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.

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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.

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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.