

Vacuum-assisted breast biopsy for breast cancer

Hai-Lin Park, Jisun Hong

Department of Surgery, Kangnam CHA Hospital, CHA University College of Medicine, Seoul, Korea

Correspondence to: Hai-Lin Park, M.D., Ph.D., Professor. Division of Breast and Thyroid Surgery, Department of Surgery, Kangnam CHA Hospital, College of Medicine CHA University 01/*9, 650-9, Yeoksamdong, Kangnamgu, Seoul, Korea. Email: phl1@cha.ac.kr.

Abstract: Sonographic examination of the breast with state-of-the-art equipment has become an essential part of the clinical work-up of breast lesions and a valuable adjunct to mammographic screening and physical examination. Fine-needle aspiration (FNA) and core-needle biopsy (CNB) are well-established, valuable techniques that are still used in most cases, whereas vacuum-assisted breast biopsy (VABB) is a more recent technique. VABB has proven clinical value and can be used under sonographic, mammographic, and magnetic resonance imaging guidance. The main indication for the use of VABB is for biopsies of clustered microcalcifications, which are usually performed under stereotactic guidance. This method has been proven reliable and should replace surgical biopsies. The ultrasound-guided procedure is still more a matter of discussion, but it should also replace surgical biopsies for nodular lesions, and it should even replace surgery for the complete removal of benign lesions. This viewpoint is gradually gaining acceptance. Different authors have shown increased diagnostic accuracy of VABB compared to FNA and CNB. VABB particularly leads to less histological underestimation. The other indications for VABB are palpable or nonpalpable nodular lesions or American College of Radiology Breast Imaging Reporting and Data System 3 and 4A lesions. For masses that are likely benign or indeterminate, we attempt to completely remove the lesion to eliminate uncertainty on later follow-up images. VABB offers the best possible histological sampling and aids avoidance of unnecessary operations. VABB complications include bleeding or pain during the procedure, as well as postoperative pain, hemorrhaging, and hematomas. But, these hemorrhaging could be controlled by the post-procedural compression and bed resting. Overall, VABB is a reliable sampling technique with few complications, is relatively easy to use, and is well-tolerated by patients. The larger amount of extracted tissue reduces sampling error.

Keywords: Breast disease; vacuum-assisted breast biopsy (VABB); breast biopsy

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Introduction

In Western countries, one in eight women develops breast cancer at some point in life (1), and about 60 percent develop benign breast disease (2). The most common benign breast diseases are fibroadenoma and fibrocystic disease. Though these diseases are not life threatening, they cause anxiety and fear in many patients. There is controversy over how to treat a suspected benign mass detected through palpation or ultrasound (US). Many recent reports have shown that the Triple Test and other methods can discriminate between benign and malignant

breast lesions with 95% accuracy, but these methods are not perfect (3-5). It may be appropriate to monitor any changes in a breast lesion for 1 to 3 years (3). Patients may go to multiple hospitals because of doubt or unnecessary anxiety, or they may neglect follow-up visits only to return later with advanced breast cancer. Therefore, a selective histological diagnosis is necessary to assure patients and to obviate a misdiagnosis for lesions higher than Breast Imaging Reporting and Data System (BI-RADS) category 3. Currently, many surgeons prefer open excision biopsies for palpable lesions (6-8), while US-guided fine-needle aspiration (FNA) biopsies or core biopsies with an

automatic biopsy gun are widely used to diagnose non-palpable breast lesions. FNA biopsy has increasingly replaced the traditional open excision biopsy because it is a more accurate and trustworthy alternative that also avoids the inevitable scarring caused by open excision procedures.

In the 1980's, the method preceding biopsy was fine needle aspiration for cytology (FNAC). While the diagnostic ability of FNAC was encouraging, the desired reliability of this procedure, as well as acceptable sensitivity and specificity, could only be achieved at specialized hospitals. Additionally, the false negative rate for carcinomas (usually identified during a diagnosis of microcalcification) and certain types of invasive breast cancer was particularly disappointing. In FNAC, the samples are insufficient in as many as 3.5-11% of procedures (9,10), and even experienced cytopathologists have difficulty interpreting the cell test accurately. Therefore, the trend in breast biopsies gradually shifted from FNAC to CNB techniques in the 1990's. CNB techniques allow cytological and morphological evaluation of breast cells and provide information for a more extensive and useful analysis. CNB is also a sensitive tool for elusive diseases such as invasive lobular carcinoma. This technique also allows magnification of the image of the core tissue sample, which allows doctors to confirm that sufficient calcification samples were obtained during the microcalcification biopsy process. Perhaps most importantly, core needle biopsies have higher sensitivity and positive predictive value for the diagnosis of benign and malignant diseases, and a lower false negative rate, compared to FNA C. Use of an automatic biopsy gun is a favored technique for breast biopsies (9,11-14). However, biopsy guns have drawbacks, including patient anxiety caused by multiple needle insertions and noise, as well as insufficient sample collection in women with dense breast tissue (15). In *Breast Journal*, Morris *et al.* reported that the heterogeneous nature of most lesions poses a problem for core biopsies (16). It is possible for the core part of the lesion, which is targeted by a biopsy, and the surrounding area to differ histologically. Therefore, targeting just one part of a heterogeneous lesion could result in a 29% rate of misdiagnosis. Joshi *et al.* reported in *Breast Journal* that biopsies that targeted a core area underdiagnosed malignant tumors in 18-88% of atypical ductal hyperplasia (ADH) cases (17). Core biopsies failed to obtain a sufficient amount of tissue for diagnosis or were targeted incorrectly in 5-10% of non-palpable lesions found during a mass screening examination (12). More samples should be taken, or correct targeting is needed, to ensure a reliable histological

evaluation of these abnormal lesions (18). Many reports have examined the shortcomings of core biopsies. These problems highlight the need for development of a device that has the same ability to give a correct evaluation as an open biopsy for any abnormal lesions identified through imaging.

History of vacuum-assisted breast biopsy (VABB)

VABB was developed in 1995 by Fred Burbank, a radiologist, and Mark Retchard, a medical device engineer, in an effort to overcome the shortcomings of core biopsies by using an automatic biopsy gun. Stereotactic VABB was introduced by Burbank and Parker in 1996 as a diagnostic tool to evaluate suspicious lesions visible on mammography. US-guided VABB was first performed by Zannis *et al.* in 1998. In Korea, VABB was introduced into several university hospitals and clinics in 2000. Next, radiologists at university hospitals adopted this procedure. Around 2002, VABB began generating publicity for its usefulness within academic circles because of efforts led by professors of surgery. At the time, there was much skepticism about the validity of other uses of VABB besides its diagnostic function. However, accumulated user experience and widespread use of 8-gauge (G) needles that made VABB easier led to more commonplace use of VABB for the therapeutic purpose of benign lesion removal. Later, the effectiveness of VABB became better known through the media and the internet. With breast examinations becoming common in women as young as their 20's, excision of benign breast tumors by using VABB became more common. According to statistics provided by Park *et al.*, of the 6,264 VABB procedures performed between January 2003 and April 2011, 61.5% of the cases were women in their 20s and 30s, demonstrating the public's high interest in the procedure (19).

Types of VABB

Stereotactic VABB

Stereotactic VABB is a percutaneous biopsy for breast lesions that appear as microcalcifications on mammograms but are invisible on US. For cases where the microcalcification is spread over a large area, the needle can be withdrawn and reinserted to allow removal of lesions in different areas. This biopsy technique allows many samples to be acquired with one incision. Accurate analysis is usually possible since samples of 100 mg can be obtained 10 to 20 times, yielding

as much as 1,000 to 2,000 mg total.

US-guided handheld VABB

A VABB HH (handheld) is equipped with computer software that facilitates easy automatic or manual sample collection. The development of the 8G needle, which has been approved by the Food and Drug Administration (FDA), has made removal of breast abnormalities (such as lumps) much easier and faster. VABB HH uses a 14G needle, which allows collection of twice as much tissue as existing core biopsies. This device also takes half the time to collect tissues compared to conventional biopsies. Such features reduce the chance of sampling errors. Compared to 14G needles, 11G needles can obtain three times more tissue. VABB has a superior ability to obtain fatty breast tissues compared to traditional core biopsies. Additionally, biopsy by using VABB is possible in otherwise potentially problematic situations, such as in patients who have undergone plastic surgeries and have synthetic materials inserted into their breasts or around their chest walls.

Magnetic resonance imaging (MRI)-guided VABB

MRI is very useful for diagnosing breast cancer that is undetected on mammogram, US, or physical examination. Many studies have shown that MRI can detect breast cancer with a sensitivity of almost 100%, but its specificity varies between 37% and 97%. As the use of MRI has rapidly increased, so has the frequency of detection of true and false positive lesions.

Until now, research on MRI-guided breast biopsy has been mostly limited to prototype equipment; that is, needle localization or FNAC and core biopsy. In comparison, few studies have evaluated VABB. Nonetheless, needle artifacts and tissue displacement during the needle insertion are drawbacks that contribute to the unpopularity of MRI-guided VABB. Another downside of MRI-guided breast biopsy is that patients must be separated from the magnet, unless it is an open machine. Since the procedure usually requires patients to lie face down on a moveable exam table, the outer surface of the breast is easily accessible, but access to the interior is difficult.

Another problem with MRI-guided biopsy involves contrast enhancement. The operator has only a short window of time after injection of the contrast agent in which they can visualize the definition of a lesion. For these reasons, use of this procedure has been performed for

lesions that are <1 cm. However, many of these problems have been solved by the recent development of several devices such as breast coils, breast fixing devices, biopsy compression devices, needle guides, and non-ferrous magnetic needles. These improvements have led to the adoption of MRI-guided VABB as a common procedure in the west.

Types of probes

VABB needles can be different diameters: 8G, 11G, or 14G. The 14G needle is the least invasive of the three needles. It can collect 40 mg of tissue with one insertion, which is more than twice the amount collected by using a biopsy gun, which collects an average of 17 mg per procedure. The 11G needle can collect 83 to 116 mg (average =100 mg) of tissue, so it can be used to completely resect lesions <1 cm. The 8G needle can collect 250 to 310 mg of tissue, which is three times the amount collected by using 11G needles. This makes 8G needles capable of resecting palpable or non-palpable breast lesions that are smaller than 3 cm, as well as some larger lesions.

Pathological preparation and interpretation of VABB specimens

Preparation of specimens

In order to obtain the optimal diagnostic result, VABB samples must be uniformly sequenced on a flat plain. The specimens can be integrated on a single surface only if the sample tissues are neatly arranged on the even surface of the sponge inside the cassette. If the tissues are not arranged on an even surface within the cassette, and are instead randomly placed, a substantial part of the sample tissues may not show up under a microscope. Some tissue sections may not be discernable even if layers of cells are chiseled off and they are viewed under the microscope again.

Diagnostic problems

Unlike samples from an excision biopsy, specimens that are obtained through a percutaneous biopsy are segmented, so it is difficult for the pathologist to reconstruct them in three dimensions in order to make a diagnosis. It is also difficult to measure the size of the lesion. Additionally, discerning special diagnoses can be more difficult with this method than with an excision biopsy. Recent studies reported that

histological underestimation rates were lower in patients diagnosed with ADH through VABB compared to patients diagnosed by using core needle biopsies (20). This is because VABB allows more extensive sample collection, and therefore increases the chance of complete resection of targeted lesions. Darling *et al.* reported that patients with lesions confirmed as malignant on surgical removal after being diagnosed with ADH through three percutaneous procedures—14G automatic gun, 14G VABB, and 11G VABB—had histological underestimation in 44%, 39%, and 19% of cases, respectively (21). Bernik *et al.* reported the discovery of micropapillary pattern ductal carcinoma in situ (DCIS) in three cases of ADH in which micropapillary patterns were confirmed on surgical excision (12). Recently, they also reported a high chance of discovering DCIS by further categorizing ADH into severe ADH versus atypical papillary features, etc. However, there is no clinical, radiological, technical, or pathological evidence to support these decisions, and it is ideal to perform an additional excision biopsy when ADH is detected. There are various concerns that fuel the controversy over whether patients who have been diagnosed with papillary lesions through a percutaneous biopsy need an additional re-excision biopsy. First, it is difficult for pathologists to distinguish among benign, atypical, and malignant papillary lesions with limited samples that were broken into pieces by performing a percutaneous biopsy (12). Such classification is challenging, even with the original lesion. Radiology cannot distinguish between benign papilloma and papillary DCIS, and it is not helpful for histological classification. Secondly, there is concern that there are not enough pathologists who are able to distinguish benign papillary lesions that are accompanied by scleroma from invasive tumors. Thirdly, doctors cannot be sure that samples taken from a percutaneous biopsy are representative of the most worrisome part of papillary lesions. It is possible that benign papillary lesions may contain ADH or DCIS (22). Follow-up of patients who were diagnosed with benign lesions by performing a percutaneous biopsy but had additional surgical biopsies showed that they were mostly diagnosed by using core biopsies. However, histological underestimation rates were 10–20%, which is relatively high, confirming the need for surgical excision in patients diagnosed with benign papillary lesions by performing core biopsies (12,22,23). Alternatively, many recent reports show a non-surgical follow-up is feasible for patients diagnosed with benign papillary lesions by using VABB samples due to the high diagnostic accuracy and low histological

underestimation rate of VABB (13,24,25). It is also still difficult to make a clear judgment about whether additional re-excision biopsies are needed in cases of benign phyllodes tumors diagnosed by performing VABB, because there are very few reports on the issue. Park *et al.* described 26 patients diagnosed with benign phyllodes tumors through histological examination after VABB excision. These patients were followed-up for an average of 33.2 months, and only one had disease recurrence, resulting in a local recurrence rate of only 3.3% (26). The recurrence rate was low, even when the short period of observation is considered. Complete removal of the lesions was confirmed at the same time as the diagnosis of the benign phyllodes tumors. If the lesions were smaller than 3 cm and no residual mass was found on follow-up sonography, there was a very low chance of recurrence, and follow-up observation was possible without another excision. However, since there are very few reports on this topic, the experience and judgment of the doctor should be used to determine whether an additional open excision biopsy should be performed.

Indications for VABB

Diagnostic indications

The most common indication for VABB is palpable or non-palpable American College of Radiology BI-RADS category 3 and 4A lesions. Use of imaging for follow-up is common for BI-RADS category 3 lesions detected on US. However, since there is a 0.5–2.0% possibility of malignancy, VABB excision may be a better option for patients with a low probability of follow-up (for geographical reasons, for pregnant women, or for women planning to undergo breast plastic surgery), patients with a lesion that changes in size or shape during the follow-up, extremely restless patients, patients who have subjective symptoms or pain, and patients with a family or personal history of breast cancer (14). VABB might also be more appropriate for lesions smaller than 5 mm because core needle biopsies can produce false negatives (27,28). Other indications for VABB are microcalcification clusters identified on US, complicated cysts, suspected intraductal papillomas, insufficient FNAC or CNB, and cases where a biopsy is necessary to facilitate adjuvant chemotherapy for category 5 and 6 lesions prior to surgery (24,29). Finally, VABB can be used to determine whether sparing the nipple is safe in women who request a nipple-conserving mastectomy for invasive cancer or carcinoma in situ. A recent study showed that the results from VABB and pathological results

from mastectomy specimens match 100% (30). VABB is also superior to FNA and CNB in its ability to diagnose inflammatory breast cancer, which is marked by the absence of a clear lump.

Therapeutic indications

Excision biopsies are recommended for patients with palpable breast lesions because they cause a great deal of patient uncertainty and anxiety. Inconclusive radiological or clinical reports aggravate these conditions, and a strong family history of cancer is also an aggravating factor. The Triple Test of physical, radiological, and histological examination has 95% accuracy in diagnosing lesions, but it is not perfect. Currently, surgical excision is still the standard treatment for palpable breast lesions (31). In 2002, the FDA approved VABB for the removal of benign lesions. The approval of VABB for this therapeutic purpose was based on the fact that VABB can obtain a large volume of tissue (32,33). Indeed, the therapeutic use of VABB is an alternative to surgical excision (34-36). Fibroadenomas are the most common benign breast lesions. They usually occur as an isolated breast mass in young women. The traditional therapy to treat symptomatic fibroadenoma is an excision biopsy that is used to histologically confirm that the lesion is benign, which frees patients from symptoms and feelings of uncertainty. Many recent studies indicate that VABB can be used as an alternative to surgical excision for treatment of fibroadenoma (34,35,37). Sperber *et al.* reported that, of 43 women who had complete removal of fibroadenoma, none had recurrence detectable on US after two years (32). March *et al.* reported that, in fibroadenoma patients who underwent VABB, residual masses were detected in 38% at the 6-month follow-up (37). Park *et al.* examined 3,126 VABB procedures and found that 1,766 (54.9%) were performed to remove fibroadenoma. Residual masses were found at follow-up in only 3% of the cases (38). For intraductal papilloma, microdocheotomy has been used both as an effective means of diagnosis and treatment. However, since Dennis *et al.* reported that VABB could be used to treat nipple discharge, US-guided VABB has emerged as an alternative to surgical excision. Papilloma is often found within 5 cm of the nipple, and VABB can obtain enough specimens to be comparable with surgical excision. Furthermore, smaller, isolated papillomas can be diagnosed with high-intensity focused ultrasound or color Doppler. Papilloma is usually a benign disease, and if it is suspected, the lesion can be biopsied by using VABB (39).

Tennant *et al.* reported that VABB could replace surgical excision for lesions that are pathologically diagnosed as B3 lesions (uncertain malignancy potential) where discerning benign versus malignant status is difficult (40). These lesions include papillary lesions, lobulated breast tumors, mucinous diseases, and atypical epithelial hyperplasias.

Lesion size suitable for VABB

There are currently no guidelines on the maximum size of a lesion that can be resected by using VABB. There are also no guidelines concerning the diameters of lesions for which 8G or 11G needles should be used. In early studies, Parker *et al.* and Fine *et al.* reported the use of 11G needles for lesions <1.5 cm, and 8G needles for lesions >1.5 cm (41,42). However, several recent reports have recommended 8G needles for resection of lesions >1 cm (25,36).

The maximum size for lesions that can be removed by using VABB is between 2.5 and 3 cm. Baez *et al.* reported that VABB should be used to resect lesions that have a diameter <2.3 cm (43), while Fine *et al.* found that complete resection was possible for lesions <3 cm (42). Park *et al.* examined a group of patients with lesions <3 cm and found that follow-up US revealed no residual masses in 96.8% of the patients, leading them to report that it is safe to use VABB to resect lesions <3 cm (36).

Incomplete excision and causes of residual masses

Fine *et al.* reported that imaging immediately after biopsy revealed complete removal of masses in 92% of the cases (42). Six months later, 73% of the patients had no US evidence of the initially diagnosed mass. Vargas *et al.* also reported complete removal of the imaged mass at the time of a 6-month follow-up US in 86% of the women (44). Chen *et al.* postulated that this reduction in complete removal occurs: because space orientation is not great under two dimensional US guidance, due to an effect of local anesthesia, or because of bleeding during the procedure that may blur the operative field and cause a visual challenge as the tumor gets smaller during the procedure (45). To solve these problems, they suggested the use of three dimensional (3D) US. Fine *et al.* cited similar reasons for the detection of residual masses in 27% of the women at the 6-month sonography follow-up (42). Specifically, they stated that sonographic excision is hindered by local anesthesia or

hematomas during the procedure. They pointed out that it is possible for the residual mass to grow again, and it is difficult to distinguish fiberization and scarring from a sonographic residual mass. The rate of successful initial complete removal of a lesion varies widely depending on the intention or experience of the VABB operator and the maximum lesion size that the operator considers suitable for VABB. In most cases, complete removal of a lesion is more feasible for small lesions, and the possibility of complete removal declines as lesion size increases.

Several conditions increase the possibility of complete lesion removal, but the most important factor is proper placement of the needle directly beneath the lesion. Other conditions include using the fast mode for bigger lesions, frequent blood suction, selecting the appropriate needle size, and minimizing bleeding during the procedure. Use of 3D or 4D US is also recommended to increase the likelihood of complete lesion removal.

Complications

Complications from VABB may include bleeding or pain during the procedure, as well as postoperative pain, hemorrhaging, and hematomas. VABB differs from open excision procedures in that post-procedural direct compression is the only hemostasis for VABB, as there is no hemostasis during the procedure. Continued bleeding after ten minutes of compression is considered to be prolonged bleeding. Simon *et al.* reported that bleeding could not be controlled by the standard ten minutes of post-procedural compression in 7% of patients following VABB (46). One patient required a procedure to tie off the damaged tissue. Previously, we performed VABB in a surgery room instead of an US room for outpatients, with monitoring of the patient's condition on electrocardiogram and vital sign monitor. Simon *et al.* reported that a vasovagal response was seen in 1% of the procedures (46), but we did not see any. Also, Ferzli *et al.* reported that dense breasts where needle insertion was impossible resulted in two surgery failures, and doctors shifted to open excisions because of severe bleeding and hemostasis failure (47). However, we did not experience these complications, and hemostasis was complete in most cases with 5 to 10 minutes of direct compression, continued compression by using adhesive compression bandages and sandbags, and bed rest. Johnson *et al.* found that wound infections required incisions and drainage in 2% of the procedures (33), but we had no cases with infections.

Future directions

The development of percutaneous VABB over the past ten years has revolutionized the diagnosis of breast cancer and breast-conserving treatment. Numerous studies attest that percutaneous VABB is less invasive, causes less damage, speeds time between detection and diagnosis, and costs less, compared to open surgery. While much progress has been made, there is still room for improvement through development of new technologies that increase accuracy, safety, and cost-effectiveness. In particular, lumpectomies that utilize 3D US examination should be performed. Additionally, MRI-guided VABB should become more common in order to capitalize on breast MRI, which is already widely performed. We also believe that the role of VABB, which is currently used to remove benign breast lesions, will be expanded to treat malignant tumors. This would provide, in the near future, a minimally invasive procedure not only for diagnosis, but also for treatment.

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