BREAST IMAGING SOCIETY, INDIA

BEST PRACTICE GUIDELINES IN BREAST IMAGING

INTRODUCTION

The purpose of these guidelines is to provide a framework for the referring doctors and practising radiologists, to enable them to choose the appropriate investigation for patients with breast symptoms and signs. Guidelines are also available for breast screening. There are guidelines for breast investigations and also algorithms for specific breast symptoms/signs in this document. The aim is to keep this framework simple and practical. We hope that these guidelines will be able to guide specialist breast radiologists as well as doctors who do not routinely deal with breast diseases, to make appropriate decisions for their patients.

There are many breast imaging guidelines from countries that have population based breast screening programmes. These programmes vary from country to country and hence there are different guidelines from different breast societies in the world. Due to lack of data specific to our country, to draw specific guidelines for India was a challenge. However a few concepts and facts are recognised all over the world and these can be applied to the Indian population in general. There are other facts that are specific to our country, such as increasing incidence of breast cancer in younger women, and guidelines have been made keeping these in mind.

Please note that these are broad guidelines for breast screening and management of patients with breast symptoms in India, intended for the use of qualified medical caregivers only. These are based on various guidelines and personal experiences and opinions of BISI members, as there is no large credible Indian data to formulate these guidelines. These guidelines are purely recommendatory and general purpose only in nature. Actual decisions for management of 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 BISI members or BISI as the organization cannot be held responsible for that in any manner.

TASK GROUP MEMBERS FOR "BEST PRACTICE GUIDELINES IN BREAST IMAGING"

Dr Suma Chakrabarthi [Task Group Lead], MRCS (Edn), FRCR (UK), CCST (UK), PGCE(Bristol,UK)
Dr Sanjay Thulkar, MD Radiodiagnosis
Dr Sikha Panwar, DMRD,DNB (Radiodiagnosis)
Dr Shilpa Lad, MD(Radiology), Fellowship Breast Imaging(U'sity Toronto, Canada)
Dr Tulika Singh, MD Radiodiagnosis
Dr Jwala Sreekala, DMRD, DNB(Rad)

BREAST IMAGING SOCIETY, INDIA

BEST PRACTICE GUIDELINES

COMMON BREAST SYMPTOMS: ALGORITHM FOR IMAGING EVALUATION

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

Purpose of clinical and imaging evaluation is to determine the cause of symptoms so that appropriate treatment can be given and secondly, to determine if the symptom is caused by underlying breast cancer. Accordingly evaluation of patient with any breast symptom should begin with detailed history and good clinical breast examination (CBE), preferably by a breast surgeon. This is to be followed by appropriate imaging as outlined below. Following a reporting system such as the ACR BI-RADS system is advised.[1]

BREAST LUMP

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

All patients presenting with breast lump should undergo Triple assessment.[2] It is a combination of clinical breast examination, imaging test and pathology test, ideally core biopsy. It is a standard and accurate method to diagnose breast cancer in symptomatic breast.[3] However, if the correlate of the breast lump is clearly benign on imaging, biopsy may be avoided.[4]

Imaging modality: Upto 30 years of age ultrasound of both breasts is the primary modality. Mammogram in this age group is performed only if there is strong clinical suspicion of breast cancer or if suspicious finding is detected on ultrasound.[4] If age is more than 30 years, then both mammography and ultrasound of both breasts are recommended.[4] In the 30 – 40 years age group clinical correlation is advised before requesting / performing a

mammogram. For example a 32 year old lady who presents with a lump that she can feel but on clinical palpation by the doctor is interpreted as normal nodular feel of breast, with a normal ultrasound may not require a mammogram for further characterization of the lump.

Dynamic Contrast Enhanced Magnetic Resonance Imaging (CE-MRI) of breast is considered only if ultrasound and mammogram are inconclusive. If mass is identified on ultrasound and mammography, MRI is not recommended for its further characterization.

Further management is according to imaging results as follows.

Simple cyst (BIRADS 2) – No further imaging. Cyst may or may not be aspirated if not responsible for symptoms. If aspirated, fluid cytology is not required. No imaging follow-up is recommended.

Complicated cyst (BIRADS 2/ BIRADS 3) – No further imaging or follow up is required if these are deemed to be benign. If any concern exists a follow-up ultrasound in 6 months' time is advised.

Cyst with suspicious solid component (BIRADS 4) - complex cystic and solid mass or a mass with partly cystic partly solid echotexture - image guided aspiration and core biopsy is advised.

Solid Definitely benign mass (BIRADS 2) – like hamartoma, calcified fibroadenoma, lipoma, fat necrosis, etc - clinical follow-up only.[4]

Solid probably benign mass (BIRADS 3) – Imaging follow-up only. Ultrasound guided core biopsy may be considered in cases of high risk factor or clinical suspicion for cancer, already diagnosed cancer in same or contralateral breast, planned pregnancy, extreme patient anxiety or if follow-up cannot be ensured.

Suspicious mass (BIRADS 4 or 5) – Image guided core biopsy.

Calcifications only: No further evaluation if typically benign. All other calcifications which are not typically benign must be subjected to core biopsy. Specimen radiograph of harvested cores is recommended to establish retrieval of calcification in harvested cores.

Biopsy results: For BIRADS 4 lesions, if biopsy result is benign, follow-up imaging after 6 months is advised. If biopsy result is malignant then appropriate treatment is advised. If biopsy result is inconclusive (equivocal or atypia only) then re-biopsy, preferably vacuum assisted biopsy is recommended.[5] For BIRADS 5 lesions, re-biopsy is must if histopathology result is not malignant on initial biopsy.

Mass on Clinical Breast Examination (CBE) but negative imaging – palpation guided biopsy if indicated clinically.

No mass on CBE as well as on imaging – no further imaging. Follow-up with CBE may be considered.

Breast lump in pregnant or lactating women - Ultrasound is the imaging modality of choice for any age as breast is mammographically dense in these situations. If mass is identified on ultrasound, further management will be as per BIRADS category. In case of suspicious or equivocal ultrasound finding, mammography can be considered during pregnancy or lactation as it is better than ultrasound in detection of calcifications and subtle architectural distortion. CEMRI of breast is not recommended during pregnancy but can be considered during lactation.[4]

BREAST PAIN (MASTALGIA) AND MASTITIS

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

Age of the patient, history and CBE will guide the imaging protocol. No imaging is required if pain is bilateral or diffuse, cyclic and CBE is normal. If breast pain or tenderness is focal or associated with mass, then imaging is required. [6]

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

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

Imaging is recommended only if mastitis is non-resolving or progressive. Ultrasound is the modality of choice as mammography is difficult to perform and interpret in acute mastitis. If mastitis has liquefied into an abscess formation, surgical or ultrasound guided drainage should be considered.[7] One or repeated aspiration with large bore needle is recommended. Indwelling catheter drainage is effective for large recurring abscess.[8]

Follow-up mammography and ultrasound is recommended in non-lactational mastitis or abscess after acute symptoms have resolved. A non-resolving lesion should be subjected to biopsy.[9]

If inflammatory breast cancer is suspected, then ultrasound of both breasts and if possible, mammography should be performed.[10] Image guided biopsy should be obtained if focal lesion is seen. If no focal lesion is seen, then Contrast Enhanced Magnetic Resonance Imaging (CEMRI) of both breasts should be performed to localize the primary tumor.

NIPPLE DISCHARGE

Usual causes include physiological, hormonal disorders, benign lesions like papilloma and duct ectasia and uncommonly, cancer. Some drugs (Methyldopa, Cimetidine, Reserpine, antipsychotics and oral contraceptives) can also cause nipple discharge.

Good CBE is initial step. Color of the discharge should be noted. Multiduct or expressible only clear, yellow, green, grey, black or white discharge indicate physiological or benign causes. CBE should be performed and if negative, then assurance is adequate. Imaging is not required. Serum prolactin levels and thyroid profile may be obtained if patient is not pregnant nor lactating and hormonal cause is suspected. If infection is suspected, then antibiotics for one week and re-assessment with CBE are recommended. Occasional bilateral bloody discharge in children is also self-limiting and no imaging is required.

Risk of breast cancer is high if nipple discharge is from single duct, spontaneous, serous or bloody, associated with lump on CBE or age is more than 50 years [11]. Presence of any one or more of these factors is considered as pathological duct discharge. Unilateral nipple discharge is uncommon in males but it is more likely to be associated with underlying cancer, than in females. Hence, good clinical and imaging evaluation is required in men with unilateral duct discharge, irrespective of age.[12]

Ultrasound only (age up to 30 years) and mammography with ultrasound (age more than 30 years) should be performed. While performing ultrasound on affected side, good attention should be given to subareolar region with different maneuvers such as peripheral breast compression, rolled nipple or using standoff pad of gel.[12]

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

Ductography is a traditional modality for evaluation of single duct discharge and it is especially accurate in detection of small intraductal lesions. However, it is technically demanding, at times painful and less widely available. Mammography combined with ultrasound, and CE MRI of beast are reliable alternatives of ductography.[12]

Papilloma is a common cause of unilateral duct discharge. These are high risk lesions and hence if found on imaging, surgical excision rather than percutaneous image guided biopsy may be considered[12]. If clinical or imaging findings are suggestive of duct ectasia or periductal mastitis, culture sensitivity of duct discharge followed by appropriate antibiotic treatment should be considered [13]. If CBE and imaging are negative and discharge is persisting, surgical exploration (microdochectomy) should be considered [14].

PATIENTS WITH OPEN, DISCHARGING OR ECZEMATOUS SKIN LESION

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

In patients suspected to have breast cancer and no definite mass is found on CBE or ultrasound, CEMRI of breasts is recommended. It is also recommended if cancer is already diagnosed on lumpectomy and breast conservation is being considered [15].

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

PATIENTS ALREADY DIAGNOSED WITH BREAST CANCER

A. IMAGING FOR LOCAL EXTENT OF BREAST CANCER

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

Preoperative CEMRI of both breasts is not routinely recommended, however, can be considered as per institutional policy. It is recommended in cases of lobular carcinoma, young women and those with dense breasts (ACR-BIRADS density C or D) [2,16]. It is also recommended for problem solving, for example if there is discrepancy in the clinically palpable extent of disease and the size of lesion on mammography and ultrasound. It may be useful in a lady with breast implants if optimum assessment for multicentricity or multifocality is not possible based on mammography and ultrasound alone.[2]Patients who have neoadjuvant chemotherapy are best monitored with breast MRI to assess response to treatment. It is also recommended if accelerated partial breast irradiation (APBI) is being considered. If additional suspicious lesion is seen on MRI and it can change the planned treatment, a biopsy of such lesion should be considered.

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

B. IMAGING FOR ASSESSMENT OF RESPONSE TO NEO-ADJUVANT CHEMOTHERAPY

If patient with large operable breast cancer or one with locally advanced breast cancer is considered for neo-adjuvant chemotherapy before surgery, then image guided core biopsy with complete histological analysis, tumor grade and ER, PER, HER2 receptor status should be obtained before initiation of chemotherapy. FNAC diagnosis only is not sufficient. If breast conservation surgery is considered in such a patient and breast mass is devoid of calcifications, placement of radio-opaque marker clip in the tumor is highly recommended [17]. This clip will help to localize the tumor in case of complete clinical and imaging resolution of the lesion after chemotherapy.

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

C. IMAGING FOR METASTATIC WORK-UP

The stages mentioned in the following paragraphs are as per anatomical staging in the 8th edition of American Joint Committee on Cancer (AJCC) Cancer Staging Manual of The American College of Surgeons (ACS).[18]

For early breast cancers (T1 or T2, N0 or N1, M0) which are up to 5 cm in size, with no axillary lymphnodes or mobile level 1/2 ipsilateral axillary lymphnodes, with no distant metastases (ie upto T2N1M0 of stage 2B, AJCC manual), routine use of investigations to detect occult distant metastasis is not advised due to false positive studies and the low yield of these investigations. [18, 19] A chest x-ray is sufficient. Any additional tests performed in early breast cancer should be directed by clinical signs and symptoms [18-20]. For example Tc99m-methylene diphosphonate (MDP) Bone scan is recommended if serum alkaline phosphatase is elevated or if patient has localized bone pain [2,18]. Abdominal imaging is to be performed if there are abnormal clinical findings or liver function tests. Similarly if there are suspicious chest symptoms a CT scan of the chest is advised.[18, 20]

Metastatic work-up with Chest x-ray, ultrasound of abdomen & pelvis and liver function tests are the basic essential tests to be performed from T3N0M0 of stage 2B of AJCC staging, and thus includes T3-4, any N as well as N2-3, any T cancers.[19] However instead of these investigations it is preferred to perform CECT Chest &abdomen and MDP Bone scan.[19] Alternatively PET-CT alone could be performed although this is not routinely advised.[19]

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

PATIENTS WITH METASTASIS FROM CANCER OF UNKNOWN PRIMARY SITE

These include women presenting with axillary lymph nodes or other lesions in the body which show malignancy on FNAC or biopsy. Bilateral mammography and breast ultrasound are recommended to exclude breast cancer. If mammography or ultrasound is positive then image guided biopsy should be performed. CEMRI is recommended if mammography and ultrasound are normal or equivocal but patient has unilateral axillary lymphadenopathy and breast cancer is suspected on FNAC/biopsy of lymph nodes [21].

PATIENTS WITH TREATED BREAST CANCER ON FOLLOW-UP

Regular physical examination and annual mammography is recommended [2]. Mammograms must be compared with previous mammograms, even if these appear normal. Any suspicious or new lesion not typically benign should be subjected to biopsy.

Follow-up systemic imaging to detect metastases is not routinely recommended, unless patient is symptomatic [22].

If metastases are detected on follow-up, its biopsy is not required if imaging findings are typical of metastases. However, image guided core biopsy of new metastasis is required to assess hormone receptor status if it has developed after long follow-up. It is also required if receptor status of breast cancer is not already known [17].

DISCLAIMER

Above mentioned are the broad guidelines for management of patients with breast symptoms in India and intended for the use of qualified medical caregivers only. These are based on various national and international guidelines and personal experiences and opinions of BISI members; as there is no large credible Indian data to formulate these guidelines. These guidelines are purely recommendatory and general purpose only in nature. Actual decisions for management of 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 BISI members or BISI as the organization cannot be held responsible for that in any manner.

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BREAST IMAGING SOCIETY, INDIA

BEST PRACTICE GUIDELINES – MAMMOGRAPHY

INTRODUCTION

Mammography has stood the test of time and is considered the best screening tool for breast cancer. It is the first line of investigation for most breast symptoms. As an investigative tool it helps characterise breast lesions and thus plays a significant role in reducing mortality and morbidity from breast cancer. Along with ultrasound it continues to be the basic investigative tool for breast diseases. Even when breast screening MRI study is performed, it is imperative that a correlating mammogram is available. As a breast radiologist, it is therefore most important to master the art and technique of performing and reporting mammography. In this document indications and technique of mammography have been discussed. Available international data as well as indian scenario and need have been taken into consideration and Breast Screening guidelines from the Breast Imaging Society, India (BISI) have been recommended in this document.

TECHNIQUE

Establishing a rapport with the client and explaining the procedure helps alleviate client's anxiety. This goes a long way in acquiring images that are optimal and useful.

Mammography should include mediolateral oblique (MLO) and craniocaudal (CC) views of each breast. These are regarded as the standard views. Even when symptoms are unilateral, bilateral mammograms are advised to assess asymmetric abnormalities. Digital mammography is preferred to film screen mammography, particularly for women aged < 50 years and for those with dense breast tissue [1]. If a suspicious abnormality is demonstrated on mammography, it is helpful to further characterise the mammographic features using magnification or spot compression views. Other views such as the laterally and medially extended CC views, and the valley view help visualise areas of the breast that are difficult to visualise on the standard views. Lateral view helps confirm if a lesion seen on the MLO view is truly in the upper or lower half of the breast.

Adequate Quality Assurance of the Mammography Unit is mandatory. 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. Most mammography units have an automated exposure control (AEC) system, which helps minimising 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.

INDICATION

Broadly the indications for Mammography fall into two categories : Screening and Diagnostic.

Screening Mammograms: These are for ladies who have no breast symptoms and no clinical signs of breast cancer. The purpose is early detection of breast cancer, when it is small and impalpable. This is to aid reduction of patient morbidity and mortality.

Diagnostic Mammograms: These are for ladies who have a symptom such as a palpable lump or blood stained nipple discharge, etc. The mammograms are acquired to identify the cause of the symptom, more specifically to diagnose if the symptoms are caused by a malignant mass.

Screening Mammograms

The population based cancer registries of India have shown significant increase in number of breast cancer diagnosed over the years in India [2]. It has been felt by different groups that breast self-examination and clinical examination are perhaps the right tools for early detection of breast cancer for the huge population of India, but no credible data is available today to prove that these are the best screening methods. Mammography has established itself as the investigation of choice for breast screening.

Breast screening related information, both potential benefits and possible risks, must be given to the lady and mammography must be performed after the lady gives an informed consent.

There are many screening guidelines from countries that have a population based breast screening programme. These programmes vary from country to country and hence there are different guidelines from different Breast Societies in the world. Due to lack of data specific to our country, currently no specific guidelines are available in India. However a few concepts and facts are recognised all over the world and these can be applied to the indian population in general. There are other facts that are specific to our country, such as increasing incidence of breast cancer in younger women, and the practice in India needs to be planned keeping these in mind. Some examples of Breast Screening Programme/ guidelines are The National Health Service Breast Screening Programme (UK) [3] and American College of Radiology Guidelines [4].

For women at average risk of breast cancer, screening mammography is thought to be beneficial between the ages of 50 and 74 years.[5] Although mortality reduction is less than that seen when screening older women, randomised control trials have shown a significant reduction in mortality in the 40–49 years age group. [6] Mammography screenings are effective and generate a 17% reduction in breast cancer mortality in women 39-49 years of age [7]. Breast cancer incidence increases with age. As a result more women in the 40-50 years age group would need to be screened to save the same number of lives as would be saved by screening women ≥50 years of age. But due to the longer life expectancy in younger women, life years gained for the women diagnosed with breast cancer by screening in their 40s is higher than in the ≥ 50 years old age group. [8]. It is known that screening women aged 40 - 49 years requires more frequent mammography and is less specific than screening in older women. Screening women 40 – 49 years of age does not however increase overdiagnosis compared with women starting screening at 50 years of age.[6] There is no evidence to support screening of women women <40 years old who are at average risk from breast cancer. [5, 6]. No upper age limit is established for screening mammography. However as the benefits of breast screening may take years to be fully realized, life expectancy and comorbid conditions should be taken into consideration to decide the upper age limit. In general screening mammography can be considered appropriate when a woman's life expectancy exceeds 5 to 7 years. [8]

Patients presenting with breast cancer are about one decade younger in developing countries in comparison to women in developed countries.[9] The proportions of young patients (< 35 years) of breast cancer vary from about 10% in developed nations to up to 25% in developing asian countries.[9] In the developing countries locally advanced cancers constitute over 50% of all patients managed indicating that diagnosis happens at a relatively late stage due to multiple causes.[9] The life expectancy at birth in 2013-17 has been 70.4 years for the female population in India. [10]

BREAST SCREENING RECOMMENDATION FROM BREAST IMAGING SOCIETY, INDIA

Taking all of the above data into consideration, 40 years is recommended as the age for starting mammography based screening in India. Although no dedicated population based screening programme exists in India, opportunistic screening of interested women, on a yearly basis, from the age of 40 years, is deemed appropriate. Annual mammography is advised till the age of 70 years. Beyond the age of 70 years, it is advised that a decision is made based on lady's comorbidities and life expectancy.

Screening (Surveillance) of contralateral breast to look for metachronous breast cancer after unilateral mastectomy for breast cancer is to be performed under the age of 40 years, if cancer was detected at < 40 years of age. Ultrasound and MRI may be required as adjuncts as younger women may have relatively dense breasts.

High Risk Group Screening (mammograms along with Breast MRI) is appropriate if there is a lifetime risk of breast cancer of ≥ 20% according to risk assessment tools that are mainly based on family history, if lady has a known BRCA1 or BRCA2 gene mutation or has a first degree relative with BRCA1 or BRCA2 gene mutation (and has not had genetic testing herself), if lady has a first degree relative with pre-menopausal breast cancer, if she has had radiation therapy to the chest when she was between the ages of 10 years and 30 years [4]. Screening with annual mammography (and annual MRI) is recommended to begin at age 30 years or 10 years before the age of diagnosis of first-degree relative with breast cancer, whichever is later. With history of mantle radiotherapy, annual mammogram (and annual MRI) should be started 8 years after radiation therapy. However screening mammography is not to be started for any lady before the age of 25 years, irrespective of the cause of high risk. Mammography and MRI are complementary examinations, and both should be performed. [4 & 8]

Diagnostic Mammograms

In the presence of breast symptoms such as a palpable lump, blood stained or serous nipple discharge, breast pain that requires investigation, mammography is used in the investigation of women aged 30 years or more. Addition of ultrasound is useful as these two modalities complement each other. In the 30 – 39 years age group clinical correlation is advised before requesting / performing a mammogram. For example a 32 years old lady with a clinically palpable small mobile mass with ultrasound features of a typical fibroadenoma may not require a mammogram for further characterisation of the lump. Mammography should not be used for opportunistic screening in the 30 – 39 years age group for women with average risk of breast cancer.

Mammography is not indicated as the first investigation for the majority of patients aged < 30 years. Ultrasound is the imaging method of choice for the majority of women aged < 30 years and during pregnancy and lactation. However mammography should be carried out in all patients with proven malignancy. Similarly mammography should be performed if there is a worrying appearance on ultrasound or clinical examination even in the < 30 years age group.

Breast pain that needs investigation such as focal persistent noncyclical pain, is often a nonspecific breast symptom. In symptomatic women less than 30 years of age, ultrasound is more accurate in making a diagnosis than mammography [11], and hence ultrasound is recommended as the first investigation. In the 30 – 39 years age group, adding mammography is advised.[11] Mammography may also be indicated in patients under the age of 30 if a suspicious lesion is found on the initial ultrasound examination, or if clinical signs justify the radiation exposure. Above the age of 40 years, mammography is recommended as the first investigation. Ultrasound is also useful in this age group as an adjunct to identify the cause of pain, especially in dense breasts.

In women presenting with a lump, diagnostic mammography is recommended if age of the lady is 30 years or more. In the 30 – 39 years age group clinical correlation is advised before requesting / performing a mammogram. Ultrasonography is more sensitive than mammography in detecting lesions in women with dense breasts, and it is the preferred imaging modality in women younger than 30 years with a palpable breast mass [12]. If ultrasound identifies a suspicious lesion, mammography is advised for the under 30 years age group also.

There are other guidelines which advise a cut off age of 40 years or 35 years for performing mammography in ladies presenting with breast symptoms [13]. Given the early onset of breast cancer in India, and given that the indian data we have is mostly from symptomatic women (rather than cancer picked up at breast screening), a lower cut off age of 30 years has been deemed appropriate for women with symptoms in our country.

Please read the guidelines on "Common Breast Symptoms: Algorithm for Imaging Evaluation", which is part of the Best Practice Guidelines of Breast Imaging Society, India for further information on the appropriate tests for patients presenting with breast symptoms.

REPORTING MAMMOGRAMS

Low ambient light is advisable in the reporting area and ambient lighting must not exceed 20 lux.[14] High quality 5 megapixel monitors are advised at the reporting work station.

The report should contain a comment on composition of fibroglandular tissue in the breast or breast density. Clear description of the mass, calcification, architectural distortion or focal asymmetry must be made, and where required advise such as further investigations or a follow up plan must be given. There are international guidelines that one may want to follow. Following a reporting system such as the ACR BI-RADS system is advisable.[15] Most importantly the report must communicate the salient findings to the referring doctor in a clear and unambiguous way.

Quality assurance aspects of reporting station are explained in detail in the Quality Assurance Guidelines.[16]

DISCLAIMER

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BREAST IMAGING SOCIETY, INDIA

BEST PRACTICE GUIDELINES – BREAST ULTRASOUND

INTRODUCTION

Breast Ultrasound is a well established and effective diagnostic modality for evaluation of breast diseases. The Indian radiologist is well versed with ultrasound as this is an easily available technique, both in large teaching hospitals as well as in small diagnostic centres across the country. Ultrasound breast is the primary imaging modality for younger women less than 30 years of age. It is an important adjunct tool to mammography especially for women with dense breasts. Technological advances and newer applications like Elastography and Automated Breast Volume Scanner (ABVS) have made ultrasound even more exciting and interesting. This document details the indications for breast ultrasound studies and also discusses the equipment, technique and reporting of breast ultrasound examinations.

INDICATIONS

Ultrasound breast is to be used as the initial imaging evaluation tool for palpable masses in younger women (less than 30 years of age) at average risk of developing breast cancer.[1] Based on the ultrasound findings and clinical features mammography may be performed as required.

Pregnant and lactating women: Absence of radiation makes ultrasound evaluation of breast symptoms in pregnant women a safe investigation. It is also an excellent tool for lactating women who are more likely to demonstrate dense breasts on mammography. Mastitis, breast abscess and galactocele are the common pathologies seen in these women and these are very well demonstrated on ultrasound.[2]

Nipple discharge: Evaluation of women with serous or sanguineous nipple discharge with high resolution ultrasound gives direct visualization of dilated ducts and their contents. Colour Doppler helps in differentiating between inspissated secretions and intraductal masses such as papillomas.

Focal persistent pain: Focal pain in the breast which is noncyclical can be because of multiple reasons such as focal mastitis, fat necrosis, breast abscess, haemorrhage in a cyst. Most of these conditions can be diagnosed and followed up on ultrasound. Diffuse bilateral cyclical breast pain does not warrant an ultrasound breast study.

As an adjunct imaging modality: It is used as an adjunct imaging modality for further assessment of suspected or apparent abnormalities which are detected on mammography. These include abnormalities demonstrated on screening mammograms as well as diagnostic mammograms. Ultrasound is very useful to differentiate a palpable solid mass from a benign cyst. In malignant masses it effectively demonstrates ductal extension of masses and is very useful to identify multifocal and multicentric disease in dense breasts.

Second-look ultrasound after magnetic resonance imaging (MRI): This allows identification of about 68% of abnormalities seen only at MR imaging.[3] Second-look ultrasound is helpful in many situations. For example screening MRI for women at high risk for breast cancer or preoperative breast MRI performed to assess multicentricity in known breast cancer patients may demonstrate MR abnormalities that were not demonstrated on mammography or ultrasound performed prior to MRI breast. Second-look ultrasound studies are highly recommended in such situations.

Breast Screening: Ultrasound breast is to be used as an adjunct to screening mammography for women with dense breasts and is deemed useful in the detection of mammographically occult cancers. Ultrasound replaces MRI for screening of women in the high risk category if they are not suitable candidates for MRI or have no availability of MRI. [1,4,5,6] However ultrasound is not established as a primary screening modality for general populations and should not to be used as a standalone breast cancer screening tool.

Follow-up of breast lesions: Sonographically well visualised BIRADS 3 lesions are best followed up in six months' time on ultrasound as there is no risk of radiation. However if the lesion is not visualised on ultrasound mammographic follow up becomes necessary.

Ultrasound guided intervention: Ultrasound is the preferred imaging modality for image guided procedures due to excellent real time needle visualisation, easy availability, patient comfort and absence of radiation. Image guided breast biopsy and other interventional procedures like marker clip placement for patients treated with neoadjuvant chemotherapy and preoperative guided hook wire localization of nonpalpable masses are all preferably performed under ultrasound guidance if the lesions are visualised sonographically. [7- 8] During treatment planning for radiation therapy ultrasound is a valuable tool that helps assess large seromas, aspirate if clinically indicated and also is essential for ultrasound guided boost irradiation of tumour cavity.[1,9]

Imaging the Axilla: Ultrasound is the modality of choice to image the axilla as well as to perform image guided procedures in the axilla such as biopsy of axillary lymph nodes.

Developing breast: Ultrasound is excellent for evaluation of developing breasts in young girls. Asymmetric breast development in this age group can be reassuringly differentiated from other pathologies by ultrasound in this age group.

Male breast: Ultrasound evaluation of the male breast helps differentiate gynaecomastia from breast masses like breast carcinoma and breast abscess. It is also the modality of choice for guided procedures in the male breast.

Augmented breast: It is the primary imaging modality for evaluation of breast implant associated problems. Sonographic assessment of implant morphology, contour, content and assessment of peri-implant tissues help evaluate implant related complications such as infection, hematoma, capsular contracture and rupture of implant.

Investigation of an unknown primary: Ultrasound of the breast along with mammography is advised for investigation of patients presenting with metastases from an unknown primary.

EQUIPMENT AND TECHNICAL FACTORS

Ultrasound breast should be performed with a real time high resolution linear array transducer (such as 12 – 5 MHz, 18 – 6 MHz) which has a centre frequency of at least 10 MHz and preferably higher. [10, 11] Characterization of breast lesions on ultrasound is highly dependent on technical factors. Depth, gain, and focal zone settings should be optimized for high quality images. Use of different modes and settings like tissue harmonic imaging and compound imaging are helpful.

The patient should be positioned to minimize the thickness of the portion of the breast being evaluated. Ipsilateral arm should be up over/under the head. Image depth should be adjusted for complete visualization of breast tissue with chest wall on the posterior margin of the image. For evaluation of nipple areolar complex region and superficial lesions, use of a thick layer of gel may be helpful.

ULTRASOUND EVALUATION AND DOCUMENTATION

Breast ultrasound should be performed in correlation with patient symptoms, clinical signs, mammographic findings and other breast imaging studies. For example in a lady presenting with nipple discharge, detailed examination of the ducts must be meticulously performed.
Ultrasound findings should always be compared with previous breast imaging studies if any, including mammography and MRI studies.
Evaluation of breast lesions should be done in at least two perpendicular planes.
Measurements of masses should be taken in three dimensions, two measurements at 90 degrees to each other in the plane of maximum length of the mass and the third measurement with the probe turned 90^{o} to the initial plane. One image should be saved without calliper markings.[10]
Proper labelling of images should be done for each image mentioning side (right or left breast), location of the lesion with o'clock position and orientation of the transducer. The probe can be transverse, longitudinal, radial or antiradial in orientation. Distance from the nipple in centimetres should also be mentioned. These details can also be marked diagrammatically.

Description of ultrasound demonstrated breast masses should include size, shape, orientation and margin of the mass as well as echogenicity, posterior acoustic features and vascularity. Following a reporting system such as the ACR BI-RADS system is advisable.[10]

ELASTOGRAPHY

Elastography is the sonographic method for imaging the elasticity of compliant tissues and provides information about stiffness of the lesion under evaluation. [12] It is known that in general malignant breast masses tend to be harder due to their desmoplastic reaction when compared to the adjoining normal breast parenchyma and most benign lesions. The evaluation of breast masses to differentiate benign lesion from malignant is one of the most important applications of ultrasound elastography.[12] It can help the radiologist to better characterise BIRADS 3 and 4A masses, thus reducing unnecessary breast biopsies.[13] However elasticity of breast masses has been included only as an associated feature in the 5th edition of ACR BIRADS [10] and should only be used as an adjunct to B-mode ultrasound, not as a replacement for gray scale ultrasound. In strain elastography size ratio and strain ratio values should be documented. In shear wave elastography elasticity value should be documented in kilopascals (kPa) or meters/second (m/s).[13]

AUTOMATED BREAST VOLUME SCAN (ABVS)

ABVS acquires a whole series of consecutive B-mode images and reconstructs 3D data sets of the entire breast volume. ABVS devices use mechanically driven wide linear array transducers that can image whole breast volumes in three dimensions. The data can be sent to a separate workstation to be independently analysed by the radiologist. [14] ABVS has potential advantages over conventional hand-held breast ultrasound as it is a standardized reproducible examination which gives dynamic cineloops of ultrasound images facilitating multiplanar and 3D reconstructions. ABVS is less operator dependent and it is being explored as a potential tool for breast cancer screening.[15] Limited inclusion of the axillary tail and axilla and artifacts in the nipple area are some of the limitations of ABVS. Lesion detected on ABVS has to be further evaluated with hand-held ultrasound.

DISCLAIMER

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BREAST IMAGING SOCIETY, INDIA

BEST PRACTICE GUIDELINES – MRI BREAST

INTRODUCTION

Magnetic Resonance Imaging (MRI) of the breasts is an established, robust and important imaging tool in the armamentarium of a trained breast radiologist for the detection and characterization of breast abnormalities. Its high sensitivity to detect breast cancer has led it being established as an excellent screening tool in women with strong family history of breast cancer and with dense breasts & further for pre-therapeutic local staging of newly diagnosed breast cancers where its role is being increasingly well accepted. It also serves as a good problem solving tool to clarify findings that are indeterminate on mammography and breast ultrasound.

Various groups and organisations have established recommendations for appropriate use of MRI, one such being the American College of Radiology (ACR) which has laid down certain guidelines to standardise various aspects of conducting and reporting breast MRI studies in the ACR Breast Imaging - Reporting and Data System (ACR BI-RADS). At present this is the most widely used MR Imaging Lexicon in India enabling clinicians across specialities to communicate well and work towards the common goal of better patient care. With increasing availability of Breast MRI in facilities across our country it is important to understand its advantages and limitations so that it can be utilised appropriately and effectively.

PRE-REQUISITES

- At least a 1.5-T magnet.
- Dedicated bilateral Breast surface Coils capable of simultaneous bilateral imaging.
- Equipment to perform mammographic correlation & directed breast ultrasonography.
- Ideally MR imaging-guided intervention facility or at least have a referral arrangement with a cooperating facility that could provide the service.

TECHNIQUE

Although, there may be minor variations in breast MR imaging acquisition protocols from centre to centre, there is a general agreement that high-quality imaging should include a technique that is bilateral, obtained using a dedicated breast coil with complete coverage of the breasts and axillae, is a dynamic multiphasic contrast enhanced study and has key pulse sequences with appropriate high spatial and temporal resolution for morphologic and kinetic assessment of the lesion.(1)

It is always a good idea to talk to the patient prior to the scan to obtain required history, clinically examine the patient and to prepare her/him by explaining the entire procedure including the unusual prone position, contrast injection and importance of not moving during scanning. Proper patient/breast positioning in the coil with application of optimal lateral compression plates to minimise movement and other inhomogenous fat suppression artefacts balanced with adequate patient comfort is imperative in obtaining images of diagnostic quality.

Contrast agent & dose - Gadolinium contrast agent injected intravenously at a dose of 0.1 mmol/kg followed by a 20 ml saline flush at a rate of approximately 2 ml/s, using a power injector.(1)

Pulse Sequences – For optimal diagnostic usefulness a fluid sensitive sequence with and without fat suppression – T2 FS/STIR, T1W & T2W 2D or 3D images of at least 3 mm or less slice thickness with a maximum in-plane pixel dimension of 1 mm or less to achieve good spatial resolution followed by a multiphase T1-W Dynamic Contrast Enhanced (DCE) series with pre-contrast, initial post-contrast in a 60 to 120s window for reasonable temporal resolution & subsequent delayed post-contrast images are required.(1) Silicone selective sequences may be acquired for implant evaluation. Intravenous contrast administration can be omitted and a plain study carried out for assessment of implant integrity. Newer techniques such as Diffusion weighted imaging (DWI) and MR spectroscopy are optional.

Abbreviated (FAST) Breast MRI as a cost effective screening protocol with similar sensitivity and specificity to a full diagnostic protocol may also be used with fewer sequences (3-4 in number) in varying combinations as per reader comfort to shorten the scan time. This would include a fluid sensitive T2 / STIR, pre and a single post-contrast fat suppressed T1W sequence.

Post processing techniques – Evaluation of images using Subtraction, Maximum intensity projections (MIP), morphologic and Kinetic analysis on a dedicated workstation.

INDICATIONS

Divided into two main categories – Screening and Diagnostic

SCREENING Breast MRI

X-ray Mammography is the investigation of choice for Breast Screening. However, mammography has its limitations especially in young high risk women with dense breasts. Among other modalities, contrast enhanced MRI has greater sensitivity compared to X-ray mammography and sonography for invasive (94-99%) and in-situ cancers (50-80%) in high risk population. Hence MRI has been widely accepted in its role in the high risk category of patients as an adjunct screening modality with X-ray mammography and not replacing it. It may also have a supplemental role in screening of the intermediate (15-20%) risk category in the future which is currently under research (2,3,4,5).

Annual screening MRI along with X-ray mammogram should be offered in high risk women i.e. those with a life time risk of breast cancer of 20% or more (2,4). This subset includes -

- Known BRCA1 or BRCA2 gene mutation
- Untested first-degree relative (mother, father, brother, sister, or child) of BRCA1 or BRCA2 gene mutation.
- Those with a lifetime risk of breast cancer of 20-25% or greater, according to risk assessment models.
- Received mantle radiation to the chest for Hodgkin's disease between the ages of 10 and 30 years.
- Having genetic disease such as Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or first-degree relatives with it.

Breast MRI may also be considered as a supplement to mammography to screen women at intermediate risk of breast cancer (15%-20%) such as those with a personal history of breast cancer and dense tissue or for those diagnosed with breast cancer under the age of 50 (6).

Patients with breast augmentation – Screening breast MRI may also be considered in patients with silicone or saline implants and/or free injections with silicone, paraffin, or polyacrylamide gel in whom mammography is difficult and for those who have undergone implant reconstruction following lumpectomy or mastectomy for breast cancer where contrast-enhanced breast MRI screening may be beneficial (6).

DIAGNOSTIC Breast MRI

In its diagnostic role Breast MRI is helpful in the following clinical settings –

Assessment of extent of disease in newly diagnosed breast cancer
Although current literature does not support widespread use of MRI for breast cancer staging in terms of increasing overall survival and reducing re-excision rates, MRI does have the superior sensitivity and accuracy for detection of invasive and in situ disease as compared with Clinical Breast Examination (CBE), mammography & ultrasound with limited specificity and hence maybe useful in select subpopulations such as

- In dense breasts to assess multifocality /multicentricity & ductal carcinoma in situ (DCIS) where it influences eligibility for Breast Conservation Surgery (BCS).
- Lobular cancers which are more accurately imaged with MRI by virtue of their pattern of growth.
- Posterior tumors better imaged with MRI for chest wall invasion
- Patients being planned for partial breast irradiation (PBI) following BCS.

However, in view of its limited specificity It is emphasised that all suspicious MR findings should be correlated with biopsy prior to definitive therapy to ensure appropriate treatment. Targeted second-look ultrasound, re-evaluation of mammograms, targeted mammographic views, or images obtained with digital breast tomosynthesis are useful, offering possibility of a biopsy under their guidance. Mass lesions identified on MRI are more likely to have a sonographic correlate than non-mass like lesions (65% vs 12%, respectively). Hence a second-look US is a useful diagnostic tool for lesions incidentally detected on breast MRI and also helps in guiding biopsies. In suspicious MR only detected lesions (BI-RADS 4 or 5) however, an MR-guided biopsy will be required (7).

Assessing Response to Neoadjuvant Chemotherapy in locally advanced breast cancers not amenable to upfront surgeries, to reduce tumor size to enable BCS and to assess tumor responsiveness to therapy.

Metastatic axillary adenopathy with occult primary on Clinical Breast Examination (CBE), Mammography and Ultrasound
MRI accurately detects the occult primary in 62-86 % of cases (8) which is then treated accordingly or when MRI too is negative, axillary nodal dissection is done along with mastectomy or Whole Breast Radiation therapy (WBRT).

Scar versus tumor recurrence

For Problem Solving in cases with equivocal or inconclusive findings on mammograms and ultrasound such as asymmetries with a suspicious appearance, multiple masses, pathological nipple discharge with no mammographic or sonographic correlate and to localise lesions for image guided biopsies and wire placements in cases where multiple solid lesions of similar characteristics are seen [to select the most suspicious (1 or 2) to biopsy and also where the lesions are difficult to resolve sonographically such as intraductal

inspissated secretions or intraductal solid lesion where MRI helps in retrospective identification on re-look ultrasound and localised].

Evaluation of Augmented breasts

MR imaging is the most sensitive imaging method to detect breast silicone implant integrity and does not require injection of intravenous contrast for assessing rupture only. Contrast may however be indicated in the evaluation of patients with silicone or saline implants and/or free injections with silicone, autologous fat, paraffin, or polyacrylamide gel as well as for those who have undergone implant reconstruction following lumpectomy or mastectomy for breast cancer. The presence of implants does not affect the sensitivity of MRI for breast cancer detection.

REPORTING BREAST MRI

Report of MRI breasts should clearly mention the clinical indication for which it is being done along with findings noted on the other conventional imaging modalities, as it should never be interpreted in isolation. It is also important to remember that mammograms are obtained in upright position, ultrasound in supine / semi lateral decubitus position and MRI in prone position, which may lead to mild variation in the lesion location described as the o' clock position, especially those bordering the quadrants and should be noted as such. Comparison must be made with any priors available. It is very important to mention the background breast parenchymal enhancement pattern (BPE) which is inherent to this modality only along with the breast composition. All findings need to be described as per standardised descriptors given in international guidelines such as the ACR BIRADS Reporting System in terms of morphology and kinetic assessment and a final impression should be mentioned indicating the worst comprehensive BIRADS category with a clear mention of further investigative advise such as biopsy or a follow up protocol (9).

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BREAST IMAGING SOCIETY, INDIA

BEST PRACTICE GUIDELINES

IMAGING GUIDED BREAST BIOPSY

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

INTRODUCTION

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

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

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

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

IMAGING MODALITIES FOR BREAST INTERVENTIONS

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

TYPES OF DIAGNOSTIC BREAST INTERVENTIONAL PROCEDURES

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

MAMMOGRAPHIC GUIDANCE

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

Indication

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

Needle Selection

- Single or dual hook localization wires

Post procedure requirement

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

STEREOTACTIC GUIDANCE

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

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

Indications

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

Needle Selection

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

Post procedure requirement

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

ULTRASOUND GUIDANCE

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

Indications

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

Needle Selection:

- **FNAC -**
    - Indications:
        1) Axillary lymph node biopsy when there is a known or suspected ipsilateral breast malignancy
        2) Investigation of suspected multicentric/multifocal malignancy when the index lesion has undergone a CNB/FNAC confirming malignancy in the index lesion
    - Limitations of FNAC [15,16]:
        1) Cytologist dependent
        2) No information on type of cancer or receptors (ER, PR, Cerb2, Ki67)
        3) Incidence of false negative and false positive higher than with CNB
        4) If cost is the only deciding factor, then FNAC could be performed acknowledging the fact that discordant imaging and FNAC findings would warrant a repeat biopsy.

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

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

Post procedure requirement

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

MRI GUIDANCE

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

Needle Selection

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

Post procedure requirements

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

ABSCESS DRAINAGE AND CYST ASPIRATION

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

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

MARKER CLIP DEPLOYMENT

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

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

ROLE OF GALACTOGRAPHY

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

CONTRAINDICATIONS FOR IMAGING GUIDED BREAST BIOPSIES

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

COMPLICATIONS OF IMAGING GUIDED BREAST BIOPSIES

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

MANAGEMENT OF COMPLICATIONS OF IMAGING GUIDED BREAST BIOPSIES

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

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

THE RADIOLOGIST'S REPORT

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

LABELING OF PATHOLOGY SPECIMEN

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

ESTABLISHING RADIOLOGY PATHOLOGY CONCORDANCE OR DISCORDANCE

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

DISCLAIMER

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

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RELEVANT LINKS

Canadian Association of Radiologists (www.car.ca)

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

American College of Radiology (www.acr.org)

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

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