Breast Cancer Experts Encourage Use of VAB for Ultrasound Guided Biopsy
Clinical studies from 1996–2013 consistently indicate that underestimation as well as false-negative rates were decreased with the use of Vacuum-Assisted Breast Biopsy (VAB) under Ultrasound guidance when compared to core needle.

“Vacuum-assisted breast biopsy plays a fundamental role in the preoperative assessment of breast lesions providing large histology samples that are useful to define diagnoses and biological parameters to guide treatment planning.” (15)

This technique has been used for nearly two decades. These studies show that VAB is safe, fast, clinically advantageous for the health care professional and well accepted by patients.

Furthermore, the transition from cytology to histology has been driven by the increased histological accuracy provided by larger tissue samples achieved by VAB. (16)

“Tissue obtained at biopsy can provide histopathologic prognostic information, such as tumor grade, that is increasingly important in helping clinicians determine treatment options and strongly correlates with long term survival rates.” (14)

For many healthcare professionals the potential to minimize/eliminate insufficient or inconclusive diagnoses has resulted in a widespread transition from CNB to VAB.

ACQUIRING MORE TISSUE REDUCES UNDERESTIMATION

Hundreds of studies support the efficacy of vacuum-assisted breast biopsy (VAB). Researchers found VAB to be “highly accurate” and to consistently demonstrate significant reductions in underestimation rates. Their conclusions include:

“The VAB devices offer consistent quality tissue samples and subsequent reduced possibility of false-negatives as well as underestimation of the disease process.” (17)

Core needle biopsy tends to underestimate tumor grade. One study found “About a quarter (24%) of all biopsies were upgraded at surgery, whereas only 7% were downgraded.” (8)

“Under-staging of malignancy has been shown to decrease with the increasing number of tissue samples, larger biopsy needle, and use of a vacuum-assisted biopsy device.” (6)

“It is very apparent that the ultrasound-guided 8G Mammatome biopsy technique is highly advantageous for allowing generous and representative tissue sampling and for high accuracy of correctly diagnosing suspicious small sub-centimeter breast lesions.” (20)

A retrospective review of 4,435 sonographically detected lesions that underwent ultrasound guided CNB between 2005 and 2012, found that the overall underestimation rate for CNB was 47.4% for 14G core needles and 48.9% for 18G core needles. “This study concluded that for mass lesions with a size ≤10 mm or for non-mass lesions, large caliber CNB or vacuum-assisted biopsy is necessary.” (20)

In addition, a meta-analysis study that pooled fifty-two studies and included 7,350 cases of DCIS showed that about one in four DCIS diagnosis at 14G CNB represented under-staged invasive breast cancer. “Preoperative variables significantly associated with under-staging include biopsy device and guidance method, size, grade, mammographic features, and palpability.” (12)

“The frequency of histologic underestimation of breast carcinoma in lesions initially diagnosed as atypical ductal hyperplasia or ductal carcinoma in situ using large-core needle biopsy is substantially lower with the 11-gauge directional vacuum-assisted device than with the automated 14-gauge needle and with the 14-gauge directional vacuum-assisted device.” (10)

“Some lesions are histologically heterogeneous: For example, they may contain areas of both atypical ductal hyperplasia (ADH) and ductal carcinoma in situ (DCIS) or DCIS and infiltrating carcinoma. In such lesions, the sample obtained percutaneously may not be representative of the most aggressive and clinically important area of the lesion. Directional vacuum-assisted biopsy instruments, which obtain larger volumes of tissue than 14-gauge automated needles, usually result in significantly lower frequencies of histologic underestimation, particularly when at least 10 specimens are obtained.” (10)
In another study researchers found, “Among our patients, it is evident that breast masses can also be histologically heterogeneous. Histologic findings from the center and periphery of breast masses differed in 7 of 21 cases (33%).” (12)

“Breast cancers are known to show significant heterogeneity with respect to mitosis within a single tumor. Mitosis is the most active on the growing edge of the tumor. It is, therefore, not surprising that random sampling inherent to the CNB procedure leads to under-scoring of the mitotic index, which, in turn, leads to an underestimation of the overall grade; the biopsy may simply miss the area of highest mitosis.” (8)

“We have transitioned from FNA/CSE to VAB devices in an effort to obtain diagnostic accuracy for suspicious breast lesions, thereby minimizing and/or eliminating insufficient or inconclusive diagnosis.” (18)

“A major issue in preoperative DCIS is upstaging to invasive carcinoma. Upstaging has a significant impact on both patients and surgeons given the consequent risk of axillary LN positivity. The overall incidence of axillary LN metastasis in DCIS is approximately 5%. However, for preoperatively underdiagnosed lesions the incidence of axillary LN metastasis increases to 10-20%.” (13)

A retrospective study concluded: “The ADH underestimate rate and DCIS underestimate rate were 20.9 and 11.2%, both were lower than the value reported by Faehn K, et al. from an early systematic review and meta-analysis (The ADH underestimate rate and DCIS underestimate rate were 29.2 and 13.7%).” With high sensitivity (98%) and specificity (nearly 100%), VAB may provide a promising alternative for open breast biopsy and permit improved treatment planning.” (16)

**VAB MORE ACCURATE THAN CNB**

“There is an abundance of studies in the literature reporting on the false negative rate for the spring-loaded 14G core biopsy approach.” (14)

The chart above references twenty-one studies specifically reporting on the false negative rate of identifying breast malignancies based upon the ultrasound-guided 14-gauge core diagnostic breast biopsy approach. (14)

Despite advances in Ultrasound technology and visibility, the false negative rate among CNB procedures has remained relatively constant, averaging 2.2% during this period.

**Vacuum-assisted biopsy (VAB) is “highly accurate” (2)**

Research has indicated that vacuum-assisted breast biopsy, specifically the Mammotome® system, is highly accurate. One study found:

“100% accuracy of its 256 patients who completed the study with no false negative results.” (2)
“VAB allows for more accurate diagnosis of breast lesions than core biopsy. This is particularly true for small masses. Since we are detecting smaller and smaller lesions through screening, VAB is a vital tool for accurate breast cancer diagnosis. Core biopsy has a 6% false negative rate for breast cancers 1 cm or smaller in size. These false negatives are avoided by using VAB. Returning to core biopsy instead of VAB will be a step backward in the standard of care for breast cancer diagnosis for women.”

Cathy Babcock, MD, Partner Radiologist, Mountain Medical, SLC UT Medical Director of Breast Imaging, McKay Dee Hospital Center, Ogden UT

Unlike automated core needle biopsy, the vacuum-assisted probe is positioned posterior to the lesion so that it does not overshadow (and thereby obscure) the lesion during ultrasound-guided VAB. Consequently, the progress of lesion removal can be monitored in real-time vacuum-assisted biopsy.”

“We can position the probe at the center of the lesion, not at the edge of the lesion.”

“The best way to obtain the most tissue and ensure proficiency and confidence, particularly with small, indistinct lesions, is to go directly to vacuum-assisted biopsy.”

Tommy E. Cupples, MD, Radiologist, Medical Director, ImageCare, LLC, Columbia SC. Author of “Dx and Bx: An Algorithm for Image Guided Biopsy Techniques”

Inappropriately selected patients, the 8 gauge vacuum-assisted biopsy approach can:

(1) minimize the overall false negative rate for diagnosing invasive breast carcinoma; (2) reduce the subsequent need for further diagnostic removal of additional tissue from the affected breast in an immediate fashion for indeterminate/inconclusive findings; and (3) reduce patient-requested further diagnostic removal of additional tissue from the affected breast in an immediate fashion despite benign finding in the original ultrasound-guided diagnostic breast biopsy procedure.”

“The importance of appropriate patient selection for either of these ultrasound-guided diagnostic breast biopsy approaches (8G VAB and spring-loaded 14G CNB) cannot be underestimated and must be well understood by those breast health care professionals utilizing ultrasound-guided diagnostic breast biopsy technology.”

**VAB OFFERS MANY ADVANTAGES TO ASSURE PROFICIENCY AND CONFIDENCE**

Studies show in addition to the decreased underestimation and false negative rate VAB offers many advantages that ensure proficiency and confidence as compared to CNB and Open Excisional Biopsy.

In 2011 the Journal of Ultrasound featured a study from the European Institute of Oncology. Below are their findings.

“In our opinion, US-guided VAB has certain features that make it superior to CB-Tru Cut. They include:

- In the evaluation of small lesions (approx. diameter 5-10 mm), the use of CB-Tru Cut carries a moderate risk of inadequate sampling.

- With VAB, contiguous samples can be collected without multiple needle insertions, and this increases the likelihood of adequate results even when the needle tip is not right in the middle of the target.

- For ultrasound-guided specimen collection, VAB allows more precise control of the position of the probe, without the excursion that occurs with CB-Tru Cut. This feature reduces the risk of injury to the chest wall during biopsy of deep lesions.

- The larger-gauge needle (11G vs. 14G) allows one to obtain larger tissue cores that are more likely to be suitable for pathological assessment.”
Ultrasound-guided VAB can be considered a second-line study performed in specialized centers; it appears to be an effective strategy in terms of diagnostic accuracy and costs in light of the improved diagnostic process. (17)

There are inherent concerns when utilizing the spring-loaded 14-gauge biopsy technique for specific types of lesions in particular. One study found:

There are key issues related to tissue sampling of larger-sized but vaguely characterized areas within the breast.

“A spring-loaded 14-gauge core biopsy approach to ultrasound-guided diagnostic breast biopsy may prove highly difficult due to the inability for the tissue acquisition chamber of the spring-loaded 14-gauge core biopsy device to correctly and completely fire through such breast tissue of increased breast tissue density that is frequently encountered in these particular situations.” (14)

“Likewise, a spring-loaded 14-gauge core biopsy approach may create concerns about the certainty of the degree of representative tissue sampling of a larger-sized but vaguely characterized area of interest within the breast.” (14)

“On the other hand, in these particular situations, an 8-gauge vacuum-assisted biopsy approach would allow for single pass, central placement of the device within such a larger-sized but vaguely characterized area of interest within the breast, despite the finding of generalized increased breast tissue density, with subsequent ease of tissue acquisition of multiple 8-gauge cores in up to a complete 360 degree rotational array.” (16)

VAB OFFERS TREATMENT OPTIONS FOR BENIGN BREAST DISEASE

An estimated 60 percent of all women will develop benign breast disease during their adult lives. These diseases, such as benign fibroadenomas, often cause patients anxiety and in some cases, physical symptoms, such as intermittent or chronic pain, discomfort and irritation. These emotional and physical symptoms can lead them to request removal of the benign breast abnormality. (3)

Surgical treatment of fibroadenomas, for example, has been reported to account for about 50 percent of open surgical biopsies, “resulting in considerable health care expenditures.” (3)

Several studies have evaluated the effectiveness of vacuum-assisted breast biopsy procedures in not only definitively diagnosing benign breast diseases but also in removing “low-risk” palpable lesions. One study concluded that vacuum-assisted diagnostic biopsy procedures are “highly successful for ultrasound-guided complete removal of appropriately selected presumed benign breast lesions.” (2)

"This type of therapy is all the more attractive as the diagnostic biopsy and definitive treatment can be performed in one step." (3)

PATIENT SATISFACTION HIGH WITH VAB

This research also evaluated patients’ satisfaction with the vacuum-assisted breast biopsy procedure.

After the procedure:

- 97% of women had no imaged mass immediately after the procedure
- 98% had no palpable mass 6 months after the procedure
- 97% would have the procedure again
- None of the women required additional diagnostic or therapeutic procedures during the 6-month follow up period
- Patient anxiety was significantly lower after the procedure (3)

![Patient Satisfaction Graph](image-url)
“OPERATING ROOM IS FOR TREATMENT, NOT DIAGNOSIS, EXPERT SAYS” (6)

The lead author of the 2009 Consensus Conference III special report, Dr. Melvin Silverstein, has likened the necessary change in attitude about minimally invasive breast biopsy to changes that occurred in the mid-1970s, when women lead physicians to abandon radical mastectomies and one-stage procedures. (8)

“Dear Colleagues – its 2009 – time to do a complete imaging workup, an image-guided needle biopsy, and completely plan the surgical approach, all before going to the operating room. When it comes to breast cancer, the operating room is for treatment, not diagnosis. The goal for those of us who treat breast cancer should be to go to the operating room one time to perform the correct therapeutic (not diagnostic) procedure.” (8)

“Open diagnostic biopsies only add unnecessary costs to our already overburdened and compromised health care delivery system and much inconvenience, morbidity, and scarring for the individual patient.” (8)

References:
11. Marla L. Rosenfield Darling et al. Atypical Ductal Hyperplasia and Ductal Carcinoma in Situ as Revealed by Large-Core Needle Breast Biopsy: Results of Surgical Excision