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ACR–SPR PRACTICE PARAMETER FOR THE SAFE AND OPTIMAL PERFORMANCE OF FETAL MAGNETIC RESONANCE IMAGING (MRI)

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 care[1]. 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 and the Society for Pediatric Radiology (SPR).

Magnetic resonance imaging (MRI) is a proven, established imaging modality for evaluating fetal anomalies that are not adequately or completely assessed by sonography [1-8]. MRI is used for problem solving and only in select circumstances for screening. Properly performed and interpreted, MRI not only contributes to diagnosis but also serves as an important guide to treatment, delivery planning, and counseling. However, sonography is the most appropriate first-line imaging screening modality in the fetus. Fetal MRI should be performed only for a valid medical reason and only after careful consideration of sonographic findings or family history of an abnormality for which screening with MRI might be beneficial.

This practice parameter addresses the use of MRI in fetal diagnosis.

Although MRI is an effective noninvasive diagnostic test for characterizing many fetal abnormalities, its findings may be misinterpreted if not closely correlated with the clinical history and sonographic findings. Adherence to the following practice parameters will enhance the probability of appropriately diagnosing such abnormalities.

II. INDICATIONS

When an anomaly is suspected on ultrasound (US), to fetal lie, descent of the fetal head into the maternal pelvis, maternal body habitus, oligohydramnios, overlying bone/gas, and/or small field of view (FOV) may limit adequate assessment of the fetus and fetal anomalies. MRI can add additional information that may impact parental counseling, perinatal management, delivery planning, and postnatal care [9-17]. Primary indications for MRI include, but are not limited to, the following:

A. Brain and Spine

1. Congenital anomalies of the brain or skull suspected or not adequately assessed by sonography [3,18-41] include, but are not limited to, the following:
    a. Ventriculomegaly
    b. Agenesis of the corpus callosum
    c. Abnormalities of the cavum septum pellucidum
    d. Holoprosencephaly
    e. Posterior fossa anomalies
    f. Cerebral cortical malformations or migrational anomalies
    g. Solid or cystic masses
    h. Cephalocele

    In addition, MRI can be helpful in screening fetuses with a family risk for brain abnormalities, such as tuberous sclerosis, corpus callosal dysgenesis, or lissencephaly.

2. Vascular abnormalities of the brain suspected or not adequately assessed by sonography [42,43] include, but are not limited to, the following:
    a. Vascular anomalies
    b. Hydranencephaly
    c. Infarction
    d. Hemorrhage
    e. Monochorionic twin pregnancy complications

3. Congenital anomalies of the spine suspected or not adequately assessed by sonography [9,13,14,29,44-48] include, but are not limited to, the following:
    a. Neural tube defects

b. Sacrococcygeal teratomas
c. Caudal regression/sacral agenesis
d. Sirenomelia
e. Vertebral anomalies

B. Skull, Face, and Neck

1. Masses of the face and neck suspected or not adequately assessed by sonography [11,33,49-52] include, but are not limited to, the following:
   a. Vascular or lymphatic anomalies
   b. Goiter
   c. Teratomas
   d. Facial clefts
   e. Congenital cysts and cystic masses

2. MRI can be helpful in assessing airway obstruction that may impact parental counseling, prenatal management, delivery planning, and postnatal therapy [11,49-52].

C. Thorax

1. Thoracic pathology suspected or not adequately assessed by sonography [53-55] include, but is not limited to, the following:
   a. Congenital airway and lung malformations (including congenital high airway obstruction, pulmonary airway malformations, bronchogenic cyst, sequestration, and congenital lobar over inflation)
   b. Congenital diaphragmatic hernia
   c. Effusions
   d. Mediastinal masses
   e. Suspected esophageal atresia
   f. Lymphangiectasia (primary or secondary from congenital heart disease)

2. MRI can be used for volumetric assessment of fetal lung parenchyma [56-60], particularly in those fetuses at risk for pulmonary hypoplasia secondary to diaphragmatic hernia, oligohydramnios, omphalocele, chest mass, or skeletal dysplasias.

D. Abdominal, Retroperitoneal, and Pelvic

1. Abdominal and pelvic pathology suspected or not adequately assessed by sonography include, but is not limited to, the following:
   a) Assessing the size and location of tumors, such as hemangiomas, neuroblastomas, sacrococcygeal teratomas, and suprarenal or renal masses
   b) Determining the etiology of an abdominal-pelvic cyst
   c) Assessing complex genitourinary anomalies, such as bladder exstrophy, cloacal malformation and anorectal malformations, or complex lower urinary tract obstruction, such as encountered in the setting of Prune Belly Syndrome
   d) Assessing renal anomalies in cases of severe oligohydramnios
   e) Diagnosing complex bowel anomalies, such as cloaca, anorectal malformations, or complex bowel obstructions [61]
   f) Assessment of complex abdominal wall defects

E. Musculoskeletal

1. Assessment of extremity masses, such as lymphatic malformations and Klippel-Trenaunay-Weber
2. Skeletal dysplasias, for assessment of associated anomalies
3. Confirmation of suspected limb anomalies

F. Complications of Multiple Gestation Pregnancies

1. Monochorionic twins: delineation of vascular anatomy prior to laser treatment of twins, assessment of morbidity after death of a monochorionic co-twin area in which MRI may be useful [62-64] because of its high spatial resolution, contrast resolution, large FOV, and multiplanar imaging capabilities.
2. Conjoined twins: further delineation of anatomy can impact parental counseling, delivery planning, and postnatal management

G. Fetal Interventions Assessment

When an abnormality is identified that may benefit from fetal interventions, MRI is a useful adjunct in confirming the diagnosis and planning potential interventional options [13,65-69]. It can also be utilized in assessing the fetal brain both before and after surgical interventions [70].

The high risk to mother and fetus of potential in utero interventions requires accurate assessment of all anomalies. This includes, but is not limited to, the following:

1. Open neural tube defects
2. Sacrococcygeal teratomas
3. Processes obstructing the airway, such as a neck mass or congenital high airway obstruction
4. Complications of monochorionic twins
5. Chest masses [71]
6. Congenital diaphragmatic hernia
7. Lower urinary tract obstruction

H. Placental Assessment

1. Although US remains the reference standard, MRI may be particularly useful for the assessment of placental disorders, such as gestational trophoblastic disorders and abnormalities of implantation [72].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [73].

Individuals interpreting fetal MRI should be familiar with both fetal and neonatal diagnoses because these knowledge bases overlap but can differ, both from each other and from those of the older pediatric and adult populations.

IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

See the ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI) [73], the ACR Guidance Document on MR Safe Practices [74], and the ACR Manual on Contrast Media [75].

A. Imaging pregnant patients, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation [76].

Present data have not conclusively documented any deleterious effects of MRI at 1.5T and 3T on the developing fetus [77-88]. Therefore, no special consideration is recommended for any trimester in pregnancy. Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of a level 2 MR personnel-designatedradiologist [74], the risk-benefit ratio to the patient warrants that the study be performed. The radiologist should review the indications and document them in the radiology report or the patient's medical record.

There are theoretical radiofrequency (RF) power considerations that are greater at long exposure times and at a higher specific absorption rate [89,90]. Radiologists should be cognizant of the increased power deposition typically accompanying some higher field studies and ensure that they do not exceed established guidelines [91,92].

B. MRI contrast agents should not be routinely administered in fetal MRIs.

There are no documented fetal indications for the use of MRI contrast. Please refer to the ACR Manual on Contrast Media for further discussion of contrast administration in pregnancy [75].

The decision to administer contrast must be made on a case-by-case basis by the covering level 2 MR personnel-designated attending radiologist who will assess the risk-benefit ratio for that particular patient. The decision to administer a gadolinium-based MR contrast agent to pregnant patients should be accompanied by a well-documented and thoughtful risk-benefit analysis. This analysis should be able to defend a decision to administer the contrast agent based on overwhelming potential benefit to the patient or fetus, outweighing the theoretic but potentially real risks of long-term exposure of the developing fetus to free gadolinium ions.

Studies have demonstrated that gadolinium-based MR contrast agents pass through the placental barrier and enter the fetal circulation [93]. From there, they are filtered in the fetal kidneys and then excreted into the amniotic fluid. In this location, the gadolinium-chelate molecules are in a relatively protected space and may remain in this amniotic fluid for an indeterminate amount of time before finally being reabsorbed and eliminated. As with any equilibrium situation involving any dissociation constant, the longer the chelate molecule remains in this space, the greater the potential for dissociation of the potentially toxic gadolinium ion from its chelate molecule. It is unclear what impact such free gadolinium ions might have if they were to be released in any quantity in the amniotic fluid. Certainly, deposition into the developing fetus would raise concerns of possible secondary adverse effects. The risk to the fetus with administration of gadolinium-based MR contrast agents remains unknown and may be harmful.

C. At this stage, the preponderance of research studies have failed to discover any reproducible harmful effects of exposure of the mother or developing fetus to the 3T or weaker magnetic fields used in the routine clinical MRI process. However, far less is known about the potential effects, if any, of the time-varying gradient and/or radiofrequency magnetic fields used during actual scanning to potentiate image generation. Furthermore, the considerable majority of our data to date comes from research involving magnetic fields of 1.5T or less. Thus, we have less information regarding the potential safety issues that may exist at higher field strength systems. These theoretical risks should be carefully balanced against the potential benefits to the patient undergoing an MR examination. A decision as to whether or not to proceed with the requested MRI study will need to be based on a thorough and thoughtful evaluation of the potential and at times unknown risks of the MR examination versus the potential benefits to the patient as well as the risks associated with declining to do so.

V. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for fetal MRI 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. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

The supervising physician must have adequate understanding of the indications, risks, and benefits of the examination as well as alternative imaging procedures. The physician must be familiar with potential hazards

associated with MRI. The physician should be familiar with relevant ancillary studies that the patient may have undergone. The physician performing MRI interpretation must have a clear understanding and knowledge of the anatomy and pathophysiology relevant to the MRI examination.

The supervising physician must also understand the pulse sequences to be used and their effect on the appearance of the images, including the potential generation of image artifacts. Standard imaging protocols may be established and varied on a case-by-case basis when necessary. These protocols should be reviewed and updated periodically.

Documentation that satisfies medical necessity includes 1) fetal gestational age and 2) relevant history (including sonographic findings and family history of pertinent abnormalities). 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.

A. Patient Selection

The physician responsible for the examination should supervise appropriateness of patient selection and preparation and be available in person or by phone for consultation. Patients must be screened and interviewed prior to the examination to exclude individuals who may be at risk by exposure to the MR environment.

Patients suffering from anxiety or claustrophobia may require sedation or additional assistance. Administration of moderate or "conscious" sedation may be needed to achieve a successful examination. If moderate sedation is necessary, refer to the ACR–SIR Practice Parameter for Sedation/Analgesia [94].

Knowledge of the gestational age of the pregnancy is important for optimal timing of the examination.

Prior to 18 weeks gestational age, the fetal MRI study can give limited diagnostic information due to the small size of the fetus and fetal movement. If the examination is limited by early gestational age, then it may need to be repeated later. The need for early diagnosis should be balanced against the advantages of improved resolution later in pregnancy, with the choice dependent on the anomalies to be assessed. Fetal motion typically occurs constantly during the examination. However, using single-shot or other rapid acquisition techniques, slices are obtained in less than 1 second; therefore, images are only degraded if motion occurs during image acquisition. Sequences may need to be repeated if motion degrades the image of the region of interest.

B. Facility Requirements

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 sizes in the patient population.

C. Examination Technique

Depending on the size of the uterus and fetal area of interest, either a torso or cardiac phased array surface coil is placed over the gravid uterus. If the patient will not fit into the magnet with a surface coil, then a body coil can be used. The mother lies supine or in the left lateral decubitus position. The maternal foot-first position helps minimize claustrophobia. Maternal sedation is not necessary in the vast majority of cases. Scout images orthogonal to the gravid uterus can be performed.

Fetal MRI single-shot acquisition sequences or other rapid acquisition sequences are employed to limit the effects of fetal motion. A T2-weighted spin-echo single-shot sequence reveals excellent anatomy. Fast acquisition T1-weighted images with gradient-echo sequences are less anatomically discriminating but help to define certain fetal tissue or fluid characteristics, such as fat, hemorrhage, liver, and meconium in bowel. It is preferable to have T1-

weighted fast gradient-echo sequences performed during a breath hold or using the respiratory trigger technique. Steady-state free precession (SSFP) sequences, Fast Imaging Employing Steady-state Acquisition (FIESTA, TrueFISP (fast imaging with steady state precession), balance fast field echo (bFFE), hydrography, diffusion-weighted imaging (DWI) or dissusion-tensor imaging (DTI), echo planar (EPI) and cine [95] imaging can also be useful sequences.

FOV (and corresponding choice of matrix and any phase-encoding oversampling) should be tailored to fetal (and maternal) size. Overlap of maternal onto maternal anatomy ("wrap-around" or spatial misregistration artifact) is acceptable if fetal structures are well visualized. A spatial resolution in the range of 1.5-mm pixel size (or better) is highly desirable to provide accurate depiction of most anatomic structures (eg, 35 FOV with 256 × 192 matrix). On DWI sequences, resolution of 2.0-mm pixel size is usually adequate.

1. Fetal brain

Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal brain. Optimal slice thickness is 2 to 3 mm, but, in some patients, a 4- to 5-mm slice thickness may be needed because of signal-to-noise consideration. A high echo time TE value (160-240) can help optimize evaluation of the brain parenchyma. The fast T1 gradient-echo sequence should be performed in the coronal or axial plane if there is suspicion of fat or hemorrhage. The use of DWI to evaluate metabolic or ischemic processes and EPI to evaluate for hemorrhage may be performed as needed [96-98].

2. Fetal spine

Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal spine. Optimal slice thickness is 2 to 3 mm, but, in some patients, a 4- to 5-mm slice thickness may be needed because of signal-to-noise consideration. Additional sequences are rarely indicated in the spine evaluation but may include EPI as noted above regarding brain evaluation. A fast T1 gradient-echo sequence may be performed if there is suspicion of a fat-containing lesion.

3. Fetal face and neck

Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal face and neck. A slice thickness of up to 5 mm should be used with knowledge of signal-to-noise considerations, with earlier gestational age fetuses having thinner slices. A fast T1 gradient-echo sequence should be performed in the appropriate plane if there is suspicion of fat or hemorrhage.

Repetitive sagittal images, including real-time cine, can be useful to visualize fluid in the oropharynx if a lesion of the palate or proximal esophagus is suspected.

4. Fetal thorax

Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal thorax. The slice thickness should be up to 5 mm. A fast T1 gradient-echo sequence can be performed in the coronal or sagittal plane to evaluate the liver and meconium in cases of congenital diaphragmatic hernia. SSFP sequences (FIESTA, TrueFISP) and cine images [99] can be used to refine assessment of the heart and vascular masses.

5. Fetal abdomen

Imaging sequences should include axial, coronal, and sagittal single-shot T2-weighted images of the fetal abdomen. The slice thickness should be up to 5 mm. The fast T1 gradient-echo sequence can be performed in the coronal or sagittal plane to evaluate the liver, meconium, fat, or hemorrhage [100]. The use of DWI to identify renal tissue may be used as needed. T2*gradient recalled echo GRE imaging can be used to screen for hemochromatosis [11,101].

6. Fetal volumetry

Various studies have established MRI-derived volumes and equations for weight [14,102-107]. The most commonly used are lung volumes to predict hypoplasia. Fetal weight has also been estimated. The technique involves adding together measured areas obtained by drawing free-form regions of interest on sequences

that allow complete imaging of the volume without motion-induced artifact and multiplying by slice thickness. Volume assessments should be reserved for specific indications.

7. Dynamic imaging
   Studies have demonstrated the utility of multisection balanced steady state–free precession cine sequences to assess fetal limb motion, swallowing, breathing**,** and cardiac motion [108-111].

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [112].

VII. EQUIPMENT SPECIFICATIONS

Equipment monitoring should be in accordance with the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment [113].

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

VIII. 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).

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.

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