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SCIENTIFIC REVIEW

The Evolving Role of Vacuum Assisted Biopsy of the Breast: A Progression from Fine-Needle Aspiration Biopsy

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Abstract

Background The management of breast disease has been greatly facilitated by the technology of needle biopsy interventions, and over the past 30 years, this has evolved from the use of fine-needle aspiration biopsy (FNAB) to the current methodology of vacuum assisted biopsy (VAB).

Methods This article provides an historical review of the application of needle interventions of the breast in the diagnosis and management of breast conditions, and discusses current indications for the use of vacuum assisted biopsies and vacuum assisted excisions.

Results Whilst FNAB continues to have a limited role in breast disease diagnosis, the necessity of achieving an histological diagnosis has preferentially seen the development and wider application of automated core needle biopsies (CNB) and VAB in the assessment and management of breast lesions. The advantages of CNB and VAB include the ability to distinguish in situ and invasive disease pre-operatively, and the ability to achieve prior knowledge of immunohistochemical tumour markers particularly in the setting of neoadjuvant drug treatments.

Conclusion Due to its ability to obtain larger tissue samples, VAB does have diagnostic advantages over CNB and indications for the utilization of VAB are discussed. VAB additionally has an expanding role as a tool for breast lesion excision.

Introduction

Breast disease and breast cancer are very common conditions in western countries with approximately 10–12% of women developing a breast malignancy during their lifetime and at least 60% being diagnosed with benign breast disease [1]. Over the past 25 years, the diagnosis of breast disease has been facilitated by advances in imaging including mammography, ultrasound and magnetic resonance imaging (MRI) as well as significant improvements

in interventional procedures such as fine-needle aspiration biopsy (FNAB), core needle biopsy (CNB) and vacuum assisted core biopsy (VAB). Although VAB is increasingly utilised in practice today and has established benefits in the world literature, there is a void in the current indications for VAB in both its diagnostic and therapeutic performance [2].

This review aims to provide an overview of the changes which have occurred in breast needle interventional procedures over the past 40 years and explores the current position of VAB in the diagnosis and management of breast pathology.

Development of fine-needle aspiration biopsy

Fine-needle aspiration biopsy was first pioneered in the Karolinska Institute in Stockholm in the 1960s with the establishment of an FNAB clinic [3, 4] although its
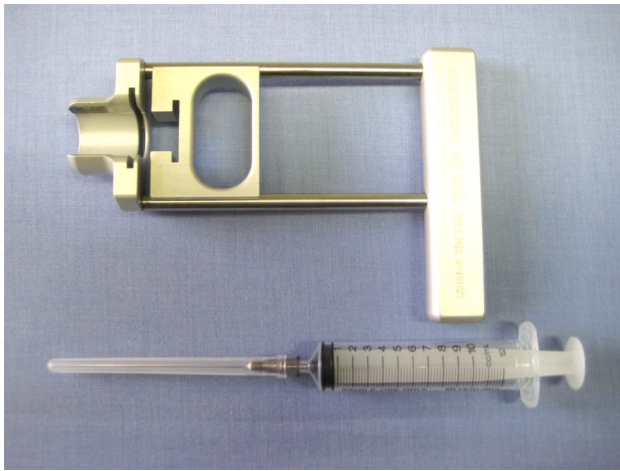
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Fig. 1 Performance of fine-needle aspiration biopsy (FNAB) can be greatly assisted with the use of a 22-gauge 6-cm needle and a pistol-grip syringe holder

diagnostic application in palpable breast abnormalities was not until the 1970s. The FNA technique consists of inserting a thin needle (0.6–0.7 mm outside diameter) into the tumour mass and aspirating cellular material into the needle hub by negative pressure produced by drawing back the plunger of a 10-ml syringe attached to the needle (Fig. 1). During sampling, the needle is moved back and forth through the tumour mass several times and at different angles, and the aspirated cellular material is then smeared onto glass slides, with usually one being air-dried and one being alcohol fixed.

One of the earliest reports on the use of aspiration cytology in breast cancer was by Blumgart in Glasgow in 1975 [5]. The diagnostic accuracy of this method was 95.5% in 237 lesions, both benign and malignant. Subsequently, FNAB was heralded as a safe procedure with a high diagnostic accuracy and represented an important step ahead in the management of breast cancer.

In a further report in 1984 by Dixon et al. [6], FNAB was used in the Royal Infirmary Breast Clinic in Edinburgh over two periods in 1978–1979 and 1981–1982 with multiple operators and a single operator, respectively. In the first period, the sensitivity was reported as 66% for malignancy rising to 99% in the single operator period.

Consequently, by the 1980s, FNA became an essential component of the triple test for breast assessment as an adjunct to clinical examination and mammography. With the inclusion of FNAB, the triple test had a diagnostic accuracy of at least 95% for benign and malignant lesions [7, 8].

As result of these and other reports [9–11], the benefits of FNAB can be summarised as:

1. It is a quick, easy and inexpensive technique to perform for palpable lesions in an outpatient setting taking less than 5 min.
2. It is suitable for patients on anticoagulants, allowing effective haemostasis by direct pressure applied on the biopsy area.
3. It is suitable for lesions close to adjacent structures such as skin, chest wall or implants.
4. The strength of FNAB lies in its ability to diagnose or confirm probable benign disease (American College of Radiology BI-RADS 3 [12]).

However, FNAB/FNAC also has disadvantages, including a high non-diagnostic rate of up to 40% [13]; high operator dependency for quality assurance with interpretation primarily relies on the competence of the cytopathologist. References [14–16] and it is also not particularly suitable for microcalcifications. FNAC cannot distinguish between in situ and invasive diseases, thus hindering preoperative decision-making in regard to issues such as sentinel node biopsy [17, 18], and hormone receptor status cannot be reliably assessed [19–21].

Transition to core biopsy

Owing to these deficiencies with FNAB, the subsequent development of automated spring-loaded core needle devices emerged. Various reports such as those of Britton et al. [22] demonstrated disappointingly high inadequate rates and low sensitivities of FNAB compared to CNB in the NHS Breast Screening Program (NHSBSP). Inevitably, by the mid-1990s, CNB became the new standard intervention replacing FNAC by the late 1990s. This transition was also mirrored in Australia in the National BreastScreen Australia Program.

In 2006, Lieske et al. [15] reported on the results from an NHS Breast Screening Unit in Bedfordshire and Hertfordshire illustrating the superiority of CNB at pre-operative diagnosis of screen-detected cancers with absolute and complete sensitivities as 80% and 93%, respectively, compared to 65% and 82% for FNAB.

A review by Willems et al. [10] comparing the diagnostic capabilities of FNAC versus core biopsy showed overall better performance for core biopsy, with having an overall success rate of 99% compared to 60–75% for FNAC, particularly for lesions < 10 mm or > 40 mm with the added ability of reliable assessment of predictive biomarkers such as ER, PR and HER 2.

Hence, the overall advantages of CNB over FNAB can be summarized as follows:

1. The absolute sensitivity for CNB is greater than for FNAC [10, 23–26].

2. The specificity and positive predictive value of CNB is higher than FNAB, especially in atypical lesions and fibroepithelial lesions [24–26].

3. The inadequacy rate of FNAB for non-palpable lesions is higher than for CNB [13].

4. CNB can distinguish between in situ and invasive malignancies [17–19].

5. Core biopsy specimens can be radiologically evaluated to confirm accurate targeting and appropriate biopsy of the required lesion.

6. In the context of increasing use of neoadjuvant therapy in breast cancer, core biopsy samples can be more appropriately assessed to allow immunohistochemical and molecular profiling of tumour samples [20, 21].

Thus, by the early 2000s, spring-loaded automated CNB offered a new diagnostic gold standard for breast lesions. Devices such as the BARD Magnum biopsy gun with needle sizes ranging from 14 to 18 gauges became mainstream. These devices allowed attachment to mammographic stereotactic units or could also be used freehand under ultrasound guidance allowing imaging localisation with the provision of a disposable coaxial guide device for multiple biopsies. Therefore, a clear role for conventional CNB in the diagnosis of breast disease evolved with particular indications including the workup of microcalcifications, the further assessment of suspicious or indeterminate FNAB findings and the definitive workup of suspicious radiological lesions including ultrasound BI-RADS 3, 4 and 5 lesions. (Table 1)

In the context of the development of breast screening programmes, many impalpable lesions are detected. In contrast to the 1990s, where standard practice for impalpable lesions was to undertake a hookwire-guided open surgical biopsy to establish a definitive histological diagnosis, the advent of CNB has enabled such a tissue diagnosis without the need to resort to surgery as the initial intervention. This has allowed a substantial reduction in the economic burden associated with open surgical biopsy. As three out of four patients with non-palpable breast lesions referred for surgical excision historically proving to be benign, the trend towards core biopsy has also reduced associated morbidity.

For patients with malignant lesions, CNB allows the establishment of a pre-operative tissue diagnosis aiding adequate surgical planning, multidisciplinary input and improved patient decision-making prior to definitive surgical treatment.

Open excision biopsy to exclude malignancy should only be used infrequently and under exceptional circumstances. For example, BreastScreen Australia National Accreditation Standards dictate that more than 75% of

Table 1 Breast imaging-reporting and data system (BI-RADS) classification is proposed by American College of Radiology and is a widely accepted risk assessment and quality assurance tool in mammography, ultrasound or MRI. http://www.acr.org/Quality-Safety/RADS

Assessment category	Management	Likelihood of cancer
Category 0: Incomplete—need additional imaging evaluation and/or prior mammograms for comparison	Recall for additional imaging and/or comparison with prior examinations	N/A
Category 1: Negative	Routine mammographic screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine mammographic screening	Essentially 0% likelihood of malignancy
Category 3: Probably benign	Short-interval (6 month) follow-up or continued surveillance mammography	< 2% likelihood of malignancy
Category 4: Suspicious	Tissue diagnosis	> 2% but < 95% likelihood of malignancy
Category 4a: Low suspicion for malignancy		> 2% to ≤ 10% likelihood of malignancy
Category 4b: Moderate suspicion for malignancy		> 10% to ≤ 50% likelihood of malignancy
Category 4c: High suspicion for malignancy		> 50% to < 95% likelihood of malignancy
Category 5: Highly suggestive of malignancy	Tissue diagnosis	≥ 95% likelihood of malignancy
Category 6: Known biopsy-proven malignancy	Surgical excision when clinically appropriate	N/A

malignancies be diagnosed without the need for an open surgical biopsy [27]. In 2014, the Queensland BreastScreen programme diagnosed 92.2% of screen-detected cancers pre-operatively using core biopsy [28].

Advanced breast biopsy instrumentation (ABBI) device

It is of historical interest that in the late 1990s, a new large bore biopsy device called the Advanced Breast Biopsy Instrumentation (ABBI) device was introduced employing computer-guided stereotactic localization to target and excise mammographic lesions under local anaesthesia, without the need for an operating theatre. Although there was initial enthusiasm, the device proved to have significant limitations and inherent mechanical problems, and in a report by Ferzli, up to 24% of cases had to be converted to an open surgical biopsy to achieve an adequate biopsy result [29]. Smathers noted it to be a poor excision tool with 85.2% of malignant lesions having positive margins following attempted excision. This device thus subsequently fell out of favour and is no longer in production [30].

Transition to vacuum assisted biopsy (VAB)

Vacuum assisted biopsy (VAB) of the breast was first developed in 1995 by a radiologist Fred Burbank [31] in California in association with Mark Retchard, a medical device engineer with the aim to improve the deficiencies of the automatic core biopsy gun technique. Burbank and Parker went on to introduce both stereotactic and sonographically guided VAB into clinical practice as an effective diagnostic tool to evaluate indeterminate lesions on mammography and ultrasound [32, 33]. In 1998, breast surgeon Victor Zannis wrote of his experience with ultrasound-guided VAB in a landmark paper which heralded the disappearance of open surgical biopsy for non-palpable breast lesions [34].

The vacuum assisted core biopsy device is essentially a core biopsy needle with an associated suction chamber and a rotating cutter. The vacuum draws tissue into the aperture of the needle which is then sliced off with the rotating cutter, and the specimen is transported to a port chamber usually without the need to remove the needle from the biopsy site (Fig. 2). Hence, multiple tissue samples can be taken through a single skin puncture without the need to repeatedly relocate the needle.

The first device was the handheld Mammotome biopsy device marketed by Johnson and Johnson; however, many
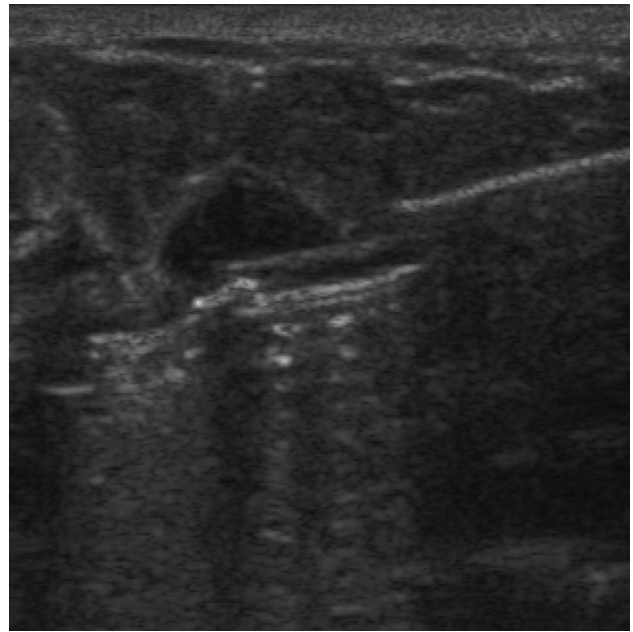

Fig. 2 Under ultrasound vision, the VAB needle is usually placed at the under-surface of the lesion to draw the mass into the hub of the needle which can then be biopsied by the advancing rotating cutter

other similar devices are now on the market including the Hologic Suros ATEC and the BARD Encore range of devices.

Sizes of VAB probes

VAB needles presently come in various diameters including 14 g, 11 g, 8 g and 7 g.

The 14-g VAB needle is the least invasive of the three needles and can collect samples of tissue 40 mg in size with one insertion, more than twice the amount collected by a conventional core biopsy probe averaging 17–20 mg per procedure.

The 11-g needle can collect samples averaging approximately 100 mg, whereas the 8-g needle sample size is approximately 300 mg of tissue. As the 8-g needle sample size is approximately three times the amount collected by a 11-g needle, it can be very appropriately used to resect breast lesions with a therapeutic intent.

VAB image guidance methods

For lesions visible only on mammography, stereotactic percutaneous VAB is the method of choice, particularly useful in indeterminate or suspicious microcalcifications. Although CNB is also useful in evaluation of microcalcifications, there is an appreciation that VAB is particularly

useful for the extremes of size of microcalcification clusters. Essentially, stereotactic VAB is particularly advantageous for sampling very small foci of microcalcification, often difficult to target with conventional CNB, and also for sampling a large or multifocal area of microcalcification suspicious for DCIS where multiple adequate samples can be taken to confidently exclude invasive cancer.

Ultrasound-guided handheld VAB provides a more time-efficient tissue collection compared to conventional biopsies taking significantly less time. The removal of a sonographically visible lesion, particularly with larger needles, can therefore be done with real time visualisation.

The role of MRI in breast assessment is valuable allowing a higher sensitivity in younger women or women with dense breasts. However, its specificity varies between 37 and 97% leading to a high rate of false positive lesions. VAB devices are now MRI compatible and are being increasingly utilized, allowing rapid exclusion of false positives [35, 36].

Defining indications for VAB

Whilst the appropriate application of VAB in the management of breast disease remains somewhat controversial and open to discussion, documented below are indications which have been proffered in the scientific literature.

Diagnostic indications

1. *Inconclusive histopathology results* In situations where the FNAB or core biopsy have resulted in an inadequate result for a clinical or radiologically detected lesion, VAB is useful to provide more tissue for further diagnostic clarity.

2. *Histological discordance* Wang et al. studied 62 patients in whom there was mismatch or discordance between the breast imaging and the CNB histology, and when these lesions were further assessed with vacuum assisted techniques, malignancy was discovered in more than 20% of instances [37]. Therefore, in the case of discordance in CNB, further assessment with VAB is beneficial.

3. *American College of Radiology BI-RADS category 4* Lesions classified in this category have an approximate 30% likelihood of being malignant, and for this reason, VAB may provide a more accurate histological diagnosis in selected cases. Cassano et al. [38] demonstrating VAB to be associated with very high negative predictive rate (99%).

4. *Difficult location of lesions* Lesions in areas, such as close proximity to the chest wall, very superficial, close to the skin or nipple or in the context of lesions close to breast implants, may be more readily biopsied by use of a VAB device rather than CNB.

5. *Small sonographic lesions* Lesions < 5 mm are more easily targeted with VAB than with a standard core.

6. *Microcalcifications of extreme size* Small foci of microcalcification may be challenging to target with a conventional core biopsy. Large diffuse areas of microcalcification, particularly where DCIS is suspected, can be managed more effectively with VAB as multiple large samples can be taken from several sites with an increased probability of detecting or excluding invasive carcinoma.

7. *Management of suspected DCIS* Avoidance of underestimation of invasive disease. Suh et al. [39] demonstrated a significantly higher underestimation rate of an invasive component in DCIS for core biopsies compared to VAB (47.8% vs. 16.1%; $p < 0.001$) using 14-gauge core needle and 8 or 11 vacuum needles, respectively. Similar results were published by Brennan et al. in a meta-analysis of 52 studies involving 7350 cases of DCIS, showing that the underestimation rate of invasive carcinoma for 14-gauge automated core biopsies was 30.3%, whereas for 11-gauge VAB biopsies, this was 18.9% ($p < 0.001$) [40].

8. *High-risk groups* VAB may also be contributory in a selected group of category 3 patients who are at high risk either due to family history or genetic alterations, or in the context of a synchronous carcinoma being diagnosed and surgery being contemplated.

9. *Atypical or borderline breast lesions (B3)* The role of VAB in the context of atypical or B3 lesions such as papillomas, lobular neoplasia, atypical ductal hyperplasia, mucinous lesions and radial scars is still evolving.

   With regards to B3 lesions, the underestimate rate of malignancy with a conventional core biopsy needle is as high as 25% and therefore, an open surgical biopsy is usually recommended [41]. Londero et al. [42] compared the malignancy underestimation rates in 300 borderline breast lesions (B3) diagnosed percutaneously using 14-gauge core needle biopsies or 11-gauge vacuum assisted biopsies and who subsequently went on to open surgical excisions. Of the 151 benign papillomas, 88 radial sclerosing lesions, 46 lobular neoplasia and 15 atypical ductal hyperplasia diagnosed, the malignancy underestimation rates was lower in the VAB group (12.5% vs. 12.7%), but particularly for certain subgroups of pathology such as papillomas (0% vs. 11%) and lobular neoplasia (23% vs. 40%).

10. *Close nipple proximity* In the context of women contemplating a nipple-sparing mastectomy for

invasive or in situ carcinoma, VAB has proven to be useful as a means of sampling the tissue immediately deep to the nipple prior to surgery to provide a pre-emptive assessment of the safety of proceeding in this fashion [43].

Therapeutic indications

VAB and ultrasound-guided VAB in particular have also been used as a safe and effective method for complete excision of benign breast lesions [44–46].

In 2002, the FDA approved VAB for the removal of benign lesions due to its ability to remove a large amount of tissue [45, 47, 48]. Whilst surgical excision is still the gold standard treatment for removal of symptomatic palpable lesions, the therapeutic use of VAB is an alternative to surgical excision. VAB is most commonly used for excision of fibroadenomas and can be heralded as an alternative treatment modality with residual or recurrent lesions. [44, 46, 49, 50] Most of these studies reported very high success rates with residual or recurrent lesions found in less than 10–15%. Lee reported that image-guided complete excision was achieved in 84.9% of benign breast lesions without residual lesions or recurrence on long-term follow-up for more than a year, with there being only minimal residual areas identified in 12.7% on follow-up [51]. The recommended lesion size to be considered for excision by VAB is recommended to be up to 2 cm in diameter [45].

Further indications for therapeutic VAB excision include recurrent cysts and intraductal or intracystic growths [45]. Dennis et al. reported that VAB could be used to treat nipple discharge and could be used as an alternative to surgical excision to excise intraductal papillomas found within several centimetres of the nipple [52].

A number of reports [53, 54] have demonstrated a potential-evolving role for the use of vacuum assisted excision (VAE) in the management of pathologically diagnosed B3 lesions (of uncertain malignant potential) which might include lesions such as radial scars, papillary lesions without atypia, mucinous lesions and some atypical epithelial hyperplasias. Whilst it remains controversial, there is an evolving view that the utilization of a large bore VAB (8 gauge) to completely excise these areas may provide histological reliability that is equivalent to an open surgical biopsy. The potential advantage of VAB under these circumstances lies in providing a minimally invasive percutaneous therapeutic option which would therefore be less expensive than proceeding to open surgical biopsy. However, whilst VAE for B3 lesions may have a role in selected instances, it is important that this is undertaken in the setting of a thorough multidisciplinary discussion.

At this stage, very little data are available in relation to the potential application of VAB excisions for breast cancers and this would not therefore be currently recommended particularly as orientation of these specimens and definitions of margins cannot be achieved.

Complications

The main complications from VAB include pain at the time the procedure and bleeding post procedurally either in the form of ongoing haemorrhaging from the skin needle entry site or a post procedural haematoma [43, 44].

The liberal use of local anaesthetic will minimize pain during the procedure and particularly if this is infiltrated below the lesion on ultrasound where the VAB needle would usually be initially placed to draw the lesion down into the cutting chamber of the device.

Bleeding following upon the VAB procedure can usually be controlled by pressure over the region of the biopsy for approximately 10 min, and the application of an ice pack to the breast for approximately 30 min after that would also be advised to minimize bruising. Most studies, however, have reported significant bleeding and haematoma formation to be a low percentage risk.

Costs

There are significant costs associated with the use of VAB breast biopsies over and above the costs of performing a CNB or an FNAB. However, as the role of VAB evolves, and by streamlining indications and guidelines for the use of VAB, it is possible that saving in health costs can be achieved.

Alonso-Bartolome et al. [55] in analysis of the financial outlays of VAB pointed out that although the costs associated with VAB systems are ten times higher than for a standard CNB, the economic costs of VAB are 82% lower than a surgical biopsy and that the time spent by the patient was 71% less with VAB than with surgery. It is therefore important that VAB cost analyses need to be considered in the context of the overall economic costs related to any potential reductions in the need for open surgical procedures.

Future directions

The development of VAB breast biopsy technology has led to significant improvements in the management of women with breast disease. It has enabled the achievement of more accurate diagnoses with less upstaging from benign to

malignant diagnoses and less upstaging from intraduct to invasive carcinoma diagnoses on open excision.

VAB is particularly useful for managing discordance between breast imaging and FNAB or CNB, and it is particularly advantageous in the context of small sonographic lesions (< 5 mm), areas of microcalcification of extreme sizes, and it has an evolving role in the management of atypical/borderline B3 breast lesions.

Increasingly, VAB is being utilized not only for diagnosis but also as a therapeutic tool in the context of its ability to completely excise benign lesions particularly fibroadenomas. Whilst presently it is not being utilized to excise small breast cancers, undoubtedly as the technology improves and as newer similar devices are developed, this undoubtedly will be the next frontier and the future will see these devices utilized to provide minimally invasive surgery to the breast for both benign and malignant lesions.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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