Imaging Pregnant and Lactating Patients[1]

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Abbreviations: ACOG = American Congress of Obstetricians and Gynecologists, ACR = American College of Radiology, ALARA = as low as reasonably achievable, FDA = Food and Drug Administration, FDG = fluorodeoxyglucose, ICNIRP = International Commission on Non-Iodizing Radiation Protection, ICRP = International Commission on Radiological Protection, V/Q = ventilation-perfusion

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SA-CME LEARNING OBJECTIVES

After completing this journal-based SA-CME activity, participants will be able to:

■ Describe the potential adverse effects of ionizing radiation on the conceptus during all stages of pregnancy and on the pregnant or lactating mother.

■ Define the specific fetal and maternal risks associated with each imaging modality and use of intravenous iodinated or gadolinium-based contrast agents and radiotracers during lactation.

■ Specify when imaging screening is required in pregnancy and how to obtain informed consent.

See www.rsna.org/education/search/RG.

As use of imaging in the evaluation of pregnant and lactating patients continues to increase, misperceptions of radiation and safety risks have proliferated, which has led to often unwarranted concerns among patients and clinicians. When radiologic examinations are appropriately used, the benefits derived from the information gained usually outweigh the risks. This review describes appropriateness and safety issues, estimated doses for imaging examinations that use iodizing radiation (ie, radiography, computed tomography, nuclear scintigraphy, and fluoroscopically guided interventional radiology), radiation risks to the mother and conceptus during various stages of pregnancy, and use of iodinated or gadolinium-based contrast agents and radiotracers in pregnant and lactating women. Maternal radiation risk must be weighed with the potential consequences of missing a life-threatening diagnosis such as pulmonary embolus. Fetal risks (ie, spontaneous abortion, teratogenesis, or carcinogenesis) vary with gestational age and imaging modality and should be considered in the context of the potential benefit of medically necessary diagnostic imaging. When feasible and medically indicated, modalities that do not use ionizing radiation (eg, magnetic resonance imaging) are preferred in pregnant and lactating patients. Radiologists should strive to minimize risks of radiation to the mother and fetus, counsel patients effectively, and promote a realistic understanding of risks related to imaging during pregnancy and lactation.

Introduction

The use of radiologic examinations in pregnant women has more than doubled over the past decade in the United States (1,2). Most of the increase is attributable to modalities that use ionizing radiation. Computed tomographic (CT) examinations experienced the greatest increase, by approximately 25% per year, followed by nuclear medicine examinations, which underwent a yearly increase of 12% (1–3). At the same time, awareness, concerns, and misconceptions about the potential fetal and maternal radiation risk posed by these modalities have grown among the public and health care workers. Surveys of family care physicians, obstetricians, and radiologists have revealed pervasive deficiencies in knowledge among practitioners on this issue

TEACHING POINTS

- A consensus has emerged that when the fetal dose is less than 50 mGy, the noncarcinogenic risk, which includes abortion or malformation, is negligible compared with other risks of pregnancy. By using typical imaging parameters, it is unlikely that a single-phase CT scan would reach these dose levels. A fetal dose of less than 100 mGy also should not be considered a reason to terminate pregnancy. In fact, the American College of Radiology (ACR) describes effects at this level as "probably too subtle to be clinically detectable," and some authors suggest that a dose less than 100 mGy be used as a no-adverse-effect level, regardless of fetal gestational age.
- Presently, the leading indications for CT as a first-line imaging modality in pregnant patients include trauma and suspected pulmonary emboli. Trauma is the leading cause of nonobstetric maternal mortality worldwide. In developing countries, venous thromboembolism is the leading cause of maternal mortality.
- The 2013 ACR Guidance Document on MR Safe Practices states that MR imaging can be used in pregnant patients regardless of gestational age when the information gained is likely to alter treatment, when it cannot be obtained through other nonionizing means, and when MR imaging cannot be delayed until completion of pregnancy.
- Before deciding to temporarily discontinue breast-feeding after intravenous administration of contrast material, the mother should be counseled that even short periods of cessation might lead to weaning. If this remains a concern for the mother after appropriate counseling, cessation of breast-feeding for a maximum of 12–24 hours can be considered.
- Before a protocol is formed and any type of imaging is approved, regardless of the pregnancy status of the patient, radiologists should routinely ask themselves *(a)* whether the information could be obtained without ionizing radiation; *(b)* if contrast material would provide important additional information, or if it could be withheld; and *(c)* if the information gained would affect patient care. If the patient is pregnant or lactating, additional specific questions that should be asked include whether US could be used instead and whether the examination could be delayed until after pregnancy or lactation.

(3–6). Such misconceptions can lead to excessive and unnecessary anxiety among patients, delays in diagnosis and treatment, or even inappropriate termination of pregnancy. In this review article, we discuss risks and safety issues related to imaging pregnant and lactating women, familiarize readers with evidence-based imaging recommendations, and provide practical guidance on counseling patients, obtaining informed consent, minimizing risks, and adhering to the "as low as reasonably achievable" (ALARA) principle.

Radiation Dose, Risk, and Pregnancy

During the 9 months of a full-term pregnancy, the estimated radiation dose to the mother from background radiation that naturally occurs averages approximately 2.3 mSv worldwide and varies according to geographic location and altitude (7–9). Average fetal dose is approximately 0.5–1 mSv because of attenuation through the mother's tissue (7–9). For radiation workers who are pregnant, the upper limits of maternal dose recommended by the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements, and the Nuclear Regulatory Commission should be less than 5 mGy. Similarly, the fetal dose for radiation workers should be less than1 mGy during the total gestational period (10–12). This dose (less than 1 mGy) is the same as that for members of the public who are incidentally exposed to radiation (ie, the fetus is an innocent bystander). Radiation workers who have voluntarily declared pregnancy should have their personal dose and calculated fetal dose monitored closely throughout pregnancy. In general, radiologists and technologists who are pregnant and take precautions to limit their exposure times related to interventional or intraoperative fluoroscopy will not find it difficult to comply with these limits.

A consensus has emerged that when the fetal radiation dose is less than 50 mGy, the noncarcinogenic risk, which includes abortion or malformation, is negligible when compared with other risks of pregnancy (11). By using typical imaging parameters, it is unlikely that a single-phase CT scan would reach this dose level (9,13). A fetal dose of less than 100 mGy also should not be considered a reason to terminate pregnancy (10,11,14). In fact, the American College of Radiology (ACR) describes radiation effects at this level as "probably too subtle to be clinically detectable," and some authors suggest that a dose less than 100 mGy be used as a no-adverse-effect level (11,14), regardless of fetal gestational age. If the fetal dose reaches levels greater than 150 mGy, there is stronger likelihood of malformation (10). Some authors suggest that radiation exposure greater than 500 mGy during neuronal development (ie, between 7 and 25 weeks gestation) may be associated with significantly increased risk for severe mental retardation, and in this setting, abortion may be recommended (10,11). However, this remains a source of controversy, and other authors (14,15) suggest that a lower fetal dose (>200 mGy) could be used as a threshold for counseling on abortion. The decision to terminate should be made on the basis of individual circumstances and additional risks, such as fetal gestational age at the time of exposure. Absorbed doses for the great majority of properly performed diagnostic examinations should be less than 50 mGy (11) unless multiple examinations must be performed during the pregnancy. Typical radiation doses for different types of imaging examinations are provided in Table 1.

Table 1: Radiation Doses Associated with Common Radiologic Examinations

Modality	Fetal Dose (mGy)	Maternal Dose (mSv)	Breast Dose (mGy)
CT			
Head or neck	1.0–10	0.9–4.0	…
Pulmonary angiography	0.01–0.66	2.7–40	8–70
Abdominal	1.3–35	3.5–25	…
Pelvic	10–50	3.3–10	…
Abdomen and pelvis	13–25	3–45	…
Aortic angiography of chest, abdomen, and pelvis, with or without contrast agent	6.7–56	4–68	16–130
Coronary artery angiography	0.1–3	7–39	10–90
Nonenhanced CT of abdomen and pelvis to evaluate for nephrolithiasis	10–11	3–10	…
Nuclear medicine			
Low-dose perfusion scintigraphy	0.1–0.5	0.6–1.0	0.1–0.3
V/Q scintigraphy	0.1–0.8	1.2–2.8	0.2–0.7
Technetium 99 (^{99m}Tc) bone scintigraphy	10–50	6.7	…
Fluorine 18 (^{18}F)–FDG PET/CT whole-body scintigraphy	9.4–21.9	13.5–31.9	14
^{18}F-FDG PET myocardial viability	6.8–8.1	7	…
Myocardial perfusion with ^{99m}Tc-sestamibi	17	11.4–14.8	…
Myocardial perfusion with ^{99m}Tc-tetrofosmin	8.45	9.3–11.6	…
Radiography			
Mammography, two views	0.001–0.01	0.1–0.7	3
Chest radiography, two views	0.0005–0.01	0.06–0.29	<0.04
Extremity and cervical spine radiography	<0.001	0.03–0.22	…
Abdominal radiography	0.1–0.3	0.01–1.1	…
Lumbar spine radiography	1.0–10	0.5–1.8	…
Other			
Intravenous pyelography	5–10	0.7–3.7	…
Double-contrast barium enema	1.0–20	2.0–18.0	…
Small bowel examination	7	3.0–7.8	…

Source.—References 6–8,10,11,16–21.
Note.—Estimated dose varies according to protocol, radiotracer type and dosage, method of dose calculation, and patient-dependent factors (eg, weight or body habitus and percentage of glandular breast tissue). FDG = fluorodeoxyglucose, PET = positron emission tomography, V/Q = ventilation-perfusion.

Imaging and Risks

Maternal Risk

The adverse effects related to radiologic examinations in pregnancy should be thought of in terms of risks to the mother and risks to the fetus. During pregnancy and in the first postpartum month, the breast tissue of the patient is more sensitive to radiation because of glandular proliferation (8,22,23). A 20-year-old nonpregnant woman who undergoes chest CT angiography and receives a dose of 10 mGy has an estimated lifetime attributable or excess risk due to ionizing radiation of 429 per 100,000 persons for being diagnosed with breast cancer and a risk of 101 per 100,000 persons for breast cancer–related mortality, according to the seventh report of the Biological Effects of Ionizing Radiation (BEIR) study (BEIR VII) (24). It is postulated that the estimated risk is higher in pregnant or lactating patients, given the peripartum proliferation of glandular breast tissue, but it is unclear to what degree (22,25). Furthermore, with more current chest CT angiography protocols, the dose to breast glandular tissue can be reduced threefold, from approximately 10 mSv in standard pulmonary embolism CT protocols to 3 mSv (6,26). Dose-reduction strategies for CT are discussed in a later section. Maternal radiation risk must be weighed with the potential consequences of missing a life-threatening diagnosis such as pulmonary embolus. In other body regions, the risk profile of the pregnant or lactating patient is largely similar to that of the nonpregnant patient.

Table 2: Potential Deterministic Effects on the Embryo and Fetus from Radiation Exposure

Parameter	Potential Deterministic Effects
<50 mGy radiation dose	
0–2 weeks gestation	Spontaneous abortion; all-or-none effect before implantation
>2 weeks gestation	Probably too subtle to be clinically detectable
>50–100 mGy radiation dose*	
2–25 weeks gestation	Teratogenic; organogenesis (eg, congenital abnormalities, intrauterine growth retardation); because of rapid neuronal development during weeks 8–15, exposure during this period may result in mental retardation and microcephaly
>25 weeks gestation	No teratogenic effect observed at diagnostic doses <100 mGy
100–500 mGy radiation dose	Decision to abort fetus should be made on the basis of individual circumstances (eg, maternal malignancy that requires serial cross-sectional imaging during pregnancy, interventional procedures, or radiation therapy)
>500 mGy radiation dose	Clinically significant fetal damage may result

*Termination is not justified on the basis of radiation risks.

Fetal Risk

Hazards from radiation to the conceptus include spontaneous abortion, teratogenesis, and carcinogenesis. These risks vary with fetal gestational age and imaging modality used and are summarized in Table 2. Any risk must be considered in the context of the potential benefit of medically necessary diagnostic imaging. It should also be considered that the innate likelihood of spontaneous abortion in pregnancy is 15%, of major malformation is 3%, of premature delivery or growth restriction is 4%, and of mental retardation is 1% (7,27).

Spontaneous Abortion.—There is an approximately 50% chance of failed pregnancy from all conceptions in women who are not exposed to radiation (28,29). Radiation exposure greater than 50–100 mGy during the first 0–2 weeks of gestation or before implantation may cause demise of the embryo. If implantation is successful, it is likely that there will be no consequence to the fetus, regardless of the radiation dose (28,30,31). This is often referred to as the all-or-none effect.

Teratogenesis.—Teratogenic effects are also referred to as deterministic (or nonstochastic) effects because a threshold radiation dose must be crossed before inherent cellular repair mechanisms fail, which results in loss of tissue function or development (28). The fetus is at risk for teratogenesis during the period of organogenesis between 2 and 20 weeks of gestation (11). The fetus is especially sensitive to radiation between 8 and 15 weeks, during which there is rapid neuronal development and migration (6,7,11,28). Radiation exposure greater than 100 mGy during this period may lead to mental retardation, microcephaly, and intrauterine growth restriction (6,11). At doses greater than 100 mGy, data from animal studies, atomic bomb survivors, and patients exposed to radiation for medical reasons estimate a decrease of approximately 0.025 intelligent quotient points per 1 mGy (6–8,11,28).

Carcinogenesis.—Carcinogenesis arises from stochastic or nondeterministic effects. Unlike deterministic effects, cellular damage from stochastic effects does not lead to loss of tissue function. Instead, these effects result in random DNA mutations, which can occur at any radiation dose. The linear no-threshold model predicts that carcinogenic risk increases linearly with increased radiation dose and that there is no minimum dose below which there is no cancer risk (14,16). The relative risks for childhood cancer are greater during early gestation. Relative risk for childhood cancer from diagnostic-level radiation has been estimated to be approximately 3.19 in the first trimester, 1.29 in the second trimester, and 1.30 in the third trimester (3,32). With a fetal dose of 50 mGy, there is an estimated twofold increase in relative risk for fatal childhood cancer compared with risk when there has been no ionizing radiation exposure (6,8). Although these data may ap-

pear alarming, it is important to remember that the baseline risk for dying from childhood cancer is extremely low (1.0–2.5 patients per 1000), and absolute risks for childhood cancer from diagnostic radiation in any individual are minimal (2,3). The excess cancer incidence for a conceptus radiation dose of 50 mGy is 1.1–3.0 patients per 1000 (2).

Fetal Dose Estimation: When Is It Necessary to Consult with a Medical Physicist?

If a patient undergoes a radiologic examination during the first 2 weeks of pregnancy, dose estimation may not be required, given the all-or-none response (28,16). In spite of reassurance, many patients who prove to be pregnant and underwent imaging during this period of early pregnancy want additional information. In general, consultation by a qualified medical physicist and good communication with the patient, radiologist, and obstetrician (assuming the pregnancy will not be terminated for other reasons) increases everyone's comfort level. Beyond 2 weeks after conception, patients who are known to be pregnant may undergo irradiation or imaging if the benefit of the information gained outweighs the risk or if they were not known to be pregnant and had to undergo irradiation or imaging in an emergent situation. Most practices do not hesitate to have a qualified medical physicist involved in either of these situations. Radiologists and radiologic technologists are trained to take steps to prospectively optimize exposure of the pregnant patient; for some modalities, such as CT, dose indexes are prospectively displayed when imaging parameters are inputted and act as an indirect surrogate for maternal dose. Familiarity with the principles of ALARA and knowledge of the idiosyncrasies of the scanner that is used are necessary to optimize dose. It is important, however, to realize that the volume CT dose index or dose-length product (even if multiplied by an appropriate body-part conversion factor) is not the maternal dose, let alone the fetal dose. Fetal dose is best and most accurately determined by a medical physicist. There are methods for rough estimation of fetal dose, for example by multiplying the effective milliampere-seconds (milliampere-seconds per pitch) or volume CT dose index by 10.8 mGy/100 mAs (2), but these are not substitutes for accurate estimation by a qualified medical physicist by using scan parameters and the patient's geometry for Monte Carlo calculations (11,33). This is the practice used in most academic and many community hospital departments. After implantation, if the estimated fetal dose is expected to be greater than 50 mGy, consultation with a medical physicist is strongly recommended (3,10). Fetal dose estimation can also be performed prospectively with placement of the dosimeter at the level of the uterus, but this is not routinely performed at many institutions (10,16).

Modality-specific Considerations

Imaging can be divided into modalities that use ionizing radiation (ie, radiography, CT, nuclear scintigraphy, and fluoroscopically guided interventional radiology) and those that do not use ionizing radiation (ie, magnetic resonance [MR] imaging and ultrasonography [US]).

Modalities That Use Ionizing Radiation

CT: Common Indications.—Presently, the leading indications for CT as a first-line imaging modality in pregnant patients include trauma and suspected pulmonary emboli. Trauma is the leading cause of nonobstetric maternal mortality worldwide (9,13). In developing countries, venous thromboembolism is the leading cause of maternal mortality (8,34).

After trauma, pregnant patients with positive findings on a Focused Assessment with Sonography in Trauma (FAST) examination should be evaluated for solid organ, hollow visceral, and vascular injury at contrast agent–enhanced CT (9,13). Although multiphasic imaging is commonly performed in patients with blunt polytrauma, a single-phase examination can usually be performed in pregnant patients to limit fetal radiation exposure (13,35,36). CT cystography may be necessary in cases where bladder rupture is suspected and can be performed by using low-dose techniques (9). In the trauma setting, MR imaging is time and resource intensive and is usually reserved as a problem-solving tool only, such as in patients with suspected pancreatic trauma, or for surgical planning and prognostication in patients with unstable spine injuries (9,35).

The American Congress of Obstetricians and Gynecologists (ACOG) and the Fleischner Society recommend pulmonary CT angiography for pregnant patients with suspected pulmonary embolism (8,37,38). CT angiography should be performed after confirming negative findings at bilateral lower extremity Doppler US because as many as one-third of pregnant patients with pulmonary embolism have deep vein thrombosis (8,37,39). Further CT angiography after confirmation of deep vein thrombosis at venous duplex imaging may not alter management. In general, pulmonary CT angiography provides a lower dose to the fetus when the fetus is small and farther from the field of view or chest compared with

V/Q scintigraphy, but it may deliver an equivocal or higher dose to the fetus when the gravid uterus is enlarged and is extended closer to the diaphragm (16,38) (Table 1). Steps may be taken to significantly reduce the dose during the perfusion portion of V/Q imaging and to eliminate the ventilation portion. There are many institutions that will do this, especially if the patient is shown to be healthy after undergoing chest radiography. Alternatively, a ventilation examination can be performed the day after imaging if the findings at perfusion imaging are abnormal but nondiagnostic (40,41). Doses can be achieved that are comparable to CT angiography in early pregnancy or even lower than CT angiography in late pregnancy (42,43).

CT: Dose Considerations and Dose-reduction Strategies.—Overall, there is negligible scatter radiation to the fetus at CT of the head, neck, and extremities, excluding the hips (11,28). The fetal dose becomes important when the fetus is in the field of view (2). Attempts should be made to adhere to the principles of ALARA. Therefore, standard protocols should not be used in pregnant patients. To achieve the lowest possible dose, the technologist should be educated and empowered to adjust imaging parameters. This includes lowering tube potential (in kilovolts) on the basis of the patient's weight, decreasing tube current–time product (in milliampere-seconds), limiting image length (ie, the z-axis), increasing pitch, and limiting the number of acquisitions to one (11,44). Additional commonly used dose-reduction techniques include automated exposure control (which may reduce dose by 40%–50%), automated tube potential selection (which may reduce dose by 33%–65%), and iterative reconstruction (which may reduce dose by 40%–50%) (45). A radiologist should also be available if consultation is necessary. Because abdominal dimensions increase late in pregnancy, automated exposure controls may increase the milliampere-seconds to compensate. The technologist may have to take steps to limit the target milliampere-seconds on the basis of the modulation method in use. Fetal absorbed dose from a single-phase pelvic CT examination can be decreased from approximately 25 mGy to 13 mGy by using some of these techniques (9,46). Abdominal shielding at pulmonary CT angiography does not lead to meaningful dose reduction because most of the fetal dose is from internal scatter radiation, but abdominal shielding may provide comfort for the mother. Internal shielding by using oral barium (with barium suspension 30% or higher) before pulmonary CT angiography can reduce the fetal dose (47). It is important to emphasize that if the CT image is not properly collimated, this may lead to increased fetal dose by including the abdominal shield or oral contrast agent in the field of view. Bismuth breast shields are infrequently used at chest CT because they can result in wasted exposure of the posterior tissues and degraded image quality. Automated exposure-control algorithms with real-time milliampere-second adjustments, such as those currently used by some vendors, may lead to increased dose (48).

Nuclear Scintigraphy.—As with radiographic examinations, risks to the fetus in nuclear medicine are related to ionizing radiation, except in cases where the mother becomes the source of radiation to the fetus. Fetal exposure is from radioactivity accumulating in maternal organs and the transport or diffusion of radiopharmaceuticals across the placenta (10). To minimize fetal exposure, the tracer dose is typically reduced (for V/Q examinations, the dose is usually decreased by half), with a compensatory increase in imaging time (10). The most frequently performed nuclear medicine examination in pregnant patients is V/Q scintigraphic imaging. V/Q imaging is usually associated with decreased maternal breast dose compared with pulmonary CT angiography (10,17). Absorbed dose to the fetus is estimated as 0.1–0.37 mGy (46). These values are in the same range as absorbed dose in the third-trimester fetus from pulmonary CT angiography. For most applications, the commonly used isotope ^{99m}Tc delivers less than 5 mGy of radiation to the fetus (10,12,17,38). For tracers such as ^{99m}Tc-mercaptoacetyltriglycine (MAG_3)and ^{18}F-FDG, which are excreted by the kidneys, adequate hydration is of utmost importance (10). Bladder catheterization to minimize irradiation of the adjacent fetus may be considered for these examinations (10).

Nuclear medicine examinations other than V/Q imaging are infrequently indicated in pregnancy. Given the increasing age of pregnant patients and concomitant increase in cardiovascular demand, peripartum cardiomyopathy is becoming more common (15,16). Cardiac imaging may be required but should be considered on a case-by-case basis. To avoid use of ionizing radiation, stress echocardiography or MR imaging that is not contrast enhanced can be performed. After the potential risks associated with use of gadolinium-based contrast agent are discussed with the patient, delayed phase contrast-enhanced MR imaging may also be considered. Nuclear medicine myocardial viability imaging with use of ^{99m}Tc agents or PET can be performed to evaluate perfusion, cell membrane integrity, and mito-

Table 3: Summary of Professional Society Consensus Statements and Recommendations for Imaging Pregnant and Lactating Patients

Modality	Recommendation
CT	ACOG and ACR: CT can be performed if deemed necessary after appropriate workup; adhere to ALARA principle.
Nuclear scintigraphy	ACOG: Use of ^{131}I-NaI is contraindicated during pregnancy. If diagnostic examination of the thyroid is essential, ^{123}I or ^{99m}Tc should be used instead of ^{131}I-NaI. Cessation of breast-feeding is suggested after administration of gallium 67 (^{67}Ga) citrate and ^{131}I-NaI. ICRP: Conception should be delayed until potential fetal dose from residual dose from radionuclides is less than 1 mGy.
US	ACR, ACOG, AIUM, SRU: US should be performed only when there is a valid medical reason; the lowest possible US output settings should be used.
MR imaging	ACOG: MR imaging is not associated with known adverse fetal effects. ACR: MR imaging can be performed in all trimesters if deemed clinically necessary and then only as an adjunct to initial US evaluation. MR imaging magnet strength should be ≤3 T. ICNIRP, NRPB: It may be prudent to refrain from MR imaging during the first trimester of pregnancy.

Note.—AIUM = American Institute of US in Medicine, ICNIRP = International Commission on Non-Ionizing Radiation Protection, NRPB = National Radiological Protection Board in the United Kingdom, SRU = Society of Radiologists in Ultrasound.

chondrial function with fetal doses less than 50 mGy, particularly with reduced radiotracer doses (15). Pharmacologic stress by using vasodilators with adenosine (U.S. Food and Drug Administration [FDA] category C) or dipyridamole (FDA category B) is not recommended in pregnant patients because these agents may lead to severe orthostatic hypotension. Treatment with sodium iodide 131 (^{131}I-NaI) is contraindicated in pregnant patients because it may lead to permanent hypothyroidism in the fetus (12,38). The ACOG recommends that this type of therapy be delayed until after delivery and that, for diagnostic thyroid examinations during pregnancy, iodine 123 (^{123}I) or ^{99m}Tc be used instead of ^{131}I-NaI because of the lower radiation dose and shorter half-life (Table 3) (31,38).

Women may inquire whether it is advisable to become pregnant after undergoing a nuclear medicine examination. There is no evidence that ^{131}I-NaI treatment affects the outcome of subsequent pregnancies; however, patients should avoid pregnancy for 1 year after treatment and until a euthyroid state has been achieved with thyroid replacement therapy (49,50). For other pharmaceuticals, the ICRP recommends that there should be less than 1 mGy of residual radiotracer before conception is attempted (31). The duration of this period will depend on the half-life of each radiopharmaceutical.

Fluoroscopy, Interventional Radiology, and Radiography.—Radiographic imaging that does not involve direct fetal or abdominopelvic exposure results in a negligible conceptus dose. Although institutional policies and procedures should be followed, determination of pregnancy status should not alter the decision to proceed with the examination (28). When the fetus is in the field of view, pregnancy status should be confirmed (28). In situations in which an interventional procedure is required, US should be used for guidance whenever possible. If fetal radiation is unavoidable, exposure should be reduced by minimizing fluoroscopic time, decreasing the number of images acquired, using magnification only when necessary, employing the lowest possible frame rate, optimizing collimation, and using image hold instead of additional exposures (51). The patient should be placed as close to the receptor as possible, with the distance maximized between the source of the x-ray and the receptor, and a lead apron should be placed between the patient and the table to minimize exposure to low-energy radiation (51).

Modalities That Result in Nonionizing Energy Deposition

MR Imaging

When feasible and indicated, MR imaging is preferred over modalities that use ionizing radiation to image pregnant and lactating patients (7,52). The 2013 ACR Guidance Document on MR Safe Practices states that MR imaging can be used in pregnant patients regardless of gestational age when the information gained is likely to alter treatment, when it cannot be obtained through

other nonionizing means, and when MR imaging cannot be delayed until completion of the pregnancy (Table 3) (16,52,53).

Unlike the risks associated with ionizing radiation, potential fetal risks related to MR imaging are teratogenic, not carcinogenic (54). The inherent properties of MR imaging, which include static magnetic field (B_0), time-varying magnetic field gradients, and radiofrequency pulses, may theoretically pose a threat to the developing fetus (52,54). The primary concerns related to MR imaging are heating associated with the radiofrequency pulse; B_0 strength, which may affect cell migration during the first trimester; and acoustic noise produced during imaging, which may damage fetal hearing once the fetal ear develops (by 24 weeks) (54,55).

Specific Absorption Rate.—Energy deposited by the radiofrequency pulse is quantified by using the specific absorption rate, which is measured in watts per kilogram (52,54,56). Heat produced related to a high specific absorption rate has been shown to cause malformations in small animals (54,57). In humans, a maternal temperature increase greater than 2°–2.5°C for 0.5–1 hour has been reported to cause heat-induced abnormality in the fetus (54,57,58). The FDA permits an upper limit–specific absorption rate of 4 W/kg for a whole-body imager for any patient. At this maximum allowable specific absorption rate, the body temperature may increase 0.6°C for 20–30 minutes of imaging (54). Heat in the gravid abdomen is greatest at the surface and minimal at the center; therefore, fetal heat is considerably less than what has been shown to result in detrimental fetal effect (54,56,59).

Sequence parameters that may increase the specific absorption rate include increased B_0, flip angle, radiofrequency pulse spacing, and decreased repetition time (3,54). Because of its fast acquisition and superior image contrast, the single-shot fast spin-echo sequence, which uses a series of 180° radiofrequency refocusing pulses, is a common sequence used to image pregnant patients suspected of having appendicitis. It is associated with a relatively high specific absorption rate compared with other sequences (3,7). Internationally accepted guidelines recommend that pregnant patients are imaged by using magnets with field strengths of 3 T or less because the specific absorption rate quadruples when the magnetic field doubles (3,7,54).

Migration.—It is known that strong magnetic fields can cause perceptual disturbances, such as vertigo or a metallic taste. For the fetus, it is postulated that the magnetic field may alter cell migration, proliferation, and differentiation in the first trimester (3,52,54). These risks remain theoretical in humans, and no detrimental effect has been reported. Nevertheless, the ICNIRP recommends postponement of elective MR imaging until after the first trimester (Table 3) (7,60).

Acoustic Noise.—Rapid gradient switching causes the so-called knocking sound when an MR imager is in use (54). At 3 T, when protocols with fast gradient switching and high amplitudes are used, 80–120 dB of acoustic noise may be produced (16,54,61). Temporary hearing loss has been reported after MR imaging, and the use of headphones or earplugs for hearing protection has become a common practice. The American Academy of Pediatrics suggests 90 dB as the upper limit; permanent damage to the fetal ear may result if this limit is not observed (54,61). Because the maternal body attenuates at least 30 dB, 90 dB may reach the fetus (54). Thus, when a sequence that causes loud noise (eg, three-dimensional fast gradient echo) is used, it is important to keep the exposure brief. Newer MR imagers have noise-dampening technology that is available for use with certain pulse sequences. If available for the specific type of examination performed, these may be beneficial for the pregnant patient.

US Examination.—Nearly every woman who receives prenatal care will undergo US during her pregnancy, usually in the first and third trimesters. US is the first-line imaging tool for evaluating the fetus and expectant mother. The ACR, ACOG, AIUM, and SRU agree that US is generally safe; however, it should be performed only when it serves a medical purpose (62), and so-called keepsake fetal US images should be avoided. Keepsake US images are also considered an unapproved use of a medical device by the FDA and may be in violation of state regulations (Table 3) (62–64). The use of over-the-counter heartbeat monitors with Doppler US is also discouraged by the FDA (63,65).

After 1992, the FDA mandated that US equipment adhere to the Output Display Standard, which includes thermal and mechanical indexes to guide users regarding energy deposition from heating and cavitation effects, respectively (66). Strict regulations have been replaced with suggested limits for thermal and mechanical indexes, reflecting a trend toward self-directed use by sonographers and radiologists. High thermal and mechanical energies have been shown to cause lung hemorrhage in a mouse model (66,67). A thermal index of 1.0 indicates conditions under which a rise of 1°C would be likely. Although no teratogenic effects have been demonstrated in humans, practitioners should attempt to adhere

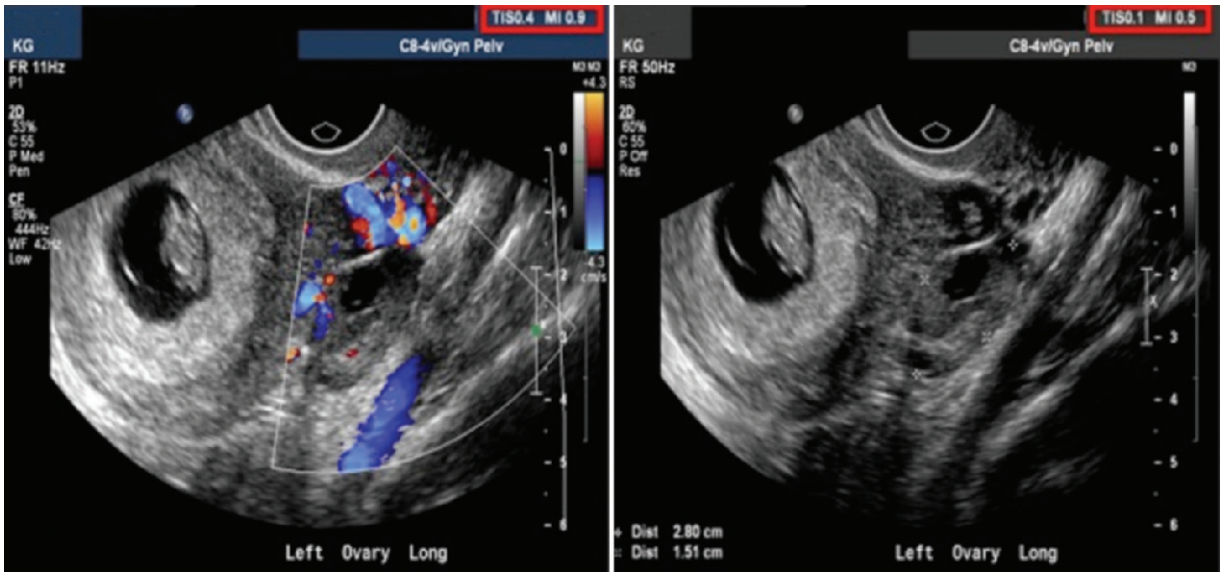

Figure. Obstetric US images obtained in the first trimester in a 29-year-old woman show increased thermal and mechanical indexes (0.4 and 0.9, respectively) on a color Doppler US image (left) compared with on a B-mode US image (right) (0.1 and 0.5, respectively). It is recommended that the mechanical and thermal indices should each be less than 1.0. The soft-tissue thermal index is used in early gestation (<10 weeks) when there is no bone formation. After bone formation, the bone thermal index is used.

to the ALARA principle by controlling output. Recommended mechanical and thermal indexes should both be less than 1 (66,68,69). There are separate thermal indexes for soft tissue, bone, and the cranium. The thermal index of soft tissue should be used in early gestation, and the thermal index of bone should be used after 10 weeks, when bone ossification is evident (Figure) (62).

Real-time two-, three-, and four-dimensional images are derived by using low-output intensity and are considered safe; nonetheless, every effort should be made to limit dwell times to less than 30 minutes (66,69). However, color, power, and spectral Doppler US require higher-intensity acoustic output (Figure). The AIUM recommends that Doppler US should not be routinely used in early pregnancy (68,70). M-mode US is recommended instead of spectral Doppler US to document heart rate (68,70).

Contrast Agent Administration in Pregnant and Lactating Patients

The single-layer chorionic epithelium of the placenta serves as an interface between the maternal and fetal circulation through which lipid-soluble, low-molecular-weight, and nonionic water-soluble molecules diffuse relatively freely (6,71). The movement of iodinated and gadolinium-based contrast agents across the placenta is somewhat restricted by their relatively high molecular weights (6,71). Studies have demonstrated measurable quantities of iodinated and gadolinium-based contrast agents in the fetus after intravenous administration to the mother (6,72). Once contrast agent enters the fetal circulation, it is filtered by the kidneys and recirculated through the gastrointestinal tract because the fetus swallows amniotic fluid. In women with a decreased glomerular filtration rate, contrast agent may persist longer in the maternal circulation and lead to increased concentrations of contrast agent in the fetus (6).

Iodinated Contrast Agent

Both iodinated intravenous and iodinated oral contrast agents are considered FDA category-B drugs (ie, no risk demonstrated in animal reproductive studies but no controlled studies in pregnant women). The 2013 ACR Manual on Contrast Media states that iodinated contrast media may be given to the pregnant patient if the information sought cannot be acquired without contrast agent, if the information is expected to affect the care of the patient and fetus during pregnancy, and if it would not be prudent to wait until after delivery (Table 4) (16,72). It may be wise to administer intravenous contrast agent to perform an examination that would normally be warranted in a patient who was not pregnant versus perform a nonenhanced CT examination and need to perform another examination because of imaging limitations (2).

To date, there is no reported teratogenic or mutagenic risk from iodinated contrast agent. The fetal thyroid begins to mature at 12 weeks and is minimally functional by 20 weeks of gestation (6). A concern regarding iodinated contrast agent administration during pregnancy is that excess iodine exposure may induce hypothyroidism. In the past 3 decades, there were

Table 4: Considerations and Recommendations on Use of Iodinated or Gadolinium-based Contrast Agents in Pregnant and Lactating Patients

Contrast Agent	Pregnancy	Lactation	Comments
Iodinated	FDA category B—no adverse effects in animal reproductive studies, but there are no controlled studies in pregnant women; informed consent is recommended	Breast-feeding is safe after intravenous iodinated contrast agent administration; systemic dose absorbed by infant from breast milk is <0.01% of dose given to mother (6)	Contrast agent should be used if it may aid diagnosis and avoid necessity to repeat nondiagnostic examination because contrast agent was not administered; newborns should be tested for hypothyroidism during first week of life (routine practice in North America)
Gadolinium-based	FDA category C—animal reproduction studies showed adverse effects on fetus, but there are no controlled studies in humans; if benefits outweigh the risks, it may be used; no case reports of adverse fetal effects; informed consent is recommended	Breast-feeding is safe after gadolinium-based contrast agent administration; systemic dose absorbed by infant from breast milk is <0.0004% of dose given to mother (6)	Gadolinium-based contrast agent may be considered if the radiologist and the referring physician deem that it is essential

no documented cases of hypothyroidism from intravenous contrast agent administration (3,6). Previously reported cases were related to amniofetography, which requires a large concentration of lipid-soluble iodinated contrast agent and is no longer performed. Out of an abundance of caution, if iodinated contrast agent is given during pregnancy, the infant should be screened for hypothyroidism in the 1st week of life, which is already a standard practice in North America (72).

Gadolinium-based Contrast Agent

Because intravenous gadolinium-based contrast agent has been shown to cause fetal demise and malformations in animal studies at repeated supraclinical doses, the FDA classified these compounds as category-C drugs (71–73). Several small retrospective studies that used 26 or fewer women who underwent gadolinium chelate–enhanced MR imaging during their pregnancy reported no adverse maternal or fetal effects (6,54,74). The ACR recommends criteria to determine appropriateness for use of gadolinium-based contrast agents that are similar to the recommendations it provides for iodinated contrast agents. A gadolinium-based contrast agent may be given if the radiologist and referring physician deem that *(a)* it is essential for diagnosis and would alter management, *(b)* delaying the imaging examination until after delivery would be impossible, and *(c)* there is no available alternative (ie, contrast-enhanced CT would not be expected to adequately address the clinical question) (73). The patient should be counseled and informed consent obtained before administration of any gadolinium-based contrast agent. Currently, the half-life and stability of gadolinium-chelate complexes in the fetus is unknown, and nonchelated gadolinium is neurotoxic (6,54). If gadolinium chelate–enhanced MR imaging cannot be avoided, agents such as gadobenate dimeglumine (MultiHance; Bracco Diagnostics, Monroe Township, NJ) or gadoteridol (ProHance; Bracco Diagnostics), which tightly bind the gadolinium ion and have high stability constants, may be safer (74). These should be administered at the lowest possible dose.

Allergic Reaction to Contrast Media

Diphenhydramine is an FDA category-B drug, and corticosteroids are category C (72). Premedication should be administered if the risks of not premedicating outweigh the risks to the fetus. If corticosteroids are given, prednisone or dexamethasone should be used because the majority of either medication is metabolized within the placenta before reaching the fetus (7,72,75). There have been reported cases of fetal adrenal suppression with use of corticosteroids in general, and methylprednisolone was linked to cleft lip if used before 10 weeks of gestation (7,72,75).

Considerations in Lactating Patients

Iodinated and Gadolinium-based Contrast Agents.—The ACR and the ACOG advise that patients continue breast-feeding after administration of intravenous iodinated or gadolinium-based contrast agents (38,72). Both iodinated and gadolinium-based contrast agents have low lipid solubility, and less than 1% of iodinated contrast agent and approximately 0.04% of gadolinium-based contrast agent are excreted into breast milk. Only 1% of the ingested iodinated or gadolinium-based contrast agent is absorbed by the gastrointestinal tract of the infant (6,7,71,73,76,77). After intravenous contrast agent is administered to the mother, the expected systemic dose from breast milk is 0.01% for iodinated contrast agents and 0.0004% for gadolinium-based contrast agents. Contrast agents are considered safe if the infant receives less than 10% of the therapeutic dose (Table 4) (6).

The American Academy of Pediatrics and the World Health Organization recommend breast-feeding as the only source of nutrition during the first 6 months of life (78,79). Before deciding to temporarily discontinue breast-feeding after intravenous administration of a contrast agent, the mother should be counseled that even short periods of cessation might lead to weaning. If this remains a concern for the mother after appropriate counseling, cessation of breast-feeding for a maximum of 12–24 hours can be considered, during which time breast milk should be pumped and discarded. Contrast agent is undetectable in the circulation of the mother after 24 hours (6,71).

Radiotracers.—After the mother undergoes a nuclear medicine examination, the breast-fed infant will be exposed to radiation through radioactivity in milk and by proximity. In 2002, the Nuclear Regulatory Commission stated that the dose to the infant in such cases should be less than 1 mSv (12). The recommended length of temporary breast-feeding interruption for different pharmaceuticals should depend on both the physical and biologic half-lives of these agents. For instance, breast-feeding interruption after ^{99m}Tc imaging depends on the particular radiopharmaceutical agent used, with 4 hours recommended for ^{99m}Tc-pertechnetate imaging and 48 hours for ^{99m}Tc-labeled leukocyte scintigraphy (80). During this period, the mother should be counseled to pump and store the milk, which can be used later after the radioactivity dissipates, or discard it (80,81). As an alternative, if the imaging examination is not emergent, the mother may pump and store the milk before she receives the radiotracer so that she may continue to feed the infant during the period of interruption. Complete cessation of breast-feeding is advised after administration of ^{67}Ga citrate and procedures that use ^{131}I-NaI because greater than 10% of the administered dose may be excreted in breast milk (80).

Diagnostic Breast Imaging in Lactating Patients

The breasts undergo important physiologic changes during pregnancy and lactation, which, in addition to firmness and engorgement, may include development of a palpable abnormality. Approximately 80% of patients will have benign disease (82,83). However, new palpable masses that persist for more than 2 weeks and spontaneous unilateral masses with bloody discharge require appropriate workup (82–85). Insignificant fetal radiation dose is associated with mammography, and pregnancy status should not influence whether a patient can undergo this examination (28,83). To minimize the effects of increased parenchymal density, it may be helpful to request that a lactating patient use a breast pump before mammography (83). Breast US has a critical role in diagnostic problem solving and when biopsy is indicated. The most common tumor during pregnancy and lactation is benign fibroadenoma because the tumor grows in response to hormonal stimuli. However, biopsy should be considered for all new solid masses despite benign characteristics because benign and malignant lesions often cannot be distinguished on the basis of imaging features alone (82–85). In the clinical setting of spontaneous unilateral bloody discharge, ductographic imaging with iodinated contrast agent can be safely performed in pregnant and lactating patients (83,86). Contrast-enhanced MR imaging should be delayed until the postpartum period unless it is deemed to be essential by the radiologist and clinician (83,86).

Counseling, Informed Consent, and Risk Management

Pregnancy Screening

Before a protocol is formed and any type of imaging is approved, regardless of the pregnancy status of the patient, radiologists should routinely ask themselves whether the information could be obtained without ionizing radiation; if contrast agent would provide important additional information or if it could be withheld; and if the information would affect patient care. If the patient is pregnant or lactating, additional specific questions that should be asked include whether US could be used instead and whether the examination could be delayed until after pregnancy or lactation (16,28).

To prevent unintended adverse effects on a pregnant patient or her fetus, the ACR recommends at least verbal screening before radiologic examinations for women 12–50 years of age (28). This age range is not a fixed number and depends on the menstrual status of the patient and relevant history, such as previous hysterectomy or tubal ligation. Different pregnancy screening policies may be instituted that depend on the type of imaging examination, anticipated radiation to a fetus, and medical urgency of the examination (7,28).

For examinations in which negligible risk to the fetus is expected (eg, extremity radiography or extremity CT [excluding pelvis], head CT, mammography, or chest radiography), screening may be unnecessary. However, in life-threatening situations such as severe trauma, screening may be impossible (such as with obtundation) or could lead to unacceptable delays in patient care (9,13,28). In these situations, it is preferable for referring physicians to document in the patient's medical record that pregnancy screening was waived (with or without consent of the patient) because of the emergent and critical nature of the examination (9,13,28). General statements made in the patient's medical chart or verbal communication with individuals only peripherally involved in the care of the patient should not be used as the sole source to confirm negative pregnancy status (28). Secondary assessment, including a screening questionnaire and/or direct questioning by the technologist, should be routinely implemented before the imaging examination. For procedures such as multiphase CT that are expected to deliver high doses of radiation (>50 mGy) or therapeutic doses of radiopharmaceuticals, the ACR and the Society of Nuclear Medicine and Molecular Imaging (the Society of Nuclear Medicine mechanical index) guidelines state that pregnancy status should be established, with the beta subunit of human chorionic gonadotropin (β-hCG) result obtained within 72 hours, a documented premenarche status, or history of hysterectomy (28,87).

Many institutions and facilities have policies and procedures that dictate more aggressive use of β-hCG screening before CT examination or even routine radiography. Although this may confer a greater margin of safety in patients with questionable pregnancy status, consideration should be given to the best course of action in patients who refuse pregnancy testing. Compliance with prevailing institutional policies (eg, policies for patients who will undergo anesthesia and refuse to be tested for pregnancy) and local patterns of practice should be taken into account. Radiologists should be familiar with their state's regulations on confidential pregnancy testing in minors; most states allow minors to undergo pregnancy tests without parental consent when prenatal care is concerned (28). Although the information provided in this section is meant to serve as a general guide, radiologists should work together with other health care professionals, such as obstetricians, emergency department physicians, and hospital medical directors, to develop the best local policies.

Pregnancy Test Accuracy

Quantitative serum pregnancy tests are more sensitive and can help detect pregnancy earlier than urine pregnancy tests (6,28,87). Serum pregnancy tests may be negative for 8–10 days after conception, and only 5% of pregnant patients test positive at day 8, a figure that increases to 98% on day 11 (87). For high-risk interventional procedures (eg, fibroid embolization or radiation therapy with ^{131}I-NaI), a test for pregnancy should be performed, and patients should also be counseled to abstain from sexual activity for 2 weeks before therapy or the examination should be scheduled within 10 days after the onset of the menstrual period; these precautions will further reduce the possible hazards of false-negative findings for pregnancy (28,87).

Counseling and Informed Consent

The objective of informed consent is to provide pregnant patients with a realistic understanding of the risks and benefits of the imaging examination to the patient and her developing fetus (10,28). It also provides an opportunity for clinicians to address the patient's questions and concerns. The key is to provide to the patient an accurate general overview of the risks that is simple and can be readily understood. If detailed referral information was provided to the radiologist, it may also be possible to provide information about the potential benefits of the examination in a balanced way. At other times, more general statements to the patient, which reflect that the referring physician feels the information to be gained from the examination is beneficial, is more appropriate. In the latter situation, in nonemergent situations some practices may offer the opportunity for patients to talk to their referring or other physicians first if they have questions, even it means deferment of the examination. A balanced approach to informed consent is always prudent; for example, if the relative risks for future childhood malignancy because of fetal exposure are described, patients should be informed of the comparatively small absolute risk (10,28). It can be a challenge to explain radiation dose, which is an abstract concept to most patients and even to some phy-

sicians. One method is to explain background radiation exposure over a year-long period as a frame of reference (6,16). Some practices also will draw comparisons to the risks of other nonmedical activities. The patient's understanding should be confirmed by asking her to acknowledge the key points as they are explained and, if appropriate, by asking her to explain the risks and benefits in her own words.

Conclusion

The most assured method to reduce or eliminate fetal radiation dose is to promote use of nonionizing examinations, such as US, whenever a question can be adequately answered by using this modality and to perform examinations with ionizing radiation or contrast agents only when the examination may change patient care, there is no alternative, and the examination cannot be delayed until after pregnancy. However, examinations that may provide essential clinical information should not be withheld on the basis of radiation concerns. Risks from ionizing radiation and MR imaging can be minimized by adhering to both the ALARA principle and established guidelines regarding contrast agent administration. As a part of the multidisciplinary team, radiologists must promote a realistic understanding regarding risks related to imaging examinations among peers, referring clinicians, and patients.

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