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CAR Practice Guidelines on Breast Imaging and Interventions: Contrast-Enhanced Mammography

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Abstract

This guideline presents Part II of the Canadian Association of Radiologists (CAR) Practice Guidelines on Breast Imaging and Intervention and addresses the clinical application of contrast-enhanced mammography (CEM). Reflecting the expanding evidence base and increasing clinical adoption of CEM since 2016, this guideline provides updated recommendations on indications, examination technique, contrast administration, image interpretation, reporting standards, quality control, and patient safety. Particular emphasis is placed on the role of CEM in diagnostic problem-solving, preoperative staging, and selected screening scenarios when breast MRI is unavailable or contraindicated. This guideline is intended to be used in conjunction with the other 4 components of the CAR Breast Practice Guidelines series, which together replace the previous consolidated guidelines and align with national and international best practices. While establishing minimum standards and best practices, this guideline recognizes the influence of evolving technology, regional resources, and patient-specific considerations, and affirms that clinical judgment remains the responsibility of the supervising radiologist.

Résumé

La présente ligne directrice expose la partie II des Lignes directrices de pratique en matière d'imagerie et des interventions mammaires de la CAR, et porte sur l'application clinique de la mammographie avec produit de contraste. Reflétant l'élargissement de la base de données probantes et l'adoption clinique croissante de la mammographie avec produit de contraste depuis 2016, cette ligne directrice fournit des recommandations mises à jour sur les indications, la technique d'examen, l'administration du produit de contraste, l'interprétation des images, les normes de rapports structurés, le contrôle de la qualité et la sécurité des patients. Une attention particulière est accordée au rôle de la mammographie avec produit de contraste dans la résolution de problèmes diagnostiques, la stadification préopératoire et certains scénarios de dépistage lorsque l'IRM du sein n'est pas disponible ou est contre-indiquée. Cette ligne directrice est destinée à être utilisée conjointement avec les quatre autres composantes de la série des Lignes directrices d'imagerie mammaire de la CAR, qui remplacent ensemble les lignes directrices consolidées précédentes et s'harmonisent avec les meilleures pratiques nationales et internationales. Tout en établissant des normes minimales et des meilleures pratiques, cette ligne directrice reconnaît l'influence de l'évolution technologique, des ressources régionales et des considérations propres à chaque patiente, et affirme que le jugement clinique demeure la responsabilité du radiologiste superviseur.

Keywords

practice guideline, mammography, contrast media, iodinated contrast agents, breast neoplasms

Preamble

The practice guidelines of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The radiologist and medical physicist may modify an existing practice guideline as determined by the individual patient and available resources. Adherence to CAR practice guidelines may not ensure a successful outcome in every situation. The practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The practice guidelines are not intended to establish a legal standard of care or conduct, and deviation from a practice guideline does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the

propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

Introduction

The **CAR Practice Guidelines on Breast Imaging and Intervention** have been published as a comprehensive five-part series in the *Canadian Association of Radiologists Journal (CARJ)* to provide targeted, modality-specific guidance. While this section focuses on **Contrast-Enhanced Mammography**, it is intended to be used in conjunction with the other 4 components of the update:

- **Part I: Mammography and Digital Breast Tomosynthesis**[1]
- **Part II: Contrast-Enhanced Mammography (CEM)**
- **Part III: Breast Ultrasound**[2]
- **Part IV: Breast Magnetic Resonance Imaging (MRI)**[3]
- **Part V: Breast Intervention and Biopsy Procedures**[4]

Together, these documents replace the previous 2016 consolidated guidelines to reflect the current evidence base and clinical landscape in Canadian breast imaging, and complement the recently published Breast Disease Imaging Referral Guidelines, which provide guidance on the most appropriate breast imaging test for a given indication or patient population.[5]

These guidelines aim to provide radiologists, technologists, and other allied staff with a consensus-based approach to performing and interpreting breast imaging. These recommendations align with those published by the Canadian and American Cancer Societies, the National Comprehensive Cancer Network, and the American College of Radiology. While the guidelines serve as an educational tool and outline best practices and minimum requirements, the Working Group acknowledges that alternative actions may be appropriate depending on available resources, patient factors, technological advances, and evolving medical knowledge.

Ultimately, the supervising radiologist is responsible for determining the most appropriate examination or intervention for each patient.

General Principles

The introduction of full-field digital mammography (FFDM) enabled the use of contrast-enhanced mammography (CEM), an iodine-based modified 2-dimensional (2D) digital mammography (DM) exam, which, like contrast-enhanced Magnetic Resonance Imaging (MRI), relies on tumor angiogenesis.[6] The current standard CEM utilizes upgraded standard mammography equipment, which enables the performing of dual-energy imaging.

These guidelines include the current applications of CEM, as well as fundamental requirements for CEM in clinical practice.

Indications

CEM is primarily used in the diagnostic setting and has shown high sensitivity, particularly with dense breasts.[7-9] Therefore, if it is estimated that enhancement information would be useful, it is legitimate to first implement CEM as an alternative to MRI or even in other diagnostic settings when MRI would not be considered due to access or patient limitations.[7-17]

Diagnostic Setting

CEM may be performed along with additional studies, including but not limited to magnification views and breast sonography.

Examples:

- Evaluation of recalls from abnormal mammogram and problem-solving
- Breast symptoms
- Pre-operative staging: to assess the extent of disease in the affected breast and to screen for occult contralateral malignancy

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- Occult breast cancer: to determine the site of a primary carcinoma in a patient presenting with metastatic breast carcinoma such as axillary lymphadenopathy or other site of bony or body metastases
- Monitoring response to treatment
- Intervention: to guide biopsy or localization procedures
- Short interval follow-up

Screening Setting

MRI is the modality of choice for supplementary screening for breast cancer in high-risk populations. The use of CEM in screening individuals with dense breasts or at intermediate risk for breast cancer has been investigated by several studies,[18-22] showing an overall high cancer detection rate when CEM was used in place of conventional DM in patients with a personal history or intermediate lifetime risk. When there is limited access to MRI or if MRI cannot be tolerated, CEM can be offered instead.

The use of CEM in screening high-risk populations was only investigated in a small number of patients.[23,24] Until further data becomes available, CEM cannot be offered as a replacement for MRI in the high-risk screening setting, especially in the scenario of BRCA mutation, where there is likely an increased risk of radiation-induced carcinogenesis.[25] However, if the patient cannot tolerate an MRI procedure, CEM can be offered as an alternative to supplementary screening ultrasound in non-BRCA high-risk patients. The best workflow for the patient needs to be discussed with the patient and the regional cancer care program representative.

Contraindications

The most significant challenge of CEM relates to the administration of Iodinated contrast and the risk of allergic reactions or, very seldom, contrast-associated acute kidney injury (AKI).[26]

For patients at risk for renal failure, evaluation of renal function is required prior to the performance of CEM following the same standard practice for Contrast Enhanced Computed Tomography (CE-CT).[27] In general, the risk for AKI is only important in patients with severe underlying chronic kidney disease (CKD) with an eGFR $\leq$30 mL/min/1.73 m^2, those with AKI, and/or those receiving a high volume of contrast especially through the arterial route. For more details, see CAR recommendations on contrast-associated acute kidney injury.[28]

Adverse reactions to low-osmolality iodine agents can occur in 1% to 3% of patients and are often mild and self-limiting.[24] However, more severe reactions can occur in approximately 0.2% to 0.7% of the cases.[24] CEM procedure must be therefore supervised by a clinician who is trained to treat patients with allergic reaction.

It is generally recommended not to premedicate patients with a history of allergic reactions given the availability of alternatives such as MRI. For additional information on premedication, see CAR guidance on managing contrast hypersensitivity reactions.[29]

Qualifications and Responsibilities of Personnel

The personnel standards for education and conduct are determined by the unique demands of mammography practice, see the personnel requirements in the Mammography section above. Additional criteria are unique to CEM.

Radiologist

A CEM accreditation program is not currently available in Canada. However, the interpreting radiologist should practice and possess knowledge of imaging and diagnosis of breast disease. As new imaging modalities and interventional techniques are developed, additional clinical training should be obtained before radiologists independently interpret or perform such examinations or procedures. Continuing professional development must meet the Maintenance of Certification Program requirements of the Royal College of Physicians and Surgeons of Canada. The supervising radiologist should be familiar with the safety policies of appropriate iodine contrast use and treatment of adverse allergic reactions.

Technologist

The technologist is primarily responsible for performing the CEM and maintaining the overall safety of patients, staff, and equipment. This includes careful screening for potential contrast iodine contraindications, ensuring patient comfort, adequate contrast delivery and adjustment of protocols (if required) to produce a high-quality exam.

As radiopaque devices to mark a palpable abnormality should be avoided with CEM, both the MRT and supervising radiologist should be aware of any sites of clinical concern to ensure adequate interpretation.

Medical Physicist

A medical physicist must take responsibility for the initial acceptance testing and for conducting and overseeing quality control testing of the dual-energy component. The medical physicist shall have a graduate degree and be certified by the Canadian College of Physicists in Medicine (CCPM) in the specialty of Mammography or its equivalent or any relevant provincial/territorial license. Please visit http://www.ccpm.ca for further information. Training and experience shall include knowledge of the physics of mammography, systems components and performance, safety procedures, acceptance testing,

quality control and CAR Mammography Accreditation Program (CAR MAP) requirements.

Equipment

The same specifications for equipment and its use apply to screening and diagnostic mammography. However, for CEM, additional software capability and copper filter which will allow performing paired low-energy (23-32 kVp) and high-energy (45-49 kVp)[7-9] images for every view.

Radiation Dose

Although CEM examination exposes the patient to a radiation approximately 30% higher than that of DM and Digital Breast Tomosynthesis (DBT), it should remain within the range of radiation doses patients receive for other common mammographic examinations[30-32] and the average glandular dose cannot exceed 3 mGy for a CC projection.

Radiation Protection

Radiation protection is not mandatory to be used for patients who are pregnant and require urgent mammographic assessment.

Specifications of the Examination

In addition to the examination specifications for screening and diagnostic mammography, there are specifications unique to CEM.

- The study begins with an Intravenous (IV) injection of non-ionic low-osmolar iodinated contrast material with a concentration of 300 to 370 mg/ml,[33] using a power injector, at a standard dose of 1.5 mL/kg, at a rate of 2.5 to 3 mL/s, through a 20-gauge cannula size, before any compression is applied.[7-9,27,34,35]
- Two minutes after the start of the injection, the breast is placed into compression. Low-energy (LE) and high-energy (HE) images are generated for each standard craniocaudal (CC) and mediolateral oblique (MLO) views.[7-9,27,34,35]
- Recombined views (RC) are formed by subtracting the LE images from the HE images, which allows the cancellation of the signal from background breast tissue and only highlights areas of iodine uptake.[27,34,35]
- The image acquisition should be completed within 7 minutes of IV contrast administration.[27,34,35]
- If known, it is recommended that the first or second image will include the side of concern and at least one view of the contralateral breast will be included within the 1st-3rd images,[27,34,35] although there is no consensus on the order of image acquisition.[7-9,27]
- If required, additional views can be obtained subsequently after 7 minutes. If a suspected lesion is not expected on the routine views, a replacing view should be included in the first or second images.[27,35]

Timing during the menstrual cycle appears to have minimal effect on the degree of background parenchymal enhancement at CEM.[27,34]

CEM is subject to a multitude of artifacts that are unique to CEM, some of which are due to inadequate positioning, abnormal timing to contrast bolus, or trapped air within skin folds.[27,34,35]

When used with breast implants, the CEM images may be hampered since the recombination will not work, specifically with the presence of silicone.[27,34,35] Therefore, dual-energy exposure should only be obtained in adequate implant displacement views.

If the patient cannot tolerate adequate compression or displacement views cannot be performed due to the immobility of the implant, then CEM should be avoided.

Documentation

The same documentation required for screening and diagnostic mammography is also mandatory for CEM.

The Diagnostic Report

The CEM images that are eventually available for interpretation are the LE and the recombined images (RC). BI-RADS v2025 contains a dedicated section for CEM including lexicon guidelines.[36] Because CEM is composed of LE images comparable to standard mammography[37,38] the mammographic descriptors of the BI-RADS® terminology[36] is adapted. Breast composition should be assessed on the LE images and characterized using categories similar to conventional mammography.

The descriptors for enhancement are similar to MRI descriptors of the BI-RADS® terminology with some minor changes that are unique for CEM. The presence of BPE of the normal breast tissue should be described similar to MRI.

Three major categories can be distinguished:

1. Findings on LE images only,
2. enhancement on RC images only,
3. findings seen on LE images with associated enhancement on RC images.

For lesions detected on both LE and RC views, a lesion measurement should include the total extent of the disease.

One must avoid the pitfall of dismissing non-enhancing suspicious finding on LE images as benign. If an abnormality has suspicious features on LE images but not on recombined ones, it should still be considered suspicious.

Quality Control

Radiologist

In addition, the responsibilities of the supervising and interpreting radiologist include:

- Review and validation of the clinical indication for the examination
- CEM protocol
- Use and dose of contrast
- Ensuring a physician is available when contrast is given
- Ensuring that medical radiation technologists have adequate training and maintenance of competence, including intravenous injection.

Recommended Qualifications. Currently, there are no qualification standards for CEM radiologists by the CAR or American College of Radiologists. Recommended qualifications are similar to those for MRI:

- Supervise/interpret/report ≥150 CEM examinations in the last 36 months

OR

- Interpret/report ≥100 CEM examinations in the last 36 months in a supervised situation
- 15 hours CME in mammography and MRI.

The criteria evaluated in the program must include the establishment and maintenance by the facility of an outcomes audit program to follow up positive interpretations and correlate histopathology with the imaging findings.

Additional staff training is required to administer contrast material and manage contrast agent–related complications. Adopting the same institutional regulations in place of the practice of Contrast Enhanced Computer Tomography (CE-CT) is suggested.

Technologist

In addition to the standard mammography practice, the medical radiation technologist will be responsible for:

- Ensuring routine cleanliness of the mammography device and removal of any spilled iodine contrast
- Performing weekly checks of image uniformity and bad-pixel tests on the high-energy images (Mo/Cu, Rh/Cu)
- Performing monthly checks of the automatic exposure control parameter selection for CEM and signal-to-noise ratio (SNR).

Physicist

In addition to the quality control requirements for the standard mammographic unit, a medical physicist must take responsibility for the initial acceptance testing and for conducting and overseeing quality control testing of the dual-energy capability as specified by the vendor. These include mammography equipment evaluation and annual check of:

- Image uniformity and bad-pixels test on the high energy images (Mo/Cu, Rh/Cu)
- Automatic exposure control parameter selection for CEM and SNR
- Artifact Evaluation, Flat Field Uniformity
- Breast Entrance Exposure, Average Glandular Dose, and Reproducibility
- Beam Quality Assessment (Half–value Layer Measurement in High Energy and Low-Energy Configuration.) It should be noted that the HVL at 49 kV should be larger than 2.5 mm for both Mo and Rh targets. Low energy is computed as in Standard mode.

Quality Assurance

The CAR has established an accreditation program for quality assurance of breast mammography that can serve as a guideline for CEM practice (see quality control above) and must follow the CAR MAP's quality control.

Original images from previous studies should be made available for consultation and second opinion where practical.

Management and Biopsy

CEM should be practiced in a facility that has the capacity for mammography, ultrasound (US), and breast intervention, including contrast imaging-guided biopsy. In the instance that negative or benign findings (BI-RADS® category 1 or 2) cannot be determined based on CEM alone, a second-look ultrasound (US) is usually needed. If CEM determines a probably benign lesion, short-term follow-up with CEM is necessary.

Suspicious findings (BI-RADS® category 4 or 5) should be sampled by percutaneous or surgical biopsy.

US-guided biopsy is an ideal technique for tissue sampling that provides real-time imaging. In case of no US abnormality to correlate to an area of abnormal enhancement on CEM, even subtle LE findings such as a mass, microcalcifications, asymmetry, or distortion can be targeted for stereotactic-guided biopsy. A stereotactic-guided biopsy is also required if the abnormality is better or only seen on the LE images. If the suspicious abnormality is visible on DBT, it could be used to guide tissue sampling. Otherwise, CEM-guided biopsy is the option to consider. If CEM-guided biopsy is not available, MRI-guided biopsy would be an alternative.

In the absence of CEM or MRI-guided biopsy, an agreement with a center that offers the procedure is mandatory.

CEM-guided biopsy can be also used to sample enhancing lesions detected by MRI, especially if access to MRI-guided

biopsy is limited.[35,39,40] As with MRI, vacuum-assisted biopsy needle is the preferred method.[39,40]

Regardless of the modality used for the biopsy, a tissue marker should be placed following the biopsy, and post-procedure mammography should be obtained in 2 orthogonal views to document the tissue marker position in relation to the initial CEM exam. Non-standard mammographic views may be required depending on the location of the lesion.

Imaging-pathology correlation is required after tissue sampling of areas of enhancement,[27] regardless of where the biopsy is performed. They should also be tracked by the radiologist who recommended the biopsy.

Excisional biopsy should be considered for any discordant results. CEM-guided preoperative localization is required for lesions detected by RC views only. Lesions detected only by recombined views and concordant benign biopsy results must be followed up with a repeat CEM exam starting at 6 months, similar to MRI.[27,35,39]

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