



ACR practice guideline for the performance of magnetic resonance imaging (MRI) of the breast

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PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question. The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was developed and written with the assistance of the International Working Group on Breast MRI and the American Society of Breast Disease.

Magnetic resonance imaging (MRI) of the breast is a useful tool for the detection and characterization of breast disease, assessment of local extent of disease, evaluation of treatment response, and guidance for biopsy and localization. Breast MRI may be bilateral or unilateral. To enhance the probability of accurate results, MRI findings should be correlated with clinical history, physical examination, and the results of other imaging examinations.

II. CURRENT INDICATIONS

A. Current indications for breast MRI include, but are not limited to:

1. Lesion characterization – Breast MRI may be indicated when other imaging examinations, such as ultrasound and mammography, and physical examination are inconclusive for the presence of breast cancer. Breast MRI may be helpful in patients who have had previous surgery for breast cancer, to distinguish between postoperative scarring and recurrent cancer. Other conditions that may impair conventional breast imaging, such as silicone augmentation or radiographically dense breasts, may warrant breast MRI depending on the clinical findings.
2. Neoadjuvant chemotherapy – Breast MRI may be employed before, during, and/or after a course of chemotherapy to evaluate chemotherapeutic response and the extent of residual disease prior to surgical treatment. MRI-compatible localization tissue markers placed prior to neoadjuvant chemotherapy may be helpful in the event of complete response with no detectable residual tumor for resection.
3. Infiltrating lobular carcinoma – Physical examination, mammography, and ultrasound may be limited in the evaluation of infiltrating lobular carcinoma. Breast MRI may be indicated for evaluation of extent, multifocality, and multicentricity.

4. Infiltrating ductal carcinoma – Breast MRI may be indicated in order to determine the extent of disease, particularly in breast conservation candidates. MRI determines the extent of disease more accurately than standard mammography and physical examination in many patients.
5. Axillary adenopathy, primary unknown – MRI may be indicated in patients presenting with axillary adenopathy and no mammographic or physical findings of primary breast carcinoma. In patients with breast cancers, breast MRI can locate the primary tumor and define the disease extent for definitive therapy. A negative breast MRI may exclude the breast as a potential primary site of cancer and avoid a mastectomy that would provide no treatment benefit.
6. Postoperative tissue reconstruction – Breast MRI may be indicated in the evaluation of suspected cancer recurrence in patients with tissue transfer flaps (rectus, latissimus dorsi, and gluteal) or implants.
7. Silicone and nonsilicone breast augmentation – Breast MRI may be indicated in the evaluation of patients with silicone implants and/or injections in whom mammography is difficult, and in patients with nonsilicone implants. In these settings, breast MRI may be helpful in the diagnosis of breast cancer and in the evaluation of implant integrity and rupture.
8. Invasion deep to fascia – MRI evaluation of breast carcinoma prior to surgical treatment may be indicated in both mastectomy and breast conservation candidates to define the relationship to the fascia, extension into pectoralis major, or extension into serratus anterior and intercostal muscles.
9. Contralateral breast examination in patients with breast malignancy – MRI can detect unsuspected disease in the contralateral breast in at least 4% - 5% of breast cancer patients. This is often in the face of negative findings on mammography and physical examination.
10. Postlumpectomy for residual disease – Breast MRI may be used in the valuation of residual disease in patients who have not had preoperative MRI and whose pathology specimens demonstrate close or positive margins for residual disease. MRI can evaluate for multifocality and multicentricity to help determine which patients could be effectively treated by re-excision or whether a mastectomy is required due to the presence of more extensive disease.
11. Surveillance of high-risk patients – Recent clinical trials have demonstrated that breast MRI can significantly improve the detection of cancer that is otherwise clinically and mammographically occult. Breast MRI may be indicated in the surveillance of women with a genetic predisposition to breast cancer. Patients should be referred for surveillance breast MRI only after genetic counseling by experts in hereditary breast cancer.
12. Recurrence of breast cancer – Breast MRI may be indicated in women with a prior history of breast cancer and suspicion of recurrence when clinical and/or mammographic findings are inconclusive.

B. Precautions

1. Screening of general population
Screening breast MRI is not recommended at the current time in the general population of asymptomatic women.
2. False positives
Breast MRI may detect additional abnormalities other than the clinically or mammographically detected lesions. These MRI-detected, clinically and mammographically occult lesions may or may not be clinically significant.
3. Treatment choices
Patients being considered for breast-conserving treatment may be converted to mastectomy based on MRI information. Caution should be exercised in

changing management based on MRI findings alone, as most mammographically occult lesions are successfully treated with irradiation and/or chemotherapy following surgical removal of the known lesion. Additional biopsies or correlation with other clinical and imaging information should be used along with good clinical judgment. Clinical trials are needed to determine the outcome significance of MRI-detected, clinically occult disease.

III. POSSIBLE CONTRAINDICATIONS

Possible contraindications to breast MRI may include, but are not limited to, the presence of cardiac pacemakers, ferromagnetic intracranial aneurysm clips, certain neurostimulators, certain cochlear implants, and certain other ferromagnetic implants, devices, foreign bodies, or electronic devices. Contraindications should be listed on a screening questionnaire. In other situations, reference to published test results and/or on-site testing of an identical device may be helpful to determine whether a patient may be safely scanned.

The decision to scan during pregnancy should be made on an individual basis. There is no known adverse effect of MRI on the fetus. The safety of gadolinium contrast has not been established for pregnant or nursing mothers. However, it is known that gadolinium-based MR contrast media crosses the human placenta and into the fetus when given in clinical dose ranges. Current data indicates that very little gadolinium is secreted in breast milk, with no known toxic effects on the infant. The supervising physician should take this into account, weighing potential risks and benefits, when counseling pregnant and lactating women referred for breast MRI. Refer to the ACR Manual on Contrast Media. Enhancement of breast tissue in pregnant or nursing mothers may make image interpretation more difficult.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging (MRI).

In addition, the facility should have access to expertise in breast imaging diagnosis and intervention and access to conventional breast imaging technology including mammography, breast ultrasound, stereotactic biopsy, and ultrasound-guided biopsy.

V. SPECIFICATIONS OF THE EXAMINATION

Patients should undergo standard mammography prior to breast MRI, and the mammography study and report should be available for review.

The written or electronic request for MRI of the breast should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination. Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. 2006 (Res. 35)

A. Patient Selection and Preparation

The physician responsible for the breast MRI examination shall supervise patient selection and preparation. Patients shall be interviewed and screened prior to the examination to exclude individuals who may be at risk by exposure to strong magnetic fields. Patients suffering from claustrophobia may require sedation or medication for anxiety. Increased parenchymal enhancement has been observed normally during the secretory phase of the menstrual cycle. This normal enhancement can give rise to false positive MRI scans. It is therefore recommended that breast MRI scans be performed during the second menstrual week whenever possible. Bilateral imaging may help to improve specificity, as enhancement characteristics vary from patient to patient and during the menstrual cycle, and enhancement of some benign conditions such as fibrocystic changes is often bilateral.

B. Facility Requirements

Facility requirements include space for patient preparation and waiting. If sedation is to be administered (see the ACR Practice Guideline for Adult Sedation/Analgesia) a recovery area is necessary, and appropriate personnel must be available to monitor the patient following sedation. Sedation shall be administered in accordance with institutional policy and state and federal law by a physician or by a nurse with training in cardiopulmonary resuscitation. An appropriately equipped emergency cart must be immediately available to treat adverse reactions.

C. Guided intervention

Since breast MRI can detect lesions not seen on other imaging methods or by physical examination, the availability of MRI-guided breast biopsy and localization is a valuable adjunct to diagnostic breast MRI.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings. The report should follow the guidelines for terminology published in the ACR Lexicon for Breast MRI. The BI-RADS® assessment category should be included in the conclusion of the report.

Staging

Of additional value for breast cancer staging is the development of an extent classification scheme based on the TNM (tumor, nodes, metastasis) prototype. These interpretation criteria will facilitate the distribution of MRI-characterized lesions into groups for better treatment planning. This approach facilitates the selection of optimal treatment options. As breast MRI is further developed and refined, additional definitions can be added that would further refine treatment.

One limitation of the TNM classification is that it is based on the size of the largest lesion. Multiple lesions of almost the same size have the same T classification as a single lesion. In an attempt to categorize interpretations in a standardized format that could potentially translate to treatment and prognostic significance, reporting of the following parameters is recommended:

1. Lesion measurements – MRI is an inherently three-dimensional method and can readily yield measurement in three axes. Measurement of masses and lesions should be a routine part of breast MRI reporting, as should the relationship to or lesion distance from the nipple and its nearest approach to the chest wall and/or skin surface.
2. Distance – The distance across multiple lesions should be reported. This

is the maximum distance across all the lesions inclusive of normal breast in between as if an imaginary lump encompasses all the lesions.

3. Chest wall – The relationship of the lesion to the chest wall should be stated. The depth of the lesion in relation to the fascia and the extent into deep musculature (serratus anterior or intercostals) can change the T stage.

VII. EQUIPMENT SPECIFICATIONS

The MRI equipment specifications and performance shall meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic field strength, maximum rate of change of magnetic field strength (dB/dT), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

Technical guidelines

1. Field strength – The selection of field strength is a major technical decision. In previous reports, field strength of 1.5 T was considered a minimum technical requirement. Improvements in other components of the scanning process have resulted in improved scan quality at lower field strengths. However, the ability to perform chemical fat suppression at higher field strength and better homogeneity of these magnets remains a distinct advantage for most users. Also, the synergy between field strength of 3 T, parallel imaging, and phased array coils provides satisfactory spatial resolution when imaging both breasts. Therefore, higher field strength is preferred because of better fat suppression and decreased motion artifacts.
2. Resolution and contrast – Higher resolution is needed to avert the problem of volume averaging effects. The slice thickness should be 3 mm or less and in-plane pixel resolution should be 1.5 mm or less. Improved contrast between tumor and surrounding tissue is important. When high-resolution images are being obtained, chemical fat suppression is helpful as a method to reduce fat signal while preserving the signal-to-noise ratio. Subtraction is often used for low resolution, dynamic imaging. Sole reliance on subtraction for assessment of enhancement may result in misregistration. Some protocols may incorporate both fat suppression and subtraction. Motion correction may be helpful in reducing artifacts encountered with image subtraction. Magnetization transfer contrast may reduce false positives by improving the contrast between ductal tissue and enhancing tumor.
3. Contrast – Gadolinium contrast enhancement is useful in the evaluation of breast cancer but is not generally necessary in the evaluation of implant integrity and rupture. Gadolinium contrast should be administered as a bolus with a standard dose of at least 0.1 mmol/kg.
4. Scan time – A precontrast scan should be obtained. Scan time in relation to contrast injection is extremely important for lesion characterization. The immediate postcontrast scan used for determining the presence of lesion enhancement should have a scan time extending no longer than 5 minutes after bolus injection. If kinetic information is reported, enhancement curves should be calculated at specified intervals.
5. All examinations should be performed with a dedicated breast MRI coil unless obesity or other patient considerations require modification of the imaging procedure.

VIII. SAFETY GUIDELINES

For information regarding MR safety, see the ACR White Paper on MR Safety. In: Kanal E, Borgstede JP, Barkovich AJ, et al. American College of Radiology

White Paper on MR Safety. AJR 2002; 178:1335-1347. Reprinted with permission from the American Roentgen Ray Society in the ACR Practice Guidelines and Technical Standards book. Current peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis to ensure patient safety.

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

Equipment monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment.

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REFERENCES/LITERATURE REVIEW

- Benichou J, Gail MH, Mulvihill JJ. Graphs to estimate an individualized risk of breast cancer. *J Clin Oncol* 1996;14:103-110.
- Brenner RJ, Rothman BJ. Detection of primary breast cancer in women with known adenocarcinoma metastatic to the axilla: use of MRI after negative clinical and mammographic examination. *J Magn Reson Imaging* 1997;7:1153-1158.
- Burke W, Daly M, Garber J, et al. Recommendations for follow-up care of individuals with an inherited predisposition to cancer. II. BRCA1 and BRCA2. *JAMA* 1997;277:997-1003.
- Claus EB, Risch N, Thompson WD. Autosomal dominant inheritance of early-onset breast cancer: implications for risk prediction. *Cancer* 1994;73:643-651.
- Colletti PM. Magnetic resonance procedures and pregnancy. In: Shellock FG. *Magnetic Resonance Procedures: Health Effects and Safety*. Boca Raton, Fla: CRC Press; 2001.
- Easton DF, Ford D, Bishop DT. Breast and ovarian cancer incidence in BRCA1-mutation carriers. Breast Cancer Linkage Consortium. *Am J Hum Genet* 1995; 56:265-271.
- Finelli DA, Rezai AR, Ruggieri PM, et al. MR imaging-related heating of deep brain stimulation electrodes: in vitro study. *AJNR* 2002;23:1795-1802.
- Fischer U, Kopka L, Grabbe E. Breast carcinoma: effect of preoperative contrast-enhanced MR imaging on the therapeutic approach. *Radiology* 1999;213:881-888.
- Ford D, Easton DF, Stratton M, et al. Genetic heterogeneity and penetrance analysis of the BRCA1 and BRCA2 genes in breast cancer families. The Breast Cancer Linkage Consortium. *Am J Hum Genet* 1998;62:676-689.
- Fowble B, Hanlon A, Freedman, G, et al. Second cancers after conservative surgery and radiation for stages I-II breast cancer: identifying a subset of women at increased risk. *Int J Radiat Oncol Biol Phys* 2001;51:679-690.
- Kollias J, Ellis IO, Elston CW, et al. Prognostic significance of synchronous and metachronous bilateral breast cancer. *World J Surg* 2001;25:1117-1124.
- Kuhl CK, Schmutzler RK, Leutner CC, et al. Breast MR imaging screening in 192 women proved or suspected to be carriers of a breast cancer susceptibility gene: preliminary results. *Radiology* 2000;215:267-279.
- Lee SG, Orel SG, Woo IJ, et al. MR imaging screening of the contralateral breast in patients with newly diagnosed breast cancer: preliminary results. *Radiology* 2003;226:773-778.
- Li CI, Malone KE, Weiss NS, et al. Tamoxifen therapy for primary breast cancer and risk of contralateral breast cancer. *J Natl Cancer Inst* 2001;93:1008-1013.
- Rezai AR, Finelli D, Nyenhuis JA, et al. Neurostimulation systems for deep brain stimulation: in vitro evaluation of MRI-related heating at 1.5 Tesla. *J Magn Reson Imaging* 2002;15:241-250.
- Sawyer-Glover AM, Shellock FG. Pre-MRI procedure screening: recommendations and safety considerations for biomedical implants and devices. *J Magn Reson Imaging* 2000;12:92-106.
- Shellock FG, Cruess JV. Invited review – magnetic resonance: bioeffects, safety, and patient management. *Radiology* 2003.
- Shellock FG. MR safety update 2002: implants and devices. *J Magn Reson Imaging* 2002;16:485-496.
- Shellock FG. Biomedical implants and devices: assessment of magnetic field interactions with a 3.0-Tesla MR system. *J Magn Reson Imaging* 2002;16:721-732.
- Shellock FG. *Reference Manual for Magnetic Resonance Safety*. 2003 edition. Salt Lake City, Utah: Amirsys, Inc; 2003.
- Shellock FG. *Magnetic Resonance Procedures: Health Effects and Safety*. Boca Raton, Fla: CRC press; 2001.

- 22 Shellock FG, Tkach JA, Ruggieri PM, et al. Aneurysm clips: evaluation of magnetic field interactions and translational attraction by use of "long-bore" and "short-bore" 3.0-Tesla MR imaging systems. *Am J Neuroradiol* 2003;24:463-471.
- 23 Tilanus-Linthorst MM, Obdeijn IM, Bartels KC, et al. First experiences in screening women at high risk for breast cancer with MR imaging. *Breast Cancer Res Treat* 2000;63:53-60.
- 24 Warner E, Plewes DB, Shumak RS, et al. Comparison of breast magnetic resonance imaging, mammography, and ultrasound for surveillance of women at high risk for hereditary breast cancer. *J Clin Oncol* 2001;19:3524-3531.
- 25 Yahalom J, Petrek JA, Biddinger PW, et al. Breast cancer in patients irradiated for Hodgkin's disease: a clinical and pathologic analysis of 45 events in 37 patients. *J Clin Oncol* 1992;10:1674-1681.