



Review Article

Stereotactic breast biopsy: A review & applicability in the Indian context

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Stereotactic biopsy is used for sampling of suspicious non-palpable lesions identified on mammography or digital breast tomosynthesis which are not visible on ultrasound. Stereotactic biopsy is preferable to surgical excision biopsy and helps avoid surgery for benign lesions. Providing tissue diagnosis in patients with early breast cancer may help in formulating a management strategy. Stereotactic biopsy can be carried out using either a dedicated prone table with the patient lying prone or an upright mammographic add-on system with the patient in a sitting or lateral decubitus position. This review focuses on the advantages and disadvantages of both these systems, the indications, contraindications and the complications inherent with this technique. The important pitfalls and their management as well as ways to ensure quality assurance have also been elaborated upon. Data regarding uptake of stereotactic biopsy in other parts of the world have been discussed using evidence from existing registries and databases and attempts made to quantify the need of the technique in the Indian set-up. In the absence of a national breast screening programme and limited resources in India, a hub and spoke model has been proposed as a viable model for healthcare providers for providing stereotactic biopsy.

Key words Breast cancer - breast screening - core biopsy - mammography - stereotactic biopsy - vacuum-assisted breast biopsy

Pre-operative image-guided biopsy of breast lesions is a well established step in the diagnostic algorithm of both screen-detected and symptomatic breast lesions. The safety and reliability of stereotactic biopsy is now well established and surgical biopsy is only required in cases where image-guided biopsy is inconclusive^{1,2}.

Impalpable breast lesions present a challenge to the surgeon and the role of a radiologist to perform image-guided breast biopsy becomes imperative. Detailed protocols and established guidelines allow for a high pre-operative diagnosis rate. As per the 2015-16

National Health Services Breast Screening Programme (NHSBSP)/Association of Breast Surgery audit of screen-detected cancers, 97 per cent of malignancies were diagnosed preoperatively. The pickup rate was as high as 99 per cent for invasive cases and 92 per cent for *in situ* cases². An accurate diagnosis not only allows for a detailed discussion on the treatment modalities and prognostication in malignant cases but is also important to avoid unnecessary surgical interventions in case of benign lesions.

Breast lesions identified on mammography or digital breast tomosynthesis (DBT) that appear

suspicious require tissue diagnosis to plan further management. If the lesions are visible on ultrasound, it is preferable to biopsy them under ultrasound guidance¹. However, occasionally, these lesions or abnormalities are not visible on ultrasound at all, or even if visible, are not clear enough to perform an ultrasound-guided biopsy. This is especially true with microcalcifications demonstrated mammographically³. Stereotactic biopsy is thus used for suspicious non-palpable lesions identified on mammography or DBT but not visible on ultrasound¹.

History

Before the late 1980s, impalpable breast lesions visualized well only on mammograms were a diagnostic challenge⁴. Mammography-guided localization of these had to be performed either with a wire, visible dye or carbon particles, followed by an open surgical biopsy⁴. As a mammogram is a two-dimensional image and breast a three-dimensional structure, the third dimension, *i.e.* the depth of the lesion from the skin, had to be assessed by the radiologist. Although experienced breast radiologists devised their own methods of determining this measurement, this was not an exact science⁴. This technique is still used commonly for pre-operative wire localizations of impalpable breast lesions, although radiological percutaneous biopsy cannot be done by this method as it lacks the precision that is demanded for a percutaneous biopsy.

The error rate for wire-guided surgical biopsies ranged between two and 22 per cent⁴. Specimen radiographs were performed for most but not all lesions⁵. Incomplete removal of some lesions due to areas with multiple calcifications, needle migration post-localization and lack of communication between the localizing radiologist and the operating surgeon have been reported as some reasons⁶. Furthermore, surgery carried a small risk of mortality due to the general anaesthesia⁴. Risks of bleeding, infection, wound healing and breast deformity if large areas were excised were other issues⁴.

To start with, stereotactic fine-needle biopsies were performed and cytology was used to confirm the diagnosis of sampled lesions⁷. As core biopsy (CB) methods became available, this was soon replaced by CB. In the early 1980s, Dr Per G. Lindgren, a Swedish radiologist in conjunction with Radi Medical Systems in Uppsala, Sweden, developed an automated biopsy device, which was the first version of the automated biopsy guns used today⁴.

In 1988, an upright fine-needle stereotactic breast biopsy system was adopted which accommodated the automated gun and the Stereotix breast biopsy system (General Electric Medical Systems, Milwaukee, WI, USA) came into being⁴. The Fischer prone table was also modified to accommodate the stereotactic biopsy unit which resulted in more comfortable biopsies for the patients. Dr Parker's first stereotactic CB on August 8, 1988, revolutionized how women with lesions seen only on mammography would be biopsied and treated⁴. Thereafter, a number of studies established stereotactic biopsy as the alternative to open surgical biopsy⁷⁻⁹. Radiologists Fred Burbank, Steve H. Parker, William R. Brody and Elias Zerhouni and a surgeon Thomas J. Fogarty successfully developed Mamotome (Biopsys Medical Instruments, Inc., San Juan Capistrano, CA, USA), the first vacuum-assisted breast biopsy (VABB) device⁴. The first VABB was performed on August 5, 1994 and multiple studies have established its success, especially to biopsy microcalcifications demonstrated on mammograms^{10,11}. With the advent of DBT, DBT-guided stereotactic biopsy was performed especially for lesions that are demonstrated on DBT alone.

Indications

Stereotactic biopsy is indicated in many different clinical scenarios. An impalpable suspicious breast lesion poorly visible or not visualized at all on ultrasound but well demonstrated on mammograms is the most common indication for stereotactic biopsy. Real-time visualization of biopsy needle traversing the lesion, absence of ionizing radiation, better patient comfort, shorter procedure time and lower costs are some of the important advantages of ultrasound-guided biopsy¹². Even some palpable lesions may benefit from stereotactic biopsy, especially those which are vaguely palpable, small, deep seated, not well demonstrated on ultrasound but better demonstrated on mammograms¹³.

The lesions that require biopsy are guided by the categorization of lesions according to the Breast Imaging Reporting and Data System, Breast Imaging Atlas (BI-RADS®)¹⁴. BI-RADS 5 (lesions that are assessed as highly suggestive of malignancy) and BI-RADS 4 (lesions that are assessed as suspicious for malignancy) abnormalities should be biopsied in the absence of clinical contraindication for biopsy¹⁵. These include masses, architectural distortions, developing asymmetries and calcifications. To plan the treatment options in presence of synchronous breast

cancer, biopsy confirmation of BI-RADS 3 (probably benign) lesions may be necessary. In addition, histological confirmation of BI-RADS 3 lesions may be required in patients awaiting organ transplantation or women planning to become pregnant¹⁵. Absence of MRI-guided biopsy facility in a centre is also a reason for stereotactic biopsy provided it can be reliably established that the lesion on the mammogram is undoubtedly the MRI-detected lesion that needs to be biopsied. Lesions that are only visualized on DBT can also be biopsied stereotactically under tomosynthesis guidance¹⁶.

Stereotactic guided wire localization can be performed prior to breast conservation surgery for biopsy-proven palpable lesions that require excision. The computer calculates the third dimension which needs to be decided by the operator in standard mammography localizations. Pre-operative stereotactic localization may be performed with radioactive seeds also¹⁷.

Equipment

There are essentially four components of the equipment required for a stereotactic procedure: the stereotactic unit, a device for patient positioning, a computer and the biopsy equipment.

Stereotactic unit: Stereotactic biopsy can be carried out using either a dedicated prone table with the patient lying prone or an upright mammographic add-on system with the patient in a sitting or lateral decubitus position. An add-on stereotactic localization device can be fitted on the mammography machine prior to the biopsy which converts a standard mammography machine into a stereotactic biopsy unit¹⁸. As the same machine is used for both mammography as well as biopsy purposes, lesion visualization at the time of biopsy is good, as the resolution and quality of the image remains the same¹⁶. Alternatively, a purpose-built prone table can be used for stereotactic biopsy⁴. The prone table is elevated and the breast that hangs inferiorly through an aperture in the prone table is biopsied. The advantages of the prone system are lesser patient movement during the procedure and a reduction in anxiety on part of the patient. This is because the biopsy is performed by the operator sitting on a chair underneath the elevated prone table, and hence, the patient cannot see the biopsy needle or the procedure¹⁶. The prone systems also minimize vasovagal reactions compared to the upright add-on systems. However, this system is expensive and requires more space. This is because unlike the upright

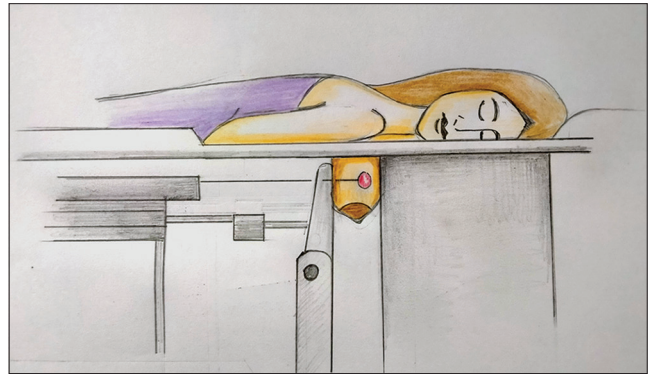


Fig. 1. Illustration of a patient lying on a prone table, with compressed breast, for stereotactic biopsy.

add-on system, it cannot be used to perform routine mammography, and therefore, separate mammography and biopsy rooms are required. Furthermore, the elderly and those with orthopaedic problems find lying prone during the procedure uncomfortable¹⁹.

Patient carrier: The patient needs to be comfortable during the procedure as the procedure may take up to 15-30 min. Movement-related complications are directly proportional to patient discomfort. Dedicated stereotactic biopsy chairs are available which allow biopsies in the sitting up and decubitus positions. However, propping up the patient and supporting the back and arms is vital. If a prone table is being used, the patient should be comfortably positioned and good padding provided where required (Fig. 1).

The computer/monitor: This is the brain of the procedure which uses the concept of Stereotaxis²⁰ and calculates the depth of the lesion. A dedicated computer could be used as is usually the case when a prone table is used for the procedure. Alternatively, the high-end monitor in the mammography room used by the technician to check the adequacy of acquired mammography images could also be used.

Stereotactic biopsy is therefore a method of precise positioning of a needle and sampling of a lesion after calculating the three-dimensional co-ordinates of the lesion. The X- and Y-axis co-ordinates of the centre of the lesion to be biopsied are easily available from the 2D images of mammography. A 'scout' image is acquired at an angle of 0°. A +15° image and a -15° image (the stereo pair) are acquired next. It can be noted that the lesion shows an apparent movement between these projections referred to as 'parallax shift' and is calculated relative to the reference point (which is unique for different machines). Basic trigonometry is applied to determine the X-, Y- and Z-axis of the lesion to be biopsied²¹. This is calculated by

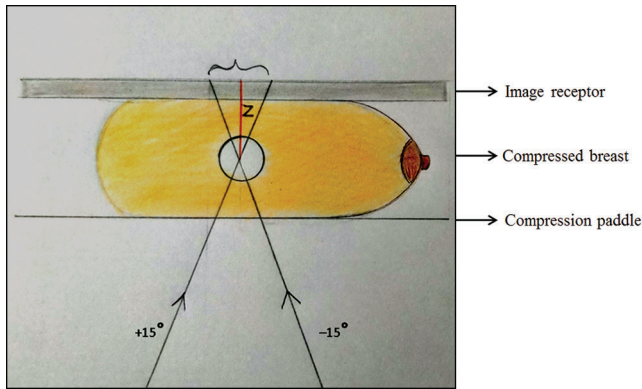


Fig. 2. Schematic diagram demonstrating 'Parallax Shift' denoted by the distance marked by the flower bracket. The circle within the compressed breast is the target for biopsy. 'Z' is the distance between the centre of the target and image receptor. Based on the target markings placed on the images on the computer by the operator, the software can calculate the distance of the target from the compression paddle.

the software in the computer using information from the markings done by the operator on the computer screen and mimics depth perception performed by the human brain (Fig. 2).

The biopsy device: Fine-needle aspiration cytology (FNAC) has now been replaced by 14 gauge CB based on evidence from several studies that demonstrated suboptimal accuracy of FNAC for non-palpable breast lesions in general and microcalcifications in particular²². In the Indian population too, the sensitivity and specificity of FNAC are significantly lower than CB and diagnostic categorization with CB is significantly better compared to FNAC²³. In fact, the accuracy of stereotactic CB has been reported to be equivalent to that of open surgical biopsies and CB is highly reproducible and reliable²⁴⁻²⁶. In this context, the importance of radiology pathology concordance cannot be overstated. In cases of discordance between radiological assessment and pathology report, re-biopsy and sometimes open surgical biopsy may be required²⁵. Some studies have shown that CB and 11 gauge VABB are equally accurate at diagnosing microcalcifications with no significant difference in surgical outcome²⁷. Other studies have shown that VABB has some advantages over CB. VABB increases pre-biopsy confidence for some difficult lesions. The biopsy action of VABB is directional and it can acquire tissues up to 5 mm away from its own position, as the vacuum action can draw the lesion into the sampling chamber and cut it away from the surrounding tissue, compensating for subtle patient movements²⁸. Ductal carcinoma *in situ* (DCIS) is more frequently underestimated with CB than with VABB²⁹.

First-line VABB use may be considered if the cluster of microcalcification is small (<5 mm) or the calcification is scanty³⁰. If representative microcalcification is not demonstrated on specimen radiography, a repeat biopsy by means of VABB is advisable. Furthermore, repeat biopsies for masses or architectural distortions are preferably done by VABB³¹. The availability of equipment, local expertise and departmental protocol dictate the choice of CB vs VABB.

The procedure

An unambiguous well demonstrated target is a prerequisite for a good biopsy. A clear protocol detailing all the steps is important for a successful stereotactic biopsy. A written informed consent must be obtained after advising the patient about the compression applied during the procedure, low dose of radiation to the breast and time taken for the procedure along with the risks of bleeding, infection and pain. History of drug allergy must be elicited, with specific reference to lignocaine. The importance of staying still during the procedure should be stressed upon to improve compliance.

View/direction of compression & approach: The mammographic view used for the procedure/direction of compression of the breast should be decided. Craniocaudal, mediolateral, lateromedial or oblique views of breast can be used for the procedure. The determination of direction of compression is based on best lesion visualization, shortest distance from skin to lesion and avoidance of arteries¹⁷. The approach could be vertical or lateral. In the vertical approach, the needle is inserted perpendicular to the compression paddle. For example, if the breast is compressed in the craniocaudal view and a vertical approach is taken, the needle will also travel craniocaudally, that is entering the superior aspect of the breast and moving towards the image receptor. However, if the breast is compressed in the craniocaudal view, and a lateral approach is taken, the needle will travel perpendicular to the craniocaudal direction, that is entering the breast from the lateral aspect or the medial aspect of the breast, and hence not pointing to the image receptor. In the lateral approach, the needle is parallel to the compression paddle³². The approach taken is irrespective of whether the underlying view/compression is craniocaudal, mediolateral, lateromedial or oblique (Fig. 3)³². The breast size, breast thickness upon compression as well as the location of the lesion influence the approach¹⁷. The view/direction of compression and the approach

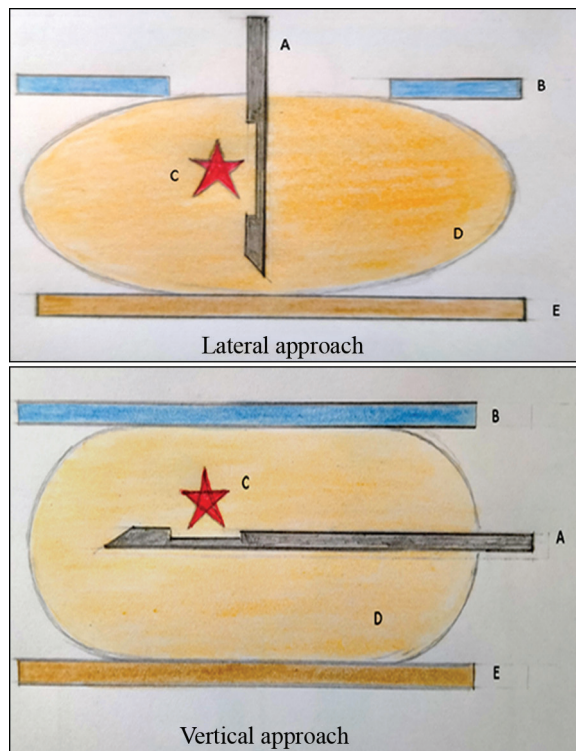


Fig. 3. Schematic diagram showing lateral and vertical approach. (A) Biopsy needle; (B) compression paddle; (C) target for biopsy; (D) compressed breast; (E) image receptor.

should be decided prior to consenting and should be explained to the patient (Fig. 4).

Positioning: The technician positions the patient compressing the breast in the predetermined view for the predetermined approach. The lady's breast is compressed between the compression plate and the image receptor in the stereotactic unit in such a way that the target is at the centre of the biopsy window of the compression paddle. This is confirmed by taking the 0° scout view which should ideally demonstrate the centre of the lesion to be biopsied at the centre of the image. Then, the $+15^\circ$ and -15° stereo pair images are obtained by moving the X-ray tube and detector assembly $+15^\circ$ and -15° relative to the 0° position on the scout image. Thus, a pair of images with 30° separation between projections are obtained²¹. These are displayed on the monitor in the biopsy room. Apparent movement or parallax shift is clearly demonstrated on the images. The operator marks the centre of the lesion on the $+15^\circ$ and -15° images on the screen of the monitor. The X, Y and Z co-ordinates of the centre of the lesion to be biopsied are calculated by the computer and then transferred to the upright add-on stereotactic biopsy unit or the prone table biopsy unit.

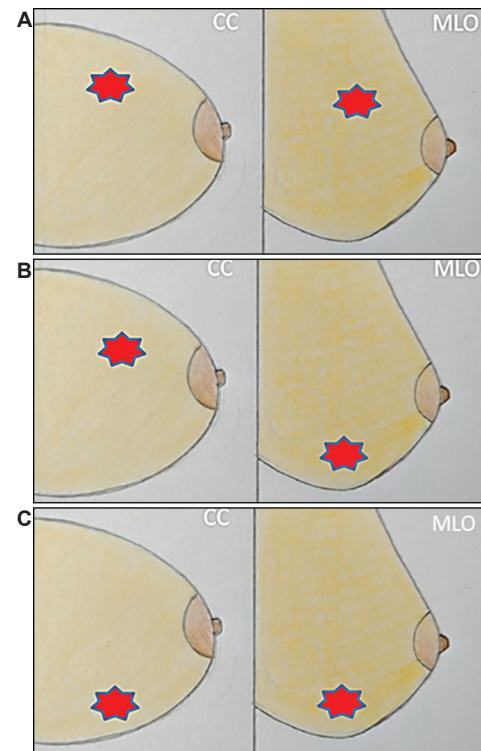


Fig. 4. Schematic diagrams of different views in which breast is compressed and approaches taken depending on lesion location. (A) Target in upper breast: Craniocaudal compression, vertical approach. (B) Target in lower outer breast: Lateromedial compression, vertical approach OR craniocaudal compression, lateral approach. (C) Target in lower inner breast: Mediolateral compression, vertical approach OR craniocaudal compression, lateral approach.

The biopsy: The operator cleans the skin and injects local anaesthesia. One per cent or two per cent lignocaine is used for CB. For VABB lignocaine one per cent for skin and lignocaine one per cent combined with 1:100,000 epinephrine can be used. Epinephrine is avoided for skin anaesthesia to avoid skin necrosis³³. A small skin bleb is raised followed by deeper injection in both CB and VABB. A 2 mm skin incision is made for a CB, the needle is inserted and pre-fire and post-fire check images are taken to confirm optimum needle position. For VABB, a larger 4 mm incision is made and firing may not be required and hence, a single set of check or positioning images may be acquired^{28,33}. VABB needles range from 7 to 11 gauge. Depending on the type of lesion and size of the biopsy needle, on an average, 6-12 samples are obtained¹⁶. However, no fixed number guarantees optimum sampling and decision about the number of samples and adequacy should be made on an individual basis. It is accepted that more number of cores need to be acquired for microcalcifications compared to masses³⁴. In addition, architectural distortions usually need more cores so as

Table. Pitfalls and solutions of stereotactic breast biopsy

| Pitfalls | Solution |
|---|--|
| The lesion is seen on only one image of the stereo pair | <ul style="list-style-type: none"> The lesion may be at the edge of the scout view and needs to be in the centre of the image on the scout view. Deeper the lesion, the more likely this is to happen on the Lorad system²¹. May happen when a posterior lesion is biopsied on the prone table with the patient's arm through the hole as the shoulder obstructs the view. Altering the position may help. Most biopsy units have target - on - scout option which can be used. One of the stereo images and the scout image can be used for targeting the lesion⁴. However, this reduces the angle between the two projections to 15° which makes it more prone to localization errors, and therefore, targeting requires greater accuracy²¹. |
| Patient moves during procedure | <ul style="list-style-type: none"> Retargeting has to be performed and the procedure started afresh. Positioning the patient comfortably and optimum local anaesthesia helps reduce movement. Marginal movement can be managed by altering the X, Y or Z co-ordinates manually by an experienced operator. |
| Negative stroke margin (NSM) | <ul style="list-style-type: none"> Altering the direction of breast compression and approach may help. Positioning the needle slightly proximal to the lesion to be biopsied helps, with the lesion to be biopsied lying in the distal part of the sampling notch of the needle upon firing the biopsy gun. Bolstering the breast by applying compression from the nipple towards the chest wall with a tape or bandage, thus thickening the breast in the region of the lesion to be biopsied³⁵. <i>Air-gap technique</i>: it involves positioning a reversed compression paddle in between the breast and the image receptor with the open biopsy windows of both compression paddles in line with the lesion. This provides a 20 mm air gap between the breast and the image receptor. The biopsy needle and breast tissue prolapse by 5 to 10 mm into the air gap, thus not hitting the image receptor⁴. Simple bubble wrap placed in place of the reverse compression plate also produces the same effect. |
| The targeted lesion is too superficial | <ul style="list-style-type: none"> Plastic aperture coverings that partially cover the needle's sample aperture are available and these can prevent skin trauma or skin sampling. Sterile saline or local anaesthetic can be injected into the subcutaneous tissue to expand it and increase the distance of the targeted lesion from the skin¹⁶. |

not to miss a small malignancy or radial scar within them¹⁶.

Post-biopsy: Checking the adequacy of sampling of microcalcifications with magnification view of samples acquired is compulsory to confirm that appropriate tissue sampling has been performed¹⁵. The biopsy specimen is usually radiographed by laying the tissue on a moist paper or Petri dish³⁵. Furthermore, the plastic lid of the formalin pot can be used to radiograph the samples. Following this, the tissue samples are placed in a 10 per cent formalin solution with appropriate patient identification³⁵. Marker clip is placed if the lesion biopsied is small and the operator is concerned that the lesion may have been totally removed. It could also be placed if the operator thinks that it may not be unambiguously visible on the mammograms after biopsy, making presurgical mammography-guided wire localization difficult. In some cases, the marker clip can also be placed if there is a doubt that the mammographically visualized lesion may not correspond to the sonographically visualized

lesion. If a marker clip is placed, lateral and craniocaudal mammograms are performed immediately after the procedure to confirm its position³¹. Important pitfalls and solutions are described in Table. In smaller breasts, the post-fire needle may pass through the breast and strike the image receptor. This is referred to as NSM. An inbuilt safety mechanism does not allow the operator to start the procedure. This can also occur in normal sized breasts if the target is too deep (Fig. 5). The air gap technique to prevent this is described in Figure 6. The technique for skin protection in superficial lesions is shown in Figure 7.

Stereotactic biopsy and anti-coagulation

Stereotactic breast biopsy is considered to be associated with a low risk of bleeding. While for CB, pre-biopsy coagulation profile tests are recommended only in the case of a personal or family history of bleeding problems or if the patient is on anticoagulation therapy¹⁹, most centres prefer a clotting screen prior to VABB. However, studies carried out on women on

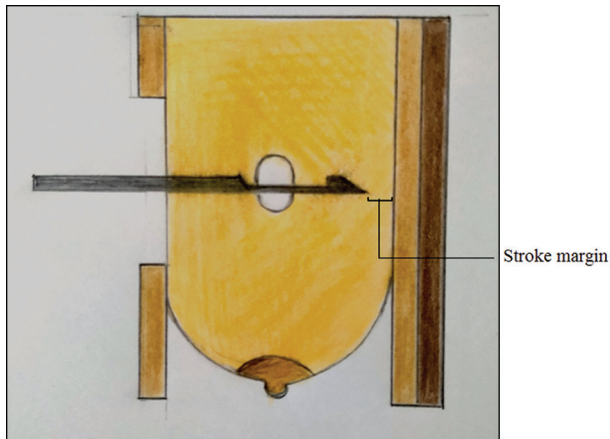


Fig. 5. Schematic diagram of stroke margin: Distance between the tip of the needle and the distal surface of the breast/image receptor.

warfarin have shown no significant increase in the risk of hematoma or bruising compared to patients not on anti-coagulation³⁶. In our practice, INR is preferred to be less than 1.5 before undertaking stereotactic biopsies.

Some of the commonly encountered medications associated with increased risk of bleeding are oral vitamin K antagonists (warfarin), oral anti-platelet agents (aspirin, clopidogrel, prasugrel, ticagrelor, cilostazol and dipyridamole) and non-steroidal anti-inflammatory drugs (ibuprofen and diclofenac sodium)³⁷. Warfarin should ideally be discontinued for five days before the intervention with a target INR <1.5. In cases where stopping warfarin is deemed unsafe for so long, heparin should be used during this period. Warfarin can be re-started within 12 h after the procedure³⁷.

Procedural issues

Inability to visualize the target breast lesion at the time of biopsy is an absolute contraindication¹⁵. Neuromuscular disorders such as Parkinson's disease may limit the capacity of the patient to lie still³⁸. For most prone tables, there is a weight limit generally between 136 and 158 kg¹⁶.

Pain, infection and hematoma are the known complications of stereotactic breast biopsy²⁸. The risk of significant hematoma after CB is one per cent and for VABB is approximately four per cent³⁹. Manual pressure over the biopsy site for 5-10 min minimizes hematoma formation. A compression dressing applied for 4-6 h should be considered after VABB, especially after complete lesion excision procedures such as excision of radial scars³⁹. Displacement of malignant epithelium is not seen after stereotactic breast biopsies⁴⁰. No cases of

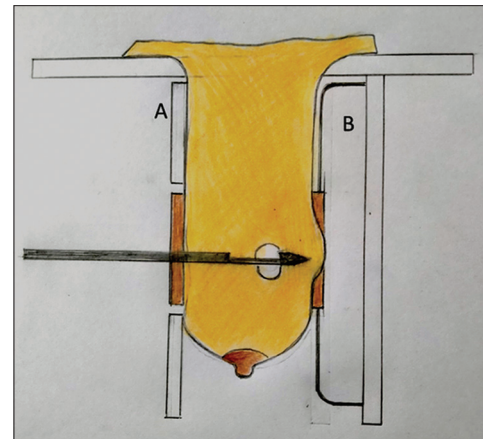


Fig. 6. Schematic diagram of air gap technique: (A) Compression paddle; (B) reversed compression paddle.

significant needle track seeding have been reported from large studies³⁸. The operator, technologist and nurse should all be optimally trained and experienced to ensure quality assurance of the procedure⁴¹. Quality assurance instructions and advice from the manufacturers should be followed to ensure that the equipment is in optimum condition. Quality assurance tests for the mammography machine must be performed as per the Atomic Energy Regulatory Board (AERB), India regulations⁴².

Concordance between the radiological appearance and the pathology result has to be established⁴³ and close communication and collaboration between the breast radiologist and pathologist is required for this to happen. In case of discordance between the histological and radiological findings or inadequate sampling, a multidisciplinary meeting should be held to plan further management.

Global Scenario

Globally, the most common lesion biopsied stereotactically is microcalcification and stereotactic biopsies are the most accepted for their assessment. Screening programmes in many countries have resulted in an increase in the detection of microcalcifications, which are often a feature of DCIS. In the UK, this has led to an increase in the age-standardized incidence of DCIS from three per 100,000 before the advent of the National Health Service Breast Screening Programme (NHSBSP) to 23 per 100,000 in 2013³⁰. The introduction of digital mammography has further increased the detection of microcalcifications^{44,45}. Data from multiple national screening programmes indicate that the recall rate and resulting biopsy for calcifications range from 0.4 to 2 per cent of females screened⁴⁶⁻⁴⁹.

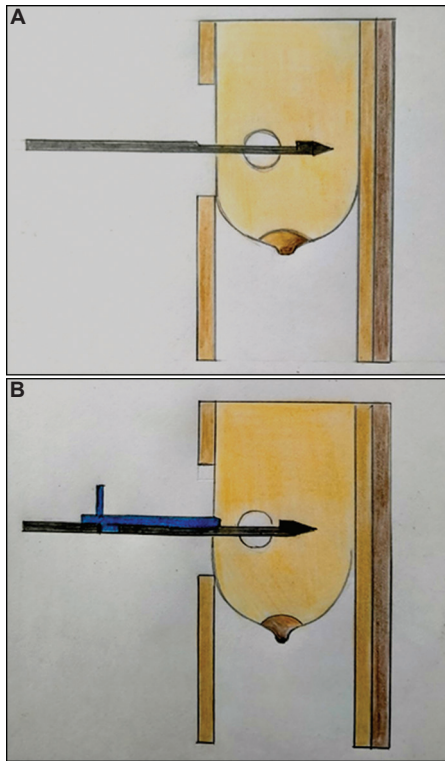


Fig. 7. Schematic diagram to demonstrate the use of skin protection device. (A) The position of the proximal part of the sample notch is such that skin will be traumatized when the biopsy gun is fired. (B) A skin protection device (coloured blue in the diagram) is placed over the biopsy needle prior to firing. The skin is protected by this device when the gun is fired.

Breast screening coverage is defined as the percentage of women residents eligible for screening at a particular point in time who actually attended their breast screening appointment⁵⁰. The NHSBSP has set and achieves a minimum standard of 70 per cent⁵¹. However, BreastScreen Australia has set a minimum standard of 70 per cent but achieves about 54.6 per cent⁵². Multiple factors influence breast screening coverage. Awareness of the importance of breast screening as well as ethnicity is known to influence uptake and countries have introduced additional measures to encourage uptake of screening programmes among women from culturally and linguistically diverse backgrounds^{52,53}.

Screening mammography inevitably leads to additional biopsies. However, the risk of false positives and need for additional biopsies have to be weighed against the lives saved by early diagnosis of breast cancer as well as the reassurance provided by biopsy-confirmed benign lesions⁵⁴.

According to published data, the minimum recall rate for calcifications following mammograms is 0.4 per

cent of women screened³⁰. A diagnosis of malignancy is made after investigations for microcalcifications in 0.3 per cent of women screened³⁰. Of the malignancies based on calcifications alone, one-third tend to be invasive cancers^{49,54}. The remaining two-third comprise DCIS. DCIS detected by mammographic screening is predominantly of high nuclear grade and only 13 per cent is low grade⁵⁴. Supplementary contrast-enhanced MRI of the breast and deep learning artificial intelligence methods may help reduce the false-positive rate and hence reduce overdiagnosis and overtreatment of DCIS in the future⁵⁵⁻⁵⁹.

Possible numbers of stereotactic biopsies in India

In India, lack of a national database or screening programme makes it difficult to accurately assess the number of stereotactic breast biopsies needed annually in India. Limited number of sub-specialist radiologists and specialist referral centres coupled with a lack of awareness regarding breast diseases in the community make population-based screening difficult in India at present⁶⁰. In urban India, an increase in awareness and facilities has led to opportunistic mammographic breast screening⁶¹.

To get an idea about the requirement of stereotactic biopsy, inferences have to be drawn from the census data in concurrence with the guidelines issued by the Breast Imaging Society, India (BISI). The guidelines state that the potential population for screening are women between 40 and 70 yr of age⁶². As per the Indian census of 2011, there were 587,584,719 women in India, constituting 48 per cent of the Indian population. Of these 405,967,794 (69%) reside in rural and 181,616,925 (31%) in urban India⁶³. In 2016, 24.8 per cent (n=145,721,010) women were between the age of 40-70 and were the potential population for screening as per the guidelines of BISI^{62,64}.

Even if one considers that only the eligible urban population participated in screening, the number of mammograms annually would be approximately 43,716,303. If 0.4 per cent of these, were recalled for biopsy, which is the minimum recalled for assessment of microcalcifications after screening mammograms⁴⁶, the number of estimated stereotactic biopsies would be 174,865 per annum nationally.

Assuming a procedure time of one hour which includes consenting, planning, actual procedure and aftercare, a dedicated breast unit performing eight stereotactic breast biopsies per day with 25 working days per month would be able to perform 2400 procedures/annum. This would mean approximately 75 breast centres

with stereotactic biopsy facilities would be needed in the country to meet the demands for urban women alone.

Setting up specialist breast units in rural and remote areas of the country is not a viable model, in fact a hub and spoke model best suits our country whereby mammography can be performed in multiple spoke centres which have a central specialist hub where stereotactic biopsy can be performed⁶⁵. This helps us provide this specialist biopsy technique to a larger geographic area. The spoke hospitals or diagnostic centres can use their resources better and ensure a much wider reach. The hub at the same time can provide specialist service with improved expertise in a financially viable milieu.

Overall, stereotactic breast biopsy is an important component in the armamentarium necessary to provide a comprehensive breast diagnosis and treatment programme. It has a well-established role in biopsying lesions that are visible on mammograms alone, thereby minimizing the number of open surgical biopsies. In the absence of a national breast screening programme and limited resources in India, a hub and spoke model appears to be a viable model for healthcare providers to consider.

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