BREAST IMAGING SOCIETY, INDIA

BEST PRACTICE GUIDELINES

IMAGING GUIDED BREAST BIOPSY

The scope of this document is limited to imaging guided percutaneous breast biopsy for diagnostic purposes and routinely performed therapeutic procedures such as abscess drainage and cyst aspiration. For additional information on therapeutic procedures reference can be made to a number of well known guidelines, such as ACR Breast Imaging and Intervention Practice Guidelines and Technical Standards and CAR Practice Guidelines and Technical Standards for Breast Imaging and Intervention (links given at the end of document).

INTRODUCTION

The objective of imaging guided percutaneous breast biopsy is to obtain a histopathology diagnosis of a suspicious breast lesion without the patient having to undergo an invasive surgical procedure. The fact is that 70-80% of breast lesions that are biopsied are benign [1,4]. If a trucut or core biopsy yields a benign diagnosis which is concordant with the imaging features surgery can be avoided [1]. While, if imaging guided percutaneous biopsy confirms the diagnosis of cancer, a single surgical procedure can be planned. Also the likelihood of obtaining clear histologic margins at first operation is higher if there is preoperative histologic diagnosis of breast cancer [2,3,4].

Image guidance should be used for biopsy of both palpable and non-palpable breast lesions such that the most suspicious part of the lesion can be targeted. Palpation guidance is advised if the lesion is not visualised by any imaging modality [5].

There are two factors that need to be considered while performing an imaging guided breast biopsy. The first factor is the selection of the imaging modality on which the breast lesion is best visualized and the second factor is the selection of the breast biopsy device.

Whenever achievable, while performing a biopsy, the shortest distance from the skin to the lesion should be used [6].

IMAGING MODALITIES FOR BREAST INTERVENTIONS

1. Mammography
2. Stereotaxis
3. Ultrasound
4. MRI

TYPES OF DIAGNOSTIC BREAST INTERVENTIONAL PROCEDURES

1. Fine needle aspiration cytology (FNAC)
2. Spring-loaded core needle biopsy (CNB)
3. Vacuum-assisted biopsy (VAB)
4. Pre-surgical wire localization
5. Marker clip deployment
6. Ductography or galactography

MAMMOGRAPHIC GUIDANCE

Mammographic guidance is used for pre-operative localization with an alpha numeric grid (typically if stereotactic guidance is unavailable).

Indication

- Suspicious pleomorphic microcalcifications
- Persisting asymmetries on mammogram with no definite sonographic correlation

Needle Selection

- Single or dual hook localization wires

Post procedure requirement

- Post procedure mammograms in two orthogonal positions must be obtained to confirm the presence of localization wire in appropriate position
- Postoperatively, specimen radiograph must be taken to confirm presence of target lesion in the surgically excised specimen

STEREOTACTIC GUIDANCE

Stereotaxy is an interventional technique which makes use of 3 dimensional coordinate system to localize small targets such as microcalcifications in the breast. Two angled mammographic images (X-axis and Y-axis) and computerized calculation of the depth (or Z-axis) using parallax are performed for fast and accurate localization of the target. Upright units with chairs and

prone tables are available for stereotactic guidance. Mammography machine is used to perform this procedure.

Indications

- Suspicious pleomorphic microcalcifications
- Architectural distortions, persisting asymmetries (seen on one or both views) and small masses seen on mammogram with no definite sonographic correlation

Needle Selection

- Fine Needle Aspiration Cytology (FNAC): FNAC is not the method of choice for sampling of microcalcifications due to higher incidence of unsatisfactory samples and subsequent upgrade to various grades of cancer.
- Spring loaded device/Core Needle Biopsy (CNB): A minimum of ten 14 gauge cores is recommended for calcifications [7] to minimize the risk of undersampling.
- Vacuum-assisted breast biopsy (VAB): Vacuum-assisted needles (14-7 gauge) are used to make a percutaneous diagnosis of indeterminate or suspicious microcalcifications [8]. Compared with the 14-gauge CNB, the VAB devices obtain larger tissue specimens, which enables an accurate pre-operative diagnosis along with significant reduction in the upgrade rate at subsequent surgery [9-14].

Post procedure requirement

- Post procedure specimen radiograph must be obtained to confirm the presence of microcalcifications in the specimen when stereotactic biopsy of microcalcifications is performed
- A post procedure radio opaque marker clip should be deployed at the site of the biopsy for microcalcifications, asymmetries as well as small masses considering the fact that these lesions may be harder to visualize following a stereotactic VAB
- Post procedure mammogram in two orthogonal positions must be obtained to document optimal deployment of the marker clip
- If there is migration of the marker clip on the post procedure mammogram, the current location of the marker clip and the distance from the original biopsy site should be documented in the report
- The shape of the marker clip deployed at the site of the biopsy should also be documented in the report
- If more than one marker clip is deployed, the location and shape of each marker clip to be documented in the report

ULTRASOUND GUIDANCE

Ultrasound guidance is the method of choice when a lesion is visualized sonographically. Prior to the performance of any ultrasound-guided percutaneous procedure, the findings should be assessed sonographically and where possible correlation with the mammographic finding should be made.

Indications

- Suspicious solid or complex solid-cystic masses (BI-RADS® 4 and 5 lesions)
- Targeted suspicious ultrasound-detected lesions following MRI (second-look ultrasound following MRI)
- BI-RADS® 3 lesions at patient request, if follow-up is not possible (usual problem in developing countries, remotely located women etc) or if there is another lesion in either of the breasts which is already diagnosed as cancer and surgery is planned (can't wait for 6 months!)

Needle Selection:

- **FNAC -**
    - Indications:

        1) Axillary lymph node biopsy when there is a known or suspected ipsilateral breast malignancy

        2) Investigation of suspected multicentric/multifocal malignancy when the index lesion has undergone a CNB/FNAC confirming malignancy in the index lesion
    - Limitations of FNAC [15,16]:

        1) Cytologist dependent

        2) No information on type of cancer or receptors (ER, PR, Cerb2, Ki67)

        3) Incidence of false negative and false positive higher than with CNB

        4) If cost is the only deciding factor, then FNAC could be performed acknowledging the fact that discordant imaging and FNAC findings would warrant a repeat biopsy.

- **CNB -** Spring-loaded 14 Gauge CNB can be used for most solid breast lesions visualized on ultrasound. When using an automated spring-loaded biopsy device, 14 gauge needle (or larger) is recommended [19]. A minimum of four 14 gauge cores is recommended for solid masses [20,21].

- **VAB –** The primary application of VAB is for stereotactic biopsy of suspicious microcalcifications or for MRI-guided breast biopsies. VAB has limited indications for ultrasound guided breast biopsies.
    - Indications [21,22]:
        1) Complex solid cystic mass
        2) Intraductal lesions
        3) Small lesions (<1 cm)
        4) Repeat biopsy for discordant Radiology-Pathology findings
        5) Occasionally for intraductal microcalcifications which are harder to target by stereotactic guidance either due to their location or if thickness of breast after compression is too small.

Post procedure requirement

- If the lesion is small, VAB may result in near complete removal of the lesion. In that case, a radio-opaque marker clip must be deployed at the biopsy site through VAB needle; before removing the needle from the breast. When marker clip is deployed please follow the post procedure requirement as explained above under stereotactic biopsy.

MRI GUIDANCE

MRI guided intervention is required when a lesion that looks suspicious on Breast MRI (BI-RADS®4 or 5) does not have a sonographic correlate on MRI-directed targeted second-look ultrasound or mammographic correlate [23,24]. A dedicated MRI grid is required to stabilize the breast with light to moderate compression. Pre-contrast T1-weighted images are obtained to confirm optimal positioning of the breast following which post-contrast sequence are obtained to confirm presence of lesion. X, Y and Z axis are determined using computer aided software. Alternately manual counting of the X and Y axis with a reference marker (such as a vitamin E capsule or other fiducial) placed on the grid can be performed. The z coordinate with the manual method is determined based on the slice thickness. Imaging in the sagittal and axial planes with the coaxial sheath and imaging obturator is required to confirm accurate targeting of the concerned lesion. Vanishing lesions which means lesions seen earlier on MRI may not persist at the time of MRI guided breast biopsy [25]. This typically occurs in hormonally stimulated normal fibroglandular tissue. This has to be documented and a six month follow-up MRI is recommended to ensure interval stability.

Needle Selection

- Vacuum-assisted breast biopsy (VAB): VAB needles (12-7 gauge) are used to obtain samples for MRI guided breast biopsies which require far more accuracy of targeting the lesion as MRI detected lesions with no sonographic or mammographic correlate are usually smaller and have a higher incidence of atypia and underestimation as compared to stereotactic breast biopsies [26].

Post procedure requirements

- There is no requirement for specimen radiograph following MRI guided breast biopsies for obvious reasons. However, all other post procedure requirements such as deployment of marker clip and obtaining a post procedure mammogram to be followed as stated in stereotactic VAB.

ABSCESS DRAINAGE AND CYST ASPIRATION

Abscesses less than 3.0 cms can be percutaneously drained under imaging guidance with a larger bore needle typically 18 gauge or larger, while abscesses greater than 3.0 cms may require percutaneous catheter insertion or surgical incision and drainage [27]. Other factors that determine the success of percutaneous abscess drainage are consistency of the abscess fluid and presence or absence of internal septations within the abscess cavity.

Typically, aspiration of non-complicated, benign cysts is not indicated. Fine needle aspiration of a cyst is indicated if a cyst gets painful, larger than 5.0 cm causing discomfort to the patient, if the patient is anxious or if there is diagnostic uncertainty. Fluid aspirated from a cyst can be discarded if it is non-bloody [28]. Cytology assessment of aspirated fluid is warranted if the fluid is hemorrhagic or the cyst does not collapse completely post aspiration.

MARKER CLIP DEPLOYMENT

Marker clips are typically deployed following imaging guided percutaneous breast biopsy of lesions which become less conspicuous or completely disappear following biopsy and are therefore difficult to identify at follow-up or at the time of localization. For example:

- Stereotactic VAB of microcalcification, asymmetries, small masses or architectural distortion
- All lesions biopsied under MRI guidance with no definite sonographic or mammographic correlate
- Complex solid cystic masses or partially collapsed cyst following aspiration of hemorrhagic or suspicious fluid
- Prior to neo-adjuvant chemotherapy. Deployment of marker clip is recommended as some malignancies may respond very well to neoadjuvant treatment and almost disappear following treatment.

ROLE OF GALACTOGRAPHY

Spontaneous, bloody or clear, unilateral nipple discharge arising from a single orifice is considered high risk. The incidence of pre-malignant or malignant lesions associated with these high risk discharges is about 15% [29,30]. Fluid cytology may be performed but is useful only when positive [31]. Ultrasound followed by mammogram remains the initial investigation. If a lesion is identified, biopsy can be performed. However, if ultrasound and mammographic findings are equivocal or non-specific, galactography may be performed. The caveat for performing galactography is that there should be nipple discharge on the day of performing the procedure. Emerging evidence suggests that breast MRI is a useful problem solving tool in the assessment of spontaneous suspicious nipple discharge especially when the mammogram and ultrasound are negative [32,33].

CONTRAINDICATIONS FOR IMAGING GUIDED BREAST BIOPSIES

- Inability to visualize lesion (absolute)
- Anticoagulation: Discussion with the referring physician on a case by case basis is recommended if reversal of anticoagulation is considered

COMPLICATIONS OF IMAGING GUIDED BREAST BIOPSIES

- Vasovagal attack (Immediate complication)
- Hematoma
- Infection
- Trauma to chest wall/pneumothorax (rare)
- Trauma to neurovascular structures in axilla
- Implant perforation
- Milk fistula during lactation

MANAGEMENT OF COMPLICATIONS OF IMAGING GUIDED BREAST BIOPSIES

- Vasovagal attack - Restoring blood flow to the brain during an impeding episode by leg elevation, tightening of leg muscles.
- Hematoma - Early post biopsy complication: compression, icepack, restricted arm movements. Watch for breast enlargement or active bleed
- Infection - Delayed post biopsy complication: Biopsy site may get red, hot with purulent discharge and fever. Usually responds well to antibiotics
- Pneumothorax - typically pneumothorax less than 1.0 cm on chest radiograph resolves spontaneously. However, pneumothorax larger than 1.0 cm may require chest tube insertion.

Typically there is no requirement for preemptive antibiotic coverage for breast biopsies as adequate aseptic precautions are taken at the time of the biopsy. Patient may benefit from SOS analgesic for pain management following the procedure. In case of an emergency, the contact details of the radiologist conducting the biopsy should be provided as finding emergency health care help is often harder in many centers across India.

THE RADIOLOGIST'S REPORT

1) Procedure performed
2) Right or Left breast
3) Gauge of biopsy needle
4) Number of passes/cores
5) Type and amount of local anesthesia
6) Location of the lesion in the breast using quadrant, clock position and distance from the nipple
7) Immediate complications and treatment, if any
8) Specimen radiograph, if performed
9) Marker clip placement, if performed
10) Post-procedure mammography and/or sonography, if performed

LABELING OF PATHOLOGY SPECIMEN

1) CNB & VAB specimen should be collected in a container with buffered formalin immediately after the procedure (within 1-2 minutes) to avoid drying artifacts
2) Patients name, age, date of birth indicated on the container
3) Specimen collection date and time
4) Clinical history
5) Side and source of tissue
6) Number of needle core biopsies submitted

ESTABLISHING RADIOLOGY PATHOLOGY CONCORDANCE OR DISCORDANCE

Radiologist plays a critical role in establishing radiologic pathologic concordance or discordance as well as providing suggestion for appropriate management follow-up, such as the need for further imaging, short interval imaging follow up, repeat biopsy or surgical consultation. Adding an addendum to the final report with appropriate recommendation is a good practice guideline [34].

DISCLAIMER

The Best Practice Guidelines of Breast Imaging Society, India are the broad guidelines for investigation, intervention and management of clients opting for breast screening and patients with breast symptoms in India, and intended for the use of qualified medical caregivers only. These are based on various national and international guidelines and personal experiences and opinions of BISI members, as there is no large credible Indian data to formulate these guidelines. These guidelines are purely recommendatory and general purpose only in nature. Actual decisions for management of patients should be individualized according to own judgement of the caregiver and tailored on case-to-case basis. As scientific knowledge is continuously improving, a regular update of the same by the caregiver is essential. Failure to do so may result in untoward patient management or outcome and BISI members or BISI as the organization cannot be held responsible for that in any manner.

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RELEVANT LINKS

Canadian Association of Radiologists (www.car.ca)

CAR Practice Guidelines and Technical Standards for Breast Imaging and Intervention(http://www.car.ca/uploads/standards%20guidelines_20131024_en_breast_imaging_practice_guidelines.pdf)

American College of Radiology (www.acr.org)

ACR BI-RADS® Atlas Mammography Fourth edition (http://www.acr.org/Quality-Safety/Resources/BIRADS/Mammography)

ACR Breast Imaging and Intervention Practice Guidelines and Technical Standards (http://www.acr.org/Quality-Safety/Accreditation/BreastMRI)