

Clinical advantages of vacuum-assisted breast biopsy

Summary

- Vacuum-assisted breast biopsy (VABB) allows larger, more contiguous tissue samples to be taken with fewer needle insertions, enhancing diagnostic accuracy of patients with high-risk breast lesions.
- VABB is more effective at retrieving non-palpable lesions compared to core needle biopsy (CNB).
- VABB results in a 22 % decreased risk for repeat biopsy compared to CNB. This reduces overall costs and eases pressure on healthcare resources.
- When using VABB over CNB, concordance rate is increased by 7 %.
- VABB has a better sensitivity compared to CNB, 94 % and 78 %, respectively.

Introduction

Since their widespread adoption in clinical practice, percutaneous image-guided breast biopsies have revolutionised the care of patients with lesions of uncertain malignant potential – high-risk or B3 lesions – offering a less invasive technique than surgery for establishing a diagnosis. In the early 1990s, the CNB technique was developed as a more accurate and efficient method compared to fine-needle aspiration, which often failed to distinguish between benign and malignant lesions. Shortly after that, vacuum-assisted breast biopsy (VABB) was introduced to further enhance diagnostic accuracy, allowing larger, more contiguous tissue samples to be taken with fewer needle insertions. This paper outlines the benefits of VABB, and discusses how its high sensitivity leads to fewer repeat biopsies and improvements in patient care overall.

What is vacuum-assisted breast biopsy?

VABB is a minimally-invasive technique that offers high diagnostic accuracy at the outset, leading to fewer repeat biopsies. This method involves the insertion of a single biopsy needle through a small incision in the breast. Target tissue is then sucked through the needle aperture using a vacuum-powered instrument, and cut into a cylindrical shape using a rotating knife. Contiguous samples are collected by rotating the needle with the aperture pointing towards a different position, and applying suction to capture more specimens.¹ In this way, multiple specimens can be retrieved from different sides of a lesion – or an entire lesion can be removed – without needing to repeatedly re-insert the needle, which is required with CNB.



Figure 1: The tip of a VABB needle with a side aperture for the collection of breast tissue specimens.

Guidance modalities

As with CNB, real-time imaging – stereotactic, MRI or ultrasound – is used to guide the procedure and correctly position the needle, ensuring that samples are collected from all the regions of interest.² The decision on which imaging modality to use is often case specific, considering the lesion's size, the presence of microcalcifications, and the location in the breast.³

Stereotactic VABB

Stereotactic VABB is widely used for microcalcifications because of its high detection rate for this kind of lesion.⁴ It uses either 2D mammography to pinpoint the site of interest, or more advanced 3D tomosynthesis-guided biopsy, which provides a clearer, more detailed view by taking multiple images from various angles.

Ultrasound-guided VABB

If a lesion is visible under both ultrasound and mammogram, then the former modality is usually recommended as the method of choice.¹ Ultrasound-guided VABB is more comfortable for the patient as there is no need for breast compression,^{4,5} it is less time consuming, no radiation is involved, and there is more flexibility for the position of the incision.¹ There is also visual reassurance in real time from an ultrasound scan if a lesion is being completely removed.¹

MRI-guided VABB

MRI is useful for positioning breast cancer that is undetectable by physical examination, mammogram or ultrasound.^{6,7} However, it is far less commonly used because of the training and experience required, both during the actual procedure and in determining radiological-pathological concordance.⁸

Clinical evaluation of VABB

Assessing the efficacy of a breast biopsy technique requires objective performance metrics that reflect its accuracy, reliability and clinical impact. A number of studies have analysed the efficacy of VABB compared to CNB in key clinical areas, of which, some of the results are discussed below.

Microcalcification retrieval rate

Microcalcifications are one of the most frequent mammographic findings during breast screening, and play a crucial role in early breast cancer diagnosis.^{4,9,10} In fact, breast microcalcifications occur in up to 50 % of breast cancers, representing an important diagnostic marker of both benign and malignant lesions.^{4,9} For example, up to 90 % of ductal carcinoma *in situ* cases are diagnosed by analysing calcifications, without any accompanying mass lesions.^{4,9} It is therefore vital to clarify the nature of suspicious calcifications as soon as possible,⁴ as retrieval failure may result in missed cancer diagnoses.

Collecting sufficient sample can be problematic for a number of reasons, including inaccurate sampling, and the size, location and chemical composition of microcalcifications.¹¹ VABB has been shown to be more effective than CNB at retrieving non-palpable lesions¹² – including microcalcifications – and has emerged as the most commonly-used biopsy method for this indication, largely because of its ability to capture more sample, improving sensitivity and specificity.⁴ For instance, Jackman *et al.* found that 14-gauge CNB failed to retrieve microcalcifications in 16 % of cases, compared to 4 % with 14-gauge VABB and 1 % with 11-gauge VABB.¹³ Overall, VABB is a better diagnostic tool compared to CNB for small lesions and microcalcifications, with a lower frequency of repeat biopsy.¹⁰

**“The failure rate of microcalcification retrieval improved from 20 % with the spring-loaded technique [CNB] to 0 with the vacuum-assisted technique.”
Huang *et al.*¹⁴**

Repeat biopsy rate

The need for repeat procedures is not uncommon to ensure accurate diagnosis following percutaneous breast biopsy, often arising from factors including discordant histological/pathological results, insufficient or inadequate specimens, and following up initial diagnosis of benign high-risk lesions.¹⁵ Repeat biopsies can heighten anxiety and distress for the patient, especially due to uncertainty of results, and inevitably delay a definitive diagnosis, leading to slower treatment initiation.

A limiting factor of CNB is insufficient sample collection, especially in women with dense breast tissue,⁶ which can prevent lesions from being correctly characterised and leads to an increase in the frequency of repeat procedures. This is significant for both masses and calcifications, with repeat biopsy rates found to be as high as 23.7 % for the latter in one study.¹⁶ In contrast, VABB has demonstrated a significant reduction in the need for repeat biopsy,¹⁶ primarily due to its ability to retrieve much larger volumes of lesion tissue during sampling.¹⁵ This increased tissue yield not only reduces sampling errors but also minimises the likelihood of histological underestimation and imaging-histological discordance.¹⁵ One study conducted by Philpotts *et al* found that the repeat biopsy rate was significantly lower with the 11-gauge vacuum suction probe (9 %) than with the 14-gauge needle and automatic gun (14.9 %).¹⁶

Concordance rate

The concordance rate is the proportion of biopsies that match surgical pathology. Breast lesions initially diagnosed as benign can be subsequently upgraded to malignant at surgical excision, and vice versa, significantly impacting patient management and overall prognosis.¹⁷ The heterogeneous nature of most lesions can pose a problem for the CNB technique, as histological findings can vary from one area of a mass to another; it is possible for the core of a lesion, which is targeted by CNB, to differ histologically from the outer regions, which are not.⁶ In these circumstances, sampling part but not all of a lesion may miss some cellular changes that are highly significant,¹⁸ leading to inaccurate results and high underestimation rates.¹⁷

While surgical diagnosis remains the gold standard, it is associated with notable drawbacks for both patients and the healthcare system. VABB has repeatedly demonstrated superiority over CNB in achieving concordance between pathological diagnosis and surgical specimens.¹⁰ For instance, Huang *et al*. found that VABB yielded better results with significantly better concordance rates than CNB – 95 % compared to 79.6 %.¹⁴ Similarly, another study reported a concordance rate of just 62.5 % for benign tumours diagnosed by CNB,¹⁷ underscoring the increased risk of false negative results with this technique in benign cases.

Morris *et al*. found that 29 % of breast masses investigated were heterogeneous, yielding different histologic results from the centre and the periphery.¹⁸

Sensitivity of VABB

The ability of the biopsy method to correctly identify malignant lesions – the sensitivity or true positive rate – is vital to ensure the early and accurate diagnosis of patients, and image guidance significantly helps to improve this by directing accurate tissue sampling.¹⁹ Several studies have compared the diagnostic accuracy of VABB and CNB in the diagnosis of indeterminate breast microcalcifications, with the former frequently showing higher sensitivity. Shrestha *et al.* found the sensitivity of VABB was 93.75 % compared to 71.88 % for CNB,¹² while Moustafa *et al.* concluded similar results, reporting 90.7 % and 60.78 %, respectively.¹⁰ A selection of other studies concluding that VABB is a highly sensitive method are listed in Table 1, all reporting an improved diagnostic accuracy and fewer repeat biopsies and follow-up examinations.¹⁶

Study	Sensitivity of VABB (%)
Thakkar (Popat) <i>et al</i> ³	96
Safioleas <i>et al</i> ⁹	98.2
Amorim <i>et al</i> ²⁰	91.7
Yu <i>et al</i> ²¹	98.1
Kettritz <i>et al</i> ²²	99

Table 1: Sensitivity of VABB found in multiple studies.

Hologic commissioned a third party to perform a systematic literature review and meta-analysis to gain detailed insights into the clinical effectiveness of VABB. Of the 959 papers that were identified as relevant, 97 were included in the final analysis based on the PICOS model (Appendix 1), with a selection of the results shown below.²³

- VABB results in a **22 % decreased risk for repeat biopsy** compared to CNB (RR: **0.78** (0.69-0.88), $p < 0.01$).
- **Concordance rate is increased by 7 %** when using VABB over CNB (RR: **1.07** (1.04-1.11), $p < 0.01$).
- **Sensitivity is increased with VABB** in comparison to CNB: the proportion of true positive tested lesions is higher when using VABB (sensitivity of 94 % (RR: **0.94** (0.92-0.97) $p < 0.05$)) compared to CNB (sensitivity of 78 % (RR: **0.78** (0.70-0.86), $p < 0.05$)).

Broader clinical benefits of VABB

Beyond these specific clinical metrics, one of the main advantages of VABB is its ability to collect larger tissue samples with a single needle insertion, improving the breadth of cell types collected. This largely addresses the issue of tissue heterogeneity, where obtaining contiguous specimens results in a more accurate diagnosis, with a lower cancer miss rate and fewer histological underestimates.¹ Because a larger amount of tissue can be collected by VABB, it is particularly useful in the biopsy of small and indefinite lesions that are more likely to be missed using other biopsy techniques, as well as for suspicious lesions that are associated with surgical scars, fibrosis or prosthetic implants.¹ In addition, VABB offers several key benefits to clinicians and pathologists, including:

- it is less invasive for the patient as the needle remains in the breast throughout the biopsy, eliminating the need to repeatedly re-target the needle for sampling and making the procedure quicker and more efficient;
- samples can be taken from different sides of a lesion, or the entire lesion can sometimes be removed, with no further surgical procedures required if it is diagnosed as benign;
- the vacuum function prevents a lesion from moving during aspiration;
- vacuum and irrigation also improve the quality of the sample, as blood is aspirated and more tissue can be sampled.

VABB has several key advantages for the patient, including its minimally-invasive nature – requiring only one needle insertion – and it generating less noise compared to CNB, which can increase patient discomfort and anxiety.⁶ Despite using lower gauge needles, VABB also results in less pain experienced by women,²⁴ and is considered a safe and efficient method, with high patient acceptance and comparable rates of minor complications to CNB.²⁵

Lacambra *et al.* highlighted that the diagnostic accuracy of VABB appeared to be independent of the number of cores sampled, whereas CNB required at least three to four cores to achieve high diagnostic accuracy.²⁶

Economic benefits of VABB

VABB initially requires a higher capital investment more expensive than CNB, however, its higher diagnostic accuracy can result in lower overall costs for a healthcare system as a whole.²³ The increased cost of one successful biopsy can be offset by the improved efficiency and fewer repeated procedures, considering that each additional biopsy effectively doubles the significant cost and use of resources – including pathology, radiology and procedural expenses – needed to make a single diagnosis. This is supported by Grady *et al.*, who found that the mean cost per diagnosis was USD 4,052 when patients were first biopsied using VABB, compared to USD 4,346 with CNB.²⁷

Conclusion and clinical implications

VABB offers clear clinical advantages over CNB – particularly in patients with non-palpable lesions – improving diagnostic accuracy and reducing repeat biopsy rates. Its superior sensitivity and higher concordance rates enhance diagnostic confidence, which can largely be attributed to its ability to obtain larger, contiguous tissue samples with a single needle insertion. This not only improves patient comfort but also ensures more accurate diagnoses, ultimately reducing false negatives and the underestimation of high-risk lesions. Furthermore, improved diagnostic accuracy can contribute to lowering the cost of reaching a clear diagnosis, suggesting that VABB can be a more cost-effective solution compared to CNB.²⁷ Given these benefits, wider adoption of VABB in routine breast cancer diagnosis could lead to greater efficiency in clinical practice, and help to improve patient outcomes.

Appendix 1

The PICOS model acts as a framework for the eligibility criteria in systematic reviews of literature. In this review, the components listed below were used to search PubMed and Cochrane Library to identify relevant studies.

Components	
Patients / population	Women with suspected breast cancer (symptomatic / non-symptomatic: no restriction regarding age or country)
Intervention	Vacuum-assisted breast biopsy
Comparison / control	(i) Core needle biopsy and (ii) fine needle aspiration
Outcomes	<ul style="list-style-type: none"> • ADH underestimation rate • DCIS underestimation rate • Underestimation rates in general (not clearly assignable to ADH or DCIS underestimation rate) • Repeat biopsy rate • Concordance rate • (Micro)calcification retrieval rate • Sensitivity* • Specificity* • Complications (haematoma, bleeding, infection, pain, ...) • Mortality • Morbidity • Quality of life • Workflow efficacy (time under compression, time period for one biopsy) <p>* Also searched for positive predictive value, negative predicted value, false-negative rate, false-positive rate, area under the curve to collect all data allowing to have a full set of true negatives, true positives, false negatives, and false positives.</p>
Study design(s)	Comparative studies (single-arm studies were excluded)

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