

ACR–ASNR–SIR PRACTICE PARAMETER FOR THE PERFORMANCE OF NON-BREAST MAGNETIC RESONANCE IMAGING (MRI) GUIDED PROCEDURES

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PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 the guidance in this document 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 purpose of this document is to assist practitioners in achieving this objective.

[1](#) *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), and the Society of Interventional Radiology (SIR).

"Procedural MRI" or "interventional MRI" describes the use of magnetic resonance imaging (MRI) techniques for guidance and/or monitoring or control of noninvasive (incisionless) or minimally invasive diagnosis and therapy with the entire procedure performed in the procedural MRI suite. MRI-guided procedures encompass multiple approaches, including endoscopic, endovascular, percutaneous, transcutaneous-focused ultrasound (US), and open techniques. Recent hardware and software improvements in MRI have resulted in an expanding and evolving role for image guidance during interventional or surgical procedures in multiple organ systems. Pulse sequence improvements have allowed for the development of rapid imaging methods as well as advances in MRI-compatible equipment.

The major benefits of using MRI for procedure guidance and monitoring are [\[1, 2\]](#):

1. The ability to continuously visualize adjacent and deep anatomic structures (ie, vessels) during the entire procedure. The high vascular conspicuity is due to flow-related enhancement effects inherent in the gradient-echo sequences used for procedure guidance. Inherent soft tissue visibility of nerves and bowel allow superior visualization for avoidance during procedures.
2. The multiplanar imaging capabilities that ensure accurate targeted placement of the interventional device (eg, biopsy needle along the axial as well as the craniocaudal dimensions in the anatomy of interest). In addition, imaging in any arbitrary plane allows the device trajectory to be tailored according to the individual case.
3. The ability to guide device navigation with continuous, near real-time imaging so the device can be redirected in a timely manner in order to avoid critical structures.
4. The ability to shift between T1-weighted, T2-weighted, and other contrasts during the procedure to maximize the anatomic/pathologic conspicuity. For example, T2-weighted techniques allow sampling of the non-necrotic regions of complex masses; thus, increasing the diagnostic tissue yield. In addition, physiologic functional information from procedural dynamic contrast-enhancement, chemical shift, and diffusion-weighted MR imaging allow for targeting of specific areas.
5. The ability to perform advanced physiologic imaging intraprocedurally; thus, monitoring the effects of intervention. For example, diffusion-weighted imaging can monitor tissue infarction, perfusion-weighted imaging can assess tissue blood flow, and thermometry can assess tissue temperature. Real-time temperature monitoring is possible using proton resonance frequency imaging allowing MRI to actively see and measure heat from laser or microwave ablation techniques.

This practice parameter specifically excludes breast biopsy and localization procedures that can be safely and appropriately performed according to the [ACR Practice Parameter for the Performance of Magnetic Resonance Imaging-Guided Breast Interventional Procedures](#) [\[3\]](#).

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

Current indications for the use of MRI to guide/monitor procedures can be classified under the following major categories:

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

1. Biopsy and aspiration

The general indications for image-guided percutaneous tissue sampling can be reviewed in the [ACR–SIR–SPR Practice Parameter for the Performance of Image-Guided Percutaneous Needle Biopsy \(PNB\)](#) and the [ACR–SIR–SPR Practice Parameter for Specifications and Performance of Image-Guided Drainage/Aspiration of Abscesses and Fluid Collections](#) [4, 5].

Because MRI guidance is not intended to substitute for other less expensive modes of biopsy/aspiration guidance, MRI-guided procedures will assume a role when the patient would otherwise be subjected to a blind (nontargeted) biopsy, surgical exploration, or open biopsy performed solely for the purpose of tissue diagnosis. Therefore, MRI-guided biopsy/aspiration will be most suited for patients who have 1 or more of the following conditions [2, 6-12]:

- a. Lesions in areas of complex anatomy (eg, suprahyoid neck, base of the neck adjacent to the brachial plexus or lung apex, adrenal glands, and liver dome lesions) needing greater contrast than available on computed tomography (CT) between tissues to delineate abnormalities and needing to target lesions not amenable to visualization by US
- b. Lesions close to vascular structures needing continuous real-time monitoring that are not amenable to US monitoring
- c. Transiently enhancing lesions that are visible using MR
- d. Skeletal muscle or soft-tissue lesions lacking sufficient tissue contrast on CT and US
- e. Bone marrow infiltrative processes
- f. Tumors with heterogenous functional activity, necessitating the need for targeted MRI biopsies to the functionally active portions
- g. Lesions seen only by MRI and not on other imaging modalities under which biopsy could be performed (eg, prostate biopsy and small liver lesions not well seen with noncontrast CT or US)
- h. At-risk populations in whom ionizing radiation exposure should be limited
- i. Particular attention should be made for these patients who are receiving serial procedures
- j. Previously unsuccessful procedure with other imaging modalities
- k. MRI is well suited for pelvic interventions (ie, aspiration, biopsy and ablation) due to the soft tissue conspicuity and due to the lack of artifact from the bony pelvis. CT has difficulty in the pelvis due to the scatter artifact from the bony pelvis

MRI guidance may also be used for joint fluid aspirations and/or injections for additional procedural safety compared to conventional fluoroscopically guided joint interventions [13].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

2. Minimally invasive percutaneous procedures

Whenever feasible, minimally invasive approaches are preferred over other surgical procedures because of the following advantages:

- Decreased morbidity and mortality.
- Decreased length of hospitalization and expense.
- The potential for treatment or cure for patients who are not open surgical candidates.

These procedures may include, but are not limited to, the following:

a. Thermal tumor ablation

The core contribution of MRI to interstitial thermotherapy is ablation monitoring over and above more precise targeting. MRI temperature mapping gives MRI its ability to monitor the zone of thermal tissue destruction during the procedure, thereby providing real-time guidance for the deposition of thermal energy (MR thermometry). Additionally, the precise millimeter visualization of the cryoablation ice edge allows ultraprecise monitoring of the cryoablation especially important when ablation is being performed near critical structures (ie, nerves or bowel). Through MRI monitoring, ablation zone size/volume and configuration can be directly controlled by the operator and adjusted during the procedure to compensate for deviations from the preoperative predictions and to define the treatment endpoint without moving the patient from the operative or MRI suite. This is an attribute of MRI imaging that cannot be reliably duplicated by any other currently used imaging modality [14, 15]. It not only permits accurate tumor destruction, including the margins, but also extends the application of radiofrequency (RF), cryoablation, focused US, and other ablation techniques to the safe destruction of tumor within the visceral organs and adjacent to vital neurovascular structures.

Interactive MRI can be used to guide and monitor tumor ablation with various sources of thermal energy such as:

- RF [6, 16-21]
- Laser [22-27]
- Cryotherapy [28-30]
- Focused US [31-37]
- Microwave [38, 39]
- MRI guidance can also be used to ablate peripheral sensory nerves for pain therapy [40]

Primary/metastatic liver tumors, renal malignancies, primary/recurrent prostate cancer and slow-flow vascular malformations are the tumors most commonly treated by MRI-guided percutaneous thermotherapy. Less common targets include, but are not limited to, breast tumors, uterine fibroids, osseous metastases, and osteoid osteomas of bone.

A systematic review of osseous metastases treated with percutaneous RF ablation, microwave ablation, cryoablation, and MR-guided focused US (MRgFUS) revealed that all techniques achieved pain relief after 1 (91%) and 3 months (95%) [41]. A recent meta-analysis found MRgFUS to be comparable to percutaneous thermal ablation for local control of bone oligometastases [42].

MRgFUS has also been used in nonneoplastic conditions, such as essential tremor and Parkinson's disease, and vascular malformations [43-45].

b. Direct intralesional, intracompartmental, and perineural diagnostic and therapeutic drug injection

Mixing the drug of interest with diluted gadolinium chelate enables interactive MRI guidance of the injection process and monitoring of drug distribution within the target tissue. Alternatively, injectants can be visualized and monitored based on their long T2 constants without or with subtraction techniques.

Indications include, but are not limited to [\[46-50\]](#):

- Chemical tumor ablation (eg, via direct ethanol injection)
- Injection sclerotherapy of low-flow vascular malformations
- Injection of a muscle or joint
- Perineural and epidural injections [\[51-54\]](#)

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

3. Open Surgical MRI

The integration of MRI systems into the traditional surgical arena is currently implemented in some of the following procedures [\[55-65\]](#):

a. Image guidance or monitoring

- Neurobiopsy or cranial cyst aspiration
- Deep brain stimulation/electrode placement
- Thermal ablation of brain tumors, epileptogenic lesions, radiation necrosis [\[66\]](#)
- Transsphenoidal pituitary resection

b. Procedure monitoring

- Craniotomy for brain and spine tumor resection, epileptogenic focus resection, or hematoma evacuation.

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

4. Catheter-based procedures

Using passive or active tracking techniques, catheter and/or guidewire navigation can be performed in the cardiovascular system in near-real-time to achieve better soft-tissue visualization and to obtain more pertinent physiological information compared to conventional X-ray fluoroscopic techniques. Studies have demonstrated the safety and feasibility of MRI guidance for diagnostic cardiac catheterization in patients with congenital heart disease and for interventional cardiac catheterization and RF ablation [\[67-71\]](#).

Vessel wall imaging using intravascular coils is an emerging application of MRI-guided procedures that has strong potential for clinical application in the near future because of its ability to map out vulnerable plaques that may not be identified with the "lumen-only" information obtained by conventional angiography [\[72, 73\]](#).

Transcatheter intra-arterial perfusion MRI can be used as a first-pass intraprocedural perfusion technique to 1)

verify anticipated distribution of injected contrast media, 2) monitor changes in tumor perfusion during transcatheter embolic therapies, and 3) exclude potential unexpected collateral supply when used in conjunction with intravenous (IV) dynamic contrast enhancement [74-77].

II. INDICATIONS AND CONTRAINDICATIONS

B. Safety Guidelines and Possible Contraindications

For contraindications to MRI scanning, see the [ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#), the [ACR Manual on Contrast Media](#), and the [ACR Manual on MR Safety](#) [78-80].

For relative contraindications to percutaneous needle procedures, see the [ACR–SIR–SPR Practice Parameter for the Performance of Image-Guided Percutaneous Needle Biopsy \(PNB\)](#) and the [ACR–SIR–SPR Practice Parameter for Specifications and Performance of Image-Guided Drainage/Aspiration of Abscesses and Fluid Collections](#) [4, 5].

Relative contraindications to percutaneous thermal tumor ablation include, but are not limited to:

1. Large size of the targeted tumor. There is no universal cutoff diameter for eligibility for percutaneous thermal ablation. However, the larger the tumor the greater the likelihood of incomplete necrosis and development of postablation syndrome. Tumors smaller than 3–4 cm in diameter are generally suitable for percutaneous ablation with curative intent. In the palliative setting, larger tumors maybe treated in conjunction with an overall treatment plan and clinical collaboration.
2. Proximity to vital structures, such as the gallbladder, renal pelvis, or bowel wall, or nontarget nerves if protective measures are not possible.
3. Proximity to large blood vessels. The presence of flowing blood in the vicinity of the tumor being ablated compromises the efficacy of treatment because of the heat sink effect.

Relative contraindications to MRgFUS of the brain include, but are not limited to:

1. Low skull density ratio (less than 0.40)
2. Extensive scalp scarring
3. Inability to lie still in the same position for approximately 3 hours

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

MRI-guided procedures must be performed by, or under the supervision of, a physician who has the qualifications specified in sections 1 or 2 below. In addition to these qualifications, a physician must also have the training specified in section 3.

1. Certification in Radiology, Diagnostic Radiology or Interventional Radiology/Diagnostic Radiology (IR/DR) by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology (AOBR), the Royal College of Physicians and Surgeons of Canada or the Collège des Médecins du Québec. Also, the physician must have demonstrated competency as primary operator in MRI-guided procedures under the supervision

of an on-site qualified physician, during which a minimum of 5 MRI-guided procedures were performed with acceptable success and completions rates documented by a case log.

OR

Completion of a diagnostic radiology residency or fellowship program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) that included 6 months of training in cross-sectional imaging, including CT and MRI, and 3 months of training in image-guided interventional radiological techniques that included percutaneous biopsy and drainage procedures and vascular catheterization. This must include performance (under the supervision of a qualified physician) of at least 5 MRI-guided procedures with acceptable success and complication rates documented by a case log.

OR

2. In the absence of the above requirements or other postgraduate certification and training that included comparable instruction and experience, physicians may meet the requirements for performing MRI-guided procedures by adhering to ALL of the following recommendations:
 - a. Documentation of hands-on training in the performance of MRI-guided procedures.
 - b. Performance and completion of at least 5 successful and uncomplicated MRI-guided procedures as primary operator under the supervision of an on-site qualified physician with acceptable success and complication rates.
 - c. Substantiation in writing by the chair of the department of the institution in which the physician will be providing these services.
 - d. Central nervous system applications of MR-guided laser thermal ablation or MRgFUS, specifically of the brain, can be performed by neurosurgeons, whose requirements are delineated by their subspecialty society.
3. In addition, physicians involved in MRI-guided procedures are expected to demonstrate competence in the following fields of knowledge and skills:
 - a. General medical background to be able to communicate appropriately with referring physicians from various specialties and to be able to discuss the appropriateness of the specific procedures in light of the patient's integrated individual history, physical findings, comorbid conditions, and preoperative imaging findings.
 - b. Basic anatomy (including congenital and developmental variants), physiology, and pathophysiology of the specific organ or tissue targeted for intervention.
 - c. Fundamental MRI physics with particular emphasis on the technical parameters that influence device visualization and navigation. The ability to operate the scanner is strongly recommended for all physicians involved in MRI-guided procedures. A thorough understanding of MRI safety related to ferromagnetic attraction of instruments and equipment (eg, oxygen tanks), instrument-related artifacts, and the generation of heat or current by magnetic induction of either permanently or temporarily implanted devices is mandatory.
 - d. Initial management of clinical emergencies that may arise during surgical MRI, including, but not limited to, the administration of basic life support and the recognition and treatment of adverse reactions to administered sedatives and analgesics.

Maintenance of Competence

Physicians must perform a sufficient number of MRI-guided procedures to maintain their skills, with acceptable success and complication rates as laid out in this practice parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates, as well as participation in postgraduate

continuing medical education (CME) courses on diagnostic and technical advances in MRI-guided procedures.

Continuing Medical Education

The physician's continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [81].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

B. Non-Physician Radiology Provider (NPRP)

NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (eg, acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

NPRPs can be valuable members of the interventional radiology team but should not perform MRI-guided procedures independent of supervision by physicians with training, experience, and privileges to perform the relevant procedures. See the [ACR–SIR–SNIS–SPR Practice Parameter for the Clinical Practice of Interventional Radiology](#) [82].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

C. Qualified Medical Physicist

See the [ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#) [78].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

D. Radiologic Technologist

See the [ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#) [78].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

E. Nursing Services

Nursing services are an integral part of the team for preprocedural and postprocedural patient management and education and may assist the physician in monitoring the patient during MRI-guided procedures.

V. SPECIFICATIONS OF THE EXAMINATION

A. Request for the Examination or Interventional Consultation

The written or electronic request for MRI-guided procedures should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). 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. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

In practice settings in which the interventional radiologist or interventional neuroradiologist performs procedures on the basis of physician referrals or direct patient referrals, an appropriate radiology clinic or consultation note should document preprocedure patient evaluation, procedure indication, and procedure medical necessity.

V. SPECIFICATIONS OF THE EXAMINATION

B. Facility Requirements

The basic requirements for setting up a procedural MRI suite are [\[83-89\]](#):

1. Hardware requirements

- a. An appropriate MRI system should be available to facilitate the patient access necessary for performing the procedures. Many different MRI system designs have been used to interactively guide procedures. Each of them has advantages and disadvantages, with a constant tradeoff between signal-to-noise ratio, patient access, useable field of view, and expense.
- b. When performing MRI-guided procedures on low-field MRI systems, sufficiently high signal-to-noise

ratios and image quality are important prerequisites to guide interactive procedures. Image acquisition times should be tailored to the indication to provide appropriate temporal resolution.

- c. Facilities should have the ability to operate the scanner and view images in the operative suite within the magnetic field through an in-room, high-resolution, RF-shielded monitor, if applicable. Combined with the patient access allowed by an appropriate MRI system, this capability allows the entire procedure to be performed with the operator maintaining constant device or instrument control while simultaneously viewing the images.
- d. Facilities should have the availability of MRI-conditional needles, probes, catheters, guidewires, etc. that are undeflected by the magnetic field and that create little or no field distortions or image degradation except as desired for passive device localization. The potential for specific devices, particularly catheters and guidewires, to be heated by imaging gradients should be understood before clinical use [90].
- e. A surgical or MRI table capable of safely transferring a patient from the operating position into the imager in case of intraoperative MRI should be present and available for rapid removal of the patient outside the MR suite in case of emergency.
- f. The 5-gauss line should be clearly defined.
- g. MRI-compatible patient monitoring equipment should be available and used as appropriate during the procedure [91].

2. Software requirements

Appropriate pulse sequences to permit adequate tissue contrast imaging device visualization and process monitoring should be available.

V. SPECIFICATIONS OF THE EXAMINATION

C. Performance Guidelines

1. Minimally invasive procedures

a. Biopsy and aspiration

The MRI-compatible biopsy needle is advanced into the targeted lesion under MRI guidance using optimized short recovery time/short echo time gradient-echo or fast and turbo spin-echo (TSE) sequences. The process uses a continuous imaging mode consisting of automated sequential acquisition, reconstruction, and in-room display of multiple sets of images to permit real-time or near real-time guided needle insertion with respect to the 3-D geometry of the lesion. This may be performed through acquisition of a set of contiguous, parallel thin (eg, 5 mm) slices centered on the needle position, or through the acquisition of image sets in multiple scan planes oriented along the shaft of the needle. Depending on the operator's preference, the procedure can be performed using free-hand methods, needle holders, MR-compatible robotically controlled arms or real-time guidance from optically linked systems [92-97]. At higher field strength, fast and TSE-based pulse sequence can be acquired fast enough for near-real-time MRI and also provide advanced metal artifact reduction with specialized pulse sequences [98]. Depending on the operators preference and technical set up, a advance and scan approach may be used to advance the needle to the target. In specialized circumstances and sites, US may be used within the MRI suite to aid in initial needle placement .

b. MRgFUS

MRgFUS is an incisionless technique that uses US energy as a thermos-coagulative method to ablate

tissue under MR guidance and monitoring[[99](#), [100](#)]. The US waves are emitted from a transducer placed close to the organ of interest (eg, in the table of the MRI system for uterine fibroid treatments, in a skull "helmet"-like transducer array for essential tremor treatments, or in a transrectal probe for prostate cancer treatment). The MRI sequences for targeting are similar as in other procedures described. MR thermometry sequences often use phase contrast for proton resonance frequency measurements and are fundamental for monitoring of MR-guided focus US. All individual sonications are imaged using the phase contrast sequence with thermometry measures obtained each time. In these procedures, the MR data are integral to the ablation determining the success/failure of the tissue necrosis at every level. After all individual sonications are delivered, thermometry is deemed satisfactory. Gadolinium contrast-enhanced MR images of the treated volume of tissue are obtained to determine interval changes in perfusion. The nonperfused volume is a critical outcome measurement.

Transcranial Focused US is a versatile, MR-guided, incisionless technology with diagnostic and therapeutic applications for neurologic and psychiatric diseases. Although transcranial ablation High-Intensity-Focused US (HIFU) has been the first FDA-approved neuroscience application, other low-intensity-focused US (LIFU) applications including blood-brain barrier (BBB) opening (diagnostic and therapeutic applications) and neuromodulation have already made it into human clinical trials.

Current FDA-approved Indications for MRgHIFU of the Brain: Ablation

MRgHIFU uses a steerable, US array to ablate brain tissue under real-time image guidance. MRgHIFU of the brain is currently FDA-approved for the treatment of Essential Tremor and Parkinson's Disease [[101](#)]. Advanced MRI techniques to delineate the target have been shown to improve treatment response, decrease treatment times, and avoid adverse effects when compared to indirect, landmark-based methods.

Brain-Focused US Future applications

BBB Disruption

Focused US in combination with IV injected microbubbles allow for safe, targeted, and reversible BBB opening in both animal models and in humans [[102-111](#)]. BBB opening can be assessed on MRI with use of IV gadolinium. Broadly speaking, this transcranial MRgFUS application has two main applications: liquid biopsy and therapeutic delivery.

LIFU Neuromodulation

LIFU neuromodulation is being investigated as potential treatment for depression, addiction, and other neuropsychiatric conditions [[112-115](#)]. In animal models, LIFU has been demonstrated to variously stimulate or suppress neural activity, depending on the specific parameters used. The mechanisms of neural activation and suppression are poorly understood areas of active

investigation. Despite the uncertain mechanism of action, LIFU neuromodulation is actively being investigated as a potential intervention in a variety of human neuropsychiatric conditions, including depression and addiction.

LIFU has several potential clinical applications, including opening of the BBB for drug delivery [116], neurostimulation of the central and peripheral nervous system, and mapping of neural circuits in neuropsychological disorders [114]. In addition to dissolving blood clots and to deliver therapeutic drugs to the ischemic regions in acute ischemic stroke, recently developed transcranial US device has been shown to facilitate recovery from acute stroke by neuromodulation of the motor cortex which enhances neuroplastic repair [117].

c. Percutaneous thermal ablation

The needle, thermal electrode, cryotherapy probe, or laser fiber is introduced into the abnormal structure or to the targeted anatomic structure using the basic technique of MRI guidance described above for biopsy and aspiration.

For thermal tumor ablation, real-time monitoring of the evolving ablation zone can be achieved using a rapid gradient-echo or fast and TSE pulse sequence. Laser ablation is generally MRI compatible and has been used effectively under MRI guidance to treat liver lesions and slow-flow vascular malformations [118, 119]. In cases of MRI-guided RF tumor ablation, imaging interference caused by the RF source can be overcome by software and hardware modifications that allow RF energy to be deposited during imaging [120]. MRI-guided microwave ablation with MRI ablation monitoring has been possible with some software and hardware modifications to allow MRI temperature mapping in real-time [121, 122]. Alternatively, T2-weighted and/or Short tau inversion recovery TSE MR images can be simply acquired intermittently between the RF deposition cycles. During cryoablation, the growing ice ball can be continuously or intermittently monitored with fast T1, intermediate, and T2-weighted TSE pulse sequences. Regardless of the source of thermal energy used, the size and shape of the developing ablation zone are directly observed as an enlarging low-signal area surrounded by high-signal tissue. Electrode repositioning into persistent foci of high-signal tumor as detected on fluid-sensitive MR images is performed in the scanner under continuous MRI guidance in an interactive manner similar to that used for initial electrode placement, or with intermittent MRI guidance. The "guide-ablate-monitor" sequence of events is repeated until the induced ablation zone is noted to encompass the entire tumor and a small cuff of normal adjacent tissue or the developing ablation zone approaches adjacent vital structures [123].

d. Lesion injection and chemical ablation

If MRI is used to guide intralesional drug injection rather than thermal ablation, the injected drug (alcohol, sclerosing agent, botulinum toxin, or anesthetic/steroid) may be mixed with an MRI contrast agent to facilitate interactive monitoring of drug distribution during injection or may be visualized based on the long T2 constant of the injectants without the addition of Gadolinium-based contrast [124-126].

2. Open surgical MRI

The performance of open surgical procedures that require interactive image guidance of devices—such as biopsy needles, aspiration devices, thermal electrodes, laser fibers, or curettes with continuous or intermittent monitoring of the result—should follow the previously described guidelines for "minimally invasive procedures," as appropriate.

The status of tumor resection, hematoma evacuation, or other invasive procedures may be intermittently

imaged so that a satisfactory result can be documented. This requires only relatively minor modification to standard imaging systems because patient access is not necessary during the monitoring process. These types of procedures may not require an open operating room MRI scanner but may be performed on conventional cylindrical superconducting systems provided that patient transfer between the surgical position and the imager is secured as discussed above in "hardware requirements." Integration with a frameless stereotactic localization system may be added in these procedures to facilitate guidance to areas of residual pathology [[127-135](#)].

3. Catheter-based procedures

After vascular access is performed, a coronal 2-D steady-state free-precession sequence is used to localize the abdominal aorta and to interactively guide the advancement of catheters and guidewires in real time from the introducer sheath to the heart or the vascular anatomy of interest. The imaging plane can subsequently be modified to best fit the route of catheter manipulation within the vascular system [[136](#)].

Visualization of catheters and guidewires is usually achieved via "passive tracking" techniques by incorporating a metal ring within the dilator tip [[137](#)] and by using catheters and guidewires modified with a ferrite mixture to induce susceptibility artifacts [[138](#)]. Another simple technique that may be used to render a catheter MRI-visible using the same theory of passive tracking is to fill the balloon of a standard angiographic catheter with a small amount of carbon dioxide gas [[67](#)].

Other methods to track catheters within the vascular system are achieved by creating "controlled locally induced field inhomogeneities." One way is to generate current in a thin copper wire wrapped around the catheter shaft. Another is to use "active tracking" techniques achieved by mounting a single or multiple microcoils connected to the receive channel of the MRI system to the tip of the catheter [[139-149](#)]. Augmented steering of catheters can currently be achieved by mechanical tip-deflecting catheters [[149-152](#)].

V. SPECIFICATIONS OF THE EXAMINATION

D. Patient Care

1. Preprocedural care

- a. The clinical history and relevant physical findings, including the vital signs and all relevant imaging, must be reviewed and recorded in a patient's medical record by the physician performing the procedure. Details regarding current medications, previous allergic reactions, and bleeding/clotting status must be recorded.
- b. The indication(s) for the procedure, including (if applicable) documentation of previous therapy, must be recorded. Any relevant previous studies should be reviewed.
- c. Explanation of the procedure along with its benefits, risks, and alternatives should be discussed with the patient by an appropriate member of the procedural team in accordance with the [ACR–SIR–SPR Practice Parameter on Informed Consent for Image-Guided Procedures](#) [[153](#)].
- d. The patient should be screened for contraindications for MRI and for MRI contrast media.
- e. Preprocedure plan formulated.

2. Procedural care

- a. Adherence to the Joint Commission's current Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings, including bedside procedures.

The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."

Anesthesia equipment, surgical scalpels, and electrocautery systems should be made of MRI-compatible materials. Physiologic monitors must be either nonferromagnetic or kept outside the fringe field of the magnet.

- b. When appropriate, patients undergoing MRI-guided procedures should have IV access in place for the administration of any required fluids and medications.
- c. When appropriate, vital signs should be obtained at regular intervals during the procedure, and a record of these measurements should be maintained.
- d. If the patient is to receive conscious sedation, pulse oximetry must be used. Administration of sedation for MRI-guided procedures should be in accordance with the [ACR–SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia](#) as appropriate [154]. A registered nurse or other appropriately trained personnel should be present and have primary responsibility for monitoring the patient. A record of medication doses and times of administration should be maintained.
- e. Certain indications require administration of IV contrast media. IV contrast enhancement should be performed using appropriate injection protocols and in accordance with the institution's policy on IV contrast utilization. (See the [ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media](#) [155].)
- f. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and size in the patient population.

3. Postprocedural care

- a. A postprocedural MRI (typically after injection of IV contrast) should be obtained before transferring the patient from the procedural MRI suite to document the procedural result and the presence and extent of any complications and to provide a baseline for future comparison imaging.
- b. A procedural or operative note should be documented in the patient's medical record, detailing the procedure, any immediate complications, and the patient's status at the conclusion of the procedure and a brief description of the postprocedure imaging to serve as reference for future imaging.
- c. During the initial postprocedural period, patients will usually require bed rest, and appropriately trained personnel should monitor the patient's vital signs and observe for bleeding.
- d. Following a postprocedural physical examination and response assessment including the interventional site and neuromuscular function, postprocedural pain should be treated as deemed appropriate by the physicians performing the procedure, nonphysician practitioners or, in certain practice settings, by the patient's referring physician or surgeon.

e. Patient discharge

Group I - Patients undergoing uneventful MRI-guided biopsy or aspiration, sclerotherapy, drug injection, catheter-based procedures, thermal nerve ablation, focused US for tremor, and other minor procedures may be discharged immediately at the discretion of the treating physician or after an observation period of 1–6 hours based on institution guidelines.

Group II - Patients subjected to percutaneous thermal or chemical tumor ablation may be admitted to the hospital for overnight observation and to be examined by the treating physician before discharge. In selected cases, when the percutaneous approach to the tumor is straightforward and the ablation is uneventful, the patient may be discharged after careful physical examination following an initial observation period of 6 hours.

Group III - The disposition (transfer or discharge) of patients undergoing open surgical MRI will be managed by the primary surgical team.

In all cases, the physician, surgeon, or health care surrogate must be available for continuing care both during hospitalization and after discharge. The patient's status at discharge must be documented in the patient's medical record. The patient should be educated about possible delayed complications.

V. SPECIFICATIONS OF THE EXAMINATION

E. Surgical and Emergency Support

When MRI-guided procedures are performed in a freestanding diagnostic center, detailed protocols for prompt transport or admission of the patient to an emergency department with a surgical facility should be formalized in writing.

VI. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings \[156\]](#). This should include the MRI and the interventional/procedural components.

VII. SUCCESS AND COMPLICATIONS RATES AND THRESHOLDS

Indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these practice parameters, a threshold is a specific level of an indicator, eg, a complication rate that should prompt a review. MRI techniques are used to guide and monitor an increasing array of diverse percutaneous and open surgical procedures. The success and complication rates and thresholds are therefore expected to demonstrate significant variations depending on the nature of the procedure and on the targeted organ. Because the primary aim of using MRI to guide and monitor procedures is to increase patient safety by improving the visualization of vascular and other vital structures and by enhancing the intraprocedural or intraoperative detectability of residual abnormalities, complication thresholds should never exceed those used for equivalent procedures performed under the guidance of other imaging modalities or for open surgery performed without MRI monitoring. There are certain MRI-specific challenges that need to be evaluated, such as technical issues related to the MRI hardware (ie, use of unsafe MRI equipment) or patient-related issues (ie, skin burns). All procedures should be done in collaboration with institutional MR safety board or individual to ensure appropriate methodology is maintained for MR conditional products and also to establish a process for bringing new equipment or procedures into the MRI environment.

Routine periodic review with audits and documentation in electronic databases is strongly encouraged for all cases, with particular attention to unexpected or unsatisfactory outcomes, and can serve as peer-reviewed learning. In the event of an unexpected event or complication, a review should be performed to determine the causes and to implement any necessary changes.

Similarly, success rates and thresholds should be viewed in light of each specific procedure, and institutional results should be compared with the published data for standard equivalent procedures and surgeries.

The only exception would involve the technical success rate. The ability to use appropriate MRI techniques to adequately visualize the target lesion and procedural device, to navigate it safely into the tissue of interest, and to unequivocally discriminate pathological tissue from adjacent structures is essential, so the technical success rate should be 100%.

At the time, these practice parameters were written, there were no published reports of comprehensive success or complication rates of institutional procedural MRI programs.

VIII. EQUIPMENT SPECIFICATIONS

Equipment monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance \(MR\) Imaging Equipment](#) [157].

The MRI equipment specifications and performance must meet all state and federal requirements. These 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 RF power deposition (specific absorption rate), and maximum acoustic noise levels. The interventional equipment should be tailored and tested for the MRI environment. Any adverse event associated with equipment in the MRI environment should be reported immediately to the institutional MR safety board or individual and the patient should be cared for in the appropriate manner as per standard institutional policies.

Specific policies and procedures related to MRI safety should be in place with documentation that is updated annually and compiled under the supervision and direction of the supervising MRI physician. Guidelines should be provided that deal with potential hazards associated with the MRI examination of the patient as well as to others in the immediate area. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination.

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

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 appearing under the heading *ACR Position Statement on Quality Control and Improvement, Safety, Infection Control and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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