

**GUIDELINES ON BREAST BIOPSY
USING VACUUM ASSISTED DEVICES
(SUCH AS MAMMOTOME)**



Academy of Medicine, Singapore

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Introduction

Breast biopsies can be performed without imaging guidance (for palpable lesions) or with imaging guidance (for non palpable lesions).

The methods of imaging guidance used most commonly are ultrasound guided procedures and x-ray guided procedures, such as mammographically guided or stereotactically guided, using digital radiography.

Procedures performed most commonly are for presurgical hook wire localisation; fine needle aspiration or biopsy and large gauge core needle biopsy.

Large gauge core biopsy needles and devices used include 14G/16G spring loaded or automated biopsy guns and 11G Vacuum assisted devices such as Mammotome (Johnson & Johnson) and MIBB devices. The ABB1 and Site Select are other large gauge core biopsy devices which are also used.

These guidelines cover the use of vacuum assisted devices for breast biopsy performed under either ultrasound guidance or radiographic guidance (including devices directly mounted as add-on upright attachments to routine mammography units or devices used in conjunction with a dedicated prone stereotactic table unit). However the general recommendations should also apply to all breast biopsies and procedures performed, with or without imaging guidance.

General Principles

For clinically palpable breast masses, management is based on clinical evaluation usually combined with appropriate imaging studies. Percutaneous biopsy is often performed by the clinician, usually a surgeon and choice of biopsy needle can include FNA or large gauge needle biopsy.

For non clinically palpable lesions, these can be detected either on mammography or on ultrasound. These imaging studies should be interpreted by qualified physicians whose reports should also include assessment category of the lesion (e.g. benign, probably benign, intermediate, probably malignant or malignant) as well as recommendations for further assessment or evaluation

Indications for Biopsy

In general vacuum assisted biopsies are solely for diagnostic purposes and although is capable of completely removing small benign lesions, should not be used or considered as a curative procedure for small malignant lesions. There is now excellent evidence that even complete mammographic removal of a malignant lesion leaves mammographically invisible residual tumour behind.

Lesions to be biopsied using the vacuum assisted device can include, but are not limited to the following lesions:

1. Masses (detected either on mammography or ultrasound)

These can be cystic or solid masses

Indications for biopsy include, but are not limited to:

- Lesions categorized as Malignant can be biopsied prior to surgery to aid surgical planning.
- Lesions categorized as Probably malignant and Intermediate suspicion for malignancy.
- Lesions categorized as probably benign can also be biopsied but are often followed up by repeat imaging study.

2. Microcalcifications

In general the recognized indications include:

- To Confirm a diagnosis of malignancy
- To Determine the extent of malignancy
- To Positively establish a benign diagnosis
- To Clarify the pathology of an indeterminate lesion

Vacuum-assisted biopsy of these lesions is particularly useful when there are only very small clusters of calcification, or if the calcifications are rather poorly defined. In this situation, automated core biopsy not infrequently yields inadequate or indeterminate specimens.

Qualifications of Physicians

As this technique of image guided large core biopsy is under the general category of image guided interventional procedures, it is recognised that radiologists with training and expertise in this area are fully capable of performing this procedure and managing the patient. In fact, this procedure was developed by radiologists specifically to address

problems with image-guided core biopsy, and the equipment is designed with a single operator in mind. Nevertheless, properly trained surgeons with special interest in breast disease are also capable of performing this procedure, but they also require expertise in interpreting mammographic images and breast sonograms before and during the procedure.

Because of the ionizing radiation involved and advanced technology required particularly with the use of upright mammographic attachments and prone dedicated stereotactic tables, it is recommended that even if a surgeon is interested in performing these procedures, a collaborative approach should be used, with both surgeon and radiologist working together. To perform the procedure cooperatively, radiologists would direct the imaging workup and targeting of lesions with surgeons involved in sampling.

For ultrasound guided biopsies, these can be performed either by a single physician or again by a collaborative approach with both radiologist and surgeon involved.

Using Mammography Unit or Prone Stereotactic Table to Guide Biopsy

Radiologist and surgeon should practice collaboratively. Because of the need to use ionizing radiation, a radiologist should be involved in the procedure.

Patient selection and quality assurance are the joint responsibility of both physicians. Either or both physicians may perform the actual biopsy.

The person responsible for the licensing of the equipment is also responsible for the proper use of the equipment and has to comply with the existing licensing requirements. This person will also ensure that the technologist or radiographer used is properly trained and licensed by the appropriate authority and will be responsible for their supervision.

The radiologist will also comply with the requirements and recommendations of "Guidelines on the Practice of Mammography, Academy of Medicine", published previously.

Both physicians should have:

1. Performed at least 12 image guided vacuum-assisted biopsy procedures using the relevant guidance equipment - whether this is a mammographic upright device or dedicated prone table
2. Or at least 3 image guided vacuum-assisted biopsy procedures under the guidance of a physician qualified through the preceding criteria
3. 2 hours of accredited CME activity in image guided breast biopsy

4. Documentation of at least 6 image guided biopsy procedures per calendar year to maintain competence.
5. Documentation of at least 1 hour of accredited CME activity in image guided breast biopsy per calendar year.

Specimen radiography (e.g. for microcalcifications) and proper handling of the specimen and marking of the specimen for the pathologist is the responsibility of both physicians

Using Ultrasound to Guide the Biopsy

1. **Radiologist or surgeon practicing independently** (e.g. in physician's office, day care facility)

This physician is responsible for patient selection and all aspects of quality assurance and quality control including documentation.

This person is also responsible for the licensing of the equipment and also responsible for the proper use of the equipment and has to comply with the existing licensing requirements.

This person will also ensure that the technologist or, if used, is properly trained and licensed by the appropriate authority and supervise them.

This physician should have:

1. Performed at least 12 images guided vacuum-assisted biopsy procedures using ultrasound
2. Or at least 3 image guided vacuum-assisted biopsy procedures under the guidance of a physician qualified through the preceding criteria
3. 2 hours of accredited CME activity in image guided breast biopsy
4. Documentation of at least 12 image guided biopsy procedures per calendar year to maintain competence.
5. Documentation of at least 1 hour of accredited CME activity in image guided breast biopsy per calendar year.

2. **Alternatively, surgeon and radiologist can practice collaboratively**

Patient selection and quality assurance are joint responsibility of both physicians. Either or both physicians may perform the procedure.

The person responsible for the licensing of the equipment is also responsible for the proper use of the equipment and has to comply with the existing licensing requirements.

This person will also ensure that the technologist or radiographer, if used, is properly trained and licensed by the appropriate authority and supervise them

Both physicians should have:

1. Performed at least 12 image guided vacuum-assisted biopsy procedures using ultrasound,
2. Or at least 3 image guided vacuum-assisted biopsy procedures under the guidance of a physician qualified through the preceding criteria
3. 2 hours of accredited CME activity in image guided breast biopsy
4. Documentation of at least 6 image guided biopsy procedures per calendar year to maintain competence.
5. Documentation of at least 1 hour of accredited CME activity in image guided breast biopsy per calendar year.

Specifications of Equipment to be used

If ultrasound is used, all ultrasound guided procedures should be performed using high resolution transducers with frequencies of 7-10MHz or greater. The ultrasound scanner should be at least a mid range level scanner, if not a high end level scanner. The use of low range scanners with poor resolution and low technical performance and specifications is not appropriate.

If radiographic localization is used, the equipment used should be a mammographic unit with a specially designed add on device for breast biopsy to which the mamotome is attached or a specially designed dedicated stereotactic breast biopsy unit, usually with digital radiography.

Documentation Required

1. All procedures performed should be documented with details of basic patient data.
2. A permanent record of the procedure should be maintained and images obtained of the procedure. Image labeling and identification should include basic patient details, designation of left or right breast, location of lesion in the breast using diagram or clock as well as pre fire and post fire images.

3. Outcome data must be kept by the facility (where joint collaboration procedures are performed) or by the physician responsible (where physician practices independently)

This data should include:

- a. Procedure undertaken
- b. Its purpose or indication
- c. Local anesthesia or other if used,
- d. Location of lesion in breast include side, diagram or clock face position,
- e. Complications (e.g. haematoma, infection, pneumothorax) and treatment if any,
- f. Specimen and post procedure mammograms or ultrasound, if any
- g. Repeat biopsy - if any
- h. Pathology result - if benign or malignant

References

Joint Guidelines from American College of Radiology, American College of Surgeons

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5. March et al. Use of Breast Core Biopsy in the United States. AJR 1997 169:697-701
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Date: October 2000

WORK GROUP MEMBERS: -

Chairman	:	Dr John Hoe
Members	:	Dr Hong Ga Sze Dr Thing Choon Hua Dr Wee Siew Bock Dr Jill Wong

These guidelines were formulated by a joint committee comprising members of the Chapter of Surgeons and the Chapter of Radiologists, Academy of Medicine, Singapore.