Percutaneous Biopsy of the Breast

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2. Discuss the advantages and limitations of ultrasound guided biopsy, stereotactic guided biopsy, fine needle aspiration biopsy, core needle biopsy, and vacuum assisted suction devices.
3. Explain the importance of concordance between the clinical impression and the pathology findings.

Article

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In the last decade there has been a dramatic increase in the use of percutaneous breast biopsy for the evaluation of breast lesions. Prior to the advent of modern imaging techniques such as high-resolution ultrasound and digital imaging, the breast biopsy was the province of the surgeon. Performing an image-guided biopsy requires many decisions. Which type of imaging modality should be chosen? Which type of sampling device will the radiologist choose, and what will he or she do with the results of the biopsy procedure? In this article we will discuss the available technologies for performing percutaneous breast biopsies, the types of sampling devices used, and the advantages and disadvantages of each. These procedures will also be compared to surgical biopsy of the breast. We will also discuss the responsibilities of the radiology team doing the biopsy and evaluating the biopsy results.

Prior to the advent of image guided percutaneous breast biopsy, most breast lesions were diagnosed by surgical excisional biopsy (figure 1). If the lesion was palpable, the surgeon would use this to guide the excision of the lesion. The lesion was usually completely removed leading to the term "excisional biopsy." Sometimes, only a portion of the mass was removed and this was called an "incisional biopsy." There are some negative aspects when the lesion in question is completely removed with the surgical procedure. Surgical biopsy often requires general anesthesia, which is not without known risks. Cosmetic defects from the open biopsy procedure can be considerable depending on the skill of the surgeon and the amount of tissue removed. Furthermore, open biopsy can cause scarring, which may have an effect on future mammogram imaging.

With the introduction of widespread use of screening mammography, small non-palpable abnormal findings were commonly detected. This created significant challenges for the surgeon who could not feel the abnormality identified on the mammogram. Mammographically suspicious nonpalpable breast lesions require a mammographically guided localization procedure to ensure that the proper area is removed at surgical biopsy. Specimen radiography is an important part of the localization and biopsy procedure for all types of lesions. The surgical biopsy specimen must be radiographed (or ultrasonaged if ultrasonographic localization was performed) to be sure that the lesion and the localizing device have been removed. If the lesion is not seen in the specimen the surgeon must be notified immediately so that he or she can remove more tissue as needed. The major advantage of open surgical biopsy is that there is no sampling error when the lesion is completely removed as verified by specimen radiography. Therefore, open biopsy is by definition, "the gold standard." The failure rate of excisional biopsy in non-palpable mammographically detected abnormalities in the literature is approximately 2% when the lesion is localized by an experienced radiologist, and excised by an experienced surgeon. The complexity of the surgical excisional biopsy, not to
mention the cost of scheduling operating room time and general anesthesia, led to the quest for a simpler image guided procedure that could be performed in the office.

Many factors influence the decision as to how to approach a breast biopsy. The typical sorts of guidance used to do a breast biopsy include a palpable approach, ultrasound approach, and mammographically guided procedures including needle localized surgical excision and stereotactic biopsy.

A typical setting is a woman presenting with a palpable lump in her breast. Often she will present to her primary care physician or a surgeon. The physician can then perform a biopsy of the lump simply based on what he or she feels.

Another typical setting is an abnormality discovered on the screening mammogram. Generally in most breast-center radiology practices, the woman is called back for further mammographic views to characterize the abnormality. If the lesion appears to be a solid mass seen on the two orthogonal views of the mammogram, often the decision will be made to further characterize the lesion on ultrasound. If the lesion is seen on ultrasound, it can then be biopsied under ultrasound guidance in most cases.

Perhaps the abnormality is seen only on one mammographic view and still looks suspicious. Investigatory ultrasound is negative and nothing is palpable. Or, the lesion seen on the mammogram is made up of small calcifications and no apparent mass is seen ultrasonographically, (often the small flecks of calcium seen on mammograms will not be seen on ultrasound) then mammographically directed modalities must be used. These include needle localized surgical excisional biopsy and the newer modality of stereotactic biopsy.

Ultrasound Guided Biopsy

In 1993, Parker et al described 181 lesions sampled under ultrasound guidance using a 14-gauge needle with 4 to 5 cores obtained per lesion. In the 49 lesions with surgical follow-up, there was 100% agreement between the results of the core biopsy and the surgery. In the 132 patients with benign results, no cancers were subsequently identified at 12 to 36 month follow-ups. Thus began the modern age of percutaneous breast biopsy.

The procedure involves finding the lesion on ultrasound. Following the cleansing of the skin and the application of local anesthesia, the sampling needle is placed in the appropriate position using ultrasound guidance and samples are taken. In the hands of most trained radiologists, the procedure takes anywhere from five to thirty minutes. The patients do not need pain medications following the procedure and routine activities are not limited. Recovery time is generally negligible and not more than 24 hours. The risks include bleeding and infection, but these are exceedingly rare. The most common finding is a bruise at the biopsy site.

The advantages of the ultrasound-guided biopsy include the ready availability of the equipment, the accessibility of all areas of the breast including the axilla, the capability for multi-directional sampling, the lack of radiation exposure, and the ability to see the needle under real time. The main disadvantage is that the lesion must be sonographically evident in order to be biopsied under ultrasonographic guidance.

Fine needle aspiration, 14-gauge core biopsy and 8-, 11- and 14-gauge vacuum assisted suction devices can all be used with ultrasound guidance for the biopsy. Ultrasound can also be used in guiding wire localization prior to surgical excision or surgical biopsy.

Stereotactic Guided Biopsy

Early studies of 14-gauge stereotactic core biopsy reported an 87-96% agreement between the results of needle biopsy and surgery. Stereotactic guidance can be used in all types of mammographically visualized lesions including masses and calcifications. It can be performed with upright "add-on" units and on dedicated prone tables.

The upright units are attached to existing mammography machines. They are less expensive and need less space but they require that the patient be sitting up during the procedure, which then allows the patient the ability to watch the entire procedure as it happens. This has been implicated in a slightly higher risk of fainting etc., during the procedure.

The dedicated prone tables are only for stereotactic biopsy. They are more expensive than the upright units and require a room
all to themselves. They have more working room, decreased likelihood of patient motion, and have the benefit of having the table acting as a physical and psychological barrier between the patient and the procedure.

In the case of the prone table, the procedure involves the woman lying on the top of the table with her breast hanging through the aperture of the table. The breast is then compressed in the same manner as in a mammogram. Localizing images are taken, usually at ten-degree angles from each other, and the area of interest is then marked on these images. The coordinates of the area of interest are then fed into the attached computer and the differences in the coordinates on the two images are used to determine the X-, Y-, and the Z-coordinates of the actual lesion for the placement of the sampling needle. Following the cleansing of the skin and the application of local anesthesia, the sampling needle is placed in the appropriate position using stereotactic guidance and samples are taken. In most trained radiologists hands the procedure takes anywhere from thirty minutes to an hour. The patients do not need pain medications following the procedure. The recovery time and the procedure risks are generally the same as that of the ultrasound-guided procedures using a similar sized sampling needle.

Fine needle aspiration, 14-gauge core biopsy, and 8-, 11- and 14-gauge vacuum assisted suction devices can all be used with stereotactic guidance for the biopsy. Stereotactic units can also be used in guiding wire localization prior to surgical excision or surgical biopsy.

**Biopsy Devices**

The types of devices used for image guided percutaneous biopsy are as varied as the imaging modalities used. All have different advantages and disadvantages and most of them can be adapted to the different types of available image guidance. Biopsy needles include the 26-gauge "fine needles," 14-gauge core or "Tru-Cut" needles (figure 2), and vacuum assisted device probes that come in 14-, 11-, and 8-gauge sizes.

**Fine Needle Aspiration Biopsy**

Fine needle aspiration biopsy (FNAB) of palpable masses in the breast has been around for many years. FNAB of the breast was first performed at the US Memorial Hospital for Cancer and Allied Disease in 1925. The procedure was popularized in Sweden in the 1970's. The first stereotactic FNAB was performed at the University of Chicago in 1986.

Fine needle aspiration biopsy involves a small amount of local anesthesia in the skin. Next, a tiny 26-gauge needle is used to retrieve cells from the lesion for cytological evaluation. These cells are "smeared" on slides and air-dried and/or fixed in alcohol. The slides are then evaluated by a cytopathologist. Because only cells are retrieved, it is difficult, although not impossible, to make a definitive diagnosis of the type and grade of the cancer. Usually the results are "benign," "malignant," or "atypia." The advantages of FNAB are that it is a minimally invasive procedure and the needed materials are inexpensive. The necessary materials are a needle, a syringe, and a few slides. The disadvantages of FNAB are that the making of adequate smears on the slides is somewhat difficult and because only cells are obtained, it is often difficult to tell if the samples are adequate for evaluation at the time of the procedure. Many facilities have a trained cytopathologist on the premises of the breast center at the time of the biopsy to say whether or not the sample is adequate for diagnosis. This, of course, makes the procedure much more expensive. Last but not least, one of the biggest disadvantages of the FNAB is that, because it only retrieves cells, it often underestimates the severity (or lack of severity) of the disease by calling malignant and benign lesions atypical. This results in the need for a second procedure with more tissue sampled in order to sort things out.

**Core needle biopsy**

Today, core needle biopsy has largely replaced FNAB. There are less sampling errors like the ones discussed above. Core needle biopsy more clearly distinguishes between intraductal and invasive carcinoma. Core needle biopsy (CNB) uses a larger needle, usually a 14-gauge, as compared to the smaller 26-gauge needle used in FNAB. CNB requires a special biopsy "gun" that is spring loaded. An inner trocar is thrust forward approximately 2 cm and, at almost the same time, the outer cutting cannula is thrust over the inner trocar filling the inside notch with the breast tissue specimen. The specimen tissue looks like a 2 cm piece of spaghettini. Again, local anesthetic is used for the procedure. There is no technical preparation of the sample before it is sent to the pathology lab. It is simply dropped in a container of 10% neutral formalin. The size of the sample gives the pathologist enough tissue for a definitive diagnosis and evaluation of a number of other prognostic factors. These factors include the exact type of the tumor, the grade of the tumor, and other bio-indicators such as hormone receptor status and Her-2-neu status. All of these factors can be used to plan the patient’s definitive surgery and future treatment options.
The material costs for CNB are greater than the material costs of FNAB. The cost of the average core biopsy gun is about a thousand dollars and the cost of each needle is about fifteen dollars compared to about two dollars for the equipment of a fine needle aspiration biopsy.

**Vacuum Assisted Suction Devices**

Vacuum assisted devices (VAD) for tissue sampling have become very popular in the last five years. These devices couple a disposable probe with a reusable probe driver. Vacuum is applied to the probe, which pulls the tissue into the cutting window and then transports the tissue outside of the breast where it can be collected while the probe stays in place. The advantages of these devices are a single insertion of the probe into the breast, contiguous larger samples, less precise targeting needed, and faster retrieval of a number of specimens (figure 3). The VAD's come in 11-, 14-, and 8-gauge sizes and in some of the more aggressive breast centers the VAD's are being used to completely remove lesions under a centimeter in size. The major disadvantage of the VAD is the price. The disposable probes cost about three hundred dollars apiece, not to mention the cost of the driver and the vacuum device.

The vacuum assisted devices were originally designed for use with stereotactic machines but in the last year have become available in hand-held models suitable for ultrasound-guided procedures (figure 4). The VAD's also have the advantage of being able to use the probe to insert a 2mm tissue marker at the end of the procedure. The clip can then be used as a landmark to identify the biopsy site if further definitive surgical intervention is needed (figure 5). The clip can also be used to mark the site of the tumor prior to the administration of neo-adjuvant or pre-operative chemotherapy. The clip marks the site of the tumor so that the appropriate area can be localized and removed in the event of a 100% response to chemotherapy.

**Breast Biopsy Concordance**

As you can see, there are many, many ways to biopsy the breast. The last and probably the most important issue regarding breast biopsy is the concept of concordance. As the radiologist and the technologist evaluate the patient by physical exam, mammography, and ultrasound, and the diagnostic opinion is decided that a breast biopsy is indicated, it is important that the following question be asked. What do I think the lesion actually is? This is the pre-test probability. Does this solid mass look like it is going to be breast cancer? Does it look like a benign fibroadenoma? Do the calcifications look like ductal carcinoma in situ? There is a system for the classification of the pre-test evaluation called the "Breast Imaging Reporting and Data System" or BI-RADS categories. The laws governing the operation of breast centers handed down from the FDA require that all examinations be given one of six categories, which are as follows:

- **BI-RADS 0** = The patient’s evaluation is incomplete and she needs further diagnostic imaging.
- **BI-RADS 1** = The evaluation is normal.
- **BI-RADS 2** = The evaluation shows benign findings that are of no diagnostic consequence.
- **BI-RADS 3** = The evaluation shows findings that are *probably* benign and some sort of definitive procedure or short-term follow-up is recommended.
- **BI-RADS 4** = The evaluation shows findings that are suspicious for malignancy and biopsy is recommended.
- **BI-RADS 5** = The evaluation shows findings that are *highly* suspicious for malignancy and biopsy is recommended.

Each patient should be fully evaluated by imaging prior to the recommendation of biopsy and a BI-RADS category should be assigned as the pre-test probability of breast cancer. Following the biopsy, the results should be compared to the pre-test probability to see if there is agreement or concordance between these results. Is the lesion that was thought to be a fibroadenoma a fibroadenoma? Is the lesion that looked like cancer in fact cancer? If the opinion was that the lesion looked like cancer but the needle biopsy comes back benign, can this be explained? If the lesion looks like a cancer and the pathology comes back benign, could it be because the area that needed to be sampled was missed on the biopsy? It is the job of every breast center performing biopsies to compare the pre-test and post-test results for concordance to assure that the lesion was adequately sampled and evaluated.

The pathologist reading the core biopsy samples also evaluates concordance. Routinely, the pathologist reading the needle biopsy sample is provided with the relevant image findings, such as the level of suspicion, including the BI-RADS final assessment and a description of the mammographic and ultrasonographic findings, such as calcifications or mass. If the biopsy is for calcifications and yet no calcifications are identified in the biopsy sample, it is the job of the pathologist to let the radiologist know this. Conversely, if the radiologist did specimen radiography and proved that there were calcifications in the specimen, and the pathologist states that no calcifications were found, it is the job of the radiologist to let the pathologist know...
that there are definitely calcifications in the specimen, so that the pathologist can re-cut the specimen and find the calcifications to evaluate.

In every breast radiology practice, the results of all biopsies must be compiled along with all of the results of the definitive surgeries on all patients diagnosed with breast cancer on needle biopsy. These results can then be compiled to give sensitivities and specificities for all radiologists performing breast imaging and image guided needle biopsies in each center. The information gathered lets each radiologist know how well he or she recognizes breast cancer on imaging. It also lets the radiologist know how well she or he does in performing biopsy procedures.

All of these image guided biopsy procedures, in the hands of an experienced breast radiologist, are a safe and effective way to histologically evaluate breast lesions. In general, they are markedly cheaper than their surgical counterparts. The recovery time from percutaneous biopsy is much shorter than the surgical biopsy. The image guided biopsy procedure results in fewer complications than the surgical procedure and leaves no scars. Having a diagnosis of cancer prior to the planning of surgery allows the woman to participate more in her care and to choose treatment options for herself. As neo-adjuvant chemotherapy becomes more popular, more women are able to undergo breast conserving therapy rather than mastectomy. As MRI becomes used more and more in the evaluation of breast lesions, image guided MRI biopsy systems will become more readily available.

Images:

1. An example of an open breast biopsy procedure.
2. An example of a "Tru-Cut" breast biopsy needle.
3. Samples on the right are those obtained with a "Tru-Cut" needle biopsy. The samples on the left are those obtained with a vacuum assisted suction device. Note that the VAD samples are much larger specimens.
4. An example of a hand-held vacuum assisted suction device breast biopsy procedure.
5. The image on the left depicts the original lesion prior to the biopsy. The image on the right shows the 2 mm clip that was inserted as a marker, once the biopsy was completed.
References or Suggested Reading


About the Author(s)

Dr. Brooke Caldwell has been a dedicated breast radiologist for over 8 years and currently is the director of the Breast Imaging Center at Orange Coast Memorial Medical Center in Fountain Valley, California. She is Board Certified by the American Board of Radiology and has several publications in major Radiology journals.

Dr. Caldwell did a fellowship in Women’s Imaging and a portion of this time involved one-on-one study with Dr. Lazslo Tabar in Sweden. She is very active clinically and also performs numerous lectures for radiography technologists, nurses, medical students, residents, fellows, and physicians.