

Image-Guided Percutaneous Biopsy of Palpable and Nonpalpable Breast Lesions

Purpose

To outline the use of minimally invasive biopsy techniques (MIBT) for palpable and nonpalpable breast lesions.

Associated ASBrS Guidelines or Quality Measures

1. Quality Measure on Preoperative Diagnosis of Breast Cancer – Approved December 15, 2010
2. Performance and Practice Guidelines for Breast Ultrasound – Revised April 30, 2012
3. Performance and Practice Guidelines for Stereotactic Breast Procedures – Revised April 28, 2010
4. Concordance Assessment of Image-Guided Breast Biopsies and Management of Borderline or High-Risk Lesions – Approved November 2, 2016

Methods

This is a comprehensive review of the modern literature on this subject. The ASBrS Research Committee developed a consensus document, which the ASBrS Board of Directors reviewed and approved.

Summary of Data Reviewed

Use of MIBT: The goals of minimally invasive biopsy techniques (MIBT) are to provide an accurate pre-operative diagnosis of malignant or pre-malignant breast lesions, and to avoid an open surgical procedure for patients with benign abnormalities.^{1,2} Using MIBT to establish a cancer diagnosis before any surgical procedure is considered a Breast Quality Measure.²⁻⁵ A preoperative diagnosis of a malignant or pre-malignant abnormality allows for consideration of additional breast imaging before initial therapy, optimizes decision-making for the surgical approach, and maintains patient eligibility for neoadjuvant systemic therapy. Furthermore, consultations for fertility, plastic surgery, and genetic testing, when appropriate, can be obtained before the definitive surgical excision is performed. A preoperative diagnosis also optimizes oncologic and cosmetic surgical planning, and facilitates preoperative axillary staging to minimize the number of surgical interventions.⁶ When a cancer diagnosis has been made preoperatively, surgery can more often be performed as a single procedure with clear margins, resulting in improved efficiency of care,

and fewer financial and nonfinancial burdens to the patient.

Techniques: MIBT include fine needle aspiration (FNA) (25-28 gauge), core needle biopsy (CNB) (8-14 gauge), vacuum-assisted needle techniques (7-11 gauge), rotating cutter, and other types of devices. The choice of percutaneous device depends on the target lesion (mass vs microcalcifications), target location (mid-depth breast vs adjacent to skin or implant vs axilla), intent to remove the entire lesion, and training and experience of the clinician. A CNB or vacuum-assisted technique is usually preferable to FNA cytology for all breast lesions because it is more sensitive⁷ and allows for characterization of the lesion architecture, marker analysis, and immunohistochemistry. FNA biopsy may be an acceptable alternative in circumstances and practice settings where access to core needle biopsy is not available. For smaller lesions (1 cm or less), percutaneous excision using a vacuum-assisted or other enhanced tissue acquisition device along with placement of a marking device (e.g. clip) should be considered. Sampling error and upgrade rates may be reduced in such cases,⁸⁻¹¹ although randomized controlled trials to compare these techniques to standard CNB have not been reported. For larger (greater than 1 cm) suspicious masses, 14-gauge core needle biopsy is often sufficient. In general, a clip or other marking device should be considered at the time of percutaneous biopsy of all suspicious lesions to improve the accuracy of future localization if there is concern the lesion may be completely removed during MIBT or if the patient is anticipated to undergo neoadjuvant therapy. Neoadjuvant treatment may result in loss of target due to tumor regression prior to surgical excision.

Image guidance for MIBT is recommended for both palpable and nonpalpable lesions to increase accuracy of sampling. A percutaneous breast biopsy of a palpable mass without the use of image guidance may lead to a false-negative result since the biopsy device cannot be confirmed to be within the lesion of interest, as some palpable lesions have a surrounding inflammatory reaction that may be palpable but does not contain malignant cells. In most instances, ultrasound (US) is preferred for image guidance in patients with palpable masses. Imaging modalities available for targeting of nonpalpable breast lesions include breast US, mammogram (stereotactic), and magnetic resonance imaging. If the lesion is visible sonographically, US guidance is preferred, as it optimizes patient positioning and comfort. Multiple professional organizations provide recommendations for proper image annotation, image archiving, and medical record documentation for MIBT.^{4,12-15}

Concordance: High success rates for pathologic and imaging concordance by MIBT are achievable.⁵ Multiple reports demonstrate a success rate of 90% or greater. After MIBT, care providers must perform imaging-histology concordance assessment to determine whether the pathology obtained correlates with the imaged target, and avoid false negative biopsies.¹⁶⁻¹⁹ Concordance of clinical breast examination, imaging, and the biopsy results must always be determined and documented.^{4,12, 13,15-20} Discordant biopsy results are an indication to either repeat a percutaneous biopsy or to proceed directly to surgical excision.

Discordance: The ASBrS had endorsed the use of MIBT for diagnostic breast evaluation as a Quality Measure.² There are other quality measures that also help define the full extent and complexity of MIBT.^{3,5,19} Surgeons who perform MIBT should track the number of discordant results that required surgical biopsy and the number of “missed cancers” in patient follow-

up, and document post-MIBT management of patients who have benign or “high-risk” lesions. A comprehensive discussion of the management of patients with “high-risk” lesions and discordant lesions is beyond the scope of this position statement, but can be found in the references below.^{16, 18,20} Care providers who offer MIBT should use a patient database to document long-term follow-up, including sensitivity, specificity, positive predictive value, and negative predictive value of their MIBT practice.^{3,5,18} The ASBrS Mastery Program provides a patient registry and synoptic templates for quality review of patients undergoing MIBT.²¹

Exclusions: There are justifiable reasons why the diagnosis of a breast abnormality cannot be made by MIBT. Lesions that cannot be accurately targeted by image guidance and some lesions immediately juxtaposed to an implant, chest wall, or skin may not be amenable to MIBT. There are also multiple patient factors that may preclude MIBT, including inability to lie prone for stereotactic or MRI-guided MIBT, mental disability that limits patient cooperation, and body habitus, such as extreme kyphosis or obesity. It is unclear how to manage patients who receive antiplatelet and anticoagulant treatment and are referred for MIBT. The risk of the patient bleeding from MIBT must be balanced against the risk of anticoagulation cessation before the procedure. This decision may require consultation with the patient’s prescribing clinician. Finally, patient preference of biopsy technique or lack of access to imaging-guided biopsy equipment may not allow MIBT. The ASBrS supports patient shared decision-making regarding MIBT.

ASBrS Recommendations

1. Breast surgeons, CGCs:

- a. The goals of MIBT are to accurately diagnose malignant or pre-malignant breast lesions and to avoid an open surgical procedure for patients with benign abnormalities.^{1,2}

2. Techniques:

- a. The choice of device depends on the target lesion, target location, intent to remove the entire lesion, and the surgeon’s training and experience.
- b. A CNB or vacuum-assisted technique is usually preferable to FNA cytology for all breast lesions. CNB is more sensitive than FNA for diagnosis of breast lesions, and the tissue obtained with a core biopsy provides histology to characterize lesion architecture and to perform marker analysis and immunohistochemistry staining.
- c. Place a clip or other marking device at the time of percutaneous biopsy of all suspicious lesions. It helps to confirm appropriate sampling and improves the accuracy of future localization if there is concern the lesion may be completely removed during MIBT or if the patient is to undergo neoadjuvant therapy.
- d. Image guidance for MIBT for both palpable and nonpalpable lesions increases the accuracy of sampling. Ultrasound, if available, is recommended for image guidance in patients with palpable masses. If the lesion is nonpalpable and visible sonographically, US guidance optimizes patient positioning and comfort.

3. Concordance:

- a. Concordance of clinical breast examination, imaging, and the biopsy results must always be determined and documented.^{4,12,13,15-20}
- b. Discordant biopsy results should prompt a repeat percutaneous biopsy or surgical excision.

4. Discordance:

- a. Surgeons who perform MIBT should track the number of discordant results that required surgical biopsy and the number of “missed cancers” in patient follow-up. They should also document post-MIBT management of patients who have benign or “high-risk” lesions.
- b. Care providers who offer MIBT should use a patient database to document long-term follow-up, including sensitivity, specificity, positive predictive value, and negative predictive value of their MIBT practice.^{3,5,18}

5. Exclusions:

- a. Lesions that cannot be accurately targeted by image guidance and some lesions immediately juxtaposed to an implant, chest wall, or skin may not be amenable to MIBT.
- b. There are patient factors that may preclude MIBT, including inability to lie prone for stereotactic or MRI-guided MIBT, mental disability that limits patient cooperation, and body habitus, such as extreme kyphosis or obesity.
- c. It is unclear how to manage patients who receive antiplatelet and anticoagulant treatment and are referred for MIBT. The risk of the patient bleeding from MIBT must be balanced against the risk of anticoagulation cessation before the procedure. This decision may require consultation with the patient’s prescribing care provider.
- d. Patient preference of biopsy technique or lack of access to imaging-guided biopsy equipment may not allow MIBT.

- References -

1. Silverstein MJ, Lagios MD, Recht A, et al. Image-detected breast cancer: state of the art diagnosis and treatment. *J Am Coll Surg*. 2005;201:586-597.
2. American Society of Breast Surgeons. Preoperative diagnosis of breast cancer quality measure. https://www.breastsurgeons.org/statements/QM/A_SBrS_Preoperative_diagnosis_of_breast_cancer.pdf Accessed July 8, 2017.
3. Stavros AT, Thickman D, Rapp CL, Dennis MA, Parker SH, Sisney GA. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. *Radiology*. 1995;196:123-134.
4. Expert Panel on Breast Imaging. ACR appropriateness criteria palpable breast masses. *J Am Coll Radiol*. 2017;14(5S):S203-S224.
5. Linebarger JH, Landercasper J, Ellis RL, et al. Core needle biopsy rate for new cancer diagnosis in an interdisciplinary breast center: Evaluation of quality of care 2007-2008. *Ann Surg*. 2012;255:38-43.
6. James TA, Mace JL, Virnig BA, et al. Preoperative needle biopsy improves the quality of breast cancer surgery. *J Am Coll Surg*. 2012;215(4):562-568.
7. Wang M, He X, Chang Y, et al. A sensitivity and specificity comparison of fine needle aspiration cytology and core needle biopsy in evaluation of suspicious breast lesions: A systematic review and meta-analysis. *Breast*. 2017;31:157-166.
8. Graham CL. Evaluation of percutaneous vacuum assisted intact specimen breast biopsy device for ultrasound visualized breast lesions: Upstage rates and long-term follow-up for high risk lesions and DCIS. *Breast*. 2017;33:38-43.
9. Killebrew LK, Oneson RH. Comparison of the diagnostic accuracy of a vacuum-assisted percutaneous intact specimen sampling device to a vacuum-assisted core needle sampling device for breast biopsy: initial experience. *Breast J*.

- 2006;12(4):302-308.
10. Milos R, Bernathova M, Baltzer PA, et al. The breast lesion excision system (BLES) under stereotactic guidance cannot be used as a therapeutic tool in the excision of small areas of microcalcifications in the breast. *Eur J Radiol*. 2017;93:252-257.
 11. Scaperrotta G, Ferranti CI, Capalbo E, et al. Performance and role of the breast lesion excision system (BLES) in small clusters of suspicious microcalcifications. *Eur J Radiol*. 2016;3:143-149.
 12. American Society of Breast Surgeons. Performance and practice guidelines for breast ultrasound. https://www.breastsurgeons.org/statements/guidelines/Performance_and_Practice_Guidelines_Breast_Ultrasound.pdf Accessed July 8, 2017.
 13. American Society of Breast Surgeons. Performance and practice guidelines for stereotactic breast procedures. https://www.breastsurgeons.org/statements/guidelines/Performance_Practice_Guidelines_Stereo.pdf Accessed July 8, 2017.
 14. American Society of Breast Surgeons. Breast US certification. https://www.breastsurgeons.org/new_layout/programs/certification/breast_ultrasound_certification.php Accessed July 8, 2017.
 15. American College of Radiology. Practice guideline for the performance of ultrasound guided percutaneous breast interventional procedures. https://www.acr.org/~media/ACR/Documents/PGTS/guidelines/US_Guided_Breast.pdf Accessed July 8, 2017.
 16. American Society of Breast Surgeons. Position statement on concordance assessment of image-guided breast biopsies and management of borderline or high-risk lesions. https://www.breastsurgeons.org/new_layout/about/statements/PDF_Statements/Concordance_and_High%20RiskLesions.pdf Accessed July 8, 2017.
 17. National Comprehensive Cancer Network. NCCN Guidelines for Breast Cancer Screening and Diagnosis. Version 1.2017. https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf Accessed July 8, 2017.
 18. Landercasper J, Linebarger JH. Contemporary breast imaging and concordance assessment: a surgical perspective. *Surg Clin North Am*. 2011;91:33-58.
 19. National Comprehensive Cancer Network. Use of minimally invasive biopsy techniques for diagnostic breast evaluation. NCCN Guidelines for Breast Cancer Screening and Diagnosis. Version 1.2017. http://www.nccn.org/professionals/physician_gls/pdf_guidelines.asp#breast_screening Accessed July 12, 2017.
 20. Degnim AC, King TA. Surgical management of high-risk breast lesions. *Surg Clin North Am*. 2013;93:329-340.
 21. American Society of Breast Surgeons. Mastery of Breast Surgery <https://www.breastsurgeons.org/mastery/> Accessed July 8, 2017.

This statement was developed by the Society's Research Committee and on November 7, 2017, was approved by the Board of Directors.