



# Best Practice Guidelines for Breast Imaging, Breast Imaging Society, India: Part–2

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## Abstract

### Keywords

- ▶ Breast Imaging Society, India
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- ▶ mammography
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- ▶ breast magnetic resonance imaging
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- ▶ vacuum-assisted breast biopsy
- ▶ stereotactic biopsy
- ▶ investigations for common breast symptoms
- ▶ imaging-guided breast biopsy

Breast imaging is a prerequisite for providing high quality breast health care. Choosing the appropriate investigation is central to diagnosing breast disease in patients who present to health professionals for treatment. These patients present to doctors of different subspecialties as well as to general practitioners in our country. It is important, therefore, to provide uniform guidance to doctors in different healthcare setups of our country, urban and rural, government and private, for optimal management of breast diseases. These guidelines framed by the task group set up by the Breast Imaging Society, India, have been formulated focusing primarily on the Indian patients and health care infrastructures. They aim to provide a framework for the referring doctors and practicing radiologists to enable them to choose the appropriate investigation for patients with breast symptoms and signs. The aim has been to keep this framework simple and practical so that it can guide not only subspecialists in breast care but also help doctors who do not routinely deal with breast diseases, so that breast cancer is not missed. Overall, the aim of this document is to provide a holistic approach to standardize breast care imaging services in India. Part 2 of these guidelines focuses on the best practice principles for breast interventions and provides algorithms for the investigation of specific common breast symptoms and signs. Ultrasound is the preferred imaging modality for image-guided breast interventions due to real-time needle visualization, easy availability, patient comfort and absence of radiation. Stereotactic mammography guided procedures are performed if the lesion is visualized on mammography but not visualized on ultrasound. 14-gauge automated core biopsy device is preferred for breast biopsies although vacuum

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assisted biopsy devices are useful for biopsy of certain abnormalities as well as for imaging guided excision of some pathologies. MRI guided biopsy is reserved for suspicious lesions seen only on MRI. Algorithms for investigation of patients presenting with mastalgia, breast lumps, suspicious nipple discharge, infections and inflammation of the breast have been provided. For early breast cancers routine use of investigations to detect occult distant metastasis is not advised. Metastatic work up for advanced breast cancer is required for selection of appropriate treatment options.

## 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.

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 to 80% of breast lesions that are biopsied are benign.<sup>1-4</sup> If a trucut or core biopsy yields a benign diagnosis which is concordant with the imaging features, surgery can be avoided.<sup>1</sup> However, 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 a preoperative histologic diagnosis of breast cancer.<sup>2-4</sup>

Image guidance should be used for the 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 visualized by any imaging modality.<sup>5</sup>

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.<sup>6</sup>

### Imaging Modalities and Types of Interventional Procedures

The imaging modalities that can be used for lesion visualization and imaging guidance are Mammography, Stereotaxis, Ultrasound, and magnetic resonance imaging (MRI).

The types of diagnostic breast interventional procedures are fine needle aspiration cytology (FNAC), spring-loaded core needle biopsy (CNB), vacuum-assisted biopsy (VAB), pre-surgical wire localization, marker clip deployment, and 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 asymmetry, mass or architectural distortion on mammogram with no definite sonographic correlation

### Needle Selection

Single- or dual-hook localization wires are selected.

### Post-Procedure Requirement

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

### Stereotactic Guidance

Stereotaxy is an interventional technique which makes the use of three-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 patient positioning for stereotactic procedures. A 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

- FNAC: FNAC is not the method of choice for the sampling of microcalcifications due to the higher incidence of unsatisfactory samples and subsequent upgrade to various grades of cancer.
- CNB: A minimum of 10, 14-gauge cores is recommended for calcifications<sup>7</sup> to minimize the risk of undersampling.
- VAB: VAB needles (14–7 gauge) are used to make a percutaneous diagnosis of indeterminate or suspicious microcalcifications.<sup>8</sup> Compared with the 14-gauge CNB, the VAB devices obtain larger tissue specimens, which enable an accurate pre-operative diagnosis along with a

significant reduction in the upgrade rate at subsequent surgery.<sup>7,9–13</sup>

### Post-Procedure Requirement

- Post-procedure specimen radiograph must be obtained to confirm the presence of microcalcifications in the specimen when the 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 a 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 should 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 wherever possible correlation with the mammographic finding should be made.

### Indications

- Suspicious solid or complex solid-cystic masses (Breast Imaging-Reporting and Data System [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 (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 (cannot wait for 6 months!)

### Needle Selection

- FNAC

Indications include:

- axillary lymph node biopsy when there is a known or suspected ipsilateral breast malignancy
- investigation of suspected multicentric/multifocal malignancy when the index lesion has undergone a CNB/FNAC confirming malignancy in the index lesion

Limitations of FNAC<sup>14,15</sup> are:

- cytologist dependence
- no information on the type of cancer or receptors (ER, PR, Cerb2, and Ki67)

- incidence of false negative and false positive higher than that with CNB
- 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—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.<sup>16</sup> A minimum of four 14-gauge cores is recommended for solid masses.<sup>17,18</sup>
- VAB—The primary application of VAB is for the stereotactic biopsy of suspicious microcalcifications or for MRI-guided breast biopsies. VAB has limited indications for ultrasound-guided breast biopsies.

Indications<sup>18,19</sup> include:

- complex solid cystic mass
- intraductal lesions
- small lesions (<5mm)
- repeat biopsy for discordant radiology–pathology findings
- occasionally for intraductal microcalcifications which are harder to target by stereotactic guidance either due to their location or if the 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 a 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.<sup>20,21</sup> A dedicated MRI grid is required to stabilize the breast with light to moderate compression. Pre-contrast T1-weighted images are obtained to confirm the optimal positioning of the breast following which post-contrast sequence images are obtained to confirm the presence of lesion. X, Y, and Z axes are determined using computer-aided software. Alternately manual counting of the X and Y axes 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 are sometimes encountered which means lesions seen earlier on MRI may not persist at the time of MRI-guided breast biopsy.<sup>22</sup> This typically occurs in hormonally stimulated normal fibroglandular tissue. This has to be documented, and a 6-month follow-up MRI is recommended to ensure interval stability.

### Needle Selection

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 with stereotactic breast biopsies.<sup>23</sup>

### 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 the deployment of marker clip and obtaining a post-procedure mammogram are to be followed as stated in stereotactic VAB.

### Abscess Drainage and Cyst Aspiration

Abscesses less than 3.0 cm can be percutaneously drained under imaging guidance with a larger bore needle typically 18 gauge or larger, while abscesses greater than 3.0 cm may require percutaneous catheter insertion or surgical incision and drainage.<sup>24</sup> Other factors that determine the success of percutaneous abscess drainage are the consistency of the abscess fluid and the presence or absence of internal septations within the abscess cavity.

Typically, the 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.<sup>25</sup> The 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 the aspiration of hemorrhagic or suspicious fluid, and
- Prior to neo-adjuvant chemotherapy. The deployment of a 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 approximately 15%.<sup>26,27</sup> Fluid cytology may be performed but is useful only when positive.<sup>28</sup> 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.<sup>29,30</sup>

### Contraindications and Complications of Imaging-Guided Breast Biopsies

Contraindications include:

- 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 include:

- 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

Complications of imaging-guided breast biopsies are managed as follows:

- Vasovagal attack—blood flow is restored to the brain during an impending episode by leg elevation and tightening of leg muscles.
- Hematoma—early post-biopsy complication: it is managed by compression, icepack, and restricted arm movements, watch for breast enlargement or active bleed.
- Infection—delayed post-biopsy complication: the biopsy site may get red, hot with purulent discharge and fever. The condition 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. The patient may benefit from SOS analgesic for pain management following the procedure. The contact details of the radiologists performing the biopsy should be provided so that the patient can access appropriate help easily in the case of an emergency.

### The Radiologist's Report

The radiologist's report should contain the following details:

- Procedure performed

- Imaging modality used for guidance
- Right or left breast
- Type and gauge of biopsy needle
- Number of passes/cores
- Type and amount of local anesthesia
- Location of the lesion in the breast using quadrant, clock position, and distance from the nipple
- Immediate complications and treatment, if any
- Specimen radiograph, if performed
- Marker clip placement, if performed
- Post-procedure mammography and/or sonography findings, if performed

### Labeling of Pathology Specimen and Establishing Radiology–Pathology Concordance or Discordance

CNB and VAB specimens should be collected in a container with buffered formalin immediately after the procedure (within 1–2 minutes) to avoid drying artifacts. The following details should be made available to the pathologist:

- Patients' name, age, date of birth indicated on the container
- Unique Hospital Identification Number, if any
- Specimen collection date and time
- Clinical history
- Side and source of tissue
- Number of needle core biopsies submitted

Radiologist plays a critical role in establishing radiology–pathology concordance or discordance as well as providing a 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 recommendations is a good practice guideline.<sup>31</sup>

### Common Breast Symptoms: Algorithm for Imaging Evaluation

Common breast symptoms include breast lump, pain, nipple discharge, inflammation, either alone or in combination. Breast imaging performed in this group of patients is called diagnostic breast imaging.

The purpose of clinical and imaging evaluation is to determine the cause of symptoms so that appropriate treatment can be given and, second, to determine if the symptom is caused by underlying breast cancer. Accordingly, the evaluation of patients with any breast symptom should begin with detailed history and good clinical breast examination (CBE), preferably by a breast surgeon. This is to be followed by appropriate imaging as outlined below. Following a reporting system such as the American College of Radiology (ACR) BI-RADS system is advised.<sup>32</sup>

#### Breast Lump

Breast lump is a common breast symptom that requires radiological investigations. Although most breast lumps are benign, it is also the most worrisome complaint as it is the most common presentation of a breast cancer.

All patients presenting with breast lump should undergo triple assessment.<sup>33</sup> It is a combination of CBE, imaging test, and pathology test, ideally core biopsy. It is a standard and accurate method to diagnose breast cancer in a symptomatic breast.<sup>34</sup> However, if the correlate of the breast lump is clearly benign on imaging, biopsy may be avoided.<sup>35</sup>

Imaging modality: Up to 30 years of age ultrasound of both breasts is the primary modality. Mammogram in this age group is performed only if there is a strong clinical suspicion of breast cancer or if suspicious finding is detected on ultrasound.<sup>35</sup> If the age is more than 30 years, both mammography and ultrasound of both breasts are recommended.<sup>35</sup> In the 30 to 40 years age group, clinical correlation is advised before requesting/performing a mammogram. For example, for a 32-year-old lady who presents with a lump that she can feel but on clinical palpation by the doctor is interpreted as the normal nodular feel of breast, a normal ultrasound is reassuring and a mammogram is not required for further characterization of the lump.

Dynamic contrast-enhanced magnetic resonance imaging (CEMRI) of breast is considered only if ultrasound and mammogram are inconclusive. If a mass is identified on ultrasound and mammography, MRI is not recommended for its further characterization.

Further management is according to imaging results as follows:

*Simple cyst (BI-RADS 2)*—no further imaging is required as this is a benign entity. Cyst may or may not be aspirated if not responsible for symptoms. If aspirated, fluid cytology is not required if the aspirate is not suspicious. No imaging follow-up is recommended.

*Complicated cyst (BI-RADS 2/ BI-RADS 3)*—no further imaging or follow-up is required if these are deemed to be benign. If any concern exists, a follow-up ultrasound in 6 months' time is advised.

*Cyst with suspicious solid component (BI-RADS 4)*—for complex cystic and solid mass or a mass with partly cystic partly solid echotexture, image-guided aspiration and core biopsy are advised.

*Solid definitely benign mass (BI-RADS 2)*—like hamartoma, calcified fibroadenoma, lipoma, fat necrosis, etc., need clinical follow-up only.<sup>35</sup>

*Solid probably benign mass (BI-RADS 3)*—imaging follow-up is only required. Ultrasound-guided core biopsy may be considered in cases of high-risk factors or clinical suspicion for cancer, already diagnosed cancer in the same or contralateral breast, planned pregnancy, extreme patient anxiety, or if follow-up cannot be ensured.

*Suspicious mass (BI-RADS 4 or 5)*—image-guided core biopsy is needed.

*Calcifications only*—no further evaluation is needed if it is typically benign. All other calcifications which are not typically benign must be subjected to core biopsy. Specimen radiograph of harvested cores is recommended to establish the retrieval of calcification in harvested cores.

*Biopsy results*—for BI-RADS 4 lesions, if the biopsy result is benign, follow-up imaging after 6 months is advised. If the

biopsy result is malignant, appropriate treatment is advised. If the biopsy result is inconclusive (equivocal or atypia only), then re-biopsy, preferably vacuum-assisted biopsy is recommended.<sup>36</sup> For BI-RADS 5 lesions, re-biopsy is a must if histopathology result is not malignant on initial biopsy.

*Mass on CBE but negative imaging*—palpation-guided biopsy may be performed if indicated clinically.

*No mass on CBE as well as on imaging*—no further imaging is needed. Follow-up with CBE may be considered.

*Breast lump in pregnant or lactating women*—ultrasound is the imaging modality of choice for any age as breast is mammographically dense in these situations. If mass is identified on ultrasound, further management will be as per BI-RADS category. In case of suspicious or equivocal ultrasound findings, mammography can be considered during pregnancy or lactation as it is better than ultrasound in the detection of calcifications and subtle architectural distortion. CEMRI of breast is not recommended during pregnancy but can be considered during lactation.<sup>35</sup>

### Breast Pain (Mastalgia) and Mastitis

Mastalgia alone is generally not a feature of breast cancer. It may be due to an aberrant response of breast tissue to the hormonal variations, especially if it is cyclic, bilateral, and associated with vague nodularity of the breast. Other causes may include infection, trauma, and some drugs (spironolactone, digoxin, haloperidol, for example).

The age of the patient, history, and CBE will guide the imaging protocol. No imaging is required if the pain is bilateral or diffuse, cyclic, and CBE is normal. If breast pain or tenderness is focal or associated with mass, then imaging is required.<sup>37</sup>

*Imaging:* Only ultrasound is needed for age up to 30 years and both mammography and ultrasound for age more than 30 years. Mammography should be avoided in lactating and highly painful breasts which preclude adequate compression during mammography. Ultrasound alone is sufficient for them. An imaging protocol as outlined for breast lumps in preceding sections may be followed.

Acute mastitis is characterized by focal breast pain, inflammatory skin changes along with fever, and malaise. It can be lactational or non-lactational. It is diagnosed clinically and managed conservatively with antibiotics.

Imaging is recommended only if mastitis is non-resolving or progressive. Ultrasound is the modality of choice as mammography is difficult to perform and interpret in acute mastitis. If mastitis has liquefied into an abscess formation, surgical or ultrasound-guided drainage should be considered.<sup>24</sup> One or repeated aspiration with a large bore needle is recommended. Indwelling catheter drainage is effective for large recurring abscesses.<sup>38</sup>

Follow-up mammography and ultrasound are recommended in non-lactational mastitis or abscess after acute symptoms have resolved. A non-resolving lesion should be subjected to biopsy.<sup>39</sup>

If inflammatory breast cancer is suspected, then an ultrasound of both breasts and, if possible, mammography should be performed.<sup>40</sup> Image-guided biopsy should be obtained if focal lesion is seen. If no focal lesion is seen, CEMRI of both breasts should be performed to localize the primary tumor.

### Nipple Discharge

Usual causes include physiological changes, hormonal disorders, benign lesions like papilloma and duct ectasia, and uncommonly, cancer. Some drugs (methyl dopa, cimetidine, reserpine, antipsychotics, and oral contraceptives) can also cause nipple discharge.

Good CBE is the initial step. The color of the discharge should be noted. Multiduct or expressible yellow, green, gray, black, or white discharges indicate physiological or benign causes. CBE should be performed and if negative, then assurance is adequate. Imaging is not required. Serum prolactin level and thyroid profile may be obtained if the patient is not pregnant or lactating and hormonal cause is suspected. If infection is suspected, antibiotics for 1 week and re-assessment with CBE are recommended. Occasional bilateral bloody discharge in children is also self-limiting, and no imaging is required.

The risk of breast cancer is high if nipple discharge is from single duct, spontaneous, serous or bloody, associated with a lump on CBE or age is more than 50 years.<sup>41</sup> The presence of any one or more of these factors is considered as pathological duct discharge. Unilateral nipple discharge is uncommon in males, but it is more likely to be associated with underlying cancer, than in females. Hence, good clinical and imaging evaluation is required in men with unilateral duct discharge, irrespective of age.<sup>42</sup>

Ultrasound only (age up to 30 years) and mammography with ultrasound (age more than 30 years) should be performed. While performing ultrasound on the affected side, good attention should be given to the subareolar region with different maneuvers such as peripheral breast compression, rolled nipple, or using standoff pad of gel.<sup>42</sup>

If an abnormality is found on imaging, further management will depend on its BI-RADS category. If no abnormality is found and discharge is serous or bloody, CEMRI should be obtained.

Ductography is a traditional modality for the evaluation of single duct discharge, and it is especially accurate in the detection of small intraductal lesions. However, it is technically demanding, at times painful and less widely available. Mammography combined with ultrasound, and CE MRI of breast are reliable alternatives of ductography.<sup>42</sup>

Papilloma is a common cause of unilateral duct discharge. These are high-risk lesions, and hence, if found on imaging, surgical excision rather than percutaneous image-guided biopsy may be considered.<sup>42</sup> If clinical or imaging findings are suggestive of duct ectasia or periductal mastitis, culture sensitivity of duct discharge followed by appropriate antibiotic treatment should be considered.<sup>43</sup> If CBE and imaging are negative and discharge is persisting, surgical exploration (microdochectomy) should be considered.<sup>44</sup>

### Patients with Open, Discharging, or Eczematous Skin Lesion

These include patients with chronic infection with sinus formation such as tuberculosis, recent lumpectomy or trauma, or those with locally advanced fungating cancers. After history and CBE, initial imaging should be with bilateral breast ultrasound. Mammography is difficult to perform in these patients. Further management will be guided by CBE and ultrasound findings.

In patients suspected to have breast cancer and no definite mass found on CBE or ultrasound, CEMRI of breasts is recommended. It is also recommended if cancer is already diagnosed on lumpectomy and breast conservation is being considered.<sup>45</sup>

If the patient has eczematous skin changes at or around nipple-areola, with or without duct discharge, dermatitis should be excluded first. Another cause is Paget's disease, and hence, CBE, mammography, and ultrasound should be performed. If it is negative, CEMRI of breast should be obtained. Image-guided biopsy of any suspicious lesion on imaging and/or eczematous nipple should be undertaken.

### Patients Already Diagnosed with Breast Cancer

#### Imaging for Local Extent of Breast Cancer

Preoperative breast imaging should include bilateral mammography and ultrasound. If an additional lesion is seen on any of these imaging tests, further management depending on BI-RADS category of the additional lesion is considered. BIRADS 2 lesions can be ignored and surgery undertaken as per the plan. If an additional lesion is BIRADS category 3,4, or 5, its image-guided biopsy is recommended.

Preoperative CEMRI of both breasts is not routinely recommended; however, it can be considered as per institutional policy. It is recommended in cases of lobular carcinoma, young women, and those with dense breasts (ACR BI-RADS density C or D).<sup>33,46</sup> It is also recommended for problem solving, for example, if there is a discrepancy in the clinically palpable extent of disease and the size of lesion on mammography and ultrasound. It may be useful in a patient with breast implants if the optimum assessment for multicentricity or multifocality is not possible based on mammography and ultrasound alone.<sup>33</sup> Patients who have neoadjuvant chemotherapy are best monitored with breast MRI to assess response to treatment. It is also recommended if accelerated partial breast irradiation is being considered. If an additional suspicious lesion is seen on MRI, and it can change the planned treatment, a biopsy of such a lesion should be considered.

Pre-operative ultrasound imaging of axilla is recommended in patients with clinically node-negative breast cancer. The detection of axillary lymph node involvement on ultrasound will lead to full axillary dissection during surgery instead of sentinel lymph node mapping. Abnormal lymph nodes detected on ultrasound may be subjected to ultrasound-guided FNAC or biopsy for the confirmation of nodal metastases. Mammography or MRI is not recommended for the preoperative evaluation of axilla.

### Imaging for the Assessment of Response to Neo-Adjuvant Chemotherapy

If the patient with large operable breast cancer or one with locally advanced breast cancer is considered for neo-adjuvant chemotherapy before surgery, then image-guided core biopsy with complete histological analysis, tumor grade, and ER, PR, HER2 receptor status should be obtained before the initiation of chemotherapy. FNAC diagnosis only is not sufficient. If breast conservation surgery is considered in such a patient and breast mass is devoid of calcifications, the placement of radio-opaque marker clip in the tumor is highly recommended.<sup>47</sup> This clip will help to localize the tumor in the case of complete clinical and imaging resolution of the lesion after chemotherapy.

Imaging is required to monitor response to chemotherapy, identify non-responders early so that chemotherapy may be changed or stopped. At the end of chemotherapy, it is required to assess the extent of residual tumor and to identify those who are likely to have achieved a complete pathological response. The combination of mammography and ultrasound is the standard modality to assess response to chemotherapy. CEMRI is the most accurate imaging modality but should be used only if pre-chemotherapy good quality MRI scan is available. Positron emission tomography-computed tomography (PET-CT) is not recommended for the assessment of response to neo-adjuvant chemotherapy.

### Imaging for Metastatic Work-Up

The stages mentioned in the following paragraphs are as per anatomical staging in the 8th edition of American Joint Committee on Cancer (AJCC) Cancer Staging Manual of The American College of Surgeons (ACS).<sup>48</sup>

For early breast cancers (T1 or T2, N0 or N1, M0) which are up to 5 cm in size, with no axillary lymph nodes or mobile level 1/2 ipsilateral axillary lymph nodes, with no distant metastases (i.e., up to T2N1M0 of stage 2B, AJCC manual), routine use of investigations to detect occult distant metastasis is not advised due to false-positive studies and the low yield of these investigations.<sup>48,49</sup> A chest X-ray is sufficient. Any additional tests performed in early breast cancer should be directed by clinical signs and symptoms.<sup>48-50</sup> For example, Tc99m-methylene diphosphonate (MDP) bone scan is recommended if serum alkaline phosphatase is elevated or if patient has localized bone pain.<sup>33,48</sup> Abdominal imaging is to be performed if there are abnormal clinical findings or liver function tests. Similarly, if there are suspicious chest symptoms a CT scan of the chest is advised.<sup>48,50</sup>

Metastatic work-up with Chest X-ray, ultrasound of abdomen and pelvis, and liver function tests are the basic essential tests to be performed from T3N0M0 of stage 2B of AJCC staging and, thus, includes T3-4, any N as well as N2-3, any T cancers.<sup>49</sup> However, instead of these investigations, it is preferred to perform contrast-enhanced computerized tomography chest and abdomen and MDP bone scan.<sup>49</sup> Alternatively, PET-CT alone could be performed although this is not routinely advised.<sup>49</sup>

Image-guided biopsy of metastatic lesions is not required if imaging findings are fairly suggestive of metastases. However, biopsy may be required if imaging findings are equivocal or if there is a single lesion which may alter the intent of management.

### Patients with Metastasis from Cancer of Unknown Primary Site

These include women presenting with axillary lymph nodes or other lesions in the body which show malignancy on FNAC or biopsy. Bilateral mammography and breast ultrasound are recommended to exclude breast cancer. If mammography or ultrasound is positive, then image-guided biopsy should be performed. CEMRI is recommended if mammography and ultrasound are normal or equivocal but the patient has unilateral axillary lymphadenopathy and breast cancer is suspected on FNAC/biopsy of lymph nodes.<sup>51</sup>

### Patients with Treated Breast Cancer on Follow-Up

Regular physical examination and annual mammography are recommended.<sup>33</sup> Mammograms must be compared with previous mammograms, even if these appear normal. Any suspicious or new lesion not typically benign should be subjected to biopsy. Follow-up systemic imaging to detect metastases is not routinely recommended, unless patient is symptomatic.<sup>52</sup> If metastases are detected on follow-up, its biopsy is not required if imaging findings are typical of metastases. However, image-guided core biopsy of new metastasis is required to assess hormone receptor status if it has developed after long follow-up. It is also required if receptor status of breast cancer is not already known.<sup>47</sup>

#### Disclaimer

The Best Practice Guidelines of Breast Imaging Society, India (BISI) 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 are no large credible Indian data to formulate these guidelines. These guidelines are purely recommendatory in nature. Actual decisions for the management of patients should be individualized according to own judgment 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.

#### Author Contributions

S.C. contributed to mammography and all other sections, S.P. contributed to breast MRI, T.S. contributed to breast ultrasound, S.L. contributed to breast interventions, J.S. contributed to breast MRI, N.K. contributed to mammography, S.M. contributed to common breast symptoms: algorithm for imaging evaluation and all other sections, and S.T. contributed to common breast symptoms: algorithm for imaging evaluation and all other sections.

#### Conflict of Interest

None declared.

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