Value Considerations for Vacuum-Assisted Breast Biopsy (VABB)

BD

Executive Summary

In a changing healthcare landscape, evidence-based decision-making has become essential, with a focus on positive patient outcomes and the provision of cost-effective care. Innovative interventions need to be supported by evidence that substantiates the economic value. Applying these principals to the breast biopsy market will be of paramount importance. This compendium provides information regarding important health-economic considerations supporting the use of Vacuum-Assisted Breast Biopsy (VABB) in the diagnosis of breast cancer and removal of benign breast lesions.

Breast biopsy needs

- Breast biopsies, conducted both surgically and through minimally invasive methods, are performed frequently in the United States due to the need to confirm presence of abnormalities after mammography.[1-4]

- Accuracy and timing of breast cancer diagnosis through breast biopsy have been shown to influence patient outcomes. For example, false negative biopsy results can reduce patient confidence and delay diagnosis and treatment of breast cancer.[13-18]

- Surgical biopsy has been the gold standard for accurate diagnosis of breast cancer; however, it is associated with limitations (e.g., scarring).[4,7,10,17,20-22] Minimally invasive methods may help overcome some of these challenges.[7,10,20,21,23]

- Core needle biopsy (CNB) was one of the first minimally invasive methods and involves insertion of a large hollow needle (multiple times) to withdraw small cylinders (cores) of tissue from abnormal areas of the breast.[26,27]

- CNB has been reported to be associated with certain limitations such as inability to excise lesions, requirement for multiple needle insertions, and limited use in certain populations.[10,17,22,27,28,32-35]

Vacuum-Assisted Breast Biopsy (VABB) can help to address certain limitations associated with CNB:

VABB is an important minimally invasive biopsy technique that is designed to help mitigate certain limitations with CNB. The sampling method of VABB consists of a combination of vacuum suction and cutting needle which can produce a larger, more contiguous sample than CNB with only one needle insertion in the majority of cases.[17,42-44]

- The benefits of a larger, more contiguous sample with VABB may yield more accurate lesion representation and the ability to partially excise lesions.[7,9,17,27,30,42,43] VABB may allow for access to lesions in areas that are difficult to access with CNB.[17,30,32]

- Several systematic reviews observed that VABB was associated with lower high-risk lesion and DCIS underestimation rates,[10,27,28,45] as well as lower non-diagnostic sampling rates[27] as compared with CNB.

  – Improved accuracy parameters are reported for VABB compared to CNB across the three potential guidance methods of ultrasound (US), stereotactic (ST) and magnetic resonance imaging (MRI).[12,28,36,37,56-60,66-68]

- Three retrospective studies demonstrated a significantly lower rate of re-biopsies with VABB vs. CNB.[33,51,71]

- VABB has been reported to be well-tolerated, with complication rates similar to CNB and lower than surgical biopsy.[28,40,48,51]

- VABB is predicted to be a cost-efficient strategy in many situations due to potential avoidance of costly surgical procedures.[32,73,74] In lesions which have been determined to be unsuitable for CNB, VABB has been shown to be a cost saving alternative.[3]

  – In lesions suitable for CNB, VABB was predicted to be approximately cost neutral compared with CNB, based on an analysis that considered both upfront acquisition and downstream intervention costs.[74]

- A BD-conducted review of the Premier Database found that in 2015 the mean procedure costs for VABB were almost 30% less than that of surgical revision for removal of benign lesions, such as fibroadenomas ($842 vs. $2,882, respectively).[54]

The need for breast biopsy as a diagnostic tool for breast cancer after mammography is high

- Mammograms may yield high false positive rates resulting in patient anxiety and high expenditures.[1,2]
- High false positive rates have created the need to confirm the presence of abnormalities following mammography.[1]
- Annually, it is estimated that 1.7 million breast biopsies are performed in the U.S.[3] and the AHRQ* reported in 2010 that ~20% of all biopsies yield a diagnosis of breast cancer.[4]
- Biopsy methods have evolved to include both open surgical and minimally invasive techniques.[5-8]
  - Open Surgery: For biopsy and excision of suspicious tissue using standard surgical techniques
  - Core Needle Biopsy (CNB): For biopsy of suspicious tissue using a mechanically-operated hollow cutting needle
  - Vacuum-Assisted Biopsy (VAB): For biopsy and partial removal of suspicious tissue using a cutting needle with vacuum suction
- Non-invasive techniques have shown value in their ability to diagnose abnormalities following mammography.[9-12]

Accuracy and timing of breast cancer diagnosis through breast biopsy can influence decision-making and patient outcomes

- It is well-known that early detection of breast cancer can lead to a greater range of treatment options and reduced mortality risk.[13,14]
- Accurately staging lesions is essential in influencing therapeutic decisions.[15,16]
- Biopsy screening errors (e.g. false negatives) may delay diagnosis and treatment of breast cancer, may impact patient confidence, may result in less successful therapy, and may result in more invasive treatment.[13,17,18]

The inherent risks associated with open surgical biopsy created the need for less invasive biopsy methods

- Surgical biopsy has been the gold standard for accurate biopsy diagnosis, however it may be associated with certain limitations:[7,10,17,19-22]
- Minimally invasive techniques, with CNB and VABB, may help overcome these challenges.[7,10,20,21,23]
- A U.S. conference panel recommends that only 5-10% of biopsies should be surgical.[25]

Possible limitations of surgical biopsy: [7,17,19,21,22]

- Pain, scarring, and patient dissatisfaction
- Complications
- Long and costly procedure

*AHRQ: Agency for Healthcare Research and Quality
Notes: False Negative results fail to indicate the presence of breast cancer; False Positives results fail to indicate the absence of breast cancer
Terminology used for breast cancer diagnoses: Benign: no cancerous changes in breast tissue; ADH: Atypical Ductal Hyperplasia, a benign breast abnormality indicating an increased risk of breast cancer; LCIS: Lobular Carcinoma in Situ, abnormal cells in lobules of breast indicating increased risk of cancer; DCIS: Ductal Carcinoma in Situ, non-invasive condition in which abnormal cells found in lining of breast; invasive cancer: cancer that has spread from its origin to surrounding tissues (stages 1 to 4).

Core Needle Biopsy was one of the first minimally invasive techniques introduced but has been associated with certain limitations

- CNB involves insertion of a hollow needle (multiple times) to withdraw small cylinders or cores of tisssue from abnormal breast tissue.[26,27]
- A 2014 systematic review and meta-analysis of 160 studies published between 1990 and 2013 quantified the diagnostic characteristics of CNB:[28]
  - High-risk lesion* underestimation rates ranged from 25-49% depending on imaging guidance, and DCIS underestimation rates at 38% and 26% for ultrasound (US) and stereotactic (ST) guidance, respectively.[28]
  - Sensitivity of CNB was reported to range from 90-99% depending on the imaging guidance method used.[28]
- Multiple needle insertions with CNB may contribute to patient anxiety.[30,31]
- CNB is spring loaded, rendering the forward throw a potential limitation for use near sensitive structures (e.g., nipple, thoracic wall, skin surfaces).[17,22,32]
- CNB has been reported to be associated with higher re-biopsy rates for calcified lesions ◊.[33,34,35]

Reported Limitations of CNB: [10,17,22,27,30,32-35]

- Underestimation of lesions
- Multiple needle insertions
- May be limited in sensitive areas (e.g., nipple)
- Potential unreliability for calcified lesions
- Cannot excise lesions

VABB is an important minimally invasive biopsy option that is designed to help mitigate certain limitations of CNB

- Only one needle insertion is required with the majority of VABB devices, whereas many insertions are required with CNB.[7,17,36,37]
  - It has been reported that no scar was observed in 96% of 752 follow-up VABB patients,38,39 and over 85% of patients were satisfied with the cosmetic results (41/48 responded to a questionnaire).[31,40,41] Another study of 189 women found that 97% were satisfied with the cosmetic results.[12]
- The sampling method in VABB consists of a combination of vacuum suction and a cutting needle, which produces a larger, more contiguous sample than CNB.[17,42-44]
  - The average sample retrieved by VABB has been reported to be up to 10 times larger in volume than that retrieved by CNB.[34,45-47]
- VABB may afford access to sensitive structures, due to absence of a forward throw of the needle.17,30,32
- Literature suggests that more tissue cores are obtained at each biopsy with VABB as compared with CNB, with ease of tissue acquisition.[48-51]
  - An accurate diagnosis after CNB has been reported to be proportional to the number of cores taken, whereas the accuracy of VABB can be independent of the number of cores.[29]
- VABB provides the ability to partially remove certain lesions, which may reduce the need for surgery when initial results are benign, and may help to alleviate patient anxiety.[17,30,52,53]
  - Removal of common benign lesions, such as fibroadenomas, with VABB may mitigate patient discomfort, physical deformity, and potential anxiety related to ongoing surveillance associated with the lesion.

Benefits of a larger biopsy sample may include: [7,9,17,27,30,42,43,52,53]

- Intact histological patterns
- Accurate representation of the lesion
- Partial excision of lesion
- Reduced likelihood of non-diagnostic samples
- Reduced re-biopsy rate

*High risk lesions include: atypical ductal hyperplasia (ADH), lobular neoplasia, phyllodes tumors, papillary lesions, mucocele-like lesions, complex sclerosing lesions and radial scars (Lee 2014, Spick 2016)
◊ Evidence based on studies using ST imaging guidance

VABB has demonstrated improved diagnostic accuracy as compared to CNB across several imaging guidance modalities

- A 2014 meta-analysis by Dahabreh, I., et al. reported on the accuracy of VABB and CNB based on 160 studies including a total of 69,804 breast lesions, and assessed underestimation rates of high-risk lesions and DCIS, sensitivity, and specificity (see data tables below for accuracy parameters).[28]
- Larger samples typically associated with VABB may help to reduce non-diagnostic sample rates and indeterminate findings.[27,51]
- A retrospective study including 464 patients reported that VABB detected calcifications in 75% of non-palpable lesions, whereas CNB was reported to detect 32% (imaging modality not reported).[29]

Ultrasound (US) Imaging Guidance

- US guidance can provide many benefits: [43,55]
  - Increased patient comfort compared to stereotactic imaging
  - Real-time visualization
  - Faster procedure times compared to other localization techniques
  - Lack of ionizing radiation
- Mismatches can often occur between US-image findings and biopsy results; however, increased tissue volumes obtained with VABB vs. CNB may enable a greater proportion of representative biopsies to be obtained.[56]
- In a retrospective analysis of 2,477 patients (2002 to 2011), US-guided VABB had a 98.7% agreement rate with excisional analyses for underestimation of high-risk lesions and DCIS†.[36]
- A number of clinical studies published since 2014 consistently showed high accuracy parameters‡ for US-VABB, with cases of improved values compared to the 2014 meta-analysis by Dahabreh, I., et al.[28,36,57-60]
  - For example, 2 studies, one including 2,477 and the other including 2,596 US-VABB procedures, demonstrated high-risk lesion underestimation rates from 0.20% to 3.1%.[36,57]

US-CNB and US VABB Accuracy Parameters

Accuracy Parameter	CNB		VABB	
	N Studies [N biopsies]	Value(s)	N Studies [N biopsies]	Value(s)
High-risk lesion Underestimation [28*]	21 [601]	**25%**	9 [20]	**11%**
DCIS Underestimation [28]	14 [307]	**38%**	5 [48]	**9%**
Sensitivity [28]	27 [16,287]	**99%**	12 [1,543]	**97%**
Specificity [28]	27 [16,287]	**97%**	12 [1,543]	**98%**
Indeterminate Findings [51]	1 [719]	**11.3%**	1 [724]	**2.5%**

*High risk lesions include: atypical ductal hyperplasia (ADH), lobular neoplasia, phyllodes tumors, papillary lesions, mucocele-like lesions, complex sclerosing lesions and radial scars (Lee 2014, Spick 2016)
†Agreement rate between histological diagnosis of samples obtained using US-VABB versus whole tumor analysis following excision
‡Parameters include: high-risk lesion and DCIS underestimation, sensitivity, and non-diagnostic rate
§Localization techniques stereotactic and magnetic resonance imaging methods (Uematsu 2012)
Terminology used for defining accuracy: Sensitivity: The proportion of positives (patients with lesions) correctly identified; Specificity: The proportion of negatives (healthy patients) correctly identified; Indeterminate Findings: The sample quality/amount is insufficient to enable a definitive interpretation of the results (i.e. cancerous/benign)

Stereotactic (ST) Guidance

- ST imaging guidance can be used for most lesion types, including both palpable and non-palpable masses, and those with calcifications.[61]
- Most ST biopsies are currently performed with vacuum-assisted devices.[62]
- Additional studies published since the 2014 meta-analysis by Dahabreh, I., *et al.* reported high accuracy performance of VABB with ST imaging guidance.[12,37,57,63-67]
  - A 2016 study of 195 patients reported a DCIS underestimation rate of only 6.1% with ST- VABB.[64]
  - A randomized controlled trial of 169 procedures using two ST-VABB devices reported sensitivities of 100% for both devices.[37]

ST-CNB and ST-VABB Accuracy Parameters

(Data primarily informed by 2014 meta-analysis[28])

Accuracy Parameter	CNB		VABB	
	N Studies [N biopsies]	Value(s)	N Studies [N biopsies]	Value(s)
High-risk lesion Underestimation [28*]	29 [357]	**47%**	40 [1,002]	**18%**
DCIS Underestimation [28]	18 [664]	**26%**	34 [1,899]	**11%**
Sensitivity [28]	37 [9,535]	**97%**	43 [14,667]	**99%**
Specificity [28]	37 [9,535]	**97%**	43 [14,667]	**92%**
Non-diagnostic Sample Rate [12,57,66,67,76]	2 [656]	**4.4-9.5%+**	5 [2,466]	**0-1.7%+**

Magnetic Resonance Imaging (MRI) Guidance

- MRI enables visualization of lesions not visible with US or ST techniques, which broadens the availability of biopsy and (partial or whole) excision of previously unidentifiable breast lesions.[68-70]
- A retrospective study of 467 patients receiving MRI-VABB reported a 95.5% agreement rate with final patient diagnoses.[69]

MRI-CNB and MRI-VABB Accuracy Parameters

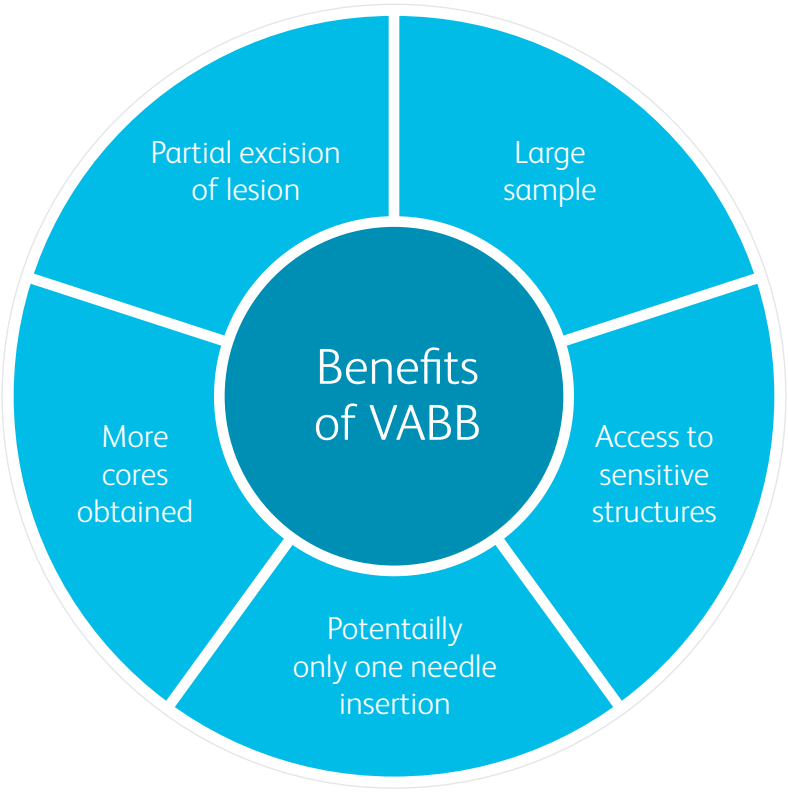
(Data primarily informed by 2014 meta-analysis[28])

Accuracy Parameter§	CNB		VABB	
	N Studies [N biopsies]	Value(s)	N Studies [N biopsies]	Value(s)
High-risk lesion Underestimation [28*]	1	**49%**	2 [184]	**14.3-19%****
DCIS Underestimation [28]	-	**N/A^**	2 [35]	**0-14.7%****
Sensitivity [28]	2 [89]	**90%**	1 [10]	**100%**
Specificity [28]	2 [89]	**99%**	1 [10]	**91%**
Non-diagnostic Sample Rate [12,57,66,67,76]	-	**N/A^**	1 [557]	**0.9%+**

*High risk lesions include: atypical ductal hyperplasia (ADH), lobular neoplasia, phyllodes tumors, papillary lesions, mucocele-like lesions, complex sclerosing lesions and radial scars (Lee 2014, Spick 2016)
+Value ranges obtained from clinical studies; meta-analysis did not report on non-diagnostic rates
**Value ranges obtained from clinical studies; meta-analysis (Dahabreh 2014) did not have sufficient evidence to report on these parameters
^No values are currently available to quantify DCIS underestimation and non-diagnostic sample rates with MRI-CNB use
§ Results should be interpreted with caution, as only 1-2 studies informed each accuracy parameter value.

VABB may offer enhanced clinical and economic value to both the patient and the facility

- VABB may reduce the need for re-biopsy given reported lower rates of non-diagnostic samples and the ability to partially excise lesions.[17,33,51,71]
  - A 2005 study of 979 lesions showed non-significantly higher re-biopsy rates (i.e., mainly surgical re-biopsy) after US-CNB vs. US-VABB (6% vs. 3.5%).[71]
- A retrospective study of 1,443 US-guided diagnostic breast biopsies showed that significantly more patients who had CNB vs. VABB requested further surgical removal of a benign finding (7.5% vs. 1.2%; p<0.001).[51]
- High rates of patient satisfaction are reported with US- and ST-VABB procedures, with two studies reporting 97% patient satisfaction.[12,31,40,41]
  - Of patients who had received VABB, 90%12 or more56 indicated that they would prefer VABB over surgical biopsy in a comparable clinical situation (i.e. if a further biopsy was required).
  - Scarring was observed in only 2-10.5% of VABB patients with US and ST-guided procedures.[72]

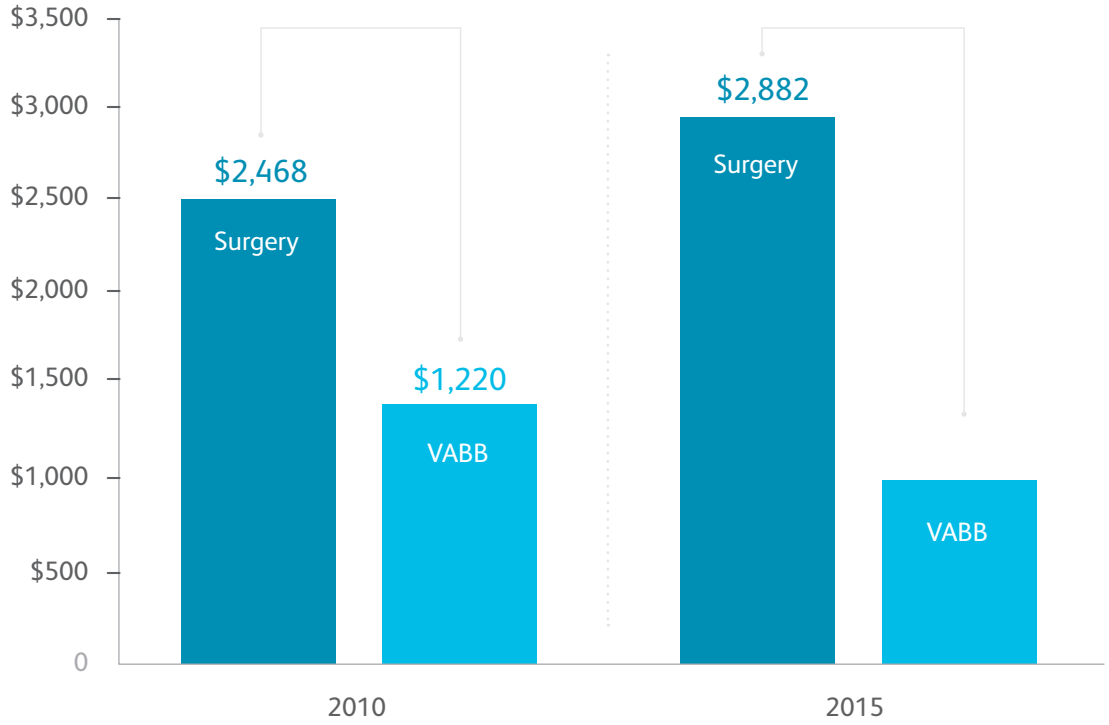


- VABB has been reported to be well-tolerated, with complication rates similar to CNB.[40,48,51]
  - CNB and VABB have reported rates of severe complications at <1%.[28]
- VABB is predicted to be a cost-efficient strategy in several situations due to potential avoidance of costly procedures.[32,73,74] In lesions determined to be unsuitable for CNB, VABB has been shown to be a cost-saving alternative.[32]
  - In lesions suitable for CNB, VABB was predicted to be approximately cost neutral vs. CNB, based on a modeled analysis of upfront acquisition and downstream intervention costs.[74]

Benign breast lesions

- A BD conducted review of the Premier Database (the BD Review) compared VABB (n=184,663) to surgical excision (n=154,667) for fibroadenoma removal[¥] and found significant economic benefits with VABB.[54]
  - In 2015, mean procedure costs of VABB were 29.2% of those for surgical excision ($842 vs. $2,882, respectively).54
  - Over time, mean procedure costs with VABB steadily decreased, while procedure costs with surgery increased, thus presenting an opportunity for providers to save money on procedural costs (2010-2015, see table).[54]

VABB mean procedural cost by year



	Mean Procedural Cost by Year					
	2010	2011	2012	2013	2014	2015
Surgery	$2,468	$2,590	$2,515	$2,678	$2,639	$2,882
VABB	$1,220	$1,183	$1,005	$1,152	$794	$842
Savings with VABB	**$1,248**	**$1,407**	**$1,510**	**$1,526**	**$1,845**	**$2,040**

- In addition, the BD Review (2010-2015) found reduced readmission rates ranging from (4% to 9%) per year for VABB compared to rates ranging from (11% to 17%) per year for surgical excision.[54]

¥ Fibroadenomas are benign, non-cancerous tumors composed of both glandular and stromal (connective) tissue. They are a common diagnosis, especially among women in their 20's and 30's.[75]

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