BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

MRI BREAST

Magnetic Resonance Imaging (MRI) Breast is a very valuable tool in breast imaging as it has a very high sensitivity. The specificity depends on various factors such as imaging equipment, radiologist expertise and patient cohorts. Indications for Breast MRI have been explained in Best Practice Guidelines of Breast Imaging Society, India.(1) These include inconclusive findings on conventional imaging, pre-operative staging in some cases, perioperative evaluation to assess residual disease, metastatic axillary lymph nodes when site of primary is not demonstrated on conventional imaging, screening of young women at high risk of breast cancer and assessment of implant integrity. Quality assurance guidelines have been formulated in this document to ensure that optimum equipment for MRI breast is used all over the country as well as to encourage uniformity and standardization of reporting templates. At the very end of the document there is a suggested reporting template for normal as well as abnormal breast MRI studies (appendix A), followed by a template for MR guided Breast biopsy report (appendix B) .

Equipment Specifications

It is widely acknowledged that a magnetic strength of at least 1.5 Tesla is required to acquire images of good resolution. The minimum requirement is an 8-channel dedicated diagnostic breast coil to perform good quality MRI of breast.(2) Simultaneous bilateral breast imaging is advised as this allows better detection of abnormal asymmetric morphology and enhancement.

It is very important to acquire images of high spatial and temporal resolution so that the abnormality can be morphologically differentiated from normal breast tissue as well as assessed optimally by the kinetics of the lesion after contrast injection. Slice thickness of 3mm or less is required and in plane pixel resolution should be 1 mm or less as this reduces volume-averaging effects to the minimum.(3) To achieve a pixel size of not more than 1 x 1 mm, a matrix of at least 300 x 300 in a 300 mm field of view (FOV) is required.(4) To be capable of detecting lesions ≥ 5 mm in size, voxel size should be less than 2.5 mm in any direction.(4)

Contrast in dose of 0.1 mmol/kg body weight should be administered as a bolus using a power injector followed by at least 10 mls of saline flush. It may be omitted if the study is being performed solely for checking implant integrity. As peak enhancement in breast cancer usually occurs within the first 2 minutes of contrast injection, the post contrast sequences should be able to acquire data from the entire breast in a short span of time, preferably 1 – 2 minutes per volume acquisition. Washout of contrast from malignant masses may be as early as 2 – 3 minutes post contrast. Hence dynamic sequence must aid measurement of contrast uptake at least at three time points i.e. a precontrast, a 1-2 minutes and a delayed volume acquisition of breast is necessary.(4) The number of acquisitions can be more depending on local protocol. Apart from visual assessment, time intensity curves must be calculated in regions of interest (ROI) for quantitative analysis of lesion kinetics. ROI should be 3 - 4 pixels maximum to reduce volume averaging.

Subtraction techniques are used for assessment of enhancement of breast abnormalities. However these are prone to misregistration artefacts due to patient motion between image acquisitions. Misregistration may result in nonvisualisation of the lesion. Hence it is important to incorporate fat suppression (FS) in the sequences acquired after contrast injection, which reduces fat signal and helps better visualization of the lesion. Protocols incorporating both fat suppression and subtraction can be used. It is important to assess the lesions on images acquired on post contrast subtraction images as well as the FS sequence images. Motion correction algorithms are advised to reduce motion artifacts in subtraction sequences.(3)

Timing & Technique

Studies have shown that there is significantly lower background parenchymal enhancement (BPE) in menstrual cycle days 7-20 than in days 21-6.(5) It is also advised that dynamic breast MRI should be performed during first half of the menstrual cycle (days 3-14) so that interpretative difficulties related to gadolinium uptake due to normal hormonal fluctuations during the menstrual cycle can be minimised.(6) Breast MRI should be performed as per departmental protocol. One suggestion is that breast MRI is performed between days 7–14 of the menstrual cycle.(7)

A dedicated bilateral breast coil must be used. The patient is positioned prone with the breasts hanging in the coil loops. Supporting the breast helps reduce motion artefacts, but breast compression should be avoided.(4)

A number of sequences help characterization of breast abnormalities. T2 weighted sequence (2D/ 3D), with or without fat saturation is very useful for analysis of cysts, edema and fluid. T1 weighted sequence without fat suppression to assess morphology of lesion, fat signal intensity within lesion, architectural distortion, clips after biopsy/ surgery is

recommended. STIR silicone selective axial/sagittal sequence with water saturation demonstrates hyperintense silicone and is very useful for assessment of implant integrity. Also silicone suppressed sequence on which water is hyperintense is very useful for implant evaluation. Dynamic contrast T1 GRE sequence is essential to assess tumour kinetics. Pre contrast T1 FS sequence followed by at least 2 post contrast T1 FS sequences with subtraction images are advised[4]. A suggested protocol of each acquisition time period of not >60 seconds (preferably not >45 seconds) for a total acquisition time of five minutes, gives a good number of time points to draw the time intensity curves.(2)

Diffusion weighted Imaging (DWI) is a promising MR technique which gives insight into the functional aspect of the lesion. This may be used depending on equipment capability and experience of radiologist. It helps to differentiate between benign and malignant lesions based on diffusivity of water molecules. Malignant lesions show less diffusivity due to increased cellularity and desmoplastic reaction when compared to benign lesions. Thus these are hyperintense on higher b values and have low values on ADC (Apparent Diffusion coefficient) images. The high b value images should always be seen in correlation with the ADC maps. A minimum of two sets of images are acquired with different b values and the recommended b values are 0 and 800.(8) The higher b value applied can vary from b800-1000 according to magnet strength.(2) The ADC value is obtained by drawing a ROI on the lesion on the ADC map (or the b = 800 s/mm^2 image when the workstation allows propagation of the ROI to the ADC map). The ROI should fall completely within the lesion, contain at least 3 voxels and avoid both artifacts and necrotic or hemorrhagic parts of the lesion[8]. DWI is performed before contrast administration to reduce artefacts.

Spectroscopy may be used depending on equipment capability and experience of radiologist. Choline is the metabolite that is detected and measured in single voxel spectroscopy and is used to differentiate between benign and malignant lesions. It is also used to predict response to neoadjuvant chemotherapy in malignant lesions.(9)

Quality Assurance of the Equipment

Quality assurance assessments should be performed as per manufacturer's instructions and hospital protocol. The quality of the images for spatial resolution, fat suppression and testing of the breast coil should be performed by qualified medical physicists at regular intervals. The MRI Breast examination should also be systematically examined and evaluated for quality control and improvement. Any adverse reactions or complications during the procedure should be reported and analyzed as a part of quality control program in the hospital. Both in house and external periodic auditing should be done for reporting standards as well as image output.

MRI guided Biopsy

Suspicious findings seen only on MRI with no correlate on second look breast ultrasound have to be biopsied under MRI guidance. Vacuum assisted breast biopsy (VAAB) device should be used. The breast should be immobilized between the grid plates. Too much compression should be avoided to prevent non visualization of the lesion. A marker clip placement is mandatory following biopsy. The marker position needs to be confirmed on post procedural mammography in two orthogonal planes.(10)

Written informed consent should be obtained by the operator prior to the procedure after explaining the steps of procedure and the possible complications such as haemorrhage, infection and cancellation of procedure due to nonvisualisation of lesion. Instructions about post procedure care should be duly explained to the patient by the radiologist conducting the procedure. History of allergy to drugs must be checked and documented.

Optimal precautions such as use of sterile gloves for performing the biopsy are mandatory. The needle length, gauge and throw should be confirmed before opening the sterile packaging of the VAAB device. The VAAB equipment must be calibrated before start of procedure. The concentration and expiry date of the local anaesthetic must be checked while preparing the procedure tray. Special care must be taken to use MR compatible equipment for the procedure.

During the procedure images that demonstrate important steps of the procedure must be saved. The images should have patient's name, Unique Hospital Identification Number (UHID), date, indication of right or left breast, name of hospital and other details as per local protocol. Special attention must be paid to disposal of all the sharps used during the procedure as per hospital protocol.

Report should contain details about the lesion targeted, type of biopsy equipment, gauge of needle, number of core specimens obtained, time of obtaining specimen and fixing in formalin and post procedure clip position. Complications of procedure if any should also be documented in the report. For example if the post biopsy mammograms demonstrate displacement of marker clip from the site of biopsy, this must be documented.

Clear mention of the clinical history, pertinent imaging findings, likely imaging diagnosis, name of procedure (VAAB), side (right/left breast), anatomic location depicted by o' clock position and distance from nipple should be mentioned on the pathology requisition form. Patient name, identification number, examination date, facility name, side (right/left breast), name of procedure should be mentioned on the container in which the sample is placed.

The cancellation rate for MR guided biopsy due to inability to visualise the targeted breast lesion at the time of biopsy after intravenous contrast injection ranges from 8% to 13%.(11) Nonvisualisation of target is an absolute contraindication to MRI guided breast biopsy.

Before cancelling the procedure it should be verified that the patient received a successful bolus of contrast and that blood inflow is not impeded by excessive breast compression. As there is a malignancy rate of 0%–10% for lesions that are not visualised at the time of attempted biopsy, follow-up diagnostic MRI should be obtained within 6 months to be certain that the lesion is indeed absent.(11,12)

The radiologist performing MR guided breast biopsies must be well versed with breast MRI, mammography and breast ultrasound interpretation, as this knowledge is essential for correlating MRI findings with mammography and ultrasound findings. This knowledge is critical for performing second look ultrasound for MRI-only lesions. After histopathology report is ready, the radiologist should correlate the radiological features with the pathology findings and add an addendum regarding radiology-pathology concordance. If discordance is found, appropriate advice must be given. Discussion with the referring clinician is of utmost importance in case of discordance.

Qualifications and responsibilities of the Radiologist

The radiologist should hold a degree in Radiology recognised by Medical Council of India. Interpreting radiologist should have all round knowledge of imaging and diagnosis of breast disease, thereby should be able to correlate MRI findings with Mammography and Breast Ultrasound. The slightly different positions in which a lesion may be demonstrated on a prone MRI, supine ultrasound and erect mammogram is best appreciated with a good knowledge of all three breast modalities. Additional training in breast MRI under supervision should be obtained before the radiologist reports Breast MRI independently. Reporting a minimum of 150 MRI Breast cases under supervision over a period of 1 to 2 years, depending on the caseload of the institute, is recommended before independent reporting.(7) Taking up a breast fellowship course or training under an experienced Breast Radiologist is strongly recommended before performing breast MRI and MRI guided interventional procedures independently. Subsequently, the radiologist is expected to report a minimum of 50 Breast MRI studies in a year to maintain reporting skills. Breast MRI should ideally be practiced in a facility having a capacity for mammography, ultrasound and breast interventions including MRI guided biopsy. If very few studies are performed in a centre or if studies are not performed for lack of technology such as a dedicated breast coil, the radiologist is encouraged to visit a centre which performs a higher volume of Breast MRI, and stay in touch with MR images and reporting. The radiologist is encouraged to attend educational courses for regular updating of MR technology and reporting techniques. If MRI guided biopsy is not offered by the centre, a referral centre with the facility should be accessible to the patient. The results of biopsies initiated on MRI findings require radiology-pathology correlation that should be tracked by the radiologist recommending the biopsy as well as by the radiologist performing the biopsy at the referral centre.

The Radiologist should review and validate clinical indication for the examination, set MRI protocol, use adequate dose of contrast, ensure an emergency physician is available when contrast is given, interpret the Breast MRI including review of pertinent prior breast imaging studies and provide a report with recommendations. Established reporting systems such as the Breast Imaging Reporting and Data System (BI-RADS) of the American College of Radiologists are encouraged for uniformity and standardization of reports.(13) The salient features to be covered in the report have been enumerated in Appendix 1 of this document. All printed films and softcopy of the MRI images must be correctly labelled with the name, UHID number, date, side and other details as per local protocol. Selected MR images that are printed are to be decided by the radiologist and should include time intensity curves of significant lesions.

Qualifications and responsibilities of the Technologist:

The technologist must have a 2 or 3 years diploma or degree such as Diploma in Radiography, Diagnostic (DRD) or Bachelor in Medical Radiotherapy Technology (BMRT) recognized by the state / central government and have specific training in MRI as part of this training programme. The technologist is expected to perform 20 Breast MRI Breast scans under supervision prior to performing Breast MRI independently. The supervised scans may be performed in a different centre that has been performing Breast MRI or can be in the technologist's own centre under the supervision of a senior MRI technologist in the department or the application specialist of the MR manufacturer if Breast MRI service is being newly set up in the hospital. The technologist should be able to manage overall safety of the patient, staff and equipment during the procedure. The contraindications for any routine MRI applies for breast MRI also, and it is the responsibility of the technologist to check for any contraindications based on the MRI questionnaire filled by the patient. He/she should be able to produce high quality images and to adjust protocols as required. Technologists are encouraged to attend periodic educational courses for continuing upgradation of technical knowledge.

DISCLAIMER

Above mentioned Quality Assurance Guidelines are purely recommendatory and general purpose only in nature. Actual decisions for investigation and management of the patients should be individualised 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 members of Breast Imaging Society, India or Breast Imaging Society, India as the organization cannot be held responsible for that in any manner.

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Appendix A

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

BREAST MRI REPORT TEMPLATE

(Based on Breast Imaging Reporting And Data System: ACR BIRADS Breast Imaging Atlas)

1. **Indication**:
2. **Technique** : Magnet strength, coil type, sequences used, contrast details, correlation with mammography and ultrasound
3. **LMP**
4. **Overall Breast Composition** : Type a,b,c,d (choose one of the below):
    - a - Almost entirely fat
    - b - Scattered fibroglandular tissue
    - c - Hetereogeneous fibroglandular tissue
    - d - Extreme fibroglandular tissue
5. **Background Parenchymal Enhancement** : (also look for symmetry)
    - a - Minimal
    - b - Mild
    - c - Moderate
    - d - Marked
6. **Clear description of significant findings**:

    MASS:

    Size

    Location : laterality (left/right), o' clock position, distance from nipple/skin/chestwall

    Shape: oval / round / irregular

    Margins : circumscribed / non-circumscribed (irregular / spiculated)

    Enhancement Characteristics : homogeneous / heterogeneous / rim enhancement / dark internal septations

    Kinetics : Initial enhancement phase : slow /medium / fast

    Delayed Phase : persistent / plateau / wash-out

    Type of Time Intensity Curve

    NON-MASS ENHANCEMENT (NME):

    Location: laterality (left/right), o' clock position, distance from nipple/skin/chestwall

    Distribution: Focal /Linear/ Segmental / Regional/ Multiple regions/Diffuse

Enhancement Patterns: homogeneous / heterogeneous / clumped /clustered ring
Kinetics:
FOCUS : Location, number, symmetry, kinetics
OTHER FINDINGS : cysts / non enhancing mass / dilated ducts/ skin thickening / nipple retraction / chest wall invasion/ intramammary lymph nodes
IMPLANTS : Material, location, integrity
SECOND LOOK USG FINDINGS
AXILLARY LYMPH NODES
INTERNAL MAMMARY LYMPH NODES
FINDINGS IN THE OTHER BREAST (similarly described in detail)

7. **Comparison** with previous MR Breast studies
8. **Impression** : BI-RADS Assessment Category & Management Recommendation
   BI-RADS : 0 (Incomplete — Need Additional Imaging Evaluation)
   BI-RADS : 1 (negative - within normal limits)
   BI-RADS : 2 (benign)
   BI-RADS : 3 (probably benign. Needs follow up in 6 months' time)
   BI-RADS : 4 (suspicious for malignancy. Core biopsy is advised)
   BI-RADS : 5 (Highly suggestive of malignancy. Core biopsy is advised)
   BI-RADS : 6 (Biopsy proven malignancy)

9. **Other important information / advice** that you wish to communicate: for example when there may be a mismatch between BI-RADS category and the management recommendation, a clear explanation for your decision should be given. Also important negative findings should be mentioned in the report in relevant clinical scenarios.

REFERENCE:

D'Orsi CJ, Mendelson EB, Ikeda DM, et al. Breast imaging reporting and data system: ACR BIRADS breast imaging atlas. Reston (VA): American College of Radiology; 2003)

Appendix B

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

MRI GUIDED BREAST BIOPSY REPORT TEMPLATE

Informed Consent: Includes explanation of steps of procedure, possibility of complications such as pain, bleeding and infection, including cancellation of procedure due to nonvisualisation of the targeted suspicious abnormality.

Indication: Suspicious finding on MRI with no clinical / other imaging (Mammogram/USG) correlate.

Method: Grid/ post & pillar method.

Description of abnormality: mass / non mass enhancement / focus

Location of abnormality: right/ left breast, quadrant, 0' clock position, distance from nipple.

Approach: Medial/ lateral/ both

Type of biopsy: Vacuum assisted biopsy, needle gauge used.

Patent position: Prone

Procedure: Preprocedural contrast MRI (type and amount of contrast used) was performed and the lesion to be biopsied was visualised. Under local anaesthesia (type and ___ mls of local anaesthetic used), after localising the target, biopsy was performed using VAAB with ___ gauge needle and about 12 (minimum) cores were obtained from the target. Post procedure MRI showed cavity at the target site. A marker clip (type and name) was placed at the site of biopsy. Post procedure check mammograms were obtained for confirmation which demonstrated optimum clip position.

Documentation of procedure:

1. MRI of target finding, MRI of coaxial needle position in prefire, MRI of VAAB needle, post biopsy cavity.
2. Mammogram in two orthogonal planes post biopsy after clip placement
3. If more than 1 lesion is biopsied, separate reports must be given for each procedure

Complications: Significant bleeding / pain – Yes/ No

Post procedure instructions: Ice packs for pain, analgesics, care of dressing.

Emergency contact no:

Addendum to the report after histopathology result:

1. Radiology – Pathology concordance
2. Advice/ Recommendation after biopsy results