Vacuum-assisted procedures of the breast: from diagnosis to therapy

By Dr. M. Javed, Dr. M. Morgan & Dr. W. Teh

Vacuum-assisted procedures have revolutionised the diagnosis and therapy of both benign and malignant breast pathologies and can be used under sonographic, mammographic, and magnetic resonance imaging guidance.

A proportion of patients being assessed for breast abnormalities require tissue sampling for histological analysis. This ensures accurate nonoperative diagnosis avoiding unnecessary surgery for benign conditions. Neoadjuvant, systemic treatment and axillary surgery can also be pre-determined in malignant disease.

Breast tissue sampling techniques have evolved considerably over the last 20 years. Fine needle aspiration was introduced in the 1930s by Martin and Ellis and its use became more prominent from the 1980s [1]. However, this technique aspirates only a small volume of cells and has low accuracy in impalpable lesions.

Core needle biopsy (CNB) introduced in the 1990s provides a larger volume of tissue albeit retrieving only one sample at a time [1]. In malignant lesions, CNB provides additional information on individual tumour biology including tumour type, histological grade, *in situ* status, lymphovascular invasion and hormonal receptor and Her-2 status. It is the favoured diagnostic tool for sampling of a sonographically visible breast lesion giving a diagnostic concordance with subsequent surgical excision of around 91% or higher [2]. Most centres in the United Kingdom use a spring-loaded, single use disposable biopsy gun and 2 or 3 cores of tissue are obtained to ensure representative sampling.

Despite the higher sensitivity rates of CNB, breast pathologies with inherent heterogeneity may be inadequately sampled by CNB leading to histological underestimation. Vacuum assisted breast biopsy (VABB) was developed in 1993 by Fred Burbank and colleagues to overcome some of the limitations of CNB. His technique utilised vacuum technology combined with larger bore needles which allowed retrieval of increased sample weights of breast tissue. A 14g CNB removes approximately 18mg of tissue per core compared with 84mg per core for 11g VAB, 121mg per core for 9g VAB and approximately 363mg for 7g VAB [3]. Therefore, 12 passes of a 7g VAB would recover approximately 4g of tissue which is the equivalent of a small surgical biopsy. [Figures 1 and 2] .

VABB utilises a console unit and disposable handpiece with needle size ranging from 7-12 gauge. Tissue collection is either automated or manually controlled by the operator using hand or foot switches. The handpiece utilises a double-lumen probe and the vacuum generated draws adjacent breast tissue in to the trough of the needle enabling the tissue to be excised by a rotating trocar. The tissue then passes into a tissue filter within a biopsy chamber ready for retrieval and histological assessment. The currently available systems are directional, allowing continuous 360 degree sampling of a lesion through a single needle puncture as a local anaesthetic procedure.

The increase in size of the tissue cores retrieved by VABB has significantly reduced sampling error and histological underestimation and in turn has reduced surgical upgrade rates of malignancy. The recent evolution in practical applications of vacuum procedures has ensured that VABB is integral to both diagnostic and therapeutic patient management pathways.

Figure 1. From top to bottom. 14g spring loaded disposable core biopsy needle; 9g VABB needle; 7g VABB needle

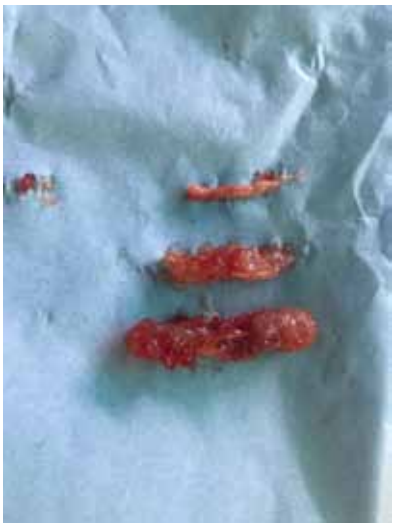

Figure 2. From top to bottom. Cores of tissue from 14g, 9g and 7g needles.

VACUUM ASSISTED DEVICES IN THE DIAGNOSIS OF BREAST PATHOLOGY

The UK NHS Breast Screening Programme (NHSBSP) requires that a minimum of 90% of invasive cancers and 85% of non-invasive cancers should be diagnosed by a minimally invasive non operative biopsy rather than a diagnostic surgical procedure. Women undergoing diagnostic

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Figure 3 The Hologic Brevera biopsy system with touch screen console and display monitor showing real time specimen radiograph of individual biopsy chamber

surgery should be minimised to ≤ 3.5/1000 at the prevalent screening round and ≤ 1.6/1000 at their incident screen (NHS BSP guidelines)..

The exponential use of VABB in the UK NHSBSP has led to a marked increase in nonoperative diagnosis rates with a concomitant fall of diagnostic surgical biopsies. At our institution stereotactic/ tomosynthesis guided VABBs, are performed as the first line procedure for all indeterminate USS occult lesions including microcalcifications, mammographic distortions or small lesions of less than 5mm.

VABB is regarded as a highly sensitive and specific biopsy method and numerous studies have shown superior results with VABB (11-8 gauge) compared with 14 gauge CNB [4, 5]. A systematic review by Fahrbach et al. demonstrated a higher frequency of technical failures with CNB than VABB (5.7 vs. 1.5%) and with non-diagnostic samples (2.1 vs. 0%). Of the non-diagnostic CNB samples, 23% were subsequently found to be malignant [6]. A systemic review by Huang *et al.* showed superior diagnostic performance by VABB compared to CNB in the diagnosis of DCIS [3].

The use of VABB as a first line procedure is supported by a recent study which demonstrated VABB to have higher sensitivity than 14g core biopsy [7]. Although 14g core biopsy is more cost effective, it is less sensitive as first line sampling for microcalcifications. There is also a trend for lower repeat biopsy rate, higher diagnostic accuracy and lower surgical upgrade with VABB [7].

Advances with VABB technology include the Brevera (Hologic) device which has a built-in specimen x-ray cabinet to streamline breast biopsy using real-time verification of calcifications [Figures 3 and 4]. This allows early confirmation of representative microcalcifications and hence potentially minimising the number of samples required. The aim is to reduce procedure time, patient discomfort and complications. Our initial results of sampling of 90 MCC clusters showed earlier confirmation of calcification retrieval during the biopsy procedure due to real-time imaging. However 18% of cancers would have been underdiagnosed if sampling was stopped as soon as calcification was confirmed to be present.

During 2016 – 2018 we performed 1900 first line stereotactic vacuum biopsies on screening patients and in the majority of cases a definitive diagnosis could be made using the tissue sample retrieved at this initial procedure. There are however a number of clinical scenarios where more tissue is required, including histology considered not to be representative of the targeted lesion (B1); lesions suspicious for malignancy (B4) and high risk lesions (B3) which are a heterogenous group of pathology with uncertain malignant potential. More tissue is required to aid diagnosis in these situations in order to confidently exclude an associated malignancy or indeed to upgrade pathological classification of a lesion with suspicious radiological features. At our institution a larger volume of tissue is retrieved by performing a vacuum assisted excision (VAE). The majority of VAE are for B3 lesions, which may coexist with malignant disease and are found in approximately 7% of breast core biopsies. This group includes Flat Epithelial Atypia (FEA) (35%), Atypical Ductal Hyperplasia (ADH) (20%), papillary lesions (PL) (20%), Lobular Carcinoma in Situ (LCIS), and radial scars (RS)/complex sclerosing lesions [8]. Surgical excision has traditionally been required to obtain a definitive histological diagnosis and to exclude associated malignancy. These lesions have different upgrade rates on CNB to malignancy on surgical excision ranging from 8.9% for RS without atypia to 50.4% for ADH in a large series of 1,025 B3 core biopsies, which also illustrated lesions with associated atypical proliferation consistently having a much higher upgrade rate [9].

Though high risk lesions are usually excised surgically, the UK NHSBSP guidance recommends VAE. This should be performed

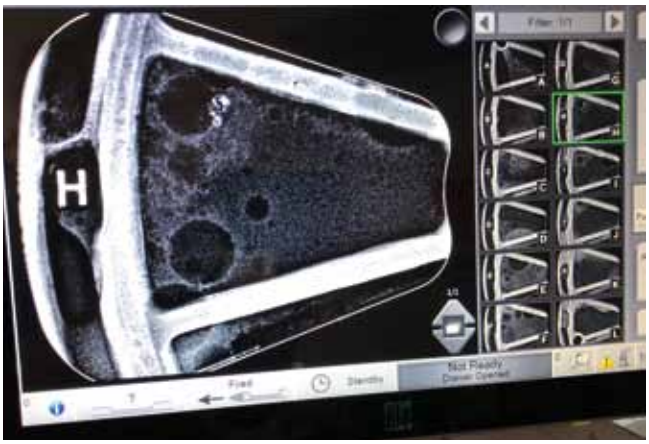

Figure 4 Display monitor with 12 thumbnails corresponding to individual tissue retrieval chambers seen on the right hand side of the screen. On the left hand side is a magnified image of an individual chamber confirming calcification within the tissue specimen.

with a larger bore needle with either 7 gauge or 8 gauge devices obtaining approximately 4 grams of tissue. This obviates the need for diagnostic surgical excision allowing either a definitive diagnosis of malignancy or the patient to be safely discharged to annual mammography.

VAE can be performed using either stereotactic, USS or MRI guidance depending on how the lesion is best visualised. USS guided vacuum sampling is a well-established and well tolerated alternative to open surgery for both diagnostic and therapeutic indications. It is a minimally invasive well tolerated procedure requiring a skin incision of less than 5mm, performed in an

outpatient setting under local anaesthesia and taking between 15-60 minutes to completion. USS VAE is generally used for excision of large mass lesions requiring further histological assessment due to lesion size and associated risk of under sampling. For lesions seen only on MRI, MRI guided biopsies are performed. Published literature has shown the overall malignancy rate for MRI biopsies in high risk patients is around 21 -23 % [10, 11].

Not all lesions can be adequately diagnosed using VAE. In particular, papillary lesions with atypia diagnosed on needle biopsy have a malignant upgrade rate of up to 36% and require surgical excision to properly assess the entire lesion [12]. We performed a retrospective analysis of 125 papillary lesions which underwent vacuum excision over a 2-year period and found a malignant upgrade of 29.6%.

"... This potential evolution in vacuum application utilises a more intelligent and considered approach to radiologically guided sampling of breast tissue..."

VACUUM ASSISTED DEVICE SYSTEMS FOR THERAPY OF BREAST PATHOLOGY

The last decade has seen significant evolution in the role of vacuum devices for the treatment and symptom control of benign breast pathologies. Therapeutic vacuum assisted excision is now being used to excise fibroadenoma. In papilloma (without atypia), excision can alleviate the symptoms of nipple discharge. There is no maximum size limit of lesion that can be removed with this technique but anecdotal evidence suggests that lesions over 3cm have an increased risk of recurrence. Wahab *et al.* found complete excision to be 100% for lesions < 15mm, but decreased to 61% for lesions between 15 -20mm [13]. We also use VAB to drain complex seromas, abscesses and post-surgical haematomas.

There is now an acceptance that vacuum assisted technology plays an integral part in the management of breast pathologies, however we are now looking to further extend the applications of this technique. As in cardiac surgery, conventional open surgical therapies have been largely replaced by imaging guided minimally invasive procedures and there is now a similar movement towards less aggressive surgical intervention in the treatment of breast cancer and node positive axillary disease. This has been made possible by our ever increasing understanding of the biology of breast cancer allowing for a more personalised treatment regime targeting a patients individual tumour characteristics with evolving neoadjuvant chemotherapy regimens and sophisticated oncoplastic techniques. This potential evolution in vacuum application utilises a more intelligent and considered approach to radiologically guided sampling of breast tissue. In certain clinical scenarios, the excision of larger volumes of tissue or excision of lesions in their entirety may significantly alter the perception of established breast treatments with conventional surgical management playing less of a key role in definitive treatment.

Multicentre trials are being conducted utilising VABB as a means of minimising the requirement for surgery. In the UK LORIS study, VABB is used to establish the diagnosis of low-grade DCIS and to randomise patients into surveillance or conventional surgical treatment. The PICASSO study aims to pilot the use of non operative vacuum excisions of small to moderate sized breast cancers in women who are unfit for surgery. A further example is the concept of performing extensive vacuum sampling for patients who have undergone neoadjuvant chemotherapy and who have demonstrated an apparent complete radiological response to treatment. This provides a more accurate assessment of the presence of residual disease than imaging alone and enables a more informed decision making process for surgical planning and treatment.

CONCLUSION

In conclusion, sampling and excision of lesions using VABB for both diagnostic and therapeutic indications has now become standard of care. In the UK we are already utilising this technique to avoid unnecessary surgery in asymptomatic women with incidental high risk lesions. However recent advances in technology and trials centred on evolving and extended applications of vacuum assisted beast tissue excision show further promise of a treatment revolution in the diagnosis and management of breast cancer.

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