/30), still suggesting that histological underestimation should be considered for ADH at VABB. Even image-guided complete removal of ADH lesions cannot replace surgical excision as reported in the previous literature [5,23].

Indications classified as calcification lesions contained microcalcifications, and those that showed malignant pathological diagnosis after VABB were mostly DCIS with microcalcifications. Non-mass lesions had heterogeneous echogenicity or distortion of breast parenchyma on US, which created difficulties in the acquisition of a representative biopsy by CNB as the lesions were broad with distinct margins. A reliable pathological diagnosis was still needed for non-mass lesions because infiltrative breast cancer could not be ruled out; therefore, VABB was performed for diagnostic purposes. The non-mass lesions that were pathologically confirmed as malignancy at VABB were confirmed as DCIS, invasive carcinoma, and even other pathology such as leukemia involvement or metastasis from signet ring cell stomach cancer. Discordant lesions have cancer rates reported to be up to 50% for US-guided 14-gauge CNBs [14]; therefore, surgical biopsy has been performed for repeat biopsy. However, in our study, VABB played an alternative role to surgical excision in order to obtain a definitive histological diagnosis in some of the discordant benign lesions, a method that has been suggested in recent reports [14,24].

The DCIS underestimation rate was 13.8%, which was calculated from 15 cases that showed DCIS in VABB and invasive carcinoma at subsequent surgical excision. A majority of the underestimated cases contained suspicious microcalcifications. US-guided vacuum-assisted biopsy is known to be an effective alternative to stereotactic-guided vacuum-assisted biopsy in cases where microcalcifications are visible with the use of high-resolution US [25]. In our study, VABB was performed in 383 cases with microcalcifications and 107 cases (28%) were category 4b, 4c, and 5. Accordingly, the PPV was very high, at 41%.

US-guided VABB is known to be a safe and effective method for complete excision of benign symptomatic lesions [4,26]. The recurrence rates (regrowth or residual) of benign breast lesions after excision have been reported to range from 3% to 39% in previous studies [26–30]. In our study, therapeutic VABB was performed for breast lesions not suspicious for carcinoma because of palpable lesions or the desire of individual patients. Image-guided complete excision was achieved in 84.9% of breast lesions without residual lesions or recurrence on long-term follow-up US for more than a year, while there were minimal residuals in 12.7% of them on follow-up. Ultrasonographically visible recurrent lesions were noted in only 2.3% that even showed probably benign US findings. Therapeutic VABB for complete excision of palpable breast lesions or conducted due to the patient's desire to remove the breast lesion seems to be a suitable method that is safe and effective.

This study has some limitations. First, classifying indications for performing VABB could lack consistency as there was often more than one reason for conducting VABB in a patient. For example, a patient could have a palpable breast lesion that shows microcalcifications on US. We tried to set an order of priority for classifying these lesions. Second, the use of US-guided VABB could vary between institutions. Our institution has breast imaging radiologists with long-term experience with breast US and long-term clinical experience with US-guided VABB. Therefore, US was performed by skilled professionals, and the decision of whether or not to perform US-guided VABB could be systematic, with intra- and interdisciplinary conferences. However, for institutions that lack VABB experience, an investigator's qualification is mandatory to obtain acceptable false negative and underestimation rates with relatively few complications from the procedure. Third, for breast lesions that did not undergo surgical excision, a definitive pathological diagnosis could not be achieved. Even if the lesions showed no evidence of recurrence for a US follow-up of 1 year, a change could be possible afterwards.

In conclusion, US-guided VABB is an accurate and safe method that can help the decision-making of the diagnostic process and can be an alternative for excisional surgery in some therapeutic circumstances.

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Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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