

## REVIEW ARTICLE

# The Current Role of Vacuum Assisted Breast Biopsy System in Breast Disease

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The gold standard for breast biopsy procedures is currently an open excision of the suspected lesion. However, an excisional biopsy inevitably makes a scar. The cost and morbidity associated with this procedure has prompted many physicians to evaluate less invasive, alternative procedures. More recently, image-guided percutaneous core-needle biopsy has become a frequently used method for diagnosing palpable and non-palpable breast lesions. Although sensitivity rates for core-needle biopsy are high, it has the disadvantage of histological underestimation, which renders the management of atypical ductal hyperplasia, papillary lesions, and fibroepithelial lesions somewhat difficult. Vacuum assisted breast biopsy (VABB) was developed to overcome some of these negative aspects of core-needle biopsy. VABB allows for a sufficient specimen to be obtained with a single insertion and can provide a more accurate diagnosis and completely remove

the lesion under real-time ultrasonic guidance. The advantage of complete lesion removal with VABB is to reduce or eliminate sampling error, to decrease the likelihood of a histological underestimation, to decrease imaging-histological discordance, to decrease the re-biopsy rate, and to diminish the likelihood of subsequent growth on follow-up. In recent years, with the advancement of VABB instruments and techniques, many outcome studies have reported on the use of VABB for resecting benign breast lesions with a curative intent. VABB is highly accurate for diagnosing suspicious breast lesions and is highly successful at treating presumed benign breast lesions. Thus, in the near future, VABB will be routinely offered to all appropriately selected patients.

**Key Words:** Breast tumor, Vacuum assisted breast biopsy

## INTRODUCTION

Recent increased concerns about breast cancer have resulted in a rise in the number of breast screening methods and have affected the diagnosis and treatment of early breast cancer. The detection rate of abnormal masses is higher with ultrasonography (USG) than with mammography because Korean women tend to have denser breasts than Western women. Furthermore, with current technical advances and accumulated user's experience, USG is becoming an increasingly important tool to diagnose breast diseases. As a result, there are debates on how to treat the mass lesions found on USG.

Sonographically visible solid masses can be characterized according to the Breast Imaging Reporting and Data System (BI-RADS) ultrasound lexicon [1]. USG criteria used to define

a probable benign solid breast mass, i.e., BI-RADS category 3, are its oval shape, circumscribed margins, parallel orientation to the chest wall, abrupt interface between the mass and the surrounding tissue, hypo- or isoechogenicity, increased or unchanged posterior echoes, and no change in the surrounding tissue. All of these criteria are required to assess a probable benign mass on USG.

When a non-palpable breast lesion detected on screening mammography or USG is categorized as probable benign, the standard practice is to perform a 6-month follow-up mammography or USG for 2 years [2]. Such lesions have a <2% risk of being cancerous. Even if such lesions are actually malignant, they can be diagnosed when patients are still asymptomatic by detecting changes during follow-up [2,3]. Although it is appropriate to monitor any changes in a breast lesion for 1 to 3 years, patients may wander from hospital to hospital having doubt or unnecessary anxiety or forget to revisit the hospital for follow-up whether or not advanced breast cancer has developed during later years. Therefore, a selective histological diagnosis is necessary to assure patients and to obviate a misdiagnosis for lesions higher than BI-RADS category 2.

Many controversies exist over the management of palpable

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lesions. Biopsy is usually recommended, even if the lesion appears as probable benign morphology on imaging [1,3], as there are relatively few data supporting the outcome of such cases [4,5].

Many studies have reported that triple tests for discriminating benign and malignant lesions have an accuracy rate of 95%, but these methods are imperfect [6]. If a palpable mass with benign morphology is malignant, the follow-up may be riskier than that of a non-palpable lesion. The risk for metastasis is higher if tissue confirmation is delayed, as palpable masses are usually larger than non-palpable lesions. Furthermore, benign-appearing malignant lesions tend to be high-grade invasive carcinomas, which usually grow rapidly [7].

Currently, the gold standard for breast biopsy procedures is open excision of the suspected lesion. However, an excisional biopsy inevitably leaves a scar. The cost and morbidity associated with this procedure has prompted many physicians to evaluate less invasive, alternative procedures [8-10]. The goal of minimally invasive biopsy procedures is to limit the physical impact of biopsies by reducing the invasiveness of the procedure and to reduce procedural costs without sacrificing accuracy.

Fine-needle aspiration (FNA) biopsy has been proposed as a less invasive, cost-effective alternative and has been adopted at several institutions. However, this method has not been widely accepted, primarily because of a high non-diagnostic rate of up to 40% [11,12]. This rate is mostly related to cytological samples with insufficient material for diagnosis. Non-diagnostic results cause unnecessary delays in diagnosis, the necessity for repeat biopsies, and increased costs.

More recently, image-guided percutaneous core-needle biopsy has become a frequently used method to diagnose palpable and non-palpable breast lesions. Although sensitivity rates for 14-gauge automated-needle biopsy are high (97%), some cancers are missed. Another shortcoming is that disease severity is sometimes underestimated, i.e., when surgical excision findings show a higher degree of pathology than that at the previous breast biopsy [13]. A carcinoma finding after a biopsy diagnosis of atypical ductal hyperplasia (ADH) or of invasive carcinoma after a biopsy diagnosis of ductal carcinoma *in situ* (DCIS), defines ADH- and DCIS-underestimates, respectively. Not only is it psychologically distressing for patients when breast cancer is underestimated, but it also implies a delay in establishing a definitive diagnosis, hence, appropriate treatment. Many of these patients will need additional surgical procedures. Difficulties in histological diagnosis using core-needle biopsies stem largely from the limited amount of material available in a core and uncertainties over whether the sample is representative. In an attempt to overcome some of these negative aspects of core-needle biopsy, vacuum assisted breast biopsy (VABB) was developed at the end of 1995 [14]. VABB allows

the operator to obtain a sufficient amount of specimen with a single insertion to provide for a more accurate diagnosis and can aid in completely removing the lesion with the guidance of real time USG [15,16].

The advantage of complete lesion removal with VABB is to reduce or eliminate sampling error, to decrease the likelihood of histological underestimation, to decrease the imaging-histological discordance, to decrease the re-biopsy rate, and to diminish the likelihood of subsequent growth on follow-up. With advancement in VABB instruments and techniques, many trials have been conducted to remove benign lesions with a curative intent [17-19]. However, VABB has many advantages but is relatively costly. We have been developing practical clinical guidelines for the indications of VABB. The objective of this review is to report the proper indications for VABB.

## INDICATIONS FOR VACUUM ASSISTED BREAST BIOPSY

### Diagnostic indications

The main indications for VABB are palpable or non-palpable ACR classification BI-RADS category 3 and small 4A nodular lesions. We usually follow-up in 3 to 6 months for benign-looking lesions (BI-RADS category 3). However, according to the ability of each radiologist, the possibility of malignancy is variable but < 3%. We recommend VABB excision instead of a core-needle biopsy if patients want a complete excision. The criteria we follow are: 1) patients with a low probability of regular follow-up, 2) patients who are planning to get pregnant, 3) extremely restless patients, 4) patients with a lesion that is increasing in size during the follow-up, 5) patients who have subjective symptoms or pain with BI-RADS categories 3 to 4 lesions [20].

Lesions smaller than 5 mm, mainly small stellate lesions, can sometimes be difficult to remove with a standard core biopsy. VABB provides a more certain histological result, because almost the entire lesion is retrieved.

Some invasive lobular carcinomas do not present as nodules because of the infiltration pattern and are, therefore, missed on mammography. Nevertheless, this can extend over a large area. Broad sampling is recommended in these cases to provide an adequate histological diagnosis.

Only broad histological sampling allows for correctly distinguishing the histology between fibrocystic changes, atypia, and *in situ* carcinoma. A solitary complex cystic area in an otherwise normal breast parenchyma must be considered suspicious and should be biopsied or removed by VABB if possible.

Small solitary papillomas can be accurately diagnosed with high-frequency USG and color Doppler, whereas galactogra-

phy is needed less often. The typical presentation is that of a small solid mass in a dilated duct or a highly vascularized cyst with low-resistance flow. It is more likely to find a papilloma close to the nipple area. If there is suspicion of a papilloma, which is a benign disease in the majority of cases, the lesion can be biopsied and removed using VABB. However, a papilloma is a lesion with an uncertain biological behavior, and it may be difficult to distinguish from intraductal carcinoma. A papilloma can become a papillary carcinoma over time. Area of DCIS can sometimes give a similar image on USG. Thus, removing these lesions is recommended, and surgery (microdochectomy) is difficult and requires good preoperative localization. VABB is a valuable alternative and has become the first choice for solitary papillomas [21,22].

Many microcalcification clusters are now visible on USG with improved US equipment. When the calcifications are surrounded by hypoechoic solid tissue, as in DCIS, they are easier to see. In difficult locations, in which the stereotactic procedure is hazardous due to the lack of real time guidance, such as close to the skin, the pectoral muscle, or the axillary region, USG guidance offers a reliable and secure alternative because of real-time monitoring.

Compared to a standard core biopsy, the absence of a forward throw of the needle reduces the risk of touching sensitive structures; therefore, we recommend the use of VABB for lesions close to the nipple, the thoracic wall, the skin, or the axillary region. With experience, the retrieval of adequate samples from these lesions in these difficult locations is perfectly feasible.

Good histological results are obtained with VABB due to vacuum aspiration and the rotating cutter, even in the hardest lesions, where adequate core sampling fails.

VABB can be used in cases of inadequate FNAC or core-needle biopsy results. The literature reports false-negative results ranging from 8 to 15% for core-needle biopsy, much higher figures for FNA, and certainly with microcalcifications [8,9]. A more confident diagnosis can be obtained with VABB because of the larger volume of tissue obtained.

### Therapeutic indications

Recently, the FDA approved use of the device for the therapeutic purpose of benign lesions [23,24]. Breast lesions, certainly when they are palpable, cause a great deal of uncertainty and anxiety for the patient. Inconclusive radiological or clinical reports aggravate these conditions, and a strong family history of cancer is also an aggravating factor. Many times, at the patient's request, the decision is made to surgically remove a lesion that looks benign on imaging. VABB can be a better and less expensive alternative for lesion removal in these situations. Recently, lesions up to 2.5-3 cm were completely removed with

minimal or no scarring [25-29]. The use of an 8-gauge needle is recommended for nodules 1 cm or larger. The lesion must be removed as completely as possible to prevent regrowth. Therefore, careful USG monitoring of the procedure is mandatory. Extra samples should be obtained in different directions to be sure that the lesion is completely removed.

Many outcome studies have been conducted on the use of VABB for resecting a fibroadenoma. Fine et al. [30] evaluated the safety, efficacy, and patient acceptance of using a 8- and 11-gauge VABB to percutaneously remove breast masses under US guidance. In a multicenter, nonrandomized study, 124 women with low-risk palpable lesions were evaluated. Complete removal of the imaged lesion was excellent (99% 8-gauge vs. 96% 11-gauge). Complications were minimal, and the patient satisfaction rate was 97%, and 98% of the patients would recommend the procedure to others.

Johnson et al. [23] hypothesized that the complete removal of small benign lesions under US guidance in an outpatient setting could be obtained with minimal morbidity using VABB. Eighty-one patients had 101 lesions excised. The average size of the lesions was  $1.15 \pm 0.43$  cm (range, 0.5-2.0 cm). Ninety-four lesions (93%) had benign pathology, five lesions (5%) were malignant, and two (2%) lesions had atypical hyperplasia. They found that using VABB under US guidance is an effective technique to therapeutically manage benign lesions. Baez et al. [20] evaluated complete excision of benign breast tumors using US-guided VABB. Twenty consecutive patients with sonographically benign breast lesions underwent three-dimensional (3D) US-guided VABB under local anesthesia, and the size of the lesion was assessed preoperatively using 2D and 3D volumetry. The excisional biopsy was considered complete when no residual tumor tissue could be seen sonographically. US follow-up examinations were performed on the following day and 3-6 months later to assess residual tissue and scarring. The patient satisfaction rate was excellent, and no incidence of bleeding or wound infection was recorded. They concluded that US-guided VABB allows for the complete excision of benign breast lesions that are 1.5 mL in volume; thus avoiding open surgery and post-operative scarring. This is a safe procedure with optimal compliance under local anesthesia.

VABB can be used to determine whether leaving the nipple is safe in women requesting a nipple-conserving mastectomy for invasive or *in situ* disease. The needle is positioned beneath the nipple, and biopsy specimens are taken in a 360° direction [31].

We have performed over 5,700 procedures in nearly 10 years of using VABB. Among these cases, 5.0% (285 cases) were malignancies, and 95.0% were benign, which eliminated the need for short-term follow-up. According to the USG BIRADS classification, 65% were classified as category 3, and 34% were cat-

egory 4A lesions. Of the category 3 lesions, 0.9% were proved to be malignant, and 14% of the category 4A lesions were malignant [27].

## LIMITATIONS

### Histological underestimates

Atypical ductal hyperplasia (ADH) is a lesion with some but not all of the features of DCIS but involves only one duct, or a lesion that has all of the features of DCIS but measures < 2 mm. Therefore, the potential exists that a small sample of a DCIS lesion may be interpreted by the pathologist as ADH. Furthermore, some lesions may contain both ADH and DCIS, or DCIS and infiltrating carcinoma. The histological underestimation in such cases may simply result from sampling error.

ADH is found in approximately 5% of all breast biopsies with mammographic calcifications. Underestimate rates in the range of 18% to 88% have been reported for the stereotactic biopsy technique [32-34]. Stereotactic ADH underestimation rates are inversely correlated with the amount of tissue excised [35-37].

VABB diminishes the histological underestimation rates, compared to core-needle biopsy, because VABB produces heavier and larger specimens with more contiguous sampling and a higher retrieval rate of calcification. Liberman et al. [38] demonstrated an increase from 4% complete lesion removal with automated core biopsy to 13% with VABB. Burbank [39] similarly reported complete removal of 48% of lesions diagnosed by VABB compared with 15% of lesions removed by large-core needle biopsy.

Despite these higher reported accuracy rates, mammographic lesions that contain ADH during stereotactic VABB still have ADH underestimate rates sufficient to mandate open surgical excision for a diagnosis [35-37]. Other benign conditions, including papillomatosis, radial scars, and lobular neoplasia also require an open excision.

Data are sparse regarding the underestimation of US-guided, vacuum-assisted biopsy. Grady et al. [16] conducted a study to ascertain accurate underestimation rates for US-guided VABB and to determine if these rates could be lowered significantly by removing all imaged lesion evidence. They reported that their ADH underestimate rate for completely excised lesions was zero, which was essentially equivalent to open surgical biopsy. Given that a complete excision produces larger tissue samples for pathological study, this technique may be more accurate than traditional sonographic biopsy, as evidenced by lower ADH underestimation rates.

### Epithelial displacement

Benign or malignant epithelium may be displaced into tissue

away from the target lesion during a variety of breast needling procedures, including FNA, core biopsy, directional VABB, local anesthetic injection, and suture placement [40]. Epithelial displacement can cause interpretive problems for the pathologist, as displaced DCIS can mimic infiltrating ductal carcinoma. A misdiagnosis of invasive carcinoma could lead to inappropriate therapy (i.e., axillary surgery or chemotherapy).

The largest study to address the epithelial displacement issue of large-core needle breast biopsies was conducted by Diaz et al. [40]. In 352 surgical excision specimens from women with a prior diagnosis of cancer by large-core needle biopsy, Diaz et al. [40] found displacement of malignant epithelium in 32% of cases. The frequency of tumor displacement is 37% after automated gun biopsy, 38% after palpation-guided biopsy, and 23% after VABB. Epithelial displacement may be less frequent after VABB than after automated core biopsy [41].

We hypothesize that firing the needle through the carcinoma is the step during the biopsy procedure most likely to result in displacement of malignant epithelium. At least five needle passes are made for masses during a core-needle biopsy, and often ten or more for calcifications. For each pass, the needle must traverse the carcinoma to obtain diagnostic material, because tissue is acquired only along the line of fire [42,43].

When the directional VABB probe is fired into the breast, it is usually fired only once, and it may be fired adjacent to rather than through the lesion [44].

There are other possible explanations for the lower frequency of epithelial displacement during VABB than during core-needle biopsy. VABB acquires larger, more contiguous samples and facilitates obtaining a greater number of specimens. Because of the larger volume of tissue removed with the directional VABB probe, displaced cells are more likely to be retrieved. Furthermore, the use of vacuum may tend to draw cells (including those from outside the line of fire) into the probe rather than displace them from the biopsy cavity. Few data have addressed the biological significance of epithelial displacement. Berg et al. [45] and Robbins et al. [46] found no difference in the 15-year survival rate in a study of stage-matched palpable invasive breast cancers treated by mastectomy after diagnosis by aspiration biopsy or open biopsy. Although no evidence exists to date that displaced carcinomatous epithelium remains viable and grows in the breast, there may be a theoretical risk for local recurrence if that needling tract is not excised or administered radiotherapy. Further studies with a long-term follow-up in women treated with breast-conserving therapy after VABB are needed.

### Incomplete excision

A benign palpable lesion can be routinely excised under so-



nographic assistance, with the clinical endpoint being the removal of all imaged evidence of the lesion as well as any evidence of a palpable mass. Fine et al. [30] reported that 97% of women demonstrated complete removal of the imaged mass immediately after biopsy. Of the women with data available at 6 months after biopsy, repeat sonography showed that 73% still had no sonographic evidence of the initially diagnosed mass. However 27% had a residual mass at the 6-month follow-up sonography. They suggested several possibilities for why a residual mass was seen at 6 months in 27% of patients, which included the following: space orientation is not so good under 2D USG guidance, due to the effect of local anesthesia, which may blur the operative field and contribute to a visual challenge when the tumor gets smaller during the procedure, as well as procedural bleeding; the mass was not completely removed and enlarged over the ensuing months; or the 6-month changes were due to post-biopsy scarring or fibrosis.

The rate of successful initial complete removal of a lesion varies widely from 22 to 100%, although most studies report rates of 75-100%. Follow-up rates without recurrence are 62-98% [28,30,47-51].

These variations may, in part, be explained by the use of differently gauged devices (ranging from 8-14 gauge), different methods for assessing the completeness of removal (including clinical, radiological, and histological), and a the range of histological lesions studied.

#### Other disadvantages

Disadvantages are the costs associated with the disposable materials of the vacuum suction system, which are 10-15 times higher than for 14-gauge automated-needle biopsy. Furthermore, VABB for a malignant lesion may lead to difficulties estimating the true size of the tumor at excision, when most of the lesion has been sampled at vacuum biopsy, which is an important indicator for adjuvant therapy

### COMPLICATIONS

Complications of this procedure may include subcutaneous bleeding, postoperative hematoma, a skin defect, or pneumothorax. The reported complication rate ranges from 0 to 9% with a mean of 2.5%. Hematoma is the most frequent post-procedure complication [15,28,48,52-54]. Most complications are mild to moderate in severity.

However, Simon et al. [52] reported five patients in whom bleeding could not be controlled by the normal 10 minutes of post-procedural compression, and one patient in whom a vasovagal response occurred. In four of the five patients, hemostasis was achieved with additional compression for no more than

20 minutes. In one patient, 90 minutes was required to achieve hemostasis. Post-procedural bleeding usually requires no specific intervention other than adequate compression of the procedural site. Parker et al. [15] reported a 5-mm skin defect that resulted from biopsy of a superficial lesion. Perez-Fuentes et al. [53] reported a case of post-procedural bleeding that was not resolved by compression and required surgical intervention. Fine et al. [30] reported two serious adverse events: one patient who suffered post-procedural bleeding required a second procedure to tie off the damaged vessel, and another patient who suffered a surgical skin tear requiring skin closure.

Therefore, great care should be taken to avoid a skin tear or hematoma during this the VABB procedure. The vacuum system coupled with compression by the ultrasound probe may lead to a skin tear. To prevent other complications, it is necessary to ensure clear visualization of the needle, use ultrasound US at all times, and to provide adequate local anesthesia.

### CONCLUSION

VABB is a very reliable sampling technique with very few complications. It is relatively easy to use and is well tolerated by patients. Because it is less invasive, is easy to use; thus, reducing the cost of repetitive follow-ups or more expensive additional examinations. Above all, VABB reduces the time between detection and diagnosis, which is very important for patient reassurance. VABB also has a prognostic impact, because tumors can be diagnosed at an earlier stage and a delayed diagnosis, with a potential medical legal impact, can also be avoided.

In the near future, open surgical biopsies for benign lesions will be eliminated at our hospital. In cases of malignancy, a one-step therapeutic operation will be planned, and the patient will be fully informed. Because of the high number of small and *in situ* lesions, breast-conserving surgery and sentinel node procedures will be performed in the majority of cases. The 8-gauge VABB system is highly accurate for a diagnostic biopsy of suspicious breast lesions and is highly successful for completely removing appropriately selected presumed benign breast lesions. Breast surgeons should replace open excision biopsy with VABB to initially manage breast lesions.

### CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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