BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

INTRODUCTION

Breast Imaging Society, India was established with the aim of improving Breast Imaging standards in India which in turn would lead to the improvement of breast health care in India. Central to improving Breast Radiology in the country is the achievement of a uniform standard of investigation and care for all Indian women irrespective of their location, monetary status and hospital/ diagnostic centre they avail services from. This is an attempt at providing all Breast imagers and imaging institutions a framework with which they can maintain optimum quality of breast imaging services. The language has been kept simple and guidelines are practical for the indian subcontinent so that radiologists and radiographers can easily understand and apply the guidelines in their day to day practice.

A task group was formed by BISI to draw Quality Assurance standards for all breast imaging modalities. The aim is to keep this framework simple and practical, so that it is easily readable and applicable in all situations. We understand that not every unit may be able to afford the best equipment for all investigations. In the absence of a national population based breast screening programme, the number of breast investigations may be too small in some units (such as small diagnostic centres) to allow investment into state of the art equipment. However it is possible to achieve optimum breast imaging standards with the application of thought and attention to the basic aspects of breast imaging requirements. For example even a small diagnostic centre can buy a linear probe with optimum features for breast imaging, when a ultrasound machine is being bought, as long as they are aware of the requirements for breast ultrasound. The purpose of this document is to set the basic optimum machine, radiographer, radiologist and working condition standards that are advisible for breast imaging in our country.

These guidelines have been formulated with the knowledge and experience of the task group members and other members of BISI, and care has has been taken to make this relevant for large institutions as well as small diagnostic centres. Recommendations have been made keeping in mind the need for this to be cost effective. We understand that our country has a unique medical system, which brings it's own positive benefits as well as it's own challenges. We hope that the medical fraternity will appreciate and follow our recommendations. Most importantly we hope that these recommendations will result in saving precious lives and make our efforts worthwhile!

The members of the Task group for Quality Assurance look forward to your comments and positive criticism. This is the first edition of these guidelines and we hope Breast Imaging Society, India will further update these guidelines in the future. Your comments will help us in this endeavour.

TASK GROUP MEMBERS FOR "QUALITY ASSURANCE GUIDELINES IN BREAST IMAGING"

Dr Suma Chakrabarthi [Lead, Task Group], MRCS (Edn), FRCR (UK), PGCE (Bristol,UK)

Dr Veenu Singla, MD

Dr Punam Bajaj, DMRD, MD, DNB, Fellowship BCRF (MSKCC, NewYork)

Dr Raju Vinod Wadhwani, DMRD, DNB

Dr Rupa Renganathan, DMRD, DNB,FRCR

Dr Janaki P Dharmarajan, DMRD, DNB, Fellowship in Breast imaging(UoT Toronto, Canada)

Dr Mukta Mahajan DNB, Fellowships in Breast Imaging & Intervention (Austria & Canada)

Dr Beenu Varghese, DMRD, DNB

Dr Bagyam Raghavan, DMRD, DNBE

Dr Shilpa Lad, MD (Radiology), Fellowship Breast Imaging (U'sity Toronto, Canada)

Dr Neha N Shah , MD, FRCR, M. MED

Dr Sangeeta Saxena, MD Radiodiagnosis

Prof Subhash K Ramani, MD Radiodiagnosis

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

MAMMOGRAPHY

Quality Assurance (QA) is defined by Atomic Energy Regulatory Board (AERB), India as 'planned and systematic actions necessary to provide adequate confidence that an item or facility will perform satisfactorily in service as per the design specifications.(1) AERB has regulations and we advise the users of mammography equipment to follow AERB rules and regulations applicable to their individual machines. In this document Breast Imaging Society, India (BISI) has advised further simple QA measures that are easy to implement at departmental / hospital level and will further improve the quality of patient care. Minimum standards for the radiologist, technologist/mammographer have also been specified in an attempt to objectively assess and implement good standards of breast imaging across all parts of our country. QA for Digital Tomosynthesis (DBT) as well as stereotactic breast biopsy has also been discussed. Quality control (QC) tests that are practical and relevant for radiologists have also been discussed and advised. Please refer to 'Best Practice Guidelines of Breast Imaging Society, India for indications of mammography.(2) At the very end of the document appendix 1 contains details of AERB documents as well as QC tests for DBT recommended for the breast radiologist and technologist. There are reporting templates for mammography and stereotactic breast biopsy in appendix 2 and 3 respectively.

MAMMOGRAPHY EQUIPMENT

Mammography units can be of three types - Digital Radiography (DR), Computed Radiography (CR) and Traditional Film based mammography units. Quality Assurance tests are mandatory for all types of mammography units and mandatory test reports are to be submitted to the Radiological Safety Division of AERB, India as per regulations.

The technique of acquisition of mammographic images must be monitored with specific attention to radiation dose and technical adequacy of films. The dose of radiation must be minimised based on the As Low As Reasonably Achievable (ALARA) principle.(1) Most mammography units have an automated exposure control (AEC) system, which helps minimize radiation for the given breast thickness and composition. Exposure time must be

as low as possible to reduce dose, to avoid motion artefact and to minimise discomfort to the lady being imaged. Optimal compression must be applied(2).

Regulatory Inspection Programme of AERB includes three types of inspections. These are planned and announced inspections, special regulatory inspection which are reactive and announced inspections, as well as surprise regulatory inspections which are reactive/pro-active and unannounced inspections.(3)

At the time of installation, submission of Survey Report detailing radiation survey levels measured around the installation is mandatory.(4) The radiation survey report contains details of maximum radiation level at various locations such as the lead glass wall, operator position, entrance door, patient waiting area, front and side walls, entrance corridor, etc. The radiation survey report also contains details of the QA tools used such as kVp and dose meter, survey meter and imaging phantom.

Typical AERB tests and measurements include performance test verification of safety system/components, radiation protection survey and area monitoring, clinical/product dosimetry and contamination checks.(3) Personal dosimeters must be given to all radiation workers, including trainees. Any unusual occurrence/incident must be documented and measures must be taken to avoid recurrence of the same.(3)

Periodic QA test reports must be submitted to AERB at least once in two years and also after any repairs having radiation safety implications.(5) Parameters tested for periodic radiation safety performance test report include accuracy of operating potential, accuracy of timer, linearity of tube current, reproducibility of output, radiation leakage level at 5 cm from the external surface of X-ray tube housing, total filtration and performance of imaging phantom.(5) Image quality is assessed by using a mammography phantom. The optimum values for the tests are provided by the manufacturer and the measurements acquired are compared against the provided optimum values and AERB standards.

For DR Mammography digital detectors must be calibrated periodically as per manufacturer's recommendations. For CR Mammography the CR cassettes must be cleaned and evaluated for artefacts as per manufacturer's instructions. In the presence of artefacts that compromise image quality (for example artefacts that mimic microcalcifications) the CR cassettes must be discarded. In Traditional Film based mammography cassettes must be similarly monitored and darkroom techniques must be as per manufacturer's instructions.

Additional recommendation for Image quality assessment by Breast Imaging Society, India

Image quality assessment by using a mammography phantom is advised at least once a week. However daily assessment prior to the first case of the day is ideal, especially for screening mammograms. To pass the mammography image quality standards at least four

fibres, three calcification groups and three masses must be clearly visible (with no artefacts) at an average glandular dose of less than 3 mGy upon mammography of the phantom.(5) Image quality has been chosen as the method of continuous assessment as this is a simple quick test that can be performed by the mammographer. This test not only confirms that the image is of optimal quality but also indirectly assesses the multiple factors that affect image quality such as operating potential, operating tube current, exposure time (msec), effective focal spot size, total filtration, leakage from tube housing and detector characteristics.(6)

Mammography image acquisition:

Technically adequate Mediolateral oblique (MLO) and Craniocaudal (CC) views are the two standard views of mammography advised for each breast, both for screening and diagnostic mammograms. For breasts with implants within, additional CC and MLO views with implant displaced optimally are advised. The minimum requirements for the MLO view include visualisation of the pectoralis up to the level of the nipple, convex anterior border of the pectoral muscle, nipple in profile, inframammary fold which should be seen and open. The minimum requirements for the CC view include visualisation of the nipple in profile and visualisation of retroglandular fat. Length of the posterior nipple line on CC should be within 1cm of the length of posterior nipple line on the MLO view. Skin folds are to be avoided on both views.

Additional views (such as spot compression view, lateral view, laterally extended CC view and medially extended CC view) could also be acquired for better demonstration of abnormalities. In case of palpable masses special attention must be paid to confirm visualization of the palpable lesion on the mammograms. Repeat films may sometimes be required, but these must be minimized. Additional views and repeat images should be justified by clinical need as well as by ALARA principle. Departmental policy on repeat exposures and additional images must be followed. The technologist assesses the acquired images for adequacy of position as well as artefacts. Degree of autonomy of the mammographer and radiologist's active supervision in these decisions depend on mammographer's work experience and expertise, and should be decided by the supervising radiologist.

CC and MLO markers must be placed as per international practice in the lateral aspect on the CC view and in the superior aspect of the MLO view. A skin lesion or mole that may mimic a mass on the mammograms should be marked on the skin with a tiny radiopaque marker which should be smaller than the skin lesion itself. These should be identified by the mammographer at the outset and mammograms should ideally be acquired after the marker is optimally positioned rather than repeating mammograms. This will avoid increased radiation dose to the patient. Palpable masses also should ideally be marked with

a radiopaque marker. This helps identify the palpable mass on the mammograms and this is extremely helpful in cases with multiple focal lesions in the breast.

Review of all mammograms by the radiologist immediately after acquisition of images is encouraged to decide need for additional diagnostic views. However screening mammograms can be acquired in the absence of the radiologist if local protocol allows. In this case the lady will need to be recalled for further views as required.

MAMMOGRAPHY PERSONNEL

Specialist Breast Technologist / Mammographer

The mammographer must have a 2 or 3 years diploma or degree such as Diploma in Radiography, Diagnostic (DRD) recognized by the state / central government. She should have specific training in Mammography as part of this training programme. Performing a minimum number of 100 mammograms under supervision before performing mammography independently is strongly recommended. After completion of training a minimum of 150 procedures should be performed per year to maintain the skills acquired. Mammographers are encouraged to attend periodic educational courses for continued upgradation of technical knowledge. Appropriate training of mammographers should be organised as this significantly improves technical adequacy of mammograms and reduces repeat images, thus reducing patient dose significantly.

Mammographers are to take lead in regular radiographic quality control procedures. They are also responsible for maintaining documentation of quality control tests. They are advised to report any breaches / incidents to the radiologist in charge.

The mammographer should counsel the lady about the procedure, especially the importance of compression during the procedure. She should be able to answer basic questions on radiation dose and importance of screening. She should be able to help the patient fill relevant patient questionnaires, check if the requisition for mammography is as per department protocol and document patient complaints as required. She should record patient contact details to ensure a seamless recall process if required. She should collect previous mammograms and relevant clinical notes and make these available during reporting. She should also explain to the patient the process and time for report collection.

Mandatory check of name and unique hospital identification number (UHID) must be performed before pressing the button that activates radiation to ensure that the right patient is being imaged. All films must be correctly labelled with the name, UHID number,

date, side and other details as per local protocol. Repeat mammograms done for technical or positioning errors must be kept to less than 3%. (7)

Breast Radiologist

The radiologist should have a medical qualification and should hold a degree in Radiology that is recognized by the Medical Council of India. She/he should have specific training in Mammography as part of her/his training programme. Taking up a breast fellowship course or training under an experienced Breast Radiologist is strongly recommended before independent reporting of mammograms. This kind of training should also help develop skills for performing mammography guided procedures such as guided hookwire localization and stereotactic biopsy. Radiologist must attend periodic continued medical activity (CME) courses for continuing upgradation of technical knowledge.

During training the radiologist is expected to report a minimum of 1500 mammograms under supervision before he/she starts reporting independently. This may be over a 1 to 2 year period depending on the volume of mammograms in the unit. To maintain skills the radiologist is expected to report a minimum of 500 mammographic examinations per year. Reporting terminology and format in accordance with ACR BI-RADS lexicon and assessment categories is advised.(8)

The lead breast radiologist is in charge of the breast unit and should take responsibility for quality related issues including equipment selection, staff selection and quality control protocols along with the hospital management team. This also includes interactions with medical physicist, biomedical engineer, vendor's application specialist and provision of training for mammography technologists. Responsibility of planning audits, delegating related work to the appropriate person and applying the lessons learnt from the audits to implement changes in the department protocols rests with the lead breast radiologist.

RADIATION DOSE & SAFETY

In both full-field digital and screen-film mammography the average glandular dose delivered by a single craniocaudal view of a 4.2 cm thick, compressed breast consisting of 50% glandular and 50% adipose tissue must not exceed 3.0 mGy (0.3 rad), although it is generally much lower.(9) The digital mammography systems automatically calculate dose making dose assessment an easy process. The mammographer and radiologist must endeavor to achieve this by following the ALARA principle. All tests, for example check mammograms after the machine is serviced, must be on a phantom and not a patient.

The requisition form must justify mammography and if any doubt exists the referring doctor should be contacted before radiating the patient. Every patient must be questioned about recent mammography examination. If mammography has been performed within the last year, mammography should be performed only if clinically justified and after discussion with the radiologist. If good quality mammograms have been acquired at one hospital they must not be repeated at the hospital where second opinion is being given. If repeat is required only those views that were suboptimal in the first instance should be repeated. At six month follow up mammography for a BI-RADS 3 lesion unilateral mammography of the side of concern must be performed rather than bilateral mammography.

The mammographer must confirm patient's name and unique hospital identification number before performing mammography, to avoid radiation incidents. After obtaining the MLO and CC views, further views should be acquired only if it is expected to add further information or clarify doubts arising from the basic images.

Routine wearing of lead shield or apron is not recommended as most of the dose to the organs is as a result of scatter in the breast tissue and enters the trunk through the breast and this minimizes the benefit of wearing a lead apron.(10)

Pregnancy & Mammography

Women of child bearing age must be checked for pregnancy status, and a pregnancy test is advised if doubt exists. The estimated dose to the uterus from an average bilateral two view mammography is less than 0.03µGy (0.003 mrad) and this can be representative of the dose to the fetus in the first trimester.(10) The use of a lead shield reduces this dose further by about a factor of between two and seven. Therefore a pregnant patient can reduce the dose to the fetus by at least one half by wearing a lead apron.(10) If a patient is not aware of her pregnancy status and happens to undergo mammography, the risk to the fetus appears to be minimal.(10) Two types of radiation related side effects are known, Deterministic and Stochastic. No known in utero induced deterministic side effects such as teratogenic fetal effects have been reported at radiation less than 50 mGy (5 rad) (11), thus no significant deterministic side effect on the fetus is expected from mammography. Stochastic risks which are the result of cellular damage, causing cancer or germ cell mutation, have no threshold dose value and the severity of radiation induced stochastic effects is independent of the radiation dose.(12) Therefore mammography should be carefully used in pregnant patients although fear of potential radiation effects on a fetus should not deter us from performing necessary mammographic studies and a case based approach to decision making is advised.(13) Although most of the dose to the uterus is from scatter radiation a lead shield should still be offered to all pregnant patients.(14) Routine screening mammography is not performed during pregnancy.(14)

Staff & Visitors

Radiation safety of staff and visitors to the department of Radiology is of utmost importance. The mammography unit must be built, maintained and checked periodically to confirm that AERB regulations are met. Application must be made to AERB for permission of installation of mammography equipment by the e-Licensing of Radiation Applications (eLORA) System (4) and mammography machine must be placed in the hospital with full compliance with AERB regulations(3). Personal dosimeters must be worn by all personnel, including trainees at all times. The effective dose received by a radiation worker should not exceed 20 mSv in a year averaged over five consecutive years (calculated on a sliding scale of five years) and effective dose in any single year should not exceed 30 mSv, as per radiation dose limits specified by AERB for radiation workers. In the case of a pregnant radiation worker once pregnancy is declared the equivalent dose limit to embryo/foetus should be 1 mSv for the remainder of the pregnancy.(15)

The mammography room must be used to perform mammography and mammography guided interventional procedures only. No other investigations, such as breast ultrasound should be performed in the mammography room. Only personnel involved in the procedures must be present in the room during the examinations. This includes trainees who are posted to breast imaging. The mammography machine should be handled only by the mammographer designated for the study. The mammographer's control panel must be situated behind a protective screen as per AERB regulations. The door of the mammography room must be shut and locked at the time of image acquisition and a red light just outside the door must be switched on so that other members of the department as well as the patients waiting outside the room are aware of the risk of radiation.

STEREOTACTIC BIOPSY

The team performing stereotactic breast biopsy should be adequately trained with regards to the equipment, procedure and possible complications of the procedure. The technologist should be well versed with mammography and preferably undergo three months of observation or supervised training for stereotactic biopsy at a specialized breast unit. Dedicated training by the application specialist of the manufacturer and performance of stereotactic procedure under supervision of application specialist before independently performing the biopsy is also acceptable.

The breast radiologist performing the procedure should be trained in stereotactic procedures at a specialised breast unit prior to performing stereotactic procedures independently. A minimum of 150 supervised image guided breast procedures (both ultrasound and mammography guided procedures included) are recommended to be

performed over a period of 1 year to train adequately. A minimum of 60 image guided breast procedures (both ultrasound and mammography guided procedures included) per year are recommended for maintaining interventional skills in breast imaging. The radiologist performing image guided breast procedures must be well versed with mammography and breast ultrasound interpretation, as this knowledge is essential for Radiology – Pathology correlation.

Stereotactic biopsy may be performed with a dedicated prone setup or with an add-on device and adjustable chair. All equipment must be calibrated as per the manufacturer's guidelines. Quality control tests for the mammographic unit used to perform stereotactic biopsy are as per manufacturer's instructions as well as AERB regulations.

At the time of installation of the stereotactic unit, an initial comprehensive performance test is to be performed by the engineers.(16) Mechanical stability of the free standing unit, smooth motion of the moving parts, stability of the image receptor holder assembly, adequate support for the needle holders & needle guides and adequate radiation shielding for the operator/technologist have to be checked and documented at the time of the installation of the unit.(16) This must be repeated each time the mammography machine is serviced or repaired due to break down of equipment. Annual quality check by a medical physicist to assess mechanical components of the equipment, collimation, focal spot performance, accuracy of kVp, half-value layer assessment, AEC performance, assessment of radiation dose and evaluation of image quality is advised.(16)

Prior to the procedure checks must be performed by the mammographer as per manufacturer's instructions to check the accuracy of stereotaxis. On the accuracy test, each of the indicated needle tip coordinates (x, y and z axes) should be within 1 mm of the actual preset needle tip location. That is, the difference between the preset location and the computer determined location should be less than 1 mm in each direction.(17) If a localization phantom is used, the localization accuracy test should result in the needle tip being within 1 mm of the targeted phantom location in each direction.(17)

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, retargeting and repeat procedure. 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 core or vacuum assisted breast biopsy (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.

During the procedure images that demonstrate the important steps of the procedure must be saved. The images should have patient's name, UHID number, date, indication of right or left breast, name of hospital and other details as per local protocol. Pre-procedure scout image documenting the lesion that is being targeted (typically microcalcifications), pre-procedure stereotactic pair images, prefire and one set of post fire stereotactic pair images would be a good set of images to save for future record. A radiograph of the samples acquired must be saved in the case of microcalcifications to document adequate sampling. As the risk of insufficient sampling is greater if no calcifications are seen on the sample radiograph(18), further sampling sometimes after retargeting should be attempted. A post-procedure scout image (demonstrating partial or complete removal of lesions) is also advised, especially if the lesion biopsied is not calcifications and hence radiography of samples cannot be used as confirmation of adequate sampling. If a marker clip is deployed (for example following complete removal of the targeted lesion), image demonstrating optimal placement of marker clip should also to be saved. After the procedure is completed formal CC and lateral mammograms of the ipsilateral breast are performed to confirm position of the marker clip.

Special attention must be paid to disposal of all the sharps used during the procedure as per hospital protocol. The biopsy room must have a sharps' bin for discarding the needles used during the procedure.

Report should contain details about the lesion targeted, direction of compression, approach, type of biopsy equipment (fully automated core biopsy or vacuum assisted biopsy), gauge of needle, number of core specimens obtained, time of obtaining specimen and fixing in formalin, findings of radiograph of samples if any and post procedure clip position if a marker clip has been positioned. 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, that must be documented.

Clear mention of the clinical history, pertinent imaging findings, likely imaging diagnosis, name of procedure (core or 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. 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 repeat biopsy, follow up scan or investigating the breast with a different modality such as MR should be advised as appropriate. Discussion with the referring clinician is of utmost importance in case of discordance.

Other mammography guided procedures such a hookwire localization and marker clip placement should also be similarly consented, documented and reported. This applies to tomosynthesis guided procedures as well.

DIGITAL BREAST TOMOSYNTHESIS

Digital Breast Tomosynthesis (DBT) is an active area of research and development with evolving clinical role. In principle DBT is a quasi-3D imaging technique in which the x-ray tube rotates along an arc around the breast and acquires several low dose images. The relative positions of structures at different depths in the breast change on the image at different angles. From these projection images a 3D data set is reconstructed and viewed as thin slices. The number of DBT installations in India is on the rise. As India embraces clinical implementation of this technological advancement, attention to QA parameters is of paramount importance. Due to the wide variation in hardware as well as processing algorithms used by different manufactures, adherence to manufacturer's QC tests becomes even more important with DBT systems. QA guidelines that may be suitable in the Indian context have been recommended in this document. In the absence of international consensus about some of the QA protocols, several international guidelines have been referenced for this purpose.

Indication

DBT is recommended as a complimentary method and not a standalone screening technique in the first 6 months to a year of installation to accommodate the learning curve of the mammographer and the radiologist and also for optimization of image quality. DBT has been universally accepted as a diagnostic mammography evaluation tool and used as an adjunct to conventional mammography in those cases requiring further workup.(19) The indications for diagnostic DBT are the same as for 2D Digital Mammography (DM). DBT may be performed in addition to CC, MLO and/or supplemental views to evaluate an area of clinical or imaging concern.(20) When used for screening complete 2-view DBT acquisitions of each breast are taken in addition to standard DM views. Synthesized 2D image (SM) can be generated from DBT dataset allowing for elimination of a separate DM exposure. Use of DM+ DBT increases the radiation dose by a factor of 2.25 compared with that for DM only examinations. If DM is replaced with SM, the radiation dose can be reduced by 45%.(21) Studies show that performance of SM + DBT is equivalent to DM + DBT.(22–24) To image breasts larger than the detector, performing DBT for all routine and additional exposures with synthesized 2D images should be considered. If both DM and DBT acquisitions are required, DBT should be restricted to views that cover largest portion of the breast to minimize radiation dose.(25) While imaging breasts with implants, DBT should be used only for implant-displaced views.(25)

Reporting terminology and format are in accordance with reporting of 2D mammography. It's preferable to use ACR BIRADS lexicon and assessment categories just as for 2D mammography. Slice number and views of findings on DBT should be included in the report. Prints of synthesized images must be labeled as such to distinguish from a DM exposure.

Prints of DBT images must include slice number, thickness, and location relative to the side of the breast.

Training and certification requirements for Mammographer and Radiologist

Basic training requirements listed in the mammography section for technicians and radiologists working in breast imaging centres must be met with. Specific training for DBT may be obtained during residency or fellowship in Breast imaging for radiologists and as part of the radiography curriculum for radiographers. However it is expected that most breast radiologists and radiographers practicing today are unlikely to have been exposed to this technique of imaging. Due to wide variation in technology it is advisable that training is acquired from individual DBT manufacturers in the form of training courses and observerships in units who have the same equipment run by qualified peers. A minimum of 8 hours of initial training with documentation in the form of a training certificate or letter is advisable prior to independently using this new mammographic modality.(26) Over and above the basic training, mammographers and radiologists are encouraged to continuously update their knowledge and skills. The lead radiologist has the responsibility of recognizing additional training requirements of the staff in order to maintain and improve the quality standards of the unit.

Image Acquisition & Archiving

As in DM, the aim in QA of DBT is to acquire the best possible quality images with lowest radiation dose as per ALARA principle. The testing procedures and requirements specified for DBT units are consistent with those specified in the DM section as per AERB guidelines. It should be noted that the manufacturers may advise some machine specific QA testing to be done that is additional to these tests.(19) Working conditions and image display requirements are also the same as DM.

There are many international guidelines available on DBT and the reader is urged to study these and apply necessary QA measures at departmental and hospital level as required. (19,25,27)

DBT images if generated in proprietary format should be converted to the DICOM standard of Breast Tomosynthesis Object (BTO) before transfer.(25) The archive device should support DICOM receipt of MG images and DBT data sets. Storage of “for presentation” or processed images is required to ensure the ability of radiologists to reproduce the original images used for interpretation. Storage of images “for processing” or raw data is encouraged but is not mandatory. The archive device should be able to query and retrieve DM and DBT data sets.

DBT-guided biopsy equipment

It is recommended but not mandatory. Procedure related QA and documentation of images for DBT biopsy are similar to the steps mentioned in the stereotactic biopsy section. If DBT guidance is not available for a tomosynthesis-only finding, it is acceptable to perform a stereotactic biopsy using adjacent tissue landmarks for guidance. However a biopsy marker should be placed with post procedure DBT images in two projections to demonstrate that the original finding was properly targeted.

THE REPORTING STATION

Luminance of the viewing light box should be a minimum of 3,000 candelas per square meter (cd/m^2) for screen-film mammography and for display of digital images printed on films.(28) Viewing boxes of appropriate size, ideally to allow comparison with previous mammograms, are required. All tubes may need simultaneous replacement to ensure they are of the same colour and intensity, therefore maintaining uniformity.

Ambient lighting must be conducive to reporting. Room lighting should be indirect and care should be taken to make sure that no illumination from room lighting falls directly on the reporting monitor. The ambient lighting must not exceed 20 lux, and should be assessed as part of Mammography QA(19). The visual inspection of ambient lighting should be done daily by designated QA technologist.

Two 5-megapixel monitors are advised for display of images at the reporting work station of the radiologist. The monitors must be checked annually by the medical physicist or a biomedical engineer, as per local protocol. One 3-megapixel monitor should be available for technologists situated close to image acquisition area. This can include the acquisition station itself.(18)

At the radiologist's work station multiple layouts of image display can be arranged and a hanging protocol for image display can be set up as per radiologist's preference. It is advisable to print the right and left MLO images side-by-side with the posterior part of the images facing each other to optimize detection of asymmetries. CC images should be displayed similarly on printed images. Comparison of current studies with prior examinations is strongly recommended. To facilitate meaningful comparison the printed images should have the magnification factor documented on them so that comparison of size of abnormalities is possible even at other centres if required. Mammographic displays should allow fast and easy navigation between previous and current studies as well as between 2D and DBT images.(28) Storage requirement estimates should therefore take into account the need to store and access current and prior images. Prior examinations may be imported from portable media. Digital mammogram image compression can provide more efficient transmission and storage. Wherever picture archiving and communications system

(PACS) is used, it must be ensured that quality of patient images is maintained in the PACS system and 5 megapixel mammography display systems are used for reporting. A lossless compression must be used during image storage or transfer thereby by definition there is no impact on the image and thus optimum image quality is ensured for interpretation(19).

Routine cleaning of monitors and viewing boxes with cleaning agents as per manufacturer‘s choice is advised. Cleaning the monitor to keep it dust free is recommended at least once a week.

Images should be printed using films and printers compatible with the mammography machine as recommended by the manufacturer and also as per local hospital regulations.

It is advisable for DR and CR facilities to maintain mammography images and reports in the permanent medical record of the patient for a period of not less than 5 years.(29) Traditional film based mammography units may save reports only for the same duration as the printed images are given to the clients.

AUDITS

Audit of mammography acquisition is advised once a year for each mammographer. This should include audit of retakes due to suboptimal positioning or other factors. A good example to follow is categorizing mammography position as perfect/ good/moderate/poor (PGMI) and auditing to see if each mammographer achieves 50% or greater P or G ratings in a PGMI evaluation of 50 randomly selected image sets. (30)

Audit of radiation dose per mammogram should also be performed at least once a year in the unit.

Audit of breast radiologists’ performance should be conducted annually. This should include review of appropriate clinical indication, accuracy of reports and correlation with pathology reports to check adequacy of sampling in cases of stereotactic procedures.

An audit of stereotactic procedures should be performed in the unit annually. Total number of stereotactic biopsies performed, total number of cancers detected, benign lesions detected, inconclusive results requiring repeat biopsy and complications should be analysed.(31)

In units with DBT additional dedicated DBT medical audits are advised, particularly in screening setting to distinguish between the two modalities with respect to performance. Examinations should be systematically reviewed and evaluated as part of the overall quality

improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examinations. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed, reported, and periodically reviewed to identify opportunities to improve patient care.

Records of all audits and training activities must be maintained in the department. The lead radiologist is in charge of planning the audits as well as applying findings of the audits to enhance patient care.

TEAM WORK & MULTIDISCIPLINARY MEETINGS

For QA measures to be effective it is important that all members of the team understand their role and participate actively in the programme. Radiologists, radiographers, breast care nurses, medical physicists, information technologists and healthcare managers need to work as a team for a good QA programme to make a difference to our patients.

Each mammography unit should develop policies and procedures related to quality control and assurance, infection control and patient safety. These should be documented and kept in the breast imaging and intervention department. These should be readily available to all team members. Audits to check compliance with local policies should be encouraged.

Regular multidisciplinary meetings (MDM) should be held so that clinical features, imaging findings and results of biopsies can all be well correlated and appropriate decision on the next best step for the patient can be taken on a case to case basis. The participation in the MDMs must be mandatory for all doctors and breast care nurses and at any given meeting representation from consultant level team members of all specialities must be mandatory.

NUCLEAR MEDICINE

Centres which have PET CT and sentinel lymph node biopsy facilities must follow AERB rules for nuclear medicine facilities. Radioisotopes handled, handling facilities, imaging equipment, availability of operating personnel and their monitoring, measuring instruments /protection level equipment (such as Radiation survey meter, Contamination monitor, dose calibrator, dosimeters), availability of documents (such as minutes of local safety committee meetings, patient information data), are all checked during the AERB regulatory inspection the frequency of which depends on the nuclear medicine equipment available on site.(3)

DISCLAIMER

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

REFERENCES

1. Radiation Safety In Manufacture, Supply And Use Of Medical Diagnostic X-Ray Equipment, AERB Safety Code No. AERB/RF-MED/SC-3 (Rev. 2), March 2016, Atomic Energy Regulatory Board, India, [Internet]. https://www.aerb.gov.in/images/PDF/RF-MED-SC-3.pdf (accessed on 5 September 2020)

2. Best Practice Guidelines - Mammography. Breast Imaging Society, India. http://www.bisi.co.in/mammography1.html (accessed on 29 June 2020)

3. AERB Safety Manual, Regulatory Inspection And Enforcement In Radiation Facilities; AERB/RF/SM/G-3; Atomic Energy Regulatory Board, India; December 2014. https://www.aerb.gov.in/storage/images/PDF/13-January-20151.pdf (accessed on 5 September 2020)

4. e-Licensing of Radiation Applications (eLORA) System Guidelines, Medical Diagnostic-Radiology Module, Atomic Energy Regulatory Board, India; July 14, 2016 https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/e-LORA-Diagnostic-Radiology-Guidelines.pdf (accessed on 5 September 2020)

5. Format for periodic quality assurance test report for Mammography equipment, Atomic Energy Regulatory Board, India https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/3-FORMAT-FOR-PERIODIC-QUALITY-ASSURANCE-TEST-REPORT-FOR-MAMMOGRAPHY-EQUIPMENT.pdf (accessed on 5 September 2020)

6. Radiation Safety Training Module: Diagnostic Radiology; Quality Assurance in Diagnostic Radiology; Radiology Safety Division, Atomic Energy Regulatory Board, India https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/QUALITY-ASUURANCE-OF-DIAGNOSTIC-X-RAY-EQUIPMENT.compressed.pdf (accessed on 5 September 2020)

7. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition--summary document. Ann Oncol Off J Eur Soc Med Oncol. 2008 Apr;19(4):614–22.

8. 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

https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Bi-Rads (accessed on 5 September 2020)

9. ACR Practice Parameter For the Performance of Screening and Diagnostic Mammography. Revised 2018 (Resolution 35). American College of Radiology https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Screen-Diag-Mammo.pdf (accessed on 5 September 2020)

10. Sechopoulos I, Suryanarayanan S, Vedantham S, D'Orsi CJ, Karellas A. Radiation Dose to Organs and Tissues from Mammography: Monte Carlo and Phantom Study. Radiology. 2008 Feb;246(2):434–43.

11. ACR–SPR Practice Parameter For Imaging Pregnant Or Potentially Pregnant Adolescents And Women With Ionizing Radiation. Revised 2018 (Resolution 39). American College of Radiology https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Pregnant-Pts.pdf (accessed on 5 September 2020)

12. Wieseler KM, Bhargava P, Kanal KM, Vaidya S, Stewart BK, Dighe MK. Imaging in pregnant patients: examination appropriateness. Radiogr Rev Publ Radiol Soc N Am Inc. 2010 Sep;30(5):1215–29; discussion 1230-1233.

13. Wagner LK, Applegate KE. Re: More cautions on imaging of pregnant patients. Radiogr Rev Publ Radiol Soc N Am Inc. 2011 Jun;31(3):891; author reply 891-892.

14. Breast Imaging of the Pregnant and Lactating Patient: Imaging Modalities and Pregnancy-Associated Breast Cancer : American Journal of Roentgenology. 2013;200: 321-328. 10.2214/AJR.12.9814 https://www.ajronline.org/doi/full/10.2214/ajr.12.9814(accessed on 5 September 2020)

15. Right To Information, Queries & Responses, Atomic Energy Regulatory Board India. https://www.aerb.gov.in/hindi/transparency-open-government/rti/rti-faq-s (accessed on 5 September 2020)

16. Quality Control: Stereotactic Breast Biopsy (Revised 12-12-19), Accreditation Support American College of Radiology https://accreditationsupport.acr.org/support/solutions/articles/11000064161-quality-control-stereotactic-breast-biopsy-revised-12-12-19- (accessed on 5 September 2020)

17. Hendrick RE, Dershaw DD, Kimme-Smith C, Pizzutiello R, Taylor C, Wilcox-Buchalla P, et al. Stereotactic Biopsy, Quality Control Manual, 1999, American College of Radiology Committee on Stereotactic Breast Biopsy Accreditation, Subcommittee of Stereotactic Breast Biopsy Quality Assurance.

18. Appavoo S, Aldis A, Causer P, Crystal P, Mesurolle B, Mundt Y, et al. CAR Practice Guidelines and Technical Standards for Breast Imaging and Intervention, September 17, 2016. Canadian Association of Radiologists.

19. Heggie JCP, Barnes P, Cartwright L, Diffey J, Tse J, Herley J, et al. Position paper: recommendations for a digital mammography quality assurance program V4.0. Australas Phys Eng Sci Med. 2017 Sep;40(3):491–543.

20. Skaane P, Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, et al. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. Radiology. 2013 Apr;267(1):47–56.

21. Tirada N, Li G, Dreizin D, Robinson L, Khorjekar G, Dromi S, et al. Digital Breast Tomosynthesis: Physics, Artifacts, and Quality Control Considerations. RadioGraphics. 2019 Mar;39(2):413–26.

22. Zuckerman SP, Conant EF, Keller BM, Maidment ADA, Barufaldi B, Weinstein SP, et al. Implementation of Synthesized Two-dimensional Mammography in a Population-based Digital Breast Tomosynthesis Screening Program. Radiology. 2016 Dec;281(3):730–6.

23. Zuley ML, Guo B, Catullo VJ, Chough DM, Kelly AE, Lu AH, et al. Comparison of Two-dimensional Synthesized Mammograms versus Original Digital Mammograms Alone and in Combination with Tomosynthesis Images. Radiology. 2014 Jun;271(3):664–71.

24. Aujero MP, Gavenonis SC, Benjamin R, Zhang Z, Holt JS. Clinical Performance of Synthesized Two-dimensional Mammography Combined with Tomosynthesis in a Large Screening Population. Radiology. 2017 Apr;283(1):70–6.

25. ACR Practice Parameter For The Performance Of Digital Breast Tomosynthesis (DBT), Adopted 2018 (Resolution 36), American College of Radiology https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DBT.pdf?la=en (accessed on 5 September 2020)

26. MQSA facility certification extension requirements for Digital Breast Tomosynthesis (DBT) System. US Food and Drug Administration. U.S. Food and Drug Administration

https://www.fda.gov/radiation-emitting-products/facility-certification-and-inspection-mqsa/digital-breast-tomosynthesis-dbt-system

27. Routine quality control tests for breast tomosynthesis (Radiographers) NHSBSP Equipment Report 1406, August 2014, NHS Cancer Screening Programmes, National Health Service, UK https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/442730/nhsbsp-equipment-report-1406.pdf (accessed on 5 September 2020)

28. ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality In Digital Mammography, Revised 2017 (Resolution 42). American College of Radiology. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Dig-Mamo.pdf (accessed on 5 September 2020)

29. Mammography Record Retention: What Should I Keep, and For How Long? U.S. Food and Drug Administration https://www.fda.gov/radiation-emitting-products/mqsa-insights/mammography-record-retention-what-should-i-keep-and-how-long (accessed on 5 September 2020)

30. Breastscreen Australia, National Accreditation Standards, BreastScreen Australia Accreditation Review Committee, 16 January 2019. http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/CA8C934AA0B7BA64CA257EFA001C67D7/$File/BSA%20NAS%20Commentary%20January%202019%20FINAL.pdf (accessed on 5 September 2020)

31. ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures, Revised 2020 (Resolution 3), American College of Radiology https://www.acr.org/-/media/ACR/Files/Practice-Parameters/stereo-breast.pdf (accessed on 5 September 2020)

Appendix 1

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

QA MAMMOGRAPHY/DBT - SUGGESTIONS TO THE RADIOLOGIST

1. **It is expected that the Indian breast radiologist will be well versed with mammography related QA aspects of the following documents of Atomic Energy Regulatory Board, India:**

- e-Licensing of Radiation Applications (eLORA) System Guidelines, Medical Diagnostic-Radiology Module, Atomic Energy Regulatory Board, India; July 14, 2016 https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/e-LORA-Diagnostic-Radiology-Guidelines.pdf (accessed on 5 September 2020)

- AERB Safety Manual, Regulatory Inspection And Enforcement In Radiation Facilities; AERB/RF/SM/G-3; Atomic Energy Regulatory Board, India; December 2014. https://www.aerb.gov.in/storage/images/PDF/13-January-20151.pdf (accessed on 5 September 2020)

- Format for periodic quality assurance test report for Mammography equipment, Atomic Energy Regulatory Board, India https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/3-FORMAT-FOR-PERIODIC-QUALITY-ASSURANCE-TEST-REPORT-FOR-MAMMOGRAPHY-EQUIPMENT.pdf (accessed on 5 September 2020)

- Radiation Safety In Manufacture, Supply And Use Of Medical Diagnostic X-Ray Equipment, AERB Safety Code No. AERB/RF-MED/SC-3 (Rev. 2), March 2016, Atomic Energy Regulatory Board, India. https://www.aerb.gov.in/images/PDF/RF-MED-SC-3.pdf (accessed on 5 September 2020)

2. **BISI Recommendation (additional to above):** Image quality assessment by using a mammography phantom is advised at least once a week. However daily assessment prior to the first case of the day is ideal, especially for screening mammograms.

3. **DBT Quality control tests to be performed by the mammographer (in addition to 2D mammography tests)*.** These tests have been chosen as they are simple and can be performed in the department by the mammographer and radiologist, with relative ease. These may be altered as per local protocol after discussion with medical physicist of the hospital. These tests do not replace the tests that are to be performed as per manufacturer's instructions or local protocol

Test	Frequency	Method	Look for
System check (Uniformity of field)	daily	Expose phantom under AEC in DBT mode and check reconstructed image slices (not the projections)	abnormal artefacts or variations in noise pattern
AEC thickness check	monthly	Expose each thickness of perspex in turn under AEC in tomosynthesis mode and check reconstructed image slices	abnormal artefacts or variations in noise pattern
Image quality check	weekly	Expose the phantom in tomosynthesis mode and find the slice at which the image of the test object appears sharpest and record that slice number. Send the image to a reporting workstation. Evaluate the image, using the slice recorded as having the sharpest image. Compare the image with a baseline image and look for significant changes in the appearance of the in-focus and out-of-focus slices	Number of sharpest slice should be within baseline ± 2 slices*

* Clear visualization of minimum number of fibres, specks and masses depends on the phantom used

REFERENCES:

- Routine quality control tests for breast tomosynthesis (Radiographers) NHSBSP Equipment Report 1406, August 2014, NHS Cancer Screening Programmes, National Health Service, UK https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/442730/nhsbsp-equipment-report-1406.pdf (accessed on 5 September 2020)

- Heggie JCP, Barnes P, Cartwright L, Diffey J, Tse J, Herley J, et al. Position paper: recommendations for a digital mammography quality assurance program V4.0. Australas Phys Eng Sci Med. 2017 Sep;40(3):491–543.

Appendix - 2

BREAST IMAGING SOCIETY, INDIA
QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

MAMMOGRAPHY REPORT TEMPLATE
(Based on ACR BI-RADS)

1. Indication
2. Pertinent physical exam details
3. Dates of comparison mammograms / correlating ultrasound / MRI
4. Scope and Technique : unilateral/bilateral, routine views acquired, additional views
5. Short description of composition :
    - The breasts are almost entirely fatty.
    - There are scattered areas of fibroglandular density in both breasts
    - The breasts are heterogeneously dense, which may obscure small masses
    - The breasts are extremely dense, which lowers sensitivity of mammography.
6. Clear description of significant findings

    MASS:

    Location : laterality (left/right), quadrant, depth (anterior / mid / posterior)

    Size:

    Shape: oval / round / irregular

    Margin: circumscribed /obscured /microlobulated/ indistinct /spiculated

    Density: high / equal / low / fatty

    Ultrasound correlation:

    Associated Features: architectural distortion / calcification / skin and nipple changes (thickening / retraction), trabecular thickening

    ARCHITECTURAL DISTORTION: laterality, quadrant, size, ultrasound correlation

    ASYMMETRIES : Asymmetry / global asymmetry / focal asymmetry / developing asymmetry

    CALCIFICATIONS:

    Location : laterality (left/right), quadrant, depth (anterior / mid / posterior)

    Size:

    Morphology : round or punctate / amorphous / coarse heterogeneous / fine pleomorphic / fine linear or fine linear branching

    Distribution: diffuse /regional / grouped / linear / segmental

    Associated Features: mass / architectural distortion / skin and nipple changes (thickening / retraction), trabecular thickening

    AXILLARY LYMPH NODES

    OTHERS : If multiple findings are present, all findings must be mentioned and described

CONTRALATERAL BREAST: Findings if any

7. Impression : BIRADS Assessment Category & Management Recommendation
    - BIRADS - 0 (Complete assessment of breasts is not possible based on mammography alone. Bilateral breast ultrasound / comparison with previous breast imaging studies is advised)
    - BIRADS - 1 (within normal limits)
    - BIRADS - 2 (within benign limits)
    - BIRADS - 3 (probably benign. Needs follow up in 6 months' time)
    - BIRADS - 4A (Low probability for malignancy. Core biopsy is advised)
    - BIRADS - 4B (Moderate probability for malignancy. Core biopsy is advised)
    - BIRADS - 4C (High probability for malignancy. Core biopsy is advised)
    - BIRADS - 5 (Highly suggestive of a malignant mass. Core biopsy is advised)
    - BIRADS - 6 (Biopsy proven malignant mass)
8. Other important information / advice that you wish to communicate – Some examples:
    - when there may be a mismatch between BIRADS category and management recommendation, a clear explanation for your decision should be given
    - Clear recommendation should be given about follow up: after 6months / 1 year & the appropriate imaging modality (mammography /ultrasound)
    - Screening breast ultrasound study (as a supplement to mammographic screening in dense breasts) is advised. (Note: Breast ultrasound is not to be used as a standalone breast screening test).
9. Normal examination : Important negative findings should be mentioned. An example:
    - No mass, architectural distortion, significant focal asymmetry, suspicious microcalcification or skin thickening is demonstrated in either breast
    - No abnormal axillary lymph node is demonstrated bilaterally
    - Regular screening mammography is advised, if ≥ 40 years of age
10. If Mammogram and Ultrasound studies are jointly performed , a composite report with one overall BIRADS assessment is advised. The most worrisome feature from either or both exams should decide the final BIRADS assessment category and management recommendation.

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 - 3

BREAST IMAGING SOCIETY, INDIA
QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

STEREOTACTIC BREAST BIOPSY REPORT TEMPLATE

PROCEDURE : Stereotactic Biopsy of right/left breast microcalcification / mass / focal or developing asymmetry / architectural distortion

Target : right/left breast microcalcification / mass / focal or developing asymmetry / architectural distortion in _____ quadrant measuring _____

Consent: Informed consent obtained after explaining the steps of procedure and possible complications (such as haemorrhage, infection, retargeting, repeat procedure)

Technique : The report should have the following points:
Patient position: prone / sitting upright
Compression: craniocaudal / lateral/oblique
Approach: vertical / lateral
Type of biopsy: 14 gauge core biopsy / VAAB of ____gauge
Local anaesthesia : name and quantity
Number of cores obtained:
Specimen Radiography obtained: If yes, mention the findings
Clip placement : If yes, mention findings of post procedure check mammograms
Complications : mention if any

Post procedure instructions: rest to ipsilateral arm, analgesics, care of dressing

Contact telephone number : in case of emergency or concern

Addendum to report after Radiology-Pathology correlation : after histopathology report, establish concordance/ discordance and advice accordingly

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

BREAST ULTRASOUND

Breast ultrasound is a well established investigation in breast diseases of women and men. Being widely available across our country, both in large institutions as well as small diagnostic centres, the Indian radiologist is well versed with this modality. It is especially invaluable as a primary imaging tool in symptomatic women less than 30 years of age. It is also the modality of choice for pregnant and lactating women. Quality assurance guidelines have been formulated in this document to ensure that optimum equipment for ultrasound 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 ultrasound studies (appendix 1). Reporting templates for ultrasound guided core biopsy, hookwire localization, marker clip placement and fine needle aspiration cytology (appendix 2, 3, 4 and 5 respectively) are also available in numerical order.

Ultrasound is the imaging technique of choice in women less than 30 years as well as pregnant and lactating women. Combination of breast ultrasound and mammography is the basic set of investigative tools used in investigation of breast complaints for women over 30 years of age. Ultrasound is useful in the evaluation and characterization of palpable masses and other breast symptoms such as nipple discharge, dimpling of skin, retraction of nipple and focal non-cyclical mastalgia. It can be used as a supplement to mammography for screening women with heterogeneously or extremely dense breasts. However ultrasound of the breasts on it's own is not advisable for breast screening.(1) Ultrasound is the modality of choice for assessment of the axilla. Please refer to 'Best Practice Guidelines' of Breast Imaging Society, India for indications of breast ultrasound in detail.(2)

Equipment And Technical Settings

A high-resolution probe (such as 12 – 5 MHz, 18 – 6 MHz) with a centre frequency of at least 10 MHz is required to perform breast ultrasound.(3,4) However depending upon the size of the breast and depth of the lesion, sometimes a convex probe may be used.

The patient is examined in a supine or oblique position. The medial portion of the breast is imaged in supine position with arm placed above the head. The side being examined is lifted (lady turns to the opposite side – semi lateral decubitus position) and the arm is placed

above the head to ensure that the breast is flattened over the chest wall while scanning the lateral aspect of breast. Application of a coupling agent such as gel on the skin is mandatory to perform ultrasound studies. A focal thick layer of gel on the skin at the site of a superficial lesion helps bring the superficial lesion into the focal zone and improves visualization of the abnormality.(3) Similar technique can be used to visualize structures in the nipple areolar complex. Scanning obliquely also helps visualize lesions in the nipple areolar complex region. Gentle pressure while scanning helps better visualization of structures in the breast.

Optimization of gray scale settings is the first step towards obtaining good quality representative and diagnostic images.(4) Focal zone should be set at the level of the lesion being assessed. Gain should be set such that subcutaneous fat appears medium gray.(3) Depth is said to be optimal when most of the screen is occupied by breast tissue and chest wall is seen at posterior margin of the screen.(4) Tissue harmonics, spatial compound imaging, colour and power doppler should be used when required. The colour box should be placed over the region of interest and only gentle pressure must be applied while scanning to get the best results in colour flow imaging.

Equipment performance monitoring should be performed as per manufacturer's instructions and local departmental protocol.

Elastography, both strain elastography and shear wave elastography, is useful as an adjunct to grayscale ultrasound. Elastography findings aid in diagnosis but it should not be used in isolation to evaluate a lesion. It is assessed in the same standard patient positions as those for grayscale ultrasound by using a linear probe. While performing elastography it is essential to make sure that the lesion of interest as well as the surrounding normal breast parenchyma are included within the elastography box thus enabling comparison of elasticity parameters. Different vendors and machine settings offer variable colour coding method (varying from hard to soft), therefore this has to be annotated in the image to avoid confusion.

Training Requirements of Doctor Performing Breast Ultrasound

Radiologists who supervise, perform and interpret breast ultrasound examinations should hold a degree in Radiology recognized by the Medical Council of India. Taking up a breast fellowship course or training under an experienced breast radiologist is strongly recommended before performing breast ultrasound and ultrasound guided interventional procedures independently. The radiologist should have a thorough knowledge of the indications for ultrasound examinations and should direct each examination in accordance with the indication. For example in a patient with nipple discharge, intraductal lesion should be vigilantly looked for. The radiologist should also be able to correlate an abnormality seen on ultrasound with findings seen on mammograms and breast MRI taking into consideration clinical findings if any.

The radiologist is expected to perform at least 1500 breast ultrasound examinations under supervision over a 1 to 2 year period, depending on the caseload of the institute, to complete adequate training. A minimum of 500 breast ultrasound studies per year is recommended to maintain their skill.

Reporting and Documentation

Ideally, the request form for breast ultrasound should provide relevant history, clinical examination findings with a diagrammatic representation of any lump if palpable and provisional diagnosis. A standard requisition form approved by the hospital / department of radiology is encouraged.

Ultrasonography has to be correlated with other breast imaging studies such as mammograms or MRI if available. Comparison with previous breast imaging should be performed. The findings of correlation with other imaging modalities and comparison with previous images must be documented in the report. Correlation with physical examination directed to area of concern should be made.

Breast ultrasound includes assessment of the axilla. The ipsilateral supraclavicular fossa, infraclavicular fossa (level 3 axillary lymph nodes) and internal mammary lymph nodes should also be checked for newly diagnosed breast cancer for quantification of locoregional lymph node disease.(5,6)

Lesion characterization with documentation of sonographic characteristics of the lesion such as size, shape, margin, orientation, echopattern, posterior acoustic features and surrounding tissue should be performed. Color flow and doppler findings if applicable should also be reported. Each lesion should be clearly identified and described. If there are multiple lesions with similar characteristics they can be described collectively. Lesion description should be followed by the most likely diagnosis and the likely nature of the lesion, such as benignity or the possibility of malignancy. Of the established reporting systems the most widely used system in our country is the Breast Imaging Reporting and Data System (BI-RADS) of the American College of Radiologists (ACR), and usage of such established reporting systems helps uniformity of lexicon in ultrasound reporting.(3) If elastography is performed findings should be documented. In strain elastography size ratio and strain ratio value should be documented. In shear wave elastography elasticity value should be documented in kilopascals (kPa) or meters/second (m/s).(7)

Images showing relevant findings should be recorded and saved, such that they can be reviewed later if needed.(8) Image of a lesion should have documentation of it's anatomic location (breast / axilla / chest wall), side (left/right), orientation of the transducer (radial /antiradial/transverse/longitudinal), quadrant and o' clock position, distance from the nipple in centimeters. Recording the depth from the skin is very useful if two lesions with

similar appearance are at the same o' clock position in the breast. Abnormality should be recorded in two perpendicular projections. Two sets of images with and without calipers are preferable, especially for tiny abnormalities, as the cursor may obscure the lesion.(3) Measurements of masses should be taken in three dimensions. Colour doppler images assessing vascularity of the lesion should also be recorded separately.

Ultrasound images should have details of the name of the hospital, a unique hospital identification number, date of examination, patient's first and last name and date of birth. Radiologist's identification number or initials should also be preferably recorded.

The minimum number of images to be recorded, saved and printed should be as per departmental protocols. Documentation of a negative whole breast ultrasound should be performed with representative images of all quadrants, retroareolar region and axilla. Important findings of targeted ultrasound of an area, for example to assess a mammographic asymmetry, should also be documented.

Ultrasound Guided Breast Biopsy (and other procedures)

Radiologists who perform breast interventions should hold a degree in Radiology, recognized by the Medical Council of India. The radiologist should perform ultrasound guided interventional procedures under supervision till she/he is competent to perform interventions independently and must be trained with regard to equipment, procedure and potential complications, preferably at a specialised centre performing breast imaging and interventions. A minimum of 150 supervised image guided breast procedures (both ultrasound and mammography guided procedures included) are recommended to be performed over a period of 1 year to train adequately. A minimum of 60 image guided breast procedures per year (both ultrasound and mammography guided procedures included) are recommended for maintaining interventional skills in breast imaging. The radiologist performing image guided breast procedures must be well versed with mammography and breast ultrasound interpretation, as this knowledge is essential for Radiology – Pathology correlation. The personnel assisting the radiologist should also be adequately trained and should be aware of the steps of the procedure as well as the possible complications of the procedure.

Written informed consent must be obtained prior to the procedure. Explanation of the steps of the procedure and possible complications in lay terms for better understanding of the patient and her/his family members is mandatory prior to obtaining consent. History of allergy to drugs must be checked and documented.

Optimal precautions such as use of sterile gloves and drapes for performing the procedure is mandatory. The needle length, gauge and throw should be confirmed before opening the

sterile packaging of the core biopsy device. The concentration and expiry date of the local anaesthetic must be checked while preparing the procedure tray.

Ultrasound guided breast interventional procedures such as core biopsies, vacuum assisted biopsies, cyst aspirations, hookwire localizations, marker clip insertions, fine needle aspiration cytology (FNAC) should be recorded with images and a formal report.(9) Documentation of the lesion biopsied, number of core specimens obtained, time of obtaining specimen and fixing in formalin, complications if any at the time of performing the procedure should be documented in the procedure report.

Thorough ultrasound examination of the area of concern should be performed prior to the intervention to confirm that the correct lesion is being targeted as well as to decide the approach of intervention.(10) Patient name, identification number, examination date, facility name, designation of right or left breast, anatomic location depicted by clock position and distance from nipple should be mentioned on the clinical images. Prior to the procedure two orthogonal images of the lesion to be biopsied should be obtained for clinical record keeping. Pre-fire image and post-fire image with the needle in long axis should be obtained. Post-fire image in the orthogonal plane is also to be obtained to confirm presence of the needle within the lesion.(9,11,12)

For hookwire localisations and marker clip insertions post procedure mammograms must be performed to confirm optimum position of the wire and marker clip respectively on both craniocaudal and lateral views.

Following the procedure, sharps must be disposed in separately assigned sharps bin as per institutional protocol. Instructions about post procedure care should be duly explained to the patient by the radiologist conducting the procedure.

Clear mention of the clinical history, pertinent imaging findings and likely imaging diagnosis should be mentioned on the pathology requisition form. Patient name, identification number, examination date, facility name, designation of right or left breast should be mentioned on the container in which the sample is sent to the department of pathology.(11)

There should be a process in place for obtaining the cytology/histopathology report from the pathology department. It is considered a good practice to add an addendum report stating whether the cytology/histopathology report is concordant or discordant with the imaging findings and communicate the final report to the patient and referring physician.(11)

Annual audit of the total number of ultrasound biopsies performed (FNAC & core biopsy), total number of cancers detected, benign lesions detected, inconclusive results requiring repeat biopsy and complications (hematoma, infection, pneumothorax) post biopsy is encouraged.(11)

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 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 members of Breast Imaging Society, India or Breast Imaging Society, India as the organization cannot be held responsible for that in any manner.

REFERENCES

1. Evans A, Trimboli RM, Athanasiou A, Balleyguier C, Baltzer PA, Bick U, et al. Breast ultrasound: recommendations for information to women and referring physicians by the European Society of Breast Imaging. Insights Imaging 2018 Aug;9(4):449-461

2. Best Practice Guidelines on Breast Ultrasound. Breast Imaging Society, India. http://www.bisi.co.in/breast-ultrasound1.html (accessed on 25 August, 2020)

3. 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

4. CAR Practice guidelines and technical standards for Breast imaging and Intervention [Online] . Available from https://car.ca/wp-content/uploads/Breast-Imaging-and-Intervention-2016.pdf (Accessed on 4th November 2019)

5. Lane DL, Adeyefa MM, Yang WT. Role of sonography for the locoregional staging of breast cancer. AJR. American Journal of Roentgenology. 2014 Nov;203(5):1132-1141. DOI: 10.2214/ajr.13.12311

6. Iyengar P, Strom EA, Zhang YJ, et al. The value of ultrasound in detecting extra-axillary regional node involvement in patients with advanced breast cancer. Oncologist. 2012;17(11):1402-1408. doi:10.1634/theoncologist.2012-0170

7. Youk JH, Gweon HM, Son EJ. Shear-wave elastography in breast ultrasonography: the state of the art. Ultrasonography. 2017 Oct 1;36(4):300–9.

8. ACR Practice Parameter for the Performance of Ultr. [Online] . Available from https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Breast.pdf (Accessed on 4th November 2019)

9. ACR Breast Ultrasound Accreditation Program Requirements, Revised: 6/14/19 https://www.acraccreditation.org/-/media/ACRAccreditation/Documents/Breast-Ultrasound/Requirements.pdf?la=en (accessed on 24th June 2020)

10. AIUM Practice Guideline for the Performance of a Breast Ultrasound Examination. J Ultrasound Med. 2009 Jan;28(1):105–9.

11. ACR Practice Parameter for The Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures , Revised 2016 (Resolution 37) https://www.acr.org/-/media/ACR/Files/Practice-Parameters/us-guidedbreast.pdf (accessed on 24th June 2020)

12. Harvey JA and Moran RE, US-guided core needle biopsy of the breast: technique and pitfalls. RadioGraphics 1998 18:4, 867-877. https://pubs.rsna.org/doi/pdf/10.1148/radiographics.18.4.9672971 (accessed on 24th June 2020)

Appendix 1

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

TEMPLATE for BREAST ULTRASOUND REPORT

1. Indication
2. Pertinent Physical exam details
3. Dates of comparison/correlation exams
4. Scope and Technique : Hand held/automated. Unilateral/bilateral. Whole Breast/Targeted
5. Type of probe used. Special techniques
6. Short description of composition (screening studies only)* :

   a - The breasts have homogeneous background echotexture - predominantly fatty .
   b - The breasts have homogeneous background echotexture – predominantly fibroglandular tissue.
   c - The breasts have heterogeneous background echotexture.

7. Clear description of significant findings with images

   MASS:

   Location : Laterality (left/right), o' clock position, Distance from nipple and depth from skin

   Shape: oval / round / irregular

   Orientation: parallel / not parallel

   Margin: Circumscribed

   Not circumscribed - indistinct/angular/microlobulated/spiculated

   Echo pattern: anechoic / hyperechoic / complex cystic and solid / hypoechoic / isoechoic / heterogeneous

   Posterior features: no posterior features / enhancement / shadowing / combined pattern

   Associated Features: architectural distortion / duct changes / skin changes (thickening / retraction), edema / vascularity (absent / internal vascularity / vessels in rim), elasticity (soft / intermediate/ hard)

   Calcifications : in a mass / outside a mass / intraductal calcifications

   SPECIAL CASES : Simple cyst, clustered microcysts, complicated cyst, mass in or on skin, foreign body including implants, intramammary lymph nodes, axillary lymph nodes, vascular anomalies (arteriovenous malformations/ pseudoaneurysms / Mondor disease), postsurgical fluid collection, fat necrosis

   AXILLA: Lymphnodes and any other pathology to be mentioned

   SUPRACLAVICULAR FOSSA : if findings suspicious for malignancy

8. Impression : BIRADS Assessment Category & Management Recommendation
    - BIRADS - 0 (Complete assessment of breasts is not possible based on ultrasound alone. Bilateral mammography / comparison with previous breast imaging studies is advised)
    - BIRADS - 1 (negative - within normal limits)
    - BIRADS - 2 (benign)
    - BIRADS - 3 (probably benign. Needs follow up in 6 months' time)
    - BIRADS - 4A (Low probability for malignancy. Core biopsy is advised)
    - BIRADS - 4B (Moderate probability for malignancy. Core biopsy is advised)
    - BIRADS - 4C (High probability for malignancy. Core biopsy is advised)
    - BIRADS - 5 (Highly suggestive of a malignant mass. Core biopsy is advised)
    - BIRADS - 6 (Biopsy proven malignant mass)
9. Other important information / advice that you wish to communicate – For example:
    - when there may be a mismatch between the BIRADS category and the management recommendation, a clear explanation for your decision should be given
    - Clear recommendation should be given about next follow up /screening test after 6months/1 year, whether mammography or ultrasound
10. Normal examination : Important negative findings should be mentioned. An example:
    - No mass is demonstrated in the breasts
    - No abnormal duct is demonstrated
    - No skin thickening is seen
    - No abnormal lymph node is demonstrated in the axillae
    - Documentation with images : all quadrants, retroareolar region and axilla
11. If Mammogram and Ultrasound studies are jointly performed, composite reports with one overall BIRADS assessment is advised. The most worrisome feature from either or both exams should decide the final BIRADS assessment category and management recommendation.

***** Short description of composition is for screening breast ultrasound studies only (as a supplement to mammographic screening in dense breasts). Breast ultrasound is not to be used as a standalone breast screening test.

REFERENCES:

- 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)
- Lee J. Practical and illustrated summary of updated BI-RADS for ultrasonography. Ultrasonography. 2017;36(1):71-81. doi:10.14366/usg.16

Appendix 2

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

TEMPLATE for ULTRASOUND GUIDED CORE BIOPSY REPORT

PROCEDURE : Ultrasound guided Core Biopsy of right/left breast mass / duct / lymphnode

Target : Right/ Left Breast mass located in _____ quadrant at ___ o' clock position, demonstrated on ultrasound dated _____.

Consent: Informed consent obtained after explaining the steps of procedure and possible complications (such as haemorrhage, infection).

Technique : Skin was cleaned and draped. Under ultrasound guidance _____ mls of _____ (local anaesthesia – name and quantity) was injected for local anaesthesia. A 2 mm skin incision was made. _____(number of cores) were acquired under ultrasound guidance with a 14 gauge fully automated biopsy gun. Dressing done (mention type of dressing, such as steristrips, if required). No complication of procedure noted (mention complications here, if any).

Aftercare : rest to ipsilateral arm, adequate pain relief , care of dressing , as per local protocol

Contact phone number in case of emergency or concern :

Radiology-Pathology correlation : appropriate recommendation after correlation.

Appendix 3

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

TEMPLATE for ULTRASOUND GUIDED HOOKWIRE LOCALIZATION REPORT

PROCEDURE : Ultrasound guided hookwire localisation of right/left breast mass

Target : Right/ Left Breast mass located in _____ quadrant at ___ o' clock position, demonstrated on ultrasound dated _____.

Consent: Informed consent obtained after explaining the steps of procedure and possible complications (such as haemorrhage, inappropriate positioning of wire, migration of wire, repeat procedure).

Technique : Skin was cleaned and draped. Under ultrasound guidance _____ mls of _____ (local anaesthesia – name and quantity) was injected for local anaesthesia. Under ultrasound guidance ____ gauge hookwire localisation needle was inserted. Once the needle was in the correct position, the fine wire within the needle was deployed. Once satisfactory position of the wire was confirmed on ultrasound, the needle was removed from the breast and discarded. The wire was gently strapped to the adjacent chest wall. No complication of procedure noted (mention complications here, if any).

Check mammograms: Post procedure mammograms confirmed optimum position on both craniocaudal and lateral views. These mammogram images were made available to the surgeon.

Aftercare : rest to ipsilateral arm, adequate pain relief , care of dressing , as per local protocol.

Specimen radiograph: The targeted abnormality was demonstrated on the postsurgical specimen radiograph (for mammography occult lesions specimen should be scanned on ultrasound).

Radiology-Pathology Correlation : After histopathology report of the excised tissue is available

Appendix 4

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

TEMPLATE for ULTRASOUND GUIDED MARKER CLIP INSERTION REPORT

PROCEDURE : Ultrasound guided marker clip insertion into right/left breast mass

Target : Right/ Left Breast mass located in _____ quadrant at ___ o' clock position, demonstrated on ultrasound dated _____.

Consent: Informed consent obtained after explaining the steps of procedure and possible complications (such as haemorrhage, infection, inappropriate positioning of clip, migration of clip, repeat procedure).

Technique : Skin was cleaned and draped. Under ultrasound guidance _____ mls of _____ (local anaesthesia – name and quantity) was injected for local anaesthesia. Under ultrasound guidance ____ gauge needle was inserted. Once the needle was in the correct position, the marker clip within the needle was deployed. Once satisfactory position of the clip was confirmed on ultrasound, the needle was removed from the breast and discarded. Dressing done. No complication of procedure noted (mention complications here, if any).

Check mammograms: Post procedure mammograms confirmed optimum position of marker clip on both craniocaudal and lateral views.

Aftercare : rest to ipsilateral arm, adequate pain relief , care of dressing , as per local protocol

Contact phone number in case of emergency or concern :

Note: At the time of surgery, ultrasound or mammography of the excised tissue is advised, to confirm that the clip has been removed.

Appendix 5

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

TEMPLATE for ULTRASOUND GUIDED FINE NEEDLE ASPIRATION CYTOLOGY (FNAC) REPORT

Note: FNAC must be considered only if core biopsy is not possible. Core biopsy is the procedure of choice for sampling of breast lesions. If core biopsy expertise is locally unavailable the patient should be referred to higher centres for core biopsy.

PROCEDURE : Ultrasound guided FNAC of right/left breast cyst / mass / duct / lymphnode

Target : Right/ Left Breast mass located in _____ quadrant at ___ o' clock position, demonstrated on ultrasound dated _____.

Consent: Informed consent obtained after explaining the steps of procedure and possible complications (such as haemorrhage, infection).

Technique : Skin was cleaned and draped. Under ultrasound guidance _____ mls of _____ (local anaesthesia – name and quantity) (this is optional and as per local protocol) was injected for local anaesthesia. Under ultrasound guidance a ____ gauge needle was used and aspiration was performed. _____ (number) slides were drawn with the aspirate and sent for cytological analysis. Dressing done. No complication of procedure noted (mention complications here, if any).

Aftercare : rest to ipsilateral arm, adequate pain relief , care of dressing , as per local protocol

Contact phone number in case of emergency or concern :

Radiology-Pathology correlation : appropriate recommendation after correlation. If any doubt a core biopsy of the target should be advised.

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.

REFERENCES:

1. Best Practice Guidelines – MRI Breast. Breast Imaging Society, India http://www.bisi.co.in/breast-mri.html (accessed on 20 June 2020)

2. Guidance on screening and symptomatic breast imaging, Fourth edition, November 2019, The Royal College of Radiologists, UK https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr199-guidance-on-screening-and-symptomatic-breast-imaging.pdf (accessed on 21st June 2020)

3. ACR Practice Parameter For The Performance Of Contrast enhanced Magnetic Resonance Imaging (MRI) Of The Breast, Revised 2018 (Resolution 34) https://www.acr.org/-/media/ACR/Files/Practice-Parameters/mr-contrast-breast.pdf (accessed on 23rd June 2020)

4. Mann, R.M., Kuhl, C.K., Kinkel, K. et al. Breast MRI: Guidelines from the European Society of Breast Imaging. Eur Radiol 2008: 18; 1307–1318

5. Müller-Schimpfle M, Ohmenhaüser K, Stoll P, Dietz K, Claussen CD. Menstrual cycle and age: influence on parenchymal contrast medium enhancement in MR imaging of the breast [published correction appears in Radiology 1997 Aug;204(2):583]. Radiology. 1997;203(1):145-149. doi:10.1148/radiology.203.1.9122383

6. Delille JP, Slanetz PJ, Yeh ED, Kopans DB, Garrido L. Physiologic changes in breast magnetic resonance imaging during the menstrual cycle: perfusion imaging, signal enhancement, and influence of the T1 relaxation time of breast tissue. Breast J. 2005;11(4):236-241. doi:10.1111/j.1075-122X.2005.21499.x

7. CAR practice guidelines and technical standards for breast imaging and intervention, 2012, Canadian Association of Radiologists. https://car.ca/wp-content/uploads/Breast-Imaging-and-Intervention-2016.pdf (accessed on 23rd June 2020)

8. Baltzer, P., Mann, R.M., Iima, M. et al. Diffusion-weighted imaging of the breast—a consensus and mission statement from the EUSOBI International Breast Diffusion-Weighted Imaging working group. Eur Radiol 30, 1436–1450 2020

9. Lia Bartella and Wei Huang. Proton (1H) MR Spectroscopy of the Breast, RadioGraphics 2007 27:suppl_1, S241-S252

10. ACR practice parameter for the performance of magnetic resonance imaging-guided breast interventional procedures. Revised 2016, (resolution 35) https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Guided-Breast.pdf (accessed on 23rd June 2020)

11. Chesebro AL, Chikarmane SA, Ritner JA, Birdwell RL, Giess CS. Troubleshooting to Overcome Technical Challenges in Image-guided Breast Biopsy. Radiographics. 2017;37(3):705-718. doi:10.1148/rg.2017160117

12. Sung JS, Lee CH, Morris EA, Comstock CE, Dershaw DD. Patient follow-up after concordant histologically benign imaging-guided biopsy of MRI-detected lesions. AJR Am J Roentgenol. 2012;198(6):1464-1469. doi:10.2214/AJR.11.7455

13. 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 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