Vacuum-assisted breast biopsy under sonographic guidance: Analysis of a 10-year experience

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<TABLE OF CONTENTS>

ABSTRACT ·····1

I. INTRODUCTION ·····3
II. MATERIALS AND METHODS ·····4
1. Patient selection ·····4
2. US-guided vacuum-assisted breast biopsy ·····4
3. Indications for US-guided vacuum-assisted breast biopsy ·····6
4. Histopathologic diagnosis ·····8
5. Post-biopsy management and follow up ·····9
6. Statistical analysis ·····10
III. RESULTS ·····10
IV. DISCUSSION ·····17
V. CONCLUSION ·····21

REFERENCES ·····22
ABSTRACT (IN KOREAN) ·····26

LIST OF TABLES

Table 1. Pathologic Results of US-guided Vacuum-Assisted Breast Biopsy in 2,920 Lesions·····12

Table 2. Chronological Trend of Reasons for Performing US-Guided Vacuum-assisted Breast Biopsy·····13

Table 3. Pathologic Results and Malignancy Rate of the Breast Lesions according to the Indications for US-Guided Vacuum-Assisted Breast Biopsy·····14

Table 4. Comparison of the Pathologic Results of 2,151 Sonography-guided Vacuum-assisted Breast Biopsies to the Gold Standard Diagnosis (subsequent surgery or follow-up US for more than 1 year) ·····15

ABSTRACT

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PURPOSE: To determine the indications and the diagnostic accuracy of vacuum-assisted breast biopsy (VABB) under ultrasonographic (US) guidance.

MATERIALS AND 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. Indications for US-guided VABB were classified into the following 9 categories: (a) calcifications, (b) complex and intraductal lesions, (c) discordant benign lesions, (d) growing lesions, (e) high-risk lesions, (f) low-suspicion lesions, (g) non-mass lesions, (h) palpable lesions, and (i) patient's desire to remove the breast lesion. The proportions of each indication for VABB were analyzed as well as the chronological trend of reasons for performing US-guided VABB. The histopathologic diagnoses and malignancy rate of the VABB lesions were analyzed. The pathologic diagnoses made by VABB and the gold standard diagnoses were compared, and the false negative rate, underestimate rate, and agreement rate were assessed. Agreement between pathologic diagnoses obtained by US-guided VABB and the gold standard diagnoses were evaluated with Cohen’s kappa statistic.

RESULTS: The proportion of each indication for VABB are as follows: palpable lesions (44.4%), low-suspicion lesions (15.7%), high-risk lesions (12.4%), calcifications (10.3%),

patient's desire to remove the breast lesion (7.4%), complex and intraductal lesions (3.8%), discordant benign lesions (2.7%), non-mass lesions (2.2%), and growing lesions (1.0%). The rate of malignancy in lesions collected by VABB was 5.4%. Calcified lesions showed the highest malignancy rate (36.8%), followed by non-mass lesions (18.5%) and discordant benign lesions (12.7%). The false negative rate was only 0.1%, and the underestimate rate of high-risk lesions and DCIS was 3.1% and 13.8%, respectively, with a 98.7% agreement rate. The agreement between the pathologic diagnoses obtained by US-guided VABB and the gold standard diagnosis was good (κ=0.611, 95% CI: 0.570-0.652). When invasive cancer and DCIS were combined into a malignant group and high-risk and benign lesions were combined into a benign group, the agreement was excellent (κ=0.946, 95% CI: 0.918-0.973). Among 1,512 therapeutic VABB cases, 84.9% showed no residual or recurrent lesions on long-term follow-up US. Complications occurred in 1% of the patients without need for surgical intervention.

CONCLUSION: US-guided VABB is an accurate and safe method that can act as an alternative to excisional surgery both in diagnostic and therapeutic circumstances.

Key words: breast, image-guided biopsy, breast cancer, ultrasound

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I. INTRODUCTION

The widespread use of mammographic screening and breast ultrasound (US) examination has led to increased detection of breast lesions and an increased need for diagnoses of the abnormalities detected in the tissue. In the past, surgical excision was the main method by which breast lesions were sampled for histological assessment, but percutaneous image-guided breast biopsy has become an alternative to surgical biopsy, since it offers a minimally invasive approach. Fine-needle aspiration cytology (FNA) and core needle biopsy (CNB) have also been reliable methods for many years [1,2], but these methods show high false negative rates (3-11%) and high underestimation rates (16-56%) [1,3,4].

With the advent of the large-lumen cannula in the mid-1990s [5], vacuum-assisted breast biopsy (VABB) was introduced as a technique enabling the removal of all visible lesions and potentially reducing the false negative and underestimation rates [3,6]. VABB allows faster acquisition of a larger volume of tissue than CNB. VABB also permits the retrieval of contiguous tissue specimens using a single insertion with a large-gauge probe, resulting in more reliable histological diagnoses [7]. The reliability of histopathologic diagnoses after VABB is nearly equivalent to that of open biopsy in some studies [8]. In addition, VABB allows the accurate diagnosis and complete image-guided removal of presumed benign breast lesions [7,9]. Compared to 14-guage CNBs of breast tissue, VABB, with an 8-guage needle (for lesions as big

as 1.3-3.0 cm) or an 11-guage needle (for lesions 1.0 cm or less), offers greater reliability, fewer complications, and more satisfactory cosmetic outcomes [10-13].

Most often, VABB is used for diagnostic purposes for palpable or non-palpable nodular breast lesions, and it is especially useful in cases where there is a disagreement between the imaging report and the CNB histological diagnosis. VABB is also useful for breast lesions with radiologically suspicious findings and for breast lesions that are too small (<5 mm) for a representative sample by CNB [7,13,14]. In addition to its diagnostic potential, VABB is also used for therapeutic purposes in the complete removal of all visible lesions when symptomatic lesions are not suspicious for carcinoma, such as fibroadenoma or recurrent cysts [7]. There have been attempts to make recommendations for the use of VABB under ultrasound guidance [7,15], but it is not yet clear when VABB should be performed, and the diagnostic accuracy of ultrasound-guided VABB is unknown. The aim of this study was to determine the indications for and the diagnostic accuracy of vacuum-assisted breast biopsy under ultrasonographic guidance based on a 10-year experience at a single center.

II. MATERIALS AND METHODS

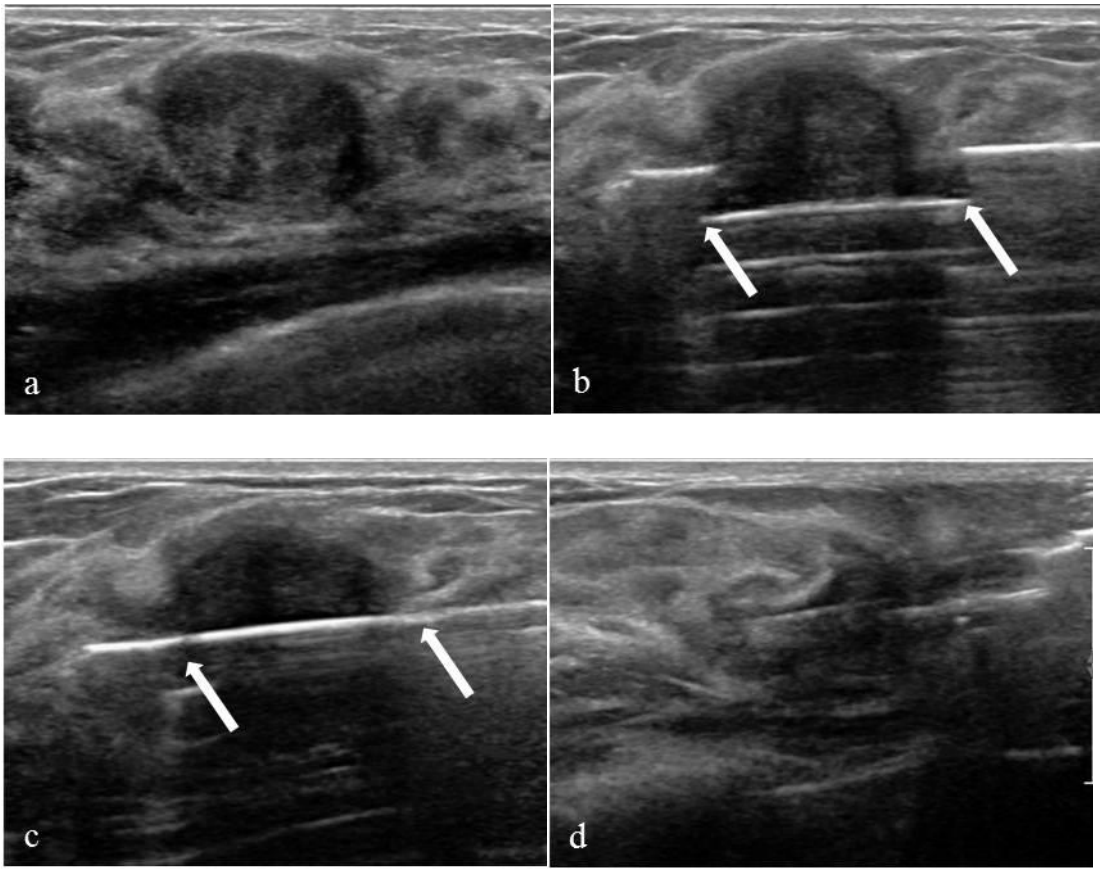
1. Patient selection

This was a retrospective, single-center study. Our hospital institutional review board approved this study, and informed consent was waived because of the retrospective design of the research. From February 2002 to December 2011, 2,920 lesions of 2,477 patients who had undergone US-guided VABB at our institution were included in our study.

2. US-guided VABB

As described by Kim et al. [16], the VABB procedure was performed 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 a 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, WA, USA). After administration of local anesthetic, the 8-gauge probe (for lesions 1.0 — 3.0 cm in the greatest dimension) or an 11-gauge probe (for lesions 1.0 cm or less in the greatest dimension) was inserted into the breast through a small skin incision. The probe was guided into biopsy position under direct US visualization. Multiple core samples were taken until the mass was completely removed, determined with real-time sonography of the biopsy site. To ensure complete mass removal during the VABB, we removed breast tissue surrounding the lesion at approximately four more sampling sites (12, 3, 6, and 9 o'clock directions). Sonographic imaging data were collected immediately after biopsy demonstrated the procedural feasibility of complete lesion removal (Fig. 1). The VABB procedure was performed by one of 24 radiologists with 2–11 years of experience in US-guided breast imaging and biopsy.



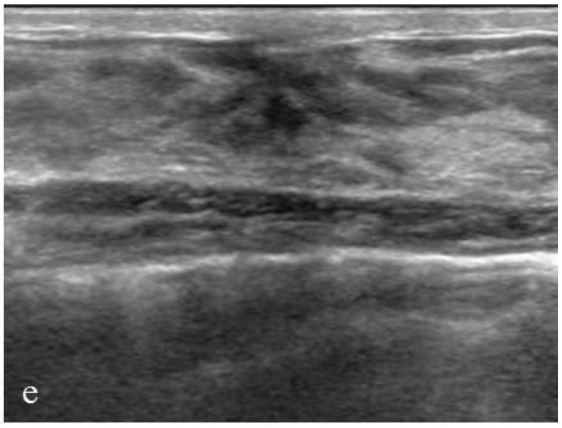


Figure 1. A 21-year-old woman underwent ultrasound (US)-guided vacuum-assisted breast biopsy (VABB) because of palpable lesion in her right breast. On a transverse sonogram, about 2.5x2.8-cm sized well-circumscribed oval hypoechoic nodule was noted with parallel orientation in the lower central portion of her right breast in the corresponding area (a). This lesion was classified as category 3, probably benign finding. The patient underwent US-guided VABB with an 8-gauge probe (b, c arrows; the opened and closed notch for capture of directional vacuum-assisted biopsy probe). Sonographic image taken immediately after biopsy (d) demonstrated the procedural feasibility of complete lesion removal. The final pathology was fibroadenoma and stromal fibrosis. There was no complication following the procedure and the follow-up US exam taken after two years (e) showed no residual or recurred lesion in the corresponding area.

3. Indications for US-Guided Vacuum-assisted Breast Biopsy

Clinical scenarios for performing US-guided VABB were analyzed to determine the most appropriate situations in which to use VABB, and then these scenarios were classified according to whether VABB was used for diagnostic or therapeutic purposes. The purpose of the VABB procedure in each patient was investigated by retrospectively reviewing previous breast ultrasonography reports, core needle biopsy results prior to VABB procedures, and patient medical records. US-guided VABB was performed for either diagnostic purposes, as clinicians aimed to obtain larger quantities of tissue than those obtained by CNB, or for

therapeutic purposes for image-guided complete excision of the tissue. The indications for US-guided VABB in each patient were classified into 9 categories: 7 indications for diagnostic purposes and 2 indications for therapeutic purposes. For diagnostic VABB, indications included calcifications, complex and intraductal lesions, discordant benign lesions, growing lesions, high-risk lesions, low-suspicion lesions, and non-mass lesions. Therapeutic VABB was used for palpable lesions and for the removal of breast lesions at the patient's request. The proportion of each indication for VABB was analyzed, and the trends of these indications were tracked over time.

Indications for VABB were specifically classified as follows:

A. Indications for diagnostic VABB

(A) Calcifications

Cases of breast lesions containing suspicious microcalcifications.

(B) Complex and intraductal lesions

Complex cystic and solid lesions and intraductal lesions that had been resected by vacuum-assisted removal with the aim of complete image-guided excision.

(C) Discordant benign lesions

Discordant benign lesions (i.e. lesions that were suspicious for malignancies upon imaging or BI-RADS category 4 or 5 lesions that demonstrated benign pathologic results after CNB was performed) that have been confirmed by diagnostic VABB [17].

(D) Growing lesions

Benign or probably benign-looking breast lesions on US that were confirmed by VABB because of their increasing size on follow-up US examinations.

(E) High-risk lesions

High-risk lesions including 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 [18-22] that were diagnosed by previous CNB. VABB was performed for reliable histological diagnoses, since it is nearly equivalent to the reliability of open biopsy with image-guided complete resection.

(F) Low-suspicion lesions

Low-suspicion lesions include VABB samples with a low suspicion for malignancy on US imaging (i.e. BI-RADS category 4A lesions), such as hypoechogenicity or ill-defined margins, especially when the breast lesions were too small (<5 mm) for a representative biopsy by CNB. Complex cystic or intraductal lesions, and lesions with microcalcification were classified as a separate category.

(G) Non-mass lesions

Breast lesions confirmed by VABB that showed diffuse heterogeneous echogenicity or parenchymal distortion without a definite focal mass lesion were categorized as non-mass lesions.

B. Indications for therapeutic VABB

(A) Palpable lesions

Palpable breast lesions lacking the above-listed findings that were removed by VABB with the aim of complete image-guided excision.

(B) Patient's desire to remove the breast lesion

Breast lesions that were excised by VABB as per the patient’s request, even if the lesion did not show any of the features above.

4. Histopathologic diagnosis

The histopathologic diagnosis and the malignancy rate of the VABB lesions were analyzed, in addition to lesions that had previously undergone CNB and lesions that were surgically excised after VABB. Histopathologic diagnoses of breast lesions were classified into four categories: benign, high-risk, ductal carcinoma in situ (DCIS), and invasive cancer. The diagnostic accuracy of sonographically-guided VABB was assessed using the 4 × 4 table method

introduced by Burbank and Parker [23]. We compared the pathologic results of US-guided VABB to the gold standard results, which were obtained from surgical excision or long-term US follow-up. The gold standard diagnoses were made based on the pathologic results of surgical excision in cases that had undergone surgery and by long-term US follow-up showing no interval changes or no evidence of recurrence for more than 1 year in benign or high-risk lesions that had not undergone surgery.

Subsequently, we calculated the agreement rate, the high-risk underestimate rate, the DCIS underestimate rate, and the false-negative rate of US-guided VABB. High-risk underestimation describes high-risk lesions diagnosed by VABB that were later upgraded to DCIS or invasive cancer upon subsequent surgery. The underestimation rate was calculated for all high-risk lesions (ADH lesions and non-ADH high-risk lesions). The DCIS underestimate rate was defined as the proportion of lesions diagnosed as DCIS by VABB that were later 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 by follow-up biopsy after a prior benign diagnosis was made by US-guided VABB. The agreement rate was defined as the proportion of lesions that were not classified as a DCIS underestimation, high-risk underestimation, or false-negative diagnosis [24].

5. Post-biopsy management and follow-up

After VABB, patients were managed differently according to their histopathologic diagnosis. Cases in which the breast lesions were diagnosed as DCIS, invasive cancer, or determined to be part of the high-risk group were referred for surgical excision. All other patients were followed with breast US at a certain interval. Follow-up US 6 months after VABB was recommended for every patient in order to evaluate any complications following the procedure and to identify any residual or recurrent lesions. For patients in the high-risk group that did not undergo surgery, a follow-up visit once every 6 months for up to 2 years was recommended.

For patients whose breast lesions were diagnosed as benign by VABB and whose imaging features also suggested benign lesions, follow-up with routine mammographic and ultrasonographic studies were recommended. In cases of discordance between the imaging and histology, surgery was recommended.

For patients who had undergone VABB for therapeutic purposes (i.e. palpable lesions or per the patient's request), follow-up US results were reviewed. We classified the follow-up US results as no residual lesion, minimal residual lesion, or recurred lesion, unless the patient underwent surgery.

If any complications of the VABB procedure occurred, they were recorded at the time of procedure and at follow-up.

6. Statistical Analysis

Agreement between pathologic diagnoses obtained by US-guided VABB and the gold standard diagnoses were evaluated with Cohen's kappa statistic using a weighted kappa value [25,26]. Cohen's kappa statistic is a statistical measure designed to assess agreement between two or more observations for categorical or nominal data. Perfect agreement is indicated by a kappa value of 1.0, whereas a kappa value of 0 indicates the level of agreement expected by chance alone. Although no absolute scale exists, prior reports have suggested the following levels of agreement between observers for the indicated kappa values: ≤0.20, poor agreement; 0.21-0.40, fair agreement; 0.41-0.60, moderate agreement; 0.61-0.80, good agreement; 0.81-0.90, very good agreement; and > 0.90, excellent agreement [27].

III. RESULTS

The average age of the 2,477 patients was 39 years, ranging between 11 and 81 years. The average size of the 2,920 lesions was 14.4 mm, ranging between 3 mm and 80 mm.

Breast lesions were classified according to the US BI-RADS score calculated during

the US examination performed before the VABB. The lesions were classified as category 1 in 2 of the lesions (0.07%), category 2 in 17 lesions (0.58%), category 3 in 1302 lesions (44.59%), category 4 in 1572 lesions (53.84%), and category 5 in 27 lesions (0.92%). The two category 1 lesions that showed negative findings on US exam underwent VABB because of their palpability in the breast.

The pathologic results of the 2,920 US-guided VABB breast lesions are summarized in Table 1. Out of the 2,920 breast lesions that underwent VABB, the pathologic diagnosis was benign in 2,302 lesions (78.84%), high-risk in 460 lesions (15.75%), DCIS in 122 lesions (4.18%), and invasive cancer in 36 lesions (1.23%). Among the 460 high-risk lesions, 30 lesions were ADH and 430 lesions were non-ADH high-risk lesions, which included papillary lesions and phyllodes tumors.

Table 1. Pathologic Results of US-guided Vacuum-Assisted Breast Biopsy in 2,920 Lesions

Finding	Number of lesions
Benign	2302
Fibroadenoma	919
Fibrocystic change	558
Fibroadenomatous hyperplasia	379
Adenosis	166
Fibrosis	114
Ductal epithelial hyperplasia	81
Columnar cell change	35
Inflammation	5
Other*	45
High-risk	460
ADH	30
Non-ADH	
Papillary lesion	355
Phyllodes tumor	53
Mucocele-like lesion	15
Radial scar	7
Malignant	158
DCIS	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 the breast	2

ADH=atypical ductal hyperplasia

DCIS=ductal carcinoma in situ

*Other included inflammation, diabetes mastopathy, epidermal cyst, galactocele, hamartoma, lobular hyperplasia, and xanthogranulomatous mastitis.

The indicated reasons for which US-guided VABB was performed were analyzed over time, and the chronological trends are shown in Table 2. Palpable lesions were the most common indication overall and at every time period from 2002 to 2011. Low-suspicion lesions and high-risk lesions were also common indications for VABB since 2006. Among the 363 previously CNB-diagnosed high-risk lesions, 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.

Table 2. Chronological Trend of Reasons for Performing US-Guided Vacuum-assisted Breast Biopsy

Indication for VABB	Overall n (%)	2002-2005 n (%)	2006-2008 n (%)	2009-2011 n (%)
Palpable lesions	1296 (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)
Calcification	302 (10.3)	72 (10.2)	102 (9.7)	128 (11.0)
Patient 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	2920	704	1055	1161

Pathologic results and the malignancy rate of the breast lesions according to the reason for which VABB was performed are shown in Table 3. The overall malignancy rate of VABB lesions was 5.4%, and calcifications were the indication with the highest malignancy rate (36.8%), followed by non-mass lesions (18.5%) and discordant benign lesions (12.7%).

Table 3. Pathologic Results and Malignancy Rate of Breast Lesions according to the Indications for US-Guided Vacuum-assisted Breast Biopsy

	Benign (n)	High-risk group (n)	DCIS (n)	Invasive cancer (n)	Malignancy rate (%)
Palpable lesions (n=1296)	1220	70	3	3	0.5
Low-suspicion lesions (n=458)	419	34	4	1	1.1
High-risk lesions (n=363)	83	272	7	1	2.2
Calcification (n=302)	163	28	96	15	36.8
Patient desire (n=216)	206	10	0	0	0
Complex and intraductal lesions (n=112)	80	30	1	1	1.7
Discordant benign lesions (n=79)	60	9	3	7	12.7
Non-mass lesions (n=65)	45	5	8	7	18.5
Growing lesions (n=29)	26	2	0	1	3.4
Total (n=2920)	2302	460	122	36	5.4

Note: DCIS = ductal carcinoma in situ

Among the 2,920 lesions with histological diagnoses after VABB, 367 lesions were surgically removed, and 1,784 lesions with benign or high-risk pathologic diagnoses underwent US follow-up and showed no interval changes or no recurrences for more than 1 year (i.e. benign diagnoses by gold standard). Therefore, 2,151 lesions achieved a gold standard diagnosis, and 769 lesions were lost to follow-up or referred to another hospital. Lesions were surgically excised when there was a malignant pathologic diagnosis, when DCIS (n=109) or invasive carcinoma (n=31) were present, if a high-risk pathologic diagnosis was made by VABB (n=96), if recurrent or residual lesions were found, if a residual lesion increased in size since the previous biopsy on follow-up US exam (n=102), or when the patient was already undergoing surgery for another breast lesion (n=29). The final pathologic 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. Therefore, the gold standard diagnosis identified 1,912 benign lesions, high-risk pathology in 84 lesions, DCIS in 106 lesions, and invasive cancer in 49 lesions, as shown in Table 4.

Table 4. Comparison of the Pathologic Results of 2,151 Sonography-guided Vacuum-assisted Breast Biopsies to the Gold Standard Diagnosis (subsequent surgery or follow-up US for more than 1 year).

		Gold Standard			
		Invasive cancer	DCIS	High-risk lesion	Benign
US-guided VABB	Invasive cancer	30	2	0	1
	DCIS	15	94	0	0
	High-risk lesion	4	8	54	323
	Benign	0	2	30	1588

Note: DCIS = ductal carcinoma in situ

Notably, the agreement between the pathologic diagnoses obtained by US-guided VABB and the gold standard diagnosis was good (κ=0.611, 95% CI: 0.570-0.652). When invasive cancer and DCIS were combined into a malignant group and high-risk and benign lesions were combined into a benign group, the agreement was excellent (κ=0.946, 95% CI: 0.918-0.973).

The false negative rate of US-guided VABB was calculated to be 0.1% (2/1620). Two false negative lesions were identified. They initially showed benign pathology upon VABB but were ultimately confirmed as DCIS after surgery. In both of these cases, VABB was initially performed due to suspicious microcalcifications, but the specimen mammography taken after US-guided VABB showed no calcification or not enough calcification, and thus, the pathologic diagnosis was considered benign. The VABB results in these patients were considered to be discordant. Surgical excision for definite pathologic diagnosis was recommended for these patients promptly, and then surgery confirmed the lesions as DCIS.

The high-risk underestimate rate was 3.1% (12/389), while the ADH underestimate rate was calculated to be 23.3% (7/30). In addition, the non-ADH high-risk lesion underestimate rate was calculated to be 1.4% (5/359), and the DCIS underestimate rate was 13.8% (15/109). The agreement rate was calculated to be 98.7% (2124/2153).

In two cases of invasive cancer confirmed with VABB, the final pathologic diagnoses after surgical excision were DCIS, most likely because the VABB procedure removed the entire invasive cancer component. In one case, invasive cancer that was diagnosed by VABB showed benign pathology without evidence of carcinoma after surgical removal. However, the patient was discovered to have undergone neoadjuvant chemotherapy prior to surgery. Therefore, we postulated that the cancer may have responded to the chemotherapy, and thus, no residual carcinoma was seen on final pathology.

Among the 1,512 breast lesions that underwent VABB for therapeutic purposes (palpable lesions or patient desire), 105 lesions were surgically removed and 910 lesions were followed with 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, 116 lesions (12.7%) showed minimal residual lesions without remarkable change through follow-up, and the remaining 21 lesions (2.3%) had recurred and showed benign US findings.

After VABB, complications occurred in 28 patients (1%). Hematoma developed in 24 patients, which resolved by the US follow-up visit. Post-biopsy bleeding persisted for some time in three patients, but the bleeding stopped after manual compression. Lastly, one patient complained of severe pain after the VABB procedure, but the pain quickly resolved.

IV. DISCUSSION

Our 10-year-data showed that US-guided VABB is useful for various diagnostic and therapeutic purposes. VABB allows fast acquisition of a large volume of tissue compared to CNB, resulting in more reliable histopathologic diagnoses after biopsy and allowing for the complete image-guided removal of breast lesions. The indications for performing VABB have not been clarified in the literature so far, despite its clear usefulness. Therefore, we classified the indications for VABB, we analyzed the pathologic results according to each indication, and we established guidelines for VABB procedures.

Over the last 10 years, palpable lesions have been the most common overall indication for VABB, and palpable lesions were the most common indication for VABB at each individual time point that we analyzed. Palpable breast lesions are the most common chief complain for patients visiting breast clinics, which may explain why palpable breast lesions are the most common indication for VABB. Low-suspicion lesions, high-risk lesions, and calcifications were the most common indications for VABB following palpable breast lesions. VABB has been performed on these lesions in order to provide definite diagnoses in lesions that were suspicious for malignancy either with or without previous CNB results.

Because high-risk lesions diagnosed after CNB show a significant underestimation rate, in the past, they were followed up with open diagnostic biopsies. These days, open biopsies are

being replaced by the less invasive VABB procedure [7,8]. In particular, US-guided, large-lumen VABB (8 gauge) is a great alternative to surgical excision for the reliable histological diagnosis and complete image-guided resection of papillary lesions diagnosed by CNB [16,28,29]. In our institution, papillary lesions diagnosed by CNB were an especially common indication for VABB, and VABB provided reliable histological diagnoses with a low underestimation rate of 1.7%. Overall, non-ADH high-risk lesions including papillary lesions, phyllodes tumors, and radial scars showed an acceptable underestimation rate of 1.4% using the VABB procedure.

To date, ADH lesions diagnosed by CNB have mainly been removed by open surgery due to a lack of sufficient evidence supporting their suitability for excision by VABB alone [7]. In our study, the VABB ADH underestimation rate was 23.3% (7/30), suggesting that histologic underestimation should be considered when using VABB for ADH. Even when the complete image-guided removal of ADH lesions is performed, VABB cannot replace surgical excision, as reported by previous literature [8,29].

Overall, the malignancy rate of all lesions sampled by VABB was 5.4%. Calcified lesions showed the highest malignancy rate (36.8%), followed by non-mass lesions (18.5%) and discordant benign lesions (12.7%). Among the calcified lesions, those containing suspicious microcalcifications and those showing a malignant pathologic diagnosis after VABB were found mostly to be DCIS with microcalcifications. The non-mass lesions often showed heterogeneous echogenicity or distorted breast parenchyma on US, which made obtaining a representative biopsy by CNB difficult, since these lesions were broad and without a distinct margin. Because infiltrative breast cancer could not be ruled out in these non-mass lesions, a reliable pathologic diagnosis was still needed, and VABB was subsequently performed for diagnostic purposes. The non-mass lesions that were pathologically confirmed to be malignant upon VABB were found to be DCIS, invasive carcinoma, and other pathology such as leukemia involvement or metastasis from signet ring cell stomach cancer. Discordant lesions have reported cancer rates up to 50% by US-guided 14-gauge CNB.[17] Therefore, surgical biopsies were performed when repeat biopsies were necessary. However, in our study, VABB served as an alternative to surgical

excision to obtain definitive histological diagnoses in some of the discordant benign lesions, as suggested in recent reports [17,30].

The DCIS underestimation rate was 13.8%, which consisted of 15 cases that showed DCIS with VABB and invasive carcinoma upon subsequent surgical excision. However, whether or not the lesions were completely removed did not change the treatment offered to these patients, since they all underwent immediate surgery. Of note, the majority of the underestimated cases contained suspicious microcalcifications. In cases where microcalcifications are visible with the use of high-resolution US, US-guided vacuum-assisted biopsy is known to be an effective alternative to stereotactic-guided vacuum-assisted biopsy [31]. However, in some cases, US has a limited role in detecting microcalcifications compared to mammography. In these cases, we were concerned that the lesions were not completely removed, leaving an invasive carcinoma component behind. Calcified breast lesions are not well delineated on US at times, so reviewing specimen mammography after US-guided VABB is necessary to confirm that a representative biopsy was obtained. If microcalcifications are not sufficiently detected on specimen mammography after VABB, and if the pathologic diagnosis is discordantly benign, surgery should be recommended to gather a definite diagnosis and to treat the possible cancer. As long as specimen mammography taken after VABB confirms that a representative tissue was obtained, US-guided VABB is a valuable tool that avoids the hazard of radiation. In addition, we suggest that stereotactic-guided VABB be recommended for breast lesions with microcalcifications that are not well delineated on US in order to lower the underestimation rate.

US-guided VABB is a safe and effective method for complete excision of benign symptomatic lesions [7,32]. The recurrence rates (regrowth or presence of residual tissue) of benign breast lesions after excision have been reported to range from 3-39% in previous studies [2,32-35]. In our study, therapeutic VABB was performed for breast lesions that were not suspicious for carcinoma when the lesions were palpable or if the patient requested them to be removed. According to long-term follow-up US for more than a year, complete image-guided excision

was achieved in 84.9% of breast lesions without residual tissue or recurrence, while minimal residual tissue was found in 12.7% of patients during this follow-up period. Sonographically visible recurrent lesions were noted in only 2.3%, and many of these findings were suggested to be benign according to US. Therapeutic VABB for the complete excision of palpable breast lesions or to honor the patient's desire to remove the breast lesion seems to be a suitable method that is safe and effective.

Only 1% of the patients undergoing the US-guided VABB procedure experienced complications. Thus, the US-guided VABB procedure offers an acceptable complication rate. The complications were not only low in frequency, but were also minor in nature. Complications included bleeding, hematoma, and pain, and they resolved quickly, requiring no secondary intervention.

This study has some limitations. Firstly, classifying indications for performing VABB can be inconsistent since there was often more than one reason for a patient to undergo VABB. For example, a patient could have a palpable breast lesion that also exhibited microcalcifications on US. To maintain consistency, we set an order of priority for classifying these lesions. For breast lesions that were recommended for VABB because of previous CNB results, such as discordant lesions or high-risk lesions, the previous pathologic diagnosis was noted to be the primary indication for VABB. If a breast lesion had specific US findings, such as calcifications, complex cystic components, or intraductal structures, they were classified into the corresponding indication category. In addition, breast lesions that did not show any findings suspicious for malignancy on US but were removed by VABB for therapeutic purpose due to palpability or patient desire were classified into the corresponding indication category. Secondly, the use of US-guided VABB could vary between institutions. Our institution has breast-imaging radiologists who are very experienced with US-guided VABB. Therefore, the US performance was skillful, and decisions regarding US-guided VABB could be systematic, with intra and interdisciplinary cooperation. For institutions that lack experience with VABB, a qualified investigator is essential in order to maintain acceptable false negative and underestimation rates

while avoiding procedure complications. Thirdly, for breast lesions that were not surgically excised, definitive pathologic diagnoses could not be achieved. Even if the lesions showed no evidence of recurrence during 1 year of US follow-up, it is possible that they could have undergone malignant changes after this period of time.

V. CONCLUSION

US-guided VABB is an accurate and safe method that can serve as an alternative to excisional surgery both in diagnostic and therapeutic circumstances.

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ABSTRACT (IN KOREAN)

유방 병변에 대한 초음파 유도 하 진공흡입보조 생검술: 10년간의 자료 분석

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목적: 유방 병변에 대한 초음파 유도 하 진공흡입보조 생검술의 적응증 및 진단적 유용성을 평가한다.

대상 및 방법: 본 후향적 연구는 2002년 2월부터 2011년 12월까지 초음파 유도 하 진공흡입보조 생검술을 시행받은 2477명의 2920개의 유방 병변에 대해 진행되었다. 유병 병변에 대해 초음파 유도 하 진공흡입보조 생검술을 시행받는 적응증은 다음과 같이 9개의 군으로 분류되었다; 석회화, 복합에코양상 이나 관내모양 병변, 양성불일치 병변, 크기가 증가하는 병변, 고위험 병변, 저의심 병변, 비종괴 병변, 만져지는 병변, 그리고 환자의 요구. 유방병변의 초음파 유도 하 진공흡입보조 생검술의 적응증의 비율과 시간에 따른 그 추이가 분석되었다. 초음파 유도 하 진공흡입보조 생검술을 통한 병리학적 진단과 악성율도 분석되었다. 유방병변의 초음파 유도 하 진공흡입보조 생검술을 통한 병리학적 진단과 황금표준 진단을 비교하여 위음성률, 저평가율, 그리구 합의율을 구했으며 Cohen의 kappa 통계를 이용하여 그 둘 사이의 일치도를 구했다.

결과: 유병 병변에 대해 초음파 유도 하 진공흡입보조 생검술을 시행받는 적응증의 비율은 다음과 같았다. 만져지는 병변 (44.4%), 저의심 병변 (15.7%), 고위험 병변

(12.4%), 석회화 (10.3%), 환자의 요구 (7.4%), 복합에코양상 이나 관내모양 병변 (3.8%), 양성불일치 병변 (2.7%), 비종괴 병변 (2.2%), 그리고 크기가 증가하는 병변 (1.0%) 순서였다. 초음파 유도 하 진공흡입보조 생검술을 통해 진단된 유방 병변의 악성율은 5.4%였고 석회화가 가장 악성율이 높았으며 (36.8%), 비종괴 병변 (18.5%)과 양성불일치 병변 (12.7%)이 그 뒤를 이었다. 위음성율은 0.1%에 불과했고 고위험 병변과 관상피내암의 저평가율은 각각 3.1%, 13.8% 였고 합의율은 98.7%에 달했다. 초음파 유도 하 진공흡입보조 생검술을 통한 병리학적 진단과 황금표준 진단 사이의 통계학적 일치도는 양호하였으며 (κ=0.611, 95% CI: 0.570-0.652), 병리학적 진단을 악성과 양성 두 개의 군으로만 나누어서 계산하였을 때 일치도는 완벽하였다 (κ=0.946, 95% CI: 0.918-0.973). 치료적 목적으로 진공흡입보조 생검술을 시행받은 1512개의 유방 병변은 84.9%에서 장기간 추적 검사 상 잔류 병변이나 새로 생긴 병변을 보이지 않았다. 합병증은 1%의 환자에서 발생했으나 추가적인 시술이나 수술은 요하지 않았다.

결론: 유병 병변에 대해 초음파 유도 하 진공흡입보조 생검술은 정확하고 안전하여 진단과 치료 목적에 있어 수술적 생검의 대체로 쓰일 수 있다.

핵심되는 말: 유방, 영상유도 하 생검, 유방암, 초음파