Thomas Jefferson University Case Study:

New Perspective in Breast Care Pathway with Contrast and Contrast Biopsy Implementation

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The Division of Breast Imaging at Thomas Jefferson University has been a center of excellence in mammography and multimodality breast imaging for more than 25 years. The Division performs approximately 40,000 procedures annually making it one of the most active breast imaging services in the United States. Procedures include multimodality imaging using digital breast tomosynthesis also known as "3D" mammography, contrast-enhanced mammography, diagnostic and screening ultrasound, including Automated Breast Ultrasound, and breast MRI with full and abbreviated protocols. Imaging-guided breast interventions include core needle biopsies under ultrasound, Digital Breast Tomosynthesis biopsies, contrast-enhanced mammography, and MRI guidance and ultrasound guided cyst aspiration. We perform ultrasound-guided cryoablation of biopsy-proven fibroadenomas. Our facilities include state-of-the-art equipment and are staffed by board-certified subspecialty radiologists, and highly trained technologists and nurses.

The Situation

True size and extent of breast cancer disease burden is essential for proper treatment decision making. For many patients, routine diagnostic imaging is able to provide this information in a relatively fast and cost effective manner in breast imaging centers around the world. However, for select patients, either through inherent increased risk, breast density, or lesion type/characteristics, routine imaging can fail to provide the whole picture prior the initiation of treatment. It is for these patients where more advanced imaging techniques with functional imaging play a critical component to their diagnostic workup. For most centers and patients, this is currently limited to breast MRI. However, given the expense, the relatively limited accessibility, and poor specificity of breast MRI, this is typically reserved for high-risk patients, patients diagnosed with lobular cancer, with an occult metastatic lymph node, with occult non-physiologic nipple discharge, or with findings concerning for multifocal/multicentric disease poorly defined on routine imaging. We believe this is where CESM and CESM biopsy can play a significant role in the care of our patients.

At our institution, we suggest radiologists consider recommending obtaining a diagnostic CESM for:

1. Screening recall patients with dense breasts and finding poorly defined on mammography or with bilateral findings
2. Patients with pathologic nipple discharge and no mammographic or sonographic correlate
3. A clinically suspicious palpable finding with no or poorly defined mammographic or sonographic correlate
4. Highly suspicious findings (BI-RADS® 4C/5) prior to biopsy – Local staging, especially in patients with dense breasts
5. Unilateral axillary adenopathy without definitive mammographic or sonographic finding within the breast
   - Except in patients with recent vaccine exposure in ipsilateral arm
6. Patients with prior breast conservation therapy with a concern for scar vs. recurrence

Recommendations to Referring Doctors

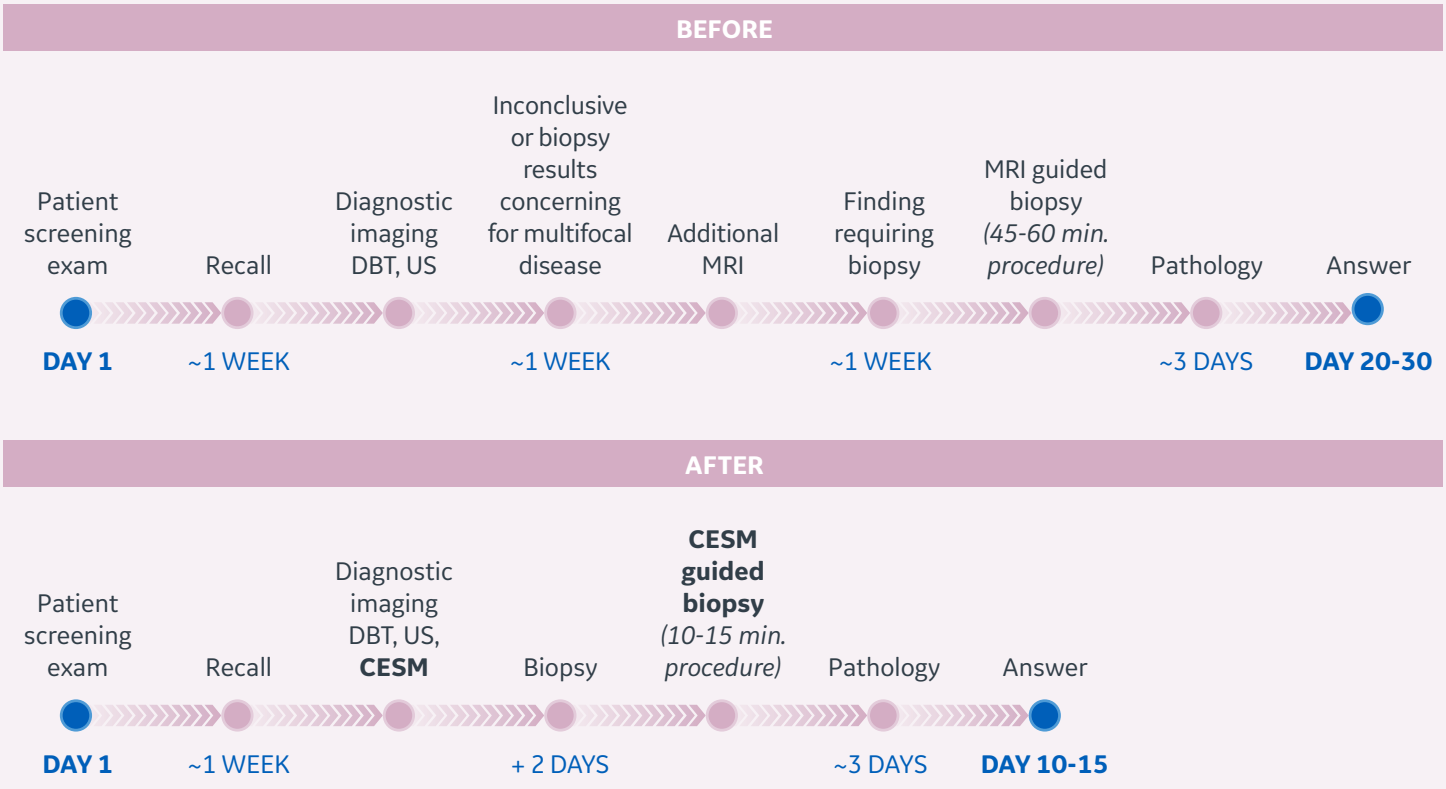
We recommend that referring providers consider ordering diagnostic CESM for the following situations:

- Concern for or diagnosis of Paget's disease
- Positive margins after breast conservation therapy
- Staging evaluation in patients with dense breasts, especially for patients with biopsy proven:
  - Invasive lobular carcinoma poorly (or inadequately) defined on mammography, ultrasound, or physical examination
  - Suspected multifocal or multicentric cancer
- Assessing response to neoadjuvant systemic therapy: CESM needed before and after treatment, especially for patients:
  - With dense breasts
  - Who are candidates for breast-conserving therapy
  - Unable to receive MRI

Management of CESM-detected Lesions

Typically, indeterminate imaging findings with a sonographic correlate would be targeted for ultrasound-guided core biopsy given its relative low cost, our ability to visualize all steps of the biopsy in real-time, and that the patient can lay in a supine/recumbent position during the procedure. Findings without a sonographic correlate would preferentially be targeted with digital breast tomosynthesis guidance, or stereotactic guidance if DBT is unavailable, followed by functional imaging guidance. It is our suggestion that this order be maintained, with contrast enhanced mammography guidance preferred over breast MRI given its significantly lower cost, reduced procedure time, potential for improved patient tolerance, ease of scheduling/integration into the clinic, and to free up the MRI unit for additional studies.[1]

Contrast Enhanced Spectral Mammography with a Biopsy Solution: Workflow Impact



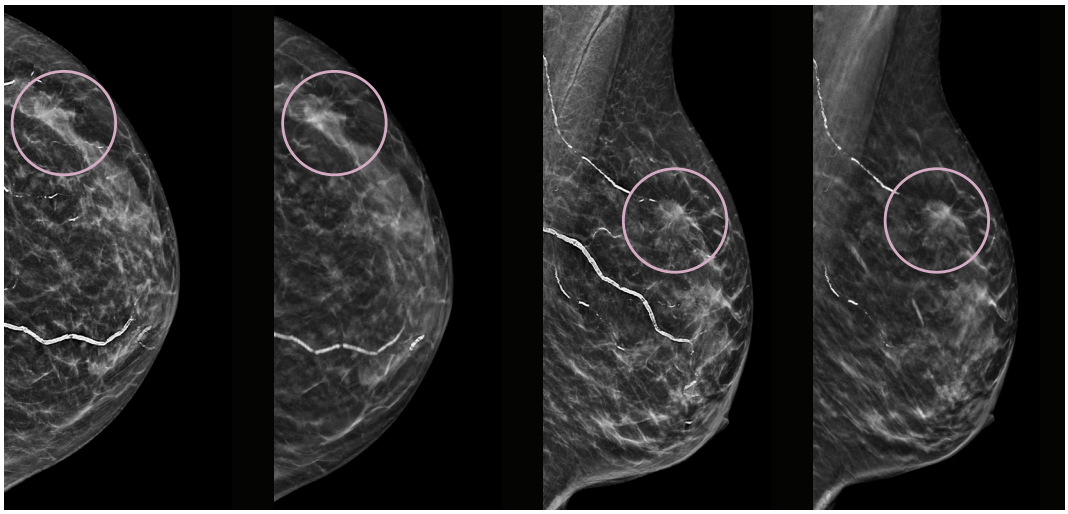
All patients diagnosed with a high-risk lesion or breast cancer are referred to the Jefferson Breast Care Center to connect with a breast surgeon to determine the necessary next steps to help them on their path to a cure. As part of the next prescribed steps, certain patients diagnosed with invasive lobular carcinoma may have a breast MRI to assess for multi-focal/multicentric disease and evidence of contralateral disease. Identified areas of suspicious enhancement will typically go onto image-guided tissue diagnosis prior to patient receiving definitive care. This may require pre-procedural evaluation by ultrasound to assess a sonographic correlate for ultrasound-guided biopsy, or patients may go straight to MRI-guided biopsy. The time from initial diagnosis to histopathologic confirmation of additional areas of enhancement can span 1-3 weeks.

Practical Case

Patient History and Background

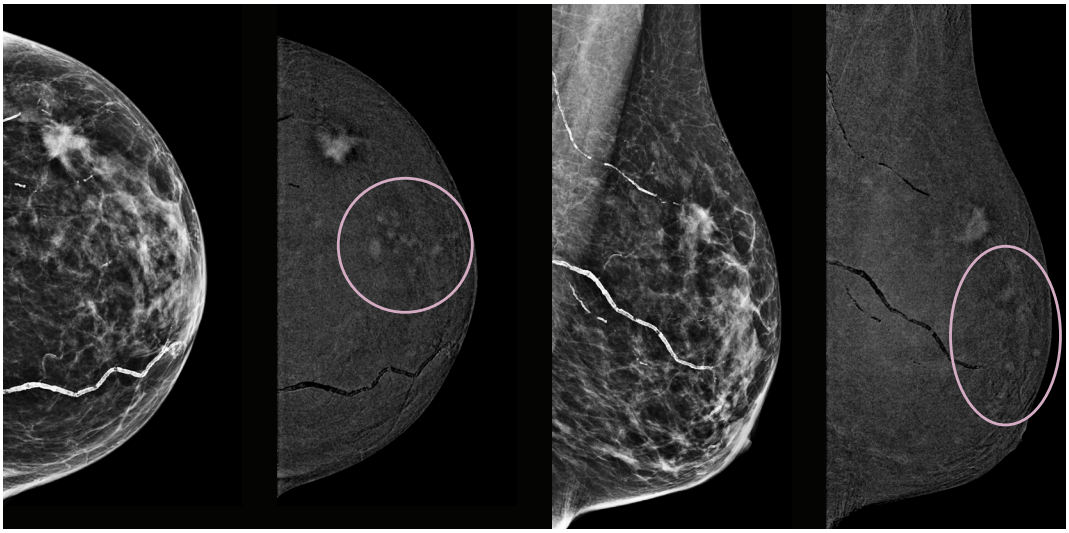
A 69-year-old female with heterogeneously dense breast parenchyma who presented for screening mammography was found to have an obscured mass in the upper outer left breast. Subsequent diagnostic mammogram, whole breast and axillary ultrasound left breast confirmed a 10 mm irregularly shaped mass with indistinct and spiculated margins at 2 o'clock, 8 cm from the nipple. The patient was scheduled for ultrasound-guided core biopsy, with contrast enhanced mammogram (CESM) to be performed prior to biopsy to assess for additional areas of concern given the difficulty with clearly assessing the margins of the mass and the patient's dense breast tissue. CESM confirmed an avidly enhancing spiculated mass, along with a 3.3 cm cluster of enhancing subcentimeter masses extending 5.5 cm anterior and medial to the dominant mass without routine mammographic or sonographic correlates. The patient underwent ultrasound-guided biopsy of the dominant mass which demonstrated moderately differentiated invasive lobular carcinoma. Subsequent CESM-guided biopsy of the anterior-most area of clustered mass-like enhancement was performed.

If this patient did not undergo CESM, nor breast MRI, as part of her staging workup after being referred to surgery, her additional areas of malignancy could have been partially detected as positive lumpectomy margins. Alternatively, these additional sites could have remained undetected until they developed enough to be detected by routine imaging or became symptomatic. While it is possible that these areas could have been successfully treated by her chemotherapy and radiation, the standard of care is to excise all known areas of malignancy to improve the patient's likelihood for successful treatment and reduce the risk of recurrence.



One lesion seen on the screening Tomo biopsied under ultrasound: Invasive Lobular Carcinoma.

Contrast Enhanced Spectral Mammography

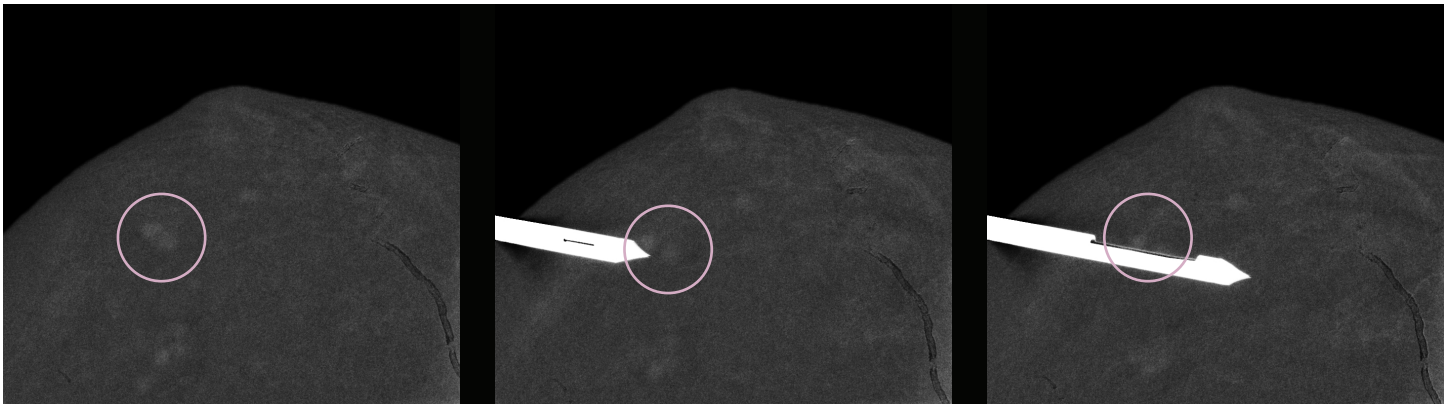


CESM detected multi focal lesion, changing treatment plan. The clinical recommendation for such multi focal lesion is in favor of a CESM-biopsy.

Contrast Enhanced Biopsy

Stereotactic core-needle biopsy with contrast guidance was performed using Pristina™ Serena Bright.™ The target was confirmed to be in the appropriate position, and the biopsy device was fired within the breast into the post-fire position. The needle system was rotated within the breast so the biopsy trough would be pointing anteriorly towards the target, and the aperture was opened prior to taking post-fire CESM stereopair images. This again confirmed appropriate positioning of the target, and six samples were obtained at the odd hour positions followed by biopsy marker placement through the biopsy device. A single CESM stereo image was obtained confirming proper clip deployment followed by removal of the needle system from the breast. Post-biopsy CESM images confirmed successful sampling of the target of interest with appropriate biopsy marker placement. Histopathologic results confirmed invasive lobular carcinoma and lobular carcinoma in situ. This clustered enhancing masses located 6 cm anterior to the primary lesion.

"Incorporating GE SenoBright™ and Serena Bright into the diagnostic workup of this patient not only allowed us to ensure proper surgical planning to enhance the patients chance for a cure and decrease the need to re-excision, but was able to be completed in 14 days of the initial presentation."



Lesion biopsied under CESM guidance, ILC confirmed.

Protocol

Using a power injector, contrast media was administered through a 22 gauge IV in the patient right antecubital fossa, followed by a 20 ml saline flush. Two minutes after the initial injection, the patient was positioned with the left breast in CC compression, and a scout CESM image was obtained to ensure the target was within the safety window. After confirmation of target visualization, a CESM stereopair was obtained and the target was set. Following preparation of the skin with antiseptic technique, superficial and deep anesthetic was administered along the biopsy track via a horizontal approach from lateral. Repeat CESM stereopair imaging was obtained confirming the target didn't significantly move post-anesthetic injection. A 10-gauge vacuum assisted core-needle biopsy system (Bard Encor Enspire) was then advanced from the lateral horizontal approach to the pre-fire position followed by additional CESM stereopairs.

Practical Case *(continued)*

Perspectives

Contrast-enhanced mammography is evolving into an excellent adjunct to diagnostic breast imaging. Providing a functional examination highlighting the neovascularity of malignancy similarly to breast MRI, CESM can help reveal true size and extent of disease, as in this case, which may be otherwise unclear or undetected by sonography or mammography.[2,3,4] Now, that CESM can be used for biopsy guidance allowing for histopathology determination of areas of suspicious enhancement, this technology has gained a critical component to be able to offer diagnostic and treatment planning impact equivalent to breast MRI.

We know that functional imaging offers incredible gains in cancer detection, assessment of extent of disease, and response to neoadjuvant therapy.[5,6] While breast MRI maintains these benefits, incorporating it into the diagnostic workup typically adds substantial time (involving preauthorization, scheduling, performing and interpreting these studies), cost, and diminished specificity.[7] However, CESM cost is covered similarly to diagnostic mammography, can be easily incorporated into the breast imaging clinic schedule, can be added onto existing mammographic equipment at a relatively low cost, is easy to learn how to interpret given its similarities with routine mammography and breast MRI, and is quick to interpret, allowing it to be more reasonably deployed to breast imaging centers around the world.

In our preliminary clinical experience, upright CESM-guided biopsy is performed, tolerated and reimbursed similarly to current mammogram-guided biopsy techniques and can be completed within 15 minutes after initial injection. While CESM-guided biopsy cannot be performed on patients with known iodinated contrast allergy, it is otherwise available to patients who have indications for breast MRI, and especially those who may not tolerate MRI such as those with claustrophobia, large body habitus or MRI incompatible implanted devices. Though more studies are needed to confirm similar radiopathologic correlation of CESM-guided biopsy compared to MRI, we believe that CESM and CESM-guided biopsy will enable improved accessibility to functional breast imaging that will lead to improved patient satisfaction, a significant reduction in the morbidity and mortality of breast cancer, and enhance the decision making and confidence of the breast cancer treatment teams.

1. Patel et al., Potential Cost Savings of Contrast-Enhanced Digital Mammography, AJR Am J Roentgenol. 2017.
2. Travieso Aja MM et al. Radiologia 2014; 56: 390-399.
3. Lalji U, Lobbes M. Women's Health (Lond) 2014; 10: 289–298.
4. Lobbes M. Women's Health (Lond) 2014; 10: 289–298.
5. Iotti, Reggio 2017.
6. ElSaid et al, 2017 Egyptian j radiol and nuc med.
7. 510(k) K172404.

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