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Growth of a Contrast Enhanced Mammography Program in an Outpatient Setting

By Julie Shisler
Director of Clinical Research and Education, Rose Imaging Specialists, Texas

Clinical Benefits

Breast MRI is well established as a supplemental modality to mammography to diagnose cancer, determine the extent of disease, and perform preoperative planning as well as screening for high-risk patients. Contrast enhanced mammography (CEM) is emerging as a viable alternative to breast MRI for many of these indications with similar clinical performance.[1,2] This paper will describe the implementation and growth of a CEM program in an outpatient center, sharing best practices and lessons learned.

Rose Imaging Specialists has been at the forefront of new technology engaging in pre-FDA trials of tomosynthesis and the Hologic SmartCurve® breast stabilization system in addition to biopsy and ultrasound research. The group reads for standalone and hospital-based imaging centers without access to onsite MRI, mainly in the suburban areas of Dallas, Houston and Austin, Texas.

CEM is FDA cleared for diagnostic use and is gaining wider acceptance as an alternative to MRI. CEM pairs the anatomical 2D full field digital mammogram (FFDM) images with the functional imaging provided by contrast to identify lesions that demonstrate neovascularity due to tumoral angiogenesis. The combination of 2D FFDM images (low energy) and high energy images are subtracted from one another to provide recombined images. The software generates the low energy 2D FFDM images and the recombined images for interpretation. The lesions are then described based on ACR BI-RADS Atlas Mammography 2013 and the Contrast Enhanced Mammography 2022 supplement.[3] This includes density and findings from the low energy images and the enhancement findings of the recombined images to assign a final BI-RADS assessment category and management recommendations.

Starting a Contrast Program

We began by securing funding for the equipment: I-View® CEM software and a copper filter installed on an existing Hologic 3Dimensions™, or Selenia® Dimensions® mammography system as well as a power injector for the contrast injection. Adding CEM is a relatively small capital expense and requires no room modifications compared to an MRI unit. Additional supplies needed are IV and power injector disposables, non-iodinated contrast, and an emergency reaction kit. Our centers are not supported by ACLS team members or equipment; therefore, our policy is to have the radiologist evaluate any potential adverse reactions, provide an oral antihistamine or an EpiPen, and call 911 if needed.

To prepare for going live with patients, we collaborated with vendors, IT, center level staff, and radiologists to set a go-live date and began the operational implementation process. During this time standard operating procedures and forms were created and shared with the center level staff and radiologists. A few weeks prior to day one, we began IV skills training that included demonstration videos, practice on an IV training arm, and completing a proficiency checklist. We relied heavily on our technologists with prior IV insertion experience to provide peer support and show best practices. One week prior to day one, the power injector training was completed onsite by the vendor. (Power injector training can be provided live or via web-based video.)

We worked with referring physicians that included surgeons and gynecologists to identify two or three women who would benefit from having CEM for pre-biopsy or pre-surgical workup to be scheduled on day one. The Hologic clinical specialists were onsite for a one-day training with the technologists and radiologists that included patient exams in the afternoon.

A concern regarding contrast reaction and acute kidney injury was raised by leadership and radiologists. Literature from the National Kidney Foundation[4] and ACR Manual on Contrast Media[3] was reviewed and shared along with peer-to-peer discussions with other radiologists that perform CEM. The data indicates < 1% of patients have a reaction,[5] and with proper patient screening risks are minimized.

The patients are made aware of the physiological effects of contrast (flushing, urge to urinate) and kept in a seated position which helps prevent vasovagal reactions. The radiologists were trained to be familiar with the emergency box location and content including how to use an EpiPen and their responsibility as the physician onsite during a contrast exam. In our experience with over 2,500 exams, fewer than five patients had mild reactions to the procedure.

Patient Selection

The patient selection criteria and screening protocols were developed and agreed upon by the radiologists. We exclude those with multiple comorbidities, GFR> 45, numerous allergies, and previous contrast reactions. Patients with renal insufficiency, > 70 years old, were required to have a creatine/GFR within 30 days prior to the exam. This was ordered by the referring physician, and the results were reviewed by the radiologists prior to receiving IV contrast. Those patients using metformin are advised to hold their dose prior to contrast injection. We have no constraints relative to menstrual cycle. We initially focused on pre-biopsy workup and pre-surgical staging patients. These patients had an area of focus already identified which supported the learning curve of the interpreting radiologists.

We later expanded our clinical indications to include women contraindicated to have an MRI, post-lumpectomy surveillance, neoadjuvant surveillance, and problem-solving cases (discordant findings, radial scars, and axillary metastasis without mammographic findings). Use of CEM with high-risk patients and patients with dense breasts is gaining much attention in current literature, although the exam is not FDA cleared for screening.

Growth of Program in Market

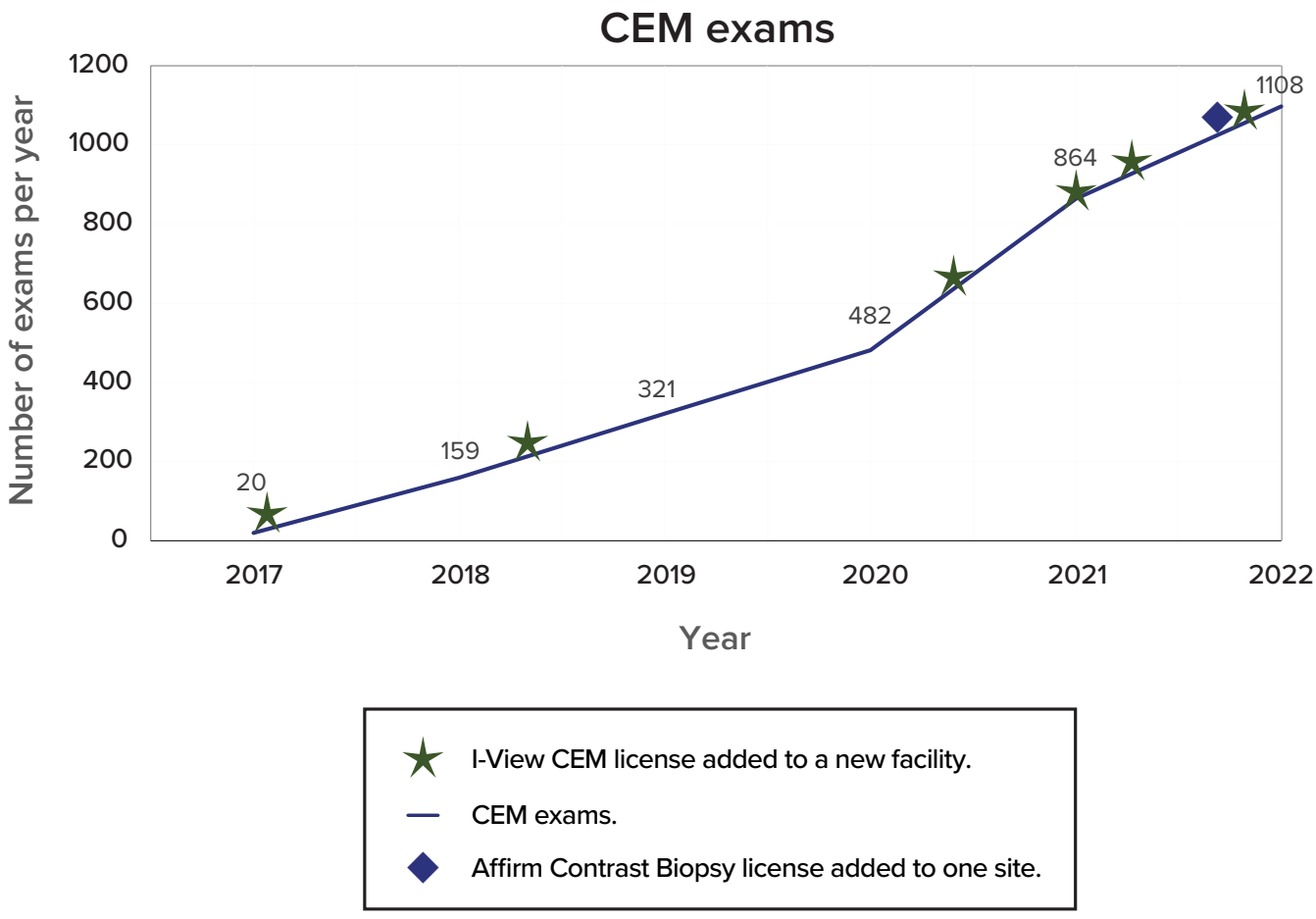


Figure 1. Increases in exams over time led to adding CEM at additional facilities.

Preparing for Billing

Procedure names and codes were placed in our RIS system, and report templates were created outlining the necessary items to include in the report. This includes CPT codes diagnostic bilateral 77066, diagnostic unilateral 77065, injection 96374, and contrast (per unit) Q9967. There were few denials by payors, and we were able to resubmit with success. Most of the claims are diagnostic mammograms with the addition of the cost for contrast.

Program Growth

With implementation in 2017, our scheduling blocks started at one hour for each exam, one day a week, for a maximum of four CEM exams per day. As volume increased and staff became more proficient, we decreased the schedule time to 20 to 30 minutes and expanded to additional days. Scheduled days are limited to diagnostic days that a radiologist is onsite. We monitored our referral patterns and patient demographics as CEM gained acceptance which assisted us in determining when to implement CEM at additional centers (see Figure 1). Offering CEM locally to those high referring groups ensured program growth. Training and implementation at each subsequent center were easier as we grew our program regionally. By providing this exam instead of referring patients out for an MRI, we decreased our loss to larger hospital-based programs.

Program Adoption

Initially, the radiologists created the buzz regarding CEM by discussing the technology with our referring community and presenting cases at local tumor board meetings (see Figure 2). We also created marketing materials to share with both patients during their visit and the larger community-based physician groups. Our website and social media also routinely provide a description of CEM including indications, experience and patient testimonials.

With our centers located in more rural areas as well as the suburbs surrounding major cities, we've made CEM more readily available than MRI in our catchment area. This has proven especially important for women suspected of having aggressive or late-stage cancer when time to treatment is of upmost importance. It's also beneficial for patients for whom travel is challenging, as well as for patients with claustrophobia, or other contraindications for MRI.

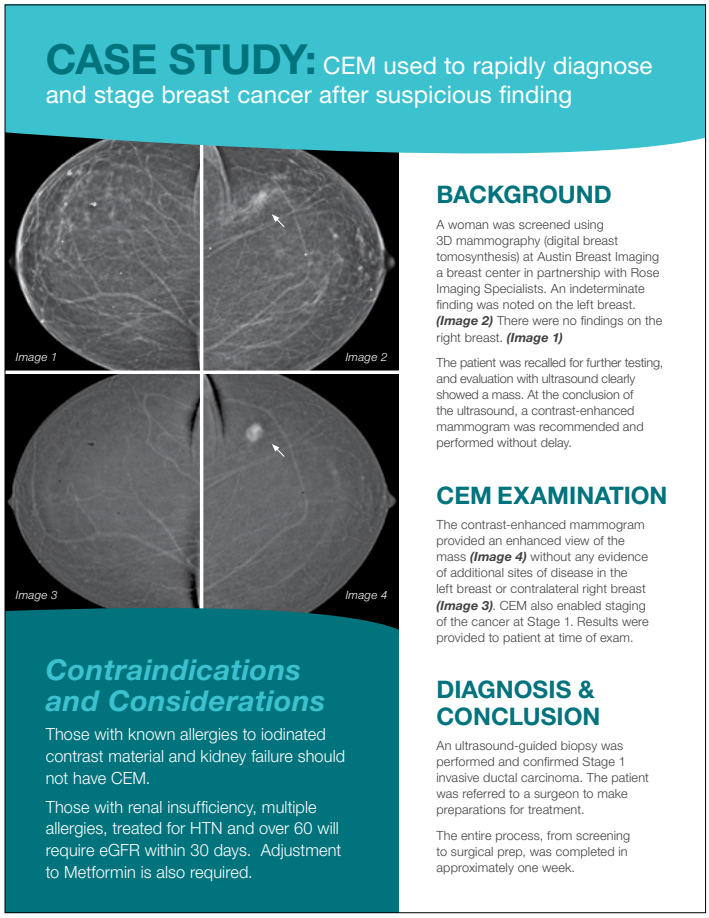


Figure 2. Case Studies shared with referring physicians.

Biopsy Options

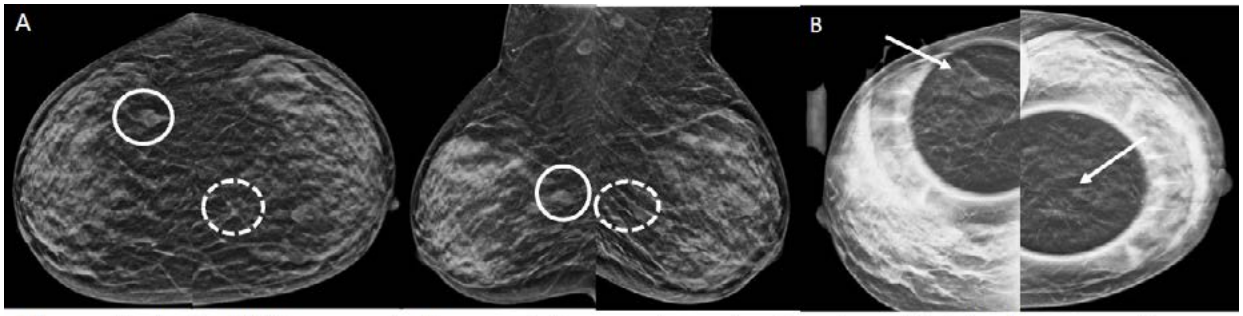
One barrier to greater adoption of CEM was the lack of contrast enhanced biopsy (CEBx). Certain lesions are only found on the recombined images, which leads to a challenge to correlate to a mammography image or second look ultrasound. Traditionally, these cases would require an additional examination with MRI.

In 2021, Hologic's Affirm® Contrast Biopsy software became available and we recently added the capability to our practice to support those instances. The dual energy images can be acquired and displayed quickly on the AWS, allowing for the procedure to be completed prior to the contrast washout period. The biopsy is performed as a stereotactic biopsy on the Affirm Breast Biopsy Guidance system with the use of the CEM imaging to localize the area of concern. In our practice, we added another I-View CEM license and an Affirm® Contrast Biopsy license to an existing Dimensions system with an upright Affirm Biopsy system, a minimal upfront capital expenditure. Though our experience with CEBx is limited to date, we anticipate that it will allow us to keep additional patients at our facilities and provides a positive experience for the patient.

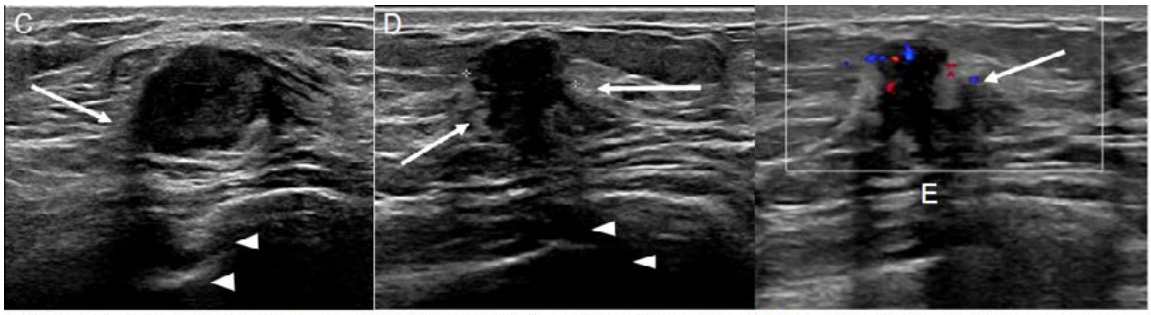
Patient Impact

Through the use of CEM, Rose Imaging Specialists has been able to significantly shorten the time between detection and treatment of breast cancer. We offer CEM exams without the delays inherent in sending patients elsewhere for MRI exams, including scheduling and pre-authorization. We are typically able to schedule CEM immediately as a diagnostic follow-up to a suspicious finding and perform the exam within a few days. Since it can also be used for pre-surgical planning, it has effectively shortened the time between detection and treatment. With our education and outreach activities we have informed referring physicians and patients, building the program in our region.

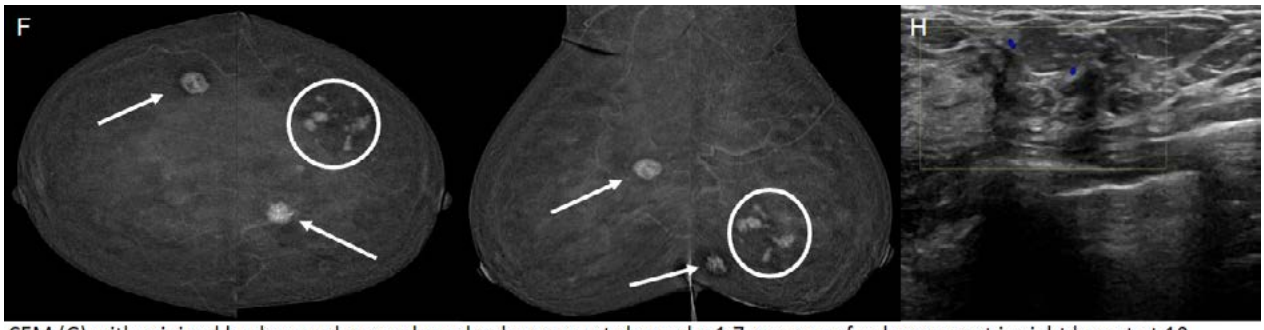
Staging and changing patient management



49-year-old called back (A) from screening for a new right upper outer quadrant breast mass (circle) and a new area of architectural distortion in the inferior left breast (dashed circle). These findings (B) persisted at the time of diagnostic mammogram (arrows).



Diagnostic ultrasound (C) of the right breast 10 o'clock position, 10 cm from the nipple showed an oval mass (arrows) with indistinct margins and posterior acoustic enhancement (arrowheads). Transverse (D) and color doppler (E) sonographic images of the left breast 7 o'clock position, 10 cm from the nipple demonstrated a 1.3 cm irregular mass with angular margins and vascularity. Contrast-enhanced mammography (CEM) with ultrasound biopsies recommended.



CEM (G) with minimal background parenchymal enhancement showed a 1.7 cm area of enhancement in right breast at 10 o'clock, 10 cm from nipple (arrows). In the left breast, a 1.7cm enhancing mass at the 7 o'clock position, posterior depth corresponds with the area of architectural distortion. Additional finding included an area of clumped non-mass enhancement (circle) in the left lower outer quadrant spanning an area measuring 4.8 cm in greatest dimension. Subtle ill-defined hypoechoic masses were noted on second-look ultrasound at this location (H). Biopsy of the right 10 o'clock, left 7 o'clock, and left 3 o'clock positions all demonstrated invasive ductal carcinoma, ER/PR+, HER2- .

Figure 3. Staging and changing patient management, courtesy of Dr. Stephen Rose, Rose Imaging Specialists.

References

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I-View CEM clearance K123873; Affirm Contrast Biopsy clearance K202294.

United States / Latin America
250 Campus Drive
Marlborough, MA 01752 USA
Tel: +1.508.263.2900
Sales: +1.781.999.7453
Fax: +1.781.280.0668
www.hologic.com

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