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The Changing Role of Vacuum-assisted Biopsy of the Breast: A New Prototype of Minimally Invasive Breast Surgery

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Over the past 25 years the diagnosis and management of breast disease has been greatly assisted by the development of new needle biopsy techniques with ever-improving technology. Fine needle aspiration biopsy (FNAB) was quickly superseded in the 1990s by automated core needle biopsy (CNB) techniques and the early 2000s saw the widespread introduction of vacuum-assisted breast biopsy (VAB) devices.

The impetus for the transition from FNAB to CNB was the improved sensitivity and specificity of CNB over the fine needle technique[1,2] and the fact that FNAB was associated with a significantly high inadequacy rate.[3] CNB also provided superiority of diagnosis in being able to distinguish between in situ and invasive malignancy according to histological assessment,[4] and additionally because the immunohistochemical and molecular profiling of tumor samples is able to be undertaken providing information in relation to estrogen receptors, progesterone receptors, and HER2 for purposes of planning systemic treatments and neoadjuvant drug therapies.[5] Additionally, the modern management of breast cancer patients importantly necessitates the ability to achieve a tissue diagnosis before definitive cancer surgery so that proper consultation can be undertaken with the patient being fully informed before definitive surgical treatment. Indeed, current preferred practice would dictate that the use of surgical excisional biopsy to establish whether a breast lesion is benign or malignant should only be used infrequently and under exceptional circumstances. BreastScreen Australia in its National Accreditation Standards requires that more 75% of malignancies should be diagnosed without the need for open surgical biopsy.[6]

Core needle biopsy as well as VAB offer the ability to achieve a diagnosis nonsurgically for breast lesions, however, recent reports have shown that VAB might have superiority in certain circumstances in terms of its diagnostic ability, and in its capacity to achieve complete excision of breast lesions.

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The vacuum-assisted core biopsy device is essentially a core biopsy needle with an associated suction chamber and rotating cutter. The vacuum draws tissue into the aperture of the needle, which is then sliced off with a rotating cutter. Although some of the earlier VAB devices required the needle to be extracted from the breast so that the specimen could be retrieved, most current VAB devices transport the specimen using suction into a port chamber without the need to remove the needle from the biopsy site, thus enabling multiple tissue samples to be taken through a single skin puncture without the need to repeatedly relocate the needle. Vacuum-assisted biopsy of the breast was first developed in 1995 by Fred Burbank, a radiologist at Stanford University, California, and although the first commercially available device was the Mammotome marketed by Johnson & Johnson (New Brunswick, NJ), many other similar devices are now available on the market including the Hologic Suros Atec (Hologic Inc, Marlborough, MA) and the BARD EnCore (Bard Biopsy Systems, Tempe, AZ) range of devices. The main advantage of the VAB devices lies in their ability to excise large specimens of tissue. For example the standard 14-gauge CNB excises a specimen of approximately 20 mg, and a 14-gauge VAB needle will extract a sample of 40 mg, however, a 7-gauge VAB needle can extract samples of approximately 300 mg, and with multiples of the samples being able to be removed.

Vacuum-assisted breast biopsy can now be used with all of the usual breast imaging modalities including mammography, ultrasound, and magnetic resonance imaging (MRI). Ultrasound is the most easily used and preferred imaging to guide the performance of VAB and from the perspective of the breast surgeon who uses ultrasound in his practice this a readily usable technique. Mammographic stereotactic percutaneous VAB and MRI-guided VAB are used when the breast lesion of concern is only visible using either of these modalities. Stereotactic needle biopsy is most commonly used for microcalcification and MRI has a particular application in younger women with dense breast parenchyma, particularly those at high risk of familial breast cancer.

In the diagnostic context the indications for VAB are continuing to expand. One of the most useful roles of VAB is when there is discordance between the breast imaging findings and the fine needle aspiration cytology or core biopsy histology. Wang et al[7] in a study of 62 patients in whom lesions were found to be ultrasound

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imaging–histologic discordant after CNB, the subsequent use of VAB was associated with the discovery of malignancy in up to 23% of cases.

There is also a good argument for advocating the use of VAB for selected cases in Breast Imaging-Reporting and Data System Category 4, particularly 4a, which is associated with a low but significant risk of malignancy in the range of 2% to10%, because VAB has been shown to have a very high negative predictive rate (99%).[8]

Vacuum-assisted breast biopsy is also particularly useful in the context of small lesions, including small sonographic lesions <5 mm as well as very small clusters of microcalcification, both of which are more easily targeted with VAB than with a standard CNB. However, microcalcifications of extreme size and particularly diffuse areas of pleomorphic microcalcification when ductal carcinoma in situ (DCIS) is suspected might be more effectively sampled with VAB to improve the probability of detecting or excluding invasive carcinoma in the context of a provisional diagnosis of DCIS. A meta-analysis by Brennan et al,[9] which included 52 studies and 7350 cases of DCIS, the underestimation rate of invasive carcinoma for 14-gauge CNB was 30.3% whereas for an 11-gauge VAB this same number was 18.9%.

Vacuum-assisted breast biopsy is also the preferred method of needle intervention for lesions that are very deep or close to the chest wall or very superficial and close the skin or nipple because the VAB mechanism does not involve a 'throw,' as is the case for CNB, which might be less safe in these circumstances.

Vacuum-assisted breast biopsy has also been shown to have an increasing therapeutic role. In view of the large sample size, which a VAB device can collect, and because multiple samples can be retrieved at each intervention, it is feasible to completely excise breast lesions. The most commonly targeted lesions have been fibroadenomas and numerous studies have now been reported using VAB as an alternative to surgical excision for the management of fibroadenomata.[10,11] Most studies have reported very high success rates with residual or recurrent lesions found in less than 10% to 15% of cases. Lesions up to 2.5 cm can be effectively removed using VAB and this is most commonly performed using ultrasound guidance.

Additionally, there appears to be an increasing role for VAB in the management of atypical B3 types of pathological lesions. The pathologic B coding system classifies lesions on core biopsy on a scale of B1 (normal and nondiagnostic) to B5 (malignant) with category B3 being lesions of uncertain malignant potential, and including a range of entities such as atypical epithelial proliferation, lobular neoplasia, radial scars/complex sclerosing lesions, phyllodes tumors, papillary lesions, and columnar cell change. In this setting B3 lesions represent a diagnostic and therapeutic dilemma, making it important to exclude the possibility of malignancy. Published literature would suggest that standard CNB has been shown to have an underestimation rate of malignancy of approximately 25% for these histological types of lesions[11] and for this reason traditionally surgical excisional biopsy has been recommended. However, some reports would indicate that VAB does perform better diagnostically than CNB in this setting of B3 lesions, particularly for certain types of nonatypical B3 lesions such as papillomas, radial scars, and fibroepithelial lesions.

Indeed, there have been some recent reports asserting a role for VAB as the definitive means of managing many of these B3 lesions and in the context of using VAB as the definitive excision method. Strachan et al[12] at Leeds (United Kingdom) developed clinical pathways for the management of B3 lesions with as well as without atypia, with VAB being offered as first- or second-line management, and with second-line VAB being the equivalent of a diagnostic excision. In this series of 398 patients, 245 (62%) of women were able to avoid an unnecessary diagnostic excisional biopsy and instead were able to be managed with VAB with median follow-up at 3 years showing no evidence of cancer being detected at the original B3 site.

Moreover, a recent international consensus conference[13] in Switzerland on the management of B3 breast lesions has recommended a new approach to these lesions incorporating therapeutic VAB in lieu of open surgical excision as an acceptable method of management for a range of B3 lesion types including flat epithelial atypia, papillary lesions, radial scars with atypia, benign phyllodes tumors, and low-grade forms of lobular neoplasia. This heralds a significant strategy shift in the management of these types of atypical lesions, and on the basis of the current emerging evidence, this approach would appear to be justifiable.

However, as a consequence of the previously mentioned reports, further studies on the role of VAB in this context are clearly required, and guidelines would need to be established regarding the management of nonconcordance between the radiology and any initial biopsy result and the final VAB pathology, and recommendations made around the placement of tissue markers and the further management of any unexpected malignancy. The avoidance of open surgery and its associated hospital costs would potentially offer significant economic advantages for this new approach to managing these types of breast lesions and would undoubtedly offset the additional costs of the VAB equipment and needles.

These changed management paradigms, particularly encompassing VAB as a new minimally invasive excision tool for benign and atypical breast lesions, will invoke further debate around the issue of which specialists should be undertaking such interventions and what training is necessary. Because most breast abnormalities are sonographically visible, most of these interventions would be anticipated to be performed using ultrasound guidance. An important question in particular for breast surgeons, who have been the traditional interventionalists in breast disease management, is what role they will play in this setting. As a breast surgeon myself, and one who has used ultrasound in his clinical practice for the past 20 years, and who currently uses VAB, I believe it is important that breast surgeons upskill themselves in ultrasound and needle biopsy techniques to be able to offer patients this latest technologically optimal care. Breast surgeons now have access to numerous recognized national and international ultrasound training programs with associated credentialing bodies to appropriately facilitate skills development in this area, and it would be essential that surgeons avail themselves of these programs and achieve the necessary accreditation.

Disclosure

The author has stated that he has no conflicts of interest.

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